HSC-PBPP End of Project Reports – January 2024

Application Reference (click on reference for EPR Summary)	Applicant	Applicant Organisation	Title and Purpose of study	Date of Approval
1718-0151	Miss Alexandra Hellyer	Royal College Obstetricians Gynaecologists (RCOG)	OASI Care Bundle Quality Improvement Project	18/04/2018
1718-0202	Glen Bramley	Heriot-Watt University	Profile of Severe and Multiple Disadvantage in Scotland – analysis of Scottish Drugs Misuse Database (version 2)	13/02/2018
1718-0221	Allan McLeod	Health Protection Scotland	Linking Scottish Infected Blood data (PSD) to Hep C data (HPS)	17/11/2017
1718-0298	Nicola Starkey	National Services Scotland	CAHMS Rejected/Redirected Referrals Audit	27/02/2018
1718-0334	Aghimien Iyayi-Igbinovia	National Services Scotland	Hospice at home data pilot	19/09/2018
1718-0141	Elizabeth Murphy	SCOTTISH SOCIETY FOR RHEUMATOLOGY	SCOTTISH SOCIETY FOR RHEUMATOLOGY WEB BASED AUDIT	02/02/2018

1718-0160	James Roy Robertson	Edinburgh University	Edinburgh Drug Cohort Study	06/02/2018
1718-0341	Professor Esther Crawley	University of Bristol Medical School	BPSU Study of severe Chronic Fatigue Syndrome/Myalgic Encephalopathy	
1718-0012	Prof Peter Murchie	University of Aberdeen	Understanding the interplay of geography and demographic characteristics in the diagnosis of eight common cancers: The NASCAR-CENSUS project	11/05/2017
1718-0004	Angela Khan	Public Health Scotland	Scottish Trauma Audit Group – development of eSTAG	
1718-0044	Prof Nick Bailey	University of Glasgow	Assessing the impact of benefit sanctions on health	
1718-0213	Michelle Nunn	University of Oxford	ASCEND (A Study of Cardiovascular Events iN Diabetes)	

Appendix: End of Project Report Summaries

1718-0012 Prof Peter Murchie

Understanding the interplay of geography and demographic characteristics in the diagnosis of eight common cancers: The NASCAR-CENSUS project

End of Project Summary

1	**Aims**	
	What did the study set out to achieve?	We explored the relationship between one year mortality for those diagnosed with one of eight common
2	**Public Benefit Impact**	
	How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered.	The relationship between distance to health services, timely cancer treatment and one-year survival were the same adjusting for both area-based and individual SES. It seems that distance to services, rather than personal
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	Our original NASCAR cohort was linked to individual census markers of SES from the 2001 and 2011 censuses. Data were as expected.
4	**Methodology**	
	How did you collect the data?	Data were linked by analysts within the ADRN-datalink
	How did you process the data?	Data were processed within the ADRN-datalink
	How did you provision/publish the information?	As publication in International Journal of Population Data Science
	Did your study scope change from its original aims? Please give brief details.	No, project proceeded as planned.
5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	Following adjustment for area-based SES measures those living more than 60 minutes from the cancer treatment centre were significantly more likely to be treated within 62 days of GP referral than those living

		within 15 minutes (Odds Ratio [OR]) 1.41; 95% (Confidence Interval [CI]) 1.23, 1.60]. Replacing area-based with individual-level SES measures from UK Censuses made little impact on the results [OR 1.39; 95% CI 1.22, 1.57].Following adjustment for area-based SES measures of socioeconomic status those living more than 60 minutes from the cancer treatment centre were significantly more likely to die within one year than those living closer by [OR 1.22; 95% CI 1.08, 1.38]. Again, replacing area-based with individual-level SES measures from UK Censuses made little impact on the result [OR 1.20; CI 1.06, 1.35
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	No further analysis of the NASCAR Census dataset are planned.

1718-0044 Prof Nick Bailey

Assessing the impact of benefit sanctions on health

End of Project Report

The Public Benefit Impact Summary

1	**Aims**	

	What did the study set out to achieve?	The study was not able to go ahead. In 2021, before data had been assembled, the Secretary of State for Work and Pensions reversed the earlier approval for data sharing. The research was therefore unable to proceed.
2	**Public Benefit Impact**	
	How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered.	n/a
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	n/a
4	**Methodology**	
	How did you collect the data?	n/a
	How did you process the data?	n/a
	How did you provision/publish the information?	n/a
	Did your study scope change from its original aims? Please give brief details.	n/a
5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	n/a
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	n/a

