CDS & WHO SMART Guidelines

Clinical Decision Support Symposium

Basel, 8 February 2023

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Department of Digital Health and Innovations

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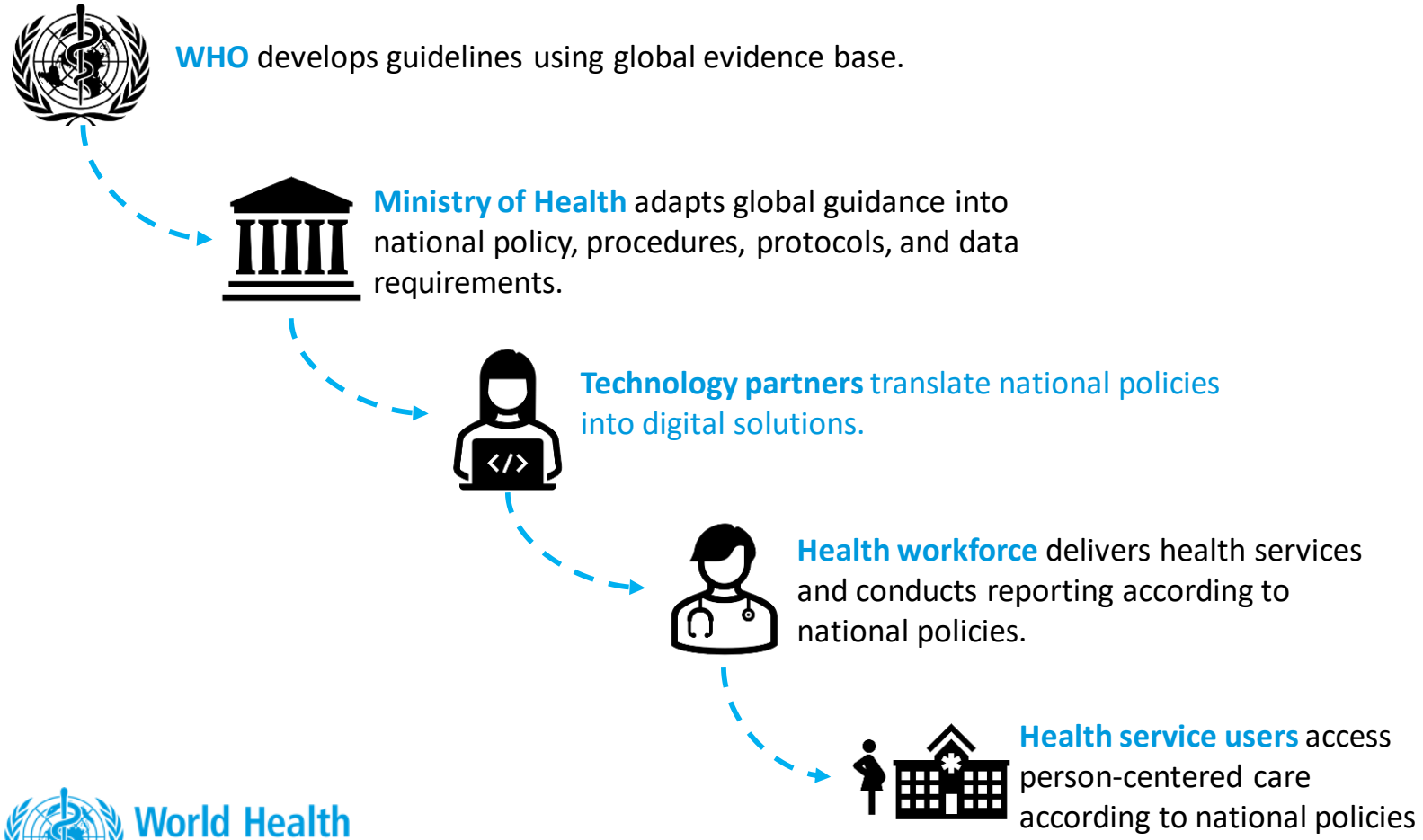
Digital tools can help facilitate the adoption and integration process, but if done inappropriately, can lead to questionable results



- **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

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Key principles driving the SMART Guidelines work

Equity

- Fostering an equitable ecosystem of global and country-level partners
- Without disproportionately favoring any single solution and/or vendor.

