



National Institute for
Health Research

Cardiometabolic Research Day



Health research today improves lives tomorrow

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Introduction

As NIHR CLAHRC (Collaborations for Leadership in Applied Health Research and Care) Directors we are proud to be organising this cross CLAHRC event looking at the latest applied health research into cardiometabolic diseases.

Cardiometabolic diseases, encompassing cardiovascular, metabolic (e.g. diabetes) and associated disorders such as hypertension and kidney disease, represent the largest health burden both nationally and globally. Their prevalence continues to rise as a result of increased risk factors, including obesity and sedentary lifestyles. A staggering 422 million people around the world currently have diabetes and this is expected to rise to 439 million by 2030. Cardiovascular disease remains the most common cause of death globally, contributing to almost one-third of all deaths around the world.

CLAHRCs bring world class academics together with NHS providers and commissioners, local health and social care organisations, industry and third sector partners, health research infrastructures, and local Academic Health Science Networks (AHSNs) to engage in key research challenges that can have the maximum impact on the frontline and improve patient outcomes as well as save the NHS valuable resources. CLAHRC research and evidence-based implementation are responsive to, and work in partnership with, collaborating organisations, patients, carers and the public. All CLAHRCs conduct applied health research that is focused on chronic disease and public health interventions and most have specialisms that include cardiometabolic diseases. We at CLAHRCs play a leading role in helping shape research in cardiometabolic diseases, using collaborative efforts to address the challenge of prevention and management in this rapidly changing area.

The projects described here are a good introduction to some of the highlights of the CLAHRC research programme. These projects have been selected for their excellence and their current and likely future impact. The selection includes examples of CLAHRCs working individually with their local partners, as well as examples of cross-CLAHRC collaboration.

Cross-CLAHRC collaborations are growing rapidly as individual CLAHRCs develop and reach out across the national space for partners to collaborate with. Furthermore, CLAHRCs see themselves as part of a unique family of research centres with the ability to shape national and international practice and patient outcomes. A recent review showed that CLAHRCs have collaborated on 71 projects/major pieces of work. We anticipate that these collaborations will grow exponentially in the future, building upon successful research production and implementation across the country. NIHR CLAHRC research is saving the NHS millions and helping to save and improve the lives of patients, carers and the public across England, the UK and internationally.

The NIHR's mission is: "To provide a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public". We believe that CLAHRCs are playing a leading role in helping deliver that mission.

We would like to thank all of the CLAHRCs for sharing their work, and the staff who supported the organisation of this event and its supporting brochure.

The programme of work shows there is huge activity in applied health research on cardiometabolic disease with 68 abstracts being included in this summary report. These include aspects of screening, prevention, management of disease and some novel methodological developments.

We would particularly like to thank Nafeesa Dhalwani, Tom Yates, Donna Richardson, and Michael Bonar of NIHR CLAHRC East Midlands and Alex Gardiner of CLAHRC Oxford. We would particularly like to thank Michelle Brown for all her hard work in co-ordinating the abstracts and for organising the meeting.

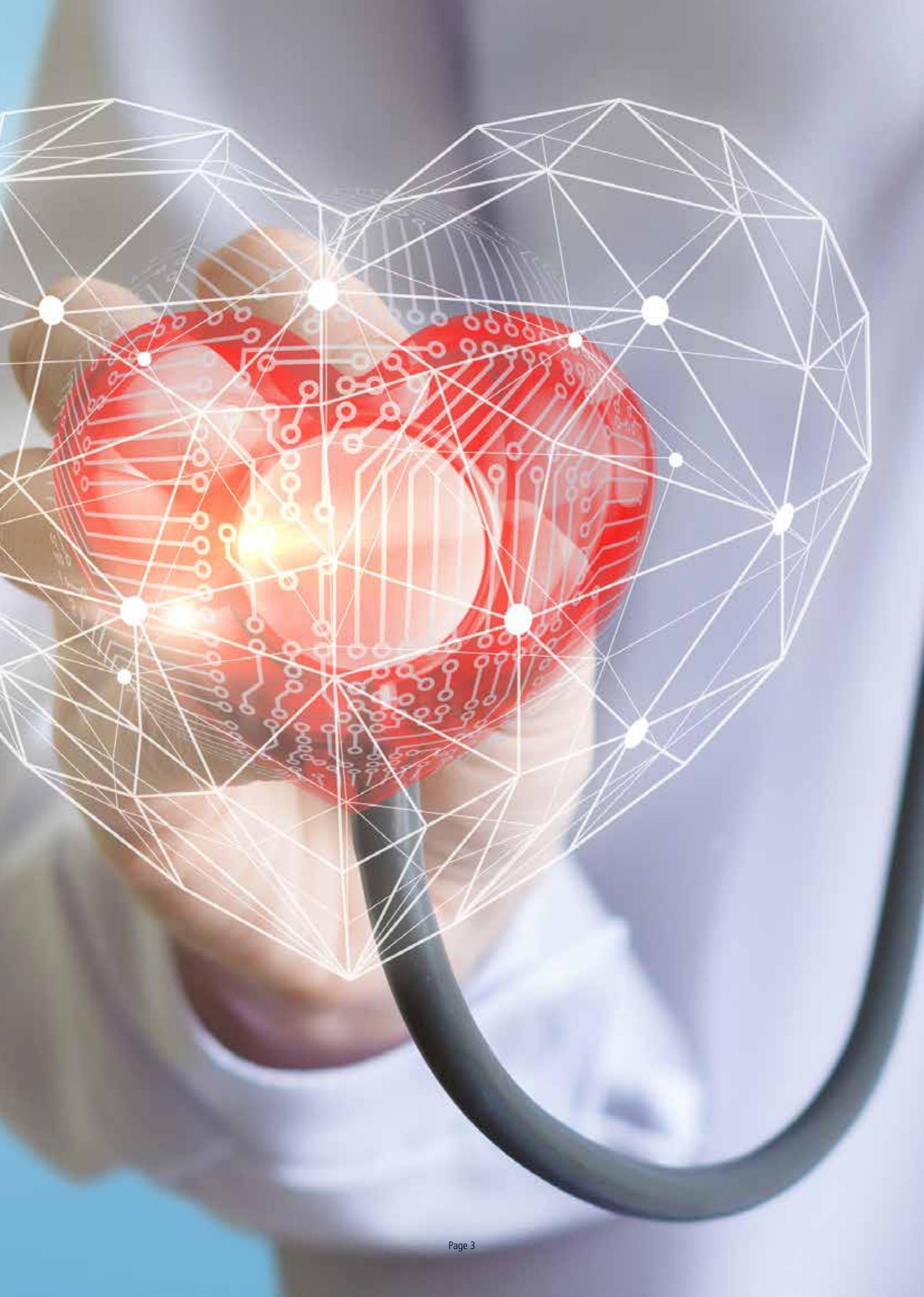
All of us at the NIHR CLAHRCs are looking forward to continuing our work and significantly improving patient access and outcomes and the quality of NHS services.

Professor Kamlesh Khunti

Director, NIHR CLAHRC East Midlands

Professor Richard Hobbs

Director, NIHR CLAHRC Oxford



Our Projects:

PROJECT TITLE	CLAHRC
1. Evaluating the process, performance and effectiveness of integrating diabetes services (Transformation Study)	East Midlands
2. Describing patterns of cardiovascular disease (CVD) risk profiles in Prisoners and exploring implications on implementation of the national primary care CVD Healthchecks Programme in prison population	East Midlands
3. The Baby Steps Study - Walking Away after Gestational Diabetes	East Midlands
4. Early Phosphate Intervention - An exploration of the perspective of children, parents and key health care professionals towards the development of an early dietary phosphate self-management strategy, to delay disease progression for children with chronic kidney disease stages 1-3, within a managed paediatric renal network: A mixed-methods study.	East Midlands
5. CLASS PAL (Physically Active Learning) - Training primary school teachers to deliver classroom physical activity	East Midlands
6. The effect of hypoglycaemia on cardiac arrhythmia risk in patients with diabetes mellitus: A systematic review and meta-analysis	East Midlands
7. Ready to Reduce Risk (3R) Study: A randomised controlled trial (RCT) of a complex educational intervention to improve medication adherence and reduce risk in the primary prevention of cardiovascular disease in high risk individuals	East Midlands
8. Cardio-metabolic profile, function and physical activity in adults with mild-moderate COPD	East Midlands
9. The PACES Study – Physical Activity after Cardiac Events - Developing and evaluating an education programme aimed at increasing physical activity in individuals with diagnosed coronary heart disease (CHD): a randomised controlled trial	East Midlands
10. An EDucational intervention to prevent Acute Kidney Injury in Primary care - The ED AKI P Study	East Midlands
11. Cardiovascular, cancer and mortality events after bariatric surgery in people with and without diabetes: a nationwide study	East Midlands
12. Patterns of multimorbidity in middle aged older adults: An analysis of the UK Biobank data	East Midlands
13. Association of glucose with in-hospital mortality in patient with myocardial infarction: role of diabetes status and ethnicity	East Midlands
14. The GP Prompt study: An implementation strategy for reducing cardiac and renal complications in people with type 2 diabetes and microalbuminuria.	East Midlands
15. The Ambulance Hypo Study	East Midlands
16. Physical activity, multimorbidity, and life expectancy: a UK Biobank observational study	East Midlands
17. Cardiometabolic with mental health illness, and years of life lost: a UK Biobank observational study	East Midlands
18. NIHR CLAHRC Greater Manchester Kidney Health Programme: Tackling the harm associated with Acute Kidney Injury	Greater Manchester
19. Development and feasibility testing of an intervention to support people to lose weight through daily weighing.	Oxford
20. Primary Care Shopping Intervention for Cardiovascular Disease Prevention: (PC-SHOP)	Oxford
21. OPTIMUM-BP: Blood pressure self-monitoring for the management of women during pregnancy with chronic hypertension: a feasibility study.	Oxford
22. SNAP-HT - Self-management of postnatal anti-hypertensive treatment: a trial development pilot study	Oxford
23. OPTiMISE: OPTimising Treatment for MIld Systolic hypertension in the Elderly	Oxford
24. Does provision of lifetime risk information influence future self-management behaviour in type 2 diabetes (T2DM)?	Oxford
25. The role of pharmacists in hypertension management in primary care settings	Oxford
26. INTERPRESS-IPD: Inter-arm blood pressure difference, cardiovascular events, cerebrovascular disease and mortality: an Individual Patient Data meta-analysis	South West Peninsula
27. UNITED - Using pharmacogenetics testing to identify monogenic diabetes earlier	South West Peninsula
28. The Rehabilitation EnAblement in CHronic Heart Failure (REACH-HF)	South West Peninsula
29. ExTraMATCH II - Exercise Training for Chronic Heart Failure: Individual participant data meta-analysis	South West Peninsula
30. Cochrane Cardiac Rehabilitation Reviews	South West Peninsula
31. Using new low dose CT cardiac imaging techniques to help define pre-operative risk of silent MI in surgery	South West Peninsula
32. Care Givers and Cardiac Rehabilitation in Heart Failure	South West Peninsula
33. Cardiac Rehabilitation and Physical Activity Levels in Heart Failure	South West Peninsula
34. Cardiac Troponin: High sensitivity troponin for the diagnosis of acute myocardial infarction in A&E - modelling impact & implementation in the SW (PenCHORD)	South West Peninsula
35. DIAT - Does a simple pre-clinic form improve patient satisfaction following a diabetes appointment?	South West Peninsula
36. Hypertension	South West Peninsula
37. CaRoTT - Cardiac Reviews of Tests and Training	South West Peninsula
38. DIABSCREEN - Can screening intervals for diabetic digital retinal photography be individualized to enhance screening performance and cost-effectiveness, on the basis of individual clinical risk? (PenCHORD)	South West Peninsula
39. NHS Health checks - Improving NHS cardiovascular health checks uptake in primary care	South West Peninsula
40. Effectiveness of mindfulness-based stress reduction and mindfulness-based cognitive therapy in vascular disease	South West Peninsula
41. SCN Urgent Care Review - Modelling provision for stroke and cardiac services in the South West region (PenCHORD)	South West Peninsula
42. STEMI - Modelling alternative reperfusion strategies for MI (PenCHORD)	South West Peninsula
43. DIABFOOT-Effectiveness of multidisciplinary foot care and foot protection teams in reducing diabetic foot complications	South West Peninsula
44. Diabetes App - Does a web based pre-clinic form improve patient satisfaction following a diabetes appointment?	South West Peninsula

