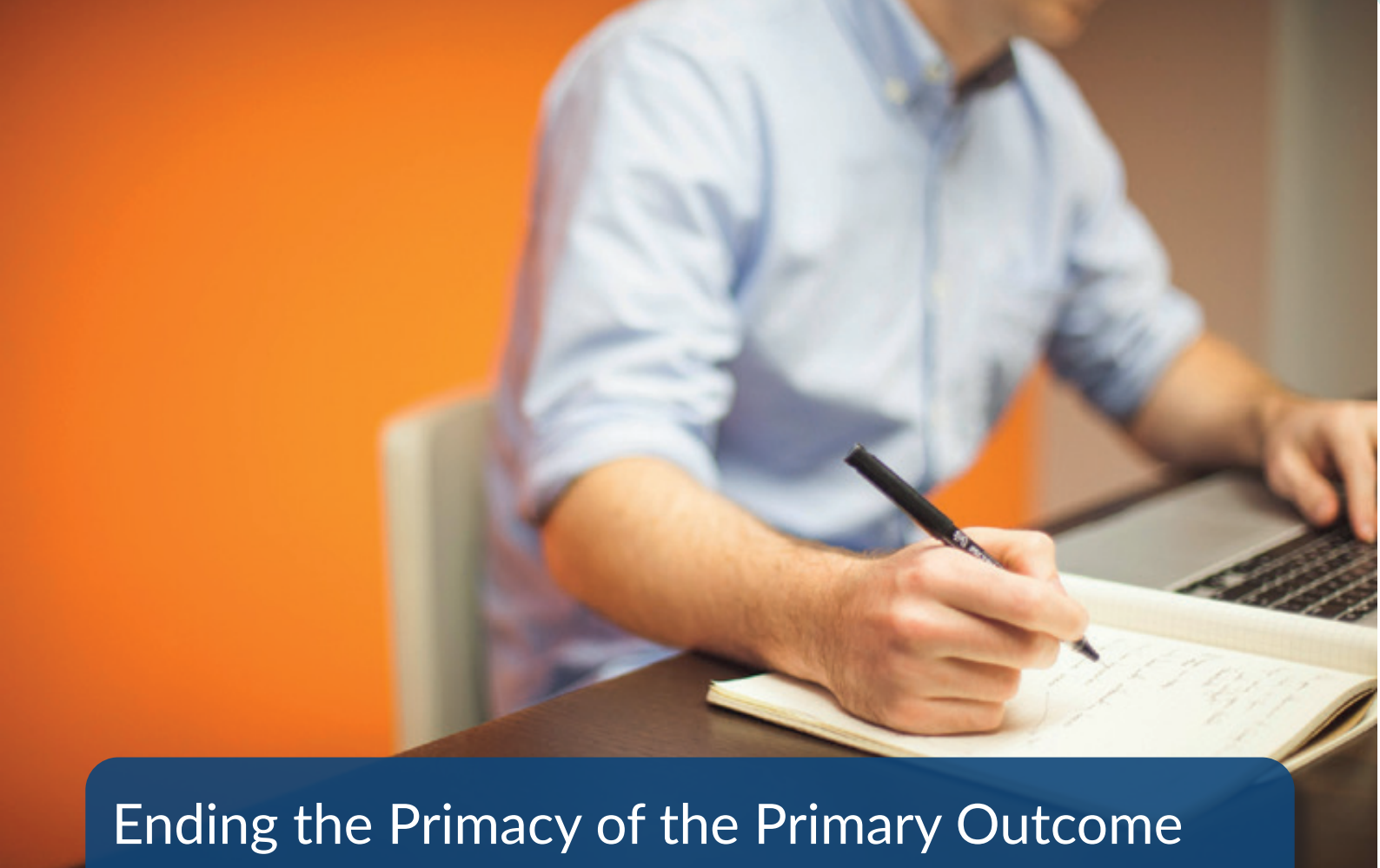


1	Ending the Primacy of Primary Outcomes	The Missing Heritability of Severe Psychiatric Disorders	9
4	The OPAL Research Project		
6	Scientific Orthodoxy and the Airborne Spread of Coronavirus	Hypertension, the Blood-Brain Barrier and Cognitive Decline	10
7	The Idea of Maximal Positive Controls to Estimate the Largest Plausible Effect Size	Association Between Coffee Consumption and Chronic Liver Disease	11
8	Clinical Excellence Awards and Heroism: the New Pre-occupation with Levelling	Latest News & Events	12
		Recent Publications	14

