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Physicians' duty to recontact and update genetic advice

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Abstract

This perspective addresses whether physicians have a duty to recontact former or current patients to update clinical advice based on newly discovered genomic information. Genetic information is unique compared with other medical data in that the underlying data do not appreciably change during the patients' lifetime, but the clinical significance of that information will continue to evolve. Based on relevant case law and guidelines, there is no general, established legal duty for physicians to affirmatively recontact former or current patients to update clinical advice based on newly discovered genetic information. However, integration of genomics into clinical practice is advancing quickly, and there may be limited, specific situations where a physician may have a duty to provide updated genetic information.

Keywords

duty to recontact; genetic sequencing; genomic medicine; liability; medical malpractice; physician–patient relationship; physicians

John makes an appointment with his primary care physician (PCP) to discuss his family history of heart disease, at which time they agree to pursue genetic sequencing of John's DNA. John has his genome sequenced at a clinical testing lab, which sends the results to John's PCP. The lab report concludes that there are no known significant genetic risk factors for heart disease in John's sequence, but flags several variants of unknown significance (VUS) that may be associated with cardiovascular risk. The PCP tells John that his genetic sequence provides no clinically actionable information regarding his risk of heart disease. Two years later, a peer-reviewed study is published linking one of John's VUS to a significant risk of cardiovascular disease and recommends that patients with the variant be prescribed a statin as a preventive measure. Nothing is communicated to John by the PCP or the testing laboratory following the publication's release. Three years later, John suffers a

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fatal heart attack, and his family sues both the PCP and the laboratory, claiming they had a duty to recontact John and update his clinical management.

Fortunately, this scenario has not yet occurred to the knowledge of these authors. However, it is likely to arise in the relatively near future. As more individuals have their DNA sequenced or tested, physicians are increasingly presented with patient genetic testing or sequence reports. As scientific knowledge about the medical significance of genetic information continues to evolve, many physicians are concerned and uncertain about their long-term obligations to update medical advice and lack clear legal direction on their responsibilities to update and recontact patients in this regard [1]. Some DNA sequencing laboratories and services have taken it upon themselves to update previous variant classifications on an *ad hoc* basis and send updated analyses directly to the patient's physician [2,3]. Further, a pending lawsuit filed in South Carolina in 2016 [4] addresses the duty of a laboratory and physician to update advice to a patient after a variant initially classified as a VUS is found to be clinically significant [5].

In this perspective, we evaluate the potential legal obligation of physicians to recontact patients with updated genetic information. We conclude that with certain limited exceptions, physicians have no general affirmative duty to recontact patients about new findings regarding a patient's genetic data, but suggest that certain physician best practices would help minimize exposure to liability and provide the best possible professional service to a patient.

A physician's general duty to update & recontact patients

Before exploring a physician's duty to follow-up with respect to new genetic information specifically, it is useful to first delineate a physician's duty to update and recontact a patient generally with new medical information. The 'duty to recontact' necessitates 'the communication of new information to a patient concerning a previously rendered service' [6]. This duty to follow-up is generally restricted to those situations where a physician is responsible for a previously rendered service that requires updates or recontact. One such situation is when a physician performs a procedure or prescribes a treatment that requires a subsequent follow-up procedure or test, in which case the physician could be liable for 'abandonment' for failing to recommend such follow-up (recognizing that the ultimate decision on whether to undergo such follow-up is the patient's choice) [7]. Abandonment has been defined as 'the unilateral severance by the physician of the professional relationship between himself and the patient without reasonable notice at a time when there is still the *necessity of continuing attention* (emphasis added)' [8].

A second limited duty to update or recontact arises if, subsequent to treatment with a drug or device prescribed by the physician, the physician becomes aware of new, potential negative health implications associated with that treatment, such as a warning issued by the US FDA [9,10]. Because the new risk arises out of the former, yet still active, specific treatment prescribed by the physician, the physician retains the responsibility to warn the patient of the risk. Healthcare providers have been successfully sued for failure to advise patients of such new risk information relating to a device or drug that the patient is still using [11,12].

Other than these two limited situations, there is no general duty to update or recontact existing or past patients with new medical information unrelated to a specific treatment or product currently prescribed by the physician. To date, and with regard to current patients, medical practice has been for physicians to:

“Rarely re-examine old records in the absence of a particular reason to do so, which is almost always triggered by a concern raised in a current patient encounter... Not surprisingly then, clinicians rarely contact patients to tell them that information obtained on a previous encounter has suddenly become relevant because of new research [13].”

