ORIGINAL RESEARCH

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

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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.
OBJECTIVE: We sought to understand patients' views about PCT-CF disclosure, including how, by whom, and the nature and extent of information provided.
DESIGN: Prospective, qualitative focus group study.
PARTICIPANTS: Focus groups were conducted in Baltimore, MD; Houston, TX; and Seattle, WA (overall $N = 66$), during July and August 2019.
APPROACH: All groups discussed a hypothetical scenario involving the detection of a PCT-CF of contraindicated medications. Participants were asked about their reactions to the PCT-CF and issues related to its disclosure.
KEY RESULTS: Reactions to learning about the PCT-CF were mixed, ranging from fear of a significant health problem, anger that the contraindicated medications had gone unnoticed and/or for being included in research without their permission, to gratitude for the information. Preferences for how such disclosures are made varied but were driven by several consistent desires, namely minimizing patient harm and anxiety and demonstrating trust and respect. Many wanted their treating clinician to be informed of the PCT-CF so that they would be prepared to answer patients' questions and to discuss treatment options.
CONCLUSIONS: The detection of PCT-CFs is likely to increase with further expansion of PCTs. As such, clinicians will undoubtedly become involved in the management of PCT-CFs. Our data illustrate some of the challenges clinicians may face when their patients are informed of a PCT-CF and the need to develop guidance for disclosing PCT-CFs in ways that align with patients' preferences and values.

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

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INTRODUCTION

Pragmatic clinical trials (PCTs), including comparative effectiveness research, are increasingly being conducted to efficiently generate evidence to inform healthcare decision-making. Many PCTs overlap clinical practice in ways similar to quality improvement activities in that some PCTs evaluate already approved interventions and do not always involve obtaining explicit patient consent.[1] With the continued expansion of PCTs, it will become more commonplace for practicing clinicians to be somehow involved, including as direct subjects of the research, study facilitators, or in caring for patient-subjects.[2]

Despite the promise of using PCTs to inform healthcare decision-making, PCTs can encounter a variety of ethical issues, such as those related to conducting research without consent, privacy of health information, and how best to monitor safety.[3] One issue that has not received much attention is the management of pragmatic clinical trial-collateral findings (PCT-CFs), that is, information that emerges in a PCT that is unrelated to the primary research question(s) but may have implications for patients, clinicians, and health systems from whom or within which the research data were collected.[4] For example, a PCT aimed at increasing uptake of cardiac care guidelines identified patients with diagnoses that increased their risk for a cardiac event based on insurance claims data, but for whom documentation that the diagnosis was communicated was lacking.[5] Furthermore, because PCTs straddle the research-clinical care boundary, there are conflicting opinions as to who is ultimately responsible for managing PCT-CFs.[4]

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Regardless of who has responsibility, when a decision has been made to disclose PCT-CFs to patients, the actual disclosure will undoubtedly involve clinicians. For example, clinicians may be called upon to directly report these findings to their patients. Alternatively, patients informed of a PCT-CF through a healthcare system or a researcher might turn to their physician for information or guidance. In some cases, both physicians and patients may be unaware that the patient was included in a research study until presented with information about the PCT-CF.

As part of a larger project exploring a variety of stakeholders' experiences and attitudes about the management of PCT-CFs, we sought to understand patients' views about how PCT-CFs should be communicated, by whom, and the type and amount of information that should be provided. Understanding patients' values and preferences in this regard will be useful to clinicians who will likely find themselves progressively more on the front lines of reporting and subsequently managing their patients' PCT-CFs.

METHODS

We designed and conducted focus groups to solicit patients' views about disclosing PCT-CFs to patients who are unaware that their data was included in a PCT. Nine focus groups were conducted in July and August 2019.

Participants and Setting

To promote demographic and geographic diversity, focus groups were conducted in Baltimore, MD; Houston, TX; and Seattle, WA. The Baltimore and Houston focus groups were conducted at Johns Hopkins University and Baylor College of Medicine, respectively. Seattle focus groups were held at a hotel. Focus group participants were recruited through advertisements on Craigslist (https://www.craigslist.org/about/sites) in all three cities. Eligibility for participation included being an adult who had been either seen by a doctor or hospitalized in the previous year, as well as being able to speak and understand English. Individuals who worked in a healthcare-related field or the pharmaceutical industry, and those who participated in three or more research studies in the past year, were excluded. Demographic information was collected from participants during screening.

