STRIDE & eConsent: Moving Towards Personalized Informed Consent

12.14.17

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Objectives For Today

• STRIDE Grant Overview

• eConsent Discussion
  o Discussion of New REDCap eConsent Add-Ons
  o Questions, Feedback, Idea Generation
The Goal

To improve racial and ethnic minority recruitment in clinical trials by creating culturally relevant tools and interventions.
STRIDE Specific Aims

**Aim 1:** Expand 3 previously developed intervention components: *Storytelling* for promotion of research literacy; *Simulation-based training* for improving culturally appropriate recruitment and informed consent; *eConsent*

**Aim 2:** Test *effectiveness* of STRIDE multi-modal intervention to improve participation of African Americans and Latinos *in ongoing clinical trials* at each of 3 partnering CTSA hubs

**Aim 3:** Promote *widespread translation/dissemination* to CTSA hubs, other research institutions and community organizations
STRIDE is a Three CTSA Collaboration

**UMASS University of Massachusetts Medical School**
- **Simulation**: training research assistants to be culturally aware when consenting participants
- **Storytelling**: participant stories to increase understanding of clinical trials

**VANDERBILT UNIVERSITY MEDICAL CENTER**
- **eConsent**
- **Community Studios** to provide feedback on intervention components
- **Dissemination**

**UAB SCHOOL OF MEDICINE**
- Intervention pilot testing
- Integrating components (storytelling, simulation, eConsent) into existing clinical trials

*STRIDE: Strengthening Translational Research in Diverse Enrollments*
Community Investigators

Fred Jenoure, UMMS
Jackie Simms, VUMC
Clarice Davis, UAB

Community Engagement Studios

Collaboration with Community Campus Partnerships for Health (CCPH)
STRIDE Intervention Approach

• Comprehensive, multi-component approach

• Aims to provide clinical trial research teams with the training and tools for culturally adapted informed consent
STRIDE Intervention Steps

1. **Develop** with community input
2. **Evaluate** in collaboration with ongoing clinical trials
3. **Disseminate** throughout the CTSA program and Trial Innovation Network
Research Assistant (RA) Training

• Simulation-based training
• Training based on previously established core competencies
• 2-day training at UMass Medical School
• Community Members serve as “acting research participants”, similar to standardized patients
eConsent

Research Assistant Training

Storytelling
Storytelling - Stories about Participation in Clinical Research

• Short video stories
• Real participants in clinical trials
• Describe personal experiences with research
• Used as an ancillary to eConsent
  • Introduce potential participants to what research is
  • Clarify what research is during the informed consent process
STRIDE Intervention eConsent

- Delivered using REDCap
- Covers all traditional elements of consent
- Adds new elements:
  - Video Library
  - Avatars
  - Hover-over definitions
  - Plan to ensure Part 11 compliance
eConsent - Video Library

• Collection of videos for 8-10 most commonly consented research procedures, available through REDCap
• IRB will review videos post production
• Videos informed by community feedback and scripts reviewed by Vanderbilt Effective Health Communication Core

Videos embedded in eConsent in-line or as a link
STRIDE: Finalized MRI, CT, PET videos

Dunkel, Leah
Harris, Paul; Lawrence, Colleen
Friday, December 1, 2017 at 3:41 PM

Show Details

This message is flagged for follow up.

Paul and Colleen,

Below you will find links to the first 3 (including the CT with contrast variant) finalized STRIDE videos:

MRI
CT with Contrast / CT PET

Please let me know if you have any questions or if there are any changes you would like me to make. Hopefully, we avoided any typos this time around.

Many thanks,
Leah

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Lumbar Puncture (V1): https://youtu.be/Daq99bbrvQg
Lumbar Puncture (V2): https://youtu.be/LCwac1wJc
Echo diagram: https://youtu.be/ID2Xc7e-6Jo
5 Strategies to Boost Participation in Clinical Trials: https://youtu.be/ZN0deRbfID0M
We’re making life better (extended): https://youtu.be/2wa5ie5P4s
We’re making life better (short): https://youtu.be/XPixU/YCHhir
Considering Clinical Trial Participation? Here’s what to ask: https://youtu.be/XHE8enZI
Importance of Clinical Trials (with CW): https://youtu.be/90JXVigK3I

There’s one more in the works (Importance of Engagement) from Consuelo’s interview, but we’re still working to get that one uploaded. May be later this week / early next week.