In other words, physicians do not have an affirmative legal duty to be the active managers of their patients’ health, despite the general trend in healthcare suggesting physicians be more proactive. A physician’s responsibility is simply to respond capably when a patient presents with a specific concern, symptom or for routine clinical evaluation, or when a physician recommends a course of treatment. For example, a physician may exercise good professional care in recommending a patient make regular appointments, but the physician faces no liability if the patient fails to make said appointment [14]. A physician may exercise good professional judgment in recommending a future course of care for an identified health risk in a specific patient, but the physician is not legally liable if the patient fails to pursue that course of action. For instance, if a physician knows that a patient had varicella as a child, that physician exercises sound professional judgment by recommending the patient consider a shingles vaccination, but there are no cases on record of a physician facing liability for failing to recommend proactively that the patient receive such a vaccination. In summary, there is no general legal requirement for physicians to contact a former patient about new information or medical advances ‘discovered after the patient’s last episode of care’ [15].

Genomics create a unique follow-up dilemma for physicians

Like many things, the practice of medicine is not what it used to be. Advancements, particularly in the realm of genomics, are occurring at incredible speed. The clinical significance and interpretation of gene variants is constantly evolving. Tens of thousands of Americans have now had whole-exome sequencing or whole-genome sequencing, numbers that will rapidly grow into the millions within the next few years. A 5-year-old interpretation of a DNA sequence is the modern equivalent of a flip-phone in that its application is rapidly outdated by advancing technology and knowledge.

What is unique about genetic sequencing is that unlike most medical tests that can, and should, be repeated over time to assess the changing status of the patient, whole-exome sequencing or whole-genome sequencing of a patient’s genotype only needs to be conducted once (although some early-adopter patients may eventually choose to resequence their genome as the accuracy and completeness of the sequencing technology improves). While a patient’s DNA sequence is essentially static, the clinical implications of that sequence will change over time as new studies and data reveal new medical implications of variants that were previously of uncertain significance. These new discoveries could have a profound health impact for the patient. This creates a unique dilemma in healthcare in which physicians face the potential opportunity and responsibility, both professional and legal, for

ongoing monitoring and updating of genetic-based medical advice that will be subject to constant modification throughout the patient's lifetime.

The question raised is whether this new medical situation creates new legal duties – specifically, whether a physician has a duty to update advice or recontact an existing or former patient upon discovery of new genetic health information that was not originally available at the time of previous patient contact. In this transitional period toward greater integration of genetic information into clinical care, it is critical that physicians be provided clear guidance on their legal obligations and responsibilities with respect to these new data [16]. The case is strongest that a physician has no duty to update or recontact when there is no ongoing physician–patient relationship, so we begin our analysis with the establishment and termination of the physician–patient relationship.

Establishment & termination of physician–patient relationship

The physician–patient relationship is the touchstone of a physician's legal duty to a patient. With few exceptions, none relevant here, an existing physician–patient relationship has been deemed necessary to advance a medical malpractice claim [17,18]. A physician–patient relationship is a consensual relationship requiring a patient, or another person acting on behalf of a patient, to engage a physician, who in turn consents to treat that patient [19]. While the formation of a physician–patient relationship is generally governed by principles of contract law, such a relationship may be implied based on the facts, making a formal agreement unnecessary [19,20]. The establishment of a physician–patient relationship typically requires the physician to offer, directly or indirectly, to see or counsel the patient, and to have undertaken at least a preliminary evaluation of the patient's condition. However, lack of personal contact will not necessarily prevent establishment of such a relationship. For example, with the emergence of digital healthcare delivery websites offering doctor consultations, a requirement for an in-person examination of a patient in order to establish a physician–patient relationship may no longer be necessary [21]. In the same way, a specialist such as a geneticist who is consulted by patient's PCP to assess and provide medical advice about the genome of a person she or he otherwise has no other contact with, would likely be subject to a physician–patient relationship [22].

While the existence of a physician–patient relationship may be found more easily than not, the subsequent question is, when does it end? US courts have established that:

“[t]he duty to attend the patient continues so long as required unless the physician–patient relationship is ended by (1) the mutual consent of the parties, (2) the physician's withdrawal after reasonable notice, (3) the dismissal of the physician by the patient, or (4) **the cessation of the necessity that gave rise to the relationship** *[emphasis added]* [23].”

If a physician–patient relationship has been properly terminated according to one of these criteria, the physician will have no ongoing relationship or duty to the former patient, except as described above for a still-active treatment that the physician prescribed, underscoring necessity.

