Quality of medicines: an ethical issue?
Some food for thoughts & a case study

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Thanks to Prof Wim Pinten, Hasselt University, for sharing many slides
1. What is “ethics”?!
What is ethics about?
Ethics is about « what matters »

- What is the right thing to do?
- Should we do this? (just because we can?)
- Does the end justifies the means?
- Is this the right way to achieve my objectives?
- Whose responsibility is this?
- What are my/others duties?
- It is not (superior) opinions, majority’s opinion, consensus, preferences, intuition, indignation, what shocks us, what we regret, the ‘bad’, what we value
± $2 /kg

± $75 /kg

± $15 /kg

± $375 /kg

± $1000 /kg
Ethics central question

How to act right?
(respectful to what matters)

Tension:
• How we live and how we should live
• How we live and how we prefer to live
• How we should live and how we prefer to live
• ‘Is’ and ‘Ought’
Define, realize, evaluate ‘what should be done’, ‘life as it should be’

• **QUESTION 1:**
  What is important to us?
  ---VALUES---

• **QUESTION 2:**
  When are our values (not) getting realized?
  ---NORMS---
  render values measurable, indicate the ‘normal’, integrate in a group

• **QUESTION 3:**
  what is left to the liberty of individuals?
  ---RULES---
  what is left to the liberty of the individual (+ sanctions if infringement)
• Plurality and diversity
• Can be conflicting
• Value conflicts
• Tension between two conflicting values:
  – which way forward?
  – Criteria?
Thus.... what is ethics?

• A systematic reflection on morality

• Relation to:
  – Personal convictions/beliefs?
  – Religion?
  – Neutrality?

• A way to embrace problems

• The ethical difference is in the way we deal with (not solve) problems
Ethical approach

Approach

- Take a stance (whatever)
- Map arguments & counterarguments ("all partially")
- Weigh the arguments
- Identify the dilemma
- Get to a conclusion

[Diagram of process]

STARTING OVER AGAIN
2. What are “ethics principles”? 
Some ethical principles (in public health and biomedical research)

- **Justice**
- **Beneficence**
- **Respect for persons**
- **Utility**
- **Liberty**
- **Reciprocity**
- **Solidarity**
Justice (or fairness)

- **Equity**: fairness in the distribution of resources, opportunities and outcomes
  - treating like cases alike
  - avoiding discrimination and exploitation
  - being sensitive to vulnerability to harm or injustice...

- **Procedural justice**: fairness in the decision-making process
  - due process, transparency
  - inclusiveness, community engagement
  - accountability, oversight
Benficence

• In general: acts done for the benefit of others
  – efforts to relieve individuals’ pain and suffering
• In biomedical research: first, do not harm
  – Risk:benefit ratio of the experimental intervention
• In public health: society’s obligation to meet the basic needs of individuals/communities
  – Nourishment
  – Shelter
  – Good health
  – Security
Respect for persons

- In general: treating individuals in ways fitting to the recognition of our common humanity, dignity and inherent rights.
- In biomedical research/public health:
  - *Respect for autonomy*: individuals make their own choices based on their *values*/preferences
  - *Informed consent* (with protection measures for those who lack decision-making capacity)
  - *Values*: privacy and confidentiality, social, religious and cultural beliefs, relationships
  - *Transparency and truth-telling*
Utility and Liberty

• *Utility*: actions are right, insofar as *they promote the well-being of individuals or communities*. It requires consideration of
  – *proportionality* (benefits vs risks)
  – *efficiency* (greatest benefits at the lowest possible cost).

• *Liberty*: a broad range of social, religious and political freedoms
  – freedom of movement, peaceful assembly, speech.
  – many aspects are protected as fundamental human rights
Reciprocity and Solidarity

• *Reciprocity*: making a “fitting and proportional return” for contributions that people have made
  – correct unfair disparities in the distribution of the benefits and burdens of research

• *Solidarity*: a social relation in which a group, nation or the global community stands together
  – collective action in the face of common threats
  – efforts to overcome inequalities that undermine the welfare of minorities and discriminated groups.
3. Ethics and pharmacy: the example of quality surveys
Ethical challenges in designing and conducting medicine quality surveys
Ethical challenges in designing and conducting medicine quality surveys


• Uphold moral and ethical obligations
• Analyze the ethical implications and consequences of our work
• impact on the local availability/access to medicines;
• confidentiality and privacy of surveyors and surveyed; q
• questions on deception of outlet staff
• need of ethical and regulatory approvals;
• how the findings should be disseminated.
• Medicine quality surveys should ideally be conducted in partnership with the national Medicine Regulatory Authorities.
4. Ethics and pharmacy: a case study
• Ethical implications of medicines’ production, distribution, selection...?

