

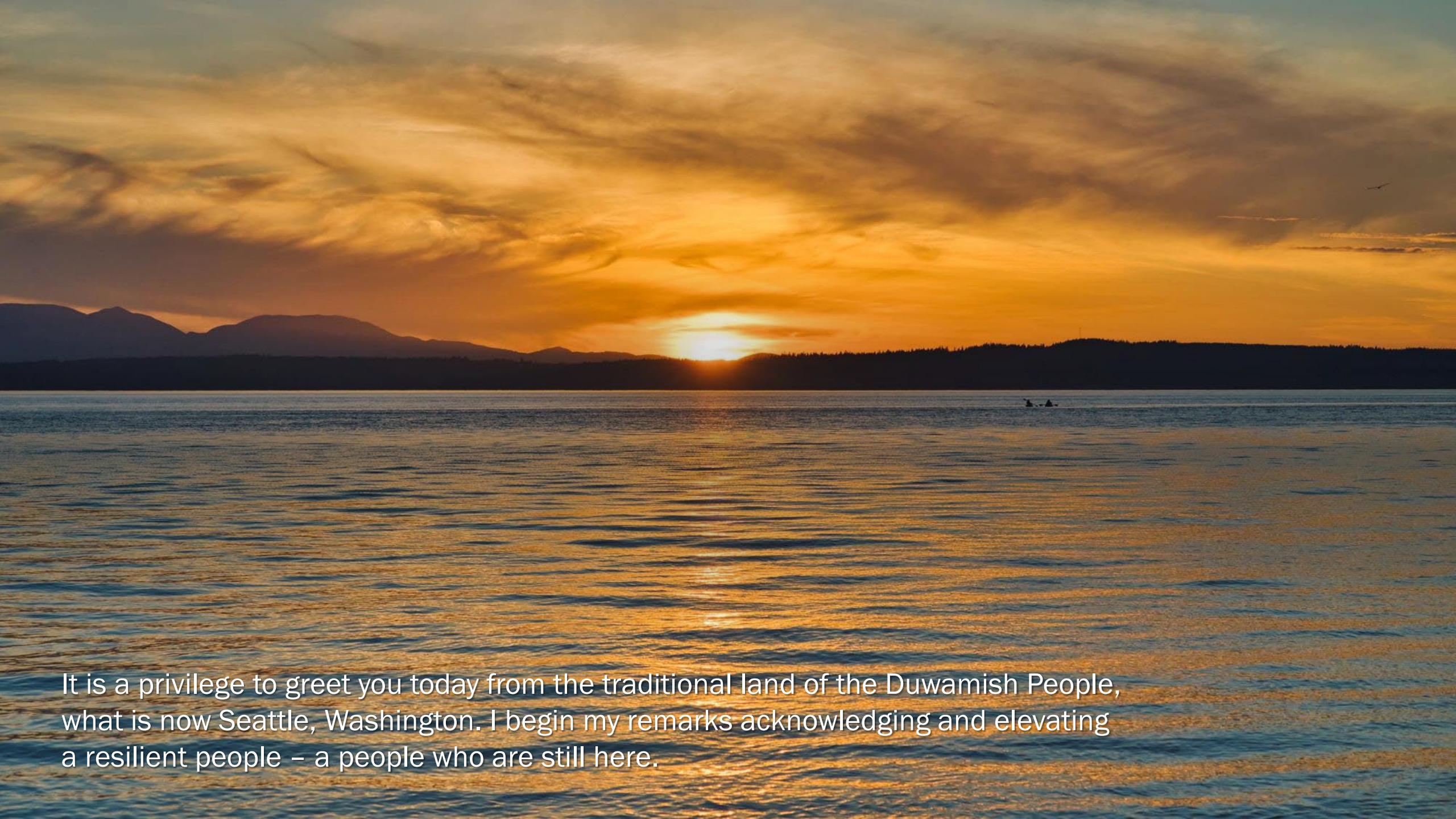
HIPAA, ethical, and logistic considerations in cascade testing

