Adoption of Health Literacy Best Practices to Enhance Clinical Research and Community Participation: Proceedings of a Workshop in Brief (2022)

DETAILS

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Proceedings of a Workshop
IN BRIEF

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Adoption of Health Literacy Best Practices to Enhance Clinical Research and Community Participation

Proceedings of a Workshop—in Brief

Clinical research is critical to developing new treatments and therapies for patients. To maximize societal benefit and health equity, it is important that clinical research information be accessible and inclusive, and participants should be representative of the patient population. To explore the role that patient comprehension of clinical research can have in delivering high-quality clinical care and in increasing the diversity of the populations enrolled in clinical research, the National Academies of Sciences, Engineering, and Medicine's Roundtable on Health Literacy held a virtual public workshop on October 28, 2021. Workshop attendees discussed current and promising resources and approaches for ensuring that the public receives clinical research information in language they can understand and that promotes health literacy; they also discussed strategies for integrating clinical research information into various care and community settings to improve research awareness and engagement.

The following sections of the Proceedings of a Workshop—in Brief present summaries of each portion of the workshop, in chronological order. The first two sections frame the importance of the workshop's material, first through the opening remarks, and then through the personal perspective shared by a patient and research participant. Next, there are summaries of the presentations of two tools for improving the health literacy of clinical research information, followed by a moderated panel discussion. The final section presents the summary of a moderated panel discussion on the integration of clinical research information into care and community settings.

OPENING REMARKS

Barbara Bierer, of Harvard Medical School and Brigham and Women's Hospital and Harvard, began the day by speaking about the importance of health literacy as it relates to clinical research. As a member of the planning committee, her opening remarks framed some of the questions that the workshop sought to explore. She noted that the majority of the diagnostics, treatments, and therapies deployed in modern medicine are the result of research and clinical trials that involve human beings. Bierer stated that research must include participants who reflect those for whom the diagnostic, treatment, or therapy is intended. There are legitimate and varied reasons, said Bierer, for why individuals have concerns and questions about research in which they might participate. She said that investigators and study teams conducting research should have the responsibility for addressing those concerns to enable potential participants to consider whether to participate in that research, saying:

> We want to make sure that participants enter clinical trials voluntarily and that they understand what they are contributing to and the risks and benefits thereof, but equally that we make sure we engage those participants appropriate to the trial and to the condition.

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Achieving that, she added, depends upon a mutual understanding and a shared exchange of information, and it depends upon trust between the investigator or clinician presenting the information and the person considering the trial.

Health literacy, she explained, can be a tool for achieving this goal. Health literacy includes not only plain language but also issues of numeracy, imagery, visualization, design, and culturally and linguistically appropriate communication. Health literate information supports communication and understanding, which is possible only when the communicator takes responsibility for ensuring that the recipient comprehends the information they are receiving. "We often talk about low health literacy or limited English proficiency, but that is essentially blaming the victim," said Bierer, who noted that it is not the responsibility of the person receiving the information to make sense of it. Rather, she said, it is the responsibility of those communicating the information to make sure they are understood and to keep trying until they are sure that the recipient of the information truly does understand and, further, that all of their questions have been answered.

In fact, said Bierer, the audience for information should be comfortable not knowing, comfortable communicating any lack of understanding, and comfortable asking questions. Currently, this may not be the experience of potential participants and especially not for those individuals whose preferred language is not English. "This is a systems problem, and we need to commit to solving that problem as a group," said Bierer.

When it comes to clinical research, said Bierer, understanding health information and engaging in shared decision making are important for recruitment, access, patient instructions, and patient-reported information. As such, she argues that it is important to have a foundation of understandable research content; this allows for researchers to have improved consent conversations that enable patients to make value-concordant decisions. Both the U.S. Department of Health and Human Services Common Rule and the Food and Drug Administration require that information provided to a "test subject or their representative,"[1] including all patient-facing information, "shall be in language understandable to the subject or the representative."[2] And beyond ensuring that researchers fulfill regulatory requirements, applying health literacy principles can help increase research engagement by demonstrating that researchers respect the potential participant and, thereby, support justice and equitable participant selection.

Health literate communications, said Bierer, must be culturally and linguistically appropriate for each population involved. In that respect, Bierer says that outreach to the communities with which researchers wish to engage is an important step; she notes that outreach must be authentic, and researchers must include those communities as partners. Such a process serves as a means of ensuring that community members can understand all materials and communications. As an example of the importance of outreach and engagement, she noted that she learned that some individuals hear the phrase *clinical trial* and hear or interpret it as *criminal trial*. Using the term *clinical studies* produced better comprehension for some community members. This points to the importance of establishing shared language so that everyone, including the investigators, is working from the same starting point.