Focus Group Discussion Guide Design

A focus group discussion guide (see Appendix) was developed by the research team and revised following two pilot focus groups conducted in Baltimore in May and June 2019. Potential PCT-CFs to prompt discussion in the focus group were identified based on an unstructured literature review, discussions with members of our project Advisory Panel (that includes members with expertise in health systems, PCTs, ethics, and law), and the experiences of members of the NIH Health Care Systems Research Collaboratory.[5, 6] Ultimately, the focus group discussion was limited to a single hypothetical scenario in order to allow ample time to guide participants through it and to explain how the PCT-CF was identified.

The selected scenario involved a hypothetical pragmatic clinical trial comparing two medications commonly prescribed to treat high blood pressure, conducted in four hospitals, each of which agreed to be randomly assigned to prescribe one of the two medications to their patients and to collect data from those patients' electronic health records. At the close of the two-year study, each hospital sent their patients' de-identified data to researchers at the lead hospital for data analysis. Through this analysis, researchers identified some patients who had been prescribed two medications that, when taken together, could cause an irregular heartbeat. Focus group participants were then told that study organizers have decided to give this information to the patients who were found to have been prescribed contraindicated medications.

Data Collection

All focus groups were facilitated by one member of the research team (JMB) with extensive experience in focus group facilitation; at least one additional team member observed and took notes (SM or EM). Each focus group lasted approximately two hours and was audio-recorded. The facilitator began by describing and giving examples of ways in which a patient may learn important, yet unexpected, information about their health. The hypothetical scenario was presented to participants using PowerPoint (see Appendix). Following the presentation, participants were asked to imagine they were one of the patients in the hypothetical study. Questions explored their reactions to the hypothetical study and the discovery of the PCT-CF, whether or not they would want to be informed about the PCT-CF, how the PCT-CF should be communicated and by whom, and the type and amount of information that should be communicated. The focus group discussion closed with the group drafting a model communication informing patients about the PCT-CF.

Conduct of the Groups

Similar to our earlier research exploring patient attitudes towards PCTs,[7] the facilitator frequently needed to remind participants of the differences between PCTs and experimental trials of new therapeutics. While the hypothetical PCT was intentionally designed to minimize misunderstanding about the pragmatic nature of the research, participants often seemed to have some trouble understanding that the medications being compared were commonly prescribed and in use for several years (i.e., not an experimental drug with unknown risks).

Data Analysis

Focus group audio-recordings were professionally transcribed and reviewed for accuracy, and personal identifiers were removed. Using an integrated approach,[8] three members (JB, GG, EM) of the research team developed the codebook, including both a priori codes drawn from our focus group guide, and emergent, inductive codes. The codebook was iteratively revised by the coding team. Each transcript was then independently coded by two members (JB, EM) of the coding team who subsequently discussed and resolved any coding discrepancies. Coded transcripts were entered into NVivo 12 (QSR International Pty Ltd, MA). Text was organized and analyzed for recurring themes.

RESULTS

Sample Characteristics

A total of 66 individuals participated in nine focus groups across the three locations. Participants were diverse with respect to gender, age, and race/ethnicity (Table 1). Here, we describe the primary results in two broad categories: reactions to the PCT-CF and issues related to its disclosure. The themes presented generally follow the domains included in the focus group discussion guide. Quotes are followed by a parenthetical indication of the particular focus group including a city abbreviation and number (e.g., Seattle Focus Group, SFG1).

Table 1 Demographic Characteristics of Focus Group Participants (n = 66)

Gender	
Male	25 (38%)
Female	41 (62%)
Age	
> 29	9 (14%)
30–49	26 (39%)
50–69	25 (38%)
70+	6 (9%)
Race/ethnicity	
Black or African American	24 (36%)
White	26 (39%)
Hispanic or Latino	6 (9%)
Asian	5 (8%)
Other	5 (8%)
Education level	
≤ High school or GED*	12 (18%)
High school + some college	12 (18%)
Trade, Associate's degree	5 (8%)
BA/BS†	31 (47%)
MA/MS‡	6 (9%)
Health insurance	
Private	29 (43%)
Medicaid/Medicare	23 (35%)
Integrated/VA§	5 (8%)
No insurance	9 (14%)

General education diploma (GED) or high school equivalency certificate
†Bachelor of Arts (BA)/Bachelor of Science (BS)*
‡Master of Arts (MA)/Master of Science (BS)*
§Veterans Affairs (VA)*

