World Health Organization

GUIDELINES

CONSOLIDATED STRATEGIC INFORMATION GUIDELINES

FOR HIV IN THE HEALTH SECTOR

MAY 2015

HIV STRATEGIC INFORMATION FOR IMPACT

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ACKNOWLEDGEMENTS

External Review Group of the Consolidated HIV Strategic Information Guide

Guide Co-chairs: Amita Pathack (National AIDS Secretariat, Mauritius), John Aberle-Grasse (United States Centers for Disease Control and Prevention (USCDC), USA).
Oluyemisi Akinwande (The Centre for Integrated Health Programs (CIHP), Nigeria), Yibeltal Assefa (Ministry of Health, Ethiopia) Paul Bouey (Office of the United States Global AIDS Coordinator, USA), Sylvere Bukiki (Global Network of People Living with HIV (GNP+), Côte d'Ivoire), Batya Elul (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Jennifer Gatsi (The International Community of Women with HIV/AIDS (ICW), Namibia), Elisabeth Girrbach (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), Timothy Hallett (Imperial College London, United Kingdom), Mindy Hochgesang (USCDC, Mozambique), Priscilla Idele (United Nations Children's Fund (UNICEF), USA), Andreas Jahn (Ministry of Health, Malawi/PATH, Malawi), Suman Jain (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), Karin Lane (United States Agency for International Development (USAID), USA), Maria Iselda Lantero (Ministerio de Salud Publica, Cuba), Fan Lu (China Center of Disease Control and Prevention, China), Binod Mahanty (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), William K. Maina (Ministry of Public Health and Sanitation, Kenya), Natalya Nizova (Ministry of Health, Ukraine), Teymur Noori (European Centre for Disease Prevention and Control (ECDC), Sweden), Elsheikh Nugud (Sudan National HIV/AIDS Control Program, Sudan), Meg Osler (University of Cape Town, South Africa), Nelson Otwoma (National Empowerment Network of People Living with HIV/AIDS in Kenya (NEPHAK), Kenya), Kristi Ruutel (National Institute for Health Development, Estonia), Siti Nadia Tarmizi (Ministry of Health, Indonesia), Thuong Vu Nguyen (Pasteur Institute, Ho Chi Minh City, Viet Nam), Assetina Singo Tokofai (Ministry of Health, Togo), Anandi Yuvaraj (The International Community of Women with HIV/AIDS (ICW), London) and UNAIDS staff.

Participants in technical consultations

Global Technical Consultation for Monitoring and Evaluation of HIV Care and Treatment

Emmanuel Abatta (Federal Ministry of Health, Nigeria), John Aberle-Grasse (USCDC, USA), Bruce Agins (HEALTHQUAL International, USA), Joseph Barker (Office of the United States Global AIDS Coordinator, USA), Aziza Bennani (Ministry of Health, Morocco), Omatayo Bolu (USCDC, Cameroon), Ivana Bozicevic (WHO Collaborating Centre, Zagreb, Croatia), Sylvere Bukiki (Global Network of People Living with HIV (GNP+), Côte d'Ivoire), Nathaniel Duke (Tobago Regional Health Authority, Trinidad and Tobago), Kam Marhoumal El Filali (Ibn Rochd University Hospital, Morocco), Batya Elul (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Peter Elyanu (Ministry of Health, Uganda), Jennifer Gatsi (The International Community of Women with HIV/AIDS (ICW), Namibia), Amy Gottlieb (USAID, South Africa), Samvel Grigoryan (National Center for AIDS Prevention, Armenia), Katherine Hilderbrand (University of Cape Town, South Africa), James Houston (USCDC, USA), Priscilla Idele (UNICEF, USA), Suman Jain (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), Nagalingeswaran Kumarasamy (YRGCARE Medical Centre, India), Natalia Ladnaia (Russian Federal AIDS Centre, Russia), Karin Lane (USAID, USA), Jeffrey Lazarus (CHIP WHO Collaborating Centre, Copenhagen, Denmark), Cheewanan

Lertpiriyasuwat (Ministry of Public Health, Thailand), Ma Ye (China Centers for Disease Control and Prevention, China), Binod Mahanty (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), James McMahon (Monash University, Australia), Christine Nabriyo (The AIDS Support Organisation (TASO), Uganda), Bora Ngauv (Ministry of Health, Cambodia), Washington Omwomo (USAID, Kenya), Ana Roberta Pati Pascom (Ministry of Health, Brazil), Gilles Raguin (GIP Esther, France), Eric Remera (Ministry of Health, Rwanda), Amee Schwitters (USCDC, USA), Myint Shwe (Ministry of Health, Myanmar), Houlio St. Preux (Unite d'Etudes et de Programmation (UEP), Haiti), Fatiha Terki (World Food Programme, Switzerland), Olga Varetska (Alliance Ukraine), Vincent Wong (USAID, USA), and UNAIDS staff.

Technical consultation with health facility, district and national programme managers from the Africa Region

Tsitsi Apollo (Ministry of Health, Zimbabwe), Khuteletso Bagapi (Ministry of Health, Botswana), George Bello (Ministry of Health, Malawi), Sisay Sirgu Betizazu (WHO Consultant, Ethiopia), Serge Billong (Comité National de Lutte contre le SIDA, Cameroon), Sylvere Bukiki (Global Network of People Living with HIV (GNP+), Côte d'Ivoire), Christine Chakanyuka-Musanhu (NPO HIV/AIDS, WHO Zimbabwe), Harriet Chanza (WHO Malawi), Innocent Chingombe (Ministry of Health, Zimbabwe), Sandile Dlamini (Ministry of Health, Swaziland), Mesmey Ebogo (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, Cameroon), Kathleen Fox (WHO Consultant, Switzerland), Tsigerida Gadisa (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, Ethiopia), Alexander Goredema (Ministry of Health, Zimbabwe), Vincent Habiyambere (WHO, Switzerland), Chika Hayashi (WHO, Switzerland), Priscilla Idele (UNICEF, USA), Theopista John Kabuteni (NPO FHP, WHO Tanzania), Mugagga Kaggwa (NPO, WHO Uganda), Joseph Kamoga (USCDC, Uganda), Akeem Ketlogetswe (Ministry of Health, Botswana), Dinnuy (Patrick) Kombate-Noudjo (WHO Regional Office of Africa), Brine Masvikeni (Ministry of Health, Zimbabwe), Mike Merrigan (FHI360, Botswana), Amon Mpofu (National AIDS Council, Zimbabwe), Etienne Mutombo Mpoyi (NPO HIV/AIDS, WHO Democratic Republic of Congo), Mirriam Munzara (Ministry of Health, Zimbabwe), Rashell Musiyambiri (Ministry of Health, Zimbabwe), Moses Mutebi Nganda (WHO South Sudan), Elizabeth Namagala (Ministry of Health, Uganda), Buhle Ncube (WHO Regional Office of Africa), Sithembile Dlami ni-Nqeketo (NPO, WHO Swaziland), Solomon Abay Nirea (Ministry of Health, Ethiopia), Innocent Nuwagira (WHO Regional Office of Africa), Elevanie Nyankesha (UNICEF, Senegal), Meg Osler (University of Cape Town, South Africa), Ochak Morris Owor (Ministry of Health, South Sudan), Nirina Razakasoa (WHO Regional Office of Africa), Eleni Seyoum (NPO HIV/AIDS, WHO Ethiopia), Teshome Desta Woldehanna (WHO Regional Office of Africa) and UNAIDS staff.

Technical Consultation on Global Guidance for PMTCT and Paediatric HIV M&E

Emmanuel Abatta (Federal Ministry of Health, Nigeria), Shabbir Ismail Abbas (Elizabeth Glaser Pediatric AIDS Foundation, USA), John Aberle-Grasse (USCDC, USA), Elaine Abrams (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Susan Adamchak (FHI360, USA), Michelle Adler (USCDC, USA), Rachel Blacher (USCDC, USA), Sarawut Boonsuk (Ministry of Public Health, Thailand), Laura Broyles (USCDC, USA), Sonja Caffe (Pan American Health Organization), Rosalind Carter (UNICEF, USA), Rebecca Cathcart (Elizabeth Glaser Pediatric AIDS Foundation, USA), Alex Cox (USCDC, USA), Mamadou Diallo (USCDC, USA), Adriana Duran (Ministerio de Salud, Argentina), Peter Elyanu (Ministry of Health, Uganda), Jacquie Firth (USAID, USA), Jennifer Gatsi (The International Community of Women with HIV/AIDS (ICW), Namibia), Monica Alonso Gonzalez (Pan American Health Organization), Chika Hayashi (WHO, Switzerland), James Houston (USCDC, USA), Priscilla Idele (UNICEF, USA), Benjamin Isquith (USAID, USA), Suman Jain (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), Emily Koumans (USCDC, USA), Caitlin Matson

(International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Vidya Mave (BJ Medical College, India), Tih Pius Muffih (Cameroon Baptist Convention, Cameroon), Alisha Myers (mothers2mothers, South Africa), Natalya Nizova (Ministry of Health, Ukraine), Innocent Nuwagira (WHO Regional Office of Africa), Ryan Phelps (USAID, USA), Laura Porter (USCDC, USA), Xenophon Santas (USCDC, USA), Eleni Seyoum (WHO Regional Office of Africa), Nathan Shaffer (WHO, Switzerland), Shanti Singh (National AIDS Programme Secretariat, Guyana), Tin Tin Sint (UNICEF, USA), Samreth Sovannarith (Ministry of Health, Cambodia), Nandita Sughandi (Clinton Health Access Initiative, USA), Fatima Tsiouris (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Marleen van der Ree (United Nations Population Fund (UNFPA), USA), Lara Vaz (Save the Children, USA), Evgeny Voronin (Scientific-Practical Centre for Care for Pregnant Women and Children with HIV/AIDS, Russia) and UNAIDS staff.

Technical guide for countries to set targets for HIV prevention, treatment and care for sex workers, men who have sex with men, and transgender people

Gillian Anderson (USCDC, USA), George Ayala (The Global Forum on MSM & HIV, USA), Rachel Baggaley (WHO, Switzerland), Stefan Baral (Johns Hopkins Bloomberg School of Public Health, USA), Gerard Belimac (Department of Health, Philippines), Irene Benech (USCDC, USA), Isabelle Bergeri (WHO, Switzerland), Parinita Bhattacharjee (University of Manitoba, Kenya), Ludo Bok (United Nations Development Programme (UNDP), USA), Jordi Casabona (Center for Epidemiological Studies on STIs and HIV/AIDS, Spain), Gina Dallabetta (Gates Foundation, USA), Jon de Wit (University of New South Wales, Australia), Anna Dovbakh (International HIV/AIDS Alliance, Ukraine), Andrea Gonzalez (Condesa, Mexico), Mauro Guarinieri (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), Chika Hayashi (WHO, Switzerland), Suman Jain (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), Bonita Kilama (The National AIDS Control Programme, Tanzania), Romel Lacson (USCDC, USA), Antonio Lee (WHO, Switzerland), Frank Lule (WHO Regional Office for Africa), N.R. Manilal (Ministry of Health and Family Welfare, India), Bradley Mathers (Kirby Institute, Australia), Rafael Mazin (Pan American Health Organization, USA), Agneta Mbithi (National AIDS and STI Control Program, Kenya), Ko Ko Naing (National AIDS Programme, Department of Health, Myanmar), Geoffrey Okumu (United Nations Population Fund (UNFPA), USA), Razia Pendse (WHO Regional Office for South-East Asia), Tonia Poteat (Office of the United States Global AIDS Coordinator, USA), Michelle Rodolph (WHO Consultant, Switzerland), Owen Ryan (amfAR – The Foundation for AIDS Research, USA), Paul Semugoma (African Men for Sexual Health and Rights, South Africa), Alfonso Silva-Santiesteban (Universidad Peruana Cayetano Heredia, Peru), Tim Sladden (United Nations Population Fund (UNFPA), Khartini Slamah (Global Network of Sex Work Projects, Malaysia), Patrick Sullivan (Emory University, USA), Siti Nadia Tarmizi (Ministry of Health, Indonesia), Igor Toskin (WHO, Switzerland), Annette Verster (WHO, Switzerland), Bea Vuylsteke (Institute of Tropical Medicine, Belgium), Sharon Weir (University of North Carolina, USA), Tisha Wheeler (USAID, USA), Cameron Wolf (USAID, USA), Pengfei Zhao (WHO Regional Office for the Western Pacific) and UNAIDS staff.

ART Working Group

John Aberle-Grasse (USCDC, USA), Anuli Ajene (USCDC, USA), Oluyemisi Akinwande (The Centre for Integrated Health Programs (CIHP), Nigeria), Joseph Barker (Office of the United States Global AIDS Coordinator, USA), Stephanie Behel (USCDC, USA), Silvia Bertagnolio (WHO, Switzerland), Paul Bouey (Office of the United States Global AIDS Coordinator, USA), Meg Doherty (WHO, Switzerland), Denise Duran (USCDC, USA), Nathan Ford (WHO, Switzerland), Monica Alonso Gonzalez (Pan American Health Organization, USA), Raul Gonzalez (WHO, Switzerland), Chika Hayashi (WHO, Switzerland), Silvia Holzinger (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), Ambereen Jaffer (USAID, USA), Michael

Jordan (WHO Consultant, Switzerland), Hamida Khattabi (WHO Regional Office of Eastern Mediterranean), Binod Mahanty (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), Amaya Maw-Naing (WHO Regional Office of South-East Asia), Eyerusalem Negussie (WHO, Switzerland), Lisa Nelson (WHO, Switzerland), Razia Pendse (WHO Regional Office of South-East Asia), Laura Porter (USCDC, USA), Giovanni Ravasi (Pan American Health Organization), Nirina Razakasoa (WHO Regional Office of Africa), Francois Renaud (WHO, Switzerland), Annemarie Stengaard (WHO Regional Office of Europe), Marco Vitoria (WHO, Switzerland), Vincent Wong (United States Agency for International Development (USAID), Dongbao Yu (WHO Regional Office of South-East Asia) and UNAIDS staff.

PMTCT Working Group

John Aberle-Grasse (USCDC, USA), Susan Adamchak (FHI360, USA), Michelle Adler (USCDC, USA), Oluyemisi Akinwande (The Centre for Integrated Health Programs (CIHP), Nigeria), Rachel J Blacher (USCDC, USA), Teagan Callahan (USCDC, USA), Rosalind Carter (UNICEF, USA), Monica Alonso Gonzalez (Pan American Health Organization), Raul Gonzalez (WHO, Switzerland), Chika Hayashi (WHO, Switzerland), James Houston (USCDC, USA), Priscilla Idele (UNICEF, USA), Shabbir Ismail (Elizabeth Glaser Pediatric AIDS Foundation, USA), Hamida Khattabi (WHO Regional Office of Eastern Mediterranean), Karin Lane (USAID, USA), Binod Mahanty (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), Amaya Maw-Naing (WHO Regional Office of South-East Asia), Lisa Nelson (WHO, Switzerland), Razia Pendse (WHO Regional Office of South-East Asia), Nirina Razakasoa (WHO Regional Office of Africa), Nigel Rollins (WHO, Switzerland), Nathan Shaffer (WHO, Switzerland), Annemarie Stengaard (WHO Regional Office of Europe), Fatima Tsiouris (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Dongbao Yu (WHO Regional Office of South-East Asia) and UNAIDS staff.

Paediatric ART Working Group

Elaine Abrams (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Anouk Amzel (USAID, USA), Dick Chamla (UNICEF, USA), Otto Diallo (USCDC, USA), Meg Doherty (WHO, Switzerland), Eric Dziuban (USCDC, USA), Ruby Fayorsey (International Center for AIDS Care and Treatment Programs (ICAP), Columbia University, USA), Jacqueline Firth (USAID, USA), Monica Alonso Gonzalez (Pan American Health Organization), Raul Gonzalez (WHO, Switzerland), Chika Hayashi (WHO, Switzerland), Priscilla Idele (UNICEF, USA), Hamida Khattabi (WHO Regional Office of Eastern Mediterranean), Emilia H Koumans (USCDC, USA), Amaya Maw-Naing (WHO Regional Office of South-East Asia), Lulu Muhe (WHO, Switzerland), Martina Penazzato (WHO, Switzerland), Razia Pendse (WHO Regional Office of South-East Asia), Benjamin Phelps (USAID, USA), Nirina Razakasoa (WHO Regional Office of Africa), Tin Tin Sint (UNICEF, USA), Annemarie Stengaard (WHO Regional Office of Europe), Dongbao Yu (WHO Regional Office of South-East Asia) and UNAIDS staff.

HIV Testing and Counselling Group

John Aberle-Grasse (USCDC, USA), Rachel Baggaley (WHO, Switzerland), Stephanie Behel (USCDC, USA), Charlene Brown (USAID, USA), Kathryn Curran (WHO Consultant, Switzerland), Denise Duran (USCDC, USA), Juliette Edzeame (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), Monica Alonso Gonzalez (Pan American Health Organization, USA), Chika Hayashi (WHO, Switzerland), Cheryl Johnson (WHO Consultant, Switzerland), Hamida Khattabi (WHO Regional Office of Eastern Mediterranean), Elizabeth Marum (USCDC, USA), Amaya Maw-Naing (WHO Regional Office of South-East Asia), Nirina Razakasoa (WHO Regional Office of Africa), Kristi Ruutel (National Institute for Health Development, Estonia), Annemarie Stengaard (WHO Regional Office of Europe), Vincent Wong (USAID, USA), Dongbao Yu (WHO Regional Office of South-East Asia) and UNAIDS staff.

Key Population Group

Stefan Baral (Johns Hopkins Bloomberg School of Public Health, USA), Irene Benech (USCDC, Tanzania), Gina Dallabetta (Gates Foundation, USA), Txema Calleja (WHO, Switzerland), Monica Alonso Gonzalez (Pan American Health Organization, USA), Annette Verster (WHO, Switzerland) and UNAIDS staff.

HIV/TB Guide committee

Yibletal Assefa (Ministry of Health, Ethiopia), Annabel Baddeley (WHO, Switzerland), Lucy Chesire (Tuberculosis Advocacy Consortium, Kenya), Charlotte Colvin (USCDC, USA), Liz Corbett (London School Hygiene and Tropical Medicine, United Kingdom), Stephane d'Almeida (Programme National de Lutte contre le SIDA et les IST (PNLS), Togo), Andrei Dadu (WHO Regional Office of Europe), Anand Date (USCDC, USA), Jacob Dee (USCDC, USA), Meg Doherty (WHO, Switzerland), Dennis Falzon (WHO, Switzerland), Haileyesus Getahun (WHO, Switzerland), Phillipe Glaziou (WHO, Switzerland), Chika Hayashi (WHO, Switzerland), Suman Jain (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), Avinash Kanchar (WHO Consultant, Switzerland) Nathan Kapata (Ministry of Health, Zambia), Masaya Kato (WHO Regional Office for the Western Pacific), Bernard Langat (Ministry of Health, Kenya), Rafael Alberto Lopez Olarte (Pan American Health Organization, USA), Lisa Nelson (WHO, Switzerland), Eric Pevzner (USCDC, USA), Harilala Nirina Razakasoa (WHO Regional Office of Africa), B.B. Rewari (National AIDS Control Organisation, India), Boniswa Sharon Seti (AIDS & Rights Alliance for Southern Africa, South Africa), Seng Sopheap (The National Center for HIV/ AIDS, Dermatology and STD Control, Cambodia), Annemarie Stengaard (WHO Regional Office of Europe), Hazim Timimi (WHO, Switzerland), Jeroen van Gorkom (KNCV Tuberculosis Foundation, Netherlands), Eliud Wandwalo (The Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland) and UNAIDS staff.

Indicator Review Panel to review new indicators

Rachel Albone (HelpAge International, London), Joy Fishel (Demographic and Health Surveys (DHS), USA), Nicole Fraser (World Bank, United Kingdom), David Hales (Indicator expert, United Kingdom), Chika Hayashi (WHO, Switzerland), Jon Hopkins (International Planned Parenthood Federation, United Kingdom), Patrick Kaburi (National AIDS Control Council, Kenya), Teymur Noori (European Centre for Disease Prevention and Control, Sweden).

Contributors for Part 2

John Aberle-Grasse (USCDC, USA), Annabel Baddeley (WHO Department of Global Tuberculosis), Rachel Baggaley (WHO Department of HIV), Isabel Bergeri (WHO Department of HIV), Silvia Bertagnolio (WHO Department of HIV), Rachel Blacher (USCDC, USA), Alex Cox (USCDC, USA), Jacob Dee (USCDC, USA), Neelam Dhingra-Kumar (WHO Department of Health Systems and Innovation), Meg Doherty (WHO Department of HIV), Shaffiq Essaje (WHO Department of HIV), Dennis Falzon (WHO Department of Global Tuberculosis), Nathan Ford (WHO Department of HIV), Haileyesus Getahun (WHO Department of Global Tuberculosis), Phillipe Glaziou (WHO Department of Global Tuberculosis), Vincent Habiyambere (WHO Department of HIV), James Houston (USCDC, USA), Priscilla Idele (UNICEF, USA), Selma Khamassi (WHO Department of Health Systems and Innovation), Evelyn Kim (USCDC, USA), Jeremy Addison Lauer (WHO Department of Health Systems and Innovation), Bradley Mathers (Kirby Institute, Australia), Eyerusalem Negussie (WHO Department of HIV), Lisa Nelson (WHO Department of HIV), Lisa Nelson (WHO Department of HIV), Philippa Easterbrook (WHO Department of HIV), Lori Newman (WHO Department of Reproductive Health and Research), Elevanie Nyakesha (UNICEF, USA), Kevin O'Reilly (WHO Department of HIV), Martina Penazzato

(WHO Department of HIV), Joseph Perriens (WHO Department of HIV), Francois Renaud (WHO Department of HIV), Raul Gonzalez (WHO Department of HIV), Nigel Rollins (WHO Department of Maternal, Newborn, Child and Adolescent Health), Julie Samuelson (WHO Department of HIV), Nathan Shaffer (WHO Department of HIV), Marco Vitoria (WHO Department of HIV), Mahesh Swaminathan (USCDC, USA) Leigh Tally (USCDC, USA), Hazim Timimi (WHO Department of Global Tuberculosis), Landry Dongmo Tsague (UNICEF, USA), Annette Verster (WHO Department of HIV), Junping Yu (WHO Department of Health System and Innovation) and UNAIDS staff.

Contributors for Part 3:

Mazuwa Banda (WHO Department of HIV), Isabel Bergeri (WHO Department of HIV) Tessa Edejer (WHO Department of Health Systems Governance and Financing), Ramesha Krishnamurthy (WHO Department of Health Systems and Innovation), Karin Lane (USCDC, USA), Binod Mahanty (Deutsche Gessellschaft fur Internationale Zusammenarbeit (GIZ) GmbH, Germany), Meg Osler (Cape Town University, South Africa), Amita Pathack (National AIDS Secretariat, Mauritius), Greet Peersman (WHO Consultant, Australia), Hapsatou Toure (WHO Department of Health Systems Governance and Financing), Nathalie Van de Maele (WHO Department of Health Systems Governance and Financing), Kavitha Viswanathan (WHO Department of Health Systems Financing).

WHO staff and consultants

Chika Hayashi (Department of HIV) coordinated the overall guideline development process with Daniel Low-Beer (Department of HIV), Gundo Weiler (Department of HIV) and Txema Calleja (Department of HIV). Daniel Tarantola (Consultant, Department of HIV) provided overall guidance on the guide and developed initial drafts of several sections. Awandha Mamahit (Consultant, Department of HIV) provided overall support for the guideline process.
The above group constitutes the WHO Guideline Steering Group.

The following WHO staff members contributed to developing the content or drafting sections of the guidelines:
Annabel Baddeley (Department of Global Tuberculosis), Rachel Baggaley (Department of HIV), Mazuwa Banda (Department of HIV), Isabel Bergeri (Department of HIV), Silvia Bertagnolio (Department of HIV), Michel Beusenberg (Department of HIV), Meg Doherty (Department of HIV), Philippa Easterbrook (Department of HIV). Dennis Falzon (Department of Global Tuberculosis), Nathan Ford (Department of HIV), Haileyesus Getahun (Department of Global Tuberculosis), Phillipe Glaziou (Department of Global Tuberculosis), Raul Gonzalez (Department of HIV), Monica Alonso Gonzalez (Pan American Health Organization), Vincent Habiyambere (Department of HIV), Masaya Kato (WHO Regional Office for the Western Pacific), Hamida Khattabi (WHO Regional Office of Eastern Mediterranean). Ramesha Krishnamurthy (Department of Health Systems and Innovation), Amaya Maw-Naing (WHO Regional Office of South-East Asia), Lulu Muhe (Department of Maternal, Newborn, Child and Adolescent Health), Eyerusalem Negussie (Department of HIV), Lisa Nelson (Department of HIV), Lori Newman (Department of Reproductive Health and Research), Kevin O'Reilly (Department of HIV), Martina Penazzato (Department of HIV), Razia Pendse (WHO Regional Office of South-East Asia), Joseph Perriens (Department of HIV), Giovanni Ravasi (Pan American Health Organization), Nirina Razakasoa (WHO Regional Office of Africa), Francois Renaud (Department of HIV), Nigel Rollins (Department of Maternal, Newborn, Child and Adolescent Health), Julie Samuelson (Department of HIV), Nathan Shaffer (Department of HIV), Annemarie Stengaard (WHO Regional Office of Europe), Hazim Timimi (Department of Global Tuberculosis), Annette Verster (Department of HIV), Marco Vitoria (Department of HIV), Junping Yu (Department of Health Systems and Innovation), Dongbao Yu (WHO Regional Office of South-East Asia).
The following WHO consultants were also involved in developing these guidelines:

Theresa Babovic, April Baller, Jhoney Barcarolo, Cheryl Johnson, Michael Jordan, Avinash Kanchar, Michelle Williams.

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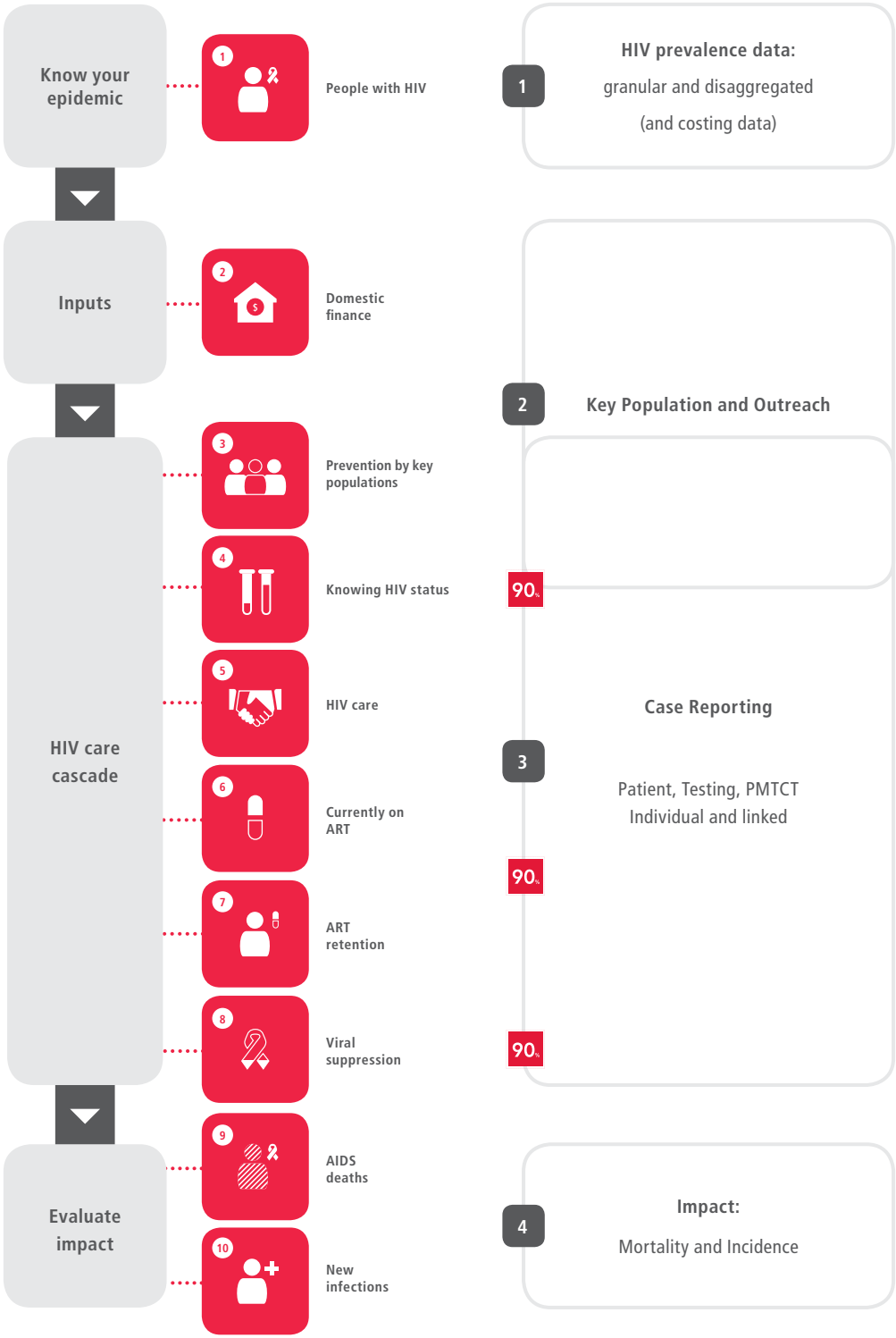
Please send any comments on this guide or suggestions to hiv-aids@who.int.

ABBREVIATIONS

3ILPMS	Three Interlinked Patient Monitoring Systems
ADR	acquired drug resistance
AEM	Asian Epidemic Model
AIM	AIDS Impact Model
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
ASA	African Studies Association
CD4	T–lymphocyte cell bearing CD4 receptor
COD	cause of death
CRVS	Civil Registration and Vital Statistics
CTX	Co-trimoxazole
DHS	Demographic and Health Survey
DQR	Data Quality Review
DSS	demographic surveillance site
EHR	electronic health record
EIA	enzyme immunoassay
EID	early infant diagnosis
EMR	electronic medical record
EMTCT	elimination of maternal-to-child transmission
EQA	external quality assurance
EWI	early warning indicator (of HIV drug resistance)
GARPR	Global AIDS Response Progress Reporting
GIS	geographic information system
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HA	Health Accounts
HBV	hepatitis B virus
HCV	hepatitis C virus
HIS	Health Information System
HIV	human immunodeficiency virus
HIVDR	HIV drug resistance
HMIS	health management information system
HRH	human resources for health
HTS	HIV testing services
IBBS	Integrated Bio- and Behavioural Surveys
ICD	International Classification of Diseases
ICT	information and communication technology
IPT	isoniazid preventive therapy
IRB	Institutional Review Board
IRIS	International Registry for Information Sharing
LFU	lost to follow-up
LTBI	latent tuberculosis infection

M&E	monitoring and evaluation
MCH	maternal and child health
MICS	Multiple Indicator Cluster Survey
MOH	ministry of health
MTCT	maternal-to-child transmission
NAAT	nucleic acid amplification testing
NASA	National AIDS Spending Assessment
NCPI	National Commitments and Policies Instrument
NNRTI	non-nucleoside reverse transcriptase inhibitor
NRTI	nucleoside reverse transcriptase inhibitor
NSP	needle–syringe programme
NSUM	network scale-up method
OECD	Organisation for Economic Co-operation and Development
OI	opportunistic infection
OST	opioid substitution therapy
OTIF	on time and in full
PDR	pre-treatment drug resistance
PEPFAR	United States President's Emergency Plan for AIDS Relief
PITC	provider-initiated testing and counselling
PLHIV	people living with HIV
PMTCT	prevention of maternal-to-child transmission
POC	point of care
PSM	procurement and supply management
PT	proficiency testing
PWID	people who inject drugs
QI	quality improvement
RDQA	Routine Data Quality Assessment
RDS	respondent-driven sampling
SARA	service availability and readiness assessment
SAVVY	sample vital registration with verbal autopsy
SHA	System of Health Accounts
SI	strategic information
SMS	short message service
SOP	standard operating procedure
SRS	sample registration system
STI	sexually transmitted infection
TB	tuberculosis
TLS	time–location sampling
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNGASS	United Nations General Assembly Special Session on HIV/AIDS
UNICEF	United Nations Children's Fund
VA	verbal autopsy
VL	viral load
VMMC	voluntary medical male circumcision
WHO	World Health Organization

Global indicators for the health sector response to HIV



Strategic information: a consolidated framework

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1. STRATEGIC INFORMATION: A CONSOLIDATED FRAMEWORK

1.1 Introduction

This guidance consolidates, prioritizes and describes key indicators to monitor the national and global response of the health sector to HIV. Its goal is to help countries choose, collect and systematically analyse strategic information to guide the health sector response to HIV. The aim of consolidation is to ensure that all indicators are in one place, are prioritized and linked in a result chain, and can be used to support quality care along the health sector cascade of HIV services.

Since its beginning in the late 1980s, the global response to HIV has placed a high priority on strategic information to improve programmes. Perhaps no other area of public health has developed such a comprehensive set of indicators, methods and tools to collect, analyse, apply and disseminate information. By bringing together indicators and prioritizing them, this consolidated guide seeks to help programmes to:

1. **select and prioritize** the indicators most relevant to national and global reporting;

2. **consolidate measurements** along the cascade of prevention, care and treatment;

3. **link services** to their outcomes to better assess coverage, quality and impact;

4. **strengthen analysis**, disaggregation and use of data to improve linkages and identify bottlenecks and priorities along the cascade;

5. **align reporting across programmes** (for example, of testing, treatment and care) and globally for simpler, better coordination;

6. **simplify global monitoring** with 10 indicators that track the health sector cascade of prevention, diagnosis, treatment and care and reflect progress toward the 90–90–90 target;

7. **provide consolidated support for country data systems** and analysis aligned with the post-2015 development agenda.

Key points in Part 1

- This guide addresses national staff that collect, analyse and use HIV-related information for decision-making.
- WHO recommends 50 national indicators, including 10 identified for global monitoring, to gauge the health sector response to HIV.
- The focused indicator list promotes generation of better quality data to:
  1. assess and improve services along the health sector cascade
  2. provide accountability for global reporting and the 90–90–90 target
  3. link services along the cascade to outcomes and impact.

Selection of indicators. This guidance aims to simplify, prioritize and update existing indicators. The World Health Organization (WHO), in collaboration with partners, has selected, primarily from among existing indicators, the indicators most relevant for HIV programme management and reporting at sub-national, national or global levels. The indicators proposed in this guidance are drawn mainly from previous WHO publications but are brought together in one place here, organized in a clear results chain to measure the health sector service cascade. This guide also aligns global reporting through Global AIDS Response Progress Reporting (GARPR), integration of the future Sustainable Development Goals (SDGs), accountability for the 90–90–90 target (see section 1.6) and selected reporting requirements of the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria. The process of selecting the indicators involved consultative meetings and establishing a steering group and working groups with partners for each programme area. Working groups focussed on prioritizing and organizing indicators and updating them in line with the most recent programmatic recommendations. With a few exceptions to fill key gaps, they did not develop new indicators.

This guide is intended primarily to serve the needs of national health sector programme staff engaged in the collection, analysis and use of HIV-related strategic information.

While this document focuses primarily on HIV care and treatment, prevention activities in the health sector are included, as they are an integral element in the continuum of prevention, care, treatment and support. Thus, this guide includes steps at which people who are HIV-negative and people who are HIV-positive need prevention services. Prevention needs and activities outside the health sector are addressed elsewhere by other partners to provide a complete set of global indicators.

Intended audiences. This guide is intended primarily to serve the needs of national health sector staff engaged in the collection, analysis and use of HIV-related strategic information, including those who set up monitoring and evaluation (M&E) systems and those who use data to improve programmes. It is also intended for stakeholders concerned with developing and analysing strategic information, including nongovernmental organizations (NGOs), private-sector care providers, civil society and academic groups involved in teaching and research. These stakeholders can participate in government-led consultative processes for the design or redesign of strategic information systems in a spirit of transparency and mutual accountability. Additionally, this guide should help international entities and donor organizations align their reporting requirements with countries' strategic information systems in order to reduce reporting burden and increase the quality and use of data. This alignment will allow better coordination of measurement and, thus, of support for better quality services along the care and treatment cascade.

1.2 Why collect and use strategic information?

Strategic information is information collected to inform policy and programme decisions. The axiom "Know your epidemic, know your response" characterizes the strategic information necessary for the response to HIV. It recognizes that epidemics and their contexts differ from place to place. Thus, knowing who is affected, how they became infected and where they are, is crucial to designing sound responses that are adapted to and reach those in need. In turn, monitoring those responses is critical to maximizing their effectiveness, responsiveness and cost-effectiveness.

An effective response to HIV at the country level requires strategic information that is systematically collected and consolidated, analysed and applied. Strategic information must go

beyond basic epidemiologic data to address service access, coverage, quality and acceptability. It needs to support quality services along the health sector cascade. Strategic information should also lead to deeper understanding of the context of the epidemic, such as the vulnerability of certain communities, the risks to which certain individuals and populations are exposed and the options for actions to alleviate the burden of HIV and mitigate its impacts.

Three roles of HIV strategic information

With the overall goal of optimizing programmes and maximizing their benefits for affected populations, strategic information plays three roles:

1. to understand the epidemic and the extent of change resulting from interventions;
2. to track and gauge the health sector's response to HIV, particularly the health system inputs, intervention coverage, quality of services, and outcomes and impact;
3. to inform programme improvement, assuring quality and maximal return on resources invested and helping to identify bottlenecks and opportunities.

Strategic information provides the critical evidence that policy-makers, programme directors and line managers need to make informed decisions to improve programmes. Some examples include:

- tracking ART expansion following revision of national ART eligibility criteria (from CD4 count of $\leq 350/mm^3$ to CD4 $\leq 500/mm^3$) by monitoring the number of people initiating ART at various CD4 levels;
- identifying opportunities for prevention services along the health sector cascade, for those testing positive for HIV and those testing negative and by population and location;
- routinely reviewing retention on ART over time at the facility level to improve efforts to keep patients in care and conducting special studies to investigate loss to follow-up;
- assembling data on HIV testing uptake and yield (numbers testing positive) from various approaches and venues (for example, testing campaigns, testing at ANC or TB facilities, voluntary counselling and testing centres, outreach testing, provider-initiated testing and counselling in other facilities) to determine which strategies are most effective for increasing voluntary uptake and case identification;
- charting attrition along the cascade of HIV care and treatment to identify gaps and missed opportunities and estimating the potential of improvements in the cascade of services to increase survival and reduce incidence and mortality.

The clear weight of the evidence provided by M&E has given decision-makers the courage to go forward even where some sectors of society have opposed certain initiatives. For example, condom use proved to be effective at reducing HIV transmission, and so almost all countries have launched condom programmes. Also, harm reduction interventions among people who inject drugs are becoming the norm, based on evidence of their effectiveness, even in some countries where laws criminalize drug use. Strategic information and evidence is often the critical basis for negotiating difficult programmatic issues in countries and among partners with different approaches.

The rapid growth of treatment programmes over the past decade has underscored the importance and role of strategic information for programme planning and evaluation. Documenting impact is crucial to the focus and sustainability of programmes; indicators of programme outcomes, including retention in treatment and viral load suppression, are particularly important. However, this programme expansion has generated more indicators, partly to meet funding requirements

but also to support quality services, and increased the reporting burden on health-care workers. Consolidated guidance and alignment of monitoring indicators along the HIV care and treatment cascade, as provided in this guide, should help to reduce that burden.

While governments have the overall responsibility for strategic information systems, NGOs and civil society as a whole should, in a spirit of transparency, have access and contribute to the collection, analysis and use of this information as a global public good. Dissemination and sharing of strategic information within and among nations promote both understanding of the dynamics of epidemics and consensus about how best to respond to HIV. Also, the consistency and availability of information are central to the accountability and transparency of decisions in the health sector. These decisions are further strengthened by analysis and regular formal reviews of the data, involving key stakeholders, to prove and improve programmes.

1.3 Organization of the document

This document consists of three parts – the strategic information framework, measurement along the cascade of health services for HIV, and data sources and use.

Part 1, Strategic information: framework and result chain, introduces this document. It explains the result chain that serves as the organizing framework for the guidelines overall and the cascade of prevention, care, treatment and support, which structures the consolidation of the indicators to support quality services. It also addresses the use of selected indicators to track accountability for programme objectives such as the 90–90–90 treatment target.

Part 2, The cascade of HIV prevention, care and treatment services, details the key indicators across the cascade. In brief, it prioritizes a set of 50 key "national" indicators applicable to the national and subnational levels. Together, these 50 indicators address all levels in the result chain and all steps in the prevention, treatment, care and support cascade. Among these 50 key national indicators are 10 indicators proposed as a minimum set for systematic global monitoring of the health sector response to HIV. "Additional" indicators also are included that are less standardized globally and are context-specific. (See section 1.5.1.)

Part 3, Effective strategic information systems, presents the data needed to report on the indicators, the data sources, systems and how data is are used to report on progress and improve programmes. It describes the key characteristics of efficient strategic information systems: the data collection methods and sources, data quality, data management, the use of electronic systems and strategic use of data for planning, programming and advocacy, as well as the analysis required to use the indicators to improve the quality, effectiveness and impact of programmes. **As HIV programmes scale up, WHO recommends a case-based surveillance system that is structured to collate data along the health sector cascade for HIV. This collation makes patient records for HIV testing, diagnosis, for ART, PMTCT and other care (for example, for HIV/TB, CD4 and viral load monitoring) and for linkage to other care (for example, MCH care) available in one place, preferably through the use of unique identifiers linking individual records across databases.**

Three levels of indicators

1. 10 global indicators – the minimum to characterize the performance of the health services cascade
2. 50 national indicators – for selection of indicators according to the national programme and context
3. Additional indicators – for more information in specific situations.

Part 4, What next: How to use this guide, describes how to apply this guide to update reporting and improve monitoring and evaluation in countries. It provides five practical steps, and stresses the importance of a dedicated analyst in each programme to make use of the data.

Annexes include indicator tables on health systems inputs and health financing and costing and sources and additional resources to support using this guidance.

A companion publication, online at http://www.who.int/hiv/topics/me/en/, includes detailed reference sheets for all indicators presented in the consolidated guide.

Key definitions

Strategic information: Information that is interpreted and used for planning and decision-making to improve the direction and focus of a programme. Relevant data may be derived from a wide variety of sources (for example, monitoring systems, evaluations, programme reviews, surveys and case studies) and should be analysed holistically and strategically to improve the direction of the programme.

Indicator: In the context of M&E, a quantitative or qualitative variable that provides a valid and reliable way to measure achievement, assess performance or reflect changes connected to an activity, project or programme.[1] The sources of data for indicators should be clearly identified.

M&E system: A set of mechanisms built into the routine operations of a programme that generates data or information on a periodic and ongoing basis to provide evidence for programme decisions.

Monitoring: Ongoing, routine reporting of priority information about a programme, its inputs and intended outputs, outcomes and impacts to observe and track progress.

Evaluation: The periodic, rigorous review of information about programme activities, characteristics and context and their relationship to programme outcomes. Evaluation aims, from an objective viewpoint, to review, prove and improve a programme's overall value.

Data: A set of values of qualitative or quantitative variables that is collected and recorded. Data are the raw building blocks of strategic information and knowledge.

Information: Through interpretation or analysis, the pattern of aggregated data is understood as information that can inform a programme.

Health sector: The sector of society consisting of organized public and private health services, the policies and activities of government health departments and ministries, health-related NGOs and community groups, and professional associations including health promotion, disease prevention and diagnostic, treatment and care services.[2]

[1] An introduction to indicators. UNAIDS monitoring and evaluation fundamentals. Geneva: United Nations Joint Programme on HIV/AIDS; 2010 (http://www.unaids.org/en/media/unaids/contentassets/documents/document/2010/8_2-Intro-to-IndicatorsFMEF.pdf).

[2] WHO Centre for Health Development. A glossary of terms for community health care and services for older persons. WHO/WKC/Tech.Ser./04.2. Kobe: World Health Organization; 2004 (http://www.who.int/kobe_centre/ageing/ahp_vol5_glossary.pdf).

1.4 The strategic framework

This guide consolidates strategic information and indictors in order (1) to measure the HIV results chain, from inputs to impacts, (2) to gauge performance along and support decisions on the cascade of health services, and (3) to track accountability for global reporting and to meet programme targets along the health sector cascade (see section 1.6).

1.4.1 The HIV result chain – from inputs to impacts

To facilitate measurement of the linkages, quality and outcomes of the health sector response to HIV, this guide organizes indicators along the HIV result chain – a logical framework built along a sequence of context analysis, inputs, outputs, outcomes and impact.[1] These indicators allow review of the entire result chain in order to identify bottlenecks and, by addressing them, improve the overall quality of the programmatic response. The result chain provides a structure for analysis and facilitates alignment in support of country data systems.

The HIV result chain (Fig. 1.1) has the following elements:

- **Know your epidemic.** The results chain starts with a overall contextual review to "know your epidemic", particularly which populations are most affected and the size and location of those populations. Disaggregation of data by age, sex, population and location is crucial at this stage. Understanding people's needs defines the direction, priorities and scale of the response. Over time, information about the epidemic also serves as the baseline for tracking progress; many of the indicators that describe the epidemic and needs are also used to measure programme impact.
- **Inputs.** Inputs are the resources invested in the health sector response to HIV. In addition to financial resources, they include human resources, health services infrastructure and governance (that is, policy and management).
- **Outputs.** The activities of the programme constitute its outputs. Examples of output measures include the number of testing and counselling sessions conducted and ART enrolment data.
- **Outcomes.** The proximate effects of programme outputs are their outcomes. For example, enrolment and retention in ART are programme outputs, while resulting viral suppression is the outcome of these outputs. Outcomes can occur at any stage of the prevention and treatment response, including changes in behaviours (prevention outcomes), which need to be carefully monitored.
- **Impacts.** The ultimate gauge of a programme is the nature and extent of its impact on epidemiologic measures such as HIV incidence (in adults and children), mortality and the rate of maternal-to-child transmission (MTCT) of HIV in the population. Other impact measures reflect progress toward goals such as equity and improved quality of life for people living with HIV.

The result chain provides the overall structure for Part 2 of this guide; sections in Part 2 address each element of the result chain in turn and present related indicators and linkages. These indicators are used to assess and understand needs, track inputs, monitor services and other outputs, and measure outcomes and impacts. Data analysis should follow the result chain, starting with a review to "know your epidemic" and ending with an evaluation of impact and determination of the components of the results chain that have made the greatest contributions to reducing mortality and incidence.

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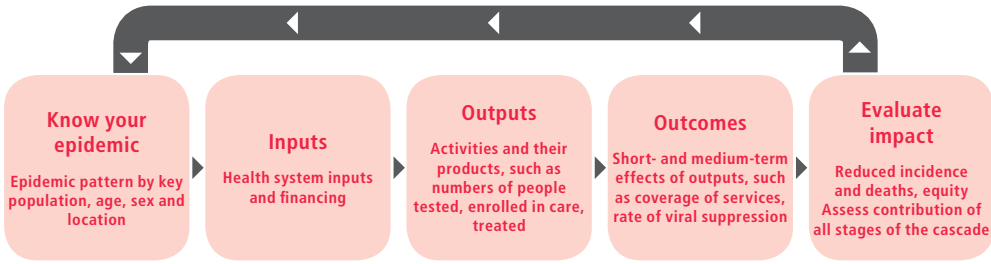
[1] Initially conceptualized in 1970 by Leon Rosenberg and colleagues of Fry Consultants Inc. for the United States Agency for International Development (see http://pdf.usaid.gov/pdf_docs/PNADW881.pdf), the logical framework concept has undergone a number of adaptations to suit its diverse uses. For example, some users have expanded these simple categories of input, output, outcome and impact by adding a temporal dimension (for example, short-, medium- and long-term).

Fig. 1.1 Result chain for the health sector response to HIV



Prevention is key at all stages – We have included prevention as the first step of the cascade. Prevention opportunities also arise in all subsequent steps – for those testing positive and those testing negative and throughout HIV care and treatment. The quality of prevention will have a direct impact on incidence and is key to achieving ending AIDS targets.

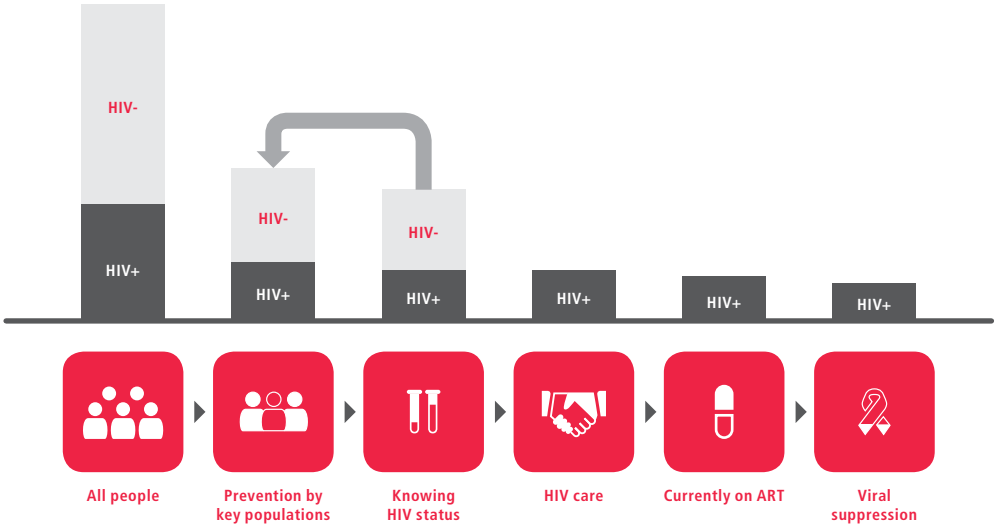
1.4.2 The HIV cascade of services – improving linkages and quality

A major reason for consolidating strategic information is to support the delivery of a cascade of linked services. Health sector services in the cascade encompass prevention, treatment and care interventions. The term "cascade" emphasizes that a sequence of services is needed to achieve desired impacts. The "cascade" concept also informs tracking of patients from one service to the next and highlights the gradual attrition of coverage of the eligible population over the steps of the sequence. Monitoring the cascade of services requires a consolidated set of indicators covering the entire sequence. Section 2.4 presents indicators of prevention, treatment and care according to the sequence of the cascade.

The term "cascade" emphasizes that a sequence of services is needed to achieve desired impacts.

Fig. 1.2 presents a conceptual depiction of the HIV cascade of services. While the graphic shows a complete cascade, individual paths through it may vary. For example, although prevention is depicted as the first step, prevention opportunities also arise in all subsequent steps – in testing and counselling for both those testing negative and those testing positive and throughout HIV care and treatment for those testing positive. Additionally, people may skip over certain services (for example, testing without exposure to specific prevention initiatives) or may leave the cascade and return to it (for example, dropping out of ART and returning months or years later).

Fig. 1.2 Populations served by the cascade of HIV prevention, care and treatment



1.5 Selection, prioritization and analysis of indicators

A key aim of this guidance is to prioritize indicators so that greater efforts can be focused on data quality, disaggregation, analysis and use to improve programmes along the cascade of prevention, care and treatment. Information systems can collect only a finite amount of information in a consistent, usable manner. Prioritization is necessary to identify the most useful indicators along the result chain to support better services. Less can be more when it comes to indicators; fewer indicators, consistently collected, fully disaggregated and well-analysed, can improve programmes more than many indicators poorly collected, poorly linked and not put to use. This document focuses on tested indicators that are most relevant for HIV programme management and for reporting at the sub-national, national or global levels.

WHO is leading an effort to foster international agreement on a consolidated set of 100 key indicators across all areas of health.[1] In line with that effort, several criteria guided selection of the indicators recommended in these guidelines. The recommended indicators should help to:

- **rationalize** and harmonize indicator reporting requirements of countries and partners along the cascade so that performance and gaps can be better identified among partners;
- **improve alignment** between global monitoring needs and country processes for monitoring progress and performance and allow global indicators to be drawn from a national set of indicators;
- **improve the quality** of results-based monitoring by focusing on better data for fewer indicators;
- **enhance efficiency and focus investments** in data sources and analyses so as to provide improved data for key programme indicators.

[1]Global reference list of 100 core health indicators. Geneva: World Health Organization; 2015 (http://www.who.int/healthinfo/indicators/2015/en/)

Why is data disaggregation crucial?

To see that services reach people in need and no one is left behind, strategic information needs to be disaggregated when it is analysed. The focus on a consolidated list of indicators promotes greater disaggregation and analysis of reporting in order to target services to populations that need services.

Disaggregation is the separation of data into component parts in order to identify and highlight differences that may exist. Disaggregation makes it possible to focus a country's responses on the people, places and situations where they will achieve impact. It is important to inform subnational, district and local responses and a key focus of the post-2015 development agenda.

In most cases HIV-related data are disaggregated according to:

1. **Age** – into standard age groups of <1, 1–4, 5–14, 15–19, 20–24, 20–49, 50+. We recommend regular data extraction (e.g. annual) to report on these age groups in paper-based systems. Five-year age groups should be used for electronic systems.
2. **Sex** – for example, to assess differences in infection and service coverage along the cascade.
3. **Key populations**, including men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people. Confidentiality, security and participation of key populations in data collection and analysis are critical.
4. **Location**: data should be regularly disaggregated subnationally so that they can be used at district and site levels.
5. **Pregnancy and breastfeeding** status.

Data may also be disaggregated according to other social, demographic or economic characteristics that influence risk, vulnerability and impact (for example, people in prisons and other closed settings compared with the general community).

Section 2.1.2 discusses disaggregation in more detail.

1.5.1 Three categories of indicators: national, global, additional

To help national programmes select indicators, this guide prioritizes proposed indicators into three categories – a set of 50 national indicators, 10 designated for global reporting from among the 50, and a set of additional indicators.

National programme indicators

This set of 50 indicators describes what the status of the HIV epidemic is and identifies how the HIV response could be improved. These indicators should be included in the national M&E monitoring system, if appropriate to the country context and the services that are delivered to populations. Typically, countries will opt to collect most of these indicators to obtain a focused but comprehensive overview that informs tracking and management of their health sector HIV programme. To ensure comparability, WHO recommends that country and donor reporting adhere to the definitions of these indicators.

The national programme indicators meet the following criteria:

- The indicator is relevant for and is recommended for use by national HIV programmes to document the status of the HIV epidemic and the health sector response, and it has direct implications for improving HIV programmes.

- The indicator is scientifically robust, needed, understandable, feasible to collect and analyse and it supports targets that are SMART (that is, Specific, Measurable, Achievable, Relevant and Time-bound).
- Extensive experience has proved the utility of the indicator or, if experience is limited, there is an urgent need to cover an emerging information need.

Global indicators

These 10 indicators, selected from among the 50 national indicators, provide an overview of the health sector response across the result chain and HIV cascade (Fig. 1.3). They provide HIV programme management with the essential information to identity key overall issues for improving the health sector response. These 10 indicators can be tracked to gauge trends in programme performance. This information also should be used to focus dialogue with global partners and policy-makers and to inform the public. Countries should report on these indicators in response to global reporting requirements in a standard and comparable manner, with relevant disaggregation and analysis. (Section 2.1.1 describes these 10 global indicators).

This WHO-recommended list of 10 global indicators seeks to provide HIV programme managers with an overview of the performance of the health sector response while reducing the burden of global reporting requirements. In addition, it aims to provide focused, consistent information for partners, whose information is often fragmented across a large number of unlinked indicators. This approach seeks to focus and align HIV programme managers and global partners on key issues in the health sector response and, thus, to improve dialogue. At the same time, this short list will help national HIV M&E teams to focus on the issues that require more extensive analysis, disaggregation and quality data to improve the impact of programmes.

The 10 global indicators recommended by WHO provide the essential information to identify key overall issues for improving the health sector response.

This focus on 10 global indicators contributes to current work by WHO to reduce the burden of health data reporting and to align the dialogue between countries and global partners on key programme issues. The benefits and burdens of any proposed additional global reporting requirements should be weighed carefully, and decisions should be negotiated between national HIV programme managers and partners. Where more indicators are required, we suggest selecting them, as much as possible, from among the 50 national-level indicators recommended here, accompanied by investments in country data systems and analytic capacity as needed.

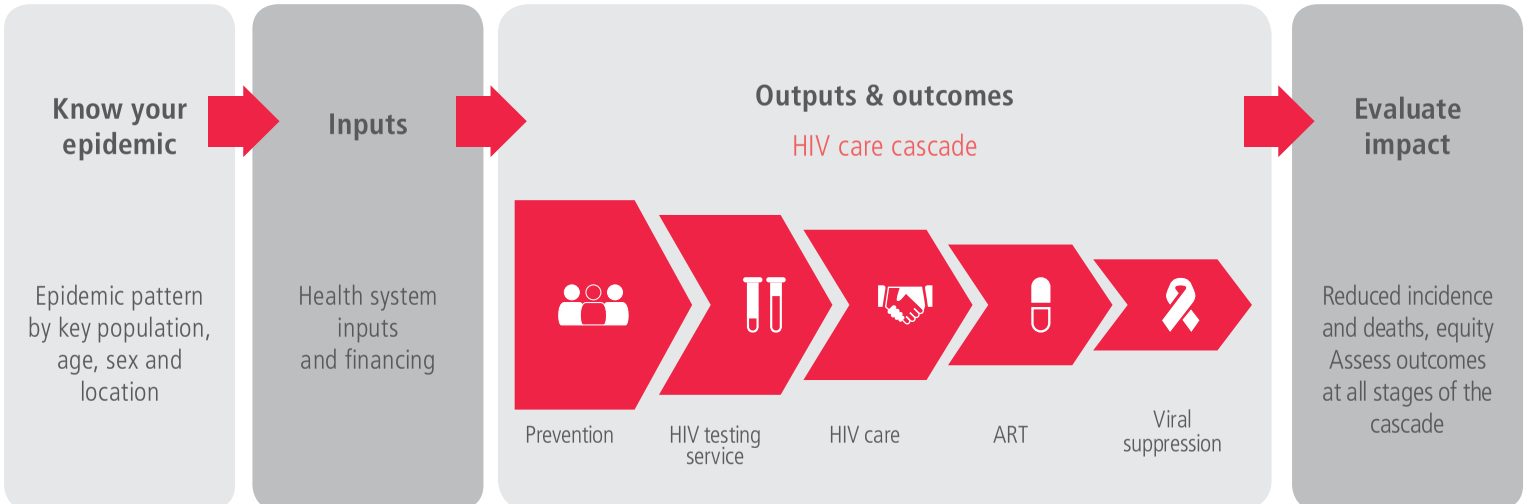
Additional indicators

These indicators may not be relevant to all countries. They can be considered on the national or sub-national level when such additional information is useful for understanding a particular country's epidemic context, needs and capacity. Countries can choose and adapt these indicators to meet their specific needs.

As the response to HIV evolves, the indicators also will need to evolve; updates will be available on the WHO website at http://www.who.int/hiv/topics/me/en/.

A list of all indicators in this guide can be found in Annex 1, page 250.

Fig. 1.3 Global indicators for the monitoring and evaluation of the health sector response to HIV



1. People with HIV

Number and % of people living with HIV (PLHIV)

2. Domestic finance

% of HIV response financed domestically

3. Prevention by key populations

% condom use among key and general populations or sterile needles per person who injects drugs*

* Count use of PrEP where relevant

4. Knowing HIV status

Number and % of PLHIV who have been diagnosed

5. HIV care

Number and % of PLHIV in HIV care (including ART)

6. Currently on ART

Number and % of PLHIV on ART, PMTCT ART

7. ART retention

Number and % of PLHIV retained and surviving on ART

8. Viral suppression

Number and % on ART virally suppressed

9. AIDS deaths

Deaths per 100 000 population

10. New infections

Number of new HIV infections per 1000 uninfected population

10 Global Indicators

90 90 90

Note: It is also important to link HIV-negative people to preventive interventions as appropriate.

1.5.2 Prioritizing indicators

National programmes should collect and review the 10 key global indicators and select other national indicators from among the rest of the recommended 50 indicators based on an assessment of their needs and circumstances. When this process of prioritization reveals gaps in data for key indicators are identified, investments should be made in M&E to fill these gaps (see box, Investing in data).

Criteria influencing the prioritization of indicators may include:

1. relevance to the most pressing HIV-related issues in the country
2. coverage of key programme areas across the result chain and health services cascade
3. coverage of key populations and other populations of interest (sometimes by disaggregation of a general population indicator and sometimes requiring specific periodic surveys)
4. relevance to key objectives, targets and sensitive components of the programme
5. sensitivity and specificity to progress, shortcomings, opportunities and threats
6. experience with the use and usefulness of the indicators
7. ease of measurement, availability and quality of data
8. usefulness at the local level.

Programmes should collect, report and analyse their priority national indicators, making sure that each programme area is covered and that data are sufficiently disaggregated (see box, Why is data disaggregation crucial?). Programmes should collect additional indicators, beyond those prioritized from among the 50 national indicators, only after carefully considering whether the additional information merits the additional burden of reporting.

Careful selection and prioritization of a limited set of key indicators will help national programmes to increase efficiency, focus management, pinpoint improvements and maximize beneficial outcomes – in sum, to provide better services to more people in need.

Investing in data

Tracking the indicators recommended in this guide requires significant investment in country data systems. Allocating 5–10% of overall programme funds to data collection and analysis is often recommended. Specifically, five key data sources need balanced investment:

1. **Facility and outreach** reporting systems (patient monitoring, care reporting, outreach data)
2. **Administrative** (financial and health systems data)
3. **Population-based surveys** (of the general population and key populations)
4. **Facility assessments** (readiness and capability)
5. **Vital registration.**

Reporting on the global indicators requires as a priority:

a. **HIV prevalence data that are granular and disaggregated** (and costing data) to focus our efforts on the epidemic (Indicators 1 and 2)

b. **Key population and outreach data** (Indicators 3 and linked to 4 and 5)

c. **Case and patient reporting:** patient, testing and PMTCT data that are increasingly individual and linked the delivery of services (Indicators 4-8)

d. **Practical impact evaluation:** to assess impact on incidence and mortality and adjust programmes accordingly (Indicators 9 and 10).

1.6 Accountability and the 90–90–90 target

In addition to informing programme improvement, the indicators in this guide provide accountability for reaching targets along the health sector cascade – including the 90–90–90 treatment target[1] – that are linked to changes in incidence and mortality. These indicators will be critical for national and global reporting as targets beyond 2015 are set and measurement systems are strengthened.

The 10 global indicators shown in Figure 1.3 are intended to standardize accountability at the global level across the HIV cascade. These 10 indicators have been carefully prioritized and aligned. Still, there is significant work to be done to link these indicators along a clear cascade and result chain, to disaggregate and analyse data, and to use them to highlight the actions needed to improve programmes so that they reach targets.

As Fig. 1.3 shows, the global set of 10 indicators can be used to monitor progress towards the 90–90–90 treatment target. The figure illustrates how the targets link to services and to impact mortality and incidence.

The consolidation of indicators in this guide along the health sector cascade supports accountability for the 90–90–90 treatment target and other global and national targets by:

- **defining a consistent set of global indicators** linked to the 90–90–90 treatment target, the health services cascade and impact in terms of incidence and mortality;
- **describing the methods needed to analyse linkage** along the health sector cascade, to identify bottlenecks and to determine the actions needed to achieve progress;
- **strengthening accountability for targets** by providing measurement methods and structuring how the data are interpreted and used by programmes for targets;
- **providing a clear prioritization** of indicators into those for global reporting and those used routinely to manage the national programme. This should strengthen the alignment of partner reporting requirements with a consistent set of targets.

The following box introduces the 90–90–90 treatment target and corresponding indicators. Assessing progress toward the targets and analysing the cascades can help identify bottlenecks and improve the coverage and quality of services.

The HIV care cascade allows review of data in several ways:

A cohort-based HIV cascade method follows a specific group of people infected with HIV from the time of their diagnosis through to the last point of service delivery. Declines in the number of people from one step to the next in the cascade measure attrition and provide direct information on the effectiveness of linkages among services and of engagement in HIV care. Longitudinal cohort analysis across the cascade requires patient unique identifiers (UIs) and electronic data management systems if people receive services at multiple service delivery points.

A cross-sectional HIV cascade, measured at a specific point in time, presents aggregate data along the continuum of care. Measurements of the cascade using cross-sectional methods can include data on the overall number of people living with HIV, the number diagnosed, the proportion receiving HIV care, the number who are receiving ART and the number who are virologically suppressed. Although different people may be measured at each step, the cross-sectional view can provide valuable insight into the overall programme response to HIV and its effectiveness at different stages of the cascade.

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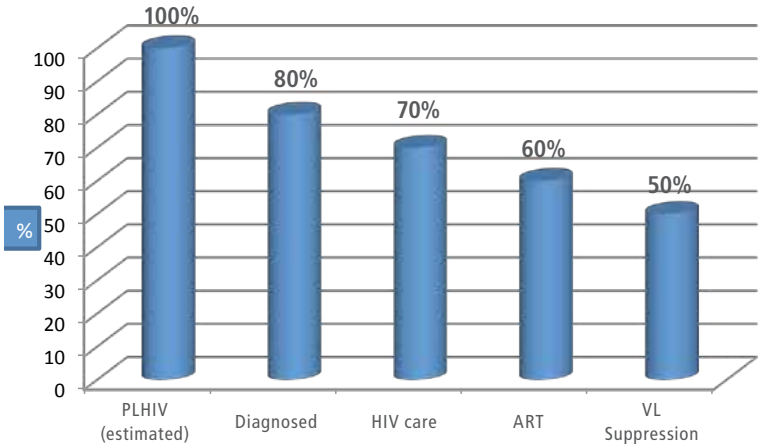
[1] 90–90–90: an ambitious treatment target to help end the AIDS epidemic. Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://www.unaids.org/sites/default/files/media_asset/90-90-90_en_0.pdf).

Cross-sectional and Cohord Cascade for Year X

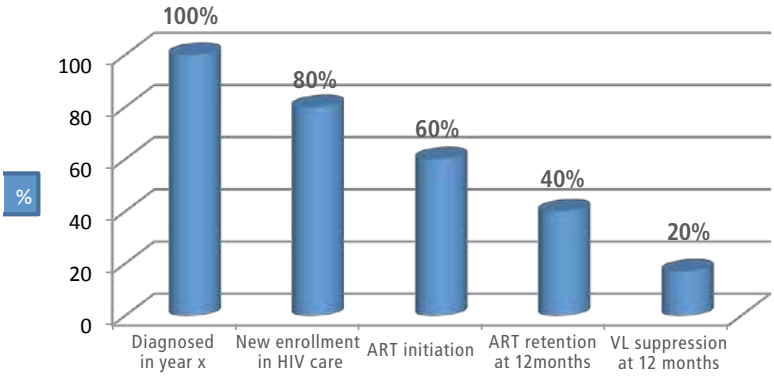


In the graph above, a cohort-based HIV cascade will illustrate how many estimated people living with HIV have been diagnosed (and aremalive), and what proportion of those diagnosed are receiving HIV care (measurement can be proxied by receiving a clinical assessment within the past 12 months), and how many of them are receiving antiretroviral therapy, and the proportion of those on ART who are virologically suppressed. Every person has to be in a previous bar (bars to the left) to be in a successive bar (a bar to the right), and the same population is followed to capture the cascade. This can be difficult to create without individual-based data systems linking all the necessary information.

In a cross-sectional cascade, the bars above will illustrate how many people were diagnosed, in HIV care, on ART and virologically suppressed at a given point in time. Aggregate data across the continuum of care is presented and different people may be measured at each step. For example, the number of people in HIV care can be counted, but it may not be possible to link each individual in care to their diagnosis records. However, creating a cascade from aggregate data that is not individually linked can still provide a snapshot of the current situation.

The 2 graphs are examples of cascades using cumulative data representing the current HIV care cascade including people who were ever diagnosed and are still alive today. It is also possible to construct a cohort cascade based on people living with HIV diagnosed in a year. This may be more feasible for countries that do not have individual-based data from the beginning of their HIV response, and also allows the construction and comparison of cohorts diagnosed in different years (see graph below).

In a cohort-based HIV cascade based on those diagnosed in a given year, the population living with HIV and diagnosed in a given year will be followed and tracked to create the cascade. In the example below, the last bars of the cascade tracks outcomes 12 months after ART initiation; thus an appropriate amount of time would need to lapse before the cohort cascade can be created.



The 90–90–90 target

Momentum has built around the 90–90–90 treatment target as the international community moves from the Millennium Development Goals to the Sustainable Development Goals and ending AIDS. In 2014 UNAIDS worked with partners to obtain a global consensus on the creation of a new target to bring HIV treatment to all who need it. These targets include that:

- By 2020, 90% of all people living with HIV will have been diagnosed.
- By 2020, 90% of all people with diagnosed HIV infection will receive antiretroviral therapy.
- By 2020, 90% of all people on antiretroviral therapy will have suppressed viral load.

Modelling suggests that reaching these targets and similar targets for prevention will mean the end of the AIDS epidemic as a public health threat by 2030.[1]

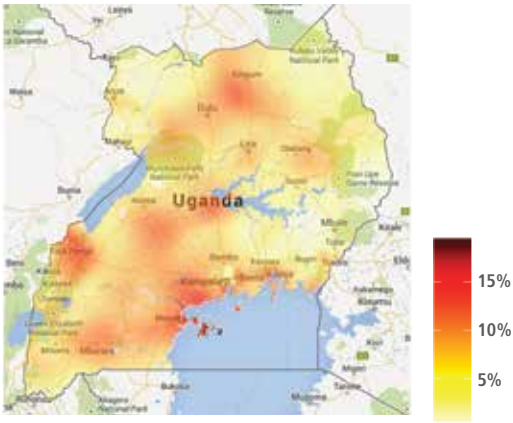
Table 1.1 shows how progress towards the 90–90–90 target will be monitored over the next five years, taking into account the availability and robustness of relevant data. Not all country monitoring systems are set up to directly measure the number of people living with HIV who have been diagnosed, making it challenging to measure the numerator of the first 90 target and the denominator of the second 90 target. Routine systems and strategies for monitoring progress toward this target will evolve and improve over time and across countries. In the meantime, ART coverage, based on the total estimated number of people living with HIV (rather than relying on the number who know their status) will be used for the second 90 target. This ART coverage indicator is already well established and a key metric for national and sub-national comparisons.

[1] Fast-track. Geneva: Joint United Nations Programme on HIV/AIDS; 2014. (http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf).

Table 1.1 The three 90s: targets, indicators, and definitions

	90	90	90
Target	**90% of people living with HIV (PLHIV) have been diagnosed**	**90% of PLHIV diagnosed are receiving ART**	**90% of PLHIV receiving ART have suppressed viral load**
Indicator	Percentage of PLHIV who have been diagnosed	Percentage of PLHIV who are receiving ART	Percentage of people receiving ART who have suppressed viral load
Numerator	Number of PLHIV who have been diagnosed with HIV	Number of people who are currently receiving ART	Number of people on ART who have suppressed viral load (VL)
Denominator	Number of PLHIV	Number of PLHIV	Number of people on ART
Interpretation	Assesses the effectiveness of HIV testing programs in reaching people living with HIV. A more detailed review, identifying which subpopulations are undiagnosed can help tailor HIV testing strategies to improve and increase diagnosis of PLHIV.	Until more countries are able to reliably report the number of PLHIV diagnosed, ART coverage among all PLHIV will be reviewed to track global progress towards the second target. The global target value for this indicator is 81% (90% x 90%) by 2020. *At the national level, it is useful to assess % of ART-eligible PLHIV on ART as well as % of people living with HIV diagnosed and on ART.*	This indicator must be interpreted in conjunction with VL coverage and ART retention rates. VL data available from facilities may be a biased sample in settings where there is low coverage of VL testing. PLHIV on ART are more likely to be virally suppressed than PLHIV who stopped taking ART. Where available, mortality rates among those lost to follow-up should be assessed. VL suppression among people on ART can be directly measured in appropriately designed population-based surveys.

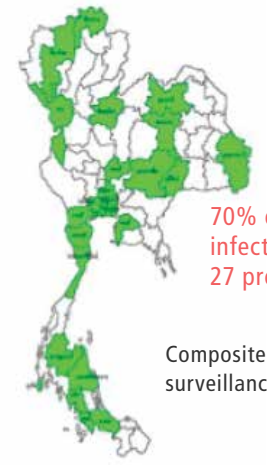
HIV prevalence: disaggregated by age, sex, key population and location



Source: Uganda developing subnational estimates of HIV prevalence and the number of people living with HIV. Geneva: Joint United Nations Programme on HIV/AIDS, 2014.