Concluding her remarks, Bierer posed three questions that the workshop would address in the subsequent presentations and discussions and from which everyone attending the workshop would benefit:

- What do participants, patients, and caregivers need to make informed decisions about clinical research?
- What do health care providers need to make research a part of their conversations?
- What do researchers and clinical research stakeholders need to do to support participants before, during, and after a research study?

A PATIENT PERSPECTIVE

Elizabeth Cahn, Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, spoke about her experiences with clinical research as a patient, family member, and caregiver, and someone who works professionally with patients, families, and caregivers. She shared that her experience as a patient began with her diagnosis with early-stage triple-negative breast cancer in 2007, which led to her enrolling in a clinical trial that worked well for her. She has also been a caregiver for others in her family who had cancer, including her 89-year-old mother, who has lived with chronic lymphocytic leukemia for 30 years, during 10 of which Cahn served as her primary caregiver. Professionally, she is the program director at Cancer Connection, a small, community-based nonprofit in Northampton, Massachusetts, that provides a wide variety of support services for people affected by all kinds of cancer. Among their services, they hold discussions about medical choices and, if a person is interested, about participating in a clinical trial.

[1] Bierer uses the term *subject*, which quotes directly from the language used in federal regulations, but notes that the preferred term is *participant*.

[2] See https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.20 (accessed January 4, 2021).

Turning to her experience, Cahn said that when she first met her oncologist, she brought with her a short document containing her medical history, her family's medical history, and the medications she was taking. She handed it to her oncologist, who after reading it, thanked her, said it was helpful, and noted that he liked the font that she had used. Cahn had once worked as an editor, and his comment intrigued her. She had a brief discussion about typefaces and preferences, and used that to guide her future communication with her doctor. The key, she said, was that she and her oncologist were on the same page regarding how they communicated with each other.

Aside from how this experience affected her relationship with her oncologist, it also led her to think about how information, whether it is about treatment or clinical research, has to be communicated in a way that works for everyone who participates in the communication system. However, said Cahn, at the outset,

> When it has to do with health- or disease-related information, we are not all on the same page, and we have to account for the fact that we are not and try to overcome the differences.

Drawing on her experiences and the experiences of those around her, Cahn offered several tips for providers and researchers to better communicate with patients and make information more patient-friendly. Her advice was the following:

1. **Slow down.** This is necessary both because the information is likely to be new to the patient but also because it might be emotionally fraught (such as would be the case with a cancer diagnosis).
2. **Speak up and speak clearly.** Older patients may be deaf or hard of hearing, and even with good hearing aids they may need speech to be louder. She noted that volume may be an especially big challenge today, given that most clinicians are wearing masks because of the COVID-19 pandemic.
3. **Face the person you are addressing.** She says that doing so may help a clinician to "orient their humanity to the other person's humanity." "How is it that I can philosophically and emotionally recognize the human reality of that person, the human rights of that person, and help them with what might be an uncomfortable situation or even a crisis that they are dealing with?" she said.
4. **Convey information in chunks.** Cahn advises that physicians do so because patients cannot take every piece of relevant information in at one time. One problem with research and health care consent documents is that they contain an enormous amount of information in a format that the average person is not prepared to assimilate. Given that fact, the person managing the consent process should be responsible for organizing information in consumable chunks; they should be prepared to repeat it as many times as necessary until the person can repeat it back and demonstrate they comprehend the information.
5. **Use trained clinical trial navigators.** Through her involvement with the Multi-Regional Clinical Trials Center, she has learned the importance of having such navigators for helping people to both enroll in and stay in trials. Clinical trial navigators give patients someone to talk to and ask questions of as they proceed through a clinical trial. She acknowledged that in a perfect world, patients would be able to ask questions of their oncologist or primary physician, but that is not practical in today's medical system. Given time and access constraints, trained clinical trial navigators can fill that role.
6. **Provide clear trial summaries.** Cahn also commented on how summaries could be made more comprehensible. To illustrate the problem, she recounted how she recently looked at her mother's most recent clinical trial document. Her mother has had nine lines of treatment and been in four clinical trials over the past 30 years. The most recent document was 31 pages long, but it had what she said was a nice two-and-a-half-page summary at the beginning of the document. From this, Cahn concluded that a visual separation between the summary and the long, detailed description of the trial would be helpful to signal to the reader that the following discussion was something they could read at a later time. In addition to a brief summary, Cahn said she would like to see trial summaries include consistent presentation of a calendar that looks like a real calendar, not just a written list of when the person will have to give blood or receive an injection or scan.

TOOLS TO IMPROVE THE HEALTH LITERACY OF CLINICAL RESEARCH INFORMATION

The workshop's first panel session featured two presentations on resources for discussing clinical research information in a language that is understandable to patients and that promotes health literacy. The first speaker was Sylvia Baedorf Kassis, who presented on several such projects underway at the Multi-Regional Clinical Trials Center of Brigham and

Women's Hospital and Harvard, with an emphasis on the development process of their clinical research glossary. Then, Barbara Kress presented on Merck's internal plain language clinical terms glossary. Catina O'Leary, Health Literacy Media, moderated a discussion session following the two presentations.

