Methodological factors conducting research with incarcerated persons with diabetes

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Objective: The aim of this study was to describe methodological issues specific to conducting research with incarcerated vulnerable populations who have diabetes.

Background: Much has been written about the ethical and logistical challenges of conducting research with vulnerable incarcerated populations. However, conducting research with incarcerated persons with diabetes is associated with additional issues related to research design, measurement, sampling and recruitment, and data collection procedures.

Method: A cross-sectional study examining the relationships of diabetes knowledge, illness representation and self-care behaviors with glycemic control in 124 incarcerated persons was conducted and serves as the basis for describing methodological factors for the conduct of research with an incarcerated population with diabetes.

Results: Within this incarcerated population with diabetes, sampling bias due to gender inequity, recruitment of participants not using insulin, self-reported vision impairment, and a lack of standardized instruments especially for measuring diabetes self-care were methodological challenges. Clinical factors that serve as potential barriers for study conduct were identified as risk for hypoglycemia due to insulin timing and other activities.

Conclusion: Conducting research with incarcerated persons diagnosed with diabetes requires attention to a set of methodological concerns above and beyond that of the ethical and legal regulations for protecting the rights of this vulnerable population. To increase opportunities for conducting rigorous as well as facility- and patient-friendly research, researchers need to blend their knowledge of diabetes with an understanding of prison rules and routines.

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1. Background

Incarcerated persons have a high burden of chronic illness, frequently experiencing multiple coexisting physical and mental health illnesses (Binswanger et al., 2012; Wang & Green, 2010; Wilper et al., 2009). Diabetes is one chronic illness that occurs in the prison population at similar prevalence to those living in the community (Binswanger, Krueger, & Steiner, 2009; Wilper et al., 2009). The American Diabetes Association (ADA; 2013) reports an estimated cost of diabetes mellitus nationally accepted guidelines of the American Diabetes Association (ADA, 2014b; NCCHC, 2014). However, there is very little research that examines diabetes-related health outcomes in this population or incarcerated patient characteristics that could affect glycemic control or the development of effective diabetes education programming. The lack of diabetes research involving incarcerated persons is in stark contrast to the abundant diabetes research conducted with community-dwelling adults.

Designed to help improve chronic disease health care outcomes, the National Commission on Correctional Health Care (NCCHC) has developed diabetes-specific disease management guidelines from nationally accepted guidelines of the American Diabetes Association (ADA, 2014b; NCCHC, 2014). However, there is very little research that examines diabetes-related health outcomes in this population or incarcerated patient characteristics that could affect glycemic control or the development of effective diabetes education programming. The lack of diabetes research involving incarcerated persons is in stark contrast to the abundant diabetes research conducted with community-dwelling adults.

The dearth of research in this area is likely the result of the general ethical and logistic challenges of conducting research with prisoners who are recognized as a vulnerable population. Challenges for conducting research with this population have been identified and discussed in the literature at length (Amory Carr, Amrhein, & Dery, 2011; Cislo & Trestman, 2013). Major challenges include ongoing stringent regulations for protection of prisoners and the conflicting agendas of corrections staff and academic researchers. The department of corrections staff focus on custody and security aspects of incarcerated patient care while researchers seek to conduct research to improve health outcomes and healthcare services (Cislo & Trestman, 2013).

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In addition to the issues and restrictions previously described, conducting research with incarcerated persons who have diabetes presents a different set of challenges for the research design, measurement, sampling and recruitment, and data collection procedures. These challenges were identified while conducting research to examine the relationships of illness representation, diabetes knowledge, and self-care behavior (SCB) with glycemic control in incarcerated persons with diabetes (Reagan, 2014). This research serves as the basis for describing methodological factors for the conduct of research with an incarcerated population with diabetes. Modifications aimed at reducing the challenges for conducting research with this vulnerable population are proposed.

