Minutes of the meeting of the Confidentiality Advisory Group

29 June 2023 via Zoom

Present:

Name	**Role**
Dr William Bernal	Alternate Vice Chair (Left during item 4c)
Dr Murat Soncul	Alternate Vice Chair
Dr Lorna Fraser	CAG Member
Dr Harvey Marcovitch	CAG Member
Mr Andrew Melville	CAG Member
Mr Dan Roulstone	CAG Member (joined after item 4b)
Mr Umar Sabat	CAG Member
C. Marc Taylor	CAG Member
Thomas Boby	CAG Member
Dr Malcolm Booth	CAG Member

Also in attendance:

Name	Position (or reason for attending)
Ms Katy Cassidy	HRA Confidentiality Advisor
Mr William Lyse	HRA Approvals Administrator
Mr Dayheem Sedighi	HRA Approvals Administrator
Ms Emma Marshall	HRA Confidentiality Specialist
Dr Paul Mills	HRA Confidentiality Advice Service Manager
Ninma Sheshi	Project Manager (attended item 3a)
Lara Amusan	Programme Manager (attended item 3a)
Julie Whitney	Clinical Lead (attended item 3a)

1. Introduction, apologies and declarations of interest

The following conflicts of interest were declared;

- COI – CAG Member Lorna Fraser has a conflict of interest with item 4c – Lucilla Poston is her Head of School at Kings College London and therefore did not participate in the development of the recommendation provided by the CAG.

- CAG Member Umar Sabat raised an interest with item 4b – the research will involve the use of General Practice Surgeries, where Umar may come in close contact. The CAG however did not note this as a conflict of interest and therefore Umar continued participation within this application review.

2. Support decisions

Secretary of State for Health & Social Care Decisions

The Department of Health & Social Care senior civil servant on behalf of the Secretary of State for Health & Social Care agreed with the advice provided by the CAG in relation to the **25 May 2023** meeting applications.

Health Research Authority (HRA) Decisions

The Health Research Authority agreed with the advice provided by the CAG in relation to the **25 May 2023** meeting applications.

Minutes:

The minutes of the following meetings have been ratified and published on the website:

- Full CAG Meeting 25 May 2023
- May sub committee
- Precedent Set Meeting 09 June 2023

3. Consideration Items

a. National Audit of Inpatient Falls (NAIF)

Secretary of State for Health and Social Care decision

The Secretary of State for Health and Social Care, having considered the advice from the Confidentiality Advisory Group as set out below, has determined the following:

1. The request to defer applying the National Data Opt-Out in relation to 23/CAG/0038 is conditionally supported, subject to compliance with the specific conditions of support.

Please note that the National Data Opt-Out should now not be applied to the confidential patient information used without consent under this application reference.

Scope of NDO deferral request

The Falls and Fragility Fracture Audit Programme (FFFAP) was conceived by The Department of Health (now Department of Health and Social Care), clinical experts, national clinical audit suppliers and the Health Care Quality Improvement Partnership (HQIP), to audit the standard of care received by patients who have suffered fragility fractures and the methods used to prevent future fractures. FFFAP includes three audits, the Fracture Liaison Service Database (FLS-DB), the National Hip Fracture Database (NHFD) and the National Audit of Inpatient Falls (NAIF). In December 2018, the applicants were given support, via submission of an amendment, to include the National Audit of Inpatient Falls (NAIF) under the existing 's251 support' for the Hip Fracture Audit (CAG 8-03(PR11)2013). In October 2022, the applicants submitted an amendment to the Hip Fracture Audit. Given the age of the existing application and the scope of the amendments, particularly the amendment to National Audit of Inpatient Falls (NAIF), new applications were requested, both to bring the applications up-to-date and to separate NAIF from the National Hip Fracture Audit.

Falls are among the most frequently reported patient safety incidents in hospitals. Around 250,000 inpatient falls occur every year in English hospitals. Hip fracture is one of the most serious consequences of a fall and of the more than 50,000 hip fractures recorded each year in England and Wales, around 2,000 are sustained in an inpatient setting. Many older people will not recover fully from a hip fracture, with around one third never regaining previous levels of mobility function. Hip fracture is also associated with increased mortality. Data are collected through retrospective audit notes and Key Performance (KPI) Indicators reflect fall prevention actions undertaken before the fall that caused the fracture as well as the immediate post-fall management. The standards measured against are taken from NICE Clinical Guidelines and NICE Quality Standards.

All patients in England and Wales with a femoral fracture sustained in any NHS commissioned inpatient setting (acute, community or mental health) are eligible for inclusion in NAIF. Confidential patient information will be entered by the NAIF team at participating trusts directly into the NAIF webtool. Patients will be cross-referenced with the NHFD for duplicate case reports. Confidential patient information is then stored by Crown Informatics, who link the data and share anonymised and aggregated data to the NAIF team at the Royal College of Physicians. Additionally, Crown Informatics will transfer identifiable, patient level audit data to NHS England and/or Digital Health and Care Wales when a request has been approved by the RCP and HQIP by way of the FFFAP Scientific and Publication committee. NHS England transfer HES and ONS to the third-party applicant NWIS transfer PEDW data to third party applicant, following application to Digital Health and Care Wales Information Services.

Data is also provided from the NHFD. Data initially arrives to the NAIF webtool from cases identified as a hip fracture occurring in an inpatient setting, entered via the NHFD.

