

Draft for comment

Summary

This interim report aims to:

- Summarise the work areas defined at the workshop.
- Provide an opportunity for workshop participants to comment, add to, or otherwise improve this draft report.
- Encourage participants to rank the work areas defined in order of their priority for achieving the workshop deliverables (Appendix I).
- Allow participants to join one or more work groups in order to refine specific work plans for the final report (Appendix I).

Background

Electronic Decision Support has been identified as a key component of a national strategy to improve healthcare delivery through improved information management. The most comprehensive recent review of activity in Australia was undertaken by the Electronic Decision Support Taskforce (www.health.gov.au/healthonline/docs/nedsrept.pdf). Released in November 2002 this report provided a valuable roadmap with 26 recommendations for future action. HL7 Australia has been acting as a catalyst to move this agenda forward.

Following a HL7 Australia conference on Clinical Decision Support Standards held in Sydney in August 2003¹, HL7 Australia formed an Electronic Decision Support Technical Committee (EDSTC). HL7 Australia also submitted an ITOL grant project proposal aimed at creating a common data interchange format for drug monographs and therapeutic guidelines. A technical workshop was held in December 2003 to progress these matters.²

The workshop was sponsored by HL7 Australia, HL7 New Zealand, the Commonwealth Department of Health & Aging (DoHA), the New Zealand Ministry of Health, the Australian Quality and Safety Council (ACSQHC), the Australian National Prescribing Service (NPS) and La Trobe University.

The two day workshop brought together 50 primarily trans-Tasman health information providers and software vendors. An update on relevant drug and therapeutic decision support projects underway in Australia, New Zealand and Canada was provided. The final workshop session identified work areas which need to be progressed to support a standards based approach to incorporating national best-practice information resources into clinical software. The prime focus was on therapeutic information resources, but diagnostics (pathology & radiology) and preventative (immunization) resources were also discussed.

The deliverables expected from the workshop included:

- Specific work plans of the tasks required to develop standards based interface (and tools) for integrating best-practice therapeutic and diagnostic information into the clinician's electronic desktop (in both hospital & general practice). It was expected that this would involve expansion and refinement of the methodology proposed in the original HL7 Australia ITOL grant application.
- A short list of information providers and software vendors who demonstrated both commitment and capacity to carry out the tasks required.

¹ <http://www.hl7.org.au/2003-SYD.htm>

² <http://www.hl7.org.au/CDSS.htm>

- A budget for the resources required to implement the work plan.
- A business case and funding models for both initial implementation and long-term sustainability.

The workshop structure, background papers and presentations are detailed in Appendix I. Background papers and workshop presentations are available at: www.HL7.org.au/CDSS.htm.

Work Areas Identified

The following list (and overview) is not intended to be exhaustive or to capture all the detail discussed in the workshop, but rather provide a basis for bringing together workgroups to advance each of the following areas:

- 1. Standards for data interchange between current electronic best-practice drug and therapeutic resources and clinical (prescribing) software** in order to:
 - 1.1. Make context specific best-practice information available (given a clinical problem &/or drug of interest) by opening a relevant resource (NPS RADAR, Therapeutic Guideline, Drug monographs) at the right page;
 - 1.2. Provide more patient specific (and succinct) information by interaction between electronic drug and therapeutic resources and the patient's electronic medical record (EHR).
- 2. Standards for identification of medication and diseases/problems required for data interchange :**
 - 2.1. Medication/substance identification sufficient for safe prescribing
 - 2.1.1. substance level identification
 - 2.1.2. package level identification
 - 2.2. Disease/problem identification
- 3. Standards for drug formulary (monograph) representation which incorporate sufficient identifiers to enable lookup.**
- 4. Standards for clinical guideline representation to enable knowledge to be presented in terms of medication and diseases/problems.**
- 5. Standards for data exchange of drug-drug interaction data and the development of standard content for the most common and serious drug-drug interactions.**

Suggested methodologies for specific work areas

1. Standards for data interchange between current electronic best-practice drug and therapeutic resources and clinical (prescribing) software in order to:

