

Communication Challenges in Precision Oncology

GALEN JOSEPH, PHD

NATIONAL CANCER POLICY FORUM

THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, MEDICINE

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Nothing to Disclose.

Health Literacy

- ☐ conceptual and cultural knowledge
- ☐ listening and speaking skills
- ☐ reading and writing skills
- ☐ **numeracy i.e. quantitative skills**

36 million adults

Struggle to

Read
Write
Do math
Use Technology

Above a 3rd grade level



The Challenges of Low Numeracy and Literacy



20% of college-educated adults do not know what is a higher risk—1%, 5%, or 10%

1/3 have basic or below basic literacy (reading and understanding a prescription label is a challenge)

Relevance for the general population

- ❑ Only 12% of US adults are fully proficient in health literacy
- ❑ Only 9% of US adults score the highest numeracy proficiency level
- ❑ Physicians commonly overestimate patients' literacy (and numeracy) levels
- ❑ Health information and the healthcare system can be difficult even for highly skilled people
- ❑ A new diagnosis or a stressful medical situation can make it hard for individuals of any literacy/numeracy level to understand

“Communication is the most common procedure in medicine”

“Numerical probabilities are challenging to communicate effectively to the lay public and **even to trained medical clinicians...**



“Our statistician will drop in and explain why you have nothing to worry about.”

Risk perception is affected by many factors other than numeracy

Cognitive/emotional traits (e.g. optimism pessimism, risk format preferences)

Consequences of risk information

Uncertainty/need to reduce uncertainty

A priori beliefs about risk level

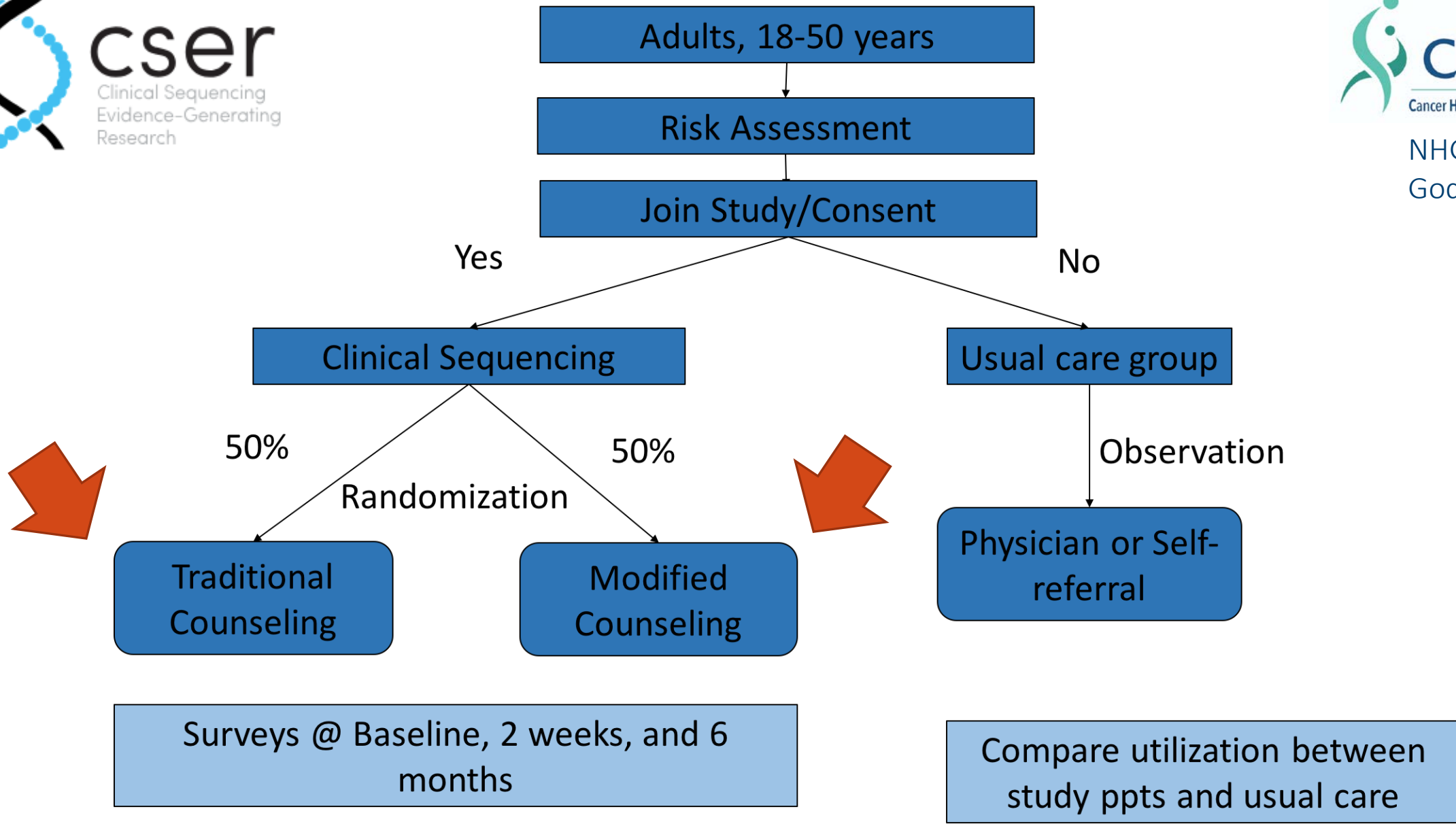
Representativeness (inferring from a small group to a large group e.g. family to population)