1718-0141 Elizabeth Murphy

SCOTTISH SOCIETY FOR RHEUMATOLOGY

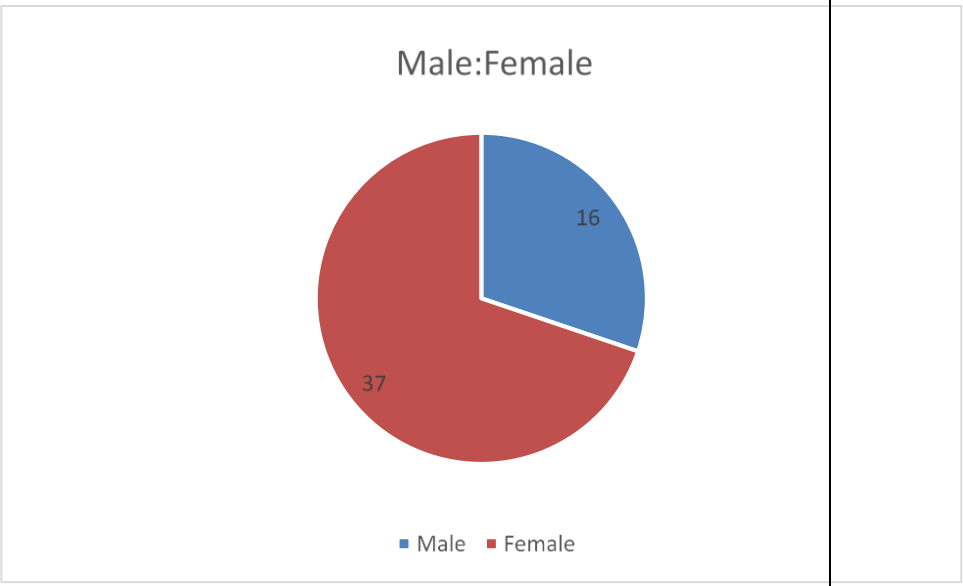
End of Project Summary

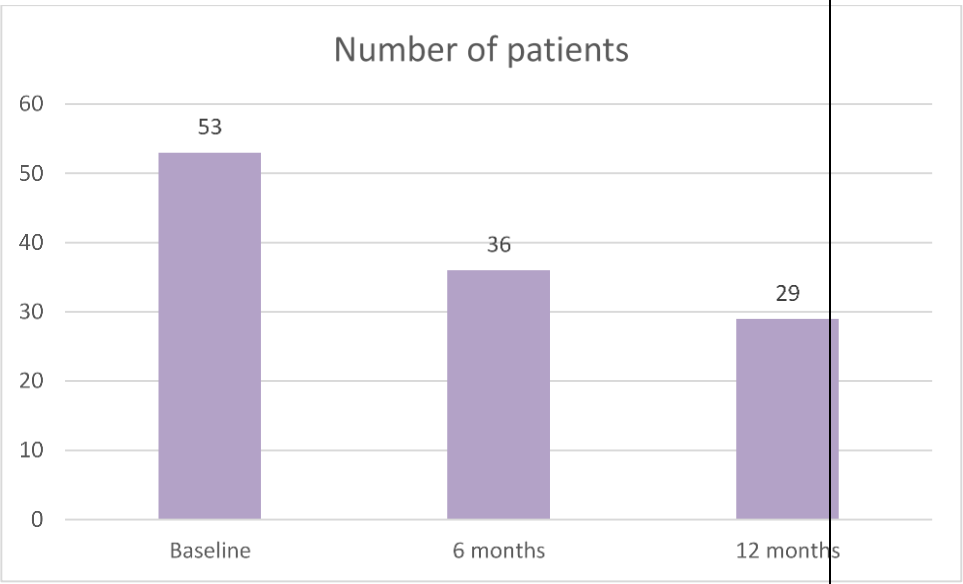
1	**Aims**	
	What did the study set out to achieve?	To audit outcomes in patients with early RA in Scotland
2	**Public Benefit Impact**	
	How will these outcomes directly result in benefit for the public? Please give details. This should be the main	Demonstration of effectiveness of treatment
3	**Data**	
	What data were received/processed/ collected? Was it as expected? Please give brief details	As per document 5 (appended)
4	**Methodology**	
	How did you collect the data?	Web based tool
	How did you process the data?	As per application

	How did you provision/publish the	No
	Did your study scope change from its original aims? Please give brief details.	Poor uptake – service pressures prevented data entry
5	**Outcomes:**	

		Small numbers.

RA AUDIT 2018





Median age 61

Median Baseline DAS ESR (36 subjects) 5.00

Number (%) of patients achieving remission

Number (%) of patients with improvement in DAS >1.2 6months

6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	Yes – agreement that this format is not fit for purpose and alternative methods will be employed in the future.

1718-0151 Miss Alexandra Hellyer

OASI Care Bundle Quality Improvement Project

End of Project Summary

Aims: This was a multi-faceted quality improvement (QI) project with the ultimate aim of reducing rates of severe perineal trauma following childbirth in the UK by standardising practice for the prevention of obstetric anal sphincter injury (OASI) in a way that is acceptable to clinicians and women. This project implemented a care bundle supported by a multi-disciplinary skills development module and campaign materials in 16 maternity units within England, Wales and Scotland (Queen Elizabeth University Hospital [Glasgow] and St John's Hospital [Edinburgh]).

