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
1920-0083	Ms Linsey Galbraith	Public Health Scotland	Weight Management Core Dataset Reporting	24/04/2020
1920-0240	Anne Birch	Mental Welfare Commission for Scotland	Deaths in Detention Reviews Project (DIDR)	12/03/2021
1920-0116	Ryan Ottridge	University of Birmingham	PD MED Trial-A Large Randomised Assessment of the Cost of Different Classes of Drugs for Parkinson's disease	10/02/2021
1920-0099	Liam Joseph Mullen	Liverpool Heart and Chest Hospital	RIPCORD 2	29/11/2019
1920-0073	Liz Watt	Managed Service Network for Children & Young People's cancer	Teenage & Young Adult cancer Palliative Care: End of Life Care Audit	
1920-0257	Julie Landsberg	Scottish Government	Scottish Health Survey (SHeS)/SMR data linkage – Legal basis change	

1920-0014	Dr Chris Cardwell	Queen's University Belfast	Use of hormone replacement therapy and survival from cancer	
1920-0137	Dr Matthew J Northgraves	University of Hull	Leukaemia In Pregnancy Study	

Appendix: End of Project Report Summaries

1920-0014 Dr Chris Cardwell

Use of hormone replacement therapy and survival from cancer

End of Project Report

1	**Aims**	
	What did the study set out to achieve?	To investigate HRT use after cancer diagnosis and risk of cancer-specific mortality in patients with common female cancers, excluding breast cancer.
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.	Our study showed little evidence of any impact of HRT on survival from cancer, excluding breast cancer. This should provide some reassurance to cancer patients receiving HRT and clinicians prescribing HRT.
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	Data were received on cohorts of female cancer patients (from cancer registry records), prescribed medications (such as HRT, from the PIS) and cancer-specific mortality (from national mortality records).
4	**Methodology**	
	How did you collect the data?	The data used are routinely captured in Scotland. No new data collection was undertaken.
	How did you process the data?	The data were analysed within the National Safe Haven.
	How did you provision/publish the information?	A manuscript has been prepared and is undergoing peer review.
	Did your study scope change from its original aims? Please give brief details.	There were no major departures from the original study aims.
5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	There was no evidence that cancer patients using HRT had higher cancer-specific mortality at any cancer site, excluding breast cancer which was not investigated.

6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	Yes, there were weaknesses in some of the available data highlighting the need for additional analyses to confirm these results.

1920-0073 Liz Watt

Teenage & Young Adult cancer Palliative Care: End of Life Care Audit

End of Project Summary

1	**Aims**	
	What did the study set out to achieve?	To identify gaps in palliative and end of life care for teenagers and young adults (TYA) age 15 – 24 years and 364 days in Scotland and their carer's.
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 information would facilitate the development of age specific palliative and end of life care initiatives in order to respond to emerging need and plan future care for young people and carer's.
3	**Data**	

	What data were received/processed/collected? Was it as expected? Please give brief details.	Non – aggregated data from SMR06 SCORATES was received from Public Health Scotland identifying teenagers and young adults who died from January 2014 to December 2019. Data collected: place of death, place of choice of death if recorded, cause of death, anticipatory care plan completed, referral to palliative care, treatment information, bereavement support and diagnosis. Data processing was not completed. Data was as expected.
4	**Methodology**	
	How did you collect the data?	Data was collected from Patient electronic records
	How did you process the data?	The data was not processed
	How did you provision/publish the information?	No publications have been produced
	Did your study scope change from its original aims? Please give brief details.	An amendment application was submitted to PBPP to add collection of high intensity treatment variable and include data transfer to Martin House Research Centre, University of York. Approval was not given for this.
5	**Outcomes:**	
	The outcomes / results of your proposal. Please give brief details.	No results cannot be defined as the audit is incomplete.
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	No

1920-0240

Deaths in Detention Reviews Project (DIDR)

End of Project Report

End of Project Report and Benefit Summary

Aims: What did the study set out to achieve?