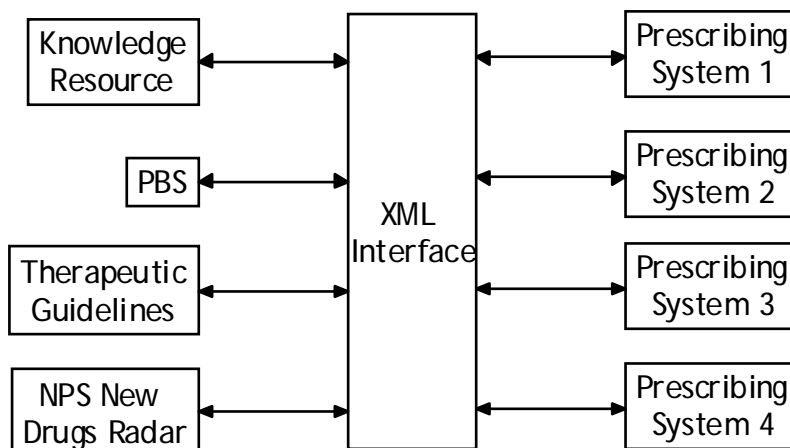
1.1. Make context specific best-practice information available (given a clinical problem &/or drug of interest) by opening a relevant resource (NPS RADAR, Therapeutic Guideline, Drug Monographs / Formularies) at the right page.

The problem

There are numerous vendors of clinical software competing in the hospital and general practice marketplace. There are also a number of Australian best-practice drug and therapeutic information providers. While all the latter provide electronic products, because they have been developed in isolation, each has different formats and data structures making it difficult and expensive for vendors and clinicians to access multiple products. A common standard for data interchange between current electronic best-practice drug and therapeutic resources and clinical software would reduce the development and maintenance costs of integrating these resources with clinical software, open and “grow” the market for innovative products³ and improve health outcomes by making the right choices the easy choices.

What is proposed?

Rather than await the emergence of standard guideline and formulary formats it is proposed to build on the work already started to incorporate NPS RADAR information into GP prescribing software. The Figure below shows a generalised architecture for this problem as described in the background paper by Lewis. The XML Interface depicted is described in more detail in the background paper.



Rationale for the XML Interface (XI)

An alternative mechanism to access information in an XML document is an XML schema for a set of XML documents and to pass the responsibility for the processing of the documents to the developers of the receiving system. However, the proposed XML Interface (XI)

³ For example, “active” guidelines that interact with the patient’s electronic medical record to give succinct advice relevant to the patient’s particular clinical situation.

approach will reduce development requirements and provide the ability to extend the interface to accommodate future integration requirements in a backwards compatible manner.

Development of such an interface will provide the following benefits:

- ***Developers do not have to interpret the structure of the XML documents.***

In order to retrieve the list of drug names from an XML document in the absence of the XI, it would be necessary to determine where the drug names were in the XML structure, and to develop a retrieval mechanism for it (such as an XSL file, or passing an XPath query).

- ***Inconsistencies between integration will be reduced***

Because there is only a single mechanism to retrieve the drug names from a document, different implementations will return consistent values.

- ***The structure of the XML documents can change without affecting integration.***

The interface specification is self documenting, eliminating the need for vendors to be aware of the structure of the XML documents and permitting easy extensibility in a backwards compatible manner.

What are the expected outcomes?

- National best-practice drug and therapeutic information available within prescribing software in both hospital and general practice.

In parallel with the above it was proposed to investigate the adoption of standards for clinical guideline representation (see section 4 below)

- 1.2. Provide more patient specific (and succinct) information by interaction between electronic drug and therapeutic resources and the patient's electronic medical record (EHR).

The problem

Current Therapeutic Guidelines provide a variety of different recommendations to cope with specific patient factors such as drug allergy, age, sex, pregnancy, etc.

Prescribing software and other EDS systems also require access to the health record components to custom decision support to specific patients.

Clinical software implementing an electronic health record (EHR) contains many of these variables in machine-readable form but there is no current standard manner to access this information (and potentially update it). One recent EDS implementer estimated that 50% of the project time was spent interfacing the system to the electronic health record – and that was for only 2 different clinical systems

What is proposed?

The development of an (Application Programming Interface) API, which connects external software applications to the EHR. The API will supply a small, concise subset of data, which has been identified as critical for EDS systems, allowing the customisation of the information to be returned. It is thought that an initial set of 5-15 modifying factors will provide significant information for useful customisations to occur. Example initial factors:

- Age
- Height and Weight

- Sex
- Pregnancy status
- Breastfeeding status
- Renal impairment status
- Pathology results for a small set of analytes (e.g HB, WCC, Platelets, Na, K, BSL, Hba1C, Cr, Chol, TG)
- Drug Allergies
- Current Medications

There are many knowledge resources e.g.

