Malpractice Liability and Mobile Health

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Most of the legal commentary regarding mobile health has focused on direct regulation. Congress and several federal agencies have begun to address the risks posed by these technologies. Commentators have urged FDA and FTC to provide more meaningful oversight to ensure that mobile health technologies are safe and effective. In this paper, prepared for a workshop sponsored by the American Association for the Advancement of Science on liability issues arising from mobile health technologies, I focus on another means for ensuring that mobile health technologies are developed and used in a safe and effective manner: indirect regulation through malpractice liability for physicians and other health professionals.

Given the dearth of case law directly on point, I extrapolate from cases addressing analogous issues to assess potential malpractice liability concerns for health professionals who: (1) participate in the design of mobile health products; (2) use—or decline to use—mobile health products for patient care, and; (3) recommend or even prescribe the use of mobile health products by patients. I suggest that the advent of mobile health technologies does not necessitate the development of novel legal doctrines. Rather, existing doctrines are adequate to apply malpractice law to the development, use, recommendation, and prescription of mobile health products by health professionals. Like any other new medical technology, mobile health products are likely to amplify existing uncertainties in the professional liability context, at least in the short term. The customary standard of care for professional malpractice could act as a temporary drag on the adoption of new mobile health technologies by professionals, who may prefer to proceed with caution until prevailing professional practices emerge with respect to mHealth use. Over time, however, if these technologies prove useful and reliable, they could be incorporated into the standard of care in some contexts. At that point, the customary standard of care might accelerate adoption of mHealth technologies by recalcitrant physicians who would otherwise face potential liability for failing to make use of applications that would benefit patients.

A Brief Survey of Mobile Health Technologies

Tens of thousands of mobile health products are now available on the market. A typology developed by Nathan Cortez, which organizes these products according to function, is a useful starting point for my analysis. “Connectors” connect smart phones and tablets to FDA-regulated devices, enabling clinicians to view scans and other biometric readings, and/or acting as wireless remote controls for medical devices, raising the possibility of patient injuries. “Replicators” turn the smartphone or tablet itself into a medical device using attachments or sensors to send data directly to the smartphone, which then processes and displays the results, and in some cases recommends diagnoses or treatment options. “Automators and customizers” use surveys, algorithms, and the like to aid clinical decisionmaking and could lead to faulty

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2 Id.
diagnosis or treatment decisions. “Informers and Educators,” which make up a significant portion of the thousands of mHealth apps now on the market, are digital versions of resources that are also available in print or would have been in the past. “Administrators” are the mHealth equivalent of practice management software—to the extent that they are confined to scheduling patient appointments and performing billing functions, there are not significant liability concerns regarding administrator apps, but as they start to incorporate automator and customizer functions to triage patients for appointments, they could expose health care providers to liability. “Loggers and trackers” allow users to record and analyze information about their diet, physical activity, sleep patterns, and so on.

Potential Malpractice Liability Associated with Mobile Health Products

To hold a physician or other health professional liable for malpractice, a plaintiff must establish four elements: First, duty—the plaintiff must establish that a doctor-patient relationship was in effect at the time of breach, such that defendant doctor owed a duty of care to plaintiff patient. Second, breach—the plaintiff must establish that the defendant doctor’s conduct fell below the standard of care. Third, damages—the plaintiff must establish that she or he suffered physical harm. Fourth, causation—the plaintiff must establish a sufficient nexus between defendant’s breach and plaintiff’s harm. As discussed in detail below, for physicians or other health professionals who participate in the design or development of mobile health products, the primary issue is likely to be duty. For those who use (or decline to use) mobile health products in the context of patient care or who recommend or prescribe the use of such products by patients, the primary issue is likely to be breach.

Malpractice Liability for Health Professionals Who Contribute to the Design of Mobile Health Products

This paper does not address ordinary negligence or products liability, which are concerns for all developers and sellers of mobile health products. Some, but far from all, mobile health products are developed with input from health professionals. Participation of health professionals in product development raises the possibility of professional malpractice liability, which is the subject of this paper.

Physicians who participate in the design of mobile health products for use by the general public are unlikely to be held liable for injuries caused to individuals with whom they have not entered into a doctor-patient relationship. A physician who exercises medical judgment in designing or developing a diagnostic automator or customizer, for example, might fall below the standard of care and her negligence might cause injury to patients who are misdiagnosed or mistreated by providers relying on the app, but in the absence of a doctor-patient relationship between the developer-physician and the injured patient, the plaintiff will not be able to establish the duty element of a malpractice claim. Other kinds of tort liability, such as products liability, could be a concern, but not professional malpractice.

