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American College of Medical Genetics and Genomics Incidental Findings: Genetic Counselors' Views on Disclosure

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Abstract

The utilization of whole exome sequencing (WES) is increasing in the clinical setting. WES technology often generates incidental findings (IF), which are defined by the American College of Medical Genetics and Genomics (ACMG) as "results of a deliberate search for pathogenic or likely pathogenic alterations in genes that are not apparently relevant to a diagnostic indication for which the sequencing test was ordered" (2013). The ACMG has recommended identifying mutations in 56 genes when labs conduct WES. This group of 56 genes, termed the minimum list, includes mutations associated with 24 medically significant conditions.

This study investigated genetic counselors' views on disclosure of IF's from the minimum list. A survey was sent to 3,209 genetic counselors through an e-blast to the membership of the National Society of Genetic Counselors; 88 responses were received. Approximately 75% of participants indicated they strongly support the expectation that patient preferences would be established by the lab prior to testing. This finding implies that, according to our respondents, the responsibility of informed consent should fall primarily on the lab rather than the clinician. This view is in direct contrast to the ACMG recommendations, which place the burden of obtaining informed consent on the ordering clinician (ACMG Board of Directors, 2013). We acknowledge that, at this time, labs are not capable of obtaining informed consent; they can only document what was obtained by the clinician.

Once results are reported by the lab, 81% of counselors reported feeling an obligation to disclose any pathogenic mutations of genes on the ACMG's minimum list, and 65% would disclose even with unknown patient preference. Although only 27% of respondents received

a report containing an IF that they felt was inappropriate to return, 60% of genetic counselors feel that there are circumstances in which disclosure is inappropriate. Additionally, 79% of genetic counselors expressed great concern about storing undisclosed IF's in electronic medical records since another clinician may unknowingly disclose unwanted information.

These scenarios are more likely to surface as WES becomes more common in clinical practice. This study suggests the clinical genetics community could benefit from guidelines on management of undisclosed incidental findings and from the development of infrastructure to support that process.

Introduction

The cost of genetic sequencing has continued to decrease, allowing whole exome sequencing (WES) to be offered in the clinical setting. While WES has been used in the research setting for many years, it is newer to the clinical field. One of the hallmarks of WES and related techniques is the frequency with which it can produce clinically significant genetic information that is unrelated to the condition under investigation (Green, Berg, Grody, et al., 2013). As the cost of sequencing continues to fall and clinical applications expand, including its use by various specialties and in a wider variety of circumstances, genetics professionals are increasingly likely to encounter incidental findings in the laboratory report that pose ethical and logistical challenges.

In 2013, the ACMG designated a list of genes, termed the minimum list, in which they recommended that mutations be sought out during WES/WGS and reported to the clinician regardless of age or patient preference. The minimum list contained 56 genes associated with 24 medically significant conditions to be analyzed for pathogenic or likely pathogenic mutations when clinical WES was ordered (Green, Berg, Grody, et al.,

2013). Most of the genes and variants were chosen due to their association with the more common etiologies of monogenic disorders that are medically actionable (ACMG 2013). The Working Group focused on disorders for which preventative measures and/or treatments are available, and disorders where individuals might be asymptomatic for long periods of time. In most cases, only variants that were known to be pathogenic or likely pathogenic were chosen to be included in the minimum list (Green, Berg, & Grody, et al., 2013). The majority of the conditions on the minimum list, but not all, have available confirmatory testing.

These recommendations sparked a heated debate amongst researchers, laboratories, clinicians, and bioethicists. Those in support of the recommendations argued that patients and families should be informed of any incidental findings on the minimum list based on the principle of beneficence (Wolf et al., 2008; Abdul-Karim et al., 2013). Those opposed argued that obtaining patient permission was vital prior to disclosure and that patients should be able to opt-out of receiving incidental findings arising from the analysis of the minimum list of genes.

Individuals who disagreed with the ACMG's recommendations argued that the mandatory analysis and reporting of mutations in 56 genes was a violation of patient autonomy and shared decision making (Ross, 2013). A major criticism of the ACMG recommendations is that they overrode a patient's right to opt out, which is a vital component of the informed consent process. In this view, patients were denied the choice for or against analysis of the target genes, and their "right not-to-know" was violated when they were informed of any pathogenic incidental findings from the minimum list (Vayena, 2013).

Ultimately, those in support of this argument claimed that patient permission is essential for disclosure of incidental findings; therefore, the default position should be nondisclosure.

The ACMG stated that clinicians have a duty to prevent harm by cautioning patients and their families about specific incidental findings and that, "this principle supersedes concerns about autonomy" (ACMG, 2013). They argued that patients have the right to decline sequencing if they feel the risks of possible discovery of incidental findings override the potential benefits of sequencing (Green, Berg, & Grody et al., 2013). Green and colleagues argued that selectively opting-out of the minimum list only gives the impression of patient autonomy, in that some patients may wish to hear some results but not others (Green, Lupski, & Biesecker, 2013). Opting-out entirely takes away the patient's decision to choose a partial list of results. Essentially, the Working Group suggested that clinicians have a fiduciary responsibility to report incidental findings that are medically actionable and have available preventative measures and/or treatment.

At the 2014 ACMG meeting, the Working Group revised their guidelines to suggest that patients be given the opportunity to opt-out of the minimum list (ACMG 2014). The group based their decision on feedback from members, including a survey that was distributed during the annual 2014 ACMG conference in Nashville, TN (ACMG 2014). Within this new framework, the responsibility will fall on the clinician who ordered clinical sequencing to explain the opt-out option and the potential benefits/limitations of receiving incidental findings during the informed consent process.

Regardless of the ACMG recommendations, situations will arise where clinicians will receive information on incidental findings that they do not wish to or cannot disclose. These situations may include, but are not limited to, the following: when a patient is referred and

preferences are unknown, when a patient changes his/her mind between the time WES was ordered and the time test results are received, and when a patient is unavailable for post-test follow up. Additionally, situations may occur where the clinician wishes to reveal incidental findings at a later date. For example, a clinician may choose to reveal incidental findings later if the testing was performed in a critical or emergency setting where disclosing results with long term implications might not be reasonable.

Pre-test counseling and consent is intended to help avoid these circumstances. During the pre-test counseling and the informed consent process, patients should be apprised of the possibility of discovering incidental findings, educated about possible implications, and given the opportunity to opt-out of receiving incidental findings. In order to obtain informed consent prior to genomic sequencing, the lab must work closely with the ordering clinician to guarantee the masking of information the patient does not desire to receive (Green, Berg, Grody, et al., 2013). When pre-test counseling/informed consent is inadequate, circumstances may arise in which the clinician feels disclosure is inappropriate. However, once results are reported by the laboratory, genetic counselors may feel a legal responsibility to share the incidental findings with the patient, potentially creating tension between the clinician's ethical and legal responsibilities (Erickson, 2014).

Similar circumstances that may result in non-disclosure after testing occur when clinicians outside of genetics order WES. Patients who have undergone WES in a specialty outside of genetics are often referred for genetic counseling for results disclosure and follow-up. In these circumstances, a genetic counselor may become responsible for a WES report that was referred to them from an outside provider. In these scenarios, the counselor or other

clinician responsible for disclosure may not know what information was presented to the patient during the informed consent process, and whether or not patient expectations and preferences were communicated to the laboratory. For example, the referring provider may fail to inform the patient that mutations in 56 genes would be sought out, or of what any given lab reports as a matter of default. Additionally, the patient may experience a change of heart after testing has been completed. In each of these cases, the genetic counselor may decide not to disclose any incidental finding(s) or to delay disclosure and thus be faced with the burden of deciding what to do with the unreported information.

Further guidance is required related to the use of test results for adult-onset conditions in minors. In these situations, the outcome may be clinically relevant but will only affect the child during his or her adult life (Van El, 2013). For example, if a test aimed at unveiling the cause of a previously unexplained disease finds that a girl is at risk for hereditary breast and ovarian cancer, tough questions arise about how to balance respect for her future autonomy without depriving her and her family of what may be vital, life-saving information (Van El, 2013).

The ACMG joined with the American Academy of Pediatrics (AAP) to release a statement that genetic testing in children should be "driven by the best interests of the child" (Committee on Bioethics, 2013) and that adult-onset conditions would not be looked for and reported as an incidental finding. However, the ACMG and AAP also noted that incidental findings detected through WES for an ill child may provide clinical importance for the health of the parents. It has been argued that if an incidental finding pertaining to an adult-onset disorder can have bearing on the health of the parents or other family members, its disclosure may reasonably be viewed as enhancing the autonomy of the child (Vayena,

2013). Additionally, the information may potentially benefit other family members who could undergo the consent process for the condition found on WES. It is common practice in genetics to help patients that desire to inform at risk family members to seek genetic counseling. The ACMG considers this act of duty under the principle of beneficence.

Clinicians may still find themselves conflicted on whether or not to disclose results of this nature. There is the risk of harming patients by disclosing sensitive incidental findings, while withholding results may indirectly harm patients by denying them access to potentially actionable or meaningful health information. Navigating between these two harms is a current challenge facing genetic counselors and other clinicians (Downing et al. 2012).

