

Workgroup: (revision of existing Objective #17 Clinical Trials)

Date: 6/10/2016

Issue Statement:

Cancer clinical trials are essential to improve the outcomes of Minnesotans who have been diagnosed with cancer. With adult participation in cancer clinical trials ~3 – 5 %, and minorities and women' participation less, we propose a state sponsored initiative to educate the public, patients and providers about study opportunities within Minnesota and supply systematic mechanisms for patients and providers to connect with current study opportunities.

Describe the issue using public health data, peer reviewed research, or other evidence:

See journal articles from literature search done on 6/17/2016

2013 Poll by Research America An Alliance For Discoveries in Health, National Poll: Clinical Research: <http://www.researchamerica.org/sites/default/files/uploads/June2013clinicaltrials.pdf> (Identifies issue, public awareness, barriers to clinical trial participation.)

-Has your doctor or other health care professional ever talked to you about medical research? 70% no, 22 % yes, 8% unsure (2013 Poll by Research America, An Alliance For Discoveries in Health, National Poll: Clinical Research)

...only 3–5 % of adult cancer patients enroll in clinical trials. Lack of participation compromises the success of clinical trials and squanders an opportunity for improving patient outcomes. Support Care Cancer (2015) 23:1169–1196

However, despite over a decade of research, only 3–5 % of all adult cancer patients participate in CTs, with minority groups greatly underrepresented [5–9] Support Care Cancer (2015) 23:1169–1196

...where patients live in relation to cancer centers hosting trials as well as their socioeconomic or financial resources to attend trials are interrelated and influence patients' ability to participate in CTs. In fact, the intersectionality of these factors is itself socially and politically significant since their relationship marginalizes certain populations from accessing CTs. This raises challenging justice considerations related to who gets the opportunity to participate in CTs and which populations benefit from research. Support Care Cancer (2015) 23:1169–1196

Cancer patients' beliefs and attitudes related to CTs and research were also important personal factors associated with CT participation. Many studies (36 %) found patients' positive beliefs about the benefits of CTs were associated with their decision to participate in cancer research. These beliefs included a desire to help others, perceived personal benefit, and hope for a cure [6, 30–41]. Support Care Cancer (2015) 23:1169–1196

Conversely, a number of studies (25 %) found patients' negative attitudes or beliefs about CTs (i.e., fear of randomization, concerns about the experimental nature of a CT, and lack of therapeutic benefit) detracted from their participation in CTs [26, 27, 31, 35, 42–46]. A few studies (8 %) examining attitudes from potentially marginalized populations (i.e., non-Caucasians and rural patients) found "fear of being a guinea pig" as a significant detractor from trial participation [44, 47, 48]. Several other studies (19 %) identified perceived drawbacks or concern about side effects associated with an experimental treatment as negatively affecting cancer patients' participation in CTs [31, 40, 43, 44, 46, 49, 50]. Support Care Cancer (2015) 23:1169–1196

Commonly identified barriers for underserved communities include fear and lack of trust of clinical research, and lack of awareness, referral, and access to clinical research opportunities [2,5,7,13,50–53]. C. Heller et al. / *Contemporary Clinical Trials* 39 (2014) 169–182

We also found that putting emphasis on the provider as the key to recruitment and enrollment required supportive infrastructure so that the provider did not have to actively recruit or enroll.... This need was evident whether the trials were for patient management of chronic conditions or for cancer trials.... For cancer trials, the more integrated the recruitment was in the patient care process, the more successful the enrollment. C. Heller et al. / *Contemporary Clinical Trials* 39 (2014) 169–182

...Guadagnolo and colleagues reported that their program to enroll American Indians into cancer clinical trials, which included research staff reviewing each chart for eligibility and assigning those who self-identified as American Indians to patient navigators, resulted in 10% of American Indian new cancer patients enrolled in a trial, three times greater than previously reported national accrual rates for American Indians [21]. C. Heller et al. / *Contemporary Clinical Trials* 39 (2014) 169–182

...approaches that systematically identify and address each potential participant in the process of accessing medical care seem to be very effective in engaging with patients and enrolling them into clinical trials. C. Heller et al. / *Contemporary Clinical Trials* 39 (2014) 169–182

