Clinical **Data P**ublication, **A**dvisory and **S**upport **T**eam (Clinical DATAPAST) - Options appraisal

Author: Amir Mehrkar (OpenSAFELY Director of IG)
Reviewers: JGPITC co-chairs: Mark Coley and Imran Khan
Consultation: OpenSAFELY: Ben Goldacre; Pete Stokes; Brian MacKenna
Michael Chapman *pending*
NHS OpenSAFELY Steering Group *pending*
Wider JGPITC *pending*
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Summary

As a service to allow access to GP data within a governance framework, OpenSAFELY requires the occasional use (but an ongoing availability) of clinical expertise to projects and researchers, to decision makers, and to output checkers. Clinical DATAPAST (a Clinical **Data P**ublication, **A**dvisory and **S**upport **T**eam) is this proposed function. Access to GP data at a national scale for research and wider analyses has had a long and complicated history, with several failed attempts.

This paper documents the type of advice and support currently provided by the Director of IG (a practising GP and clinical informatician), and an options appraisal for an interim and sustainable Clinical DATAPAST. The interim proposal is for the Director of IG to have additional senior researchers from the Bennett Institute to help provide advice, with a sustainable solution to be established by NHS England and the GP profession by April 2025.

1. Background

In the early phase of the COVID-19 pandemic, the OpenSAFELY service was rapidly established with consultation from key stakeholders. A condition of support from the GP profession (as represented by the Joint GP IT Committee of the BMA and RCGP) for OpenSAFELY to process GP data was that each project's final output for publication (e.g. manuscript, report, presentation) would receive GP feedback and advice, independent of the publication's primary authors/project leads, before being submitted to NHS England for final approval.

This feedback from GP advisors[1] is one of several mitigations established by the OpenSAFELY service to address the GP profession's requirements:

- to maintain alignment with the project's approved purpose;

[1]including clinicians from other relevant professions with the necessary experience and skills to provide project-specific advice.

- to maintain the quality of the publication content by advising project leads regarding how clinical interactions are coded within GP EHR systems;
- to help ensure conclusions on clinical policies and services are supported by the data.

OpenSAFELY rapidly established a minimum GP advisory function (advice provided by the OpenSAFELY Director of IG, a practising GP and clinical informatician) to support the project leads in addressing the requirements of the GP profession. Due to the high volume of outputs being produced by the OpenSAFELY platform this advisory function is no longer sustainable or scalable with one individual; a pool of clinicians is required. We will refer to the proposed pool as the Clinical Data Publication, Advisory and Support Team (Clinical DATAPAST).

2. Scope of Clinical DATAPAST

The Clinical DATAPAST should provide advice only, and may not mandate any changes or determine the actions of others.

In addition to providing advice to study leads at the publication stage, the Clinical DATAPAST should function as an escalation support service for the output checking service (not to advise on disclosure controls but, for example, to help contextualise aspects of the data being analysed or describe how the data is collected and for what purpose) and be made available to approved project leads to provide early advice or support if required.

The Clinical DATAPAST should be available to the output checking service, for NHS England publication approval and to approved project leads.

The Clinical DATAPAST advice and responses from study leads should be made public; sent to the NHS England team that provides final publication approval; and shared with the GP Profession Advisory Group (PAG) who are initially involved in providing NHS England with advice regarding the initial support for a project.

The function should be budgeted for by NHS England as part of the wider OpenSAFELY services, but there should be no additonal charge made for its use by, for example, the output checking service, NHS England's publication approval team, and for any advice given to approved project leads.

Importantly, the OpenSAFELY team at the Bennett Institute are not the right organisation to host the Clinical DATAPAST in the long-term: the team should be an independent group of GP/clinical informaticians; the OpenSAFELY team's expertise is in the technical work of building and running a data platform.

