

# Minimizing liability risks under the ACMG recommendations for reporting incidental findings in clinical exome and genome sequencing

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**Disclaimer:** In the United States, tort law is state rather than federal law. This article describes principles followed in many states, but your state may differ. Consult a lawyer licensed in the states where you work.

Recent recommendations by the American College of Medical Genetics and Genomics (ACMG) for reporting incidental findings present novel ethical and legal issues. This article expresses no views on the ethical aspects of these recommendations and focuses strictly on liability risks and how to minimize them. The recommendations place labs and clinicians in a new liability environment that exposes them to intentional tort lawsuits as well to traditional suits for negligence. Intentional tort suits are especially troubling because of their potential to inflict ruinous personal financial losses on individual clinicians and laboratory personnel. This article surveys this new liability

landscape and describes analytical approaches for minimizing tort liabilities. To a considerable degree, liability risks can be controlled by structuring activities in ways that make future lawsuits nonviable before the suits ever arise. Proactive liability analysis is an effective tool for minimizing tort liabilities in connection with the testing and reporting activities that the ACMG recommends.

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## INTRODUCTION

The American College of Medical Genetics and Genomics (ACMG) recommends that whenever clinical sequencing is performed, the laboratory should conduct a deliberate search for medically significant mutations in a minimum list of 56 genes and report them to the patient's clinician or care team, who would be responsible for counseling the patient.<sup>1,2</sup> These activities—like any new activity—will expose laboratories and clinicians (together, “providers”) to new tort liabilities. This article describes proactive liability analysis, a process for assessing liability exposures and minimizing them.

Strategies to minimize liability risks are crucial to successful implementation of the ACMG's recommendations. The goals should be (i) to minimize liability risks by carefully structuring the new activities ACMG recommends and (ii) to develop appropriate liability coverage and indemnification arrangements to address residual risks that remain. Proactive liability analysis is a useful tool for accomplishing these goals.

## DISCUSSION

The activities ACMG recommends can be structured in various ways. This choice will have a profound impact on liability risks. Some health-care activities indisputably are part of the

physician–patient relationship (PPR), but for many activities—and this is particularly true of new health-care services—there is a choice whether to position them inside or outside of the PPR. Alternatives, for example, include:

1. Integrated delivery as part of the existing PPR. This model positions the new activities within the original PPR, so assessment and reporting of incidental findings are treated as an integral part of the care the patient is receiving for the health condition that initially created the need for clinical sequencing.
2. Laboratory-centered service delivery. Laboratories would assess incidental findings and engage nonphysician intermediaries such as genetic counselors to interface with the patient outside of the existing PPR. A variant is biobank-centered delivery when biobanks are involved,<sup>3</sup> although the feasibility of this option is debated.<sup>4</sup>
3. Physician-centered delivery of separate health-care services. Physicians (possibly including the treating physician with whom the patient has an established PPR) would act as learned intermediaries who order tests and report the results, but they would do so through well-crafted business structures that are separate from the physicians' traditional medical clinics (e.g., an affiliated wellness clinic). The goal

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would be to position the new services outside the existing PPR by delivering them through stand-alone business structures carefully designed to avoid Stark law (physician self-referral) and related concerns.

It is not a lawyer's job to identify alternatives or assess their practical merits. That is for providers and other stakeholders to do, because only they know what each structure involves. Once a list of alternatives is complete, lawyers can help assess liability exposures for each structure on the list.

### The new tort landscape

Failing to disclose clinically actionable incidental findings may generate malpractice liability in clinical settings.<sup>5</sup> Negligence suits more broadly include both malpractice and ordinary negligence actions, and both have been studied in relation to research,<sup>6</sup> to return (or nonreturn) of results from research or insurance and preemployment physicals,<sup>7-9</sup> and to failures to inform patients about innovations in clinical care.<sup>10</sup> This article takes the inclusive view that the ACMG's recommended activities may generate either type of negligence suit.

It also considers intentional tort suits, which address injuries caused by purposeful behavior as opposed to unintended harms, which are the focus of negligence law. Intentional torts allow claims for emotional and dignitary harms, such as having one's wishes ignored, even if no physical injury actually resulted. Intentional torts do not replace negligence suits, and patients can bring both types of suits at once.

This article uses *return of results* to mean actual return of results. Tort law sometimes holds providers liable for acquiescing in patients' refusal to receive needed testing.<sup>11</sup> By implication, a mere offer to return test results—even if it satisfies bioethical requirements—may not always absolve providers of liability for failing to return results. This article takes the cautious view that the legal duty (if any) to return results may not always be satisfied by merely offering return.

