Erasmus School of Law

The Oviedo Convention and Health Care Access: Key challenges

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Access to New Medical Technologies

'Revolutionary' new class of cancer drugs approved

By James Gallagher
Health and science correspondent, BBC News

TOP 10 MOST PROMISING EXPERIMENTAL CANCER TREATMENTS

Crowdfunding for Unproven Stem Cell–Based Interventions

Jeremy Snyder, PhD[1]; Leigh Turner, PhD[2]; Valorie A. Crooks, PhD[3]

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JAMA. 2018;319(18):1935-1936. doi:10.1001/jama.2018.3057

Prevalence and Determinants of Physician Bedside Rationing

NHS denied treatment for migrants who can't afford upfront charges

Calls for action on patients denied £100,000 cystic fibrosis drug

Article 3

Equitable access to health care

‘ Parties, taking into account health needs and *available resources*, shall take appropriate measures with a view to providing, within their jurisdiction, *equitable access to health care* of *appropriate quality.’*

Meaning of Article 3

- Social Right
- Equitable access: avoiding unjustified discrimination
- What are the health needs?: Reference ESSC classification & professional standards
- Available resources restriction
- Reference to Article 12(2) ICESCR; General Comment No. 14 on Health (14.7.2000)
    - Minimum core obligations
    - AAAQ
    - Non-retrogression
    - Monitoring effectiveness measures

Content of Equal Access: National law

- Constitutional/Statutory Right

  including:

  - Equitable distribution & non-discriminatory access;

  - treaty obligations/core content outlined in international law, including OC

- Monitoring/review system (accountability)

Article 3 Challenges: Precision Medicine

- Super Responder patients: a patient diagnosed with Stage IV gastric cancer [HER-2+] and given six months to a year to live. He was put on trastuzumab every 3 weeks; he is alive seven years later. Cost has been $17,000 every three weeks; roughly $1.5 million so far.
- Others with that “same cancer” [HER-2+] gained only 1-2 extra years of life

- **Did all have an equal just claim to the medicine?**

- Still others might only gain 3 extra months of life with 6 months to a year of treatment (and related costs). Do they too have an equal just claim to trastuzumab, especially if we knew before the fact that this would be the outcome?

- **How should we think about this from the perspective of either solidarity or health care justice?**

Problem #2

- Trastuzumab has essentially the same price per month, whether an individual gains six extra months of life or six extra years of life.
- But then we have CAR T-cell immunotherapy for B-cell lymphoma (cost of $475,000).

- 30% of these patients will only gain an extra year of life, primarily because of resistance.

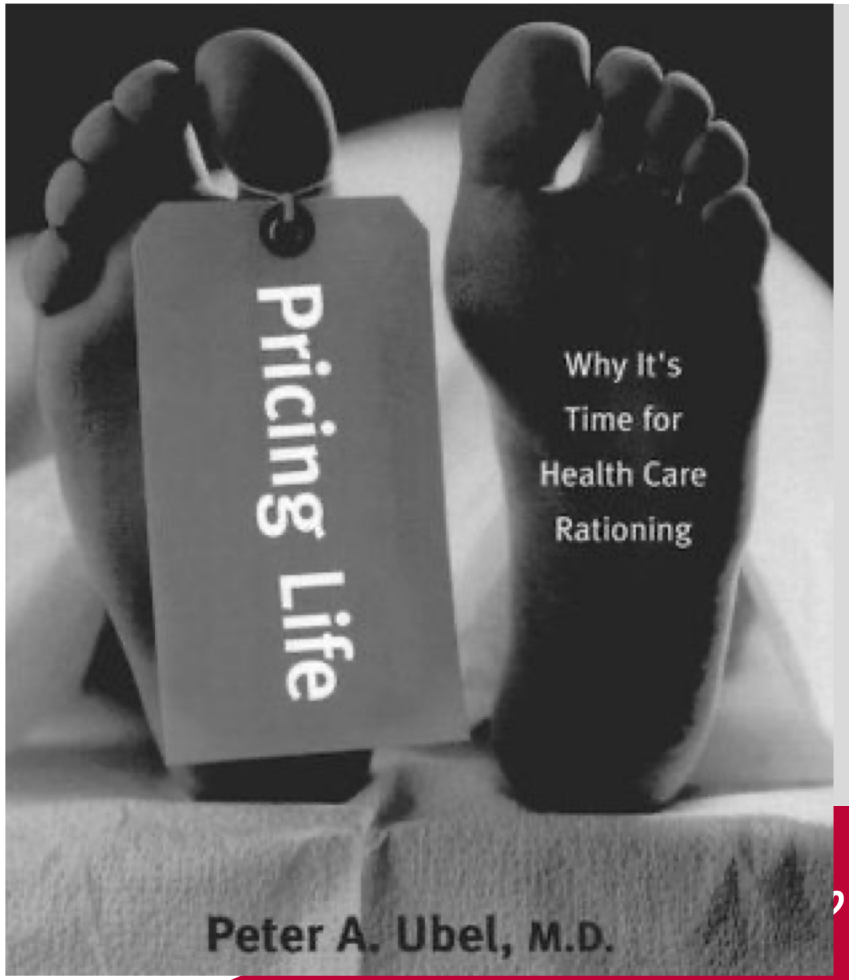
- **If we have biomarkers that can identify such patients before the fact, may they justly be denied access to this therapy at social cost because it would do too little good at too high a cost?**

- **Or does a commitment to solidarity, “equal concern and respect” for all, require that all patients with B-cell lymphoma who have ANY degree of likely benefit have a just claim to this therapy as a matter of solidarity?**

