Challenges and solutions for conducting research in correctional settings: The U.S. experience

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A B S T R A C T

Through the mid–1970s, most new drug clinical trials were conducted in America’s jails and prisons. Due to the extensive human rights violations acknowledged at that time, laws were enacted that essentially brought corrections-based research to a halt. The Code of Federal Regulations, 45 CFR 46 subpart C, specifies the limitations upon research with correctional populations that are currently in place. These guidelines both informed the ethical conduct of research and arguably created a significant problem in today’s correctional environment — prisoners are under-studied. We know far less about the health and health care needs of people under conditions of incarceration than those in the community. Linked with the extraordinary explosion over the last 20 years in the population of America’s jails and prisons and with a disproportionate number of mentally ill inmates, inadequate knowledge currently exists to guide clinical decision-making. Over the last decade, a gradually growing body of work, ethically developed and clinically focused, has been evolving. This article presents the challenges of conducting correctional research in health and healthcare delivery. Legal, ethical, and pragmatic barriers are reviewed. Further, practical solutions that allow meaningful research to be conducted are presented. Such research can create a foundation for developing both public policy and clinical practice.

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1. Introduction

While basic and applied mental health research is being vigorously pursued across a wide variety of community and hospital settings, very little mental health research of any kind is currently being conducted in America’s jails and prisons. There is a great deal of history that contributes to the current state of affairs. There is also a real and pressing need to improve our recognition and understanding of the mentally ill who become incarcerated. The need extends to include how to develop or improve the treatments the mentally ill receive, and how to support the ongoing development of the systems of care in the nation’s correctional institutions. This article will discuss aspects of the history, the current challenges researchers face, and some of the solutions and opportunities that exist in this critical area.

2. Inmates overprotected and understudied

The history of research on inmates is replete with examples of coercion, involuntary participation, and the introduction of illness or disease without the knowledge or consent of the subjects (Hornblum, 1997; Kalmbach & Lyons, 2003; Leopold, 1958; Stanley, 1922). In reaction to these abuses, oversight of and regulations on such research were implemented. Prisoners subsequently became an “overprotected population” in research (Moser et al., 2004, p. 1). As such, few clinical trials have been conducted on prison populations in recent years. Yet, evidence is required to inform policies, procedures and treatments for this vulnerable population, leading one observer to declare that research involving prisoners is a “moral imperative” (Weisburd, 2003, p. 336).

This view is defensible from the position of the needs of prisoners themselves. According to recent reports, there are roughly 735,600 inmates in U.S. jails (Bureau of Justice Statistics, 2012) and 1,605,000 inmates in U.S. state and Federal prisons (Bureau of Justice Statistics, 2011). Large proportions of these inmates contend with chronic and disabling health conditions including serious mental illness and substance use disorders (Bureau of Justice Statistics, 2006), hypertension, obesity, arthritis, asthma, and hepatitis (Binswanger, Krueger, & Steiner, 2009). In order to provide constitutionally mandated medical treatment in an effective manner, evidence is required to establish best practices. Only through well-designed research efforts with prisoners, taking into account their particular population characteristics and contextual contingencies, will it be possible to design and deliver appropriate and informed health services.

3. A brief history of medical research in correctional settings in the United States

Prior to World War II, medical research with imprisoned subjects in the U.S. was rare (Comfort, 2009; Hornblum, 1997). This changed...
however when the war effort in Europe and Asia put soldiers at extreme risk for understudied conditions. An urgent need for novel medical prevention and intervention developed. The incarcerated was seen as an ideal population for medical experimentation; inmates represented a highly routinized and captive convenience population who were easily recruited into research participation (Hornblum, 1997). In this context, medical ethics took a back seat to the war effort in prison-based research.

Ostensibly, prisoners volunteered to participate in research. Few were concerned with the question of whether prisoners could truly consent to research participation within institutions that were coercive by design. At the same time, there was a prevailing sentiment that all Americans — including prisoners — had an obligation to contribute to the war effort (Schroeder, 1983). In addition, prisoners were seen as owing a particular debt to society. They were increasingly used as research subjects through the war years and were, at times, compensated through sentence reductions or outright release into the community.