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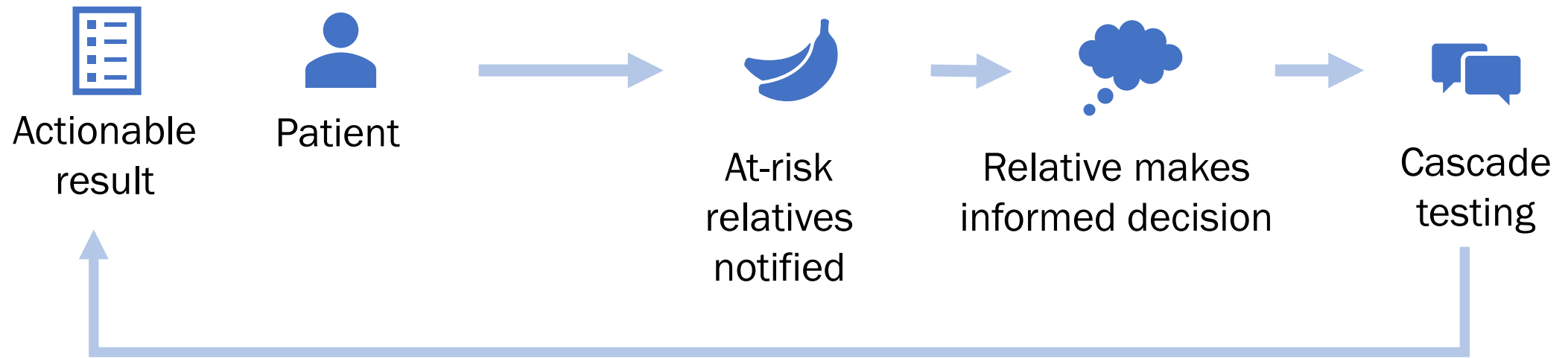
Kaiser Permanente Washington Health Research Institute, Seattle WA

Implementing Precision and Equitable Public Health in Cascade Testing for Genetic Disorders - A CDC Mini-Symposium and Virtual Panel Discussion

February 10 2022



It is a privilege to greet you today from the traditional land of the Duwamish People, what is now Seattle, Washington. I begin my remarks acknowledging and elevating a resilient people – a people who are still here.



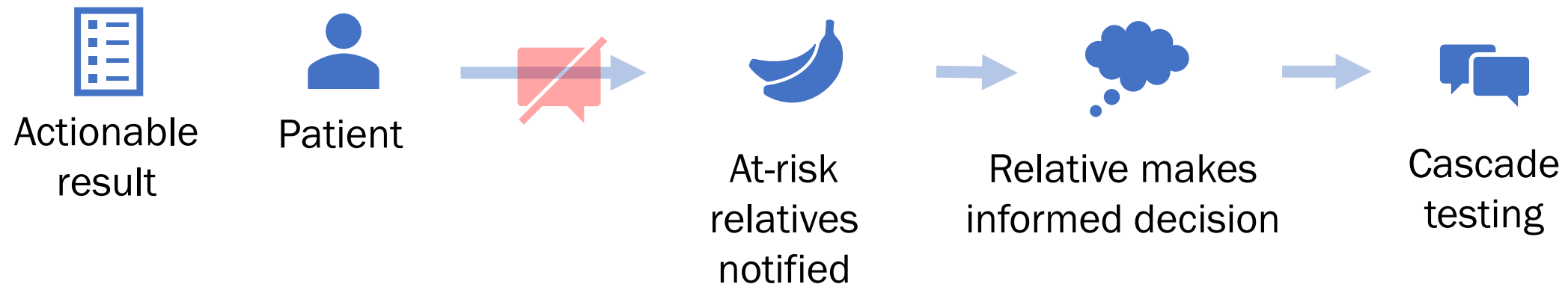
Current standard: patient-led disclosure

Disclosure to relatives incomplete

- BRCA 73%-75% (Taber 2015, Graves 2014, Fehniger 2013)
- Lynch 67%-98% (Stoffel 2018, Graves 2014)

Uptake of cascade testing is low

- 21%-44% HBOC,
- 41%-94% Lynch (Menko 2019)



Care team support for patient-led disclosure

PMC7926393 2021; PMID: 34994636 2021



Family letters

Family genetic
counseling

Communication
support /
training

Why not notify an at-risk relative?

- ❖ Burden
- ❖ Unaware of benefit to family
- ❖ Strained relationships
- ❖ Concern about accuracy, genetics knowledge
- ❖ Concern about stressing relatives
- ❖ Patient, relative privacy

Why is patient-mediated disclosure the current standard?

