WHO R&D Blueprint and data sharing in outbreaks/emergencies

Vasee Moorthy MRCP PhD

Data sharing focal point

WHO R&D Blueprint

& Team Leader,

Vaccine Development,

WHO Geneva

World Health Organization

What kind of data in outbreaks?
Individual, aggregate, raw, analysed

- Epidemiological
- Surveillance (clinical, laboratory)
- Emergency response
- Health facility data
- Research data including surveys, observational studies, clinical trials of diagnostics, therapeutics and preventives
- QC'd interim results
- Final research results
- Ancillary research results
- 'Negative' and inconclusive results

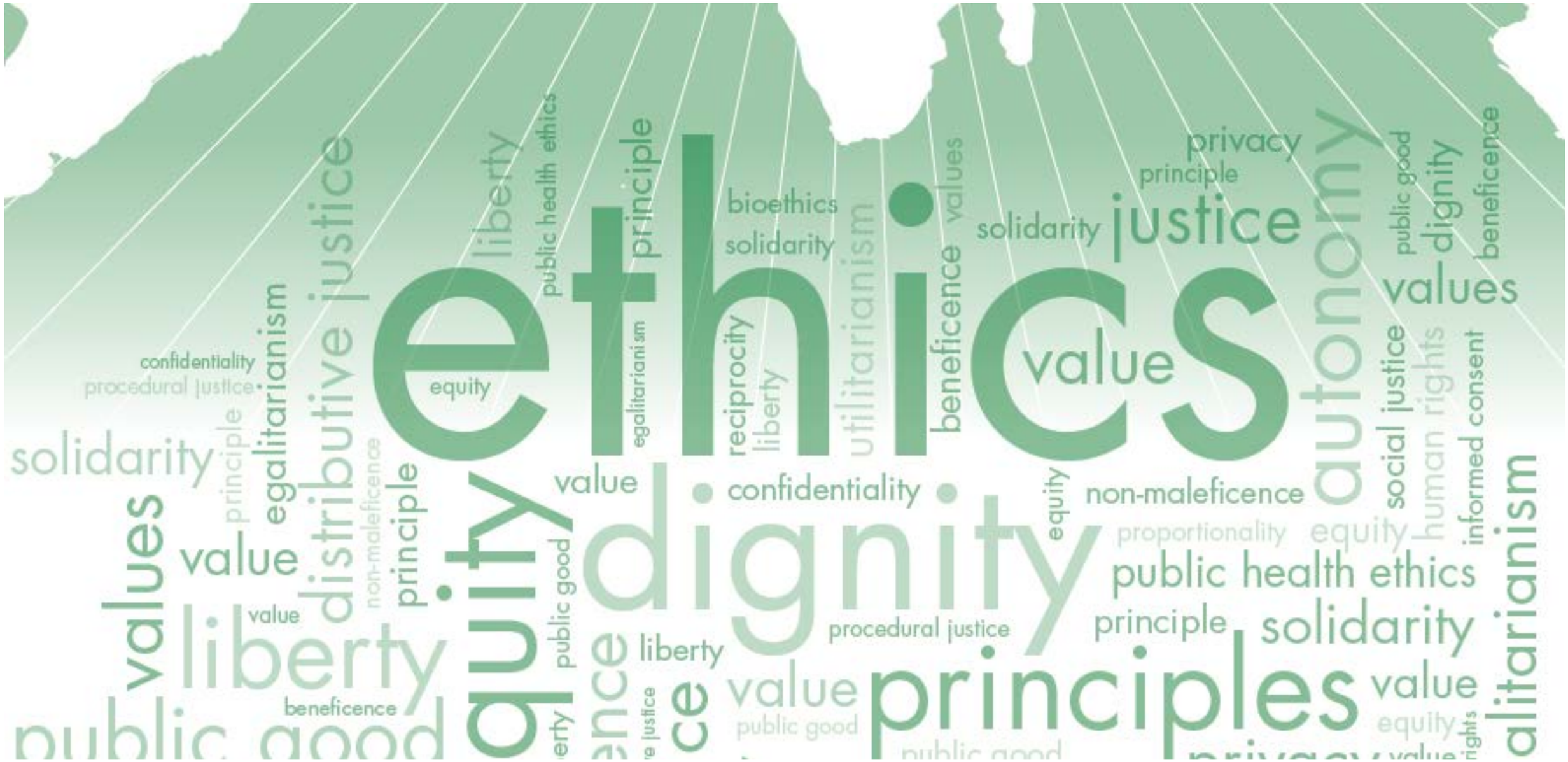
WHO Blueprint for accelerating R&D in epidemics and health emergencies

In May 2015, the Sixty-Eighth World Health Assembly
"…welcomed the development of a blueprint, in consultation with Member States and relevant stakeholders, for accelerating research and development in epidemics or health emergency situations where there are no, or insufficient, preventive, and curative solutions, taking into account other relevant work streams within WHO".

