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ELSI Priorities for Brain Imaging

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Abstract

As one of the most compelling technologies for imaging the brain, functional MRI (fMRI) produces measurements and persuasive pictures of research subjects making cognitive judgments and even reasoning through difficult moral decisions. Even after centuries of studying the link between brain and behavior, this capability presents a number of novel significant questions. For example, what are the implications of biologizing human experience? How might neuroimaging disrupt the mysteries of human nature, spirituality, and personal identity? Rather than waiting for an ethical agenda to emerge from some unpredictable combination of the concerns of ethicists and researchers, the attention of journalists, or after controversy is sparked by research that cannot be retracted, we queried key figures in bioethics and the humanities, neuroscience, media, industry, and patient advocacy in focus groups and interviews. We identified specific ethical, legal and social issues (ELSI) that highlight researcher obligations and the nonclinical impact of the technology at this new frontier.

Keywords

neuroethics; neuroimaging; policy

Modern techniques for imaging the brain have given medical scientists and clinicians powerful new tools to measure brain function and to demonstrate links between the brain and behavior (Illes et al. 2003). The ability to map how we reason through difficult moral decisions, make conscious and unconscious value judgments, and how we cooperate and compete with others presents a significant challenge to traditional ways of understanding human nature and agency and raises significant and controversial ethical questions. Much remains to be said about the epistemological challenges of using brain mapping data for understanding personal identity (Illes and Racine 2005), but our human curiosity about these topics is inescapable. The field is proceeding apace but with comparably less attention focused on the ethical and practical issues that are following in its wake, a situation that may create unpredictable roadblocks to progress. In order to replace “reactive ethics”—where the public, ethicists and regulatory agencies must grapple with ethical issues raised by science and its applications after research has already been completed—with “proactive ethics” (Cho et al. 1999; De Vries 2004), we organized several focus groups and interviews with stakeholders with interests in the neuroimaging sciences. We borrowed the term “ELSI”—ethical, legal and social implications—from the National Human Genome Research Institute’s (NHGRI) extramural funding program, and queried participants about the future of the field and about the roles they perceive for themselves, as professionals, as citizens, and as consumers of the products of science.

METHOD

Focus Groups and Individual Interviews

We assembled leaders and representatives from bioethics, neuroscience, law, and the humanities from major academic institutions, the National Institutes of Health and private sector sponsors of research, along with interested members of the media, patient advocate groups, and of the neuroimaging industry. They were selected on the basis of their publications, leadership in relevant professional organizations or academic institutions, and expressed interest in the imaging neurosciences, and were recruited by invitation of the first author. Background reading was made available by direct emailing of key journal articles to participants and by access to others available at http://neuroethics.stanford.edu. With IRB approval, we held six focus groups around the country (with a total of 57 participants) and conducted 15 individual interviews. Because our goal was to learn how participants defined the ethical and policy issues presented by neuroimaging—using functional MRI (fMRI) as a model—we asked them simply to describe their enthusiasm and concerns about neuroimaging. This allowed us to gain an understanding of the areas our participants found most acute and most promising.

We organized five focus groups by professional background, with a separate group for bioethicists, neuroscientists/neuroimagers, patient advocates/research sponsors, journalists, and religious scholars. Because a few participants represented more than one area there was some overlap between groups. Our sixth focus group comprised individuals from a variety of disciplines who serve on the Advisory Board for one of the grants funding this work. They were included to allow comparison with responses from the more homogeneous groups (Table 1).

Focus groups were facilitated by a chair who instructed the group and by a moderator whose role was to ensure the flow of discussion and even participation by all members. Focus groups lasted for approximately one hour and were audiotaped. Each participant was given approximately two minutes for an opening comment. The remaining time was allocated to discussion.

As a supplement to our focus group data, we conducted interviews (in person or by telephone) with 15 individuals who indicated a desire to participate but who could not attend their respective focus groups. Each interview lasted approximately 20 minutes. Interviews were audio taped or recorded by written notes.

