Methods to Improve Informed Consent Procedures for Research Subjects with Low Literacy: A Systematic Review

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Background: Research subjects do not adequately understand information presented to them during the informed consent (IC) process. Inadequate health literacy may exacerbate the limited understanding of the informed consent. The purpose of this study is to evaluate the evidence supporting interventions to improve comprehension of the IC process in low literacy research subjects.

Methods: A MEDLINE database search (1966 to November 2011) supplemented by manual searches of bibliographies of key relevant articles was performed. We selected all studies in which an intervention was tested to improve comprehension of informed consent and the intervention was evaluated in low literacy populations. The main outcome evaluated was comprehension measured using written test or verbal comprehension.

Results: Our search strategy yielded 58 studies, of which only 4 met our eligibility criteria. The four studies included 593 research participants. The table summarizes the results of each study. The studies predominantly included populations that were older (median age 61 range 49-64), ethnic minority, and with literacy level of 8th grade or below. Only one study had a randomized design. The specific intervention differed in each study. Two of the studies included the teach-back method or teach to goal method and achieved the highest level of comprehension. An intervention that involved changing the readability level of the informed consent document resulted in the lowest comprehension among study subjects.

Conclusions: The evidence supporting interventions to improve the informed consent process in low literacy populations is extremely limited. Efforts to improve understanding through the use of multimedia and enhanced consent forms have had only limited success. As in the field of health education having a study team member spend more time talking one-on-one to study participants is the most effective available way of improving research participants understanding. Additional research is needed because of the lack of randomized controlled trials.
Trends in Ethics Consultation Practices in a Large Health System

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Background: The discipline of health care ethics consultation (EC) has been limited by the lack of both high quality data and quality standards. To promote high quality ethics consultation practices, staff at the National Center for Ethics in Health Care within the Veterans Health Administration (VHA) developed 2 specific EC tools, ECWeb and the EC Feedback Tool. ECWeb is a web-based database tool that promotes process standards consistent with “CASES,” VA’s systematic approach to ethics consultation. The EC Feedback Tool, which links to ECWeb records, enables consultation participants to rate their experience on various aspects of EC. This paper describes the ethics consultation requests, processes, and evaluations from all facilities in our system.

Methods: We analyzed data from completed ethics consultations from ECWeb records initiated between October 2008 and September 2011. For each consultation record, users documented in ECWeb the data related to utilization of the EC service (e.g., type of consultation request, requester role (i.e., physician, nurse, patient). Additionally, ECWeb users documented, as applicable, various processes performed during the ethics consultation (e.g., capacity assessment (y/n), a face-to-face patient visit (y/n), and if the consult was identified as being symptomatic of underlying issues that are best addressed at the systems level). The EC Feedback Tool asked respondents to rate the ethics consultant(s) on 12 specific ethics knowledge and skill areas as well as their overall experience with ethics consultation, both on a 5 point Likert scale.

Results: We analyzed ECWeb data for 4628 completed consults from 140 facilities across the VHA health system. Median consultation volume per facility was 7 in 2009 (mean = 9.6, range = 0-60), 8 in 2010 (mean = 12.4, range = 0-106), and 8 in 2011 (mean =12.1, range = 0-119). The majority of consultations were classified by the consultants as related to shared decision making (73%). Most consultations (63%) related to patients in the inpatient setting, 25% in the outpatient setting, and 10% in long term care settings.

EC processes showed minimal change over the time period studied with the exception of an increase in underlying systems issues recorded from 37% in 2009 to 42% in 2011.

Of all completed ethics consultations, 32% had at least one evaluation recorded. From 2009 to 2011, participant ratings improved for the overall experience, as well as for all 12 specific knowledge and skills. In particular, ratings of the consultant on “providing a helpful service” and “clarifying decisions that had to be made” rose from 85% to 89% and 79% to 85% respectively over the time period studied.

Conclusions: Data from over 4,500 ethics consultations highlight the current trends in ethics consultation requests, processes, and evaluations in our integrated health system. Developing and implementing these EC tools has set EC standards for VHA, helped to promote a quality improvement approach to EC practices, and in the case of participant satisfaction, demonstrated improved ethics quality.

Further work is needed to establish relationships between these data elements and other measures of EC quality such as desirable outcomes and overall content quality. Wider adoption of EC standards outside of VA is recommended to better understand EC practices and improve EC quality as well as to establish its accountability.
Financial Considerations in Residents’ Decisions About End-Of-Life Care

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Background: One of the most contentious issues in end-of-life care is that of financial concerns in decisions made on the behalf of patients by patients’ surrogates. While physicians emphasize the emotional cost involved, some patients emphasize the financial costs, including the fear that the patient’s family would suffer financially if the patient died. Since there have been no studies which examine physicians’ decisions to withdraw life-sustaining treatment based on the influence of surrogates’ financial gain from such decisions we studied internal medicine residents regarding their attitudes about withdrawing life-sustaining treatment when financial considerations are involved.

Methods: A survey was developed which was pre-tested for face and content validity among 40 general internal medicine physicians. The survey contained 8 scenarios in which a patient who was terminally ill and lacked capacity had a decision to make regarding withdrawal of the ventilator. The life sustaining treatment had been deemed by the ethics committee to be medically futile. Nested variables included agreement or disagreement between the surrogate and patient, decision to withdraw or continue the ventilator, and financial gain or no financial gain for the surrogate based on the decision. Residents were asked how likely they were to withdraw the ventilator in each scenario based on a 4 point Likert scale. The survey was administered to all internal medicine residents at UCSD. The differences between scenarios in which there was the presence or absence of each of the three nested variables was analyzed via T tests.

