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Improving our messages about research participation: a community-engaged approach to increasing clinical trial literacy

“Most commonly reported barriers to recruitment related to communication or awareness about clinical trials.”

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We are all aware that recruiting individuals for clinical trials (CTs) is not an easy task and it can be even more challenging to recruit within underserved populations. Numerous barriers to participation have been reported including individuals' limited awareness and knowledge about CTs, misperceptions and fear of research and distrust of doctors and researchers [1–4]. We argue in this report that the way we as researchers and scientists communicate about CTs and research participation in general is also a significant barrier to recruitment, enrollment and participation [5]. There is tremendous potential to improve our messaging about research, which, in turn, can improve the 'clinical trial literacy' of those most in need of these studies and whose participation could help advance science. Providers tend to overestimate patients' health literacy skills and the clarity of their own communication [6]. Results from the 2012 Program for the International Assessment of Adult Competencies, for example, demonstrated that the US average literacy score was 270 or at Level 2 (Level 5 or scores between 376 and 500 demonstrate highest proficiency) [7]. Respondents who self-reported 'poor' health often scored at or below Level 1 in literacy (38%), numeracy (52%) and problem solving (81%). Poor health-related literacy is associated with negative health outcomes [8]. Use of jargon-free language (at a ~Grade 5–6 level) is strongly recommended for all health-related content [8,9]. At the national level, the

US President signed the Plain Writing Act into law in 2010 requiring federal agencies to use 'communication that the public can understand and use' [10]. So why not apply principles of plain language communication to our messages about research participation?

In this paper, we present our approach to researching CT communication needs and message strategies. We encourage other teams to consider similar methods to guide their CT messaging.

Phase I: we examined the current state of CTs in one southeastern US state to determine to what degree rural residents were represented in CTs

An online survey was conducted with 119 CT principal investigators (PIs) from our state's five main academic medical centers. Secondary analyzes were also conducted using data from health insurance plans (e.g., Medicaid, State Health Plan), clinical risk groupings and the American Community Survey. Principal investigators reported having the most difficulty recruiting from rural areas and that rural residents were least likely to be represented in research, behind both the general public and African Americans (AAs) [5]. Most commonly reported barriers to recruitment related to communication or awareness about CTs. Rural residents were significantly more likely than other groups to be perceived as lacking knowledge and understanding about CTs, having lower literacy and lacking



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health information. Principal investigators also rarely communicated about clinical research outside of the medical setting to reach individuals in underserved communities. However, the secondary data analyses showed that the majority of rural citizens (75%) covered by the State Health Plan or Medicaid were indeed eligible for CTs [11]. Although CT PIs were correct in considering barriers in these areas, there still exists a large pool of potentially eligible CT participants. This initial research phase consisting of the PI survey and secondary data analysis revealed that increased communication between PIs and rural communities and better education of PIs on communication strategies were needed to enhance CT participation in more rural and remote areas. Although investigators relied heavily on local physicians to recruit patients, our research suggested that there may be limited communication between the investigators and local physicians and between these local doctors and patients.

Phase II: we assessed adults' current CT knowledge and beliefs, communication sources & information needs

We employed a mixed methods approach using focus groups [1,12] and a telephone survey [2,3]. First we conducted 19 focus groups and eight interviews statewide with a total of 212 participants. Participants were stratified into eight focus group types according to geographic location (rural vs urban), race (AA and white) and gender. Discussions assessed participants' beliefs, perceptions and sources of information about CTs, preferred strategies for communication about CTs and willingness to participate in a CT in the future. Urban and rural participants expressed similar beliefs about CTs. Common misperceptions were that CTs were intended for people who could not afford care or who were terminally ill. Rural residents were less willing than urban residents to participate in a CT in the future. Urban residents more frequently discussed their distrust of the medical system as a reason for nonparticipation. Many individuals expressed that their participation would depend on whether their doctor spoke with them about it or whether the trial would benefit a family member's health. Both rural and urban participants reported financial incentives as the top motivator to CT participation. Focus group participants recommended partnering with community organizations, schools and churches as well as using word-of-mouth to educate CT participants and encourage their enrollment in medical research. Urban groups also recommended media promotion. Findings from this phase were important for informing CT recruitment and communication strategies in both urban and rural communities. For example, other

qualitative work specifically examining AA communities' communication needs about cancer CTs [4,13] contributed to the development of a prostate cancer and research participation education program for AAs that was disseminated statewide [14].

