Integrating the Healthcare Enterprise

IHE

IHE Quality Research and Public Health (QRPH)
White Paper

Extracting Indicators from Person Level Data

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Foreword

This is a white paper of the IHE Quality, Research and Public Health domain.

30 This white paper is published on December 29, 2021. Comments are invited and can be submitted at https://www.ihe.net/QRPH_Public_Comments.

General information about IHE can be found at IHE.

Information about the IHE Quality, Research and Public Health domain can be found at IHE
35 Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at Profiles and IHE Process.

The current version of the IHE Quality, Research and Public Health Technical Framework can be found at Quality, Research and Public Health Technical Framework.

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1 Introduction

105 This document, the IHE QRPH Extracting Indicators from Patient Level Data White Paper, describes how to use Clinical Quality Language (CQL)[1] to extract health related indicators from data in Health Level 7 International's (HL7[®2]'s) Fast Healthcare Interoperability Resources (FHIR[®3]) data.[4] It describes how implementers, including software developers, business analysts, informaticists, etc. may use these technologies in conjunction with appropriate IHE

110 Profiles. This whitepaper will not describe deidentification. It has been left out of scope due to the depth required. The appropriate resources have been listed in Section 2.5 Privacy and Security. Mapping ADX to mADX has been left out of scope for this paper as it warrants a full investigation and should be independent of the CQL work.

1.1 Purpose of the Extracting Indicators from Patient Level Data
115   White Paper

Significant effort and resources are expended in low- and middle-income countries (LMICs) to collect and synthesize health, health system and social determinants of health-related indicators using paper-based and digital data systems. Reporting on these indicators allows different stakeholder groups to perform a number of functions, including:

120   • National governments are able to monitor and evaluate their health system performance through quality measures.
    • Program managers are able to determine programmatic impact on health outcomes and improvements to health system performance.
    • Regional and global health agencies are able to collect aggregate data for public health
125   monitoring reported from member organizations.
    • Global donors can track the effectiveness of their investments in a country to programmatic goals.

This whitepaper outlines a staged digital health interoperability framework, which enables extraction and sharing of indicators from individual digital client records using FHIR and related

130 IHE profiles. The indicators described capture aggregate data between health or community workers and clients. That data must have been recorded digitally, whether directly by the practitioner or by another individual after first being recorded on paper. It must be noted that digitally recorded indicators may reduce the data collection efforts if well implemented.

The framework is designed for use in LMICs as countries transition through different levels of

135 digital health maturity. As the framework can be applied to use cases across domains, examples are included from multiple health program areas:

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[1] https://cql.hl7.org/
[2] HL7 is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.
[3] FHIR is the registered trademark of Health Level Seven International and the use does not constitute endorsement by HL7.
[4] http://hl7.org/fhir/

- HIV [5, 6, 7, 8]
- Immunization / Vaccine Delivery [9]
- Reproductive, Maternal, Newborn and Child Health [10]
140
- Health Workforce [11]

Improvements in connectivity and infrastructure make national scale deployments of digital client records and other transactional systems increasingly feasible. The framework leverages these advancements, as it supports efficient and scalable extraction of indicators directly from client or patient-facing systems, such as digital client records. The measurement and evaluation
145 of the digital health investments through routine indicators provides a critical feedback cycle to improve the effectiveness of these investments.

Current monitoring and evaluation (M&E) standard practices for the collection and management of aggregate service delivery data have several challenges including:
- Health workers are diverted from their primary role of providing clinical care in order to
150 tally and produce the required reports;
- Additional workforce cadres are often required to transfer data from paper-based to electronic client-facing systems to facilitate reporting of aggregate indicators. The cost of aggregate data collection tools, whether paper or electronic, is high and diverts resources from the provision of care services; and
155
- Data quality cannot be automatically evaluated or compared with other jurisdictions.

Through the utilization of a common standard, a computable means of defining indicators, and the ability to share datasets across systems and jurisdictions, this framework also aims to create cost efficiencies and mitigate challenges in the indicator reporting workflow by:
- Reducing the effort required to align the narrative definitions and reporting requirements
160 for indicators across multiple stakeholders (e.g., national governments, global donors, international development agencies, and multilateral organizations). [12]
- Allowing for narrative indicator definitions to be consistently interpreted when translated into source code for numerator or denominator collection and calculation.
- Reducing the need for functionality that extracts and calculates indicators to be
165 redeveloped across digital health system components.
- Reducing the change management burden caused by frequent updates to routine reporting requirements (e.g., additional training and updates to training materials).

This interoperability framework is described by a Data Sharing Specification (DSS) that provides a staged set of technical resources applicable at different levels of digital health maturity.

[5] https://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_ADX-HIV.pdf
[6] https://www.pepfar.gov/documents/organization/263233.pdf
[7] https://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en/
[8] https://www.who.int/hiv/pub/guidelines/person-centred-hiv-monitoring-guidelines/en/
[9] https://www.gavi.org/results/measuring/2016-2020-indicators/
[10] https://www.measureevaluation.org/prh/rh_indicators/indicator-summary
[11] https://www.who.int/hrh/documents/brief_nhwa_handbook/en/
[12] http://www.unaids.org/sites/default/files/media_asset/global-aids-monitoring_en.pdf

170   Maturity levels are defined according to the HIS Stages of Continuous Improvement,[13] and the HIS Interoperability Maturity Model.[14,15] These resources are designed around three different levels of maturity:

- **Siloed** - a standalone digital health system using a bespoke data model running on a low-powered and often disconnected device that wants to report an indicator directly and
175   requires a precise definition of an indicator.
- **Integrated** - a standalone digital health system that can share data, is locally connected, and that wants to offload indicator calculation to a locally available service.
- **Exchanged** - a connected digital health system operating within a health information exchange that wants to contribute data to a longitudinal client record, upon which
180   indicator calculations are performed.

Provided that appropriate patient-level data protections and data sharing agreements are in place, the DSS defines the following to support sharing of digital client records between stakeholders and health or administrative jurisdictions:

- Inclusion and exclusion criteria for a population cohort.
185 - A minimum data set (MDS) of de-identified data for the population cohort, expressed in the HL7 FHIR data model.
- One or more indicator calculations that can be applied to an MDS, expressed in the Clinical Quality Language (CQL)[16]
- At the highest level of maturity, this whitepaper assumes the existence of the following:
190 - One or more **digital client record systems**, compatible with the HL7 FHIR data model, deployed at various points of service, which capture transactional information during various points in clinical care workflows.
- A **master facility registry**, compliant with the IHE mCSD Profile, which maintains health facility data at all places of service, as well as relevant organizational or
195   geographic hierarchies.
- A **terminology service**, compliant with HL7 FHIR, which maintains standard terminologies (e.g., LOINC®[17], ICD 10), indicator metadata such as the codesets for disaggregators and the mappings between them as indicator definitions change.
- A **client registry**, compliant with the IHE PIXm/PDQm/Patient Resources for Identity
200   Management (PRIM) Profiles, that is used to cross-reference clients as they interact at multiple points of service and contains basic client demographic data.
- A **health worker registry**, compliant with HL7 FHIR/mCSD, which contains metadata and multiple identifiers for health workers, including their deployment locations.
- A **longitudinal client record**, compliant with HL7 FHIR, which serves as a repository of
205   client information across multiple points of service.

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[13] https://www.measureevaluation.org/resources/publications/tl-19-27
[14] https://www.measureevaluation.org/resources/publications/tl-17-03c/
[15] Digital implementation investment guide: integrating digital interventions into health programmes. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. e.g., Fig 1.3.1 and p. 13
[16] https://ecqi.healthit.gov/cql-clinical-quality-language
[17] LOINC® is registered United States trademarks of Regenstrief Institute, Inc.

- A **CQL Engine**, which computes required indicators expressed by operating on the longitudinal client record.

Finally, the digital health interoperability framework aims to be responsive to current trends in global health including:

210
- National governments developing and investing in digital health roadmaps.
- The WHO's release of guidelines on the effectivity of digital health interventions, in response to the call by member states.[18]
- Global donors aligning along the Principles of Donor Alignment for Digital Health (Digital Investment Principles).[19]

215 The Mobile Aggregate Data Exchange (mADX) Profile[20] defines transactions for sending indicator data values and the exchange of the underlying metadata, including identifiers for the location of health facilities, and geographic or organizational reporting units as well as required disaggregation elements. Disaggregation is the breaking down of indicators into subgroups and is frequently used for identifying populations within a broader group, for example age or sex. This
220 white paper leverages the mADX Profile and outlines three architectural patterns using the HL7 FHIR data model and HL7 CQL to create computable indicators from transactional health information solutions such as electronic medical record (EMR), supply chain, health financing and health workforce information systems.

The digital health architectural patterns for indicator reporting and health system monitoring in this whitepaper are intended to comprise a common data infrastructure that aligns with other
225 digital health workflows. Figure 1.1-1 illustrates how routine clinical workflow data, captured electronically using HL7 FHIR, can be leveraged for secondary data usage workflows using a Health Information Exchange (HIE). The diagram includes three examples of possible uses: clinical decision support, case-based reporting, and health system monitoring. In this diagram the
230 HIE would be collecting information from the various kinds of repositories described above; and data from that entity could be used for case based reporting, health system monitoring, and clinical decision support based on CQL. This paper only covers the person level reporting aspect of this diagram.

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[18] http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_ACONF1-en.pdf
[19] http://digitalinvestmentprinciples.org/
[20] https://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_mADX.pdf

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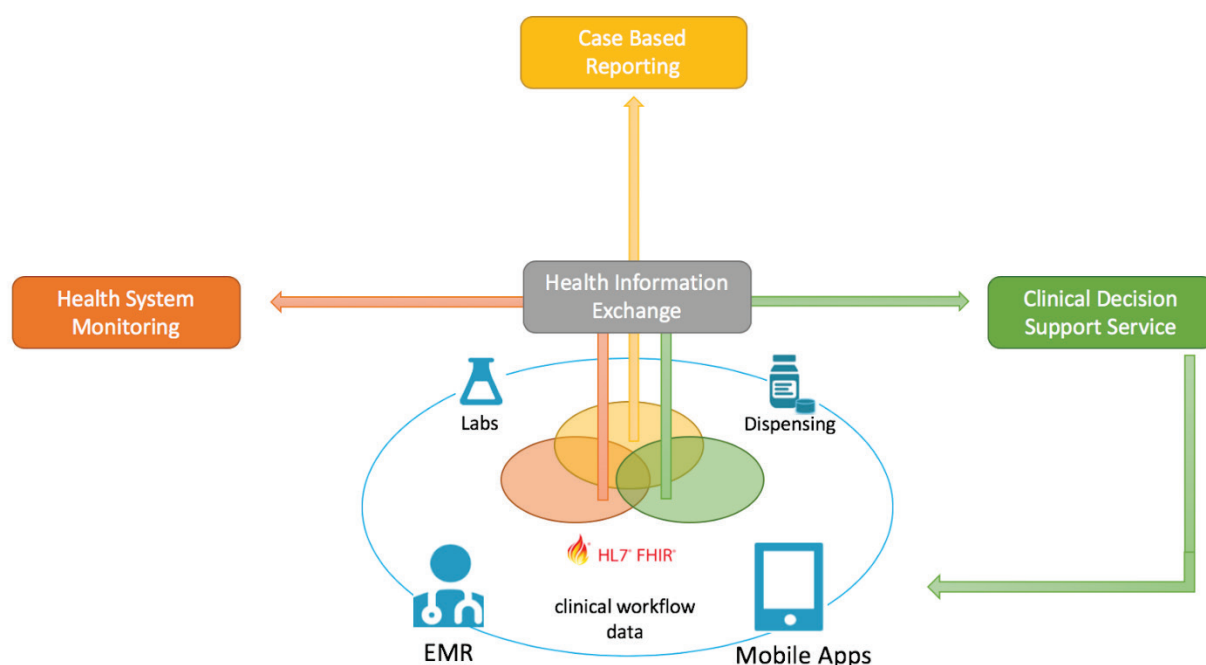
Figure 1.1-1: Clinical workflow data supporting multiple information needs

1.2 Intended Audience

The digital health interoperability framework described in this paper enables the extraction and sharing of indicators from point of service or other transactional systems, including digital client records, in support of program management and reporting data use-cases from facility to global level. The consolidation of investments around such a system will allow donors to focus resources on transactional systems rather than disparate aggregate data collection systems, better utilizing scarce human and financial resources and allowing for greater focus on supporting clinical care.

The inclusion of a maturity model, aligned with the Digital Investment Principles, provides tiered entry points to allow countries to opt in to the framework as they are able.

The intended audiences of this whitepaper include:
- *Health System Program Managers:* Individuals at public health institutions, including Ministries of Health and organizations that want to collect and share aggregate or de-identified person-level data with quality agencies, funders, external communities, and institutions. May also include individuals at funding organizations, decision-makers and M&E staff looking to increase the timeliness of routinely reported data, and to receive deduplicated and/or de-identified person-level data for analysis.
- *Software Developers:* Software vendors and implementers looking to collect data for improved reportability. May also include managing or IT staff of healthcare institutions, quality agencies, research organizations, and epidemiology institutions that want to share

or integrate with other institutions to perform healthcare quality assessments, research, or epidemiology studies.

260 • *Business Analysts/Knowledge Engineers:* Individuals, including those from Ministries of Health, vendors, implementers, or other organizations, looking to document requirements, which software developers can use to meet business needs.

