



Mobile for Development mHealth

Maternal mHealth: Solution / Product
and Technology Framework

CONTENTS

BACKGROUND AND INTRODUCTION	4
Drivers of Maternal Mobile Health in Africa	4
Mobile Maternal, Newborn and Child Health.....	4
<i>Current Challenges of mHealth</i>	4
National Health Information Systems	5
Product and Technology Framework	5
PRODUCT / SOLUTION FRAMEWORK.....	6
Introduction	6
Interoperability Solutions	8
<i>Interoperability Principles</i>	8
<i>Architecture Standards Catalogue</i>	9
<i>Interoperability Maturity Model</i>	10
<i>Health Interoperability and Information Exchange Solutions</i>	11
Logical Architecture for Maternal mHealth Interoperability	13
<i>Maternal mHealth Information Exchange</i>	13
<i>Maternal mHealth Workflows and Business Processes</i>	15
Product Framework	18
TECHNOLOGY FRAMEWORK.....	20
Overview	20
<i>Mobile Application Services</i>	20
<i>Health Information Mediator</i>	20
<i>Client Registry</i>	21
<i>Shared Health Record</i>	21
<i>Subscription Database</i>	21
<i>HMIS</i>	21
Standards used within the Technology Framework	21
<i>Foundational standards and terminologies</i>	22
<i>Interoperability profile standards</i>	22
<i>Mapping of Standards and Profiles to the OpenHIE</i>	23
Workflows.....	24
<i>Registration and Identification</i>	24
<i>Subscription</i>	27
<i>Patient Administration</i>	28
<i>Save Clinical Encounter Example Template</i>	31

CONCLUSION	40
REFERENCES	44
ACKNOWLEDGEMENTS AND DISCLOSURES	46
ABBREVIATIONS, TERMS AND DEFINITIONS	47
Abbreviations	47
Definitions	49
ABOUT the GSMA	50

BACKGROUND AND INTRODUCTION

Drivers of Maternal Mobile Health in Africa

Selected drivers of maternal health policy in Africa are as follows:

1. At an international level, improving maternal health is a global priority and, as the fifth Millennium Development Goal¹ (MDG), has the following targets:
 - a. Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio;
 - b. Achieve, by 2015, universal access to reproductive health.
2. The African Union Commission (AUC) launched the Campaign on Accelerated Reduction of Maternal, Newborn and Child Mortality in Africa² (CARMMA) during the fourth session of the AU Conference of Ministers of Health held in Addis Ababa, Ethiopia in May 2009. CARMMA was endorsed at the fifteenth ordinary session of the African Union Assembly held in Kampala, Uganda in July 2010.

Mobile Maternal, Newborn and Child Health

Mobile health (mHealth) technology has been proposed as a means to improve healthcare in low resource settings, including maternal health [1]. Among others, mHealth applications can have the following potential benefits:

1. Positively influence pregnant women to engage with the public health system, including:
 - a. Attend and register for antenatal care early in their pregnancy, preferably within the first trimester.
 - b. Attend all recommended antenatal care visits.
 - c. Deliver in a health facility.
2. Reduce the three delays leading to increased maternal mortality in low resource settings [2]:
 - a. Delay in deciding to seek care
 - b. Delay in reaching care in time
 - c. Delay in receiving adequate treatment

Current Challenges of mHealth

A significant number of mHealth applications have been developed and implemented, often resulting in a complex system of overlapping services. As a result, one of the most important current limitations of mHealth and its ability to deliver solutions is the fragmentation between different mHealth applications providing both similar and different functionality across geographic regions, health services, levels within the health system as well as the continuum of care.

¹ <http://www.un.org/millenniumgoals/maternal.shtml>

² <http://www.carmma.org/>

National Health Information Systems

Coiera et al have described three approaches to the development of National Health Information Technology (NHIT) and patient-based systems: top-down, bottom-up and middle-out [3] [4], and recommended the middle-out approach for developed countries [5]. It appears that a similar approach could be relevant in low-resource environments [6]. The middle-out approach also seems appropriate to aspects of maternal mHealth for the following reasons:

1. The approach applies to the evolution of patient-centric health applications, similar to those targeted by many mHealth applications.
2. The approach applies to the problem of developing national systems at scale that is a common goal in low resource environments.
3. The approach recommends a combination of 'embracing' systems that have already been developed (bottom-up) and 'extending' the functionality through a top-down process of connecting systems together and to the national system, which reflects the many mHealth applications that have been implemented.
4. The approach fits with an evolutionary approach and convergence of systems according to some kind of maturity model.

Product and Technology Framework

This mHealth Product / Solutions and Technology (P&T) Framework provides principles, models, concepts, and guidelines for delivering interoperable mobile solutions for maternal health. It broadens and extends previous work developed by the GSMA and others and was developed based on information and research carried out towards implementing mobile and maternal health programs and projects in African countries including a maternal health information exchange and a maternal messaging program.

This P&T Framework is limited to a single solution to the challenge of providing a national interoperable solution and technology infrastructure for mHealth messaging. Other frameworks exist, notably the MoTeCH suite [7] [8].

The P&T framework has the following objectives:

1. Guide further discussion around maternal mHealth services among stakeholders, including Ministries of Health, funders and private sector partners.
2. Provide a basic approach to the development of interoperable mobile maternal services at a system level.
3. Provide recommendations to guide developers and implementers of mHealth applications in low resource settings.
4. Guide future expansion of present systems to other functions and areas of health service provision.

A previous study by the GSMA and others investigated the predicted contributions to maternal registrations and estimated that a combination of systems could make a significant single contribution to maternal registration, as shown in Figure 2, below.

The projections considered three maternal messaging workflows:

Subscription - referring to the process of signing up a person to a messaging service.

Identification - referring to the process of identifying a client and storing the client data in a database

Registration - referring to the process of formally recording a pregnancy or pregnant woman following a diagnostic test conducted by a registered healthcare provider in an authorized facility.

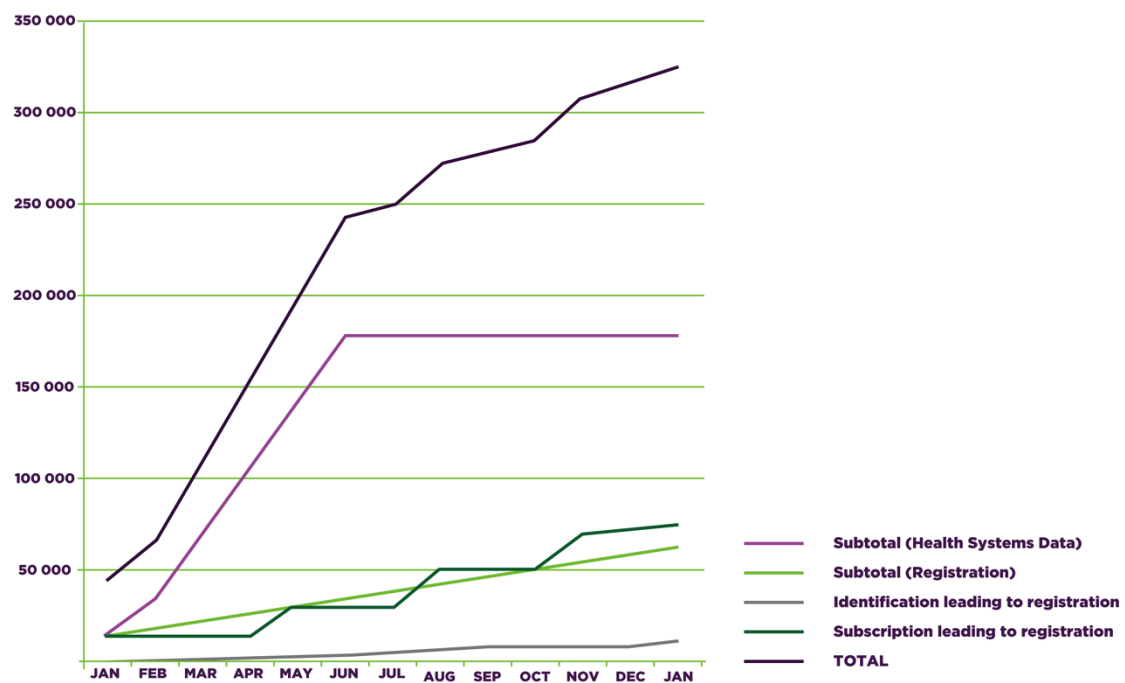


Figure 2. Estimates of combined maternal registrations based on a model African case study

The above workflows could also be analyzed in terms of a complex system dynamic model that could result in synergistic effects between different workflows, as shown in Figure 3, below.

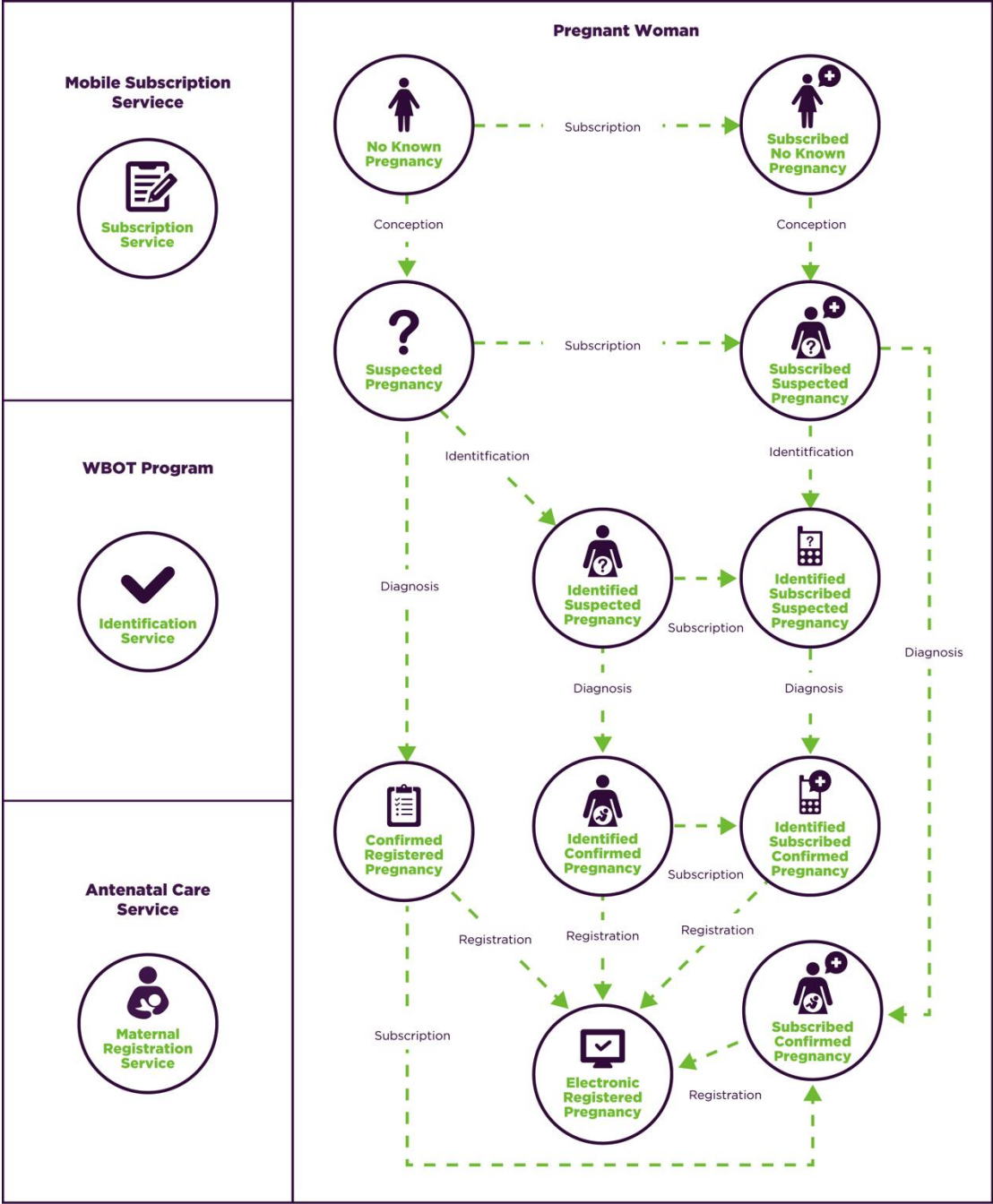


Figure 3. Estimates of combined maternal registrations in South Africa

Interoperability Solutions

Interoperability Principles

An early study funded by the Mobile Health Alliance (MHA) entitled 'Barriers and Gaps Affecting mHealth in Low and Middle Income Countries' identified Interoperability as a key issue for mHealth [9]. The MHA subsequently published an interoperability framework providing guidance to harmonization in a real-world setting [10]. An open mHealth architecture with standardized interfaces between applications has also been proposed to address the

lack of interoperability between mHealth applications [11]. Others have proposed an open data model for mHealth applications [12]. A review of interoperability and standards applied to health in low resource settings has also been published [13].