PROJECT TITLE	CLAHRC
45. VTE - A Realist Evaluation of the Implementation of a VTE Prevention Strategy at 4 NHS Acute Trusts toward understanding the barriers to screening and prophylaxis	South West Peninsula
46. Chest pain diagnosis – costs and consequences (PenCHORD)	South West Peninsula
47. A feasibility study and pilot RCT to establish methods for assessing the acceptability, and clinical effectiveness and cost effectiveness of enhanced psychological care in cardiac rehabilitation services for patients with new onset depression compared with treatment as usual: (CADENCE)	South West Peninsula
48. The use of a new generation online social network tool to support the self-management of diabetes, heart disease and other long term conditions: How Genie can help people link up with the community online and stay well.	Wessex
49. Exploring the understanding and perception of cardiovascular risk in younger women, and their perceptions of barriers and facilitators to behaviour change in primary prevention of cardiovascular disease	West Midlands
50. The Oxford Renal Cohort Study (OxRen) and NEW onset Kidney Impairment study (NewKI)	Oxford
51. The PERMIT Project - Personalised Renal Monitoring via Information Technology	North West Coast
52. Benefits of Aldosterone Receptor Antagonism in Chronic Kidney Disease Trial (BARACK-D)	Oxford
53. Establishing research priorities to improve the management of patients with advanced heart failure using the James Lind Alliance method	Oxford
54. Screening for valvular heart disease in primary care: Impact on patient outcomes and GP workload (OxValve sub-study)	Oxford
55. Biochemical detection of non-adherence to cardiovascular medications	East Midlands
56. Echocardiographic Heart of England Screening (ECHOES) study	Oxford
57. The REFER (REFER for Echocardiogram) study: a prospective validation and health economic analysis of a clinical decision rule, NT-proBNP, or their combination, in the diagnosis of heart failure in primary care	Oxford
58. The impact of interventions to prevent diabetes in England – a simulation model	North Thames London
59. Trends in hospital admissions for hypoglycaemia in England: a retrospective, observational study.	East Midlands
60. Predicting hospital stay, mortality and readmission in people admitted for hypoglycaemia: prognostic models derivation and validation.	East Midlands
61. Risk factors and outcome differences in hypoglycaemia-related hospital admissions. A case-control study in England	East Midlands
62. Global burden of hypoglycaemia mortality in 109 countries, 2000–2014: an analysis of death certificates.	East Midlands
63. Comparison of glucose-lowering agents following dual therapy failure in type 2 diabetes. Systematic review and network meta-analysis of randomised controlled trials.	East Midlands
64. Association of walking pace and handgrip strength with all-cause, cardiovascular, and cancer mortality: a UK Biobank observational study	East Midlands
65. Barriers to Uptake of (type 1) Diabetes Education (BUDIE)	South London
66. The South London Diabetes (SOUL-D) Follow-up Study: Testing the long-term effects of elevated inflammation on mental- and physical health in people with type 2 diabetes	South London
67. Approaches to early prevention of type 2 diabetes in children of South Asian and African origin	South London
68. Development of a meal replacement programme to offer in primary care for weight management	Oxford

01 Evaluating the process, performance and effectiveness of integrating diabetes services (Transformation Study)

What we are doing: We are assessing whether a new care model for diabetes improves outcomes for patients, by assessing its effectiveness in improving HbA1c (primary outcome) and other health, process and system outcomes in people with Type 1 or Type 2 diabetes. We will use a quasi-experimental interrupted time series design, which involves estimating the mean HbA1c and other outcomes for all participants on a monthly basis before and after implementation of the model to account for underlying secular trends.

Why we are doing it: Diabetes is a highly prevalent long term condition that is one of the NHS's biggest and most expensive challenges, but diabetes complications are largely avoidable through better care. Therefore, in Leicester, Leicestershire and Rutland, the NHS organisations responsible for delivering diabetes services across the healthcare community reconfigured these services. Working together, they developed an innovative care model to integrate diabetes services across community, primary and acute care resulting in a more cost-effective, accessible and high quality service for all patients.

What the benefits will be: This work is both timely and important when considering the current state of reorganisation in the NHS. Importantly the locality of this new care model, with its diverse mix of social deprivation and ethnic populations, means that findings could be generalised to the wider UK population, especially since the principles underlying the redesign are increasingly being advocated in the commissioning of services for long-term care more generally, not only in diabetes.

Who are we working with: This project is a collaboration between the University of Leicester, University Hospitals of Leicester NHS Trust, and the University of Nottingham. We are working with the Leicester City, East Leicestershire and Rutland, and West Leicestershire CCGs, GEM-CSU, and MSD Informatics to obtain the data.

Study lead: Dr Danielle Bodoicoat (Lecturer in Epidemiology, University of Leicester) / Dr Emer Brady (Senior Research Associate, University Hospitals of Leicester NHS Trust)

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02 Describing patterns of cardiovascular disease (CVD) risk profiles in Prisoners and exploring implications on implementation of the national primary care CVD Healthchecks Programme in prison populations

What we are doing: This project is investigating the profile of cardiovascular disease (CVD) and risk factors in male prisoners aged 40-75 years old, the uptake of NHS Health Checks and subsequent interventions. Anxiety and depression will be analysed alongside such factors as it is currently unknown how poor mental health patterns affect prisoners participating in opportunities to

help reduce risk. Focus groups will be utilised to understand the barriers and facilitators of participating in the NHS Health Checks within the prison environment.

Why we are doing it: Prisoners have some of the highest rates of CVD vulnerability, risk of loss to follow-up from health services, and poor lifestyle behaviour of any group in society, despite this, there is very limited evidence of the actual CVD risk profiles. There is also no published data on any linkage of physical risk factors to measures of anxiety or depression despite these factors being well established associations with cardiovascular risk.

What the benefits will be: The ability to link Health Check metrics to mental health markers and to information on uptake and barriers to implementation will enable better design of interventions and targeting of risk factors in this vulnerable population. Results will provide a means to review longer-term outcomes to reduce CVD risks. It will also determine the extent to which mental health services need to integrate with physical healthcare services in order to promote sustainable changes in CVD risks within and following prison terms.

Who are we working with: Nottinghamshire Healthcare NHS Trust currently operates physical healthcare in a number of prisons. Mitie Care and Custody also operate within this area. We will be recruiting participants from 8 prisons in the Nottingham and Doncaster area. The project has been shared with the Department of Health Advisory Group to determine if the results will assist with their research. Organisations involved consist of:

- Nottinghamshire Healthcare NHS Trust
- Mitie Care and Custody
- University of Nottingham
- University of Leicester

Study lead: Dr Chris Packham, Associate Medical Director, Nottinghamshire Healthcare NHS Trust

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03 The Baby Steps Study - Walking Away after Gestational Diabetes

What we are doing: We are developing and implementing face-to-face and online education programme meeting the needs of women who have previously had gestational diabetes. The women will be randomly allocated to usual care or to the study intervention.

Why we are doing it: Women who have previously had gestational diabetes have a seven-fold risk of developing type 2 diabetes within 10 years of their pregnancy. Observational evidence suggests a healthy lifestyle is associated with reduced risk of developing type 2 diabetes in women with a history of gestational diabetes.

What the benefits will be: An increase in physical activity of around 30 minutes per day is sufficient to reduce type 2 diabetes risk by 30 to 50 percent, as part of a healthy lifestyle. Women will wear a physical activity monitor for seven days before, during and after the study. The education programmes will be deemed successful if physical activity increases by 30 minutes per day.

Who are we working with: This is a joint project of the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) East Midlands and the NIHR CLAHRC West Midlands and the East Midlands Academic Health Science Network (EMAHSN). The project will be conducted in conjunction with the Leicester-Loughborough Diet, Lifestyle and Physical Activity Biomedical Research Unit.

Study lead: Professor Kamlesh Khunti, Professor of Primary Care Diabetes and Vascular Medicine, University of Leicester

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04 Early Phosphate Intervention - An exploration of the perspective of children, parents and key health care professionals towards the development of an early dietary phosphate self-management strategy, to delay disease progression for children with chronic kidney disease stages 1-3, within a managed paediatric renal network: A mixed-methods study.

What we are doing: A three-phase mixed-methods study will comprise, a (1) systematic review (2), semi-structured interview with 15 individuals, namely children, parents and Health Care Professionals (HCP), and an online (3) Delphi survey with 30 parents and HCPs. The study will seek to access the individual's unique perspective on the key issues that need to be considered when developing and delivering of an early dietary phosphate self-management strategy for children with CKD 1-3.

Why we are doing it: The provision of an early dietary phosphate self-management strategy for children with CKD 1-3, a group who routinely don't receive dietetic input, and are not aware of the need for input, may reduce Fibrin Growth Factor-23 levels. Fibrin Growth Factor-23 has been shown to significantly correlate to disease progression. Health Care Professionals managing Chronic Disease recognise the importance of early interventions to delay disease progression and improving outcomes. However, they have differing views with regards to what a self-management strategy should look like.

What the benefits will be: The provision of an early dietary phosphate self-management strategy to children with CKD stage 1-3, may delay disease progression and the associated complications of advancing Chronic Kidney Disease. Thus, delaying the transition to dialysis and transplantation, and improving growth and cardiac health. This will inform developments in local, national and international policy, to improve early phosphate self-management, which may improve health outcomes and reduce healthcare utilisation and costs.

Who are we working with:

- Children's Renal & Urology Unit, Nottingham Children's Hospital, Nottingham, UK
- University of Nottingham, UK
- East Midlands, East of England and South Yorkshire (EMEESY) Paediatric Renal Network

Study lead: Pearl Pugh

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05 CLASS PAL (Physically Active Learning) - Training primary school teachers to deliver classroom physical activity

What we are doing: We are working with schools to support primary teachers to integrate physical activity into the classroom, through a training workshop and website of teaching resources. The types of activity could include active routines (e.g. 'Stand up, Hand up'), activity breaks (e.g. Dancing to YouTube video), activity breaks incorporating academic content (e.g. jumping to solve mathematical sums), or more comprehensive physically active lessons (e.g. physically embodying punctuation marks as teacher reads story aloud).

Why we are doing it: Prolonged sedentary (i.e. sitting) behaviour has been associated with a number of negative health outcomes in childhood and adulthood. Primary school aged children spend considerable time across their day in sedentary behaviours. Within the school day children typically sit for prolonged periods in the classroom to engage in academic lessons. Integrating physical activity into normal classroom time therefore has potential to reduce and break-up sitting time in class, but also to engage pupils with their learning.

What the benefits will be: Classroom physical activity has been shown to have a positive impact on behaviours related to learning such as attention to task, motivation to learn, and enjoyment of lessons. In addition for some children, in some subjects engagement in classroom physical activity may lead to increased educational performance.

Who are we working with: We have worked with the Affinity teaching school alliance to access and co-design CLASS PAL alongside a number of schools and teachers across the Leicestershire area. In addition we have collaborated with the Youth Sport Trust for the development and delivery of the teacher training workshop, as well as the website of supporting teaching resources.

Study lead: Dr Lauren Sherar

Contact: l.b.sherar@lboro.ac.uk

06 The effect of hypoglycaemia on cardiac arrhythmia risk in patients with diabetes mellitus: A systematic review and meta-analysis

What we are doing: We conducted a systematic review and meta-analysis to consolidate and critically appraise the literature exploring the effects of both experimentally induced, or spontaneous clinical hypoglycaemia identified through continuous glucose monitoring (CGM), on the development of acute vascular changes contributing to cardiac arrhythmia risk. We included studies of adult patients with type 1 and type 2 diabetes and which compared acute cardiac changes relating to QTc interval

length, heart rate variability and cardiac arrhythmias between hypoglycaemic and euglycaemic periods.

Why we are doing it: Cardiovascular disease (CVD) remains the leading diabetes related complication and has been a driver for a plethora of research to explore the area and the underlying pathophysiological mechanisms linking the two conditions. Whilst convincing evidence demonstrates the detrimental effects of hyperglycaemia, further evidence suggests that hypoglycaemia may also contribute to cardiac dysfunction. Many episodes of hypoglycaemia are unrecognised making the exact mechanism underpinning this relationship difficult to establish. This review aims to highlight potential mechanisms linking the conditions.

What the benefits will be: The findings from this systematic review will help to consolidate the literature relating to the acute effects of hypoglycaemia on the cardiovascular system contributing to increased cardiac arrhythmia risk. As the exact mechanism between hypoglycaemia and its increased association with cardiac arrhythmia risk is unclear, the findings from this review may help to further our understanding of the potential causal link by which hypoglycaemia may increase cardiac arrhythmia risk.

Who are we working with:

- University of Leicester
- Leicester Diabetes Centre
- CLAHRC – East Midlands

Study lead: Dr Sudesna Chatterjee, Diabetes Research Centre

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07 Ready to Reduce Risk (3R) Study: A randomised controlled trial (RCT) of a complex educational intervention to improve medication adherence and reduce risk in the primary prevention of cardiovascular disease in high risk individuals

What we are doing: An open RCT with 12 months follow-up. Participants (n=210) will be recruited from primary care and randomised on a 1:1 basis, stratified by gender and age, to either a control group (standard, routine care) or an intervention group involving two education sessions with telephone and text messaging follow-up support. The primary outcome will be a change in medication adherence to statins from baseline to 12 months compared to standard care. Secondary outcomes will include changes in modifiable risk factors.

Why we are doing it: Identifying people at high risk of CVD and supporting them to reduce their risk is a public health priority. Structured education is well recognised in the UK for promoting self-management in long-term conditions, but no national strategy exists to offer people who are at risk of CVD such education. Instead, they receive information about lifestyle changes and medication on an ad hoc basis. An approach offering structured education and support may be beneficial to both patients and health professionals.

What the benefits will be:

- Improved medication adherence to statins
- Reduction in cardiovascular risk and individual modifiable risk factors
- Better engagement of patients
- Increased patient knowledge about CVD risk and how to reduce it
- Less pressure on GPs and practice nurses

Who are we working with: We work closely with the R&I team at the Northamptonshire Healthcare NHS Foundation trust to promote and implement the study at a number of practices across the county.

Our education intervention and telephone support has been developed in collaboration with the team that developed the successful DESMOND education for people with type 2 diabetes, based at the Leicester Diabetes Centre

We have also collaborated with a team of researchers in Australia to use validated text messages from a successful study published in JAMA

Study lead: Prof Kamlesh Khunti

Contact: Dr Jo Byrne (jo.l.byrne@uhl-tr.nhs.uk)

08 Cardio-metabolic profile, function and physical activity in adults with mild-moderate COPD

What we are doing: A retrospective analysis of the Physical Activity and Respiratory Health (PhARaoH) dataset which contains data from physician confirmed COPD patients. Physical activity and sedentary behaviour was measured using a wrist worn accelerometer, exercise capacity was measured using the Incremental Shuttle Walk Test (ISWT), muscular strength was assessed using a Quadriceps Maximal Voluntary Contraction (QMVC) and body composition, anthropometrics and blood pressure were also measured. Participants had a venous blood sample taken; Triglycerides, HDL & LDL Cholesterol and Glucose were analysed.

