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ARC West Midlands News Blog

22 October 2021
Implementing evidence is a perennial problem and the basis of so-called ‘implementation science’. Our ongoing work shows that clinical research findings often fail to change practice. Most often the reason for non-adoption lies in the findings themselves. They may be null (within a context where the intervention is not already in use), unconvincing, or nuanced (showing both benefits and harms). However, findings from evaluations of health technology are more likely to be adopted than those from Health Services and Delivery Research (HS&DR). I can identify three reasons for this, one to do with the nature of the evidence (the seed), and two to do with the service barriers (the soil).

First, the nature of HS&DR evidence is typically more nuanced than evidence for HTA studies. In part, this is because effectiveness of service delivery interventions are (even) more context-dependent than technology assessments – the effect of interventions, such as financial incentives or private vs. independent providers, are typically heterogeneous across contexts, such that the results cannot be encapsulated in a simple ‘message’. Second, service interventions usually involve considerable financial outlay, even if they are cost-saving in the long-run, and the service that makes the expenditure may not be the service that reaps the savings. Lastly, there is less of a tradition of evidence-based practice among managers than among clinicians, as mentioned by Prof Judith Smith, herself a previous manager, in her inaugural lecture.

How then can research commissioners maximise the impact of their work? The headline message is encapsulated by the term ‘engagement’. Engagement can take many forms, but starts with demand, not supply. That is to say, it is crucial to involve (and even be directed by) managers in determining what is researched.
In ARC West Midlands we recognise that research requiring prospective data collection requires active engagement with service managers who are responsible for the interventions – the cost of the intervention and of collaborating with ARC WM researchers is recognised as co-funding, as explicated in previous News Blog articles.[1-2] Our researchers may play a role in knowledge management and study design, and then go on to carry out an independent evaluation, as exemplified in our recent study of a hospital-wide intervention to improve uptake of seasonal flu vaccinations among frontline staff.[3] However, notwithstanding some excellent examples, the vast majority of NHS Interventions are not evaluated; they are an untapped source of research potential. ARCs must continue to engage with health and social care providers to get in at the grass-roots and support the development and/or evaluation of interventions that they implement. However, ARC Directors have limited budgets, which are soon committed. A further idea is to seek applications from service managers to undertake research of interventions they are committed to evaluate. I had experience of such a scheme when I served as a member of the grant-awarding committee of the Canadian Patient Safety Research Programme. I propose a rapid response service funding scheme targeted specifically at service managers. I also think that representation of service managers should be strengthened on funding committees of all programmes concerned with funding Applied Service Research, perhaps especially at the outline stage.

Many service initiatives originate at the policy level, rather than the level of individual health and social care institutions. England has an exemplary, if recent, record for evaluating policies across government, especially in the case of education,[4] and I am a member of the UK Government Cabinet Office ‘What Works Trial’ on prospective policy evaluation. The Department of Health and Social Care funds research through the Policy Research Programme, and NHS England is funding research on the enduring potential influence of COVID-19 on service configurations through ARCs/AHSNs and the HS&DR programme. Continued engagement is necessary to ensure that evaluations of policies is reflexive so that, when appropriate, the evaluations can be prospective (and therefore more robust); a win-win for service and research alike.

On the supply side, engagement should exploit existing structures. It should also be guided by a piece of research from John Lavis showing that over 80% of the interventions managers make are driven by edicts from on-high (i.e. policy makers and respected leaders), rather than the literature, academic advice, or monitoring service quality or service user feedback.[5] Like other professions, they listen to their ‘guilds’ and are influenced by organisations they respect, such as Nuffield Trust, NHS Federation, King’s Fund in England. The corollary here is to actively engage with these respected organisations. Our work on control charts in ARC WM was summarised in Health Service Journals [6] (following publication in BMJ Quality & Safety [7]) and this in turn was picked up by NHS Improvement, leading to an intervention to improve uptake of Statistical Process Control charts in NHS hospitals, which has recently been evaluated (paper under revision). That said, it is important to return to the point made in the beginning of this article, namely that service delivery results are seldom ‘cut and dried’, such that a single study is sufficient to drive implementation. Rather, the literature needs to be assessed in the round to examine how it works (in a ‘realist’ tradition), and what factors (either in the design of the intervention or the context in which it is applied) may drive its profile of benefits and harms. This means that
publication of a report is not the end of the line. It is but the beginning of a process of assimilation, including updating evidence reviews. A fashion has emerged for making this the responsibility of the researchers, but this is an abrogation of responsibility by funders. Researchers may not have the funds or expertise to take responsibility for the assimilation process, and may be seen as partisan. I see a large role for funders here, but not each funder in isolation, rather all service funders working with respected, independent professional organisations and policy-makers. Part-and-parcel of this broader dissemination/engagement activity should be a study of the research commissioning process itself. How this is designed and executed will determine the quality, usefulness and importance of the research findings.

