Management of Collateral Findings in PCTs

October 17, 2020

Baylor College of Medicine

CENTER FOR MEDICAL ETHICS & HEALTH POLICY

JOHNS HOPKINS BERMAN INSTITUTE of BIOETHICS

Panelists

- Stephanie Morain, PhD, MPH; Assistant Professor, Baylor College of Medicine *(moderator)*
- Debra Mathews, PhD, MA, Associate Professor, Johns Hopkins Berman Institute of Bioethics
- Julie Bollinger, MS, Associate Faculty, Johns Hopkins Berman Institute of Bioethics

Pragmatic Clinical Trials (PCTs): The Promise

- Embed research into routine clinical care
- Avoid need for parallel research infrastructure
- Improve the efficiency & relevance of research

Pragmatic Clinical Trials (PCTs): The Challenge

- Should consent processes resemble that for research or for clinical care?
- Which risks count as “research” risks?
- Which trials involve “no more than minimal risk?”

Additional challenge….

Incidental & Secondary Findings

- **Incidental finding (IF**)- finding that has potential importance for health, reproductive decision-making or personal utility that is "discovered in the course of conducting research but is beyond the aims of the study" (Wolf, 2013).

- **Secondary finding (SF)-** finding that is "actively sought by a practitioner that is not the primary target" (Presidential Commission, 2013).

MOTIFS: Management of Trial Incidental Findings

- Project Team
  - Juli Bollinger
  - Gail Geller
  - Jeffrey (Jerry) Jarvik
  - Debra Mathews
  - Elizabeth May
  - Stephanie Morain
  - Jeremy Sugarman
  - Kevin Weinfurt

PCT Context & Implications for “IF/SF”-Like Findings

Three features challenge assessment/ethical management in PCT context:

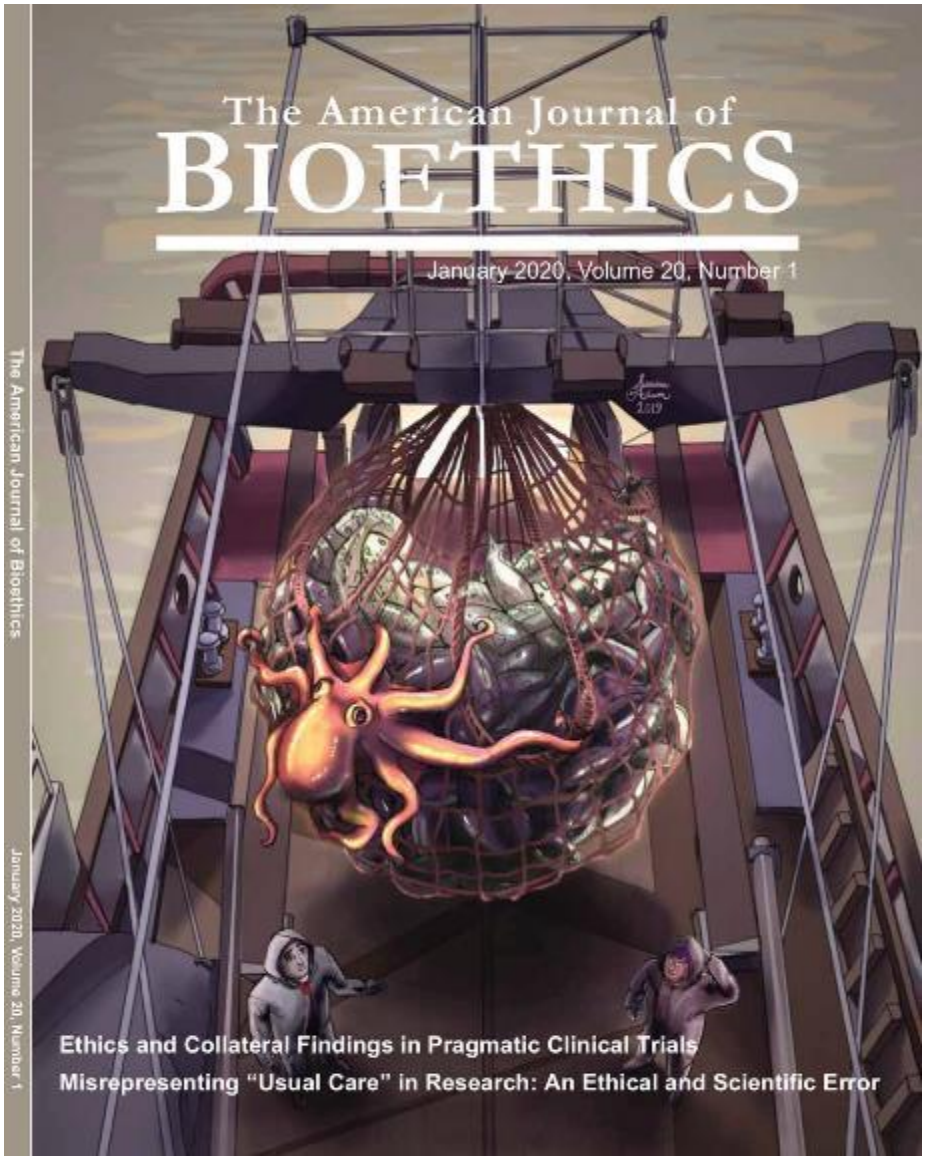
a. (Potential) lack of prospective consent/disclosure

b. Nature of researcher-subject relationship

c. Large scale of PCTs

PCT-Collateral Findings (PCT-CF)

- Findings arising in PCTs (discovered intentionally or unintentionally) that may have implications for health, but which were not generated to address the PCT's primary research questions



THE AMERICAN JOURNAL OF BIOETHICS
2020, VOL. 20, NO. 1, 5–18
https://doi.org/10.1080/15265161.2019.1689601

Taylor & Francis

TARGET ARTICLE: FRONTIERS IN BIOETHICS

Ethics and Collateral Findings in Pragmatic Clinical Trials

Stephanie R. Morain[a], Kevin Weinfurt[b], Juli Bollinger[c], Gail Geller[c,d], Debra JH Mathews[c,d], and Jeremy Sugarman[c,d]

[a]Baylor College of Medicine; [b]Duke University School of Medicine; [c]Johns Hopkins University; [d]Johns Hopkins University School of Medicine

ABSTRACT

Pragmatic clinical trials (PCTs) offer important benefits, such as generating evidence that is suited to inform real-world health care decisions and increasing research efficiency. However, PCTs also present ethical challenges. One such challenge involves the management of information that emerges in a PCT that is unrelated to the primary research question(s), yet may have implications for the individual patients, clinicians, or health care systems from whom or within which research data were collected. We term these findings as "pragmatic clinical trial collateral findings," or "PCT-CFs". In this article, we explore the ethical considerations associated with the identification, assessment, and management of PCT-CFs, and how these considerations may vary based upon the attributes of a specific PCT. Our purpose is to map the terrain of PCT-CFs to serve as a foundation for future scholarship as well as policymaking and to facilitate careful deliberation about actual cases as they occur in practice.

