The *open*EHR Foundation
- Some Lessons of Experience in Standardising the EHR

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Patient-Centred Approaches to R&D
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The openEHR Foundation
- Some Lessons of Experience in Standardising the EHR

• Context - five decades of innovation in health care and IT

• The openEHR Foundation - working towards EHR standards, experimentally

• Some related new open source and open data initiatives
Context - Five decades of innovation in health care and IT
Co-evolving health care and informatics focus over 5 decades

Pervasiveness of information systems

1960’s: Mainframe/IBM
1970’s: Mini/DEC
1980’s: Micro/Microsoft/Intel
1990’s: Internet/Google
2000’s: Grid/Smartphone/Cloud...
2010’s: Apple/Amazon/Facebook,..

Clinical Specialism
Healthcare Management

Quality & Safety
Bioinformatics, e-Health

Personalised Medicine, & Self-Management

Medical Practice
Primary Care & Public Health

Medical Physics
Health Systems, Data Standards, ontology

Healthcare Management
Health Care

Clinical Specialism

Self-Management, & Public Health

Grid/Smartphone/Cloud...
Apple/Amazon/Facebook,..
The current scene

• Biomedical science is being transformed
  • ‘bioinformatics is core discipline of biology’ – Royal Society 2005

• Health care and research are increasingly technology and information intensive
  • ‘information is the heart of medicine’ – BMA 1994

• Multiple legacy information systems and frameworks are in use
  • supporting and linking health care, research and industry

• Governments want a pervasive and standardised (open source) ICT infrastructure for health care

• Many initiatives, commercial and public domain, are creating relevant infrastructures
Records capture and organise knowledge and data to represent and communicate facts, opinions and events, in context and with implied meaning.

The purposes for which the record is captured, organised and communicated, reflect in both its structure and its meaning.

Common usage of these terms is loose and varied, although Latin and Greek roots help to preserve some clarity.

**Information** - has specialist meanings in physics and engineering.

‘Knowledge for the purpose of effective action’ is an interesting one here. Also:

**Data** -

‘Facts, given, from which others may be inferred’
A study at Berkeley estimated that after taking 300,000 y to generate 12 Exabytes ($10^{18}$) of information, the rate of accumulation today is around 5 Exabytes per annum.
In summary

- Massive change in pretty well all aspects of health care and IT
- Continuing fragmentation and re-integration of professional discipline and teamwork
- Knowledge/information/data overload coupled with loss of focus on patients and care
- Repeating failure to align national information policy with the state of the art of what is computable and implementable
- Health IT characterised by local successes, dependent on visionary innovators, but global failures

Oxfam – Think globally, act locally
Health IT spending has tended to do the opposite
Amazing pioneers

Arthur Guyton (with Ruth), President of the American Physiological Society, who transformed quantitative analysis of the circulatory system – forerunner of the Virtual Physiological Human

Octo Barnett, Professor of Medicine and Computer Science, who conceived and developed MUMPS at Harvard Medical School, underpinning the most successful period of innovation in hospital IT systems, worldwide

Successful pioneers combine attention to detail, leadership, courage and ability to work across boundaries. This is the pathway from local excellence to achieving global impact and change.
Ingram and Dickinson, 1971
Ingram, 1973
First encounter with electronic health records

University College Hospital, London - Neonatal Unit, 1974
Electronic record of neonatal artificial ventilation management

*Ingram and Allan, 1974 – Gas exchange and acid-base balance in neonates*
A successful research and development project

But none of this work exists or could run today, due to factors such as:

- obsolescence of the hardware and software technologies
- inability to sustain, develop and improve innovation to the level of viable product

First Digital Equipment Corporation PDP11/45, RSX11-D system in UK.
Providing 24x7 clinical service for several years
IT can help the good get better - and the bad get worse!

“To err is human, to really mess things up use a computer”!