This identifiable information is then transferred from the NHFD team to the same trusts' NAIF team to confirm the fracture was a result of a fall that occurred in their trust or to allocate to the appropriate trust if the fracture occurred in another NHS organisation. Once the case has been received at the appropriate trust, Crown informatics (IT contractors), will then link validated identifiers and use the data in the webtool to inform the live KPI performance data. Upon finalising the analysis of the data, the analyst contractors will then share anonymised and aggregated data to the RCP NAIF team for commentary and to publish the annual report. Additionally, IT contractors will transfer identifiable, patient level audit data to NHS England and/or Digital Health and Care Wales when a request has been approved by the RCP and HQIP by way of the FFFAP Scientific and Publication committee. NHS England transfer HES and ONS to third party applicants (following application to NHSD DARS, facilitated by Crown and the RCP). Digital Health and Care Wales transfer PEDW data to third party applicant, following application to NWIS Information Services (facilitated by Crown and the RCP).

Confidentiality Advisory Group advice

1. Deferral rationale: patient safety

Falls are amongst the most frequently reported patient safety incidents in hospitals. Around 250,000 inpatient falls occur every year in English hospitals. The patients who form the NAIF cohort have sustained a hip fracture while in hospital. This patient cohort is amongst the frailest of the population. A high proportion experience cognitive impairment or delirium and, in 2021, over half (52%) of cases had delirium prior to the femoral fracture. 30-day mortality for this cohort is 12%.

These patients face poorer prognosis, including risk of death or institutional care placement, following a fall or fracture, and are a key target for the benefits that the work of the audit has been demonstrated to confer, including reduced risk of fall related injury and/or improved recovery after hip fracture and surgery.

A recent study based on the NHFD by Sheehan et al (2020), demonstrated that different patient groups experience very different care and outcomes after a hip fracture. Socioeconomically deprived patients receive different types of surgery from those from less deprived backgrounds.

According to the National Data Opt-Out open data dashboard as of 1 May 2023, patients that are in the age groups that would qualify for the NAIF audit (ages 60-79) had opt out rates of ~6% which is slightly higher than the national average (5.4%). In addition, there is geographical variability in opt-out rates. This means that trusts in some areas will produce less reliable data, simply because of the proportion of missing data that will arise as a result of application of the National Data Opt-Out. Some hospitals will therefore be falsely reassured of the quality of care they are providing, whereas patients and staff in other hospitals may be misidentified as a concern for the

same reason. This will affect the audits' patient safety monitoring responsibilities to Welsh Government, GIRFT, Model Hospital and the Care Quality Commission (CQC).

This audit currently examines the care of people who sustain a femoral fracture in each hospital. Since the average trust submits data on fewer than 10 patients each year, any reduction in numbers could have a serious effect on the reliability of the data that informs the trust level Key Performance Indicators (KPIs). Should NDO deferral not be granted to NAIF this would result in loss of data that would reduce the reliability of the audit outputs including KPIs that trusts use to monitor patient safety and identify areas for improvement. There is a risk that this will lead to organisations losing trust in the audit. The consequences of this would be lack of participation, including not submitting data for patients without opt-out, and poor engagement with the audit findings in driving improvement activities, thereby feeding into practices that could put patient safety at risk. The impact of this could cross over into confidence and participation with related audits such as the National Hip Fracture Database (NHFD).

2. Deferral rationale: Introduction of bias

NAIF is valued by the clinical teams who participate, who make use of the national and trust level data, as well as our related resources to improve the quality of inpatient fall prevention and post-fall management, both of which have a vital role in upholding patient safety. Any loss of data would threaten the generalisability and integrity of the data. If the audit data were less reliable, trusts/local health boards may be less likely to engage with the audit and the improvement resources. This is a particular risk concerning trust level data where loss of any cases could reduce the utility of the audit data in supporting local improvement activities and monitoring patient safety.

3. Deferral rationale: technical impacts

The FFFAP as a whole has an ongoing commitment to improving the transparency of currently available literature through patient information leaflets and web resources offered to patients and the public. The public facing RCP website, the active involvement of the patient representative and patient groups on the NAIF Advisory Group and the requirement for every patient to receive a patient information leaflet with the 'opt out' option, is part of that commitment.

NAIF has a fair processing statement which includes information for patients including what the national audit of inpatient falls is, what a clinical audit is, how patients can opt-out, how patient information is processed, and how to raise concerns.

The applicants provided a Fair Processing Statement.

The applicants also aim to create an easy-read version of the materials, with links to a more detailed document for further information. This patient notification will explain how patients can opt-out.

Informing the patient population

The CAG noted that the Fair Processing notice provided was unchanged from the version provided with the resubmitted application and had not yet been revised in line with the conditions placed on that application.

As part of the resubmitted application, the applicants had been asked to adopt a layered approach to patient notification. This was to include simplified, easy-read versions of the patient information, with more detailed information to be provided on request. Members noted that information on a layered approach to patient notification is available on the ICO website.

The materials also needed to explain how patients can request the removal of their data. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data. The patient notification materials also need to contain a clear explanation of the exemption of application of the National Data Opt-Out.

Confidentiality Advisory Group advice conclusion

The CAG would like to note that the decision to overrule patient's wishes expressed through their enrolment in the National Data Opt-Out is not taken lightly, and that the Group is only minded todo so in exceptional circumstances. The CAG recommendation is based on the documentation provided. Following thorough review of the request rationales, members agreed that the patient safety rationale and bias issues were strong and provided appropriate rationale for advising why the National Data Opt-Out should not be applied to this data flow.

Whilst a patient notification strategy and draft notification materials were provided, the CAG felt that the applicant could improve the patient notification materials, and CAG should have oversight of these within 6 weeks.

The CAG agreed that they were supportive, in this specific instance, of the request for the application of the National Data Opt-Out to be disapplied in relation to the non-research activities contained within 23/CAG/0038. The CAG therefore recommended to the Secretary of State for Health and Social Care that the National Data Opt-Out deferral request be conditionally approved.