Multi-Regional Clinical Trials Center: Health Literacy in Clinical Research and a Common Plain Language Glossary

To begin her presentation, Sylvia Baedorf Kassis described the vision of the Multi-Regional Clinical Trials Center, which is to "improve the integrity, safety, and rigor of global clinical trials." She and her colleagues work toward this vision by "engaging diverse stakeholders from across the research ecosystem to help define the emerging issues" that individuals working in the clinical trial space are facing. In addition, these stakeholders provide input that guides how the center can work to "create and implement ethical, actionable, and practical solutions."[3] Before delving into the details of the glossary, Baedorf Kassis shared a few other projects the center has undertaken to improve health literacy around clinical trials. In 2017, the center released guidance on how investigators should return both aggregate and individual trial results to study participants. This guidance was created in response to the European Union's mandate that plain language summaries be provided to study participants in Europe. What Baedorf Kassis and her colleagues learned in that work was that investigators need to apply health literacy, clear communications, plain language, numeracy, and superior design not only to end-of-study results summaries but throughout the clinical trial life cycle. Then, in 2018, Baedorf Kassis led an effort to complete a multistakeholder initiative focused on health literacy in clinical research that led to launching a website of the same name in 2019.[4] The website aims to serve as a comprehensive source of information on how to integrate health literacy throughout the clinical trial life cycle for trial sponsors, investigators, institutional review boards, and interested patients and participants.

Over the past couple of years, Baedorf Kassis has been designing clinical research-focused health literacy trainings for different organizations and groups. She also noted that in 2020, the center developed pamphlets to help support the understanding of clinical research relevant to COVID-19 for individuals who are considering participating in a clinical trial.[5] This pamphlet serves as a primer that individuals can read before someone approaches them about a specific COVID-19-related research study. The center has also developed a suite of materials for adolescents and young adults that can serve as an introduction to clinical research, as well as materials for that same audience related specifically to COVID-19 clinical research. One document, titled Assent to Consent,[6] is designed for use by minors who come of age and explains some of the things they need to consider if they want to continue on in a study they started when they were still minors.

Throughout these project processes, stakeholders continued to raise the need for a common clinical glossary tailored specifically for the clinical research space. Such a glossary, they imagined, could help harmonize definitions across the industry. In so doing, Baedorf Kassis contended, it could help the research enterprise to better support patients, participants, and caregivers in understanding health research information. The Clinical Research Glossary Pilot Program (Baedorf Kassis et al., 2020), which started in 2020, sought to accomplish this by bringing together patients, advocates, medical writers, an independent health literacy consultant, and representatives from academia, nonprofit organizations, and life science companies. Baedorf Kassis noted that approximately one third of this group were individuals who represent patients with different health conditions, including individuals with cancer and neurological conditions, as well as a teenager, a pediatric member and their mother, and a young college student who was deaf or hard of hearing. This group aimed to cocreate the glossary with patients and to design it to be health literate, such that the public would understand it and industry and academic stakeholders across the clinical research ecosystem would find it acceptable.

The group's approach consisted of (1) selecting 50 words from various participant-facing materials, (2) creating plain language definitions, (3) collecting feedback from the group, (4) refining the definitions based on that feedback, and (5) repeating the process. At first, they used a cloud-based process in Google sheets to iteratively define the words, but it failed to reach consensus for many of them. Instead, they decided to turn to virtual meetings with the stakeholders to achieve consensus on the definitions within the group. Baedorf Kassis and her team then created supplemental information and a web template, finalized the website, and launched it in June 2021.[7] The pilot has ongoing patient advocacy engagement and iterative usability testing.

[3] The full vision and mission can be found at https://mrctcenter.org/about-mrct/overview (accessed December 17, 2021).

[4] Available at www.mrctcenter.org/health-literacy (accessed January 19, 2022).

[5] See https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers (accessed January 19, 2022).

[6] See https://mrctcenter.org/blog/resources/pediatric-research-informational-materials (accessed January 19, 2022).

[7] Available at http://www.mrctcenter.org/clinical-research-glossary (accessed January 19, 2022).

Hallmarks of the project, said Baedorf Kassis, included:

- codevelopment with patients and participants with user testing;
- the development of plain language definitions and use in context; and
- the addition of associated images and graphics, and inclusion of an auditory pronunciation guide.

Baedorf Kassis also commented on the dissemination efforts. The pilot project team developed a word-of-the-week social media campaign on Twitter and LinkedIn. Baedorf Kassis suggested that the workshop attendees could take words from the glossary and post them in their social media feeds.