Escher: Order and Chaos
The Best - Health IT in all NHS acute hospital trusts c 2000 - Clinical approval and value for money

30 years experience of tertiary cancer institute IT systems development and operation at Royal Marsden Hospital, London
Demonstrating the importance of sustained innovation
Health IT in all NHS acute hospital trusts c 2000 - % of information items obtained by paper only
Health IT in all NHS acute hospital trusts c 2000 - Total expenditure and obtaining information
Communication and integration of services, across patient communities tells a different story

Survey of 750 patients with chronic conditions in each of USA, UK, Canada, Australia, New Zealand

- UK: 2/3 of patients not engaged in discussion about own treatment and care; 40% did not have goals of treatment made clear; 20% received conflicting information from different professionals
- UK: 20% were victims of medical error in past 2 years, 9% with serious consequences
- UK: 13% (US 22%) sent for duplicate tests, 1/2 have to repeat health history for different professionals, medical records not reaching consultation on time

Health Affairs, May 2003
State of patient records leaves a lot to be desired


- 36% of case notes not immediately available
- Multiple records for patient in 75% of hospitals
- 40% of records poorly kept or not up-to-date
- 30% of history sheets inadequate
- 20% of prescriptions illegible
- 90% of discharge summaries contain no reference to information given to patients or relatives

US Institute of Medicine reported similar findings
Regulation - the letter of the law

Confidentiality Issues

Data Protection Act 1984
Access to Personal Files Act 1987
Access to Medical Records Act 1988
Access to Health Records Act 1990
Data Protection Directive 95/46/EC
Data Protection Act 1998 in force
Human Rights Act 1998 in force
NHS Plan
MRC Guidance: Responsibility in the use of Personal Medical Information for Research
MRC Guidance: Personal Information in Medical Research
GMC Guidance: Confidentiality
GMC Guidelines: Confidentiality: Protecting and Providing Information
BMA Guidance: confidentiality and disclosure of health information
DoH: Protection and use of Patient Information
Caldicott Committee
Meanwhile private investigators can acquire personal medical records within days
Loose talk!

A consultant writes:‘ Our approach towards CRM stems from the interaction of 4 key elements: Strategy, People, Technology and Process. These 4 elements combine in a "Cogwheel process" that drives the organisation.’

CRM=Customer Relationships Management

These gearwheels can’t turn
Try too hard and one will surely break the system

Loose talk, based on little or no evidence, purporting to integrate policy, requirements, and design & implementation of systems causes trouble – this is aspirational engineering
There’s a lot around and it has led to health care information systems that are dangerously opaque and entangled.

Clinical aspects

Technical aspects

This entanglement costs us all, hugely, in many ways.


Organisational aspects
Barriers to progress

- Data standards
- Global – local requirements
- Governance
- Sustainability
- Multi-level, competing initiatives, lacking common strategy
- Restrictive IP – much that needs to be openly shared, debated and learned from is hidden from view
An international, on-line community, pooling efforts so that clinicians, developers and patients, everywhere, can work towards and benefit from compatible and high quality electronic healthcare records, based on an open, freely sharable, tried and tested common approach

www.openEHR.org

The openEHR Foundation - Working towards EHR standards, experimentally
EU Framework Programme: Objectives for Health Care, 1989

• Unify European activities by providing the means for efficient communication of medical records and knowledge so that these may be understood and compatible, thereby permitting the integration of health information systems
  • Strengthen competitiveness ... , Improve the quality of life ...
• AIM Framework 4, The GEHR Project, 1991-1994; to research and prototype the foundations of electronic health record architecture
• FP5, Services for Citizens; FP6, Knowledge Centres and the GRID; FP7, Integrated projects, Networks of Excellence

Niels Rossing, DG of AIM
An overview of requirements

Ingram, EU GEHR Project, 1991
Taking forward the GEHR results

European standardisation

Local implementation, evaluation, refinement and dissemination

Ongoing research & development

GEHR architecture & object model

En 12265

CEN TC/251

En 13606

ISO En 13606

CIMI

openEHR

Australian GEHR & Ocean Informatics

GEHR

6WINIT

MEDICATE

E-Science CLEF

SynEx

Synapses

CIMI

EHR

SupA
LEGO® design analogy

- The components of the openEHR Reference Model are like LEGO bricks
- openEHR Archetypes are instructions/designs constraining the use of LEGO bricks to create meaningful structures
openEHR artefact ecosystem
The essence of openEHR architecture

Locally customised (templated) clinical information archetypes, managed by generic clinical record middleware.
openEHR exists to help untangle clinical systems, so they can work better.