Sustainability

- Enable member states to actively develop, implement, and support interoperable solutions, of their choice
- Solutions that can be sustained and scaled, with in-country stakeholders leading strategic direction and development.

Consolidation of resource demand

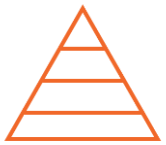
- Instead of every country redundantly expending limited resources to conduct requirements gathering of their own, WHO is focusing on the creation of baseline global public goods
- Support and accelerate the digitization process, so that countries can focus their limited resource on the contextualization and localization of normative global guidance.

Continuous improvement

- Health science and technology is constantly evolving and the systems that enable and enforce best practice will need to be constantly updated overtime.
- Focus on creating building blocks, rather than the end products to support the update and maintenance in a scalable manner.

Design with the end user

- It is assumed that the implementation of digital health tools, based on the SMART Guidelines, will be adapted to the context of where the tool is deployed.
- This will require the implementer to work directly with health workers in their country to understand what their needs are and adapt requirements accordingly.



Secondary use of data

- Health workers are inundated with administrative tasks taking away time from delivering care and focusing on quality of care. E.g., a large portion of their time is spent on reporting.
- Any digital tool intended for health workers should add value to health workers by increasing efficiencies.
- Data collected at the point of care can and should be used for reporting as well.
- Data required for reporting should be able to be generated from primary data collection.

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Key assumptions

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Software development lifecycle

- Software development (generally) requires multiple steps.
- Each of the SMART Guidelines' layers are intended to intervene at different parts of the software development lifecycle process.
- Digital Adaptation Kits (L2) facilitate with documentation, which is already considered software development best practice
- Machine-readable Guidelines (L3) are intended to support adoption of interoperability standards

Competition in design

- Digital health involves significant engagement with the private sector for development of digital tools.
- Although the SMART Guidelines are a baseline requirement, we anticipate a health level of market competition among software vendors to allow them to compete against things like design, service level, etc.

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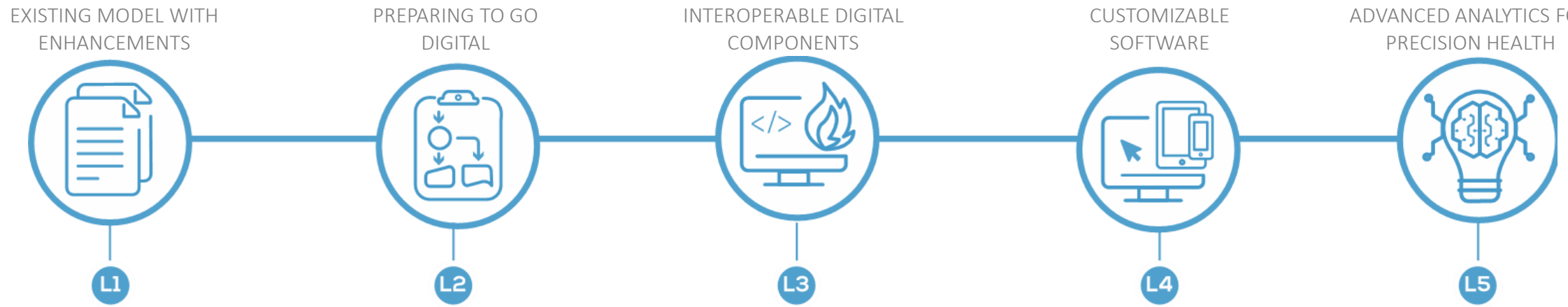
Adapted from Feuerstein (1993)

SMART Guidelines are a new approach to representing WHO content as digital health components to preserve fidelity and accelerate uptake

Standards-based, **M**achine Readable, **A**daptive, **R**equirements-based, **T**estable



Narrative

- Reinforces operational specificity in existing guidelines
- Digital curation of recommendations
- Panels include informatics and standards experts

Operational

- Consolidation of L1 content
- Digital Adaptation Kit (DAK) – requirements document
- Human-readable components
- Describes how a digital tool should function

Machine Readable

- FHIR Implementation Guide (IG)
- Based on Clinical Practice Guidelines IG
- Software agnostic