Why we are doing it: It is often shown that adults with COPD have higher rates of the metabolic syndrome compared to adults without. Furthermore, data often suggests adults in the milder stage have higher prevalence rates compared to COPD patients with more severe airflow obstruction. However, there is conflicting information regards the interplay between exercise capacity, physical activity and cardio metabolic health in COPD.

This is novel as most participants were recruited from primary care, an under-researched population and had mild airflow obstruction.

What the benefits will be: The metabolic syndrome is a cluster of cardiovascular risk factors. Identifying associations between exercise capacity, physical activity levels and metabolic syndrome in patients with mild disease may demonstrate the need for an early lifestyle intervention.

Who are we working with:

The PhARaoH study was funded by NHS England.

The PhARaoH research study was supported by:

- The National Institute for Health Research (NIHR) Leicester Biomedical Research Centre
- The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care – East Midlands (NIHR CLAHRC – EM)
- The Primary Care Research Network (PCRN).

Study lead: Dr Lauren Sherar (Senior Lecturer in Physical Activity and Public Health, Loughborough University)

Prof Sally Singh (Head of Cardiac and Pulmonary Rehabilitation, University Hospital Leicester)

Contact: Amy V Jones a.v.jones@lboro.ac.uk

09 The PACES Study – Physical Activity after Cardiac Events - Developing and evaluating an education programme aimed at increasing physical activity in individuals with diagnosed coronary heart disease (CHD): a randomised controlled trial

What we are doing: This randomised controlled trial (RCT) is recruiting participants (n=290) aged ≥ 18 years who are 12 to 48 months post diagnosis of a CHD event. The primary objective is to increase physical activity by implementing a structured education programme with text message support over 12 months. Identifying whether the delivery of a structured education programme focusing on physical activity, to individuals who have a history CHD, would be an effective, acceptable and cost-effective strategy for increasing average daily physical activity.

Why we are doing it: In the UK CHD is the cause of death in nearly one in six men and more than one in ten women. After a CHD event such as a myocardial infarction, further events are greatly increased, unless there is intensive management of CHD risk factors such as physical activity, smoking, diabetes, hypertension, hyperlipidaemia, and obesity. Through PPI work with previous patients and health care professionals, it is clear that support 12 to 48 months after a CHD event is limited and would be beneficial if available.

What the benefits will be: The PACES education programme combined with follow-up text message support aimed at long term self-management is cost effective in application whilst designed to complement the current post-operative services available and easily translated into post-operative cardiac care should the intervention be successful.

Who are we working with:

- University Hospitals of Leicester
- University of Leicester
- Leicester City Council

Study lead: Professor Melanie Davies

Contact: Dr Louisa Herring - louisa.herring@uhl-tr.nhs.uk

10 An Educational intervention to prevent Acute Kidney Injury in Primary care - The ED AKI P Study

What we are doing: Working with 28 primary care practices across Leicestershire covering a population of 300,000 adults. We educating primary care health care staff on the topic of Acute Kidney Injury, in addition we are gathering data for epidemiology analysis. So far we have collected over 1.5 gigabytes of baseline clinical data for analysis/study. At the end of the study there will be over 3 gigabytes of follow-up data for analysis.

Why we are doing it: Acute Kidney Injury has a mortality of over 30% in secondary care. However we understand little about the disease in primary care. We know many primary care healthcare staff are keen to learn about the topic, and understand how best to treat these patients. We are also exploring how using novel informatics software (IMPAKT-CKD) may help GPs work more efficiently.

What the benefits will be: Improving the knowledge of primary care physicians about AKI will help to improve care. Understanding the epidemiology of AKI in the community will help to inform future healthcare policy and identify any potential ways to prevent/identify AKI using informatics solutions.

Who are we working with: 28 primary care practices across Leicestershire and Leicester city. Size of practice range from a list size of 4000 to 34,000. 162 health care staff have already had face to face education on AKI. Follow-up data collection and feedback of relevant clinical information is now underway.

Study lead: Dr Gang Xu

Contact: gx1@le.ac.uk

11 Cardiovascular, cancer and mortality events after bariatric surgery in people with and without diabetes: a nationwide study

What we are doing: We used Hospital Episodes Statistics data linked to mortality data on 35,887 people who underwent bariatric surgery between 2006 and 2014 to examine the risk of mortality, cardiovascular, cancer, readmission events following bariatric surgery in adults with and without diabetes and compare mortality risk to the general population. We found the risk of all-cause mortality to be 26% higher after bariatric surgery in people with diabetes compared to those without. The risk of all cardiovascular outcomes including MI, stroke, unstable angina, and heart failure was also greater in adults with diabetes, with the risk of MI being over twice as high in adults with diabetes compared to people without diabetes. The risk of cancer was 21% higher following bariatric surgery in people with diabetes compared with people without.

Why we are doing it: For people with diabetes, bariatric surgery has been associated with better survival and reduction in cardiovascular events compared to obese patient with diabetes who did not undergo surgery. However, there is very limited data comparing outcomes in people with and without diabetes who undergo bariatric surgery.

What the benefits will be: In the largest cohort study on bariatric surgery conducted to date we found that despite the reported improvements in biomarkers and outcomes after surgery, and no significant difference in 30-day mortality between people with and without diabetes, people with diabetes carry a residual risk of adverse CVD outcomes and mortality. Therefore, patients undergoing bariatric surgery should be made aware of this residual risk before the procedure.

Who are we working with:

- CLAHRC West Midlands (University of Warwick, University Hospitals Birmingham)

Study lead: Nafeesa Dhalwani/ Kamlesh Khunti

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12 Patterns of multimorbidity in middle aged older adults: An analysis of the UK Biobank data

What we are doing: Data on 36 chronic conditions from 502,643 participants aged 40-69, with baseline measurements between 13th March 2006 and 1st October 2010, from the UK Biobank were extracted. We combined cluster analysis and association rules mining (ARM) to assess patterns multimorbidity overall and by age, sex and ethnicity. A maximum of three clusters and 30 disease patterns were mined. Comparisons were made using lift as the main measure of association. We found that conditions including diabetes, hypertension and asthma are the epicentre of disease clusters for multimorbidity. A more integrative multidisciplinary approach focusing on better management and prevention of these conditions which are potentially part of the trajectories of several other chronic conditions, may help prevent other conditions in the clusters.

Why we are doing it: To date, a number of studies have investigated patterns of multimorbidity. However, many of these studies are limited either by their small sample sizes or a small number of conditions used to define multimorbidity. Furthermore, these methods investigate overall patterns but do not elucidate associations between individual conditions within the patterns well. NICE recommends an approach that focuses on the interactions between a person's health conditions and treatments and benefits and risks of following recommendations from guidance on single health conditions. Moreover, a systematic review assessing the effectiveness of interventions for management of multimorbidity concluded that interventions targeted either at specific groups of conditions or at specific problems for patients with multiple conditions, may be more effective than a blanket approach. Therefore, it is not only important to understand the patterns of multimorbidity but also to recognise associations between conditions within these patterns, which requires new approaches to assess disease patterns within a population with multimorbidity.

What the benefits will be: The study provides more insight into how different conditions are interlinked within multimorbidity disease clusters and sheds light on diseases that are the epicentre of these clusters. This has important implications on prevention and management of multimorbidity in primary care.

Who are we working with:

- CLAHRC East Midlands
- Leicester Biomedical Research Centre

Study lead: Nafeesa Dhalwani/ Kamlesh Khunti**Contact:** nnd2@le.ac.uk

13 Association of glucose with in-hospital mortality in patient with myocardial infarction: role of diabetes status and ethnicity

What we are doing: We are making use of the Myocardial Ischaemia National Audit Project (MINAP) data linked, containing over 1.25 million records, with mortality data, within a longitudinal cohort design. This study includes all admissions for myocardial infarction (STEMI and NSTEMI) occurring between Jan 2003 and Dec 2013 in patients aged 18 years or older. For multiple admissions of the same patient, the earliest record will be considered. We will use logistic regression to estimate odds ratio of in-patient mortality, adjusting for potential confounders. The main exposure will be glucose levels and associations with all-cause mortality (in-hospital)

Why we are doing it: Diabetes mellitus and cardiovascular disease (CVD) are two inter-related chronic conditions with complex pathophysiological associations. Abnormalities of glucose metabolism including hyperglycaemia, hypoglycaemia, insulin resistance and beta-cell dysfunction have been linked to adverse prognosis for patients with CVD and coronary heart disease. Previous studies have found an elevated admission glucose level to be a risk factor for in-hospital and short-term mortality in patients with acute myocardial infarction (MI). However, most of these studies were either limited by their small sample sizes to assess risk stratified by diabetes status and glucose levels or did not adjust for important confounders. Similarly, there is uncertainty on the association between hypoglycaemia and mortality post-MI. Furthermore, studies examining the association between admission blood glucose and long-term mortality present inconclusive evidence. Considering the increased predisposition to visceral adiposity, metabolic syndrome and atherosclerosis in South Asians and higher cardiovascular mortality compared to other ethnicities, it is also important to assess whether the association between blood glucose and mortality post-MI varies by ethnicity. To our knowledge, none of the previous studies have examined these ethnic differences

What the benefits will be: This research aims to further explore the role of blood glucose in predicting survival after an MI. The results can help modify the practices around blood glucose management around the time of MI, which may potentially improve survival in patients, therefore the research is relevant to the specific group of patients who have an MI.

Who are we working with:

- Leicester Biomedical Research Centre
- University College London
- Queen Mary University of London

Study lead: Nafeesa Dhalwani/ Kamlesh Khunti**Contact:** nnd2@le.ac.uk

14 The GP Prompt study: An implementation strategy for reducing cardiac and renal complications in people with type 2 diabetes and microalbuminuria.

What we are doing: We are evaluating the effectiveness of a multifactorial intervention delivered to GP practice staff, in improving the proportion of patients with type 2 diabetes and microalbuminuria meeting cardiovascular risk factor targets (blood pressure, total cholesterol, HbA1c). The intervention consists of training for practice staff, a software prompt, quarterly audit performance data and an email 'hotline' to a study clinician with experience in managing patients with T2DM and MA. The intervention is being delivered over 2 years finishing in November 2017.

Why we are doing it: Tighter control of blood pressure, total cholesterol and HbA1c in patients with T2DM and MA has proven to be effective in reducing the risk of further cardiovascular complications and mortality. To date strategies that have achieved tighter control have been individualised for each patient and resource intensive to deliver. The GP Prompt study will aim to provide a cost-effective intervention aimed at healthcare professionals that is deliverable within current levels of resource available in primary care.

What the benefits will be: We hope that the intervention will prove successful and inform the delivery of care to patients with T2DM and MA and may be transferrable to a number of other chronic conditions. The results of this study will also be relevant to the use of routinely held patient level primary care data and evaluating practice level interventions as part of a cluster randomised control trial design.

Who are we working with: We are working with Leicester City and County CCG who have assisted with recruitment of practices to this study. We are working with PRIMIS at Nottingham University who have been responsible for the design of an electronic software alert which highlights eligible patients not meeting cardiovascular risk factor targets. PRIMIS have also co-ordinated remote anonymised patient level data extraction to allow our analysis in addition to providing intervention practices with quarterly feedback data 'benchmarking' them against other participating practices.

Study lead: Dr Andrew Willis**Contact:** aw187@le.ac.uk/ 0116 2588995

15 The Ambulance Hypo Study

What we are doing: We are evaluating the effectiveness of an enhanced care pathway for patients with diabetes who require an ambulance call out to treat an episode of hypoglycaemia. Patients offered the intervention are given an information booklet by an ambulance staff member and receive a phone call from a

diabetes nurse within two days to discuss possible causes for the hypoglycaemia. The nurse will then send any recommendations regarding changes to medication to the patient's GP. This pathway is being compared to normal care whereby ambulance staff notify the patient's GP of the call out.

Why we are doing it: Hypoglycemia is relatively common and often experienced by people taking medication to help manage diabetes. In some cases symptoms are so severe that they may require emergency medical treatment. National audit data from the ambulance service shows that people often suffer repeat occurrences of hypoglycaemia and are at an increased risk of cardiovascular complications and mortality. We are carrying out this study to test a new care pathway for patients with hypoglycaemia to reduce the rate of repeat ambulance call outs and hospitalisation.

What the benefits will be: An effective care pathway for hypoglycaemia would be of great benefit to both the patient and ambulance service. Early intervention from a trained diabetes nurse will hopefully reduce the risk of repeated episodes which are unpleasant for the patient and a burden on the ambulance service through an increased number of call outs. Pre-hospital research in this area is under-researched and the results of the study (uptake and consent rates) will also help inform the development of future studies in this area.

Who are we working with: The project is being run in collaboration with East Midlands Ambulance Service and Diabetes Nurse Teams from the participating sites. The project is also being supported by the Clinical Research Network to facilitate collection of follow up data from participant's primary care medical records at the end of the study in June 2018.

Study lead: Dr Helen Dallosso**Contact:** Helen.Dallosso@uhl-tr.nhs.uk

16 Physical activity, multimorbidity, and life expectancy: a UK Biobank observational study

What we are doing: We analysed one of the largest datasets to assess the association between physical activity with mortality and life expectancy in people with multimorbidity. We used three different measures of physical activity; subjectively measured by leisure-time physical activity and through a modified version of the International Physical Activity Questionnaire which assessed total physical activity, and in a sub-sample objectively measured by the wrist-worn accelerometer.