In October 2021, Baedorf Kassis also shared the glossary on screens around the Brigham and Women's hospital system for health literacy month. She and her colleagues are now working toward deploying the glossary on a clinical trial recruitment website. Baedorf Kassis suggested that one strategy to help people feel comfortable with clinical research and understand its benefits would be for organizations to conduct their own awareness campaigns. Such an effort could help their clients and patients feel comfortable with the idea that research is happening in their communities and provide them with examples of how that research may have benefited the community. It could also help people recruited in the future to participate in research studies feel more comfortable participating in a study or recommending it to someone else.

Baedorf Kassis ended her talk by sharing what the pilot project team's next steps will be.

1. They are urging the research industry to commit to using common definitions.
2. The team is also exploring expanding the glossary and moving the concept to something that is more sustainable and expansive. Doing so, she says, would require adding new words in real time to reflect what is happening in the popular press and on social media.
3. They plan to translate the glossary into other languages.
4. They will create a diverse and downloadable image library to accompany the glossary.

Merck Health Literate Glossary Initiative

Before presenting on Merck's Health Literate Glossary initiative, Barbara Kress shared a bit about her personal experience with the importance of health literacy. Before working at Merck, Kress was an emergency department trauma and critical care nurse who also served as a translator of medical language to basic English for patients, their families, and caregivers. "This was and is a critical component of the job," said Kress. "An individual cannot make important informed decisions without understanding the content before them. Health literacy is that ability." In her view, health literacy plays important roles related to control, choice, collaboration, and consequences; it allows patients to take control of their own well-being by making informed choices that they discuss collaboratively with their health care team to avoid negative health consequences. Additionally, Kress underscored that health literacy helps patients and their caregivers understand how to access and use available services, how to manage their chronic health conditions using up-to-date, actionable information, and how to navigate the health system.

She transitioned to laying out the many touchpoints that a pharmaceutical company like Merck has with patients, families, and caregivers, and at which health literacy might be important. Even before a clinical trial begins, a pharmaceutical company will prepare and make public recruitment materials, including the all-important consent document. During a trial, a company may provide updates to the trial participants about how the trial is progressing, and when the trial ends a company might provide participants with a summary of trial results. In addition, there will be patient-reported outcomes, labeling and packaging, and consumer advertisements to prepare. These numerous touchpoints with patients provide an opportunity to use health literacy as a guiding principle so participants can control, choose, and collaborate, said Kress.

The immediate impetus for Merck to create its glossary came when the European Union and United Kingdom announced that they would require plain language summaries beginning in 2022. Merck decided to create its own glossary because it could not find an external health literacy glossary to use when it was pilot testing procedures for authoring the summaries. These regulations require companies to prepare these summaries at a middle school reading level, and her team was spending too much time working on language that would satisfy that requirement. "It became clear that asking highly skilled, seasoned medical writers to author in plain language was not an easy task," said Kress.

When she reached out to Merck's internal health literacy team, it referred her to Health Literacy Media, an organization that then trained her staff in health literate principles.

Even with that training, Kress shared that her team was still taking too long to produce the plain language summaries. Team members started compiling a list of terms that appeared consistently in the documents they were preparing, and in short order that list turned into a thousand-word glossary that today includes terms and definitions. As a result, Merck now has an internal health literate glossary to use throughout the clinical trial life cycle and at all of its touchpoints with participants.

This project started in 2019 by enlisting company physicians to review the terms and definitions for accuracy. The team then piloted the initial glossary across 10 internal groups, made changes based on feedback from those groups, and conducted a cultural competency review through the company's employee business resource group and the Merck Nurses Network. Her team launched the glossary for internal use in October 2021 as part of the company's celebration of health literacy month.

Kress noted there were challenges to developing something new without a prescribed template. The team reached out to many different groups in the company to align terms with existing health literate materials the groups were already using. She said there was a wide range of reaction, from people not having enough bandwidth to provide the terms, pilot the glossary, or offer feedback, to others who wanted to do so much more with the glossary than the team was ready for at the time.

Another challenge was that Merck requires that all reviews of the glossary be kept internal to the company. In response, the team involved the internal cultural competency group to review the glossary. She provided an illustration of the types of feedback they received through this process. Initially, the definition the glossary used for human papillomavirus (HPV) only mentioned cervical cancer; the suggestion to expand the glossary's definition to highlight other parts of the body that HPV can affect came from a representative of the LGBTQIA+ staff group. Kress noted that the feedback the team received from its internal reviewers not only helped with the glossary's development, but it engaged the employees and showed them that their contributions were valuable and that they could improve patients' lives.

