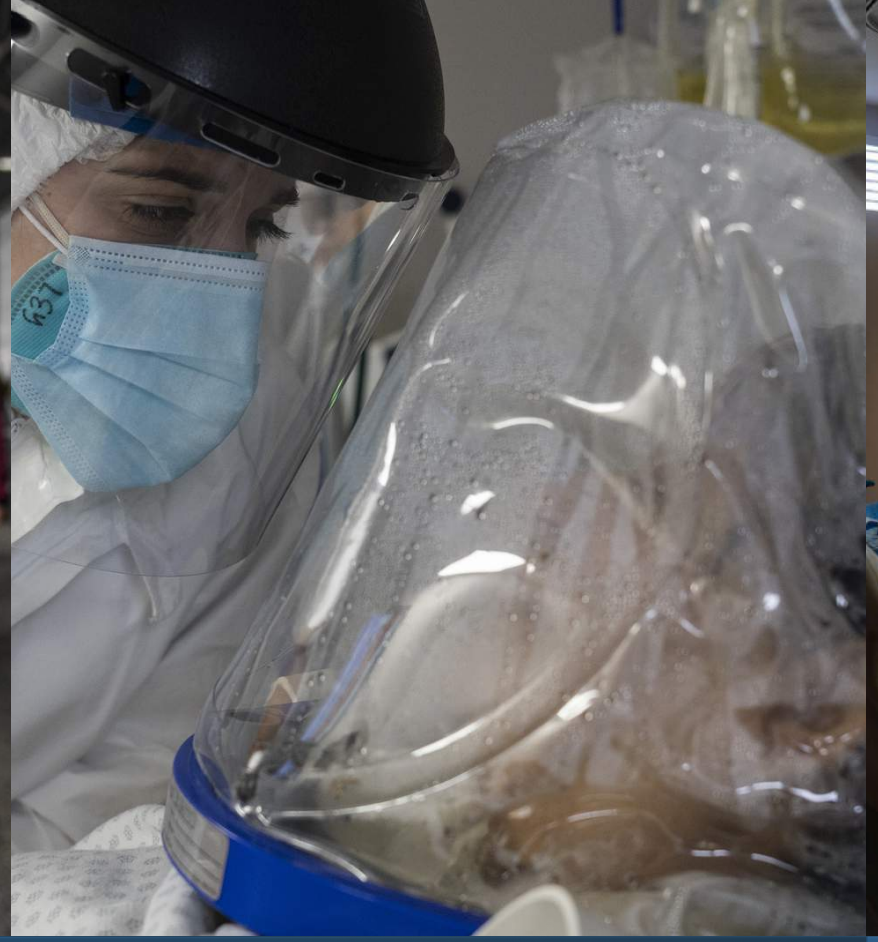
Penn Nursing
University of Pennsylvania
School of Nursing

ETHICS: EMERGING ISSUES AND TRENDS IN CLINICAL RESEARCH

CONNIE M. ULRICH, PHD, MSN, RN, FAAN
Lillian S. Brunner Chair in Medical-Surgical Nursing
Professor of Bioethics and Nursing
University of Pennsylvania

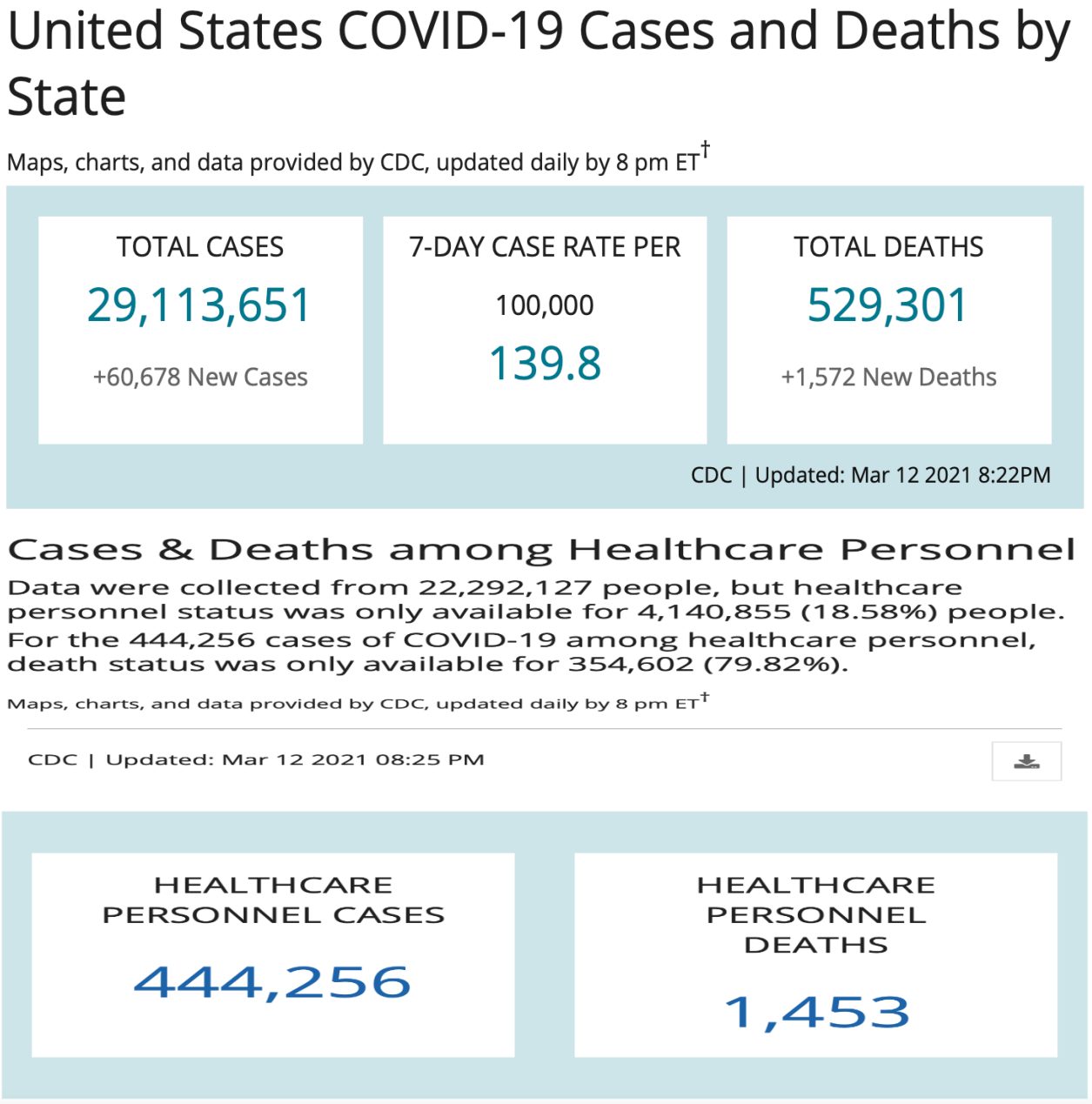




2020: The Toll of COVID-19

Global Pandemic

- Global cases: 119,207,662
- Global deaths: 2,641,907
- Healthcare Workers: ~7000

https://coronavirus.jhu.edu/map.htmllobally



3544

US healthcare worker deaths

are under investigation by the Guardian and KHN. This is the most comprehensive count in the nation, and our year-long series of investigative reports into this tragedy poses a disturbing question:

Did they have to die?



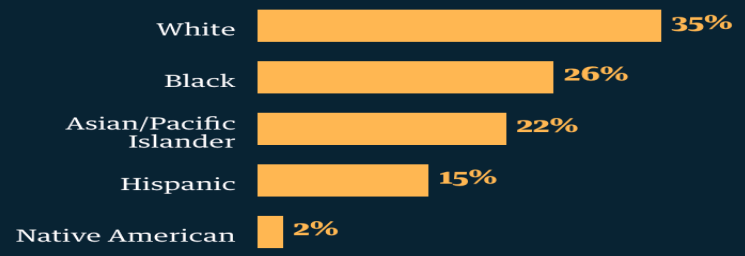




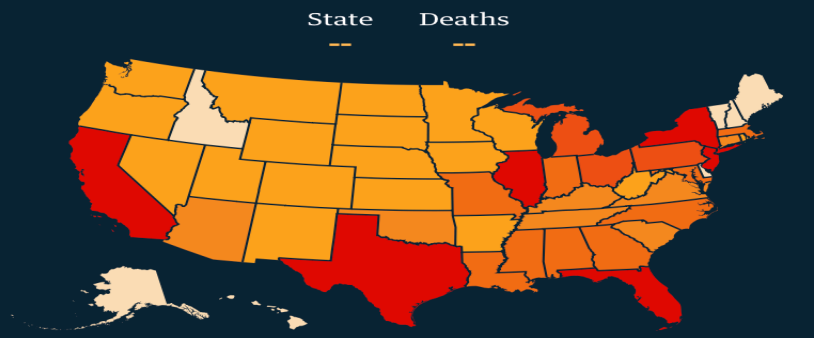

DEATHS BY OCCUPATION

Nurse	32%
Healthcare support	20%
Physician	17%
Medical first responder	7%
Admin/ Admin support	6%
Diagnosing clinician	4%
Healthcare technologist	4%
Community or social worker	3%
Cleaner	2%
Other	2%
Security personnel	1%
Culinary/food services	1%
Coroner	0%

