Assuring safety and quality in clinical practice guidelines

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http://www.schin.ncl.ac.uk/        http://www.prodigy.nhs.uk/
Format

Minimal lecturing +
Maximal "workshopping"

Information sharing goals:
Process
Content
Safety Assurance for CDSS

Why?

Don’t need to be very clever to do S&QA
But, it is not very clever not to do S&QA

How?

FMEA — Fault Modes and Effects Analysis

What components?
For each component, What can go wrong?
For each “error”, Why did it happen?
For each cause, How can it be prevented?
Why assure safety of CDSS?

There *are* hazards
Some are significant
Many are hard to detect and monitor
Potential hazard

A similar, but wrong item, can be selected with the user being unaware of the error.
A potentially hazardous recommendation

Patient presents to A&E with SVT
CDSS recommends: “Rx verapamil”
But patient is on a beta-blocker and has a fatal reaction
A potentially hazardous recommendation

Order KCL IV
Potassium chloride given intravenously is fatal if too much is given too quickly

Why assure safety of CDSS?

There are hazards
  Some are significant
  Many are hard to detect and monitor

Credibility

Legal obligations

Safety assurance is effective (we assume)
FMEA
Fault Modes and Effects Analysis

**Identify:**
- components
- functions
- fault modes
- effects (local and system)
- methods of protection

**Prioritise preventive actions according to cost-effectiveness:**
- Likelihood
- Severity of effect (cost, morbidity, non-economic adverse outcomes)
- Cost of prevention
N.B. There is only one Term server at run-time (executable).
Similarly, there is only one drug info server at run-time (executable).
Both instances have access to the respective knowledge bases, even though not depicted on the 'clones' in this diagram.
What components?

Design ontologies → Search for evidence → Appraise and synthesize evidence

Publish guidelines ← Populate knowledge bases ← Write background guidance document

Install & update guidelines ← Use decision support system ← Ongoing monitoring for hazards
What can go wrong?

Guideline content

Search strategy does not find all relevant evidence
New significant evidence since last search
Inadequate appraisal and synthesis of evidence
Wording, format or structure that facilitates misunderstanding
What can go wrong?

Guideline computerisation
(population of knowledge-bases)

Misunderstanding, conceptual error

Typographical error

Design of knowledge-bases makes building/maintenance error-prone
What can go wrong?

Guideline publication

Delay in publication/release
  by CDSS developer, CDSS distributor

Delay in installing update

Errors in version control
  by CDSS developer, CDSS distributor, user
What can go wrong?

Clinical Decision Support System use

CDSS used incorrectly
- Insufficient data entered by users
- “Wrong” data entered by users
- Potentially beneficial recommendation ignored or over-ridden
- Potentially hazardous recommendation not recognised, or not ignored

CDSS not used
- Insufficient time available to user
- Inadequate skills to use system effectively
- Awkward “triggering” mechanism
- Awkward user interface
- Resistance to change
- CDSS not available (organisational/software/hardware problem)
What can go wrong?

Monitoring for hazardous incidents

- Failure to implement Q&SA (including testing, monitoring, audit)
- Feedback not encouraged
- Feedback not acted on
Preventive actions

Hazards in guideline content

• Training
  - Evidence-based medicine
  - Technical writing

• Policies and procedures
  - EBM methodologies
  - Horizon scanning
  - Scheduled updates
  - Internal review
  - External review: formal, informal (pre-, post-publication)
Preventive actions

Hazards in guideline computerisation

• Training
  – Technical (use of software tools)
  – Design and usability

• Policies and procedures
  – Style and documentation (traceability) guides
  – Reviews of design and final product
  – Use of specialists for specialist tasks
  – Version control
Preventive actions

Hazards in guideline publication

• Training
  – In version control for developers, distributors, users

• Policies and procedures
  – Version control systems and procedures
Preventive actions

Hazards from CDSS use (or non-use)

• Training
  – Specific: Use of PRODIGY CDSS
  – General: benefits and limitations of CDSS

• Policies and procedures
  – User interface (“prescribing points”, user choice, …)
  – Usability studies
  – Reliability standards in procurement contracts
  – Plausibility, consistency checking
  – User must document reason for variation
  – Alerts / reminders to supplement full guidelines
  – …
Preventive actions

Hazards from on-going monitoring

• Training
  – Users: of need for and methods of monitoring and reporting incidents
  – Staff: Of need for and methods of responding to incident reports

• Policies and procedures
  – Re-accreditation and re-licensing of CDSS
  – Feedback software, systems, and procedures
  – Post-implementation surveillance
Safety assurance

Experience of Theory In PRODIGY

• Release 1: comprehensive
• Release 2: in development
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