### The two negligence frameworks

There are two views of a negligent act. Malpractice portrays it as a lapse of good medicine; ordinary negligence portrays it as a general act of human carelessness akin to a car wreck. Plaintiffs sometimes argue both versions simultaneously, as in *Ande v. Rock*,<sup>12</sup> the only published American court opinion addressing failure to return a research finding<sup>8</sup> (the plaintiff lost both suits). Usually, the facts of a case force the use of one narrative or the other: only one version makes sense and complies with the legal precedents.

Providers can minimize negligence exposure by harnessing two facts: (i) malpractice and ordinary negligence suits differ in important ways that can be outcome determinative (who wins/who loses), and (ii) it is possible to structure one's activities in ways that predispose them to fall under whichever negligence framework is more favorable to oneself.

With some exceptions, it is often true that providers fare better if suits over incidental findings fall under ordinary

negligence law rather than malpractice law. An illustration is that some states have different statutes of limitation/repose for malpractice and ordinary negligence.<sup>13</sup> These statutes limit the amount of time a plaintiff has to file a lawsuit. If the plaintiff waits too long, the suit is time-barred and dies on the vine. Time bars are crucial in situations—such as return of results—where there may be a long delay before the plaintiff's injury is discovered. If a provider fails to return a medically actionable finding that predicts cancer susceptibility, many years may pass before the patient actually develops a cancer that could have been averted through timely reporting.

Most states give plaintiffs 2–4 years to file personal injury negligence suits. In many (not all) states, the clock starts ticking in an ordinary negligence suit on the date when the provider failed to return the results. Such suits often will be time-barred before the patient ever discovers the injury. By contrast, many states have special statutes for malpractice that start the clock ticking only *after* the patient discovers the injury. Under these statutes, a malpractice suit for failure to return results would not be time-barred.

Duty, standard of care, and other elements of a negligence suit are beside the point if the suit is time-barred. Even when ordinary negligence suits are not time-barred, they may be harder for plaintiffs to win. Some states offer plaintiff-friendly malpractice doctrines (such as the lost-chance theory for proving that a delay in diagnosis caused a patient's injury)<sup>14</sup> that are unavailable in ordinary negligence suits.

Which framework is better varies from state to state. For example, some states have enacted malpractice reforms that cap malpractice damages or create barriers to malpractice claims.<sup>13</sup> Providers must assess which framework is the lesser of two evils in the state(s) where they operate.

### Positioning activities in the preferred negligence framework

Defense attorneys weep when they hear geneticists rushing to declare that the return of results amounts to medical practice. One hears the claim that return of results “quacks like” practice of medicine, and therefore it *is* the practice of medicine. This claim is legally inaccurate, and it is downright dangerous because it concedes malpractice liabilities that might easily be avoided through a more nuanced legal analysis of how incidental findings fit into the PPR. Never voluntarily impale yourself on the malpractice system if there is a chance to distance yourself from it.

The “unbending” legal rule traditionally has been that medical malpractice suits can arise only when there is medical practice<sup>15</sup>—a rule that may be starting to bend but is not broken yet.<sup>8,16</sup> In *Ande v. Rock*,<sup>12</sup> the research laboratory failed to inform parents that an infant enrolled in the control arm of a study had cystic fibrosis. Failing to return this result delayed the child's treatment, and the parents conceived a second child with cystic fibrosis during the delay. Their ordinary negligence claim was time-barred. Their malpractice claim failed because the court held that research is not practice of medicine.

An activity is medical practice only if there is a PPR *and* clinical care is taking place.<sup>13,15</sup> In insurance and preemployment physicals, doctors examine people without entering a PPR.<sup>8,13</sup> Suits for failure to return results from these examinations typically proceed as ordinary negligence rather than malpractice suits.<sup>13</sup> Some states have, however, created special doctrines that help plaintiffs establish the duty element of the tort (which can be devilish to prove in ordinary negligence cases) in these situations.<sup>8</sup>

Once established, a PPR continues until the patient is cured, the relationship ends by mutual consent of the parties, or the physician properly terminates the relationship.<sup>13</sup> This fact sometimes gives legal laypeople the false impression that everything a clinician does during the pendency of a PPR amounts to practice of medicine. This is obviously false. If clinician/investigators were considered to be practicing medicine while conducting a clinical trial, they would instantly be liable for malpractice to the 50% of research subjects randomized to receive nonstandard care. This does not happen, because informed consent documents—whatever their failings as ethical instruments—do the legal work of notifying patients that treatment and research are two different things. This notice interrupts the care-related PPR for purposes of the research, absent exceptional circumstances that impermissibly transgress the line between research and clinical care.

