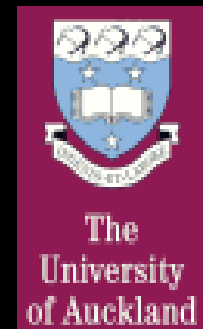


HISO DSS Forum

Quality & Safety of CDSS- the use of computers to advise on patient care

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Overview- presentation

- Ethical considerations
- Options for establishing quality methodologies

- All technologies like any other clinical intervention will have negative as well as positive effects
- Possible that someone may be harmed or even die from faulty CDSS
- If something goes wrong due to faulty CDSS advice, who is responsible?
 - The software developers?
 - The providers of the knowledge content?
 - Or the clinician who makes the ultimate decision?
- How can we minimise risk of harm to patients?

Ethical considerations

" The use of a DSS in the process of medical diagnosis and treatment requires that the DSS be brought into the system of trust that is integral in the medical process". (Green, 2004)

Trust to Do Good, Do no Harm

- Clinician accepts duty of care for a patient
- Patient trust clinician to act in best interest & have adequate knowledge and competency
- Competency/knowledge extends to tools used in care

Trust includes the tools/equipment

- Clinicians trust tools will perform repeatedly, reliably, predictably, safely.
- Clinicians place their trust in the designers and maintainers of these systems that quality & safety methods in place
- Patients rely on clinician's faith that tools are trustworthy

CDSS Duty of Care

- To employ quality and safety methods in order to minimise the risk of harm to patients
- No different from any other electronic, technical, or engineering systems whose daily business has implications for public safety

Options for establishing methodologies appropriate for CDSs

- Field is relatively immature
- generic approaches to quality & safety
- software engineering quality practices and
- internationally accepted standards (*ISO 9000* and *IEC 61508*)

Six dimensions of quality for healthcare (IOM 2001)

- Safe*
- Timely
- Effective*
- Efficient
- Equitable
- Patient-centred

Quality of CDSS- Efficacy & Effectiveness

- Does it work?
- Does it work in routine clinical practice?
- Standard method evaluation-rigorous RCT- harms and benefits
- For CDSS depends on
 - quality of software design,
 - quality of knowledge content,
 - interaction between clinicians/software/knowledge content
 - quality of implementation, ease of fit into clinical work processes and systems of healthcare delivery.

Quality of CDSS- Four primary safety approaches (Fox 2002)

- ✍️ Use rigorous software engineering to ensure reliability of platform
- ✍️ Systematic quality control medical content & evidence base
- ✓✍️ Explicit hazard management
- ✓✍️ Comprehensive documentation

SW additional primary approaches

- Use rigorous software engineering to ensure reliability of platform
- Systematic quality control medical content & evidence base
- Build systematic quality control into the interaction between clinicians-knowledge content-platform
- Explicit hazard management
- Comprehensive documentation, safety culture, clinical guardianship

1. Rigorous software engineering methods

- Safety critical applications-
ALARP principle
- level of investment to maximise
safety \approx risk involved
- Development lifecycle
 - design, development, implementation, maintenance
- IEC 61508

IEC 61508 (International Electrotechnical Commission)

- Generic standard applying to electrical or electronic or programmable electronic technologies
- Concerned with "functional safety" of any system with safety implications
- Functional safety= system or equipment operating correctly in response to its inputs
- Examples of such systems:
 - Railway signalling system
 - Fly by wire aircraft flight control surfaces
 - Information-based decision support tool where erroneous results affect safety
- Functional safety determined by initial hazard analysis and ensuring adequate protection against each significant hazard

2. Systematic quality control of knowledge content and evidence base

- Well-defined scope- condition, exclusions, users, location, requirements, evidence-base
- Quality processes that verify consistency, completeness, congruence with evidence-base
 - Examples decision tables, documentation/explanation of each recommendation plus source of evidence, logic verification eg, automated analyses internal inconsistencies, use case testing by sub-topic and overall patient fit
 - peer review, vignette testing, provision for end-users to report queries and problems, documentation of all of this

3. Risk assessment- hazard management

- Identify potential hazards
- engineer to prevent errors from occurring,
- mitigate any errors when they arise
- manage unforeseen errors that occur to avoid them causing harm in the future
- Communication and documentation

Example Hazard Analysis: CVD Risk Assessment- simple code (Anderson et al. Am Heart Journal 1991)

- I $\beta_0 = 18.8144$
- J $\beta_1 = -1.2146*(A)$
- K $\beta_2 = -1.8443*LN(B)$
- L $\beta_3 = \text{Blank}$
- M $\beta_4 = 0.3668*L$
- N $(B)*(A)N\beta_5 = \text{Blank}$
- O $\beta_6 = -1.4032*LN(C)$
- P $\beta_7 = -0.3899*(D)$
- Q $\beta_8 = -0.539*LN((E)/(F))$
- R $\beta_9 = -0.3036*(G)$
- S $\beta_{10} = -0.1697*(G)*(A)$
- T $\beta_{11} = -0.3362*(H)$
- U $\beta_{12} = \text{Blank}$
- V $q_1 = 0.6536$
- W $q_2 = -0.2402$
- X $m = \text{SUM}((I):(T))$
- Y $g = \text{EXP}((V)+((W)*(X)))$
- Z Time (years) (Set at 5 years)

