

Teleconsenting as a Method for Facilitating Clinical Research Enrollment in a Population with Healthcare Disparities.

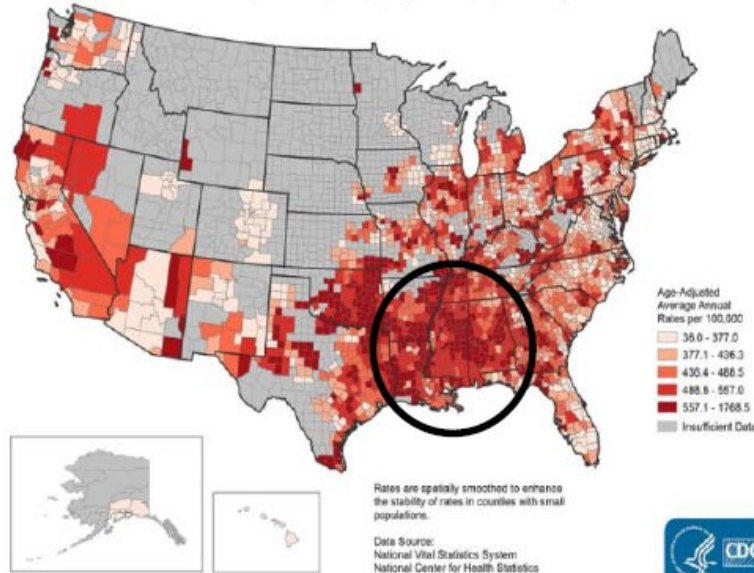
Donald Clark III, MD, MPH, Richard L. Summers, MD



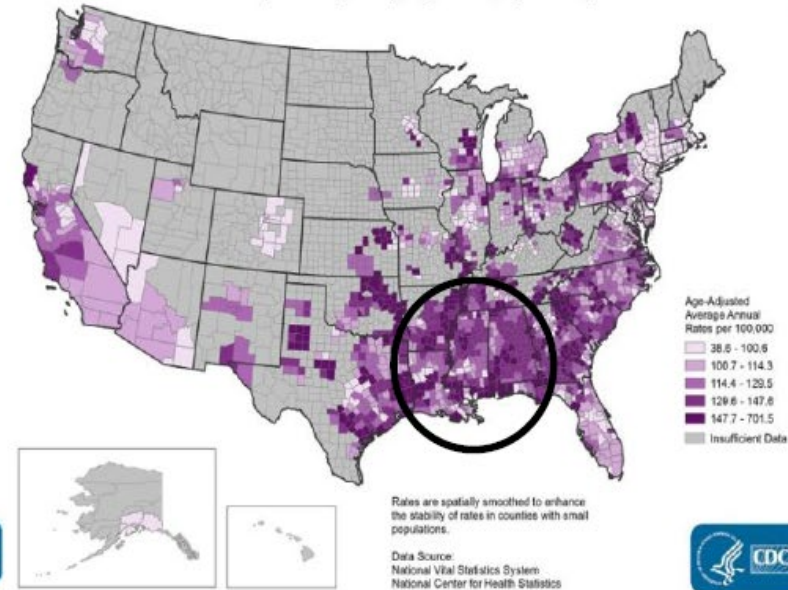
Acknowledgement

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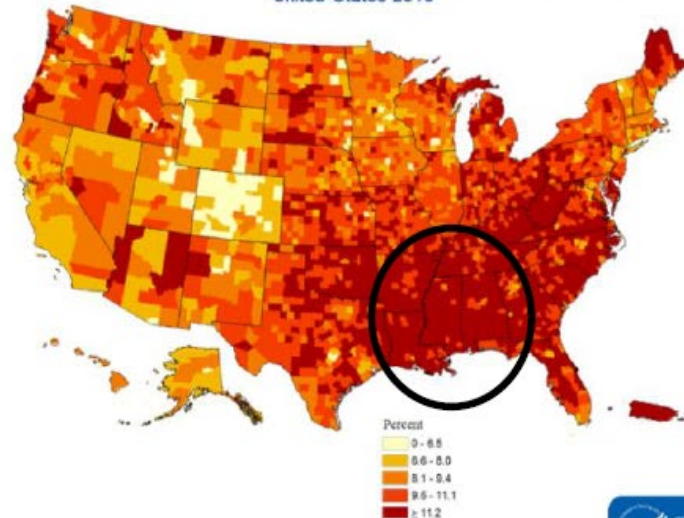
Heart Disease Death Rates, 2008-2010
Black (non-Hispanic), Ages 35+, by County