KEYWORDS
pragmatic clinical trial
incidental findings research
ethics learning
health systems

INTRODUCTION

Pragmatic clinical trials (PCTs) are becoming widespread, driven by their promise to generate knowledge more efficiently than traditional explanatory trials and to inform real-world health care decisions (Califf and Platt 2013; Weinfurt et al. 2017). Funding agencies, including the National Institutes of Health (NIH) and the Patient-Centered Outcomes Research Institute (PCORI), are making substantial investments in both individual trials and research infrastructures to support the future expansion of PCTs (Hernandez et al. 2015; NIH 2013).

PCTs have generated several notable successes. For example, PCTs likely contributed to a significant reduction in deaths from myocardial infarction within United States (US) hospitals and to increasing life expectancy for patients with cystic fibrosis (Califf and Sugarman 2015). However, PCTs may also present ethical challenges (Califf and Sugarman 2015). One such challenge that has not yet been well-described involves what do when PCTs generate information that is unrelated to the primary research question(s), yet may have implications for the individual patients, clinicians, or health care systems from whom or within which research data were collected. For example, a PCT aimed at increasing the uptake of cardiac care guidelines using insurance claims data identified individuals with diagnoses that increase their risk for a cardiac event, but not corresponding documentation that the diagnosis was communicated to the patient, suggesting that a critical opportunity might have been missed to reduce such risk (Sabin et al. 2019). In addition, a PCT exploring strategies to increase colonoscopy screening rates consistent with clinical guidelines unexpectedly revealed that screening tests used by some clinics have far higher positive results than others. This suggested higher rates of false positives among some tests, potentially driving unnecessary follow up testing, and thus creating burdens for patients, clinicians, and health systems (Nielson et al. 2018).

How should researchers and health systems manage such findings? Prior scholarship of the return of results that may have clinical implications for individuals in explanatory trials and clinical care has examined various ethical issues. In explanatory research, an *incidental finding* (IF) has been defined as a finding that has potential importance for health, reproductive decision-making, or personal utility that is "discovered in the course of conducting research but is beyond the aims of the study" (Wolf 2013). A *secondary finding* (SF) is a finding that is "actively sought by a practitioner that is not the primary

Insights from (& Limits of) Existing Scholarship

Semi-analogous areas:

1. Clinical care
2. Quality improvement (QI)
3. Clinical research
4. Population genomics
5. Environmental health research
6. Public health surveillance

Relevant (Dis)Similarities to PCTs: Clinical Care

Similarities	Dissimilarities
• Need to consider both potential benefits & harms from disclosure	• Physician-patient relationship distinct from that of researcher-subject • Individual informed consent may not have occurred • Timeliness in identification

Relevant (Dis)Similarities to PCTs: QI

Similarities	Dissimilarities
• May involve similar methods, similar (low) risk • May assume individual duty to participate	• Routine QI typically conducted within single institution; PCTs generally multi-institutional • Some PCTs may confer additional risks, suggesting greater obligations of reciprocity

Relevant (Dis)Similarities to PCTs: Clinical Research

Similarities	Dissimilarities

• Findings identified by researchers
• In biobanking, research with stored samples…
  • researcher-subject has similarly distal relationship;
  • related challenge of the “cold call”
	• PCTs embedded into clinical care
	• Individual informed consent may not have occurred
	• Timeliness in identification

Relevant Attributes for PCT-CF Management

1. *What* is the nature of the finding?
2. *When* was it identified?
3. *Where* did it occur?
4. *Why* and *how* did it arise?
5. *Who* knows the information?

Takeaways

1. Liminal nature of PCTs challenges traditional research-care paradigm

2. Existing scholarship offers some guidance, but many open questions

3. Importance of future conceptual & empirical work

Stakeholder Interviews

Study Population

- 39 Interviews
  - 22 Collaboratory
  - 8 Non-Collaboratory
  - 9 Delivery system leaders
- 26M/13F
- 22 PIs, 5 IRB, 1 Quality leader, 9 Delivery system leaders, 1 Clinician, 1 Legal counsel

Interview Domains

- Experience with PCTs
- Experience with PCT-CFs
- Management of PCT-CFs (actual/hypothetical)
- Factors relevant to PCT-CF management

Learning Health Systems
Open Access

RESEARCH REPORT | Open Access

Stakeholder perspectives regarding pragmatic clinical trial collateral findings

Stephanie R. Morain, Debra J. H. Mathews, Kevin Weinfurt, Elizabeth May, Juli M. Bollinger, Gail Geller, Jeremy Sugarman

First published: 28 August 2020 | https://doi.org/10.1002/lrh2.10245

Funding information: National Center for Complementary and Integrative Health, Grant/Award Number: U24AT009676; National Institutes of Health (NIH) Health Care Systems Research Collaboratory, Grant/Award Number: U24AT009676

Themes

- Layers of ambiguity challenge classification of PCT-CFs
- PCT-CF management is context-specific
- Wide diversity of attitudes regarding researcher responsibilities for PCT-CFs
- Prospective planning critical—but not widely undertaken

Layers of ambiguity challenge classification

- Extensive discussions needed about PCTs, CFs before engaging in discussion of whether they had occurred, and how to manage
- Uncertainty about both:
  - Nature/scope of PCTs, "blurry" boundaries of research vs QI
    - *"…I've been the PI for a lot of randomized controlled trials and I at the time did not necessarily categorize them or consider them PCTs but I have seen them described that way by others."*
  - Categorization of unanticipated results
    - Same PCT-CF classified as an "*incidental finding*," the identification of a "*gap in care*," versus something emanating out of something "*closer to a QI exercise, or QA, rather than part of the research that's being done*"
    - Corresponding implications for whether/how/whom should manage