Prisoners were subjected to a vast array of medical risks through research participation. Perhaps most conspicuous was the introduction of malaria into hundreds of prisoners at the Illinois Stateville Penitentiary during medical experiments beginning in 1944 (Comfort, 2009). While the U.S. put prisoner-subjects at risk in research, medical doctors of the Third Reich demonstrated extraordinary cruelty in this regard (Ivy, 1949). At the conclusion of the war, the Nuremberg Trials included the “Doctors’ Trial” which re-focused attention on prisoner research. Medical doctors of the Nazi party defended themselves against accusations of atrocities committed upon prisoners of concentration camps, pointing to similar practices in the U.S. However, Nazi experiments included attempts to alter genetics, unnecessary transplantations, the introduction of poisons, and intentional freezing. These “experiments” frequently resulted in death.

Following the war, the continued practice of using inmates as subjects in the U.S. was supported by a committee report to the Governor of Illinois published in the Journal of the American Medical Association (Ivy, 1948). This publication legitimized the practice of using prisoners as research subjects to the medical community. This was despite the articulation of the Nuremberg Code (1949), which by that time had been repurposed for guiding the inclusion of prisoners in research in a more conservative fashion. The U.S. continued the practice largely unabated through the 1960s and 1970s.

Public opinion in the mid-1960s began to shift as general concern for civil rights grew and the public became more aware of potential breeches of ethics in research employing prisoners and other vulnerable populations. In 1966, Henry Beecher published a seminal article in the New England Journal of Medicine reviewing questionable ethics in clinical research involving prisoners (Beecher, 2001). This was picked up by the mainstream press. The public also became aware of the design of the Tuskegee Syphilis Study (1932–1972), commissioned by the U.S. Public Health Service. In brief, this study enrolled hundreds of black sharecroppers in Alabama and followed the natural course of syphilis in these men without intervention (Katz et al., 2008).

The growth of the drug industry largely relied on the prisoner-subject. By the late 1960s, eighty-five percent of new drugs were tested on prisoners (Seigel, 1981). In 1980, the FDA proposed a ban on experimental drug research on prisoners which was later amended to result in a de facto ban on prisoner research (Schroeder, 1983). As a result of increasing public awareness of real or potential research ethics violations and/or increasing regulatory oversight of research, few clinical studies involving prisoners remained by the early 1980s.

4. Regulations and oversight

The development of human subject research regulations and oversight spanned several decades and continues today. In the 1948 report to the Governor of Illinois mentioned above, the authors recommended three points of consideration for human subjects research (Ivy, 1948):

1) That all subjects should be volunteers in the absence of coercion in any form;
2) Before volunteering, they should be adequately informed of the hazards, if any, and;
3) That the choice of volunteers should be made on the basis of established criteria.

These basic points have been retained in various forms throughout the development of current research protocols. At the core of these points is the requirement of informed consent, whereby the subject is made aware of potential risks involved in participation and voluntarily agrees to participation in the absence of coercion.

The Nuremberg Code was developed in 1947 during the post-war Nuremberg Trials to serve as a guide for judging war crimes perpetrated by the Nazis. The U.S. and the international community sanctioned former Nazi researchers during the “Doctors’ Trial” for atrocities committed while conducting human research. However, the U.S. did not apply the standards of the resulting Nuremberg Code internally. Instead, these ethical standards were seen only to apply to Nazi scientists (Hornblum, 1997). Still, the Nuremberg Code was a turning point as a statement of ethical principles of human experimentation. It includes ten directives. According to Shuster (1997, p. 1439), “the key contribution of Nuremberg was to merge Hippocratic ethics and the protection of subjects’ human rights into a single code.” It also emphasizes the basic requirement of informed consent, and includes mandates for anticipated benefits, risk/benefit analysis, and the right of subjects to withdraw from the study. These considerations continue to be required by IRB committees today, though a few additional tweaks have been made.

