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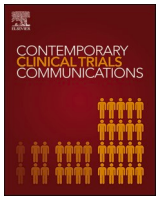

Participant perspectives on management and communication of incidental findings identified on radiographic imaging performed during a clinical research trial: A single site pilot study

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ABSTRACT

Background: Incidental findings (IFs) in radiographic imaging are unexpected discoveries unrelated to the purpose of the scan. While the protocol for communicating IFs is better defined for clinical providers, little formal guidance on communicating IFs identified on research scans to participants is available. This study explored participants' experience with communication and management of IFs found on imaging identified in a clinical research trial.

Methods: Participants who completed the parent clinical trial, which included imaging, were invited to participate. A survey, developed by the study team, was administered telephonically, and consisted of multiple choice and open-ended questions.

Results: Thirty participants enrolled in the survey study. Ninety-three percent of all participants (with and without IFs) reported they would participate in another research study to learn information that was important to their health. Seventeen participants reported being notified about an IF on their study scan(s). Ninety-four percent of those participants with an IF were satisfied with how the IF was communicated, and 71 % were grateful to find out about a health problem before it became an issue. Forty-one percent reported that learning about the IF led to improved health. Content analysis of the data from the open-ended questions revealed categories and themes which enriched the quantitative data.

Conclusion: Participants generally wanted to know when an IF was discovered unexpectedly on their imaging scan, as they learned important information about their health. Findings underscore the importance of having a clear protocol for communicating IFs to research study participants that undergo evaluation with radiographic imaging.

1. Introduction

Incidental findings (IFs) in radiographic imaging are newly made discoveries unrelated to the indication for the scan, which may or may not have clinical relevance. Regardless of their impact on medical health, IFs can have implications on the psychological health of patients. IFs can be found on imaging in both clinical and research settings. When found in the clinical setting, it is the obligation and well-accepted practice of the healthcare provider to manage, communicate these findings, and provide counseling to the patient; however, when it comes to research scans, the guidelines are not as clear. While aggregate study results are published and made available to the public, disclosure of individual-level findings to the participants themselves and how the research team will handle results should be outlined and addressed in human research protocols [1].

The Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations do not explicitly require or prohibit the reporting of IFs to study participants [2]. However, the FDA in the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 Good Clinical Practice has stated that the investigator should inform the participant if additional medical care is required to address the IF [3].

Abbreviations: Incidental findings, (IFs).

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The communication, management, and counseling plan for IFs found on participant research study scans is often unclear or inconsistent across studies and institutions. Since IFs are discoveries that are unrelated to the indication of the study, there is often little formal guidance provided by the Institutional Review Boards (IRBs) on how to manage and communicate these findings, especially for clinical investigators who are not engaged in the longitudinal medical care of the participant. Best practice may involve IRB oversight on how IFs are managed and communicated in research studies[1,4]. While specific data regarding the frequency of IFs is not available, it does vary depending on the type of imaging being done, specifically imaging of the thorax and abdomen may yield more IFs than imaging of other areas of the body [10].

The potential for incidental findings should be included in the informed consent form (ICF), so that participants are informed of this possibility before agreeing to participate in the study. It may be important for ICFs not only to describe the potential for the occurrence of IFs, but also the potential ramifications. In this regard, there should be further details outlining how the IFs will be communicated, how IFs could lead to withdrawal from the study, and how IFs could lead to additional clinical workup outside of the study. Furthermore, it should also be noted that IFs identified on research scans may cause potential emotional distress for the participant as they may be learning something new or worrisome about their health.

Given the paucity of research on communicating IFs to participants and the growing need for policy as the complexity and use of imaging is increasing in clinical trials, this pilot study explored participants' knowledge and perception of incidental findings on radiographic imaging identified in a single clinical research trial. The current communication process for sharing incidental findings identified on study-related radiographic imaging from the perspective of the research participant was explored.

2. Methods

2.1. Design

This survey study was conducted from August 2022 through January 2023. Participants who were previously enrolled in a clinical trial known as the Mineralocorticoid Receptor Antagonism for Cardiovascular Health in HIV (MIRACLE HIV) Study [5] were invited to participate. This parent study, conducted at an academic medical center in the greater Boston area (Massachusetts, United States), was a 12-month randomized controlled trial investigating the effects of mineralocorticoid receptor antagonism on the cardiovascular health of adults with human immunodeficiency virus (HIV). The parent study included the following imaging modalities: abdominal computed tomography (CT), cardiac positron emission tomography (PET), cardiac magnetic resonance imaging (MRI), coronary CT angiography, and aortic fluorodeoxyglucose (FDG) PET/CT.

