

Independent Group Advising on the Release of Data (IGARD)

Minutes of meeting held 26 July 2018

Members: Anomika Bedi (items 2.8 – 2.14), Chris Carrigan, Nicola Fear (Items 2.1-2.7), Jon Fistein, Kirsty Irvine (KI) (Chair)

In attendance: Victoria Byrne-Watt, Louise Dunn, Rachel Farrand, Dickie Langley, Karen Myers, Kimberley Watson, Vicki Williams.

Apologies: Sarah Baalham, Joanne Bailey, Eve Sariyiannidou.

1	<p>Declaration of interests</p> <p>Jon Fistein noted professional links to HQIP (The Royal College of Surgeons of England NIC-358185-N3R6Q and Royal College of Obstetricians and Gynaecologists NIC-44356-Y8N6R) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Kirsty Irvine noted professional links to the Royal College of Obstetricians and Gynaecologists (NIC-44356-Y8N6R) but noted no specific connection with the application or staff involved and it was agreed this was not a conflict of interest.</p> <p>Review of previous minutes and actions</p> <p>The minutes of the 12 July 2018 IGARD meeting were reviewed by IGARD and agreed as an accurate record of the meeting.</p> <p>The outstanding actions were reviewed.</p> <p>Out of committee recommendations</p> <p>An out of committee report was received (see Appendix B).</p>
2	Data applications
2.1	<p><u>The Nuffield Trust: Prisoner health: Understanding prisoners' healthcare needs, their use of healthcare services and quality of care received (Presenter: Dickie Langley) NIC-195377-M9L8Z</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data. The 'Prisoner Health' project aims to improve understanding of prisoners' health care needs, their use of health care services and the quality of care received for prisoners compared to the non-prison population.</p> <p>The application had been previously considered on the 5th July when IGARD were unable to recommend for approval: the application required an update to the abstract sections on Article 6 and 9 of GDPR to reflect recent discussion including reference the public interest condition under the DPA 2018; to clearly state in section 5a the legitimate interest relied upon, as related to the purpose of the research; confirmation that NHS Digital have assessed the LIA and deemed it satisfactory; to update the source of funding in section 8b; clarification of the control cohort including a clearer description; to clearly state that in section 5 that the prison postcode will only include the prison population; a clear explanation within section 5 of the roles and responsibilities of the IT infrastructure, including any access to data; and to clearly state within section 4 the steps undertaken to inform the prison population of the study and how they can access the information.</p>

	<p>Discussion: IGARD noted that the study was using the prison postcode as a proxy to identify patients in the penal establishment, however for those prisons located in residential areas or for those living on the prison site suggested that section 5a point 6 and the abstract of the application be updated to state that the prison postcode will 'usually' include only the prison population and not those working in the prison or residential properties in close proximity.</p> <p>IGARD had previously queried how the control group was being derived, however NHS Digital confirmed there was no specific control group created. It was suggested that section 5 and the abstract of the application include a clear statement that no specific control group was created for this study.</p> <p>IGARD noted the various amendments made to the application reflecting the discussion at the IGARD meeting of 5 July and acknowledged that discussions were ongoing within NHS Digital about how best to document an applicant's legitimate interest under GDPR. This topic was also discussed more generally; see minutes under AOB.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To clarify in section 5a point 6 and the abstract that the prison postcode will 'usually' include on the prison population and not those working in the prison or residential properties in close proximity. • To include within the abstract and in section 5 a clear statement that no specific control group was created for this study.
2.2	<p><u>Royal Liverpool University Hospital NHS Trust: A Risk-adjusted and anatomically Stratified Cohort Comparison Study of Open Surgery, Endovascular Techniques and Medical Management for Juxtarenal Aortic Aneurysms: The UK COMPlEx Aneurysm Study (UK-COMPASS) (Presenter: Dickie Langley) NIC-161422-Q0K1M</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES) data and Diagnostic Imaging Dataset (DID). Abdominal aortic aneurysm (AAA) is a common condition where the aorta, the largest artery, begins to bulge abnormally. The aim of the study is to answer the research question identified by the National Institute for Health Research – Health Technology Assessment (NIHR-HTA) Commissioning Board – 'What are the clinical and cost effectiveness of strategies for the management of juxtarenal abdominal aortic aneurysm, including fenestrated endovascular repair'.</p> <p>Discussion: IGARD queried if the extensive list of named collaborators within supporting document 2.0 'UK COMPASS protocol v3' would have access to the raw data or the outputs. NHS Digital confirmed that they would not have access to the raw data. It was suggested that it be expressly stated within section 5 (processing) plus the inclusion of a special condition in section 6 that only those organisations listed within the application will have access to the data disseminated by NHS Digital and, for the avoidance of doubt, this excludes any other collaborators named within the protocol.</p> <p>IGARD noted that the HRA CAG application referred to HES data but that NHS Digital had included a detailed explanation in the abstract about why they would also be disseminating DIDs under this agreement. It was suggested that, for transparency purposes, NHS Digital write to HRA CAG to inform them that they will be releasing DIDs under this agreement and this was the interpretation of the CAG application and supporting documents taken by NHS Digital.</p> <p>IGARD noted that the applicant was using NHS Digital data to define a cohort of interest who had had treatment between November 2017 and October 2019, however noted that section 5a</p>

