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Identifying Consanguinity through Routine Genomic Analysis: Reporting Requirements

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Introduction

Increasingly, genomic analysis is being utilized to diagnose children with developmental delay or dysmorphic facial features suggestive of a congenital disorder. Genetic testing has rapidly evolved, and the genome-wide tests that we use today are significantly different from the more targeted single-gene tests of the last decade. Chromosomal microarray analysis (CMA) is now a first line test for children with multiple birth defects, children with intellectual impairment (including autism), and children with an unusual constellation of symptoms that do not fit with a known disease.¹ There are three types of CMA that are currently clinically available. CMA by oligonucleotide array-based comparative genomic hybridization (aCGH) compares the hybridization signal from the patient's DNA to that of a reference DNA sample for each oligonucleotide on the array. Depending on the specific array, this can range from tens of thousands to hundreds of thousands of oligonucleotides. A relative loss of signal from the patient's DNA is interpreted as a deletion, whereas a relative gain is interpreted as a duplication (or, in rare cases, a triplication or quadruplication). aCGH can detect very small losses or gains of DNA and typically uncovers genetic abnormalities in about 10–20% of cases.² CMA by single nucleotide polymorphism (SNP) analysis uses a completely different technology to genotype the individual at hundreds of thousands to millions of single nucleotides that are commonly polymorphic in the genome. Gains and losses of DNA are detected by relative increases or decreases of the signal at each SNP relative to the other SNPs on the array, as well as by the specific genotypes seen at SNPs that are located in tandem in the genome.³ Like aCGH, SNP analysis will detect losses or gains of DNA, but it will sometimes miss very small changes that aCGH can detect. However, SNP analysis, unlike aCGH, can also detect areas where chromosome pairs or parts of the chromosome pairs are identical to one another. Most recently, hybrid arrays have been developed that combine both technologies into a single test.

Since one copy of each pair of chromosomes is inherited from the mother and the other pair of each chromosome is inherited from the father, when parts of chromosome pairs are identical (i.e., there is an absence of heterozygosity (AOH)), there are two possibilities. If

only one chromosome is involved, then the cause could either be uniparental isodisomy (meaning the child inherited two identical copies of a chromosome from one parent and no copy of the same chromosome from the other parent), or distant consanguinity (meaning the parents are distant blood relatives).⁴ If multiple chromosomes are involved, then the parents must be blood relatives of one another. The closeness of the relationship between the parents can be estimated based on the number and size of the chromosome blocks that are identical. Analysis of parental samples is not required to make this determination, but it can confirm the finding and can conclusively identify the father of the child.

In February 2011, our colleagues at Baylor College of Medicine (BCM) reported several children with intellectual or developmental disability or with multiple congenital abnormalities who were referred for genetic testing and in whom SNP analysis revealed large regions of AOH on multiple chromosomes.⁵ Since that publication, clinicians at BCM have seen a total of seven children in whom SNP-analysis revealed large regions with AOH accounting for between 19–25% of the genome, which is consistent with a finding that the child was conceived by first-degree relatives (i.e., parent-child or full siblings) (Table 1). The children ranged in age from newborn to 11 years old. None of the mothers were themselves under the age of 18 at the time of testing, but at least four were minors when the child was conceived. In only 2 of the 7 cases was consanguinity suspected prior to testing. As is common practice in many states, testing was performed without the requirement for specific informed consent, so the possibility of identifying AOH was typically not addressed prior to receiving the results, unless consanguinity was already suspected. In all of these cases, questions were raised about whether the physicians had an obligation to report the findings to Child Protective Services (CPS) or whether doing so would be an unethical breach of patient confidentiality.

Informed Consent for Genetic Testing

The U.S. does not have a uniform federal policy requiring specific informed consent for clinical genetic testing. Requirements for obtaining legally adequate informed consent are generally determined by state law. The majority (n=37) of states, including Texas, do not require specific informed consent to order a genetic test⁶ because it is considered a routine diagnostic test that is authorized under the general consent to treat that patients sign upon admission to a hospital or clinic. Out of the thirteen states that do require specific informed consent for genetic testing, inconsistencies exist as to what information should be disclosed.⁷ Six states only require that the patient sign a written informed consent document prior to testing. The remaining seven states expressly list what information the informed consent document must include.⁸ These states typically require that, at a minimum, the consent form explain the purpose of the test, the intended use of the genetic information derived, and a description of what conditions will be tested for.⁹ Not surprisingly, no state specifically addresses the possibility of identifying cases of AOH or that it could lead to suspicion of child abuse if the mother is a minor, triggering state mandated reporting requirements.

