First Global Forum on Medical Devices

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What is the Place of Ethics in Examining All Aspects of Medical Devices?

Ethics is essential for defensible government policymaking on medical devices, for decent business practices among manufacturers, and for professional behavior among physicians and others using medical devices.
**Ethical Theories**

**Principlism** holds that an action is right if the actor fulfilled duties such as:

- **Nonmaleficence**: the duty to do no harm
- **Beneficence**: the duty to advance another’s interest
- **Autonomy**: respect for a person’s self-choices
- **Justice**: the obligation to promote equity and fairness
- Other principles: dignity, solidarity, cultural diversity

**Consequentialism** holds that an action is right if it produces the best outcome

- Utilitarians seek the greatest good for the greatest number
- Contractarians seek the fulfillment of the explicit/implicit social contract
Meaning of Ethics for Decisions about Medical Devices

Ethics is about “ought” and “choice”

“Ought” refers to the reasons that you should act in a way other than you would if you were acting solely based on self-interest or profit-maximization.

• “Choice” means recognizing that competing goods exist and having a valid justification for selecting one course of action over another.
The Missing “A”

• The agenda for WHO in *Medical Devices: Managing the Mismatch* is to **ensure that medical devices produce maximum public health benefit in all settings**

• This agenda rests on medical devices being Available, Accessible, Appropriate, and Affordable

• **What is missing?**

• The actor—in government, business or the health profession—who determines the “4 A’s” are present is **Accountable** to public/patient for that judgment

• Must explain and defend that the decision is **ethical**: it is the right choice, the decision that ought to be made under the circumstances
The Accountability Model

Obligations of gov’t & system leaders
To ensure that health technologies, particularly medical devices, are:

- **Assessment** (safety & efficacy)
- **Selection** (cost-effectiveness)
- **Appropriate**
- **Regulation** (research data; quality)
- **Management** (planning; operation)
- **Use** (qualifications; indications)

- **Available** (equitable access based on need)
- **Accessible** (obtained by all served by health system)
- **Affordable** (to individuals & to system compared to other uses of the funds for health care & other goods)
The Accountability Model

Obligations of health professionals:
To ensure that health technologies, particularly medical devices, are:

- **Assessment** (safety & efficacy)
- **Selection** (suitability for patient)
- **Regulation** (research data; quality)
- **Management** (planning; operation)
- **Use** (understand; apply correctly)
- **Appropriate**
- **Available** (able to obtain for patient in need)
- **Accessible** (helps patient to overcome barriers)
- **Affordable** (to individuals & to system compared to other uses of the funds for health care & other goods)
Ethical Aspects of Health Professional’s Accountability

**Appropriate use**: using without full understanding or using when not suitable

= violates duty of **nonmaleficence**

**Accessibility & Availability**: failure to advocate for patient to have access to a needed device or failure to help patient obtain a device that is available

= violates the duties of **beneficence** and **justice**
Ethical Aspects of Health Professional’s Accountability

**Appropriate selection**: choosing a medical device because of advantages to the clinician not the patient

**NOTE**: can’t rely on getting patient’s consent *(autonomy)* because choice is really made by physician not patient

= therefore violates duty of *beneficence*

Considerable evidence that this occurs globally

1. Physician self-referral to facilities/devices increases usage 400-700%

2. Pharmaceutical companies’ “free lunch” and consulting & speaking honoraria influence prescription behavior & increase spending

AGAIN: “disclosure” isn’t a remedy
Ethical Aspects of Health Professional’s Accountability

Relationship between health professionals and device companies is more complicated because of greater need for education and training than with drugs.

Some limits still appropriate:

- No honoraria without real services
- Strict controls on the role that company representatives can play in operating room, especially in influencing surgeon’s selection of device to implant.
Ethical Aspects of Government Official’s Accountability

**Appropriate selection:** kickbacks or promises of later rewards (high-paid jobs)

= violates **beneficence** (duty to the public)

  - Manifest in criminal penalties for bribery

**Available & Accessible:** failure to adopt innovation policies and allocate research funds to support discovery of new devices for prevention, diagnosis and treatment of neglected diseases as well as to adapt existing technologies for patients in remote locations or those with poor human and technical infrastructures

= violates **beneficence** and **justice**
Harder than the “oughts” are the “choices”

- Choosing a device that will have somewhat better results, perhaps in terms of ease of use, pain, or life-expectancy, but that is much more expensive than the device now used for the same condition.
- Choosing to allocate limited funds for a device for one condition (such as dialyzing all patients with end-stage renal failure) when that would mean funds would not be available to treat another condition (such as advanced artificial limbs for amputees).

= Measuring the relative utility based on:

- Number of patients involved?
- one condition being fatal and the other not?
Companies don’t have an obligation to develop products for neglected diseases when such products would not be profitable.

• Based on Principal-Agent theory: the officers of a corporation are supposed to serve the interests of their stockholders not distribute corporate assets to the public.

• May be advantageous to be seen as a “good corporate citizen”

• Easier to do in privately held companies
Ethical Aspects of Company’s Accountability

- Companies have an obligation to obey the law, not offer bribes, and so forth.
- Device manufacturer associations have formulated ethical codes and established compliance programs aimed at stopping undue inducements to physicians while still permitting educational and training activities and collaboration in developing and improving medical devices.

BUT: unlike the ethical duties of physicians, those of device manufacturers are not obligatory unless governments make them legally enforceable and invest efforts in monitoring compliance.
Conclusions

• These problems are relevant to all, not just rich countries and to systems with a large private-practice segment

• All governments—to fulfill their own ethical responsibilities to their citizens—ought to ensure that they have rules on the relationship of companies and clinicians.

• In LMIC countries, the absence of affordable and appropriate technologies may seem the most serious ethical failing, as compared with misuse and overuse in richer countries, but all governments—in service of the ethical obligations of justice and beneficence—ought to take steps to ensure rational use of medical devices (that is, appropriate licensing, acquisition, training, and guidelines) and develop a system of post-market surveillance.

• Policies need to be developed in a transparent and contestable process, where all stakeholders can have their views considered.

• This is a central feature of equitable treatment and hence essential for all ethically defensible decisions.
Finally, WHO should ensure that the guidance it provides to countries developing policies on medical devices pays careful attention to achieving ethically defensible decisions because that will be the only way to ensure that medical devices produce maximum public health benefits in all settings.