Informally regulated innovation systems: Challenges for responsible innovation in diagnostics

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Preventing Overdiagnosis: Winding back the harms of too much medicine
September 22, 2016
Barcelona, Spain

Institute of Health Policy, Management & Evaluation
UNIVERSITY OF TORONTO

Addressing overdiagnosis

- Overdiagnosis as a result of …
  - Technological change – e.g., Genomics
  - "Culture"

  … Apart from social, economic, political arrangements & practices
- Overdiagnosis managed by …
  - Shared decision making and informed consent by patients
  - Ethical and informed practice by clinicians
  - Clinical governance or financial regimes of audit and feedback, academic detailing, payment (dis) incentives, etc.

Political economy of overdiagnosis

- Arising from the political economy of diagnostic innovation
- Innovation "system"
  - How science is organized and incentivized
    - Science policy – Research "impact", Technology transfer and commercialization
  - How new technologies are adopted and diffused into practice
    - Regulatory arrangements and practices – Statutory and non-statutory "polycentric" regulation
  - ... The relative roles of for-profit firms and public sector actors

Innovation systems in diagnostics

Formally regulated - commercial

(Hogarth et al, 2012; Hopkins & Hogarth, 2012)

- "Blockbuster diagnostics" – "pharmaceuticalizatio n"
  - IP in biomarkers
  - High cost

Firms as lead providers of services

- E.g., Oncotype DX, NIPT

Informally regulated - clinical

(Hopkins & Hogarth, 2012; Hopkins, 2006)

- Hospital-based laboratory developed tests
  - Clinically-oriented research
  - Mission driven

Firms as supports for technical performance

- E.g., Clinical cytogenetics, Clinical

Method

- "Personalized oncology" clinical feasibility study
  - Across 5 hospitals in Ontario, Canada
- Patients with advanced cancer, eligible for phase 1/2 clinical trials
  - Tumour biopsied
  - Targeted genome sequencing
  - Findings deliberated by Expert Pa
  - "Actionable" mutations reported

Ethnographic observation of weekly EP deliberations, over 1 year

Informally regulated diagnostic innovation

- How science is organized and incentivized
  - Translational, “impactful” research
    - Not to test emerging technology but to facilitate its entry to clinic
    - To be among first internationally to demonstrate the feasibility of clinically deploying these technologies
      - Accommodate global standards while developing local heuristics and practices for search, synthesis, management of genomic data
  - Mission driven
    - Felt clinical obligations to report – to enable “options”
      - Assess fresh tissue, report “actionable” mutations → Assess any tissue, report any mutations not established as “non-actionable”

Informally regulated diagnostic innovation

- How new technologies adopted & diffused into practice
  - Statutory regulation of commercial platform technologies
    - Not approved by statutory regulators for clinical use; sold ‘for research use only’ and ‘not for use in diagnostic procedures’
  - Laboratory licensing
    - Findings to be reported to patients to be validated by lab licensed and accredited to conduct molecular pathology testing for patients in Ontario
      - Aligning findings and quality/ validation norms and protocols across clinical and research labs and technical platforms
  - Clinical practice
    - Aligning the study process with clinical timelines

Conclusions

- Exploring political economy of diagnostic innovation
  - Go beyond narrow explanations of cause – and partial strategies for management – of overdiagnosis
- Diagnostic innovation systems are not the same as pharmaceutical innovation systems
  - Though diagnostic innovation may evolve in a parallel manner
- At present, both formally regulated and informally regulated diagnostic innovation systems contribute to overdiagnosis