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Guidance in an uncertain world

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Running title: **Guidance in an uncertain world**

Summary

In the face of the coronavirus pandemic, clinicians are looking to multiple sources for guidance. Good guidance provides a helpful tool to support decision making by experienced and highly-trained healthcare professionals. However, in the context of a readily changing landscape there are risks of guidance that hinders rather than helps, duplicates effort and fails to consider the front-line implications. Conversely, an overly conservative approach may result in good guidance never seeing the light of day, or being published too late.

We suggest that there are key principles that may help guideline producers to improve the process. These include: addressing directly and transparently the competing risks and benefits to individual patients, staff and the wider community; making greater efforts to find reliable data to inform recommendations; ensuring duplication of effort and conflict with extant guidance is minimised; involving front-line staff in development and consideration of real-world implications of delivery; and ensuring that feedback and revisions are integral to the process.

The MORAL Balance framework has previously been advocated for making complex individual patient level decision in critical care. We believe the same process can be applied as a framework for guideline development groups.

Key words:

Clinical guidelines; COVID-19; coronavirus

In the face of the coronavirus pandemic, clinicians are looking to multiple sources for guidance. Clinical experience and professional training remain the bedrock for every healthcare practitioner, but guidance to support difficult decisions is needed. In an ideal world there might be a series of definitive randomised controlled trials covering key areas – who benefits from critical care admission, what are the risks of operating, or not operating? Even good quality observational data would be helpful with all the caveats of confounding, association and causation. To a large extent these are lacking for obvious reasons. So, healthcare workers and national organisations are trying to respond at great speed in a rapidly changing environment with the production and implementation of guidance. These are inevitably at best based on partial data, translation of theory and evidence from other situations, and collective wisdom.

Just as evidence-based medicine has a hierarchy of evidence, so we can consider a hierarchy of guidance. International guidance (World Health Organisation), national guidance from the 'centre' (Government, courts, NHS England / Improvement in England, UK[1], Centers for Disease Control and Prevention in the US[2]), followed by national collegiate guidance (such as Colleges and speciality associations[3]), local (NHS Trust or hospital grouping / hospital), departmental and so on. Whether this translates into a hierarchy of acceptance of such guidance is unclear. There is some evidence that in normal times for doctors, sources of influence from colleagues from the medical profession are judged more legitimate than professional or medical associations,[4] we are not aware of empirical evidence of how healthcare professionals prioritise guidance in a crisis situation. There is inevitably a tension

between a perceived need for military-style ‘command and control’ and the professional and individual autonomy to create and challenge centrally produced guidance.

Clinical guidelines normally take months or even years to produce[5, 6], and are then subject to regular review and critique and updated as the evidence changes. Guidance is often required precisely because the evidence base is weak, or conflicted, and can therefore act as a catalyst for better quality data. Guidance in the COVID pandemic is coming out in days, and new versions of the same guidance days after that. The inevitable consequence will be that some is simply wrong, some is poorly written and some is found to be wanting in hindsight. Duplication of effort and, perhaps worse, contradictory guidance, wastes time and energy and undermines trust. The corollary is that some good guidance will never see the light of day, be published too late, or lost in the tidal wave of information overload we are all experiencing.

Rather than criticising any particular guidance, we would like to draw on recent experience of writing some national guidance[7, 8], and the implementation and training of national guidance at a local level. We hope to draw out for readers, and perhaps for guideline groups, some of the issues that we face.

A fundamental question is which competing outcomes are we are trying to balance.

There might be risks to the patient directly. Does coronavirus infection make outcomes worse after surgery, and importantly how does that compare to not having that surgery? Is having a different operation, or none at all, likely to produce a short or long-term harm or

benefit for the patient? The coronavirus epidemic is not a short-lived crisis. Choosing to limit investigation and treatment of curable life-limiting diseases – benign or malignant – is going to cause significant harm to those otherwise barely touched by coronavirus infection.