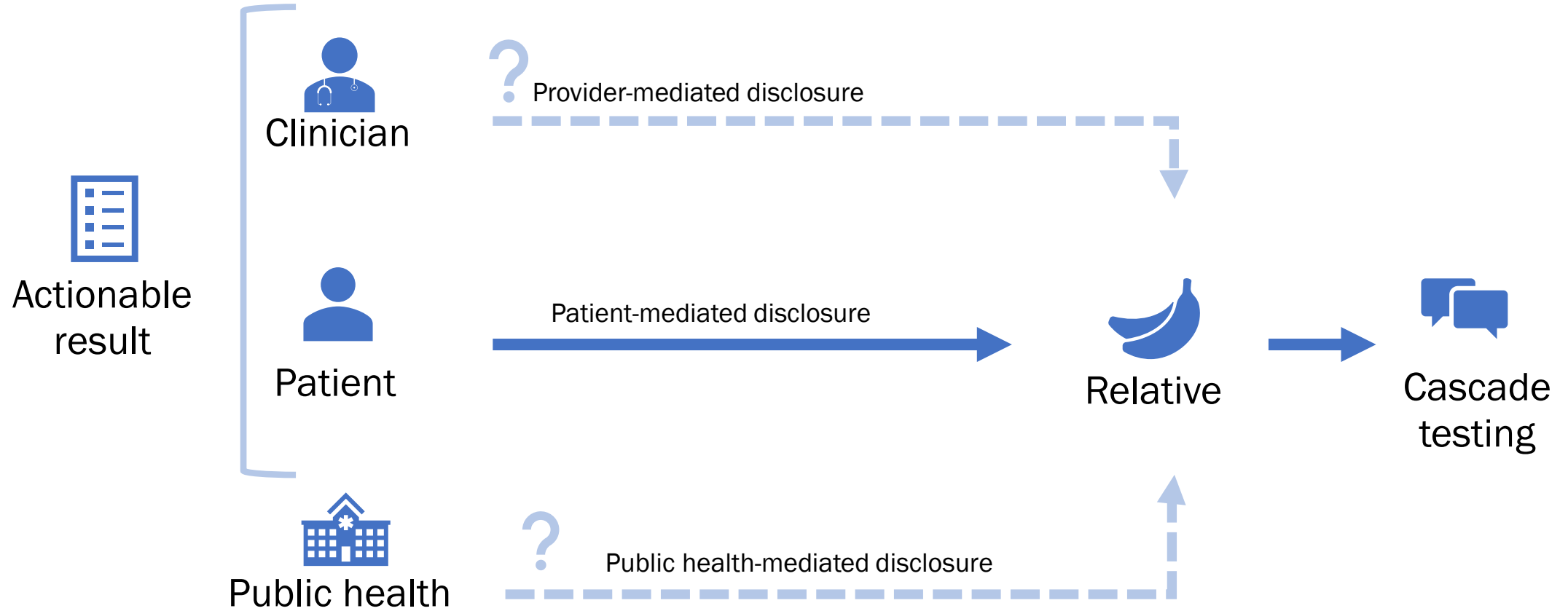
- ❖ Care and coverage systems designed for 1:1 care
- ❖ Clinician duty, scope of practice
- ❖ Liability
- ❖ Patient, relative privacy

Why can't someone other than the patient notify at-risk relatives?

- ❖ Direct contact programs combined with patient-led contact reach more relatives than patient-led contact alone
- ❖ People conceptualize shared genetic information, family implications

Oh, yeah. I think [health system-led risk notification] would be wonderful ... it would be so much easier instead of me trying to spit out what I think they need to have done or whatever. You folks could do it in a more -- they know what they're talking about and in a more business-like, you know, informational way than I could.

Alternate paths for disclosure



Research questions:

Is direct contact of relatives to recommend cascade testing consistent with HIPAA privacy rule?

Is direct contact acceptable to U.S. patients and families?

Is direct contact of relatives to recommend cascade testing consistent with HIPAA?

