NHS Scotland
Scottish Medication Content Models
Overview Document

Version History

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Contents

1 Background

The use of health IT to facilitate safer medications management and reduce patient harm is a key part of Scottish NHS e-Health strategy via support for medicines reconciliation and improved access to ECS by hospital clinicians.

As a longer-term goal, there is also increasing interest in a single, shared community medication record to cover all GP and community prescribing, including hospital outpatient and discharge prescribing. A similar project "'FMK'[1],[2]is already operational in Denmark, a country of very similar size and health delivery to Scotland.

As part of eHealth strategy to facilitate better medicines management and reconciliation, the ECS and KIS projects were asked to improve the richness of information obtained from GP systems e.g. to includedm+dmedicines coding and improved allergies support. The subsequent requirements analysis highlighted the lack of standardisation of medication modelling across the various SCI-XML based message outputs e.g. SCI-Referral, e-Pharmacy and ECS. At the same time, further medicines information modelling has taken place to support initiatives such as the Ensemble Group National Data Services project and various regional e-Forms projects, introducing more even variation in the representation of medication.

This lack of standardisation forces both the producers of the information, commonly GP system vendorsand,of course, information consumers, to re-program and support all of these variations in their software efforts. It also forces each host project to duplicateclinical business analysis and approval, which is costly in time and resource.

Project aim

The aim of this project is to establish set of computable Medication Models to support a broad range of eHealth projects in improving medicines management,along with a governance and maintenance mechanism that can supportinevitable ongoing change in response to steadily emerging service requirements and new clinical ideas.

2 Clinical content development

If we are to support medicines management across the service by moving computable information between service providers, it is imperative that some single 'source-of truth' is established for medication models, including allergies. Such standardisation is, of course, an absolute pre-requisite for any attempt to establish a single, shared medication record.

Past experience of clinical content standards development and maintenance has been fraught and the effort largely unsustainable, and itis not surprising that there islittle appetite for a return to a 'top-down', clinical standards development but we cannot ignore the increasing demand from clinical practitioners for interoperable models to support clinical workflow, efficiency and safety. Fortunately, new approaches have emerged, based on open-source, web-based collaborative methods,which support a much more agile, bottom-up approach to clinical content modelling, with output which can be directly incorporated into systems and messages.

[1] Video in English describing Danish Shared Medication Record
[2] Effects of Danish Shared Medication Record at admission-a randomised clinical trial

2.1 Content development principles

Considerable progress has been made at national and international level to identifya number of pre-requisites for a successful and sustainable clinical standards development process:

- High-level clinical engagement and governance as envisaged in the recent RCP/Joint Working Group proposal for a UK Professional Records Standards Development Board[3],to ensure adherence to professional standards and best-practice., including input from clinical safety organisations such as Health Improvement Scotland [4]and the Scottish Medicines Consortium[5]
- High-level technical oversight to ensure that the models are consistent with e-health standardse.g NHS Scotland Design Authority Standards.
- A mechanism to gather requirements from a very broad community of clinical and industry stakeholders, almost certainly web-based and drawing on open-source community working methods to minimise the time commitments and slow response associated with traditional face-to-face committee/workgroups.
- Foster a collaborative approach, encourage discussion and debate, and be inclusive of legitimate variations of particular clinical groups or settings. This helps establish a much broader base of understanding,
- The requirements process must be agile, clinically understandable and accessible, yet capable of expressing eventual models in a formal computing language such as UML, XML or ADL and including strict technical version control. Clinicians should not need any special training to understand the clinical sense of the models and any required technical infrastructure should be hidden, without reducing the technical rigour.
- The most difficult challenge in clinical content development is to be able to respond quickly to inevitable requests for change from stakeholders. The problems described above with SCI-XML medication message mis-alignment are almost wholly due to this issue and meeting this challenge is absolutely key to success since clinical information requirements change very frequently. A web-based approach akin to open source bug-tracking/ change request logging, such as Atlassian JIRA[6], is likely to offer the best solution.