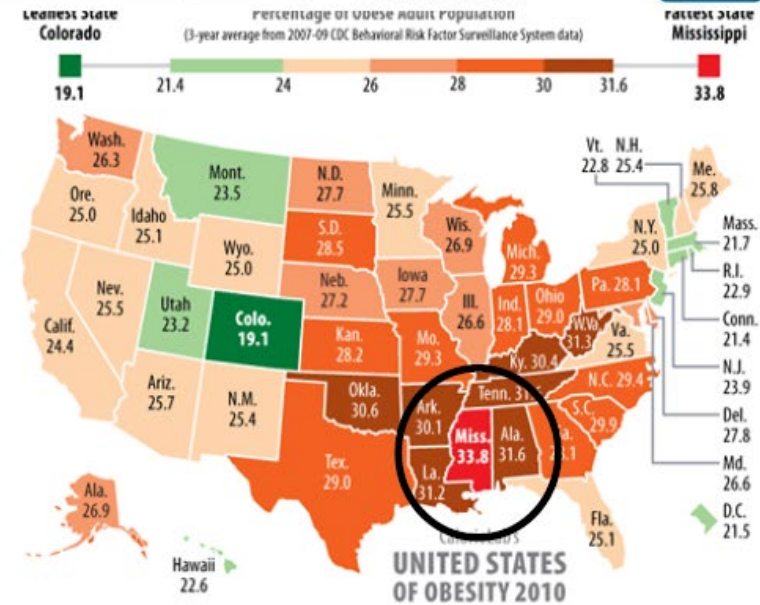
Stroke Death Rates, 2008-2010
Black (non-Hispanic), Ages 35+, by County