Data: *What data were received/processed/collected? Was it as expected? Please give brief details.*
The primary clinical outcome measure was the OASI rate which was evaluated using patient-level data from each of the 16 participating unit's Maternity Information System (MIS). To this end, an 18-month extract of patient level data (to include pre-rollout, a 3 month transition and implementation periods) were analysed for each participating site. While data for a longer period for pre-rollout is available, we followed the recommendation that primary analyses need to be based mainly on data from those exposed to the intervention or control while clusters are in both conditions, supplemented only by data from immediately before or after the roll-out period.
The pre-defined data specification included perineal trauma during previous births (this will need to be extracted from the full cohort from SMR02 and SBR), perineal trauma during recorded births over observed period, maternal characteristics (e.g. age, body mass index (BMI), parity) and intrapartum care (e.g. episiotomy, induction of labour, epidural use, shoulder dystocia and mode of birth).
The dataset did not include any patient identifiable information. It was transferred to and stored at a secure server, and only named individuals from the Project Team had access to the dataset. All participating units have signed a Data Sharing Agreement with the RCOG, and all users of the data are obliged to fully comply with Data Protection Legislation.

Methodology: *What did you do with the data? How did you process the data? How did you collect the data? How did you provision/publish the information? Did your study diverge from its original aims? Please give brief details.*
Prior to analyses, the data from each unit was cleaned and re-coded to ensure consistent definitions for all variables. Data quality was assessed by checking data completeness, plausible distributions and internal consistency.

All singleton, live, vaginal births were included in the study. Births at home/in transit, water births and births during the transition period were excluded. The multi-level logistic regression to estimate the impact of the intervention on OASI rate adjusted for secular time trends and risk factors for OASI (age, ethnicity, BMI, parity, birthweight, mode of delivery), and included a random effect to account for clustering at the unit level.
Our study did not diverge from its original aims, as outlined in our published protocol: (https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-018-1965-0)

Outcomes: *The outcomes / results of your proposal. Please give brief details*.
There are six key findings:

- The project highlighted a general need and interest across England, Scotland and Wales to better manage perineal care
- Preliminary results show a statistically significant decrease in obstetric anal sphincter injuries (OASI) in all vaginal births. The most improvement was seen in spontaneous vaginal deliveries (SVDs)
- Exploratory qualitative data suggests that the care bundle appears to be acceptable to women and that women feel that it is important to understand about perineal trauma antenatally
- The project looked at barriers and enablers to implementing the care bundle and these can be translated to other QI projects within maternity
- The project demonstrated the value of the key partnership between the two Royal Colleges and midwives and obstetricians
- Key to the project was the hard work and time given by the local champions within the participating units

Public Benefit Impact: *How will these outcomes directly result in benefit for the public and/or patients? Please give details. This should be the main section.*
OASI have both short- and long-term impacts on the women who sustain them during childbirth. In the short-term, women experience pain, longer hospital stays, an operation to repair the tear, follow up care and often impact mother-baby bonding in first hours and weeks. The long-term impact can include a need for, physiotherapy, psychological support, further operations as well as have an impact on future births and relationships.
As a result, the care required for that woman has an impact on the healthcare service due to the ongoing care they require, and there are also high litigation costs associated with these injuries.
This project sought to reduce the number of severe tears across the participating units, and more widely in the future, by standardising practice using evidence-based interventions to improve maternal outcomes.

Future Questions: *Have the processes / results raised further questions for future exploration? Please give brief details*.
The team identified many gaps in resources over the course of the project, one being widely accessible women's stories of their experiences of OASI. The project team, along with three women who have suffered OASI, have developed animated videos telling their stories. These can be found on the RCOG website: https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/oasi-care-bundle/oasi-videos/

1718-0160 James Roy Robertson

Edinburgh Drug Cohort Study

End of Project Summary

1	**Aims**	
	What did the study set out to achieve?	Follow up of a cohort of injecting dug users in NW Edinburgh
2	**Public Benefit Impact**	
	How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered.	These data are of importance to policy makers and clinicians in local and national agencies. Guiding the management and funding of mental health services in this sector has never been of more importance and cooperation with public health and Scottish Government has been a useful extension of the study
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	Death certificates from NRS have been supplied for people flagged at central registry
4	**Methodology**	
	How did you collect the data?	Above
	How did you process the data?	Anonymised records were collated and analysed by the researchers
	How did you provision/publish the information?	Attached summary
	Did your study scope change from its original aims? Please give brief details.	No

5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	As in the attached pre publication report results of deaths over several decades were reported
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	As ever with research among the conclusions are the suggestions for further research and the implications for policy at National and local levels. The project, we think, has important messages for clinical practice.

