Consenting Adults: An Innovative Informed Consent Workshop

The Problem

As much as BIDMC is committed to an informed consent process that is patient-centered and respectful of cultural and linguistic characteristics, it was recognized that education on the informed consent process was provided separately for researchers and for clinicians and at the same time, the process of obtaining informed consent can be similar in both domains. There were also opportunities to make available specific guidelines for construction and vocabulary of a patient-readable form as clinicians and researchers obtaining informed consent could benefit from clear and specific instruction to obtain informed consent that allows for maximal patient/subject understanding of the material.

Aim/Goal

To develop an educational program for members of the BIDMC community that would teach clinicians and researchers alike how to perform the informed consent process more comfortably and effectively while also making it more patient-centered.

The Team

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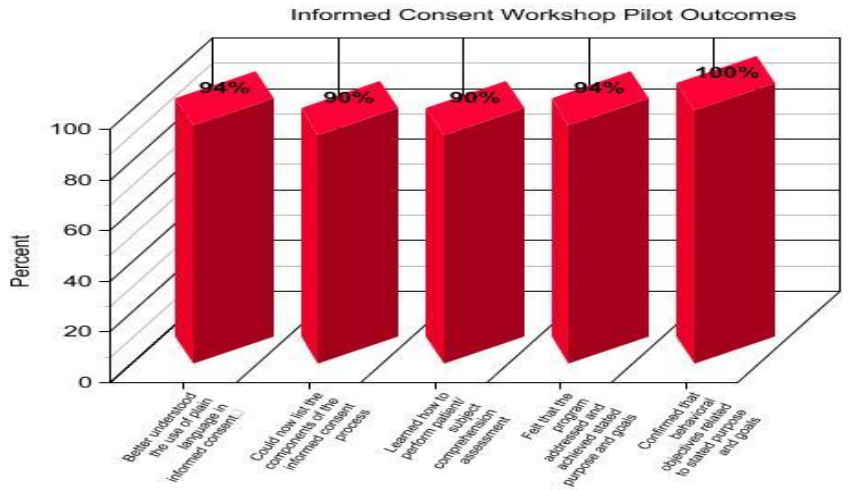
The Interventions

- Meetings to identify similarities and differences in the informed consent processes for clinical and research purposes.
- Developed a pilot informed consent program that was presented on 10/29/09.
- Prepared a compendium of resources to aid clinicians and researchers in the informed consent process
- Review of pilot program's participatant evaluations and feedback to improve subsequent programs.

The Results/Progress to Date



Lessons Learned

There is great interest and demand for resources to help clinicians and researchers with the informed consent process for patients with low health literacy, and/or from diverse cultural and linguistic backgrounds. Both verbal interpretation of procedures/protocols and written translation of the informed consent form require financial resources for which funds are not routinely set aside. Working with the Clinical Trials Office, we have been able to create a mechanism through which questions about interpretation and/or translation are asked during the research approval process.

Next Steps/What Should Happen Next

- Second pilot program to be presented on 1/28/2010.
- Publish an on-line resource tool-kit to include information on health literacy, a thesaurus of plain language medical terms, interpreter services and translation sources.
- We will offer opportunities for participants to be observed performing informed consents – both for clinical consents and research studies.

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