When situations arise where genetic counselors do not wish to disclose information about incidental findings immediately, or even at all, the question of what to do with the report containing incidental findings is not clear-cut. Once they have the report in hand, some genetic counselors may feel a legal duty to disclose everything that is in it to the patient, creating conflict between their ethical and legal duties (Erickson, 2014). Clayton and colleagues addressed the possible risk of medical malpractice created by not disclosing incidental findings (Clayton et al., 2012). They stated that clinicians may face liability in two ways: for failing to prevent future disease and/or for failing to report incidental findings to other clinicians and patients. Furthermore, once test results from WES become available in the electronic medical record, other providers may access these results and disclose incidental findings to the patient regardless of their previously stated preferences (Klitzman et al., 2013).

The ACMG guidelines focus on lab practices, and decisions regarding what goes into their report, and do not address how and where incidental findings that are reported but not

disclosed should be stored. In most cases, the results of clinical sequencing would likely be entered into the patient's medical record, raising the potential that another clinician, unaware of the patient's wishes, discloses that unsolicited information to the patient (Erickson, 2014). Further exploration is needed regarding the ethical and social implications of generating incidental findings in view of questions related to informational privacy (Van El, 2013). Currently, there is no universally agreed-upon Protocol for handling undisclosed incidental findings.

This study aimed to investigate the storage and handling of incidental findings from the ACMG's list of 56 medically actionable genes, when they are not reported at the time the results are returned. We evaluated clinical situations where genetic counselors might potentially be forced to function as custodians of genetic information following WES, how test results and follow-up would be handled in those particular cases, and what would be done with test results that reveal a medically significant variant when the patient does not want to learn that information.

Methods

The survey was piloted with 4 genetic counselors to assess its content and clarity. Revisions were made to reflect comments and suggestions. The final survey was created using SurveyMonkey (https://surveymonkey.com) and was offered through an e-blast administered by the National Society of Genetic Counselors (NSGC). Eligibility criteria included membership in the NSGC and participation in clinical genetics practice in the United States or Canada. The initial email was sent on February 8, 2015 to 3,209 members of NSGC. A reminder email was sent on February 21, 2015, and the survey was closed on February 27, 2015. A total of 88 responses were received. Informed consent was obtained

from all individual participants and responses were anonymous and kept securely. This study was approved by the ANDRUS Institutional Review Board.

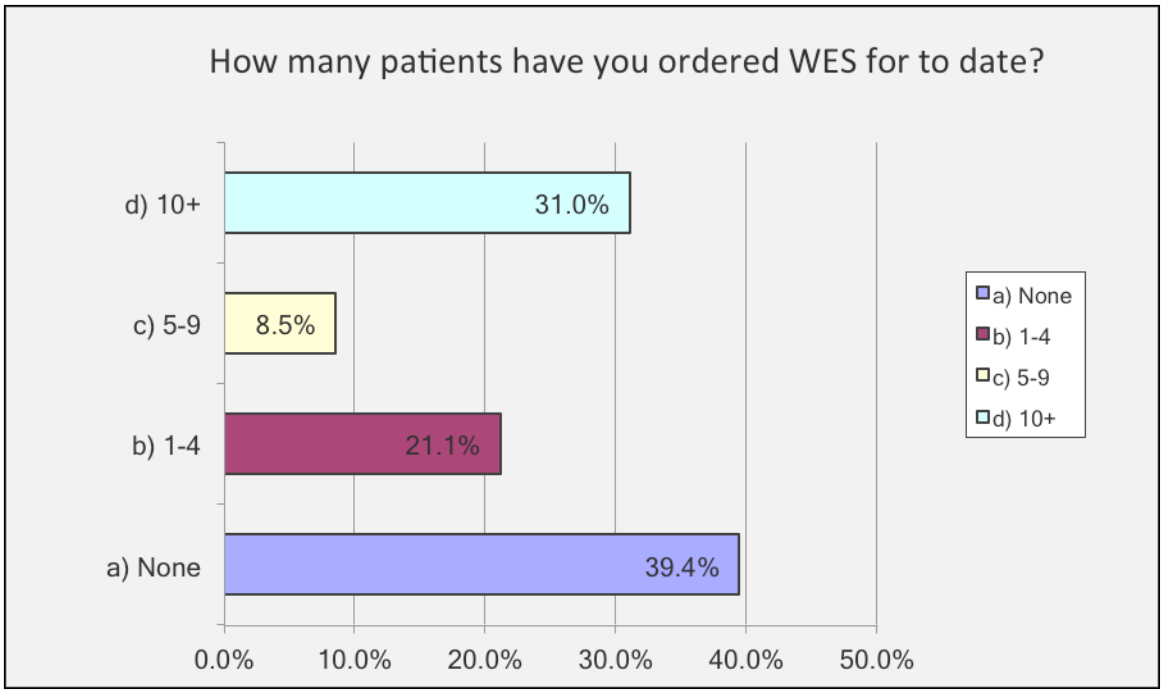
Results

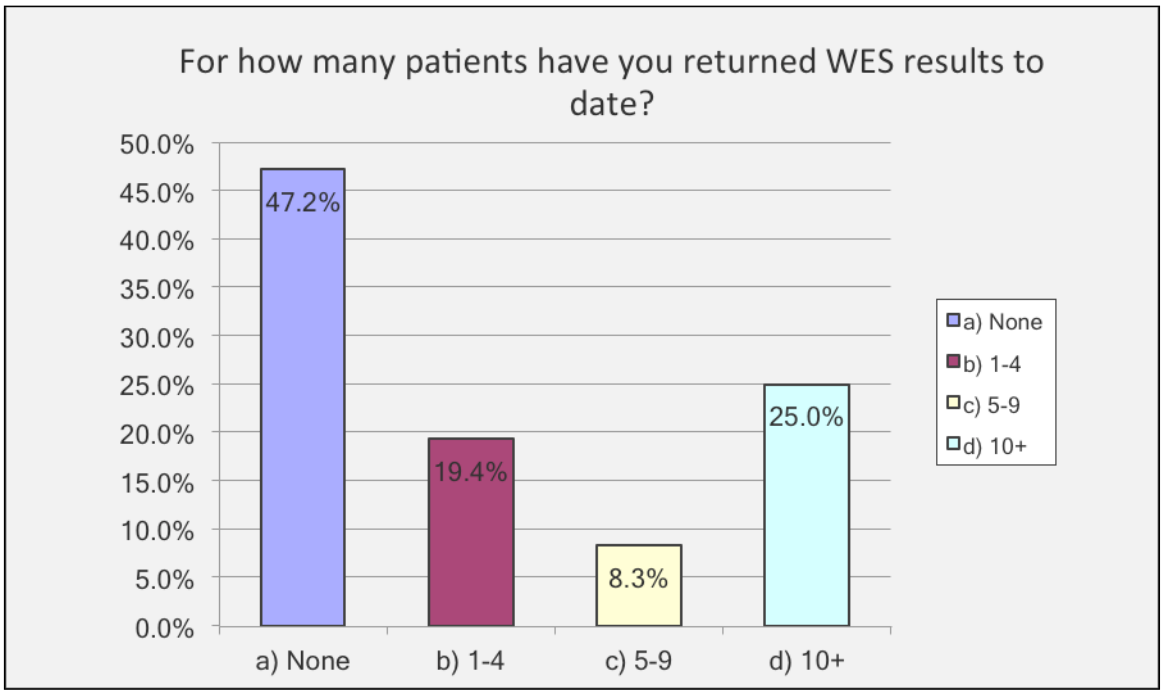
Please identify your primary specialty:		
Answer Options	**Response Percent**	**Response Count**
a) Prenatal	11.1%	8
b) Pediatrics	38.9%	28
c) Adult	4.2%	3
d) Cancer	27.8%	20
e) Other	18.1%	13
answered question		72
skipped question		16

Experience with WES

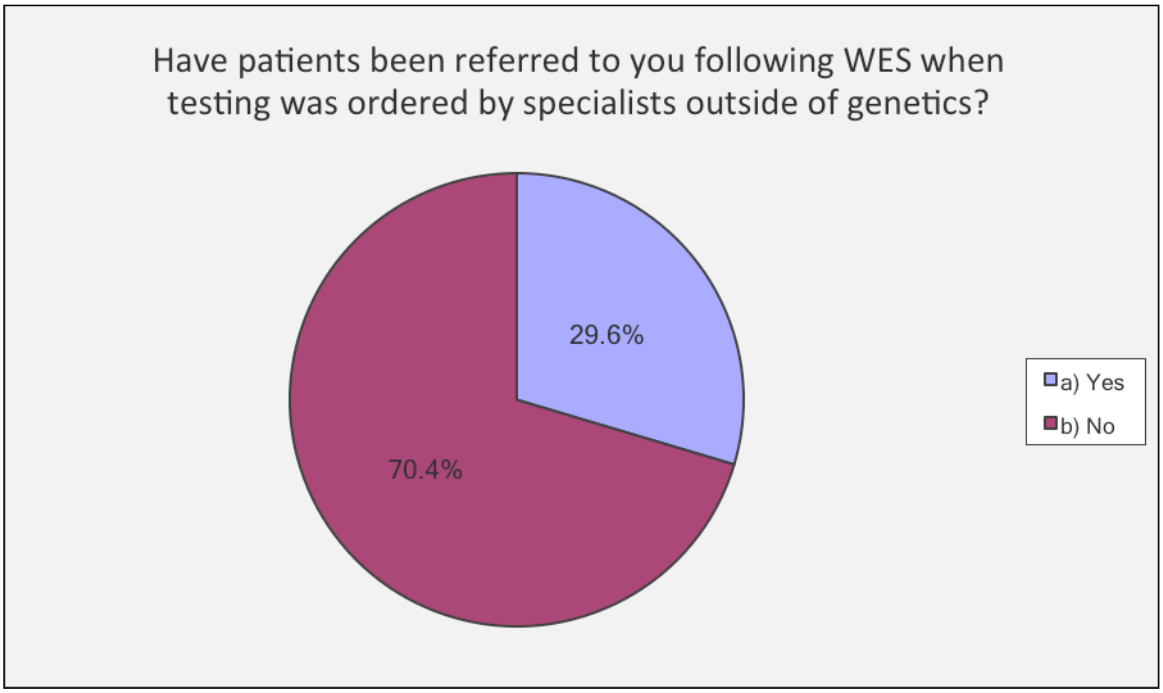
Have you or anyone working in genetics at your practice/institution ordered WES?		
Answer Options	**Response Percent**	**Response Count**
a) Yes	70.8%	51
b) No	26.4%	19
c) Don't know	2.8%	2
answered question		72
skipped question		16

