The Living Approach to WHO normative products and country implementation

Member State Briefing

31 Oct 2022
Session outline

Member State Briefing: The Living Approach to WHO normative products and country implementation

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Living Guidelines
Guideline recommendations that are updated as frequently as is necessary and feasible as evidence improves over time.

Living Adaptation & Implementation
Guideline recommendations adapted to be usable and implementable, with uptake monitored and learnings used to inform innovation and better design.

Evidence to Policy
Strategies to promote evidence use in national policies, and the development of evidence support systems use to support policy decision-making.

SMART Guidelines
A stepwise process of translating guideline and data recommendations into specifications and reusable digital components which facilitate interoperability and accurate representation in digital systems, to reinforce recommended health and data practices.

Country Adoption, Effective Implementation, Refinement and Institutionalization
The Living Approach to WHO normative products and country implementation

DOWNSTREAM

Outcomes captured

Recommendation prioritization

UPSTREAM

Evidence surveillance and screening

Evidence evaluation and synthesis

Strategies to improve uptake of evidence and guidelines country level

Digital

Executable: localized software

Digitization: operational and machine readable

Access by end users

Adaptation

Fidelity: adherence to guideline

Utilization: data generated through digital use

Publication, dissemination and translation

Formulation of recommendations

Evidence to Policy

Living Guidelines

Living Implementation

SMART Guidelines
What are we doing now?
WHO GUIDELINES

... driving impact in countries
Guideline development process

- **Scope the guideline**
- **Consider logic models**
- **Consider all relevant evidence**

**Set up guideline panel and external review group**
- Formulate PICO/SPICE or other questions and select outcomes
- Evidence retrieval, assessment, synthesis
- Appraise certainty of the body of evidence

**Include explicit consideration of:**
- Benefits and harms
- Resource use/feasibility
- Health equity/non-discrimination
- Human rights/sociocultural acceptability

**Formulate recommendations**

**Disseminate, implement**

**Evaluate impact**

- **GRC approval - Proposal**
- **GRC approval**
- **Final guideline**

Manage declarations of interest

6-24 months

6-12 weeks
Information collated in a publication, disseminated globally & translated if needed

Experts assess evidence and other factors, make recommendations

Formulation of recommendations

Publication, translation and dissemination

Adaptation for country-level use

Implementation and monitoring

Revise highest priority recommendations needed

Systematically search and screen all available evidence

Systematically evaluate and synthesize all available evidence

Countries adapt recommendations for their needs

WHO GUIDANCE DEVELOPMENT ECOSYSTEM

Recommendation prioritization

Evidence surveillance and screening

Evidence evaluation and synthesis

WHO GUIDANCE DEVELOPMENT ECOSYSTEM

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Countries adapt recommendations for their needs
Standard WHO guidelines

Management of chronic pain in children


**Current Model:**
Intermittently updated guidelines

**EXISTING MODEL**

Source: top right figure from Julian Elliott, Living Evidence network

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The **usually**

- take 1-2 yrs min to develop
- published only as static pdf, dense text, long
- not structured for in digital formats
- challenging to translate for interoperability and digital systems
- updated only every 3-5 years, so not always “informed by best available and up-to-date evidence”
What needs to change?
Living guidelines: trustworthy and up-to-date

Standard WHO guidelines are updated every 3-5 years

‘Living’ guidelines are updated every week / month / ?

and/or triggered by rules or algorithms that determine when emerging evidence would change a recommendation

REMDESVIR GUIDELINE

SOLIDARITY trial data 15 Oct 2020

GDG recommendations

Publication 20 Nov 2020

36 days
What makes a guideline ‘living’ (vs static)

**Living guideline**
- starts with standard ‘base’ systematic review
- then prioritize which recommendations need more frequent updating (due to expected new evidence)
- definition: a guideline with at least one recommendation is in ‘living mode’
- main feature: underpinned by ‘living systematic review’
Living systematic reviews underpin living guidelines

Evidence surveillance frequency?