	<p>and the protocol suggested that individual patients would continue to be followed up for 5 years. It was therefore suggested that the statement within section 5a "...and collect 5 years follow up data" is not part of this agreement and would be subject to a further application to NHS Digital.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To expressly state within section 5 (processing) and to include a special condition that only those organisations named within the application will have access to the data disseminated by NHS Digital and, for the avoidance of doubt, this excludes any other collaborators named within the protocol. • To clarify that statement within section 5a "...and collect 5 years follow up data" is not part of this agreement and would be subject to a further application to NHS Digital. <p>The following advice was given:</p> <ul style="list-style-type: none"> • IGARD suggested that NHS Digital write to HRA CAG to inform them that they will be releasing DIDs under this agreement and this was the interpretation of the CAG application and supporting documents taken by NHS Digital.
2.3	<p><u>University of Oxford: Tracking the impact of Gestational Age on Health, Educational and Economic outcomes: a Longitudinal Record Linkage Study (TIGAR) (Presenter: Louise Dunn) NIC-09637-Y8T1N</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data with national births data as part of a research database currently held by the Office for National Statistics (ONS) which is part of the analyses for the TIGAR study which is investigating the effect of gestational age on health, educational and economic outcomes up to the age of 11 years.</p> <p>NHS Digital noted ongoing work with regard to opt outs.</p> <p>Discussion: IGARD welcomed the application and supported the overall aims of the project.</p> <p>IGARD queried whether education data would be used and suggested that section 5 of the application clearly signpost at what stage this data would be introduced. It was also suggested that as this was preliminary work for a larger study that section 5 be updated to include further headline statements and key sentences explaining the benefits relating to the small subset study, rather than the overall long-term aims.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however noted that the abstract should include reference to further supporting legislation such as the Universities Act 1997 or Higher Education and Research Act 2017.</p> <p>IGARD suggested that all acronyms upon first use of the application be fully spelt out and suggested that NN4B within section 4 be clearly described.</p> <p>IGARD noted that NHS Digital had undertaken a review of the applicant's fair processing notice and that it did not meet the criteria set.</p> <p>Outcome: recommendation to approve subject to the following condition:</p> <ol style="list-style-type: none"> 1. To be explicit in section 5 that this is a small subset study of a larger study, to explain which of the benefits relate to this particular aspect of the study and include clear headline statements explaining the subset aspect for transparency and the lay reader.