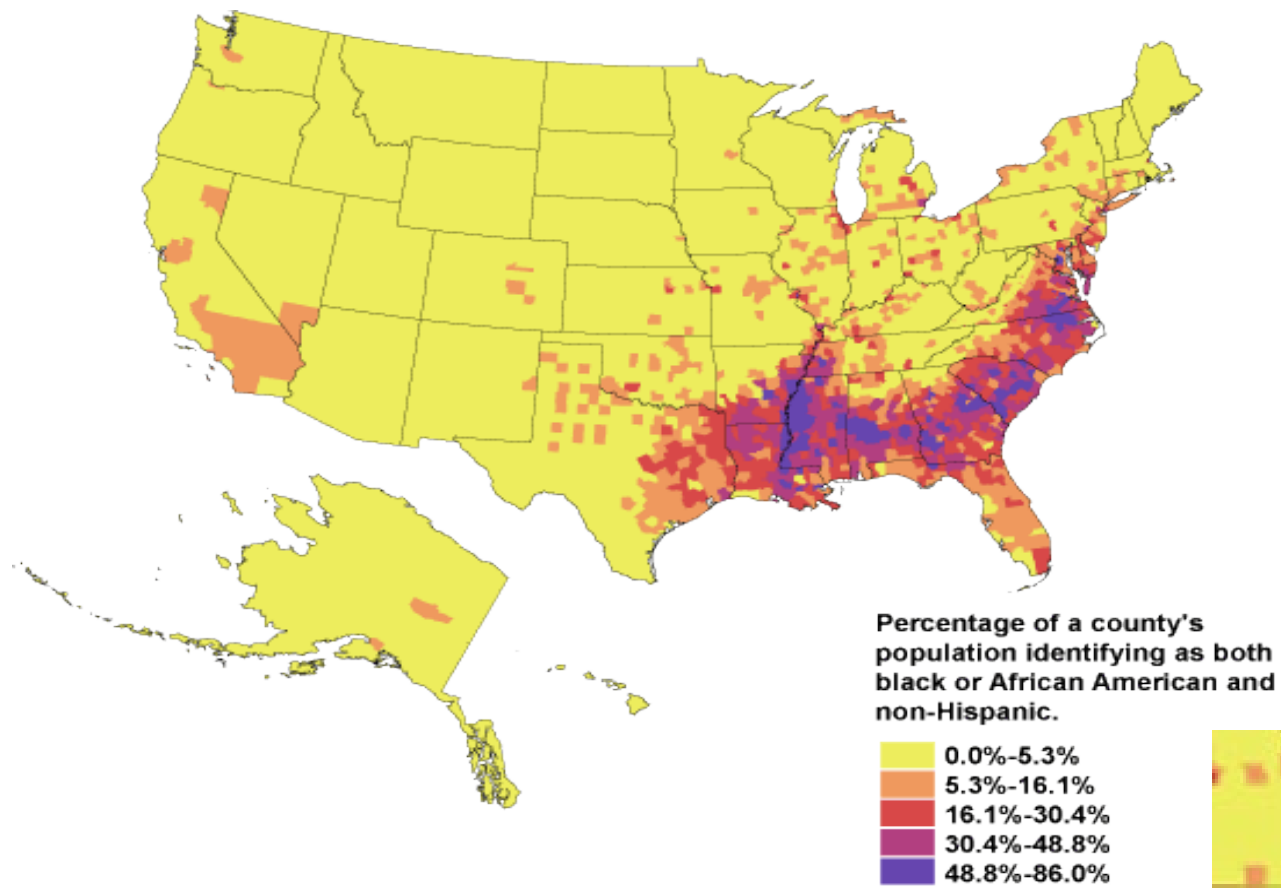


County-level Estimates of Diagnosed Diabetes among Adults aged ≥ 20 years:
United States 2010

