NTD Masterplans
2021-2025

A Shared Vision for NTD Safety

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Why safety?

Primary ethical responsibility
Deliver health benefits
‘Do no harm’ (safety)
Why safety for NTD programs?

Increased NTD programme reach and visibility
Increased scrutiny and liability
More frequent drug co-administration during MDA
WHO NTD Roadmap (2021-2030)

“Mainstreaming into national health systems, coordinating with adjacent sectors”
“Country ownership and financing with NTDs integrated in national health plans”

Source: NTD Roadmap, 2021-2030
2. **URGES Member States:**

(1) to recognize patient safety as a health priority in health sector policies and programmes, making it an essential component for strengthening health care systems in order to achieve universal health coverage;

(2) to assess and measure the nature and magnitude of the problem of patient safety including risks, errors, adverse events and patient harm at all levels of health service delivery including through reporting, learning and feedback systems that incorporate the perspectives of patients and their families, and to take preventive action and implement systematic measures to reduce risks to all individuals;

(3) to develop and implement national policies, legislation, strategies, guidance and tools, and deploy adequate resources, in order to strengthen the safety of all health services, as appropriate;

(4) to work in collaboration with other Member States, civil society organizations, patients’ organizations, professional bodies, academic and research institutions, industry and other relevant stakeholders to promote, prioritize and embed patient safety in all health policies and strategies;

(5) to share and disseminate best practices and encourage mutual learning to reduce patient harm through regional and international collaboration;
Current WHO efforts to promote NTD safety

Guidance document: Safety in administering medicines

Training modules

- NTD program managers
- Community drug distributors

Aide-mémoires

- NTD program managers
- Community drug distributors

I. Preparing for Preventive Chemotherapy

Organizational and systems preparedness

- Safety-related goals, objectives, and activities articulated in national NTD Master Plan
- National and sub-national pharmacovigilance agencies informed of preventive chemotherapy location, dates, drugs used, diseases targeted, and estimated number of participants
- Protocols and procedures for managing, reporting and investigating adverse events (AEs) and serious adverse events (SAEs), including standard case definitions, are clearly established and communicated to all relevant stakeholders (particularly the national pharmacovigilance center)
- Medical teams are prepared to respond rapidly to AEs and SAEs
## NTD Master Plan: Safety Readiness – Where are you now? Where will you be in 2025?

### Domains

<table>
<thead>
<tr>
<th>Number</th>
<th>Domain</th>
<th>... Basic readiness</th>
<th>Improved safety</th>
<th>Integrated safety</th>
</tr>
</thead>
</table>
| 1      | Organisational and systems preparedness | - NTD programmes manage community mobilisation, drug distribution, AE management, SAE reporting.  
- Coordination within MoH | - Joint responsibility with pharmacovigilance (PV) for SAE management, reporting  
- PV informed in advance of MDA  
- PV collaboration in Master Plan | - Shared planning, goals, AE management, annual review between NTD and PV programmes |
| 2      | Drug supply and management      | - Donated NTD drugs WHO-prequalified or comply with stringent regulatory authority (SRA) guidelines  
- Good supply chain management | - Donated and purchased NTD drugs WHO-prequalified or comply with SRA guidelines  
- Drugs to manage AEs and SAEs available in health facilities | - All NTD drugs WHO-prequalified or comply with SRA guidelines, approved by regulatory agencies  
- Drugs to manage AEs and SAEs available at local health units |
| 3      | Communication                   | - CDDs share information with community about disease, safety, AE risk                | - Communications plan, press statements for rumours, SAEs  
- Press statements drafted  
- Media spokespersons prepared | - Comprehensive communications plan ready, rehearsed, including social media  
- Cross-sectoral planning |
| 4      | Ensuring safety: Preventing choking | - Adherence to WHO guidelines on drug formulation, MDA exclusion, not forcing children  
- Treatments directly observed | - Periodic observational assessments to monitor safety  
- CDDs familiar with choking management | - All CDDs trained, prepared, and able to perform choking maneuvers (e.g., Heimlich maneuver) |
| 5      | Ensuring safety: Managing SAEs  | - CDDs recognize and advise treatment for AEs  
- SAE response teams prepared  
- SAE reporting procedures clear | - Enhanced CDD training (role play)  
- SAE response planning  
- Post-MDA review, analysis of AEs and SAEs | - Integrated NTD-PV oversight; annual analysis of AEs, SAEs  
- Joint safety Task Force  
- Integrated safety targets |

Source: Aide Memoire for NTD Programme
A culture of safety

• Embedding safety in all aspects of NTD programmes
• NTD Master Plans
  – A crucial enabler of safety programming

Annex 6: Safety

Safety is critical for the success of programmes to control and eliminate neglected tropical diseases (NTDs). Attention to safety is also required to fulfil the core ethical obligation of public health programmes to ‘do no harm’ while delivering health benefits. Safety should be embedded in, and permeate, all aspects of NTD programmes, including training, supervision, drug supply and management; preventive chemotherapy; communication with communities; programme monitoring; and prompt SAE investigation and reporting.

Safety has long been a consideration for NTD programmes. For example, drugs that are donated for preventive chemotherapy are manufactured according to the highest standards of safety and quality. However, maintaining safety requires ongoing vigilance, particularly in administering preverved chemotherapy, which now reaches more than 1 billion persons each year. For example, deaths continue to be reported among children who choke on tablets during preventive chemotherapy.

