ONE PATIENT'S PERSPECTIVE ON RETURNING RESULTS TO PATIENTS IN CLINICAL RESEARCH

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DISCLOSURE

- Consultant/Advisor, National Academy of Medicine

BACKGROUND (WEARING MANY HATS)

- Cancer Health Services Researcher
- PCORI Alumna
- Past IRB Member
- Patient with high health and healthcare literacy
  - Stage 3C Endometrial Cancer
  - Currently NED
  - No trials were open to me at time of diagnosis

FREQUENT, WELL-KNOWN OBSTACLES TO RETURNING RESULTS

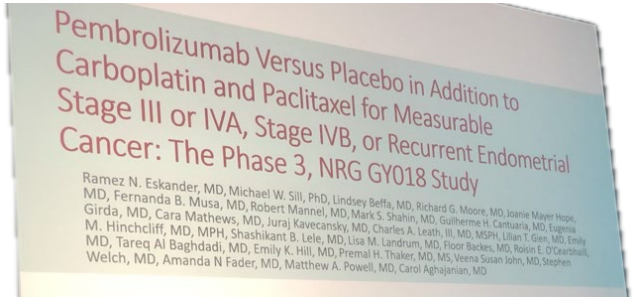
- Successfully re-contacting patient-participants, often years later
- IRB reluctance and/or variable dispositions about recontacting patients
- Preparing understandable plain language summaries of results
  - A skill gap, and sometimes an attitude gap ("they won't understand…")
- When funding ends, ability to meaningfully disseminate often ends with it
- Not generally *required* by sponsors/funding agencies, though Common Rule encourages doing so
- If it were *required*, we would FIND ways to overcome the challenges

CONSIDERATIONS & CHALLENGES IN SHARING RESULTS: WHAT, WHEN, HOW, BY WHOM?

- What should be shared? Circumstances for individual vs. summarized reports
- At what juncture should results be shared?
- Are the results clinically actionable? Are they time-sensitive?
- Who should be on point to share results? Researcher? Patient's clinician?
- Patients give up their time, energy, and data to participate in trials – what are they owed?
- When shouldn't we share results?
- Was the person a study participant, or are they a potential beneficiary?
- The obvious and easy answer to these questions is "It depends!"
- Two examples…

A HEALTH SERVICES RESEARCH EXAMPLE

- 6 site study, n = 967 women at increased risk for breast cancer who had undergone prophylactic mastectomy
- Look at the title of this paper!
- Should all women who are considering prophylactic mastectomy know about this?
- Were we able to return results to these women? Sort of
- Is this publication behind a paywall? **Yes.**



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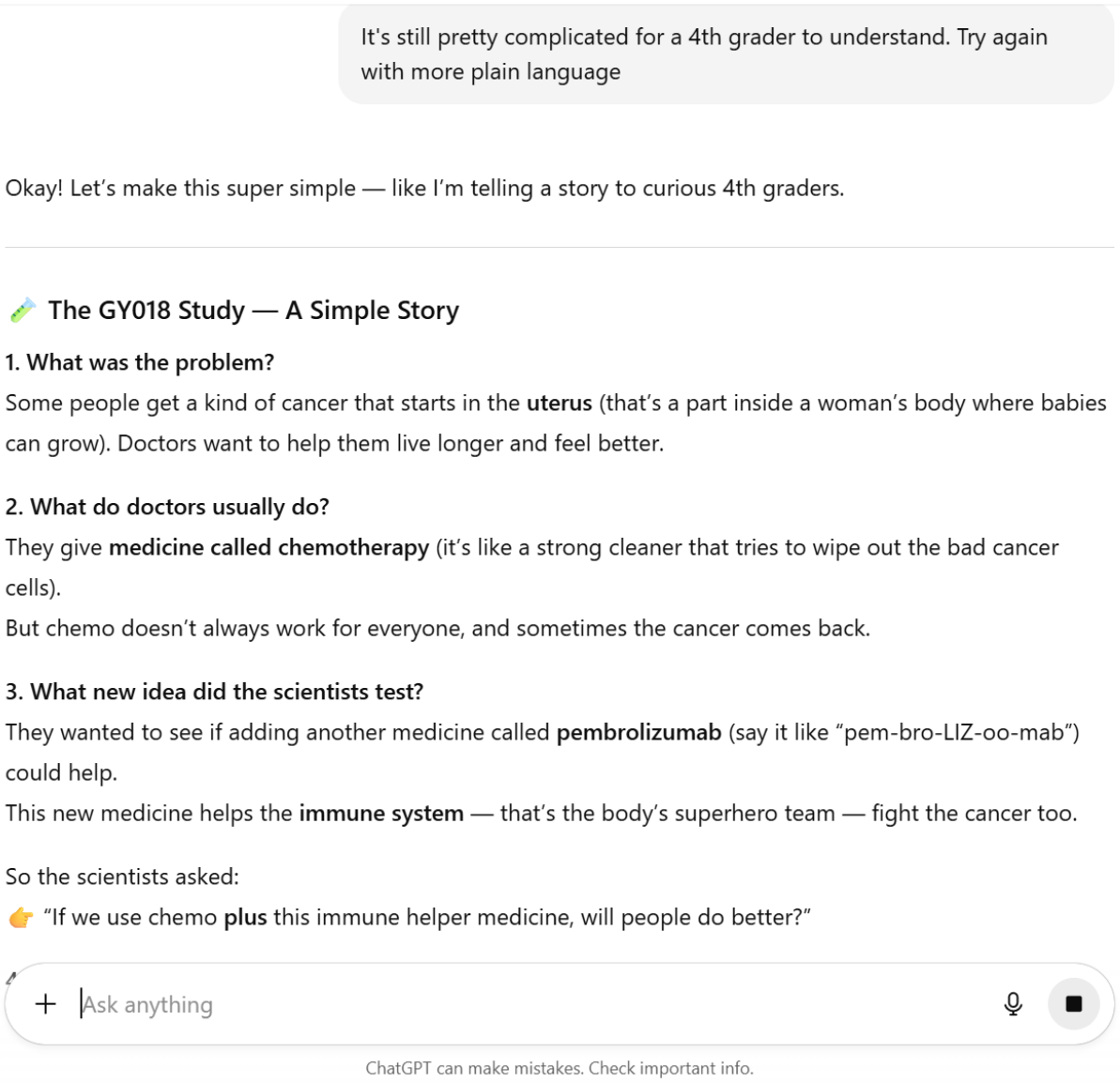
EXEMPLARS & RESOURCES EXIST

- TAPUR Trial creates plain language summaries
- Open-source tools like the PRISM Readability Toolkit support ability to communicate in plain language
- So does ChatGPT with the right prompt: "Acting as a 4th grade teacher, explain results of the GY018 Trial"



ZOOMING OUT: WAYS WE MIGHT MOVE FORWARD

Can we craft a universal rubric or set of guiding principles focused on why, what, when, and how to share (perhaps adapting PCORI's work)?

Cognizant of the legal, privacy, and clinical implications, how can we make sharing the default expectation in research culture?

Can we enhance researcher and organizational commitments to sharing results toward the aim of ***increasing trust in science and research?***

THANK YOU!
(FROM ONE PATIENT, WHO HAS A PERSPECTIVE.)

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