Two key and complementary objectives

- to develop and implement a roadmap for R&D preparedness for known priority pathogens, and
- to enable roll-out of an emergency R&D response as early and as efficiently as possible

WHO Guidance for managing ethical issues in infectious disease outbreaks - 2016



http://apps.who.int/iris/bitstream/10665/250580/1/9789241549837-eng.pdf.

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WHO R&D Blueprint consultation on data sharing Sep 2015

Developing Global Norms for Sharing Data and Results during Public Health Emergencies

A longer statement of principles arising from the 1-2 Sep 2015 consultation is available here.

The statement below was issued the evening of 2 Sep 2015 immediately after the consultation.

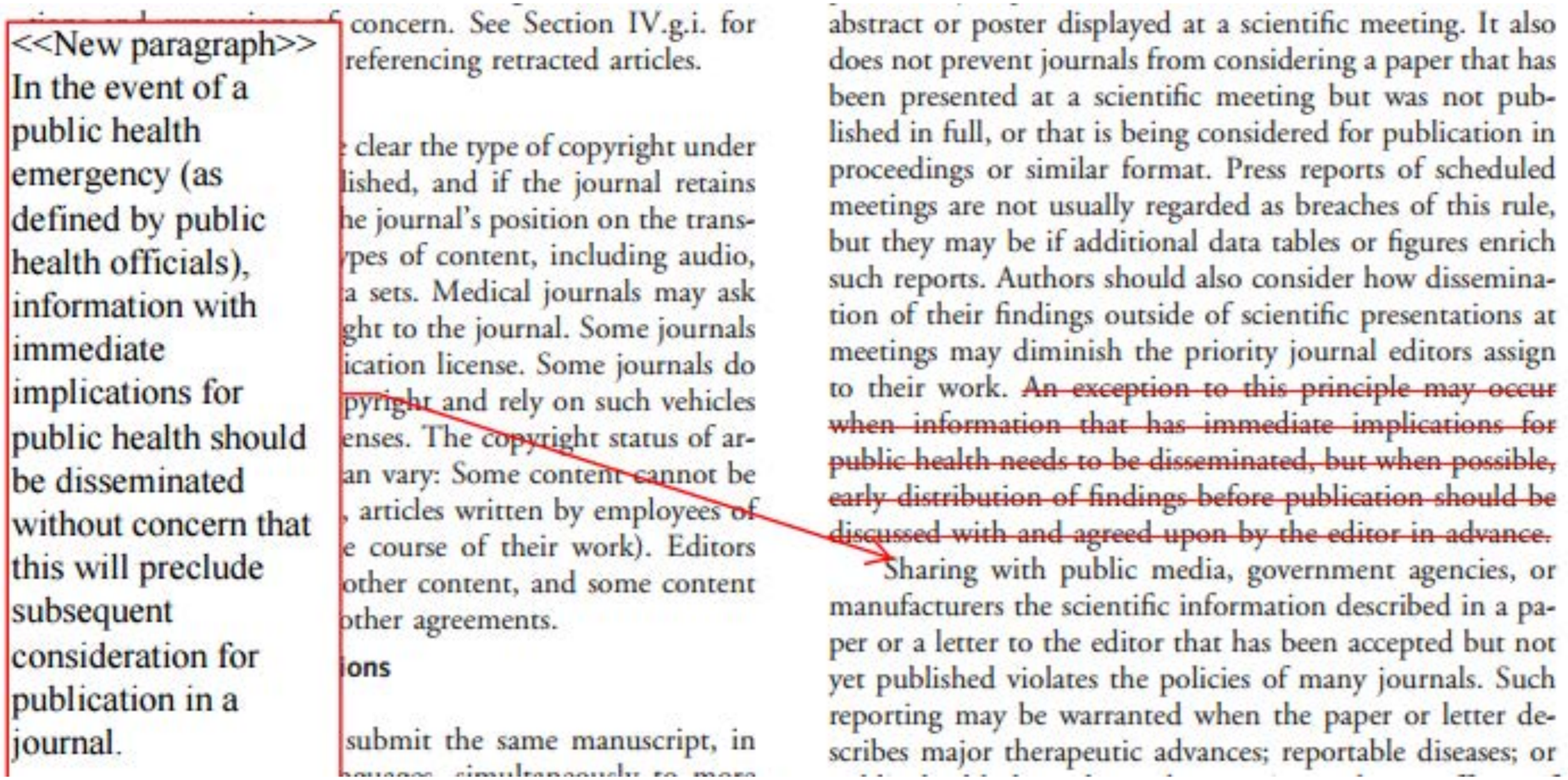
WHO Consultation 1-2 September 2015: Summary and Key Conclusions

