NIHR | Applied Research Collaboration West Midlands

NIHR | Midlands Patient Safety Research Collaboration

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ARC West Midlands & Midlands PSRC News Blog

9 April 2025

Including Diverse Groups in Clinical Trials – the Right Policy for the Wrong Reason

Richard Lilford, ARC WM Director, PSRC Midlands Co-Director

Dr Ameeta Retzer, Research Fellow & EDI Lead for ARC WM

Diverse Groups & Clinical Trials

Strenuous efforts are being made in many countries to ensure, as far as possible, that clinical trials include all groups in society, roughly in proportion to their presence in the general population. So much so that the Economist recently featured an article on this very topic, arguing that involving diverse research participants will lead to new medical insights.[1] As a paid-up grant holder under the NIHR I have attended events around this issue. The argument put forward by many speakers and the Economist is incomplete. But there is a further argument for entry of diverse groups that is strong. Against the backdrop of the USA, a world leader in enhancing clinical trial diversity and equity, visibly halting its efforts,[2] it is important to consolidate our rationale for including diverse groups in clinical trials. Before covering these technical arguments, we would like to address non-technical ones – ethical and political points.

Moral Argument

The ethical argument (often implicit rather than explicit) is a social justice argument for inclusion of diverse groups. This argument is predicated on the notion that it is unfair to 'exclude' certain groups from trials. We will tackle later the issue of 'fairness' in terms of future benefits to groups who may benefit from the findings of trials. Here we consider whether it is unfair from the point of view of the participants in these trials. This argument cannot be sustained unless there is some benefit in participating. However, clinical trials are not intended to benefit participants, since the moral basis for trials is equipoise between trial arms.[3,4] People may benefit from participating in a trial, but only if the intervention turns out superior or if the intervention group receives treatment guidelines unethically withheld from controls. [5] Under equipoise there is no expectation of net benefit, and the argument that a group not included loses out does not hold. An exception might arise in 'equipoise-plus' trials. Here there is an expectation of benefit, but the experimental intervention is restricted to trial participants. [6] In that case, a fairness argument arises and there is a strong case to ensure that groups are not systematically excluded.

Technical / Scientific Arguments

Two scientific arguments are advanced for including diverse groups. The first is based on the principle of generalisability – trial findings will be generalised to the population at large and should therefore be derived from trial populations that represent groups in proportion to the general population. This argument is not as strong as it first seems. This is because guidelines are not based on national populations – as large as Britain is, only about 6% of the world's trials are based there. Most of our guidelines are currently based on populations different from the UK. Nevertheless, there is still an argument that, across countries, populations should be diverse so that, ultimately, a wide range of different characteristics have gone into the mix.

The second scientific argument is the converse – since there may be differences in treatment effect by group, outcomes should be hypothecated by group. This calls for particularisation rather than generalisation. The problem here is that precision falls off rapidly when sub-group interaction effects are tested.[7]

The article in the Economist does not mention this inconvenient truth. Yet, the article is correct in arguing that there may be some reason to suspect an interaction between says ethnic group or age, and (absolute) treatment effect.

Here we need to consider the evidence that informs clinical guidelines – seldom are guidelines based on but one trial. Rather, it is synthesis of all the relevant evidence in meta-analyses that drives changes in practice. The corollary is that efforts should indeed by made to include diverse groups. Then, in the early trials, the results will be suitable for generalisation. In the longer term, they will be available for particularisation. In essence, this is an extension of the arguments that small (so-called 'underpowered' trials ate not unethical.[8] Making anonymised trial data publicly available will assist sub-group analyses as part of future meta-analyses.[9, 10]