With the emergence of new genetic technologies, like CMA, it is increasingly common for genetic tests to reveal clinically relevant incidental findings, as well as unanticipated

variants of uncertain significance not directly related to the patient's phenotype. In some cases, parents may choose not to receive this information, especially if it is not immediately clinically actionable. There is much debate about how much authority parents should have to make these decisions on behalf of their minor children.¹⁰ In all cases, however, parents have the right to refuse genetic testing for their child, unless doing so would result in serious harm or imminent death. In order to make this decision, it is important that parents are adequately informed of the risks and benefits of genetic testing, including the potential to identify unanticipated findings (like AOH) and variants of uncertain significance. However, it does not necessarily follow that the possibility of discovering information that could lead to a suspicion of child abuse should also be disclosed. For most patients, this information will be irrelevant but could cause unnecessary anxiety and could even lead to the refusal of an important diagnostic test. Further, there are many clinical tests that are performed that have the potential to reveal findings that could lead to suspicion of abuse. Consider, for example, chest X-rays performed on children who present to the emergency department with respiratory issues. Parents are not typically informed that the results of the x-ray may lead to suspicion of abuse (if, for example, unexpected rib fractures are discovered), which would trigger mandatory reporting. Rather, the issue is dealt with only when there is a suspicion of abuse and usually in consultation with relevant experts. This approach, which avoids unnecessary harm and protects children who are potential victims of abuse, should also be adopted in the context of genetic testing.

Reporting Requirements

Physician-Patient Confidentiality

Physician-patient confidentiality is derived from the special relationship created when a patient seeks the advice, care, and treatment from a physician. Confidentiality is a core concept of professional medical ethics. It protects patients from potential harm that could result from unauthorized access to sensitive information and is considered essential for maintaining trust and encouraging honesty in the physician-patient relationship. It also respects patients' rights to make autonomous decisions about with whom they choose to share personal information. The ethical obligation to maintain confidentiality typically extends broadly to any information disclosed during the course of the relationship and dates back to the Hippocratic oath, which states:

Whatever, in connection with my professional practice or not in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.¹¹

The duty to maintain confidentiality in medicine is also codified in many contemporary professional codes of ethics. For example, the American Medical Association's Code of Medical Ethics explains:

The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree....The physician should not reveal confidential communications or information without the expressed consent of the patient, unless required to do so by law.¹²

The legal exceptions to the general rule of confidentiality are defined by federal and state laws and regulations, and by the courts. Exceptions are limited and generally address issues related to public health.

Reporting Consanguinity

Sexual relations and/or marriage between blood relatives is illegal in most states. The elements of these crimes are usually: (a) sexual relations between persons having a particular prohibited level of consanguinity (or affinity through adoption or marriage); and (b) the defendant's awareness of that relationship.¹³ However, statutory definitions of what constitutes a crime vary significantly among the states, and what is considered criminal conduct in one state may be permissible in another state.

Although a consanguineous relationship may be an illegal activity, physicians who become aware of a consanguineous relationship during the course of the physician-patient relationship typically cannot report it. In fact, health care professionals are generally forbidden from reporting criminal activity under state confidentiality statutes. To do so would be a breach of patient confidentiality, which in most states is a misdemeanor.

