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Recognising the rising tide in service delivery and health systems research

Yen-Fu Chen, Associate Professor; Richard Lilford, ARC WM Director

With rising demands and finite resources, health systems worldwide are under constant financial pressure. The US has been at the extreme end of high spending, with health expenditure consisting of 17% of its GDP in 2017 – compared with 9.8% for the UK and 8.7% for the average of the OECD countries (OECD).[1] Therefore, the imperative of containing healthcare cost is mounting in the US. Under the Affordable Care Act (ACA), alternative payment models (often known as value-based payments) have been widely introduced to replace the fee-for-service model.

A recent article in JAMA highlighted a paradox,[2] in which an apparent plateau in overall healthcare expenditure (at around 18% of US GDP) is contrasted with lack of significant success reported in individual evaluations of these alternative payment models. Why has health spending as a proportion of GDP plateaued when the interventions to reduce spending have been ineffective in doing so? The authors ruled out the explanation that the growth in GDP has outpaced the growth of health expenditures as the latter seems to be genuinely flattening. So how can this discrepancy be reconciled?

The authors offered three explanations:

1 Anticipation of ACA-driven expansion of alternative payment models may have induced changes in the psychology and practice of clinicians and health care organisations, leading to curbs on spending irrespective of the introduction of alternative payment models.

2 Primed by the above change in mindset, clinicians and health care organisations may

have been influenced by their peers and emulate their practice. This would cause a wider spread of the change beyond the institutions where the alternative payment modelled were first introduced and evaluated (e.g. from within the Medicaid system to those covered by commercial insurers).

❸ Simultaneous introduction of a large number of alternative models in different places may have led to contamination of control groups in individual evaluations, where the control group chosen in one evaluation may be subject to the introduction of another alternative payment model.

Taken in the round, these explanations suggest a secular trend of system-wide changes (in this case cost containment), which may take various forms and be achieved through different means, but which are triggered by heightened awareness of the same issue and shared social pressure to tackle it across the board – what we have described as the 'rising tide phenomenon'.[3] The phenomenon is by no mean a rare occurrence in health services and systems research and so is well worth considering when a null finding is observed in a controlled study. The corollary is that when there is a rising tide, null findings do not disprove the potential effectiveness of the intervention being evaluated. A more nuanced interpretation taking into account the secular trend is required, as the authors of the aforementioned paper did.

References:

1. Organisation for Economic Co-operation and Development. Health. 2020. Available at: https://stats.oecd.org/Index.aspx?ThemeTreeId=9

2. Navathe AS, Boyle CW, Emanuel EJ. Alternative Payment Models—Victims of Their Own Success? *JAMA*. 2020; **324**(3):237-8.

3. Chen Y-F, Hemming K, Stevens AJ, Lilford RJ. Secular trends and evaluation of complex interventions: the rising tide phenomenon. *BMJ Qual Saf*. 2016; **25**(5): 303-10.

ARC WM Quiz

Which ground-breaking surgeon once said: *'stupid doctors become surgeons – all we have to do is cut things out, put things in and sew things up'?*

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

Answer to previous quiz: Dr Frances Oldham Kelsey refused to authorise **Thalidomide** for the US market in 1960.

Congratulations to Richard Grant who was first to answer correctly.

When Waiting is Not Enough

Paul Bird, Head of Programme Delivery (Engagement), Richard Lilford, Director

Healthcare is emerging from the immediate crisis response of COVID-19 into a hugely uncertain environment. One of the very few things of which we can be sure is significantly longer waiting times for elective procedures.

The Health Foundation recently published a report drawn from pre-COVID data,[1] which starkly portrayed the challenges around the 18 weeks *Referral to Treatment* target. The report estimated that the NHS needed to treat an additional 500,000 patients per year for the next four years to restore delivery of the target. Using data from NHS England following the first month of COVID-19 induced elective shut-down, Dr Rob Findlay noted a jump, both in the number of patients waiting over 52 weeks, and the average wait time for patients, which rose to 6 months.[2] These figures are likely to increase further in coming months. The article also noted that very few long-wait patients were treated. Longer wait patients should be de facto low clinical urgency, as it is this that has made them appropriate to wait.

There are two significant decision-making points for the treatment of patients on waiting lists. Clinical urgency, which of course affects those near the start of their waiting time, and being in imminent danger of breaching a waiting time target, which necessarily affects those towards the end. Between these decision-making points at the start and end of the waiting list lie a huge volume of patients with little categorisation or prioritisation.

Herein lies a significant future challenge: as waiting times increase and a growing number of patients breach waiting time targets, how do you ensure that limited elective capacity is targeted towards those with greatest clinical need?