	<p>The following amendments were requested:</p> <ol style="list-style-type: none"> 1. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including reference to the Universities Act 1997 or Higher Education and Research Act 2017 or similar. 2. To explain the acronym NN4B. <p>It was agreed that that condition would be agreed OOC by the IGARD Chair.</p>
2.4	<p><u>University of Oxford: The delivery of major trauma care in England – impact and effectiveness following a whole system reorganisation (Presenter: Dickie Langley) NIC-177392-B8T1Z</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) and Office for National Statistics mortality (ONS) data. The data is required for use in the TRAuma Care Reorganisation (TRACER) Project, which is looking at the clinical and cost-effectiveness of the reorganisation of trauma care services into Regional Trauma Networks (RTNs) and Major Trauma Centres (MTCs).</p> <p>The application had been previously considered on the 5th July when IGARD had deferred making a recommendation pending: an update to the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions; to correctly list the DPA 2018 schedule 1 Part 1 references against any Article 9 legal basis cited and clearly describe how the schedule conditions are met; to clarify the legal basis under GDPR for NHS Digital to receive the data from the Trauma Audit & Research Network (TARN); to clarify the role of TARN and the University of Manchester; to update the application to ensure the legal basis stated is consistent with the data flows; provide confirmation that the Big Health Data Group are a department of the University of Oxford; confirmation within section 5b that the applicant will not link the data further; to update section 8 to clearly state that it is the researcher who is NIHR funded and not the project; to clarify reference to “MTC 22” within section 5c; to complete the ethics approval section; and to remove a reference to ‘identifiable data’ in the legal basis section and the abstract and replace with ‘pseudonymised data’.</p> <p>Discussion: IGARD noted that NHS Digital had included within the abstract the applicant’s legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however noted that the abstract should include reference to further supporting legislation such as the Universities Act 1997 or Higher Education and Research Act 2017.</p> <p>IGARD queried reference to the Big Health Data Group noting that they were a part of the University of Oxford and suggested that the opening section in 5a “The Big Health Data Group at the University of Oxford...” be updated to read “The Big Health Data Group which is part of the University of Oxford...”.</p> <p>At the 5th July meeting IGARD had asked for clarification of the legal basis GDPR for NHS Digital to receive the data from the Trauma Audit & Research Network (TARN) and suggested that NHS Digital should assure themselves that their obligations under GDPR are met in relation to NHS Digital’s receipt and processing of the TARN data.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To amend the sentence in section 5a “The Big Health Data Group at the University of Oxford...” to “The Big Health Data Group which is part of the University of Oxford...”.

	<ul style="list-style-type: none"> To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including reference to the Universities Act 1997 or Higher Education and Research Act 2017. <p>The following advice was given:</p> <ul style="list-style-type: none"> IGARD suggested that NHS Digital should assure themselves that their obligations under GDPR are met in relation to NHS Digital's receipt and processing of the TARN data.
2.5	<p><u>University of Oxford: All cause mortality within 12 months following hip fracture (Presenter: Louise Dunn) NIC144057-G4S0Q</u></p> <p>Application: This was a new application for pseudonymised Office for National Statistics (ONS) mortality data and Hospital Episode Statistics (HES) data. The aim of the study is to investigate the causes of death's in patients with hip fractures and to understand the causes behind the high mortality rates. There has been research into the rates of mortality after hip fracture, but systematic large-scale analysis of the causes is lacking.</p> <p>NHS Digital noted that ONS data was still to move to NHS Digital controllership, under the new name of Civil Registrations Data.</p> <p>Discussion: IGARD noted that Civil Registrations Data was the new name for ONS mortality data once under NHS Digital controllership.</p> <p>IGARD noted that NHS Digital had included within the abstract the applicant's legal basis under the General Data Protection Regulation (GDPR) Article 6 and 9, however noted that the abstract should include reference to additional supporting legislation such as the Universities Act 1997 or Higher Education and Research Act 2017.</p> <p>IGARD queried reference to NDORMS and if they were part of the University of Oxford. NHS Digital noted that they were a department of the University, however it was suggested that confirmation be provided that NDORMS were part of the University.</p> <p>IGARD noted within the privacy notice supplied as a supporting document reference to a 'pre-direct study' and suggested that section 5a of the application clarify how the pre-direct study relates to the wider study and analysis undertaken under this agreement.</p> <p>Outcome: The application was recommended for approval from such time as ONS data has moved to NHS Digital controllership</p> <p>The following amendments were requested:</p> <ol style="list-style-type: none"> To clarify within section 5 that NDORMS are part of the University of Oxford. To clarify within the privacy notice what the pre-direct study is and how it relates to this study and to include within section 5a how the analysis is linked to the pre-direct study. To update the abstract section on Article 6 and 9 of GDPR to reflect recent discussions between NHS Digital and IGARD including reference to the Universities Act 1997 or Higher Education and Research Act 2017 or similar.
2.6	<p><u>University of Dundee: Data linkage request for (TIME) Treatment in Morning versus Evening Study (Presenter: Dickie Langley) NIC-67135-G7D9V</u></p> <p>Application: This was a new application for identifiable Hospital Episode Statistics (HES), and identifiable and pseudonymised mortality data from the Office for National Statistics (ONS). The aim of the study is to determine if morning or evening administration of blood pressure lowering (antihypertensive) medications is more effective in the prevention of heart attacks and</p>

