



*National Institute for
Health Research*

**NIHR Collaboration for
Leadership in Applied Health
Research and Care
West Midlands (CLAHRC WM)**

**Second Annual Report
April 2015 – March 2016**



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Welcome



Welcome from Prof Richard Lilford

Director of the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care West Midlands (CLAHRC WM); Chair in Public Health, University of Warwick.

People sometimes ask me “*what is so special about the CLAHRC?*” The point about the CLAHRC is that it opens up research opportunities in a way that no other organisation can. This is because the CLAHRC is as thoroughly embedded in the local service as a life scientist is in the laboratory. Before you can apply to be a CLAHRC you have to demonstrate that the local services want to collaborate with you, and they have to commit at least £10m of matched funds over the five-year lifespan of a CLAHRC. This means the money used to improve the services is linked to the research money, which can contribute to the design and evaluation of service innovations. So it was that we evaluated, for example, a commissioning package to improve rates of home haemodialysis in the region. We showed that the West Midlands rose from the bottom to the top of the table for home haemodialysis rates; that this was largely due to the commissioning incentive; and demonstrated barriers to further improvement.

This example also illustrates one of the main challenges for modern services – to work efficiently across organisational boundaries. These days, episodes of care are seldom managed as a single episode; care is ongoing across many boundaries – hospital and primary care, primary care and community nursing, community nursing and social services, to name just a few. Creating services that work effectively across these barriers and providing the right skill mix are key to managing chronic diseases, such as severe mental illness, diabetes, Parkinson’s disease, and the increasing numbers of people who suffer from multiple diseases.

I am proud to present this report of our achievements over the past year. We are using this opportunity to make real improvements in the service, to prevent waste, and to generate new knowledge. Our papers appear in top journals, such as the Lancet and the Journal of the American Medical Association, and we have an excellent track record of bringing in money from blue chip resources, such as the NIHR and research councils. I am also pleased that we have been able to export our model of evaluation to low- and middle-income countries, particularly in Africa, where our work includes the role of community health workers, promotion of breastfeeding, and the health of people who live in poor and informal settlements or slums. We have shown that being responsive to local needs and producing high-quality research are not in opposition to one other.

CLAHRC WM in Numbers

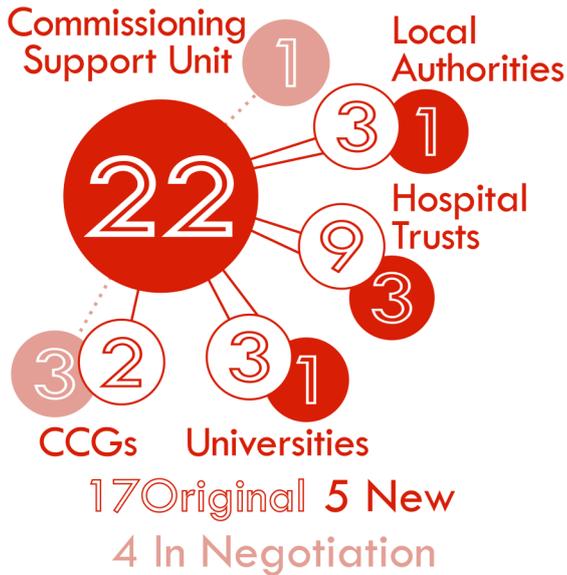
4 Service Themes

- Maternity & Child Health (1)
- Youth Mental Health (2)
- Prevention & Detection of Diseases (3)
- Chronic Diseases (4)

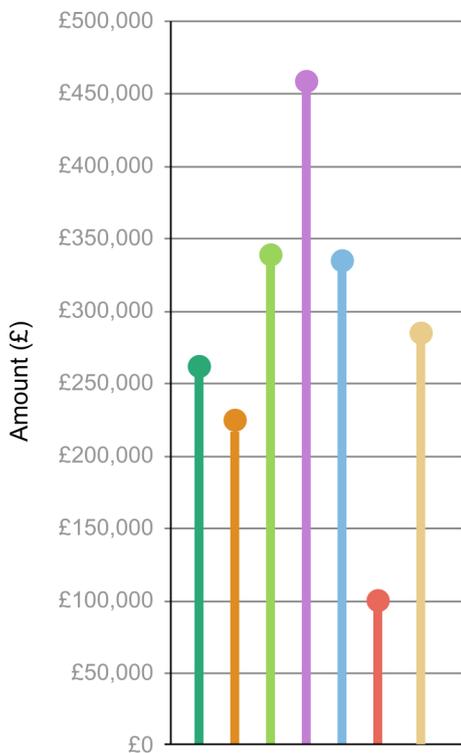
2 Cross-Cutting Themes

- Implementation & Organisational Studies (5)
- Research Methods (6)
- Other**
 - Legacy and CLAHRC-BBC Pilot
 - Central CLAHRC team

Partners

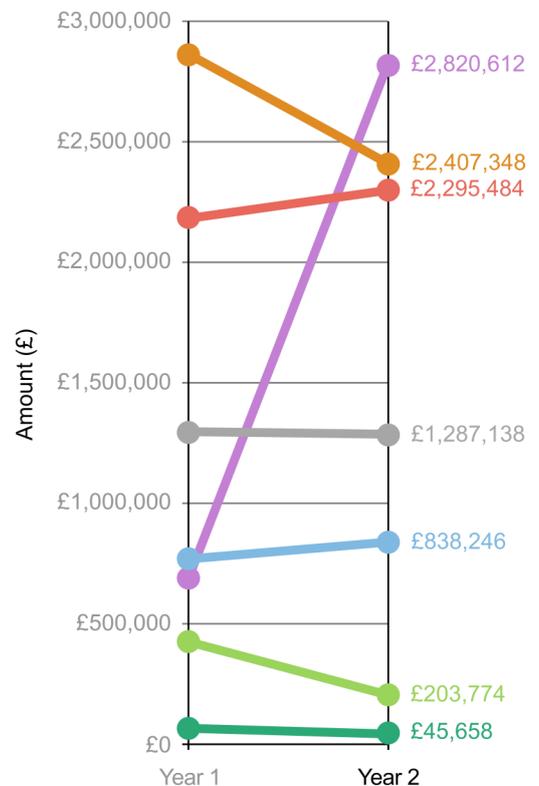


Staff



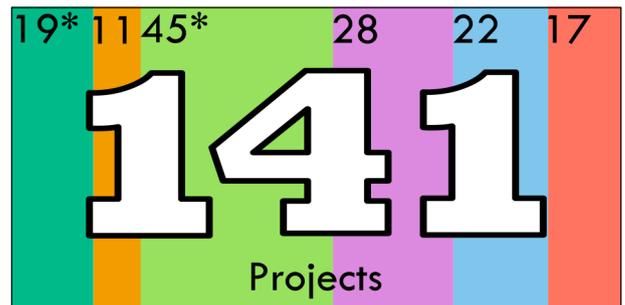
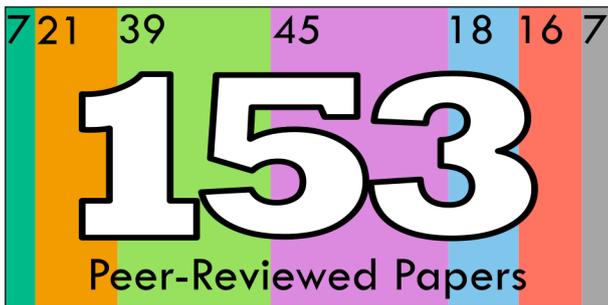
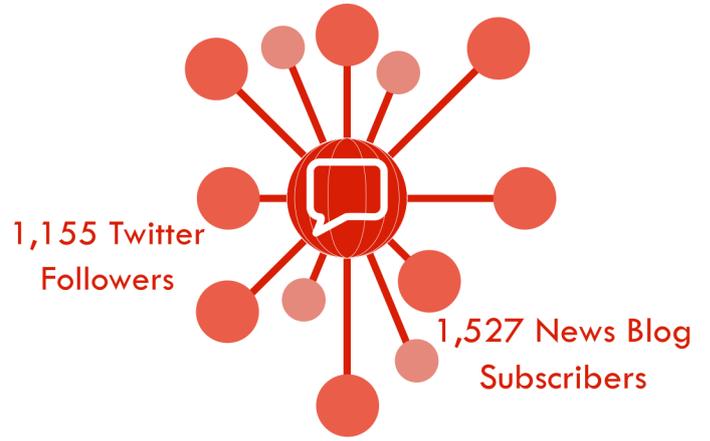
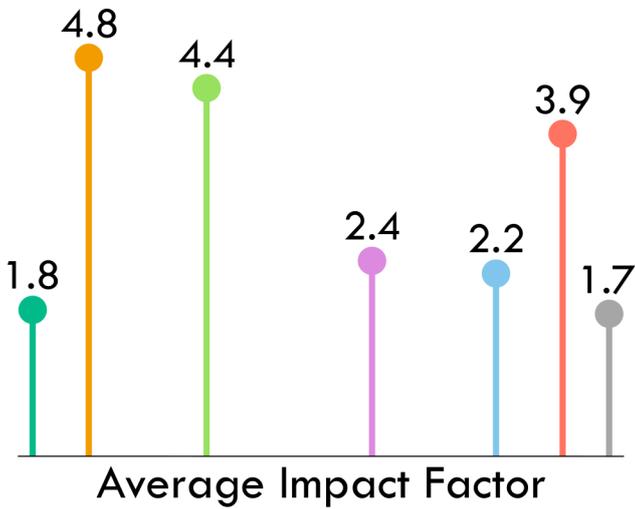
Expenditure

£2,000,063

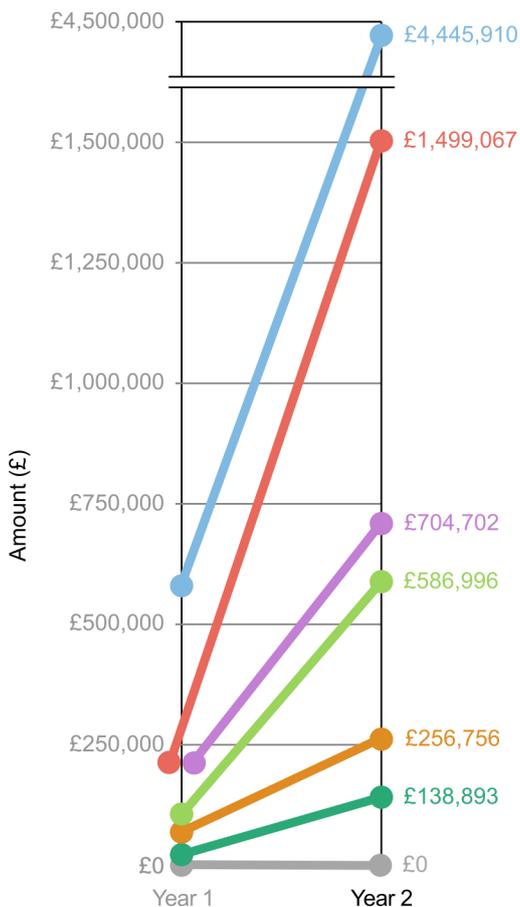


External Funding

£9,898,260

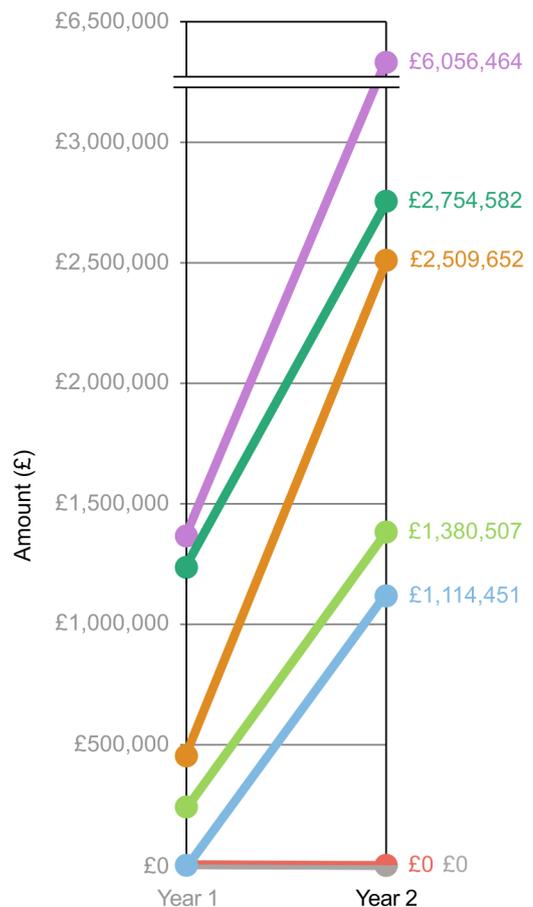


(*1 project is under both themes)



Matched Funding (Research)

£7,632,323

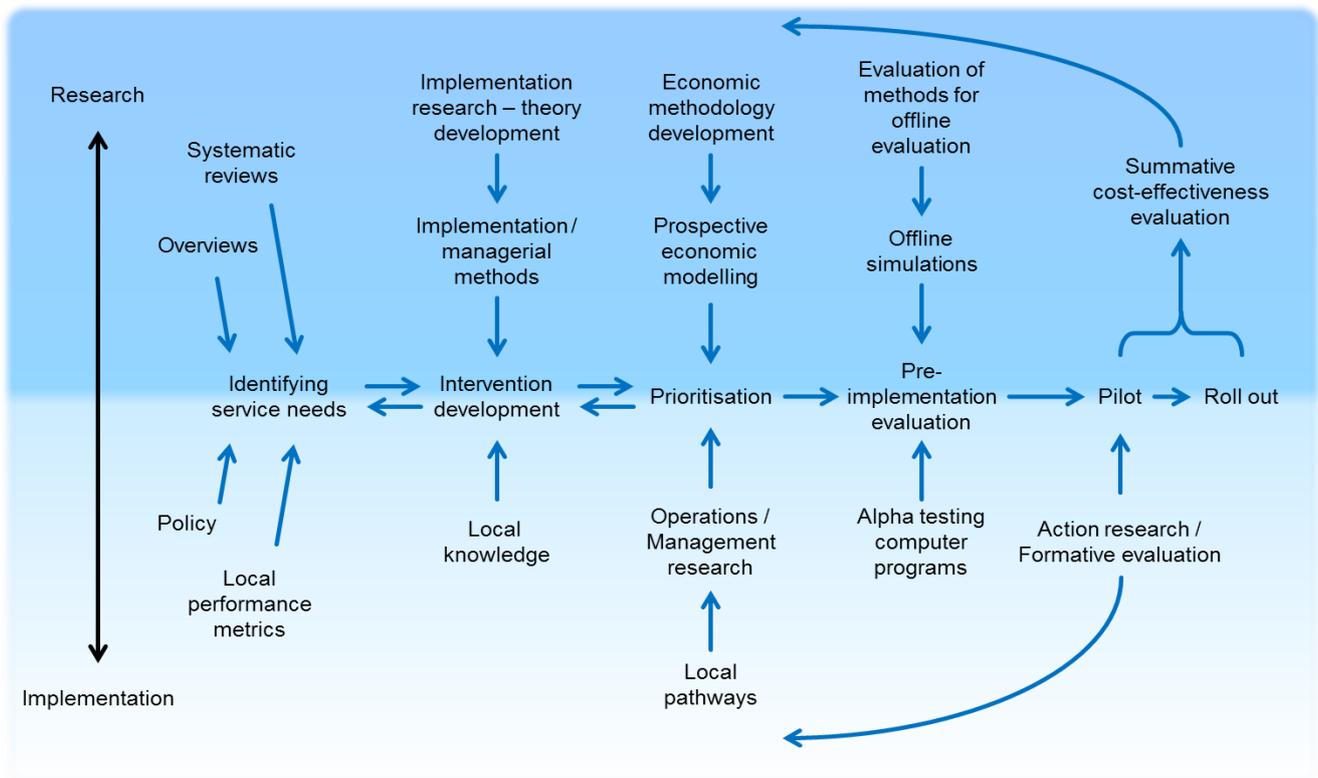


Matched Funding (Implementation)

£13,815,656

Overview of Activities

The short-, medium- and long-term objectives of CLAHRC West Midlands are implicit and described through the lens of the IDEaL framework. This sets out our core principles to **Identify, Develop, Evaluate and Lead** service delivery research in collaboration with partner organisations.



The IDEaL Framework

Short-term objectives: to identify and develop projects

- We have identified the knowledge needs of services through local engagement informed by systematic reviews and policy analyses to develop a number of feasibility and/or pilot studies.
- Our inputs have been pivotal to the development of the service intervention in a number of projects, using co-production approaches.
- We have been asked to evaluate pre-developed interventions *in vitro* for a number of projects. For example, a text-based weight management system (pages 26-27).

