A Collaborative Approach to Targeted Treatment Development for Schizophrenia: A Qualitative Evaluation of the NIMH-MATRICS Project

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Introduction: In 2002, the National Institute of Mental Health (NIMH) initiated a multistakeholder research process designed to stimulate the development and evaluation of medications targeting the cognitive deficits associated with schizophrenia. The first phase, Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS), sought consensus on laboratory measures for cognition, clinical trial outcome measures, and drug registration requirements. MATRICS constitutes a unique drug development model because it targeted a specific endophenotype of schizophrenia and because it engaged academic, industry, and government stakeholders in a consensus-oriented process. This study offers a preliminary qualitative evaluation of the NIMH-MATRICS project. Method: Interview data are used to describe how MATRICS participants regard 3 aspects of the development of cognitive medications: the definition of the treatment target, stakeholders' role in the early development process, and anticipated dissemination complexities. Results: MATRICS participants describe the treatment target in highly varied ways and envision a wide range of public health benefits. MATRICS is perceived as inclusive, despite minimal representation from some end users. According to informants, clinical detection, documentation, and monitoring of cognition and functioning may prove problematic. More thoroughly than non-industry-employed informants, industry-employed MATRICS participants articulate strategies by which treatments can be integrated into clinical practice. Discussion: The MATRICS process did not produce a clinical concept of cognitive impairment in schizophrenia, and significant challenges remain to be addressed regarding the rational clinical use of novel pharmaceuticals for cognition. Broader inclusion of end users in translational science projects may streamline implementation and facilitate improvements in real-world outcomes.

Key words: schizophrenia/cognition/psychotropic drugs, therapeutic use/diffusion of innovation/qualitative research

Introduction

Improving real-world outcomes in schizophrenia remains a high priority for consumers, health professionals, and the public.1–2 Schizophrenia affects 1.1% of the population but incurs disproportionately large costs from hospitalization, treatment, and lost productivity.3–4 Too often, available treatments are not appropriately used. Poor treatment guideline adherence,5–6 high rates of polypharmacy with unclear benefit,7 and low rates of evidence-based care8–9 have been well documented. Even with the best treatment, persons with schizophrenia experience residual symptoms10 and functional problems, including low employment rates.11

Advances in neuroscience offer the potential to develop treatments for impairments such as the cognitive deficits associated with schizophrenia. Cognition in schizophrenia is a core aspect of the illness12–13 that, cross sectionally and longitudinally, correlates more strongly than positive symptoms with a variety of functional outcome measures.14–16 The growing literature on cognition, its neuronal mechanisms, and its link to functioning led the National Institute of Mental Health (NIMH) leadership to decide that a treatment development program targeting cognitive impairment was scientifically promising and relevant to public health.17 The first phase of the development effort, Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS; www.matrics.ucla.edu), was recently concluded.18,19

The MATRICS process exemplifies recent National Institutes of Health (NIH) policies to accelerate the translation of basic science into clinical treatments. The NIH Roadmap Initiative20 encourages collaboration with industry21–22 and novel partnerships23–24 and emphasizes innovative approaches to chronic conditions with significant disease burden. NIMH leadership have argued

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that accelerating treatment development in psychiatry requires a reorientation of psychopharmacology toward novel targets independent of descriptive diagnostic categories. They argue that endophenotypes—measurable indicators of pathophysiological processes unseen by the unaided eye but identifiable with diagnostic technologies—and subsyndromes that cut across or lie within DSM categories—such as anhedonia and impulsivity—may relate more directly than clinical phenomenology to core pathophysiological processes.

MATRICS involved divergent constituents in a consensus-oriented process. MATRICS included 6 conferences, 5 committees, expert surveys, literature reviews, and over 250 participants—academic physicians and neuropsychologists, industry researchers and strategists, NIMH and Food and Drug Administration (FDA) officials, and consumer representatives. Participants forged agreement on the domains that best describe the cognitive deficits of schizophrenia, the preferred features of a cognitive battery and clinical trial outcome measures, and promising molecular targets. Participants also forged a pathway for drug registration. MATRICS allowed for the selection of dependent variables and outcome measures acceptable to the scientific community, industry, and the FDA. MATRICS addressed the FDA’s reluctance to accept drug labeling for subsyndromes by providing a forum in which researchers argued to the FDA that cognitive deficits constitute a core component of schizophrenia and a reliable therapeutic target. The process was structured to encourage industry investment in treatments for cognition and to permit multiple stakeholders to influence how compounds are evaluated.