- Clinical aspects
- Technical aspects
- Organisational aspects
Responding to the challenge of communicating EHRs

Current attempts to standardise the capture, representation and communication of clinical data rely upon:

- generic models for representing clinical data
  - e.g. openEHR RM, ISO/EN 13606-1, HL7 CDA Release 2
- agreed clinical data structure definitions
  - e.g. openEHR/13606 archetypes, templates, data sets
- clinical terminology systems
  - e.g. SNOMED-CT, LOINC

The challenge is how to combine these most effectively to achieve the faithful and consistent sharing of clinical meaning.
Structure and membership

• Not-for-profit organisation, based at University College London (UCL)
• Established by UCL and Ocean Informatics in 2002, to own the specifications and other collective intellectual property (IP). Based on 16 years of R&D
• Now a worldwide collaboration overseen by
  • Foundation Board – 5 strong, 4 clinical
  • Specifications Group – CEN, ISO, CIMI, IHTSDO
  • Software Group – JAVA, Ruby, .NET, Python
  • Clinical Editorial Group – 800 clinicians using CKM
  • Localisation Group – Japan, New Zealand, Brazil, Europe
Technical motivation of openEHR

The openEHR approach has been to develop a technical and semantic platform for health information systems which addresses four challenges:

- **Meaning preservation** - throughout systems and communications
- **Information sharing** – among systems and applications
- **Information aggregation** - leading to computability
- **Evolution** - of systems and information over time
Technical approach of openEHR

- A semantic framework within a services architecture
- Development by engineering design team with open review and formal change management
- All specifications are implemented and tested before release
- Specifications all mutually consistent
- *Living* specifications – a programme for maintenance
Technical deliverables

- A powerful reference information model
- *open*EHR archetypes: software-independent clinician-authored models of content
- *open*EHR templates: a formal basis for localised re-use of content models
- Practical and bounded use of terminologies
- Control over data entry quality
- Portable query language for health records
- A knowledge-enabled service interface to the EHR
Banks of curated, clinician-defined archetypes
Archetype structure

Blood gas assessment: Observation

Data: TREE

Concept | Description | Type | Cardinality | Values
---|---|---|---|---
Q | PaO2 | The oxygen pressure in the arterial blood | Quantity | optional 0.1 | Property = PRESSURE Units: kPa (\(\geq 0\))
Q | PaCO2 | The carbon dioxide pressure in the arterial blood | Quantity | optional 0.1 | Property = PRESSURE Units: kPa (\(\geq 0\))
Q | pH | The negative logarithm of the Hydrogen ion concentration in blood | Quantity | optional 0.1 | Property = CONCENTRATION Units: [pH], (0.14)
Q | Base excess | The relative excess of alkaline | Quantity | optional 0.1 | Property = CONCENTRATION Units: mmol/L, (-30..30)
Q | Alveolar-arterial pO2 difference | The difference between the pressure of oxygen in the alveolar and the artery | Quantity | optional 0.1 | Property = PRESSURE Units: kPa (0..1000)
Q | SaO2 | The saturation of haem binding with oxygen | Quantity | optional 0.1 | Property = PROPORTION Units: \(\{0, 1\}\)
T | Site | The site of sampling | Coded text | optional 0.1 | Terminology
Q | CaO2 | The oxygen content of arterial blood | Quantity | optional 0.1 | Property = CONCENTRATION Units: (VOLUME/VOLUME) (\(\geq 0\))
Multi-lingual capability
Architecture specifications

5 EHR Package

5.1 Overview

The ehr package is illustrated in FIGURE 11. The EHR class is the root access point of the health record for a subject of care, and is a change-controlled repository of the kind described in the openEHR Common Information Model. Accordingly, it contains the identifiers of various versioned objects, as well as the list of Contributions made to it. The versioned objects consist of:

- an EHR Status object, in the form of a VERSIONED_EHR_STATUS instance;
- a directory, in the form of a VERSIONED_FOLDER instance (defined in the Common IM);
- Compositions in terms of VERSIONED_COMPOSITIONs.

