

Informed Consent with Homeless Patients

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Phoenix in partial fulfillment of the requirements for the
Degree of Doctor of Medicine

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Dedication:

This work is dedicated Dr. Adele O'Sullivan and the Healthcare for the Homeless Clinics across the country. We are forever grateful to the wonderful, loving, compassionate care you provide.

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Abstract:

Access to healthcare for homeless persons is a significant problem within the United States. However, as barriers are lessened through federally funded or philanthropic organizations, attention must be paid to ensuring quality healthcare. The homeless population has disproportionately high rates of substance abuse, mental health disorders, and traumatic brain injuries. This places these patients at greater risk for lacking capacity to consent. This study was designed to examine the informed consent practices of healthcare practitioners in the primary care setting of clinics having received the federal Healthcare for the Homeless grant. Due to the poor response rate, no data of statistical significance were obtained and the study was treated as a pilot study. Patient demographics closely mirrored national statistics of homelessness excepting ethnicity. Likewise, patients seen in these clinics experience high rates of substance abuse and mental health disease. Providers reported only low rates of traumatic brain injuries in their population, contrary to national statistics demonstrating high rates of this disorder. Despite the high prevalence of risk factors for incapacity to consent, providers rarely questioned their patients' decisional capacity. Practices involving informed consent varied widely. Further studies need to be conducted to evaluate informed consent practices though it is apparent that studies of this nature may be impractical and unethical, if not impossible.

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Introduction:

Informed consent to treatment is the cornerstone of modern medicine. In American medical practice, the patient has an irrefutable right to self-determination if the proper criteria for informed consent have been met. Criteria include both ethical and legal constructs that continually evolve. Prior to the Nineteenth Century, simple assent was all that was required of physicians but failure to inform the patients of interventions would result in battery (Appelbaum and Grisso, 1995). By 1914, the Supreme Court decision given by Justice Cardozo in the case of Schloendorff v. Society of New York Hospitals stated “Every human being of adult years and sound mind has a right to determine what shall be done with his own body.” It was generally accepted that patients with mental illness were an exception and did not possess the necessary “sound mind” for self-determination. By the 1970s, American courts began to require formal hearing prior to determining incompetence in patients with mental illness. Without formal standards of decision making competence, courts lacked a valid and consistent means of determining a given person’s abilities. Today the legality of informed consent and the required faculties have become increasingly well-defined.

Ethics of Consent:

Informed consent to medical treatment is an individual’s authorization for medical intervention predicated on an honest exchange of information between patient and practitioner. It is a legal process that protects the physician from liability as well as the patient from undue harm. Failure to obtain legal consent can result in civil litigation and possibly criminal prosecution. Ethically, it protects patient autonomy and respects the patient’s right to self-determination. Valid informed consent requires disclosure of information, voluntariness in the decision making process, and patient capacity to consent (Moye, Gurrera, Karel, Edelstein, and O’Connell, 2006). It requires a conversation between physician and patient about the nature of the illness and treatment, possible risks and benefits, as well as alternatives including nontreatment (Whitney, McGuire, and McCullough, 2003). Many organizations and policy groups advocate the use of written consent documents. While this is legally advisable, it does not guarantee the sufficiency of the consent. The validity of the

consent depends on the nature of the interaction and conversation between the patient and practitioner (Worthington, 2002).

The relationship between patient and physician has shifted away from the historically accepted paternalistic approach. This model failed to include the patient in decision making and resulted in patient noncompliance and dissatisfaction with care and healthcare outcomes. It has been replaced by the modern “mutual participation model,” in which the patient and physician relationship is more egalitarian (Mead and Bower, 2007). It regards the patient’s preferences, experiences, and treatment goals as valuable and grants them the right to autonomous decision making, full disclosure of information, and respect. By fostering a more patient-centered approach, the patient-physician relationship can then take form as a therapeutic alliance. Research suggests that this allows patients and physicians to agree on treatment goals and improve the patient’s perception of the relevancy of a given intervention and thereby increase compliance and success. This process is referred to as “shared decision making” and has been implicated in improved health outcomes through patient empowerment (Woolf et al, 2005).

While this model is ethically sound, it is complicated by real-world challenges faced daily in physicians’ offices. Certainly, the exchange of information is central to shared decision making. However, what information must be disclosed? Physicians facing time constraints, limited reimbursement, and urgency for timely care are forced to decide which information is critical to discuss and which may be irrelevant, confusing, or result in unnecessary delays (Worthington, 2002). Physicians are expected to disclose information that would allow the patient to make an intelligent, reasoned choice (Merz and Fischhoff, 1990). Legal standards for disclosure vary by state. Some states maintain “The Professional Standard,” in which information given to the patient must be similar to information that would have been provided by a professional in similar circumstances and with similar training (Merz and Fischhoff, 1990). Other states have adopted the “Prudent Patient” standard, in which “the physician is bound to disclose only those risks which a reasonable man would consider material to his decision” (Merz and Fischhoff, 1990). Several states have gone so far as to codify what is required of informed consent disclosure. State legislation may include requirements for written consent outlining possible risks, probabilities of risks, and

witnesses. Though the “Professional Standard” may be all that is mandated in some states, the “Prudent Patient” standard is more closely aligned with the goals of informed consent: to provide the patient with needed information to make a decision that best meets the needs of that patient.

It is clear that each practitioner must be aware of their state requirements for informed consent and disclosure. However, much remains within the physician’s discretion, including determining the need for informed consent. In general, informed consent is required only when an intervention poses a significant risk (Whitney et al., 2003). Low risk decisions may require only simple consent, including explanation of the intervention, patient assent to treatment, and instructions for use. This is considered ethically and legally acceptable practice. However, high risk situations or situations where patient preference may play a key role require a more formalized informed consent process. It is up to the physician to determine the degree of risk and the level of consent required.

Respect for a patient’s autonomy lies at the heart of informed consent and the therapeutic alliance. As medical knowledge and treatment options expand, patients are increasingly faced with an expanded set of clinical options. The patients then face a more difficult task in weighing the risks and benefits of treatment. Because of this, the best choice may then depend more heavily on patient preferences (Woolf et al, 2005). Personal values, therapeutic goals, and economic considerations may each play a role in the decision making process. Taking this into account, a patient may choose a controversial course of action. An unpopular decision, such as one that seemingly places the patient at odds with a medical intervention, must be equally respected (Wong, Clare, Gunn and Holland, 1999). As such, a “lawful death” may result from a decision (Worthington, 2002).

Once information is properly disclosed and a choice is rendered, it is important to consider the next aspect of informed consent: voluntariness. Voluntarism is an ambiguous concept, difficult to quantify, infrequently litigated or considered in findings of competency (Roberts, 2002; Appelbaum and Grisso, 1995). It demands that the decision maker be free from coercion to choose based on personal values and beliefs. Roberts defines voluntarism as “ideally encompassing the individual’s ability to act in accordance with one’s authentic sense of what is good, right, and best in light of one’s

situation, values, and prior history” and “involves the capacity to make this choice freely in the absence of coercion” (2002, pg. 706). There are many factors that may influence the voluntariness of a patient’s choice. These include external factors such as financial considerations, cultural expectations, and family roles and dynamics. Patients who are homeless, imprisoned, or institutionalized have altered perceptions of voluntariness and freedom of choice and may have limited or impaired capacity for voluntary decision making (Roberts, 2002; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978). Intrinsic factors, such as cognitive abilities, developmental status, the severity of illness, and psychiatric symptoms may limit the patient’s ability to voluntarily choose.

Regardless of the nature and quality of information disclosure and the voluntariness of the patient’s decision, a decision rendered by a patient without the capacity to consent is irrelevant. Ethical and legal informed consent requires a capacious patient. It is felt that respecting the decision of a patient lacking the necessary decision making abilities violates the ethical principles of respect for persons, autonomy, and beneficence (Saks and Jeste, 2006). In the event this is not the case, a surrogate decision maker would be employed. This person may be a relative, friend, caregiver, or court appointed proxy. The surrogate is asked to make the decision using one of two potential models: the best interest model or the substituted judgment model (Wong et al., 1999).

Legal Standards of Capacity:

It is necessary to distinguish between a patient’s capacity to consent and competency to do so. Competency refers to a judicial ruling on a person’s decision making abilities and may refer to medical, legal, financial, or personal decisions. It can only be determined by judicial process. Capacity, however, is a clinical determination of a patient’s decision making skills and is both decision and situation dependent. Capacity is determined by the healthcare professional providing services to the patient. It is a simple “yes” or “no.” A patient either has capacity to consent to that decision or does not. While this may seem simple, it is a reflection of the patient’s decisional abilities at a given time and is likely to change in different situations.

Four legal standards of competence are generally accepted: the ability to express a choice, understanding, appreciation, and reasoning

(Appelbaum and Grisso, 1988). The first standard regards the patient's ability to communicate a choice regarding the decision at hand. A patient who is unable to clearly express a choice, either through medical or mental illness, is not deemed competent to consent. Consistency of that choice is also a component of this standard (Saks and Jeste, 2006). The patient must be able to consistently arrive at the same conclusion and express that choice clearly to others. The second standard is understanding. This addresses the patient's ability to comprehend relevant diagnostic and treatment information. The third legal standard is the ability to appreciate the situation and its consequences. This requires the patient to apply the information to their situation. Failure to apply the knowledge of a disease process or treatment option to oneself may signify a deficit in identifying reality, as would be seen in a delusional disorder, or may reflect cultural or personal non-delusional beliefs (Moye et al., 2006). The two scenarios must be identified separately as the first is evidence of incapacity while the second is not. The final standard is reasoning. The patient must be able to manipulate the information rationally within the context of their beliefs, values, and goals. It requires a logical processing of information but does not require that the clinician agree with the outcome. For example, the clinician may find it irrational for a patient to refuse life saving treatment, but this does not negate the refusal if the patient has logically come to the conclusion when considering personal values or goals (Appelbaum and Grisso, 1995).