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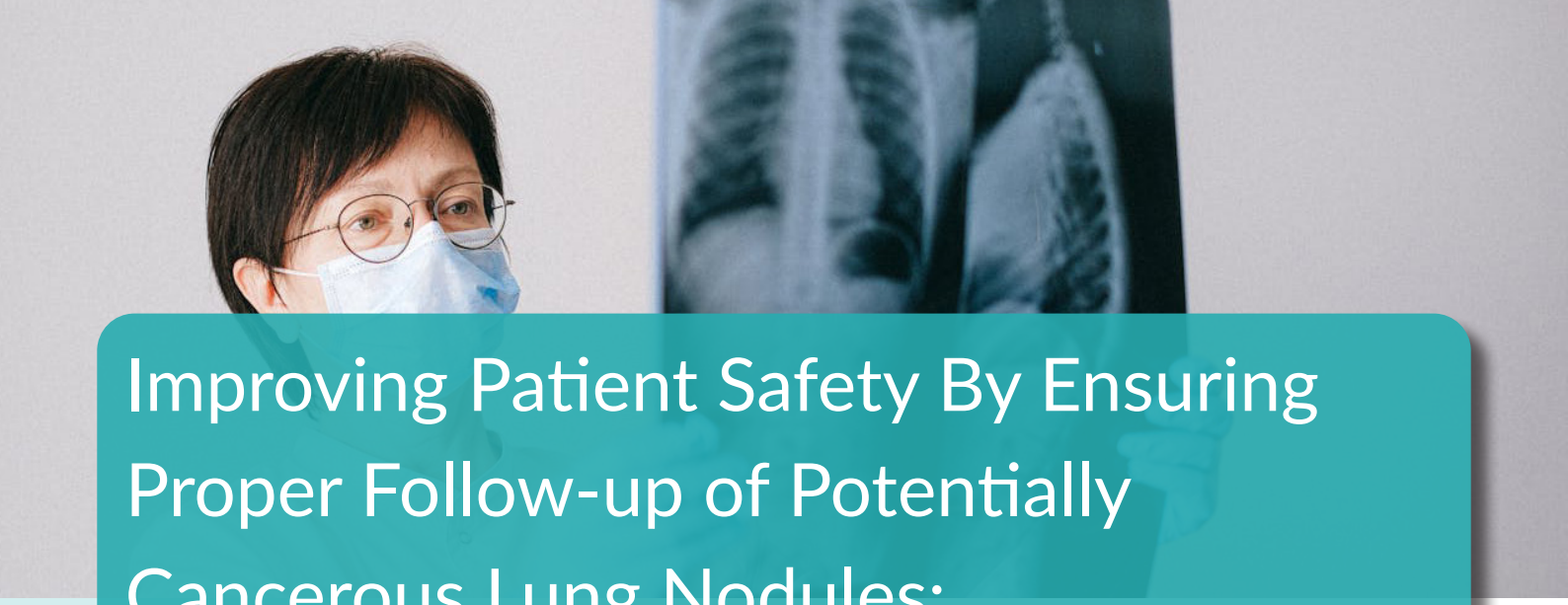

Improving Patient Safety By Ensuring Proper Follow-up of Potentially Cancerous Lung Nodules: Findings From a Systematic Review

Dr Justin Aunger, Pathways and Culture Research Fellow;
Prof Alice Turner, Midlands PSRC Co-Director

Lung cancer is one of the most common and deadliest cancers worldwide, with 50,000 new cases each year in the UK alone. Unfortunately, survival rates have shown little improvement over the past 50 years, with only about 10% of patients in the UK surviving 10 years or more after diagnosis.[1] A significant reason for this is that many patients are diagnosed at a late stage, when treatment options are limited. Early detection is key, and screening programs such as the UK's targeted lung health checks, aim to identify lung cancer at an early, more treatable stage. However, a major challenge is the management of pulmonary nodules – small lumps in the lungs that are often detected during these screenings. These nodules are also found during other routine procedures that involve scanning the chest, and this can be an important way to identify potential cancers in non-screening populations.

Pulmonary nodules are found in about 35% of people who undergo CT scans of the chest, and while most are benign, some can signal early-stage lung cancer. Proper follow-up of these nodules is critical to ensure that cancer is detected early and treated promptly. Yet, research shows that many patients do not receive appropriate follow-up, leading to delays in diagnosis and, ultimately, worse outcomes.