![Diagram of EHR Package](image-url)
UML representation
Change management
Example: Change request

A #198: Change DV_Date/Time/Duration to have value as attribute
- Up to the Change Requests Instance

View (Anonymous)

**issuesdate**
- **Submitter:** Sam Heard
- **Date Raised:** 2006-02-14 00:00:00
- **Classification:** Enhancement
- **Category:** Design
- **Importance:** Medium
- **Analyst:** Sam Heard, Thomas Beale, Heath Frankel
- **Affected Components:** openEHR.rm.datatypes
- **Approved By:** Architecture Review Board
- **Implementor:** Thomas Beale
- **Target Release:** Release 1.0.1
- **Date Closed:** 2006-03-20 00:00:00
- **Status:** Completed
- **Assigned To:**

**process**
- **Deadline:** 2006-02-28 14:46
- **Hours estimated:** 0
- **Hours needed:** 0
- **Percent done:** 0

**contact**
- **Name:** Sam Heard
- **E-Mail:** sam.heard@oceaninformatics.biz

**Problem Description:**
The current date/time classes (data_types.quantity.date_time package) are defined with a number of data attributes, e.g. DATE is defined to have year, month and day as separate INTEGER attributes. This is fine for in-memory representation and processing, but is fairly inconvenient for persistence, particularly in XML, since it would prevent the use of the XML standard ISO8601 based date/time types.

A single attribute of type string in ISO 8601 standard syntax would be more efficient and would have no effect on the semantics of the classes.

ISO 8601 provides syntax for all the date/time types defined in openEHR, including the partial ones.

**Change Description:**

Changes made:
- the classes DV_DATE, DV_TIME, DV_DATE_TIME and DURATION and their PARTIAL XX
Features and benefits

• Enables clinical control of semantic interoperability through archetypes
• Allows evolution of representation of clinical concepts over time
• Dissociates electronic health care records from dependency on particular clinical software applications or particular health care information infrastructures
• ‘Future-proofs’ health records for lifelong care
• Has been shown to provide a more sustainable code base for clinical systems, up to 8x more time-efficient to maintain than traditional database methods
State of play, today

• Comprehensive EHR specification
  • Information model, Archetype model, Communication specification, Service specification

• Growing
  • base of implementation experience and learning, in real-life settings
  • set of tools - .NET, JAVA, Ruby, Python
  • community of developers and users, organised within national/regional associations

• Linkage with clinical research, clinical trials standards and education
Outcomes

*open*EHR is now found...

- in CEN/ISO EN13606-1 and -2
- in around 15 commercial products
- in the CIMI content standardisation initiative
- in the e-health programmes of the UK, Denmark, Sweden, Australia and Brazil, with another 10 or so countries moving towards it
- In national chapters in Japan, New Zealand and Brazil
- in dozens of universities
- in a growing number of enterprise clinical and secondary applications
Need to extend openEHR’s governance, in order to:

• Broaden input to openEHR policy and strategy, through strategic partnership and collaboration
• Strengthen its mission, while enabling it to sustain its focus on clinical implementation
• Widen clinical and health informatics community, government and industry acceptability of what it offers
• Attract financial support
• Promote higher and more active profile and role in e-health programmes
Cancer genomics clinical trials, ophthalmology, machine learning

Some related new open source and open data initiatives
Towards personalized medicine

Clinical champion – Norbert Graf, paediatric oncologist

- **Data integration**
  - Clinical data, imaging data, molecular data, etc.
- **Legal and ethical issues**
- **System biology models**
- **Tools and models**
  - Clinically driven, re-usable, modular, interoperable
  - Evaluated and user friendly
  - Validated and standardized for reuse
  - Certified
- **Logistics**
  - IT infrastructure handling vast amounts of data
  - Access to high performance computing
  - Availability of data in due time
- **Sustainability**
Why?

