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## Subjects' Expectations in Neuroimaging Research

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### Abstract

**Purpose**—To explore subjects' attitudes and expectations concerning the detection and management of incidental findings in neuroimaging research.

**Materials and Methods**—Healthy control subjects ( $N = 105$ ) who previously participated in neuroimaging studies in medical and nonmedical settings were surveyed about their expectations and attitudes toward unexpected clinical findings on their research brain scans. We hypothesized that even though the participants consented to a scanning procedure for research purposes alone, they would still expect pathology, if present, to be detected and reported to them.

**Results**—Fifty-four percent of participants reported that they expected research scans to detect abnormalities if they existed. Nearly all subjects (>90%) reported that they would want findings communicated to them, and many (59%) preferred this to be done by a physician affiliated with the research team. The participants responded in similar ways whether they were scanned in medical or nonmedical settings.

**Conclusion**—Clarity about procedures for handling incidental findings when obtaining written and verbal informed consent is essential to ensure that the subjects' expectations are consistent with the purpose and scope of the research.

### Keywords

incidental findings; neuroethics; neuroimaging; fMRI; informed consent; therapeutic misconception

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MEDICAL IMAGING TECHNIQUES have proved to be powerful tools in diagnosing, monitoring, and managing human disease. Many imaging methods, such as magnetic resonance imaging (MRI), computerized tomography (CT), and ultrasound (US), are also used routinely in research environments to study human physiology and behavior. Each year thousands of subjects are recruited to participate in research studies either as normal controls or as patients representing specific disease entities. During both research and medical scanning it is possible to detect suspicious anatomical abnormalities that are unrelated to the purpose of the scan. These are referred to as incidental findings. Hundreds of case reports and retrospective studies that examined incidental findings in imaging studies conducted for medical reasons (1–4) have

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been published, but there are only a few studies of incidental findings in healthy controls scanned for research purposes.

Recently published data regarding functional brain imaging demonstrated clinically significant incidental neuroradiological abnormalities in 2–8% of asymptomatic adult (5–7) and pediatric research participants (8). In a study that characterized the frequency and severity of potential incidental findings in brain MRIs in adults, Illes and colleagues (7) found that older adults ( $\geq 60$  years) have a high occurrence of incidental findings, most of which can generally be classified as routine (e.g., nonspecific white matter lesions). In contrast, the majority of findings in younger adults—however infrequent—require urgent referral (e.g., nonacute intraparenchymal or extra-axial lesions other than small white matter foci). Although only a fraction of findings are categorized as requiring routine clinical referral, and even fewer as requiring urgent or immediate medical referral, the overall rate of incidence in brain imaging is at least double the 1% threshold for adverse reaction warnings on drug labels. Nonetheless, subjects are not always alerted to the possibility of incidental findings and/or missed abnormalities in their informed consent documentation.

In a related study, 82% of neuroimaging investigators who conduct functional brain MRI (fMRI) studies in the United States and abroad reported incidentally detecting abnormalities in the course of their research (9). This study also found substantial variability in the procedures for handling incidental findings and communicating them to the subjects. For example, reviews by a neuroradiologist were routinely performed in only 36% of the responding laboratories (9). In 41% of laboratories, students (graduate and undergraduate) may have primary responsibility for scanning. Handson and/or safety training was the only requirement for scanning in 44% of the responding laboratories. Further, only 53% reported that they had standardized procedures in place for handling incidental findings and communicating with subjects. Of the six consent forms that were submitted to this survey, four did not contain any language specifically related to incidental findings.

Research neuroimaging studies are not advertised as having diagnostic or therapeutic value; however, without proper safeguards, it is reasonable for subjects to anticipate that research-related MRI scans will detect anatomical abnormalities or disease if present. Subjects might also assume that all individuals conducting these scans are competent to detect abnormalities. If this is true, then some subjects are leaving research MRI scans with a false sense of confidence that their brain is normal and without pathology.

In the light of these potential misconceptions, and given the rapidly increasing numbers of research fMRI scans done each year (10–12), we surveyed subjects who had participated in research brain scans to address the following questions about incidental findings in imaging research: 1) If a suspicious abnormality existed, would the subjects expect it to be detected? 2) If an incidental finding occurred, would the subjects want to be informed of the finding? 3) If so, how would they want the finding communicated to them?