DEATHS BY RACE AND ETHNICITY

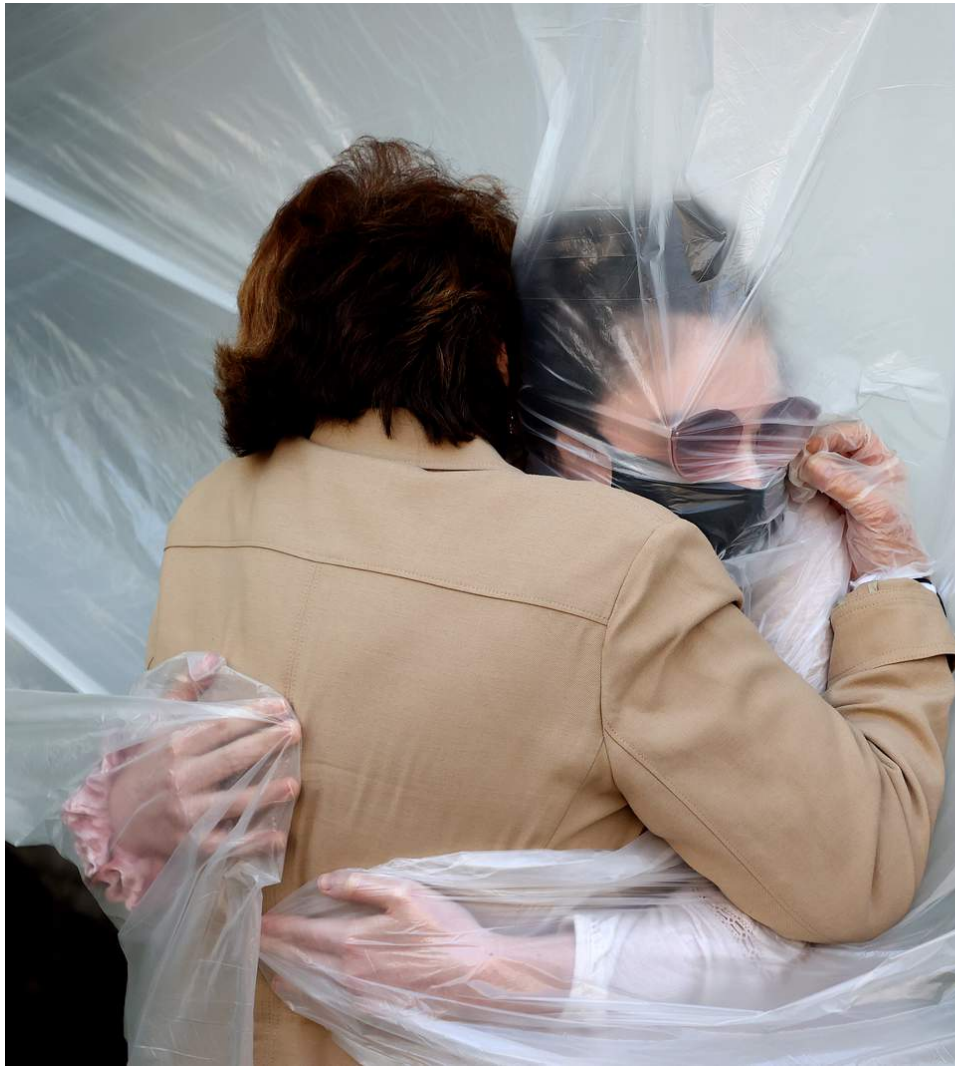


DEATHS BY STATE



Graphics are based on subsets of data for which we have the relevant information. For more, see the methodology

https://www.theguardian.com/us-news/ng-interactive/2020/aug/11/lost-on-the-frontline-covid-19-coronavirus-us-healthcare-workers-deaths-database

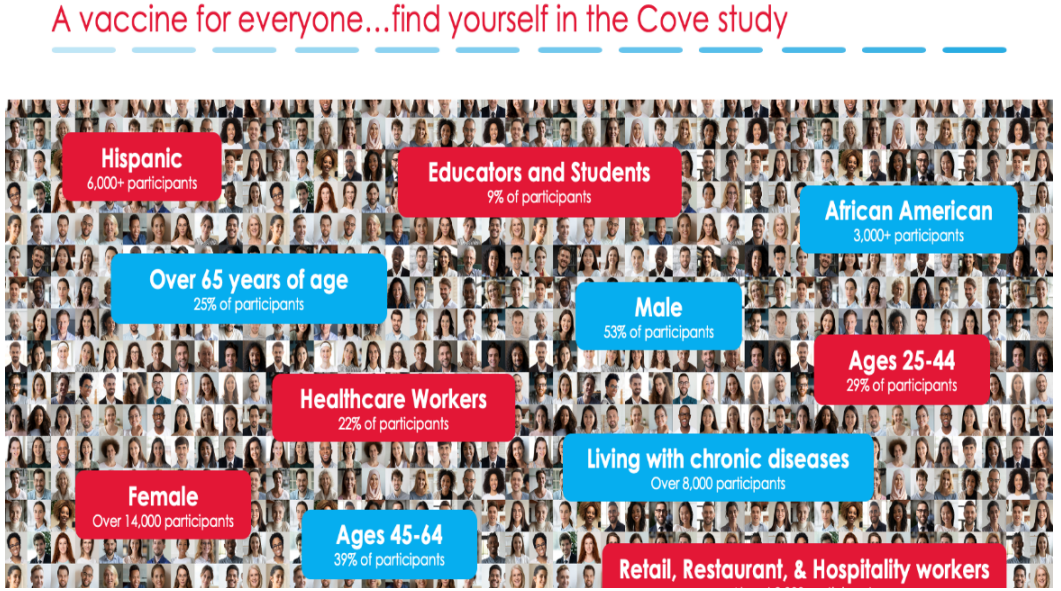


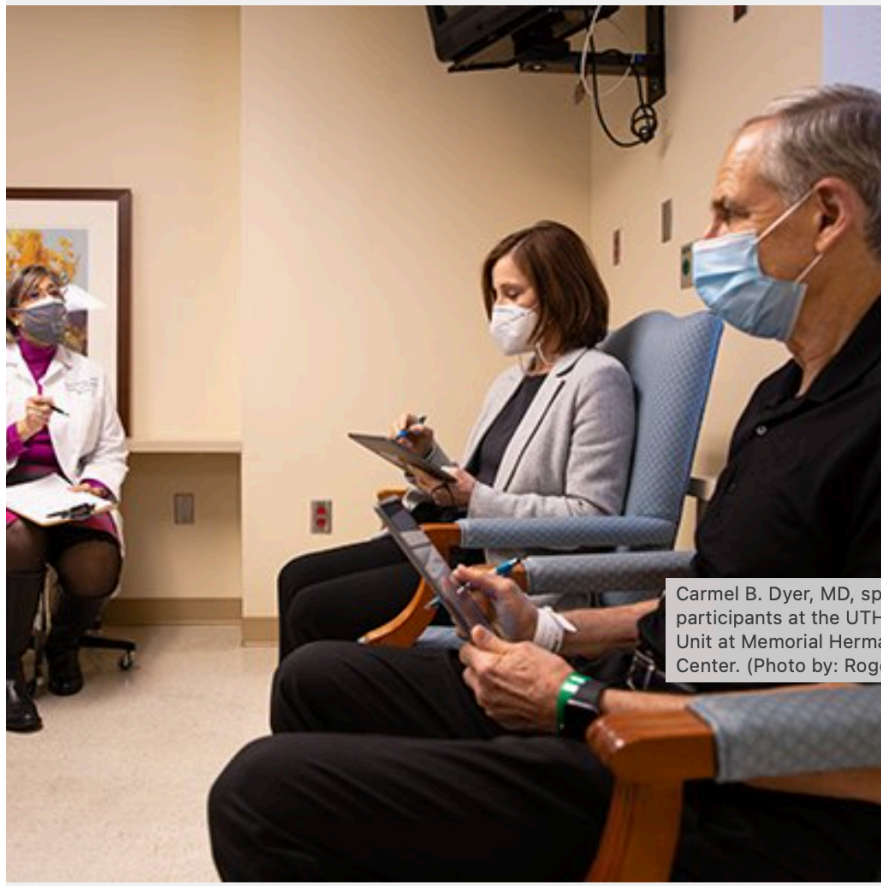
Headlines

- Fauci: Vaccinations Are Increasing in a 'Glimmer of **Hope**'
- 2021 Begins with Expanded Coronavirus Restrictions — and Glimmers of **Hope**
- Covid-19 vaccine is a source of **hope** for health care workers. But it comes too late for hundreds of them
- Light at the end of the tunnel': America's nurses share their **hope** and relief over COVID-19 vaccine rollout
- 'A Shot of **Hope**': What the Vaccine Is Like for Frontline Doctors and Nurses

Does Research Provide Hope?

- 30,000 Volunteers for Moderna COVID-19 trial
- 44,000 Volunteers for Pfizer COVID-19 trial





eaks to two trial participants at the UTHealth Clinical Research Unit at Memorial H
by: Roger Castro/UTHealth)

We thank all those who participate in research to advance scientific knowledge of diseases, especially those who most recently participated in the COVID-19 vaccine trials.

Why Does or Doesn't the Public Participate in Research?

https://www.uth.edu/news/story.htm?id=d8828fdc-b5b1-4f0e-9641-0091e1ebd88c

Delays

https://www.cognizant.com/whitepapers/patients-recruitment-forecast-in-clinical-trials-codex1382.pdf

"Roughly 80% of clinical trials fail to meet enrollment timelines"

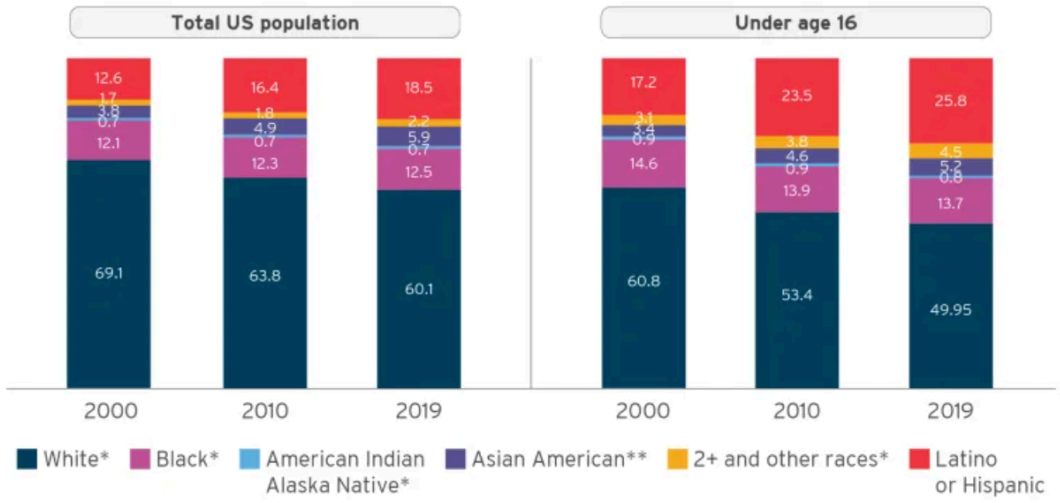
↓

"Approximately one-third (30%) of phase III study terminations are due to enrollment difficulties."