	<p>strokes. The study tests the hypothesis that nocturnal dosing of antihypertensive medications reduces the risk of cardiovascular events compared with conventional morning dosing.</p> <p>Discussion: IGARD thanked the presenter for the excellent GDPR legal basis summary in the abstract and suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: “NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented”.</p> <p>IGARD noted that visitors to the study website had to input their usernames and passwords which created a barrier to them accessing study information. IGARD noted that study participants may be inputting their own data into the study website but suggested that the applicant may wish to adopt a more granular approach to accessing information and providing data.</p> <p>IGARD noted that supporting document 5 ‘DIVINE Move Consent Form 2.0’ had been provided however there was no reference to DIVINE within section 5 of the application and asked for clarification as to how this study related to the current TIME Study.</p> <p>It was suggested that section 1b of the application be updated to remove reference to “bricks and mortar”.</p> <p>IGARD noted that Iron Mountain was listed as a storage location and stated their view that it may be more appropriate to also list this organisation as an additional data processor. It was acknowledged that there was currently an open action with NHS Digital regarding storage locations and how to reflect their role as data processors.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To update the abstract to amend references to patient consent and the common law duty of confidentiality to: “NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented”. • To remove reference to “bricks and mortar” from section 1b. • To clarify within section 5 what is the DIVINE Study and how this relates to the current study. <p>The following advice was given:</p> <ul style="list-style-type: none"> • IGARD noted that usernames and passwords may be a barrier to accessing the website information and for transparency suggested that the applicant may wish to use a more granular approach to accessing information and providing data.
2.7	<p><u>Society of Endocrinology: MR1030 - To assess outcome of patients with Acromegaly in the UK (Presenter: Louise Dunn) NIC-147893-ZFLWG</u></p> <p>Application: This was a renewal application for identifiable Medical Research Information Service (MRIS) reports for their cohort. The request for the data is to support the work being done on the The UK Acromegaly Database. Patients with acromegaly have morbidities and may have diabetes, mellitus, hypertension, or endocrine dysfunction related to the pituitary tumour.</p> <p>NHS Digital noted that supporting document 1 ‘SLSP 2018’ should not have been included in the agenda pack.</p>

	<p>Discussion: IGARD suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: “NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented”.</p> <p>NHS Digital noted they had assessed the applicant’s Legitimate Interest Assessment (LIA) and was satisfied it met GDPR requirements (see also further discussion under AOB) and suggested that the abstract be updated to state that the consent material had been reviewed by NHS Digital and deemed to have met the common law standard, including date reviewed, who reviewed and confirming a copy had been kept on file.</p> <p>IGARD noted that Newcastle University would be processing aggregated tabular form data with small numbers suppressed and that The Society for Endocrinology had confirmed that no record level data would be accessed or processed outside of the Society’s Bristol office, however IGARD queried if this was correct. NHS Digital confirmed they had spoken with the applicant and confirmed that the University would only be getting aggregated data to run their analysis and for publication of journal articles.</p> <p>It was suggested that the abstract be updated to state that the applicant’s privacy notice does “not” meet General Data Protection Regulation (GDPR) requirements.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To update that abstract to state that the privacy notice does “not” meet GDPR requirements. • To update the abstract to amend references to patient consent and the common law duty of confidentiality to: “NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented”. • To remove the security supporting document from the CRM holder. • To update the abstract to state that the consent material had been reviewed by NHS Digital and deemed to have met the common law standard.
2.8	<p><u>NHS South Devon and Torbay CCG: Joint South Devon & Torbay and NEW Devon CCGs access to pseudo HES data (Presenter: Rachel Farrand) NIC-181880-M8W1T</u></p> <p>Application: This was a new application for pseudonymised Hospital Episode Statistics (HES) data. This request is to support both CCGs in delivering some of their statutory functions, ensuring they are getting maximum value for public money, and enabling them to build upon the commissioning for value project performed by NHS RightCare, which involves drilling down into national level data, from areas either identified by NHS RightCare or other areas as they are discovered on an ad-hoc basis.</p> <p>Discussion: IGARD queried why the applicant was requesting national HES data and NHS Digital noted they would be potentially using the data for a pilot in order to inform all CCGs in England with regard to areas of improvement and benchmarking. However, IGARD queried if the applicant had explored using benchmarking data already in the public domain and suggested that if this data was not available to explicitly state this in section 5 of the application. It was also suggested that the applicant may wish to consider using HES Data Interrogation Service (HDIS) to access the data for their pilot or part of the HDIS analysis available.</p> <p>IGARD suggested that a clear explanation be given as to how the benefits derived from this study would inform all CCGs in England and that the applicant consider if any yielded benefits</p>