2. Overview of the research study

Using a cross-sectional design, 124 incarcerated persons with diabetes were surveyed regarding diabetes knowledge, illness representation, and SCB. Measures included the Spoken Knowledge in Low Literacy in Diabetes Scale [SKILLD] for diabetes knowledge (Rothman et al., 2005), Brief Illness Perception Questionnaire [BIPQ] for illness representation (Broadbent, Petrie, Main, & Weinman, 2006) and the Self-Care Inventory Revised [SCI-R] for SCB (La Greca, 2004; Weinger, Butler, Welch, & La Greca, 2005). The ability of summary scores and items from these instruments to predict glycemic control (A1C) was evaluated using linear regression analyses. Covariates in these analyses included age, gender, education, incarceration length, health literacy, insulin use, medication count, and illness duration. A hybrid backward and forward variable selection strategy was used to identify a parsimonious multivariable model. Logarithmic transformation of A1C accounted for heteroscedasticity. Participants (12.9% type 1 diabetes; 85% using insulin; 93.5% male; 40% Black; 37% White; 23% Latino; 77% high school education or less; mean age 47.3 years) had a mean hemoglobin A1C (A1C) of 8.2% (SD ± 1.96). The final regression model was statistically significant (F = 124, p = 0.001, R² = 19.2%). Higher log10 A1C was associated with lower personal control beliefs (B = −0.007, t = −2.42, p < 0.05), higher self-report of diabetes understanding (B = 0.009, t = 3.12, p < 0.05) and using on insulin (B = 0.06, t = 2.45, p < 0.05). Metabolic control was suboptimal for incarcerated participants in this study.

3. Methodological issues

3.1. Research design challenges

Variations in diabetes-related policies from institution to institution and national to international prison systems could make designing randomized control trials (RCTs) with adequate sample size problematic. RCTs are considered the gold standard for evaluating programs (National Institute Justice [NIJ], 2014) but very few have been conducted in the criminal justice system (CJS). Currently, the NIJ (2014) is challenging researchers to develop timely and effective RCTs that address relevant questions or problems in the CJS.

In the current study, a cross-sectional design was used. The policies for self-care behavior and the use of a blood glucose meter in the system studied were the same across all facilities. The care process utilized did not provide incarcerated patients with access to a blood glucose meter in their cell; they waited in line to self-check their blood glucose at prescheduled times in the presence of correctional nurses and had their insulin administered by correctional nurses. However, some participants were allowed to keep oral medications in their cell (KOP—keep on person), thus allowing some engagement in the SCB of medication taking. These policies were not problematic for the cross-sectional design of the current study. However researchers would need to consider the variation in procedures across patients if testing an intervention using an experimental or RCT design. For example, researchers examining the effects of an intervention on medication adherence should anticipate the need for a larger sample size or the use of a more complex study design to account for variations in medication administration. A second design challenge lies in finding comparator groups for use in translational or patient-centered outcome research related to self-care management. Numerous research reviews such as Cochrane and systematic reviews draw on findings of completed research to compare the effectiveness of varied interventions for self-care management in community-dwelling persons with diabetes. However, findings from these reviews are not directly transferrable to the closed system environment of the prison. Cislo and Trestman (2013) cite the value of conducting a small pilot study first and working closely with the Department of Corrections (DOC) and other key stakeholders at every step of the way.

Another factor to consider when designing research with this population is the frequent movement or transfer of incarcerated persons between facilities for population management or release (Cislo & Trestman, 2013). Depending on the research design, facility transfer or release of research participants can impact multiple points in the research process. In this case example, four participants required the use of an interpreter to assist the researcher administer the Short Assessment of Health Literacy for Spanish Adults [SAHLSA-50] which was used to evaluate health literacy for Spanish reading participants (Lee, Bender, Ruiz, & Cho, 2006). When Spanish-reading participants were enrolled, a certified translator needed to be present to administer the SAHLSA. None of the four participants were released from prison system during the study period, but two were transferred between facilities. Frequent communication with the DOC administration was necessary to obtain help in locating these two participants.

Additionally, as a result of the frequent movement of incarcerated patients, studies with longitudinal or repeated measure designs can be difficult in this environment or, at a minimum, increase the costs of conducting the research. Such movement in an experimental or RCT could affect important variables of interest. The issue of frequent movement of potential participants can also present challenges for attrition and the length of time to complete the research, often taking months to years longer to complete a study (Cislo & Trestman, 2013; Trestman, 2006). These factors all need to be addressed when designing research proposals, and protocols.

