Electronic Patient Record Stakeholder Forum

The development and implementation of clinical and associated technical standards in the development and implementation of the electronic patient record in England

Hosted by the Royal College of Physicians Health Informatics Unit in London on 1st May 2008

Attendees:

RCP Health Informatics Unit
Iain Carpenter, Clinical Lead; John Williams, Director; Mala Bridgelal-Ram, Project Manager; David Richard-Warmate, Project Co-ordinator

System suppliers
Cerner - Wale Lawal, Andrea Dantas, Physician Execs
Fujitsu - Lester Russell, Chief Medical Office; Zachary Swann, Solution strategist (Clinical Domain Practice)
CSC - Rajan Madhok, Clinical Director; George Davies, Director of Clinical Safety
BT - Nick Booth, Director of Health Informatics

CFH
Care Records Service - Martyn Forrest, Programme Director; Ken Lunn, Director of Data Standards and Products; Laura Sato, Informatics Standards Lead (Data Standards and Products)
Common User Interface - Mike Bainbridge, Clinical Architect, Technology office
Clinical Content Service – Mark Davies, Medical Director for the National Programme, Rowena Herbert, Programme Manager; Tony Shannon, Clinical Lead/ Consultant in Emergency Medicine; Beverley Harvard, Project Manager
Clinical Leads- Marlene Winfield, National Patient Lead / Head of Public Engagement; Gifford Batstone, Pathology Clinical Lead; Joe McDonald, Psychiatric Clinical Lead
SHA – Brenda Fowler (Northern, Midlands & Eastern Programme); Wendy Caddick (Southern Programme)
Mark Dancy, Consultant Cardiologist/Informatician

Information Standards Board
Martin Severs, Chair of ISB; Jane Millar, Head of Information Standards Service; *A*nne Casey, Clinical Domain Lead

Dipak Kalra, Senior Clinical Lecturer, Health Informatics, University College London (CHIME)
Mark Boult, Principal Consultant, DNV
Virginia Jordan, Head of Standards & Classifications (Information Centre for Health & Social Care)
Jayne Morgan, Information Scientist Swansea University

Objective

The objective of the workshop was to bring together representatives of the key stakeholders in the development of the Electronic Patient Record to gain a mutual understanding of the major aims and constraints of the programme. Three key areas were considered starting with presentations from two different perspectives.

Update on Clinical Content and Assurance Programme

Mark Davies, Medical Director for the National Programme, gave an update on the establishment of the Clinical Content Service in the Office of the Chief Clinical Officer for Connecting for Health.

There is a real time pressure to generate 'clinical content' and CFH are on still on a steep learning curve. Clinical Content Development takes time, so priorities are on high volume generic NHS activities. Piloting of content development for specific areas has been tested in NME (North/Midlands and East) and is being expanded on a larger scale. There needs to be a balance between local activity/innovation and national standardisation has to be developed to ensure maximimum effectiveness of clinical effort across the Programme. Multidisciplinary work is also high on the agenda.

There will be a programme for national 'assurance', which is required for content developed at a local level to ensure that locally developed content is fit for purpose at a national level. There are different dimensions of assurance all of which have a role: local, national professional body, multidisciplinary, and the Information Standards Borad. The model being proposed for the assurance process is a series of 'collaborating centres conducting assurance projects possibluy with a single national coordinating centre.

There will also need to be an easily accessible repository of content (including links to available guidance andstandards) so that integrity can be maintained across the programme.

Discussion:

Four areas were raised in discussion:

There is a tension for the system suppliers in implementation of clinical content.

- Where there is an existing application such as the Cerner Millenium product, there is resistance from clinicians who do not want to use them in that format
- Where a system is being developed in the presence of emerging standards, a supplier will want to implement developing standardisation. However suppliers can be challenged with requests for 'local tweeks' to accomodate a local problem. This creates a tension with the drive to national standardisation.

At the national level the challenge is in 'playing catch up' to deliver a huge required volume of standardised clinical content and also in addressing issues in relation to IPR such as copyright of content owned by individual suppliers. Developing standardised approaches is a huge task, as even within one hospital there can be variations in simple things such as TPR (temperature, pulse rate, respiratory rate) charts.

While there is recognition that the professions should be leading the development of clinical content, the view of the NHS, is that the centre has to be pragmatic as it must deliver the content in manageable timescales. The professions do have a major role in relation to professional developed content standards, as where there are standards, there must also be some responsibility for implementation, maintenance and regulation in relation to those standards.

Finally, and most importantly, it must not be forgotten that patients are at the centre of the whole of NHS activity, and they have a strong desire for clinical information about them to be accurate and available wherever and whenever they need health care services. Access to their own clinical information is also very important.

