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## ARC West Midlands News Blog



24 March 2023

# The Safety of Inpatient Health Care: Secular Trends

*Julian Bion, Professor of Intensive Care Medicine, University of Birmingham*

Patient safety research is big business. The landmark Harvard Medical Practice study [1, 2] has been cited nearly 7,000 times since receiving a boost in 2000 following the publication of The Institute of Medicine's report 'To Err is Human' which has itself been cited more than 25,000 times.[3] In 2006, Lilford, et al. [4] referred to an 'explosion of interest' in the subject when there were around 100 citations a year relating to safety and associated subjects: now there are almost 2,000 citations each year for patient safety alone. With so much research, one could have expected a marked improvement in care quality over time. Is this in fact the case?

Bates, et al. have attempted to answer this question by repeating the essentials of the Harvard study in 11 hospitals in Massachusetts in 2018.[5] A team of nine trained nurses evaluated the in-patient electronic health records of a random sample of 2,809 admissions staying two or more nights in hospital (a separate study will examine out-patient care). The nurses searched for 'trigger' events known to be associated with adverse events (AEs). They used a standard taxonomy for classification of AEs, wrote a narrative summary of each and a summary of the whole admission, and these were then submitted randomly to eight physician reviewers to accept, reject or revise, before assessing severity and preventability, and recording their level of confidence in assigning each AE to healthcare management. Subsequent analysis of agreement between adjudicators was good (Kappa 0.7). What did they find?

Of 1,946 occurrences of harm, the physician adjudicators classed 978 as AEs, affecting 663 (23.6%) admissions. Of these 978 AEs, a total of 316 (32.3%) were classed as serious (265), life-threatening (44) or fatal (7). Two hundred and twenty-two AEs (22.7%) were classed as preventable, and 29 admissions (1%) were classed as having suffered a preventable serious, life-threatening or fatal AE. Preventable AEs were associated with age, male sex, non-Asians, longer hospital stay, and larger hospitals. Adverse drug events were the most common (39%); diagnostic errors were rare.

In the Harvard Medical Practice Study (HMPS), data were retrieved from the case records of 30,195 patients admitted to 51 hospitals in 1984. They found 1,278 (4.2%) with AEs, of which 306 (23.9%) were classed as 'negligent' (i.e. preventable), occurring in 1% of admissions. The AE detection rate by Bates, et al. is therefore much higher, the preventable AE rate similar, and the serious adverse event rate identical to the HMPS. It is difficult to draw conclusions about changes over time between these two studies given differences in methodology, changes in case mix and in the conduct of medical practice, and new technologies such as electronic prescribing and data capture.

An alternative approach is to use sequential cross-sectional studies. Eldridge, et al. have recently published an analysis of the abstracted Medicare case records of 244,542 patients admitted to 3,156 hospitals in the USA between 2010 and 2019. They found a significant

reduction in adverse event rates overall (218 to 139 per 1,000 discharges) and for four disease entities (myocardial infarction, heart failure, pneumonia and major surgery); but not in the group representing all other conditions combined, in which the AE rate was already well-below that of the other conditions. While this methodology leaves unanswered the question about how many of these residual AEs are preventable, the improvement noted in the four diseases could represent the beneficial effect of evolving process controls embedded in these well-defined care pathways. However, using a similar methodology to Bates, et al. and not restricting the area of enquiry to specific diseases, the Office of the Inspector General in the USA has found that 25% of 770 randomly selected Medicare patients experienced harm events in 2018, similar to the incidence in 2008 (27%), and of these 43% were judged to be preventable.[7]

To explore factors influencing patient safety in more detail, we examined changes in care processes during the implementation of the government's policy of [Seven Day Services](#) in England. The High-intensity Specialist Led Acute Care (HiSLAC) study [8] supported by ARC West Midlands aimed to determine possible causes for the higher mortality affecting weekend emergency admissions to hospital. Following training, 79 senior doctors performed structured judgement reviews of 3,966 emergency admissions to 20 acute hospitals in England at two time periods: 2012-13, and 2016-17, during implementation of the 7-day services policy. Half the admissions were at weekends. One or more errors in care (1,618 in total) were identified in 996 records (25.1%). In contrast to the US studies, the most frequent errors were related not to medication (13.2%) but to clinical assessment, investigation or diagnosis (31.9%) – tasks traditionally ascribed to doctors. National early warning scores were calculated in only half of admissions and consultant review within 14 hours of admission was documented in only one third. There were 128 AEs (91 classed as