2.2. Participants

Participants in the parent study who gave permission to be notified about future studies were contacted by phone, email, or mail. Participants were eligible for this study if they completed the parent study.

2.3. Study procedures

The study survey was created after consultation with the Massachusetts General Hospital Division of Clinical Research Education Survey Research Consultation service. The survey consisted of up to 36 questions and included a combination of open response, multiple choice, "yes"/"no", and "select all that apply" questions. The survey was designed to elicit sociodemographic data and information regarding participant experience with IFs in the parent study.

The survey was administered over the phone by a single research investigator. All participants were provided with an information sheet before the survey was administered and verbal consent was obtained prior to study procedures. Participants were assigned a study identification code upon study entry, and all data were de-identified. Survey responses were recorded for purposes of data capture. Participants received a gift card for completing the study. IRB approval was obtained by the Mass General Brigham Human Research Committee prior to commencement of study procedures.

2.4. Analysis

Quantitative data were analyzed using descriptive statistics in SAS JMP 16. Data are reported as mean (standard deviation) for normally distributed variables and proportions for categorial variables. Qualitative data were analyzed using content analysis [6,7]. Open response questions were transcribed by a professional transcription service. Transcripts were reviewed independently by two members of the study team and content analysis was performed to establish themes and categories that emerged from the open response data. The two study team members then reconvened to review, and mutually agreed upon the final categories and themes.

3. Results

3.1. Demographics

Of the 33 participants who were invited to enroll, 30 (91 %) chose to participate in the study. Sociodemographic data of the participants are shown in Table 1. Most participants identified as men (70 %, n = 21). The mean age was 59(7) years. Sixty percent (n = 18) of participants reported white race and 17 % (n = 5) reported Hispanic ethnicity. Half of the participants had an undergraduate degree or higher (undergraduate 30 %, n = 9; graduate 20 %, n = 6), and the majority had an annual

Table 1
Participant demographics and clinical characteristics (N = 30).

Characteristic	
Gender Identity, n(%)	
Man	21(70)
Woman	8(27)
Nonbinary	0(0)
Other	1(3)
Age, years, mean(SD)	59(7)
Race, n(%)	
Asian	0(0)
Native Hawaiian or Other Pacific Islander	0(0)
American Indian or Alaskan Native	0(0)
White	18(60)
Black	8(27)
More than one race	4(13)
Other	0(0)
Ethnicity, n(%)	
Hispanic	5(17)
Non-Hispanic	25(83)
Highest year of education completed, n(%)	
Less than high school	2(7)
High school/GED	13(43)
Undergraduate degree	9(30)
Graduate degree	6(20)
Annual household income, n(%)	
<$25K	10(33)
$25–50K	9(30)
$50–75K	5(17)
$75–100K	0(0)
$100–125K	2(7)
>$125K	4(13)
Has a PCP, n(%)	29(97)
HIV provider serves as PCP, n(%)	22(73)

Abbreviations: SD, standard deviation; GED, graduate equivalency degree; K, thousand; PCP, primary care provider; HIV, human immunodeficiency virus.

household income of $50,000 or less [<$25,000 (33 %, n = 10), $25,000–50,000 (30 %, n = 9)]. Almost all participants (97 %, n = 29) reported having a primary care provider (PCP), and for most participants (73 %, n = 22), their HIV provider served as their PCP. English was the preferred language among all participants.

3.2. Quantitative analysis of survey responses

3.2.1. Investigator-participant discussion regarding potential for IFs

Fifty-three percent (n = 16) of the participants reported that they remembered the potential for IFs being discussed during the informed consent process for the parent study, which had concluded March 2022. Most participants (77 %, n = 23) reported feeling grateful that they might find out about an IF before it could become a health issue. Ninety-three percent (n = 28) of all participants (with and without IFs, n = 30) reported they would participate in another research study to learn about medical findings that were important to their health. One participant indicated that the possibility of an IF would not affect their decision to participate in a future study. Another participant stated in an open-ended response question that they think of IFs as a positive, "… I would look at that as a good thing because somebody found something …" [PT28].

