

The “Practical Wisdom” of the EDICT Policy Methodology: Applying a Systems Approach to Research Policy

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Though never officially adopted as the moral base for the EDICT Policy Arm, the EDICT Policy Methodology is remarkably consistent with the Aristotelian notion of *phronesis*, or practical wisdom.¹ The concept of *phronesis* is important as a guide to public health policy inasmuch as it (1) focuses attention on the particulars of the case; and (2) is directed to

practices.

This translates well into public health policy, because any policy approach that is not attuned to the particular context, stakeholders, and interests at issue in pursuing any given policy is unlikely to be successful. Moreover, *phronesis* requires a kind of pragmatism, a focus on practices that coheres well with the EDICT Team’s focus on pursuing actual policy change.

From the outset, the EDICT Team committed itself to pursuing policy change. Not content with issuing position statements or white papers, the EDICT Team set more ambitious goals related to the dissemination of its recommendations so as to achieve actual policy change. Given the complexity of the policy context relating to disparities in clinical trials, the EDICT Team, assisted by several expert process consultants, adopted a systems approach.

What is a systems approach?

Systems theory posits that overall system behavior is a product of the interactions of multiple causal factors operating simultaneously rather than sequentially and linearly.²

Understanding the complex policy interactions that tend to cause disparities in clinical trials requires an approach that addresses all identifiable causal

factors, both vertical and horizontal. The EDICT Team has therefore stressed the inadvisability of focusing on any one factor or set of factors.

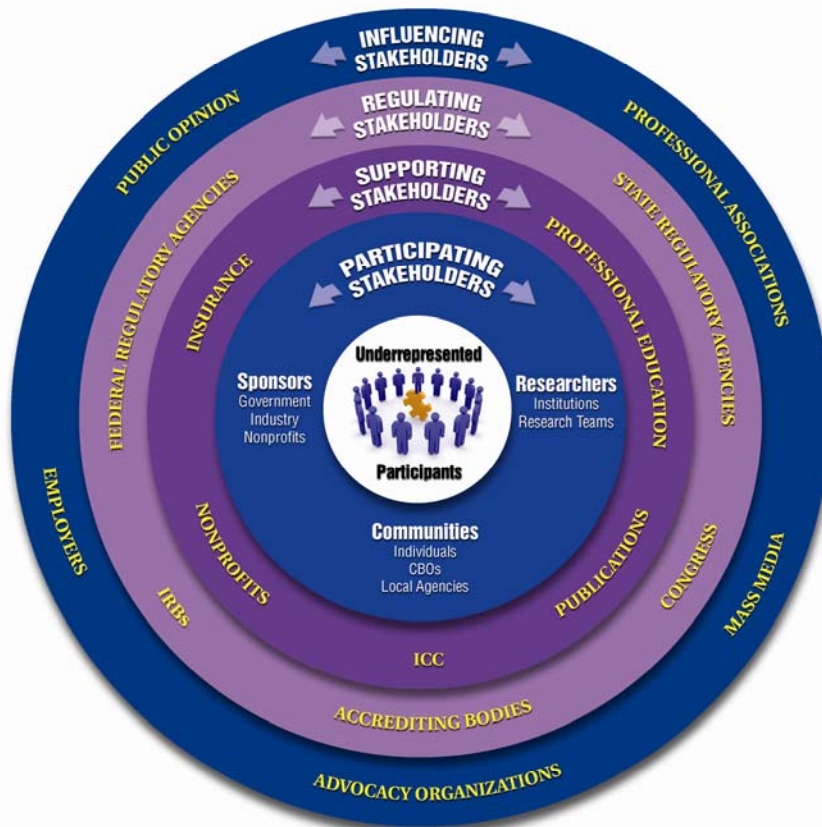
Accordingly, EDICT participants identified root causes of barrier to participation in nine distinct areas, which areas they viewed as opportunities for policy change. Those nine areas were:

1. Allocation of research dollars;
2. Insurance coverage for costs associated with clinical trials;
3. Professional education;
4. Public education;
5. Community participation;
6. Participant navigation;
7. Industry sponsorship;
8. Publications; and
9. Regulatory climate.