The Problem of Improper Follow-Up

Improper follow-up of pulmonary nodules can occur for several reasons. It may be due to errors in recording findings, scheduling follow-ups, or communication breakdowns between healthcare providers.[2] Sometimes, patients themselves may miss appointments or fail to understand the importance of follow-up. Whatever the cause, the result can be devastating – undiagnosed cancer that progresses to a more advanced stage.

A retrospective study from a large US medical centre highlights the dangers of improper follow-up. Among 314 patients with incidentally detected pulmonary nodules, 22% did not receive guideline-adherent care. Of these, 14.49% experienced a delayed cancer diagnosis, compared to no delayed diagnoses in patients who received guideline adherent care.[3] This shows the potential fatal consequences of not adhering to clinical guidelines for nodule management. Luckily, there have been a number

of interventions developed to try to improve patient follow-up and early diagnosis of lung cancer. To assess the effectiveness of these, we performed a systematic review, which has now been published in *CHEST*.[4]

Results of the Systematic Review

The review synthesised various interventions aimed at improving the follow-up of patients with pulmonary nodules. Our systematic review identified 31 interventions, with six main types (Figure 1), including:

1. Process improvement approaches – streamlining the steps healthcare providers take to ensure proper follow-up.
2. Radiologist reporting templates – standardised templates that ensure all necessary information about nodules is recorded.
3. Patient involvement improvements – strategies to better engage patients, such as phone calls or reminders through online portals.
4. Clinical decision support tools – software that helps doctors make decisions in line with clinical guidelines.
5. Natural language processing (NLP) systems – AI-based tools that analyse CT scan reports to identify nodules and recommend follow-up actions.
6. Tracking systems – comprehensive systems that track patients and send automated reminders to both healthcare providers and patients.

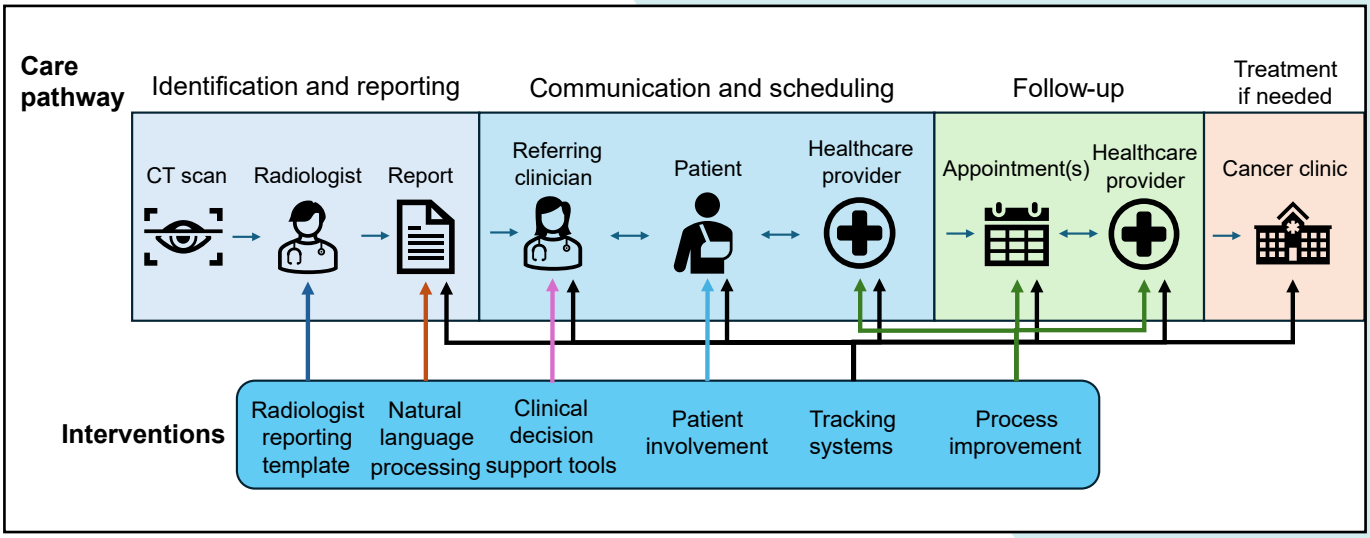

Figure 1. Intervention types and how they impact the care pathway.
Reproduced from Aunger et al. (2025) under CC-BY license.[4]

