BMTS 2019

CBMRT

Building a Network of Research Transparency Ambassadors

Hello,

Welcome to CBMRT's first newsletter - we're delighted to share with you the key points to emerge from our 2nd Biomedical Transparency Summit, held on February 15th in Bethesda, MD. **If you couldn't attend, read on to catch up on what you missed!**

In line with CBMRT's mission to increase transparency in biomedical research practices, we host a 5-year Biomedical Transparency Summit series in the US and Europe, the objective being to promote discussion and collaboration amongst diverse stakeholders in the movement towards greater transparency. This year's US event built on the success of the inaugural Summit in 2018, with an outstanding speaker line up and many participants returning for their second BMTS.

Keynote Speaker Dr Shai Silberberg: "Rigor and Transparency are Inseparable"

Dr Silberberg is Director for Research Quality, NIH National Institute of Neurological Disorders & Stroke and a passionate advocate for excellence in research practices. Speaking from personal experience (and not on behalf of NIH), his introductory remarks around publication, experimental and expectation biases served as a stark reminder of how easy it can be to lose sight of methodological rigor and the significant consequences of doing so. Dr Silberberg proposed greater reporting on methodological quality parameters (randomization, blinding etc) as integral to addressing bias.

Dr Silberberg also discussed bias in the context of the broader research ecosystem, describing what he called the "Paper Money" cycle. That is, researchers work within a tense rolling four-year cycle in which, assuming success in securing funding, publication becomes critical to ongoing survival/success. And the key to publication success is producing research that will likely yield a high impact factor once written up; is novel and innovative in its design; and produces 'significant' results. This in turn helps open the door to further funding, and the "Paper Money" cycle re-starts.

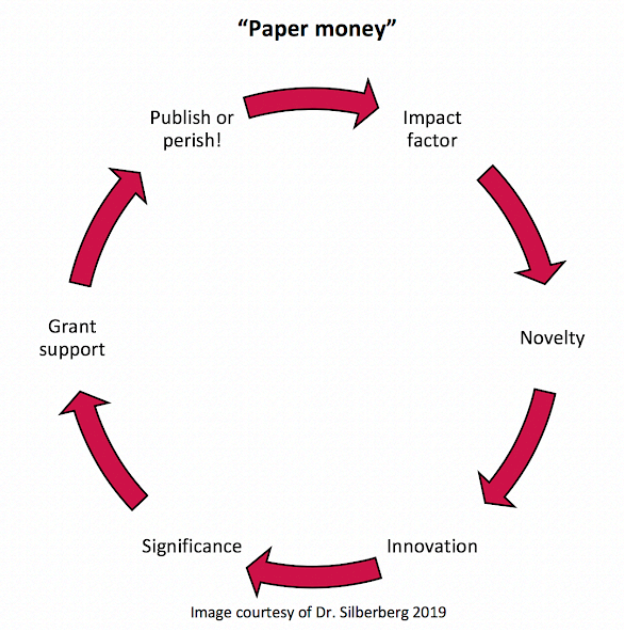

Image courtesy of Dr. Silberberg 2019

Dr Silberberg suggested that by devoting more attention to methodology reporting, a higher degree of transparency is instilled in the research process and in turn the incentive to strive for methodological excellence is increased - thus, rigor and transparency are inseparable.

"In conducting and reviewing research, the focus should be on rigor not glitter."

The NIH grant process expects full transparency in proposing and reporting experimental details so that reviewers may assess the proposed research and others may reproduce and extend the findings. It will take "communities of champions" such as that being built by CBMRT to drive the culture change required to make this standard practice.

Null Hypothesis: Say it how it is

Dr Sandra Petty (CEO, the Center for Biomedical Research Transparency) provided an update on CBMRT's Null Hypothesis (H0) initiative. H0 is a home for well-designed yet negative or inconclusive studies, and replication work that is difficult to publish presently through traditional scholarly channels. Dr Petty noted the significant value in publishing these under-reported research outcomes in terms of informing future research design, reducing funding wastage, and saving study participants from avoidable risks.

"As a physician, this issue is concerning; it is no less concerning for patients."

H0 is published in partnership with major scholarly societies and journal publishers using their existing infrastructure to source and peer review papers. The first print edition of H0 will appear as a supplement to the medical journal Neurology® later this year; numerous H0 Neurology® papers have already been

accepted and published online ahead of print on the Neurology® website. The H0 concept will be expanded into other therapeutic areas over 2019, the goal being to build momentum and positive exposure for the write-up and publication of negative, inconclusive, and replicative research studies.

"We aim to have Neurology® Null Hypothesis arrive on the screens, kitchen and labs of every Neurology reader, freely available."

Preprints - what's new?

Rather a lot according to the four preprints experts who presented and then chaired an engaging open discussion on the expansion of preprints into clinical medicine. Dr John Inglis (Executive Director of Cold Spring Harbor Laboratory Press and Co-Founder of preprints server bioRxiv) used his presentation to announce the forthcoming launch of a new server for health science preprints, medRxiv. MedRxiv will be operated by CSH Laboratory and managed in partnership with BMJ and Yale University and will cover 51 medical categories. Dr Inglis examined both the benefits and risks of medical preprints and outlined how medRxiv will mitigate the latter; specifically through rigorous submission requirements and in-house screening, and prominent 'health warnings' against preprint reliance in clinical practice.