We also tested for the effect of the setting (medical or nonmedical) on the responses to these questions.

## MATERIALS AND METHODS

Neuroimaging investigators at two locations on the west coast of the United States were identified and sent e-mail invitations to participate in the study. One of the locations was an imaging facility that was equipped with 1.5T and 3T GE MRI systems, and was affiliated with and located immediately adjacent to a medical center (hereafter referred to as the “medical setting”). The other location housed a 4T Varian MRI scanner in a temporary structure adjacent to a university psychology building (the “nonmedical setting”). The scanners in both settings

are dedicated to research purposes only and are shared by several principal investigators and their personnel. Both facilities permit research assistants and students to have primary responsibility for scanning.

Language pertaining to incidental findings was included in the informed consent forms at both facilities. In the medical setting the language was as follows:

The investigators for this project are not trained to perform radiological diagnosis, and the scans performed in this study are not optimized to find abnormalities. The investigators and [name of institution] are not responsible for failure to find existing abnormalities in your MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. When this occurs, a neuroradiologist will be consulted as to whether the finding merits further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting neuroradiologist, and [name of institution] are not responsible for any examination or treatment that you undertake based upon these findings. Because the images collected in this study do not comprise a proper clinical MRI series, these images will not be made available for diagnostic purposes.

The relevant informed consent language in the non-medical setting was as follows:

This study is part of a research protocol, and is not intended to provide a comprehensive clinical MRI examination of the brain. If, however, a potential abnormality is identified on your MRI scan, you will be immediately notified and your scan will be forwarded to your family physician.

Investigators at the two imaging facilities were asked to e-mail subjects who had participated as healthy controls in their fMRI research more than one month prior to the launch of this study, and invite them to complete a Web-based survey. The survey consisted of 18 questions dealing with subjects' expectations about incidental findings in neuroimaging research, followed by four demographic questions. Half of the questions either required a yes/no response or were in multiple-choice format. The remainder of the questions required responses on a seven-point Likert scale. Standard descriptive statistics were used to analyze the data. To account for unequal sample sizes, a weighted average was used when data from the two institutions were combined. When questions based on the Likert scale were analyzed, responses in the two categories of most agreement (i.e., categories 1 and 2) were combined. The survey took approximately five to 10 minutes to complete. The subjects were offered compensation for their time.

This study was conducted under an institutional review board (IRB)-approved protocol at both institutions. Informed consent, which was provided by clicking an "Accept" box on an IRB-approved form, was required before the subjects could access the survey. All surveys were completed anonymously.

## RESULTS

### Subject Demographics

A total of 105 surveys (78 from the medical setting, 27 from the nonmedical setting) were accessed and completed partially or fully. The average age of the respondents was  $24.5 \pm 4.9$  years ( $24.3 \pm 4.2$  years for the medical setting,  $25.3 \pm 6.6$  years for the nonmedical setting). Fifty-four percent of all respondents were female (43/78 from the medical setting, 14/27 from the nonmedical setting) and 46% were male (35/78 from the medical setting, 13/27 from the nonmedical setting). Seventy-two percent of the surveys were completed by undergraduate,

graduate, or postdoctoral students (57/78 in the medical setting, 19/27 in the nonmedical setting), and the remainder of the surveys were completed by faculty, staff, or members of the local community. The subjects at both institutions represented several ethnic groups, with the majority being Caucasian (59%), Asian (28%), or Hispanic (7%). Three subjects were eliminated because they did not meet the age eligibility criteria.

Fifty-six percent reported that this was the only brain imaging study they had undergone. Seventy-seven percent of subjects (58/76 for the medical setting, 21/27 for the nonmedical setting) had never undergone an imaging study for medical reasons. Additionally, 93% of the participants (69/74 from the medical setting, 25/27 from the nonmedical setting) had never participated in an imaging study of other organ systems.

Table 1 shows the subjects' reported motivations for participating in a research neuroimaging scan. A majority of the subjects participated for either financial compensation or course credit. A smaller fraction participated as a favor to the experimenter or as a way to contribute to scientific knowledge. A single subject from the medical setting cohort reported participating in a research brain scan because he was worried about a health problem.

### Subject Expectations

Fifty-four percent of the subjects (51% 40/78 in the medical setting, and 63% 17/27 in the nonmedical setting) reported that if a brain abnormality existed they would expect it to be detected. This is despite the fact that 84% reported that they did not expect a physician to review all of the research scans.