- Therapeutic Guidelines (TGL), which provide best-practice information on therapeutic care
- Drug resources (AMH, AusDI and MIMS) which provide drug product information.
- Pathology use and interpretation guidelines
- Immunisation guidelines
- Mental Health management guidelines

All require access to patient specific data from the EHR for use in EDS systems.

Connection of these diverse knowledge resources to EDS systems would be incorporated in the interface specification to be developed in work item 1.1

What is being done now?

The GPCG have identified the potential value of a "demographic server" which would handle demographic information collection, exchange and updating in a standard way. There is an existing, well proven, HL7 standard for integration of different applications, the Clinical Context Object Workbench (CCOW) (www.HL7.org.au/CCOW.htm). This standard describes a method for communication between programs to exchange demographic and other patient related data. It can be extended to exchange data related to any mutually agreed "object".

The work of the OpenEHR team (Archetype based EHR's) and emerging standardisation of vocabularies also holds out the promise of a standard clinical data format and structure.

What is proposed?

Formation of a working group to investigate the issue of standards for communication of demographics, key EHR components, requirements for write-back from the EDS systems to the EHR and options for integration of key knowledge resources to provide an electronic decision framework for principal clinical activities eg prescribing, investigation, ordering.

As CCOW is a mature standard, implementation of a demonstration CCOW server and demonstration applications utilising this interface would provide a basis for evaluation of other proposed components.

Currently emerging standards and implementations of EHR systems based on Archetypes (Open-EHR) should also be investigated to assess their applicability to EDS systems and the likely timeframe of availability of these standards with a view to future implementation.

What are the expected outcomes?

- An improved understanding of the requirements of EDS system and EHR/Clinical Desktop developers.
- Investigation of the extent to which the OpenEHR approach can create a standard for data interchange
- Local expertise and experience with the CCOW standard and an interface with wide applicability to EDS and other clinical software systems (e.g. transfer of patient records, reporting of patient demographics, clinical calculators etc)
- The potential, in combination with the other proposals, to provide patient-specific best-practice advice to clinicians through their clinical software system.

2. Standards for medication and disease/problem identification

2.1. Australian Drug terminology

The problem

In Australia there are no agreed medication or disease/problem identifiers to enable sharing of core drug descriptive data and on which to link additional drug &/or therapeutic knowledge. The core requirements are the ability to describe drugs in machine readable form for the following applications:

- Electronic Prescribing (by brand or generic name in such ways as are common in both hospital and community practice)
- Computer assisted dispensing of medication
- Linkage of drugs to knowledge resources (Electronic Decision Support)
- Drug Utilisation reporting
- Supporting electronic commerce/drug order and supply chain management

A drug terminology provides the core descriptive information, which is required to describe and define key drug information components. It is more than a product list and is required to also contain or link with terminologies describing core drug components such as active ingredients, drug dose forms, prescribable therapeutic moieties, drug classification or grouping structures, units of measure for drug strength. A drug terminology does not generally contain detailed knowledge about drugs of the type supplied in current drug information resources, intending to provide a common basis for describing core drug concept.

What is proposed?

1. A rapid and thorough analysis of the current content and expected outputs of the Australian Medicines Coding project, currently being undertaken by the Department of Health and Ageing and Drug Coding work undertaken in New Zealand, paying particular attention to:

- 1.1. The capacity of the proposed system to identify key classes of drug information necessary for hospital medication management and decision support. A draft list of key items is attached.

- 1.2. The degree of completeness and timelines for the national drug coding project and its potential usefulness to application developers and drug information resources
- 1.3. The data outputs from the EAN repository and an analysis of the degree of manipulation required to produce a basic drug formulary, which could be used as the basis of a national drug terminology.

The UK NHS could be requested to provide access to the team who have developed the structure of their national drug terminology to conduct the above evaluation.

2. Exploration of the potential to build on existing drug databases used in Australia to create an interim standard drug terminology which can be linked with the EAN drug identification system. This project would create a map to the drug databases of systems which support its development. Subject to the outcomes of the above investigation, it is likely that this work would work in cooperation, but parallel to the development of the EAN drug information repository.

Alternatives to be considered:

Subject to the result of the review of current Australian and NZ work, wait for the outcomes of the current developments prior to planning an extension to support decision support and hospital applications. This is unlikely to meet the expressed industry need for standardisation to support integration of drug information.