A MATRICS-like model has facilitated cancer treatment development, but the model’s advantages for psychiatry are unknown. Questions can be raised: Which scientific opportunities warrant federal incentivization of industry research and development? Which stakeholders should assist in the earliest phases of treatment development? What role do consumer priorities and clinical feasibility play in treatment development and evaluation? How do laboratory-defined endophenotypes of cognitive impairment correlate with patient experiences and clinician perceptions? Who will determine how clinicians identify and describe deficits as target symptoms for new drugs? Finally, given that a substantial gap remains between best practice guidelines and treatment in community settings, what will ensure that new medications yield public health benefits?

This article offers a descriptive, qualitative evaluation of the NIMH-MATRICS program. It details 3 aspects of cognitive treatment development as described by 20 MATRICS participants: the definition of the treatment target, the role of stakeholders in the development process, and anticipated shifts in schizophrenia treatment practices. Results highlight specific complexities of the development and introduction of pharmaceutical innovation to improve cognition in schizophrenia. The results are interpreted in relation to how stakeholders view their responsibilities in the drug development process. While this study cannot address the range of policy, clinical, and ethical questions raised by targeted collaborative science, it indicates some important aspects of multistakeholder efforts to speed treatment development.

Methods

Data were collected through semistructured interviewing using grounded theory methodology. Unlike methods that test hypotheses drawn from existing theoretical frameworks, researchers using grounded theory generate hypotheses as they collect data. As interviews were conducted, analysis of qualitative data, identification of emergent themes, and articulation and validation of hypotheses took place. In this manner, conclusions were reached inductively. Participant observation at 4 MATRICS meetings, informal interviewing, and literature reviews were used to contextualize interview data. The Office for the Protection of Research Subjects of the University of California, Los Angeles, and the West Los Angeles Department of Veterans Affairs Medical Center Subcommittee for the Protection of Human Subjects approved the study. Twenty semistructured interviews lasting between 30 and 45 minutes were conducted with MATRICS participants.

“Participant” was defined as any person attending 1 or more MATRICS conference. I sent a solicitation e-mail to all 211 individuals involved in the MATRICS process to that date; 50 agreed immediately to interview. Purposive sampling for maximum variation was used to select informants varying by expertise, employment, training, degree of MATRICS buy in (as assessed by an analysis of social networks within MATRICS), and clinical experience (table 1). A small number of first respondents was interviewed. To capture the range of opinions and to maximize the likelihood of finding disconfirming cases, this subset was compared with other social networks within the MATRICS group (committees, large versus small companies, established collaborations, competing research teams, minimally involved participants). Informants likely to present differing views were solicited and interviewed.

I conducted all interviews. I asked informants their impression of the MATRICS initiative and collaboration: what other stakeholders could have been included; what practitioners understand about cognition in schizophrenia; how they will learn to use medications, and what dissemination complexities may occur; what may influence practitioners to prescribe; and how the role for other treatments may change.

Interviews were conducted by telephone, audio-recorded, and transcribed. Interviewing continued until theme saturation was reached. Two informants reviewed
and slightly edited their interview transcripts. Coding of interview transcripts was performed using Atlas.ti, a computerized qualitative data-management program.

Results
These results summarize how MATRICS participants describe 3 themes: (1) the definition of the treatment target, (2) the involvement of stakeholders in the development process, and (3) anticipated shifts in treatment practices. Interview questions explored other themes, but only 3 are summarized here for the following reasons: more than other themes, these were highly elaborated within an interview (especially theme 1); they emerged consistently across interviews (especially theme 2); and informants’ comments on the 3 were judged to be timely and constructive (especially theme 3).

Definitions of the Treatment Target
Informants used the designation “cognitive deficits” to describe an array of nonspecific and contradictory clinical phenomena such as “slow inefficient thinking,” behavioral disturbances, thought disorders, or “true deficits of executive function.”

Cognition as Clinical Phenomena. Most informants recognized cognition in contextualized behaviors and daily activities rather than in patterns of thinking. No informant explained cognition by referencing specific neuropsychological tests. Some cited cognitive deficits as the core cause or explanation for disability.

This informant fit numerous features of patients’ lives under the “cognition” rubric: “Patients, even when they’re quote–unquote in control, most really aren’t capable of working; many are not in stable relationships; they really have a hard time with basic daily function such as organizing their apartment or room, or cooking, cleaning, managing finances, shopping, even taking the bus, being on a plan.” Another said the cognitive deficits are “a major reason people couldn’t return to work.”” Cognitive deficits affect “their ability to solve the kinds of problems that folks run into every day,” such as remembering appointments, responding in social interactions, and arranging housing. Or cognitive deficits “cause these folks for the rest of their lives to only go so far.” That is, “most ... patients don’t have jobs, and most ... patients can’t hold relation[ships]—... all of those other aspects that ... the cognitive deficits bring to bear.”

