Appendix 1: Unanalyzed Qualitative Data

Box 1:

Situation in which provider is primary decision maker
• 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.

Informed Consent With Homeless Patients

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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 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 disproportionally 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 clinics 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.

Acknowledgements

I would like to thank the following people for their support and guidance throughout this project:

• Tyler Coles for creating of the custom web-based data entry portal and database.

• Dr. Jason Robert for his mentoring and guidance.

This project is dedicated to Healthcare for the Homeless Clinics. We are forever grateful to the wonderful, loving, compassionate care you provide.

Provider Consent Practices

Informed Consent Clinical Practice	Never	1-3 Times Per Month	1-5 Times Per Week	1-5 Times Per Day	6 or more times per day
Provide Written Instructions	0	33.33	33.33	16.67	16.67
Provide Verbal Instructions	0	0	8.33	0	91.67
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

Informed Consent Practices by Providers: Patient Informed consent practices by healthcare providers to obtain and evaluate informed consent. This data 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 a least a weekly basis, despite evidence that the MMSE is a poor tool to evaluate capacity.

Vignette

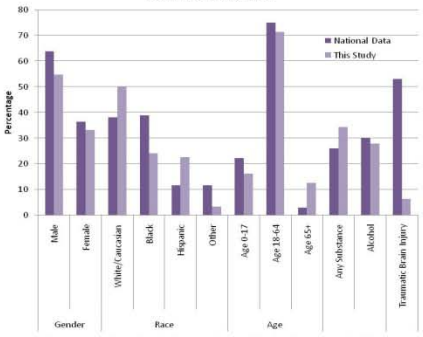
Ms. T is a 35 year old woman who frequents your clinic. She has no insurance and is living on the street. She has a boyfriend but no other family in the area. She is a heavy drinker but denies other drug use. The reason for every visit to the clinic is to follow her pregnancy. You have conducted numerous 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 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."

Clinical Vignettes: Four clinical vignettes were randomly distributed to healthcare providers completing Survey 2. Each vignette presented a situation in which capacity to consent may be lacking and the provider was asked what each would do in that situation. Data is unedited for content, grammar, or style. This vignette had six responders and demonstrated a variety of approaches to the question. This demonstrates how free text evaluation of informed consent issues may not provide real insight into actual practices. Clinicians to provide the "best" answer, rather than a true answer. They may fear admitting inadequate 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. It must be considered that these practices are absolutely what they practice but cannot be verified in this format.

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[3]. This study correlates closely with national data as the typical" homeless 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. A significant exception is 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 race 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 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.

If patient refuses treatment, what do you do?

- 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.

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

Perceived Obstacles to Informed Consent by Providers: Unanalyzed qualitative data obtained as free text responses on Survey 2. Data is unedited for content, grammar, or style. Of the twelve surveys returned, nine participants responded to each question. When faced with patient refusing treatment, respondents frequently gave "best practices" answers and may not reflect true practices. Answers demonstrate that responders do not see a reason for a legal determination of incompetence or do not see any 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 secure surveys, offering incentives to participants, and reducing the length and complexity of the survey tools.

• 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.

• Future research could also use this data and compare with similar data from providers seeing homed 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 ability to research such ethical questions.

Literature Cited

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