Regular and practical impact reviews - to focus programs on the epidemic and link services

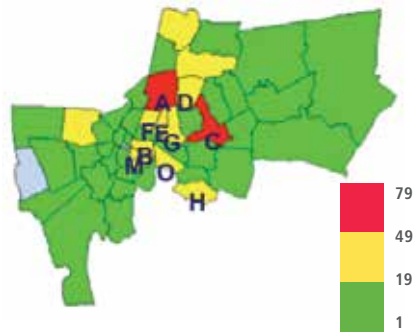
Focus program on impact



70% of new HIV infections happen in 27 provinces

Composite index based on surveillance date

Link local services



December 2011 - December 2012, based on survey date

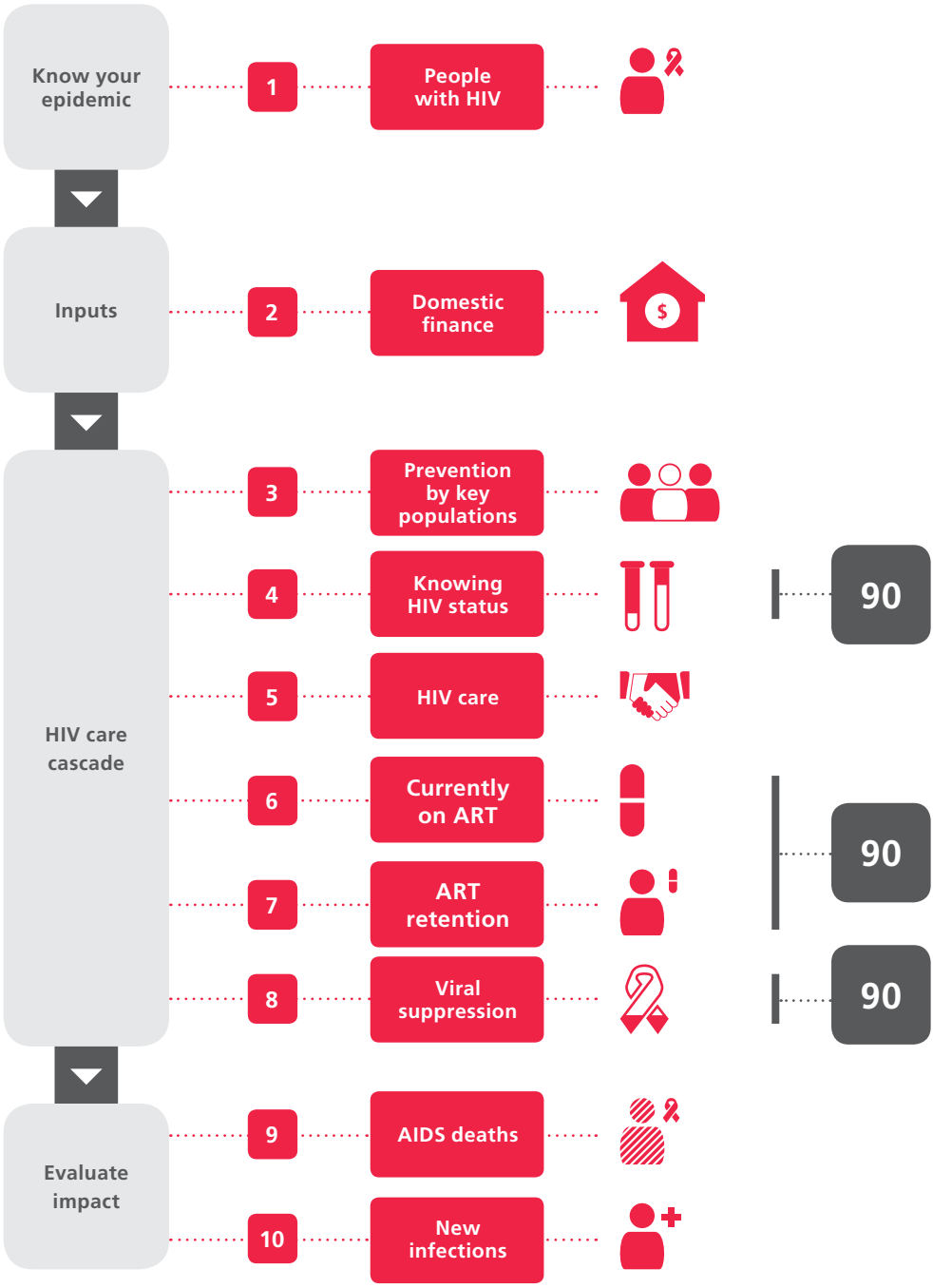
Before: Program response focused evenly across provinces

After: Focus and coverage, package from information to linked services

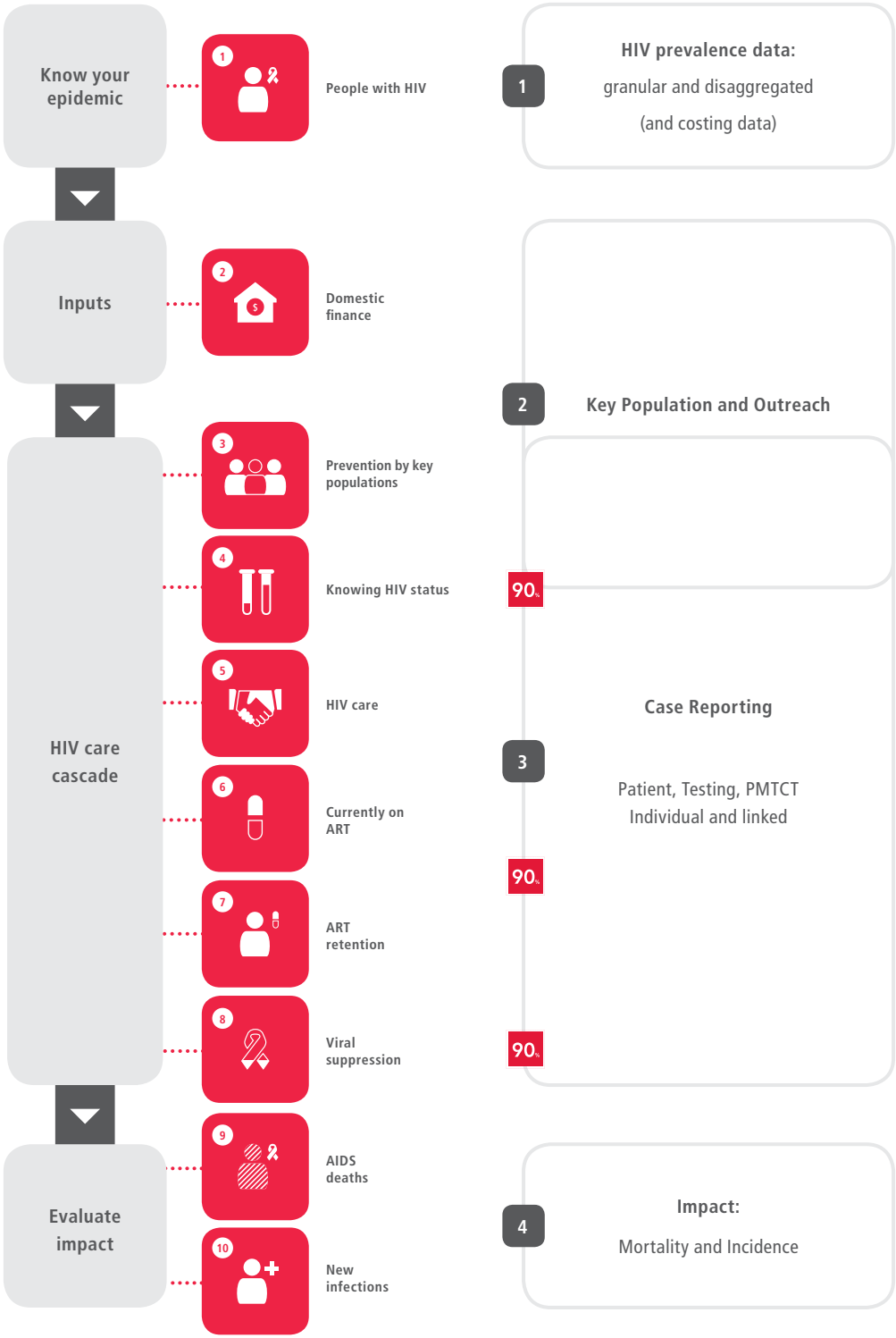
The guide stresses that indicators should be disaggregated and linked to data. Four key types of data are needed, illustrated in the figures. Firstly HIV prevalence data which is as disaggregated as possible by age, sex, key population and location. This should be supplemented by key population data. Data should then be linked along the cascade of services, supported by case reporting where possible. Secondly there should be regular and practical impact evaluation, to ensure that programs are focused on the impact, that the cascade of services is provided, and that adjustments can be made to improve impact on incidence and mortality.

Source: Epi review presentation by Daniel Low Beer. Geneva: WHO, 2015.

Summary of 10 indicators for global monitoring of the health sector



Global indicators for the health sector response to HIV



Prevention, care and treatment services along the HIV cascade

2

2. PREVENTION, CARE AND TREATMENT SERVICES ALONG THE HIV CASCADE

2.1 Introduction

Part 2 describes the key indicators along the HIV cascade and how to select and prioritize them. It begins by highlighting the 10 indicators for global monitoring of national health sector responses to HIV. The remainder of Part 2 presents the 50 national indicators and the additional indicators. To promote better analysis and use of data, the indicators are organized according to the result chain and the HIV services cascade. In each section the text discusses the framework and practical considerations for monitoring, followed by a table detailing the recommended indicators. These indicator tables include a summary of the indicator's numerator and denominator, recommended disaggregations, measurement method and programme relevance. Detailed reference sheets for the indicators are published separately online at http://www.who.int/hiv/topics/me/en/.

Key points in Part 2

- 10 global indicators are proposed to represent the key stages and linkages in the result chain.
- 50 indicators are recommended from which countries can select those most relevant to their strategic information needs; these 50 include the 10 global indicators.
- Disaggregating data by age, sex, key populations and location is critical in analyzing the indicators to focus programme improvement efforts.

2.1.1 The 10 global indicators

The 10 global indicators constitute a minimum set recommended for global monitoring. As Fig. 1.3 on page 30 shows, each of the 10 global indicators reflects a key step in the HIV prevention, care and treatment cascade. Taken together, the 10 global indicators summarize the overall performance of the health system response to HIV and provide information on key linkages and bottlenecks. Table 2.1 summarizes the 10 global indicators. Since they are a subset of the 50 national indicators, they appear again, with additional detail, in subsequent tables in Part 2 (as indicated in the far right column of Table 2.1).

To create a common ground for global monitoring and comparisons among countries, national managers should include the 10 global indicators among the national indicators selected for their M&E framework. To the extent possible, countries should adhere to the definitions, purposes, means of measurement and interpretation of the 10 global indicators.

Criteria for selection of the 10 global indicators

Taken together, the 10 global indicators summarize the performance of the health system response to HIV.

The following criteria guided their selection:

1. Validity
2. Relevance to a particular step and linkage along the result chain and the health services cascade
3. Feasibility of measurement and availability of data
4. Usefulness to HIV monitoring on both the national and the aggregate global levels
5. Worldwide applicability and comparability.

Table 2.1 Ten global monitoring indicators of the health sector response to HIV

Indicator	Relevance to cascade	Rationale for global monitoring	Disaggregation	Indicator reference
1. People with HIV Number and % of people living with HIV N: Number of people living with HIV. D: Population.	Target population for the HIV care cascade. Serves as numerator or denominator for several other estimates along the cascade.	Reflects epidemic and service needs. Disaggregated analysis key to focusing programs on the epidemic.	Sex, location, key population,* pregnancy status, ART eligibility, HIV prevalence among TB patients (LINK.13),	NEEDS.1[1] Derived from surveillance, surveys and programme data, "know your epidemic" review, internationally consistent modelling.
2. Domestic finance % of HIV response financed domestically N: HIV domestic public expenditure. D: Total HIV expenditure.	Important for the sustainability of financing the response to HIV.	Used to assess government commitment and ownership and to identify funding gaps. Funding by service area and people with HIV also important for program planning.	Key population and other target population, programme categories such as prevention, treatment and care.	RES.31 Health Accounts (HA) and National AIDS Spending Assessment (NASA) can help capture expenditures and track trends.

1 Indicator labels such as "NEEDS.1" identify indicators in the tables throughout Part 2.
* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

3. Prevention by key populations a) for sex workers, % reporting condom use with most recent client b) for men who have sex with men, % reporting condom use at last anal sex with a male partner c) for people who inject drugs, needles–syringes distributed per person d) for general population, % of women and men who had more than one partner in the past 12 months who used a condom during their last sexual intercourse	Reflects prevention interventions in key population and the general population to control transmission risk and prevent new HIV infections. Prevention is key to the cascade and should be assessed at all stages.	Condom use with non-regular or high-risk sexual partners and clean needle–syringe provision reflect key interventions and can be consistently measured across all countries. These should be carefully analysed by age, sex, population, and in relation to behaviours.	Sex (female, male, transgender), age, behaviours (e.g. number of partners, type of partner, including regular and non regular partners). Prevention data on activities, e.g. condoms, and behaviours are key at each stage of the cascade and should be analysed carefully by age, sex, time and location. They should also be assessed alongside evaluation of outcomes and impact and their determinants.	a) PREV.1.a b) PREV.1.b c) KPOP.2 d) PREV.1.d Collected through surveys. Needs to be interpreted based on coverage and sampling of survey. Include use of pre-exposure prophilaxis (PrEP) where relevant.
4. People living with HIV diagnosed Number and % of people living with HIV who have been diagnosed N: Number of people living with HIV who have been diagnosed and received their results D: Number of people living with HIV.	Diagnosis and awareness of HIV-positive status are precursors to care and treatment. Also, HIV testing may influence adoption of preventive behaviours among both HIV-positive and HIV-negative people.	HIV testing is key to effective responses to HIV.	Sex, location, key population,* pregnant women, TB patients, other target populations.	HTS.1 Data for specific populations should also be assessed: a. key populations b. pregnant women c. TB patients. Programme data (including case reporting), populations based surveys, and key population surveys.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

5. HIV care coverage Number and % of people living with HIV who are receiving HIV care (including ART) N: Number of people living with HIV who received HIV care in the past 12 months OR CD4 count OR viral load OR currently receiving ART. D: Number of people living with HIV.	Reflects linkage to care by measuring HIV care coverage and progress towards universal access to care (including ART).	Helps to track global trends in coverage of care and treatment across populations of people living with HIV.	Sex, age, location, key population,* pregnancy status, treatment status (i.e. pre-ART or ART).	LINK.2 The numerator is based on programme data counting people living with HIV who receive a clinical or lab assessment or are on ART, as proxies for receipt of care. The denominator is usually estimated. Sources include pre ART and ART registers.
6. Currently on ART Number and % of people living with HIV who are currently receiving ART N: Number of people living with HIV who are currently receiving ART D: Number of people living with HIV.	Measures the extent to which needs for ART are met.	Tracks trends in ART coverage nationally and globally.	Sex, age, location, key population,* regimen.	ART.3 The numerator is based on programme statistics; the denominator is usually estimated using an internationally consistent model. For consistency in global reporting, people living with HIV is used as denominator. For national use coverage should also be calculated applying national ART eligibility criteria to estimate the denominator (ART.2).

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

7. ART retention Number and % of people living with HIV and on ART who are retained on ART 12 months after initiation (and 24, 36, 48 and 60 months) N: Number of ART patients alive and on ART 12 months (or 24, 36, 48, 60 months, etc.) after initiating ART D: Number of patients initiating ART up to 12 months (or 24, 36, 48, 60 months, etc.) before the beginning of the reporting year. This includes those who have died since starting therapy, those who have stopped therapy and those lost to follow-up as of month 12 (or 24, 36, 48, 60, etc.)	Once on ART, treatment is lifelong. Retention on ART is important to achieve the desired outcomes of the HIV care cascade.	Indicates quality of services and continuing engagement of people living with HIV on ART.	Sex, age, location, pregnancy/ breastfeeding at initiation; optional: coinfection with TB also for 24, 36 months and longer periods.	ART.5 Follows cohorts of people living with HIV initiating ART. Systematic analysis of those lost to follow-up is required to determine true outcomes, including mortality patterns.
8. Viral suppression Number and % of people on ART who have suppressed viral load N: Number of people living with HIV and on ART who have a suppressed viral load (<1000 copies/ mL). D: Population-level denominator: Number of people on ART in the past 12 months.	Gauges the proportion of people on ART who have suppressed viral load. A high proportion with suppressed viral load implies a low rate of onward transmission. Viral load suppression among a cohort 12 months after ART initiation should also be monitored (VLS.1).	Viral suppression is an indicator of treatment success and reduced potential for transmission.	Sex, age, location.	VLS.3 Provides a cross-sectional view of viral load suppression among people on ART. Can also be assessed by time since initiation of ART, as a cohort. Suppressed viral load is defined as <1000 copies/mL.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

9. AIDS-related deaths Number of AIDS-related deaths per 100 000 population N: Total number who have died of AIDS-related illness in a 12-month period D: Population (100 000).	Measure the ultimate negative outcome of past incidence and care and treatment failure.	Shows trends in deaths among people with HIV; can be compared with other causes of death.	Sex, age, location, HIV-positive TB.	IMP.1 Analysis of sample and site mortality data. Ongoing improvement of vital registration will facilitate measurement of this indicator. Number of deaths can be compared with the number of people living with HIV to review trends.
10. New infections Rate of new HIV infections: number of new HIV infections per 1000 uninfected population N: Number of new infections D: 1000 uninfected population, which is the total population minus people living with HIV.	Reflects the impact of HIV prevention and treatment.	Important for monitoring epidemic trends, detecting possible shifting patterns and projecting needs.	Sex, age, location, mode of transmission (for children), key population,* other target populations.	IMP.2 Estimates should be calculated through internationally consistent modelling, cohorts and age-specific HIV prevalence data. Predicts the direction of epidemics.

2.1.2 Data disaggregation for better programming

The overall HIV response has reached millions of people with HIV services. However there are specific populations that still have high unmet need. Monitoring HIV disease burden and coverage of related services by age and sex and other characteristics will assist with better focusing services for the populations who need them most and monitor equity.

Disaggregation is the separation of data into component parts in order to identify and highlight differences within data aggregates. Disaggregation makes it possible to focus a country's responses on the people, places and situations where it will achieve impact. At regular intervals data should be disaggregated by sex, age, key population and location (e.g. subnational or site level).

Disaggregation of indicator data provides the information needed to tailor responses to the specific epidemic situation and the people most in need. The consolidated core set of indicators presented in this guide can be disaggregated by age, sex, key population and location (to subnational or site level) for more intensive analysis that can guide programming (Fig. 2.1). Disaggregation of data is critical to guiding the response to HIV. Ending HIV as a public health issue will require much greater granularity of data and analysis.

In most cases HIV related data are disaggregated for key indicators according to:

- **Age** – into standard age groups <1, 1-4, 5-14, 15-19, 20-24, 20-49, 50+. We recommend regular data extraction (e.g. annual) to report on these age groups in paper based systems. 5 year age groups should be used for electronic systems.

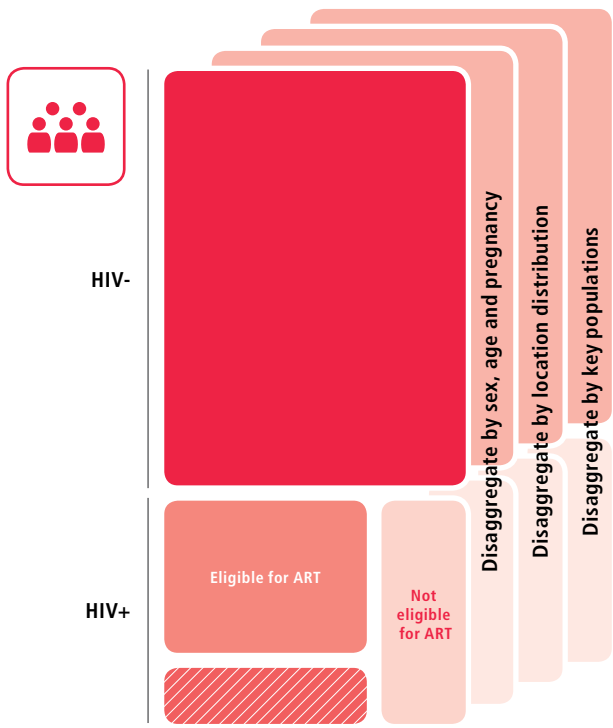
- **Sex** – for example to assess differences in infection and service coverage along the cascade

- **Key populations** – including men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers, transgender people. Confidentiality, security and participation of key populations in data efforts are critical

- **Location** – data should be regularly disaggregated sub-nationally so that it is used at district and site levels

- **Pregnancy** and breastfeeding status – as appropriate

Fig. 2.1 Disaggregations of HIV health sector data



Disaggregation of data routinely collected through paper systems requires more effort than data collected by electronic systems. For paper-based systems we therefor recommend data extraction exercises (e.g. annual or more frequently) to report on standard age groups, 5 year age groups should be used for electronic systems. We are also supporting strengthening patient and case reporting, which can provide more individual and linked cascade data relevant to service delivery.

Disaggregation by key population

Key populations are groups of people who are at increased risk for HIV across epidemic settings due to specific behaviours. Legal and social barriers further contribute to their vulnerability. Overall, the risk behaviours and vulnerabilities of key populations and their networks greatly affect the dynamics of all types of HIV epidemics.

Key populations are:

- men who have sex with men
- people who inject drugs
- people in prisons and other closed settings
- sex workers
- transgender people.

Due to their higher risk of HIV transmission and the presence of barriers to prevention and care services, key populations require services that are specifically tailored to their needs. Disaggregating indicators by key population enables programmes to specifically monitor and evaluate the epidemic and the response for each relevant population group. Section 2.4.1 discusses services for key populations in more detail.

Information about key populations – and about people living with HIV, whether they are from key populations or not – must be collected and stored securely. A breach of the confidentiality of this information may not only jeopardize future data collection and seriously damage people's trust in the health services; it may even put people's well-being and lives at risk if they are subjected to social stigma or legal repression. Thus, utmost care must be taken to ensure confidentiality, security and participation of key populations in data efforts.

Other populations at specific risk. Other populations also require HIV services tailored to their specific needs. It is important for countries to identify the vulnerable groups in their setting and to specifically monitor and evaluate the HIV risk of these groups and their access to services. For example, in addition to key populations, populations of interest may include migrant workers, refugees, long-distance drivers, military personnel, miners, people living with disabilities and people with concurrent chronic illnesses. Although such groups are not systematically listed in this guide,[1] they should be considered in monitoring and evaluation plans, as relevant to the context. This guide does consider those eligible for ART regardless of CD4 count as subgroups of potential interest for data disaggregation: pregnant women, children under age five, serodiscordant couples and people living with dual infections (for example, tuberculosis (TB) and HIV).

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[1]Strategic information for such groups is specifically addressed elsewhere – for example:

Strategies to support the HIV-related needs of refugees and host populations. Geneva: Joint United Nations Programme on HIV/AIDS; 2005 (http://data.unaids.org/Publications/IRC-pub06%2Fjc1157-refugees_en.pdf).

The GAP report 2014. People aged 50 years and older. Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://data.unaids.org/Publications/IRC-pub06/jc1157-refugees_en.pdf) or (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2014/gapreport12pops/12_Peopleaged50yearsandolder.pdf).

The GAP Report 2014. Migrants. Geneva: Joint United Nations Programme on HIV/AIDS, 2014 (http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2014/gapreport12pops/04_Migrants.pdf).

HIV and population mobility. Geneva: International Organization for Migration; 2010 (http://www.iom.int/jahia/webdav/shared/shared/mainsite/activities/health/hiv-population/IOM-Global-HIV-GN2010.pdf).

Age-and-sex disaggregation. While it is important to consider the unique traits of both age and sex when disaggregating indicators (see below), patterns of HIV disease burden typically emphasize a specific combination of the two. Consequently, planning disaggregation according to age-and-sex categories makes data obtained from survey or programme data more informatic.

Age disaggregation. Disaggregation by age is important to understand changes in prevalence and incidence, to characterize how the epidemic is evolving, to monitor equity of access to services and to support the planning of programme responses in specific age groups such as children under five, adolescents, young adults and older adults. In general, age and sex disaggregation by 5-year age groups is recommended, with further breakdown of age <5 into <1 and 1–4. While age disaggregation is very labour-intensive in a paper-based reporting system, age- and sex-disaggregated data are very valuable to programming; countries should consider it carefully when reviewing their M&E systems. Routinely disaggregating data into every 5-year age group may not be feasible; in such cases some standard age groups to consider would be <1, 1–4, 5–14, 15–19, 20–49 and 50+.

The tables in this guide list age groups for disaggregation according to the level of available resources and capacity. The minimum number of disaggregation categories are listed for routine use in low-resource settings with paper-based monitoring systems. Additional age categories are also recommended for reporting; while higher resource settings can extract them routinely, lower resource settings can consider annual extraction, at least at sentinel sites if it is not feasible to collect the data at every site. In settings with electronic data systems, it is recommended to disaggregate data by 5-year age groups.

The three categories are listed with the following sub-headings:

1. electronic system, with 5-year age groups.
2. annual (or more frequently) data extraction of more age categories for disaggregated data if not reported routinely
3. minimum for paper-based (routine)

Sex disaggregation. The role of sex or gender as a factor for HIV risk depends on the epidemic context. Where HIV transmission is largely through heterosexual sex, as is typical in generalized epidemics, women may be at greater risk of infection than men. Women have a biologically higher risk of infection when exposed to HIV. They may also have a higher risk of exposure to HIV for social reasons, such as their male partners' multiple sexual partnerships, women's relative lack of economic and social power in relationships and in society, and patterns of sexual exploitation and violence against women. In contrast, men may be at greater risk than women in some concentrated epidemics where transmission is mainly through sex between men and through drug injection.

"Gender" refers to a socially constructed role associated with men or women. "Transgender" refers to people whose self-identified gender differs from their biological sex at birth. Transgender people are considered to be a key population; many are at particularly high risk of HIV infection due to their sexual behaviours as well as social marginalization. Including transgender in sex disaggregation is important to identify gaps in the HIV programme response because health services generally fail to identify and respond to the prevention, care and treatment needs of the transgender population.

Disaggregation by location

To better understand the epidemic and to focus services to respond effectively, disaggregation by location, to inform subnational, district and site level programming and other locations of interest, is central to the effectiveness of the health sector response to HIV. Collecting, analysing and disaggregating data on the geographical location of HIV transmission and of service coverage and uptake valuable information for HIV programme managers. High rates of HIV transmission,

morbidity and mortality often cluster in specific locations. Data collection and analysis should be sensitive also to emerging geographic trends, such as increasing prevalence along a transportation route. Disaggregation by location also allows tracking of access to and use of services in selected locations over time, such as HIV testing services or other points of care within the catchment areas of health facilities. Location information can reveal possible inequities in access to and use of services affecting certain populations or environments (for example, rural, urban or suburban), thereby drawing greater attention to underserved communities. Conversely, finding better programme performance in particular locations could spotlight innovative prevention, care and treatment activities that the entire programme could learn from. Data disaggregated by location to subnational and site level are important to help focus and prioritize the response to the areas where it can have the greatest impact. Mapping exercises have also been important to focus outreach and prevention services on specific sites, places and populations.

Denominators matter, too

While much attention goes to counting numerators for the indicators presented in this guide, denominators also are important. In general, there are two types of denominators:

Population denominators: The denominator is the number of people in a group, regardless of whether or not they come into contact with the health-care system. For example, the number of people living with HIV is often used as a population denominator. Indicator ART.3, Number and % of people living with HIV who are receiving ART, uses this population denominator. (ART.3 is a global indicator.) Population denominators, although usually estimated, are helpful because they can be used for a number of indicators along the cascade, which helps to make attrition obvious.

Programme denominators: The denominator is a number that is known to the health-care system (such as the number of people in care or the quantity of supplies ordered). For example, the number of people who have been diagnosed with HIV is a programme denominator. Indicator ART.2, % of eligible people living with HIV who are receiving ART, can make use of this programme denominator. Programme denominators are useful for programme planning purposes.

As with information on key populations, information on location should be limited to what is needed for programme design and management and kept strictly confidential.

2.2 Know your epidemic

This guide focuses on using data to maximize the coverage, quality and impact of HIV services. This can be achieved only when services and outreach are tailored to the populations to be served – both those living with HIV and those at risk. Knowing your epidemic and understanding needs, eligibility and context are the foundation for all aspects of the response, including programme design, planning and direction.

2.2.1 Key variables for measurement

The HIV prevention, care and treatment cascade starts with knowing your epidemic: understanding the size and distribution of the epidemic, behaviours that drive the epidemic, estimates of prevalence and new infections, and changes in these measures over time, including among key populations.

Four numbers concerning people in need are key to guiding the health sector response to HIV:

1. number of people living with HIV, disaggregated by age, sex, key population and location

2. sizes of key populations

3. number of people eligible for ART

4. number of women and their children eligible for MTCT prevention, treatment and care.

This section describes these four key numbers. Table 2.2 details all the recommended indicators of needs for HIV prevention and treatment.

1. People with HIV
Indicator: NEEDS.1. Number and % of people living with HIV

Knowing the number of people in a country who are living with HIV is fundamental for planning programmes and monitoring impact. The estimated number of people living with HIV provides the potential size of the group entering the care and treatment cascade, and it also serves as the denominator for the first two of the 90–90–90 treatment target. It is generated using globally consistent estimation methods that rely on country-specific demographic, HIV surveillance and programme data and also data from HIV case-based surveillance.

1. People with HIV

Number and % of people living with HIV

Knowing the total number of people living with HIV is only the first step. Disaggregating these data by sex, age, different key population groups and location distribution is crucial for tailoring a country's response to needs. Disaggregation is also necessary for monitoring programme coverage and impact. (For more on disaggregation, see section 2.1.2.)

2. Key populations
Indicator: NEEDS.2. Estimated sizes of key populations

Key populations are, by definition, crucial to the dynamics of any HIV epidemic. The most commonly defined key populations are men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers and transgender people. Estimating the sizes of these key populations is important to assess and ensure that services and support are adequate to meet the needs of people from these populations.

In addition to prioritizing allocation of programme resources, estimates of the size of key populations can be used for advocacy. For example, information on key populations helps to support requests for increased resources, attention and prioritization for these groups. Population size estimates also provide essential denominators for calculating several M&E indicators.[1]

Size estimation methods include census and enumeration, programmatic mapping, capture and re-capture, multiplier method and the network scale-up method (NSUM). In recent years various new methods and approaches have also been proposed and used, including "wisdom of the crowds" and the proxy respondent method. Most methods require surveys, such as the Integrated Behavioural and Biological Surveillance (IBSS) survey. The UNAIDS/WHO Global Surveillance Working Group has developed guidelines for population size estimates.[2]

Different methods often yield different estimates. Therefore, using several methods can be helpful to understanding the sensitivity of the estimates. Estimates should be rounded to the nearest 100 or 1000 to suggest that these are, indeed, estimates and not counts. In addition, the geographic

[1] For detailed guidance see: Tool for setting and monitoring targets for prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; forthcoming.
[2] Guidelines on estimating the size of populations most at risk to HIV. Geneva: UNAIDS/World Health Organization Working Group, 2010 (http://www.who.int/hiv/pub/surveillance/estimating_populations_HIV_risk/en/).

validity of the data must be considered as well as how data collected in relatively small areas can be extrapolated to larger administrative areas, up to the national level. Countries can convene a stakeholder meeting, including representatives of key populations, to consider the various estimates and decide on a plausible number. The goal is to generate sound and agreed estimates for scaling up services for key populations. Since population size estimates do not change dramatically from year to year, the process can be conducted at intervals of three to five years.

3. ART eligibility
Indicator: NEEDS.4. Estimated number and % of people living with HIV eligible for ART

The number of people eligible for ART provides information on the extent of services and commodities required if ART needs are to be completely met. It also serves as the denominator for the ART coverage indicator based on eligibility – that is, the percentage of those eligible for ART who are receiving ART (ART.2).

ART eligibility criteria vary by country. They are laid out in national policies and care and treatment guidelines based on scientific evidence, national standards of public health and clinical practice, global recommendations and other considerations. Global recommendations have evolved over the last decade, gradually expanding eligibility. WHO guidelines[1] recommend that, among HIV-positive individuals, ART should be initiated for:

- anyone age five years or older with a CD4 count of ≤500 cells/mm^3
- all children over age five regardless of CD4 count if they are in WHO clinical stage 3 or 4 or have active TB disease
- all children under five years old, including infants
- all pregnant and all breastfeeding women
- all serodiscordant couples
- all people coinfected with TB
- all people coinfected with hepatitis B who present with chronic liver disease.

At the population level, estimating the number of people eligible for ART relies on the same epidemiological models used to estimate the number living with HIV. The models calculate this number by adding those already in treatment (that is, those who have met previous or current eligibility criteria) plus those who are eligible based on the current criteria but not yet in treatment. Modelled estimates are preferable to numbers derived from programme data because programme data cannot capture those who are eligible but have not been identified.

As noted, eligibility criteria for initiating ART have changed over the last decade. Comparison of treatment coverage levels that takes into account changing eligibility criteria is complicated. Furthermore, as eligibility criteria expand, the number of eligible persons will approach the total number of persons living with HIV. In light of this, measuring and comparing treatment coverage over time using the total number of people living with HIV as the denominator (ART.3) is simpler and can provide more comparable information both over time and across countries.

4. HIV-positive pregnant women
Indicator: NEEDS.5. Estimated number and % of pregnant women who are HIV-positive

According to the latest global guidelines,[1] all HIV-positive pregnant women should take ART to avoid transmitting the virus to their children and for their own health. Thus, the number of pregnant women eligible for services for the prevention of mother-to-child transmission (PMTCT) is simply the number of women living with HIV who are pregnant. This number, ideally disaggregated by location, provides the basis for determining whether the coverage of PMTCT interventions is adequate.

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[1] Ibid.

In most situations modelling is required to estimate the number of women eligible for PMTCT. In settings where the coverage of antenatal care (ANC) is nearly universal and ANC clients are systematically tested for HIV, programme data could theoretically reflect the number of HIV-positive pregnant women. Some countries try to estimate the number of HIV-positive pregnant women by multiplying the HIV prevalence obtained from antenatal clinic surveillance by the annual number of births in the country. This approach is appropriate only if ANC surveillance is representative of the entire country or it is possible to adjust for sources of bias due to the selection of sites; this is not the case in most countries, however, because ANC surveillance is focused on urban areas. Even with the trend toward expansion to rural sites in recent years, ANC surveillance is most often conducted at facilities that serve large numbers of pregnant women, potentially biasing prevalence data.

2.2.2 Measurement methods

The number of adults, children and pregnant women with HIV and the numbers eligible for ART often come from estimation models. A globally consistent estimation method such as the UNAIDS-supported Spectrum modelling tool should be used to produce common HIV-related estimates. For some countries, particularly those with very low-level or concentrated epidemics, it may be difficult to model estimates accurately due to the lack of data or data quality for the variety of data elements needed for more precise estimates. It is nonetheless important for countries to collect and review available data to better understand the dynamics of their epidemic.

Five of the 10 global indicators require the use of estimation approaches in many countries. Making results comparable from one country to another requires using the same assumptions in these calculations. For this reason the UNAIDS Reference Group on Estimates, Modelling and Projections has been formed to review and improve these methods. Currently, the group recommends an internationally consistent modelling estimates (e.g. Spectrum AIDS Impact Model), using the Estimation Projection Package, the AIDS Epidemic Model or the incidence fitting tool in that package.

Estimation models

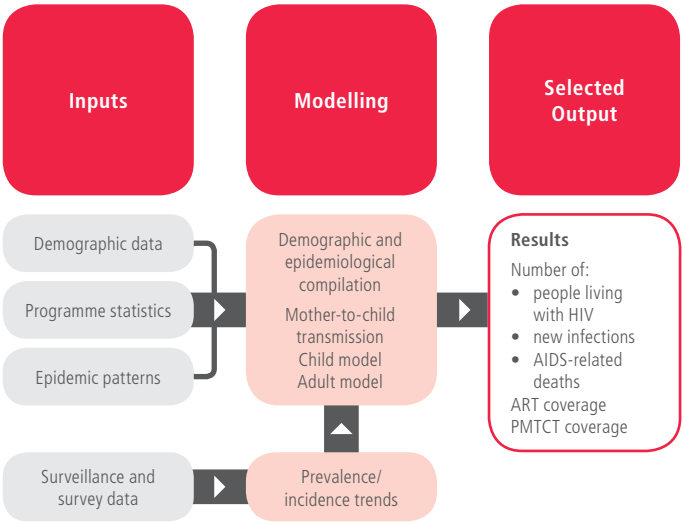
Data collected in-country and an assessment by the national HIV programme form the basis for estimates of the number of people living with HIV and the number of people eligible for ART. The assessment should use programme, surveillance (including case-based surveillance) and survey data, disaggregated by sex, age, key population and location.

The Spectrum AIM model can help to fill gaps. The software can be downloaded free of charge from http://www.avenirhealth.org/spectrum.aspx. UNAIDS makes the most recent AIM files available for those countries that allow their distribution, at http://apps.unaids.org/spectrum/.

The Spectrum AIDS Impact Model uses country-specific data to produce national estimates. Demographic data, such as the size and structure of the population and fertility, mortality and migration rates, are incorporated into the model. Users enter additional data, including programme data on the number of people receiving ART and PMTCT care and all available HIV surveillance and survey data that describe levels and trends in HIV prevalence. For countries with strong HIV reporting and vital registration systems, HIV case and AIDS-specific mortality data may also be used to construct or inform the estimates. Assumptions about disease progression and the distribution of incidence by sex and age are incorporated into the model. The user can modify those values if more appropriate country data are available. The model uses the combination of these inputs and assumptions to produce a variety of impact indicators commonly used to monitor the HIV epidemic, as shown in Fig. 2.2.

The UNAIDS Reference Group on Estimates, Modelling and Projections provides technical guidance on the development of the HIV model in Spectrum (http://www.epidem.org). This

Fig. 2.2 Schematic of Spectrum AIDS Impact Model



group recommends revisions and improvements to the software annually, with input from HIV programme staff, mathematical modellers, statisticians, demographers and epidemiologists. Also, countries update the surveillance and programme statistics included in the models, leading to a more accurate understanding of the national or subnational epidemic. As a result, the most recent estimates (that is, for the current year) are more accurate and reliable than those produced in previous years. They should not be compared with estimates from previous years because different methods and data of varying accuracy may have been applied in previous rounds.

When using Spectrum outputs, the uncertainty ranges around the estimates should be reviewed (see box below). Estimates for very narrowly defined groups may be less reliable if there are large uncertainties around the data entered into the model. For example, estimates for larger groups, such as all children under 15 years of age, may be more reliable than estimates for smaller populations, such as HIV-positive children ages 5–9 years.

Uncertainty in modelled estimates

Uncertainty is often expressed as bounds around modelled estimates. Two factors determine the width of the bounds. The first is the quantity and source of the HIV surveillance data that inform the modelled estimates. Estimates from countries with good surveillance data will have smaller uncertainty ranges around their estimates than countries with sparse or infrequent surveillance data. The second factor is the number of assumptions required to arrive at the final estimate of interest. Estimates based on fewer assumptions, such as the number of adults living with HIV, will have smaller uncertainty bounds than those that require a greater number of assumptions, such as the number of children living with HIV. For children, additional assumptions, including the prevalence among pregnant women, the probability of mother-to-child HIV transmission and estimated survival times for HIV-positive children, are all required to estimate prevalence. These many assumptions introduce additional uncertainty in the accuracy of the estimate.

How Spectrum AIM calculates HIV estimates

The number of people living with HIV

Spectrum AIM estimates the number of people living with HIV, disaggregated for adults and children, as follows:

For adults (ages 15+ years)

- HIV prevalence data from the country's HIV surveillance system are used to estimate the trajectory of the HIV epidemic over time. HIV case and AIDS-specific mortality data may also be used to construct or inform the incidence estimates in countries where those data are of sufficient quality.
- Annual HIV incidence is calculated based on prevalence and the number of people receiving ART, as entered into the model by the country.
- Assumptions about the population's demographic structure and those newly infected, including disease progression as determined by CD4 count at time of diagnosis, and survival among those receiving and not receiving ART are applied to the incidence estimates to estimate the number of adults living with HIV in any given year.
- The model outputs provide disaggregation of the number of people living with HIV by age, sex and pregnancy status for women. Depending on the structure of the model, estimates are also available by geographic area and key population.

For children (ages <15 years)

- The model's estimates of the number of adults living with HIV are used to determine the number of births to HIV-infected mothers.
- The number of children infected annually through mother-to-child transmission during pregnancy, delivery or breastfeeding is calculated.
- Assumptions about the survival of HIV-infected children, depending on time since infection, time since diagnosis and the proportion of children on ART (as entered by the country) are applied to determine the number of children living with HIV annually.
- The model outputs provide disaggregation by age and sex.

The estimated number of people living with HIV is the sum of the number of children and adults infected with HIV as described above.

The number of people eligible for ART

Spectrum AIM estimates the number of people eligible for ART as follows:

- The proportion of the population that is eligible based on CD4 count or other criteria (for example, under age five, pregnancy, co-infection with TB, serodiscordant couples, hepatitis B/C) and the approximate proportion of the population living with HIV where known, are entered into or calculated in the model. Countries can modify these values if they have more accurate information. ART eligibility for children can also be stipulated in the model by CD4 count, CD4 percentage or the age of the child.
- The estimated number of people infected with HIV, disaggregated by CD4 count and the other factors, including pregnancy, as determined by model inputs, are compared with the national treatment guidelines to estimate the number of people newly eligible for ART.
- This number is added to the number of people receiving ART in previous years that remain alive to estimate the number of people eligible for ART in the country.

The number of pregnant women eligible for PMTCT

The number of pregnant women eligible for PMTCT is estimated by multiplying the number of women living with HIV in each 5-year age group from 15–19 through 45–49 by age-specific fertility rates and then adjusting to account for differences in fertility between women living with HIV and HIV-negative women by age groups.[1] The fertility adjustments, which are applied to HIV-positive women who are not receiving ART, are based on default values, but countries can change the values if country-specific data are available.

Journal articles describing the methods and assumptions of the Spectrum AIM model can be found at http://www.epidem.org/publications.

[1] Chen W-J, Walker N. Fertility of HIV-infected women: insights from Demographic and Health Surveys. Sex Trans Infect 2010;86(Suppl 2):ii22eii27.

Table 2.2 Key indicators of HIV prevention and treatment eligibility

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
NEEDS.1 People with HIV Number and % of people living with HIV Global indicator	N: Number of people living with HIV. D: Population.	Sex, age (<1, 1–4, 5–14, 15–24, 15–49, 50+; adolescents 10–19 where relevant, feasible, available), location, , key population* (ages <25, 25+), pregnancy status, ART eligibility, HIV prevalence among TB patients. Also, ages 15–24 (15–19, 20–24) for surveys and surveillance.	Survey, surveillance (including case-based surveillance) and national demographic and programme data, with globally consistent estimation method.	Basis for determining size of epidemic and HIV care and treatment service needs; denominator for coverage data and for tracking impact.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

NEEDS.2 Key populations Estimated size of key populations	Specifically, men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers, transgender people.	Sex, age (15–24, 25+), HIV status, adolescents (ages 10–19) where relevant, feasible, available.	Recommended methods of of estimating population size.[1]	Basis for determining national and subnational service needs; denominator for coverage data and for tracking impact.
NEEDS.3 Coinfection Estimated number and % of people living with HIV who have coinfections/ conditions	N: Number of people coinfected with HIV and specific other diseases. D: Number of people living with HIV.	Breakdown per coinfection (e.g. active TB, hepatitis B/C).	Internationally consistent modelling estimates (e.g. Spectrum AIM) for HIV/TB coinfection.	Basis for determining national and subnational needs for and coverage of prevention, care and treatment of co-morbidities.
NEEDS.4 ART eligibility Estimated number and % of people living with HIV who are eligible for ART	N: Number of people eligible for ART. D: Number of people living with HIV.	Breakdown by national eligibility criteria or, globally, by CD4 ≤500, CD4 ≤350 (for prioritization), <5 years of age, pregnant women, TB or hepatitis B/C coinfection, serodiscordant couples.	Internationally consistent modelling estimates (e.g. Spectrum AIM).	Basis for determining national and subnational needs for and coverage of ART care and treatment.
NEEDS.5 HIV-positive pregnant women Estimated number and % of pregnant women who are HIV-positive	N: Estimated number of HIV-positive pregnant women (all of whom need ART). D: Estimated total number of pregnant women.	None.	Internationally consistent modelling estimates (e.g. Spectrum AIM); surveys; programme data if universal ANC with HIV testing.	Basis for determining national and subnational needs for and coverage of ART for PMTCT.

[1] For guidance on estimating the sizes of key populations, see: Guidelines on estimating the size of populations most at risk to HIV. Geneva: UNAIDS/World Health Organization Working Group, 2010 (http://www.who.int/hiv/pub/surveillance/estimating_populations_HIV_risk/en/).

2.2.3 Stigma and discrimination

Conceptual framework

Stigma and discrimination are long-standing obstacles to effective HIV prevention, care and treatment – both at the public health level and for the individuals involved. Stigma and discrimination often are directed against key populations at higher risk of HIV, such as sex workers, men who have sex with men and people who inject drugs, as well as against all people living with HIV. Some health-care providers may discourage or exclude these people from health services. Stigma and discrimination, particularly when meted out by health-care providers, discourage people from knowing their status, adopting preventive behaviour and enrolling in care and treatment services. Such behaviour by providers may arise from lack of knowledge and a fear of HIV, both of which may reflect inadequate training.

While stigma and discrimination are often linked and result in social exclusion, the two terms differ in important ways. Stigma is a negative judgement cast by society – or some parts of society – often generated by ignorance, fear or false beliefs. Discrimination is the result of actions limiting or denying certain individuals or communities the enjoyment of their rights. Protection against discrimination is an international human right. In many countries non-discrimination against people living with HIV is embodied in the national constitution or in legislation.

Documenting the pervasiveness of stigma and discrimination in the general population and how often people living with HIV and people from key populations experience discrimination in clinical settings helps programmes assess needs for training and policy changes to remove these barriers. Data can be collected through representative sample surveys of key populations and of the general population, as well as through exit interviews of patients leaving service sites.

The People Living with HIV Stigma Index (http://www.stigmaindex.org) provides for an in-depth look at stigma through a survey of people living with HIV. Since 2008 more than 50 countries have completed the study. More than 1300 people living with HIV have been trained to conduct the survey, and more than 50 000 people living with HIV have been interviewed. The Stigma Index was developed by the Global Network of People Living with HIV/AIDS (GNP+), the International Community of Women Living with HIV/AIDS, the International Planned Parenthood Federation and UNAIDS.

Table 2.3 Indicators of stigma and discrimination against people living with HIV

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
Additional indicators				
NEEDS.6 General stigma % of people ages 15–49 with discriminatory attitudes towards people living with HIV	N: Number of people ages 15–49 who respond "No" or "It depends" to either of two survey questions on stigma against people with HIV.[1] D: Number of women and men ages 15–49 years who have heard of HIV.	Sex, age, if possible, location (e.g. urban, rural), educational attainment, employment status.	N&D: General population survey.	Measures the background level of stigma held by the general population against people living with HIV.

[1] The two questions, which are included in the DHS, are:
"Would you buy fresh vegetables from a shopkeeper or vendor if you knew that this person had HIV?"
"Do you think children living with HIV should be able to attend school with children who are HIV-negative?".

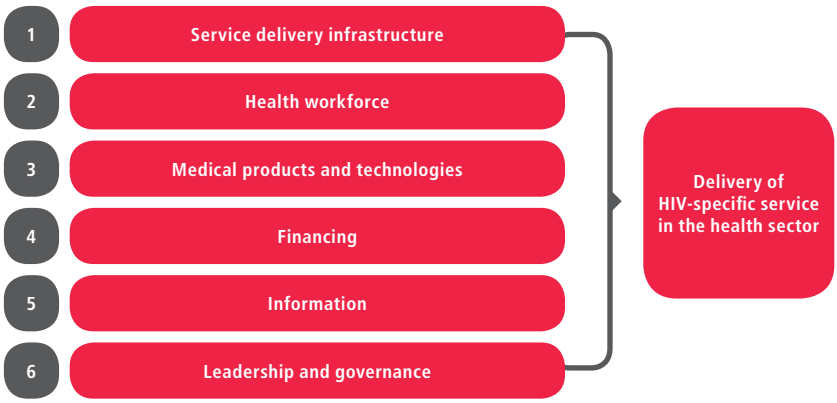
NEEDS.7 Key population experience with discrimination % of people from key populations who have experienced discrimination by health workers *Cross-referenced with Key populations section KPOP.7*	N: Number of people from key populations who experienced discriminatory actions towards them by health workers within the past 12 months. D: Number of people from key populations who sought clinical services within the past 12 months.	Sex, age, location, key population,* type of health facility (e.g. dedicated to HIV, general health care, outreach services, referral facility).	*Proposed, untested indicator* Could be assessed through key population surveys/ interviews or in exit interviews at health facilities. Measure once every 2–3 years.	Measures discrimination in health care against key populations, which may inhibit future use of health sector services and discourage people's participation in programme activities.
NEEDS.8 Health facility staff observed enacting stigma[1] Health facility staff observations of stigmatizing or discriminatory behaviour against people living with HIV	N: Among health facility staff who reported observing people living with HIV in their facility in the past 12 months, the number who report observing either of two situations reflecting stigmatizing or discriminatory behaviour in the facility against people living with HIV.[2] D: Number of health facility staff who report observing people living with HIV in their facility within the past 12 months.	None.	*Proposed, untested indicator* Interviews or surveys of health-care providers.	Documents health-care workers' observations of stigma and discrimination in the health-care setting towards people living with HIV, which may inhibit their further use of services.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.
[1] A set of new indicators for stigma and discrimination in health-care facilities, approved by the UNAIDS MERG indicator working group, can be found in the Indicator Registry at http://www.indicatorregistry.org/?q=taxonomy/term/677.
[2] The two situations are: 1) health-care workers unwilling to care for a patient living with or thought to be living with HIV; 2) health-care workers providing poorer quality of care to a patient living with or thought to be living with HIV.

2.3 Tracking critical resource inputs

The delivery of HIV prevention, care and treatment services depends on the capability of the underlying health system. WHO has defined six building blocks of functional health services – service delivery infrastructure, the health workforce, medical products and technology, financing, information, and leadership and governance (Fig. 2.3).[1] Together, these building blocks provide the necessary inputs of the health system and, for the health sector response to HIV, a framework for assessing the availability of these critical inputs. Deficiencies in any of these key components will immediately affect the system's capacity to deliver HIV services.

Fig. 2.3 Health system building blocks and the health sector response to HIV



Source: Adapted from http://www.who.int/entity/healthsystems/strategy/everybodys_business.pdf

2.3.1 Health system inputs

Infrastructure

A prime goal of HIV programmes is to ensure that sufficient high-quality facilities and services are available to meet the need for prevention and treatment of HIV. Consequently, programmatic monitoring should track service availability, service readiness, quality and oversight as well as linkages between services. The Service Availability and Readiness Assessment (SARA)[2] is a WHO tool designed to assess and track indicators of the health system's readiness and service availability by means of health facility surveys (see section 3.2.4, Facility assessment).

Service availability. To assess service availability, HIV programmes should maintain a reliable list of the health facilities providing HIV prevention, care and treatment services. Health facilities should be assigned unique identifier codes – ideally, the same codes used in the national master facility list.[3] The list should identify which HIV services are routinely provided (for example, HIV testing services (HTS), ART initiation, ART dispensing, CD4 count testing) as well as which populations are served (in situations where facilities serve specific populations). Monitoring the availability of HIV services can be carried out through routine reporting and through evaluations and special studies

[1] Everybody's business: strengthening health systems to improve health outcomes: WHO's framework for action. Geneva: World Health Organization; 2007 (http://www.who.int/entity/healthsystems/strategy/everybodys_business.pdf).
[2] More information on service availability indicators can be found at: http://www.who.int/healthinfo/systems/SARA_ServiceAvailabilityIndicators.pdf.
[3] Each country should have a national master facility list of all public and private health-care facilities. Establishing and maintaining such a list usually requires censuses. Instructions on how to construct such a list are available from WHO at http://www.who.int/healthinfo/systems/WHO_CreatingMFL_draft.pdf.

as needed. When the national/provincial/district master health facility list is being drawn up or updated, this is a convenient opportunity to assess the availability of HIV services.

Service readiness. Both general and specific indicators assess service readiness. General health service indicators cover: 1) basic amenities; 2) basic equipment; 3) standard precautions for infection prevention in health services; 4) diagnostic capacity; and 5) availability of essential medicines. HIV-specific service readiness indicators assess the availability of tracer items, such as HIV rapid diagnostic tests, antiretroviral (ARV) drugs and co-trimoxazole; availability of laboratory tests for CD4 cell counts (on-site or by sample referral), early infant diagnosis (EID) and viral load; and the availability and presence on site of the health-care personnel needed to provide the services. The list of tracer items should fit the expectations for service delivery at each level of the health-care system.

Service readiness is assessed by surveying a representative sample of health facilities at national and subnational levels. Service readiness assessment should also be incorporated into supportive supervision of health-care personnel. Service availability assessments can identify areas in need of further investment to ensure adequate service delivery at all levels and to detect specific gaps in equipment, supplies and staff at an individual facility. Service readiness checklists can also be used in the accreditation of health services for specific service delivery.

Service quality. To promote and assure quality ART services, national programmes, district management offices and health facilities should have components in place and functioning to support service quality. At both the programme level and the facility level, several indicators in this guide can be used to benchmark the quality of service delivery for the purpose of monitoring and guiding quality improvement efforts. Examples of global indicators that can be used to monitor quality at the facility level are ART retention (ART.5/Global indicator 7) and viral suppression (VLS.3/Global indicator 8) (see Table 2.1). At the facility level, a below-average reading on these indicators could trigger support to facility-based quality improvement efforts. Facilities' use of quality management methods focused on performance measurement data, as well as standardized, routine supportive site supervision, should be monitored.

Service quality also encompasses the acceptability of services and client satisfaction. Exit interviews and hotlines can collect clients' feedback about waiting times, availability of health-care providers during clinic hours, convenience of clinic location and hours of service, and staff attitudes. The information can be used for quality improvement efforts at the site level and to help supervisors to address problems of responsiveness to clients' needs. Indicators for responsiveness have so far not been introduced.

Achieving and sustaining the highest attainable level of quality also entails ensuring that biomedical technologies are appropriately used. HIV programmes are particularly concerned with clinical laboratory capacity and performance for a range of tests across the entire prevention, care and treatment cascade. From a strategic information perspective, laboratories should be reviewed for capacity (that is, infrastructure, dedicated laboratory personnel and equipment) to:

- diagnose HIV infection with rapid test, enzyme immunoassay (EIA), Western blot or molecular methods;
- conduct ART monitoring tests, including viral load and/or CD4 count; and
- perform clinical laboratory tests in any of the following areas: haematology, clinical chemistry, serology, microbiology, TB diagnosis and identification, malaria diagnosis and diagnosis of opportunistic infections (OIs).

Proficiency testing and external quality assurance (EQA) schemes are essential to verify that standards of laboratory practices are met and that improvements are made where needed.

Service linkages. Across the cascade from HIV-positive diagnosis to entry into care through retention in care, initiation of ART, retention in ART and viral suppression, linkages must

be monitored to ensure that ART programmes are generally improving patients' health and preventing transmission. However, tools and monitoring systems to assess these linkages are not always easy to use.

Evaluations should be undertaken to assess linkages in service delivery and to guide implementation of systems to track clients through these linkages. The integration of ART with other services, especially TB, maternal, neonatal and child health, and community-based services should also be emphasized in M&E strategies. Monitoring should cover ART initiation in these programmes and linkage of eligible patients to continuing ART services.

Service linkage does not occur in a vacuum. Clear responsibilities must be assigned, and referral pathways must be identified in standard operating procedures (SOPs). The availability of and adherence to those SOPs can be audited to inform quality improvement efforts (RES.3).

See Annex 2 for Table 2.4. Indicators of service availability, quality and linkages.

Health workforce

Information on the health workforce is required for planning, implementing, monitoring and evaluating health sector programmes and strategies. Describing and understanding the dynamics of the health workforce help to identify opportunities for and limitations on scaling up interventions. The size and distribution of the health workforce depend on the inflow and outflow of workers into the labour force as well as the circulation of workers between sectors and, through migration, among geographical locations and between countries. To assess human resource capacity to deliver essential health services, the most basic information to monitor is coverage, rate of new graduations in the health professions and the vacancy rate.[1]

For HIV programmes, disaggregating these measurements by cadre of health-care workers, region, specialization and place of work (urban/rural and facility type) can paint a more detailed picture of human resource capacity for specific HIV-related needs. It is important to assess not only the number of health-care workers in HIV services but also whether their geographic distribution matches the pattern of the epidemic (hotspots, urban/rural, regional) and whether the needs of specific priority populations are being met.

See Annex 2, Table 2.5. Indicators of the health-care workforce.

Medical products and technologies[2]

Effective HIV programmes depend on the continuous availability of essential drugs and supplies. Tracking key aspects of the procurement and supply management system can identify gaps and bottlenecks so that the necessary corrective actions can be taken to avoid both stock-outs and over-stocks. WHO has developed tools to measure key aspects of the pharmaceutical sector and systematically monitor the progress of efforts to improve access to essential medicines. These tools can be used to assess comprehensively the integrity of the supply of medicines and health products in HIV programmes.[3]

For assessment of the drug and procurement system for HIV, TB and malaria programmes, WHO and partners have as developed a set of 12 core indicators. These indicators use routinely collected data to monitor and evaluate the most critical components of the supply chain. They are relevant for all national procurement and supply management systems, donors and institutions.[4]

See Annex 2, Table 2.6. Indicators of medical product and technologies.

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[1] For help establishing or maintaining a health workforce registry, see: Human resources for health information system: minimum data set for health workforce registry. Geneva: World Health Organization; 2015 (http://who.int/hrh/documents/hrh_minimum_data_set.pdf).

[2] This section focuses on supply management for commodities. Access to lab technology has been covered under health infrastructure, services and human resources (Table 2.4).

[3] Development of country profiles and monitoring of the pharmaceutical situation in countries. Geneva: World Health Organization (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/).

[4] More information on these indicators is available at http://www.who.int/hiv/pub/amds/monitoring_evaluation/en/.

Strategic information

Assessing whether the health system has the necessary information to manage the response to the HIV epidemic requires regular tracking of 1) the presence of key characteristics of successful strategic information systems, 2) the availability and quality of key data and 3) whether available data are optimally used for monitoring and improving policies, programming and planning.

In this guide, indicators that should be reported on a regular basis are marked as global and national indicators. The availability, reliability and completeness of information for those core indicators can serve to assess how well the information system is functioning and whether it is able to generate at least the essential information required to inform policy and planning of the health sector response to HIV.

See Annex 2, Table 2.7. Indicators of strategic information.

Governance, leadership and the policy environment

Policies, regulations and laws affect every step of the continuum of prevention, care, treatment and support. They are important structural factors that can determine the success or failure of responses to the HIV epidemic. In 2012, the United Nations Development Programme published the report of the Global Commission on HIV and the Law.[1] The Commission stated, "… punitive laws, discriminatory and brutal policing and denial of access to justice for people with and at risk of acquiring HIV are fuelling the epidemic". The Commission made a series of practical recommendations to combat discrimination; repeal laws criminalizing HIV transmission, exposure and non-disclosure; create a non-discriminatory and otherwise supportive environment for key populations; end all forms of violence against women and girls; ensure that the birth of every child is registered; guarantee HIV-sensitive social protection to orphans and early sex education to all children; and change national and international laws and agreements hampering affordable and timely access to HIV medicines.

Monitoring and evaluating the outcomes and impacts of ART must take into account policies and laws and verify whether they are 1) consistent with best public health practices, 2) known to governmental and nongovernmental service providers and members of affected communities, and 3) actually implemented. Policies and laws to be documented include both those that positively influence ART access, use and retention (for example, mandating gender-sensitive, equal and equitable universal access to quality ART; promoting non-discrimination, the protection of privacy and access to voluntary HIV testing and counselling; and protecting freedom of movement) and those with negative impacts, which drive key populations underground by criminalizing their behaviours and discouraging their access to programmes and services.

To document the impact of policies and laws on prevention, treatment coverage, outcomes and impacts, UNAIDS and partners have developed a National Commitments and Policies Instrument (NCPI) to measure progress in the development and implementation of national HIV policies, strategies and laws. Complementing this instrument is a set of policy and practice questions developed by WHO in the context of the 2013 Guidelines on the Use of ARV for the Prevention and Treatment of HIV. Both sets of questions are included in the Global AIDS Response Progress Reporting (GARPR)[2] and should be reviewed and reported regularly (annually or biennially).

See Annex 2, Table 2.8. Indicator of governance, leadership and the policy environment.

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[1] HIV and the law: risks, rights and health. New York: United Nations Development Programme; 2012 (http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/hiv-and-the-law--risks--rights---health/).

[2] Global AIDS response progress reporting 2014: construction of core indicators for monitoring the 2011 United Nations Political Declaration on HIV and AIDS. Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://www.unaids.org/en/media/unaids/contentassets/documents/document/2014/GARPR_2014_guidelines_en.pdf).

2.3.2 Financing and costing

Funding for the global HIV and AIDS response reached its highest level ever in 2013,[1] with an estimated US$ 19.1 billion made available for programmes in low- and middle-income countries. Development assistance for health in general, and particularly for HIV and AIDS, appears to be levelling off, however, as a result of economic constraints in high-income countries. At the same time, international commitments have become more ambitious, and needs for live-saving services and products continue to increase. Thus, it is imperative for governments and global health funders to accomplish more with existing resources. Donors are beginning to insist on cost-sharing assurances from the governments of low- and middle-income countries and more cost-effective use of funds.

Policy-makers and analysts can use the indicators in this section to track and evaluate the flow of funds for the AIDS response, the allocation of funds and the impact of financing on sustainability, efficiency and equity.

2. Domestic finance

% of HIV response financed domestically

Data for the financial sustainability indicators can be obtained from both the National AIDS Spending Assessment (NASA)[2,3,4] and the Health Accounts (HA).[5,6] Through the Health Accounts Country Platform, WHO provides countries with the accounting framework System of Health Accounts (SHA) 2011 to set up and institutionalize a harmonized, integrated platform for timely annual collection of health expenditure data, including health expenditures for HIV/AIDS. The NASA enables countries to track both health expenditures and non-health expenditures such those on social mitigation, education, labour, justice and other sectors related to the multisectoral HIV response. The NASA also addresses how resources are allocated among HIV/AIDS programmes, which provides the basis for conducting an allocative efficiency evaluation and making smart, evidence-based investments.[7] In addition, the NASA provides data on spending for targeted beneficiary populations to help assess whether adequate resources have been allocated.[8] Overall, the HIV/AIDS subaccounts of the HA and the NASA are the main sources for monitoring the flow of funds, documenting the use of health monies, and evaluating how funding has contributed to meeting overall health policy goals that are relevant for low- and middle-income countries.

Value for money, efficiency and impact are fundamental criteria for strategic investment in health at national and global levels. Focusing on more cost-effective activities is equivalent to raising new funds, all else being equal. Once the amount of funds available for national HIV programming is known, cost-effectiveness analysis helps countries and donors ensure that they get the best value for money, taking into account the needs of eligible populations. However, cost-effectiveness analysis is only part of the priority-setting process; it needs to be considered along with other concerns, such as equity, gender, equality and human rights, and the need to

[1] The gap report. Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://www.unaids.org/en/resources/documents/2014/20140716_UNAIDS_gap_report).
[2] National AIDS Spending Assessment (NASA): classification and definitions. Geneva: Joint United Nations Programme on HIV/AIDS; 2009 (http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/manual/2009/20090916_nasa_classifications_edition_en.pdf).
[3] Guide to produce National AIDS Spending Assessment (NASA). Geneva: Joint United Nations Programme on HIV/AIDS; 2009 (http://data.unaids.org/pub/BaseDocument/2009/20090406_nasa_notebook_en.pdf).
[4] National AIDS Spending Assessment (NASA) country reports. Geneva: Joint United Nations Programme on HIV/AIDS (http://www.unaids.org/en/dataanalysis/knowyourresponse/nasacountryreports/).
[5] Health accounts. Geneva: World Health Organization (http://www.who.int/nha/create/en/).
[6] A system of health accounts. 2011 edition. Organisation for Economic Co-operation and Development, Eurostat, World Health Organization; 2011 (http://www.oecd-ilibrary.org/social-issues-migration-health/a-system-of-health-accounts_9789264116016-en).
[7] Smart investments. Geneva: Joint United Nations Programme on HIV/AIDS; 2013 (http://www.unaids.org/sites/default/files/media_asset/20131130_smart-investments_en_1.pdf).
[8] The gap report. Geneva: United Nations Joint Programme on HIV/AIDS; 2014 (http://www.unaids.org/en/resources/documents/2014/20140716_UNAIDS_gap_report).

meet quality standards for prevention, care and treatment while avoiding impoverishing those who seek services.

WHO has developed a set of complementary tools and activities to help countries prioritize health interventions. Tools for sector-wide priority setting are available on the WHO–CHOICE website.[1,2] Once a country has decided on a set of priorities for action, it is important to carry out a situation assessment and agree on targets. CHOICE helps to determine a cost-effective allocation of resources ("What to do"). The OneHealth tool addresses resource needs, costs and impacts based on feasible and affordable targets ("How to achieve it").[3] Currently, the assumptions underlying the WHO–CHOICE estimates of the cost-effectiveness of HIV/AIDS activities are being revised. When this is completed, WHO will make available updated tools for country-specific contextualization of cost-effectiveness estimates.

With a special focus on two essential components where sufficient stable, predictable funding is needed, ART provision and prevention among key populations, the proposed indicators measure:

- the level of resources mobilized by the national response (standardized, for comparability, by number of people living with HIV)
- the share of health expenditure devoted to HIV health services (distributed by funding source)
- the prevention expenditures share and composition
- the domestic public contribution to HIV spending: current situation and past trends.

See Annex 2, Table 2.9. Indicators of financing and costing for HIV programmes.

2.4 HIV prevention, care and treatment cascade

2.4.1 Services for key populations

Conceptual framework

Key populations are defined populations that, due to specific behaviours, are at increased risk of HIV irrespective of the epidemic type or local context. People from key populations often face legal and social issues related to their behaviours that further increase their vulnerability to HIV. Key populations are important to the dynamics of HIV transmission, but services remain largely inadequate.

These guidelines focus on five key populations (see box, Who are the key populations?):

- men who have sex with men
- people in prisons and other closed settings

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[1] Cost effectiveness and strategic planning (WHO–CHOICE): planning. World Health Organization (http://www.who.int/choice/en/).
[2] Hogan D, Baltussen R, Hayashi C, Lauer JA, Salomon J. Achieving the millennium development goals for health: Cost effectiveness analysis of strategies to combat HIV/AIDS in developing countries. BMJ. 2005;331:1431–1435. See also:
Evans DB, Adam T, Tan-Torres Edejer T, Lim SS, Cassels A, Evans TG for the WHO Choosing Interventions that are Cost Effective (CHOICE) Millennium Development Goals Team. Achieving the Millennium Development Goals for health: time to reassess strategies for improving health in developing countries. BMJ. 2005;331:1133–1136.
Evans D, Tan-Torres Edejer T, Adam T, Lim SS, for the WHO Choosing Interventions that are Cost Effective (CHOICE) Millennium Development Goals Team. Achieving the millennium development goals for health: methods to assess the costs and health effects of interventions for improving health in developing countries. BMJ. 2005;331:1137–1140.
Evans D, Lim SS, Adam T, Tan-Torres Edejer T, for the WHO Choosing Interventions that are Cost Effective (CHOICE) Millennium Development Goals Team. Achieving the Millennium Development Goals for health: evaluation of current strategies and future priorities for improving health in developing countries. BMJ. 2005;331:1457–1461.
[3] Cost effectiveness and strategic planning (WHO–CHOICE): OneHealth tool. Geneva: World Health Organization; [nd] (http://www.who.int/choice/onehealthtool/en/).

- people who inject drugs
- sex workers
- transgender people.

Section 2.2 discusses estimating the size of key populations.

3. Prevention by key populations

Condom use and, for people who inject drugs, sterile needles–syringes distributed per person

Key populations are essential partners in an effective response to the epidemic. Experience has shown that engaging key populations in decision-making about what and how services are provided results in a more effective and efficient response to the epidemic. Many funding organizations and international reporting mechanisms stipulate active participation by civil society groups in the design and direction of services. There is still a long way to go, however, before policy-makers and national HIV programme managers routinely encourage community members from key populations to play active roles in policy change, programme planning and the design of strategic information systems.

A comprehensive package of interventions to address HIV among key populations includes both essential health sector interventions and strategies to create an enabling environment (see box, The comprehensive package of interventions to address HIV among key populations). These interventions are described in more detail in the *WHO consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations* (2014).[1]

Who are the key populations?

Definitions used in this guideline are aligned with current consensus definitions used in the Global Health Sector Strategy on HIV/AIDS 2011–2015 and by the United Nations, as described in the UNAIDS "Guidance note on HIV and sex work"[2] and other documents from WHO and other UN organizations.

Men who have sex with men refers to all men who engage in sexual and/or romantic relations with other men. The words "men" and "sex" are interpreted differently in different cultures and societies and by the individuals involved. This term encompasses the wide variety of settings and contexts in which male-to-male sex takes place, regardless of the motivation for engaging in sex, self-determined sexual and gender identity, and identification with specific communities or social groups.

People in prisons and other closed settings refers to people in prisons and other closed settings are included in these guidelines because of the often high levels of incarceration of people from the other key population groups and the increased risk behaviours and lack of HIV services in these settings. There are many different terms used to denote places of detention, which hold people who are awaiting trial, who have been convicted of a crime or who are subject to other conditions of security. Similarly,

[1] Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. Geneva, WHO, 2014 (http://www.who.int/hiv/pub/guidelines/keypopulations/en/).
[2] UNAIDS guidance note on HIV and sex work. Geneva: Joint United Nations Programme on HIV/AIDS; 2012 (http://www.unaids.org/en/media/unaids/contentassests/documents/unaidspublication/2009/JC2306_UNAIDS-guidance-note-HIV-sex-work_en.pdf).

different terms are used for those who are detained. In this guidance document the term "prisons and other closed settings" refers to all places of detention, and the terms "prisoners" and "detainees" refer to all those detained in criminal justice and prison facilities, including adult and juvenile males and females, during the investigation of a crime, while awaiting trial, after conviction, before sentencing and after sentencing. This term does not formally include people detained for reasons relating to immigration or refugee status, those detained without charge, and those sentenced to compulsory treatment and to rehabilitation centres. Nonetheless, most of the considerations in these guidelines apply to these people as well.

"People who inject drugs" refers to people who inject psychotropic (or psychoactive) substances for non-medical purposes. These drugs include, but are not limited to, opioids, amphetamine-type stimulants, cocaine, hypno-sedatives and hallucinogens. Injection may be through intravenous, intramuscular, subcutaneous or other injectable routes. People who self-inject medicines for medical purposes – referred to as "therapeutic injections" – are not included in this definition. The definition also does not include individuals who self-inject non-psychotropic substances, such as steroids or other hormones, for body shaping or improving athletic performance. These guidelines focus on people who inject drugs because of the specific risk of HIV transmission due to the sharing of blood-contaminated injection equipment; much of this guidance is also relevant for people who inject other substances.

Sex workers include female, male and transgender adults (18 years of age and above[1]) who receive money or goods in exchange for sexual services on a regular or occasional basis. Sex work is consensual sex between adults, can take many forms, and varies between and within countries and communities. Sex work also varies in the degree to which it is formal and organized and the degree to which it is criminalized or is tolerated despite being illegal.

"Transgender" is an umbrella term for people whose gender identity and expression does not conform to the norms and expectations traditionally associated with the sex assigned to them at birth; it includes people who are transsexual, transgender or otherwise gender non-conforming. Transgender people may self-identify as transgender, female, male, transwoman or transman, trans-sexual or, in specific cultures, as *hijra* (India), *kathoey* (Thailand), *waria* (Indonesia), *mahu*, *fa'a fafine* and *fakaleiti* (Pacific Island) or one of many other transgender identities. They may express their genders in a variety of masculine, feminine and/or androgynous ways. The high vulnerability and specific health needs of transgender people necessitate a distinct and independent status in the global HIV response. This population is often socially excluded, leading to a reliance on transactional sex as a means of economic survival, with consequent increased risk of exposure to HIV.

Source: The text in this box is excerpted and slightly adapted from: Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2014, pp. xi-xiii (http://www.who.int/hiv/pub/guidelines/keypopulations/en/).

[1] Children engaging in transactional sex are considered to be subjected to sexual abuse and exploitation.

The comprehensive package of interventions to address HIV among key populations

Essential strategies for an enabling environment

Structural factors such as societal norms, policies, laws and economic factors influence HIV risk and may impede or assist the delivery and impact of interventions. Addressing these factors is not the sole responsibility of the health sector. However, the impact of health sector interventions will be constrained if they are not addressed. Multi-sectoral input and cooperation are required to ensure that these factors contribute to an enabling environment that reduces HIV risks and enhances effort. The following interrelated strategies for a supportive environment are essential components of the response to HIV and STIs among key populations:

- supportive legislation, policy and financial commitment, including decriminalization of certain defining behaviours of key populations
- addressing stigma and discrimination, including making health services available, accessible and acceptable to key populations
- community empowerment
- addressing violence against key populations.

Essential health sector interventions

The following interventions yield the most benefit when they are available in combination and when the enabling environment factors are in place. Still, the implementation of any of these interventions should not be delayed, even in the absence of these enabling environment factors.[1] These interventions include:

- comprehensive condom and lubricant programming
- harm reduction interventions for substance abuse, particularly needle–syringe programmes and opioid substitution therapy (OST)
- behavioural interventions
- HIV testing and counselling
- HIV treatment and care
- prevention and management of coinfections and co-morbidities, including viral hepatitis, tuberculosis and mental health conditions
- sexual and reproductive health interventions.

[1] In principle, interventions should be in accordance with the law. It should be noted, however, that national practices regarding needle exchange programmes were initiated in Asian countries under prohibitive legislation, with the tacit agreement of tolerant national authorities. In many of these countries, law reforms followed the availability of evidence generated by small-scale projects in the country itself or in the region.

The essential health sector interventions in the comprehensive package, with the exception of harm reduction interventions for substance use, are not specific to key populations. In most countries most of these interventions are available in a form that is accessible to the general population. However, existing services or the manner in which interventions are provided may not meet the specific needs of key populations. The services may not be readily accessible or

acceptable to members of key population groups, and they may face barriers to obtaining these services. Accordingly, a comprehensive response to HIV requires both services tailored specifically for key populations and mainstream services that meet the needs of people from key populations. Specifically, addressing health workers' stigma and discrimination against key populations (NEEDS.7) is critical to improving their use of mainstream services.

A comprehensive response to HIV requires both services tailored specifically for key populations and mainstream services that meet the needs of people from key populations.

Indicators to monitor interventions for key populations along the treatment cascade are the same as for the general population, with disaggregation by key population to assess issues of equity in coverage and service quality. More details on setting targets for these interventions and indicators for key populations can be found in the forthcoming WHO publication, *Tool for setting and monitoring targets for HIV prevention, diagnosis, treatment and care for key populations*.

M&E issues for key populations

Using programmatic data to measure coverage among key populations

While programmes that focus on key populations may be able to provide data specific to the populations they serve, this information may not be readily available from programmes that provide services to many different groups or to the general population. Service providers may not know, or may not record, whether a client is a man who has sex with men, a sex worker or transgender, as this information may not be relevant to the provision of services. Furthermore, clients of these services may not wish to disclose this information, and requiring them to do so might deter them from seeking care. In some circumstances, disclosing one's status as a man who has sex with men, a person who uses drugs, a sex worker or a transgender person may make a person vulnerable to discrimination, violence or criminal prosecution. Hence, where these issues of safety and discouraging use of services are a concern, routine collection of such information may not be advisable.

Some interventions for key populations, such as the provision of sterile injecting equipment or condoms, are provided continuously. To determine the number of people who received an intervention during a specified period of time, it is necessary to avoid double-counting those who may have received the intervention more than once during that reporting period.

Data collection systems can use a unique identifier code for each client so that multiple visits by the same individual can be noted. Such a data collection system must maintain clients' confidentiality and, as far as possible, their anonymity. Alternatively, the "recall last contact" method can be used, in which each individual is asked, when using a service, if this is the first time that he or she has done so within the reporting period. National coverage can be more accurately estimated if different service providers all use the same unique identifier coding system. In settings, however, key population-specific data cannot be collected from routine programme data; surveys will be required.

Conducting surveys and surveillance among key populations

Information about service access and coverage can be gleaned from surveys of people from key populations that ask specifically about use of services and exposure to interventions. Many countries already undertake behavioural and sero-surveillance surveys of key populations periodically as part of the ongoing monitoring of the HIV epidemic. (General population surveys are not suitable for gathering this type of information from people from key populations.)

The generalizability of survey findings depends on how representative the sample is of the broader key population. In particular, significant bias may result if samples are drawn from a limited number and range of locations. In many cases, survey results apply only to the location from which the sample was drawn. For example, samples drawn only from sites where services are provided or that are selected by peer educators delivering the intervention are likely to be biased towards members of the key population who are in contact with services, thereby overestimating levels of coverage. Methods such as respondent-driven sampling may reduce such bias, but they require specific technical capacity and resources and can take more time to complete.

Other types of potential bias are social desirability bias, which occurs when respondents give answers about their behaviour or use of services that they assume will please the interviewer, and recall bias, which occurs when respondents deliberately or inadvertently recall experiences selectively. Altogether, these constraints may limit the utility of survey data to identify local problems and inform the response. Using multiple sources of strategic information on key population services and triangulating the findings offers some protection against the weaknesses of any one methodology.

Diversity within key populations

Within each key population there are multiple subgroups with a range of characteristics associated with differing HIV risk, patterns of mobility and service utilization and health outcomes. For example, street-based sex workers may face different risks and challenges than those who work in brothels, bars or clubs, and the patterns of sex work may vary over time depending on law enforcement practices, client demand and the financial needs of the sex workers.

Key populations overlap substantially in most settings; individuals may be members of more than one key population at a time. For example, men who have sex with men, people in prisons and other closed settings, sex workers and transgender people may inject drugs; people from other key populations, such as men who have sex with men, transgender people, and people who inject drugs, may engage in sex work; and people from each of the key populations are typically over-represented in prisons and other closed settings, often as a consequence of the criminalization of their identities or behaviours. Accordingly, disaggregating indicators, not only by age and gender but also by relevant key population subgroups, and allowing for the recording of more than one defining behaviour will help programmes to better tailor their services to needs.