In addition, over 90% of participants at both institutions reported that they would want to be informed of an incidental finding regardless of its significance (Table 2). We also examined whether the desire to seek further medical evaluation depended on the clinical significance of an incidental finding (i.e., benign, malignant but curable, malignant and not curable, or life-threatening emergency; Table 3). Except for benign findings, over 95% of the subjects reported that they would seek further medical evaluation. As shown in Table 4, most subjects (59%) would want to be informed of an incidental finding by a physician on the research team. Again, this result occurred even though 84% reported that they did not expect a physician to review all of the research scans. A smaller percentage of participants (35%) reported that they would want to be informed by the individual responsible for the experiment or by the researcher who actually ran the experiment. Very few subjects wanted to be informed by their primary care physician.

## DISCUSSION

In this exploratory study we found that although subjects provide written consent to a scanning procedure for research purposes alone, most of them still expect any existing pathology to be detected and communicated to them. Therefore, clarity about procedures for handling incidental findings when obtaining written and verbal informed consent is essential to ensure that the subjects' expectations are consistent with the purpose and scope of the research being conducted. Language should also be clear about the risks of false positive findings.

Certain limitations of this study must be taken into consideration before the results can be interpreted and carried forward to practical implementation. First, the study samples from the two participating institutions were unequal in size. Second, the participants at both institutions were mostly students and academics. Similar surveys in other populations could yield different results. Third, the time between the subjects' participation in the imaging protocols and their participation in the present study varied between several months to a few years. While we were cognizant of this uncontrolled variable in the design of the project, we believed it would have

been inappropriate to ask the subjects to complete the survey either before or immediately after the fMRI scan was conducted, because that might have provoked anxiety. To obtain even the relatively small  $N$ , we had to extend the post-participation time to about three years.

Fourth, the language about incidental findings included in the consent forms may have biased the subjects' responses to the survey. If so, this would highlight the importance of attending to the effects of such language. In fact, the difference between the two consent forms in terms of the language used may account for the higher expectations of the responders from the nonmedical setting. However, the bioethics literature suggests that subjects rarely read written consent forms carefully, if they attend to them at all (13–17), and we are aware that verbal explanation of the policy regarding incidental findings did not consistently take place at either site. Therefore, this potential biasing effect remains unclear.

Given the mismatch between the research subjects' expectations about incidental findings as suggested by our results, and the purpose and scope of the research described in the consent forms, subjects could be inadvertently harmed by their participation if they were to acquire a false sense of security about their health and not seek medical assistance if needed (18–20). Obtaining informed consent for imaging research, as currently practiced, does not appear to adequately mitigate this possibility. Since it is neither feasible nor ethically required that every research scan be examined by a qualified specialist, careful consideration is needed, in the context of each study, regarding who conducts the scanning, and the possibilities for access to a neuroradiologist or another physician by the research team. Even though after many years of brain imaging there has never been a lawsuit related to such imaging (to our knowledge), legal considerations are important. They should not, however, drive our assessment of the issues or the scope of improvements.

In a workshop held after this study was conducted, initial recommendations for the detection and management of incidental findings were developed (21). Members of the workshop (including authors J.I. and M.P.K.) urged the development of an explicit plan for managing incidental findings for all neuroimaging protocols, and disclosure of physician-verified findings first to the subject, or to a surrogate in the case of a minor or adult without decisional capacity. No further disclosure to a health-care provider should occur without authorization from the subject. Since functional neuroimaging is increasingly being used to study diverse subject populations, including subjects with neurological and psychiatric disorders (12), and those who are un- or underinsured, it is imperative that referral options and other support avenues be identified upstream in the protocol prepared for IRB review, and downstream for participants who have been informed of an incidental finding. This is of paramount importance given that one report showed that even when subjects have health insurance, only 30% will act on an incidental finding (4). The reasons cited in that study underscore the importance of having affordable and convenient options.

In addition to the present work, several other recent studies (22–28) have focused on subjects' attitudes and expectations about research. For example, Barnitt and Partridge (22) evaluated the ethical practices of clinical research studies involving physical therapy patients. They found that despite informed participation, subjects later had concerns about their involvement. These concerns included confidentiality and relevant to our findings, unmet expectations and the resulting sense of disappointment.