Architecture Standards Catalogue

Interoperability is fundamentally dependent on the use of standards. The case for the application of interoperability standards in Africa has been made [13]. An example of a standards catalogue with a partial list of standards that may be applicable to maternal mHealth in different settings is shown in Table 1, below.

#	Standard	Name
1	ISO/DIS 12967-1	Health informatics - Service Architecture - Part 1: Enterprise viewpoint
2	ISO/DIS 12967-2	Health informatics - Service Architecture - Part 2: Information viewpoint
3	ISO/DIS 12967-3	Health informatics - Service Architecture - Part 1: Computational viewpoint
4	IHE - ATNA	Audit Trail and Node Authentication
5	IHE - PIX	Patient Identifier Cross Referencing
6	IHE - PDQ	Patient Demographic Query
7	ISO/TS 22220:2009	Identification of subjects of care
8	ISO/TS 27527:2010	Health informatics -- Provider identification
9	ISO/TS 18308:2004	Requirements for an electronic health record architecture
10	ISO/TR 20514:2005	Electronic health record -- Definition, scope and context
11	ISO 13606-3:2009	Electronic health record communication -- Part 3: Reference archetypes and term lists
12	ISO 13606-5:2010	Electronic health record communication -- Part 5: Interface specification
13	ISO/IS 13606-1	Electronic health record communication -- Part 1: Reference model ISO/HL7 21731:2006 HL7 version 3 -- Reference information model
14	ISO/IS 13606-1	Electronic health record communication -- Part 1: Reference model ISO/HL7 21731:2006 HL7 version 3 -- Reference information model
15	ISO/IS 21090	Harmonized Data Types for Information Interchange
16	ISO/HL7 DIS 27931	HL7 Messaging Standard Version 2.5 -- An application protocol for electronic data exchange in healthcare environments
17	ISO/DIS 17113.2	Exchange of information between healthcare information systems -- Method for development of messages
18	ISO/TS 17369:2005	Statistical Data and Metadata Exchange – Health Domain (SDMX)

19	ASTM E2369-05	Standard Specification for Continuity of Care Record CCR
20	ISO/IS 13606-3	Electronic health record communication -- Part 3 - Archetypes and Term List Interchange Specifications
21	ISO/IS 13606-2	Electronic health record communication -- Part 2 - Archetype Interchange Specifications
22	ISO/IS 13606-5	Electronic health record communication -- Part 5 - Interface Specification ISO/HL7/IS 27932 Clinical Document Architecture
23	ISO/HL7/IS 27932	Clinical Document Architecture
24	ISO/TS 22600-1:2006	Health informatics -- Privilege management and access control -- Part 1: Overview and policy management
25	ISO/TS 22600-2:2006	Health informatics -- Privilege management and access control -- Part 2: Formal models
26	ISO/TS 22600-3:2009	Health informatics -- Privilege management and access control -- Part 3: Implementations
27	ISO 27799:2008	Health informatics -- Information security management in health using ISO/IEC 27002
28	ISO 17090-1:2008	Health informatics -- Public key infrastructure -- Part 1: Overview of digital certificate services
29	ISO 17090-2:2008	Health informatics -- Public key infrastructure -- Part 2: Certificate profile
30	ISO 17090-3:2008	Health informatics -- Public key infrastructure -- Part 3: Policy management of certification authority

Table 1. Applicable Interoperability Standards for maternal mHealth

Interoperability Maturity Model

Converging on interoperability is generally seen as a process that can be described in terms of a maturity model. The Australian National eHealth Transition Authority (NEHTA)⁴ has produced an Interoperability Framework [14], an eHealth Standards Catalogue [15] and a Maturity Model [16]. The NEHTA Interoperability Maturity Model (IMM) leverages the Capability Maturity Model Integration (CMMI) approach. The IMM also identifies a number of interoperability goals from the NEHTA Interoperability Framework. The third component of the IMM is an assessment framework to measure the interoperability maturity level. The IMM describes five interoperability maturity levels based on four areas: technical, semantic, process and institutional operability. These can be summarized as follows:

1. Initial

- Early awareness of mHealth interoperability requirements and characteristics and perhaps some early mHealth interoperability solutions adoption, typically localized within defined application or geographical domains;
- Technical capability to export and import data in a standard format and supporting clearly defined and outlined workflows and processes.

2. Managed (or under development)

⁴ National eHealth Transition Authority, Australia, (2007). NEHTA Interoperability Framework.

URL <http://www.nehta.gov.au/connecting-australia/ehealth-interoperability>

- Initial accomplishment of certain mHealth interoperability goals, such as adoption of defined eHealth and interoperability standards;
- Initial, shared understanding of data, services or internal processes;
- Initial governance framework in place;
- Workflows and processes documented and implemented and providing access points between services;
- At an institutional level, identification of areas where services interact with defined institutional aspects such as social or regulatory aspects.

3. Defined

- Organization has a defined set of guidelines for the adoption of mHealth standards for data, services and processes, according to lessons learned from previous maturity levels;
- Explicit focus on policy and legal compliance;
- Governance is well defined and defined levels of organizational readiness for interoperability outcomes are established;
- Communication standards for interaction with internal and external partners are established, supported by adherence to international interoperability profiles, and with data fully mapped to published standard terminologies or national terminologies;
- Supporting organizational structures facilitating a shared understanding across technical and semantic issues are also in place.

4. Measured

- Organizations have established processes for appraising and measuring mHealth interoperability before the system is deployed such as through conformance and compliance activities or during the operation of the system, i.e. run-time monitoring
- Technical interoperability layer functions as part of a backend system with other services including eHealth and registry services;
- Data is consumed by additional internal and external services utilizing the mapping of data and workflows/processes within the service.

5. Optimized

- Organization has implemented processes to support continuous interoperability improvements, driven by feedback from monitored processes, with the aim of improving overall mHealth interoperability capability.

Health Interoperability and Information Exchange Solutions

At least two solutions for interoperability and health information exchange have been developed and applied to maternal mHealth in low resource settings, (i) the Mobile Technology for Community Health⁵ (MoTeCH) suite, and; (ii) the Rwanda Health Information Exchange (RHIE) and Open Health Information Exchange⁶ (OpenHIE).

⁵ <http://motechsuite.org/>

⁶ <http://ohie.org>

Mobile Technology for Community Health

The MoTeCH suite of mHealth tools was one of the first approaches to provide common services for mHealth. The application has been applied to five key functional areas: (i) improving demand for health services; (ii) managing patient data; (iii) improving front-line worker performance; (iv) managing the last-mile supply chain, and; (v) tracking patient compliance with treatment [17].

The MoTeCH system was piloted and is operational in a district of the Upper East Region in Ghana [8], where it supports community healthcare by leveraging low cost mobile devices. The technology stack leverages existing applications that have been previously used in African countries, including OpenXData⁷, OpenMRS⁸ and IntellivR⁹. OpenXData is used for mobile phone data collection while OpenMRS is used to maintain personal health information, centrally. Finally IntellivR delivers voice messages using interactive voice response (IVR) that are, for example, used to inform patients about best health practices and to give them appointment reminders. Using these applications MoTeCH allows for the integration of patient-centric healthcare data from mobile phones, an electronic medical record system and IVR messages.

MoTeCH is an application stack comprising the following elements [8]:

1. SMS gateway
2. IVR system
3. M-forms upload adapter
4. Outbound message processor
5. Inbound message processor
6. Web forms
7. Reports
8. Event engine
9. Messaging

Rwanda Health Information Exchange and Open Health Information Exchange

The Rwanda Health Information Exchange¹⁰ (RHIE) [18] focuses on the implementation of a national health information exchange focused on maternal health [18]. It is currently implemented in the National Data Centre in Kigali and serves maternal care in the Rwamagana district in Rwanda.

The architecture is based around a set of national registries that are accessed by distributed clinic and mobile systems in order to enable the access and exchange of a mother's antenatal care record.

⁷ www.openxdata.org

⁸ www.openmrs.org

⁹ www.yo.co.ug

¹⁰ <https://jembiprojects.jira.com/wiki/display/RHEAPILOT/RHIE+Architecture+Documentation>

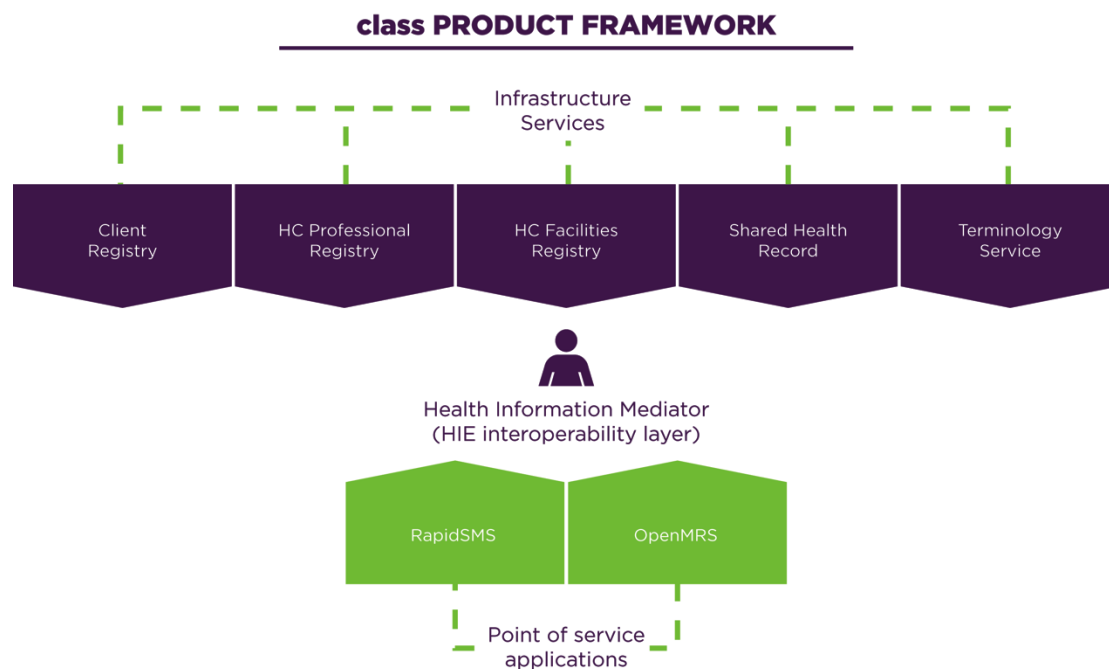


Figure 4. Logical Structure of the Rwanda Health Information Exchange

The components of the exchange are as follows:

- Health Information Mediator: Facilitates interoperability and provides a central point of control for the national registries
- Client Registry: A Master Patient Index (MPI)
- HC Professional Registry: A database of healthcare providers
- HC Facilities Registry: A database of facilities
- Terminology Service: Identifies and provides authority on the standardized code sets in use
- Shared Health Record: A repository storing a patient's clinical encounters
- Point of Service Applications: The client systems in the exchange

The Rwanda architecture has been generalized to the OpenHIE¹¹ [19] with a focus on the creation of an open architecture for health information exchange. Beginning with the RHIE architecture, a number of sub-communities were formed, representing each component type.

OpenHIE focuses on architecture, inter-registry workflows and recommendations for standards and tools.

Logical Architecture for Maternal mHealth Interoperability

Maternal mHealth Information Exchange

The logical architecture of a maternal mHealth information exchange (mMHIE) is shown in Figure 5 below. The architecture is based on an interoperability framework elaborated in the Canada Health Infoway EHRS Blueprint

¹¹ <http://ohie.org>

[20] and Health Normative Standards Framework for Interoperability in eHealth in South Africa (HNSF) [21]. The Demographic and Clinical Repositories and Health Information Exchange are based on the design of the Rwanda Health Information Exchange [18] and the Open Health Information Exchange.

