OPTIMAL DECISION MAKING MAY BE HAZARDOUS TO YOUR HEALTH: PROSPECTS FOR A NEW SCIENCE OF IMPLEMENTATION

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ABSTRACT

Initiatives to improve the quality of healthcare delivery include the introduction of treatment guidelines and the development of implementation science, which overcomes barriers in bringing evidence-based practices to routine clinical care. The implementation strategy is to identify impediments to guideline adherence, then develop means of changing behavior to increase conformance. Achievements to date have fallen short of the objectives, and the tactics oftentimes have provoked resistance. This response may illustrate the significance of the problem, but it may also indicate that the methods of implementation science tend to overstate the quality of evidence, ignore instances in which the appropriateness of a given practice cannot be clearly determined, and overlook the complexities of applying general knowledge to specific cases. This essay proposes that an inability to contextualize evidence is inherent to patient-oriented services research. The essay draws from discussions of deep uncertainty in the risk perception literature, to illustrate that a risk perception problem predicates the disparity between services research and clinical practice. It draws on situation awareness theory from human factors research, to describe the task of understanding complex clinical situations and discuss how this task facilitates effective decision making. It draws on image theory from naturalistic decision making, to develop and illustrate a multi-phase strategy that features a new standard and test for examining how practitioners incorporate guideline recommendations into decisional processes. The essay closes by highlighting the challenges posed by multi-operator systems such as shared decision making, and the prospect of a new, revitalized, science of implementation.

Keywords

Risk perception, situation awareness, clinical judgment, naturalistic decision making, implementation science

1. INTRODUCTION

The 1990s brought significant changes to the healthcare system. They were spurred by problems in management, quality, and cost. In the previous decade, healthcare expenses had increased by 283%; by 1997, the increase was 442%.[1] Significant regional variations in service delivery contributed to uneven access and quality.[2] Opportunities for innovation had been missed owing to system inflexibility of poor management of resources. Accountability was lacking, and the needs and concerns of consumers and families tended to be discounted or overlooked. Problems were pervasive, but they were felt particularly in public mental health, where glaring deficiencies had gone uncorrected for decades and an overhaul was long overdue.[3-5]

In response, two sets of initiatives were quickly introduced: Systems and structures were the targets of reorganization, cost control, and resource management efforts.[6] Concomitantly, programs and services were affected by the development and dissemination of treatment guidelines, whose intended purpose was to improve quality especially by standardizing service delivery and reducing or eliminating inappropriate practices.[7] As Blumenthal noted,[8] these initiatives had an immediate and profound influence on the practice of medicine: "Just a few years ago, physicians could be confident that they alone had a social mandate to judge and manage the quality of care. Now, that mandate is contested daily in industrial boardrooms, legislative-hearing rooms, and even medical-consultation rooms" (p. 891). The programmatic and systemic changes that had

been ushered had changed the discussion about how services are assessed, how quality is determined, and perhaps more fundamentally, who makes these determinations.

Such sweeping initiatives were bound to evoke controversy and invite critical responses.[9-11] Perhaps the most penetrating critique came from services researchers, who had been empowered to conduct patient outcomes research—patient-level studies about treatment effectiveness.[12, 13] They found that quality improvement initiatives were not promoting adherence to guidelines in either policy or practice.[14, 15] A survey found that only 15-38% of patients with a panic disorder received an evidence-based treatment in 1993, and by 1998 the percentage had actually decreased.[16] In their report on translating behavioral science into action, The National Advisory Mental Health Council observed that "too few researchers are attempting to bring across basic, clinical, and services research, and not enough are working with colleagues in related allied disciplines to move research advances out of the laboratory and into clinical care, service delivery, and policymaking.[17, v]

A number of distinguished investigators and policy makers drew attention to what can be called the "dissemination gap"—a disparity between knowledge and its implementation.[18-21] Perhaps the most cogent and challenging observation came from Congressman George Brown, who had established the Environmental Protection Agency, the Office of Science and Technology Policy, and the first federally-funded climate change research program: "All the basic science funding in the world will have no positive effect on the well-being of our nation if the research is not carried out within a system that can effectively digest and apply the results."[22, p. 131]