If NHS England and NHS Improvement do not relax waiting time restrictions, maximum wait times will continue to be an important decision-making point. This incentivises providers to make a trade-off and treat longer waiting, but clinically less urgent, patients over short waiting, but clinically more urgent, ones. This would be a difficult position to justify ordinarily but in a time of likely constrained resource, the policy is likely to do far more harm than good.

It is crucially important to use *need* as the basis for prioritising which patients to treat. A recent literature review described some of the efforts made around the start of the millennium to develop a more systematic and transparent approach to prioritisation based on need. This approach developed from the Western Canada Waiting List Project [3] and the New Zealand Priority Criteria Project.[4] These approaches were rigorously reviewed through a range of academic articles and evaluated well, showing both transparency and consistency of decision making and prioritisation. Importantly, they also carried strong public support when reviewed with focus groups.

These 'point-count' systems work by creating a scoring chart for each clinical condition, such as cataract surgery, major joint replacement, coronary bypass graft. However, they have also been successfully used and evaluated for topics such as the use of Magnetic Resonance Imaging (MRI) and children's mental health. The scoring grid is unique to each clinical condition and developed through consensus discussion with clinicians to balance a range of clinical and social factors. The objective is to prioritise patients for treatment who will gain the most substantial benefit from intervention.

'Point-count' systems have translated successfully into several healthcare settings but not to the NHS. Often these types of changes are put in to the 'too difficult' category as the resource required to implement them is seen to be greater than the benefit gained. However, we are moving to a different paradigm post COVID-19 where integrated care systems are more accountable to their population and a more objective and transparent decision-making process is desirable.

Think too of the benefits of a shared language of waiting lists. We should not forget that many non-clinical staff are involved in the booking and scheduling of elective patients. A common currency in which objective comparisons can be made on the likely benefit of surgery or intervention across clinical indications and specialties is highly appealing.

One of the most keenly-debated elements of the development of these 'point-count' systems was what factors should be considered as part of the scoring criteria. Repeatedly the idea of including some reflection of how long a patient had waited was considered, and strongly rejected. Instead a measure of 'potential for disease progression' was included to ensure those, for instance, waiting for a joint replacement procedure, were not constantly usurped by patients with a more acute presentation. However, it guards against the current system of those waiting longest receiving priority at the potential expense of another who would derive greater clinical benefit.

So, as a policy directive there is a clear indication – the maintenance of the current maximum wait times will prioritise many clinically less urgent patients over more urgent cases. It remains to be seen whether the evidence base is substantial enough, and whether there is sufficient appetite within the NHS to revisit some of these clinical prioritisation approaches, but their use should be considered and their implementation would make a fascinating piece of research in the coming years.

References:

1. Charlesworth A, Watt T, Gardner T. Returning NHS waiting times to 18 weeks for routine treatment. *The Health Foundation.* 2020.

2. Findlay R. Average waiting time for NHS operations hits six months thanks to covid. *Health Serv J.* 2020.

3. Noseworthy TW, McGurran JJ, Hadorn DC, et al. Waiting for scheduled services in Canada: development of priority-setting scoring system. *J Eval Clin Pract.* 2003; 9(1): 23-31.

4. Hadorn DC, Holmes AC. The New Zealand priority criteria project. Part 1: Overview. *BMJ.* 1997; 314: 131.

Vitiating Randomisation by Adjustment

Richard Lilford, ARC WM Director

When I first became involved in randomised controlled trials (RCTs) the fashion was to make no statistical adjustment for potential confounders unless the trial had wide standard errors (SEs). This practice was based on a sound philosophical principle: randomisation maximises the chance that confounders will be equal across comparator groups ensuring accuracy (internal validity), and imprecision was described by a statistical test.

Econometricians did not follow this practice – randomisation was just one binary variable in their regressions.

I discern that it has become increasingly common to carry out post-randomisation adjustment in medical RCTs, even in large trials with narrow SEs. To be clear, my concern here is with purely statistical adjustments, as opposed to pre-stratification where sub-groups are created before randomisation.

I have grave concerns about making these statistical adjustments, for all that they might marginally improve precision. My concern is that these adjustments can introduce bias. It is well known that adjustment can introduce bias – this has been demonstrated empirically in cases comparing RCT findings with findings from unadjusted vs. adjusted observational studies. It sometimes occurs that the unadjusted observational studies produce findings more in line with RCTs than the adjusted observational studies.[1]

How can adjustment introduce bias? First, an adjustment may be made for a variable that is on the causal pathway. Second, there may be interaction between co-variates when adjustment is made for more than one co-variate. It is impossible to adjust for more than a few of these interactions when there are many variables with many possible levels. Third, and most lethal, adjustment may be made for a collider – a variable that is a common effect of an exposure and outcome. The difference between a confounder and collider is shown by the direction of arrows linking Exposure (E), Outcome (O) and Confounder or Collider (C) in Figure 1.