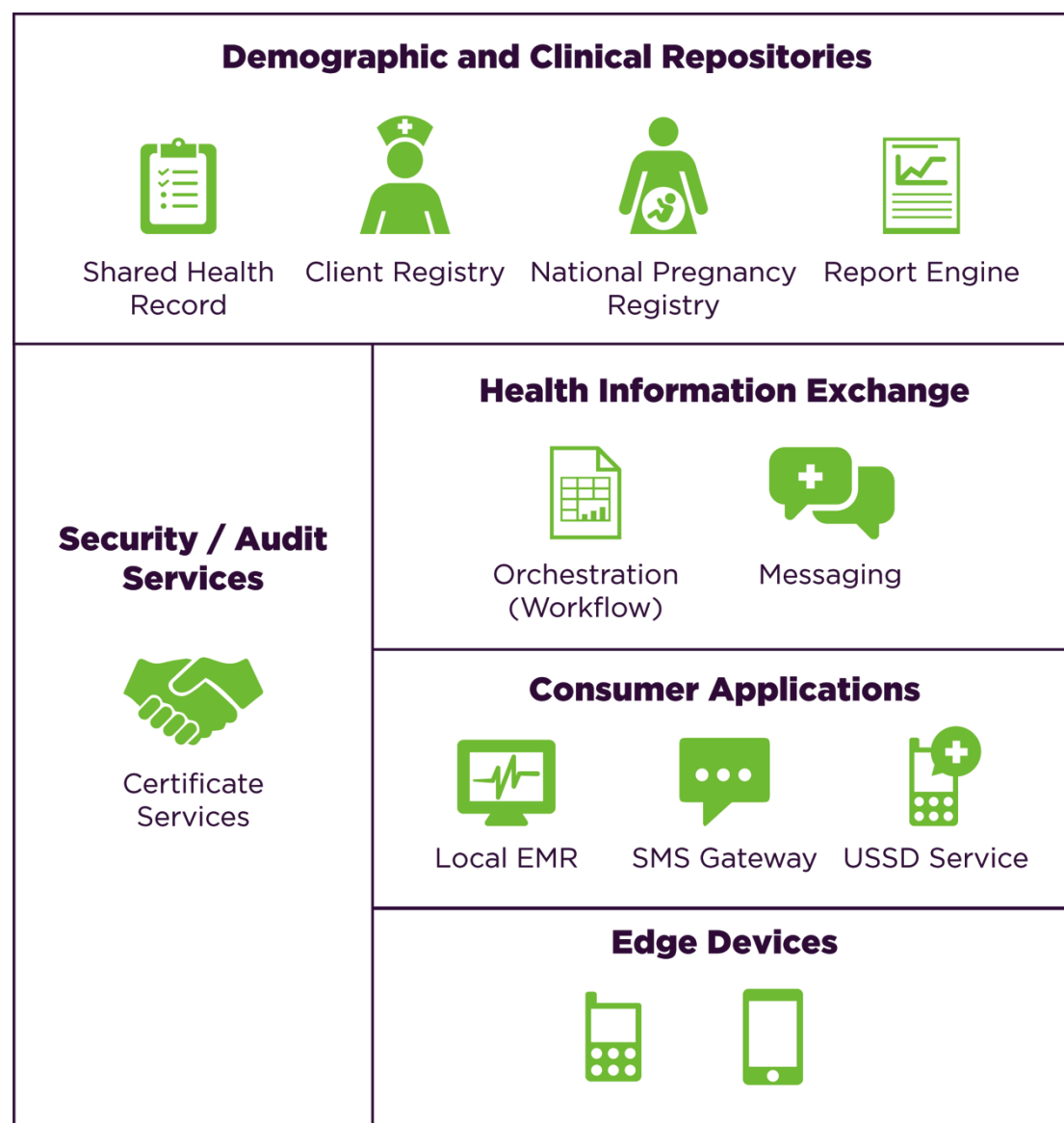


Figure 5. Logical Architecture of a maternal mHealth Information Exchange modeled on the architecture specified in the HNSF [21]

The elements of the P&T Framework reuse the architecture in the HNSF [21], as follows:

- **Edge Devices** include mobile phones and other computing devices that are responsible for collecting, collating and transmitting data to the Consumer Applications.
- **Consumer Applications** include mHealth applications and services providing value-added services to end-users. These could include electronic medical record (EMR) services.

- **Health Information Exchange** is a centralized platform. Technical implementation of the HNSF is responsible for providing a single interoperability layer to receive and send messages in a well-specified, standard format between Consumer Applications and Demographic and Clinical Repositories.
- **Demographic and Clinical Repositories** are centralized repositories of information and functionality, including the national pregnancy registry (NPR) that stores demographic details of pregnant women as well as Client, Provider and Facility registries.
- **Security / Audit Services** include basic certificates and encryption to ensure the security of the messages being passed through the system.

Maternal mHealth Workflows and Business Processes

mHealth business functions are generic business functions that add value to health. The functions can be obtained by mapping existing health services and requirements as well as existing software mHealth products and solutions that have been successfully deployed in South Africa and other low resource settings. A comprehensive list of maternal eHealth processes is detailed in the HNSF [21] (Appendices I-L).

Specific business processes include the following:

1. Register a pregnant woman
2. Identify a pregnant woman
3. Subscribe a pregnant woman
4. Stage a pregnancy
5. Monitor ANC attendance
6. Send pregnancy messages
7. Send alerts and reminders
8. Pre-register a pregnant woman

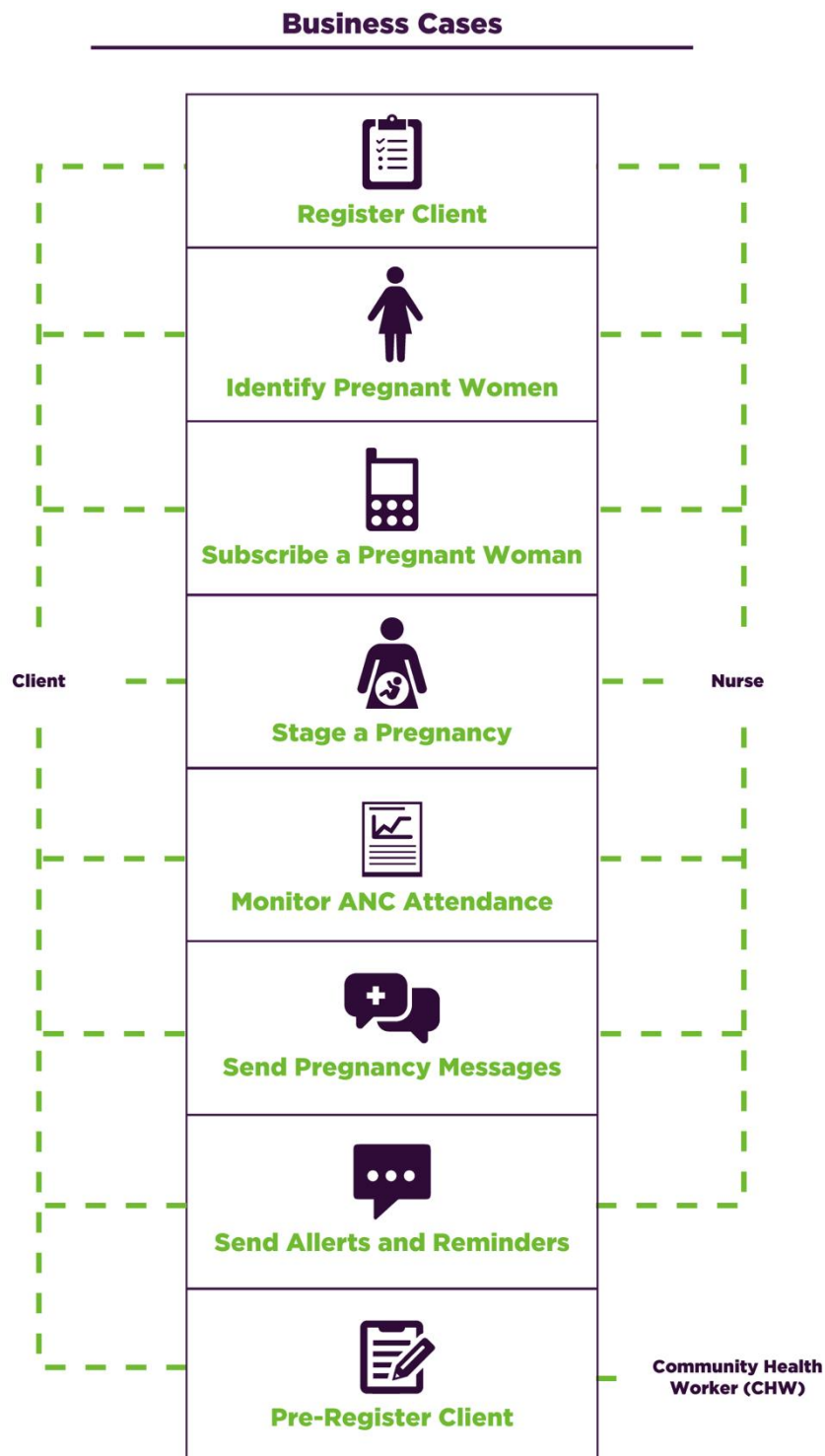


Figure 6. Business Use Cases

Several workflows can be supported by this architecture including those where mobile phones can be used to improve identification of pregnant women and facilitate the sending of informational messaging to pregnant women. Representative examples of these workflows include the following:

General Individual Subscription

Following a prompt (promotional message, etc.), a pregnant woman decides to subscribe to receive health promotion messaging during her pregnancy. She dials a dedicated short code or downloads a mobile application

and submits basic information about herself (cellular phone number, acknowledgement of suspicion of pregnancy etc.) to the mHealth service provider. The system then sends an acknowledgement confirming her subscription to receive health promotion messages, including an opt-out dialing code. The main message will be encouragement to go to the clinic to receive care and get registered.

Clinic Registration

A woman visits an ANC facility. Her suspected pregnancy is confirmed by means of a diagnostic test. During the visit, the nurse advocates and the woman consents to register her pregnancy on a national pregnancy registry that will enable her to receive health promotion messages using her own mobile phone. If the woman does not have a phone, the nurse may use the nurse's own or another (e.g. facility) phone to register the woman. Using USSD, SMS or a mobile application the nurse enters basic information about the pregnant woman including a unique identifier, her due date and a facility code that allows the system to identify at which clinic the registration took place. The pregnancy is confirmed. The nurse then completes the session by entering the client's language preference for messages. The system sends an acknowledgement confirming her registration and her subscription to receive health promotion messages, including the opt-out dialing code.

Remote Pre-Registration

In some cases clinicians (nurses) are based outside of health facilities (i.e. schools). In these cases nurses can either register or pre-register (identify) pregnant women. For example: A woman presents herself to the school nurse with health/pregnancy concerns. The nurse suspects that the woman is pregnant and either administers a pregnancy test or refers her to an ANC clinic. In the case of the former the nurse will confirm whether or not the young woman is pregnant and if the answer is yes she will register her following the clinic registration workflow. In the case of the latter, the nurse pre-registers the woman following the Community Health Worker (CHW) identification workflow (described below) and refers the woman to the health center for a pregnancy test. During the visit, the nurse advocates and consents the woman to record her pre-registration on the national suspected pregnancy registry and to simultaneously subscribe to receive health promotion messages using the woman's own phone.

Community Health Worker Identification

In this case, a CHW visits households within his/her catchment area and identifies a pregnant woman. During the visit, the CHW advocates and consents the woman to record her suspected pregnancy on a national suspected pregnancy registry and to simultaneously subscribe to receive health promotion messages using the woman's own phone. If the woman does not have a phone, the CHW may use his/her own or another phone (e.g. other household member phone). Once the woman agrees, the CHW enters data that uniquely identifies the woman by entering a unique identifier, basic information and the woman's language preference for messaging. At the end of the workflow, the system sends an acknowledgement after which an SMS is sent confirming her initiation and subscription to receive health promotion messages, including the opt-out dialing code.

In more complex mHealth service systems identification on the suspected pregnancy registry triggers a referral message sent to the mobile phone at the local health facility, making them aware that the individual was referred to the facility for a specific service. If the individual does not attend the referral a reminder is sent to the CHW who registered the individual to prompt follow up with the household.

It is also possible on some systems for the CHW to capture the woman’s due date and to establish what trimester she is in. This information can be inputted into the mHealth service and a schedule of notifications is created, including reminders to go to clinic and informational messaging.

