

Bioethical Frameworks and Standards of Prevention

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Initial Questions

- When must investigators make new HIV prevention tools available to all study participants?
- Can we justify reconsidering the level and type of prevention tools provided to all trial participants?



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Review of Literature and Guidance Documents

- Twelve international guidance documents.
- Eleven meeting and technical consult reports.
- Twenty-seven public presentations.
- One hundred and six articles from primary literature.



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Existing Ethical Frameworks

- Many of the ethical arguments used in existing guidance are framed in terms of the three major principles of medical ethics:
 - Respect for persons.
 - Beneficence.
 - Justice.



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Existing Ethical Frameworks (2)

- Other ethical frameworks include:
 - Good Samaritan (Duty of rescue).
 - Standard of care.
 - Therapeutic obligation.
 - Clinical Equipoise.



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Existing Ethical Frameworks (3)

- Finally, there is a broader meta-ethical principle that we must always consider:

“Ought Implies Can”



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Core Bioethical Principles

1. Respect for persons

- Voluntary informed consent.
- Protection of vulnerable persons.

2. Beneficence

- Maximise benefits and minimise harms.

3. Justice

- Non-exploitation.
- Individuals and groups that participate in trials should benefit from participation.



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Alternative Articulations of Core Ethical Principles

Nuffield Council on Bioethics (2002):

- The duty to alleviate suffering.
- The duty to show respect for persons.
- The duty to be sensitive to cultural differences.
- The duty not to exploit the vulnerable or less powerful.



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Core Bioethical Principles (3)

These principles require that:

- Participants be informed of the risks and benefits of participation;
- Risks minimised and benefits maximised by providing an appropriate HIV prevention package; and
- Trial participants and communities are not chosen solely for expedience or cost.



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Duty of Rescue

- This is the notion that everyone has an obligation to help those in need.
- This duty implies an obligation to provide some level of care and prevention beyond that required to conduct the study.



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Standard of Care

- Within the HIV prevention field, the term “standard of care” has been used to:
 - Define the care and treatment that investigators agree to provide all trial participants.
 - Describe the quality of care that provided to people in the control arm of trial.



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De Jure Versus De Facto Standards of Care

	Global	Local
De jure	International Guidelines	National Guidelines
De facto	International Medical Practice	Local Medical Practice



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Standard of Care (2)

There is still considerable debate about how to determine the standard of care that researchers must provide:

Global versus Local?

De facto versus De jure?



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Therapeutic Obligation

- The Hippocratic Oath obligates a physician to do what is best for the patient, without consideration of other personal or social obligations
- If true, this therapeutic obligation poses a challenge for physicians engaged in clinical research.



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Clinical Equipoise

- Most clinical trials thus violate a researcher's therapeutic obligation unless there is *equipoise*.
- Equipoise exists when there is "genuine uncertainty ... about the comparative therapeutic merits of each arm of a clinical trial."



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Therapeutic Obligation and Clinical Equipoise

- Most often applied to debates about the use of placebos in clinical trials.
- Such trials would violate equipoise except in certain circumstances, e.g.:
 - No treatment exists;
 - Standard treatment is unavailable or cannot be tolerated; or
 - Add-on studies where all participants also “receive all medications that would normally be prescribed.”



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Therapeutic Obligation and Clinical Equipoise (2)

- There is still considerable debate about how clinically-derived principles like these would apply to non-therapeutic research.
- Questions also remain about how to determine what consensus exists about the merits of different treatments or prevention tools.



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Conclusions

- Current UNAIDS/WHO guidance is rooted in the bioethical principles that have been discussed here.
- Guideline 13 obligates researchers to provide trial participants with information about and access to a range of HIV prevention services.



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Conclusions (2)

- These guidelines recognize that the package may vary in the type and the way services are provided.
- The prevention package provided should be:
 - Developed in consultation with the community; and
 - Address the specific needs of the community



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Conclusions (3)

- Thus, it may not be obligatory to always provide or ensure access to a full range of HIV prevention tools.
- No single ethical framework provides clear guidance as to the nature of the prevention package that investigators must provide.



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