In 1964, the World Medical Association (WMA) developed the Declaration of Helsinki, a “...statement of ethical principles for medical research involving human subjects...” (World Medical Association, 1964, p. 1). Importantly, from the perspective of research involving prisoners, the introduction of the Declaration states “Populations that are underrepresented in medical research should be provided appropriate access to participation in research” (World Medical Association, 1964, p. 2). Though also recognized was the need to offer special protection to vulnerable populations, including those who may be particularly vulnerable to coercion. Included among the twenty principles are informed consent and the requirement to have an independent research ethics committee to review the study protocol prepared by the investigation team. The subject also has the right to refuse participation or withdraw from the study at any time. Principle 17 speaks most directly to research involving prisoner-subjects:

Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research (World Medical Association, 1964, pp. 3–4).

This is noteworthy because, while an individual prisoner may not benefit directly from research results, e.g., if released, their population (i.e., prisoners) nonetheless may. Principle 29 introduces special guidance for research involving prisoners with mental conditions who are incapable of directly providing informed consent. It allows for proxy consent and stipulates conditions under which research can proceed without any consent with the oversight of the ethics committee.

Subsequent litigation, notably Kaimowitz v Michigan (Kaimowitz, 1973), contributed legal authority to restraint of invasive medical research. In this situation, the proposed research involved psychosurgery. Specifically, in this landmark ruling, the court held that an inmate cannot give free consent to a dangerous medical experiment.
In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research produced the influential “Belmont Report.” This report outlines three basic ethical principles for conducting research involving human subjects: Respect for Persons, Beneficence, and Justice. The Report also provides guidance regarding the application of these principles. The report incorporates most, if not all prescriptions for the ethical conduct of research previously articulated. These include informed consent, Hippocratic ethics, risk–benefit assessment, review of protocols by ethics committees, careful selection of subjects, voluntary participation, and enhanced protection of vulnerable populations.

The Report explicitly uses the example of prisoner-subjects in research in illustrating a deliberation seeking to accommodate the principle Respect for Persons:

On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to “volunteer” or to “protect” them presents a dilemma (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979, p. 4).

As this illustration makes clear, the Report is intended to provide a set of ethical principles as guidelines as opposed to serve as a diagnostic tool informing a particular case. Ultimately, the principles are to be debated and accommodated by research investigators and review committees.

An important consideration for research on prisoners and other vulnerable populations in the Report is the notion of undue influence. This acknowledges that, while explicit coercion to a potential participant may be absent, the rewards for participation may be so great as to constitute de facto coercion. For example, the promise of release into the community may constitute coercion for the potential prisoner-subject.

Similar to the Nuremberg Code and the Declaration of Helsinki, the Belmont Report recognizes the ethical responsibility to “…recognize the longer term benefits and risks that may result from the improve-ment of knowledge and from the development of novel medical, psychotherapeutic, and social procedures” (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979, p. 5). Moreover, the Report acknowledges that the fruits of research may not directly benefit the particular research subjects but rather a group to which they belong — nonetheless the research might be considered ethical. Applying this to research on prisoners with serious mental illness, it may be justifiable to include a subject in a treatment-as-usual as opposed to an experimental group because the information attained could reasonably be expected to benefit the subject or the subjects’ group in the future. This example is most clearly informed by the principle of Justice.

The Belmont Report influenced the Federal Policy for the Protection of Human Subjects which is the current standard in the US for guiding ethical research. The Policy was first published in 1991 and was last revised in January 2009. Subpart A of the Policy is widely known as the “Common Rule,” as it has been adopted by 15 Federal departments and agencies. The Common Rule provides general guidelines for research on human subjects. Here, we focus on Subpart C, which deals specifically with research including prisoners as a special population.

The regulations contained in Subpart C, “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects,” apply to all research under the jurisdiction of the Department of Health and Human Services (HHS) involving prisoners as subjects. A prisoner is defined as “…any individual involuntarily confined or detained in a penal institution” (Protection of Human Subjects, 2009, p. 11). The Subpart specifies additional requirements for the composition of review boards, additional duties of review boards and restrictions on the types of studies that can be conducted, as well as processes involved with receiving permission to proceed with protocol. As an unintended consequence of these protections, conducting needed research involving prisoners became exceedingly difficult.