Why we are doing it: Management of multimorbidity including conditions such as diabetes, stroke, myocardial infarction, and chronic kidney disease has recently become an emerging priority for health care professionals and health care systems. Physical activity is recommended as one of the main lifestyle factors in the management of several chronic conditions worldwide, yet it is not clear whether and to what extent the benefits of physical activity apply to people with multimorbidity.

What the benefits will be: We found that although people with multimorbidity have lower life expectancy compared to people without multimorbidity, mortality benefit of physical activity was greater in people with multimorbidity, especially at younger ages. We also found that the difference in life years gained between moderate and high physical activity was small and even as little as additional 6 minutes or 18 minutes of 'brisk walking for exercise' per day on average was associated with 51% and 71% lower risk of mortality, respectively.

Who are we working with: We are working with the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care – East Midlands (NIHR CLAHRC – EM), the Leicester Clinical Trials Unit and the NIHR Leicester Biomedical Research Centre.

Study leads: Dr Nafeesa Dhalwani / Yogini Chudasama

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17 Cardiometabolic with mental health illness, and years of life lost: a UK Biobank observational study

What we are doing: We aim to investigate the association between the combinations of diabetes, stroke, myocardial infarction, alongside the most prevalent mental health condition; depression with the years of life lost. We additionally explore the years of life lost according to physical activity levels in people with cardiometabolic and mental health illnesses, using both subjective and objective physical activity measures.

Why we are doing it: Cardiometabolic conditions are most commonly experienced with mental health illnesses. These comorbidities consequently lead to poor prognosis, lower quality of life and the risk of premature death. Previous research shows there is a strong association between cardiometabolic physical illness and emotional distress, and demonstrate a significantly higher risk of mortality. However, to date no studies have estimated how many years of life is lost due to these particular comorbidities. Many lifestyle behaviours contribute to a decrease in life expectancy, where physical inactivity has been identified as the key lifestyle behaviour.

What the benefits will be: The findings will enable us to quantify the exact number of years lost, and provide evidence for future self-management interventions involving physical activity.

Who are we working with: We are working with the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care – East Midlands (NIHR CLAHRC – EM), the Leicester Clinical Trials Unit and the NIHR Leicester Biomedical Research Centre.

Study leads: Dr Nafeesa Dhalwani / Yogini Chudasama

Contact: Yogini Chudasama yc244@leicester.ac.uk

18 NIHR CLAHRC Greater Manchester Kidney Health Programme: Tackling the harm associated with Acute Kidney Injury

What we are doing: Aligned with national priorities, the NIHR CLAHRC Greater Manchester Kidney Programme entails a series of projects that focus on tackling the harm associated with Acute Kidney Injury (AKI).

Projects include an evaluation of sick day guidance to prevent AKI; an ethnographic study evaluating quality improvement initiatives in secondary care; a RAND consensus study that informed Think Kidneys guidance to support better recognition and response to AKI in primary care; and a mixed methods study evaluating the implementation of approaches to improve post-AKI care.

Why we are doing it: Acute Kidney Injury is common, harmful, costly and potentially avoidable. It is a marker of illness severity and is estimated to complicate between 5 to 6% of all hospital admissions. To date, AKI quality improvement initiatives have largely focused on improving management in secondary care.

Our programme seeks to develop an evidence base around the implementation of effective interventions in primary care and across the interface with secondary care. Our work aims to provide a platform for collaborative large scale evaluation.

What the benefits will be: In the context where general practice workload is reaching 'saturation point', an overarching principle guiding the Kidney Health Programme is to navigate the challenge: How can we maximise the clinical utility of AKI without increasing treatment burden for patients and carers or creating unnecessary workload for health and care professionals?

Who are we working with: The CLAHRC GM Kidney Health Programme is a collaboration between The University of Manchester and local NHS partners in both secondary and primary care: Salford Royal and Central Manchester University Hospital NHS Foundation Trust; as well as Bury, Central Manchester and Salford CCGs.

Through the establishment of an RCGP AKI Quality Improvement Project, we are also working in partnership with Think Kidneys, Kent Surrey Sussex AHSN and North East & Cumbria AHSN. We will develop an AKI toolkit and disseminate shared learning from use of AKI case note review templates to support reflective practice.

Study lead: Drs Tom Blakeman (GP Clinical Academic Lead) & Susan Howard (Programme Manager)

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19 Development and feasibility testing of an intervention to support people to lose weight through daily weighing

What we are doing: Daily Weighing aims to develop and test the feasibility of a behavioural app to track weight and coach users to follow steps leading to successful weight loss. We will trial the app in people who are overweight and trying to lose weight.

The participants will be randomised 1:1 with weight measured in both groups at 2 months. We will interview participants and analyse data from the trial to assess whether the intervention worked as we expected.

Why we are doing it: Observational evidence suggests many successful weight loss maintainers weigh regularly. Trials show that adding daily self-weighing to a weight loss programme increases weight loss. The evidence suggests that self-weighing is effective because it encourages people to reflect on their past energy balance and make corrective actions to control their weight or maintain their weight loss. Our randomised trial that simply instructed people to do this without other support showed no evidence of effect, implying that further coaching is needed.

What the benefits will be: The study aims to create a brief intervention to help GPs intervene to manage patient's excess body weight. Excess body weight is the second largest cause of preventable mortality and morbidity in the UK. It will provide new evidence on how self-weighing promotes weight loss and whether minimally guided self-weighing can be effective. The app developed in this study, if effective, will be available to patients and GPs as a tool to maintain and aid weight loss.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with Nuffield Department of Primary Care Health Sciences, University of Oxford and Oxford Wolfson Marriot Graduate Scholarships

Study lead: Kerstin Frie, University of Oxford

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20 Primary Care Shopping Intervention for Cardiovascular Disease Prevention: (PC-SHOP)

What we are doing: PC-SHOP aims to develop and test the a behavioural intervention to promote reductions in saturated fat (SFA) intake through healthier food purchasing among patients in primary care with raised LDL-cholesterol. We will randomise people to usual care, brief advice from a practice nurse, or brief advice combined with personalised feedback on food purchases and suggestions of healthier food swaps over 12 weeks. We will measure changes in SFA intake as a measure of efficacy.

Why we are doing it: Poor diet is a major contributor to cardiovascular disease (CVD). There is evidence that decreasing intake of saturated fatty acids (SFA) reduces LDL cholesterol, but progress in reducing SFA through public education programmes is slow, and SFA intake in the UK (13.5%) remains well above the recommended value of <10%. There is a lack of evidence for approaches targeted at individuals that are sufficiently scalable and practical for routine delivery in primary care. Improving the quality of purchases presents a clear opportunity to intervene.

What the benefits will be: We will partner with a major supermarket which will allow patients to receive direct information on the nutritional content of their shopping without the need for specialist dietary assessment by health professionals. The potential

low cost and scalability of this intervention means it could make a substantial contribution to helping the NHS manage the large number of patients who may benefit from this type of information and support.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with the Nuffield Department of Primary Care Health Sciences, University of Oxford; industry partner (leading supermarket)

Study lead: Dr Carmen Piernas-Sanchez, University of Oxford

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21 OPTIMUM-BP: Blood pressure self-monitoring for the management of women during pregnancy with chronic hypertension: a feasibility study.

What we are doing: We have undertaken an early phase study randomising 60 pregnant women with chronic hypertension to receive usual antenatal care or usual care in addition to measuring their BP at home. Observing routine appointments with women and their clinicians to help determine how home readings are being used to help decide treatment for improved blood pressure control. We have interviewed women and clinicians to find out about their experiences of using the home BP monitoring; determining preferences and improvement suggestions.

Why we are doing it: Pre-eclampsia is a condition which affects pregnant women, and can put both mother and baby at risk. The warning signs of pre-eclampsia include high blood pressure and protein in urine. One possible solution to this problem is pregnant women self-monitoring their blood pressure at home. Self-monitoring at home may be able to detect rising blood pressure sooner, and women can then share this information with their care teams. This could lead to earlier diagnosis and treatment to prevent complications developing.

What the benefits will be: This project has the potential to improve the health of women with chronic high blood pressure in pregnancy. This could lead to fewer complications during pregnancy, protecting the health of both mother and baby. Additionally, if self-monitoring of blood pressure reduces the use of NHS resources, this will free them up for other uses across a wide range of other conditions.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with Nuffield Department of Primary Care Health Sciences; Oxford Radcliffe Hospitals NHS Foundation Trust; Academic Division of Women's Health, Guy's and St Thomas' NHS Foundation Trust (GSTT); Faculty of Life Sciences & Medicine, King's College London

Study lead: Dr Louise Pealing, University of Oxford

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22 SNAP-HT - Self-management of postnatal anti-hypertensive treatment: a trial development pilot study

What we are doing: Women with gestational hypertension or pre-eclampsia requiring on-going anti-hypertensive medication in the postpartum period were randomised usual care, or self-management of blood pressure.

Women randomised to usual care had their blood pressure monitored by their community midwife, and their anti-hypertensive medication adjusted by their GP. Women randomised to BP self-management had individualised medication adjustment schedules and were provided with, and taught to use, a validated home blood pressure monitor, and performed daily blood pressure readings until treatment was discontinued.

Why we are doing it: Around one in ten pregnant women develop 'new-onset' hypertension which sometimes leads to pre-eclampsia presenting complications for mother and baby. High blood pressure in pregnancy is a risk factor for developing strokes, and can lead to other complications for mother and baby. Medication can help lower high blood pressure, reducing the risk of developing complications. Raised blood pressure in pregnancy is also a risk factor for developing chronic raised blood pressure, heart disease and stroke later in life.

What the benefits will be: Postpartum BP control can be challenging due to other pressures on women and healthcare professionals. This trial may lead to reductions in length of inpatient stay, readmissions and postpartum visits, with cost-saving implications for primary and secondary care. Importance of BP control in the immediate postpartum period has been demonstrated to affect women's cardiovascular risk up to 15 years after delivery. Successfully increasing women's adherence to effective treatment regimens has potential to influence their healthcare needs well into the future.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with Nuffield Department of Primary Care Health Sciences

Study lead: Alex Cairns, University of Oxford

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23 OPTiMISE: Optimising Treatment for Mild Systolic hypertension in the Elderly

What we are doing: We are aiming to establish whether medication reduction can be achieved in older patients (>80) without clinic systolic blood pressure increasing beyond clinically safe levels (defined here as <150 mmHg) at 12 week follow-up. A strategy of medication reduction will be considered non-inferior to usual care if the difference in clinic systolic blood pressure control between both groups is less than 10% at 12 week follow-up.

Why we are doing it: The number of individuals aged >80 years is increasing and so are the number of older patients who would be

eligible for withdrawal of antihypertensive medication in this study. Local estimates extrapolated to national data, reveal approximately 1,257,376 older persons in the UK would currently be eligible for antihypertensive medication if it were proved to be safe.

What the benefits will be: With the number of individuals aged >80 years and the burden of medication expected to rise over the next 30 years, the issue of whether or not it is safe to withdraw antihypertensive medication in older patients is becoming ever more pertinent. Establishing whether or not withdrawal is safe in this population is likely to have a significant impact on future clinical guidelines and patient care, and will reduce the burden on the NHS leading to significant cost savings.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) and the NIHR School for Primary Care Research in collaboration with Nuffield Department of Primary Care Health Sciences; Oxfordshire CCG; Oxford AHSN; University of Cambridge and University of Southampton.

Study lead: James Sheppard

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24 Does provision of lifetime risk information influence future self-management behaviour in type 2 diabetes (T2DM)?

What we are doing: Based on recent studies investigating risk perceptions and risk attitudes in T2DM populations, we have developed tailored risk communication intervention for people with T2DM. This intervention aims to increase patients' awareness of their risk of complications / impact of self-management and, encourage adoption of recommended self-care behaviours. The objectives of the full trial are to assess feasibility and measure the expected impact of such an intervention, in order to inform the design of a larger RCT.

Why we are doing it: People with T2DM underestimate their risks of developing complications. Existing risk communication interventions yield mixed results, with many participants barely understanding the explanations of health professionals about risks and having poor recall of risk information, necessitating need for better risk communication interventions. Interventions, through which personalised risks are communicated, may help to correct erroneous risk perceptions and motivate better adherence to self-management behaviour.

What the benefits will be: The intervention aims to increase patients' awareness of their risks of complications / impact of self-management, and, as a result, encourage the adoption of recommended self-care behaviours. This may have an impact on health outcomes, improving quality of life for patients and reducing the burden on NHS resources in the treatment of preventable complications.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for

Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with Nuffield Department of Primary Care Health Sciences and the Health Economics Research Centre, University of Oxford

Study lead: Thomas Rouyard, University of Oxford

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25 The role of pharmacists in hypertension management in primary care settings

What we are doing: A mixed methods approach will be used to explore current practice during pharmacist-patient hypertension consultations, as well as to determine how pharmacy measured blood pressure compares with home and GP clinic readings. This work will inform a feasibility study, where a developed blood pressure intervention will be assessed.

Why we are doing it: Hypertension affects 8 million adults in the UK, and persistently high blood pressure dramatically increases risk of suffering from heart disease and stroke. Treatments are effective yet control is poor and diseases caused by hypertension cost the NHS ~£2billion each year (PHE). Hypertension related GP consultations are ~1 in 12 per year. Alternative models of care are needed to ensure long-term management of hypertension, utilising community settings. Community pharmacies are conveniently located sources of medication advice, and accessible without appointment.