Safety is not automatic. It must be considered, planned for, and integrated across all components of NTD programmes. Few NTD Master Plans currently include safety-related objectives or targets. As a result, safety has not received the attention it deserves. NTD programmes are not alone in this regard; in response to the growing problem of ‘medical error,’ WHO recently launched a world patient safety initiative to improve safety in all medical and public health settings (WPAT2.6). Including safety as an integral part of NTD Master Plans can ensure that safety receives adequate attention in NTD programming. This annex provides guidance to NTD programme managers in addressing safety as they draft and implement national NTD Master Plans.
Opportunities to include safety in NTD Masterplans

• “Do no harm” as a guiding principle

Section 2.3: Guiding Principles

Table 13. Guiding principles

| Guiding principles | National leadership and ownership, |
|                   | Commitment to collaboration and sharing, |
|                   | Mutual accountability of national authorities and partners, |
|                   | Transparency and accountability, |
|                   | Community engagement and participation |
|                   | Safety: ‘Do no harm’ while providing health benefits |

Guiding Principles are a broad philosophy that encompass your personal beliefs and values and guide the programme throughout its life in all circumstances, irrespective of changes in its goals, strategies or type of work. They create a programme culture where everyone understands what's important.
Opportunities to include safety in NTD Masterplans

I. Strategic analysis

<table>
<thead>
<tr>
<th>Table 2. Six Health System Building Blocks</th>
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</thead>
<tbody>
<tr>
<td><strong>Medical products</strong></td>
</tr>
<tr>
<td>Describe the system for safe handling of medical products including the norms, standards, policies, procurement, supplies and management systems, and drug quality assessment. Describe the constraints to the supply logistics for the control of NTDs. Also describe the existing pharmaco-vigilance system and list existing opportunities for information exchange and incorporating the activities and processes of the pharmaco-vigilance system into NTD programming.</td>
</tr>
<tr>
<td><strong>Leadership and governance</strong></td>
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<tr>
<td>Describe the administrative hierarchy of the ministry of health and responsibilities at each level. Some of the questions to consider are:</td>
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<tr>
<td>• What government sector is responsible for pharmacovigilance and for investigation, analysis, and reporting of serious adverse events (SAEs)? What level of communication and cooperation exist between NTD control activities and this pharmacovigilance unit? Are staff within this unit aware of when and where mass drug administration is planned, and do they participate in investigation and reporting of SAEs?</td>
</tr>
</tbody>
</table>
Opportunities to include safety in NTD Masterplans

I. Strategic analysis

Section 1.5: Building on NTD Programme Strengths

From the analysis on data on country profile, health system, and NTD programme status, conduct a SWOT analysis of the NTD programme and summarize this information in a table such as table 4.

1.5.1. Opportunities and Threats

Opportunities and threats are external—things that are going on outside your programme or ministry of health. You can take advantage of opportunities and protect against threats, but you can’t change them. Examples include prices of programme supplies, stigma and discrimination against people with NTDs, spread of rumours of adverse events associated with preventive chemotherapy.

1.5.2. Strengths and Weaknesses

Strengths and weaknesses are internal to your programme or ministry of health—things that you have some control over and can change. Examples include who is on your team, the status of monitoring and evaluation of the NTD programme, and preparedness for managing and investigating serious adverse events (SAEs).

Indicate the weaknesses and threats you anticipate in reaching the 2030 goal, e.g., “what is preventing you from reaching elimination? What can you do about it?”
Opportunities to include safety in NTD Masterplans

I. Strategic analysis

1.4.2. NTD Programme Performance

- In this section, information on key results, impact and trend analysis of the NTD programme should be provided. List the past and on-going NTD control programmes. This information should be organized into the following sections:
  - Completeness of the mapping and survey need
  - Geographical coverage for all NTDs and expansion need
  - Impact assessments survey results for all NTDs (TAS, Trachoma, SCH and STH prevalence change) and need of survey
  - Reduction of number of people requiring NTD intervention and evolution of the need of tablets for PC.
  - Safety assessment (correctness of dosing; frequency of SAEs; incidence of young children choking on tablets; successful management of safety-related episodes that cause community concern)
Opportunities to include safety in NTD Masterplans

II. Strategic agenda

2.4.2. Strategic Priorities

Table 14. Strategic Priorities for the Elimination of Neglected Tropical Diseases

<table>
<thead>
<tr>
<th>Examples of Strategic Pillar</th>
<th>Examples of priorities</th>
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<tbody>
<tr>
<td><strong>Pillar 1. Accelerating programmatic action</strong></td>
<td>Ensure timely, safe, and effective supply chain management of quality- assured NTD Medicines and other products up to the last mile</td>
</tr>
<tr>
<td><strong>Pillar 2. Intensify cross-cutting approaches</strong></td>
<td>Strengthen identified platforms with similar delivery strategies and interventions (MDAs, skin NTDs, Morbidity management, SBCC, WASH etc) for integrated approaches across NTDs</td>
</tr>
</tbody>
</table>

- Mainstream delivery platforms within the national health system
- **Integrate safety across NTD planning, implementation, and monitoring**

| **Pillar 3. Operating Models and culture to facilitate country ownership** | Promote and strengthen country ownership and leadership through organizational structures at national and local government with dedicated funding |
| | Empower local government and authorities in social mobilization, risk and crisis communication, behavioural change and building local support for NTD interventions |
Additional Information


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Thank you

PROMOTING SAFETY OF MEDICINES FOR CHILDREN

Safe mass drug administration and trachoma elimination

Simple measures and new Zithromax® dosing guidelines protect children and ensure the safety of mass drug administration.

Mass drug administration (MDA), which involves giving medicines to a whole community at one time, usually once a year, is a major component of the SAFE strategy to eliminate trachoma. Surgery, Antibiotics, facial cleanliness, and Environmental improvement are components.

World Health Organization