Of these, tracking systems showed the most promise.[5-8] They tackle the problem from multiple angles, improving communication between healthcare providers, often creating backend software databases to keep track of patients, and ensuring that follow-ups are not missed. The review suggested that tracking systems can improve follow-up completion rates to as high as 90%, a significant improvement over current practice.

The review found that tracking systems not only improve follow-up rates but also increase the likelihood of early cancer diagnosis. Studies showed that tracking systems could boost the detection of early-stage lung cancer, with two studies reporting odds ratios as high as 1.939, meaning patients in these systems were nearly twice as likely to have their cancer diagnosed early compared to those not in tracking systems.

Clinical decision support tools also demonstrated effectiveness, particularly in improving adherence to clinical guidelines. In some cases, guideline adherence improved by up to 25% after the introduction of these tools. Radiologist reporting templates helped improve the completeness of radiology reports, which can lead to better clinical decisions later in the care pathway.

Interestingly, interventions that involved greater patient involvement showed mixed results. For instance, one study compared four methods of notifying patients about the need for follow-up: standard notification, as well as additional phone calls, letters, and an online portal. The phone call intervention was the most effective, with a 60% follow-up completion rate, while the online portal performed the worst, with only 36% of patients completing follow-up.[9]

NLP systems, which use a form of basic artificial intelligence to read CT scan reports, showed high levels of accuracy in identifying nodules and recommending follow-up actions. However, these systems are still in the early stages of development, and some studies found that general-purpose algorithms, such as OpenAI's GPT models, were not suitable for clinical use due to lower sensitivity and specificity.

Discussion & Implications for Practice

Studies in the review were at high risk of bias, meaning that these results must be interpreted with caution. However, tracking systems seem to be the most effective intervention type for improving follow-up care for pulmonary nodules. By addressing multiple points of potential failure in the care pathway - such as missed follow-up appointments or poor communication between healthcare providers - tracking systems can significantly reduce the risk of delayed cancer diagnoses.

One interesting finding of the review was the variation in baseline follow-up rates across different studies. Some healthcare systems had higher initial follow-up rates than others, which influenced the effectiveness of the interventions. This suggests that healthcare providers should assess their current follow-up processes before implementing new interventions, as the effectiveness of a given approach may depend on the starting point.[2] Some interventions did not even reach the level of performance that other health systems started at. No intervention achieved 100% tracking, which begs questions regarding what the realistic maximum follow-up completion target for organisations may be.

This could be due to factors beyond the healthcare provider's control, such as patient non-compliance or social and economic barriers that prevent some patients from attending follow-up appointments. Research shows that factors like education level and race can affect a patient's likelihood of receiving proper follow-up care, with lower-educated individuals and black patients in the US being less likely to attend follow-up appointments.[10, 11] Future interventions should consider these disparities and aim to reach the patients most at risk of being lost to follow-up.

Conclusion: Moving Forward with Caution and Optimism

The review highlighted that while several interventions have been developed to improve the management of pulmonary nodules, tracking systems are the most effective at reducing patient harm by ensuring proper follow-up. These systems can improve the early diagnosis of lung cancer, ultimately saving lives. However, the evidence is not without its limitations. All identified studies took place in the Americas, and more studies are needed in other healthcare systems, particularly in the UK and Europe, where follow-up care for pulmonary nodules is also likely to be inconsistent. By investing in interventions like tracking systems and addressing disparities in care, we can help ensure that more patients receive the timely, life-saving care they need.