There are many exemplary projects that demonstrate we are achieving these short-term objectives. For example, the Place of Birth study led by the **Maternity and Child Health theme (1)** arose from a service knowledge gap. A supporting systematic review has been published, and a service intervention developed in co-production with midwives in one trust will now be rolled out to other trusts in the region and evaluated (pages 14-15).

Medium-term objectives: to evaluate

- We are conducting a number of local feasibility or pilot studies to test service interventions.
- We feedback to partner organisations in order to refine the intervention and inform local decision-making.
- It is envisaged that results from feasibility and pilot studies will inform national implementation and evaluation studies, supported by further research grants in the longer term.

The ENHANCE study, led by the **Chronic Diseases theme (4)**, demonstrates that we are

achieving this objective (see our 1st annual report). This study exemplifies the stages of the IDEaL model, encompassing: i) development of service intervention in co-production with patients/staff following evidence synthesis and a service need to integrate care for people with osteoarthritis pain, anxiety and depression; ii) development of a training package to deliver the intervention, simulated with patients/staff; and iii) piloting a step-wedge trial to evaluate and refine the intervention. Analysis of the pilot study is underway, which will inform the full trial that we anticipate will be supported by further research grant income.

Long-term objectives: to lead

- In order to lead service delivery research, we are building a community knowledgeable in applied health research, where academic/service/patient collaborations become the usual way of working.
- We are developing and supporting both our service-based community and academic-based faculty to understand research and apply this knowledge to practice. Highlights include developing and maintaining a '*research midwives forum*' (page 16) and supporting faculty in academic endeavours (pages 11, 50-51).

In addition to the formal objectives listed above, we have esoteric ambitions to deliver substantial high-quality academic outputs leading to changes in policy and/or practice at service-level. We are realising this overarching mission and report academic output as one of our three top achievements this year (pages 8-9). Furthermore, we can report major service impact on:

- The management of people with low back pain through the regional and national implementation of the STarT Back tool (pages 32-33).
- Youth mental health, as the new 0-25 years service for Birmingham went live on 1 April 2016, delivered by Forward Thinking Birmingham. Other CLAHRCs are instigating similar service redesigns akin to our model (page 19).
- National screening policy, demonstrated by the decision of the National Screening Committee to introduce a non-invasive prenatal test for Down's syndrome in pregnancy (pages 22-23).

We have strengthened leadership through the appointment of a third Deputy Director, Prof Christian Mallen (Keele University). The Director and Deputies now represent the main University partners – Warwick Medical School (Director, Prof Richard Lilford), Warwick Business School (Prof Graeme Currie), the University of Birmingham (Prof Tom Marshall) and Keele University (Prof Christian Mallen).

We have developed an **industry engagement strategy** in close collaboration with our stakeholders, to reinforce and align to existing regional strategies developed by West Midlands Academic Health Science Network (WM AHSN) and supported through the Birmingham Institute of Translational Medicine. We continue to collaborate with other parts of the NIHR infrastructure, mainly with other national CLAHRC initiatives and locally through the West Midlands Clinical Research Network (WM CRN). In response to the '*NIHR at 10*' media campaign, we have established a regional NIHR communications group, continue to support the regional Patient and Public Involvement group (PPI), and promote opportunities to collaborate in training and other related research and implementation activities. Our work will feature in a national '*NIHR at 10*' document, highlighting initiatives from all 13 CLAHRCs.



University of Warwick, University of Birmingham, Keele University

We continue to deliver our strategy to develop capacity for service delivery research in academia, the health service, and among patients and the wider public. Highlights include a programme of support for **Leadership Fellows (LFs)** who are embedded in our partner organisations and are engaged in research and implementation activity. We have focused some provision to support local authority staff, as we have a growing suite of collaborative projects in the field of public health (pages 28-29). Furthermore, we continue to strengthen our training environment through multidisciplinary teams, utilising expertise from a number of West Midlands universities to provide both structured and peer-to-peer support for early career researchers and those involved in service delivery (pages 50-51).

Top achievements:

1. NHS engagement and system for monitoring matched funding: We have strengthened our engagement capability through a senior appointment, seconded from our host trust, University Hospitals Birmingham NHS Foundation Trust (UHBFT). This has enabled us to work more closely with existing partners and to develop new partners. A further Higher Education Institute (HEI), Newman University Birmingham, will join the collaboration shortly, contributing research matched funding to support postgraduate students supervised by our **Youth Mental Health theme (2)**. We held our inaugural matched funders forum in June 2015, which was well attended by partners, and are hosting a second forum in June 2016, embedded within our international Scientific Advisory Group (pages 40-41). We have also developed a sophisticated system to monitor and audit matched funding commitments to provide reassurance to our partners and governance committees.

2. Systematic review capacity: Our **Prevention and Detection of Diseases theme (3)** has developed a large capacity for conducting high-quality systematic reviews (pages 24-25). Many of these have been published in the Cochrane Database of Systematic Reviews, recognised as publishing papers with the highest standard in evidence-based healthcare. During the reporting year the team have published 12 reviews in the journal, along with a further four review protocols.

The theme has also established a strong relationship with the National Screening Committee (NSC), part of Public Health England, and this has allowed the expansion of research priorities and maximised opportunities for impact on national policy and practice. Work completed for the NSC has translated into a change in screening policy and practice for prenatal screening for Down's syndrome, as mentioned above (pages 22-23).

3. Academic outputs: We have published 153 peer review papers during the second reporting year (141 during the first year) with a further 18 published or accepted for publication since 1 April 2016, including one in JAMA and one in the Lancet. This includes 22 papers published in journals with an impact factor of at least 6, and a further seven papers published in management journals rated 4* by the Chartered Association of Business Schools (ABS). We have secured a *total grant income* of £60,190,156 to date, of which £12,932,875 is 'new income' from successful grants obtained within the reporting year. This represents an *in-year award* of £9,898,260. CLAHRC WM is supporting 84 PhD students. Ten students have completed their studies successfully, while we welcomed 17 new students this reporting year. We support a further number of NIHR fellowship faculty and NIHR training advocates. Regional collaboration across a number of HEIs has provided a highly productive and successful environment to deliver academic excellence (pages 50-51).

Forward Look:

We will continue to deliver and progress our NHS engagement activity and refine the system to monitor matched funding activity centrally. We plan to discuss sustainability and future collaboration with partner health and social care organisations at our upcoming Matched Funders Forum. We are maximising opportunities for industry engagement through the delivery of our industry engagement strategy and in collaboration with existing regional structures.

We will continue to lead the regional NIHR Communications group, formed in response to the national '*NIHR at 10*' media campaign and are planning a document to showcase the impact of collaborative work funded or supported by the NIHR in the West Midlands.

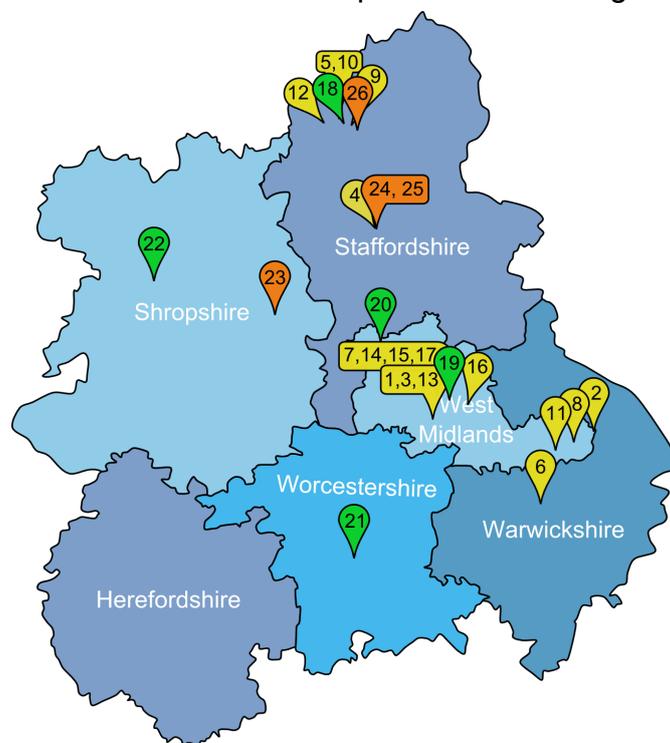
We will continue to host training events and workshops to build the research capacity of our partner organisations.

We are also supporting a number of collaborative events, including one with the NSC to focus on Health Screening, and one with the NIHR School for Public Health Research for local authority staff to understand why and how to evaluate. We are also disseminating our work at a number of key events, including at Prato, Italy as a key collaborator in the Monash Warwick Alliance, Health Services Research UK Symposium, the Society for Academic Primary Care conference, and the Society for Social Medicine Annual Scientific Meeting.

A full list of current projects is available in a supplementary document at: <http://goo.gl/IAVWT7>

Partner Organisations

We continue to grow, incorporating five further organisations through our 'deed of adherence' governance process, bringing our number of formal partners to 22, from the 17 originally detailed in our bid. We are also in negotiation with four further organisations. This adds depth to our coverage within the West Midlands area and indicates our reputation and strength of engagement.



- | | |
|---|--|
| 1. University Hospitals Birmingham NHS Foundation Trust | 14. Birmingham Children's Hospital NHS Foundation Trust |
| 2. University Hospitals Coventry & Warwickshire NHS Trust | 15. Birmingham and Solihull Mental Health NHS Foundation Trust |
| 3. Birmingham Women's NHS Foundation Trust | 16. Heart of England NHS Foundation Trust |
| 4. South Staffordshire & Shropshire Healthcare NHS Foundation Trust | 17. Sandwell and West Birmingham Hospitals NHS Trust |
| 5. Staffordshire & Stoke-on-Trent Partnership NHS Trust | New Partners: |
| 6. Warwickshire County Council | 18. University Hospitals of North Midlands NHS Trust |
| 7. Birmingham City Council | 19. Aston University |
| 8. Coventry City Council | 20. The Royal Wolverhampton NHS Trust |
| 9. Stoke-on-Trent Clinical Commissioning Group (CCG) | 21. Worcestershire County Council |
| 10. North Staffordshire CCG | 22. Shrewsbury & Telford Hospital NHS Trust |
| 11. University of Warwick | In Negotiation: |
| 12. Keele University | 23. Telford & Wrekin CCG |
| 13. University of Birmingham | 24. Cannock Chase CCG |
| | 25. Stafford & Surrounds CCG |
| | 26. Midlands and Lancashire Commissioning Support Unit |

Matched Funding

The main development for matched funding has been through the appointment of the Head of Programme Delivery (Engagement) to focus on NHS, AHSN and industry engagement. One of the key undertakings from this has been to catalogue and increase the cohort size of our Leadership Fellows (LFs) – key individuals in our NHS partners who are engaged in service delivery and act as knowledge brokers to translate CLAHRC WM research into practice. We provide high-quality workshops to support them with involvement from academia and the wider NHS and NIHR infrastructure. We also run events to encourage involvement in research (we ran a ‘Big Data’ contest in conjunction with a partner Trust) which cover both applied health research and implementation.

One of the challenges with matched funding is that it is a relatively intangible concept so we have compiled a database of our LFs to ensure we can precisely account for all of our matched funding. This allows us to report on our progress with confidence, to target information at specific professional groups or hospital sites, and provides a living legacy for a future CLAHRC in the region. This database includes 293 LFs, and the details of 673 attendances at various engagement sessions, amounting to a projected matched funding income of £21,516,239 over the lifespan of the CLAHRC WM. One of the main successes of the project has been to recruit the Annex U programme at one of our main partners (UHBFT) to the LF programme. These are 20 graduate management trainees who are studying Masters degrees Healthcare-related subjects and offers us an opportunity to ensure that the next generation of senior managers within the NHS in the region have a solid grounding in applied health research and implementation. As part of this novel agreement, some students will be completing their MSc dissertations on CLAHRC WM projects, giving them first-hand experience of working with leading academics and researchers (pages 50-51).

Alongside these overall developments we also have a wide range of examples of our LFs working to implement NIHR CLAHRC WM research, including the Birmingham Symptom specific Obstetric Triage System (BSOTS) (page 12); the redesign of youth mental health services in Birmingham to cover the 0-25 age range (page 19); STarT Back (pages 32-33); the implementation and evaluation of the HECTOR project and Supported Integrated Discharge (page 30), and evaluation of end of life renal care (page 30).

We have also secured additional academic matched funding through the Warwick-Monash Alliance, bringing together experts in healthcare from Warwick Business School and Monash University in Melbourne (pages 34-35); a new partnership with Aston University to provide support to the evaluation of the implementation of electronic prescribing at Birmingham Children’s Hospital under the **Maternity and Child Health theme (1)**; and a new collaboration with Newman University Birmingham which sees additional PhD students joining the **Youth Mental Health theme (2)** to evaluate their work on eating disorders and anti-bullying programmes within schools.

1. Maternity and child health

Theme Lead: Prof Christine MacArthur, University of Birmingham
c.macarthur@bham.ac.uk

Leadership: Dr Sara Kenyon (maternity lead) has recently been appointed as an NIHR Midwifery Training Advocate and continues to lead capacity development for this specialist group (page 16).

Strategy & New Activity Initiated: In response to the knowledge needs of the service, a number of new projects are being developed, including fathers' perspective of home birth as little is currently known about their views and midwives have identified that fathers can be a barrier to home birth.

Major Grants Awarded: **High Or Low Dose Syntocinon** for delay in labour (HOLDS) (£1.8m funded by NIHR HTA); **Antenatal Prophylactic Pelvic floor Exercises And Localisation** (APPEAL) (£1.8m funded by NIHR Programme Grant for Applied Health Research, in collaboration with CLAHRC South West Peninsula, CLAHRC East Midlands and CLAHRC South London).

Research Highlights: A number of papers have recently been published, including:

- Systematic review examining evidence regarding the discussions between midwives and women about their options for where to give birth.^[3]
- Systematic review protocol to examine the effect of early postnatal discharge from hospital on women and infants.^[4]
- Study protocol to evaluate implementation of an e-prescribing system in a paediatric ward.^[1]
- An RCT evaluating lay support for pregnant women with high social risk (pages 14-15).^[5]

Maternity researchers have also developed and tested a tool to allow rapid analysis of qualitative data during the evaluation of home birth service.

Implementation Highlights: The **Birmingham Symptom specific Triage System** (BSOTS), developed and piloted at Birmingham Women's NHS Foundation Trust (BWNFT), is being implemented at three further maternity units in the West Midlands (University Hospitals North Midlands, New Cross Wolverhampton and Shrewsbury & Telford Hospital NHS Trust) and will be evaluated by this theme. It has involved a group of 15 key LFs leading the implementation and evaluation within a much wider team of midwives. Other maternity sites across the country may be interested in adopting the system and the results from the regional implementation could be used to inform a national study of this type. Study lead, Dr Kenyon, recently completed a secondment at the University of Melbourne, Australia and collaborators were extremely enthusiastic about the system and are interested in implementing it in their own maternity units (pages 42-43).



Place Of Birth (POB) intervention package, developed in co-production with midwives at BWNFT, will be rolled out to other maternity trusts in the region. The intervention has been designed to improve the discussions that midwives have with women about their options for where to give birth. It is due to be incorporated into the commissioning contracts across two trusts in the region during 2016/17 and will be evaluated by the theme (pages 14-

15).



Examples of Impacts on Health & Wealth:

Sites implementing BSOTS have signed licence agreements to protect the IP of the system.

Dr Kenyon has established a *Midwives Research Forum* – it is envisaged that this may lead to improved recruitment to trials and improve understanding about evidence from maternity research studies conducted in the region and nationally (page 16).

Progress, Achievements and Challenges Against Objectives:

Short-term objectives: i) to carry-out feasibility study of BSOTS; ii) to examine effects of early hospital discharge; iii) to evaluate e-prescribing system. These have all been realised, as above. In addition, we have progressed in assessing the implementation of advance care plans for children through the evaluation of 'Magnolia House', a new space/palliative service created by the Birmingham Children's Hospital (pages 48-49).

Medium-term objectives: to undertake evaluation of funder innovation. This has been delivered through a number of studies, including i) evaluation of home birth service – findings have been fed back to the trust and an action plan developed; ii) place of birth discussions in maternity services – package developed and being implemented across the region (pages 14-15); iii) development of a tool for rapid analysis of qualitative data – as above. The objective to set-up networks for collaborative working is being achieved through the *Research Midwives Forum* (page 16), while we also have links with Monash and Melbourne universities in Australia.