Efforts to develop a science-to-practice strategy coalesced under the heading of "implementation science."[23] The term "implementation" was drawn by an essay by Lomas that described three approaches to conveying healthcare information:[24] Diffusion,[25] the wide and fairly indiscriminate broadcasting of information, had been developed by social capital and mass communication researchers.[26, 27] The second approach is dissemination, in which messages are tailored to specific targets.[28, 29] Implementation, the third and novel approach, includes tactics that increase "uptake"—that is, the assimilation of information into everyday practice.[30] This implementation strategy has four steps: 1) Identify evidence-based practices, typically by consulting guidelines; 2) determine how fully the guidelines have been adopted by practitioners; 3) identify barriers to their adoption; 4) develop interventions that are designed to increase uptake.

Notwithstanding some successful demonstrations and an explosion in the quantity of implementation research, there has been relatively little progress in achieving its aim of increasing the adoption of treatment guidelines, and the gap between science and service has not been overcome.[31, 32] Much of the current research has focused on step two of the strategy by documenting the incidence non-conformance and identifying sundry impediments such as lack of knowledge, unfamiliarity with guidelines, and unwillingness to change.[For examples, see33, 34-36] The ineffectiveness of current initiatives to close the implementation gap was quantified in a recent editorial: The hope of the Institute of Medicine's Roundtable on Value and Science-Driven Health Care is that by 2020, "90% of all clinical healthcare decisions will be supported by accurate, timely information and reflect integration of the best evidence available. This objective stands in stark contrast to

current estimates that only 15% of practice today is supported by evidence and that between 60% and 90% of attempts to implement evidence based practice (EBP) fails."[37, p. 179]

2. WHY ARE IMPLEMENTATION INITIATIVES FAILING?

A review of 76 studies[38] that identified specific barriers to the implementation of clinical guidelines by physicians. The review identified impediments at both the organizational and practitioner levels. Most of the organizational problems included had been identified in other studies.[39-41] They included administrative and management complications such as confusing unfunded mandates that are passed down from policy making bodies to agencies, programs, and service providers.[42, 43] Frequently, systemic commitment is uneven,[44] organizations remain inflexible,[45] and their climates may not be cultivate a learning environment.[46-48] Evidence about treatment effectiveness is rapidly emerging, but quality improvement initiatives tend to be erratic rather than continuous, and treatment guidelines are frequently out of date.[49, 50]

Notwithstanding these problems, the most proximate and significant barriers lie with providers themselves, notably their lack knowledge about guidelines, disagreement with guideline recommendations, and outright unwillingness to change current practices. To understand these sources of resistance, services researchers have cited or joined with the behavioral decision making research, and applied models inspired by classical decision theory: To say that a treatment is "evidence based" is to assert that it has a higher probability of achieving a treatment outcome than a non-evidence based alternative. Practices should be chosen that maximize expected value, and guidelines are intended to

facilitate sound decision making.[51] Consequently, nonconformance to guidelines exemplifies sub-optimal decision making.[52] Sub-optimal performance has become a theme of the implementation literature. Explanations included violations of expected value, Bayesian calculation errors, and miscalculations of relative risk,[53-56] and the use of cognitive heuristics and related biases.[57-63]

Declaring that implementation science is failing is a harsh assessment. Its supporters might be quick to point out that the impediments summarized here actually illustrate the success of the implementation strategy, because identifying the barriers is a predicate to overcoming them. However, at some point, lack of progress does not signify that the impediments are many and great, but that the strategy is flawed. Non-conformance may signify the unwillingness or inability of practitioners and organizations to change their ways; it may also indicate their disaffection with the entire thrust of the implementation project, or more specifically that guidelines are misused when they are treated as quality indicators or criteria of sound decision making. For the implementation strategy to work, adherence to guidelines should improve quality of care by circumscribing discretion and bringing behavior into conformance.[64, 65] To be sure, guidelines were developed for the purpose of standardizing and improving quality of care. But even early on, the Institute of Medicine depicted them not as standards or quality indicators, but as *decision aids*, that is: "systematically developed statements to assist practitioner and patient decisions."[66, p. 8] Current practice guidelines continue to emphasize that their purpose is to guide practitioners and not to evaluate the quality of their work.

