Health Informatics — Summary Report from the Task Force on Patient Safety and Quality

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Contents

Foreword ..............................................................................................................................................iv
Introduction...........................................................................................................................................v

1 Scope ................................................................................................................................................1
2 Definitions .........................................................................................................................................1

3 What do we mean by Quality Healthcare? ......................................................................................5
  3.1 Leveraging ISO 9000 ..................................................................................................................6
  3.2 Developing a health informatics framework .............................................................................8
    3.2.1 Workflow definitions ...........................................................................................................8
    3.2.2 Reportable metrics ..............................................................................................................8
    3.2.3 Control logic .........................................................................................................................8
    3.2.4 Control actions ......................................................................................................................8

4 A brief primer on process control, quality assurance, and quality control .....................................9
  4.1 Feedback control .......................................................................................................................10
  4.2 Feedforward control ..................................................................................................................10
  4.3 Inferential control ......................................................................................................................11
  4.4 Quality assurance .......................................................................................................................11
  4.5 Quality control and measurement ............................................................................................12
  4.6 Examples of quality assurance, quality control and process control techniques in healthcare ................................................................................................................................12
  4.7 The importance of patient-centricity .........................................................................................13

5 Review of existing standards and ongoing work ............................................................................14
  5.1 Workflow definitions ..................................................................................................................14
  5.2 Reportable metrics .....................................................................................................................15
    5.2.1 HL7 Health Quality Measurement Framework (HQMF) ......................................................16
    5.2.2 IHE Quality, Research and Public Health Domain (QRPH) ...............................................16
    5.2.3 WHO Family of International Classifications ......................................................................16
  5.3 Control logic ...............................................................................................................................18
    5.3.1 WS-BPEL .................................................................................................................................18
    5.3.2 GELLO ..................................................................................................................................18
    5.3.3 ARDEN ..................................................................................................................................19
  5.4 Control actions ............................................................................................................................20

6 Recommendations ...................................................................................................................... ...20

Bibliography .......................................................................................................................................23

7 Opportunities ..................................................................................................................................23

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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This document is to be produced by the ISO/TC 215 Task Force on Patient Safety and Quality.
Introduction

The present ISO work effort is motivated by an important but alarming fact. In other high-reliability sectors such as nuclear power generation or aviation, error rates are in the range of 1 per 10,000 events, or 0.01%. According to research conducted by Roger Resar, MD, of the Institute for Healthcare Improvement (IHI) in the US, in healthcare, the rate of error (failing to administer the correct medication dose, for example) is over 1000 times higher; on the order of 10-20%.

The human impact of this astoundingly high error rate was measured and reported in 2000 by the US Institute of Medicine (IOM) in their seminal report: To Err is Human: Building a Safer Health System which reported that, in the US, there are over 98,000 deaths per year due to preventable adverse healthcare events. Similar studies conducted in other countries show that patient safety and quality of care is a pervasive, international challenge (see Table 1, excerpted from WHO report: World Alliance for Patient Safety, Forward Programme 2005). In the face of research that indicates only a small proportion of adverse healthcare events are actually reported (Leape, L.L. 1994. Error in Medicine. JAMA 272 (23):1851-7), the scope of this worldwide problem can be appreciated as truly worrisome.

In the 2001 IOM report, Crossing the Chasm, healthcare quality was defined in terms of 6 metrics: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity. The Canadian Patient Safety Institute (CPSI) defines patient safety as: “The pursuit of the reduction and mitigation of unsafe acts within the health care system, as well as the use of best practices shown to lead to optimal patient outcomes.” In the ISO 9000:2000 standard, quality is defined as the “degree to which a set of inherent characteristics fulfills requirements.” From these IHI, CPSI and ISO definitions we can begin to develop a definition and scope for patient safety and quality of care. Indeed, the 2005 IOM report, Building a Better Delivery System: A New Engineering/Health Care
ISO Partnership, describes the importance of The Role of Engineering in the Transformation of Healthcare (p. 14) as follows:

In 2001, IOM documented the connections among crises in American health care, set forth a compelling vision for a transformed, twenty-first century, patient-centered health care system, and appealed to engineering for help. IOM identified six interrelated dimensions of quality for the health care system that must be improved. A transformed system must be safe, effective, patient-centered, timely, efficient, and equitable (IOM, 2001):

- **Safe**—avoiding injuries to patients from the care that is intended to help them.
- **Effective**—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
- **Patient-centered**—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- **Timely**—reducing waiting times and sometimes harmful delays for those who receive and those who give care.
- **Efficient**—avoiding waste, including waste of equipment, supplies, ideas, and energy.
- **Equitable**—providing care that does not vary in quality because of personal characteristics, such as gender, ethnicity, geographic location, and socioeconomic status.

IOM identified “patient-centeredness” as the unifying and guiding principle for redesigning and improving the health care system to achieve these performance goals.

This patient-centered vision for the twenty-first century health care system not only provides a compelling case for increasing investment in information/communications technology and improving collaboration between medicine and engineering in health care delivery, but also offers a clear functional road map for transformation of the existing system. The IOM report underscores the importance of information/communications technology for meeting multidimensional performance challenges and identified proven, fundamental engineering concepts, such as designing for safety, mass customization, continuous flow, and production planning, that could be brought to bear immediately to redesign and improve care processes.

The premise of this ISO/TC215 work item is straightforward. It is expected that health informatics can play a useful, or perhaps even fundamental role in helping address these important issues of patient safety and quality of care. It is believed that the tenets of quality process and practice reflected in the ISO 9000 family of standards may be applied to clinical workflows. Health informatics may be employed to develop standardized models for representing quality healthcare processes, and may be leveraged to yield the systemic quality assurance practices and quality control metrics that will support process control of these “best practices”. This report is intended to inform and guide ISO/TC215 regarding a comprehensive standards framework necessary to fulfill these important goals.