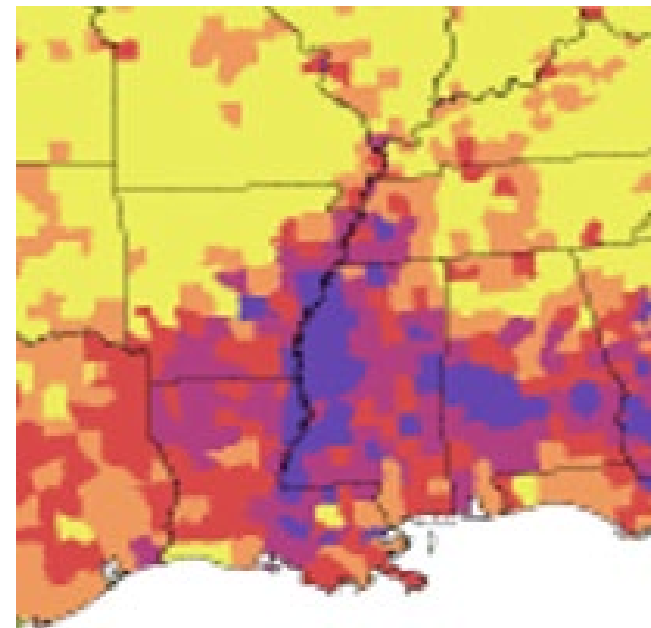


www.cdc.gov/diabetes





U.S. African American Population



UIMMC Presence Across the State





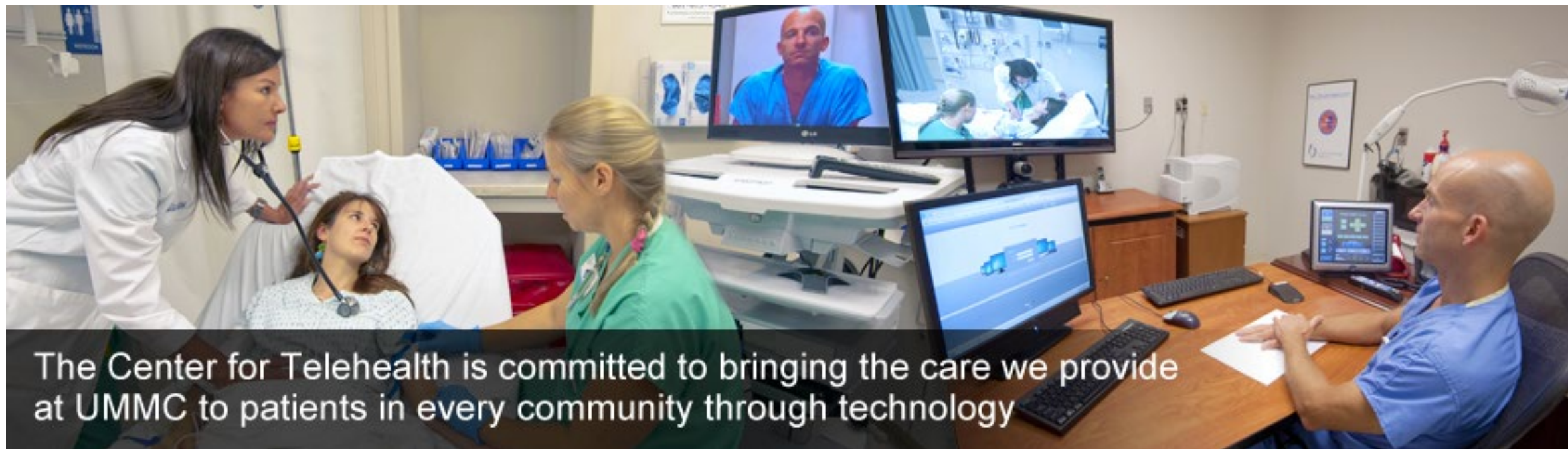
Expert Care is just a screen away

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
CENTER FOR TELEHEALTH



TELE-EMERGENCY TELE-EMERGENCY

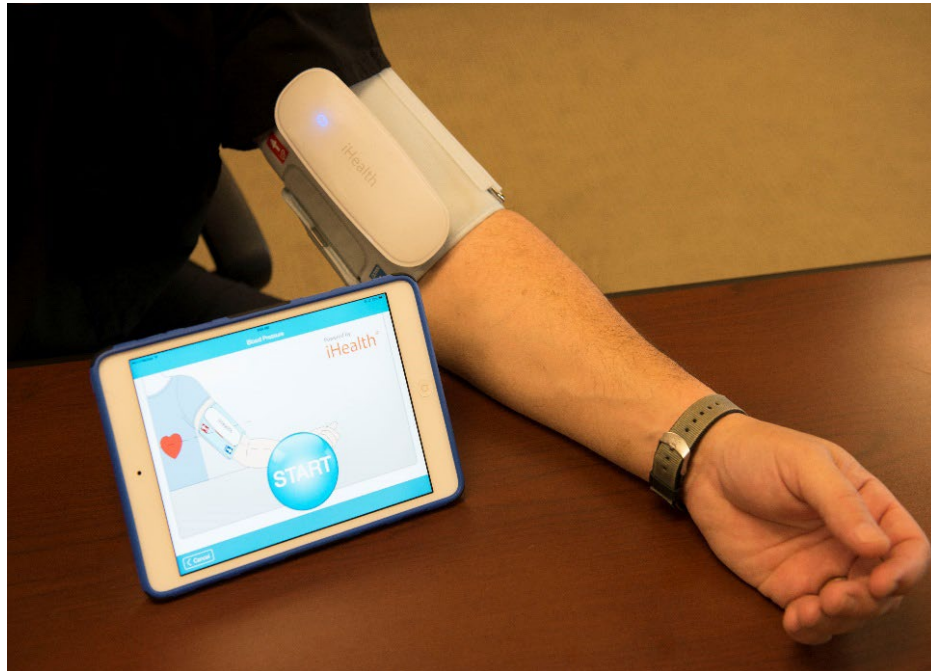
University of Mississippi
Medical Center
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The Center for Telehealth is committed to bringing the care we provide at UMMC to patients in every community through technology

Remote Patient Monitoring (RPM)

Chronic disease management in the patient's home including:



