Assuring safety and quality in clinical practice guidelines

Michael Power, Sharon Smart, Bob Sugden

Sowerby Centre for Health Informatics

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

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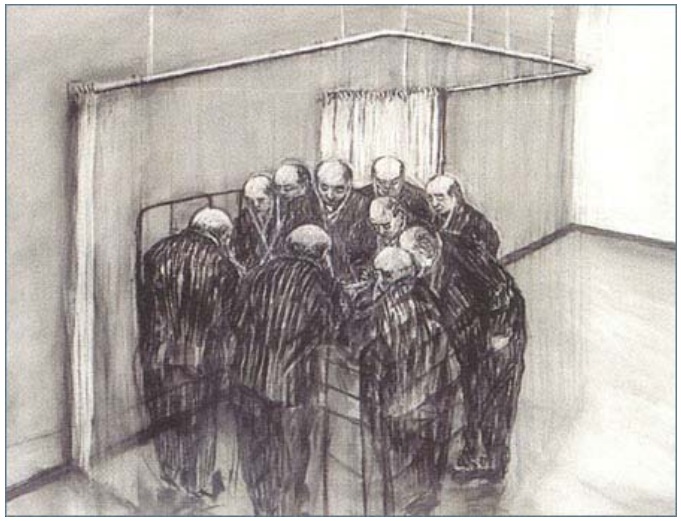
Format

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*?

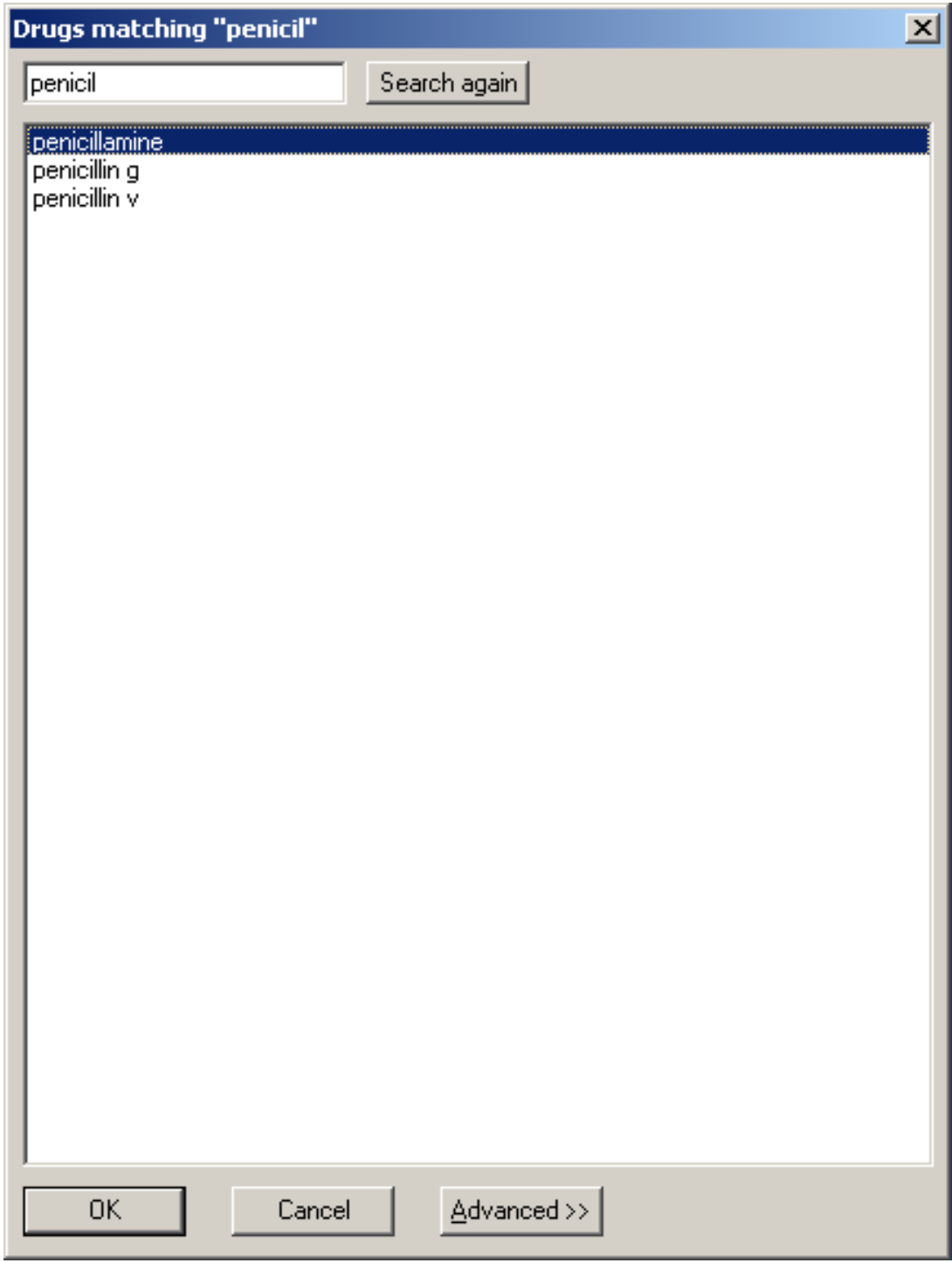
For each "error", *Why did it happen*?