Executable

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

Dynamic

- Advanced analytics for greater local relevance and precision
- AI-based decision support

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Components of a L2 Digital Adaptation Kit (DAK)

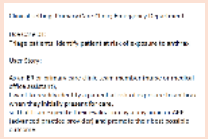
1 Health Interventions & Recommendations

Relevant health interventions and recommendations from the WHO guideline and guidance

2 Generic Personas

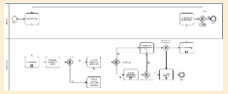
Roles, responsibilities, and essential interventions performed by targeted personas

3 User Scenarios



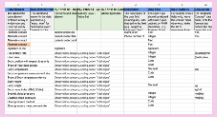
Brief narrative description of how the targeted personas may engage with the digital system

4 Business Processes & Workflows



Generic workflows representing clinical and non-clinical processes

5 Core Data Elements



Data elements, used for clinical decision-making, indicators, and other data needs

6 Decision Support Logic

Decision tables representing counselling and treatment algorithms, scheduling logic

7 Indicators & Monitoring

Indicators for reporting & monitoring with numerator, denominator of data elements

8 Functional & Non-functional Requirements

A non-exhaustive list of key functions and non-functional requirements for a digital tracking and decision support system

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Images are illustrative

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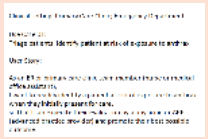

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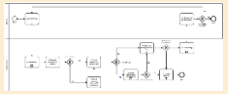

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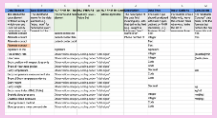

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Decision Model and Notation (DMN) Tables

7 Indicators & Monitoring

Indicators for reporting & monitoring with numerator, denominator of data elements

8 Functional & Non-functional Requirements

A non-exhaustive list of key functions and non-functional requirements for a digital tracking and decision support system

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SMART Guideline Scope – Example for Immunization

Interventions referenced in this digital adaptation kit based on WHO's Universal Health Coverage List of Essential Interventions:

- General vaccine administration practices for all age groups, including children
  - Counselling on the vaccine(s) to be administered
  - Observe for any adverse event following immunization (AEFI) Targeted history and physical examination for vaccination
  - Follow-up visit(s)
- Vaccination based on individual characteristics. Vaccinations include:
  - Bacillus Calmette–Guérin (BCG)
  - Cholera
  - Dengue
  - Diphtheria, Tetanus and Pertussis (DTP)-containing vaccines
  - Haemophilus influenzae type B
  - Hepatitis A
  - Hepatitis B
  - Human papillomavirus (HPV)
  - Japanese Encephalitis
  - Measles
  - Meningococcal
  - Mumps
  - Polio
  - Pneumococcal conjugate
  - Rabies
  - Rotavirus
  - Rubella
  - Tick-borne encephalitis
  - Typhoid
  - Seasonal Influenza
  - Varicella
  - Yellow Fever

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SMART Immunization - Key Personas

Table 2. Descriptions of key generic personas

Occupational Title	Description	Different Names	ISCO Code
Community Health Worker	Community health workers provide health education, referral and follow-up; case management and basic preventive health care; and home visiting services to specific communities. They provide support and assistance to clients by reminding clients to take their vaccinations, responding to emergencies, and reporting births.	Volunteer assistant, Volunteer health worker	3253 (Worker, community: health)
Health Worker (HW)	Health workers facilitate education sessions, administers immunizations, provide counselling when needed, record stock movements, and compiles/generates reports.	Nurse, Registered Nurse, Practical Nurse	3221 (Nursing Associate Professional)
Expanded Programme of Immunization (EPI) Manager	Responsible for: developing annual and multi-annual plans; immunization communication and mobilization; management of logistics, the cold chain, and vaccines; monitoring, supervision and evaluation of immunization services; and coordination of EPI activities at the national level.	Program Manager	1342 (Manager, health service

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L1: SMART Immunization Guidance Summary

Table 2: Summary of WHO Position Papers - Recommended Routine Immunizations for Children