The project aimed to establish a baseline dataset to inform the development of a new system for reviewing and reporting on deaths of individuals who, at the time of death, were subject to an order under either the Mental Health (Care and Treatment) (Scotland) Act 2003 or part VI of the Criminal Procedure (Scotland) Act 1995 (whether in hospital or in the community, including those who had their detention suspended). The data will aid us in our duty to monitor the outcome of detention mental health law in Scotland. The overall project was funded by Scottish Government.

The Mental Welfare Commission for Scotland holds the Scottish national dataset on patients who are detained under the Mental Health (Care and Treatment) (Scotland) Act 2003, or the Criminal Procedure (Scotland) Act 1995. This data can be partial or incomplete.

We aimed to audit our data to :

- Clarify how information on deaths of people who have been detained for the care and treatment of their mental health are recorded and reported and make suggestions for improvement.

- Report more fully on deaths in detention, and access to healthcare in previous months, and make recommendations about how such deaths are reported on in future.

- Explore the usefulness of extending the routine collection of data to include people who die in the 4 weeks period after detention

Public Benefit and Impact How did/will these outcomes directly result in benefit for the public?

The project informed development of the Commission's business case proposal to Scottish Government for implementation of a new system for investigating deaths including how such deaths are notified and reported on in future.

The detailed examination of individual cases, identified via data linking (i.e. cases not otherwise known to the Commission), and exploration of previous pattern of treatment, has helped to identify shortfall in the existing system and to inform improvements.

We found that 6.7% of deaths in detention were not being notified to the Commission. The linked data provides a baseline data set against which the new system can be monitored.

The publication of aggregate data, via the Commission website, in monitoring reports, will provide the first national level data on deaths in detention and characteristics of the individuals concerned e.g. aggregate data on gender, age group, ethnicity. www.mwcscot.org.uk

Data: What data were received/processed/collected? Was it as expected?

A download was taken from the Commission's database of mental health orders.

This was matched via PHS with datasets: NRS Deaths, SMR00-Outpatient attendance, SMR01-Inpatients, SMR04-Mental Health Inpatients, SMR25/SDMD –Drugs misuse and ScotSID (Scottish Suicide Information Database).

The data was received and processed as was expected and in line with the approved PBPP application. The data for the SMR25-SDMD dataset arrived later than originally anticipated (i.e. mid March 2022), and analysis work is continuing on this.

The issue of Significant Adverse Event Reviews following deaths in detention has been examined from a practice perspective. Due to inconsistency of data available on this and the level of administrative burden on the Commission it proved not possible to report quantitatively on this.

Methodology: How did you collect the data? How did you process the data? How did you publish the information? Did your study scope change from its original aims?

Data was analysed via Excel to map the accuracy of the Commission records against NRS Death records for people fulfilling the inclusion criteria. (All deaths occurring 1st Jan 2015 to 30 Apr 2020 whilst subject to a compulsory order or within one month of an order ceasing to apply. Several years' data allowed us to include cases which would occur infrequently (e.g. deaths of persons with learning disabilities under detention, cases from smaller health boards).

The analysis entailed univariate and bivariate descriptive statistics e.g. notified or not notified to the Commission/ on an order at death or death one month post order - by e.g. order at death, location, age gender, health board.

Matching the cohort with other PHS data sets and exploration of individual cases on the Commission database enabled exploration of questions around the individual context of death (natural, unnatural, undetermined) and reviewing processes.

Outcomes:

An initial brief summary of top level data was published in the Commission's consultation paper on proposals for the new system to review these deaths.(08/12/21)

https://www.mwcscot.org.uk/news/new-consultation-investigating-deaths-during-compulsory-care-and-treatment-under-mental-health

A brief summary was also included in the Commission's end of project report and proposals to the Scottish Government (by 31 March 2022) (Publication date to be advised).

Brief aggregated data has been shared with Health Improvement Scotland Adverse Events Review team.

Brief aggregate data has been shared with the Commission participation and engagement officer (carers) for the bereaved carer view.

Future Questions: Have the processes/results raised further questions for future exploration?