Law provides flexibility to position incidental findings within or outside the PPR. Law views PPRs as contractual in nature because a PPR can arise only by mutual consent of the physician and patient.<sup>13</sup> It is “permissible for the parties, if they choose to do so, to define with some precision the role that the doctor is to play.”<sup>17</sup> They typically limit the scope of their PPR by defining it in relation to specific medical conditions for which the patient is seeking care. Cardiologists typically owe no duties with respect to patients’ orthopedic care and, outside emergencies, cannot unilaterally decide to render orthopedic care unless the patient agrees to add that to the scope of their existing PPR. The ACMG defines incidental findings as “not apparently relevant to [the] diagnostic indication for which sequencing was ordered.”<sup>21</sup> This definition positions incidental findings outside the existing PPR, unless doctor and patient both agree to place them within it. Various structural alternatives are possible.

Alternative 1 (integrated delivery as part of the existing PPR) virtually ensures that negligence suits fall under malpractice law. Other structures can transform these suits into less-threatening ordinary negligence cases. By carefully structuring activities as in alternative 3 (physician-centered delivery of separate health-care services), it may be possible for treating physicians to order and report incidental findings without triggering the malpractice liability that would come if they seem to have agreed to treat the conditions thus discovered. Courts may see through this veil of separation, though, and it risks confusing patients. A safer choice is to position incidental findings farther outside the existing care relationship, as in alternative 2, or by referring the patient to a different doctor at the affiliated wellness clinic, as in alternative 3. Whichever option providers choose should be clearly explained to the patient ahead of time.

### Why intentional torts are relevant

Informed consent is not merely an ethical device that protects patients and research subjects. It is also a legal device that protects providers from intentional tort suits, which have little chance of success if the victim consented to the allegedly harmful act.<sup>18</sup> A key question is how law views the consent to incidental findings. The ACMG’s incidental findings are “the results of a deliberate search” for alterations in genes that are “not apparently relevant” to the condition for which the patient sought treatment.<sup>1</sup> Before consenting to sequencing, patients would be told that it includes analysis and reporting of these unrelated genes, which they can decline only by foregoing sequencing altogether.<sup>1</sup>

Law distinguishes a knowing consent from a voluntary consent. Law generally respects people’s informed decisions and is not in a paternalistic rush to invalidate them. But tort law views consent as ineffective when it is given under duress.<sup>18</sup> The Blackstonian (18<sup>th</sup>-century) definition of duress was quite narrow (imprisonment or actual fear of loss of life or limb), but the modern view includes “any wrongful act or threat which overcomes the free will.”<sup>19</sup>

The ACMG’s recommendations conceivably may exert duress. Suppose a clinician orders sequencing for a patient with a serious illness. The clinician advises the patient (and the patient’s insurer for reimbursement purposes) that sequencing is medically necessary. It later becomes clear that the medically necessary testing is available only if the patient agrees to a battery of tests that are “not apparently relevant” to the illness. If the patient fears that saying “no” would lower the odds of recovering, even Sir William Blackstone would see duress.

Patients in less exigent circumstances can allege the modern form of duress caused by a defendant’s wrongful acts. If a clinician refuses to provide care after portraying the care as medically necessary, the denial of care (or the threat thereof) may itself constitute a tort. Threatening to subject patients to torts if they do not consent is duress.

Alternatively, patients could claim that the medically necessary sequencing and incidental findings were tied together in a way that left them with no choice but to consent to both. Tying arrangements that force consumers to buy things they do not want in order to get things they need are coercive for purposes of antitrust and consumer protection statutes such as sections 1 and 2 of the Sherman Antitrust Act, section 3 of the Clayton Act (which applies to products, not services), section 5 of the Federal Trade Commission Act,<sup>20,21</sup> and state consumer protection laws. Tying exerts duress that may invalidate patient consent as to the incidental findings. Duress will be harder to prove if the patient had alternatives. Cases may turn on how many local laboratories follow the ACMG’s recommendations and whether the clinician expressed willingness to work with multiple laboratories.