Accordingly, termination of the physician–patient relationship would extinguish any general duty to recontact a former patient about new genetic information. However, with continually emerging genetic data potentially relating to past patient encounters, it may be difficult to validate the cessation of the necessity that gave rise to the relationship. It is, therefore, advisable that a physician or specialist providing genetic advice to a patient on a one-time basis and with no expectation of ongoing care, expressly state in the *ex ante* informed consent and/or the *ex poste* disclosure of results that the provision of the advice terminates the physician–patient relationship and that there is no intention for an ongoing relationship. According to Clayton *et al.*, “(i)t seems unlikely that liability would accrue for information that was not known or knowable during the tenure of the doctor–patient relationship. Once the relationship has ceased, the duty is generally concluded”[24]. However, a genetic specialist who expressly terminates the doctor–patient relationship may discourage patients from pursuing ongoing integration of genetic advice into their healthcare, and therefore this strategy should only be used when there is clearly no need or intention for further follow-up, and the termination of the relationship is consistent with a patient’s original purpose and needs in engaging the physician.

A limited duty to current patients for genetic updates?

The greatest uncertainty pertains to whether a physician has an affirmative duty to proactively update genetic advice to a current patient. The unique opportunities for potentially helpful interventions from proactive scanning of a patient’s genome for new actionable findings puts pressure on the traditional rule that a physician does not have a legal duty to be proactive in identifying new opportunities to promote a patient’s health. With some limited exceptions discussed below, several factors when taken together provide a compelling case that physicians should not be held liable for failing to proactively update genetic advice to existing patients.

First, a general duty to update genetic recommendations is much broader and fundamentally different from the recognized duty to update patients with new information or follow-up procedures on a specific treatment administered by the same physician. Requiring the physician to identify new genetic risks or actions that are unrelated to any existing treatment is imposing an affirmative duty on the physician to proactively initiate a new patient engagement. This represents a fundamental departure from the current understanding of the limits and duties of the physician–patient relationship. As noted by Letendre and Godard:

“We do not think that the legal precedents regarding the duty to recontact theory, such as previously unknown risks related to drugs and medical devices... can be interpreted as a basis for the establishment of a legal duty to recontact patients of new genetic advances [25].”

Second, the uncertain significance of most new genetic information does not justify the radical step of over-riding traditional tenets of the physician–patient relationship. New genetic discoveries and their implications may, for a period of time, be unreliable, insufficient and subject to challenge and refutation. This is due, in part, to polygenic and epigenetic factors affecting health risks, the limited magnitude of these risks (which may vary among individuals) and environmental and social factors affecting both risk and clinical

management. In addition, most physicians lack sufficient knowledge and tools to evaluate new clinical implications of genetic sequence data [25]. Unilateral disclosure of new genetic information by physicians may thus be ill-advised, except in cases of clear patient benefit.

Third, imposing a duty on a physician to regularly check each patient's genome sequencing data, consisting of potentially hundreds or thousands of variants per patient, most of unknown significance, would be unduly burdensome. At least until better tools are available, it could take a PCP or other provider several hours to update all the variants for a given individual. The clinical laboratory that did the original sequencing of the patient would be better suited to periodically re-evaluate genetic sequence results for new actionable results, but no court decision has, to date, imposed such a duty on laboratories. It is likely that algorithms will be developed in the future that will simplify and expedite this re-analysis of sequencing data, but such algorithms are not in general use today. Therefore, incorporating genetics-related reporting and clinical management into general clinical practice presents a significant challenge. Quality of care would likely suffer if physicians were tasked with updating patient genetic advice as a routine matter. Physicians would be unable to evaluate the same number of patients per day, be required to dedicate large amounts of typically uncompensated time gaining the requisite knowledge, be obliged to remain informed on the latest genetic research outcomes, need to become familiar with various genetic diagnostic tools and develop a legally compliant medical record flagging and recontact system, among other vital responsibilities. Although not determinative of legal duty, insurance payers are unlikely to reimburse physicians for their time in these respects.

Fourth, not all patients will want to be informed of new genetic risks. The public is highly heterogeneous in what genetic information it wants to know [26], and some ethicists argue for a qualified right not to know [27]. Accordingly, patient consent is an important factor with regard to updating or recontacting patients with new genetic information. The American College of Medical Genetics and Genomics (ACMG) has recognized 59 pathogenic gene variants that should be disclosed to patients [28], but the controversy over this list suggests that not all patients desire disclosure of even these variants. There remains even more uncertainty about variants not appearing on the aforementioned ACMG list. Given the inherent ambiguity and heterogeneity surrounding patient views, and the potential psychological and discriminatory harms that could result from disclosure of unwanted genetic information [29], imposing a legal duty on physicians to unilaterally identify and communicate new genetic information to patients may be ethically problematic.