Diversity in Clinical Trials

FIGURE 1

Race-ethnic profile for total US and under age 16 populations
2000, 2010, and 2019



* members of race group who do not identify as Latino or Hispanic
* non-Latino or Hispanic Asians, Hawaiians and other Pacific Islanders

Source: William H Frey analysis of 2000 US Census and Census population estimates, released June 25, 2020

Metropolitan Policy Program at BROOKINGS

THE READOUT LOUD

Covid-19 clinical trials are failing to enroll diverse populations, despite awareness efforts

By ADAM FEUERSTEIN @adamfeuerstein, DAMIAN GARDE @damiangarde, *and* REBECCA ROBBINS / AUGUST 14, 2020

Reprints

https://www.statnews.com/2020/08/14/covid-19-clinical-trials-are-are-failing-to-enroll-diverse-populations-despite-awareness-efforts/

Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity

Updated Mar. 12, 2021 Print

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases[1]	1.7x	0.7x	1.1x	1.3x
Hospitalization[2]	3.7x	1.0x	2.9x	3.1x
Death[3]	2.4x	1.0x	1.9x	2.3x

https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html

Table 1: Race/Ethnicity of Participants in Pfizer-BioNTech and Moderna COVID-19 Vaccine Clinical Trials			
	Total US Population Age 16+	**Pfizer-BioNTech***	**Moderna**
Total	**258 million**	**40,277**	**27,817**
Race			
White	73.6%	81.9%	79.4%
Black	12.3%	9.8%	9.7%
Asian	5.9%	4.4%	4.7%
American Indian/Alaska Native	0.8%	0.6%	0.8%
Native Hawaiian or Other Pacific Islander	0.2%	0.2%	0.2%
Ethnicity			
Hispanic	17.6%	26.2%	20.0%
Non-Hispanic	82.4%	73.2%	79.1%

NOTES: *Pfizer-BioNTech data are for all participants globally; of which 76.7% are in the United States. Pfizer results provided for Phase 2/3 trial, Moderna results for Phase 3 trial. The Pfizer trial included those ages 16 and older. The Moderna trial included those ages 18 and older.
SOURCES: Racial/ethnic distribution of total population age 16 or older based on KFF analysis of 2019 American Community Survey data; FDA, Briefing Document: Pfizer-BioNTech COVID-19 Vaccine, December 10, 2020; FDA, Briefing Document: Moderna COVID-19 Vaccine, December 17, 2020

https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-diversity-within-covid-19-vaccine-clinical-trials-key-questions-and-answers/

Diversity in Clinical Trials

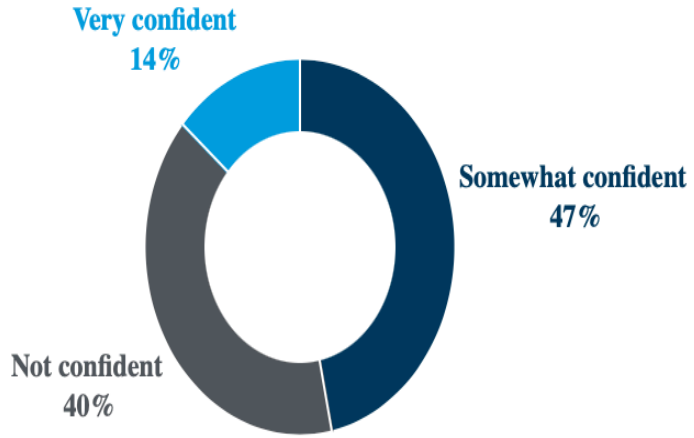
According to a Pew Research Center survey released in September, only 32% of Black adults said they would definitely or probably get a COVID-19 vaccine, compared with 52% of white adults, 56% of Hispanics and 72% of Asian Americans.

UMBC president volunteered for Moderna vaccine trial to reassure people of color it's safe

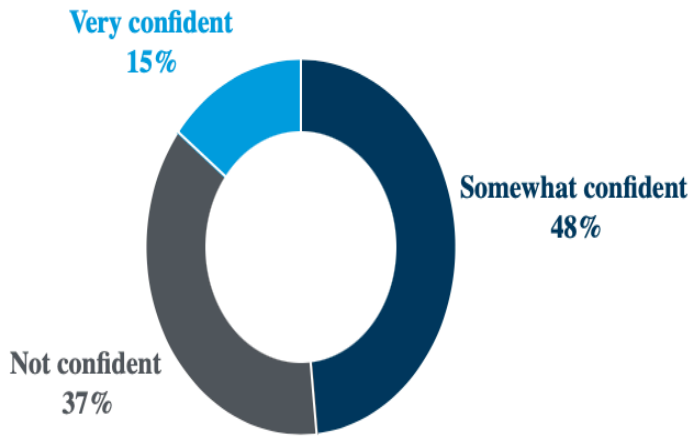
https://www.pewresearch.org/science/2020/09/17/u-s-public-now-divided-over-whether-to-get-covid-19-vaccine/

Vaccine Development Process

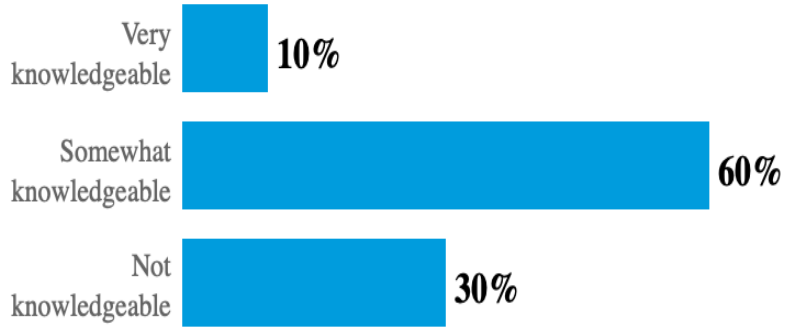
How confident are you in the vaccine development process for COVID-19?



How confident are you that a COVID-19 vaccine(s) will be safe and effective?



How knowledgeable do you feel about the vaccine development process for COVID-19?



If your employer **does not** require it, would you voluntarily vaccinate yourself against COVID-19?

VACCINE HESITANCY AMONG RNs

ANA Survey of >13,000 Nurses (October 2020)

- https://www.nursingworld.org/news/news-releases/2020/new-survey-of-13k-u.s.-nurses-findings-indicate-urgent-need-to-educate-nurses-about-covid-19-vaccines/

Oxford-AstraZeneca volunteers kept in dark about dosing error

Letter obtained by Reuters news agency shows clinical trial volunteers were not informed of COVID jab dosage blunder.

How Does This Headline Affect Research Participants and Participation?

What Would You Want to Know, and Would You Participate?

2 days ago | Comments

Coronavirus pandemic

Scientists want to understand more about the virus and test vaccines against new variants

"Although ordinary citizens are at times included in research ethics deliberations, they play a minor role. Most surprising---and disturbing---is the omission of people who know what it is like to be a research subject. Few people with direct experience as subjects have been involved in the creation and application of rules and guidelines for human subject research. Their exclusion has deprived the oversight system of morally relevant information."

Research Study

- Sequential explanatory mixed-methods design
- Contacted 595 patients with 498 (83.7%) consenting. Of these 335 returned the survey; after adjusting for patients who died, response rate of 79%.
- Conducted 45 follow-up qualitative interviews
- Conducted 20 qualitative interviews with those who withdrew from their trials
- Conducted 20 qualitative interviews with caregivers

Ulrich, et al. Retention in Cancer Clinical Trials: Modeling Patients' Risk-Benefit Assessments (R01CA196131)

A Diagnosis of Cancer

- In 2020, more than 1.8 million Americans were expected to be diagnosed with cancer and >600,000 to die from the disease.
- About a third of cancers are diagnosed at late stage.
- Patients and their families immediately must make difficult decisions related to their care with multiple options:
  - Surgery
  - Chemotherapy
  - Radiation
  - Clinical Trials
  - Palliative Care
  - Hospice

American Cancer Society. (2020). Cancer facts and figures. Retrieved from https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf

Cancer Clinical Trials (CCT)

- Essential to advance scientific knowledge, reduce disease burden, generalize knowledge, and to some extent, provide patients and their families with options (treatments) that might not otherwise be available to them.
- Currently, more than 120,000 CTs are registered in the U.S. alone (https://www.clinicaltrials.gov/ct2/resources/trends)
  - ~19,248 currently recruiting as of February 23rd, 2021 [NIH].
- Estimates indicate that ~5% of adults participate in CCTs (and minorities less so).
- Various reasons for lack of participation in CCT.

Fears

- Fear of forgoing standard of care
- Fear of being used (means to an end) without benefit
- Historical abuses of research participants (e.g., Tuskegee Syphilis Study)
- Death of a research participant (e.g., Jesse Gelsinger)
- Fear of potential side effects
- Fear of receiving the placebo
- Fear of information

As one of our study participants told us: “of course when you first get this diagnosis, sometimes the first thing a lot of people do, is you go to Dr. Google and I did, and it is extremely depressing”.

Due to their genetic and physiological similarities to humans, lab rodents have become the cornerstone of animal research. (Olena Kurashova/iStock)

Patient or Guinea Pig? Dilemma of Clinical Trials

By Denise Grady

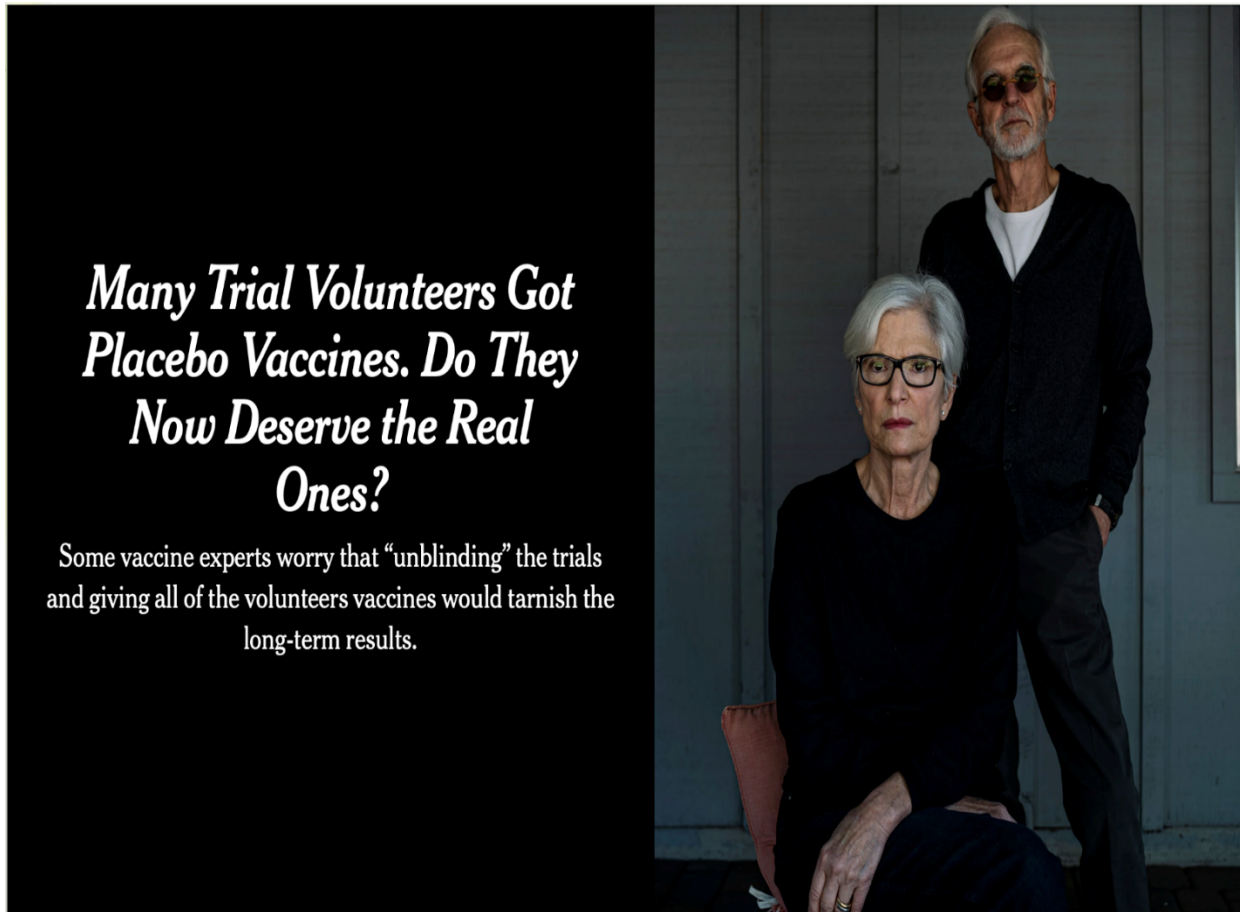
Jan. 5, 1999

"Everybody thinks don't use me as your guinea pig; use somebody else, and nobody participates."