	<p>demonstrated from the study could be transferable or made more widely available, including more publicly available.</p> <p>IGARD noted that the applicant was listed in section 1 of the application as a Data Controller and Data Processor, but that this be updated to clearly state that the applicant was a Data Controller who also processed data.</p> <p>IGARD noted that Stem Group and DELT Shared Services Ltd were listed as storage locations and stated their view that it may be more appropriate to also list these organisations as additional data processors. It was acknowledged that there was currently an open action with NHS Digital regarding storage locations and how to reflect their role as data processors</p> <p>It was suggested that section 1b of the application be updated to remove reference to “bricks and mortar”.</p> <p>Outcome: recommendation to defer</p> <ol style="list-style-type: none"> 1. To clarify if the applicant have explored using benchmarking data already in the public domain and if this is not available to explicitly state this 2. To clarify if the applicant has considered using HDIS to access the data they require for the pilot. 3. To clearly explain how they will use the benefits derived from this study to inform CCGs across England. 4. The application should be updated to clarify that NHS South Devon and Torbay CCG and NHS Northern Eastern and Western Devon CCG are Data Controllers who also process data. 5. IGARD suggested that the applicant consider how the benefits of the study will be transferable to other CCG settings or made more widely available.
2.9	<p><u>Derby Teaching Hospitals NHS Foundation Trust: MR1176 - The Renal Risk in Derby (R2ID) Study (Presenter: Rachel Farrand) NIC-147788-X0G5L</u></p> <p>Application: This was an extension application to continue to retain and process identifiable Hospital Episode Statistics (HES) from 2008/09 to 2014/15 and Medical Research Information Service (MRIS) mortality data from December 2009 to March 2017. The study is a cohort of approximately 1800 individuals with chronic kidney disease recruited from primary care and the aim is to use the data to provide insight into the renal and cardiovascular outcomes in the study group.</p> <p>NHS Digital noted this was a 1 year extension.</p> <p>Discussion: IGARD suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: “NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented”.</p> <p>NHS Digital noted they had assessed the applicant's Legitimate Interest Assessment (LIA) and was satisfied it met GDPR requirements and suggested that the abstract be updated to state that the consent material had been reviewed by NHS Digital and deemed to have met the common law standard, including date reviewed, who reviewed and confirming a copy had been kept on file.</p> <p>IGARD suggested that the abstract be updated to clearly define the various legal basis' for disseminating data under this application. It was also noted that the Data Sharing Agreement (DSA) end date in section 1 be updated to reflect a 1 year extension.</p>

	<p>IGARD noted that the applicant was to inform patients in 2019 as part of their 5 year link into General Practitioners however it was suggested on renewal that the applicant provide further details of pathways for disseminating the outputs of the study to patients and the public, and within section 5 of the application.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To update the abstract to amend references to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented". • To update the abstract to state that the consent material had been reviewed by NHS Digital and deemed to have met the common law standard. • To update the abstract to clearly set out the various legal basis for disseminating the different types of data. • To update the DSA end date in section 1 to reflect a 1 year extension. <p>The following advice was given:</p> <ul style="list-style-type: none"> • IGARD suggested on renewal that further details of pathways of dissemination of the outputs be provided including examples of public / patient engagement.
2.10	<p><u>Healthcare Quality Improvement Programme (HQIP) GDPR / Legal Basis Briefing Paper (Presenter: Kimberley Watson)</u></p> <p>The briefing note outlines HQIP's legal basis under GDPR as being Article 6(1)(e) and Article 9(2)(i); this briefing outlines how this decision was reached and the justification.</p> <p>IGARD welcomed the briefing note and noted its content.</p>
2.11	<p><u>The Royal College of Surgeons of England: National Vascular Registry (NVR) - Small Numbers Unsuppressed Tabulation Request (Presenter: Kimberley Watson) NIC-358185-N3R6Q</u></p> <p>Application: This was a renewal application for pseudonymised Hospital Episode Statistics (HES) data. The NVR is based on prospectively-collected, patient-level data on patients who have had vascular surgery and the data will show the number of procedures performed at NHS trusts and a national level and will be used by the NVR to calculate case-ascertainment for English NHS Trusts and nationally.</p> <p>Discussion: IGARD queried if any additional linkages would be undertaken and that it be explicit within section 5b of the application that the applicant will not link data in this application except those permitted under this application / data sharing agreement.</p> <p>IGARD noted that historic phrasing was being used in section 4 Fair Processing and it was suggested that new standard wording for use with pseudonymised data be used: "All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 3 months". IGARD noted their endorsement of NHS Digital's review of HQIP's privacy notice and suggested they update in line with GDPR requirements.</p>