What the benefits will be: The purpose of this research is to determine how pharmacists can provide a blood pressure management service, utilising both community pharmacists and general practice based pharmacists to reduce the number of GP consultations required to manage hypertension. This study could also lead to better rates of blood pressure control, which is currently thought to be achieved in only 50% of diagnosed hypertensive patients.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with Nuffield Department of Primary Care Health Sciences

Study lead: Ali Albasri, University of Oxford

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26 INTERPRESS-IPD: Inter-arm blood pressure difference, cardiovascular events, cerebrovascular disease and mortality: an Individual Patient Data meta-analysis

What we are doing: INTERPRESS-IPD is an international collaboration to find out more about the link between from inter-arm differences in blood pressure (IAD) and mortality risk, by combining individual patient data from IAD cohort studies into a single large dataset for meta-analysis.

The project seeks to develop a new prognostic model for cardiovascular risk estimation that includes IAD, and to provide robust evidence to inform clinical care and future guidelines.

What the benefits will be: Previous research has confirmed an association between IAD and increased cardiovascular and all cause mortality, through study level meta-analyses. However, several questions remain which such methods cannot answer, which this project seeks to address:

- What is the independent contribution of IAD to prognostic risk estimation for cardiovascular and all-cause mortality?
- What minimum cut-off value for IAD defines elevated risk?
- What is the incremental association between IAD and mortality risk?
- Do different IAD measurement techniques affect prognostic value of IAD measurements?

What the benefits will be: With this project, we hope to inform clinical practice through updated international blood pressure guidelines, and provide patients and clinicians with robust evidence to inform health care decisions when an inter-arm difference is detected.

- A positive outcome from this study will offer:
- Confirmation of the role of IAD as a risk marker
- Definition of the minimum clinically important size of IAD
- Increased precision of cardiovascular risk estimation, to inform patients and inform their lifestyle choices more accurately.

Who are we working with: The CI Dr Chris Clark, NIHR Clinical Lecturer in General Practice and Primary Care, UEMS is responsible for running the study, supported by Professor John Campbell, Professor of General Practice and Primary Care, UEMS (joint CI) and Professor Rod Taylor, NIHR Senior Investigator, UEMS.

The development of this proposal has had considerable PPI input from members of the Patient Participation Group, PenPIG (PenCLAHRC's user involvement group) and by lay reviewers from the South West Research Design Service.

Study lead: Dr Chris Clark / Prof John Campbell

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27 UNITED - Using pharmacogenetics testing to identify monogenic diabetes earlier

What we are doing: We undertook an economic evaluation of four strategies to identifying individuals with monogenic diabetes from the perspective of the NHS, and compared them to a strategy where no attempt to identify individuals is made.

We have developed a decision analytic model to evaluate these strategies. This evaluation is part of a larger study to estimate the prevalence of monogenic diabetes and assess the impact on patients of changing their treatment (based on a misdiagnosis) to more appropriate treatment based on a diagnosis of monogenic diabetes.

Why we are doing it: Monogenic diabetes usually presents in patients under the age of 30 years, and so is often misdiagnosed as type 1 diabetes leading to patients receiving more invasive and

costly treatment than is necessary. Identifying these individuals and changing their treatment to that which is more appropriate could lead to cost savings to the NHS.

Study lead: Professor Christopher Hyde / Dr Jaime Peters

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28 The Rehabilitation EnAblement in Chronic Heart Failure (REACH-HF)

What we are doing: The REACH-HF trial is part of a research programme designed to develop and evaluate a health professional facilitated, home-based, self-help rehabilitation intervention to improve self-care and health-related quality of life in people with heart failure and their caregivers.

The trial will assess the clinical effectiveness and cost-effectiveness of the REACH-HF intervention in patients with systolic heart failure and impact on the outcomes of their caregivers.

Why we are doing it: The overarching aim of REACH HF is to develop and evaluate a nurse facilitated, home-based heart failure (HF) Manual to enhance the quality of life and self-management of people with heart failure (and their caregivers). This trial will assess how effective the HF Manual is as a self-help manual for patients with systolic heart failure as well as usual care, compared to usual care alone. This study will also enable the research team to see whether the HF Manual is good value for money and to ensure the manual is delivered consistently.

What the benefits will be: The study results provided valuable information for clinicians, policymakers, patients and their caregivers about the role of self-directed rehabilitation interventions and has the potential to positively impact on the current dearth in the provision and uptake of rehabilitation services for people with HF and caregiver support.

Who are we working with: The research team uniquely brings together the investigators in Birmingham, York, Leicester, South Wales, Exeter, Dundee and Cornwall who have led and published the five major trials of cardiac rehabilitation in the UK.

A REACH-HF Programme Steering Committee (Chair: Professor Martin Cowie and four other independent members including a PPI representative) oversees the conduct of the trial with a review by an independent Data Monitoring Committee. The study is sponsored by Royal Cornwall Hospitals NHS Trust and the Heart Manual Service, NHS Lothian is a key collaborator.

Study leads: Professor Rod Taylor from the University of Exeter Medical School and Dr Hayes Dalal from the Royal Cornwall Hospital and University of Exeter Medical School

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29 ExTraMATCH II - Exercise Training for Chronic Heart Failure: Individual participant data meta-analysis

What we are doing: Funded by the NIHR Health Technology Assessment Programme, The Exercise Training Meta-Analysis for Chronic Heart Failure (ExTraMATCH II) seeks to undertake an individual patient data (IPD) meta-analysis project aims to determine which heart failure patient subgroups benefit most from exercise-based rehabilitation.

Data from existing clinical trials studying the effects of exercise-based interventions in heart failure patients are combined into a single dataset. This IPD meta-analysis will be carried out in order to:

- Obtain definitive estimates of the impact of exercise-based rehabilitation on all-cause mortality, hospitalisation, exercise capacity, and health-related quality of life in heart failure patients
- Determine the sub-group effects of exercise-based interventions in heart failure patients according to: age, gender, left ventricular ejection fraction, aetiology (ischaemic or non-ischaemic), NYHA class, and baseline exercise capacity.

The study is registered with PROSPERO: registration number CRD42014007170

Study lead: Dr Sarah Walker / Prof Rod Taylor,

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30 Cochrane Cardiac Rehabilitation Reviews

What we are doing: Following support from a 3-year National Institute of Health Research (NIHR) Programme Grant in 2000, we have continued to develop a vibrant programme of Cochrane reviews of cardiac rehabilitation. These reviews seek to address a range of policy and clinical practice issues, including the comprehensive nature of cardiac rehabilitation intervention (exercise, psychological support and education), the widening population of patients (e.g. post-myocardial, post-revascularisation, heart failure) receiving these services, and the various settings in which these services can be delivered (e.g. home vs hospital).

These Cochrane reviews have played a pivotal role in informing evidence-based policy and clinical guidelines both in the United Kingdom and internationally.

Study lead: Dr Linda Long / Prof Rod Taylor,

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31 Using new low dose CT cardiac imaging techniques to help define pre-operative risk of silent MI in surgery

What we are doing: This study aims to improve the prediction of risk of cardiac events in patients about to undergo major operations and improve patient's outcomes.

The key objectives of this project are:

- To systematically review the best current methods of predicting cardiac risk.
- To assess the feasibility of prospective axial cardiac CT scans.
- To make a direct comparison between the spiral scans and the prospective axial scans objectively and subjectively for image quality.
- To assess the number of coronary artery segments in each patient that can be seen and are assessable in this patient population.
- To evaluate the addition in predictive risk likely to flow from use of prospective axial cardiac CT scans.

Why we are doing it: Recent advances in CT technology have made it possible to perform cardiac CT using a new technique – prospective axial scanning. This scan only requires a small part of the cardiac cycle to obtain images and has been shown to be as accurate as a spiral CTCA in selected patients. This technique is more dose efficient and is typically less radiation than a standard CT scan.

Study lead: Chun Lap Pang / Dr Carl Roobottom

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32 Care Givers and Cardiac Rehabilitation in Heart Failure

What we are doing: The overarching aim of this PhD proposal is to improve the understanding of the impact of involvement of care givers in the management of HF patients and in particular cardiac rehabilitation programmes. Specific objectives are:

- To undertake a systematic review to determine the experiences of informal caregivers when supporting people with heart failure, COPD, and coronary artery disease
- To undertake a systematic review of interventions for chronic disease that includes caregivers in the design and the delivery of intervention.
- To examine the association between the outcomes of patients with heart failure and their care-givers and impact of involvement of carers on patient outcome – using the REACH-HF project data.

Why we are doing it: Caregivers (informal unpaid caregivers) are providing more care than ever before because of greater care needs and decreasing homecare support. In the UK an estimated 6.8 million people currently provide care and this is expected to rise to 9 million caregivers by 2037. Caregivers currently contribute estimated value of £132 billion per year. This value is likely to be under-estimated as many caregivers do not recognise their role as caregivers believing that their activities are a normal part of their relationship

Study lead: Miriam Noonan, Prof Rod Taylor,

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33 Cardiac Rehabilitation and Physical Activity Levels in Heart Failure

Why we are doing it: People with heart failure (HF) experience marked reductions in their exercise capacity which has detrimental effects on their activities of daily living, health-related quality of life, and ultimately their hospital admission rate and mortality. Cardiac rehabilitation (CR) is a key element in the management of HF and is a process by which patients, in partnership with health professionals, are encouraged and supported to achieve and maintain optimal physical health. In spite of this wealth of evidence, the impact of CR on HF patient outcomes including mortality, risk of hospitalisation, exercise capacity and health-related quality of life, the impact of CR on the physical activity remains unclear.

Study lead: G Dibben

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34 Cardiac Troponin: High sensitivity troponin for the diagnosis of acute myocardial infarction in A&E - modelling impact & implementation in the SW (PenCHORD)

What we are doing: This project has brought together the available evidence, with analysis of service activity locally, to explore the potential impact on heart attack care pathways in the South West, if high sensitivity troponin is implemented consistently. This was achieved through the use of simulation modelling by the PenCHORD team to assess the possible impact of reconfiguring services on both patients and the NHS.

Why we are doing it: This study addressed the following questions to support the development of a clear strategy for using high sensitivity troponin:

- How does the use of high sensitivity troponin vary across the South West?
- How many patients are currently being admitted for observation of acute chest pain suspected of being a heart attack and how does this vary across the South West?
- How might the use of high sensitivity troponin affect current patterns of health service use?
- What are the barriers and facilitators to consistent and efficient use of high sensitivity troponin across hospitals in the South West?

What the benefits will be: The review confirms the very high predictive value of the test, demonstrating that a single test at presentation might be sufficient to rule out acute myocardial infarction, leading to earlier discharge of patients without AMI.

The overall length of stay in the Emergency Department (ED) and subsequently at short stay wards could be reduced by approximately 180 minutes. The new tests also have a positive impact on the utilisation of short stay wards, which are often managed by ED staff.

Who are we working with: In this project we worked with the Peninsula Heart and Stroke Network and a number of local specialists to identify relevant research topics and produce systematic reviews that could help clinicians, policy makers and patients to make better decisions about diagnostic tests and, ultimately, achieve better outcomes.

Study lead: Professor Martin Pitt, Associate Professor at PenCLAHRC and Director of PenCHORD

Contact: M.Pitt@exeter.ac.uk / Z.Zhelev@exeter.ac.uk

35 DIAT - Does a simple pre-clinic form improve patient satisfaction following a diabetes appointment?

What we are doing: We tested a 'pre-consultation' intervention in the half hour prior to a hospital clinic appointment with a Consultant Diabetologist. This involved seeing a Health Care Assistant (HCA) who supported the patient in completing an electronic questionnaire aimed at helping them to identify important areas for discussion (their 'agenda') in the consultation with their Diabetologist. We anticipate that this may enable the patient to play a more active role in that consultation and subsequently make them more confident (and hence more successful) in managing their condition.

Why we are doing it: Diabetes is a chronic condition associated with many long-term complications, the management of which is costly to the NHS. People with diabetes need to be actively involved in managing their condition, which can often be a complex business. They receive advice in regular, but typically infrequent, consultations with health care professionals. However, they do not always discuss things which concern them in these consultations, perhaps because of perceived limited time or embarrassment.

Study lead: Nicky Britten/Julia Frost

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36 Hypertension

What we are doing: We have published a systematic review of nurse led interventions in hypertension and plan to extend this work by reviewing the evidence base for allied health professional led interventions to improve the control of hypertension. We aim to elucidate whether nurse or pharmacist prescribing is an important component of this complex intervention.

We have also helped to establish the prevalence of the inter-arm blood pressure difference phenomenon and its associations with peripheral vascular disease and reduced cardiovascular event-free survival. Whilst the majority of GPs are aware of this phenomenon and its use as a marker for increased cardiovascular risk, only a minority check for it and there is an implementation gap between knowledge and clinical practice. We therefore intend to develop a means of disseminating the importance of this finding along with methods for implementing the use of inter-arm difference detection in primary care.

Study lead: Christopher Clark

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37 CaRoTT - Cardiac Reviews of Tests and Training

What we are doing: We worked with the Peninsula Heart and Stroke Network and a number of local specialists to identify relevant research topics and produce systematic reviews that could help clinicians, policy makers and patients to make better decisions about diagnostic tests and, ultimately, achieve better outcomes. We conducted two systematic reviews that focused on the same condition—acute coronary syndrome (ACS)—but assessed the diagnostic accuracy of two different tests:

- Coronary computed tomography angiography (CCTA) - an imaging technique that uses x-rays to create a 3D picture of the heart's arteries in order to identify obstructions to the blood flow; and,
- Highly sensitive cardiac troponin (hs-cTn) assay - a blood test that, when positive, indicates damage to the heart muscle.

The CaRoTT project also helped develop the research capacity of a team of systematic reviewers in conducting diagnostic accuracy reviews—a specific type of systematic reviews that differs from the familiar effectiveness reviews both in focus and methodology and requires additional knowledge and skills.