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

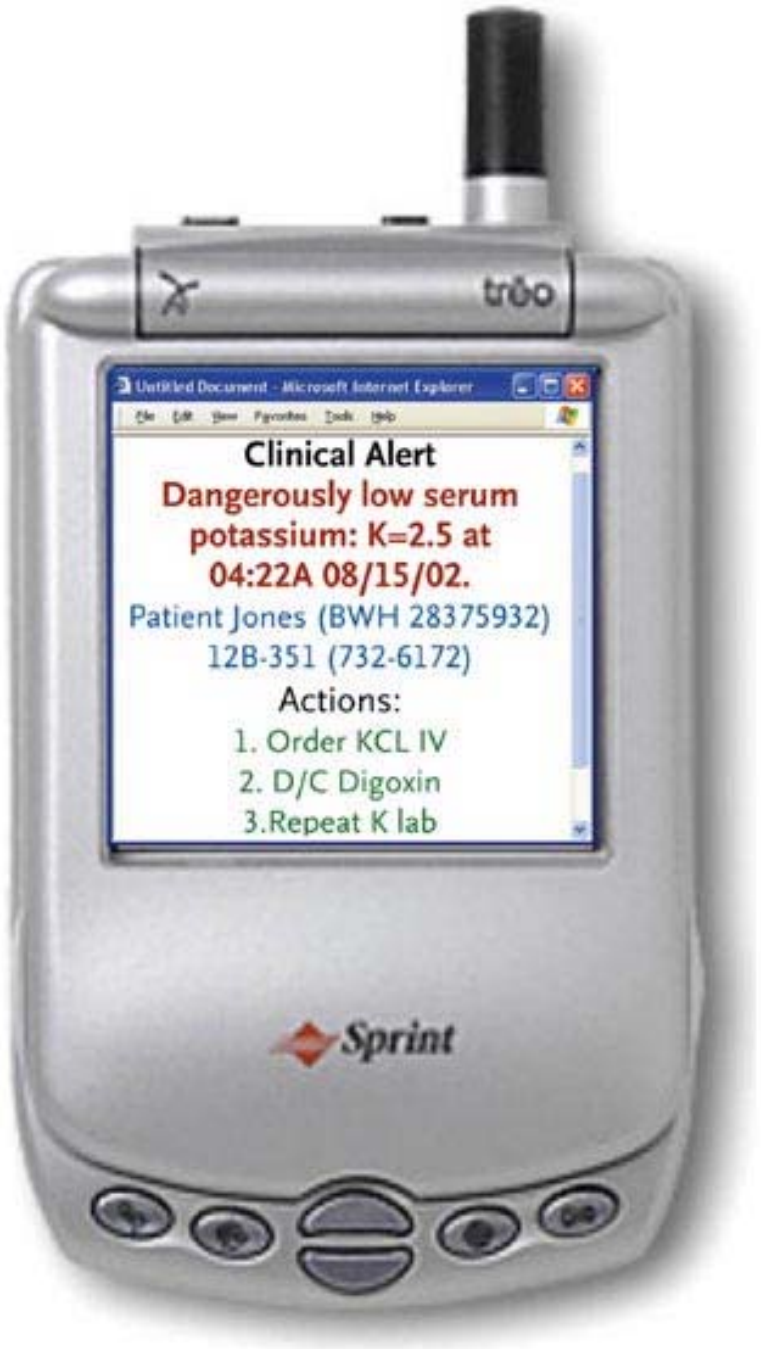
A similar, but wrong item, can be selected with the user being unaware of the error