Antigen		Age of 1st Dose	Doses in Primary Series	Interval Between Doses			Booster Dose	Considerations (see footnotes for details)
				1st to 2nd	2nd to 3rd	3rd to 4th		
Recommendations for all children								
BCG [1]		As soon as possible after birth	1					Birth dose and HIV; Universal vs selective vaccination; Co-administration; Vaccination of older age groups; Pregnancy
Hepatitis B [2]	**Option 1**	As soon as possible after birth (<24h)	3	4 weeks (min) with DTPCV1	4 weeks (min) with DTPCV2			Premature and low birth weight Co-administration and combination vaccine High risk groups
	Option 2	As soon as possible after birth (<24h)	4	4 weeks (min) with DTPCV1	4 weeks (min) with DTPCV2	4 weeks (min),with DTPCV3		
Polio [3]	**bOPV + IPV**	bOPV 6 weeks (min) IPV 14 weeks (min)	5 (3 bOPV and 2 IPV)	bOPV 4 weeks (min) with DTPCV2 IPV 4 months (min)	bOPV 4 weeks (min) with DTPCV3			bOPV birth dose Type of vaccine Fractional dose IPV Alternative early IPV schedule Transmission and importation risk
	IPV / bOPV Sequential	8 weeks (IPV 1st)	1-2 IPV 2 bOPV	4-8 weeks	4-8 weeks	4-8 weeks		
	IPV	8 weeks	3	4-8 weeks	4-8 weeks		(see footnote)	IPV booster needed for early schedule (i.e. first dose given <8 weeks)
DTP-containing vaccine [4]		6 weeks (min)	3	4 weeks (min) - 8 weeks	4 weeks (min) - 8 weeks		3 Boosters 12-23 months (DTP-containing vaccine); 4-7 years (Td/DT containing vaccine), see footnotes; and 9-15 yrs (Td)	Delayed/ interrupted schedule Combination vaccine; Maternal immunization
***Haemophilus influenzae* type b** [5]	**Option 1**	6 weeks (min) 59 months (max)	3	4 weeks (min) with DTPCV2	4 weeks (min) with DTPCV3		(see footnote)	Single dose if >12 months of age Not recommended for children > 5 yrs Delayed/ interrupted schedule Co-administration and combination vaccine
	Option 2		2-3	8 weeks (min) if only 2 doses 4 weeks (min) if 3 doses	4 weeks (min) if 3 doses		At least 6 months (min) after last dose	
Pneumococcal (Conjugate) [6]	**Option 1 3p+0**	6 weeks (min)	3	4 weeks (min)	4 weeks			Schedule options (3p+0 vs 2p+1) Vaccine options HIV+ and preterm neonate booster Vaccination in older adults
	Option 2 2p+1	6 weeks (min)	2	8 weeks (min)			9-18 months	
Rotavirus [7]		6 weeks (min) with DTP1	2 or 3 depending on product	4 weeks (min) with DTPCV2	For three dose series – 4 week (min) with DTPCV3			Not recommended if >24 months old
Measles [8]		9 or 12 months (6 months min, see footnote)	2	4 weeks (min) (see footnote)				Co-administration live vaccines; Combination vaccine; HIV early vaccination; Pregnancy
Rubella [9]		9 or 12 months with measles containing vaccine	1					Achieve and sustain 80% coverage Co-administration and combination vaccine; Pregnancy
HPV [10]		As soon as possible from 9 years of age (females only)	2	6-12 months (min 5 months)				Target 9-14 year old girls; Temporary suspension of multi-age cohort vaccination; Off-label use of extended interval of 3-5 years; Pregnancy; Older age groups > 15 years 3 doses; HIV and immunocompromised

Refer to **https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers** for table & position paper updates.

This table summarizes the WHO vaccination recommendations for children.The ages/intervals cited are for the development of country specific schedules and are not for health workers.