Currently, the team is struggling with developing graphics—which Kress notes is an important tool for health literate communication—to accompany the glossary, and this is one of her biggest concerns going forward. Considerations for 2022, she said in closing, include translation into additional languages, expanding use of the glossary within the company, and expanding the glossary to include terms related to medical devices, packaging, and prescribing instructions. Kress also noted that her team will be collaborating with Baedorf Kassis' group to create new glossary terms.

Panel Discussion

Catina O'Leary began the panel discussion with two technical, clarifying questions regarding Kress's presentation. These questions came from the audience members. Kress confirmed that when they started their work, her team did review MedDRA codes developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.[8] Another audience member wondered if Kress's team applied the glossary to patient-centered information posted as part of the clinical trials registration on ClinicalTrials.gov. That, said Kress, is the next big challenge her team hopes to accomplish in 2022, as well doing the same thing for the European Union's clinical trials registration site.[9] O'Leary then asked Baedorf Kassis and Kress to speak more broadly about the strategies they have used to engage multicultural audiences during both development and implementation of the tools. Speaking about engagement during the development process, Kress replied that she turned to Merck's cultural competency group and nurses' network, which was particularly valuable when they learned that terms they thought of as self-explanatory were not for all audiences. Baedorf Kassis then shared that she and her collaborators were able to have broad representation in the piloting process for the tool; they also availed themselves of many patient advocacy organizations, which she said can represent diverse cultures and perspectives. She noted that MRCT will seek to increase diversity and representation as it continues with efforts to expand implementation of the glossary. For starters, she noted that her team has put the glossary on screens around all of their health systems facilities, half of which are in Boston's communities of color. She hopes that they will continue to seek feedback on the tool, and that it will serve as a jumping off point for patients to have more detailed conversations about medical research. O'Leary commended the two speakers for taking an iterative process in developing and updating their glossaries; she noted that because the way that people use various terms can change over time, it is important that large glossaries in this context continue to be updated with community input.

[8] Additional information is available at https://www.meddra.org (accessed January 19, 2022).

[9] Available at https://eudract.ema.europa.eu (accessed January 19, 2022).

As a final question, O'Leary asked the panelists to share examples of times when feedback from a particular community changed the direction they were going with their glossaries. Baedorf Kassis responded that input from the team member who is deaf or hard of hearing led to the pilot creating an auditory pronunciation guide to accompany the glossary, which can be helpful both for those who are deaf or hard of hearing and additionally for people who may not speak English as their native language and are learning to pronounce words. This is the kind of action that her team needs to think about to be more inclusive. She said that they will continue to adapt the tool to accommodate a wide variety of abilities. Kress noted that the auditory pronunciation guide is one of the reasons her group will be partnering with Baedorf Kassis's team, as they would like to develop one for their own glossary.

INTEGRATING CLINICAL RESEARCH INFORMATION INTO CARE AND COMMUNITY SETTINGS

The workshop's final session consisted of a full-panel discussion on tactics and strategies for engaging the community around clinical research and what role health literacy might play in those strategies. It was moderated by Amanda J. Wilson, National Library of Medicine, and Silas D. Buchanan, Institute for eHealth Equity. The moderators began by allowing each of the four featured panelists to introduce themselves, their work, and how it connects to the topic. The four panelists were Michael Paasche-Orlow, Boston University School of Medicine; Monique Hill, Medical University of South Carolina; Rebekah Angove, Patient Advocate Foundation; and Karriem Watson, *All of Us* Research Program, National Institutes of Health (NIH).

Michael Paasche-Orlow explained that he is a general internist who sees patients at Boston Medical Center but spends most of his time conducting health literacy research. Since the start of the COVID-19 pandemic, he has been working on health literacy in the context of drug trials, with an emphasis on diversity, equity, and inclusion. He is also the inclusion lead for the NIH-sponsored Community Engagement Alliance against COVID-19 Health Disparities Network (CEAL Network) for Massachusetts, which is one of 21 such state-level initiatives to promote diversity, equity, and inclusion in clinical trials.

In her introductory remarks, Monique Hill said that she has been the program manager for one of her institution's community outreach health literacy projects for 11 years, as well as most recently being appointed health literacy and partnership engagement advisor for the National Network of Libraries of Medicine Region 2 Medical Library (housed at the Medical University of South Carolina). The majority of her work in health literacy has been based in the community and on developing coursework, trainings, and seminars on health literacy for her institution's clinicians and students. She noted that personal experience prompted her to work in the field, before she even knew what the term *health literacy* meant.

Rebekah Angove explained that her expertise and formal training is on integrating the patient voice into research policy and health system transformation. She said she started her career coordinating drug and device trials for a major academic medical center and serving as engagement director for the National Patient-Centered Clinical Research Network (PCORnet). In her current role at the Patient Advocacy Foundation, she serves as a principal investigator on a variety of projects integrating the patient, community, and provider voice into research. She also leads her organization's efforts to learn from patient experiences and amplify their voice in clinical and health research. Along those lines, her organization has partnered with clinical and academic researchers to initiate patient-driven research projects. She also conducts internal survey and data projects focused on patients' willingness, ability, and confidence to engage in health care and research projects.