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Quiz

The Apgar score is used to evaluate the health of newborns a few minutes after birth, but where does it get its name from?

email your answer to: arcwm@contacts.bham.ac.uk

Answer to previous quiz: Haemophilia B / Factor IX deficiency is also known as **Christmas disease**, named after Stephen Christmas, the first patient described with the condition.

Congratulations to Prof Mark Gabbay who was first to answer correctly.

Crowded A&E Departments with Prolonged Trolley Waits – What is to Be Done?

Richard Lilford, ARC WM Director & Midlands PSRC Co-Director

Newspapers in the UK have carried very alarming reports of overcrowded Accident and Emergency departments with prolonged waits on trolleys, which can go on for more than 24 hours.[1] While they are on trolleys, patients cannot be properly looked after. Such trolley waits are unsafe. Not only are they unsafe, but they are almost unbearably unpleasant. There have even been reports of one patient vomiting on top of another.[2]

There is not much that can be done about this at the supply-side. At least not in the short-term. The wards are full and there is insufficient capacity in social care to absorb demand. This suggests that we should look carefully at the demand-side. I noticed in the report by The Times newspaper [2] that most of the human stories they reported related to people in their 90s, who often had dementia. This made me wonder whether they should have been referred to hospital in the first place. Would many of these people, if they were aware of circumstances that awaited them in the hospital, have chosen to remain where they were? Many were presumably sent in from nursing homes where the care may have been no worse than what they would receive in hospital.

So, I propose that nursing homes and community clinicians should receive an up-to-date stream of information about conditions in local emergency departments. Then they could legitimately take these into account when counselling patients who are able to give consent and in making decisions on behalf of those who are unable to consent. As hospital-at-home / integrated care is rolled-out, we can hope (maybe even anticipate) that a policy of non-referral will become ever more acceptable.

In many circumstances, keeping a patient in the community would be both more humane and no less safe than sending them to hospital. Such a policy should be officially endorsed to minimise the risk that staff would be compelled to send people to hospital, to remove the threat of litigation or investigation.

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Potential Use of Vitamin D to Manage Multiple Sclerosis

Peter Chilton, Research Fellow ARC WM

Multiple sclerosis (MS) is a chronic autoimmune disease affecting a person's central nervous system, and it has a number of risk factors, including female sex, obesity, smoking and vitamin D deficiency. It has previously been shown that vitamin D has various roles in the immune response, so therapies focussed on improving vitamin D levels might be able to reduce MS activity.

Researchers in France carried out an RCT of around 300 patients who had recently been diagnosed with clinically isolated syndrome (CIS) – often an early clinical stage of MS. Patients were treated with either high-doses of oral cholecalciferol (a form of vitamin D3) every two weeks, or a placebo. After two years, around 74% of patients who received the placebo showed disease activity (relapse and/or MRI activity), compared to around 60% of patients who received the vitamin D supplement (p=0.04). As secondary outcomes, MRI activity (p=0.02), new enhancing lesions (p=0.03), and contrast-enhancing lesions (p=0.001) were all observed less frequently in patients who had taken the vitamin D supplement. Furthermore, the median time before seeing any type of disease activity was significantly longer for those who had taken vitamin D (p=0.003).

Based on these results, it is hoped that further studies can investigate the potential of high-dose vitamin D supplements to be an add-on therapy for managing MS.

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Bias in AI-Driven Chest X-ray Diagnostics: Implications for Healthcare Disparities

Peter Chilton, Research Fellow ARC WM

Recent advancements in Artificial Intelligence (AI) have demonstrated the potential of vision-language foundation models for medical image analysis, including in detecting pathologies in chest X-rays.[1] However, a recent study published in Science Advances has revealed concerning biases within a leading self-supervised foundation model designed for this purpose.[2]

The research investigated the model's performance using diverse datasets from the United States, Spain, and Vietnam. While the AI achieved diagnostic accuracy comparable to board-certified radiologists overall, it exhibited consistent underdiagnosis in specific demographic groups: Black patients, female patients, and individuals under 40 years old. Notably, the underdiagnosis rates were exacerbated when these demographic attributes were combined, such as in Black female patients.