This task force was initiated by a Resolution of ISO/TC 215 April 30, 2009:

“Resolved that ISO/TC215 approves the Executive Council recommendation for an ISO/TC 215 patient safety/quality task force to review the need for increased activities in health informatics for
patient safety and quality. Delegates and NMB’s who would like to participate please send your request to the TC secretary for participation. TC 215 will consult TC 251 on these issues."

The TF-PSQ shall develop a report for delivery to the Executive Council for the ISO/TC 215 plenary meeting (May 9-13, 2010) which should be available for circulation to the TC one month prior to that date.
Health Informatics — Summary Report from the Task Force on Patient Safety and Quality

1 Scope

This report will serve as a guiding document for ISO/TC 215 to enable a better understanding on how ISO/TC 215 can support Patient Safety and Quality of Care by its standardization activities.

This report will analyse the terms and present a general model of issues related to patient safety and quality management in a broad sense. It will further present a view on the possible role of health informatics to support patient safety and quality.

Despite its importance, this report will not address issues of safety and quality of health informatics products as such, hardware and software since this issue is already addressed in various ways by ISO/TC 215 by WG 4 Security and Privacy, and WG7 Devices in collaboration with other TC and SC Liaisons (IEC62, IEC62a).

The report will present a review of existing standards deliverables and ongoing activities where health informatics supports safety and quality. This shall include ISO/TC215 standards as well as other initiatives.

The report will indentify gaps, where standardization is lacking, and propose actions by ISO/TC 215 working groups and possibly required liaisons with other organizations such as ISO/TC 176 Quality Management Systems. The recommendations may possibly be in the form of concrete New Work Item Proposals and/or continuing the TF or developing a new working group.

2 Definitions

For the purposes of this document, the following terms and definitions apply.

2.1 Adverse events:

An injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdose) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy). Adverse drug events may result from medication errors, but most do not. Also called, Never Events, in some countries.

National Center for Patient Safety – Department of Veteran’s Affairs NCPS P.O. Box 486 Ann Arbor MI 48106-0486 www.va.gov/ncps/

2.2 Algorithm:

Step-by-step problem solving procedure with a specified number of steps.
2.3

Attribute:

An attribute expresses characteristics of a basic elemental concept. Attributes are also known as roles or relationship types. Semantic concepts form relationships to each other through attributes.

Health Level 7 (HL7) 3300 Washtenaw Avenue, Suite 227 Ann Arbor, MI 48104
www.hl7.org

2.4

Attribute, measured:

The smallest unit increment to which an attribute value is measured.

www.ciesin.org/metadata/documentation

2.5

Control Actions:

If the control logic may be thought of as a way to define “trigger conditions”, the control action describes what happens when the trigger fires. This may be as simple as the communication of an alert message to a care provider or as complex as the provision of advanced clinical decision support or the execution of sophisticated workflow actions.

2.6

Control logic:

There must be a mechanism to describe the circumstances under which a control action should be taken. The logic used to describe these circumstances may be simple (e.g. data element x is EQUAL to set point value y) or complex (e.g. x <= y AND NOT (x = z OR x > a)). This logic defines the conditions that describe when the process is “in control” and when it is “out of control”. This definition must be expressible in terms of a standardized set of workflow definitions, reportable metrics and control logic operators.

2.7

customer satisfaction
customer’s perception of the degree to which the customer’s requirements have been fulfilled

[ISO 9000:2000]

NOTE 1 Customer complaints are a common indicator of low customer satisfaction but their absence does not necessarily imply high customer satisfaction.
NOTE 2 Even when customer requirements have been agreed with the customer and fulfilled, this does not necessarily ensure high customer satisfaction.

2.8

**Error of Commission**

An error which occurs as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong side of the body; and transfusion errors involving blood cross-matched for another patient. Joint Commission.

2.9

**Error of Omission**

An error which occurs as a result of an action not taken, for example, when a delay in performing an indicated cesarean section results in a fetal death, when a nurse omits a dose of a medication that should be administered, or when a patient suicide is associated with a lapse in carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes. Joint Commission.

2.10

**Feedback:**

The return of a portion of the output of a process or system to the input, especially when used to maintain performance or to control a system or process.

2.11

**Feed forward:**

The inputs to a process are measured and these are fed to the control logic algorithm to determine what should be the control action.

2.12

**grade**

category or rank given to different quality requirements for products, processes (or systems having the same functional use

[ISO 9000:2000]

**EXAMPLE**  Class of airline ticket and category of hotel in a hotel guide.

**NOTE**  When establishing a quality requirement, the grade is generally specified.

2.13

**Harm**

Any hurt or injury to a person that interferes with the health or comfort of the person and that is more than merely transient or trifling in nature. Canada
Near miss
An unplanned event that did not result in injury, illness, or damage - but had the potential to do so

2.15
Patient Safety
2.15.1 Freedom from accidental or preventable injuries produced by medical care. [Agency for Healthcare Research and Quality].

2.15.2 The pursuit of the reduction and mitigation of unsafe acts within the health care system, as well as the use of best practices shown to lead to optimal patient outcomes. [Canadian Patient Safety Institute].

2.15.3 The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum. WHO

2.15.4 Is enhanced by the use of health care processes, working practices and systemic activities that prevent or reduce the risk of harm to patients. Patient Safety Agency, UK

2.16
Patient Safety Event
a process or act of omission or commission that resulted in hazardous health care conditions and/or quality on harm to the patient. An event is identified by a generalized high-level, discrete, auditable term or group of terms. The terms have good face validity. [World Health Organization: The World Health Organization World Alliance for Patient Safety Project to Develop an International Patient Safety Event Classification. 2006]

2.17
process
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 9000:2000]

NOTE 1 Inputs to a process are generally outputs of other processes.

NOTE 2 Processes in an organization are generally planned and carried out under controlled conditions to add value.

NOTE 3 A process where the conformity of the resulting product cannot be readily or economically verified is frequently referred to as a “special process”.

2.18
process control
function of maintaining a process within a given range of capabilities and capacities.