References:


4. Lilford RJ. UK Takes Over From the US as the Home of Trials of Educational Interventions. NIHR CLAHRC West Midlands News Blog. 1 June 2018.


Since January 2018, a research team at Warwick Business School has been leading the national evaluation of a five-year partnership between the NHS with Virginia Mason Institute (VMI), a healthcare-based consultancy based in Seattle, USA. Following a competitive process, five hospitals were selected in 2015 to receive five years of intensive coaching and support across all levels of leadership to build a management system shaped by Lean production principles and improvement methods. The aim of the partnership was two-fold: first, to foster a sustainable culture of continuous improvement capability in each of the five organisations through the transfer of knowledge and methods from VMI. Second, to generate lessons for NHS leaders about how to foster a culture of continuous improvement across the wider NHS system.

Most NHS organisations in England have experimented with lean-based improvement methods and tools during the last two decades, but very few organisations have implemented lean across the whole organisation, much less sustained implementation for five years or more. There is growing evidence, however, that a systematic approach to quality improvement across the whole organisation is positively correlated to organisational performance. For example, a report by the CQC (2018) identified the majority of hospitals rated ‘outstanding’ in England had adopted a systematic, organisation-wide approach to quality improvement, for more than five years.

The NHS-VMI partnership was formally a ‘capability building’ initiative, where each of the five partner hospitals aimed to learn how to foster a sustainable continuous improvement culture. Emphasis was placed upon learning, with a view that each partner hospital should expect to see improvements in quality, safety, morale and financial position. In other words, success was cast in vague and ambiguous terms, reflecting the belief that developing improvement capability would ultimately lead to improved outcomes, but with recognition that any transformation in performance would take several years. In contrast however, external commentators were calling for more objective and tangible measures of success. For example: are the five hospitals now safer than they would have been without involvement in the partnership? Are patient outcomes better? Has money been saved as a result of the partnership? And, have the five NHS Trusts improved in ways that significantly exceed that of other similar organisations not part of the partnership?

Such questions are deserving of answers. To that end we might summarise our findings in light of what we can objectively quantify. For example, between December 2015 and July 2019, the five hospital partners collectively conducted 113 rapid process improvement workshops across 28 value streams. As a direct result of this targeted improvement work, we can say that:

Lean Methods Are Not New to the NHS
Process times (i.e. lead time) were reduced by 62%. This represents over 3020 hours of time saved (equivalent to approximately 126 days).

Quality defects fell from 57% to 21%.

All five hospital Trusts reported approximately 50% improvement and over in all outcomes targeted for improvement by RPIWs.

We also have data from one organisation that suggests a positive ‘return on investment’ of at least 15:1.

Of course, this simplistic analysis neglects the more pertinent question of whether involvement in the NHS-VMI partnership produced performance outcomes in excess of similar hospitals that were not part of the partnership. This is a far more challenging question to answer. The NHS ‘Model Hospital’ offers a promising tool to examine this question, particularly given the ability to compare hospitals with a group of ‘peers’, i.e. those hospitals with similar operating characteristics. Our analysis, however, was inconclusive, the reasons for which are discussed in detail in our final report.

The brief snapshot of outcomes above tells us little about the learning generated by the partnership and its evaluation. Our evaluation goes above and beyond the numbers to understand what it takes to lead improvement in NHS organisations, the importance of a receptive context in shaping the success of improvement programmes, and what are the antecedent conditions of a receptive context. Further, this unique partnership between senior members of the regulator’s improvement directorate and the five senior leaders (CEOs) fostered new and effective ways of working, producing what Burgess and colleagues described as a soft form of governance enabled by the emergence of ‘relational authority’ between the regulator and the five CEOs.[1] Indeed, the most illuminating aspect of the evaluation was the importance of understanding people as social resource for improvement, and creating opportunities for cross-professional collaboration.