Reporting Abuse

A notable exception to the legal duty to maintain patient confidentiality is the mandatory reporting of child abuse. Child abuse is defined by the federal Child Abuse Prevention and Treatment Act (CAPTA)¹⁴ and also by state laws. At the state level, child abuse may be defined under both criminal and civil statutes, and is generally characterized to include the physical, emotional, or sexual harm of a child either purposefully or due to neglect. The majority (n=34) of states define a child for the purpose of the statute to be under the age of 16;¹⁵ six states define a child as under the age of 17, and ten states define a child as under the age of 18. However, just over half of the states provide a "Romeo and Juliet" exception, which allows for consensual sexual contact with a minor if the minor is only a few years younger than his or her partner.¹⁶ For example, in Texas, sexual contact with a child under the age of 17 is considered child abuse. However, if the child is between 14 and 17 years of age, his or her sexual partner is less than 3 years older, and the sexual activity was consensual, then it does not meet the statutory definition of abuse and no report must be made.¹⁷

In all states, persons suspecting child abuse are required to report it.¹⁸ Forty-eight states and the District of Columbia specify certain professional groups as mandatory reporters.¹⁹ The specified groups are those who have frequent contact with children, such as social workers, teachers, physicians, and childcare providers.²⁰ The type of situations under which a mandatory reporter must make a report vary from state to state, but usually the standard is that a report must be made when a reporter suspects, reasonably believes, or has knowledge that a child has been abused.

Privileged communication may conflict with state mandatory reporting statutes, and all but three states (Connecticut, Mississippi, and New Jersey) have restricted this privilege for mandatory reporters.²¹ "Privileged communication" is the legal acknowledgment of the right to maintain confidential verbal exchanges between professionals and their patients or

congregants. While the attorney-client privilege is frequently recognized by the courts, the physician-patient privilege is usually denied by the states, and the clergy-penitent privilege is often limited to confessional communications, or eliminated altogether.²²

For individuals who are not mandatory reporters, permissive reporting is allowed when the relevant state standard for reporting child abuse is met. The majority of states require a report to be made when there is “reasonable cause” to suspect it or the individual has a “reasonable belief” or “reason to suspect” it has occurred.²³ The District of Columbia,²⁴ Maine,²⁵ Massachusetts,²⁶ Missouri,²⁷ and Ohio²⁸ also allow for reporting of child abuse when a child is suspected of being in immediate danger, at substantial risk, or faces a threat of abuse (Figure 1). Nineteen states specifically include “incest” as part of their child abuse statutes.²⁹ All nineteen states require the reporting of past and ongoing abuse, including incest, but only Hawaii allows for the reporting of a substantial risk of abuse or incest, as long as it is within the “reasonably foreseeable future.”³⁰

Implications

This review of state law suggests that if a healthcare provider suspects that a child is being abused, he or she is obligated to make a report. In most cases, a finding of consanguinity through SNP analysis that involves a mother who herself is a minor will create a suspicion of abuse and an obligation to report. The purpose of the report is to stop ongoing abuse, usually by removal of the victim from the home and by initiating criminal charges against the perpetrator.

When the mother is an adult at the time of testing but was a minor when the child was conceived, the health care professional’s obligation to report is less clear and will be case-specific. If the mother denies the consanguinity, then the decision to report is more difficult. Importantly, SNP analysis can confirm consanguinity, but it cannot conclusively inform us who the biological father is. Parental samples are necessary to definitively identify the biological father. Thus, it is important to take a thorough family and social history to assess who may potentially be the biological father and whether there is a continued threat of abuse. If, for example, the biological mother has no brothers and her father is living with other minor children, then a report may be justified to investigate the well-being of those children. If no other children are at risk, then a report may still be made so that criminal charges can be initiated for the past abuse of the mother (which may still be ongoing but because the mother is now an adult, it is no longer child abuse). The statute of limitations for filing child abuse charges differs depending on the state and the circumstances surrounding the abuse, but generally there is no criminal statute of limitations for child abuse that qualifies as a first-degree felony in the pertinent state.³¹ The District of Columbia, Georgia, Iowa, and Utah have specific statute of limitation rules for child abuse that involves incest.³² Several states also have criminal tolling provisions. When a statute is tolled, the start of the limited time period to charge the defendant is suspended until the specified event stated in the legal statute takes place. Georgia, Indiana, and Tennessee specifically extend its criminal statute of limitations for child abuse crimes involving incest.³³ Seven states have allowed, in limited cases and under restricted circumstances, for conclusive evidence resulting from DNA testing to revive prosecution where the defendants were previously protected by a

lapse in the statute of limitations.³⁴ However, it is still unclear whether this will apply to DNA tests of a child that suggests consanguinity but cannot conclusively identify the biological father.