Analysis

We transcribed all focus group sessions *in extenso* and analyzed the transcripts using a strategy grounded in the inductive methods common to qualitative research (Boyd et al. 2003; DeVries et al. 2002; Glaser and Strauss 1967; Schatzman and Strauss 1973; Stewart and Shamdasani 1998; Strauss and Corbin 1998). Given our goal, we developed an analytic approach that mapped the focus group conversation and allowed us to measure both the quality and quantity of participant comments. All team members read the transcripts, after which we developed a list of themes and sub-themes discussed in the focus groups. One member of the team (RdV) then divided the transcripts into coherent units based on the themes identified. Because the unit of analysis in focus group research is the *group*, not the *individuals* in the group, we did not attempt to correlate mention of a certain topic with characteristics of individual members (such as gender, age, ethnicity, highest degree). Instead we mapped themes of the conversation, dividing the transcripts into blocks with a consistent theme. In some cases these blocks would extend across the comments of several focus group members, in other cases, a single contribution from a focus group member included two or more separate blocks. Next, in order to insure inter-observer agreement, two of us coded the transcripts independently, identifying the themes and sub-themes found in each block. Together we reviewed codes for matches and discrepancies and achieved consensus. This coding method allows us to compare the discussions about fMRI across different focus groups both qualitatively (looking at the content of the comments) and quantitatively (measuring the percentage of each discussion devoted to specific topics). Because the data from individual interviews were different in nature from the focus groups—they were conducted on a one-on-on basis and did not have the benefit of open discussion—they were not coded per se, but were used for cross-reference to our focus groups and to enrich our understanding of those data.

RESULTS

Our analysis of the focus group transcripts yielded a total of 333 thematic blocks revolving around three major areas of emphasis: 1) researcher obligations; 2) the clinical and non-clinical impact of technology; and 3) philosophical and theoretical issues. These themes, and the sub-themes that formed them, are mapped by focus group and shown in Table 2.

Note the varied areas of emphasis in each focus group: the bioethics group was most concerned with non-clinical applications of the technology, as was the neuroscientist group; the patient advocate group paid most attention to the obligations of researchers; journalists, not surprisingly, focused on the role of the media; the mixed focus group (Advisory Board) distributed their concerns broadly; and the religious scholars' primary concern was with issues theoretical and philosophical. In the following sections we use the rich detail of our transcripts to flesh out the nature of these issues and concerns.

Obligations of Researchers

The first major theme under researcher obligations—experimental issues—included challenges associated with the acquisition and interpretation of neuroimaging data. The acquisition of images raised methodological issues related to accuracy, standards, and reproducibility; problems of interpretation include over- and misinterpretation of data, handling of artifacts, and understanding and translating results. We heard many comments about the need for more care in the translation of research for lay audiences. A participant in the neuroscience group noted:

> To the extent that the science isn't really ready, or is over-generalized, or over-interpreted, it has both a negative impact in terms of how it's used in society . . . and what that does in the long run in terms of our science.

Another neuroscientist called attention to how the lack of formal theory creates problems for the interpretation of complicated neuroimages:

> Why is it that neuroscience and psychology, which sit above physics and below economics and sociology and population biology, standout as the only scientific disciplines that don't have formal theory as part of their backbone? Now, there are a million excuses: you can say that it's too complicated. But the weather is pretty complicated, but we at least we have to try . . . [o]ther fields, I don't think are quite as susceptible [to these problems of interpretation] because they know that their theories and the intellectual tradition in the field grows out of an understanding of the complex.

A third member of the neuroscientist group commented on the pressures imposed by the contrast between the ease of collecting neuroimages and the difficulty of interpreting them:

> You know, it's easy to generate data, there's a hungry public for it, and [neuroimages] carry lot of face validity and we are not being taught how to really do the science in a way that, you know, presents it in its full complexity that it actually reflects.

Problems of interpretation led one member of the neurosciences community who also provides leadership at a major funding agency, to invoke the metaphor of a sausage maker to describe the way imaging techniques are used:

> I think we need to pay more attention to the specific validation of whatever the imaging modality is with the actual, behavioral, observable, clinical context. I think that it's quite simplistic at the moment and that simplistic interpretation of the pretty pictures . . . is a potential danger. . . . I think that we haven't paid enough attention to the, and made known, to the consumers of these technologies what the advantages and limitations of the different imaging modalities are. So we have PET, we have SPECT, we have fMR, we have MR, we have all of these, but we [also] have the concomitant physiological techniques. In our research laboratories, we tend to throw everything at our subjects to see what comes out of the sausage maker. But it's not necessarily done in a paradigmatic way, it's not necessarily hypothesis driven.