Confidentiality of strategic information on key populations

Key populations face significant stigma and discrimination and are often subject to punitive laws and penalties. There have been some instances in different countries of authorities using information from mapping exercises to conduct raids or arrest members of key populations. Key population members commonly have heightened concern about the reliability and safety of data collection and may not readily see advantages to participating in efforts to collect strategic information. Engaging the community, their organizations and leaders to be fully involved in surveys can improve trust.

At the same time, confidentiality must be maintained. Policies and resources need to be in place to protect the confidentiality of any data with personally identifying information, including patient medical records. There should be commitment from authorities and legal provisions that disallow the use of these data for purposes other than improving services. Staff responsible for collecting and storing data should receive appropriate training in protecting confidentiality. Data that cannot be properly secured should not be collected.[2] Data on key populations are necessary to an effective programme response to these populations. At the same time, privacy, confidentiality and safety are major concerns and should be carefully addressed in the collection and use of these data.

[2] Certain countries have laws requiring retention of health-related personal data collected through surveys or other studies over periods of 10 years or more. The precautions for confidential safekeeping of such data must be planned accordingly.

Selection and use of indicators

The national programme indicators for key populations focus on the coverage of targeted interventions. Programmes that find low coverage rates must examine their services to determine the causes – whether it is because interventions have not been implemented at sufficient scale or because services seem inhospitable, inaccessible or inappropriate to these populations.

In many countries legal and policy barriers have inhibited the scale-up of prevention interventions for key populations. These barriers can range from lack of political support to the arrest of service providers for offering some of the prevention services in the recommended package. Programmes must compare coverage of key populations with coverage of the whole population and relative levels of coverage among key populations to determine whether there may be inequity in access or discrimination in the provision of services to key populations. In particular, coverage indicators for HIV testing and counselling and ART, which are the services most often available in general health-care settings, should be disaggregated by key population group where possible. Data from these indicators can be triangulated with periodic surveys of key populations asking individuals about the range of HIV services that they used in the last year.

A long-term impact of effective prevention programming should be a reduction in new infections among key populations. Thus, assessing trends in incidence is critical. Measuring incidence and trends in incidence is challenging, particularly in key populations. Various indirect estimation methods may be used, but the limitations of each method must be considered when interpreting results. Generally, analysis and evaluation of a number of data sources are required.

Inferring incidence from case reporting systems for newly noted infections has limitations, generally resulting in an underestimate (see section 2.5.2). Also, an individual's drug use, sexual behaviour, transgender identity or participation in sex work may not be recorded in these case notification systems, and the recorded mode of transmission category may not identify an individual as a member of a key population. Testing and notification data from sentinel sites serving people from key populations may provide a more specific estimate of incidence. How representative these data are of the entire key population needs consideration, however.

The prevalence of HIV among young people in key populations or those new to sex work or recently starting to inject can be used as a proxy measure of incidence for the key population of interest. This requires surveillance and survey data to be disaggregated not only by sex and age but also to include information on the time since starting injecting drug use, sex work or, for men who have sex with men, since becoming sexually active. Cohort analysis can then assess HIV infection in successive age groups or cohorts from these groups.

Table 2.10 Programme indicators for key populations

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues	Programme relevance and interpretation
National indicators				
KPOP.1 HIV testing coverage of key populations % of people from key populations who received an HIV test in the last 12 months and who know the results *Cross-referenced with HTS section HTS.7*	N: Number of key population respondents previously unaware of their HIV-positive status who were tested for HIV and received their results within the past 12 months. D: Number of key population respondents in the survey who did not previously know themselves to be HIV-positive.	Key population (men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers, transgender), sex, age (<25, 25+; if possible 15–19, 20–24, /25+; 10–14 if survey covers this age group), HIV status.	N&D: Survey of key populations.	Measures the programme's effectiveness in encouraging HIV testing both as a prevention tool and as an entry point for early care and treatment for key populations. Targets for the percentage of key populations that know their status should be higher than for the general population.
KPOP.2 Needle–syringe distribution Needles–syringes distributed per person who injects drugs Global indicator	N: Number of sterile needles–syringes distributed in past 12 months by needle–syringe programmes. D: Number of people in the country who inject drugs.	Sex, age, type of setting (community, prison/closed setting).	N: Programme records, e.g. needle–syringe programme log books. D: Size estimation exercises.	The quantity of sterile needles–syringes that are distributed serves as an estimate of the total number of clean units of injecting equipment in circulation that might be used by the population of people who inject drugs. Target is 200 per person per year.

KPOP.3 Key population ART coverage % of key population living with HIV who are receiving ART *Cross-reference with ART section ART.2 and 3*	N: Number of people from key populations living with HIV who are currently receiving ART. D: Number of people from key populations living with HIV.	Key population (men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers, transgender), sex, age (<25, 25+).	N: 1. Survey of key populations 2. Programme records, * e.g. ART registers. D: 1. Survey of key populations 2. Key population size estimate.	When compared with overall ART coverage, this indicator assesses whether coverage among key populations is equitable. If programme data are used, the numerator requires knowledge of recipients' key population status to be recorded in ART registers; caution should be taken to avoid adverse consequences of this.
Additional indicators				
KPOP.4 OST coverage % of people who inject drugs receiving opioid substitution therapy (OST)	N: Number of people who inject drugs who are on OST at a specified date. D: Number of opioid-dependent people who inject drugs in the country.	Sex, age (<25, 25+).	N: Programme records, e.g. OST registers. D: Size estimation exercises.	Measures the programme's ability to deliver OST among people who inject drugs as a method of directly reducing injecting frequency. Target is 40%. The population size estimate used as the denominator should be appropriate for the numerator; not all OST recipients will have a history of injecting and not all people who inject drugs will use or be dependent on opioids.

*In many settings key population-specific data cannot be collected from routine programme monitoring;surveys are required.

KPOP.5 Retention in OST % receiving OST for 6 months	N: Number of people from the cohort still in treatment 6 months after starting OST. D: Number of people starting OST during the time period defined as the cohort recruitment period.	Sex, age (<25, 25+).	N&D: Programme records, e.g. OST registers.	Measures retention on OST, using a cohort approach. Evidence shows that maximum benefit from OST is gained when treatment lasts at least 6 months. Reflects the programme's ability to retain patients in care (quality indicator).
KPOP.6 Key population HIV prevalence % of members of key populations who are HIV-infected *Cross-referenced with Impact section IMP.5*	N: Number of key population respondents who have tested positive for HIV. D: Number of key population who have tested for HIV.	Key population (men who have sex with men, people in prisons and other closed settings, people who inject drugs, new initiators of injecting drug use; sex workers, transgender), sex, age (15–19, 20–24, 25+); young (15–19) men who have sex with men; pregnancy status; coinfected with TB; ART eligibility; pregnancy status; location.	N&D: Sentinel surveillance. Trends in prevalence provide an overview of the changing HIV burden, but they need to be interpreted in light of the number of people on ART to understand what proportion of people living with HIV is attributable to new infections.	Measures the overall state of the epidemic among key populations. HIV prevention among various populations is a core indicator. Policy-makers should understand that the number of people living with HIV may be increasing thanks to effective treatment and longer survival and not or only partly due to new infections.
KPOP.7 Key population experience with discrimination by health workers % of members of key populations who experienced discrimination by health workers *Cross-referenced with Stigma and discrimination section IMP.10*	N: Number of people from key populations who experienced discriminatory actions towards them by health workers within the past 12 months. D: Number of people from key populations who sought clinical services within the past 12 months.	Sex, age (15–19, 20–24, 25–49), key population/ risk behaviour, in care or not, selected social and economic attributes (e.g. race, ethnicity, migrant status), source of stigma and discrimination (e.g. prospective employer, neighbourhood, health-care providers, other service providers).	*Proposed, untested indicator* Could be assessed through key population interviews or in exit interviews at health facilities. Measure once every 2–3 years.	Measures discrimination against key populations, which may inhibit use of health sector services and discourage participation in programme activities.

2.4.2 Health sector prevention

2.4.2a Male and female condom programming in the health sector

Conceptual framework

Condom programming addresses both the demand and supply sides of increasing the use of male and female condoms. It encompasses creating a supportive social and political environment for condom use, promoting consistent and correct condom use among men and women, and ensuring the acceptability, availability and affordability of condoms and condom-compatible lubricants.

Condom promotion and mode of distribution vary according to the target population. For example, condom use in the general population or by clients of sex workers is often promoted through social marketing campaigns directing people to conventional retail outlets that sell condoms, often at subsidized prices. Other sales venues may be included, particularly when addressing adolescents or young people. Condoms for some key populations (sex workers, men who have sex with men, transgender populations) may be distributed either free or at a subsidized price at places where high-risk sex is solicited or takes place (for example, brothels, entertainment venues) or through peer outreach. Condoms are also distributed through health services, for example, in family planning, sexually transmitted infections (STI) and HIV services, to people who inject drugs at needle–syringe services and OST centres and through workplace programmes.

3. Prevention by key populations

- % of sex workers reporting condom use with most recent client
- % of men reporting condom use at last anal sex with a male partner
- for the general population, among people who had more than one sexual partner in the past 12 months, % who report condom use at last sex.

It is essential to include condoms in service packages for key populations in all epidemics and to promote them vigorously to all audiences for HIV prevention in generalized epidemics. The health sector offers important venues for the promotion and distribution of condoms. Every contact with clients living with HIV or at risk of acquiring HIV or STI should be taken as an opportunity to advocate condom use and to deliver these commodities, offering an ample supply, such as a presumed 3-month supply of 30 condoms.

M&E issues

The most basic measure of the effectiveness of condom programming is the percentage of people who use condoms, particularly during sex acts associated with greater risk. For key populations indicators of condom use among sex workers (PREV.1a) and men who have sex with men (PREV.1b) have been designated for global reporting. Indicators of other components of prevention by key populations should also be globally reported where these are collected in

national indicators. The selected indicator of condom use for the general population (PREV.1.d) focuses on sexually active adults who have had non-regular sexual partners in the preceding 12 months and whether a condom was used during the most recent sexual act.

In addition, condoms are most effective when their use is consistent, not occasional. This should be assessed, as well as use with regular and non-regular partners, which varies significantly

In many countries condoms are also promoted as part of family planning services and for HIV/STI prevention. This type of condom promotion may support efforts to normalize condom use, but it may be difficult to determine whether condoms are being used during high-risk sexual encounters (for HIV/STI prevention or as part of dual protection) or in lower-risk sex – for example, primarily for contraception.

Table 2.11 Programme indicators for condom programming in the health sector

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
PREV.1.a Condom use among sex workers % of sex workers reporting condom use with most recent client Global indicator	N: Number of sex workers who report using a condom with their most recent client. D: Number of sex workers who report having commercial sex.	Sex (female, male, transgender), age (<25, 25+; adolescents (ages 10–19) where relevant, feasible, available).	Behavioural surveillance or other special surveys every 2 years.	Condoms are most effective when their use is consistent, rather than occasional. This indicator measures condom use during a single sex act and, therefore, would overestimate the level of consistent condom use.
PREV.1.b Condom use among men who have sex with men % of men reporting condom use at last anal sex with a male partner Global indicator	N: Number of men who have sex with men who report that a condom was used the last time they had anal sex. D: Number of men who have sex with men who report having had anal sex with a male partner.	Age (<25, 25+; adolescents (ages 10–19) where relevant, feasible, available).	Behavioural surveillance or other special surveys.	For men who have sex with men, condom use at last anal sex with a male partner gives a good indication of overall levels and trends of protected and unprotected sex. In countries where many men in the sub-population surveyed are likely to have partners of both sexes, condom use with female as well as male partners should be investigated.

PREV.1.c Condom use among people who inject drugs % of people who inject drugs reporting condom use at last sexual intercourse	N: Number of people who inject drugs who reported that a condom was used the last time they had sex. D: Number of people who report having injected drugs and having had sexual intercourse.	Sex, age (<25, 25+; adolescents (ages 10–19) where relevant, feasible, available).	Behavioural surveillance or other special surveys.	Contributes to understanding the patterns of sexual mixing and condom use among people who inject drugs and between people who inject drugs and the wider population.
PREV.1.d Condom use in general population % of people who have more than one sexual partners who used a condom at last sexual intercourse Global indicator	N: Number of respondents who have had more than one sexual partner in the last 12 months who report the use of a condom the last time they had sex. D: Number of respondents who have had more than one sexual partner in the last 12 months.	Sex, age (15–24, 15–49 or 15+). Review age groups 15–19, 20–24 where possible (check whether survey is sampled to provide representative data). Adolescents (ages 10–19) where relevant, feasible, available.	N&D: General population survey. Health facility records could also collect this routinely in specialized clinics, e.g. adolescents' HIV clinics, STI clinics, male health clinics.	Measures the extent to which condoms are used by people who are likely to have higher-risk sex. Trends should be interpreted along with changes in the percentages of people that have had more than one sexual partner within the last 12 months.

2.4.2b Medical male circumcision

Conceptual framework

In 2007 an international consultation convened by WHO and UNAIDS concluded that there is compelling evidence that male circumcision reduces HIV transmission from women to men. The consultation recommended that male circumcision be recognized as an important additional strategy for prevention of heterosexually acquired HIV infection in men, particularly in settings with generalized epidemics and low prevalence of male circumcision.[1] WHO and UNAIDS recommend providing male circumcision services as part of a comprehensive service package that also includes, at a minimum, HIV testing services, STI management, risk reduction education and condom promotion and provision.

Men seeking voluntary medical male circumcision (VMMC) should be tested first, as VMMC has no preventive value for men who test HIV-positive. These men should be linked to appropriate care and treatment services. Although they will not have the benefit of HIV prevention from circumcision, these men should not be denied circumcision if they want nonetheless.

[1] WHO, UNAIDS. New data on male circumcision and HIV prevention: policy and programme implications. WHO/UNAIDS technical consultation: male circumcision and HIV prevention: research implications for policy and programming, Montreux, 6–8 March 2007 (http://www.who.int/hiv/pub/malecircumcision/research_implications/en/index.html).

M&E issues for medical male circumcision

Establishing strategic information systems for a new service

For the most part monitoring and evaluation systems for male circumcision programmes are new; many governments currently rely on their implementing partners to collect and report data. During the current catch-up phase, ministries can be setting up information systems to monitor the longer-term, sustainable VMMC services needed to maintain a high proportion of circumcised males in the population of reproductive age.

This guide prioritizes the number of male circumcisions performed (PREV.2) as the indicator of VMMC programme performance. For deeper evaluation of VMMC programmes, WHO, UNAIDS and PEPFAR have collaborated to develop a common set of indicators for national VMMC programmes. To support the development of VMMC M&E systems, the *UNAIDS/WHO guide to indicators for male circumcision programmes in the formal health-care system*[1] details indicators for national programmes to consider. This guide identifies two *purpose* indicators that focus on the number of males circumcised and five *key objective* indicators that focus on supply, demand and safer sexual behaviour following male circumcision. A further 12 *component objective* indicators are proposed for adaptation to country-specific activities. The adapted component objective indicators support achievement of the key objective indicators, which in turn support the achievement of the purpose indicators. Countries are encouraged to use the development of M&E system for VMMC as an important opportunity to improve the collection of other HIV/AIDS and sexual and reproductive health information on men who may interact with the health system infrequently. Such data might cover HIV testing, linkages to care and treatment for men who test HIV-positive and the prevalence of STIs and condom use.

It is important to monitor the quality of VMMC services. One objective indicator focuses on the safety of male circumcision services – the number and percentage of circumcised males experiencing at least one moderate or severe adverse event during or following surgery (that is, death or hospitalization within 30 days after VMMC, permanent disability, all cases of tetanus and all serious cases of glans, penile or urethral injuries) (PREV.3). With the introduction of new methods of circumcision that use prequalified devices, systems for post-marketing surveillance including will need to be compatible with the routine monitoring system. To provide useful planning information, all indicators should be disaggregated (for example, by age and by service site).

The source of most information on VMMC services will be health facilities' records or special surveys; collection of data from the private and traditional sectors is limited. As best practices for obtaining such information develop, countries can learn from each other.

Assessing the impact of VMMC by HIV status of recipient

As a prevention strategy VMMC has different effects on male-to-female, female-to-male and male-to-male transmission probabilities. To help assess the impact of MMC on new infections prevented, coverage data on VMMC should be disaggregated by age and the HIV status of the male being circumcised. As coverage increases, special surveys may be able to detect changes in incidence and prevalence.

Selection and use of indicators

During a 2012 meeting on VMMC,[2] 14 countries prioritized the number of male circumcisions performed (PREV.2) as an indicator of successful scale-up for national and global level

[1] UNAIDS/WHO guide to indicators for male circumcision programmes in the formal health-care system. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241d598262_eng.pdf?ua=1).
[2] Clearinghouse for male circumcision for HIV prevention. Joint PEPFAR/WHO Meeting on Accelerating the Scale-up of Voluntary Medical Male Circumcision (VMMC) for HIV Prevention in East and Southern Africa. Raleigh, North Carolina, USA: FHI360, 2014 (http://malecircumcision.org/resources/PEPFAR_WHO_VMMC_meeting_east_southern_Africa.html).

reporting. This indicator counts only male circumcisions that are performed according to national standards. Prevalence as estimated from special surveys has also been proposed as an indicator; interpretation of this indicator must take into consideration inaccuracies in self-reported circumcision status. Additional priorities proposed for monitoring at the national level include indicators of male circumcision safety, HIV testing and counselling, safe sex practices, number of institutions delivering VMMC services, human resources availability, supply availability, adequate financing, enabling policy and legislative environment, and demand creation.

Table 2.12 Programme indicators of voluntary medical male circumcision

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues	Programme relevance and interpretation
Additional indicator (national in certain countries)				
PREV.2 MMC scale-up Number of male circumcisions performed	Number of medical male circumcisions within the past 12 months performed according to the national standard.	Age (<1, 1–9, 10–14, 15–19, 20–24, 25–49, 50+), HIV status, male circumcision method (surgical, elastic collar compression type device, collar clamp type device). Optional: type and location of facility, cadre of provider.	Programme records, VMMC registers.	The total number of male circumcisions carried out over time indicates change in the supply of services and/or change in demand. Comparing current results with previous values shows where male circumcision services have been newly instituted or where male circumcision volume has changed. When numbers of male circumcisions are disaggregated by HIV status and age, it will be possible to adjust inputs used in models to determine the impact of male circumcision programmes on HIV incidence and, if a country has prioritized services to, or set targets for, particular age groups, determine success in meeting those targets. Disaggregation by age can help determine how well age-specific strategies to increase demand are working.

PREV.3 MMC adverse events Number and % of circumcised males experiencing moderate or severe adverse events during or following surgery	N: Number of circumcised males experiencing at least one moderate or severe adverse event during or following the procedure. D: Number of men undergoing voluntary medical male circumcision.	Age, timing of adverse event (intra-operative, postoperative), service site.	Programme records For information data recording and tools, see manual for male circumcision under local anaesthesia.[1] Adverse events are defined as either moderate or severe. Adverse events are defined as follows. Intraoperative: • pain • excessive bleeding • anaesthesia-related • excessive skin removal • damage to the penis • sharps injury to personnel Postoperative: • abnormal pain • excessive swelling • infection • haematoma • bleeding • difficulty urinating • wound disruption • delay in healing with appearance (including scar or disfigurement) • injury to the glans • excessive skin removal.	Male gonorrhoea incidence is an excellent early warning measure of unprotected sex. Because gonorrhoea among women is often asymptomatic, incidence among women is more difficult to measure and interpret.

[1] Manual for male circumcision under local anaesthesia. geneva: World Health Organization, United Nations Joint Programme on HIV/AIDS, Jhpiego;2009. (http://www.who.int/hiv/pub/malecircumcision/who_mc_local_anaesthesia.pdf).

2.4.2c Post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP)

PEP conceptual framework

Post-exposure prophylaxis (PEP) is short-term antiretroviral treatment to reduce the likelihood of HIV infection after potential exposure, occupationally, through sexual intercourse or through injecting drug use. Within the health sector PEP should be provided as part of a comprehensive package of universal precautions that reduces the exposure of health-care personnel to infectious hazards at work.[1]

Monitoring and evaluation of PEP programmes may be conducted through local data collection and a national registry of exposure, PEP prescriptions and HIV infection. This type of surveillance allows programme managers to evaluate investments and policies, identify progress and gaps in service provision, assess safety and quality control and allocate resources. Just as for patient records in general, and especially for records related to HIV status, PEP data must be kept securely, and patient confidentiality must be maintained.

PrEP conceptual framework

Pre-exposure prophylaxis (PrEP) is the use of antiretroviral drugs by HIV-uninfected individuals before exposure to HIV to reduce the risk of HIV acquisition. Randomized controlled trials have demonstrated the efficacy of daily oral PrEP, when used consistently, among men and women. In 2012, based on the evidence available,[2] WHO recommended that countries consider daily oral PrEP as an additional prevention strategy for uninfected partners in serodiscordant couples[3] as well as for men and transgender women who have sex with men.[4] WHO also called for demonstration projects to show how oral PrEP could be implemented safely and effectively.

Some countries have approved the use of PrEP, but others are waiting for the results of ongoing demonstration projects before making decisions. Countries and programmes that include PrEP as part of combination prevention strategies should develop plans to monitor and evaluate PrEP prescriptions, retention, adherence, safety and effectiveness. The best-practice recommendation is to monitor PrEP programmes through a registry of known discordant couples or by conducting occasional surveys or studies in populations that may use PrEP as a prevention method.

Selection and use of indicators

This guide does not propose indicators for monitoring and evaluating PEP or PrEP in the health sector for reporting at the global or the national level. Two additional indicators are suggested (Table 2.13).

Coverage of PEP is best measured in terms of how broadly PEP is available at local health facilities (PREV.4).[5] Availability of PEP reflects the institutional commitment to develop protocols, train personnel and maintain sufficient ARV drug supplies to adequately treat individuals who are exposed to HIV. Programmes can compare cost-effectiveness across facilities by tracking patterns of utilization and costs.

When PrEP is offered to specific populations, coverage is measured in terms of service utilization rates among the targeted groups (PREV.5).

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[1] WHO, ILO. Post-exposure prophylaxis to prevent HIV infection; joint WHO/ILO guidance on post-exposure prophylaxis to prevent HIV infection. Geneva; World Health Organization; 2007 (http://www.who.int/hiv/pub/prophylaxis/pep_guidelines/en/).

[2] Anglemyer A, Rutherford GW, Egger M, Siegfried N. Antiretroviral therapy for prevention of HIV transmission in HIV-discordant couples (review). (The Cochrane Collaboration). John Wiley & Sons, Ltd., 2011 (http://apps.who.int/rhl/reviews/CD009153.pdf).

[3] In this guidance a couple is defined as two persons in an on-going sexual relationship; no distinction is made between heterosexual and same-sex couples.

[4] Guidance on pre-exposure oral prophylaxis (PrEP) for serodiscordant couples, men and transgender women who have sex with men at high risk of HIV: recommendations for use in the context of demonstration projects. Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/guidance_prep/en/).

[5] Core indicators for national AIDS programmes. Geneva: UNAIDS; 2008. (http://apps.who.int/iris/bitstream/10665/43925/1/9789291737161_eng.pdf?ua=1).

Table 2.13 Programme indicators of post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP)

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues	Programme relevance and interpretation
Additional indicators				
PREV.4 PEP access % of health facilities where PEP is available	N: Number of health facilities with PEP is available. D: Total number of health facilities.	Type of health facility.	Health facility survey.	Used to plan for service expansion, especially in high-risk areas.
PREV.5 PrEP coverage % using PrEP in priority PrEP populations	N: Number of members of the selected PrEP priority groups using PrEP within the last 12 month. D: Number of people in the selected PrEP priority groups.	Priority group.	N&D: Surveys of priority groups.	Measures the coverage of PrEP in selected priority populations where PrEP has been introduced.

2.4.2c Injection safety

Universal precautions in health-care settings include injection safety and safe disposal of injection equipment as part of best public health practice to prevent nosocomial transmission of bloodborne agents – HIV, hepatitis B and C and syphilis. WHO and the Safe Injection Global Network (SIGN) Alliance have designed the *Tool for the assessment of injection safety and the safety of phlebotomy, lancet procedures, intravenous injections and infusions*.[1] The indicators proposed in Table 2.14 come from this tool, which has been and continues to be successfully used to conduct national surveys on injection safety.

Selection and use of indicators

Systematic application of injection safety principles requires programmes to use new, disposable, single-use injection equipment for all therapeutic injections[2] (PREV.6) and to ensure that all health facilities have sufficient supplies of these consumables (PREV.7).

[1] Tool for the assessment of injection safety and the safety of phlebotomy, lancet procedures, intravenous injections and infusions. Geneva: World Health Organization; 2008 (http://www.who.int/injection_safety/Injection_safety_final-web.pdf?ua=1).
[2] WHO, SIGN. A guide on indicators for monitoring and reporting on the health sector response to HIV/AIDS. Geneva: World Health Organization; 2011 (http://www.WHO.int/hiv/data/UA2011_indicator_guide_en.pdf).

Table 2.14 Programme indicators of injection safety

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues	Programme relevance and interpretation
National indicator				
PREV.6 Facility-level injection safety % of health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment	N: Number of sampled health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment. D: Number of facilities sampled.	Facility type.	Health facility survey.	Assesses the implementation of policies to ensure that all health facilities practice injection safety.
Additional indicator				
PREV.7 Supply of needles–syringes % of facilities with no stock-outs of needles–syringes	N: Number of sampled facilities reporting no stock-outs of new single-use needles–syringes within the past 12 months. D: Number of facilities sampled.	Facility type.	Health facility survey.	Measures the programme's ability to maintain supplies necessary for injection safety in health facilities.

2.4.2d Blood transfusion safety

Conceptual framework

There are five key components to eliminating the risk of HIV transmission through blood transfusion:

- establishment of well-organized, nationally coordinated blood transfusion services
- collection of blood from unpaid volunteer blood donors from low-risk populations
- quality-assured testing for transfusion-transmissible infections, blood grouping and compatibility testing
- safe and appropriate use of blood and a reduction in unnecessary transfusions
- quality assurance and enhancement systems covering the entire transfusion process.

Approximately half of the 107 million blood donations collected globally each year are collected in low- and middle-income countries.[1] The higher prevalence of HIV in blood donations in middle- and low-income countries (0.1% and 0.6%, respectively) compared with high-income countries (median of 0.003%) reflects the higher underlying general population prevalence of HIV and more frequent use of higher-risk donors.

Globally, many countries are working toward maintaining a stable base of regular, voluntary, unpaid blood donors by promoting voluntary blood donations and discontinuing paid blood donation; across 156 countries blood donations from voluntary, unpaid donors increased by an average 7.70 million a year between 2004 and 2011. Nevertheless, nearly half (73 of 151) of the countries surveyed in 2013 collected more than half of their blood supply from family/replacement[2] or paid donors. Paying blood donors increases the likelihood that key population members, whose access to other sources of income may be restricted, donate blood. Also, the higher HIV incidence among key populations increases the probability that HIV-positive individuals donate blood within the window period, that is, soon after infection and prior to detectable levels of antibodies, thus testing falsely as HIV-negative.

WHO recommends that all blood donations be screened for HIV, hepatitis B (HBV), hepatitis C (HCV) and syphilis prior to use. Yet, in 2011 nearly one-quarter of blood donations in low-income countries were not screened according to basic quality procedures, which include documented standard operating procedures and participation in an external quality assurance scheme.[3]

Selection and use of indicators

The national programme indicator selected for blood transfusion safety (PREV.8) reflects whether national programmes have the capacity and resources to ensure that every unit of blood used for transfusions has been screened. Complete (that is, 100%) screening is the expected norm for a functioning national blood system.

Table 2.15 Programme indicators for blood transfusion safety

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues	Programme relevance and interpretation
National indicator				
PREV.8. Facility-level blood safety % of health facilities providing blood transfusion that meet requirements for sufficient and safe blood transfusion	N: Number of health facilities that meet requirements.[4] D: Number of health facilities providing blood transfusion.	Facility type.	Health facility survey.	Assesses the effectiveness of policies and programmes to enable health facilities providing blood transfusion to have sufficient and safe blood supply.

[1] Blood safety and availability, WHO fact sheet N°279, updated June 2013 (http://www.who.int/mediacentre/factsheets/fs279/en/). This fact sheet is based on data obtained through the WHO Global Database on Blood Safety (GDBS) for the year 2011, which were reported by 163 countries.
[2] Family members and friends of the person in need of a blood transfusion may donate blood directly to the patient, or their blood may be used to replace the stored blood used by the patient.
[3] Blood safety and availability, WHO fact sheet N°279, updated June 2013 (http://www.who.int/mediacentre/factsheets/fs279/en/).
[4] Defined by the Service Availability and Readiness Assessment (SARA) indicators Index as "% of facilities providing blood transfusion with tracer items on the day of the assessment" (http://www.who.int/healthinfo/systems/sara_indicators_questionnaire/en/).

Additional indicator				
PREV.9. Blood screening coverage % of blood units screened for bloodborne diseases	N: Number of donated blood units tested for HIV, HBV, HCV and syphilis. D: Number of donated blood units.	Facility type, location.	N&D: Programme records, e.g. blood donation logs, laboratory records.	Less than 100% screening signals a breakdown in proper processing of blood units (e.g. lack of test kits or personnel) and must be addressed.

2.4.2e Sexually transmitted infections

Conceptual framework

Globally, in 2012 there were an estimated 362 million new cases of curable sexually transmitted infections (that is, syphilis, gonorrhoea, chlamydia and trichomoniasis). Untreated STI can lead to complications such as pelvic inflammatory disease, infertility, stillbirths and neonatal death, and they increase the risk of acquiring or transmitting HIV. For these reasons improving access to STI services is an important part of WHO's global strategy for universal access to reproductive health care.

As outlined in the WHO Global Strategy for the Prevention and Control of Sexually Transmitted Infections,[1] effective STI control depends on reliable, routine STI surveillance. The objectives of STI surveillance are primarily to ascertain the prevalence of STIs in target populations, in order to improve programme management, and to inform treatment recommendations that contribute to improved patient care. At a minimum, the core components of STI surveillance should include:

- case reporting
- prevalence assessments
- assessment of the etiology of STI syndromes
- monitoring of antimicrobial resistance.

STI surveillance is an important component of HIV "second generation" surveillance systems.[2] Because STIs are markers of unprotected sexual intercourse, surveillance for incident STI (for example, urethral discharge in men, primary and secondary syphilis, and gonorrhoea) could serve as: 1) an early warning of the epidemic potential of HIV via sexual transmission in a particular population and 2) an indication of ongoing high-risk sexual activity that may need more vigorous programme interventions. At the same time, data obtained through second generation HIV surveillance, such as size estimates of key populations, and behavioural surveys are also useful for targeting STI control activities.

In light of new technologies (such as rapid syphilis tests) and changing epidemiology (including the spread of antimicrobial-resistant *Neisseria gonorrhoeae*), WHO released updated STI surveillance guidelines in 2012.[3]

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[1] Global Strategy for the Prevention and Control of Sexually Transmitted Infections, 2006–2015: Breaking the chain of transmission. Geneva: World Health Organization; 2007 (http://www.who.int/reproductivehealth/publications/rtis/9789241563475/en/).
[2] Strategies and laboratory methods for strengthening surveillance of sexually transmitted infection 2012. Geneva: World Health Organization; 2012 (http://www.who.int/reproductivehealth/publications/rtis/9789241504478/en/).
[3] Ibid.

M&E issues for monitoring STIs

Implementing the four core STI surveillance components depends on the availability of laboratory testing for routine clinical care and on existing health information systems. Data on each of the components should be analysed together to provide a more complete picture of the burden of STIs in a country.

Strengthening STI case reporting

Depending on the resources available, case reporting can be based on either syndromic or etiologic approaches. In countries with sufficient laboratory capacity for etiologic diagnosis in most clinical settings, etiologic surveillance of syphilis, congenital syphilis and gonorrhoea is recommended. Countries with poor laboratory capacity rely on syndromic case reporting. Urethral discharge and genital ulcer disease are the syndromes most useful to report for STI surveillance purposes, as vaginal discharge does not necessarily represent an STI.

STI cases identified through either case-finding or screening should be captured by the surveillance system and reported. Clear case definitions are critical for ensuring the quality of case reporting, and all probable and confirmed cases should be reported. Universal case reporting allows surveillance of the entire population served by health facilities, but interpreting trends can be challenging if data quality is poor. Sentinel site surveillance obtains higher quality data. This approach can limit the generalizability of the findings, however, if the selected sites are not representative of the populations of interest.

Instituting periodic prevalence assessments

Prevalence assessments are cross-sectional surveys conducted every three to five years in selected population groups. The data are used to develop national estimates of STI prevalence, identify population groups at high risk for STI/HIV, guide funding and resource allocation for STI/HIV prevention programmes, and monitor the effectiveness of prevention programmes. At a minimum, STI prevalence surveys should include testing for *C. trachomatis* (chlamydia), *N. gonorrhoeae* (gonorrhoea), *T. pallidum* (syphilis) and *T. vaginalis* (trichomoniasis). STI prevalence surveys should also be conducted in key populations at higher risk of STI, such as sex workers and men who have sex with men. The most common general population prevalence assessments are based on serological testing test for syphilis in antenatal clinics and blood donation sites. Surveys of chlamydia prevalence in adolescent and young women are also of value. In settings that screen for STIs in asymptomatic individuals, these routine programme data can sometimes serve as a proxy for more formal prevalence assessments.

Etiologic studies of STI syndromes to inform clinical management

In countries where case reporting is based on syndromic management, it is critical to conduct periodic etiologic assessments to update information on the causative microorganisms for the common STI syndromes. This information is essential to update treatment recommendations. Such etiologic assessments should be conducted in different types of populations and in different geographical locations every two to three years for urethral discharge, genital ulcer disease and vaginal discharge. If resources are particularly limited, however, it is advisable to begin with an assessment of urethral discharge and genital ulcer disease in at least 100 patients with each syndrome in one or more STI clinics that can perform high quality, nucleic acid amplification testing (NAAT) and syphilis serology.

Monitoring gonococcal resistance. Because resistance has emerged to every known class of antibiotic recommended for the treatment of gonorrhoea, WHO recommends routine monitoring for antimicrobial resistance. A minimum of 100 *N. gonorrhoeae* urethral isolates from symptomatic men should be collected in the monitoring period, and the collected isolates should

be evaluated for resistance to any antimicrobial treatment currently recommended in the country. When the proportion of resistant strains is at a level of 5% or more, or when any unexpected increase (even if below 5%) is observed in key populations with high rates of gonococcal infection, national guidelines for gonorrhoea treatment should be modified so as to propose an alternate treatment regimen, and gonococcal surveillance should be enhanced.

Selection and use of STI indicators

Key STI indicators in the context of monitoring HIV in the health sector are those that most accurately reflect unprotected sexual exposure in either key or general populations (Table 2.16).[1]

Special considerations by setting and population

STIs in pregnant women

STIs in pregnant women are of great public health importance due to their potential to cause stillbirth, prematurity, low birth weight, neonatal death and diseases such as congenital malformations, ophthalmia and pneumonia in the newborn. However, recommendations for STI testing in pregnancy are generally only for syphilis, as low-cost, simple and high-performing diagnostics for gonorrhoea and chlamydia are not yet widely available. Surveillance and monitoring of syphilis in pregnancy is particularly important, in keeping with global and regional initiatives to eliminate mother-to-child transmission (EMTCT) of syphilis.[2,3] Surveillance and monitoring are together considered one of the four critical pillars of efforts to eliminate congenital syphilis. It is advised that every country monitor the four indicators necessary for basic monitoring and management of the EMTCT of syphilis programme as well as for validation of EMTCT of syphilis in those countries seeking to document success:

- testing of ANC attendees for syphilis at first visit
- positive syphilis serology in ANC attendees
- treatment of syphilis-seropositive ANC attendees
- the congenital syphilis case rate.

STIs in key populations

The seroprevalence of syphilis among sex workers and among men who have sex with men are considered core indicators for guiding the national response to STIs, and they are collected through global reporting systems.[4] Given the greater likelihood of previous infection than in the general population, diagnosis of active syphilis infection in these populations should be based on both positive treponemal and a non-treponemal test results. Data on these populations can be obtained through routine health information systems, sentinel surveillance or special surveys.[5] However, trends over time should be interpreted with caution unless the same method is used and the same population is surveyed at each round.

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[1] Global AIDS response progress reporting, Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://www.unaids.org/sites/default/files/media_asset/GARPR_2014_guidelines_en_0.pdf).
[2] Elimination of mother-to-child transmission (EMTCT) of HIV and syphilis. Global guidance on criteria and processes for validation. Geneva: World Health Organization; 2014 (http://www.who.int/reproductivehealth/publications/rtis/9789241505888/en/).
[3] Methods for surveillance and monitoring of congenital syphilis elimination within existing systems. Geneva: World Health Organization; 2011 (http://www.who.int/reproductivehealth/publications/rtis/9789241503020/en/).
[4] Global AIDS response progress reporting, Geneva: Joint United Nations Programme on HIV/AIDS; 2014 (http://www.unaids.org/sites/default/files/media_asset/GARPR_2014_guidelines_en_0.pdf).
[5] Strategies and laboratory methods for strengthening surveillance of sexually transmitted infection 2012. Geneva: World Health Organization; 2012 (http://www.who.int/reproductivehealth/publications/rtis/9789241504478/en/).

Table 2.16 Key indicators for sexually transmitted infections

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
PREV.10 ANC syphilis screening coverage % of ANC attendees who were tested for syphilis	N: Number of women attending ANC services within the past 12 months who were tested for syphilis. D: Number of women attending ANC services within the past 12 months.	Visit of testing (first visit versus any visit).	N&D: Programme records, e.g. ANC registers.	To prevent congenital syphilis, also primary prevention of HIV transmission. Measures the extent of routine syphilis screening among pregnant women at first visit (ideally) or at any visit.
PREV.11 Syphilis treatment Treatment of syphilis in seropositive ANC attendees	N: Number of syphilis-seropositive ANC attendees within the past 12 months who received adequate treatment. D: Number of syphilis-seropositive ANC attendees within the past 12 months.	None.	Programme records.	Measures the coverage of treatment of syphilis-seropositive ANC attendees. Treatment is necessary to prevent congenital syphilis.
Additional indicator				
PREV.12 Syphilis seroprevalence % of individuals seropositive for syphilis	N: Number of people testing seropositive for syphilis within the past 12 months. D: Number of individuals tested for syphilis within the past 12 month.	Sex, age (15–24, 25+), key population (sex workers, men who have sex with men), pregnancy status.	N&D: Programme records, sentinel surveillance, special surveys.	Measures syphilis seropositivity in a population group. Syphilis seropositivity in ANC attendees can be used to model syphilis incidence in the general population.

PREV.13 Gonorrhoea incidence Gonorrhoea rate among adult males	N: Number of cases of gonorrhoea reported among adult males within the past 12 months D: Number of adult males.	Sex, age	N: STI surveillance case reporting system. D: Census.	Male gonorrhoea incidence is an excellent early warning measure of unprotected sex. Because gonorrhoea among women is often asymptomatic, incidence among women is more difficult to measure and interpret.
PREV.14 Urethral discharge incidence Urethral discharge rate among adult males	N: Number of cases of urethral discharge reported among adult males within the past 12 months. D: Number of adult males.	None.	N: STI surveillance case reporting system. D: Census.	Early warning measure of unprotected sex among men in countries without widely available STI diagnostics.
PREV.15 Congenital syphilis incidence Rate of congenital syphilis	N: Number of cases of congenital syphilis (live births and stillbirths) reported within the past 12 months. D: Number of live births within the past 12 months.	None.	N: STI surveillance case reporting system. D: Census.	Trends may suggest the impact of programmatic interventions for EMTCT of syphilis.

2.4.3 Awareness of serostatus: HIV testing services

Conceptual framework

HIV testing services (HTS) include pre-test information, HIV testing and diagnosis, post-test counselling when applicable, and referral and linkage to prevention, care and treatment services. They are the gateway to the continuum of HIV care. In recent years there has been a global focus on scaling up HTS to achieve universal access to HIV testing and, thereby, universal knowledge of serostatus.[1] Progress has been considerable, with 120 million people testing for HIV in 2013 alone.[2] Still, it is estimated that only about half of all people with HIV globally have been diagnosed.[3] In terms of monitoring, the need is to go beyond counting outputs such as the number of tests and to begin measuring population outcomes, such as the proportion of people living with HIV who have been diagnosed, which constitutes the first 90 of the 90–90–90 targets. This guide emphasizes that shift from counting outputs to estimating coverage.

HIV testing services should always be voluntary and conducted in accordance to WHO's 5Cs: Consent, Confidentiality, Counselling, Correct test results and Connection (linkage to prevention, care and treatment). Coerced or mandatory testing, including inappropriate implementation of provider-initiated testing and counselling (PITC) guidance, persists in many settings. Therefore, in 2012 WHO issued a statement recommending review of national HTS policies and practices to eliminate all non-voluntary forms of HIV testing.[4]

4. People living with HIV diagnosed

Number and % of people living with HIV who have been diagnosed.

Various combinations of HTS approaches can be used to reach those at highest risk of and vulnerable to acquiring HIV, for example, pregnant or breastfeeding women, infants and children, adolescents (ages 10–19), serodiscordant couples, key populations, tuberculosis (TB) patients and other context-specific priority groups (see box, next page). Depending on the epidemiological and social context, as well as available resources, countries can utilize multiple HTS approaches. Using strategic information, programmes can tailor service delivery approaches to maximize coverage and uptake and thereby diagnose more people who are living with HIV. Disaggregating service statistics by HIV test result, by service delivery point and/or by population sub-group can help countries set HTS targets and align HTS with prevention, treatment, care and support services.[5]

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[1] Guide for monitoring and evaluating national HIV testing and counselling (HTC) programmes. Geneva: WHO; 2011. http://whqlibdoc.who.int/publications/2011/9789241501347_eng.pdf.
[2] Global AIDS response progress reporting 2014. Geneva: WHO and UNAIDS; 2014.
[3] UNAIDS report on the global AIDS epidemic 2013. Geneva: UNAIDS; 2013 (http://www.unaids.org/en/resources/campaigns/globalreport2013/globalreport).
[4] Statement on HIV testing and counselling: WHO, UNAIDS re-affirm opposition to mandatory HIV testing. Geneva: World Health Organization and Joint United Nations Programme on HIV/AIDS; 2012 (http://www.who.int/hiv/events/2012/world_aids_day/hiv_testing_counselling/en/).
[5] Service delivery approaches to HIV testing and counselling (HTC): A strategic policy framework. Geneva: WHO; 2012. http://www.who.int/hiv/pub/vct/htc_framework/en/.

Recent developments in HTS

Rapid testing. HIV rapid diagnostic tests (RDTs) have been available since the 1990s. Their use can greatly expand access to HTS in facility and community settings. Many countries still limit use of RDTs, and restrict who can perform them (that is, excluding trained lay providers or nurses).[1] Nonetheless, in recent years more sites have been able to use HIV RDTs to provide same-day test results and diagnoses. This has spurred interest in using other testing technologies at the point of care (POC), such as CD4 instruments to determine the disease stage of people at the time they are diagnosed with HIV infection, thereby streamlining linkages between testing and HIV care and treatment.

Self-testing. Interest and the number of national policies on HIV self-testing are increasing.[2] While there is no formal WHO recommendation on HIV self-testing, technical guidance and considerations are available.[3] Countries should begin to consider and plan how to monitor and report on self-testing. Some countries – for example, Kenya – have already introduced monitoring of self-testing and reporting into national population-based surveys.[4]

Definitions of HIV testing and counselling

- **Voluntary counselling and testing (VCT)** is a form of client-initiated HIV counselling and testing, offered at stand-alone clinics or sites or integrated into facilities that can provide HTS.
- **Provider-initiated HIV testing and counselling (PITC)** is HIV testing offered routinely by health-care providers to patients as a standard part of medical care. Testing should be performed only after the client has given informed consent. Common entry points for PITC include TB and STI clinics; ANC, childbirth and postpartum services; family planning and maternal and child health settings; paediatric care; and services for people who inject drugs.
- **Community-based HIV testing services** are a form of client-initiated HTS conducted outside of conventional health facilities or centres at a variety of locations – for example, homes, workplaces, schools/colleges, churches, mobile vans, moonlight clinics, campaigns, door-to-door, and sports or entertainment events.[1]
- **Couples and partner HIV testing services** employ a testing strategy whereby couples come for testing together at a facility or community setting. This approach encourages mutual disclosure, support and access to prevention, care and treatment services.
- **Partner testing** refers to an approach in which individuals who have been tested (regardless of HIV status) are encouraged to bring in their regular sexual partners for voluntary testing.
- **Mandatory HIV testing** is testing conducted as a requirement or prerequisite for entry or enrolment or as a legal stipulation (for example, for immigration, entry into a profession, application for a marriage license or in a legal investigation). It is sometimes conducted without a person's knowledge. Such testing plays no role in medicine or public health and in many countries is prohibited by law under all circumstances.

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[1] Flynn D, Johnson C, Sands A, Wong V, Baggaley R. An analysis of the role of lay providers in HIV testing and counselling in 48 countries. WHO Consolidated guidelines on HIV testing services. Geneva: World Health Organization, 2015 (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/).

[2] Policies that allow HIV self-testing have been adopted in Australia (2014), China (including Hong Kong) (2008), Kenya (2008), Malawi, South Africa (in some settings), the United Kingdom and the United States of America. The European Union has a policy that allows its member states to introduce HIV self-testing. Countries currently developing or revising policies include Brazil, France, Peru, South Africa, Thailand, Zambia and Zimbabwe.

[3] Supplement to the 2013 Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization, 2014 (http://apps.who.int/iris/bitstream/10665/104264/1/9789241506830_eng.pdf)

[4] KENYA AIDS INDICATOR SURVEY 2012: Final report. Kenya: KAIS 2012 Collaborating Institutions, 2014 (http://www.nacc.or.ke/attachments/article/403/KAIS_II_2014_Final_Report.pdf)

- **HIV self-testing (HIVST)** is a process in which a person who wants to know his or her HIV status collects a specimen, performs a test and interprets the result by himself or herself, often in private. HIVST does not provide a definitive diagnosis. Instead, it is an initial test. A reactive self-test always requires further testing according to relevant national testing algorithms; a person who has a non-reactive test result should be advised to repeat the test if he or she has had recent or has ongoing HIV risk or has any uncertainty about reading the test result correctly.
- **Repeat testing** refers to a situation where additional testing is performed for an individual immediately following a first test during the same testing visit due to inconclusive or discordant test results; the same assays are used and, where possible, the same specimen.[2]
- **Retesting** There are three different types of retesting that WHO recommends within HIV programmes: (1) retesting people at on-going risk for HIV infection (for example, in settings of high HIV prevalence and incidence, pregnant women in their third trimester or in the breastfeeding/post-natal period and key populations retesting at least annually); (2) retesting people with inconclusive test results; and (3) retesting to verify HIV-positive diagnosis. HTS guidelines recommend periodic retesting over time, especially among populations at high on-going risk for HIV infection.[3,4,5]

[1] Suthar A, Ford N, Bachanas P, Wong V, Rajan, J, Saltzman A, et al. Towards universal voluntary HIV testing and counselling: a systematic review and meta-analysis of community-based approaches. PLOS, 2013 DOI: 10.1371/journal.pmed.1001496 (http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001496).
[2] Delivering HIV test results and messages for re-testing and counselling in adults. Geneva: World Health Organization; 2010 (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/).
[3] WHO reminds national programmes to retest all newly diagnosed people with HIV. Geneva: World Health Organization; 2014.(http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-plhiv-full/en/
[5] WHO Consolidated guidelines on HIV testing services. Geneva: World Health Organization, 2015 (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/).

Quality issues. There have been concerns about the quality of HTS and the potential misclassification of test results,[1] particularly in countries adopting WHO ARV guidelines that recommend immediate ART initiation following a positive diagnosis regardless of clinical stage in some sub-populations (for example, pregnant or breastfeeding women (PMTCT Option B/B+ regimen[2]), children under age five, TB patients and certain people with hepatitis infection). This concern has spurred renewed efforts to strengthen strategic information on quality improvement, quality assurance and quality control of rapid HIV test kits and protocols for counselling and for interpreting test results. It also has highlighted the importance of retesting all persons who have received an HIV-positive diagnosis with a second specimen at the time of ART initiation, to rule out misdiagnosis.[3] Initiatives to scale up and decentralize testing services should ensure that all testing is of good quality and that correct results and diagnoses are being made.

M&E issues for HTS

Measuring the global target on people living with HIV who have been diagnosed

A key focus in compiling a treatment cascade is the kowledge among people living with HIV of their HIV status. In fact, this is the first of the three 90–90–90 global treatment targets.

[1] Shanks L, Klarkowski D, O'Brien D.P. False positive HIV diagnoses in resource limited settings: operational lessons learned for HIV programmes. PLoS One, 2013 Mar 20. doi: 10.1371/journal.pone.0059906 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3603939/pdf/pone.0059906.pdf.).
[2] O'Brien L, Shaffer N, Sangrujee N, Abimbola T. The incremental cost of switching from Option B to Option B+ for the prevention of mother-to-child transmission of HIV. Bulletin WHO, 2014;92:162–170 (http://www.who.int/bulletin/volumes/92/3/13-122523.pdf).
[3] Service delivery approaches to HIV testing and counselling (HTC): a strategic policy framework. Geneva: WHO; 2012 (http://www.who.int/hiv/pub/vct/htc_framework/en/).

Household surveys often report the percentage of people tested in the last year, but this indicator misses all those who are living with HIV and already know their status and thus have not been retested. The number of tests performed in the previous year has a similar bias in addition to substantial double-counting of individuals who feel they are at increased risk and so test more often than once a year. An alternate approach is to ask survey respondents directly whether they know their HIV status and to compare their responses with their HIV status. A number of studies have suggested that respondents in surveys hesitate to provide this information to interviewers, however. Also, the quality of the responses will vary depending on the ability and training of the interviewer and overall survey implementation.

Another indicator collected routinely in surveys is the percentage of people who report never having been tested for HIV. When cross-tabulated with HIV status, this indicator provides an estimate of those who definitely do not know their status. Along with the percentage who were tested in the past year – and who therefore likely know their status – these data provide a range of estimates of the number living with HIV who know their status.

Adjusting for retesting in HTS coverage estimates

As noted, there are three different of retesting that WHO recommends within HIV programmes: (1) retesting people at on-going risk for HIV infection (that is, re-testing pregnant women in settings of high HIV prevalence and incidence in their third trimester or in the breastfeeding/post-natal period, and retesting key populations at least annually), (2) retesting people with inconclusive test results and (3) retesting to verify HIV-positive diagnoses. HTS guidelines recommend periodic retesting over time, especially among populations at high on-going risk for HIV infection.[1,2,3,4]

Many HTS indicators are more meaningful as measures of access and coverage if they count the number of individuals who have been tested rather than the number of tests performed.[5] When using *routinely collected programme data* to determine coverage, counting unique individuals over the period of a year as well as across many sites is challenging. Using unique identifiers for individuals is one way to account for retesting and avoid double reporting if electronic systems are available to easily link data through these unique identifiers. Another approach is to record information about prior testing on the HTS client register.[6] Then, the retests can be counted and subtracted from the total number of tests performed for the same individual. *Population-based surveys* are another method that avoids double-counting of retestsers. Surveys are particularly helpful to determine testing coverage among hard-to-reach populations. In many settings key population-specific data cannot be collected from routine programme monitoring; therefore, WHO recommends investing in surveys to estimate service use that are more representative and appropriately powered.

Handling disaggregation by several variables

Disaggregation of HTS data at the national level is important to ensure that critical populations are accessing HTS (see box, next page). The optimal examination of HTS strategic information requires simultaneously disaggregating service statistics by multiple dimensions, such as numbers of individuals tested by age, sex, diagnosis, service delivery point and key population status. However, tabulating these figures from paper-based registers can be time-consuming.

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[1] WHO reminds national programmes to retest all newly diagnosed people with HIV. Geneva: World Health Organization; 2014. (http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-plhiv-full/en/)

[2] Delivering HIV test results and messages for re-testing and counselling in adults. Geneva: World Health Organization; 2010. (http://www.who.int/hiv/pub/vct/hiv_re_testing/en/)

[3] WHO Consolidated guidelines on HIV testing services. Geneva: World Health Organization, 2015 (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/).

[4] Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people. Recommendations for a public health approach. Geneva: World Health Organization; 2011 (http://apps.who.int/iris/bitstream/10665/44619/1/9789241501750_eng.pdf?ua=1).

[5] Ibid.

[6] Ibid.

Special efforts are needed to design paper-based tools that support disaggregation of these data without placing an undue burden on those responsible for collecting and analysing the information.

Categories to consider for disaggregation of variables

Below is a list of variables to be considered for disaggregating HTS data as appropriate for strategic information analysis and intended use:

- **Age:** <1, 1–4, 5–9, 10–14, 15–19, 20–49, 50+
- **Sex:** male, female, transgender
- **Test result:** positive, negative, inconclusive, unknown (not confirmed)
- **Population:** pregnant or breastfeeding women, partners, key populations (men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers, transgender people), serodiscordant couples, infants and children, adolescents, TB patients, hepatitis patients
- **Geographic area:** district, region, province, other administrative unit
- **Service delivery point:**
  - facility-based, for example, ANC clinics, outpatient care, in-patient care, TB clinics, STI clinics, HTS clinics, integrated HTS
  - community-based, for example, home-based, door-to-door, mobile outreach
  - other, for example, workplace programme, self-testing
- **HIV self-testing**
- **Retesting status:** new tester, retester
- **Earliest CD4 count at diagnosis**, where CD4 testing is routinely available: ≤200; 200–349; 350–500; >500 cells/mm^3.

Selection and use of indicators

Monitoring and evaluation of HTS has expanded from measuring coverage in terms of the number of people tested to measuring knowledge of HIV status among different populations and estimating the proportion of people living with HIV who have been diagnosed. There is increasing interest in determining what populations are underserved by HTS as well as how programmes can engage people from populations at highest risk who do not know their HIV status.

Thus, HTS effectiveness is not measured in terms of more testing, but rather more people knowing their HIV status, particularly among those at highest risk. The most critical outcome indicator is the number and proportion of people living with HIV who have been diagnosed (HTS.1).

In some populations people living with HIV who are already receiving services for other reasons (for example, pregnancy or TB) are more accessible for HIV testing, and their data are relatively easily captured. In contrast, data are scarce on the proportions of key populations (HTS.7), marginalized populations and young people living with HIV who have been diagnosed. More efforts to measure these populations are needed, especially where new HIV infections are common in these groups.

Analysing HIV testing and quality data further, by type of site, is critical for determining where national programmes should allocate resources. Each national programme should have a reliable list of sites providing HTS, disaggregated by the service delivery setting – facility type (for example, ANC, TB, obstructive pulmonary disease, STI, in-patient, nutrition services and under-five clinics) and community-based services (for example, VCT, mobile and home-based).

In addition to achieving high coverage rates, the quality of HTS depends on accurate diagnosis and effective linkage to HIV prevention, care and treatment services. Monitoring the quality of HTS starts with the review of national testing policies and standards, quality of test kits and algorithms being used, accuracy of diagnoses and quality of counselling and referrals. Also, the laboratory-based aspects of HTS need to demonstrate quality, as measured through documentation, standard operating procedures, quality control sampling and proficiency testing (see section 2.3.1, health system inputs). It is critical, as well, to monitor and measure linkage to care (LINK.1) so that missed opportunities to link newly diagnosed people to HIV care are identified and gaps are closed (see section 2.4.4 on linkage to care). Finally, monitoring of the quality and effectiveness of HTS should employ indicators that monitor the compliance of HIV policies, programmes and practices with human rights norms and standards,[1] especially in HTS for key populations.

Special considerations by setting and population

WHO recommends different strategies for increasing uptake of testing among priority populations. These recommendations include:

- PITC for 1), in generalized epidemics, everyone (for example, adults, adolescents and children) attending all health facilities and 2), in concentrated and low-level epidemics, everyone who presents with signs and symptoms of medical conditions that could indicate HIV infections (including TB), HIV-exposed children, symptomatic infants and children, and people from key populations;
- Community-based HTS with linkage to care and treatment for everyone in generalized epidemics and for key populations in all epidemics;
- HTS for couples and partners, with support for mutual disclosure, for individuals with known HIV status (whether positive or negative) and their partners in ANC settings.

HTS for pregnant women

PITC in PMTCT programmes is widely implemented and accepted.[2] However, HIV testing is only the first step in a cascade spanning a period of risk for mother-to-child transmission of more than 18 months if breastfeeding. See section 2.4.7 for more on PMTCT programme objectives and indicators.

HTS for couples and partners

The potential benefits of HTS for couples and partners include HIV prevention within couples, increased uptake and better adherence to ART and/or PMTCT, safer conception and

[1] Global AIDS response progress reporting 2014. Geneva: World Health Organization, Joint United Nations Programme on HIV/AIDS; 2014. (http://www.unaids.org/sites/default/files/media_asset/GARPR_2014_guidelines_en_0.pdf).
[2] Guidance on provider-initiated HIV testing and counselling in health facilities. Geneva: World Health Organization, Joint United Nations Programme on HIV/AIDS; 2007 (http://www.who.int/hiv/pub/vct/pitc/en/).

contraception. Offering HTS to the partners and family members of people living with HIV is an efficient way to identify people living with HIV and support earlier linkage to ART, as well as to identify people in serodiscordant relationships to support prevention of HIV transmission to the negative partner. In sub-Saharan Africa up to half of HIV-positive people in on-going relationships have HIV-negative partners.[1] A significant number of new infections occur in serodiscordant couples each year, in part because many couples are unaware that they are in a serodiscordant partnership, and one partner or both do not know their own HIV status.

Serodiscordant couples may be offered male and female condoms, male circumcision (if the HIV-negative partner is male), and treatment of any STIs, daily oral PrEP for the uninfected partner and immediate initiation of ART for the HIV-infected partner. In 2012 WHO recommended that HIV-positive partners in HIV-serodiscordant couples should be offered ART regardless of WHO clinical stage or CD4 cell count.[2] This recommendation was based on data from a randomized clinical trial that showed significant reductions in HIV transmission with early initiation of ART.[3]

HTS for infants and children

WHO recommends that national programmes establish the capacity to conduct early virologic testing of HIV-exposed infants at four to six weeks, or as soon as possible thereafter, to allow timely initiation of ART.[4] Special considerations concerning infants and children are disaggregating data by early infant diagnosis (EID) (tested within two months of birth) (HTS.5) versus later testing and by HIV test result, as well as following up to collect data on final HIV status/diagnosis and outcomes. (See section 2.4.5b on paediatrics for more on HTS for infants and children and section 2.4.7 on PMTCT.)

HTS for adolescents

The WHO 2013 adolescent HIV guidelines[5] call for better understanding of the needs and behaviour of adolescents so as to strengthen services for them. For this better understanding, national health management systems must stratify data by an adolescent-specific age group (10–19 years) or, preferably, sub-groups (10–14, 15–19 years). Age disaggregation by these categories is particularly important for assessing uptake of testing, linkages with treatment and care, and trends in loss to follow-up among adolescents.

Country policies vary on age of consent to HIV testing (that is, the age at which consent of a parent or caregiver is not necessary for an adolescent's test). WHO encourages countries to consider examining and revising consent policies to reduce age-related barriers to access and uptake of HTS and linkages to prevention, treatment and care.

HTS for key populations

Due to key populations' increased risk and vulnerability to HIV and the potential for stigma and discrimination that inhibits their access to services, key populations are a priority population for scaling up acceptable HTS and providing strong linkages to prevention, care and treatment. The marginalized and hidden nature of many people from key population communities makes both providing services and monitoring coverage and quality particularly challenging. (See section 2.4.1 for more on addressing the needs in the health sector of key populations.)

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[1] Chemaitelly H, Cremin I, Shelton J, Hallett TB, Abu-Raddad LJ. Distinct HIV discordancy patterns by epidemic size in stable sexual partnerships in sub-Saharan Africa. Sex Transm Infect. 2012;88:51–57.
[2] Guidance on couples HIV testing and counselling – including antiretroviral therapy for treatment and prevention in serodiscordant couples. Recommendations for a public health approach. Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/guidelines/9789241501972/en/).
[3] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011;365(6):493–505 (http://www.nejm.org/doi/pdf/10.1056/NEJMoa1105243).
[4] Diagnosis of HIV infection in infants and children. WHO recommendations. Geneva: World Health Organization, 2010 (http://www.who.int/hiv/pub/paediatric/diagnosis/en/).
[5] HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV. Geneva: World Health Organization; 2013 (http://www.who.int/hiv/pub/guidelines/adolescents/en/).

Table 2.17 Programme indicators for HIV testing services

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
HTS.1 People living with HIV diagnosed[1] Number and % of people living with HIV who have been tested HIV-positive  	N: Number of people living with HIV who have been diagnosed and received their results D: Number of people living with HIV.	Sex, age (<1, 1–4, 5–9, 10–19, 20–24, 25–49, 50+ years[2]), key populations, other target populations.	Best estimate based on available data sources, e.g. 1. Based on facility data: N: Cumulative number of reported new HIV diagnoses minus deaths; D: national PLHIV estimate based on internationally consistent modelled estimates, e.g. Spectrum AIM 2. Based on population-based surveys collecting HIV serostatus and with a question to assess whether respondents know their positive status. The indicator will be calculated as PLHIV who report knowing their status 3. Based on population-based surveys collecting HIV serostatus without a question to assess whether respondents know their positive status. Construct a plausible range and midpoint based on: the higher value of (the percentage of PLHIV respondents in the survey who have been tested in the past 12 months and received the results) and (the percentage of all PLHIV on care) as the lower end of the range, and the percentage of PLHIV ever tested as the upper end of the range. Other surveys, related programme data and modelled estimates can be used as additional data sources for developing and triangulating estimates.	Critical to determine the proportion of people living with HIV who know their HIV status, as this knowledge is the entry point to the continuum of care Disaggregated estimates can reveal gaps in diagnosing people living with HIV. The proportion of people living with HIV who know their HIV-positive status should also be globally reported for target populations where these are collected as national indicators, including: 1. % of key populations 2. % of pregnant women who have been tested in the past 12 months and know their status.

[1] This is a newly recommended indicator.
[2] In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

HTS.2 HTS scale-up Number of people who were tested for HIV and received their results within the past 12 months	N: Number of people who were tested for HIV and received their results within the past 12 months. D: n/a. Although not required for this indicator, a denominator may be gauged by using the general population size in generalized epidemics or the sizes of key populations and other priority populations in low-level and concentrated epidemics.	Test result, sex, age (<1, 1–4, 5–9, 10–14, 15–19, 20–49, 50+ years), key population (where available), other target populations if relevant.	D&N: Programme records, e.g. HTS registers Count only people's first test or else subtract retesters to calculate the number of *individuals* tested.	Measures trends in scale-up of HIV testing and counselling.
HTS.3 HTS retest Number of people who were retested for HIV within the past 12 months	N: Number of people who were tested and received their results more than once within the past 12 months. D: n/a. Although not required for this indicator, a denominator may be gauged by using the general population size in generalized epidemics or the sizes of key populations and other priority populations in low-level and concentrated epidemics.	Sex, age (<1, 1–4, 5–9, 10–19, 20–49, 50+ years), key population* (where available), other target populations if relevant. Type of retester: 1. Retesting (at on-going risk). 2. Retester after discrepant result. 3. Retester to verify diagnosis.	Programme records	Quantifying the number of retesters and subtracting retesters from the total number of testers helps to determine the *number of individuals* tested. Knowing the reasons for retests can help explain retesting patterns.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

HTS.4 PMTCT testing coverage % of pregnant women with known HIV status *Cross-referenced with PMTCT section MTCT.1*	N: Number of pregnant women attending ANC and/or having had a facility-based delivery who were tested for HIV during pregnancy or already knew they were HIV-positive. Population-based denominator: Number of pregnant women who delivered within the past 12 months. Programme-based denominator: Number of pregnant women who attended ANC or had a facility-based delivery in the past 12 months.	HIV status/test results: 1. known HIV infection at ANC entry. 2. tested HIV-positive at ANC during current pregnancy. 3. tested HIV-negative at ANC during current pregnancy. Total identified HIV-positive women = 1 + 2 Optional disaggregation: pregnant women who inject drugs.	N: Programme records, e.g. ANC registers, labour and delivery registers. Population-based denominator: Estimates from central statistics office, UN Population Division or vital statistics. Facility-based denominator: Programme records, e.g. ANC registers, labour and delivery registers.	Measures coverage of the first step in the PMTCT cascade. High coverage enables early initiation of care and treatment for HIV-infected mothers. The total number of identified HIV-positive women provides the facility-specific number of pregnant women with HIV to start a facility-based PMTCT cascade.
HTS.5 Coverage of early infant diagnosis % of HIV-exposed infants receiving a virological test for HIV within 2 months of birth *Cross-referenced with PMTCT section MTCT.6*	N: Number of HIV-exposed infants born within the past 12 months who received an HIV test within two months of birth D: Number of HIV-positive pregnant women who delivered within the past 12 months. (proxy measure for the number of infants born to HIVinfected women).	Test results: 1. positive 2. negative 3. indeterminate 4. other.	N: Programme records, e.g. PMTCT registers, laboratory records. D: Internationally consistent modelling estimates, e.g. Spectrum AIM.	Measures early HIV diagnosis in infants, a critical first step toward early treatment. High coverage of early virological testing of infants helps initiate ART early in children with confirmed HIV infection and supports counselling on efforts to prevent seroconversion of those with a negative early test result.

HTS.6 HIV testing among TB patients % of registered new and relapsed TB patients with documented HIV status *Cross-referenced with TB/HIV section LINK.15*	N: Number of new and relapsed TB patients registered during the reporting period who had an HIV test result (whether positive or negative) recorded in the TB register. D: Number of new and relapsed TB patients registered in the TB register during the reporting period.	Sex, age (0–4, 5–14, 15+), HIV status (positive, negative, unknown).	N&D: Programme records, e.g. TB treatment card, TB register.	Measures the extent to which HIV status of notified TB patients is ascertained. Knowing their HIV status enables linking these people with the appropriate HIV services.
HTS.7 HIV testing coverage of key populations % of people from key populations who received an HIV test in the last 12 months and who know the results *Cross-referenced with Key population section KPOP.1*	N: Number of key population respondents previously unaware of their HIV-positive status who were tested for HIV and received their results within the past 12 months D: Number of key population respondents in survey.	Key population (men who have sex with men, people in prisons and other closed settings, people who inject drugs, sex workers, transgender), sex, age.	N&D: Survey of key population.	Measures the programme's effectiveness in encouraging HIV testing, which can serve as both a prevention tool and an entry point for early care and treatment for key populations. Targets for the percentages of key populations that know their status should be higher than for the general population.
Additional indicators				
HTS.8 Retesting to verify diagnosis at ART initiation % of ART initiators who were retested to verify diagnosis	N: Number of people with HIV who initiated ART within the past 12 months who had a retest to verify HIV diagnosis. D: Number of people living with HIV who initiated ART within the past 12 months.	Facility or geographical area of interest.	Programme records, to be recorded in ART monitoring tools.	Quality measure to assess whether retesting to verify HIV diagnosis at the time of ART initiation is taking place.

HTS.9 Self-testing % of people who have tested for HIV using a self-test kit	N: Number of people who have tested for HIV using a self-test kit. D: Number of people surveyed.	By specific populations of interest.	DHS generic question that can be included in general population surveys: "Have you ever tested yourself for HIV using a self-test kit?"	Measures % of the general population surveyed that has used an HIV self-test kit. The DHS also includes a knowledge question: "Have you heard of test kits people can use to test themselves for HIV?" The AIS also asks about willingness to use an HIV home self-test kit.
HTS.10 General annual HTS coverage % of people who have been tested for HIV in the last 12 months and received the results	N: Number of adult respondents who have been tested for HIV within the past 12 months and received the results. D: Number of adult respondents (15 years and older).	Sex, age (15–19, 20–24, 25–49, 50+).	N&D: Population-based survey of the general population.	Measures proportion of the general population covered by HTS in the preceding 12 months. Especially relevant for generalized epidemics, in which broad-based efforts to scale up testing should be assessed.
HTS.11 Partner testing % of HIV-positive adults receiving HIV care whose partner's status is known *Cross-referenced with Linkage section LINK.6*	N: Number of HIV-positive adults receiving HIV care within the past 12 months whose sexual partner's HIV status is documented in the patient record. D: Number of HIV-positive adults who received HIV care within the past 12 months and who have a sexual partner.	By specific population of interest.	N&D: Programme records, e.g. patient clinical records. Data can be collected during annual review at all facilities or at a sample of sentinel sites. (Interpret results appropriately).	Measures the programme's ability to identify and test the sexual partners of people receiving HIV care, who are at high risk for HIV infection, in order to: 1. prevent ongoing transmission in sero-discordant couples and 2. identify HIV-positive partners with the aim of enrolling them in HIV care services.

HTS.12 HTS quality improvement activities % of sites with quality improvement (QI) activities *Cross-referenced with Service availability, availability and linkage section and medical product and technologies section RES. 5 and RES. 25*	N: Number of HTS sites with quality improvement activities implemented in the last 6 months that address clinical HIV programme processes or outcomes and have documented results. D: Number of health facilities providing HTS in the last 12 months.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site, prison or other closed setting).	Facility records and observation, consolidated data from supervisory visits (sampled or exhaustive).	Critical component of capacity building for quality service provision.
HTS.13 HTS-related stock-outs % of HTS sites with stock-outs of HIV diagnostic tests or reagents *Cross-referenced with Medical products and technologies section RES.12*	N: Number of HTS sites that had a stock-out of HIV diagnostic tests or reagents during a reporting period. D: Number of reporting HTS sites.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site), type of HIV diagnostic test or reagent.	Routine programme management (PM) system.	Assesses the ability of the supply chain to prevent stock-outs; can serve as a surrogate indicator for the overall functionality of the procurement system The target is 0% HTS sites that experience stock-out – i.e. 100% of sites with no stock-out.

HTS.14 Laboratory capacity for HIV testing Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests *Cross-referenced with Service availability, availability and linkage section and medical product and technologies section RES. 5 and RES. 25*	Number of testing facilities (laboratories) with capacity (i.e. infrastructure, dedicated laboratory personnel and equipment) to perform: • HIV diagnosis with rapid test, EIA, Western blot or molecular methods; • HIV/AIDS care and treatment monitoring with CD4 count or HIV viral load testing • clinical laboratory tests in any of the following areas: haematology, clinical chemistry, serology, microbiology, TB diagnosis and identification, malaria diagnosis, OI diagnosis.	Testing facility (e.g. clinical laboratory, POC testing site), type of laboratory test performed, location.	Programme records.	Provides valuable information on trends in the availability of laboratory services. However, it does not measure the adequacy of coverage of laboratory services because of the different levels of capacity among laboratories. This indicator does not attempt to measure the quality, cost or effectiveness of services provided.
HTS.15 Laboratory performance % of laboratories with satisfactory performance in external quality assurance/ proficiency testing (EQA/PT) *Cross-referenced with Service availability and quality and Linkage sections RES.6*	N: Number of testing laboratories with satisfactory performance in EQA/PT. D: Number of testing laboratories participating in EQA/PT.	Type of laboratory, type of test.	Laboratory EQA programme records at national reference laboratory. Following standard procedures for EQA/PT, a national or sub-national reference laboratory sends pretested samples to laboratory facilities for testing and computes the rate of agreement between participating and reference laboratories.	Measures laboratory performance, as determined by the accuracy and reliability of laboratory diagnostics, to monitor whether laboratory quality has kept pace with the expansion of HIV testing services. The aim is to ensure the validity of test results across the biomedical infrastructure, detect low performance and address weaknesses through tighter supervision, verification and upgrading of equipment, timely supply of equipment and reagents.

2.4.4 Linkage, enrolment and retention in care

Conceptual framework

Linking people who test HIV-positive to prevention, treatment and care is a crucial step in the HIV cascade. Linking people who test HIV-negative to appropriate prevention services is important as well.[1] Linking serves as the bridge between testing and care. Without it, the full personal and public health benefits of knowing one's HIV status cannot be realized. HIV diagnosis without enrolment in care indicates a serious problem in patient and programme management. As much effort must be invested in linking/enrolling people who test HIV-positive into care as is put into scaling up HIV testing services.

The term "HIV care" refers broadly to all aspects of HIV-related health services provided to people with HIV, including assessment of eligibility and preparation for ART, provision of ART (see section 2.4.5), prevention, detection and treatment of coinfections/co-morbidities such as TB,[2,3] prevention of HIV transmission, nutrition care and support and social support.

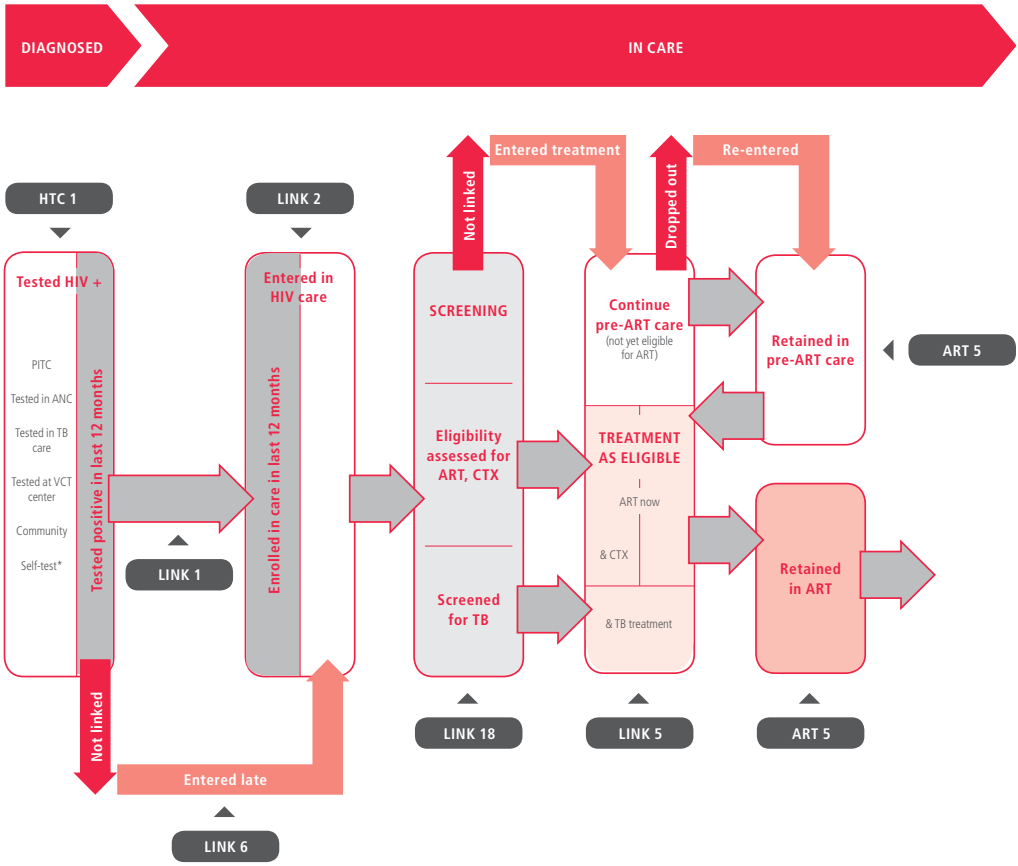
5. HIV care coverage

Number and % of people living with HIV who are receiving HIV care (including ART).

Due to the benefits of early initiation of treatment, eligibility for ART should be assessed as soon as possible after HIV diagnosis. Those who are not initially eligible for ART should still be enrolled in HIV care, including periodic reassessment of ART eligibility and prevention and early diagnosis of TB and other opportunistic infections (see Fig. 2.4). Many programmes face a challenge retaining in care those not initially eligible for ART. Leaving pre-ART care can delay initiation of ART, thus hastening AIDS-related deaths.