PCT-CF management is context-specific

“I think it depends [on the finding]”

PCT-CF management is context-specific

Key relevant factors:

- Clinical relevance
- System-level impact & opportunity costs
- Consent

PCT-CF management is context-specific

Clinical relevance

- Severity, medical actionability
  - *"severity and meaningfulness to that person's clinical care"*
  - *"likelihood of benefit"* related to follow-up

- Timing of identification, whether "uniquely known"
  - *"Has a responsible provider already seen and made a decision whether or not to act on this information? If so, then we say, 'There's nothing more to be done. That's not our job to go back and second-guess the decision of that provider who was on the spot.' On the other hand, if we say, 'No reasonably qualified and responsible provider has access to or knew about this, then we need to pass that information on….we're on duty."*

PCT-CF management is context-specific

System-level impact & opportunity costs

- Burden of (unfunded) management
  - *"…is the infrastructure present within a particular health care system to deal with whatever needs to be done following the return of information? So, if PCPs, for example, have to have a conversation with their patients about this, do they have the time? Is there a way of easily bringing the patients in or contacting them, setting up that conversation? Who's going to pay for the extra time that it takes in order to do this? ... So I think that the flexibility and the ability of the existing infrastructure to deal with this extra workload as well as the costs associated with it are real considerations that everyone needs to think about*."
- Risk of undermining "broader mission" of PCTs and/or priorities of clinical care

PCT-CF management is context-specific

Consent

- Absence of prospective informed consent complicates decision-making
- Heterogeneity of views as to whether consent creates a higher or lower bar for disclosure

Wide diversity of attitudes regarding researcher responsibilities for PCT-CFs

Do researcher obligations differ from those of clinicians in PCT-CF context?

- *"Yeah, it's a great question…. Instinctually I don't think I would see it differently. I totally understand the distinction you're drawing, but I guess from where I stood the same criteria of magnitude of the stakes and plausibility of constructive intervention would be my guiding principles regardless of whether the source of the collateral finding was a protocolized 'extra-usual-care phenomenon' or merely part of usual care*."

- *"I was of the opinion that this was a clinical trial. This was a trial. And that patients were deidentified for a reason and that we shouldn't contact the patients and we shouldn't contact the providers. It should be just like any other study because I think that you could, whenever you have this much data that you could find all kinds of things…it's kind of a slippery slope…the health system had agreed to do this [study] and now you can't really go back and say 'oh now we're going to dump all this other stuff on you that you weren't expecting and that you didn't agree to."*

Wide diversity of attitudes regarding researcher responsibilities for PCT-CFs

Appropriateness of wide versus narrow lens for data collection/analysis, and implications for likelihood of identifying PCT-CFs:

- Good research practice means "*collecting exactly the data you need;*" collecting data elements beyond those "*directly relevant to some element of your conceptual model or the outcomes of your study*" is a "*misuse of system resources*"

- "*[a]s an investigator, I feel like we're obligated to use our federal resources to glean as much valuable information as possible in the context of the study. I mean beyond our primary and secondary aims… if we can address broader system level issues at the end of the day then all the better.*"

Prospective planning critical—but not widely undertaken

- *"…honestly, I hadn't thought about [PCT-CFs] before, but I'm not even slightly surprised, and I'm sure this is the tip of the iceberg in terms of other potential [collateral] findings that may be of clinical relevance that were never considered in the original design."*

- *"…there's only so much that can be anticipated when you have a bunch of people sitting around in a room. When you actually go out into the real world…you will inevitably encounter things that you weren't expecting, maybe you should've expected, or maybe there's just such a novel finding that it has never been seen before….[but] even though you can't anticipate all the things you might find, anticipate that there's at least going to be something that you're going to find that you didn't anticipate."*

Takeaways

- Liminal nature of PCTs complicates downstream issues for PCT-CFs, from identification to assessing responsibilities whether/how/by whom to manage
- No “one-size-fits-all” approach to management
- Lack of agreement about continued relevance of research-practice distinction, with implications for both management & likelihood of identification
- PCT-CFs generally not on peoples’ radar, but shared belief anticipation/planning is critical

Focus Groups

Methods

- Focus groups (n=11, including 2 pilots)
  - Baltimore, MD
  - Houston, TX
  - Seattle, WA
- Recruitment
  - Craigslist ads posted in each location
  - Eligible participants had to have seen a doctor or have been hospitalized in the past year.
- Single moderator (JB)
- $75 incentive

Gender	
Male	25
Female	41
	66

Race/ethnicity	
Black or African American	24
White	26
Hispanic or Latino	6
Asian	5
Other	5
	66

Health insurance	
Private	29
Medicaid/Medicare	23
Integrated/VA	5
No insurance	9
	66

Age	
<20	0
20-29	9
30-39	11
40-49	15
50-56	17
60-69	8
70-79	6
	66

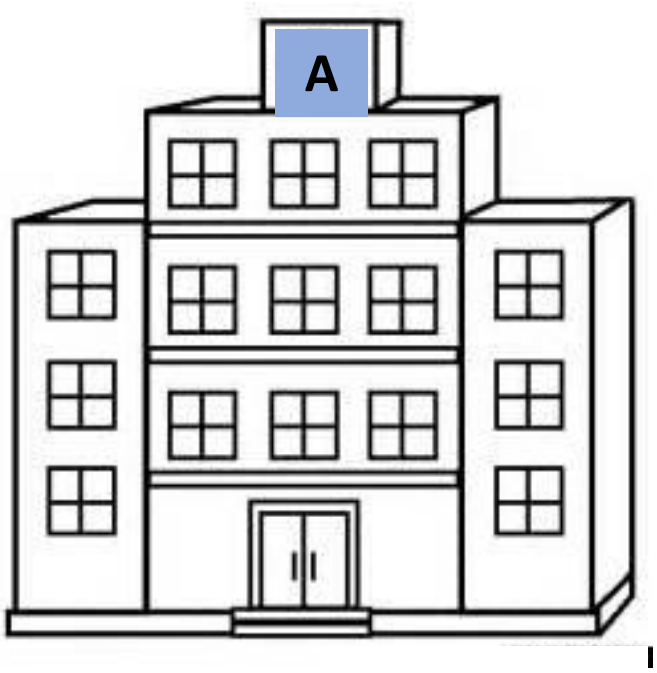
Education level	
<High school	1
High School/GED	11
High Schoool + Some College	12
Trade	2
AA	3
BA/BS	31
MA/MS	6
	66