This first data-linking exercise between the Commission and PHS has proved the concept and benefit of the exercise. The Commission will consider a request to Scottish Government for funding to repeat the exercise within the next five years.

1920-0257 Julie Landsberg

Scottish Health Survey (SHeS)/SMR data linkage – Legal basis change

End of Project Summary

1	**Aims**	
	What did the study set out to achieve?	To inform past participants of the Scottish Health Survey (as far as is possible) of the change in legal basis for the collection and linkage of the survey and what it means for them.
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 process was viewed as a proportionate response due to the requirement to inform individuals of use of their data by law. Continuing linkage from a survey collected by consent without informing individuals of this would be unethical. Additionally, the contact served to: • inform individuals that their survey responses continue to provide vital information that supports policy decisions • maintain trust in public bodies that data is used ethically Although there is no further direct public benefit from the contact, there is much public benefit from the continued linkage, which this project allows.
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	Latest addresses for past respondents of the Scottish Health Survey who had not previously opted out of their survey answers being linked to their health records. Yes
4	**Methodology**	
	How did you collect the data?	The CHILI team matched the identifiers of past respondents to the Scottish Health Survey (provided by NatCen) to the CHI database and returned to NatCen the most recent names and addresses of all living participants who could be traced.
	How did you process the data?	NatCen used the latest name and address details to issue letters to past respondents of the survey about the linkage with health records.

	How did you provision/publish the information?	No information was published.
	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.	A total of 772 individuals contacted requested that their Scottish Health Survey answers no longer be linked to their health records.. The linkage will now proceed for those who did not opt-out.
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	No

1920-0083 Ms Linsey Galbraith

Ms Linsey Galbraith

End of Project Summary

1	**Aims**	
	What did the study set out to achieve?	To enable national reporting, for the first time, on referrals to tier 2 and 3 weight management services, based on a new standardised core dataset.

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.	Overweight and obesity is the main modifiable risk factor for developing type 2 diabetes. Scottish Government have been investing in the development of weight management services; this reporting provides initial insights into referrals to, and outcomes from, weight management interventions in Scotland.
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	Referrals to NHS Board commissioned weight management services (tier 2 and tier 3) for children and adults; data collected using the new standardised core dataset. The Covid-19 pandemic impacted on data provision during the second half of the reporting year.
4	**Methodology**	
	How did you collect the data?	One-off data submission from each NHS Board in Scotland (on behalf of their weight management services) to PHS, via secure file transfer.
	How did you process the data?	As stated in PBPP application
	How did you provision/publish the information?	As stated in PBPP application
	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.	Published results present information on referrals to, and intervention pathways for, weight management services in NHS boards. referrals to and intervention pathways. This includes: the characteristics of individuals referred. Significant data quality and completeness issues identified; and impact of Covid-19.
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	This initial reporting has provided helpful insights for a future review of the core dataset and associated data collection mechanisms.

1920-0099 Liam Joseph Mullen

RIPCORD 2

End of Project Report

1	**Aims**	

	What did the study set out to achieve?	To compare two strategies for the management of patients undergoing angiography for the investigation of coronary artery disease. The study aimed to determine if the routine use of pressure wire assessment in this context is superior to conventional angiography; both in terms of improved clinical outcomes for patients and in terms of a reduction in overall incurred healthcare costs
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 results of this study have been important in adding to the evidence base regarding the usage of pressure wire technology. The results have been of interest to the scientific community and will be part of a changing landscape for how the technology is best applied to help provide best care for our patients. It is likely this evidence will be cited in next iterations of European/British cardiac guidelines on the subject.
3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	SMR 00, SMR01, A&E and NRS deaths data for 38 study participants recruited from Scottish hospitals, total 12 month data follow up for each. Data was as expected- not a large volume as majority of cohort in study were from English hospitals.
4	**Methodology**	
	How did you collect the data?	Data was electronically transferred to us as per application.
	How did you process the data?	Data was processed on site at LHCH only as planned on secure server. The processing mainly involved the use of Microsoft excel and Microsoft Access databases, and our bespoke algorithms to enable us to determine outcome measures (clinical outcome events as well as hospital costs)
	How did you provision/publish the information?	The data was published in aggregate anonymised form- publication in major cardiology journal (Circulation) and results presented at major cardiac conference (ESC 2022).
	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.	The outcome was the routine pressure wire usage compared with angiography alone did not result in a significant reduction in cost or improvement in quality of life, nor did it result in any difference in clinical outcome events at 12 months.
6	**Future Questions:**	
	Have the processes / results raised further questions for future exploration? Please give brief details.	The results indicate the pressure wire usage should not be mandated or routine in all coronary lesions. There is significant preceding evidence for its benefit in other studies however. Therefore further research questions will likely relate to allowing us to better identify in which select or specific group of patients it provides the benefit (as clearly total systematic use is non beneficial).

