

**Report HL7 Meeting**

– Cleveland May 2003

**International Drug Modelling Conference**

–National Library of Medicine (Lister Hill) – Bethesda May 2003

**Peter MacIsaac**

Sn. Medical and Health Informatics Advisor  
Information and Communication Division

***Lister Hill Conference on Drug Modelling***

Key findings:

The 3 national drug terminology models are developing along similar lines:

The Australian model is heavily influenced by the environment in which it was developed and specific use case for Community prescribing and dispensing, hence lacks some of the features of the US and UK models. We have developed a product database with some of the features of a terminology. The current W&T based development program does not recognise the issue of the limitations of the planned product eg in hospital usage or recommend a strategy for completing the job.

There are elements of our model which may not be consistent with the others eg the equivalent ingredients table

There may be the potential for different systems to share components of the model eg the vocabularies for drug dose form, and active ingredients vocabulary;

International experience highlights the importance of pragmatic and consistent business or editorial rules in creating the terminologies. This will require adequate technical expertise during the building process.

The meeting identified all the elements of each national drug model and has created a format for representing these. The meeting then worked on a few simple examples to see which elements of the model were by each approach. The results of this comparative analysis are not yet complete however demonstrate a high level of agreement on core drug model elements.

A list of some 12 test drugs was identified and each group will provide their modelling approach to each of these. The drug types were selected to maximally stress the models and tease out key differences and approaches to challenging situations. **Support from the Drug Coding team with this comparative exercise would be appreciated**

Since I have not been recently involved in the Australian drug terminology project it is difficult for me to know how useful this exercise might have been for the Medicines Coding team, however the other participants from the UK and USA clearly found this meeting useful in suggesting solutions to some of the more vexing issues faced.

There is no doubt that drug modelling is covered by the 80/20 rule. This is a highly complex domain which must be sorted out as medication management has been widely identified as one of the key areas where there is evidence for cost effectiveness and improved patient outcomes in the implementation of information technology.

In the UK and USA the job of building the drug terminologies and models has been a highly multi-disciplinary task with reasonably extensive project teams which involve not only computer consultants but also drug information pharmacists, pharmacologists, professional modellers, clinicians, decision support developers, and public servants. (this was reflected in the participant list of the meeting). Having such a wide range of expertise and backgrounds and knowledge of the end user environments really helped the discussions. In Australia we attempted to get this input informally via the MCCA and its expert groups rather than build the wide range of expertise into the team. **I believe that the lack of breadth of experience and resources may be a significant issue in the next stage of the Medicines Coding Project.**

### ***Dose instructions:***

It is widely agreed that standards for representation of drug dosage instructions is a core requirement for prescription order, dispense and administration systems. HL7 has a Version 3 standard for describing timed events – the Global Timing System. The HL7 medication information group is working on an implementation guide. A watching brief is required as in my opinion there is a strong case for MediConnect messages to adopt structured dose instructions. **Consultation with IT14-6-4 on whether this can be done in V2 messages is needed.**

### ***Active Ingredients and Dose Forms***

The US Food and Drug Administration and the National Library of Medicine The National Library of Medicine (which produces products such as the MESH – used internationally for bibliographic searching, and the Unified Medical Language System (UMLS)) has entered into agreement with FDA to publish:

1. Basic drug identification information covering substance, strength, form, packsize etc.
2. A knowledgebase which holds drug information supplied in the product information (known in the USA as the Drug Labelling.) eg interactions, indications

For active ingredients the NLM will accept structural information on chemical structures as they are reported in the drug literature or are supplied and provide these to the FDA who will **manage and issue a standard identifier** to the NLM to include in various publically available databases such as MEDSH & UMLS. Likewise the FDA will maintain a comprehensive set of dose form & route terminology tables and provide these to the NLM. The FDA can do this while maintaining high level of confidentiality for information provided in the early stage of the registration process. The prospect of having an international standard identification system for drug ingredients is excellent and would be a core element of a common international drug

terminology model. The International Committee on Harmonisation is considering whether to push for a WHO maintained list. The US FDA is hoping to gain support of UK and Australia for it and the NLM to take on this task and make the resource internationally available. This needs further discussion with TGA.