Barriers to CT participation have been studied extensively and include patients' limited awareness of CTs, misperceptions, distrust of doctors and researchers, and fear of CTs and general medical research [6–11]. Healthcare providers may also contribute to low enrollment in trials because of limited awareness about CTs or lack of communication with patients about CTs [10,12,13]. Furthermore, the technical language that physicians and/or researchers use [14] and the difficulty level of CT education resources provided to patients [15] can serve as barriers to recruitment and enrollment. Providers often overestimate their patients' health literacy skills [16] and the clarity of their own communication [17]. D.B. Friedman et al. / *Contemporary Clinical Trials* 38 (2014) 275–283

This is the first study to assess the content and readability of a sample of CT recruitment materials (N = 127) provided by five large academic medical centers in one southeastern U.S. state. D.B. Friedman et al. / *Contemporary Clinical Trials* 38 (2014) 275–283

If investigators are intending to recruit minorities into research studies, more culturally appropriate strategies (e.g., relevant images; reflections of historic and cultural beliefs, values, norms) will be needed so communities understand that they are eligible to participate [67–70]. D.B. Friedman et al. / *Contemporary Clinical Trials* 38 (2014) 275–283

While the majority of resources provided a telephone number for further information, few provided other mobilizing information such as an email address, website link, or a contact name. Explicit calls to action such as “visit this website to enroll” or “call this number to find out more” were also rarely included on recruitment documents. Without this type of directive that mobilizes people to act on their pre-existing attitudes, potential study participants may not take any action regarding the information (e.g., telephone number, website, etc.) presented to them [39,47,65,77]. D.B. Friedman et al. / *Contemporary Clinical Trials* 38 (2014) 275–283

Results from this study found no significant differences in readability level between materials with or without photographs or illustrations. Typically inclusion of images such as photographs, illustrations, and visual aids (e.g., tables or flowcharts) can help improve readability and are recommended for health education resources [43,48,80]. D.B. Friedman et al. / *Contemporary Clinical Trials* 38 (2014) 275–283

For example, communities have expressed that the personal benefit to themselves and/or their families is a motivator to participation in research [11,41]. D.B. Friedman et al. / Contemporary Clinical Trials 38 (2014) 275–283

Guided by principles of plain language, health communication, and health literacy ([23,26,42,43,47,48,70,77,81,82]),

we recommend that researchers consider the following when developing CT recruitment resources:

1. Specify that CT was approved by an IRB to establish trust with potential participants;
2. Present a combination of text and images to enhance readability and draw in the target population;
3. Promote CTs using both print and Web-based resources if/as appropriate in order to extend the reach of CT materials for the target population;
4. Include relevant and culturally appropriate visuals of the population (i.e., gender, age, race/ethnicity) being recruited for the specific trial;
5. If/as permitted by IRB, specify CT inclusion criteria and participant incentives;
6. Include an active call to action with contact information (i.e., telephone number, email address, website) to mobilize potential participants to follow up;
7. Conduct formative research (e.g., interviews/focus groups) with the intended population to ensure that potential participants will relate to the content and __ message frame(s) being used to recruit them for CTs;
8. Attempt to keep content readability at a Grade 5–6 level by including bullet points, short sentences, and avoiding medical jargon.
9. Pilot test all CT recruitment resources with members of the intended population to ensure comprehension. During pilot testing, ask questions to gauge understanding and consider using comprehension tests (e.g., multiple choice tests, teach-back).

D.B. Friedman et al. / Contemporary Clinical Trials 38 (2014) 275–283

“Financial barriers likely discourage patients from participating in clinical trials. Implementation of a cancer care equity program(CCEP) seeking to reduce financial barriers by assisting with travel and lodging costs was associated with increased trial accrual. The CCEP provided assistance to patients particularly in need, including those living farther away, those with lower incomes, and those reporting financial barriers related to trial participation. These findings suggest that financial concerns represent a major barrier to patient participation in clinical trials and underscore the importance of efforts to address these concerns.” Ryan D. Nipp, et al. The Oncologist 2016;21:467–474

-In particular, groups with historically lower financial resources, such as uninsured and minority patients, are frequently underrepresented in cancer clinical trials [1, 9–11]. Conversely, study participants of higher socioeconomic status (SES) are over-represented in cancer clinical trials [12–15]. Ryan D. Nipp, et al. The Oncologist 2016;21:467–474

-Additionally, clinical trials offer the possibility of early access to novel treatments; therefore, lack of access because of financial constraints represents a disparity in care. Ryan D. Nipp, et al. The Oncologist 2016;21:467–474

-Keeping Up with the Times: Supporting Family Caregivers with Workplace Leave Policies Lynn Feinberg AARP Public Policy Institute “The report highlights three public policy solutions to extend protections for working caregivers: unpaid family and medical leave, paid family and medical leave insurance, and earned sick time.”