Results: Residents were more likely to withdraw the ventilator when requested to do so, than when it was requested to be continued, despite the scenario indicating futility of care (p < 0.001). They were also more likely to withdraw the ventilator when there was agreement in the decision between the surrogate and patient (p < 0.001). Residents were more likely to withdraw or withhold the ventilator when financial benefits were not an issue for the spouse, than when the spouse was likely to accrue such benefits (p = 0.032). This difference was largely due to the scenario in which there was disagreement between the surrogate and patient but in which the ventilator was requested to be removed, where residents were significantly more likely to remove the ventilator when financial benefits were not to be accrued by the surrogate (p = 0.02).

Conclusions: Internal Medicine residents make some decisions about whether to withdraw life sustaining treatment based on financial considerations for the patient’s surrogate. Residents also make such decisions based on the wishes of the surrogate and the agreement or disagreement of the patient and surrogate, despite determination of futility by and ethics committee. There needs to be ongoing communication with residents and education about end-of life decisions in terminally ill patients where conflicts may exist between the surrogates and patients and between the surrogates and physicians.
HIV Knowledge and Testing Among Pregnant Women In Rural Mozambique: Validation of the HIV Knowledge Scale-27 (HK-27)

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Background: The prevalence of HIV infection in Mozambique was 14% among women in 2009, yet it is estimated only 18% of women have comprehensive HIV knowledge. Limited knowledge may have negative implications for testing uptake and treatment adherence, but research has been limited by the lack of a comprehensive, validated instrument to measure HIV knowledge in Mozambique.

Methods: We adapted items from existing measures of HIV knowledge (HIV-KQ-45, BSS, DHSAIDS) and added items about HIV treatment. The adapted scale (the HK-27) was translated into Portuguese and Echuabo and orally administered to women seeking prenatal care at two clinics in rural Mozambique. The HK-27 consists of 27 items that assess knowledge across several HIV content domains; for each item, respondents could agree, disagree, or state that they were uncertain. A summary score is based on the percent correct (range 0-100%). Sociodemographic characteristics and HIV testing were determined by self-report. HIV status was abstracted from medical records. Analyses were stratified by survey language. Kuder-Richardson (KR-20) coefficients estimated internal reliability. Construct validity was established by testing bivariate associations between HK-27 score and sociodemographic characteristics chosen a priori. The association between knowledge and HIV test utilization was estimated by multivariable logistic regression.

Results: Participants (N=348) had a median age (IQR) of 24 (20-28); 188 spoke Portuguese, and 160 spoke Echuabo. Over half (57.6%) had no formal education. Mean HK-27 scores were higher for Portuguese-speaking participants (68.3, SD 18.6) than Echuabo-speaking participants (42.2, SD 22.6). Internal reliability was strong (KR-20>0.8) for scales in both languages. Higher HK-27 scores were significantly (p≤0.05) correlated with more education, more media items in the home, and maternal work outside of the home (Table 1). Eighty-five percent of women reported past HIV testing. Women with higher HIV knowledge had higher odds of past HIV testing, even after adjusting for study language, site, travel time to the clinic, and maternal work in the multivariable model (aOR 5.0, 95%CI:1.2-22.1, p=0.03).

Conclusions: HK-27 is a reliable and valid measure of HIV knowledge of Portuguese and Echuabo-speaking women seeking prenatal care in rural Mozambique. HIV knowledge was higher than in previous estimates, though gaps remain especially for non-Portuguese speakers. HIV knowledge was associated with HIV testing in this cross-sectional sample, though the study design limits its ability to prove causation. Further work should explore the relationship among HIV knowledge and health-seeking behaviors in low income settings.
A Systematic Review of Longitudinal Population-Based Studies On The Predictors Of Smoking Cessation In Adolescent And Young Adult Smokers

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Background: Tobacco use causes more than five million deaths worldwide annually. In Canada in 2009, the prevalence of smoking was 13% among adolescents aged 15-19 years, and 23% among young adults aged 20-24 years. Many young smokers express the desire to quit, but most have a great deal of difficulty doing so. Empirical reviews have generally concluded that smoking cessation programs in youth have limited efficacy. In order to provide a solid knowledge base for future tobacco control interventions, the determinants of self-initiated cessation of duration of at least 6 months in youth need to be better understood.

Methods: A systematic search of the PubMed and EMBASE databases using smoking, tobacco, cessation, quit and stop as keywords was performed. Limits included articles related to humans, in English, published between January 1984 and August 2010, and study population aged 10-29 years. A total of 4502 titles and 871 abstracts were reviewed independently by 2 and 3 reviewers, respectively. Nine articles were retained for data abstraction. The number of studies that reported a statistically significant association between each determinant investigated and cessation were tabulated, from among all studies that assessed the determinant.

Results: Three of the nine studies retained defined smoking cessation as abstinence of at least 6 months and six studies defined it as abstinence of 12 months. Despite heterogeneity in methods across studies, five factors robustly predicted quitting across studies in which the factor was investigated: not having friends who smoke, not having intentions to smoke in the future, resisting peer pressure to smoke, being older at first use of cigarette and having negative beliefs about smoking. Additional factors are significant in some studies but not others or only once assessed.

Conclusions: The literature on longitudinal predictors of cessation in adolescent and young adult smokers is not well developed. Cessation interventions for this population will remain less than optimally effective until there is a solid evidence base on which to develop interventions.