A similarly nuanced view is required when identifying the agents for policy change, as the relevant set of stakeholders is composed of a variety of different individuals and entities, representing diverse interests in the public, private, and community sectors. The EDICT Team understands that policy change is virtually impossible without a collaborative effort, and so the “opportunity teams” were composed of a mixture of contributors drawn from government (federal, state, and local), industry, and community

organizations. All told, approximately 300 people partnered in staffing the opportunity teams. Each opportunity team composed its own Charter, setting forth its objectives and intended deliverables, and named a Chair or Chairs to shepherd the team through the policy process.

Based on its Policy Methodology, the EDICT Team consulted with professional graphic designers for assistance in capturing some of the key features of its systems approach in a single diagram. The designers, working with the core EDICT Team, created the EDICT Policy Context Model, reproduced below:



These concentric circles must be imagined to be moving constantly, as a systems approach eschews static models of the relevant policy context. At the center of the policy context is, of course, those underrepresented in clinical trials. Participating stakeholders – sponsors, communities, and researchers – typically exert the most immediate influence on recruitment and retention of the underrepresented, but supporting stakeholders, regulating stakeholders, and influencing stakeholders are all important components of the overall policy context. If for

example, editors of biomedical journals scrutinized manuscripts closely to determine the sufficiency of the inclusion plans, such action would no doubt support efforts to increase appropriate representation in clinical trials.

More specifically, the core EDICT Team, in conjunction with two expert process consultants, developed a set of seven Policy Process Questions. These questions built off policy-making work begun by Dan Bustillos, J.D., Ph.D, and the realities of the policy context explicated primarily

by Deborah Stone, an independent scholar and health

policy expert.³ The seven Policy Process Questions are:

1. What is the problem? How does it manifest itself?
2. What would success look like? (Goal)
3. Whose behavior needs to change in order to achieve the goal? (Target Audience)
4. Who has the ability to change the behavior of the target audience? (Political Actor)
5. What policy is recommended to achieve the behavior change in the target audience? (Ignore perceived limitations)
6. What is the feasibility of this policy?
 - Unintended consequences
 - Social, political, ethical, financial obstacles
7. What is the underlying thinking on why this policy will be effective?

The development of these policy process questions involved considerable time and effort, all of which was strongly influenced by the evidence base regarding public health policy and the process consultants' expertise in managing group initiatives to maximize resources and deliverables. Stone's admonition that policy is nothing if not contested space⁴ guided both the formulation of the Policy Process Questions and the process in which each opportunity team

attempted to answer the Questions.

Several of the questions seemed to prove particularly challenging for the opportunity teams. Rarely were the problems (question (1)) each opportunity team set out to address self-evident; much work was needed to specify the particular problem to be remedied. Moreover, the difference between questions (3) and (4) is crucial, as it may often be the case that the audience

whose behavior is to be changed is not identical to the political actors that have the power to implement policy change. For example, even if institutional review boards' are an appropriate target for enhancing professional education of disparities in clinical trials, individual IRBs do not possess the political capacity to effect policy change. Instead, the relevant opportunity team identified as the primary political actors the federal Office of Human Research Protections, and the private IRB accrediting body, the Association for the Accreditation of Human Research Protection Programs, Inc.

Using the Policy Process Questions as a template, each opportunity team went on to draft policy recommendations pertaining to their specific focus, but kept in mind the larger vision for the Recommendations, embodied in the EDICT Credo:

- All individuals will have the opportunity and necessary support to participate voluntarily in clinical trials for which they are eligible.
- Participants and researchers will understand and promote the benefits of diversity in clinical trials.

- Results from clinical research will benefit the participants' communities and society at large.

These Policy Recommendations have in turn been the subject of an extensive revision process that began in earnest in September 2007. At that time, the EDICT Team held a Core Leadership Conference, which constituted a "soft launch" of the Policy Recommendations. Subsequently, in December 2007-January 2008, the EDICT Team conducted three "Waves" of review with both internal EDICT members and targeted external stakeholders.