Daily Health
Sessions

Personalized
Interventions

Targeted Education

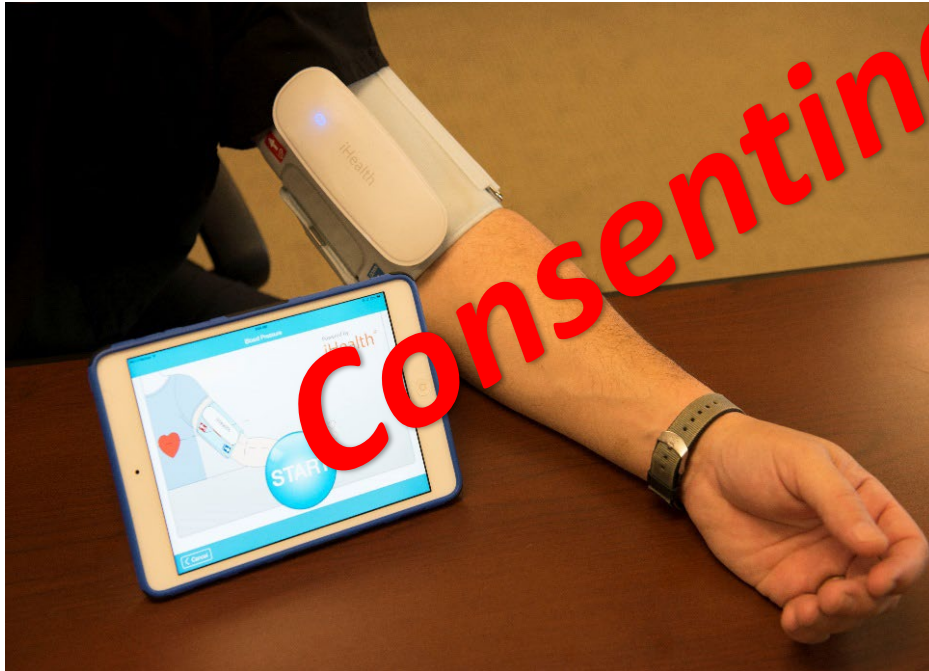
Health Coach

Behavior
Modification

Patient
Empowerment

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Chronic disease management in the patient's home including:



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Literature

- Welch BM, et al. Teleconsent: A Novel Approach to Obtain Informed Consent for Research. Contemp Clin Trials Commun. 2016 Aug 15;3:74-79.
- Khairat S, et al. Teleconsent - A New Modality for Informed Consenting. Eur J Biomed Inform. 2018 Sep;14(4):63-64.
- Khairat S, et al. Facilitating the Informed Consent Process Using Teleconsent: Protocol for a Feasibility and Efficacy Study. JMIR Res Protoc. 2018 Oct 17;7(10):e11239.
- Newline T, et al. Assessing the Satisfaction of Citizens Using Teleconsent in Clinical Research. Stud Health Technol Inform. 2018;247:685-689.

Objective

- Recruitment of subjects for clinical trials from areas with the greatest disparities is difficult and leads to biased research cohorts.
- Difficulties with participant recruitment from this underrepresented population often hinges on the ability to obtain informed consent in their local environment.
- Teleconsenting is a telemedicine mediated approach to obtaining informed consent and offers a unique solution in overcoming the limitations of traditional consent approaches in areas that are difficult for research personnel to access.
- As a proof-of-concept for this approach, teleconsenting was utilized in the enrollment of remote subjects in a home-based hypertension clinical trial.

Methods

- Potential participants that were identified by electronic health record review or direct physician referral were screened by telephone.
- Individuals meeting eligibility criteria were mailed a kit including a consent form and an electronic tablet with broadband connectivity.
- The informed consent process occurs during a study onboarding session with a research nurse via an audiovisual encounter on the tablet.
- To begin the onboarding session, personal identifying information is confirmed including name, address, date of birth, and social security number.
- The consent form is reviewed in detail and all questions answered.
- Consent to participate is confirmed by the push of a button on the tablet which generates a time and date electronic signature that is securely transmitted to the participant's electronic health record.

