Integrating the Healthcare Enterprise

# IHE Quality, Research and Public Health (QRPH)

# White Paper

# Operationalizing Integrated Care Pathways (ICP) Using IHE Profiles

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## Foreword

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE Profiles. IHE publishes each profile through a well-defined process of public review and trial implementation and gathers profiles that have reached final text status into an IHE Technical Frameworks.

This white paper is published as of February 23, 2017. Comments are invited and can be submitted at http://www.ihe.net/QRPH_Public_Comments.

General information about IHE can be found at www.ihe.net.

Information about the IHE Quality, Research and Public Health domain can be found at ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Quality, Research and Public Health Technical Framework can be found at http://www.ihe.net/Technical_Frameworks.

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# Introduction

This document, the *Operationalizing Integrated Care Pathways (ICP) Using IHE Profiles* White Paper, explores how Business Process Modeling Notation (BPMN) and a collection IHE profiles may be leveraged to operationalize support for Integrated Care Pathways (ICPs) within the context of a Health Information Exchange (HIE). ICPs are a long-running, orchestrated patient care plans that cross systems boundaries. IHE's Quality, Research and Public Health committee's (QRPH) Retrieve Process for Execution (RPE) Profile describes how BPMN-based workflows may be managed and executed. This white paper describes an applied research effort that explores how the RPE Profile and complementary profiles from IHE's Patient Care Coordination (PCC) and IT Infrastructure (ITI) committees may be leveraged to support ICPs.

## 1.1 Purpose of the Operationalizing Integrated Care Pathways (ICP) Using IHE Profiles White Paper

QRPH's RPE Profile is the IHE profile for collaborative workflow or collaborative process management. It specifies how workflow instructions that have been expressed using BPMN may be invoked to satisfy a pre-defined process. The purpose of the present white paper is twofold:

1. to explore the capabilities of BPMN to describe evidence-based care guidelines; and,
2. in the face of such BPMN-based descriptions, to explore the ways RPE and other complementary IHE profiles may be leveraged to operationalize these care guidelines within the context of a Health Information Exchange (HIE).

These research questions are explored through prototyping. Two example care guidelines from WHO, adult HIV care[1] and child immunizations[2], were explored, modeled and experimented with using BPMN. RPE actors were then integrated into an IHE-based HIE, OpenHIE (www.ohie.org), to enable the HIE to act as a "Mealy machine"[3]; a state-based engine capable of executing the defined processes and, in so doing, operationalizing the guideline-based ICPs. The prototype designs and preliminary experimental results are reported in this white paper.

## 1.2 Intended Audience

The intended audiences for this white paper are country-level healthcare decision makers, national or multilateral funders (or donors) and health informatics thought leaders, researchers and members of standards organizations. This white paper articulates a business case for ICPs, provides insight into the challenges in implementing these within the fabric of an HIE, and informs avenues of potential further research on this important topic. It is expected that the

[1] http://www.who.int/hiv/pub/guidelines/en/

[2] http://www.who.int/immunization/policy/immunization_tables/en/

[3] A Mealy machine is a finite state machine whose outputs are based on both its current state and its current inputs. http://en.wikipedia.org/wiki/Mealy_machine

technical results reported here will be especially interesting to developers and implementers. That said, it is the primary goal of this white paper to support and inform those who must make funding decisions regarding further exploration of this topic.

## 1.3 Comment Process

IHE International welcomes comments on the IHE initiative. They can be submitted by sending an email to the co-chairs and secretary of the QRPH domain committees at qrph@ihe.net.

## 1.4 Open and Closed Issues

None

# 2 Overview

## 2.1 How is this white paper laid out?

This white paper is laid out in six parts:

Part 1 introduces the white paper and its target audience.

Part 2, (this section) provides top-level background information regarding the business case for operationalizing guideline-based care at national scale and introduces some of the cornerstone concepts and technologies leveraged by this exploration of the topic. A non-jargoned, business-level description is given of Integrated Care Pathways (ICPs), of Business Process Modeling Notation (BPMN), and of the OpenHIE health information exchange, its underlying enterprise architecture and the IHE profiles it leverages.

Part 3 describes the two WHO care guidelines that are considered in this research. Narrative descriptions are given for guideline-base HIV care management and child immunization. As an example, using the computable "language" of BPMN, a vaccine administration guideline is modeled.

Part 4 provides a top-level description of how guideline-based care, once it has been described using BPMN, might be operationalized by an HIE. This section reports on prototyping done by the mHealth and eHealth Development and Innovation Centre (the MEDIC lab) at Mohawk College in Hamilton, Canada. A design is described that was developed based on a collection of IHE actors and transactions. These actors were mapped to software components in the OpenHIE architecture.

Part 5 discusses results and lessons learned from the present prototyping effort. Areas of further research are identified.

In Part 6, the white paper is concluded.

In order to ensure the document is readily digestible by a non-technical audience, systems engineering and software developer-focused content has been omitted from the main body of the document. This content, where it importantly contributes to a more fulsome understanding of the technology, is included in the Appendices.

## 2.2 Why is this an important topic?

There is significant scientific literature on the positive impact of guideline-based care on care outcomes.[4] Indeed, it is somewhat of a tautology to claim that care guidelines improve care; that's how the guidelines are developed in the first place! One of the reasons this topic is of particular interest to the IHE community is that there is a growing body of literature on the positive impact that eHealth can have on improving adherence to care guidelines. This

[4] http://www.medicine.ox.ac.uk/bandolier/extraforbando/forum2.pdf

improvement in guideline adherence is evidence of eHealth's role in helping close what the WHO calls the "know-do gap"[5]; the sometimes wide chasm between what we ***know*** to be impactful care interventions and what we actually ***do,*** on the ground, in our care delivery networks.[6] Importantly, eHealth infrastructure, when implemented at scale, provides a mechanism to not only meter the health system, but to also exert process control upon it.[7] It is a core premise of this white paper that eHealth is a way to narrow, or even close, the know-do gap.

This is important, not only because of the potentially large improvement in population health outcomes, but also because of how cost effectively benefits can be realized. Randomized controlled trials (RCT) published in the Lancet in 2011 showed that simple SMS reminders *to health workers* regarding Malaria treatment guidelines improved their adherence to correct practices by 24%. That same year, another RCT reported that weekly SMS reminders *to HIV patients on antiretroviral therapy* (ART) significantly improved their adherence to the drug regime and their viral suppression. The present white paper's authors believe it is of particular importance that these impacts are being realized in low income / low resource settings. Research has shown the low and middle income countries (LMICs) face a disproportionately high global burden of disease[8] and yet these countries are most challenged in dealing with these health issues.

## 2.3 What are ICPs?

Integrated Care Pathways (ICPs) can be defined as "care plans that detail the essential steps in the care of patients with a specific clinical problem and describe the expected progress of the patient."[9] ICPs are expressed, sometimes, as lists of rule-based clinical recommendations (care guidelines) or as diagrammatic, flow chart-based algorithms. The role of the ICP is to lay out a "standard" longitudinal care plan for any person who is diagnosed with a specific condition (or conditions). In this way it may be contrasted with an individual, bespoke, patient-specific care plan that may have been developed by a clinician.

Ideally, a patient-specific care plan should always be based upon an evidence-based guideline. In practice, this is not always the case. Operationalizing guideline-based care is a key goal for any jurisdiction. It has a significant positive impact on health outcomes and on costs. Some countries have national bodies whose responsibility is to curate the country's ICPs. An example of such a body is the UK's NICE (National Institute for Health and Care Excellence). [10] On an

[5] http://www.who.int/kms/WHO_EIP_KMS_2006_2.pdf

[6] http://www.twigh.org/twigh-blog/2015/2/1/closing-the-know-do-gap-in-global-health-through-implementation-science

[7] https://vimeo.com/108627029

[8] http://www.healthdata.org/gbd

[9] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2665398/pdf/9462322.pdf

[10] https://www.nice.org.uk/

international basis, WHO is the curator of a broad array of care guidelines (including the ones employed by this research exploration).[11]

## 2.4 What is BPMN?

The Object Management Group (OMG) is a global standards development organization (SDO) focused on the development and curation of IT specifications. One such standard is the Business Process Model and Notation (BPMN) specification.[12] BPMN 2.0 specifies a set of graphical constructs that may be employed to describe a workflow in a computable format. The most common BPMN diagrams are the "swimlane" diagrams often used to document business processes, especially during re-engineering efforts.

BPMN underpins the Public Health Informatics Institute's (PHII) collaborative requirements development methodology (CRDM).[13] This methodology has been employed by a number of ministries of health to document complex workflows including national immunization programmes, health system supply chains, and health insurance / financing. An example CRDM diagram is shown in Figure 1; this diagram illustrates a basic immunization workflow.

[11] http://www.who.int/publications/guidelines/atoz/en/

[12] http://www.bpmn.org/

[13] http://phii.org/crdm/

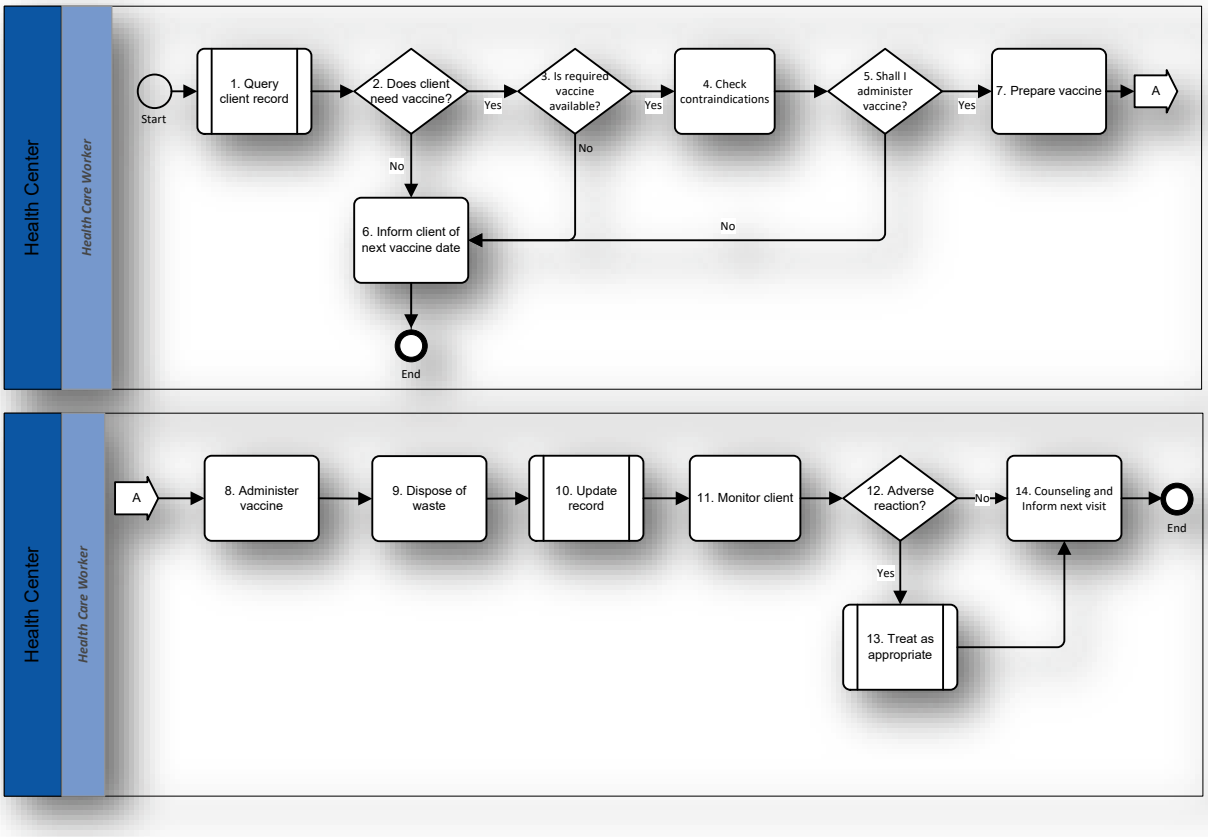



**Figure 1: Basic CRDM Diagram**

220 The BPMN standard describes a set of graphical "primitives" that can be connected together to visually describe a workflow. The basic graphical elements are shown in Figure 2.