3.2. Measurement challenges

Most instruments used for conducting diabetes behavioral research in the community have not been tested in prison populations. For this study, instruments that had face validity for, or characteristics relevant to the incarcerated population were used. However, there were still issues with lower than recommended levels of internal consistency. All survey instruments with the exception of the Rapid Estimate of Adult Literacy in Medicine [REALM] (Davis et al., 1993), a health literacy measurement, were verbally administered to the incarcerated participants because of the anticipated low literacy (Carson & Sabol, 2012). Only the SKILLD, designed for persons with low literacy, has been tested and used in prior research as a verbally administered survey for a community dwelling sample (Rothman et al., 2005).

Self-care behaviors (SCB) were measured for the current study. Although an important construct for diabetes behavioral research (AADE, 2014), instruments designed to measure SCB in research with community-dwelling adults do not translate well for measurement of self-care in the prison. As previously mentioned, all participants in this study, being from one correctional system, followed uniform policies related to blood glucose monitoring and insulin administration. However, personal factors such as low socioeconomic status influenced whether incarcerated patients had the potential to perform certain SCBs included on the Self-Care Inventory Revised Instrument (Weinger et al., 2005).

For example, in the current study, one of the SCBs examined was whether the incarcerated patient was reading food labels. This item was rated on a five-point Likert scale with “0” being never reads food labels and “5” being always reads food labels. In the prison, some patients with the financial means have the opportunity to purchase commissary foods. These individuals may be reading food labels at the commissary,
However, there are no easily available options to read food labels for the foods provided at scheduled mealtimes. Incarcerated persons without access to commissary food will not have opportunities for reading food labels.

To illustrate this point, consider two participants in this study who responded “never” to the SCI-R item asking about frequency of checking food labels. These two participants had no money to purchase commissary food, making performance of that SCB not within their power. Understanding the meaning behind the “never” response is important if the researcher is examining the effect of an intervention on diabetes self-care behavior such as frequency of reading food labels. It calls into question the validity of using such measures given that incarcerated persons have limited or no access to purchasing food options.

Measuring diabetes SCB in prison requires that the researcher have an understanding of factors, even if non-modifiable, that influence the performance of SCB beyond the effects of an intervention or a participant’s motivation and self-efficacy for self-care. Socioeconomic status, still a disparity in the prison, can be an influencing and constraining factor for the performance of some SCBs (Secrest et al., 2011).

When selecting instruments and variables, personal factors affecting self-care need to be explored, accounted for, and modifications made when possible. Research modifications include: reading the instruments to participants and pilot testing this process; incorporating participatory processes with incarcerated persons; and having knowledge of prison life so that additional questions can be asked, such as “Do you have access to the commissary?” Additionally, asking participants about their job in prison would be important. For example, individuals working in the kitchen or in a community garden may have access to extra meal trays or other nutritional food. These factors may alter nutritional intake and confound results. Controlling methodologically or statistically for these factors will improve research rigor.

These examples illustrate the hidden challenges of conducting research within a closed yet not entirely controlled system. Factors including low literacy and/or low health literacy, limited English proficiency (LEP), ethnic diversity, and constraints to SCB, all within the realm of possibility in this environment, require that instruments be pilot tested and that data from participatory processes with incarcerated persons such as focus groups be used when developing instruments for future research.

### 3.3. Recruitment and sampling challenges

In the current study, recruiting incarcerated persons with type 2 diabetes (T2d) not on insulin was challenging. Eighty-five percent of the participants surveyed were using insulin therapy. Incarcerated persons using insulin came to a medication line to check their blood glucose and receive their insulin once or twice a day; those not using insulin could have keep on person (KOP) medications in their cell. Incarcerated patients not using insulin might come to the medication line once a day to check their blood sugar or might have it checked at less frequent intervals. Those who came to the Medline had an opportunity to pick up recruitment flyers available at Medline or in the clinic. There were also opportunities for incarcerated patients to speak with a researcher at the chronic care clinic to ask questions about the study. Incarcerated persons who did not come to the Medline or the clinic on a regular basis may have seen flyers posted in the medical clinic or housing units as opposed to picking up the flyer and taking it back to their cell. The variation in exposure to the recruitment flyer at the Medline and in the clinic may have been one of the reasons for the low number of participants in this study who were not using insulin.