We recommend these types of focus group questions to help engage communities in CT message development and dissemination:

- When you hear the term 'clinical trials,' what comes to mind?
- What are the benefits of CTs?
- What would motivate you to participate in a CT?
- If you were in charge of getting the word out to your communities about the benefits of CTs and helping recruit community members for CTs, what would you do to make sure people received the information?

Focus group findings influenced development of a statewide telephone survey that was conducted with 511 randomly selected residents 18+. The sample was stratified according to race and residence and included 126 urban AAs, 133 urban whites, 126 rural AAs and 126 rural whites. Survey findings revealed that AAs were significantly less willing than whites to participate in a CT. We found that lack of general knowledge about CTs and perceived risk were significant predictors of AAs' willingness to participate in a CT. Rural residents indicated greater lack of knowledge about CTs than urban groups. Results from the focus groups and statewide survey indicated that future messaging needs to improve basic knowledge about CTs and address key misperceptions within rural, urban, AA and white groups. Community members also made key recommendations for CT information dissemination, including providing information that is simple and easy to understand, using a trustworthy source of information (e.g., local doctor) and working with local media (e.g., television, radio).

Phase III: we analyzed current communication messages & channels being used to recruit & educate communities about CTs

We partnered with CT research staff from our state's five major academic medical centers to request their CT recruitment materials. We also searched for relevant information resources on the websites of the centers. A total of 127 CT materials were collected and analyzed [15]. Out of these, 37.8% were print and 62.2% were web-based resources. The overall mean reading level (based upon the SMOG measure of read-

ability) was Grade 11.7 ± 2.3, indicating that an upper high school education was required to read the CT materials [8]. While still written at a high school level, materials that included a call to action (e.g., ‘call this number to enroll’) [16] were at a lower readability level. Typically, studies on the readability and comprehension of CT information have focused on informed consent resources, so this phase of our research provided insight into the content and difficulty level of recruitment education materials. We suggest carefully considering the messages we include on all CT recruitment and promotional materials. We acknowledge that content requirements made by institutional review boards may result in CT recruitment and other materials with technical language that is not understood completely by individuals with lower literacy. However, there are strategies we should be using (e.g., bullet points, graphics, etc.) to improve our communication about CTs [8,15].

When working with potential CT participants, consider using a quick screening tool such as the Single Item Literacy Screener to establish a crude assessment of their health literacy levels [17]. Results will motivate us (i.e., researchers, scientists, providers) to modify and improve our verbal and written communication style. It will be important to assess if perceived understanding of health and medical information is associated with willingness and intention to participate or actual participation in a CT. Collectively, the formative research described in this

paper can inform and improve the messages we use to promote CTs and increase communities’ understanding of the importance of medical research. We should also consider social marketing principles that stress the use of consumer-driven research approaches to understand our audiences [18]. Collaborating with community and clinical partners, stakeholders and local media in the development, implementation and evaluation of CT communications will be critical for improving the health [19] and CT literacy [20,21] of our communities.