preventable) affecting 103 patients (2.6%). Using a difference-in-difference analysis, we showed that errors, adverse event rates and care processes were similar for weekend and weekday admissions, but all improved between the two epochs. However, care processes in the community preceding admission were notably worse at weekends, and deteriorated over time, resulting in the admission of sicker and more dependent patients. We concluded that the additional focus on and investment in consultant staffing had improved care quality across all days of the week in hospitals, but the absence of similar investment in weekend community care was driving the 'weekend effect'.

What conclusions can we draw from these studies and the wider safety literature? The majority of adverse events are expressions of the underlying disease, not of errors in care, but that does not mean that they are not modifiable. Errors in healthcare are common, and while most are detected by vigilant staff before harm occurs, they still represent potentially unsafe systems. The proportion of preventable serious adverse events is small, and while this still represents a sizable number of patients suffering avoidable harm, the frequency is too low to be monitored through organisation-level metrics such as hospital standardised mortality ratios which are poor indicators of hospital quality. [9] [NHS England](#) has developed a new strategy for (voluntary) reporting and learning from patient safety incidents, the '[Learn from patient safety events \(LFPSE\) service](#)', supported by the appointment of local patient safety specialists in all NHS Trusts. The emphasis here is less on producing benchmarked performance indicators than on creating a system in which organisations and individuals are held accountable for demonstrating that they are monitoring, managing, preventing and learning from patient safety incidents. If this is to be achieved, it will need an integrated whole-pathway approach that links community, primary and secondary care, and which takes into account the socio-behavioural aspects of healthcare.[10, 11]



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1. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients — results of the Harvard Medical Practice Study I. *N Engl J Med.* 1991; **324**: 370-6.
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9. Girling AJ, Hofer TP, Wu J, et al. Case-mix adjusted hospital mortality is a poor proxy for preventable mortality: a modelling study. *BMJ Qual Saf.* 2012; **21**(12):1052-6.
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# The Need to Demonstrate Impact in Research

*Richard Lilford, ARC WM Director*

**A**ppplied research describes research directed to a specific target decision, rather than answering a fundamental theoretical / scientific question. Of course, this is crude, as few targeted research questions are devoid of theoretical interest and questions of theoretical interest have practical applications in the long-term. But, for the time being, let us go with the above Frascati definition.

Now, let us examine the applied end of the research spectrum. Broadly, there are two classes of question that research (that is applied research) may address. The first we refer to as trivial issues. These are issues where one study can, at least theoretically, answer the question. For example, which of two toothpastes is more effective in reducing plaque or cavities? Alternatively, is radiotherapy or chemotherapy more effective in the treatment of cancer of the lachrymal duct? Thus, a single study of sufficient size and rigour can answer the question all by itself.

However, if you consider policy or even service delivery issues of this type, they are not trivial in the sense that one study can, all by itself, lay the matter to rest. Consider, for example, conditional versus non-conditional transfers that aim to improve human welfare. Some types of transfer may be more effective than others according to the circumstances in which they are deployed. And, the question may turn not just on empirical information, but on preferences or values. For this reason the implications of the research must be subject to a political process

and a wider societal discourse played out in the public space. Therefore, it is ridiculous to demand of researchers that they demonstrate the impact of their research. Clearly, impact in such circumstances cannot be hypothecated just on one single study. Yet the issues that fall into this more complex category are far more important practically and interesting scientifically than those in the class that I have called trivial. Of course, I do not mean that they are trivial in the sense of providing no important information of great value to those people who are actually affected by the condition concerned. But they drive much less value across society as a whole.

Since these more complex policy issues are of much greater practical importance than those at the more specific end of the continuum, it would be a massive disservice to society to discriminate against those of us who boldly go! In judging impact, it is critically important for policy-makers to go beyond a simplistic 'one study - one impact' paradigm.