Whilst these pre-requisites are undoubtedly challenging across the breadth of clinical content development, they are readily achievable if applied to a small area of practice such as Medication with clear clinical need and a wealth of UK-wide expertise from which to draw.

2.1.1 Medication Content Modelling Group

It is proposed that a 'Medication Content Modelling Group" is established, relying heavily on web-based communications and operations. The key role of this Group is to develop and maintain a set of common, core medication models delivered by a small group of 'editors' but drawing on a very, much wider group of stakeholders. The Group will operate almost entirely using web-based tools and communications, including response to change requests and problem reports.A important requirement will be to publicise the Group's role to a broad range of consumers so that it becomes the prime contact point for any current or future medication content requirements or advice.

See Appendix 2 for a more detailed proposal.

[3] Developing standards for health and social care records
[4] Health Improvement Scotland
[5] Scottish Medicines Consortium
[6] AtlassianJIRA

3 Appendix 1 Technical issues

4 Archetypes and Templates

4.1 Archetypes

The various facets of medication record have been modelled using the 'archetype' approach developed by ISO13606/openEHR. An archetype is a small, detailed model of part of a clinical record e.g. A 'Medication record', 'blood pressure' or 'Procedure' and is not dissimilar to the approach taken in current SCI-XML / NDS modeling.

Archetypes are intended to be inclusive of all applicable clinical content i.e. a "Medication Item" archetype will be a superset of the content required by a broad range of clinical stakeholders, professions, projects, applications and care settings. This allows ever-changing clinical requirements to be gathered in 'bigger chunks', to some degree pre-empting future requirements and reducing the need to continually respond to change.

"Clinically accessible but technically precise"

An important aspect of archetypes is that they must be easily understood by clinicians but at the same time technically precise and capable of being implemented almost directly by developers.

Currently each archetype is technically defined using XML Schema but UML (as used by GP2GP) or ADL (Archetype Definition Language) are future alternative approaches

4.2 Templates

In most cases, a specific user, project or application will require only a subset of the elements within the archetype. This can be defined by using a 'Template' to hone-down the exact requirements. Templates also allow archetypes to be aggregated together e.g. by combining a 'Medication Recommendation' archetype and a 'Medication Issue' archetype as part of an Emergency Care Summary 'Template' to represent 'Recent medication'.

4.3 'Reference model' requirements

Clinical information is complex and often has to be accompanied by supporting medico-legal or workflow and process information if it is to be interpreted correctly. Most modern clinical information models such as HL7v3, ISO13606 and openEHR make use of a 'Reference model', a more technical layer of supportive information structures which define how to handle, for example:

- medico-legal details "Provenance "of a clinical document (author, date recorded, organization etc),
- thestate of a clinical workflow process e.g. a lab test request or referral
- broad clinical documentation structures e.g. Clinical Document, Headings, clinical Entries or statements.

- fine-grained datatypes e.g. Text, Coded Text , Quantities, Multimedia, Dates and Times

Inevitably these reference models can be complex to understand and to implement in their entirety. Although some formal commitment to a recognized reference model will have to be made before a Shared Medication Record Service can be implemented, this is not necessary for the immediate scope of work, where only a subset is required to allow the clinical content to be expressed clearly.

The approach taken is heavily based on EN13606/openEHR/CDA structures and as suchis very closely aligned to that adopted by GP2GP, the Welsh IHR and theScottish National Data Services project.

4.3.1 Document structures

The overall structuring of the Medication Records follows the ISO13606/openEHR model but is also very close to the structures used for GP2GP Extracts.