"With preprints, the pace and transparency of research is accelerated."

Dr Deborah Sweet (Vice President of Editorial, Cell Press) provided fascinating insight into journal preprints strategy; emphasizing the very personal nature of a researcher's decision to preprint and the interplay between preprints and social media. Yet another interesting perspective was presented by Dr Jessica Polka (Executive Director of ASAPbio, a non-profit promoting transparency and innovation in life

"Preprint proliferation"

Image compiled by Jeroen Bosman (@jeroenbosman) via Bianca Kramer (@MsPhelps)

sciences publishing) who presented data indicating the increasing amount of time elapsing to publication of papers, especially for early career researchers. There is a significant role for preprints to play in addressing this, yet many preprints are not open access (CC-BY) and journals' preprint policies are nuanced.

What was clear from the ensuing audience discussion was that whilst the proliferation of preprint servers brings the significant benefit of early access to preliminary findings, the 'health warning' attached to such findings which are yet to be peer reviewed cannot be ignored.

The wonderful world of data sharing

Dan Valen of Figshare set the scene for the data sharing session, highlighting the current reproducibility crisis across science and outlining Figshare's adoption of the FAIR data sharing principles (Findable, Accessible, Interoperable, and Reusable). He also introduced the aspirational concept of the "Research Object"; a system where researchers record *all* research activity, with links to *all* data, analyses, output, etc., that is intelligently searchable and accessible from anywhere - and not just by humans but by machines.

Dr Joseph Ross (Yale School of Medicine) discussed the experiences and lessons learned from data sharing through the YODA (Yale University Open Data Access) Project, which seeks to address the problem of unpublished and selectively published clinical evidence. Intriguingly, the Project's origin was a 2011 RFP for two comprehensive independent reviews of all patient-level data from 17 clinical trials of marketed product rhBMP-2. To instill public confidence, the reviews were conducted independently of each other over the same timeframe and published simultaneously (they reached the same conclusions).

Since then, the YODA Project has approved 100 applications for access to third party data from 305 clinical trials which has led to 14 publications (and 9 under peer review). It is evidence of the power of evidence synthesis, data sharing, peer review, and reproducible research. Dr Ross noted a key lesson learned by the YODA Project has been the criticality of a robust policy for data sharing that is developed iteratively and collaboratively amongst stakeholders.

"Responsible data sharing strengthens science and positions research as a public good."

Ethicist Dr Jennifer Miller of Bioethics International reiterated the importance of projects such as YODA in increasing public trust in the pharmaceutical industry at a time when it is at an all time low. In discussing her organization's Good Pharma Scorecard initiative, Dr Miller emphasized her message with three numbers: Number 1 (what the industry used to be: the most admired business sector in the

world); 18 (years ago pharmaceutical companies still ranked among the top ten most admired companies); and 10 (percent of Americans trust that pharmaceutical companies are honest and ethical).

Dr Frank Meng (Veterans' Affairs Office of R&D) then proceeded to astound participants with his discussion of the Veterans' Affairs vast dataset and the complex mechanisms for researchers to access its potential richness. VA is one of the largest healthcare systems in the world; its data warehouse contains over 20 million patient records. Dr Meng outlined the challenges In sharing these clinical, genomic, and imaging data; from addressing consent and privacy issues to aggregating, de-identifying, cleaning and curating the data. The VA's data sharing efforts are nonetheless yielding benefits, including in precision oncology and the study of how genes affect health.

Ashley Farley (Bill & Melinda Gates Foundation) rounded out the Summit with a discussion of the Gates open access journey, which started with the publication of its open access policy in 2015. As a Plan S adopting funder, the Gates Foundation policy will integrate the Plan S principles into its policy over the next year. The Gates open access infrastructure, which all grantees must use, involves rapid (one week) publication (including source data) on Gates Open Research followed by an open peer review process. Researchers are then connected with over 26,000 compliant journals via the Foundation's Chronos portal, with the Foundation covering all publishing fees. Ms Farley acknowledged persistent obstacles to open access, including the impact on publishing decisions of career advancement concerns, and the fear of being 'scooped'.

"Change is hard and often it feels that the system is taking forever. But its hopeful and the future is bright. Everyone in this room has the power to take steps to build a more open and impactful future for research."

Thanks again to our fantastic speakers and participants for making BMTS'19 US a success. We'll be uploading speakers' presentations and summary videos to Figshare shortly - please email us if you'd like to receive the link. In the meantime, we invite you to share this newsletter with interested colleagues/contacts so that we can continue to develop our network of ambassadors for research transparency. Please also let us know of any of your European colleagues/contacts we should be inviting to BMTS Paris (May 15th, 2019). Finally, we'd appreciate your feedback and ideas on this newsletter (and CBMRT's initiatives more broadly)... and don't forget to follow us @CBMRT_org.

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