- ❖ Multidisciplinary working group
- ❖ Family vignette, literature review,

HIPAA: Health Insurance Portability and Accountability Act of 1996

Journal of Law and the Biosciences, 1–14
doi:10.1093/jlb/ljaa071
Original Article



What guidance does HIPAA offer to providers considering familial risk notification and cascade genetic testing?

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Patient-mediated approaches

Considering only HIPAA and not any relevant state laws, may the covered entity (provider):



- ✓ give their patient information or a 'consent to contact' form for family members? Yes.

Provider-mediated approaches

Considering only HIPAA and not any relevant state laws, may the covered entity (provider):



..directly contact their patient's adult relatives to recommend testing?



directly contact the relative's provider to recommend testing



with patient permission



without patient permission*



over the patient's objection*

*absent public health approach

Public health approach

Considering only HIPAA and not any relevant state laws, may the covered entity (provider):



directly contact public health authorities to report a patient's genetic risk?

- No, unless state public health law makes genetic risk a 'reportable condition'

Are direct contact programs acceptable to patients and families?

Roberts, M.C.; et al. *Health Aff (Millwood)* 2018, 37, 801-808

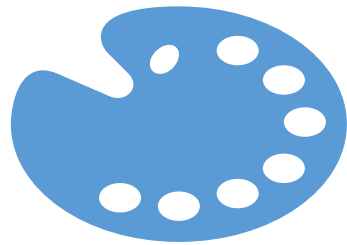
Menko, F.H et al. *Fam Cancer* 2019, 18, 127-135

Andersson, A et al. *Hered Cancer Clin Pract* 2020, 18, 18.

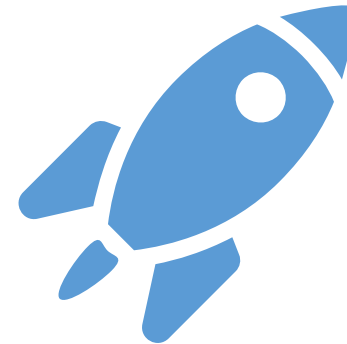
Current work

NHGRI-funded R01HG010144 (Henrikson)

Focus: HBOC, Lynch



Aim 1: Co-design direct contact program with patients and families (complete)



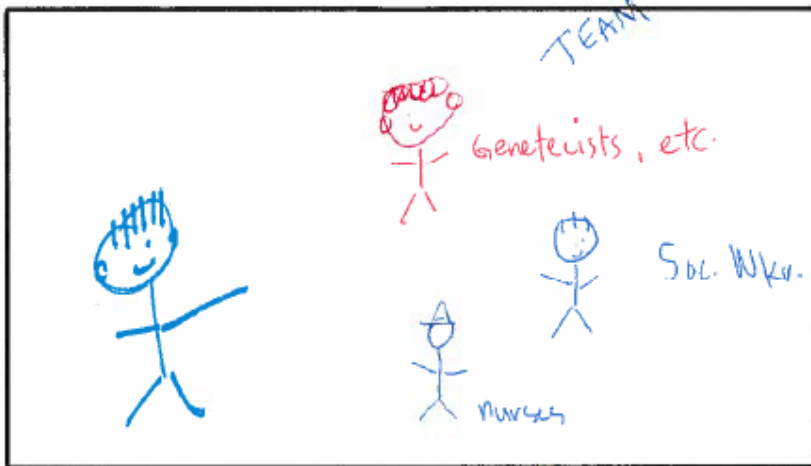
Aim 2: Feasibility trial of KPWA-led direct contact (in process)