- https://www.nytimes.com/1999/01/05/science/patient-or-guinea-pig-dilemma-of-clinical-trials.html
- https://www.smithsonianmag.com/science-nature/history-lab-rat-scientific-triumphs-ethical-quandaries-180971533/

“Although intellectually I understand the importance of blind trials, I have found now that I am actually participating in one, that I am experiencing more anxiety than I had expected in trying to accept the uncertainty as to whether I actually received the vaccine or placebo.

On the one hand, there is relief that I might be spared possible side effects but at the same time disappointment that I might not have received something that could be of benefit. For me, not knowing is difficult and might keep me from participating in any future research.”



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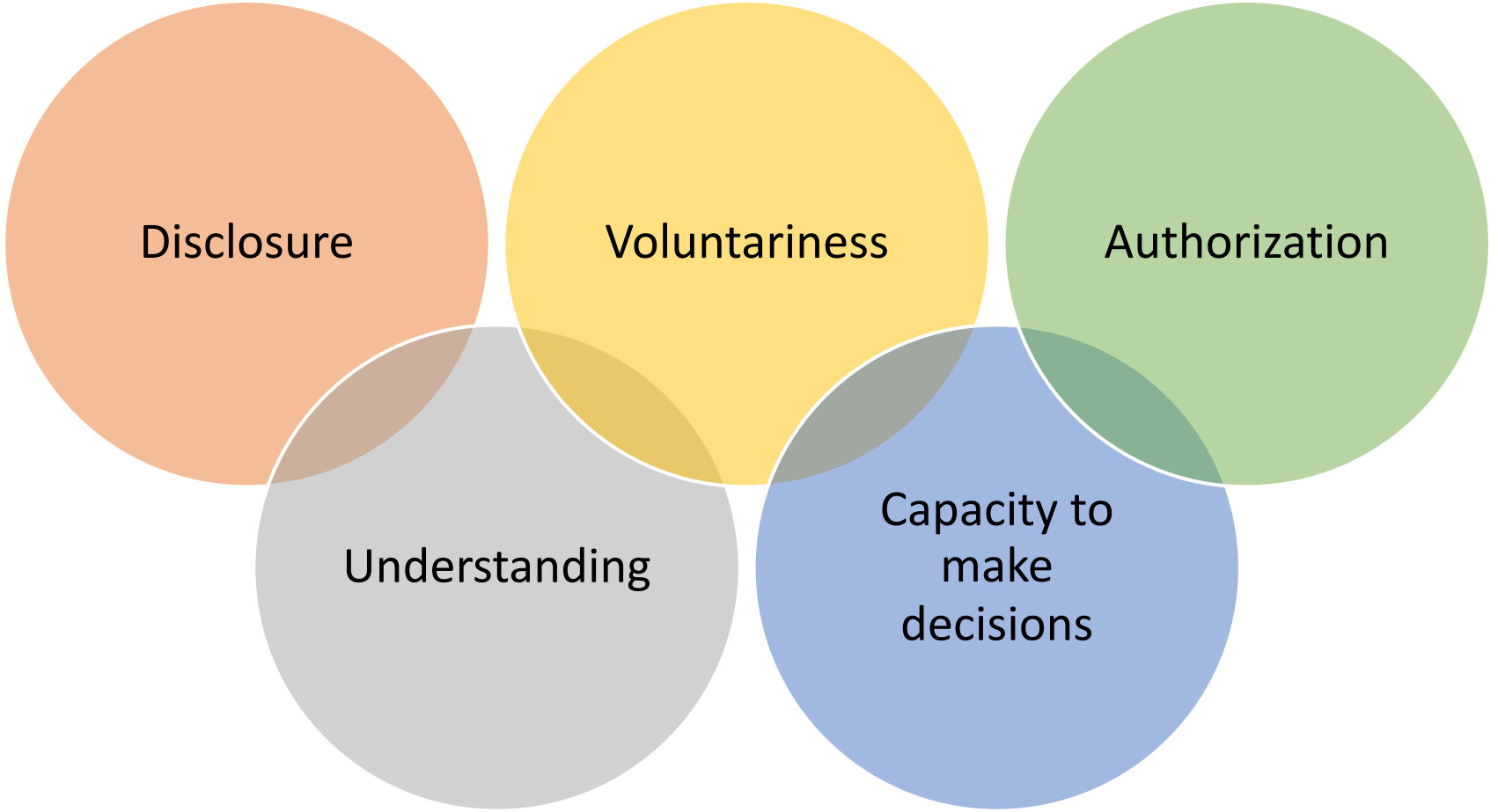
Informed Consent: What Do We Want People to Know?

Informed consent is an ethical, regulatory, and legal requirement that affords an individual the opportunity to express their autonomous authorization of an activity (e.g., healthcare treatment, research)

"The practice of informed consent varies by context, and the reality often falls short of the theoretical ideal."

Grady, C. Enduring and emerging challenges of informed consent. *NEJM,* 2015; 372:855-862.
Faden, R., & Beauchamp, T. A history and theory of informed consent. Oxford University Press, 1986.

Components of Informed Consent



Informed consent <u>is necessary but not sufficient</u> for the ethical conduct of research with patient-participants; other elements may be perceived to be more important to patient-participants than the actual consent document.

Informed Consent

Systematic reviews

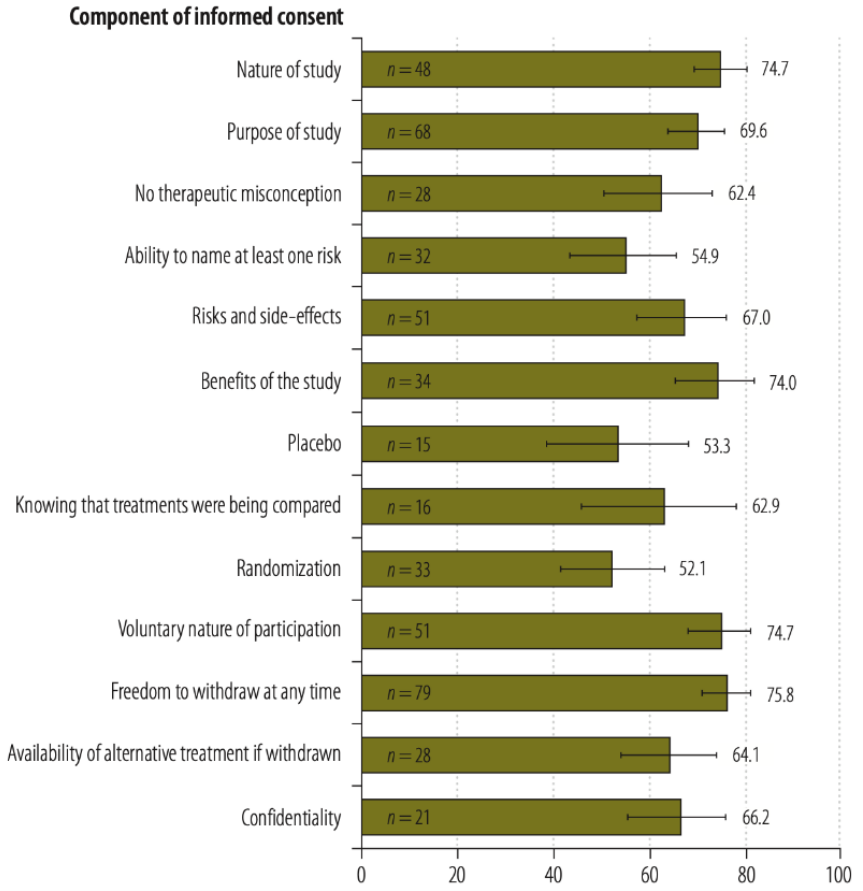
Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis

Nguyen Thanh Tam,[a] Nguyen Tien Huy,[b] Le Thi Bich Thoa,[a] Nguyen Phuoc Long,[a] Nguyen Thi Huyen Trang,[c] Kenji Hirayama[d] & Juntra Karbwang[b]

Objective To estimate the proportion of participants in clinical trials who understand different components of informed consent.
Methods Relevant studies were identified by a systematic review of PubMed, Scopus and Google Scholar and by manually reviewing reference lists for publications up to October 2013. A meta-analysis of study results was performed using a random-effects model to take account of heterogeneity.
Findings The analysis included 103 studies evaluating 135 cohorts of participants. The pooled proportion of participants who understood components of informed consent was 75.8% for freedom to withdraw at any time, 74.7% for the nature of study, 74.7% for the voluntary nature of participation, 74.0% for potential benefits, 69.6% for the study's purpose, 67.0% for potential risks and side-effects, 66.2% for confidentiality, 64.1% for the availability of alternative treatment if withdrawn, 62.9% for knowing that treatments were being compared, 53.3% for placebo and 52.1% for randomization. Most participants, 62.4%, had no therapeutic misconceptions and 54.9% could name at least one risk. Subgroup and meta-regression analyses identified covariates, such as age, educational level, critical illness, the study phase and location, that significantly affected understanding and indicated that the proportion of participants who understood informed consent had not increased over 30 years.
Conclusion The proportion of participants in clinical trials who understood different components of informed consent varied from 52.1% to 75.8%. Investigators could do more to help participants achieve a complete understanding.

Tam, et al.. *Bull World Health Organ,* 2015; 93(3):186-98H. doi: 10.2471/BLT.14.141390.

