2024/2025 Applications approved by HSC-PBPP to 30th April 2024

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Application Reference	Applicant	Applicant Organisation	Title of Study	Approved/ Approved with conditions	Level of Approval	Clocked Time (days)
2324-0110 SR187	Dr Simon Cox	University of Edinburgh	Lothian Birth Cohort 1936 (LBC1936) study: renewal of deaths linkage application for SR187 (previously 1718-0327)	Approved	Tier 1 Review	12
2223-0090	Dr Alexander Doney	University of Dundee	Prediction of Individual Risk of Dementia (PIPaRD)	Approved	Tier 1 Panel Meeting	48
2324-0136 SR335	Dr Esther Ainley	Picker Institute Europe	Redesign of Urgent Care Evaluation	Approved	Tier 1 Review	46
2223-0016	Ashra Khanom	Swansea University	Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries.	Partial Approval (Approved with conditions)	Tier 1 Review	13
2122-0207	Rafael Pinedo-Villanueva	University of Oxford	The Fractured Ankle Management Evaluation (FAME) Trial	Approved with conditions	Tier 1 Panel Meeting	6

Lay summaries for approved applications

2122-0207   Rafael Pinedo-Villanueva   University of Oxford
The Fractured Ankle Management Evaluation (FAME) Trial

Ankle fractures can cause pain and physical impairment for months or years after injury. Treatment aims to maintain the alignment of the ankle joint while reducing the risk of complications. Unstable fractures involve bones and ligaments, which can tear or pull off a small chip of bone where they attach. They are usually treated with surgery, but this can cause complications. Non-surgical treatments like close contact casting (CCC), which involves applying a snug plaster cast carefully shaped to your ankle to hold the bones correctly while they heal can avoid surgical complications but may yield inferior outcomes compared to surgery. A previous study showed that outcomes for ankle fractures in patients over 60 years of age were equivalent for patients treated with CCC or surgery.

This trial aims to investigate whether CCC treatment for unstable ankle fractures in younger adults will yield similar outcomes compared to surgical treatment. Specifically, the objective of the trial is to determine whether ankle function, four months after treatment in patients with unstable ankle fractures treated with CCC, is not worse than in those treated with surgical intervention, which is the current standard-of-care. A comparative cost-effectiveness analysis between the trial treatment groups over five years will be conducted alongside the trial.

Randomisation will be used to produce two groups of patients: those who undergo surgery, and those who undergo CCC. Participants will be asked if they consent for their confidential information to be shared for the purposes of the trial analysis. The results will be presented and published internationally. The findings of this trial will also inform the NICE 'non-complex fracture' (i.e. those that can be treated in the emergency department or orthopaedic clinic) recommendations at their anticipated update in 2024. A report of long-term outcomes at five years will be produced at the end of the project.

2223-0016   Dr Ashra Khanom   Swansea University
Building an understanding of Ethnic minority people's Service Use Relating to Emergency care for injuries.

BE SURE aims to understand how people from minority ethnic backgrounds present their injuries to emergency ambulance services and emergency departments. We want to know if there are differences in the care they receive and what happens to ethnic minorities when presenting with injuries, compared to the white British population.

Part 1: We will examine past health records between August 2016 and July 2021 for those that went to hospital or were seen by an ambulance with an injury. These records are anonymous so that individual identities are protected. We will compare the health care treatments provided and care outcomes of people from ethnic minority backgrounds to those with a white British background.

We hope to publish our findings in scientific journals, social media outlets and public websites to increase awareness of any disparities and hopefully improve our NHS.

2223-0090 Dr Alexander Doney University of Dundee
Prediction of Individual Risk of Dementia (PIPaRD)

Dementia, particularly Alzheimer's, remains largely a clinical diagnosis, which means it is based on a doctor's assessment of symptoms such as memory impairment and other psychological tests. Brain scans may be used to exclude other possible diseases of the brain, but the disease process underpinning dementia occurs at a microscopic level throughout the brain tissue and even well-trained clinical radiologists are not able to see or describe the subtle indicators of its presence.   We have been developing an artificial intelligence (AI) algorithm that can "look" at a brain scan and distinguish the presence of very early disease in people who therefore have high future risk of developing dementia symptoms.