Long-term objectives: to disseminate work is being achieved through a number of avenues, such as academic papers, forum meetings, and dissemination events, including one held with the National Childbirth Trust in collaboration with other CLAHRCs and universities.

Additional objectives: adopted by the theme include: i) a study to explore educational needs of parents to enable them to support young people's transition to adult care; ii) development of a parenting intervention for parents and children experiencing life-changing admissions to hospital.

Links with NIHR Infrastructure: We have worked with the West Midlands Clinical Research Network (WM CRN) to create a *Research Midwives Forum*. We have also consulted the Young People's Advisory Group, based at Birmingham Children's Hospital on their priorities and perspectives on mental health and the wellbeing of children and young people with chronic conditions.

We are collaborating with CLAHRC Oxford on the POPS 2 study looking at weight management in pregnancy. We are currently liaising with CLAHRC NWL to explore opportunities for collaborative projects to improve maternity and obstetric services.

Case Study: Impact on Maternity Services in the West Midlands

ELSIPS – Evaluation of Lay Support in Pregnant Women with Social Risk

A Pregnancy Outreach worker (POW) service for first-time mothers (over the age of 16, less than 28 weeks pregnant) with identified social risk factors was evaluated by a randomised trial with the aim of improving engagement with maternity services, such as antenatal care (and thus birth outcomes), and reducing postnatal depression (as measured on the Edinburgh Postnatal Depression Scale [EPDS]). The trial recruited 1,324 first-time mothers from three maternity trusts in Birmingham (16 community midwifery teams), who were randomly allocated to standard care or the addition of referral to the POW service. POWs were integrated into the community midwifery teams and were trained to provide individual case management and support. Their objectives were to encourage women to attend antenatal appointments, make healthy lifestyle choices, provide social/emotional support, and help ensure benefits. They also provided postnatal advice on breastfeeding and infant care.

The study^[5] found that the mean EPDS for women with two or more social risk factors was significantly improved with the addition of the POW service, although there was no overall difference between groups. There was no difference in the number of antenatal attendances between groups; while mother-to-infant bonding was improved for all women.

The evidence from this trial strengthens existing evidence, and demonstrates the overall benefit of lay interventions in preventing postnatal depression. This is important given the known effect of maternal depression on longer term childhood outcomes. The POW service continues to operate alongside other health and social care services in Birmingham to support pregnant women and to reduce factors that can cause infant mortality.

The trial and the researchers were originally funded by the pilot CLAHRC for Birmingham and Black Country, and continues to be funded by CLAHRC WM. The POW service was originally commissioned by Heart of Birmingham PCT and continues to be delivered by Gateway Family Services.

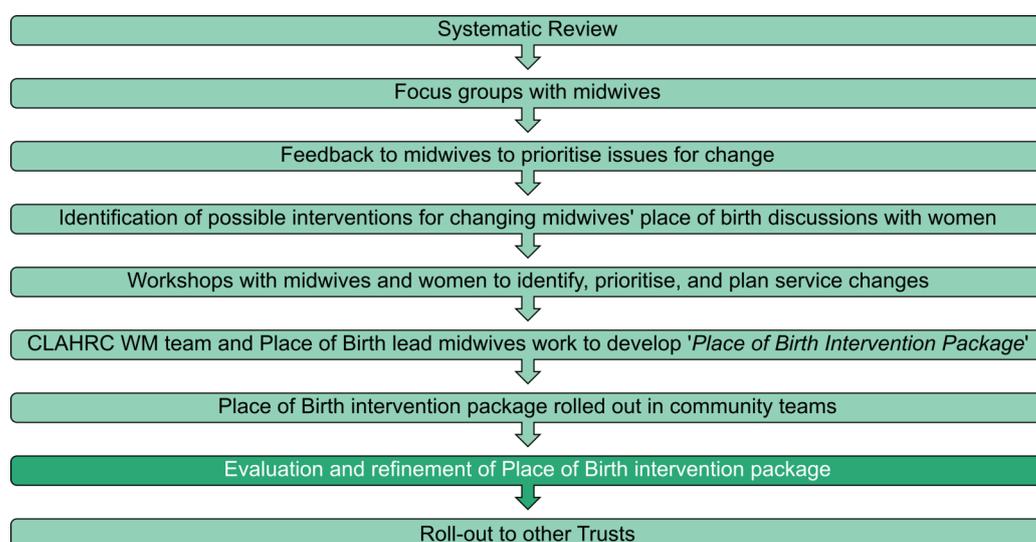
Translation of evidence on safety of Place of Birth (PoB) setting to local practice

This project exemplifies the stages of the IDEaL model – a knowledge gap was identified, a service intervention was developed through coproduction with midwives, and it was then evaluated.

Following a formative evaluation in one trust, the intervention will be introduced into other

maternity settings in the region and evaluated by the **Maternity and Child Health theme (1)**.

Evidence from the Birthplace Study showed that for low-risk women who had already given birth to more than one child (multiparous), there was no significant difference in the composite



perinatal outcome between those who gave birth in obstetric units, alongside or in freestanding midwifery units, or at home (*BMJ. 2011;343:d7400*). For women who had not previously given birth (nulliparous) there was an increase in adverse perinatal outcomes associated with birth at home, although the absolute risk remained low (9 per 1,000 births at home, compared to 5 per 1,000 in other settings). The researchers also observed fewer maternal interventions in women giving birth in midwife-led settings and low transfer rates for both multiparous (9-13%) and nulliparous (36-45%) women. This was used to inform NICE guidelines on care during childbirth for healthy women and babies [GC190], which recommended that women are given information and advice about all available birth settings so that they can make a fully-informed decision (*NICE. Intrapartum Care: care of healthy women and their babies during childbirth. 2014*).

Despite these recommendations, our research, together with existing literature, suggests that:

- Many women consider hospital birth the “default option”.
- Recent history and social norms are strong influences on women choosing hospital birth.
- The medicalised presentation of childbirth in the media influences women’s perspectives.

Our researchers are continuing to explore and support the translation of evidence from the Place of Birth study, and the resulting NICE guidelines on intrapartum care, into local practice. Since 2015, the team have been working with Birmingham Women’s NHS Foundation Trust (BWNFT) to support their objective to increase homebirth rates from 1 to 3% over three years, through a dedicated homebirth team. The homebirth team was established in 2014 and identified early on that community midwives are key to the discussion about low-risk women’s options to give birth. We are aiming to standardise these discussions. As a result of the co-production between BWNFT and CLAHRC WM it has been agreed that all low-risk women should be given a certain minimum level of information about their birth place options, and discussion should take place at the 16-week appointment with information about safety, intervention, and transfer rates related to each option. Further discussion would continue as the pregnancy progresses. A ‘place of birth intervention package’ has been developed and will be implemented by the trusts and evaluated by CLAHRC researchers. This will consist of:

- A PoB Update Session, consisting of information on safety and practicalities of giving birth in different settings.
- A PoB Script to support midwives when explaining information.
- A PoB Leaflet to help explain safety, intervention and transfer rates
- Appointment of a PoB Lead Midwife within each team to support change in practice.
- Monthly PoB community team meetings to discuss successes and challenges.



Future Work: We plan to look at the extent to which the ‘place of birth intervention package’ has been implemented at BWNFT. Formative feedback will inform the refinement of the package, before wider implementation and introduction at two further maternity trusts in the region – Heart of England NHS Foundation Trust and Sandwell and West Birmingham NHS Trust. Strategies for successful implementation at other sites will be discussed with scientific experts at the next Scientific Advisory Group, as it has potential national importance.

Case Study: Building Capacity through a Research Midwives Forum

In 2014 we established a *Research Midwives Forum*, bringing together research midwives from across the West Midlands to encourage engagement and collaboration, and to build capacity for applied health research across trusts. This was the first of its kind in the region and was set up by our Maternity research lead, Dr Sara Kenyon who recognised that there was no existing regional support network for research midwives. The West Midlands Clinical Research Network supported this forum and ensured research midwives attended from across the region. Dr Kenyon also sought out research midwives through engagement with local R&D offices within trusts.



Forums are held twice a year at the University of Birmingham with attendance being considered as part of the formal role of a research midwife, with their contribution captured as CLAHRC 'matched funding'. Four forums have taken place since the start of CLAHRC West Midlands, and have included midwives from across 12 NHS organisations. There are approximately 32 research midwives in the West Midlands with around 15 midwives attending any one session.

The content of the research forums is largely driven by the research midwives themselves and provides opportunities for:

- Shared learning and dissemination.
- Sharing good practice around individual trials.
- Career development opportunities and discussing the experiences of those who have undertaken further research training.
- Knowledge exchange, for example, the researchers discuss new studies and feedback results from studies that research midwives have previously recruited to. New trials in the pipeline are also discussed and the Deputy Director of Birmingham Clinical Trials Unit attends to update the midwives. Current issues in maternity are also shared for wider discussion.

Formal evaluation of the forum meetings show high satisfaction scores, with the midwives enjoying the opportunity to engage and network with their peers and to learn from others. They also enjoy finding out about the results of studies they have recruited to.

Midwives are inspired to continue or develop research interests with some looking to apply for formal training, such as HEE/NIHR Masters in Clinical Research (MRes) at University of Birmingham and Coventry University, or the Clinical Academic Internship Partnership at UHBFT.

It is anticipated that the forum has led to improved recruitment to trials in the West Midlands, which may attract more industrial collaboration, although these have not been formally measured. We plan to monitor the sustainability of the initiative by monitoring ongoing engagement and enthusiasm from midwives and participating trusts. We are also exploring opportunities to further support research midwives by offering secondments to work alongside the **Maternity and Child Health theme (1)**.

The four NIHR Advocates for Midwifery met recently, led by Prof Jane Sandall (CLAHRC South London), and agreed that there is a need for more research midwives forums across the UK due to local success and no current national opportunity.

This case study was featured in a national document demonstrating how CLAHRCs are supporting capacity development for non-medical allied health professions. This was launched by Lord Willis in May 2016 and is available to download at: <http://goo.gl/S4QKKY>

2. Prevention and early intervention in youth mental health

Theme Lead: Prof Max Birchwood, University of Warwick
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Leadership: The research team has transferred employment from Birmingham and Solihull Mental Health NHS Foundation Trust (BWHFT) to the University of Warwick, due to key changes in the delivery of Child and Adolescent Mental Health Service (CAMHS) in Birmingham.

Strategy & New Activity Initiated: Our pilot work informed the recent decision to develop a new 0-25 youth mental health service to replace the existing service and improve transition between CAMHS and adult mental health services. The contract has been awarded to BCH, in partnership with Worcestershire Health and Care NHS Trust, the Priory Group, Beacon UK, and The Children's Society. We have successfully secured the contract to evaluate the new service (page 19).

Major Grants Awarded: **ECLIPSE** – Building Resilience and Recovery through Enhancing Cognition and quality of Life in the early PSychoEs (£2m); **MILESTONE** – Managing the Link and Strengthening Transition from Child to Adult Mental Health Care (£4.8m) in collaboration with CLAHRC East of England; **PARTNERS2** – a pilot trial of primary care based collaborative care for people with serious mental illness (£2m) in collaboration with CLAHRC South West Peninsula.

Research Highlights: Published research on key topics, including: *treatment delays in first episode psychosis, risk and resilience among young people; transitions between child and adult mental health services; and joint crisis planning in mental health care.*^[17,26] Presented the results of a proof-of-principle, quasi-experimental intervention to reduce duration of untreated psychosis at the 3rd International Youth Mental Health Conference, Montreal.



Implementation Highlights: We will complete a prospective evaluation of the new 0-25 years service, assessing mobilisation and impact, including relevant outcome indicators, in the NHS Outcomes Framework. The 'Birmingham' model of 0-25 youth mental health services is being implemented in other parts of the country, including Norwich, Oxford and Mersey Care NHS Trust. We are taking forward a youth mental health working group to look at national collaboration and implementation of best practice (page 19).

Examples of Impacts on Health & Wealth: Our research on treatment delays in first episode psychosis led to the UK Government's new £120m **waiting time initiative in first episode psychosis**. Prof Birchwood is a member of the DH task group supporting implementation. Evidence shows treating psychosis rapidly can improve patients' chances of recovery and lead to potential savings in hospital admissions. We supported the BIG Lottery in developing a £70million investment in **HeadStart** to improve resilience in young adolescents. Birmingham City Council /

Birmingham HeadStart (led by The Children's Society) has been awarded £500,000, to enable work in schools and with families, community groups, and charities.



Evidence produced by the pilot CLAHRC demonstrating bottlenecks in specialist services, together with local information on young people being lost in the transition between CAMHS and adult services, led to the reconfiguration and recommissioning of youth mental health services to offer support from 0 to 25 years. We recently published the first 'SUPER BITE', bringing together the evidence that led to the reconfiguration of services. Early findings from the 0-25 service evaluation will be

disseminated at the youth mental health event and will include a specialist workshop on the recommissioning process employed by Birmingham South Central Clinical Commissioning Group.

Progress, Achievements and Challenges Against Objectives:

Short-term objectives: i) Establishing a *Centre for Mental Health Research and Wellbeing* to act as the engine of public mental health innovation within our AHSN is being supported by CLAHRC Research Capability funding awarded in 2015/16; ii) Conducting pilot trials of three interventions:

- 1) Early detection of eating disorders through school-based screening – additional schools are being recruited to participate in the second wave of surveys.
- 2) Promoting resilience and mental health outcomes among looked-after young people in social care – we have completed qualitative interviews with care-leavers and staff, and are preparing for a full programme grant application.
- 3) Early detection of depression in young people in primary care – the protocol has been published and we have applied to evaluate the new service comparing it to a 'traditional' service configuration, and have been invited to proceed to the full stage application.

Medium-term: Completing trials focusing on three interventions and securing grant funding to conduct definitive studies. The LYNC study concludes soon and a full application to conduct a pilot study is being planned; our pilot CLAHRC PhD student has successfully completed and published her PhD (a trial to improve mental health awareness and help-seeking in schools).^[11] Our current PhD student is conducting research into risk factors and resilience in young people.

Long-term: i) We aim to implement and monitor the impact of prevention-focused youth mental health. Following collaboration with Prof Tom Marshall we are considering a primary care-based system to transform delivery of care for young people with depression; ii) we have advanced our objective to implement school-based screening for emerging mental health problems by launching an eating disorder screening trial using online methodology in conjunction with vision360 – the trial has been successfully received by our five network schools; iii) we aim to secure a public health programme grant to monitor the impact of our 'stand-alone', school specific website Youthspace.me. Our long-term aim is for West Midlands schools to adopt this site.

Forward Look: A recent paper has compared guidelines on psychosis and schizophrenia produced by NICE with SIGN (the equivalent quango in Scotland) following an editorial claiming that SIGN guidance favours psychosocial treatments over drug treatments (*Br J Psychiatry*. 2016;208:316-9). We found that although there are some differences, the claims are unfounded.

Case Study: Impact on Youth Mental Health Services in Birmingham & Beyond

Background: Evidence produced by the pilot CLAHRC demonstrated that young people in Birmingham who present with first psychotic symptoms experience long treatment delays due to bottlenecks within the specialist mental health services together with poor help-seeking behaviour (*Br J Psychiatry*. 2013;203:58-64). Further research findings produced by the same research group, revealed that many young people were being 'lost' and becoming 'disengaged' at the period of transition between child (0-16) and adult mental health services (16+) – the most vulnerable point in their mental health (*BMC Health Serv Res*. 2008;8:135 // *Br J Psychiatry*. 2010;197:305-12).

From this evidence-base, a ground-breaking service for young people in Birmingham emerged, first to provide services up to the age of 25, and second to build this around public mental health and early detection principles. This aims to respond predominately to domain 2 of the NHS Outcomes Framework, *to enhance quality of life for people with mental illness*, but it is also likely to affect elements of all five of the domains.

The new 0-25 years Birmingham model was mentioned in the recent UK Government policy paper '*Future in Mind*' aimed at improving mental health services for young people: "*we also note that in some parts of the country, such as Birmingham and Norfolk, there is a move to develop mental health services for 0-25 year olds. This... will be watched with considerable interest.*"

Recent updates: The new 0-25 youth mental health service is being implemented by Forward Thinking Birmingham on behalf of Birmingham Children's Hospital. It will be evaluated by our **Youth Mental Health theme (2)**, along with researchers from the **IOS theme (5)**. We are working with Forward Thinking to identify LFs who will be key in both implementation and evaluation. Supported by CLAHRC managers, CLAHRC WM will spearhead a national network of youth mental health researchers and service managers to explore opportunities for collaboration, adoption and spread of best practices. The new service is already being exported to other parts of the country, including Norwich, Oxford and Mersey Care NHS Trust.