Product Framework

Based on the above described architecture and workflows a generic framework for interoperable maternal mHealth (shown in Figure 7, below) has been developed.

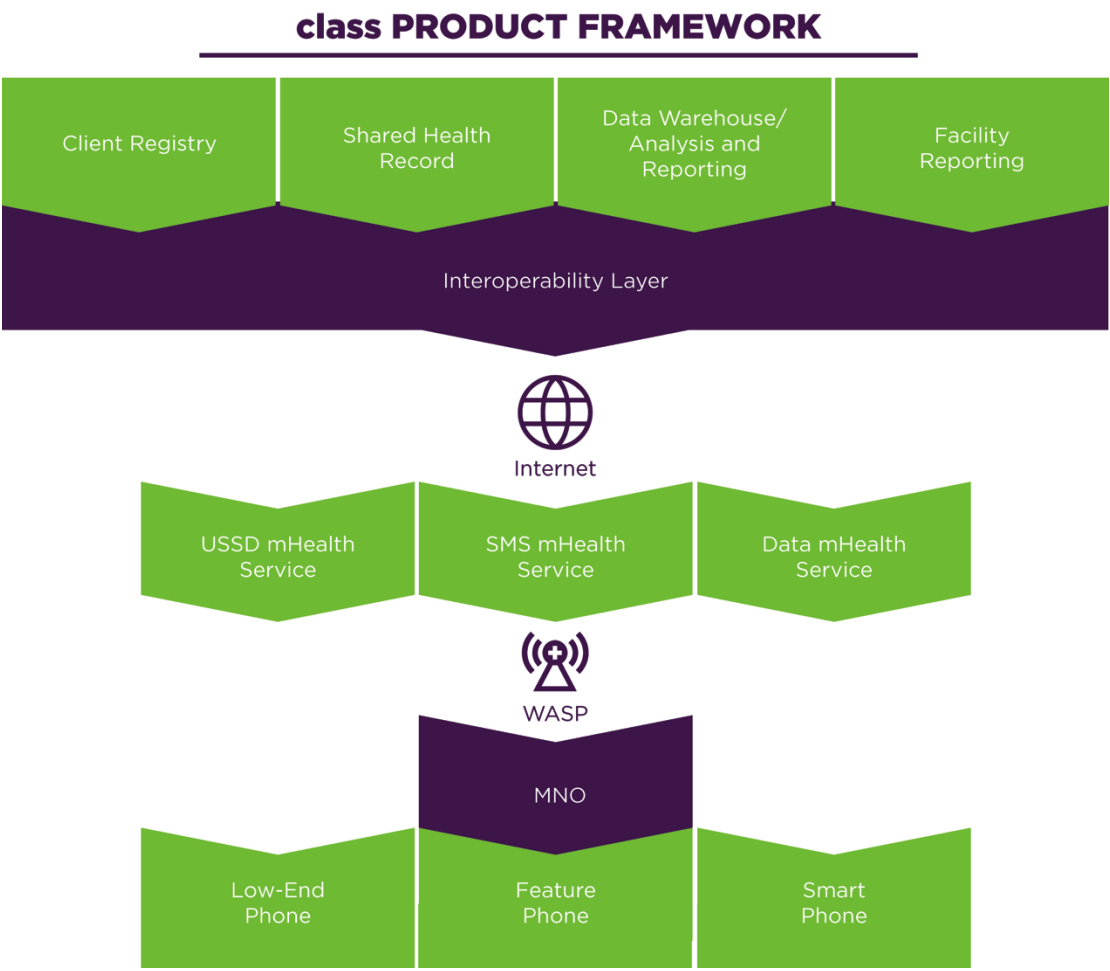


Figure 7. Generic Product Framework for Interoperable maternal mHealth

The generic product framework makes use of the maternal mHealth exchange to provide a measure of interoperability among different mHealth applications servicing different use cases. The system can be implemented incrementally, and successive services added over time.

The main mechanism for achieving this interoperability is through integration of data from the different applications. This serves to provide continuity between the different mHealth applications and also provides data for reporting as well as monitoring and evaluation, as shown in Figure 8, below.

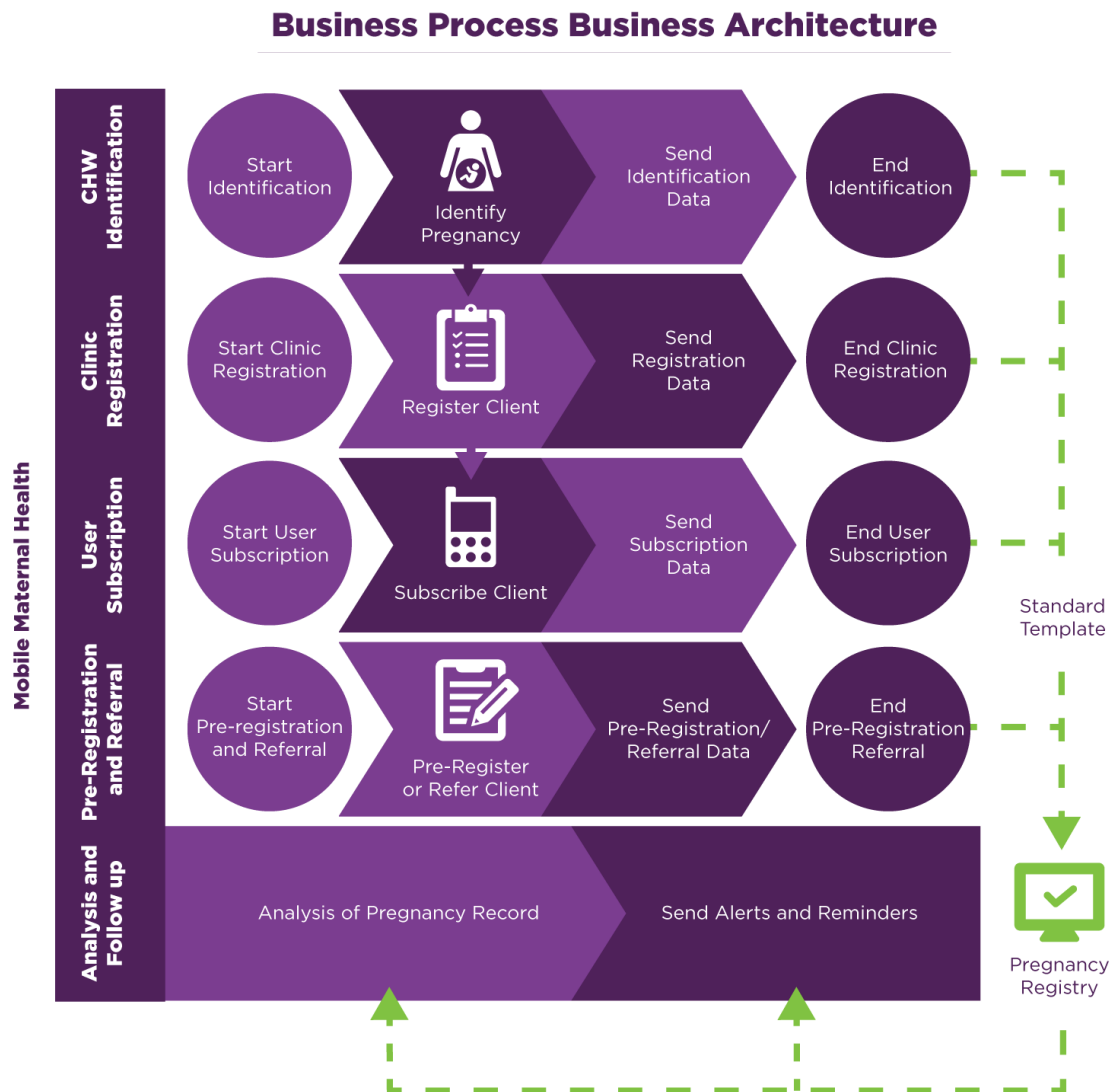


Figure 8. Process and Data Integration

TECHNOLOGY FRAMEWORK

Following the previous discussion of an mHealth Product Framework, this section next describes a generic Technology Framework for mHealth that seeks to realize the concepts of the product framework at a technological level, such as to provide the basis for an in-country implementation in a low resource setting. This technology framework is based on use cases from African countries and based on the OpenHIE framework.

Overview

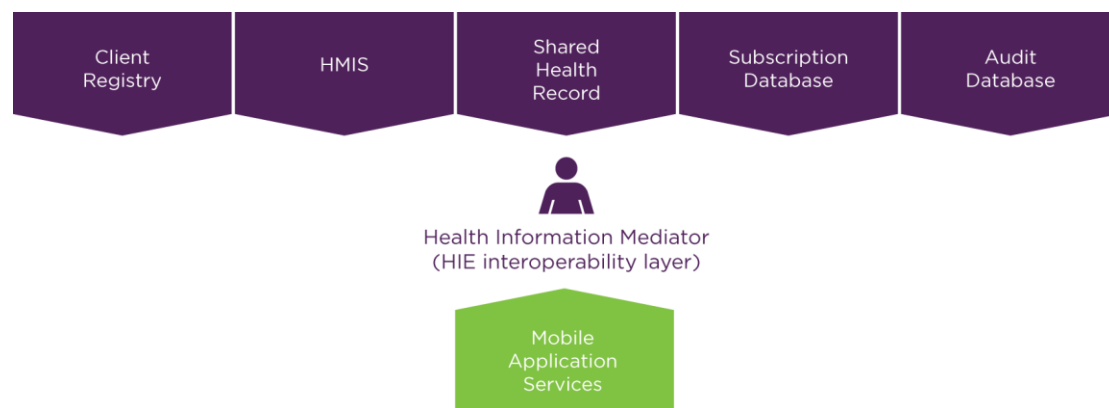


Figure 9. Logical view of a mHealth Information Exchange Architecture

The architecture presented here is designed around a set of national infrastructure components that facilitate the exchange and aggregation of healthcare information from disparate mobile application services, resulting in a platform for interoperability.

For each of the workflows, above, information is captured on a mobile device and sent to the national mHealth Information Exchange (mHIE). The components that form the national mHIE infrastructure are:

- a Health Information Mediator (HIM) that facilitates interoperability between systems and provides security and auditing (Audit Database),
- a Master Patient Index or Client Registry (CR) for managing the identities of patients, a Shared Health Record (SHR) that stores clinical encounters at a patient level, forming their national health record,
- a Subscription Database for capturing the information from the messaging subscription flow, and
- a Health Management Information System for providing reporting and tracking of registrations (HMIS).

Mobile Application Services

mHealth providers provide the applications and service infrastructure for capturing patient information.

Health Information Mediator

The HIM provides the primary access point for mobile application services accessing the exchange and forms a central point of control for the exchange. This component's role is to:

- Expose standards-based interfaces;
- Route transactions to target components and perform orchestrations (such as patient look-ups);
- Translate messages to infrastructure component specific interfaces, and;
- Provide security, auditing and monitoring.

Client Registry

The CR comprises a database of persons as well as functionality to manage their identities. Its role within the exchange is to:

- Resolve patient identifiers to a common Enterprise Client ID (ECID) that can be used across the exchange to uniquely identify patients;
- Store person demographic information, and;
- Perform matching in order to link patient records that are in fact a single person.

Shared Health Record

The SHR stores a patient's national health record. Its role is to:

- Store patient encounters and clinical observations such as estimated delivery date, and;
- Provide clinical decision support.

Subscription Database

The subscription workflow is not a clinical workflow and can be performed by a pregnant woman herself without any validation by a healthcare professional. Subscription data is therefore kept in a separate database within the exchange. Its role is to:

- Store subscription data, and;
- Triangulate with data from other person-based workflows.

HMIS

The HMIS provides for the capture of aggregated data and its reporting. Its role within the exchange is to:

- Manage and report on healthcare indicators;
- Provide facility management and validation, and;
- Aggregate patient-level data to a provincial and national level.

Standards used within the Technology Framework

Standards are a fundamental requirement for interoperability and a foundational pillar of any interoperability framework. The South African HNSF developed by the National Department of Health can be used as the basis for the development of a basic standards catalogue. mHealth standards could be considered as extending the standards and profiles covered in the HNSF.

Several different categories of standards could be considered for inclusion in the standards catalogue. The international standards that may be applicable within the generic framework and supported workflows are:

Foundational standards and terminologies

These are used to directly encode information or define the syntax and semantics of messages.