ARC West Midlands News Blog





Ending the Primacy of the Primary Outcome

Richard Lilford, ARC WM Director; Sam Watson, Senior Lecturer

The requirement to state a primary outcome for a trial has become accepted, even required, practice. The primary outcome is commonly described as “*the pre-specified outcome considered to be of greatest importance to relevant stakeholders.*”[1] The influential CONSORT statement on clinical trials requires that the primary outcome be pre-specified.[1]

In this article we argue that the concept of the primary outcome is not justified on either practical or scientific terms. Specifying a primary outcome should be abandoned forthwith.

The relative importance of any outcome for a decision analysis turns on its probability and its utility. A single scenario can dispel the notion that the results of a study must turn on a single

primary outcome. Imagine a scenario where a study has three outcomes: A, B and C. Imagine that A has a utility value of five, while B and C have utility values of four and three respectively. Thus B and C together would have more impact on the decision than A. In this scenario making A primary makes no sense.

The need to nominate one outcome as primary also forces an arbitrary decision to which the interpretation of the findings becomes hostage. Take a recent trial of prophylactic antibiotic vs. no antibiotic prior to evacuation of the uterus in low-income countries published in the *New England Medical Journal*. [2] The researchers had a choice between two widely used measures of post-procedure infection. They jumped the wrong way, choosing as primary outcome a definition yielding a p value of 0.06, while the designated secondary outcome yielded a p value

of 0.04. To interpret this trial in terms of the arbitrary decision on the primary outcome is clearly nonsense. Moreover, a recent multi-indication review found that antibiotic prophylaxis is effective across all surgeries,[3] so the prior probability already favoured the intervention. This scenario is surely evidence that the requirement to nominate a primary outcome can do more harm than good. Statisticians teach that p value cut offs are arbitrary and yet many continue to argue for primary outcomes. Ground control, we have a problem and it is an implementation problem. Admittedly, the CONSORT statement does say that multiple primary outcomes can be selected. However, the text immediately goes on to discourage the practice of selecting more than one primary outcome, as it *“incurs the problems of interpretation associated with multiplicity of analyses... and is not recommended.”*[1] This qualification takes us to our next point about the unscientific nature of insisting on one primary outcome.

From our perspective, the above statement regarding the risks of multiple end-points stands scientific logic on its head. While we fully concede that multiple null hypothesis significance tests among unrelated variables increases the probability that some will be positive just by chance; in a more formal language the risk of a type one or false positive answer increases as the number of unrelated statistical tests increases. The proposed treatment for this problem of researcher error by CONSORT and others is to limit the number of primary outcomes to one. The problem with this cure is that it totally ignores notions of causality that lie at the heart of scientific reasoning, and the development and evaluation of scientific theory. Statistical inference is better seen as a way of evaluating the compatibility of data with a scientifically-grounded statistical model. Patterns in the data across multiple outcomes must provide more powerful evidence than any single data item alone. If a number of clinical outcomes all respond to an intervention as predicted

by scientific theory, then we should be more confident in the interpretation of our findings. To adjust and thereby down-weight evidence from all but one outcome does not make sense. For example, if a lipid-lowering or anti-platelet medicine reduced the risk of stroke, heart attack and ischaemic ulcer, then this is more powerful evidence than if it reduced one alone. What's more, there exist several Frequentist methods for ensuring test statistics have the correct properties when looking at multiple outcomes, or one could just jointly model the outcomes at once. So there really is no good reason to limit so severely which outcomes are examined.

This notion, of looking for and explaining patterns in data to build scientific knowledge, is consistent with the way scientific theories, such as evolution and the big bang, came about. It is known as abduction, but could also be referred to as **triangulation**. The casual pathway is our scientific theory, and observing signals across this pathway provides evidence for or against this proposed model being correct. Consider evaluation of a medicine to reduce cholesterol. Exploration of the causal pathway would include adherence to the medicine as prescribed, effect on blood lipids, the incidences of angina and transient cerebral ischaemia, along with heart attack and stroke rates, and (given a sufficiently large sample) overall death rates.