In line with open access policies, the timely sharing of information on clinical, epidemiologic and genetic features of emerging infectious diseases as well as information on experimental diagnostics, therapeutics and vaccines, is critical for actions during a rapid public health response.

WHO held a consultation in Geneva, Switzerland, on 1-2 September 2015 to advance the development of global norms on data and results sharing in public health emergencies. Government representatives, public health agencies, scientists, research funders, ethicists and industry representatives attended the consultation. Acknowledging the years of work that many groups have engaged in to support data sharing in health research, the following consensus emerged from the meeting specific to the emergency perspective.

It was recognized that epidemiologic data belong to the countries where they are generated, but there was consensus that the default option is that data should be shared (i.e. opt-out policy) to ensure that the knowledge generated becomes a global good.

Updated Dec 2015 ICMJE Recommendations included changes



<<New paragraph>>
In the event of a public health emergency (as defined by public health officials), information with immediate implications for public health should be disseminated without concern that this will preclude subsequent consideration for publication in a journal.

concern. See Section IV.g.i. for referencing retracted articles.

clear the type of copyright under lished, and if the journal retains he journal's position on the trans- pes of content, including audio, a sets. Medical journals may ask ght to the journal. Some journals ication license. Some journals do pyright and rely on such vehicles enses. The copyright status of ar- an vary: Some content cannot be , articles written by employees of e course of their work). Editors other content, and some content other agreements.

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submit the same manuscript, in

abstract or poster displayed at a scientific meeting. It also does not prevent journals from considering a paper that has been presented at a scientific meeting but was not published in full, or that is being considered for publication in proceedings or similar format. Press reports of scheduled meetings are not usually regarded as breaches of this rule, but they may be if additional data tables or figures enrich such reports. Authors should also consider how dissemination of their findings outside of scientific presentations at meetings may diminish the priority journal editors assign to their work. ~~An exception to this principle may occur when information that has immediate implications for public health needs to be disseminated, but when possible, early distribution of findings before publication should be discussed with and agreed upon by the editor in advance.~~

Sharing with public media, government agencies, or manufacturers the scientific information described in a paper or a letter to the editor that has been accepted but not yet published violates the policies of many journals. Such reporting may be warranted when the paper or letter describes major therapeutic advances; reportable diseases; or

10 Feb 2016 Statement “Data Sharing on Zika” by over 30 organizations

Journal signatories will make all content concerning the Zika virus free to access. Any data or preprint deposited for unrestricted dissemination ahead of submission of any paper will not pre-empt its publication in these journals.

Funder signatories will require researchers undertaking work relevant to public health emergencies to set in place mechanisms to share quality-assured interim and final data as rapidly and widely as possible, including with public health and research communities and the World Health Organisation.

We urge other organisations to make the same commitments.