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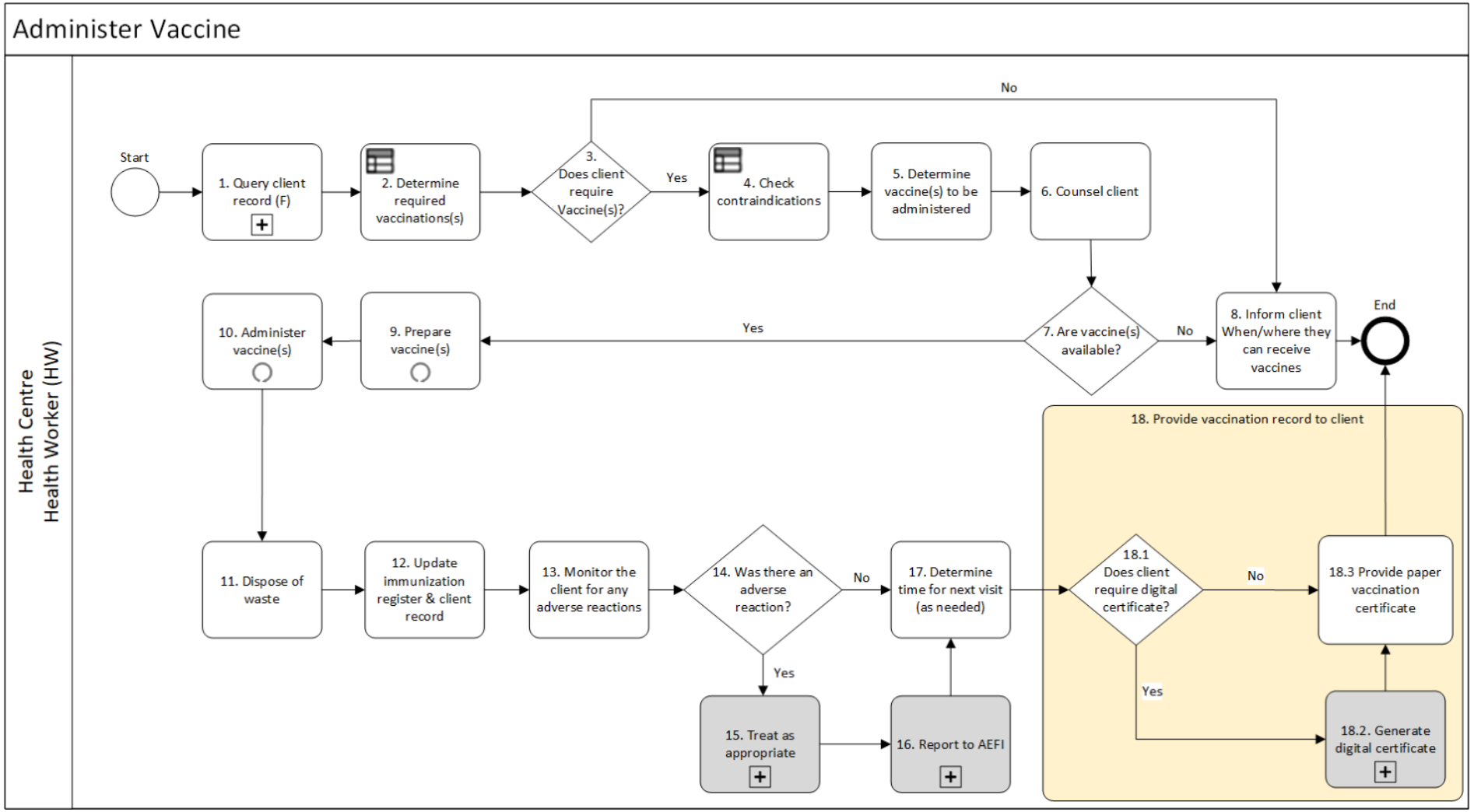
L2: Operational | Preparing to go digital