Reactions to the PCT-CF

Focus group participants' reactions to learning about the PCT-CF were mixed. Overall, most initial reactions were negative. Participants expressed surprise that the contraindicated medications had gone unnoticed, concern about the medical implications of the finding, confusion as to how researchers (and not their doctor) were the ones to detect the PCT-CF, and anger toward their clinicians and/or the healthcare system. Participants were angry with clinicians for not knowing about (or being responsible for) the contraindicated medications. As one participant stated, "What is going on? How long it's been going on? Why are they telling me? My doctor should be telling me to be aware of this." (HFG3). Anger was also directed at healthcare systems for including patients in the research without their explicit permission. "All I see is that, okay, you've been doing a study on me without me knowing. And now, you find something bad. It's been two years. You tell me now? I'm going to sue you." (SFG2).

Conversely, there were also positive reactions to learning about PCT-CF. Several participants expressed being grateful the finding was uncovered, believing that this information was potentially life-saving, and would not have come to light had the study not been conducted. While some expressed increased confidence in their care as a result of learning this information, a few participants stated the information would lead them to find another doctor. "[The doctor] should have been the one who caught it. I mean, I would be grateful for the information, but I would be wondering, like, does he have too many patients that he can't deal with me personally…? But I would be grateful for it, but still, I'd still have some concerns about him." (BFG1).

It was not uncommon for participants to have mixed reactions to the information or for their views to evolve over the course of the discussion. One said, "I'd be happy to find out about it, definitely. But I'd be very upset." (BFG2), while another "would appreciate that information… [and not] be too upset." (SFG2). Many of those who were upset their information was included in the research study came to realize that the finding may not have come to light but for the research study.

Participants viewed the PCT-CF as significant and medically actionable. "I would definitely want to know this information. I think it's very important and I would hope that they would share it with my primary care physician or any other physician that I have." (HFG2). Many viewed the discovery of the PCT-CF as potentially life-saving. "I mean, it may have taken two years to find this, but this could be something that could be a life-saver." (HFG3). Participants understood that in order to act on the information, they would obviously need to be notified of it.

Notification

Several aspects related to notification emerged from our data: who should notify the patient; how notification should occur;

factors associated with preferences for notification; and content of the notification. We discuss each of these in turn.

Who Should Notify the Patient?. Participants' preferences for who should inform patients about the PCT-CF varied. Approximately half wanted their doctor to inform them. In the words of one participant: "I would want to know from my primary care doctor, because they know me better than another hospital would." (BFG2). In contrast, the other half did not have a strong preference as long as the individual was qualified, knowledgeable, and trustworthy. Suggestions of alternatives to provide findings included researchers who discovered the finding, pharmacists, nurses, and health system representatives. "It's immaterial to me...I think it would be someone who's medical somehow, but it doesn't have to be my physician." (SFG2). However, a few participants were adamant that the notification should *not* be reported through their clinician since these participants viewed their clinicians as culpable and not to be trusted.

> "Yeah, yeah. I don't think the doctor is a good choice at all….The doctor has already allowed this to happen. Whether it's an oversight or not… if you're getting two prescriptions, the drugs really come from the doctor. They have already made that mistake. Then you're now putting the trust back in the same person that whether they told you or not, they've already made the mistake or allowed the mistake to happen. I don't think the doctor is a credible person at that point." (BFG3)

Participants who had an established relationship with a particular clinician wanted them to be informed of the PCT-CF so that they would be prepared to answer their questions and to discuss treatment options. "I want the doctor [notified] as well. So when I walk in there, he's not blindsided…He's ready, prepared. So he…knows it's coming. We have a nice discussion." (HFG3). Whether or not clinicians are notified about their patient's PCT-CF, it was clear that if informed of such a finding, participants would turn to clinicians for guidance. "I'll probably be contacting my doctor to say, 'Hey, I was in this study, this is what I was told'. I need to know what we going to do about this. What's our next step in changing this?" (HFG1)

How Should the Notification Occur?. Participants' preferences for how a PCT-CF should be communicated varied. Their suggestions included, but were not limited to, letters, phone calls, notifications in the patients' electronic health record, and text messages. In all groups, participants advocated for a multi-modal notification approach. Not only did participants recognize that others may have different notification preferences, but they also wanted to minimize the risk of missing or overlooking the notification.