[1] Prevention services for those testing HIV-negative may include, for example, VMMC and PrEP, as appropriate.
[2] Guidelines on post-exposure prophylaxis for HIV and the use of co-trimoxazole prophylaxis for HIV-related infections among adults, adolescents and children. Recommendations for a public health approach – December 2014 supplement to the 2013 consolidated ARV guidelines. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_dec2014/en/). Updated guidelines for co-trimoxazole (CTX) provision specify when to initiate and when to discontinue CTX in adults, adolescents and children depending on the background prevalence of malaria and/or severe bacterial infections in the setting.
[3] WHO policy on collaborative TB/HIV activities. Guidelines for national programmes and other stakeholders. Geneva: World Health Organization; 2012 (http://whqlibdoc.who.int/publications/2012/9789241503006_eng.pdf).

Fig. 2.4 Linkage to care for adults testing HIV-positive



* HIV self-testing does not provide a definitive diagnosis. Instead, it is an initial test. A reactive self-test always requires further testing according to relevant national testing algorithms.

Definitions of linkage, enrolment and retention in HIV care

Linkage to HIV care is defined as the duration of time starting with HIV diagnosis and ending with enrolment in HIV care or treatment.[1]

Enrolment in HIV care begins when a person with HIV presents to the facility where HIV care is provided and a patient file or chart is opened. WHO recommends that all patients be enrolled in HIV care at their first facility visit following an HIV-positive diagnosis (which may take place on the same day as the HIV diagnosis).

Retention in HIV care describes when a patient who is enrolled in HIV care routinely attends these services, as appropriate to the need. This excludes people who have died or were lost to follow-up.

Lost to follow-up (LFU): Three months or more (90 days or more) since last missed appointment.

[1] Retention in HIV programmes: defining the challenges and identifying solutions: meeting report. 13–15 September 2011. Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/meetingreports/retention_programmes/en/).

M&E issues in linkage, enrolment and retention in HIV care

In national M&E systems, monitoring and evaluating HIV care has received less attention than M&E of ART. Many of the indicators in this section may appear new, but they are based on review of data elements that programmes often already collect.

Tracking patients from testing to HIV care

A lack of suitable M&E tools and unique identifiers to track HIV-positive individuals makes it difficult to measure whether individuals with HIV are linked to and enrolled in care. Enrolment in care may be particularly difficult to ascertain where diagnosis and HIV care take place in different settings and in facilities where people who test are not assigned a unique identifier. In settings where the patient is referred to a HIV care clinic outside the testing facility, it is useful to have a system to verify and document linkage to care. Civil society organizations, in particular networks of people living with HIV, can play an active advocacy and support role to help people enter and remain in HIV care.

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Standardizing registers for patients in HIV care but not on ART

In some settings there are no standard operating procedures (SOPs) for recording all patients enrolled in HIV care who are not yet eligible for ART. Specific instructions are needed to ensure that registers cover all patients receiving HIV care in all sites, including sites that may not primarily serve populations of people living with HIV (for example, ANC, MCH and TB clinics), and to avoid double-counting patients who move between different services. The SOPs need regular review to see that they remain up-to-date and aligned with national HIV care guidelines and practices.

Tracking retention in pre-ART care

Because of high attrition and mortality rates in pre-ART care, it is important to consider monitoring a new indicator of pre-ART retention in settings where this is an issue or where a

sizeable number of people living with HIV know their status but do not start ART (LINK.10). Calculating the number of people receiving and retained in pre-ART care may be time-consuming in facilities with high patient loads and paper-based record systems. The decision whether to monitor pre-ART retention will depend on an assessment of the potential benefit of the information versus the reporting burden.

Selection and use of indicators

Table 2.18 presents recommended indicators of linkage to and enrolment in HIV care. The key indicator is the overall coverage of HIV care services – that is, the number and proportion of people currently in HIV care among all people living with HIV or among people living with HIV who are aware of their HIV-positive status (LINK.1). While coverage and retention on ART are also measured separately (see section 2.4.5), this HIV care indicator includes both those on ART and those in pre-ART care, who are not yet eligible for ART. This indicator is designated for global reporting.

Good performance on the HIV care coverage indicator (LINK.2) requires effective programme performance in a number of areas – diagnosis of HIV, timely and effective linkages between diagnosis and entry into HIV care and, once enrolled, retention in care. Weakness in any of these areas will lower the value of this indicator. Other measures address an array of interventions that are part of HIV care, including co-trimoxazole prophylaxis, partner testing, meeting family planning needs and TB screening. (Monitoring of coinfections and co-morbidities, such as HIV/TB, is covered in sections 2.4.4A and 2.4.4B.)

Several indicators measure delayed initiation of HIV care among people living with HIV who are eligible for ART, which is associated with increased mortality. The proportion of adults newly enrolling in HIV care with advanced disease and low CD4 count (LINK.8) reflects a combination of factors, including the timing of initial diagnosis (see HTS indicators) and the time between diagnosis and enrolment in HIV care services (see LINK.1 and LINK.2). Indicator LINK.11 identifies delays in ART initiation among children under five years, all of whom are eligible for ART. Once enrolled in HIV care, monitoring the time between determination of eligibility for ART and initiation of treatment (LINK.8) provides information on programmatic efficiency in providing treatment.

Special considerations by setting and population

Paediatric patients

Tracking service coverage of infants, children and adolescents as they age and move between different facilities can identify gaps in serving these important populations. Data collection systems should disaggregate data by age group, account for multiple possible entry points into care and avoid double-counting individuals who move through the system. (See the Paediatrics section, 2.4.5B, for more information on age disaggregation and needs of infants, children and adolescents.)

Pregnant and breastfeeding women

WHO recommends that all HIV-positive pregnant and breastfeeding women start ART, regardless of CD4 count. Thus, pregnant women initiating ART as part of PMTCT services should be counted in general indicators for linkage and retention in HIV care. (See section 2.4.7 for detail on monitoring PMTCT.)

Key populations

Monitoring linkage to, enrolment in and retention in pre-ART care among key populations is particularly important due to their generally higher burden of disease and greater difficulty accessing care and treatment services than the general population faces. Key populations present specific challenges for tracking linkages from diagnosis to care and retention in care.

People may not wish to identify themselves as members of a key population at the time of testing or enrolment in care, particularly where key population behaviours are criminalized or subject to high levels of stigma and discrimination. In these situations data on linkage, enrolment and retention in HIV care may have to be obtained through surveys of key populations. It is vitally important to ensure the confidentiality of all information concerning people from key populations.

Calculating coverage of key populations requires, as denominators, estimates of the sizes of key populations (see section 2.2, Know your epidemic, and section 2.4.1, Services for key populations).

Table 2.18 Programme indicators of linkage to and enrolment in care

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
LINK.1 Linkage to care Number and % of newly diagnosed HIV-positive people newly enrolled in and receiving care LINK.1a (preferred): Number and % of newly diagnosed people linked to HIV care (individual-level linkage) LINK.1b (if LINK.1a not feasible): Number of HIV-positive people newly enrolled in and received care and ratio relative to number of people who test positive for HIV (cross-sectional proxy for linkage)	N: Number of people who were newly enrolled in HIV care and received clinical HIV care services in the past 12 months (as proxied by receipt of at least one of the following during the reporting period: clinical assessment (WHO staging) OR CD4 count OR viral load count OR currently receiving ART.) D: Number of people newly diagnosed with HIV within the past 12 months. Includes pregnant women and TB patients diagnosed HIV-positive.	Age (<1, 1–4, 5–14, 15–19, 20–49, 50+ years), pre-ART/ART, sex, key population, pregnant women, breastfeeding women.	N: Programme records for HIV care, e.g. including pre-ART registers, ART registers, other facility registers (e.g. HIV testing, ANC, TB); case-based surveillance data. D: Programme records, e.g. HIV testing registers, laboratory records, case reporting. Track individuals' linkage to care through recording in a testing register or through case reporting or electronic M&E systems that link data on patient diagnosis with data on HIV care (facilitated by the use of unique IDs). If that is not possible, try to review the cross-sectional proxy for linkage: Compare number newly in HIV care (including ART) with number diagnosed HIV-positive within the reporting period (12 months). Includes pregnant women and TB patients diagnosed HIV-positive.	Indicates programme performance in linking people diagnosed HIV-positive to care. Where possible, individual-level linkage to care should be measured to accurately determine the percentage of newly diagnosed people who were linked to care. Where it is currently not possible to measure individual level linkage, a cross-sectional numerator and denominator can be compared to get a broad sense of linkage from testing to HIV care. (Different individuals are counted in the numerator and denominator and, therefore, this figure is a ratio, not a true proportion.)

* If it can be assumed that those on ART have been assessed clinically.

LINK.2 HIV care coverage Number and % of people living with HIV who are receiving HIV care (including ART) 	N: Number of people living with HIV who received HIV care in the past 12 months (as proxied by receipt of at least one of the following during the past 12 months: clinical assessment (WHO staging) OR CD4 count OR viral load OR currently receiving ART. D: Number of people living with HIV.	Sex, key population,* pregnancy status, pre-ART/ART), received care for the first time in the reporting year, age (<5, 5–14, 15+; additional age categories in settings where more detailed age information is needed and feasible to collect (e.g. electronic system): <1, 1–9, 10–14, 15–19, 20–49, 50+).	N: Programme records, e.g. pre-ART and ART registers, visit records. Denominator (estimated population living with HIV): internationally consistent modelling estimates, e.g. Spectrum AIM.	Measures the proportion of people living with HIV who are receiving HIV care (both ART and pre-ART services). Time trends can be monitored to assess progress in increasing % of people in care. Reviewing the number of people who are receiving HIV care out of the number of PLHIV diagnosed can be useful as well.
LINK.3 Enrolment in care Number of people newly enrolled in HIV care	N: Number of people who were newly enrolled in HIV care. Include pregnant women and TB patients. D: None.	Age (<1, 1–4, 5–14, 15–19, 20–49, 50+ years), pre-ART/ART, sex, key population,* pregnant women, breastfeeding women, TB patients.	Programme records, e.g. HIV care register, pre-ART register. Avoid double-counting people initiating ART who may have been captured in another HIV care register.	Indicator captures the number of people newly enrolled in HIV treatment or initiating ART during the reporting period.
LINK.4 Unmet need for family planning % of HIV-positive women attending HIV care and treatment services who have unmet need for family planning *Cross-referenced with PMTCT section MTCT.10*	N: Number of HIV-positive women of reproductive age (15–49 years) attending HIV care and treatment services who have an unmet need for family planning. D: Number of HIV-positive women of reproductive age (15–49 years) attending HIV care and treatment services.	Age (15–19, 20–49).	Exit interviews using a series of standard questions related to unmet FP need as defined in surveys such as DHS.	Suggests whether HIV-positive women's need for family planning services to prevent unintended pregnancy is being met (Prong 2).

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK.5 TB screening coverage in HIV care Proportion of people in HIV care (including PMTCT) who were screened for TB in HIV care and treatment settings *Cross-referenced with TB/HIV section LINK.18*	N: Number of HIV-positive people enrolled in HIV care (pre-ART or ART) in the past 12 months whose TB status was assessed and recorded at their last visit during the reporting period. D: Number of HIV-positive people enrolled in HIV care (pre-ART or ART) within the past 12 months.	Recommended disaggregations depend on type of monitoring system: Electronic system: Sex, age (0–4, 5–14, 15+), pregnancy status, key population* Paper-based system: None.	N&D: Programme records, e.g. HIV care register, pre-ART register, ART register, PMTCT register.	Gauges implementation of the recommendation that people living with HIV be screened for TB at diagnosis and at every follow-up visit. Indicators to monitor the entire cascade of intensive TB case finding can be found in the WHO TB/HIV M&E guide.[1]
Additional indicators				
LINK.6 Partner testing % of adults receiving HIV care whose partner's status is known[2] *Cross-referenced with HTS section HTS.11*	N: Number of adults receiving HIV care within the past 12 months whose sexual partner's HIV status is documented in the patient record. D: Number of adults receiving HIV care within the past 12 months who have a sexual partner.	By specific population of interest.	N&D: Programme records, e.g. patient clinical records. Data can be collected during annual review at all facilities or at a sample of sentinel sites. (Interpret results appropriately.)	Measures the programme's ability to identify and test the sexual partners of people living with HIV, who are at high risk for HIV infection, in order to a) prevent ongoing transmission among sero-discordant couples and b) identify HIV-positive partners to enrol them in HIV care.
LINK.7 CTX coverage % of eligible HIV-positive individuals who received co-trimoxazole (CTX) *Cross-referenced with TB/HIV section LINK.22*	N: Number of eligible HIV-positive individuals who received CTX D: Number of HIV-positive individuals enrolled in HIV care who are eligible for CTX.	Age (<2 months, <15, 15+), new and relapsed TB patients.	N&D: Programme records, pre-ART and ART registers, laboratory records. Data can be collected during annual review at all facilities or at a sample of sentinel sites. (Interpret results appropriately.)	Measures the uptake of CTX prophylaxis, an essential component of quality care, among eligible individuals in HIV care.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.
[1] A guide to monitoring and evaluation for collaborative TB/HIV activities, 2014 revision. Geneva: World Health Organization; 2015 (http://www.who.int/tb/publications/m_and_e_document_page/en/)
[2] Countries can use a similar indicator for index case testing.

LINK.8 Late HIV care initiation % of people enrolling in HIV care with CD4 ≤350 cells/mm^3 and symptomatic disease	N: Number of people living with HIV initially enrolled in HIV care within the past 12 months who had a baseline CD4 count of ≤350 cells/mm^3 and symptomatic disease (Stage 3 or 4) at enrolment in care D: Number of people living with HIV who were initially enrolled in HIV care within the past 12 months and who have a baseline CD4 count.	Sex, key population* where available, other target populations, age (<15, 15–19, 20–49, 50+ years; additional age categories in settings where more detailed age information is needed and feasible to collect (e.g. electronic system): <1, 1–9, 10–14, 15–19, 20–49, 50+).	N&D: Programme records, e.g. pre-ART and ART registers, laboratory records.	Measures the effectiveness of programme efforts for early identification and enrolment in care of HIV-positive adults. Where CD4 counts are not performed at the same time (and in the same venue) as the HIV test, the CD4 count nearest to the time of diagnosis is considered the count "at enrolment in care".
LINK.9 Pre-ART retention at 12 months % of HIV-positive people in pre-ART care and not yet eligible for ART who are still engaged in care at 12 months after enrolment	N: Number of HIV-positive people enrolled in HIV care and not ART-eligible 12 months before the start of the reporting year who were still alive and receiving HIV care (pre-ART or ART) 12 months after enrolment D: Number of HIV-positive people enrolled in HIV care and not ART-eligible 12 months before the start of the reporting year.	None.	N&D: Programme records, e.g. pre-ART and ART registers. Requires cohort review and reporting.	Measures medium-term retention in care of patients not initially eligible for ART.
LINK.10 Eligible but not started on ART Number and % of people living with HIV who are eligible for ART but have not started ART	N: Number of HIV-positive people who were assessed as eligible for ART within the past 12 months but are not on ART by the end of the reporting year. D: Number of HIV-positive people and children who were assessed as eligible for ART within the past 12 months.	Sex, age (<5, 5–14, 15–19, 20–49, 50+), co-morbidities (e.g. TB, hepatitis).	N&D: Programme records, e.g. pre-ART and ART registers.	Can provide insight into the size of the ART waitlist in settings where patients visit facilities but cannot start ART. A programme's ability to calculate this indicator also demonstrates that a system is in place to track people who are eligible for but not yet on ART.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK.11 Timely linkage from diagnosis to treatment among children under 5 years of age % of children under age 5 who initiated ART within 1 month after diagnosis	N: Number of children under age 5 years living with HIV who initiated ART within 1 month after diagnosis within the reporting period D: Number of children under age 5 years living with HIV who initiated ART within the reporting period.	None.	N&D: Programme records, e.g. ART registers, HIV testing registers Ideally collected routinely on all children, especially in settings with electronic systems for patient data. May be conducted in a sample of sentinel sites in settings with paper-based systems.	Measures efficiency of programme linkages between diagnosis and treatment among HIV-positive children, all of whom are eligible for immediate ART regardless of CD4 count; quality of care indicator.

2.4.4a HIV-associated tuberculosis

Conceptual framework

Tuberculosis remains the leading cause of death among people living with HIV, even in the era of scale-up of ART. Of the estimated 35 million people living with HIV, in 2013, 3% developed TB, and one-quarter of all HIV-related deaths were attributed to TB. In 2013 people living with HIV accounted for 1.1 million (13%) of the estimated 9 million people globally who developed tuberculosis, and 25% of all TB deaths were HIV-related.

It is important that national TB programmes and national AIDS control programmes work together to ensure that joint services are available.

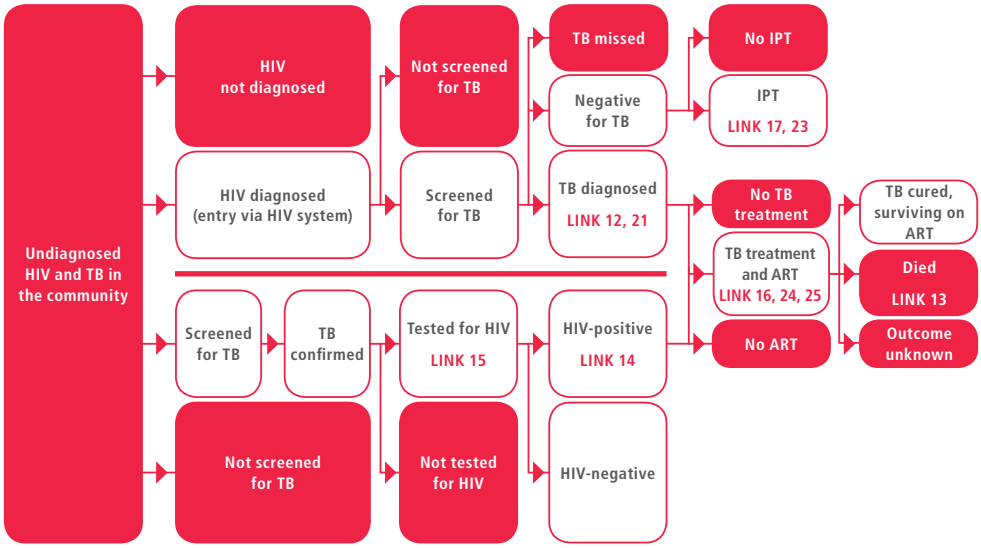
ART should be started as soon as possible, regardless of CD4 count, for all people with concomitant HIV infection and active TB disease. An early start to ART is crucial to reducing mortality. Therefore, it is important that national TB programmes and national AIDS control programmes work together to ensure that joint services are available. WHO published its policy on collaborative TB/HIV activities in 2012.[1] The key components of the WHO policy on collaborative TB/HIV activities serve as a basis for the recommended monitoring and evaluation activities.

The cascade of services for TB/HIV coinfection depends on whether a person enters through the HIV diagnosis and care system or through the TB system (Fig. 2.5). A person diagnosed with HIV should be tested for TB; a person diagnosed with TB should be tested for HIV. Understanding the cascade of services helps to identify opportunities to improve service provision and reduce losses to follow-up.

TB can be prevented by avoiding exposure to a person with infectious TB (through better overall TB control, including prompt detection and initiation of TB treatment and by implementing standard TB infection control measures to reduce transmission[2]), by providing treatment with isoniazid preventive therapy (IPT) for latent TB infection (LTBI) to people living with HIV to prevent its progression to active TB disease and by scale-up of ART, which also has significant effect preventing TB in persons living with HIV.

[1] WHO policy on collaborative TB/HIV activities. Geneva: World Health Organization; 2012 (http://www.who.int/tb/publications/2012/tb_hiv_policy_9789241503006/en/).
[2] WHO policy on TB infection control in health-care facilities, congregate settings and households. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf).

Fig. 2.5 Cascade of care for TB/HIV coinfection



Recent developments in TB/HIV

The last decade has seen progress in the scale-up of collaborative TB/HIV activities, with high coverage of HIV testing among TB patients, TB screening among people living with HIV, and ART among HIV-positive registered TB patients. Also, new research findings highlight the effectiveness of the combination of early ART and ionized preventive therapy (IPT) in preventing HIV-associated TB as well as the impact of ART in reducing HIV-associated TB. mortality when started within eight weeks of TB treatment initiation.[1] In addition, in 2013 WHO recommended use of Xpert MTB/RIF[2] as the initial TB diagnostic test among people suspected of having HIV-associated TB; This test simultaneously detects the presence of both drug-sensitive and rifampicin-resistant *Mycobacterium tuberculosis* from the sputum specimen in less than two hours. This test is more sensitive and specific than the conventional sputum microscopy. Also, the 2011 Political Declaration on HIV/AIDS,[3] unanimously endorsed by United Nations Member States, provided crucial impetus to implementation of collaborative TB/HIV activities. Greater attention is now being paid to tracking HIV-associated TB deaths, and efforts have been made to include better estimates of TB burden and mortality in the Spectrum AIM model, which many countries use. Finally, in recent years TB among children and women has received more attention, including how best to screen and diagnose TB in maternal, neonatal and child health settings.[4]

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[1] Blanc FX, Sok T, Laureillard D, Borand L, Rekacewicz C, Nerrienet E, Madec Y et al. Earlier versus later start of antiretroviral therapy in HIV-infected adults with tuberculosis. N Engl J Med, 2011, 365(16):1471–1481 (http://www.nejm.org/doi/full/10.1056/nejmoa1013911). Havlir D, Kendall MA, Ive P, Kumwenda J, Swindells S, Qasba SS et al. Timing of antiretroviral therapy for HIV-1 infection and tuberculosis. N Engl J Med, 2011, 20;365(16):1482–91 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3327101/). Abdool Karim SN, Naidoo K, Grobler A, Padayatchi N, Baxter C, Gray AL et al. Integration of antiretroviral therapy with tuberculosis treatment. N Engl J Med, 2011, 20;365(16):1492–501 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3233684/).

[2] Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children: policy update. Geneva: World Health Organization; 2013 (http://www.who.int/tb/laboratory/xpert_launchupdate/en/).

[3] Political declaration on HIV/AIDS: intensifying our efforts to eliminate HIV/AIDS, A/RES/65/277, 10 June 2011. (https://www.unodc.org/documents/southeastasiaandpacific/2012/02/hlm-hiv/20110610_UN_A-RES-65-277_en.pdf).

[4] Guidance for national tuberculosis programmes on the management of tuberculosis in children. Second edition. Geneva: World Health Organization; 2014 (http://www.who.int/tb/publications/childtb_guidelines/en/).

WHO has recently published the 2015 revision of its guide to monitoring and evaluation of collaborative TB/HIV activities,[1] which emphasizes measuring patient outcomes and programme quality and impact. The revised guide reduces the total number of indicators for global-level monitoring from 13 to seven and adds new indicators to monitor the cascade of intensified TB case finding, access to rapid TB diagnostic tests and early ART and compliance with treatment for latent TB infection.

M&E issues for TB/HIV

The data required to track collaborative TB/HIV activities are collected by both national TB programmes and national HIV programmes, using different databases. As a result, the numbers reported by the two programmes often do not agree. It has been difficult to harmonize results and arrive at a single set of national data on key indicators (such as how to calculate the proportion of HIV-infected TB patients who receive ART) (LINK.16). Adding to the confusion, the two programmes use different indicator definitions and time frames; generally, TB data are reported quarterly and are not cumulative, while HIV data may be annual and cumulative.

Reporting on TB/HIV indicators is often inconsistent and incomplete. A few indicators are not reported by all countries, such as IPT coverage, and it is not known whether, in countries not reporting, activities are not undertaken or the activity is implemented but not reported. In addition, some countries report numerators but fail to report the respective denominators, making coverage impossible to measure. This may be due to lack of basic data elements such as "number of people living with HIV newly enrolled in HIV care during the reporting period". Other activities such as TB infection control, although important, have been difficult to measure. The 2015 revision of the TB/HIV monitoring and evaluation guide offers more clarity for these measurements.

Selection of indicators

It is important to monitor the entire cascade of care from screening and testing through treatment for people coinfected with HIV and TB (Fig. 2.5). Countries should track key TB/HIV interventions such as coverage of HIV testing among TB patients (LINK.15) and TB screening among persons living with HIV (LINK.18), linkage of HIV-positive TB patients to both TB treatment and ART (LINK. 16) and treatment of latent TB infection among HIV-positive persons who do not have active TB (LINK.17). TB infection control measures at health-care facilities should also be monitored periodically, particularly use of a rapid molecular tests such as Xpert MTB/RIF (LINK.26). Further, it is important to monitor outcome and impact of TB/HIV interventions in terms of completion of the course of IPT (LINK.23), HIV-associated TB mortality (LINK.14) and development of TB among health-care workers (LINK.19). To assess the quality of services, countries should also monitor loss to follow-up along the cascade of care.

Special considerations by setting and population

WHO, UNODC and UNAIDS have developed general guidance for a number of special populations at elevated risk for HIV and TB or for whom special service delivery considerations are required. These include the *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations*[2] and the *Policy guidelines for the integrated management of TB, HIV and viral hepatitis in people who inject drugs* (revised guidance nearing completion). Guidance specifically on monitoring and evaluation of TB services appears in the *Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for*

[1] A guide to monitoring and evaluation for collaborative TB/HIV activities, 2014 revision. Geneva: World Health Organization; 2015 (http://www.who.int/tb/publications/m_and_e_document_page/en/).
[2] Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/guidelines/keypopulations/en/).

injecting drug users.[1] Other populations in whom TB/HIV merits special consideration include prisoners and miners (who are often at risk of drug-resistant TB) and health-care workers (who face an occupational risk of TB and drug-resistant TB).[2] Measurement of the risk of TB among health-care workers relative to the general population is a recommended core global and national indicator in the 2014 revision of the guide to monitoring and evaluation of collaborative TB/HIV activities. This measurement also can serve as a proxy for the impact of infection control activities in health facilities.

Table 2.19 Programme indicators for TB/HIV coinfection

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues/*cross-reference to TB/HIV guide*[3]	Programme relevance and interpretation
National indicators				
LINK.12 TB prevalence in HIV care % of people living with HIV and newly enrolled in HIV care who have active TB disease	N: Number of persons living with HIV and newly enrolled in HIV care during the reporting period who have active TB disease. D: Number of persons living with HIV newly enrolled in HIV care during the reporting period (pre-ART plus ART).	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. pre-ART and ART registers, TB register at the TB basic management unit. *Core global and national indicator A3*	Measures the burden of active TB disease among people living with HIV who are newly enrolled in HIV care. Early detection of TB among people living with HIV enables prompt TB treatment and early ART. This indicator also measures indirectly the extent of efforts to detect HIV-associated TB.

[1] WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users – 2012 revision. Geneva: World Health Organization, 2013 (http://www.who.int/hiv/pub/idu/targets_universal_access/en/).
[2] Joint WHO/ILO policy guidelines on improving health worker access to prevention, treatment and care services for HIV and TB. Geneva: World Health Organization; 2010 (http://www.who.int/occupational_health/publications/hiv_tb_guidelines/en/).
[3] Stop TB Department and Department of HIV/AIDS, World Health Organization, United States President's Emergency Plan for AIDS Relief, Joint United Nations Programme on HIV/AIDS. Guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2009 (http://HYPERLINK "http://www.who.int/hiv/pub/tb/hiv_tb_monitoring_guide.pdf" who.int/hiv/pub/tb/hiv_tb_monitoring_guide.pdf).
* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK.13 HIV prevalence among TB patients % of registered new and relapsed TB patients with documented HIV-positive status	N: Number of new and relapsed TB patients registered during the reporting period who are documented as HIV-positive D: Number of new and relapsed TB patients registered during the reporting period having a documented HIV status, positive or negative.	Sex, age (0–4, 5–14, 15+), key population,* new or relapsed TB case, place of residence, socioeconomic status.	N&D: Programme records, e.g. TB treatment card, TB register. *Core global and national indicator A2.*	Assesses the prevalence of HIV among registered TB patients. As HIV testing among TB patients approaches 100%, this indicator will provide a more accurate estimate of the true HIV prevalence among TB patients in the country. This indicator also defines a population group eligible for co-trimoxazole preventive therapy and ART. Measuring HIV prevalence among TB patients helps guide resource allocation and monitors effectiveness of HIV prevention interventions.
LINK.14 Mortality among HIV-positive TB patients % of HIV-positive new and relapsed TB patients who died	N: Number of HIV-positive new and relapsed TB patients who died before or during TB treatment D: Number of HIV-positive new and relapsed TB patients registered during the reporting period.	Sex, age (0–4, 5–14, 15+), key population,* new or relapsed TB case, place of residence, socioeconomic status.	N&D: Programme records, e.g. TB register. *Core global and national indicator A1.*	Trends may suggest changes in the impact of collaborative TB/HIV activities on mortality due to HIV-associated TB.
LINK.15 HIV testing among TB patients % of registered new and relapsed TB patients with documented HIV status *Cross-referenced with HTS section HTS.6*	N: Number of new and relapsed TB patients registered during the reporting period who had an HIV test result (whether positive or negative) recorded in the TB register D: Number of new and relapsed TB patients registered in the TB register during the reporting period.	Sex, age (0–4, 5–14, 15+), HIV status (positive, negative, unknown).	N&D: Programme records, e.g. TB treatment card, TB register. *Core global and national indicator A6.*	Measures the extent to which HIV status of notified TB patients is ascertained. Knowing their HIV-positive status allows those people to access the appropriate HIV services.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK.16 ART coverage during TB treatment % of HIV-positive new and relapsed TB patients on ART during TB treatment	N: Number of HIV-positive new and relapsed TB patients started on TB treatment during the reporting period who are already on ART or who start on ART during TB treatment D: Number of HIV-positive new and relapsed TB patients registered during the reporting period.	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. TB treatment card, TB register, pre-ART and ART registers. *Core global and national indicator A4.*	Measures the extent to which HIV-positive TB patients receive ART during TB treatment. Both treatments are necessary to minimize mortality. High coverage indicates strong collaboration between the national HIV and TB programmes.
LINK.17 IPT/LTBI coverage % of people newly enrolled in HIV care who are started on TB preventive therapy	N: Number of people living with HIV newly enrolled in HIV care who are started on treatment for latent TB infection (e.g. IPT) during the reporting period D: Number of persons living with HIV newly enrolled in HIV care, that is, registered in the pre-ART or ART register during the reporting period, excluding confirmed TB cases.	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. HIV care register/ ART card, HIV care register, ART register. *Core global and national indicator A5.*	Measures the extent to which people newly enrolled in HIV care are started on treatment for latent TB infection (LTBI). Treatment of LTBI reduces the burden of TB in people living with HIV.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK.18 TB screening coverage in HIV care % of people in HIV care (including PMTCT) who were screened for TB in HIV care and treatment settings *Cross-referenced with Linkage section LINK.5*	N: Number of HIV-positive adults and children enrolled in HIV care (pre-ART, ART, PMTCT) within the past 12 months whose TB status was assessed and recorded at their last visit during the reporting period D: Total number of HIV-positive adults and children enrolled in HIV care (pre-ART, ART, PMTCT) within the past 12 months.	Recommended disaggregation depends on type of monitoring system: Electronic system: Sex, age (0–4, 5–14, 15+), location, key population, * pregnancy status Paper-based system: None.	N&D: Programme records, e.g. HIV care register, pre-ART register, ART register, PMTCT register. *Core global and national indicator B1.*	Gauges implementation of the recommendation that people living with HIV be screened for TB symptoms at HIV diagnosis and at every follow-up visit Indicators to monitor the entire cascade of intensive case finding can be found in the WHO TB/HIV M&E guide, 2015.[1]
Additional indicators				
LINK.19 Relative risk of TB among health-care workers Risk of TB among health-care workers employed in facilities providing care for TB or HIV relative to risk in the general adult population	N: The TB notification rate among health-care workers, i.e. the total number of TB cases registered among health-care workers per unit number of health-care workers in the reporting unit during the reporting period D: The TB notification rate in the general adult population, i.e. the total number of TB cases registered per unit number of adult population in the reporting unit during the reporting period.	None	N& D: Occupational health records, programme records, e.g. TB register Adjusted for age and sex if appropriate. *Core global and national indicator A7.*	Indirectly measures the effectiveness of TB infection control activities in health facilities. If these measures are effectively implemented, exposure can be minimized, risk of acquiring TB reduced, and the relative risk of TB disease would be close to 1.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.
[1] A guide to monitoring and evaluation for collaborative TB/HIV activities, 2014 revision. Geneva: World Health Organization; 2015 (http://www.who.int/tb/publications/m_and_e_document_page/en/).

LINK.20 TB case-finding rate % of HIV-positive new and relapsed TB patients detected and notified out of the estimated number of incident HIV-positive TB cases	N: Number of HIV-positive new and relapsed TB patients registered during the reporting period D: Estimated number of incident TB cases among people living with HIV (with low and high uncertainty bounds).	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. pre-ART and ART registers, TB registers D: Recent country-specific annual estimates of number of incident TB cases among people living with HIV can be obtained from WHO at http://www.who.int/tb/country/en. *Core global and national indicator B10.*	Reflects overall case finding efforts, which would include PITC among TB patients; intensive TB case finding at all HIV care and treatment sites at every visit, effective delivery of services to key populations and linkages between the national HIV and TB programmes.
LINK.21 TB diagnostic test for people living with HIV % of people living with HIV having TB symptoms who receive a rapid molecular test (e.g. Xpert MTB/RIF) as a first test for diagnosis of TB	N: Number of people living with HIV and having TB symptoms who were investigated using a rapid molecular test (e.g. Xpert MTB/RIF) as a first test D: Number of people living with HIV and having TB symptoms identified through intensified case finding at HIV care and treatment facilities during the reporting period.	Sex, age (0–4, 5–14, 15+), location, key population, *	N: Programme records, e.g. laboratory register for smear microscopy and Xpert MTB/RIF D: Programme records, e.g. pre-ART and ART registers. *Core global and national indicator B6.*	Measures the use of rapid diagnostic molecular tests as the first test for early diagnosis of TB among people living with HIV.
LINK.22 CTX coverage % of HIV-positive new and relapsed TB patients who receive co-trimoxazole (CTX) preventive therapy *Cross-referenced with Linkage section LINK.7*	N: Number of HIV-positive new and relapsed TB patients registered during the reporting period who are started or continued on CTX during TB treatment D: Number of HIV-positive new and relapsed TB patients registered during the reporting period.	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. pre-ART and ART registers, TB register. *Core global and national indicator B11.*	Measures commitment and capacity of programmes to provide CTX preventive therapy, an essential component of quality of care, to HIV-positive TB patients.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK.23 IPT/ LTBI treatment completion % of people living with HIV who complete the course of TB preventive therapy	N: Number of persons living with HIV and in HIV care who completed the course of treatment (i.e. IPT alone or in combination with ART) for latent TB infection (LTBI) during the reporting period D: Number of persons living with HIV and in HIV care who were newly started on treatment for LTBI 12 to 15 months earlier.	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. pre-ART, ART registers or latent TB infection treatment register if available. *Core global and national indicator B13.*	Measures completion rate of treatment for LTBI among people in HIV care and indirectly measures effectiveness of adherence support mechanisms.
LINK.24 Early ART for HIV-positive TB patients % of HIV-positive new and relapsed TB patients who are started on ART within 8 weeks after TB diagnosis	N: Number of HIV-positive new and relapsed TB patients started on ART within 8 weeks after TB diagnosis D: Number of HIV-positive new and relapsed TB patients identified during the reporting period.	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. TB registers, TB treatment card, pre-ART register, ART register. *Core global and national indicator B8.*	Assesses the timeliness of ART initiation after TB diagnosis among people living with HIV.
LINK.25 Early ART for profoundly immunosuppressed HIV-positive TB patients % of HIV-positive new and relapsed TB patients with profound immunosuppression (CD4 cell count ≤50) who are started on ART within 2 weeks of TB diagnosis	N: Number of HIV-positive new and relapsed TB patients with CD4 counts ≤50 cells/mm^3 who are started on ART within 2 weeks of TB diagnosis D: Number of HIV-positive new and relapsed TB patients identified during the reporting period having CD4 counts ≤50 cells/mm^3.	Sex, age (0–4, 5–14, 15+), location, key population, *	N&D: Programme records, e.g. TB registers, TB treatment card, pre-ART register, ART registers. *Core global and national indicator B9.*	Measures timeliness of ART initiation for profoundly immunosuppressed HIV-positive TB patients.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

LINK 26 TB infection control % of health-care facilities providing services for people living with HIV (including PMTCT) that have TB infection control practices	N: Number of health-care facilities having "demonstrable" TB infection control practices that are consistent with international guidelines. (See WHO guide to M&E of collaborative TB/HIV activities, 2015 revision,[1] for criteria.) D: Number of health-care facilities evaluated for TB infection control practices within the reporting period.	Facility type.	N&D: Supervisory visit reports or annual infection control surveys. *Core global and national indicator B12.*	Measures implementation of TB infection control policies at HIV service sites. These should be implemented in all health facilities in countries having generalized HIV epidemics and at least in HIV and TB care facilities in countries with low-level or concentrated HIV epidemics.

2.4.4b Other co-morbidities

HIV co-morbidities, both infectious and noncommunicable diseases (NCDs), are being seen more often as the number of persons on ART increases and detection of these conditions improves. In low- and middle-income settings, TB, severe bacterial infections and other opportunistic infections (OIs) continue to be the major cause of HIV-associated morbidity and mortality, regardless of age.

Worldwide, an estimated 3.6 million people ages 50 years and older are living with HIV; this amounts to 10% of all adults living with HIV. Compared with HIV-uninfected peers, people living with HIV are at increased risk of NCDs, including cardiovascular diseases, diabetes and several cancers, as they live longer on ART and are exposed to the compounded risks of acquiring NCDs associated with ageing and chronic conditions inherent to HIV infection. Also, some mental health disorders tend to be more common among people living with HIV than in the general population. At the other end of the age range, even children and adolescents living with HIV are subject to co-morbidities; the long-term effects of HIV or ARV toxicity can lead to poor growth and stunting, delayed development and chronic lung disease.

In high-income countries, with increasing use of ART there has been a shift in the pattern of co-morbidities in adults: The contribution of chronic liver disease due to hepatitis B and C, cardiovascular disease and non-AIDS malignancies has increased. In low- and middle-income countries, as HIV-infected children and adolescents live longer thanks to ART, a similar profile of co-morbidities is expected. Earlier and more effective treatment for children may reduce the risks of stunting and chronic lung disease, but it may increase the risk of ARV-related toxicity. Better longitudinal data are needed.

HIV-related opportunistic infections

In both adults and children, TB, severe bacterial infections and other OIs account for most of the five- to nine-fold greater mortality in low income settings than in high-income areas,

[1] A guide to monitoring and evaluation for collaborative TB/HIV activities, 2014 revision. Geneva: World Health Organization; 2015 (http://www.who.int/tb/publications/m_and_e_document_page/en/).

largely due to late diagnosis of HIV and treatment initiation, treatment failure and/or poor adherence to ART. In general, the relative burden of the different OIs and the impact of ART on their incidence at the country level are not well documented. Except for TB, diagnoses of OIs are not currently included in national monitoring and reporting systems.

Cardiovascular disease and diabetes

Several factors are responsible for the increase in cardiovascular disease and diabetes among people living with HIV. These include the chronic inflammatory effects of HIV infection, the side-effects of some ARV drugs, life style factors (for example, smoking) and the ageing process. In coming years WHO will endeavour to better understand HIV–NCD co-morbidities among people living with HIV to inform both prevention and control of NCDs. Interventions are also needed to reduce the main modifiable risk factors for NCDs, such as tobacco smoking, unhealthy diet, physical inactivity and excessive use of salt and alcohol. WHO in collaboration with partners will review how best to monitor and evaluate the impacts of interventions to mitigate the effects of NCDs in people living HIV.

Cancers

Certain cancers affect HIV-infected people disproportionately compared with non-infected individuals of the same age. Among these, three cancers – Kaposi sarcoma, non-Hodgkin lymphoma and cervical cancer – are known as "AIDS-defining malignancies". ART lowers the risk and increases survival for Kaposi sarcoma and non-Hodgkin lymphoma but does not reduce the incidence of cervical cancer among HIV-infected individuals.[1] The incidence of several other cancers, particularly Hodgkin lymphoma and anal cancer, has been increasing among HIV-infected individuals since the introduction of ART. The influence of ART on the risk of these other cancers is not well understood. The increase in certain cancers is likely also affected by the ageing of the population living with HIV; the incidence of most cancers increases with age in both HIV-infected and uninfected populations.

The prevention, early diagnosis, treatment and follow-up of cancer among people living with HIV should adhere to standards of clinical best practice. WHO has recently issued guidelines on skin and oral manifestations in people with HIV that highlight treatment recommendations.[2]

In many parts of the world, HIV programme monitoring systems do not capture data to assess the extent of HIV-related malignancies. Programmes can make use of other data sources (such as cancer registries or vital registration systems), which may help to gauge the burden of the AIDS-defining malignancies at the population level, especially in high-burden settings.

Mental health disorders and diseases of the central nervous system

HIV may cause encephalopathy, depression, mania, cognitive disorder and frank dementia, often in combination.[3] Infants and children with HIV are more likely to experience deficits in motor and cognitive development than uninfected children.[4] Further, mental disorders are often associated with the use of substances such as recreational drugs and alcohol, which independently increase behaviour that risks exposure to HIV. Certain ARV drugs, such as efavirenz, are associated with central nervous system side effects.

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[1] HIV infection and cancer risk. Fact sheet. National Cancer Institute; 2011(http://www.cancer.gov/cancertopics/factsheet/Risk/hiv-infection).
[2] Guidelines on the treatment of skin and oral HIV-associated conditions in children and adults. Geneva: World Health Organization; 2014 (http://www.who.int/maternal_child_adolescent/documents/skin-mucosal-and-hiv/en/).
[3] Ibid.
[4] Ruel TD, Boivin MJ, Boal HE, Bangirana P, Charlebois E, Havlir DV, Rosenthal P et al.. Neurocognitive and motor deficits in HIV-infected Ugandan children with high CD4 cell counts. Clin Infect Dis. 2012;54(7):1001–1009 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3297647/)

Mental health disorders and diseases of the central nervous system are rarely monitored in the context of the health system response to HIV.[1] The monitoring and evaluation of HIV-related mental health disorders would help to determine their epidemiological patterns, to assess needs and to respond appropriately. Data on HIV-related mental health conditions are few, however. Even when these conditions are occasionally recorded at the facility level for individual clinical follow-up, they are seldom included in routine monitoring and evaluation systems.

HBV and HCV coinfections

It is estimated that between 5% and 25% of the approximately 34 million HIV-infected persons worldwide also have chronic hepatitis B virus and/or hepatitis C virus.[2] The burden of coinfection with hepatitis B is greatest in low- and middle- income countries, particularly in South-east Asia and sub-Saharan Africa. Data on the prevalence of HIV–HCV coinfection in Africa are particularly scarce, and many of the studies on which estimates are based were limited by small sample sizes or non-representative study populations and relied on HCV-antibody assays with high false-positive rates.

There is currently no routine screening for HBsAg or HCV antibodies in ART programmes, nor is there guidance on routine screening strategies. The WHO HIV department is developing guidelines that will include recommendations on screening.

HIV coinfection increases the severity of HBV and HCV infection; concurrent HIV increases the risk of death due to cirrhosis, hepatocellular carcinoma and liver-related mortality and reduces response to treatment.[3] Although most of the data on HIV/hepatitis coinfection come from high-income settings, where liver disease has emerged as a leading cause of death in HIV–HBV coinfected persons, there is no evidence to suggest a difference in natural history or in HCV treatment response in other regions or settings.

[1] HIV/AIDS and mental health. Report by the Secretariat, Executive Board 124th session, EB124/6. Geneva: World Health Organization; 2008 (http://apps.who.int/gb/ebwha/pdf_files/EB124/B124_6-en.pdf).
[2] See, for example, Easterbrook P, Sands A, Harmanci H. Challenges and priorities in the management of HIV/HBV and HIV/HCV coinfection in resource-limited settings. Semin Liver Dis. 2012;32:147–157.
[3] Ibid.

Table 2.20 Programme indicators for other co-morbidities

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
LINK.27 Hepatitis B screening % of people in HIV care who were screened for hepatitis B	N: Number of people in HIV care who were screened for hepatitis B during the reporting period using HBsAg tests. D: Number of people in HIV care during the reporting period.	Sex, age.	Clinical and/or laboratory records.	Monitors the extent and trends of hepatitis B screening of HIV-infected patients, an intervention critical for assessing needs related to the management of hepatitis B. Presence of HBsAg for a minimum of 6 months indicates chronic hepatitis B, thus informing clinicians on the need for further clinical and laboratory evaluation and treatment. Knowing HIV/hepatitis B status makes possible prescribing ARVs effective against both HBV and HIV infections.
LINK.28 Hepatitis C screening % of people in HIV care who were screened for hepatitis C	N: Number of adults and children in HIV care who were screened for hepatitis C during the reporting period using HCV antibody tests. D: Number of adults and children in HIV care during the reporting period.	Sex, age.	Clinical and/or laboratory records.	Monitors the extent and trends of hepatitis C screening, an intervention critical for assessing needs related to the management of hepatitis C. Presence of HCV antibodies provides information on HIV/hepatitis C coinfection rates, thus informing clinicians on the need for further clinical and laboratory evaluation and treatment.

2.4.5 Provision of ART

2.4.5a ART among adults

Conceptual framework

More than ever, antiretroviral therapy (ART) is now a core component of the national health sector response to HIV. Thus, capturing progress in ART scale-up is critical to monitoring the overall HIV prevention and treatment cascade. The indicators in this section follow a person living with HIV from initiation and/or re-entry into treatment through to key outcomes, such as retention on ART, treatment discontinuation, loss to follow-up, and death (Fig. 2.6).

Global indicator

6. ART coverage

Number and % of people living with HIV who are receiving ART.

The key measures of ART provision assess whether:

- patients who are eligible for ART initiate treatment and do so in a timely manner (ART.1)
- the ART prescribed is appropriate and consistent with national treatment guidelines (ART.2 and ART.3)
- patients on ART adhere to regimens (ART.7) and are retained on treatment (ART.5), and
- treatment is successful in terms of patient outcomes (that is, virological suppression (ART.9) and survival (ART.11)).

Recent developments in ART

Responding to emerging evidence on the benefits of earlier initiation of ART for patients' clinical prognosis and for reducing HIV transmission, WHO revised its recommendations for ART treatment initiation in 2013.[1] Under the new recommendations eligibility for ART expanded to adults and older children with CD4 counts of ≤500 cells/mm^3.[2] (The previous recommendation was to reserve treatment for CD4 counts of ≤350 cells/mm^3). Other groups, including children under the age of five years, serodiscordant couples, pregnant women and TB patients, are eligible regardless of CD4 count. Using the new criteria, an estimated 85% of all people currently living with HIV are eligible for ART.[3] New recommendations also promote the use of fixed-dose combination ART regimens and routine monitoring of viral load as the primary indicator of treatment success.

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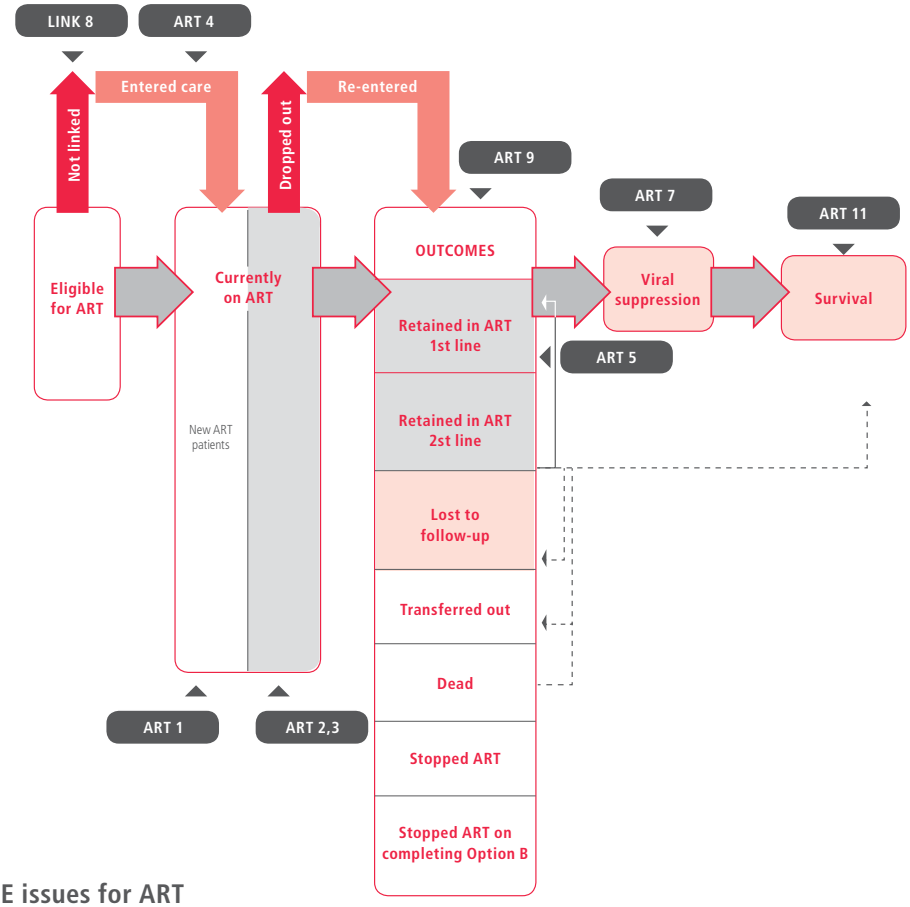
[1] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach. Geneva, World Health Organization; 2013 (http://www.who.int/hiv/pub/guidelines/arv2013/download/en/).
[2] The Consolidated Guidelines recommend, as a priority, to initiate ART in all individuals with severe/advanced disease (WHO clinical stage 3 or 4) or CD4 count ≤350 cells/mm^3.
[3] Global update on the health sector response to HIV, 2014. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/progressreports/update2014/en/). OR UNAIDS report on the global AIDS epidemic 2013. Geneva: UNAIDS; 2013 (http://www.unaids.org/en/resources/campaigns/globalreport2013/globalreport).

Fig. 2.6 ART cascade



M&E issues for ART

Denominators for ART coverage

At the global level the indicator to monitor ART coverage is the percentage of all people living with HIV who are receiving ART (ART.3). The point of this indicator is not to advocate a change in ART eligibility criteria to initiate ART for all people living with HIV. Rather, it makes possible comparisons of ART coverage among countries with different ART criteria. In addition, it facilitates tracking of trends in ART coverage in a country. While countries should also use also calculate coverage among those eligible for ART (ART.2), for global reporting the appropriate denominator is "all people living with HIV".

Analysis of longitudinal patient outcomes

Most data required for the key ART indicators come from aggregated patient records in either electronic or paper-based patient monitoring systems. Both cohort (longitudinal) and cross-sectional views of the data are important. Electronic data systems greatly facilitate cohort analysis by making it easier to track patients from one contact with the health-care system to the next. At the same time, however, as ART services decentralize to primary health-care settings, data systems must be designed to suit limited local resources and staff capacity; and paper-based record-keeping usually continues, even when an electronic system handles higher levels of data aggregation. Where the burden of analysing all patient records is too great, sampling of programme records and extraction of data from sentinel sites or sites with electronic systems can measure selected additional indicators or disaggregations.

Transferring patients and their treatment records between facilities presents a major challenge to effective clinical management of ART patients and to monitoring retention. Gaps in data can be reduced by using a single system of unique patient identifiers throughout a country and electronic patient monitoring systems that are compatible across facilities. Avoiding loss to tracking is particularly important as initiation of ART expands into more facilities, such as those providing MCH care and TB services, and as people who require lifelong ART transfer from these facilities to general HIV clinics. (See box on definitions for tracking.)

Measuring retention and other treatment outcomes

Retention of patients on ART is a critical measure of programme quality and an early warning indicator of HIV drug resistance (HIVDR) (see section 2.4.5D).

Retention and other treatment outcomes, such as viral suppression, death and loss to follow-up, are measured among cohorts of patients after specific durations on ART. Monitoring retention and other patient outcomes at 12 months is a standard WHO recommendation and used for global reporting (ART.5), but additional measures at 6, 24, 36, 48 and 60 months, etc. after initiation of ART are also recommended. Monitoring loss to follow-up often requires special studies to investigate and estimate how many patients were truly lost to follow-up and how many transferred to a different site or died.

7. ART retention

Number and % of people living with HIV retained on ART 12 months after initiation.

Countries that cannot currently report retention at all ART sites and for all patients can, in the interim, obtain nationally representative estimates of retention by sampling a subset of clinics and patients, using either early warning indicator (EWI) methods or methods outlined in the guidance for surveillance of acquired HIV drug resistance.[1,2,3,4]

Retention in treatment and adherence to the ART regimen are crucial not only for patient outcomes but also to slow the development of resistance to ARVs (know as HIV drug resistance, or HIVDR). For discussion of HIVDR indicators, see section 2.4.5D.

Definitions for tracking ART care

- **Newly on ART:** Patients who start ART include treatment-naive patients, with no prior use of ART; patients who have previously received only PEP or PrEP; and non-naive patients with or without records who received ART from sources outside the formal health-care system and have not been counted as new in a system that is being monitored nationally.
- **Currently on ART:** A facility counts as current patients those started on ART at the facility, plus patients who are transferred in, minus patients who are transferred out, dead or lost to follow-up or who stopped ART. These numbers are summed across facilities for a national total.

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[1] Surveillance of HIV drug resistance in adults initiating antiretroviral therapy (pre-treatment HIV drug resistance) Concept note. Geneva: World Health Organization; 2014. (See Annex 1.3.) (http://www.who.int/hiv/topics/drugresistance/protocols/en/).
[2] HIV drug resistence in adults receiving ART. Concept note. Geneva: World Health Organization; 2014. (See Annex 1.3.) (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).
[3] EWI meeting report, appendix 8: page 129, Table 2 (http://www.who.int/hiv/pub/ewi_meeting_appendix.pdf).
[4] Site-level estimates with confidence intervals can be obtained by sampling a sufficient number of patient records at each clinic as outlined in: Using early warning indicators to prevent HIV drug resistance. Report of the Early Advisory Indicator Panel meeting (11–12 August 2011). Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/meetingreports/ewi_meeting_report/en/).

- **HIV care and ART retention:** The retention rate is often used to describe a cohort of people living with HIV who are alive and receiving HIV care, including ART, at a specific time point after initiating HIV care or ART specifically. Retention in care can be monitored for all patients in HIV care and also separately for those in pre-ART care and those on ART. The number of people retained is those who started HIV care minus deaths, loss to follow-up and discontinuation of treatment as of the time of measurement. Retention in HIV care can operationally be defined based on attendance at clinic appointments or based on interventions. The Three Interlinked Patient Monitoring Systems (3ILPMS)[1] defines ART retention generally as the number of people who are still alive and on ART at 12 months (or other specified time intervals) after initiating treatment. When aggregated at the facility level, this figure does not include those who transferred out by 12 months, those who have died, those who are known to have stopped ART or those lost to follow-up.
- **Lost to follow-up (LFU):** Three months or more (90 days or more) since last missed appointment.
- **Stopped ART:** Patients stop their ARV regimen for various reasons and are coded accordingly.[2] There may be overlap between the "LFU" and "stopped ART" categories, since patients who stop treatment without notifying the clinic staff are classified as LFU.

[1] Three Interlinked Patient Monitoring Systems for HIV care/ART, MCH/PMTCT and TB/HIV: standardized minimum data set and illustrative tools. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/77753/1/9789241598156_eng.pdf?ua=1).
[2] In the 3IPLMS reasons for stopping ART that are coded include toxicity/side-effects, adverse drug reaction, pregnancy, treatment failure, poor adherence, illness, hospitalization, drugs out of stock, the patient lacks finances, other patient decision, planned interruption of prescription medications, and end of MTCT risk period in countries using Option B for PMTCT.

Measuring ART adherence

Adherence is important for successful treatment outcomes and for minimizing HIVDR. Although monitoring drug pick-up is the recommended *proxy* indicator for monitoring adherence (ART.7), the most reliable method for measuring adherence is to monitor rates of viral load suppression (ART.9) (see section 2.4.6). When viral load testing is not routinely available, viral load suppression can be assessed in a representative sample of patients on ART, using an HIVDR survey.[1,2]

Several alternative assessment methods are commonly used to measure adherence, each with its own strengths and weaknesses. Patients' adherence to drug pick-up schedules (ART.7) is a recognized and standardized proxy for adherence to treatment. This measure relies on drug possession over a short time period and does not report whether the patient has taken the drugs as prescribed. Nonetheless, pick-up of drugs has been shown to be associated with viral suppression.[3]

[1] Using early warning indicators to prevent HIV drug resistance. Report of the Early Advisory Indicator Panel meeting (11–12 August 2011). Geneva: WHO; 2012. (http://www.who.int/hiv/pub/meetingreports/ewi_meeting_report/en/).
[2] HIV drug resistence in adults receiving ART. Concept note. Geneva: World Health Organization; 2014. (See Annex 1.3.) (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).
[3] EWI meeting report, appendix 8: page 129, Table 2 (http://www.who.int/hiv/pub/ewi_meeting_appendix.pdf).

Patients' self-reported adherence and pill counts are usually assessed in all patient encounters and routinely documented through patient monitoring systems. Although they are easy to record, they generally overestimate adherence. Conducting pill counts during unscheduled home visits is a more reliable method, but it is labour-intensive and not practical for routine monitoring.

Selection and use of indicators

Within the ART stage of the HIV prevention, care and treatment cascade, overall ART coverage (ART.3) provides a summary measure of progress in scaling up treatment. As a global indicator, it makes comparisons across countries possible. At the national level, if coverage is low, countries should assess whether this is due to lack of resources and/or inefficient use of available resources. A complementary indicator, the number of patients who start ART (ART.1), provides information on the programme's ability to identify people living with HIV who are eligible for but have not started ART and to link them to treatment.

The indicators in this section measure determinants of ART coverage and quality that contribute to the long-term survival of people living with HIV and to reducing transmission of HIV. High quality ART patient management – that is, early treatment initiation, adherence to treatment regimens and retention in care – directly increases the likelihood of viral suppression and avoidance of drug resistance.

Programmes with high numbers of patients with low CD4 counts at ART initiation need to investigate the reasons for delayed treatment. If people living with HIV are being diagnosed late in disease progression, a programme may need to reconsider its strategy for testing and post-test counselling. If lack of retention in pre-ART care or if referrals to facilities with ART are not followed, contributing to late ART initiation, programmes may need to improve patient tracking systems to keep people in care.

Programmes with low ART adherence rates (as measured by lack of viral suppression and/or low drug pick-up rates) should identify barriers to adherence, such as ART stock-outs, inappropriate drug regimens (side-effects and/or drug resistance) or barriers to clinic access and to taking the drugs as prescribed.

Poor ART retention rates should spur managers to further investigate the outcomes of ART patients (ART.6) – how many died, were lost to follow-up or experienced drug toxicity. Section 2.4.6 presents more information on use of the viral load suppression indicators. Disaggregation of ART monitoring indicators by key population and other specific priority populations and by age group may uncover specific barriers to access to services.

Special considerations by setting and population

Paediatric and adolescent patients

The care and treatment needs of children and adolescents vary by age group. For example, early initiation of ART is a priority among infants and children less than five years of age, all of whom are eligible for ART. At the other end of the paediatric age spectrum, adolescents often have high ART attrition rates and high mortality rates. Monitoring systems need to track children through the HIV cascade as they progress from infancy to childhood, obtaining treatment from different sites and eventually making the transition to adult services. Disaggregation of ART data by age group among children and adolescents can monitor the quality of services at each stage and inform programme planning and drug procurement forecasting. (See section 2.4.5B on paediatric HIV.)

Pregnant and breastfeeding women

ART coverage and retention among pregnant and breastfeeding HIV-positive women are national indicators in the PMTCT cascade (MTCT.2 and MTCT.3). Indicators of ARV coverage

among pregnant HIV-positive women include both HIV-positive women who are diagnosed and start treatment during pregnancy and those who initiated treatment before becoming pregnant. Among women who started ART during pregnancy, retention is measured at 12 months after the date of initiation. As with other ART patients, retention at earlier time points (for example, 3, 6, 9 months) can be considered as well, to explore during PMTCT roll-out whether retention is an issue. When these women transfer from MCH services to ART service sites, it is important to avoid double-counting them as newly enrolled clients (see section 2.4.7).

Key populations

As discussed in section 2.4.4, on linkages to HIV care, disaggregating ART coverage and retention indicators by key population is important to assess equity in receiving services. Special efforts, usually in the form of surveys, are needed to measure ART coverage and retention among key populations since patient records usually do not include information identifying specific risk groups. Calculating coverage also requires denominator estimates of the size of key populations (see section 2.4.1).

Tuberculosis and hepatitis B

The 2013 WHO treatment guidelines recommend that people living with HIV who are coinfected with active TB or who have hepatitis B with severe chronic liver disease should start ART regardless of CD4 count. Measuring uptake of ART by people living with HIV who have these conditions provides specific information on initiation, retention and outcomes (see section 2.4.4b) in this special group that maybe prone to more adverse outcomes if not treated.

Table 2.21 Programme indicators for antiretroviral therapy

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
ART.1 New ART patients Number of people living with HIV who initiate ART	N: Number of people living with HIV who initiated ART within the past 12 months D: n/a.	Sex, age (<1, 1–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+), key population* where available, reason for starting ART, pregnant or breastfeeding women, other specific priority population, sero-discordant partner, CD4 ≤500 cells/ mm^3, provider type (public/private).	Programme records, e.g. ART register.	Measures overall scale-up of ART programme. Disaggregation provides additional information to assess enrolment among specific priority populations and age groups (infants, children, adolescents, adults).

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

ART.2 ART coverage 1 % of eligible people living with HIV who are receiving ART	N: Number of people living with HIV who are currently receiving ART D1: Estimated number of people living with HIV who are eligible for ART according to national treatment guidelines D2 (programme denominator): Number of people living with HIV who have been diagnosed (numerator of HTS.1).	Sex, key populations,* regimen type (e.g. first line, second line), provider type (public/private) Age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual data extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age groups	N: Programme records, e.g. ART register, reporting forms D1: Internationally consistent modelling estimates, e.g. Spectrum AIM D2: Programme records, e.g. testing register.	Used to assess progress towards providing ART to all eligible people living with HIV Disaggregations can indicate degree of equity in enrolment among specific priority populations. Where there is no other way to forecast paediatric ARV needs, data can be disaggregated by <3, 3–10, and 10+ years, corresponding to age groups with differing preferred first-line ART regimens.
ART.3 ART coverage 2 Number and % of people living with HIV who are receiving ART Global indicator 90	N: Number of people living with HIV who are currently receiving ART D: Number of people living with HIV.	Sex, key populations,* regimen type (e.g. first line, second line) Age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age groups	N: Programme records, e.g. ART register and reporting forms D: Internationally consistent modelling estimates e.g. Spectrum AIM.	This coverage measure is independent of changing national treatment guidelines and therefore more useful for monitoring trends and for international comparisons of ART coverage than ART.2, where eligible people living with HIV is the denominator. Starting in 2014, this indicator has been included in UN global reporting.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

ART.4 Late ART initiation % of HIV-positive people who initiate ART with a CD4 count of ≤200 cell/mm^3 , and ≤350 cell/mm^3	N: Number of HIV-positive adults initiating ART within the past 12 months with a baseline CD4 count of ≤200 cell/mm^3, and ≤350 cell/mm^3. D: Number of HIV-positive adults initiating ART within the past 12 months who have a baseline CD4 count.	Sex, age (<1, 1–4, 5–9, 10–14, 15–19, 20–49, 50+), key population* where available, other priority populations Optional: Also calculate indicator using cut-offs of, ≤500 cells/mm^3 and >500 cells/mm^3 at ART initiation Optional: mean, median CD4 count.	N&D: Programme records, e.g. ARV register, laboratory records Monitoring mean and median CD4 counts may be more feasible with electronic patient record systems than with paper-based systems.	Measures late initiation of ART, a risk factor for treatment failure. A person with a CD count of ≤200 cells/mm^3 would be considered a late presenter with advanced disease. Disaggregation by priority population provides an indication of equity in enrolment.
ART.5 ART retention Number and % of people living with HIV and on ART who are retained on ART 12 months after initiation Also recommended at 24, 36, 48, 60 months, etc. *Cross-referenced with PMTCT section MTCT.3* Global indicator	N: Number of ART patients alive and on ART 12 months (or 24, 36, 48, 60 months, etc.) after initiating ART D: Number of patients initiating ART up to 12 months (or 24, 36, 48, 60 months, etc.) before the beginning of the reporting year. This includes those who have died since starting therapy, those who have stopped therapy and those lost to follow-up as of month 12 (or 24, 36, 48, 60, etc.).	Sex, pregnancy at initiation, breastfeeding at initiation where relevant, Age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5 year age groups Optional: coinfection with TB, coinfection with hepatitis B, people who inject drugs.	N&D: Programme records, e.g. ART registers and cohort reporting forms Ideally collected on all patients from all ART clinics. Where this is not possible, this indicator can tentatively be generated from a sample of patients from a subset of representative ART clinics.[1] Allowing a 3-month grace period before concluding a patient is lost to follow-up; the cohort assessed should be those who start ART between 27 and 15 months before the survey start date.	A high retention rate is an important measure of programme success and overall quality. As an early warning indicator (EWI) for HIVDR: good performance is >85%, passable performance is >75%, immediate remediation needed if ≤75%.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.
[1] Surveillance of HIV drug resistance in adults receiving ART (acquired HIV drug resistance). Concept note. Geneva: World Health Organization; 2014 (http://apps.who.int/iris/bitstream/10665/112801/1/9789241507073_eng.pdf?ua=1).

ART.6 Medium-term ART outcomes % of ART patients with specific outcomes at 12 months *Cross-referenced with PMTCT section MTCT.8*	N: Number of ART patients with specific outcomes 12 months after initiating ART: • on first-line ART • on second-line ART • dead • lost to follow-up • stopped ART • stopped ART on completion of Option B D: Number of patients initiating ART in the 12 months prior to the beginning of the reporting period.	Sex, pregnant or breastfeeding at ART initiation. Age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual data extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age groups Optional: coinfection (e.g. TB, hepatitis B), site level, sites with retention rates <75%.	N&D: Programme records, e.g. ART register, cohort reporting forms Ideally collected on all patients but may be collected on a sample Age disaggregation can be conducted routinely in settings with electronic systems for patient data or, in settings with paper-based systems, in a sample of sentinel sites.	Measures 12-month retention and provides information on the relative contributions of death, loss to follow-up and discontinuation of treatment among those not retained in treatment. However, programmes cannot always reliably distinguish among these three due to silent transfers and unreported deaths. Therefore, the distribution of outcomes and magnitude of loss to follow-up need to be interpreted with caution and explored further.
ART.7 ART adherence proxy % of ART patients who pick up all prescribed ARV drugs on time	N: Number of patients who pick up all prescribed ARV drugs no more than 2 days late at the first pick-up after a defined baseline pick-up D: Number of patients who picked up ARV drugs on or after the designated sample start date.	Sex, age (<10, 10–19, 20–49, 50+).	N&D: Sample of programme records, e.g. ARV register, pharmacy records.[1]	A method for evaluating population-level ART adherence through the proxy of on-time ARV pick-up. Although this method has limitations, it can be useful and feasible in limited-resource settings. EWI for HIVDR: good performance is >90%, passable performance is >80%.

[1] Assessment of World Health Organization HIV drug resistance early warning indicators, meeting report. Geneva: World Health Organization; 2011 (http://apps.who.int/iris/bitstream/10665/75186/1/9789241503945_eng.pdf?ua=1).

ART.8 Viral load testing coverage % of people on ART with viral load test results at 12 months after ART initiation *Cross-referenced with Viral suppression section VLS.2*	N: Number of people living with HIV and on ART with VL test result available at 12 months D: Number of people on ART for 12 months.	Sex, age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual data extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age groups	N&D: Programme records, e.g. ART register, cohort reporting forms, patient records; lab records; survey. Denominator excludes patients who have died, transferred to another clinic or been classified as lost to follow-up and those who have not received a viral load test by month 12 of ART. It is critical to de-duplicate records and avoid double-counting when identifying the appropriate numerator.	This indicator is critical to deciding whether the next indicator (ART.9) can be reported using routine data. If the coverage of routine data is less than a certain percentage representative of the eligible population, data should not be reported as a national figure. In some settings 70% or 80% is used as a cut-off. By the 15-month time point, all patients on ART should have received at least one VL test. This indicator assesses the extent to which VL is available in the country.

ART.9 Viral load suppression at 12 months after ART initiation % of people living with HIV and on ART who have virological suppression (<1000 copies/ml) at 12 months after initiating treatment *Cross-referenced with Viral suppression section and Drug resistance section VLS.1 and ART.15*	N: Number of people living with HIV who initiated ART 12 months (±3 months) before the start of the reporting period and who have a suppressed viral load (VL) (<1000 copies/mL) at 12 months after initiating ART D: Number of people living with HIV who initiated ART 12 months (±3 months) before the start of the reporting year.	Sex, age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age groups. Pregnancy at initiation, breastfeeding at initiation where relevant.	N&D: Programme records, e.g. ART register, cohort reporting forms, patient records, combined with estimates for the population with no VL data Programmes should capture this information routinely. Where not available from programme records, it can be estimated through acquired HIVDR surveillance survey, which can provide a nationally representative estimate of viral load suppression among patients on ART for 12 months (see section 2.4.5D).	Measures clinical outcomes of patients in care and overall quality of care as ART programmes expand. Also, viral load suppression is the best available measure of patient adherence to ART. Specific levels of VL suppression can be expected in a cohort of patients who have started ART and continued to different time points; data can be compared with an established benchmark.
ART.10 ARV stock-out % of facilities with stock-outs of antiretroviral drugs *Cross-referenced with Medical products and technologies section RES.12*	N: Number of ART sites that had a stock-out of any ARV drugs during a reporting period D: Total number of reporting ART sites.	Site level (community, primary, secondary, tertiary), location (e.g. region/ district), type of site (e.g. general clinic, MCH site, TB site), type of drugs.	N&D: Routine programme records, e.g. pharmacy logs The HIVDR EWI on ARV stock-out monitors the % of months in the reporting year without ARV drug stock-outs. This can be measured at the facility-level and aggregated for the national estimate.	Assesses performance of the supply chain system. At the facility level, measures ability of facilities to maintain supply of ARV drugs and avoid interruption of ART EWI indicator for HIVDR: Target is 0% (i.e. all sites have continuous stock of ARV drugs).

ART.11 ART survival % of people living with HIV who are alive at 12, 24, 36 months, etc. after ART initiation	N: Number of people living with HIV alive at 12, 24, 36 months, etc. after initiating ART D: Number of people living with HIV initiating ART up to 12, 24, 36 months, etc. prior to the beginning of the reporting year.	Sex, age (<5, 5–14, 15–19, 20–49, 50+) Additional age categories in settings where more detailed age-specific information is needed and feasible to obtain (e.g. electronic system): <1, 1–4, 5–9, 10–14.	N&D: Based on ART registers and data in cohort reporting form, with a special study to ascertain outcomes of those lost to follow-up and to reclassify their outcome status Denominator includes those who have died since starting therapy, have stopped therapy, or are recorded as lost to follow-up at month 12, 24, 36, etc.	Measures or estimates true survival among ART patients. Also provides insight into possible misclassification and magnitude of silent transfers and unreported deaths. Can support programme improvement by identifying ways to improve patient tracking and capturing data on outcomes.

2.4.5b Paediatric HIV care

Conceptual framework

Paediatric HIV care and treatment lag behind that of adults; compared with adults, a smaller proportion of children living with HIV is diagnosed and receives care.[1] Worldwide, the most common route of HIV acquisition by children is during pregnancy, delivery or breastfeeding – known as mother-to-child transmission (MTCT), or vertical transmission (see section 2.4.7 on prevention of MTCT). Reducing the number of children dying of HIV requires prevention of new mother-to-child infections through effective interventions and promptly identifying and treating infants and children who are infected with the virus. Without treatment, half of all children with HIV will die before the age of two.[2]

Older children and adolescents can also be infected through sexual transmission and injecting drug use. An overwhelming majority of infections among those under age 15 were acquired through mother-to-child transmission, while most new infections among those ages 15 and older are acquired through unprotected sex or by injecting drugs using contaminated equipment. Thus, people living with HIV under age 19 are a mixed group with different needs for prevention and treatment.

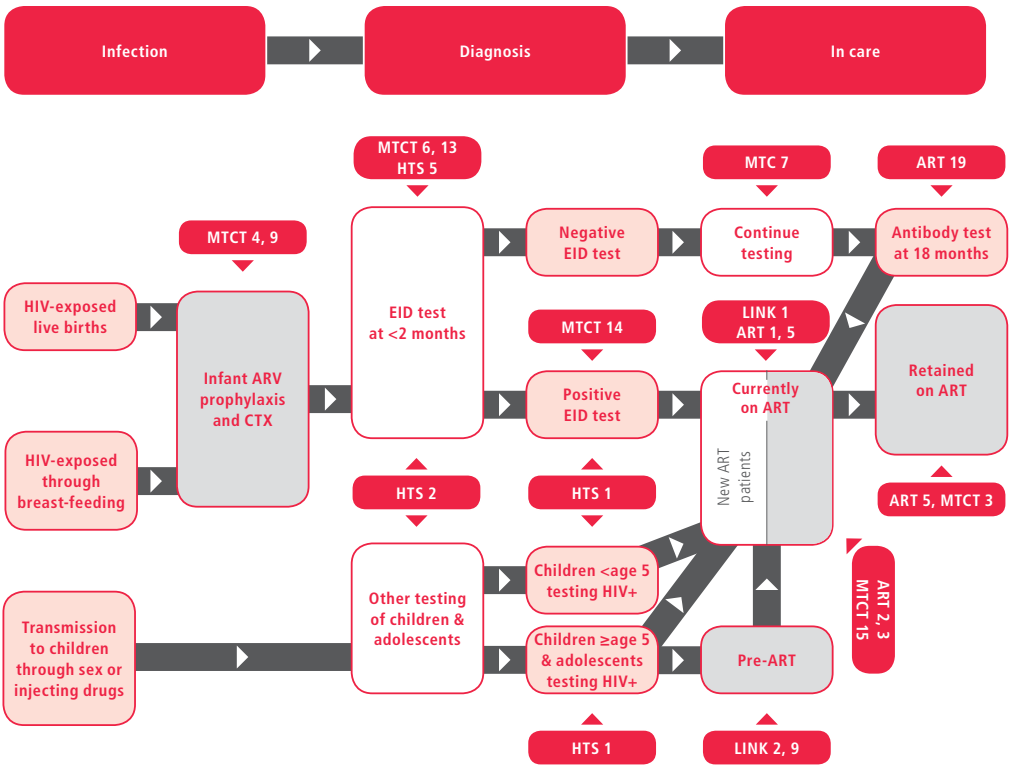
Children and adolescents can also be infected through blood transfusions and unsafe medical practices. In some settings this is an important cause of paediatric infection and should be monitored.

The cascade of care is the same for HIV-infected infants and children as for adults – diagnosis, linkage, enrolment, treatment and viral suppression (Fig. 2.7). Thus, most of the paediatric HIV indicators are identical to those for the adult population, with specific age disaggregation providing the information on children. However, the collection, organization, reporting and interpretation of strategic information for children living with HIV presents specific challenges.

[1] Global update on the health sector response to HIV, 2014. Geneva, WHO, 2014. (http://www.who.int/hiv/pub/progressreports/update2014/en/).
[2] Children and HIV: Fact sheet. Geneva, UNAIDS, 2014. (http://www.unaids.org/sites/default/files/media_asset/FactSheet_Children_en.pdf).