Some informants described disparate clinical phenomena—psychomotor retardation, amotivation, behavioral

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disturbances, or thought disorders—as indicative of cognitive impairment. Pharmacological interventions may “help these people think a little more clearly, not have their thoughts blocked … energize those areas of their brain that will help them organize their thoughts.” An informant anticipated that medications that improve cognition may help “aggressive” and “difficult to control” patients in nursing homes. Others described the cognitive deficits as “interpersonal” in nature, consisting of aspects like “an emotional lack of awareness” or poor social judgment. One informant said that cognitive problems are so prevalent that “I don’t even know how to explain [them].”

Cognition as General or Specific. Informants used “cognition” to describe both a general characteristic and specific thought processes. Informants anchored a description of cognition by prioritizing 1 of its comprehensible components and then linking or equating that domain to more general deficits. Informants differed on which aspect of cognition is most central, but they anticipated that improving 1 domain would concomitantly improve global deficits.

Informant P envisioned pharmacologic treatments that “can improve learning and other aspects of cognition.” Later, P said, “Attention is a major component of cognitive functioning, and … a lower level of attention may lead to an impact on functioning, including simplest activities like driving to a given place or reading newspapers.” Another described executive functioning as most important. Since it relates to “being able to plan, organize,” it “seems to be 1 of the more important domains to try to treat, which directly relates to day-to-day function.”

Informant E understood cognition as equivalent to speed or efficiency of thought: patients are “very used to … their thoughts being processed a lot more slowly than everyone else around them.” Later E prioritized other domains: “If they are successful in enhancing memory, for instance, or helping to organize thoughts,” the medications may have an impact “in terms of reducing anxiety.” An informant “was glad when they also added that social cognition piece” to the list of domains; another informant called the domain of social cognition “so obvious” to recovery.

Expected Treatment Outcomes. Almost all informants posited a strong link between pharmacological treatment of cognition and improvement in a wide range of distal, real-world outcomes. Though the theme was not directly prompted, 17 of 20 informants described the impact of cognitive medications as an improvement in relationships, quality of life, subjective competence, self-esteem, societal involvement, and employment. Pharmaceuticals, not psychosocial treatments, were described as the efficacious component of treatment to achieve these outcomes.

Targeting cognition may result in “returning people to work,” helping patients get “on with their lives,” or “getting some of these patients actually back into … society and a lifestyle that is reasonable.” The “key issue” to another was, “Does it mean we will get people … back into the community?” Such expectations are highly motivating. One informant said that if cognitive drugs can be developed, “I would be ecstatic. I would feel like this was the most worthwhile thing I’ve been involved in” because of the likely benefit to quality of life.

Stakeholder Involvement

All informants felt that collaboration was beneficial; as summarized by an informant, “The problems that we all are dealing with … are so complex that not any 1 group has the classic answers.” All informants described the collaboration as inclusive; most felt that “everyone” was there. MATRICS included over 250 academic and industry personnel; 3 consumer representatives or advocates participated, as did 3 FDA representatives and 1 health services researcher. No purchasers, payers, or non-research clinicians participated.

Practitioner Participation. No informant endorsed a belief that community practitioners would add to the MATRICS process. Informants said that practitioners would be unwilling or uninterested in participating, could not offer useful ideas, or were adequately represented by academic researchers. One said that their questions would have added “mayhem” to the process; another suggested they are “too diverse” to be included—though MATRICS intended to maximize diversity among researchers. Two informants said that state commissioners or purchasers could have helped design efficacy trials.

Though also content with the level of inclusiveness, the 6 industry-employed informants described a need to attend to the demands of the broad clinical community. One said, “Your end users should be part of your initial planning…. [Y]ou always have to have your end users for any kind of product. … [I]f you’re developing a runner’s shoe, you wanna make sure your runner’s gonna wear it. Otherwise it’s gonna be in the closet.”

Consumer Perspectives. Participants valued consumer involvement. Yet informants described consumer involvement as a way to validate—not shape—the project. Some informants suggested that more consumer participation could encourage the FDA to recognize the importance of cognition or “just to sort of advocate.” Another expressed skepticism that consumers could contribute because “there are relatively few people who are at the level that they can talk with great insight about their experience.” Several informants stated that new treatments for cognition will be accepted and welcomed by families and consumers.
Anticipated Clinical Practice Changes
Informants suggested complexities to the rational dissemination of cognitive-enhancing medications, including difficulties reliably identifying the treatment target, documenting the deficit, educating practitioners, and monitoring functional outcomes. Informants disagreed as to whether these are significant hurdles that call for active strategizing or will be uncomplicated.