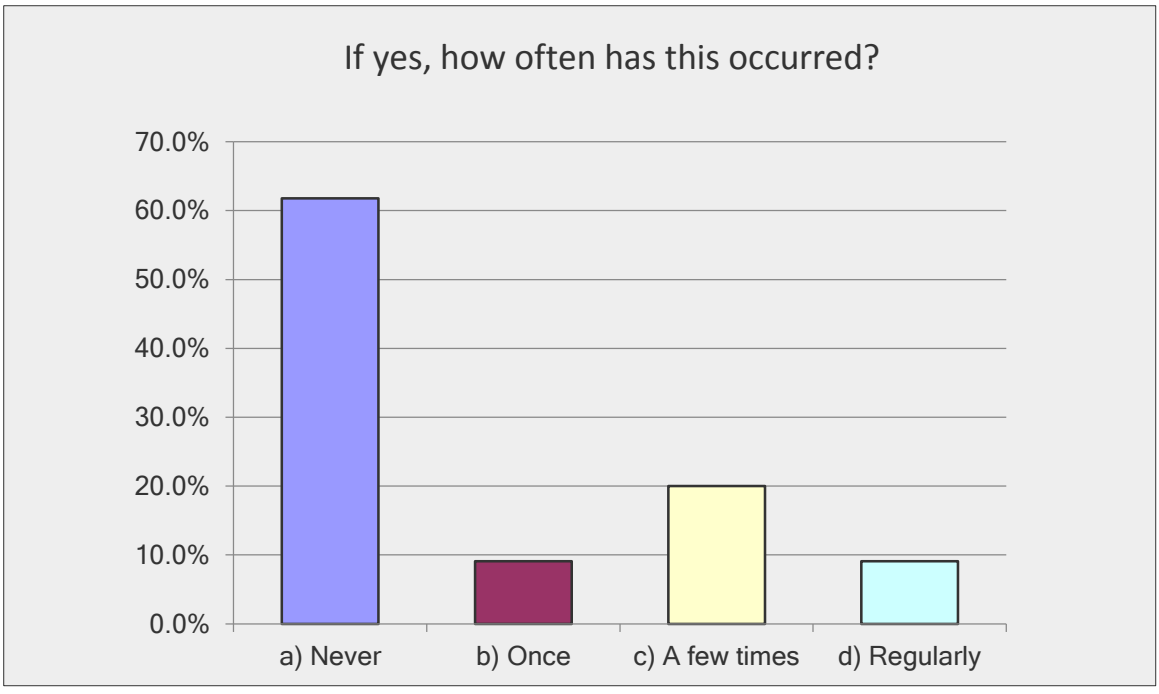
Is WES used by other specialties at your institution?		
Answer Options	**Response Percent**	**Response Count**
a) Yes	52.8%	38
b) No	33.3%	24
c) N/A	1.4%	1
d) Don't know	12.5%	9
answered question		72
skipped question		16


How many patients have you ordered WES for to date?
d) 10+
31.0%
c) 5-9
8.5%
b) 1-4
21.1%
a) None
39.4%
0.0%
10.0%
20.0%
30.0%
40.0%
50.0%
a) None
b) 1-4
c) 5-9
d) 10+

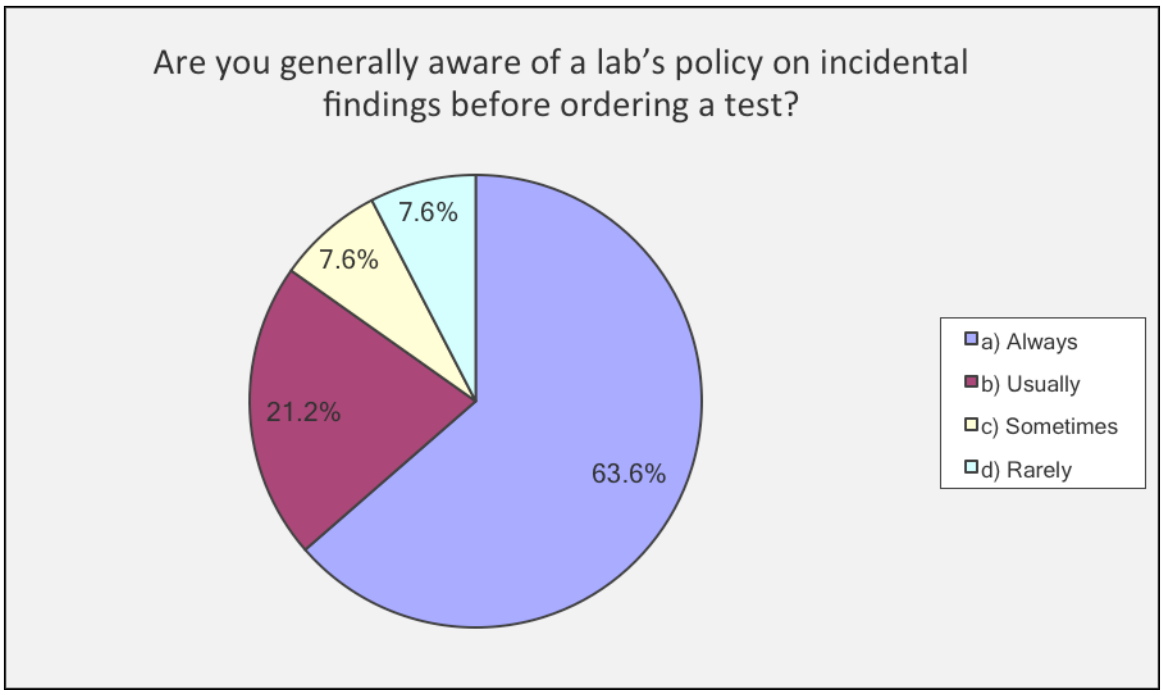

For how many patients have you returned WES results to date?
50.0%
45.0%
40.0%
35.0%
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
47.2%
19.4%
8.3%
25.0%
a) None
b) 1-4
c) 5-9
d) 10+
a) None
b) 1-4
c) 5-9
d) 10+

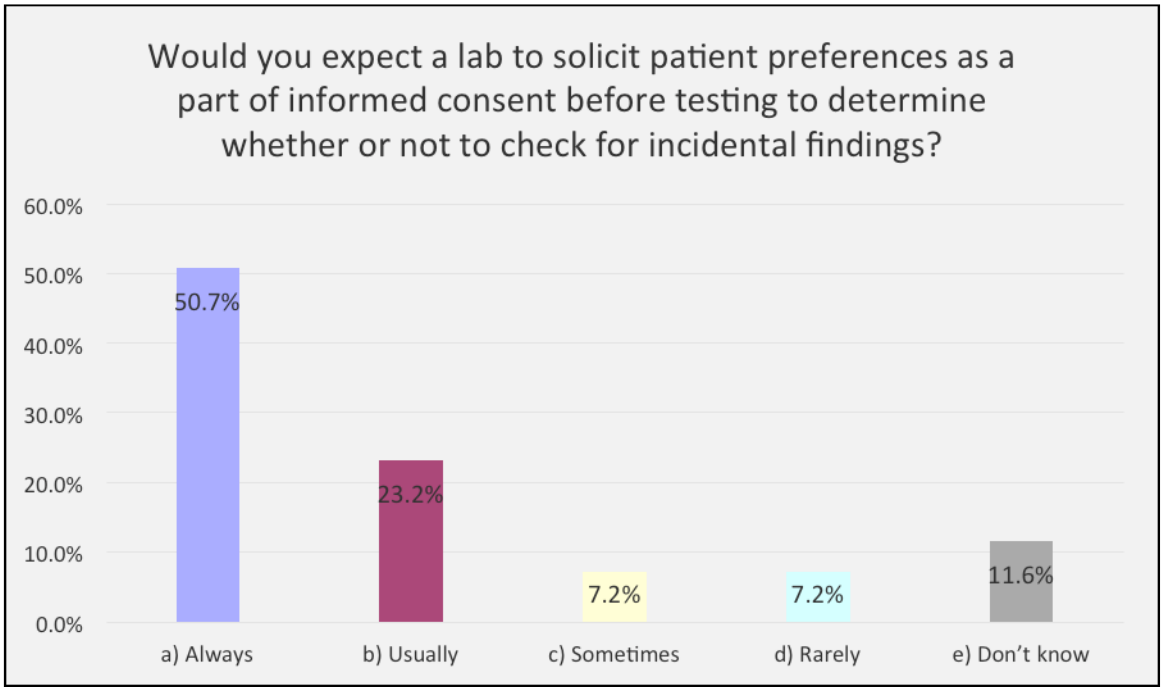
Referrals


Have patients been referred to you following WES when testing was ordered by specialists outside of genetics?
29.6%
70.4%
a) Yes
b) No