How often to look for new, relevant evidence?
- usually at least every 3-6 months, for how long?
- could be ‘continuous’ ‘real time’ e.g. daily, weekly during COVID-19
- may need AI support tools
- can be triggered by off-cycle information e.g. new RCT published
Possible actions following surveillance time point?
Agile authoring and publication platforms

Authoring, publishing & dissemination modes that are
- digital, flexible, agile, real-time
- can be embed elsewhere e.g dept webpages, create derivative products
The WHO Therapeutics and COVID-19: living guideline contains the Organization’s most up-to-date recommendations for the use of therapeutics in the treatment of COVID-19. The latest version of this living guideline is available in HTML format (via the ‘Download’ button) and via a dedicated online platform and is updated regularly as new evidence emerges.

This tenth version of the WHO living guideline now contains 17 recommendations, including two new recommendations regarding nirmatrelvir-ritonavir. No further updates to the previous existing recommendations were made in this latest version.

The WHO Therapeutics and COVID-19: living guideline currently includes:

- **NEW** strong recommendation for the use of nirmatrelvir-ritonavir in patients with non-severe illness at the highest risk of hospitalization (published 22 April 2022);
- **NEW** conditional recommendation against the use of nirmatrelvir-ritonavir in patients with non-severe illness at a low risk of hospitalization (published 22 April 2022);
- **UPDATED** conditional recommendation for the use of remdesivir in patients with non-severe COVID-19 at the highest risk of hospitalization (first published 20 November 2020, updated 22 April 2022);
- conditional recommendation for the use of molnupiravir in patients with non-severe COVID-19, at highest risk of hospitalization (excluding pregnant or breastfeeding women, and children) (published 03 March 2022);
Online authoring & publication platforms

- Clearly flags new / updated recommendations
- Jumps directly to specific recommendation
- Can click through multiple layers of info, including evidence underpinning the recommendation
To achieve truly ‘living approach’ for all NSPs, we need:

- **Fewer** (most impactful, only *truly* prioritized recommendations)
- **Faster** (rapid, shorter, current/up-to-date)
- **Fit-for-purpose** (user-friendly, implementable, permits monitoring & evaluation)
- **Findable** (digital, interoperable, derivative products)
- **Fairer** (accessible, adaptable, easily-translatable)
Information collated in a publication, disseminated globally & translated if needed

Experts assess evidence and other factors, make recommendations

Formulation of recommendations

Publication, translation and dissemination

Adaptation for country-level use

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Recommendation prioritization

Evidence surveillance and screening

Evidence evaluation and synthesis

WHO GUIDANCE DEVELOPMENT ECOSYSTEM

Systems track recommendation implementation and monitor health impacts

Countries adapt recommendations for their needs

Systematically search and screen all available evidence

Systematically evaluate and synthesize all available evidence

Revise highest priority recommendations needed
**WHO GUIDANCE DEVELOPMENT ECOSYSTEM**

- **Recommendation prioritization**
- **Evidence surveillance and screening**
- **Evidence evaluation and synthesis**
- **Formulation of recommendations**
- **Publication, translation and dissemination**
- **Adaptation for country-level use**
- **Implementation and monitoring**
- **Revise highest priority recommendations**

**DOWNSTREAM COMPONENTS**

- **Information collated in a publication, disseminated globally & translated if needed**
- **Countries adapt recommendations for their needs**
- **Systems track recommendation implementation and monitor health impacts**
- **Experts assess evidence and other factors, make recommendations**
- **Systematically search and screen all available evidence**
- **Systematically evaluate and synthesize all available evidence**
Living adaptation and implementation at country-level
Main barriers to WHO guidelines’ uptake & use

- Leadership and governance, lack of policy coherence
- Information/intelligence/data/evidence/
- Health workforce capacity
- Inadequate health care infrastructure and resources
- Funding limitations
Priorities for investment to optimize uptake at country level

- Leadership and ownership at country level
- Awareness raising and investment to enhance capacity of countries to develop/adapt/implement guidelines
- System level investments (beyond capacity development)
  - institutionalizing systematic guideline development and adaptation at regional and country level
  - HQ level (Optimization of content development for improved accessibility, including translation into all official languages)
  - Regional level (within WHO): For technical and strategic leadership
  - Country level (WHO and national partners): to put in place systems, structure and resources (human, financial, regulatory, data/evidence/intelligence, etc)
- Engaging implementing partners, including NGOs
- Need for accountability, feedback from country level discussion to technical programmes
To have demonstrable country impact, guideline recommendations need to be usable/implementable, with uptake monitored and learnings used to inform innovation/better design.
## WHO-GUIDES: Technical package for countries