With respect to issues of research ethics, the second theme under researcher obligations, focus group members raised concerns about informed consent. Like all researchers and ethicists, participants worried about how to get consent from someone with impaired capacity to consent, but they also had concerns about the special problems with consent inherent to neuroimaging. In particular, they pointed to the difficulty of properly informing a patient or a research subject about the risks and benefits of neuroimaging given the great uncertainty about what the image portends for a person's health. As one research sponsor stated:

> You are talking about the situation where we have insufficient knowledge about the actual predictive validity of what we see. But even if it were, even if we had the predictive validity, there are the ethical issues about what do you do about it if the current state of therapy is such that there's nothing that would change in terms of how that patient is treated.

In an interview, a clinical investigator highlighted how problems with consent bias the recruitment of subjects and thus the direction of research and development:

> In autism, the spectrum is huge (low intellectual functioning to high)—[the] high functioning are easy to deal with. So technology is very much high functioning oriented—[the] low functioning are being neglected.

Technology Impact—Nonclinical

Growth of the industry, in terms of increasing professional pressure and expanding commercial development, were emerging sub-themes for technology impact and diffusion outside the medical arena. Of concern to a participant in the bioethics group, for example, was:

> . . . the contextual issues of the way this science and the way these new technologies will be developed given the current political economic environment of research funding in the U.S. and . . . the breaking down of barriers between industry and the Academy.

Public opinion was a separate sub-theme of this area, encompassing issues surrounding the public's interpretation, perception, and understanding of the limitations of neuroimaging results. Our participants were concerned about the shaping of public opinion by the media, especially given its selective coverage of research and the power of the brain map as a visual image. Closely related to discussions both about researcher obligations, as described above, and to issues of public opinion, were comments about the interaction of neuroscientists with the media (one interviewee defined members of the media as "*predators looking for stories*"). A neuroscientist noted an immediate need for: *". . . responsibility in terms of educating the public and making sure what is actually coming out is appropriate*."

Echoing this call for responsibility, another neuroscientist, a leader of a major academic institution, called attention to the role that researchers have in the spread of misinformation:

> The issue is that it's not just the general public and the media, it's scientists who don't understand complexity [of neuroimages], just don't understand. They [scientists] think linearly, they can think one spot at a time, one gene at a time. And while . . . what we are seeing [is] a statistical hotspot that is part of a big network, people don't think that way. And so the press doesn't get it from nowhere.

Our participants frequently referred to the power of neuroimages: *"There is something very seductive about brain imaging data."* A journalist, who is also a neuroscientist, explained the nature of this seductive power:

> I think neuroimaging papers are intrinsically newsworthy because they obviously touch on things that are . . . of profound human importance and we can all identify with, you know, trust, love, moral reasoning, justice, racial prejudice . . . I mean, you can hardly fail to attract a journalist's attention if you claim to have discovered something about how the brain controls those things.

The sub-theme of uses, approaches, and policy includes jurisprudence (i.e., the use of neuroimages in the courts), prediction of behavior in custody and abuse cases, and other forensic uses of neuroimages. The potential of this technology to be used for surveillance and screening—a concern for all groups—was particularly worrisome for bioethicists. One bioethicist described his fears about the potential for the use of neuroimaging in the forensic context and in the law, the use of diagnostic neuroimaging with psychiatric disorders, and the potential for new forms of surveillance:

> A scenario that comes to my mind, so to speak, is that we could identify areas of the brain that are associated with hostile or violent ideation and that we could screen everybody who comes into a sensitive public area, like an airport or train station, and footnote that, I am persuaded there is no science, registered science, that is published in the United States that isn't read by somebody in the CIA, or the NSA, or many, many contractors. There are tens of thousands of contractors. Many of them are very competent scientists who work for the agencies. So, I'm sure all of that is of great interest to those guys as well. And, it's warranted for people in bioethics to think about those things.