These biases were observed across various pathologies and demographic attributes. Further analysis indicated that the model was able to encode demographic information (sex, age and race) about patients more successfully than experienced radiologists, and the authors suggest that this may be contributing to the observed diagnostic biases.

Despite the AI's radiologist-level diagnostic capabilities, the presence of systematic biases raises critical ethical and regulatory concerns. The potential for these biases to exacerbate existing healthcare disparities among marginalised populations necessitates careful consideration before deploying such algorithms in real-world clinical settings. Future research should prioritize the development of de-biasing techniques and rigorous validation protocols to ensure equitable AI-driven healthcare solutions.

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Latest News and Events

ARC WM & Midlands PSRC Seminar Series

Our next seminar will take place on 9 April 2025, 2-3pm with Dr Justin Aunger talking on '*Two sides of the same coin? How realist methods and behavioural science can enhance our understanding of interventions – a case study on reducing staff-to-staff unprofessional behaviours in healthcare*'

Upcoming Seminars:

- 20 May 2025, 11am-12pm, Dr Punith Kempegowda
- 4 July 2025, 10-11am, Dr Hayley Crawford
- 24 September 2025, 12pm-1pm, Dr Julia Gauly - *The usage, experiences and impact of the QI Notify-EmLap mobile app.*
- 6 November 2025, 10am-11am
- 9 December 2025, 1pm-2pm - Dr Kiyah Hurley

Further information will be publicised nearer the dates.

For details on how to attend, please contact: arcwm@contacts.bham.ac.uk

Round 2: ARC WM Pre-Application Support Funding

Round 2 of the NIHR Pre-Application Support Funding has been launched. The fund allows individuals keen to develop their career in health and care research to protect their time, undertake relevant training and gain additional support to develop a competitive application for a future NIHR personal fellowship.

Further details are available at: www.arc-wm.nihr.ac.uk/research-capacity-development/nihr-pre-application-support-funding/

Deadline for submission is **30 April 2025**. Funding must be spent by 31 March 2026.

Prof Sara Kenyon MBE

Congratulations to Prof Sara Kenyon, ARC WM Maternity Theme lead, who recently received her MBE from Princess Anne at Buckingham Palace. Sara shared the following:

"It is the most wonderful surprise and a fantastic day. My very first thought when I received the news was how proud my parents would be. I am very pleased and proud to be recognised for outstanding achievement within maternity care and the difference the work I have been involved in has made. No-one works in isolation, so I want to thank all those who I have worked with and my family."

Latest National NIHR ARC Newsletter

The April issue of the NIHR ARCs Newsletter is now available at: http://eepurl.com/jaYdv2. It features work on electric scooter schemes reducing risk of bicycle collisions; an anti-bullying programme for primary schools; and identifying barriers to breast cancer care for South Asian women.

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

Far Away From Home Study Research

A new study, conducted by a collaboration of researchers from various ARCs, has highlighted the challenges of under-18s admitted to adult mental health wards.

The research reveals significant concerns and calls for urgent reforms to improve age-appropriate care.

A press release is available at: https://www.psychiatry.cam.ac.uk/news/new-study-highlights-challenges-under-18s-admitted-adult-mental-health-wards.

Multiple Long-Term Conditions Cross-NIHR Collaboration

The Multiple Long-Term Conditions (MLTC) cross-NIHR collaboration are now accepting applications for new members of their Health Inequalities Group. Further information can be found at: https://www.linkedin.com/pulse/multiple-long-term-conditions-mltc-cross-nihr-collaboration-cnc-seuge/

To apply, please complete the form available at: https://forms.office.com/e/t4RhwMjvQe

Closing date for applications is: **9 May 2025**.

Please contact Eleanor.Lockhart@newcastle.ac.uk for any queries.

Birmingham Public Involvement Newsletter

The *University of Birmingham Public Involvement Hub* have recently published the March edition of their newsletter. It features a number of patient and public involvement opportunities; research engagement events; and research news.