[ISO 15531-1:2004]

2.19
quality
degree to which a set of inherent characteristics fulfil requirements (}

[ISO 9000:2000]

NOTE 1 The term “quality” can be used with adjectives such as poor, good or excellent.
NOTE 2 “Inherent”, as opposed to “assigned”, means existing in something, especially as a permanent characteristic.

2.20
quality assurance
QA
all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for expected quality.

[ISO 15531-1:2004]

2.21
quality control
QC
part of quality assurance intended to verify that systems and components conform with predetermined requirements

[ISO 19238:2004]

2.22
Reportable metrics
The use of metrics not confined to one group of health care providers

2.23
requirement
need or expectation that is stated, generally implied or obligatory

[ISO 9000:2000]

NOTE 1 “Generally implied” means that it is custom or common practice for the organization (3.3.1), its customers (3.3.5) and other interested parties (3.3.7), that the need or expectation under consideration is implied.

NOTE 2 A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement.

NOTE 3 A specified requirement is one which is stated, for example, in a document (3.7.2).

NOTE 4 Requirements can be generated by different interested parties.

2.24
system
set of interrelated or interacting elements

[ISO 9000:2005]

3 What do we mean by Quality Healthcare?

It is proposed, for purposes of this report, that patient safety be defined as noted in section 2.: The definitions point out the two distinct error modes which must be addressed in order to achieve patient safety:
1. errors of commission

2. errors of omission

It is asserted that the risk of patient harm from these two threats may be mitigated by the adoption of quality clinical practices, where “quality practices” are those that will avoid both events that should not occur (sometimes called never events) and errors of omission, where actions that should have been taken are missed. In this way, patient safety and quality of care are inexorably linked to each other; one achieves patient safety by delivering high quality care. The challenge to this taskforce, therefore, is to develop a health informatics framework that describes how standards may be leveraged to support quality clinical processes.

3.1 Leveraging ISO 9000

In setting out and defining the parameters of this framework, guidance may be found in the ISO 9000 family of quality standards. The ISO 9000:2005 standard asserts that “to lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner” (0.2 Quality management principles, page v). Regarding how this is to be accomplished, the standard asserts a number of quality management principles including that “a desired result is achieved more efficiently when activities and related resources are managed as a process” and that “identifying, understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its objectives”. It also points out that “effective decisions are based on the analysis of data and information”.

ISO 9000 has, at its heart, the premise that quality is attained by adopting a process approach. This approach is illustrated in the figure below, which is found on page 3 of the ISO 9000:2005 document.

![Model of a process-based quality management system](source: ISO 9000:2005, p. 3)

Section 2.3 of ISO 9000:2005, Quality management system approach, indicates:

An approach to developing and implementing a quality management system consists of several steps including the following:
a) determining the needs and expectations of customers and other interested parties;
b) establishing the quality policy and quality objectives of the organization;
c) determining the processes and responsibilities necessary to attain the quality objectives;
d) determining and providing the resources necessary to attain the quality objectives;
e) establishing methods to measure the effectiveness and efficiency of each process;
f) applying these measures to determine the effectiveness and efficiency of each process;
g) determining means of preventing nonconformities and eliminating their causes;
h) establishing and applying a process for continual improvement of the quality management system.

An ISO International Workgroup Agreement (IWA) was convened in 2001 to explore how ISO 9000 tenets could be applied to healthcare. The (updated) output from that meeting is IWA 1:2005 Quality management systems – Guidelines for process improvements in health services organizations. Section 0.2.1 of this document mapped the ISO 9000-based quality management processes to a healthcare setting. This section described the process as follows:

The primary health service process, with the patient/client depicted as the, is shown in the diagram below. The basic product of the health service delivery organization in this diagram is the planning, design, and delivery of patient/client care. This model would also apply to other health service processes, for example education and training for preventive/wellness medicine. Design-responsibility, asterisked below, is either with the customer or the supplier. If the customer does not provide the design, then the supplier is design responsible, even if they choose to subcontract the design to an outside organization or health professional. The care plan and clinical guidelines are examples of quality system documentation, while the patient/client health record is an example of a quality record.

Model for Health Service Organizations with Patient/Client as “Customer” (source: IWA 1, page xiii)
3.2 Developing a health informatics framework

Leveraging guidance from ISO 9000 and from IWA 1, one may assert that quality care, and therefore patient safety, will arise from clinical processes that are controlled in a systematic and transparent manner; where interrelated processes are managed as a system; and where decisions are based on the analysis of data. The quality management system would treat the patient as the “customer” and patient outcomes as the measures of quality. Therefore, to develop a Health Informatics Framework that systemically supports quality care, it is recommended that a process control model be adopted (see section 4 for definitions and explanations regarding process control models).

A process control model would rely upon the following elements:

- Workflow definitions
- Reportable metrics
- Control logic
- Control actions.

3.2.1 Workflow definitions

In order to be able to determine whether or not there has been a deviation from a care guideline, there must be a mechanism to define that care guideline or care plan/pathway. In order to be computable, this care plan/pathway or guideline must be expressed in a standardized way.

3.2.2 Reportable metrics

The definition of reportable events, or other specified outputs, requires that there is a standardized data model. In the face of this data model, it is possible to establish a “set point” by indicating the value or allowable range (including absence/presence) for a specific data element defined in the data model.

3.2.3 Control logic

There must be a mechanism to describe the circumstances under which a control action should be taken. The logic used to describe these circumstances may be simple (e.g. data element $x$ is EQUAL to set point value $y$) or complex (e.g. $x \leq y \text{ AND NOT } (x = z \text{ OR } x > a)$). This logic defines the conditions that describe when the process is “in control” and when it is “out of control”. This definition must be expressible in terms of a standardized set of workflow definitions, reportable metrics and control logic operators.