3. What we learnt: advice and support for publications

During the pandemic many of the OpenSAFELY processes were initiated in good faith and without a full description of the work involved because of the urgency of the situation; as a result the OpenSAFELY team was "learning by doing" in a pilot phase.

With the pandemic over, following feedback from users, and in preparation for the new Direction to extend the processing of GP data beyond COVID-19 purposes, the OpenSAFELY Director of IG has documented in Appendix A the key types of advice and support for publications provided over the last four years before publication materials were submitted to NHS England for approval.

Importantly, Appendix A will provide the Joint GP IT Committee of the BMA and RCGP (JGPITC) with an opportunity to consider if these advisory and support activities continue to be necessary for a long-term Clinical DATAPAST function, what amendments might be needed, and to help JGPITC identify suitable GPs/clinical informaticians to take forward this function from April 2025.

4. Setting up the Clinical DATAPAST: practical considerations

Based on our experience, these are some of the practical considerations needed for NHS England and JGPITC to set up a Clinical DATAPAST to run at scale (not in chronological order):

1. Personnel required:
    a. Coordinator
    b. GP / clinical informatician advisors
2. Skills and knowledge needed in GP advisors:
    a. Qualified GP working in the NHS General Practice / registered and regulated clinical informatician / another member of the general practice team (appropriate for the project in question).
    b. Some knowledge of EHR data
    c. Some knowledge of quantitative research methods
3. Recruitment considerations:
    a. researchers in UK Primary Care departments
    b. Generalist GPs / clinical informatician in-training with relevant skills
    c. GP Health informatics forums / Digital Health forum
4. Personnel decisions and actions required:
    a. Payment by NHS England
5. Written documents
    a. Write role profile and job description
    b. Write ToR and objectives for clinical advisors; providing list of non-exhaustive areas for advice and support
    c. As service develops: write training/education/CPD material for clinical advisors.
    d. As service develops: write a test for potential clinical advisors
6. Dissemination process for advice template
    a. To whatever broader oversight group (eg the GP Profession Advisory Group; NHS England Publication Approval team; JGPITC; etc)
    b. Online location for advice where they can be attached to the project.
    c. An advice template to incorporate responses from authors.

   d. The advice template might be on a version of the paper that is very different to what eventually gets published: need to ensure date and version is specified when posted online. *Note: the OpenSAFELY policies for researchers specify that the results and conclusions must be final for material that is submitted for publication approval to NHS England*.
7. Governance
   a. Each publication submission to have at least two advisors; if possible three.
   b. Reporting to NHS OpenSAFELY Steering Group, JGPITC and GP Profession Advisory Group for oversight and audit of process and activity.
8. Who owns the advice reputationally?
   a. JGPITC: GPs/clinical informaticians are providing advice and support on behalf of the BMA and RCGP (e.g. BMA / RCGP representative roles).
   b. Not OpenSAFELY and not Bennett Institute (Bennett cannot be employer, or responsible for the independent advisory content).
   c. Not NHS England: cannot be employer, or responsible for the independent advisory content.
9. Foreseeable practical challenges
   a. Might be hard to recruit and retain good clinicians to provide the advice.
   b. The advice provided might (sometimes, or often) fall well short of expectations from key stakeholders (JGPITC, PAG, NHS England, OpenSAFELY team) on quality, consistency, and covering the relevant issues.
   c. Set-up and oversight especially in early days might be time consuming. Such activities include: administrative; recruitment; education and training; communications; etc.

