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In Particular Circumstances Attempting Unproven Interventions Is Permissible and Even Obligatory

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I shall do less whenever I shall believe what I am doing hurts the cause, and I shall do more whenever I shall believe doing more will help the cause. I shall try to correct errors when shown to be errors; and I shall adopt new views so fast as they shall appear to be true views. (Abraham Lincoln, Letter to Horace Greeley, August 22, 1862)

Shah, Wendler, and Danis (2015) consider whether it can be permissible to offer certain types of “unproven” interventions to seriously ill patients. They view unproven treatments as those “with a limited evidence basis to patients outside the context of research” and as those “given without prior testing in humans for safety and/or efficacy” (12). The limited situations they discuss against the backdrop of the Ebola crisis appear unnecessarily to weight arguments against interventions that have not been proven by a relatively high evidence-based standard akin to the double-blinded, randomized controlled trial (RCT) or some other irrefutable benchmark. This overly stringent standard of evaluation risks distorting the more commonly accepted understanding of when interventions are permissible and obligatory.

For example, as the authors point out, there appears to be historical precedent for using unproven interventions in some cases, particularly when the patient is dying, and when mainstream or “accepted” treatments are not effective or beneficial. In such situations it seems reasonable that physicians are permitted and even obligated to offer unproven interventions when the risk–benefit ratio assessment undeniably tilts in the patient’s best interests, and the patient’s preferences are respected. However, the evidence on which a responsible physician makes this assessment rarely meets an RCT-like standard or analysis. In many cases, these interventions are contestable and open to debate, but may still meet the threshold for permissibility.

It may be useful here to recall the ethical arguments that HIV–AIDS patients made in the early 1980s when the context for understanding and treating HIV–AIDS was somewhat comparable to Ebola. Those arguments supported offering unproven—yet believed by some to be possibly effective—treatments earlier than would be possible if subjected to RCT-like evaluation and before being “approved” by some authoritative entity or “widely accepted” by physicians. (Fauci 2012) Patients at risk then claimed that a health care delivery system interested in promoting good care for individuals who are seriously ill or dying (beneficence), and in providing better care for the community (justice), should counterbalance provider fears or worries, within reason, about the possible harms from unproven or unapproved treatments (nonmaleficence). Recently, these patient and physician views were dramatically portrayed in the Academy Award-winning Dallas Buyers Club (Borten and Wallack 2013). Such contexts permit and may require physicians to tailor medical interventions and employ modified standards of informed consent in ways that acknowledge the evolving and dynamic nature of situations that do not permit the imprimatur or luxury of knowledge gained from RCTs. Of course, there are professional limits to what interventions are morally permissible for dying patients. Even in situations where the physician determines that there is “nothing to lose” in the care of a dying patient by trying an unproven intervention, the assessment still must—first and foremost—be based on a reasonable belief that more benefit than harm will follow, even if the benefit is marginal. It is this due diligence assessment of available evidence and sound

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professional judgment that provides the moral basis for permissibility to provide any intervention. Moreover, a
greater degree of likely benefit along a sliding scale may
shift what is permissible to what is obligatory within this
flexible framework. And it is this same framework that
finds much support and wide acceptance in ethics and law
to accommodate constantly evolving good and better
and best practices.

The argument that physicians in some cases are ethi-

cally required to suggest or provide unproven treatments
can be buttressed by at least three commonly articulated
pillars of medicine. First, ethical physicians must be com-
petent practitioners, which means they must keep up with
the ever-changing aspects of medicine and incorporate bet-
ter methods and technologies in practice. As Pellegrino
said: “A doctor binds himself to competence as a moral
obligation” and “places the well-being of those he pre-
sumes to help above his own personal gain” (Langer 2013).
Competent physicians are watchful, observant, open-
minded, and they continuously reevaluate how to provide
quality care in its many aspects, from washing one’s hands
(as suggested by Semmelweis in the 1850s) (Best and Neu-
hauer 2004), to ligating a patent ductus arteriosus (as did
Gross in 1938) (Mormile, Quadriini, and Sguarcia 2013), to
considering complementary and alternative interventions
today (National Center on Complementary and Alterna-
tive Medicine 2014). Many therapeutic innovations—not
just improvisations necessitated by the moment, but
thoughtful, considered, and indeed groundbreaking impro-
vements in treatments—derive from the innovative practices of competent physicians and may not be tested
by RCTs.