3.2.4 Control actions

If the control logic may be thought of as a way to define “trigger conditions”, the control action describes what happens when the trigger fires. This may be as simple as the communication of an alert message to a care provider or as complex as the provision of advanced clinical decision support or the execution of sophisticated workflow actions.
4 A brief primer on process control, quality assurance, and quality control

As indicated in the graphic shown above, a system may be thought of as a set of one or more subprocesses, each of which may be independent from each other. As is true for each subprocess, this system itself will exhibit characteristic properties and behaviours. Although each of these subprocesses may themselves be under some manner of process control, the overall system will also require control in order for it to operate within set parameters.

In the example above, classic feedback control is illustrated. The control points are:

- Measured attribute (yellow)
- Control logic (red), and
- Control actions (teal).

The way these control points are leveraged is indicative of the type of process control that is being employed. Following are descriptions of 3 classic process control methods and examples of each in a healthcare context:

- Feedback
- Feedforward, and
- Inferential control.
4.1 Feedback control

Feedback control is illustrated in the graphic shown below. In feedback control, the outputs of a process are measured and these are fed to the control logic algorithm to determine what should be the control action.

An example, from a healthcare setting, might be to administer drugs, check fever, and alter dosage as needed. An important attribute of feedback control is that the system is allowed to respond to the input before a control action is taken. It is by monitoring these system responses, and then altering the actions accordingly, that the system is maintained under control.

4.2 Feedforward control

Feed-forward control is illustrated in the graphic shown. In feed-forward control, the inputs to a process are measured and these are fed to the control logic algorithm to determine what should be the control action.

An important attribute of feed-forward control is that both the measured attribute and the control action occur upstream of the system under control. For this reason, feed-forward control is preferred over feedback control in cases where it is not advisable to allow the system to respond to the input before taking the control action. An example of feed-forward control in a healthcare setting would be the application of computerized physician order entry (CPOE) or e-Prescribing. Such systems are designed to catch and avoid a dangerous drug-to-drug interaction at the time of the medication order, upstream of administering the drug to the patient.
4.3 Inferential control

Inferential control is illustrated in the graphic shown. Inferential control is used in cases where it is not practical to directly measure the “measured attribute” needed to drive the control logic. Instead, an inference regarding the control attribute is made based on other measured outputs or inputs. (The graphic shown above illustrates inferential feedback control, so an output is being measured. Inferential feedforward control may also be used.)

The inferred, but non-measured attribute is fed to the control logic algorithm to determine what should be the control action. As a healthcare example, consider a care plan that is being managed and fine tuned based on using white blood cell count as a proxy for the presence or degree of cancer.

4.4 Quality assurance

Generically, quality assurance (QA) is achieved by adopting standardized procedures and methods. Its role is to increase the repeatability of a process or outcome. The premise of QA is that one cannot expect consistent results from inconsistent activities. In this way, another role QA plays is to establish a baseline against which actual process activities can be measured. This yields a metric of “process adherence”.

QA, as a patient safety and quality tool, helps reduce the occurrence of “never events” (things that should not ever happen, such as leaving an instrument in a patient after surgery). It also is a way to prevent errors of omission. This latter class of errors are vexing and difficult to trap because the absence of a signal is not a signal.

In a healthcare context, an evidence-based care plan is an example of QA. For instance, for patients with type II diabetes, the Canadian Diabetes Association has established that the recommended, evidence-based care plan should include:

- One or more HbA1c tests per year;
- A urine test for protein at least once per year;
- A dilated eye exam at least once every two years; and
- A foot exam for sores or irritation by a health professional at least once per year.

These four guidelines represent QA for diabetic care.
4.5 Quality control and measurement

Quality control (QC) is a measurement tool; it is used to confirm adherence to a pre-defined specification. QC can confirm adherence to an output specification (is the output within an acceptable tolerance?) or to a process specification (were the process steps followed?). QC reflects the adage: you cannot manage what you cannot measure.

If a systemic issue is uncovered through QC (e.g. output measurements are always higher than the specified value, and always outside the accepted tolerance) then it may require a systemic alteration to the standard process. In this way, QC can provide feedback to QA. This continuous improvement cycle is referred to in industrial engineering circles as “Kaizen” (so named from practices defined in the Toyota Production System, which originated in Japan).

Healthcare examples of QC include reportable metrics which may be required by regional or national authorities. In Canada, for instance, for each patient discharged from hospital an anonymized discharge abstract must be submitted to the Canadian Institute for Health Information (a national organization) which uses these statistics to measure adherence to national and regional care guidelines and to help inform national healthcare policy.

4.6 Examples of quality assurance, quality control and process control techniques in healthcare

Using the type II diabetes scenario (above), the following examples may be drawn:

- The Canadian Diabetes Association’s care guidelines represent an example of QA.
- Measuring HbA1c is one control guide for measuring diet, exercise and kidney function; this is an example inferential process control.
- Providing a family physician with a list of their diabetic patients that are coming due for their tests (HbA1c, urine test, eye exam and/or foot exam) is an example of feed-forward process control.
- Providing a family physician with a measure of their adherence to the Canadian Diabetes Association care guidelines (e.g. 71% of their cohort of diabetic patients are within all 4 care guidelines, compared to a peer metric of 83% for other family physicians in their health region) is an example of feedback control.

It is worthwhile to note a number important points regarding the use of process control techniques in healthcare:

1) Unlike many mechanical or industrial systems, humans do not respond identically or consistently to the same stimuli.
2) Something which is statistically true across a population may not be true for a particular individual.
3) Sometimes, even when a care guideline is followed, the clinical outcome will be poor. This is not an adverse event, and therefore not a QC “signal”, unless the poor outcome is due to an error of commission or an error of omission.
4) Indeed, sometimes a care guideline should be modified for a particular patient. Again, this is not indicative of an adverse event unless the modification constitutes an error of commission or omission. If there are sound medical reasons to alter a care guideline then it actually is an error to slavishly follow the standard guideline. The true QC signal, worthy of a
control action, is to catch occasions where there are systemic cases of non-adherence or non-explained deviations from standard protocols or processes.