Study lead: Christopher Hyde/Zhivko Zhelev

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38 DIABSCREEN - Can screening intervals for diabetic digital retinal photography be individualized to enhance screening performance and cost-effectiveness, on the basis of individual clinical risk? (PenCHORD)

What we are doing: We developed a simulation model to predict the impact on patient vision of screening patients with Type 2 diabetes for diabetic retinopathy every two years, rather than annually, for those who had not yet developed retinopathy. We used agent-based modelling to simulate the retinopathy progression of individual patients, their attendance at screening appointments and their treatment. The model was populated with data obtained from the Royal Devon and Exeter NHS Foundation Trust.

What the benefits will be: Our model predicted that by screening patients who have not yet developed retinopathy every two years until they are identified with retinopathy, there would be no impact on the proportion of patients who would lose their vision but there could be a 25% saving on screening costs.

Study lead: Dan Chalk

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39 NHS Health checks - Improving NHS cardiovascular health checks uptake in primary care

What we are doing: There were two key parts to this research:

- Stage 1. To map the methods that practices within the Torbay region are routinely using to invite eligible people for an NHSHC and to quantitatively explore the influence of these different models on health check uptake.
- Stage 2. To qualitatively explore eligible patients' choices around their (i) willingness to attend for an NHSHC at their local practice, and (ii) for those who completed an NHSHC, their views and experiences of undergoing the cardiovascular risk assessment and their future willingness to engage with the programme.

Why we are doing it: To improve the uptake of NHS cardiovascular health checks in primary care by identifying factors that influence older people's willingness to engage with primary preventative health care programmes.

Study lead: John Campbell

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40 Effectiveness of mindfulness-based stress reduction and mindfulness-based cognitive therapy in vascular disease

What we are doing: The purpose of this systematic review was to establish whether MBSR and MBCT are effective in the management of both depressive and physical symptoms in individuals with vascular disease and those at high risk of vascular disease.

Why we are doing it: Vascular disease is a leading cause of morbidity and mortality. Both the disease itself and its associated clinical events, such as heart attack and stroke, are significant and distressing life events. Depression, anxiety, and psychological distress, in turn, are independent risk factors for vascular disease morbidity and mortality.

What the benefits will be: There is a recognised need to equip patients with vascular disease with skills and coping strategies to help reduce or manage perceived psychological stress. Mindfulness-based approaches have been advocated as one promising psychosocial approach. Two of the main mindfulness-based approaches are Mindfulness-Based Stress Reduction (MBSR), and Mindfulness-Based Cognitive Therapy (MBCT).

Study lead: Rebecca Abbot

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41 SCN Urgent Care Review - Modelling provision for stroke and cardiac services in the South West region (PenCHORD)

What we are doing: Computer modelling was used to try and determine the best configuration of hospitals to provide heart attack and stroke services for nearly five million people across the South West of England, from Gloucester to the Isles of Scilly. The model tried to balance the need for services to be large enough to provide round the clock specialist emergency treatment, with the need for these services to be close enough to where people live so they can get fast treatment for a heart attack or stroke.

The main aim of the project was to investigate the relationship between the number of hospitals in the South West and key performance criteria, including:

- Transfer times to hospital.
- Time from onset of stroke/heart attack to treatment (with improved in-hospital arrival-to-treatment times in centralised centres of clinical excellence).
- Number of admissions per hospital per year (substitute for measuring experience and clinical excellence) and ability to meet recommended minimum admissions/year.
- Predicted clinical outcome (disability-free patients for stroke and one-year mortality for heart attack).
- Cath lab load/utilisation.
- Ambulance time required (centralisation increases ambulance time required).

In addition, the best locations of hospitals for any given number of hospitals, including providing a range of possible near-equivalent scenarios, was investigated.

Study lead: Mike Allen/Kerry Pearn

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42 STEMI - Modelling alternative reperfusion strategies for MI (PenCHORD)

What we are doing: The standard care for acute ST-elevation myocardial infarction (STEMI) is Primary Percutaneous Coronary Intervention (PPCI), otherwise known as coronary angioplasty. Administering PPCI treatment requires a patient to be transferred to a centre specialising in the technique.

STEMI heart attacks were previously treated with thrombolysis (clot-busting drugs) administered by paramedics before patients were taken to hospital. With the national roll-out of emergency angioplasty (PPCI) this was replaced by transfer to a centralised PPCI centre.

Why we are doing it: Data analysis suggests that in rural areas, overall mortality has not been improved by this change in treatment and people living furthest away from the PPCI centres may potentially be disadvantaged.

Working with Taunton and Somerset NHS Foundation Trust, PenCHORD modelled the 'winners and losers' in the transition from pre-hospital thrombolysis to centralised PPCI, and investigated the potential benefit of a mixed-model approach combining emergency thrombolysis (for those furthest from a PPCI centre) with centralised PPCI.

Study lead: Mike Allen/Kerry Pearn

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43 DIABFOOT-Effectiveness of multidisciplinary foot care and foot protection teams in reducing diabetic foot complications

What we are doing: The project aimed to implement and evaluate a method for identifying patients at risk and provide them with a structured one to one education package that supports patients to perform daily preventive self-care and to encourage behaviours that minimize precipitating factors of foot ulceration.

Why we are doing it: Current NICE guidelines on type 2 diabetes on prevention and management of foot problems state that people with high risk of foot ulcers should be seen between every one to three months by a foot protection team. The guidance also suggests that research needs to be carried out to assess the appropriate level and combination of risk factors at which patients should be categorised as at high risk for ulceration and be offered attendance on a protection programme.

Study lead: Ken Stein

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44 Diabetes App - Does a web based pre-clinic form improve patient satisfaction following a diabetes appointment?

Why we are doing it: Discussions with doctors at diabetes clinic appointments have often been regarded by young people with diabetes (YPD) as lacking in relevance, and therefore providing ineffective support for diabetes self-management.

What the benefits will be: This study will benefit young people with diabetes (YPD) by developing and testing the feasibility and use of Internet or mobile phone-based applications ('apps') with which young people will engage with their clinician and focus diabetes clinic appointments on their own agenda. The immediate benefit of this study will be the availability of 'apps' developed by YPD and tested by 200 YPD in one consultation. The longer term benefit is in having a defined intervention and evaluation methods for a subsequent study leading to improved attendance at, and satisfaction with, clinic consultations.

Study lead: Jonathon Pinkney

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45 VTE - A Realist Evaluation of the Implementation of a VTE Prevention Strategy at 4 NHS Acute Trusts toward understanding the barriers to screening and prophylaxis

What we are doing: The study assessed what models for implementing venous thromboembolism (VTE) risk assessment and VTE prevention were applied in four hospitals in the NHS South of England region. We examined how each hospital compared in terms of design, assumptions and conditions for implementation. A before and after observational design study was used to evaluate the implementation of the NICE guideline and investigate changes in VTE risk assessment and the prescribing of appropriate thromboprophylaxis. Two specialities were covered in the study; one with a relatively high proportion of elective patients (Orthopaedics) and one with a high proportion of emergency admissions (General Medicine). We were able to conclude that the documentation of risk assessment improved following the implementation of NICE guidance; however it is questionable whether this led to improved patient safety when prescribing prophylaxis.

Study lead: Rod Sheaff

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46 Chest pain diagnosis – costs and consequences (PenCHORD)

What we are doing: PenCHORD worked with the South West Peninsula Cardiac Network to develop a tool to compare cost, overall diagnostic accuracy, adverse events and uncertainty in these estimates between two competing diagnostic pathways.

Why we are doing it: Recent NICE guidance for the diagnosis of angina provides a framework for the selection of the most cost effective tests based on the level of risk a patient represents. This risk stratification approach to diagnostic test selection presents a substantial change to the current service provision in the South West of England. In current service provision, for example, the majority of patients initially undergo an exercise tolerance test (ETT) on a treadmill and based on the result and other clinical information may then go on to further testing such as invasive angiography (IA). NICE recommends that ETT is no longer used as part of a diagnostic pathway and instead the use of tests such as IA should be initially decided upon by clinical history alone.

Study lead: Martin Pitt

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47 A feasibility study and pilot RCT to establish methods for assessing the acceptability, and clinical effectiveness and cost effectiveness of enhanced psychological care in cardiac rehabilitation services for patients with new onset depression compared with treatment as usual: (CADENCE)

What we are doing: To examine the feasibility and acceptability of embedding enhanced psychological care (EPC) within cardiac rehabilitation we tested the feasibility of developing/implementing EPC, and documented key uncertainties associated with undertaking a definitive evaluation.

We designed a two-stage multi-method study. Uncontrolled pre-post feasibility study and qualitative evaluation, followed by an external pilot cluster randomised controlled trial with nested qualitative study.

Our conclusions are that Cardiac rehabilitation nurses can be trained to deliver EPC. Whilst valued by both patients and nurses, organisational and workload constraints were significant barriers to implementation. We obtained important data informing definitive research regarding participant recruitment and retention, and optimal methods of data collection.

Study lead: John Campbell

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48 The use of a new generation online social network tool to support the self-management of diabetes, heart disease and other long term conditions: How Genie can help people link up with the community online and stay well

What we are doing: We created a website tool called Genie. It helps people with a long term condition, like diabetes, heart or kidney disease manage their illness better. People work with a facilitator to identify who is in their circle of contacts and how often they see them. They then link to a database of local support. For example, a friend taking them shopping could also take them to a local diabetes group. We have been testing and evaluating Genie across communities.

Why we are doing it: Our previous research discovered that the richness of a persons' social network has a strong positive influence on how they manage their wellbeing, especially if they have a long term condition. We have developed the Genie tool to: raise awareness of the benefits of social networks, help people get better access to health resources, and learn about managing illness better. In one study (BRIGHT) for Chronic Kidney Disease (CKD) we found improvements in blood pressure and wellbeing using Genie.

What the benefits will be: Our research across a number of long term conditions shows that enabling people to expand their social network and plug into local community resources helps them manage illness well in the community and empower them. Estimates have shown a saving of £175 per patient over a year with the Genie intervention by reducing reliance on acute

hospital and GP services. People often feel more in control of managing their condition too and have better health literacy.

Who are we working with: We have been working closely with NIHR CLAHRC Greater Manchester, before centring the development of the Genie tool at the University of Southampton. We are upgrading and developing Genie further, working with some commercial organisations to establish a wider network across England. Councils and health commissioners (CCGs) in Wessex, England and abroad are also looking to implement the Genie approach. They aim to integrate it into their communities for people with a wide range of conditions and needs.

Study lead: Professor Anne Rogers, Dr Ivaylo Vassilev

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49 Exploring the understanding and perception of cardiovascular risk in younger women, and their perceptions of barriers and facilitators to behaviour change in primary prevention of cardiovascular disease

What we are doing: We aim to better understand the perceptions of younger women about:

- their cardiovascular disease risk
- factors influencing behaviour change pertaining to reducing cardiovascular disease risk

To do this we will be undertaking a systematic review, examining existing, relevant research evidence before undertaking a qualitative study to explore these issues in greater depth.

Why we are doing it: We want to support primary care clinicians and public health policy to deliver high quality, effective primary prevention to younger women. Special focus on this particular population is necessary as younger women have not experienced the same pattern of reduction in CVD mortality reflected by the general population. This seems to be, in part, due to more limited success in risk factor modification in this group.

What the benefits will be: We are using behavioural theory (protection motivation theory) as a framework for this study, to ensure that we identify the understanding and perceptions that are relevant for influencing positive behaviour change. An output of this study will be recommendations to improve primary prevention of CVD in younger women which, if implemented, may result in health benefits across this population.

Who are we working with: We will be working with local general practices to recruit participants and the PPIE within the Primary Care and Health Sciences, Research Institute at Keele University.

Study lead:

Dr Randula Haththotuwa (NIHR ACF ST3 – primary care)

Dr Elizabeth Cottrell (NIHR ACL – primary care)

Prof Carolyn Chew-Graham (Professor of primary care)

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50 The Oxford Renal Cohort Study (OxRen) and NEW onset Kidney Impairment study (NewKI)

What we are doing: The Oxford Renal Longitudinal Cohort Study (OxRen) was established by the University of Oxford in 2011 and has recruited within the Thames Valley Region of the UK. The objectives were to determine the prevalence and progression of Chronic Kidney Disease (CKD) in a population with reasonable demographic similarity to the whole UK, to define the prevalence of selected risk factors and establish the distribution of estimated kidney function in patients detected by a targeted screening programme.

Why we are doing it: CKD is a largely asymptomatic condition of diminished renal function and is increasingly recognised as a global public health concern. CKD is usually asymptomatic until later stages of the disease, but even earlier stages are associated with increased mortality and cardiovascular risk. There is an age-related decline in renal function, and from age 60 years, CKD prevalence increases rapidly. It may, therefore, be reasonable to systematically screen in this age group to enable early detection.

What the benefits will be: This study has determined the prevalence of CKD and the number of previously undetected cases in a population aged over 60 years. Cost effectiveness of screening for CKD in primary care will be established and by re-screening the CKD-free group in NewKI, data on incidence of CKD can be collected. Follow-up of those with CKD in NewKI, will help to determine the rates of progression of CKD and identify risk factors for rapid progression to later stages of CKD and identify cardiovascular events.

Who are we working with: This study is taking place in general practices in the Thames Valley region of the UK. We are working with GP surgery staff to recruit a cohort demographically representative of the UK primary care population.