In sum, the value of the NHS-VMI partnership is not derived from an objective assessment of numbers that bear little correlation to the stated aim (i.e. to build capability). Instead, the impact of the partnership is derived from changes in the way the organisation manages for continuous improvement. Lessons are derived from understanding how internal and external contextual conditions shape the way organisations engage with improvement.

Our final evaluation report is due to be released in the coming months within which we highlight many examples of how the partnership has developed a sustainable culture of continued improvement capability in each of the five partner organisations. However, the most compelling evidence of the impact of the partnership we report, lies in the way each of the five hospital partners embraced lean principles, methods and tools across the externally mandated gold, silver and bronze command structures, to shape their response to COVID-19.

You can read more about the NHS-VMI partnership at: warwick.ac.uk/fac/soc/wbs/research/vmi-nhs/

Reference:

To mark ‘Black History Month’, our first blog article celebrates the life of Henrietta Lacks.

**Henrietta Lacks**

*Born: 01 August 1920  
Died: 04 October 1951*

Most people will never have heard of Henrietta Lacks. Although few people recognise her name, Henrietta’s unique contribution to biomedical research has been quite extraordinary. Sometimes referred to as the ‘mother of modern medicine’, in a special way, Henrietta has made a vital, if unintentioned, contribution to ground-breaking medical discoveries, from developing the polio vaccine in 1952 to the development of the SARS-CoV2 vaccine.

**Henrietta’s Life**

Henrietta was born in 1920 in Virginia, USA. After her mother died in childbirth, Henrietta moved to Baltimore, Maryland, where she was raised by her grandfather. Like many members of her community, Henrietta found work in the tobacco plantation. She got married, set up home and had five children. She loved to dance, to cook and those who remembered her recalled her love of wearing bright red nail polish.

After the birth of her fifth child, Henrietta visited the John Hopkins hospital in Baltimore, complaining of a ‘knot’ in her stomach. Investigations led to a diagnosis of an aggressive form of cervical cancer and Henrietta began a course of radium therapy. Despite intensive therapy, Henrietta died in 1951 when she was just 31 years old.

**Contribution to Science**

In her early visits to John Hopkins hospital, cell biopsies were taken from Henrietta to aid diagnosis. The tissue was sent to the nearby lab, partly to diagnose her condition but also to be used for research purposes. No consent was given by Lacks for her cells to be used in this way, although this practice was not uncommon at the time.
The head of tissue culture at John Hopkins, Dr. George Gey, discovered that Henrietta’s cells not only survived outside the human body, but reproduced. The cell line was called HeLa after the first two letters of Henrietta’s first and last names, and Gey shared the cell line with researchers in the US and internationally.

The characteristics of the HeLa cell line meant that it could be used to test medical innovations without the need for human experimentation. Just one year after Henrietta died, the HeLa cell line was used in developing a vaccine for polio, and the HeLa cell line has since been used to develop pioneering treatments for cancer, immunological conditions, and infectious diseases. Key medical breakthroughs involving the HeLa cell line include: HIV (1984), breast cancer (1985), tuberculosis (1993) and, most recently, a vaccine for SARS-COV2.

**Ethical Conduct**

Lacks’ family only found out that Henrietta’s cells were being used for medical research purposes in 1975. A researcher who wanted to take blood samples managed to trace the family and it was only then they became aware of the HeLa cell line and how it was being used. Although the family are now involved in decision-making about how the HeLa cell line is used, the case has highlighted violation of personal rights. Whilst Henrietta’s cells were taken when consenting processes were different, the profile of the case has underlined the need for careful examination of research processes, ensuring that full, informed consent is given by patients and that tissue is not used or retained without consent at all stages.

**Henrietta’s Legacy**

Although Henrietta died in 1951, her legacy still lives on. The HeLa cell line is still used in laboratories in universities and hospital laboratories around the world. There are a reported 17,000 patents using the HeLa cells[1] and some 60,000 academic articles [2] are based on research using HeLa cells.

