

A duty of care in CDSSs: from quality and safety to ethics and the management of liability

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“Information technology and computerised decision aids have an important role to play in supporting the quality of care and safety of patients.” Bates DW, Gawande AA. *Improving safety with information technology. N Engl J Med* 2003; 348 (25): 2526-34.

This commentary draws on “Issues in the use of clinical decision support systems: efficacy and safety, ethics and liability” and material on the OpenClinical web site

www.openclinical.org

Decision support systems: A duty of care

Software quality lore

1. Software should be designed, implemented, tested and documented using established quality methods (e.g. the ISO 9000 standard).
2. An explicit quality plan should be developed, covering all phases of implementation, testing, maintenance of the system.
3. Testing should be carried out against this plan, with all tests and their results recorded for subsequent review.
4. In cases of significant levels of clinical risk, formal design and verification of critical components of the system may be required.

A new problem? Medical content

1. Peer review. This may include *static reading* of content and *operational review* (practical testing against standard clinical cases).
2. User review. All content should also be visible to the professionals who use the system in static form (e.g. as intelligible text) and in context (e.g. as patient-specific explanations).
3. Where risks are high, automated design and checking of the knowledge content and logic will increasingly have a role.

PROforma:
A level 3 technology for decision support and careflow management

Decision

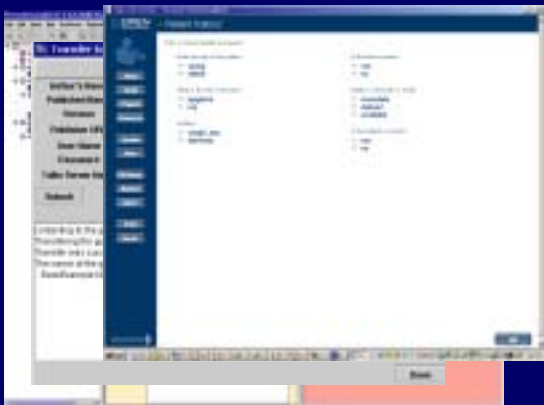
```

decision :: 'Diagnosis_decision';
caption :: "Diagnosis decision";
candidate :: "peptic ulcer";
argument :: for, age < 35 OR weight = normal attributes
argument_name :: 'age < 35 OR weight = normal';
end attributes;
recommendation :: netsupport(decision_11, 'peptic ulcer') >= 1;
candidate :: 'cancer';
argument :: for, biopsy = abnormal attributes
argument_name :: 'biopsy = abnormal';
end attributes;
argument :: for, age >= 50 AND Weight = down attributes
argument_name :: 'age >= 50 AND Weight = down';
caption :: "Elderly patient has lost weight";
end attributes;
recommendation :: netsupport(decision_11, 'cancer') >= 1;
end decision.
    
```

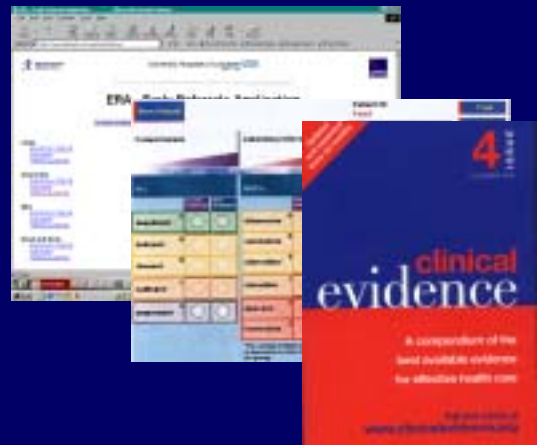
Plan

```

plan :: 'Sydney_example';
caption :: "Example for presentation in Sydney";
abort :: patient_discharged = yes;
terminate :: patient_recovered = yes;
component :: 'Diagnosis_decision';
schedule_constraint :: completed('Patient_history');
number_of_cycles :: 1;
component :: 'Patient_history';
number_of_cycles :: 1;
component :: 'Pathway_1';
schedule_constraint :: completed('Diagnosis_decision');
number_of_cycles :: 1;
component :: 'Pathway_2';
schedule_constraint :: completed('Diagnosis_decision');
number_of_cycles :: 1;
end plan.
    
```



The Syntax and Semantics of the PROforma guideline modelling language



Tallis publishing lifecycle



Patient safety

1. Standard lore: lessons from software safety engineering (IEC 61508)
2. HAZOP) is an important established technique. Each hazard represents an obligation on developers to make appropriate design changes.
3. Testing must demonstrate all safety obligations have been discharged.
4. A "safety case" should be prepared to document identified hazards, management options, design choices and associated safety arguments
5. Applications may include active risk and hazard management during operation, such as automatic situation monitoring and appropriate human or software interventions

Ethics

- The ethical implications of decision support and related developments are not (to my knowledge) being widely discussed.

Legal liability

- Questions about legal liability in the use of decision support software are long-standing
- If a decision support system gives bad advice then who is responsible?
 - the software designers?
 - the providers of the medical knowledge that it uses?
 - the healthcare professionals who are responsible for the final clinical decision?
- No-one knows; so far as we can establish there is no case law to establish the relevant precedents.

Disclaimers?

- “The Software is provided “AS IS”, without any warranty as to quality, fitness for any purpose, completeness, accuracy or freedom from errors”
- “In providing this expert system, [the company] does not make any warranty, or assume any legal liability or responsibility for its accuracy, completeness, or usefulness, nor does it represent that its use would not infringe upon private rights”.

Conclusions

- CDSSs have the clear potential to lead to patient harm as well as benefit.
- Suppliers of DS technologies (and standards organisations), and the healthcare providers who adopt them, owe a duty of care to pursue the highest standards of quality and safety in their design and deployment.

More ...

- Nancy Leveson classic book *Safeware*
- Felix Redmill et al *Software HAZOP*, Wiley 1999
- Fox and Das, *Safe and Sound: Artificial Intelligence in Hazardous Applications*, MIT Press 2000.
- www.openclinical.org
 - A service to the community: resources on knowledge management, decision support, workflow etc.
 - 2-3000 visitors a month
 - Technology reviews; projects and products; application archive; demonstrations; white papers on quality and safety