Selection of an existing drug information resource to provide a standard terminology. This option was rejected in 1999 due to the difficulties of achieving agreement on this approach given the competitive nature of the drug information market, and the failure to identify any particular system which met the basic design requirements for a standard drug terminology. This situation may need to be reviewed given the time and system developments which have occurred since.

What is being done now?

This analysis should draw on the experience of the UK Medicines Drug Dictionary Project which has been developed to support all of the above clinical requirements. Australia has been participating in an international workgroup with the US health department and UK NHS to explore the drug terminology models and drug dose forms used in various countries.

Clearly the outcomes of the Medicines Coding Council work and current DoHA activities need to be considered as discussed above.

New Zealand has had a system of standard drug codes for some years, however it is not clear to what extent this constitutes a drug terminology.

What are the expected outcomes?

- Development of a drug terminology meeting the needs of all sectors using computer systems for drug information management.
- Identification of the degree to which current drug vocabulary work meets the needs of drug information and drug management systems.

- Governance linked with the national Classifications and Terminologies workgroup and processes for governance of the medicines coding project, and a process for maintenance.

Key element examples:

Packaged medications (Actual Medicinal Product Packs)	Amoxil 250mg/5 ml liquid, 5 ml ampoule, pack of 5)
Medication units (Actual Medicinal Product)	Amoxil 250mg/5ml liquid, 5 ml ampoule
Medication family name (Actual Medicines Group)	Amoxil
Generic equivalent to packaged medication (Virtual Medicinal Product Pack)	Amoxycillin 250mg/5 ml liquid, 5 ml ampoule, pack of 5)
Generic equivalent to medication unit (Virtual Medicinal Product)	Amoxycillin 250mg/5 ml liquid, 5 ml ampoule
Clinical Drug	Amoxycillin 250mg/5 ml liquid
Virtual Medicinal Product	Amoxycillin
Active Ingredients	Amoxycillin trihydrate
Dose form	Liquid
Strength units	Mls.

2.2. Disease terminology

The Problem

Standardised clinical problem (disease) terminology enables an appropriate therapeutic guideline to be selected for a particular clinical problem being dealt with by a clinician. It is also vital for the follow-up of patients with particular diseases, for research and statistical purposes. Without such a standardised problem terminology, drug/problem interaction detection is impossible e.g. warning the clinician of the serious potential consequences of prescribing a B-blocker for an asthmatic patient. Current coding schemas such as ICD10AM and SNOMED-CT are overly complex for routine clinical use. There are a number of alternate clinical problem coding systems currently in use with prescribing systems.

What is proposed?

A pilot project to encode diagnosis codes from the ICD10AM index and SNOMED-CT. These resources would then be integrated with existing clinical and prescribing systems.

What are the expected outcomes?

- An understanding of the suitability of the clinical coding systems selected for this purpose and feed back to the drug terminology project.
- Demonstration of the improved functionality of the EDSS, which would support user uptake by reducing time to seek information and write a prescription.
- Demonstration of potential to improve patient safety with incorporation of drug/problem interaction detection into prescribing systems.

3. Standards for drug formulary (monograph) representation.

The Problem

Australia and New Zealand have several commercial and publicly funded drug information resources which all are some way down the path of electronic publishing and use a form of XML data representation. Integration of these into clinical software has been limited and requires a custom interface for each information source. This process adds to the cost of information integration and limits the ability of the end customer to specify their drug information resource of choice.

What is proposed?

The exploration of an acceptable and maintainable technical solution to enable the integration of multiple drug information resources into clinical software for presentation in a human readable form;

The sharing and publication of drug information XML schema

The development of a common XML format with agreement of issues such as tag names

Alternatives to be considered

Is the Structured Product Label (based on HL7 Clinical Document Architecture) format being commissioned by the US FDA suitable?

Does the DrugRef format support a common interface?

Hatrix have already integrated multiple drug (and therapeutic) information sources, how generic is their solution?

HCN have integrated different information through a common search engine, are there lessons from that work?

Visual Health indicated work already done in this area and support for participation.

The NZ Ministry of Health is interested in supporting a cross Tasman approach (in keeping with pending merger of the drug regulatory systems).

What are the expected outcomes?

- The development of a common drug information format which will allow either interchange of drug information resources or reduced cost to access more than are currently available.

- This will also pave the way for the structuring of information currently embedded in drug information but not accessible eg drug interaction data.

4. Standards for clinical guideline representation

The problem

Clinical guidelines have become established as one of the key components of strategies to improve health outcomes by supporting the application of evidence based practice and reducing variation in clinical practice associated with poorer health outcomes. A key strategy to assist with implementation of guidelines and clinical knowledge resources is to incorporate them in electronic format into the clinical desktop and to support integration with the electronic health record. It is important that such knowledge can be separated from the applications which use it.