Clinicians intuitively use feedback control in their care provision (e.g. altering a medication dosage until the desired impact is achieved). Where they are informed of systemic non-adherence to clinical guidelines, it has been shown that clinicians will use the same intuitive sense of feedback control to alter their practices across populations of patients under their care.

It is also useful to be clear regarding the role of the process control mechanisms. In many cases, the most appropriate control action is simply to inform or alert a clinician of an out-of-bounds condition. This ‘trigger action’ is quite separate from clinical decision support (where actual care options/recommendations might be made), although it may be used to support it.

4.7 The importance of patient-centricity

The impact of patient-centric vs. provider-centric system scope

It is fundamentally important that the “system” be defined from the point of the view of the patient. The reason for this is illustrated by the graphic shown above.

1) Based on the diagnosis made by Physician 1, it was correct to prescribe drug 1 (the inhaler) to the patient. This was, from the point of view of Physician 1, a successful clinical interaction.

2) Based on the diagnosis made by Specialist 2, it was correct to prescribe drug 2 (oral medication) to the patient. From the point of view of Specialist 2, it was a successful clinical interaction.

3) Where the system, however, is defined in terms of the patient, these two together represent a fundamentally unsuccessful clinical encounter. The drug to drug interaction between drugs 1 & 2 was toxic, and dangerous, to the patient. Sadly, although it is not supposed to happen, in the absence of interoperable “systems” and/or mutual access to a patient-centric shared health record, the two clinicians will not be aware of each other’s prescribing activities.
5 Review of existing standards and ongoing work

Following is a summary of existing standards and ongoing work categorized based on the 4 elements of our proposed health informatics framework:

- Workflow definitions
- Reportable metrics
- Control logic
- Control actions.

5.1 Workflow definitions

There are initiatives in a number of countries to develop and deploy standardized, electronic clinical pathways. These clinical pathways or care guidelines reflect evidence based care plans that are generally developed for specific diseases by local or national clinical colleges. Often, eHealth initiatives in support of clinical pathways are centered on the implementation of a particular software product which is used to define and codify the care plans.

The UK’s NHS published an analysis in 2005 of various projects which had been undertaken to explore standardized solutions for expressing care pathways (Care Pathways Version 1.0 (final), 8 August 2005). On 5 of this document, the following summary is given of the 4 products/approaches that were investigated and page reported upon:

**PROforma** is a guideline specification language, developed by Cancer Research UK (CRUK), which specifies each decision in terms of any number of candidate options and the arguments for and against each candidate. Each candidate is evaluated in terms of the available evidence for and against it. Decisions are contained within plans, which may also specify actions to be done and enquiries, which obtain evidence. PROforma is a declarative language, focusing on what is or is not known about the patient, as opposed to procedural languages that focus on the sequence in which tasks are carried out. In this way PROforma reflects clinical practice. PROforma has been developed over the past 12 years and an impressive body of published evidence has been accumulated, which demonstrates its practical value. PROforma is a platform-independent language, which at present has two platform-specific implementations (Infermed’s Arezzo and CRUK’s Tallis).

The Map of Medicine is an online clinical knowledge browser that provides desktop access to a wide range of specialist clinical information and evidence-based practice. The Map of Medicine is platform independent and can be localised to meet local needs.

**BPMN** (Business Process Modeling Notation) is a new standard for business process modeling. It is now part of the OMG (Object Management Group). It provides facilities for documenting events, such as triggers, and for decomposing processes into sub-processes and tasks.

The HL7 Version 3 Clinical Statement Pattern is the model used for all clinical messages, including the exchange of patient records, in the NPfIT. Preliminary analysis suggests a fit between the needs of care pathways and the HL7 Clinical Statement Pattern, but this has not been demonstrated in practice and requires further work to identify issues and document recommendations.

In the NHS report, the terms Guidance, Clinical Protocol and Care Pathway are defined.
Guidance is a systematically developed statement designed to assist practitioner and patient on decisions about appropriate health care for specific clinical circumstances. It is an evidence-based recommendation for the treatment of a particular problem focusing on what should be done and why. Guidance is not specific to any particular organisation (or patient). NICE (the National Institute for Clinical Excellence) produces guidance.

The term “guidance” is used, rather than “guideline”, in part because this is the term adopted by NICE, and in part because guideline is often used as an umbrella term for guidance, clinical protocol and care pathway.

A Clinical Protocol is an agreed statement about a specific issue, with explicit steps based on guidance and/or organisational consensus. A protocol is not specific to a named patient but is usually specific to an organisation. It is locally owned.

A Care Pathway maps out a pre-defined set of activities and/or choices within a specified scope, which may be applied to one or more issues or problems. It defines what should be recorded about the care delivered in such a way that variance between proposed and actual care can be audited and local practice refined accordingly. A care pathway may specify the goal and/or expected outcome, the data required, decisions and choices that may be appropriate (with supporting arguments) and actions to be carried out, when and by whom. A care pathway may reference guidance or protocols.

The relationship between these terms is illustrated in the UML diagram shown below.

5.2 Reportable metrics

Many countries have defined, or are defining, a set of reportable metrics which will be used by their respective health systems to measure system performance, quality of care, and/or other data or interest. A non-exhaustive sampling of these initiatives is described below.
5.2.1 HL7 Health Quality Measurement Framework (HQMF)

From the HL7 HQMF website (http://www.hl7.org/v3ballot/html/domains/uvqm/uvqm.htm): “The Health Quality Measures Format (HQMF) is a standard for representing a health quality measure as an electronic document. A quality measure is a quantitative tool that provides an indication of an individual or organization’s performance in relation to a specified process or outcome via the measurement of an action, process or outcome of clinical care. Quality measures are often derived from clinical guidelines and are designed to determine whether the appropriate care has been provided given a set of clinical criteria and an evidence base. Quality measures are also often referred to as performance measures or quality indicators.”