For example, HIV-exposed infants and young children may be lost to follow-up before determination of their HIV status, making it difficult to accurately count the number of HIV-positive children. Adolescents may not be able to provide consent to HIV diagnosis and care, and they are often excluded from surveys, making it difficult to understand and document the HIV epidemic and the response in this population. The consequent dearth of data on children has limited the capacity of programmes to tailor their services to young clients and to monitor how well they are meeting needs.

Fig. 2.7 Cascade of prevention, care and treatment for children



M&E issues in paediatric HIV care

Age disaggregation

Age disaggregation is essential to monitor and evaluate the paediatric HIV cascade. As a child living with HIV grows from birth to adolescence and adulthood, care and treatment needs and responses change. Information along the care and treatment cascade for various age groups can help identify gaps and monitor the scale-up of services in priority age groups.

Following the UN Convention on the Rights of the Child,[1] WHO and UNICEF define a "child" as a human being below the age of 18. At the same time, adolescence is defined as ages 10 through 19 years. In HIV epidemiology, however, it is common to count boys and girls ages 0–14 years as children, while ages 15 years and above are considered together with adults. Reasons for this include the need for consistency in trend data, the homogeneity of the population under age 15 in terms of timing and mode of acquisition of HIV (that is, almost entirely through MTCT) and the feasibility in most countries of disaggregating by standard 5-year age groups.

The standard proposed age categories for disaggregating HIV-related data from birth through adolescence are: <1, 1–4, 5–9, 10–14 and 15–19 years or combinations of these age groups (for example, <5, or 10–19 years for adolescents). Age disaggregation of data on the early years of life is particularly important for ART initiation because all HIV-diagnosed children under age five are eligible for treatment, and starting ART in the first months of life minimizes mortality. Throughout childhood and adolescence, finer age disaggregation can reveal gaps in ART coverage of specific age groups and provide essential information for planning age-appropriate approaches to service delivery.

The degree of age disaggregation (that is, number of age categories) should be decided by carefully weighing the programmatic need for the age-specific information with the feasibility of collecting and reporting the data. While age disaggregation is needed for most paediatric indicators, the degree of disaggregation required depends on the intent of the indicator. Some indicators need full age disaggregation, while others may require only partial disaggregation. The burden of reporting depends on the M&E systems in place; age disaggregation is labour-intensive in paper-based systems but can be much more easily accomplished in electronic data sets. Where age-disaggregated information is needed (for example, for ART coverage, retention, adherence and virological suppression) but too labour-intensive, countries may collect more detailed disaggregation from a selected sample of sites or only from areas with electronic systems.

Determining the size of the populations of children exposed to and living with HIV

Indicators such as early infant diagnosis (MTCT.6) and HIV care and ART coverage (LINK.2, ART.2) require the estimates of the number of children exposed to or living with HIV in the denominator. Spectrum AIM software produce these estimates based on data on HIV prevalence among women of reproductive age, fertility rates among HIV-positive women, coverage of ARVs throughout pregnancy and breastfeeding, maternal viral load, the number of children receiving ART (available from programme data), timing of infection (in utero, perinatally or during breastfeeding), number of deaths due to other causes and the number who transition out of this population as they become adults. There are also a large number of assumptions built into the model which means that the estimates have a broad range of uncertainty; this should be made clear and taken into account when using them to calculate indicators.

[1] The United Nations Convention on the Rights of the Child defines a child as "a human being below the age of 18 years unless, under the law applicable to the child, majority is attained earlier".

Data are seldom collected on the numbers of new infections among children and adolescents attributable to sexual transmission or injecting drug use, occurring particularly in their second decade. Surveys do not often interview people in these age groups since most have not reached the age of consent. Where this is an issue, the number of children acquiring HIV through these modes of transmission should be estimated to better understand and tailor prevention and treatment efforts.

Monitoring children and adolescents across multiple sources of care

Tracking children through the cascade of care and treatment is challenging. There are many service provision points where HIV-infected children are identified and enrolled to care – for example, referral hospitals, ANC clinics, ART sites, MCH settings, immunization clinics and well-child clinics. Children are often diagnosed in one facility and then referred to another facility to start care. Then, they may be transferred to yet another site to continue treatment, due to the perceived higher complexity of treating children, frequent shortages of paediatric ARV formulations and the relative scarcity of health workers trained in paediatric HIV care. The multiplicity of service points provides opportunities to enhance ART coverage. At the same time, however, it increases the risk of gaps in care due to insufficient linkages between services and loss to follow-up. As for patient tracking, unique identifier codes for users and computerized information systems can help improve data linkage over time and across services.

Selection and use of indicators

Monitoring the paediatric HIV care cascade, from diagnosis to enrolment and retention in HIV care and treatment, is based on age-disaggregated data on indicators describe in the HTS, linkage to care, ART, viral load suppression, HIVDR and PMTCT sections. (See Table 2.22; detailed indicator descriptions can be found in the relevant sections.)

The HIV care and ART coverage indicators (LINK.2 and ART.2) provide an overall measure of programme effectiveness in identifying, tracking and retaining children and adolescents in care services. If treatment and care coverage rates are low, programmes should assess HIV diagnosis strategies as well as uptake and retention in care. Trends in the number of children who are tested each year (HTS.5) help determine whether children have access to HIV testing and are being diagnosed. The trend in percentage of eligible children initiating ART (ART.2) can be monitored to assess progress in improving uptake and increasing the scale of treatment services.

Review of PMTCT indicators, such as early infant diagnosis (EID) (HTS.5, MTCT.6) and the final status of HIV-exposed infants (MTCT.8) may help identify gaps in identification of HIV-infected children and strategies for improving early diagnosis of children at risk. While all infants identified and confirmed HIV-positive are eligible to start ART immediately, HIV-exposed infants (but not confirmed HIV-positive) need to be followed over time until their final HIV status is determined. Infected infants and children may drop out of the cascade at various stages and, once lost to follow-up, experience higher mortality rates.

Indicators on the linkages between services provide valuable information on possible delays in accessing ART, including timely linkage from testing to ART for children under age 5 years (LINK.11) and the proportion of HIV-positive infants who initiate ART within the first year of life (LINK.1).

Several quality-of-care indicators monitor the effectiveness of programmes addressing children and adolescents. In the case of low ART retention (ART.5), programmes should track children who were lost to follow-up and investigate why they stopped treatment. Low rates of viral load suppression (ART.9/VLS.1) may indicate low levels of patient adherence (also measured by drug pick-up (ART.7) and/or development of HIV drug resistance).

Disaggregation of indicators by age group can provide further insight into reasons for low performance. Infants, children and adolescents access services at different treatment points and may experience very different barriers to HIV-testing, HIV care services and ART retention and adherence based on their age and developmental stage. For instance, retention in care and adherence to medication regimens among infants and young children depends largely on their parents, while adolescents are expected to play an active role in treatment decisions and compliance.

Table 2.22 Summary of programme indicators for paediatric HIV

Indicators	Paediatric programme description
National indicators	
HTS.1 % people living with HIV diagnosed	% of children and adolescents living with HIV who are diagnosed
HTS.2 HTS scale-up	Number of children and adolescents tested for HIV and received their results
HTS.5/MTCT.6 Early infant diagnosis coverage	% of HIV-exposed infants receiving a virological test for HIV within 2 months of birth
LINK.1/MTCT.15 ART initiation, Infant ART initiation	% identified HIV-positive infants who initiated ART by 12 months of age
LINK.2 HIV care coverage	Number and % of HIV-positive children receiving HIV care
LINK.9 Pre-ART retention at 12 months	% of HIV-positive children in pre-ART care and not yet eligible for ART who are still engaged in care at 12 months after enrolment
ART.1 New ART patients	Number of children who initiate ART
ART.2 ART coverage 1	% of eligible children receiving ART
ART.5 ART retention	% of children known to be alive and on ART 12, 24, 36 months, etc. after initiating ART
ART.6 Medium-term ART outcomes	% of children and adolescents with specific outcomes at 12 months after initiating ART
ART.11 ART survival	% of children who are alive at 12, 24, 36 months, etc. after ART initiation
MTCT.4 Coverage of infant ARV prophylaxis	% of HIV-exposed infants who initiated ARV prophylaxis
MTCT.7 Final MTCT transmission rate	% HIV-infected among HIV-exposed infants born in the past 12 months
MTCT.8 Final outcome status	% distribution of HIV-exposed infants by final outcome status
MTCT.9 Co-trimoxazole prophylaxis coverage	% of HIV-exposed infants started on CTX prophylaxis within 2 months of birth
Additional indicators	
LINK.5 Co-trimoxazole coverage	% of eligible children on CTX prophylaxis
LINK.11 Timely linkage from diagnosis to treatment	% of children under age 5 years who initiated ART within 3 months after diagnosis
ART.7 ART adherence proxy	% of children and adolescents on ART who pick up all prescribed ARV drugs on time

ART.8/VLS.2 Viral load testing coverage	% of children and adolescents on ART with VL results at 12 months
ART.9/VLS.1 Viral load suppression at 12 months after ART initiation	% of children and adolescents on ART who are virally suppressed at 12 months
ART.19 HIVDR among infants	% of infants and children under age 18 months diagnosed with HIV who have any HIVDR
MTCT.13 Turnaround time of EID results	% of early infant diagnosis test results returned in a timely manner
MTCT.14 6-week MTCT rate	% of infants born to HIV-positive women who are HIV-positive at 6 weeks
For related PMTCT indicators, see section 2.4.7.	

2.4.5c Toxicity monitoring

Conceptual framework

As ART is scaled up, with earlier and more prolonged exposure to ARVs among adults, adolescents and children as well as pregnant and breastfeeding women, toxicity monitoring has become a critical component of treatment and prevention programmes. Of concern, ARV-associated toxicities are among the most common reasons reported for ART non-adherence, treatment discontinuation or substitution of drugs. WHO recommends that countries use a standardized approach to integrate toxicity monitoring into national M&E systems.[1] The proposed approach defines minimum set of data elements for reporting on the magnitude of toxicities and their impact on treatment discontinuation. WHO recommends, to complement routine monitoring, with active toxicity surveillance through special studies and surveys at sentinel sites as needed to address specific concerns.

Routine monitoring for ARV toxicity

Routine monitoring provides data on the incidence and clinical significance of serious ARV toxicities and their impact on patient outcomes and attrition. This information can inform guidance to prevent and limit the severity of drug toxicity and thus to optimize patient retention in treatment and care and improve treatment effectiveness.

The key indicator for routine toxicity monitoring is the percentage of patients on ART with treatment-limiting toxicity – defined as life-threatening illness, death, hospitalization, disability or resulting in treatment discontinuation or substitution (ART.12). For the first time this indicator is designated for national programme monitoring. Disaggregation by ART regimen, sex, age, pregnancy, TB/HIV coinfection and, if data are available, key population, using data collected from patient clinical records and ART registers, provides additional information on populations at higher risk for toxicity due to environmental and behavioural factors, co-morbidities and concomitant use of other medications. (See Table 2.23.)

Surveillance for ARV-related toxicity

WHO recommends strengthening surveillance of key ARV toxicities at sentinel sites, when more data are needed to inform policy and improve treatment outcomes. WHO provides guidance on conducting special studies in two main areas:

[1] WHO technical briefs on surveillance of antiretroviral drug toxicity in ART programmes are available at http://www.who.int/hiv/pub/arv_toxicity/en/.

- active surveillance for specific ARV toxicities in existing sentinel cohorts. There is a large benefit to nest active toxicity surveillance within existing cohorts set up in a country for monitoring and evaluation purposes. These cohorts have a reliable system for capturing clinical and toxicity data. A focus on one drug or the incidence of key toxicities will improve the accuracy of their assessment.
- surveillance of ARV toxicity during pregnancy and breastfeeding: a prospective pregnancy-exposure registry for toxicity among pregnant women and neonates, a birth defects surveillance system for assessing birth outcomes and a prospective monitoring of cohorts of mother–infant pairs for toxicity from birth through the breastfeeding period.

WHO offers technical guidance and assistance on toxicity monitoring for routine M&E or through special surveys at http://www.who.int/hiv/topics/arv_toxicity/en/index.html.

Special considerations by setting and population

Pregnant and breastfeeding women

WHO recommends routine monitoring of ARV toxicity during pregnancy and the breastfeeding period with three areas of focus:[1,2]

- maternal adverse outcomes: monitoring treatment-limiting toxicities associated with ART in pregnant women;
- adverse birth outcomes: monitoring toxicity in the fetus in utero, manifesting as stillbirths, preterm births and low birth weight or manifesting as major congenital anomalies or early infant deaths;
- adverse infant and child outcomes: monitoring health outcomes in infants and young children exposed to ARV drugs via breast milk, particularly any impact on growth and development.

Adverse birth outcomes may be routinely monitored by integrating an additional indicator into the national M&E system. In particular, if preterm deliveries (<37 weeks) (ART.13) are reported at a frequency equal to or higher than a rough estimate of their expected incidence, formal assessment is warranted. (See Table 2.23 for detailed information and reporting elements.)

[1] Surveillance of antiretroviral drug toxicity during pregnancy and breastfeeding, Technical brief. Geneva: World Health Organization, 2013 (http://apps.who.int/iris/bitstream/10665/91768/1/WHO_HIV_2013.125_eng.pdf?ua=1).
[2] Surveillance of the toxicity of antiretroviral drugs during pregnancy and breastfeeding. March 2014 supplements to the 2013 consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. (See Chapter 11, Monitoring and evaluation.) (http://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_march2014/en/).

Table 2.23 Programme indicators for toxicity monitoring

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
ART.12 Toxicity prevalence % of ART patients with treatment-limiting toxicity	N: Number of people living with HIV and on ART within the past 12 months who have stopped treatment or switched regimen due to toxicity D: Number of people living with HIV who were on ART in the past 12 months.	Regimen, sex, age (<3, 3–9, 10–14, 15+), pregnant and breastfeeding women, key population,* TB/HIV coinfection, toxicity categories as adapted from patient card or ART register.	N&D: Programme records, e.g. ART registers Numerator includes deaths.	Measures the impact of toxicities on treatment outcomes. Helps guide national policy on ART regimens, diagnosis, strategies for preventing toxicities, health-care worker training and retention in care.
Additional indicator				
ART.13 Toxicity-related pre-term deliveries % of preterm deliveries among women on ART *Cross-referenced with the PMTCT section MTCT.20*	N: Number of HIV-positive women who received ART and delivered in the past 12 months and had a preterm birth (<37 weeks gestation) D: Number of women living with HIV and on ART who delivered in the past 12 months.	Regimen, age, initiation of ART before conception during 1st, 2nd and 3rd trimester, gestational age of pre-term birth (<28 weeks, 28 to <32 weeks, 32 to <37 weeks).	N&D: Programme records, e.g. MCH card with integrated PMTCT record.	Higher than expected rate suggests the need for more formal assessment and consideration of national policy on use of ARVs during pregnancy.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

2.4.5d Drug resistance

As ART is scaled up, the emergence of significant population-level HIV drug resistance (HIVDR) has become a global concern. Emergence of HIV drug resistance threatens the effectiveness of ART and sustained reductions in HIV-related morbidity and mortality. As documented in WHO's global report on HIVDR in 2012,[1] levels of drug resistance have been slowly increasing. Resistance has not yet reached the level that endangers the effectiveness of ART programmes. However, the trend is worrying, especially in the context of rapid scale-up of national ART programmes. Efforts to slow the development of HIVDR are a priority. WHO recommends that HIVDR prevention and assessment be integrated into every national HIV programme.[2]

WHO recommends that HIVDR prevention and assessment be integrated into every national HIV programme.

Routine monitoring

Comprehensive HIVDR surveillance involves both monitoring routinely, with early warning indicators (EWIs), the performance of the ART programme in treatment facilities and conducting periodic HIVDR surveys in specific populations. To prevent the emergence of drug resistance, the WHO HIVDR strategy (developed in 2005 and revised in 2012) promotes the monitoring of key EWIs and using them for quality improvement. WHO EWIs of HIVDR are quality-of-care indicators that alert clinic and programme managers to conditions favouring virological failure and the emergence of population-level HIVDR. EWIs are included in the ART and viral suppression indicators (Tables 2.21 and 2.25). In addition, the recommended strategy assesses whether HIVDR is increasing to levels that might undermine the effectiveness of ART programmes.

The EWI are:

1. on-time ARV drug pick-up (ART.6 ART adherence proxy)
2. retention on ART at 12 months (ART.5)
3. ARV drug stock-out (ART.9)
4. viral load suppression at 12 months after ART initiation (VLS.1)
5. dispensing practices.

Guidance on EWIs published in 2012 describes methods for making site-specific estimates of HIVDR through a sampling of patient records. Updated EWI guidance, to be published in 2015, will include methods that will also allow for nationally representative estimates through a random sampling of clinics providing ART. If the purpose is only to obtain nationally representative estimates, and not to obtain specific facility-level results, estimates of retention and viral load suppression can be developed through surveys of acquired HIVDR.

The primary source used for EWI reporting should be routine programme data. However, the routine data may not be optimally available. If the coverage of routine data is less than a certain percentage representative of the eligible population,[3] EWI data should not be reported as a national figure.

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[1] Phillips A, Cambiano V, Nakagawa F, Magubu T, Miners A, Ford D, et al. (2014) Cost-effectiveness of HIV drug resistance testing to inform switching to second line antiretroviral therapy in low income settings. PLoS ONE 9(10): e109148. doi: 10.1371/journal.pone.0109148
(http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0109148).

[2] Ibid.

[3] In some settings 70% or 80% is used as a cut-off.

HIVDR surveys in specific populations

In addition to routine monitoring of EWI of HIVDR, periodic surveys in specific populations are important to inform the selection of regimens and the frequency of viral load monitoring. WHO provides detailed guidance on how to perform surveys of HIVDR.[1] These periodic surveys make possible nationally representative assessments of the prevalence of HIVDR and tracking of its evolution in four priority populations:

- **newly initiating ART (pre-treatment HIVDR, or PDR),** to inform the national choice of first-line ART as well as choices for prophylactic regimens (ART.14).
- **already on ART (acquired HIVDR, or ADR),** to inform selection of second-line regimens and recommended frequency of viral load measurement (ART.16). The survey in this population also can provide a nationally representative estimate of retention in treatment and viral load suppression that can be used to guide quality improvement efforts.
- **recently infected with HIV (transmitted HIVDR),** to document and characterize the transmission of drug-resistant virus (ART.18).
- **infants under 18 months of age,** to inform selection of the first-line regimen for children (ART.19).

Table 2.24 presents HIVDR indicators derived from special surveys.

WHO suggests that countries with generalized epidemics assess pre-treatment HIVDR every three years – for example, the PDR assessment in years 1, 4 and 7 and the ADR assessment in years 2, 5 and 8. Countries should consider how best to sequence the surveys depending on the type of epidemic and on the status and coverage of the national ART programme. HIVDR data should be available to support national decision-making, especially when updating adult and paediatric ART guidelines.

WHO will soon publish a detailed briefing note, with budget examples, to help countries as they prepare their national strategies.[2] Essential information on HIVDR is available on the WHO web site at http://www.who.int/hiv/topics/drugresistance/en/index.html.

Table 2.24 Indicators for HIV drug resistance from special surveys

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method and issues	Programme relevance and interpretation
National indicators				
ART.14 HIVDR prevalence at ART initiation % of people living with HIV and initiating ART who have resistance to HIV drugs	N: Number of people living with HIV who initiated ART within the past 12 months and who have HIV drug resistance. D: Number of people living with HIV who initiated ART within the past 12 months.	Prior ARV exposure status, drug class (NRTI, NNRTI, PI).	N&D: Nationally representative survey.[3]	Informs decisions on how to manage 1st line treatment (e.g. intensity of monitoring for treatment failure, choice of drugs).

[1] Surveillance of HIV drug resistance in adults receiving ART. Concept note. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).
[2] Guidance note on HIV drug resistance surveillance. Geneva: World Health Organization; (forthcoming).
[3] Surveillance of HIV drug resistance in adults receiving ART. Concept note. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).

ART.15 Viral load suppression at 12 months after ART initiation % of people living with HIV on ART with viral load suppression (<1000 copies/ml) at 12 months after initiation *Cross-referenced with Viral suppression section and ART section VLS. 1 and ART. 9*	N: Number of people living with HIV who initiated ART 12 months (±3 months) before the survey and have suppressed viral load (<1,000 copies/mL) at the time of the survey. D: Number of people living with HIV who initiated ART 12 months (±3 months) before the start of the reporting year.	Sex, Age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age group. Pregnancy at initiation, breastfeeding at initiation where relevant.	N&D: Programme records, e.g. ART registers and cohort reporting forms, patient records. Programmes should routinely capture this information from all patients in all ART clinics and review it annually. Where this is not possible, the data can be estimated through acquired HIVDR surveillance, which provides methods for developing nationally representative estimates of VL suppression among patients who have been on ART for 12 months[1]	Measures clinical outcomes of patients in care and overall quality of care as ART programmes expand. Also, viral load suppression is the best available measure of patient adherence to ART. As an EWI of HIVDR, reflects ability of facility to attain a level of care that avoids HIVDR. Good performance is >85%; passable performance is >70%.
Additional indicators				
ART.16 Acquired HIVDR prevalence % of people living with HIV failing on ART at 12 (±3) months who have any HIVDR	N: Number of people living with HIV on ART for 12 months (±3 months) and failing ART (≥1000 copies/mL) who have any type of drug resistance. D: Number of people living with HIV and on ART for 12 months (±3 months) who are failing ART (≥1000 copies/mL).	ART regimen (1st line, 2nd line), drug class (NRTI, NNRTI, PI).	N&D: Nationally representative survey of acquired drug resistance.	Measures level of acquired drug resistance among those on treatment for 12 months. Acquired drug resistance may compromise the effectiveness of 2nd and 3rd line ART.

[1] Surveillance of HIV drug resistance in adults receiving ART. Concept note. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).

ART.17 Acquired HIVDR long-term % of people living with HIV on ART for at least 48 months and failing ART with any HIV drug resistance	N: Number of people living with HIV on ART for at least 48 months and failing ART (≥1000 copies/mL) at the time of the survey who have any HIV drug resistance. D: Number of people living with HIV and on ART for at least 48 months who are failing ART (≥1000 copies/mL) and have been successfully genotyped.	ART regimen (1st line, 2nd line), drug class (NRTI, NNRTI, PI).	N&D: Nationally representative survey of acquired drug resistance.	Measures the extent of acquired drug resistance, which may compromise the effectiveness of 2nd and 3rd line ART.
ART.18 Transmitted HIVDR prevalence % of recently HIV-infected adults with HIV drug resistance	N: Number of adults recently infected with HIV with any drug resistance. D: Number of adults recently infected with HIV.	ART regimen (1st line, 2nd line), drug class (NRTI, NNRTI, PI).	N&D: Nationally representative survey of transmitted HIVDR (embedded in HIV sero-surveillance or DHS AIDS indicators).	Determines the extent of transmitted HIVDR.
ART.19 HIVDR among infants % of infants and children under age 18 months diagnosed with HIV who have any HIVDR	N: Infants and children under age 18 months diagnosed with HIV by EID within a 12-month period who have any drug resistance. D: Number of infants and children under age 18 months who are diagnosed with HIV through EID in the same reporting period.	Exposure to PMTCT.	N&D: Nationally representative survey of drug resistance in infants and children under age 18 months.	

2.4.6 Viral suppression

Conceptual framework

The individual-level relationships among ART, viral load (VL) and HIV transmission were first reported in the Rakai studies in Uganda in 2011.[1] Extrapolated to the population level, these relationships are used to measure of treatment success in a cohort of ART patients by monitoring VL suppression rates. VL suppression also is used to estimate the overall transmission potential within a community in order to gauge the effectiveness of ART in preventing transmission.

Currently, VL is not routinely monitored in many settings. However, VL suppression in populations is a key outcome indicator of HIV programme performance; its monitoring should be scaled up.

Global indicator

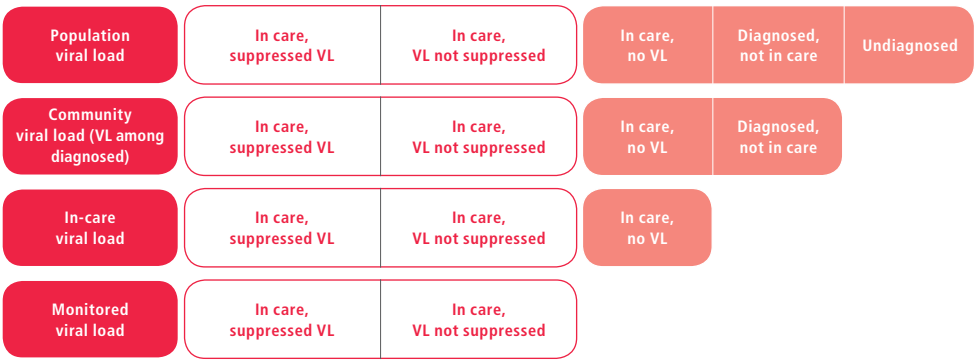
8. Viral suppression

Number and % of people living with HIV and on ART who are virologically suppressed.

The current level of viral suppression among those who are receiving treatment, indicator VLS.3, is designated for global monitoring.

The conceptual framework for viral load measures proposed by Hall[2] (Fig. 2.8) summarizes different options for VL metrics and facilitates review of the implications for measuring each VL metric, its interpretation and its limitations. Adjustments need to be made to account for the several sources of "unknowns" shaded in pink.

Fig. 2.8 Conceptual framework for viral load measures



Source: Adapted from Guidance on community viral load: a family of measures, definitions, and method for calculation. Atlanta, Centers for Disease Control; 2011. (http://www.ct.gov/dph/lib/dph/aids_and_chronic/surveillance/statewide/community_viralload_guidance.pdf).

[1] Palis B, Gray R H, Bwanika J B, Kigoz G, Kiwanuka N, Nalugoda T, et al. Effect of hormonal contraceptive use prior to HIV seroconversion on viral load setpoint among women in Rakai, Uganda. J Acquir Immune Defic Syndr. 2011 February 1; 56(2): 125–130. doi:10.1097/QAI.0b013e3181fbcc11 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3023004/pdf/nihms253001.pdf).

[2] Hall I. Viral load measures: patients, populations, and Interpretations. 20th Conference on Retroviruses and Opportunistic Infections. Atlanta, March 3–6 2013. Abstract 165.

According to this framework, a summary measure of viral load can be taken at four levels:

- **Population viral load:** VL metric of all people infected with HIV including those who are not diagnosed (VLS.5);
- **Community viral load (VL among diagnosed):** VL metric of all people who are diagnosed with HIV infection, but some may not yet be in care and some may not have had their VL measured;
- **VL of people in care:** VL metric of all people in care and treatment including those who are in care but with no VL measurement;
- **VL monitored:** VL metric of all people in care who have a VL measurement (VLS.4).

All four metrics build on available VL data (middle columns with red border in Fig. 2.8). VL needs to be measured or estimated for the other population groups (shaded in pink), such as those in care but with no VL measurement, those diagnosed but not in care, and those undiagnosed.

When the coverage of VL testing is insufficient (for example, less than 70–80% of the eligible population receive a VL test result), population viral load and in-care viral load can be measured through surveys. VL among the population with no VL measurement can be estimated through modelling based on a set of assumptions. At the minimum a national HIV care programme should review available VL data to monitor the current level of VL suppression observed in the population on ART. In a well-performing ART programme, the majority of people on ART are expected to have suppressed VLs, thus effectively reducing the transmission probability per risk act between an infected and an uninfected person. Viral load suppression is determined by the efficacy of the drugs used and levels of retention and adherence among people living with HIV.

M&E issues on viral load metrics

VL testing coverage and data availability

To interpret VL data, it is necessary to know its coverage – for example, whether it represents all or a selected proportion of people on ART and, if only a proportion, what biases may exist in these VL data. In some settings where VL data are scarce, VL testing may be targeted for those with indications of treatment failure, thus skewing the results towards higher viral load. At the same time, since VL data are available only for those who come to facilities, VL data may be biased toward a more positive (that is, lower) outcome, assuming that people visiting facilities are those with better retention and adherence and thus are more likely to be virally suppressed. For estimates of VL in populations beyond those who have VL measurements (VLS.5), indicator values may be adjusted on the basis of assumptions about the viral load levels of patients who are not on ART and of people who do not know their sero-status.

VL measurement time point

Some lapse of time is expected between ART initiation and VL suppression. To use a default time point, VL data can be aggregated to measure VL suppression in a population from six months after ART initiation.

Measures of VL at specific durations of treatment or among all people on ART regardless of duration of treatment

Cross-sectional VL measurement (that is, for example, among all people on ART regardless of duration of treatment) provides a snapshot of overall VL suppression in the population, whether the population on ART, the population in HIV care, the population diagnosed HIV-positive, or the population living with HIV. By quantifying a general level of VL in the population, this metric could provide insight into HIV transmission dynamics.

In contrast, measures of VL at specific durations of treatment make possible assessment of disease progression. Longitudinal measurement is proposed as a direct measure of the outcome of an HIV care programme (VLS.1). It is a valuable metric for setting targets, as certain levels of VL suppression can be expected in a cohort of patients who have started ART and continued to different time points (for example, VL suppression among ART patients 12, 24 and 36 months after initiating treatment).

VL levels and definition of VL suppression and detection

The definition of an undetectable viral load depends on the sensitivity of the test (what level of virus it can detect). For the VL indicators in this guide, VL suppression is defined as less than 1000 copies/mL.[1] However, countries can review an additional threshold that has meaning in their context.

VL metric options

The desired outcome for an individual on ART is reaching and maintaining viral load suppression. Measuring programme effect, however, requires population-level VL data, which summarize the differing VL levels in that population. Researchers have proposed several ways to express viral load at the population level:

- mean viral load of people living with HIV in a specific population
- median viral load of people living with HIV in a specific population
- cumulative viral load of people living with HIV in a specific population
- percentage of a specific population of people living with HIV who have achieved viral load suppression.

Mean viral load measures pose a problem due to the skewed distribution of viral load measures, which are often presented on a log scale. Median viral load adjusts for the skew in viral load distribution but loses meaning when more than half of the population has an undetectable viral load. Cumulative viral load, the summation of values of all viral load measures in the population, has been suggested[2] as a way to characterize the absolute potential for transmission in a community; if calculated comprehensively, it would distinguish between communities with large and small populations living with HIV. Lastly, calculating the percentage of people living with HIV who have suppressed viral load is a simple, intuitive measure of "protection", similar to describing the proportion of people who inject drugs who use sterile injecting equipment.

[1] Meeting report on framework for metrics to support effective treatment as prevention. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75387/1/9789241504331_eng.pdf).

[2] Das M, Chu PL, Santos GM, Scheer S, Vittinghoff E, McFarland W, et al. Decreases in community viral load are accompanied by reductions in new HIV infections in San Francisco. PloS One, 2010, DOI: 10.1371/journal.pone.0011068 (http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0011068).

Table 2.25 Programme indicators of viral load suppression

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
VLS.1 Viral load suppression at 12 months after ART initiation % of people living with HIV on ART with viral load suppression (<1000 copies/ml) at 12 months after treatment initiation *Cross-referenced with ART section and HIVDR section ART. 9 and ART. 15*	N: Number of people living with HIV who initiated ART 12 months (±3 months) before the start of the reporting year and have a suppressed viral load (<1000 copies/mL) at 12 months after initiating ART. D: Number of people living with HIV who initiated ART 12 months (±3 months) before the start of the reporting year.	Sex, age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age group. Pregnancy at initiation, breastfeeding at initiation where relevant.	N&D: Programme records, e.g. ART registers and cohort reporting forms, patient records. Programmes should routinely capture this information from all patients in all ART clinics and review it annually. Where this is not possible, the data can be estimated through acquired HIVDR surveillance, which provides methods for developing nationally representative estimates of VL suppression among patients who have been on ART for 12 months.[1]	Measures clinical outcomes of patients in care and overall quality of care as ART programmes expand. Also, viral load suppression is the best available measure of patient adherence to ART. As an EWI of HIVDR, reflects ability of facility to attain a level of care that avoids HIVDR. Good performance is >85%; passable performance is >70%.

[1] Surveillance of HIV drug resistance in adults receiving ART. Concept note. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).

VLS.2 Viral load testing coverage % of people on ART with viral load test result at 12 months after ART initiation *Cross-referenced with ART section ART.8*	N: Number of people living with HIV and on ART with VL test result available at 12 months. D: Number of people on ART for 12 months.	Sex, age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age group.	N&D: Programme records, e.g. ART registers and cohort reporting forms, patient records, case-based surveillance data; lab records; survey. Denominator excludes patients who have died, transferred to another clinic or been classified as lost to follow-up and those who have not received a VL test by month 12 of ART. It is critical to de-duplicate records and avoid double-counting when identifying the appropriate numerator.	This indicator assesses the extent to which VL is available in the country. This indicator is critical to deciding whether the previous indicator can be reported using routine data. If the coverage of routine data is less than a certain percentage representative of the eligible population, data should not be reported as a national figure. In some settings 70% or 80% is used as a cut-off. By the 15-month point, all patients on ART should have received at least one VL test.
VLS.3 Viral suppression Number and % of people living with HIV and on ART who are virologically suppressed  	N: Number of people living with HIV and on ART who have a suppressed viral load (<1000 copies/mL). Population-level denominator: Number of people living with HIV who are currently receiving ART (Numerator of ART 2 and 3).	Sex, age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age group.	ART registers and cross-sectional report, patient records. Population-based survey, such as the Health-Impact Assessment surveys, that collects data on ART coverage and viral suppression.	With the programme-based denominator, measures virologic suppression achieved among all those currently on treatment who received a VL measurement, regardless of when they started ART. Corresponds to the third 90 of the 90–90–90 target (90% of those on ART have suppressed viral loads).

VLS.4 Viral load monitoring % of people living with HIV and on ART who obtained at least one VL test result during the past 12 months	N: Number of people living with HIV and on ART who have obtained at least one VL test result during the past 12 months. D: Cross-sectional: Number of people living with HIV and on ART who had VL measured in the last 12 months. Cohort: Number of people living with HIV and on ART who had VL measured 12 (± 3) months after ART initiation.	Sex, age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5-year age group.	ART register with cross-sectional and cohort forms; patient records; survey.	Measures the % of people who have VL monitoring, cross-sectionally and for ART initiation cohorts. Essential for interpreting VLS. 3 Indicates the scale-up of VL testing.
Additional indicators				
VLS.5 Population viral load % of all people living with HIV who have suppressed viral load	N: Number of people living with HIV who have suppressed viral loads (<1000 copies/mL). D: Number of people living with HIV, comprising total numbers of people in care with VL measured, people in care with no VL measurement, people diagnosed but not in care, people undiagnosed.	Age (<15, 15+) Priority population where feasible.	Programme data, surveys, internationally consistent modeling estimates.	The population estimate of VL level can provide insight into transmission dynamics in the overall population.
VLS.6 Early viral load testing % of people on ART who had VL monitored at 6 months	N: Number of people living with HIV who had their VL measured at 6 months after ART initiation. D: Number of people living with HIV who initiated ART 6 months before the start of the reporting period.	Sex, age (<15, 15+), VL suppression.	ART register with cross-sectional and cohort forms; patient records.	Quality indicator for an early VL assessment. (VL is expected to be suppressed 6 months after treatment initiation.)

VLS.7 Long-term viral suppression % of people whose viral load is suppressed 48 months after initiating ART	N: Number of people living with HIV who initiated ART at least 48 months ago and have suppressed viral load (<1000 copies/mL). D: Number of people living with HIV who have been on ART for at least 48 months.	First-line ART, NNRTI-based first-line ART.	N&D: Nationally representative survey of acquired drug resistance.	Measures long-term clinical outcomes of patients in care and reflects quality of care as patients manage chronic HIV disease.

2.4.7 Prevention of mother-to-child transmission

Conceptual framework

Mother-to-child transmission accounts for over 90% of paediatric HIV infections. Transmission can occur during pregnancy, labour, delivery and breastfeeding. In the absence of any antiretroviral intervention, the overall risk of transmission is 30–35%. The use of highly effective triple ARVs as recommended can reduce this risk to less than 5%.[1]

As recommended by the United Nations, the comprehensive approach to the prevention of mother-to-child-transmission (PMTCT) has four prongs:[2]

1. primary prevention of HIV infection among women of childbearing age

2. preventing unintended pregnancies among women living with HIV

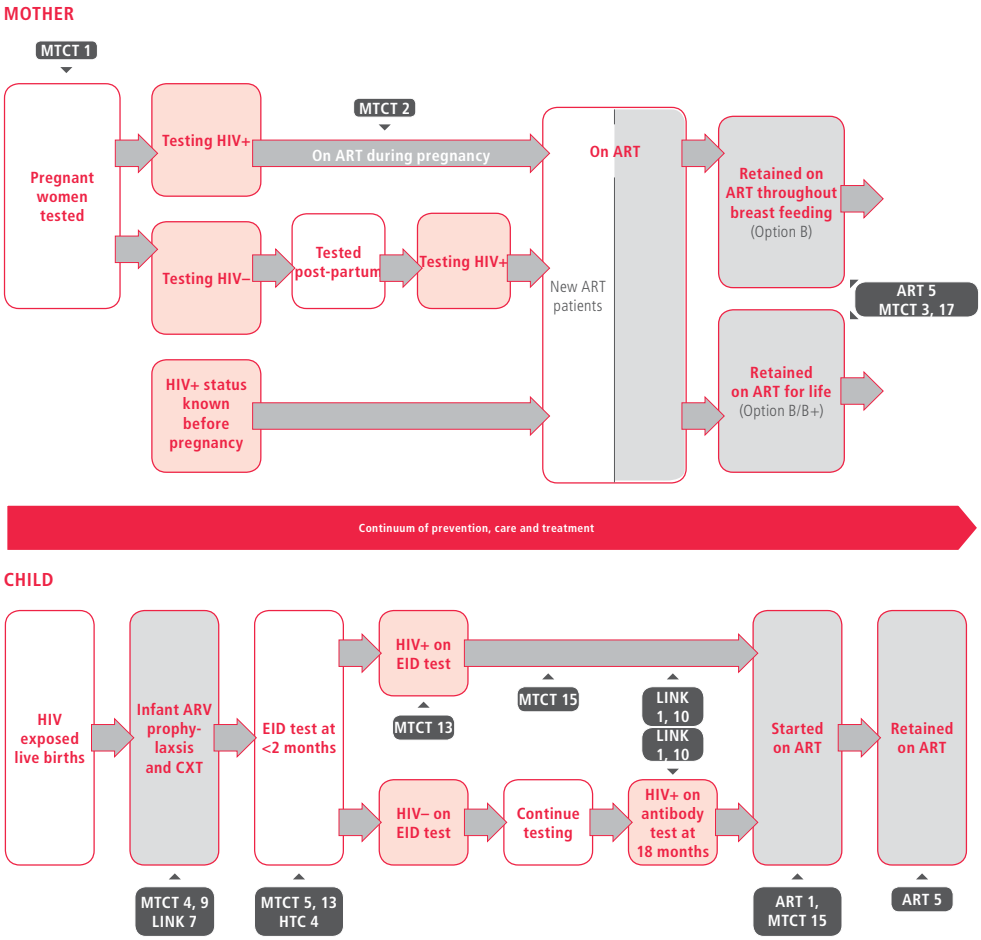
3. preventing HIV transmission from pregnant women living with HIV to their infants

4. providing appropriate treatment, care and support to mothers living with HIV and their children and families.

The PMTCT cascade (Fig. 2.9, is similar to the HIV care and treatment cascade described in section 1.3.2, but it includes both the mother and the child. Monitoring the entire cascade provides information on what proportion of mother–baby pairs received the sequence of recommended interventions. The PMTCT cascade starts with the total number of pregnant women and follows them through finding out their HIV status, provider-initiated HIV testing for male partners and primary prevention services for pregnant women in discordant partnerships; the delivery of ARV for HIV-positive pregnant and breastfeeding women, early testing and final ascertainment of exposed children's HIV status, early treatment of HIV-infected infants and linkage to chronic HIV treatment for HIV-positive women at the end of the MTCT risk period. The continuum of HIV care and the expanded package of prevention and care services are embedded in the PMTCT services provided to HIV-positive women and their exposed children.

[1] New guidance on prevention of mother-to-child transmission of HIV and infant feeding in the context of HIV. Geneva: World Health Organization; 2010 (http://www.who.int/hiv/pub/mtct/PMTCTfactsheet/en/).
[2] Strategic approaches to the prevention of HIV infection in infants: report of a WHO meeting, Morges, Switzerland, 20–22 March 2002. Geneva: World Health Organization; 2002 (http://www.who.int/hiv/mtct/StrategicApproaches.pdf).

Fig. 2.9 Prevention of mother-to-child transmission



Recent developments in PMTCT

The 2013 WHO recommendations simplified PMTCT ARV interventions in terms of regimen, eligibility criteria and duration of treatment. While a choice of two different options is recommended to countries, the new approach is that all pregnant and breastfeeding women with HIV start triple ARVs (the first-line adult fixed-dose combination regimen) and continue them at least through the end of the MTCT risk period. These regimens are referred to as either Option B, in which all HIV-positive pregnant and breastfeeding women receive ART until they finish breastfeeding and those not then eligible for lifelong ART stop while the others continue, or Option B+, in which all HIV-positive pregnant and breastfeeding women, regardless of other ART eligibility criteria, start and continue on ART lifelong.[1] As countries adopt these guidelines, an increasing number of women are on long-term ART, preferably on a single-pill, fixed-dose combination drug. To accommodate this expansion, countries have made a number of shifts in the health system, such as integrating ART services into more MCH clinics, decentralizing, task-shifting, enhancing supply chains, strengthening linkages to chronic ART care and investing in greater laboratory capacity at MCH clinics. Tracking these system changes is part of monitoring HIV and PMTCT programmes (see section 2.3, on tracking critical resources input).

[1] Programmatic update: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. Executive summary. April 2012. Geneva: World Health Organization; 2012 (who.int/hiv/PMTCT_update.pdf).

Key M&E issues in PMTCT

Following the cascade across multiple service delivery points

The PMTCT cascade spans multiple interventions over a lengthy period, across multiple service delivery points, for both mother and child. Data must be collated from ANC visits, during labour and delivery, during HIV care and at postpartum and child health visits. Tools to collect data must reflect the patient care work flow of these different service delivery points and be able to track mother–baby pairs from one such point to another. The M&E of PMTCT relies on robust systems for assigning unique IDs to link the records of the mother or the mother–baby pair, integrating HIV information into existing MCH cards or using electronic systems to facilitate this process (see section 3.3.4, on data management).

Shifting to long-term ART monitoring tools

In settings where HIV-positive pregnant and breastfeeding women receive ART throughout the MTCT risk period (Option B) or lifelong (Option B+), data collected in the context of PMTCT must be compatible with the ART monitoring system designed for long-term follow-up (see box, Evolving M&E for PMTCT). As noted, if ART is initiated at MCH facilities, women on long-term ART must transfer to HIV care facilities postpartum, and their patient records must also be transferred. This will require MCH facilities to track ART services in relation to time since ART initiation, rather than by ANC visit, in order to be compatible with general ART data collection tools. If MCH facilities are not yet using tools harmonized with the national ART system, countries must undertake a careful review of tools to develop a clear mechanism for transferring data between patient monitoring systems. Such a transfer mechanism ensures proper patient monitoring of women on lifelong ART and facilitates use of data on this important population for programme monitoring. Even where women not ART-eligible themselves stop ART at end of the MTCT risk period (Option B), adopting the tools used for long-term monitoring of ART (that is, ART registers and facility-held client cards) is recommended.

Toxicity monitoring

As with all other patients on ARVs, toxicity surveillance is recommended to monitor adverse reactions in pregnant women and infants receiving PMTCT services.[1] (See section 2.4.5c.)

Monitoring ARV retention and final status of HIV-exposed infants

The effectiveness of PMTCT services depends on the continued use of ARVs throughout the risk period. As the new guidelines for maintaining mothers on ART throughout the MTCT risk period are adopted, monitoring retention and adherence becomes even more critical. Unfortunately, monitoring ARV coverage during breastfeeding and the final assessment of the exposed infant's HIV status have been weak areas of monitoring the cascade. Countries must invest in improving the completeness of data from the latter part of the cascade as they scale up PMTCT, and they must seek to validate the elimination of mother-to-child transmission of HIV (EMTCT). To support countries in collecting accurate programme data to measure and validate progress, the Global Plan Towards Eliminating New Paediatric Infections and Keeping Mothers Alive[2] includes a comprehensive set of indicators and 10 targets at global and country levels.[3] All data elements of these 10 targets appear in various sections of this guide.

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[1] Surveillance of antiretroviral drug toxicity during pregnancy and breastfeeding. Technical brief. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/91768/1/WHO_HIV_2013.125_eng.pdf?ua=1).

[2] A short guide on methods: measuring the impacts of national PMTCT programmes – towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75478/1/9789241504362_eng.pdf?ua=1).

[3] Global guidance on criteria and process for validation: elimination of mother-to-child transmission of HIV and syphilis. Geneva: World Health Organization, 2014 (http://apps.who.int/iris/bitstream/10665/112858/1/9789241505888_eng.pdf?ua=1&ua=1).

Evolving M&E for PMTCT

M&E systems face new challenges as they adjust to new programmatic recommendations for PMTCT (Option B/B+) that require monitoring HIV-positive pregnant women over longer periods and across multiple service delivery points. An added challenge with Option B is that ART is discontinued at the end of the MTCT risk period (i.e. at the end of breastfeeding) for some mothers, while others with more advanced disease continue on ART lifelong.

All pregnant women initiating ART (Option B or B+) should receive ART IDs, be registered in the ART programme and be recorded in the ART monitoring systems. To promote quality of care, Option B and B+ countries should use ART cards/files to monitor ALL pregnant and breastfeeding women on ART. Women on Option B should continue to be followed in HIV care (pre-ART) after they stop breastfeeding, and their CD4 levels should be monitored regularly to ensure timely restarting of ART when indicated. Treatment records and national ART IDs should be maintained to ensure the continuity of data linkages for all pregnant and postpartum women on ART.

ART retention should be monitored for all pregnant and breastfeeding women initiating treatment. Pregnant women who initiate ART at MCH facilities and transfer to HIV care facilities postpartum should be assigned to an ART retention cohort that corresponds to their date of initiation of treatment, not the date that they transferred into a facility specializing in HIV care. ART retention will be monitored among the subset of pregnant and breastfeeding women who are newly initiating ART. Pregnant women who are already on ART when they become pregnant are in a different ART initiation cohort. When calculating the percentage of pregnant and breastfeeding women alive and on ART 12 months after ART initiation (MTCT.3), programmes should exclude women on Option B who have completed ART (e.g. stopped breastfeeding and do not need to continue ART) from both numerator and denominator. These women should be classified under an additional outcome of "completed ART for PMTCT" so that their inclusion does not lower the retention rate when tallying cohort outcomes.

HIV-exposed infants should be followed to determine their outcomes. Monitoring these infants beyond early infant diagnosis is recommended, using indicator MTCT.8 to report their final outcome status. This indicator measures progress toward ensuring that all infants born to HIV-positive women have either confirmed HIV infection and are linked to ART services or are confirmed as HIV-uninfected based on a negative virological test at around six weeks of age in the absence of breastfeeding or, if breastfeeding, on a negative HIV antibody test at 18 months (or later if breastfeeding continues beyond 18 months). Many countries monitor HIV-exposed infants using registers or facility-held cards that identify these infants at birth or at the first infant follow-up visit and then track them until their final outcome is established. This can be done with either a paper-based or an electronic system as long as information is organized by birth month of infants for birth cohort reporting.

Integrating PMTCT patients into ART measures of coverage

While assuring continuity when transferring PMTCT clients from MCH to ART service sites, monitoring systems must avoid double-counting transferring PMTCT patients as "newly enrolled ART patients". This problem can be minimized if MCH facilities adopt the ART registers used by other ART sites and use compatible patient IDs for HIV-positive women who begin ART. Countries with an Option B programme will need to distinguish between women on lifelong ART for their own health and those on triple ARV prophylaxis for PMTCT. Similarly, PMTCT services must be able to include new pregnancies among women already on ART, an event that will become increasingly common as roll-out of Option B+ continues.

Selection and use of indicators

Although the PMTCT cascade consists of many steps, the coverage measures selected as national programme indicators reflect the most common bottlenecks in scaling up PMTCT coverage: HIV testing of pregnant women and children and provision of ART to HIV-positive pregnant women. Several direct outcomes of PMTCT programmes are included in this set of indicators: the MTCT rate (MTCT.7) and the final HIV status of HIV-exposed children (MTCT.8), which includes the number of new child HIV infections due to MTCT. These indicators serve as the evidence base to validate the elimination of mother-to-child transmission and are directly influenced by ART coverage for HIV-positive pregnant or breastfeeding women and HIV-exposed infants.

When coverage rates are low, programmes must carry out additional assessments to determine whether this indicates insufficient resources system-wide, a need for additional staff training, or a need to change workflows to increase the proportion of mother–baby pairs that progress between steps in the cascade. Good performance on many of the PMTCT indicators requires collaboration and cooperation among several different areas, including ANC, paediatrics, ART and laboratory services, to ensure linkages among services for HIV-positive pregnant women as they transfer to general adult services for ART after delivery and for their infants who should be followed in paediatric clinics for early diagnosis and treatment of HIV infection. Poor ART retention rates among HIV-positive pregnant women should spur managers to look more closely at the linkages between ANC and general HIV/ART services as well as to assess outcomes for all ART patients, for example, how many have died, been lost to follow-up, experienced drug toxicity, etc., to determine how retention rates can be improved.

Several proposed indicators monitor quality of care in the follow-up of HIV-exposed infants and the early diagnosis and treatment of HIV-infected infants. Many of these indicators require testing or treatment interventions at specific time points and/or repeated interventions over time. When performance is poor (for example, late infant testing, low rates of documented final outcomes for infants), countries should review and improve the tracking and follow-up system for mothers and infants.

Countries should select quality indicators that reflect the key challenges to local PMTCT programmes, particularly newly introduced components. For example, countries that institute retesting of pregnant women should track the percentage of women initially testing negative at first ANC visit who receive subsequent test (MTCT.11) and should adjust their testing strategy as needed to improve performance. Programmes rolling out Option B+ may need to focus on improving data on the proportion of pregnant and breastfeeding women initiating ART who are retained for 12 months (MTCT.3).

Special considerations by population and setting

The Global Plan recommends that all pregnant women be tested for HIV, regardless of HIV prevalence in the general population. However, in low prevalence settings where resources are scarce, HIV testing among pregnant women can focus on women at higher risk of HIV. Countries in this situation should also assess coverage within the higher risk groups. For example, where drug injection is the main driver of the epidemic, it is important to estimate the number of HIV-positive pregnant women who inject drugs or who have regular sexual partners who inject drugs and to monitor what proportion receive which PMTCT interventions along the cascade, to ensure that this key population has adequate access to all interventions.

Table 2.26 Programme indicators for prevention of mother-to-child transmission

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
MTCT.1 PMTCT testing coverage % of pregnant women with known HIV status *Cross-referenced with HTS section HTS.4*	N: Number of pregnant women attending ANC and/or who had a facility-based delivery who were tested for HIV during pregnancy or already knew they were HIV-positive. Population-based denominator: Number of pregnant women who delivered within the past 12 months. Programme-based denominator: Number of pregnant women who attended ANC or had a facility-based delivery in the past 12 months.	HIV status/test results: 1. known HIV infection at ANC entry 2. tested HIV-positive at ANC during current pregnancy 3. tested HIV-negative at ANC during current pregnancy Total identified HIV-positive women = 1+2. Optional disaggregation: Pregnant women who inject drugs.	N: Programme records, e.g. ANC registers, labour and delivery registers. Population-based denominator: Estimates from central statistics office, UN Population Division or vital statistics. Facility-based denominator: Programme records, e.g. ANC registers, labour and delivery registers.	Measures coverage of the first step in the PMTCT cascade. High coverage enables early initiation of care and treatment for HIV-infected mothers. The total number of identified HIV-positive women provides the facility-specific number of pregnant women with HIV to start a facility-based PMTCT cascade.

MTCT.2 PMTCT ART coverage Number and % of HIV-positive pregnant women who received ART during pregnancy	N: Number of HIV-positive pregnant women who delivered within the past 12 months and received ART during the MTCT risk period. Population-based denominator: Number of HIV-positive pregnant women who delivered within the past 12 months. Facility-based denominator: Number of HIV-positive pregnant women who delivered within the past 12 months and attended ANC or had a facility-based delivery.	1. Already on ART 2. Newly on ART 3. Other regimen categories specific to setting. Optional disaggregation: Pregnant women who inject drugs.	N: Programme records, e.g. PMTCT registers, ARV registers. Population-based denominator: Internationally consistent modelling estimates, e.g. Spectrum AIM. Facility-based denominator: Programme records.	Measures whether ART has been provided to HIV-positive pregnant women. Does not reflect adherence to the ARV drug regimen throughout the MTCT risk period.
MTCT.3 ART retention % of HIV-positive pregnant and breastfeeding women retained on treatment at (6 and) 12 months after initiating ART Also recommended at 24, 36, 48, 60 months, etc. *Cross-referenced with ART section ART.5*	N: Number of HIV-positive pregnant women who are on ART at (6 and) 12 months (or 24, 36, 48, 60 months, etc.) after initiating ART (if initiated ART after becoming pregnant). D: Number of HIV-positive pregnant women who initiated ART (6 and) 12 months (or 24, 36, 48, 60 months, etc.) prior to the beginning of the reporting period. This includes those who have died since starting therapy, those who have stopped therapy and those recorded as lost to follow-up at (6 and) 12 months (or 24, 36, 48, 60 months, etc.).	Sex, pregnancy at initiation, breastfeeding at initiation where relevant, Age: 1. Minimum for paper-based (routine): <15, 15+ 2. Annual extraction of disaggregated data if not reported routinely: <5, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ 3. Electronic system: 5 year age groups Optional: coinfection with TB, coinfection with hepatitis B, people who inject drugs.	N&D: Programme records, e.g. ART registers and cohort reporting forms Ideally collected on all patients from all ART clinics. Where this is not possible, this indicator can tentatively be generated from a sample of patients from a subset of representative ART clinics.[1] Allowing a 3-month grace period before concluding a patient is lost to follow-up, the cohort assessed should be those who start ART between 27 and 15 months before the survey start date.	Measures retention among pregnant women newly initiating ART, a key population group due to their eligibility to start ART immediately and the need to maximize prevention of transmission during the MTCT risk period. Provides information on the ability of the programme to retain and track HIV-positive women as they move from MCH to HIV services. As an early warning indicator (EWI) for HIVDR: good performance is >85%, passable performance is >75%, immediate remediation needed if ≤75%.

MTCT.4 Coverage of infant ARV prophylaxis % of HIV-exposed infants who initiated ARV prophylaxis	N: Number of HIV-exposed infants born within the past 12 months who were started on ARV prophylaxis at birth. Population-based denominator: Number of HIV-positive women who delivered within the past 12 months. Facility-based denominator: Number of HIV-positive women who delivered in a facility within the past 12 months.	None.	N: Programme records, e.g. PMTCT registers. Population-based denominator: Internationally consistent modelling estimates, e.g. Spectrum AIM. Facility-based denominator: Programme records, labour and delivery registers.	Measures the effectiveness of programme efforts to reduce the risk of MTCT in the immediate postpartum period (Prong 3).
MTCT.5 ARV coverage for breastfeeding infants % of HIV-exposed breastfeeding infants whose mothers are receiving ART at 3 months (and 12 months) postpartum	N: Number of HIV-exposed breastfeeding infants born within the past 12 months whose mothers are receiving ART at 3 months (and 12 months) postpartum. Population-based denominator: Estimated number of HIV-exposed infants breastfeeding at 3 months (and 12 months) (including the estimated number of infants not attending clinic and who are still breastfeeding). Programme-based denominator: Number of identified HIV-exposed infants born within the past 12 months who are breastfeeding at 3 months (and 12 months) of age.	None.	N: Programme records, e.g. PMTCT registers, ART registers. Population-based denominator: Survey data for the general population as a proxy; other estimates. Programme-based denominator: Programme records.	Measures the programme's ability to reduce the risk of transmission through breastfeeding (Prong 3).

MTCT.6 Coverage of early infant diagnosis % of HIV-exposed infants receiving a virological test for HIV within 2 months of birth *Cross-referenced with HTS section HTS.5*	N: Number of HIV-exposed infants born within the past 12 months who received a virological HIV test within two months of birth. D: Number of HIV-positive women who delivered within the past 12 months (proxy measure for the number of infants born to HIV-infected women).	Test results: 1. positive 2. negative 3. indeterminate 4. other.	N: Programme records, e.g. PMTCT registers, laboratory records. D: Internationally consistent modelling estimates, e.g. Spectrum AIM.	Measures early HIV diagnosis in infants, a critical first step toward early treatment. High coverage of early virological testing of infants helps initiate ART early in children with confirmed HIV infection and supports counselling on efforts to prevent seroconversion of those with a negative early test result.
MTCT.7 Final MTCT transmission rate % HIV-infected among HIV-exposed infants born in the past 12 months	N: Number of HIV-exposed infants born within the past 12 months who were infected during the MTCT risk period. D: Number of HIV-positive women who delivered within the past 12 months.	None.	N&D: Internationally consistent modelling estimates, e.g. Spectrum AIM. Approaches are described in the short guide to measuring PMTCT impact.[1]	Measures overall rate of transmission over the entire MTCT risk period. Validation criterion for the elimination of MTCT of HIV. Numerator could be used as a source to evaluate the other EMTCT validation criterion of <50 new child HIV infections per 100 000 births.
MTCT.8 Final outcome status % distribution of HIV-exposed infants by final outcome status *Cross-referenced with ART section ART.6*	N: HIV-exposed infants born within the past 12 months (or 24 months in breastfeeding settings) with various final outcome statuses. D: Number of HIV-positive women who delivered within the past 12 months (or 24 months in breastfeeding settings).	Outcome status: 1. HIV-positive 2. HIV-negative, no longer breastfeeding 3. HIV status unknown a. died b. lost to follow-up c. transferred out d. active in care, but not tested at 18 months.	N: Programme records. D: Internationally consistent modelling estimates, e.g. Spectrum AIM.	Directly measures final outcome status. Also measures programme quality in terms of follow-up of HIV-exposed infants until final status is ascertained (Prong 3).

[1] A short guide on methods: measuring the impacts of national PMTCT programmes – towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75478/1/9789241504362_eng.pdf?ua=1).

MTCT.9 Co-trimoxazole (CTX) prophylaxis coverage % of HIV-exposed infants started on CTX prophylaxis within 2 months of birth	N: Number of HIV-exposed infants born within the past 12 months who started on CTX within 2 months of birth. D: Number of HIV-positive women who delivered within the past 12 months.	None.	N: Programme records. D: Internationally consistent modelling estimates, e.g. Spectrum AIM.	Measures provision of CTX to reduce OIs and bacterial infections. Serves as a proxy for follow-up care for HIV-exposed infants.
MTCT.10 Unmet need for family planning % of HIV-positive women attending HIV care and treatment services who have unmet need for family planning *Cross-referenced with LINK.4*	N: Number of HIV-positive women of reproductive age (15–49 years) attending HIV care and treatment services who have an unmet need for family planning. D: Number of HIV-positive women of reproductive age (15–49 years) attending HIV care and treatment services.	Age (15–19, 20–49).	Exit interviews using a series of standard questions related to unmet FP need as defined in surveys such as DHS.	Suggests whether HIV-positive women's need for family planning services to prevent unintended pregnancy is being met (Prong 2).
Additional indicators				
MTCT.11 Seroconversion among pregnant women % of HIV-negative pregnant women who are re-tested for HIV, by seroconversion status	N: Number of pregnant women attending ANC who were re-tested for HIV after an initial negative HIV test during pregnancy. D: Number of women attending ANC who had an initial negative HIV test result during pregnancy within the past 12 months.	Seroconversion status: A. remained HIV-negative B. seroconverted to HIV-positive Optional disaggregation where routine data collection is feasible: Pregnant women who inject drugs and other key population.	N&D: Programme records, e.g. ANC registers, PMTCT registers.	Measures the effectiveness of programme efforts to prevent transmission to uninfected pregnant women (Prong 1).

MTCT.12 Testing coverage of pregnant women's partners % of pregnant women attending ANC whose male partners were tested for HIV during pregnancy	N: Number of pregnant women attending ANC within the past 12 months whose male partners were tested or were already known to be HIV-positive. D: Number of pregnant women attending ANC within the past 12 months.	Test result.	N&D: Programme records, e.g. ANC registers, PMTCT registers.	Measures the effectiveness of efforts to test partners of pregnant women. Identifying serodiscordant couples is the first step in prevention of HIV infection in both women during pregnancy (Prong 1) and male partners of pregnant women.
MTCT.13 Turnaround time of EID results % of early infant diagnosis test results returned in a timely manner	N: Number of EID tests conducted within the past 12 months with results returned within 4 weeks of specimen collection (or in keeping with national standard). D: Number of EID tests conducted within the past 12 months.	None.	N&D: Programme records, e.g. PMTCT registers, laboratory records.	Virologic test results of infants should be returned to the clinic and child/mother/caregiver as soon as possible, but no later than 4 weeks after specimen collection (Prong 4).
MTCT.14 6-week MTCT rate % of infants born to HIV-positive women who are HIV-positive at 6 weeks	N: Number of HIV-exposed infants born within the past 12 months who are infected by around 6 weeks of age. D: Number of HIV-positive women who delivered within the past 12 months.	None.	N&D: Internationally consistent modelling estimates, e.g. Spectrum AIM. Approaches are described in the short guide to measuring PMTCT impact.[1]	Measures efforts to reduce transmission during the peripartum period (Prong 3).

[1] A short guide on methods: measuring the impacts of national PMTCT programmes – towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75478/1/9789241504362_eng.pdf?ua=1).

MTCT.15 Infant ART initiation % of identified HIV-positive infants who initiated ART by 12 months of age	N: Number of infants started on ART by 12 months of age. D: Number of infants identified as HIV-positive by 12 months of age.	None.	N: Extraction by age from routine reporting of number of children initiating ART. D: From central database systems or age disaggregation from facility-level reports on number of children diagnosed HIV-positive.	Important quality of care and linkage indicator. Measures extent of diagnosis and ART initiation among HIV-infected infants, when mortality risk is highest (Prong 4). This indicator is an age disaggregation of indicator LINK.1.
MTCT.16 Integration of ART into MCH sites % of MCH facilities that provide ART	N: Number of health facilities providing MCH services (e.g. ANC, MCH or child health facilities) that provide ART. D: Number of health facilities providing MCH services.	Service type (ANC, MCH, other).	N&D: Health facility survey.	Measures strengthening of link between testing and ART among HIV-positive pregnant women by integrating ART into routine MCH services (Prong 3).
MTCT.17 Early retention rate % of pregnant or breastfeeding women on ART at 1 month and 3 months after initiating ART	N: Number of pregnant or breastfeeding women on ART still alive and on treatment at 1 and 3 months after initiating ART. D: Number of pregnant or breastfeeding women who initiated ART 1 or 3 months prior to the beginning of the reporting period.	None.	N&D: Programme records, e.g. ARV registers. Ideally, collected on all patients, but may be collected from a sample.	A high rate of early retention is an important measure of PMTCT programme success and overall quality. Experience with early rollout of Options B/B+ shows that women are most likely to drop out soon after initiating ART.

MTCT.18 Coverage of baseline CD4 counts or clinical assessments in ANC % of HIV-positive pregnant women assessed by CD4 count or clinical staging at ART initiation	N: Number of HIV-positive pregnant women attending ANC within the past 12 months who were assessed by either CD4 count or clinical staging by the time of ART initiation. D: Number of HIV-positive pregnant women who attended ANC within the past 12 months.	None.	N&D: Programme records, e.g. PMTCT registers, ARV registers, laboratory records.	Measures the extent of clinical assessment of HIV-positive pregnant women, which is recommended, although not a requirement, for ART initiation.
MTCT.19 In-facility deliveries % of HIV-positive pregnant women who deliver at a health facility	N: Number of HIV-positive women who delivered at a health facility within the past 12 months. D: Number of HIV-positive women delivering within the past 12 months.	None.	N: Programme records, e.g. PMTCT registers, labour and delivery records. D: Internationally consistent modelling estimates, e.g. Spectrum AIM. HIV-positive pregnant women serves as proxy.	Measures the programme's ability to identify HIV-positive pregnant women and enable their uptake of PMTCT services at delivery (Prong 3).
MTCT.20 Toxicity-related pre-term deliveries % of pre-term deliveries among HIV-positive pregnant women on ART *Cross-referenced with Toxicity monitoring section ART.13*	N: Number of HIV-positive women who received ART and delivered within the past 12 months who had a preterm birth (<37 weeks gestation). D: Number of HIV-positive women who received ART and delivered within the past 12 months.	Regimen, age, initiation of ART before conception during 1st, 2nd or 3rd trimester, gestational age of pre-term birth (<28 weeks, 28 to <32 weeks, 32 to <37 weeks).	N&D: Programme records, e.g. MCH card with integrated PMTCT record.	Higher than expected rate suggests the need for more formal assessment and consideration of national policy on use of ARVs during pregnancy.
MTCT.21 EMTCT case rate Case rate of new paediatric HIV infections due to MTCT of HIV per 100 000 live births.	N: Number of new paediatric HIV cases due to MTCT. D: Estimated numbers of births within the same calendar year (100 000).	None.	N: Case reports, estimates from HIV facility survey. D: Vital statistics, estimates of live births such as from UN Population Division estimates, estimates from surveys.	Impact indicator for EMTCT validation to demonstrate very low rate of MTCT of HIV. Needs to be reviewed with the other EMTCT validation impact indicator on MTCT rate (MTCT.7), and the three process indicators for EMTCT validation: ANC coverage, testing coverage (MTCT.1) and treatment coverage (MTCT.2). Investigations of each case is important to understand reasons for transmission. Sensitivity analyses can help understand range if data are incomplete.

2.5 Evaluating impact

Impact measurement aims to collect evidence on the ultimate overall effects of HIV prevention, care and treatment programmes. The impacts of the epidemic and of the health sector response to HIV can be monitored and evaluated from the perspective of mortality, morbidity and disability as well as from the perspective of other changes such as behavioural, societal and economic trends. AIDS-related deaths (IMP.1) and New infections (IMP.2) are the most important health impact indicators for evaluating the effectiveness of HIV programming in the health sector. While these indicators pose challenges for direct measurement, trying to measure them is important.

9. AIDS deaths

Number of AIDS-related deaths and ratio to people living with HIV

Otherwise, the effects of the health sector response can be assessed only with output indicators such as retention and viral load suppression. A health programme needs to be clear about its impact measurement and trends – in particular, mortality and incidence. These are the end values of the health sector cascade and of the result chain. Also, measuring impact is essential to evaluating the contribution of each stage, for example prevention can have a direct impact on incidence. Often, review should start with impact and work backwards along the results chain. A programme needs to relate impacts to outcomes, including preventive behaviours and treatment, at each stage of the cascade. This stage of evaluation and review is critical to understanding the reasons for changes in HIV incidence and mortality, the contributions of interventions at different stages of the cascade and how the health sector response can be improved.

2.5.1 Mortality measurement

One of the clearest indicators of national programme success in the scale-up of HIV prevention, treatment and care is a decrease in mortality due to HIV-related causes.[1,2] Without these data countries are unable to effectively assess the impact of their national response to the HIV epidemic. Global AIDS Response and Progress Reporting (GARPR) (formerly known as UNGASS), the Millennium Development Goals, and the Road Map for Universal Access to HIV Prevention, Treatment, Care and Support all have at least one indicator measuring HIV-related mortality.

A robust vital registration or civil registration system that provides high quality, directly measured HIV-related mortality data is the best way to monitor mortality. For every death, civil registration systems should collect information such as date and cause of death, age, sex and place of residence. If analysed and disaggregated carefully, mortality data by age and sex (without cause of death) can often be used to highlight trends in HIV mortality, particularly among those ages 15–49.

Few countries have high quality civil registration systems, however; information on cause of death (COD) is particularly lacking.[3] In such situations mortality can be analysed in a sample of facilities, cohorts or sites.

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[1] Lallemant C, Halembokaka G, Baty G, Ngo-Ngiang-Huong N, Barin F, Le Couer S. Impact of HIV/AIDS on child mortality before the highly active antiretroviral therapy era: a study in Pointe Noire, Republic of Congo. J Trop Med. 2010. Article ID 897176, (http://dx.doi.org/10.1155/2010/897176).

[2] Le Coeur S, Khlat M, Halembokaka, G, Augereau-Vacher C, Batala-M'Pondo G, Baty G, et al. HIV and the magnitude of pregnancy-related mortality in Pointe Noire, Congo. AIDS. 2005;19(1):69–75 (http://link.springer.com/10.1186/1742-4755.6.6).

[3] Mathers CD, Ma Fat D, Inoue M, Rao C, Lopez AD. Counting the dead and what they died from: an assessment of the global status of death data. Bull World Health Organ. 2005;83:171–77. (http://www.who.int/bulletin/volumes/83/3/171.pdf).

Recognizing the need to build on existing data collection systems, WHO and UNAIDS recommends both short- and medium-term goals for measuring HIV-related mortality.[1] The short-term goals focus on obtaining the best possible measures of HIV-related mortality using existing systems and resources. The medium-term goals look to identifying opportunities and advocacy strategies for creating stronger civil registration systems.

Short-term use of available measures of mortality

In the absence of complete records or reliable cause-of-death data in civil registration systems, the following options for measuring HIV-related mortality are suggested:

Facility-based mortality surveillance. HIV surveillance officers are already responsible for HIV case reporting based on data from HTS and treatment and care services. In such surveillance deaths among HIV-infected individuals should be a reportable condition. There are major drawbacks to relying on HIV case-based surveillance to measure mortality: It is not representative of the entire population, since many people do not know their HIV status. Also, coverage is often incomplete, since some areas lack HIV treatment and care services. Further, HIV case reporting systems are often weak in the same countries that lack civil registration systems. Still, in many countries mortality data by age and sex from a sample of hospitals or health centres can be used to establish trends in AIDS-related deaths. These data have to be analysed and extrapolated to the population with care. Over time, training in cause-of-death and International Classification of Diseases (ICD) coding can make this an important source of mortality data.

Other health information systems may already document AIDS deaths, including hospital discharge records, jail or prison registers, other infectious disease surveillance systems (for example, TB case-based registries) and facilities that serve higher risk populations (for example, drug or alcohol treatment or needle–syringe exchange programmes). Each of these sources of data is incomplete on its own, and in some cases data sources may overlap, duplicating counts. Using these mortality data sources singly or in combination requires initially assessing whom the data represent and the quality of the information that was the basis for determining cause of death. Further, the recorded information may not identify HIV-specific mortality accurately, as the death may have been attributed to the immediate cause of illness (for example, cancer, cardiovascular or neurological disease), overlooking underlying HIV-related disease. Conversely, a person living with HIV who has responded well to ART may die from a drug overdose, accident or any other condition unrelated to HIV.

Verbal autopsy. Verbal autopsy (VA) is the mortality measurement tool most commonly used in the absence of reliable civil registration data. A VA involves the interview of family members or close friends about the events surrounding the death of a person, conducted by a trained interviewer who codes data using a structured format. Based on this documentation cause of

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[1] WHO/UNAIDS Working Group on Global HIV/AIDS and STI Surveillance. Guidelines for HIV mortality measurement. Geneva: World Health Organization; 2014 (http://www.who.int/hiv/pub/surveillance/2013package/module6/en/).
[2] Soleman N, Chandramohan D, Shibuya K. Verbal autopsy: current practices and challenges. Bull World Health Organ. 2006;84:239–245 (http://www.who.int/bulletin/volumes/84/3/239.pdf).
[3] Verbal autopsy standards: ascertaining and attributing causes of death. Geneva: World Health Organization; 2007 (http://www.who.int/healthinfo/statistics/verbalautopsystandards/en/).
[4] Lopman B, Barnabas RV, Boerma JT, Chawira G, Gaitskell K, Harrop T. Creating and validating an algorithm to measure AIDS mortality in the adult population using verbal autopsy. PLoS Med. 2006;3:e312.
[5] Hill K, Lopez AD, Shibuya K, Jha P. Monitoring of Vital Events (MoVE). Interim measures for meeting needs for health sector data: births, deaths, and causes of death. Lancet. 2007;370(9600):1726–35. doi:10.1016/S0140-6736(07)61309-9.
[6] Verbal autopsy standards: ascertaining and attributing causes of death. Geneva: World Health Organization; 2007 (http://www.who.int/healthinfo/statistics/verbalautopsystandards/en/).
[7] Setel PW, Sankoh O, Velkoff VA, Mathers C, Gonghuan Y, Hemed Y. Sample registration of vital events with verbal autopsy: a renewed commitment to measuring and monitoring vital statistics. Bull World Health Organ. 2005;83:611–617 (http://www.who.int/bulletin/volumes/83/8/611.pdf).
[8] Ngo AD, Rao C, Hoa NP, Adair T, Chuc NT. Mortality patterns in Vietnam, 2006: Findings from a national verbal autopsy survey. BMC Res Notes. 2010;3:78. doi: 10.1186/1756-0500-3-78.

death is determined, most often by a physician trained in VA methods.[2] Studies have found that VA measures AIDS deaths consistently.[3]

The main limitation of VA is recall bias, that is, remembering events differently from the way they happened or remembering incompletely.[4] Good interviewers and well-trained coders are essential for a valid VA system. For measuring AIDS-related deaths, identification of HIV-related cause of death has been simplified by the use of seven signs and symptoms.[5] WHO has developed standards for VA.[6]

Measuring national-level HIV-related mortality by means of VA can be done in several ways (listed in order of priority on the basis of presumed relative data quality):

- through sample vital registration with verbal autopsy (SAVVY). Nationally representative SAVVY systems have been proposed as a cost-effective alternative to full national civil registration.[7] SAVVY allows countries not yet ready to establish full national systems to collect data that provide an accurate estimate for the population as a whole. Currently, Bangladesh, China, India and Pakistan have standardized nationally representative SAVVY systems. Other countries are developing such systems.[8]
- by adding VA to general population surveys such as the Demographic and Health Surveys and asking retrospectively about deaths among family/household members.
- by including VA in prospective cohort studies such as the Demographic Surveillance Systems, which identify deaths over time among a nationally representative sample.
- through VA in conjunction with burial systems such as cemetery surveillance, burial society and parish registries, and morgue surveillance with cadaver autopsy. Burial system surveillance builds on existing registration systems by adding training on conducting verbal autopsy and understanding local terms for AIDS-related deaths.[1] There are some limitations, including the fact that the sample is unlikely to be nationally representative. For example, burial registration fees that discourage formal burials may lead to undercounting of women's and children's deaths.[2]

Verbal autopsy can also be used to measure AIDS-related deaths in key populations and other specific sub-populations, for example, deaths identified among clients of drug treatment centres.[3]

Spectrum modelling to estimate the mortality impact of AIDS. UNAIDS regularly publishes global, regional and national estimates of the number of AIDS-related deaths. The Spectrum standardized modelling tools generate these estimates. These tools provide the flexibility to adjust parameters to the country-specific epidemic situation and context.[4] Regular updates and training workshops are undertaken every two years to improve the way that data are used and the fit of the models.