We are leading a prospective evaluation of the new service to assess its mobilisation and impact, including relevant outcome indicators in the NHS Outcomes Framework. Early findings will be presented at our upcoming dissemination event, which will also include a specialist workshop on the recommissioning process employed by the Birmingham South Central CCG.

A 'Shout Out for Youth Mental Health' dissemination event will be held on 7 June 2016, aimed at communicating the evidence that contributed to the recommissioning of the service to commissioners in the region. It will showcase the latest research regarding the reconfiguration of Birmingham CAMHS, as well as the evaluation of the service.

Forward Look: Dr Giovanni Radaelli, **IOS theme (5)**, is leading work into '*Mental Health Service for Children and Young Adults aged 0-25*' in the Greater Birmingham Area. This is aimed at investigating (i) how different partners developed their proposal (how evidence was acquired, assimilated and transformed to elicit positive responses from CCGs); (ii) how CCGs have identified the preferred provider and managed the bidding process; (iii) how the knowledge/evidence embedded in service proposals are translated and transformed during implementation in real-life contexts (and the fidelity between the original proposal and the implemented service); (iv) how evidence has been selected, used, interpreted, adopted and created; and (v) the interactions between different personnel within a heterogeneous network of healthcare, social care, and other organisations.

3. Prevention and detection of diseases

Theme Leader: Prof Aileen Clarke, University of Warwick
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Leadership: Prof Aileen Clarke has recently been appointed as Chair of Faculty of Medicine at Warwick Medical School.

Strategy & New Activity Initiated: We have strengthened our relationship with the UK National Screening Committee (NSC), which has amplified our systematic review capacity and maximised the impact of research activities on policy and practice (pages 24-25).

Major Grants Awarded: **Healthy Dads, Healthy Kids** – evaluation of a weight management programme for fathers of young children (£446k from NIHR Public Health Research Programme). **Exploring hand hygiene compliance** in collaboration with the **IOS theme (5)** (£100k from The Health Foundation). **Evaluating the Coventry GP alliance** in collaboration with the **Chronic Diseases theme (4)** (£65k from the Prime Minister’s Challenge Fund). A **variety of evidence synthesis reviews** (£310k from NSC and Cancer Research UK).

Research Highlights:

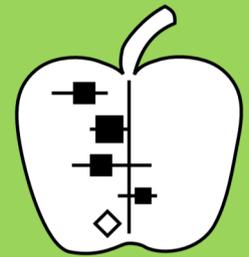
- Twenty-three systematic reviews have been completed to date, with a number of others underway (pages 24-25). A grant application is being developed for a meta-analysis of cardiovascular disease reviews.
- The NSC has commissioned a number of reviews, including non-invasive prenatal testing for trisomies (pages 22-23), an evidence review of NSC, and a review to explore implications of extending blood spot screening. Cancer Research UK has commissioned a further review to look at evidence underpinning blood spot test for cancer.
- Published papers on outlining a prediction model for diagnosis of depression in young adults from primary care data sources; development of an electronic frailty index using routine primary care datasets;^[20,32] the findings from the evaluation of a local-authority deployed intervention to maintain adherence to weight-management programmes (pages 26-27)^[62]; and the economic evaluation of iodine supplementation for pregnant women in a moderately-mild-deficit population.^[58]



Implementation Highlights: The **Changing case Order to Optimise patterns of Performance in mammography Screening (CO-OPS)** trial, led by Dr Sian Taylor-Phillips, found that there was no decline over time in the accuracy of medical staff who analyse mammogram scans for indication of breast cancer. It is anticipated that this will have impacts on breast screening policies and practice across the country and internationally.

Examples of Impacts on Health & Wealth:

- Provided evidence to the NSC on the accuracy of NIPT for trisomies. As a result, the NSC have endorsed the use of NIPT for screening for Down’s syndrome in the NHS (pages 22-23).
- Provided technology assessment advice to NICE on the effectiveness of ataluren for treatment



Prevention and detection of diseases

of Duchenne Muscular Dystrophy (DMD), which affects 8-13 newborn boys in the UK each year. Ataluren is the first licensed treatment for DMD that addresses the loss of dystrophin, the underlying cause of the condition. NICE guidance is being drafted [ID428] and relates to people with DMD from a nonsense mutation in the dystrophin gene.

- Provided advice and evidence to support NICE guidance on a diagnostic test (LISA-TRACKER) in Crohn's disease [DG22].

Progress, Achievements and Challenges Against Objectives:

Short-term objectives: to i) complete five systematic reviews; ii) disseminate findings from evaluation of weight management interventions; iii) undertake feasibility studies with local partners; and iv) carry out case finding studies. These have been achieved (see above and pages 24-29). In addition, the theme continues to v) maintain and develop a prevention and detection network across the region, which has supported organisations with implementing and evaluating the health checks programme, for example.

Medium-term objectives: Providing evidence from systematic reviews to plug evidence gaps and inform the development of grant applications to support RCTs is ongoing. Two new studies are under development to analyse audit data from breast surgery to understand predictors of outcomes in breast screening; and to look at the feasibility of e-cigarettes for smoking cessation.

Long-term objectives: We are realising the long-term objective to complete RCTs and reviews for widespread dissemination. Three RCTs have recently been completed and dissemination of findings is underway. Two of the trials (**Families for Health** and **Lighten up Plus**) have resulted in services being discontinued (pages 26-27). Findings from the third trial (**CO-OPS**) have recently been published in JAMA.

Additional objectives: include i) further collaborative studies with local authority partners (pages 28-29); ii) methodological development of new public health outcome measure (WALY – Wellbeing Adjusted Life Year); and iii) Team capacity development through local leadership courses and NIHR fellowship schemes.

Links with NIHR Infrastructure: Prof Clarke has made links with the Public Health CRN team nationally and will attend their stakeholder meetings. We are collaborating with CLAHRC East Midlands and CLAHRC South West Peninsula on the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) programme study.

We are continuing to work with WM AHSN to evaluate the barriers to implementation of the Hydrate for Health water bottle system. There has already been some significant and useful findings from the implementation, including feedback around how best to develop elements of the hydration system and how best to target this at professional groups.

Forward Look: We plan to widely disseminate the recently published findings from the CO-OPS trial through our News Blog, the website, via social media, and with a BITE.

We have submitted further collaborative grants to the NIHR on the management of obesity and long-term conditions.

We will continue to bolster our systematic review capacity with a number of subsequent reviews underway, commissioned by NICE, NSC and by the knowledge needs of our partner organisations (pages 22-25).

Case Study: Safer and More Accurate Test for Down's Syndrome on NHS

Background

The NHS currently offers screening to women 11 to 14 weeks into their pregnancy to test for three genetic disorders in the foetus – Down's, Edwards and Patau syndrome. A combination of information from an ultrasound scan, blood test, the mother's age, and other factors such as smoking are used to assess the likelihood of a baby having any one of these conditions. Those who have a greater than one-in-150 chance of having a baby with any one of these conditions is considered 'high-risk' and is offered an invasive diagnostic test. This can be either amniocentesis, where a needle is used to extract a sample of amniotic fluid surrounding the foetus, or chorionic villus sampling where a sample of chorionic villi is removed from the placenta through the cervix or the abdominal wall. Both of these invasive tests are considered risky procedures – current estimates suggest that amniocentesis can induce miscarriage in one in every 200 women.



Research Findings and Evidence

Recently the UK National Screening Committee (NSC) endorsed a new non-invasive prenatal blood test (NIPT) for Down's syndrome, to reduce the risk of miscarriage. NIPT uses a sample of cell-free foetal DNA from the pregnant mother's blood to assess the risk of Down's, Edwards and Patau syndrome. These syndromes are all caused by the presence of an extra copy of a chromosome, a trisomy, which can be detected by the test. The test is already in wide use across the world, for example it has been rapidly adopted in the USA, where there has been a corresponding decrease in combined test and invasive testing, such as amniocentesis or chorionic villus sampling.

The **Prevention and Detection of Diseases of Diseases theme (3)** were commissioned by the NSC to conduct a systematic review and meta-analysis to consider the accuracy of NIPT in assessing the risk of the three trisomy disorders in first trimester pregnancies. A clear summary of test accuracy is needed to ensure that results are not misinterpreted and to inform the NSC's decision on the introduction of this test into current foetal abnormality screening in the English NHS. This is especially important for those who would abort a pregnancy on the basis of a positive NIPT test. Sensitivity findings from the review and synthesis showed that in 100,000 pregnancies from the general obstetric population, NIPT could detect:

Syndrome	True Positives	False Positives
Down's	417 (out of 435)	94 (out of 99,565)
Edwards	89 (out of 102)	154 (out of 99,898)
Patau	40 (out of 52)	42 (out of 99,948)

These findings demonstrated that NIPT has high sensitivity and very high specificity and can contribute to national screening programmes, but cannot be considered diagnostic. From the data, it can be estimated that 82% of pregnancies that test positive for Down's syndrome will actually have Down's syndrome; 37% that test positive for Edwards's syndrome will have it; and 49% that test positive for Patau syndrome will have it. Therefore, while NIPT is broadly accurate, it is vital a positive NIPT result is followed by an invasive diagnostic test to confirm the presence of trisomy if the woman is considering a termination on this basis. NIPT may be more attractive to patients who would not consider a termination, but would like to find out if the pregnancy is affected by one of these syndromes.

The evidence synthesis work has been recently published in BMJ Open.^[64] A final report was shared with the NSC that included a parallel economic evaluation and a model that assessed the impact introducing NIPT would have on the existing NHS foetal anomaly screening programme. This unpublished economic evaluation suggested that the addition of this test was 'cost neutral' but would result in a reduction in number of test-related miscarriages. This is due to fewer women would be offered an invasive test thanks to the improved accuracy of the NIPT compared to traditional combined tests. Further estimates suggest between 3,000 and 5,000 amniocenteses each year will no longer be necessary resulting in a direct cost saving for health service (exact monetary value unknown).



The UK NSC has commissioned further evaluative work to better understand both practical and implementation issues to consider ahead of national implementation. Work conducted by the **Prevention and Detection of Diseases theme (3)** suggested that communicating to clinicians and patients that this genetic test is not perfect will be key for safe implementation, and pre-and post-test information provision and counselling for positive and negative NIPT results should be given careful consideration.

For more information see the NSC website at: <http://legacy.screening.nhs.uk/downs>

Case Study: Impact of Systematic Reviews on Policy & Practice

Members of the **Prevention and Detection of Diseases theme (3)** have developed a large capacity for conducting high-quality systematic reviews, which have been widely disseminated and will inform future feasibility studies. Many of these have been published in the Cochrane Database of Systematic Reviews, recognised as publishing papers with the highest standard in evidence-based healthcare. In reporting year 2, 12 systematic reviews have been published in the Cochrane Database (along with four protocols), building on the four reviews (and three protocols) published in reporting year 1.

Two such reviews were highlighted on the home page of the Cochrane Library website due to their potential impact on future work:

- The effectiveness of dietary fibre for the primary prevention of cardiovascular disease (CVD), which found that increased fibre intake was associated with a beneficial reduction in low-density lipoprotein (LDL) and total cholesterol, and in diastolic blood pressure.^[46]
- The effectiveness of various parent-only interventions on reducing the weight of overweight children aged 5 to 11 years. There was some evidence that such interventions could help reduce the BMI of children, but the authors could not find firm evidence of any advantages over longer follow-up periods, or any comparisons of various types of interventions. They did identify ten ongoing trials that they hope will contribute to future updates of their review. This work was also disseminated by Cochrane through their blog, 'Evidently Cochrane'.^[52]



Six further Cochrane systematic reviews were also published, though as there were only a few high-quality studies, firm conclusions could not be drawn:

- Reviewing the effectiveness of vitamin K supplementation at reducing, amongst other things, cardiovascular death, and CVD.^[43]
- The effects of antioxidant coenzyme Q10 (CoQ10) on primary prevention of CVD. The authors did, however, find a number of ongoing studies, which could be added in a future update.^[37]
- The effectiveness of transcendental meditation on CVD risk.^[45]
- The effects of varying levels of omega 6 fatty acids on primary prevention of CVD, which found no differences on blood lipids or blood pressure from increased or decreased omega 6 intake.^[30]
- The effectiveness of diet, physical activity and behavioural interventions for the treatment of overweight or obesity in preschool children (up to 6 years of age).^[33]
- Comparing the effectiveness, costs and adverse effects of types of risk assessment for the primary prevention of CVD. Five ongoing trials were identified, which will be incorporated in a future update.^[35]

The team also produced four updated Cochrane systematic reviews on effects of various interventions on CVD:

- The potential benefits of influenza vaccination for prevention of CVD, which found some evidence that vaccination may reduce mortality from CVD, but higher-quality evidence is still needed.^[31]
- The effectiveness of multiple risk factor interventions at improving CVD risk factors in low- and middle-income countries. Although there was some evidence that they lowered blood pressure levels, body mass index, and waist circumference in high-risk patients, there was considerable heterogeneity between trials and so no firm conclusions could be drawn.^[67]
- The effectiveness of the meditative practice of qigong on the primary prevention of CVD, which found very limited evidence on its effectiveness, with most trials at high-risk of bias.^[44]
- The effect of nut consumption on CVD clinical events in primary prevention and CVD risk factors, which found a lack of published studies.^[56]

The team have also completed and published a number of systematic reviews in a variety of other journals. This includes work on self-management for patients with chronic obstructive pulmonary disorder; exercise-based rehabilitation for heart failure; diabetic retinopathy screening; the effectiveness of self-weighing for weight loss; socio-economic status and weight in children; monitoring during chemotherapy; non-invasive prenatal testing for genetic syndromes; and quality improvement in primary care.

These reviews will inform future feasibility studies and suggest avenues for future research. Some of the Cochrane systematic reviews found a number of ongoing trials that will be incorporated into updated reviews in the future.

Furthermore, there are a number of ongoing systematic reviews, which will be published in the future, including:

- A Cochrane systematic review looking at vitamin C supplementation for the primary prevention of CVD.^[38]
- A Cochrane systematic review looking at the effect of exercise training for chronic obstructive pulmonary disease.^[57]
- Accuracy and timeliness of real-time polymerase chain reaction tests for Group B *Streptococcus* maternal colonisation in pregnant women in labour, compared to antenatal culture.
- Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in children aged 5 to 11 years.
- Diet, physical activity and behavioural interventions for the treatment of overweight or obesity in children aged 12 to 17 years.
- Community onset sepsis.
- Perceptions and beliefs related to weight status for minority ethnic groups.
- Comparison of risk scoring systems for colorectal cancer screening.

Case Study: Evidence from Evaluation Leads to Discontinuation of Services

Background:

Health and social care decision makers recognise the importance of identifying areas for 'disinvestment', where resources could be released by discontinuing services or treatments, although typically one intervention is substituted for another rather than being subtracted from use entirely (*Health Policy. 2009;91(3):239-45*). We can provide a growing number of examples where interventions or services have been discontinued or decommissioned based on evidence produced from local service delivery evaluations conducted by the pilot CLAHRC and current CLAHRC West Midlands. This demonstrates evidence-based decision making resulting in disinvestment in services in West Midlands region, contradicting previous claims.

Two randomised controlled trials (RCTs) to evaluate weight management interventions/services have recently been completed and were supported by the **Prevention and Detection of Diseases theme (3)** based at Universities of Warwick and Birmingham. Both trials showed a negative result and led to the decommissioning or disinvestment in these services within the region.

	Lighten Up PLUS	Families for Health
Intervention, designed by CLAHRC WM team members	SMS texts to adults for three months after commercial weight loss programme reminding them to weigh themselves	10 week detailed family / parenting skills programme for overweight or obese children, 6-11 years
Recruitment and follow-up	380 adults randomised. 9 months	115 Families randomised. 12 months
Outcome and results	Weight regain (kg): -0.45 (95% CI -1.67, 0.78)	BMI z-score change: 0.114 (95% CI -0.001, 0.229)
Commissioning conclusions	Service recommended for de-commissioning across the West Midlands	Recommended that service should not be commissioned across the West Midlands

Researching weight management services – a summary from two highly successful negative RCTs

Families for Health:

A multi-centre, investigator-blind, randomised controlled trial to determine the effectiveness and cost-effectiveness of 'Families for Health' – a family-based weight management intervention delivered in a community setting for parents/carers and children to attend parallel 2.5 hour educational sessions for 10 weeks. The trial recruited 120 families from Coventry, Warwickshire and Wolverhampton, with at least one child aged 6 to 11 years who is overweight or obese and randomly assigned families to receive the 'Families for Health version 2' intervention or to usual care. Findings from the study showed that the intervention did not improve the BMI of the child after 12 months' follow up. The full report has been submitted to the HTA with an anticipated publication date of August 2016.