<table>
<thead>
<tr>
<th>Governance</th>
<th>Users</th>
<th>Information</th>
<th>Decisions &amp; decision makers</th>
<th>Enabling environment</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verifying availability and applicability of the guideline establishing governance for the issue(s) being addressed</td>
<td>Tailoring for users’ needs, context and priorities</td>
<td>Identifying appropriate &amp; quality information for planning, decision making, execution, monitoring &amp; evaluation</td>
<td>Involving relevant implementing partners at all levels for effective decision making</td>
<td>Creating enabling environment for effective delivery</td>
<td>Having a clear plan for step-wise execution</td>
</tr>
</tbody>
</table>
Working towards mutual accountability of delivering on living guidelines

- **6 months after launch**: Monitor outreach of N&S recommendation
- **2 years after launch**: Monitor uptake of N&S recommendation
- **5 years after launch**: Monitor impact of N&S recommendation
SMART Guidelines for Consistent and Interoperable Digitization of Health Systems
Digital tools can help facilitate the adoption and integration process, but if done inappropriately, can lead to questionable results.

WHO develops guidelines using global evidence base.

Ministry of Health adapts global guidance into national policy, procedures, protocols, and data requirements.

Technology partners translate national policies into digital solutions.

Health workforce delivers health services and conducts reporting according to national policies.

Health service users access person-centered care according to national policies.

- Difficult to operationalize intentionally vague guideline content into digital systems with fidelity
- Infrequently digitized with interoperability standards, and architectural good practice, leading to siloed systems
- “Black box” digital systems become difficult to maintain sustainably in the long-term
In order to deliver greater reach of WHO’s evidence-based content, we need to invest more time in providing our content in digital-ready packages, bringing our core mandate of public health, data, and clinical normative content into the digital age – rather than building more siloed software apps.
SMART Guidelines are Content Digital Public Goods for Digitization

**Standards-based, Machine Readable, Adaptive, Requirements-based, Testable**

**EXISTING MODEL WITH ENHANCEMENTS**

**PREPARING TO GO DIGITAL**

**INTEROPERABLE DIGITAL COMPONENTS**

**CUSTOMIZABLE SOFTWARE**

**ADVANCED ANALYTICS FOR PRECISION HEALTH**

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**SMART**

**Layers**

**L1** Narrative
- Reinforce operational specificity in existing guidelines
- Digital curation of recommendations
- Panels include informatics and standards experts

**L2** Operational
- Digital Adaptation Kit (DAK) – requirements document
- Human-readable components
- Describes how a digital tool should function
- Data dictionaries mapped to ICD, LOINC

**L3** Machine Readable
- FHIR Implementation Guide (IG) documentation
- Based on Clinical Practice Guidelines IG
- Consistent execution across systems - software as a function
- Decision support services (CQL)

**L4** Executable
- Fully executable software tools
- Mechanism for real-time updates
- Interoperate with national systems

**L5** Dynamic
- Advanced analytics for greater local relevance and precision
- AI-based decision support
- Mechanisms in support of learning systems

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World Health Organization

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WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age - The Lancet Digital Health
WHO SMART Antenatal Care Guidelines Examples

EXISTING MODEL WITH ENHANCEMENTS

PREPARING TO GO DIGITAL

INTEROPERABLE DIGITAL COMPONENTS

CUSTOMIZABLE SOFTWARE

ADVANCED ANALYTICS FOR PRECISION HEALTH

Image: Anastasia Yarmolinskaya
What does this digitized future look like for WHO, countries, technologists and health providers?