Fig 1. *On the left C is a confounder where cause goes from C to E and O, whereas on the right C is a collider and the arrows are reversed.*

Adjusting for a collider has produced some notorious erroneous associations. For example, adjusting for birth weight removes the association between smoking and neonatal death seen in the unadjusted data; smoking appears protective against early death. It turns out that birth-weight is a collider; Figure 2.

In a project to test a regenerative treatment to promote healing of leprosy ulcers we are going to measure weight bearing during the healing period to detect any possible co-intervention (a type of post-randomisation bias) that might arise if the intervention group are more careful to avoid weight bearing. We will measure weight bearing somewhat indirectly by asking all participants in the trial to wear a pedometer from which we will harvest data electronically. We do not expect to find any difference. However, in the unlikely scenario where we did find a difference in weight bearing across groups, it would be wrong to adjust for weight bearing in the analysis. This will introduce a collider, as per Figure 3.
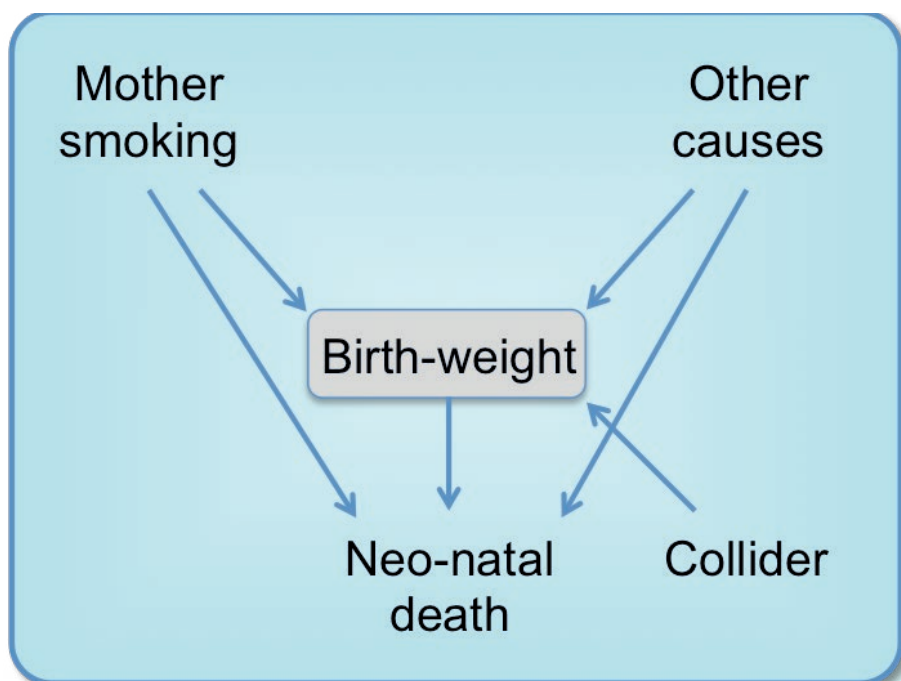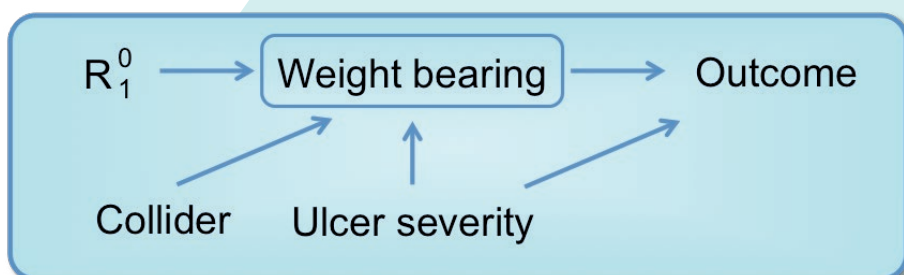

Fig 2. Examples of Collider Bias

Fig 3. Collider Bias if Adjusting for Weight Bearing

Reference:
1. Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovitch C, Song F, et al. Evaluating non-randomised intervention studies. *Health Technol Assess.* 2003;7(27).

England versus the US: The health of people between the ages of 55 and 64 by income group

Richard Lilford, ARC WM Director

A recent study in JAMA medicine compared the health of people in the above age groups.[1] How could you do that? The authors compared health using two data sets. In the US they used the health retirement survey. In the UK they used the longitudinal aging survey. The latter has been designed deliberately to mirror the US study.