Study lead: Professor Richard Hobbs

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51 The PERMIT Project - Personalised Renal Monitoring via Information Technology

What we are doing: We are developing a clinical guideline for monitoring renal function in heart failure patients, addressing an important gap in national guidelines. Without guidance, patients are monitored at the discretion of their GP, and renal function can be overlooked, resulting in gradual decline of renal function and avoidable hospital admissions due to renal failure. Our solution is to build a machine learning algorithm that can predict patient risk of renal decline, allowing GPs to accurately decide on the safest monitoring plan.

Why we are doing it: Acute kidney injury from diuretics is the second most common cause of medication-related hospital admissions. This project aims to create a standardised clinical decision tool to predict which heart failure patients are most at

risk of renal decline, in order to intervene before they require hospital admission. However, since each patient reacts differently to diuretic doses, guidance needs to be personalised to each patient's risk factors and medication tolerances, hence the novel machine learning approach.

What the benefits will be: Overall, the PERMIT study aims to improve the well-being of all heart failure patients by making the monitoring of their medication easier and their management safer, thus avoiding preventable hospital admission and mortality. Based on this research we expect future technologies to develop which can aid the prediction of health outcomes for these patients such as home-monitoring systems which allow renal function of these patients to be measured in their own homes.

Who are we working with: We have involved both patient representatives as well as GPs, cardiology and renal consultants and clinical data experts within the PERMIT project team. The project proposal is funded by CLAHRC NWC, with partnership from the Royal Liverpool University Hospital as well as Liverpool Heart and Chest Hospital. The analysis team is also made up of data science experts from the University of Liverpool, University of Manchester and the Max Planck Research Institute in Munich.

Study lead: Prof Sir Munir Pirmohamed

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52 Benefits of Aldosterone Receptor Antagonism in Chronic Kidney Disease Trial (BARACK-D)

What we are doing: BARACK-D aims to recruit 3022 participants with evidence of chronic kidney disease (CKD) stage 3b or low 3a (eGFR 30-50 ml/min/1.73m²) from the primary care setting. Eligible patients are randomised 1:1 to receive routine care or spironolactone in addition to routine care. Patients will be followed up for 3 years following randomisation. The primary objective is to determine the effect of spironolactone on the time from randomisation to onset or progression of heart disease, heart failure, stroke or death.

Why we are doing it: CKD is increasingly common, affecting around 10% of the entire population. CKD is associated with an age-related decline in renal function that is accelerated in hypertension, diabetes mellitus, obesity and primary renal disorders. The most important component of CKD in terms of mortality and morbidity is cardiovascular disease. This can be devastating for patients and their families, and is associated with high costs for healthcare systems.

What the benefits will be: Better treatment options to provide protection from vascular events or delay progression of CKD are urgently needed, especially given the increasing burden of the disease. This trial will determine whether spironolactone can improve survival and reduce cardiovascular outcomes in patients with CKD. If we are able to find effective treatments for CKD both patients and healthcare systems are likely to benefit.

Who are we working with: The study is funded by the National Institute for Health Research Health Technology

Assessment Programme (NIHR HTA). We work with GP practices from Clinical Research Networks including:

- Thames Valley, West of England, Eastern, Kent, Surrey & Sussex
- Wessex, NW London, South London, North Thames, SW Peninsula,
- North West Coast, Greater Manchester, North East & North Cumbria
- West Midlands, Abertawe Bro UHB, Aneurin Bevan UHB, Betsi Cadwaladr UHB, Cardiff & Vale UHB, Cwm Taf University Health Board
- Hywel Dda UHB, Powys Teaching HB

Study lead: Professor Richard Hobbs, University of Oxford

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53 Establishing research priorities to improve the management of patients with advanced heart failure using the James Lind Alliance method

What we are doing: A steering group of people directly affected by advanced heart failure including patients, carers and clinicians will oversee the project. An initial survey will determine what the priorities for advanced heart failure research should be. A review of the literature will be carried out to identify where priorities have already been addressed, and where research gaps exist. Priorities will then be sorted to generate a shorter list for discussion at a final workshop where a 'Top 10' priority list will be agreed.

Why we are doing it: Heart failure is a complex clinical syndrome affecting 1-2% of the adult population. It places a heavy burden on both patients and their carers which often increases in the advanced stages of the illness. Research priorities have traditionally been set by researchers and funders but involving patients in the process can lead to more valid, credible and relevant research findings.

What the benefits will be: This project sets out to establish the research priorities for advanced heart failure identified by those most affected by the condition. The priorities will be disseminated widely to researchers and funders to ensure this project has the maximum impact on the advanced heart failure research agenda.

Who are we working with: The Universities of Oxford, Bristol and Cambridge have established an Advanced Heart Failure Priority Setting Partnership (PSP) using the James Lind Alliance method. The members of the steering group will promote the survey through their 'wider partner networks' which include patient groups, healthcare clinics and through relevant websites such as heart failure charities and local NHS trusts.

Study lead: Dr Clare Taylor and Professor Richard Hobbs

Contact: Linnemore Jantjes-Robertson (PSP co-ordinator) at linnemore.jantjes@phc.ox.ac.uk

54 Screening for valvular heart disease in primary care: Impact on patient outcomes and GP workload (OxValve sub-study)

What we are doing: This study will explore the outcome of participants with and without valvular heart disease from the OxValve cohort by using linkage to hospital episode statistics and mortality data. The findings will be compared with a large routinely collected dataset from the Clinical Practice Research Datalink (CPRD). The utility of natriuretic peptide testing in identifying patients with valvular heart disease will also be explored. The potential workload implications for primary care of screening patients for valvular heart disease will be modelled using data from the OxValve cohort and CPRD.

Why we are doing it: Screening for valvular heart disease has both consequences for patients and potential resource impact for any health system. Primary care in the NHS is currently experiencing unprecedented workload and there is no capacity for any additional demand on services. The outcomes of patients following a diagnosis of valvular heart disease at screening are currently unknown.

What the benefits will be: This study will improve our understanding of outcomes following a diagnosis of valvular heart disease, explore the value of natriuretic peptide testing and demonstrate the impact on GP workload of screening a large community population.

Who are we working with: The Heart Failure team at the Nuffield Department of Primary Care Health Sciences team is working with the OxValve study team led by Prof Bernard Prendergast and Prof Saul Myerson at the John Radcliffe Hospital, Oxford.

Study lead: Dr Clare Taylor and Professor Richard Hobbs

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55 Biochemical detection of non-adherence to cardiovascular medications

What we are doing: We, in the Department of Chemical Pathology and Metabolic Diseases, University Hospitals of Leicester NHS Trust, are the first in the world to develop a robust and objective biochemical method to detect presence of medications in urine using liquid chromatography -tandem mass spectrometry. Our panel can detect 60 of the most common cardiovascular medications including those for treating hypertension, diabetes and dyslipidaemia. We have set up a National Centre for Adherence testing (NCAT) in Leicester and receive samples from 25 centres across UK.

Why we are doing it: Non-adherence to cardiovascular diseases is a pandemic and is one of the most important factors associated with poor outcomes and repeat hospital admissions. Until recently, there were only cumbersome or subjective methods available to diagnose non-adherence.

What the benefits will be: We have demonstrated non-adherence rates to antihypertensive medications of >30% in a

cohort of 1348 patients attending hypertension clinics in two countries. We have performed a similar, first of its kind study, in 116 primary care patients with diabetes. This has revealed that non-adherence rates to statins are around 30% as compared to 10% for anti-diabetic medications.

Moreover, we have shown that the test has a therapeutic role. We have shown in a study of 331 patients that it helps reduce systolic blood pressure by around 20 mmHg ($P=0.001$) after the results are discussed with patients. A health economic analysis based on this data shows biochemical detection of non-adherence can lead to cost savings of more than £850 per patient with hypertension. Thus, biochemical detection of non-adherence is an important and clinically useful tool to address non-adherence. Its role can be expanded to a variety of fields both in the clinical and research settings.

Study lead: Pankaj Gupta

56 Echocardiographic Heart of England Screening (ECHOES) study

What we are doing: The Echocardiographic Heart of England Screening (ECHOES) study is the largest community based cohort ever screened for heart failure in the United Kingdom. In the original study, conducted between 1995 and 1999, 6162 participants underwent clinical assessment and echocardiography. The cohort was followed up in the ECHOES-X study between 2008 and 2011. The team continue to collect mortality data on the cohort to report survival rates and causes of death.

Why we are doing it: Heart failure remains a major public health burden. 1-2% of the adult population have the condition which causes unpleasant symptoms and reduced quality of life. The natural history of heart failure in community populations is still poorly understood. Survival data are a vital part of the epidemiological information used by clinicians, public health experts and healthcare commissioners to inform the way care is provided at an individual and population level.

What the benefits will be: The ECHOES study is a large, well-phenotyped cohort which has been followed-up over a long period of time. The Office for National Statistics provides the study team with accurate mortality data which allows calculation of both survival rates and causes of death. This information adds to our understanding of the disease trajectory for patients with heart failure in the community population.

Who are we working with: The Heart Failure team in the Nuffield Department of Primary Care Health Sciences at the University of Oxford work with the Office for National Statistics and NHS Digital to continue to report survival rates for the ECHOES cohort.

Study lead: Professor Richard Hobbs and Dr Clare Taylor

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57 The REFER (REFER for Echocardiogram) study: a prospective validation and health economic analysis of a clinical decision rule, NT-proBNP, or their combination, in the diagnosis of heart failure in primary care

What we are doing: The REFER study was a prospective, observational, diagnostic validation study and economic evaluation carried out in 28 general practices in central England, United Kingdom. Participants were primary care patients over the age of 55 years presenting with recent new onset shortness of breath, lethargy or peripheral ankle oedema of over 48 hours duration. A clinical decision rule was not effective in diagnosing heart failure but a natriuretic peptide blood test alone could be used to rule out the condition although the cut-off values remain in doubt. The team are undertaking further work to establish the optimal threshold for natriuretic peptide testing in primary care.

Why we are doing it: Heart failure is an important syndrome affecting 1-2% of the adult population and increasing with age. Patients experience unpleasant symptoms such as shortness of breath, fatigue and ankle swelling. There are many treatments which can improve quality of life and survival but diagnosis can be challenging. Access to echocardiography in primary care is limited.

What the benefits will be: Natriuretic peptide testing alone performed better than the validated clinical decision rule in determining which patients presenting with symptoms went on to have a diagnosis of heart failure. The current natriuretic peptide cut-off level used in the United Kingdom may be too high meaning patients with heart failure may not be appropriately referred for further investigation and diagnosis. International consensus on the optimal natriuretic peptide threshold for onward referral is needed to ensure cases are not missed whilst also optimising resource use.

Who are we working with: The Heart Failure team in the Nuffield Department of Primary Care Health Sciences at the University of Oxford are working with colleagues in Utrecht, Netherlands to establish a merged dataset which will allow an individual patient data meta-analysis to determine optimal natriuretic peptide cut-offs for referral for further testing in patients presenting to primary care with symptoms suggestive of heart failure.

Study lead: Professor Richard Hobbs and Dr Clare Taylor

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58 The impact of interventions to prevent diabetes in England – a simulation model

What we are doing: We developed Markov models to simulate the impact of three interventions to prevent or delay the onset of type 2 diabetes in those at high risk (namely, the National Diabetes Prevention Programme, metformin and a "sugar tax"). The models estimated the number of diabetic cases prevented by each intervention, associated costs and QALYs for each year over the next 20 years. For each intervention we developed different scenarios to reflect uncertainty in the inputs and ran sensitivity analysis.

Why we are doing it: Prevention of type 2 diabetes is a priority for England because of the projected diabetes 'epidemic'. Interventions that aim at individual behavioural change are cost-effective in delaying or preventing the onset of diabetes in those at high-risk. The cornerstone of the National Diabetes Prevention Programme (NDPP) is based on such interventions. Pharmacological interventions (e.g. metformin) are also recommended in national clinical guidelines, but inconsistently offered. The Government proposes to introduce a sugar tax, a population-wide intervention that can lower the prevalence of diabetes.

What the benefits will be: In our work we estimate the impact at the population level of the selected interventions. For an average English local health economy with a population of 300,000, in 20 years' time the cases of diabetes are projected to increase from 22,000 to 30,000. The NDPP is estimated to prevent about 30 cases of diabetes; metformin, if prescribed to half of those at high-risk, about 200; and a sugar tax about 600. These results show that interventions that are effective and cost-effective may have negligible impact on the diabetes 'epidemic'.

Who are we working with: In the development of the model, we involved clinicians and modellers. We ran the model using data for the London Borough of Newham, where we engaged with about 30 local stakeholders in a half day workshop. We are currently organizing focus groups with people at high risk of diabetes and clinicians to explore their views on metformin as an intervention for diabetes prevention.

Study lead: Gwyn Bevan, Professor of Policy Analysis, London School of Economics and Political Science

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59 Trends in hospital admissions for hypoglycaemia in England: a retrospective, observational study

What we are doing: We collected data for all hospital admissions listing hypoglycaemia as primary reason between 2005 and 2014, using the Hospital Episode Statistics database, which contains details of all admissions to English NHS hospital trusts. We calculated crude and adjusted (for age, sex, ethnic group, social deprivation, and Charlson comorbidity score) trends in admissions for hypoglycaemia; in admissions for hypoglycaemia per total hospital admissions and per diabetes prevalence in England; and in length of stay, in-hospital mortality, and 1-month readmissions for hypoglycaemia.

Why we are doing it: Studies in the USA and Canada have reported increasing or stable rates of hospital admissions for hypoglycaemia. Some data from small studies are available for other countries. We aimed to gather information about long-term trends in hospital admission for hypoglycaemia and subsequent outcomes in England to help widen understanding for the global burden of hospitalisation for hypoglycaemia.