Generally, all four standards must be met for a patient to have capacity to consent. While standards are at times related and may overlap, it is possible for some standards to be met while others are not. In this situation, the patient does not meet criteria necessary for capacity to consent.

Impact of Mental Health on Decisional Capacity:

Mental illness may impact capacity to consent through alterations in cognitive functioning, attention, mood, and memory. However, the diagnosis of mental illness does not definitively diagnose a lack of capacity to consent. The specific cognitive abilities impacted by mental illness or substance abuse vary according to diagnosis and within diagnostic groups. Cognitive impairments, if present, may not impact the four legal standards of capacity and the patient would remain capable of self-determination and informed consent. The

literature demonstrates that the majority of patients with mental health disorders retain capacity to consent despite their diagnosis. One study demonstrated that half of schizophrenic patients and greater than 75% of depression patients met all four standards of capacity (Grisso and Appelbaum, 1995). It is important to note, however, the research evaluating mental health disorders, cognition, and decisional capacity face significant limitations. Patients lacking an ability to express a choice are almost always excluded from research, reducing the apparent prevalence of incapacity in the study (Grisso and Appelbaum, 1995). Degree and severity of illness also impacts potential cognitive deficits and are not always adequately controlled for in studies. Patients with acute or severe disturbances in thought process or content are frequently ineligible for study enrollment. A severe limitation in empirical study is the subjective nature of the finding of incapacity (Grisso and Appelbaum, 1995). Determinations of capacity do not have a specific cut-off or numerical quantification that can be utilized but instead require a judgment call on the part of the researcher or clinician. Capacity is also limited to a specific situation and the research parameters reflect only one situation.

Many mental health disorders have been studied in regards to capacity to consent. The most commonly studied is schizophrenia, a highly heterogeneous condition. The majority of patients with schizophrenia retained decisional capacity, with a minority having difficulty with understanding, appreciation, or reasoning (Cadilis et al., 2008; Grisso and Appelbaum, 1991; Wong et al., 2000). One study found that schizophrenics had a widely variable range of scores on standardized instruments of capacity with some performing as well as non-mentally ill controls (Grisso and Appelbaum, 1991). This study concluded that schizophrenia did place patients at higher risk of poor understanding, particularly those patients with cognitive disorganization as compared to patients with affective symptoms. Palmer and Jeste (2006) found increased risks in patients with negative symptoms for poor understanding that improved with repeated information disclosure. Schizophrenic patients, especially patients in catatonic, mute, or apathetic states, are also at increased risk to lack ability to express a choice (Appelbaum and Grisso, 1995; Grisso and Appelbaum, 1995). Hospitalized schizophrenic patients had poorer performance on understanding, appreciation, and reasoning

than outpatient patients or medically ill patients (Appelbaum and Grisso, 1995). However, age, level of insight, and individual cognitive abilities did not specifically correlate with decisional capacity while decreased cognitive test scores in general was a higher predictor in incapacity to consent (Palmer and Jeste, 2006).

Patients with major depression are also commonly studied for capacity to consent. Like schizophrenia, this disorder is highly heterogeneous with some patients facing greater degrees of impairment than others (Grisso and Appelbaum, 1995). However, again like schizophrenia, the majority of patients matched non-mentally ill controls in measures of capacity. The vast majority of women in outpatient settings with major depression were found to meet criteria for capacity to consent in all four legal standards (Appelbaum et al., 1999). This study found that in patients with questionable capacity, appreciation was the most likely to be deficient.

Decisional capacity may not be related to the diagnosis but rather to symptoms. Acute psychosis is associated with decreased capacity but was found not to be dependent on the etiology of the psychosis (Howe et al., 2005). This study agreed with Grisso and Appelbaum's earlier conclusion: cognitive disorganization placed the patient at greatest risk for incapacity while hallucinations and negative symptoms were not associated. Cognitive deficits, rather than diagnosis, may also be directly related to decisional capacity and may have more of an impact than specific symptoms (Palmer and Savla, 2007; Palmer and Jeste, 2006).

Impact of Substance Abuse on Decisional Capacity:

The diagnostic criteria in the DSM-IV for substance dependence include "continued use despite the knowledge that it causes or worsens physical or psychological problems." This equates to impaired decisional capacity with regard to the use of that substance. They are also at increased risk for impaired capacity when making treatment decisions as well. Though minimal research exists, substance-dependent persons engage in riskier behaviors, are more likely to select choices with smaller short-term gains and higher long-term losses, and are willing to take unnecessary or risky actions in reward seeking behaviors (Jeste and Saks, 2006). However, like patients with mental illness, this is a diverse group with heterogeneous disorders and substance abuse does not necessarily equate to a lack of capacity

to consent. As a higher risk population, careful evaluation and further consideration regarding decisional capacity must be employed. Providers must also be vigilant for comorbid psychiatric disorders that may impair capacity to consent in this population.

Education and Informed Consent:

Education, literacy, and health literacy also play a key role in informed consent. Information disclosure often utilizes written informed consent documents that are frequently more complete than verbal disclosure. However, at least 40 million American adults are functionally illiterate and another 50 million are only marginally literate (Christopher et al., 2007). Patients with mental illness suffer from much higher rates of complete or marginal illiteracy (Sentell and Shumway, 2003). These patients also may inflate their literacy levels, creating difficulties for clinicians in estimating literacy (Christensen and Grace, 1999). Many patients may lack the educational level to read and understand informed consent documents used by physicians, especially patients with mental health disorders.

Homelessness:

Homelessness in the United States is a serious problem. As defined by the Stewart B McKinney Act (1994), a homeless person is a person who “lacks a fixed, regular, and adequate night-time residence; and...has a primary night time residency that is: (A) a supervised publicly or privately operated shelter designed to provide temporary living accommodations...(B) an institution that provides a temporary residence for individuals intended to be institutionalized, or (C) a public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings” (National Coalition for the Homeless, 2007). The National Law Center on Homelessness and Poverty estimated that nearly 3.5 million people will experience homelessness each year. The majority of these will be ethnic minority males of middle age (2009 Annual Homeless Assessment Report).

Many homeless individuals suffer from a mental health or substance abuse disorder. The US Conference of Mayors in 2005 found that approximately 16% of single adult homeless person suffer from a persistent and severe mental health disorder. Thirty eight percent are dependent on alcohol and 26% abuse other substances (National Coalition for the Homeless, 2009). A significant and increasing

number of individuals find themselves homeless following release from detoxification, rehabilitation, or correctional facilities (2009 Annual Homeless Assessment Report). While not every homeless person is so challenged, these disorders and problems

Purpose of this Study:

Members of the homeless population are extremely vulnerable. They face numerous and often seemingly insurmountable barriers to healthcare, including physical, bureaucratic, financial, social, and emotional barriers (Kim et al., 2007). However, there are increasing efforts to increase access to health care. As more members of this population become patients, it is important that their treatment meets all ethical, legal, and clinical standards. It is certainly not true that all homeless patients lack capacity to consent. However, this patient population has high rates of substance abuse and mental health disorders. It is then possible that these individuals may have higher rates of incapacity to consent and providers must consider this when managing informed consent with this population.

There is currently no published literature looking at informed consent in the homeless population. It is important that this vulnerable population is protected and given quality medical treatment. This would of course require adequate informed consent. The purpose of this research is to determine if the current clinical practices meet the needs of the homeless population and if primary care providers feel that they face significant barriers to informed consent with this population exist.

Methods:

Study Population:

This study surveyed the medical directors, clinicians, and other healthcare professionals identified through the National Health Care for the Homeless Council Grantee Directory. Identified clinics were grantees of the federal Health Care for the Homeless Program Section 330(h) of the Public Health Services Act, administered by the Health Resources and Services Administration. To receive this grant, these clinics have demonstrated that they provide primary care services as well as substance abuse services to homeless patients. A homeless individual is defined by this legislation as “an individual who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations and an individual who is a resident in transitional housing” (42 USCS § 254b). Of 185 clinics identified by this directory, 114 clinics were selected for recruitment. Clinics were excluded if they were a mobile clinic without permanent structure, did not perform primary care services, or if the clinic did not provide services to persons aged 18 years or older. Clinics were also excluded if the medical directors did not have either an M.D. or D.O. degree. These clinics are found across the United States in a variety of urban and rural locations.

Survey Design:

Two surveys were composed to gain insight into the patient demographics, clinic demographics, and consenting practices by health care providers at each clinic site. The first survey (Survey 1) consisted of predominantly multiple choice and fill in the blank questions and was designed to be completed by the medical director. This survey gathered data on patient demographics, employee demographics, and funding for the clinic. The second survey (Survey 2) was to be completed by health care professionals who are responsible for obtaining informed consent for treatment from patients. Such professionals include physicians, nurses, physician assistants, and psychologists. The survey gathered data on the informed consent practices of that practitioner. It consisted of multiple choice and short answer questions. The survey concluded with two vignettes (taken

from any of four possible vignettes) that presented the responder with a clinical scenario and asked the participant for a narrative describing what that participant would do in each situation.

Data Collection:

Three surveys (one copy of Survey 1 and two copies of Survey 2) were mailed to each clinic at the address found in the National Health Care for the Homeless Council directory. Each clinic was randomly assigned a three digit number using a random number generator. This number was then entered into a database. Each survey was also assigned a letter (A, B, or C) which corresponded to the survey number (Ex: Survey 1 at Clinic X may be assigned the number 123A and the first copy of Survey 2 at Clinic X assigned 123B, etc). Because each clinic received two copies of Survey 2, this letter allowed me to identify which survey was returned from each clinic. After labeling each survey with the appropriate number, the database associating a clinic with the three digit number was destroyed. This numbering system allowed me to group the three returned surveys as belonging to a single clinic but without knowledge of which specific clinic site.