In the American Psychiatric Association schizophrenia guideline,[67] the distinction between decision aid and standard of care could not be stated more clearly:

> This practice guideline is based on available evidence and clinical consensus and offers recommendations to help psychiatrists in assessing and treating adult patients with schizophrenia. This report is not intended to be construed or to serve as a standard of medical care....The ultimate judgment regarding a particular clinical procedure or treatment plan must be made by the psychiatrist in light of the clinical data presented by the patient and the diagnostic and treatment options available."

The recommendations in this guideline include the importance of early diagnosis, establishing a therapeutic alliance, and developing a comprehensive treatment plan. Recommendations are coded '1', '2', and '3', not to reflect the quality of research evidence that supports them, but to represent the review panel's level of confidence in their clinical appropriateness.

The American College of Rheumatology's biologic agent treatment guideline contains a similar disclaimer:[68] "Guidelines and recommendations developed and/or endorsed [here]...are intended to provide guidance for particular patterns of practice and not to dictate the care of a particular patient. The ACR considers adherence to these guidelines and recommendations to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's individual circumstances." One might view these statements as rhetorical expedients or efforts to insulate physicians from litigation. However, the qualification is clearly warranted by the quality of research support for the guideline's recommendations.

The ACR guideline describes the practice known as "treat-to-target,"[69] which involves adjustments in a treatment regimen if symptoms (which are called "disease activity" indicators) exceed a numeric threshold. These adjustments may involve a dosage increase

or a switch to a new agent. The guideline classifies the quality of evidence favoring every recommended switch as 'A', 'B', or 'C'. There is a total of 110 recommended switches for patients with established RA whose disease activity scores exceed the threshold. Of these, only 7% received the highest grade of 'A', which indicates support from multiple randomized control trials, while 66% were graded 'C', which indicates support from case studies or consensus opinion. Of the 14 switches that involved the medication adalimumab (marketed under the trade name, Humira), 93% were graded 'C'. Evidence favoring the recommended target, a disease activity rating of 'remission' or 'near remission,' was also graded as 'C.' This rating indicates that the treat-to-target tactic itself lacks strong research support.

If a guideline recommendation is a standard or quality indicator, clinical decision making is transductive, and optimality is judged by a *conformance* standard. If a guideline is a decision aid, decision making is a discretionary practice and its use is tested against an *incorporation* standard.[70] The argument favoring discretion and incorporation runs as follows: There is surprisingly limited support for the claim that following guidelines improves quality of care.[71, 9] A guideline that lacks clear empirical support is unsuitable as a quality indicator. When evidence is insufficient, guidelines must be contextualized in order to become practical and robust.[72] "Contextualized" means, applied with expertise and discretion in order to be useful in a given case. Attempting to reign in discretion by imposing a conformance standard is not likely to improve quality of care.[73-75] Despite the beneficent aims of implementation science, the pursuit of optimal decision may be dangerous to your health.

3. IMPLEMENTATION'S OVERREACH

It is tempting to pass the implementation findings up the administrative ladder and attribute distorted views of guidelines, overstatements of evidence, and insistence on conformance tests as indications of naïveté, dogma, or outright chicanery. There is evidence of all three, but such accounts overlook that the conformance standard is a scientific and statistical product first and foremost, and it is inherent to the nature of implementation science as currently practiced. Clinical practices are approved or authorized for specific domains. Typically, these domains are disease categories, illnesses, problems, or complications. There is always uncertainty about whether a given practice will work, and well-meaning parties may disagree about the criteria for assessing effectiveness. Services research can guide practice by identifying and testing relevant criteria, and assessing overall effectiveness by linking practices to outcomes under specified domains. These studies are not case-specific; they involve aggregate data and the use of frequentist statistical methods.

