


Research Article

Data Sharing Statements: The Case of the TSUNAMI Trial in Italy

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Abstract

Data sharing statements represent a fundamental pillar of transparency in science. We report here a case study showing the total failure of data sharing in a relevant clinical trial during the COVID-19 pandemic and advocate for urgent policy changes.

Keywords: COVID-19; JAMA;

Text

Data sharing represents an important part of transparency in peer-reviewed publications. When it comes to practice-changing clinical trials, access to anonymized datasets is a fundamental part of verification, with many journals mandating access to anonymized database upon reasonable requests.

We report here our odyssey at getting access to the raw dataset of the TSUNAMI randomized controlled trial investigating COVID-19 convalescent plasma in hospitalized patients in Italy, for which both authors served as co-investigators. The study was funded by public promoters (the Italian Health Institute – Istituto Superiore di Sanita' (ISS) - and the Italian Drug Agency – Agenzia Italiana del Farmaco (AIFA), and 487 patients were randomized at 27 sites since July 15 to December 8, 2020. The last patient concluded the 30-day follow-up on March 8, 2021. A brief press was promptly released by the study promoter on April 8, 2021, which reported an overall negative result but a positive subgroup analysis in patients with moderate disease [1]. During discussion of results in remote meetings, we reported an anomaly, where recruiting site 02 (contributing 20% of all enrolled patients) had an excess mortality in the CCP arm, entirely reverting the otherwise study outcome: nevertheless, the assistant editor demanded removal of all positive signals from abstract and manuscript, and one of us (M.F.) withdrew from co-authorship. The manuscript was never posted on preprint servers, and was published in JAMA Network Open on November 29, 2021 with the principal investigator as lead author [2]. Amazingly, during the review process at JAMA Network Open one of the reviewers raised identical concerns on the deviation at site 02. On December 14, 2021 we submitted to the European Journal of Internal Medicine a letter detailing our concerns on research integrity, made available online on January 9, 2022 [3].

On March 11, 2022 one of us (D.F.) initiated an informal interlocution with the public sponsor of the RCT in order to get access to the anonymized database to double check the results, but this request was denied on the basis of the RCT contract granting dataset access to the promoter only (adding that neither the principal investigator ever had access). On March 15, 2022, I initiated a formal request according to the Italian transparency laws (art.5, co.2, Legislative decree no. 33/2013), i.e., as every citizen could do. The sponsor of the trial, the ISS, raised privacy concerns about the risk

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of reidentification for the anonymized Italian recruits, something that would be practically impossible to do given that during the timeframe of TSUNAMI recruitment up to 17,000 patients per week were hospitalized across Italy [4]. Then on September 15, according to Italian laws I filed an appeal to the person responsible for transparency within the promoter institution, who on November 7 replied to me again that the promoter was "not able to accurately anonymize the data with internal resources". This sounded a silly reply, given that it was declared in the manuscript that the promoter used RedCap to maintain the dataset, and RedCap grants anonymized data extraction very easily (<https://docs.redcap.qmul.ac.uk/crf-design/anonymised-data/>, accessed online at on May 16, 2023). We are aware that a similar reply has been provided to at least one more interested citizen.

On January 12, 2023 we finally informed the JAMA Network Open editor-in-chief of our vain attempts, since their data sharing statement for the TSUNAMI paper recited in Supplement 4 [2] that deidentified participant data were available from GIMEMA (an affiliate of ISS) at the time of publication. The assistant editor just replied us that "While the JAMA Network journals endorse the principle of data sharing and have adopted a policy to encourage the sharing of data, sharing is not mandated by the JAMA Network and the journals are not in a position to enforce data sharing."

This story makes clear how such statements have very little to no value to the scientific community, potentially leading to unverifiable practice-changing conclusions. Accordingly, CCP usage in Italy was largely discontinued after the AIFA press release. Current regulations by the International Committee of Medical Journal Editors (ICMJE) do not yet mandate data sharing, but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions [5]. Investigators denying access to other interested parties after having stated in their publication declarations that their datasets would be available should not be allowed to disobey this agreement without consequences. We urge the ICMJE to mandate member editors to retract publication in situations where the

request to access data (previously declared as available) is refused by the corresponding authors, since this precludes post-publication checking on the accuracy of the data. We reason that this would be hardly a spontaneous initiative by the journal editors, given that it comes with the risk of reimbursing article processing charges.

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