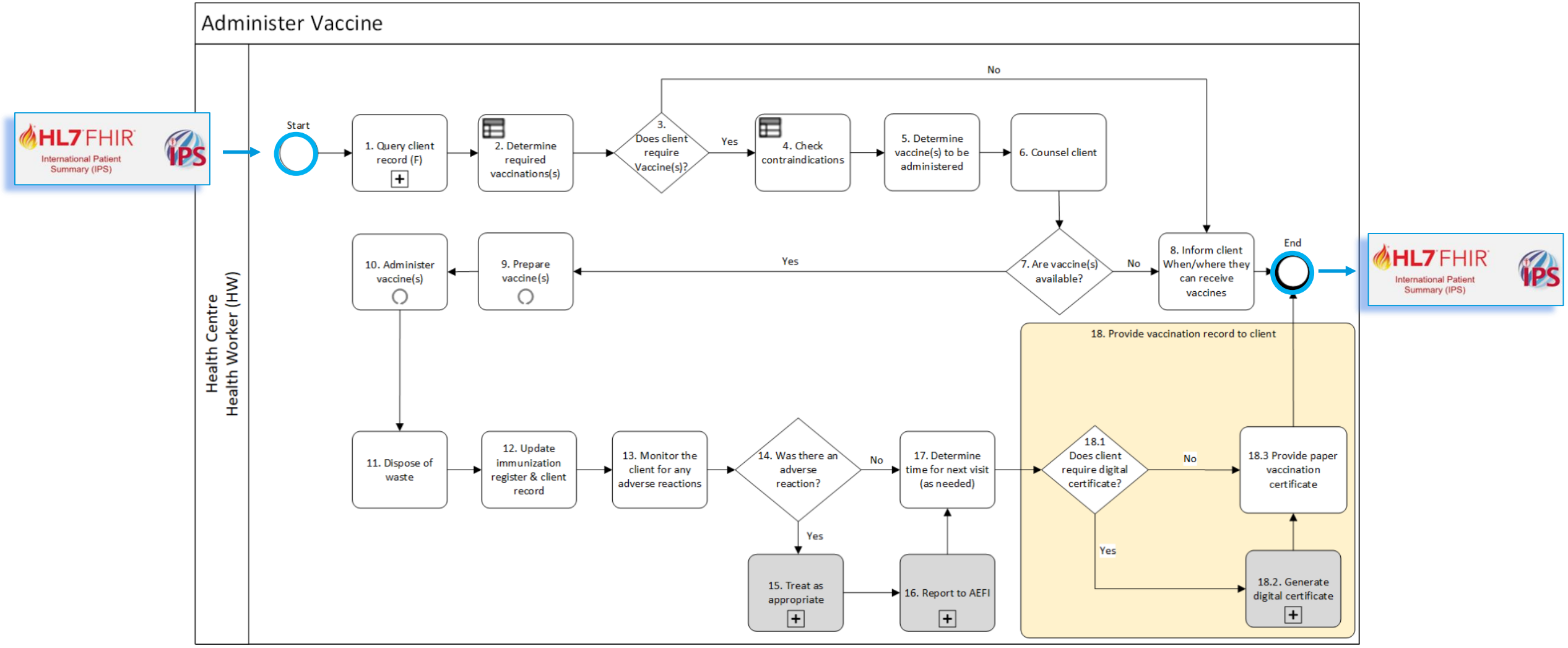
Immunization workflows



Source: Digital Adaptation Kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems

L2: Operational | Standardized health content

Immunization workflows



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L2: Operational | Preparing to go digital

Decision support logic table for Rabies vaccination

Decision ID	IMMZ.DT.18.Rabies				
Business rule	IF patient has not been vaccinated against Rabies and is at high risk of exposure to Rabies Virus (RABV) and/or patient has been exposed to RABV., THEN give Rabies vaccine				
Trigger	IMMZ.G2 Determine Required Vaccinations if any				
Inputs		**Output**	**Action**	**Annotations**	**Reference(s)**
"Rabies vaccine immunization history" = "No-doses"	"Individual is at high risk of RABV exposure" = TRUE	Immunize Patient for Rabies (PrEP strategy) - No Doses	Should vaccinate patient with Rabies vaccine (PrEP strategy) on 2 dose scheme	Provide Rabies immunizations – using the "PrEP vaccination strategy – NO PREVIOUS" schedule (2 dose scheme)	WHO recommendations for routine immunization - summary tables: https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/who-recommendations-for-routine-immunization---summary-tables
"Rabies vaccine immunization history" = "1 dose"	"Date last Rabies dose given" >= "7 days"	Immunize Patient for Rabies (PrEP strategy) - 1 Dose	Should vaccinate patient with Rabies vaccine (PrEP strategy) on 2 dose scheme	Provide Rabies immunizations – using the "PrEP vaccination strategy – 1 PREVIOUS" schedule (2 dose scheme)	WHO recommendations for routine immunization - summary tables: https://www.who.int/teams/immunizatio

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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 BCG Immunization coverage

Indicator code	Indicator name	Description	Numerator		Denominator
			Definition	Computation	Definition
IMMZ.IND.1	Immunization coverage for BCG (Estimated Denominator)	Compares the doses of BCG vaccine administered with the estimated number of live births as a percentage.	Number of administrations of BCG during the reporting period	COUNT immunization events WHERE administered product is a BCG vaccine (IMMZ.A1.DE1) during reporting period	Estimated number of live births.