Specific conditions of support

1. The below revisions to the patient notification strategy need to be made and reported to the CAG within 6 weeks of the issuing of this outcome letter.

    a. A layered approach to patient notification is to be adopted.

b. The materials need to explain the project-specific dissent mechanism and include telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.
c. The patient notification materials also need to contain a clear explanation of the exemption of application of the National Data Opt Out.

2. The National Data Opt-Out is not to be applied to patients included in the activities specified in 23/CAG/0038.
3. A local patient objection mechanism must continue to be used in relation to 23/CAG/0038.

4. New Applications

a. 23/CAG/0078 - AD|ARC (Administrative Data Agri-Research Collection) England: Linking Individual and Farm Level Data for Agricultural Research

Context

Purpose of application

This application from Queens University Belfast set out the purpose of examining the physical and mental health of farmers, farm households and farm workers.

Agriculture is currently facing a number of challenging, including the potential impact of both economic and environmental change on farm household incomes and on the health and well-being of farming households. Climate change is also a growing concern, which will require the entire agricultural sector to change significantly over the next few years. Supply chain disruptions and the energy crisis have also added to the stresses on the sector. The aim of the project is to use data linking to create an anonymised agricultural dataset for all farms in England. The dataset will include all farmers, farming household members and farm workers. The data will be used to investigate the composition and characteristics of farming households and farming household health compared to a rural control group.

ONS will use the 2010 EU Farm Structure Survey to create a spine of around 105,000 farms in England and undertaken further linkages to the Census of Population 2011, the Inter-Departmental Business Register and existing Growing up in England Research Ready Dataset. The process of creating this dataset is outside the scope of s251 support and the data is not confidential patient information. ONS will disclose the

list of all Lower Super Output Areas (LSOAs) in England that contain at least one farm to NHS Digital, who will then provide the health data for all residents within each of the listed LSOAs by linking to GPES Data for Pandemic Planning and Research (COVID-19), Hospital Episode Statistics Outpatients and Civil Registration – Deaths. The linked dataset will then be returned to ONS and held in the ONS SRS.

A recommendation for class 1, 2, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	• All household members residing at a farm address in England, • All household members of a residence in England where one or more individuals have stated their occupation is farming on the census of population, • The control group will comprise of all residents residing in an LSOA in England that contains one or more farms
Data sources	1. NHS England held datasets: a. GPES Data for Pandemic Planning and Research (COVID-19) Hospital Episode Statistics Outpatients b. Hospital Episode Statistics Accident and Emergency c. Hospital Episode Statistics Admitted Patient Care d. Civil Registration – Deaths 2. EU Farm Structure Survey, held by DEFRA 3. The 2011 Census of population, held by ONS 4. Growing up in England Dataset, held by ONS and Department of Education 5. Inter-Departmental Business Register, held by ONS

Identifiers required for linkage purposes	1. Name 2. Date of birth 3. Date of death 4. Postcode – unit level
Identifiers required for analysis purposes	1. Year of birth 2. Month and year of death 3. Gender 4. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG agreed that this research was in the public interest, however members agreed that the medical purpose in the activity was unclear. Members noted that the remit of s251 covers processing of confidential patient information for health-related purposes only, while the application had a wider remit. The CAG requested that the applicant provide an explicit research plan that explains how the health data will be used and clarifies the specific health-related research questions.

Scope

The members noted difficulty in understanding the data flow diagram and therefore, requested for a revised data flow diagram in line with guidance from the CAG website: Guidance for CAG applicants - Health Research Authority (hra.nhs.uk)

The CAG noted that the GPES Data for Pandemic Planning and Research (COVID-19) Hospital Episode Statistics Outpatients would be linked to. The members understanding was that this data was created exclusively for the use of Covid-19 related research and requested confirmation that this data could be used in wider health research.

Members requested further details on the potential size of the cohort involved, noting that not only farm owners would be included in the scope of the project, but also the control cohort and farm workers, including seasonal workers.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

The CAG noted that much of the information required was potentially already collected in existing datasets held by the Office of National Statistics (ONS), particularly data relating to the control cohort. Members asked that the applicants discuss with ONS whether existing datasets could be used.

- **Feasibility of consent**

The applicants noted that consent was not feasible as this is a data linkage project conducted at a national level and collecting data for approximately 105,000 farms. It would not be practicable to contact all the data subjects in order to gain consent.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

NHS England require access to confidential patient information to undertake the linkages to the GPES Data for Pandemic Planning and Research (COVID-19) HES datasets and Civil Registration – Deaths. As noted above, the CAG asked that the applicant explore whether the ONS already collect some or all the required data.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

During the set up and data acquisition phase of the project (since August 2020), the applicants have posted information about the project and regular blogs on the ADR UK website. This information was shared on social medial by the Stakeholder Reference Groups to members of the farming and wider rural community alongside the project's contact details and a link to the website.

The applicants noted that the website and public materials have been targeted primarily at farming households. Over the next few months, the applicants will be extending this to incorporate the wider rural population more explicitly. No linkage will take place until the website covers this adequately.

A project website page had been created. The project website advises patients that their data cannot be identified and removed and from the database and directs patients to the National Data Opt-Out. Flyers about the project including the link to the website are being distributed at agricultural shows around the UK. This did not advise patients that they could opt-out. NHS England will apply the National Data Opt-Out.

The CAG agreed that a project-specific dissent mechanism would need to be created. The patient notification materials needed to advise that patients can opt-out and explain how to do so.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have conducted public engagement activities to obtain the views of stakeholders and the general public. Many farmers had assumed that this work was going ahead without all the controls that are in place.