Other studies have looked at communication and miscommunication between physicians and patients/research subjects (23,29–31). For example, Meropol and colleagues (23) found that patients in clinical trials tend to expect both a higher likelihood of benefit and a lower likelihood of adverse reactions than do their physicians. The investigators also noted significant discordance between physicians and patients concerning the nature of treatment-related

information discussed during consultations. In another report, patients in a phase I clinical cancer trial said that they understood all or most of the information provided about the trials in which they had decided to participate (30), but only a small minority appeared to have an adequate understanding of its purpose as a dose-escalation/dose-determination study.

The bioethics literature has explored the phenomenon that many apparently well-informed patients tend to see research as providing benefits even when the consent forms explicitly state otherwise (32–35). Appelbaum (32) suggested a number of potential sources of such “therapeutic misconception,” the most relevant of which, in our context, is that subjects may transfer expectations of a clinical type of environment to research. However, in a nonmedical setting the misconception must have a different source. One possibility is the use of indeterminate language in the consent forms (23). For example, the consent forms in the studies we investigated were clear about the research purpose of the studies, but still alluded to the possibility of a medical diagnosis. It is thus possible that the subjects tended to misinterpret statements such as “If, however, a potential abnormality is identified on your MRI scan, you will be immediately notified” as evidence of an effort to detect existing abnormalities. Also, the consent form used in the nonmedical setting states that the study “is not intended to provide a comprehensive clinical MRI examination of the brain.” This could be read by the subjects as an offer of a noncomprehensive but still clinical brain scan. A recent review of published studies of interventions designed to avoid such misconceptions found that the most effective intervention is to have a qualified person on (or even off) the research team spend more time talking one on one to the study participants (34). It is important for the research to be understood without therapeutic misconception. For nondiagnostic neuroimaging studies, this implies that every effort should be made to not include potential research subjects who continue to believe that the study will benefit them even after they are given a clear explanation about the goals and scope of the study.

In summary, we observed that the majority of the participants in neuroimaging research, in both medical and nonmedical settings, expected that medical anomalies would be discovered if present. The subjects generally had the same motivations for participating, and wished to be informed about an incidental finding—preferably by a physician affiliated with the team. Careful thought and more research are needed to elucidate the underlying causes of subjects’ misconceptions, and to optimize protocols for managing incidental findings and the informed consent process.

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**Table 1**  
 Motivations for Volunteering for Research MRI Studies

Reason for volunteering	Total	Medical	Non-medical
Financial compensation or course credit	64/104 (62%)	52/77 (68%)	12/27 (45%)
Contribute to scientific knowledge	22/104 (21%)	10/77 (13%)	12/27 (45%)
Favor to experimenter	17/104 (16%)	14/77 (18%)	3/27 (11%)
Worried about a health problem	1/104 (1%)	1/77 (1%)	0/27 (0%)

Table 2

Desired Disclosure of Incidental Finding Based on Severity of the Finding

Significance of finding	Total	Medical	Non-medical
Benign	95/104 (91%)	70/77 (91%)	25/27 (93%)
Malignant, but curable	105/105 (100%)	78/78 (100%)	27/27 (100%)
Malignant, not curable	102/105 (97%)	75/78 (96%)	27/27 (100%)
Life-threatening emergency	105/105 (100%)	78/78 (100%)	27/27 (100%)

**Table 3**

Intention to Seek Further Medical Evaluation Based on Severity of Finding

Significance of finding	Total	Medical	Non-medical
Benign	79/104 (76%)	59/77 (77%)	20/27 (74%)
Malignant, but curable	102/104 (98%)	75/77 (97%)	27/27 (100%)
Malignant, not curable	103/105 (98%)	77/78 (99%)	26/27 (96%)
Life-threatening emergency	103/105 (98%)	76/78 (97%)	27/27 (100%)

Table 4

Professional Desired for Disclosure of Incidental Finding

Who should inform participants	Total	Medical	Non-medical
Researcher who ran experiment	16/104 (15%)	9/77 (12%)	7/27 (26%)
Individual responsible for the experiment	21/104 (20%)	15/77 (19%)	6/27 (22%)
MD on research team	61/104 (59%)	49/77 (64%)	12/27 (44.5%)
Primary care physician	6/104 (6%)	4/77 (5%)	2/27 (7.5%)