1718-0202 Glen Bramley

Profile of Severe and Multiple Disadvantage in Scotland – analysis of Scottish Drugs Misuse Database (version 2)

End of Project Summary

Public Benefit Impact

The main ***intended benefits*** of this research are to provide new insights and evidence to support more effective policy and service delivery, in order to change the life course, outcomes and quality of life for people experiencing Severe and Multiple Disadvantage (SMD), while also saving significant service and cost burdens on the NHS, local government, other public sector, as well as society more broadly

Aims

The ***overall aim*** of this project is to build on a previous study by developing a clear picture and analysis of adults experiencing 'severe and multiple disadvantage' (SMD) in Scotland, and thereby provide new insights and evidence to support more effective policy and service delivery

The ***main objectives*** of this proposal, as part of the wider project, are to to make robust national estimates of the numbers of adults involved with serious drug and alcohol misuse in combination with other disadvantages (homelessness, offending, mental ill-health), their socio-demographic profile, economic situation, and geographical distribution. We will also seek to provide a profile of the health/quality of life and other outcomes experienced by these groups, draw out evidence on background circumstances and potential causal factors, and estimate the extent of use and cost of services.

Data

This data used in this part of the study was the Scottish Drug Misuse Database anonymised individual records for the period 2008-16, with linked geographic identifiers to facilitate analysis of

geographical incidence and attachment of additional variables for modelling of severity and outcomes.
SDMD was only one of 12 datasets used in the wider study. In the final reporting most analyses involve weighted combinations of estimates derived from varying numbers of datasets depending on the variables and sub-groups of interest.

Methodology
Within SDMD (as with other datasets) the analysis involved identifying indicators of whether subjects were experiencing each of five broad types of severe disadvantage (homelessness, drug and/or alcohol misuse/dependency, offending, mental ill-health, and domestic violence/abuse (the latter was not identifiable in SDMD). We then focused particularly on people experiencing combinations of these disadvantages, and generated profiles of the demographic, social, economic, and geographical characteristics of these groups, and also where possible indicators of outcomes of services or number/durations of episodes. Some statistical modelling was performed to identify factors associated with more complex need, or better/worse outcomes.
The quantitative analysis has also involved estimating overall profiles based on weighted combinations of different datasets as appropriate.
This has been complemented by an important programme of qualitative research including 15 national key informant interviews, two lived experience focus groups and 6 area case studies involving 25 local key informants, 8 focus groups with frontline workers, and 42 in-depth interviews with service users.
Outcomes
The key conclusions of the research (quantitative and qualititative together) include the following headline findings
 People's routes into SMD generally involve a background of poverty, adverse childhood experiences, a troubled young adulthood and a pervasive threat of violence in many different settings
 Key missed opportunities for early intervention are identified in early secondary schooling, early contacts with criminal justice, and unstable/uneven support from childcare system
 The criminal justice system seems to provide the last resort safety net in many cases, the only way people can get appropriate services
 Homeless services often 'carry the can' but lack the command over key health services and provide uneven services and support
 Mental health services are the biggest gap, being severely rationed by lack of resources and inappropriate procedures
 Substance misuse services have retreated to some extent and could be more timely and sustained
 There is a gap in provision for some women with SMD
 The development of trauma-informed services has been limited and there is a need for clarity in lead responsibilities.
So far the results of the research have been shared with two advisory groups (one technical, one policy), with a group of senior local government officers, and with a very well-attended seminar involving many divisions from across the Scottish Government. There will be a major national media launch on Monday 24 June, following which organisations working in the sector are being supported by Lankelly Chase to undertake their own dissemination activities. There will be a further major national event in autumn 2019.

1718-0221 Allan McLeod

Linking Scottish Infected Blood data (PSD) to Hep C data (HPS)

End of Project Summary

Public Benefit Impact

Contamination of blood for transfusion and blood products (clotting factors derived from blood to treat haemophilia and associated clotting disorders) with blood borne viruses such as hepatitis C (HCV) in the 1970s and 1980s was a significant public health issue. While heat treatment of blood products and screening of donated blood (established in 1987 and 1991, respectively) have eliminated this as a transmission route in Scotland, there remain hundreds of individuals who were infected through blood and blood products and still alive. From 2017, the Scottish Infected Blood Support Scheme (SIBBS) took over from existing UK schemes in providing *ex-gratia* payments for these individuals. Under the previous payment scheme, patients were split into those with advanced liver disease (who receive a one off payment and an annual payment of over £20K) and those without advanced liver disease (who receive a one off payment and an annual payment of under £5K). This arrangement did not take into account other, non-liver related morbidity associated with HCV infection, including the side-effects from treatment. This project informed an option appraisal by the Clinical Review of the Impacts of Chronic Hepatitis C group, which examined these factors and may result in an increase in support for some patients.

Aims

This project aimed to describe the contact with HCV services among those infected through blood or blood products to gain a better understanding of the impact on their health and wellbeing and calculate (1) time between infection and diagnosis, (2) time between diagnosis and treatment, (3) characterise attendance at specialist services, HCV treatment uptake and treatment outcomes.

