Ethics in quality improvement research

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QI – an ethical problem?

- Health care aims to help people
- All doctors want to give good quality care
- Hippokrates’ oath: .. Help people, without harm
- the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
How do we know the care is of good quality?

- Not, if we do not measure
How do we know the change is giving better quality?

- Not, if we do not measure
It is unethical

- Not to follow up the quality
Ljubljana declaration of WHO

- No changes in health care, if the value of it is not proven before
- Only changes that give a health gain
Research should precede health care reforms and system changes

- What kind?
- How much?
- ....

[Image]
Research should precede health care reforms and system changes

- Patient level
- In a service unit
- In a service chain (PHC – Sp.C)
- National
It is unethical

- Not to follow up the quality
- Not to start with research when the care (service) is changed
..if research shows, that

- Medicine A lowers HF fatality 50 % compared to medicine B
- Which medicine will you use?
..if research shows, that

- Medicine A lowers HF fatality 50 % compared to medicine B
- Who uses medicine B if it costs 50 % less than medicine A?
..if research shows, that

- rehabilitation A lowers permanent hospitalisation 50% compared to rehabilitation B
- Who uses rehabilitation B?
It is unethical

- Not to follow up the quality
- Not to start with research when the care (service) is changed
- To go back to the old process, if results better with the new process
Health data privacy and confidentiality

- Keep health information private
- Only those that are involved in the care can use the personal health data
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- Only those that are involved in the care can use the personal health data
- What about researchers?
When do we need patient consent?

- Helsinki declaration:
  - For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse.
  - There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.
When do we need patient consent in QI or QIR?
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Continuum of increasing evidence
When do we need patient consent in QI or QIR?

- In phase II – exploratory trial
- and III – main trial
How about phase IV

- Continuous monitoring of “normal” functions
- Maybe agreement from the ethical committee
Example

The study evaluated a protocol designed to routinely implement five evidence-based procedures:
- having clinicians wash their hands,
- using full-barrier precautions during insertion of central venous catheters,
- using chlorhexidine for skin cleansing before catheter insertion,
- minimizing the use of the femoral site for catheter insertion,
- and removing unnecessary catheters.

In addition to the training of clinicians in such standard infection-control procedures, the project involved the use of a checklist to ensure adherence to the protocol.
OHRP decision

- Research project – ethical permission
  - Published – generalizable case
- Internal enough
- Informed consent
IRB

- Standard procedures
- Non-identified data
- Patients should not hinder normal follow up
IRB

- Standard procedures
- Non-identified data
- Patients should not hinder normal follow up

- OHRP admitted that check list can be used, now that it is normal clinical practise
It is unethical

- Not to follow up the quality
- Not to start with research when the care (service) is changed
- To go back to the old process, if results better with the new process
- Not to ask for ethical permission when research (not necessary in routine praxis, but good practice to have the gov. body’s approval)
EQuiP position paper – draft on the use of data from patient record

- Several interest groups
- Many kinds of needs to use the data
- Data from patient record (what is it collected for)
- GPs’ acceptance
- If used for administrative purposes, a patient consent
- GPs urged to follow up the quality of their work
Specially careful with ethical aspects, if...

- Controlled trials – patient gets a treatment she doesn’t like
Ways to go around

- Comprehensive cohort design – those that strongly favour can choose
Specially careful with ethical aspects, if...

- Controlled trials – patient gets a treatment she doesn’t like
- Change the process in all units at once (often political decisions)
Ways to go around

- Comprehensive cohort design – those that strongly favour can choose
- Randomised stepped wedge design
Summary how to guarantee the ethical side QIR

- Appropriate data monitoring – control points
- Functioning steering committee – ask too much, not too little