Lomas, who coined the term implementation, described its task and by identifying what he called "zones of practice":[76] The white zone consists of interventions that are likely to work; the black zone consists of interventions that are likely not to work or to cause harm. The third zone is gray, and comprises practices that are neither black nor white. Gray zone practices are also called "toss-ups." The task of implementation science is to minimize or eliminate the use of black zone practices and increase the use of white zone practices. Implementation is called for when practitioners and researchers disagree about the classifications. The onus is on implementation scientists to develop behavior-change

interventions, and on practitioners to change their behavior. This task is illustrated in Figure 1.

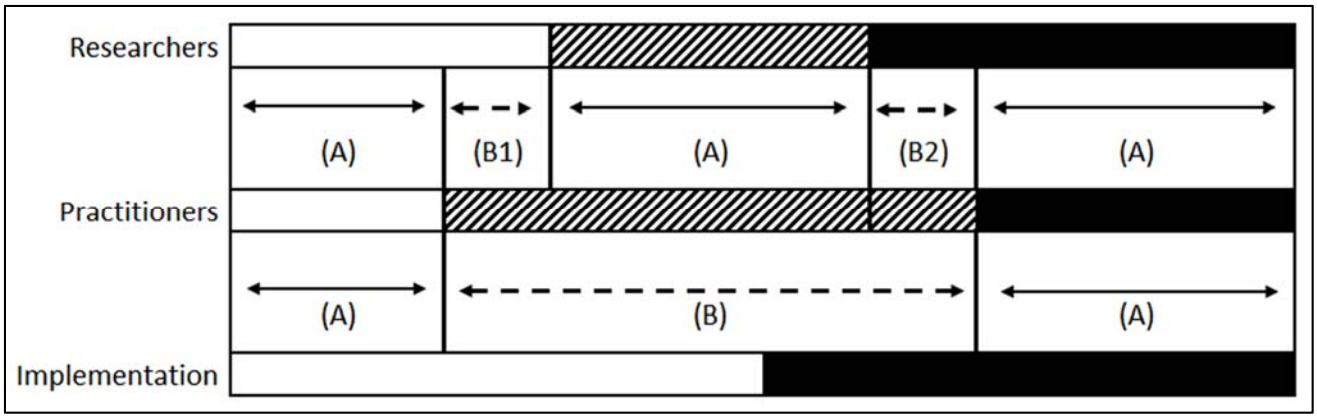


Figure 1: The implementation task—how researchers, practitioners, and implementation scientists classify zones of practice (adapted from Lomas and Lavis[76])

The three zones are represented by their respective colors. Looking only at the researchers and practitioners panels, the solid arrows (A) indicate where the parties agree. The scope of implementation is indicated by the broken arrows (B). B1 represents situations in which practitioners are reluctant to use effective interventions; B2 represents situations in which practitioners are inclined to use ineffective or harmful interventions. As the figure indicates, the size of the gray zone sharply limits the scope of implementation. Consequently, if gray zone practices were classified only as black or white, implementation's scope would increase significantly. According to Lomas, the scope of implementation has been inflated by expanding the black and white zones and eliminating the gray zone (p. 8). A picture of this move is represented by the bottom panel of Figure 1.

A review of the pertinent literature shows that the expansion forecasted by Lomas has actually occurred. The review of 76 studies, cited above, [38] bears the provocative title, "Why don't physicians follow clinical practice guidelines?" However, some of the studies included guidelines, while others focused practice parameters, clinical policies, recommendations, and consensus statements (p. 1459). These categories reflect qualitative differences in purpose, range of application, and level of research support, but the review treated them as equivalent. An early review of guideline adherence selected 59 studies[77] in which guidelines were introduced into routine practice. Guidelines were defined generously, as "systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances" (p. 1317). As there were no procedures for gauging the quality of a guideline, it cannot be determined whether any given "systematically developed statement" is actually beneficial, harmful, or ineffective. This lapse is especially important because some of the systematic statements that were reviewed fall well outside any customary understanding of a practice guideline. For instance, physicians in one study were instructed in how to talk to smokers about quitting. The "statements" were reminders written on fluorescent stickers and placed in patient charts.[78] The study did not examine whether these reminders were even consulted.

