

Human-important outcomes and evidence-based medicine during the coronavirus disease 2019 pandemic

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To the editor The authors of this commentary are all clinician-researchers / methodologists who espouse rational decision-making that incorporates the principles of evidence-based medicine (EBM).¹⁻³ With the advent of coronavirus disease 2019 (COVID-19) we try to continue on our paths of research relevant to patients and evidence informed clinical care. Now, after the hectic pace of the first few months of the pandemic has abated (at least here in Canada), we have the opportunity for reflection.

EBM includes a guiding principle that “evidence does not make decisions, people do.”⁴ Another key principle is that evidence may be high or low quality, but either way people must make decisions. The initial paucity of high, moderate, or sometimes even low quality evidence, and the very rapid cycle of information has generated situations where we had to make decisions based on preliminary data, prepublication manuscripts, and societal pressure.

We became familiar with “surges,” “flattening of the curve,” mean differences for remdesivir and relative risks for dexamethasone, and the proper donning and doffing of personal protective equipment. Unfortunately, we have also become familiar with a pursuit to rapidly “publish something” regardless of underlying confidence in the findings, familiar with lowering of the methodological rigour of scientific papers up to the point of retracting articles published in prominent journals^{5,6} and familiar with changing or conflicting clinical practice guidelines.^{7,8}

As clinicians, our paramount responsibilities are often to individual patients. Imagine yourself in the context of a real clinical situation of which we are aware. You are involved in the care of a complex patient admitted to the hospital for over 3 weeks with a condition not related to COVID-19. With the advent of COVID-19, the families of the hospitalized are not allowed to visit. They ask frequently if visits are possible,

and the response, according to established rules, is that they are not. They communicate by telephone and video screen to hear and see their loved one. But they cannot feel, smell, or touch her, and this severely limits—in their and the patient’s perception—the comfort they can provide.

One evening, this patient rapidly deteriorates and death seems imminent. According to the rules, the family is now allowed visitation rights. The patient dies shortly thereafter, never regaining consciousness. A few days later, the family writes to physicians about the implication of physical separation: “(...) we do want people to know a family’s anguish and to reflect and make any changes (in the visitation policy) possible. So no other family has to endure seeing their mom (after) being coded, and (so that the) policies for non-COVID patients be revisited. Please remember her when you face these challenges in the future. (...) Please forward this to whomever if it helps another family – it has served its purpose. May God bless us all and keep all of us safe in these times.”

This situation occurs in a context of medical and social events evolving worldwide. A week later, you talk to your colleague, a researcher, who laments that research which is not COVID-19 related is slowed-down or even halted. Research personnel’s employment is terminated and the team whose expertise and experience was crafted over years is on the brink of collapse. What was important a few weeks ago seems unimportant now. Your world is changing and all you can do is watch.

And then, you talk to your physician colleagues who are musicians or who are connected to musicians and other artists. Their ensemble is idle, their concerts cancelled, but they are the fortunate ones who only dabble in the arts—the real artists have lost their jobs, income, and sustenance. The loss of performing arts has robbed us of one of the means to connect to each other and to our own psyche. Performances by Zoom

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have limited appeal. It is the live experience as a collective that we (often unknowingly) crave.

And then, a friend calls you. He asks if you could prescribe him an antidepressant. You try to hear what lurks behind his off-the-cuff remark, you try to be professional, and ask him about energy, drive, joy, and other neuro-vegetative features—he ticks off most of the boxes. Within a few short days, you get a similar call from another friend who effectively has stopped functioning.

Coming back to EBM. One of its important concepts is that of “patient-important outcomes.”⁹ This distinguishes what we like to measure (eg, easy to measure physiological parameters such as forced expiratory volume in 1 second [FEV₁], hemoglobin A_{1c}, or ejection fraction) from those more difficult to measure but more important outcomes: mortality, morbid events and, at times even more important, ability to function, and quality of life. Frequently, decisions depend on the balance among those outcomes that influence patients in opposite directions—for example, in patients with atrial fibrillation, we trade-off a reduced stroke risk with an increased risk for gastrointestinal bleeding.

The pandemic brought with it an entire new realm of human suffering that is only indirectly related to disease itself—it relates to the societies’ ways of dealing with the illness. We have not even mentioned closed schools, bookstores, and restaurants, the disappearing tourist industry and closing of small family businesses and large factories. The lists goes on.

We propose that when making decisions about healthcare interventions during this and during future pandemics, those “human-important outcomes” are carefully considered.

Our aim is not to downplay the role of interventions designed to limit the spread of COVID-19 such as restricting visits to hospitals and long-term care institutions or constraining public gatherings and interactions. Those interventions are important or even crucial, especially in environments of high risk (high prevalence of the disease). At the same time, those interventions brought a new category of outcomes, outcomes that we should not ignore, especially in the environments of low prevalence of COVID-19. We are asking to consider the balance of pros and cons of specific interventions.

Considering human-important outcomes may shift this balance for some decisions. Perhaps instead of limiting or forbidding particular activities, we should insist that all involved take personal precautionary measures. Consider an intervention that may decrease the likelihood of getting an infection by 3-fold. Or 5-fold. Or 15-fold, from 15% to 1% or less. We are referring to surgical masks, eye protection with goggles, and keeping a distance of at least 1 meter apart (better 2).¹⁰ Those effects may multiply. Perhaps if we were to employ those interventions, we could open schools and offices sooner, visit our loved ones sooner, and resume our lives sooner. Perhaps we

could do less unintentional and mostly unforeseen harm, harm that we need to recognize and find ways to measure, so we can make our decisions based on evidence.

Would the tragedies of huge numbers of COVID-19 deaths we are now witnessing worldwide be dramatically less if the protections we propose had been available, mandated, and adhered to? Would it allow fewer restrictions or easing of locking down? Our hypothesis is that it would. The best available evidence, albeit far from allowing high confidence, suggests so. In the environment of easing of restrictions, it may be well worth testing out. Pending better evidence, let’s behave consistently with the best we have and use individual precautions, especially in areas of high disease prevalence. At least the adverse effects on human-important outcomes will be manageable.

ARTICLE INFORMATION

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