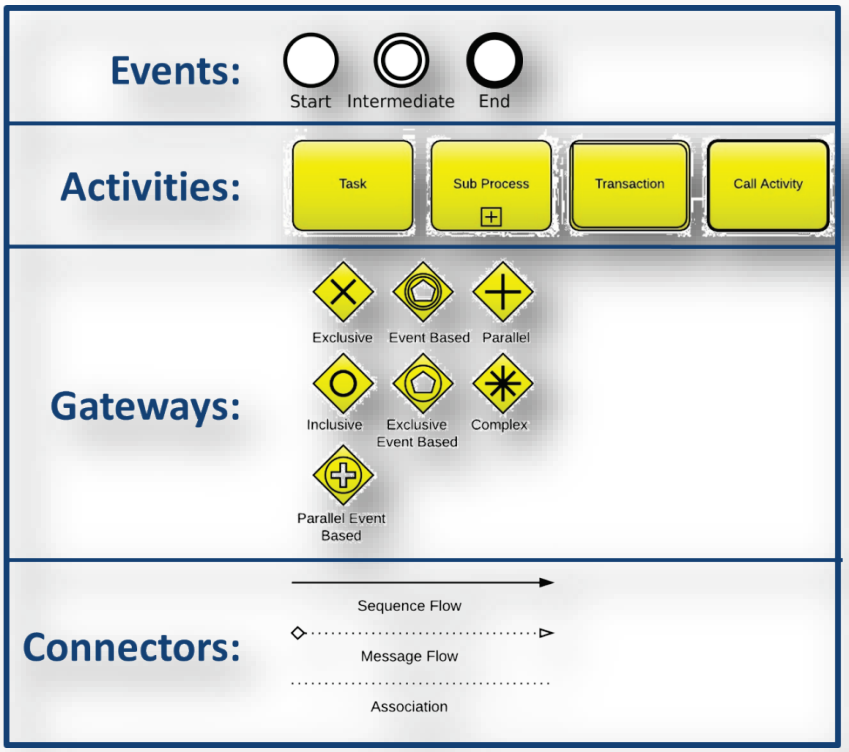



**Figure 2: BPMN Diagram Graphics**

BPMN is one of the standards employed by QRPH's Retrieve Process for Execution (RPE) Profile; it is used to codify the process description.

## 2.5 What is OpenHIE and how does it work?

As described earlier, this white paper will particularly explore two of WHO's ICPs: adult HIV treatment and child immunizations. IHE's RPE Profile will be employed to prototype the operationalization of BPMN-based expressions of the care guidelines within the context of a health information exchange (HIE). The HIE used for the prototyping is OpenHIE.

The Open Health Information Exchange (OpenHIE) community "works to help underserved environments better leverage their electronic health information through standardization."[14] The

[14] https://ohie.org/

OpenHIE architecture design is based on Canada Health Infoway's electronic health records system (EHRS) blueprint[15]; OpenHIE's architecture is illustrated in Figure 3.

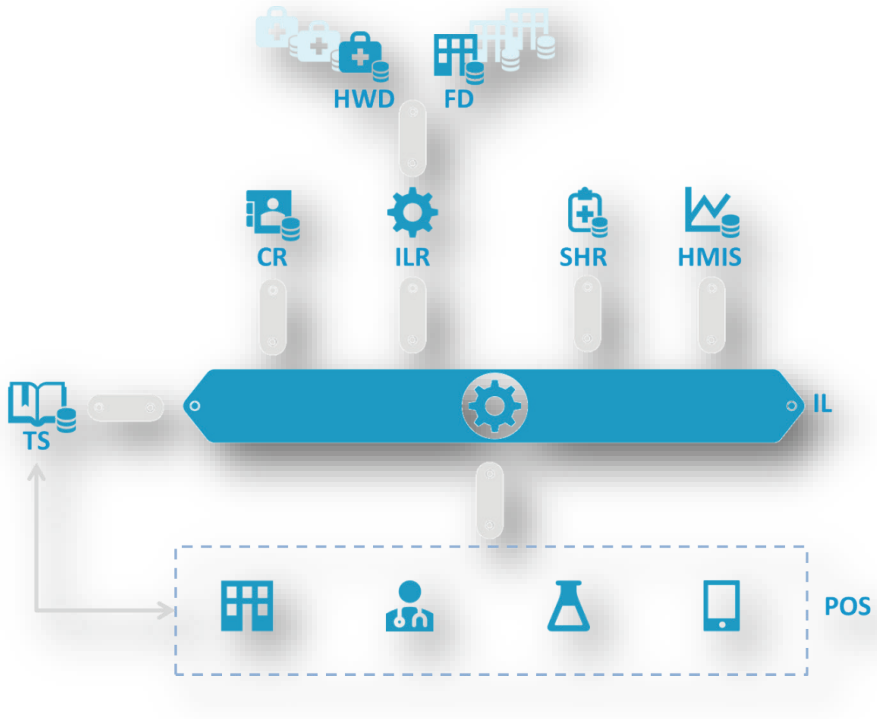



**Figure 3: OpenHIE Architecture**

The elements of the OpenHIE architecture are:

- POS – point-of-service applications (e.g., local m/eHealth systems such as electronic medical records, lab systems, pharmacy systems, and mHealth systems such as RapidPro, DHIS2 Tracker, etc.)
- IL – interoperability layer, a service bus which provides centralized authentication, audit, and process orchestration services
- TS – terminology service, which maintains, verifies and cross-references code sets and terminologies (e.g., ICD-10 for diagnoses, ATC codes for drugs, LOINC for lab order codes, etc.)
- CR – client registry, which maintains a definitive demographic record for each subject of care and cross references multiple local IDs to a single enterprise ID for the client

[15] https://www.infoway-inforoute.ca/en/component/edocman/resources/technical-documents/391-ehrs-blueprint-v2-full?Itemid=101

- HWD – health worker directory, a database of care provider information (including demographic information), indexed by a unique ID; there may be multiple HWDs
- FD – facility directory, a database of facility information indexed by a unique ID; there may be multiple FDs
- ILR – interlinked registry, a cross-referenced database of facilities, providers, organizations and services, indexed by enterprise IDs; the ILR consolidates/federates multiple HWDs and FDs, where necessary
- SHR – shared health record, a longitudinal database of time-stamped, person-centric, coded health content indexed by the *enterprise* subject, provider and location IDs
- HMIS – health management information system, a database of health system management data that supports analytics, reporting and decision-making

OpenHIE leverages a family of IHE profiles to support its 8 core workflows. These profiles are listed in Figure 4. A full technical description of OpenHIE's workflows may be found at the OpenHIE wiki.[16]

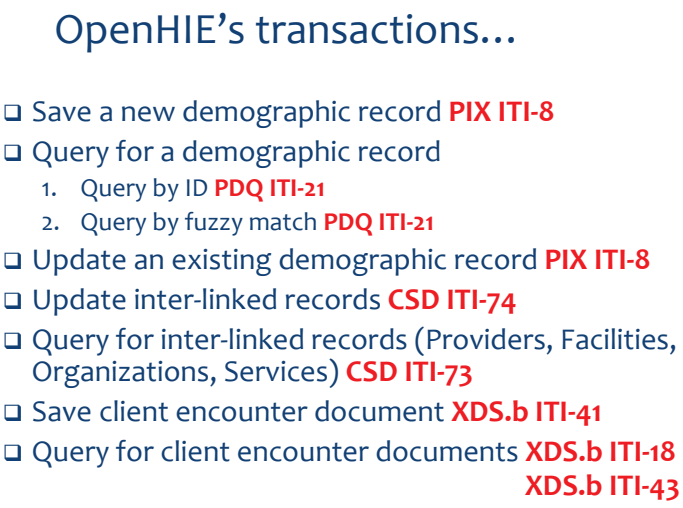



**Figure 4: OpenHIE's Core Workflows**

The following profiles are identified in Figure 4:

- PIX – Patient Identity Exchange
- PDQ – Patient Demographic Query
- CSD – Care Services Discovery

[16] https://wiki.ohie.org/display/documents/OpenHIE+Workflows

- XDS.b – Cross-enterprise Document Sharing (version b)

Implementations of OpenHIE have leveraged specific IHE content profiles such as Antepartum Summary (APS), Antepartum History and Physical (APHP), Immunization Content (IC) and an extended version of the Medical Summary (XDS-MS) Profile.

Elements of the OpenHIE open source stack have successfully participated at the 2013, 2014 and 2015 IHE Connectathons. New profiles (mACM, ADX), developed with assistance from OpenHIE community members, were conformance tested at the 2016 IHE North American Connectathon.

# 3 Integrated Care Pathways (ICPs)

As introduced in Section 2.3, ICPs are evidence-based guidelines that describe a patient's long-running, multi-organizational care plan. They are particularly well-suited to scenarios where orchestration of care and coordination of care over time and across multiple sites is the key to a successful health outcome. To illustrate the application of ICPs, two examples were explored:

1. Adult HIV treatment
2. Child immunization.

## 3.1 HIV Treatment

WHO publishes a broad array of care guidelines regarding various aspects of HIV care and treatment. This white paper leverages the *Consolidated Guidelines on the use of Antiretroviral Drugs for Treating and Preventing HIV Infection – Recommendations for a Public Health Approach (June 2013)*.[17] Section 7 of the WHO HIV Guidelines expresses the adult HIV care guidelines of interest:

- As a priority, antiretroviral therapy (ART) should be initiated in all individuals with severe or advanced HIV clinical disease (WHO clinical stage 3 or 4) and individuals with CD4 count ≤350 cells/mm3 (strong recommendation, moderate-quality evidence).
- ART should be initiated in all individuals with HIV with a CD4 count >350 cells and ≤500/mm3 regardless of WHO clinical stage (strong recommendation, moderate-quality evidence).
- ART should be initiated in all individuals with HIV regardless of WHO clinical stage or CD4 cell count in the following situations:
  - Individuals with HIV and active TB disease (strong recommendation, low-quality evidence).
  - Individuals coinfected with HIV and HBV with evidence of severe chronic liver disease (strong recommendation, low-quality evidence).
  - Partners with HIV in serodiscordant couples should be offered ART to reduce HIV transmission to uninfected partners (strong recommendation, high-quality evidence).
  - Pregnant and breastfeeding women with HIV

Specifically regarding pregnant women:

[17] http://www.who.int/hiv/pub/guidelines/arv2013/en/ [NOTE: subsequent to the authoring of this white paper, the WHO guidelines regarding HIV treatment were updated to reflect the "test and treat" approach. The experiments conducted and reported on here, however, were based on the arv2013 guideline.]

- All pregnant and breastfeeding women with HIV should initiate triple ARVs (ART), which should be maintained at least for the duration of mother-to-child transmission risk. Women meeting treatment eligibility criteria should continue lifelong ART (strong recommendation, moderate-quality evidence).
- For programmatic and operational reasons, particularly in generalized epidemics, all pregnant and breastfeeding women with HIV should initiate ART as lifelong treatment (conditional recommendation, low-quality evidence).
- In some countries, for women who are not eligible for ART for their own health, consideration can be given to stopping the ARV regimen after the period of mother-to-child transmission risk has ceased (conditional recommendation, low-quality evidence).

The medications regime for HIV care is shown below (from the WHO HIV Guidelines).

- First-line ART should consist of two nucleoside reverse-transcriptase inhibitors (NRTIs) plus a non-nucleoside reverse-transcriptase inhibitor (NNRTI)
  - TDF + 3TC (or FTC) + EFV as a fixed-dose combination is recommended as the preferred option to initiate ART (strong recommendation, moderate-quality evidence).
  - If TDF + 3TC (or FTC) + EFV is contraindicated or not available, one of the following options is recommended (strong recommendation, moderate-quality evidence):
    - AZT + 3TC + EFV
    - AZT + 3TC + NVP
    - TDF + 3TC (or FTC) + NVP
- Countries should discontinue d4T use in first-line regimens because of its well-recognized metabolic toxicities (strong recommendation, moderate-quality evidence).
- A once-daily fixed-dose combination of TDF + 3TC (or FTC) + EFV is recommended as first-line ART in pregnant and breastfeeding women, including pregnant women in the first trimester of pregnancy and women of childbearing age. The recommendation applies both to lifelong treatment and to ART initiated for PMTCT and then stopped (strong recommendation, low- to moderate-quality evidence: moderate-quality evidence for adults in general but low-quality evidence for the specific population of pregnant and breastfeeding women and infants).

The lab tests recommended for HIV management are shown below (Table 7.13 from the WHO HIV Guidelines).