The lead author of the review was the co-author on another paper published 20 years later how to increase conformance to guideline recommendations.[79] The paper asserted that *every case of cancer world-wide* could be prevented, cured, or effectively treated if "management consistently complied with existing guidelines" (p. 1). The single reference in support of this claim was a World Health Organization cancer fact sheet[80] that

contained bullet points for risk factors such as smoking, sexual practices, and exposure to sunlight. These too are "systematic statements," but the fact sheet contained no references to practice guidelines, no description of interventions, and no assessment of effectiveness.

In these examples, expansions of the white zone by researchers and policy makers targeted practitioners' behavior. In perhaps the most infamous case of guideline overreach in the early days of implementation, the shoe was on the other foot. As part of a comprehensive overhaul of the U.S. healthcare system, Congress authorized the creation of the Agency for Healthcare Policy and Research (AHCPR) as the policy arm of the National Institutes of Health. The agency created fourteen research centers that were organized around specific disorders such as ischemic heart disease and schizophrenia. Each center was populated by an expert panel that was responsible for creating treatment guidelines that could serve as quality of care indicators and spur further research. The guideline issued by the back pain group questioned whether spinal fusion surgery was being overused in treating acute back pain.[81] This challenge was adamantly opposed by a vocal group of back surgeons, who found allies in conservative members of Congress. The latter were smarting from their recent unsuccessful effort to shut down the government. Together, they decried federal intrusion into healthcare and the AHCPR was put on the chopping block.[82] Ultimately, the agency was saved by being rebranded and stripped its policy-making authority. The irony is that the expert panel had issued a cautious report that highlighted limitations in the knowledge base and emphasized that definitive practice recommendations were premature.[83] In other words, spinal fusion for treating acute back pain was classified as a gray zone practice. The surgeons and politicians saw this recommendation as putting spinal fusion into the black zone, and creating a "wolf in

sheep's clothing" that would lead inevitably to sanctions by regulative bodies such as Medicaid and claim denials by insurance companies.

Diminishing the gray zone has the effect of blurring the line between science and advocacy. In some instances, the motive is frankly political, but more frequently it illustrates sheer exuberance by well-intentioned researchers who are dedicated to improving the quality of healthcare. There is a sense of déjà vu, insofar as a few decades prior, criminal justice policy makers turned to social scientists for guidance about how to diminish the incidence of crime. The researchers then were making an honest effort to address what was commonly understood as a pressing social problem; nonetheless, their findings were overstated and recommendations were unrealistic and unworkable.[84] Why is history repeating itself?

4. ZONES OF PRACTICE AND THE PERCEPTION OF RISK

Only one year after his seminal paper on implementation, Lomas had become wary about the science that he presaged—not because practitioners were unwilling to change or researchers were unable to develop effective tactics. Rather, his analysis showed that the gray zone was collapsed because implementation scientists and practitioners were operating from disparate models of risk perception. This disparity gives rise to different concepts of knowledge and different approaches to decision making. Lomas' paper reviewed studies of 8 practices, including blood transfusion and angioplasty.[76] It found that the percentage of gray zone decisions ranged from 9 to 33%, with a median of 26%. A contemporaneous paper reviewed RAND Panel studies of four procedures, including gastrointestinal endoscopy and coronary angioplasty.[85] It found that gray zone practices

ranged from 11 to 38%, with a median of 32%. The RAND panel procedure began by compiling a list of indications and contra-indications for each service by conducting a literature review. Criteria for inclusion were efficacy, risk, and timing. The literature review, list, and relevant definitions were distributed to a panel of experts, who rated the appropriateness of each indication. The panelists reviewed their ratings in a face-to-face meeting, and they re-classified each indication as appropriate, equivocal, or inappropriate. The classifications were then used to rate a sample of cases drawn at random from an administrative database.[86]

An *appropriate* procedure may not be *effective*. Appropriate procedures are likely to work in most cases, and the benefits are likely to far outweigh the risks of performing them. However, appropriateness is determined case-by-case, by examining the relationship between the indicators, the intervention, and the clinical presentation. In contrast, effectiveness is determined by examining the relationship between the procedure and outcomes over a large sample of cases. Typical examples of outcomes are reduction in symptoms, change in laboratory data, improvement in functioning, and increase in quality of life. Judgments of effectiveness are applying frequentist models and related statistical tests.