Comparisons were made by income decile. A large number of reported and directly observed health measures were used. The former included items such as breathlessness on climbing a flight of stairs. The latter included measurements such as blood pressure.

Guess what: on almost all measures, direct and indirect, the UK citizens fared better. Interestingly, this applied across all income deciles.

The authors mention a number of limitations, but miss the limitations that weigh most heavily on the mind of the ARC-WM Director. Getting into a retirement survey and a longitudinal population analysis must introduce not inconsiderable selection bias, for which standard adjustment is likely to be incomplete. Indeed, the retirement condition involves considerable self-selection; it is hardly a random event. People in this age range in the US are probably particularly vulnerable, since they have the income insecurity associated with early retirement, but have not yet come under the universal national health insurance system (MediCare) that cuts in at age 65.

Reference:

1. Choi HJ, Steptoe A, Heisler M, et al. Comparison of Health Outcomes Among High- and Low-Income Adults Aged 55 to 64 Years in the US vs England. *JAMA Intern Med.* 2020; **180**(9): 1185-93.

Does Medical Litigation Create an Incentive for Better Quality Care?

Richard Lilford, ARC WM Director

As you may know, the ARC WM Director spent much of his professional life as a specialist obstetrician and gynaecologist – the front line specialty for medical negligence claims.

It is well known that a high risk of negligence claims results in defensive medicine. Defensive medicine involves procedures that add cost and risk for no material patient benefit. High rates of Caesarean sections are an example of such defensive practice. But what about the effect of the risk of litigation, and the safety and quality of medical practice?

To answer this question, the reviewers of a recent article in JAMA carried out a systematic review.[1] They retrieved articles where the exposure was a measure of the risk of litigation; for example, the incidence of litigation or the expenditure on cases of tort. The outcome was a measure of harm, such as obstetric injury, readmission or mortality. The largest proportion of studies were, unsurprisingly, in my previous field of obstetrics.

It was not possible to conduct a meta-analysis because of the heterogeneity in the type of study and measurement carried out. However, both in obstetric practice and across other specialties, there was no consistent association between litigation on the one hand and the safety or quality of practice on the other. Studies were either null, or had a few positive associations out of a large number of correlations made.

I do not think this disproves the possibility of a correlation between litigation incidence and care quality, but it does suggest that any such correlation is small. Certainly, incentives to increase litigation cannot be relied upon as a quality assurance mechanism. Of course, there are other reasons to maintain a tort system, including compensating the victims of medical negligence. The debate concerning different types of compensation mechanism, including no fault compensation, lies beyond the scope of this article.
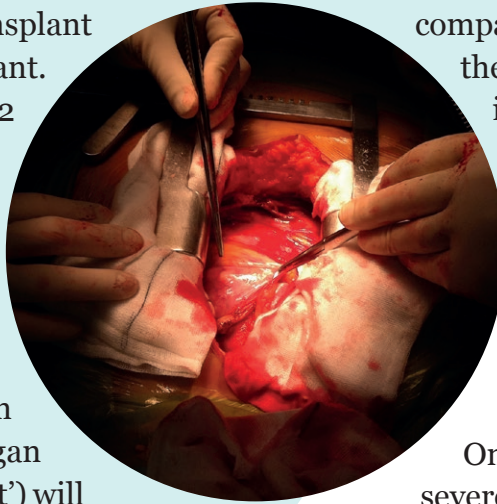
Reference:

1. Mello MM, Frakes MD, Blumenkranz E, Studdert DM. Malpractice Liability and Health Care Quality: A Review. *JAMA*. 2020;**323**(4):352–66.

Is It Safe to Transplant Hearts from Severely Obese Donors?

Peter Chilton, Research Fellow

Next Tuesday (29 September) is World Heart Day. As of last week (18 September) there are 333 adults in the UK who are on the active transplant list waiting for a heart transplant. [1] However, a total of only 172 heart transplants were carried out in the previous financial year (2019-20).[1] The latest estimate is that the average wait for a non-urgent patient is almost three years.[2] The recent change in organ donation law in England (where the organ donation system is now 'opt-out') will hopefully improve these figures; in fact, there has been a 23% increase in transplants carried out in the period April to August 2020 compared to the same period in 2019.[1] But is there an opportunity to improve this further?