Participants in other focus groups also expressed concern about the use of neuroimaging to monitor and predict behavior in public areas, for lie detection, and for discrimination in employment or insurance. A representative from industry, in reply to an interview question about uses of fMRI outside the academic or medical setting, mentioned its possible use for national security:

> You can also think of the question in airports 'Are you a terrorist?' and then you try to find out . . . and I'm a little bit skeptical of putting these things in schools or airports

Recalling lessons learned from genetics, a participant in the group of religious scholars worried about the use of fMRI to reify biological explanations of differences in behavior and, by implication, the possibility of creating hierarchies among groups based on these differences:

> One of the dangers that I see in neuroimaging is as we learn more about patterns of activity in the brain, we will, I guarantee it, start looking comparatively between

> groups of people. Do men do this more than women do? Do women do this more than men do? What about different ethnic groups?

In the context of this sub-theme, we also heard about the varied roles of different disciplines in bringing ethical thinking to neuroimaging, such as foreseeing problems, raising questions and considering the future impact and consequences of frontier neurotechnology on society. For example, a participant in the patient advocacy and sponsor group, noting the American proclivity for seeking legal remedies, commented on the need for neuroscientists to call upon the expertise of lawyers:

> [In creating] any type of guidelines, or proactively setting up standards . . . the legal profession [should be included] because they will, in their job play a huge part. . . . [I]f something goes wrong, they can be your worst enemy or your biggest friend. And if you get them involved early on, you can prevent them from being your worst enemy. Because any ethical issues that arise, any resulting problems, culturally at least in this country, is immediately going to [the courts].

A member of the bioethics community, participating in that same mixed group, commented on the need for a bioethical presence in neuroimaging: "*The role of bioethicists is to raise questions about where technology might lead us.*"

An equally prominent bioethicst describes another role for her discipline in striking a careful balance between benefit and risk: "*We need to protect knowledge for individual privacy rights but still advance knowledge for society.*"

Commenting on the role of industry, a vendor foresaw the need for policy to the ethical challenges of neuroimaging in the future: "*We have not had to face the issue of [the use of imaging for] job selection but will develop a public and political position when needed for both marketing and selling*."

Technology Impact—Clinical

While issues of clinical impact did not emerge as prominently as the other themes, focus group members did identify a number of challenges. Here also we heard about the power of neuroimages, in this case about how diagnoses are made more forceful and more real when they are conveyed by pictures. We also concern about introduction of technology before it is ready. Commenting on technical readiness and introducing new technology as a complement or replacement to an existing gold standard, a neuroscientist commented: *"It's a very different matter when somebody shows you a picture and says, this means you are depressed."*

We also heard questions about the wisdom of using neuroimaging for diagnosis and predictive screening. One vendor stated: "A sensitive, delicate issue is who do you screen? Where do you draw the line? Will you have Alzheimer's later in life? Will you be susceptible?"

A clinical bioethicist, who is also a physician, expressed his concern about the prematurity of clinical applications of this technology:

> I guess the first worry I have is the 'not-ready-for-prime-time' worry about jumping in and announcement of results or even entering into clinical practice before the results are really validated in the same way that's been a real problem in genetics.

A clinical researcher agreed:

> Interpretation of research is extremely difficult to understand even for people within the field. How do you report back to parents? How do you use this technology clinically? This is especially difficult in fMRI—with low N's and complex technique. Very few physicians truly understand the technique. One must understand physics

> and mathematics—it takes years to understand just the analysis. What do we tell parents or people who are affected?"

A science writer, commenting on health policy in her interview, warned about the temptation to use neuroimaging because of public misconceptions about the technology:

> The biggest danger in neuroimaging is not what we can do or what the technology allows, but what society believes it can do. Society has been promised results that are greater than the reality. If neuroimaging is used as diagnosis, accuracy doesn't matter. The technology is accepted and policy is shaped, even if it is inaccurate—that is terrifying.

Our participants also noted that the clinical use of neuroimaging is intimately related to the development of the technology. In an interview, one leading manufacturer of state-of-the-art MRI equipment stated: "*. . . technical development, together with clinical developments . . . that's basically setting the trend for neuroimaging development.*"

A second vendor would concur:

> What drives us in the functional neuro arena today is the priorities of a lot of the researchers that we collaborate with that really drive what we're doing. Now we're beginning to see a transition into more of a clinical arena. . . . I would argue that functional neuroimaging has a role in personalizing medicine—based on genetic makeup; predisposition to disease.