3.2.2. Impact on participant health among those who reported being informed about an IF

Seventeen participants (57 %) reported being told there was an IF on their research study imaging scan (Table 2). Seventy-one percent (n = 12) of those 17 participants were grateful to learn of the finding before it became a health issue, and 35 % (n = 6) were anxious about finding something unexpected. One participant, [PT20], reported feeling "concerned and … panicky" when learning about the IF, as they felt it might be related to their prior history of smoking. Ninety-four percent of the participants (16 out of 17) were satisfied with how the IF was communicated to them by the study team (Table 3).

Of those who reported having an IF identified on their research scan, 29 % (n = 5) reported that the IF was a health problem that was identified early and had been treated by their medical provider, and 41 % (n = 7) reported that the IF was identified as a potential health problem and subsequently monitored (Table 3). One participant reported that follow up with a specialist was deferred due to the COVID-19 pandemic. Another participant engaged in follow up with a medical provider, though expressed anxiety about ongoing monitoring due to limited continuity of care with their provider. For 3 participants (out of the 17), the IF had no further impact on their health.

Forty-one percent (n=7) of the participants reported that learning about the IF led to improved health. None of the participants reported that learning about the IF led to unnecessary worry or unnecessary medical procedures. One participant was glad to be notified about the IF, and another participant reported that the finding made them aware of their own health habits (Table 3).

3.3. Content analysis of open response questions

Four categories emerged from the content analysis of the open

Table 2
Experience with incidental findings among all participants (N = 30).

Question	
Do you remember the potential for incidental findings, or findings discovered by chance on one of the research study scans, being discussed during the informed consent process for the MIRACLE study?	
YES, n(%)	16 (53)
Did you think there would be incidental or unexpected findings on your research study imaging scans?	
YES, n(%)	6(20)
NO, n(%)	11 (37)
Did not think about it, n(%)	13 (43)
How did you feel when you learned there might be incidental or unexpected findings on your research study imaging scan?, n(%)[a]	
Anxious about what may be found	6(20)
Grateful to find out about something before it becomes an issue	23 (77)
Not sure how to feel	3(10)
Don't remember the potential for IFs being discussed	3(10)
How did learning about an IF or lack of an IF affect willingness to participate in another research study?, n(%)[a]	
Would participate in another study to learn things that are important to my health	28 (93)
Would not participate in another study because I learn things that are unnecessary to my health	0(0)
Other[b]	2(7)
During the research study, were you told that there was an incidental or unexpected finding on your study imaging scan?	
YES, n(%)	17 (57)

Abbreviations: IF, incidental finding.
[a] Participants could choose multiple responses.
[b] "Other" responses to the survey questions yielded participant-specific experiences and details not captured by pre-specified multiple-choice responses.

Table 3
Experience with incidental findings among participants who reported being told about an incidental finding (N = 17).

Question	
How did you feel when you were told there was an incidental or unexpected finding(s) on your research study imaging scans?, n(%)[a]	
Anxious about finding out something unexpected	6(35)
Grateful to find out before it became an issue	12(71)
Did not change how I felt	3(18)
Other[b]	1(6)
Were you satisfied with the way this information was shared or communicated with you?	
YES, n(%)	16(94)
NO, n(%)	0(0)
NEUTRAL, n(%)	1(6)
Did your primary care provider know you were involved in the research study?	
YES, n(%)	17 (100)
Did you want your primary care provider to know you were involved in the research study?	
YES, n(%)	17 (100)
Did you want the incidental or unexpected findings shared with your primary care provider or specialist?	
YES, n(%)	17 (100)
Were you able to follow up with your primary care provider or specialist about the incidental or unexpected finding?	
YES, n(%)	17 (100)
What impact did this finding have on your life: n(%)[a]	
A health problem was identified early and treated	5(29)
A potential health problem was identified and is now being monitored	7(41)
The finding turned out not to be serious	1(6)
Had to spend a lot of money for this problem to be worked up	0(0)
The incidental finding caused unnecessary worry	0(0)
No impact	3(18)
Other[b]	4(24)
Learning about IFs led to: n(%)[a]	
Improved health	7(41)
Reassurance about health	4(24)
Unnecessary worry	0(0)
Unnecessary procedures	0(0)
Did not change anything about health	6(35)
Other[b]	3(18)

[a] Participants could choose multiple responses.
[b] "Other" responses to the survey questions yielded participant-specific experiences and details not captured by the pre-specified multiple-choice responses.

response questions answered by the participants (Table 4).