In the above example, adherence rates and blood lipid levels are mediating variables between the intervention and the clinical outcome. There has been a resurgence in causal thinking among statisticians over the last two decades. It is now increasingly common to analyse the relationship between changes in mediating variables and outcomes using structural equation models. A beautiful recent example explored the mechanisms through which stress can increase the risk of vascular disease.[4] These methods are also very useful in public health and in service delivery research. For example, microbiological examination of the

environment helped explain why recent large-scale sanitary interventions had limited benefit in reducing childhood diarrhoea.[5] Likewise, a detailed study of hospital case notes showed that higher mortality among people admitted over the weekend was not the result of low-quality care.[6] In these examples the pattern in the data sheds light on a hypothesised causal chain and leads to scientific progress.

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ARC WM Quiz

The feast of St Vitus, a Sicilian martyr and patron saint of dancers, fell on 15 June. What is the condition *St Vitus' dance* also known as?

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



Answer to previous quiz: The Scoville scale is a measurement of the pungency of chilli peppers (how hot/spicy they are). Congratulations to Mark Gabbay who was first to answer correctly.



The OPAL Research Project: Creating a one-to-one peer support programme for family and friends of patients treated in hospital under the Mental Health Act



Domenico Giacco, Associate Clinical Professor (Warwick Medical School)

Background to OPAL

Mental Health Act review & impetus for this research

Under the Mental Health Act (MHA), a person can be detained, or ‘sectioned’, i.e. treated in hospital without their agreement, if they are at risk of harm to themselves due to an acute and severe episode of a mental health condition. This is a sometimes unavoidable, but highly stressful experience for both the patients and their ‘informal carers’.[1,2]

Informal carers are family members, partners or friends of people with a health condition, who provide support to them on a regular basis. Previous research on experiences of carers of patients treated under the MHA showed that most carers feel isolated and unsupported. [1,2] They need help to overcome feelings of frustration and guilt and to restore relationships with their loved ones and services.[3] At present, in the NHS, there are no one-to-one interventions to support informal carers during this difficult time.[2]

In 2018, an Independent Review of the MHA 1983 set out recommendations for government on how the Act and associated practice needs to change. The provision of appropriate information and support to “informal carers” was emphasised. The MHA review recommendations generated a [call from the National Institute for Health Research](#). This call focused on funding research that will help the NHS to work towards addressing those recommendations with evidence-based changes to service provision.

The OPAL project was funded by this call to identify and develop evidence-based support for carers. It will be led by the Coventry and Warwickshire NHS Partnership Trust and the University of Warwick.

What will OPAL try to achieve?

OPAL will establish an evidence-based approach to support family and friends of patients treated under the MHA. This approach will consist of training carers with previous experience of supporting someone who was treated under the MHA, to become “peer supporters” for other carers.

This programme follows from the increasing popularity in the NHS of peer support programme for patients. It takes inspiration from a programme, widespread in Germany,[4] in which carers acting as peer supporters have reduced caregiving stress and improved quality of life of other carers.

What will the research team do?

The systematic development work towards establishing the carer peer support programme will be carried out in different NHS sites, including urban and rural locations.

In the **first phase**, carers, patients and clinicians will be involved in generating ideas through individual interviews and group workshops on how one-to-one carer peer support can be delivered in England.

In the **second phase**, we will develop the training programme using a ‘train the trainer’ model and test it in two stages, initially involving a limited number of carers and hospitals and then on a higher scale. Experiences, costs, engagement of carers and carer peer supporters, quality of life of carers, and any adverse events will be assessed.

The project will have a national Lived Experience Advisory Panel (LEAP), including mental health

carers and patients throughout England.

The end-product of OPAL will be clear guidelines for how to train, practice and organise one-to-one carer peer support in England. This will provide much needed support to carers who face the stressful experience of having a relative or friend treated in hospital under the MHA.

When and how will our findings and research outputs be shared?

The project will run from June 2021 to November 2023. The findings and the developed carer peer support programme materials will be discussed, as they become available, through online engagement. Towards the end of the project, we will organise workshops with key stakeholders: carers, users, professionals, academics, policy makers, and charities. In addition to this, we will publish findings in academic journals and in publications designed for service users and carers and produce guides about the peer support programme for carers and policy makers.