Overlapping Information Standards

The Data Standards and Products service (DS&P). Ken Lunn, CFH, Director of DS & P

The DS&P service (Data Standards and Products) provides a broad range of services to all development programmes in the National Programme for IT, and to the NHS in General. The intent is that there should be one way of doing things, including commissioning. The service runs the UK terminology service and aims to develop, support and harmonise standards across the NHS and to resolve conflicts. Conflicts arise as some of the functions of some of the standards overlap with each other and some UK standards conflict with International standards. DS&P is resolved to be always available for discussion and gain a better understanding of the issues to ensure openness and transparency.

The standards and products are structured in functional areas:

Terminologies — to ensure that information reflects best practice, is comparable across settings and is 'searchable' and yet is also precise while still being expressive. The relevant standards are: Read, Clinical Terms version 3, Snomed CT and DM+D (dictionary of medicines and devices)

Classifications — to categorise data in such a way that 'primary' clinical data can be used for 'secondary' purposes. The relevant standards are: OPCS, ICD10, the Data Dictionary

Information Models — detail the structure of information so that it can be collected, stored, searched and retrieved for the puproses of communication, registration and location. Information models include:

Open EHR/Clinical Archetypes (CEN 13606)	data collection information structure model search and retrieval
HL7 RIM (Reference Information Model)	information structure model
HL7 version 3	communication search and retrieval
CDA (Clinical Document Architecture for documents rather than data) (documents)	information structure model communication (documents)
SNOMED CT	communication search and retrieval
XDS (a standard for images eg Xray)	registration and location
The NHS Spine	registration and location

Wale Lawal
Perspective from system suppliers

For system suppliers', standards standardise the medical language, support information sharing, ensure predictable retrieval of information, support inter-system connectivity and operability, maintain a consistent information model and provide rules for messaging and communication, all while supporting a rich clinical content within their systems. Within the UK, there are required standards that have strategic importance for the NHS. These have to be introduced in the context of existing historical standards which must be replaced while ensuring backward compatibility because of the importance of clinical data. The historical standards include for example, READ, ICD10, OPCS4 and HL7 version 2.

There is also a substantial quantity of non strategic standardised information which has to be managed. For existing clinical systems this includes within system transactional information and system specific terminology. There are also some local and national 'codesets' that have to be accommodated, adding a further complication.

System developers and suppliers have particular problems where there is a) overlap in the domains of the strategic standards and b) they have to co-exist with non-strategic standards. The overlapping domains of the strategic standards are illustrated in the table:

	Content standard	Information model	Information structure	Messaging standard
SNOMED CT	√	√	√	
openEHR archetypes	√	√		
HL7 RIM		√	√	
HL7 CDA			√	
HL7 v3			√	√

System suppliers have to resolve these conflicts as they develop and implement their systems. There is a risk that one supplier will adopt solutions to resolve the conflicts which differ from those of another supplier. This can create silos of information that cannot be communicated or inter-operate between suppliers.

There are challenges that require a shared understanding.

- The national programme has to develop a clear roadmap for the transition from historical standards to strategic standards as they will likely have to co-exist within systems. This roadmap must make

clear expectations on when and how strategic standards will or should be implemented into existing systems

- There has to be harmonisation of those areas of overlap so that role for each strategic standard is unambiguous.
- This will likely require some of the strategic standards being implemented only in part.

Discussion

Patient focussed, patient level information is the key to a system that works in practice for clinical care and will also deliver information for management, policy and research purposes. Thus standards where clinical content drives the information structure are preferrable to structures that are driven primarily by technical requirements such as electronic messaging.

When decisions are made on adopting standards and there are systems already in place or well into development, the decisions must be supported by a clear road map on how they should be implemented and who has the responsibility.

It is challenging as the very large NHS information systems are based on long standing standards and technology that are now out of date and unfit for purpose. True understanding of this requires a major culture change in the viewpoints of policy makers and health care professionals.

Risk Management

Medical Record Content Standards and the role of the Safety Case

Mark Boult

The purpose of the risk assessment is to determine the risk associated with the use of a standard. For example, could a particular standard be mis-understood or mis-interpereted.

The aim of developing a Safety Case is to create demonstrable assurance that the standard's content (guidance and requirements and how it could foreseeably be (mis)understood will not result in an unacceptable level of patient safety risk. In this context, it is not about developing the safety case for any system (IT or not) which is developed using the standard nor ensuring that ensuring that use of the standard that will absolutely be free from risk.

