Relevant Standards Development Organisations

- **Health Level 7**
  - Now HL7 International Affiliate Organisations in 15 European Countries
  - More European involvement in HL7 than in CEN TC251 and ISO TC215 (and increasing in HL7)

- **CEN TC251**
  - Nominally represents all EU + some EFTA countries
  - Meetings approx. 50-60 delegates

- **ISO TC215**
  - Few European countries involved (unless held in Europe) 100-200 delegates
Relevant Standards Development Organisations

But UK is well represented and BCS HIF is active in ALL

What do the three SDO’s contribute?
Strengths – HL7

- Very large membership (approx 600 delegates to each meeting)
- Major involvement by industry
- Very high work rate and output
- High degree of product integration
- Highly successful in message development
- Useful and usable tool development
- Very accessible as an organisation
Weaknesses – HL7

• No consensus on how to handle and develop standards for large vocabularies
• EHR standardisation
• Device communication
• International affiliates may develop their own ‘HL7-like’ solutions (particularly relevant to UK)

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• Standardisation process driven by major players (including NHS): therefore difficult for smaller countries to get any significant involvement in standardisation
Strengths – CEN TC251

- Focus on formalisation of concepts
  - Message Development Framework (adopted and extended by HL7)
  - EHR Architectures (as used in GP2GP, HL7 Clinical Statement, etc.)
  - HISA – Service Architectures
  - Categorial Structures for categorisation of medicinal artefacts (e.g. anatomical, medical devices, etc.)
  - Continuity of Care communication standard
  - Device Communication standards (EN11073) adopted by ISO and IEEE

- Growing link with ISO TC215
Weaknesses – CEN TC251

- Tendency for creation of ‘meta-standards’, i.e. standards for standards makers rather than standards for direct implementation
- Many service/consultant/academic – little commercial involvement
- Poor communication of achievements
- Slow development process
Strengths – ISO TC215

- World-wide
- Strong involvement from non-EU and non-US nations
- ISO standards have highest (legal) priority in many countries
- Seen as the ‘best’ resource for harmonisation of outputs of the various standards development organisations
Weaknesses – ISO TC215

- Poor levels of activity
- Multi-country involvement
- Slow development process
- Costly participation
- Volunteer, unfunded effort
- ‘Invisible’, partly because it is ‘younger’
What happens and where?

- HL7 is the major focus for messaging and document communication standardisation.
- CEN TC251 is mainly focussed on infrastructure standards – EHR and information components.
- ISO TC215 is the forum for ‘universal’ acceptance and harmonisation.
- HL7, CEN & ISO all produce standards for the standards makers.
How they fit together

HL7 submits standards for universal adoption

ISO
How they fit together

HL7
- Message Development Framework
- Reference Information Model
- HL7 Version 2.5

ISO

Submits standards for universal adoption
How they fit together

HL7: Submits standards for universal adoption

ISO: Submits standards for universal adoption

CEN
How they fit together

HL7: Submits standards for universal adoption

ISO: Submits standards for universal adoption
- 11073 Device Communication
- 13606 ehrCOM

CEN
How they fit together

**HL7**
- Submits standards for universal adoption

**CEN**
- MAY Submits standards for universal adoption
  - Drug Administration Syntax?
  - Clinical Statement?

**ISO**
- Submits standards for universal adoption
National Bodies

- National (All inclusive)
  - BSI IST-35

- NHS (Specific)
  - NHS ISB

- As of December 2005, Jeremy Thorpe of CfH became the chair of IST-35
A ‘trivial’ Case Study…

- What information is more fundamental than clinical terms for clinical systems?
- How about ‘Date & Time’?
- Here we simplify by considering just ‘Date’
  - Any?  ISO 8601/ EN28601 : YYYY-MM-DD
  - ‘simple’ single date, e.g. Tuesday, 17-Jan/2006
  - Date ranges
  - Fuzzy or incomplete dates
  - etc…
- How many different types of ‘Date’ operation?
  - Display, Entry, Store, Communicate, Calculate…
  - Different representations?
Date: Different representations

Date Display Requirements:

Who for?
Natural?
Unambiguous?
Complete?
…?
Date Entry

Requirements:

Who by?
How?
Complete?
…?
Date: Different representations

Date Storage

Requirements:

Who cares?
Proprietary?
…?
Date Communication

Requirements:

Who cares? Mappings? …?
‘Date’ in Data Type Standards…

ISO 11404

ISO 2190

(1) (2) (3)

ISO 11404
(Prog.L(g) & Software Interfaces)
Standards Policy/ Challenge

- Foundational …unchanging but have to cope with change
- Ruthless standardisation excellent, but…
  - Consensus --- Competition --- Compliance
- Process:
  - Slow or Fast (agreements… integrity)
- Stages:
  - Development & Maintenance
- Pervasive:
  - Global markets… global requirements… isolation
- Control:
  - To influence or be influenced

Stakeholder involvement is neither cheap nor optional…
In Summary

- Strengths & Weaknesses of HL7, ISO, & CEN
- How the three SDOs relate to NHS & national SDO activity
- Case study: A subset of ‘date’ operations, showing responsibilities and dependencies in scoping a ‘simple’ standard
- Previous and current efforts to standardise ‘date’ :
  - ISO 8601, ISO 11404, <ISO 2190>, & CfH
- Ruthless Standardisation and tensions
- ‘In it to Win it’ and an opportunity to ‘make friends and influence’!

Thank you for listening