This white paper provides a framework and Data Sharing Specification (DSS) Intake Template, defined in Section 2.4.2.1, intended to be used by a business analyst in documenting the needs across the various stakeholders. The DSS Intake Template can then be used to define the DSS by

265 a software developer. The intended process is illustrated in Figure 1.2-1.[21]

Computable Care & Secondary Data Usage
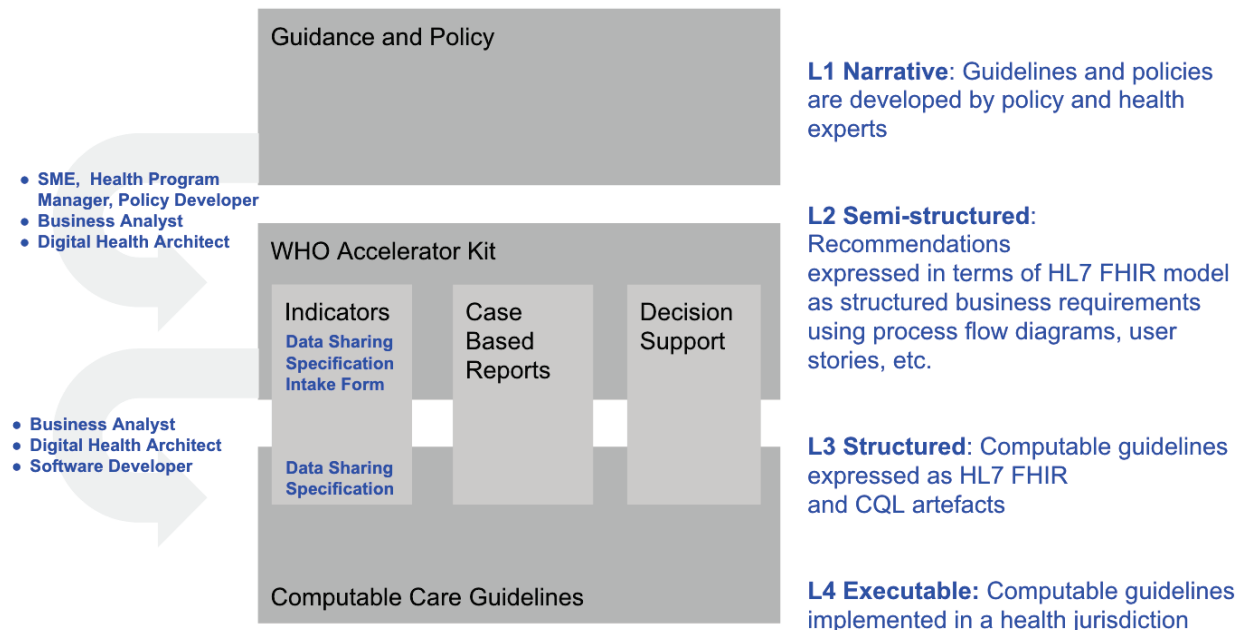
Figure 1.2-1: Process flow for the development of Data Sharing Specification

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[21] Aziz A Boxwala, Beatriz H Rocha, Saverio Maviglia, et al. (2011). "A multi-layered framework for disseminating knowledge for computer-based decision support". Journal of the American Medical Informatics Association, Volume 18, Issue Supplement_1, Pages i132–i139.
https://academic.oup.com/jamia/article/18/Supplement_1/i132/797073

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2 Patterns and Architecture

This section describes the problem, and general approaches to how to use CQL in order to extract patient level indicators.

2.1 Problem Description

Data captured during clinical workflows in transactional systems can be used for a variety of functions (see Figure 1.1-1), including planning and forecasting, resource allocation and distribution, disease surveillance, and health system performance monitoring. While these data are invaluable, the systems and processes used in data collection are rife with challenges, several of which are described below.

2.1.1 Reporting Burden in LMICs

Indicator reporting imposes a particularly high burden on LMICs and strains the limited pool of resources that are available. Examples of resource inefficiencies and added costs resulting from this include:

- Redirection of health workers, including clinicians and nurses, from the provision of care to manually entering and summing data solely for M&E reporting needs.
- Hiring of additional staff specifically to perform data entry activities for indicator reporting, who also may focus specifically on a single health vertical (e.g., HIV or Malaria).
- Printing of paper-based aggregate reporting forms, as well as paper registers for tallying of aggregate data.

In LMICs, patient data are typically captured on paper encounters or registers during visits and later entered into EMR systems. Facility data used for indicators are aggregated every month and submitted to the national aggregate information system. The reports demanded of the facility are complex and labor intensive, so there are considerable benefits in terms of reducing reporting burden. Simplifying the routine of M&E reporting which should result in reducing program costs, savings which can be applied to broadening countries' and organizations' provision of care.

The approach outlined in this white paper also provides a path forward towards simplifying resource intensive routine M&E reporting, with the potential to reduce program costs which could instead be applied to broadening the provision of care. For the health worker, health organization, and government body, reducing the reporting burden would result in time savings and the ability to refocus efforts on the provision of clinical care.
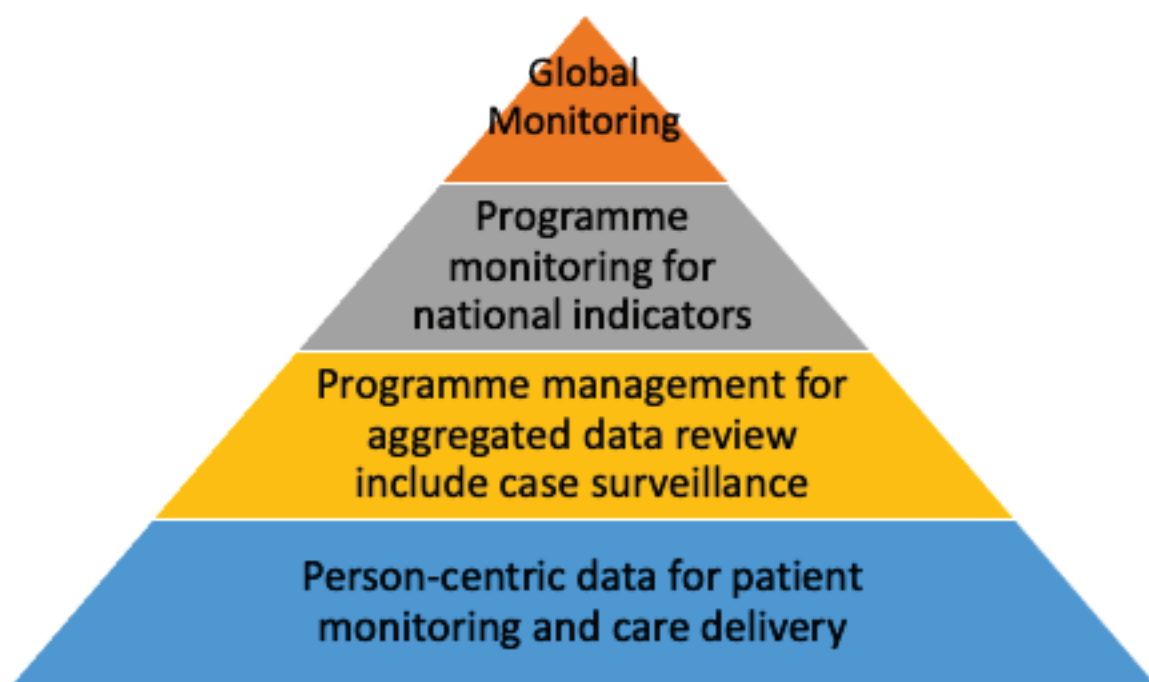
Figure 2.1.1-1: Health data use

2.1.2 Deduplication and Double Counting

Data used in the existing aggregate reporting workflows do not allow for deduplication of records and consistently double count in the numerator (or denominator) of an indicator. For example, when only aggregate data are used, there is no way to identify patients whose data are captured across multiple transactional systems.

2.1.3 Health System Challenges

The global health community faces a number of challenges that require health systems interventions. These challenges may be specific to a health vertical or span the health system. For example, immunization and vaccination are a single vertical, however patient management extends beyond this use case. Assets created for managing patients in immunization should ideally be reused in other verticals. In this section, the main challenges under consideration in this white paper are described. It is intended that the architectural patterns developed can be used to address the range of Health System Challenges identified by the WHO.[22]

2.1.4 Sustainable Monitoring and Evaluation Infrastructure

Global donors' investments in LMIC health system have included significant resources allocated towards M&E processes and systems. For example, the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) has recommended that countries requesting funding allocate 5-10% of the award towards M&E, which includes strengthening data systems for

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[22] https://www.who.int/publications/i/item/9789240010567

320 reporting.[23] As countries' systems mature and they transition from donor funding, a sustainable infrastructure is needed that will enable national governments to continue to track their progress within their budget constraints.

2.2 Definitions and Conventions

This section details the conventions and definitions used in the white paper, which are reflective
325 of the current and planned digital health information ecosystems that exist within LMICs. A general architectural approach under which transactional systems can be interoperable with an M&E reporting system is described, as well as standards for data exchange. Additional definitions can be found in Appendix C. The electronic Clinical Quality Measure (eCQM) initiative in the United States offers an example of how this might work, and makes use of the
330 same HL7 FHIR data model and CQL resources described in this paper.[24]

The basic architectural pattern utilized in this white paper assumes the existence of two or more transactional information systems which capture and manage patient-level or health system resource data at a point of service. Although in practice such transactional systems may either be paper-based or electronic, the white paper does not address the digitization of data from paper-
335 based systems.

The concepts below relate the terms described in the introduction in relation to HL7 FHIR, and/or their appropriate IHE profiles. This whitepaper assumes the existence of the following systems and services based on those standards:

- One or more **digital client record systems**, compatible with the HL7 FHIR data model,
340   deployed at various points of service, which capture transactional information during various points in clinical care workflows.
- A **master facility registry**, compliant with the IHE mCSD Profile, which maintains health facility data at all places of service, as well as relevant organizational or geographic hierarchies.
345 - A **terminology service**, compliant with HL7 FHIR, which maintains standard terminologies (e.g., LOINC, ICD 10), indicator metadata such as the codesets for disaggregators and the mappings between them as indicator definitions change.
- A **client registry**, compliant with the IHE PIXm/PDQm/PMIR Profiles, that is used to cross-reference a client as they interact at multiple points of service and contains basic
350   client demographic data.
- A **health worker registry**, compliant with HL7 FHIR/mCSD, which contains metadata and multiple identifiers for health workers, including their deployment.
- A **longitudinal client record**, compliant with HL7 FHIR, which serves as a repository of client information across multiple points of service.
355 - A **CQL Engine**, which computes required indicators expressed by operating on the longitudinal client record.

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[23] https://www.theglobalfund.org/media/3238/lfa_manual09sectiong_manual_en.pdf?u=636727910980000000
[24] https://ecqi.healthit.gov/

We describe three patterns that can be used for calculation of indicators from these electronic transactional systems. The transactional systems described later in this section are primary sources of data that can be used for indicator reporting. In LMICs, these indicators are usually reported into a centralized Health Management Information System (HMIS).

2.3 Maturity Model for Health

This section described three progressive levels of digital health maturity. Maturity levels are defined according to the HIS Stages of Continuous Improvement,[25] and HIS Interoperability Maturity Model.[26] Technical resources included in the white paper are designed around the following three maturity scenarios for digital health systems which may be used to collect person level data:

- **Standalone/Siloed** - A siloed digital health software tool using a bespoke data model running on a low-powered and often disconnected device that requires customization to report an indicator, or manual transcription of data.
- **Integrated** - A standalone digital health software tool that can share data and is locally connected and capable of interoperable exchange of information.
- **Exchanged** - A connected digital health software tool operating within a functional health information exchange that wants to contribute data to a centralized longitudinal client record on which indicator calculations are performed, case reports are generated, or decision support services are executed against.

In any of these scenarios certain privacy considerations should be considered. For example, in the case that the point of service system is not within the same jurisdiction as the HMIS, appropriate privacy and security considerations around small-sets. Small-sets are data sets which are too small to properly anonymize, should be applied to the Minimum Data Set Message (MDSM) and data sharing agreements should be established (see Section 2.5).[27]

2.3.1 Standalone System

There are no assumptions that the transactional system leverages the HL7 FHIR data model for an internal data store. In such cases, a business analyst will need to map their requisite subset of the transactional systems internal data model to the FHIR data model to enable interoperability.

In the Standalone System Scenario, indicator calculations are performed directly within a transactional system at a point of service and reported into an HMIS. For each indicator definition, the following steps are required:

- Rewrite the indicator definition, as expressed in CQL, in terms of the software development language and internal data model used by the transactional system.
- Generate a valid mADX message.

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[25] https://www.measureevaluation.org/resources/publications/tl-19-27
[26] https://www.measureevaluation.org/resources/publications/tl-17-03c/

[27] If a data set is not sufficiently large, it may be possible to identify a specific patient, e.g., an outlier in a rural community, whereas with a large enough data set, it becomes impractical to identify a specific patient. See IHE QRPH De-identification White Paper https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Handbook_De-Identification_Rev1.1_2014-06-06.pdf

- Submit the mADX message to HMIS.
- Alternatively: Manually collect the data and submit via spreadsheet

This process is illustrated in Figure 2.3.1-1.
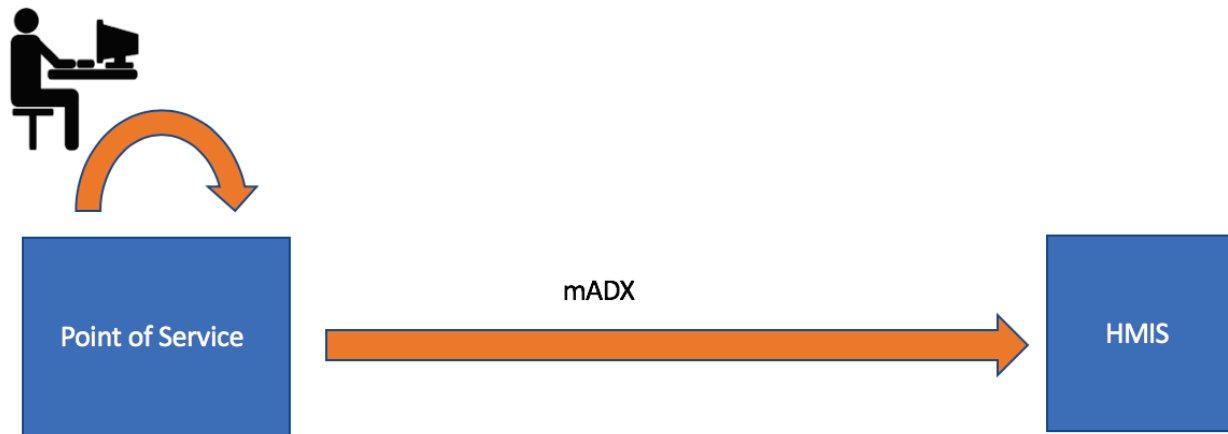
395 **Figure 2.3.1-1: Direct Calculation of Indicators**

While this process is often easy and relatively inexpensive for a software developer to perform for a single indicator, this pattern can be very difficult to scale economically and is not practically feasible as the number of indicators required for reporting grows and varies by jurisdiction. There are often only a limited pool of available software developers who understand
400 the data model of a particular transactional system, and often it can be challenging to train new developers on an existing transactional model

2.3.2 Integrated

In the Integrated Scenario, indicator calculations are performed by a third-party CQL engine based on an MDSM reported from a point of service transaction system via HL7 FHIR resources.
405 For each indicator definition, a software developer is required to:
- Generate an MDSM message of HL7 FHIR resources from the internal data model containing the MDS of transactional data required for calculation of the indicator.
- Submit the MDSM message to a CQL engine.

The CQL engine is responsible for performing the indicator calculation on the MDSM for
410 submission as a mADX message to the HMIS. This process is illustrated in Figure 2.3.2-1.
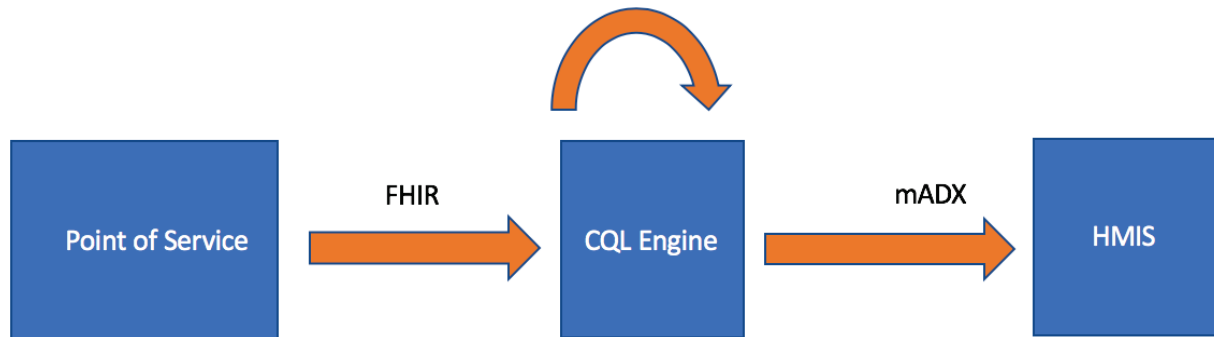
Figure 2.3.2-1: Calculation of Indicators Using a CQL Engine on a Constrained Message

This pattern is less resource intensive than the Direct Calculation method as a software developer is not required for translation of the indicator definition in CQL into another programming language. The needs for a software developer are potentially further reduced, as the same MDS can be used as the basis for the calculation of several indicators.