The HQMF specification:
- is derived from HL7 RIM, Version 2.30
- uses the HL7 Version 3 Data Types, Release 2 abstract and Release 1.1 XML-specific specification
- is a “Constrained Information Model” (CIM) (previously known as a “Refined Message Information Model (RMIM)), derived from a broader “Domain Information Model” (DIM) (previously known as a "Domain Message Information Model" (DMIM)
- Is based on the HL7 V3 XML Implementable Technology Specification for V3 Structures.

5.2.2 IHE Quality, Research and Public Health Domain (QRPH)

From the IHE QRPH website (http://wiki.ihe.net/index.php?title=Quality): “IHE Quality, Research and Public Health Domain (QRPH) addresses the infrastructure and content necessary to share information relevant to quality improvement in electronic patient care and health care records, improves the liaison between the primary care system and clinical research and it serves in cases where population base surveillance is needed. The three components addressing the different aspects of the QRPH domain have all in common the secondary or the repurposing of data.

- Quality – Repurposing of data
- Clinical Research – Secondary use of data
- Public Health – Population base surveillance

The QRPH work enables the stakeholders to focus on the workflow cycle of queries for data and selection of population cohorts from within the clinical record. In addition, the QRPH incorporates the output from the query specification within the clinical system workflow to enable clinical decision support and defines profiles for adverse event reporting especially with reference to medication-related adverse outcomes.

5.2.3 WHO Family of International Classifications

From the document World Health Organization Family of International Classifications (http://www.who.int/patientsafety/taxonomy/WHOFICFamily.pdf): “The WHO Family is a suite of products that may be used in an integrated fashion to compare health information internationally.

Internationally endorsed classifications facilitate the storage, retrieval, analysis, and interpretation of data and their comparison within populations over time and between populations at the same point in time as well as the compilation of internationally consistent data. Populations may be Nations, States and Territories, regions, minority groups or other specified group.”
The aims of the WHO Family are to:

- provide a conceptual framework of information domains for which classifications are, or are likely to be required for purposes related to health and health management;

- provide a statement of endorsed classifications for particular purposes defined within the framework;

- promote the appropriate selection of classifications in the range of settings in the health field across the world,

- establish a common language to improve communication; permit comparisons of data across Nations, States and Territories, health care disciplines, services and time, and between Nations; and

- to provide systematic classification schemes for health information systems; and

- stimulate research on health and the health system.

The relationship between these various WHO classification specifications is shown in the figure below.
5.3 Control logic

There are various methods and means to describe the control logic that would be used to determine whether and when to “trigger” a control action. Following is a non-exhaustive listing of a number of options.

5.3.1 WS-BPEL

From Wikipedia (http://en.wikipedia.org/wiki/Business_Process_Execution_Language): BPEL is an Orchestration language, not a choreography language (see Web Service Choreography). The primary difference between orchestration and choreography is executability and control. An orchestration specifies an executable process that involves message exchanges with other systems, such that the message exchange sequences are controlled by the orchestration designer. A choreography specifies a protocol for peer-to-peer interactions, defining, e.g., the legal sequences of messages exchanged with the purpose of guaranteeing interoperability. Such a protocol is not directly executable, as it allows many different realizations (processes that comply with it). A choreography can be realized by writing an orchestration (e.g. in the form of a BPEL process) for each peer involved in it. The orchestration and the choreography distinctions are based on analogies: orchestration refers to the central control (by the conductor) of the behavior of a distributed system (the orchestra consisting of many players), while choreography refers to a distributed system (the dancing team) which operate according to rules but without centralized control.

BPEL’s focus on modern business processes, plus the histories of WSFL and XLANG, led BPEL to adopt web services as its external communication mechanism. Thus BPEL’s messaging facilities depend on the use of the Web Services Description Language (WSDL) 1.1 to describe outgoing and incoming messages.

In addition to providing facilities to enable sending and receiving messages, the BPEL programming language also supports:

- A property-based message correlation mechanism
- XML and WSDL typed variables
- An extensible language plug-in model to allow writing expressions and queries in multiple languages: BPEL supports XPath 1.0 by default
- Structured-programming constructs including if-then-elseif-else, while, sequence (to enable executing commands in order) and flow (to enable executing commands in parallel)
- A scoping system to allow the encapsulation of logic with local variables, fault-handlers, compensation-handlers and event-handlers
- Serialized scopes to control concurrent access to variables

5.3.2 GELLO

From openclinical.org (http://www.openclinical.org/gmm_gello.html): The GELLO expression language is designed to meet the following requirements:

- the need for a standard, object-oriented language to formulate expressions for manipulating clinical data and providing decision support in various clinical applications.
• the need to support sharing of clinical knowledge between applications in heterogeneous clinical environments.

• the need to be vendor independent, platform independent, object oriented and compatible with the HL7 Reference Information Model (RIM), easy to read and write, free of side-effects, extensible and shareable.

GELLO is a class-based, object-oriented (OO) language made up of both query and expression (sub-) languages. GELLO is based on the Object Constraint Language (OCL) developed by the Object Management Group. Much of the functionality of OCL has integrated into GELLO to provide a suitable framework for manipulation of clinical data for decision support.

The GELLO language can be used to:

• "Build up queries to extract and manipulate data from medical records.

• "Construct decision criteria by building up expressions to reason about particular data features/values. These criteria can be used in decision support knowledge bases such as those designed to provide alerts and reminders, guidelines, or other decision rules.

• "Create expressions, formulae, and queries for other applications. The query and expression languages share a common OO data model since the expressions must operate on data supplied by queries."

"The GELLO query language has been designed within the context of a guideline execution model proposed in the HL7 CDSTC. This model proposes the use of a vMR (virtual Medical Record) that provides a standard interface to heterogeneous medical record systems..."

"The GELLO expression language can be used for specifying decision criteria, and abstracting or deriving summary values. The object-oriented approach of the language has the flexibility and extensibility that is needed for implementation in a broad range of applications. The expression language is strongly typed. In order to facilitate the process of encoding and evaluation of expressions and more importantly, to maximize the ability to share such queries and expressions, GELLO includes basic built-in data types while providing the necessary mechanisms to access an underlying data model with all its associated classes and methods. This is especially important in enabling decision rules and guidelines to successfully support different data models, inasmuch as classes and relationships specified could vary from one data model to another."

