

Delays faced by researchers trying to access data from HSCIC

Timely access to patient data is essential for research. Researchers have recently experienced significant delays – often of more than a year – when trying to access data from the Health and Social Care Information Centre (HSCIC)¹. The twelve case studies in this briefing demonstrate the nature and substantial impact of these delays.

A wide range of research has been affected by the delays, including clinical trials, cohort studies, research for health services planning, and audit and evaluation work. In some cases, researchers have not been allowed access to data even where participants have consented to the research, or where the data requested are at an aggregate, anonymised level. Delays have typically lasted more than 12 months.

The delays have meant that much needed research has not been completed, delaying the potential health benefits of the work, preventing analysis of the risks and benefits of drugs that are already in use, and meaning that service planning has been based on out-of-date data. In some cases, additional funding has been needed to complete research because of the long delays and significant extra staff time has been spent trying to negotiate the complex access processes.

The longer it takes to resolve the issues with care.data, the more research will be placed under threat. There must be processes in place that patients, the public, healthcare professionals and researchers can trust. But in the meantime, research that could potentially save lives is being unnecessarily blocked.

Cause of delays

Many of the delays were the result of HSCIC's suspension of data releases, and the resulting backlog when HSCIC 'reopened' for business. However, as the case studies show, there are also growing concerns about the increasingly fragmented and complex system for data access:

- Changes to data sharing requirements have led to more stringent conditions for access, even in the context of data provided with individual's consent or non-identifiable data.
- Lack of communication about the need for new data sharing agreements following the Care Act.
- Lack of clarity on who can do data linkage; the requirement for data linkage to be done by the HSCIC has further delayed access to the data.
- Processes surrounding the Data Access Advisory Group mean that it is not functioning as effectively as it might, and minor misunderstandings can take a long time to resolve.
- Poor communication and inefficient systems, with the same information often requested several times.

¹ The term HSCIC is used throughout, where used prior to April 2013 this refers to the NHS Information Centre

1. CLINICAL TRIALS AND COHORT STUDIES

Many of these studies require identifiable data, where individuals have given consent for their data to be shared.

- **SABRE Study**

The SABRE study is a large, tri-ethnic population-based cohort study. The third visit for study participants is due to take place over the next two years. Building on information gathered at previous visits, the third phase will focus on ethnic differences in diabetes and circulation and how well people are keeping as they get older. Researchers require cancer notification data, participant addresses and GP contact details to ensure they are able to follow the same group of individuals throughout the study. They also need mortality data to prevent letters being sent to participants who have died, causing distress to the family.

Despite applying for the data in March 2014 the researchers are yet to receive it, an on-going delay of at least ten months. The delays seem to be due to two factors; firstly the backlog of requests at HSCIC, which has also resulted in the need for them to resubmit applications, and secondly due to changes with their data sharing agreement. Specifically they were informed that they were in breach of their agreement as a result of having moved institutions despite having informed the HSISC of their move five months before asking for data. A new data sharing agreement is currently being drafted, fifteen months after they initially informed the HSISC of their move.

The delay in data receipt has led to substantial delays. Without the data researchers risk causing distress to the families of those who have died, and wasting resource by using potentially out of date addresses. There is also a significant risk that participants will be lost to follow up, which may increase bias and compromise the reliability of the results of the study.

- **CATCH Trial**

CATCH is a randomised controlled trial comparing the effectiveness of different central venous catheters for the prevention of hospital acquired blood stream infection in children. The researchers required consented data linkage to understand the cost effectiveness of this intervention as a means of preventing infections in paediatric intensive care units across the NHS. The data was applied for in 2013, but – despite consent - not received until November 2014, a delay of at least 12 months. The delay was as the result of the original request falling in the HSCIC's period of shutdown, but has meant the end date of the trial was extended twice, delaying completion of the work and publication of the results.

- **Cancer Prevention Programme**

The Cancer Prevention Programme at the Wolfson Institute of Preventative Medicine identifies individuals at increased risk of specific cancers and assesses the prognosis in those with cancer. It also develops ways of preventing cancer in high risk individuals, including clinical trials to find the effectiveness of chemoprevention treatments in women at a high risk of developing breast cancer. To do this the researchers require HES and cancer registry data from the HSCIC, which was requested at the end of 2013 and has not yet been received, an ongoing delay of 14 months. As a result of the delays a wide range of trials and work into preventing cancers have struggled or been delayed.