What are required are standard formats for the electronic knowledge representation (eKR) in guidelines in a form that is appropriate to support their use in clinical software applications. These forms can include XML based publication formats to present the text of the guideline, appropriate structure, mark-up and terminologies to allow computation of the guideline content, systems for managing the clinical workflow relevant to the guidelines, and rule based knowledge representation to support computerised inference. It is unlikely that one system can handle all of the above, and so a combination approach may be needed for eKR

What is being done now?

The August HL7 Decision Support Workshop considered several options for handling knowledge representation based on both local (Australian and NZ) and international efforts (as represented at HL7 International). The NZ guidelines group and the December workshop concluded that the GEM currently provided the most robust international basis for clinical guideline representation; however it does not handle the workflow or execution components although this is being worked on. In addition, it was primarily devised for single, large and complex guidelines, not multiple small guidelines (such as those found in the Australian Therapeutic Guidelines). In the Australian Integrated Care Project (ICP) workflow was managed using a modification of an Australian developed Decision Support Mark-up Language (DSML). However, this lacks widespread acceptance.

Arden Syntax is the current international standard for representation of medical rule based knowledge but has not been found so useful to represent guideline based logic.

HL7 Australia will be holding a series of seminars in February led by Robert Genders (one of the original authors of Arden and Co-Chair of the HL7 Arden Syntax special interest group) to clarify the role that Arden may play in guideline representation.

What is proposed?

1. The ICP project should be encouraged to submit their work on DSML to the HL7 Decision Support workgroup with a view to its incorporation into international and Australian standards. A technical expert associated with the ICP project should attend the April International HL7 meeting (San Antonio) to present the work undertaken with DSML as a method of handling workflow. This would facilitate the DSML Australian Guideline representation approach, to be developed in harmonisation with international efforts.

2. Recent guidelines developed for stroke (NZ), diabetes (Aust. NHMRC) and cardiovascular risk management (Australia and NZ) explore the use of GEM, DSML and ARDEN as possible standard guideline representation and implementation methods.
3. The above guidelines are then to be incorporated into demonstration systems in a small number of Australian Divisions of General Practice and New Zealand Independent Practitioner Associations. (A number of software vendors indicated willingness to participate in this process)

What are the expected outcomes?

- The major outcome will be the development of a standard guideline / knowledge representation system for use in Australia and New Zealand based on one of the leading international eKR systems.
- The field test would further develop local experience in incorporating guidelines into clinical applications in ways which allows reuse of eKR across multiple systems while maintaining the separation of knowledge and applications.

5. Standards for data exchange of drug-drug interaction data and the development of standard content for the most common and serious drug-drug interactions

The problem

Drug to drug interactions have proven to be one of the first forms of EDS implemented in both community and hospital systems. A range of issues have emerged during the first decade of their use including:

- variation in the interactions identified and not identified;
- over reporting of clinically insignificant interactions;
- lack of standards for grading of interaction significance
- variation in the way drug interactions are computed (drug-class, class-class and drug-drug);
- variation in the classification of drugs used for drug-drug and drug-condition interactions.

It has been suggested that clinical decision support software should operate with a degree of standard user interface and performance as would be expected from any conventional medical device.

What is being done now?

Clinical Pharmacologists have identified a relatively small number of drugs which are responsible for the common and serious incidents. Most of the current drug monograph report on drug interactions and some are planning to design their data structures to allow extraction of this information. A small number of drug interaction databases are incorporated into some commercial drug information resources and clinical software using proprietary drug interaction systems.

The Anatomical Therapeutic and Chemical (ATC) Classification is the Australian and international classification for drug utilisation analysis. It is not clear to what extent this classification is useful for drug decision support, e.g. interaction checking.

What is proposed?

1. Development of a standard format for recording drug-drug interactions;
2. Consideration of the most effective user interface for drug-drug interactions in hospital and community medication management systems.
3. Review of drug classification systems appropriate for supporting drug electronic decision support
4. Preparation of standard data on drug-drug interactions to cover the most 100 common and serious problems occurring in hospital and community practice. Any drug monograph or drug interaction database contributing to this effort would ensure that it met a minimum standard of quality of coverage.
5. Development of a governance and maintenance system.

Alternatives to be considered.