5.3.3 ARDEN

From openclinical.org (http://www.openclinical.org/gmm_ardensyntax.html): The Arden Syntax for Medical Logic Systems encodes medical knowledge in knowledge base form as Medical Logic Modules (MLMs). An MLM is a hybrid between a production rule (i.e. an "if-then" rule) and a procedural formalism. Each MLM is invoked as if it were a single-step "if-then" rule, but then it executes serially as a sequence of instructions, including queries, calculations, logic statements and write statements.

Arden was developed for embedding MLMs into proprietary clinical information systems. It was designed to support clinical decision making in particular: an individual MLM should contain sufficient logic to make a single medical decision. Sequencing tasks can be modeled by chaining a sequence of MLMs. MLMs have been used to generate clinical alerts and reminders, interpretations, diagnoses, screening for clinical research studies, quality assurance functions, and administrative support.
With an appropriate computer program (known as an event monitor), MLMs run automatically, generating advice where and when it is needed, e.g. to warn when a patient develops new or worsening kidney failure.

The initial version of the Arden Syntax was based largely on the encoding scheme for generalized decision support used in the HELP (Health Evaluation through Logical Processing) system for providing alerts and reminders, developed at the LDS hospital in Salt Lake City.

5.4 Control actions

It is anticipated that the primary control action will be to alert a clinician. For this rudimentary use case, the solutions which support control logic (see above) will generally suffice for alerting as well.

6 Recommendations

Potential ‘home’ for PSQ efforts:

— Patient Safety is a topic with threads in a number of TC 215 WGs: Specifics of the following WGs were not addressed in this report; which was designed to provide an overview of patient safety issues.
  — Terminology (Not addressed in this report)
  — Safety, privacy, security (Not addressed in the report)
  — Patient safety in Pharmacy (Not addressed in this report)
  — Work items on Patient Safety in Medical Devices (Not addressed in this report)
  — Data Definitions
  — Harmonization across multiple WGs and liaisons with outside groups
  — Administrative issues could be needed to bring these issues together

— Possibly let this task group live on as a task group to coordinate the efforts and progress


— Also note Opportunities for additional work, at the end of Annex A.

Annex A

Review of existing Standards and other work some ongoing:

<table>
<thead>
<tr>
<th>Standards</th>
</tr>
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<tbody>
<tr>
<td>Standard</td>
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<tr>
<td>-----------</td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>Topic</th>
<th>Provider</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare Quality Measures Format (HQMF)</td>
<td>HL7</td>
<td>The HL7 HQMF Standard is a formalism for encoding quality measures (aka creating eMeasures). The HL7 HQMF Standard is part of the HL7 Version 3.0 family of standards, based on a Reference Information Model (RIM). Visit <a href="http://www.hl7.org">http://www.hl7.org</a> for more information.</td>
</tr>
<tr>
<td>Quality Reporting Document Architecture (QRDA)</td>
<td>HL7</td>
<td>This Implementation Guide describes constraints on CDA Release 2 Header and Body elements for Quality Reporting Documents. Quality Reporting Document Architecture (QRDA) is a document format that provides a standard structure with which to report quality measure data to organizations that will analyze and interpret the data that is received. The balloted portion of this guide which covers Category 1.</td>
</tr>
<tr>
<td>Patient Level Export of Quality Data (PEQD)</td>
<td>IHE</td>
<td>The Patient-level Quality Export of Quality Data (PEQD) profile addresses the need for consistent communication of Quality data to the local, regional or third party Analyzer/Aggregator for consistent, standardized evaluation of quality structural, process and outcome measures.</td>
</tr>
<tr>
<td>White Paper: Quality Measurement Data Element Structured for EHR Extraction</td>
<td>IHE</td>
<td>The intent of this white paper is to identify a standard mechanism to enable extraction of quality measures from EHRS.</td>
</tr>
<tr>
<td>Quality Report Sharing – Quality Report Document</td>
<td>IHE</td>
<td>This profile constrains QRDA patient data sections for common quality data elements needed for measurement.</td>
</tr>
<tr>
<td>Plan of Coordination</td>
<td>TC 215</td>
<td></td>
</tr>
<tr>
<td>GELLO</td>
<td>HL7</td>
<td></td>
</tr>
<tr>
<td>ARDEN</td>
<td>ISO</td>
<td></td>
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<tr>
<td>Common Logic</td>
<td>ISO</td>
<td></td>
</tr>
<tr>
<td>BPL</td>
<td>ISO</td>
<td></td>
</tr>
<tr>
<td>Patient Plan of Care</td>
<td>IHE</td>
<td>(RE: best practices), based on CDA/CCD; uses the nursing process – scientific notation: adapted into nursing care; assessment, setting a goal/patient outcome; planning phase; implementation phase; evaluation phase; re-assessment;</td>
</tr>
<tr>
<td>Plan of Coordination</td>
<td>IHE</td>
<td>(RE: best practices), based on CDA/CCD</td>
</tr>
<tr>
<td>Newborn Screening – follow-up on abnormal results</td>
<td>IHE</td>
<td>Leveraging the CDA Plan of Care; Hand-offs</td>
</tr>
<tr>
<td>Proforma</td>
<td>ISO</td>
<td>Guideline modeling language</td>
</tr>
</tbody>
</table>
### BPMN

<table>
<thead>
<tr>
<th>Process/Model</th>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HL7 V3 Clinical Statement Pattern</td>
<td>HL7</td>
<td></td>
</tr>
<tr>
<td>Clinical Research</td>
<td>HL7</td>
<td></td>
</tr>
<tr>
<td>Medcin</td>
<td>Proprietary</td>
<td></td>
</tr>
<tr>
<td>Public Health Reporting</td>
<td>HL7 (PHER, Patient Safety)</td>
<td></td>
</tr>
<tr>
<td>Public Health Functional Model</td>
<td>HL7</td>
<td></td>
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<tr>
<td>Detailed Clinical Models (DCM)</td>
<td>HL7/ISO</td>
<td></td>
</tr>
<tr>
<td>Pediatric Workflow</td>
<td>IHE</td>
<td></td>
</tr>
</tbody>
</table>