Karriem Watson, the new chief engagement officer for the NIH *All of Us* Research Program, trained as a community health scientist with a research background in cancer prevention and control. Prior to joining *All of Us*, his research involved community stakeholders with a focus on diversity, equity, and inclusion in clinical trials; he has also focused on ensuring that populations that have been historically underrepresented in research participate in all aspects of research, from design to implementation, including involving researchers from historically underrepresented groups. As he put it, he does research *with* communities and *for* communities, rather than *on* communities.

Before beginning the discussion, Wilson explained that the moderators wanted to focus on three topics, or "buckets," in addition to the audience questions. Those three areas were:

1. **Community engagement strategies around clinical research**, focusing on the implementation experiences, opportunities, and challenges associated with such strategies;
2. **How clinical research might intersect with other literacies**, including digital literacy or research literacy and numeracy, and how these all relate back to improving health literacy; and
3. **The concept of organizational health literacy**, or how the research system might meet patients or partners where they are in terms of health literacy.

Before posing the first question to the panelists, Buchanan said the discussion would explore tactics and strategies for engaging communities of color, both urban and rural, as a means of improving how clinical research can more equitably integrate clinical research information in both care and community settings. For context, he noted that poorly addressed disparities in heath and health care has generated distrust of the health care system writ large, and the clinical trial and research enterprise specifically. He noted that if properly harnessed, the burgeoning collective energy and resources emerging around diversity, equity, inclusion, and accessibility—the latter of which is important for individuals with a disability—could benefit clinical research and, in turn, the health outcomes of underserved community members.

Building Trust and Leveraging Community Partnerships

With that last thought in mind, he asked the panelists how they leverage trust that community members have in leaders of community-facing organizations, including faith-based organizations, in the context of clinical trials. He asked how the research enterprise might more effectively partner with such organizations to lead conversations and share information about clinical research.

Watson responded with two examples of what he calls "trust by proxy." One of his previous projects aimed to engage Black men as "citizen scientists." This project intended to disprove the idea that Black men are hard to reach for enrollment and engagement in clinical trials, the presumed reason why biomarker screening studies do not include Black men. Using social network theory, he and his two coprincipal investigators—a Black urologist and a leader of a community-based organization—recruited a group of trusted experts from their own social networks, which included pastors, fraternity leaders, and other Black men in the community who were trusted messengers. Watson and his colleagues adapted a citizen scientist curriculum to engage these men so they could in turn engage their social networks to engage and recruit participants for a prostate cancer screening biomarker study. This effort was so successful that they exceeded their goals for recruiting Black men for this study.

In his current work, the *All of Us* Research Program is providing grants to community-based organizations, including faith-based partners, who are trusted and have national reach. One such organization is the National Baptist Association, one of the largest faith-based associations in the country and one that is trusted among Black communities. "We still have to build relationships, but we start off with a trusted messenger," said Watson, adding that they make sure trusted messengers have all the resources they need.

Referring to his comment about trust by proxy, he emphasized that partnering with trusted actors does not free the researcher from doing the work needed to build trust. For example, when he collaborates with barbers, a trusted messenger in many communities, it is crucial that he first build a relationship that allows them to trust him before they will help him recruit his clients to participate in a clinical trial.

Angove also highlighted this idea, stating that partners who serve as messengers are putting their reputations on the line, and it is important to ensure that trust is created between the research team and the messenger. She added that, putting the burden on patients or communities to put their trust in a researcher feels one sided. Rather, she argues, researchers and organizations should look at themselves and ask if they are being trustworthy and demonstrating trustworthiness before expecting others to build relationships with them. She underscored Watson's point that a cornerstone of building trust is to bring them the services and resources they need before attempting to recruit them as a partner in research. As an example, Watson noted that, during the COVID-19 pandemic, getting patients the food they needed to get through their cancer treatment became much more important than asking them to participate in a clinical trial; his institution had spent years building a structure that enabled them to get those resources into the hands of its patients.

Another way that Angove said that research entities could demonstrate trustworthiness is to engage with a community in an ongoing manner. Toward that end, Angove said her first ask is never, "Can I enroll you in a clinical trial?" Rather, her first ask is whether a community leader can identify and engage with her and be a coprincipal investigator and advisor on projects so they can focus on what is most important to the community.