Three meetings were held with stakeholder reference groups (SRG) to discuss the detailed project plans, what datasets the project would be using, how the datasets would be stored and analysed alongside the legal and safety considerations. The Stakeholder Reference Groups represent the wider rural community e.g. the Prince's Countryside Fund and the Country Land and Business Association. The applicants

planned to continue to meet regularly with their stakeholders to co-produce the research, discuss preliminary results, and consult on current and future data acquisitions.

The CAG noted that it was important to include groups other than farm owners in the patient and public involvement. A revised application would need to include feedback from consultations with representatives of the control group and farm workers, including seasonal workers. Feedback on discussions of the specific issue of use of confidential patient information without consent also needed to be included.

The CAG requested clarity on the construction of the stakeholder reference group. The CAG wished to see expert representation within this group, specifically experts who have worked with a similar volume of data before.

Exit strategy

The applicants advised that year of birth will be sufficient for analyses using the de-identified dataset.

Month and year of death only will be held by the project for analysis. Month and year only will also be applied to any other data such as admissions.

The CAG was content with the proposed exit strategy.

Confidentiality Advisory Group advice conclusion

In line with the considerations above, the CAG agreed that, on the basis of the information provided, they did not have sufficient information to provide a recommendation under the Regulations.

Following advice from the CAG, the Health Research Authority recommended that the application was deferred.

Further information required

To support a future application(s), the below points should be taken into consideration. A detailed covering letter should be provided to support the revised application submission, which addresses the below points and sets out where revisions have been made to the revised CAG application.

1. A plan needs to be provided which explains how the health data will be used and clarifies the specific health-related research questions.

2. A revised data flow diagram needs to be provided.

3. A project-specific dissent mechanism needs to be created and explained in the patient notification materials.

4. Clarify whether the GPES Data for Pandemic Planning and Research (COVID-19) Hospital Episode Statistics Outpatients can be used for research other than Covid-19 specific research.

5. Further details on the potential size of the cohort involved need to be provided.

6. Clarify whether the Office of National Statistics (ONS) already holds data that could be used.

7. Feedback from consultations with representatives of the control group and farm workers, including seasonal workers, needs to be sought during patient and public involvement. Feedback on discussions of the specific issue of use of confidential patient information without consent also need to be included.

8. Provide clarification on the construction of the stakeholder reference group, including whether any members would be experienced in working with similarly large datasets.

b. 23/CAG/0076- Using artificial intelligence (AI) to characterize the dynamic inter-relationships between MUltiple Long-term condiTIons and PoLYpharmacy and across diverse UK populations and inform health care pathways (AI-MULTIPLY)

Context

Purpose of application

This application from Newcastle University set out the purpose of medical research that seeks to determine how multiple long-term conditions and polypharmacy interact and this interaction is modified by inequalities.

Multiple long-term conditions (multimorbidity)(MLTC-M) are defined as having two or more long-term conditions (LTC) and are associated with premature mortality, significant treatment burden for patients and carers, and increased healthcare use. Healthcare systems and research infrastructure are not configured to address MLTC-M. Previous work on MLTC-M have focused on older populations due to the increased prevalence in this group. However, the number of people aged under 65 and who have a diagnosis of MLTC-M is higher. Polypharmacy (the simultaneous use of five or more medications) and MLTC-M polypharmacy are associated with MLTC-M, but the relationships between polypharmacy, MLTC-M and health outcomes are poorly understood. The aim of this application is to characterise MLTC-M and polypharmacy trajectories and to define the relationships between MLTC-M clusters, polypharmacy, and healthcare outcomes. Two work packages are involved. In Work Package 1, data from several large national and local datasets will be collected. Use of AI techniques to analyse the data will be conducted in Work Package 2.

Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH), Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (CNTW) and GP practices will disclose confidential patient information to the North of England Commissioning Support Unit (NECS). NECS will apply a common pseudonym to support linkage across datasets, using the NHS number and date of birth to create a shared dataset containing all data from each of the contributing NHS trusts for each participant. This pseudonymised data will then be shared to the Axym datasystem, held within NECS. The research team will not receive access to the pseudonymisation key. Axym will provide an individual secure data access environment allowing designated users from Newcastle University to interrogate their data.

A recommendation for class 1, 4 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Adult patients aged 18 years and over with 2 or more multiple-long term conditions confirmed. Around 4.4 million patient records will be included.
Data sources	1. Patient records at participating NHS trusts: a. Newcastle upon Tyne Hospitals NHS Foundation Trust b. Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust 2. Patient records at participating GP practices: a. Roseworth Surgery b. Park Medical Group c. Walker Medical Group d. West Road Medical Centre e. Walker Road Medical Centre f. Benfield Park Medical Centre g. Heaton Road h. Westerhope Medical Centre i. Regent Medical Centre j. St Anthony's Health Centre k. Denton Turret Medical Centre l. Dilston Road Surgery
Identifiers required for linkage purposes	1. NHS number 2. Date of birth 3. Postcode – sector level
Identifiers required for analysis purposes	1. Date of birth 2. Date of death 3. Postcode – sector level 4. Gender 5. Ethnicity

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Following consideration of the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

Scope

The CAG noted that it was stated the data leaving the Trusts was going to be pseudonymised and for that reason the application was only requesting section 251 support for the initial linkage. However, the CAG noted that the dataset would later be sent to the Commissioning Support Unit in the North-East to be linked again, which means that the data will not be completely anonymised as they were able to re-identify those patients. The CAG requested clarification on why support was not required for the data that was leaving the Trusts, as it would be possible to re-identify those patients.