Factors Associated with Preferences for Notification. When discussing how and by whom the PCT-CF should be communicated, two underlying themes appeared to drive participants' preferences: the need for timely delivery of the information and the need for assurance that the information is coming from a trusted, legitimate source.

Participants preferred individuals and methods that would result in receiving the information in the most expeditious manner. As one participant stated: "I want [whoever]'s going to get it to [me] first." (BFG1). Participants' desire to receive the information as soon as possible further underscored their view that the information was significant, immediately actionable, and potentially life-threatening if ignored/not reported. When asked how the information should be reported, one participant responded, "I would want a personal phone call…something urgent because I don't have time for a letter. I don't have time for a report. This is vital information." (BFG1)

In addition, participants favored approaches that would maximize the likelihood that the patient not only receive the information, but take notice of it. Some provided suggestions on how to attract the patient's attention including sending letters by certified mail, using brightly colored envelopes, and sending text messages directing patients to call their doctor or log into their patient portal.

Participants preferred learning the information from a trusted, familiar source. For some, this meant from a specific clinician: "I might feel a little bit iffy if the hospital called me. But if my doctor called me, then I would feel more relaxed with the authentication [*sic*] of the information." (HFG3). Others found different mechanisms acceptable as long as the communication came in a manner that conveyed that the information was legitimate (e.g., a letter on institutional letterhead, notification in a patient portal). "If it's not like my doctor or someone in that branch, you know, someone in my comfort zone, I'm going to feel like you guys are violating my privacy." (BFG3)

Content of the Notification. When discussing what information about the PCT-CF should be communicated, participant recommendations centered upon two overarching goals: demonstrating respect for the patient, and minimizing patient harm and undue anxiety. While participants offered a variety of practical suggestions for communicating PCT-CF results to patients (Table 2—Features of communication), in all groups there were conflicting views about the amount and type information that should be reported to meet those needs. Specifically, participants held differing opinions as to whether or not to include the fact that the PCT-CF was discovered through a research study.

A majority of focus group participants advocated for excluding any mention of the research study, believing the information was irrelevant, distracting, and could lead to undue anxiety, confusion, and anger. Furthermore, the fact that

Table 2 Disclosing PCTs to Patients: Key Features of a Communication as Developed by Focus Group Participants

Key feature	Suggestions
Demonstrate respect	Personalize the communication. Do not send a form letter or bulk communication. Use a respectful tone and clear, direct language. Ensure that source of the information is easily recognized as legitimate and reputable. Include some limited patient-specific information that both signals a personal approach and instills confidence that the communication is legitimate (e.g., copy the patient's doctor).
Minimize patient harm and undue anxiety	Communicate the information through a trusted clinician. Include the patient's personal physician in the notification process. Provide a clear path for patients to access additional information or to speak with someone who can address the patient's questions. Do not mention patients consent for the study was not required. Do not mention the study involved randomization.

the study design involved randomization and a lack of patient consent were viewed as particularly alarming:

> "I think it's too much information. Honestly, okay… You want to randomize me, whatever. What difference does it really make? Why do I need to know that? What good could come of me finding out? There's no good, so I don't really feel like I need that." (SFG2)

> "I agree with [just] the basics…and if they want to know more, they'll call you and ask you. But once you open up the door and say, 'Oh, by the way, we took all your data. We gave it to another hospital'…you can't tell people everything and expect them not to panic." (BFG3)

Those advocating for a minimal approach expressed concern that including detailed information about how the PCT-CF was discovered could be inadvertently harmful by obfuscating the important, potentially life-saving message about the finding of contraindicated medications and the need to contact a clinician to address the issue.

> "You open a can of worms because now you've realized, 'Wait, my information's gotten out there, someone's studying me? What is this?' it totally distracts you from what is the most important thing which is you're taking a potential combination of medicines and causing a problem, it's veering off the main issue." (SFG1)

As one participant summed it up, "Just keep it simple, I mean if somebody asks you for the time, you don't have to tell them how to build a watch." (SFG1)

On the other hand, a minority of participants believed that being fully transparent about the research study demonstrated respect for patients. For those participants, not informing them about how the PCT-CF was discovered would be deceptive.