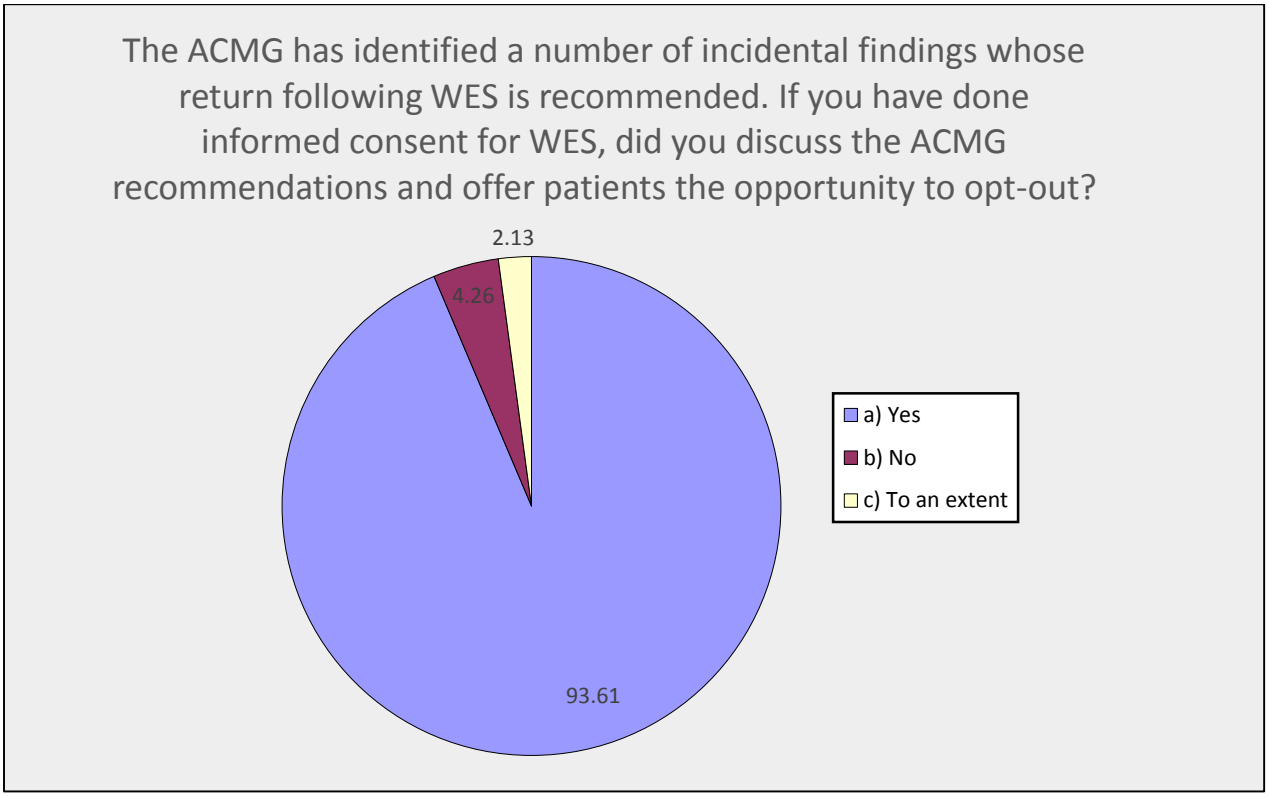

If yes, how often has this occurred?
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
a) Never
b) Once
c) A few times
d) Regularly

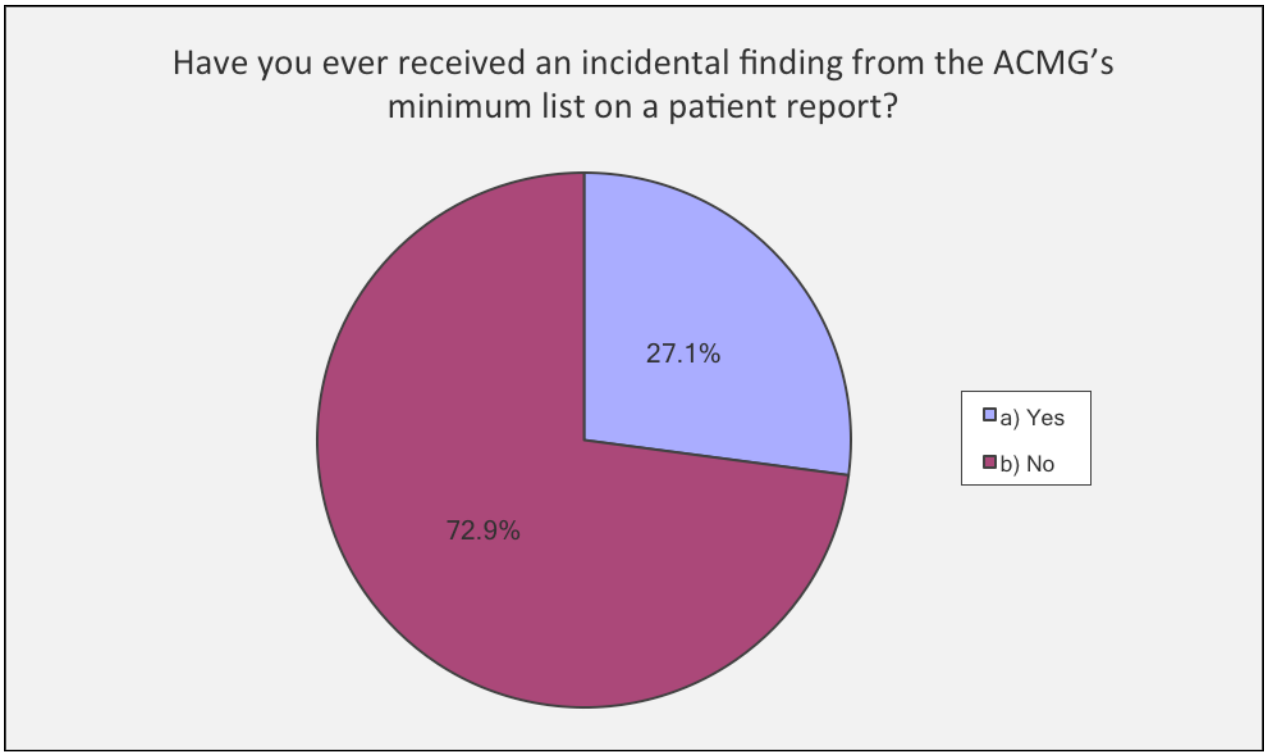
Lab Policy

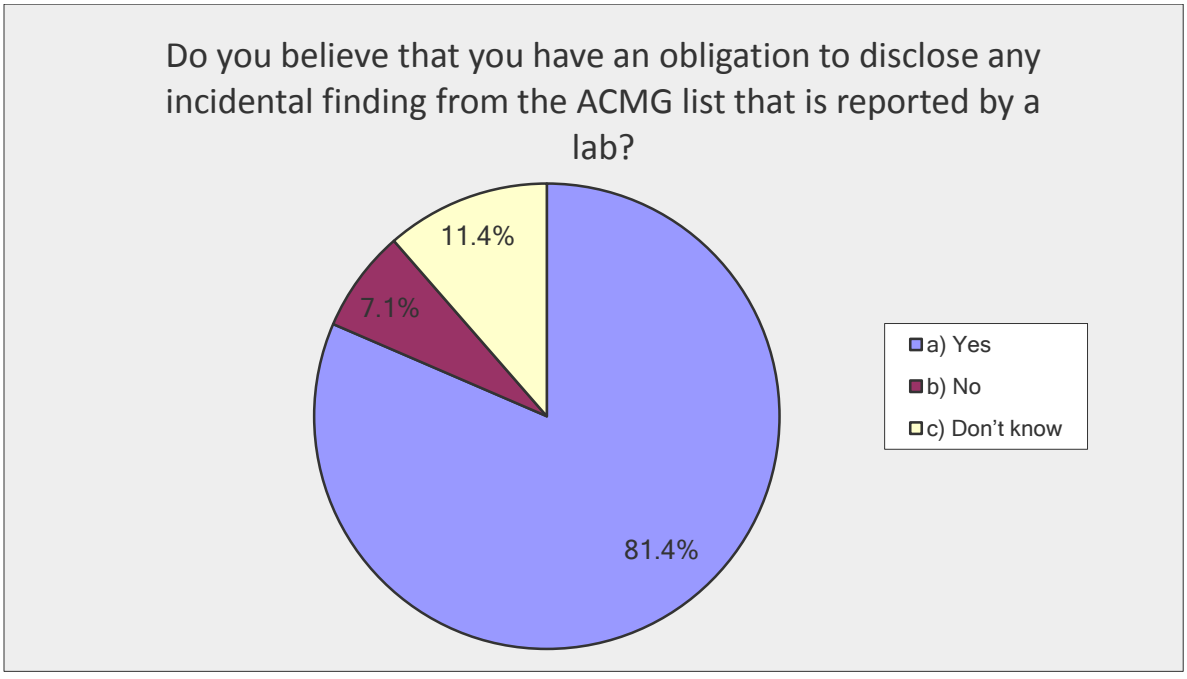

Are you generally aware of a lab's policy on incidental findings before ordering a test?
7.6%
7.6%
21.2%
63.6%
a) Always
b) Usually
c) Sometimes
d) Rarely