Finally, new legal duties should not be imposed upon physicians without clear guidance or express advance requirements. There is a lack of legal precedent, judicial and statutory, imposing a duty to recontact affected parties with regard to new genomic findings. In addition, there is a general lack of specific practice guidelines. The ACMG issued a Policy Statement in 1999 on the duty to recontact, but it is limited to a physician having a duty to recontact a consulting geneticist if and when a physician becomes aware, through patient interaction, of patient circumstances necessitating follow-up [30]. In most jurisdictions, medical malpractice is defined by custom, or what other physicians in the same practice area (and often same geographic area) would do under similar circumstances. Thus, to impose an

affirmative duty to recontact retroactively in the courts could reasonably be interpreted as unfair and inappropriate.

For all these reasons, as a recent review of the duty to recontact concluded, in the field of clinical genetics, a 'reasonable degree of care' has not yet involved a duty to recontact [1]. No legislation, regulation, clinical guidelines or court decision to date imposes a duty to recontact patients to update genetic advice.

What should physicians do?

While we conclude physicians do not have an existing general duty to proactively update genetic advice to a patient, given the absence of any existing statute, regulation, clinical guideline or court precedent that imposes such a duty, the growing role of genetics in healthcare will create new opportunities and duties, ethical if not legal, to apply this new information to promote patient health [15]. A challenge with the liability system, in general, is that even when there is no existing legal duty, a court may identify and extend a new legal duty in resolving a particular case and apply that new duty retroactively to the litigants in the matter. Healthcare providers therefore cannot be content relying only on existing established legal duties, but must also look proactively ahead for new duties courts may impose in the future, and which could apply *ex post facto* to their current activities. Such foresight necessarily involves a significant degree of speculation, uncertainty and unease.

There are some specific situations that can be identified now where a physician may have an ethical, and perhaps legal, duty (even in the absence of existing legal precedent), to engage in limited updating and recontact of patients with new genetic information. These include:

- Some genetic testing and genome sequencing laboratories are revisiting previous analyses in response to new information, and occasionally communicate new findings about a patient to the physician. For example, the laboratory may realize that a variant it had previously classified as of unknown significance is now believed to be pathogenic. The laboratory, rather than the physician, is best positioned to reanalyze sequencing data, but like the physician, has no existing duty to do so as established by an existing court decision or codified law. Yet, a laboratory that failed to pass on a known updated analysis that indicated a previous VUS was now known to be pathogenic, or a physician who received such an updated analysis from the lab but failed to pass it on to the patient, would be at risk of creating a new legal precedent by a court that found such inaction to be negligent. Thus, while updates from laboratories are neither routine nor standard, if a physician receives updated information about a patient that is of clinical significance, the physician should make reasonable efforts to communicate that updated information to the patient. One complication related to recontact is whether the patient wants to be recontacted. As discussed below, it would be prudent for any physician providing genetic advice to ask the patient if they wish to be recontacted if pertinent new information becomes available, and to only recontact and update if the patient provides such consent. If the physician

does not obtain patient's consent, the physician should only recontact and update the patient in cases of very significant and actionable new risk information.

- Pharmacogenetic data are being added to labeling on an increasing number of pharmaceuticals, such as warfarin (Coumadin®) and clopidogrel (Plavix®), with directions for genetic testing patients to help establish appropriate dosing. The current standard of care does not require genetic testing prior to commencing treatment with such drugs, largely because of the cost and the delay in treatment associated with testing. However, if a patient was previously genetically tested or sequenced for the relevant variants, the physician may have a duty to consult that available data in selecting an appropriate pharmaceutical starting dose [31].
- More generally, when a patient consults a physician about a specific concern or complaint, and the physician has access to previously collected genetic test or sequence data for that patient, the physician should consult that genetic information for possible association with the patient's health problem. While no bright line guidance currently exists for when a clinician should consult genetic information, relevant considerations include the indicators of a family history of the condition or disease, the severity of the condition, the availability of accessible algorithms or other clinical tools that identify potential relevant variants relating to the patient's health condition or risk and the availability of known effective preventive or treatment interventions if there is a genetic cause of the disease.