Work is progressing on harmonisation of the Drug dose form model and I feel it is likely that an overarching terminology will be developed, which various countries or organisations can extract the list of dose forms which meets their needs. There are major differences between the ways dose forms are described by regulators (the manufactured dose form eg powder for reconstitution) and clinicians (the administered dose form eg. syrup)

### ***Product Information***

The FDA is attempting to provide the pharmaceutical industry with an electronic option for the drug labelling (product information) which will allow health professionals to access this information in their clinical computer system or on the internet. The NLM is taking on the role of repository and publisher of the electronic drug labels. This will obviate the need to include the PI with drug packaging hence reducing costs and facilitating updates and maintenance.

A HL7 standard for Structure Product Information was passed in the recent ballot which provides a standard XML schema for product information (called the label in the USA).

### ***SNOMED-CT***

There have been no further official announcements, however informal discussions at the NLM indicate that:

- A very satisfactory agreement has been reached for a US national licence for SNOMED-CT;
- This licence will make SNOMED-CT available for wide uptake and evaluation in the field, however SNOMED-CT will not be immediately declared a US standard. I believe it is likely to be taken up immediately by all major Government health agencies which will give it a major push in the market;
- The pricing arrangements are regarded as reasonable and should not lead to prohibitive costs for other countries;
- SNOMED-CT will be published in the UMLS. As such it will be possible for Australians to access SNOMED-CT once either individual or national licences have been obtained. Thus it will not be necessary for Australia to consider duplicating a publication strategy;
- The US contract has acceptable exit strategies in the event of wishing to discontinue the licence or in the event of College of American Pathologists being unable to continue to support it;
- It is not clear what the arrangements will be for the medication component of SNOMED as the FDA/NLM approach will be publishing the drug terminology independently.

## ***Consolidated Health Informatics (CHI): Adoption of IT Standards by the in US Government.***

Presentation by Cynthia Wark

Two processes for Government to engaging with Standards:

1. Active participation in HL7 family of standards by various agencies over several years;
2. Consolidated Health Informatics (CHI). An interdepartmental process under the Presidents e-Government policy.

Brings together health agencies for the purpose of agreeing government use of health informatics standards in health. Main players are Dept. Health, VA and Dept. of Defence. A number of agencies have health information issues while not being primarily a health agency. This is solely a Government initiative. Have created dialog with National Council on Vital Health Statistics ( and HL7. Has a aim of identifying standards in some 20 areas over a year or two at most.)

Have a clear set of areas and classification of standard development lifecycle. Cross disciplinary teams work on each standard area. Result in recommendations for action but within the timeframe for the agency.

The first round of standards included V2 HL7, and identified V3 as needing fast tracking. The process of CHI will act as a “tipping point” to move industry towards standards without heavy legislative or consultative processes.

Talking to those involved there are however issues such as the capacity of Government agencies to effectively evaluate the technical issues (and they have significantly more in-house capacity that the Australian public sector.). By the nature of US bureaucratic procedures this has to happen as a “purchasing” process and be completely inhouse hence is potentially disconnected from other national IT standards processes, however they are looking to HL7 and their National Committee on Vital Health Statistics for support.

It is certainly worth considering an adaptation of this process in Australia, starting within the Commonwealth Health related agencies (Health Portfolio, DVA, DoD)

### ***HL7 Messaging Version 3.***

Progress is continuing with HL7 V3 messaging model development for community, order and dispense, hospital order, dispense and administer, and medication history enquiry. This may not be immediately relevant to MediConnect developments, however it is possible that Australia will move to the new version of HL7 at some time. Countries such as the UK and Netherlands are only working in V3 for their comparable systems. **I would recommend that any future message development projects using V2 should be based on a formal model (using V3 development methodology) to facilitate eventual migration.**

Further description of the UK V3 development strategy is attached.

During discussions between Graeme Grieve (Australia) and Charlie Mackay (UK) it seemed that there was common interest in establishing a network of test Version 3 message servers which would enable organisations interested in V3 to test and debug messages developed starting with simple components such as the message wrapper. This method was used to rapidly sort out the SOAP communication protocol via international collaboration. **HealthConnect may like to consider supporting this.**

Following the last HL7 meeting Dick Harding (Qld Health) and Peter MacIsaac (Commonwealth Dept Health) developed the use cases and interaction models which are being adopted for the next ballot instead of previous efforts which were overly complex and lacked international perspective.