It can be viewed online at: https://www.arc-wm.nihr.ac.uk/wp-content/uploads/2025/04/Birmingham-PPIE-Newsletter-March-2025.pdf

You can sign up to receive the newsletter directly by contacting: ppi@contacts.bham.ac.uk.

i4i THRIVE Funding Opening Soon

The NIHR Invention for Innovation (i4i) programme is opening on 14 April 2025, and will be accepting applications to their new researcher and clinician-led THRIVE (Translate Healthcare Research through InnoVation and Entrepreneurship) funding and training opportunity. This aims to accelerate the translation of healthcare innovations tackling health inequalities from bench to bed.

Closing date is 16 May 2025, 1pm.

For more information, please visit: https://www.nihr.ac.uk/funding/i4i-thrive-april-2025/2025288

DEM-FEST

DEM-FEST, the *National Festival of Applied Dementia Research*, is a series of events hosted across England and online during Dementia Action Week, 19th - 25th May 2025.

These events will celebrate the work of applied dementia research across the ARCs, and is aimed at those concerned about, or living with dementia, including family carers, or practitioners or researchers working in this area.

For more information, including links to register for the various events, please visit: https://www.arc-wx.nihr.ac.uk/demfest25

Co-Developing Theatre on Sensitive Subjects

NIHR Bristol BRC are holding a webinar to launch a new how-to guide for co-developing theatre as a format for disseminating research on sensitive subjects. Researchers, theatre-makers and public contributors will share their thoughts and ideas stemming from a community play - *Hard Evidence*, which was co-created with survivors of domestic abuse and inspired the how-to guide.

The webinar should be of particular interest to qualitative research, and those working on sensitive subjects.

It will also be of interest to our Midlands PSRC Patient-Choice group, as we are using theatre to improve the design of services to assist choice in maternity care.

The webinar will be held **1:30-2:30pm on 15 May 2025**.

To find out more and register, please visit: https://www.eventbrite.com/e/1299324507579

Implementation Science & Health Economics Network

ImplementEcon is a new network bringing together the disciplines of implementation science and health economics for collaboration and better methods. It aims to connect researchers, including implementation scientists, health economists, researchers from other fields, health and care professionals, and public contributors. Read more at: https://arc-w.nihr.ac.uk/news/new-network-aims-to-unite-implementation-scientists-and-health-economists/

Their first webinar is being held on **29 May 2025**.

To register, please visit: https://events.teams.microsoft.com/event/3b50793d-21fa-4cc9-a509-05d9a0a8541f@b2e47f30-cd7d-4a4e-a5da-b18cf1a4151b

UK Knowledge Mobilisation Forum

Registration for the 2025 online UK Knowledge Mobilisation forum is now open. The forum will be held on **Monday 28 April - Friday 2 May 2025**, with sessions running from 12:00-2:00pm each day. Tickets are £49 (£25 for students). The forum will provide opportunities to share knowledge, experiences and methods, and provide access to some of the most up-to-date thinking and practice in the field.

For more details and to register, please visit: https://www.tickettailor.com/events/ukknowledgemobilisationforum/1484194.

Community Support for People with Dementia

The School of Social Policy & Society at the University of Birmingham are hosting an online event on *Community Support for People with Dementia and Their Families: Issues and Opportunities* on **Tuesday 29 April 2025**, 08:00-09:30am.

This is a joint collaboration with Monash University and will feature three speaks who will explore current insights from practice and research, and explore opportunities for greater co-design and collaboration in developing new approaches.

For more details, and to register, please visit: https://www.eventbrite.co.uk/e/community-support-for-people-with-dementia-and-their-families-tickets-1298953076619

Recent Publications

Bajpai R, Partington R, Muller S, Forrester H, Mallen CD, Clarson L, Padmanabhan N, Whittle R, Roddy E. Prognostic factors for colchicine prophylaxis-related adverse events when initiating allopurinol for gout: retrospective cohort study. *Rheumatol*. 2025; **64**(3):1147-54.

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