October marks Black History Month. It’s important we recognise and express gratitude for the immense contribution Henrietta Lacks has made to medicine. To quote Henrietta’s grandson:

“[The cells] were taken in a bad way, but they are doing good for the world.”[1]

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**References & Further Reading:**


Getting into life and getting out of life are not straightforward. Dying, in particular, is a bit of a messy business. Research showed, a long time ago, that many people went through a process that they would rather have had managed differently according to their stated preferences. Death, like many births, did not go according to plan. So the remedy was obvious. Make a birth plan, and then make a death plan.

Well, it turns out that neither of these processes does much good. The ARC WM Director is reminded of the pugilist Mike Tyson, who said that “everybody has a plan until they get punched in the mouth.” When it comes to birth or death, you can plan as much as you want, but it won’t make much difference to the quality of your experience. So says a very interesting article published recently in the Journal of the American Medical Association.[1] All this business, setting goals and so on, fails to improve end-of-life care according to a review of no less than 80 systematic reviews plus 62 recent, high-quality articles.[2] There is no evidence of an effect on quality of life, reaching one’s goals, health care use or anything else.

Another good idea bites the dust. But why? I guess it comes down to Mike Tyson: the gap between what you imagine and the reality you then encounter. In many situations in life, following an ordered and algorithmic process leads to much better outcomes. It’s just that birth and death are not one of these situations.

Lots of people, of course, have built their careers and their sense of self-worth around this whole advanced care plan concept. Certainly, I thought that advanced care plans were a good idea, and I even have one. Consider it scrapped. Given all this evidence, I will just make ‘in the moment’ decisions as my life winds down to its end. One must expect that one’s ability to make autonomous decisions declines as the embrace of death draws near. My family know that I want lots of pain killers, human touch and no heroic efforts to prolong the agony.

And no, I do not wish to rage against the ending of the light; I hope that I shall go gently into that good night.

References:
The first ever paper written by the ARC WM Director, while still a medical student, concerned the admission criteria for medical school. [1] Subsequently, we showed that psychological tests were extremely poor predictors of performance and they are easily gamed. [2]

Celia Brown, ARC West Midlands collaborator, has now co-authored a paper that throws further doubt on the value of situational judgment tests. [3] The authors created a national retrospective cohort to examine the association between the different types of test (situational judgement and educational achievement) in the medical entrance examination and the probability of subsequent disciplinary action in the first five years of professional practice.

While an increase of one standard deviation in the educational performance measure reduced the risk of disciplinary action by about 50%, there was no correlation between the situational judgment result and risk of disciplinary action. The finding that educational achievement is associated with lower risks of antisocial behaviour (in addition to future academic attainment) corroborates an extensive previous body of work referenced in the article.

What is the mechanism? High academic achievement is a marker of self-discipline and commitment, attributes that are also necessary for good conduct. It turns out that academic achievement is the best test of overall fitness to practice. Michael Sandel has argued forcibly against ‘merit’ in selection for high status professions, arguing instead for a lottery system. [4] Brown and colleagues show what poor policy that would be – patients would pay the price in the case of medical care.

References:
News Blog readers know that the ARC WM Director loves orthopaedic trials, for reasons spelled out in a previous news blog.\[1\] He also likes umbrella reviews, having written extensively on a type of umbrella review, the multiple indication review.\[2\] \[3\] So the ARC WM Director was fascinated to read an umbrella review of orthopaedic trials written by Ashley Blom and his colleagues in the BMJ.\[4\]

The umbrella review covered orthopaedic surgery versus conservative management across the ten most frequently performed elective orthopaedic operations. The authors selected the most authoritative and recent systematic reviews in this monumental piece of work. What did they find?

In only two cases, total knee replacement and carpal tunnel decompression, did they find clear evidence that surgical intervention was superior to conventional treatment. In the case of rotator cuff repair, subacromial decompression, lumbar spine decompression, lumbar spine fusion, and reconstruction of the anterior cruciate ligament, the evidence suggests that any benefit must be small to non-existent. Given the cost and side-effects of surgery, the use of these procedures must be called into doubt. What about total hip replacement, do I hear you say? Well, there were no RCTs comparing total hip replacement with no treatment. Lastly, regarding treatment for meniscal damage, it would appear that while meniscal repair is of some value, partial meniscectomy is of little or no value. Since I myself have had a partial meniscectomy, and since I suffer recurrent symptoms, I was most interested in this finding.