2.3.3 Exchanged

In the Exchanged scenario, the most mature scenario, this whitepaper assumes the existence of one or more digital client record systems, a master facility registry, a terminology service, a client registry, a longitudinal client record, and a CQL Engine, which computes required indicators expressed by operating on the longitudinal client record.

With these systems in place, it is assumed that metadata management issues are resolved by utilizing common components within an HIE.

In the Shared Health Record (or Data Warehousing) pattern, data from potentially multiple transactional systems are combined into a longitudinal record (or data warehouse) against which indicator calculations are performed. In this pattern, the data warehousing role is played by a FHIR Server.
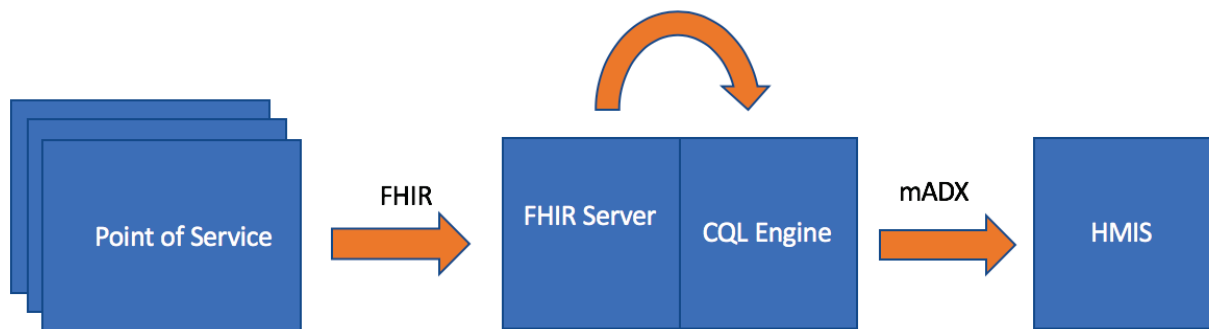
Figure 2.3.3-1: Calculation of Indicators using a CQL Engine on a Shared Health record or Data Warehouse

This pattern is no more resource intensive than the MSDM pattern. It will be less intensive if the Point of Service system already supports enough of the HL7 FHIR API that it can provide synchronization of the required MDS to a FHIR Server. The pattern has the added advantage that the FHIR Server can be used as a basis for non-routine reporting data analysis and case-based surveillance.

In the case that the Point of Service system is not within the same jurisdiction of the FHIR Server, appropriate privacy and security considerations should be applied to the FHIR message and data sharing agreements should be established (see Section 2.4.2).

In the case that the Point of Service system is not within the same jurisdiction as the HMIS, appropriate privacy and security considerations around "small-sets" should be applied to the FHIR message (see Section 2.5).

2.4 Data Models And Standards

This section outlines the data models and artifacts that will be utilized in the white paper. These include:

- **HL7 FHIR Resources** The underlying data models used to describe the minimum data set that is required for the calculation of indicators.
- **mADX** A profile of the HL7 FHIR used for indicator reporting
- **HL7 Clinical Quality Language (CQL)** The query and calculation language that can be applied to appropriate HL7 FHIR resources for the calculation of indicators.

2.4.1 Leveraged Standards and Profiles

Several existing standards and profiles are utilized and referenced in this white paper.

The Aggregate Data Exchange (ADX) Profile supports interoperable public health reporting of aggregate health data, allowing for the exchange of aggregate indicators (data elements) leveraging the Statistical Data and Metadata Exchange (SDMX) standard.[28] These typically take the form of routine reports (weekly, monthly, quarterly, etc.) from a health facility to some administrative jurisdiction such as a health district, though there are numerous other use cases such as international reporting and community health worker reporting.

The Mobile Aggregate Data Exchange (mADX) Profile is functionally equivalent to ADX but expressed in terms of the HL7 FHIR data model and transactions.

The Aggregate Data Exchange HIV (ADX-HIV)[29] Content Profile builds off of ADX. It addresses the problems associated with not having a common data structure across existing systems for HIV-related aggregate data reporting for organizations such as ministries of health, and WHO, and to health initiatives such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund), and UNAIDS.

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[28] https://ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_ADX.pdf
[29] https://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_ADX-HIV.pdf

The Mobile Care Services Delivery (mCSD)[30] Profile is leveraged by mADX and provides a means for exchanging the identifiers and other metadata for the location of reporting such as a health facility or geographic or organizational unit.

The Sharing Valuesets and Codes and Maps (SVCM)[31] specification is leveraged by mADX and provides the means of sharing value sets that are used for disaggregation of indicator data.

The HL7 Clinical Quality Language (CQL) is an authoring language standard focused on clinical quality and targeted at measure and decision support artifact authors. The language provides a way to express logic that is human readable, while still being structured enough for processing a query electronically. It supports the effort to harmonize standards used for electronic Clinical Quality Measures (eCQMs)[32] and clinical decision support (CDS), allowing logic to be shared between measures and with decision support. Note that this whitepaper does not explicitly consider CDS, though many of these tools may be used for CDS use cases.

Finally, guidance on security and privacy concerns are further addressed in the Analysis of Optimal De-Identification Algorithms for Family Planning Data Elements (IHE ITI Handbook) and Using IHE profiles for Healthcare - Secondary Data Access White Paper.[33]

2.4.2 Data Sharing Specification

The architectural patterns described in Section 2.3 may be applied within a jurisdiction or across multiple jurisdictions. Examples of common cross-jurisdictional exchange of indicators includes:

- Reporting of national indicators to regional health agencies such as the West African Health Organization, East African Health Research Commission, or Africa Centres for Disease Control and Prevention; and
- Reporting of national indicators to global donors such as PEPFAR, the Global Fund, and Gavi, the Vaccine Alliance.

Data sharing agreements are formal contracts between two or more parties, which include clearly documenting what data are being shared and how data may be used. In addition, the applicable laws of the jurisdiction that must be followed, agreements further define privacy, security, and confidentiality responsibilities of the parties, including policies and procedures. Examples of topics typically defined in agreements include: the period of the agreement, intended use of the data and limitations for its use, individuals' rights and confidentiality of participants' data, data security safeguards, operating policies and procedures, enforcement, and breach-handling procedures. An informative example of an agreement is the Data Use and Reciprocal Support Agreement (DURSA), in use in the United States.[34]

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[30] https://wiki.ihe.net/index.php/Mobile_Care_Services_Discovery_(mCSD)
[31] https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_SVCM.pdf
[32] This whitepaper expands the use of CQL from just clinical quality measures to include health system, cost efficiencies and other organizational performance measures. https://ecqi.healthit.gov/cql?qt-tabs_cql=1
[33] https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_WP_Analysis-of-DeID-Algorithms-for-FP-Data_Elements.pdf
[34] https://sequoiaproject.org/wp-content/uploads/2014/10/restatement_i_of_the_dursa_9.30.14_final.pdf

To ensure data provenance and governance, having data sharing agreements in place for these cross-jurisdictional situations is critical. The data sharing agreement should clearly describe the needed data for exchange, which is defined via a Data Sharing Specification in Section 2.4.2, and provide a means to ensure privacy considerations are upheld, as described in Section 2.5.

A Data Sharing Specification (DSS) provides computable means to define:
- **Inclusion and exclusion criteria** for a population cohort on which indicators should be calculated.
- The **minimum data set** required to calculate the indicator and determine the inclusion/exclusion criteria in terms of HL7 FHIR resources.
- The calculations required for the **numerator and denominator of an indicator**, expressed using CQL.

Section 3 of this white paper provides the narrative definitions for these components for a number of examples and Appendix A provides the computable definitions.

The computable version of the DSS (detailed below in Section 2.4.2.1) is specified in terms of an HL7 FHIR Measure according to the non-normative conventions described in Table 2.4.2-1 which are reflective of the intended usage of the DSS. In addition to providing a format to share the computable definitions of the DSS, the FHIR Measure resource can be used to handle additional metadata needed, for example, to track the authorship and variation of the indicators over time. Examples of FHIR instances of a DSS can be found in Appendix A.3 DSS Examples as a FHIR Resource.

Table 2.4.2-1: Measure Data element Table

FHIR R4 Measure Data Elements	Description
group[].population[].criteria	Contains a reference to a defined population in the CQL library attached to the measure.
group[].population[].criteria.language	Should be "text/cql"
group[].population[].criteria.expression	The name of a defined population in the attached CQL Library which applies the inclusion-exclusion criteria for this indicator.
group[].stratifier[].component[].criteria	An expression (valueset) defined in the attached CQL Library.
library[]	Contains a single Library resource, which is a library of CQL definitions for indicator calculation and inclusion-exclusion criteria as well as a computable definition of the MDS.
library.description	A narrative description of the DSS.
library[]. type.coding[]	The "system" should be set to "http://terminology.hl7.org/CodeSystem/library-type" and "code" should be set to "logic-library".
library.[].content[]	The "contentType" should be set to "text/cql" and "data" should contain the base64 encoding of CQL library which contains:

	• the numerator of the indicator definition • the denominator of the indicator definition • the definition of the population for the inclusion-exclusion criteria as indicated by group[].population.criteria.expression[]
library[] .dataRequirement[]	Defines the Minimum Data Set required to be sent from a Point of Service system in order to calculate the indicator and determine if the specified inclusion-exclusion criteria apply. This is a list of Structure Definitions, one for each of the FHIR resources needed in the MDS (e.g., Observation or Encounter).

Note: The MDS includes all data elements required for evaluating the inclusion and exclusion criteria.

2.4.2.1 Data Sharing Specification Intake

Table 2.4.2.1-1 below is a framework for a Data Sharing Specification (DSS). A DSS can be used to establish the minimum data requirements for an indicator, and may prove valuable during a requirements gathering exercise. It provides a helpful framework for indicator creators to create and share those indicators with implementers.

A DSS can be created from a WHO Digital Adaptation Kit (DAKs) or on its own. WHO DAKs provide structured data elements for reporting which can be translated into an indicator, and may even provide some example indicators that could be collected. Implementers can readily use these or translate them and add necessary details using the DSS. For example an implementer may wish to include the specific FHIR elements to be captured with standardized terminology, and those can be readily represented in the DSS in addition to a CQL statement to retrieve that data and construct the measure. This provides an additional layer of clarity to implementers looking to operationalize the indicator as they will be able to readily see all the requirements necessary to calculate that specific indicator. This approach can be especially helpful when creating a FHIR Measure, as it allows implementers to clearly specify the requirements. Example DSSs may be found in Section 3. Use Cases.

Table 2.4.2.1-1: A Data Sharing Specification Table

Element	Description
Author:	Individuals and/or organizations responsible for creating and updating the DSS.
Identifier:	Author's identifier for the DSS
Name:	Fully specified name of the DSS.
Background:	A narrative explaining the DSS in further detail.
Population Cohort:	Parameters and constraints of a population cohort on which indicators will be calculated. It includes data to be included and/or excluded in order to meet the DSS, expressed in terms of FHIR Resources.
Minimum Data Set:	Includes enumerated FHIR Resources and data fields expected in the returned message. It specifies data required for the population cohort to calculate the indicator and determine the inclusion/exclusion criteria. Specified as a FHIR profile. Appropriate privacy and security considerations should apply.
For Each Indicator:	For each indicator a Background, Numerator, and Denominator should be defined.

Element	Description
Background:	Narrative description of indicator.
Numerator Definition:	Narrative description of numerator.
Denominator Definition:	Narrative description of denominator.
Version:	Value that denotes the version of the DSS. Versions less than 1.0 imply a DSS pre-release. Uses semantic versioning.
Signature:	Digital signature providing provenance of authorship. (Optional)
Location:	URL where this DSS can be found.
Change Log:	A running log of changes to the DSS such as one of its indicators. Example: • ver-0.0.1 : initial commit of the template. Feb-1-2019. • ver-0.0.2 : fixed formatting of indicator.

2.4.3 Minimum Data Set Message

A Minimum Data Set Message (MDSM) is used in the architectural pattern defined in Section 2.3.3.2 in which only the minimum data set needed to calculate an indicator (or related set of indicators) is communicated by a point of service system to a CQL Engine, a service which calculates the requisite indicator(s) using appropriate CQL statements as defined by a DSS. Example CQL and Library files can be found in Appendices A.1 and A.2 respectively. The data fields required in an MDSM are defined in a DSS.

This white paper does not specify a normative standard for the MDSM message, the HL7 FHIR data model and associated API provide sufficient means to do so. For example a point of service system generating an HL7 FHIR Bundle of resources which contain the required data fields for a client that is sent to the CQL Engine using the HL7 FHIR Messaging standard.[35] See Appendix A.4 for an example.

2.4.4 FHIR Structured Data Capture

FHIR Structured Data Capture (SDC) can be leveraged to standardize the forms used to input data. This data can be transformed automatically into FHIR resources to be analyzed by the types of measures described in this paper. Identifying data for its full lifecycle, from capture to analytics, can lead to higher quality data and more opportunities for data analysis. Each FHIR SDC form is represented as a Questionnaire, data is captured in the QuestionnaireResponse, then is converted to the appropriate resources.

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[35] https://www.hl7.org/fhir/messaging.html
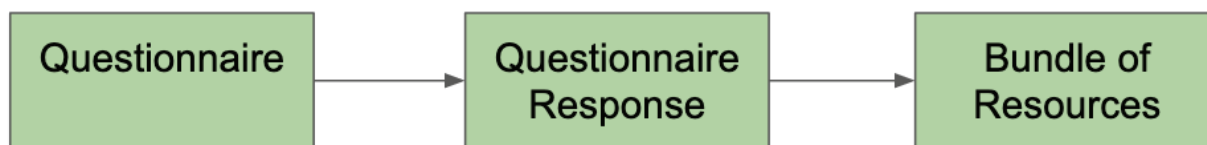
Figure 2.4.4-1: FHIR SDC Conversion to FHIR Resources

SDC offers three (3) types of data extraction: Observation-based, Definition-based, and StructureMap. Observation-based converts all questions and answers to Observations.
560 Definition-based means that a specific resource is to be written to, for example a question may be about a procedure and therefore should be represented as a Procedure resource.[36] StructureMap is the most complex way to extract resources from an SDC QuestionnaireResponse, but it allows for very complex mapping based on codes to be used in order to create a new set of resources.[37]

565 Definition-based extraction is the preferred data extraction technique due to its semantic accuracy. Questionnaires often contain data that should be captured in other resources than Observations. The Questionnaire can specify Questionnaire.item.definition, which defines the resource the data should be written to. However, StructureMap offers several advantages in terms of its flexible approach and lower maintenance burden in the future compared to
570 Definition-based extraction.