Scene: It's now the care team's job to contact Irene



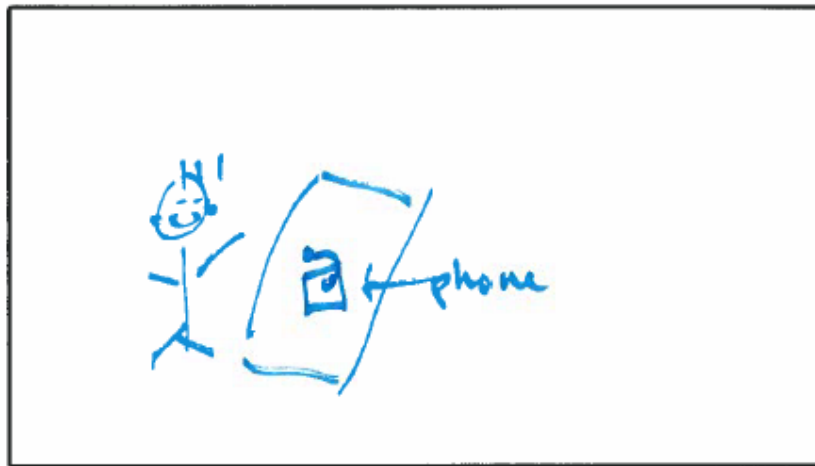
Molly asks Dr. Lee to tell Irene

Scene: Dr. Lee consults



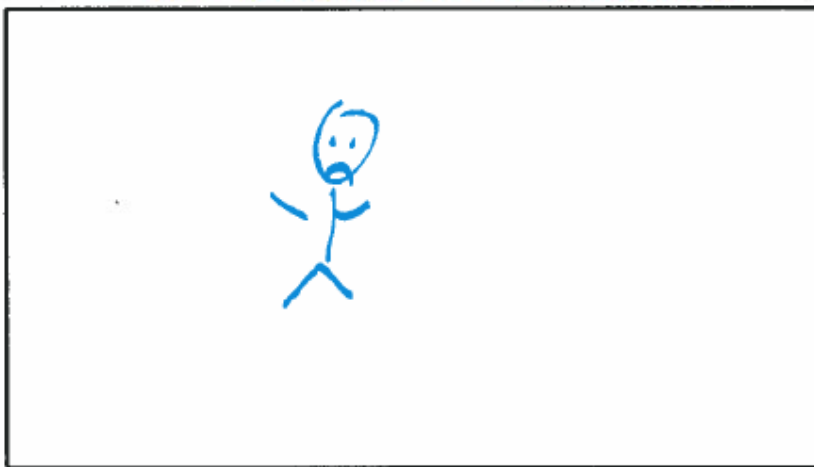
Dr. Lee consults w/others to determine what to include in a call or letter.

Scene: Dr. Lee calls



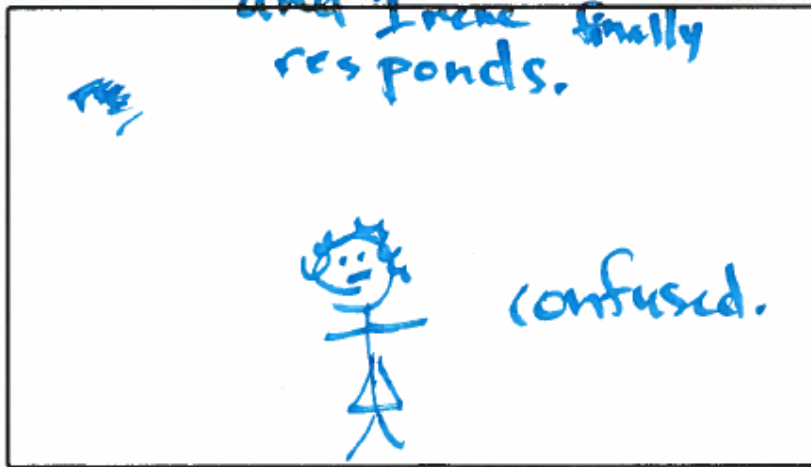
He calls; no answer. He sends letter.

Scene: Dr. Lee is unable to contact.



