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."

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How do we know the care is of good quality?

- Not, if we do not measure

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How do we know the change is giving better quality?

- Not, if we do not measure

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It is unethical

- Not to follow up the quality

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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

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Research should precede health care reforms and system changes

- What kind?
- How much?
- ….

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Research should precede health care reforms and system changes

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

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It is unethical

- Not to follow up the quality
- Not to start with research when the care (service) is changed

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..if research shows, that

- Medicine A lowers HF fatality 50 % compared to medicine B
- Which medicine will you use?

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..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?

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..if research shows, that

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

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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

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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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Health data privacy and confidentiality

- Keep health information private
- Only those that are involved in the care can use the personal health data
- What about researchers?

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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.

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When do we need patient consent in QI or QIR?

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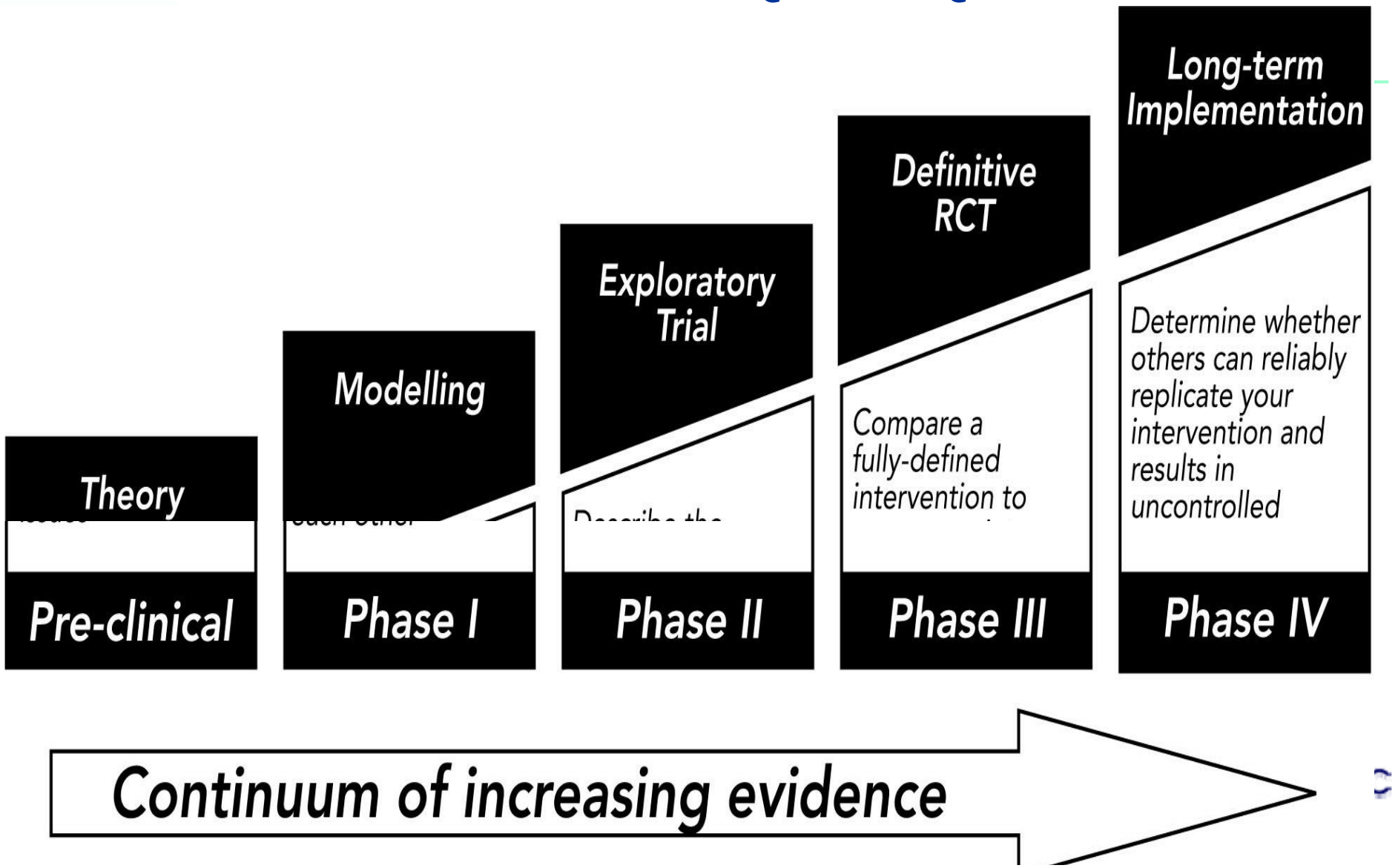
When do we need patient consent in QI or QIR?



When do we need patient consent in QI or QIR?

- In phase II – exploratory trial
- and III – main trial

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How about phase IV

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

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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.

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OHRP decision

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

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IRB

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

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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

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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)

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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

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Specially careful with ethical aspects, if…

- Controlled trials – patient gets a treatment she doesn't like

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Ways to go around

- Comprehensive cohort design – those that strongly favour can choose

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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

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Summary how to guarantee the ethical side QIR

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

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