5. Institute of Medicine (IOM) proposal

In 2006, the Institute of Medicine (IOM) produced a report commissioned by HHS for the purpose of informing updates to 45 C.F.R. Part 46, Subpart C (Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research, 2007). While the IOM committee that produced the “Ethical Considerations for Research Involving Prisoners” report acknowledges that research with prisoners may be required to improve the particularly poor health profile of this population, they nonetheless recommend additional regulation of such research. The five recommendations contained in the report are in brief:

1. expand the definition of “prisoner”
2. ensure universal, consistent ethical protection
3. shift from a category-based to a risk–benefit approach to research review
4. update the ethical framework to include collaborative responsibility
5. enhance systematic oversight of research with prisoners.

The committee’s first recommendation is to expand protections to individuals whose liberties are restricted by being on parole or probation in the community. As mentioned above, the current definition of “prisoner” includes only the institutionalized. The second recommendation is to ensure oversight for all prisoner research, as opposed to only that conducted under the jurisdiction of HHS, the Central Intelligence Agency and the Social Security Administration, as is the status quo. In addition, this recommendation calls for a “…publicly accessible national registry of research involving prisoners.” The third recommendation is to make a risk/benefit analysis a primary consideration in reviews. The report suggests that permissible research promises benefits directly to the participant. Potential benefits to the subject’s group would not be permissible. As the authors acknowledge, “Biomedical research in correctional settings would be severely limited” (Institute of Medicine Brief, 2006 pp. 2–3). “Collaborative responsibility” in the fourth recommendation refers to a requirement to involve all relevant stakeholders in all parts of the research process. The last recommendation is to update current Office for Human Research Protections (OHRP) regulations as suggested by the committee and make the regulations universal across all public and private institutions funding research involving prisoners. In our view, should these recommendations be adopted, needed research involving the health and healthcare of prisoners would become even more rare than is the case today.

6. Current status

Currently, we make use of many locally-developed interventions and use few evidence-based correctional mental health practices. There are, indeed, many impediments to actually doing so. Correctional settings are generally poorly funded, and are often driven to respond immediately to crises and to the demands of acute care. Furthermore, there often exists an environment that is rigid and change-averse. While advances in healthcare delivery are developing rapidly in community settings, little of this work has been tested or adapted for use in correctional settings. There are many distinct differences that exist in correctional settings that may render inappropriate or useless many of the practices developed in the community. These differences lie both in the setting as well as the populations served.
7. Organizational structure of prisons and research logistics

The challenges of conducting research in corrections have been well documented (e.g., Brewer-Smyth, 2008; Kalmbach & Lyons, 2003; Quina et al., 2007) and the need for developing a research infrastructure has been duly noted (Innes, 2003; Magaletta, Morgan, Reitzel, & Innes, 2007; Trestman, 2006a, 2006b, 2007; Wakai, Shelton, Trestman, & Kesten, 2009). The challenges that must be addressed to conduct research in a correctional setting are numerous but addressable. For example, just entering the facility typically requires permission from the commissioner and warden, safety training, a background check, clearing a metal detector, and two sources of official identification.

The timeline for completing a research project in a correctional environment will take months, if not years, longer than a comparable one conducted in a community setting (Trestman, 2006a, 2006b). The delays are due in large part to facility related constraints such as lock-downs, turnover of contact people, shift changes, lack of a private interview area, and escort status of visitors. Retaining research participants is always a concern for researchers but inmates have exceptionally high attrition rates due to a variety of factors (e.g. transfers, releases, court dates, administrative segregation, count time, commissary hours, work, school, therapeutic groups) which are often unexpected and unannounced.