What the benefits will be: We found that 72% of hospital admissions for hypoglycaemia occurred in people aged ≥ 60 years. Admissions increased from 2005 to 2010 (49% increase)

and then remained more stable until 2014. With differences across regions, from 2005 to 2014 the same-day discharge increased by 43.8%; in-hospital mortality decreased by 46.3%; and 1-month readmissions decreased by 63.0%. This information will help clarify the best approach to reduce hospital admissions for hypoglycaemia and identify at what stage resources should be allocated.

Who are we working with: Nottingham University Hospitals & East Midlands Academic Health Science Network, Nottingham, UK.

Study lead: Francesco Zaccardi

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60 Predicting hospital stay, mortality and readmission in people admitted for hypoglycaemia: prognostic models derivation and validation

What we are doing: We used data on all hospital admission to NHS hospital trusts in England to extract admissions for hypoglycaemia between 2010 and 2014. We developed, internally and temporally validated, and compared two prognostic risk models for each outcome. The first model included age, sex, ethnicity, region, social deprivation and Charlson score ('base' model). In the second model, we added to the 'base' model common medical conditions ('disease' model). We used C-index and calibration plots to assess model performance.

Why we are doing it: Hospital admissions for hypoglycaemia represent a significant burden on individuals with diabetes and have a substantial economic impact on healthcare systems. To date, no prognostic models have been developed to predict outcomes following admission for hypoglycaemia. We aimed to develop and validate prediction models to estimate risk of inpatient death, 24h-discharge and one month readmission in people admitted to hospital for hypoglycaemia.

What the benefits will be: We found that the two models had similar discrimination. In derivation samples, C-indices for the base and disease models, respectively, were: 0.77 and 0.78 for death, 0.57 and 0.57 for one month readmission, and 0.68 and 0.69 for 24h-discharge. Similar values were observed in validation samples. Calibration plots showed good agreement for the three outcomes. We developed a calculator of probabilities for inpatient death and 24h-discharge which can improve the quality of care through personalised approaches and optimise resource allocation.

Who are we working with: Nottingham University Hospitals & East Midlands Academic Health Science Network, Nottingham, UK.

Study lead: Francesco Zaccardi

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61 Risk factors and outcome differences in hypoglycaemia-related hospital admissions. A case-control study in England

What we are doing: We used all admissions for hypoglycaemia in people with diabetes to English NHS hospital trusts between 2005 and 2014 (101,475 case admissions) and three random admissions per case in people with diabetes without hypoglycaemia (304,425 control admissions). Risk factors and differences in the three outcomes hospital stay, mortality and readmission were estimated with logistic and negative binomial regressions.

Why we are doing it: Published studies have identified clinical, demographic, and socioeconomic factors associated with the risk of hypoglycaemia, although evidence available from large observational studies on the association of these factors with hospitalisation for hypoglycaemia in patients with diabetes is more limited. Moreover, evidence is also limited on differences in outcomes, such as length of hospital stay, inpatient death, and hospital readmission, comparing admissions for hypoglycaemia vs those for other causes in people with diabetes.

What the benefits will be: Compared to Caucasians, Bangladeshi, Pakistani, and Indians had lower and Caribbean higher risk of admission for hypoglycaemia. Hospitalisation was 26% shorter while risk of rehospitalisation 65% higher in people admitted for hypoglycaemia. Compared to admissions for hypoglycaemia, inpatient mortality was 50% lower for unstable angina but higher for AMI (3 times), acute renal failure (5), or pneumonia (8). This information could help recognise at-risk patients and guide the implementation of appropriate individual- and population-level strategies.

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Study lead: Francesco Zaccardi

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62 Global burden of hypoglycaemia mortality in 109 countries, 2000–2014: an analysis of death certificates

What we are doing: Using information on the underlying cause of death reported in death certificates, we aimed to comprehensively investigate the global burden, national differences, and temporal trends of deaths reporting hypoglycaemia as the underlying cause. We used WHO and United Nations data to compare, across countries and over time, proportions (defined as number of hypoglycaemia deaths divided by total diabetes deaths, i.e. the sum of hypoglycaemia and diabetes deaths) and rates (hypoglycaemia deaths divided by mid-year population) of hypoglycaemia-related mortality.

Why we are doing it: Severe hypoglycaemia can result in short-term complications, including injuries, car accidents, and fatal cardiovascular events due to an increased risk of arrhythmias, particularly in elderly patients and in those at high risk or with

a history of cardiovascular disease. Large observational studies have reported increasing trends of severe hypoglycaemia in the USA, Canada, England, and Japan possibly related to the rising prevalence of diabetes in older people; yet, the global burden of hypoglycaemia mortality is unknown.

What the benefits will be: We observed that most South American, Central American, and Caribbean countries had the highest proportions of diabetes deaths attributable to hypoglycaemia and rates of hypoglycaemia deaths, with rising trends between 2000 and 2014 in Brazil, Chile, the USA, Argentina, and Japan. While country-level, socio-economic determinants should be first addressed in middle-income countries, a strategy focusing on individual patients could be the priority in high-income countries.

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63 Comparison of glucose-lowering agents following dual therapy failure in type 2 diabetes. Systematic review and network meta-analysis of randomised controlled trials

What we are doing: We electronically searched, from Jan 1, 2000 to July 9, 2017, randomised controlled trials (RCTs) of 24 to 52 weeks duration and reporting data on cardiometabolic and hypoglycaemia (all episodes) outcomes for glucose-lowering agents added to metformin-based dual treatments in patients with inadequately controlled glucose levels. Data were synthesised with network meta-analyses.

Why we are doing it: Current guidelines for the management of hyperglycaemia in type 2 diabetes increasingly recommend pragmatic choice of a third glucose-lowering agent once individualised glycosylated haemoglobin thresholds are exceeded with a combination of two drugs ("dual failure"). We aimed to assess the evidence supporting the choice of third-line agents in adults with type 2 diabetes.

What the benefits will be: 70% of published RCTs examined third-line agents when added to the combination of metformin and sulphonylurea or thiazolidinedione; the evidence for other third agents is much more limited and far less clear. Third-line agents are not equally effective when added to metformin and sulphonylurea or thiazolidinedione as SGLT-2i are associated with a better glucometabolic control compared to other options. In suggesting third-line agents, future guidelines should recognise the widely different evidence across possible dual failures.

Study lead: Francesco Zaccardi

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64 Association of walking pace and handgrip strength with all-cause, cardiovascular, and cancer mortality: a UK Biobank observational study

What we are doing: We aimed to quantify the associations of self-reported walking pace and handgrip strength with all-cause, cardiovascular, and cancer mortality in men and women from UK Biobank and to investigate whether associations are maintained across categories of age, BMI, and smoking status.

Why we are doing it: Physical fitness, composed of cardiorespiratory fitness and muscle strength, is an important predictor of mortality and an established target for cardiovascular disease prevention. Cardiorespiratory fitness has shown a strong graded association with the risk of all-cause and cardiovascular mortality and is advocated as a clinical vital sign with importance for risk classification. Therefore, pragmatic methods of harnessing cardiorespiratory fitness for risk stratification are warranted.

What the benefits will be: In this study we found that a slow self-reported walking pace was associated with a higher risk of all-cause and cardiovascular mortality in women and men with associations remaining robust across multiple layers of adjustment. Associations were stronger in those with low BMI. Self-reported walking pace could therefore represent an important measure of physical fitness with potential applicability for risk stratification within the general population, particularly those presenting with low BMI.

Who are we working with: Glasgow University; Lund University; Umea University

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65 Barriers to Uptake of (type 1) Diabetes Education (BUDiE)

What we are doing: We seek to understand and address reasons for non-attendance at therapeutic education empowering people with type 1 diabetes (T1D) to self-manage their long-term condition. We studied local adults with, or providing care for people with, T1D:

- Comparing attenders with non-attenders using an NHS service-use database.
- Surveying adults with T1D and conducting semi-structured interviews and a provider survey.
- Focus groups.

Analysis included exploratory regression models, thematic analysis of interviews, and quantifying data using a mixed methods matrix.

Why we are doing it: Outcomes of type 1 diabetes remain suboptimal. High-quality structured education courses run by the NHS have proven benefit in terms of diabetes control, reduced emergency access, improved mental state and quality of life but uptake is low. If we can understand reasons for poor attendance, we can seek to adjust provision of courses to address barriers and improve outcomes, using T1D as an exemplar for other long term conditions.

What the benefits will be: If successful, the SOUL-D follow-up study will i) demonstrate that simple blood tests of inflammation can provide valuable prognostic information for both physical- and mental health at diagnosis of type 2 diabetes; and ii) provide support for the use of targeted anti-inflammatory treatments to improve both depression and diabetes outcomes in the growing population with depression and type 2 diabetes.

Who are we working with: We have worked with people with type 1 diabetes living in S London; the community based Diabetes Eye Complications Screening service; health care professionals in primary and secondary care; IT providers within the NHS and commissioners.

Study lead: Stephanie A Amiel; Henrietta Mulnier, Sophie Harris

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66 The South London Diabetes (SOUL-D) Follow-up Study: Testing the long-term effects of elevated inflammation on mental- and physical health in people with type 2 diabetes

What we are doing: The South London Diabetes (SOUL-D) cohort was a unique group of 1735 people (55% male; 60% were asymptomatic at diagnosis and 51%, 38% and 11% were of white, black and South Asian/other Ethnicity respectively), recruited at diagnosis of type 2 diabetes from 2008-2012. The SOUL-D follow-up study will now test whether people with elevated inflammation at diagnosis of type 2 diabetes experience long-term mental ill-health (depression, cognitive decline) and physical ill-health (diabetes complications, blood sugar control, premature death).

Why we are doing it: Depression affects 20% of people with type 2 diabetes and predicts increased risk of dementia, diabetes complications and premature death. However, the reasons for this are poorly understood. In the original SOUL-D study, we demonstrated that people with depression had higher levels of inflammation (measured using blood tests) than those without depression. This suggests that inflammation may provide a common link between depression and type 2 diabetes, and moreover could be a target for potential treatments.

What the benefits will be: If successful, the SOUL-D follow-up study will i) demonstrate that simple blood tests of inflammation can provide valuable prognostic information for both physical- and mental health at diagnosis of type 2 diabetes; and ii) provide support for the use of targeted anti-inflammatory treatments to improve both depression and diabetes outcomes in the growing population with depression and type 2 diabetes.

Who are we working with: We will be working with people with diabetes in south London from the original SOUL-D cohort, who were originally recruited collaboratively with 96 GP surgeries in Lambeth, Southwark, Lewisham and Bromley. We will be reviewing medical records from the whole cohort to assess outcomes at 10 years and therapies used to achieve these, while recruiting 400 of the original SOUL-D cohort for detailed in-person assessment.

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67 Approaches to early prevention of type 2 diabetes in children of South Asian and African origin

What we are doing: High type 2 diabetes risks among UK South Asians and Africans origins are already emerging in childhood.

This research is investigating approaches to early prevention of type 2 diabetes. One approach has examined the scope for improving childhood body fatness assessment. Simple BMI adjustments for South Asian and African children provide adjusted BMI values which relate to total body fatness as in European children. A second approach is identifying nutritional approaches to reducing emerging type 2 diabetes risk in children.

Why we are doing it: Type 2 diabetes is a major challenge among UK South Asians and Africans; the onset of the condition is markedly earlier in these ethnic minority groups and is preceded by increased insulin resistance in childhood. The need for effective prevention is paramount, though causes of the higher risks are poorly understood. Excessive body fatness is an important determinant of type 2 diabetes risk; steps to facilitate overweight-obesity prevention in ethnic minority groups are potentially critical.

What the benefits will be: Effective strategies for the early prevention of emerging type 2 diabetes risks, particularly in ethnic minority groups, could substantially reduce the high long-term type 2 diabetes risk in UK ethnic minority populations.

Who are we working with: We are currently working with childhood obesity experts (UCL, LSHTM, CLAHRC North London), Public Health England and the National Child Measurement Programme. Our nutritional studies involve collaborators at the Universities of Oxford and Newcastle and primary schools and pupils across the London Borough of Wandsworth.

Study lead: Peter Whincup

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68 Development of a meal replacement programme to offer in primary care for weight management

What we are doing: We have analysed evidence for the effectiveness of meal replacements as weight loss aids. We have estimated the weight people lose in 12 months after encouragement to use meal replacements, relative to other ways of losing weight to identify factors associated with successful weight loss using meal replacements. Drawing on experience of providing weight management advice in primary care to develop a programme that healthcare professionals, such as GPs or practice nurses could recommend for people to follow at home.

Why we are doing it: Excess weight is a major contributor to morbidity and premature mortality. Modest weight loss brings significant clinical benefits but there is a pressing need to identify effective interventions to be delivered at scale and within the capacity of the NHS workforce. Solutions promoting active self-management are an attractive option. Meal replacements intended to aid self-directed weight loss are widely available in community

outlets and have been shown to be effective but little is known about their effectiveness in routine practice.

What the benefits will be: Overweight, obesity, and associated comorbidities, place a significant strain on the NHS patients living with these conditions. Identifying effective ways to tackle obesity at the population level has potential to free up NHS time and budget, and improve the quality of life of patients. Currently there are a limited number of evidence based weight management strategies to offer patients in primary care. Understanding and developing evidence-based interventions encouraging and supporting active self-management would reduce the pressure on the NHS.

Who are we working with: The study is funded by the National Institute for Health Research Collaborations for Applied Health Research and Care at Oxford (NIHR CLAHRC) in collaboration with Nuffield Department of Primary Care Health Sciences

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Notes:

The National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care East Midlands (CLAHRC EM) is a partnership between Nottinghamshire Healthcare NHS Foundation Trust and the Universities of Nottingham and Leicester.

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