AA $U = (LN(Z)-(X))/(Y)$ AB Probability of CVD = $1-\text{EXP}(-\text{EXP}(AA))$ AC

Relative risk reduction (Set at 25% for one intervention, 45% for 2 interventions and 55% for 3 interventions)

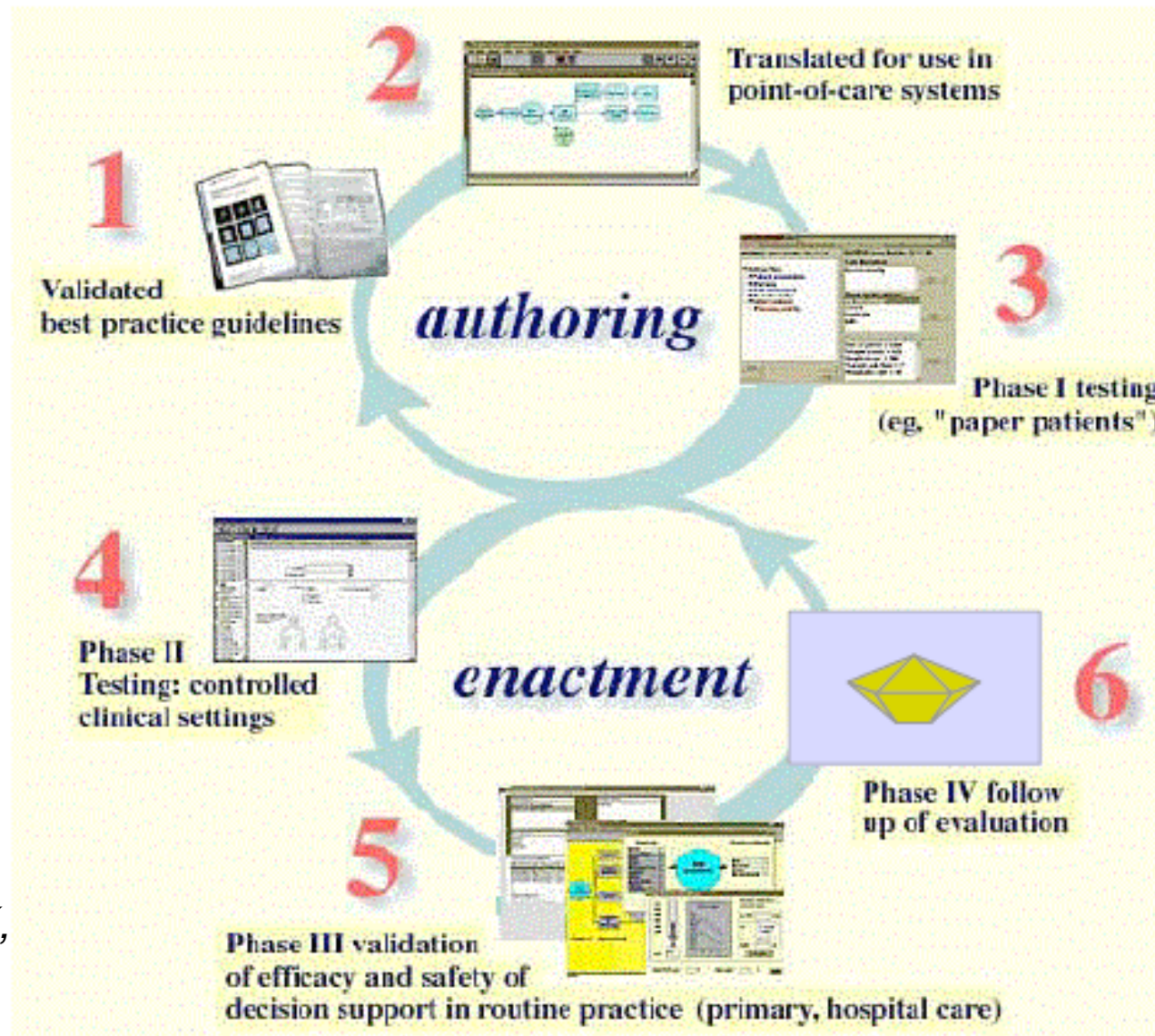
AD Absolute risk reduction = $(AB)*(AC)$

AE NNT = $1/(AD)$

Hazard simulation-Where can it go wrong?

- User confusion eg ambiguous or changed definition of input data (GLD)
- Template interface allows/facilitates data entry error eg SBP14080, ineligible pts, non-prioritisation ethnicity, no cross checks fields
- Risk calculation incorrect
- Adjustment and classification incorrect eg interpretation of guideline
- Display of risk/risk chart incorrect includes NNT, number events prevented
- Integration with other software incorrect
 - Eg self-population from PMS, storage input/decision support into PMS, transfer of data elsewhere (Get Checked)

PROforma quality model



Fox J, 2001
Advanced
Computation
Laboratory,
Cancer
Research UK,
London

4. Other

■ Safety culture

- Safety needs to be part of the thinking of all individuals developing, supporting, marketing, implementing CDSS

■ Clinical guardianship

- Clear understanding of clinical setting- practical needs, constraints, problems
- Verification that has captured current state clinical opinion, and evidence formalised via recommendations
- Cycle of maintenance and resources for update

■ Comprehensive documentation