

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?

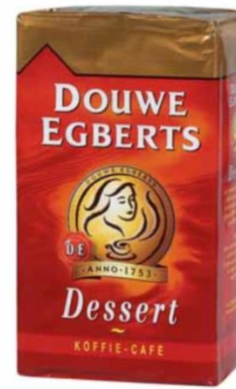


Ethics is about « what matters »

- 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



± \$15 /kg



± \$75 /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'

What is ethics about?

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)

Values, norms, rules, dilemmas

- 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)



Identify the
dilemma



Weigh the
arguments



Map arguments & counterarguments
("allpartially")



Get to a
conclusion



2. What are “ethics principles”?

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

Beneficence

- 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



Taberner P, Parker M, Ravinetto R, Phanouvong S, Yeung S, Kitutu FE, Cheah PY, Mayxay M, Guerin P, Newton P. Ethical challenges in designing and conducting medicine quality surveys. Trop Med Int Health 2016; 21(6): 799-806

- 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?

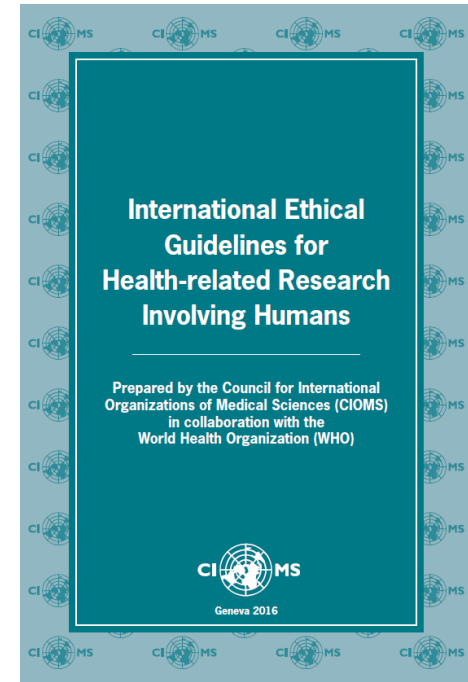
- Surveys on API content of misoprostol tablets, in Bangladesh, Egypt, Cambodia, Kenya, India, Mexico, Nigeria, Peru, Pakistan, Vietnam, Nepal, Argentina, Indonesia, Philippines and Kazakhstan (n = 215)
- Challenge: exposure to water and moisture may drive degradation
- 40% underdosed, 5% slightly overdosed, 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



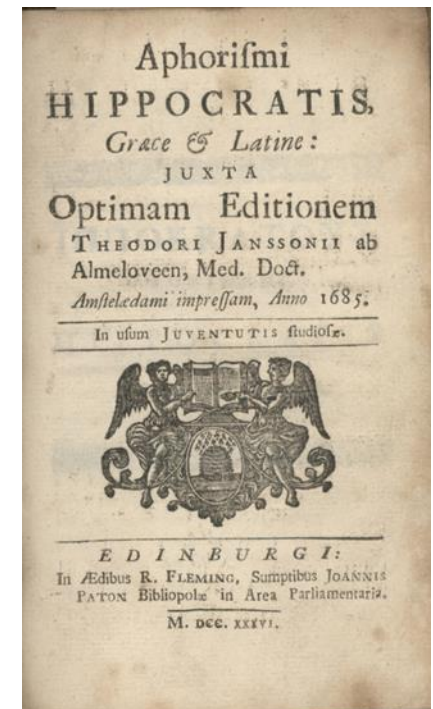
- Better taking a reasoned risk (« compromise »), to avoid a worst scenario
- If I expect poor efficacy, I can increase the dosage
- Is the stock-out unavoidable? What about stock management?
- What is the price difference between PVC and Alu-Alu?
- What if « compromise » becomes routine?
- What is the « 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?
-

Some possible reasonings

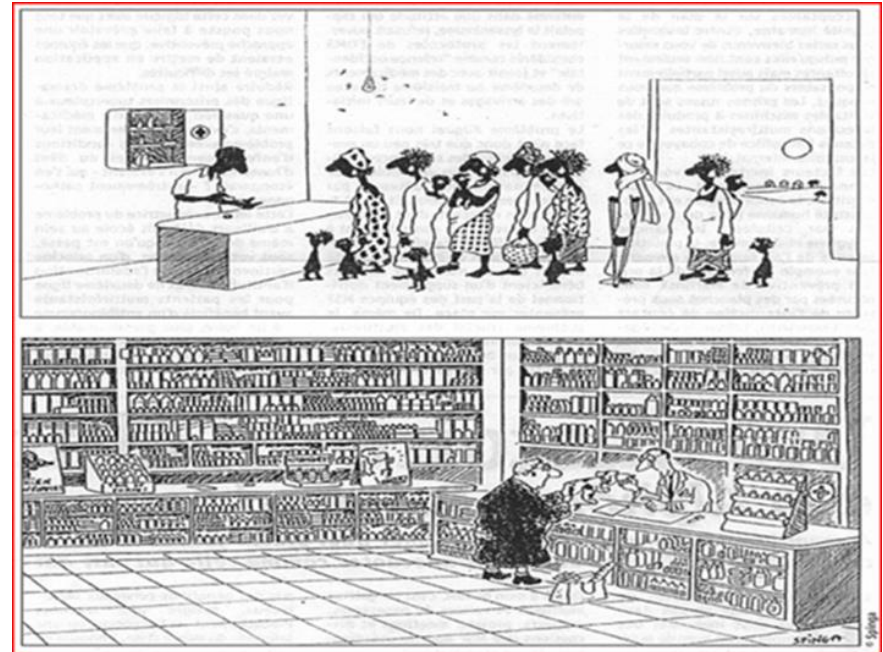


- **« Is the decision making reasoning the same in the four contexts »?**
- **YES:** “so many other standards are different (e.g. transports). Why should we make an exception for medicines?”
- **NO:** “medicines are an exception. They are too important for health”
- **May we think of other scenarios 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?

Regulation



- Poor regulation/regulatory oversight exposes end-users to sub-standard products, resulting in avoidable **harm**

Production



- 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 “programmatically errors can”

Quality = an ethical issue?



- 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-a-vis* a dilemma

Quality = an ethical issue?



- 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.

Quality = an ethical issue?



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- Where do we go from here?
- What about an « Ethical Charter » for Medicines Production and Distribution?