The process for developing a Safety Case is as follows:

- Examine the draft standard and what could go wrong
  - How important is this – what is the likelihood of something going wrong and what would the consequences be
  - What can be done about it
- Document why the revised standard supports the delivery of "safer care"
  - This can include modifying the content, how it is presented or how it is implemented
- The completed safety case will demonstrate that these actions have been completed

Risk management in the development and implementation of a clinical information system

George Davies

The development and implementation of a clinical system has some areas of risk which are within the control of system developers and some that are not. Those that are within their control are the design, build and testing of the system and then the management of incidents once implemented, including updating and

amending the system. Those that are not within the control of the developer are the definition of the scope and requirements for the system and the actual implementation of the system. The safety management system covers hazard identification, classification and registration, safety training and testing, assurance and reporting of safety testing, pre-deployment approval, incident management.

Within the development of the Lorenzo system, there were 340 safety design issues identified and 27 hazards of which 13 were considered very low risk, 11 low risk and 3 medium risk. All 340 safety issues were were mapped against the 27 identified hazards and built into the testing requirements.

Deployment of the system goes through a series of steps. First the system is implemented by Early Adopters following which interim Clinical Authority to Release (CATR) is granted by the Strategic Health Authority. Prior to the early adopter deployment, a Clinical Safety Officer and Clinical Safety Engineer have to be in post. Once full CATR has been granted, the system is implemented by 'Fast Followers' who will benefit from lessons learned during by the Early Adopters.

External factors create significant challenges for ongoing deployment. These include:

- National Patient Safety Agency Initiatives: eg Right Patient, Right Care, Hospital at Night
- Considerable business change: eg. Required use of the NHS Number in place of Hospital Number, a new interface for system users which includes loss of the historical separation between Clinical and Administration systems
- Development of national medical record clinical content structure standards
- Information Governance issues: consent to store, consent to share
- Tensions between local and national configurations

System suppliers and the NHS therefore have to manage complex issues.

Clinical systems take a long time to develop and are therefore now already nearly complete.
The very high intensity of activity in secondary care means that clinical activity cannot be interrupted during deployment.
Deployment is the critical stage for compliance with standards and ensuring patient safety.
There are different degrees of readiness for deployment across the NHS

Development of profession led national clinical content standards is an extremely important step in this context. It should support robust clinical engagement and be extended to other professional groups. The local representatives of professional groups (such as the Medical Royal Colleges) have an important role to play in ensuring that the potential for improvement in quality and safety of clinical practice is realised.

Discussion

The management of Risk clearly has two major components:

- 'Central' responsibility such as in the development of standards or clinical systems, which is generally fairly well done
- 'Local' responsbility which relates to matters ensuring that people know what they are doing and how they should do it. This applies to the implementation of professional standards as well as implementation of IT systems. Education and training are essential, and individuals have a responsibility to ensure that they are proprerly informed and trained.

Patients are the people who have the greatest interest in being sure that those who are caring for them are well trained and work to the appropriate standards.

The tension between national standards and local development and implementation

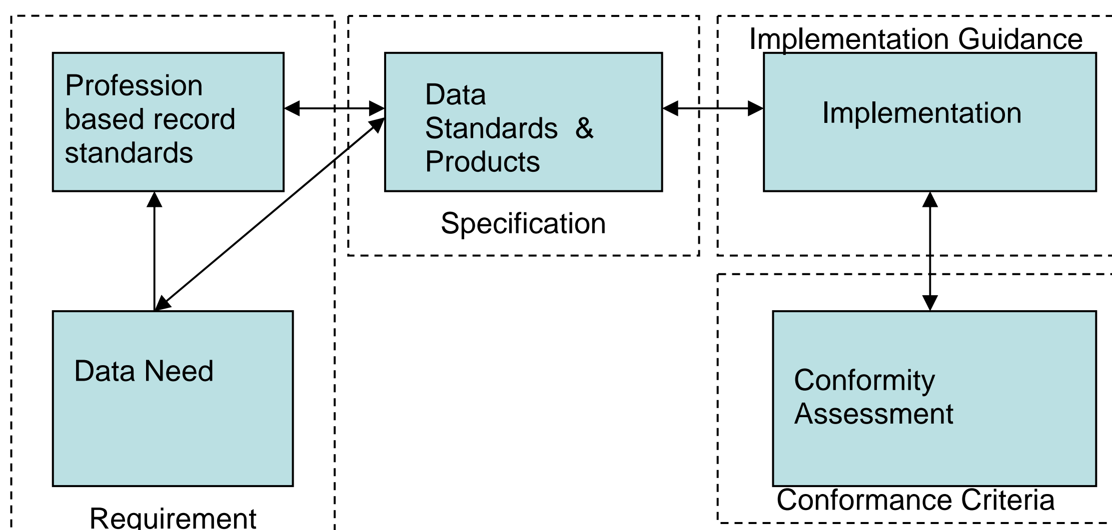
The perspective from the Information Standards Board for Health and Social Care (ISB)

