Glasgow, UK

margaret@margaretmccartney.com
Follow Margaret on Twitter at @mgtmccartney

Cite this as: *BMJ* 2020;370:m3473
http://dx.doi.org/10.1136/bmj.m3473
Published: 07 September 2020

We need better evidence on non-drug interventions for covid-19

Non-drug interventions should be based on evidence. We need to generate this to inform the covid-19 and future pandemics, argues Margaret McCartney

Margaret McCartney *GP partner*

Almost 1300 controlled trials have been registered for drug interventions for covid-19.[1] Among them have been large, well powered, international trials that have assessed the effectiveness of treatments such as dexamethasone and hydroxychloroquine. But why have non-drug interventions not been subject to the same interrogation?

The BESSI Collaboration (Behavioural, Environmental, Social, and Systems Interventions (for pandemic preparedness)) is currently being developed. But so far only 10 controlled trials of non-drug interventions have been registered, with three reported.

This makes no sense. Drug interventions are generally aimed at a relatively small group of people who have been infected and are ill. Non-drug interventions, such as physical distancing, face coverings, or school patterns of re-opening, are aimed at whole population groups, and yet these are hardly being tested.

But these interventions affect more people. In the initial weeks of a pandemic, I understand the need to make urgent decisions using best guess judgment. But over time we have ample opportunity to consider which other interventions in use are effective, which are not, and which have unintended consequences that outweigh potential benefits. We take drug trials seriously because we recognise the possibility of iatrogenic fatalities: we seek the protection of a data monitoring committee and acknowledge that good intentions are not enough. Why is this not the case for non-drug strategies?

It is as though non-drug interventions are not considered capable of doing harm, or regarded as either too hard to investigate, or too obviously beneficial to bother with trials. I think this is an error. A recent analysis in *The BMJ* argued that concern about risk compensation was a "dead horse" that "now needs burying to try and prevent the threat it poses through slowing the adoption of effective public health interventions."[2] Using the example of face masks, evidence was cited which found no clear reduction in concurrent hand washing with mask wearing. But this is not the only possible form of risk compensation. The fundamental question is whether face coverings reduce harm to people in the population. For example, do supermarkets rely on face coverings instead of physical distancing and is this harmful? Do face coverings give people confidence to leave home more, and take more risks when they are out?

There are large gaps in our knowledge and without clear evidence on the use of cloth masks in the community we may be wearing false reassurance.[3 4] Observation of the use of face coverings, in real life, finds that they are commonly worn incorrectly.[5] Nor have we considered enough the broader societal impact. People with histories of trauma, or who have hearing difficulties, are placed at disadvantage.[6] Yet those who do not wear face coverings are categorised, by proponents of face coverings, as "deviants from the new norm."[7] Societal cohesion is risked by dividing rather than understanding behaviour. These are all harms. Nor do we have a clear "end" strategy. We need less panic and more practical, pragmatic research.

But how? In the past few days the UK government has changed its mind over face masks in schools. It would be far more honest and transparent for the government to explain the difficulty of making recommendations without evidence and for medical advisers to explain the need to obtain it. Without underestimating the effort required, it would be possible to randomise schools in geographical areas to "usual care" or "masks supplied," giving children resources and instruction on how to use them, obtaining data on infections both in the school and in the community. Stepped wedge trials would also be possible. Knowing what works will either support roll out or ensure we do not waste resources. If we can do international trials of drugs, we should be able to work across local authorities. Public health departments, with their intimate knowledge of regions, could support researchers in the community. The UK public should be allowed the opportunity to contribute, in keeping with the partnership model between patients and clinicians that the NHS supports. If we want public trust—possibly the most important thing in the management of a pandemic—we must earn it.

Another argument is that large scale trials, say of face mask use in schools, are impossible, because of the belief that every child would need a guardian to consent, making recruitment practically impossible. But this is deeply problematic. This suggests that the government can choose and implement any policy, without requiring any individual consent, as long as it is not called a trial. For as long as this double standard is allowed to persist, giving less powerful results and unnecessary uncertainty, people may come to avoidable harm. Nor does valuable information come only from randomised controlled trials. Complex interventions require multiple disciplines and types of research for assessment. But where are they?

And so bravo to the Germans for the Restart19 project, which is a study comprised of several sub projects to assess the risk of holding a major sporting or cultural

event indoors.[8] Chapeau to the Danish, who have set up two trials. The DANMASK randomised controlled trial, will study whether face masks protect the wearer against covid-19.[9] Another Danish group is running a trial of community made cloth masks in Guinea-Bissau.[10] In Norway, trialling full opening versus partial re-opening in all primary schools over four weeks was planned, but the government withdrew support.[11] The researchers intend, however, to prepare a similar trial so that it can begin if infections in Norway rise. Further, they are planning a prospective study of university students to assess whether on-campus teaching is associated with a higher risk of covid-19 infection compared with online learning.[12] This work can rationally inform what we do now and in the future. Further, detailed research can identify health inequalities and generate information on how to reduce them.