SDC can be used to ensure that semantically accurate data has been created from a point of service to when it is utilized by a Measure. Implementation Guide Authors can create Questionnaires that allow implementers to capture data that will match the Measures, thereby reducing the effort to create a custom Questionnaire or other data entry form.

575 ## 2.5 Privacy and Security

In an implementation, a number of security and privacy considerations may apply. The International Organization for Standardization (ISO) defines principles and services required to support the communication and use of health information across policy domain boundaries relevant to this section within ISO 22600 *Health informatics — Privilege management and*
580 *access control*.[38] The multipart standard includes the following three parts:
- An overview and policy management, which includes scenarios and critical parameters for information exchange across policy domains.
- Formal models, which includes an explanation of architectures and underlying models for privilege management and access control for secure information sharing.
585 - Implementations, which includes examples of implementable specifications of application security services and infrastructural services.

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[36] http://build.fhir.org/ig/HL7/sdc/extraction.html#definition-extract
[37] http://build.fhir.org/ig/HL7/sdc/extraction.html#map-extract
[38] https://www.iso.org/obp/ui/#iso:std:iso:22600:-3:ed-1:v1:en

The scope of the data reporting in this white paper may or may not include the transmission of identifiable, person-centric data to new secondary parties. In this case, it is recommended that appropriate security mechanisms, such as the ITI Audit Trail and Node Authentication (ATNA) Profile be utilized.

Even with aggregate data, implementers must be sensitive to the possibility of approximate personal identification arising from aggregate data derived from small population sets. Transport of such data should be safeguarded according to jurisdictional guidelines and the IHE IT Infrastructure Handbook – De-Identification should be referenced for these protections.

This document is not focused on other specific privacy and security requirements (e.g., patient's consent management and access control systems and policies) of the underlying transactional systems as these are often dictated by a given jurisdiction. However, this white paper does consider cases in which transactional data are shared between two parties. In this case, the source system may wish to only transmit de-identified transactional data.

3 Use Cases

This section provides the content needed for a Data Sharing Specification, as described in Section 2.4.2, which includes narrative descriptions of the inclusion-exclusion criteria for a population cohort, a minimum data set of transactional data required, and the indicator definitions. The use cases below do not assume the maturity model of the implementation, however siloed, and integrated models may require more additional manual work in order exchange this kind of M&E data, than an exchanged model. This section is intended to provide an example for business analysts of the level of information needed to define indicators

Appendix A contains technical resources for each of these uses cases geared for engineers and software developers.

3.1 HIV

While person-level data has long been desired for M&E, it is now needed in order to monitor changes and achieve epidemic control. Organizations and countries are working towards the 95-95-95 goal for ending the AIDS epidemic by 2030, which is for 95% of people living with HIV to know their HIV status, 95% of those living with HIV on treatment and 95% of those on treatment are virally suppressed.

This use case describes reporting of both person-level and aggregate data from systems with person-level data, such as EMR systems, to an aggregate data system such as a national HMIS.

The development of person-level metrics across jurisdictions is important to supporting patient-centered outcome measurement. A use case example may be found, for example, in the global HIV 95-95-95 initiative. This initiative aims to track three crucial metrics:
1. that 95% of those persons living with HIV will have been tested, and will know their status; and
2. 95% of those who are HIV positive will be on anti-retroviral (ARV) medications; and
3. 95% of those on ARV will be virally suppressed.[39]

Presently, multiple information systems are used to monitor progress towards achieving epidemic control and the 95-95-95 global goals.

Tracking the "third 95" requires that an individual person's arc of care can be monitored to measure whether or not they are continuing with their course of ARVs and, if they are, whether or not their lab tests indicate they are virally suppressed.

In practice, the data elements and disaggregations used for reporting HIV care and treatment indicators are dependent on the organization or jurisdiction publishing them. We give three examples of DSS that can be used to calculate indicators across the clinical cascade:
- DSS: HIV Known first 95, one indicator
- DSS: On ART and not in other groups second 95, two indicators
- DSS: HIV Suppression third 95, one indicator

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[39] http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf

3.1.1 Inclusion Exclusion Criteria

DSS: HIV Known
- Number of people who have been tested for HIV and received their test results.
- Patients with a condition updated in the reporting period should be included. All patients not excluded with an encounter of testing & counseling in the reporting period should be included.

DSS: On ART
- A Patient resource is considered in the cohort of analysis if they are HIV+. This is determined by the patient.

DSS: HIV Suppression
- A Patient resource is considered in the cohort of analysis if they are HIV+. This is determined by the patient having the appropriate diagnosis.
- This use case calculates epidemic control monitoring indicators on a cohort of patients who are HIV+ and have been on ART for at least three months over the last 12 months.

3.1.2 Minimum Data Set

DSS: HIV Known
- For patients included, all of the testing & counseling encounters in the reporting period should be returned. The encounter effective date should also be included.

DSS: On ART
- For patients included, all of the observation resources within the last twelve months should be included in the bundle for a valid.

DSS: HIV Suppression
- Viral load test results for people living with HIV should be included for those with over six months on ART.

3.1.3 Indicator Definitions

The Data Structure Specifications for HIV are defined below are based on the latest guidance from the WHO. The eCQM provides a more detailed and complete example of how indicators can be structured as a DSS-like format.[40] The eCQMs also make available some FHIR resources on their site which are similar to the artifacts described in this example.[41]

DSS: HIV Known
- Number of individuals who received HIV Testing Services (HTS) and received their test results The HTS_TST indicator reports the number of people who have been tested for HIV during the reporting period and who know their status. It is expressed as a number; there is a numerator but no denominator. It can be disaggregated by age group, gender, HIV test result, key populations, TB status, and testing entry point.

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[40] https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS349v4.html
[41] https://ecqi.healthit.gov/ecqm/ep/2022/cms349v4?qt-tabs_measure=0

DSS: Initiated ART
- Number of people living with HIV who initiated antiretroviral therapy (ART)
- Reports the number of HIV positive persons who were newly started on ART during the reporting period. It is expressed as a number; there is a numerator but no denominator. The data element is disaggregated by age group, gender, key populations, and other priority populations.

DSS: On ART
- Proportion of people living with HIV who are receiving antiretroviral therapy (ART)
- Reports the proportion of people living with HIV who are receiving ART. It is expressed as a percentage. The numerator is the number of people living with HIV currently receiving ART at the end of the reporting period. The denominator is the estimated total number of people living with HIV. Generally, this denominator is not generated from individual health facilities, but it is estimated using modelling estimates such as Spectrum AIM. The data element is disaggregated by age group, gender, and key populations.

DSS: HIV Suppression
- <u>Proportion of people living with HIV and on ART who are virologically suppressed</u> This indicator reports the proportion of patients on ART with a viral load result documented within the past 12 months with a suppressed viral load. It is expressed as a percentage. The numerator is the number of people living with HIV and on ART who have a suppressed viral load (<1000 copies/mL) recorded in the reporting period. The denominator is the number of people number of people living with HIV and on ART who have a viral load result in the reporting period.

3.1.4 Data Sharing Specification

This section contains a DSS Intake Template for two DSS. Appendix A.1.1 contains a CQL Library which is referenced by the DSS. Example of the Measure resources defining the DSS is provided in Appendix A.1.2. A sample Minimum Data Set Message is provided in A.1.3.

Element	Description
Author:	IHE QRPH - Planning Committee 2021
Identifier:	DRAFT-WHO-FIRST-95
Name:	HIV first-95
Background:	One indicator from the WHO Consolidated HIV Strategic Information Guidelines is defined for the first step of the 95-95-95 clinical cascade: People living with HIV who know their HIV Status. The indicator is drawn from the WHO HIV Digital Adaptation Kit [1] which aligns HIV indicators across the following jurisdictions and agencies. [1]
Initial Population:	Number of people living with HIV who have been tested and know their HIV status

Element	Description
Minimum Data Set:	Patient All Patient resources meeting the inclusion/exclusion criteria are sent in the Bundle. Minimum fields needed for analysis include: Patient * identifier. * gender. * birthDate. * deceased. Condition Minimum fields needed for analysis include: * Condition.code * Condition.recordedDate Minimum fields needed for analysis include: * Encounter.location * Encounter.effectiveDateTime
For each Indicator:	
Background:	This indicator reports the number of people who have been tested for HIV during the reporting period and who know their status. It is expressed as a number; there is a numerator but no denominator. It can be disaggregated by age group, gender, and key populations.
Numerator Definition:	CQL Statement (for examples see Appendix A 1.1)
Denominator Definition:	N/A
Version:	0.0.1
Signature:	URL where this DSS can be found.
Location:	* ver-0.0.1 :first draft based on Feb 1, 2019 conference in DC
Change Log:	A running log of changes to the DSS such as one of its indicators Example: * ver-0.0.1 : initial commit of the template. [Date]

Element	Description
Author:	IHE QRPH - Technical Committee 2021
Identifier:	DRAFT-WHO-Second-95
Name:	HIV 2nd & 3rd-95

Element	Description
Background:	Calculates epidemic control monitoring indicators on a cohort of patients who are HIV positive and have been on ART for at least six months.
Initial Population:	A Patient resource is considered in the cohort of analysis if they are HIV Positive and on antiretroviral therapy. The constraint(s) on associated resources are given below. Condition The Patient should have an associated Condition resource that indicates that the patient is HIV Positive
Minimum Data Set	Patient All Patient resources meeting the inclusion/exclusion criteria are sent in Bundle Minimum fields needed for analysis include: * identifier: an identifier for the patient. sender is responsible for anonymizing it appropriately. * gender: * birthDate: Condition The Condition resource should be included in the bundle if Condition.code is within the value set for "HIV status" = "HIV Positive" Minimum fields needed for analysis include: * Condition.code * Condition.recordedDate Observation All Observation resources should be included in the bundle if Observation.code within the set of valid LOINC codes for viral load calculations (25836-8) and if they were tested in the reporting period. Minimum fields needed for analysis include: * Observation.code * Observation.subject * Observation.effective.effectiveDateTime * Observation.value[] * Observation.encounter.location MedicationStatement All MedicationStatement resources should be included in the bundle if the inclusion/exclusion criteria is met. * MedicationStatement.medication.medicationCodeableConcept within Already on ART and New on ART: * MedicationStatement.effective.effectiveDateTime
For Each Indicator:	

Element	Description
Background:	This indicator reports the proportion of people living with HIV who are receiving ART. It is expressed as a percentage. The numerator is the number of people living with HIV currently receiving ART during the reporting period. The denominator is the estimated total number of people living with HIV. Generally, this denominator is not generated from individual health facilities but it is estimated using modelling estimates such as Spectrum AIM. It can be disaggregated by age group, and by sex.
Numerator Definition:	CQL Statement (for examples see Appendix A 1.1)
Denominator Definition	CQL Statement (for examples see Appendix A 1.1)
Background:	This indicator reports the proportion of patients on ART with a viral load result documented within the past 12 months with a suppressed viral load. It is expressed as a percentage. The numerator is the number of people living with HIV and on ART who have a suppressed viral load (<1000 copies/mL) documented within the past 12 months. The denominator is the number of people living with HIV and on ART who have a viral load result documented in the past 12 months. They are disaggregated by age group, gender, and key populations.
Numerator Definition:	Use "Living with HIV and on ART with suppressed viral load results (<1000 copies/mL)" as defined in Appendix A.1.1
Denominator Definition	Cannot be calculated from the data in a digital client record.
Version:	0.0.1
Location:	URL where this DSS can be found.
Change Log:	* ver-0.0.1

3.1.5 Discussion

700 A number of programmatic questions were identified during the development of this white paper, which require clarification or decisions from HIV technical experts, based on reporting needs. These included:

- To calculate the indicator as a proportion requires an estimate of the people living with HIV for the location to be used as the denominator, which is not discussed here.

705 - Data may be incomplete, such as in the event that the submitted code set cannot be completely constructed from the Point of Service system. As an example, EMR systems may not record specific monitoring data that Point of Service systems are required to report on, such as pregnancy status for HIV positive women. It may be necessary to join data, from external sets if available, in order to rectify these gaps. In this example, a value

710 set could be created for the monitoring organization (e.g., PEPFAR). Select logic 'if no

record exists with a SNOMED®[42] code, use the external entity's code for pregnancy status (PRG) and return its value, if it exists.

3.2 Immunization

In the first 18 months of a child's life, it is common for a country's immunization schedule to include 15 or more scheduled vaccine doses. Even with an EMR or electronic immunization registry of a single child's vaccination history, matching a child's record against the country's immunization schedule, as well as factoring in the child's age, is a complex task. However, these checks are needed at the child level to tell how many children have been fully vaccinated, as opposed to only looking at the number of doses delivered. Other high quality data collection methods may be used, such as Demographic and Health Surveys (DHS). However, data from these other sources have significant limitations, including timeliness, the data are not routinely collected, and the process is highly resource intensive.

Countries have different definitions of when a child is counted as a defaulter (e.g., considered a defaulter after three days).

An example DSS is provided in Appendix A.2 for the indicator(s) described below.

The number of individuals in the target group for each vaccine that has received the last recommended dose in the basic series. For vaccines in the infant immunization schedule, if coverage is measured by the administrative system it would be the birth cohort for BCG and Hepatitis B birth dose and surviving infants for the other antigens, in countries where measles is administered during the first year of life will be children 12–23 months old.

3.2.1 Inclusion Exclusion Criteria

Data for all patients under two years old in the reporting period will be included.

3.2.2 Minimum Data Set

Data for all Immunization resources should be included in the bundle, including the status, the date administered, the dose number, and the vaccine. Additionally, date of birth and gender will be sent.

3.2.3 Indicators Definition

The first indicator will calculate the percentage of on-time vaccinations over the period for each antigen.

Percentage of children under two that have received the last recommended dose of the basic series for each vaccine recommended in the national schedule through MR2. This should include all vaccines within a country's routine immunization schedule.

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[42] SNOMED is a registered trademark of the International Health Terminology Standards Development Organisation, all rights reserved.