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Scientific Orthodoxy and the Airborne Spread of Coronavirus

Richard Lilford, ARC WM Director

I thank Jim Parle for drawing my attention to a provocative article on the sociological reasons behind the initial rejection and slow acceptance of the airborne spread of coronavirus.[1] In short, senior officials at the World Health Organization and in many countries, rejected the ‘airborne theory’ by conflating absence of evidence with evidence of absence. As a result, protective measures were targeted at prevention of droplet spread between people in close proximity, rather than preventing airborne spread over much larger distances.

The authors of the article, published in Wellcome Open Research, unpack the sociology behind premature rejection of the airborne hypothesis. Taking a hermeneutic approach, and leaning heavily on the theories of Pierre Bourdieu, Greenhalgh and colleagues show how medical orthodoxy led to closed minds and the dissemination of a flawed narrative. In a beautifully written article, the authors paint a vivid picture of the way that dissenting voices were shut out. Using heavy duty sociological theory concerning group dynamics and the maintenance of symbolic power they show how certain scientific ideas were privileged; the droplet theory crowded out the aerosol theory. Incomplete direct evidence favoured

by the medical establishment was given too much weight over indirect evidence from physicists and mathematicians. The authors present a contrasting case study from Japan,[2] where the leading epidemiologist kept an open mind, confirmed the importance of aerosols and implemented a much more effective infection control strategy. For an excellent article on the accumulating evidence for aerosol spread over long distances see the recent *Economist* (29 May 2021).[3]

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The Idea of Maximal Positive Controls to Estimate the Largest Plausible Effect Size

Richard Lilford, ARC WM Director

A RCWM News Blog reader, Gus Hamilton, recently drew my attention to this article by Joseph Hilgard from Illinois State University.[1] To rather simplify the idea, it is to take a more extreme example of an intervention and test that. If the effect from a less extreme intervention was greater than that of the more extreme, then that supports a conclusion that something serious has gone wrong. In one of the examples given, he examines an article where a rather short exposure to a moderately violent video game produced subsequent aggressive responses on a story completion task. However, when Hilgard used more prolonged exposure to even more violent video games, he achieved a smaller response than that previously reported in the suspect article.

I wondered about medical analogies and cast my mind back over my files. Patrick Vandekerckhove, myself and others were the first people to carry out meta-analysis of treatments for infertility,[2] where there was one researcher who, on three occasions, found improvements in fertility that were way out of the range of other studies of the same treatment. In the area of preventing miscarriage, we found a study claiming a 50% reduction in miscarriage rate with hormonal treatment. This seemed implausible, since at least half of all miscarriages are caused by a serious chromosomal problem with the embryo. Arguably positive responses to homeopathic treatment exceed the plausible value. None of these examples are strictly analogous to the elegant experiments carried out by Hilgard. The idea of an upper plausible effect is an important one.

I have long advocated modelling potential plausible effect sizes on the basis of what is already known to examine the upper limits of plausibility. There have been many randomised trials of antenatal screening for risk of stillbirth

in unselected populations of pregnant women. However, Martin de Bono and I showed, many years ago, that such trials would have to randomise about half of all the pregnant women in England to have even an 80% chance of avoiding a false negative result. This was based on prevalence, plausible likelihood ratios for a test and two tailed sample size calculations.[3]



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Clinical Excellence Awards and Heroism: the New Pre-occupation with Levelling

Richard Lilford, ARC WM Director

The ARC WM Director was somewhat provoked by two initially dissimilar articles; one in JAMA [1] and the other in the BMJ.[2]

The JAMA article concerned a topic previously covered in your News Blog – heroism in medicine.[3] The BMJ paper was concerned with the Clinical Excellence Award Scheme, which it wants to get rid of after 72 years.

Among the arguments used, both invoked the importance of teams as the basis for excellence. Paraphrasing the JAMA article, heroism is an obstacle to team performance, while the BMJ article argues that Excellence Awards reward individuals for team performance.

Both ideas are misplaced. This is not to decry the importance of teams – I am committed to the idea that team performance is much more than the sum of individual performances. No, my problem lies in sublimating individual performance within the notion of team performance. The whole point of teams is to allow individuals to succeed (even shine), and there is no merit in subordinating the importance of leadership in team functioning. In football, the ball must be passed by the team to the striker, but then the individual striker must score. And there is only one keeper in the goal. The surgeon must perform meticulous surgery, even as the other members of the team provide the necessary conditions for a successful operation. On the other hand, heroism must not topple over into hubris – and it can do so. It is all a question of balance.