Focus Group Discussion Guide

- Introduction
  - Examples of ways people can learn about new, unexpected information important to their health
  - Explanation of EHRs
- Scenario
  - Multi-center, cluster-randomized, pragmatic clinical trial (no expressed consent) using EHRs
  - PCT-CF: patients taking contraindicated medications
- Discussion
  - Communicating the PCT-CF: Do you want it? How? Who? What? When?
  - Drafting the communication

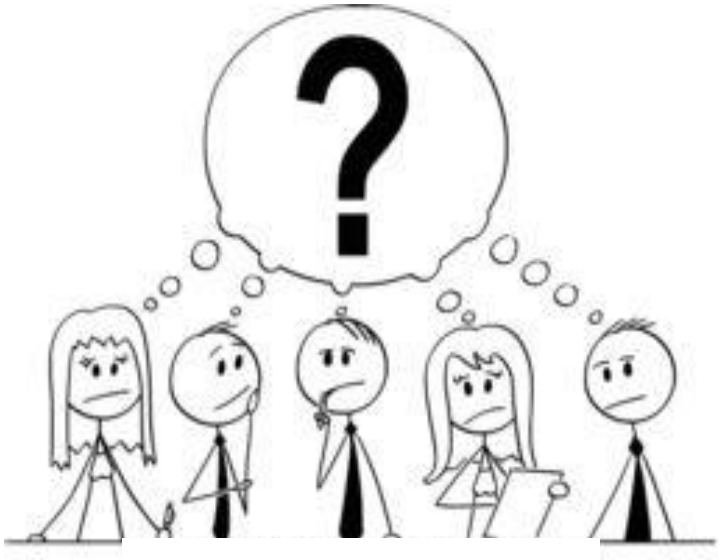
Hospital A

- Let's imagine you receive your care at Hospital A.
- Hospital A, like other hospitals, looks for ways to improve the care they offer to their patients.
- Hospital A can use the vast amounts of information, *already collected* in their patient EHRs, to answer questions about health care.



For example:

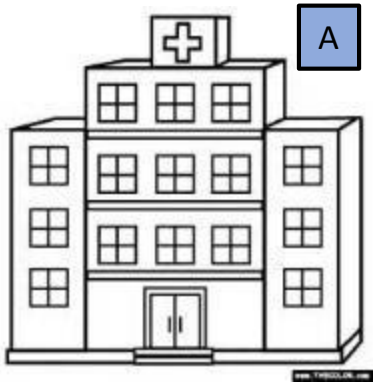
- The team at Hospital A wants to compare two medications commonly prescribed to treat high blood pressure



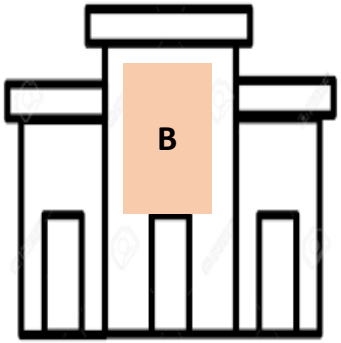
Hospital A staff

Which medication works better - DILAX or Relaxil?

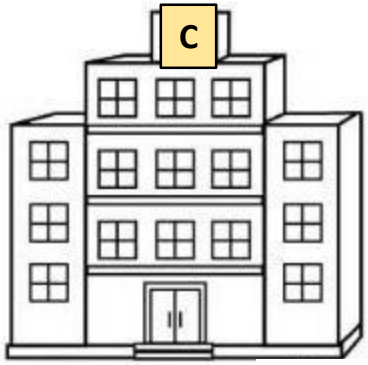
Your hospital, Hospital A, works with three other hospitals to figure out which medication works best.



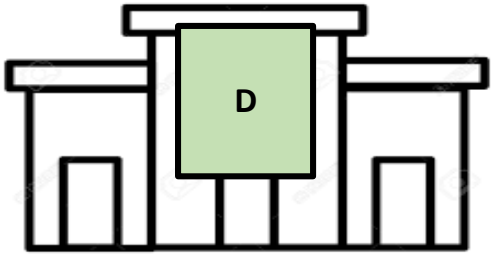
Hospital A



Hospital B



Hospital C

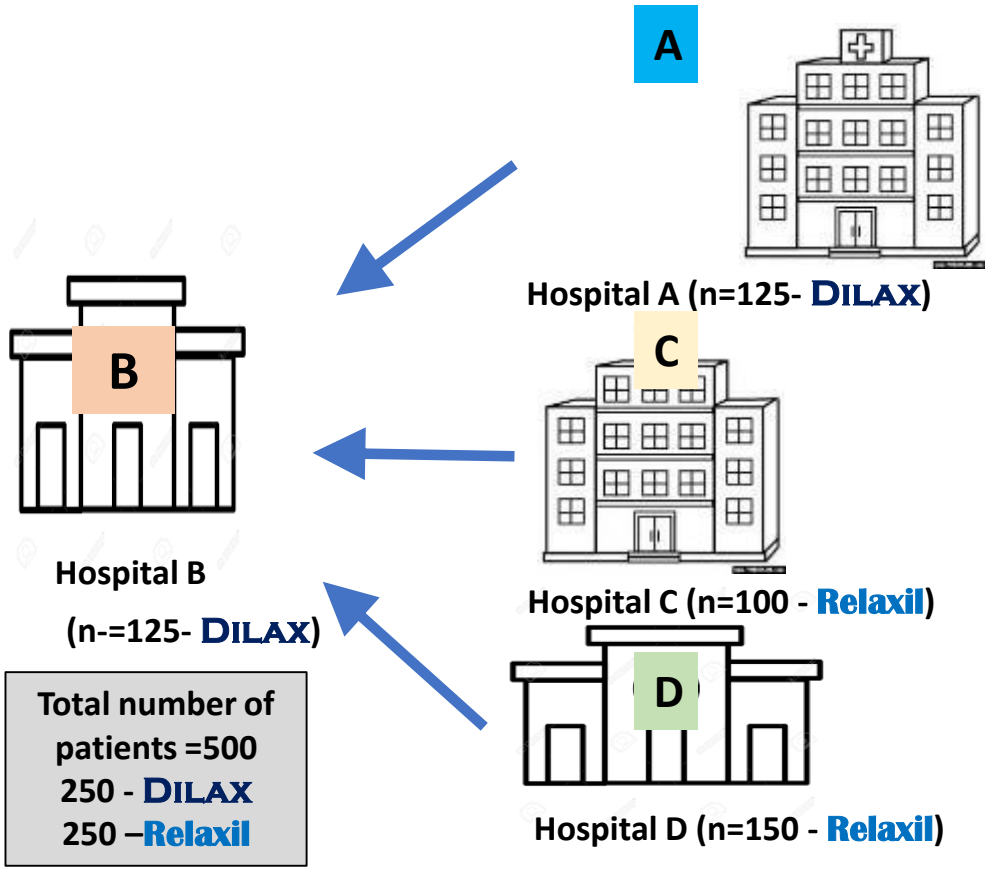


Hospital D

Each hospital shares their data with the team at Hospital B who will combine all the data and analyze it together.