### ***HL7 Version 2 Messaging***

Australian recommendations for revisions to Version 2.5 were accepted with thanks. There had been some key information lost in the publication of the new ballot which was noticed by the IT14-6-4.

### ***Immunisation Codes***

Contacts with officials from the Centres for Disease Control indicate a readiness to accept new immunisation codes. The contact person at the CDC is Sarah Ryan. It is recommended that HL7 Australia affirm the decision that IT14-6-4 maintain the Australian immunisation code list and communicate our requirements to CDC who maintain the codeset on behalf of HL7.

Consultation may be required with TGA and PHD on this issue.

## Attachment A - UK HL7 Development Strategy;

### Background:

The UK Government has announced a major program of health informatics development and implementation involving \$Aust15 billion over 3 years. The NHS has made it clear that interoperability is a key requirement

The 3 major GP suppliers agreed to a data exchange format based on the draft CEN ??? EHR standard. However at that time it was not clear that this standard had a clear future in the light of Open EHR and HL7 developments

One of the key messaging development projects (GP2GP) aimed at exchange of GP information had settled on the HL7 V3.

Suppliers have arrived at a policy for dealing with Gov in IT development projects:

1. Projects will be fully funded
2. Projects will use standards so that there is some lasting/generalisable outcome
3. Projects will be developed within the HealthCare Interoperability Forum (HCIF)

The HCIF is a loose group of 20 vendors (under guidance of HL7 UK) who collaborate and fund message development

