Erasmus School of Law

Precision cancer medicine and equal access to health care: Key challenges

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Access to New Medical Technologies

Revolutionary new class of cancer drugs approved

Crowdfunding for Unproven Stem Cell-Based Interventions

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

James Gallagher
Health and science correspondent, BBC News

TOP 10 MOST PROMISING EXPERIMENTS

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NHC J

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 Oviedo Convention

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.' No income inequality, equal access to healthcare and education, no borders, no fascism, no privatized property, no worker exploration, no racism, no war, no imperialism, no police, and no state.



LEFTIST PARADISE

Meaning of Article 3 Oviedo Convention

- 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)



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

- Targeted therapies metastatic cancers as well as immunotherapies for metastatic cancer
- Roughly 90 such therapies have FDA approval in the USA
- The "targets" are genetic features of a tumor
- Costs: > \$100,000 for a course of treatment or per year with some costing \$475,000 upfront (CAR-T cell therapy for B-cell lymphoma)
- None of these therapies are curative (because cancers have proven to be much more genetically complex than was initially understood)
- Life expectancy gains: marginal, measurable in months, not years.

Article 3 Challenges: Precision Medicine & Solidarity

- 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.
- 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?

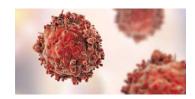
Cancer: Early Detection and the risk creating a population of (costly) hypochondriacs?

- Recently announced blood test can detect at the earliest possible stages eight different cancers!!!
 WOW!!! Cost: \$500
- More recently (Oct 1, 2019) test developed by GRAIL can detect 20 different cancers in very early stages examining free-cell DNA
- Problem: 170 million adults in the US; if everyone got this test, \$85 billion PER YEAR!!!
- Who should pay for these tests? Who should be denied access to these tests at social expense?





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
- 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?

Age-based Rationing: Immoral or unavoidable?

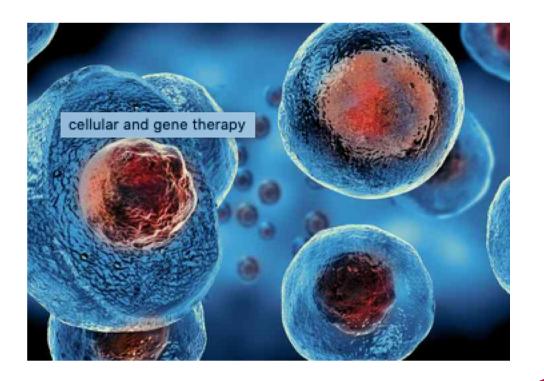
- Excluding elderly patients from specific life-extending treatment options for cost constraints
- Age level as a threshold: "fair-innings" argument
- Discriminatory by nature or justified for specific reasons?
- CESCR General Comment no. 20 Non-discrimination (E/C12/GC/20)



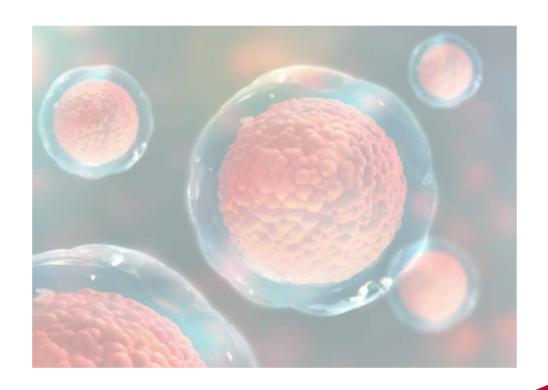
Deliberative Justice and Solidarity

- Need for tradeoffs is inescapable
- Creating fair and inclusive processes of rational democratic deliberation is the key to building social solidarity, legitimacy and trust in a diverse society respectful of value pluralism





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