**Table 7.13 Recommended and desirable laboratory tests at HIV diagnosis and monitoring on ART**

| Phase of HIV management | Recommended | Desirable (if feasible) |
|---|---|---|
| HIV diagnosis | HIV serology, CD4 cell count<br>TB screening | HBV (HBsAg) serology[a]<br>HCV serology<br>*Cryptococcus* antigen if CD4 count ≤100 cells/mm³[b]<br>Screening for sexually transmitted infections<br>Assessment for major noncommunicable chronic diseases and comorbidities[c] |
| Follow-up before ART | CD4 cell count (every 6–12 months) | |
| ART initiation | CD4 cell count | Haemoglobin test for AZT[d]<br>Pregnancy test<br>Blood pressure measurement<br>Urine dipsticks for glycosuria and estimated glomerular filtration rate (eGFR) and serum creatinine for TDF[e]<br>Alanine aminotransferase for NVP[f] |
| Receiving ART | CD4 cell count (every 6 months)<br>HIV viral load (at 6months after initiating ART and every 12 months thereafter) | Urine dipstick for glycosuria and serum creatinine for TDF[c] |
| Treatment failure | CD4 cell count<br>HIV viral load | HBV (HBsAg) serology[a] (before switching ARV regimen if this testing was not done or if the result was negative at baseline) |

[a] If feasible, HBsAg testing should be performed to identify people with HIV and HBV coinfection and who therefore should initiate TDF-containing ART.

[b] Can be considered only in settings with a high prevalence of cryptococcal antigenaemia (>3%) *(180)*.

[c] Consider assessing the presence of chronic conditions that can influence ART management such as hypertension and other cardiovascular diseases, diabetes and TB.

[d] Among children and adults with a high risk of adverse events associated with AZT (low CD4 or low BMI).

[e] Among people with a high risk of adverse events associated with TDF: underlying renal disease, older age group, low BMI, diabetes, hypertension and concomitant use of a boosted PI or potential nephrotoxic drugs.

[f] Among people with a high risk of adverse events associated with NVP, such as being ART-naive, women with HIV with a CD4 count >250 cells/mm³ and HCV coinfection. However, liver enzymes have low predictive value for monitoring NVP toxicity.

**Figure 5: Table 7.13 of WHO's HIV Care Guideline**

345

The decision criteria regarding when to switch ARV regimen is described below (Table 7.14 and Figure 7.1 from the WHO HIV Guidelines).

**Table 7.14 WHO definitions of clinical, immunological and virological failure for the decision to switch ARV regimens**

| Failure | Definition | Comments |
|---|---|---|
| **Clinical failure** | **Adults and adolescents**<br>New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage 4 condition)[a] after 6 months of effective treatment<br>**Children**<br>New or recurrent clinical event indicating advanced or severe immunodefiency (WHO clinical stage 3 and 4 clinical condition with exception of TB) after 6 months of effective treatment | The condition must be differentiated from immune reconstitution inflammatory syndrome[b] occurring after initiating ART<br>For adults, certain WHO clinical stage 3 conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure[a] |
| **Immunological failure** | **Adults and adolescents**<br>CD4 count falls to the baseline (or below)<br>or<br>Persistent CD4 levels below 100 cells/mm³<br>**Children**<br>Younger than 5 years<br>Persistent CD4 levels below 200 cells/mm³ or <10%<br>Older than 5 years<br>Persistent CD4 levels below 100 cells/mm³ | Without concomitant or recent infection to cause a transient decline in the CD4 cell count<br>A systematic review found that current WHO clinical and immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure *(182)*. The predicted value would be expected to be even lower with earlier ART initiation and treatment failure at higher CD4 cell counts. There is currently no proposed alternative definition of treatment failure and no validated alternative definition of immunological failure |
| **Virological failure** | Plasma viral load above 1000 copies/ml based on two consecutive viral load measurements after 3 months, with adherence support | The optimal threshold for defining virological failure and the need for switching ARV regimen has not been determined<br>An individual must be taking ART for at least 6 months before it can be determined that a regimen has failed<br>Assessment of viral load using DBS and point-of-care technologies should use a higher threshold |

[a] See the list of clinical conditions associated with advanced or severe HIV disease in Annex 1.
[b] Section 6.1 discusses immune reconstitution inflammatory syndrome.

**Figure 6: Table 7.14 of WHO's HIV Care Guideline**

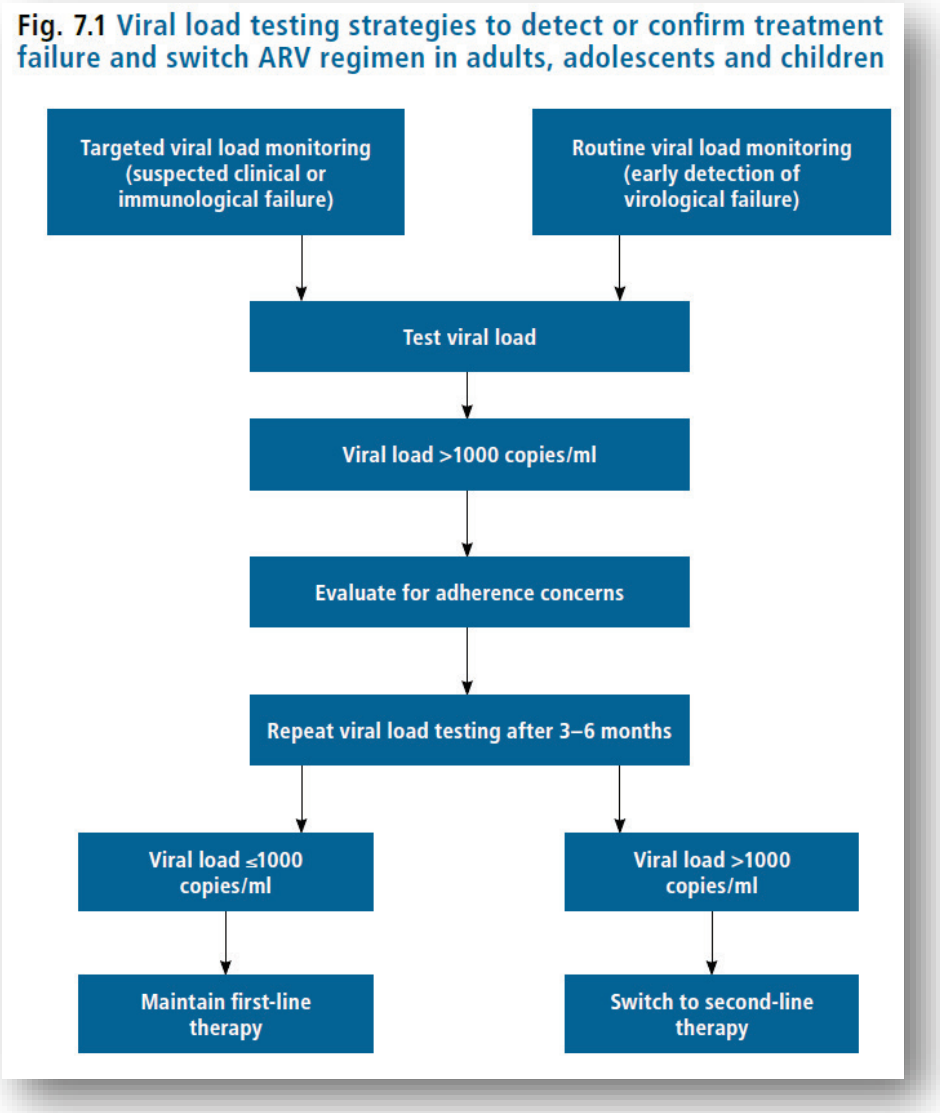



**Figure 7: Figure 7.I of WHO's HIV Care Guideline**

The preceding narrative distills a 272-page document into 5 summary pages. It is obvious that the adult HIV care guideline is an involved and nuanced ICP. The purpose of outlining the HIV ICP at even this summary level of detail is to be illustrative of the complicated nature of the problem taken on by this research.

## 3.2 Child Immunization

Child immunization presents an intricate medications management challenge. Certain vaccines cannot be introduced too early in a child's life; it would be unsafe to do so. The timespan between vaccinations must be carefully tracked; giving the antigens too close together is also unsafe. Certain vaccines should not be given after a child is "too old" for them to be efficacious; to do so is wasteful. For children with certain immunodepressed conditions (e.g., HIV positive children), particular vaccines present a danger and must be avoided. For any child that has exhibited an adverse reaction to a vaccine, care must be taken on subsequent visits to ensure they are kept safe from a potentially dangerous or even fatal anaphylaxis. As is the case with HIV care, this is a complicated problem.

WHO's top-level recommendations for the Extended Programme for Immunization (EPI) are published as a set of three tables with an accompanying guidebook that explains how and when to use the tables.[18] Page 9 of the WHO guidebook outlines the various parts of the EPI tables and how they inform the immunization process. It is shown in Figure 8.

[18] http://www.who.int/immunization/policy/immunization_tables/en/

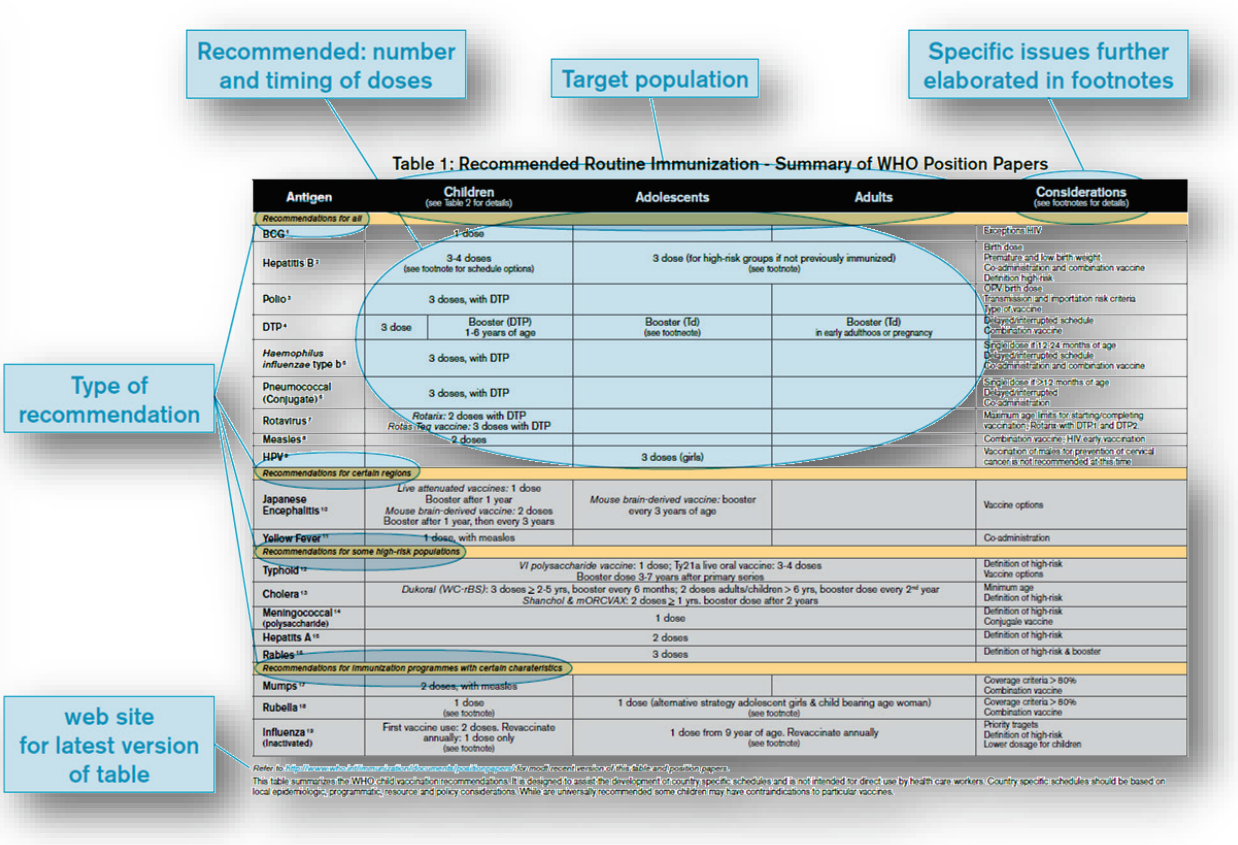
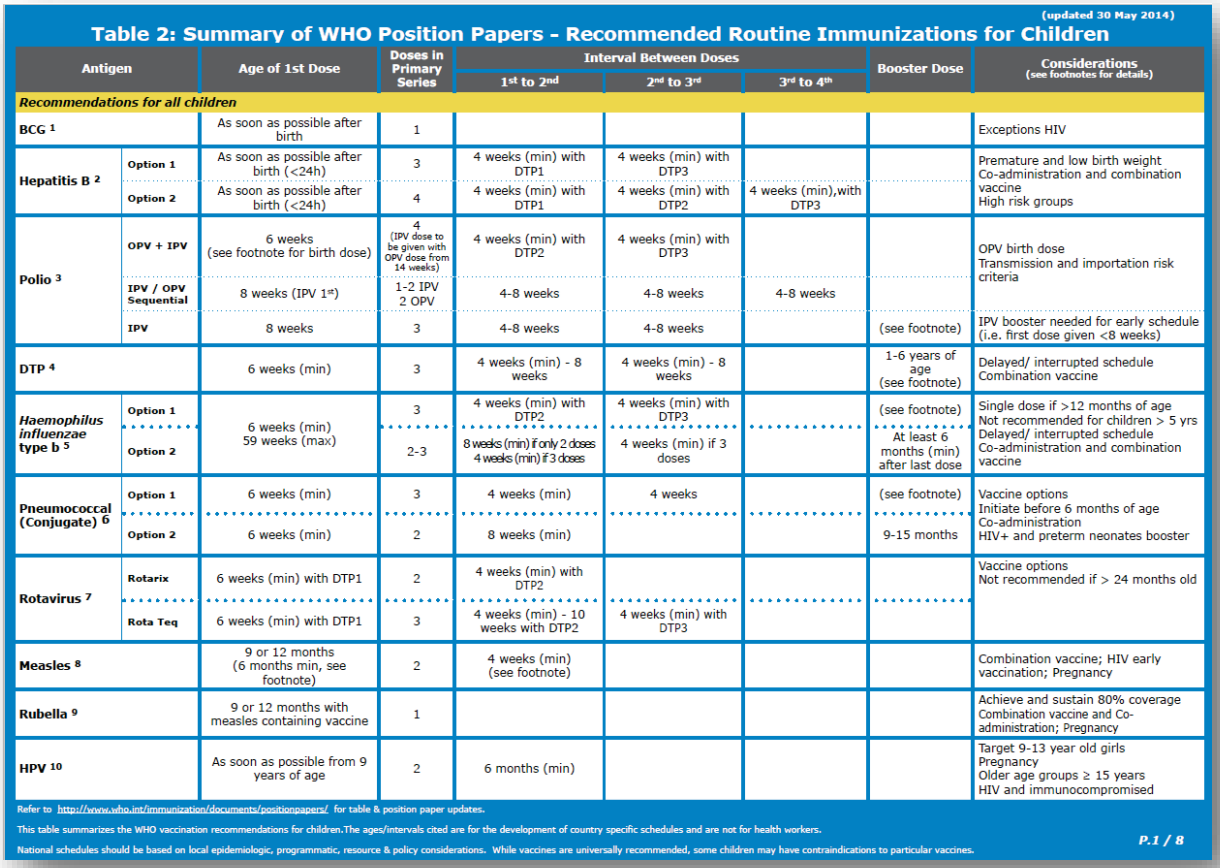