The authors compare these findings with guidelines, and many of the guidelines are consistent with the empirical evidence; for example advising against lower back surgery. Many of the procedures are in the lower value-added category in the US. The authors make the excellent point that, while waiting lists remain long, there is an excellent opportunity to conduct RCTs of surgery in different sub-categories and across different levels of severity. Indeed, I have argued that randomisation is a fair way to distribute resources under such circumstances.\[5\] If I know the said Blom, he will be planning such ‘waiting list trials’ even as I write.

References:

1. Lilford RJ. Why the CLAHRC WM Director Loves Orthopaedic Trials. NIHR CLAHRC WM News Blog. 23 February 2018.


In collaboration with ARC East Midlands, our ARC WM is investigating hand-held or point-of-care ultrasonography. This is part of our broader efforts to improve care in the community and to reduce the need for hospital admission, especially for elderly patients.

We were therefore interested in a recent editorial in JAMA Internal Medicine, which argued for more formal evaluation of this ‘visually satisfying’ technology. The technology has a secure place in directing invasive procedures, especially in the acute trauma situation. However, its role in diagnosis is less well established. Existing evidence shows that hand-held ultrasonography is very sensitive for diagnosis of some conditions, such as plural effusion, but less so for others, such as kidney stones. A large trial of use of the technology for hypotension in the emergency department showed no benefit on clinical outcomes. However, very few diagnostic tests show benefit by this exacting standard.

While calling for more research, the article admits that the form this research should take is somewhat uncertain. One possibility that we are investigating is the amount of training necessary to reach a reasonable level of competence. One feels that this technology must offer some advantage over the standard clinical examination. However, training is necessary for proper use, just as it is for the traditional clinical examination. How training should be organised, and what dose is required to reach the asymptote, are questions we shall seek to answer.

**References:**


ARC WM News Blog readers will know that we have a large interest in causal chain analysis.[1-2] This means that investigators need to go way beyond the old exposure, confounder, outcome framework. Instead, the assumed causal model should be represented graphically including exposure, mediator, outcome, and possible confounders. Those who took to heart our previous News Blog article on causal chains [3] will appreciate the need to consider also possible colliders.

Given all this, I was interested to see a guideline for reporting mediation analysis as a special communication in JAMA.[4] This article confirms the importance of an assumed causal model and usefully provides a short form check list. It is important to control not just for confounding of the exposure outcome relationship, but also the relationships between exposure and mediator and between mediator and outcome. And beware the lurking collider!

The article does not deal in any serious way with the problem that there are frequently many mediators between exposure and outcome. In that case, it is necessary to construct a score representing the combined effect across colliders or, perhaps preferably, to conduct a principal component analysis.

In any event, I was delighted to see this important article, which supports a move away from non-causal thinking.

References:


The ARC WM Director loves discontinuity designs. There has been great concern in the USA, as elsewhere, that people who are poor and have less access to healthcare might have worse outcomes from COVID-19. If so, there should be a discontinuity at the age of 65, when all people become eligible for the Medicare program. A recent article in JAMA Health Forum examined publicly available data to test this hypothesis.[1]

There was no evidence of discontinuity. The authors speculate that this lack of evidence, that uninsured people would have worse health outcomes, arises because the government made extra money available for the care of COVID-19 cases. In any event, it turns out that the American healthcare system served its vulnerable population reasonably well during the COVID-19 pandemic.

Reference:
Historically, people from minority ethnic groups have had worse experiences of mental health care than White British people. This may have caused the higher rates of coercive treatments in some minority ethnic groups. For example, it was estimated that the rates of detentions under the Mental Health Act are four times higher in Black people than in White people.

COVID-19 related mortality and morbidity and the economic downturn have very significantly affected vulnerable groups and deprived areas, also causing additional problems with accessing health care for mental health problems. We need urgent solutions to make sure that people from minority ethnic groups access care when they need it and have a positive experience of it. This would enable the NHS to provide treatments can be prompt and beneficial and to prevent mental health crises requiring coercive treatment.

To identify these solutions, the ARIADNE project (AddRessing the ImpAct of coviD-19 paNdEmic on the access to experience of mental health care of people from Black, Asian and Minority Ethnic groups) will work with mental health service users from minority ethnic groups, and their family members and professionals. This project is funded by the NIHR Policy Research Programme and led by Dr Domenico Giacco and Prof. Swaran Singh at the University of Warwick, who are also leads for the Mental Health theme of the NIHR ARC West Midlands.