Second, physicians should—to the degree possible—
consider, suggest, and provide insightful, studied, and
cogent innovative—but not necessarily “proven”—treat-
ments that are peer-acknowledged, peer-accepted, or peer-
reviewed. Certainly, it would be awkward, if not almost
impossible, for a reasonably prudent, competent physician
to offer an unproven treatment as a lone wolf, acting in a
manner radically afield from similarly situated practi-
tioners without some collegial involvement and support.
Ethical physicians meet the accepted standard of care,
even when the standard is in flux or evolving, and when
the standard is a minority position. (Centers for Disease
Control and Prevention [CDC] 2014b) But practitioner
thoughtfulness and reflection must have some basis in the-
ory or practice acknowledged by peers, extending to those
who passionately disagree. New treatments—many
unproven—typically do not appear magically out of
nowhere overnight. For the vast majority of developing
interventions, there is no bright line that readily separates
the proven from the unproven early on. This may be what
Shah, Wendler, and Danis are suggesting when they seem
to validate the use of approved drugs for unapproved uses
in some cases. Moreover, the continual revisions of the
Centers for Disease Control and Prevention’s Interim U.S.
Guidance for Monitoring and Movement of Persons with
Potential Ebola Virus Exposure (Centers for Disease
Control and Prevention [CDC] 2014a) to reflect peer-
accepted best practices is a vivid reminder of how practi-
tioner consensus changes in the face of many medical
uncertainties. While these points may seem self-evident,
reflecting on them can help us explain why interventions
are permissible or obligatory and may shed light on the
moral permissibility of other, more controversial
“unproven” interventions. In a nutshell, what explains
why these “unproven” interventions (such as sophisticated
personal protective equipment or degrees of isolation in
the case of suspected Ebola contacts) are permissible or
obligatory is the fact that they are buoyed and indeed vali-
dated by the collective reasonable judgment of competent
caregivers. The fact that there exists a measure of consen-
sus among able and prudent providers suffices to make
particularly innovative interventions permissible or obli-
gatory, even if other providers disagree and there remains
disagreement in the medical community at large over the
status of these treatments as standard of care.

Third, ethical physicians hold themselves accountable
by reporting outcomes—whether positive or negative—
when they employ innovative interventions in caring for
patients. One only needs to review the many volumes of the
New England Journal of Medicine or the Journal of the
American Medical Association before the germ theory of
infectious disease was scientifically confirmed to see that
reporting cases is a long-standing tradition within medi-
cine. Openness and transparency about which treatments
are effective or beneficial adds to scientific knowledge
and leads to helpful change. Moreover, regardless of out-
comes—whether good or bad or the same, or if innovations
meet or fail to meet expectations—ethical physicians
are obligated to use reasonable and suitable means to pass rel-
levant information along to other caregivers in the best
interests of individual patients, even when the data are
potentially embarrassing personally or professionally
(Jena et al. 2015).

In conclusion, “unproven” interventions can be per-
missible and indeed obligatory when good doctors in diffi-
cult and swiftly evolving clinical contexts have some peer-
acknowledged idea or indication that the intervention
could be beneficial, when coupled with a clear and con-
vincing risk–benefit determination based upon diligent
and reasonable evaluation of available evidence. Many
such unproven, innovative interventions will not have
been subjected to an RCT and will not enjoy the level of
evidentiary support that an RCT-like evaluation provides.
Shah, Wendler, and Danis conclude their article with this
sentence: “Another challenge for future research is to
determine when it is ethically obligatory, rather than per-
missible, to offer unproven interventions to patients.”
Some would assert that the future they describe is now,
and really always has been, from the very beginning of
medicine as a profession. The line between knowing when
interventions are permissible versus obligatory is always a
matter of assessing how compelling the available credible
evidence is within a particular, evolving research or eval-
uation context that rarely meets the level of an RCT. [\[\]

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Infection Control Measures and Debts of Gratitude

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Healthcare workers (HCWs) returning home from Ebola-infected regions are subject to various infection control measures (ICMs), including investigating, diagnostic, and liberty-restricting measures. Public health laws justifying the use of ICMs, such as quarantine, have been invoked in recent cases involving HCWs returning home from areas affected by Ebola, such as for Maine nurse Kaci Hickox. Upon her return to the United States, Hickox was issued with a 21-day quarantine order by the Maine Department of Health and Human Services (Temporary order 2014), which she successfully challenged in court.

In the final court order on the matter, Judge LaVerdiere acknowledged that while protecting others from harm can serve as a justification for the use of quarantine in such cases, the fact that Hickox had been asymptomatic, and hence unlikely to infect others with Ebola, rendered such measures illegitimate (Order pending hearing 2014). This was an instance where, as Steven Miles (2015) notes in his article, “a government motivated by antiscience, irrational fear, or politics attempts to abuse public health laws to infringe on civil liberties” (18). Instead, the court held that the proportionate response would be for Hickox to comply with direct active monitoring (DAM), which provides public health authorities with the ability to conduct the requisite surveillance activities in a way that would not violate her civil rights.

Interestingly, in his order, Judge LaVerdiere claimed that “we owe her and all professionals who give themselves [to fighting Ebola] a debt of gratitude” (Order pending hearing 2014, 3). On what basis and in what ways does one exactly discharge a debt of gratitude in the case of Hickox and other professionals who are fighting Ebola? There are many facets to both questions, but we argue that making progress on them depends on distinguishing between two senses of gratitude and understanding how each sense impacts the legitimacy of using ICMs.

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