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Ming Tang

Chief Data and Analytics Officer

NHS England

Sent by email

21 September 2023

Dear Ming,

Joint GP IT Committee supports a Direction to establish and operate an information system inside OpenSAFELY-TPP and OpenSAFELY-EMIS platforms for analytic purposes other than COVID-19 (initially for research, service evaluation, clinical audit and health surveillance but with the facility to extend to direct care, population health and commissioning analyses).

As you know, the committee has maintained an active interest in the development, implementation and use of the OpenSAFELY platform during the COVID-19 pandemic, including having representation on the OpenSAFELY Oversight Board[1]. Such close engagement with the profession culminated in the BMA writing to the Secretary of State for Health and Social Care in the summer of 2022 in support of OpenSAFELY[2] and the RCGP providing a private statement of support for Trusted Research Environments (TREs), such as OpenSAFELY, for the processing of GP data linked to other health and care datasets.

In addition, a GPES Data for Pandemic Planning and Research (GDPPR) assessment checklist[3] was created by the Profession Advisory Group, incorporating various privacy and transparency requests (all of which are implemented by OpenSAFELY). The checklist recognises OpenSAFELY as one possible TRE that the profession supports for COVID-19 related analyses on GP Data. Moreover, the England General Practitioners Committee of the BMA proposed that OpenSAFELY, along with three other national TREs, be assessed for their capabilities to provide all or part of the Federated Data Platform service[4].

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[1] OpenSAFELY, Governance

[2] 18.08.2022 BMA letter to Professor Ben Goldacre

[3] 2021-22 BMA/RCGP GP Data access standard

[4] Motion 12, page 28, LMC Conference 2022

The committee believes the recent successful passing of the OpenSAFELY COVID-19 Service Data Provision Notice[5] is testament to the genuinely collaborative involvement of key stakeholders in the development, implementation, and rules governing the use of GP data by the OpenSAFELY platform inside EMIS and TPP. In addition to the profession's involvement, we recognise the critical input of the public (three Citizens' Juries were commissioned by NIHR, NHSx and the National Data Guardian[6]; OpenSAFELY's Oversight Board also includes lay representation via a Digital Critical Friends Patient Advisory Group who input into the platform design and services developments[7]), privacy and patient advocates (such as medConfidential[8] and UseMyData[9]), colleagues in NHS England and the Department of Health Transformation Directorate, the OpenSAFELY team of software developers, clinicians and academics from the Bennett Institute at the University of Oxford and the London School of Hygiene and Tropical Medicine, and the GP system suppliers EMIS and TPP who provided their infrastructure and expertise on a pro-bono basis during the pandemic. Furthermore, the OpenSAFELY team quickly established a programme to invite and train external users[10], currently involving over 20 organisations[11]; this user group's research activities and feedback have directly shaped the development of the platform to improve user experience and the extensive online documentation[12].

The OpenSAFELY research and analyst community has rapidly adopted OpenSAFELY's privacy and transparency enhancing approach to the processing of patient data, as evidenced by the significant number of OpenSAFELY publications, many of which have been published in the most prestigious scientific journals[13].

Over the last three years, the committee has witnessed how the OpenSAFELY platform, and the services run by the OpenSAFELY team, have matured to become a critical component of NHS analysis infrastructure, providing value to patients and the NHS, whilst at the same time raising the bar on patient privacy and analysis transparency. In line with NDG advice regarding evidencing public benefit[14] when using patient data, the OpenSAFELY Data Provision Notice to practices outlines numerous benefits already achieved through the use of OpenSAFELY during the pandemic[15]; these benefits cover areas such as: enhancing patient privacy and transparency of the use of data; reducing

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[5] NHSD, OpenSAFELY COVID19 DPN

[6] NIHR, Data Sharing in a Pandemic: Citizens Juries

[7] OpenSAFELY, Oversight Board ToR

[8] https://twitter.com/medconfidential/status/1699759840724423121

[9] https://www.usemydata.org/advisory.php

[10] OpenSAFELY, Onboarding new users

[11] OpenSAFELY, Approved Projects

[12] OpenSAFELY, Website

[13] OpenSAFELY, Research

[14] NDG, Guidance - What do we mean by public benefit? Evaluating public benefit when health and adult social care data is used for purposes beyond individual care

[15] P. 4, Benefits, NHSD, OpenSAFELY COVID19 DPN

burden on GPs for data access; and a broad area of existing and future research and analysis such as COVID-19 vaccine effectiveness.