What about other patients? We are working in a severely resource constrained environment. Most obvious is intensive care capacity – personnel, space and equipment, but other resources are at a premium. Operating theatre time is limited – due to the triple hits of staff sickness, diversion of staff to other areas and longer turnaround times for infection prevention and control. Impacts elsewhere in health and social care must not be forgotten – avoiding surgery or changing operative approaches to mitigate impact on the operating room may have a fairly predictable effect of increasing workload on nursing and social care staff – to the detriment of others.

And what about the staff themselves? All healthcare workers are exposing themselves to risk working with patients with known and unknown coronavirus status. At the benign end COVID is an unpleasant illness, at its worst it has caused the deaths of nurses and doctors in several countries. The knock-on effect of staff absence through self-isolation is significant, and in turn impacts on patients and colleagues.

Are there any solutions to these complex issues? We will hesitantly suggest a few questions guideline writers might consider:

We have previously described an ethical decision making framework - MORAL Balance[9, 10] - to guide clinicians in making patient-centred shared decisions. An explicit ethical framework

helps ensure decisions take account of the available facts and data, recognise all of the relevant outcomes to the individuals and groups involved, before reaching a balanced decision. We suggest decision frameworks are applicable to organisational decisions as well.

BOX

Make sure of the Facts. Has the group considered the robustness of the data they are using? Are they extrapolating from other scenarios in a reasonable way? If there is uncertainty can it be quantified? There are some good data out there, and some research groups have made huge strides in trying to synthesise the research evidence in impressively short spaces of time.[11] These groups are responsive and expert – so there seems little reason not to seek their advice.

Have other stakeholders been involved in the decisions? Some guideline development groups seem to have involved more than others. Making pronouncements that affect colleagues outside our own professional groups, without seeking their views, hardly engenders trust and risks making simple, avoidable mistakes.

It is vital that all outcomes of relevance for all those involved in the decision are taken into account and specified. For example, who is going to benefit from the decisions and recommendations in the guidance and how? Where is the harm, is it physical, psychological, financial, emotional? Are there other outcomes, perhaps difficult to articulate or admit that are influencing decision making, for concerns about liability in a legal or a moral sense, or

worries about media and public scrutiny? If so, are these influences justified and commensurate?

The use of a framework doesn't solve these problems or resolve all disagreements, and certainly doesn't prevent conflict between competing outcomes, for example staff versus patient safety. But it does facilitate a clear understanding of which factors are influencing decision making. Subsequent decisions are more transparent, better justified, and more robust.

Guidance without implementation is pointless. If there is conflict between existing documents, is the subsequent impact (need for rapid change, confusion, misunderstanding) justified? Is implementation credible in the real-world - have the implications for personnel, training, time and equipment been considered? Have clinicians with current, front-line experience been actively involved in development?

Finally, what is the mechanism to adapt and revise? No guidance is ever perfect – even before these times. Clearly a balance needs to be struck between endless revisions leaving people confused, and a responsive, responsible attitude that realises when guidance just doesn't work or the data have improved. It is good science to change our view when new evidence comes to light.

High level guidance is the science and the art of translating a complex, messy, constantly evolving picture into some semblance of order. We will get it wrong, but we mustn't stop trying.

Author's contributions

IKM: Article design, writing and revising all drafts of the article, final approval of version to be published; DJRH: Original concept of MORAL balance, writing and revising all drafts of the article, final approval of version to be published. DG: Original concept of MORAL balance, critical revision of the article, final approval of version to be published. All authors fulfil all the requirements of ICMJE.

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BOX

	Action	**Example**
M	**M**ake Sure of the Facts	Evidence base, uncertainty, applicable cohort, existing guidance
O **R**	Identify **O**utcomes of **R**elevance to the	Mortality, morbidity, safety, capacity, resource utilisation, system efficiency, psychological & emotional impact
A	**A**gents involved	To whom do these outcomes accrue? Who has a moral stake in the outcome ? Patients, families, staff, public, future patients, government
L	Populate then **L**evel out the arguments	Specify these outcomes within the four ethical principles (beneficence, non-maleficence, autonomy, justice). To which principle might each fact and outcome be applied?
Balance	Use a balancing box	Consider asking three questions: (i) Anything of particular note?

		(ii) Where is the greatest conflict? (iii) Where is the greatest congruence (agreement)?

Adapted from references 8 and 9.