Lighten Up PLUS:

A randomised controlled trial to evaluate the effectiveness of a text-based weight management programme offered for 12 months after participants had attended a free 12-week commercial weight management programme. Previous evidence produced by the same research group demonstrated that commercial weight management programmes, such as Slimming World, were more effective than 'own grown' programmes developed by General Practices and recommended that local practices disinvest in 'own grown' services in favour of commercially provided services (*Br Med J. 2011;343:d6500*). The Lighten Up PLUS study recruited 380 participants, randomly assigned to receive the text-based weight management programme for 12 weeks or to receive usual care with no intervention. The results showed no significant difference in weight change between the intervention and usual care groups: participants in both study groups maintained weight loss in the short term, but regained weight over the longer term. The authors recommended further research is needed into how tele-health can support behaviour change, and future research should focus on providing personalised information about diet and/or physical activity, and setting weekly weight-related goals.^[62]

The precursor Lighten Up study was supported by the pilot CLAHRC for Birmingham and Black Country. The Lighten Up PLUS study was supported by NIHR CLAHRC West Midlands grant. Both studies were supported by CLAHRC matched-funding provided by Birmingham City Council and University of Birmingham.

Forward Look:

In both scenarios presented here, the evidence from the evaluation showed that the service intervention had no effect or no additional benefit. This information was incorporated in local evidence-based decision making and, in all cases, led to a disinvestment decision and services were discontinued. This contradicts previous evidence, suggesting that one service intervention is usually substituted in favour of another, over being subtracted entirely from use (*Health Policy. 2009;91(3):239-45*).



Case Study: Working with Local Authorities to Meet Health Priorities

The CLAHRC WM has developed relationships and established ongoing collaborations with local authorities to identify evidence gaps and develop and evaluate interventions that influence policy and investment decisions. There are several ongoing research projects that have been developed, designed and implemented in collaboration with local authorities in the West Midlands. Some examples are as follows:

Gavin Rudge of the **Research Methods theme (6)** is leading on a programme of work developed in partnership with **Worcestershire County Council (WCC)**, in response to the specific health priorities of their local population. Projects include:

- Embedding public health in planning: Jenny Shepherd (a collaborator on this programme of work) drove the adoption of the Health Impact Assessment (HIA) process by facilitating workshops for WCC staff.
- Providing evidence for public health intervention: Created a 'Census Atlas' and the findings were presented to key groups at the local authority via two 'health geography' seminars. This included Public Health consultants, Health Improvement Co-ordinators and intelligence colleagues.
- Social care simulation modelling: produced a model of the Adult Social Care System in Worcestershire (with support from Gavin Rudge). This followed a number of conversations with members of WCC Social Care Team in order to gain an understanding of the ACS system, staffing numbers, processes, etc. in WCC.
- Domestic abuse needs assessment: worked on a review, evaluation and assessment of domestic abuse services, systems and processes in WCC. This includes analysis of the extent of the problem in Worcestershire, impact on certain groups and the current service response. This evidence will help to inform the recommendations for future Worcestershire domestic abuse services.

Prof Kate Jolly of the **Prevention and Detection theme (3)** was a co-investigator on an evaluation of the Startwell Programme delivered by **Birmingham City Council**, an intervention providing training for early years staff to incorporate healthy nutrition and physical activity into their day-to-day practices. The evaluation aimed to determine whether there was any change in the self-reported behaviours of staff in early years settings as a result of the Startwell programme. The final report concluded that there were some improvements in self-reported nutrition and physical activity related behaviours during the evaluation, and that programmes such as Startwell would have a beneficial effect on childhood obesity. The findings from the evaluation were fed back to local authority commissioners and the evidence was used to inform the decision to recommission the service for an additional year. The evaluation report was a crucial element in the recommissioning decision taken by the local authority.

A project evaluating the NHS Health Checks programme has been undertaken by researchers from both the **Prevention and Detection of Diseases Theme (3)** and **IOS theme (5)**, led by Dr Chris Stinton at Warwick Medical School, in collaboration with **Public Health Coventry, Public Health Warwickshire and Public Health Dudley**.

The Public Health Projects (Housing and Health Data Linkage) are supported by CLAHRC West Midlands grant, as well as matched funding provided by Worcestershire County Council and University of Birmingham.

The Startwell evaluation study was supported by CLAHRC West Midlands as well as by CLAHRC matched-funding provided by Birmingham City Council and University of Birmingham.

The NHS Health Checks study was supported by CLAHRC West Midlands grant and also by CLAHRC matched-funding provided by Public Health Coventry, Public Health Warwickshire and Public Health Dudley.

Worcestershire County Council projects

Embedding public health in planning: The Health SPD will be embedded as part of the planning process in Worcestershire. Health and wellbeing is now to be considered in all policies at Worcestershire County Council (a template has been developed by Jenny Sheperd which is similar to an Equalities Impact Assessment screening) to consider whether an HIA is required. Providing evidence for public health intervention: The Census Atlas facilitates a better spatial understanding of the wider determinants of health and risks to health and wellbeing at a local level. This intelligence will help to target public health interventions and contribute to improved health and wellbeing outcomes in Worcestershire.

Social care simulation modelling: The model was presented to WCC's Director of Public Health and the ACS Project Manager with a view to develop it further, refining its assumptions and workings. This will include working through Social Care Worker reported activity logs to gain a greater understanding how they spend their time on a day-to-day basis.

Domestic abuse needs assessment: The researchers met with the WCC Director of Public Health to discuss refining and reworking the document. The next draft is due to be completed by mid-April, with the final document to be completed by June.

Startwell: The final report concluded that there were some improvements in self-reported nutrition and physical activity related behaviours during the evaluation, and that programmes such as Startwell would have a beneficial effect on childhood obesity. However, the authors recommended a more robustly designed evaluation with objective measures and a higher proportion of follow up to provide more reliable evidence of effectiveness.

Disinvestment: We have been working with local authorities in Birmingham and Warwickshire to evaluate weight-management services (Lighten up PLUS and Families for Health, respectively). In both examples, evidence from the evaluation has led to services being discontinued (pages 26-27).

4. Chronic diseases

Theme Lead: Prof Jon Glasby, University of Birmingham
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Leadership: Prof Christian Mallen was appointed Deputy Director of the CLAHRC WM, representing our colleagues at Keele University and aligning more closely to the WM AHSN hub and spoke model.

Strategy & New Activity Initiated: We have added several new projects in response to priorities of local organisations and interventions being developed. We have extended our reach by involving new health and social care organisations through deeds of adherence (page 10).

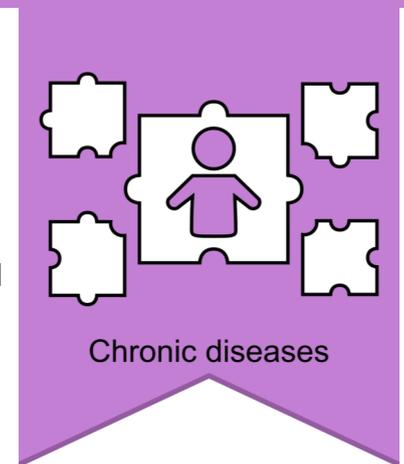
Major Grants Awarded: **NOTEPAD:** NOn-Traditional Providers to support the management of Elderly People with Anxiety and Depression (£300k for a feasibility study). The **FACTUAL STUDY:** Chondroitin sulphate for hand osteoarthritis (£1.1m). A feasibility and pilot trial of exercise therapy and orthotics in the **treatment of plantar heel pain** (£250k). **Smart Rehabilitation at Home before and after Lung Surgery** (£66k in collaboration with Heart of England NHS Foundation Trust (HEFT)). Evaluation of the **Coventry Alliance: Best Care, Anywhere** (£65k in collaboration with the **Prevention and Detection theme (3)**). An **NIHR Knowledge Mobilisation Fellowship** awarded to Prof Krysia Dziedzic (£340k).

Research Highlights: Developed a number of protocols responding to clinical priorities identified by LFs, including Supported Integrated Discharge, a collaboration with HEFT to evaluate the system for emergency hospital admissions with a potential stay of 14+ days; evaluation of the **Older Person's Assessment and Liaison service** (OPAL) project, led by Dr Kiran Kalirai with UHBFT; and the **Heartlands Elderly Care, Trauma & Ongoing Recovery** (HECTOR) project. The protocol for the ENHANCE study, Improving the Care of People with Long Term Conditions, was published along with an editorial on challenges of multi-morbidity in primary care.^[76,108] Research dissemination days were hosted with NHS partners to share the initial results of the BEEP and SUPPORT trials.

Implementation Highlights: One hospital in North Staffordshire has used evidence provided by the theme to produce a business case for psychological support for dialysis patients (funding not confirmed). A training session for the LDF on qualitative methods was delivered by the Keele academic group, with very positive feedback. Following the roll out of the STarT Back tool across the West Midlands, audit data has shown a reduction in physiotherapy waiting times and greater use of the tool by GPs. It is being introduced to other parts of the country through the AHSN/ CLAHRC networks and infrastructure (pages 32-33).



Examples of Impacts on Health & Wealth: i) Three of the five doctors involved in the evaluation of two pilot interventions to provide emotional and psychological support to dialysis patients, reported incorporating at least one of the interventions into their everyday practice; ii) We provided advice to the North Bristol NHS Trust on the set up of a renal patient peer support programme, in response to a journal article from our research (*Health Expect.* 2016;19(3):617-30); iii) Findings from the evaluation of the renal home therapies project were discussed with the national clinical director for renal services, and submitted to the All Party Parliamentary Kidney Group contributing to their report on home



dialysis; iv) We have been heavily involved in the NICE consultation process to update clinical guidance for low back pain in adults [CG88] and we anticipate that the STarT Back will be used as an example of best practice (pages 32-33). Prof Caroline Chew-Graham is a member of the NICE multi-morbidity guideline development group, and NICE depression update group.

Progress, Achievements and Challenges Against Objectives:

Short-term objectives: i) Map current service innovations across participating centres: the Overview Study protocol (review of systematic reviews on integrated care for long-term conditions) was published in *Systematic Reviews*, and the full results were written up for submission to peer-reviewed journals; ii) Identify innovations for formative evaluation: HECTOR pathway and LACE risk prediction tool; iii) develop and pilot GP intervention to improve pain management and mental health care in patients with chronic conditions: we achieved strong NHS engagement at our stakeholder workshops, and have worked closely with NIHR CRN to identify practices to invite into the trial; iv) Develop and test an intervention helping GP receptionists identify 'red-flag' symptoms of stroke: an online training course is in development, building on pilot CLAHRC work.

Medium-term objectives: i) Complete the process evaluation of the ENHANCE feasibility study and complete analysis of data sets: recruitment is closed, and follow-up data collection and analysis will be complete early 2017. A practice nurse stakeholder event is planned in September 2016 and we will reconvene our Patient Advisory Group to input into the trial design; ii) Develop and test an intervention to improve trauma care: a follow-up study is due to commence in January 2016 which aims to explore the patient and carer experience of being treated on the pathway; iii) Identify and prioritise new service interventions for development: a new service intervention identified for development and evaluation: the Coventry and Rugby CCG's GP Access Scheme.

Long-term objectives: i) Initiate new projects using the IDEaL model as part of a rolling programme as funds are released when projects complete or are absorbed in national studies: we are in the process of recruiting a research fellow to assist with translating the ENHANCE trial into a main trial application; ii) we continue to develop and expand the programme of work on emotional and psychological support for renal patients. A large study is underway with considerable interest, and so we have been able to be selective in the sites we work with. The work has attracted national interest, resulting in an invitation to speak to at a national forum for renal clinical psychologists, and a visit to the House of Lords.

Links with NIHR Infrastructure: The ENHANCE study has collaborated with Keele Clinical Trials Unit (part funded by the NIHR) and is engaging more widely with the WM CRN to assist with set up and recruitment for the pilot trials. This theme also completed work in 2015 for the Sheffield NIHR HTC to develop a cost effectiveness model for frequent home haemodialysis. We have been working with CLAHRC Oxford on the PROMPT study of weight gain following renal transplantation.

Links with Industry: Pharma: We continue to collaborate with the Royal Pharmaceutical Society and are engaged through the WM AHSN with general support to the pharma industry.

Non-life sciences companies: We are collaborating with a number of companies, including the EMIS group, SystemOne and INPS, to integrate the e-STarT Back and ENHANCE tools within clinical systems, so other AHSNs can adopt the implementation of these tools at the same scale and pace as the West Midlands. The toolkit is also being introduced into private healthcare settings through a collaboration with AXA PPP Healthcare (pages 32-33).

Case Study: Wider Adoption of an Approach to Manage Low Back Pain

Back pain is the most common reason middle-aged people visit their GP and the second most common reason for sickness absence from work. Keele University, supported by the **Chronic Diseases theme (4)**, along with a team of LFs and WM AHSN, developed a strategy for the roll out of the STarT Back approach for the management of low back pain in everyday clinical practice. STarT Back is an example of stratified care for low back pain, whereby patients are screened for the type and likely duration of back pain and matched to appropriate care pathways. STarT Back has been shown to be both clinically and financially effective, by reducing over-treatment of low-risk groups, ensuring the management of this group remains in primary care, with more effective and efficient matched, and targeted treatment for medium- and high-risk groups provided by physiotherapists in community and secondary care settings. The effectiveness of the tool and links with industry partners were described in our first annual report. The original evaluation included a health economic evaluation, which is summarised below. The published evaluation showed that the STarT Back approach reduced healthcare costs with an average saving of £34.30 per patient. Modelling this for implementation (with nationally available benchmark data per 1,000 patients referred to physiotherapy), the current cost of service provision for community physiotherapy is estimated at £224,000 per 1,000 new referrals. STarT Back helps to assign patients to matched treatments as follows:

Risk Group	% of Referrals	No. of appointments
Low	26%	1 = assessment, advice, discharge
Medium	46%	5 = 1 new, 4 follow up
High	28%	6 = 1 new, 5 follow up

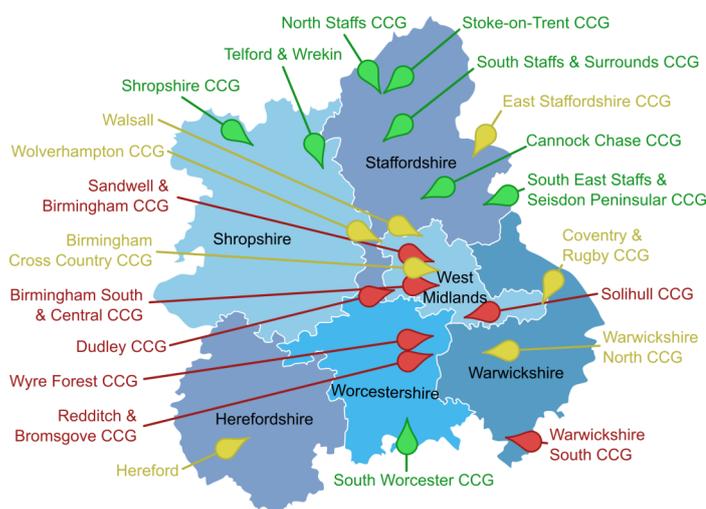
Applying these ratios to 1,000 new back pain physiotherapy appointments per annum adopting a stratified care model implies the following service costs:

Activity	New appts	Follow-up	COST FYE
Usual Care: Physiotherapy Direct Costs	1,000	5,000	£224,000
Option 1, Stratified Care: All low-, medium- and high- risk patients managed by physiotherapy	1,000		£162,400
Option 2, Stratified care: Low-risk managed by GP; medium- and high-risk groups managed by physiotherapy	740 (physio)		£121,520

These costs demonstrate a minimum saving of £61,000 per 1,000 patients referred and represent the direct costs associated with physiotherapy services. Audit of implementation sites show that physiotherapy services are not utilising 5 follow ups for high-risk patients, with the average being 3 follow-up appointments, the figures quoted above are, therefore, conservative estimates of savings per 1,000 patients. The STarT Back Trial identified broader health and social care savings including: reduction in the number of GP consultations, reduction in the number of visits to NHS consultants, reduced investigations (MRI/x-rays), reduction in epidural injections and medication usage. No attempt has been made to quantify the reduction in these costs as part of this model (*Ann Rheum Dis. 2012;71:1796-802*). Subsequently, we report progress on both the regional implementation and the national adoption of the tool through other CLAHRCs and AHSNs. A detailed account of the project has been submitted to feature as an NIHR at 10 impact case study and a summary of the work was recently published in a special healthcare and life

sciences supplement of the Birmingham Business Quarterly magazine (see page 44-45 of digital edition here).