The committee, therefore, supports the use of OpenSAFELY-EMIS and OpenSAFELY-TPP to cover any approved research analyses (specifically, research, service evaluation, clinical audit and health surveillance), on the following basis:

- GP practices continue to remain the data controller for the pseudonymised event-level GP data (held in Level 1 - see Appendix)[16].
- The Profession Advisory Group (PAG), with representation from the BMA and RCGP (and funded by NHS England), provides independent professional check and challenge for all OpenSAFELY applications, as it does for COVID-19 GDPPR applications.
- OpenSAFELY aligns with patient dissent / opt-outs as per policy.
- Research studies continue to receive Research Ethics Committee review.
- The profession is involved as collaborators in the development, implementation and rules governing the use of GP data by the OpenSAFELY platform, including the review of all OpenSAFELY Data Provision Notices issued to practices.
- Only anonymous and aggregated data is permitted for release from OpenSAFELY. However, once OpenSAFELY is operationally open for new applications, the profession, as per the existing GDPPR assessment checklist[17], expects to support the wishes of participants who have given consent to process and link their GP data for research in another accredited environment, subject to the following conditions:
    - the participant consent process and materials (owned by the organisation conducting the research/study) have the support of the Advisory Group on Data;
    - such analysis cannot reasonably be conducted inside OpenSAFELY-EMS/-TPP, for example, where the transfer of specialist data to EMIS/TPP, such as genomic data, would pose an unnecessary cost if it is already hosted in another approved specialist TRE/SDE (simply “environment” from here on);
    - the receiving environment is both NHS England and Profession Advisory Group approved;
    - NHS England works with the Profession Advisory Group to agree the standards that must be met by the receiving environment before any coded patient-level cohort data is extracted. This coded patient cohort refers to OpenSAFELY’s Level 3 intermediate study outputs[18], i.e. only a curated patient-level dataset for those consented patients is extracted, with this dataset defined using OpenSAFELY’s study definition/ehrQL method (see Appendix). This method supports the GDPR principles, in particular data minimisation.

[16] OpenSAFELY, Security Levels

[17] Item 10, 2021-22 BMA/RCGP GP Data access standard

[18] OpenSAFELY, Security Levels

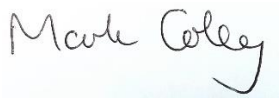
We believe the position of the committee also aligns with the recommendations of the Goldacre Review, for example:

- page 11: “Promote and resource “Reproducible Analytical Pipelines” (RAP, a set of best practices and training created in GDS and ONS) as the minimum standard for academic and NHS data analysis: this will produce high quality, shared, reviewable, re-usable, well-documented code for data curation and analysis; minimise inefficient duplication; avoid unverifiable “black box” analyses; and make each new analysis faster.”
- page 141: “Where an organisation has consent to extract patient data, it is reasonable for EHR data to flow there. More generally, a more appropriate paradigm is likely to be that data is minimised at source in one TRE, and the minimally disclosive transfer is subsequently made between TREs: so an analysis using sparse genomic data, but detailed EHR data, might be done better in an EHR TRE than a genomic TRE.”

We hope this letter helps you to expedite discussions with the Department of Health and Social Care and the Secretary of State on establishing a new Direction for the use of OpenSAFELY-EMIS and OpenSAFELY-TPP to now include non-COVID-19 analyses.

Finally, we are keen to hear from you about progress on implementation of the Type-1 Opt Out control for the OpenSAFELY COVID-19 Service, and when the service will re-open to new applicants.

Yours sincerely,



Dr Mark Coley
BMA Co-Chair Joint GP IT Committee

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Professor Ben Goldacre MBE, Joint Principal Investigator OpenSAFELY
Dr Amir Mehrkar, Director of IG and External Relations OpenSAFELY
Bennett Institute for Applied Data Science, University of Oxford
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Appendix
OpenSAFELY COVID-19 Service architecture, dataflows and access levels summary diagram.