**Figure 8: Using the WHO Immunization Tables**

375 Table 2 of the WHO EPI guidelines focuses on the immunization of children. The first page of this table lists the most commonly applied vaccines. This EPI ICP is shown in Figure 9.



(updated 30 May 2014)

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

| Antigen | | Age of 1st Dose | Doses in Primary Series | Interval Between Doses | | | Booster Dose | Considerations (see footnotes for details) |
|---|---|---|---|---|---|---|---|---|
| | | | | 1st to 2nd | 2nd to 3rd | 3rd to 4th | | |
| *Recommendations for all children* | | | | | | | | |
| BCG [1] | | As soon as possible after birth | 1 | | | | | Exceptions HIV |
| Hepatitis B [2] | Option 1 | As soon as possible after birth (<24h) | 3 | 4 weeks (min) with DTP1 | 4 weeks (min) with DTP3 | | | Premature and low birth weight<br>Co-administration and combination vaccine<br>High risk groups |
| | Option 2 | As soon as possible after birth (<24h) | 4 | 4 weeks (min) with DTP1 | 4 weeks (min) with DTP2 | 4 weeks (min),with DTP3 | | |
| Polio [3] | OPV + IPV | 6 weeks (see footnote for birth dose) | 4 (IPV dose to be given with OPV dose from 14 weeks) | 4 weeks (min) with DTP2 | 4 weeks (min) with DTP3 | | | OPV birth dose<br>Transmission and importation risk criteria |
| | IPV / OPV Sequential | 8 weeks (IPV 1st) | 1-2 IPV<br>2 OPV | 4-8 weeks | 4-8 weeks | 4-8 weeks | | |
| | IPV | 8 weeks | 3 | 4-8 weeks | 4-8 weeks | | (see footnote) | IPV booster needed for early schedule (i.e. first dose given <8 weeks) |
| DTP [4] | | 6 weeks (min) | 3 | 4 weeks (min) - 8 weeks | 4 weeks (min) - 8 weeks | | 1-6 years of age (see footnote) | Delayed/ interrupted schedule<br>Combination vaccine |
| *Haemophilus influenzae* type b [5] | Option 1 | 6 weeks (min)<br>59 weeks (max) | 3 | 4 weeks (min) with DTP2 | 4 weeks (min) with DTP3 | | (see footnote) | Single dose if >12 months of age<br>Not recommended for children > 5 yrs<br>Delayed/ interrupted schedule<br>Co-administration and combination vaccine |
| | Option 2 | | 2-3 | 8 weeks (min) if only 2 doses<br>4 weeks (min) if 3 doses | 4 weeks (min) if 3 doses | | At least 6 months (min) after last dose | |
| Pneumococcal (Conjugate) [6] | Option 1 | 6 weeks (min) | 3 | 4 weeks (min) | 4 weeks | | (see footnote) | Vaccine options<br>Initiate before 6 months of age<br>Co-administration<br>HIV+ and preterm neonates booster |
| | Option 2 | 6 weeks (min) | 2 | 8 weeks (min) | | | 9-15 months | |
| Rotavirus [7] | Rotarix | 6 weeks (min) with DTP1 | 2 | 4 weeks (min) with DTP2 | | | | Vaccine options<br>Not recommended if > 24 months old |
| | Rota Teq | 6 weeks (min) with DTP1 | 3 | 4 weeks (min) - 10 weeks with DTP2 | 4 weeks (min) with DTP3 | | | |
| Measles [8] | | 9 or 12 months (6 months min, see footnote) | 2 | 4 weeks (min) (see footnote) | | | | Combination vaccine; HIV early vaccination; Pregnancy |
| Rubella [9] | | 9 or 12 months with measles containing vaccine | 1 | | | | | Achieve and sustain 80% coverage<br>Combination vaccine and Co-administration; Pregnancy |
| HPV [10] | | As soon as possible from 9 years of age | 2 | 6 months (min) | | | | Target 9-13 year old girls<br>Pregnancy<br>Older age groups ≥ 15 years<br>HIV and immunocompromised |

Refer to http://www.who.int/immunization/documents/positionpapers/ for table & position paper updates.

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

National schedules should be based on local epidemiologic, programmatic, resource & policy considerations. While vaccines are universally recommended, some children may have contraindications to particular vaccines.

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**Figure 9: WHO ICP for Child Immunization (Most Common Vaccines)**

From the table, and from the footnotes that accompany the table, the ICP for oral and intraveneous polio vaccine administration (OPV and IPV, respectively) may be described in narrative text as follows:

- WHO no longer recommends an OPV-only vaccination schedule. For all countries currently using OPV only, at least 1 dose of IPV should be added to the schedule.
- In polio-endemic countries and in countries at high risk of importation and subsequent spread, WHO recommends an OPV birth dose (a zero dose) followed by a primary series of 3 OPV and at least 1 IPV doses.
- The birth dose of OPV should be administered at birth, or as soon as possible after birth, to maximize the seroconversion rates with subsequent doses and to induce mucosal protection.

- The primary series consisting of 3 OPV doses plus 1 IPV dose can be initiated from the age of 6 weeks with a minimum interval of 4 weeks between the OPV doses. If 1 dose of IPV is used, it should be given from 14 weeks of age (when maternal antibodies have diminished and immunogenicity is significantly higher) and can be co-administered with an OPV dose.
- The primary series can be administered according to the regular schedules of national immunization programmes, for example at 6, 10 and 14 weeks (OPV1, OPV2, OPV3+IPV) or at 2, 4 and 6 months (OPV1, OPV2+IPV, OPV3 or OPV1, OPV2, OPV3+IPV). Both OPV and IPV may be co-administered with other infant vaccines.
- For infants starting the routine immunization schedule late (age > 3 months) the IPV dose should be administered at the first immunization contact.

It is noteworthy that the WHO EPI tables generally treat the immunization schedule of each vaccine as being independent. That is to say, the logic of each vaccine administration can be determined without knowing what other vaccines are also being given to the child. This assumption makes modeling the vaccine administration simpler.

## 3.3 A BPMN example: Child Immunization Schedule

To illustrate how BPMN may be employed to codify an ICP, a BPMN diagram was developed to codify the polio immunization schedule described in Section 3.2. This diagram is shown in Figure 10.

 

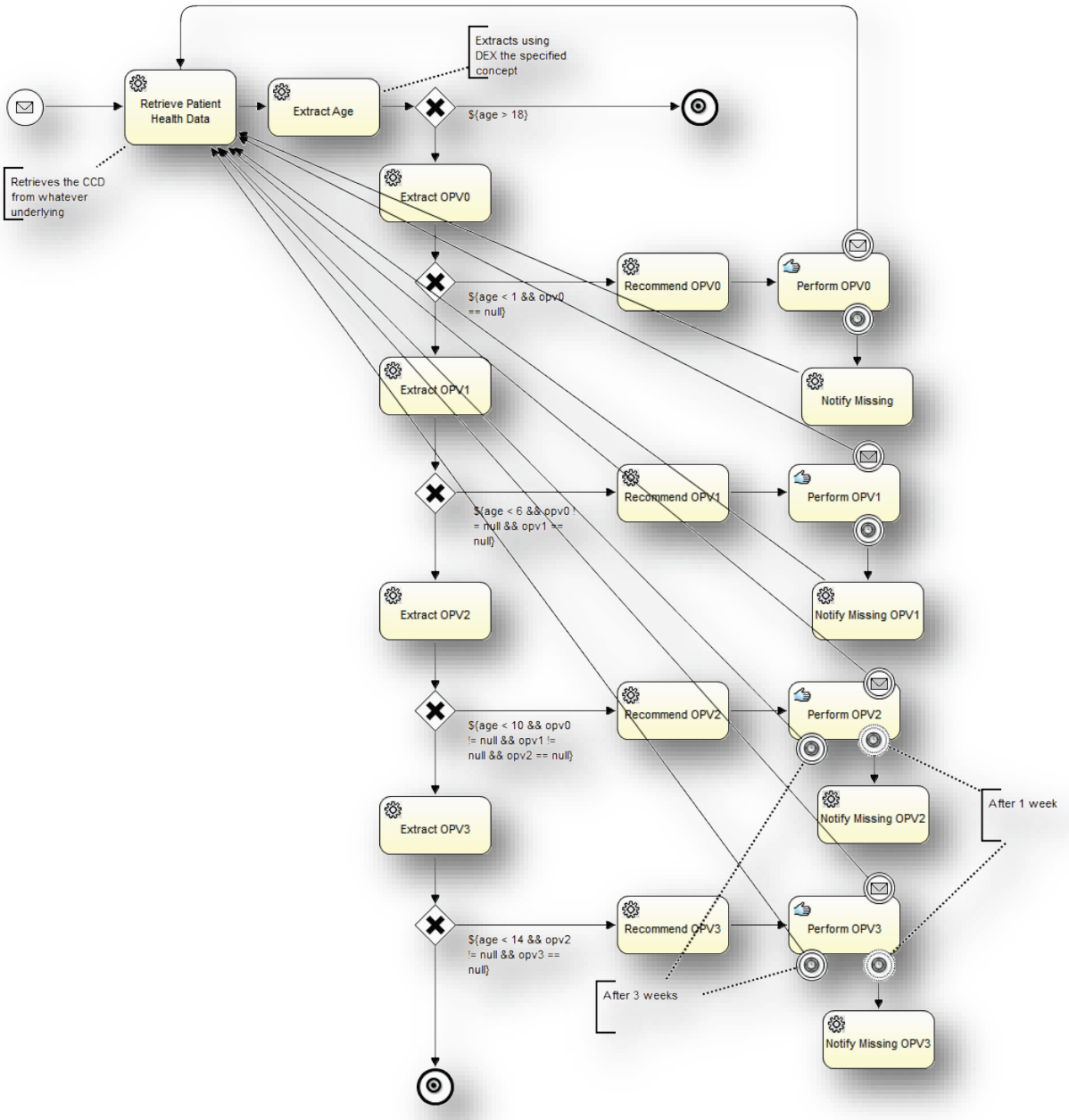


**Figure 10: A BPMN Representation of the Polio Vaccine Schedule**

The BPMN representation of the polio vaccination schedule introduces important computing constructs into the immunization workflow. The following narrative describes the flow of the diagram through its first few steps:

1. The workflow begins. The child's present health data are retrieved. These data include the present state of the child's vaccine administrations.
2. From the health dataset, the child's age is determined.
3. If the child is over the age of 18 years old, the workflow ends.
4. If the child is not over the age of 18 years old, the status of the OPV0 dose is determined (Extract OPV0)
5. If the child is less than 1 year of age and OPV0 has not been administered then "order" OPV0 for the child (Recommend OPV0) and administer the vaccine (Perform OPV0). If the vaccine is administered, update the child's health record accordingly. If the vaccine could not be administered (e.g., if there was a stock out) then update the child's health record that OPV0 was not administered because it was missing (Notify Missing)

As is evident from Figure 10, the process logic for the other steps in the polio immunization workflow are similarly described using the BPMN graphical primitives. (NOTE: for simplicity of representation, this BPMN diagram intentionally omits the IPV step). The next section describes a system design engineered to operationalize this workflow by leveraging a collection of IHE profiles woven into the fabric of an OpenHIE-based health information exchange.

 

# 4 Prototyping IHE4ICP

A key research question for this exploration was: "can BPMN be employed to represent an integrated care pathway?" One of the reasons for framing the investigation in this way was to be able to leverage the broad adoption of this specification and the wide range of tools that can work with BPMN. Another reason was to evaluate using IHE's Retrieve Process for Execution (RPE) Profile to manage the workflow and the Data Element Exchange (DEX) Profile for extracting key content from within a clinical document. Within these constraints, prototyping work was undertaken by the mHealth and eHealth Development and Innovation Centre (the MEDIC lab) at Mohawk College in Hamilton, Canada. In the following sections, the engineering design project is described.

## 4.1 High-level Engineering

The major features of the MEDIC lab's engineering design project may be described as follows:

1. Provide an implementation of an RPE-conformant "Process Activity Executor" Actor which can, given a predefined, well understood, computable BPMN model, execute the process described in the model in a durable, efficient manner
2. Provide an implementation of supporting functions (BPMN services) which can be used to express the following basic infrastructural elements required to execute a care pathway process:
    a. Retrieve Patient Summary Information
    b. Extract Data Elements from a Patient Summary
    c. Propose actions to be performed using the patient's current summary
    d. Update textual "Care Plan" information in the Patient's Summary
    e. Notify a patient/provider/user on an arbitrary event
3. Provide a mechanism for defining, in a configurable manner, data elements of interest to an ICP process using the DEX Profile
4. Provide sample ICP processes, expressed in BPMN, using the elements defined in feature #2, which implements guidelines for HIV care
5. Optionally, provide sample ICP processes expressed in BPMN, using the elements defined in feature #2, which implements guidelines for childhood immunizations
6. Provide a mechanism or pattern for designing ICP processes using either native BPMN or a subset of BPMN as a Domain Specific Language (DSL) for the purposes of ICP.

 

## 4.2 Detailed Design

The project's high level engineering design was decomposed into a set of software components and the specific requirements for these components were expressed. The deliverables for the design/development effort may be described as follows:

| Deliverable | Description | Priority |
|---|---|---|
| DEX Registry | An implementation of a DEX Metadata Source Actor. | M |
| ICP Executor | An implementation of RPE and necessary consumer roles to support the ICP services identified in feature #2. | VH |
| OpenHIE Environment | A test environment with OpenHIE actors for CR and SHR. | VH |
| ODD for OpenXDS | An implementation of the necessary ODD elements for OpenXDS | H |
| mACM Stub | A stub service implementing the mACM Profile for the notification feature listed in #2 | H |

The functional requirements of these deliverables may be described as follows:

### 4.2.1 Functional Requirements

#### 4.2.1.1 ICP Executor Deliverable

REQ-1. The ICP executor shall be capable of executing BPMN processes including BPMN constructs: gateway, service task, message event, timer event.

REQ-2. The ICP executor shall provide implementations of all BPMN services listed in Feature #2 of this document. These services are defined in further detail in Section 4 of this document.

REQ-3. The ICP executor shall persist, at minimum, the state of the process upon a wait/boundary event, and should persist the outcome of each service task.

REQ-4. The ICP executor shall provide a mechanism to define business process (via BPMN) definitions which provide access to the services described Feature #2.

### 4.2.2 User Interface Requirements

#### 4.2.2.1 ICP Executor Deliverable

The ICP executor deliverable introduces the following requirements:

REQ-5. The ICP executor shall provide a mechanism for an administrator of the system to review the currently executing processes, the load on system, and to terminate processes currently being executed.

 

REQ-6. The ICP executor shall provide a mechanism for an administrator of the system to upload new ICP definitions (BPMN processes) to be shared via an RPE process definition management WS interface.

#### 4.2.2.2 DEX Registry Deliverable

REQ-7. The DEX registry shall provide a basic interface for viewing and defining ICP concepts as well as the path within a document to retrieve the defined data element, and the bound vocabulary.

### 4.2.3 Communications Interfaces

**Table 4.2.3-1: Communications Interfaces**

| Deliverable | Interface | IHE Transactions |
|---|---|---|
| ICP Executor | Document Consumer | ITI-18, ITI-43 |
| | Document Source | ITI-41 |
| | Content Consumer | [19]CCD®[20]+ |
| | Content Creator | CCD+ |
| | Metadata Consumer | QRPH-44 |
| | Document Metadata Notification Recipient | ITI-53 |
| | Document Metadata Subscriber | ITI-52 |
| | Process Definition Manager | QRPH-20 |
| | Process Activity Executor | QRPH-20, QRPH-25, QRPH-26, QRPH-27, QRPH-28 |
| | Process State Manager | QRPH-25, QRPH-26, QRPH-27, QRPH-28 |
| | Alert Reporter | ITI-X01 |
| DEX Registry | Metadata Source | QRPH-44, QRPH-43 |
| [21]ODD for OpenXDS | Document Registry | ITI-18, ITI-42 |
| mACM Stub | Alert Manager | ITI-X01, ITI-X02 |

[19] The OpenHIE project leverages a generic content profile which is an extended superset of the IHE PCC XDS-MS Profile. This content profile is referred to within the OpenHIE community as a *Continuity of Care "plus"* (CCD+) profile.

[20] CCD is the registered trademark of Health Level Seven International.

[21] ODD is the *On Demand Document* Option of the IHE ITI XDS.b Profile.

## 4.3 Software Architecture

The software architecture for the solution requires several components to be implemented where current standards based solutions do not exist or are not available as open source options.

### 4.3.1 ICP Executor Architecture

The ICP executor will run as a Java based servlet running within a container such as Tomcat. This servlet will leverage the Activiti[22] engine runtime components. The following figure provides a high level overview of the libraries and toolkits involved in the ICP executor to fulfill the roles identified by the actors.

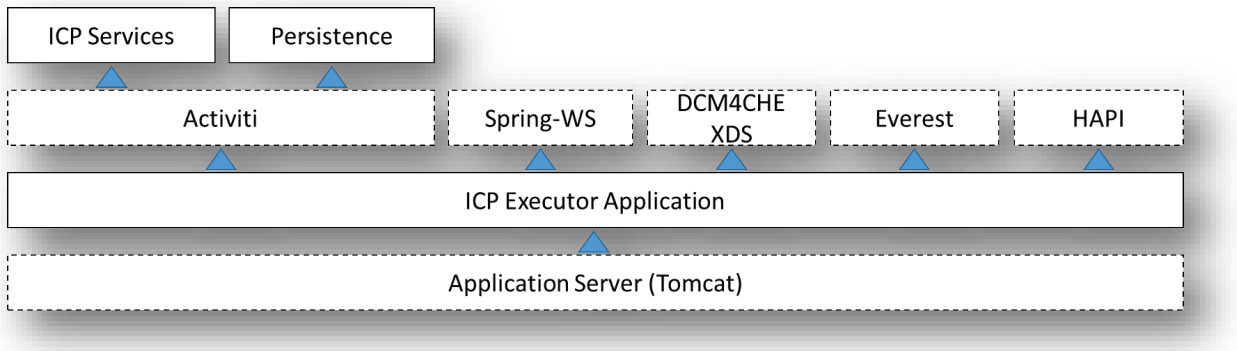


**Figure 11: ICP Executor Architecture**

The components identified in the component diagram are described in more detail below.

**Table 4.3.1-1: Architectural Component Descriptions**

| Component / Toolkit | Support Actors | Description / Rationale |
|---|---|---|
| Application Server | | |
| ICP Executor Application | | Responsible for tying together the applications. |
| Activiti | Process Executor (RPE)<br>Process Definition Manager (RPE) | BPMN interpretation and service framework. |
| Spring-WS | All WS Based Transactions | |
| DCM4CHE | Document Consumer (XDS)<br>Document Source (XDS)<br>Secure Application (ATNA) | Constructing and consuming XDS metadata.<br>Constructing and sending audits |
| Everest | Content Creator<br>Content Consumer | |

[22] The open source Activiti BPMN engine was leveraged for this prototype: http://activiti.org/

| Component / Toolkit | Support Actors | Description / Rationale |
|---|---|---|
| ICP Services | | Service implementations as described below. |
| Persistence | Process State Manager (RPE) | Used to persist the state of a workflow. |

### 4.3.2 ICP Services

All key components of ICP interaction with the HIE will be performed via BPMN services. For example, the OPV administrative workflow (see Figure 10) is simplified by the use of BPMN services. These services allow implementation specifics (to the runtime engine) to be written in a language more suited to complex messaging (such as Java or C#).

#### 4.3.2.1 Retrieve Patient Data

Since the notification which will trigger a workflow may not be a direct XDS message with content (more likely will be a DSUB notification message), the retrieve patient data service will be implemented. The use of this BPMN service will initiate an ITI-18 and ITI-43 message to retrieve a patient summary (or the document which was notified, this may be a discussion point). The service to retrieve a patient summary is a serviceTask in BPMN and is represented as follows in Activiti:

```
<serviceTask id="servicetask1" name="Retrieve Patient Health Data"
activiti:class="org.ohie.icp.core.services.DataService"
activiti:resultVariableName="patientCcd">
      <extensionElements>
        <activiti:field name="resultVariableName">
          <activiti:string><![CDATA[patientCcd]]></activiti:string>
        </activiti:field>
        <activiti:field name="notificationDocument">
          <activiti:expression>notificationDocument</activiti:expression>
        </activiti:field>
      </extensionElements>
    </serviceTask>
```

Additional prototyping work should be undertaken to represent this service as a standardized BPMN serviceTask call.

#### 4.3.2.2 Extract Data Element

The developer of an ICP BPMN could (and should) use a Business Rules Task to perform business rules or decisions on future flows. The extract data element service is provided to allow developers to choose not to use this option and extract single data elements from the retrieved patient data. The extract data element uses DEX to determine where the data element is extracted.