A few important things to note:

- Before sharing their patient information with Hospital B, each hospital removes the names of their patients (along with any other identifying information) and replaces it with a code.
  - For example, John Smith becomes HABPP2 (Hospital A, blood pressure patient 2)
- Hospital B does not have access to any identifying information about the patients from the other hospitals.



Unexpected finding

While doing their analysis, the team at Hospital B notices that some patients are taking two medications that can cause an abnormal heartbeat when taken together.

The team has decided to provide this information to patients.

Results

- Reactions
- Desire for the PCT-CF
- Communicating the PCT-CF
  - How should the PCT-CF be returned?
  - Who should return the PCT-CF
  - What information should be returned?
  - When should the information be returned?
- Lack of consent
- Takeaways

Reactions were mixed

- Concern/anger
  - How did my doctor miss this?
  - Why was this not caught before?
- Gratitude
  - It might not have been found but for the researchers
  - Potentially life-saving

Desire for PCT-IF

- All participants wanted the PCT-CF
- Reasons
  - The finding was viewed as serious, potentially life-threatening
  - The finding was actionable
- Datedness of the information did not diminish interest

How should the finding be returned?

- Mode
  - Diverse preferences
  - Multi-modal approach favored
    - Accommodates preferences
    - Ensures receipt
- Delivery features
  - Attracts attention
  - Conveys legitimacy

Who should return the finding?

- A recognizable person or entity
- An individual or entity with the expertise to interpret the finding for the patient

What information should be returned?

- Substantive facts
  - What was found, what to do next, who to contact for more information, etc.
- Level of detail
  - “Less is more” - avoid distracting information

“If a man asks you for the time, you don’t tell him how to build a watch.”

When should the information be returned?

- In all groups, ***timely*** delivery of the PCT-CF was important
  - Influenced preferences for “who” and “how”
  - Underscored views about the importance of information

Reactions to the lack of consent

- In most groups, the lack of consent did not register
  - Issue had to be raised by the moderator
- Mixed reactions
  - Disrespectful
  - Efficient

Reactions to the lack of consent

- Explanation led to resigned acceptance
  - This type of research is common and permissible
  - “We probably signed something” about this on a form
- Did not diminish desire for the PCT-CF

Takeaways

- All participants wanted the PCT-CF
- Preferences for *“who”* and *“how”* varied
- Multi-modal approach favored
- Minimal detail preferred
  - Include: what was found, what to do, who to contact for more information, etc.

Takeaways

The communication should:

- Be delivered in a timely fashion
- Come from recognizable/trusted source
- Attract attention, but minimize alarm/anxiety
- Limit distracting details

Patients' Views About the Disclosure of Collateral Findings in Pragmatic Clinical Trials: a Focus Group Study

Juli M. Bollinger, MS[1], Gail Geller, ScD, MHS[1,2], Kevin Weinfurt, PhD[3], Elizabeth May, MA[1], Stephanie R. Morain, PhD, MPH[4], Debra J. H. Mathews, PhD, MA[1,5], and Jeremy Sugarman, MD, MPH, MA[1,2]

[1]Berman Institute of Bioethics, Johns Hopkins University, Baltimore, MD, USA; [2]Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD, USA; [3]Department of Population Health Sciences, Duke University School of Medicine, Durham, NC, USA; [4]Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, TX, USA; [5]Department of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, MD, USA.

BACKGROUND: Pragmatic clinical trials (PCTs) are increasingly being conducted to efficiently generate evidence to inform healthcare decision-making. Despite their growing acceptance, PCTs may involve a variety of ethical issues, including the management of pragmatic clinical trial-collateral findings (PCT-CFs), that is, information that emerges in PCTs that is unrelated to the primary research questions but may have implications for patients, clinicians, and health systems.

CFs in ways that align with patients' preferences and values.

KEY WORDS: pragmatic clinical trial; patient perspective; collateral finding.

J Gen Intern Med
DOI: 10.1007/s11606-020-06113-5

Survey “Sneak Peak”

Objective

- Our prior data revealed some uncertainty regarding how to return PCTs to patients
  - Who should report the finding to the patient?
  - What should be communicated (describe the PCT?)
  - Do the effects of the "who" and "what" depend on the nature of the finding?

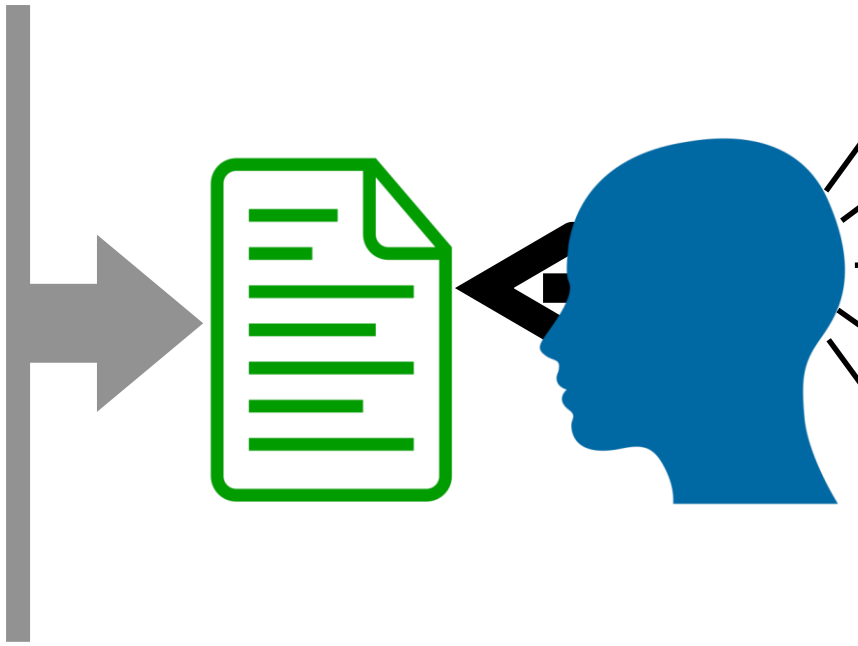
- We conducted a web-based experiment to test the effect of these three factors on people's *actions*, *reactions*, and *questions* to receiving a letter disclosing a PCT.

