RAPID DIAGNOSTICS IN DETECTING ANTIMICROBIAL RESISTANCE: A BIOETHICS PERSPECTIVE

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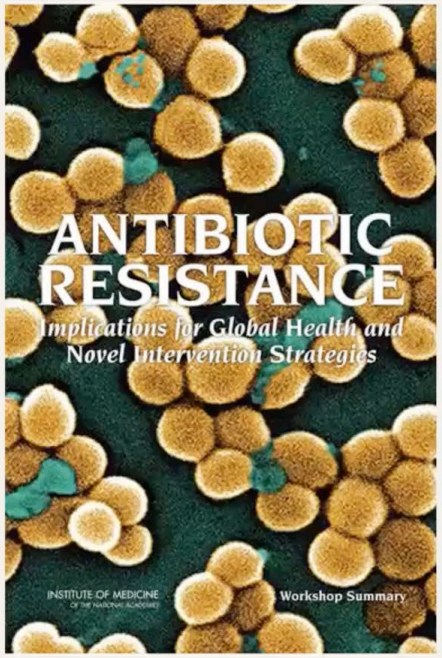
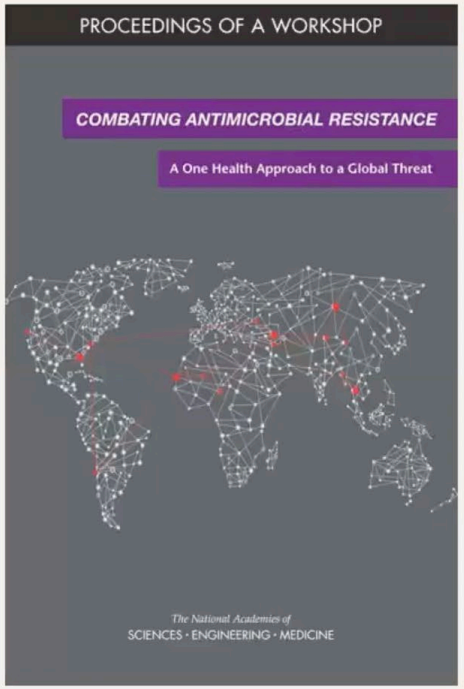
PRIOR NASEM WORK – NO MENTION OF EQUITY



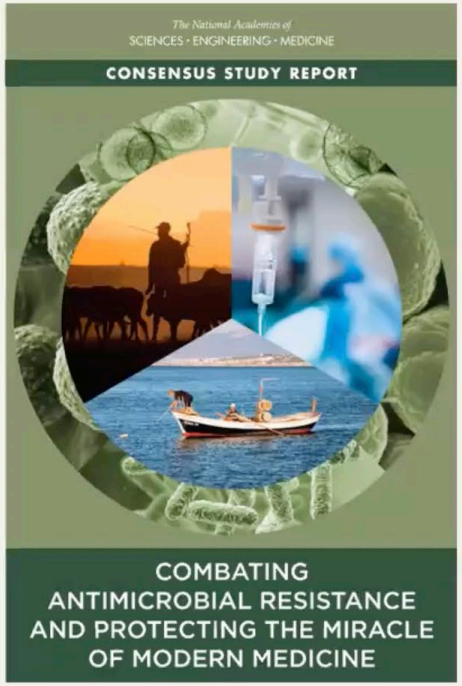
2010

2014



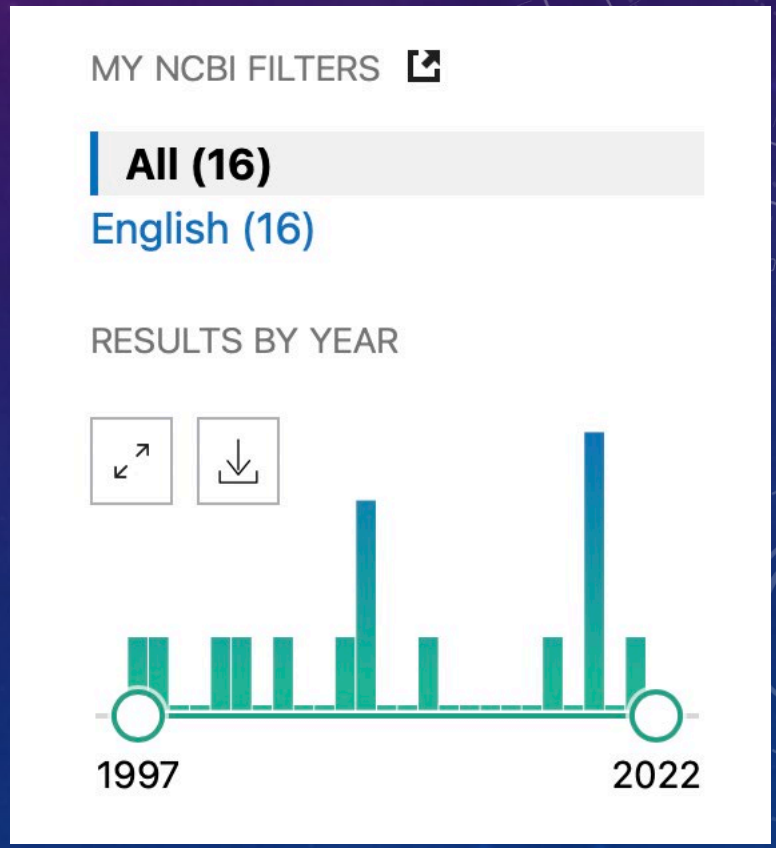
2017

2022



WHAT DOES BIOETHICS HAVE TO SAY ABOUT AMR AND HEALTH EQUITY?

- Not much – because bioethics has largely ignored AMR—or *drug resistance of any kind*
  - And possibly because, on methodological/disciplinary grounds, this seems like a no brainer?
- However, those papers that do address AMR regard preventing/slowing AMR as an issue of distributive justice
  - The fair allocation of social goods in society.
- In the context of rapid diagnostic development and use, we can identify three pressing issues
  - The use of samples in research
  - Diagnostic data and sample sharing
  - Cost and access



RESEARCH ETHICS IN PUBLIC HEALTH CONTEXTS

(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

- US: what counts as research?
  - Generalizable knowledge
  - But *not* routine public health surveillance activities
- Globally: more diversity, *but* less focus on the US focus/exemptions (which are somewhat idiosyncratic)
- Should AMR Dx constitute research?
  - Yes—why?
  - Overcoming logistics and regulatory concerns
  - Data management and harmonization

DIAGNOSTIC DATA AND SAMPLE SHARING

- In past efforts, there has been lack of consistent attention and effort to domestic and international data and sample sharing in public health response:
  - Example 1: Indonesia's decision to withhold avian influenza H5N1 samples
  - Example 2: Sierra Leone's inability to retrieve Ebola virus disease samples due to UK national security restrictions
- Yet sample data and sample sharing are core concerns for global health equity and justice
  - Ensuring access to results and samples for host nations
  - Costs of isolationism

COST AND ACCESS

- AMR is regarded in bioethics as an issue of distributive justice
  - Its *cause* is an issue of distributive justice, in that antibiotics are often overprescribed to the wealthy and underprescribed to the poor (Selgelid, 2007).
  - The failure of market-based health(care) allocation
- So too the issue of diagnostics can become an issue of distributive justice if applied in the same way
  - Example: “free” COVID-19 tests in 2020 (with very not-free administration in some healthcare centers)
- Diagnostics that are unaffordable globally, are a waste of resources
- Ethics of design and implementation
  - Partner nations and public health departments
  - The public health ground game for AMR Dx