We need trials because we cannot presume that non-drug interventions won't do harm or waste resources, thereby diverting attention and money. There is past form on this. In Australia, baby simulators were used to try and reduce teenage pregnancy but a cluster randomised controlled trial found that it had the opposite effect.[13] The "Scared Straight" programme was used to try and deter young people at high risk of committing criminal acts, but resulted in increasing criminality, at large cost.[14] Dr Spock's well meaning, seemingly sensible advice to lay babies on their fronts to sleep was associated with at least 50 000 infant deaths.[15]

In Scotland, arrangements for blended learning (a mix of online and in-class teaching) were abandoned with a decision to have all children return to school full time after preparations had been made. Yet this would have been a good opportunity for a trial, randomising across geographical areas. It could have given rapid, helpful results, and opportunity for qualitative research on the wider social impacts. Trials for colleges and universities need to be planned right now. Covid-19 is not going away anytime soon, and we are squandering the opportunity to learn for this pandemic—and the next.

Competing interests: MMcC is a senior fellow for evidence and values at the Royal College of General Practitioners, and a freelance writer and broadcaster who receives royalties for three books. She gives a small amount regularly to Keep our NHS public and is honorary fellow at the CEBM Oxford.

Not commissioned; peer reviewed.

1 BESSI Collaboration. About us. www.bessi-collab.net.
2 Mantzari E, Rubin GJ, Marteau TM. Is risk compensation threatening public health in the covid-19 pandemic? *BMJ* 2020;370:m2913. doi: 10.1136/bmj.m2913 pmid: 32713835
3 Bakhit M, Krzyzaniak N, Scott AM, Clark J, Glasziou P, Del Mar C. Downsides of face masks and possible mitigation strategies: a systematic review and meta analysis. medRxiv 2020.06.16.20133207 [Preprint]. www.medrxiv.org/content/10.1101/2020.06.16.20133207v1.
4 Iversen BG, Vestrheim DF, Flottorp S, Denison E, Oxman AD. *Covid-19: should individuals in the community without respiratory symptoms wear facemasks to reduce the spread of covid-19?* [Covid-19: Bør personer i samfunnet bruke ansiktsmasker for å redusere spredningen av covid-19? Hurtigoversikt 2020] Norwegian Institute of Public Health, 2020.
5 Prendergast A, Waldron S, Balasegaram S. Re: Is risk compensation threatening public health in the covid-19 pandemic? [electronic response to Mantzari E, Rubin GJ, Marteau TM. Is risk compensation threatening public health in the covid-19 pandemic?] BMJ [2020]. www.bmj.com/content/370/bmj.m2913/rr-2.
6 Chodosh J, Weinstein BE, Blustein J. Face masks can be devastating for people with hearing loss. *BMJ* 2020;370:m2683. doi: 10.1136/bmj.m2683 pmid: 32646862
7 van der Westhuizen HM, Kotze K, Tonkin-Crine S, Gobat N, Greenhalgh T. Face coverings for covid-19: from medical intervention to social practice. *BMJ* 2020;370:m3021. doi: 10.1136/bmj.m3021 pmid: 32816815
8 Restart-19. What is RESTART-19? https://restart19.de/das-projekt.
9 Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, et al. Face masks for the prevention of COVID-19 - Rationale and design of the randomised controlled trial DANMASK-19. *Dan Med J* 2020;67:.pmid: 32829745
10 Bandmin Health Project. Locally produced cloth face mask and covid-19 like illness prevention. Clinical trials identifier NCT04471766. https://clinicaltrials.gov/ct2/show/NCT04471766.
11 ISRCTN registry. School opening in Norway during the covid-19 pandemic. ISRCTN44152751. www.isrctn.com/ISRCTN44152751.
12 Oslo Metropolitan University, Norwegian Institute of Public Health. Association between in-person instruction and covid-19 risk (campus and corona). Clinical trials register NCT04529421. https://clinicaltrials.gov/ct2/show/NCT04529421.
13 Brinkman SA, Johnson SE, Codde JP, et al. Efficacy of infant simulator programmes to prevent teenage pregnancy: a school-based cluster randomised controlled trial in Western Australia. *Lancet* 2016;388:2264-71. doi: 10.1016/S0140-6736(16)30384-1 pmid: 27570178
14 College of Policing. "Scared Straight" programme. 19 February 2005. https://whatworks.college.police.uk/toolkit/pages/Intervention.aspx?InterventionID=2.
15 Gilbert R, Salanti G, Harden M, See S. Infant sleeping position and the sudden infant death syndrome: systematic review of observational studies and historical review of clinicians' recommendations from 1940 to 2002. *Int J Epidemiol* 2005;34:874-87. doi: 10.1093/ije/dyi088 pmid: 15843394