Terminology coding standards

These include

1. ICD-10. International Classification of Diseases. ICD-10 is used for all major disease and diagnostic coding in a number of African countries.
2. SNOMED CT. Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT).
The most comprehensive, multilingual clinical healthcare terminology in the world (<http://www.ihtsdo.org/snomed-ct/>)
3. LOINC –Logical Observation Identifiers Names and Codes is a database and universal standard for identifying medical laboratory observations, developed and is maintained by the Regenstrief Institute.

Messaging protocols /data transfer standards

These include

1. HL7 version 2, and;
2. HL7 version 3.

Interoperability profile standards

These standards describe patterns of application of foundational standards to achieve a particular interoperability goal.

IHE (Integrating the Healthcare Enterprise) profiles

Cross-Enterprise Document Sharing (XDS)¹²

XDS facilitates the registration, distribution and access to patient electronic health records across health enterprises. It is focused on providing a standards-based specification for managing the sharing of documents between any healthcare system and it is managed through federated document repositories and a document registry to create a longitudinal record of information about a patient within a given clinical affinity domain.

Mobile Access to Health Documents (MHD)¹³

The MHD profile defines a simple HTTP interface to an XDS like environment. It defines transactions to:

1. submit a new document and metadata from the mobile device to a document receiver;
2. get the metadata for an identified document;
3. find document entries containing metadata based on query parameters, and;
4. retrieve a copy of a specific document.

These transactions leverage the document content and format agnostic metadata concepts from XDS, but simplify them for access by constrained environments such as mobile devices. The MHD profile does not replace XDS. It can be used to allow mobile devices constrained access to an XDS health information exchange.

¹² http://wiki.ihe.net/index.php?title=Cross_Enterprise_Document_Sharing

¹³ http://wiki.ihe.net/index.php?title=Mobile_access_to_Health_Documents

Patient Administration Management (PAM) Integration Profile¹⁴

The PAM profile ensures that the applications involved in the health services provision or document sharing workflow of a particular domain, rely on synchronized and accurate patient demographic and encounter data. It specifies two transactions to fulfil two important objectives for applications cooperating in healthcare:

1. **Patient Identity Feed:** Maintain consistency of patient demographics (i.e. patient identification, full identity and persons related to the patient) across applications operating in different healthcare settings.
2. **Patient Encounter Management:** Coordinate the exchange of patient account, encounter and location information within and between applications.

Patient Identifier Cross-Reference (PIX/PDQ)¹⁵

PIX/PDQ provides cross-referencing of patient identifiers from multiple Patient Identifier Domains. These patient identifiers can then be used by identity consumer systems to correlate information about a single patient from sources that know the patient by different identifiers. This profile uses HL7 V2 as the message format.

Patient Demographics Query (PDQ)¹⁶

PDQ provides ways for multiple distributed applications to query a central patient information server for a list of patients based on user defined search criteria and retrieve a patient's demographic data. This profile uses HL7 V2 as the message format.

Document content standards - CDA (HL7v3 Clinical Document Architecture)¹⁷

The purpose of the Clinical Document Architecture (CDA) document is to capture clinical data about a patient. This can include clinical observations, allergy information and other information, such as estimated delivery date and a delivery date narrative. A CDA document consists of a header, which contains patient demographic information, provider details and other meta-data about a clinical encounter, and a body, which contains the clinical data. There are different levels of CDA interoperability, specifying the degree to which a document can be understood¹⁸.

Mapping of Standards and Profiles to the OpenHIE

IHE profiles and standards can be mapped to specific workflows and components of the mobile maternal HIE. **Figure 10** shows the logical structure of a CDA document and the levels of interoperability mapping to specific elements of the document. The levels of interoperability provide an implementor with a standards adoption path where one can start by providing support at level 1, and basic interoperability and work towards full semantic interoperability at level 3.

¹⁴ http://wiki.ihe.net/index.php?title=Patient_Administration_Management

¹⁵ http://wiki.ihe.net/index.php?title=Patient_Identifier_Cross-Reference_HL7_v3

¹⁶ http://wiki.ihe.net/index.php?title=Patient_Demographics_Query_HL7_v3

¹⁷ http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

¹⁸ <http://www.hl7standards.com/blog/2011/06/02/cda-levels-of-interoperability/>

Degree of interoperability

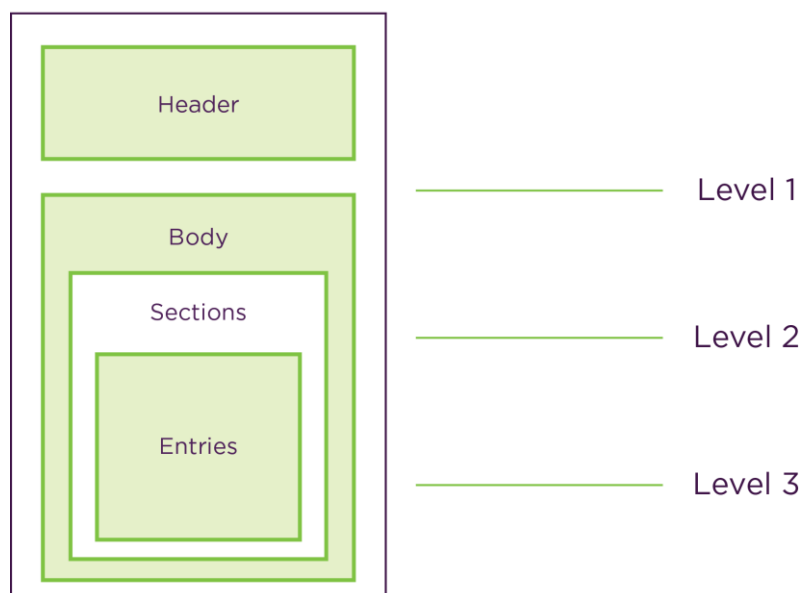


Figure 10. CDA Structure and Interoperability Levels

Workflows

Workflows realize the main use-cases of the pregnancy registry architecture. The core workflows making up the exchange, in this example, are:

- Registration of a pregnant woman by a healthcare worker in a clinical or non-clinical setting;
- Identification of pregnant woman by a community health worker, and;
- Subscription of a pregnant woman to a messaging service.

Various patient administration flows support the administration of patient records, including

- Updating of patient demographics and identifiers,
- Capture of deliveries, and
- Updating of a woman's clinical status such as termination of pregnancy or miscarriage.

Registration and Identification

In addition to basic patient demographic information, such as date of birth, a clinical registration can also capture a pregnancy status along with a delivery date, such as an estimated delivery date. Since a clinical observation is being captured, the registration encounter provides the opportunity for starting a patient's shared health record. A registration can therefore be captured as a clinical encounter and modeled using CDA.

Demographic data can be captured in the CDA header, along with information such as the healthcare provider, facility and encounter date. Meanwhile the pregnancy status and delivery date can be expressed as a clinical statement in the document. The MHD profile can be used by mobile application services in order to send registration documents through to the back-end infrastructure.

Figure 11 illustrates the process of capturing a registration modeled as a “Save Clinical Encounter” transaction. A mobile application provider would capture a registration using an appropriate method, such as with a mobile application or a USSD service. They would then submit the registration to the exchange infrastructure using an MHD transaction to send through a CDA document capturing the details of the registration (the combination of MHD and CDA which we will refer to as MHD+CDA).

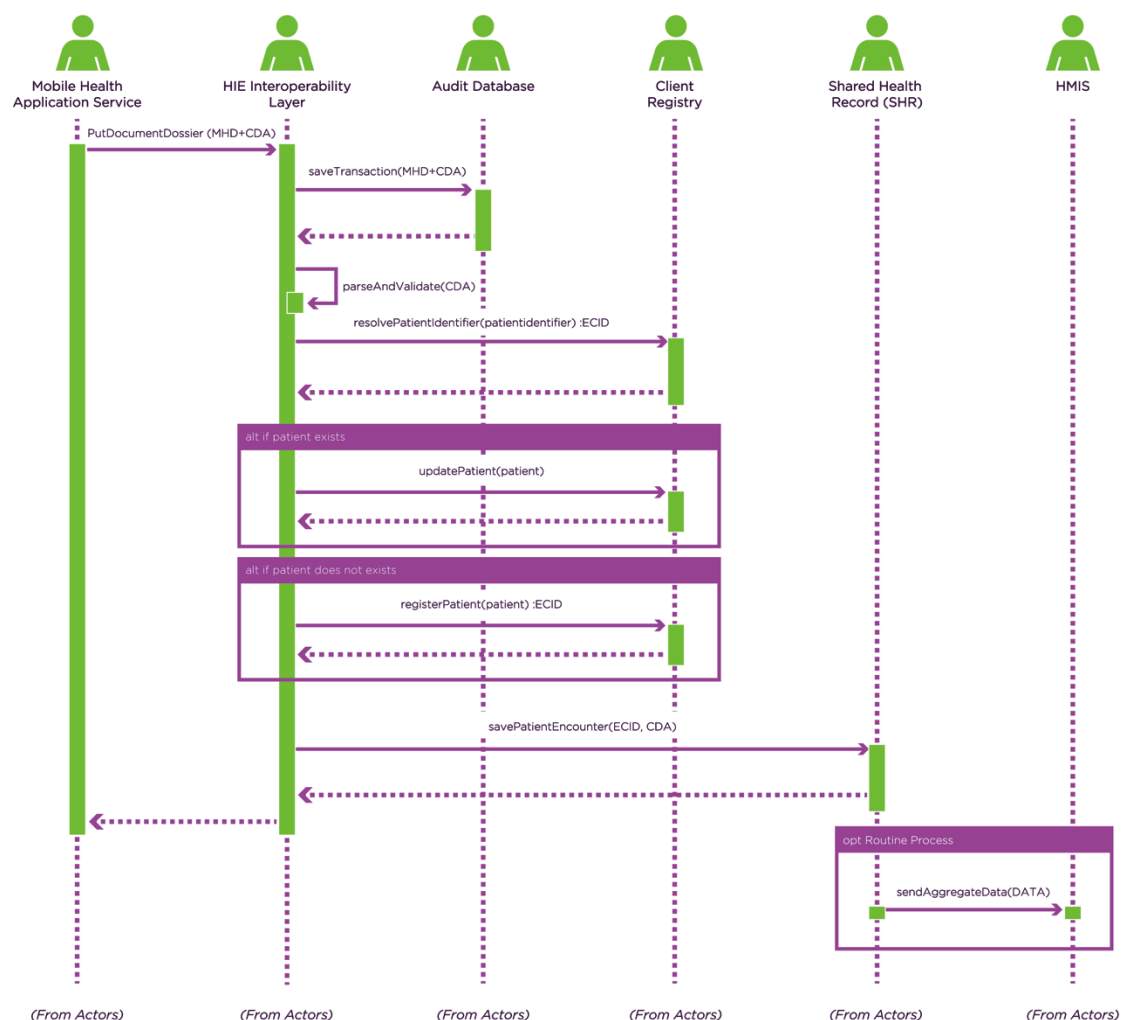


Figure 11. Registration/Identification Sequence Diagram

Upon receipt, the HIM will audit the transaction and then proceed to parse and validate the MHD metadata as well as the CDA document¹⁹, in particular retrieving the patient identifier.

Next the HIM will either create a new patient entry in the Client Registry using the patient's demographic data, or update their entry if it already exists. The PIX profile can be used to query the Client Registry and see if the patient's record exists, while the PAM profile can be used to add/update the patient entry.

In this model the mobile application services only need to send a clinical encounter and do not enter the patient data themselves in the Client Registry, as the HIM takes on this role. However, it is also possible to push the burden of

¹⁹ Note that in this model the CDA document would only need to be parsed at level 1. This means that only the document header needs to be “understood” by the HIM.

adding a patient to the mobile application service. In this case they would need to use the PIX/PDQ/PAM profiles to first ensure that the patient exists in the Client Registry before sending registration messages. The HIM would then simply reject any messages where the patient does not exist.

The HIM will retrieve an Enterprise Client ID (ECID) for the patient from the Client Registry. This identifier will be used throughout the exchange, and especially in the Shared Health Record, for uniquely identifying the patient. It is therefore the Client Registry's task to map other identifiers, such as a national ID or passport number, to an ECID. The mapping of identifiers to an ECID is important so that patients can be unambiguously identified and allows for the use of multiple identifier types by mobile application services.

The last step in the flow is to save the encounter in the Shared Health Record using the patient ECID. This data should be routinely be aggregated and submitted to the HMIS system for reporting, but this process can be asynchronous.