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Development and pilot testing of a video-assisted informed consent process.
Author information
Abstract
The informed consent process for research has come under scrutiny, as consent documents are increasingly long and difficult to understand. Innovations are needed to improve comprehension in order to make the consent process truly informed. We report on the development and pilot testing of video clips that could be used during the consent process to better explain research procedures to potential participants. Based on input from researchers and community partners, 15 videos of common research procedures/concepts were produced. The utility of the videos was then tested by embedding them in mock-informed consent documents that were presented via an online electronic consent system designed for delivery via iPad. Three mock consents were developed, each containing five videos. All participants (n = 61) read both a paper version and the video-assisted iPad version of the same mock consent and were randomized to which format they reviewed first. Participants were given a competency quiz that posed specific questions about the information in the consent after reviewing the first consent document to which they were exposed. Most participants (78.7%) preferred the video-assisted format compared to paper (12.9%). Nearly all (96.7%) reported that the videos improved their understanding of the procedures described in the consent document; however, the comprehension of material did not significantly differ by consent format. Results suggest videos may be helpful in providing participants with information about study procedures in a way that is easy to understand. Additional testing of video consents for complex protocols and with subjects of lower literacy is warranted.

Videos on youtube:
BODPOD: https://www.youtube.com/watch?v=FxMiFzmPMQc
DEXA: https://www.youtube.com/watch?v=DDFcvXmmpVI
BIOPSY: https://www.youtube.com/watch?v=mz4D1BcFNa4
MRI: https://www.youtube.com/watch?v=eoqqWkkx5SBA
CAT SCAN: https://www.youtube.com/watch?v=1sjgw_SscYs
ULTRASOUND: https://www.youtube.com/watch?v=SkK922_ZXk8
Biorepository: https://www.youtube.com/watch?v=3cT9VFXNP3w
Infusion: https://www.youtube.com/watch?v=CABoH6E8A
STRIDE Intervention Evaluation

- Quasi-experimental design:
  - Intervention: Integration into ongoing clinical trials at UAB, UMass and Vanderbilt (n=3 trials)
  - Comparison: Usual protocol (n=3 trials)

- Interrupted time-series design

- Assess number/rates of recruitment of under-represented minorities before and after the STRIDE intervention is introduced
STRIDE Intervention Dissemination

• Scientific publications
• REDCap consortium
• CTSA conferences and other channels
• STRIDE Toolkit
Objectives For Today

• STRIDE Grant Overview
• Call to Action - STRIDE Grant Participation

• eConsent Discussion
  o Discussion of New REDCap eConsent Add-Ons
  o Questions, Feedback, Idea Generation
(According to the PI – Paul Harris)
bored.
bored.
Patients can “sign” an eConsent document by:

- Typing in their name
- Signing their name via stylus/finger
- Entering a personalized PIN number
eConsent - Avatars

• eConsent platform will use Avatars to guide participants through the consent process

• Scripted voice-over

• Avatar can respond to questions, repeat information and provide additional information
eConsent - Hover-Over Features

• Participants may hover-over keywords to see pronunciation, definitions or more information about a word

• Gives participants ownership

• Researcher will determine keywords and information that appears

Each year on the first Wednesday in June, people across the United States participate in National Running Day. This day was designated as a day for runners to reaffirm their passion for running.
eConsent – Part 11 Compliance

• Virtual repository to serve as an institution-wide “lock box” for consents
• Specific meta-data elements can be used to link consents in the repository to their respective studies
• Working with Vanderbilt, UMass, UAB IRBs to ensure this repository will fulfill standards of Part 11 compliance
Participants wishing to see the entire consent document before continuing with the consent process can download and view it by clicking on the link below.

Attachment: VirtualConsentMockUp_VirtualCo.pdf (0.05 MB)

What will happen and how long will you be in the study?

You will be given an MRI before and after the 6 month study period. If you would like more information please watch the short informational video below.
NOW YOU'RE TALKING. We're listening.
For More Information About STRIDE or eConsent or Video Library

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• Video links:
  o STRIDE:  
    https://www.youtube.com/channel/UCKOqWFdtVU7XsxWs2fpfvNQ/videos?disable_polymer=1