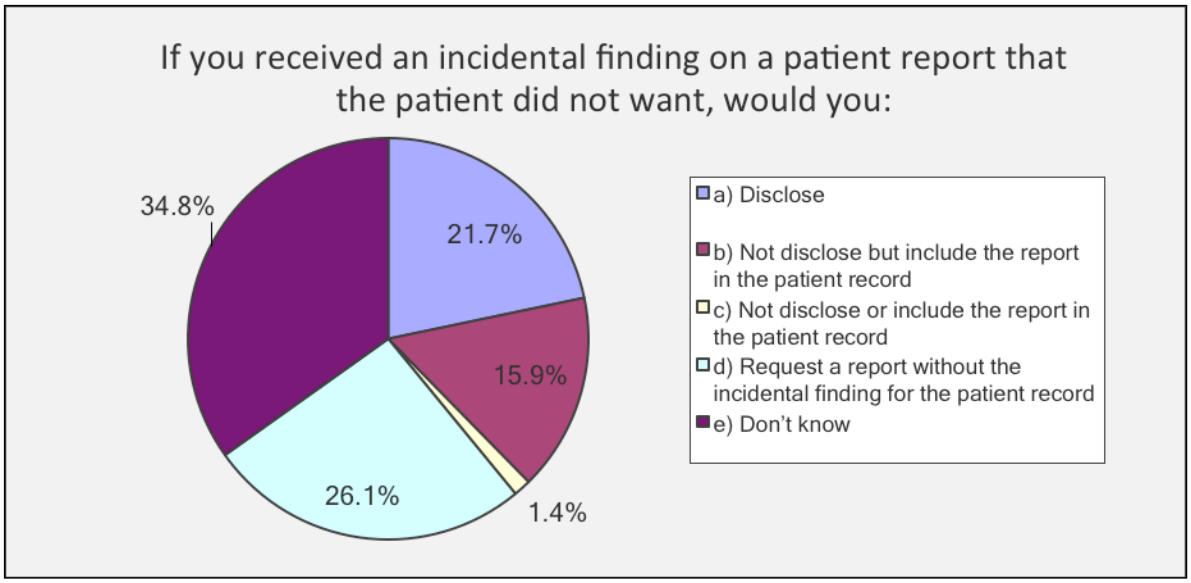

Would you expect a lab to solicit patient preferences as a part of informed consent before testing to determine whether or not to check for incidental findings?
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
50.7%
23.2%
7.2%
7.2%
11.6%
a) Always
b) Usually
c) Sometimes
d) Rarely
e) Don't know

Reporting of incidental findings

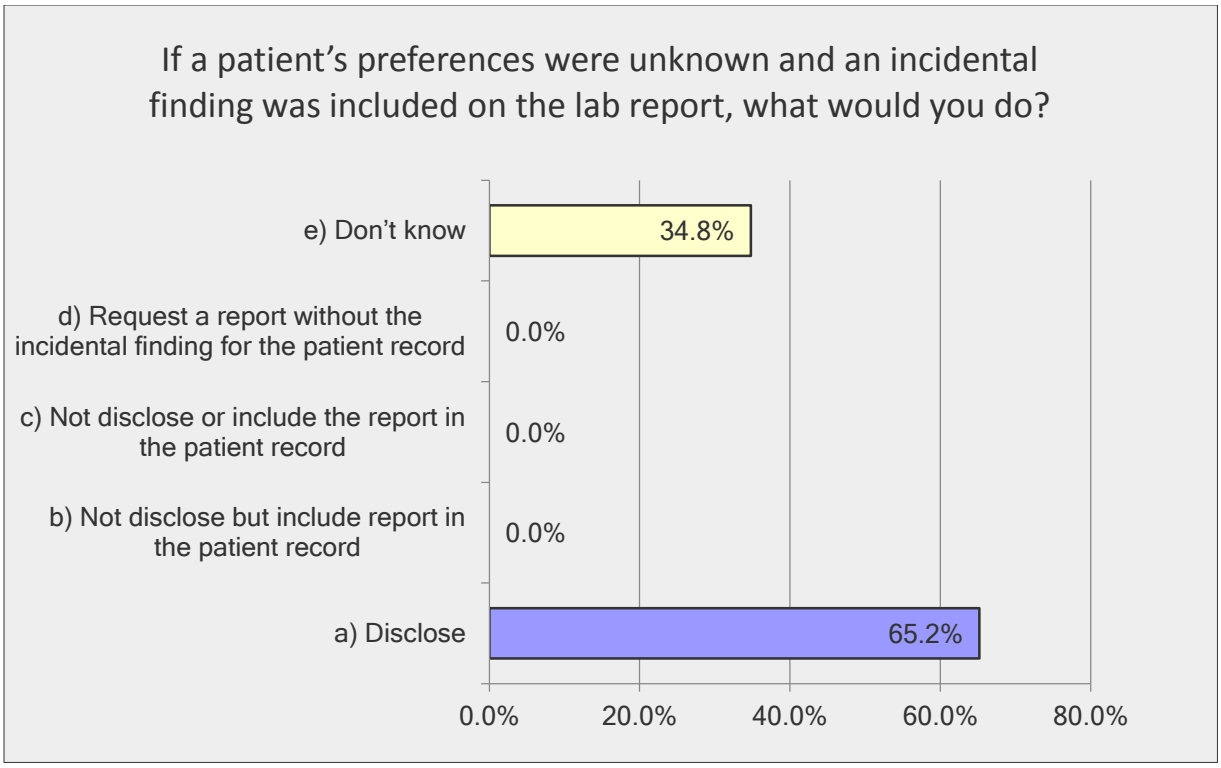


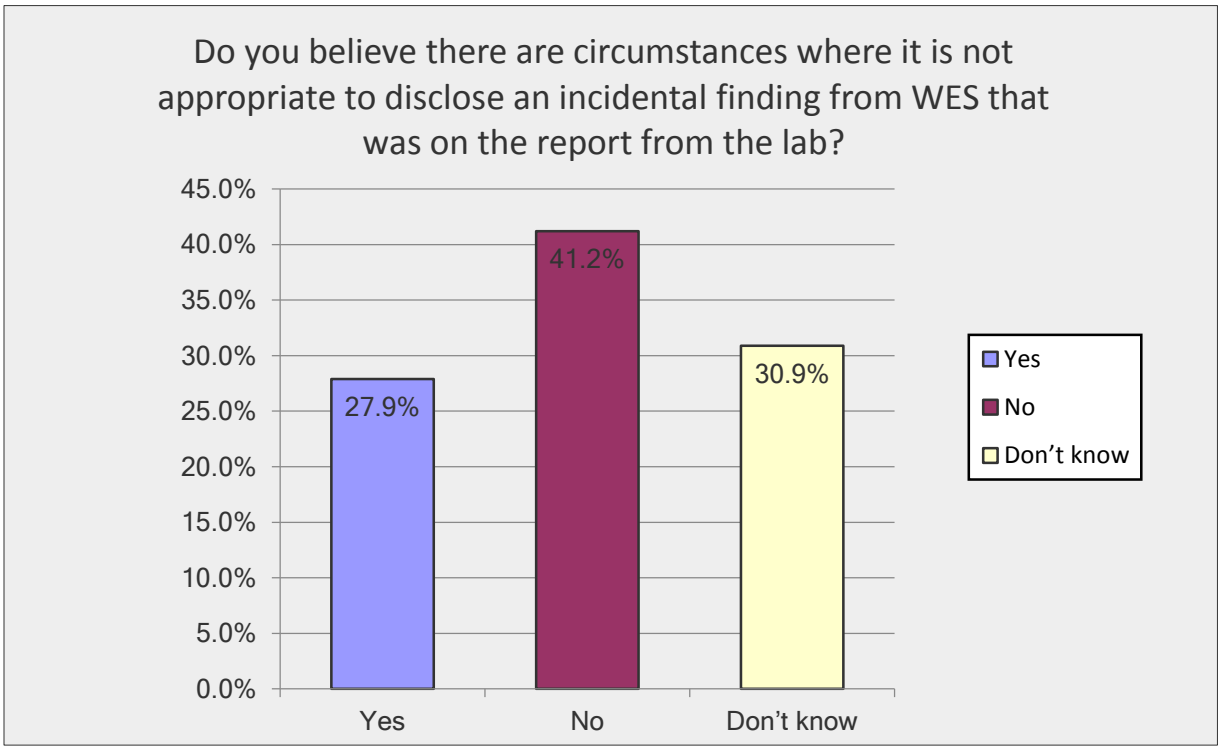

Have you ever received an incidental finding from the ACMG's minimum list on a patient report?
27.1%
72.9%
a) Yes
b) No