Practitioner Education. All informants mentioned that practitioners either do not understand that patients have cognitive deficits or think of cognitive deficits simplistically—noticing, for instance, that patients think slowly. Four informants with direct experience educating practitioners described practitioner knowledge as minimal and often erroneous. Informants called cognition “a psychologist’s domain” or the purview of neurologists.

Yet informants disagreed on the type of information practitioners need to treat cognition. Some informants described cognitive impairment as an obvious clinical deficit that is “not that subtle.” For them, “a lot of patients and certainly a lot of clinicians” will decide that “a substantial portion of [patients] are cognitively impaired.” Another said, “It won’t be difficult to convince psychiatrists ... that this is an aspect of the illness that needs to be addressed.” For another, “you don’t necessarily need some fancy cognitive test to tell you it’s a problem.”

Another set of informants described cognitive deficits as complex to recognize and difficult to measure. They said that the cognitive deficits in schizophrenia are less detectable than those of dementia or than other symptoms of schizophrenia: “Psychosis, it’s easy, ... you don’t even really need a formal rating to understand when somebody might be floridly psychotic, ... Cognition is not like that.” And “the problem with cognitive dysfunction is there are a lot of people who are not, do not have a lot of insight on this dysfunction, so they’re not aware of it.”

Means to Practice Change. Marketing, education, and detailing conducted by pharmaceutical companies were the most consistently mentioned means by which knowledge about cognitive treatments will reach practitioners. Informant Z articulated the majority viewpoint: “Most of us would like it if a preponderance of clinical evidence suggested a product’s value, but we know it’s the endorsements and marketing that matter.”

All industry-employed informants described explicit strategies for training practitioners to use new medications. Industry researchers used inclusive phrasing—“We probably also need to develop” clinical tools (M), or “We will need a number of consistent efforts” (P)—to describe the communication needed with practitioners to effect innovation. Informant U provided a plan:

I would think there is going to be a very large educational requirement. I think that they do not know how to diagnose these patients presently; their tools for doing it are ... not part of their clinical armamentarium; they don’t give neuropsychological tests ... to make an accurate diagnosis. ... I think there’s a lot of work that has to be done in terms of getting them the education and potentially the tools to make an accurate diagnosis and to use the medication appropriately.

Non-industry-employed informants’ plans for practitioners were not as thorough and often lacked detail. A government-employed informant said, “I think they’d learn very quickly and would be very eager to take any information. ... I’d be very confident that clinicians ... would be very eager to try using these medications.” An academic said, “They might go for some CME [continuing medical education] kind of activity somewhere or other” and then learn through trial and error.

Discussion
This report uses qualitative data to describe the NIMH-MATRICS project, a targeted treatment-development endeavor involving multiple stakeholders. Results show that informants described the clinical treatment target, cognitive deficits, in varying ways. Informants said that improving cognition pharmacologically will lessen disability and have high public health relevance. Informants were comfortable with the inclusiveness of the project despite minimal involvement of practitioners, consumers, purchasers, and payers. Some informants but not others anticipated problems with the detection, documentation, and monitoring of cognition and functioning. Tacitly or explicitly, informants assumed that dissemination complexities would be addressed by pharmaceutical company efforts. More thoroughly than academic or government informants, industry informants articulated a range of activities involved in moving the innovation into practice.

Taken together, these results support the conclusion that specific clinical, policy, and ethical issues warrant further exploration. First, the MATRICS process did not produce a clinical concept of cognitive impairment in schizophrenia. Even expert informants most readily described cognition in behavioral terms; many were not clear whether to describe cognition as a general or a specific impairment; some equated cognition with thought processes or social awkwardness; and informants disagreed on whether cognition is a subtle or obvious
clinical phenomenon. Informants intuited the clinical relevance of cognitive capacities but did not describe a symptom complex for which the treatment is meant that can be reliably documented and monitored for response. Indeed, as anticipated by Hyman and Fenton, the clinical target that corresponds to the endophenotype appears to have been “taken for granted.”

Like informants, clinicians may call a range of behaviors, thought processes, or affects “cognitive” in nature, instead of reliably characterizing cognitive capacities. Brief rating scales and clinical protocols will help, but clinicians do not readily adopt rating scales, relying instead on patient report or clinical impression. Yet patients’ and practitioners’ perceptions of cognition correlate poorly with research constructs. Medalia and Lim report poor accuracy among clinicians and patients in detecting laboratory-verified cognitive impairment. Patients had more difficulty accurately perceiving that their cognitive skills were intact.