Copies of the three surveys as well as a fact sheet and recruitment letter were mailed to the clinic with three previously addressed and stamped envelopes. An electronic form of the survey was considered but rejected because an email address was not provided for every medical director on the National Health Care for the Homeless Council directory. The medical director at each clinic was asked to distribute the surveys and return envelopes to the appropriate personnel. Separate return envelopes for each participant were utilized to encourage honest responses without fear of the medical director or other participants viewing the completed survey. No identifying information of a given participant was acquired during this study. This study was designed to be entirely anonymous without any data linking the participant to their answers in order to secure honest information and maintain confidentiality.

Because it was impossible to know which clinics had returned the surveys, a follow up email was sent to every clinic initially recruited to increase the response rate. Email addresses were also obtained through the National Health Care for the Homeless Council directory. Clinics without an email address did not receive a follow-up email.

This study was undertaken with the approval of the University of Arizona Internal Review Board.

Data Processing and Analysis:

Of the 342 surveys sent out, 22 surveys were returned. Surveys responses were entered into a database using a custom, secure web-portal created by a software engineer. Data were then presented in raw form. No statistical analysis was performed because of the low response rate. If a higher response rate had been obtained, ANOVA would have been used to test for significant differences between groups and Pearson correlations would have been used to test first-order associations between continuous variables. Ordinary least squares regression equations would have been formed to examine associations while controlling for relevant covariates.

Results:

Two surveys were composed to gain insight into the patient demographics, clinic demographics, and consenting practices by health care providers at each of the 114 clinic sites that met inclusion criteria. Survey 1 consisted of questions for the medical director of each clinic predominantly seeking insight into clinic operations, demographics, and patient population served (Tables 1-4). Of the 114 surveys mailed to each clinic, 10 copies of Survey 1 were returned and represented 10 different clinical sites. While this is an extremely poor response rate, these data can be used as a small sampling of characteristics and operations within the diverse network of clinics that were grantees of the federal Health Care for the Homeless Program Section 330(h) of the Public Health Services Act. Within this small sample, clinical characteristics varied considerably. Both small and large clinics were represented, with employee numbers ranging between 7-250 employees with a mean of 84.8 employees (Table 1). These clinic employees represent a wide variety of medical professionals, including physicians, nurses, nurse practitioners, physician assistants, and social workers (Table 1). The majority of provider visits lasted on average 15-30 minutes (in 60% of responding clinics).

Few clinics employed additional specialists who may have greater insight into informed consent capacities of patients with varying barriers to consent. These include psychiatrists, psychologists, addictions specialists, and ethics consultants (Table 1). Only 10% of the responding clinics employed at least one psychiatrist full time and 10% of clinics had either a part time or unpaid volunteer psychiatrist. A greater number employed a psychologist, with 40% of responding clinics maintaining a full time psychologist on staff (Table 1). Half of the clinics in this sample employed a full time addictions specialist, appropriately reflecting the higher prevalence of substance abuse issues in this population (2009 Annual Homeless Assessment Report). This also reflects the requirement that clinics that receive the Healthcare for the Homeless grant must demonstrate that they provide substance abuse treatment for their patients (Health Care for the Homeless Program Section 330(h) of the Public Health Services Act). Interestingly, one clinic employs three full time ethics consultants, while no other clinic employs any ethics consultant on either a part time, full time, or volunteer basis (Table 1).

Table 1:

Clinic Demographics Per Medical Director				
Clinic Characteristic	Range	Mean	Median	
Number of Employees	7-250	84.8	47.5	
Number Full Time Employees	1-220	66	35	
Types of Employed Professionals	Range	Mean	Median	Mode
Physician	1-12	5.6	4.5	1, 3
Nurse	1-40	9.2	4	2
Physician's Assistant	0-6	2	0	0
Nurse Practitioner	0-6	2.6	4	4
Social Worker	1-36	6.7	3	3
Additional Specialist Employment (Percent Clinics Employing ≥ 1)	Part Time	Full Time	Unpaid Volunteer	
Psychiatrist	10	10	10	
Psychologist	10	40	0	
Addictions Specialist	0	50	0	
Ethics Consult	0	10	0	
Interpreter	70			
Patient Population (Percent responding clinics)	Yes	No	Uncertain	
Only Homeless Patients	40	60	0	
Immigrants Obtained US Citizenship or Permanent Residency	90	0	10	
Immigrants Not Having Obtained US Citizenship or Permanent Residency	90	10	0	
Average Provider Time Spent with Patient	0-15 Min	6-15 Min	15-30 Min	> 30 Min
	0	40	60	0

Table 1: Clinic demographics tabulated from surveys conducted of medical directors of Healthcare for the Homeless grantee clinics. Ten medical directors representing ten clinics completed and returned Survey 1. Clinic characteristics and types of healthcare professionals employed are represented by numerical counts of employees meeting the given criteria. Additional specialist employment statistics demonstrate the percentage of responding clinics that employ at least one of the given specialist populations part time, full time, or as unpaid volunteers. The patient population describes the percentage of responding clinics that see the above patient populations at their clinic.

Seven of the ten responding clinics employed an interpreter in a part time, full time, or volunteer position (Table 1). Six of these clinics have Spanish interpretation abilities and 3 have Russian capabilities as well. Several other languages were provided at various clinics, including Vietnamese, Ukrainian, and Creole, representing the needs of the local population. All clinics reported seeing patients who spoke English as their primary language and 80% reported Spanish as a common primary language. Russian and Creole were found to be primary languages for patients in 30% and 20% of the responding clinics respectively.

In order to receive the federal Healthcare for the Homeless Program grant, these clinics must provide primary care for homeless patients. Only 40% of this sample solely sees homeless patients, while the remaining 60% also see patients that do not meet the federal criteria for homelessness (Table 1). Ninety percent of the clinics will see immigrants that have or have not obtained US citizenship or permanent residency.

Despite each clinic being a grantee of the federal Health Care for the Homeless Program Section 330(h) of the Public Health Services Act, only 70% of medical directors reported a federally sponsored grant as a funding source for the clinic (Table 2). Half of the clinics reported state sponsored grants as sources of clinic funding and forty percent reported foundational grants and private donations as funding. Patients are also asked to pay a portion of their care at 80% of the clinics. Half of these accept insurance or co-pays, largely the government insurances Medicare and Medicaid. A significant portion (60%) also requires some cash for service (Table 3).

Table 2:

Sources of Funding (Percent Responding Clinics)						
	Federally Sponsored Grant	State Sponsored Grant	Foundational Grant	Private Donation	Fundraising/Philanthropy	Other
Clinic	70	50	40	40	30	60
Salaries	50	20	20	20	30	60
Facilities	70	30	20	30	30	60
Medications						
Free of Charge*	80	20	0	0	0	50
Financial Assistance for offsite meds**	25	0	50	0	25	25

Table 2: Sources of Funding for the clinics as provided by the medical directors on Survey 1. Data is presented as percent of responding clinics that utilized the source of funding to finance some or all of the clinical needs, including overall clinic costs, employee salaries, and facilities expenses. Seven of the ten responding clinics are aware of some form of requirement from the funding sources regarding informed consent practices. *Eight of the ten represented clinics have onsite pharmacies. Of those eight clinics, five provide medications free of charge. The table demonstrates the percentage of the five clinics that utilize each funding source to provide this service. **Four clinics provide financial assistance to purchase medications off site. The table demonstrates the percentage of those clinics that utilize each funding source to provide this service.

Table 3:

Patient Payment for Services (Percent Responding Clinics)				
Patients Pay Portion of Care	Yes	No		
	80	20		
If Yes:	Insurance/Co-Pay	Medicare/Medicaid	Cash for Service	Other
	50	70	60	0

Table 3: Patient payment responsibilities as provided by the medical directors of the 10 represented clinics on Survey 1. Eight of the ten require patients to pay some portion of their care. Of those, data is given demonstrating how patients are asked to provide payment.

Table 4a:

Patient Demographics Per Medical Director				
	Range	Mean	Median	Mode
Average Number Patients Seen Per Day	8-500	129	80	30
Patient Characteristics (Estimated Percent of Patients Seen At Each Clinic)	Range	Mean	Median	Mode
Male	40-80	54.7	50	40
Female	20-60	33.2	50	60
Child and Adolescent (Ages 0-17)	1-50	16.1	20	20
Adults (Ages 18-64)	30-99	71.3	74.5	None
Adults (adages 65+)	1-25	12.6	13.5	1
American Indian	0-5	0.5	0.83	0
Asian or Pacific Islander	0-10	2.43	1	0
Black	2-50	24	25.5	30
White/Caucasian	10-94	50.2	48.5	60
Hispanic	3-60	22.5	16.5	3, 15
Other Ethnicity	0-10			
Typical Education Level of Patients	Percent Responding Clinics			
Little to No Formal Education	0			
Elementary School (Grades 1-8)	40			
High School (Grades 9-12)	60			
Some College	0			
Completed Undergraduate Degree	0			
Graduate Degree	0			
Primary Language(s) of Patients				
English	100			
Spanish	80			
Other (Including Below)	60			
Polish	10			
Russian	30			
Creole	20			
Arabic	20			
Vietnamese	20			
Other Not Previously Mentioned	10			

Table 4b:

Patient Demographics Per Medical Director	
Typical Employment Status	Percent Responding Clinics
Unemployed and not seeking employment	70
Unemployed and seeking employment	20
Employed Part Time	10
Employed Full Time	0
Student	0
Patient Primary Housing	
Shelter	50
With Family/Friends	40
On the Street	20
Common Mental Health Disorders	
Schizophrenia	90
Personality Disorders	80
Major Depression	90
Bipolar	100
Other	30
Common Substances of Abuse	
Cocaine	100
Heroin	60
Marijuana	90
Methamphetamine	50
Other (Includes narcotics, alcohol)	30

Table 4a and 4b: Patient demographics as provided by the medical directors of the ten clinics that completed Survey 1.