 

```
    <serviceTask id="servicetask2" name="Extract DOB"
activiti:class="org.ohie.icp.core.services.MetadataExtractionService"
activiti:resultVariableName="dob">
      <extensionElements>
        <activiti:field name="dataElement">
          <activiti:string><![CDATA[dob]]></activiti:string>
        </activiti:field>
        <activiti:field name="inputDocument">
          <activiti:expression>patientCcd</activiti:expression>
        </activiti:field>
        <activiti:field name="class">
          <activiti:string><![CDATA[java.lang.Integer]]></activiti:string>
        </activiti:field>
      </extensionElements>
    </serviceTask>
```

Additional processing on source data (example: converting date of birth to an age) may need to be performed in order to make a decision which matches a clinical care guideline. Again, using a business rules task with a backing technology such a DROOLS would be much easier at implementation time.

#### 4.3.2.3 Submit Clinical Data

TO DO: This is a complex operation as the data to be suggested or submitted is in CDA®[23] and will be quite complex and will vary from use case to use case. There are several options to deal with this limitation:

1. Use template data via data inputs. This is how the example RPE workflows provided by QRPH work. The limitation here is that Activiti does not support data in/out shapes and thus a change in BPMN engines would need to be performed.
2. Construct the CDA in services. This option means that a developer would implement services such as “Create Prescription” or “Create OPV0 Appointment” which would construct the appropriate CDA sections using a framework of choice.
3. Have a super smart “submit clinical data” service which would accept a parameter of type of entry being created and construct an appropriate entry at the appropriate part of a CDA based on templates stored in some pre-configured way (database or XML file of templates).

[23] CDA is the registered trademark of Health Level Seven International.

 

## 4.4 Communications Architecture

### 4.4.1 IHE Actors and Transactions

The solution will leverage IHE profiles for the purposes of conveying responses to infrastructure, as well as triggering workflow actions to occur. Illustrates the IHE actors to be implemented as well as the deliverables each relates to.

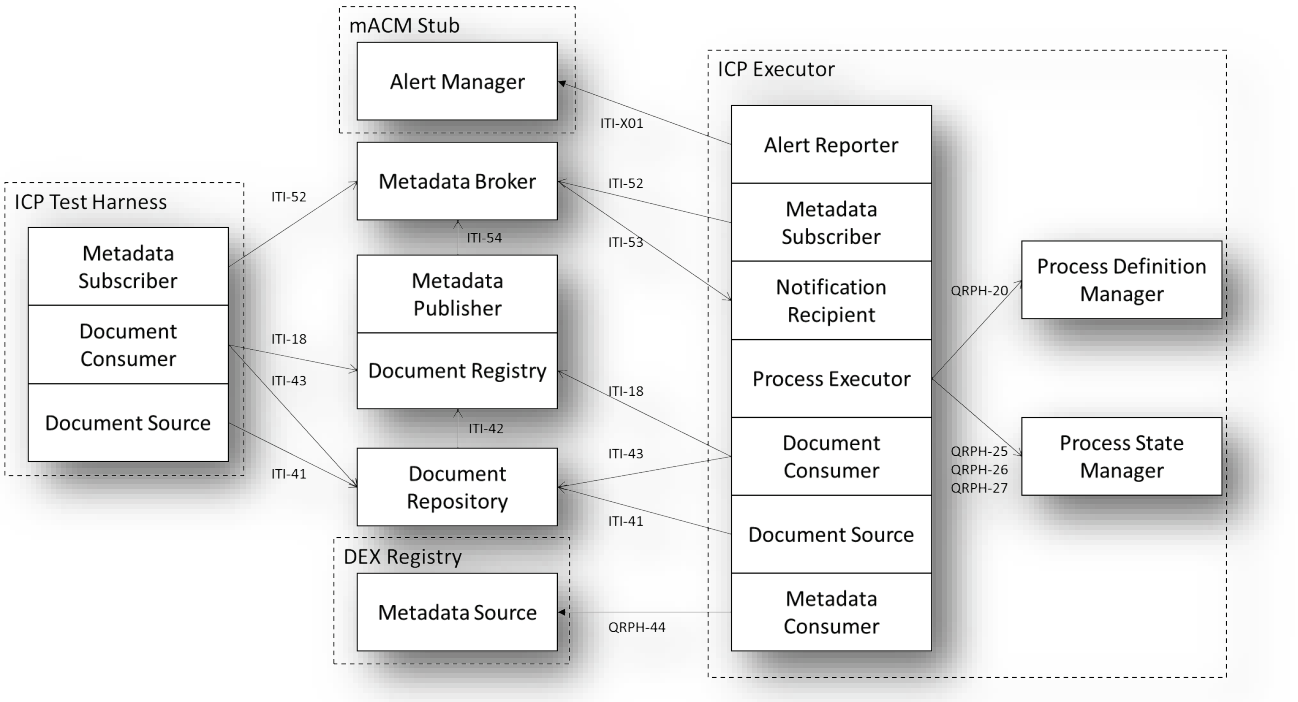


**Figure 12: IHE Actors and Transactions**

#### 4.4.1.1 ICP Executor

The ICP Executor will be a modified version of the Activiti workflow engine with various IHE actor components implanted to trigger workflow actions within the engine. Additionally workflow services will initiate communications with external systems. The list below indicates how each IHE actor interacts with the Activiti engine and BPMN services.

- **Alert Reporter (mACM):** The Alert Reporter Actor will be implemented in the "Notification" service. BPMN processes which leverage the notification shapes will issue an ITI-X01 message to an alert manager. The "Notification" process is described more in the software architecture section.
- **Metadata Subscriber (DSUB)**: The Metadata Subscriber role is implemented to handle the cancellation and subscription of messages. In general, this will relate to process

termination events. Whenever a process is terminated, the subscriber actor will issue a cancel subscription message to the metadata broker. Additionally every time a BPMN process pauses to wait for a message (via receive task or via message boundary event) the DSUB subscriber will be responsible for indicating that notifications should "waken" the process.

- **Metadata Notification Recipient (DSUB)**: The Notification Recipient will be used to fulfill message events in a BPMN process running within Activiti. A notification received from a the DSUB metadata broker will cause the ICP executors' notification recipient to check if any active BPMN processes are waiting for a message event, and if so, whether the subscription ID matches the subscription ID of the inbound message. Additionally, this actor will be responsible for activating new BPMN processes for which the subscription data applies.
- **Process Executor (RPE)**: The Process Executor Actor implementation will mainly consist of controller code to initiate and run the activiti workflows.
- **Document Consumer (XDS)**: The Document Consumer Actor will be called from the "Retrieve Patient Health Information" BPMN service. This actor will use the current BPMN context variables (passed as parameters to the service) to retrieve CDA documents from the XDS infrastructure (in our deployment SHR).
- **Document Source (XDS)**: The Document Source Actor will be called from the "Propose" service and is primarily concerned with inserting sections, entries, or documents themselves into the patient's SHR using the XDS infrastructure.
- **Metadata Consumer (DEX)**: The Metadata Consumer Actor will be executed from the "Extract" BPMN service. This service will use DEX to retrieve the named metadata element (passed via parameter) from the provided CDA document, returning the result of the XPATH expression provided by the DEX registry.

### 4.4.2 Sequence Flow

There are several sequences which occur to technically support the execution of BPMN processes within the architecture.

 

#### 4.4.2.1 Patient Registration

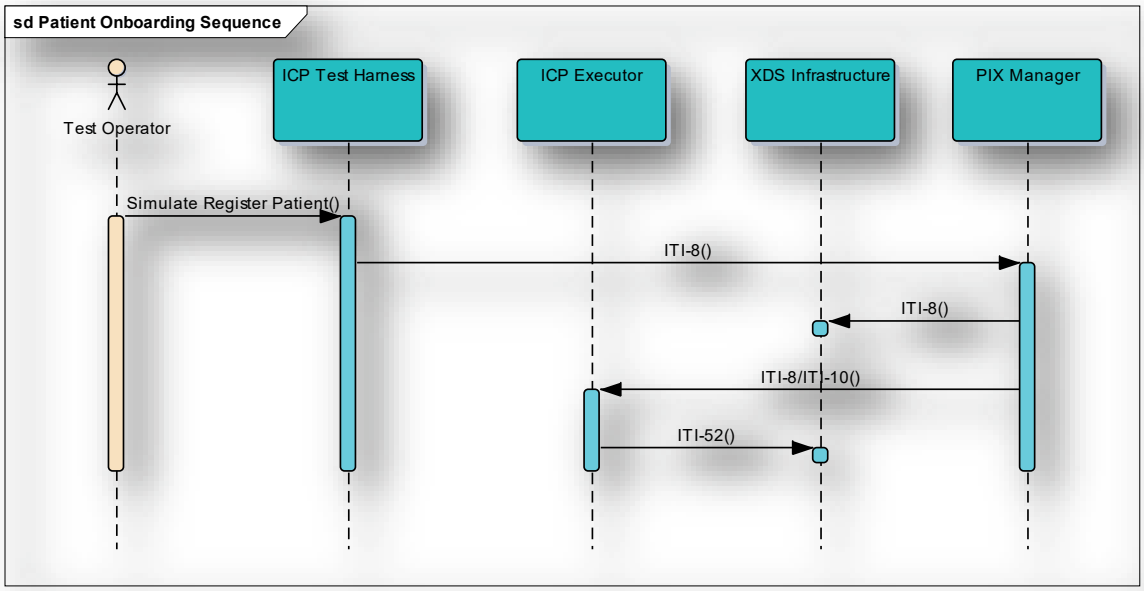


**Figure 13: Patient Registration**

The first sequence that must occur is the instantiation of a subscription to infrastructure for new documents which are created for a patient. This subscription will contain the registered patient's enterprise client ID (ECID).

A sample message (ITI-52) is provided to get an idea of what data is subscribed to. The ICP Executor deliverable will need to store active subscription identifiers and current workflows that are being executed for the particular patient in order to correlate subsequent notifications to active or persisted BPMN processes.

```
<?xml version="1.0" encoding="UTF-8"?>
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
            xmlns:a="http://www.w3.org/2005/08/addressing"
            xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
            xmlns:wsnt="http://docs.oasis-open.org/wsn/b-2"
            xmlns:rim="urn:oasis:names:tc:ebxml-regrep:xsd:rim:3.0">
  <s:Header>
    <a:Action>http://docs.oasis-
open.org/wsn/bw2/NotificationProducer/SubscribeRequest</a:Action>
    <a:MessageID>382dcdc7-8e84-9fdc-8443-48fd83bca938</a:MessageID>
    <a:To s:mustUnderstand="1">http://shr.instance.ohie.org:8080/services/dsub</a:To>
  </s:Header>
  <s:Body>
    <wsnt:Subscribe>
      <!-- The Recipient on whose behalf the subscription is requested - the address
where 695 the notification is to be sent -->
      <wsnt:ConsumerReference>
        <a:Address>https://NotificationRecipientServer/xdsBnotification</a:Address>
      </wsnt:ConsumerReference>
      <wsnt:Filter>
        <wsnt:TopicExpression Dialect="http://docs.oasis-
open.org/wsn/t1/TopicExpression/Simple">ihe:MinimalDocumentEntry</wsnt:TopicExpression>
        <rim:AdhocQuery id="urn:uuid:aa2332d0-f8fe-11e0-be50-0800200c9a66">
          <rim:Slot name="$XDSDocumentEntryPatientId">
            <rim:ValueList>

<rim:Value>'ecid10293945^^^&amp;amp;1.3.6.1.4.1.21367.2005.3.7&amp;amp;ISO'</rim:Value>
            </rim:ValueList>
          </rim:Slot>
        </rim:AdhocQuery>
      </wsnt:Filter>
      <wsnt:InitialTerminationTime>2060-05-
31T00:00:00.00000Z</wsnt:InitialTerminationTime>
    </wsnt:Subscribe>
  </s:Body>
</s:Envelope>
```

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#### 4.4.2.2 New Data Available