Anchoring in initial number presented

Binarization (50/50, present/absent, will or will not occur)

Complexity (e.g. when multiple risk numbers are presented together/sequentially)

Communication in Precision Cancer Screening Studies



Communication Study Findings

1. Profound mismatch between the information counselors routinely provided and the information patients wanted to know
2. Genetics was unfamiliar
3. The amount of information was overwhelming
 - a. Complex terminology and conceptually difficult
 - b. Not perceived as relevant
4. Patients didn't participate in decision-making
 - a. Counselors unintentionally inhibited patient engagement and question-asking
 - b. Screening and prevention recommendations were vague
5. Healthcare Interpreters had as much trouble as patients

Results Disclosure Communication Approach

TRADITIONAL: USUAL CARE

Conceptually and linguistically complex

- ☐ Analogies/hypotheticals
- ☐ Jargon/technical language
- ☐ Passive voice to convey uncertainty indirectly

Emphasis on Education

- ☐ Detailed genetic information
- ☐ Unidirectional transfer of information from counselor to participant

MODIFIED: LITERACY FOCUS

Conceptually and linguistically simplified

- ☐ Direct/concrete
- ☐ Lay/Plain language
- ☐ Active voice to clarify/minimize uncertainty

Emphasis on Communication and Psychosocial Counseling

- ☐ More dialogue/participant engagement
- ☐ Focus on relationship building (rapport/empathy)

Principles of Effective Communication

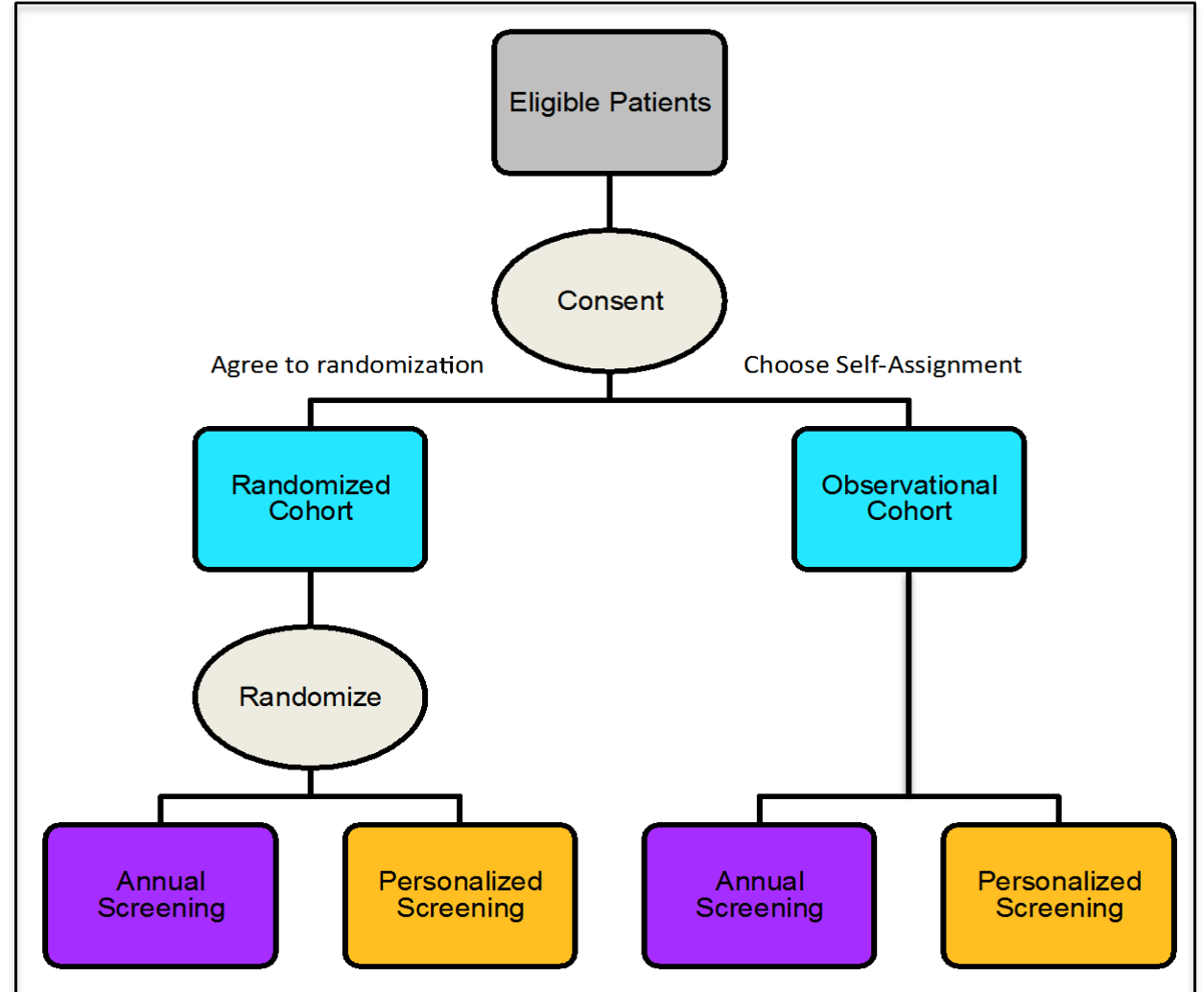
- The clinician, not the patient, is responsible for effective communication.
- The 'universal precaution principle': *all patients may benefit* from plain language or 'living room talk'
- Patient comprehension can and should be verified
- Adapting for literacy/numeracy level requires commitment, flexibility, and practice.