What is the impact of different types of letters?

Who is letter from?

Include that finding arose from a research study?

Type of finding?



Do next?

Emotional reaction

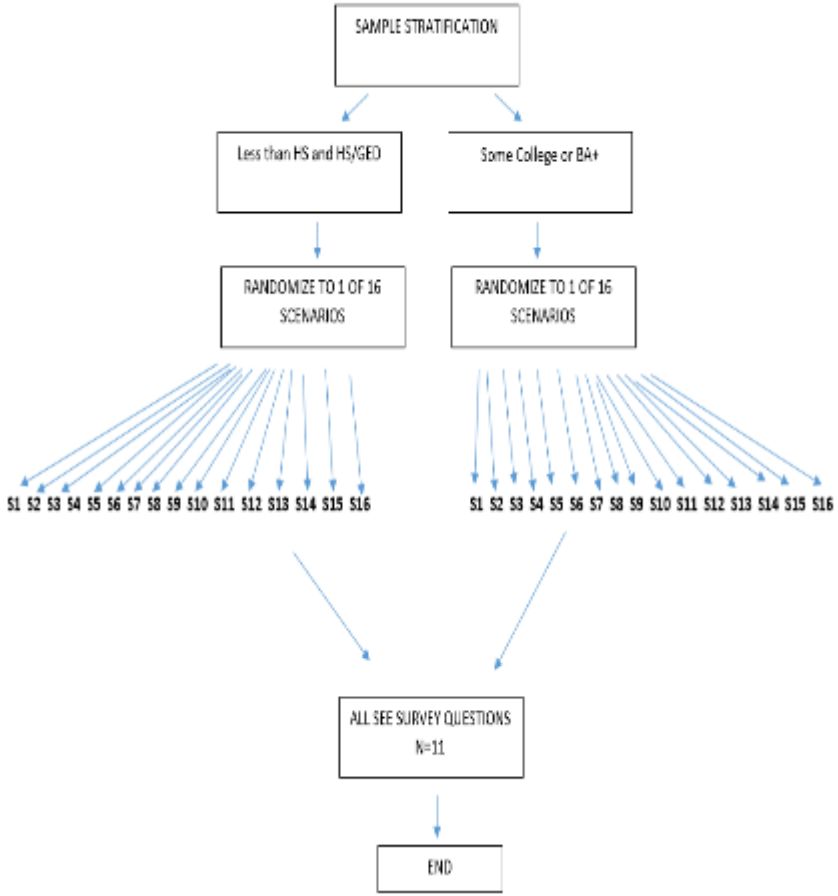
Questions?

Subjective understanding

Other perceptions re: communication

Survey design

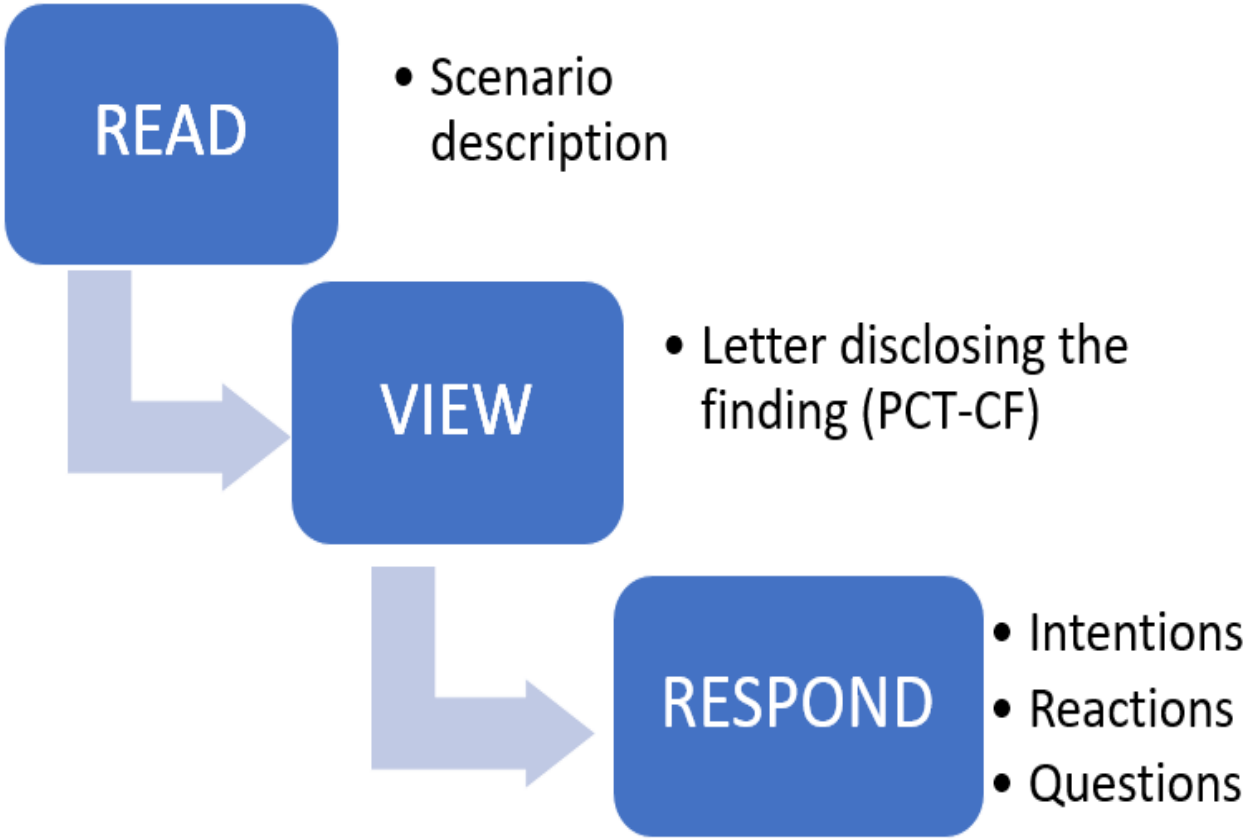
- Online survey of English-speaking U.S. adults age 18 years and older
- Respondents were stratified by education and randomly assigned to view and respond to 1 of 16 possible scenarios