We did this using data from the Scottish Health Research Register (SHARE) which comprises individuals across Scotland who have consented to their medical records being used for research. We used healthcare data collected over many years to find patients who had undergone brain Magnetic Resonance Imaging (MRI) for any reason in the past. We then excluded all patients who, on or near the date of the MRI brain scan, already had evidence of a diagnosis of dementia in their medical record. We then found those who developed evidence of dementia in the medical record after the scan and then trained an AI algorithm to "look" at MRI brain scans to distinguish between these patients and those who remained dementia free.

In SHARE we were only able to make a dataset of 500 individuals. To further train the AI algorithm to have a clinically meaningful accuracy as well as external validity (ie be broadly applicable to many healthcare settings) we require a much larger training dataset. Using data from people across the whole of Scotland will provide the required scale and population-wide representativeness, long-term follow-up, and real-world variation needed to achieve this.

People who have very early dementia disease but no symptoms yet, have the most to gain from disease prevention strategies and medical treatments. Demonstrating the ability to detect such individuals using a routine image of the brain could in future empower people to manage their own risk of brain diseases, streamline trials of new treatments, and support improved healthcare delivery.

2324-0110 SR187 Dr Simon Cox University of Edinburgh
Lothian Birth Cohort 1936 (LBC1936) study: renewal of deaths linkage application for SR187 (previously 1718-0327)

This proposal outlines the continuation of a vital linkage research project that tracks the lives of a group of people born in 1936, known as the Lothian Birth Cohort 1936 (LBC1936). Since 2004, this group has been regularly studied to understand how ageing affects the

brain, health, and overall well-being. Importantly, this project connects data collected from this group with official records of when and why people pass away.

This linkage project is extremely valuable: It allows researchers to answer critical questions about the LBC1936 group, like how long they live and what causes their deaths. Additionally, it helps us understand factors that influence their chances of survival and what role early-life experiences, such as childhood intelligence, education, and social background, play in their later health and lifespan. By regularly connecting the data collected from this unique group with information about when they pass away, we can also keep accurate records of the cohort. This helps us stay in touch with them, invite them for follow-up assessments, and share important knowledge and events related to their health.

In essence, the LBC1936 study is a treasure trove of information that helps us better understand ageing, health, and longevity. The study is ongoing and this proposal is a request to continue to receive notifications of death records at quarterly intervals. Mortality records are vital to our research programme and help to guide policies that benefit the ageing population. We wish to highlight that the deaths data requested here should cause minimal privacy concerns due to their being publicly-available data.

2324-0136 SR335   Dr Esther Ainley   Picker Institute Europe
Redesign of Urgent Care Evaluation

In December 2020, Scotland's urgent care pathway was re-designed with the aim to improve the way people access urgent and unscheduled care. The Scottish Government has commissioned Picker to conduct an evaluation of the Redesigned Urgent Care pathway (RUC). As part of this evaluation, we want to understand the experiences of patients and carers using redesigned pathways.

We will conduct a paper postal survey to understand the experience of people who have called NHS 24 111 and accessed the redesigned urgent care pathway (i.e., selected the A&E option via the Interactive Voice Response system). NHS 24 will select a sample of eligible adults who called 111 over a two-week period.

The questionnaire will be mailed to a sample of 3,500 patients following their contact with NHS 24. Recipients will have the option to access the survey online if preferred. The questionnaire will cover people's experiences of calling NHS 24 111 and any other urgent care services accessed before or after their call. The respondent's answers will be put together with the answers of other people (aggregated) to understand how the changes have affected people's experiences of accessing urgent care and to show where improvements are needed. The aggregated findings will be presented in an evaluation report that will be published by the Scottish Government here:
https://www.gov.scot/publications/