To be clear, voiding the consent is much easier than proving a violation of antitrust law. Tying—by itself—may void patient consent for purposes of intentional tort lawsuits, but proving an antitrust violation requires tying *plus* several additional

elements.<sup>20,21</sup> Still, antitrust concerns are increasingly relevant to professional societies such as the ACMG as they draft ethics guidelines and policy statements. The ethics committee of the American Society for Reproductive Medicine published a position statement on oocyte donor compensation that was widely followed in the industry. The Society is now in federal court defending itself from an antitrust/price-fixing suit that claims its policy statement orchestrated an industry-wide conspiracy to restrain trade.<sup>22</sup> In today's legal environment, it is wise for guidelines to avoid *my-way-or-the-highway* statements even when the goal is to inspire universal compliance.

### Potential intentional torts

The intentional tort of battery occurs when there is harmful or offensive touching of an unconsenting person.<sup>18</sup> The fact that the actor meant well does not eliminate liability.<sup>18</sup> Battery occasionally occurs in health care—for example, wrong-side surgeries<sup>23</sup>—but it is not the tort to worry about under the ACMG's recommendations. The ACMG calls for “opportunistic”<sup>24</sup> testing that piggybacks unconsented tests onto clinical sequencing performed for another medical purpose. The beauty of opportunistic testing is that it uses a preexisting blood draw or specimen, so there is no incremental touching of the patient to support a battery claim. Even if the patient is deceived about the reason for the blood draw, many states would consider the consent valid as to the blood draw itself.<sup>25</sup>

Intrusion on seclusion (IOS) and intentional infliction of emotional distress suits arise in connection with unconsented HIV testing,<sup>25</sup> and they warrant concern here. IOS occurs when a person “intentionally intrudes, physically or otherwise, upon the solitude or seclusion of another or his private affairs or concerns” if the intrusion would be “highly offensive to a reasonable person.”<sup>18</sup> The intrusion can include the use of technology to enhance the intruder's senses in ways that reveal private matters not otherwise on display.<sup>18</sup> Two variants are possible. The first is IOS for unconsented testing. Laboratories could be liable for sifting through people's raw sequencing data to discover medically significant facts about them, and clinicians could be liable for ordering such a search. Past cases have found liability for deliberate searches through people's papers or their garbage. Sifting through patients' leftover sequencing data fits these precedents.

The second variant is IOS for reporting of the test results. Reporting results to unconsenting patients arguably disturbs the “tranquility” of the medical treatment encounter, a concept courts recognize in other contexts.<sup>26</sup> The PPR has a mutually agreed scope within which patients have a high expectation of privacy. The plaintiff would argue that it intrudes on the agreed PPR to force out-of-scope information into it. The clinician might claim the privilege of acting to prevent harm to the patient, but this privilege (which acts as a tort defense) requires the harm to be imminent in a way that genetic risks typically are not.<sup>18</sup> This variant is a novel application of the IOS tort but appears strong enough to survive dismissal and get the case into court. Once there, the costs of defending a tort are daunting regardless of the outcome.

Reporting results also may draw suits for intentional infliction of emotional distress. This tort requires that there be extreme or outrageous conduct that intentionally or recklessly causes severe emotional distress.<sup>18</sup> Some scholars regard opportunistic testing as “indefensible” and label it “the most serious challenge to patient autonomy we are facing in the twenty-first century.”<sup>24</sup> These allegations appear sufficient to create a genuine question for the jury: Is it outrageous? Some states set a low threshold of what is outrageous<sup>27</sup> (e.g., “conduct that offends against generally accepted standards of decency and morality”).<sup>28</sup> Expert testimony of bioethicists is admissible in court to establish the accepted standard of morality,<sup>29,30</sup> and it should be easy to find at least one bioethicist prepared to testify that morality requires informed consent.

### Managing intentional tort risks

Structural solutions are not effective at eliminating intentional tort suits, which are directed at specific acts by individuals without regard to whether they were practicing medicine or doing something else at the time. Structural choices do, however, affect the available defenses. The First Amendment offers a strong defense to IOS and intentional infliction of emotional distress torts for reporting information to a nonconsenting person.<sup>31</sup> Unfortunately, this defense may not work if incidental findings are integrated into the existing PPR (alternative 1), because medical professional speech receives reduced First Amendment protection under various legal doctrines.<sup>26,32</sup> Other structural alternatives may enjoy stronger defenses but, even in the best case, residual risks will remain, and they can have ruinous financial impacts on clinicians and laboratory personnel.