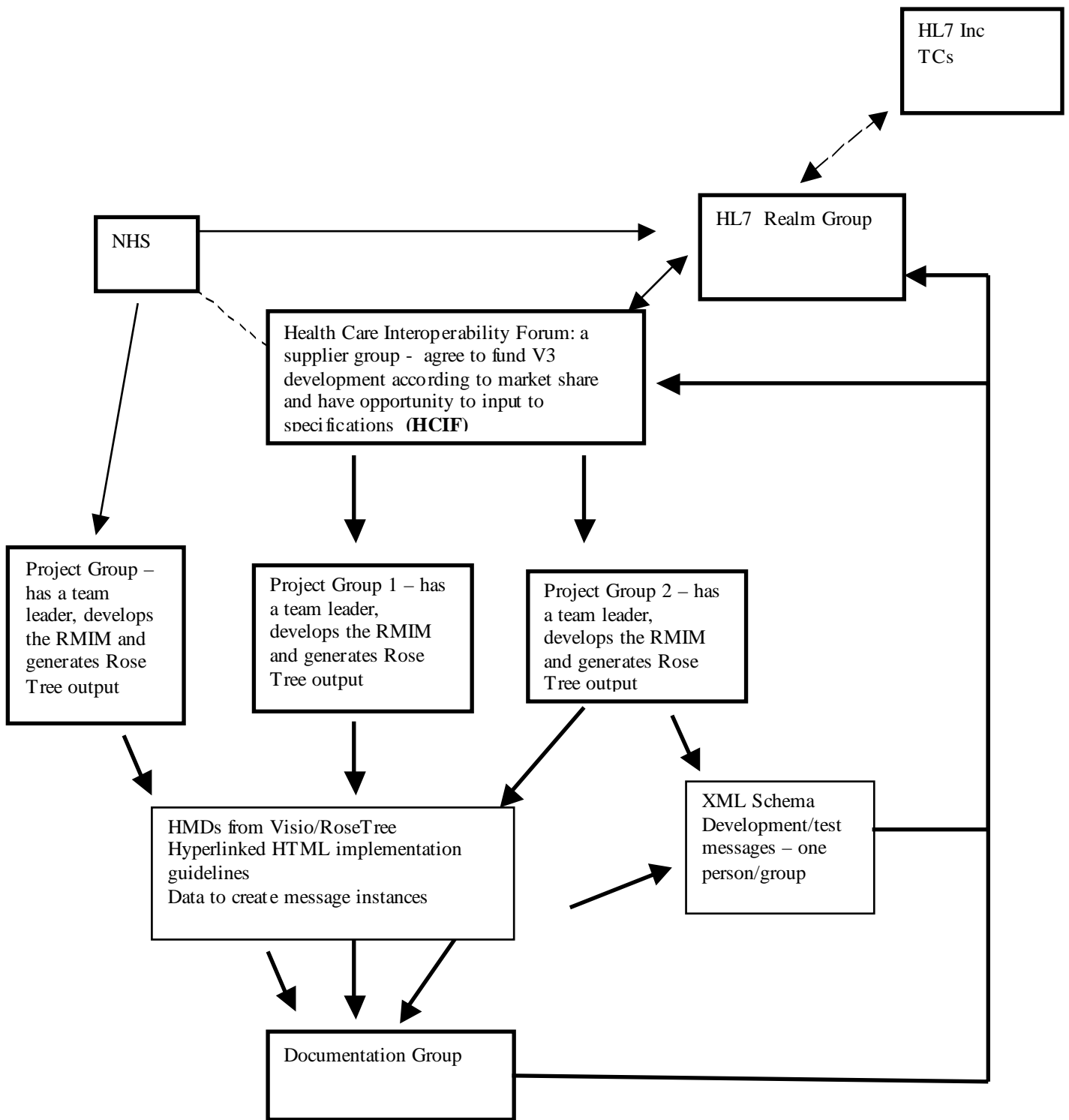
### V3 Usability

The UK has adopted a pragmatic approach which is resulting in message schema and test messages which are claimed to be clearly derived from basic HL7 structures such as the RIM and use the HL7 Development Framework (HDF)

Currently messages are 95% autogenerated from the RMIMs and this is likely to increase of 99% in the next few weeks.

### Variation to HL7 model

# UK. V3 Development Model



- Current Project Groups are:**
- Test Request
  - Out of Hours
  - Shared Care

## Attachment B – note to Terry Slater re FDA and drug ingredient issues

I have been attending the Health Level 7 meeting this week in Cleveland and next week will be participating in an international meeting on drug information models along with representatives of UK NHS and US National Library of Medicine, US Dept of Veterans Affairs and the US Food and Drug Administration.

### Background:

Attached is a summary of the meeting background and objectives. The major objective is to clearly define the process for electronically defining medicines. This will have to touch on issues such as sub-vocabularies for issues such as dosage form, route of administration, and identification of active ingredients.

The National Library of Medicine (which produces products such as the MESH – used internationally for bibliographic searching, and the Unified Medical Language System (UMLS)) has entered into agreement with FDA to publish:

3. Basic drug identification information covering substance, strength, form, packsize etc.
4. A knowledgebase which holds drug information supplied in the product information (known in the USA as the Drug Labelling.) eg interactions, indications

The way this will work is that the NLM will accept structural information on chemical structures as they are reported in the drug literature or are supplied and provide these to the FDA who will manage and issue a standard identifier to the NLM to include in various publically available databases such as MEDSH & UMLS. Likewise the FDA will maintain a comprehensive set of dose form & route terminology tables and provide these to the NLM. The FDA can do this while maintaining high level of confidentiality for information provided in the early stage of the registration process.

The FDA is attempting to provide the pharmaceutical industry with an electronic option for the drug labelling (product information) which will allow health professionals to access this information in their clinical computer system or on the internet. The NLM is taking on the role of repository and publisher of the electronic drug labels.

It should be noted that the NLM is likely to be the repository and publisher for SNOMED-CT once the US government licence arrangements have been finalised. As such it will be possible for Australians to access SNOMED-CT once either individual or national licences have been obtained.

### Issues:

Randy Levin, Director for Information Management, from the FDA, has requested input from the Australian Health Department/TGA the issue of international standardisation of drug ingredients. They are proposing for the US to continue the

process above, to do this in collaboration with the NLM and make this information available internationally to countries such as Australia..

There has been debate at the European Medicines Evaluations Agency (EMEA) and the International Conference for Harmonisation (ICH) on this. There is a proposal regarding the World Health Organisation providing the international reference service for drug ingredients.