1920-0116 Ryan Ottridge

PD MED Trial-A Large Randomised Assessment of the Cost of Different Classes of Drugs for Parkinson's disease

End of Project Report

1	**Aims**	
	What did the study set out to achieve?	The objective of the PD MED study is to determine the relative cost-effectiveness of the different classes of PD medications for Early disease patients (newly or recently diagnosed for less than 6 months) and for Later disease patients, who need additional medications to control their motor symptoms.
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.	Results from the PD MED trial will benefit PD patients because the results will have an impact on which medications clinicians will prescribe to treat PD patients with Early and Later disease. Results will also benefit the NHS. Results from the analyses of Early disease patients' data after ten years follow-up were published in *Lancet* in 2014 resulting in updated 2017 NICE guidelines for Early disease PD treatment. (https://www.nice.org.uk/guidance/ng71/evidence/full-guideline-pdf-4538466253) Published in *JAMA Neurology* in 2022, results from analyses of Later disease patients' data after 10 years of follow-up indicates that patient-rated quality of life was inferior when COMT inhibitors were used as adjuvant treatment compared with MAO-B inhibitors or dopamine agonists among people with PD who experienced motor complications that were uncontrolled by levodopa therapy. The MAO-B inhibitors produced equivalent disease control, suggesting that these agents may be underused as adjuvant therapy. On 31 Dec 2019, 20 years of follow-up for the PD MED patients was completed. PD MED is the only Parkinson's Disease trial with such an extended follow-up period. Analyses of the data after 20 years of follow-up for Early and Later disease PD patients will provide further insight into the cost-effectiveness of the four different classes of PD medications used in the trial and will reveal whether treatment with any of these medications can delay onset of dementia, time to residential care and/or death. These last analyses are why the centrally held data, which we are requesting, are important, both to PD patients and to the NHS.

3	**Data**	
	What data were received/processed/collected? Was it as expected? Please give brief details.	From NHSCR, we received a one-off set of death and cancer registry data from the period Oct 2018 to April 2022. We requested data for 119 Scottish patients that were recruited to the PD MED trial. We received mortality data for 91 patients. The data that we received is currently being processed by our statistics team so for now, we cannot determine whether the data is as expected. After completion of analyses by our statisticians, the data will be transferred to Dr Emma McIntosh, at Glasgow University, who will complete the Health Economics analyses.
4	**Methodology**	
	How did you collect the data?	Utilising the University of Birmingham's BEAR DataShare, which is a secure method of transferring up to 50GB of data, NHSCR sent us a spreadsheet with the mortality and cancer registry data of 91 patients.
	How did you process the data?	The mortality data was entered into the PDMED database. The PDMED statisticians will use survival analysis methods to determine time to onset of motor complications, dementia, need for institutional care and mortality. This will be compared across treatment arms. Kaplan-Meier survival curves will be constructed and compared using log-rank methods. If important co-variables are unbalanced between groups, a secondary analysis will be carried out using a Cox proportional hazards or an extended Cox model to account for any differences.
	How did you provision/publish the information?	Plans are to publish the results in a peer review journal such as *Lancet.* We will also need to submit the trial's final results in the form of a final report, to our funder, NIHR/HTA.
	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.	Results are still pending because our statisticians have not completed the analyses.
6	**Future Questions:**	

	Have the processes / results raised further questions for future exploration? Please give brief details.	Unable to answer the query because we don't have the results yet.