The patient demographics when compared between the various clinics tend to be more consistent than the clinic demographics. Though the range of numbers of patients seen daily varies widely (from 8-500 patients per day), the patients are predominantly male adults age 18-64, and Caucasian (Table 4). These patients tend to have an education level no higher than high school and are unemployed without seeking employment (Table 4). According to the medical directors' responses, their patients speak a variety of languages. The languages provided by the healthcare practitioners correlate well with the languages listed by the medical directors that have interpreters available. Fifty percent clinics responded that shelters are a primary housing for their patient population while forty percent of clinics see patients primarily housed with family or friends. Only 20% of clinics reported that the street served as primary housing for their patient population (Table 4).

Each medical director responding to Survey 1 was asked to comment on which psychiatric illnesses were commonly seen in their practice. Every clinic responded that bipolar disorder was commonly seen in their patients while ninety percent of clinics frequently provided care to schizophrenic patients or patients with major depression (Table 4). Eighty percent commonly saw patients with personality disorders as well. Additional disorders were mentioned by three of the ten responding clinics. These included substance abuse, anxiety, and post traumatic stress disorder. When asked about substances of abuse (excluding tobacco), each clinic frequently sees patients abusing cocaine and ninety percent see marijuana use. Fifty percent or greater commented on heroin and methamphetamine abuse as well.

Survey 2 consisted of questions seeking to examine provider demographics and informed consent practices (Tables 5-7, Appendix 1 Boxes 1-7). Each of the 114 clinics was sent two different copies of this survey. The only difference between each copy was which two of the four possible clinical vignettes at the end were provided. Otherwise, the questions regarding demographics and informed consent practices were identical between the surveys. Of the 228 surveys mailed to clinics, 12 were returned representing each of the 10 different clinics that completed and returned Survey 1. This poor response rate may not provide the breadth of provider practices but can provide clues as to a small sampling of differing practices.

Table 5a:

Respondent Provider Demographics				
Provider Characteristics	Percent Responders			
Male	41.67			
Female	58.33			
American Indian	8.33			
Asian or Pacific Islander	0			
Black	0			
White/Caucasian	66.67			
Hispanic	25.00			
	Range	Mean	Median	Mode
Age	31-69	45.17	53	54
Religious Preference	Percent Responders			
Protestant	16.67			
Catholic	33.33			
Jewish	0			
Islamic/Muslim	0			
Other	16.67			
No Preference	33.33			
Provider Training	Percent Responders			
MD or DO	83.33			
Nurse Practitioner	8.33			
Psychologist	8.33			
Residency Completed in US	100.00			
Fellowship Trained	16.67			
	Range	Mean	Median	Mode
Years After Residency Graduation	2-36	15	12	12
Board Certification	Percent Responders			
Family Medicine	50.00			
Internal Medicine	8.33			
Psychiatry	16.67			
Pediatrics	0			
Other	8.33			
Not Applicable	16.67			

Table 5b:

Employment Characteristics	Percent Responders			
Part Time	33.33			
Full Time	58.33			
Volunteer	8.33			
	Range	Mean	Median	Mode
Employment Term With Clinic (Years)	2-21	9	8	8

Table 5a and 5b: Demographics of the healthcare providers responsible for informed consent that completed and returned Survey 2. Categories with data presented as “Percent Responders” demonstrate the percentage of responding providers that identified with the given characteristic.

Table 6:

Patient Demographics Per Healthcare Provider				
Patient Characteristics	Range	Mean	Median	Mode
Average Number Patients Seen Per Day	0-24	14	16.5	20
Disorders Affecting Capacity (Percent Patients Seen In Practice)	Range	Mean	Median	Mode
Any Substance Abuse	10-70	34.17	25	None
Alcohol Abuse/Dependence	5-75	27.78	20	20
Illicit Drug Abuse/Dependence	5-75	26.67	25	5
Prescription Drug Abuse/Dependence	0-30	12.25	10	5, 10
Traumatic Brain Injury (TBI)	1-20	6.25	5	1, 5
Reported Head Injury	0-20	6.25	2	0, 2
Schizophrenia	1-20	7.50	2.5	2
Major Depression	5-85	35.00	32.5	10, 40
Bipolar	3-50	22.00	20	20
Personality Disorders	3-80	22.00	15	10
Dementia	0-10	3.86	5	5
Doubt Capacity to Consent	1-5	3.33	3	5

Table 6: Demographics of patients seen by the healthcare providers that completed and returned Survey 2. Providers were asked the percentage of patients that met criteria for disorders possibly affecting capacity to consent and the percentage of patients the provider doubts the capacity to consent.

Table 7a:

Provider Consent Practices					
	Never	1-3 Times Per Month	1-5 Times Per Week	1-5 Times Per Day	6 or more times per day
Informed Consent Clinical Practice					
Provide Written Instructions	0	33.33	33.33	16.67	16.67
Provide Verbal Instructions	0	0	8.33	0	18.33
Utilize Family Member as Interpreter	33.33	50	8.33	0	0
Utilize Friend As Interpreter	66	33.33	0	0	0
Patient Asked to Repeat Back Treatment Plan	0	25	50	8.33	16.67
Patient Asked to Describe Diagnosis	16.67	33.33	16.67	16.67	16.67
Patient Asked to Explain Why Treatment Plan Recommended	8.33	33.33	25	33.33	0
Ask Patient What They Believe is Wrong	16.67	41.66	16.67	16.67	8.33
Ask Patient Why Reject or Accept Treatment Plan	16.67	8.33	41.66	25	8.33
Utilize Brain Injury Screening Questionnaire (BISQ)	83.33	16.67	0	0	0
Utilize Clinical Interview to Evaluate Capacity	25	50	0	0	25
Use Validated Instrument to Evaluate Capacity	66	16.67	0	16.67	0
Nonvalidated Questionnaire to Evaluate Capacity	58.33	25	8.33	8.33	0
Refer to Specialist to Evaluate Capacity	50	50	0	0	0
Utilize Mini Mental State Exam (MMSE)	8.33	41.66	33.33	8.33	8.33
Lied to Patient to Convince to Follow Prescribed Treatment	18.33	0	8.33	0	0
Treated Patient Without Informing Patient	100	0	0	0	0
Omitted Side Effects or Risks to Convince Patient	83.33	16.67	0	0	0
Know What is Best for Patient	0	8.33	16.67	33.33	33.33
Consider Finances in Treatment Plan	0	0	8.33	16.67	75

Table 7b:

Provider Consent Practices	
Informed Consent Documents	Percent Responders
Languages Supplied on Consent Form:	
English	100.00
Spanish	66
Other	25
Languages Supplied on Written Instructions:	
English	100.00
Spanish	83.33
Other	33.33
Always Use Primary Language of Patient	83.33
Who Makes Decisions Regarding Patient's Treatment?	
Doctor	18.33
Nurse	41.66
Patient	83.33
Family Members	50
Social Worker	33.33
Other Professionals	41.66
Believes Manages Informed Consent Differently Than Other Physicians	
Yes	0
No	58.33
Uncertain	16.67
No Response	25
Believes Practices Medicine Differently Than Other Physicians	
Yes	50
No	25
Uncertain	8.33
No Response	16.67
Discusses Resource Scarcity/Financial Concerns	25

Table 7a and 7b: Consent practices of healthcare providers responsible for informed consent. Twelve surveys were returned representing ten clinics.

Of the twelve surveys returned, the healthcare providers were predominantly female and Caucasian. The ages of responding providers ranged from 31-69 with the mean age of 45.17 years old (Table 5). The healthcare professionals ranged in training. Physicians with an MD or DO predominantly responded (83.33%) while one nurse practitioner and one psychologist also responded to the survey. All had completed residency or training within the United States and few went on to be fellowship trained. Two of the responders had sought additional training in gastroenterology or obtained a Masters of Public Health.

The largest represented group in this sample was board certified in Family Medicine (Table 5). These practitioners were primarily employed in a full time capacity with a third employed as part time employees. One responder was serving in a volunteer role. These providers tended to be more experienced providers, having completed residency 15 years on average prior to completing this survey. However, the average length of employment with the current clinic was 9 years, suggesting that these providers had experience working in other clinics and raising the possibility of work with other patient populations.

Each provider was asked if they identified with a certain religious preference (Table 5). One third of the responders identified themselves as Catholic while another third had no religious preference. The remaining responders identified with other religious faiths.

Survey 2 also sought to determine the characteristics of the patients seen by these providers. Providers saw on average 14 patients per day, with a range from 0-24 patients per day. Providers were asked to then estimate the percentage of these patients that they felt met criteria for various disorders that are commonly associated with increased risk to lack capacity to consent (Table 6). These disorders included substance abuse, mood disorders, thought disorders, and traumatic brain injury (Appelbaum and Grisso, 1995). The most commonly estimated disorder in this sample was major depression followed closely by substance abuse. Of the substances of abuse, alcohol abuse had the highest estimated prevalence followed closely by illicit drug abuse. Illicit drug abuse was not further subdivided into specific substances of abuse in this study. Prescription drug abuse had a significantly lower prevalence. Bipolar disorder and personality disorders were also commonly seen by these providers, estimating on

average 22% of their patient population. Relatively few reported seeing patients with dementia, traumatic brain injury, or reported head injury. This may reflect a low rate of screening for these injuries, as 83.33% of providers never use the Brain Injury Screening Questionnaire (Table 7). Despite the significantly high rates of psychiatric disorders and substance abuse, the healthcare professionals responding to this survey infrequently questioned the patient's capacity to consent. The responses ranged from 1-5% of patients seen, doubting capacity to consent with only 3.33% of patients on average (Table 6). After determining a patient lacks capacity, many felt that they faced no barriers to a legal determination of incompetence or were simply unsure about the process (Box 3).