Approach to Communication in CHARM

- ☐ All materials, consent, surveys etc. designed for accessibility for limited health and genomic literacy
- ☐ Everything translated and culturally adapted to Spanish
- ☐ Web-based consent with illustrations and audio
- ☐ All results disclosure via phone
 - ☐ Exploring video options
- ☐ Training Medical Interpreters on exome sequencing for results disclosure

Women Informed to Screen Depending on Measures of Risk: a pragmatic, preference-tolerant randomized controlled trial

- ❑ Annual vs. “personalized” or “risk-based” breast cancer screening
- ❑ Recruitment Goal: 100k women aged 40-74
- ❑ PCORI (2015-2020)
- ❑ PI: Laura Esserman, MD, MBA



Aims: to evaluate the efficacy, safety, and cost-effectiveness of risk-based screening

ANNUAL ARM

- ❑ Breast Cancer Surveillance Consortium (BCSC) Risk Calculator
 - ❑ age
 - ❑ race
 - ❑ family history
 - ❑ breast density
 - ❑ history of breast procedures

PERSONALIZED ARM

- ❑ BCSC plus genomic screening
 - ❑ 9 high & moderate penetrance *breast cancer* genes
 - ❑ Polygenic Risk Score: 200+ SNPs

Screening Assignments:

No screening yet (age 40-49)

Biennial Mammogram

Annual Mammogram

Annual Mammogram + annual MRI



Embedded ELSI study

Precision Genomics in the WISDOM Pragmatic Clinical Trial: An “Embedded” ELSI Study of Risk-based Breast Cancer Screening

- ❑ NCI R01 CA211999 (2017-2021)
- ❑ PIs: Barbara Koenig & Galen Joseph
 - ❑ Project Director/Ethnographer: Jennifer James, PhD
 - ❑ RA/Project Coordinator: Leslie Riddle, MPH

ELSI Aim & Methods

Aim: To examine the ethical and social implications of genomic population screening.

- ❑ Ethnography of trial implementation
- ❑ Audio recording of disclosure calls
- ❑ Interviews with study participants at all risk levels
- ❑ Survey of mutation carriers
- ❑ Bioethics Working Group to provide ongoing ethics advice

Ethical and Social Challenges of Genomic Population Screening

☐ **All online study/No pre-test counseling or discussion**

- ☐ Is online consent process adequate for informing participants?
- ☐ What is impact on women receiving high risk results?