Liability insurance policies typically exclude coverage for intentional torts.<sup>33</sup> Why should the insurer pay when the defendant deliberately chose to do the harmful act? Courts work hard to construe malpractice policies in ways that favor covering a physician's tort,<sup>34</sup> but courts cannot rewrite the basic insurance contract. Providers facing an intentional tort suit may find themselves in court without the support of their insurers' legal defense team and, if they lose, may pay the damages themselves.<sup>35</sup>

They also cannot depend on their institutions to help defend them. Traditionally, institutions were not vicariously liable for intentional torts committed by employees<sup>36</sup> and thus had little reason to get involved. The modern trend holds employers responsible when employees commit intentional torts within the scope of their work.<sup>37</sup> But in states that follow the traditional rule, institutions may not be named as defendants, leaving employees to face these suits alone. These are the torts that can replace a doctor's Mercedes with a Moped and land the doctor's kids at the local community college in lieu of attending Harvard. Intentional tort damages may not be dischargeable in bankruptcy and can continue to haunt defendants even after bankrupting them.<sup>38</sup>

Intentional tort suits allow a wider array of damage claims than courts typically allow in negligence suits.<sup>39</sup> Law assumes that when people intentionally commit torts, justice is served by

holding them fully accountable for the harms.<sup>18</sup> Negligence suits limit recovery of pure economic harms (losses plaintiffs suffer in the absence of a physical injury or property damage).<sup>18</sup> Pure economic harms are a foreseeable outcome of unconsented testing—for example, if a patient’s life-insurance rates go up because of an unwanted genetic finding. With intentional torts, “the ultimate limits . . . are not yet determined,”<sup>18</sup> and these harms may be recoverable. Punitive damages, which are almost never awarded for mere negligence, also may be available. Punitives are rare in the absence of flagrant or outrageous behavior, but not getting consent is one of the things that law sometimes has tended to view as outrageous in health-care contexts.<sup>40</sup>

Providers should work with liability insurers and employers to develop ways to insulate clinicians and laboratory personnel from the financial risks of intentional tort suits. Solutions could include, for example, negotiating safe-harbor provisions that provide insurance coverage for IOS and intentional infliction of emotional distress claims arising when findings are returned using agreed procedures and safeguards. Insurers and employers have every reason to help address this problem, even if they may not directly bear the costs of intentional tort suits. If fear of intentional tort suits makes clinicians and laboratories afraid to return results, this may cause an uptick in negligence suits for failure to return results, and insurers and employers *do* bear risks in connection with the latter suits. It is in everybody’s interest to level the financial risks so that decisions about whether to return results are driven by science and by concern for patient welfare, rather than being skewed by worries over which liability risks are insured and which are not.

## Conclusion

Intentional and negligence torts interact to create lawsuit equipoise: providers can be sued whether they do or do not follow the ACMG’s recommendations. The lawsuits are just different, with different insurance coverage and potentially different personal impacts.

If providers follow the ACMG’s recommendations, they may face intentional tort suits. Patients may be able to bring additional negligence claims if the testing and/or reporting were ineptly performed, leading the patient to pursue harmful or unnecessary follow-up care. Providers who follow the recommendations also may face negligence suits if they fail to reevaluate patients’ sequencing data whenever the ACMG updates its minimal list of medically significant gene variants. The recommendations call for annual updates<sup>1</sup> but do not specify whether laboratories should reanalyze patients’ past sequencing data as the list evolves. If laboratories accept a duty to analyze these variants once, juries may infer a duty to follow through and reanalyze sequencing data as new variants are added. A traditional excuse for not reanalyzing patients’ old test data would have been that the patient never consented to the reanalysis, but if the ACMG is discarding traditional consent norms, it is discarding this defense.

If providers reject the ACMG’s recommendations, this eliminates the intentional torts but may leave providers facing

negligence liability for nondisclosure or delayed disclosure of medically significant findings. Such suits would allege that failure to return results caused the patient to lose the chance to mitigate health risks. Do not be deceived because the list of torts in this paragraph seems shorter than the list in the previous paragraph. Suits for nonreturn of actionable findings can carry large damage awards for serious personal injury and wrongful death.

Lawsuit equipoise has the advantage of freeing providers to choose whether to implement the ACMG’s recommendations based on the scientific and medical merits. Liability lurks on all sides, so do what is right. Law does not dictate what is right; this is a matter of medical and scientific judgment. The choice has legal consequences, but torts are not an overwhelming force of nature in the face of which mankind is helpless. With planning and foresight, smart people minimize their risks.

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## DISCLOSURE

The author declares no conflict of interest.

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