The CAG was unclear about the list of data sources given in the application. It was noted that the data sources were going to be anonymised and there were no plans to link the data sources to the datasets that they were creating. The CAG requested clarification from the applicant to explain at what stage in the research the data sources listed in the application are going to be incorporated in the research.

The members also commented that the data flow diagram was quite difficult to understand and asked that a revised data flow diagram was provided.

The CAG noted that the research is separated in two different phases, Phase 1 and Phase 2. The CAG requested confirmation on whether the applicant was requesting support only for phase 1 which included the initial linkage and 11 GP practices.

The CAG was also unclear whether the research was planning to use free text data for the data that they were collecting from the practices and hospitals, the members requested clarification. The CAG noted that if the research is going to use free text data in the research, then they would expect an explanation on how the free text data will be anonymised.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

The applicants advised that, as Work Packages 1 and 2 involve the analysis of large datasets that include a significant number of patient records from primary and secondary care. Seeking consent was not feasible due to the resources required.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

NECS require access to confidential patient information in order to link data from the two participating trusts to GP data.

Confidential patient information is required to link patients across different datasets.

The CAG was content that using anonymous information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

'Notification of dissent' notices are available to be displayed as posters in waiting rooms of relevant local sites. Notices will include information on how to opt out. The notice notifies participants that they are able to dissent from the use of their records for the research and provides the email contact of the Data Protection Officer (DPO) at the local site as the person to contact to withdraw /dissent.

The 'Notification of dissent' notifies participants that they can dissent from the use of their records for the research and provides the email contact of the Data Protection Officer (DPO) at the local site as the person to contact to withdraw /dissent.

The CAG noted that the National Data Opt-Out will be applied at the sources for the hospital trusts however it is unclear how this will work for GP practices. The CAG requested clarification.

The CAG requested that a layered approach to patient notification was used, where simplified, easy-read information was provided in the first instance, with more detailed information available on request. An explanation of the AI component of the research needed to be provided in lay language and an explanation of the use of the data and how the algorithm was going to work.

The CAG requested that the patient notification explain how a patient can request the removal of their data, both via a local opt-out and the National Data Opt-Out.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The applicants have worked with a number of PPIE members to co-develop a patient and public involvement strategy, website, plain English information sheets and lay summaries.

Patient and public involvement members recommended forming multiple small groups, to ensure representation across the MLTC spectrum, and that individual representations are heard. In collaboration with patient and public involvement collaborators, the applicants have developed a network of groups with shared geographies, or healthcare experiences. A ‘you said, we did’ feedback approach has been used to highlight how the project has responded to patient and public voices following each interaction.

During the initial development of the current research application, the applicants consulted with 35 patients from the North-East and East London, representing underserved, socio-economically disadvantaged, and ethnic minority communities, and seven community pharmacists and GPs with experiences of polypharmacy and MLTC.

Since receiving funding, the applicants have held workshops with a further 50 members of the public across the UK, from a range of sociodemographic backgrounds. The information shared included an overview of the project and the work packages within it. This included the methods to be used in the project and how data would be used to investigate the project's aims. The applicants shared a list of the 204 conditions which are to be used to determine the data cohort shared as the GNCR-ADS. Feedback on this list was encouraged.

The CAG noted that they were impressed with the proportion of the patient and public involvement undertaken for phase 1, however if the research is going to expand eventually, the CAG expects a strategy on engagements as it will be useful to see how that strategy will evolve.

Exit strategy

Data linkage will be required for the duration of the project plus three years, to enable data to be checked following publication of the results. NECS will delete the confidential patient information provided to facilitate linkage 36 months after the project completion. The dataset disclosed to the research team will be pseudonymised by NECS. NECS will retain the key and will not share with the research team.

Data will be held for five years after project completion to allow for requests to check data analysis following publication.

The CAG was content with the exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

In order to complete the processing of this application, please respond back to all of the request for further information, and actions required to meet the specific conditions of support where indicated, within one month.

Request for further information

1. Clarify why support is not required for the data that is leaving the Trusts.

2. Explain at what stage the data sources listed in the application are going to be incorporated in the research.

3. An updated data flow diagram needs to be provided, in line with the advice in this letter.

4. Confirm that this application is requesting support only for phase 1 of the research which includes the initial linkage and the 11 GP practices.

5. Confirm whether the research is planning to use free text data for the data collected from practices and hospitals. If yes please explain how you will ensure that the free text data will be anonymised.

6. Explain how the National Data Opt-Out will be applied within GP practices.

7. Patient notification materials need to be created. The materials must include the following:

    a) In layered approach and lay language explain the AI component of the research and justify the use of data, and how the algorithm is going to work.

    b) An explanation on how patients can request their data the removal of their data, either via a local opt-out or the National Data Opt-Out needs to be provided. The CAG usually expects that telephone, email and postal contact details are provided, should patients have queries or wish to dissent to the inclusion of their data.

8. A strategy engagement needs to be provided which explains how further patient and public involvement will be undertaken as the project expands.

Once received, the information will be reviewed by a sub-committee of members in the first instance and a recommendation and decision issued as soon as possible. At this stage it may be necessary to request further information or refer to the next available CAG meeting. If the response is satisfactory and the outstanding actions listed in the specific conditions of support are met, a final support outcome will be issued.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Confirmed: 30 March 2023**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. See section below titled 'security assurance requirements' for further information. **Confirmed:**

   The NHS England **21/22** DSPT review for **Newcastle University, Newcastle upon Tyne Hospitals NHS Foundation Trust, North of England Commissioning Support Unit and Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04 July 2023)

   Due to the number of participating organisations involved it is the responsibility of Newcastle University and Newcastle upon Tyne Hospitals NHS Foundation Trust as controller, to ensure that participating GP practices meet the minimum required standard in complying with DSPTs, and take remedial action if they become aware of any that fall below this, or where any concerns are raised.

c. 23/CAG/0080 - eLIXIR Research Tissue Bank/Database

Context

Purpose of application

This application from King's College London set out the purpose of seeking support under s251 for an existing research tissue bank and database, set up to investigate the temporal and demographic influences on the health of pregnant women and their children.