Extract “ECS”

Composition “Emergency Care Summary”

Section “Current Medication”

Entry “RecommendedMedicationEntry”

Cluster “MedicationItem”

Element of Data type “Described Medication”

4.3.1.1 Extracts

Primary Extract

A primary extract faithfully expresses the clinical information as originally entered as far as possible. This is the approach required for the GP2GP Extract and which will also be required for a Single, Shared Medication Record.

e.g. The record for a single medication will comprise the original Medication and all subsequent Authorisations, Issues and eventual Discontinuation records

Recommended Medication

ActionStep: Recommended 01-Jan-2012

Medication:“Atenolol 50mg tabs 1 tab daily” 01-Jan-2012

AuthorisedMedication

ActionStep: Authorised

ActionStepDate01-Jan-2012

IssuedMedication 01-Jan-2012

DispensedMedication

Dispensed 05-Jan-2012

IssuedMedication

Issued 02-Feb-2012

DispensedMedicationEntry 01-Jan-2012

Summary Extract

A summary Extract will commonly 'compress' or summarise the originally recorded information to make it more easy to understand for particular care settings or messages. This is what would normally be used to contruct an Emergency Care Summary or provide details of 'Recent Medication' to a web service call.

Recommended Medication

Medication:"Atenolol 50mg tabs 1 tab daily" 01-Jan-2012

First recommended 01-Jan-2012

First authorised:

First issued:

Last Issued:

Last dispensed:

Discontinued:

4.3.1.2 Compositions

The Composition equates to a single clinical document or encounter, perhaps a referral or discharge letter, or a single GP consultation. It acts as a top-level container. Most Extracts will contain only one Composition.

4.3.1.3 Sections

Sections equate to the broad headings in clinical records as defined by the RCP Clinical Headingshttp://www.rcplondon.ac.uk/sites/default/files/clinicians-guide-part-2-standards_0.pdf

or by the Scottish portal clinical information requirements

These are intended to broadly organize the structure and content of a high quality clinical record in a consistent fashion for human consumption, without describing the detailed aspects of e.g. a Medication record in terms that a computer can process.

Section archetypes have not been modelled in the first draft of this paper.

4.3.1.4 Entries

An Entry represents a single clinically meaningful statement or assertion e.g "The Diagnosis is diabetes mellitus", "Blood pressure 120/80 mmHg, sitting position" or "Medication Issued was Trimethoprim tab 200mg take one twice a day, quantity 10".

Each Entry must have a recorded author and other provenance information.

4.3.1.5 Clusters

Cluster archetypes are used to share sub-components between Entries e.g the Medication Cluster is used to record the name, form, strength of a medication in various medication-related Entries i.e in the Recommended medication entry to specify the medication which has been recommended and in the Administered Medication Entry to specify the medication actually given.

4.3.1.6 Elements

Elements hold the individual pieces of information within an Entry or Cluster e.g. the Medication name, or Date Administered.

4.3.2 Entry Provenance

As each Entry represents a meaningful 'clinical statement', it must be accompanied by a minimum of medico-legal provenance information. In a fully-implemented reference model this would be carried by reference model structures but for ease of technical modeling and to simplify clinical review, it is being carried as a Cluster archetype within each Medication Entry archetype.

Aspects of this approach and the design ofthe provenance cluster remain open for discussion, particularly the way that 'Parties' are defined i.e. the identity of clinical authors, other participants and organizations. This varies between HL7 models such as GP2GP and simpler SCI-XML/ IHR models. For now these are simply represented as anabstract PARTY class, pending further discussion.

4.3.3 ISO 21090 Datatypes

It is suggested that a subset of ISO21090 "Health informatics -- Harmonized data types for information interchange" datatypes are adopted. These are currently recommended for use within ISO13606 messages and are very closely aligned with the HL7v3 datatypes used by GP2GP.

Only a very small subset of 'profiled' ISO 21090 datatypes are required to support the Medications Model and some preparatory work has been already done in Wales along similar lines, for IHR purposes.