In these Waves, online web conferencing technology was used to present the background, context, and Policy Recommendations, and to conduct real-time, online polling of the participants. The polling and online conferencing provided critical feedback on the feasibility and importance of these Recommendations. Some of these participants were active members of one or more opportunity teams, while others had little direct involvement in the policy-crafting process. Such a mixture of reviewers ensured the Policy Recommendations would

receive the benefit of critiques from both familiars and relative strangers to the EDICT policy-crafting process.

The audio and online worksheets for each web conference were recorded and reviewed in the process of revising and incorporating into the Policy Recommendations the criticisms and suggestions received during the three “Waves.” EDICT then sought input from the public, as a reflection of both the inclusive deliberation process and EDICT’s own research that revealed that more community involvement led to stronger recommendations.

Aside from the concerns of pragmatism that influenced the pathways along which EDICT collaborators traveled in crafting policy, several additional EDICT Projects reflect the commitment to pursuing practical change in public health policy. The EDICT Project features a Field Research Arm headed by Placido Grino, M.D., in which the research team developed a series of educational interventions designed to ameliorate disparities in clinical trials. Dr. Grino’s team is currently in the assessment phase of its research plan. In addition, primarily through grants provided by the Department of Health & Human Services (“HHS”) - Office of Minority Health and the HHS -

Office on Women’s Health, EDICT Team members are also working on “CLAS-ACT” and the Backpack Project.

“CLAS-ACT” is an acronym for “Culturally and Linguistically Appropriate Services Applied to Clinical Trials,” and refers to 14 CLAS standards promulgated by the Office on Minority Health.⁵ The CLAS-ACT Project is intended to assist in the translation of the CLAS standards into recruitment, retention, and general communication practices in the clinical trial enterprise. The Backpack Project is intended to serve as a compilation of best practices and approaches that have already proven successful in ameliorating disparities in clinical trials. The compilation can then be ported and used by relevant stakeholders in initiating policies designed to ameliorate disparities in clinical trials. Both of these affiliated EDICT projects cohere with the concept of *phronesis* in policy-making, inasmuch as they both take careful note of the particular context and stakeholders involved, for example, in promulgating the CLAS standards, and in currently practicing ways of ameliorating disparities in clinical trials.

This twin emphasis on the particular features of the policy

context and the need to translate policy analysis into practice shows how the concept of *phronesis* is integral to the EDICT Policy Methodology. Blending a focus on such *phronesis* with a systems approach and the prime objective

of changing policy through advocacy, the EDICT Team hopes and believes that this unique approach renders more likely the possibility of changing policy that drives increasing disparities in clinical trials.

¹ Aristotle develops the concept of *phronesis* in *Nicomachean Ethics*, but the literature on the topic is immense. Excellent starting points include Alasdair MacIntyre's *AFTER VIRTUE* (2d. ed. 1984) and various articles and books authored by Martha Nussbaum. For consideration of the role *phronesis* can play in conceiving of ethics in clinical practice and research, see Michele A. Carter, *A Synthetic Approach to Bioethical Inquiry*, 21(3) *THEORETICAL MEDICINE & BIOETHICS* 217 (2000).

² Though, again, there are many sources explicating the role of systems theory in changing conceptions of scientific practice, Evelyn Fox Keller's *MAKING SENSE OF LIFE: EXPLAINING BIOLOGICAL DEVELOPMENT WITH MODELS, MACHINES & METAPHORS* (2002) is a particularly good point of departure.

³ See Deborah Stone, *POLICY PARADOX: THE ART OF POLITICAL DECISION MAKING* (rev. ed. 2002). Another excellent resource is Amy Gutmann & Dennis Thompson's article, *Just Deliberation About Health Care*, in *ETHICAL DIMENSIONS OF HEALTH POLICY* 77 (eds. Marion Danis, Carolyn Clancy, and Larry R. Churchill 2002).

⁴ Stone, *supra* note 3, at 18-19.

⁵ See Office on Minority Health, National Standards on Culturally and Linguistically Appropriate Services (CLAS), available at <http://www.omhrc.gov/templates/browse.aspx?lvl=2&lvlID=15> (last accessed Mar. 17, 2008).