A study carried out in the USA has looked at the impact of transplanting hearts from severely obese donors on recipient outcomes.[4] Currently, transplant centres register maximum donor weights that they are willing to accept for a patient, and the International Society of Heart and Lung Transplantation recommend that potential donors weigh within a range of 30% of the recipient's weight.[3]

The authors evaluated 26,532 first-time adult heart transplants conducted between 2003-2017 – of these 939 (3.5%) came from donors who had a BMI above 40. Although these donors were significantly more likely to have had diabetes mellitus (10.4% vs. 3.1%, p<0.01) and hypertension (33.3% vs. 14.8%, p<0.01) compared to donors with a lower BMI, there were no significant differences in short-term outcomes for the recipient, including graft failure (p=0.37), survival at one-year post-transplant (10.6% vs. 10.7%), or risk-adjusted long-term survival (p=0.30).

Only 19.5% of hearts from severely obese donor candidates were transplanted, compared to 31.6% of hearts from other donor candidates (p<0.01). Therefore there is the potential to safely expand the donor pool by increasing the evaluation of hearts from severely overweight donors.

References:

1. NHS Blood and Transport. Statistics about organ donation. 18 September 2020.

2. NHS Blood and Transport. Heart transplant waiting list grows. 24 September 2019.

3. Costanzo MR, Dipchand A, Starling R, et al. The International society of heart and lung transplantation guidelines for the care of heart transplant recipients. *J Heart Lung Transplant*. 2010;**29**:914–56.

4. Krebs ED, Beller JP, Mehaffey JF, et al. How Big Is Too Big? Donor Severe Obesity and Heart Transplant Outcomes. *Circulation Heart Failure*. 2020.

No Benefit and Possible Harm from Knee Surgery

Peter Chilton, Research Fellow

A tear in the meniscus (cartilage) of the knee is one of the most common knee injuries, resulting from either sudden trauma or age-related degeneration. Although rest and pain-relief is enough to relieve the pain in many cases, it can require surgical repair. As such, arthroscopic partial meniscectomy (APM) is one of the most common orthopaedic surgeries carried out. However, there is a growing body of evidence suggesting that such surgery offers only little benefit to the patient. A team of researchers in Finland have recently completed a five-year follow-up study comparing APM with diagnostic knee arthroscopy (as a placebo).[1]

The study randomised 146 adults (mean age 52 years) who had a degenerative medial meniscus tear in their knee to receive either APM or placebo surgery. Patients whose symptoms were clearly due to trauma were excluded. After five years the study found that there was a slightly increased risk of knee osteoarthritis of the knee in the APM surgery group compared to the control, and no relevant differences in patient-reported outcomes in knee pain. The authors have previously published follow-ups at 12 and 24 months,[2-3] which also showed no difference in patient-reported outcomes.

Although the study focussed only on patients with degenerative tears, and excluded patients whose damage was likely the result of trauma, the authors argue that the patients selected were those who were thought to be most likely to benefit from undergoing APM.

The ARC-WM Director and his colleague both had degenerative medial meniscus tears around five years ago. The Director had surgery and his colleague did not. They compared notes a few years later and they had both made good recoveries!

References:

1. Sihvonen R, Paavola M, Malmivaara A, et al. Arthroscopic partial meniscectomy for a degenerative meniscus tear: a 5 year follow-up of the placebo-surgery controlled FIDELITY (Finnish Degenerative Meniscus Lesion Study) trial. *Br J Sports Med.* 2020.

2. Sihvonen R, Paavola M, Malmivaara A, et al. Arthroscopic partial meniscectomy versus sham surgery for a degenerative meniscal tear. *N Engl J Med.* 2013;**369**:2515–24.

3. Sihvonen R, Paavola M, Malmivaara A, et al. Arthroscopic partial meniscectomy versus placebo surgery for a degenerative meniscus tear: a 2-year follow-up of the randomised controlled trial. *Ann Rheum Dis.* 2018;**77**:188–95.

Reporting Guidelines for AI

The SPIRIT-AI and CONSORT-AI Working Group have published the first reporting guidelines for clinical trials evaluating AI interventions in Nature Medicine, the BMJ and Lancet Digital Health. *"These reporting guidelines will provide a clear, transparent framework to support the design and reporting of AI trials that will help improve quality and transparency and deliver effective AI-led medical interventions to patients quicker."* Alastair Denniston.

SPIRIT-AI guidelines:

- Rivera, et al. *BMJ*. 2020; **370**: m3210.

- Rivera, et al. *Lancet Digital Health*. 2020; **2**(10):e459-60.

- Rivera, et al. *Nature Medicine*. 2020; **26**:1351-63.

CONSORT-AI guidelines:

- Liu, et al. *BMJ* 2020;**370**:m3164.

- Liu, et al. *Lancet Digital Health*. 2020; **2**(10):e537-48.

- Liu, et al. *Nature Medicine*. 2020; **26**: 1364-74.