Data

Practitioners Services Division (PSD) of NSS maintains a database of all individuals registered on the SIBSS. HPS maintains a databases of all laboratory confirmed diagnoses of HCV in Scotland and a database of all individuals attending specialist services for HCV treatment and monitoring.

Methodology

The databases were linked deterministically using CHI number. Primary infectees (i.e. those who acquired their HCV infection from blood or blood products) were included and categorised as "chronic HCV" or "advanced HCV" based on the previous support scheme classifications. Descriptive analysis was undertaken comparing the time of diagnosis, route of HCV acquisition, receipt of HCV treatment, and treatment outcome across the two groups. Aggregated results were included in the final report of the Clinical Review and can be found here.

Outcomes

Based on a review of evidence, including the results of this project, the Clinical Review group recommended that people with chronic HCV (including those who cleared virus through treatment), or widows/widower or partners, who are (or who become) SIBSS beneficiaries should self-declare HCV impact on their health as not appreciably affecting their life, affected and continued to affect their life, or seriously affected their life. Scottish Ministers accepted all of the recommendations.

1718-0298 Nicola Starkey

CAHMS Rejected/Redirected Referrals Audit

End of Project Summary

Aims

I. To provide recommendations which will improve the experience of children, young people (CYP) and their families referred to CAMHS Tier 2, 3 and 4 services, but who may not subsequently receive them (rejected) and understand outcomes for CYP whose referrals are redirected.

II. To understand referrals to CAMHS specialist services in terms of their volume, purpose, source and nature.

III. To understand the causes and reason for rejected/redirected referrals across Scotland and the impact this has on children, young people and their families. To ensure particular groups are not being disproportionately affected and to consider solutions to any issues found.

IV. To understand what happens to a redirected CAMHS referral in terms of signposting to other services or not.

V. To provide recommendations around improvements and any ongoing data requirements.

Data

Data was received from the seven Health Boards involved in the audit including data items specific to the audit along with SMR01 and Unscheduled Care Database data. The data received and processed as was expected and inline with the approved PBPP application.

Methodology

The Mental Health Access Improvement Support Team (MHAIST) analysts took forward a qualitative audit of Children and Adolescent Mental Health Service (CAMHS) rejected referrals at seven Health Boards. They did this by collating the required data items from data already captured at their Health Board during February 2018 before sending it to the ISD-based core team MHAIST analysts via NHS Mail for analysis and reporting at the end of the data collection period. The data was sent as either two csv or Excel files and saved separately on the ISD secure server once received. This data was then analysed by the named core team analysts to produce the results for the joint publication and inform the recommendations for improvement to CAMHS referrals.

The study did not deviate from it's original aims.

Outcomes

The outcome of the audit was a joint publication with the Scottish Association for Mental Health (SAMH) which was published by the Scottish Government on 29th June 2018.

Public Benefit Impact

The published report found that children and young people are not being given adequate explanations for the refusal, or directed to alternative support services. The report gave 29 detailed

recommendations including further research, meeting the needs of children, young people and their families, practical changes to the existing system, and improving data collection.

To drive forward these changes and recommendations, a new CAMHS Taskforce has been created, backed with £5 million of investment from the Scottish Government with the aim of reshaping and improving child and adolescent mental health services (CAMHS) across Scotland. Internationally respected mental health expert Dr Dame Denise Coia is heading the taskforce and in December 2018 they published their detailed delivery plan (see below).

1718-0334 Aghimien Iyayi-Igbinovia

Hospice at home data pilot

End of Project Summary

Public Benefit Impact
Contribute to understanding hospice at home services and patient journeys towards the end of life. -Help promote awareness and the use of hospice at home service provision in local areas. By reporting on hospice at home activities, service providers, planners and commissioners will have a better understanding of service user's changing needs and ensure that equality of access is provided, regardless of age, gender, diagnosis, social group or location.
Provide hospice managers with an understanding of service utilisation and demand, and supporting local planning, performance management and national benchmarking.
Supports the SG's Shifting the Balance of Care policy for more people to be cared for in the community as opposed an acute setting.

Aims
Engage with Hospices to identify those that provide a hospice at home service and ascertain current level of local data collection.
-Agree a definition for hospice at home service.
-Develop a minimum data set for data collection to enable reporting.
-Assess the sufficiency of the minimum data and if other data items should be considered prior to future data collection.
-Test data submission of hospice at home activities.
-Develop management information reports using pilot data. The pilot will report on data quality, patient profile, the number of people receiving hospice at home care services, number of hours of care received, main condition of care and additional patient journey information before the end of life.
-Contribute to understanding Hospice at home service on patient/client outcomes, demand on services and patient journeys towards the end of life as a significant proportion of hospice services are provided within the community.
-To establish the feasibility of a more systematic national submission in the future.

Data
Data was received from three Hospices (Strathcarron, Ayrshire and Children's hospice across Scotand (CHAS)). It contained information at patient level for individuals that received a hospice at home service. Data was provided on demographics, referral details, hospice at home start and end, and discharge information.