As a result, how cognitive enhancers will be rationally prescribed in clinical practice remains to be clarified. Industry-sponsored educational efforts may seek to capitalize on a nebulous definition of cognition rather than provide prescribers with evidence to specify and narrow it. One industry-generated CME pamphlet states that “cognitive dysfunction is present in varying degrees (often severe) in the majority of patients with schizophrenia” and that all domains are affected. Similarly, an industry-sponsored clinician survey conflates cognition with functioning, asking about “domains” of functioning that include insight, motivation, and independent living skills. Each tactic discourages and complicates rational treatment targeting. Despite this, most informants accepted (and occasionally welcomed) industry marketing as the most effective means to practice change.

Second, therefore, clinical implementation of novel pharmaceuticals may present challenges that translational science policies have not yet addressed. In fact, when asked to rank important criteria for cognitive test selection, MATRICS participants ranked as least important that cognitive tests have a clear relationship to clinical symptoms. While MATRICS participants discussed within meetings how clinicians would detect cognitive impairment in their patients, the lack of inclusion of community practitioners precluded asking those who see patients day to day. Informants’ negative opinion of practitioners and delegation of implementation responsibilities to others pose further problems, particularly in light of perceptions that practitioners know little about cognition. The well-documented problems in quality of care in psychiatry may well worsen with the introduction of novel drug targets like cognitive impairment, negative symptoms, or anhedonia. Proactive policies to plan how innovative treatments can be rationally introduced into practice—not just aggressively marketed—will complement efforts to accelerate the translation of basic science.

Third, the MATRICS process demonstrates that translational science teams will need to negotiate how collaboration and consensus will be defined and by whom. That is, participants may demonstrate a subjective bias in assessing inclusiveness: those who attended often perceived that “everyone” was present. However, some informed investigators who disagreed with the approach taken within MATRICS simply stopped participating. Some involved and uninvolved researchers expressed a concern that too little effort was taken to elicit dissident views or divergent expertise. Within a collaboration, this self-selection process naturally drifts a group toward consensus, yet not necessarily through ongoing debate and resolution of emergent issues. Sustained efforts to assess stakeholder inclusion and research team diversity may help. Nonetheless, inclusiveness within collaborations may be best judged by outside observers.

Moreover, participants assumed that representatives from academic, industry, and government sectors constitute the core drug development community. However, the contributions of consumers, practitioners, purchasers, services researchers, and rehabilitation/psychosocial researchers may have helped the MATRICS group meet its fundamental objectives. For instance, MATRICS participants expressed hopes that pharmacological interventions for cognition would improve a surprisingly broad range of real-world outcomes. Of course, cognitive enhancers alone cannot put patients back to work. Since a host of intervening variables mediates the pathway between cognitive abilities and community functioning, the minimal involvement of community-based end users contrasts with participants’ ultimate motivations and ambitions for advances in cognition treatment. If research aims for improvement in community-oriented outcomes, more can be done to include those who can speak directly to how to effect these changes.

In fact, the industry-employed informants interviewed in this study were well versed in the notion that communication between producers and consumers of scientific knowledge forms an integral part of the innovation process. Consumer and family experiences, supported employment and psychosocial treatment outcomes, and processes of recovery can inform neuroscientific perspectives on cognition. Clinicians, commissioners, payers, and purchasers can suggest what data might facilitate pharmaceutical adoption in care systems. Apace with efficacy trials, data linking functional end points to real-world outcomes can be generated, and, as initially suggested, adjunctive psychosocial therapies can be explored within trials of cognitive enhancers. In this way, efforts toward novel scientific products can be engineered to meet the needs of the wide range of clinical constituents.

Since it is based on qualitative data collected in 1 time frame, this study cannot ascertain that such changes would have improved the outcome of the MATRICS project. The study’s goal was to explore the effects of stakeholders-rich group dynamics on the conduct of the MATRICS collaborative process. If we understand this to mean that clinicians, consumers, and other stakeholders “do not readily adopt rating scales,” then this study fails to support that claim.
process, only that they would have altered it. Results reflect the viewpoints of a modest number of diversely affiliated participants in the MATRICS process and cannot be generalized to the entire community of cognition researchers. In addition, the suggestions presented in the discussion represent a single author’s conclusions culled from data and countless discussions regarding these findings over 18 months. Despite its limitations, this study demonstrates that exploratory studies during treatment development can help anticipate the services implications of innovations. Coupling the substantial progress in the neurosciences with sustained attention to community exigencies offers an exciting opportunity to improve outcomes in schizophrenia.

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