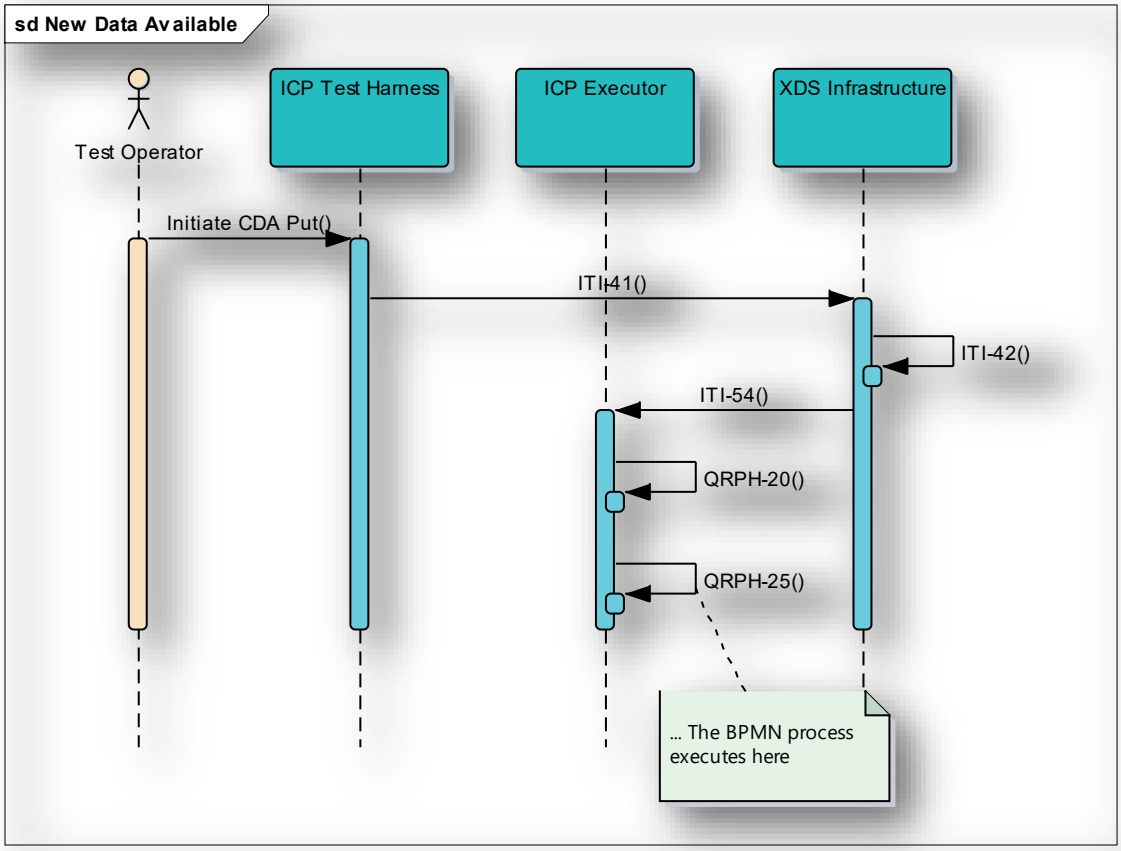


**Figure 14: Store New Clinical Data**

In this sequence the test harness initiates the recording of a new clinical document. After the XDS infrastructure has completed the persistence of this data (SHR in the case of OpenHIE) it will perform a DSUB notification received by the executor. The executor:

1. Checks configuration to determine if any formatCode/typeCode combinations match a BPMN process id and, if necessary
    a. Retrieve the process (QRPH-20)
    b. Initiate the process (QRPH-25)

This process is used for indicating that a message has triggered the start of the process and is fed into the message object of the start event object in the BPMN process.



 

#### 4.4.2.3 Halt / Wait Process

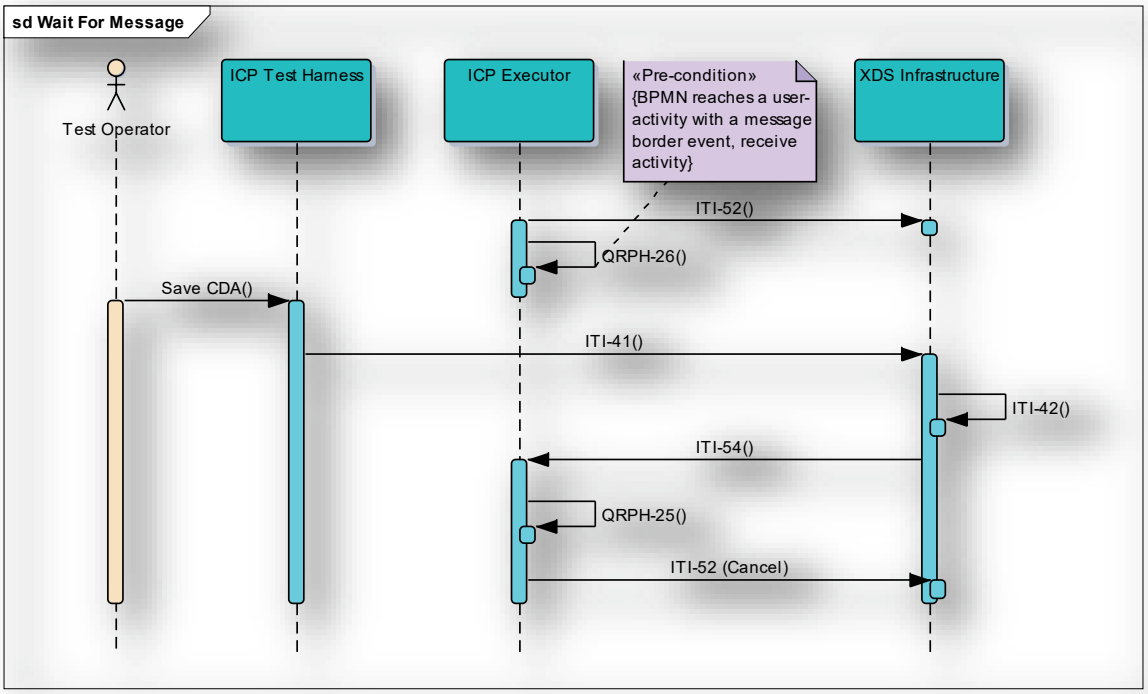


**Figure 15: Wait for Signal**

This sequence describes the halt/wait (e.g., wait for a signal) process. This occurs when the BPMN process encounters an activity for which there is a message event which can interrupt the wait state. For example, the following BPMN process would result in the ICP executor creating a subscription to catch the message signal event.

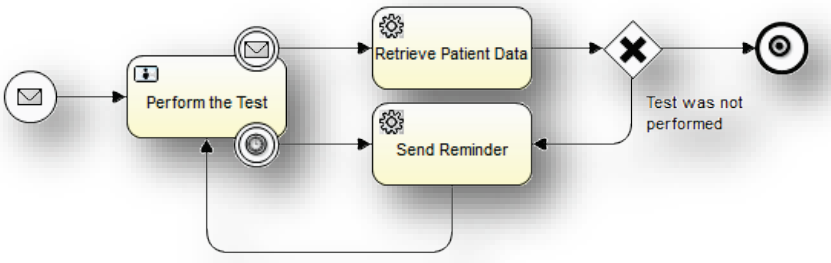


**Figure 16: Example BPMN "Wait" Process**

#### 4.4.2.4 Retrieve Patient Data

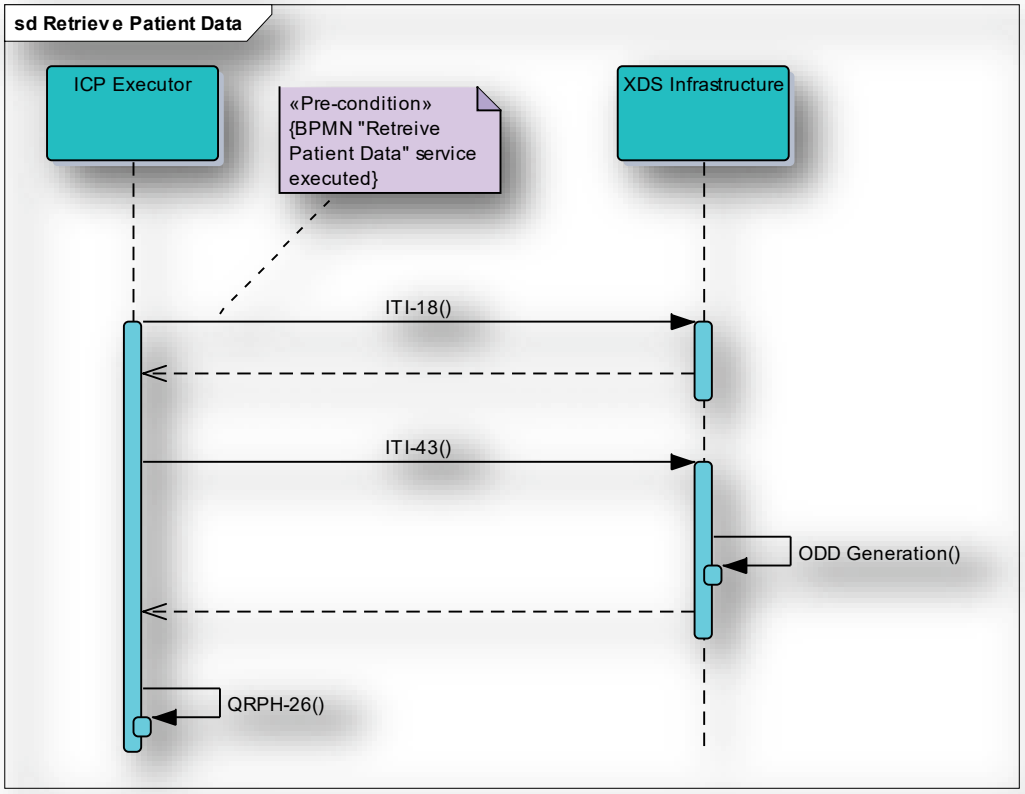


**Figure 17: Retrieve Patient Data**

670 The retrieve patient data sequence is executed whenever the retrieve patient data BPMN service is called. This service is responsible for querying for the current CCD/CCD+ for the patient (ODD is preferred and will be used in OpenHIE) and returning the document to the process so it may be further queried/operated upon.

#### 4.4.2.5 Extract Data Element

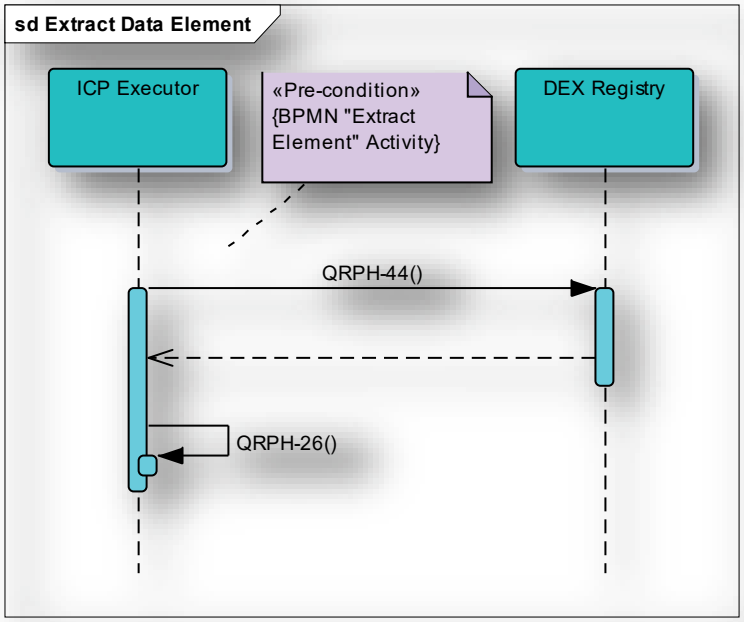


**Figure 18: Extract Patient Data**

The extract data element process is executed whenever the "Extract Data" BPMN service is called form the ICP process. The extract data element uses DEX (QRPH-44) to determine how to extract the data element from the CDA being used within a jurisdictional infrastructure.

The following message shows a sample QRPH-44 message which could be used to extract a data element named "DOB" which extracts the date of birth of the patient.