Medium-term strategic planning for measuring AIDS deaths

Civil registration is the continuous, permanent, mandatory and universal recording of important life events (for example, birth, death, marriage) in accordance with the legal requirements

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[1] Araya T, Reniers G, Schaap A, Kebede D, Kumie A, Nagelkerke N, et al. Lay diagnosis of causes of death for monitoring AIDS mortality in Addis Ababa, Ethiopia. Trop Med Int Health. 2004;9(1):178-86. (http://www.ncbi.nlm.nih.gov/pubmed/14728623).
[2] Reniers G, Araya T, Davey G, Nagelkerke N, Berhane Y, Coutinho R, Sanders AJ. Steep declines in population-level AIDS mortality following the introduction of antiretroviral therapy in Addis Ababa, Ethiopia. AIDS. 2009;23(4):511–518. doi: 10.1097/QAD.0b013e32832403d0 (http://www.ncbi.nlm.nih.gov/pubmed/19169138).
[3] Cleland CM, Desjarlais DC, Perlis TE, Stimson G, Poznyak V. WHO Phase II Drug Injection Collaborative Study Group. HIV risk behaviors among female IDUs in developing and transitional countries. BMC Public Health. 2007;7:271 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2140060/).
[4] Case KK, Hallett TB, Gregson S, Porter K, Ghys PD. Development and future directions for the Joint United Nations Programme on HIV/AIDS estimates. AIDS 2014;28 Suppl 4:S411–414. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4247265/pdf/aids-28-s411.pdf).

of a country.[1] It includes the process of analysing, presenting and sharing these data. WHO guidance is available to help countries establish or strengthen civil registrations systems.[2] Civil registration systems should be strengthened at all levels, as this has major benefits for HIV programmes, other health programmes and beyond.

Cause of death is a critical element of indicators used to evaluate the impact of any health programme, including HIV prevention, treatment and care programmes. The International Statistical Classification of Diseases and Related Health Problems, version 10 (ICD-10) provides the current version of standard codes for causes of death. Using these codes helps to assure consistency within viral registration systems and among countries.[3] However, few low- or middle-income countries document cause-of-death nationally; when they do, data quality can be poor.[4] It is estimated that cause of death remains unregistered in more than two-thirds of the world's population.[5]

Several electronic resources can help with coding cause of death, for example,, the United States National Center for Health Statistics' Mortality Medical Data System.[6] WHO supports the process of simplifying or abridging ICD-10 codes. Efforts to standardize the simplified coding are underway. In Cape Town, South Africa, for example, the simplified coding makes helpful information on the distribution of diseases, including HIV, quickly available.[7]

The most appropriate medium-term strategies will focus on establishing or strengthening a civil registration system. Such a system will facilitate HIV mortality surveillance. HIV surveillance officers can contribute to strengthening the health information system, by sharing information and HIV expertise, forming strategic partnerships with civil authorities and researchers and creating linkages with HIV prevention, treatment and care services that can report deaths.

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[1] Rao C, Osterberger B, Dam Anh T, MacDonald M, Kim Chúc N, Hill P. Compiling mortality statistics from civil registration systems in Viet Nam: the long road ahead. Bull World Health Organ. 2010;88:58–65. doi: 10.2471/BLT.08.061630. (http://www.who.int/bulletin/volumes/88/1/08-061630/en/).

[2] Improving the quality and use of birth, death and cause-of-death information: guidance for a standards-based review of country practices. Geneva: World Health Organization; 2010 (http://www.who.int/healthinfo/tool_cod_2010.pdf).

[3] International statistical classification of diseases and related health problems. Geneva: World Health Organization; 2010 (http://www.who.int/classifications/icd/ICD10Volume2_en_2010.pdf?ua=1).

[4] Mathers CD, Ma Fat D, Inoue M, Rao C, Lopez AD. Counting the dead and what they died from: an assessment of the global status of cause of death data. Bull World Health Organ. 2005;83:171–177.

[5] Rao C, Lopez AD, Hemed Y. Chapter 5. In: Jamison DT, Feachem RG, Makgoba MW, Bos ER, Baingana FK, Hofman KJ, et al., editors. Disease and mortality in sub-Saharan Africa. 2nd edition. Washington (DC): World Bank; 2006. (http://www.ncbi.nlm.nih.gov/books/NBK2279/).

[6] United States Centers for Disease Control. Mortality Medical Data System (http://www.cdc.gov/nchs/nvss/mmds.htm).

[7] Dorrington R, Bradshaw D, Bourne D. Two steps forward, one step back: comment on adult mortality (age 15–64) based on death notification data in South Africa for 1997–2001. S Afr Med J. 2006;96(10):1028. (http://blues.sabinet.co.za/WebZ/Authorize?sessionid=0:autho=pubmed:password=pubmed2004&/AdvancedQuery?&format=F&next=images/ejour/m_samj/m_samj_v96_n10_a6.pdf).

Table 2.27 Characteristics of mortality measurement data sources

	Vital statistics (civil registration)	Retrospective (household survey)	"Facility"	Prospective (community surveillance)
Example	National civil registration system	Census, Demographic & Health Survey	Sample of hospital or health centre records, cancer registry, burial society records	Demographic Surveillance Site
Coverage	National	National	National sample, or less, but typically no denominator	Limited
Representative sample?	SAVVY sample registration system can be representative	Yes	Possible but would require sample of sites based on use rates	No
Key analytical concerns	Event report completeness and accuracy	Reporting biases in numerator and denominator	Facility use/ coverage; denominator is estimated	Completeness of event reports; numerator is estimated
Verbal autopsy (VA) versus medical certificate (medical certificate implies physician diagnosed cause of death)	National VA system is more costly and logistically challenging but can complement medical certificate system	Use VA	Medical certificate possible in medical facilities, but VA used in most circumstances	VA; medical certificate if linked to health facilities with physicians

Table 2.28 shows how more routine mortality statistics, initially by age and sex, and then by cause, should be developed, depending on the coverage of civil and vital registration.

Table 2.28 Strategies for civil registration and vital statistic system (CRVS) development plan in order to generate reliable, continuous and representative mortality statistics, including causes of death

	Registration coverage <60%	Registration coverage 60–79%	Registration coverage ≥80%
CRVS Platform	Increase multi-sector coordination; improve registration coverage; apply verbal autopsy to registrated deaths	Improve registration coverage; apply verbal autopsy to registered deaths; absorb sample registration system (SRS)/ SAVVY into CRVS	Focus on completeness
Innovation	Sample vital registration (SVR) in representative CRVS areas with verbal autopsy; link to health sector	Record linkage across mortality databases through unique individual IDs	Record linkage across mortality databases through unique individual IDs
Facilities statistics	Birth and death notification; certification and coding of cause of death (ICD short list)	Birth and death notification; data quality assurance; death certification and coding using full ICD	Data quality assurance; death certification and coding using full ICD
Optimizing data from multiple sources	Analytical use of partial data from urban areas; capacity development for data quality assurance; data analysis, interpretation and use	Analytical use of partial data from urban areas; capacity development for data quality assurance; data analysis, interpretation and use	Capacity development for data quality assurance; data analysis, interpretation and use

Source: Improving mortality statistics through civil registration and vital statistics systems. Guidance for country strategies and partner support. Geneva; World Health Organization; 2014 (http://www.who.int/healthinfo/civil_registration/CRVS_MortalityStats_Guidance_Nov2014.pdf?ua=1)

Table 2.29 Programme indicators for AIDS-related deaths

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
IMP.1 AIDS-related deaths Estimated number that have died due to AIDS-related causes and rate of AIDS-related deaths per 100 000 population Global indicator	N: Total number who have died of AIDS-related illness in a 12-month period D: Population (100 000).	Sex, age (<5, 5–14, 15+), geographical location.	Internationally consistent modelled estimates, e.g. Spectrum AIM. *See also box, next page.*	AIDS-related mortality rate measures the health impact of HIV care and treatment. Progressive improvement of vital registration will facilitate measurement of this indicator. AIDS-related mortality rate

Resources for country mortality surveillance systems

1. Data collection: death registration tools (forms, variables and specifications of data elements)

Automated data collection tools: International Repository for Information Sharing (IRIS) interactive coding system for causes of death, electronic forms. http://www.cepidc.vesinet.inserm.fr/inserm/html/IRIS/iris_project.htm

2. ICD-10: training tools, electronic version, manuals

ICD-10 interactive self-learning tool: full ICD-10 training and cause of death certificate, version 10. Geneva: World Health Organization; 2010 (http://apps.who.int/classifications/apps/icd/icd10training/).

Download and run on local computer:

http://apps.who.int/classifications/apps/icd/ClassificationDownload/DLArea/OfflineTrainingPackage.zip

3. Cause of death certificate ICD-10 interactive self-learning tool

Geneva: World Health Organization; 2010

(http://apps.who.int/classifications/apps/icd/icd10training/ICD-10%20Death%20Certificate/html/index.html).

4. Cause of death on the death certificate: quick reference guide

Geneva: World Health Organization; 2010

(http://apps.who.int/classifications/apps/icd/icd10training/ICD-10%20Death%20Certificate/html/ICD-10_Resources/causeofdeathflyer.pdf).

5. WHO–FIC Network Mortality Forum

(https://sites.google.com/site/mortalityforum/).

6. International statistical classification of diseases and related health problems, 10th revision (ICD-10)

Geneva: World Health Organization; 2010

(http://www.who.int/classifications/icd/en/).

7. Verbal autopsy (WHO short form, WHO research questionnaire)

Verbal autopsy standards. Geneva: World Health Organization; 2012

(http://www.who.int/healthinfo/statistics/verbalautopsystandards/en/index.html).

8. Tools for cause-of-death ascertainment: physician coding, InterVA

InterVA is a software to facilitate interpreting VAs. http://www.interva.net/.

9. Editing, analysing and presenting/communicating causes of death data

ANACOD tool: http://www.who.int/healthinfo/topics_standards_tools_data_collection

CODEdit: http://www.who.int/healthinfo/civil_registration/en/

CODPresent: http://www.who.int/healthinfo/civil_registration/en/

10. Analysing mortality levels and causes-of-death – ANACOD

World Health Organization, University of Queensland, Health Metric Network, 2013 (http://www.who.int/healthinfo/topics_standards_tools_data_collection).

2.5.2 HIV prevalence and incidence

The estimation of new HIV infections – that is, the rate at which new HIV infection is acquired in a population – is the gold standard for evaluating the impact of HIV prevention programmes. Surveillance of HIV incidence aims to identify patterns, through comparisons over time or between population groups, so as to inform policy-makers' decisions about resource allocation.

10. New infections

Number and % of new HIV infections

New infections tends to require not only monitoring and modelling but also evaluation to establish trends and to identify plausible determinants along the health sector cascade. A number of different methodological approaches have been used to estimate new HIV infections; each has its strengths and limitations.

It is important to consider all available means of measuring incidence and to triangulate the findings, taking into account the strengths and limitations of the approaches. Incidence that is derived from more than one method is likely to be more credible than one based on a single method. Inconsistencies between results with different methods also can be illuminating, as the methodological differences may provide sufficient explanation.

Incidence may be measured in the context of a comprehensive HIV surveillance system or in special studies designed to evaluate specific interventions. Also, it can be measured for the general population or for selected (that is, sentinel) subpopulations that are perceived to be at higher risk of infection.

In the context of an evaluation study, incidence ratios can be used to evaluate the impact of an intervention – that is, comparing incidence between two time periods or between two populations. The main challenge of such a study is to select populations in which enough new infections will occur in the study period to provide sufficient power for estimating absolute levels of incidence.

Direct methods

There are two direct method of measuring incidence:

- **Longitudinal follow-up of individuals who do not have HIV infection.** This method involves repeated testing of the selected cohort to determine the proportion that has acquired infection over time. This method requires substantial resources, and the generalizability of these estimates to a wider population is limited because the study participants are selected rather than identified randomly, and the intensive engagement that comes with enrolment in a cohort study or trial, often involving risk reduction counselling and other prevention measures, leads to behaviour that differs from that of the larger population.
- **Estimation using laboratory tests for recent HIV infection.** The development of laboratory tests that can distinguish recent infections from long-standing infections is a promising approach to measuring new HIV infections. This method can be applied to specimens collected in cross-sectional surveys rather than requiring repeated data collection from a cohort over time. However, biases can arise through the choice of sampling frame and the potential for longstanding infections to be misclassified as recent (the so-called "false recent rate"). Another challenge to using this approach with currently available assays has been the variation in assay performance across HIV clades and population groups.

Continued reliance on HIV prevalence rather than new HIV infections measures

Despite the importance of incidence as a public health indicator, most prevention programmes and surveillance systems have focussed on measuring the population point prevalence of HIV infection (the proportion currently living with HIV infection) rather than incidence, due to the

difficulty of obtaining reliable incidence estimates. Even in high incidence settings, such as eastern and southern Africa, the occurrence of a new, or incident, infection is a relatively rare event. Thus, very large sample sizes are required to measure incidence.

Prevalence is a useful public health index. When analysed carefully by age, sex and cohort, it can be used to assess trends in underlying incidence, particularly in younger age groups. Confounders, such as survival, migration and birth rates, have to be carefully assessed and taken into account. Moreover, with the large-scale expansion of ART programmes in many countries and the longer survival of people living with HIV, treatment needs to be taken into account as well, particularly in older age groups.

Indirect methods

Due to the much greater feasibility of HIV prevalence studies, a number of indirect methods have been developed for using prevalence data to estimate the incidence of HIV in a population.

- **Modelling estimation of incidence from serial prevalence surveys.** This approach, which is used in modelling tools such as Spectrum, assumes that trends in HIV prevalence observed in HIV surveillance are the net effect of the incidence between estimates, after accounting for changes in mortality, levels of in- and out-migration among people living with HIV, and ART coverage. This approach has been used widely to project national HIV incidence estimates in the general population and key populations, particularly in countries that have ongoing, routine sero-surveys of pregnant women attending antenatal clinics (ANC surveillance).[1]
- Recently, newer models have used HIV prevalence data from two sequential national population-based household surveys, where incidence was inferred for age cohorts, similarly using assumptions about mortality and migration.[2] The main limitations to this approach are the lack of reliable information on migration and mortality among people living with HIV and the lack of nationally representative population-based prevalence surveys at frequent intervals. However, there are also important advantages of this approach, when the data are analysed carefully.
- **Modelling estimation of incidence using assumptions about risk behaviour and HIV transmission.** These models focus on populations with available HIV prevalence data and relevant risk behaviour data (for example, frequency of unprotected sex, rate of partner change) to produce estimates of the numbers of new infections.[3] This approach depends on good information on risk behaviours and prevalence and relevant transmission rates.
- **Indirect estimation from HIV prevalence in young, recently exposed populations.** This method assumes that, in populations in whom the time since first exposure to HIV infection is believed to be short, trends in prevalence approximate trends in incidence. For example, in populations where women first have sex at age 15 on average, trends in the prevalence of HIV in women ages 15–24 have been used as an approximation of trends in incidence in the broader male and female adult population. This approach depends on the availability of HIV testing for a large number of young people and careful analysis of trends by age, sex and cohort (particularly where data can be disaggregated to single-year ages).

[1] UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance: When and how to use assays for recent infection to estimate HIV incidence at a population level. Geneva, UNAIDS and WHO, 2011 (http://www.who.int/diagnostics_laboratory/hiv_incidence_may13_final.pdf).
[2] Ibid.
[3] Methodology – understanding the HIV estimates. Geneva, UNAIDS, 2013 (http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/20131118_Methodology.pdf).

Table 2.30 Indicators of HIV incidence and prevalence

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
IMP.2 New infections Number and % of new HIV infections 	N: Number of new infections D: 1000 uninfected population, which is the total population minus people living with HIV.	Sex, age (0–14, 15–24, 15–49), key population* (ages <25, 25+), for children: mode of infection (including MTCT) location.	Analysis of country data on HIV prevalence, particularly among young age groups and, where available, direct HIV incidence data; internationally consistent modelled estimates, e.g. Spectrum AIM.	This indicator is important for monitoring both epidemic trends and dynamics within the population monitored. It is most often derived from analysis of country HIV prevalence by age, sex and cohort, HIV incidence (as available) and the application of epidemiological estimation models. The reporting of newly diagnosed HIV cases – mandatory in certain countries – may provide another reference value. Used as a numerator to estimate a ratio to population size.
Additional indicators				
IMP.3 Incidence Rate/year	N: Number of new infections per year. D: Total population x 100.	Sex, age (0–14, 15–24, 15–49), time period.	Internationally consistent modelled estimates, e.g. Spectrum AIM.	Incidence should be expressed in terms of population and time period, generally per year.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

IMP.4 Prevalence % of people infected with HIV	N: Total number of infections. D: Total population.	Sex, age (for general population: <1, 1–4, 5–14, 15–24, 15–49, 50+; also 15–24 (15–19, 20–24) for surveys and surveillance), pregnancy status, coinfected with TB, ART eligibility, location.	Surveys of general population and key populations. See also surveillance guidelines for general or key populations. Data are directly applicable only to survey location; statistical approach needed to extrapolate to national level.	Trends in prevalence provide an overview of the changing HIV burden, but they need to be interpreted in light of the number of people on ART to understand what proportion of people living with HIV is attributable to new infections. Policy-makers should understand that the number of people living with HIV is increasing thanks to effective treatment and longer survival and not or only partly due to new infections. Prevalence in key populations is an important indicator of the burden and spread of HIV. Prevalence in young populations can be the basis for a proxy of incidence (see IMP.2).
IMP.5 Key population HIV prevalence % of people from key populations who are HIV-infected *Cross-referenced with Key populations section KPOP.6*	N: Number of key population respondents who have tested positive for HIV. D: Number of key population tested for HIV.	Key population (men who have sex with men, people in prisons and other closed settings, people who inject drugs, new initiators of injecting drug use; sex workers, transgender), sex, age (15–19, 20–24, 25+); young (15–19) men who have sex with men; pregnancy status, coinfected with TB, ART eligibility, location.	N&D Sentinel surveillance. Trends in prevalence provide an overview of the changing HIV burden, but they need to be interpreted in light of the number of people on ART to understand what proportion of people living with HIV is attributable to new infections.	Measures the overall state of the epidemic among key populations. HIV prevention among various populations is a core indicator. Policy-makers should understand that the number of people living with HIV may be increasing thanks to effective treatment and longer survival and not or only partly due to new infections.

2.5.3 MTCT rate

Success in preventing mother-to-child transmission of HIV is the ultimate measure of PMTCT programmes. One of the key recommended indicators for PMTCT programmes is the MTCT rate (MTCT.7; see Table 2.26).[1,2] This is a direct outcome measure of vertical transmission. It can be defined as the estimated percentage of HIV infections among the infants of HIV-positive women delivering in a time period, usually the past 12 months. Scaling up PMTCT programme coverage to provide ART along with safer infant feeding practices could reduce the incidence of HIV infection among children born to HIV-positive mothers (for example, HIV-exposed infants) to below 5% in low- and middle-income countries. The Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive,[3] launched in June 2011, has set a global goal to reduce MTCT to less than 5%. This level also is one of the criteria to validate the elimination of mother-to-child transmission in a country. If this target is achieved, mother-to-child transmission will become a controllable condition rather than a missed opportunity to apply a known solution to a public health problem.

It is difficult to measure the MTCT rate directly. First, in breastfeeding populations the numerator – the number of HIV-positive children born – should be assessed after cessation of breastfeeding. The resulting prolonged window of possible transmission lends complexity to the direct measurement of the mother-to-child transmission rate; many HIV-exposed children are lost to follow-up and their outcomes are unknown. For these reasons an approach combining direct measurement and modelling (using the Spectrum AIM package or an alternative modelling tool) is recommended for measuring this indicator. Second, the denominator of the MTCT rate is the total number of women living with HIV who have given birth (population level); it is not limited to the number of women diagnosed as infected with HIV. Thus, both numerator and denominator must be estimated.

The MTCT rate is calculated in a model using the following information:

1. the distribution of HIV-positive pregnant women receiving ARV regimens prior to and during delivery (peripartum) by CD4 category of the mother;

2. the distribution of women receiving ART after delivery (postpartum) by CD4 category of the mother;

3. the percentage of infants in PMTCT programmes who are breastfeeding, by age of the child;

4. the probabilities of MTCT of HIV based on various categories of ARV drug regimen, mother's CD4 level and duration of infant feeding.

The MTCT rate can be modelled every year, but it should be validated against estimates from other, more direct data collection and assessment methods, which are summarized in Table 2.31 and in a 2012 WHO guidance document on assessing PMTCT impact.[4] Triangulating the modelled results with direct measures must be done at a two- to three-year lag due to the need to follow up children past the age of breastfeeding and the greater feasibility of measuring infant infections using the recommended antibody-based diagnostics. The number of new child HIV infections (MTCT.7; see Table 2.26) can be estimated through similar approaches.

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[1] M&E Working Group of the Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children. Global monitoring framework and strategy for the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (EMTCT). Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75341/1/9789241504270_eng.pdf?ua=1).

[2] M&E Working Group of the Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers, and Children. Global monitoring framework and strategy for the Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive (EMTCT). Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75341/1/9789241504270_eng.pdf?ua=1).

[3] Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. Geneva: Joint United Nations Programme on HIV/AIDS; 2011 (http://www.zero-hiv.org/wp-content/uploads/2014/06/Global-Plan-Elimination-HIV-Children-Eng.pdf).

[4] A short guide on methods. Measuring the impact of national PMTCT programmes – towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/75478/1/9789241504362_eng.pdf?ua=1).

Table 2.31 Summary of methodologies to measure the impact of PMTCT programmes

Method	How it is done	What it can measure	Pros and cons	Sustainability, cost
Modelling				
1. Models	Uses HIV sentinel and population-based surveillance data and programme data in a demographic model to estimate results; validated with available country data.	National-level estimates: • Mother-to-child transmission rate • Number of children living with HIV • Number of new HIV infections in children • HIV-related adult and child deaths Sub-national models can be developed as well.	• Relatively easily implemented • Good results require many data. Results are only as valid as the data and the assumptions that go into the models. • Does not help the child or mother get services or know their HIV status.	Internationally consistent software (Spectrum AIM) is available to everyone free of charge. Training in its use is available for country teams every two years.
Surveys and surveillance				
2. Immunization clinic survey	• Test all children attending clinics for DPT 1 immunization to assess HIV exposure (antibody test) and early (around 6 weeks) infection/ transmission (PCR test) • Questionnaire can collect information on intervention uptake to allow for further analysis, interpretation • Later follow-up of identified HIV-exposed children can provide data on later or final infection/ transmission status.	National or sub-national population-level • Early transmission rate • Numbers of HIV-exposed and HIV-positive children • Later or final transmission rate and survival can be assessed, but validity will depend on % of all children who can be tracked at later scheduled immunization visits or followed up from the initial entry point of the study.	• In settings with high immunization coverage, can capture real data on population-level transmission and early infant HIV infection. DPT 1 coverage is usually high • Relatively quick to undertake and can be repeated to provide trend data, especially if a modest amount of additional data is collected at same time • Provides results for children whose mothers did not attend antenatal clinics or receive PMTCT care • Misses children who have died before immunization • Effort needed to minimize loss to follow-up when assessing later/final transmission.	Can be expensive, depending on scope and whether many extra staff must be employed.

3. Household surveys (nationally representative)	• Test children in nationally representative household surveys • Survey can ask questions about PMTCT-related service uptake. (Currently, DHS do not permit questions related to ARVs; however, other population-based surveys have covered them.)	National: • Estimated MTCT rate (if mother also tested) • Number and % of children who are HIV-positive, by age and sex • HIV-free survival, if mother's HIV status also ascertained Data can be further interpreted if additional questions are included.	• Can be conducted as part of periodic population-based surveys usually conducted every 3–5 years (e.g. DHS, MICS) • Adult HIV prevalence must be high (2% or more) or sample size must be large. • Surveys every 3–5 years are not frequent enough but can provide valuable information to triangulate other assessments in high prevalence countries. • Need to address ethics and means of providing test results to people who want to know their status and of linking to care and treatment services.	Expensive to undertake surveys large enough to estimate HIV prevalence among children. Practical only in high prevalence countries.
4. Demographic surveillance site (DSS)	• Household survey asking behavioural and other questions of interest • Test children born to HIV-positive women when conducting routine periodic interviews (e.g. every 6 months or 1 year) • Can also collect data on uptake of PMTCT interventions.	Sub-regional, smaller populations (limited geographical coverage): • Transmission rate • Number of HIV-positive children • Estimation of new HIV infections in DSS population.	• Some DSS already exist. • More appropriate for research than for routine periodic assessment of national impact.	• Not always sustainable over time • Inexpensive if added to existing surveillance sites.

Programme data				
5. Analysis of EID data	• Analyse routinely collected early infant diagnosis (EID) data. Postnatal transmission can then be estimated in order to predict final transmission rate. • Questions can be added in lab requisition forms to collect additional data.	• In settings with almost universal EID coverage, national EID-positive rate • In settings with suboptimal EID coverage, combine with estimates of population lost to follow-up and their outcomes to get a more nationally representative estimate.	• EID lab registers usually consolidate these data from patient-specific registers. • Where EID coverage is low, results should be interpreted cautiously.	Should be systematically analysed as part of EID database.
6. Collection of cohort data	• Retrospective or prospective construction of cohort data, e.g. identify women from ANC files, follow up and try to link with child records; test children as necessary • Routine linking and reporting of PMTCT intervention data and outcomes by ANC visit or birth cohort • Prospective cohort data collected at selected facilities or from a representative sample.	National or sub-national: • Transmission rate • Number of HIV-positive children by age • Survival of mother and child • HIV-free survival of child.	• Collection of outcome data should be part of routine programme monitoring. • Requires names and addresses of all clinic attendees; may need mobile staff to locate women. • Effort needed to minimize loss to follow-up and to trace those lost to follow-up. • Loss to follow-up can be large especially if >3 years. • When various PMTCT interventions (for mother and child) are provided at multiple service delivery points, linking records can be time-consuming, especially without unique patient ID numbers that can be linked.	• Finding all women and children lost to follow-up can be expensive. • Special technology can be used but may be costly – e.g. an electronic system storing all patient histories and test results.
7. Case reporting	Confirmed cases of HIV infection are reported – both prevalence and incidence cases.	National number of new HIV infections by age and sex and location of residence.	• Numbers will be underreported if testing coverage is poor. • Currently, no HIV case reporting system in sub-Saharan Africa.	Sustainable and inexpensive if built into routine monitoring system.

Other useful assessment: Triangulation of existing data				
8. Triangulation of various data sources	Trend data on PMTCT/HIV interventions (e.g. PMTCT ARV coverage, EID coverage, ART coverage) and other health statistics (MCH programme indicators, vital statistics, hospital admissions data, records of other major health events) are reviewed together to explain trends and impact of various HIV services on other health outcomes and mortality.	Review of trends in HIV intervention coverage vis-à-vis other health intervention coverage and outcomes. For example, child mortality rates can be reviewed alongside PMTCT ARV coverage trend.	• Good way to use various data collected from multiple sources and make inferences • Data quality not always ideal.	• Cost to extract data if not readily available • Once a foundation is established, similar exercises can be repeated periodically.

2.5.4 Equity

WHO defines the concept of equity as *"the absence of unfair and avoidable or remediable differences in health among populations or groups defined socially, economically, demographically or geographically"*.[1] Health equity is an ethical principle founded on basic notions of fairness and distributive justice. The concept is closely related to the human rights principle of equal opportunity for all people to be healthy.

Equity and inequity have different meanings from equality and inequality. Equality refers to people's rights to enjoy certain entitlements and, from a legal perspective, to be treated the same way, particularly by the State. While there is general agreement that equity and equality are different concepts and values, the terms are often used in a combined fashion: *"The concept of health equity focuses attention on the distribution of resources and other processes that drive a particular kind of health inequality – that is, a systematic inequality in health (or in its social determinants) between more and less advantaged social groups, in other words, a health inequality that is unjust or unfair"*.[2]

For purposes of monitoring and evaluation, measuring inequity has proved to be more practical, revealing and meaningful to the assessment of public health policy and programme performance than establishing that equity has been achieved.

Inequality can result from random variations, or it can be systematically associated with certain population characteristics, as may be particularly the case for key populations and under-served communities. Inequity is inequality that is systematically associated with socially disadvantaged groups. In the context of HIV prevention, care, treatment and support, blatant inequities need to be detected, monitored, evaluated and redressed, whether they result from deliberate discrimination or from an inadequate appreciation of needs.

[1] Health systems: equity. Geneva: World Health Organization; 2014 (http://www.who.int/healthsystems/topics/equity/en/).
[2] Braveman P, Gruskin S. Theory and methods: defining equity in health. J Epidemiol Community Health. 2003;57:254–258 doi:10.1136/jech.57.4.254. (http://jech.bmj.com/content/57/4/254.full).

In practical terms, the process of identifying inequity consists of detecting inequalities and assessing whether they are systematically associated with social advantage or disadvantage. Inequities may occur anywhere in the result chain: input, process, output, outcome or impact (see section 1.3.1). That is to say, inequities may be seen in both the differing health of advantaged and disadvantaged social groups (outcome and impact) and the distribution of health resources and services across social groups (input, process, output). Inequities may affect a large segment of the population or only particular individuals with a certain combination of characteristics such as gender, age, social status or other defining personal or community characteristics. Therefore, systematic disaggregation of M&E data is necessary to identify differentials within a population sample that may hide beneath group averages. For example, early signs of inequity in access to and use of services may come from disaggregation of programme management data on the proportion of eligible people living with HIV who are treated at care facilities or on their rates of retention in treatment. Significant variance across communities and population strata by gender,[1] age, social, economic or other status may suggest inequity and prompt investigation into the causes.

A variety of methods can monitor and evaluate inequality and inequity.[2] A practical way to detect inequities is to compare the percentage of people in a certain population group (for example, people who inject drugs) who have access to a particular service (for example, ART) with the equivalent percentage among all people living with HIV (IMP.6). For example, 20% of eligible people living with HIV who inject drugs have access to ART, while overall 40% of all eligible people living with HIV have access to ART. If access were equitable, these percentages would be equal.

While IMP.6 focuses on inequity in access to treatment, many of the indicators in this guide can be disaggregated to reveal differences that may reflect inequities. The design and use of indicators to monitor inequity will prioritize populations highly vulnerable to stigma and discrimination and other under-served populations.[3] They will use selected parameters of inputs, outputs, outcomes and impacts measured in these populations and compare them with similar parameters measured in reference populations, such as the population as a whole or another key population or a comparable key population in a different geographic area.

[1] WHO, UNAIDS. Policy statement: ensuring equitable access to antiretroviral treatment for women. Geneva: World Health Organization; 2004 (http://www.who.int/hiv/pub/advocacy/en/policy%20statement_gwh.pdf).
[2] Handbook on health inequality monitoring. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/85345/1/9789241548632_eng.pdf).
[3] Health equity monitor – compendium of indicator definitions. Geneva: World Health Organization; 2013 (http://www.who.int/gho/health_equity/outcomes/health_equity_compendium.pdf).

Table 2.32 Programme indicator of equity

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
IMP.6 Equitable access to ART Ratio of % of a sub-population receiving ART to general population ART coverage rate	Example: N: % of all HIV-positive people who inject drugs and are eligible for ART who are receiving ART as of a specified date. D: % of eligible general population receiving ART as of the same date.	None.	Programme records or surveys depending on the sub-population being compared. Data on key populations are often collected through surveys. Comparisons of ART coverage in different age groups or geographical areas can be extracted from registers or routine records (numerators), as long as there is an estimate of the number of people living with HIV in the sub-population. Example for people who inject drugs (see IDU target setting guide, indicator ART.C.2b.[1]): The numerator is the number of all ART recipients at a specific date with a history of ever injecting drugs divided by the estimated number of people who inject drugs and need ART. The denominator is the number of people in the general population or other comparison population who are receiving ART as of a specific date divided by the estimated number of people in that population who are eligible for ART.	Measures equity in ART coverage by comparing ART use in various groups. Disparities merit further investigation. For example, a disadvantage in one group may be due to stigma or prejudice against a specific group or to stockouts of ARVs in specific types of facilities. Obstacles to equitable access should be analysed and addressed.

[1] WHO, UNODC, UNAIDS technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/77969/1/9789241504379_eng.pdf?ua=1).

2.5.5 Reviewing health and other outcomes

It is important to use the results chain not only to monitor current results, but also to explain trends in impact and to identify opportunities to improve health sector programmes. Trends in mortality and incidence need careful examination to assess how they might reflect programme performance at each stage of the health sector cascade as well as behavioural and non-health factors. This analysis provides critical information to guide the health sector response, identifying where it can be credited with helping reduce new HIV infections or, if mortality or incidence are not declining, where and how prevention and treatment can be improved and expanded.

Regular programme reviews, every one to two years, should start by establishing impact trends and then should work backwards through the stages of the health sector cascade to assess the health sector and non-health factors that may be responsible. These reviews then should focus on the linkages and stages that appear to be key to improving the health sector response. The organization of the indicators in this guide according to the stages of the health sector cascade and the results chain should help make this review systematic.

Programme reviews or more focused epi-reviews should address five basic questions:

1. Are the right actions being taken at each stage of the cascade?

2. Are they being done in the right way, and what will improve them?

3. Are they being done on a large enough scale, and where are there bottlenecks to scaling up?

4. Are the right people being reached, by age, sex, key population, location?

5. Is the programme making an impact?

Table 2.33 summarizes the different types of review that should be undertaken on a regular and predictable schedule.

Regular programme reviews should start by establishing impact trends and then should work backwards through the health sector cascade to assess health-sector and non-health sector factors that may be responsible.

In addition, health outcomes of the health sector response to HIV go beyond HIV-specific morbidity, new HIV infections and equity. They can include reduction in health care expenditures, reduced widowhood and orphanhood and improved health-seeking behaviour, especially seeking preventive services. Therefore, the outcomes and impacts of HIV care and treatment should be documented, monitored and evaluated not only in terms of direct health outputs, outcomes and impacts (for example, service coverage and the reduction of mortality, morbidity and disability) but also in terms of indirect health outcomes and impacts (for example, changing behaviours, nutrition) and other, non-health outcomes and impacts (for example, on productivity or in social terms). Both health and non-health outcomes and impacts cut across the entire sector of human development, and they can be monitored and evaluated on both the individual and collective levels. Table 2.34 provides examples of such health and non-health outcomes.

Table 2.33 Periodic programme reviews

Type	Objective	Focus	Timing and frequency	Review team	Duration
Annual review	Assess implementation Modify implementation plans	Concerned with how well the programme is being implemented: assessing inputs, activities and outputs	Annually or biannually, depending on the country's schedule for regular HIV or health sector reviewing, planning and budgeting	Mostly internal	<1 month
Mid-term review	Assess progress towards achieving programme objectives Inform reprogamming	Considers whether the programme is moving in the desired direction, emphasizing outputs and outcomes as well as impact, where this can be demonstrated	Around the mid-point of the programme cycle	Mixed internal and external	1–3 months
End-term review	Assess the overall performance of the programme Inform the development of a new strategic plan	Examines what the programme has achieved, emphasizing impact and outcomes and associated factors	Toward the end of the programme cycle, before planning for the new cycle	Mixed but with a strong external or independent element	3–6 months

Source: Guide to conducting programme reviews for the health sector response to HIV/AIDS: guidance. Geneva; World Health Organization; 2013 (http://www.who.int/hiv/pub/toolkits/hiv-response-guide.en/)

The impacts of HIV on individuals, families, communities and nations have been well documented and publicized in a rich and growing literature. This evidence has helped to justify expanding responses to the epidemic. Less documented – although increasingly so – are the impacts of HIV care and treatment on the lives of individuals, on communities and on society as a whole. In particular, evidence clearly shows that the introduction, scaling up and quality improvements of ART are having a favourable impact on health and well-being. Evidence is weaker for a favourable impact, at either the personal and collective level, of HIV prevention, care, treatment and support on other factors shaping the relationship between people living with HIV and their societal environment.

Table 2.34 Examples of health and non-health outcomes and impacts of successful health sector response to HIV

	Direct	Indirect
Health outcomes and impacts	**Individual level** • reduced morbidity, disability and mortality • increased quality of life • lower risk of MTCT **Collective level** • reduced transmission of HIV and TB • reinforced community health-seeking behaviours (for example, HIV testing)	**Individual level** • improved nutrition • reduced need for hospital admission • reduced catastrophic health expenditures • reduction of widowhood and orphanhood • reduction of stigma and discrimination in health facilities **Collective level** • lower opportunity cost at health facilities
Non-health outcomes and impacts	**Individual level** • reduction of stigma and discrimination • better fitness to work • reduced absenteeism from work • better school enrolment and attendance, particularly among girls (less need to provide home care for family member) **Collective level** • sustained productivity and livelihoods • less need for retraining	**Individual level** • greater participation in public affairs • sustained housing and employment • reduced stigma and discrimination against the individual **Collective level** • community cohesion • reinforced community trust in health system • increased labour supply • reduction of stigma and discrimination towards key population community • availability of responsive public services (health, schools, transportation, social services) • increased food supply

At the level of the individual, the direct health outcomes and impacts of ART include measurable improvements in health status, life expectancy, and reproductive choices and outcomes among people infected and affected by HIV. Indirect health benefits of ART accrue as well, to people living with HIV and to their families and friends, as the adverse social and economic consequences of unattended HIV infection are alleviated. For example, the availability of treatment for HIV, when accompanied by effective community organization and education, gradually reduces the stigma and discrimination associated with HIV and such associated diseases as TB and cancer. Such trends have been noted in countries where access to ART is good, although efforts still must be increased throughout the world to promote and protect the social inclusion of key populations, particularly people from key populations who are living with HIV. From a financial perspective, publicly or privately funded ART, provided free to the client or on a basis of fairly shared cost, reduces both personal out-of-pocket

expenditures and the public cost of hospital care. These savings should be factored into the cost–benefit analysis of new therapies and supporting biomedical monitoring.

Better health made possible by a successful ART programme benefits individuals living with HIV and their families in many other ways. Better health restores opportunities to earn income and increases self-reliance as members of the labour force return to work, their productivity increases, and absenteeism declines. Also, better health diminishes the burden of care placed on the family (which is often heavier on women and girls than on their male relatives). Better health allows children to benefit from sustained parental support and extends opportunities for girls and boys to attend school and vocational training. It protects the integrity of family ownership, in particular of a home and in rural areas of land, livestock and other means of food production.

On the collective level (that is, communities and other populations groups) successful ART programmes can help reduce the inequalities and inequities that people vulnerable to, or living with, HIV are exposed to as a result of social exclusion and/or lack of access. Social, economic, cultural, civil and political factors may still impede timely and sustained use of ART. But at the same time, access to ART and resulting improved health can restore people's ability to live productive and dignified lives and to claim their rights.

The opportunity and ability of all people living with HIV to exercise the range of their human rights is bound up with equitable access to HIV prevention, care, treatment and support.

Human rights principles, norms and standards provide a clear and practical framework for monitoring and evaluating non-health outcomes and impacts of ART. The capacity to exercise human rights should be monitored and evaluated as one potential impact of HIV programmes. In practical terms, the exercise of human rights can be gauged by the extent to which people living with HIV can, free from discrimination, obtain education, housing and employment, obtain food and maintain adequate nutrition, receive and impart information, establish a family, travel or participate in public affairs (see, for example, IMP.11, IMP.14). At the same time, the opportunity for health is itself a human right. The opportunity and ability of all people living with HIV to exercise the range of their human rights is bound up with equitable access to HIV prevention, care, treatment and support.

The health sector alone cannot and should not be held accountable nor credited for all of these outcomes and impacts on the lives of people living with HIV, their families and their communities. Nevertheless, the ability of the health sector to provide, collaboratively with other sectors, evidence of the extensive positive health and non-health outcomes and impacts of ART will strengthen arguments in favour of expansion and sustained investments in the health sector response.

As an illustration of M&E indicators of health and non-health impacts, the tables present a set of selected health indicators on nutrition among people living with HIV and orphans[1] (Table 2.35) and a set of non-health indicators (Table 2.36) concerning stigma and discrimination towards people living with HIV,[2] food security, access to education, per-capita household expenditures and external support for poor families. Many other indicators exist of non-health impacts of the health sector response to HIV. It may not always be possible to attribute

[1] Heap AN. Harmonized indicators for nutrition and HIV. [Washington, DC: United States Agency for International Development; 2012] (http://www.healthqual.org/sites/default/files/Summary%20-%20Harmonized%20Indicators%20for%20Nutrition%20and%20HIV%20Final%202%2012.pdf).

[2] The People Living with HIV Stigma Index: An index to measure the stigma and discrimination experienced by people living with HIV. Geneva: Joint United Nations Programme on HIV/AIDS; 2008 (http://www.stigmaindex.org/sites/default/files/page-attachments/UserGuide_FINAL_complete0055.pdf).

particular impacts to specific health sector interventions. Still, the plausible association between successful health outcomes on the individual and collective levels and improvements in human security, social inclusion and quality of life argues for sustained efforts and investments in HIV prevention, care and treatment.

Table 2.35 Examples of indicators of health impacts of HIV and ART: nutrition

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
Additional indicators				
IMP.7 Undernutrition in people living with HIV Number and % of people in HIV care and treatment with undernutrition	N: Number of people in HIV care and treatment who were identified as undernourished at any point during the reporting period. D: Number of people living with HIV who are under HIV care and treatment.	None.	Review of facility records.	n/a.
IMP.8 Malnutrition/ underweight Prevalence of malnutrition/ underweight among orphaned and vulnerable children compared with other children	N: Number of orphaned children meeting malnutrition/ underweight criteria. D: Population in same age group.	Sex, age.	Cross-sectional surveys among orphans and other children.	n/a.
IMP.9 Food access of people living with HIV Number and % of people receiving HIV care and treatment services whose households have poor access to food	N: Number of people receiving HIV care, treatment and support services with poor access to food as indicated on the Household Hunger Scale. D: Number of people receiving HIV care, treatment and support services.	Sex, age (15–19, 20–24, 25–49), key population,* geographic location, socioeconomic variables.	Population-based survey and/or facility-based prevalence survey.	Suboptimal access to food may be a factor in vulnerability to poor care outcomes. It can result from the inability of people living with HIV to ensure stable livelihood due to illness.

* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

Table 2.36 Examples of indicators of non-health outcomes and impacts of ART: stigma and discrimination

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
Additional indicators				
IMP.10 Attitudes towards people living with HIV % of people ages 15–49 expressing accepting attitudes towards people living with HIV	N: Number of adults in survey sample expressing accepting attitudes towards people living with HIV. D: Number of adults interviewed.	Sex, age (15–19, 20–24, 25–49), education level (none, primary, secondary or higher).	Population-based surveys.	n/a.
IMP.11 Key population experience with discrimination % of member of key populations who experienced discrimination *Cross-referenced with Key population section KPOP.7*	N: Number of people living with HIV interviewed who report experiencing stigma and discrimination within the past 12 months. D: Number of people from key populations who sought clinical services within the past 12 months.	Sex, age (15–19, 20–24, 25–49), key population/ risk behaviour, in care or not, selected social and economic attributes (e.g. race, ethnicity, migrant status), source of stigma and discrimination (e.g. prospective employer, neighbourhood, health-care providers, other service providers).	Proposed, untested indicator Could be assessed through key population interviews or in exit interviews at health facilities. Measure once every 2 - 3 years.	Measures discrimination against key populations, which may inhibit use of health sector services and discourage participation in programme activities.

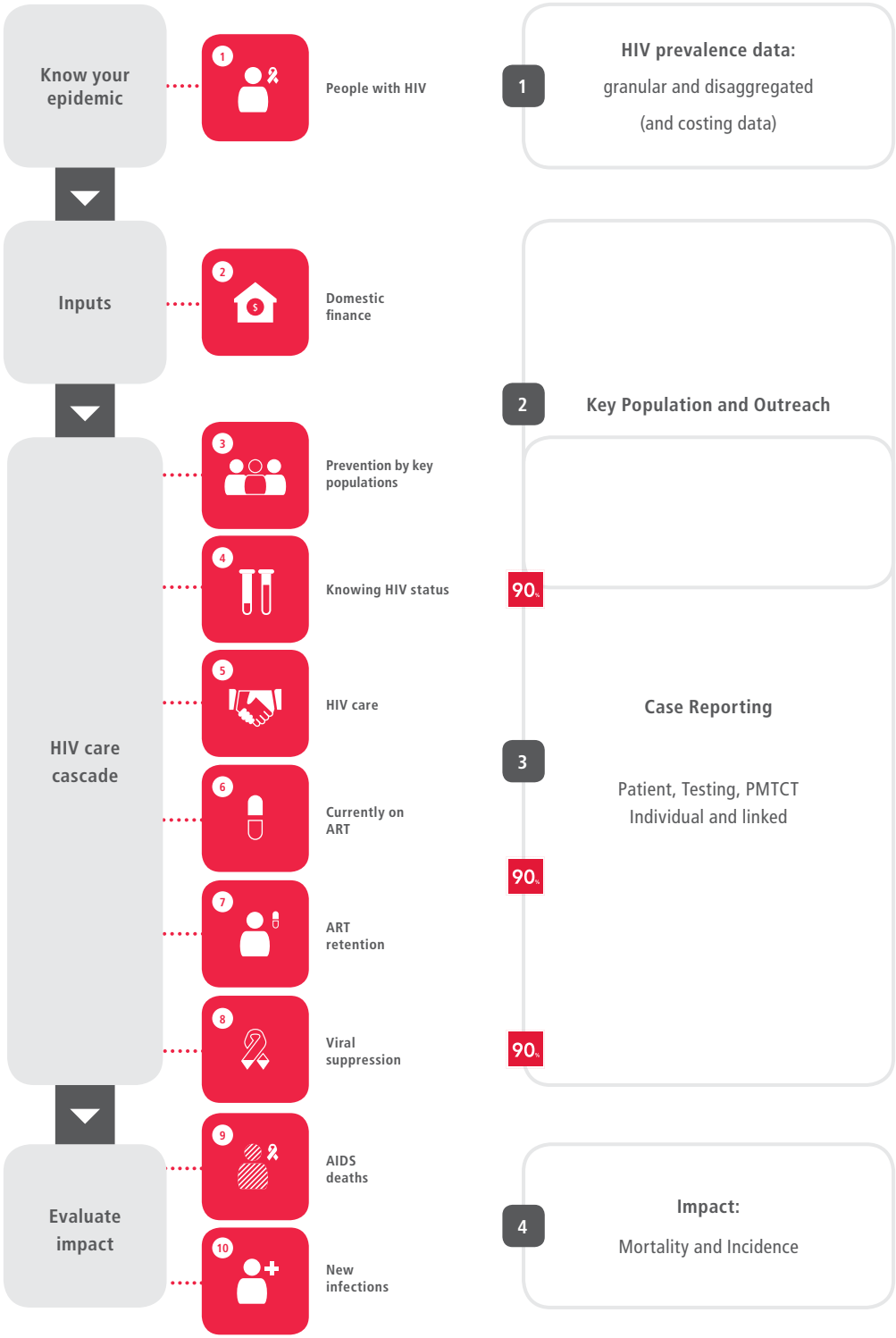
* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

IMP.12 Per-capita household expenditures % change in average per-capita household expenditures among HIV-affected households	N: Difference between per-capita household expenditures in HIV-affected households at the reference point in time and the equivalent value at a later point in time. D: Per-capita household expenditures in HIV-affected households at a point in time (reference point).	None.	Population-based surveys such as DHS, AIDS Indicator Survey, MICS or other nationally representative survey.	Indicates trends in financial burden over time in households affected by HIV.
IMP.13 External economic support to the poorest households Proportion of the poorest households who received external economic support in the last 3 months	N: Number of the poorest households affected by HIV that received any form of external economic support in the last 3 months. D: Total number of poorest households affected by HIV.	None.	Population-based surveys, household surveys, population census.	Trend measures progress in providing external economic support to poorest households affected by HIV.

IMP.14 School attendance Current school attendance among orphans and non-orphans	N: A. Number of children who have lost both parents and who attend school. B. Number of children both of whose parents are alive, who are living with at least one parent and who attend school. D: A. Number of children who have lost both parents. B. Number of children both of whose parents are alive who are living with at least one parent.	Sex, age (10–14 or primary school age, secondary school age).	Household surveys.	Trend measures progress towards preventing relative disadvantage in school attendance among orphans. For more specific application of this indicator, see Indicator 10.1, orphans' school attendance, page 102 of UNAIDS Indicator Registry.[1]

[1] UNAIDS Indicator Registry. http://www.indicatorregistry.org/.

Global indicators for the health sector response to HIV



EFFECTIVE STRATEGIC INFORMATION

3

3. EFFECTIVE STRATEGIC INFORMATION

3.1 Introduction

A functional and effective M&E system is the engine that generates, analyses and uses strategic information. The M&E system for the health sector response to HIV should ensure that **relevant and good quality** information is **accessible** (to all stakeholders) along the cascade **at the right time, in the right place and in the right format for use**. In describing an effective M&E system for the health section response to HIV, this chapter draws heavily from the UNAIDS "12 components",[1] the WHO/IHP+ M&E framework (Figure 3.1)[2] and the Health Metrics Network framework for country health information systems.[3]

In Part 3	
Section	**Content**
3.2	Data sources
3.3	Data systems, including unique IDs and electronic systems
3.4	Data quality assurance
3.5	Analysis and use of strategic information
Box	Key questions for reviewing an M&E system

An effective M&E system:

- employs a **core set of indicators** that measure what is important and relevant to the programme;
- has organized **data collection systems** so that routine data collection employs standardized forms and aggregation procedures;
- efficiently collects data by planning for and **streamlining data elements** to be collected from various data sources;
- improves systems to **facilitate generation of strategic information** – for example, implementing a system of unique IDs or making appropriate use of electronic systems; and
- has a system to ensure data quality and to analyse and use data for decision-making.

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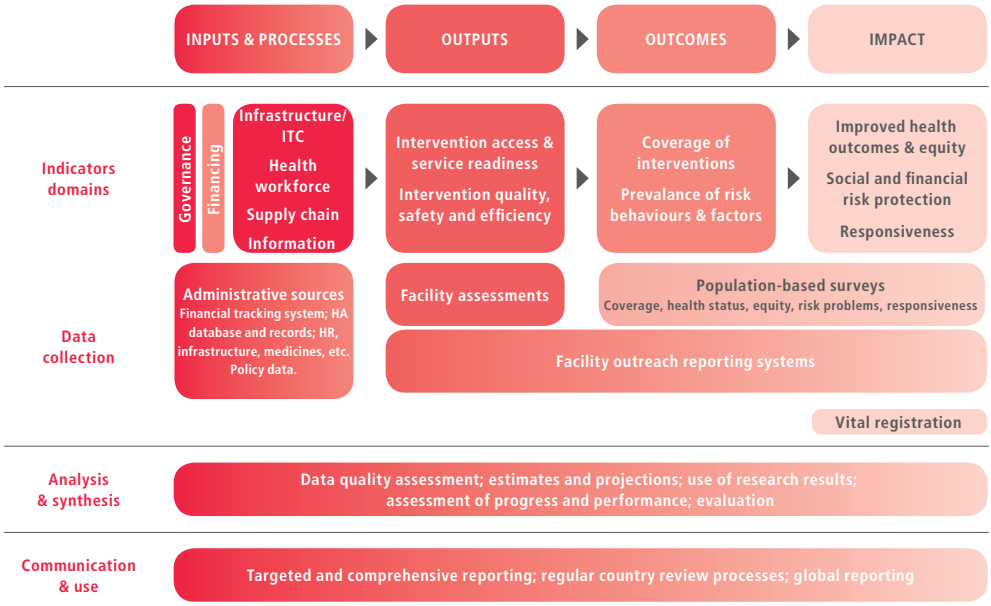
[1] UNAIDS's "12 components" define the necessary parts of an effective HIV-related strategic information system for the health sector. These 12 components are: 1. organizational structures with HIV M&E functions, 2. human capacity for HIV M&E, 3. partnerships to plan, coordinate and manage the M&E system, 4. a national multi-sectoral HIV M&E plan, 5. an annual costed national HIV M&E work plan, 6. communication, advocacy and culture for HIV M&E, 7. routine HIV programme monitoring, 8. surveys and surveillance, 9. national and subnational HIV databases, 10. supportive supervision and data auditing, 11. an HIV evaluation and research agenda and 12. data dissemination and use. The 12 steps are not intended to be implemented sequentially but rather are components that all need to be in place and functioning at an acceptable standard.
See http://www.unaids.org/sites/default/files/sub_landing/files/2_MERG_Strengthening_Tool_12_Components_ME_System.pdf.
[2] Framework and standards for country health information systems. Geneva: WHO Health Metrics Network; 2008 (http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf?ua=).
[3] Monitoring, evaluation and review of national health strategies: a country-led platform for information and accountability. Geneva: WHO IHP+; 2011. (http://www.who.int/healthinfo/country_monitoring_evaluation/1085_IER_131011_web.pdf).

The strategic information system of the health sector response to HIV links to the broader health information system as part of "an integrated architecture for a national health management information system (HMIS)". Standards, guidelines and tools are available to support planning and obtaining funding for assessments of health information systems and the use of HMIS data, including data on HIV.[1]

Fig. 3.1 IHP+ common M&E framework



Source: Monitoring, evaluation and review of national health strategies: a country-led platform for information and accountability. Geneva: WHO IHP+; 2011.
http://www.who.int/healthinfo/country_monitoring_evaluation/1085_IER_131011_web.pdf.

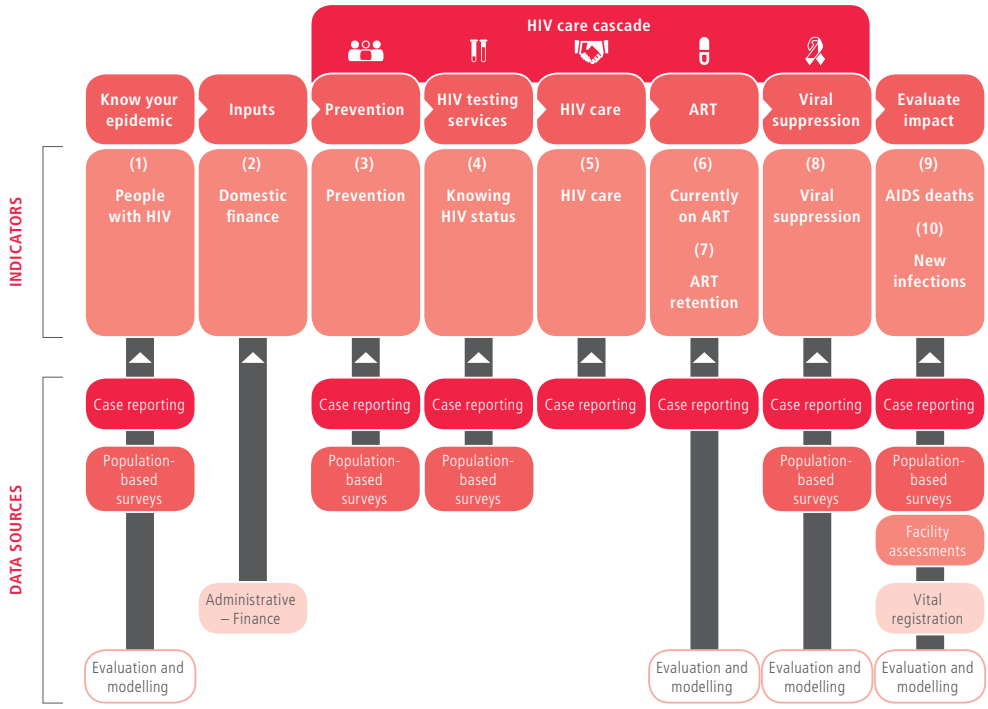
3.2 Data sources

To cover all crucial elements of the HIV services cascade, data must come from various sources and be supported by a system that brings together the different data sources and facilitates data quality and use.

Facility-generated data – that is, routine patient monitoring and case reporting – form the backbone of data collection to measure the indicators of the health sector cascade, with additional information coming from surveillance and health facility surveys and from administrative sources, population-based surveys, facility assessments and vital registration (see box, page 199). These five types of data sources can provide a wealth of data to monitor the HIV epidemic and response. As an example, Figure 3.2 shows how these five data sources provide the data for the 10 indicators highlighted for global monitoring.

[1] Assessing the national health information system: an assessment tool. WHO Health Metric Network. Geneva: WHO; 2008 http://www.who.int/healthmetrics/tools/Version_4.00_Assessment_Tool3.pdf?ua=1.

Fig. 3.2 Indicators and data sources for global monitoring of the health sector response to HIV



Note: For indicators 5 and 6, the denominators are estimated using the same methods as for indicator 1.

Routine patient monitoring and case reporting data from clinical treatment facilities, testing and outreach provide an ongoing flow of real-time information.[1] Other important information is collected periodically, from nationally representative and key population surveys, which can include biomarkers, as well as from health facility assessments. Administrative sources provide data on financial and human resources for programme management. Vital registration provides basic data on births and deaths. All five types of data sources are likely to need strengthening to provide the data as needed.

Several of these data sources serve areas other than HIV (for example, disease surveillance, patient management, supply chain management and survey data on other health indicators). Integrating HIV-related M&E activities and HIV indicators into the broader HMIS where feasible is an efficient and sustainable approach.

[1] Routine patient monitoring will be the subject of a more detailed guide upcoming from WHO.

Key questions for planning and implementing the strategic use of data

1. **What indicators** best describe the programme?

- The choice of data collection strategies depends on the nature of the epidemic. "*Know your epidemic, know your response*" is the starting point. Important questions include: *What are the trends? What is the main mode of transmission? Where is the epidemic happening now (that is, where will the next 1000 infections occur)? Does the epidemic affect population groups differently? Which are the affected population groups that are driving the epidemic, and where are they located? Is the epidemic concentrated in certain geographic areas? What does our programmatic response look like? What should it look like?*
- Consider which indicators need to be disaggregated in order to monitor the epidemic more equitably and to ensure that the programme is effective. Critical information may be obtained from disaggregation by sex, age group, key population, geographic hot spots, pregnancy status and co-infections.
- Review current indicators. Identify and prioritize the indicators that are most appropriate based on epidemic context, national priorities and goals, taking international reporting commitments into account. When considering the indicators presented in Part 2, each country needs to assess its HIV information needs and its existing information system platforms before deciding which indicators to collect, which indicators to disaggregate and how best to support decision-making and reporting. Differences in the sophistication of the M&E system – particularly whether the majority of the system is paper-based or computerized – influence the ease of collecting specific data and help to determine whether additional indicators can be collected and whether current indicators can be further disaggregated.

2. **Which data sources** will provide the required information?

- Assess whether the M&E system is geared for fully monitoring the epidemic and the programmatic response. Important questions include: *What data sources do we need to adequately monitor the epidemic? How should these data sources link or connect to make possible triangulation of data?*
- As part of developing the national M&E plan, review the data generation system and the periodicity of reporting, and plan required surveys and evaluations. Ensure that the various data generation sources are functioning well and that the required strategic information is being generated.

3. **How do data systems capture and store** the required information?

- Assess the capability of data systems, including individual patient records, registers and summary reports; the formats of paper and electronic systems; and the use of unique patient IDs to collect, store and report information. Review how periodically collected survey data are stored. Important questions include: *Are standardized tools and standard operating procedures (SOPs) adequate, and does everyone follow them? What electronic systems are being used? Are there more sites suitable for electronic systems? Will some sites be paper-based? Can there be sentinel sites for in-depth data abstraction?*

4. Are **data management and quality assurance** systems adequate?

- *What is the data flow? How can it be improved? Are the data complete, and do they meet quality standards?*
- *Is the data quality assurance system functional, with sufficient scope and frequency of assessment?*

5. Are there clear systems, processes and capacities for **data triangulation, analysis and use** for programming, planning, clinical patient care and advocacy?

6. Are all **stakeholders** involved?

- Consider whether the national M&E system involves all stakeholders, including clinicians, service providers, community programmes and civil society groups and representatives, including those focusing on key populations. It should be clear to everyone how all stakeholders provide inputs to, have access to and use the information generated by the national M&E system.
- HIV M&E data are a public good and should be accessible to all stakeholders. At the same time, a high standard of confidentiality and protection of privacy should be maintained.

Overview of sources of strategic information on HIV in the health sector

1. FACILITY AND OUTREACH REPORTING SYSTEMS (continuously collected minimum data sets)

- **a. Patient monitoring data:** extracted from individual patient records. Data are entered into electronic databases or, in paper-based systems, transferred to written registers and aggregated on routine reporting forms. Includes data from laboratory and pharmacy records.
- **b. Case reporting data:** from routine surveillance, based on newly diagnosed HIV cases reported to the central level by health facilities and providers, preferably as individual electronic records with key information (age, sex, transmission mode, CD4 and viral load at diagnosis).
- **c. Outreach data:** based on records, maintained by NGOs conducting outreach and/or community health and outreach workers, who may or may not be linked to a facility, of peer education, HIV testing (or referrals) and linkage to care for specific populations, for example, key populations, pregnant women and HIV-exposed infants, or in specific locations.

2. ADMINISTRATIVE SOURCES (routine, periodic or one-time data collection)

- **a. Financial and health systems data:** budgets, financial records, Health Accounts (HA), National AIDS Spending Assessment (NASA), procurement and supply management system data, human resources data and key policies related to HIV, prevention, treatment and care.
- **b. Facility list** (with unique facility IDs).

3. POPULATION-BASED SURVEYS (periodically collected)

- **a. General population:** for example, Demographic and Health Survey (DHS), AIDS Indicator Survey (AIS), Multiple Indicator Cluster Survey (MICS)
- **b. Key populations:** Integrated Bio- and Behavioural Surveys (IBBS).

4. FACILITY ASSESSMENTS (periodically collected)

- **a. Facility census or survey:** for example, Service Availability and Readiness Assessment (SARA), Service Provision Assessment (SPA), surveys of Pre-treatment HIV Drug Resistance (PDR) and Acquired HIV Drug Resistance (ADR).
- **b. Sentinel surveillance** data collected over time at sentinel sites.

5. VITAL REGISTRATION (continuous, compulsory recording).

- **a. Civil registration** system data: birth and death records; death records may include information on cause of death.

3.2.1 Facility reporting systems

1.a Patient monitoring data

A facility information system routinely collects data on the clinical management of individual patients. All health facilities serving people living with HIV should routinely collect a minimum set of monitoring data to ensure continuity of care and to monitor the quality of clinical care provided assessment of performance at the facility level allows timely corrective action as needed. In addition, key data are reported periodically (for example, quarterly) for sub-national and national programme management.

Patient records take different forms, depending on the country and type of facility. In some situations health-care providers enter patient information directly into a computer database. More commonly, health-care providers write clinical management information on facility-held patient records and/or patient-held cards; this information is later abstracted and entered into an electronic database or a paper register for monitoring purposes. In paper-based systems data are aggregated at the facility level from paper registers and reported to the district or provincial level in a specified template for data entry or import into the national database.

The patient monitoring system can generate both cross-sectional and cohort data related to:

- *use of services:* characteristics of clients (demographic and baseline data) and proportion of eligible patients who received different types of services;
- *retention across the HIV cascade of services:* proportions and characteristics of those in each step or moving from one step to the next in the cascade of care and treatment or PMTCT services;
- *clinical and immunological parameters:* for example, CD4 levels, clinical progression, treatment regimens;
- *HIV treatment outcomes:* for example, survival, viral suppression and MTCT rate.

The routine monitoring system provides data to enhance the quality of patient care and management of facility services as well as to meet national reporting requirements. Electronic data systems can also maintain a central database of anonymous individual-level data that can be used to assess the health sector response and generate summary population-level statistics on uptake and outcome of treatment and to measure the quality and impact of service delivery.

What are some challenges and opportunities?

One of the key challenges to data collection is that HIV infection is complex and lifelong. Most patients with HIV need to be monitored over a long period as they move through the HIV care cascade from diagnosis to treatment and sustained viral suppression. Patients may need services in multiple facilities or in different service delivery settings within the same facility. Tracking linkages and successful referrals across different services is a challenge in many health systems.

The use of a unique identifier (UI) associated with a single individual makes possible linking of information over time and across multiple service delivery points. This provides a longitudinal record of the individual's access to services and the clinical outcomes. In the aggregate such a system also can improve understanding of overall access to and use of multiple health services, the efficiency of the referral system and epidemiological trends. Section 3.3.4 provides more information on UI.

What are some key resources?

To help countries build patient monitoring systems that support quality care as well as provide essential information on programme performance, WHO and its partners developed the "Three interlinked patient monitoring systems" (3ILPMS). Specifically, this system provides tools (forms

and formats, registers, lists, etc.) for (1) MCH/PMTCT, (2) care and treatment and (3) TB/HIV services. The 3ILPMS can be a useful source for both paper-based and electronic tools that specify data elements to collect and record at multiple facilities and to link these via a patient identifier (see section 3.3.4).[1]

WHO is now preparing *Patient monitoring and case surveillance system guidance for HIV in the health sector*. The aim of this new guidance will be to consolidate patient monitoring and case reporting/surveillance systems along the health sector cascade for HIV so that patient records for ART, PMTCT, HIV testing, HIV/TB and links to maternal and child health and key surveillance data are available in one place.

Other health-related records: laboratory and pharmacy records

Laboratories and pharmacies are important sources of information for clinical programme management. Laboratory records include data on diagnosis of HIV infection (as well as coinfections, such as TB and hepatitis) and eligibility for ART. New HIV infections diagnosed at testing facilities are commonly reported centrally (see next section for discussion of case reporting). Pharmacy records include data on ARV drug dispensing to individual patients, which can serve as a proxy for adherence monitoring. The drug stock register lists the monthly consumption of drugs, including specific ARV drugs and should be linked to a stock-control system.

What are some challenges and opportunities?

Challenges include maintaining complete and accurate linkages among records in the HIV testing facilities, the ART clinics and the associated pharmacies. When the records are closely linked and well maintained, they are a source of important information to strengthen needs assessments, procurement planning and stock management.

1.b Case reporting

HIV case reporting is a form of passive (routine) surveillance based on newly diagnosed cases reported to the central level by health facilities and health-care providers. As HIV epidemics have evolved and more people are being tested, HIV case reporting is becoming both more extensive and more relevant. HIV case reporting is a component of second-generation surveillance. Its objectives are to detect any spike or other unusual increase in the number of cases (especially in areas of generally low prevalence); to provide qualitative and quantitative information on the distribution of the epidemic (who is infected and where and by what mode of transmission); to provide information about evolving trends overall and by subgroup; and to contribute to the estimation of the treatment and care burden as well as of incidence and the proportion undiagnosed, for guiding the HIV response.

A national protocol for HIV case reporting should be in place, based on nationally agreed standard definitions of adult and paediatric cases. Documenting key information (for example, demographics, mode of transmission) greatly enhances the value of case reporting data. As with all HIV surveillance, ethical standards must be observed to protect the privacy of individuals. These include removal of all personal identifiers.

What are some challenges and opportunities?

Appropriate interpretation of HIV case reporting data requires understanding the underlying pattern of HIV testing, diagnostic capability and reporting by different facilities. While in some countries, case reporting may greatly underestimates the number of people with HIV, as many

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[1] Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy) and TB/HIV: Standardized minimum data set and illustrative tools. Revision 2012. Geneva: WHO; 2012 (http://apps.who.int/iris/bitstream/10665/77753/1/9789241598156_eng.pdf?ua=1).
[Important note: this guidance is currently under revision; check the WHO website for updates.]

cases go undetected, solid case reporting systems are capable of producing timely information on distribution and trends by sub groups and geographic location and inputs into estimation of incidence, people living with HIV and the undiagnosed fraction though tools using back-calculation methods from information on HIV/AIDS diagnoses and CD4 at HIV diagnoses. These data can also be used for programme planning in combination with national-level information provided through modelling packages (for example, Spectrum AIM).

What are some key resources?

The use of HIV case reporting data for surveillance is described in the UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance guidelines for second-generation HIV surveillance,[1] particularly Module 1 (Guidelines for second-generation HIV surveillance: an update: know your epidemic) and Module 7 (Evaluating a national surveillance system). A specific module for HIV case reporting (Module 4: Surveillance of HIV infection using HIV case notification) is forthcoming.[2] In addition, WHO has released guidance on HIV and AIDS case definitions for surveillance.[3]

1.c Outreach data

Outreach data are based on records maintained by NGOs and/or community health and outreach workers, who may or may not be linked to a facility. Depending on local policies, laws and practices, NGOs may provide HIV testing (or referrals), offer peer education and support and ensure critical follow-up and linkage to care for the populations they serve. Their records provide important information on the link between health facilities and communities.

NGO outreach registers may include data on key populations, including the reach of HIV prevention services and referrals for HIV testing and treatment follow-up. NGO records also may provide the basis for estimating the size of key population groups and contribute to the sampling frame for surveys to assess treatment coverage and treatment outcomes among key populations or other populations. The records of community health and outreach workers include data on the numbers of people in the community who are on ART, pregnant women and HIV-exposed infants and their mothers.

A formal link for data management needs to be established among health facilities, NGO outreach and communities in an area. This arrangement should cover recording, reporting and referral procedures and tools to record and forward essential information while protecting confidentiality both within and outside health facilities.

What are some challenges and opportunities?

The completeness and quality of community data depend on the M&E capacity of NGOs and community health and outreach workers. National guidance should address community monitoring, including routine data quality review (DQR) (see section 3.4). It is important, assessing gaps in outreach capacity, to determine the training needs of NGO staff members and community outreach workers. Community data collected by NGOs should be reported and integrated into the central reporting system in most situations as long as confidentiality can be maintained. In many cases NGOs are responsible for outreach to key populations, many of whose members engage in stigmatized or illegal activities. It is particularly important to maintain the anonymity of key population data while assuring adequate follow-up and continuity of care.

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[1] Surveillance of the HIV/AIDS epidemic: a comprehensive package. Geneva: WHO; 2013 (http://www.who.int/hiv/pub/surveillance/2013package/en/).
[2] Guidelines for second generation HIV surveillance: an update: surveillance of HIV infection using HIV case notification (Module 4). Geneva: WHO; 2013 (http://apps.who.int/iris/bitstream/10665/90893/1/9789241506248_eng.pdf).
[3] WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children. Geneva: WHO; 2007 (http://www.who.int/hiv/pub/guidelines/hivstaging/en/).

3.2.2 Administrative sources

Administrative data at the facility level

Administrative data systems are used to facilitate smooth operation of health facilities and provide important information for management concerning reach, coverage and quality. Sources of administrative data include lists of all health facilities in a country (with unique ID numbers), records of human resources in the health sector by cadre and by facility, and information on supplies and commodities from the procurement and supply management system and the logistics management system. The types of data collected are mostly counts of services provided or supplies consumed (for example, doses of ARVs, number of tests performed) rather than data related to the care provided to specific patients. Supervisory visits to facilities and quality assessments can provide complementary information.

What are some challenges and opportunities?

Collating data from different health facilities is a necessary step in constructing many of the indicators at national or subnational levels. However, different facilities may use different administrative systems, depending on available resources and local capacity to establish and maintain them. These differences make it difficult to pool the data at the central level.

Administrative data can provide information on the functioning of systems essential to quality of care. In particular, stock-outs of supplies (for example, drugs, test kits, printed reporting forms) suggest that treatment or other services were disrupted, affecting the quality of care. Stock management monitoring can identify where gaps in procurement and distribution occurred and suggest how to prevent future stock-outs. Some strategic information systems generate a "dashboard" to display early warning indicators, which alert programme managers before stock-outs occur.

2.a Financial data sources

Health expenditure data are collected to inform policies at the national level and also for reporting internationally. To understand the financing context, it is important to describe the complete flow of funds from the source to those who decide how to spend the funds, to those receiving the funds and providing care, and ultimately to those who receive the care. Health expenditure data can also describe what has been purchased with the funds (for example, salaries, commodities) and for what purpose (for example, preventive, curative).

Two international standards systems currently exist for tracking health spending by function or spending category, by beneficiary and by funding source – the National AIDS Spending Assessments (NASA) and the Health Accounts (HA) with full. Incountries these systems provide the most complete information available on HIV/AIDS and overall health spending.

In the past countries have either produced full NASAs and/or reported on disease-specific "subaccounts" attached to "general" Health Accounts – including for HIV/AIDS – using the System of Health Account (SHA 2011) methodology.[1,2] Both NASA and HIV subaccounts have made possible more detailed reporting of expenditure categories – down to specific beneficiaries, such as men who have sex with men, and specific interventions, such as PMTCT.[3] In 2011 WHO, together with OECD and Eurostat, released new global standard for reporting health expenditures, the System of Health Accounts 2011 (SHA 2011).[4] The SHA 2011 standardizes

[1] De S, Dmytraczenko T, Chanfreau C, Tien M, Kombe G. Methodological guidelines for conducting a National Health Accounts subanalysis for HIV/AIDS. Bethesda, Maryland, USA: Abt Associates; 2004 (http://pdf.usaid.gov/pdf_docs/Pnacy509.pdf).
[2] http://www.unaids.org/en/dataanalysis/datatools/nasapublicationsandtools.
[3] A comparison of the two approaches can be found at http://www.pepfar.gov/reports/guidance/framework/120738.htm.
[4] http://www.who.int/health-accounts/methodology/en/.

reporting and allows comparisons within the country and across countries through the years. SHA 2011 recommends that health expenditures be fully distributed across beneficiaries and described in terms of disease (for example, HIV/AIDS), age, sex and location. A full distribution can describe the relative allocation of expenditures by disease, for example, HIV/AIDS expenditures as a percentage of current or capital health expenditures. A full distribution of health expenditures by disease provides greater technical rigour, as it standardizes allocation of joint expenditures such as health service delivery expenditures at the facility level.

Both the Health Accounts with full disease distribution and NASAs are now meant to be conducted regularly. Health Accounts, with a full distribution of expenditure by disease, including HIV/AIDS, are conducted annually and whenever more detailed expenditure information is needed. NASAs are to be done concurrently with the Health Accounts whenever possible. In the future the goal is that these systems should be increasingly integrated with countries' systems for reporting budgets, budget execution and expenditures to produce more timely (T minus 1 year) information.

National AIDS Spending Assessments

UNAIDS describers NASA as follows:[1]

NASA "is designed to describe the financial flows and expenditures using the same categories as the globally estimated resource needs. This alignment was conducted in order to provide necessary information on the financial gap between resources available and resources needed and in order to promote the harmonization of different policy tools frequently used in the HIV/AIDS field.

"NASA provides indicators of the financial country response to AIDS and supports the monitoring of resource mobilization. Thus, NASA is a tool to install a continuous financial information system within the national monitoring and evaluation framework.

"NASA serves several purposes within different time-frames. In the short term, NASA might be useful to provide information on the UNGASS indicator for public expenditure; in the longer term, the full information provided by NASA may be used to:

- monitor implementation of the national strategic plan;
- monitor advances towards completion of internationally or nationally adopted goals such as universal access to treatment or care;
- provide evidence of compliance with the principle of additionality required by some international donors or agencies; and
- fulfill other information needs.

"NASA is not an accounting system. Rather, it tracks spending as reported by countries. Donor and government spending is divided in NASA into eight spending classes or chapters of AIDS Spending Categories (ASC): prevention, care and treatment, orphans and vulnerable children, strengthening programme management and administration, incentives for human resources, social protection and social services, enablement of environment and community programmes and research."

[1] National AIDS Spending Assessment (NASA): classification and definitions. Geneva: UNAIDS; 2009 (http://www.unaids.org/sites/default/files/media_asset/jc1557_nasa_en_0.pdf).

Internet resources on HIV/AIDS spending

For countries to upload AIDS spending data (GARPR):

https://aidsreportingtool.unaids.org/

For HIV/AIDS spending data (absolute) from countries (NASA reports):

http://www.unaids.org/en/dataanalysis/knowyourresponse/nasacountryreports/

For HIV/AIDS spending within disease distribution data (absolute and relative) from countries (forthcoming):

WHO Global Health Expenditure Database. http://www.who.int/health-accounts/ghed/en/

For HIV/AIDS planned funding and expenditure data from major donors:

The United States President's Emergency Plan for AIDS Relief (PEPFAR): http://data.pepfar.net/

The Global Fund to Fight AIDS, Tuberculosis and Malaria: http://web-api.theglobalfund.org/

Health Accounts

HA are broader. They track all health spending in a given country over a defined period of time (usually fiscal or calendar year) regardless of the entity or institution that financed and managed that spending. This generates consistent and comprehensive data on health spending in a country, which in turn can contribute to evidence-based policy-making. Thus, they can be used as a monitoring and evaluation tool to track changes in policy priorities if the introduction of reforms and new programmes resulted in changes in health resources allocation and expenditure. For monitoring and evaluation purposes, they need to be produced regularly and in a timely manner. HA are meant to be conducted annually, and depending on the country, on the basis of T minus 1 (provisional) and T minus 2 (final, using audited expenditure data).