WHO

✓ Increased precision of global guidelines through digitization process
✓ Increased fidelity and uptake of guidelines
✓ Increased access to country level data, with potential to increase ability for localization of clinical and public health guidelines and guidance to countries

Ministries of Health & Technology partners

✓ Reduced costs and time of software development cycle by reusing common requirements and computable assets
✓ Consistent representation of standardized datasets, calculations, and metadata for consistent functionality, and interoperability between systems
✓ Countries can confidently evolve legacy paper systems into digital connected solutions
✓ Availability of digital solutions consistent with recommendations, and technical specifications
✓ Decreased reliance on foreign firms for technology development & opportunity to grow capacity of health tech sector

Health care providers

✓ Longitudinal records and patient access to their personal health record for continuity of care
✓ Greater trust in digital tools used for decision support following clinical best practice
✓ Optimized data collection – collect once for clinical care, and use many times for aggregate reporting & performance management

Individuals

✓ Access to their health data anytime, anywhere, for whatever purpose they need it for
Illustrative example:
Anaemia & Iron Folic Acid Supplementation

Recommendations from the WHO
recommendations on antenatal care for a positive pregnancy experience

Source: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/
**L1: Narrative | Existing model with enhancements**

Current guideline format from the guideline document

<table>
<thead>
<tr>
<th>Iron and folic acid supplements</th>
<th><strong>A.2.1:</strong> Daily oral iron and folic acid supplementation with 30 mg to 60 mg of elemental iron(^b) and 400 (\mu)g (0.4 mg) of folic acid(^c) is recommended for pregnant women to prevent maternal anaemia, puerperal sepsis, low birth weight, and preterm birth.(^d)</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>A.2.2:</strong> Intermittent oral iron and folic acid supplementation with 120 mg of elemental iron(^e) and 2800 (\mu)g (2.8 mg) of folic acid once weekly is recommended for pregnant women to improve maternal and neonatal outcomes if daily iron is not acceptable due to side-effects, and in populations with an anaemia prevalence among pregnant women of less than 20%.(^f)</td>
<td>Context-specific recommendation</td>
</tr>
<tr>
<td>Anaemia</td>
<td><strong>B.1.1:</strong> Full blood count testing is the recommended method for diagnosing anaemia in pregnancy. In settings where full blood count testing is not available, on-site haemoglobin testing with a haemoglobinimeter is recommended over the use of the haemoglobin colour scale as the method for diagnosing anaemia in pregnancy.</td>
<td>Context-specific recommendation</td>
</tr>
</tbody>
</table>

Source: https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/
L2: Operational | Preparing to go digital

ANC Consultation workflow

Source: Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems
<table>
<thead>
<tr>
<th>Decision ID</th>
<th>ANC.DT.25 Anaemia, iron and folic acid supplementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business Rule</td>
<td>Testing for anaemia is recommended for all pregnant women. Regardless of test results, iron and folic acid supplementation is recommended. The amount of iron and folic acid supplementation will vary depending on anaemia diagnosis, population prevalence of anaemia, and whether the woman has side-effects due to supplements.</td>
</tr>
</tbody>
</table>

### Decision support logic table for Anaemia, iron, and folic acid supplementation

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Output</th>
<th>Action</th>
<th>Annotations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood haemoglobin test result ≤ 110 g/L</td>
<td>Population prevalence of anaemia ≥ 20%</td>
<td>Anaemia diagnosis = &quot;Positive for anaemia&quot;</td>
<td>Conduct REQUIRED anaemia counselling</td>
</tr>
<tr>
<td>Blood haemoglobin test result = 110 g/L</td>
<td>Constitutional age ≥ 28 weeks</td>
<td>Anaemia diagnosis = &quot;Negative for anaemia&quot;</td>
<td>Anaemia counselling conducted IS OPTIONAL</td>
</tr>
<tr>
<td>Blood haemoglobin test result ≤ 205 g/L</td>
<td>Population prevalence of anaemia ≥ 40%</td>
<td>Anaemia diagnosis = &quot;Positive for anaemia&quot;</td>
<td>Conduct REQUIRED anaemia counselling</td>
</tr>
<tr>
<td>Blood haemoglobin test conducted = FALSE</td>
<td>Pallor present = TRUE</td>
<td>Anaemia diagnosis = &quot;Positive for anaemia&quot;</td>
<td>Conduct REQUIRED anaemia counselling</td>
</tr>
<tr>
<td>Blood haemoglobin test result ≥ 110 g/L</td>
<td>Constitutional age ≥ 12 weeks</td>
<td>Population prevalence of anaemia ≤ 20%</td>
<td>Anaemia diagnosis = &quot;Negative for anaemia&quot;</td>
</tr>
<tr>
<td>Blood haemoglobin test result ≥ 110 g/L</td>
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<td>Population prevalence of anaemia ≥ 40%</td>
<td>Anaemia diagnosis = &quot;Negative for anaemia&quot;</td>
</tr>
</tbody>
</table>