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa="http://www.w3.org/2005/08/addressing"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
    <wsa:MessageID>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a183</wsa:MessageID>
    <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadata</wsa:Action>
  </soap:Header>
  <soap:Body>
    <dex:RetrieveMetadataRequest xmlns:dex="urn:ihe:qrph:dex:2013">
```

```
      <dex:id>DOB</dex:id>
      <dex:registrationAuthority>TZ-HIV</dex:registrationAuthority>
    </dex:RetrieveMetadataRequest>
  </soap:Body>
</soap:Envelope>
```

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With a response of:

```
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:wsa="http://www.w3.org/2005/08/addressing"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <soap:Header>
    <wsa:Action>urn:ihe:qrph:dex:2013:RetrieveMetadataResponse</wsa:Action>
    <wsa:RelatesTo>urn:uuid:f43f7bda-a5f9-42b1-b8dc-e78be1a2a183</wsa:RelatesTo>
  </soap:Header>
  <soap:Body>
    <dex:RetrieveMetadataResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:dex="urn:ihe:qrph:dex:2013">
      <dex:DataElement>
        <dex:id>DOB</dex:id>
        <dex:registrationAuthority>TZ-HIV</dex:registrationAuthority>
        <dex:version>0.1</dex:version>
        <dex:displayName>PDDOB</dex:displayName>
        <dex:definition>The date of birth of the patient</dex:definition>
        <dex:contextualDomain>CCD</dex:contextualDomain>
        <dex:creationDate>2010-01-01</dex:creationDate>
        <dex:effectiveDate>2010-02-01</dex:effectiveDate>
        <dex:expirationDate>2020-01-01</dex:expirationDate>
        <dex:objectClass>TS</dex:objectClass>
        <dex:property>DOB</dex:property>
        <dex:valueDomain>
          <dex:dataType>xsd:string</dex:dataType>
        </dex:valueDomain>
        <dex:mappingSpecification>
          <dex:contentModel>
```



 

```
            <dex:id>2.16.840.1.113883.10.20.1</dex:id>
            <dex:name>HL7 CCD</dex:name>
          </dex:contentModel>
          <dex:type>XPATH</dex:type>
          <dex:mappingScript>
            ./ClinicalDocument/recordTarget/patientRole/patient/birthTime/@value
          </dex:mappingScript>
        </dex:mappingSpecification>
      </dex:DataElement>
    </dex:RetrieveMetadataResponse>
  </soap:Body>
</soap:Envelope>
```

#### 4.4.2.6 Submit Clinical Data

This was not prototyped; there are issues to consider that were beyond the scope of available time and budget in this investigation and are recommended for further work (see Section 5.3). This process would entail consideration of several of the BPMN shapes such as Suggest Meds, Suggest IZ, Suggest Procedure, etc.

#### 4.4.2.7 Notify

This was not prototyped. As a note for further exploration, the notify process would be executed whenever the *notify* BPMN service is executed. The process issues an ITI-84 transaction (mACM Mobile Report Alert) to the configured alert aggregator.

# 5 Results

This section describes results from the prototyping effort and recommends next steps that would further the research on this important topic.

## 5.1 Results of the prototyping effort

The constraints placed on the MEDIC lab's development team by the top-level research question proved daunting and the full scope of prototype development was not completed. As a fundamental research question, this investigation committed to using BPMN as the mechanism for describing integrated care pathways. As a reportable result, it is the opinion of the prototype developers that BPMN is not well-suited to expressing ICPs and a rules-based engine, such as DROOLS, should be preferred.

Another of the design constraints was that standards-based IHE profiles would be leveraged to operationalize the ICP execution. As is evident from Figure 12, this constraint caused the software design to become complicated. That said, the decomposition of ICP processing into a generic set of transactions and interfaces will, by necessity, require a software design to be able to determine its behavior at runtime (rather than at design-time, which is typical). It is not clear whether such complexity can be avoided in situations where the HIE's software stack is expected to behave in such a way.

A pattern for operationalizing such a generic "ICP engine" behavior did emerge from the research effort; this pattern is illustrated by Figures 13-18. It may be generally described as follows:

1. A client is "associated" with a care plan (Figure 13) by establishing a relationship between a specific ICP and the client's unique ID (ECID). An example would be that an inbound CDA carrying a diagnosis indicating a client is HIV+ could trigger the HIV care ICP to be associated with the client.
2. When new clinical information is saved that pertains to this client (e.g., a CDA associated with the ECID), the ICP Executor looks for a pre-existing reference to an associated ICP (Figure 14). As an example, an inbound CDA containing lab results for an HIV+ client could inform a decision point on the HIV care ICP.
3. The logic described in the ICP may require "content" about the client in order to execute its care path algorithms. To support this, the present health summary record for the client is retrieved (Figure 17) and the required content is extracted from it (Figure 18). Following the lab test results example, the CD4 count and viral load are key values for the HIV care ICP logic; these specific values would need to be extracted from the overall clinical content.
4. Based on the inbound "new" clinical information (step 2, above), and specific values extracted from it (step 3) the ICP algorithms may inform recommended actions or alerts to be communicated (to the clinician, to the patient, etc.). The communication of such

 

actions/alerts may also be triggered by a "tick of the clock". This latter case is illustrated by Figures 15 & 16. Following the HIV care example, CD4 count or viral load values in a new lab test result could trigger an escalation of care or a change in the client's medication regime. Or, an alert might be raised because lab results should be obtained for HIV patients every 6 months and it has now been 7 months since a lab result was recorded. This "absence of a signal" could raise an alert, based on the tick of the clock.

Recalling the figures in this white paper, it is clear the Point-of-Service (POS), HIE and ICP Engine "entities" are composed of multiple IHE actors participating in pattern-based communication as defined by various IHE profiles. This overall, top-level communication pattern is illustrated by Figures 19 and 20.

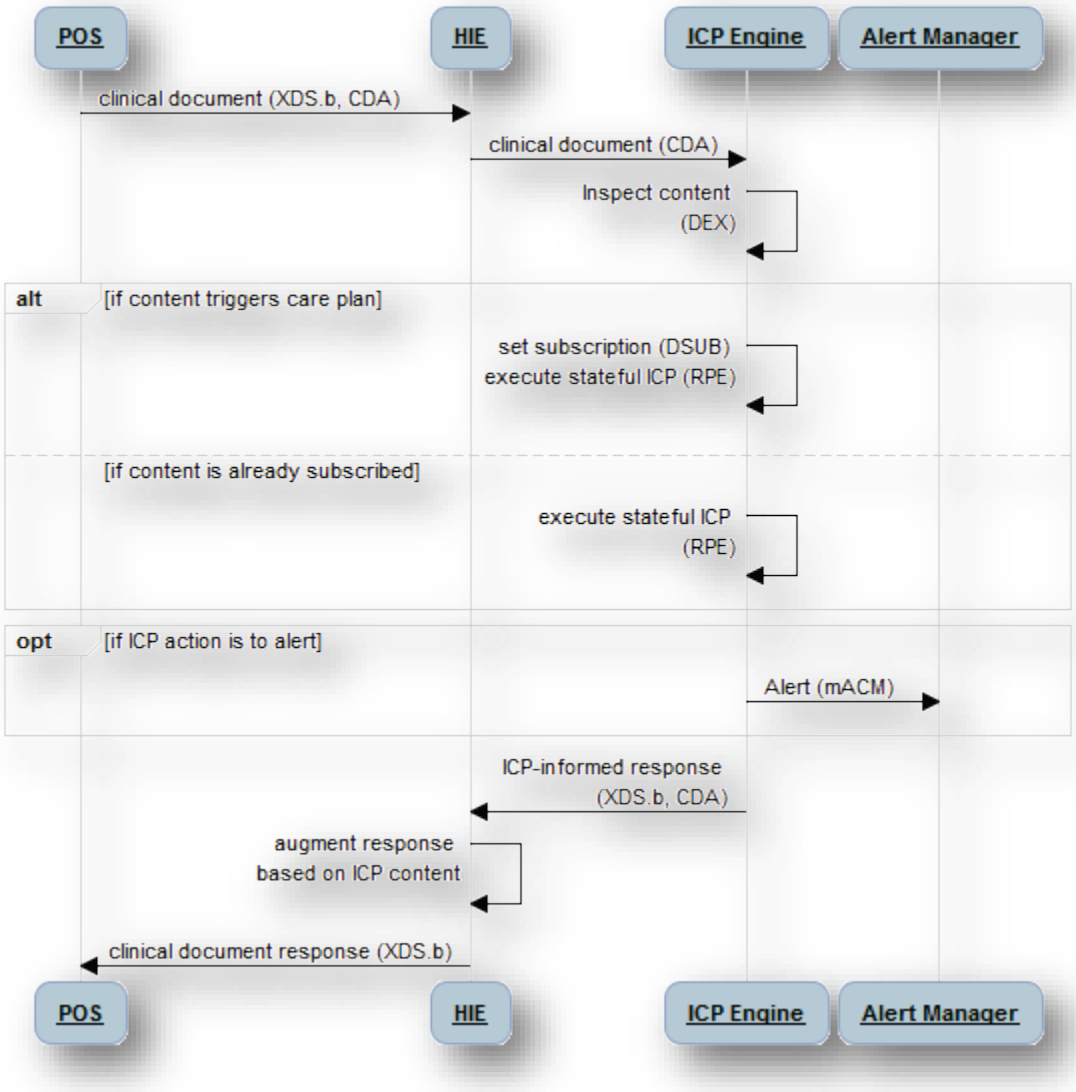


**Figure 19: Top-level ICP Operationalization Pattern**



 

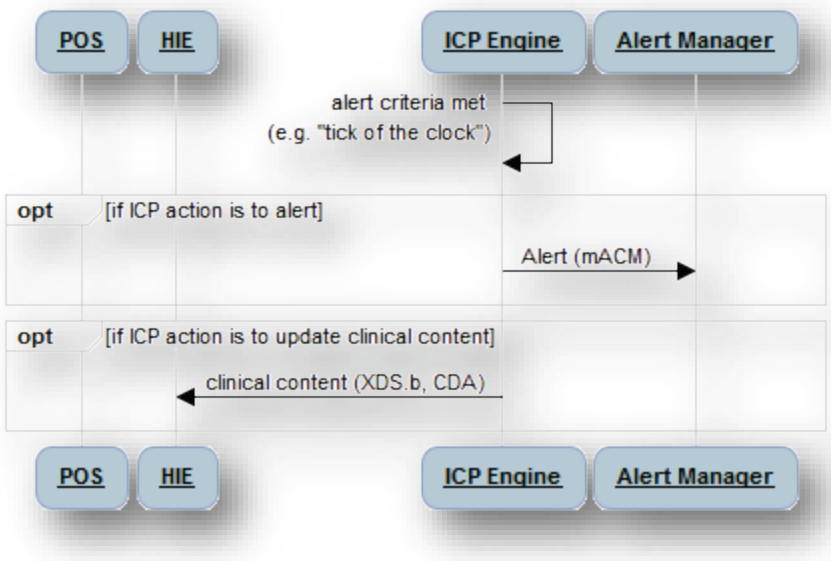


**Figure 20: Tick-of-the-Clock ICP Actions**

## 5.2 Lessons learned

The primary finding of the software development team regarding BPMN as a means of expressing ICPs represents a key lesson. Both of the example care workflows, adult HIV treatment and child immunization, are expressed as sets of rules. The permutations of these rules mapped to a BPMN-expressed workflow in a very convoluted way. One of the lessons, therefore, is that rules-based care guidelines are better mapped to a rules-based paradigm than a workflow-based paradigm. A caveat to this conclusion/lesson is that the coordination of care across multiple entities was not one of the modeled use cases. It remains an open question whether such an ICP would map more readily to BPMN's "workflow" paradigm.

Another key lesson that emerged from this research was the importance of an orchestration engine. This quite obvious conclusion is not a trivial one; it points to the important role played by HIE architecture. The OpenHIE architecture presumes the presence of an Interoperability Layer "actor" whose role is to orchestrate the processing of clinical document puts and gets. Without such an architectural element, adding the ICP processing would be made extremely challenging, if not impossible.

## 5.3 Recommended next steps

Based on the lessons learned by this research, a number of important research questions should be pursued:



 

1. A rules-engine based technology stack, such as DROOLS, should be prototyped as a means for expressing ICPs in a computable format. The effect on the resulting communication patterns should be investigated and gaps/issues documented.
2. Use cases involving cross-enterprise care coordination should be explored. Such an inquiry may be well-served by leveraging a hybrid approach based on both a rules engine and a workflow engine.
3. Renewed focus should be placed on the base standards / specifications needed to express ICPs. A literature search is recommended to uncover and document current best practice in this area. If warranted, work items should be launched within IHE to develop interoperability profiles that operationalize promising specifications.

 

# 6 Conclusion

This white paper explored the challenges associated with employing IHE profiles to operationalize integrated care pathway (ICP) support within the fabric of a health information exchange (HIE). The challenges are real; but the approach also shows real promise. There is clear evidence that this is a worthwhile undertaking. Operationalizing ICPs affords us a way to close the know-do gap. Doing this will create significant positive health impact.

This white paper recommends that the issues that have been uncovered be further investigated and that potential solutions be prototyped. It is expected that the outcomes of this further research will inform new profile development on the part of the IHE community.