Starting from 2016, health accounts using SHA 2011 with full disease distribution will be capturing top-level elements of NASA's AIDS spending categories on a yearly basis. Health accounts codes and data collection tools have now been revised to better systematically track HIV/AIDS-related expenditure. As more countries start to generate health accounts using SHA 2011, data on HIV/AIDS and other disease expenditures will be made available on the WHO Global Health Expenditure Database (see box).

3.2.3 Population-based surveys

3.a Surveys in the general population

With the advance of testing technologies in the past decade, many countries have included HIV testing in nationally representative surveys such as the Demographic and Health Survey (DHS), which includes population, health, HIV and nutrition questions, or the AIDS Indicator Survey (AIS), which collects only HIV-related data. These household-based surveys are typically conducted every five years and target the general population (although they may sometimes be conducted within certain age or sex/gender groups only). In addition to HIV testing, information is collected on self-reported risk behaviours, service utilization, and knowledge and/or attitudes about HIV-related stigma and discrimination, availability of services and other variables. Recently, measures of HIV incidence, CD4 count, viral load or ARV testing have been incorporated into these surveys.

Surveys provide a "snapshot" of the status of HIV-related indicators in a representative sample of the population. The results can be used for programme planning, particularly to identify gaps in services and areas where additional resources should be applied. When analysed together, as a set of indicators, data about knowledge, attitudes, behaviours and HIV prevalence provide insights into the inter-relationships among these variables, which research and evaluation studies can explore further. When surveys are repeated over time, trends can be analysed to monitor progress towards country-specific and global goals. They can also be used together with other data sources to determine the effectiveness of the overall HIV response and/or its components and to identify where improvements are needed. In addition, they can provide estimates of CD4 levels, HIV incidence and the number of people receiving ART.

What are some challenges and opportunities?

Household surveys to obtain HIV-related indicators are not recommended in countries with concentrated or low-level epidemics, for several reasons: (1) a household sampling frame has limited ability to reach key populations, and (2) the sample size would have to be very large to achieve representative samples for different sub-populations; this would add complexity and cost. More targeted surveys are usually necessary to make possible the level of analysis and disaggregation needed to address key populations and vulnerable groups (see below).

What are some key resources?

On conducting general population surveys:

- Demographic and Health Surveys. http://www.measuredhs.com/What-We-Do/Survey-Types/DHS.cfm
- AIDS Indicator Survey. http://www.measuredhs.com/What-We-Do/Survey-Types/AIS.cfm

On using general population surveys to monitor the HIV epidemic:

- UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance. Guidelines for measuring national HIV prevalence in population-based surveys. Geneva: UNAIDS/WHO; 2005 (http://www.who.int/hiv/pub/surveillance/measuring/en/index.html).
- UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance. Technical guidance note: HIV prevalence measurement in national household surveys for countries with low HIV prevalence. Geneva: UNAIDS/WHO; 2010 (http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/20101207_HIVtesting_in_surveys_WG_en.pdf).

3.b Surveys in key populations

Surveys in key populations at higher risk for HIV infection, such as sex workers, people who inject drugs and men who have sex with men, are needed to obtain representative data on their sero-prevalence, risk behaviour and service provision and utilization. Such Integrated Bio- and Behavioural Surveys (IBBS), as they are called, are particularly important where national strategies focus on key populations. Even in generalized epidemics, key populations can contribute significantly to the HIV burden, as their prevalence and incidence rates may be several times higher than those in the general population. IBBS data provide information on the burden of disease and treatment needs among key populations, and they inform resource allocation and priority-setting for HIV programming at the local level.

In a key population survey, high mobility, stigmatization and behaviours that are illegal in many countries make selecting a representative sample difficult. Special sampling methods are required. The two most commonly used are time–location sampling (TLS) and respondent-driven sampling (RDS). Special sampling methods like these contribute to making IBBS resource-intensive. Due to cost, IBBS usually are conducted in selected locations at intervals of two to three years.

Typically, trained data collectors or evaluators conduct IBBS. IBBS should be carefully planned and included in the national M&E plan. Local involvement and community participation ensure both that survey findings are pertinent and that they are used to their full potential.

What are some challenges and opportunities?

Management of all HIV-related data should comply fully with ethical standards. This is particularly important for key populations; any breeches may risk doing harm due to stigma, economic loss or legal prosecution.

Analysis of IBBS data has to include in-depth assessment of the representativeness of the survey sample. Supplemental information (such as qualitative data and programme content information) and triangulation of data from different sources are also needed to overcome some of the inherent weaknesses in IBBS and to obtain a more complete picture of the HIV status of key populations.

What are some key resources?

New approaches to IBBS and updated questionnaires being developed by the United States Center for Disease Control and Prevention, FHI360, UNAIDS and WHO are expected in 2015. New questions will allow estimation of the size of key populations either by using a multiplier or through respondent-driven sampling. Currently available resources include WHO guidelines on surveillance among most-at-risk populations[1] and guidelines specifically for bio-behavioural surveys among people who inject drugs.[2]

3.2.4 Facility assessments

4.a Health facility surveys

Facility assessments monitor the capability of facilities to deliver care and their performance. There are two types: either administrators or selected health-care providers provide information about the way the facility operates or else clients at the facility are interviewed. These assessments provide information that usually is not routinely captured or reported upstream. They can gauge whether actual practice follows policies and protocols and whether providers feel they have a supportive work environment and the necessary resources, supervision and training to deliver high quality care. Findings from facility assessments can validate or supplement information derived from patient monitoring systems or administrative data systems.

Surveys of clients can assess whether patients experience care that meets quality standards, feel satisfied with the care provided, or have difficulties with access and use of the services or with the overall environment of the facility. In addition to information about the services provided, a survey of clients may also collect biological data (such as in blood samples at immunization clinics).

Specific health facility survey tools include the SARA and SPA facilities surveys and the World Bank's Service Delivery Indicator Survey.[3]

The **Service Availability and Readiness Assessment (SARA)** survey, developed by WHO, aims to generate reliable and regular information on service delivery (such as the availability of key human and infrastructure resources); on the availability of basic equipment, basic amenities, essential medicines and diagnostic capacities; and on the readiness of health facilities to provide basic health-care interventions relating to family planning, child health services, basic and comprehensive emergency obstetric care, HIV, TB, malaria and non-communicable diseases.

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[1] Guidelines on surveillance among populations most at risk for HIV. Geneva: WHO and UNAIDS; 2011 (http://www.unaids.org/en/media/unaids/contentassets/restore/20110518_Surveillance_among_most_at_risk.pdf).
[2] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)/DRID. DRID Guidance Module: Methods of bio-behavioural surveys on HIV and viral hepatitis in people who inject drugs — a short overview. Lisbon: EMCDDA; 2013 (http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CDEQFjAB&url=http%3A%2F%2Fwww.emcdda.europa.eu%2Fattachements.cfm%2Fatt_220260_EN_DRID_module_study_methods_final.pdf&ei=cur9UuyIKMSukgW-moHwBA&usg=AFQjCNGXWVBx_QkqMIjq4lb_On4_MzD0gw).
[3] http://www.sdindicators.org/methodology/.

The **Service Provision Assessment (SPA)** surveys, a Demographic and Health Survey tool, assess the overall availability of various facility-based health services in a country and their readiness to provide those services as well as the quality of care. The questionnaire includes a specific section for HIV-related services. The SPA survey incorporates many of the questions from the SARA questionnaire.

Surveys of pre-treatment HIV drug resistance (PDR) and acquired HIV drug resistance (ADR), developed in 2014, enable countries to assess critical outcomes concerning drug resistance in a nationally representative manner, using a random sample of 15–40 clinics that provide ART. PDR surveys assess the prevalence of pre-treatment HIV drug resistance as well as the prevalence of ARV exposure before the start of treatment. ADR surveys assess acquired HIV drug resistance in populations receiving ART for 12 months and for more than 48 months. ADR surveys also provide nationally representative estimates of viral load suppression at these time points as well as retention in treatment at 12 months. These methods are particularly helpful where routine facility data cover less than 70%-80% of the eligible population and therefore cannot be used for reporting viral load suppression and retention indicators.

What are some challenges and opportunities?

Health facility surveys aim to use a representative sample of facilities from across the health sector, both public and private. However, it is not always feasible to include and/or gain access to private facilities. An effort should be made to establish an appropriate mechanism for collecting private sector information, especially where a significant proportion of the population receives private health care.

Some surveys aim to assess not only the availability of services but also their quality; doing the latter well requires appropriate tools and additional resources (time, skill, funding). Methods such as client interviews, clinical observations and vignettes can be used to assess the care provided. Appropriate training and protocols should be followed. Client testimonies about satisfaction with services should not be obtained in the presence of the care providers. Failing to safeguard confidentiality may lead to obtaining socially desirable answers of little value or could cause conflicts between patients and care providers.

What are some key resources?

Detailed guidance on methodology and tools are available for SARA, SPA, PDR and ADR:

- **SARA:** "Service Availability and Readiness Assessment (SARA) tool to standardize the approach for conducting health facility surveys" [slide presentation] (http://www.who.int/healthinfo/systems/sara_introduction/en/).
- **SPA:** The Service Provision Assessment (SPA) surveys (MEASURE DHS website) http://www.measuredhs.com/What-We-Do/Survey-Types/SPA.cfm.
- **PDR:** Surveillance of HIV drug resistance in populations initiating antiretroviral therapy (pre-treatment HIV drug resistance). Geneva: WHO; 2014 (http://www.who.int/hiv/pub/drugresistance/pretreatment_drugresistance/en/).
- **ADR:** Surveillance of HIV drug resistance in adults receiving ART (acquired HIV drug resistance). Geneva: WHO; 2014 (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en/).

4.b Sentinel surveillance

Protocols vary, but generally sentinel surveillance is an annual or biennial seroprevalence survey conducted at a fixed selection of sites among specific populations. Sentinel surveillance methods were developed early in the global response to HIV[1] to track the trends and the magnitude of HIV

[1] UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance. Guidelines for conducting HIV sentinel sero-surveys among pregnant women and other groups. Geneva: UNAIDS, WHO; 2003 (http://www.who.int/hiv/pub/surveillance/anc_guidelines/en/).

prevalence among populations experiencing the impact of evolving HIV epidemics. Most countries employ some type of sentinel surveillance system as a core component of their second-generation HIV surveillance system.

Surveillance data are the basis for periodic estimates and projections of the number of people living with HIV. These estimates are then used as the population denominator for a range of indicators, including those for monitoring of the cascade of services. Sentinel surveillance is not intended as a method for diagnosing individuals and referring them for treatment; HIV testing and counselling should be offered independently of the surveillance procedures.

Sentinel surveillance is conducted regularly, its frequency largely determined by the populations covered and the methods used. The number of sites and the populations included are based on the characteristics of the epidemic its severity and diversity, most often the available resources and the feasibility of regular seroprevalence surveys and the severity and diversity of the epidemic. The most common populations involved are ANC attendees and key populations. For quality assurance and trend analysis, sero-surveillance should follow well-established procedures that meet standards of best practice and are fully documented.

Since 2000 the second-generation surveillance strategy has promoted tailoring the surveillance system to the epidemiological profile of the country. This entails:

1. focusing surveillance resources where they will yield the most needed and reliable information;

2. concentrating data collection in populations considered most at risk of becoming infected with HIV;

3. strengthening information systems to monitor trends in HIV prevalence and sexual and drug injecting behaviours, as well as the impact of interventions;

4. making effective use of other existing sources of information to more fully understand the HIV epidemic.

What are some challenges and opportunities?

Simple, low-cost sampling methods, such as facility-based sampling and convenience sampling, are commonly employed to make annual seroprevalence studies feasible. However, these methods limit the generalizability of the findings. In most cases the results from sentinel surveillance surveys may flag important trends, but prevalence among pregnant women may not reflect HIV seroprevalence in the full adult population, and findings at sites serving a key population may not reflect the broader community. Because HIV epidemics are diverse and heterogeneous in their spread, sentinel sites are representative only of the places and populations that are sampled. New approaches that are now widely used, such as respondent-driven sampling (RDS), aim to achieve better representativeness. Also, modelling techniques have been developed to allow for more accurate extrapolations; still, these always retain some degree of inherent uncertainty. Currently, many countries are using routine PMTCT programme data to monitor HIV prevalence among pregnant women instead of periodic ANC surveillance.

What are some key resources?

Responding to the recent expansion of PMTCT and ART programmes, the UNAIDS/WHO Global HIV Surveillance Working Group produced a new comprehensive package for second-generation surveillance in 2013: WHO/UNAIDS Working Group on Global HIV/AIDS and STI Surveillance. Surveillance of the HIV/AIDS epidemic: 2013 comprehensive package. Geneva: World Health Organization; 2013 (http://www.who.int/hiv/pub/surveillance/2013package/en/index.html).

Assessing service readiness in Malawi

As part of its programme assessment in 2013, the Government of Malawi assessed the readiness of its HIV clinical services. The report states: "682 public and private sector facilities were visited for clinical HIV programme supervision between 7th and 25th October 2013. The large number of sites was covered by 72 supervisors, working in 20 teams. The teams spent a total of 1785 working hours at the sites. Each site visit lasted an average of 2.6 hours, but up to two days were spent at the busiest sites. Some 206 clinic teams were awarded a *Certificate of excellence* for excellent performance. The number of sites with excellent performance decreased from the previous quarter due to a more rigorous application of performance criteria. 58 sites had significant weaknesses and were rated to require intensive mentoring".

This example illustrates the feasibility of carrying out supportive supervision. Although it required many people, the total time that the supervision team needed on site was only 224 person-days. If travel to the service sites required the same amount of time as that spent on site, and if the supervision team consisted of a supervisor and a driver, the amount of person-time needed for supervision nationally would be four full-time equivalents for field work, to which the same amount of person-time should be added to support sourcing/delivering technical assistance to the sites with performance problems.

Source: Integrated HIV programme report, October–December 2013. Lilongwe: Ministry of Health, Malawi; 2014.

3.2.5 Vital registration

Vital statistics are collected and reported by the civil registration system that countries use to maintain records on births and deaths of residents. Civil registration is the continuous, permanent, compulsory and universal recording of the occurrence and characteristics of events, including vital events such as births and deaths,[1] pertaining to the country's population, as provided by decree or regulation in accordance with the legal requirements of the country. While civil registration records are designed for administrative, demographic and legal purposes, they also provide a wealth of information for compiling valuable epidemiological and health statistics on a regular basis.

National governments are responsible for setting up and operating civil registration and vital statistics systems (CRVS). If the system is fully functional, it records not only deaths but also the cause(s) of deaths as indicated on death certificates. In the context of HIV impact assessment, the primary use of these data is for calculating AIDS mortality rates, survival rates (including of those lost to follow-up) and outcome information for cohorts.

What are some challenges and opportunities?

The completeness and accuracy of vital registration varies from country to country. In many low- and middle-income countries, several factors constrain the use of civil registration data for HIV M&E purposes. Where compliance with reporting requirements is poor, deaths may be underreported. Also, reporting of the cause of death may not take into account primary and underlying causes, resulting in misclassification or an incomplete listing of causes. In some cases HIV is not listed as a cause of death in an effort to protect the confidentiality of the deceased and his or her family. Within countries the completeness and accuracy of civil registration may vary across populations (for example, less complete for key populations and

[1] UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance. Guidelines for HIV mortality measurement. Geneva: WHO; 2014 (http://apps.who.int/iris/bitstream/10665/127890/1/9789241505574_eng.pdf?ua=1&ua=1).

other marginalized populations) and certain geographic areas (for example, rural versus urban). Key characteristics of the deceased individual that are relevant to HIV programming, such as whether the person belongs to a particular HIV risk group, may not be recorded. This makes difficult the calculation of differential mortality rates among population groups.

Where there is an appropriate and legally acceptable way of linking individual data across different service delivery points, it may be possible to cross-reference the number of AIDS-related deaths captured in vital statistics systems with facility records of patient deaths. Such data from a range of data sources (such as census, vital statistics and specific HIV databases) have been successfully linked in several countries, including Brazil and South Africa.

What are some key resources?

To encourage governments to invest in civil registration and vital statistic systems, in 2012 the WHO Health Metrics Network published *The case for investment in civil registration and vital statistics systems*.[1] The document discusses the need for a functioning CRVS as well as its scope and cost. WHO and UNAIDS have recently also published guidance on measuring HIV mortality.[2]

3.3 Data systems

The function of the health information system is to collect data from a range of sources (described in the previous section) in a form that can be combined, analysed and shared with stakeholders to support programme planning and decision-making. This process requires standardized protocols and procedures from the point of collection through aggregating, editing and analyzing data at all levels to ensure data relevance and quality.[3] To assess the health sector cascade, it is critical to organize data in an overall data system.

This section describes the health information system from the bottom up, from patient to programme. It begins with the process of collecting and reporting HIV diagnosed, case reporting and patient monitoring data and continues with good practices for data management, including use of unique identifiers, security and confidentiality, interoperability and data flow. Subsequent sections cover data quality, analysis and use.

3.3.1 Individual patient records

Standardized individual patient records serve several functions that support quality services at individual, health facility, district and national levels.

As a clinical management tool, patient records help health-care providers deliver the appropriate services to individuals in a facility or through outreach activities. As an M&E tool patient records record information in a format that facilitates transcription of key data elements into a monitoring system that supports facility, district, national and international levels. Nationally standardized forms ensure that the same information is collected in the same format at all sites and is reported in the same manner from multiple sites for aggregation.

Patient care information is recorded on the individual patient record (HIV care card or patient file); key information is then transferred into longitudinal registers for easy patient follow-up and reporting. Patient records should be stored in a filing system with restricted access, to protect the confidentiality of patients. Individual records should be easily retrievable for patient

[1] WHO Health Metrics Network. The case for investment in civil registration and vital statistics systems. Geneva: WHO; 2012 (http://www.who.int/healthmetrics/resources/CRVS_investment_case.pdf?ua=1).
[2] Guidelines for second generation HIV surveillance: an update: Know your epidemic. Geneva: UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance; 2013 (http://apps.who.int/iris/bitstream/10665/85511/1/9789241505826_eng.pdf).
[3] Health facility information systems. Key components, attributes and resources. Geneva: World Health Organization (forthcoming).

care and data quality audits. Where patient-held cards are used, patient information should also be recorded in facility-held records for safe keeping.

Individual clinical record forms should be laid out for quick access to patient care data, both for the clinicians treating the patient and for the person transcribing data elements into a reporting system. In contrast to unstructured and often difficult-to-read notes written freehand by clinicians, structured patient clinical records include specific fields where details, such as history and risk factors, laboratory results, opportunistic infections, medications and follow-up plans, are written in the same place for every patient at every visit. Some visit summary sheets present multiple visits on one page – one column per visit. This format makes it possible to review immunological status and drugs over multiple visits by simply scanning across a row. User-friendly written guidelines and job aides help ensure that forms are correctly and fully completed.

A well-structured and standardized individual clinical record improves patient care by:

- using row or column labels as prompts to trigger a comprehensive assessment, especially in clinics employing locums or clinicians new to the service;
- using a table structure to collect multiple visits on one page, with rows (or columns) assigned to specified data elements, so that patient management (for example, treatments, routine testing requirements) can be easily scanned across recent visits to improve continuity of care;
- allowing for quick review by clinicians and supervisors to ensure completion of all data elements.

What are some challenges and opportunities?

Busy health-care providers often do not complete their paperwork in a timely fashion. To ensure completeness and accuracy of information in the individual patient record, providers need to be trained in the proper procedures, and supervisors should regularly review records for completeness. A user-friendly layout that is not overcrowded on the page and follows the flow of patient care makes completing the records easier and quicker. The amount of information to be entered should be limited to elements that directly relate to patient care or key national reporting indicators. Monthly reporting data can be summarized at the facility level and shared with clinic staff to make the data collection process relevant to their work and to increase their buy-in.

What are some key resources?

- Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy) and TB/HIV: standardized minimum data set and illustrative tools. 2012 revision. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/77753/1/9789241598156_eng.pdf?ua=1). [Important note: This guidance is currently under revision; updates will be published on the WHO website.]
- WHO Health Metrics Network. Framework and standards for country health information systems. Geneva: World Health Organization; 2008 (http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf?ua=1). This publication discusses individual patient records in the framework of the national health information system.

3.3.2 Paper registers and reporting forms

In many health information systems, data elements for multiple patients are compiled in paper registers that facilitate tracking patients over time. These aggregated patient data are then transferred to reporting forms on a regular basis and sent to the district health office. Enrolment, retention, clinical status and outcomes can be reported using paper registers if they are set up with a simple, easy-to-tally structure.

Registers used in HIV clinics are usually longitudinal, following individual patients over time. Paper registers can be used to follow a cohort of people over time based on a defined starting point (for example, baseline initiation of ART, first HIV care visit). In some cases, however, registers count the number of patients who engage in a service without following them over time. For example, laboratory test registers record the patients who receive a specific test and their test results.

The registers should be set up to collect a defined data set, determined by the questions that the monitoring system needs to answer. Reporting forms should clearly define the service, clinical assessment and patient status elements to be entered. In general, reporting forms should be designed to collect the required data in the least burdensome way. The frequency of reporting of different data elements should be based on data use requirements; some data elements may need to be tracked on a monthly basis (for example, enrolment in HIV care), since they describe the ability of a facility to scale up a new or dynamic service, while others can be reported on a quarterly, semi-annual or annual basis.

Extraction of data from the columns in a paper register requires time and trained personnel. Paper reports should be verified and signed off by an operations or facility manager and sent to the next level of the health system according to the schedule for reporting.

Well-designed paper registers:

- collect a limited and defined data set (as required for patient follow-up and the national monitoring system);
- record each patient only once per facility (that is, one patient per row) in longitudinal registers, or each episode is written only once (that is, one episode per row) in cross-sectional registers;
- include demographic and baseline data as well as follow up the clinical and immunological status of a cohort of patients;
- are limited to one disaggregation category (that is, age, sex) per register to avoid the need to cross-reference data to specific baseline elements;
- have adequate space to record data elements and totals at the bottoms of columns or ends of rows, as needed.

What are some challenges and opportunities?

As with individual patient records, the completeness and quality of data in registers need to be ensured. This requires training of staff, regular supervision and data quality checks, and staff buy-in. In countries or sites using paper registers, the value of disaggregated data should be carefully weighed against the time and effort required to collect the additional information. The benefit of disaggregated data depends on its usefulness for programme management

and service improvement and varies by the indicator measured. Stratifying baseline or cross-sectional data in a paper register is not very labour-intensive since it requires simply filling in one or more additional columns. By comparison, stratifying outcome data in a cohort requires a separate register for each subcategory. The ability to disaggregate data also depends on the availability and capacity of staff members; inadequately staffed clinics may be overburdened by the extra work, while clinics with more staff may be able to accommodate it easily. How much to disaggregate data deserves careful consideration. National protocols should include guidance for different settings to avoid overburdening health workers and, as a result, compromising data quality.

What are some key resources?

- Three interlinked patient monitoring systems for HIV care/ART, MCH/PMTCT (including malaria prevention during pregnancy) and TB/HIV: Standardized minimum data set and illustrative tools. Revision 2012. Geneva: WHO; 2012 (http://apps.who.int/iris/bitstream/10665/77753/1/9789241598156_eng.pdf?ua=1). [Important note: This guidance is currently under revision; updates will be published on the WHO website.]

3.3.3 Electronic data systems

Electronic data systems are an important tool to improve patient follow-up and for storage and retrieval of data. Electronic systems record the same data elements as paper registers, but they have numerous advantages over paper-based systems:

- Patient-level data can be tracked over time and linked to other data sources such as death certificates.
- Individual-level data can be more easily and more quickly aggregated at successively higher levels of the reporting system, up to the national level.
- Electronic systems make disaggregation of data by important variables easy, thus making possible richer, more detailed analysis of clients' needs and the reach of services.
- Using unique patient identifiers, online software can track patients' movement across multiple facilities, giving all clinicians the patient's full history. The patient's demographic data can be collected just once rather than in each facility.
- Networked online software can link to other software to import laboratory and pharmacy data, for a more comprehensive understanding of patient services and outcomes.
- Individual-level data are preserved more easily at the different levels of the reporting system.
- Electronic systems, including simple offline systems, make possible more detailed and timely reports. These reports can enhance patient management and provide insight into the management and quality of services. Data that track staff burden are available. Staff members can be held accountable for meeting workload thresholds and maintaining service quality.

Many countries use some combination of paper-based and electronic medical records, depending on human and financial resources and the information and communication technologies (ICT) available (see below, page 218).

There are two types of electronic data management systems—offline and online.

Electronic offline systems use a simple, robust software that requires only a computer (or other electronic device that supports the specified software) and a stable supply of electricity. Offline systems can be scaled up rapidly at reasonable cost due to the minimal hardware requirements (computer and flash drive). In addition, close alignment of the electronic form

with the structure of paper registers already in place makes it simple for staff with basic computer literacy to adapt to the new technology. An offline electronic register can be designed for rapid capture of data from paper registers, avoiding laborious back-capturing directly from patient clinical records, if the paper registers have been kept up-to-date and are filled in accurately.

Electronic online systems are often called electronic patient medical records (EMRs) because the data follow the patient regardless of service delivery point, provided the delivery point is networked to the software. (If not, the software can print comprehensive referral or transfer letters for clients going to a facility without the online software.) The flow of folders (patient cards) through the clinic needs to be structured to ensure that data staff can enter the data from all assessments prior to re-filing the folders. The database usually sits centrally on a main server, with the application either on the web platform (online) or on facility computers. The software is networked and often has the ability to communicate with other software, including laboratory, pharmacy and other health service software. Staff can collect data for EMRs retrospectively, after a clinical assessment, or in a point-of-care system, with clinicians directly capturing data during a patient's visit. Point-of-care entry systems also can provide decision support for clinicians. Networked electronic monitoring systems share much the same benefits and challenges of offline electronic systems.

When adopting electronic data systems, several points should be considered. The software should be robust enough to protect the format and patient linkages during user activity. Incorporated validations and prompts will improve the accuracy of initial data entry. Data security measures should include user profiles protecting levels of access to data and functionality. Exported files should be encrypted and/or password-protected. Employing electronic systems means that a dedicated staff is needed to accurately transcribe data into the electronic software. Also, a staff needs to be hired or contracted for trouble-shooting, fixing or facilitating the maintenance and repair of hardware.

What are some challenges and opportunities?

When moving from paper-based to electronic platforms, managers and analysts are tempted to increase the number of variables captured, since the number is no longer constrained by the space available in the register. But managers should exercise restraint when moving to electronic platforms so as not to over-burden collection points with a larger data set that, inevitably, will be poorly collected.

Electronic data systems are more expensive than paper-based systems and require capacity-building, equipment and ongoing technological support. Online systems are more expensive than offline electronic systems because they require cabling to the sites, network points within the sites and a team to maintain the network. Multiple service points (for example, reception, pharmacy) can talk to a single online software, but this requires more computers per facility, increasing costs. Nevertheless, there is an important shift towards online reporting systems in many countries. Where resources are available, introducing the EMR is the first step towards a fully digitized health service in the future.

What are some key resources?

- The World Health Assembly adopted a resolution (WHA66.24) on eHealth standardization and interoperability in 2013 (http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R24-en.pdf).

The National eHealth Strategy Toolkit is a practical guide for governments and stakeholders to the development and implementation of a national eHealth vision, action plan and monitoring framework.

- National eHealth strategy toolkit: overview. Geneva: World Health Organization and International Telecommunication Union; 2012 (http://www.who.int/ehealth/publications/overview.pdf).
- WHO Forum on Health Data Standardization and Interoperability. Geneva: World Health Organization; 2012 (http://www.who.int/ehealth/WHO_Forum_on_HDSI_Report.pdf).
- Framework and standards for country health information system. Geneva: World Health Organization; 2008 (http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf).

Issues to consider when choosing a patient information software product

- Can the database expand to collect an ever-increasing number of patients with increasing visit data?
- Is the software free to use, and will it continue to be free to use in the future? If not, are there enough funds to continuously improve and update the software when there are protocol and policy changes?
- Is there a person who can be responsible across platforms to provide stewardship regarding interoperability and functionality?
- Will the software work in your context (platform and infrastructure requirements)?
- Does the software require more than the collection of the minimum data set of required indicators?
- Will the owners of the software provide support and maintenance of the software at a reasonable rate?
- How many computers and personnel are required at the facility level to operate the system?
- Will the owners of the system hand over all source code if they can no longer support the software to the standards that the ministry of health requires?
- Are the owners of the system networked enough to continue supporting the system over time (if self-raising funds)?
- Will the raw data be readily accessible to clients approved by the ministry of health?
- Do the reports validate and provide the required data in the correct format?

Multi-tiered routine monitoring approach

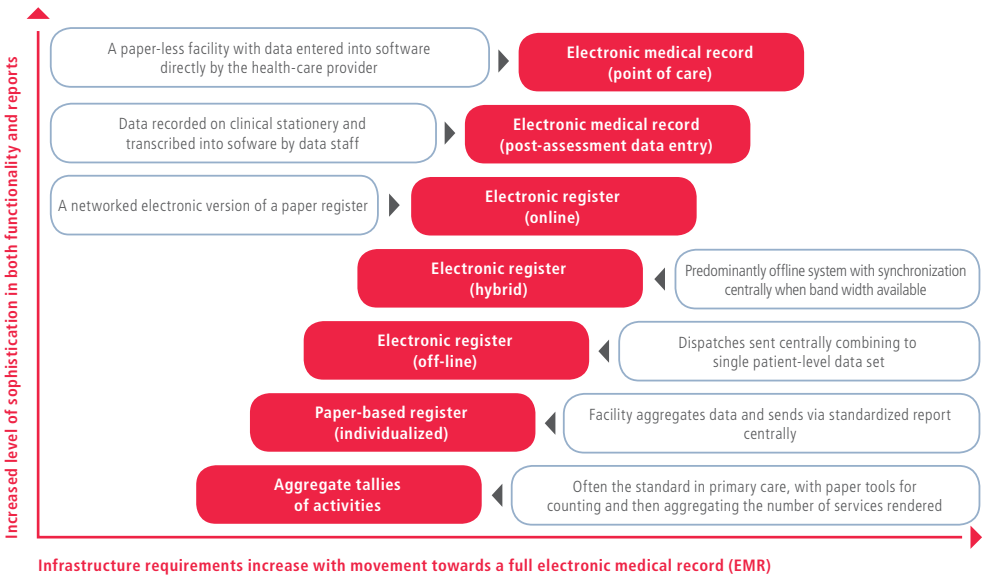
Strategic choice of the most appropriate monitoring approach for each health facility is determined by the resources (money and staff) and infrastructure (Internet, networks and electricity) available at the facility. Each monitoring approach used (Fig. 3.3) should produce the same nationally required reports, using standard definitions of variables and value formats for aggregation at the national level. This interoperability also facilitates a smooth transition when upgrading to a more sophisticated system.[1]

More sophisticated levels of the system can produce more sophisticated reports. Offline electronic systems can provide, for example, lists of patients who have missed appointments

[1] Osler M, Hilderbrand K, Hennessey C, Arendse J, Goemaere E, Ford N, et al. A three-tier framework for monitoring antiretroviral therapy in high HIV burden settings. J Int AIDS Soc, 2014; 17(1):18908 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4005043/).

or who are on waiting lists for ART that paper-based reporting systems cannot produce. At a higher level online EMR systems also provide useful management tools, such as appointment systems and access to pharmacy and laboratory data. However, more sophisticated monitoring systems are more complex and require more staff capacity and support. Therefore, a facility should prove its capability at a lower tier before moving up to the next level. Also, programme managers should be making full use of the reports at the current level; there is no point in upgrading to a capacity that will require more investment and yet will not be used. For support all tiers need trained staff, protected time to capture data, a structured folder flow within the facility, standardized patient clinical records that are completed accurately by clinicians and a smoothly operating registry.

Fig. 3.3 Different candidate tiers in a multi-tiered monitoring system



Source: Osler M, Hilderbrand K, Hennessey C, Arendse J, Goemaere E, Ford N, et al. A three-tier framework for monitoring antiretroviral therapy in high HIV burden settings. J Int AIDS Soc, 2014; 17(1):18908 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4005043/).

What are some challenges and opportunities?

The ministry of health needs to select carefully the monitoring approaches for the country, to ensure interoperability among systems and to facilitate training. It is not feasible or efficient to support a large number of different monitoring approaches. Three approaches (paper, an offline electronic solution and an EMR) have had the most success at country level to date.

A multi-tiered approach makes possible a single national database without requiring electricity or Internet access at every health facilities. Still, ensuring interoperability is not a one-off procedure. As protocols and policies change, both paper forms and computer software, including the file exchange enabling interoperability, need to be updated. Supporting multiple tiers requires training to support each monitoring system. As a facility evolves to the next tier, more resources and training support are required.

Given improvements in technology and connectivity, many countries are moving towards simplified electronic reporting at all levels and eliminating paper-based reporting.

DHIS 2 software for district-level health information

While household surveys remain an important means of collecting population-based health information, the strengthening of primary health-care services with electronic data systems provides an important source for routine collection of health information. This is an important development, which WHO actively supports throughout health-care systems, including in HIV services.

DHIS 2[1] is a software tool for collection, validation, analysis and presentation of aggregate statistical data, tailored (but not limited) to integrated health information management activities. DHIS 2 is a modular web-based software package built with free and open-source Java frameworks. It is a generic tool with a flexible user interface that allows users to design the contents of an information system without the need for programming.

DHIS 2 allows collection, management and analyses of transactional, case-based data records and makes it possible to store information about and track people's records over time using a flexible set of identifiers. As an example, DHIS 2 can collect and share essential clinical health data records across multiple health facilities. Clients can be enrolled for longitudinal programmes with several stages. One can configure SMS reminders, track missed appointments and generate visit schedules, among other tasks. DHIS 2 has advanced features for data visualization, such as a geographic information systems (GIS), charts, pivot tables and dashboards.

As a first step DHIS 2 serves as a data collection, recording and compilation tool. Data can be entered in lists of data elements or in customized, user-defined forms that can be designed to mimic paper-based forms that may be familiar to personnel.

As a next step DHIS 2 can be used to improve data quality. At the point of data entry, the data can be checked to see if they fall within an acceptable range for that data element. Such checking can help to catch typing errors. Further, validation rules can be defined to identify violations.

When data have been entered and verified, DHIS 2 can help to complete reports. Routine reports can be predefined, so that all routine reports can be generated automatically. Also, DHIS 2 can help in the generation of analytical reports through comparisons – for example, of indicators across facilities or over time. Graphs, maps, reports and health profiles are among the outputs that DHIS 2 can produce. These should routinely be produced, analysed, and acted upon by managers.

[1] DHIS 2 is an open and globally distributed process, managed by the Health Information Systems Programme (HISP), with developers currently in India, Ireland, Norway, the United Republic of Tanzania and Viet Nam. The University of Oslo, with core support from NORAD Development, coordinates development. For more information see https://www.dhis2.org/overview.

Sample or sentinel monitoring facilities

Sentinel monitoring facilities are strategically selected sites that collect a larger data set in order to answer more complicated clinical questions. The sentinel monitoring facilities collect data into an electronic platform for analysis. This approach is used for drug resistance surveillance monitoring. The data should be assessed for accuracy and completeness more closely than facility data from routine monitoring.

Using sentinel monitoring sites reduces the burden of large data sets for other HIV and ART routine reporting facilities. Variables that not change based on location of service delivery or quality of service do not need to be collected at each and every service point. Such variables can be collected at a few facilities and projections can be made for the larger population that uses the health service.

Sentinel monitoring facilities need additional staff to capture the larger data set and closely monitor data quality. These sites should have research officers with the skills to manipulate data in order to answer ad-hoc questions from the province/state or ministry. In fact, often a site is chosen as a sentinel monitoring site because it receives additional staff and resources from an academic or non governmental partner.

3.3.4 Data management

Good practices in data management

Strategies for storing and managing data (whether in paper files or electronic form) and how the data will be used should be decided at the planning stage and described in the strategic information and M&E plans so that data recording and collection can be designed with use in mind.

Good data management includes developing effective processes not only for consistently collecting and recording data but also for storing data securely, cleaning data, backing up data and modifying data so that they can be transferred between different types of software for analysis.

Even when data have been collected using well-defined procedures and standardized tools, they need to be checked for any inaccurate or missing data. This data cleaning involves finding and dealing with any errors that occurred along the way from initial recording of information through to data entry.

Good data management extends to presenting data appropriately – that is, turning data into information – so that findings are clear and conclusions and recommendations can be substantiated. Often, this also involves making the data themselves accessible so that others can verify the analysis or use the data for other purposes such as synthesizing findings from multiple evaluations (that is, systematic review, meta-analysis, realist review or other meta-evaluation).

Other important elements of good data management are:

- data security
- confidentiality
- data access and sharing
- use of unique identifiers
- interoperability.

While data access and sharing are important, data security and the confidentiality of individual patient records are crucial, especially for information on key populations.[1]

Using unique identifiers

A unique identifier (UI) is a numeric or alphanumeric string associated with a single individual within a data management system. Using UIs provides stronger linkage across the cascade of services and, as a result, more efficient and effective care.

Patients may receive multiple health-care services, in different sites and at different times (for example, for HIV and TB). The use of UIs gives the ministry of health the capacity to reliably link all health data pertaining to a particular individual. Purposes include:

1. obtaining an exact count of the numbers eligible for or needing health care; such counts inform planning, monitoring the progress of service delivery and help to evaluate impact across different providers, sites and health sector departments.

2. giving health-care providers each patient's comprehensive longitudinal disease and medical care history; this information informs decisions about patient care.

UIs have huge potential for the day-to-day operations of health-care organizations. They are used routinely for:

- coordination of patient care services through interaction among service domains;
- clinical documentation and information management – collecting and organizing information such as prescriptions, procedures, results and notes in a patient chart; the patient chart can be on paper or an electronic medical record;
- administrative functions including billing and reimbursement;
- aggregation of patient data from multiple sources – collecting, aggregating and analysing data on groups of patients to monitor and evaluate treatment efficacy and safety and inform research as well as for statistical reporting and planning.
- Linking databases to construct longitudinal prevention and care cascade measurements.

In the continuum of care across any health system, reliable patient identification is often mandatory for services such as blood transfusion, invasive testing, surgical procedures and administration of medication.

The UI can be a national ID number, a national health number, a programme-specific identifier or a biometric identifier. Each of these has its own challenges, such as patient confidentiality when utilizing a national identifier or resources if implementing a biometric identifier.

In regions where all facilities participate in a networked system, introducing a system of unique identifiers is a matter of choosing correct software. Generating UIs in a decentralized system is more difficult. An opportunity today is to use mobile phones to implement a country-wide patient management index that generates UIs. Software to store patient registration data and several patient identifiers could reside in a central server. This software could also generate a unique identifier for patients who are not yet registered. When patients enter a health faculty without a patient-held card showing their unique identifier, a reception staff member could use a mobile phone to contact the central server and first look up the patient and then, if he or she is not in the system, to register that person through a simple form filled in on the phone. For this approach to work, mobile phone charges for calling the central server need to be reverse-charged to the department of health so that callers do not incur costs.

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[1] Interim guidelines on protecting the confidentiality and security of HIV information. Proceedings from a workshop, 15–17 May 2006. Geneva: UNAIDS and PEPFAR; 2007 (http://data.unaids.org/pub/manual/2007/confidentiality_security_interim_guidelines_15may2007_en.pdf).

If an mHealth solution like this is not a viable option, there are manual options. Particularly helpful are a structured algorithm for generating a unique number per patient and a patient-held document that he or she shows at reception at every health facility. An algorithm for generating a UI number structures a combination of numbers and/or letters constructed of data familiar to the person concerned (see box for example from Mauritius). Using familiar information permits a health-care staff member to reconstruct the UI for a person who has forgotten it or has failed to bring his or her UI.

To help ensure that patients keep and produce their patient-held cards at every visit, patients should be offered an incentive. For example, those who bring their UIs get in line to be seen by a clinician (using the patient-held card as a place holder), while those requiring a card need to wait while the UI is generated and the card written or printed prior to getting in line. Another benefit could be having a table on the card where each next appointment date and type of visit can be filled in. Also, plotting patient progress (such as CD4 count) on the card empowers the patient with self-information, which adds to the benefit of the card.

What are some challenges and opportunities?

Individual-level health information is increasingly used to monitor and evaluate the effectiveness, efficiency, equity, acceptability and quality of service provision at facility, regional or national levels. Use of individual information in this context requires the protection of personally identifiable health information by, for example, transforming it into anonymized or pseudo-anonymized information. The use of individual-level information must be carefully balanced with the risks associated with breaching confidentiality. In this regard an advantage of UIs over other methods of registration and patient tracking is its enhanced confidentiality and protection of privacy, since neither the name nor other personally identifiable information is used.

Aggregated data are always needed. Aggregate data can be affected by errors in patient identification that result in double-counting or missing data. Use of UIs can provide reliable estimates of the patient identification error rate; data managers can use that rate to gauge and improve the accuracy of aggregate reporting. In the absence of UIs, data from population surveys are used to adjust reported aggregated counts through triangulation methods. This can be useful if necessary, but it does not guarantee a high degree of accuracy.

UIs can be useful in both cross-sectional and longitudinal studies. Cross-sectional data can provide a snapshot of a certain population whose health status can be determined before or after sample selection on the basis of UI. In longitudinal studies, using UIs to track patients over time permits more comprehensive data analysis, including assessment of the linkages between services along the continuum of care.

Experience with the use of UIs in Mauritius

The Monitoring and Evaluation Section of the Mauritius National AIDS Secretariat developed a UI system in order to ensure the confidentiality of clients and to eliminate double-counting in the compilation of programme data. Unique Identification Codes (UICs) provide an anonymous and reliable system for tracking clients through prevention, treatment and care services and create a confidential service recognition system that minimizes barriers to HIV services, particularly for key populations. In the Mauritius HIV programme, both health professionals and civil society organizations use the UICs.

In Mauritius the introduction of UICs was particularly important in prisons, where almost no one has an identity card. For identification in prison the inmate is photographed and his or her name is written on the photo. The most commonly available information about a person is name and date of birth. Probably, only about 5% do not have this information.

The UIC is allocated as follows:

First letter identifying the sex of the person –M/F (male/female), for example, **M**;

Date of birth (DD/MM/YYYY) – for example, **10/07/1960**;

First letters of all other names – for example, Joseph Louis Frederic Michel = **JLFM**;

First and last letter of surname – for example, Olivier = **OR**

Thus, the UIC is **M10071960JLFM-OR**.

Initially, all stakeholders resisted use of the UIC. The programme proceeded with a pilot implementation, first through peer outreach among people living with HIV enrolled in care, prison inmates and men who have sex with men and then to demonstrate its importance and advantages to all stakeholders. Health professionals, NGO staff and peer educators received training in the use of the UIC. Thereafter, use of the UIC was progressively extended to the methadone substitution programme, outreach among sex workers by peer educators and to all other HIV services.

The use of the UIC has contributed to the following:

1. enabling analysis of treatment cascades through continuum-of-care indicator data
2. avoiding double-counting of clients attending services
3. identifying individuals newly engaging with services from prevention through to treatment
4. assessing the mobility of key populations through outreach services and health facilities
5. helping to reorient services to meet needs and attendance patterns of key populations
6. creating connections between outreach and facility health data
7. tracking coverage of key populations by the national HIV programme.

While UIs have clear benefits, they also have weaknesses. It can be difficult to follow up a patient outside of the health-care system (such as for services received in the community) on the basis of a UI, as the patient's address may not be coded in the UI. In addition, the UI system needs a physical marker to prevent assigning the same UI to more than one person. Conversely, re-registration of the same patient who declares different characteristics may lead to entering the same individual twice, with two numbers. It is also conceivable to have breaches into the database, as the information could be of interest to employers, insurance companies, traders and others. All these problems have been documented in high-income countries. Mechanisms are needed to monitor the use of UIs and related systems and to provide redress in case of any breeches.

What are some key resources?

- Considerations and guidance for countries adopting national health identifiers. Geneva: UNAIDS; 2014 (http://www.unaids.org/en/resources/documents/2014/national_health_identifiers).
- Developing and using individual identifiers for the provision of health services including HIV. Montreux: UNAIDS; 2010 (http://www.unaids.org/en/media/unaids/contentassets/documents/dataanalysis/20110520_Unique_Identifiers_Meeting_Report_Montreux.pdf).
- Appavu S. Analysis of unique patient identifier options final report. Prepared for the U.S. Department of Health and Human Services, 1997 (http://ncvhs.hhs.gov/app0.htm).
- Standard guide for properties of a universal health care identifier (UHID). West Conshohocken, Pennsylvania, USA: ASTM International; 2007. ASTM E-1714-00 (http://www.astm.org/Standards/E1714.htm).
- Guide for implementation of a voluntary universal health care identification system. West Conshohocken, Pennsylvania, USA: ASTM International; 2007. ASTM E-2553-00 (http://www.astm.org/Standards/E2553.htm).
- Health informatics. Identification of subjects of health care. Geneva: International Organization for Standardization; 2011. ISO/TS 22220:2011 (http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=59755).

Interoperability

Reliable and timely health information is an essential foundation for health systems strengthening and public health action, both nationally and internationally. Functional health information systems depend on data elements that are harmonized and interoperable between and within systems through the adoption of health data standards and information technology (IT) standards.

Interoperability is the extent to which systems and devices can exchange data and interpret those shared data. For two or more computer system to be interoperable, they must be able to exchange data seamlessly and subsequently present those data in a way that a user can understand.[1]

Interoperability is important to collecting and holding data from multiple sources in a single national database. Consolidating all information in a single database facilitates in-depth analysis of access, services rendered, epidemiological trends and population health profiles.

A structured data exchange template utilizing health data standards and health IT standards should be used so that all health data can be collected regardless of software used. The ministry of health needs to establish a working group with overall responsibility for the interoperability exchange template and for deciding which data standards are used.

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[1] Definition taken from Definition of interoperability approved by the HIMSS Board of Directors April 5, 2013 (http://www.himss.org/files/FileDownloads/HIMSS%20Interoperability%20Definition%20FINAL.pdf.)

What are some challenges and opportunities?

- Achieving interoperability is not a simple process, but it is a critical goal for every system created for clinical and public health interests.
- The interoperability of electronic medical record (EMRs) or electronic health record systems (EHRs) is critical for achieving patient-level data exchange between computer systems. However, building interoperability functionality into software is not a one-off procedure. As protocols and policies change, software needs to be updated, and this includes the file exchange that assures interoperability.
- Choosing a highly coded standard exchange template can increase efficiencies in terms of data processing. However, it may make data more difficult to use and analyse and less accessible to data analysts.
- Data must be secured at all times; the data exchange template needs to be encrypted or coded to ensure patient confidentiality.
- Data warehousing is expensive to set up but will be extremely useful in the long term if done properly from the start.
- The adoption of EMRs at health facilities can greatly enhance the storage, retrieval, transfer, and analysis of patient information for healthcare and public health surveillance purposes. This is especially important for longitudinal collection of patient data. Implementing reliable computer-based health information system and EMRs depends upon adequate human and financial resources and the appropriate use of ICT.
- Although numerous EMRs and EHRs exist, the lack of seamless data exchange (interoperability) between computer-based health information systems remains a major problem and impediment to health systems strengthening efforts. Due to lack of interoperability, the enormous amount of electronic health-related data stored in electronic systems, including in EHRs and EMRs, are underutilized by public health agencies.
- Lack of interoperability between health information systems leads to fragmentation and can hinder effective provision of health-care services. Thus, enhancement of current efforts towards interoperability at national and subnational levels is essential to realize the full potential of ICT in health systems.
- Exchange of personal, administrative and clinical data between EMR systems cannot occur without utilizing appropriate standards for interoperability. Therefore, it becomes necessary to implement eHealth standards in electronic systems for EMR interoperability at the point of care. This will allow patient data captured at health facilities to be sent through the district and intermediate (province and region) levels to the national level and used at all levels.

What are some key resources?

- WHA resolution on eHealth standardization and interoperability. Geneva: World Health Assembly; 2013 (http://www.imia-medinfo.org/new2/GA/2013Copenhagen/A66_R24-en.pdf).
- Report on the Joint Inter-Ministerial Policy Dialogue on eHealth Standardization and Second WHO Forum on eHealth Standardization and Interoperability. Geneva: World Health Organization; 2014 (http://www.who.int/ehealth/events/final_forum_report.pdf?ua=1).
- WHO Forum on Health Data Standardization and Interoperability. Geneva: World Health Organization; 2012 (http://www.who.int/ehealth/WHO_Forum_on_HDSI_Report.pdf?ua=1).
- T. Benson. Principles of Health Interoperability HL7 and SNOMED, HI. Chapter 2, pages 25–26, London: Springer; 2010.

• Health Metrics Network. Framework and standards for country health information systems. Geneva: World Health Organization; 2008 (http://www.who.int/healthmetrics/tools/framework/en/en/).

3.3.5 Health management information systems

A health management information system (HMIS) is an information system specially designed to assist the management and planning of health programmes, as contrasted with delivery of care.

An HMIS is most often designed as a system to collect a predefined set of data from multiple health services and feed it into a single national database. The HMIS may collect both programme and logistics data and may include data management and analysis functions. As data flow from the facility through the different management levels to the ministry of health, programme managers should be able to access, validate, sign off and use the data at each health level. With paper-based and multi-tiered systems still commonplace in most resource-constrained countries, the data collected by the HMIS often consist of aggregate counts of services rendered or cases presented. Tally sheets or log books are often used to facilitate the aggregation of the data at the facility level. The HMIS software may capture a smaller data set than the routine programme data software; not everything collected needs to be sent to the national level. However, as more countries become able to collect longitudinal data on their HIV and TB programmes, HMIS software is starting to collect aggregated clinical, immunological and outcome data as well. HMIS software may sit at a subdistrict or district level, and aggregated paper reports generated at facility level are entered manually into the HMIS there.

HIV programme information should routinely flow through to the HMIS either in paper format or in an electronic import file. The data in the HMIS software should be available for use in the form of reports, raw data and pivot tables for programme managers at all levels of health care. Forums at the different levels of care should present and discuss the data, learning from participants' sharing of challenges overcome. Measurably successful innovations developed in the field should inform health policy decisions at the central level.

What are some challenges and opportunities?

Challenges include the following:

- HMIS software needs to be maintained and updated to remain in line with changing national protocol and policy.
- Data quality needs to be kept at a high level in order for the data to be used to inform policy.
- Specific health programmes may have software that collects a larger data set than required by the HMIS. These patient-level data often are collected in a more robust, auditable way than conventional tally sheets or log books allow. It is important that all software used in health-care facilities work interoperably with the national HMIS software. In the long-term countries should move toward eliminating parallel reporting systems.

What are some key resources?

- Health information systems: toolkit on monitoring health systems strengthening, Geneva: WHO; 2008 (http://www.who.int/healthinfo/statistics/toolkit_hss/EN_PDF_Toolkit_HSS_InformationSystems.pdf).

3.4 Data quality review

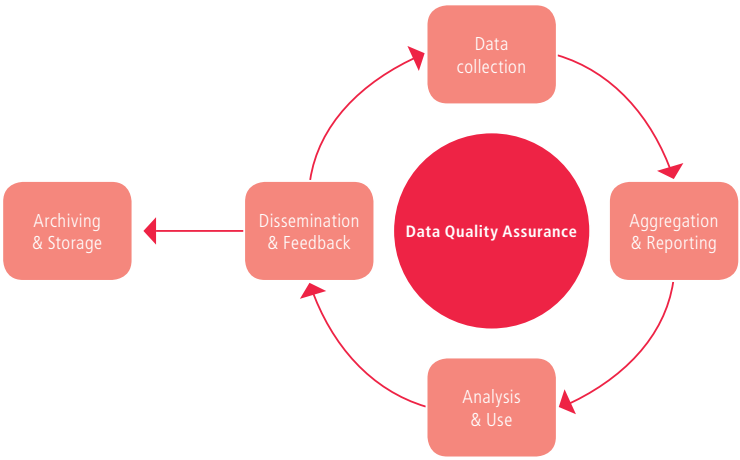
High quality data are critical for monitoring programme effectiveness and making programmatic decisions as well as for ensuring a high quality of care. Using data of unknown or low quality may result in a flawed analysis and wrong decisions. The Data Quality Review (DQR) seeks to ensure that data accurately reflect the status of the populations and the performance of the programmes that they represent.

The DQR framework is a collaborative effort of WHO, the Global Fund and Gavi to create a harmonized approach to assessing the quality of data on HIV; TB; malaria; reproductive, maternal, newborn and child health; and immunization from the level of health facilities to the national level. This framework builds on existing data quality assurance mechanisms. Its methodology and indicators have been developed and selected through broad consultation with international health programme experts from leading donor and technical assistance agencies. The DQR complements routine monitoring, supervision and evaluation to strengthen programmes.

Dimensions of data quality

- **Validity:** the degree to which the data measure what they are intended to measure
- **Accuracy:** the percentage of data fields containing correct data
- **Availability:** ability of the system to report the data, including availability of registers to validate reported data and percentage of facilities submitting monitoring reports
- **Completeness:** the proportion of data fields that are complete (not missing data)
- **Timeliness:** the proportion of reports submitted on time.

Fig. 3.4 Data quality review system



Source: Data quality assurance standards and tools for PMTCT programmes. Geneva: IATT, (forthcoming).

The DQR examines the quality of data for a set of core tracer indicators[1] on maternal health, immunization, HIV, TB and malaria generated by health facility-based information systems across different dimensions of quality. It determines whether any problems found are programme-specific or more systemic. Through analysis of these standard indicators, it quantifies problems of data completeness, accuracy and external consistency and thus provides valuable information on "fit-for-purpose" of health facility data.[2]

The data quality dimensions included in the DQR are:[3]

- **Completeness and timeliness:** This dimension measures the extent to which the data reported through the system are available and on time.
- **Internal consistency of reported data:** This dimension examines the plausibility of reported results for selected programme indicators based on the history of reporting for the indicators. It assesses programme indicators that have a predictable relationship to determine whether, in fact, the expected relationship exists between those two indicators. A final aspect of this dimension is an assessment of reporting accuracy for selected indicators through the review of source documents in health facilities.
- **External consistency with other data sources:** This dimension assesses the level of agreement between two sources of data measuring the same health indicator.
- **External comparisons of population data:** This dimension determines the adequacy of the population data used in the calculation of health indicators, as these serve as denominators in the calculation of a rate or proportion and provide important information on coverage.

The DQR methodology includes:

1. a desk review component, where the quality of reported aggregate data for recommended programme indicators is examined using standardized metrics;

2. a facility survey that has two components:

- a health facility data verification component, where data from source documents are compared with data reported to district authorities;
- a system assessment (SA) tool, which measures the capacity of the reporting system to produce good quality data, thus providing insight into the causes of data quality problems.

DQR is not a one-time activity. Therefore, the DQR framework proposes a multi-pronged approach that includes:

- **Routine** and **regular** (that is, monthly) reviews of data quality that are built into a system of checks of the HMIS or other existing parallel programme reporting systems; these reviews are part of a feedback cycle that catches mistakes and corrects them soon after they happen.
- An **annual** assessment that examines the quality of health facility data used for annual health sector planning and programme monitoring.

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[1] While it is advisable to select indicators from the core list, countries can select other indicators or expand the set of indicators based on their needs and available resources.

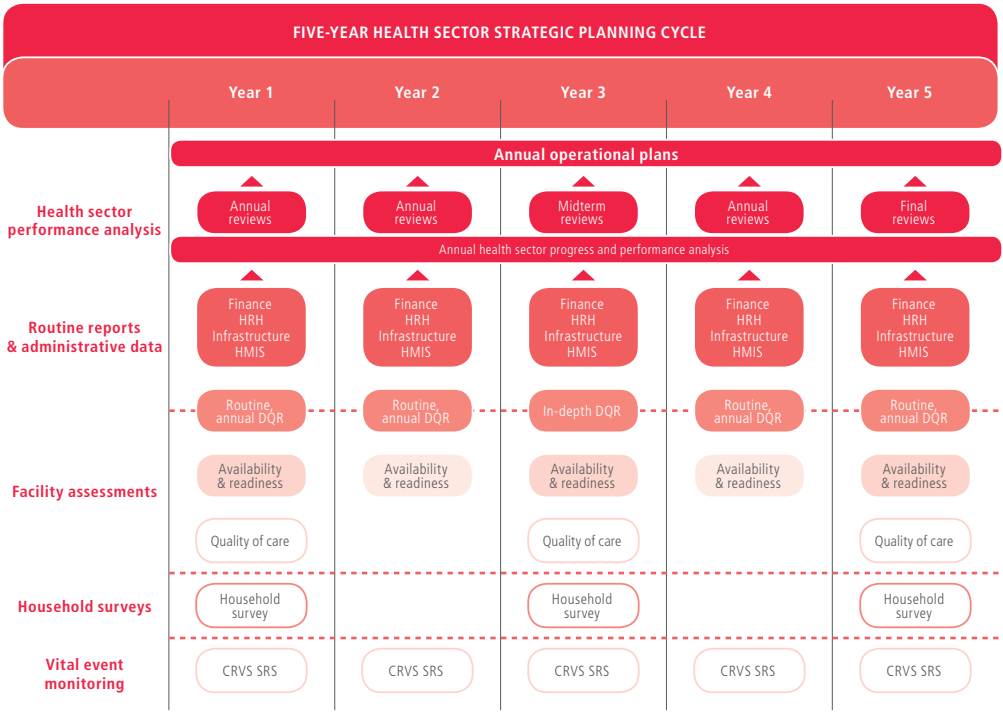
[2] A toolkit, including guidelines and tools, has been developed that lays the foundation for a common understanding of data quality such that a regular mechanism for data quality assessments can be institutionalized in country. These guidelines and tools present a core DQR that should be conducted annually. However, these tools are flexible and can be adapted or applied equally to routine or ongoing and in-depth programmatic DQRs. This toolkit includes: 1) DQR Framework and Metrics Document; 2) DQR Technical Guide; 3) DQR Data Collection Tools; 4) a spreadsheet tool that will automate analyses of all the data quality metrics except for the data verification component and 5) data collection forms for electronic data entry using tablets. This toolkit will be published in 2015.
Additional tools to facilitate analysis are also being developed and will be added to the toolkit when completed. There is also work underway to incorporate some of the DQR metrics into the DHIS 2 system. For countries that have the DHIS 2 system as their HMIS, this addition will greatly facilitate regular data quality assessments. Other, existing tools that fit into this framework can also be used.

[3] Data Quality Review: A toolkit for assessing health facility data quality. Geneva: World Health Organization, (forthcoming).

- **In-depth** reviews of data quality that typically focus on a sole disease or programme area are conducted periodically (such as every three to five years) and feed into programme reviews.

It is especially important that DQRs should fit into the overall health sector strategic planning cycle, as shown in Fig. 3.5.

Fig. 3.5 DQR in health sector strategic planning



Quality review for electronic databases

Many data quality assurance standards do not distinguish between the source of data, whether electronic or paper-based. For many of the data verification tools, the comparison of "what was reported" with "what is in the system" would be the same for a paper-based register or record and for an electronic medical record. However, if a country has EMRs or databases housing data at any level, it is important to adapt data quality assurance tools to explicitly address issues pertaining to such systems.

For M&E systems assessments, it may be necessary to include individuals with an information technology background on the site visit teams to identify electronic systems issues.

A national data quality assurance plan should set forth expectations for partners' use of standardized national databases or a set of criteria or specifications for partner databases and an explicit timeline for information sharing.

As technology evolves and becomes further integrated, standards will be revisited and made more explicit, and tools specifically for data quality assurance for EMRs and databases will be developed.

Source: Data quality assurance standards and tools for PMTCT programmes. Geneva: Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Their Children, (forthcoming).

What are some key resources?

Partners have developed a range of tools for DQA, which can be adapted for use in different contexts:

- The MEASURE Evaluation website compiles tools developed and used by multiple agencies for DQA of programme indicators, data audits and overall M&E system assessments. (http://www.cpc.unc.edu/measure/tools/monitoring-evaluation-systems/data-quality-assurance-tools).
- The Global Fund offers an on-line training module on data quality procedures and tools for use in HIV, TB and malaria programmes, as well as associated guidelines and tools. (http://www.theglobalfund.org/en/me/documents/dataquality/).
- HEALTHQUAL International provides a searchable database that contains publications, tools and resources related to quality management and improvement. (http://healthqual.org/search-qi-learning).
- Data quality assurance standards and tools for PMTCT programmes. Geneva: Interagency Task Teamon the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children, (forthcoming).
- Performance monitoring and evaluation TIPS: Conducting data quality assessments. Number 18, 1st edition. Washington, DC: United States Agency for International Development; 2010 (http://www.innonet.org/resources/node/636).
- Data quality assurance tool for programme-level indicators. MEASURE Evaluation; 2007 (www.pepfar.gov/documents/organization/79628.pdf).
- 12 components monitoring & evaluation system assessment: guidelines to support preparation, implementation and follow-up activities. Geneva: Joint United Nations Program on HIV/AIDS; 2010. (http://www.unaids.org/sites/default/files/sub_landing/files/1_MERG_Assessment_12_Components_ME_System.pdf).

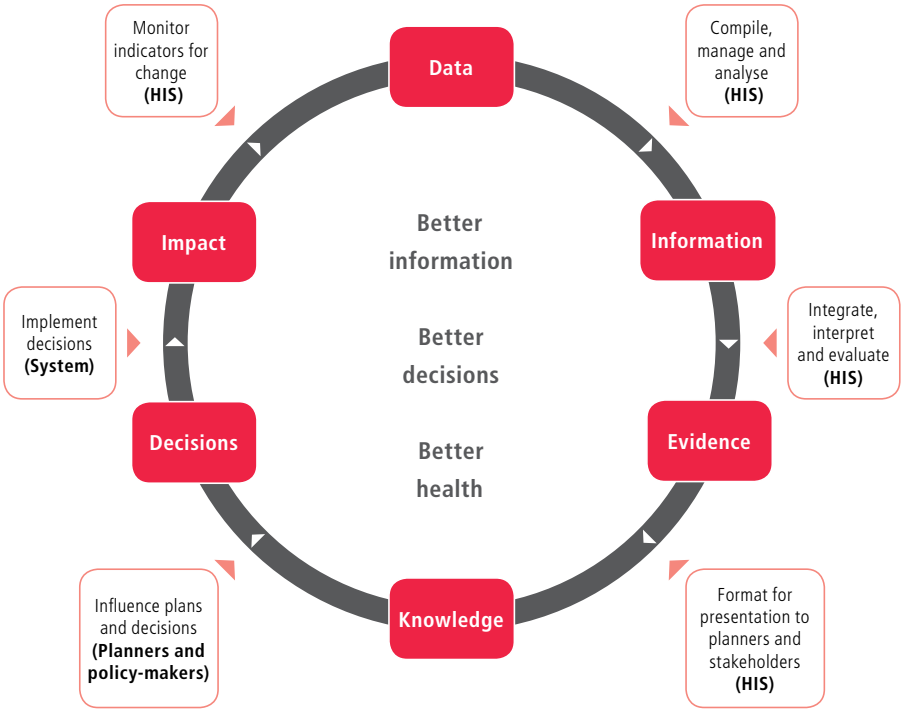
3.5 Data analysis and use

The ultimate goal of M&E is to provide data for decision-makers to use at all points of the HIV programme cycle. Through routine indicator reporting, programme reviews, evaluations, operational/implementation research and modelling, strategic information forms the evidence base for programming the response to HIV. The M&E system produces large amounts of raw data. These data have little intrinsic value, however, until analysed, synthesized and transformed into usable strategic information that is accessible and understandable to managers, planners and other stakeholders (Fig. 3.6).

Strategic information is also used in advocacy and resource mobilization, for academic purposes and in research and development. Civil society, including NGOs and academia, should have access to data and contribute to the collection, analysis and use of strategic information as a global public good. Also, strategic information should be shared within and across nations to facilitate global learning on how best to prevent and respond to the HIV epidemic. Transparent sharing of data is important to promote the value and use of strategic information.

"The point of a health information system is not just to generate high-quality data and hope that it will be used, but to convert it into credible and compelling evidence that informs local health system decision-making."[1]

Fig. 3.6 Transforming data into information and evidence for decision-makers



Source: Health Metrics Network. Framework and standards for country health information system. Geneva: WHO; 2008system. Geneva: WHO; 2008

[1] Health Metrics Network. Framework and standards for country health information system. Geneva: WHO; 2008 (http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf).

3.5.1 Analysis of the cascade

Data analysis is the process of synthesizing data and summarizing the health situation and trends that they depict for use by decision-makers. Analysis turns raw data into information that is strategic for decision-making. It looks closely at the linkages between different aspects of the epidemic and response, such as policy, programme implementation, behaviour change and HIV prevalence.

Analysis should consider several key factors that could affect the interpretation of findings, including data collection methodologies, data sources, comparison across different sources and/or data sets and variation or inconsistencies between different data sets. For an accurate analysis, it is critical to understand the context in which the data were collected and identify and account for biases.

Data triangulation methods should be used to pull together, compare and integrate data from a wide range of sources, including quantitative and qualitative information from both the public and private sectors. Data triangulation reduces the likelihood of over-reliance on any one type or source of data; this is important because one type or source of data is unlikely to provide the perspective or insights required to fully understand linkages and to identify trends.[1]

Cohort-based and cross-sectional cascade analysis

The consolidation of indicators in this guide supports analysis across the health sector cascade of HIV testing, care and treatment. Cascade analysis shows where the biggest attrition, or "leaks", occurs between services so that appropriate targeted responses can improve linkages and retention in care. The HIV cascade starts with the general (or at-risk) population of a catchment area, followed by the numbers tested, found to be HIV-positive, linked to HIV care, started on ART, retained on ART and virally suppressed. Points of high attrition along the cascade highlight areas in need of improvement. Cascades can be cohort-based or cross-sectional.

A **cohort-based cascade** follows a specific cohort of people infected with HIV from the time of HIV diagnosis through to the last point of service delivery for each individual in the group. This type of analysis requires unique patient identifiers (UIs) or costly and difficult probabilistic methodology requiring multiple identifiers (surname, given name, date of birth, gender, folder number, location accessing care) in the centrally held data set. A cohort-based cascade is usually considered the gold standard, but it can be misleading for regions with high rates of out-migration.

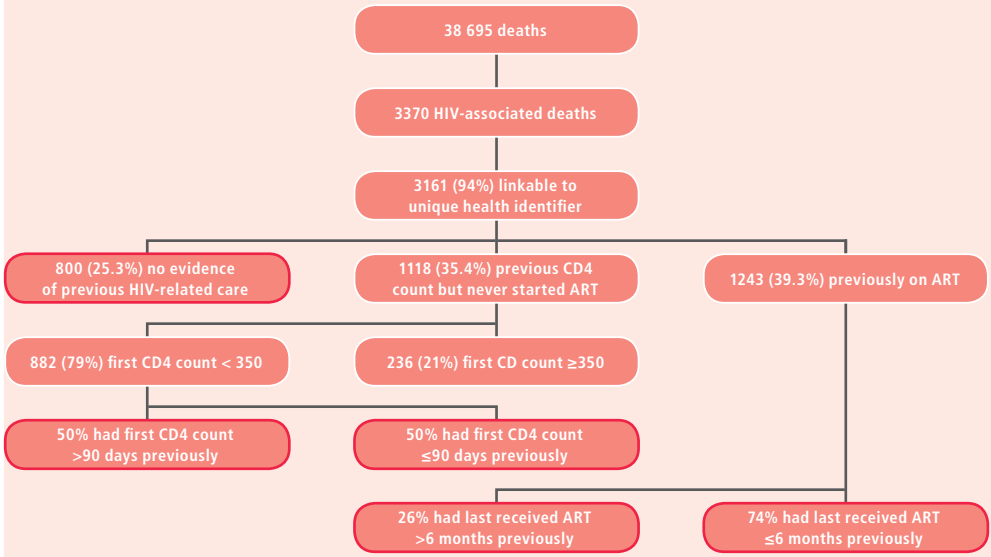
A **cross-sectional cascade** looks at aggregate service delivery data across the continuum of care at a specific time. It includes data on all people tested HIV-positive, as well as people who were linked to HIV care, initiated ART or were retained in care in a specified period because the data are cross-sectional, thus, the same people are not followed through the cascade. Even though different people are measured at each stage of the cascade, cross-sectional analysis can identify weak points in the system. For paper-based systems this type of cascade analysis can provide very good insight, even though it is not as accurate as a linked data set from EMRs, where each individual patient can be tracked. Cross-sectional data sets should be interpreted with caution, as people may enter the cascade at any time (sometimes after long interruptions in care) or may be first accessing a service in the middle of the cascade because they entered the cascade outside the catchment area.

[1] World Health Organization, Joint United Nations Program HIV/AIDS, Global Fund to Fight AIDS, Tuberculosis and Malaria. HIV triangulation resource guide. Geneva, 2009 (http://www.who.int/entity/hiv/pub/surveillance/hiv_triangulation_guide.pdf).

Cascade mortality analysis

A mortality analysis along the cascade is another approach to understanding gaps. Fig. 3.7 presents an example. In this cross-sectional study of all HIV-associated deaths in the mortality surveillance system, routine monitoring data were examined retrospectively, using UIs to determine prior HIV care as indicated by a CD4 count, prior ART as indicated by a viral load test and/or patient monitoring system, most recent CD4 count, time between linkage to care and death, and treatment interruptions. The results highlight gaps and areas where services need improvement. Of the patients who died, 25% never had a CD4 count recorded. Another 25% of deaths might have been averted if patients had been fast-tracked into treatment. Another 33% of deaths might have been averted by tracing and recalling patients lost to pre-ART and ART care.[1]

Fig. 3.7 HIV-associated adult mortality, Western Cape, 2012



[1] Boulle A, Zinyakatira N, Evans J, Osler M, Coetzee D, Pienaar D, et al. Understanding high ongoing HIV-associated mortality in the era of antiretroviral therapy in the Western Cape Province of South Africa. Cape Town: Western Cape Government; 2014. Slide presentation (http://sahivsoc2014.co.za/wp-content/uploads/2014/10/Thurs_Andrew_Boulle-Understanding-high-ongoing-HIV-associated-mortality.pdf).

3.5.2 Data use at national, subnational and service delivery levels

Decision-makers' use of data at each level of the health system requires analysis of the raw data, presentation and dissemination of the information in a usable format and a culture of data use for evidence-based decision-making. The main uses for strategic information are in programme planning, prioritization, improvement and accountability at all levels.

Information needs vary among levels of the health-care system:

- *At the service level*, medical professionals and health workers need essential information both for day-to-day management of quality care and for long-term planning.
- *At the national and subnational levels*, health programme managers need reliable and timely information to identify needs and effective ways to respond to them. They use strategic information to assess whether programmes are on track in terms of access, coverage and quality and to guide corrective action where needed.
- *At the global and national levels*, ministries of health, international health programmes and agencies (for example, the Global Fund, WHO, UNAIDS) require reporting on progress towards specific targets. Funders use strategic information to make evidence-based decisions about where to invest resources and how to fill gaps. Managers and decision-makers use data to plan and coordinate health interventions from a national, regional or global perspective. Strategic information also helps to focus the dialogue between partners and countries on evidence and results and at the right strategic level. (See box, next page).

The national strategic plan for HIV, which describes the role of the health sector and the national M&E plan, should include an explicit data use plan. A data use calendar provides a clear time table for major data collection efforts (for example, population surveys, evaluation studies) linked to national and global reporting deadlines and decision-making needs, such as multi-year and annual planning and resource allocation schedules or key decision points for programme scale-up.

The box on page 237 presents a case study of the effective use of data for decision-making in Mauritius. In this example programme planning and data use intertwined; the initial IBBS data prompted additional questions from decision-makers, which were answered by additional data collection. The results led to changes in the prevention programme to better focus on people at highest risk of HIV transmission.

Strategic information needs at different levels of the health system

Service level (for health-care providers):

- ensuring good clinical patient management (service quality)
- monitoring loss to follow-up
- monitoring HIV drug resistance
- monitoring access to and coverage of services
- improving facility management
- establishing accountability for work.

National and subnational levels (for health programme managers):

- developing programme targets and linkages between HIV testing and pre-ART/ART services
- adjusting the focus of outreach interventions and programming for key populations
- estimating the number of HIV-positive pregnant women for targeting the ART/PMTCT programme
- projecting needs based on current use of services (procurements, staff/patient ratio)
- measuring the equity of services
- assessing drug toxicity and development of drug resistance
- developing business plans
- informing policy
- informing resource allocation
- evaluating interventions/innovations/pilot tests.

Global and national levels (for ministries of health, international health programmes and agencies):

- monitoring impact: national or subnational incidence, prevalence, mortality trends
- measuring outcomes: coverage and access
- cohort reporting and analysis for drug resistance surveillance
- costing calculations
- lives-saved calculations
- triangulating data to project unmet needs
- modelling.

Evidence-based decision-making in Mauritius

Three rounds of IBBS in Mauritius confirmed the prevalence of HIV to be high in key populations: 44.3% among people who inject drugs, 22.3% among female sex workers and 20% among men who have sex with men. To obtain more detailed information that could improve the efficiency of programming for key populations, the National AIDS Secretariat conducted a national mapping of key populations using the "geographic/programmatic mapping approach" developed by the University of Manitoba.[1] The approach involves defining high-risk activities for HIV, determining who is involved and estimating the size of each of the populations. The methodology also identifies various "hot spot" locations where high-risk activity takes place and prepares a detailed profile of these locations.

In collaboration with people from key populations, the risks and benefits of the study were carefully assessed before it was begun. The key population representatives led development of the implementation strategy and provided inputs on operational details.

The mapping study estimated a total number of 5046 (range: 4139–5952) people who inject drugs spread over 694 locations, increasing to 7598 (range: 6463–8732) on peak days of use. People who inject drugs were mostly male (86.8%), with a small percentage of females (11.6%) and a few transgender people. Active female sex workers were estimated to number 5508 (range: 4091–6223), increasing on peak days of activity (for example, weekends) to 6223 (range: 5090–7356), with an average of 8.5 sex workers per location. Based on the numbers derived from both geo-mapping and virtual site mapping, the study estimated an average number of 4739 (range: 4494–4984) men who have sex with men at hot spots, increasing to 5466 (range: 5041–5892) on peak days. The estimated total number of transgender people present at hot spots was 1038 (range: 798–1278), which increased to 1407 (range: 1165–1649) on peak days.

This information served as the foundation for planning and designing targeted interventions; it allowed resources to be re-allocated to achieve the maximum return on investment in terms of new HIV infections averted. Most programme activities had hitherto been concentrated around the capital, Port Louis, and in the beachside resort in the north of the country. Based on the population concentrations indicated by the mapping, the programme spread its resources more equitably over the island. The mapping exercise also provided more accurate data on the coverage of HIV prevention activities among key populations and indicated the need to scale up outreach programmes and to set targets that were more likely to achieve the required impact.

[1] Odek WO, Githuka GN, Avery L, Njoroge PK, Kasonde L, Gorgens M, et al., Estimating the size of the female sex worker population in Kenya to inform HIV prevention programming, PLOS One. 2014; doi: 10.1371/journal.pone.0089180 (http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0089180 s3).

What are some challenges and opportunities?

Despite the vast amount of data collected, data are not always accessible in a form useful to the people who need the information. Adequate numbers of trained staff members are needed to analyse and present the data in a timely fashion and in an understandable form, with graphs and explanations and tailored to the needs and purposes of the stakeholders. Reports (for example, quarterly and annual reports and final reports of needs assessments, surveys and

operational research) should be catalogued for later reference and made publicly available on websites as well as distributed in print when appropriate. This helps avoid loss of information when staff members who conduct research or write reports are no longer in the same jobs. Both governmental and non governmental reports should be included in the central library of information.