Matched funding, provided by Keele University and trusts in the North spoke of the region, supports the regional implementation of the STarT Back tool (see also part 1 section 10). The **IOS theme (5)** is undertaking a project to study the implementation approaches and the role of 'distributed leadership'.



Currently, 15 CCGs (out of 22), and 15 provider trusts, are introducing the tool within their care pathways and clinical systems. The tool is also being introduced in the private healthcare setting through provider AXA PPP Healthcare.

A number of implementation toolkits have been developed, together with a suite of training programmes, to support the CCGs with adopting the tool.

The Keele-based group has been working with industry partners (EMIS health, patient.info and now also SystemOne) to integrate the STarT

Back tool into the GP clinical systems, to automate the calculation of risk score in patients with low back pain, thereby allowing auto-referral of patients to appropriate matched treatments according to risk group. A PPI group helped to develop a short high-quality patient information leaflet within patient.info for use in GP consultations. The e-STarT Back tool has been installed in 17 practices in Staffordshire during the period from January to November 2015. A total of 886 patients were consulted for back pain during this period and the e-tool was used on 190 patients (22%) with 97 (51% in medium/high-risk groups) patients referred to physiotherapy services. The remaining 93 (49%) patients in the low-risk category were managed by the GP. WM AHSN has provided implementation funding to support to this programme during 2014-16.

National adoption and spread:

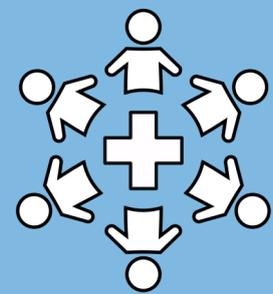
The STarT Back approach is being introduced in other parts of the country, supported by local CLAHRC and AHSNs, where applicable. The tool is being implemented in the North West Coast and North East Coast regions. The London and Eastern AHSNs are also considering introducing the tool in their localities.

Links with other national organisations:

The Keele group has been working with Public Health England to embed the STarT Back approach within the 'Making Every Contact Count' toolkit for low back pain. They have also been involved in the NICE consultation process to update NICE clinical guidance on early management of low back pain in adults [CG88]. The new guidance will be published shortly (anticipated in September 2016). Collaborations with industry partners (EMIS, SystemOne, patient.info) to develop an IT solution to allow integration of the e-STarT Back tool within clinical systems – enabling automatic calculation of risk score in patients, immediate access to patient information and referral for matched treatments for medium/high-risk patients thereby allowing low-risk patients to be managed by the GP. This toolkit is now readily available for anyone to utilise. More information is available at: <http://www.keele.ac.uk/sbst/>

5. Implementation & Organisational Studies

Theme Leader: Prof Graeme Currie, University of Warwick
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Implementation and organisational studies

Strategy & New Activity Initiated: The theme has played a key role in formulating the industry engagement strategy and accordingly has focused on continuing to improve collaboration with professional services firms including a new collaboration with GE Finnamore, and early stage collaborations with KPMG and Kaiser Permanente.

Major Grants Awarded:

- Monash-Warwick Alliance to support global healthcare improvement initiative with Professorial appointments in both the UK and Australia to facilitate improvements in healthcare improvement science (£2m) (pages 42-43).
- The theme is supporting the **Maternity and Child Health theme (1)** in evaluating the antenatal Prophylactic Pelvic floor Exercises and Localisation Programme (APPEAL) (£1.5m).
- Evaluation of Leadership Programme at University Hospitals Coventry and Warwickshire (£50k).

Research Highlights:

- 11 papers have been published or are in press for ABS 4 or 4* journals, with a further 4 published or in press for ABS 3 ranked journals.
- We highlight findings from work on the role of nurses as hybrid middle managers in the implementation of NICE guidance (see also below and section 5). ^[115,126]
- The theme hosted a world café event on Patient and Public Involvement (PPI) in research implementation.

Implementation Highlights: The theme is offering evaluative support to two other CLAHRC WM themes on significant projects which may have wide-reaching policy and implementation impact: the evaluation of the 0-25 service with the **Youth Mental Health theme (2)** (page 19); and the BSOTS Maternity Triage system with the **Maternity and Child Health theme (1)** (page 12).

Examples of Impacts on Health & Wealth: As mentioned above, CLAHRC WM has developed an industry engagement strategy which has been significantly shaped by the activities and expertise of theme. Professional services firms provide significant decision making and evaluative support to NHS organisations so we are working to improve this capacity and capability further by providing academically rigorous tools which can support these processes and improve their outputs.

Our host trust UHBFT has established an internal graduate management trainee programme called the Annex U scheme (pages 50-51). These trainees are all undertaking health related Masters level qualifications and all 20 of these individuals have been recruited as Leadership Fellows. This offers a fantastic opportunity to target the future generation of middle and senior managers within the NHS and develop their research knowledge and interest through our existing educational programmes, which should provide reach and impact far beyond the lifespan of the CLAHRC WM.

Led by Deputy Director, Prof Graeme Currie, our implementation theme has published a body of work in journals rated 4 star by the ABS to demonstrate the role of nurses as hybrid middle managers (HMM) in the implementation of NICE clinical guidelines. Specifically, the role of chronic heart failure nurse consultants in the implementation of NICE guidelines for chronic heart failure [CG108] was examined at two hospitals. The study confirmed previous findings that HMM are uniquely placed for translating both management and clinical strategies into practice and that this ability could be further enhanced through mediating professional hierarchy, to uphold them from multiple clinical logics, and by buffering them from financial pressures. An additional study, led by Warwick Business School, funded by NIHR HS&DR and supported by CLAHRC WM, will explore how the process of service redesign in CCGs might be improved by focusing on use of NICE guidelines and will be led by Prof Jacky Swan.

Progress, Achievements and Challenges Against Objectives:

Short-term objectives: i) to use Implementation Research Fellows (IRFs) from within the theme to support the four main clinical themes with evaluation which can be demonstrated through the evaluation mentioned in implementation highlights, above. Also a 2 year behavioural science informed study of healthcare improvement has been funded by the Health Foundation and will commence in April 2016. ii) Nine PhD projects are underway with data collection underpinned by the theoretical construct of 'absorptive capacity'. iii) initial data collection and analysis is underway on an exploration of the roles and experiences of PPI advisors within CLAHRC WM.

Medium-term objectives: i) the theme has successfully identified a wide range of applied research studies in conjunction with NHS partners and 13 protocols have now been generated and peer-reviewed. ii) the PhD projects and IRF protocols which have been developed will feed into the proposed evaluation of how absorptive capacity develops (or fails to develop) in health organisations using the ACAP psychometric tool to evaluate self-development.

Long-term objectives: i) The implementation of projects undertaken thus far will give the required level of coverage to assess the spread of absorptive capacity across the CLAHRC WM footprint and beyond.

Links with NIHR Infrastructure: We have been particularly involved with the Patient and public Involvement and Lay Accountability in Research and innovation (PILAR) group which is a PPI forum tying together many strands of work from across the local NIHR infrastructure through Dr Sophie Staniszewska. Dr Staniszewska is also an active member of the INVOLVE CLAHRC network and Vice Chair of the Breaking Boundaries Review and is able to contribute and collaborate to PPI across all parts of the NIHR infrastructure as part of this.

Links with industry: Prof Graeme Currie has met with the Chairman of the Global Health Partnership and discussions are ongoing to create a thought leadership programme. Prof Currie has also been working with the research and development teams of Kaiser Permanente at their headquarters in California to create a formal collaboration with Warwick Business School.

We are working with Boots Alliance to look at the historical influence high street pharmacists have had on personal choices and population health; and with Ernst and Young to interrogate and improve the understanding derived from Hospital Episode Statistics (HES) data.

We have worked with GE Finnamore to develop a formal evaluation partnership through Warwick Business School and have submitted several joint bids for projects as a result during 2015.

6. Research Methods

Theme Leader: Prof Richard Lilford, University of Warwick
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Strategy & New Activity Initiated: We undertook consultancy work on the economic evaluation of liaison and diversion services for RAND, focusing on the impact of services on criminal justice and health outcomes. Members of our team were commissioned for work on benefits of human milk banking (£3,000); Bayesian approaches to evaluation (£20,000); and to write two papers on slum health for a special Lancet series. We are working with various African organisations to forge new research ideas, and add value to existing ideas. For example, looking at salt-intake in sub-Saharan Africa and developing initiatives for reduction; and impact of user fees on access to healthcare in Neno, Malawi (pages 42-43).

Major Grants Awarded:

- Model to implement integrated, comprehensive, community-based health care for vulnerable communities in South Africa. £660,000 (£94,694 to University of Warwick).
- Walking away from Gestational Diabetes, with CLAHRC East Midlands (£249,457).
- Patient Experience and Reflective Learning. £1,051,696 (£98,237 to Warwick).
- Determining feasibility of scaling-up a baby-friendly, community-based approach for improving maternal, new-born and infant nutrition practices in Kenya. £160,000.
- Improving health literacy of Lay Community Health Workers in Southern Africa. £149,923.
- Pilot study of the interface between hospital and community in India. £100,000.
- Self-management, information and computing technology and lifestyle education in women with a history of gestational diabetes (SMILE). £375,000.
- Mathematical modelling, global network for neglected tropical diseases. £5,000,000.

Research Highlights: Our team continue to lead the way in step-wedge design and have continued to publish papers, and present at numerous international conferences.^[133,136,140] We are leading a package of methodological work on integrating multiple sources of evidence, presenting at an international symposium, and producing an e-book chapter. We have published a number of papers, in particular on the rising tide phenomenon in complex interventions, and on current and future directions for the headroom approach to device development (*Int J Technol Assess Health Care*. 2015;31:331-8).

Implementation Highlights: A paper on new approaches to evaluating complex health and care systems was widely disseminated, with a call to action that “complexity needs to be embraced, not eliminated”.^[137]

Examples of Impacts on Health & Wealth: A report on unplanned hospital care in Worcestershire has been submitted to NHS England.

Progress, Achievements and Challenges Against Objectives:

Short-term objectives: We have provided **methodological expertise** and applied research support for the four service themes, including statistical support, systematic reviewing, health economic analysis, data analysis, modelling; and determining maximum benefits and cost-effectiveness thresholds. Projects included provision of emotional and psychological support for



renal patients; Heartlands Elderly Care, Trauma & Ongoing Recovery project (HECTOR) with the **Chronic Diseases theme (4)**; High Intensity Specialist Led Acute Care (HISLAC); service quality improvements in weekend services on preventable mortality and adverse events; and the impact of seven-day services in the NHS. Many projects are still in the development and/or result collection phase and so do not yet require methodological expertise.

Medium-term objectives: **Conducting methodological research** on research methods:

- Several systematic reviews and meta-analyses on:
 - Health and economic consequences of patient-level adverse events, using results to estimate benefits of seven-day NHS services and evaluate HISLAC and e-Prescribing.
 - Causal modelling and Bayesian evidence synthesis methods for the evaluation of health service delivery interventions using multiple sources of data.
 - Publication bias in health services and delivery research (applying for NIHR HS&DR grant).
 - Early childhood cognitive interventions for promoting child development.
- Economic evaluation of the GP recruitment process in the UK.
- Reviewing methodologies and reporting techniques that maximise impact and uptake in educational policy and practice, with paper submitted on 'beyond synthesis impact chain'.
- Conducting analysis on the effect of large sample sizes in biased RCTs and its practical consequences, arguing that large sample sizes exacerbate the problems of biases.
- Methodological project on interventions designed to stimulate local innovation rather than adhere to pre-formed protocol, stimulated by Coventry City Council.
- Comparing passing standards for written finals examinations in UK medical schools over three academic years. Results presented at two research meetings/conferences.
- Modelling associations between housing improvement and health improvement.
- Examining association of alcohol retail outlets and alcohol-specific hospital admission of young people.

Long-term objectives: To **promote public engagement** with applied science we have presented a short workshop on the use of Bayesian methods in health services research at a one-day meeting at the Health Foundation; and been featured on local radio shows discussing weekend hospital admissions, and NHS finances.

Links with NIHR Infrastructures:

National NIHR CLAHRC Collaborations: Following an approach to the CLAHRC Directors in September 2015, it has been agreed that CLAHRC WM will lead a piece of work nationally on behalf of the CLAHRCs to develop the science around the health economics of service delivery. The aim is to populate the MRC framework with evidence on tools and techniques to use in service delivery research. A meeting for the CLAHRCs chaired by CLAHRC WM was held in January 2016, with further events and publications planned.

We have been collaborating with CLAHRC North West London (CLAHRC NWL) on the STATS study to evaluate the use of statistical process control within hospital board papers to support better decision making with papers now published.

NIHR Infrastructure: Prof Richard Lilford is Chair of the MRC/NIHR Methodology Advisory Panel. Prof Lilford and Dr Sam Watson also leads the health economics components of a NIHR Programme grant on e-prescribing in English hospitals and a NIHR HS&DR grant named HiSLAC

which is examining the issue of seven day consultant cover in hospitals.

West Midlands AHSN: The Head of Programme Delivery (Engagement) role has seen an increase in engagement and joint working with WM AHSN. One of the key projects for the West Midlands has been the launch by the AHSN of the Meridian innovation platform. CLAHRC WM has been an important stakeholder in providing methodological tools and support for product evaluation and sharing networks of research active and interested NHS staff who can provide critical appraisal of technology or innovation from a service delivery perspective.

Links with Industry: Medtech/Devices. We continue to work closely with all relevant partners within the ITM on medical technology and devices including the NIHR HTC, MidTech, Medilink and the WM AHSN. In particular we are working to include the 'headroom method' through an Engineering and Physical Sciences Research Council (EPSRC) grant to work with the Meridian online innovation platform. This allows early appraisal of the financial viability of products and devices and can significantly accelerate the innovation pathway.

Forward Look: Co-authors on a paper recently accepted by the Lancet that reports findings from weekend specialist intensity and admission mortality in acute hospital Trusts in England. The work chimes with previous findings published by the same research group recommending that policy makers should exercise caution before attributing the weekend effect primarily to differences in specialist staffing.^[138]



Case Study: Measure Health Economic Impact of Service Delivery Research

While health economics methods are well developed in areas such as Health Technology Assessment (HTA) for devices and drugs, they have significant issues when applied to examples of service delivery, such as the redesign of a service or treatment pathway. For example, the output often sought for measurement is 'adverse events,' which can come in many forms and sizes, and are therefore difficult to detect accurately and comprehensively. Similarly, complex service change can result in a large number of end-points at multiple levels within a healthcare system and these causal chains need to be defined and modelled accurately. Bayesian methods could potentially provide solutions to some of these issues, but it is not widely accepted and requires further development. Finally, a distinction needs to be drawn between theoretical cost-effectiveness and affordability within the real life health and social care contexts.

If an improved and academically endorsed theoretical model can be developed this will provide a significant contribution to service development and redesign within the NHS and beyond. Many current assessments of cost-effectiveness are fundamentally flawed and therefore developments may be being promoted that are less cost-effective than current models. To address this conceptual issue, we wrote to all other CLAHRCs asking about experiences they had had of these issues and inviting them to collaborate on finding an improved theoretical framework. This collaborative approach should provide a more comprehensive coverage of the known issues with current methodology, and, if the inputs to the model are pre-agreed, it should be easier to adopt and embed the outputs in practice at scale and pace.

Following this agreement, we hosted a national cross-CLAHRC meeting, which resulted in a draft publication. A national symposium is also planned for summer 2016 in conjunction with Universities UK to discuss the initial findings and to further develop the theoretical framework. The aim will be to submit a grant application for a wider and more definitive solution, or to have this area of work adopted as a work stream within a research organisation such as The Health Foundation, Academy Health or the Medical Research Council methodological framework. The economic impact of this project could be extremely significant as it has the potential to change the way all service redesign projects are costed within healthcare, and is likely to expose flaws in previous calculations of the cost-effectiveness of healthcare services.

We hope that this novel cross-CLAHRC collaboration will lead the way for other issues of significance to be tackled in this way, leading to quicker and more comprehensive resolutions of problems and the development of solutions that are more readily accepted and implemented by the academic health research community at large.

If, as expected, the proposal results in a new methodological framework to underpin the cost-effectiveness calculations of new and redesigned services then this will be a very significant contribution to applied health research, which will be solely attributable to the CLAHRC initiative. The opportunity to consult with the various subject matter experts and academic partners within the wider CLAHRC network has been invaluable in providing a diverse and comprehensive coverage of the issues encountered in this field.