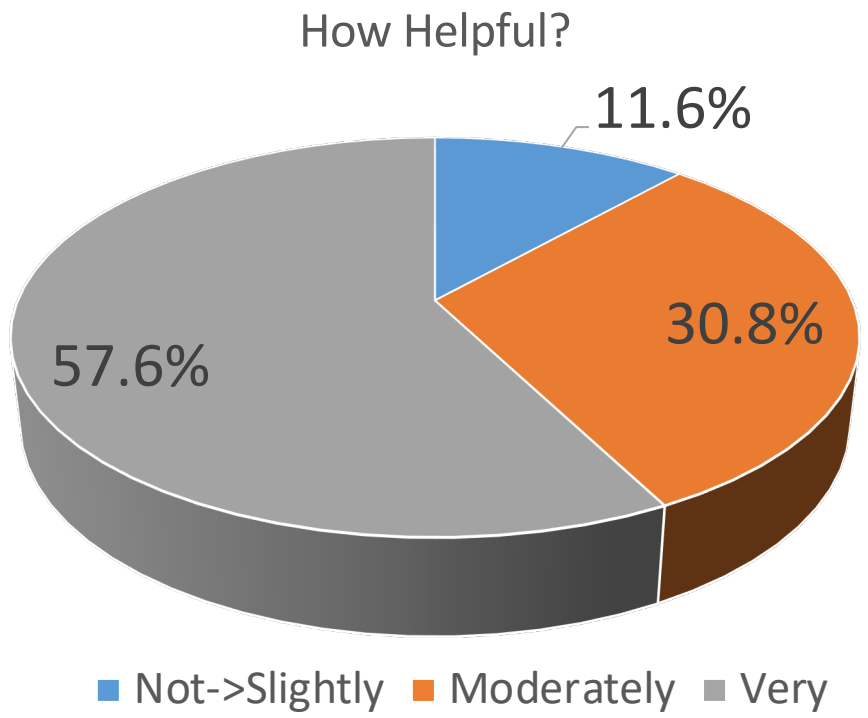
Fig. 2. **Participants' understanding of components of informed consent in clinical trials, by meta-analysis[a]**



Is Informed Consent in the Decision to Enroll in Research Helpful?

How carefully did you read the informed consent?	
Less than very carefully	148 (44.8%)
Very carefully	182 (55.2%)

How much of the written informed consent did you read?	
None or Some	58 (17.6%)
Most	182 (19.4%)
All	208 (63.0%)



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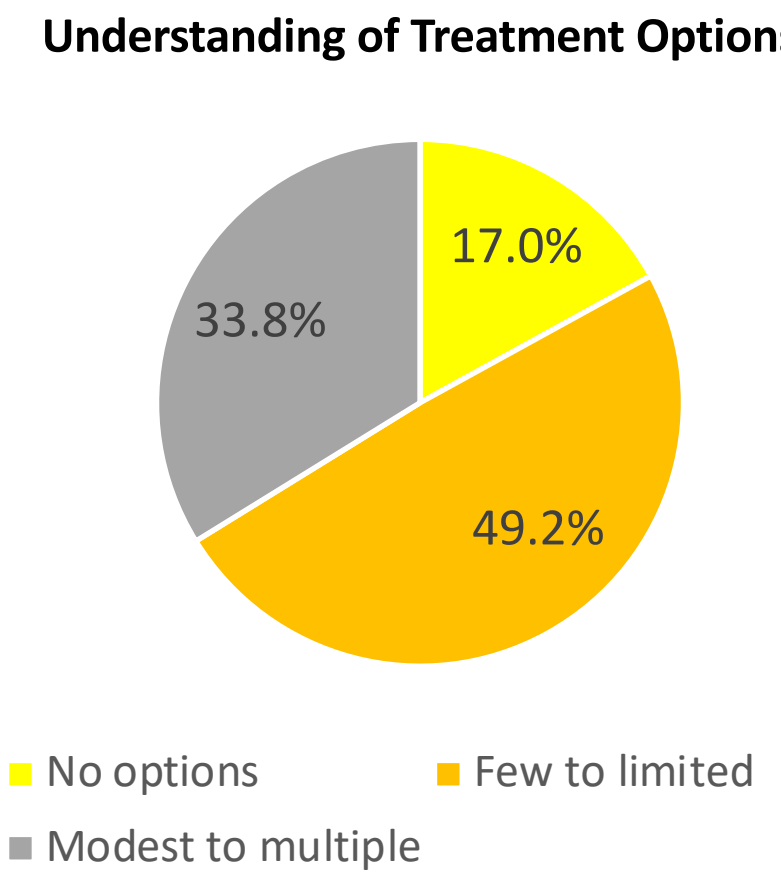
Seriously Ill Population



- Trusted my physician to know what was best for me or most beneficial.
  - Agree: 85.6%
  - Neutral: 12.2%
  - Disagree: 2.2%

- Trusted my physician to know what degree of risk(s) were acceptable to me.
  - Agree: 81.9%
  - Neutral: 15.3%
  - Disagree: 2.8%

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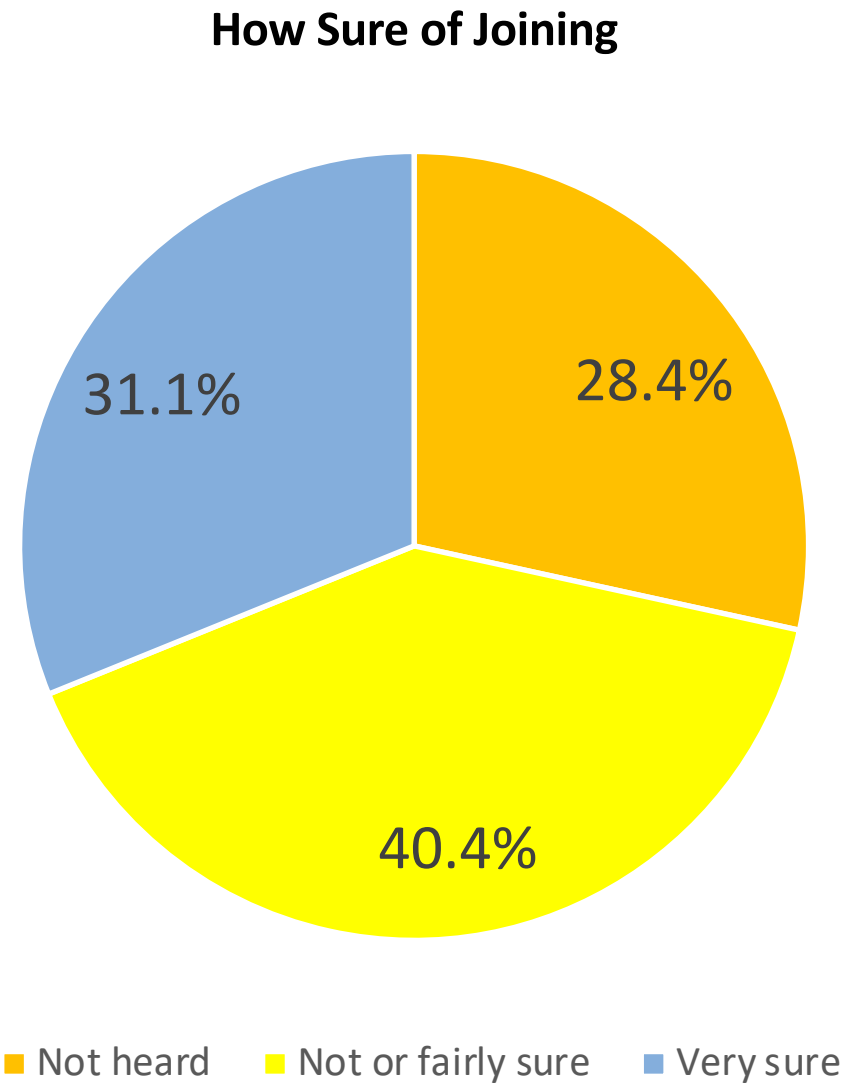
How Sure of Joining Trial Before Coming to the Clinic



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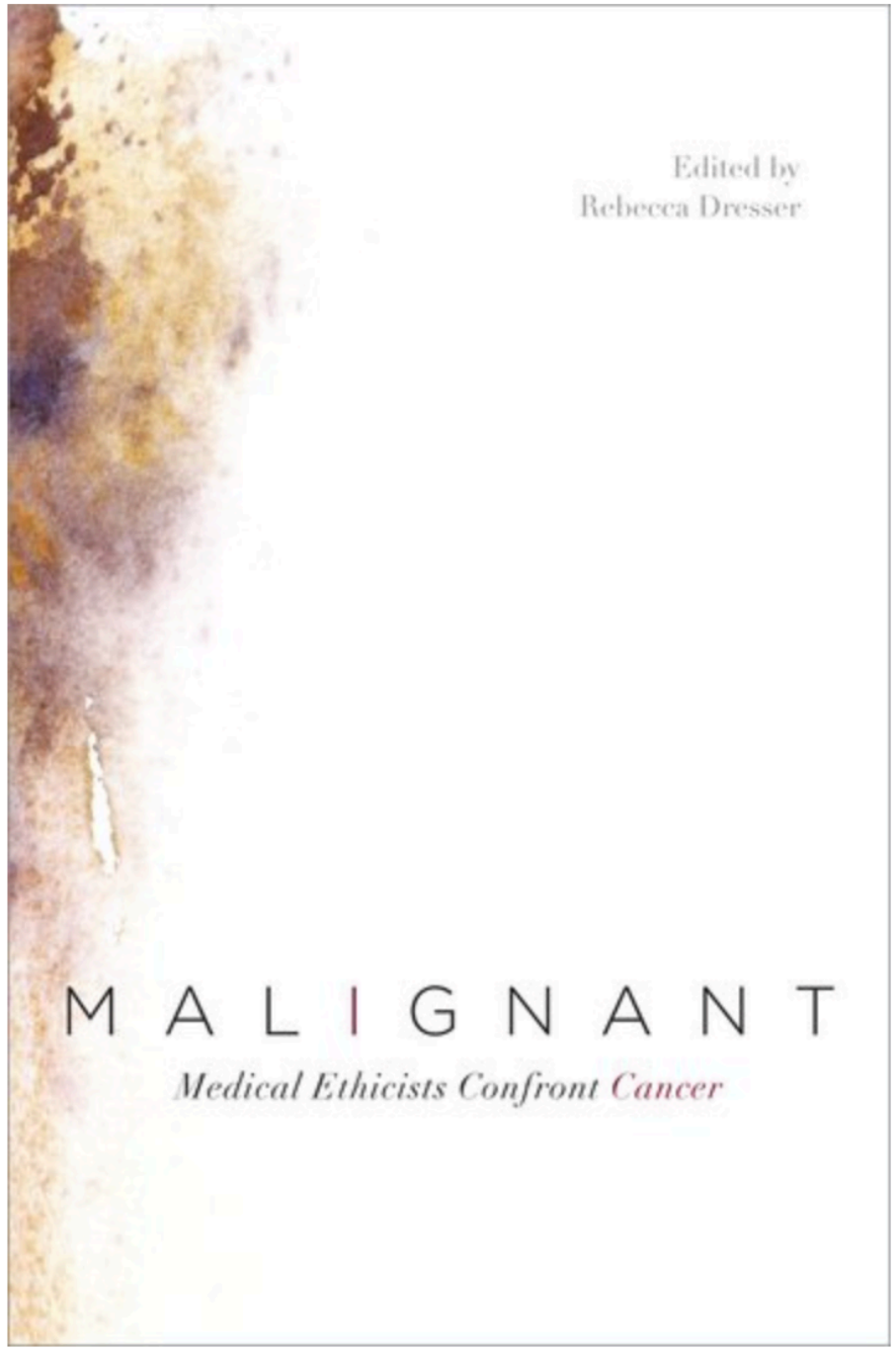


"When we are ill or injured, we often lack the skills or energy for demanding cognitive tasks. Our highest priority is to get help from others and in particular from others with relevant skills and knowledge."