5. Options Appraisal

	Options	**Pros**	**Cons**
1	**No Exit Reviews**	No further time and resources required to maintain and run a publication advice service. Reduces user administrative burden as only NHS England publication approval step. No risk of users perceiving an advisor might be attempting to censor any analysis which could appear reputationally negative to GPs.	Absence of a GP profession requested advisory service is highly likely to result in the BMA and RCGP losing confidence in GP data (recorded primarily for direct care purposes) being appropriately used and interpreted in secondary use analyses; the profession may formally withdraw support for OpenSAFELY to access GP data; another national GP data analysis programme fails. Risk of publications not complying with: approved purpose; OpenSAFELY

			policies; of poor quality with respect to GP data and primary care pathways inferences; unreasonable discussion and conclusions relating to care processes which creates unintended anxiety to patients, clinicians, and care teams. Reduces patient trust in GPs, primary care teams, care services. Reduces GP trust in how researchers use GP patient data; affects future data sharing initiatives; data analytics to improve services and for research.
2	**Temporarily continue existing OpenSAFELY clinical advisory service**	No further time and resources required to establish a new publication advice service; existing clinical advisory service well understood with adequate systems in place. Has worked for all publications till now.	Not sustainable or scalable: one person is a single point of failure due to the productivity of the OpenSAFELY platform. The throughput of applications will need to be restricted and this will significantly affect user experience; significant risk of loss of users who are keen to work using transparent and reproducible methods. Unreasonable responsibility on one key person: Director of IG. Outside of pandemic unacceptable conflict of interest for the Director of IG who has close working operational relationships with BMA and RCGP (via JGPITC).
3	**Temporarily continue existing OpenSAFELY clinical advisory service, with the three alterations:**	No further time and resources required to establish a new publication advice service; existing clinical advisory service well understood with	Identifying individuals with appropriate skills is hard: OpenSAFELY team is optimised for technical work on data platforms, and OpenSAFELY is trying to move non technical tasks

	1. temporarily relaxing the window period for providing advice from 2 weeks to 4 weeks **2. Allow wider Bennett Institute staff (qualified clinician or senior researcher with experience of the NHS data) to step in as second reviewer.**	adequate systems in place. Has worked for all publications till now. Shared formal responsibility for advice amongst the Director of IG and senior researchers who have expertise in clinical informatics and GP data. Reduces the conflict of interest for the Director of IG by having an additional individual formally providing advice on each paper reviewed. Drawing on wider Bennett Institute staff reduces the immediate workload burden on the Director of IG. Will ensure at least one advisor is a clinician with expertise in general practice.	such as this to NHSE or others. There are no other GPs in the Bennett Institute to provide advice for each publication; the Director of IG may lack sufficient understanding of all GP data and GP pathways of care and processes. Director of IG continues to have a wide portfolio of other responsibilities. Perceived lack of independence. Approved project leads or clinical professional groups may feel that staff at the Bennett Institute are too conflicted e.g. could provide more favourable reviews for the approved projects of Oxford/Bennett Institute staff, or be excessively concerned with reputation or other interests of the platform.
4	**Establish Clinical DATAPAST**	Service is clearly labelled as advice but also transparent, akin to journal peer reviews; involves GPs/clinical informaticians with relevant experience. Improves patient, clinician, public and GP profession trust regarding how GP and linked health data is used: in addition to all OpenSAFELY study code being public, there is a public narrative document (with response from users) for individuals who do not understand computer code.	Requires investment in time and modest resources to run the service; likely to take 6 months to fully establish. Scaling could be limited if unable to recruit sufficiently skilled GP advisors.

		Advice (and user responses) provides a rich learning resource to improve the quality of published material.	

6. Preferred Options

1. In the **interim immediately implement option 3** to provide additional support to the Director of IG;
2. For NHS England and JGPITC to build on the knowledge in this paper so that an update on progress to establish Option 4 (the Clinical DATAPAST function) can be presented at the March/April 2025 NHS England OpenSAFELY Steering Group and JGPITC meetings, with the intention that the Clinical DATAPAST will be fully implemented **from April 2025**.

Appendix A - Advice and support activities

Clinical **DATA P**ublication, **A**dvisory, and **S**upport **T**eam **(DATAPAST)** Template

This completed template will be placed in the public domain.