The sub-theme of treatment and intervention included comments about the use of neurotechnology for monitoring therapeutic response, neurocognitive enhancement, personalized medicine, understanding the effects of drugs, feedback to patients about neuroimages, and other issues including follow-up care. Focus group members raised questions about distributive justice—access, affordability, and other economic implications—with regard to the clinical use of neuroimaging.

Privacy and confidentiality as related to "real-world" clinical applications included commentary on labeling, stigma, and issues commensurate with privacy in genetic testing. In spite of these concerns, optimism about neuroimaging remains. A patient advocate in the mixed group remarked:

> I am not as concerned about stigma [referring to concerns about stigma raised by others in group]. . . . I think a lot of the clients I work with and a lot of the people in my organization will tell you that having an additional tool is something that is very positive.

Philosophical and Theoretical Issues

Participants raised philosophical and theoretical issues that have long attended the study of the brain. For example, a participant in the neuroscience group cautioned: . . . *there is an area for this and an area for that and then suddenly we are modern day phrenologists running on a high budget*."

While issues pertaining to philosophical notions of consciousness, spirituality, faith, and ideas about selfhood emerged in many of the focus groups and interviews, they were a particularly significant theme in the bioethicist and religious scholar focus groups. In this context we heard concerns about how our concepts of personal identity are challenged by the use of the brain as a shorthand way of talking about the person, the individual, and the self. Some participants discussed how these challenges are compounded by the demystification of human experience. Religious scholars were the most vocal on this subject. One religious scholar noted:

> [There is the danger of] reducing spirituality to merely a “thing,” of reducing concepts of spirit, the concept of mind. You already have problems reducing the mind to the brain, [now] there are other issues of reducing spirituality to the mind.

Not all religious scholars shared this concern. One commented:

> The advantage of this research is that it reminds us of how embodied we are as individuals. . . . So on the one hand we want to be non-reductionist. We don’t want to say just because we are bodies doesn’t mean our religious experience isn’t true. On the other hand there is an extraordinary value in learning that every dimension of the human experience has a physiological component—if not even just substructure to it.

A journalist who frequently covers brain imaging stories summarized the issues at play here:

> The world of science, neuroscience, is becoming more complicated and nuanced. The irony is that people need to understand better but don’t. They need to better understand promises and risks. Spirit and neuroscience are closely united in how we self-identify.

In an intriguing bridge between themes that span basic science and philosophy, an academic leader in religious studies warned about using old ways of thinking to understand the new type of information provided by neuroimaging:

> There’s a tendency to divide brain functions into cognitive functions, emotional functions, and so on. That’s perhaps the standard that is used in western science, but it raises very important questions about whether those kinds of classificatory systems are themselves problematic. . . . We must be careful that we don’t import the categories that are comfortable for us . . . because once the science is framed in certain categories, those categories tend to take over. There’s a very important ethical issue right at the outset about the development of the science itself and the way it will categorize things.

DISCUSSION

Responding to an image of bioethicists as naysayers, one of our participants asked: “*When is ethics positive?*” Our answer to this question is: *Now*. Rather than waiting for ethical, legal, and policy issues to emerge for neuroimaging, necessitating defensive responses, we have taken a positive step to identify those issues preemptively. From our sample of key members of the bioethics, humanities and neuroimaging communities, consumers and vendors, we heard how neuroimaging is perceived to have the potential to change the way we view ourselves and others, to give us the power to modify behavior, to place things that were previously thought of as unknowable into the realm of the knowable, and to create peculiar problems for researchers and clinicians (Farah and Wolpe 2004; Illes and Racine 2005; Moreno 2003). We conclude from the data that researcher obligations and the perceived non-clinical impact of the technology are areas of first priority and action.

Armed with these insights we can begin to respond to the ELSI challenges associated with neuroimaging. Our findings on the concerns and enthusiasm for neuroimaging are supported by observations about the publication of, use, and public reaction to application of these technologies. For example, questions about the possible misuse and commercialization of neuroimaging are already on the public agenda, brought to the fore by the recent controversy over industry-sponsored neuroimaging for studies of product preference (Brammer 2004). Backlash against this work arose from use of expensive neuroimaging resources for the purposes of improving marketing—arguably a potential form of human manipulation—and bold statements about what the technology can deliver. In a letter sent to the Senate Commerce Committee urging an immediate halt to this work, an organization called Commercial Alert wrote:

> What would happen in this country if corporate marketers and political consultants could literally peer inside our brains, and chart the neural activity that leads to our selections in the supermarket and the voting booth? What if they then could trigger this neural activity by various means, so as to modify our behavior to serve their own ends?. . . 'Orwellian' is not too strong a term for this prospect. (Commercial Alert 2004)

The issue of when neuroimaging technologies are ready for clinical application, identified by our groups is particularly salient, given the tens of thousands of fMRI citations in PubMed, and 761 fMRI abstracts at the 2004 annual meeting of the *Society for Neuroscience* alone (Raichle 2004). Such volume of activity makes it difficult to justify to the public that the technology is not ready for prime time. These problem is made even more acute by the emergence of a sense of "neurorealism" in the press (Racine et al. 2005)—an expression of how the study of a phenomenon with neurotechnology such as fMRI uncritically reifies that phenomenon. This is the case even if results from related studies are identified as preliminary or inconclusive. Public impatience with the pace of science is already visible: single photon emission computed tomography (SPECT) scans are now directly marketed to adult consumers worried about Alzheimer's disease and to parents of underachieving school-age children, and neuroimaging data from EEG recordings and PET scans are being used in our courtrooms (see e.g., *State of Iowa v. Terry Harrington* [284 N.W.2d 244; 1979 Iowa Sup.]).

It is imperative for researchers to be attuned to, and to take ownership of these issues (Greely 2004), especially if the widening scope of neurotechnology in the public domain comes to lead, rather than trail, our well-intentioned but still academic neuroethics debates. Our findings suggest that taking ownership means being clear about the implications and limitations of research results, including limits of accuracy and validity, how the data may or may not be interpreted, and being careful not to prevent inferences that drift beyond the data. It also means being aware of how the public or media might misperceive research results or misuse neuroimaging technologies in and outside of the medical environment, and actively working towards policies that will discourage and limit this.

This study is not without shortcomings. Our data represent a relatively small sample of thinkers. The diversity and degree of expertise in neuroimaging of the participants are both a potential strength and a weakness. Our results are limited by the time constraints and dynamics of focus group studies. Nonetheless, the data defined some first priority issues for the continued ethical consideration of neuroimaging as one prototype for neuroscience today; more studies are needed to validate these results and identify new priority areas as they emerge. With increasing concern about advances in neurotechnology (Fukuyama 2002; President's Council on Bioethics 2003), it is imperative that we actively search for solutions that promote and protect good science.

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Table 1

Primary Composition of Focus Groups and Interviews

Primary Focus Group Composition	***Group (N)***	***Interview (N)***	***Total (N)***
Bioethics	11	1	12
Neuroscience Neuroimaging	12	3	15
Patient Advocacy Research Sponsorship	10	2	12
Print and Radio Media	2	7	9
Community and Academic Religious Scholars	9	0	9
Mixed Group	13	0	13
MRI Equipment Vendors	N/A	2	2
Total	57	15	72

Table 2

Priority Areas and Emerging Focus Groups Themes for the Imaging Neurosciences.

	Bio-ethicists	*Neuro-scientists*	*Patient Advocates*	*Journalists*	*Religious Leaders*	*Mixed Group*
I. Researcher Obligations						
Experimental Issues (%)						
Data acquisition	4	0	11	0	4	2
Data interpretation	5	20	16	0	10	21
New challenges						
Research Ethics (%)						
Informed consent	8	2	24	0	0	2
Incidental findings	0	2	3	0	2	0
Conflict of interest	5	0	0	0	0	2
II. Technological Impact						
Non-clinical (%)						
Growth of industry	11	16	10	0	4	12
Media and public opinion	5	23	7	57	10	19
Uses, approaches and policy	33	11	5	38	2	12
Clinical (%)						
Diagnosis	3	4	3	0	0	2
Prediction	3	7	5	0	0	0
Treatment and intervention	3	4	7	0	4	15
Privacy and confidentiality	1	9	4	0	2	10
III. Theoretical & Philosophical Issues						
Precedent (%)						
Prior challenges	3	4	1	5	18	0
Personhood (%)						
Consciousness	18	0	4	0	45	4

Note. Shown is the percentage of sub-themes occurring in each focus group discussion per the total number of coded sub-themes in that focus group. Totals may deviate from 100% due to rounding