- **Heart Protection Study**

The Heart Protection Study is a randomised controlled trial of the use of statins for cardiovascular disease. Ongoing prolonged follow up of participants post-trial has been carried out to assess whether statin therapy is associated with any excess non-vascular mortality or significant morbidity. This requires information on mortality and cancer registrations for consented participants; HSCIC provided these data monthly or quarterly.

However since June 2014 the researchers have not received these data. As well as the eight months of missing data there continue to be unresolved issues that prohibit the continued supply of data by HSCIC. The reasons for the delay are complex and relate primarily to the data sharing agreement. The original data sharing agreement (DSA) contained a clause requiring review for termination or extension by July 2013. However the HSCIC failed to initiate this review at that time, and even approved a revision to the DSA regarding a change in research staff in October 2013. In October 2014 when the researchers queried why that had not received data they were told that their DSA had expired and would need to be renewed before data linkage could continue. The researchers responded to questions relating to a new DSA in January 2015 but do not yet know when the agreement will be reviewed.

The researchers were also told by HSCIC in June 2014 that as the result of the Care Act they would no longer be able to receive patient identifiable data even with explicit patient consent or with a section 251 exemption. Since then they have submitted new applications and have been in discussion with the Confidentiality Advisory Group of the Health Research Authority about this. There is now a suggestion that a new Research Ethics Committee review may be needed, but the advice given has been inconsistent.

The delays in the receipt of this data prevent any further ongoing analysis on the risks and benefits of statin therapy in this trial population.

- **Bariatric Surgery Study**

Cancer researchers are seeking to extend a data linkage study to assess whether individuals who have had bariatric surgery are at a higher risk of developing bowel cancer than those who were obese. The researchers have done a lot of similar cancer data-linkage work previously as part of an academic team within a cancer registry, and hence approached the setup of this study in the same way as their previous work.

However during the period of their funding Public Health England was established and the regional cancer registries were merged into a national system. This meant that the data linkage method they had used previously was no longer possible. The researchers therefore had to apply for new information governance and ethical approval to undertake the study, this process was made more difficult and time consuming as limited information was available on the proposed data flow from PHE. New approval was granted for the researchers to carry out the linkage within PHE, however PHE then declined this preferring the HSCIC to do the linkage and then then supply the data. The researchers have now applied to the HSCIC for access to the data and are awaiting the outcome. This process has taken two years and at present the study remains on hold.

The delays have lasted beyond the duration of the original funding grant and the study is still on hold. The researchers are seeking a no cost extension but it is difficult for the World Cancer Research Fund to recommit funds when there is such uncertainty.

2. Research with potential use for health services planning

Much of this research uses linked data or non-patient identifiable data

- **Policy Research Unit for Children, Young People and Families (CPRU)**

The CPRU are examining the pattern of the use of secondary care by children and young people throughout their lives to understand the patterns of A&E and clinic attendances, admissions and subsequent outcomes, particularly for vulnerable groups and those with chronic conditions.

The request for data was submitted to the HSCIC in October 2013, but the data has still not been received, an on-going delay of fifteen months. The researchers report that they were on the verge of receiving the data in December 2013 just as problems arose in the HSCIC. The delays have meant the planned research has been delayed, it is anticipated that the outcomes of this research will be highly relevant in addressing several major policy questions including the current crises in A&E attendance and the role of integrated care.

- **Asthma UK**

Asthma UK routinely uses data on asthma emergency admissions and performs further analysis to look for trends and improvements. The tabulated HES data were requested in January 2014 and to date Asthma UK have not received it, an on-going delay of more than a year. In contrast Asthma UK has received the equivalent data from Wales, Northern Ireland and Scotland.

The delays were a result of the changes in data sharing agreement arrangements and the subsequent freeze on data release and backlog. During this time the HSCIC have asked Asthma UK for the same additional information on more than one occasion and have failed to confirm receipt of a new data sharing agreement.

The delays mean that the researchers have been unable to use data to study trends and look for improvements which, in turn, has delayed other projects that require this information. The latest figures Asthma UK has access to are now two years out of date.

- **Arthritis Research UK**

Arthritis Research UK, in collaboration with Imperial College London, has been developing the Musculoskeletal Calculator. The calculator is a series of local prevalence models for four musculoskeletal conditions: osteoarthritis, rheumatoid arthritis, back pain and fragility fracture risk, it will allow users to compare the prevalence of these conditions in different areas across England.