This project is based on a methodology called experience-based co-design. It will involve these stakeholders in directly designing actions and service changes to improve access to and experience of mental health care for people from minority ethnic groups. The research will start from interviews with a large numbers of stakeholders and then involve some of them in group activities, i.e. focus groups to prioritise areas for intervention and series of workshops, to design the improvements in care together with senior NHS managers and leaders. We will work in four areas of England: Coventry and Warwickshire, East London, Sheffield and Greater Manchester.

The result of this co-production effort will be local and national actions to improve access and experience of mental health care of people from minority ethnic groups. This will be made possible by the presence of experts in behavioural and organisational change within our team. The will supervise the co-production process in order to enable the development of clear and achievable action plans for service improvement by end of the project, in May 2022.

The research activities are currently in progress and we would like to invite all interested mental health service users, carers and professionals in the NIHR ARC West Midlands consortium to contribute to the project.
The October issue of the national NIHR ARC newsletter is now available online, with news including cancer-risk research; a new report on eating disorders; whether Preston is ‘Building Back Better’ post-COVID; and more. There are also links to recent blogs and details of upcoming online events.

To subscribe to future issues, please visit: https://tinyurl.com/ARCsnewsletter.

The Future of Health and Social Care Research

Various organisations involved in the West Midlands Social Care Research Partnership have produced online videos discussing how they support social care research in the region:

- Jenny Harlock, Research Design Service West Midlands: https://youtu.be/hp0OYZ-g5BE
- Sophie Wilson, Birmingham Voluntary Service Council: https://youtu.be/BO7HreZNKZY
- Paul Bird, Academic Health Sciences Network: https://youtu.be/gotymDffoos

ARC WM Quiz

The Hungarian biochemist Albert Szent-Györgyi died 35 years ago, on October 22 1986. In 1937 he won the Nobel Prize in Medicine for what achievement?

email your answer to: ARCWM@warwick.ac.uk

Answer to previous quiz: Diogenes / Plyushkin syndrome presents as extreme self-neglect, social withdrawal, and compulsive hoarding, among other things. Congratulations to those who were first to answer correctly.
NIHR Population Health Career Scientist Award

The NIHR have recently launched the Population Health Career Scientist Award (PHCSA), which aims to enable senior researchers to make the next step to Reader/Professor level. This new award will help answer the most important research questions facing decision-makers at local and national levels to improve health and reduce inequalities.

Applicants representing the wide range of disciplines that undertake research in any area that impacts the determinants of health (e.g. environmental science, mathematics, architecture, engineering, geography, education, social sciences, social policy, or arts) are welcome.

The deadline for proposals is **13 January 2022**. For more information and to apply, please visit: https://www.nihr.ac.uk/funding/population-health-career-scientist-award/28901

Incorporating Equality, Diversity & Inclusion in PPI

The NIHR are hosting a webinar on incorporating equality, diversity and inclusion (EDI) into patient and public involvement, focusing on its importance, and how to overcome the barriers to applying it. They will also offer practical guidance, tips and resources on how to adapt a PPI programme to incorporate EDI successfully.

The event will be held at **2pm on 1 December 2021**. For further information and to register, please click here.

NIHR Blog: Research Participants’ Thoughts on How Their Contributions are Valued

Results from the 2020/21 NIHR Clinical Research Network Participant in Research Experience Survey showed that 93% of research participants felt their contribution to research was valued by researchers and study teams. The professionalism, knowledge and friendliness of the research teams were highlighted as contributing to their positive experiences of taking part in research, with 94% of respondents saying they would consider taking part in research again.

You can find out more by reading the blog at: https://www.nihr.ac.uk/news/high-numbers-of-research-participants-believe-their-contribution-is-valued-by-researchers/28912

Adult Social Care Call Specification

The NIHR Programme Development Grant are seeking research proposals to address the challenges and aim to improve the evidence-base for adult social care (including transition from children’s services).

The deadline for proposals is **1pm on 24 November 2021**. For more information, and to apply, please visit: https://www.nihr.ac.uk/documents/programme-development-grants-adult-social-care-call-specification/28833.
Recent Publications