There were issues with data submissions. Some sites could not provide data items within the defined timescales and others took longer to submit data due to resource challenges, and further verification.

Methodology

The pilot was a retrospective data collection of activities on individuals referred to a hospice at home service from 1st April 2017 to 31st March 2018 (inclusive).

Data for the pilot was recorded in a Microsoft Excel Spreadsheet via a user form developed by the Information Services Division (ISD). The spreadsheet was sent out by email to named contacts at each pilot site for completion as per data items agreed. Data was submitted to ISD via Globalscape, a security approved method already in use for submission of data to ISD.

Outcomes

Improved understanding of hospice at home service provision, variations offerings across organisation and a need for standardisation to enable better reporting.

1718-0004 Angela Khan

Scottish Trauma Audit Group – development of eSTAG

The Public Benefit Impact Summary

1	**Aims**	
	What did the study set out to achieve?	Major trauma describes serious and often multiple injuries where there is a strong possibility of death or disability and is the most common cause of death in young people in the UK. The Scottish Trauma Audit Group (STAG), part the Scottish National Audit Programme (SNAP) of Public Health Scotland (PHS) initially audited the management of seriously injured patients in Scotland from 1992-2002 and recommenced this audit in 2011. The aim of the audit is to improve the care and outcomes of patients with serious injuries through measuring compliance against nationally agreed standards of care to support local quality improvement. The STAG at this time includes patients of all ages, in 28 hospitals with an Emergency Department (ED) in Scotland. Reports are provided via the visualisation tool Tableau™ to participating hospitals and an annual national report is also published on the STAG website www.stag.scot.nhs.uk
2	**Public Benefit Impact**	

	How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered.	Increased capacity for local/ national reporting against agreed national key performance indicators for the Scottish Trauma Network (STN); Ability to respond efficiently and timeously to information needs of the Scottish Government and NHS Boards across Scotland. In particular, the requirement from the Scottish Government to measure the effectiveness of the STN, which was implemented from 2017; Improved data quality; and Efficient and timely data collection practices.
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	**Data relating to patients:** Forename, surname, CHI number, full post code, sex, date of birth, personal and health data. The majority of the data are already collected in local systems within the emergency departments and trauma wards across Scotland (individual patient paper/ electronic case-notes/ patient records).
4	**Methodology**	
	How did you collect the data?	Data for STAG are collected via eSTAG from various locations, e.g. NHS systems such as TRAKcare, OPRA, PACs etc. Some of the information entered onto eSTAG will be directly from patients written or electronic notes by local audit coordinators trained to do this role. Data will be transferred via secure electronic transfer, i.e. SWAN. eSTAG also links with data in the corporate data warehouse relating to Scottish Ambulance Service activity.
	How did you process the data?	Data was analysed using SPSS/ R on the PHS secure Posit server area and reports were presented in data visualisation, for example via Tableau/ RShiny and access to these is managed following the current PHS protocols.
	How did you provision/publish the information?	As noted above - the most recent STAG publication utilising data from eSTAG was published here on 22nd August 2023 by PHS.

	Did your study scope change from its original aims? Please give brief details.	No.
5	**Outcomes:**	
	The outcomes/ results of your proposal. Please give brief details.	All outcomes and results can be viewed in the recent publications - here.
6	**Future Questions:**	
	Have the processes/ results raised further questions for future exploration? Please give brief details.	The Scottish Trauma Audit Group continues to collect data and continues to adapt to allow reporting of key situations in collaboration with the Scottish Trauma Network.

1718-0341 Professor Esther Crawley

BPSU Study of severe Chronic Fatigue Syndrome/Myalgic Encephalopathy

The Public Benefit Impact Summary

1	**Aims**	
	What did the study set out to achieve?	To investigate incidence, clinical presentation and clinical management of severe Chronic Fatigue Syndrome/Myalgic Encephalopathy
2	**Public Benefit Impact**	

	How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered.	The figures of incidence/prevalence are original findings and no good figures existed before this study. Analysis and publication are still on going Estimated prevalence was 3.18 per million children (95%CI 2.19 to 4.47). Including possible/probable severe ME/CFS gave 8.88 per million children (95%CI 7.16 to 10.9). The incidence rate was 0.90 per million children-years (95%CI 0.43 to 1.65) [1.97 per million children-years (95%CI 1.24 to 2.99)]. These outcome will directly benefit the public because no prior prevalence for Severe ME/CFS was known, and provision of treatment for these patients is difficult. This finding will inform decision-making towards service provision for this severely affected group of patients. Service provision can include domiciliary visits and is hence expensive and an accurate sense of case numbers is of high value.
3	**Data**	