1920-0137 Dr Matthew J Northgraves

Leukaemia In Pregnancy Study

End of Project Report

The Public Benefit Impact Summary 1 Aims What did the study set out to achieve? The Leukaemia in Pregnancy study aimed to monitor and record the current treatment and outcomes of patients diagnosed with acute leukaemia during or prior to pregnancy since August 2009. 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. There is no clear evidence-based guidance on how to treat patients who are diagnosed with leukaemia during pregnancy. Therefore, the information collected by the leukaemia in pregnancy database, adds to the limited evidence base that currently exists. In combination with the other literature that has previously been published, clearer guidance in the treatment of patients who are diagnosed with leukaemia during pregnancy may be published enabling healthcare professionals to have greater confidence in managing these patients, leading to a more standardised approach to providing high quality care. This will benefit National Health Service (NHS) Trusts and patients across the UK through more informed clinical decision making with regards to the care they receive. 3 Data DocuSign Envelope ID: DF4CD904-B904-435F-84BC-0AB259A00084 Public Benefit and Privacy Panel for Health and Social Care End of Project Declaration and Summary 1920-0137 Northgraves End of Project Declaration and Summary Report V1.0 01.12.2023 What data were received/processed/collected? Was it as expected? Please give brief details. Data was received from the participating health board relating to the treatment of women who had diagnosis of acute leukaemia (AL) or high-risk myelodysplasia (MDS) in pregnancy, or who have conceived after receiving treatment for either AL or high-risk MDS. These included details of treatment received, information relating to the pregnancy and delivery, the outcome of the pregnancies and longer-term survival (up to 4 years) of the women. No directly identifiable information was collected beyond name when consent was provided. Consent forms were logically separate from the rest of the data. Out of the information collected, for certain variables the data quality was limited. 4 Methodology How did you collect the data? Data was collected directly from the patient's case notes by the treating consultant and entered it into the LIPS research database. DocuSign Envelope ID: DF4CD904-B904-435F-84BC-0AB259A00084 Public Benefit and Privacy Panel for Health and Social Care End of Project Declaration and Summary 1920-0137 Northgraves End of Project Declaration and Summary Report V1.0 01.12.2023 How did you process the data? Consent was sought whenever reasonably possible from patients who were still in follow-up / in contact with the clinical care team to process their data. However, there was a subgroup where seeking consent was not possible (deceased) or not appropriate (e.g. no longer in active follow-up or contact with the clinical care team). These cases were collected when there was no evidence of previous dissent

recorded with the local hospital records. Once the consent had been gained / relevant checks for previous dissent were made, the data was entered into the LIPS database within the Hull Health Trials Units instance of cloud-based data capture system REDCap Cloud. The dataset has now been anonymised with full dates changed to days from diagnosis. Other potentially information such year of events and specific sites have been deleted so that all the data from across the UK is under one group. All free text has been reviewed with any potentially identifiable information (e.g. Lab locations, dates) have been redacted. How did you provision/publish the information? The results have yet to be published as manuscript preparation is still ongoing. We are planning to present the results at national conferences and publish in peer reviewed journals. Did your study scope change from its original aims? Please give brief details. There was no change in the scope of the study from its original aims. 5 Outcomes: The outcomes / results of your proposal. Please give brief details. The results are still being written up for dissemination and will be published in due course. DocuSign Envelope ID: DF4CD904-B904-435F-84BC-0AB259A00084 Public Benefit and Privacy Panel for Health and Social Care End of Project Declaration and Summary 1920-0137 Northgraves End of Project Declaration and Summary Report V1.0 01.12.2023 6 Future Questions: Have the processes / results raised further questions for future exploration? Please give brief details. Issues with getting more health boards / NHS trusts involved and subsequent missing data raises the questions whether may be available using routine datasets.