3.2.4 Data Sharing Specification

Element	Description
Author:	IHE QRPH - Technical Committee 2021
Identifier:	DRAFT-WHO-Immunization-1
Name:	Vaccines Scheduled at 18 Months
Background:	Calculates number of children who have had on time vaccines under 2 years of age
Initial Population:	A Patient resource is considered in the cohort of analysis if they are 2 years of age or younger Condition The Patient should be 2 years of age or younger
Minimum Data Set:	Patient All Patient resources meeting the inclusion/exclusion criteria are sent in Bundle Minimum fields needed for analysis include: * identifier: an identifier for the patient. sender is responsible for anonymizing it appropriately. * gender: * birthDate: Minimum fields needed for analysis include: * Immunization.vaccineCode * Immunization.occurence
For Each Indicator:	
Background:	This indicator captures all persons under 2 years of age, and which vaccines have been administered to them. It can be disaggregated by age group, gender, and key populations.
Numerator Definition:	Vaccines administered
Denominator Definition:	Persons under 2 years of age
Background:	This indicator captures the timeliness of that vaccine according to that country's vaccine schedule. It can be disaggregated by age group, gender, and key populations.
Numerator Definition:	Dates vaccines administered to person
Denominator Definition:	Vaccine schedule (country specific)
Version:	0.0.1
Location:	URL where this DSS can be found.
Change Log:	* ver-0.0.1

3.2.5 Discussion

745 Immunization indicators at the person-level require performing date calculations at the "day" level, as opposed to the month or year. Depending on the architectural pattern, additional privacy and security measures may be required for deidentification or other data protection.

3.3 Maternal, Newborn, and Child Health

Antenatal care can save lives by reducing the number of preventable maternal and perinatal
750 mortality. While the Sustainable Development Goals target a maternal mortality rate of under 70 per 100,000 births, as of 2015 the rate in LMICs was 239 deaths per 100,000 births.[43] To address health inequalities, quality connections with healthcare providers through ANC visits are seen as a way to reduce preventable maternal and perinatal mortality, as well as to improve women's experience of care.[44]

755 UNICEF and WHO evidence-based guidelines specify a minimum recommended number of ANC visits and recommend the first ANC visit within the first twelve weeks of pregnancy. In 2016, the UNICEF and WHO guidelines increased the recommended number of antenatal care visits from at least four visits to at least eight contacts (with contact implying an active connection with the healthcare provider during the encounter). The change was made based on
760 evidence that eight or more visits can reduce perinatal deaths by up to eight deaths per 1000 pregnancies.[45]

We give three examples of DSS that can be used to calculate indicators based on the WHO ANC Digital Adaptation Kit:[46]
- DSS: 1st ANC visit before 12 weeks
765 - DSS: At least 4 ANC visits
- DSS: At least 8 ANC visits

3.3.1 Inclusion Exclusion Criteria

DSS: 1st ANC visit before 12 weeks

A patient is considered in the cohort of analysis if there is a finding that the patient is pregnant.
770 This is indicated with a Condition code of pregnant.

DSS: At least 4 ANC visits and DSS: At least 8 ANC visits

A patient is considered in the cohort of analysis if there is a finding that the patient is pregnant or the patient gave birth within the reporting period. This is indicated with a Condition code of pregnant or a Condition code of a birth.

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[43] https://www.who.int/news-room/fact-sheets/detail/maternal-mortality
[44] https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/
[45] https://www.who.int/reproductivehealth/publications/maternal_perinatal_health/anc-positive-pregnancy-experience/en/
[46] https://www.who.int/publications/i/item/9789240020306

3.3.2 Minimum Data Set

DSS: 1st ANC visit before 12 weeks

For patients included, all of the Procedure resources should be included in the bundle for ANC visits, given by SNOMED code of 18114009 for "Prenatal examination and care of mother" as well as Condition resources for SNOMED code 169750002, which indicate the patient is pregnant.

All Observation resources should also be included in the bundle that give the length of the gestation period. This includes all child codes that specify the number of weeks of gestation, as well as a more general code for the trimester, if that code is used.

DSS: At least 4 ANC visits and DSS: At least 8 ANC visits

For patients included, all of the Procedure resources should be included in the bundle for ANC visits, given by SNOMED code of 18114009 for "Prenatal examination and care of mother" as well as Condition resources for SNOMED code 169750002, which indicate the patient is pregnant.

Additionally, for patients included as having given birth, all Patient and Condition resources should be returned for Condition resources for births. This would include a SNOMED code of 3950001 or any codes that are children of this code.

3.3.3 Data Sharing Specification

Element	Description
Author:	IHE QRPH - Technical Committee 2021
Identifier:	ANCIND06
Name:	Pregnant women who received counselling on danger signs (%) during at least one ANC contact
Background:	This is an Antenatal care indicator of the number of women counselled on danger signs versus the overall
Initial Population:	A Patient resource is considered in the cohort of analysis if Condition The patient is pregnant The patient has received danger signs counselling during an ANC contact
Minimum Data Set:	Patient All Patient resources meeting the inclusion/exclusion criteria are sent in Bundle

Element	Description
	Minimum fields needed for analysis include: * identifier: an identifier for the patient. sender is responsible for anonymizing it appropriately. * gender: * birthDate: Minimum fields needed for analysis include: * Procedure.code * Observation.code
For Each Indicator:	
Background:	This indicator It can be disaggregated by age group, gender, and key populations.
Numerator Definition:	Number of pregnant women who received counselling on danger signs
Denominator Definition	Total number of antenatal clients with a first contact
Version:	0.0.1
Location:	URL where this DSS can be found.
Change Log:	* ver-0.0.1

3.4 Family Planning

795 The Executive Director of the United Nations Population Fund, Dr. Natalia Kanem, stated that, "expanding options and choices for the poorest women and adolescent girls is the most important thing we do." Existing Family Planning 2020 (FP2020) indicators include the percentage of women with an unmet need for modern methods of contraception, however this is a percentage based on total counts and does not give information about first time users or women who have
800 discontinued using contraception even though they wish to avoid pregnancy.[47] Even when there are transactional systems in place that provide a longitudinal patient record, indicators are not being calculated from these data. Instead indicators are calculated using data from the DHS and other survey data.

WHO's 2018 Global Reference List of 100 Core Health Indicators includes a family planning
805 indicator which is the proportion of women of reproductive age (aged 15–49 years) who have their need for family planning satisfied with modern methods [SDG 3.7.1]. To calculate this indicator requires including the unmet family planning need.

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[47] http://www.track20.org/pages/data_analysis/core_indicators/overview.php

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A majority of the unmet need for contraception is from women who have not used it previously.[48] Existing indicators do seek to look at the number of new or additional users for the reporting period. However, these indicators must look at aggregates when there is not a way to identify whether clients are in fact first time users. As a proxy for universal health coverage, WHO has also defined an indicator for the number of clients that accept a contraceptive method for the first time. To calculate this requires knowing the number of first time users.[49]

Another primary way to meet family planning demand is by providing those clients already taking contraceptives with choices and making it possible for them to switch methods, for example if they are experiencing side effects with their current method. The ability for clients already using contraception to have choices and be able to switch methods is also necessary to meet family planning demand. To track method switching and discontinuation of methods requires having data on a client's past use of contraceptives.

3.4.1 Inclusion Exclusion Criteria

The WHO Family Planning Digital Adaptation Kit provides some examples on how indicators should be structured and calculated: https://www.who.int/publications/i/item/9789240029743.

DSS: New users of modern contraceptive methods
- New contraceptive users

DSS: Method switching
- A Patient is considered in the cohort of analysis if they are changing contraceptive methods

3.4.2 Data Sharing Specification

Element	Description
Author:	IHE QRPH - Technical Committee 2021
Identifier:	FPIND01
Name:	Pregnant women who received counselling on danger signs (%) during at least one ANC contact
Background:	This indicator calculates the number of new users using modern contraceptive methods. https://www.who.int/publications/i/item/9789240029743.
Initial Population:	New users of modern contraceptive methods

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[48] Jain, A., F. Obare, S. RamaRao, and I. Askew. 2013. "Reducing unmet need by supporting women with met need," International Perspectives on Sexual and Reproductive Health, 39(3): 133–141. doi: 10.1363/3913313. 6 Ross, J. and J. Stover. 2013. "Use of modern contraception"

[49] WHO. 2019. Analysis and Use of Health Facility Data: Core health facility indicators Working Documentxx… Available at: https://www.who.int/healthinfo/FacilityAnalysisGuidance_Indicators.pdf?ua=1

Element	Description
Minimum Data Set:	Patient Observation The Patient and the Observation resources would be required to calculate this indicator. The Patient resource should capture the known data on the contraceptive user and an Observation should be used to store if they are a new user of contraception in a coded field. Requires: * Patient.gender * Patient.birthDate Patients who have are new users of contraceptive methods captured in an Observation. * Procedure.code: Counselling on family planning * Observation.code: Contraceptive method at intake * Observation.value: Method or service provided
For Each Indicator:	
Background:	This indicator must be disaggregated across gender, age, and method. Therefore, we require the patient resource.
Numerator Definition:	Patients using a new contraceptive method
Denominator Definition:	Patients who have received family planning counselling
Version:	0.0.1
Location:	URL where this DSS can be found.
Change Log:	* ver-0.0.1

830   3.4.3 Discussion

Modern contraceptive methods can also be purchased at pharmacies in a number of countries without going through a provider. In particular, adolescents may avoid health facilities in seeking contraception. This white paper does not address contraception that is sought out anonymously outside of health facilities.

835   Systems may not capture family planning method data or pregnancy intention or, when captured, the data may not be captured in a standardized way. While this white paper does not address this standardization, past IHE QRPH work identified family planning interoperability standards including for standardizing data elements. These included data elements for the contraceptive method at intake and, if no method is being used, the reason why. If these data elements were 840   being captured, it would be possible to calculate these indicators without longitudinal data. However, this relies on more data needing to be captured at each visit.

3.5 Health Workforce

In order to ensure the provision of high quality care, the health system must have adequate human resources for health which are properly trained and certified. Globally there is a deficit of

845 appropriately trained workforce, and a vision to progress towards universal health coverage and the UN Sustainable Development Goals by ensuring equitable access to health workers within strengthened health systems.[50]

In 2016, the 69th World Health Assembly adopted Resolution 69.19, Global Strategy on Human Resources for Health: Workforce 2030. National Health Workforce Accounts (NHWA) were
850 developed under the direction of the World Health Organization (WHO) Health Workforce Department to support the implementation of the Global Strategy on Human Resources for Health: Workforce 2030.

NHWA provide for the aggregation of health workforce data for evidence-based workforce policy decisions, labor market analysis, policy design, and the tracking and support of workforce
855 strengthening efforts towards universal health coverage (UHC) and the SDGs and the Global Strategy milestones. NHWA are oriented around three crucial labor market components: the education component, the labor force component and the component serving population health needs.

IHE profiles for person-level aggregate data exchange are critical not only for patient-level data
860 but also for practitioner-level aggregated data as demonstrated by the NHWA.

NHWA Module 1

National Health Workforce Accounts are oriented around three crucial labor market components: education, labor force, and the component serving population health needs. 'NHWA Module 1: Active health workforce' stock addresses the composition and distribution of the health
865 workforce, including distributions by gender, cadre, geography and other factors.

In this use case, data are extracted directly from the health worker registry and represented as an ADX summary report to be consumed by the national HMIS.

Extracting directly from the health worker registry to be consumed by the national HMIS has the benefits of either reducing the reporting burden at the facility by replacing the manual data entry
870 or to supplement it by acting as a control to detect staffing anomalies. The report extracted from the health worker registry would contain data for a single time period but for multiple health facilities.

As an example, in Sierra Leone the two systems central to the management of the health system are the national HMIS and the human resource system, or health worker registry (HWR). A
875 routine human resource report is reported by the health facility every six months. The reports consist of counts of health worker cadres working at the facility (number of doctors, nurses, community health workers etc.). There is an additional disaggregation on all report rows which indicates the salaried status of the employee.

This use case calculates indicators 1-01, 1-02, 1-03, and 1-04 for the National Health Workforce
880 Accounts Module 1 according to the WHO standard as directed in the NHWA Handbook.[51]

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[50] https://www.who.int/hrh/resources/pub_globstrathrh-2030/en/
[51] https://www.who.int/hrh/statistics/nhwa/en/

Depending on need, the indicators can be calculated for existing workforce density or for retrospective density (e.g., specific years or months). 2.5.2.1.2.1 Inclusion Exclusion narrative

NHWA 1-01 Density of Health Workers per 10 000 population are the number of health workers defined in headcounts divided by the total population. The indicator should be disaggregated by occupation and by occupation and activity level.

NHWA 1-02 Density of active health workers per 10 000 population at the subnational level are the number of active health workers at subnational administrative units, defined in headcounts, divided by the total population at subnational level. Disaggregation is by occupation.

NHWA 1-03 Percentage of active health workers in different age groups are the number of active health workers in a specific age group (> 25, 25–34, 35-44, 45–54, 55–64, ≤ 65) divided by the total number of active health workers, defined in headcounts. Disaggregation is by occupation.

NHWA 1-04 Percentage of female health workers in active health workforce are the number of active female health workers divided by the total number of active male and female health workers, defined in headcounts. Disaggregation is by occupation.

Health workers are defined using International Standard Classification of Occupations (ISCO) classification codes as noted in WHO guidance.[52] A health worker is also included in the cohort depending on the time period that the analysis will target.

3.5.1 Data Sharing Specification

The following DSS demonstrates how one might be created for NHWA 1-04:

Element	Description
Author:	WHO
Identifier:	NHWA 1-04
Name:	Percentage (%) of female health workers in active health workforce
Background:	Percentage (%) of female health workers in active health workforce are the number of active female health workers divided by the total number of active male and female health workers, defined in headcounts. Disaggregation is by occupation.
Initial Population:	Practitioners who are female in the health workforce.
Minimum Data Set:	All Practitioner resources meeting the inclusion/exclusion criteria are sent in a Bundle. Minimum fields needed for analysis include:

---

[52] https://www.who.int/hrh/statistics/workforce_statistics/en/

Element	Description
	* Practitioner.identifier: an identifier for the Practitioner. Sender is responsible for anonymizing it appropriately. * Practitioner.gender * Practitioner.birthDate The Practitioner's Role Resource gives information on present and former roles. There is a potential many-to-one relationship as a Practitioner MAY have more than one Role. Requires: * Practitioner: For identification with Practitioner. If identifiers in both resources on anonymized it requires they are in agreement. * Practitioner.code: Code for the PractitionerRole. Health workers are defined by ISCO codes adapted to the health workforce. * Practitioner.location: Required for subnational analysis. * Practitioner.period On classification: https://www.who.int/hrh/statistics/workforce_statistics/en/ The Practitioner's Role Resource gives information on present and former roles. There is a potential many-to-one relationship as a Practitioner MAY have more than one Role. Requires: * PractitionerRole.practitioner: For identification with Practitioner. If identifiers in both resources on anonymized it requires they are in agreement. * PractitionerRole.period: Dates of activity for the Role if necessary for inclusion/exclusion. Practitioner.gender Location.type
For Each Indicator:	
Background:	This indicator must be disaggregated across age, location, and role (occupation)
Numerator Definition:	Number of health care workers who are female.
Denominator Definition:	Number of active health care workers
Version:	0.0.1
Location:	URL where this DSS can be found.
Change Log:	* ver-0.0.1

3.5.2 Discussion

Calculating the available health workforce may be an essential piece of data for many health systems and has significant utility when working with other indicators. Making this data available can inform capacity planning in many low resource contexts. It can also be aligned with other indicators such as the ones described in this white paper.

Calculating these types of indicators benefits from registries of health workers such as those described in the Mobile Care Services Discovery (mCSD) Profile also mentioned in this paper. A FHIR enabled registry such as this could provide valuable data for indicator calculation and allow stakeholders the ability to make informed decisions about health service delivery.