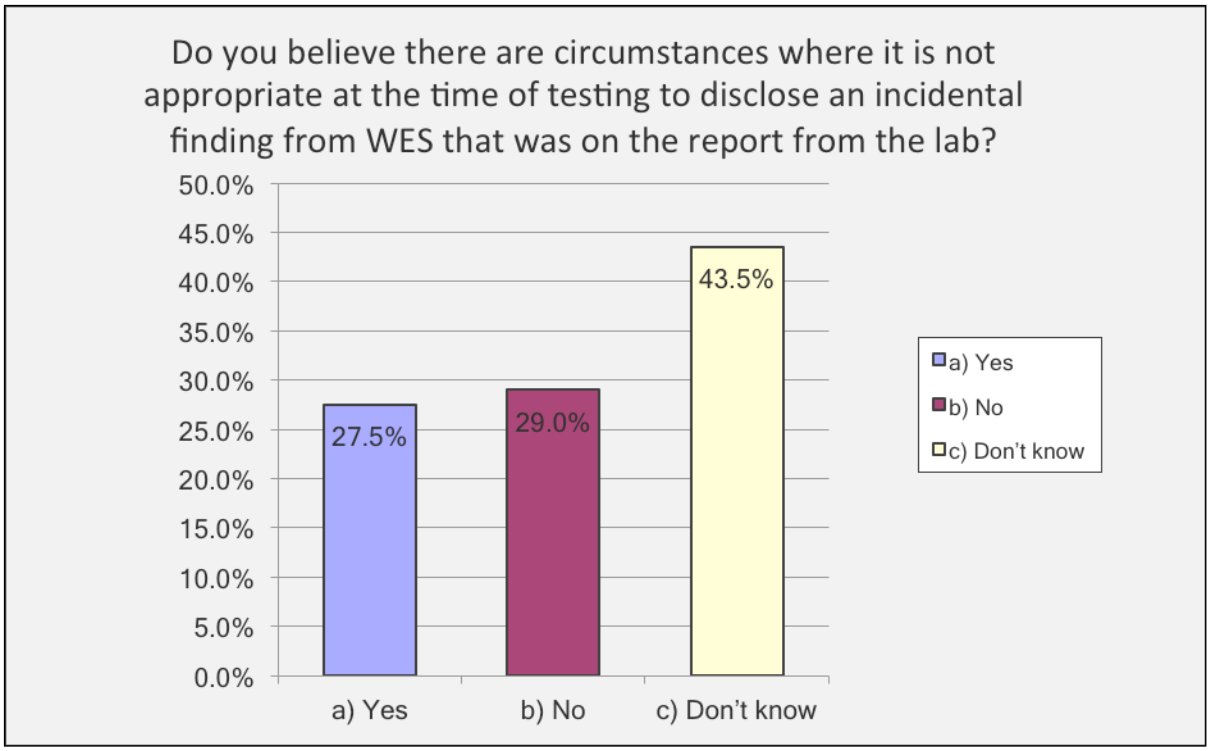

Do you believe that you have an obligation to disclose any incidental finding from the ACMG list that is reported by a lab?
11.4%
7.1%
81.4%
a) Yes
b) No
c) Don't know



Issues around disclosure


If a patient's preferences were unknown and an incidental finding was included on the lab report, what would you do?
e) Don't know
34.8%
d) Request a report without the incidental finding for the patient record
0.0%
c) Not disclose or include the report in the patient record
0.0%
b) Not disclose but include report in the patient record
0.0%
a) Disclose
65.2%
0.0%
20.0%
40.0%
60.0%
80.0%


Do you believe there are circumstances where it is not appropriate to disclose an incidental finding from WES that was on the report from the lab?
45.0%
40.0%
35.0%
30.0%
25.0%
20.0%
15.0%
10.0%
5.0%
0.0%
27.9%
41.2%
30.9%
Yes
No
Don't know
Yes
No
Don't know

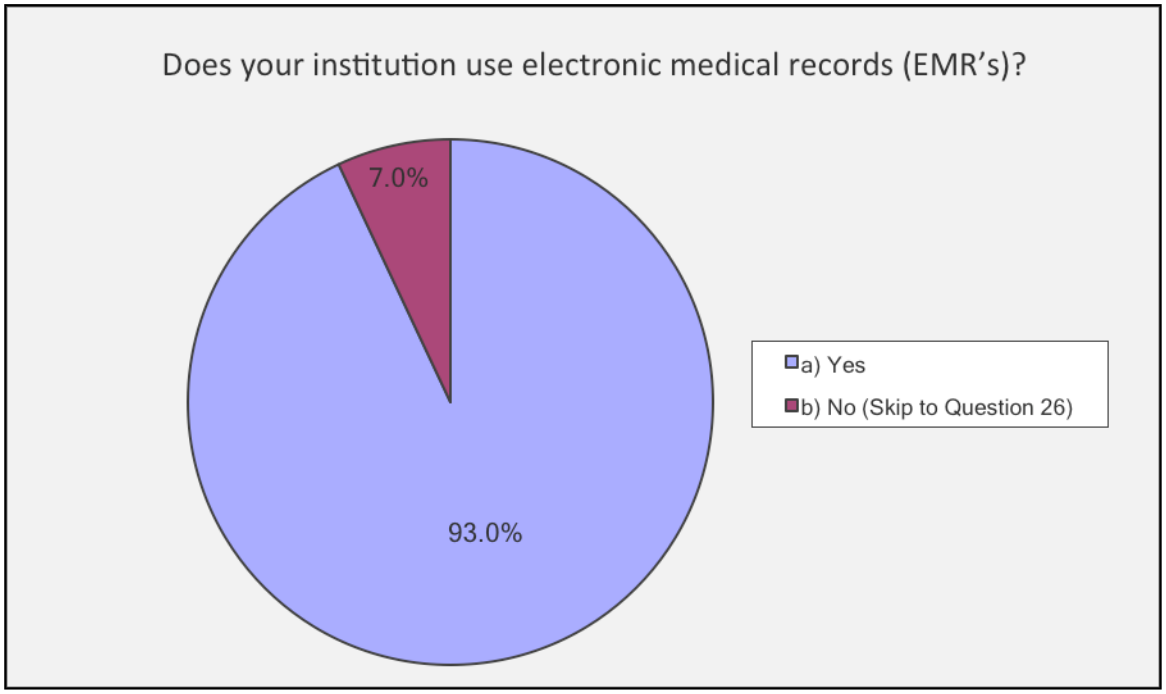


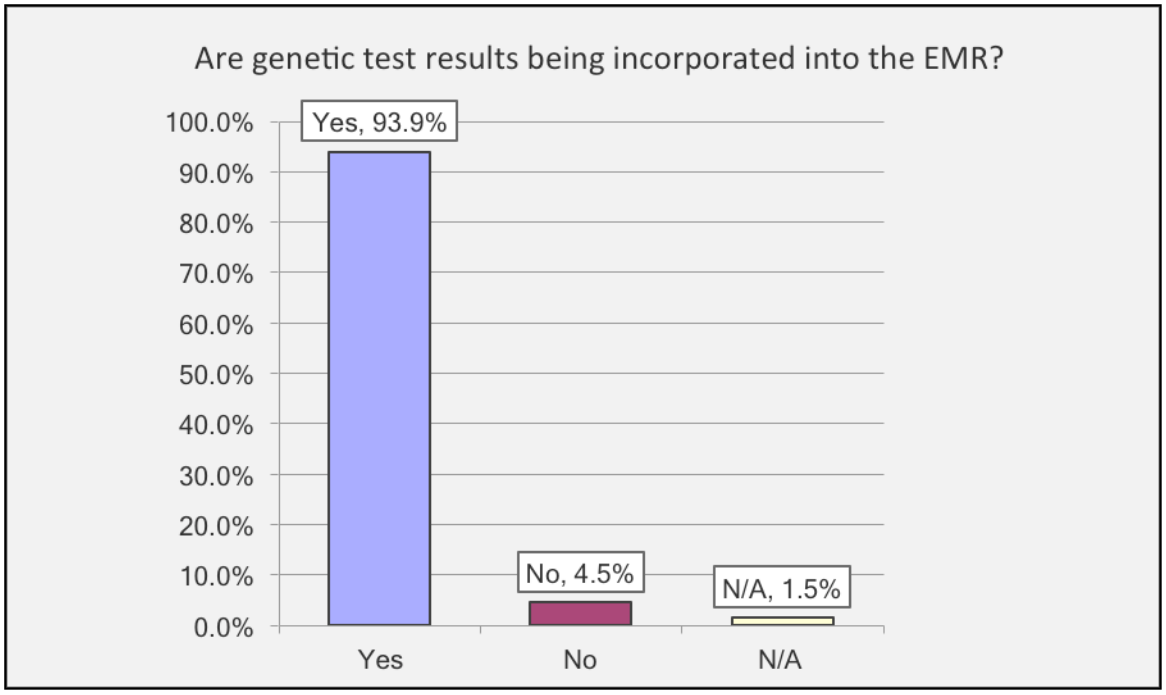
In which of these circumstances, if any, do you believe that it is not appropriate to disclose incidental findings: (select all that apply)