Providers were also questioned regarding the frequency of various practices used to aid in determining or ensuring morally, ethically, and legally responsible informed consent to treatment (Table 7). This includes evaluating information disclosure, ensuring understanding, assessing voluntariness and appreciation.

Provider practices regarding disclosure of information about treatment plans and options was questioned (Table 7). As would be expected, the most commonly used practice was providing verbal instructions to a patient regarding treatment (11 out of 12 responders performed this practice 6 or more times a day). It can be inferred from the large portion of non-English speaking patients (Table 3) that language barriers may present a significant barrier to information disclosure. Use of family or friends as interpreters rather than licensed medical interpreters may result in reduced effectiveness of information disclosure. Half of responders reported using family members as interpreters 1-3 times per month and one third reported using patients' friends as interpreters as frequently. Written instructions were also commonly provided, although significantly less frequently than verbal instructions. Most responders (8/12) provided written instructions to patients between 1-3 times per month and 1-5 times per week. When using written instructions, 10 of 12 responders used the patient's primary language.

Common clinical methods of evaluating patient understanding for capacity to consent include asking patients to repeat back to the practitioner critical information as well as paraphrasing diagnosis and treatment plans (Jeste and Saks, 2006). Each of these tools were utilized by clinicians in this sample frequently, with half reporting

asking patients to repeat back treatment plans 1-5 times per week and one third asking patients to describe their diagnoses 1-3 times per month (Table 7). However, 2/12 providers never utilized this simple clinical method for determining a patient's understanding and only 3/12 providers used the repeat back technique on a daily basis. A wider variance is seen between providers when asked how frequently they ask patients to explain the rationale behind a recommended treatment plan. One third frequently pose this question (1-5 times per day) while one third less commonly pose this question (only 1-3 times per month). One of the twelve responders never asks patients to explain why a given treatment plan was recommended.

When evaluating appreciation in a capacity evaluation, it is necessary to determine whether the patient can apply information to their unique situation and themselves within that context. A commonly used practice is to ask patients what they believe is wrong and why they accepted or rejected the proposed treatment plan (Jeste and Saks, 2006). These questions also may be used to evaluate voluntariness and to help to unmask any cultural barriers or beliefs that need to be adequately addressed by the practitioner to provide the patient with the most appropriate treatment plan. When asked what frequency each provider posed these questions, two of the twelve responders never asked either question (Table 7). Five of twelve asked patients to describe what their beliefs were regarding their illness 1-3 times per month with the remaining responders split between 1-5 times per week to 6 or more times per day. Five of twelve responders ask patients why they accept or reject their treatment plan 1-5 times per week.

There are several methods for evaluating capacity to consent in a more formalized manner. These include validated instruments, clinical interviews, other non-validated questionnaires, and the use of specialists. Few providers used any of these methods on a daily or even weekly basis. Those that did use any of these options used them on a monthly basis or less. The most commonly used methods were clinical interviews and referral to specialists (Table 7). Fifty percent of responders utilized a clinical interview to evaluate capacity 1-3 times per month while the remaining responders were split evenly between never utilizing a clinical interview in this context and using it 6 or more times a day. Specialists were consulted for capacity evaluation by fifty percent of the responders 1-3 times per month. The other fifty

percent never consulted a specialist for this evaluation. Only four of twelve responders ever used a validated instrument to evaluate capacity to consent and five of twelve used some other questionnaire for this purpose. The Mini Mental State Exam (MMSE) is frequently used by these practitioners; it is not an ideal measure of capacity. Cognitive functioning as measured by the MMSE is a good predictor of decisional capacity, particularly the understanding standard (Jeste and Saks, 2006). However, it is simply a predictor and does not equate with a lack of capacity to consent. Further evaluation into the four components of capacity must be undertaken.

This survey also sought to determine if providers used techniques that circumvent informed consent (Table 7). Providers were asked how often they lied to patients to convince them to follow a prescribed treatment. Only one of twelve responded that they had done this, and wrote in the margins of the survey that they would present “partial information” until the patient is “less psychotic.” The rest responded that they never lie to their patients. All stated that they have never treated a patient without informing the patient, though this appears to contradict the statement above by a responder that they withhold information until a patient’s psychosis is reduced. One sixth of the providers admitted to omitting side effects or risks of a treatment plan to convince a patient to assent. The remainder stated that they had never done this.

Providers were asked about their beliefs around informed consent and their patient population. All felt that they knew “what was best for the patient” at least some of the time, with one third responding to each category of 1-5 times per day and greater than 6 times per day each (Table 7). Nearly all felt that they were responsible for making decisions regarding patient’s treatment while fewer than half believed that nurses, family members, social workers, or other professionals shared this responsibility. When asked to provide a situation in which they might serve as the primary decision maker, three of eight responses centered on the patient requesting this (Box 1). Fascinatingly, two responders did not include the patient as a responsible party in the decision making (Table 7). No providers believed they managed informed consent differently from other physicians, though 2 were uncertain and 3 did not respond to the question. However, half felt that they practiced medicine differently from other physicians, frequently citing resource scarcity and financial

concerns. This correlates closely with the 75% of responders who consider financial concerns when formulating a treatment plan at least 6 times per day.

Discussion:

There is little doubt that significant barriers to accessing healthcare exist for homeless persons. However, as access to treatment increases through programs like the federally funded Healthcare for the Homeless grant, there exists little data that looks to the quality of that healthcare. This study was designed to examine the demographics of the clinics, providers, and patients at primary care facilities serving homeless populations across the United States and to identify any possible deficiencies or barriers to adequate informed consent to treatment. One hundred fourteen clinics were surveyed but only ten clinics responded. This is a response rate of only 8.7%. This extremely poor response rate causes significant hardships in analyzing the data and identifying the issues or barriers sought by this study.

There are several possible reasons to explain the low response rate. Simple logistics may have played a large role. The surveys were relatively long (each taking 20 to 30 minutes to complete), which may have been too large a demand for busy healthcare professionals. Many of the questions were in a free text format rather than a multiple choice format, increasing the variety of possible answers yet making the survey more time consuming and difficult to complete for the responders. Paper copies of the surveys were mailed to each clinic. The providers were then asked to respond and return the completed survey via the previously addressed and stamped envelope. A higher response rate may have been achieved using surveys online through a secure website. However, this option was not selected when beginning this project because of concerns about older providers having difficulty using an internet based medium and therefore skewing the results towards a younger demographic. Another barrier to online surveys was the lack of email contact information for providers at each clinic. Clinic addresses were found through the National Health Care for the Homeless Council online directory which did not consistently list email contact information for each clinic. Because of the number of surveys sent to each clinic that were meant to be completed by different healthcare professionals employed at that clinic, more than one email address would have been required as well.

The low response rate poses several problems when seeking to analyze the data appropriately. Primarily, it is unclear whether the data is a true representative sampling of these clinics and their

providers. It is possible that the results reveal a realistic representation of all of the clinics that have received the federal Healthcare for the Homeless grant. However, these data may suffer from a selection bias. The providers who are most willing to complete a survey may be the providers most willing to work harder to achieve higher standards of care for their patients. If this were the case, the data would be skewed to reveal a more positive reflection of provider informed consent practices. For the purposes of this paper, the data will be analyzed as a representative sample from a pilot study.

The surveys of the clinics having received the federal Healthcare for the Homeless grant demonstrate that the “typical” patient seen is male, adult age 18-64, Caucasian, achieving no higher than a high school education, living in a shelter and unemployed without seeking employment (Table 4). National statistics for homelessness correspond closely to the demographics of this patient population. According to the 2009 Annual Homeless Assessment Report, a typical homeless person in the United States is a middle aged, adult male. Adult men are overrepresented in the homeless population, comprising 63.7% of all sheltered homeless persons compared to 48.7% in the general population. This study found that on average, 54.7% of patients seen at these clinics were male. Men are seen disproportionately in this population for several reasons, including higher rates of substance abuse and prior institutionalization or incarceration than women (2009 Annual Homeless Assessment Report). This study also found that the majority of patients seen were adults aged 18-64. Nationally, 75% of homeless individuals are adults age 18-61. Only 2.8% are over age 62 (2009 Annual Homeless Assessment Report). These clinics may see an unusually high proportion of elderly patients. At the surveyed clinics, patients over 65 years averaged 12.6% of the patient population. This may reflect greater healthcare needs and medical morbidity for the elderly population as well as increased access to government insurance such as Medicare. It is important to note that the homeless population is aging, with increasing numbers of persons over 50 (2009 Annual Homeless Assessment Report). Healthcare providers working with elderly populations must be aware of cognitive changes, increase prevalence of dementias, and higher healthcare demands that may impact informed consent.

A significant deviation between national homeless demographics and the demographics of the patients seen by the providers in this

study was found when examining patient ethnicity. The 2009 Annual Homeless Assessment Report found that 62% of homeless persons in the United States belonged to an ethnic minority, with African American being the most common. However, this study found that on average 50.2% of patients were identified as White/Caucasian (Table 4). Hispanics were also overrepresented in this patient population, averaging 22.5% as compared to the 11.6% of all sheltered homeless persons and 9.6% of the general population. This raises several key questions when looking at the patient populations of clinics serving homeless patients. It is possible that the responding clinics do not reflect the national data because of local differences in population. However, it is also possible that there still remains a significant barrier to access for homeless patients belonging to an ethnic minority.