3.6 COVID-19

The COVID-19 pandemic highlighted how electronic Case Reporting (eCR), the automated generation and transmission of case reports from EHRs, can speed response and analysis to the pandemic.[53] This removal of manual steps to collect and store data can increase effective pandemic responses and outbreak management.

eCR effectively automates the reporting steps required to send a report, then the approach of this paper for person-level reporting can be used to conduct analysis, by defining the requirements for measurement of the eCR data.[54] Utilizing eCR in conjunction with the approach outlined with this paper has the potential to create an end-to-end automation of data capture to indicator reporting.

3.6.1 Data Sharing Specification Intake

The following DSS demonstrates how one might be created for CDC Patient Impact and Hospital Capacity based on a FHIR Measure from the HL7 Situational Awareness for Novel Epidemic Response (SANER) Working Group:[55]

Element	Description
Author:	HL7 – Situational Awareness for Novel Epidemic Response (SANER) Working Group
Identifier:	measure-CDCPatientImpactAndHospitalCapacity
Name:	CDC Patient Impact and Hospital Capacity
Background:	Demonstrates reporting on ventilator availability and use at a facility location based on CDC/NHSN reporting requirements.
Initial Population:	Patients and ventilators counts
Minimum Data Set:	All Patient resources meeting the inclusion/exclusion criteria are sent in a Bundle. Minimum fields needed for analysis include:

---

[53] https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html
[54] https://www.ama-assn.org/delivering-care/public-health/why-it-s-essential-improve-data-collection-and-reporting
[55] http://hl7.org/fhir/uv/saner/STU1/Measure-CDCPatientImpactAndHospitalCapacity.html

Element	Description
	* Patient.identifier * Condition.code where that code is COVID-19 related The Encounter resource gives information on when patients entered the hospital for treatment for COVID and determining in patient or out patient status. Requires: * Encounter.status * Encounter.class * Encounter.type * Encounter.serviceType Device resources are required to identify ventilator use * Device.status * Device.statusReason * Device.type
For Each Indicator:	
Background:	
Numerator Definition:	Number of Patients
Denominator Definition:	Number of functioning ventilators
Version:	0.0.1
Location:	URL where this DSS can be found.
Change Log:	* ver-0.0.1

925

3.6.2 Discussion

The approaches outlined in this paper can be applied to COVID-19 and used to effectively respond to future pandemics or even smaller outbreaks. It is arguably a critical piece of digital health infrastructure to ensure that public health agencies around the world can utilize accurate
930   data quickly.

4   Conclusion

The aim of this paper is to provide guidance on reducing the reporting effort of indicators by describing how, through the use of standardized technology, data for these indicators can be automatically extracted from the patient record instead of manually collected and synthesized. This automation could potentially assist in reducing the reporting burden to the multiple levels of stakeholders, and allow health workers to focus more on treatment and less on reporting. IHE Profiles, FHIR, CQL, and other HL7 standards could help enable this kind of simpler reporting and standardize how aggregated indicators are collected and calculated. By creating statements which are machine readable and calculable, the reporting burden could be reduced to focus on clinical care.

The Data Sharing Specification and methodology outlined in this paper provide a framework for how this might be done in the future. As discussed, translating DAKs into DSS and making them more readily implementable and simpler to digest with concise information about the specific indicators. DAKs provide significant value in their terminology mapping and indicator definitions, but do not explicitly tie all potential standards required to consistently extract those indicators. The use cases provide examples of how this standardization could benefit implementations, and reusability of data and indicators to reduce the reporting burden on health workers, particularly those in LMICs.

Appendices

Appendix A – Data Sharing Specifications and Example FHIR Artifacts

A.1 CQL File Example

The CQL Library in Figure A.1-1 is an example extracted from an HL7 FHIR Library resource example at https://www.hl7.org/fhir/library-hiv-indicators.html. This library should be defined in terms of HL7 FHIR Library Resources as in Figure A.2-1 (and made available in this example at http://ohie.org/Library/hiv-indicators). This library should also be referenced by the two DSSs described in 3.1 for HIV via DSS Intake Forms as in Section 3.1.4.

⚠ **WARNING:** This is provided as example and has not been validated against the requirements described in Section 3.1.

```
library HIV_Indicators version '0.0.0'

/*
The content in this library is draft content developed as part of a working
OpenHIE
session on the use of FHIR quality reporting functionality to report public
health
indicators: https://wiki.ihe.net/index.php/Aggregate_Data_Exchange_-_HIV
*/


using FHIR version '3.0.0'


// SNOMED-CT, International Edition
codesystem "SNOMED-CT": 'http://snomed.info/sct/900000000000207008'


// LOINC, 2.63+
codesystem "LOINC": 'http://loinc.org'


codesystem "ISO-8601-Derived Periods": 'http://ohie.org/ValueSet/iso-8601-
derived-periods' // { 'P0Y--P1Y', 'P1Y--P5Y', ... }
codesystem "PMTCT HIV Status Codes": 'TBD' // { 'known-positive', 'newly-
identified-positive', 'newly-identified-negative' }
codesystem "PMTCT ART Status Codes": 'TBD' // { 'already-on-art', 'new-on-
art' }


valueset "HIV Testing Services": 'TBD' // Should use HIV tests
valueset "Viral Load Test": 'TBD'
valueset "HL7 Administrative Gender":
'http://hl7.org/fhir/ValueSet/administrative-gender'
valueset "ART Medications": 'TBD' // ART medications
valueset "Antenatal Care": 'TBD' // Antenatal Care
valueset "Delivery Procedures": 'urn:oid:2.16.840.1.113762.1.4.1045.59' //
Used by CMS113
```

```
valueset "Human Immunodeficiency Virus (HIV) Laboratory Test Codes (Ab and
Ag)": 'urn:oid:2.16.840.1.113762.1.4.1056.50' // Used by CMS349

//. HIV Test Results
code "HIV Negative": code '165815009' from "SNOMED-CT" display 'HIV
Negative'
code "HIV Positive": code '165816005' from "SNOMED-CT" display 'HIV
Positive'
code "HIV 1 and 2 tests - Meaningful Use set": '75622-1' from "LOINC"
display 'HIV 1 and 2 tests - Meaningful Use set' // Used by CMS349

// History of ART Therapy
code "History of antiretroviral therapy (situation)": '432101000124108' from
"SNOMED-CT" display 'History of antiretroviral therapy (situation)'

// Age Groups
code "P0Y--P1Y": code 'P0Y--P1Y' from "ISO-8601-Derived Periods" display '<
1 year'
code "P1Y--P5Y": code 'P1Y--P5Y' from "ISO-8601-Derived Periods" display '1-
4 years'
code "P5Y--P10Y": code 'P5Y--P10Y' from "ISO-8601-Derived Periods" display
'5-9 year'
code "P10Y--P15Y": code 'P10Y--P15Y' from "ISO-8601-Derived Periods" display
'10-14 year'
code "P15Y--P20Y": code 'P15Y--P20Y' from "ISO-8601-Derived Periods" display
'15-19 year'
code "P20Y--P25Y": code 'P20Y--P25Y' from "ISO-8601-Derived Periods" display
'20-24 year'
code "P25Y--P30Y": code 'P25Y--P30Y' from "ISO-8601-Derived Periods" display
'25-29 year'
code "P30Y--P35Y": code 'P30Y--P35Y' from "ISO-8601-Derived Periods" display
'30-34 year'
code "P35Y--P40Y": code 'P35Y--P40Y' from "ISO-8601-Derived Periods" display
'35-39 year'
code "P40Y--P50Y": code 'P40Y--P50Y' from "ISO-8601-Derived Periods" display
'40-49 year'
code "P50Y--P9999Y": code 'P50Y--P9999Y' from "ISO-8601-Derived Periods"
display '50+ years'

// PMTCT ART status
code "Already on ART": 'already-on-art' from "PMTCT ART Status Codes"
display 'Already on ART'
code "New on ART": 'new-on-art' from "PMTCT ART Status Codes" display 'New
on ART'

// PMTCT HIV status
code "Known Positive": 'known-positive' from "PMTCT HIV Status Codes"
display 'Known Positive'
code "Newly Identified Positive": 'newly-identified-positive' from "PMTCT
HIV Status Codes" display 'Newly Identified Positive'
```

```
code "Newly Identified Negative": 'newly-identified-negative' from "PMTCT
HIV Status Codes" display 'Newly Identified Negative'

parameter "Measurement Period" Interval<DateTime>

define "ART Therapy Observation":
  ["Observation": "History of antiretroviral therapy (situation)"] O
    where O.status = 'final'

define "ART Therapy Condition":
  ["Condition": "History of antiretroviral therapy (situation)"] C
    where C.verificationStatus = 'confirmed'
      and C.clinicalStatus in { 'active', 'relapsed', 'well-controlled',
'poorly-controlled' }

define "ART Therapy Medication":
  ["MedicationDispense": "ART Medications"] M
    where M.status = 'completed'

define "ART Dates":
  ("ART Therapy Observation" O return O.effectiveDateTime)
    union ("ART Therapy Condition" C return C.onsetDateTime)
    union ("ART Therapy Medication" M return M.whenHandedOver)

define "Date of First Evidence of ART":
  Min("ART Dates")

// PMTCT ART status
define "PMTCT ART Status":
  case
    when "Date of First Evidence of ART" before start of "Measurement
Period" then "Already On ART"
    when "Date of First Evidence of ART" during "Measurement Period" then
"New On ART"
    else null
  end

//code "Already on ART": '432101000124108' from "SNOMED-CT" display 'Already
on ART'
//code "New on ART": '432101000124108*' from "SNOMED-CT" display 'New on
ART'

define "On ART":
  exists ("ART Dates" D where D during "Measurement Period")
    or exists (
      "ART Therapy Condition" C
        where Interval[C.onsetDatetime, C.abatementDatetime] overlaps
"Measurement Period"
    )

define "HIV Test Observation":
```

```
  (
    [Observation: "Human Immunodeficiency Virus (HIV) Laboratory Test Codes
(Ab and Ag)"]
      union [Observation: "HIV 1 and 2 tests - Meaningful Use set"]
  ) O
    where O.status = 'final'
      and O.value is not null

define "HIV Positive Observation":
  "HIV Test Observation" O where O.value ~ "HIV Positive"

define "HIV Negative Observation":
  "HIV Test Observation" O where O.value ~ "HIV Negative"

define "Is HIV Positive":
  exists ("HIV Positive Observation")

define "Is HIV Negative":
  exists ("HIV Negative Observation")

define "Date of First Evidence of HIV Status":
  Min("HIV Test Observation" O return O.effectiveDateTime)

define "Date of First Evidence of HIV Positive":
  Min("HIV Positive Observation" O return O.effectiveDateTime)

define "Date of First Evidence of HIV Negative":
  Min("HIV Negative Observation" O return O.effectiveDateTime)

// PMTCT HIV Status
define "PMTCT HIV Status":
  case
    when "Date of First Evidence of HIV Positive" before start of
"Measurement Period" then 'Known Positive'
    when "Date of First Evidence of HIV Positive" during "Measurement
Period" then 'Newly Identified Positive'
    when "Date of First Evidence of HIV Negative" during "Measurement
Period" then 'Newly Identified Negative'
    else null
  end

//code "Known HIV positive": code '165816005**' from "SNOMED-CT" display
'Known HIV positive'
//code "Newly identified HIV Positive": code '165816005*' from "SNOMED-CT"
display 'Newly identified HIV Positive'
//code "Newly identified HIV negative": code '165815009*' from "SNOMED-CT"
display 'Newly identified HIV negative'


// QRPH_ADX_ART3_N:
```

```
// Number of adults and children currently receiving antiretroviral therapy
(ART)
  // Stratifiers: AGE_GROUP,SEX
define "Receiving antiretroviral therapy (ART) during measurement period":
  exists ("ART Dates" D where D during "Measurement Period")
    or exists (
      "ART Therapy Condition" C
        where Interval[C.onsetDatetime, C.abatementDatetime] overlaps
"Measurement Period"
    )

define "Year Preceding the Measurement Period":
  Interval[start of "Measurement Period" - 1 year, start of "Measurement
Period")

define "Month Before the Year Preceding the Measurement Period":
  Interval[start of "Year Preceding the Measurement Period" - 1 month, start
of "Year Preceding the Measurement Period")


// QRPH_ADX_VLS3_N:
// Number of people living with HIV and on ART who have a suppressed viral
load result (&lt;1000 copies/mL).
  // Stratifiers: AGE_GROUP,SEX
define "Living with HIV and on ART with suppressed viral load result (<1000
copies/mL)":
  "Is HIV Positive"
    and "Receiving antiretroviral therapy (ART) during measurement period"
    and exists (
      "Viral Load Test Result" R
        where R.effectiveDateTime during "Measurement Period"
          and R.value < 1000 '{copies}/mL'
      )


// Stratifiers

// Age Group
define "Age Group":
  case
    when AgeInYearsAt(start of "Measurement Period") in Interval[0, 1) then
"P0Y--P1Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[1, 5) then
"P1Y--P5Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[5, 10) then
"P5Y--P10Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[10, 15)
then "P10Y--P15Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[15, 20)
then "P15Y--P20Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[20, 25)
then "P20Y--P25Y"
```

```
    when AgeInYearsAt(start of "Measurement Period") in Interval[25, 30)
then "P25Y--P30Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[30, 35)
then "P30Y--P35Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[35, 40)
then "P35Y--P40Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[40, 50)
then "P40Y--P50Y"
    when AgeInYearsAt(start of "Measurement Period") in Interval[50, null]
then "P50Y--P9999Y"
    else null
  end


// Sex
define "Sex": Patient.gender



// HIV Test Results
define "HIV Test Results":
  case
    when "Is HIV Positive" then "HIV Positive"
    when "Is HIV Negative" then "HIV Negative"
    else null
  end
```

Figure A.1-1: CQL File for HIV Examples

A.2 Example Library File

An example FHIR Library Resource for the CQL File in A.1-1. This file can be used to share the file through a FHIR API.