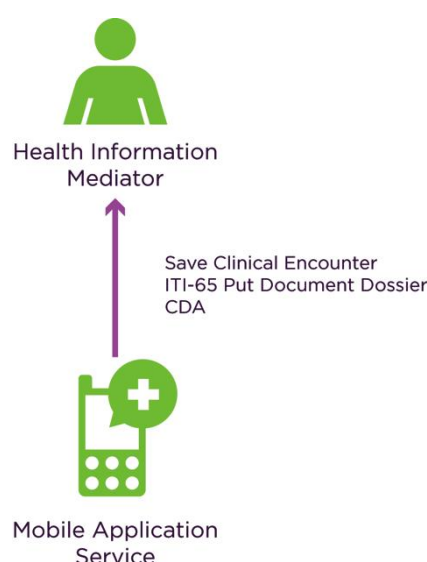


Figure 12. Put Document Dossier

The ITI-65 transaction from the MHD profile can be used by mobile application services for sending the encounters. Both the registration and identification workflows can be captured using MHD+CDA as described, the only difference between the two workflows is that the registration will capture a confirmed pregnancy (for example using the code **SNOMED CT 77386006** for coding the pregnancy status), while for identification the pregnancy is unconfirmed (for example using the code **SNOMED CT 102874004**).

Data Fields

A registration encounter should at a minimum capture a suitable identifier for a patient along with demographic information and a delivery date. In addition an identifier for the healthcare provider should be captured as well along with a code identifying the facility.

A minimum data field set could be as follows:

Field	Description
Identifier	An unique identifier for a patient such as their national ID or passport number
MSISDN	The mobile phone number stored inside the handset smart card
Date of Birth	The Client's Date of Birth
Name(s)	The given and family names of the Client
Provider ID	An unique identifier for the healthcare provider such as their national ID or passport number
Facility Code	An unique code identifying the healthcare facility
Language Preference(s)	The language in which the Client wishes to receive messages
Encounter Date/Time	The date and time that the data for this encounter is recorded and sent
Pregnancy Status	Mainly depends on the workflow, but options such as "delivered" or "terminated" may also be necessary
Delivery Date	A date of delivery such as an Estimated Delivery Date (EDD)

Table 2. Registration/Identification Data Fields

Subscription

Subscription refers to the workflow whereby a pregnant woman subscribes to a mobile messaging service. This workflow doesn't involve an interaction with a healthcare worker and therefore the mother's pregnancy and her identity cannot be confirmed. Therefore data from a subscription message cannot contribute to a patient's shared health record (SHR). Subscriptions should be captured separately from registrations and identifications and custom messages can be used rather than MHD+CDA messages.

Figure 13 illustrates the process of capturing a subscription message from a mobile application service. In this scenario, the mobile application service would provide an appropriate mechanism that a person could interact with, for example using USSD services, and then formatting the captured message into an acceptable format and sending the subscription through to the HIM.

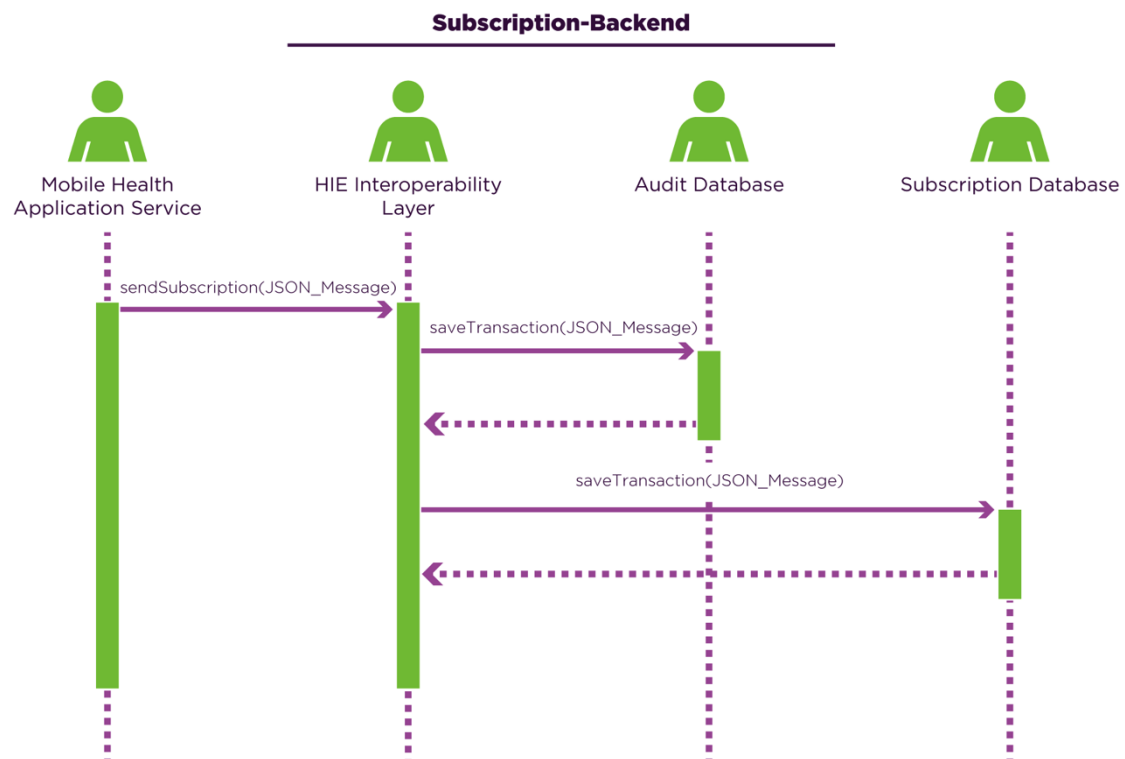


Figure 13. Subscription Sequence Diagram

The data fields do not need to be as comprehensive as with the registration workflow. At a minimum the mobile number, language preference and delivery date should be captured. The delivery date is important in order to provide stage-based messaging.

Patient Administration

It is crucial in any health information system to cater for the updating of a patient's details and health information, such as their demographics or amending a clinical encounter. In this section we briefly look at these flows.

Update Patient Demographics

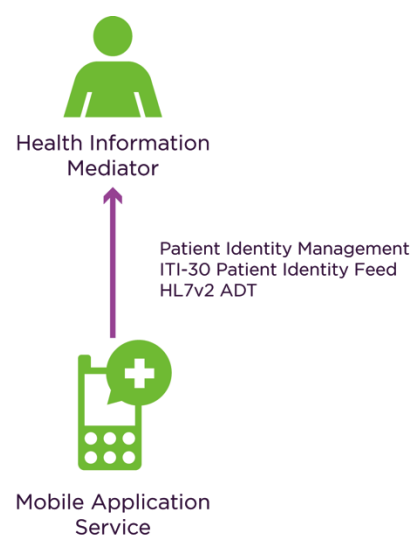


Figure 14. Patient Identity Management

The Patient Administration Profile (PAM) can be implemented by systems in order to send and process update demographics transactions. The profile specifies the use of HL7 ADT messages for capturing these transactions. To implement a demographics update message, a mobile application service needs to capture a patient's updated demographic information and send an ADT transaction to the HIM, which in turn will forward the transaction to the Client Registry.

The ITI-30 Patient Identity Feed transaction can be used to transmit patient demographic information and updates are here sent via an HL7 A31 trigger with an ADT^A31^ADT_A05 message.

Amending Clinical Encounters

It may happen that the clinical information captured in a registration or identification is incorrect and needs to be amended. An example of such an event would be if an incorrect estimated delivery date were captured. In this scenario a mobile application service can send a CDA document capturing the corrected details. The new document would have to include a reference to the original document, stating that it replaces the information found there. Document relationships can be captured in CDA using the related Documents tag with a REPL (replace) type code.

Follow-up Encounters

Although the capture of antenatal visits and comprehensive labor and delivery summaries is out of scope for this document, additional encounters updating the patient's clinical status is essential. For example a delivered status or other events, such as miscarriages, would need to be captured. These events can be captured as new CDA documents with clinical statements in the CDA body to express the status change.

The following xml examples illustrate clinical statements expressing delivery narratives in CDA. The statements capture the pregnancy status and delivery date. For reference we first illustrate clinical statements for confirmed and unconfirmed pregnancies such as would need to be captured for registrations and identifications, and then we illustrate a clinical statement capturing a delivery date.

Pregnancy Confirmed (Registration)

```
<entry>
  <!-- Pregnancy Status -->
  <observation classCode="OBS" moodCode="EVN">
    <code code="11449-6" displayName="Pregnancy status"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <text/>
    <statusCode code="completed"/>
    <effectiveTime value="20140217"/>
    <value xsi:type="CE" code="77386006" displayName="Pregnancy confirmed"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
    <entryRelationship typeCode="SPRT" inversionInd="true">
      <!-- Delivery Date -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="11778-8" displayName="Delivery date Estimated"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <text/>
        <statusCode code="completed"/>
        <value xsi:type="TS" value="20141017"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>
```

Pregnancy Unconfirmed (Identification)

```
<entry>
  <!-- Pregnancy Status -->
  <observation classCode="OBS" moodCode="EVN">
    <code code="11449-6" displayName="Pregnancy status"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <text/>
    <statusCode code="completed"/>
    <effectiveTime value="20140217"/>
    <value xsi:type="CE" code="102874004" displayName="Unconfirmed pregnancy"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
    <entryRelationship typeCode="SPRT" inversionInd="true">
      <!-- Delivery Date -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="11778-8" displayName="Delivery date Estimated"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <text/>
        <statusCode code="completed"/>
        <value xsi:type="TS" value="20141017"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>
```

vPatient Delivered

```
<entry>
  <!-- Pregnancy Status -->
  <observation classCode="OBS" moodCode="EVN">
    <code code="11449-6" displayName="Pregnancy status"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
    <text/>
    <statusCode code="completed"/>
    <effectiveTime value="20140217"/>
    <value xsi:type="CE" code="289256000" displayName="Mother delivered"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
    <entryRelationship typeCode="SPRT" inversionInd="true">
      <!-- Delivery Date -->
      <observation classCode="OBS" moodCode="EVN">
        <code code="397836004" displayName="Time of delivery"
codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
        <text/>
        <statusCode code="completed"/>
        <value xsi:type="TS" value="20141017"/>
      </observation>
    </entryRelationship>
  </observation>
</entry>
```

Save Clinical Encounter Example Template

As described, a registration or identification can be captured as a clinical encounter using CDA+MHD. This section provides sample templates that describe such an encounter.

Note that the templates are purely provided for illustrative purposes and are presented as a guideline and starting point for modeling documents for use in a real world implementation.

CDA Template

The following template specifies the CDA document structure that could be used for capturing a registration or identification encounter. The relevant fields that need to be captured are identified with parameters (e.g. `{createdTime}`) needs to be replaced with a value such as 20140217121212).