Case Study: International Reach & Scientific Development of Themes

Our second international Scientific Advisory Group (SAG) involved a number of applied health research experts from across the globe, and significantly influenced the scientific development and the theoretical advancement of our themes. During the event we held 'speed dating' sessions, where particular scientific challenges emerging from CLAHRC WM research activities were presented for discussion and development with the scientific advisors on the topics of *Implementation and Study Design; Modelling, Mathematics and Statistics; Study Design and Economics; and Implementation Science*. From this key points and advice emerged:

On methodology:

- Suitable study design, including defining primary outcome of service delivery evaluations.
- Modelling, health economics and decision support for disinvestment and/or recommissioning decision-making.

On the intervention itself:

- Considering the specific training needs required for health and social care services to deliver new practice/services and use of 'simulation' to support staff training.
- Tackling the diversity of clinical settings and the role of context through application of theory of change models to understand the implementation.

On progression and future work:

- Considering exploiting evidence or knowledge gaps.
- Collaborating with other national or international groups to encourage wider rollout.
- Establishing recommendations for reviews by ranking trials by intervention/treatment rather than effect size.

Subsequently, our themes have used the advice and support to develop project protocols, implementation plans, papers and further grants. Here we showcase three examples:

The **Chronic Diseases theme (4)** presented plans for evaluation of a hospital-supported early discharge service for frail patients, which aims to provide integration across settings between acute care and the patient's home. The current service is provided to over 65s admitted to hospital as an emergency and who are likely to stay in hospital for at least 14 days. The new service offers early discharge, with two weeks of home rehabilitation from hospital trust staff, followed by six weeks of re-ablement therapy, co-ordinated by the local authority. SAG advisors suggested ways to plan a robust evaluation. Specific feedback included:

- To manage the expectations of the Trust in terms of what could be achieved if robust data on costs, etc. were available versus what can be achieved with the existing data, as a conventional evaluation may not be possible or desirable.
- As post-hoc evaluations are difficult to design effectively, an 'implementation assessment' may be more appropriate. This would include detailed mapping of the discharge service, qualitative work with staff and patients to ascertain satisfaction, workloads, perceptions of effectiveness and integrated working, and basic analysis of routine data, such as length of stay.
- To understand the difference between what was planned and what was implemented, along with tracking changes and evolution of the service over time, and their rationale.
- Relevant publications that could be useful in planning the evaluation, and informing the study.

- To focus on understanding how the burden of service provision shifts between providers – for example, there may be apparent cost savings that may be attributed to the discharge service, but which may be due to costs shifting elsewhere, so cost-efficiency was suggested as being more important to ascertain than conventional cost-effectiveness.

The **Maternity and Child Health theme (1)** presented the BSOTS project (see page 12), a feasibility study for implementing a maternity triage system in other maternity trusts. Currently, there is no established system within maternity care for the initial assessment (or triage) of women and their babies when they attend for an unscheduled visit. The BSOTS system was developed to standardise the initial assessment of women's clinical condition and prioritise the order in which they are seen. Initial evaluation found that more women were seen and assessed within 15 minutes of arrival, and those who needed to see a doctor quicker. The system is now being rolled-out to other maternity units. Feedback from SAG advisors included:

- Using a central trainer could mitigate the fidelity of training, as it may be poor.
- A two-step approach may be required: the study needs to look at causation as well as the process in order to understand the delivery of the intervention in diverse settings. By observing the training in other sites the researchers could explain varying outcomes at different sites. This could be done through observation of different training in different centres; surveying trained staff; exploring how the training is implemented; and/or examining whether women are being categorised accurately to assess whether the training has been correctly implemented.
- Self-efficacy of the midwives carrying out the triage assessments is a key outcome and so could be measured as a training outcome. For example, asking about their confidence, experience, the impact of training, etc. It could be incorporated into training as a behaviour change tool in order to help change current practice.

As a direct outcome the study design was amended to observe training as it was rolled out, in order to increase understanding of the delivery of the intervention in diverse settings. This also led to subsequent discussions around the possibility of introducing other forms of training so that midwives have more confidence when delivering training.

The **Prevention and Detection of Diseases theme (3)** presented the Health Checks programme and their plan to evaluate it using three connected work packages. Advisor feedback included:

- Focusing on a single element of the Health Check programme, such as overtreatment/over diagnosis. The best evidence is around statin prescribing as data are best recorded for this.
- Using Health Checks as a healthcare tracer study to look at GP engagement, service-user uptake and Local Authority engagement.
- Conducting a comparative study – Quality and Outcome Framework (opportunistic) versus NHS Health Checks (systematic).
- Advised of an in-press study on why GPs don't engage with the Health Checks programme. CLAHRC WM researchers could investigate the use of social norming among GP practices to increase participation.

We plan to replicate the successful 'speed dating' sessions with experts for themes and postgraduate faculty at our next international scientific advisory group.

Case Study: International Collaborations

‘CLAHRC for Africa’: This is an international applied health research centre aiming to bring together individuals, disciplines, and organisations to develop practical solutions to health needs, transform health systems, and improve the health of populations in low- and middle-income countries (LMICs). It is directed by the CLAHRC WM Director, Prof Richard Lilford, and CLAHRC WM has formed a strategic partnership with the Liverpool School of Tropical Medicine.

Research methods developed by the **Research Methods theme (6)** can often be translated to low- and middle-income settings, including assessing economic value; Bayesian approaches to knowledge for decision-making; and the design of trials, in particular cluster step-wedge design.

Since the inception of ‘CLAHRC for Africa’, the team has won funding for a training intervention to improve the health literacy of lay Community Health Workers in rural Southern Africa (£150k).

They are also working with international collaborators to provide methodological expertise on study design and health economics. For example:

- Implementing integrated comprehensive, community-based health care for vulnerable communities (South Africa).
- Determining the feasibility, effectiveness and cost-benefit of scaling up a baby-friendly, community-based approach for improving maternal, newborn and infant nutrition practices; and implementation of a baby-friendly workplace support initiative (Kenya). It is anticipated that these will inform the development of guidelines for workplace support in Kenya and beyond.
- A multicentre, randomised trial to reduce surgical site infection following emergency gastrointestinal surgery in LMICs.
- Evaluating the impact of the introduction of user fees (Malawi).
- Facilitating multi-centred research to improve the evidence base underpinning potential responses to the increase of cardiovascular disease, in particular workplace health programmes (Nigeria).
- A business case around the short- and long-term benefits of human milk banking, including its effectiveness and cost-effectiveness (South Africa).

CLAHRC for Africa have also developed a number of major grant applications, including work around perioperative antibiotic use in LMICs; effectiveness of a peer-led diabetes self-management programme in a Nairobi slum; a consortium for advanced research training across Europe and Africa; improving diabetes care at primary healthcare level in Cameroon through community-based peer support; and improving integration of care for chronic diseases through enhanced clinical handover in India.

A number of papers have also been published.^[29, 40, 141, 143, 144]

Prof Lilford also sits on the board for the Consortium of Advanced Research Training in Africa, which aims to strengthen doctoral training in Africa to enhance local production of high-quality, world-class and well-trained researchers and scholars.

CLAHRC Australia: In addition to work on low- and middle-income countries, CLAHRC WM has built on existing relationships with academics and research institutions in Australia (including the University of Monash, Macquarie University, Monash University, and the Royal Children’s Hospital, Melbourne), aiming to promote the CLAHRC brand, export models of care internationally, and accelerate the exchange of ideas and information. Prof Helena Teede, Director of the Monash

Centre for Health Research and Implementation (the closest thing to a CLAHRC model in Australia), has been instrumental in developing this mutually beneficial relationship. During a visit to the UK Prof Teede gave a well-received guest presentation to our Programme Steering Committee, exchanging knowledge and discussing challenges relating to applied health research in Australia. To cement our commitment to future collaboration we have recently invited Prof Teede to join our Scientific Advisory Group

These links with Monash University build on our current links with applied health research in Australia in the form of Prof Jeffrey Braithwaite, a member of our Scientific Advisory Group from Macquarie University. Prof Braithwaite is an internationally-renowned expert in service improvement (particularly in acute settings), health services and systems research, and is Founding Director of the Australian Institute of Health Innovation. At our Scientific Advisory Group meeting in June 2015, Prof Braithwaite gave an eloquent critique of work on modelling causal pathways in health services, arguing that health services are so complex that they cannot be evaluated by quantitative means. This generated a spirited debate, epitomising the spirit of the event, which aims to contribute to the theoretical advancement of our cross-cutting themes.

Dr Sara Kenyon, **Maternity and Child Health theme (1)**, visited the '*Healthy Mothers, Healthy Families*' research group at the Royal Children's Hospital in Melbourne, Australia, and has since been appointed as an Honorary Fellow. Dr Kenyon is also a co-applicant on a grant application for a targeted RCT of an antenatal mindfulness intervention to reduce maternal anxiety and improve infant cognitive development. Jane Yelland, a Senior Research Fellow with the group is scheduled to give a seminar on her work with a particular focus on vulnerable women and their families. We hope to collaborate in the future.

Our cross-cutting themes are undertaking several research projects with Monash University, facilitated by the Monash-Warwick Alliance, a research-led partnership between the Universities of Warwick and Monash that aims to promote knowledge transfer and academic collaboration.

Prof Graeme Currie is the 'International Advisor' on a Linkage Project funded by the Australian Research Council (AU\$0.5m directly funded, plus almost AU\$1m of matched funding) designed to support transformation of healthcare system in Victoria State. Evaluation is fed back in real time to ongoing transformation, drawing on lessons derived from the **IOS theme (5)**. This is part of a £2m portfolio of activity funded by Warwick and Monash Universities to develop international collaboration in healthcare improvement science.

The **Research Methods theme (6)** is also working on a grant application to the Australian Research Council in collaboration with University of Monash on stepped wedge trials.

CLAHRC WM has provided a model of carrying out collaborative applied health research to improve health systems, which we have been able to disseminate internationally, as well as contributing to the development research projects to potentially improve the health of populations in LMICs. It has allowed us to develop special expertise in research methods such as supply side health economics, step-wedge cluster design, and Bayesian bias modelling, which are now being translated internationally.

Case Study: Communication with Patients and Wider Public

CLAHRC West Midlands News Blog

Our News Blog is issued every two weeks to ~1,500 readers spanning academia, health and social care partners, and stakeholders, aiming to inform and encourage debate, and keep people up to date.

The content has continued to evolve based on feedback. We removed the dedicated international section in order to tighten the main focus, and increased the number of shorter posts on important papers.

Currently, each issue features:

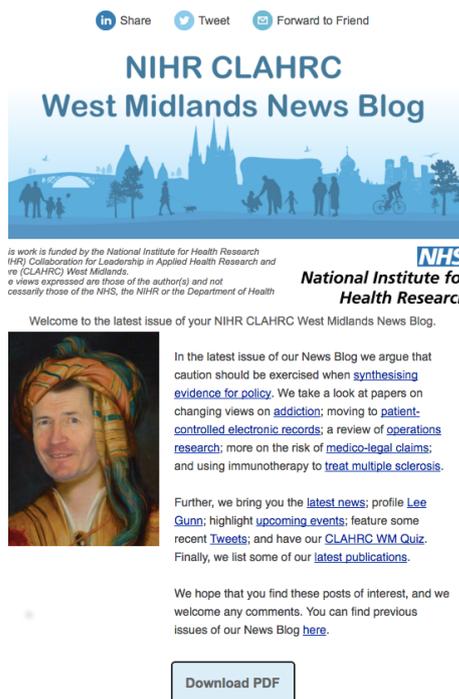
- An in-depth blog on a topic of interest, for instance an idea for future research/practice, recommendations, or recent research. Examples include the impact information technology could have on staffing levels; and the development of lay community health workers.
- Five or six short blogs focused on interesting papers.
- An occasionally 'Guest blog', such as on using real-time simulation to improve dialogue when discussing place of birth options.
- A PPI section on news, activity and the impact of CLAHRC WM research on PPI, often written by the PPI advisors or PPI leads from each theme. This provides a means of communicating opportunities for future PPI engagement and participation, and has raised awareness of PPI within CLAHRC WM, helped contextualise how the PPI strategy is implemented, and shared examples of good practice.
- A profile of a member of staff, increasing their visibility and providing networking opportunities.
- Selected replies, often featuring insightful views with links to further information.
- News, including calls for abstracts, meeting reports, job opportunities, achievements, etc.
- Upcoming events from various institutions, including the WM AHSN, NIHR organisations, other universities, etc.
- Recent publications/grants from CLAHRC WM authors (with links where available).
- A quiz question and answer (with links to more information), which receives many responses.
- Brief summaries of recent BITEs, with links to the full version.
- Key tweets, such as from ourselves, the NIHR, research charities, health policy commentators.

We also provide a PDF version for accessibility and a link to previous issues online. Further, we endeavour to be inclusive, by mailing hard copies to those who do not have online access. Other CLAHRCs have commented that they have used our blog as a template for their own blogs. We have plans to link the blog with other commentators in the health research sector, such as Head of the HSMC Judith Smith, whose regular blog covers similar topics.

In its first two years of publication, our subscriber list has risen steadily from 468 to 1,511, with over 240 new readers in the previous year. Even with the growth in subscribers, the percentage confirmed to open each issue has remained consistent at 25-27%. In absolute terms, the number of people opening each issue has grown by ~50% since last year from an average of 231 during

12 Feb 2016

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NIHR CLAHRC West Midlands News Blog

is work is funded by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and re (CLAHRC) West Midlands. e views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health

NHS
National Institute for Health Research

Welcome to the latest issue of your NIHR CLAHRC West Midlands News Blog.

In the latest issue of our News Blog we argue that caution should be exercised when [synthesising evidence for policy](#). We take a look at papers on changing views on [addiction](#); moving to [patient-controlled electronic records](#); a review of [operations research](#); more on the risk of [medico-legal claims](#); and using immunotherapy to [treat multiple sclerosis](#).

Further, we bring you the [latest news](#); profile [Lee Gunn](#); highlight [upcoming events](#); feature some recent [Tweets](#); and have our [CLAHRC WM Quiz](#). Finally, we list some of our [latest publications](#).

We hope that you find these posts of interest, and we welcome any comments. You can find previous issues of our News Blog [here](#).

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year 1 to 350 during year 2, with a recent peak of 411 opens. These figures are likely an underestimate due to the method of data collection used by the hosting platform. While most of our readership is based in the UK, the News Blog has a substantial international reach with subscribers in 61 different countries opening at least one issue, including a significant number in the USA, Canada, Russia and South Africa.

The new-look CLAHRC WM website, www.clahrc-wm.nihr.ac.uk

We recently launched our new-look website at the University of Warwick. We have added several new sections developed in consultation with CLAHRC faculty, PPI advisors and NIHR trainees and aim to continually update and evolve in response to user feedback. Notable changes include:

[Patient and Public Involvement](#)

(clahrc-wm.nihr.ac.uk/ppi). This was developed with input from our PPI Supervisory Committee, and was created by Ray Fiveash, a PPI Advisor. It is structured into three distinct areas to mirror the definition of PPIE set out by NIHR INVOLVE: **Involvement**, providing details about how PPI Advisors influence the creation and design of research; **Engagement**, providing information and knowledge about research; and **Participation**, where Advisors are invited to take part in research studies. We also link to other resources, glossaries of health research terms, and the one-page PPIE strategy.

[CLAHRC Impact](#) (clahrc-wm.nihr.ac.uk/impact). This allows us to communicate examples of impact on the service, both locally and nationally. It links to our BITEs; national CLAHRC newsletter articles on CLAHRC WM research; the *World Class Research Making a Difference* document; key statistics from our Annual Report; and the published version of our Annual Report.

[Capacity Building](#) (clahrc-wm.nihr.ac.uk/about/building-capacity) Developed with input from our NIHR trainee representatives, we aim to publish a database of all our related NIHR postgraduate students and trainees, including their supervisors, project title, and contact details. This new section facilitates networking and collaboration between trainees, and with wider stakeholders.

[Our Research](#) (clahrc-wm.nihr.ac.uk/research) Following consultation with Theme Leads, we now feature a full list of profiles for all research team members; an up-to-date table of current projects (including lay summaries); and regularly updated publications where themes can request other relevant resources, reports or documents to be made available. We also link to relevant BITEs.