- 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

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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

ANC.DT.25 Anaemia, iron and folic acid supplementation:
When: *named-event:* ANC.B9. Conduct laboratory tests and imaging
Then:

Anaemia can be diagnosed if Hb level is less than 11 in first or third trimester or Hb level less than 10.5 in second trimester; OR there is no Hb test result recorded, but woman has pallor. If a woman is diagnosed with anaemia during pregnancy, conduct counselling for managing and treating anaemia. Her daily elemental iron should be increased to 120 mg until her haemoglobin (Hb) concentration rises to normal (Hb 110 g/L or higher). Thereafter, she can resume the standard daily antenatal iron dose to prevent recurrence of anaemia. The equivalent of 120 mg of elemental iron equals 600 mg of ferrous sulfate heptahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate. Please refer to iron sources listed below for additional guidance that can be provided.

If: *applicability:* ((((("Blood haemoglobin test result" < 110 g/L) AND ("Gestational age" ≤ 12 weeks)) OR (("Blood haemoglobin test result" < 110 g/L) AND ("Gestational age" ≥ 28 weeks))) OR (("Blood haemoglobin test result" < 105 g/L) AND (13 weeks ≤ "Gestational age" ≤ 27 weeks))) OR (("Blood haemoglobin test conducted" = FALSE) AND ("Pallor present" = TRUE)) *(Should Conduct REQUIRED anaemia counselling)*
Then:

Conduct REQUIRED anaemia counselling:
"Amount of iron prescribed" = 120 mg:
"Type of iron supplement dosage provided" = "Daily":
"Amount of daily dose of folic acid prescribed" = 0.4 mg:


```
"id" : "1",
"title" : "Conduct REQUIRED anaemia counselling",
"description" : "Conduct REQUIRED anaemia counselling",
"textEquivalent" : "Anaemia can be diagnosed if Hb level is less than 11 in first or third trim
ester or Hb level less than 10.5 in second trimester; OR there is no Hb test result recorded, but woman h
as pallor.\n\nIf a woman is diagnosed with anaemia during pregnancy, conduct counselling for managing and
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mg of ferrous sulfate heptahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate.\n\nPlease
refer to iron sources listed below for additional guidance that can be provided. ",
"documentation" : [
  {
    "type" : "citation",
    "label" : "WHO ANC recommendations (2016): B1.1, A.2.1, A.2.2 (3)\nPregnancy, childbirth, p
ostpartum and newborn care guide (2015): C4 (1)"
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],
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  {
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ge\" ≤ 12 weeks))\n  OR ((\"Blood haemoglobin test result\" < 110 g/L)\n  AND (\"Gestational age\" ≥ 28 w
eeks)))\n  OR ((\"Blood haemoglobin test result\" < 105 g/L)\n  AND (13 weeks ≤ \"Gestational age\" ≤ 27
weeks)))\n  OR ((\"Blood haemoglobin test conducted\" = FALSE)\n  AND (\"Pallor present\" = TRUE))",
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  }
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  },
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  },
  {
    "title" : "\"Type of iron supplement dosage provided\" = \"Daily\""
  },
  {
    "title" : "\"Amount of daily dose of folic acid prescribed\" = 0.4 mg"
```


HL7® FHIR® & Clinical Quality Language (CQL)

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Source: WHO.FHIR.ANC-CDS\ANC.DT.25 Anaemia, iron and folic acid supplementation - FHIR v4.0.1

SMART Guidelines - Clearinghouse L2 and L3 compliance summary

Testing area \ Testing acceptance criteria	**L2 Compliance (Health and Data Content) Steps 3 & 4**	**L3 Compliance (Interoperability) Step 5**
	Manual verification process (video capture and/or screen shots)	Manual verification process (video capture and/or screen shots) & evidence of HL7 FHIR compliance (e.g. IPS document, API transactions)
Is there evidence that the digital health tool collects the required core data set for a given business process / workflow?	Applicable	Applicable
Is there evidence that clinical decision support logic is executing correctly?	Applicable	Applicable
Are the system-to-system interoperability requirement satisfied?	Not applicable	Applicable
Is there evidence that indicator calculations are executing correctly?	Not applicable	Applicable