This work was led by Prof Alastair Denniston, Dr Xiaoxuan Liu, Prof Melanie Calvert (a co-I in NIHR ARC WM) and Dr Samantha Cruz Rivera. The development of SPIRIT-AI and CONSORT-AI was an international collaborative effort that included 100+ experts from the AI and ML community and the EQUATOR Network.

These guidelines were possible thanks to The Wellcome Trust, The Alan Turing Institute, Research England, Health Data Research UK, the University of Birmingham, Birmingham Health Partners, and the University Hospitals Birmingham.
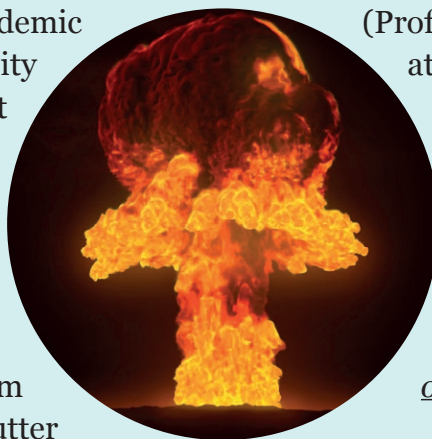
The authors would also like to emphasise the important role that patient partners played in the development of these guidelines. Patient partner Elaine Manna wrote about her perspectives for Nature Medicine online.

INSIGHT 2020 Festival

The Strategy Unit are hosting INSIGHT 2020, a 6-week festival of virtual events exploring some of the challenges facing decision-makers in health and care in 2020 and beyond, including emerging models of practice to make best use of analysis to inform decision-making.

Sessions will be bite-size, varied and flexible and you can attend as few or as many sessions as you'd like. If you aren't able to make the live event, most of the sessions will be recorded so you can fit them into your schedule in a way that suits you. Every session is free. The event will run from **28 September - 13 November 2020**. Further details and how to register can be found online.

Nuclear War: Learning Lessons from COVID-19

While the current COVID-19 pandemic has us focused on our vulnerability to communicable disease, it should also serve as a wake-up call to the cataclysmic impact that would befall the world if nuclear weapons were ever to be used again.

Prof Lilford, colleagues from ARC WM, and Prof Andrew Futter (Professor of International Politics at University of Leicester), have recently published an article arguing that there is an urgent need for renewal of public education, interest, and activism in reducing nuclear dangers.

It is available online in the _Bulletin of Atomic Scientists_. 2020; **76**(5).

Future Focused Leadership programme

Cohort 3 of the Future Focused Leadership programme is now open for applications. This is a 12 month programme that has been has been developed specifically for the NIHR and is designed around exploring leading yourself, leading others, and leading beyond authority.

It incorporates residential workshops, a 360 feedback activity, action learning sets, individual coaching and virtual reality coaching.

The deadline for applications is **2 October 2020**. More information, and how to apply, can be found online.

National NIHR ARC Newsletter

The latest issue of the national NIHR ARC newsletter is now available online.

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

Research for Social Care Roadshow

Registration is now open for the NIHR Research for Social Care Roadshow. This event is to showcase the forthcoming RfSC competition for social care proposals, that has the aim to fund topics and research methodologies that increase the effectiveness of social care services, provide value for money, and benefit service users and carers.

Although the event is aimed at those in the South Central region, all are welcome to attend.

The online event will be held from 09:45-13:00 on **Wednesday 7 October 2020**. For more information, and to register, please click here.

Latest Funding Opportunities

NIHR HTA Programme

The Health Technology Assessment (HTA) Programme funds research about the clinical and cost-effectiveness and broader impact of healthcare treatments and tests for those who plan, provide or receive care from NHS and social care services. They are currently accepting stage 1 applications to the following researcher-led workstreams:

- 20/89 HTA Programme Researcher-led (evidence synthesis)
- 20/90 HTA Programme Researcher-led (primary research)

Deadline for proposals is 1pm on 6 January 2020.

NIHR Development & Skills Enhancement Award

NIHR Academy members who have recently completed, or will soon complete, a funding Award, may be eligible for the Development and Skills Enhancement (DSE) Award, which is now open for applications. The award provides a maximum of 1 year of funding for post-doctoral NIHR Academy Members to gain skills and experience for the next phase of their research career. Applications from health data science, clinical trials, or entrepreneurship and working with industry are particularly welcome.

The deadline for proposals is 1pm on 26 November 2020. For more information, and to apply, please click here.

EPSRC Transformative Healthcare Technologies

The EPSRC is looking to invest in ambitious and highly adventurous healthcare technologies research driven by curiosity, which align to their strategic priorities. The healthcare technologies theme is keen to build on the previous call by expanding its portfolio of potentially transformative healthcare grants.