Although there is controversy over which model and test is most appropriate,[87] all frequentist models have quantitative tests of statistical inference. In contrast, the RAND panel classifications are not calculable because the attributes that contribute to the classifications may be qualitatively different or inconsistent.[88] In lieu of applying a quantitative test, the RAND panelists reached what Birnbaum called a judgment of "evidentiary value."[89, also see 90, 91]. Consequently, the RAND panel procedure is

systematic, but it does not comprise a method for assessing effectiveness and making quantitative judgments of risk.

In sum, there are three crucial differences between the procedures that lead to a judgment of appropriateness and the methods that assess effectiveness:

1. How they are evaluated: *Appropriateness* is evaluated by examining the relationship between attributes and their entities. *Effectiveness* is evaluated by examining the relationships among the attributes across entities, such as interventions, outcomes, conditions, patients.
2. The relationship among attributes: *Appropriateness* (i.e., indications and contra-indications of treatment) is evaluated with attributes that may be qualitatively different, even inconsistent. *Effectiveness* is evaluated with attributes are calculated and compared numerically.
3. The object of evaluation: The entity that is examined for *appropriateness* is a case-specific relationship between a patient, a condition, and an intervention. The entity that is examined for *effectiveness* is an intervention that applies to a population of cases.

These contrasts are reminiscent of the distinction in philosophy between epistemic and aleatory uncertainty.[92] Epistemic uncertainty is assessed by evidentiary value and not on strictly quantitative grounds. Aleatory uncertainty is assessed quantitatively, but statistical comparisons cannot gauge evidentiary value.[93, 94] Curiously, epistemic and aleatory are complementary forms of uncertainty that were developed together and co-exist in reason and discourse.[95] The prospect that soured Lomas on his own creation is the tendency of implementation science to supervene processes and procedures of judgment with its

methods and analyses, and interpret rates of non-conformance as impediments rather than evidence of a disparity between what is known is general and what should be done in a given case.

This section has described two models of risk perception—an aleatory model of effectiveness that is favored by implementation science, and an epistemic model of appropriateness that typifies clinical practice. As Lomas[76] showed, the models can be displayed on the same chart. However, comparing them belies a fundamental difference that he believed would not be overcome, owing to the inveterate tendency of implementation to diminish the gray zone of practice. The aleatory-epistemic distinction has been introduced to the risk perception literature through discussions of *deep uncertainty.*[96, p. 2084] As noted in Figure 2, this concept has been portrayed schematically by Walker and associates as a continuum that ranges from determined knowledge to a complete absence of knowledge.[97] The schema includes four intermediate levels, designed as 1 through 4. Deep uncertainty emerges at level 3. It is characterized by a variety of plausible consequences, system models, outcomes, and valuations. In Cox's view,[98] these characteristics render the optimization models of classical decision theory inadequate to address situations of deep uncertainty. This observation is crucial because gray zone practices are exemplars of deep uncertainty and implementation science follows classical decision theory by regarding the most effective treatment as the one that maximizes expected value over the long run.[51]

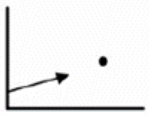
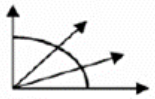
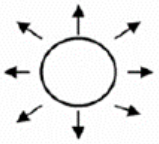
Determinism		Level 1	Level 2	Level 3	Level 4	Total ignorance
				Deep Uncertainty		
	Context	A clear enough future 	Alternate futures (with probabilities) 	A multiplicity of plausible futures 	Unknown future 	
	System model	A single system model	A single system model with a probabilistic parameterization	Several system models, with different structures	Unknown system model; know we don't know	
	System outcomes	A point estimate and confidence interval for each outcome	Several sets of point estimates and confidence intervals for the outcomes, with a probability attached to each set	A known range of outcomes	Unknown outcomes; know we don't know	
	Weights on outcomes	A single estimate of the weights	Several sets of weights, with a probability attached to each set	A known range of weights	Unknown weights; know we don't know	