> "I think the patient should know [about the study]. 'Okay, so know that this was accidentally discovered', not a diligent doctor saying, 'Oh we were really caring about you and found this problem.' It's 'Hey, you would have never known.'" (BFG2)

One participant suggested that the communication should explain that researchers are permitted to conduct this type of research without consent. "I would let them know … we're a research hospital. So at times, we do conduct research. It wasn't really invasive. I would kind of want to smooth it over a little bit." (HFG3)

Another participant suggested that the communication specify that the research was done in compliance with HIPAA to reassure patients that their privacy was protected.

In all groups, participants eventually compromised on a communication that was limited to the most pertinent information: what was found (the PCT-CF of contraindicated medications), what that patient should do now (e.g., call your doctor, do not stop your medications without consulting a professional), and how to access more information (e.g., a phone number or website address). "If I get a letter and it says, 'This is Hospital A,' I'm going to pay attention to everything. I'm going to appreciate that 1-800 number at the bottom, but I want you to get to the point and let me know how to fix it." (BFG3). Furthermore, some acknowledged that patients may wonder how the PCT-CF was discovered. "At some point, I'd want to know how they figured it out, but I don't know that it's necessarily important right in that letter. But I think it is important to know." (SFG2)

DISCUSSION

This is the first study exploring patient reactions to, and preferences for, receiving information about a PCT-CF. The

detection of PCT-CFs is likely to increase with the expansion of PCTs to inform healthcare decision-making. As such, clinicians will undoubtedly become involved in the management of PCT-CFs—either by directly reporting PCT-CF results to their patients or indirectly when patients bring their PCT-CF results to them seeking information and guidance. Our previous research revealed that while many clinicians are familiar with PCTs, few have direct experience with these studies.[2] Taken together with the findings from the current study, it is possible to suggest several important considerations for clinicians related to the disclosure of PCT-CFs, and also illustrate some of the challenges clinicians might face if their patients are informed of a PCT-CF by others in the health system.

First, clinicians should expect patients to have mixed reactions when informed of a PCT-CF, including anger and gratitude, and should be prepared to respond to patients accordingly. Second, clinicians should be prepared for some patients to direct anger at them and/or the healthcare system, especially when patient consent for the study was not obtained. Furthermore, in some instances, patients may blame clinicians for the PCT-CF. Participants in our study were angry with their clinician for failing to detect (or being responsible for prescribing) the contraindicated medications. Third, clinicians should expect that patients' desire for information will differ with respect to both amount and type. Furthermore, this may change over time, as patients assimilate the new information. And sometimes the desire for information seems contradictory. Notably, while many individuals were surprised and angered to learn they were included in a research study without their expressed consent, not all believed that this information should be included in the disclosure. Regardless of the amount of information disclosed, clinicians should expect questions from their patients not only about how the PCT-CF might affect their care but also about how the PCT-CF was detected, and, in some cases, why they were included in a PCT without their consent. Finally, in cases where the clinician is responsible for reporting the PCT-CF to a patient, disclosure should be personalized and occur in a manner that minimizes the patient's anxiety, satisfies their informational needs, and demonstrates respect, just as in situations where clinicians deliver bad news or information about a medical error.[9, 10]

Our findings are consistent with literature on the related issue of incidental findings (IFs) in clinical care or research, which are unanticipated findings arising due to diagnostic or other interventions.[11, 12] Specifically, patients who receive information about IFs often turn to their clinicians for guidance, regardless of whether or not the clinician ordered the test or if the information was obtained through a research study.[13, 14] In addition, the IF literature documents that clinicians are concerned about increased burdens and challenges to workflow when reporting and/or managing IFs. [9] The reporting and management of PCT-CFs are likely to raise similar concerns.

LIMITATIONS

This study has several potential limitations that should be considered when interpreting our results. First, we assessed participants' reactions and issues related to the disclosure of a single PCT-CF; it is possible the findings might be different for a qualitatively different PCT-CF. For example, participants might react differently to a PCT-CF related to a false-positive rate of a test. [4, 15] Furthermore, during the focus group discussions, we frequently had to remind participants of the differences between PCTs and experimental trials of new therapeutics. While we took time to address misunderstandings, we cannot be sure that participants understood and kept in mind the important distinctions between PCTs and experimental trials. In addition, we have not explored other background influences on participants' reactions and preferences. These include baseline level of trust/distrust in doctors, medical research and the healthcare system, patients' typical information-seeking behaviors (i.e., how much information they usually prefer), and whether or not they have a relationship (positive or negative) with a doctor. Finally, as with all qualitative research, our findings cannot be quantified or generalized to other populations and contexts.