Derived from L.Fleck, 18 Nov PM Conference Salerno

Health Care Rationing Challenges

- Understanding Health Care Rationing
- Defining Health Care Rationing
- Who decides?
- What criteria?
- Methods



Rationing and Human Rights

- Human Rights
- Legitimacy
- Liability

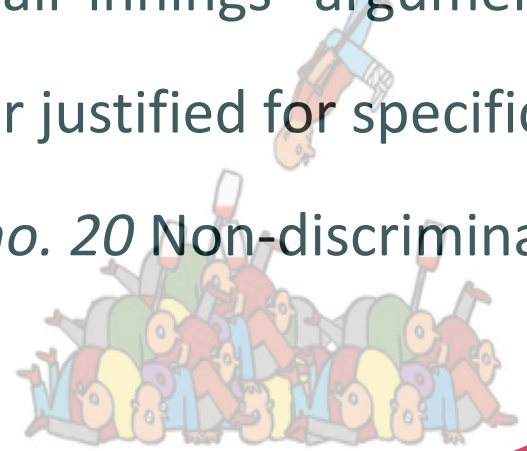
Bedside rationing example. The use of scarce MRI slots

A neurologist works at a county hospital that does not have a magnetic resonance image (MRI) scanner. The hospital puts money aside each year so that six patients can receive an MRI at a nearby hospital. A physician evaluates a patient who has a ‘soft indication' for an MRI. The physician could order an MRI for the patient. However, he knows that if he requests an MRI for this patient, he denies an MRI to another patient, who may need it more. Thus, he tells the patient that an MRI is unnecessary.

Derived from P Ubel, *Recognizing Bedside rationing*, AIM 1(1997), 74

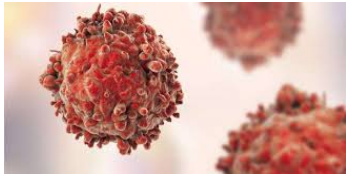
Age-based Rationing: Immoral or unavoidable?

- Excluding elderly patients from *specific* life-extending treatment options for cost constraints
- Age level as a threshold: “fair-innings” argument
- Discriminatory by nature or justified for specific reasons?
- *CESCR General Comment no. 20* Non-discrimination (E/C12/GC/20)



illustratie merlijn draisma

Ibrutinib: Wicked Rationing Challenge



- Some CCL patients fail ibrutinib after 1-2 years; others fail after 5-6 years or more; this is the problem of cancer drug resistance. Some of these patients might be in their 50s; others in their 70s; what then?

- CD 19 CAR T-cell therapy is an alternative (€425,000). In one trial 55% survived less than 9 months; 10% survived seven years.

- Challenge: Assume future research gives us a biomarker that can tell us with 90% confidence which CLL patients will not survive one year with CAR T-cell therapy. **Would age-based rationing allow us to deny such patients this therapy at social cost? Would it matter that some of these patients were in their 50s, others in their late 70s?**

Derived from L.Fleck, 18 Nov PM Conference Salerno

Health Care Rationing & the Judiciary: Some experiences

Rationing Litigation in the UK

- NICE and cost-effectiveness threshold
- Postcode lottery
- General rule: courts will not interfere with the decision about how money is allocated unless that decision is ‘frankly irrational’
- Meaning of rationality ?
- *Swindon NHS Primary Care Trust* (Herceptin litigation)

Challenging Rationing Decisions: Germany and Switzerland

- New technologies and limited cost-effectiveness:

  - *Nikolausbeschluss* (BVG 6 Dec 2005) German CC:
    - lifesaving (experimental) medicine and Constitutional rights
    - "*spürbare positive Einwerkung*"
    - Elaborated by Fed. Social Crt (BSG) 2006

  - Narrowed in IVIG therapy: life-threatening, critical situation
    Off-label use BVG 11 April 2017

- *Myozyme cases I & II*, Sw. Supreme Crt. 23 Nov 2010; 2015
  - Cost-effectiveness threshold 100.000 CHF QALY
  - "limited cost-effectiveness"

Rationing (Litigation) in the Russian Federation

- Explicit rationing and Constitutional law: no legal basis?
- Implicit rationing by health professionals
- Variety in daily practice (control commissions, guidelines, lists of treatment options, etc.)
- Rationing challenged in courts?

Source: V. Vlassov et al, '*Why HCR is not acceptable in Russia*', (in press)

Rationing and the ECtHR: Reduction in night-time care for an elderly lady

- *McDonald v United Kingdom*, No 4241/12, 28 August 2014
- The applicant complained that a reduction in night-time care disproportionately interfered with her right to respect for her private life under Article 8 ECHR.
- ECtHR: State did not exceed the margin of appreciation

EUCJ: Is Thalys the solution?

- *Decker/Kohll case* C-120/95
- *Smits/Peerbooms & Müller-Fauré/van Riet* cases C-157/99 and C-385/99
- *Elchinov*, case C-173/09
- *Cie. v Frankrijk*, case C-512/08
- *Petru*, case C-268/13

Discussion: recent Developments

- Use of Health Technology Assessment (HTA) - But do not forget human rights
  - Draft regulation on HTA COM(2018) 51 final
- Statutory HTA requirement (and cost-effectiveness threshold) in SHI Act?

Conclusions

- Rationing unavoidable and necessary
- Rationing litigation: Need for public debate on fair rationing: democratic deliberation (L. Fleck) (plea for explicit rationing)
- Incorporating HTA in rationing debate
- Role of the courts: triggering that debate and holding health rights justiciable