965

```
{
  "resourceType": "Library",
  "id": "hiv-indicators",
  "text": {
   "status": "generated",
   "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\"><p><b>Generated Narrative with
Details</b></p><p><b>id</b>: hiv-indicators</p><p><b>url</b>:
<b>http://ohie.org/Library/hiv-indicators</b></p><p><b>identifier</b>: hiv-
indicators</p><p><b>version</b>: 0.0.0</p><p><b>title</b>: HIV
Indicators</p><p><b>status</b>: draft</p><p><b>experimental</b>:
true</p><p><b>type</b>: Logic Library <span>(Details :
{http://terminology.hl7.org/CodeSystem/library-type code 'logic-library' = 'Logic Library',
```

```
given as 'Logic Library'})</span></p><p><b>date</b>:
03/08/2018</p><p><b>description</b>: HIV Indicators Reporting
Example</p><p><b>relatedArtifact</b>: </p><p><b>content</b>: </p></div>"
  },
  "url": "http://ohie.org/Library/hiv-indicators",
  "identifier": [
    {
      "system": "http://ohie.org/Library/",
      "value": "hiv-indicators"
    }
  ],
  "version": "0.0.0",
  "title": "HIV Indicators",
  "status": "draft",
  "experimental": true,
  "type": {
    "coding": [
      {
        "system": "http://terminology.hl7.org/CodeSystem/library-type",
        "code": "logic-library",
        "display": "Logic Library"
      }
    ]
  },
  "date": "2018-08-03",
  "description": "HIV Indicators Reporting Example",
  "relatedArtifact": [
    {
      "type": "derived-from",
      "url": "http://wiki.ihe.net/index.php/Aggregate_Data_Exchange_-_HIV"
    }
```

```
  ],
  "content": [
    {
      "contentType": "text/cql",
      "data":
```
"bGlicmFyeSBISVZfSW5kaWNhdG9ycyB2ZXJzaW9uICcwLjAuMCcKCi8qClRoZSBjb250
ZW50IGluIHRoaXMgbGlicmFyeSBpcyBkcmFmdCBjb250ZW50IGRldmVsb3BlZCBhcyBw
YXJ0IG9mIEgd29ya2luZyBPcGVuSElFCnNlc3Npb24gb24gdGhlIHVzZSBvZiBGSElSIHF
1YWxpdHkgcmVwb3J0aW5nIGZ1bmN0aW9uYWxpdHkgdG8gcmVwb3J0IHB1YmxpYyB
oZWFsdGggcmluZGljYXRvcnM6IGh0dHBzOi8vd2lraS5paGUubmV0L2luZGV4LnBocC9
BZ2dyZWdhdGVfRGF0YV9FeGNoYW5nZV8tX0hJVgoqLwoKdXNpbmcgRkhJUiB2ZXJz
aW9uICczLjAuMCcKCi8vIFNNOT01FRC1DVCwgSW50ZXJuYXRpb25hbCBFZGl0aW9uC
mNvZGVzeXN0ZW0gIlNOT01FRC1DVCI6ICdodHRwOi8vc25vbWVkLmluZm8vc2N0Lzk
wMDAwMDAwMDAwMDIwNzAwOCcgCgovLyBMT0lOQywgMi42MysK29kZXN5c3R
lbSAiTE9JTkMiOiAnaHR0cDovL2xvaW5jLm9yZycKCmNvZGVzeXN0ZW0gIklTTy04NjA
xLURlcml2ZWQgUGVyaW9kcyI6ICdodHRwOi8vb2hpZS5vcmcvVmFsdWVTZXQvaXNv
LTg2MDEtZGVyaXZlZC1wZXJpb2RzJyAvLyB7ICdQMFktLVAxWScsICdQMVktLVA1W
ScsIC4uLiB9CmNvZGVzeXN0ZW0gIlBNENUIEhJViBTdGF0dXMgQ29kZXMiOiAnVEJ
EJyAvLyB7ICdub93bi1wb3NpdGl2ZScsICduZXdseS1kZVudGlmaWVkLXBvc2l0aXZlJ
ywgJ25ld2x5LWlkZW50aWZpZWQtbmVnYXRpdmUnIH0KY29kZXN5c3RlbSAiUE1UQ1
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saXR5LWJhc2VkIGRlbGl2ZXJ5IHdpdGhpbiB0aGUgcmVwb3J0aW5nIHBlcmlvZAogIC8vI
FN0cmF0aWZpZXJzOiBOb25lCnJlZmluZSAiQW50ZW5hdGFsIENhcmUgaXNpdCBvciBMa
XZlIEJpcnRoIGR1cmluZyBNZWFzdXJlbWVudCBQZXJpb2QgYW5kIFBvc2l0aXZlIEhJVi
BTdGF0dXMiOiAgICAgYW5kIGJpIEdMSVYgUG9zaXRpdmUiCiAgIklzIEhJViBQb3NpdGl2Z
SIgIGFuZCAiQW50ZW5hdGFsIENhcmUgaXNpdCBvciBMaXZlIEJpcnRoIGR1cmluZyBNZW
FzdXJlbWVudCBQZXJpb2QiCgovLBRUlBIX0FEWF9NVENNl9OOOgovLBOdW1iZXIgb2
YgSElYLXBvc2l0aXZlIHByZWduYW50IHdvbWVuIHdob3J5ZWNlaXZlZCBBUlQgdG8gcm
VkdWNlIHRoZSByaXNrIG9mIG1vdGhlci10by1jaGlsZC10cmFuc21pc3Npb24gZHVyaW5nIH
ByZWduYW5jeQogIC8vIFN0cmF0aWZpZXJzOiBQTVRDVF9SRU1fU1RBVVMKcmVmaW5l
ICBwcmVnbmFudCwgYW5kIHJlY2VpdmluZyBhbnRpcmV0cm92aXJhbCB0aGVyYXB5IC
hBUlQpIHRvIHJlZHVjZSB0aGUgcmlzayBvZiBtb3RoZXItdG8tY2hpbGQtdHJhbnNtaXNz

aW9uIGR1cmluZyBwcmVnbmFuY3kiOgogICJJcyBISVYgUG9zaXRpdmUiCiAgICBhbmQ
gIiklzIFByZWduYW50IgogICAgYW5kICJSZWNlaXZlZpbmcgYW50aXJldHJvdmlyYWwgdG
hlcmFweeSAoQVJUKSBkdXJpbmcbWVhc3VyZW1lbnQgcGVyaW9kIgoKZGVmaW5lICJ
WaXJhbCBMb2FkIFRlc3QgUmVzdWx0IjoKICBbIk9ic2VydmF0aW9uIjoglZpcmFsIExvY
WQgVGVzdCJdIE8Kc3RhdHVzID0gJ2ZpbmFsJwogICAgICBhbmQgT
y52YWx1ZSBpcyBub3QgbnVsbAoKLy8gUVJQSF9BRFhfVkxTM19OOGgoLyBOdW1iZXI
gb2YgcGVvcGxlIGxpdmluZyB3aXRoIEhJViBhbmQgQVJUIHdobyBoYXZlIGEgc3Vw
cHJlc3NlZCB2aXJhbCBsb2FkIHJlc3VsdHMgKCZsDsxMDAwIGNvcGllcy9tUwpIjoKICAiSXMgSElWIFBvc2l0aXZlIgogICAgYW5kI
CJJZWNlaXZpbmcgYW50aXJldHJvdmlyYWwgdGhlcmFweeSAoQVJUKSBkdXJpbmcbW
Vhc3VyZW1lbnQgcGVyaW9kIgogICAgYW5kIGV4aXN0cyAoCiAgICAgICJWaXJhbCBM
b2FkIFRlc3QgUmVzdWx0IiBSCiAgICAgICAgd2hlcmUgUi5lZmZlY3RpdmVEYXRlVGltZ
SBkdXJpbmcgIk1lYXN1cmVtZW50IFBlcmlvZCIKICAgICAgICBhbmQgUi5ZhbHVlID
wgMTAwMCAne2NvcGllc30vbUwnCiAgICApKICAgICCi8vIFFSUEhfQURYX1
UzJfTjoKLy8gTnVtYmVyIG9mIGluZGl2aWR1YWxzIHdobyByZWNlaXZlZCBISVYgVG
VzdGluZyBTZXJ2aWNlcyAoSFRTKSBhbmQgcmVjZWl2ZWQgdGhlaXIgdGVzdCByZXN
1bHRzCiAgLy8gU3RyYXRpZmllcm06IEFHRV9HUk9VCxTRVgsKZGVmaW5lIgIlJlY2Vpd
mVkIEhJViBUZXN0aW5nIFNlcnZpY2VzIChIVFMpIGFuZCBSZWNlaXZlZCBUZXN0IFJl
c3RpbmcgU2VydmljZXMiXSBPCiAgICAgd2hlcmVPLnN0YXR1cyA9IGZpbmhbCcKIC
AgICAgYW5kIE8udmFsdWUgaXMgbm90IG51bGwgIAoKZGVmaW5lICJmaXJzdCBhbnRl
bmF0YWwgY2FyZSB2aXNpdCI6CiAgRmlyc3QoIkFudGVuYXRhbCBDYXJlIFZpc2l0IiB
WIHNvcnQgYnkgc3RhcnQgb2YgcGVyaW9kKQoKLy8gUVJQSF9BRFhfVkRWDFfTjoK
Ly8gTnVtYmVyIG9mIHByZWduYW50IHdvbWVuIHdpdGgga25vd24gSElWIHN0YXR1cy
BhdCBhbnRlbmF0YWwgY2FyZSB2aXNpdAogIC8vIFN0cmF0aWZpZXJzOiBQ
TVRDVF9ISVZfU1RBVFVTCmRlZmluZSAiSElWIFN0YXR1cyBLbm93biBhdCBGaXJzd
CBBbnRlbmF0YWwgQ2FyZSBWaXNpdCI6CiAgIkhhdGUgb2YgRmlyc3QgRXZpZGVuY2
Ugb2YgSElWIFN0YXR1cyIgb24gb3IgYmVmb3JlIHN0YXJ0IG9mICJGaXJzdCBhbnRlbm
F0YWwgY2FyZSB2aXNpdCIucGVyaW9kCgovLyBRUlBIX0FEWF9WTFMzX0Q6Ci8vIE5
1bWJlciBvZiBwZW9wbGUgb24gQVJUIHdobyBoYYQgYSBWTCBtZWFzdXJlbWVudCB
pbiB0aGUgcGFzdCAxMiBtb250aHMuCiAgLy8gU3RyYXRpZmllcm6IEFHRV9HUk9VU
CxTRVgKZGVmaW5lICJSZWNlaXZpbmcgYW50aXJldHJvdmlyYWwgdGhlcmFwdHkg
EFSVCkgYW5kIFpmaXJhbCBMb2FkIE1lYXN1cmVtbnQgaW4gdGhlIHBhc3QgMTIgbW9
udGhzIjoKICAiUmVjZWl2aW5nIGFudGlyZXRyb3ZpcmFsIHRoZXJhcHkgKEFSVCkgZH
VyaW5nIG1lYXN1cmVtZW50IHBlcmlvZCIKICAgIGFuZCBleGlzdHMgKAogICAgICAiV
mlyYWwgTG9hZCBUZXN0IFJlc3VsdCIgUgogICAgICAgIGhlcmUgUi5lZmZlY3RpdmVk
RGF0ZVRpbWUgZHVyaW5nICJZZWFyIFByZWNlZGluZyB0aGUgTWVhc3VyZW1lbnQg
UGVyaW9kIgogICAgKQoKLy8gU3RyYXRpZmljZXJzCgovLyBBZ3VSdXdXAKZGVmaW5
lIEZZWFyc0JZHdodTpZXhyczoglJZWFzdXJlbWVudCBQZXJpb2QiLmJvdXAKZGVma
W5lICJBZ2UgQXRIGlhc2UKICAgIGhvZXhgQWdlSW5ZZWFyc0F0KHN0YXJ0IG9mI
CJZZWFzdXJlbWVudCBQZXJpb2QiKQoKZGVmaW5lICJBZ2UgR3JvdXAKICAgIGNhc2
UKICAgICAgaHoZXhgQWdlSW5ZZWFyc0F0KHN0YXJ0IG9mICJZZWFzdXJlbWVudCBQ
ZXJpb2QiKSBpbiBJbnRlcnZhbFswLCAxKSB0aGVuICJQMC0tLVA1IgogICAgICBoZXhgQ
WdlSW5ZZWFyc0F0KHN0YXJ0IG9mICJZZWFzdXJlbWVudCBQZXJpb2QiKSBpbiBJbnR
lcnZhbFsxLCA1KSB0aGVuICJQMVktLVA1WSIK

```
ICAgIHdoZW4gQWdlSW5ZZWFyc0F0KHN0YXJ0IG9mICJNZWFzdXJlbWVudCBQZXJp
b2QiKSBpbiBJbnRlcnZhbFs1LCAxMCkgdGhlbiAiUDVLLQMTBZIgogICAgd2hlbiBBZ2
VJblllYXJzQXQoc3RhcnQgb2Ygik1lYXN1cmVtZW50IFBlcmlvZCIpIGluIEludGVydmFsW
zEwLCAxNSkgdGhlbiAiUDEwWS1QMTVYIKICAgIHdoZW4gQWdlSW5ZZWFyc0F0K
HN0YXJ0IG9mICJNZWFzdXJlbWVudCBQZXJpb2QiKSBpbiBJbnRlcnZhbFsxNSwgMjApI
HRoZW4gIlAxNVktLVAyMFkiCiAgICB3aGVuIEFnZUluWWVhcnNBdChzdGFydCBvZiA
iTWVhc3VyZW1lbnQgUGVyaW9kIikgaW4gSW50ZXJ2YWxbMjAsIDI1KSB0aGVuICJQ
MjBZLS1QMjVZIgogICAgd2hlbiBBZ2VJblllYXJzQXQoc3RhcnQgb2Ygik1lYXN1cmVtZ
W50IFBlcmlvZCIpIGluIEludGVydmFsWzI1LCAzMCkgdGhlbiAiUDI1WS1UDMwWSIKI
CAgIHdoZW4gQWdlSW5ZZWFyc0F0KHN0YXJ0IG9mICJNZWFzdXJlbWVudCBQZXJpb
2QiKSBpbiBJbnRlcnZhbFszMCwgMzUpIHRoZW4gIlAzMFktLVAzNSkiCiAgICB3aGVuI
EFnZUluWWVhcnNBdChzdGFydCBvZiAiTWVhc3VyZW1lbnQgUGVyaW9kIikgaW4gSW
50ZXJ2YWxbMzUsIDQwKSB0aGVuICJQMzVZLS1QNDBZIgogICAgd2hlbiBBZ2VJblll
YXJzQXQoc3RhcnQgb2Ygik1lYXN1cmVtZW50IFBlcmlvZCIpIGluIEludGVydmFsWzQwLC
A1MCkgdGhlbiAiUDQwWS0tUDUwWSIKICAgIHdoZW4gQWdlSW5ZZWFyc0F0KHN0Y
XJ0IG9mICJNZWFzdXJlbWVudCBQZXJpb2QiKSBpbiBJbnRlcnZhbFs1MCwgbnVsbC0gd
GhlbiAiUDUwWS0tUDk5OSIgIgogICAgZWxzZSBudWxsCiAgZW5kCgovLyBTZXggKZG
VmaW5lICJTZXgiOiBQYXRpZW50LmdlbmRlcgoKLy8gQWdlIEdyb3VwL1NleApkZWZp
bmUgIkFnZSBHcm91cC9TZXgiOiAiQWdlIEdyb3VwIi5jb2RlICsgJzon2UIlNleCIKCi8vIF
ByZWduYW50L0JyZWFzdGZlZWRpbmcKZGVmaW5lICJQcmVnbmFudC9CcmVhc3RmZ
WVkaW5nIjoKICBjYXNlICAgICB3aGVuICJJcyBQcmVnbmFudCIgdGhlbiAiUHJlZ25hbn
QiCiAgICB3aGVuICJJcyBCcmVhc3RmZWVkaW5nIiB0aGVuICJCcmVhc3RmZWVkaW5n
IgogICAgZWxzZSBudWxsCiAgCi8vIEhJViBUZXN0IFJlc3VsdHMKZGVmaW5l
lICJISVYgVGVzdCBSZXN1bHRzIjoKICBjYXNlICAgICB3aGVuICJJcyBISVYgUG9zaXR
pdmUiIHRoZW4gIkhJViBQb3NpdGl2ZSIKICAgIHdoZW4gIklzIEhJViBOZWdhdGl2ZSIgd
GhlbiAiSElWIE5lZ2F0aXZlIgogICAgZWxzZSBudWxsCiAgCmRlZmluZSAiQ
WdlIEdyb3VwL1NleC9ISVYgVGVzdCBSZXN1bHRzIjoKICAiQWdlIEdyb3VwIi5jb2RlICs
gJzonICsgIlNleCIgKyAiOiIgKyAiSElWIFRlc3QgUmVzdWx0Ii5jb2RlCg==",
```

        "url": "library-hiv-indicators-content.cql"

      }

  ]

}

Figure A.2-1: FHIR Library Resource containing CQL File

A.3 DSS Example as a FHIR Measure

This resource is specified in IHE mADX, defining what content needs to be collected in order to create MeasureReports for indicators. The resource below shows HIV indicators.