• Specific ethical challenges in LMICs?
Surveys on API content of misoprostol tablets, in Bangladesh, Egypt, Cambodia, Kenya, India, Mexico, Nigeria, Peru, Pakistan, Vietnam, Nepal, Argentina, Indonesia, Philippines and Kazakhstan (n = 215)

Challenge: exposure to water and moisture may drive degradation

40% underdosed, 5% slightly overdosed, 14 did not contain API.

OOS almost absent (1/48 samples) with SRA approval

PVC or PVDC/aluminium blisters are inadequate

Alu-Alu blister necessary - but not sufficient - to ensure quality

Is it ethical to buy in a PVC blister, if you know all the above?
• **Scenario A** *Public* rural hospital in sub-Saharan Africa (SSA). Stock-out. Needs quick purchase, to fill the gap before the next scheduled order from the capital. Only PVC-sources available locally (Alu-Alu in the capital)

• **Scenario B** Rural hospital in SSA, *run by an European NGO, funded by an EU agency*. Stock-out. Needs quick purchase, to fill the gap before the next scheduled order from the capital. Only PVC-sources available locally (Alu-Alu in the capital)

• **Scenario C** A *public* teaching university hospital in a capital city in SSA. Time to put the next order. Limited budget. Easy access to the National Procurement Center and private distributors. Different blisters available, PVC is cheaper than Alu-Alu.

• **Scenario D** Teaching university hospital in a capital city *in Western Europe*. Time to put the next order at the usual supplier. No info on the kind of blister.
• 30’ work in group

• One group per scenario

• One facilitator per group

• What you decide?

• How do you justify your choice?

• 5’ feedback per group
5. Ethics and pharmacy: discussion
3. Ethics discussion
6. Optional slides to orient the discussion
Some possible reasonings

• Better taking a reasoned risk (« compromise »), to avoid a worst scenario
• If I expect poor efficacy, I can increase the dosage
• Is the stock-out unavoidable? What about stock management?
• What is the price difference between PVC and Alu-Alu?
• What if « compromise » becomes routine?
• What is the « cost » of investigating new suppliers?
• What if the medicine was for a family member or friend?
• Is the decision making reasoning the same in the four contexts?
• ..................................
• « Is the decision making reasoning the same in the four contexts »?

• **YES**: “so many other standards are different (e.g. transports). Why should we make an exception for medicines?”

• **NO**: “medicines are an exception. They are too important for health”

• May we think of other scenarios where we need a reasoned approach to the “compromise on standards”?

• Is it better to have “no school” or “poor quality” school? How do I weigh the risks and benefits of the two option? (How) should I contextualize the risk?
• The Hippocratic “Do no harm,” is a long-standing fundamental principle of medical ethics, for both medical practice and medical research.
• Do no **harm**!

• Lack of access to essential medicines harms

• It is perceived as an ethical issue, related to the principle of justice

• What about “quality” of essential medicines?
• Poor regulation/regulatory oversight exposes end-users to sub-standard products, resulting in avoidable harm
• The implementation of adequate standards in pharmaceutical production is too often taken for granted

• Deliberate falsification of medicines is a crime

• What about sub-standard production/negligence? Negligence in production exposes end-users to sub-standard products, resulting in avoidable harm

• Risks cannot be 100% eliminated, but “programmatic errors can”
Most issues in bioethics are addressed with ‘reflection’. Issues as quality are supposed to be resolved by ‘procedural’ approaches.

Pharmaceutical standards in resource poor countries: ‘procedural’ approaches often fail, due to lack of resources and stringent regulatory oversight.

So we need ethical reflection!

E.g., on the misoprostol case: you need ethical reflection to justify your choice vis-à-vis a dilemma.
• Correcting the problem of variable pharmaceutical standards is an ethical imperative, linked to the principles of **beneficence** and **non-maleficence**.

• The moral responsibility of “not harming” does not concern only those with a direct relationship with the patient, but all those whose activities may have a **positive or negative impact on the patient’s safety and protection**, including regulators, manufacturers and distributors.
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• Where do we go from here?
• What about an « Ethical Charter » for Medicines Production and Distribution?