Transformative Healthcare Technologies is a high-risk, high-return initiative that will be implemented in two phases. Phase 1, the development phase, will identify projects that demonstrate readiness in order to deliver an ambitious programme of research in Phase 2. In the programme delivery phase, those successful in the development phase will be invited to bid into a second call, where four to six substantive programmes of research are planned to be supported.

The deadline for proposals is 4pm on 14 October 2020. For more information, and to apply, please click here.

Ahmed SAKS, Ajisola M, Azeem K, Bakibinga P, Chen YF, Choudhury NN, Fayehun O, Griffiths F, Harris B, Kibe P, Lilford RJ, Omigbodun A, Rizvi N, Sartori J, Smith S, Watson SI, Wilson R, Yeboah G, Aujla N, Azam SI, Diggle PJ, Gill P, Iqbal R, Kabaria C, Kisia L, Kyobutungi C, Madan JJ, Mberu B, Mohamed SF, Nazish A, Odubanjo O, Osuh ME, Owoaje E, Oyebode O, Porto de Albuquerque J, Rahman O, Tabani K, Taiwo OJ, Tregonning G, Uthman OA, Yusuf R. Impact of the societal response to COVID-19 on access to healthcare for non-COVID-19 health issues in slum communities of Bangladesh, Kenya, Nigeria and Pakistan: results of pre-COVID and COVID-19 lockdown stakeholder engagements. *BMJ Glob Health*. 2020;**5**(8):e003042.

Ayorinde AA, Williams I, Mannion R, Song F, Skrybant M, Lilford RJ, Chen Y. Publication and related bias in quantitative health services and delivery research: a multimethod study. *Health Serv Deliv Res*. 2020;**8**(33).

Fraze TK, Briggs ADM, Witcomb EK, Peck KA, Meara E. Role of Nurse Practitioners in Caring for Patients With Complex Health Needs. *Med Care*. 2020; **58**(10):853-60.

Futter A , Watson SI, Chilton PJ, Lilford RJ. Nuclear war, public health, the COVID-19 epidemic: Lessons for prevention, preparation, mitigation, and education. *Bull Atom Sci*. 2020;**76**(5):271-6.

Hinks TSC, Barber VS, Black J, Dutton SJ, Jabeen M, Melhorn J, Rahman NM, Richards D, Lasserson D, Pavord ID, Bafadhel M. A multi-centre open-label two-arm randomised superiority clinical trial of azithromycin versus usual care in ambulatory COVID-19: study protocol for the ATOMIC2 trial. *Trials*. 2020;**21**(1):718.

Jones E, Taylor B, MacArthur C, Bradshaw S, Hope L, Cummins C. Early Postnatal Discharge for Infants: A Meta-analysis. *Pediatrics*. 2020; **146**(3):e20193365.

Jones J, Stanbury M, Haynes S, Bunting KV, Lobban T, Camm AJ, Calvert MJ, Kotecha D. Importance and Assessment of Quality of Life in Symptomatic Permanent Atrial Fibrillation: Patient Focus Groups from the RATE-AF Trial. *Cardiology*. 2020:1-10.

Kletter M, Plunkett E, Plunkett A, Hunt H, Bird P, Brown C. Impact of the learning from excellence programme in NHS Trusts: an exploratory study. *Br J Healthcare Manage*. 2020;**26**(8):1-10.

Knight T, Clare S, Smallwood N, Lasserson DS. Gaps in point of care ultrasound provision and the cost of ultrasound equipment provision: results of a nationwide audit of acute medical units. *Acute Med*. 2020;**19**(2):64-8.

Lee LYW, Cazier J-B, Starkey T, Briggs SEW, Arnold R, Bisht V, Booth S, Campton NA, Cheng VWT, Collins G, Curley HM, Earwaker P, Fittall MW, Gennatas S, Goel A, Hartley S, Hughes DJ, Kerr D, Lee AJX, Lee RJ, Lee M, Mckenzie H, Middleton CP, Murugaesu N, Newsom-Davis T, Olsson-Brown AC, Palles C, Powles T, Protheroe EA, Purshouse K, Sharma-Oates A, Sivakumar S, Smith AJ, Topping O, Turnbull CD, Várnai C, Briggs ADM, Middleton G, Kerr R. COVID-19 prevalence and mortality in patients with cancer and the effect of primary tumour subtype and patient demographics: a prospective cohort study. *Lancet Oncol*. 2020.

Lilford P, Rajapakshe OBW, Singh SP. A systematic review of care pathways for psychosis in low-and middle-income countries. *Asian J Psychiatr*. 2020; **54**: 102237.