*Here endeth the rant of the ARC WM director!*

# Massive Study of Misdiagnosis: What a Wasted Opportunity

Richard Lilford, ARC WM Director

A very large and expensive study has examined diagnostic errors in acute medical care.[1] Their findings confirm that diagnostic errors were the most important single source of medical legal claims. However, instead of categorising these errors by the specific error type, they classified them by broad diagnostic groups. Sure enough, common presentations are the most represented source of error in diagnosis. The data therefore tell us almost nothing! Instead of working backwards from the disease missed, such as breast cancer or myocardial infarction, it would have been far more useful to identify specific symptoms and signs that have been missed or misinterpreted. For example, failing to recognise that sudden onset thoracic pain could be a marker of dissecting aneurysm, or that relapsing temperature in a mainlining drug addict could be a sign of right-sided endocarditis.

A small number of diagnoses are specific enough to provide a clear indication of diagnostic pitfalls. First, spinal abscess is as big a source of claims leading to as many misdiagnoses as the much more common condition of pneumonia. But in general, like much medical literature, this paper starts not with presentation, but with outcome. This is the wrong way around. In our patient safety research collaboration, we tackle diagnostic error from the combination of presenting symptoms and look for patterns in the data in real time; our aim to trap errors even before they are perpetuated to the patient.

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1. Newman-Toker DE, Schaffer AC, Yu-Moe CW, et al. Serious misdiagnosis-related harms in malpractice claims: The “Big Three” - vascular events, infections, and cancers. *Diagnosis (Berl)*. 2019; 6(3): 227-40.

## ARC WM Quiz

Svante Arrhenius was the first person to postulate the concept of global warming caused by emissions of carbon dioxide. Though who coined the term *anthropocene*, referring to the time during which humans have had a substantial impact on our planet?



email your answer to: [ARCWM@warwick.ac.uk](mailto:ARCWM@warwick.ac.uk)

*Answer to previous quiz:* Thomas Willis coined the medical term *diabetes mellitus* after noting the sweetness of patients' urine (mellitus being Greek for “like honey”)

Congratulations to those who answered correctly.





# Effects of Fortified Balanced Protein & Energy Supplements on Child Growth

Richard Lilford, ARC WM Director

**T**his News Blog once reported on a trial that compared use of nutritional supplements, including essential fatty acids, with controls carried out in North Africa. [1] This study found that child growth was improved in the intervention group and there were even signs of improved brain development on MRI scans. Nutritional supplements may be given to the woman while she is pregnant, to the child after birth, and to the mother when she is lactating.

A recent trial published in PLoS Medicine,[2] examines the effect of protein energy supplements given to lactating mothers on child growth. Generally, malnourished mothers do not produce depleted milk. The exception relates to essential fatty acids, which are depleted in malnourished woman's milk. In the event this trial did show an effect on foetal outcomes, including foetal growth. An earlier trial by the same authors had shown similar benefits on foetal growth from similar nutritional supplementation in mothers. [3]

The recent literature contains numerous trials of nutritional supplements with inconsistent results even across different countries in the same study. However, the potential benefits of essential fatty acid supplements seems to be hardening. Brain development is heavily

dependent on fatty acids and the above biological imaging results strengthen the likelihood of a positive causal effect. The ARC WM Director is collaborating on a study that aims to improve hygiene and nutrition at around the time of weaning in Mali. We are therefore watching the accumulating literature very carefully and expect to see some meta-analysis of nutritional supplements in the near future.

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2. Argaw A, de Kok B, Toe LC, et al. [Fortified balanced energy–protein supplementation during pregnancy and lactation and infant growth in rural Burkina Faso: A 2 × 2 factorial individually randomized controlled trial](#). *PLoS Med*. 2023.
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# A Truly Remarkable Study of WASH Interventions, Combined with Nutrition, Before Conception and After Birth

*Richard Lilford, ARC WM Director*

There are few matters more important than the start a child has in life (as discussed in the blog above). Moreover, it is important to remember that the start of a life is at conception. Children who are born small for their gestational ages have an increased risk of developmental problems in childhood and cardio-metabolic disease in adulthood compared to normal birth weight children. Growth after birth is also impaired by poor nutrition and possibly chronic, enteric infections. Previous studies have shown that birth weight can be increased by a small amount by supplements of iron and folic acid. Additionally, education and complementary foods can reduce stunting after birth.

The issues of pre- and post-natal development were recently reported in the BMJ.[1] A factorial designed trial resulted in four groups: pre-conception interventions only; pregnancy and early childhood interventions only; pre-conception and pregnancy and early childhood interventions; and finally, a control group.

