Commentary: Invitation

Stop, Listen, and Learn: Using Mixed Methods to Add Value to Clinical Trials*

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Abstract
This commentary discusses the concept of value-based or value-focused health care as a rationale for researchers to incorporate mixed methods study designs a priori into clinical trials evaluating traditional, complementary, alternative, and integrative medicine (TCAIM). Along with assessing patient outcomes, information about patients’ experiences and preferences are needed to determine the value of an intervention. Incorporating a mixed-methods approach can improve the quality of clinical trials and provide important information about the potential value of the intervention.

Keywords
mixed methodology, complementary and alternative medicine (CAM), clinical trials, integrative medicine, value-based purchasing

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Value is the latest buzzword driving health care decisions about service delivery, funding, and policy. It has emerged in response to the rising demand for health care, concurrent resource constraints, and an increasing number of efficacious and cost-effective interventions. Demonstrating evidence of safety, efficacy, and cost-effectiveness is no longer enough in conventional medicine. The intervention, investigation, or service must also demonstrate value. These same requirements will also apply to traditional, complementary, alternative, and integrative medicine (TCAIM).

Despite an exponential growth of clinical trials evaluating the efficacy of TCAIM interventions, translating these results into mainstream clinical practice guidelines, service delivery, and policy is proving to be a lot more challenging.1 While the reasons for this are complex and multifactorial, incorporating mixed-methods study designs a priori into programs of TCAIM research that include clinical trials may not only improve the quality of the clinical trial but also provide important information about the potential value of the TCAIM intervention.

What Is Value Health Care?
Value in health care can be thought of as the costs associated with providing quality care that is safe, effective and appropriate. The concept is challenging however, because various stakeholders (patients, practitioners, providers, insurers, policy makers, and even countries) often have different definitions, viewpoints, and priorities about what they think is important.2

As part of a national survey exploring stakeholders views, the University of Utah suggested the following definition; value is the product of the quality of care plus the patient experience at a given cost. This can be expressed as Value = Quality * Service / Cost.3

What Do Patients Value?
While there is a plethora of research reporting the frequency and reasons for TCAIM use, much of these data are not being linked to the specific TCAIM interventions that are being evaluated in clinical trials. Furthermore, according to Downey et al,4 clinical trials often fail to evaluate what patients value:

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You never ask how important it is to me to receive this service . . .
I so much look forward to it . . . I’m amazed you don’t ask me
this question. It should be the featured question.

Along with measuring patient outcomes—be they objective
or subjective—the results of clinical trials can therefore be
strengthened by reporting the patients’ experiences. This may
include collecting data on patient satisfaction, tolerability of
side effects, acceptability of risks, logistics around accessing or
using an intervention, and other factors such as a person’s
preferences, beliefs and values that influence health care
choices.

The Role of Clinical Trials
Randomized controlled trials play a key role in evaluating the
outcome of interventions. They can be undertaken in a variety
of environments, from those in more “controlled” environ-
ments, where trials are often designed to assess efficacy (so
called explanatory trials), to those undertaken in community
settings (often called pragmatic trials) where there is a focus
on effectiveness. There is not, as sometimes assumed, a dichot-
omous choice between efficacy and effectiveness but rather
trials exist on a continuum between explanatory and effective-
ness. Trials all along this continuum can be considered ran-
domized controlled trials providing they meet certain
characteristics. Trials that tend to sit on the pragmatic end
of the continuum are common in TCAIM.

Using Mixed Methods to Improve the Quality
of Clinical Trials
Mixed methods can be used to collect essential background
information for clinical trial design. Mixed-methods research refers to the integration of methods, often that collect
both quantitative and qualitative data, either sequentially or
concurrently, as part of a single program of inquiry. The
role of mixed methods in health services research, or as part of the
process for developing or validating patient reported outcome
measures, is commonplace. Increasingly, the role of mixed
methods as an integral part of a clinical trial is being recog-
nized, with TCAIM researchers often leading the way.

TCAIM are often complex interventions consisting of multiple “characteristic” components that are likely to contrib-
ute to the therapeutic outcome. Furthermore, outcomes that participants may value highly may be quite different from those
that researchers think they will. It is common, however, for
trialists to focus on the most obvious “active” component, such as
needle insertion in acupuncture, and ignore or minimize
other characteristic components such as holistic, patient-
centered care. Indeed, many patients using TCAIM in the
community report wide-ranging changes in their health that may
fall outside the narrower range of condition specific outcomes
that are commonly evaluated in clinical trials and are important
to patients.

Another issue for trial design is that most TCAIM interven-
tions, in contrast to pharmaceutical interventions, lack early
phase studies and therefore information on a suitable “dose”
may be lacking. This has been a significant issue in acupuncture
research, where clinicians report that research design does
not reflect contemporary clinical practice due to marked differ-
ences between frequency of treatment in clinical trials and in
clinical practice for example. Using a mixed-methods approach when designing and pilot testing clinical trials can
promote input from a diverse group of practitioners and other
experts on trial design, ensuring that the intervention has suf-
icient model validity or clinical relevance, including a suit-
able “dose” and incorporation of other important clinical
components. Failure to do this can mean that only a facsimile
of the intervention is being examined and any results may be
irrelevant to how that intervention is practiced or used in the
community.

Using Mixed Methods to Evaluate the Costs
Trialists are continually being encouraged to include eco-

omy evaluations, such as measuring the cost-effectiveness
of a TCAIM intervention. Along with potentially high out-of
pocket costs to patients, there are health service resource impli-
cations that must be considered. However, the resources
required to conduct a robust economic analysis are often pro-
hibitive for researchers or are difficult to justify if it is a pilot
study. Including patient-reported outcome measures (PROMs)
that use algorithms to calculate quality-adjusted life years (QALYs) are relatively easy to include and measures such as
the SF-36/12 (36-/12-item Short Form Health Survey) or the
AQoL (Assessment of Quality of Life) can be used for both
health-related quality of life and for QALYs. Some chronic
conditions have disease-specific cost of illness measures that
are suitable to be included as part of a TCAIM clinical trial.
Even if this is not possible, at the very least, by incorporating
mixed methods, the cost of providing/accessing the interven-
tion(s) can be estimated and reported.

Using Mixed Methods in Clinical Research
to Demonstrate Value
Rather than waiting (or hoping) for a second round of funding
once the intervention is proven to work, along with clinical
outcomes, research that might otherwise only consist of a ran-
domized controlled trial can benefit from incorporating mixed
methods to also provide relevant information about the poten-
tial value of the intervention. An a priori mixed-method study
design can facilitate the integration of quantitative clinical and
economic data with qualitative data about patient’s experi-
ences, preferences and values. Qualitative data can augment
the quantitative results by providing richness and context to the results that cannot be captured by numbers alone.
Using a mixed-method approach that combines quantitative and qualitative data collection may further help
uncover context, outcomes, and experiences that are important
to patients and may otherwise be missed. Mixed methods can
also be used to evaluate practical aspects from the
practitioners’ perspectives about providing or recommending a TCAIM intervention, along with organizational barriers and facilitators to implementing the intervention.20,21

Conclusion
Designing and conducting high-quality clinical trials is all consuming. It is tempting to think that demonstrating safety and efficacy, as opposed to value, is the only priority. Yet patient experiences are increasingly becoming important when making value-based health care decisions. Taking the time to stop, listen, and learn from patients along with practitioners, service providers and policy makers may make all the difference when it comes to translating the results of TCAIM clinical trials research into practice and policy.

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JH and MA, both conceived and wrote the article.

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