☐ **Results disclosure by phone or letter**

- ☐ Mutation carriers and high risk due to PRS get phone call
- ☐ Negative results and/or not at elevated risk -Letter only
- ☐ VUS not returned

☐ **Pragmatic trial/Learning healthcare system**

- ☐ Blurs clinical care and research
- ☐ Adaptive Risk Model: incorporate new patient information and genomic data periodically
- ☐ Screening recommendations are recommendations; not clear that participants/clinicians will follow

Challenges of Online enrollment/consent

Some participants don't:

- ☐ read consent carefully
- ☐ understand basis of risk assessment and screening assignment
- ☐ understand scope and limitations of the test
- ☐ think about implications of genomic testing until they get a positive result

Challenges of online consent

I understood I'd be giving a saliva sample. I have to say – this is why I volunteered to be part of this – that even though it should've been really obvious to me from the study, **it didn't even cross my mind that one of the outcomes would be that I would be found to have BRCA1.**

...I was just like oh, they're going to tell me to get mammograms once a year or every three years, like that, or whatever... **It wasn't even on my radar that one of the outcomes would be oh, the reason you have to get it more frequently is 'cause you're -- ...I wasn't really thinking through what it meant to have a personalized assessment...**

(mis)understanding of the limitations of the test

Well honestly, one question I do have that I haven't asked anybody..., **is like what did this test for? Or more importantly, what did it not test for, and would I --** I mean, I don't think this mutation is particularly associated with any other mutation, at least I haven't read that, such that it's indicated that I should do some more testing. But, you know, I don't know.

Understanding the Screening Recommendation

- P: What if something develops right after my last mammogram and then I don't see it for two years, you know? But at the same time, I guess I'm thinking it's – trying to think it through about, you know, **you guys did your saliva test and maybe that shows that I don't have any particular genes to be predisposed to that. You know what I mean?... I was just surprised. I thought oh, for sure with my family history, they'll tell me to go every year... I figure you guys know a lot more about it than I do. Or I hope you do. (chuckles)... I'm putting my life in your hands. (chuckles)**
- I: Do you really – I mean, do you feel that way, like you're putting your life in the hands of the study?
- P: No, no, of course not. You know, **I really doubt that you guys would be making recommendations to people like that without some significant basis.** I mean, not to just say, "Oh, let's just see what happens. You know, if she waits two years, let's just see," you know.

Communicating PRS

So we looked at 79 different small genetic variations that we call polymorphisms or SNPS for short, and each of them has been proven to be associated with breast cancer risk and can give you, you know, again, a tiny predisposition or a tiny protective effect. And we add all those up together and incorporate that into your overall risk assessment. **So all of these factors actually go into a calculator together to generate that number that I just gave you, about six and a half percent. But for you, the major big thing that pushed that number up was those small genetic risk factors.**

P: she said I had like a 6% chance of getting breast cancer, you know, compared to, I don't know, three or four percent for most people. So that's just not that big of a difference. You know what I mean?

I: Yeah. Is that 6% -- like what did she mean -- what was your sense of what she meant by a 6% chance?

P: So I'm a 57-year-old woman with a particular set of breast characteristics, right, and certain -- well actually, those went into the probability calculations. So I'm of a certain age, right? If you take a hundred women just like me of my same age, six of them will develop breast cancer in the next five years 'cause that's a five-year risk of cancer that she was giving me. So you know, but that also means there's 94 that don't get it.

Understanding PRS

I: When [the BHS] spoke with you, she mentioned that they also tested for single nucleotide polymorphisms or SNPS.

P: Yeah, it was interesting '... So that means I don't have a mutation but something's a little wonky in that DNA. I don't quite understand it. I always say **I'm a kindergarten math girl. I don't get it.**

I: You know, like you've mentioned the 25% that [the BHS] talked about. How do you feel about having a number? Does that help you?

P: Hmm. [Chuckles] I think that the number is kind of weird until it gets explained to you, you know, that it's sort of misleading. **Like I would think 25% more chance meant that I would be one in four, right? I don't know why. Maybe that's just stupid math. But like as an artist and not a mathematician, you know, when I heard 25% at first it was like whoa, you know, it seemed like way more risk than what I took away after my conversation with her.**

Conclusions

- ❑ Access is not enough
 - ❑ Effective communication is necessary for the equitable and ethical implementation of precision oncology
- ❑ Risk communication, low literacy and low numeracy present communication challenges for precision oncology and computational medicine
- ❑ All individuals benefit from clear communication
 - ❑ Relative risk and shifting risk timeframes are confusing
- ❑ Precision population screening presents specific communication challenges
 - ❑ Providing complex information, remotely, in a public health context
 - ❑ screen once a year → screen more or less depending on risk
- ❑ Value of ELSI research and collaborations to elucidate and guide precision oncology

Questions for Discussion

What are the implications for computational oncology of the challenges of numeracy, literacy, and risk communication?

- ☐ Does computational anything belong in the clinic?
- ☐ To what extent do the advances in computational oncology need to be communicated to the patient?
- ☐ What can CHARM and WISDOM teach us about communicating effectively about omics?

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