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

Bates DW, Gawande AA. Improving safety with information technology. N Engl J Med 2003;348:2526-34

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

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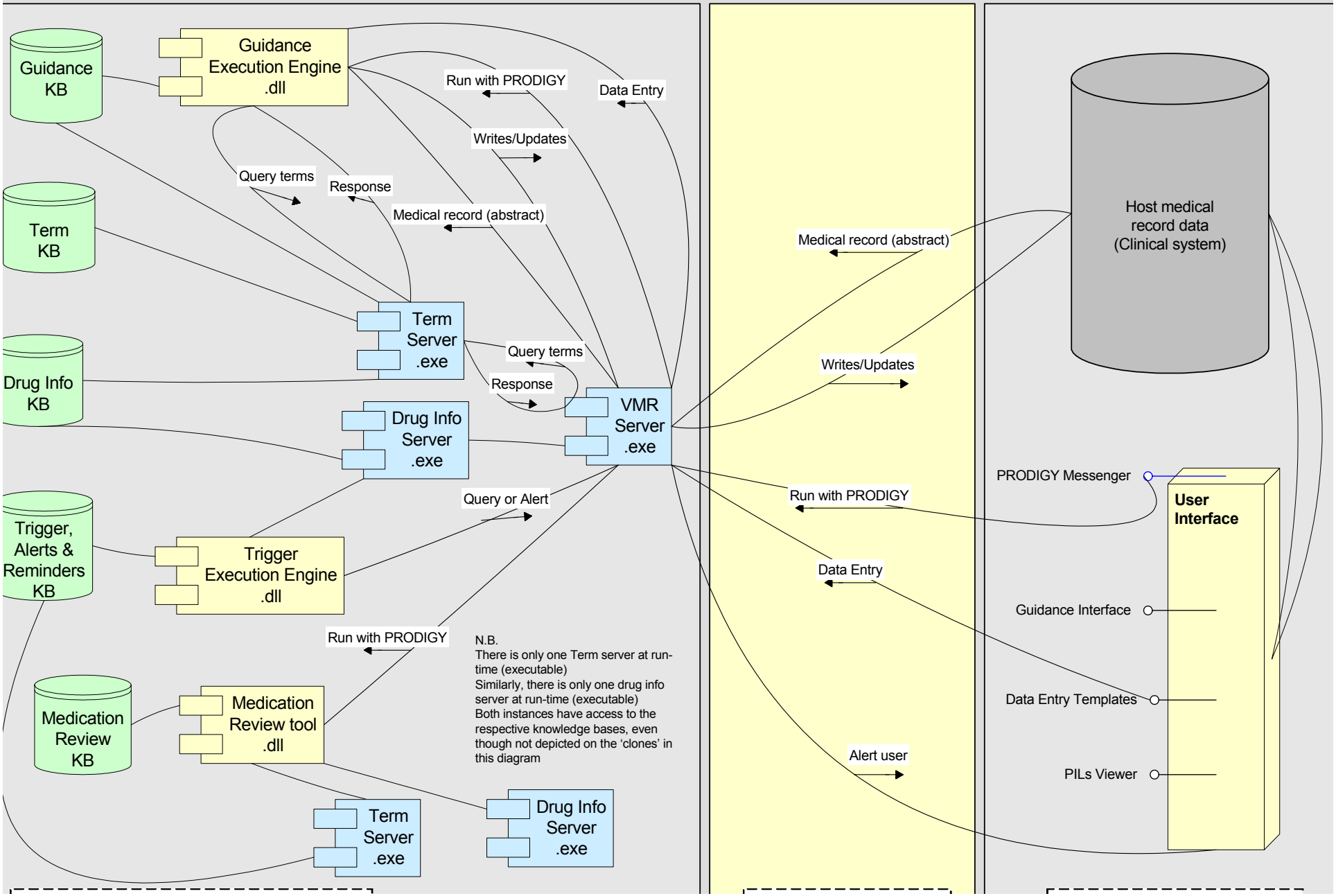
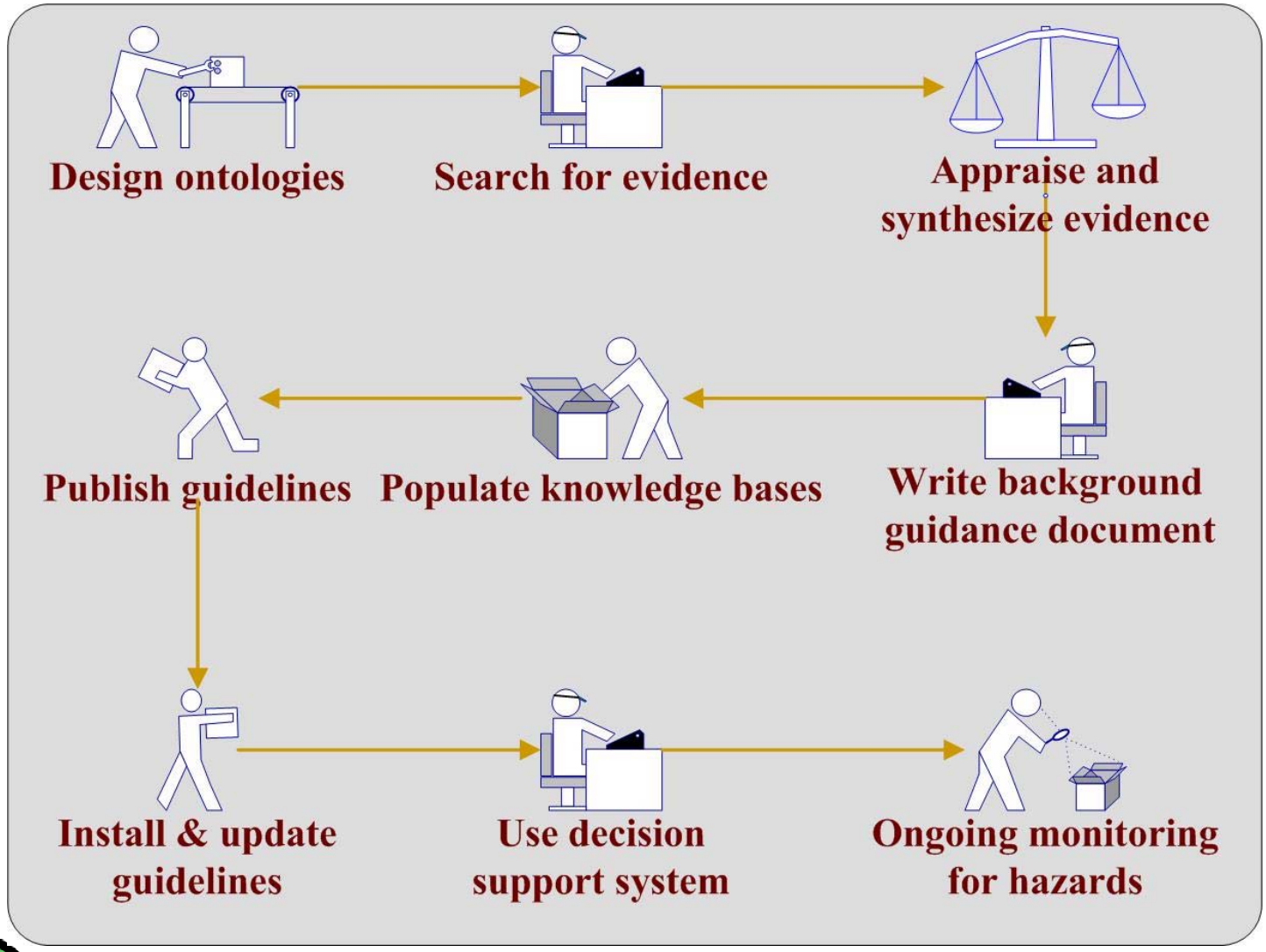
Prodigy R2 technical architecture