Implementation

Of the seven cases we have seen at Baylor College of Medicine, only three resulted in a report to CPS (Table 1). In two of the cases that were not reported, the birth mother admitted to being raped by a first-degree relative, but in one case, the father who was the accused perpetrator was incarcerated on unrelated charges, and in the other case the brother who was the accused perpetrator was deceased. In two other cases, the birth parents were not available at the time of testing and a report was not made because CPS or law enforcement was already involved in the case and the child was not living with the birth parents. The remaining three cases were reported to CPS. In one case, the birth parents were not available at the time of testing and could not be located. The remaining two cases involved situations where the birth mother vehemently denied consanguinity. In one case, the mother was 24 years old at the time of testing but under the age of 18 at conception of the child. All first-degree male relatives lived in one house with minor children so there were concerns about the risk of abuse of those children. A report was made to CPS, and a recommendation was made that family members move to separate residencies, but no legal action was taken to ensure that this occurred. In the second case, the birth mother was 18 years old at the time of testing and had just given birth. The only first-degree male relative was her father so a report was made to CPS. The mother denied consanguinity and her 14-year-old sister denied any inappropriate behavior from her father. The case was therefore closed with no further action taken.

Conclusion

The rapid pace at which genomic technologies are advancing raises important ethical challenges for clinicians. The potential to discover large amounts of potentially important incidental information during the course of genomic analysis has been identified as one of the greatest challenges to genomic medicine.³⁵ Debate has focused on what obligations physicians have to look for incidental findings, communicate them to the patient, and follow up on them through further testing, referral, intervention, or preventative measures. These cases illustrate how genomic analysis can uncover incidental information that gives rise to additional obligations; namely, the obligation to report potential child abuse to the appropriate authorities. As is true in all cases involving suspected child abuse or neglect, the decision to report must take into account the strength of the evidence supporting the suspicion and the probability of harm to the child or other children. The decision is complicated when the biological mother is an adult at the time of testing but was a minor when her child was conceived. Physicians faced with this decision should utilize existing hospital resources, such as child protection teams, special needs clinics, and social workers. It is important to maintain confidentiality in cases where the parental relationship may have been illegal but was a consensual relationship between two adults and therefore does not suggest any past or ongoing abuse. However, in cases of potential child abuse, the ultimate goal must be to protect the biological mother (who is or was a child) and any other at-risk

children from harm, without compromising the care of the patient (i.e., the child who is being tested and is found to be the product of a consanguineous relationship).

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21. *Id.* (U.S. Dept. of Health and Human Services).
22. *Id.* New Hampshire, North Carolina, 400 Oklahoma, Rhode Island, Texas, and West Virginia do not recognize the clergy-penitent privilege as adequate grounds for failing to report suspected child abuse.
23. See Wang, *supra* note 15.
24. DC. Ann. Code § 16–2301
25. ME. Ann. Stat. Tit. 22 § 4002
26. MA. Code of Mass. Regs. Tit. 110, § 2.00
27. MO. Ann. Stat. § 210.110
28. OH. Rev. Stat. §§ 2151.031.
29. *Id.*; These states are: Alabama, AL. Ala. Code § 26-14-1(1)-3., Arizona, AZ. A.R.S. § 13-3620., California, CA. West's Ann. Cal. Penal Code § 11165.9 (2011), Welf. & Inst. Code § 300., Hawaii, HI. Rev. Stat. § 350-1., Idaho, ID. Idaho Code § 16-1602., Indiana, IN. Ann. Code § 31-34-1-3., Maryland, MD. Fam. Law § 5-701., Mississippi, MS. Ann. Code § 43-21-105., Montana, MT. Ann. Code § 41-3-102., Nevada, NV. Rev. Stat. §§ 432B.100., New Hampshire, NH. Rev. Stat. § 169-C:3., New Mexico, NM. Ann. Stat. § 32A-4-2., North Carolina, NC. Gen. Stat. § 7B-101., Oklahoma, OK. Ann. Stat. Tit. 10A, § 1-1-105., Oregon, OR. Rev. Stat. § 41B.005., Pennsylvania, PA. Cons. Stat. Tit. 23 § 6303. Tennessee, TN. Ann. Code § 37-1-602., Utah, UT. Ann. Code § 78A-6-105l., and Vermont, VT. Ann. Stat. Tit. 33 § 4912.
30. HI. Rev. Stat. § 350–1.
31. See Wang, *supra* note 15.
32. The District of Columbia allows years from when the victim turns 21 years old, DC. Ann. Code § 16-2301; Georgia's limitation is seven years from the earlier of the victim turning 16 years old or discovery GA. Ann. Code § 19-7-5(b); Iowa allows 10 years from when the victim turns 18 IA. Ann. Stat. § 232.68; and Utah has a eight year grace period if reported within four years of the offense UT. Ann. Code § 78A-6-105.
33. In Georgia, the time period of prosecution for incest of a victim less than 16 110, §years old does not begin to run until the earlier of when the victim reaches 16 or reports the crime GA. Ann. Code § 19-7-5(b); Indiana allows for prosecution up until the victim is 31 years old, IN. Ann. Code § 31-34-1-3.
34. See Wang, *supra* note 15. The states that allow for a DNA evidence exception are: Georgia, GA. Ann. Code § 19-7-5(b), Michigan, MI. Comp. Laws § 722.622, Minnesota, MN. Ann. Stat. § 626.556, Subd. 2, Montana, MT. Ann. Code § 41-3-102, Oklahoma, OK. Ann. Stat. Tit. 10A, § 1-1-105, Pennsylvania, PA. Cons. Stat. Tit. 23 § 6303, and Utah, UT. Ann. Code § 78A-6-105l.
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Biography