	<p>It was suggested that supporting document 5, data flow diagram be updated to correctly show the nature of the data flowing from HES to the NVR project team.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • Confirmation within section 5b of the application that the applicant will not link the data further and the only data linkages are those permitted under this application • To update section 4 with the standard wording “All data required by the Data Controller under this application is pseudonymised and therefore is considered as personal data under the GDPR. All Data controllers are expected to provide a privacy notice that is compliant with the GDPR notice requirements within a reasonable period after obtaining the personal data, but at least within 3 months”. • To update the data flow diagram in supporting document 5 to correctly show the nature of the data flowing from HES to the NVR team.
2.12	<p><u>Royal College of Obstetricians and Gynaecologists: NMPA-HES-ONS-MSDS Linked Dataset (Presenter: Kimberley Watson) NIC-44356-Y8N6R</u></p> <p>Application: This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data and identifiable Office for National Statistics mortality (ONS) data. The purpose is for the Healthcare Quality Improvement Partnership (HQIP), National Clinical Audit and Patients Outcomes Programme’s National Maternity and Perinatal Audit (NMPA) to deliver a clinically meaningful and methodologically robust audit of NHS maternity services to enable decision making and support the improvement of quality of care.</p> <p>The application had been previously considered on the 5th July when IGARD had deferred making a recommendation pending: an update to the abstract sections on Article 6 and 9 of GDPR to reflect recent discussions; to clearly state that ONS data is being requested as part of the application; to amend reference to all data being both pseudonymised and identifiable within section 5a; to include the standard ethics approval wording; the wording in section 6 reference ‘data destruction’ should be removed; and to update the abstract to remove reference to previous summary iterations.</p> <p>Discussion: IGARD noted that NHS Digital had updated section 5a to clearly reference data being both pseudonymised and identifiable however since General Data Protection Regulations (GDPR) did not apply to deceased people suggested that section 4 clearly state that the identifiable data related only to those babies stillborn or who die shortly after birth.</p> <p>IGARD noted their endorsement of NHS Digital’s review of HQIP’s privacy notice and suggested they update in line with GDPR requirements.</p> <p>IGARD noted that RedCentric PLC was listed as a storage location and stated their view that it may be more appropriate to also list this organisation as an additional data processor. It was acknowledged that there was currently an open action with NHS Digital regarding storage locations and how to reflect their role as data processors.</p> <p>Outcome: recommendation to approve</p> <p>The following amendment was requested:</p> <ul style="list-style-type: none"> • To amend section 4 to clearly state that only identifiable data relates to the deceased infants.