970

⚠ **WARNING:** This is provided as example and has not been validated against the requirements described in Section 3.1.

```json
{
   "resourceType": "Measure",
   "id": "hiv-indicators",
   "url": "http://ohie.org/Measure/hiv-indicators",
   "identifier": [
   {
      "system": "http://ohie.org/Measure/",
      "value": "hiv-indicators"
   }
   ],
   "version": "0.0.0",
   "name": "DRAFT-IHE-QRPH--HIV-SECOND-THIRD-90",
   "title": "HIV 2nd & 3rd-90",
   "date": "2019-04-20",
   "publisher": "HE QRPH - Technical Committee 2019",
   "description": "Calculates epidemic control monitoring indicators on a cohort of patients who are
HIV+ and have been on ART for at least three months over the last 12 months

Three indicators from the ADX-HIV content profile are defined for the second and third step of the 90-
90-90 clinical cascade: on antiretroviral therapy (ART); and viral load is suppressed.

The indicators are drawn from the IHE ADX-HIV content profile[1] which aligns HIV indicators across
the following jurisdictions WHO/UNAIDS, PEPFAR, Global Fund, Kenya, Rwanda. Disaggregators
and conditions are extracted from the PEPFAR MER 2.0 indicators[2].

[1]
http://www.ihe.net/uploadedFiles/Documents/QRPH/IHE_QRPH_Suppl_ADX_HIV_Rev1.0_PC_2018-
05-29.pdf
[2] https://ovcsupport.org/wp-content/uploads/2018/01/MER-2.0-Indicator-Reference-Guide-V-2.2-
Updated-Release-24-Jan-2018.pdf",
   "subject" : {

   "subjectCodableConcept" {
      "coding" : [
      "code" : "Patient"
      ]
   }
   },
   "group": [
   {
      "code": {
      "coding": [
```

```
        {
        "system": "http://pepfar.gov",
        "code": "TX_CURR"
        }
    ]
    },
    "description": "This indicator reports the proportion of people living with HIV who are receiving
ART. It is expressed as a percentage. The numerator is the number of people living with HIV currently
receiving ART during the reporting period. The denominator is the estimated total number of people
living with HIV. Generally, this denominator is not generated from individual health facilities but it is
estimated using modelling estimates such as Spectrum AIM.

It can be disaggregated by age group, and by sex.

See the definition of the QRPH_ADX_ART3_N indicator in the ADX-HIV Content Profile for more
guidance.",
    "population": [
    {
        "code": {
        "text": "cohort"
        },
        "criteria": {
        "language": "text/cql",
        "expression": "Newly enrolled on antiretroviral therapy (ART) during measurement period"
        }
    }
    ],
    "stratifier": [
    "component" : [
        {
        "code": {
            "coding": [
            {
                "system": "http://ihe.net/qrph/adx/",
                "code": "AGE_GROUP"
            }
            ]
        },
        "criteria": {
            "language": "text/cql",
            "expression": "Age Group"
        }
        },
```

```
        {
        "code": {
          "coding": [
          {
             "system": "   http://hl7.org/fhir/ValueSet/administrative-gender",
             "code": "Sex"
          }
          ]
        },
        "criteria": {
          "language": "text/cql",
          "expression": "Sex"
        }
        },

    ]

   },
  },
  {
    "code": {
    "coding": [
      {
      "system": "http://pepfar.gov",
      "code": "TX_PVLS"
      }
    ]
    },
    "description": "This indicator reports the proportion of patients on ART with a viral load result
documented within the past 12 months with a suppressed viral load. It is expressed as a percentage. The
numerator is the number of people living with HIV and on ART who have a suppressed viral load
(<1000 copies/mL) documented within the past 12 months. The denominator is the number of people
living with HIV and on ART who have a viral load result documented in the past 12 months.

They are disaggregated by age group, and by sex. There is an additional disaggregation for those who
are pregnant and breastfeeding mothers.

See the definition of the QRPH_ADX_ART1_N indicator in the ADX-HIV Content Profile for more
guidance.",
    "population": [
    {
      "code": {
      "text": "cohort"
```

```
        },
      "criteria": {
      "language": "text/cql",
      "expression": "Living with HIV and on ART with suppressed viral load results (<1000
copies/mL)"
        }
    }
    ],

    "stratifier": [
    "component" : [
      {
      "code": {
        "coding": [
        {
          "system": "http://ihe.net/qrph/adx/",
          "code": "AGE_GROUP"
        }
        ]
      },
      "criteria": {
        "language": "text/cql",
        "expression": "Age Group"
      }
      },
      {
      "code": {
        "coding": [
        {
          "system": "http://hl7.org/fhir/ValueSet/administrative-gender",
          "code": "SEX"
        }
        ]
      },
      "criteria": {
        "language": "text/cql",
        "expression": "Sex"
      }
      }

    ]

    }
```

```
    }
  ],
  "relatedArtifact": [
  {
     "label" : "AGE_GROUP",
     "url" : "http://ihe.net/qrph/adx-hiv-agegroups",
     "type" : "depends-on"
  },
  {
     "label" : "SEX",
     "url" : "http://hl7.org/fhir/ValueSet/administrative-gender",
     "type" : "depends-on"
  }

  ],
  "library": [
  "http://ohie.org/Library/hiv-indicators"
  ],

}
```

Figure A.3-1: A FHIR Measure resource example

A.4 Minimum Data Set Message Example in FHIR

⚠ **WARNING:** This is provided as example and has not been validated against the requirements described in Section 3.1.

```
{
 resourceType: "Bundle",
 meta: {
   profile: [ "http://datim.org/fhir/StructureDefinition/TX_PVLS_Bundle"]
 },
 type: "message",
 timestamp: "2019-04-10T09:55:00"
 entry: [
   {
     fullURL: "",
     resource: {
       resourceType: "MessageHeader",
       text: {
```

```
        status: "generated",
        div: "<div xmlns=\"http://www.w3.org/1999/xhtml\"><p>This is the MDS for
TX_PVLS.</p></div>"
      },
      eventCoding: {
        system: "",
        code: ""
      },
      destination: {
        name: "DATIM"
      }
    }
  },
  {
    fullURL: "",
    resource: {
      resourceType: "Patient",
      meta: {
        profile: [ "http://datim.org/fhir/StructureDefinition/TX_PVLS_Patient"]
      },
      id: "12345",
      gender: "female",
      birthDate: "1999-04-19"
    }
  },
  {
    fullURL: "",
    resource: {
      resourceType: "Encounter",
      meta: {
        profile: [ "http://datim.org/fhir/StructureDefinition/TX_PVLS_Encounter"]
      },
      status: "finished",
      id: "123abc",
      subject: "Patient/12345",
      location: [
        location: {
          identifier: { system: "MFL", value: "aBKlrjL"}
        }
      ]
    }
  },
  {
```

```
    fullURL: "",
    resource: {
     resourceType: "Condition",
     meta: {
      profile: [ "http://datim.org/fhir/StructureDefinition/TX_PVLS_Condition"]
     },
     id: "999abc",
     subject: "Patient/123abc",
     verificationStatus: "confirmed",
     code: {
      coding: [
        {
         system: "http://snomed.info/sct",
         code: "165816005"
        }
      ]
     },
     recordedDate: "2018-12-12T12:12:12"
    }
   },
   {
    fullURL: "",
    resource: {
     resourceType: "MedicationStatement",
     meta: {
      profile: [ "http://datim.org/fhir/StructureDefinition/TX_PVLS_MedicationStatement"]
     },
     id: "999def",
     subject: "Patient/12345",
     medicationCodeableConcept: {
      coding: [
        {
         system: "http://snomed.info/sct",
         code: "432101000124108"
        }
      ]
     },
     effectiveDateTime: "2019-03-22"
    }
   },
   {
    fullURL: "",
    resource: {
```

```
      resourceType: "Observation",
      meta: {
       profile: [ "http://datim.org/fhir/StructureDefinition/TX_PVLS_Observation"]
      },
      id: "456def",
      code: {
       coding: [
         {
          system: "http://loinc.org",
          code: "10351-5"
         }
       ]
      },
      encounter: "Encounter/123abc",
      subject: "Patient/12345",
      performer: {
       reference: {
         identifier: {
          system : "HR Reg",
          code: "abcd-efg-hij-klm"
         }
       }
      }
      effectiveDateTime: "2019-04-10T10:00:00",
      valueQuantity: {
       value: 400,
       unit: "/mL"
       system: "http://unitsofmeasure.org",
       code: "/mL"
      }
     }
    }
   ]
  }
```

980   **Figure A.4-1: A Bundle containing the FHIR resources that would be included in a
minimum data set**

Appendix B – FHIR Maturity Model

B.1 FHIR Maturity Model

985 Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE domain determines that an emerging standard has high likelihood of industry adoption, and the standard offers significant benefits for the use cases it is attempting to address, the domain may develop IHE profiles based on such a standard. During Trial Implementation, the IHE domain will update and republish the IHE profile as the underlying standard evolves.

990 Product implementations and site deployments may need to be updated in order for them to remain interoperable and conformant with an updated IHE profile.

This white paper references content from Release 4 of the HL7® FHIR® specification. HL7 describes FHIR Change Management and Versioning at https://www.hl7.org/fhir/versions.html.

HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model
995 (FMM): level 0 (draft) through N (Normative). See http://hl7.org/fhir/versions.html#maturity.

The FMM levels for FHIR content referenced in this white paper are:

FHIR Resource Name	FMM Level
CodeSystem	N
Condition (Problem)	3
Encounter	2
Measure	2
MeasureReport	2
MedicationStatement	3
Observation	N
Patient	N
Practitioner	3
PractitionerRole	2
StructureDefinition	N
ValueSet	N

Glossary

1000   The complete IHE Glossary is available [here](#).

Term	Definition
Case-Based Reports	This level of reporting is the ability to dissect an individual case, also known as an encounter, in a person's medical record. Data are typically generated from an EMR, Lab, or Dispensing Information System, based on sentinel events for tracking cases. Whether there is identifiable data will vary, based on how the system is implemented and jurisdictional requirements. Data on cases are essential for patient-level reports to be generated.
Claims Adjudication System	A system used to adjudicate claims for reimbursement of health services through a health financing scheme, for example health insurance. The system links patient, provider, and payor data.
Client Registry	A system used to manage demographic data of health system clients and provide identification services across jurisdictions. Profiles of HL7 FHIR, such as PIXm and PDQm, can be used to describe the expected behavior.
CQL Engine	A data service that performs calculations and queries, specified in the CQL language, against the HL7 FHIR data model and produces a valid mADX message.
Denominator	The number of the population (e.g., persons, events) meeting the criteria for inclusion in the denominator of the indicators. If no criteria are specified, the denominator is formed includes cases in the dataset.
Digital Registers	Electronic organizers of data that may be at the encounter level. In LMICs, these are often paper-based forms, or digital representations thereof, that are filled out for patients' encounters, maintained at the health facility, and specific to a health vertical. In the ADX use cases they will often contain clinical data. These can be queried like electronic medical records and aggregated.
Health Facility Registry	A system to manage the metadata and multiple identifiers for health facilities as well as their organizational and geographic inter-relations. Profiles of HL7 FHIR, such as mCSD, can be used to describe the expected behavior.

Health Management Information System (HMIS)	The national health management information system (HMIS) which gathers aggregate data from all health facilities. The system allows for the generation, comparison, and analysis of indicators on population health and facility service utilization. Historically, the HMIS has been the system of record for the management and definition of health system indicators.
Health System Indicators	A specific type of indicator that tracks health system resources and health system performance such as medical commodities, health spending, and health workforce.
Health Workforce Registry	A system to manage the metadata and multiple identifiers for health workers including their deployment, certification and training data. Profiles of HL7 FHIR, such as mCSD, can be used to describe the expected behavior.
HR Management	HR Management databases can be valuable sources of data to query who delivered care to a given patient. This may be relevant if a project is conducting provider level reporting.
Labs	Labs conduct tests on patients and collect a significant amount of information. If this information is accessible it can provide valuable person-centric metrics as Labs often create a significant amount of data.
Minimum Data Set	The required data fields needed to calculate the indicator from a transactional system.
National Health Workforce Accounts	National Health Workforce Accounts is a system by which countries progressively improve the availability, quality, and use of data on health workforce through monitoring of a set of indicators to support achievement of Universal Health Coverage, Sustainable Development Goals and other health objectives.
Numerator	The number of the population meeting the criteria for inclusion in the numerator(s) of the indicators. Unless noted, the criteria for the numerator(s) are a subset of those selected for the denominator(s) below.
Patient Health Records	A person's individual medical records. These may be digital, physical, or both. They should contain a person's entire medical history.
Patient Level Monitoring	The observation of patients at an individualized level. Patient-level monitoring may be conducted to treat the patient or as part of M&E, often for comparative analysis.

Person-Centered Outcome (PCO) Indicator	A specific type of indicator that tracks health outcomes across an identified population cohort. The calculation of it may include data extracted and aggregated from patient-level systems.
Population Cohort	The group the particular measure is about.
PreService & InService Training	Training that the health workforce undergoes before and during working to ensure that they are able to deliver care in a consistent way.
Product Registry	A system used to manage the metadata and multiple identifiers for medical commodities. Standards such as GS1's Global Data Synchronization Network (GDSN) can be used to describe the expected behavior.
Professional Certification	Certifications that a healthcare worker should receive prior to providing care. These are often managed by a professional council such as a medical or nursing board.
Secondary Data Usage Community	A funding body, research organization, Public Health Organization, epidemiology organization, quality reporting agency, or any other organization which collects and uses a patient's data for purposes other than the direct care of the patient and where personal data identifying specific patients might not be allowed and/or necessary.
Terminology Service	A system used to manage clinical and health system terminologies. Capability statements of HL7 FHIR compliant terminology service are available at https://www.hl7.org/fhir/terminology-service.html.