2nd letters & calls

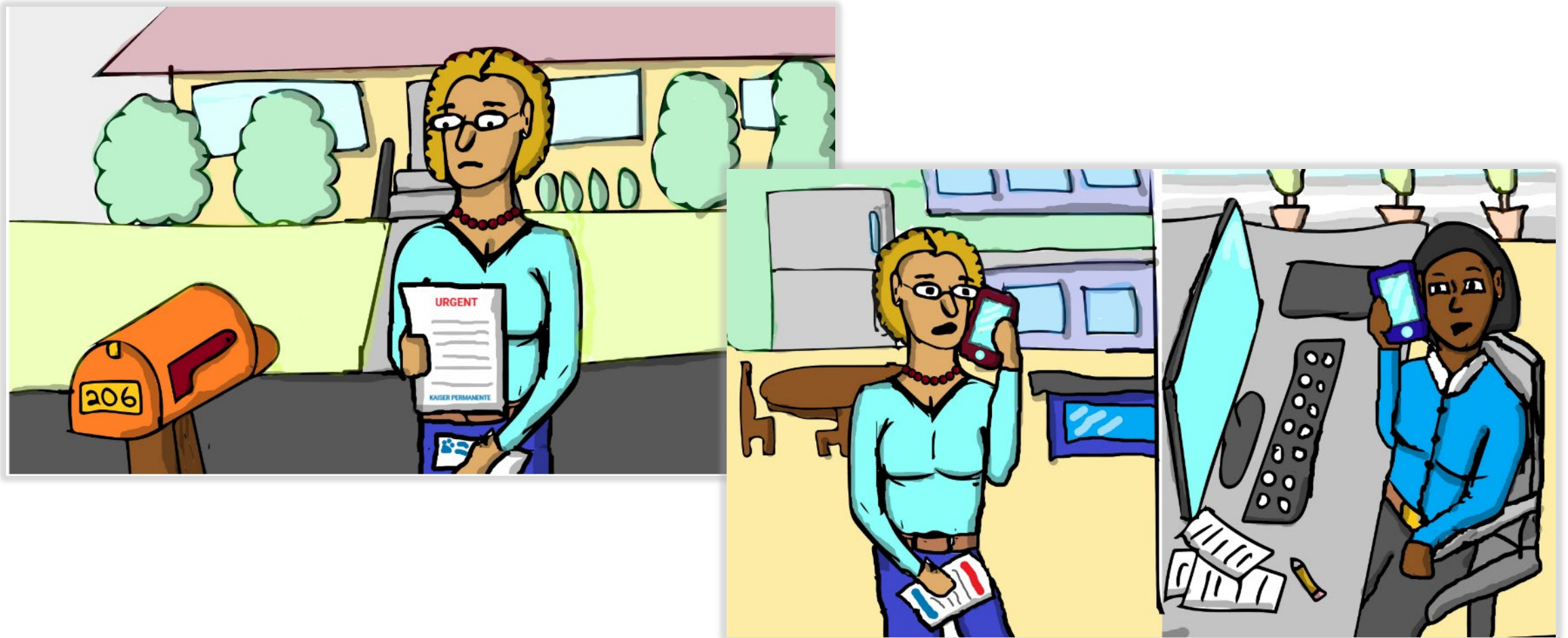
Scene: Other means are used, and Irene finally responds.



Scene: Irene returns call and is invited to meet Dr. Lee or others



Design round 2 - video



Regardless of the feelings I may have, ultimately after I calm down, I would want to know if I had a greater risk of dying like my sister did at 41. [relative]

The potential health benefit of notifying relatives of actionable genetic risk is the main rationale for direct contact programs.

SPEAKER 1: Where the doctor knows that someone is at high risk, I mean, shouldn't they contact somebody? ...It's a tradeoff, the privacy versus the health -- the lifesaving information. That's what it amounts do, doesn't it?

SPEAKER 2: Maybe. But I think we're forgetting that, like, Molly can also reach out. It's not, like, if the doctor doesn't do it, they're not going to get this information.#

Aspects of direct contact programs were new and raised concerns about whose duty it is to notify relatives and about how privacy would be maintained.

I kind of wonder if, like, if you need consent to do that, like, in your initial intake with Kaiser or, you know, how every so often, is your contact information up to date or all that. And you, like, say can we contact you based on family member information, like, would it be okay if we reached out to you if we find something that might be pertinent to you based on a family member.

Participants thought that direct contact of relatives should be a program, not an individual provider's responsibility. Pre-consenting programs were frequently suggested.

Requirements for direct contact of relatives

Henrikson 2021 PMID: 34200550 J Pers Med

U.S.-based health system-led direct contact of relatives

- ❖ Has clear potential benefit
- ❖ Should take a programmatic approach
- ❖ Should include early, pre-disclosure consent of relatives
- ❖ Should complement patient-mediated disclosure
- ❖ Should allow relatives to control information flow

Current work

- ❖ Direct contact intervention with patient preference for relative contact
 - Letter with phone follow up
 - Relative consultation with genetic counselor
- ❖ Pilot study (n=60 probands), KPWA
- ❖ Outcomes: acceptability, feasibility, limited efficacy



Thank you
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