### Actions

- Blood haemoglobin test result conducted = TRUE
- "Constitutional age" = 12 weeks
- "Population prevalence of anaemia" = 20%
- Has side-effects from iron and folic acid supplements = TRUE
- "Anaemia diagnosis = "Negative for anaemia" |
- Anaemia counselling conducted IS OPTIONAL
- String ε "Amount of iron prescribed ≤ 60 mg"
- Type of iron supplement dosage provided = "Daily"
- Amount of daily dose of folic acid prescribed = 0.4 mg

### Annotations

- "Anaemia diagnosis = "Positive for anaemia"
- Conduct REQUIRED anaemia counselling
- Amount of iron prescribed = 30 mg
- Type of iron supplement dosage provided = "Daily"
- Amount of daily dose of folic acid prescribed = 0.4 mg

- "Anaemia diagnosis = "Negative for anaemia"
- Anaemia counselling conducted IS OPTIONAL
- String ε "Amount of iron prescribed ≤ 60 mg"
- Type of iron supplement dosage provided = "Daily"
- Amount of daily dose of folic acid prescribed = 0.4 mg

### Source

Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems
L2: Operational | Preparing to go digital

Indicator calculation for % of women who have received iron and folic acid supplements

<table>
<thead>
<tr>
<th>Indicator code</th>
<th>Indicator name</th>
<th>Numerator Definition</th>
<th>Computation</th>
<th>Denominator Definition</th>
<th>Computation</th>
<th>Disaggregation</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC.IND.2</td>
<td>Percentage of pregnant women who received iron and folic acid (IFA) supplements for 90+ days</td>
<td>Number of pregnant women who received the recommended number of IFA tablets during all previous contacts</td>
<td>COUNT of number of women who were prescribed IFA tablets at each ANC contact they have had</td>
<td>Total number of antenatal clients with a first contact</td>
<td>COUNT of all women whose records were closed (ANC close form) in the last reporting period due to any of the reasons below:</td>
<td>Age (10–14, 15–19, 20+)</td>
<td>WHO ANC monitoring framework (43)</td>
</tr>
</tbody>
</table>

- Indicators can be aggregated from individual level data rather than a separate reporting system
- Each ‘variable’ must be encoded to a standard terminology (ICD, ICHI, ICF, LOINC)
- Data dictionary, decision support logic, indicator tables, functional and non-functional requirements are in spreadsheet formats

Source: Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems
L3: Machine-readable | Interoperable digital components

Same recommendations in standards-based software code format

```
L3: Machine-readable | Interoperable digital components

Source: WHO.FHIR.ANC-CDSSANC_DT.25.Anaemia, iron and folic acid supplementation - FHIR v4.0.1
```
L4: Executable Forms | Customizable software

Same recommendations manifested in reference software applications that can be adapted and deployed in countries...
SMART Guidelines: Scenarios of use

- **Digital system does not exist or is yet to be identified**
  - Kick start the requirements gathering process to design the system

- **Digital system established**
  - Update and align content to WHO standards and guidance

- **Update existing paper registers and decision support**
  - Update content within existing digital system to align WHO standards, guidance
WHO will develop SMART guidelines for all primary health care domains to facilitate evidence-based digital transformation globally.

Partnership is sought to accelerate this work.
Next steps
Expanding the Living Approach

• Transformational moment for WHO

• Member State have considerable experience and technical expertise to assist with this process

• Aim to leverage such experience, and ensure member-state engagement to ensure value and impact at country-level