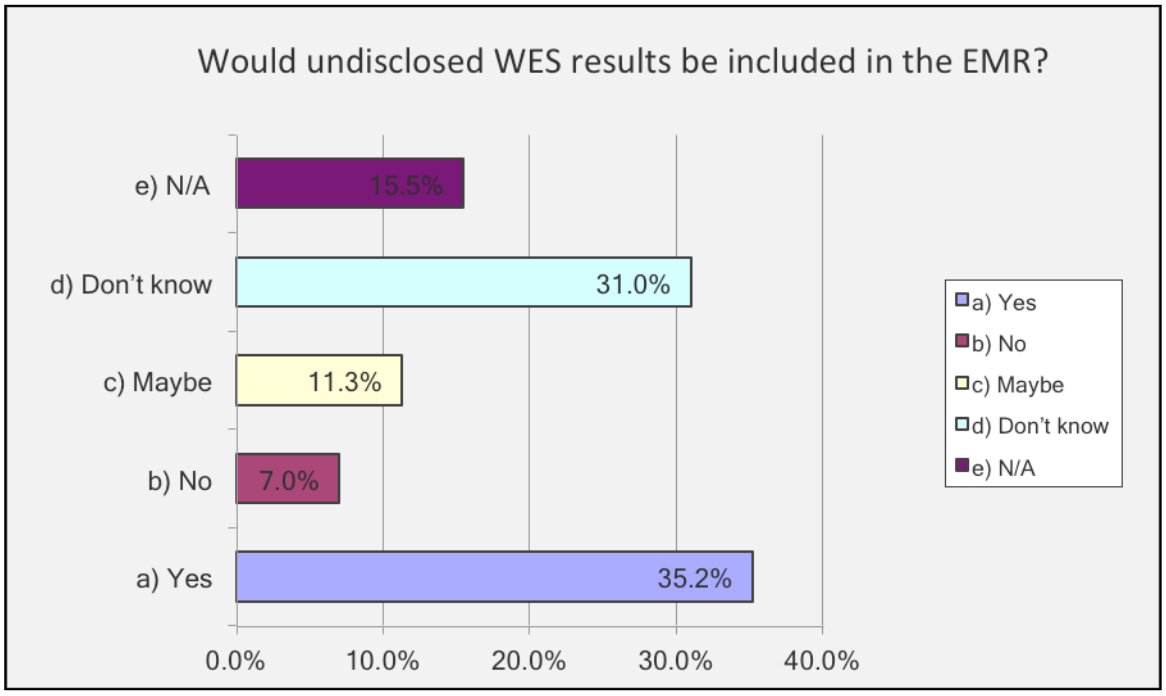
Answer Options	Response Percent	Response Count
a) Pediatric cases where parental carrier status is revealed	4.5%	3
b) Pediatric cases where parental gene status is revealed	4.5%	3
c) Patient tested is critically ill	3.0%	2
d) Pediatric cases involving adult-onset conditions	22.4%	15
e) When the patient has died and the immediate next of kin is unresponsive	29.9%	20
f) None	40.3%	27
g) Other	25.4%	17
answered question		67
skipped question		21

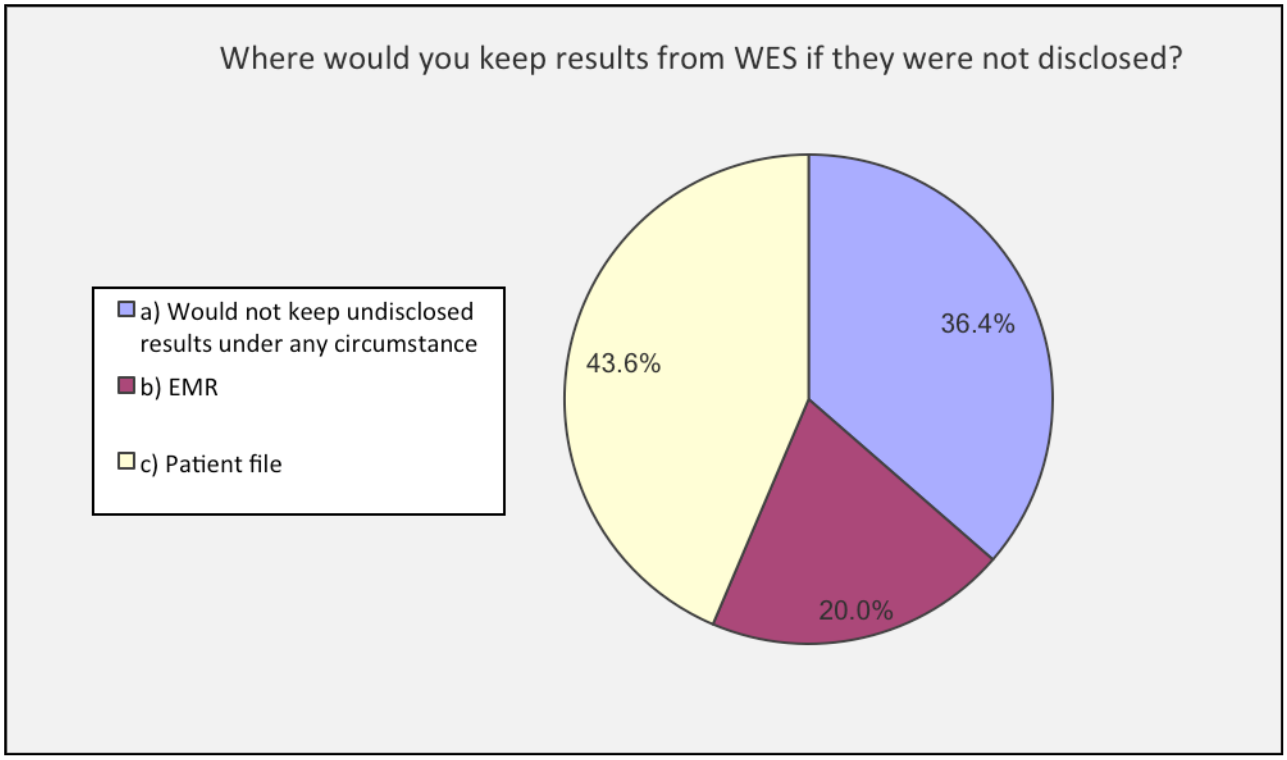
In which of these circumstances, if any, do you believe that it is not appropriate to disclose incidental findings when results are returned: (select all that apply)		
Answer Options	**Response Percent**	**Response Count**
a) Pediatric cases where parental carrier status is	4.5%	3
b) Pediatric cases where parental gene status is	4.5%	3
c) Patient tested is critically ill	6.1%	4
d) Pediatric cases involving adult-onset conditions	13.6%	9
e) When the patient has died and the immediate next of kin is unresponsive	22.7%	15
f) None	50.0%	33
g) Other	27.3%	18
	answered question	**66**
	skipped question	**22**

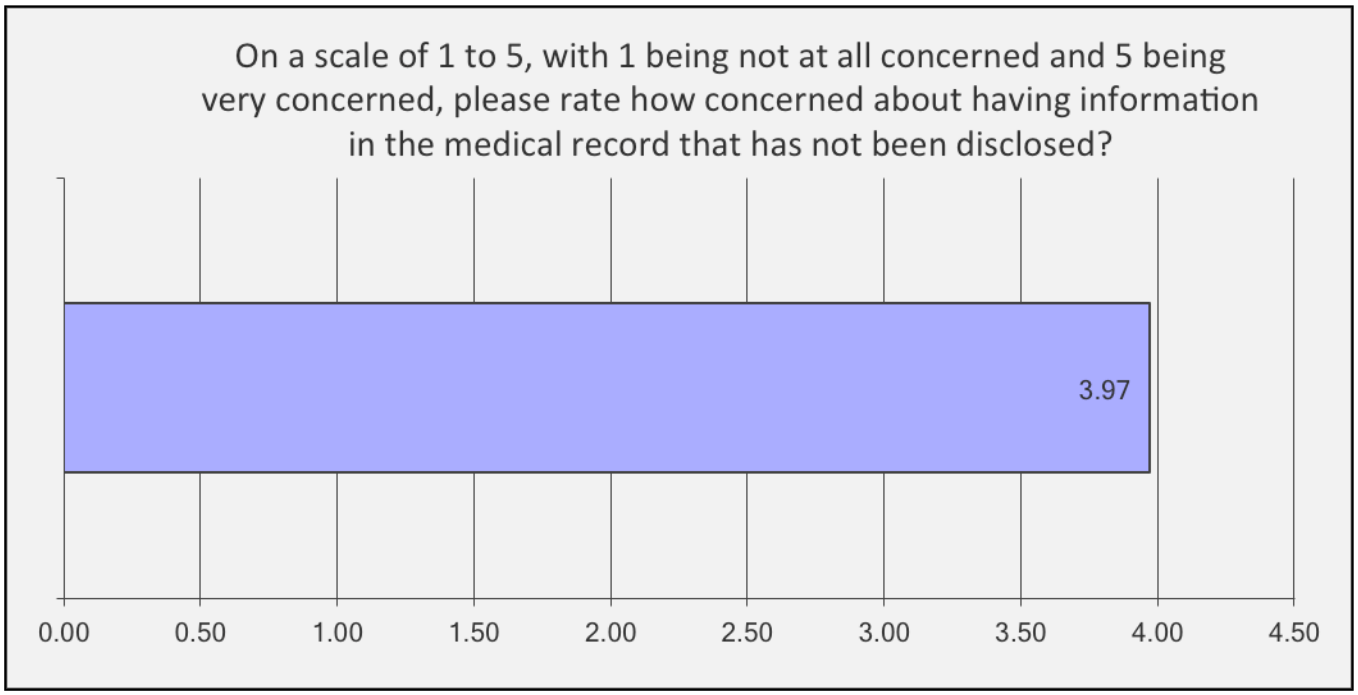
Electronic medical record




Are genetic test results being incorporated into the EMR?
100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
Yes, 93.9%
No, 4.5%
N/A, 1.5%
Yes
No
N/A