To develop the calculator 2012-13 Hospital Episodes Statistics data were required, and would normally have been released by the HSCIC six months after the end of the year. However, HES data for 2012-13 did not become available until November 2014, a delay of almost a year. The delay coincided with the review and subsequent halt of data releases by the HSCIC.

The delay forced Arthritis Research UK to change their research plans and postpone the distribution of their findings.

3. Evaluation, audit and service improvement research

Much of this research requires linked data and routine data releases

- **National Joint Registry**

The National Joint Registry (NJR) for England, Wales and Northern Ireland collects information on joint replacement surgery and monitors the performance of joint replacement implants. It is managed by the Healthcare Quality Improvement Partnership. Monthly HES data are required to maintain the Registry. As a result of the suspension and subsequent backlog in data release from the HSCIC, receipt of the HES data was delayed by six months.

Delays in the receipt of data from the HSCIC have had a number of consequences. The NJR requires HES data to monitor, measure and report on healthcare provider compliance with the registry on a timely basis. As a mandatory national audit, working with providers to identify accurately low areas of compliance, the ongoing monitoring of implant, hospital and surgical performance is important to ensure patient safety. These data are also reported in the public domain through various NJR information services and are relied upon across the orthopaedic community. Comparing HES and NJR data also forms the basis of the NJR's subscription funding model and the Best Practice Tariff for hip and knee replacement and there is a risk that both providers and the registry could be financially disadvantaged from April 2015.

- **National Joint Registry-PROMS**

NJR-PROMS links patient reported outcome measures (PROMS) to the clinical outcomes data in the NJR to provide a more comprehensive picture of the outcome of operations. To do this annual PROMS data is required from the HSCIC (under a 251 exemption).

The PROMS data receipt was delayed by 14 months as a result of the HSCIC review and resulting suspension and backlog in data release. As a result in 2014 the NJR was unable to publish linked NJR-PROMS analysis as part of its annual outcomes reporting, despite this being a priority area for development. The same data is also supporting in-depth study work on patient reported outcomes, which is also now delayed. Understanding what influences the success rate of operations from a patient's perspective is an important area for the whole sector.

In addition, looking forward to 2015, there is also a lack of clarity as to who will undertake the linkage between the two data sets (the Registry and PROMS). Previously this has been carried out by the registry's data services contractor, with an established process developed over nine years. The HSCIC are yet to clarify if they intend to undertake all data linkage before its release following the review, what charges might apply and crucially, how long it would take them to carry out this work. If a new process is established, additional time would also be needed for quality assurance on the registry's part.

- **Missing data in PROMS - DPhil Research project**

Patient reported outcome measures (PROMS) are increasingly being used in routine care to assess the effects of interventions such as hip and knee replacements on health and quality of life. PROMS data are usually collected through the use of questionnaires before and after surgery. This project seeks to assess the impact of missing questionnaire data and consider how missing data should be handled in statistical analysis. To complete this work the researcher needs access to the national PROMS dataset and applied to the HSCIC for this in February 2014.

Access to these datasets had still not been provided by February 2015. The cause of the delay is not clear and the researcher has been asked to supply substantial additional information not requested in the original application. As a result, the planned 3-year DPhil project has had to be rescheduled. The findings of this project will be important for other researchers wanting to make better use of PROMS data.

- **Be Clear on Cancer campaign evaluation**

Cancer Research UK is evaluating the impact of the Department of Health's Be Clear on Cancer, a national campaign aimed at raising awareness of the signs and symptoms of cancer and prompting those with relevant symptoms to visit their doctor. Cancer Research UK's statistical information team has requested National Lung Cancer Audit data from the HSCIC to complete this evaluation.

There was a delay in receiving these data, as a result of the need for a new data sharing contract. There was a delay of over three months between the original data request and receipt of the new contract from the HSCIC. In addition the new contract is more restrictive than the previous agreements in its requirements from the organisation and its IT infrastructure.

The delay in receiving these data has the potential to reduce how comprehensive the evaluation report may be, leading to a less optimal evaluation which could lead to poor decision-making about the programme and future use of taxpayer funds. In addition the delays and additional restrictions have required additional staff resource to contact the HSCIC for a response, and in seeking guidance on matters surrounding the new contract.