Martin Severs

The ISB has responsibility for assuring and approving information standards for use in the NHS in England and in its communications with other sectors. It is independent and accountable to the NHS Chief Executive with its Board members drawn from across the health and social care professions and agencies. It also works with Local Government and the Department for Children, Schools and Families. A key function is the harmonisation of the UK with international standards.

NHS Information Standards are information and communication technologies which achieve interoperability between independent computer systems [functional interoperability] and between independent users particularly patients, clinicians, and managers [semantic interoperability]". They are are important because they enable large scale interoperability between computers, organisations and services. They replace non standard with validated information making possible automatic processing and reducing re-recording and duplication. They have huge cost saving potential but the benefits are only realised if they are effectively implemented.

National standards that are established by the ISB must have a number of components: a statement of requirement, a specification, implementation guidance and conformance criteria. In the context of clinical record content standards they are illustrated below:



The national clinical content standards that are developed and agreed by the Medical Profession have an impact in a number of areas. These areas include the headings that relate to how the record looks, the data which is input within each heading, the business context to which they apply (eg admission, handover and discharge), the whole structure of the clinical record and how it is communicated. They also reflect required or desirable ways in which clinical 'business' should be conducted.

What then are the issues in relation to locally developed content? It is possible to create specialty or activity specific standards within a generic standards structure, the obverse is not possible – create sound generic standards from specialty specific. The ways in which national clinical content standards are deployed and how content is developed locally have to be clear and explicit. Individual trusts should not be creating localised specific content that does not fit within national generic standards.

The professional bodies will also have to consider the risk/impact of having clinicians who do not 'turn up for training' and also ensure that there are feedback loops so that standards can be updated and maintained.

Deploying local implementations across the national system

Martyn Forrest

The major issue for the development and implementation of the NHS Electronic Patient Record is the required rate of development of the clinical content of clinical systems. There is an estimated need for 8000 data entry 'forms' over the next 18 months. At the time of this forum, there are just 15 agreed forms in the systems being implemented in the 3 early adopter sites within the North/Midlands/Eastern areas. The rate of development will therefore have to increase from a current rate of 1 form per week to 100 per week.

Completed pilots of local content development have covered:

- Paediatric Acquired Hearing loss
- Adult Learning Disabilities
- Children's Community Nursing
- National Pathology Test Catalogue
- National Radiology Investigation Catalogue
- National Service Order item Catalogue
- Body diagrams
- A series of commonly used tools and measures

Lessons learned from the pilots and early adopter sites suggest that there are some essential requirements to support the creation of clinical content forms. These include clear communication and collaborative working with significant clinical resource input, strong governance and project management, and well defined scope with a toolkit to support the development. The impact of future functionality and deployment across the whole NHS has to be managed.

The structure that has been developed to support the process includes the establishment of content and configuration boards and a national Requirements and Content Board. Appropriate methods for establishing professional assurance of locally developed content are being developed and will be soon be in place. The focus will be on high value high volume areas of clinical activity.

'There is no tension between local implementations and national standards'. There is a clear concensus that there should be just one way of recording data items and there will be a process for clinical assurance. Many elements of locally developed content will become standards, there just needs to be a different way of developing them than has been the case to date.

Discussion:

The tensions lie between systems with existing clinical content, locally developed content which is likely necessary because of the demand for rapid very large scale development, and ensuring compatability, inter-operability and comparability at a national level. The process that pulls these three components together must be based on an extremely clearly stated process.

Education is fundamentally important to ensure that care professionals understand the context in which clinical content is being developed and the way in which clinical systems are implemented – as they will have to use them. There will need to be a culture change - training will have to be mandatory and appropriate. Strategically it should be built into undergraduate and pre qualification training.

Summary/possible topics for a future problem solving meeting

1. How to develop a road map that addresses accommodating
    - Emerging clinical content standards into a system without losing existing clinical data that is based on historical standards
    - Technical standards (that may overlap in their domains of coverage) in systems that also have their own system specific standards

2. Training and education in relation to the challenge of ensuring that relevant training and education is delivered and that professionals have taken part in the appropriate training during the implementation of clinical systems.

3. The nature, content and use of a repository of standards, which also includes information in relation to managing of conflicting standards.