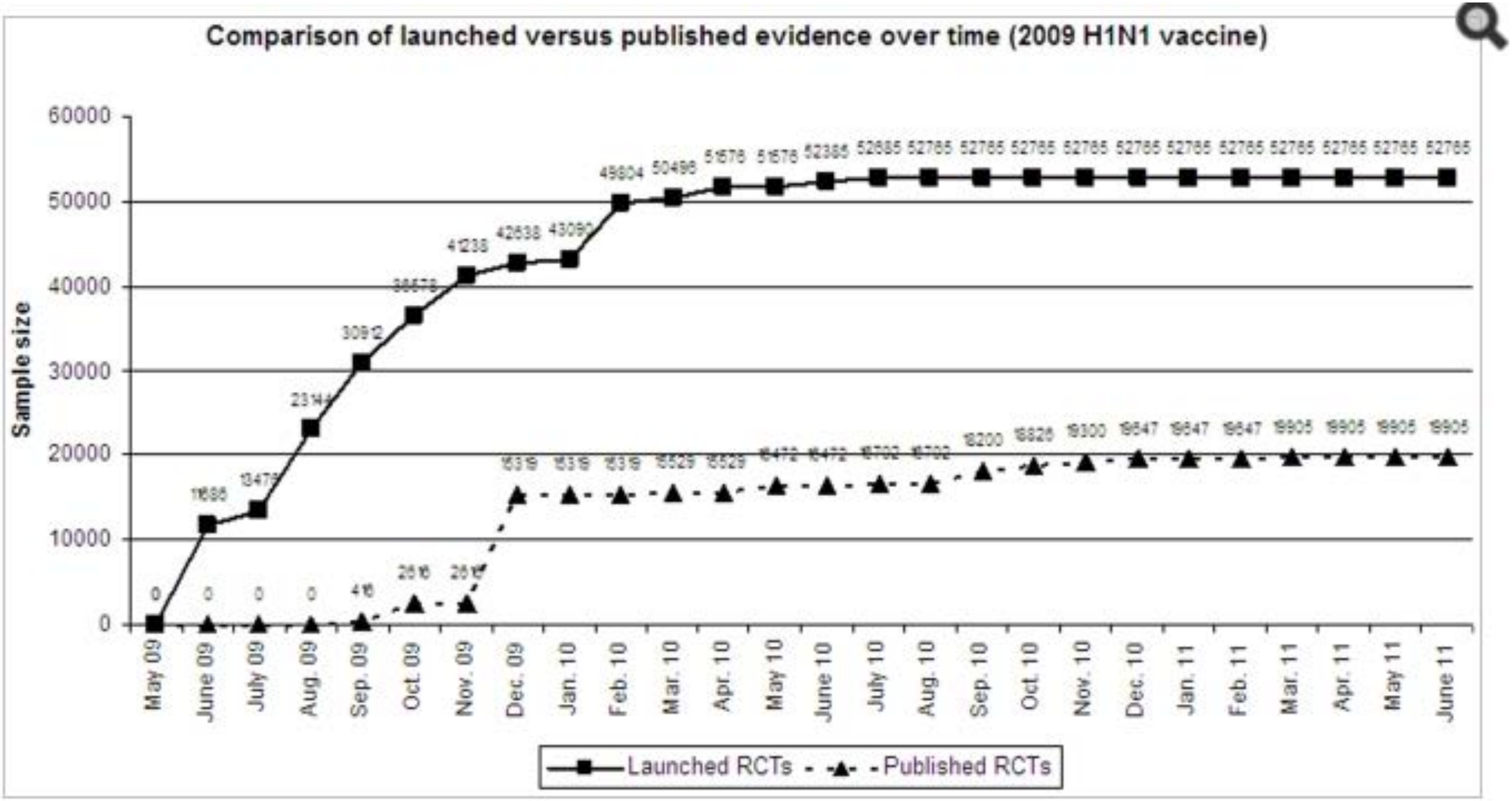
This commitment is in line with the consensus statement agreed at a WHO expert consultation on data sharing last year whereby researchers are expected to share data at the earliest opportunity, once they are adequately controlled for release and subject to any safeguards required to protect research participants and patients.

May 2016 WHO Statement on data sharing in emergencies

A WHO policy statement on data sharing by WHO in the context of public health emergencies has been adopted and was published in the Weekly Epidemiological record in May 2016. Under this policy, the WHO Secretariat will disclose data in accordance with the relevant provision of the IHR.

http://www.who.int/ihr/procedures/SPG_data_sharing.pdf

Delayed / non-reporting of pandemic vaccine trials: reporting bias remains a major issue