It is also worth remembering that clinical practice also requires individual excellence. When I was a gynaecologist I worked with teams in the operating theatre, outpatient department, general ward, and labour ward. But the decision

to recommend a Caesarean section, breaking bad news about a congenital abnormality, or whether to recommend a certain treatment; these were when I was accountable for my individual performance. The JAMA article argues for more ‘humanism’. For sure, but remember that humanism is built on human relationships – individual human relationships.

So, yes, teamwork is important but that is no reason to disallow a little heroism or scrap Clinical Excellence Awards. It was on the basis of Excellence Awards that high achieving doctors stayed in this country or, in my case, eschew private practice. And when I served on the committee for Clinical Excellence Awards it was as plain as day that some doctors really do go ‘above and beyond’, and it seems right that they should be rewarded for their exceptional contributions. And all for about 0.1% of NHS expenditure.



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The Missing Heritability of Severe Psychiatric Disorders

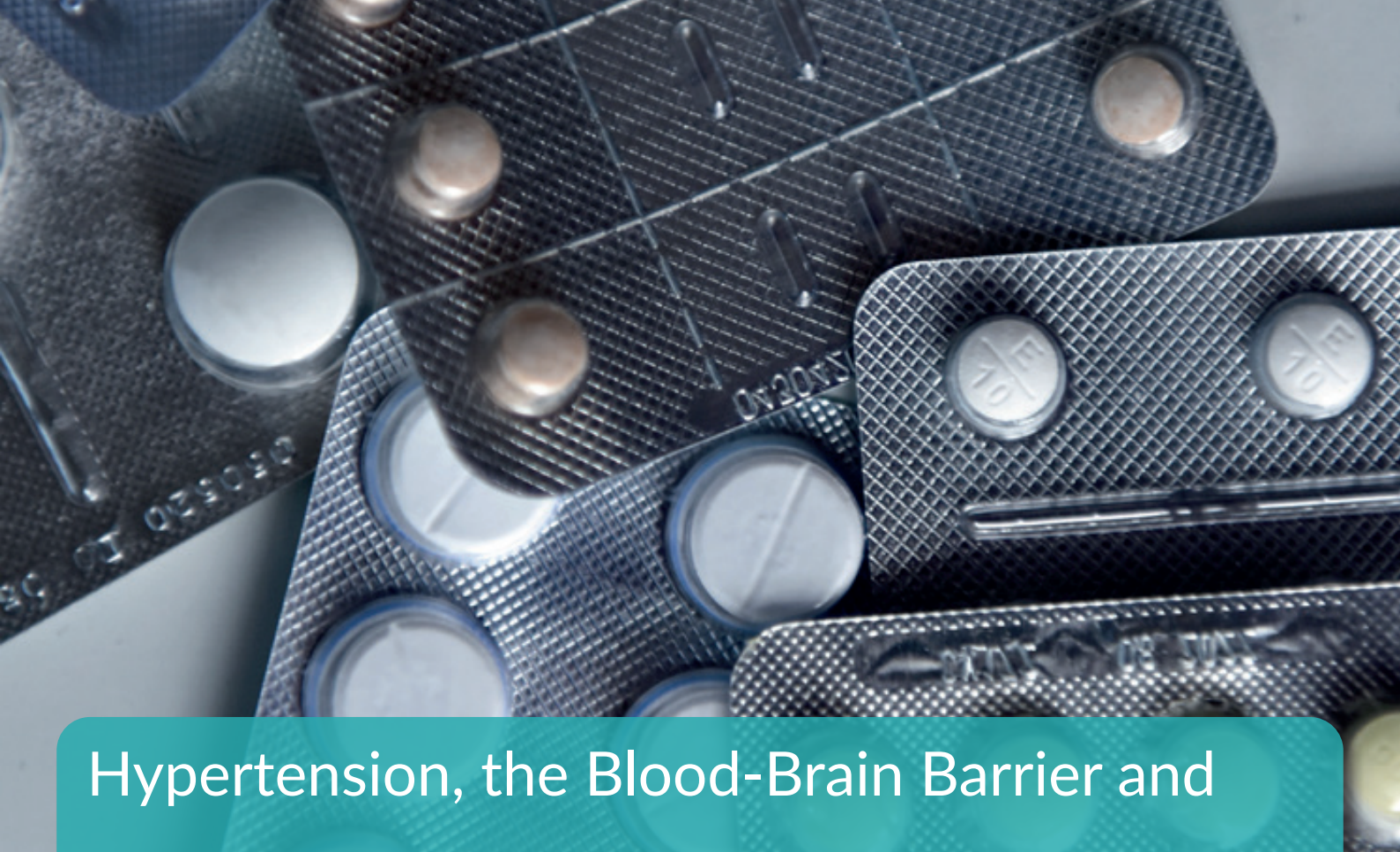
Richard Lilford, ARC WM Director

Genome-wide association studies show a lower summary statistic for heritability of psychiatric disease than epidemiological studies, such as identical twin studies. A recent article by Owen and Williams in the journal *World Psychiatry*, offered two explanations.[1] First, only polymorphisms with a population frequency of over 1% are included in genome association studies, as a rule. Since there is considerable downward selection pressure on severe psychiatric disease we may expect that there are lots of unfavourable mutations with a lower than 1% prevalence in the population. Second, the methodology detects small genetic rearrangements, not larger rearrangements.

I think that this is an intriguing subject. A number of environmental factors interact with genes to create the conditions we observe. There may also be a stochastic element, arising at times of massive neuronal division and synaptic pruning, as discussed in a previous news blog for CLAHRC WM.[2]

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Hypertension, the Blood-Brain Barrier and Cognitive Decline

Peter Chilton, Research Fellow

Previous research has already established that high blood pressure (hypertension) is a risk factor for cognitive decline and the onset of dementia, and it has been suggested that antihypertensive treatments may help. Renin-angiotensin system (RAS) drugs have been highlighted as potentially effective, and in particular those that are able to cross the blood-brain barrier (a border of cells that allows only certain solutes in blood from crossing into the central nervous system). A meta-analysis has recently been carried out that aimed to evaluate cognitive benefits of RAS drugs that could cross the blood-brain barrier, compared to RAS drugs that could not.[1]