What factors contribute to this issue? What racial, economic, geographic and other barriers contribute to this issue?

Multiple barriers contribute to poor accrual to adult cancer clinical trials. Gaps in education regarding the importance of clinical trials and lack of awareness of clinical trial availability by both the provider and the patient contribute to low participation. Economic barriers such as lack of insurance coverage, cost of transportation and unpaid time away from work, disproportionately affect individuals of lower socioeconomic status. Lack of access due to geographic distance to centers with clinical trial availability disproportionately affects underserved patients in rural areas. Cultural and literacy barriers also disproportionately affect patients of minority and underserved populations.

In a study of 1,256 cancer patients assessing barriers to cancer clinical trial participation, worries about health insurance coverage of clinical care costs represented one of the strongest barriers [36]. A second study, which sought to evaluate why patients decline cancer clinical participation, demonstrated that distance from the cancer center and insurance denial were common reasons for refusal to participate [5]. A third study of black patients found that economic stress played an important role in their willingness to participate in trials [45]. Therefore, efforts to improve clinical trial participation must include interventions targeting the financial barriers that often influence patients’ decisions to participate in trials. Ryan D. Nipp, et al. The Oncologist 2016;21: 467–474

What are the gaps in policy, systems and/or environmental services that give rise to this issue?

1. Lack of awareness – Research America survey
2. Literacy
3. Financial - including impact to patient, need for caregiver paid leave, etc.
4. IT resources

POLICY, SYSTEMS, and/or ENVIRONMENTAL (PSE) CHANGE: What are the policy, systems and/or environmental change opportunities to address this issue?

Support of legislation that requires insurers to cover non-standard costs of cancer clinical trial participation and program for coverage of caregiver paid time off.

-Media Campaign like Department of Health initiative to increase colon cancer screening.

-State sponsored website – ex. Georgia, Breastcancertrials.org, Emerging Med

[https://www.clinicaltrials.gov/ct2/show/study?term=georgia/](https://www.clinicaltrials.gov/ct2/show/study?term=georgia)

<http://www.emergingmed.com/>

https://www.breastcancertrials.org/bct_nation/home.seam

What strategies would you recommend to achieve PSE change?

Statewide education and media campaign

Establishment of centralized database for healthcare providers/ patients to locate accurate study information

Establish a cancer care equity program (CCEP) (ex. Massachusetts) -to help assist with travel and lodging costs associated with cancer clinical trial participation..

HEALTH EQUITY: Which strategies promote health equity? Describe how they promote health equity.

The current plan includes training navigators to help with underserved populations. This may never have been implemented. Plan would emphasize training lay navigators to target patient populations with cultural barriers (Somali, Hmong, Native American, etc).

Insurance transparency regarding covering routine care costs associated with clinical trial participation.

To help overcome barriers, creation of a resource similar to Minnesota Board on Aging's free Senior Linkage Line Model which provides statewide information and assistance. This would serve as a central database with updated clinical trial opportunities and include information on transportation, lodging, meal allowance programs, child care assistance, paid family leave.

ALIGNMENT: Who are the partners already working on those strategies? What agencies and organizations should work together to address those conditions, gaps?

University of Minnesota, Mayo Clinic, Park Nicollet, HealthPartners/ Regions, Minnesota Oncology, Fairview, Essentia Health, HCMC, Allina Health, CentraCare (Coborn), Sanford Health, Metro_MN Community Oncology Research Consortium, Minnesota Department of Health, National Cancer Institute, Pharmaceutical companies, Biotech companies, ACS, LLS, PANCAN, MOCA, PAF, AARP, and other array of organizations representing patients and minorities. Could include IBM, which is involved with WATSON for clinical trial matching.