Would undisclosed WES results be included in the EMR?
e) N/A
15.5%
d) Don't know
31.0%
c) Maybe
11.3%
b) No
7.0%
a) Yes
35.2%
0.0%
10.0%
20.0%
30.0%
40.0%
a) Yes
b) No
c) Maybe
d) Don't know
e) N/A


Where would you keep results from WES if they were not disclosed?
a) Would not keep undisclosed results under any circumstance
b) EMR
c) Patient file
36.4%
20.0%
43.6%


On a scale of 1 to 5, with 1 being not at all concerned and 5 being very concerned, please rate how concerned about having information in the medical record that has not been disclosed?
3.97
0.00
0.50
1.00
1.50
2.00
2.50
3.00
3.50
4.00
4.50

Discussion

Pretest Considerations

Among respondents, there was a strong expectation that patient preferences regarding the disclosure of incidental findings would be established by the laboratory prior to testing. Approximately 75% of respondents indicated that they would expect laboratories to solicit patient preferences as part of informed consent, at least most or all of the time. Of those responses, 69% indicated that they would expect the laboratory to solicit preferences all of the time. This expectation implies that the responsibility for enforcing informed consent falls primarily on the laboratory rather than the clinician. This reliance on the laboratory may become increasingly important as more non-genetic specialists begin to order WES. Consistent with this, 30% of participants reported receiving referrals following WES from specialists outside of genetics; 9% indicated they receive these referrals on a regular basis. This further underscores the value and necessity of a comprehensive informed consent provided by the laboratory as a part of the ordering process.

Additionally, our results suggest a strong preference for laboratories with a set policy on which incidental findings are returned and honoring patient preferences with regard to those findings. One participant stated, "*I will not order from a lab that does not offer the family an opt-out option*", highlighting the expectation held by many genetic counselors that the lab will take patient preference into account and report accordingly. In fact, 26% of our respondents indicated that if they received an incidental finding on a report that the patient did not want, they would request a rewritten report without the incidental finding. Overall, these responses imply that pretest ascertainment of patient preferences, as a part of informed consent, is absolutely critical in ordering WES.

Tendency to disclose

With regard to disclosure, 81% of respondents indicated that they feel an obligation to disclose any finding associated with the ACMG minimum list of genes that is reported by the lab. Multiple respondents indicated they felt compelled to disclose any and all findings listed on a report.

"I will disclose anything that is reported, and what is reported is based on what the patients consented to in our initial conversation"

"All reported findings should be disclosed to the patient."

The inclination toward disclosure does not seem to be tempered by a concern that patients may prefer not to receive the information. This may reflect the earlier reported belief that genetic counselors rely on laboratories to adhere to patient preferences obtained at the time of consent and report accordingly.

Even when patient preferences are unknown, 65% of participants indicated they would disclose any incidental finding. Interestingly, 22% of our participants indicated they would disclose an incidental finding that the patient did not want if it was included in the report, while 35% reported they do not know what they would do, and only 1% said they would definitely not disclose it. This reluctance is in contrast to the respondents' emphasis, discussed previously, on honoring patient preferences. The variation suggests a strong disinclination to withhold information once it is reported. Once the information is in the hands of the clinician, many may feel that disclosure is the only option.

The most complicated scenarios present themselves when counselors receive unanticipated WES results. When the ACMG developed their policy statement on WES, they acknowledged the possibility that testing may be ordered by specialists outside of

genetics but did not address clinical challenges that may arise such as responsibility for interpreting and contextualizing results without participation in the ordering process (Green, Berg, Grody et al., 2013). When presented with this circumstance, one participant stated that he/she would not disclose but would include the result in the patient record, while another participant stated that he/she would consult an ethics board. In any case, no consensus existed among our respondents on the best course of action concerning reported incidental findings that are not desired by the patient. Overall, our data suggests that there are both ethical and practical dilemmas associated with incidental findings that are reported, yet unwanted.

Issues around Disclosure

Approximately 73% of respondents indicated they had not experienced a clinical situation in which they received an incidental finding that they did not feel was appropriate to return. However, a larger number of counselors suggested that circumstances are likely to arise in which it may not be appropriate to return an incidental finding. Roughly half of our respondents either agreed or weren't sure that circumstances exist in which disclosure would not be appropriate at the time of testing, or even at all.

Although the ACMG recommendations on incidental findings provide some concrete guidance in the reporting of WES, uncertainties remain and continue to arise. One example is the deceased patient; 30% of participants agreed that disclosure is inappropriate in circumstances in which the patient has died and the immediate next of kin is unresponsive. There is ambiguity in the research field regarding the handling and mechanism of disclosure (or lack thereof) of WES results for deceased individuals

(Bredenoord et al., 2011; Chan et al., 2012). This situation is relatively new in the clinical realm, and a protocol regarding disclosure to deceased individuals has yet to be put in place.

Additionally, 22% of participants agreed that disclosure is inappropriate in pediatric cases involving adult-onset conditions. These responses align with the traditional recommendation to defer testing for late-onset conditions until adulthood. However, given the current guidelines, these and other circumstances are likely to arise, in which test results are included that many genetic counselors in our study consider inappropriate to disclose.

Storage and handling of incidental findings

Nearly all of our participants (93%) reported that they use electronic medical records (EMR) to store genetic test results, including those obtained from WES. By and large, these results are discussed with the patient prior to or shortly after being entered into the EMR. However, when WES results are not discussed with the patient, only 20% would enter the results into the EMR and 44% would keep it in the patient's file. Interestingly, 36% said they would not keep undisclosed findings under any circumstance. One respondent justified not entering the results into the EMR by stating, "under absolutely no circumstances should undisclosed genetic test results be available in the EMR where any old provider could happen upon them and then blabber on about it to the patient - that sounds like a recipe for disaster".

Many participants implied that they are uncomfortable with being gatekeepers of genetic information, meaning that they don't want to be held accountable for negative repercussions associated with nondisclosure. On a scale of 1 to 5, with 1 being 'not at all concerned' and 5 being 'extremely concerned', 75% responded that they were either 'very concerned' or 'extremely concerned' with having undisclosed results in the EMR. There is a high level of discrepancy and discomfort regarding clinicians' perceived ethical and practical

responsibilities regarding the storage of undisclosed incidental findings. Several participants expressed concern that another clinician might access and unknowingly disclose unsolicited information.

"If an incidental finding is [not] reported, I would feel responsible if something happened to that patient or family member because I did not disclose the results… I would also feel extremely uncomfortable having that information in their medical record and potentially having another healthcare provider mentioning it to them on accident. I would rather have the difficult conversation with them myself."

Practice Implications

Results from this study affirm the need for shared perspectives with regard to the management of undisclosed incidental findings. Based on our results, the clinical genetic counselors in our study have a strong expectation that the laboratory will provide a comprehensive informed consent. Therefore, laboratory genetic counselors may find this information useful when updating the informed consent portion on their test requisition forms. A small percentage of genetic counselors are unaware of laboratory policies with respect to incidental findings; laboratory genetic counselors may make use of ordering WES as an educational opportunity. In general, relying on the assumption that the report from the lab will reflect patient preferences requires a strong cooperative effort between the clinical and lab personnel.

Study Limitations

There are a number of limitations to this study. The relatively small sample of 88 participants limits the generalizability of results. The small number of participants likely reflects the limited number of genetic counselors ordering WES at the time of the survey.

Quite possibly, respondents who had experience ordering WES were more likely to self-select for participation, creating a smaller though more knowledgeable participant pool. Several of our survey questions were potentially hypothetical and might not be viewed as reflection of actual decisions in real cases but over half of all counselors responding had first-hand experience. We were not able to make generalizations on data obtained from open-ended responses and, in some cases, responses for individual criteria items addressed multiple issues.

Research Recommendations

Future studies will be necessary to determine the genetic counselor's optimal role in the management of incidental findings as ACMG recommendations are further revised. Our data suggests that WES is often ordered by specialists outside of genetics. It would be beneficial to gain a better understanding of those specialists' understanding of the appropriate handling of incidental findings. Furthermore, it would be interesting to investigate their compliance with practice guidelines in offering informed consent to their patients. Lastly, further investigation into larger and more comprehensive clinician populations will be valuable for the continuing discussion surrounding the management of incidental findings in WES.

Conclusion

Our study found that the clinical genetic counselors responding to our survey have a strong expectation that patient preferences regarding the disclosure of incidental findings would be established by the laboratory prior to testing. This view is in direct contrast to the ACMG recommendations, which place the burden of obtaining informed consent on the ordering clinician (ACMG Board of Directors, 2013). We acknowledge that at this time, laboratories are not capable of obtaining informed consent; they can only document what was

consented to. When an incidental finding on the minimum list is reported by the lab, most genetic counselors feel an obligation to disclose, whether or not preferences are known. Even when preferences are known and the patient does not want this information, genetic counselors are uncomfortable with not disclosing these results.

Most genetic counselors in our study indicated they had not experienced a circumstance in which they had received an incidental finding that they felt would be inappropriate to disclose. However, many genetic counselors feel that these circumstances do exist. Additionally, there is concern over having undisclosed results in the EMR for fear that another provider might accidentally reveal them to the patient. As WES becomes more common in clinical practice, these scenarios are more likely to surface. This study suggests the clinical genetics community could benefit from guidelines on management of undisclosed incidental findings as well as the development of infrastructure to support that process.

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