Further exploration of the reasons for a low number of participants in this study who were not using insulin is needed. Research modifications include: arrange for in-person information session about the study at varied times and locations; if identification of incarcerated persons with diabetes not using insulin is possible via an electronic records or another database, send a letter to all incarcerated persons with diabetes informing them of the study; specify in the recruitment flyer that persons with diabetes not using insulin are welcome to participate.

### 3.4. Data collection challenges

In the current study, all participants had diabetes and 66% (82) of 124 participants had hypertension. In 2005–2008, the **Centers for Disease Control and Prevention** [CDC] (2011) reported that 4.2 million (28.5%) persons with diabetes 40 and older had diabetic retinopathy. Hypertension is an independent predictor of retinopathy (Klein, Myers, Lee, & Klein, 2010). Recent evidence suggests that hypertension and diabetes have synergistic effects on retinal microvasculature resulting in endothelia dysfunction and retinal microvascular changes (Mohamed et al., 2012). Additionally, glaucoma and ocular trauma have been found to be more prevalent among incarcerated patient and oftentimes in the case of ocular trauma more severe than in non-incarcerated patients (Trivedi, Wu, Leffler, & Schwartz, 2003).

Given these facts, it was not surprising that many of the participants in this study reported having vision impairment or an eye problem. For the current study, the researcher used large font print for the recruitment flyer and the REALM health literacy instrument. Many of the participants commented on their preference for the larger font. However, large font was not used for the informed consent document and initially incarcerated patients were not reminded to bring their glasses to the study meeting. As a result, two participants had to retrieve glasses from their cells in order to read the informed consent. On one occasion, the researcher had to come back on another day to meet a participant who did not have his glasses at the time of the initial meeting and was not able to come back on the same day due a scheduled period of restricted movement within the prison.

Based upon the scientific evidence for diabetes and hypertension associated vision impairment and observations from this study, we suggest modifications to account for anticipated vision impairment in this population. Research modifications include providing instructions to incarcerated participants especially those with diabetes or hypertension to bring their glasses for the consent process and other research-related procedures and providing large print documents to participants.

### 3.5. Communication challenges

The potential for issues with communication exists from inception of the research question to the dissemination of results of research conducted with incarcerated persons. A great deal has been said in the literature about the effect of the research on the general operations and flow of the correctional facilities and strategies for enhancing communication have been identified (Cislo & Trestman, 2013). However, an important area for improving communication when conducting research with incarcerated persons with diabetes is in regard to the prevention of adverse outcomes associated with the occurrence of hypoglycemia. Most researchers working with participants who have diabetes are well aware of the potential for hypoglycemia, but there are some additional considerations for working with incarcerated participants using insulin.

In this study, 60% of 124 participants surveyed responded that they “rarely” or “never” carried a fast-acting sugar to counteract the effects of hypoglycemia. Forty percent (n = 49) of the participants could not correctly identify the signs and symptoms of hypoglycemia. If the interview or study procedures were conducted at a time when the participant could not return to his or her cell, they would need to sit in the waiting area until the movement restriction was lifted. With these cases, researchers must be aware of the appropriate chain of command to advocate on behalf of that participant to assure their health needs are addressed. And if the participant was not carrying a fast acting sugar to counteract the effects of hypoglycemia, this information would need to be communicated.

During this study, there were occasions when participants were sent for the interview at potentially high risk times for hypoglycemia, such as before meals, after insulin administration or after recreation. It is important to ask the participant if the study interview was going to interrupt meal time or medication administration. For the current study, on one
occasion, the researcher sent the potential participant to dinner rather than initiating study procedures. Only once did the researcher need to notify a nurse that the participant was reporting symptoms of hypoglycemia.