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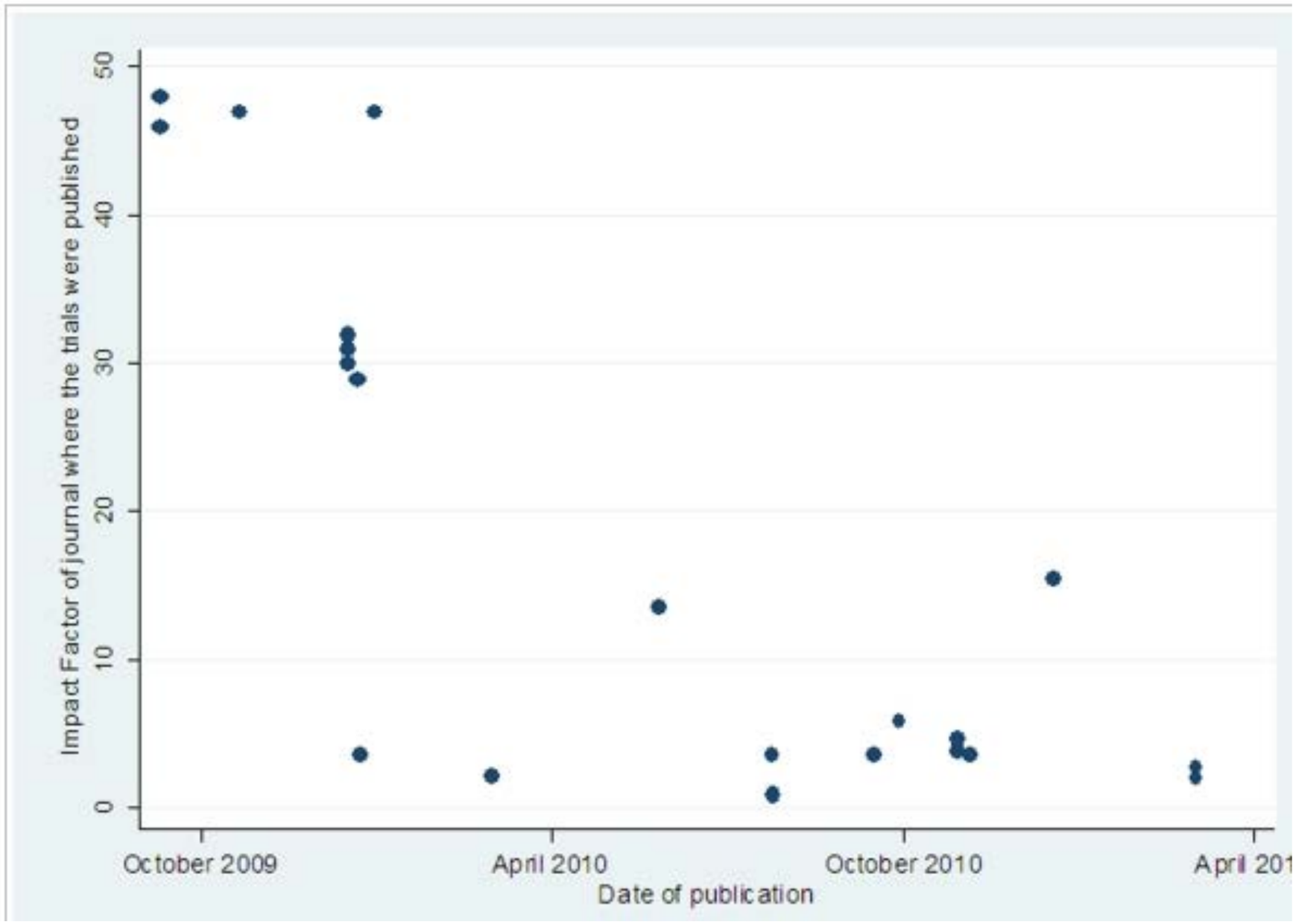
Impact Factor and time since emergency declared



PLoS One. 2011; 6(12): e28346.

Publication Delay of Randomized Trials on 2009 Influenza A (H1N1) Vaccination

J. P. A. Ioannidis et al.

World Health Organization

Key areas of implementation of agreed principles on data sharing

- Modalities for timely and transparent information sharing of the best available research evidence and data?
- **Incentives for data originators to share?**
- **Perspectives on credit for data originators?**
- Enhancing sharing of data before publication, where appropriate?
- Data sharing and sample sharing have distinct considerations

WHO is engaging with Wellcome Trust, GLOPID-R on development of a decision tree to **implement** enhanced data sharing in outbreaks and emergencies

WHO is engaging with development of frameworks for more open data sharing related to all of the following:

- Investigators/researchers
- Funders
- Medical Journals
- Commercial entities/manufacturers
- Ethics
- Regulatory authorities
- Governments
- NGOs
- Outbreak responders

Normative work on data sharing in emergencies

OPEN ACCESS

POLICY FORUM

Developing Global Norms for Sharing Data and Results during Public Health Emergencies

Kayvon Modjarrad, Vasee S. Moorthy ✉, Piers Millett, Pierre-Stéphane Gsell, Cathy Roth, Marie-Paule Kieny

Published: January 5, 2016 • http://dx.doi.org/10.1371/journal.pmed.1001935

http://www.who.int/medicines/ebola-treatment/data-sharing_phe/en/

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Decision Tree for data sharing in development by WHO, Wellcome Trust & GLOPID-R

Decision Tree: a concrete action plan for data sharing during emergencies

What is the critical data to be shared to enable the emergency response?

When should key types of data be shared?

By whom and with whom?

What data (and information) are needed at what stage (what is missing)?

How do the needs of responders differ from researchers?

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