	What data were received/processed/collected? Was it as expected? Please give brief details.	Data was in the form of completed Questionnaires, using the well-known BPSU methodology. Answers to questionnaires covered: • Reporting Dr details (contact details and hospital and whether referral centre) • Case details (demographics: NHS/hospital numbers, sex, dob, ethnicity, partial postcode) • Presentation/clinical features (dates of symptom onset/diagnosis etc) • Clinical features of fatigue and associated symptoms (including impact) • Symptom checklist • Functional impact (incl school attendance) • Investigations and management: blood tests completed and whether normal results • Investigations and management: treatment received Processed – anonymisation, then application of exclusion criteria followed by analytic case definition to judge whether Severe. 285 case notifications, 56 questionnaires not received, 10 duplicates 33 confirmed severe ME/CFS cases, and a further 59 possible/probable severe ME/CFS. No good estimates of prevalence/incidence predated this study. Our reported case numbers far exceeded our own prior estimates (crude estimates including use of the ALSPAC data), though overall confirmed prevalence was approximately the same.
4	**Methodology**	
	How did you collect the data?	1. BPSU regular monthly bulletins sent by BPSU to Consultant Paediatricians across UK and ROI 2. Case notifications/nil returns sent back to BPSU by clinicians. 3. Questionnaires sent to clinicians – with receipts provided 4. Questionnaires received and entered into secure spreadsheets

	How did you process the data?	Entered into spreadsheet – scrutinised and exclusion criteria applied. Anonymisation and then scrutiny by Expert panel with Analytic case definition applied. Data anonymised by removing of any sensitive identifiers, leaving only BPSU IDs (as serials to identify cases)
	How did you provision/publish the information?	Still ongoing
	Did your study scope change from its original aims? Please give brief details.	1. Some cases (n=55) were reported directly from specialist centres and not via BPSU case notifications. They were sent blank questionnaires, which were sent directly to study team. 2. Intention to complete a 1-year follow-up was not carried out. This was due to the difficulties of carrying out a surveillance study during a global pandemic.
5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	**Primary outcome**: Estimated prevalence was 3.18 per million children (95%CI 2.19 to 4.47). Including possible/probable severe ME/CFS gave 8.88 per million children (95%CI 7.16 to 10.9). The incidence rate was 0.90 per million children-years (95%CI 0.43 to 1.65) [1.97 per million children-years (95%CI 1.24 to 2.99)]. **Secondary outcome**: Median age at diagnosis was 13.2 years and 57.6% of confirmed cases were female. Median time to diagnosis was at 0.47 years. The commonest symptoms were impaired memory and concentration, followed by post-exertional malaise and sleep disturbance.
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	Fewer females and non-white patients were seen in this population of patients with Severe ME/CFS. Possible future exploration could be done into whether barriers to diagnosis and treatment exist for these populations.

1718-0213 Michelle Nunn

ASCEND (A Study of Cardiovascular Events iN Diabetes)

The Public Benefit Impact Summary

1	**Aims**	
	What did the study set out to achieve?	ASCEND aims to find out whether long-term treatment with aspirin and/or omega-3 fatty acids (FA) is beneficial in people with diabetes, who did not have problems with their heart or blood circulation when they joined the study.
2	**Public Benefit Impact**	
	How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered.	The ASCEND main trial (2005-2017) showed that aspirin prevented serious vascular disease in these individuals, but the benefits were largely counterbalanced by major bleeds and there was no effect on the development of cancers. Knowing this means that the risks of major bleeds can be avoided by the very large number of diabetic patients who have been treated with aspirin. The ASCEND results have influenced National & International guidelines such as: • The June 2022 NICE guideline Type 2 diabetes in adults: management [NG28] (https://www.nice.org.uk/guidance/ng28) • The Dec 2022 American Diabetes Association Standards of Medical Care in Diabetes guidelines (https://professional.diabetes.org/content-page/practice-guidelines-resources)

		• The Feb 2023 update to the NICE guideline Cardiovascular disease: risk assessment and reduction, including lipid modification [NICE guideline CG181] https://www.nice.org.uk/guidance/cg181 The data collected from central NHS registries during the long-term follow-up phase of the study, will be used to assess whether any benefits or harms of aspirin observed within the trial, continue long-term or additional benefits or harms emerge during longer-term follow-up. It had been suggested that low-dose aspirin might protect against cancer, and ASCEND provides one of the first opportunities to test this hypothesis. The analyses conducted so far, based on the study treatment phase, showed no reduction in any cancers during a mean 7.3 years of follow-up. However, the main focus of the analyses will be after long-term follow-up, when there will be much better power to detect plausible differences in cancer incidence between the arms due to larger numbers of events. Dementia and cognitive impairment present major health care and social burdens which are increasing globally with increasing lifespan. In observational studies, diabetes is associated, not only with a 2-3 fold increased risk of vascular events, but also with a 50% increased risk of dementia and a 20% increase in the rate of cognitive decline. Therefore, it is of particular importance to obtain randomized evidence of the effects of therapies for