The meta-analysis included participant data from 12,849 individuals, from 14 cohorts across six countries. The authors focussed on seven cognitive domains (e.g., attention, language, recall, etc.) and found that people taking renin-

angiotensin drugs that could cross the blood-brain barriers had significantly better memory recall over the follow-up period (up to three years) compared to those taking medications that could not cross the barrier. Those taking the non-penetrative drugs did have better attention, though the authors believe this could be explained through lower vascular risk burden.

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Association Between Coffee Consumption and Chronic Liver Disease

Peter Chilton, Research Fellow

Worldwide there is an increasing number of people suffering chronic liver disease, such as alcohol-related liver disease, chronic hepatitis B and C infection, and non-alcoholic fatty liver disease. The 2017 Global Burden of Disease Study estimated that 2.4% of deaths worldwide could be attributed to chronic liver disease.[1] It is a particular problem in low- and middle-income countries due to limited treatment options. Previous observational and lab-based studies have shown evidence that coffee may offer some protection against chronic liver disease (*along with various other health conditions, as discussed in a previous News Blog [2]*) and this has been touted as a potential intervention to prevent onset and progression. However, the chemical composition of coffee varies (for example, there is little caffeine in decaffeinated coffee, while filtered and instant coffee have lower concentrations [kahweol](#) and [cafestol](#) than ground coffee), and it is uncertain how preparation and type may affect the protective effect.

Using data from the UK Biobank the authors of a recent study in BMC Public Health [2] looked at the records of nearly half a million participants whose coffee habits were recorded, and their linked hospital, death and cancer records. Data were adjusted for age, sex, ethnicity, BMI, deprivation, alcohol consumption, smoking

status, and diabetes. Around 78% of participants drank some form of coffee (median of 2 cups per day) and follow-up data were available for a median of 10.7 years. Coffee drinkers were found to have lower adjusted hazard ratios of incidence of chronic liver disease (HR 0.79, 95% CI 0.72-0.86), chronic liver disease or steatosis (HR 0.80, 95% CI 0.75-0.86), and death from chronic liver disease (HR 0.51, 95% CI 0.39-0.67) when compared to non-coffee drinkers. These lower hazard ratios were proportionally associated with the amount of coffee drunk, up to 3-4 cups per day, after which there were no additional benefits. There were no significant differences shown regarding type of coffee (decaffeinated, instant or ground).