Liu X, Rivera SC, Moher D, Calvert MJ, Denniston AK; The SPIRIT-AI and CONSORT-AI Working Group. Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension. *Nat Med*. 2020;**26**(9):1364-74.

[As above] Lancet Digital Health. 2020; **2**(10): e537-48.

[As above] *BMJ*. 2020; **370**:m3164.

Morrison AP, Pyle M, Maughan D, Johns L, Freeman D, Broome MR, Husain N, Fowler D, Hudson J, MacLennan G, Norrie J, Shiers D, Hollis C, James A; MAPS group. Antipsychotic medication versus psychological intervention versus a combination of both in adolescents with first-episode psychosis (MAPS): a multicentre, three-arm, randomised controlled pilot and feasibility study. *Lancet Psychiatr*. 2020;7:788-800.

Nikiphorou E, de Lusignan S, Mallen C, Khavandi K, Roberts J, Buckley CD, Galloway J, Raza K. Haematological abnormalities in new-onset rheumatoid arthritis and risk of common infections: a population-based study. *Rheumatol*. 2020;59(5):997-1005.

Nikiphorou E, de Lusignan S, Mallen C, Roberts J, Khavandi K, Bedarida G, Buckley CD, Galloway J, Raza K. Prognostic value of comorbidity indices and lung diseases in early rheumatoid arthritis: a UK population-based study. *Rheumatol*. 2020;59(6):1296-1305.

Partington R, Muller S, Mallen CD, Sultan AA, Helliwell T. Mortality among patients with polymyalgia rheumatica: A retrospective cohort study. *Arthritis Care Res*. 2020.

Rivera SC, Liu X, Chan AW, Denniston AK, Calvert MJ; on behalf of the SPIRIT-AI and CONSORT-AI Working Group. Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI Extension. *BMJ*. 2020;370:m3210.

[as above] *Lancet Digital Health*. 2020; 2(10): e459-60.

[as above] *Nature Med*. 2020;26:1351-63.

Roulet C, Rozsnyai Z, Jungo KT, A van der Ploeg M, Floriani C, Kurpas D, Vinker S, Kreitmayer Pestic S, Petrazzuoli F, Hoffmann K, Viegas RPA, Mallen C, Tatsioni A, Maisonneuve H, Collins C, Lingner H, Tsopra R, Mueller Y, Poortvliet RKE, Gussekloo J, Streit S. Managing hypertension in frail oldest-old-The role of guideline use by general practitioners from 29 countries. *PLoS One*. 2020;15(7):e0236064.

Sanchez Santos MT, Williamson E, Bruce J, Ward L, Mallen CD, Garrett A, Morris A, Lamb SE; OPAL study team. Cohort profile: Oxford Pain, Activity and Lifestyle (OPAL) Study, a prospective cohort study of older adults in England. *BMJ Open*. 2020;10(9):e037516.

Schmidtke KA, Vlaev I, Kabbani S, Klauznicer H, Baasiri A, Osseiran A, El Rifai G, Fares H, Saleh N, Makki F. A randomized controlled trial evaluating text prompts in Lebanon to encourage health-seeking for hypertension. *Int J Clin Prac*. 2020.

Shantsila E, Shahid F, Sun Y, Deeks J, Calvert M, Fisher JP, Kirchhof P, Gill PS, Lip GYH. Spironolactone in Atrial Fibrillation With Preserved Cardiac Fraction: The IMPRESS-AF Trial. *J Am Heart Assoc*. 2020;9(18):e016239.

Smith KA, Bishop FL, Dambha-Miller H, Ratnapalan M, Lyness E, Vennik J, Hughes S, Bostock J, Morrison L, Mallen C, Yardley L, Everitt H, Little P, Howick J. Improving Empathy in Healthcare Consultations-a Secondary Analysis of Interventions. *J Gen Intern Med*. 2020.

Tallouzi MO, Moore DJ, Bucknall N, Murray PI, Calvert MJ, Denniston AK, Mathers JM. Outcomes important to patients with non-infectious posterior segment-involving uveitis: a qualitative study. *BMJ Open Ophthalmol*. 2020;5(1):e000481.

Taylor CJ, Ordóñez-Mena JM, Jones NR, Roalfe AK, Lay-Flurrie S, Marshall T, Hobbs FR. National Trends in Heart Failure Mortality in Men and Women, United Kingdom, 2000-2017. *Eur J Heart Fail*. 2020.

Twohig H, Owen C, Muller S, Mallen C, Mitchell C, Hider S, Hill C, Shea B, Mackie S. Outcomes Measured in Polymyalgia Rheumatica and Measurement Properties of Instruments Considered for the OMERACT Core Outcome Set: A Systematic Review. *J Rheumatol*. 2020.