The eLIXIR Research Tissue Bank (RTB) was created in 2018. The aim of the Research Tissue Bank and Database is to investigate the mechanisms underlying common and less common disorders of pregnancy and neonatal health and their longer-term effects on the health of the mother and child.

Support is sought to allow researchers, who are not part of the direct care team, to pre-screen the medical records of potential donors to identify suitable participants and make contact ahead of their antenatal appointments to seek consent to participate in the Tissue Bank. The applicants also seek to retain a minimal dataset about potential participants who decline taking part, to ensure that the recruitment is representative of the general population served by Guy's and St Thomas' NHS Foundation Trust.

A recommendation for class 1, 2, 3, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Patients receiving antenatal care at Guy's and St Thomas' NHS Foundation Trust
Data sources	1. Electronic maternity records at Guy's and St Thomas' NHS Foundation Trust
Identifiers required for linkage purposes	1. Name 2. NHS Number 3. Hospital ID Number 4. Date of birth 5. Postcode – sector level
Identifiers retained in the database	1. Initials 2. Full name 3. Address 4. NHS number 5. Hospital ID number 6. GP registration 7. Date of birth 8. Year of birth 9. Date of death 10. Postcode
Additional information	The identifiers held in the database will be held under consent.

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Health Research Authority.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006. The CAG agreed that the application was strongly in the public interest.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Feasibility of consent**

Eligible patients are contacted to seek consent.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The research team require access to confidential patient information in order to screen for eligible patients.

The CAG was content that using anonymous information was not a practicable alternative.

'Patient Notification' and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as 'patient notification'. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

A poster was provided. This will be displayed in relevant antenatal clinics and on the website for Guy's and St Thomas' NHS Foundation Trust. It will also be included in the distribution of information about the data linkage, to ensure it reaches all women booking for antenatal care in the Trust. The poster explained that patient records will be screened, and eligible patients will be contacted. Eligible patients are contacted to seek consent.

The poster advises that patients can opt-out and provided an email address for patients to register dissent. The poster also informed patients that, should they dissent, their NHS number, age, ethnicity, and de-identified postcode will be retained so that they are not re-contacted.

Patients opt-out status will be checked before any data is recorded. No data will be stored from patients who have completed the National Data Opt-Out.

The CAG highlighted an inconsistency regarding reference to the National Data Opt-Out. The CAG requested for the applicant to remove references to the National Data Opt-Out as a route to avoiding being approached for inclusion in research.

Patients are advised to contact the local Patient Advice and Liaison Service (PALS) to opt-out. Members queried whether this was practicable in all participating Trusts.

A contact telephone number and postal address need to be included in the patient notification materials.

Information for patients who dissent to inclusion will be kept on record to ensure that patients are not reapproached for participation. However, the CAG noted that this is a long-term study and patients may wish to be included in future pregnancies. Members asked if a mechanism could be created to allow for patients who may wish to join the study at a later date.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The eLIXIR study has been presented to patients, service users and the public on various occasions. When the Tissue Bank was initially set up in 2018, the applicants presented information to several patient interest groups.

At these meetings, patient and public involvement and engagement members contributed to identifying relevant research interests for the public, helped to develop the consent and confidentiality process, enquired about how samples were stored and

accessed by researchers and how their personal information would be used. All questions and concerns were clarified, and suggestions incorporated into the original eLIXIR Tissue Bank IRAS REC application.

Building on this original consultation, ongoing consultation with specific stakeholders, such as women using maternity services and those with lived experience of complex pregnancies, has been conducted by way of the eLIXIR Oversight Committee. The Committee has met every three months for the past five years. It comprises of at least two patient representatives who have lived experience in utilising maternity services and complex pregnancies, information governance experts, academic and clinical researchers, and representatives from community partners. This committee considers and approves all new research proposals on a project-by-project basis.

The applicants have also undertaken engagement activities with community groups, such as Lambeth Early Years Partnership (LEAP,) an organisation in South London which provides a community for mothers residing in the catchment area, and a platform for them to have a say in their healthcare. Moving forward, as part of the new MRC Longitudinal Population Cohort grant, a bespoke eLIXIR PPIE group will be set up, comprising parents in the South London area who will meet on a regular basis to provide ongoing feedback on all aspects of the Tissue Bank.

At a recent meeting, held online with 6 people who had received antenatal care at Guy's and St Thomas' NHS Foundation Trust, a presentation about the study was given. This described the tissue bank and the data linkage. The difference between opt-in consent for the tissue bank and opt-out consent for the data linkage was explained. The presentation outlined that women will be approached in antenatal clinics, having been identified as eligible via screening of their medical records. No objections were raised about the process of recruitment to the tissue bank.

The patient and public involvement conducted appears proportionate to the scale of the breach in the common law duty of confidentiality.

The CAG congratulated the applicant on their contribution of patient and public involvement. However, members asked that the applicant provide output of discussions within the next annual review submission. The CAG also asked that increased participation and contribution from younger individuals was included in the ongoing patient and public involvement.

Exit strategy

Consent is the exit strategy.