Figure 2: The Situation Awareness Schema (from Walker et al. [97])

5. DEEP UNCERTAINTY AND CLINICAL DECISION MAKING

The deep awareness schema is similar to Svenson's conceptual structure of decision situations,[99] where level one situations are apprehended immediately and the familiarity leads to a non-deliberated reaction. This is analogous to the "determined" anchor of the uncertainty schema. In contrast, level four situations present novel or unfamiliar decision problems and call for an adaptive response, in which alternatives are elicited or created rather than merely invoked. Svenson's structure is analogous to how Walker and others have described deep uncertainty, and the risk perception literature also advocates an adaptive response. Swanson has identified seven adaptive policy tools [100] that include

built-in policy adjustment, multi-stakeholder deliberation, enriching social capital, and de-centralized decision making. What is remarkable about the list its diametrical opposition to principles of implementation science, which include persistence in policy, hierarchical decision making, and discourage movement between organizational boundaries.[cf. 101, 102]

Although these schemas have heuristic value, especially in showing the complexities that emerge at higher levels of uncertainty, they provide only a partial vista of how deep uncertainty can be recognized by policy makers and practitioners and incorporated into their decisional processes. What the schemas are missing is a means of applying them—that is, of apprehending the level of uncertainty, understanding the situation in its complexity, and making an appropriate response. The percentage of gray zone practices attests to the frequency with which clinical practitioners confront deep uncertainty; for Weiner, these situations call for an appropriate decision strategy:[103]

> Clinical decision making can be described as answering one question: "What is the best next thing for this patient at this time?" In addition to incorporating clinical information, research evidence, and patient preferences, the process requires considering contextual factors that are unique to each patient and relevant to their care. The failure to do so, thereby compromising that care, can be called a "contextual error" (p. 281).

Sometimes in clinical practice, the patient's condition and clinical presentation are immediately understood and an effective treatment approach is patent. This is analogous to level 1 uncertainty and a classic illustration of white zone practice. Sometimes, there are unknowns that can be factored into a tactical response. For instance, the desired outcome may be known, progress toward the outcome can be reliably measured, and there are

several good interventions to choose from. However, the first provider's first choice may be unavailable, undesirable, or the patient may have an idiosyncratic response. The treatment plan can be changed if the situation is understood properly and the switch is timely. This is level 2 uncertainty. It also illustrates white zone practice, although clinical acumen plays an important role.

On other occasions, the clinical picture is murky, the evidence for any intervention is equivocal, and the level of uncertainty is subject to change throughout the course of treatment. This situation represents level 3, or deep uncertainty, and the gray zone practice. The unwitting but nonetheless inherent tendency of implementation science, owing to its reliance on calculable knowledge, is to change the level of uncertainty from 3 to 2. Clinicians who follow this tack simplify the clinical situation and adopt a "paint by numbers" approach to treatment, which promotes reliance on ineffective interventions, and misleads and alienates patients.[104, 105] Coping effectively with deep uncertainty requires judgments of evidentiary value—what Tonelli calls "compellingness."[106] But gray zone practices require a decision strategy that recognizes and fully acknowledges the vicissitudes of the situation.[107]

6. DECISION MAKING AND SITUATION AWARENESS

The link between uncertainty and decision making has been discussed extensively in human factors research, especially under the heading of situation awareness (SA) theory. SA theory was designed specifically for decision making in dynamic and complex situations.[108] Its principles are perhaps deceptively simple: The guiding principle is that understanding complex situations is a predicate of effective action. Understanding

develops progressively and sequentially. It begins at level 1, with an apprehension of a few salient attributes, then proceeds to comprehending the situation as a whole at level 2. The move from level 1 to 2 involves valuation of attributes and specification of goals by the decision maker (or "system operator"). SA culminates at level 3, where the current understanding is projected forward and enriched by contingencies and eventualities.[108, 109]