3.3.1. Category 1: Communication of the IF to study participants

3.3.1.1. Theme 1: Investigator characteristics that reduce participant anxiety. Participants were asked how information related to the IF was shared. IFs were consistently shared by the study principal investigator (PI)—a physician—or the study nurse practitioner via telephone. Several participants shared that the IF was explained to them in a calm manner and that the interaction with the study team was positive. One participant remarked, "… [The study co-investigator] called me and went over [it] in very big detail … she was very good about it. It was very calming …" [PT11]. Another participant stated, "… they told me in a way so that I wouldn't be scared that they found something …" [PT15].

3.3.1.2. Theme 2: Facilitation of medical follow-up. Four participants shared that the study team notified their respective PCPs about the IF. One participant recalled his experience of being notified he had an IF that required urgent follow-up "… I believe I heard first [about the IF] from my primary care provider who told me to go to an emergency room as soon as possible, if not immediately, and then I believe I received a phone call from the [study] nurse practitioner …" [PT30].

3.3.1.3. Theme 3: Reporting an IF to participants. Participants who did not report having an IF identified on the research scan (n = 13) were asked to list up to 3 ways they would like an incidental or unexpected finding to be communicated or shared with them if an IF is identified in the future. Participants endorsed the following methods (participants could endorse up to 3 methods): phone call (n = 4), in-person (n = 3), digitally (n = 2), via the medical record (n = 2), and mailed letter (n = 1). Two participants specifically stated they wanted this to be communicated by the study team and 2 mentioned they wanted it communicated by their PCP. One participant stated, "Just be told that there was [an IF], that's all. I mean, because [IFs] shouldn't be kept a secret … I'm doing a study for [the study team] to find something, if you find something, [it is] common courtesy I guess," [PT07].

3.3.2. Category 2: Satisfaction with the communication and timeliness of reporting IFs

3.3.2.1. Theme 1. Clarity with communicating incidental findings. PT22 noted, "… they told me completely what they had encountered …" Another participant, PT21, reported they were satisfied with how the IF was communicated, "because the [medical] tests are too expensive … so I am grateful to know what they found." PT27 stated, "[The IF] was clearly communicated, and it was helpful information."

3.3.2.2. Theme 2. Timeliness of communication. Timeliness of reporting IFs was also important to participants. PT30 stated: "… The importance of [the IF] was conveyed to me immediately, and I was informed as soon as possible … and there was really good follow up …" Another participant, PT23, shared: "… my doctor was able to see exact[ly] what was happening and treat me accordingly."

3.3.2.3. Theme 3. Limitations with communication. One participant, PT20, who experienced an IF that was of unclear clinical significance felt neutral about the IF communication process. The study investigator shared all available information related to the IF; however, the participant was seeking more comprehensive information from the study investigator, "… I don't think I got any help from [the study team] necessarily on what [the IF] was. It was something where I had to follow up with my PCP about it …" Another participant, PT29, stated, "They [said], well, we found a nodule and at this time we really can't help you, you have to go back home and work with your physicians … I was just hoping they would set up [a plan] … I felt like, well, it was just a study and they couldn't help me pursue this nodule situation …" This quote describes the limitations that clinical investigators experience during research studies. Specifically, they may identify an IF through study procedures, though their obligation is to connect the participant with appropriate medical care, and not treat the IF themselves.

Table 4
Qualitative findings from open-ended response questions.

Category 1: Communication of the IF to Study Participants
Theme 1. Investigator characteristics that reduce participant anxiety "… they told me in a way so that I wouldn't be scared that they found something …" [PT15]
Theme 2. Facilitation of medical follow-up "… I believe I heard first [about the IF] from my primary care provider who told me to go to an emergency room as soon as possible, if not immediately, and then I believe I received a phone call from the [study] nurse practitioner …" [PT30]
Theme 3. Reporting an IF to participants "Just be told that there was [an IF], that's all. I mean, because [IFs] shouldn't be kept a secret … I'm doing a study for [the study team] to find something, if you find something, [it is] common courtesy I guess," [PT07]
Category 2: Satisfaction with the Communication and Timeliness of Reporting IFs
Theme 1. Clarity with communicating incidental findings "… they told me completely what they had encountered …" [PT22]
Theme 2. Timeliness of communication "… The importance of [the IF] was conveyed to me immediately, and I was informed as soon as possible … and there was really good follow up …" [PT30]
Theme 3. Limitations with communication "… I don't think I got any help from [the study team] necessarily on what [the IF] was. It was something where I had to follow up with my PCP about it …" [PT20]
Category 3: Strategies to Improve or Change the Communication of Incidental Findings
Theme 1. Research participant perspectives "… You can send a fax to somebody right now, but all I'm hearing from people is, 'oh, we're overwhelmed with the virus' … and everybody's [healthcare providers are] all backed up …" [PT29]
Category 4: Communication and Management of IFs in the Parent Trial
Theme 1. Research participant experiences "… I think it's great that the [investigators] make people aware [of IFs]. I think that for people to know … [findings] about their health that they wouldn't have known otherwise," [PT23]