Even when data are available in a usable form, the information may not be used due to institutional and behavioural barriers. Institutional mechanisms and incentives are needed to establish a culture of evidence-based decision-making, such as indicator-driven planning and applying strategic information to the budgeting process.

What are some key resources?

In addition to the references listed in footnotes in this section, the MEASURE Evaluation website provides a range of trainings (webinar recordings) and tools for increasing data demand and data use as well as for documenting good practices.[1]

3.5.3 Programme reviews

Regular programme reviews are an integral part of the programme cycle. They enable managers and other stakeholders to take stock of programme performance over a period of time. Programme review seeks to assess programme results in relation to the priorities defined in the strategic and operational plans and to identify factors affecting the achievement of intended results. The findings of a programme review are used to improve ongoing implementation, to inform development of new strategic and operational plans and to help shape national policy. This is a key stage, in which strategic information is reviewed and used to make decisions that will improve a programme.

For programme reviews to be useful, they must be based on good strategic information. Programme review must assess performance of the national HIV programme across the results chain. Reviews must begin with analysing the impact achieved by the programme in terms of HIV incidence, prevalence and mortality. The impact should be linked back to the programme outcomes, which, in turn, should be linked back to inputs and outputs. Recommendations of the review should highlight critical changes at the various levels of the results chain that are necessary to increase impact and improve programme performance.

There are essentially three stages to conducting national programme reviews. The *desk analysis* stage involves compiling available data on the areas to be covered in the review. This should start with impact data (for example, HIV prevalence, incidence and mortality) at national and subnational levels. It should include data on related outcomes (for example, coverage of HIV services, behaviour change and risk reduction) and inputs (for example, policies, plans, resources and service availability). The desk analysis identifies programme achievements.

The second stage is the *field review*. Its purpose is to assess the organization, capacity and delivery of services in real time. It involves interviews and discussions with key informants at the various levels of the health system as well as inspection and assessment of facilities and service delivery processes.

The third stage of a programme review includes an overall *analysis of the findings from the first two stages and recommendations* for moving forward. The analysis is often framed by four key questions. The principle question is (1) whether the programme is having its intended impact and achieving its targets. Related questions are (2) whether the right interventions are being implemented, (3) whether they are being done in the right manner and (4) whether they are being carried out at sufficient scale.

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[1] Measure Evaluation: Data demand and use tools. UNC Carolina Population Center (http://www.cpc.unc.edu/measure/tools/data-demand-use/data-demand-and-use-strategies-and-tools.html).

Countries should own their programme reviews. The reviews should be synchronized with national programme cycles and should contribute to wider national development efforts without placing undue burden on the implementation capacity of the national programme. Programme reviews can be carried out at different stages of the programme cycle and tailored for different purposes.

Annual programme reviews are an internal light review of routine reporting data to improve on-going implementation, either modifying existing plans or developing new implementation plans.

Mid-term reviews (at the mid-point of a multi-year strategic plan) are usually conducted by a team of internal and external reviewers to determine whether implementation is on track to meet targets. Mid-term reviews may result in reprogramming of the strategic plan by modifying targets, priority groups or types of interventions.

End-term reviews are conducted at the end of the strategic plan cycle. They are comprehensive reviews of the programme, conducted primarily by independent external reviewers. End-term reviews produce a situation analysis, which forms the basis for the next strategic plan. In addition, limited programme reviews may be undertaken to assess specific components of the national programme, such as thematic areas (for example, ART, PMTCT, key populations, male circumcision), programme management components (for example, decentralization, procurement, community services) or special initiatives or projects on the basis of specific funding sources, population subgroups or geographical areas.

What are some challenges and opportunities?

A good programme review requires reliable and recent data, which in turn depends on the strength of national strategic information and data systems.

The core elements of national strategic information systems described in this guide are essential to conducting programme reviews that will correctly assess performance and identify viable policy and programmatic options for improvement.

A common weakness of programme reviews is a focus on how programmes are being implemented without enough attention to results. A programme review should, first and foremost, consider the impact that the programme is having on HIV incidence, prevalence, mortality and morbidity among the people that it is intended to serve.

It is important to define the scope of the review and set clear objectives at the outset to avoid covering too many issues and collecting more information than can be analysed, which can interfere with the ability to reach conclusions and make relevant recommendations. At the same time, results of limited or specific project reviews should be interpreted with caution; some results may be due to or influenced by other factors and may not reflect project activities alone.

What are some key resources?

WHO has published a detailed guide to help countries plan and manage programme reviews. The guide describes the principles and processes for reviewing programmes and provides checklists of key review questions.

- Guide to conducting programme reviews for the health sector response to HIV/AIDS. Geneva: WHO; 2013 (http://www.who.int/hiv/pub/toolkits/hiv-response-guide/en/).

Also UNAIDS has issued a guide to conducting multisectoral joint reviews, to assess the entire national AIDS response including the contributions of health and other sectors.[1]

3.5.4 Evaluation and operational research and implementation science

In addition to analysing routine programme data, programmes need to conduct regular evaluations and to undertake special research to answer more complex questions or to test new approaches. Evaluation, operational research and implementation science employ research methods to address such issues. Appropriate use of evaluation and research along with routinely collected data helps ensure that ongoing programme and service improvement are based on the best available evidence. Given that resources are limited, it is crucial to focus investment on programmes and services that are appropriate to the needs, can be well-implemented and are effective and efficient.

Evaluation is intended to guide decisions about a programme, project or policy by assessing its impact or the efficiency and quality of its processes. *Impact evaluation* is the most rigorous form of evaluation; it assesses the true impact of a programme, project, or policy by comparing what actually happened with what would have happened in the absence of the intervention. *Process evaluation* assesses how programme outcomes and impacts were achieved and describes the challenges and successes in implementation. *Formative evaluation* is conducted during the course of programme implementation to assess what is and what is not working and, thus, inform mid-course changes. While many formative evaluations focus on processes, a formative evaluation also can assess impact if the programme is being implemented over a long-enough period. *Summative evaluation*, conducted at the end of a programme cycle, informs decisions about whether to continue, terminate, replicate or scale up a programme. Evaluations use a range of methods for data collection, including review of routine data and collection of new data using quantitative and qualitative methods.

In impact evaluation data collection and analysis should be geared to answering key questions using evaluative criteria (for example, OECD–DAC criteria[2]). Defining in advance what constitutes success, by constructing specific evaluative rubrics (that is, standards or desired levels of performance of the programme) provides a basis for evidence-based, transparent judgements about the value of the programme or policy.

Operational research is the systematic and objective assessment of the availability, accessibility, acceptability, quality and/or sustainability of services. It assesses the effects of changes that are under the control of programme managers, such as improving the quality of services, increasing training and supervision of staff members and adding new service components. As with evaluation, it uses formal research methodologies (qualitative and/or quantitative) for sampling and data collection.

Implementation science is an emerging field that studies methods to promote the application of research findings and evidence to health-care policy and practice. It seeks to improve the adoption, sustainability and implementation of interventions by studying the behaviour of implementers (for example, health-care providers) and other stakeholders. Implementation science investigates and addresses obstacles and bottlenecks in the social, behavioural, economic and management spheres that hinder effective implementation; tests new approaches; and uses research methods to determine a causal relationship between the intervention and impact.[3]

A frequent source of strategic information is **periodic programme evaluation**. Such evaluation brings together the findings of programme monitoring, surveys and operational research with data generated by the evaluation itself. Programme evaluations provide valuable opportunities to incorporate data from these multiple sources into an overall assessment of programme planning, implementation and results. If appropriately designed to answer pre-determined questions, sharply focused on the most important issues and competently conducted, periodic programme evaluation can be a valuable source for learning and can provide an evidence-based rationale for changes in policies and programmes.

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[1] Joint reviews of national AIDS responses. A guidance paper. Geneva: UNAIDS; 2008 (http://www.unaids.org/sites/default/files/media_asset/jc1627_joint_reviews_en_0.pdf).
[2] DAC criteria for evaluating development assistance. OECD webpage on evaluation of development programmes (http://www.oecd.org/dac/evaluation/daccriteriaforevaluatingdevelopmentassistance.htm).
[3] What is implementation science? Frequently asked questions about implementation science. Bethesda, Maryland, USA: National Institutes of Health, Fogarty International Center. (http://www.fic.nih.gov/News/Events/implementation-science/Pages/faqs.aspx).

Often, evaluation and research studies are carried out in an ad hoc fashion or according to the parochial needs of particular individuals or organizations. It is more efficient to establish a national process for identifying evaluation or research gaps and coordinating studies relevant to the national strategic plan for HIV, including the health sector response. This coordination helps to ensure that studies are relevant to the country's needs and can produce actionable recommendations; that research efforts avoid duplication; and that study results are shared and available for use in decision-making. The box presents the example of prioritized evaluation questions related to prevention, treatment, care and support services in the national AIDS programme of Thailand.

National evaluation agenda-setting: An example from Thailand

The National AIDS Management Center (NAMc), the Bureau of AIDS and STI (BATS), the Department of Disease Control, the Thai NGO Coalition on AIDS (TNCA) and the Thai Network of People Living with HIV (TNP+), in collaboration with representatives from academia, UN organizations, US government organizations and other key stakeholders, participated in *A Consultative Workshop on Developing a National Evaluation Agenda for HIV/AIDS in Thailand*, 14–16 June 2010. This expert group:

- agreed on high-priority evaluation questions to guide provision of universal access to effective HIV/AIDS services that are sensitive to human rights, gender issues and stigma and discrimination;
- discussed key issues in: (a) the implementation of the evaluation studies (that is, ensuring financial resources and technical quality); (b) the use of the findings to improve programmes (that is, ensuring capacity to interpret and apply findings); and (c) institutionalizing the process of evaluation agenda-setting linked to evidence-based decision-making in the national AIDS programme (that is, establishing a supportive infrastructure);
- identified data gaps and the specific needs of the national and subnational HIV/AIDS programmes for evaluation.

As part of this process, the meeting gave priority to the following evaluation questions concerning HIV/AIDS treatment, care and support for children and adults:

QUESTION 1:

a. Is the current service delivery system (continuum of prevention, treatment, care and support services) of good quality? appropriately holistic? providing services to all in need?

b. Is the existing monitoring system adequate to track these key issues so that timely corrections can be made?

QUESTION 2:

a. Does the universal coverage programme increase access to services by every population sub-group?

- If there is high service usage by a population sub-group, what facilitates it?
- If there is low service usage by a population sub-group, what are the barriers?

b. Does the programme effectively support the participation of people living with HIV and civil society groups?

The prioritized evaluations were undertaken immediately to ensure that the findings would be available to inform evidence-based planning and resource allocation for the new National Strategic Plan (2012–2016).

Source: Policy brief. Making evaluation a priority: consensus recommendations for evaluating HIV/AIDS programmes. Bangkok: National AIDS Management Center; 2010.

What are some challenges and opportunities?

The major challenge is to establish and maintain a regular evaluation agenda focused on impact and the key areas that a programme needs to improve. Research and evaluation studies should be planned and managed as discrete projects with formal processes and oversight.

There should be a good understanding of what data are already available so that evaluation design can focus on checking information and filling gaps rather than gathering redundant data. A good evaluation design is tailored to the specific information gap being addressed and the particular evaluation needs and available resources. It requires technical expertise to develop. Adoption of standardized, generic evaluation designs is not advisable; they often are unsuited to country-specific settings, needs and capacities.

What are some key resources?[1]

DAC criteria for evaluating development assistance. OECD webpage on evaluation of development programmes (http://www.oecd.org/dac/evaluation/daccriteriaforevaluating developmentassistance.htm).

Peersman G. Overview: data collection and analysis methods in impact evaluation. Methodological briefs: Impact Evaluation 10. Florence: UNICEF Office of Research; 2014 (http://www.unicef-irc.org/KM/IE/).

3.5.5 Strategic information capacity

Data analysis and use depend on an effective strategic information system, which in turn requires functional capacity in multiple areas. The technical elements of the strategic information system (for example, data collection from multiple sources, data management systems, surveys and surveillance, evaluation and research) cannot function effectively without the support of organizational structures and processes, including human resources, coordinated planning and management of the M&E system, and adequate funding.

In the monitoring, evaluation and review platform for national health strategies,[2] a key attribute that speaks directly to data analysis and use is that "data analysis and synthesis work is specific, and data quality issues are anticipated and addressed". Programmes should have a plan for data analysis and synthesis with delineated roles and responsibilities, clear and transparent use of analytical methods, an annual report on progress and performance against objectives and targets, and good quality data available at subnational levels. In addition, data quality should be routinely monitored.

Another key aspect of strategic information capacity is regular and effective data dissemination and communication. Indicators for national and global reporting should be produced in a timely fashion, and a feedback mechanism should operate at all levels. A data repository with an effective data sharing mechanism should be in place to provide public access to data and reports.

Managing strategic information functions requires adequate levels of staff at all levels trained in data management and analysis methods. This involves:

- securing dedicated (part-time or full time) staff at various levels, from data clerks at facilities to M&E specialists at the national level. Job requirements need to define clearly the types of staff needed at various levels (linked to their functions) and types of facilities.

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[1] BetterEvaluation provides a freely accessible interactive platform (http://betterevaluation.org/"http://betterevaluation.org) for producing and sharing information about choosing and using evaluation events and methods, including tools to address common evaluation challenges.
The International Initiative for Impact Evaluation (3ie) (http://www.3ieimpact.org/) funds impact evaluations and systematic reviews that generate high quality evidence on what works in development (including health) and why.

[2] Monitoring, evaluation and review of national health strategies: a country-led platform for information and accountability. Geneva: WHO IHP+; 2011. (http://www.who.int/healthinfo/country_monitoring_evaluation/1085_IER_131011_web.pdf).

- ensuring that the strategic information staff members have the skills to perform their functions, from data collection, entry and management to analytical skills. Expectations need to be made explicit, and staff members need appropriate support for professional development.
- training for stakeholders at all levels in the interpretation and use of data for evidence-based decision-making.

What are some challenges and opportunities?

A national M&E assessment can identify strengths and weaknesses in the system, identify gaps and recommend corrective actions to improve capacity. A capacity-building plan should be developed, including activities to increase capacity at the individual, organizational and system levels.

Adoption of the indicators recommended in this guide needs concomitant investments in data sources, systems, data quality and the capacity to use data effectively for decision-making.

What are some key resources?

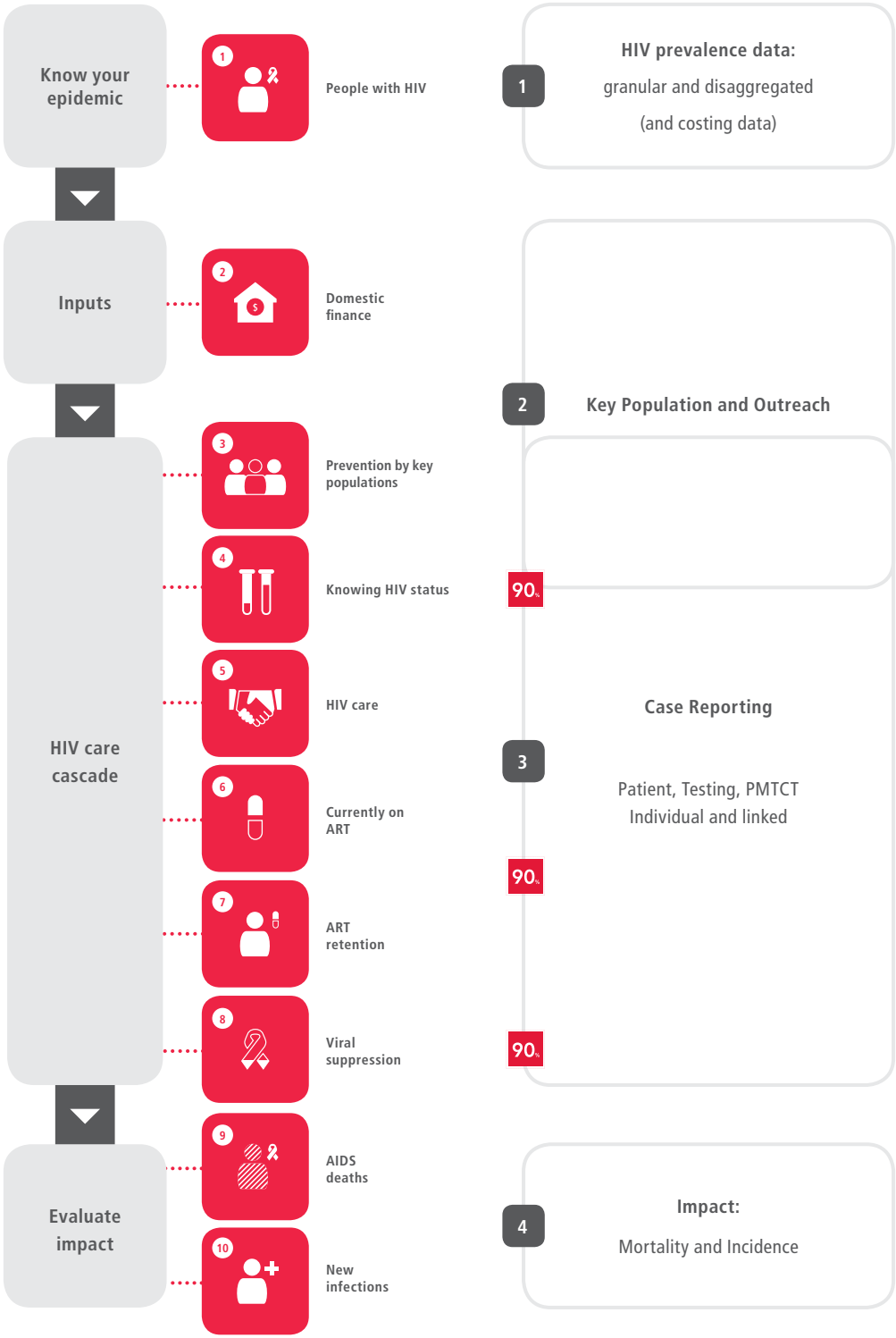
A description of the components of M&E systems and tools for national review can be found in:

- Monitoring, evaluation and review of national health strategies: a country-led platform for information and accountability. Geneva: World Health Organization and IHP+; 2011 (http://www.who.int/healthinfo/country_monitoring_evaluation/1085_IER_131011_web.pdf).
- Framework and standards for country health information systems: World Health Organization Health Metrics Network. Geneva: WHO; 2008 (http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf?ua=1).

Guidance on capacity-building can be found in:

- Guidance on capacity-building for HIV monitoring & evaluation. Geneva: Joint United Nations Program on HIV/AIDS; 2010 (http://www.unaids.org/en/media/unaids/contentassets/documents/document/2010/5_4_MERG_Guidance_HIV_ME_Capacity_Buidling.pdf).

Global indicators for the health sector response to HIV



WHAT NEXT: HOW TO USE THIS GUIDE

4

4. WHAT NEXT: HOW TO USE THIS GUIDE

This guide has consolidated indicators and guidance in one place to facilitate measurement of the health sector cascade and the 90–90–90 target and so that strategic information is more relevant to the delivery of linked services. The 10 global indicators should form the basis of consistent reporting globally, and the 50 indicators, for the on-going monitoring of national programmes.

The indicators in this guide build on those already used by countries and partners. They should be used to strengthen and consolidate what is already in place. The guide provides a framework to link measures and to collect and use data to support quality services. This should reduce the fragmentation of reporting and, with the aid of a clear results chain, improve the practical analysis and use of data for decision-making.

This guide has also consolidated indicators so that they can be updated in a consistent manner, with a cycle of review every one to two years to respond to new developments – for example, in viral load testing, testing guidelines or incidence measurement.

As countries update their M&E reporting systems, this guide should be used to strengthen each stage of strategic information and its use for programme decisions to:

1. **consolidate and prioritize indicators** for consistent global and national reporting;
2. **identify data sources and surveillance priorities** to strengthen data;
3. **plan disaggregations and build analysis capacity** to assess data in a linked manner along the health sector cascade, including knowing your epidemic and evaluating impact;
4. **use data for decisions to improve the delivery of health sector services** and for regular programme reviews and strategic planning;
5. **evaluate the impact** of each stage of the cascade on outcomes, incidence and mortality so that we can prove and improve the response.

Within this cycle **national programmes should update their M&E reporting over the next 1–2 years**, link existing indicators along the results chain, identify any gaps in national reporting and plan how to close them. They should use this guide as a basis for the next review of their national reporting and as targets are set for the post-2015 HIV and development agendas.

At the same time, national programmes should take this opportunity to **assess sources of data** to measure these indicators and effectively link them along the health cascade and to incidence and mortality. The concept of the health sector cascade places priority on developing routine patient and case reporting to support individuals along a cascade of services. In addition, key surveys and evaluation of impact should be included in national M&E plans. We suggest that countries develop a **prioritized country agenda to invest in data** to get the best from the M&E strategy conceptualized in this guide.

It is important to **invest in the demand for and use as well as the supply of data**. A critical component of successful application of this guide will be investing in the analytical capacity to use data along the health sector cascade. A greater effort and investment in data analysis is required to make strategic information relevant for programme decisions. Consistency in reporting and data quality assessments will be important to link data, benchmark performance and analyse cascades of services. Each programme will need a

dedicated analyst to explore the data, assess cascades and feed back compelling reports and visualizations regularly. This crucial analytical capacity is often overlooked in allocating time and money for the definition and collection of indicators.

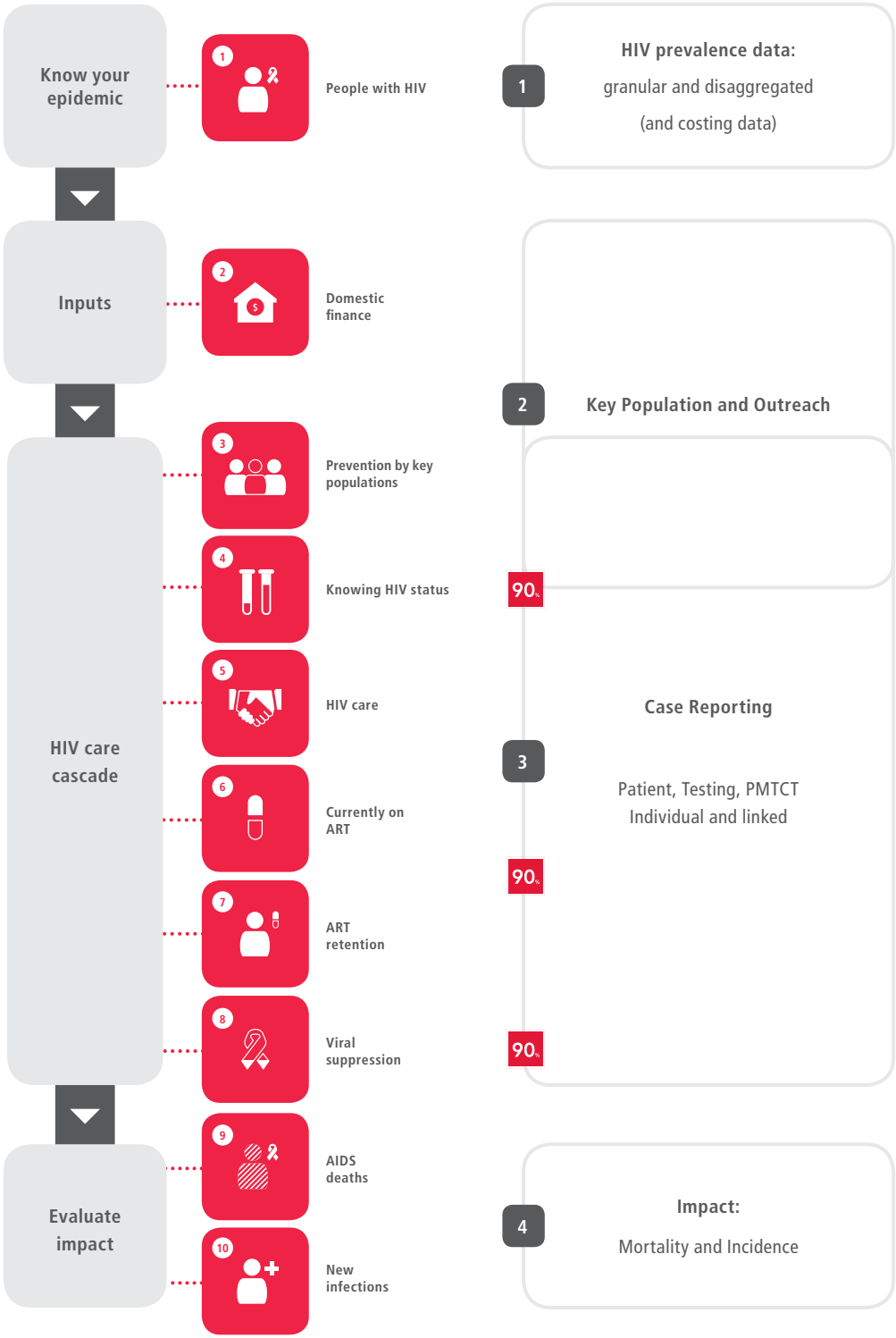
Finally, it is important to **review the programme regularly** against the indicators and data suggested in this guide, so that the information becomes strategic, that is, it is used for policy- and decision-making. Cascade analysis should support focused recommendations on how to scale up quality services to achieve the 90–90–90 target and to lower incidence and mortality. The results chain in this guide allows individual indicators to be linked to each other and linked to outcomes and impact on incidence and mortality.

Practical impact evaluation will play a key role by assessing the contribution of each stage of the cascade to outcomes, incidence and mortality, for example, how prevention activities for both those HIV-positive and those HIV-negative in the early stages of the cascade have a direct impact on incidence, as does viral suppression among those on ART.

To have an important impact on incidence, mortality and transmission, we will need to use strategic information to learn rapidly how to scale up effective, linked services that meet crucial goals such as the 90–90–90 target for 2020. A strong, consistent cascade of strategic information will be needed to support services. The next steps are to **use this guide, indicators, and analysis to make information more strategic for decisions** – decisions to improve programmes and the delivery of services to individuals.

WHO will aim to provide further support on how to use this guide, with reference sheets on each indicator and updates of definitions and guidance on measurement and analysis available at http://www.who.int/hiv/topics/me/en/.

Global indicators for the health sector response to HIV



ANNEXES

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5. ANNEXES

Annex 1 - Consolidated list of health sector HIV indicators

Indicators of HIV prevention and treatment eligibility		
National Indicators		
NEEDS.1 Global indicator	People with HIV	Number and % of people living with HIV
NEEDS.2	Key populations	Estimated size of key populations
NEEDS.3	Coinfection	Estimated number of people and % of people living with HIV who have coinfections/conditions
NEEDS.4	ART eligibility	Estimated number and % of people living with HIV who are eligible for ART
NEEDS.5	HIV-positive pregnant women	Estimated number and % of pregnant women who are HIV-positive
Indicators of stigma and discrimination against people living with HIV		
Additional Indicators		
NEEDS.6	General stigma	% of people ages 15–49 with discriminatory attitudes towards people living with HIV
NEEDS.7	Key population experience with discrimination	% of people from key populations who have experienced discrimination by health workers
NEEDS.8	Health facility staff observed acting out stigma	Health facility staff observations of stigmatizing or discriminatory behaviour against people living with HIV
Indicators of service availability, quality and linkages		
National indicators		
RES.1	Service availability	Number and % of facilities providing HIV-specific services, such as: • HIV HTS • ART • Prevention of mother-to-child transmission (PMTCT) • Opioid substitution therapy/needle–syringe programme (OST/NSP) • Voluntary medical male circumcision (VMMC) • CD4 count • Viral load testing

Additional indicators		
RES.2	Service quality	Number and % of facilities with availability of: 1. basic amenities 2. basic equipment 3. procedures and equipment for standard precautions for infection prevention 4. diagnostic capacity 5. access to essential medicines and medicines needed to deliver HIV-specific services
RES.3	Tracking SOP	% of ART sites implementing a standard protocol for tracking ART patients
RES.4	Quality improvement activities	% of ART sites with quality improvement (QI) activities
RES.5	Laboratory capacity for HIV testing	Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests
RES.6	Laboratory performance	% of laboratories with satisfactory performance in external quality assurance/proficiency testing (EQA/PT)
RES.7	Supportive supervision	% of ART sites with at least 4 quarterly supportive supervision visits in the last 12 months
Indicators of the health-care workforce		
Additional indicators		
RES.8	Vacancy rate	% of job positions vacant
RES.9	Health workforce density	Core medical professionals per 10 000 population
RES.10	Annual new graduates	Number of graduates from health workforce educational institutions (including schools of dentistry, medicine, midwifery, nursing, pharmacy) during the last academic year per 10 000 population
RES.11	Outreach through peer-educators	Number and % of people from key populations and people living with HIV reached by peer educators
Indicators of medical products and technologies		
National indicators		
RES.12	Availability	% of ART sites with stock-outs of: • any ARVs • reagents for rapid diagnostic tests, CD4 counts, VL tests, EID at relevant sites • co-trimoxazole (CTX)
RES.13	Quality control of ARV medicines	% of batches tested that met the defined quality standards

Additional indicators		
RES.14	Rational ARV use	% of people living with HIV receiving ART in line with the national guidelines
RES.15	Forecasting	% of ARV drugs planned for that are actually received
RES.16	Consumption	% of quantities of ARV drugs consumed
RES.17	Procurement efficiency	The ratio between the median price of the preferred first-line ARV regimen paid by the country and the median price of the same regimen in the region
RES.18	Delivery (supplier) performance	% of orders delivered by suppliers on time and in full (OTIF) during a reporting period
RES.19	Performance in port clearance	% of orders cleared within the defined deadline
RES.20	ARV drug registration	% of recommended ARV formulations registered
RES.21	Distribution	% of ART sites that received all orders OTIF from the central or regional stores
RES.22	Inventory control	% of ART sites that submitted a complete inventory control on time during the reporting period
RES.23	Loss	% of procured ARV quantities that are lost
RES.24	Minimum stock level	% of ART sites that placed their order while the stock at hand was below the minimum stock level
RES.25	Laboratory capacity	Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests
Indicators of strategic information		
Additional indicators		
RES.26	Completeness of indicators	Availability of information on each of the nationally defined indicators of the health sector response to HIV
RES.27	System reviews	Regular performance of reviews of the M&E system
RES.28	Publishing data	% of indicator data published annually
Indicators of governance, leadership and the policy environment		
Additional indicators		
RES.29	Completion of the National Commitments and Policies Instrument (NCPI) questionnaire for HIV/AIDS	NCPI questionnaire for HIV/AIDS
RES.30	Completion of WHO HIV health sector response policy questions	Country's completion of WHO policy questions
Indicators of financing and costing for HIV programmes		
National indicator		
RES.31 Global indicator	Domestic finance	% of HIV response financed domestically

Additional indicators		
RES.32	Health spending on HIV programmes	Proportion of HIV spending in national health budget
RES.33	Country progress in domestic financing	Relative Variation Index
RES.34	Domestic private expenditure	% contribution of domestic private sources to HIV financing
RES.35	Unit cost of HIV interventions	Per capita expenditure on HIV health programmes
Indicators for key populations		
National indicators		
KPOP.1	HIV testing coverage of key populations	% of people from key populations who received an HIV test in the last 12 months and who know the results
KPOP.2 Global indicator	Needle–syringe distribution	Needles–syringes distributed per person who injects drugs
KPOP.3	Key population ART coverage	% of key population living with HIV who are receiving ART
Additional indicators		
KPOP.4	OST coverage	% of Health spending on HIV programmes receiving opioid substitution therapy (OST)
KPOP.5	Retention in OST	% receiving OST for 6 months
KPOP.6	Key population HIV prevalence	% of members of key populations who are HIV-infected
KPOP.7	Key population experience with discrimination by health workers	% of members of key populations who experienced discrimination by health workers
Indicators for condom programming in the health sector		
National indicators		
PREV.1.a Global indicator	Condom use among sex workers	% of sex workers reporting condom use with most recent client
PREV.1.b Global indicator	Condom use among men who have sex with men	% of men reporting condom use at last anal sex with a male partner
PREV.1.c	Condom use among people who inject drugs	% of people who inject drugs reporting condom use at last sexual intercourse
PREV.1.d Global indicator	Condom use in general population	% of people who have more than one sexual partner who used a condom at last sex
Indicators of voluntary medical male circumcision		
Additional indicators (national in certain countries)		
PREV.2	MMC scale-up	Number of male circumcisions performed
PREV.3	MMC adverse events	Number and % of circumcised males experiencing moderate or severe adverse events during or following surgery

Indicators of post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP)		
Additional indicators		
PREV.4	**PEP access**	% of health facilities where PEP is available
PREV.5	**PrEP coverage**	% using PrEP in priority PrEP populations
Indicators of injection safety		
National indicator		
PREV.6	**Facility-level injection safety**	% of health-care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment
Additional indicator		
PREV.7	**Supply of needles–syringes**	% of facilities with no stock-outs of needles–syringes
Indicators for blood transfusion safety		
National indicator		
PREV.8	**Facility-level blood safety**	% of health facilities providing blood transfusion that meet requirements for safe and sufficient blood transfusion
Additional indicator		
PREV.9	**Blood screening coverage**	% of blood units screened for bloodborne diseases
Indicators for sexually transmitted infections		
National indicators		
PREV.10	**ANC syphilis screening coverage**	% of ANC attendees who were tested for syphilis
PREV.11	**Syphilis treatment**	Treatment of syphilis in seropositive ANC attendees
Additional indicators		
PREV.12	**Syphilis seroprevalence**	% of individuals seropositive for syphilis
PREV.13	**Gonorrhoea incidence**	Gonorrhoea rate among adult males
PREV.14	**Urethral discharge incidence**	Urethral discharge rate among adult males
PREV.15	**Congenital syphilis incidence**	Rate of congenital syphilis
Indicators for HIV testing services		
National indicators		
HTS.1 Global indicator	**People living with HIV diagnosed**	Number and % of people living with HIV who have been tested HIV-positive
HTS.2	**HTS scale-up**	Number of people who were tested for HIV and received their results within the past 12 months
HTS.3	**HTS retest**	Number of people who were retested for HIV within the past 12 months
HTS.4	**PMTCT testing coverage**	% of pregnant women with known HIV status

HTS.5	Coverage of early infant diagnosis	% of HIV-exposed infants receiving a virological test for HIV within 2 months of birth
HTS.6	HIV testing among TB patients	% of registered new and relapsed TB patients with documented HIV status
HTS.7	HIV testing coverage of key populations	% of people from key populations who received an HIV test in the last 12 months and who know the results
Additional indicators		
HTS.8	Re-testing to verify diagnosis at ART initiation	% of ART initiators who were re-tested to verify diagnosis
HTS.9	Self-testing	% of people who have tested for HIV using a self-test kit
HTS.10	General annual HTS coverage	% of people who have been tested for HIV in the last 12 months and received the results
HTS.11	Partner testing	% of HIV-positive adults receiving HIV care whose partner's status is known
HTS.12	HTS quality improvement activities	% of sites with quality improvement (QI) activities
HTS.13	HTS-related stock-outs	% of HTS sites with stock-outs of HIV diagnostic tests or reagents
HTS.14	Laboratory capacity	Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests
HTS.15	Laboratory performance	% of laboratories with satisfactory performance in external quality assurance/proficiency testing (EQA/PT)
Indicators of linkage to and enrolment in care		
National indicators		
LINK.1	Linkage to care	Number and % of newly diagnosed of HIV-positive people newly enrolled in and receiving care LINK.1a (preferred): Number and % of newly diagnosed adults linked to HIV care (individual-level linkage) LINK.1b (if LINK.1a not feasible): Number of HIV-positive adults newly enrolled in and received care and ratio relative to number of adults who test positive for HIV (cross-sectional proxy for linkage)
LINK.2 Global indicator	HIV care coverage	Number and % of people living with HIV who are receiving HIV care (including ART)
LINK.3	Enrolment in care	Number of people newly enrolled in HIV care
LINK.4	Unmet need for family planning	% of HIV-positive women attending HIV care and treatment services who have unmet need for family planning
LINK.5	TB screening coverage in HIV care	Proportion of people in HIV care (including PMTCT) who were screened for TB in HIV care and treatment settings

Additional indicators		
LINK.6	Partner testing	% of adults receiving HIV care whose partner's status is known
LINK.7	CTX coverage	% of eligible HIV-positive individuals who received co-trimoxazole (CTX)
LINK.8	Late HIV care initiation	% of people enrolling in HIV care with CD4 ≤200 cells/mm^3
LINK.9	Pre-ART retention at 12 months	% of HIV-positive people in pre-ART care and not yet eligible for ART who are still engaged in care at 12 months after enrolment
LINK.10	Eligible but not started on ART	Number and % of people living with HIV who are eligible for ART but have not started ART
LINK.11	Timely linkage from diagnosis to treatment among children under 5 years of age	% of children under age 5 who initiated ART within 1 month after diagnosis
Indicators for TB/HIV coinfection		
National indicators		
LINK.12	TB prevalence in HIV care	% of people living with HIV and newly enrolled in HIV care who have active TB disease
LINK.13	HIV prevalence among TB patients	% of registered new and relapsed TB patients with documented HIV-positive status
LINK.14	Mortality among HIV-positive TB patients	% of HIV-positive new and relapsed TB patients who died
LINK.15	HIV testing among TB patients	% of registered new and relapsed TB patients with documented HIV status
LINK.16	ART coverage during TB treatment	% of HIV-positive new and relapsed TB patients on ART during TB treatment
LINK.17	IPT/LTBI coverage	% of people newly enrolled in HIV care who are started on TB preventive therapy
LINK.18	TB screening coverage in HIV care	% of people in HIV care (including PMTCT) who were screened for TB in HIV care and treatment settings
Additional indicators		
LINK.19	Relative risk of TB among health-care workers	Risk of TB among health-care workers employed in facilities providing care for TB or HIV relative to risk in the general adult population
LINK.20	TB case-finding rate	% of HIV-positive new and relapsed TB patients detected and notified out of the estimated number of incident HIV-positive TB cases
LINK.21	TB diagnostic test for people living with HIV	% of people living with HIV having TB symptoms who receive a rapid molecular test (e.g. Xpert MTB/RIF) as a first test for diagnosis of TB
LINK.22	CTX coverage	% of HIV-positive new and relapsed TB patients who receive co-trimoxazole (CTX) preventive therapy

LINK.23	IPT/LTBI treatment completion	% of people living with HIV who complete the course of TB preventive therapy
LINK.24	Early ART for HIV-positive TB patients	% of HIV-positive new and relapsed TB patients who are started on ART within 8 weeks after TB diagnosis
LINK.25	Early ART for profoundly immunosuppressed HIV-positive TB patients	% of HIV-positive new and relapsed TB patients with profound immunosuppression (CD4 cell count <50) who are started on ART within 2 weeks of TB diagnosis
LINK 26	TB infection control	% of health-care facilities providing services for people living with HIV (including PMTCT) that have TB infection control practices
Indicators for other co-morbidities		
National indicators		
LINK.27	Hepatitis B screening	% of people in HIV care who were screened for hepatitis B
LINK.28	Hepatitis C screening	% of people in HIV care who were screened for hepatitis C
Indicators for antiretroviral therapy		
National indicators		
ART.1	New ART patients	Number of people living with HIV who initiate ART
ART.2	ART coverage 1	% of eligible people living with HIV who are receiving ART
ART.3 Global indicator	ART coverage 2	Number and % of people living with HIV who are receiving ART
ART.4	Late ART initiation	% of HIV-positive people who initiate ART with a CD4 count of <200 cells/mm^3 , and <350 cells/mm^3
ART.5 Global indicator	ART retention	Number and % of people living with HIV and on ART who are retained on ART 12 months after initiation. Also recommended at 6, 24, 36, 48, 60 months, etc.
ART.6	Medium-term ART outcomes	% of ART patients with specific outcomes at 12 months
ART.7	ART adherence proxy	% of ART patients who pick up all prescribed ARV drugs on time
ART.8	Viral load testing coverage	% of people on ART with viral load test results at 12 months
ART.9	Viral load suppression at 12 months after ART initiation	% of people living with HIV and on ART who have virological suppression at 12 months after initiating treatment
ART.10	ARV stock-out	% of facilities with stock-outs of antiretroviral drugs
ART.11	ART survival	% of ART people living with HIV who are alive at 12, 24, 36 months, etc. after ART initiation

Summary of programme indicators for paediatric HIV		
National indicators		
HTS.1	People living with HIV diagnosed	Number and % of children and adolescents living with HIV who are diagnosed
HTS.2	HTS scale-up	Number of children and adolescents tested for HIV and received their results
HTS.5/MTCT.5	Early infant diagnosis coverage	% of HIV-exposed infants receiving a virological test for HIV within 2 months of birth
LINK.1 / MTCT.15	ART initiation, Infant ART initiation	% identified HIV-positive infants who initiated ART by 12 months of age
LINK.2	HIV care coverage	Number and % of HIV-positive children receiving HIV care
LINK.9	Pre-ART retention at 12 months	% of HIV-positive children in pre-ART care and not yet eligible for ART who are still engaged in care at 12 months after enrolment
ART.1	New ART patients	Number of children who initiate ART
ART.2	ART coverage 1	Number and % of eligible children receiving ART
ART.5	ART retention	Number and % of children known to be alive and on ART 12, 24, 36 months, etc. after initiating ART
ART.6	Medium-term ART outcomes	% of children and adolescents with specific outcomes at 12 months after initiating ART
ART.11	ART survival	% of children who are alive at 12, 24, 36 months, etc. after ART initiation
MTCT.4	Coverage of infant ARV prophylaxis	% of HIV-exposed infants who initiated ARV prophylaxis
MTCT.7	Final MTCT transmission rate	% HIV-infected among HIV-exposed infants born in the past 12 months
MTCT.8	Final outcome status	% distribution of HIV-exposed infants by final outcome status
MTCT.9	Co-trimoxazole prophylaxis coverage	% of HIV-exposed infants started on CTX prophylaxis within 2 months of birth
Additional indicators		
LINK.5	Co-trimoxazole coverage	% of eligible children on CTX prophylaxis
LINK.11	Timely linkage from diagnosis to treatment	% of children under age 5 years who initiated ART within 3 months after diagnosis
ART.7	ART adherence proxy	% of children and adolescents on ART who pick up all prescribed ARV drugs on time
ART.8/VLS.2	Viral load testing coverage	% of children and adolescents on ART with VL results at 12 months
ART.9/VLS.1	Viral load suppression at 12 months after ART initiation	Number and % of children and adolescents on ART who are virally suppressed at 12 months
ART.19	HIVDR among infants	% of infants and children under age 18 months diagnosed with HIV who have any HIVDR

MTCT.13	Turnaround time of EID results	% of early infant diagnosis test results returned in a timely manner
MTCT.14	6-week MTCT rate	% of infants born to HIV-positive women who are HIV-positive at 6 weeks
Indicators for toxicity monitoring		
National indicator		
ART.12	Toxicity prevalence	% of ART patients with treatment-limiting toxicity
Additional indicator		
ART.13	Toxicity-related pre-term deliveries	% of preterm deliveries among women on ART
Indicators for HIV drug resistance from special surveys		
National indicators		
ART.14	HIVDR prevalence at ART initiation	% of people living with HIV and initiating ART who have resistance to HIV drugs
ART.15	Viral load suppression at 12 months after ART initiation	Number and % of people living with HIV whose viral load is suppressed at 12 months after initiating ART
Additional indicators		
ART.16	Acquired HIVDR prevalence	% of people living with HIV failing on ART at 12 (±3) months who have any HIVDR
ART.17	Acquired HIVDR long-term	% of people living with HIV on ART for at least 48 months and failing ART with any HIV drug resistance
ART.18	Transmitted HIVDR prevalence	% of recently HIV-infected adults with HIV drug resistance
ART.19	HIVDR among infants	% of infants and children under age 18 months diagnosed with HIV who have any HIVDR
Indicators of viral load suppression		
National indicators		
VLS.1	Viral load suppression at 12 months after ART initiation	Number and % of people living with HIV on ART with viral load suppression (<1000 copies/mL) at 12 months after treatment initiation
VLS.2	Viral load testing coverage	% of people on ART with viral load results at 12 months
VLS.3 Global indicator	Viral suppression	Number and % of people living with HIV and on ART who are virologically suppressed
VLS.4	Viral load monitoring	% of people living with HIV and on ART who obtained at least one viral load test result during the past 12 months
Additional indicators		
VLS.5	Population viral load	% of all people living with HIV who have suppressed viral load
VLS.6	Early viral load testing	% of people on ART who had viral load monitored at 6 months

VLS.7	Long-term viral suppression	% of people whose viral load is suppressed 48 months after initiating ART
Indicators for prevention of mother-to-child transmission		
National indicators		
MTCT.1	PMTCT testing coverage	% of pregnant women with known HIV status
MTCT.2	PMTCT ART coverage	Number and % of HIV-positive pregnant women who received ART during pregnancy
MTCT.3	ART retention	Number and % of HIV-positive pregnant and breastfeeding women retained on treatment at (6 and) 12 months after initiating ART
MTCT.4	Coverage of infant ARV prophylaxis	% of HIV-exposed infants who initiated ARV prophylaxis
MTCT.5	ARV coverage for breastfeeding infants	% of HIV-exposed breastfeeding infants whose mothers are receiving ART at 3 months (and 12 months) postpartum
MTCT.6	Coverage of early infant diagnosis	% of HIV-exposed infants receiving a virological test for HIV within 2 months of birth
MTCT.7	Final MTCT transmission rate	% HIV-infected among HIV-exposed infants born in the past 12 months
MTCT.8	Final outcome status	% distribution of HIV-exposed infants by final outcome status
MTCT.9	Co-trimoxazole (CTX) prophylaxis coverage	% of HIV-exposed infants started on CTX prophylaxis within 2 months of birth
MTCT.10	Unmet need for family planning	% of HIV-positive women attending HIV care and treatment services who have unmet need for family planning
Additional indicators		
MTCT.11	Seroconversion among pregnant women	% of HIV-negative pregnant women who are re-tested for HIV, by seroconversion status
MTCT.12	Testing coverage of pregnant women's partners	% of pregnant women attending ANC whose male partners were tested for HIV during pregnancy
MTCT.13	Turnaround time of EID results	% of early infant diagnosis test results returned in a timely manner
MTCT.14	6-week MTCT rate	% of infants born to HIV-positive women who are HIV-positive at 6 weeks
MTCT.15	Infant ART initiation	% of identified HIV-positive infants who initiated ART by 12 months of age
MTCT.16	Integration of ART into MCH sites	% of MCH facilities that provide ART
MTCT.17	Early retention rate	% of pregnant or breastfeeding on ART at 1 month and 3 months after initiating ART
MTCT.18	Coverage of baseline CD4 counts or clinical assessments in ANC	% of HIV-positive pregnant women assessed by CD4 count or clinical staging at ART initiation
MTCT.19	In-facility deliveries	% of HIV-positive pregnant women who deliver at a health facility

MTCT.20	Toxicity-related pre-term deliveries	% of pre-term deliveries among HIV-positive pregnant women on ART
MTCT.21	EMTCT case rate	Case rate of new paediatric HIV infections due to MTCT of HIV per 100 000 live births
Indicators for HIV mortality		
National indicator		
IMP.1 Global indicator	AIDS-related deaths	Estimated number that have died due to AIDS-related causes and rate of AIDS-related deaths per 100 000 population
Indicators of HIV incidence and prevalence		
National indicator		
IMP.2 Global indicator	New infections	Number and rate of new HIV infections
Additional indicators		
IMP.3	Incidence rate/year	Number and rate of new HIV infections
IMP.4	Prevalence	% of people infected with HIV
IMP.5	Key population HIV prevalence	% of people from key populations who are HIV-infected
Indicators of equity		
National indicator		
IMP.6	Equitable access to ART	Ratio of % of a subpopulation receiving ART to general population ART coverage rate
Indicators of health impacts of HIV and ART: nutrition		
Additional indicators		
IMP.7	Undernutrition in people living with HIV	Number and % of people in HIV care and treatment with undernutrition
IMP.8	Malnutrition/underweight	Prevalence of malnutrition/underweight among orphaned and vulnerable children compared with other children
IMP.9	Food access of people living with HIV	Number and % of people receiving HIV care and treatment services whose households have poor access to food
Indicators of non-health outcomes and impacts of ART: stigma and discrimination		
Additional indicators		
IMP.10	Attitudes towards people living with HIV	% of people ages 15–49 expressing accepting attitudes towards people living with HIV
IMP.11	Key population experience with discrimination	% of member of key populations who experienced discrimination
IMP.12	Per-capita household expenditures	% change in average per-capita household expenditures among HIV-affected households

IMP.13	**External economic support to the poorest households**	% of the poorest households affected by HIV that received external economic support in the last 3 months
IMP.14	**School attendance**	Ratio of current school attendance among orphans and other children

Annex 2 - Indicator tables for tracking critical resources 2.3:

Table 2.4 Indicators of service availability, quality and linkages

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
RES.1 Service availability Number and % of facilities providing HIV-specific services, such as: • HIV HTS • ART • Prevention of mother-to-child transmission (PMTCT) • Opioid substitution therapy/ needle–syringe programme (OST/NSP) • Voluntary medical male circumcision (VMMC) • CD4 count • Viral load testing	N: Number of facilities offering one or more of the services being assessed. D: Total number of facilities registered or assessed.	Site level (community, primary, secondary, tertiary); location (e.g. region, district); type of site (e.g. clinic, maternal and child health (MCH) site, TB site, prison or other closed setting); type of service.	Facility census; register of accredited service outlets; surveys of facilities (sampled or exhaustive).	Number of sites can be related to number of people living with HIV or people eligible for ART and their geographical distribution. Critical information to track national scale-up.

Additional indicators				
RES.2 Service quality Number and % of facilities with availability of: 1. basic amenities 2. basic equipment 3. procedures and equipment for standard precautions for infection prevention 4. diagnostic capacity 5. access to essential medicines and medicines needed to deliver HIV-specific services	N: Number of surveyed facilities meeting the set criteria, the components of which may be determined nationally to reflect relevant norms. D: Total number of facilities surveyed.	Site level (community, primary, secondary, tertiary); location (e.g. region/ district); type of site (e.g. general clinic, MCH site, TB site, prison or other closed setting); type and number of criteria met.	Special survey of a representative sample of health facilities. Checklists completed during supervisory visits.	Critical information to direct investment in quality of service delivery.
RES.3 Tracking SOP % of ART sites implementing a standard protocol for tracking ART patients	N: Number of ART sites implementing a standard, functioning patient tracking system. D: Number of health facilities dispensing ARVs in the last 12 months.	Site level (community, primary, secondary, tertiary); location (e.g. region, district); type of site (e.g. general clinic, MCH site, TB site, prison or other closed setting).	Surveys/site visits documenting existence of a protocol to track patients.	Critical component of capacity-building for quality service provision.
RES.4 Quality improvement activities % of ART sites with quality improvement (QI) activities *Cross-referenced with HTS section HTS.12*	N: Number of ART sites with quality improvement activities implemented in the last 6 months that address clinical HIV programme processes or outcomes and have documented results. D: Number of health facilities dispensing ARVs in the last 12 months.	Site level (community, primary, secondary, tertiary); location (e.g. region, district); type of site (e.g. general clinic, MCH site, TB site, prison or other closed setting).	Facility records and observation; consolidated data from supervisory visits (sampled or exhaustive).	Critical component of capacity-building for quality service provision.

RES.5 Laboratory capacity for HIV testing Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests *Cross-referenced with Resources section RES.25 and HTS section HTS.14*	Number of testing facilities (laboratories) with capacity (i.e. infrastructure, dedicated laboratory personnel and equipment) to perform: • HIV diagnosis with rapid test, EIA, Western blot or molecular methods; • HIV/AIDS care and treatment monitoring with CD4 count or HIV viral load testing • clinical laboratory tests in any of the following areas: haematology, clinical chemistry, serology, microbiology, TB diagnosis and identification, malaria diagnosis, OI diagnosis.	Testing facility (e.g. clinical laboratory, POC testing site), type of laboratory test performed, location.	Programme records.	Provides valuable information on trends in the availability of lab services. However, it does not measure the adequacy of coverage of laboratory services because of the different levels of capacity among laboratories. This indicator does not attempt to measure the quality, cost or effectiveness of services provided.
RES.6 Laboratory performance % of laboratories with satisfactory performance in external quality assurance/ proficiency testing (EQA/PT) *Cross-referenced with HTS section HTS.15*	N: Number of testing laboratories with satisfactory performance in EQA/PT. D: Number of testing laboratories participating in EQA/PT.	Type of laboratory. Type of test.	Laboratory EQA programme records at national reference laboratory. Following standard procedures for EQA/PT, a national or subnational reference laboratory sends pretested samples to laboratories for testing and computes the rate of agreement between results from participating and reference laboratories.	Measures laboratory performance, as determined by the accuracy and reliability of laboratory diagnostics, to monitor whether laboratory quality has kept pace with the expansion of HIV testing services. The aim is to ensure the validity of test results across the biomedical infrastructure, detect low performance, and address weaknesses through tighter supervision, verification and upgrading of equipment and timely supply of equipment and reagents.

RES.7 Supportive supervision % of ART sites with at least 4 quarterly supportive supervision visits in the last 12 months	N: Number of ART sites with at least 4 supportive supervision visits in the last 12 months. D: Number of ART sites dispensing ARVs in the last 12 months.	Site level (community, primary, secondary, tertiary); location (e.g. region, district); type of site (e.g. general clinic, MCH site, TB site, prison or other closed setting).	Health management information system.	Critical component of capacity-building for quality service provision.

Table 2.5 Indicators of the health-care workforce

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
Additional indicators				
RES.8 Vacancy rate % of job positions vacant	N: Number of vacant job positions. D: Number of job positions.	Cadre,[1] type of facility, urban/rural.	National human resources for health (HRH) registry.	Assesses whether planned health worker positions are filled; can further explore recruitment and retention of health workers.
RES.9 Health workforce density Core medical professionals per 10 000 population	N: Number of currently deployed health-care workers in the reporting period. D: Total population/10 000.	Cadre: core professionals (physicians, midwives, nurses); specific cadres such as specialists (surgeons, psychiatrists, etc.), other cadres (dentists, pharmacists). Distribution: place of employment (urban/rural, district).	National HRH registry.	Assesses whether there are enough health-care workers to deliver services; accepted target is 23 per 10 000 inhabitants.

[1] Recommended cadres include physicians, nursing and midwifery personnel, pharmacists, environment and public health professionals, community health workers, psychiatrists and other categories relevant in the national context.

RES.10 Annual new graduates Number of graduates from health workforce educational institutions (including schools of dentistry, medicine, midwifery, nursing, pharmacy) during the last academic year per 10 000 population	N: Number of health-care workers who graduated from pre-service training within the reporting period. D: Total population/10 000.	Level and field of education, sex, age at graduation, home postcode on entry to education institution.	National HRH registry.	Counts how many potential health workers are being educated and prepared in the country.
RES.11 Outreach through peer-educators Number and % of people from key populations and people living with HIV reached by peer educators[1]	N: Number of targeted individuals reached by HIV peer educators. D: Current estimated number of people from key populations and people living with HIV (targeted individuals).	Geographic zones of peer educators' activities. Possibly, key population,* people living with HIV.	N: Daily records maintained by peer educators provide an aggregate numerator. D: Estimates from surveys and internationally consistent modelled estimates, e.g. Spectrum AIM.	Estimates coverage achieved by HIV peer educators through fixed and outreach services.

[1] Peer educators are people recruited from civil society and who often belong or are strongly connected to key populations. They distribute condoms and sterile needles and syringes (where permitted) and promote HIV testing. In certain countries they may be trained and equipped to perform first-line HIV testing and refer to facilities for further testing when indicated.
* In many settings key population-specific data cannot be collected from routine programme monitoring; surveys are required.

Table 2.6 Indicators of medical products and technologies

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicators				
RES.12 Availability % of ART sites with stock-outs of: • any ARVs • reagents for rapid diagnostic tests, CD4 counts, VL tests, EID at relevant sites • co-trimoxazole (CTX) *Cross-reference with HTS section and ART section HTS. 13 and ART. 10*	N: Number of ART sites that had a stock-out of any of the specified drugs during a reporting period. D: Total number of reporting ART sites.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site, other), type of drugs or biological products (ARVs, CTX, essential laboratory tests and reagents).	Routine procurement and supply management.	Assesses the performance of the supply chain; can serve as a surrogate indicator for the overall functioning of the drug procurement system The target is 0% HTS sites that experience stock-out, i.e. 100% of sites with no stock-outs. The indicator can be applied to ARVs and to other commodities for which stock management tools provide information on the quantity available, quantity delivered, consumption and stock-outs.
RES.13 Quality control of ARV medicines % of batches tested that met the defined quality standards	N: Number of tested ARV batches that met quality standards. D: Total number of ARV batches tested.	Source of supply and destination; type of medicine tested.	Routine procurement and supply management.[1]	Assesses quality of ARV drugs delivered; essential requirement to secure the safety and effectiveness of ART programmes. Mandated by most donors.

[1] Alternatively, if quality control cannot be directly assessed, the % of ARVs procured that are WHO pre-qualified (or US Food and Drug Administration (USFDA)-approved) might be used as an indicator of ARV quality; N = Number of procured WHO pre-qualified ARVs (or USFDA-approved ARVs); D = Total number of procured ARVs. Target: 100%.

Additional indicators				
RES.14 Rational ARV use % of people living with HIV receiving ART in line with the national guidelines	N: Number of patients receiving ART in accordance with national guidelines at the end of the reporting period (usually 12 months). D: Total number of people on ART at end of reporting period.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site).	Routine procurement and supply management.	Assesses whether treatments are in line with national standard ART guidelines.
RES.15 Forecasting % of ARV drugs planned for that are actually received	N: Quantities of all ARVs received (procured plus donated) during a reporting period. D: Total quantities of ARVs quantified (forecast) for procurement and donated in a reporting period.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site), type of ARV.	Routine procurement and supply management.	Assesses whether the quantities received from procurement and donations correspond to the quantities forecast for supply: If more was received than planned, loss by expiry may occur; if less received than planned, stock-out may occur and/ or programme scale-up may be constrained.
RES.16 Consumption % of quantities of ARV drugs consumed	N: Quantities of all ARVs consumed during a reporting period. D: Total quantities of ARVs available for consumption after deducting quantities to cover the buffer stock.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site), type of ARV.	Routine procurement and supply management.	Measures correlation between the quantities of ARVs received and consumed: If quantities on hand exceed programme usage, there is an overstock, with risk of loss due to expiration; if quantities consumed exceed the quantities on hand and the buffer stock is consumed, a stock-out occurs.

RES.17 Procurement efficiency The ratio between the median price of the preferred first-line ARV regimen paid by the country and the median price of the same regimen in the region	N: The median price of the preferred first-line ARV regimen in a country. D: The median price of the same regimen in the same region (e.g. sub-Saharan Africa) or in neighbouring countries with same economic level; or last year's median price in the country.	None.	Routine procurement and supply management.	Assesses transparency in the procurement of ARV medicines: Ratio should be <1 and decreasing over time. In contrast, a ratio of >1 suggests that the country is paying more than others in the region are paying, and further investigation is needed.
RES.18 Delivery (supplier) performance % of orders delivered by suppliers on time and in full (OTIF) during a reporting period	N: Number of orders delivered OTIF during a reporting period. D: Total number of orders placed and expected to be delivered during the same period.	National procurement services: source of procurement.	Routine procurement and supply management.	Assesses supplier performance in meeting delivery schedule and quantities specified in the procurement contract; can be disaggregated by supplier to provide more detailed information.
RES.19 Performance in port clearance % of orders cleared within the defined deadline	N: Number of orders cleared within the defined deadline. D: Total number of orders delivered at the port.	National procurement services: source of procurement.	Routine procurement and supply management.	Measures performance in timely clearance of goods from the port. Delayed clearance may result in deterioration of drugs and contribute to stock-outs.
RES.20 ARV drug registration % of recommended ARV formulations registered	N: Number of preferred formulations for adults and Interagency Task Team optimal paediatric ARV formulary registered in the country. D: Total number of preferred formulations for adults and Interagency Task Team optimal paediatric ARV formulary.	None.	Source: national regulatory agency.	Assesses performance of the national registration system in registering preferred ARV formulations for adults and children. Registration is essential to increase access to and affordability of preferred ARV formulations.

RES.21 Distribution % of ART sites that received all orders OTIF from the central or regional stores	N: Number of orders received OTIF by ART sites during a reporting period. D: Total number of orders placed during the same period.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site).	Routine procurement and supply management.	Assesses the performance of the national distribution system in supplying ARV medicines to health facilities.
RES.22 Inventory control % of ART sites that submitted a complete inventory control on time	N: Number of ART sites that submitted a complete inventory control report on time during the reporting period. D: Total number of ART sites.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site).	Routine procurement and supply management, audit or programme evaluation.	Assesses performance of the ART programme in fulfilling its reporting requirements. Timely reports are critical to the performance of procurement and supply management functions and effective M&E.
RES.23 Loss % of procured ARV quantities that are lost	N: Monetary value of ARV drugs lost (due to expiry, damage, diversion or theft) during a reporting period. D: Total value of ARVs procured during the same period.	None.	Routine procurement and supply management, central-level inquiry by audit or programme evaluation.	Measures loss from procurement & supply management system; if >1%, further analysis of causes of loss and corrective action are required.
RES.24 Minimum stock level % of ART sites that placed their order while the stock at hand was below the minimum stock level	N: Number of ART sites that placed an order for ARV drugs in a reporting period when the stock at hand was below the minimum stock level. D: Total number of ART sites that placed an order for ARV drugs during the same period.	Site level (community, primary, secondary, tertiary), location (e.g. region, district), type of site (e.g. general clinic, MCH site, TB site).	Routine procurement and supply management, audit or programme evaluation.	Assesses whether the logistics management information system is being used effectively: If orders are submitted when the stock at hand is below minimum stock level, the risk of stock-out is high.
RES.25 Laboratory capacity Number of testing facilities (laboratories) with capacity to perform clinical laboratory tests *Cross-referenced with Resources section RES.5 and HTS section HTS.14*	Number of testing facilities (laboratories) with capacity (i.e. infrastructure, dedicated laboratory personnel and equipment) to perform: • HIV diagnosis with rapid test, EIA, Western blot or molecular methods; • HIV/AIDS care and treatment monitoring with CD4 count or HIV viral load testing • clinical laboratory tests in any of the following areas: haematology, clinical chemistry, serology, microbiology, TB diagnosis and identification, malaria diagnosis, OI diagnosis.	Testing facility (e.g. clinical laboratory, POC testing site), type of laboratory test performed, location.	Programme records.	Provides valuable information on trends in the availability of lab services. However, it does not measure the adequacy of coverage of laboratory services because of the different levels of capacity among laboratories.

Table 2.7 Indicators of strategic information

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
Additional indicators				
RES.26 Completeness of indicators Availability of information on each of the nationally defined indicators of the health sector response to HIV	(Including the 10 indicators designated for global monitoring; see section 2.1).	Location, population.	Review of strategic information system. Should be completed at least twice in each 3- to 5-year planning cycle (at mid-term and end).	Assesses which data are available and which are missing so as to inform planning; enables improvement of the strategic information system.
RES.27 System reviews Regular performance of reviews of the M&E system	Number of reviews of the M&E system per planning cycle.	None.	Review of strategic information system. Target: 2 reviews per planning cycle.	Indicates how committed national authorities are to assuring that they can base decisions on factual information.
RES.28 Publishing data % of indicator data published annually	N: Number of indicators for which information has been published in a publicly available document or website according to the assessment schedule. D: Number of indicators for which information was due according to the assessment schedule.	None.	Review of strategic information system.	Indicates how willing national authorities are to share information with other stakeholders.

Table 2.8 Indicators of governance, leadership and the policy environment

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
Additional indicators				
RES.29 Completion of the National Commitments and Policies Instrument (NCPI) questionnaire for HIV/AIDS[1] NCPI questionnaire for HIV/AIDS	n/a.	n/a.	NCPI questionnaire for HIV/AIDS (as part of GARPR).	Covers whether the country has a multisectoral strategic plan on HIV/AIDS and whether the plan: • covers all sectors and target populations • was developed with full involvement and participation of civil society • has the endorsement of external development partners • is aligned with the national strategy and • has been integrated into other development plans.
RES.30 Completion of WHO HIV health sector response policy questions Country's completion of WHO policy questions	n/a.	n/a.	Global AIDS Response Progress Reporting, 2014, Part 2; see page 179 and following for health sector-specific indicators applicable for GARPR and universal access.	Closer focus than NCPI on the health sector – useful for decisions in the MOH. Health sector-specific questions address ART, PMTCT, key populations and M&E.

[1] The NCPI is currently being revised to assess the purpose of the tool in the post-2015 environment. It is expected that the new tool will be available for the 2016 round of Global AIDS Response Progress Reporting.

Table 2.9 Indicators of financing and costing for HIV programmes

Indicator	Numerator (N)/ denominator (D)	Disaggregation	Measurement method	Programme relevance and interpretation
National indicator				
RES.31 Domestic finance % of HIV response financed domestically 	N: HIV domestic public expenditure. D: Total HIV expenditure.	ART spending, key population spending.	NASA, HA.	Shows country's ownership and willingness to pay. When available for a number of years, it tracks trends in country ownership.
Additional indicator				
RES.32 Health spending on HIV programmes Proportion of HIV spending in national health budget	N: Health spending on HIV programmes. D: Total health expenditure.	Domestic public HIV health spending divided by public health expenditure. Donor-funded HIV health programmes divided by rest-of-world health expenditure.	NASA, HA.	Indicates weight of HIV health activities in the national health budget. Explores options to increase contribution from public and international health financing to HIV health programmes.
RES.33 Country progress in domestic financing Relative Variation Index	N: The product of domestic public HIV expenditure, latest year, times total HIV expenditure in base year. D: The product of domestic public HIV expenditure in the base year times total HIV expenditure, latest year.	ART spending, key population prevention spending.	NASA, HA.	Tracks trends in self-sustained response to HIV, with special focus on ART and prevention among key populations. Results greater than 1 signify progress in domestic financing.
RES.34 Domestic private expenditure % contribution of domestic private sources to HIV financing	N: Domestic private expenditure. D: Total HIV expenditure on HIV activities.	HIV spending category.	NASA, HA.	Shows contribution of domestic sources other than public financing. Shows options to increase and diversify sources of private contribution.

RES.35 Unit cost of HIV interventions Per capita expenditure on HIV health programmes	N: Expenditure per specific health programme in response to HIV. D: Number of people reached by specific health programme in response to HIV.	HIV spending category.	NASA, HA.	Overtime, monitors changes in average expenditure per person reached or service delivered. Can be benchmarked to countries with similar income level or epidemic burden.

BIBLIOGRAPHY

Enhancing results by applying the Paris Declaration at sector level: progress update and lessons learnt from aid effectiveness in AIDS responses. Geneva, Joint United Nations Programme on HIV/AIDS, 2008 (http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/report/2008/20081023_accraprogressupdate_en.pdf, accessed 21 May 2013).

Evaluating HIV/AIDS prevention projects: a manual for nongovernmental organizations. Calverton, Maryland, USA: MEASURE Evaluation; 2000 (http://www.cpc.unc.edu/measure/tools/hiv-aids/evaluating-hiv-aids-prevention-projects, accessed 21 May 2013).

Global health sector strategy on HIV/AIDS 2011–2015. Geneva: World Health Organization; 2011 (http://www.who.int/hiv/pub/hiv_strategy/en/index.html, accessed 21 May 2013).

Guidance on evaluation and review for DFID staff. London: Department for International Development; 2005 (http://www.dfid.gov.uk%2Faboutdfid%2Fperformance%2Ffiles%2Fguidance-evaluation.pdf&ei=mpyHUM2kC8nRsgavn4Ag&usg=AFQjCNHhb5NB8FNEjjE7TbDSVQ5GWmK4Tw, accessed 21 May 2013).

Guidelines for conducting a review of a national tuberculosis programme. Geneva: World Health Organization; 1998 (http://www.who.int/tb/publications/1998/en/index.html, accessed 21 May 2013).

Guidelines for conducting a review of the health sector response to HIV/AIDS. Manila, WHO Regional Office for South-East Asia, 2008 (http://203.90.70.117/PDS_DOCS/B2150.pdf, accessed 21 May 2013).

Guidelines for conducting focused programme review. Geneva: World Health Organization; 1997 (https://whqlibdoc.who.int/hq/1997/WHO_CHD_97.10.pdf, accessed 21 May 2013).

International Health Partnership [website]. (http://www.internationalhealthpartnership.net/en, accessed 21 May 2013).

Joint reviews of national AIDS responses: a guidance paper. Geneva: Joint United Nations Programme on HIV/AIDS; 2008 (http://www.unaids.org/en/ourwork/programmebranch/programmeeffectivenessandcountrysupportdepartment/strategiccountrysupportdivision, accessed 21 May 2013).

Malaria programme reviews: a manual for reviewing the performance of malaria control and elimination programmes. Trial edition. Geneva, World Health Organization, 2010 (http://www.who.int/malaria/publications/atoz/whomprmalariaprogramperformancemanual/en/index.html, accessed 21 May 2013).

Monitoring and evaluation of health systems strengthening: an operational framework. Geneva: World Health Organization; 2010 (http://www.who.int/healthinfo/HSS_MandE_framework_Oct_2010.pdf, accessed 21 May 2013).

Monitoring, evaluation and review of national health strategies. Geneva, International Health Partnership and related initiatives, 2011 (http://www.internationalhealthpartnership.net/en/tools/me-platform/).

Planning guide for the health sector response to HIV. Geneva: World Health Organization; 2011 (http://www.who.int/hiv/pub/guidelines/9789241502535/en/index.html, accessed 21 May 2013).

Primary health care reviews: guidelines and methods. Geneva: World Health Organization; 1992 (http://apps.who.int/iris/handle/10665/39118?locale=ar, accessed 21 May 2013).

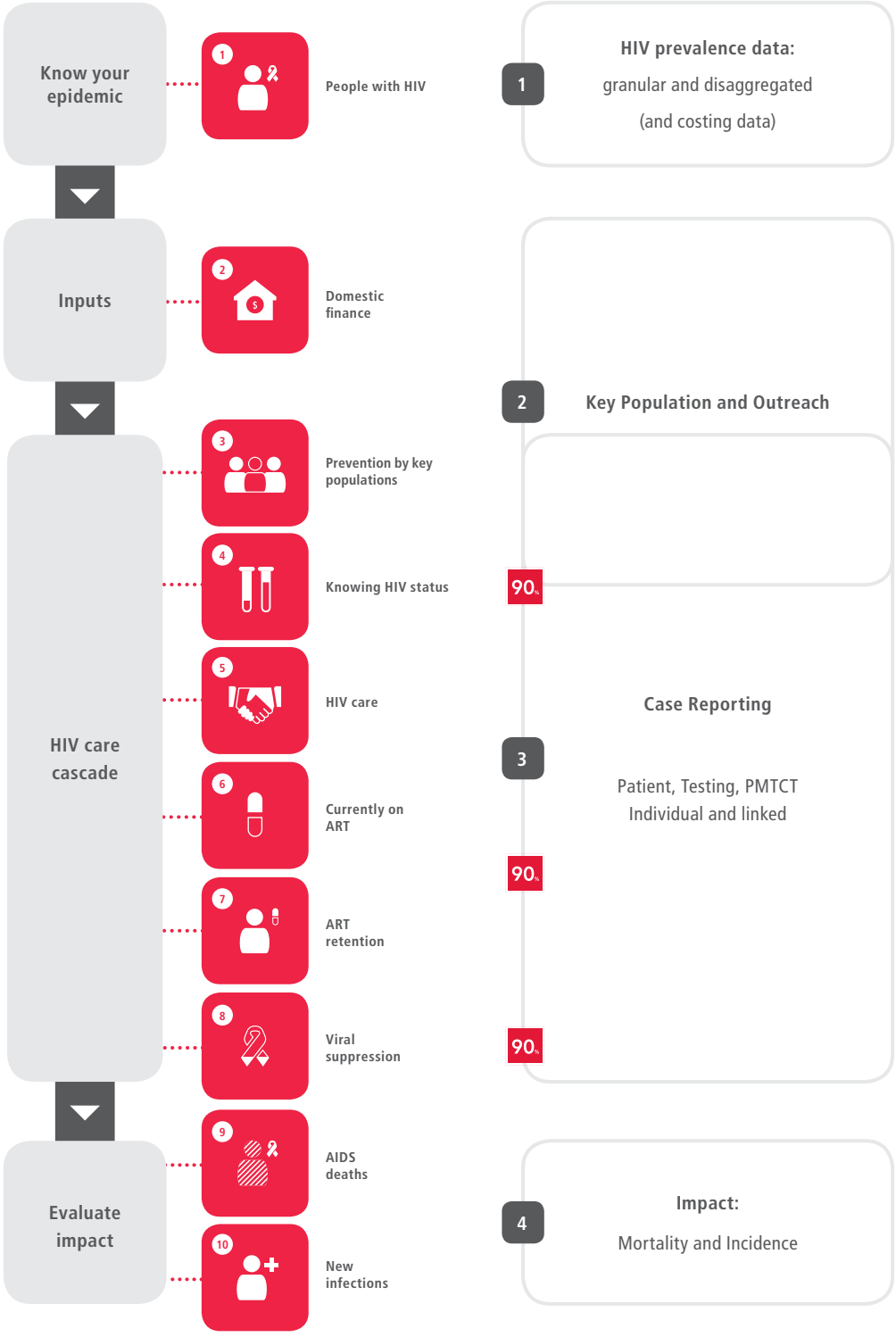
Schwartlander B, Stover J, Hallet T, Atun R, Avila C, Gouws E, et al.: Torwrads an improved investment approach for an effective response to HIV/AIDS. Lancet. 2011; 377:2031–41.

UNAIDS, WHO and MEASURE. *National AIDS programmes: a guide to monitoring and evaluation*. Geneva: World Health Organization; 2000 (http://www.who.int/hiv/pub/surveillance/unaids0017e.pdf, accessed 21 May 2013).

United Nations General Assembly. *Political declaration on HIV and AIDS: intensifying our efforts to eliminate HIV and AIDS*. New York: United Nations General Assembly; 2011 (http://www.un.org/Docs/journal/asp/ws.asp?m=A/65/L.77, accessed 21 May 2013).

WHO, UNAIDS, Global Fund to Fight AIDS, Tuberculosis and Malaria, USAID, CDC, HHS, UNICEF and the World Bank. *Monitoring and evaluation toolkit: HIV/AIDS, tuberculosis and malaria*. Geneva: World Health Organization; 2004 (http://www.who.int/hiv/pub/epidemiology/en/me_toolkit_en.pdf, accessed 21 May 2013).

Global indicators for the health sector response to HIV



TEN INDICATORS TO TRACK THE HIV RESPONSE

Data for Decisions

1. **PEOPLE WITH HIV**
   Number and % of people living with HIV (PLHIV)
2. **DOMESTIC FINANCE**
   % of HIV response financed domestically
3. **PREVENTION BY KEY POPULATIONS**
   % condom use, sterile needles per person who injects drugs
4. **KNOWING HIV STATUS**
   Number and % of PLHIV who have been diagnosed
5. **HIV CARE**
   Number and % of PLHIV in HIV care (including ART)
6. **CURRENTLY ON ART**
   Number and % of PLHIV on ART, PMTCT ART
7. **ART RETENTION**
   Number and % of PLHIV retained and surviving on ART
8. **VIRAL SUPPRESSION**
   Number and % on ART virally suppressed
9. **AIDS DEATHS**
   Deaths per 100,000 population
10. **NEW INFECTIONS**
    Number of new HIV infections per 1000 uninfected population

FRAMEWORK FOR USING THE DATA

Know your epidemic | **Monitor the HIV service cascade** | **Evaluate Impact**

For more information, contact:

World Health Organization
Department of HIV/AIDS
20, avenue Appia
1211 Geneva 27
Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv

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