The researcher must also consider the burden to the correctional system. Researchers put additional, although unintended, demands on Correctional Officers for escorting researchers, transporting inmates, and providing security. In addition, the importance of having a contact person who can act as a liaison on behalf of the researcher cannot be over-emphasized. It is wise to prepare for the fact that the challenges encountered in the system are on-going and a realistic part of conducting a research project. Researchers need to plan consent procedures, recruitment processes and data collection in ways that both minimize the burden on corrections staff and minimize subject movement. No two correctional facilities (or their policies) are exactly alike; that said, the early part of a study is spent in establishing realistic and appropriate protocols for recruitment, consent and data collection.

8. Recognition of diverse missions

The missions of academic researchers and corrections professionals are quite distinct, requiring initial conversations to establish common ground. Prisons are designed to incarcerate inmates, to control behavior, and to provide adequate basic care. It is important for academicians to recognize that “...from the perspective of the correctional staff, safety always comes first, treatment is second, and research a distant third (if even considered)” (Trestman, Candilis, Silberberg, & Temporini, 2005, p.11). In fact, DOC is perhaps the only major multi-billion dollar industry that spends far less than one percent of its resources on research and development (Magaletta et al., 2007). In contrast, academic health care comes from a more entrepreneurial perspective that stresses the importance of knowledge generation to improve care. Researchers also are usually in a protected position, able to write papers with objectivity without concern about how unfavorable outcomes may be used against them in potential litigation. Further, researchers have their own priorities that typically include generating grants, publishing results, meeting multiple deadlines, working with trainees, and so forth.

The challenges and divergent needs described above are real. How then to overcome these barriers that limit appropriate studies and implementation of evidence based practices that are potentially beneficial to inmates, correctional facilities, and correctional systems? An effective way to mitigate these challenges is to develop a partnership between researcher, custody, and clinicians and encourage each group to contribute their expertise to the research process. One exemplar of this approach is detailed elsewhere (Wakai et al., 2009).

9. Stakeholder discussion

The first, often-overlooked step is quite simply to identify and gather the key stakeholders. At a minimum, these individuals include those with: 1) responsibility at a system and policy level from the Department of Correction or equivalent; 2) operational responsibility; and 3) an interest in pursuing a research agenda. Different settings yield people with different titles. The process at this stage is fundamentally information sharing and the creation of a common language. Developing trust and mutual respect is the goal for this stage of the process. That said, it is a process and not an event: these conversations ideally evolve into an oversight or coordinating committee to ensure continued coordination and confidence. Membership in this group might logically include individuals with titles (and equivalent perspectives) such as a warden, an inmate advocate, an Institutional Review Board (IRB) representative, a Director of Quality Improvement, a Director of Offender Programs and Health Care, and one or more researchers.

10. Experienced research collaborators

Most researchers historically did not start out with a focus on correctional mental health. The expertise these individuals bring to the table is in the safe, ethical and successful conduct of research in the community. Correctional professionals bring a range of skills and a depth of knowledge about the unique challenges of the correctional environment to the table. Through thoughtful collaboration, a research agenda can be articulated, projects developed, external funding sought, the study implemented, and results examined. Such results have the potential to shape the standard of care, inform improved policies, and become knowledge that can advance the field nationally. An issue that clearly needs to be discussed at this stage is data ownership and autonomy. Most Departments of Correction are very politically sensitive and hold tightly to final authority to review any potential publication or presentation before submission. Defining and developing a clear understanding of these policies will reduce the risk of unfortunate subsequent misunderstandings. It is a reasonable expectation that as more research is conducted, the more open the system becomes, that the risk of the research findings being used in an adversarial way to support potential litigation decreases. The shift becomes one of simple respect, responsible behavior and courtesy: collaborators agree on paper/presentation submissions in advance.

11. Define opportunities and interests that support the institution’s mission

While seemingly obvious, this stage is, in practice, often overlooked. Researchers may come with a narrow interest that may be of interest and value to external parties, but the local correctional system may not see it as important or timely. On the other hand, the DOC may have specific interests (for example, in a particular kind of program or intervention) that the researcher may not have skill, expertise, or interest in pursuing. The great opportunity for all stakeholders lies in defining areas of overlapping concern, interest, and skill. When such an area (or areas) is found, everyone is in a position to work collaboratively to overcome the inevitable impediments and obstacles.