Patients who do not respond to contact attempts will be considered to have dissented. NHS number, age, ethnicity and pseudonymised postcode will be retained for dissenting patients for the duration of the Tissue Bank project. This is to enable the

applicants to monitor the representation of the local population for ED&I purposes. The applicants will also track whether particular groups of people decline participation, so their recruitment approach can be tailored to be more inclusive. The applicants also seek to avoid contacting patients who have declined the biobank but don't want to decline all research by completing the NHS National Data Opt-Out.

The CAG was content with the proposed exit strategy.

Confidentiality Advisory Group advice conclusion

The CAG agreed that there was a public interest in this activity, were supportive in principle of this activity proceeding, and therefore recommended to the Health Research Authority that the activity be provisionally supported. However, further information and actions would be required prior to confirming that the minimum criteria and established principles of support have been adequately addressed.

Request for further information

1. Clarify whether contacting the local Patient Advice and Liaison Service (PALS) to opt-out is practicable in all participating Trusts. If so, a contact telephone number and postal address need to be included in the patient notification materials.

2. Clarify your opinion on not maintaining data on dissenters, in order to re-approach them upon their next pregnancy.

3. Clarify what mechanism is in place for individuals who wish to re-join the study.

4. Make the following changes to the patient notification material:

    a. Regarding the outcome to query 3, ensure the notification clearly specifies that retention of identifiers will be kept for those individuals who have dissented from the study.

    b. Remove references to the National Data Opt-Out as a route to avoiding being approached for inclusion in research.

5. Provide output from patient and public involvement discussions within the next annual review submission. Furthermore, ensure that there is an increase in participation and contribution from younger individuals.

Specific conditions of support (Provisional)

The following sets out the provisional specific conditions of support. These may change in the final outcome letter depending on the responses to queries.

1. Favourable opinion from a Research Ethics Committee. **Pending**

2. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed**:

   The NHS England **21/22** DSPT review for **Guy's and St Thomas' NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04/07/2023)

   The NHS England **22/23** DSPT review for **King's College London - Department of Women and Children's Health** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04/07/2023)

d.23/CAG/0079- The Manchester Self-Harm Project

Context

Purpose of application

This application from the University of Manchester sought continuing support for a non-research project, for the purpose of monitoring self-harm as part of the National Suicide Prevention Strategy for England.

Self-harm is recognised as an important national and international public health issue. There are more than 220,000 emergency department presentations for self-harm in England each year, at an estimated cost of over £120 million. People who present to

hospital following self-harm are more than 50 times more likely to go on to die by suicide compared to people in the general population. This increased risk is reflected in the National Suicide Prevention Strategy for England, where people with a history of self-harm are identified as a key group for research and intervention. As well as increased risk of suicide people who self-harm often have additional co-morbidities, mental health problems, and difficult social and financial situations. Self-harm is distressing for the individual, family and friends, and has broad socio-economic impacts.

The Manchester Self-Harm Project has been running since September 1997. Patients admitted to any of the three general hospital emergency departments in the city of Manchester following a deliberate act of self-harm will be included. Once a case is determined to be self-harm, patient details will be entered into an access database and then transferred to the Project team at University of Manchester. Confidential patient information from Greater Manchester Mental Health NHS Foundation Trust will be disclosed to the University of Manchester for patients who received a psychosocial assessment from a member of the psychiatric liaison team while in the emergency department. Once a year, the dataset will be uploaded to NHS England to collect follow-up data.

A recommendation for class 1, 4, 5 and 6 support was requested to cover access to the relevant unconsented activities as described in the application, which can be got from the CAT assessment form, class support requested section.

Confidential patient information requested

The following sets out a summary of the specified cohort, listed data sources and key identifiers. Where applicable, full datasets and data flows are provided in the application form and relevant supporting documentation as this letter represents only a summary of the full detail.

Cohort	Manchester Self-Harm Project: all people who present to one of three general hospital emergency departments in the city of Manchester, following an act of self-harm. The core Project database currently runs from 1997 to 2017 and contains information on 39,000 individuals and 68,000 presentations. Data is collected on around 1800 new individuals each calendar year.
Data sources	1. Electronic patient records at Manchester University NHS Foundation Trust 2. Electronic patient records at Greater Manchester Mental Health NHS Foundation Trust

	3. ONS mortality data, NHS England
Identifiers required for linkage purposes	1. Full forename and surname 2. Date of birth 3. Sex 4. Postcode 5. NHS number 6. Date of death 7. Cause of death
Identifiers required for analysis purposes	1. Date of birth 2. Sex 3. Postcode 4. Date of death 5. Cause of death

Confidentiality Advisory Group advice

The following sets out the Confidentiality Advisory Group advice which formed the basis of the decision by the Secretary of State for Health and Social Care.

Public interest

The CAG noted that this activity fell within the definition of medical research and was therefore assured that the application described an appropriate medical purpose within the remit of the section 251 of the NHS Act 2006.

Following consideration of the risks to patient confidentiality versus the benefits of the study the CAG agreed that the application was in the public interest.

Scope

The CAG noted that this is a clinical audit application, and they were only providing s251 support for clinical audit purposes. The CAG also noted that they would expect a separate research application for any research purposes.

Practicable alternatives

Members considered whether a practicable alternative to the disclosure of confidential patient information without consent existed in accordance with Section 251 (4) of the NHS Act 2006, taking into account the cost and technology available.

- **Minimising flows of identifiable information**

The CAG noted that a number of items of confidential patient information were required for data linkage. Members noted that the applicants had stated that some patients would not have NHS numbers, however the CAG agreed that most patients would. Members asked for further justification on why so many identifiers were needed.