• The conduct of clinical trials in Europe is characterized by
  • Redundant paperwork
  • Liability tangle
  • Complicated legal and ethical regulations causing an unending bureaucracy
  • Lack of easy to use open-source data management systems
• Translational Research needs an infrastructure and more funding
  • The gap between clinical research and basic research is increasing
• p-medicine solving many of the above mentioned items needs:
  • Maintenance and
  • Sustainability
• More patients have to be enrolled in clinico-genomic trials
• Patients have to play a more active role in clinical trials
• Not all patients do receive the best available treatment
  • Wrong treatment harms patients and increases health costs unnecessarily
• Information overload covers relevant and reliable information
• Curricula of Medical Schools have to adapt to the need of IT possibilities to achieve the goal of a personalized and better medicine in future
Collaborations

• SIOP, ENCCA, GPOH, BBMRI, ECRIN, EURECA, ...
• US Food and Drug Administration (FDA)
  • Biovista’s Clinical Outcome Search Space™
    • Predictions of adverse events
      • Verification with foreign academic community
      • Usage in the design of future clinical trials
• European Medicines Agency (EMA)
  • Biomarker Qualification procedure
    • Guidance document for qualification of Biomarker
    • Advice and input from
      • Innovation Task Force
      • Pharmacogenomics Working Group
General aspects

• Three cancer domains
  • Acute lymphoblastic leukemia
  • Breast cancer
  • Nephroblastoma

• Scenario based
  • 52 use cases are defined

• Legal and ethical framework
  • Informed consent
  • Anonymization/pseudonymization
  • Contracts

• Open source, retro- and prospective data
  • Clinical, DICOM, molecular, ...
Sustainability

- Business goals
  - Discover knowledge
  - Explore hypothesis
  - Personalize treatment
  - Empower patients
  - Share data
  - Share knowledge
Sustainability
OpenEyes Collaboration for Ophthalmology Records

Clinical champion – Bill Aylward, ophthalamic surgeon, Moorfields Eye Hospital, UCL Partners
What will OpenEyes do?

1) Get data into electronic form

2) Integration
Record successfully saved

Date: 8th November 2010  User: John Saunders  Event: Visual field

Right Eye:
Pattern: 10-2 Strategy: SITA Standard

Left Eye:
Pattern: 10-2 Strategy: SITA Standard
# Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feb 2010</td>
<td>Project initiated</td>
</tr>
<tr>
<td>Nov 2010</td>
<td>Pilot (Paediatric A&amp;E)</td>
</tr>
<tr>
<td>Jan 2012</td>
<td>V0.9 (Booking, WL management)</td>
</tr>
<tr>
<td>Jun 2012</td>
<td>V1.0 (Cataract/glaucoma)</td>
</tr>
<tr>
<td>Dec 2013</td>
<td>All subspecialties covered</td>
</tr>
</tbody>
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Clinical data management for machine learning: Opereffa framework

- Data mining tools and frameworks are usable mostly for statisticians, computer scientists
- They are expensive. More expensive if you want to scale
- Open-source frameworks help with the cost, but they are still tools for the few, and don’t mean much to clinicians
- openEHR has been helping clinicians take control, to deliver efficient clinical information systems
- Can it also help them improve CDS/mathematical modelling/machine learning?
- Opereffa attempts to find out
Opereffa Architecture

Clinical model building

Clinical model based query language and its extensions

Data storage and AQL based data access, with relational databases, are already being published open-source

Archetype Query Language

Clinical information systems

Persistence Transformations Layer

Hadoop
PostgreSQL
MongoDB
...

Use case optimized persisted data

Future work:
Machine learning
Data mining
Decision Support
Opereffa framework: plans for future

- Proven, open source persistence stacks aligned along the scale axis: PostgreSQL, MongoDB, Hadoop
- High performance open source parallel processing frameworks for scaling up: Akka, Hadoop
- Tooling to eliminate complicated technology & infrastructure management process: Eclipse framework
- Number 1 domain to learn from: finance.
- Bring all these technologies together with a strongly model driven approach, for outcomes that are portable to other domains.
Case for greater use of open-source frameworks

- Promote effective and efficient developer communities
  - pioneers traditionally have had to build whole local infrastructures
  - many wheels still being reinvented, unnecessarily
- Pool costs of development and maintenance of essential infrastructure
- Enable research interface – discipline grows through sharing, review and testing of methods
- Improve procurement – ability to see what’s under the bonnet
- Support integration – combat fragmentation

But there must be a business case – government and industry support is needed for the transition to an open-source community
The growing worldwide community of openEHR would welcome your participation in its future development

THANK YOU