Agreeing with Angove's comments, Hill said that too often researchers try to figure out how to work through a community instead of going to the community and asking it what it needs. She cited the example of an 8-year effort that a colleague undertook to build the Community Compass Project, which was so named because the community told her colleague what direction the project needed to go and what it wanted from the institution. This ongoing project engaged the community throughout the year; then, when it was time to recruit individuals for a research project, community members were willing to do so because there was an already-formed and ongoing relationship. Hill feels that, by contrast, the research community tends to move into a community only when there is a more pressing need that the community could fill for the researchers.

Paasche-Orow said he strongly agreed with each of his fellow panelists' comments, and added that when academics talk about trust, it is often very "othering" and comes with finger-pointing at community members as the source

of the issue. "I think it is important to get the issue of what it looks like for us to be trustworthy," said Paasche-Orlow. In his opinion, health literacy is a part of the solution to a larger endeavor of building trust, and most consent forms and the consent process as they currently exist are too complex and do not engender trust. He emphasized that trust and community engagement must begin with relationships that make community members feel comfortable and valued. Buchanan agreed that the messenger is sometimes more important than the message, and added that health literacy can be used to "arm" messengers with the right tools so they can impart the knowledge to the community in an effective manner. Leading into the next question, Paasche-Orlow asked whether the infrastructure currently exists to enable such training.

Trusted Messengers and Health Literacy

Buchanan then presented that question to the entire panel, asking them to comment on what infrastructure exists to empower community leaders to serve as trusted messengers around health research, using health literacy. Angove shared an example of a project that attempted to address this challenge. The project established community research cafes, where she and her collaborators would bring community members together and engage in a structured conversation around increasing research literacy. More importantly, she said, these gatherings normalized conversations within communities about what research is, both among community members and leaders and among researchers. She said similar programs that create spaces to have those conversations and build relationships are increasing in number. She reiterated that health literacy researchers need to recognize that health literacy also relies on having strong relationships.

Watson agreed and reiterated his earlier example about providing resources to community members on an ongoing basis, in addition to asking them to enroll in research. He then challenged the idea of what health literacy training should look like. One of the citizen scientists that he partners with remarked that the training for improving health literacy is often unidirectional, with the patient or community member being held responsible for learning the language of medicine, while providers receive little training to learn to speak to community members about their illness. Paasche-Orlow agreed that health literacy does need to be bidirectional. He said that health literacy is not only about words, adding:

> It's about power and social capital. Who has the capital to ask questions and [make] demands on the system? If you are not thinking about how power works in relationships...then you are not going to able to empower people.

Buchanan agreed that conversations about health literacy need to include discussions about where power lies, marginalization, and mistrust. Angove agreed with that statement and added that efforts to include health literacy also have to include shifts that give communities the power to obtain and access information.

Misinformation, Disinformation, and Health Literacy

Wilson posed a question from a workshop participant who wanted to know how, when working in community settings, the panelists deal with the misinformation and disinformation that some individuals might see on social media. Hill replied that misinformation is almost impossible to avoid today, when most of the information the public receives comes via social media. In her projects, she trains individuals on how to filter through and find reliable information. In her opinion, the solution has two parts: disseminating good information and training communities and individuals on how to identify what is not good information.

Watson emphasized that communities are already having conversations in which they are trying to sort out the good from the bad in terms of medical information. Too often, he said, there is a misconception among academics that such conversations are not happening because the academics are not a part of them. In his work, he conducts listening sessions to find out what the community is already discussing, and then asks the community what resources and information his organization can provide so the community can continue those productive conversations. Following this model, he proposes that instead of leading conversations, perhaps the medical community can provide technical support and subject matter to the leaders of organizations that are already having these conversations.

Paasche-Orlow seconded this idea, and noted that he thinks academics sometimes "finger-wag" and assume that there is misinformation in circulation, when the central issue may in fact be mistrust. He shared a story of restorative justice circles held by Boston Medical Center, during which they spoke with 40 African American residents of Boston who had decided not to get the COVID-19 vaccine. Much of the discussion centered around their experiences of racism in health care and how those experiences drove the decision to not get vaccinated. In other words, he felt that sometimes decisions that providers may assume result from misinformation or a lack of health literacy may have other explanations, and providers must talk with the community.

Additionally, Angove wondered if eliminating the fees sometimes required to access journal articles (paywalls) and requiring researchers to prepare lay summaries of their papers could be effective strategies. Doing so might allow people to access the original research and not have to rely on someone else's interpretation—such as might be found on social media—and help people access credible information more readily. Sometimes, people might be fully capable of understanding information if they are given access to it.

Messaging About Research's Relevance to the Community

Buchanan said that he has been in many church basements, watched someone from the health care enterprises drop off some fliers to stick on the church bulletin board, only to see those fliers put right into the trash because they did not come from the community or were not representative of the community. He also highlighted that these materials were not cocreated with the community. He wondered if the panelists had recommendations for how to better communicate to a community how a research project is relevant to them.