The interventions combined health, nutrition, psychosocial care and WASH (water, sanitation and hygiene). The nutritional interventions did not seem to include various fatty acids, which were studied in a previous trial, as reported in your news blog.[2] (*See also the above blog for more evidence on their importance.*)

The trial took place in India, which has one of the highest rates of stunting in the world, and included a remarkable 13,500 participants.

By itself, the pre-conception intervention produced a remarkable 15% relative risk reduction in low birth weight. Likewise, the risk of stunting at 24 months was reduced by about a half in the groups that received pregnancy and early childhood interventions. Pre-conception interventions alone did not reduce the risk of stunting.


This was a huge and complex trial, funded by the Indian government and the Bill and Melinda Gates foundation. The authors observed a greater effect than in previous studies of nutritional interventions. They postulate that the combination of several interventions, including psychosocial care encouragement and support, produce a result that is greater than the sum of its parts.

This is a trend-setting study that repays careful reading.

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1. Taneja S, et al. [Impact of a package of health, nutrition, psychosocial support, and WaSH interventions delivered during preconception, pregnancy, and early childhood periods on birth outcomes and on linear growth at 24 months of age: factorial, individually randomised controlled trial](#). *BMJ* 2022; **379**: e072046.
2. Lilford RJ. [A Must-Read Study on the Fact of Food Supplementation on Cognitive Function of Under-Nourished Children](#). *NIHR ARC West Midlands News Blog*. 2020; **2**(12): 15.





# Conditional Cash Transfer: RCT with Long-Term Follow-Up of Interventions and Control Clusters

*Richard Lilford, ARC WM Director*

According to Cahyadi, et al.,[1] most RCTs of conditional cash transfers (CCTs) extend the intervention to control districts after about two years, so longer term effects (that may be accumulative with time) are not evaluated. However, a CCT intervention in Indonesia provides longer follow-up opportunities. The government originally randomised 736 sub-districts, each of around 50,000 people. Subsequently, the intervention was spread out over the vast country, but leaving 60% of the original control districts unaffected. This meant that the randomised controls could be compared with the original intervention sites six years later, controlling for baseline conditions.

The investigators find that the health and education effects persist for six years, and include an approximate halving of non-attendance rates at school and a 23% relative risk reduction in incidence of stunting. Interestingly, however, there were no enduring effects on household income or wealth. The conditions for the cash transfers were educational and health-related but no spill-over on economic benefits were observed.

ARC WM investigators, operating under a separate NIHR Global Health grant, are investigating a combined intervention to improve both health and wealth outcomes in Nepal.[2] We think that more such interventions are needed. The study quoted above suggests that interventions focussed on health and education affect only health and education, even over eight years of follow-up. We hypothesise that combined interventions will be more transformative.

## References:

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2. Lilford RJ. [Self Help: A Critical Factor in Healthcare for Many People](#). *NIHR ARC West Midlands News Blog*. 2021; **3**(4): 1-2.



# Fraud in Health Science

*Richard Lilford, ARC WM Director*

**T**he Economist published an interesting report on doctored data in its February 25 edition.[1] The study is well worth reading, though it is disturbing. It is hard to know exactly how common the problem is, but it is significant.

While no country is exempt, some have particularly bad records. The above article singles out China in this respect. Our NIHR Applied Research Collaboration published an article showing that clinical trials in Asia are much more likely to publish positive results than trials testing the same hypotheses in Europe.[2] Most of these positive trials came from China.

It appears that researchers who have committed one fraud tend to repeat the turpitude. When I was editor of the Cochrane Infertility group, I noticed an author who consistently got strong positive results, while other studies produced a null result.

When I was National Clinical Trials advisor, I promoted the development of trials centres, to ensure that data and their analysis were

independent of investigators who may have a vested interest in the results. I also initiated and provided funding to create the West Midlands Clinical Trials Unit, now I believe the second largest in the country.

The Economist article cites several instances where fraudulent papers influenced clinical practice in the wrong direction. These include the use of intravenous starch to treat shock, and the use of beta-blockers as prophylaxis during routine surgery. I was surprised and alarmed to see that the iconic studies of steroids to prevent neonatal respiratory distress in premature babies contained some bad apples.