Concerns about variation in performance of existing drug knowledge resources could lead to accreditation of drug interaction resources by compliance checking with an externally provided "gold standard" list of interactions which should or should not be reported.

What are the expected outcomes?

- Identification of current best practice in recording and presenting drug-drug interactions;
- Reduction in inter-system variation in reporting common and serious interactions;
- Development of an industry based system of governance.

Peter MacIsaac
Ken Harvey
Vincent McCauley
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12 February 2004

Appendix I: Comment Sheet:

Please add your Name, Contact Details and email address and return to: Vincent McCauley (vincem@mccauleysoftware.com) by COB 27.Feb.04

Work Item	Priority (1 - not important to 10 - critical)	Your interest in participation (Not interested, Observer, Active Participant)
1.1 Standards for data interchange between electronic best-practice drug and therapeutic resources and clinical (prescribing) software 1.2 Standards for data interchange between clinical EHR and other EDS components		
2. Standards for drug and disease terminology: 2.1 Drug terminology 2.2 Disease terminology		
3. Standards for drug formulary (monograph) representation		
4. Standards for clinical guideline representation.		
5. Standards for data exchange of drug-drug interaction data and the development of standard content for the most common and serious drug-drug interactions		

General Comments:

Appendix II: Workshop details

Background papers made available prior to the workshop

- Bates. Ten Commandments for effective decision support.
- Del Fiol. HL7 Infobutton API proposal.
- DoHA. Central medicines repository update.
- Gelston. Towards standards for dynamic decision support.
- Harvey. Australian drug and therapeutic information resources.
- Harvey. Funding models for implementation and sustainability.
- Heard. Linking guidelines to electronic health records.
- HL7 Australia. ITOL Round 10 grant application.
- Johnson. Standard interface for clinical guidelines integration.
- Lewis. Format and integration of clinical guidelines.
- Sheehan. RCPA Manual implications.

Day 1 Presentations (Thursday, December 11, 2003)

Background to the workshop, including a brief overview of Australian & New Zealand government initiatives regarding clinical decision support.

- Ken Harvey (Workshop background)
- Irene Krauss (Australian DoHA)
- John Youngman (ACSQHC-NPS)
- Philip Gandar (New Zealand MoH / PHARMAC)

Demonstration of current electronic therapeutic resources (by information providers).

- Therapeutic Guidelines Ltd. (Jonathan Dartnell)
- Australian Medicines Handbook (Simone Rossi)
- AusDI (Dianne Bicopoulos)
- Adverse Drug Reaction Bulletins (TGA) (Patrick Purcell)
- MIMS (Margaret Prichard)
- New Zealand Guidelines Group / G-I-N (Catherine Marshall)

Gap analysis discussion: what is required to integrate these resources into clinical software?

- Led by Vincent McCauley, MSIA.

Technical demonstration of various approaches to best-practice clinical information representation and software integration.

- La Trobe University-Therapeutic Guidelines-NPS SPIRT project and NPS Radar project (Bryn Lewis)
- NPS / GPCG / University of Melbourne DS data modelling project (Iain Morrison)
- Hatrix Pty. Ltd. (Jon Glanville)
- Pen Computing (Brett Esler)

- Allette Systems (Christophe Lauret)
- Enigma Pty. Ltd. (Martin Entwistle)
- HL7 Clinical Document Architecture (Sandy Boyer)

Discussion of pros and cons of different approaches.

- Led by Vincent McCauley (MSIA)

Demonstration of open source initiatives

- OSCAR (David Chan)
- DrugRef.org (Horst Herb)

Day 2 Presentations (Friday December 12, 2003)

Brief summary of what was learnt from Day 1

- Branko Cesnik

Integrating information resources with the EHR and decision support

- Sam Heard (Open EHR).

Implications for diagnostic and preventative guidelines.

- Pathology (Catherine Sheehan)
- Radiology and Immunisation (Peter MacIsaac)

Response from selected clinical desktop software vendors (hospital & GP, including open source).

- Orion Systems (Mike Craig)
- Cerner Corporation (David Maggs)
- Visual HealthCare (Rob Robertson)
- IBA/Medical Spectrum (Cameron Jaffrey)
- HCN/MD (Andrew Magennis)

Small group work:

- Formulate a specific work plan of the tasks required to achieve an "open source" standards based integration including a budget (using the original HL7 Australia ITOL grant application as a starting point).
- Consider a business case and funding models for both implementation and long-term sustainability.

Plenary presentation of small group conclusions