From the drug terminology perspective it is essential to have a standard list of active ingredients (at least in Australia, and preferably internationally) Modern terminological practice allows also for the use of hierarchies to manage levels of specificity and also to cope with language and linguistic variation through the use of synonyms. A good example of this has been a recent process where the FDA working with HL7 has collected all drug dose forms used internationally and is putting them into a common structure (without impairing the ability of a specific realm to use their own subset – they just all come from the one “bucket”)

It appears to me that there is a possibility to exploit the existing information processes rather than establish a new structure (which will in any case need to draw on the FDA/NLM resources ) There appears to be a possibility that the FDA are prepared to include international input to the process.

The alternatives are to have the FDA pass on this role to someone else (?WHO) or alternative to have multiple sources of drug ingredient codes and identifiers. This could result in additional costs and complexity if it is decided that there have to be maps or link tables between the systems.

Specific questions:

I don't feel that it is necessary to respond immediately to this, however it raises issues which will need coordination between TGA/ICD (relating to drug information and standards)

1. Does the Department/TGA have a view on these issues?
2. Are we prepared to consider using the FDA/NLM process to provide the international reference for drug ingredients for Australia, or to have this contribute to existing processes?
3. Are we prepared to support the FDA/NLM process if this arises in international forums such as ICH in July 2003.
4. From the drug information processes such as MediConnect, are we prepared to consider sourcing such information in government sponsored to operated drug terminologies, product lists or databases?

Contact person at the FDA:

Randy Levin  
[LevinR@cderr.fda.gov](mailto:LevinR@cderr.fda.gov)  
301 8277756

## Attachment C: HL7 Vocabulary Technical Committee

HL7 vocabulary TC has recommended that there should be vocabulary domain standards in each realm/context (eg. UK, USA Veterinary) which apply across health domains eg. the same drug identifiers used in GP, Community, Specialist and Hospital domains. From a HL7 perspective this affects the process of validation or conformance to HL7 standards. This will require consideration for action in Australia in relation to existing version 2 standards.

HL7 is progressing with a structured approach to downloading HL7 maintained and registered vocabularies. A central terminology service is being developed both as a physical repository (based on LDAP server model) and a common API specification.

The US Government (in addition to other health standards development processes) has established a cross Divisional process called Consolidated Health Informatics (CHI). This set standards directions for Government agencies and will act as an influence on industry and opportunity for Government leadership without recourse to regulation. Standards have already been released for messaging (HL7v2 and v3 to be fasttracked). **It should be noted that all the major US Government agencies are active participants in several HL7 standards areas.**

### HL7 Vocabulary Report

A paper presented on policy for identifying standard vocabularies and terminologies for use in HL7 messages/domains. Clearly agreed that:

1. system communication requires semantic interoperability;
2. there should where possible be international standardisation on vocabulary
3. realms have the capacity to recommend standards for their ;

There was debate about whether there should be a universal, preferred, recommended vocabulary or a process to record the use case and reasons for selection and/or a process for reporting on which realms are using particular options. On one hand this could provide useful advice to affiliates, members and industry, on the other it could allow the dominance of a particular solution which may or may not be supported by a due process.

### 1. HL7 Vocabulary Table Distribution

A paper (attachment B) has been presented which broadly allows anyone to download HL7 V3 vocabularies (except those with require licences). This allows the addition of local codes where these represent concepts which are not already covered. It is not allowed to use HL7 codes to produce competing systems.

### 3. Centralised Terminology Services

Aim is to develop a common API to access terminology content related to HL7 business. HL7 has a need to have a system for storage and management of HL7 defined and registered codesets. The CTS is a specification

CTS is aimed to provide the minimal acceptable solution. Others may have more complex requirements which this will support.

There are five components:

	Runtime	Brower
Message API	Message runtime	Message browser
Vocabulary API	Message runtime	Vocabulary browser
Mapping/Translation	Vocabulary Mapping	

There will need to be tools for entry of data into HL7 maintained code tables.

Example functions:

Validate code

Validate translation

Translate code

Fill in details

List valid codes

Etc

The key role is to manage terminology for current use. There was a lot of discussion about the issue of previous coding system versions. Agreed that the CTS needs to allow for knowing the dates when a particular version was active eg.