2018

The Effect of Electronic Informed Consent Information (EICI) on Residual Newborn Specimen Research

NCT03141307

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Hospital EICI intervention protocol

3/6/2018

Run-in Phase

We will conduct a "run-in" of the EICI in each of the participating hospitals with 10 women and then will conduct a follow up interview with all of these participants.

Inclusion and Exclusion Criterion

Inclusion criteria for the intervention include: adult (≥ 18 years) English speaking women who are already being approached for participation in the BioTrust.

Exclusion criteria include mothers of infants that are in the NICU and any situation adoption or legal guardianship is unknown at the time of birth.

Recruitment

Our research procedures are designed to mirror the current practice at the individual hospoitals as much as possible. Typically, nurses discuss the BioTrust informational brochure shortly after moving into the Mother & Baby unit as part of the packet of information related to their stay in the unit. Once the baby is 24 hours old, the nursery tech comes to complete newborn screening and asks for BioTrust consent at that time.

Our approach will use a full time research assistant (RA) at each hospital. All potential participants will receive the brochure as part of standard practice during their welcome to the Mother & Baby Unit. At some point after admission to the Unit, the RA will approach the patient, briefly describe the study and content of data collected, and seek verbal consent for participation in the study. If they consent, the RA will activate the study-provided electronic tablet to see the study group assignment; study staff and healthcare providers will be blind to the study group assignment until this point. Participants will be randomized into the video intervention group (Group A), interactive intervention group (Group B), or standard of care group (Group C). The patient will then complete the intervention (Groups A and B) or continue the BioTrust discussion with the nurse (Group C).

Intervention Groups A and B

Following randomization, participants in Groups A or B will be given the electronic tablet with the intervention loaded on the screen and provided with instructions. In order to allow particpants as much time as necessary to explore the app, the RA will leave the room while the patient is working on the tablet and return within an hour to pick up the tablet. Participants in Group A will be asked to watch a 6-minute video about what it means to consent to have the NBS bloodspots retained by the Michigan BioTrust. Participants in Group B will be provided with the same information in an interactive app form, and will be asked to explore the informational sections at their preferred level of depth. After the video ends or participants

reach the end point of the educational app, they will automatically be directed to complete the associated questionnaires. When the RA returns, she will collect the tablet and provide the participant with a $25 gift card to Amazon. The next day, the Nursery Tech will visit the patient's room to gather NBS bloodspots and consent for the BioTrust, following the **standard consent process**.

Control Group C

Participants who are randomized to Group C will complete the questionnaires immediately following the BioTrust discussion with the nurse. The RA will stay in the room while the surveys are being completed then provide the participant with a $25 gift card to Amazon. The next day, the Nursery Tech will visit the patient's room to gather NBS bloodspots and consent for the BioTrust, following the **standard consent process**. The RA will review collected consent cards to document the patient's choice to consent or deny.

Survey Tools

All participating women will complete a survey 1) immediately following the intervention/control on the electronic tablet and 2) by telephone 2-4 weeks follow up. Participants will receive an additional $25 gift card to Amazon after the follow-up survey. Outcome measures include:

- knowledge of the elements of consent and key aspects of the biobank
- decisional conflict
- satisfaction with the consent process and attitudes toward the clinical program the samples were collected for and research with these samples
- rates of parental permission

We will also collect demographic information on the participants and contact information for contact by telephone 2-4 weeks later. All identifying information will be kept in a secure data storage system separate from data used for analyses.

Partners

Research indicates that the partners of pregnant women are typically not *approached* for consent for the retention of specimens in the biorepository.[24] Our Process Observations revealed that fathers were in the room during the consent process in roughly half of the cases and were vocal and involved in the process in two thirds of those situations. Therefore we will not attempt to recruit those who are in the hospital although partners will be welcomed to participate in the intervention if they are present. The role of partners may be important in decision-making about biobanking whether or not they are typically approached. All participants will be asked in the 2-4 week follow-up survey about the role of their partner in decision-making about specimen biobanking. Additionally, whoever completed the survey in the hospital will be the same person to complete the 2-4 week survey, regardless of status as birth mother or partner.

Clinical Site Coordination

Drs. Rothwell, Botkin and Johnson along with Ms. Langbo from the Michigan Department of Health will provide guidance for the coordination of the clinical sites. Drs. Botkin and Rothwell will visit each site prior to implementation of data collection to introduce the project to staff and discuss issues sites may have. To ensure success, there will be at least weekly meetings with all three site RA and the Research Director, Dr. Johnson. RAs will provide weekly reports of activities and recruitment. In addition, we will hold monthly teleconference with the research team and the Site PIs to discuss any larger issues and potential adverse events. Consistency among the sites will be monitored with these reports and communication strategies. Research team coordination with communication and meetings is based on the successful accomplishment of previous research project (R01 HD058854).

Analysis Plan

Summary statistics for baseline demographics (age, ethnicity, race, income, etc.) will be calculated and reported for each intervention group (App or Video) versus Control. We will utilize multilevel generalized mixed modeling (via SPSS and R) under an intent-to-treat (ITT) approach to compare primary, secondary outcomes, and exploratory outcomes.

Hypothesis Testing: To evaluate the fixed effect of the two different groups upon knowledge we will utilize a single level model that includes the fixed effect of group (G).

$$Y_i = [\gamma_0 + \gamma_1 G_i] + [\zeta_i + \epsilon_i]$$

where Y is the composite score for knowledge. **G** is an indicator for the different groups (App or Video, Control). We will set alpha = 0.05. The two group model reduces to a 2 sided, t-test approach.