## References:

1. The Economist. [There is a worrying amount of fraud in medical research.](#) *The Economist*. 22 February 2023.
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# A Competitive Process for Hospital CEOs Leading to Reduced Mortality

*Peter Chilton, Research Fellow*

**E**stimates for worldwide spending on the public sector by governments are thought to be around 30% of world GDP. It is therefore crucially important to ensure that this money is used effectively. One way to achieve this could be to employ better managers. However, it can be difficult to provide empirical evidence of improved management in the public sector on objective and verifiable performance outcomes. To this end, a recent publication looked at a policy change in Chile that affected the selection process for all top-level managers in the public sector, with a specific focus on public hospitals.[1] The policy change meant that the selection process became public, competitive and transparent; included pay incentives based on performance; and increased base wages to make them more comparable to those in the private sector.

This paper looked at data from all public hospitals in Chile, across the period 2001-2019. Using a difference-in-difference approach, the authors were able to show that a competitive selection system for recruiting top-level managers was associated with reduced overall hospital mortality (by an average of 8%). This was achieved predominantly through improved efficiency of operating rooms and reductions in

staff turnover. This reduction was seen regardless of patient composition, use of payment for performance, or increased wages.

The authors concluded that the change in selection process meant that older doctors who had no management training tended to no longer be selected, and instead younger CEOs with undergraduate management qualifications were hired. There was also evidence that the policy change led to doctors who had top-level management aspirations to invest in management courses.

## Reference:

1. Otero C & Muñoz P. [Managers and Public Health Performance](#). 2022.



# Latest News and Events

## NIHR ARCs COVID-19 Report

This week, on the third anniversary of the first UK COVID-19 lockdown, NIHR Applied Research Collaborations (ARCs) have launched a publication looking at the contribution of the ARCs to the fight against COVID-19.

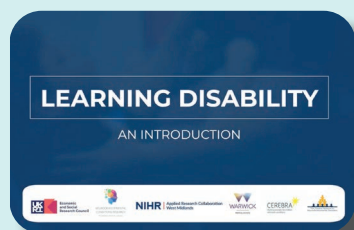
The new publication, [NIHR ARCs: Supporting the fight against COVID-19](#), outlines the response of the ARCs, both collectively and individually, to this challenge.

ARCs were involved in over 400 COVID-19 research projects during the pandemic. The publication showcases selected projects from across a range of themes.

One project from each ARC has also been highlighted in the national ARC newsletter: <http://eepurl.com/imuM7s>.

## Videos on Key Information About Learning Disability

Dr Hayley Crawford and Dr Hayley Trower from Warwick Medical School have created a series of four videos on key information about people with learning disability, suitable for healthcare professionals, parents and carers. The series is available to view on YouTube:



- An Introduction  
<https://youtu.be/GM9mfbves34>
- Behaviours that Challenge in People with Learning Disability  
[https://youtu.be/OUmMLoUN\\_ak](https://youtu.be/OUmMLoUN_ak)
- Healthcare Appointments with People with Learning Disability  
<https://youtu.be/sc3qHdHuVq8>
- Identification of Health Conditions  
<https://youtu.be/BXrfMyTt3CM>

## Latest National NIHR ARC Newsletter

The latest issues of the national NIHR ARC newsletter are now available online at <http://eepurl.com/ijeUjn> and <http://eepurl.com/ilYIOg>

The *February* issue includes reports on the vulnerability of children in the North to the cost of living crisis; the changes in children's mental health and parental financial crisis following the COVID-19 pandemic; and a national programme to help prevent cerebral palsy in premature babies.

The *March* issue includes reports on developing resources for inclusive involvement in research; exploring the best ways for AI, clinicians and patients to work together; and how increased digitalisation since the COVID-19 pandemic has impacted finance management for people with dementia and their carers.

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



## ARC WM PPIE Journal Club

The next ARC WM PPIE Journal Club is scheduled to take place online on **Wednesday 29<sup>th</sup> March, 13:00 – 13:50**.

In the session Magdalena Skrybant, ARC WM Public Involvement and Engagement Lead will lead discussion of '*Distinctions and blurred boundaries between qualitative approaches and public and patient involvement in research*' ([McMenamin, Isaksen, Manning & Tierney, 2022](#)).

This article explores features (e.g. philosophy, ethics, and power dynamics) of qualitative approaches and public and patient involvement in communication disorder research and explicates the blurred boundaries between them.

To register to attend please visit: <https://www.eventbrite.co.uk/e/arc-wm-ppie-journal-club-march-2023-tickets-595760675217>.