Comparable to national statistics, 50% of patients described by this study were staying in shelters while 40% primarily lived on the street (Table 4) (2009 Annual Homeless Assessment Report). This is significant because 27% of all homeless are chronically homeless and 58% of those are primarily unsheltered (2009 Annual Homeless Assessment Report). Persons who are chronically homeless and disproportionately living on the street have higher rates of disabilities that may impact capacity to consent, including substance abuse and mental health disorders. It is necessary to recognize that when managing a patient who is unsheltered, there is an increased risk for lack of capacity to consent.

Substance abuse and mental health disorders are more prevalent in this population and also place the patient at higher risk to lack capacity to consent. The US Conference of Mayors in 2005 reported approximately 16% of single adult homeless persons suffer from some form of persistent severe mental health disorder. Each of the clinics in this study reported seeing patients with mental health disorders such as schizophrenia, personality disorders, and major depression (Table 4, 6). Providers estimated that 35% of patients suffered from major depression disorder and 22% suffered from bipolar disorder. Roughly 38% of the homeless are dependent on alcohol and 26% abuse other substances (National Coalition for the Homeless, 2009). An increasing number of homeless persons in shelters and assisted living programs came there from detoxification and rehabilitation institutions, increasing from 3.6% in 2007 to 5.3% in 2009 (2009 Annual Homeless Assessment Report). Commonly abused

substances included cocaine, heroin, and marijuana. Consistent with national data, the providers estimated that 34.17% of their patients abused some substance and 27.78% abused alcohol (Table 4, 6). The data demonstrate that clinics are working toward meeting the needs of the mentally ill with 50% employing a full time addictions specialist and 40% employing a full time psychologist (Table 1).

Traumatic brain injuries (TBIs) may also produce cognitive impairments that could limit capacity to consent to treatment. A recent study found a 53% lifetime prevalence of traumatic brain injury in the homeless, with 12% of those cases having a moderate to severe event (Hwang et al, 2008). Another study found that 33.33% of the homeless population may have suffered from a potential TBI incident without a positive screen for TBI (Hux et al., 2009). Physical abuse, assault, motor vehicle collisions, substance abuse, and mental health disorders place the patient at risk for future TBI and serve as possible outcomes from prior TBI. All are common in the homeless population. One study found that 70% of respondents suffered from the TBI prior to homelessness, suggesting a possible cause of homelessness (Hwang et al., 2008). It is significant to recognize TBI in these patients, as it may produce cognitive impairment, impacting social functioning, memory, concentration, learning, and impulsivity; all of which may impact capacity to consent to treatment. Despite the evidence for significant prevalence of traumatic brain injury in the homeless population, healthcare providers responsible for informed consent in this study found that 6.25% of their patients on average had a traumatic brain injury or reported head injury (Table 6). Only 16.67% of providers ever used the Brain Injury Screening Questionnaire (BISQ), a validated screening tool. It is noteworthy that under-recognition of this condition may result in under-recognition of cognitive deficits in this population and in turn incapacity to consent to treatment. This failure to diagnose and respond to traumatic brain injuries can be easily remedied with the use of validated screening instruments, such as the BISQ, or through clinical interviews with specific questions regarding prior head injury and any sequelae (Hux et al., 2009).

This study correlates strongly with current literature that recognizes high rates of substance abuse, mental health disorders, and other risk factors for cognitive deficits. Recognizing these risk factors is necessary for clinicians when considering informed consent practices

and capacity to consent. Despite the high rates of these risk factors, the providers in this survey questioned their patients' capacity to consent in only 3.33% of patients seen (Table 6). Certainly, these disorders often do not negate a patient's ability to consent. This number may simply reflect that fact. However, it is also possible that the low rates of questioning capacity to consent in the face of such high prevalence of impairing conditions may simply be a failure of clinicians to recognize risk factors for incapacity and inadequate informed consent.

Clinicians must identify those with or without risk factors who suffer from a cognitive deficit that may impair consent. While cognitive deficiencies frequently do not equate to incapacity to consent, these must be considered as a risk factor and further probing into capacity must be considered (Grisso and Appelbaum, 1995). This requires a clinical interview to determine the patient's understanding, appreciation, voluntariness, and ability to express a choice. The treating healthcare provider in the primary care setting is in the ideal position to perform this function. Likely, these practitioners have the greatest knowledge of the patient, including personal beliefs, cultural expectations, and medical history. This increased knowledge of the patient can allow the clinician to determine if the consent to or refusal of treatment corresponds well with the patient's goals, beliefs, and values. If the providing clinician does not feel comfortable, referral to psychiatrists, ethics consultants, social workers, or other specialists may be required. In this study, only 25% of providers utilized a clinical interview to evaluate capacity to consent on a daily basis and 50% utilized it only 1-3 times per month. Another 25% never utilized a clinical interview. However, 91.67% used a Mini Mental State Exam (MMSE) with 50% using this tool on a least a weekly basis (Table 7). While the survey did not evaluate the specific situations in which this tool is being used, it is important to note that the MMSE is a poor tool for evaluating capacity to consent. It is designed to identify specific cognitive deficits in memory, language, orientation, and visual-spatial tasks. It is not designed to evaluate the components necessary for capacity to consent. The consistent use of this tool and the lack of consistent use of clinical interviews when evaluating capacity raises an important question: are providers adequately trained regarding informed consent and evaluating capacity to consent? It is possible that healthcare practitioners in this study are substituting a poor

measure of capacity for the “gold standard”. A lack of training may be responsible and providers may not be able to identify the difference between capacity, cognition, and mental status. Further research would need to be conducted to see whether this holds true for these providers and to determine if the primary care providers serving homeless patients are trained as well as providers serving homed patients.

Further questions regarding the quality of the consent practices can be raised based on the typical questions providers ask to assess capacity to consent in a clinical interview (Table 7). The use of these questions and techniques varied widely amongst the providers and may reflect variations in clinical training, patient population, and time constraints. A larger study would be needed for statistical significance to be determined. Further research comparing use of techniques to demonstrate capacity by providers seeing homeless patients and providers seeing homed patients may elucidate this.

The majority of providers felt that they did not manage informed consent differently from other physicians but half felt that they practiced medicine differently (Table 7). It is unclear what the meaning of this may be. This could suggest that all physicians, regardless of patient population, manage informed consent equally well or equally poorly. It could also point to a flawed perspective by the primary care physicians seeing these patients. It may be necessary to manage informed consent differently in this population due to the higher prevalence of risk factors for incapacity to consent. If a physician feels that they must practice medicine differently from other physicians due to resource constraints, it is reasonable that informed consent may need to be handled differently.

Future Directions:

Further studies must be conducted to answer the many remaining questions. Because of the low response rate, it is impossible to draw conclusions of statistical significance. Response rates may be increased by online secure surveys, offering incentives to participants, and reducing the length and complexity of the survey tools.

Higher response rates would allow for further examination to identify correlations between variables. It would be interesting to examine correlations between clinic size, clinic demographics (including funding sources, employment characteristics), patient demographics, and provider demographics with informed consent practices and concerns. Such analysis would clarify whether this small sample represents clinics that use only best practices or are representative of these clinics as a whole. Provider characteristics such as age, religion, training, specialty, gender, and years in practice may correlate with informed consent practices and might provide insight as to how clinicians manage informed consent with their patients. Future research could also use these data and compare with similar data from providers seeing homebound patients to see whether informed consent practices are different between the two populations.

Most importantly, however, this study may highlight an essential problem with studying informed consent practice. It is possible that providers will not answer questions regarding their informed consent practices accurately or honestly. This question was raised by the responses to Survey 2 question, "If the patient refuses treatment, what do you do?" Several providers answered with textbook correctness (Appendix 1, Box 2). One writes, "Counsel risks and benefits, ask for reason of refusal, and try to address obstacles." In the first vignette, when faced with managing a difficult patient who may lack appreciation and therefore lack capacity, the responder writes that he/she would "Evaluate her mental status (decision making capacity) and then find out if she understands the risk and benefits of treatment" (Appendix 1, Box 4). These answers would suggest that providers are handling these difficult situations with flawless practices. The free text responses are contradicted by the low rates of use of a variety of clinical interview questions that seek to evaluate capacity to consent (Table 7). When asked how obstacles they face when seeking legal determination of incompetence, many replied that

they faced no obstacles, saw no benefit, or were unsure (Appendix 1, Box 3). This would suggest that either they have no experience with this legal route or find no value in its use. Experientially, this does not seem to be the case and I hypothesize that it is unlikely that providers in this situation are meeting this high standard without problems. It is possible that the providers responding in this survey are self-selected to represent the best providers and clinics who truly face no issues and always use best-practices when managing informed consent and evaluating capacity. It also raises the concern that these subjects may not be adequately studied using this format.

Such free text evaluation of how a clinician would handle informed consent issues may not provide real insight into actual practices. This allows clinicians to provide the “best” answer, rather than a true answer. They may fear admitting inadequate or subpar informed consent practices for fear of legal ramifications, despite the anonymity of the survey. These answers may reflect aspirational goals, how clinicians wished that they practiced. Providers may also truly believe that these are in fact the practices they utilize when faced with these situations, though actual practices may be different than their perceptions. Of course, it must be considered that these practices are absolutely what they practice but cannot be verified in this format.