2.13	<p><u>Wilmington Healthcare: Amendment and Renewal to DARS-NIC-16016-Y9H1D (Presenter: Kimberley Watson) NIC-16016-Y9H1D</u></p> <p>Application: This was an amendment application for pseudonymised Hospital Episode Statistics (HES) data and Diagnostic Imaging Dataset (DIDs). The application had been previously considered on the 19th October 2017 when IGARD had recommended for approval for 3 months for the applicant to hold the data but not otherwise process it. The data will be used to support the NHS either directly through the delivery of tools and bespoke analysis or indirectly through non-NHS organisations, where solutions are provided with the NHS as the end beneficiary.</p> <p>NHS Digital noted that this application had been previously recommended for 3 months but was subsequently approved in March 2018 by the Director of Data Dissemination.</p> <p>Discussion: IGARD noted that on the 19th October 2017 the application had been recommended for approval for 3 months for the applicant to continue to store data but not otherwise process it and when it was subsequently re-presented on the 21st December 2017 IGARD had deferred making a recommendation because the information previously requested for the 3 month approval had not been provided for IGARDs consideration. It was noted that Director of Data Dissemination had approved the application in March 2018 for the applicant to store and process data. NHS Digital noted that this application was to add an additional storage and processing address for Nasstar PLC and to also request the Mental Health Services Dataset (MHSDS).</p> <p>IGARD noted the decision made by NHS Digital but their position remained the same as the points raised in October and December 2017 did not appear to be addressed by the application and supporting documents.</p> <p>Outcome: IGARD were unable to make a recommendation as there was insufficient information received on the substantive points raised previously in October and December 2017.</p>
2.14	<p><u>Intensive Care National Audit & Research Centre (ICNARC): MR1467 - The 65 Trial: Evaluating the clinical and cost-effectiveness of permissive hypotension in critically ill patients aged 65 years or over with vasodilatory hypotension (Presenter: Kimberley Watson) NIC-96444-N2B7K</u></p> <p>Application: This was a new application for Medical Research Information Service (MRIS) data. The 65 Trial is a pragmatic, multi-centre, parallel group randomised clinical trial (RCT) aiming to evaluate the clinical and cost-effectiveness of permissive hypotension (a mean arterial pressure (MAP) target range 60-65 mmHg whilst receiving vasopressors) in critically ill patients aged 65 years or over with vasodilatory hypotension. This research will look at emerging evidence from a meta-analysis suggesting that using a lower MAP target (permissive hypotension) to guide vasopressor treatment may increase survival in older critically ill patients. The application had previously been considered on the 15th February by IGARD for advice on consent.</p> <p>Discussion: IGARD suggested that the abstract be amended to reference patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented".</p> <p>NHS Digital noted they had assessed the applicant's Legitimate Interest Assessment (LIA) and was satisfied it met GDPR requirements (see also discussion under AOB) and suggested that</p>

	<p>the abstract be updated to state that the consent material had been reviewed by NHS Digital and deemed to have met the common law standard, including date reviewed, who reviewed and confirming a copy had been kept on file.</p> <p>IGARD noted that the applicant was listed in section 1 of the application as a Data Controller and Data Processor, but that this be updated to clearly state that the applicant was a Data Controller who also processed data.</p> <p>It was noted that this was a National Institute for Health Research (NIHR) funded application.</p> <p>Outcome: recommendation to approve</p> <p>The following amendments were requested:</p> <ul style="list-style-type: none"> • To update the abstract to amend references to patient consent and the common law duty of confidentiality to: "NHS Digital has determined that the processing in this application is not incompatible with the consent and likely to be within the reasonable expectations of those that have consented". • The application should be updated to clarify that ICNARC are a Data Controller who also process data. • To update the abstract to state that the consent material had been reviewed by NHS Digital and deemed to have met the common law standard.
3	<p>AOB</p> <p>During a discussion prompted by application 2.1, IGARD observed that a standard was being developed by NHS Digital in respect of "legitimate interests" under GDPR. IGARD noted that as this was a developing area, they would reserve their position to revisit how an applicant's legitimate interests were described and evidenced in future applications.</p>

Independent Group Advising on Releases of Data (IGARD): Out of committee report 20/07/18

These applications were previously recommended for approval with conditions by IGARD, and since the previous Out of Committee Report the conditions have been agreed as met out of committee.

NIC reference	Applicant	IGARD meeting date	Recommendation conditions as set at IGARD meeting	IGARD minutes stated that conditions should be agreed by:	Conditions agreed as being met in the updated application by:	Notes of out of committee review (inc. any changes)
NIC-84254-J2G1Q	University of York	14/06/2018	1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met.	OOC by IGARD members	Quorum of IGARD members	N/A
NIC-315999-W2W4C	University of Leeds	14/06/2018	1. To provide the relevant sections under Article 6 and 9 of GDPR and a clear justification for the choice of each section in terms of how the specific criteria and additional requirements are met. 2. Providing relevant evidence that funding is in place to June 2019. 3. To clarify the wording within section 5a the sentence "...the other organisations noted in the collaboration do not have any rights to the data disseminated for this project" 4. To be explicit in section 5b that the work packages within the application are not part of workstream two.	OOC by IGARD members	Quorum of IGARD members	N/A

In addition, the following applications were not considered by IGARD but have been progressed for IAO and Director extension/renewal:

- None notified to IGARD

DRAFT