Abbreviations: IF, incidental finding.
Exemplar quotes are provided for each theme.

3.3.3. Category 3: Strategies to improve or change the communication of incidental findings

3.3.3.1. Theme 1: Research participant perspectives. Participants were asked 3 ways the process of communicating incidental or unexpected findings to research participants could be improved. Thirteen of the 17 participants who experienced IFs did not recommend any improvements to the process. Suggestions to improve the process shared by the other participants included: improvement with how medical records are shared between systems and more open communication between patients and their physicians. This comment was specifically in reference to the influence of the COVID-19 pandemic on patient-provider communication: "… You can send a fax to somebody right now, but all I'm hearing from people is, 'oh, we're overwhelmed with the virus' … and everybody's [healthcare providers are] all backed up …" [PT29].

Changes to the process of managing and communicating IFs were recommended by some of the participants. Specifically, participants were asked to list up to 3 ways the process could be changed. One participant, PT10, referenced that emotional preparation may be needed, stating, "… I think other people might be way too sensitive for [learning that an IF was found] without any counseling prior [to learning of the IF] or [having] a loved one with them …. I mean, I live with HIV … So, hearing cancer or something down the road, I'm not afraid of that … But most people aren't living with that, or they don't know what's going on in their health because they barely see their doctors …"

3.3.4. Category 4: Communication and management of IFs in the parent trial

3.3.4.1. Theme 1: Research participant experiences. Overall, participants generally felt the management of the IFs was handled professionally and the information was communicated clearly. PT11 mentioned that participating in the study was a positive experience, "… I'm really pleased with team with the research and [the team is] just awesome. And I was happy to be a part of that process because my overall health has improved greatly because of the research." Another stated, "… I think it's great that the [investigators] make people aware [of IFs]. I think that for people to know … [findings] about their health that they wouldn't have known otherwise," [PT23].

Overall, participants reported that participating in the parent study was a positive experience. As shared by one of the participants, PT11: "… I just think it was a really great experience and I felt fortunate to be a part of [the study]. I'm grateful for, quite frankly, for the incidental findings because it got me in with a cardiologist and on some medication … I was just really grateful, and I don't know if it would've been found as quickly or as easily had I not been on this study." Another participant, PT25 stated, "I want to add that I'm very grateful to all of the people that worked in that study because they saved my life."

4. Discussion

IFs are commonly discovered in research trials, especially in studies that utilize advanced imaging techniques. While IFs should be anticipated in these types of studies, there is not always a standardized plan detailed in the protocol to address and manage these findings. The current survey study aimed to understand, from the participant's perspective, the experience of participating in a study where there was the potential for discovering IFs, and explored how IFs, if discovered, were communicated. Over half of the study participants reported learning about an IF on at least one of the parent study scans, and participants largely endorsed that the IFs were communicated in a timely, thoughtful, and clear manner by members of the investigative team.

While not every participant reported being informed about an IF on their study scan, of those surveyed, most recognized the opportunity to potentially find out about an IF before it became a health issue, and almost all the participants would participate in another study to learn clinical findings that they feel are important to their health. For those who were notified about an IF on their study imaging scan, the majority were satisfied with how this information was communicated to them, and they were all able to follow up with their PCP or a specialist about this finding. The finding did have an impact on the participant's life; either it was a health problem that was identified early and treated or a potential health problem that was identified and monitored. The consensus among participants was that learning about IFs on study imaging scans is a benefit of participating in research.

While the study population was exclusively comprised of persons living with HIV, these findings support the need for additional studies across other disease processes/conditions to gain insight into the perspectives of people living with other illnesses. It is worth noting that the participants for this specific study were not representative of a high-income group, most participants having an annual household income of $50,000 or less. Healthcare costs in the United States are rising. Obtaining radiographic imaging and other tests that can be performed in a research study, which may not be covered by medical insurance or may be accompanied by a high out-of-pocket cost, could be desirable and a motivator for participating in clinical research.