### Whitepapers/Tools

<table>
<thead>
<tr>
<th>Whitepapers/ tools</th>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Map of Medicine</td>
<td>UK</td>
<td>(University of London or UCL)</td>
</tr>
<tr>
<td>Care pathways V1.0</td>
<td>UK (NHS)</td>
<td>Scope – look for unidiciplinary, multidis, cross-discipliniary, cross- Reporting early results</td>
</tr>
<tr>
<td>Spain (Andalucia)</td>
<td></td>
<td></td>
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<tr>
<td>AHRQ</td>
<td></td>
<td></td>
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<tr>
<td>IHE</td>
<td></td>
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<tr>
<td>CA</td>
<td></td>
<td></td>
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<tr>
<td>Spain</td>
<td></td>
<td></td>
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<tr>
<td>AU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WHO</td>
<td></td>
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</tbody>
</table>

### National Initiatives and Frameworks

<table>
<thead>
<tr>
<th>National Initiative and Frameworks</th>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPSI</td>
<td>CA</td>
<td>Spain (regional)</td>
</tr>
<tr>
<td>HITSP</td>
<td>US</td>
<td></td>
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<tr>
<td>Best Practices, Practice Guidelines</td>
<td>US</td>
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<td>-----------------------------------</td>
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</tr>
<tr>
<td>AHRQ Common Formats</td>
<td>US</td>
<td><a href="http://www.pso.ahrq.gov">www.pso.ahrq.gov</a></td>
</tr>
<tr>
<td>IOM</td>
<td>US</td>
<td></td>
</tr>
<tr>
<td>Integrated Care Plan (ICP)</td>
<td>UK</td>
<td></td>
</tr>
<tr>
<td>EPSOS</td>
<td>EU</td>
<td>for instance, needs to identify standards</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other initiatives</th>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Conceptual Framework for the International Classification for Patient Safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Map of Medicine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital Care plans</td>
<td></td>
<td>Need to broaden to cross-community settings</td>
</tr>
</tbody>
</table>

### 7 Opportunities

Gaps that exist today where TC 215 framework is not served by existing standards or where the existing standards must be extended in order to support the Patient Safety system view the PSQ TF have articulated. If appropriate,
the basic scope of new work items that might be raised to fill in these gaps.

<table>
<thead>
<tr>
<th>Gap</th>
<th>Type</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Support for Quality and Patient Safety applicable to all aspects</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Logic Expressions</td>
<td>Logic expressions</td>
<td>Rules expression (ISO Common logic, Arden, Gello, BPEL)</td>
<td>No obvious location within TC215</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trigger logic for triggers, Clinical guideline, reporting criteria</td>
<td></td>
</tr>
<tr>
<td>Harmonize the concepts: concept maps</td>
<td>Terminology</td>
<td>addition of terms supporting patient safety and quality</td>
<td>WG3</td>
</tr>
<tr>
<td>Value Sets</td>
<td>Terminology</td>
<td>To express the reported results for comparison to guidelines, care-plans</td>
<td>WG3 (possibly with another WG)</td>
</tr>
</tbody>
</table>

expression of evidence-based care and clinical pathways, definition of standards of care and expectations

<p>| Avoidance of HIT Associated events       | Procedural          | Standards for risk assessment of software.                                 | WG7; IEC 80001 (JWC harmonization for devices) |
|                                          |                     | Potential for software systems to introduce errors and create patient safety events; |                                               |
|                                          |                     | *NOTE: Device patient safety work is out of scope for this document, but it is recognized here that current WG7 JWG activities are addressing these topics. |                                               |
| Need a standard to                       | Technical / Structure | Should be able to be                                                        | No obvious location                |
|                                          |                     |                                                                            |                                 |
| Expression of clinical statements | Terminology, models | Patterns for developing a document to record activity (clinical models) | WG1, WG3, HL7 |
| Logic Expressions | Logic expressions | Rules expression (ISO Common logic, Arden, Gello, BPEL) No obvious location within TC215 |
| Need to be able to support hand-offs of care plans | Workflow management and Technical / Structure specification | Continuity of care: Individual’s care plan conformance: PPOC (IHE), Hearing screening plan of care (IHE QRPH EHDI) – across care settings Integrated care plans Physicians handing off care, across settings | No obvious location within TC215; WG3? – need clinician perspective Related to continuity of care work from WG3 |
| Input to health system management process | | | |
| Need protocol technical format to express reportable criteria | Technical / Structure specification | Application across (HL7 HQMF, Public Health needs additional criteria) | WG1 |
| Need standard expression of clinical content for reporting clinical content | Technical / Structure specification, Terminology | Overlapping/ competing standards are limiting factors (e.g. OpenEHR, HL7 V3); | WG1, WG3 |
| Logic Expressions | Logic expressions | Rules expression (ISO Common logic, Arden, Gello, BPEL) No obvious location within TC215 |</p>
<table>
<thead>
<tr>
<th>Trigger logic for triggers, Clinical guideline, reporting criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Reporting Protocol</td>
</tr>
<tr>
<td>health system management process/ Measurement output</td>
</tr>
<tr>
<td>evaluation phase</td>
</tr>
<tr>
<td>Individual’s care plan conformance: PPOC (IHE), Hearing screening plan of care (IHE QRPH EHD1)</td>
</tr>
<tr>
<td>Aggregated reporting</td>
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<tr>
<td>Aggregated reporting</td>
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<tr>
<td>Adoption of existing standards in ISO</td>
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</tbody>
</table>

No obvious location within TC215; may need to stay within the tack group or new home for PSQ.

Research – WG6
BRIDG – WG1/WG2