Ethical principles in unproven methods - is there a need for regulation?

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Conflict of interest

Cancer x 3 (including pancreatic cancer)

Offered allogeneic stem cell transplantation

3 in the world

First-hand experience

- serious illness
- decision on very limited data

Paolo Macchiarini

Karolinska Institute and Karolinska Hospital

transplantations with synthetic tracheas

seeded with stem cells

massive scientific and public attention

2015-2016

Joint report
The Royal Swedish Academy of Science
Swedish Society of Medicine
June 2016

Clinical guidelines for the use of unproven methods in the treatment of seriously ill patients

Report
The Swedish National Council on Medical Ethics
November 2016

Ethical assessments at the border between health and medical care and research

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Points of departure

- Research is regulated through the Act on Ethical Vetting (EPL)
- Health care is regulated through the Health and Medical Services Act (HSL)
- There is no ”grey zone” in between these two legislations

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Key concept: VBE

- Vetenskap och beprövad erfarenhet

- Science and proven experience

- Legal foundation for every action taken in Swedish health care
  (Patient Act 2014:821; Patient Safety Act 2010:659)

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Smer's position

- Principle rule: Unproven methods should be developed and implemented as research projects
- Unproven methods may, however, be offered outside a research project under some strictly defined preconditions
- The **aim** should only be to help an individual patient
- The Helsinki declaration article 37 is highly problematic with no requirement for an independent ethical review. The declaration needs to be read as a whole document.

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Medical obligations

- Health care based on science and proven experience
- Clinical research
- Extraordinary situations with a single, critically ill patient where everything else already has been tried
- Should there be a possibility to use unproven methods?

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Primary ethical questions

- Should it be permissible at all to use new and untested methods outside research projects?
- If so, does a special ethical assessment need to be carried out in these cases ?
- How should the risk-benefit assessment be done before using the unproven method?
- How can infomed consent be obtained from the patient?

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Unproven methods

- Methods used in other patient groups
- Methods used on other indications
- Methods in a developing phase
- The aim is to help a seriously ill patient where every other treatment is tried and no other treatment is available

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Preconditions - general

- Exceptional cases for single patients
- Severe suffering or extensive impairment of quality of life
- Effective conventional methods lacking or conventional treatment options depleted
- Potentially effective methods based on theoretical scientific reasoning
- Animal studies and/or human studies (e.g. in other disorders)
- Expected benefits in reasonable proportion to possible risks

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Preconditions - practical

- Informed consent
- Decision by the head of the department
- Written plan
- External ethical assessment
  - ethical, legal and medical expertise
- All results reported nationally

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Acute or subacute situations

- Consultation with at least one colleague with adequate competence in the area
- Written plan before acting
- Focus on the reasoning behind the decision
- Decision by the head of the department or his/her deputy
- Information to the specific committee

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Relation to research

- If the treatment is planned to be used on several patients, this has to been done within the format of a clinical study and should then be performed as regular clinical research

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Ongoing discussion

- Governmental commission in dec 2017 suggested that everything which is done is hospitals lacking ”science and proven experience” has to be research
- Accordingly; an ethical decision is needed
- If acute; ethical permission can be sought retroactive

- Strong critique
- The question has not moved forward yet

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