We have entered the genomic era. More and more patients will have genetic sequence data connected to their electronic health record. Automated systems will become available for reanalyzing sequence data and updating the significance of a patient's genetic information. Physicians will, therefore, increasingly assume a duty to access and apply those data, where relevant. There are existing resources such as ClinVar and ClinGen that can provide updated information on genomic variants, but it is not reasonable to expect non-genetic specialists to be familiar with such resources at this time. With narrow exceptions, any new duty of a physician will likely be limited to updating existing patients in ongoing care rather than taking the initiative to recontact current or past patients.

More generally, it is unfair and confusing to expect clinicians and laboratories to try to predict what new or extended legal duties may evolve through court precedents in the future. Legislators, regulators and clinical guideline organizations should be vigilant to rapidly changing scientific knowledge and capabilities and attempt to clearly identify new legal duties and expectations as the science progresses, and courts should be reluctant to retroactively impose new duties on providers without due notice.

In addition, there are steps a proactive physician may elect to undertake, if not too resource burdensome, to help clarify the duration and nature of the physician–patient relationship to both enhance patient care and protect the physician from unwarranted liability risks. These steps may include:

- Given the contractual nature of the physician–patient relationship, set out the specific terms and limitations of the relationship, including termination and any

recontact provisions related to relevant and reliable genomic findings, at intake or in the form of a patient update. These terms and limitations should be tailored to the initial purpose of the physician engagement and the patient's need for ongoing treatment and advice. The terms should not be too narrow so as not to render the contract unenforceable or to dissuade the patient from pursuing appropriate follow-up;

- At intake, or in the form of an annual update, request a time-limited patient recontact consent for updated relevant genetic information. This consent would put clear limits on the time period that the patient may expect physician recontact (e.g., 1 year), and would specify the types of updated genetic information the patient chooses to receive (e.g., only significant actionable risk data).
- Emphasize to all patients the importance of remaining in regular contact with the physician's office if there is an ongoing physician–patient relationship and to provide current phone number and address updates;
- Provide the patient with links to applicable, informative and reliable healthcare websites; and
- As it becomes available, purchase software that is compliant with healthcare privacy laws that facilitates matching new genomic information to current and former patients.

It is also important to recognize that such steps, if undertaken by a significant number of providers, may create a new standard of care to require such actions, which in most jurisdictions is based on the practice of similarly-situated providers.

Conclusion

Examination of existing legal precedent, doctrine and trends suggests that a general legal duty to recontact patients about new genetic findings does not exist at this time, even though the unique nature of genetic data challenges traditional medical custom. This lack of duty to recontact is most clear in situations where there is no ongoing physician–patient relationship, so physicians would be well advised to clearly document the limited duration or termination of the physician–patient relationship when that is the parties' intent. For an ongoing relationship, there appear to be sufficient distinctions between newly discovered, relevant genomic health information and instances where a duty to recontact has been recognized in the past relating to an ongoing treatment regime. Imposing a general duty on the physician to take the initiative to unilaterally update a patient's genetic health record would be inconsistent with traditional roles of physician and patient, would impose undue practical and economic hardships on the physician, may violate the patient's autonomy rights and is not consistent with existing case law and guidelines. Nevertheless, given the fast pace of integration of genetics into clinical practice, some limited duties to recontact and update certain patients' genetic advice may exist, as outlined above.

Future perspective

It is likely that genomic information and DNA sequence data will become a standard component of clinical practice within the next decade. This type of health information is unique in that although the actual health data do not change as time passes, the clinical significance of those data will evolve with new scientific findings and understanding. Physicians will likely be held responsible for updating clinical advice in response to evolving genetic knowledge. This will represent a fundamental shift in the traditional physician–patient relationship, imposing a much more active role on physicians to proactively manage their patients' health.

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Executive summary

A physician's general duty to update & recontact patients

- A physician's duty to follow-up with a current patient has traditionally been limited to providing advice regarding an ongoing treatment originally prescribed by the physician.

Genomics create a unique follow-up dilemma for physicians

- The rapid adoption of genomic sequencing of patients is presenting unique challenges to physicians about their duty to follow-up previous genetic analyses with updated information, including potentially recontacting patients.

Establishment & termination of physician-patient relationship

- Given the potential for ongoing duties to patients regarding new genetic information, physicians should be more explicit on when a physician-patient relationship is terminated.

A limited duty to current patients for genetic updates?

- Consistent with traditional practice and practical and ethical considerations, a physician has no general duty to affirmatively follow-up with or recontact patients to provide updated genetic advice not related to an ongoing treatment.

What should physicians do?

- There may be limited duties for a physician to recontact patients with updated genetic information, such as when a laboratory sends the physicians an updated analysis of the patient's genetic information.