To establish how the website is being used, we have recently started to measure its impact through web analytic reports. Although we only have limited data at present, we intend to continue monitoring activity on a monthly basis in order to provide a greater depth of analysis and further improve the impact and usability of our website. Between 8 March 2016 and 18 April 2016, there were over 1,500 views of our website, with an average of 2.87 pages viewed per session. The most popular page is the homepage (443 views), followed by the research pages for the **Prevention and Detection of Diseases theme (3)** (166 views), and the capacity building section (66 views). Of note, 15% of page views are made using a mobile device, so we intend to review our webpages and ensure they are optimised for mobile browsing. As with the News Blog, we have seen considerable international interest, with visitors from the USA, India, Australia and China.



Patient and Public Involvement and Engagement

Meaningful involvement of our 13 Patient and Public Involvement (PPI) Advisors continues to enhance the quality of research undertaken by CLAHRC WM. Patients and the public are powerful agents of change and their knowledge and expertise can make a real difference to research. They provide insightful contributions at all stages of research: project initiation; research and service design, delivery and analysis; and disseminating findings (pages 48-49). CLAHRC WM is committed to further enhancing its Patient and Public Involvement and Engagement (PPIE) strategy, and developing and sharing areas of outstanding practice. A PPIE Officer has been appointed to drive the strategy forward.

Patient and public involvement: CLAHRC WM's PPIE strategy is clearly signposted on our website. Key points include: involving patients and the public in the management of science; involving patients and the public in the design of service interventions; developing a programme for engagement in applied research; and ensuring the voices of 'seldom heard' groups are acknowledged. Working in close partnership with the PPI Steering Committee, the PPIE Officer will develop our PPI strategy, making it clearer and ensuring our vision is aligned to NIHR's 'Going the Extra Mile' and local PPIE strategies.

Themes: PPI Advisors are embedded in each theme, and a researcher within each theme acts as a liaison, ensuring that PPI benefits are maximised. There is no definition of how each theme should work with its representatives, but we advocate a flexible approach to develop a model of working that incorporates the Advisors' skills, knowledge, interests, and experience.

Steering Committees: The PPI Steering Committee has met three times over the year and has developed and approved its own Terms of Reference. These meetings have been an effective forum to discuss the breadth and depth of PPI within CLAHRC WM: advisors have shared their experiences of good practice with regard to PPIE in applied health research, and discussed strategies to ensure that involvement is more meaningful. They have also provided an opportunity for researchers to discuss research ideas in their embryonic stage and gain valuable feedback from the Advisors. The Steering Committee maintains a strong link with researchers on the **IOS theme (5)**. Lee Gunn and Alison Hipwell are investigating PPI and implementation, and have presented their progress to the Advisors, generating valuable discussion and debate. Researchers at Keele University have recently published their work on PPI good practice and sustainability.^[68,79]

CLAHRC Steering and Executive Committees: In accordance with the CLAHRC WM PPI strategy, there is patient and public representation on CLAHRC WM's Steering and Executive Committees. The elected Chair of the PPI Steering Committee, Reverend Barry Clark, sits on both Committees to ensure continuity. In response to feedback from Advisors and in alignment with NIHR's 'Make it Clear' campaign, theme leads now provide lay summaries for research projects to be discussed at meetings. Advisors ensure that the patient voice is heard, and there have been valuable contributions from advisors at the Steering and Committee meetings.

Public engagement: We are continually exploring ways in which PPIE can be enhanced, and are working to raise the profile of PPIE in applied health research and share knowledge and experience of good practice.

PPI Internships: This new initiative is designed to provide support to PhD students and early career researchers to better understand the role of patients and the public in health service delivery research. There are three types of opportunity available through the Internship:

- 1) An opportunity to shadow PPI professionals to offer insights into coordinating patient and public involvement;
- 2) To access feedback from the PPI Advisors through theme / Steering Committee;
- 3) To 'buddy' a PPI Advisor and gain an understanding of their role.

Although in its infancy, PhD students have expressed an interest and some have requested feedback from PPI Advisors through theme / Steering Committee meetings. We hope to generate more interest and uptake by promoting positive testimonials through the CLAHRC WM news blog.

PPI in Implementation: The **IOS theme (5)** hosted a workshop on how patients and the public can be involved in research implementation. The planning and facilitation of the workshop benefited from input and involvement from PPI Advisors.

Raising awareness of research and implementation activity: There have been significant revisions to the PPI section of our website over the last year and there is now a prominent link from the landing page. There was significant input regarding the design and content of the website and a PPI Advisor was recruited to work on incorporating the suggestions to the final pages. It is now structured around three key areas: involvement, engagement and participation. Lay summaries on the website provide information about CLAHRC WM's research projects and there is information about the ways in which patients and the public have influenced research design and implementation. Development of the website is ongoing with further enhancements planned including: profiles of PPI Advisors; a diagram illustrating the breadth of networks our PPI Advisors are linked to; and case studies highlighting areas of outstanding practice.

We have also developed a template for researchers to use when recruiting patients and the public to their studies, ensuring that the recruitment process is transparent and that prospective representatives are informed of expectations and obligations.

CLAHRC WM is committed to ensuring that researchers are aware of the benefits of meaningful PPIE and are informed about best practice. Presentations have been delivered at a number of events with positive feedback, including to Leadership Fellows, Postgraduate/Early Career Researchers; and University Hospitals Postgraduates. Several researchers attending the workshops have contacted CLAHRC WM regarding involving patients and the public in their projects.

CLAHRC WM also aims to ensure that information about PPI reaches a wide and diverse audience. Central to raising the profile of PPI is the dedicated PPI section to the CLAHRC WM blog (pages 44-45). This also provides a valuable opportunity to promote opportunities for involvement, participation and engagement not just within CLAHRC WM, but through organisations such as the NIHR; HTA and Healthwatch. In addition, our Twitter feed has promoted campaigns such as 'OK to ask', 'Make it Clear' and 'Going the Extra Mile'. We are also looking to communicate messages using short films to further our reach.

The PPIE Officer plans to develop a series called 'Methods Matters' to help explain methods applied in service delivery research (such as Forest plots, and control charts) to a wide audience, including CLAHRC faculty and the wider public.

Case Study: Impact on Patient Care from Patient and Public Involvement

We are committed to working with patients and the public, and have appointed 13 PPI Advisors to ensure that patient views are represented at all levels (pages 46–47). Patients and the public can use their knowledge and experience of the patient journey to work with researchers to design and carry out studies that ask the right questions, collect the best data, and result in improved service, better quality research, and better outcomes.

There are many different ways such partnerships can work and below we highlight some of the innovative approaches our researchers have taken. By highlighting examples of good practice and demonstrating innovation we aim to help researchers better understand the benefits of PPI and inspire researchers on how to involve patients and the public. CLAHRC WM researchers have recently published work as an example of best practice and sustainability.^[68,79]



STarT Back – Subgroups for Targeted Treatment Back Trial. This investigated the way in which patients with back pain were cared for. The project developed a model of managing treatment that ensured the **right treatment was delivered to the right patient at the right time**. Patients and the public helped to roll out the evidence-based model to routine clinic appointments. This has reduced disability; reduced waiting time for physiotherapy appointments; and reduced time off work for patients with

back pain. Their contributions were critical to ensuring the success of STarT Back; in particular, they helped develop a range of written materials about STarT Back in different formats that were used throughout the study. Their knowledge and experience of back pain meant that they knew what was most important, and they made sure that the main messages were easy to understand and that the language and layout was clear and easy to follow. These included a **written information leaflet** for all patients to help in their recovery; a **website** (for which a patient came up with the strapline: ‘*get the right treatment to the patient*’); a **manual for Allied Health Professionals** (e.g. physiotherapists, podiatrists, occupational therapists) to use when having conversations about back pain as part of the *Every Contact Counts* initiative, including examples of how a conversation about back health could be started. Researchers were also keen to find out what patients thought of the new model of care and patients and the public helped design a **questionnaire** to capture the patient experience.

Osteoarthritis in Primary Care. Researchers on this project worked closely with a ‘*People with Arthritis and Rheumatism*’ group in all stages of the research cycle. Using their personal experiences, patients and the public worked with researchers to develop a **model GP consultation**, sharing ideas about what does and does not work. This was later trialled. To ensure the model was delivered properly, patients and the public participated in the production of a training video for GPs and practice nurses. They also helped produce a **guidebook** for patients on self-management of osteoarthritis, advising on what information to include, how this should be presented, and ensuring the language and important messages were clear. Researchers also wanted to find out how patients rated their experience of management of osteoarthritis in primary care. Patient advisors were able to advise on what to include in a **questionnaire**, how to word the questions, and when the questionnaires had been completed, helped researchers understand what patients said and how it could be used to improve the quality of care patients receive.

ENHANCE study. This pilot stepped wedge trial to test the feasibility and acceptability of a novel practice nurse consultation is aimed at improving care for people with long-term conditions. The study aims to integrate case finding and initial management of osteoarthritis and anxiety and/or depression into routine primary care chronic disease reviews. The team have used multiple methods to develop the content and format of the new nurse-led enhanced consultation (evidence synthesis, stakeholder workshops, practice nurse and patient advisory groups). In addition, the new consultation was pre-tested (offline) using simulated patients from the *Arthritis Research UK Primary Care Centre*. This highlighted issues related to (1) the language that the nurse might use when discussing multi-morbidity, (2) ease of moving between questions in the enhanced review; and (3) research processes e.g. timing of giving the patient the research pack. Amendments were made to the enhanced review to improve the experience from a patient perspective and learning was fed into the nurse training. This has optimised delivery of the new review for patients attending their long-term condition review with the practice nurse.

Magnolia House. This is a building in Birmingham where families and staff can prepare for the death of a child. Researchers understood that families who had been through the difficult and distressing experience of losing a child would know best what kind of place Magnolia House should be and what improvements could be made to make the experience easier. It was also important for researchers to find out what the staff who worked in Magnolia House thought and to consider their suggestions. It is not easy for families to talk about experiences related to the death of a child, so the research needed to be done sensitively. Researchers held a **Family Art Participation Day**, with bereaved parents, staff from Birmingham Children's Hospital, funding/charity representatives, and members of the Young Person's Advisory Group. The purpose of this was to produce artwork for Magnolia House and to share information about Magnolia House and the service it provides. At the start of the event, participants were given a questionnaire and informed of the purpose of the evaluation. Researchers did not want the questionnaire to impact on producing artwork, so participants were told they could complete the questionnaire when they wanted, to only complete the sections that were meaningful to them, and that they weren't obligated to complete the questionnaire. Questions were based around one main question: '*How will we know if Magnolia House is working well?*' Participants could also talk to researchers if they wanted to discuss Magnolia House and ideas they had.

The evaluation found that families valued feeling safe, secure and welcome in Magnolia House; wanted to be treated with compassion and dignity; and to feel a sense of belonging and togetherness. Families also said it was important for Magnolia House to be homely and peaceful so that they could have the time and space to think and reflect. Not all hospitals have a place like Magnolia House, and researchers were able to use this information to describe the importance of places like Magnolia House and what the environment should be like to make the experience for families as bearable as possible.

The four case studies above demonstrate that CLAHRC WM has worked in partnership with patients and the public in all stages of the research cycle. In each of the cases, researchers developed ways of working with patients and the public to ensure that their knowledge, skills and experience could be captured and would contribute to the research project. In all examples, the valuable contributions of patients and the public helped produce better research, which, in turn, helped design better quality of care for patients.

Capacity Development & Training

We continue to deliver our strategy, to develop capacity for service delivery research in academia, the health service and among patients and the wider public.

Development of staff in all clinical and non-clinical professionals: We continue to develop the capacity of both clinical and non-clinical health staff embedded in our partner organisations in the form of matched funded **LFs**. We have developed a bespoke training package, based on the knowledge and skills gap of this group, following a 'needs assessment exercise'. The most recent event in this series focused on health informatics to provide an introduction to the types of data that are available and how they can be used to underpin health services research.

LFs also receive 'specialist' support from the themes to which they may be attached. For example, the *research midwives forum* - an initiative established by the **Maternity and Child Health theme (1)** to support and develop the capacity of this specialist group (page 16).

Furthermore, we have a number of joint appointments between service and academic organisations, which support collaborative working. Professor Tom Marshall is funded by both the University of Birmingham (NIHR funding) and Heart of England NHS Foundation Trust (matched funding) resulting in an additional grant to look at hand hygiene. Further, Dr Valerie Tan, an academic GP, has been embedded in the ENHANCE study at Keele University (NIHR funded study) and is undertaking an MPhil to complement evaluation of the ENHANCE nurse-led long term condition review (matched funding).

We are working collaboratively with public health LFs based within local authorities in the region who attend our training seminars. Six fellows, including two from Birmingham City Council and four from other healthcare partners, were funded to complete masters programmes with the majority opting to complete the Masters in Public Health (MPH) and all are achieving a minimum award of merit or distinction in assessments.

Our **Prevention and Detection of Diseases theme (3)** is collaborating with local authorities in Coventry and Warwickshire on a project to evaluate the '**health checks**' programme. This project was the outcome of a successful training event to support the local implementation. Furthermore, this theme organised a sell-out, one-day '**health screening masterclass**', that took place on 3 May 2016. The event was supported by the NSC and covered the definition of screening, availability of programmes available in UK, policy making processes and the remit of the NSC.

Particular strengths of the training environment

The NIHR funded faculty are supported by multidisciplinary teams both at individual theme level and through the expertise and support from other themes bridging the Universities of Birmingham, Keele and Warwick. We provide opportunities for inter-CLAHRC collaboration and this has stimulated new collaborative projects, grants and papers. For example, a paper recently published in *Early Intervention in Psychiatry Journal* was the product of a collaboration between primary care case-finding experts from the **Prevention and Detection of Diseases theme (3)** and early intervention in psychosis researchers from the **Youth Mental Health theme (2)**. The paper demonstrate a predictive model to identify early warning signs of depression in young people in primary care.^[20]

Extending the academic capacity across a number of university campuses maximises our areas of expertise so creating an intellectually strong and dynamic training environment for both the NIHR funded and supported faculty and the LFs supported by matched funding. The Universities

of Birmingham and Warwick currently provide academic placements for public health trainees and in the future placements may also be available at Keele University.

We have recently formalised the link with our host Trust's (UHBFT) postgraduate training programme (Annex U) with a number of students undertaking specific CLAHRC projects as part of their dissertation. For example, one health economics student is working with our **Chronic Diseases theme (4)** and a geriatrician at UHBFT to evaluate a service designed to prevent the admission to hospital for frail elderly patients. We have recently supported a successful application to deliver a pre-Masters Clinical Academic Internship Programme (CAIP) and Masters to Doctorate Bridging Programme and continue to collaborate with CAIP to deliver our respective training objectives.

We have developed two specific masters (MSc) programmes. The MSc in Health Research Methods at Birmingham will receive its first students in September 2016 and CLAHRC faculty will receive a discount on tuition fees (<http://goo.gl/2sQITJ>). A MOOC is being developed as a precursor to the MSc in Healthcare Innovation and Leadership at Warwick Business School and it is anticipated that these will launch in early 2017. CLAHRC researchers will be invited to provide some of the content for the above formal courses to showcase case studies from empirical applied health research investigations.

Our approach to ensure that research student/support staff receive a high quality development experience

Postgraduate students are embedded within our themes and are supported by the multidisciplinary academic environment provided by the initiative. A training plan for 2016 was agreed with the postgraduate faculty, following an event held on 19 November 2015 to explore career opportunities and consider how CLAHRC could further support a shared learning experience. Additional learning objectives identified by the group included ethics/governance, PPI and collaboration/engagement for successful applied health research. The first of these graduate tutorials, *setting up research in the NHS: ethical and practical considerations*, was held on the 24 February 2016 and included external speakers from the Health Authority Agency (HAA), West Midlands CRN, South Birmingham Research Ethics Committee and ethicist from University of Birmingham.

Jennifer Cooper (University of Warwick), has been successful in her application to the NIHR Infrastructure Doctoral Exchange Scheme and will undertake a placement at the University of Birmingham, supervised by Prof Tom Marshall, to gain technical primary care database skills and will explore the use of routinely recorded data from electronic GP records (THIN database) to improve colorectal cancer screening and referral. Amy Grove, the first successful exchange student, completed her placement at CLAHRC Yorkshire & Humber in summer 2015. Amy was embedded in the Translating Knowledge into Action theme where she gleaned some practical approaches to knowledge mobilisation and is working collaboratively on two papers; one to be submitted to Implementation Science and a further paper to Social Science and Medicine.

Collectively, we already hold a number of NIHR fellowships and one professorship and have recently supported further fellowship applications for round 9 of the scheme, which closed in January 2016. We are supporting several more in their applications to the NIHR Knowledge Mobilisation Fellowship and we currently support two NIHR Training Advocates – one for Midwifery (Dr Sara Kenyon, University of Birmingham) and one for Physiotherapy (Prof Nadine Foster, Keele University).

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