The Clinical DATA Publication, Advisory, and Support Team exists as one of several mitigations established by the NHS England OpenSAFELY service to address the GP profession's requirements:

- to maintain alignment with the project's approved purpose;
- to maintain the quality of the publication content by advising project leads regarding how clinical interactions are coded within GP EHR systems;
- to help ensure conclusions on clinical policies and services are supported by the data.

The DATAPAST function has the support of the Joint GP IT Committee of the BMA and RCGP; it is currently in a interim phase and the team providing advice includes clinicians (such as a GP or clinical pharmacist), as well as data scientists and epidemiologists with strong experience in GP data.

Following learning from this interim phase, it is envisioned that all advisors will be clinicians or clinical informaticians (or another member of the general practice team appropriate for the study in question).

Date completed	
Advisor Name (and clinical qualifications)	
Job Title	
Organisation	
Approved project link	
Conflicts of Interest	
Other notes	

Advice and support activities (this list is not exhaustive):

1	**Compliance with study purpose and policies for researchers** (do not copy over large bodies of content or tables, graphs or data into the template)
a	Does the publication material align with the purpose for which the study leads had their project approved?
STUDY LEAD RESPONSE:	
b	Does the publication material contain additional analyses that might be considered outside of scope of the approved purpose?
STUDY LEAD RESPONSE:	
c	Does the publication material satisfactorily obscure information (e.g. name, listsize) that identifies, or could identify, ICBs, Local Authorities (including MSOA identifiers), Primary Care Networks (PCNs) and individual GP practices?
STUDY LEAD RESPONSE**:**	
d	Are there any concerns that the publication material is produced to performance manage GP practices or PCNs? No performance management is permitted unless there exists explicit agreement and in writing that has been obtained through normal

	negotiating routes with the BMA and can be evidenced by the study leads (*this would be expected to be obtained at the application approval stage).*
2	**Quality** (do not copy over large bodies of content or tables, graphs or data into the template)
a	Is the paper written to an acceptable standard of clarity about GP data analytics?
STUDY LEAD RESPONSE:	
b	Have the results been interpreted correctly and are they informed by adequate knowledge of primary care data and primary care workflows? For example, have the QoF rules been interpreted correctly and applied appropriately to the study analysis and conclusions.
STUDY LEAD RESPONSE:	
c	Clarification may be sought about particular methods used, primarily to understand how the methods may take into account any nuances in the way clinical activity is coded (especially in primary care), and how clinical pathways are managed.
STUDY LEAD RESPONSE:	
d	Does the study create any risk prediction models (a requirement of the analytics methods policy is that any risk prediction model is detailed in the "Study Information" on the application, and must state if the model is intended for use in clinical practice).
STUDY LEAD RESPONSE:	
3	**Discuss and conclusions** (do not copy over large bodies of content or tables, graphs or data into the template)

a	Where there are criticisms of clinical policies or services, are these justified by the findings of the paper; and expressed in a way to avoid unnecessarily creating unintended anxiety to patients, clinicians, and care teams?
STUDY LEAD RESPONSE:	
4	**Any other comments** (do not copy over large bodies of content or tables, graphs or data into the template) Note: Use section 2 for advice regarding data and methods
STUDY LEAD RESPONSE:	

NOTES:
For the avoidance of doubt:

- a DATAPAST function is not intended to ascertain whether the statistical analyses are appropriate; this would be expected to be in the scope of the journal peer reviewers and the responsibility of study authors to assure. At the same time, members of DATAPAST can ask clarifying questions about statistical methods, such as to understand how any particular confounding variables that are unique to clinical care, GP management, or primary care pathways have been addressed, especially if it possible that such confounders may not be fully understood by the study leads.

- a DATAPAST function is advisory and does not censor content, whether it be safety concerns or evidence that care is suboptimal to audit standards, or other relevant comparators; study leads (and authors) maintain their intellectual right to how they describe their work in the discussion and conclusion sections. DATAPAST is there to provide helpful advice to how statements could be phrased constructively.