Current status of DAK development in WHO

Health Domain (L1)	Digital Adaptation Kits (L2)
Antenatal Care (**ANC**) *+ Adolescent Sexual Reproductive Health (ASRH) overlay*	✓
Family Planning (**FP**) *+ ASRH overlay*	✓
Sexually Transmitted Infections (**STI**) *+ ASRH overlay*	Will be published soon
HIV	✓
Immunizations **(EIR)**	Will be published soon
Child Health in Emergency Settings **(Em Care)**	Will be published soon
Digital Documentation of COVID-19 Certificates: **Vaccination Status**	✓
Digital Documentation of COVID-19 Certificates: **Test Results**	✓
Self Care – Sexual and Reproductive Health	In progress
Tuberculosis **(TB)**	In progress
Neglected Tropical Diseases **(NTD)**	Being discussed
Nutrition	In progress
Postnatal Care **(PNC)**	Being discussed
Health financing	Being discussed
Primary Health Care	Being discussed
Emergency Care	In progress
Cervical cancer	Being discussed
Intrapartum care	Being discussed

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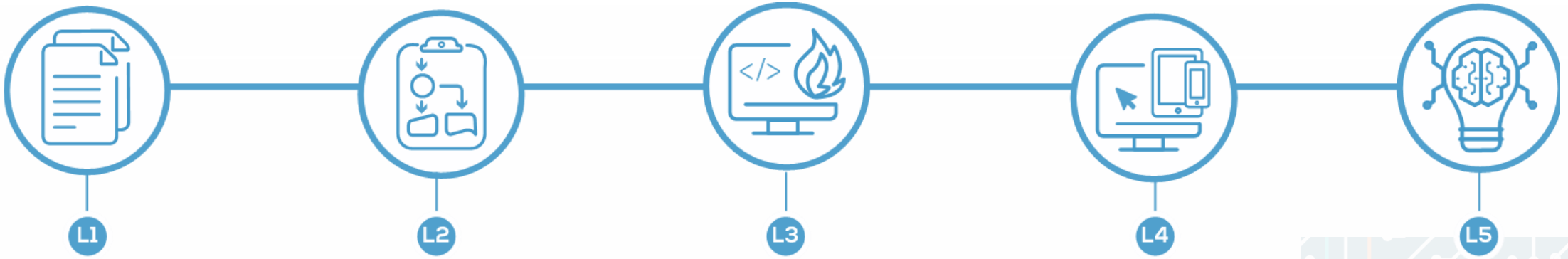

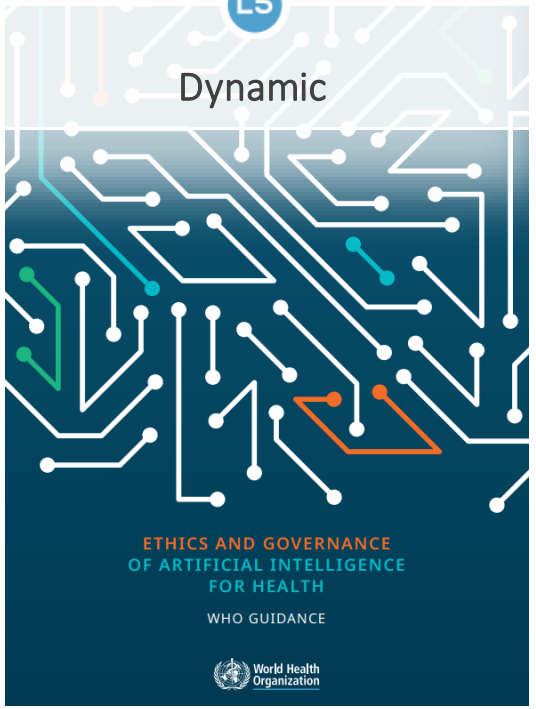

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Thank you

For more information, please contact:
SMART@who.int

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