Last, calling ahead or having a contact within the system to call you is important for the researcher’s time management. During this study, a nursing supervisor, identified as the researcher’s contact, called twice with notification of a lockdown and advised the researcher not to come to the facility. Notification of lockdowns was important to the researcher because this research was conducted in five facilities across the state requiring more than a 50 minute commute each way.

To summarize, research modifications to consider include: timing of research activities to avoid interrupting the usual insulin administration and meal schedule; calling the facility prior to traveling or establishing a call notification with an onsite contact obtaining approval for and providing refreshments that support diabetic health. The latter modification could be problematic if it was viewed as an incentive and would need to be approved by the IRB and the DOC.

4. Discussion

Conducting research with incarcerated persons with diabetes requires attention to a set of safety and methodological concerns above and beyond the ethical and legal regulations for protecting the rights of this vulnerable population. Researchers must consider the needs of these individuals, both pathophysiology and the effects of the prison structure. Researchers designing these studies need to blend their knowledge of diabetes with an understanding of prison culture and the rules. Researchers unfamiliar with the correctional setting or external to the system must consult and collaborate on all levels including with administration, correctional officers, nursing staff and incarcerated persons.

Policies and procedures that could affect the recruitment of an adequate sample, safety issues related to hypoglycemia, and infringement on incarcerated person’s already limited time out of the cell need to be factored in when developing the research proposal. In addition to the researchers’ responsibility for ensuring the safety of individuals with diabetes during the research process, organizational policies supporting the use of KOP medications or fast-acting sugar by incarcerated patients to counteract hypoglycemia and the provision of guidelines for correctional staff working with these individuals should be reinforced. Key elements of policies and guidelines serving to identify who should have KOP medications should address the assessment of inmates’ health literacy and literacy, identification of Limited English Proficient (LEP) inmates, and how knowledge including skill performance were evaluated. Additionally, procedures for integrating custody staff concerns and reports of the inmates’ prison behavior e.g. discipline and violence issues into this assessment and processes for determining candidates for having KOP medications and other self-care responsibilities should be thoroughly outlined. Pilot testing these targeted multidisciplinary assessments prior to implementation will ensure that the concerns and expertise of custody (safety) personnel, and nursing and medical professionals are included in the decision making process.

Furthermore, incarcerated persons should have the opportunity to be involved in the research process especially when designing interventions and developing instruments. In a maximum security prison in England, Cowburn and Lavis (2013) described the use of a participatory research approach to explore the experiences of prisoners in diverse minority groups and the prison strategies for meeting the needs of this group. They used “reciprocal collaboration” (Gottesdiener, 2002), an approach that gives participants the opportunity to form and contribute ideas and solutions to identified problems. Although engaging incarcerated persons in this manner may seem counterintuitive, this type of research has the potential to not only improve care and buy-in for policy or care delivery changes but also to enhance individual problem solving and communication skills. Enhancing these skills is especially important for diabetes self-management and has been the focus of much research with community-dwelling individual with diabetes. It is possible that diabetes or chronic illness research or quality improvement initiatives using participative processes are occurring in various local and state departments of corrections organizations. However, if this is the case, it is not apparent in the literature. Publishing or sharing the experiences of using these approaches should be required on an international and national level.

It is critical that funding agencies be made aware of these issues and plans for managing these issues when conducting research with incarcerated persons and in a prison setting. Providing feedback to funding agencies about these issues at the onset of the research and ongoing throughout the project will give funding agencies an opportunity to adjust timelines for research completion. As noted in this study and others, the problem with recruiting female participants requires innovative and likely lengthy recruitment and oversampling procedures.

5. Conclusion

Research with incarcerated persons who have diabetes is especially challenging. Research conducted in this area is needed for all aspects of the incarceration experience from entering the prison through re-entry and reintegration to the community. Although research, especially experimental and RCT, is desperately needed to improve diabetes-related outcomes and self-care behavior for this vulnerable population, researchers must conduct rigorous and well-thought-out research with respect to the needs of all parties involved. Having an understanding of what the issues are and making modifications increase the opportunities for conducting rigorous as well as facility and incarcerated patient friendly research.

References


