Research and Clinical Audit

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Importance of knowing the differences

Clinical audit and research processes

The differences between research and clinical audit

The problem of seeing the differences

The solution
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Importance of identifying research properly

| **Participants in research** may not benefit from the research |
|**Participants in research need to be safeguarded through ethics review** |
| The ethics review system for research is bureaucratic |
| Clinicians can ‘game’ the system by calling a research project a clinical audit |
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The solution
Clinical audit is a *quality improvement process* that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

The quality improvement process is a systematic, data-guided activity designed to bring about immediate, positive changes in the delivery of health care in particular settings.

For quality improvement to occur, the information produced by quality assessment must be translated into systematic improvements in healthcare practices.
Clinical audit process

Let's do a clinical audit on a subject!

Decide on — Reason Who is involved Cases

Define quality and formulate measures

Measure day-to-day practice

Devise a plan and implement it

Identify — Problems Causes Improvements

As rapidly as possible

Ask: Does day-to-day practice meet expectations?

Later ask: Have things changed or need to monitor?

Feed back to those involved — celebrate — and maintain good practice

Yes

No

Refer to evidence
Rapid-cycle approach to clinical audit

Positive effect of care on patients

% of patients

Time period 1 | Time period 2 | Time period 3 | Time period 4

Action for improvement

More action for improvement

More action to sustain improvement

Continue to monitor
Implications of clinical audit as a **quality improvement** model

<table>
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<tr>
<th>‘Trials’ of actions for improvement — ‘experiments’</th>
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<tr>
<td>Action may be ‘strong’ action — redesigning the care system</td>
</tr>
<tr>
<td>Pre-and-post ‘trial’ measurement</td>
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<tr>
<td>Continues until care meets standards</td>
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*Could people see this model as research?*
Research is the attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods.

Research process

1. Decide to do research
2. Define the research question
3. Review the literature
4. Design the research study
5. Get ethical and other approvals
6. Collect, collate and analyse the data
7. Interpret the findings
8. Prepare a report
9. Disseminate the findings

Get funding

Is funding needed?
Yes
No
Implications of research model

‘Trials’ of interventions — ‘experiments’

Effects of interventions may be unknown

Pre-and-post or treatment and control group ‘trial’ measurement

Should research be redefined to relate to natural processes, particularly the nature and function of human beings and their environment?
Activity as —

- **Description** — or observation — of current practice (sometimes called service evaluation)

- **Measurement** of current practice using quality-of-care measures
<table>
<thead>
<tr>
<th></th>
<th>Evaluation study</th>
<th>Clinical audit</th>
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<tbody>
<tr>
<td><strong>What</strong></td>
<td>How many times something happens to patients</td>
<td>How many patients had care that meets quality-of-care measures — criteria, indicators or standards</td>
</tr>
<tr>
<td><strong>Why</strong></td>
<td><em>What</em> is happening now</td>
<td><em>If what is</em> happening now is what <em>should be</em> happening</td>
</tr>
</tbody>
</table>
| **How quality is measured** | Inferred from data  
No stated standard  
Expect variation | Explicitly defined  
Stated standard  
Examine variation |
| **Outcomes**     | Data — may stimulate change                                                      | *Confirmation or improvement*                                                                      |
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Ideas used to differentiate research and clinical audit

- Purpose or intent — generalizable knowledge
- Focus on improvement
- Systematic nature
- Focus on human subjects
<table>
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<th>Idea</th>
<th>Research</th>
<th>Clinical audit</th>
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<tr>
<td>Purpose or intent</td>
<td>Produce new knowledge that can be generalized</td>
<td>Improve care — but can produce new generalizable knowledge</td>
</tr>
<tr>
<td>Focus on improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systematic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intent to publish</td>
<td></td>
<td>Not primary intention, but can</td>
</tr>
<tr>
<td>Focus on human subjects</td>
<td>Discover new natural process</td>
<td>Discover how to implement a standard of care</td>
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National Research Ethics Service (England) criteria

- Intent — generalizable new knowledge
- Treatment/service — interventions
- Allocation by protocol
- Randomization

Criteria for randomized controlled trials — but not all types of research?
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The solution
A specialist team collects data on end dialysis lab values (which is an indicator of the quality of dialysis) for several dialysis centres. The team:

- feeds back findings to the centres
- educates ‘low performers’ on QI
- requires ‘low performers’ to implement QI plans

The team repeats data collection 9 months later to see if there is improvement.

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<th>The team learned that improvement was happening because doctors prescribed longer than needed dialysis times to counterbalance a tendency for the centres to deliver shorter dialysis times than prescribed</th>
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<tbody>
<tr>
<td>The team published the work to alert others to watch for creating compensating errors in dialysis, since counterbalancing errors do not create reliable excellence</td>
</tr>
<tr>
<td>The project was determined later to meet the definition of human subjects research because it was published as generalizable knowledge — so it must be research!</td>
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</table>
ICU central-line associated bloodstream infection ‘project’

A specialist team:
- defines evidence-based practice for catheter insertion
- develops a checklist for staff to use and asks staff to use the checklist in 103 ICUs
- collects data on compliance and infections from the 103 ICUs
- publishes the findings showing up to 66% reduction in rates of infection

What is the activity?
Following publication, the project was determined to be a research project because ‘human subjects’ were involved, with informed consent needed from all patients involved.

Can people tell the difference? — *Research studies*

<table>
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<th>UK, 2008 —</th>
<th>32.6% agreement on type of project — research or clinical audit</th>
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<tbody>
<tr>
<td>• R&amp;D leads</td>
<td></td>
</tr>
<tr>
<td>• Clinical governance department managers</td>
<td></td>
</tr>
<tr>
<td>• Research ethics experts</td>
<td></td>
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<tr>
<td>• Senior researchers</td>
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<tr>
<td>UK, 1999 —</td>
<td>4/25 directors of public health recognized a clinical audit — 21 sent to research committees</td>
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</tr>
<tr>
<td>• Directors of public health</td>
<td>• Research committee chairs</td>
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<tr>
<td>Australia, 2008 —</td>
<td>15 of 27 committees required full ethical review for a low risk clinical audit</td>
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<tr>
<td>Australia, 2004 —</td>
<td>50% of hospitals required a QA project to go through a research committee review</td>
</tr>
<tr>
<td>• Research ethics committees</td>
<td>Maxwell DJ, Kaye KI. Multicentre research: negotiating the ethics approval obstacle course. <em>Med J Aust</em> 2004;181(8):460</td>
</tr>
</tbody>
</table>
UK, 2002 —

| Medical directors of large hospitals | 47% of research committee chairs |
| Research committee chairs            | 66% of journal editors           |
| Medical journal editors              | 20% of medical directors         |

believed a QI study should be subject to research review

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The conclusion

Don’t use research vs clinical audit as the basis for deciding if ethics review is needed

Instead –

If it’s research, it requires ethical review

If it has ethical implications, it requires review

Key issue: Balance of benefits and harms in the project
Summary

- It is important to recognize a research project as research.
- The research and clinical audit processes are different — clinical audit has improvement cycles.
- People are having difficulty telling research and clinical audit apart.
- The solution is to recognize ethical issues in either a research or clinical audit project — and handle the issues properly.
National Health Service (England)

- Guide on recognizing and acting on ethical issues in clinical audit and quality improvement

- Sample organizational policy on ethics and clinical audit and quality improvement

Available at —
www.hqip.org.uk