12. Develop a relationship with the Institutional Review Board (IRB)

A critical component for the successful design and conduct of correctional research is understanding the guidelines in 45 CFR Part 46 Subpart C, and in working with the local IRB of cognizance to ensure that they too understand both their obligations and the range of authority allowed within the current regulations. The researcher should be very active in building a close working relationship with the IRB,
both with the Administrator and the Chair. The successful researcher will invest the time to become very familiar with the IRB process and protocols, be available to answer questions and review the proposal in advance of the IRB meeting, and if appropriate, be available to answer further questions at the meeting. This process takes time; it is advisable to anticipate that the first few proposals reviewed by the IRB will likely require revision and resubmission until all parties become skilled in the process.

13. First conduct a small study

Start small. Start simple. It is important for the group of collaborators to experience a successful study and work out any issues in the process before being challenged with a major initiative. The first study might be one that requires no external funding and might indeed be a quality improvement initiative. In structuring it this way, research can be seen as valuable to the system and have tangible benefits.

It is also very important to recognize that communication at all stages is critical to continued support and success. Discuss the project with staff in the facility. Be available to problem solve and answer questions. Schedule a time to provide feedback to the staff that enabled the study to take place. Share the information more broadly in the system to demonstrate the potential benefits of the process. If possible, publish even these results, and be sure to include as many correctional staff and administrators as possible as meaningful contributors to the paper with co-authorship.

14. Types of studies

As with mental health research in the community, a full spectrum of studies may be considered in correctional settings. The issues for consideration are feasibility, compliance with the federal regulations, and the benefits to the participants and the system. The categories of this research span preclinical, clinical, translational, and public health domains.

14.1. Preclinical research

Issues regarding diagnostic typologies, population subtyping, and underlying factors to criminal offender behavior all are included in this category. Questions specifically involving genetics, neurophysiology, and neuroimaging need to be framed in a way to assure they meet one of the 45 CFR Part 46 Subpart C categories, and do not expose inmate subjects to the potential of legal risks.

Psychiatric genetics and biomarker research are rapidly expanding. There are many potential questions of relevance to the correctional population. One obvious area of interest is that of factors contributing to a predisposition to impulsivity and violence (Moffitt, 2005). The moral and ethical appropriateness of conducting such research on incarcerated populations, however, has yet to be addressed. Similarly, neurophysiologic studies of brainstem evoked potentials, startle reflex, and response latencies associated with impulsivity are of interest (Kiehl, Hare, McDonald, & Brink, 1999; Lorenz & Newman, 2002; Newman, Kosson, & Patterson, 1992; Sutton, Vitale, & Newman, 2002). Logically, a population of individuals incarcerated for crimes of impulsive violence would be a very appropriate group to examine. Neuroimaging, both structural and functional, is yielding substantial data giving us insight into an array of disorders where the prevalence is elevated in correctional settings. For example, if findings of reduced prefrontal gray matter in criminal psychopaths (Gregory, Ffytche, Simmons, et al., 2012; Yang et al., 2005) are replicated, psychotherapeutic interventions that compensate for information processing inadequacies may be developed. Noninvasive techniques such as functional magnetic resonance imagery, activity of the brain at rest and in response to stimulation, are now open to examination in explicit detail (Birbaumer et al., 2005). Distinguishing relevant neurophysiologic and structural characteristics between subgroups of mentally ill offenders and comparison populations may guide development of improved therapeutic interventions.

A real concern, noted above, is the potential misuse of such information. Despite federal Certificates of Confidentiality, confidentiality may still be breached and this type of data be used in court. Of course, that is a concern in any research study. Deidentifying the data is a standard and effective method of protecting the research participant from exposure to consequences of research participation. Further, reflecting the intent of the federal guidelines is the potential to conduct the study on populations in the community; for example, study participants might be offenders who are no longer under correctional supervision, parole or probation. If that is possible, community-based studies might arguably be preferable in many situations where incarceration per se is not a critical factor.