Other studies may yield more representative data to the actual practices of clinicians in primary care settings with homeless patients. Video recordings of patient encounters could be utilized. However, if the clinician is aware of the recording devices, they may alter their practices, skewing the data. Providers would need to be kept unaware of the surveillance to get data that represents their true practices when managing informed consent. Patients would also need to be blinded to this to ensure that their behaviors and responses remain unchanged. This type of study would be near impossible to perform and at best would be ethically questionable. Patients would also need to be screened for capacity to consent with a validated tool, both to verify the clinician’s findings regarding capacity in each encounter as well as to ensure patient safety throughout the research process as a human subject. This population is already vulnerable and if the concern is that the patient lacks capacity to consent to treatment, they are at significant risk to lack capacity to consent to research.

Therefore, research into informed consent practices in this population that yields accurate data may be impossible to perform. All

study methods are significantly flawed. This leaves us with an empirical agnosticism: the answers to pressing questions may simply not be knowable. We are currently planning future research into the ability to research such ethical questions.

Conclusions:

Barriers to accessing healthcare for homeless patients in the United States are great and difficult to combat. However, many organizations and providers are working every day to lessen those barriers and increase access to healthcare. As barriers begin to crumble, it is necessary next to look to the quality of healthcare that homeless patients are receiving. Homeless patients are at higher risk than the housed populations for substance abuse, mental health disorders, cognitive impairment, and traumatic brain injury. These disorders do not equate to a lack of capacity to consent. Most patients suffering from such conditions maintain capacity to consent and should be provided with every legal, ethical, and moral right to assent or refuse proposed treatments. However, these conditions do place patients at higher risk for lacking capacity to consent and the prevalence in the homeless population raises the risk that a homeless person would lack capacity to consent. Recognizing the patient with increased risk should prompt further evaluation and consideration for informed consent issues.

This study sought to determine informed consent practices and barriers to appropriate informed consent with homeless patients in primary care settings. Due to the extremely poor response rate, no data of statistical significance was found and the study must be handled as a pilot study. It is unclear if the responding clinics and healthcare providers represent the clinics with best-practices, worst-practices, or are a representative sampling of clinics that have received the federal Health Care for the Homeless Program Section 330(h) of the Public Health Services Act. Regardless, it is clear from this study that the every clinician has room for improvement and that informed consent practices are not yet ideal. Simple measures can be taken to improve informed consent practices. Additional explanations of the treatment on multiple occasions, use of written instructions in the patient's primary language, appropriate use of interpreters, repeat back techniques, and clinical interviews are time and cost efficient and may improve the quality of informed consent.

It is also apparent that further research must be conducted in this area. This study suggests that providers seeing homeless patients may not always sufficiently manage informed consent. They are undeniably faced with extreme difficulties that cannot be ignored and

are certainly heroic in the care that they are able to provide when dealing with resource scarcity, lack of support, and a population in crisis. However, their struggles with capacity to consent and informed consent practices may not only reflect the challenging environment in which they must work. It may reflect on clinicians as whole, regardless of the patient population or environmental barriers. Clinicians may not be well trained to provide this care to patients and better education almost certainly needs to be employed. Research comparing the two provider populations may elucidate this.

Finally, it is clear that this research is difficult to perform and accurate and honest data reflecting informed consent may not be feasible.

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Appendix 1: Unanalyzed Qualitative Data

Box 1:

Situation in which provider is primary decision maker
<ul style="list-style-type: none">• When the patient asks me to make the decision• Pt unable to decide for themselves and no DPOA available• If they are imminently dangerous to self or others• Patients often, when asked if they agree to the treatment plan, will say “You’re the doctor – it’s up to you.”• I usually always make choice as team w/ client but occasionally a client will say “You’re the doctor, you choose” then I will choose and give client my rationale• Medication for HTN• Acute emergency and if incapacitated without family available• Since we are on strictly outpatient service and we do not do procedures, the provider recommends the treatment the patient decides.

Responses unedited for grammar and style.

Box 2:

If patient refuses treatment, what do you do?
<ul style="list-style-type: none">• If the patient has also mental problems I will refer him for mental health evaluation. Otherwise I will encourage him to have a 2nd opinion. But this has not happened to me with homeless patients in general they accept my recommendations but compliance with it is another issue.• Request the pt secure a 2nd opinion if not able to convince myself• Try to explain the damaging effects on body over the long term of not treating. Try to discuss by asking pt why or what they think and feel.• Motivated interviewing/enhancement. Keep collaboration going.• Acknowledge their choice, but be clear they know consequences of choosing to refuse treatment, review alternatives and leave door open to review the issue if change their mind• I advise them that this is against my advice but that the decision is ultimately up to the pt• Voluntary treatment. Might question reasons for their concern.• Counsel risks and benefits, ask for reason of refusal, and try to address obstacles• Give the options. Discuss risk/benefit.

Responses unedited for grammar and style.

Box 3:

If you determine patient lacks capacity to consent, what obstacles do you face when seeking legal determination of incompetence?

- I have not had this situation yet
- We do not seek legal determination. Attempt to get social services or APS to intervene
- Secure administrative assistance and thus not an obstacle
- ?
- If have presented with family, advise them about issue re: medical power of attorney, etc/ guardianship
- Little. The clinic has a lawyer who can resolve these issues
- Consult mental health professionals deemed necessary to determine competence/involuntary status
- Unsure
- No time, unsure of process. Unclear about value added

Responses unedited for grammar and style.

Box 4:

Vignette #1:

Ms. R is a 73 year old woman with a history of peripheral vascular disease and neuropathies secondary to uncontrolled diabetes. She uses a wheelchair at all times and is living at the homeless shelter frequented by your outreach team. She is pleasant to talk to, alert and oriented. However, you find that she has poor hygiene. You notice that she has bandages wrapped around both legs. When questioned why, she informs you that she sometimes falls from her wheelchair and scrapes her legs. On exam, you discover large, open wounds filled with maggots. You explain to her that her wounds are infected with maggots and you would like to take her to the emergency room. She refuses but agrees that if anyone were in that situation they should certainly seek medical attention.

Responses: 5/6 Responses; 1 No Response

- Evaluate her mental status (decision making capacity) and then find out if she understands the risks and benefits of treatment.
- NA
- I would try and treat some at the outreach site and then try and convince to go to ER for further help with tx.
- Utilize every potential resource to convince her of the need for tx. Outline potential consequences and secure written refusal for care. Would attempt to involve other agencies to ensure needed care was completed. "Competence eval" might prove necessary.
- Will have mental health/social worker get involved

Responses unedited for grammar and style.

Box 5:

Vignette #2:

Mr. M is a 61 year old Caucasian man being seen today in your clinic.

He has a 10 year history of diabetes and is presenting with multiple foot ulcerations and peripheral vascular disease. You have determined that his great toe on his right foot is gangrenous and needs immediate attention and possible amputation. Mr. M refuses to go to the emergency room. He has no history of a mental health disease or substance abuse disorders. He has no living relatives and is staying at the local homeless shelter.

Responses: 6/6 Responses

- Careful assessment of his real and perceived barriers to get further care, problem solving, clear explanation of risk, daily followings if continues to refuse, engagement of social work with patient, emergent psych eval
- Ask why he refuses?
 - Money- have him see DSHS social worker
 - Fear- Discuss
 - Pain- Reassure
 - If still no, counsel risk of refusal and attempt outpt tx
- Not application, PhD
- Contact patient's social worker @ the clinic. With the social worker and pt in the room, describe that this condition, if untreated, will result in death. Evaluate pt's competence via MMSE and exam. If pt is competent, set up c hospice.
- I'll offer a second opinion
- I would explain to him that his situation is life-threatening and ask why he doesn't want to go to ED. Conversation would then address resistance and offers to call taxi service.

Responses unedited for grammar and style.

Box 6:

Vignette #3:

Ms. L is a 31 year old Caucasian female with a 6 year history of schizophrenia presenting in your clinic today with sleep disturbance.

She says that she hasn't slept well in weeks and is asking you to prescribe some sleep medication. She also has worsening symptoms of schizophrenia including auditory hallucinations, delusions, and paranoia. The auditory hallucinations are becoming more abusive. She refuses to take any psychiatric medication, claiming that it makes her feel "not like herself." She wants only sleeping pills. You notice scarring on her arms and legs and are concerned that she is self-mutilating. You are unaware of any family in the area and Ms. R. is sleeping in a local park.

Responses: 6/6 Responses

- Baker Act. Referral to crisis unit.
- Evaluate mental status. Work with her on some psychoeducation that sleep may be related to voices and hear what her past experiences have been with psych meds. Review pros and cons of various options both antipsychotics and other sedatives. Often that some may also benefit sleep. Assess for safety. Review options for vol crisis unit- place to stay more safely and get stabilized.
- Prescribe sedative atypical. If refuses, try agent hasn't hear of Eg: paliperdone. If still refuses, perhaps social work to get in safe place and trazadone
- I would try and get her into a crisis bed and talk with her about meds to help sleep and though/abusive behavior issues.
- Contract for safety at of self and others. Behavioral health involvement paramount.
- Will consult with my mental health counselors to Bake Act her

Responses unedited for grammar and style.

Box 7:

Vignette #4:

Ms. T is a 35 year old woman who frequents your clinic. She has no insurance and is living on the street. She has a boyfriend but no other family in the area. She is a heavy drinker but denies other drug use. The reason for every visit to the clinic is to follow her pregnancy. You have conducted numerous pregnancy tests and have determined that she is not pregnant. However, you have noticed abdominal distension and increased abdominal girth. Because she believes that you doubt her pregnancy, she will not let you complete an abdominal or pelvic exam.

Responses: 6/6 Responses

- Discussion about why she thinks she's pregnant, what the pregnancy means to her. Use a doppler to demonstrate absence of heart tones. Inform her of alternative explorations, possible risk of liver disease, etc. Leverage her desires for pregnancy to get her to stop- drink. Close follow up. Engage psych and social work as patient persists. Warm hand offs.
- Explain that medical problem may be interfering c ability to become pregnant, thus needs testing. Offer subst abuse referral
- Not applicable, PhD
- Have pt evaluated by volunteer psychologist for mental illness or dementia. Check Uhcg, CMP and order an abdominal US.
- Refer her to psychiatrist
- If I could convince her that I was possibly wrong in my assumption and needed to perform abdo/pelvic exam as part of further investigation, then could proceed with pelvic/abdo exam. Otherwise might order further lab or US under pretense of "following the pregnancy."