Survey administration

- Sample selection, study consent, and execution was managed online by Ipsos
- Respondents received the equivalent of $5 for their time
- IRBs of Duke University Health System and Johns Hopkins University approved this research

Survey flow


READ
• Scenario description
VIEW
• Letter disclosing the finding (PCT-CF)
RESPOND
• Intentions
• Reactions
• Questions

Scenario

- The respondent visits their doctor, Dr. Lee, at City Medical Center for one of three possible indications:
  - High blood pressure
  - Back pain
  - Routine screening for colon cancer
- Two years later, the respondent receives a letter from City Medical Center reporting a finding (the PCF-CF) that may be important to their health.

Survey letters (n=16)

- Letters were created to reflect all possible combinations of *Signatory, PCT description (+/-)*, and type of finding (the *PCT-CF)*
- All letters included a recommendation to contact their physician immediately

Experimental Factor	Level
Signatory (2)	Personal physician
	Quality assurance/research administrator
PCT Description (2)	No
	Yes
PCT/CF (4)	A/B Drug Trial (BP) - Contraindicated Medications
	A/B Drug Trial (BP) – Hematuria
	Multi-Site Imaging Study- Contraindicated Medications
	Colon Cancer Screening - Under-performing Colon Cancer Test Kit

Survey letters (n=16)

City Medical Center

Date

RE: Important information about your health

Dear [Your Name],

The purpose of this letter is to give you some information that was recently learned that could be important to your health.

What was learned about your health

City Medical Center participates in activities to help provide the highest quality care to our patients. A review of your electronic health record showed that you had a urine test done last year. A small amount of blood was detected in that test. Blood in your urine may or not be related to underlying disease or illness, but additional testing is needed to figure that out. Your electronic health record doesn't indicate whether any follow-up of this laboratory finding was done.

What you should do next

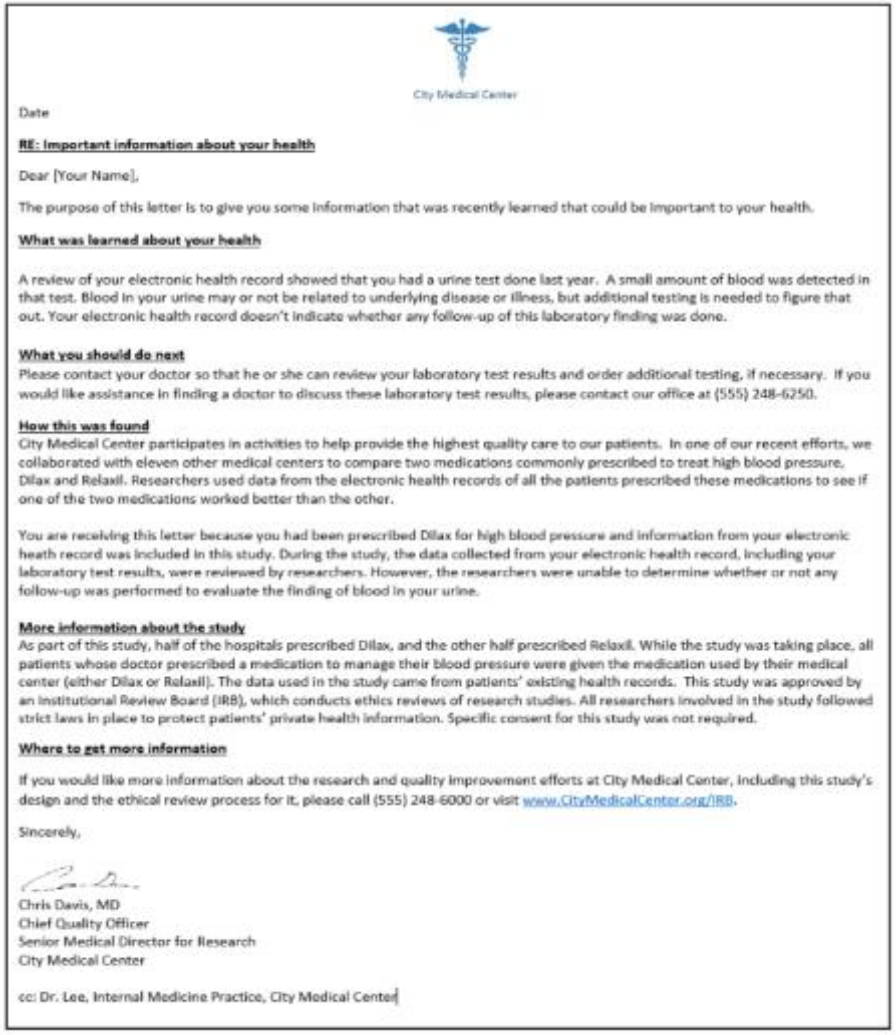
Please contact my office at (555) 248-6250 so that we can review your laboratory test results and order additional testing, if necessary.

Where to get more information

If you would like more information about the research and quality improvement efforts at City Medical Center, please call (555) 248-6000 or visit www.CityMedicalCenter.org/IRB.

Sincerely,

Chris Lee, MD
Internal Medicine Practice
City Medical Center



City Medical Center

Date

RE: Important information about your health

Dear [Your Name],

The purpose of this letter is to give you some information that was recently learned that could be important to your health.

What was learned about your health

A review of your electronic health record showed that you had a urine test done last year. A small amount of blood was detected in that test. Blood in your urine may or not be related to underlying disease or illness, but additional testing is needed to figure that out. Your electronic health record doesn't indicate whether any follow-up of this laboratory finding was done.

What you should do next

Please contact your doctor so that he or she can review your laboratory test results and order additional testing, if necessary. If you would like assistance in finding a doctor to discuss these laboratory test results, please contact our office at (555) 248-6250.

How this was found

City Medical Center participates in activities to help provide the highest quality care to our patients. In one of our recent efforts, we collaborated with eleven other medical centers to compare two medications commonly prescribed to treat high blood pressure, Dilax and Relaxil. Researchers used data from the electronic health records of all the patients prescribed these medications to see if one of the two medications worked better than the other.

