Data Sharing in Health needs to be FAIR-ER than in Science.

Susan E Smith 13/05/2022

The FAIR data principles: Findable, Accessible, Interoperable, and Reusable were designed as guiding principles to ensure scholarly output and research objects are reusable (Mons, et al. 2017) and to encourage more rigorous scholarship. Since publication in 2016, the original paper by Wilkinson et al., “The FAIR Guiding Principles for scientific data management and stewardship” has been cited 6689 times (to mid-2022) and continues to be widely interpreted and adopted.

The development of the principles focussed on scientific and scholarly data and products which infers some level of scrutiny of the activity should have already occurred via review of the research study design during the academic process. However the rapid uptake of the FAIR principles more broadly may risk a somewhat unfit application in non-academic environments. This could be especially critical in healthcare where large quantities of data are becoming more readily available through Digital Health and provide an increasingly valuable tool driving precision health as well as underpinning health system improvement through the Learning Health System.

The FAIR Guiding Principles were not intended to be stand-alone but were designed as a complement to proper data governance and data stewardship (Wilkinson et al. 2016). The Principles’ authors explain the ‘A’ in FAIR stands for ‘Accessible under well-defined conditions’ and emphasize ‘explicitly and deliberately’ that they do not address moral and ethical issues pertaining to the openness of data (Mons, et al., 2017). This is of particular importance in the re-use of Health data outside of the academic environment, where the FAIR Principles are increasingly being applied. As such some authors suggest modification of the FAIR principles for application to the health context. For example the CARE Principles were developed as an adjunct to FAIR by The Global Indigenous Data Alliance (Carroll, et al. 2019). The ‘CARE Principles for Indigenous Data Governance’: Collective benefit, Authority to control, Responsibility, and Ethics, relate to the *people* and *purpose* of data.

Similarly, Kozera et al. (2018) propose an extension of the FAIR Principles in relation to data and biological material from biorepositories should include: (1) quality aspects related to research reproducibility, (2) incentives to stimulate enrichment of data sets and biological material collections, and (3) privacy-respecting approaches.

The CARE Principles effectively include key considerations in health data re-use and the FAIR-Health Principles extend important aspects. However some may be duplicative or included in generally understood data management dimensions, such as data quality and reproducibility. Collective Benefit could be considered a key consideration in the Ethical harm vs benefit balance equation, while Responsibility encompasses critical concepts such as the secondary user’s responsibilities and accountabilities as well as the data curator’s responsibilities to the data donor, arguably including provision of authority to control and review their own data. However these concepts are not touched on by the FAIR Principles.

Just as the current data curation environment provides a one-sided position leading to lamentable barriers in health data sharing, the FAIR Principles could also be suspect of providing a somewhat one-sided approach. In contrast, the NHMRC Principles for accessing and using publicly funded data for health research (National Health and Medical Research Council, 2015) emphasize firstly the importance of maximising the use of health-related data for research but also highlight the responsibilities of the data custodians and the researchers:

1. Maximise the use of publicly funded health and health-related data for research
2. Data custodians should recognise their responsibilities and accountabilities when providing access to data for research
3. Researchers should recognise their responsibilities and accountabilities when accessing and using publicly funded health and health related datasets

Responsibilities also alludes to Reciprocity, a principle key to holistically addressing a range of socio-ethical issues related to data and biospecimen sharing (Gottweiss et al., 2011). This acknowledges that data donors should expect to see the return on their personal contribution and emphasizes the need for participant partnership, for feedback and transparency in outcomes, and which engages society, promotes data use and enhances trust.

Re-use and sharing of data in health is special; it is not the same as the sharing of academic scientific data products in science in general. Realising the benefits from health data sharing will be well assisted by applying the dimensions of the FAIR Principles -Findable, Accessible, Interoperable, and Reusable- but we should synchronously encourage key accountability controls in the principles applied to health data i.e. Ethics and Responsibility/Reciprocity. Therefore clearly, data sharing in health needs to be FAIR-ER than in science.

References:

Carroll, S. R., Herczog, E., Hudson, M., Russell, K., & Stall, S. (2021). Operationalizing the CARE and FAIR Principles for Indigenous data futures. *Scientific Data*, *8*(1), 1-6.

Gottweis, H., Gaskell, G., & Starkbaum, J. (2011). Connecting the public with biobank research: reciprocity matters. *Nature Reviews Genetics*, *12*(11), 738-739.

Holub P, Kohlmayer F, Prasser F, et al. (2018) Enhancing Reuse of Data and Biological Material in Medical Research: From FAIR to FAIR-Health. *Biopreservation and Biobanking*.16(2):97-105. DOI: 10.1089/bio.2017.0110. PMID: 29359962; PMCID: PMC5906729.

Mons, B., Neylon, C., Velterop, J., Dumontier, M., da Silva Santos, L. O. B., & Wilkinson, M. D. (2017). Cloudy, increasingly FAIR; revisiting the FAIR Data guiding principles for the European Open Science Cloud. *Information Services & Use*, *37*(1), 49-56.

National Health and Medical Research Council (2015) *Principles for accessing and using publicly funded data for health research.* Canberra: National Health and Medical Research Council.

Wilkinson, M. D., Dumontier, M., Aalbersberg, I. J., Appleton, G., Axton, M., Baak, A., ... & Mons, B. (2016). The FAIR Guiding Principles for scientific data management and stewardship. *Scientific data*, *3*(1), 1-9.

FAIR-ER: Findable, Accessible, Interoperable, Reusable – Ethical, Responsible/Reciprocity