Angove commented that what she believes is often missing when a researcher approaches a community is an explanation of why their study is important for the individual and the community; instead, they often only emphasize why they need the patients and communities. For example, she stated that her organization is focusing on explaining to potential participants that without their participation, researchers will create solutions that do not include their community and their perspective, and that participating gives them a voice. She stated that crafting that message in a clearer way is part of the challenge of creating health literate outreach materials.

Paasche-Orlow added that he has an ongoing project that seeks to explain to medical interpreters why research is important, how it is a public good, and why it is important to have diversity and inclusion in research. He said that all staff, including doctors and nurses who are not part of research teams themselves, should be trained to understand why diversity is important in the context of research.

Hill wondered if that would be useful information to convey to study coordinators, too, and if there are existing curricula to train those coordinators in health literacy and appropriate communication strategies, as she feels most of them do not currently effectively engage with study participants or potential recruits. She feels that recruiters should emphasize how research is connected to care.

Paasche-Orlow agreed that study coordinators could be trained in health literacy principles to improve their work in clinical research. In addition to training principal investigators, he feels that the research team that is on the ground communicating with participants must also be trained in communicating clearly and effectively. He also notes that health literacy must be a focus in all stages of the research process, not just during the consent process where he feels the focus of these conversations often lies. He noted that throughout the research process, the research team must encourage and empower participants to ask clarifying questions. He noted that individuals with low health literacy are less likely to ask questions because they do not feel they have the social capital to do so, so the onus must be on the research team. "If you're not getting to the questions, you haven't finished the job."

In addition to training research teams in health literacy, Watson shared that increasing representation within the research teams can help improve the appropriateness and acceptability of research within a community. For example, he shared that when he was a community health worker at a church, a research team came in and brought recruitment fliers that did not feel representative to his community. He approached them, and the research team decided to give him a voice at the decision-making table to help direct their work using his lived experience.

Community-Level Data and Health Literacy

Buchanan noted that community partners often do not receive data about their communities, even when they participate in the research that generates that data. He asked if there was a mechanism by which deidentified, aggregated data gets back to those organizations at the community level so they can use it to seek their own funding to engage in their own projects to address the health issues their communities face.

Watson said that he had received one grant that included funds to provide office hours and technical assistance to do just that in one community. His team even disseminated data back to elected officials; in one case, they were surprised to learn that more men in their community were dying of prostate cancer than gun violence, and by the degree of health disparities that existed in their community. In some cases, though, community members responded that they were aware of these issues but did not have the data to enable them to make a case for increasing resources for their communities. Overall, he stated that researchers conducting community needs assessments need to ensure that the research provides value to the communities. "There need to be policies [that allow] us to disseminate information back to communities in a way that they dictate and determine is helpful to them," said Watson.

Hill agreed and added how important it is to also explain what the data mean and to help community-based organizations use the data once they have it to improve their projects and make a case to funders. Paasche-Orlow

shared one example of a resource about health literacy that goes to the census tract level.[10] He and a team at the University of North Carolina cocreated the resources, and said that it is free to be used by any local group to enable them to communicate with their local governments about some of the issues addressed during the workshop.

A Potential Role for Community Institutions

Wilson remarked that the speakers throughout the day had presented examples of different influencers, trust brokers, and clinical trial champions that can help address health literacy regarding clinical research. She then asked if social service agencies, libraries, and other community institutions could play a similar role in improving health literacy.

Angove said her organization fits the description of a social service provider and partners with them. She noted that the important consideration for anyone who wants to partner with one of these community organizations is to make sure there are significant resources, including money, available for that potential partner. It is also important to expect those organizations to be a full collaborator and influential partner in the process, whether that involves clinical trial recruitment or improving health literacy in a community. Investing in partners, letting them be part of the process, and helping them develop their own programs and secure grant support is an effective way to build trust and strong relationships, she added.

Hill said that early in her career, she worked on a program that aimed to ensure that service workers conducting home visits were discussing important health subjects with their clients, talking to mothers about the importance of topics such as well-baby checkups and getting their children vaccinated. It was only when she got involved in the health literacy field that she realized that some of those workers themselves might not have actually understood the information they were conveying. She noted that tapping into this workforce could be a great opportunity to promote health literacy, as providers working directly in the home may already have a greater level of trust with their clients. She emphasized that one of the benefits of this approach is that there are structures and home visiting programs that already exist, including Healthy Families through Prevent Child Abuse America, and Healthy Start. Paasche-Orlow added there is a need to be creative about collaborating with all of the other partners that exist in a community for promoting health literacy, such as Meals on Wheels and health ministries in faith-based organizations. He reiterated Angove's point that sharing money and power is key to forming these partnerships. ◆◆◆

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[10] See http://healthliteracymap.unc.edu (accessed January 4, 2021).

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