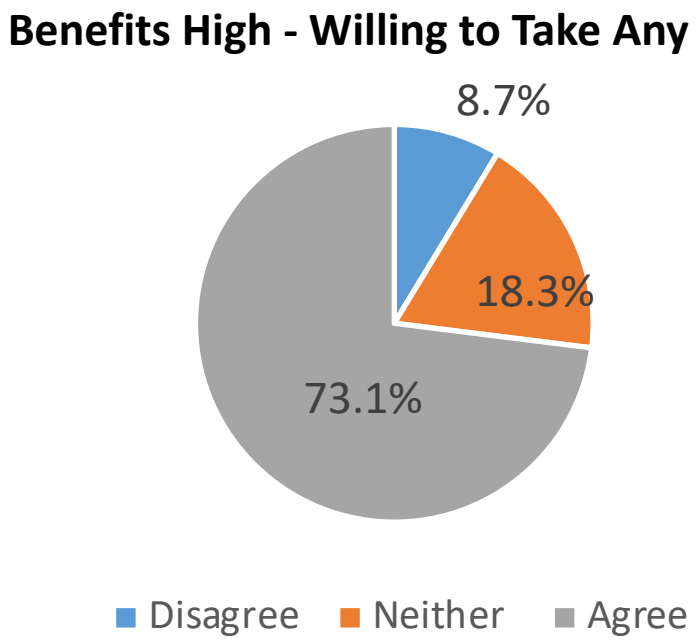
"Patient autonomy can be a challenging business. Even the most educated and savvy patients facing serious medical decisions may not be very good at applying their values and preferences to this new kind of choice."

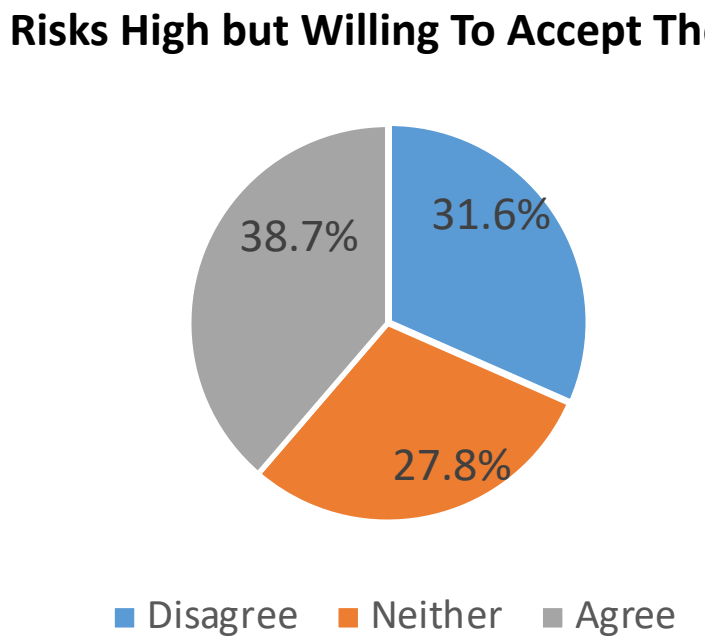
Dresser, R. (2012). Malignant: Medical Ethicists Confront Cancer. Oxford University Press.

The Benefits and Risks of Research Participation

"The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate."

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xassess





Risk-Benefit Assessment

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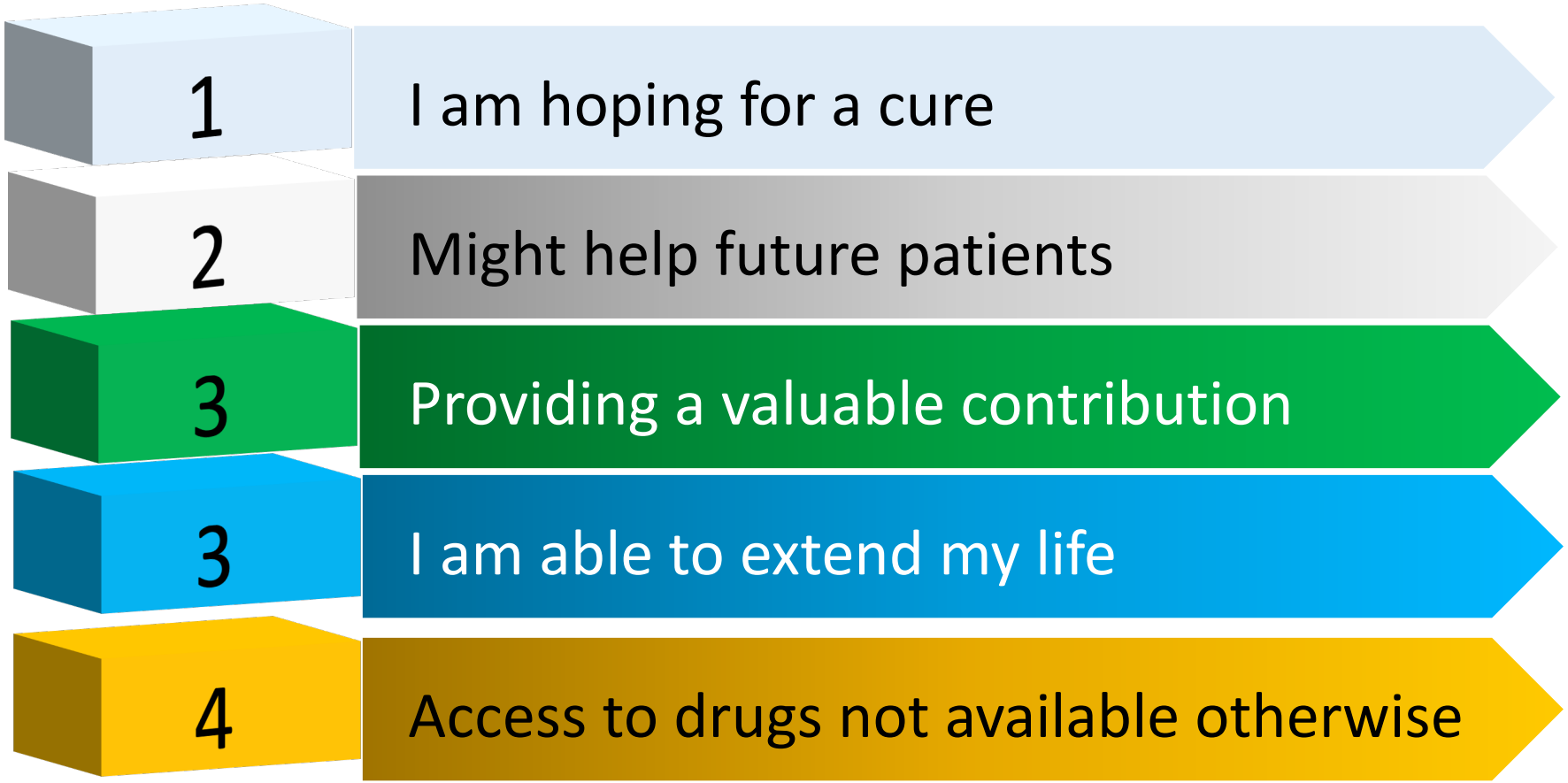
Top Benefits



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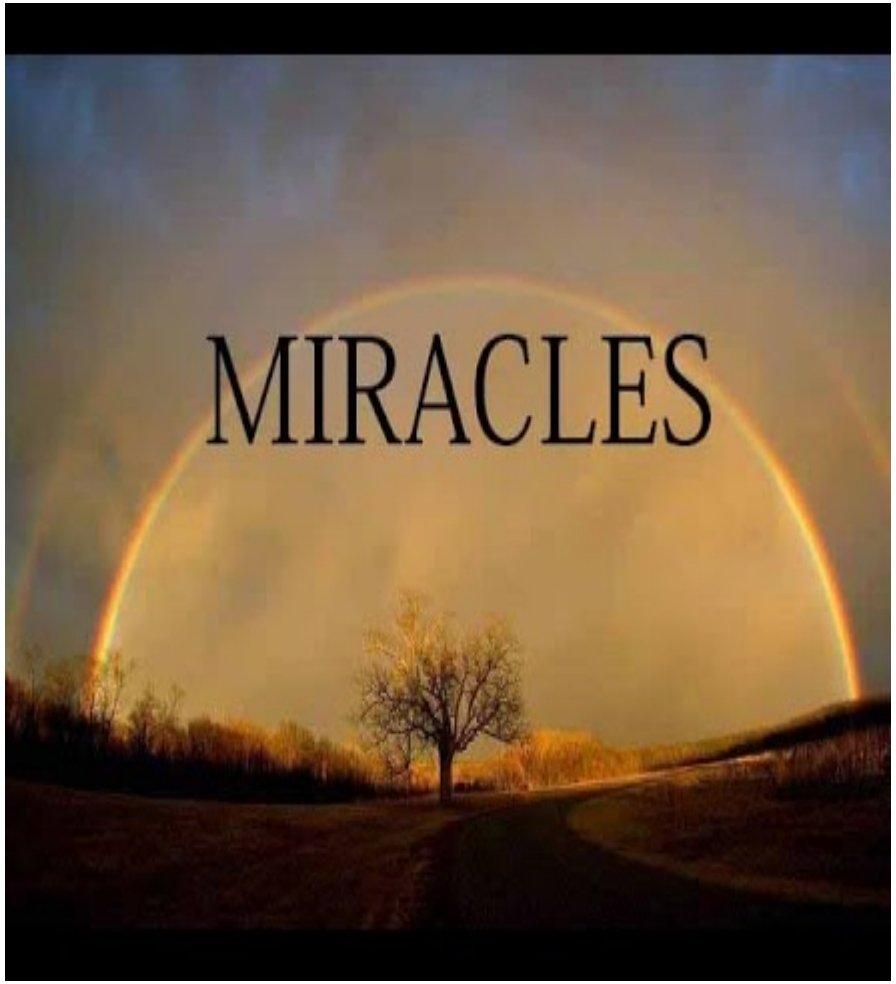
Other Benefits