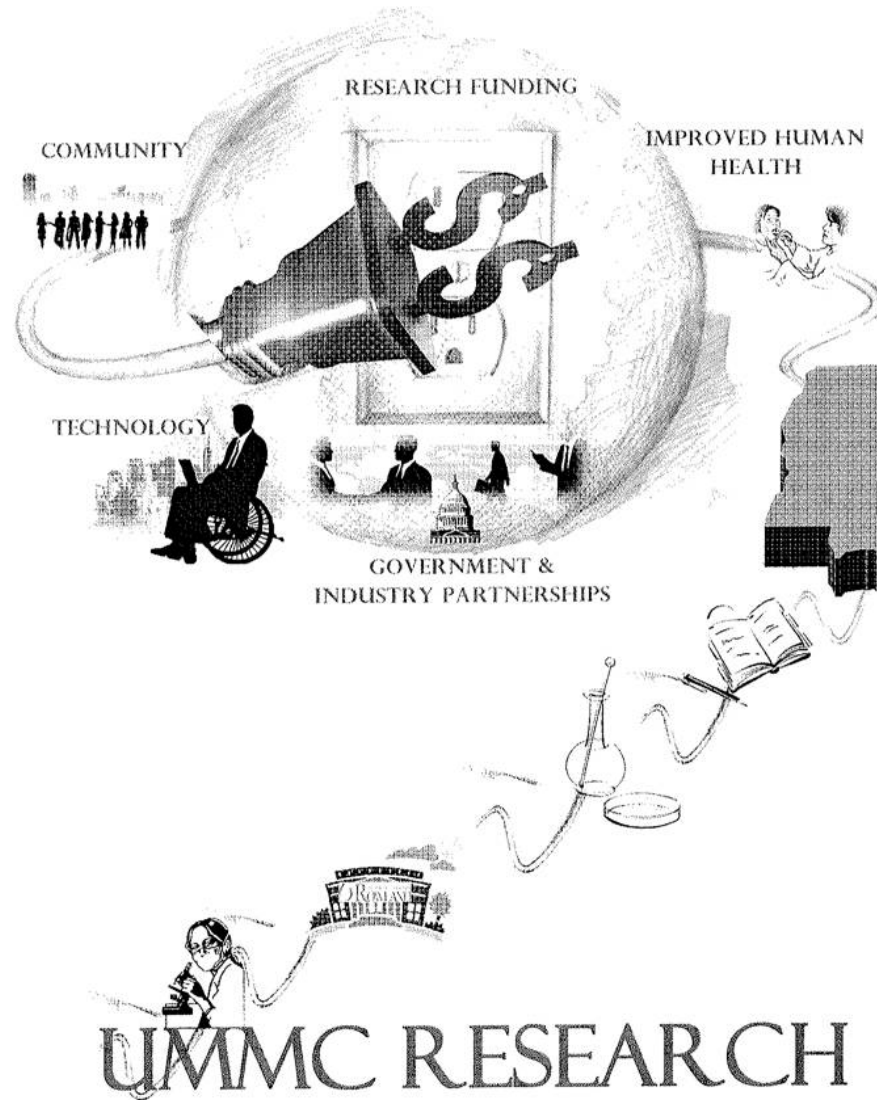
Results

- Through the protocol described in the methods section, 75 subjects were remotely enrolled in a clinical trial that was facilitated through a teleconsenting process.
- 50.1% were females, and 50.1% were African American.
- Three potential participants did not complete enrollment due to:
 - insufficient device connectivity
 - time restraints preventing participation
 - exclusion criteria not identified during the initial telephone screening.
- A substantial percentage of enrollees were found to reside in a rural county.

Conclusions

- Patients residing in remote geographies with inherent disparities in healthcare and barriers to access are often underrepresented in clinical trials.
- Teleconsenting can potentially improve research subject recruitment by reducing the barriers related to informed consent while preserving the context of human interactions.
- This process may also assist with the challenges related to study coordinator travels and regulatory management of subjects at remote sites.
- ***In this proof-of-concept study, teleconsenting was successfully utilized to remotely enroll a large number of subjects in a home-based hypertension clinical trial.***

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