FUTURE WORK

To address some of these limitations, we are conducting quantitative work to assess whether our findings are generalizable to different types of PCTs and PCT-CFs. We hope that these data will problematize the issue of PCT-CFs for those conducting PCTs as well as inform the development of approaches for disclosing PCT-CFs in ways that align with patients' preferences and values.

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Compliance with Ethical Standards:

The institutional review boards of Johns Hopkins Medicine, Baylor College of Medicine, and Duke University Health Systems approved this research. Participants provided written informed consent and

were provided $75 compensation, reimbursement for parking, and a light meal.

Conflict of Interest: *Dr. Sugarman is a member of Merck KGaA's Bioethics Advisory Panel and Stem Cell Research Oversight Committee, IQVIA's Ethics Advisory Panel, and Aspen Neurosciences' Scientific Advisory Board; he has consulted with Portola Pharmaceuticals. None of these is related to the material described in this manuscript. None of the other authors has relationships to disclose.*

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REFERENCES

1. **Finkelstein JA, Brickman AL, Capron A, Ford DE, Gombosev A, Greene SM, et al.** Oversight on the borderline: Quality improvement and pragmatic research. Clin Trials. 2015;12(5):457-66.
2. **Topazian R, Bollinger J, Weinfurt KP, Dvoskin R, Mathews D, Brelsford K, et al.** Physicians' perspectives regarding pragmatic clinical trials. J Comp Eff Res. 2016;5(5):499-506.
3. **Califf RM, Sugarman J**. Exploring the ethical and regulatory issues in pragmatic clinical trials. Clin Trials. 2015;12(5):436-41.
4. **Morain SR, Weinfurt K, Bollinger J, Geller G, Mathews DJ, Sugarman J**. Ethics and Collateral Findings in Pragmatic Clinical Trials. Am J Bioeth. 2020;20(1):6-18.
5. **Sabin JE, Cocoros NM, Garcia CJ, Goldsack JC, Haynes K, Lin ND, et al.** Bystander Ethics and Good Samaritanism: A Paradox for Learning Health Organizations. Hast Cent Rep. 2019;49(4):18-26.
6. Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials [Internet]. [cited 3/24/2020]. Available from: https://rethinkingclinicaltrials.org/.
7. **Weinfurt KP, Bollinger JM, Brelsford KM, Crayton TJ, Topazian RJ, Kass NE, et al.** Patients' Views Concerning Research on Medical Practices: Implications for Consent. AJOB Empir Bioeth. 2016;7(2):76-91.
8. **Bradley EH, Curry LA, Devers KJ**. Qualitative data analysis for health services research: developing taxonomy, themes, and theory. Health Serv Res. 2007;42(4):1758-72.
9. **Fallowfield L, Jenkins V**. Communicating sad, bad, and difficult news in medicine. Lancet. 2004;363(9405):312-9.
10. **Coffey M, Espin S, Hahmann T, Clairman H, Lo L, Friedman JN, et al.** Parent Preferences for Medical Error Disclosure: A Qualitative Study. Hosp Pediatr. 2017;7(1):24-30.
11. **Kang SK, Spector-Bagdady K, Caplan AL, Braithwaite RS**. Exome and Genome Sequencing and Parallels in Radiology: Searching for Patient-Centered Management of Incidental and Secondary Findings. J Am Coll Radiol. 2016;13(12 Pt A):1467-72.
12. **Wouters RHP, Cornelis C, Newson AJ, Bunnik EM, Bredenoord AL**. Scanning the body, sequencing the genome: Dealing with unsolicited findings. Bioethics. 2017;31(9):648-56.
13. **Pet DB, Holm IA, Williams JL, Myers MF, Novak LL, Brothers KB, et al.** Physicians' perspectives on receiving unsolicited genomic results. Genet Med. 2019;21(2):311-8.
14. **de Boer AW, Drewes YM, de Mutsert R, Numans ME, den Heijer M, Dekkers OM, et al.** Incidental findings in research: A focus group study about the perspective of the research participant. J Magn Reson Imaging. 2018;47(1):230-7.
15. **Nielson CM, Petrik AF, Jacob L, Vollmer WM, Keast EM, Schneider JL, et al.** Positive predictive values of fecal immunochemical tests used in the STOP CRC pragmatic trial. Cancer Med. 2018;7(9):4781–4790; https://doi.org/10.1002/cam4.1727.***Publisher's Note*** *Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.*

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