The datatypescurrently used in the Scottish Medications Content Model are:

Clinical name	ISO 29010 datatypename	Description	Examples / Notes
Plain text	String ST	Simple plain text	Dispense weekly
Codedexpression	Concept Descriptor CD	Allows coded expressions from an external terminology e.g. SNOMED/dm+d ,along with mappings to other coding systems if required.	Free text can be carried if necessary.
Coded value	Coded value CV / CNE = no other values allowed /CWE = other values allowed	Allows coded terms from a precise list of terms.	Select from 'Active', 'Complete' or Discontinued'
Integer	Integer number INT	An integer number	10
Quantity	Physical Quantity PQ	Includes the value and units (SI orDose units)	10mg 1 tab
Encapsulated	Encapsulated Data ED	Plain text or structured content e.g. XML blob or images	Currently only plain text is used in the models

DateTime	Point in Time TS	Allows full dates, partial dates and date only or date+time	1992 06-Dec-2004 06-Dec-2004:13.52
DateTime Interval	Interval of Time IVL<TS>	Allows for start date, end date and/or duration	06-Dec-2004 to -8-Dec-2004 for 7 days 06-Dec-2004 + 7 days

4.4 Implementation guidance

4.4.1 Templating for specific use cases

Since the medication models are purposely designed as inclusive and maximal of all potential uses cases, it is inevitable that a number of the elements in any model will be redundant and not required in specific projects. It is also often the case that elements which are optional in the base models will need to be made mandatory in some specific contexts of use, or that a set of possible values need to be more restricted.

In these circumstances a system of use-case constraint or templating is required. In an XML-schema environment this equates to 'schema restriction' and should be familiar to SCI-XML modellers.

4.4.2 Examples

e.g. The record for a single medication will comprise the original Medication and all subsequent Authorisations, Issues and eventual Discontinuation records

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Medication:“Atenolol 50mg tabs 1 tab daily” 01-Jan-2012

First recommended 01-Jan-2012

First authorised:

First issued:

Last Issued:

Last dispensed:

Discontinued:

5 Appendix 2 Governance issues

It is proposed that a Medication Content Modelling Group is established, relying heavily on web-based communications and operations. A key role is to 'market' the Group to as broad a range of stakeholders as possible so that the Group becomes the prime contact point for any medication content requirements.

5.1 Proposed Medication Content Modelling Group

Overall governance

- under direct auspices of ECS / KIS / SCIMP

Project manager

- responsible for communications, stakeholder engagement and 'marketing'

Editorial team

- 3-4 clinical informaticians/terminologists
- responsible for reviewing stakeholder comments, updating models, 'Publishing' models, responding to ongoing change requests and problem reports
- needs some technical support for XML Schema maintenance
- ? Half-yearly face-face meetings, ad-hoc web-conferencing to review progress

Broad informal, collaborative group

- Responsible for the key domain knowledge input
- Drawn from
    - SCI-XML projects,National Data Services and other Ensemble group projects
    - e-Forms community, Medicines management/reconciliation community
    - Data Recording Advisory Service, Terminology services
    - Vendors – primary and secondary care, NHS Wales Informatics Service, CfH GP2GP, Northern Ireland
    - Any other individual clinician, technical staff or project with an interest in sharing medications information.
    - Technical standards assurance - Design Authority,
    - Professional standards assurance - RCP/RCGP, SACottish Medicines Consortium

Infrastructure / operations

- Has to be available outside N3 to allow home-working, broad engagement
- Short-term
    - Wiki-like tool for background material, reference documentation, discussion
        - ? Wikispaces (used by US govt eHealth standards developers)
    - Email distribution of Word documents for review/comment
    - Project manager email as contact point for new stakeholders / change requests
- Long-term
- On-line discussion and model review facilities.

    - Draw from ideas in openEHR Clinical Knowledge Manager www.openEHR.org/knowledge as state-of-art custom web application – **please note Declaration of Interest below**[7]**.**

- Bug-tracking / simple project management tooling to support change request and tracking
    - Consider Atalassian JIRA and comparative products

[7]Declaration of Interest. The primary author of this document, Ian McNicoll, is co-developer of the Ocean Informatics Clinical Knowledge Manager product, acts as a consultant to Ocean Informatics and is an investor in this company.