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References

- Friedman DB, Bergeron CD, Foster C, Tanner A, Kim SH. What do people really know and think about clinical trials? A comparison of rural and urban communities in the South. *J. Community Health* 38(4), 642–651 (2013).
- Kim SH, Tanner A, Friedman DB, Foster C, Bergeron CD. Barriers to clinical trials participation: a comparison of rural and urban communities in South Carolina. *J. Community Health* 39(3), 562–571 (2014).
- Kim SH, Tanner A, Friedman DB, Foster C, Bergeron CD. Barriers to clinical trial participation: comparing perceptions and knowledge of African American and white South Carolinians. *J. Health Commun.* (2014) (In press).
- Owens OL, Jackson DD, Thomas TL, Friedman DB, Hebert JR. African-American men’s and women’s perceptions of clinical trials research: focusing on prostate cancer among a high risk population in the South. *J. Health Care Poor Underserved* 24(4), 1784–1800 (2013).
- Tanner A, Kim SH, Friedman DB, Foster C, Bergeron CD. Barriers to medical research participation as perceived by clinical trial investigators: communicating with rural and African American communities. *J. Health Commun.* doi: 10.1080/10810730.2014.908985 (2014) (Epub ahead of print).
- Howard T, Jacobson KL, Kripalani S. Doctor talk: physicians’ use of clear verbal communication. *J. Health Commun.* 18(8), 991–1001 (2013).
- Goodman M, Finnegan R, Mohadjer L, Krenzke T, Hogan J. Literacy, numeracy and problem solving in technology-rich environments among US adults: results from the program for the international assessment of adult competencies 2012: first look (NCES 2014–2008). US Department of Education. National Center for Education Statistics, DC, USA (2013). <http://nces.ed.gov/surveys/piaac/>
- Friedman DB, Hoffman-Goetz L. A systematic review of readability and comprehension instruments used for print and web-based cancer information. *Health Educ. Behav.* 33(3), 352–373 (2006).
- Meade CD, McKinney WP, Barnas GP. Educating patients with limited literacy skills: the effectiveness of printed and videotaped materials about colon cancer. *Am. J. Public Health* 84(1), 119–121 (1994).
- Plain Language Action and Information Network (PLAIN). Plain Language: It’s the Law. www.plainlanguage.gov/plLaw
- Bergeron CD, Foster C, Friedman DB, Tanner A, Kim SH. Clinical trial recruitment in rural South Carolina:

- a comparison of investigators' perceptions and potential participant eligibility. *Rural Remote Health* 13, 2567 (2013).
- 12 Friedman DB, Foster C, Bergeron CD, Tanner A, Kim S-H. A qualitative study of recruitment barriers, motivators and community-based strategies for increasing clinical trials participation among rural and urban populations. *Am. J. Health Promot.* (2014) (Epub ahead of print).
 - 13 Jackson DD, Owens OL, Friedman DB, Hebert JR. An intergenerational approach to prostate cancer education: findings from a pilot project in the southeastern USA. *J. Cancer Educ.* (2014) (Epub ahead of print).
 - 14 South Carolina Cancer Alliance Prostate Cancer Work Group. 2014 Prostate Health Conference. <http://vimeo.com/scahec/2014prostate>
 - 15 Friedman DB, Kim SH, Tanner A, Bergeron CD, Foster C, General K. How are we communicating about clinical trials? An assessment of the content and readability of recruitment resources. *Contemp. Clin. Trials* 38(2), 275–283 (2014).
 - 16 Tanner A, Friedman DB. Health on the Web: an examination of health content and mobilizing information on local TV Websites. *Inform. Health Soc. Care* 36(1), 50–61 (2011).
 - 17 Morris NS, MacLean CD, Chew LD, Littenberg B. The single item literacy screener: evaluation of a brief instrument to identify limited reading ability. *BMC Fam. Pract.* 7, 21 (2006).
 - 18 Friedman DB, Hooker SP, Wilcox S, Burroughs EL, Rheaume CE. African American men's perspectives on promoting physical activity: "We're not that difficult to figure out!" *J. Health Commun.* 17(10), 1151–1170 (2012).
 - 19 Greiner KA, Friedman DB, Arp Adams S *et al.* Effective recruitment strategies and community-based participatory research: Community Networks Program Centers' recruitment in cancer prevention studies. *Cancer Epidemiol. Biomarkers Prev.* 23(3), 416–423 (2014).
 - 20 White B, Madden A, Hellard M *et al.* Increased hepatitis C virus vaccine clinical trial literacy following a brief intervention among people who inject drugs. *Drug Alcohol Rev.* 32(4), 419–425 (2013).
 - 21 George S, Moran E, Duran N, Jenders RA. Using animation as an information tool to advance health research literacy among minority participants. *AMIA Annu. Symp. Proc.* 475–484 (16 eCollection) (2013).