- It is a way to actively treat my cancer
- My cancer is watched more closely
- It may reduce my future cancer risk
- It gives me a sense of hope
- It may help my children or other family in the future
- I trust my researcher knows what is best
- It does not interfere with other responsibilities

Higher Benefit = Less Likely to Drop Out of Trial

Quotes on God, Faith, Spirituality, and Miracles

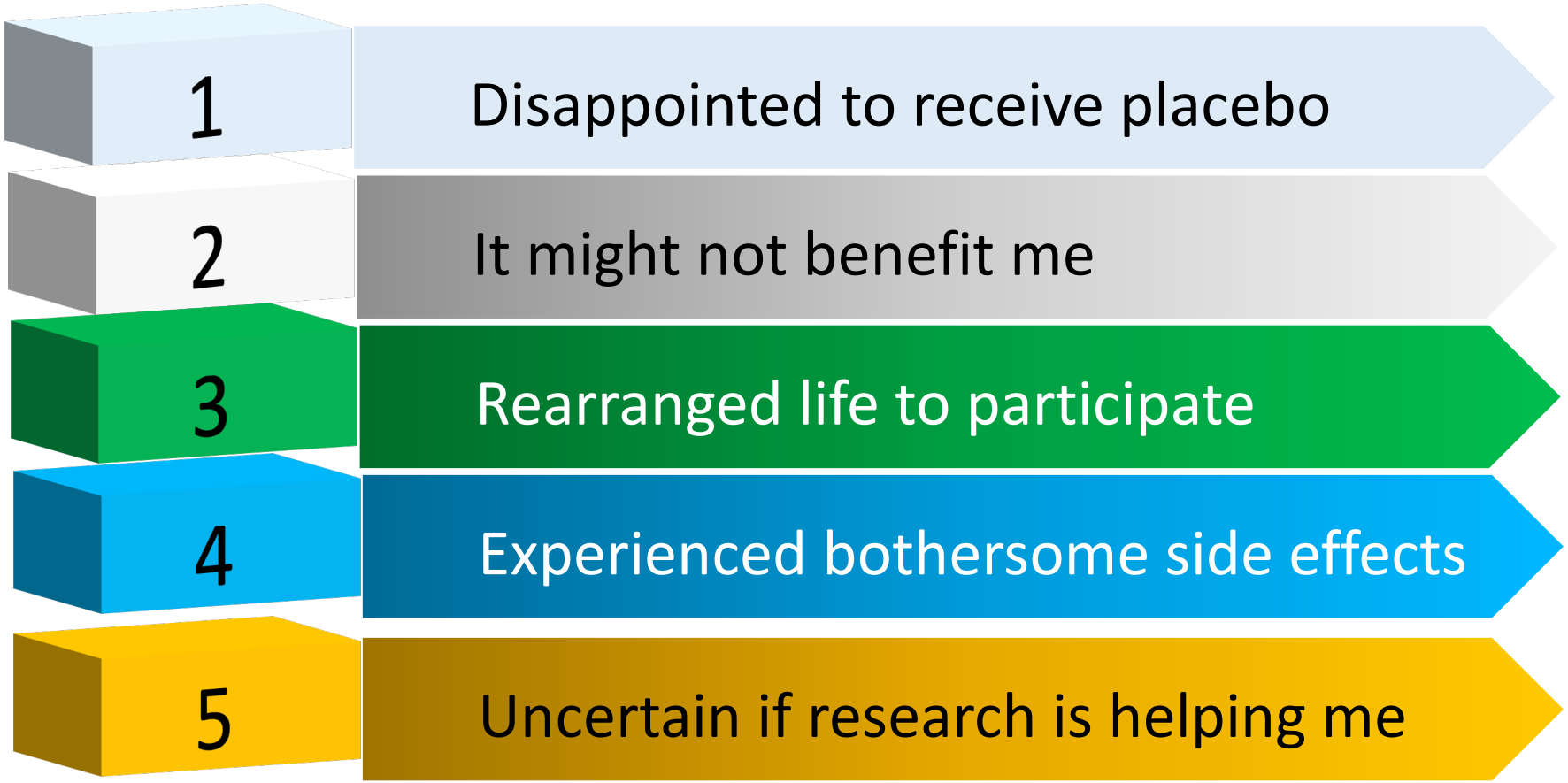


- "Because I knew he couldn't continue on it, and yet I was so fearful of what it could mean not being on it, and yet at the same time, I know that…you know, its not (the patient) and I driving the…I mean…how do I want to say it? God is always with us. And…and my understanding of who God is, and it's not that God makes this happen or he gave (the patient) this disease or anything like that. It's just within the whole realm of God walks with us through the good and the bad. And so there…I drew a lot of comfort knowing, okay, so whatever happens, you know, it will happen. I won't…you know, we'll deal with it."

- "My husband puts a lot of faith in his doctors and God."

- "I understand it's pretty severe. The doctors consider it to be incurable and that they can treat it with medications but that will ultimately, at some point, stop working. I also understand that, but I understand that we've been waiting for a miracle from God. We're not counting things out."

5 Top Burdens



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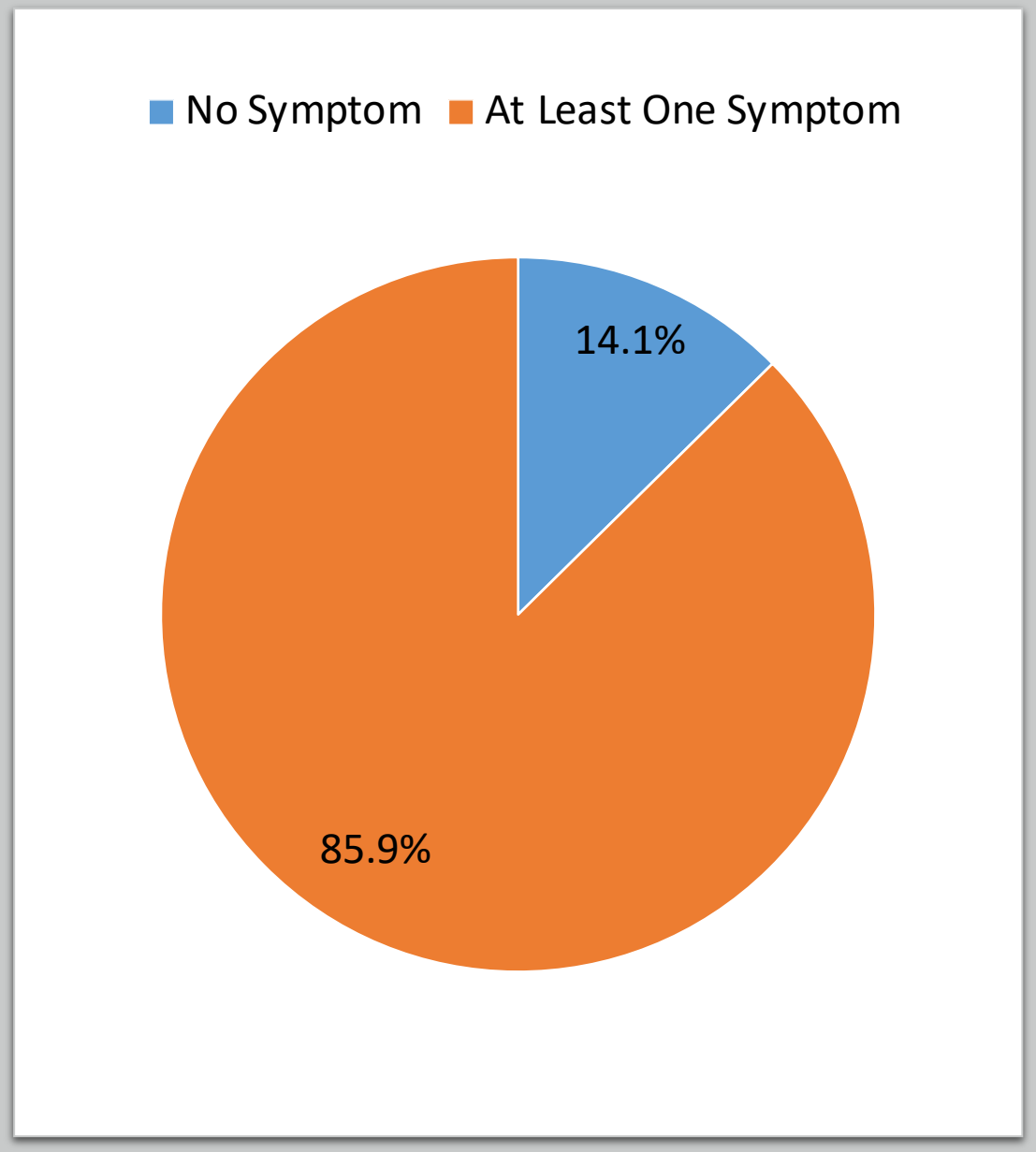
Other Burdens

- Makes me worry family members are at risk for cancer
- It is costing me money out of pocket
- Made me realize the seriousness of my cancer
- It has added stress to managing my cancer
- Unknown side effects
- I am not learning more about my cancer

Higher Burden = More Likely to Drop Out of Trial

Symptom Distress

- 25.2% reported experiencing moderate to overwhelming pain during their research participation
- 77.1% reported moderate to overwhelming symptoms including fatigue, nausea, coughing, diarrhea, constipation or nosebleeds
- 56.2% rated their fatigue as 5 or higher on the VAS
- 21.2% rated nausea as 5 or higher



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How Important is the Research Team?