Responses unedited for grammar and style.

Informed Consent With Homeless Patients
Sarah Whitley
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Introduction

Informed consent to treatment is the cornerstone of modern medicine. In American medical practice, the criteria for legally and ethically sound informed consent include capacity to consent, voluntariness, consent including capacity to consent, voluntariness, and information disclosure.¹ Capacity is a clinical determination of a patient's decision making skills and requires the ability to express a choice, understanding, appreciation, and reasoning.² Mental health disorders, substance abuse, and traumatic brain injury as well as socioeconomic variables affect capacity to consent. Because the homeless population experiences disproportionately high rates of such disorders, they may be at greater risk to lack capacity to consent. This study was designed to examine the informed consent practices of healthcare practitioners in the primary care setting of homeless that have received the federal Healthcare for the Homeless grant.

Methods

Study Population: Healthcare professionals were identified through the National Health Care for the Homeless Council Grantee Directory as grantees of the federal Health Care for the Homeless Program Section 330(h) of the Public Health Services Act. Of 185 clinics identified by this directory, 114 clinics were selected for recruitment.

Survey Design: Two surveys were composed. Survey 1, completed by the medical director, consisted of predominantly multiple choice questions regarding patient and employee demographics. Survey 2 was completed by health care professionals responsible for obtaining informed consent for treatment from patients and gathered data on the informed consent practices of that practitioner.

Data Collection and Analysis: Three anonymous surveys (one copy of Survey 1 and two copies of Survey 2) were mailed to each clinic. Of the 342 surveys sent out, 22 surveys were returned. No statistical analysis was performed because of the low response rate.

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Provider Consent Practices

Intervention	How often	1-3 months		3-6 months		6-12 months	
		Times Per Month	Times Per Week	Times Per Month	Times Per Week	Times Per Month	Times Per Week
<p>Informed Consent: Clinical Practice</p> <p>Provide Written Instructions</p> <p>Utilize Family Member as Interpreter</p> <p>Utilize a Remote Language Plan</p> <p>Patient asked to Describe Diagnostic Plan</p> <p>Patient asked to Explain Why Treatment Plan Recommended</p>	0	33.33	33.33	16.67	16.67	16.67	16.67
<p>Ad Patient Who They Believe is Wrong</p> <p>Ad Patient Who Accept to Accept Treatment Plan</p> <p>Utilize Risk Injury Screening (RBIS)</p> <p>Utilize Clinical Interview to Evaluate Capacity</p> <p>Use Validated Instrument to Evaluate Capacity</p> <p>Baroreflexed Questionnaire to Evaluate Capacity</p>	0	33.33	33.33	16.67	16.67	16.67	16.67
<p>Refer to Specialist to Evaluate Capacity</p> <p>Utilize Mini Mental State from (MMSE)</p> <p>Utilize a Remote Language Plan</p> <p>Prescribed Treatment</p> <p>Treated Patient Without Informing Patient</p> <p>Confined Side Effects or Risks to Convince Patient</p>	0	33.33	33.33	16.67	16.67	16.67	16.67
<p>Inform Patient of the Side Effects of the Treatment</p> <p>Inform Patient of the Side Effects of the Treatment</p> <p>Inform Patient of the Side Effects of the Treatment</p> <p>Inform Patient of the Side Effects of the Treatment</p> <p>Inform Patient of the Side Effects of the Treatment</p>	0	33.33	33.33	16.67	16.67	16.67	16.67

providers to obtain and evaluate informed consent. This trend demonstrates widespread use of written and verbal instructions and the MMSE. The use of clinical interview questions and techniques varied widely amongst the providers and may reflect variations in clinical training, patient population, and time constraints. Only 25% of providers utilized a clinical interview to evaluate capacity to consent on a daily basis while 25% never utilized a clinical interview. However, 91.67% used a Mini Mental State Exam (MMSE) with 50% using this tool on at least a weekly basis, despite evidence that the MMSE is a poor tool to evaluate capacity.

Vignette

Ms. T is a 35-year-old woman who frequents your clinic. She has no insurance and is living on the street. She has a boyfriend but no other family in the area. She is a heavy drinker but denies other drug use. The reason for every visit to the clinic is to follow her pregnancy. You have conducted numerous pregnancy tests and have determined that she is not pregnant. However, you have noticed abdominal distension and increased abdominal girth. Because she believes that you doubt her pregnancy, she will not let us complete an abdominal or pelvic exam.

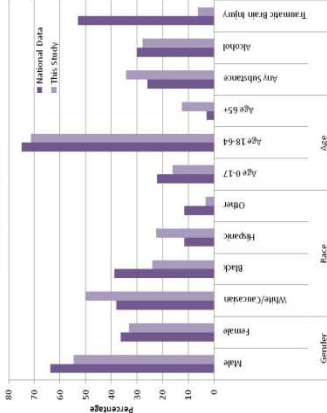
- Discussion about why she thinks she's pregnant, what the pregnancy means to her.
- Responses
- Explain that medical problem may be interfering c ability to become pregnant, thus needs testing. Offer subcutaneous referral

- Not applicable, PhD
- Have pt evaluated by volunteer psychologist for mental illness or dementia. Check UHcg, CMP and order an abdominal US.

- Refer her to psychiatrist
- If I could convince her that I was possibly wrong in my assumption and needed to perform abdo/pelvic exam as part of further investigation, then could proceed with pelvic/abdo exam. Otherwise might order further lab or US under pretense of "following the treatment."

Clinical vignettes: four clinical vignettes were randomly distributed to healthcare providers completing Survey 2. Each vignette presented a situation in which capacity to consent had to be assessed for the patient, and asked which would be in that situation, total or transferred for control, guardian, or, if none, who would be in that situation. The vignettes were: (1) a patient with a severe mental illness who had been in a psychiatric hospital for 10 years; (2) a patient with a severe mental illness who had been in a psychiatric hospital for 10 years; (3) a patient with a severe mental illness who had been in a psychiatric hospital for 10 years; (4) a patient with a severe mental illness who had been in a psychiatric hospital for 10 years.

Homeless Demographics



Patient Demographics: Compiled patient demographic data from Survey 1 and Survey 2

compared to national data on homelessness demographics obtained from the US Conference of Mayors in 2005 and the 2009 Homelessness Assessment Report.¹ This study correlates closely with national data as the typical¹ homeless patient seen in male, ages 35-44, Caucasian, achieving no higher than a high school education, living in a shelter, and with a history of substance abuse. The 2009 National Homeless Assessment Report found that 62% of homeless persons living in the United States belonged to an ethnic minority, with African American people being the most common. However, this study found that on average 50.2% of patients were identified as White/Caucasian. Patients utilizing shelters as primary housing are also overrepresented in this sample. Rates of mental health disorders and substance abuse were consistent with national data. Despite the evidence for significant prevalence of mental health disorders in this study, only 10% of patients were screened for mental health problems. Informed consent in this study found that 6.25% of their patients on average had a diagnosed brain injury or traumatic head injury.

patient refuses treatment. what do you do?

1. **Voluntary treatment.** Right questions revolve for their concerns. What are the risks and benefits? For a person of ethical, and try to address obstacles. For the sake of the patient, and the doctor, and the society.

If you determine patient lacks capacity to consent, what obstacles do you face when seeking legal determination of incompetence?

- I have not told this situation yet
 We do not seek legal determination. Attempt to get social services or APS to intervene
 Secure administrative assistance and thus not an obstacle
 ?
 I have presented with family, advise them about issue re: medical power of attorney, etc./guardianship
 Little. The time has a lawyer who can resolve these issues
 General mental health professionals deemed necessary to determine competence/decisional ability
 Unsure
 No time, unsure of process. Unclear about value added

perceived obstacles to informed consent on Survey 2. Data is unfiltered for content, grammar, or relevance as free text responses on Survey 2. Participants responded to each question, or a subset of questions, depending on the question they were asked. Of the twelve surveys returned, nine participants responded to each question, one participant responded to 11 questions, and one participant responded to 10 questions. When faced with patient refusal/treatment, respondents frequently gave "best practices" answers and may not reflect true practices. Answers demonstrate that respondents do not see a reason for a legal determination of incompetence or do not see barriers to obtaining the legal ruling.

Conclusions

1. This study correlates strongly with current literature that recognizes high rates of substance abuse, mental health disorders, and other risk factors for cognitive deficits. Recognizing these risk factors is necessary for clinicians when considering informed consent practices and capacity to consent.
2. Due to the extremely poor response rate, no data of statistical significance was found and the study must be handled as a pilot study.
3. It is unclear if the responding clinics and healthcare providers represent the clinics with best-practices, worst-practices, or are a representative sampling of clinics
4. Every clinician has room for improvement and current informed consent practices are not yet ideal.

Future Directions

- Response rates may be increased by online surveys, offering incentives to participants, and reducing the length and complexity of the survey tools.
- It would be interesting to examine correlations between clinic site, clinic demographics (including funding sources, employment characteristics), patient demographics, and provider demographics with informed consent practices and concerns.
- Future research could also use this data and compare with similar data from providers seeing non-patients to see if informed consent practices are different between the two populations.
- Research into informed consent practices that yields accurate data may be impossible to perform. All study methods are significantly flawed. This leaves us with an empirical agnosticism; the answers to pressing questions may simply not be knowable. We are currently planning future research into the availability to research such ethical questions.

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