		vascular prevention on cognitive decline among people with diabetes. Furthermore, the higher risks of cognitive decline and dementia among people with diabetes make them a potentially powerful population for investigating cognitive effects. The effects of aspirin on dementia and cognitive impairment (identified through the trial follow-up procedures or in the hospital and death linked data were published in 2022 and showed no effect of aspirin on dementia risk but longer follow-up is needed to reliably assess this question. Analyses of the effects of aspirin on cognitive outcomes are therefore planned for 5 and 10 years after the end of the scheduled treatment period. Heart failure is a major cause of disability and people with diabetes are at increased risk of developing heart failure. The current work in confirming heart failure events identified from the trial follow-up procedures and the linked health records, will be used to assess the impact of aspirin on heart failure during the scheduled treatment period. This will also allow algorithm development to reliably identify heart failure events in the long-term follow-up to allow the assessment of the effects of aspirin on long-term heart failure risk. The results from the ASCEND long-term follow-up work could inform future guidance and provide clarity to diabetes patients on the harms and benefits of taking aspirin and omega-3 FA. Any results would be relevant to millions of people worldwide and their health care providers.

3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	The following datasets were received: **PHS**: SMR00, SMR01, SMR04, SMR06, A&E, Deaths **NHSCR**: Deaths, Cancers, Members & Postings Data was mostly as expected. The ASCEND team have not yet received the annual data drop for 2021 data from PHS. This is now going to be included with the follow-on application (ref 2324-0062). In addition the ASCEND study team requested the SMR04 data to identify dementia (using Dementia related ICD-10 codes). However, the file received contained only 1 patient record (between 01-Apr-1997 and 15-Jan-2016). To investigate further how dementia outcomes can be identified from this dataset the ASCEND study team are re-requesting (in application ref 2324-0062) the SMR04 data with all specialities and codes.
4	**Methodology**	
	How did you collect the data?	Data has been collected directly from participants, from Electronic Health Records (held by NHS Registries), and occasionally from a participant's GP.

	How did you process the data?	Data was received by the ASCEND study team from Public Health Scotland, and the NHSCR. It was linked to data collected from participants during the trial, and to other Central Registry datasets e.g. from NHS England. Processing took place within NDPH. All work involving the Scottish data took place within the NDPH NHS DSPT compliant environment. Only members of the study team had access to the data as was necessary for their work e.g. Programmers, Analysts, Statisticians, Clinicians. Data was pseudonymised prior to analysis. No PHS or NHSCR/NRS individual level participant data has been shared with anyone other than substantive employees of the data controller.
	How did you provision/publish the information?	Publications have been made to journals. Presentations have been made at conferences, and information has been provided on the ASCEND study website.
	Did your study scope change from its original aims? Please give brief details.	Some of the original aims have been met (and results reported – see 5. Outcomes). The ongoing aims are as per the protocol and are to provide robust information about the long-term outcomes for the ASCEND participants.
5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	The ASCEND main trial (2005-2017) showed that aspirin prevented serious vascular disease in these individuals, but the benefits were largely counterbalanced by major bleeds and there was no effect on the development of cancers. Ongoing long-term follow-up work has identified the following:

		1. The Cognitive Function and Dementia analysis (presented at the American Heart Association (AHA) in November 2021, and published in the European Heart Journal 2022;43(21):2010-2019), found that there was no statistically significant effect on dementia outcomes in participants taking aspirin and that trials with larger numbers of incident dementia cases are needed to assess whether there are any benefits after 5-7 years of aspirin use. In the UK routine electronic health data provided a cost-effective means of assessing the impact of vascular preventive therapies on dementia. 2. Results on the effects of omega-3 fatty acids were presented at the European Society of Cardiology in August 2022. This analysis showed that omega-3 fatty acid supplementation had not detectable effect on dementia or cognitive function. 3. Results (also reported at the ESC 2022) showed that data linkage with routinely collected data, followed by adjudication of clinical and routinely collected data, allowed the ASCEND trial to identify many additional participants with heart failure compared to patient reported events alone. This finding will allow for more effective assessment of the effects of aspirin and omega-3 on heart failure. 4. Post hoc analyses of the ASCEND trial suggest that routinely collected hospital admission and death registry data in the UK could be used as the sole method of follow-up for myocardial infarction, ischemic stroke resulting in hospitalization, vascular death, and arterial revascularization in primary prevention cardiovascular trials, without the need for

		verification by clinical adjudication. These results were published in Heart 2023; 109:1467-1472
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	ASCEND will be following up the participants until 2037. It is anticipated that 20-year follow-up (from the end of the on-treatment phase in 2017) will provide important information about the effects of aspirin and omega-3 FA on the development of dementia and cancer, as well as heart failure, heart attacks and strokes, in this population. The study team believe that it could take many years to get a reliable answers, and intend to undertake analysis at 5-yearly intervals. The ASCEND team will shortly be submitting a follow-on application (Ref 2323-0062) to apply to retain data already received, and to request additional data to continue the research.