14.2. Clinical research

The category of relevant clinical research includes studies of epidemiology, assessment tools, factors relevant to suicide risk and risk management, psychotherapeutic interventions, pharmacology, and transition to the community. While a body of literature is now evolving, much is yet to be done. Multiple studies have been conducted over the last 15 years examining the psychiatric epidemiology of incarcerated populations. From these studies, it is clear that disproportionate numbers of individuals with mental illness and substance abuse are incarcerated (Abram, Teplin, & McClelland, 2003; Teplin, 1994; Trestman, 2007). However, given the changing characteristics of offender populations over time and the unique distinctions among jurisdictions, this category of study requires ongoing refinement and replication.

Clinicians are well aware that assessment of mental illness is a challenge and ongoing concern in the community. In correctional settings, the challenges and the situational demands vary substantially. Decades of research have helped develop, test and validate the psychometric properties of assessment tools in community settings. Little exists, however, to document the reliability and validity of such instruments in correctional settings. The issues relate both to initial triage screening and subsequent more extensive diagnostic and needs assessments. Where the diagnoses have been well established in the community and such records are accessible, some of these concerns are diminished. In practice, though, such a situation is unusual if not rare. Clinicians in the jail or prison intake setting are often confronted with an inmate and without access to past records. While this is obviously problematic, it also creates some opportunities for diagnostic clarification as well. The needs for appropriately validated initial screening tools in jail and prison settings are only recently being addressed (Ford, Trestman, Wiesbrock, & Zhang, 2007; Steadman, Scott, Osher, Agnese, & Robbins, 2005).

An inmate may present with claims of community-diagnosed illness and offer pharmacy-verified prescriptions as proof. One common diagnostic example in recent years is bipolar disorder. In fact, co-occurring substance abuse may have been the unrecognized or hidden factor behind the symptomatic presentation. Incarceration may provide a drug-limited environment to clarify these issues. In one study, fully 33% of individuals who present with Bipolar Disorder diagnoses are actually suffering with a substance induced mood disorder (Kamath et al., 2011). It is an important point to note that the context of incarceration provides a rare opportunity to monitor and observe behavioral changes over time objectively in an environment with limited access to substances of abuse.

With regard to more formal diagnostic tools, while intermittent use of the Mini International Neuropsychiatric Interview (MINI) and the Structured Clinical Interview for Diagnosing DSM-IV Disorders (SCID) may occur in selected correctional settings (e.g., Black, Arndt,
Hale, & Rogerson, 2004), neither has actually been standardized for use in these environments as of yet. Quite reasonably, consistent with developments in the community, psychometric standardization would yield more reliable and valid information.

Suicide risk assessment, self injurious behavior, and risk reduction are areas that have received a fair degree of attention in descriptive assessment (e.g., Appelbaum, Savageau, Trestman, Metzner, & Baillargeon, 2011; Blaauw, Kerkhof, & Hayes, 2005) and practical intervention (Pompili et al., 2009) in correctional settings, but limited if any rigorous research studies have been conducted in this critical area.

Psychotherapy efficacy and effectiveness research has been a focus in the community setting for over 20 years. While some work has been conducted on substance abuse therapies in correctional settings (Belenko & Peugh, 2005), very limited work on psychotherapy has been conducted in jail and prison settings (Black et al., 2008; Sampl, Wakai, & Trestman, 2010; Shelton, Kesten, Zhang, & Trestman, 2011). Indeed, the vast majority of work has been limited to program evaluation. Even more limited is the work conducted on those with co-occurring mental illness and chemical dependence (Zlotnick, Najavits, Rohensten, & Johnson, 2003). Treatment of impulsivity in general, impulsive aggression, emotional instability, conflict resolution, suspiciousness and paranoia are all relevant to successfully cope with incarceration, and subsequently to succeed at community reintegration. Studies tend to suggest that fully 70% of mentally ill offenders re-offend after community reentry (Lovell, Gagliardi, & Peterson, 2002); enhancement of coping and interpersonal skills while incarcerated would reasonably benefit in improved community transition (Kesten et al., 2012). Given the high prevalence and problematic management of prisoners with severe personality disorders (Trestman, 2000; Trestman, 2007), this is a topic of high potential impact. It should be noted, however, that randomized controlled trials of psychotherapy with incarcerated populations may not use placebo comparators; waiting list controls or no therapy options are expressly forbidden by OHRP guidelines. This creates the need to conduct comparative effectiveness studies where inmates are randomized to two potentially effective therapies, substantially expanding the sample size required to achieve an adequate effect size and interpretable result.

