



**Ethics & HTA – Case Study**  
**Industry-sponsored**  
**Medication Access**  
**Programmes**

# Medical Ethics

- System of moral principles that apply values to the practice of clinical medicine and in scientific research
- Involves examining a specific problem, usually a clinical case, and using values, facts and logic to decide what the best course of action should be
- Four basic principles of medical ethics

# Principles of Medical Ethics

- Beauchamp & Childress, Principles of Biomedical Ethics, 1979
- Four *prima facie* principles
- To be morally right, an action should obey these four principles
- Each principle is binding, unless it conflicts with another moral principle
- Limitation of principlism – no procedure for resolving conflicts

# Principles of Medical Ethics

- **Respect for autonomy**
  - Individual right to make choices affecting oneself
  - Informed consent
  - Respect for dignity
- **Non-maleficence**
  - Do no harm
- **Beneficence**
  - Do good
- **Justice**
  - Do right by all – distributive justice
  - Efficiency & cost-effectiveness

# Application of Medical Ethics

- Examine the proposed course of action in terms of the four principles
- Doesn't necessarily provide answers but gives an indication of where the issues lie

Case Study



**INDUSTRY-SPONSORED  
MEDICATION ASSISTANCE  
PROGRAMMES (MAP)**

# Industry-sponsored MAP

- Any arrangement between a company and healthcare provider for assistance to help patients pay for specific medications
- For example, cash subsidies, free or reduced prices for medication
- AKA compassionate use, cost-sharing, patient access

# For example

- A pharmaceutical company manufacturing a cancer drug offers a scheme where patients meeting financial criteria are given free drugs for a certain number of months



# Group Discussion

- Discuss and list the possible ethical issues that may arise from MAPs
- Should MAPs be permitted? If so, how should they be regulated?



# **EXERCISE**

# MAPs – Respect for Autonomy

- MAPs may help patients but also restrict their choice to the company's specific drug
- MAPs may funnel patients away from less expensive but equally effective treatment
- MAPs may be limited in time/no. of cycles of the drug and lock patients into the specific drug

# MAPs – Non-maleficence & Beneficence

- Patients may opt for drugs on MAPs because they are less expensive than safer drugs
- Drugs on MAPs are often high cost drugs for small groups of patients and the evidence base for effectiveness may not be as strong

# MAPs - Justice

- Cost-effectiveness is a major issue
- Companies may try to market drugs with poor cost-effectiveness through MAPs
- Sustainability – what happens when the MAP ends/runs out?

# UK NICE Patient Access Scheme Liaison Unit

- Patient Access Schemes (PAS) are specifically to improve cost-effectiveness of the drug
- Explicitly subject to NICE's code on conflict of interest
- A key consideration is not to increase the administrative burden by having the scheme

# US – Various Assistance Programs

- Run by industry, non-profit groups and states e.g. Partnership for Patient Assistance
- Healthcare payers/insurers unhappy with some schemes that pay for patient co-payment, but not insurer's component



**THANK YOU**