Quality, safety and ethics in the delivery of decision support

New wine and old bottles

John Fox
An example of a clinical decision support system: ERA
To make a referral, click on "Electronic referral" under the appropriate heading (ERA overview and tutorial).

- **Lung**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Breast**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Upper Gastrointestinal**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Colorectal**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Haematological**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Sarcoma**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Skin**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Neurological**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Cynaecological**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Head and Neck**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Urological**
  - Electronic referral
  - Key points
  - Referral guidelines

- **Paediatric**
  - Electronic referral
  - Key points
  - Referral guidelines
### BREAST

**Patient Details:**

- **Age:** 47
- **Gender:** F

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**Referral information** (please tick boxes):

<table>
<thead>
<tr>
<th>Breast lumps</th>
<th>Pain</th>
<th>Nipple discharge / changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discrete lump</td>
<td>Intractable pain</td>
<td>Discharge</td>
</tr>
<tr>
<td>Asymmetrical nodularity persistent at review</td>
<td></td>
<td>Blood stained</td>
</tr>
<tr>
<td>after menstruation</td>
<td></td>
<td>Large volume</td>
</tr>
<tr>
<td>Abscess</td>
<td></td>
<td>(sufficient to stain clothes)</td>
</tr>
<tr>
<td>Persistent / refilling cyst</td>
<td></td>
<td>Bilateral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eczema</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Recent retraction or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>distortion (&lt;3 mths)</td>
</tr>
</tbody>
</table>

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**Skin changes:**

- Nodule
- Distortion
- Ulceration

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**OK**
ERA recommendations
These are made on the basis of the clinical features presented to the system, they are intended to aid, not replace, clinical judgement:

A 2-week referral may not be appropriate because none of the standard indications for a 2-week referral apply to this patient.

A referral to a breast specialist, though not necessarily urgent, would be appropriate

The following criteria apply to this patient:

- asymmetrical nodularity persistent at review after menstruation

Patient Details:
Age: 47
Gender: M ☐️ F ☐️
ERA: possible consequences

• Inappropriate clinical advice
  – Software errors
  – Incorrect or incomplete content

• Communication failures
  – Appointment not made correctly
  – Patient not informed

• Downstream problems (e.g. recovery from cancellations …)
Quality issues

• Clinical guarantees
  – Appointment is guaranteed within 2 weeks or encounter is explicitly closed and documented
  – Patient will be informed of appointment within N days

• Technological obligations
  – Advice based on best current evidence, properly documented
  – Operation is clinically validated
  – Performance explicitly monitored and reported
PROforma quality model

1. Validated best practice guidelines
2. Translated for use in point-of-care systems
3. Phase I testing (eg, "paper patients")
4. Phase II Testing: controlled clinical settings
5. Phase III validation of efficacy and safety of decision support in routine practice (primary, hospital care)
6. Phase IV follow up of evaluation
Safety issues: “safety case”

• Demonstrate
  – Sound, reliable design
  – Anticipation of possible hazards
  – Quantification of risk where possible
  – Strategies for controlling and containing consequences of actual hazards

• Record and analyse adverse events, near misses and other significant clinical incidents
Two stream safety engineering

**Efficacy**
- Requirements and design
- System specification
- Logical verification
- Bench testing
- Clinical trials and routine operation assessment

**Safety**
- Scenarios, use models and communications analysis
- HAZOP (HAZards and OPerability studies)
- Safety verification
- Hazard simulation and testing
- Operational safety management
HSE ‘software’ and the law, discussion paper 2001

• UK Health and Safety at Work Act (1975, well before IT revolution)
  – “You are not expected to spend disproportionate amounts of money in reducing negligible risks”

• What are “disproportionate costs”, “negligible risks”?

• What would constitute an acceptable safety case?