You are receiving this letter because you had been prescribed Dilax for high blood pressure and information from your electronic heath record was included in this study. During the study, the data collected from your electronic health record, including your laboratory test results, were reviewed by researchers. However, the researchers were unable to determine whether or not any follow-up was performed to evaluate the finding of blood in your urine.

More information about the study

As part of this study, half of the hospitals prescribed Dilax, and the other half prescribed Relaxil. While the study was taking place, all patients whose doctor prescribed a medication to manage their blood pressure were given the medication used by their medical center (either Dilax or Relaxil). The data used in the study came from patients' existing health records. This study was approved by an Institutional Review Board (IRB), which conducts ethics reviews of research studies. All researchers involved in the study followed strict laws in place to protect patients' private health information. Specific consent for this study was not required.

Where to get more information

If you would like more information about the research and quality improvement efforts at City Medical Center, including this study's design and the ethical review process for it, please call (555) 248-6000 or visit www.CityMedicalCenter.org/IRB.

Sincerely,

Chris Davis, MD
Chief Quality Officer
Senior Medical Director for Research
City Medical Center

cc: Dr. Lee, Internal Medicine Practice, City Medical Center

Analysis

- Primary outcome: Contact doctor (Yes/No)
  - Multiple logistic regression model that included Signatory, PCT detail, and Finding and all 2-way and 3-way interactions among these

- Open text fields field responses to the survey item, “What questions, if any would you have?” were independently coded by two members of the research team
  - 14-item codebook developed based on common recurring themes

Preliminary results

Sample

- Final analytic set included 4,080 respondents
- Median completion time was 6 minutes

Characteristic	Overall (n = 4080) [n (%)]
Age, No. (%)	
18-29 y	471 (11.5)
30-44 y	842 (20.6)
45-59 y	1085 (26.6)
≥ 60 y	1682 (41.2)
Education level, No. (%)	
Less than high school	329 (8.1)
High school	1685 (41.3)
Some college	845 (20.7)
Bachelor's degree or higher	1221 (29.9)
Race/ethnicity, No. (%)	
Black, non-Hispanic	368 (9.0)
Hispanic	486 (11.9)
Two or more races, non-Hispanic	130 (3.2)
White, non-Hispanic	2930 (71.8)
Other, non-Hispanic	166 (4.1)
Sex, No. (%)	
Female	2023 (49.6)
Male	2057 (50.4)

Intention – “What would you do next?”

- Intention to contact a doctor immediately (vs not) did not vary by a noteworthy degree by *signatory*

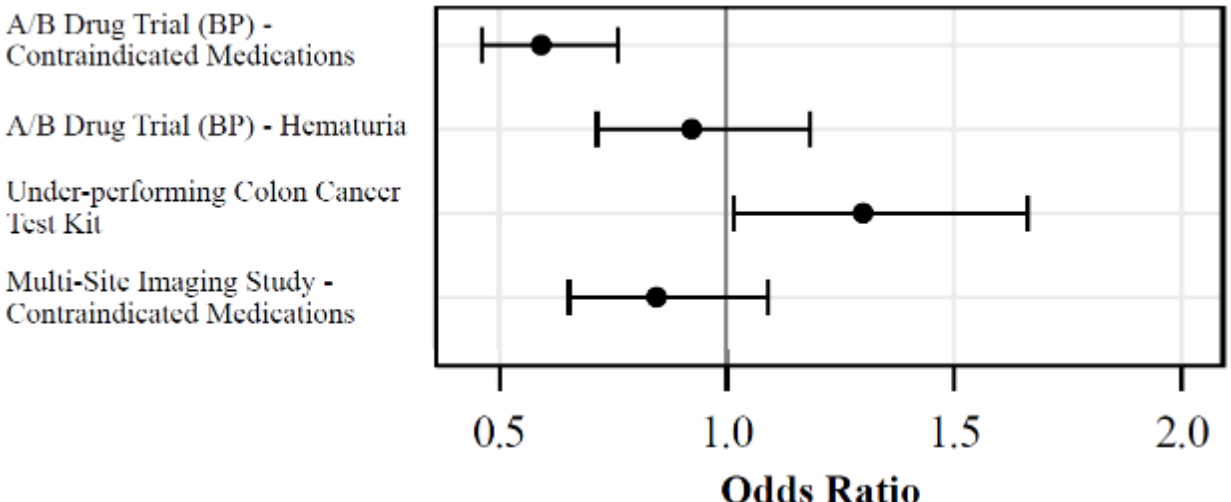
Signed by personal MD

vs

Signed by Chief Quality Officer/Sr Med Dir of Research

NO Effect

- There was an interaction between *PCT description* and the PCT-CF



Reactions - “How does this letter make you feel?”

- Range of emotions reported
  - 70% endorsed all *negative* emotions
  - 5% all *positive* emotions
  - 14% *mixed*
  - 10% no emotions

Emotion	N	Percent
Concerned	2436	59.7
Worried	1546	37.9
Irritated / Annoyed	1121	27.5
Surprised	1018	24.9
Confused	958	23.5
Fearful	787	19.3
Angry	685	16.8
Grateful	544	13.3
No feeling	408	10.0
Overwhelmed	373	9.1
Hopeful	174	4.3
In Control	151	3.7
Relieved	132	3.2
Other feeling	122	3.0

Questions – “What questions, if any, do you have?”

- The number of respondents who asked questions was similar for respondents who did (57%) and did not (52%) include details about the PCT
- Distribution of codes was consistent between these two groups
- In both groups, the most frequently asked questions addressed:
  - Next step
  - Health concerns
  - Negative impact on trust/confidence

Takeaways

- In general, people's intention to contact their doctor immediately or their initial emotional reaction was not affected by the signatory *or* whether or not the letter described the underlying research activity
- Initial reactions to the letter were predominantly negative
- Including a description of the PCT in the letter did not increase or diminish the number, or types, of questions raised

Takeaways for Policy/Practice

- Neither the “who” or “how found” make a difference for primary patient welfare consideration
- HOWEVER, interesting ethical questions remain re: about whether/not we should disclose the “how found”
  - Argument from respect for persons to be transparent
  - Yet also, data from focus group study suggests informed patients think that you should NOT disclose—at least not in the initial contact
- Patients will want more info—and health systems need to plan accordingly

Discussion

Thank you!

CENTER FOR
MEDICAL ETHICS
& HEALTH POLICY