As previously noted, up to 85% of American clinical pharmacologic research was conducted on inmates in the 1960s and early 1970s (Hornblum, 1997). Since then, the shift to community-based research has occurred in the context of a dramatic expansion in the number and efficacy of psychopharmacologic agents available. While the efficacy of these medications has been studied in community populations, virtually none has been examined for efficacy, let alone effectiveness, in correctional settings and populations. In a review of clinical trials conducted in correctional settings over the past 30 years (Trestman & Macura, 2002), only 8 such trials were found. Subsequent studies have generally been focused on addiction-related disorders (e.g., Gordon, Kinlock, Schwartz, & O’Grady, 2008; Springer, Chen, & Altice, 2010). While small studies have been conducted (e.g., Kamath et al., 2011), these are still exceedingly few and limited in scope. Under Subpart C regulations, efficacy studies are not prohibited, but must meet the following criteria in addition to the normal requirements of clinical research: 1) FDA approved indications only may be studied; 2) no placebos at all; and 3) the comparator arm must be active (and an accepted treatment). It should be noted that these regulations technically apply only to funding agencies under the DHH – notably Food and Drug Administration and the National Institutes of Health. Nevertheless, most funding agencies, foundations and IRBs adhere to these standards uniformly.

14.3. Translational research

A need that has become evident over the past decade is the translation of efficacy studies conducted using carefully chosen subjects and a rigorous protocol to the real world of more complex diagnostic conditions, co-occurring disorders, and difficulties with adherence to the protocol. Bringing such clinical advances to the practical world of clinical care is typically called “translational” research. In practice, it is challenging enough to do this work in community-based offices or hospitals, let alone to do so in jails and prisons. Furthermore, simply because something has been found to work in the community does not assure that the intervention will be successful in the correctional setting. It is in this context that studies of psychotherapy and psychopharmacology are very much needed (Trestman & Macura, 2002). Adapting evidence based practice developed in the community for use in correctional settings is a priority in order to meet the needs of the incarcerated mentally ill. The opportunities herein are broad, and include such topics as: objective measurement of symptom severity and functional capacity at baseline and throughout treatment; basing treatment decisions on best or evidence-based protocols; modifying treatment for an individual on the basis of consistent, reliable and valid data; and changing population treatment on the basis of overall group outcomes. One pragmatic approach to doing this work in correctional settings may be to leverage pre-existing Quality Assurance or Quality Improvement committees or initiatives. When such efforts are framed in ways that are comfortable to participating clinicians, engagement and support more easily follow.

14.4. Policy, economics, and public health

Incarceration of those with serious mental illness is a profoundly significant issue in the United States. When over 700,000 offenders with serious mental illness are incarcerated, substantial social, economic, and public health problems emerge (Restum, 2005). What are the appropriate parameters to examine? What is the impact on the families of the seriously mentally ill and on the reintegration of these offenders into the community upon release (Pogorzelski, Wolff, Pan, & Blitz, 2005)? What are the economic consequences: direct and indirect costs, impacts in terms of productivity and quality of life years?

15. Summary

The history of research abuse in prison settings in the first half of the 20th century led to the near elimination of research in the latter third. In parallel with a dramatic growth of the incarcerated population in general, and the mentally ill in particular, this situation has created a landscape where we do not know nearly enough about the population of incarcerated mentally ill people. Guidelines exist to allow for meaningful research at all levels, and the expertise and interest in making use of these opportunities are growing. There are certainly many political, operational, and financial challenges to conducting research in correctional settings with and for the mentally ill. By embracing this opportunity, we are in a position to transform correctional mental health care into what may become a beacon of quality in public health and public healthcare delivery.

References