- **Feasibility of consent**

Patients attending hospital following self-harm are often distressed and it would not be feasible to seek consent at this point. Seeking consent at a later point would not be possible as it would be difficult to locate.

The applicants also noted a risk of bias, as some groups are less likely to consent than others, meaning these groups are underrepresented in the data, potentially impacting on the ability to accurately report on the healthcare needs to vulnerable groups.

The CAG was content that consent was not a practicable alternative.

- **Use of anonymised/pseudonymised data**

The team at the University of Manchester require access to confidential patient information to link together different self-harm presentations made by the same patient over time. NHS England also require confidential patient information to provide the required mortality data.

The team at the University of Manchester require access to confidential patient information to link together different self-harm presentations made by the same patient over time. NHS England also require confidential patient information to provide the required mortality data.

The CAG was content that using anonymous information was not a practicable alternative.

‘Patient Notification’ and mechanism for managing dissent

It is part of the CAG responsibility to support public confidence and transparency in the appropriate sharing and use of confidential patient information. Access to patient information without consent is a privilege and it is a general principle of support for reasonable measures to be taken to inform the relevant population of the activity and to provide a right to object and mechanism to respect that objection, where appropriate. This is known as ‘patient notification’. This is separate to the local obligation to comply with the principles of the General Data Protection Regulation and Data Protection Act 2018.

Detailed information about the project is included on the project website. This includes contact details for patients to use should they wish to opt out of the Project.

When seeking support for deferral of application of the National Data Opt-Out, the applicants created an infographic) that has been posted in patient areas of the local emergency departments where data is collected. The applicants also post about the Project on a dedicated Twitter account and individual staff accounts. Many reports are free to access on the Project website alongside a number of easy-to-read infographics showing the results of the work.

Detailed information about the project is included on the project website. This included email and postal contact details for patients to use should they wish to opt out of use of their data.

In 2022, the applicants were granted exemption of application of the National Data Opt-Out.

The CAG requested a clear explanation added to notifications for clarity to explain why the application was granted exemption of application of the National Data Opt-Out.

The CAG requested that the patient notification include an explanation on how a patient can request the removal of their data via local opt-out.

The CAG noted that if participants want to opt-out they were required to provide an explanation for why they wanted to opt-out. The CAG requested that the process of opting out was rephrased to explain that patients can object to use of their data without providing a reason for their objection.

Patient and Public Involvement and Engagement

Meaningful engagement with patients, service users and the public is considered to be an important factor for the CAG in terms of contributing to public interest considerations as to whether the unconsented activity should go ahead.

The Project has collaborated with a local patient and public involvement group, set up within the Centre for Mental Health and Safety. Mutual Support for Mental Health Research (MS4MH-R) is a dedicated patient and public involvement group with members affected by suicidal behaviour or self-harm. MS4MH-R are regularly consulted on specific aspects of work, such as proposed work programmes and the development of infographics and other materials for wider dissemination. They are paid an hourly rate for time. MS4MH-R was also involved in the previous application for exemption from the National Data Opt-Out.

The CAG was satisfied with the proportion of patient and public involvement and engagement that was undertaken for this application.

Exit strategy

The project keeps personal data in a form which the data subject can be identified only for as long as it is required for the purposes for which it was collected. The cleaned dataset is pseudonymised and kept separate from patient identifiers. In line with University of Manchester records policy the Project will keep data for 5 years following the final publication of results or the end/termination of the Project.

The CAG requested that the applicant clarify at what point the identifiers used for linkage would be deleted.

The CAG requested that the applicant clarify whether they needed to share such a large data set with NHS England. If so, how would NHS England keep it secure, and what is the length of retention.

Confidentiality Advisory Group advice conclusion

The CAG agreed that the minimum criteria under the Regulations appeared to have been met, and therefore advised recommending support to the Secretary of State for Health and Social Care, subject to compliance with the specific and standard conditions of support as set out below.

Specific conditions of support

1. Members asked for further justification on why so many identifiers were needed.

2. Clarify at what point the identifiers will be deleted after linkage is completed.

3. Clarify whether the research team needed to share such a large data set with NHS England. If so, how would NHS England keep it secure, and clarify the length of retention.

4. Update the patient notifications to explain why the application was granted exemption of application of the National Data Opt-Out.

5. Update the patient notifications to explain how a patient can request the removal of their data via local opt-out.

6. The wording around opting-out or objection needs to be rephrased to avoid asking participants to provide a reason for requesting to opt-out.

7. Confirmation provided from the DSPT Team at NHS England to the CAG that the relevant Data Security and Protection Toolkit (DSPT) submission(s) has achieved the 'Standards Met' threshold. **Confirmed:**

   The NHS England **21/22** DSPT review for **University of Manchester – Manchester Self-Harm Project and Manchester University NHS Foundation Trust** was confirmed as 'Standards Met' on the NHS England DSPT Tracker (04 July 2023)

   Pending:

   The NHS England **21/22** DSPT review for **Greater Manchester Mental Health NHS Foundation Trust** is pending

As the above conditions have been accepted or met, this letter provides confirmation of final support. I will arrange for the register of approved applications on the HRA website to be updated with this information.

6. Any other business

The CAG members highlighted difficulties upon reviewing late submission of documents. The CAG requested for applicants to be issued a cut off where submissions of documents would no longer be possible, or if required the application would be deferred to a future meeting.

The Chair thanked Members for their attendance and the meeting was closed.

Signed – Chair	Date
Dr Murat Soncul, Professor William Bernal, CAG Alternate Vice-Chairs	*12 July 2023*

Signed – Confidentiality Advice Team	Date
Ms Kathleen Cassidy	*06 July 2023*