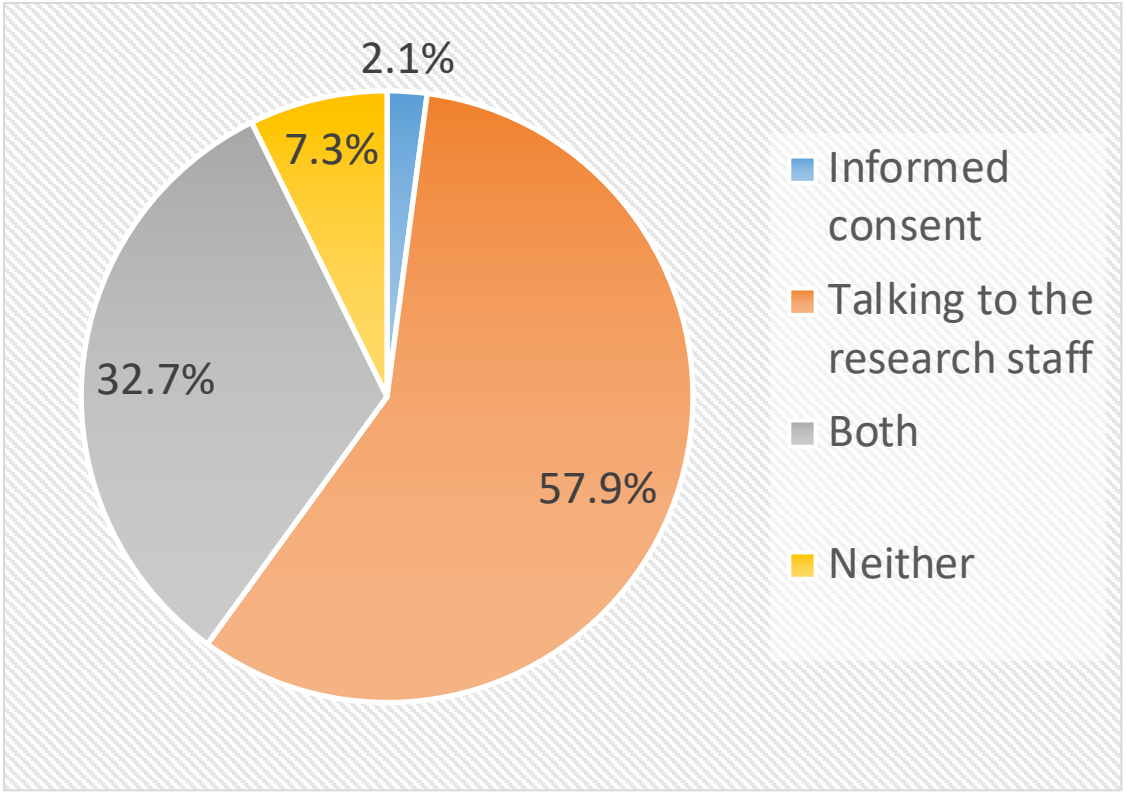
When Did You Decide to Participate?

19.1%
Prior to formal discussion

47.3%
During the discussion

33.5%
Following the discussion

Which Had a Greater Influence on your Decision?



- Ulrich, et al. Retention in Cancer Clinical Trials: Modeling Patients' Risk-Benefit Assessments (R01CA196131)

Therapeutic Misunderstanding

We worry about Therapeutic Misunderstanding in Clinical Research

Misconception: Conflating research with treatment

Misestimation: Over or underestimate the benefits and over or underestimate the risks

Optimism: Unduly hopeful or excessively optimistic about one's outcomes

- Horng S, Grady C. Misunderstanding in clinical research: distinguishing therapeutic misconception, therapeutic misestimation, and therapeutic optimism. IRB. 2003 Jan-Feb;25(1):11-6.
- Lidz CW, Appelbaum PS. The therapeutic misconception: problems and solutions. Med Care. 2002 Sep;40(9 Suppl):V55-63.

"Enthusiastic Optimists"

In similar ways that symptoms are clustered and affect patient outcomes, we found that the comforting characteristics of hope, optimism, and presence of spiritual beliefs also represent a cluster of characteristics that may contribute to overall well-being and coping with one's disease.

- Highly spiritual
- Highly optimistic
- Highly trusting
- More likely to perceive the benefits outweigh the burdens
- More likely to have a therapeutic misconception
- Used a mixture of emotions to make decisions
- Wanted to be involved in decision-making

What is it about spiritual beliefs and other virtue-based characteristics that aid patients to endure suffering in the hopes of a cure?

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Withdrawing from Trial

- Patients with a higher burden score were more likely to withdraw (p=0.014)
- Patients who were more bothered by symptoms were more likely to withdraw (p<0.001)
- Patients with a high symptom burden score were more likely to withdraw than those with a low symptom burden score (p=0.019)
- Patients who didn't think the risks seemed reasonable were more likely to withdraw than those who agreed the risks seemed reasonable (p=0.005)
- Patients with a larger difference between benefit and burden scores were less likely to withdraw (p=0.004)
- Patients with a higher RN communication score were less likely to withdraw than those with a lower score (p=0.009)
- Patients with a high RN communication verifying subscale score were less likely to withdraw than those with a low score (p=0.043)

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Physician Communication

- Patients with a higher physician communication score had a lower odds of having thought about dropping out (p=0.013)
- Patients with a higher physician communication relational subscale had lower odds of having (p=0.007)
- Patients with a higher physician communication information seeking subscale had lower odds of having thought about dropping out (p=0.023)

A Team Approach

- Interdisciplinary integrity is essential to research participation and we define it as a commitment on the part of the clinical and research teams to provide honest and clear information about the benefits and burdens of clinical trials in an atmosphere that respects the rights of human participants as active partners in decision-making.

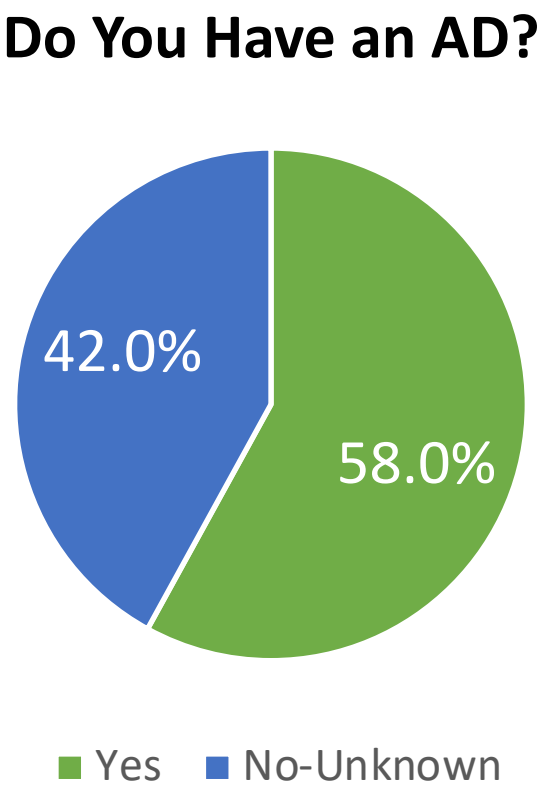
- These interdisciplinary partnerships include building trusting relationships reflective of caring attitudes, competence and factual knowledge of research and its effects.
  - Ulrich & Wallen (2011). Does Research Integrity Start and End with the Primary Investigator?: Making a Case for Interdisciplinary Integrity

Emerging Issues

What Do We Owe Participants Post-Trial?

- ~24% of participants had concerns about remaining in the trial.
- Most of the focus on post-trial clinical care has been on providing participants with access to any benefits that result from the trial, as affirmed in the Declaration of Helsinki.
- Are there a broader set of post-trial responsibilities that we need to discuss with participants and their families?
  - Advance care planning and end-of-life
  - Community needs-medical resources
  - Access to other trials

Advance Directives in CCTs



- 39% and 34.2% of those who are Stage IV and Stage III do not have an AD.
- Of those who indicate they have no-few other options, 43.8% have no AD.
- Of those who indicate they have no other options, 46.3% have no AD.
- Having an AD increased with age ($p<.001$).

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Communication

- 27.6% of our participants felt that the research staff did not explain the trial very well
  - Can we allay misinformation and misunderstandings?
  - What type of communication skills are needed?
  - What is the role of care partners?

Dr. Chris Pernell, Strategic Integration and Health Equity Officer
University Hospital, Newark, New Jersey

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Informal Caregivers

- At some point in our lives, many of us will become informal caregivers.
- More than 1 in 6 Americans working full-time or part-time report assisting with the care of an elderly or disabled family member, relative, or friend.
- Caregivers are essential to the lives of those who are ill and require treatment as well as those participate in research trials, but they too suffer [physically, psychological, spiritually, financially].

https://www.caregiver.org/caregiver-statistics-work-and-caregiving

What Do We Do With Informed Consent?

- Enhanced consent documents?
- Use of social media?
- More time to explain information?
- Focus on other elements of informed consent beyond understanding?
- Focus on presentation of information (reframing, storytelling approaches)?
- Public education on clinical research?

Learning Health Systems

The Competing Demands of Patient Privacy and Clinical Research

Connie M. Ulrich, Christine Grady, George Demiris, and Therese S. Richmond

ABSTRACT Privacy and confidentiality of personal medical information are cornerstones of ethical clinical care and ethical research. But real-world research has challenged traditional ways of thinking about privacy and confidentiality of information. In today's world of "big data" and learning health care systems, researchers and others are combining multiple sources of information to address complex problems. We present a case study that highlights the ethical concerns that arise when a patient who is employed by an academic medical center learns through a research invitational letter that her private information was accessed at this center without her consent. We discuss the ethical challenges of balancing patient privacy with advancing clinical research and ask, what level of privacy and confidentiality can and should patients expect from their clinician providers, fellow research colleagues, and institutions?

KEYWORDS ethics, learning health system, employees, privacy, research

Ulrich, C. M., et al., "The Competing Demands of Patient Privacy and Clinical Research," *Ethics & Human Research* 43, no. 1 (2021): 25-31. DOI: 10.1002/eahr.500076

Jane received a letter from a researcher who works in the same academic medical center as she does, inviting her to participate in a study "targeting" ways to improve early diagnosis of uterine cancer for individuals diagnosed with endometrial cancer. Jane recently had gynecological surgery at this academic medical center (and, as part of her preadmission testing, had a chest x-ray). As you might imagine, she did not disclose or release information related to her gynecological care and treatment at the hospital to her colleagues and expected it to remain private. What a surprise, then, to receive an invitational research letter at her home that identified her private health information, including her name and her cancer diagnosis, along with incidental lung nodule findings from the chest x-ray of which she was not aware. In the letter, the study team, some of whom she knows as colleagues, noted that they had already contacted her surgical oncologist to obtain through the electronic medical records system her personal medical history that they needed for the research. The institutional review board (IRB) had approved the study and the invitational letter. Jane subsequently spoke to the chair of the IRB, the hospital's privacy officer, and a colleague who is a bioethicist, asking how to note in her medical record to not allow researchers access to her personally identifiable information without her explicit permission. She was told that this was not possible given that this was an academic medical center and that, by agreeing to receive care within the system, she was agreeing to allow her records to be used for IRB-approved research.

Confidentiality of personal medical information is a cornerstone of ethical clinical care and ethical research. Indeed, codes of ethics published by professional societies, federal and local rules, hospital practices, and other guidance require clinicians and researchers to protect the confidentiality and privacy of their patients and research participants. Federal guidance defines private information as "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording

The Value of Research Participants

"Subjects are the only people who know what it is like to confront complicated consent forms and discussions and make important personal decisions based on them. Subjects are the only people to bear the actual burdens and inconveniences of study participation, and to juggle the responsibilities of participation with the demands of everyday life."

—Rebecca Dresser, 2016

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- Research Team
- Patients and families who gave of their time to help us better understand their issues.

Q&A Session