Research exploring strategies and protocols to communicate IFs to study participants is limited. Vander Wyst et al. conducted a study that specifically addressed developing a pathway to identify and communicate IFs found on MRI to an underrepresented population [8]. The developed pathway included (1) real time screening of the study MRIs by the MRI technologists; (2) if a critical or serious finding was identified, the MRI technologists notified the pediatric radiologist; (3) the research team was notified; and (4) the research provider notified the participant/family and PCP if determined to be a serious IF. Twenty-five of the 86 youth who were imaged as a part of this study had at least one IF discovered on their research scan. The findings from this study generated a list of recommendations for researchers, including highlighting the possibility of discovering unrelated, unintended but potentially clinically relevant findings during the informed consent process [8].

Another study used focus groups of participants who had previously been enrolled in an MRI study to examine the experiences and expectations of study participants [9]. A key theme that emerged from the analysis was that some participants joined this study primarily to undergo MRI to confirm that they were healthy. The participants had expectations that findings from the MRI would be communicated to them and their providers in a timely manner. Ultimately, de Boer et al. concluded that prior to recruitment of participants, researchers should have a well thought-out protocol in place for the communication of IFs identified during studies that utilize radiographic imaging [9]. These two studies reinforce the importance of having a standardized protocol and workflow, at the institution level, for managing and communicating IFs to research participants.

While there is evidence to support communicating important results to research participants, determining which research results should be reported can be complex. Participant levels of health literacy, understanding of results, and personal preference to learn about results may vary widely. Some research participants may enroll in studies to serve as a substitute for routine medical care. Therefore, communication of IFs in the research setting may be particularly important for vulnerable populations with limited resources or healthcare access, as the research visit may be one of their few interactions with the healthcare system. Having a clear and transparent process for managing and communicating IFs in the research setting is essential to providing continuity of care. For example, as part of the participant safety management plan, IFs should be part of the care pathway given that IFs may trigger early termination/withdrawal from a study. IFs may also require confirmatory scans based on the standard of care, and this information should be provided in clear language in the informed consent form. Lastly, the IFs need to be

conveyed in a way in which the participant understands the findings and the necessary follow up.

This pilot study presents novel information about the participant experience with IFs in a clinical research study. Few studies have been performed to understand participants' experience with the research process. There were a few limitations. The study was retrospective in nature, as participants were surveyed after completing the parent study and may not have fully recalled their experience, since some participants may have completed the parent study years prior to completing the survey. The number of study participants was small and not all participants reported being informed of an IF. Nonetheless, those who reported being notified about an IF provided key information which allowed us to discern specific categories and themes relevant to the study objectives. Some participants had previously interacted with the primary investigator of the survey study, which could have influenced the participants' responses. However, questions were written and asked in a neutral manner to remove bias. Moreover, a strength of this study was the use of a combination of different question strategies (multiple choice, open-ended), which allowed the collection of both quantitative and qualitative data. The open-response questions allowed the participants to provide context to their responses, enriching the data.

5. Conclusions

The discovery of IFs is a common occurrence on imaging scans, both in the clinical and research realms, and should be anticipated when planning a research study that includes imaging techniques. While there is currently little formal guidance about the management of IFs in the research setting, it is important to have a plan in place for managing and communicating these findings. The sample in this study preferred to be notified when an unexpected incidental finding was encountered during scan review. This study demonstrated a largely positive experience with IF communication and provides prefatory data on the participant experience in a research study involving several advanced imaging techniques. The results of this pilot study support future research on IFs, specifically examining the perspectives of participants in larger prospective studies. Findings from this study may lead to improvements to the informed consent process, specifically, including content that describes the possibility of identifying study-related IFs and how the IFs should be communicated to the participant. Study findings may also help inform the development of formal protocols to address the management and communication of IFs that can be implemented and tested in future studies.

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CRediT authorship contribution statement

Allie R. Walpert: Writing – review & editing, Writing – original draft, Resources, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Carolyn Dunderdale:** Writing – review & editing. **Suman Srinivasa:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Sara E. Looby:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Quantitative data can be made available upon reasonable request. Open ended responses are confidental to protect individual participant privacy.

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