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Figure 1.
United States Child Abuse Reporting Requirements by State (2012)

Table 1

Cases of First-Degree Consanguinity Identified through SNP Analysis

Case	Patient Age	Reason for consult	Age of mother at time of consult	Was consanguinity suspected?	Mb of autosomal AOH (%)	Was consanguinity reported when the result was disclosed?	Was CPS contacted?	Why/ why not?	Outcome of CPS action
1	3 yo <i>J Law Med Ethics. Author manuscript; available in PMC 2014 May 22.</i>	Dysmorphic facies, hearing impairment, developmental regression	Unknown (child adopted)	No	668 (23%)	No	Yes	To investigate the well-being of the birth mother	Birth parents of the child were never located
2	5 yo	Dysmorphic facies, microcephaly, failure to thrive, developmental delay	24 yo	No	720 (25%)	No	Yes	Mother was a minor at the time of conception, and all first-degree male relatives lived in the same house with contact with minor children	CPS recommended that family members move to separate residences but did not take any legal action to ensure that this occurred
3	5 mo	Speech delay, hirsutism	Unknown (child in foster care)	Yes	688 (24%)	No	No	Law enforcement already involved; birth parents not in the country	
4	4-week-gestation newborn	Collodion baby	18 yo	No	634 (22%)	No	Yes	Mother was a minor at the time of conception, and her only first-degree male relative was her father; concern for the well-being of the mother's minor sister	Mother denied consanguinity to CPS. Mother's sister denied any inappropriate behavior from her father. Case was closed with no further action taken.
5	5 ½ yo	Dilated cardiomyopathy, heart failure	22 yo	No	639 (22%)	Yes—mother reported being raped by her father	No	Father was already incarcerated on	

Case	Patient Age	Reason for consult	Age of mother at time of consult	Was consanguinity suspected?	Mb of autosomal AOH (%)	Was consanguinity reported when the result was disclosed?	Was CPS contacted?	Why/ why not?	Outcome of CPS action
6	9 yo	Dysmorphic facial features, developmental delay, endocrine insufficiency	Unknown (child adopted)	Yes	543 (19%)	No	No	unrelated charges; unrelated charges	McGuire et al.
7	11 yo	Bilateral cataracts, corneal haziness, developmental delay	Late 20s	No	705 (24%)	Yes— mother reported being raped by her brother	No	CPS had previously been involved and had removed this child from the care of his birth mother Mother's brother was deceased	

NOTE: Percentages are based on the assumption that the autosomal portion of the genome is 2,881 Mb in size.

ABBREVIATIONS: Mb = megabases (i.e., 1,000,000 base-pairs), AOH = absence of heterozygosity, CPS = child protective services.