Person Note CDA Template

```
<?xml version="1.0"?>

  <ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:cda="urn:hl7-org:v3"
xmlns:voc="urn:hl7-org:v3/voc" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:pcc="urn:ihe:pcc:hl7v3" xmlns:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
xmlns:sdtc="urn:hl7-org:sdtc" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="2.16.840.1.113883.10" extension="IMPL_CDAR2_LEVEL1"/>
  <id root="{uniqueId}"/>
  <code code="51855-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
  <title>Pregnancy Registration - Patient Note</title>
  <!-- Creation time of document, e.g. 20140217121212 -->
  <effectiveTime value="{createdTime}"/>
  <confidentialityCode code="N" displayName="Normal"
codeSystem="2.16.840.1.113883.5.25" codeSystemName="Confidentiality"/>
  <languageCode code="en-UK"/>
  <!-- Client details -->
  <recordTarget>
```

```

<patientRole>
  <!-- Patient Identifier -->
  <id extension="{patientId}" root="{patientIdAssigningAuthority}"/>
  <!-- Telephone number in RFC3966 format, e.g. tel:+27731234567 -->
  <telecom value="tel:{cellNumber}"/>
  <patient>
    <name>
      <given>{givenName}</given>
      <family>{familyName}</family>
    </name>
    <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
    <!-- Format yyyy[MM[dd]] e.g. 19700123 or 197001 for an estimated date -->
    <birthTime value="{birthDate}"/>
    <languageCommunication>
      <languageCode code="{languageCode}"/>
      <preferenceInd value="true"/>
    </languageCommunication>
  </patient>
</patientRole>
</recordTarget>
<!-- HCW Details -->
<author>
  <time value="{time}"/>
  <assignedAuthor>
    <id extension="{hwcCode}" root="833f2856-b9e1-4f54-8694-c74c4283755f"
assigningAuthorityName="HCW Code"/>
    <telecom value="tel:{cellNumber}"/>
    <assignedPerson>
      <name>
        <given>{hwcGivenName}</given>
        <family>{hwcFamilyName}</family>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id extension="{facilityCode}" root="9a560d61-85f1-4d7b-8ee2-
090d2900f836"/>
    </representedOrganization>
  </assignedAuthor>
</author>
<author>
  <time value="{time}"/>
  <assignedAuthor>
    <id root="9a560d61-85f1-4d7b-8ee2-090d2900f836"/>
    <assignedAuthoringDevice>
      <code code="{mobileHealthApplicationCode}" codeSystem="56877fb7-e3a9-4ad5-
bfb5-64d48a045e83"/>
      <softwareName>{softwareName}</softwareName>
    </assignedAuthoringDevice>
  </assignedAuthor>
</author>
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="a5881e6c-b42e-4559-a1fd-d1dc52379658"/>
      <name>Ministry of Health</name>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
<documentationOf>
  <serviceEvent classCode="PCPR">

```



```

        <effectiveTime value="\${encounterDateTime}"/>
    </serviceEvent>
</documentationOf>
<component>
    <structuredBody>
        <component>
            <section>
                <code code="57060-6" displayName="Estimated date of delivery Narrative"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                <text>
                    <table>
                        <thead>
                            <tr>
                                <td>Pregnancy status</td>
                                <td>Note Date</td>
                                <td>Delivery Date (Estimated)</td>
                            </tr>
                        </thead>
                        <tbody>
                            <!-- e.g. -->
                            <tr>
                                <td>Pregnancy confirmed</td>
                                <td>2014-02-17</td>
                                <td>2014-10-17</td>
                            </tr>
                        </tbody>
                    </table>
                </text>
                <entry>
                    <!-- Pregnancy Status -->
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="11449-6" displayName="Pregnancy status"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                        <text/>
                        <statusCode code="completed"/>
                        <!-- e.g. 20140217 -->
                        <effectiveTime value="\${effectiveTime}"/>
                        <!-- one of 'value' -->
                        <value xsi:type="CE" code="77386006" displayName="Pregnancy
confirmed" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
                        <!--<value xsi:type="CE" code="102874004"
displayName="Unconfirmed pregnancy" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT"/>-->
                        <!--<value xsi:type="CE" code="60001007" displayName="Not
pregnant" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>-->
                        <!--<value xsi:type="CE" code="289256000" displayName="Mother
delivered" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>-->
                        <!-- Remove entryRelationship if 'Not pregnant' -->
                        <entryRelationship typeCode="SPRT" inversionInd="true">
                            <!-- Delivery Date -->
                            <observation classCode="OBS" moodCode="EVN">
                                <!-- one of 'code' -->
                                <code code="11778-8" displayName="Delivery date
Estimated" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                                <!-- <code code="8665-2" displayName="Last menstrual
period start date" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/> -->
                                <!-- Delivery Date (if 'Mother Delivered') -->
                                <!-- <code code="397836004" displayName="Time of
delivery" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT "/> -->
                                <text/>
                                <statusCode code="completed"/>

```

```

        <!-- e.g. 20141017 -->
        <!-- use yyyyMM if only estimated up to month level -->
        <value xsi:type="TS" value="{date}"/>
    </observation>
</entryRelationship>
</observation>
</entry>
</section>
</component>
</structuredBody>
</component>
</ClinicalDocument>

```

CDA Header

The CDA header describes the type of document and captures the mother's demographic details, as well as that of the health worker.

Document Type and Creation Time

```

<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<templateId root="2.16.840.1.113883.10" extension="IMPL_CDAR2_LEVEL1"/>
<id root="{uniqueId}"/>
<code code="51855-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
<title>Pregnancy Registration - Patient Note</title>
<!-- Creation time of document, e.g. 20140217121212 -->
<effectiveTime value="{createdTime}"/>
<confidentialityCode code="N" displayName="Normal"
codeSystem="2.16.840.1.113883.5.25" codeSystemName="Confidentiality"/>
<languageCode code="en-UK"/>

```

The various identifiers, templates and codes in the header identify the document type and confidentiality. A document must be uniquely identified by a unique id. This id must be generated by the sender and take the form of an OID. See [Appendix B](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2x.pdf) in http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2x.pdf for details.

The creation time of the document is captured by the effectiveTime element and should be in ISO8601 format (yyyyMMddHHmm[ss][+|-ZZzz]). Note that this element captures the date and time that the actual CDA was created, not the encounter date and time (which is captured elsewhere in the header).

Patient Details

```

<!-- Client details -->
<recordTarget>
    <patientRole>
        <!-- Patient Identifier -->
        <id extension="{patientId}" root="{patientIdAssigningAuthority}"/>
        <!-- Telephone number in RFC3966 format, e.g. tel:+27731234567 -->
        <telecom value="tel:{cellNumber}"/>
        <patient>
            <name>
                <given>{givenName}</given>
                <family>{familyName}</family>
            </name>
            <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1"/>
            <!-- Format yyyy[MM[dd]] e.g. 19700123 or 197001 for an estimated date -->

```

```

        <birthTime value="\${birthDate}"/>
        <languageCommunication>
            <languageCode code="\${languageCode}"/>
            <preferenceInd value="true"/>
        </languageCommunication>
    </patient>
</patientRole>
</recordTarget>

```

The recordTarget element identifies the subject of care for the document, in this case the pregnant woman. The following fields need to be captured:

- Patient identifier
- The mother's cellphone number in RFC3966 format.
- The mother's given and family names.
- Gender.
- The mother's birthdate in ISO8601 format (yyyyMMdd). If only the mother's age is known or the date of birth is estimated, then the value should be truncated to a year or year/month value (yyyy[MM]).
- Primary language preference. Should be specified as a 2-letter ISO 639 language code.

Healthcare Worker Details

```

<!-- HCW Details -->
<author>
    <time value="\${time}"/>
    <assignedAuthor>
        <id extension="\${hwcCode}" root="833f2856-b9e1-4f54-8694-c74c4283755f"
assigningAuthorityName="HCW Code"/>
        <telecom value="tel:\${cellNumber}"/>
        <assignedPerson>
            <name>
                <given>\${hwcGivenName}</given>
                <family>\${hwcFamilyName}</family>
            </name>
        </assignedPerson>
        <representedOrganization>
            <id extension="\${facilityCode}" root="9a560d61-85f1-4d7b-8ee2-
090d2900f836"/>
        </representedOrganization>
    </assignedAuthor>
</author>

```

The healthcare worker's details are captured similarly to the mother's details. In addition, the following fields need to be captured:

- The time the document was authored by the provider (time). This will likely be the same value as encounterDateTime described in the next section. The field is however available should this not be the case.
- Facility id.

mHealth Application Provider

```
<author>
  <time value="${time}"/>
  <assignedAuthor>
    <id root="9a560d61-85f1-4d7b-8ee2-090d2900f836"/>
    <assignedAuthoringDevice>
      <code code="${mobileHealthApplicationCode}" codeSystem="56877fb7-e3a9-4ad5-
bfb5-64d48a045e83"/>
      <softwareName>${softwareName}</softwareName>
    </assignedAuthoringDevice>
  </assignedAuthor>
</author>
```

The mobileHealthApplicationCode and softwareName fields can be used to identify the mobile provider and software stack used to capture the encounter.

Encounter Date

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="a5881e6c-b42e-4559-a1fd-d1dc52379658"/>
      <name>Ministry of Health</name>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
<documentationOf>
  <serviceEvent classCode="PCPR">
    <effectiveTime value="${encounterDateTime}"/>
  </serviceEvent>
</documentationOf>
```

The last few elements in the header simply identify the custodian of the document and capture the date and time of the encounter.

CDA Body

The document body captures clinical observations for the patient.

Estimated Date of Delivery Narrative

The delivery date narrative section describes the patient's delivery date as it relates to her pregnancy status. The narrative consists of a text section as well as a coded entry section.

Text

```
    <text>
      <table>
        <thead>
          <tr>
            <td>Pregnancy status</td>
            <td>Note Date</td>
            <td>Delivery Date (Estimated)</td>
          </tr>
        </thead>
        <tbody>
          <!-- e.g. -->
```

```

        <tr>
            <td>Pregnancy confirmed</td>
            <td>2014-02-17</td>
            <td>2014-10-17</td>
        </tr>
    </tbody>
</table>
</text>

```

Any content in this section is treated as "free" text and is designed to be rendered to a human user. This is in contrast to the coded contents in the entry section which is designed to be machine processable. The content listed in the template is only an example and any content appropriate to the delivery narrative may be entered.

Coded Entry

```

<entry>
    <!-- Pregnancy Status -->
    <observation classCode="OBS" moodCode="EVN">
        <code code="11449-6" displayName="Pregnancy status"
codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
        <text/>
        <statusCode code="completed"/>
        <!-- e.g. 20140217 -->
        <effectiveTime value="{effectiveTime}"/>
        <!-- one of 'value' -->
        <value xsi:type="CE" code="77386006" displayName="Pregnancy
confirmed" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>
        <!--<value xsi:type="CE" code="102874004"
displayName="Unconfirmed pregnancy" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT"/>-->
        <!--<value xsi:type="CE" code="60001007" displayName="Not
pregnant" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>-->
        <!--<value xsi:type="CE" code="289256000" displayName="Mother
delivered" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>-->
        <!-- Remove entryRelationship if 'Not pregnant' -->
        <entryRelationship typeCode="SPRT" inversionInd="true">
            <!-- Delivery Date -->
            <observation classCode="OBS" moodCode="EVN">
                <!-- one of 'code' -->
                <code code="11778-8" displayName="Delivery date
Estimated" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>
                <!-- <code code="8665-2" displayName="Last menstrual
period start date" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/> -->
                <!-- Delivery Date (if 'Mother Delivered') -->
                <!-- <code code="397836004" displayName="Time of
delivery" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT "/> -->
                <text/>
                <statusCode code="completed"/>
                <!-- e.g. 20141017 -->
                <!-- use yyyyMM if only estimated up to month level -->
                <value xsi:type="TS" value="{date}"/>
            </observation>
        </entryRelationship>
    </observation>
</entry>

```

The delivery narrative is captured as a set of coded observations and needs to describe the patient's delivery date. Since there are multiple ways to describe this date (estimated, already delivered, etc.), a pregnancy status

observation is captured as well. The above template describes a delivery narrative using such a status observation along with the date observation. The entryRelationship element inversely relates these two observations together, i.e. the template reads as: the "delivery date" is supported by the "status" observation.

MHD Template

See http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_MHD.pdf for full details around the MHD profile. Note that MHD is essentially designed as a RESTful façade to an XDS.b infrastructure. It is therefore an option to also use XDS.b for transporting the CDA documents.

The transaction takes the form of a MIME multipart message (multipart/form-data) sent as a POST transaction to an endpoint such as:

[https://{him-server}/registration/net.ihe/DocumentDossier/?PatientID=\\${pid}](https://{him-server}/registration/net.ihe/DocumentDossier/?PatientID=${pid}).

The message consists of two mime parts:

1. a JSON entry describing the document metadata, and
2. the document contents (the CDA).

Document Metadata

The document metadata is expressed as JSON in the first MIME part of the message transaction. The MIME type for this entry should be set to application/json and the Content-Disposition should be form-data with the name ihe-mhd-metadata.

A metadata entry should consist of a single documentEntry section. For the purposes of this example use-case of registering the maternal pregnancy encounter, only a subset of the required fields are listed within the documentEntry section. Additionally, since the content is known it is even possible for the HIM to infer the other fields from the CDA document and complete the metadata entry.

Field	Description
patientId	The patient identifier
uniqueId	A unique identifier OID for the document. This should be generated by the sender.
entryUUID	A UUID to uniquely identify the entry. This should be generated by the sender and expressed as an urn (with a prefix urn:uuid:).
classCode	Classifies the submitted document. For the example CDA template this would be: { "code": "51855-5", "codingScheme": "2.16.840.1.113883.6.1", "codeName": "Patient Note" }
typeCode	Classifies the submitted document. For the example CDA template this would be: { "code": "51855-5", "codingScheme": "2.16.840.1.113883.6.1", "codeName": "Patient Note" }
formatCode	Classifies the submitted document. For the example CDA template this would be: { "code": "npr-pn-cda", "codingScheme": "4308822c-d4de-49db-9bb8-275394ee971d", "codeName": "NPR Patient Note CDA" }
	<div> <div>mimeType</div> <div>The document MIME type. This should be text/xml.</div> </div> <div> <div>hash</div> <div>SHA1 hash of the CDA document</div> </div> <div> <div>size</div> <div>Size of the CDA document in bytes</div> </div>

Document Contents

The second MIME part in the message transaction will contain the CDA document itself. The MIME type should be text/xml and the Content-Disposition should be set to form-data with the name content.

Example Transaction