## Online Musculoskeletal Research Event

The NIHR Clinical Research Network West Midlands are hosting an online event on musculoskeletal research, including an overview of past and present research across the region and details on the establishment of a multidisciplinary MSK Research Collaborative.

The event will take place on **18 April 2023, 14:00-16:00**. For more details and to sign-up, please visit: <https://www.eventbrite.co.uk/e/musculoskeletal-research-ms-teams-event-tickets-526515029627>.

## Vi and Vincent the Jibber Jabbers Book

Prof Celia Brown, Professor of Medical Education at Warwick Medical School and part of ARC WM Research Methodology theme, has recently published a book for children, *Vi and Vincent the Jibber Jabbers*, explaining how vaccines

work, and how they keep many people safe and healthy. Further information is available at: <https://www.austinmacauley.com/book/vi-and-vincent-jibber-jabbers>

The 16<sup>th</sup> HSR UK Annual Conference will be held at the University of Birmingham and online on **4-6 July 2023**.

The planned conference programme is now available showcasing the promotion of health services research in policy and practice.

Registration is now open, with Early Bird fees available until 8 April. (A *limited number of complimentary spaces are available to patients, carers and public contributors*.)

For more information, please visit: <https://t.co/9Wd6JP8Lri>.

## HSR UK Conference 2023

## BMJ Opinion Pieces

Patricia Apenteng (ARC WM Research Methods theme) and Richard Lilford (ARC WM Director) have written an *Opinion* piece for the *BMJ* arguing that, while uptake of training in point-of-care ultrasonography has been slow in UK medical schools, it should still be included in medical training - <https://www.bmj.com/content/bmj/380/bmj.p574>.

Daniel Lasserson (ARC WM [Acute Care Interfaces](#) theme lead), together with Tim Cooksley, have also written an Opinion piece, urging that virtual wards must not distract from the urgent need for long term workforce, clinical, and capacity plans - <https://www.bmj.com/content/bmj/380/bmj.p343>.

# Recent Publications

Adams L, Nakafero G, Grainge MJ, Card T, Mallen CD, Van-Tam JSN, Williams HC, Abhishek A. [Is vaccination against COVID-19 associated with psoriasis or eczema flare? Self-controlled case series analysis using data from the Clinical Practice Research Datalink \(Aurum\).](#) *Br J Dermatol.* 2023; **188**(2): 297-9.

Aiyegbusi OL, Cruz Rivera S, Oliver K, Manna E, Collis P, King-Kallimanis BL, Bhatnagar V, Herold R, Hopkins J, Campbell L, Croker A, Leach M, Calvert MJ. [The opportunity for greater patient and public involvement and engagement in drug development and regulation.](#) *Nat Rev Drug Discov.* 2023.

Aiyegbusi OL, Davies EH, Myles P, Williams T, Frost C, Haroon S, Hughes SE, Wilson R, McMullan C, Subramanian A, Nirantharakumar K, Calvert MJ. [Digitally enabled decentralised research: opportunities to improve the efficiency of clinical trials and observational studies.](#) *BMJ Evid Based Med.* 2023.

Aiyegbusi OL, Hughes SE, Peipert JD, Schougaard LMV, Wilson R, Calvert MJ. [Reducing the pressures of outpatient care: the potential role of patient-reported outcomes.](#) *J R Soc Med.* 2023; **116**(2): 44-64.

Akanuwe JNA, Siriwardena AN, Bidaut L, Mitchell P, Bird P, Lasserson D, Apenteng P, Lilford R. [Practitioners' views on community implementation of point-of-care ultrasound \(POCUS\) in the UK: a qualitative interview study.](#) *BMC Health Serv Res.* 2023; **23**(1): 84.

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Barker RO, Atkin C, Hanratty B, Kingston A, Cooksley T, Gordon A, Holland M, Knight T, Subbe C, Lasserson DS. [National Early Warning Scores Following Emergency Hospital Transfer: Implications for Care Home Residents.](#) *J Am Med Dir Assoc.* 2023.

Chen YF, Takwoingi Y, Grove A. [Mapping review could be seen as a sub-type of scoping review, and differentiating between the action of mapping evidence and presentation of evidence as maps may be helpful: response to Khalil et al.](#) *J Clin Epidemiol.* 2023.

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