The three levels of SA are preliminary to deliberative decision making. They produce what Klein refers to as "option awareness," and initiate a consideration of the next best course of action: whether to alter the current trajectory, and if so, to select the next best alternative.[110] Klein's approach falls within the purview of naturalistic decision making,[111] a movement that joins behavioral decision theory with human factors research.[112, 113] The idea that decision making proceeds in stages—from envisioning the situation and recognizing that a decision may be required, to matching the situation with viable alternatives, and finally to selecting the best available course of action—is fundamental to Beach's naturalistic approach, as embodied in his image theory,[114] and his narrative-based decision theory.[115]

A distinctive characteristic of these theories is their ability to examine how situation awareness leads to invoking a decision strategy.[116] Image theory also provides a conceptual understanding and empirical test of what it means of for clinicians to incorporate guidelines into treatment decisions. As noted above, implementation studies regard a guideline as a quality indicator or standard; they almost invariably conclude that practitioners are resistant to change because rates of concurrence are low. In contrast, image theory predicated a study that examined whether guideline algorithms are *incorporated* into decisional processes to the extent that their general recommendations

match specific clinical indicators. The study used a switching guideline for patients with schizophrenia. A chart review that compare guideline recommendations to treatment recommendations obtained a concurrence rate of only 5%.[117]

Five clinical indicators were systematically manipulated and inserted into a series of brief case vignettes: quantitative measures of symptom severity and recent progress, categories of treatment adherence, number of treatment switches, and an expected treatment outcome represented as likelihoods of a positive, neutral, and negative response. Medical residents were familiarized with the guideline and then made treatment recommendations. The indicators are qualitatively different and were combined using an epistemic counting rule.[118] The overall concurrence rate was 42%, but ranged from 91% with no mismatches, to 50% with one mismatch, and 32% with five. The relationship between indicator mismatches and concurrence rates was found to be consistent within practitioners.[70]

While SA plays no viable role in applications where it is presumed that the situation is already known and adequately represented, the importance of SA in complex and dynamic environments has been demonstrated in a number of disciplines and specialties,[119] including aviation,[120] healthcare[121, 122], and in implementing organizational processes through training, teamwork development, and system design.[123, 124] Questions have also been raised about the adequacy of the SA model,[125] and whether SA is best understood as psychological construct or an distributed process.[126, 127] The SA model is commonly described from a psychological viewpoint, and emphasizes cognitive processes that draw heavily on working memory and require considerable conceptual and practical knowledge.

However, the ergonomic or distributed cognition approach may be most consistent with clinical practice. In the RAND procedure, a practice is understood as a dynamic relationship among a medical condition, a treatment, and a patient-specific clinical presentation. This relationship can change over time, as the a product of the patient's response to treatment, and particularly as the patient asserts him- or herself into the decision making process. The mandate for encouraging patient inclusion originated in the doctrine of informed consent,[128, 129] but it has been spurred by discussions of patient centered care and shared decision making (SDM) as fundamental to the delivery of quality healthcare in the twenty-first century.[130, 131]

SDM carries several distinct meanings. Charles and associates suggest that its various approaches be classified broadly into two models: An "informed" model relies on information exchange in order to establish and maintain a partnership; a "shared" model involves a simultaneous sharing of information, knowledge, and perspective in order to develop common understanding.[132] Juxtaposing these models against the levels of uncertainty, the informed model is most appropriate to levels 1 and 2, where clear and sufficient information can be exchanged about symptoms, progress, and treatment options. The shared model is amenable to level 3, where information must be elicited and developed rather than merely conveyed, goals and criteria are established rather than simply followed, and preferences must be constructed.[133, 105] In clinical practice, the nature and quality of the relationship between patient and provider that human factors research refers to as distributed cognition is called "shared mind."[134]

The discussion of how deep uncertainty can be addressed through SA and SDM has moved us well beyond the scope of implementation science as it is currently envisioned

and practiced. Lomas was not sanguine about the prospect of bringing gray zone practices under the purview of implementation science. Perhaps he was right, and its beneficent aims will always outstrip its execution. There is an alternative that might be called "Implementation 2.0," which recognizes deep uncertainty and develops responses founded on situation awareness and naturalistic decision making. Obviously, this prospect has yet to be developed, but the fundamentals are in place and need for an appropriate and effective response has never been greater.

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