```
{
  "documentEntry": {
    "patientId": "patientId",
    "uniqueId": "2.15.278071478427527610493133229150878247572",
    "entryUUID": "urn:uuid:d1329e63-0408-4f45-b5ba-35f9afa72a94",
    "classCode": { "code": "51855-5", "codingScheme": "2.16.840.1.113883.6.1",
"codeName": "Patient Note" },
    "typeCode": { "code": "51855-5", "codingScheme": "2.16.840.1.113883.6.1",
"codeName": "Patient Note" },
    "formatCode": { "code": "npr-pn-cda", "codingScheme": "4308822c-d4de-49db-9bb8-
275394ee971d", "codeName": "NPR Patient Note CDA" },
    "mimeType": "text/xml",
    "hash": "587e159120b29eeb6c542131aabc7b49325a26a0",
    "size": "5222"
  }
}
```

CONCLUSION

In this technical report, we have presented a product / solution and technology framework for maternal mHealth in low resource settings. The framework adopts a particular architectural approach that is to develop an interoperable solution for maternal mHealth, based on mHealth solutions that have already been implemented in the health system or are readily available. This open architectural approach seeks to be maximally inclusive of existing stakeholders and also maximize the existing technology investment. These goals are particularly appropriate for low resource settings with the limitations in skills and resources.

The technology framework uses a typical health information exchange architecture that includes an interoperability middleware application mediating and orchestrating messages and services between point of care applications on the one end and a set of registries and services on the other end. Typical registries and services include a Client Registry, Provider Registry, Facility Registry, Terminology Service, Shared Health Record, Health Management Information System, Subscription Database and Audit Database. The system allows for the capture of maternal registrations, identifications and subscriptions from mobile application services. The middleware, registries and services are configured to support international base standards and interoperability profiles that are configured around the services that need to be supported.

The system stores data in a consistent way that includes longitudinal patient or pregnancy record, validation of client, provider and facility data as well as terminology management. A major function of the mediator component is to accept messages in a well-defined and standardized format (e.g. an HL7 CDA document) and then to orchestrate the message and populate the registries of the HIE according to the metadata content. The open architecture is defined by virtue of the open messaging specifications as well as a common data model. This creates the opportunity for application providers implementing any workflow to interoperate through shared services and data exchange.

The P&T Framework presented in this document focuses on a fairly limited set of maternal use-cases but the principles and architecture are applicable to a wider domain, both within maternal health as well as other services in healthcare and in other domains. The framework extends the HNSF developed for South African eHealth interoperability, by creating an interoperability specification from a number of IHE profiles and base standards such as the Clinical Document Architecture. This provides a starting point that can be extended to include more comprehensive workflows, in future, such as capturing antepartum summaries.

Recommendations for Implementation

We have the following recommendations for low resource environments, based on our implementation experiences. Some of which may apply in high resource environments, as well.

Policy Decision Around Interoperability and mHealth. It is well known that executive sponsorship is one of the most important requirements for successful IT implementation projects. Interoperability projects are particularly complex and no exception. Strong drivers, well-articulated rationale, alignment with Ministry of Health objectives and executive buy-in and commitment are absolutely required preconditions without which any project will almost certainly fail.

Governance, Regulation and Legal Environment. The regulatory environment should also be conducive to the development of the project. This includes the required legislation empowering data collection and allowing unique identifiers to be collected. It is difficult or impossible to run a system with patient-level data collection without some

form of patient identifier and there also needs to be some agreement on standards or an approach to standards selection. The interoperability framework provides guidance around the adoption of standards but it is necessary to have additional guidance in the adoption of standards and any customization. Many overlapping standards and profiles exist and the implementation team will necessarily need to make selections during the development of a particular interoperability specification. The regulatory environment can also help with the function of compliance testing that will likely be needed should the project proceed to the next step that is to recommend particular products for implementation.

Develop an Interoperability Framework and Standards Catalogue for mHealth and eHealth. An Interoperability Framework is a very important document to create a context for interoperability between applications both mobile and eHealth applications. The framework should ideally resemble the South African Health Normative Standards Framework or the Interoperability Framework drafted by the Australian National eHealth Transition Authority. The former has more content relevant to low resource environments while the latter has more content regarding approaches to content coding. The interoperability framework should also contain a standards catalogue that includes both international coding standards and local standards developed specifically for the country. The standards catalogue creates a superset that can be used to select base standards and profiles for any particular workflow or interoperability specification.

Formulate a Maturity Model. A maturity model is important to define the different stages that a system might go through. Although several different maturity models have been published, there may be local adaptations that are important to consider in making the model locally relevant and useful for the purposes of adaptation and compliance testing, should this be implemented at some point. In low resource environments, the system may be dominated by paper records that create a different starting point for an interoperability implementation in such a setting.

Develop an Open Architecture for Health. An open architecture is an approach to system development that includes aspects such as adoption of open standards or implementation guides that are readily accessible. It may also include the standardization of workflows and processes as well as the publishing of a national data dictionary. Access to international standards can be a real difficulty in low resource settings because of the cost involved. In addition, these standards often need to be localized in order to be relevant to the local context. As a result, it is often useful to create implementation guides that can be distributed locally at no or much reduced cost.

Develop enterprise and/or domain-level architectures. The interoperability framework provides a starting point for interoperability but needs to be extended further to be practically useful. One way to do this is to create an enterprise or domain-level architecture from the Interoperability Framework. Common Enterprise Architecture (EA) methodologies often divide the process into three main parts, (i) requirements definition and management; (ii) specification and modeling, and; (iii) implementation, governance and change management. Following requirements definition, in Phase 2, the specifications in the Interoperability Framework can be applied to the particular domain of interest and selections made from among the standards and profiles listed in the Interoperability Specification or Standards Catalogue to achieve the particular vision and goals for the system elaborated in Phase One. The selection of base standards and profiles should ideally be carried out by, or in association with, a national standards authority such that it meets the requirements for an overall architectural vision for the country at a national enterprise level. There is a danger that allowing proliferation of implementations using different sets of standards and profiles will exacerbate a system where interoperability is already a challenge at an application level, by having different sets of 'standard' implementations. A national eHealth standards authority is one way to alleviate this problem but it needs to be agile and expert in order to make a contribution.

Harmonizing Data and Processes. Having adopted bases standards and profiles, it is possible to harmonize the processes and data collected using different applications into a single workflow or continuum of care. This is one of the most important goals to achieve where much value is created. However, it is a difficult goal to achieve and requires a large measure of 'organizational interoperability' and working together. The MOH can 'own' the Interoperability Framework and convene implementing partners around the supported workflows, using compliance testing to ensure that partner applications are aligned and contribute to the national public health system. However, it is likely that the convening function of the MoH will need to be supplemented by expert skills provided by a one or more neutral third party, such as a national authority, non-governmental organizations, acting as honest brokers or a broad-based industry body.

Balance Between Immediate Utility and Future Proofing. It is important to understand that implementations are something of a moving target. Users mature in their interaction with systems and their expectations grow. Success breeds success, resulting in successful systems being scaled and expanded to deliver new services. It is important to adopt standards and profiles that satisfy immediate requirements and that are reasonably scalable and interchangeable. One implementation decided to adopt an HL7 v3 standard (CDA) that was initially considered 'overkill' for the basic registration requirement that could have been achieved more easily with a simpler MHD profile. However, the decision was validated when the system was expanded to include clinical observations from other processes and workflows.

Adopt a systems approach with evaluation. The impact of an intervention, such as mobile maternal messaging will likely have system-wide effects. For example, increased subscription to messages advocating antenatal clinic attendance will likely result in an increase in clinic registrations as will household visits by community health workers. Interoperability and data integration creates a real opportunity to collect data about the implementation of these workflows and to critically evaluate for effectiveness. A systems approach and modeling techniques such as systems dynamic modeling can help tease out the effects of different workflow interventions and the impact of interventions on one another. Careful data collection and gathering will allow the contribution of the different workflows to be quantified and their respective contribution to improved system performance estimated more accurately. This is an important part of the monitoring and evaluation process.

Benefits

Some of the potential benefits of the P&T Framework are detailed, below:

Providing Continuity of Care. A significant advantage of interoperability is that it allows the central authority to integrate and take advantage of multiple processes and workflows. Taken together and with the integrated data model, from a patient's perspective, the whole can result in continual service delivery supplemented with a continuity of care record. In the mobile maternal example, a particular pregnancy may be identified and pre-registered in a household or school by a community health worker or nurse and followed up by registration in the antenatal care facility.

Maximizing Existing Investment and Resources. The interoperability approach results in what is colloquially referred to as an 'embrace and extend' approach being followed as opposed to a 'rip and replace' approach. This means that existing systems that have been implemented and tested are embraced and extended.

More Robust and Sustainable Systems. Interoperable systems are inherently more robust than monolithic single-provider systems in several ways. While some degree of variation is important for the reasons mentioned, above,

too much variation can be inefficient and paralyze the system. Software tends to naturally gravitate towards supporting a defined workflow or set of processes, e.g. an electronic medical record system, a maternal messaging system and a supply-chain management system. Having a limited number of options supporting each workflow in an interoperable environment seems like a good approach to achieving a balance between consolidation and healthy variation. This approach would seem to be more robust to failure and change.

Maximizing Data Use. Data is expensive to collect and maintain, particularly when data recording requires scarce healthcare worker time. One of the main benefits of an interoperability framework is its support for data integration and triangulation. This results in maximum use of data as well as data quality.

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ABBREVIATIONS, TERMS AND DEFINITIONS

Abbreviations

Acronym	Description
ANC	Antenatal Care
CDA	Clinical Document Architecture
CHW	Community Health Worker
CMMI	Capability Maturity Model Integration
CR	Client Registry
DHIS	District Health Information System
ECID	Enterprise Client Identifier
GSMA	GSM Association
HL7	Health Level Seven
HIE	Health Information Exchange
HIM	Health Information Mediator
HMIS	Health Management Information System
HNSF	South African Health Normative Standards Framework
ICD	International Classification of Diseases
IHE	Integrating the Healthcare Enterprise
IMM	Interoperability Maturity Model
ISO	International Standards Organization
IVR	Interactive Voice Response
LOINC	Logical Observation Identifiers Names and Codes
MHA	Mobile Health Alliance
MNCH	Maternal, Newborn and Child Health

MoTeCH	Mobile Technology for Community Health
NDOH	South African National Department of Health
NEHTA	National eHealth Transition Authority
NHIS	National health information System
NHIT	National health information Technology
OHIE	Open Health Information Exchange
PAM	Patient Administration Management
PDQ	Patient Demographics Query
PIX	Patient Identifier Cross-Referencing
PR	Provider Registry
RHIE	Rwanda Health Information Exchange
SHR	Shared Health Record
SMS	Short Message Service
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
USSD	Unstructured Supplementary Service Data
WHO	World Health Organization
XDS	Cross-Enterprise Document Sharing

Definitions

Term	Description
Client	A Client is defined as a woman with a suspected or confirmed pregnancy or a woman with a child less than two years of age
Identification	Identification refers to the process of identifying a Client and storing the Client data in a database. The main contribution of this process to Client registration is to promote attendance at an ANC facility.
Provider	A Healthcare Provider ("Provider") is defined as a person delivering healthcare and registered with the Health Professions Council of South Africa (HPCSA)
Registration	Registration refers to the process of formally recording a pregnancy or pregnant woman and requires a diagnostic test conducted by a registered Healthcare Provider in an authorized facility. Electronic Registration refers to the process of registering a pregnancy, as above, either directly in an electronic medical record system or via a paper register.
Subscription	Subscription refers to the process of signing up a person to a messaging service. The main contribution of this process to Client registration is to promote attendance at an ANC facility.

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