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Latest News and Events

Job Opportunities

Our ARC WM [Maternity theme](#) are looking to recruit a full-time Research Fellow based at the University of Birmingham.

The successful applicant will support the development of new projects and grant applications to investigate how to improve outcomes in maternity care. Mixed methods research will be undertaken across healthcare settings in the maternity pathway from antenatal, intrapartum and postnatal care and, in particular examining processes and outcomes of care when mothers cross boundaries or interfaces between services, or areas of concern are identified by stakeholders.

For further details, and to apply, please visit: jobs.ac.uk/job/CGQ943/research-fellow

Closing date for applications is **4 July 2021**.

There is also a job opportunity for a full-time Research Fellow with our ARC WM [Social Care theme](#), based at the University of Birmingham.

The post holder will have two main responsibilities: coordinating a network of people with lived experience to participate in the activities of a national collaboration of ARCs with experience of adult social care research; and undertaking research on the topics identified through the current prioritisation exercise.

For further details, and to apply please visit: jobs.ac.uk/job/CGL269/research-fellow-adult-social-work-and-social-care

Closing date for applications is **30 June 2021**.

Best Research for Best Health: The Next Chapter

The NIHR have recently published *Best Research for Best Health: The Next Chapter*, which sets out their operational priorities now and into the future. It re-affirms the core workstreams of the NIHR and details seven areas of strategic focus, where there is a need to work with urgency

and in fundamentally different ways in order to deliver transformative change.

It is available online at: nihr.ac.uk/documents/best-research-for-best-health-the-next-chapter/27778.

National NIHR ARC Newsletter



The June issue of the national NIHR ARC newsletter is now [available online](#), with reports on community-based volunteering during the COVID-19 pandemic; the impact of COVID-19 on people living with dementia; and mental health of children and adolescents over the past year. There are also details of a number of upcoming online events.

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

Growing Social Care Research in the West Midlands Event

The West Midlands Social Care Research Partnership are hosting a free half-day event on **Tuesday 19 October 2021** regarding *Growing Social Care Research in the West Midlands*.

This event is aimed at those passionate about improving social care services; those looking to develop their ideas for social care research and/or improving practice; and those aiming to understand more about how research is relevant to social care and how research can make a difference to social care practice.

The event will enable attendees to:

- Find out about how to develop research or practice improvement idea(s), and what support is available.
- Learn about funding opportunities available for social care research through the NIHR.

- Understand more about contemporary issues in adult social care and how research can impact social care practice.
- Network and connect with other researchers, practitioners, people with lived experience, commissioners and providers in the social care field.
- Attend a choice of in-depth sessions on key aspects of social care research and the research grant application process, to help take ideas forward.

Further details, including how to register, will be forthcoming.

Health Services Research UK Conference 2021

Registration is still open for this year's Health Services Research UK Conference, which will take place online from **6-8 July 2021**.

A wide range of live plenaries, workshops and discussion groups are being offered across the three days, as well as over 150 research presentations that which will be accessible on demand.

Plenaries will include:

- Long COVID: patient experience and the

developing research agenda.

- Meeting future challenges for the NHS workforce.
- Diversity and inclusion in health and care research.
- Science, evidence and government policy: lessons from the COVID-19 pandemic.

For more information, and to register, please visit: www.eventsforce.net/hsruk2021.

General Practice Recruitment for Asthma Study

ARC North Thames are currently assisting recruitment of general practices to the IMP²ART study. This is a UK-wide cluster RCT designed to help general practices deliver supported self-management in asthma. The study uses a team-based strategy designed to facilitate a practical

approach to meeting the needs of patients, professionals and the practice to develop skills in delivering asthma care.

More information can be obtained at: ed.ac.uk/usher/imp2art or by emailing: IMP2ART@ed.ac.uk.

Recent Publications

Grove A, Osokogu O, Al-Khudairy L, Mehrabian A, Zanganeh M, Brown A, Court R, Taylor-Phillips S, Uthman OA, McCarthy Noel, Kumar S, Clarke A. [Association between vitamin D supplementation or serum vitamin D level and susceptibility to SARS-CoV-2 infection or COVID-19 including clinical course, morbidity and mortality outcomes? A systematic review.](#) *BMJ Open.* 2021; **11**(5): e043737.

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