What components?



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)

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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
  - …

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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 cf Theory In PRODIGY

- **Release 1: comprehensive**
- **Release 2: in development**

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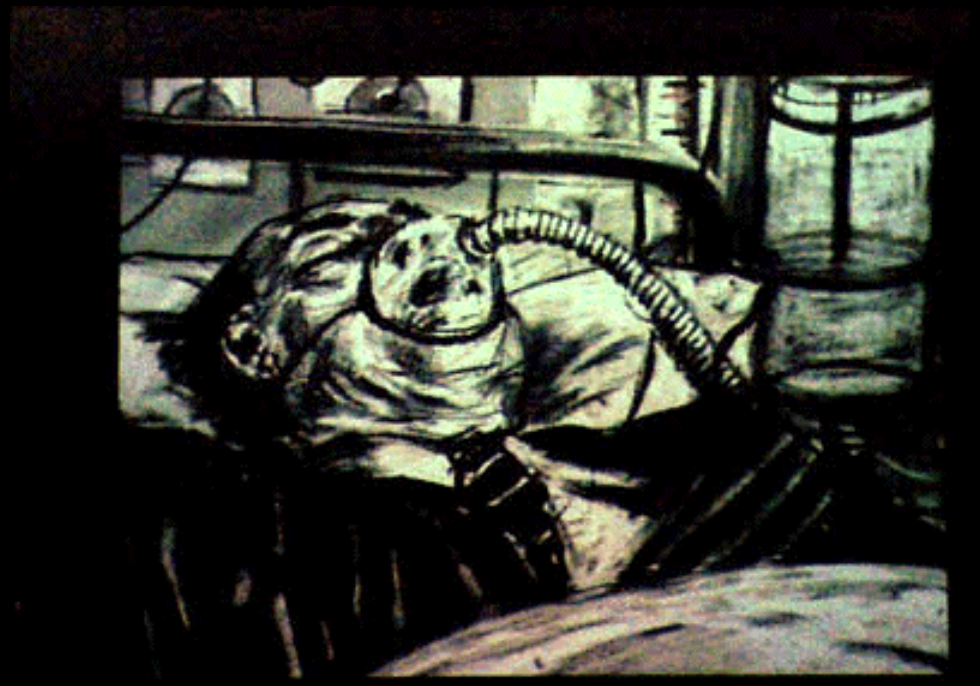

Corresponding author:

Dr Michael Power
Michael.Power@ncl.ac.uk

Sowerby Centre for Health Informatics at Newcastle
Bede House, 1st floor South
Pilgrim Street
Newcastle upon Tyne
NE1 2ES