Where there is no nexus at all between the patient-plaintiff and the developer-physician, the duty element would not be satisfied. On the other hand, if the developer is also the treating physician—i.e., a physician develops an app and then uses it for the care of her own patients—then the duty element would be met and the court would move on to breach and causation to determine whether the case should be brought before a jury. There is, perhaps, a murky middle
Ground where a physician develops an app and then shares it with other physicians in her practice or network, who then rely on it for diagnosis and treatment or prescribe it for use by their patients. As detailed below, in analogous situations, courts often find that a doctor-patient relationship is formed based on minimal interaction between the two parties, but some form of engagement of the physician with a particular patient’s case is generally required. Thus, it is unlikely that physicians would be held liable for malpractice based on app development except in cases where the defendant-physician’s own patients are harmed.

**Liability cases**

A doctor-patient relationship can be formed with quite minimal contact between the doctor and patient, or even no direct contact between the two at all. The question is typically whether medical judgment has been exercised with regard to a particular patient’s case. For example, in *Bienz v. Central Suffolk Hospital*, 557 N.Y.S.2d 139 (N.Y. App. Div. 1990), the defendant doctor was sued for malpractice by an individual who had called the doctor’s office “for the purpose of initiating treatment.” The doctor moved for summary judgment, arguing that a telephone call to initiate treatment does not form a doctor-patient relationship. The court affirmed the denial of summary judgment, finding that a relationship may have formed and that more fact-finding was necessary to determine whether any medical advice had been given during the call. Similarly, in *Adams v. Via Christi Regional Medical Center*, 19 P.3d 132 (Kan. 2001), a malpractice claim was filed against an obstetrician following the death of a woman due to an undetected ectopic pregnancy. Although the defendant doctor had treated the woman previously, he had not seen her as a patient for several years. On the evening she died, her mother called the doctor and asked questions about her daughter’s abdominal pain. The doctor explained to the patient’s mother that such pain is typical in the early stages of pregnancy, recommended she go to the ER if her condition worsened, and to go see a doctor (not necessarily him) in the morning. Later that evening, she was taken to the ER and died. The doctor moved for judgment as a matter of law, arguing that he had not re-formed a doctor-patient relationship based on a conversation with the girl’s mother over the phone. The court affirmed the judgment against the doctor, finding that, because he did not decline to provide his medical opinion on her case, he cannot say that he declined to form a doctor-patient relationship.

Where physicians have provided telemedicine consults, courts have sometimes allowed the jury to determine, based on the specific facts of the case, that a doctor-patient relationship was formed. In *White v. Harris*, 36 A.3d 303 (Vt. 2011), for example, the parents of a psychiatric patient who committed suicide sued a psychiatrist who had one online video consultation with the girl, as part of a research study on telemedicine. The court reversed the lower court’s grant of summary judgment, finding that the one-time consultation formed a doctor-patient relationship, which gave rise to a duty of care. The court remanded for the lower court to permit discovery on the scope of the duty and whether the doctor met that duty. Another example, *Bovara v. St. Francis Hospital*, 700 N.E.2d 143 (Ill. App. Ct. 1998), was a malpractice claim against two doctors who reviewed a patient’s film from an angiogram and informed the treating physician that the plaintiff was a candidate for angioplasty. The court found that the doctors, despite their lack of contact with the patient directly, could have formed a doctor-patient relationship with him. Because the question was one for the jury, the court reversed summary judgment for the physicians.

**No liability cases**
On the other hand, courts have sometimes found no treatment relationship in cases where the consulting physician did not have sufficient contact with the patient. In *Jennings v. Badgett*, 230 P.3d 861 (Okla. 2010), for example, the parents of a prematurely delivered child sued, among others, Dr. Schlinke, who had consulted over the phone with the treating physician. The parents contended that Schlinke was liable because his advice prompted the treating physician to deliver the baby prematurely. The court found that no doctor-patient relationship was formed and that “even though Dr. Badgett chose to rely on Dr. Schlinke’s opinion, Dr. Badgett was free to exercise his independent judgment.” Similarly, in *Hill ex rel. Burston v. Kokosky*, 463 N.W.2d 265 (Mich. Ct. App. 1990), the mother of a child born with cerebral palsy sued the doctors who had consulted with her treating physician about alternative birthing options. The plaintiff alleged that the doctors provided substandard advice to the treating physician. The court found that the consulting physicians could not be held liable based on a telephone call with the treating physician because neither of the consulting physicians had talked with the patient, examined her, or reviewed her chart.

Although the cases on duty are far from uniform, and cases are divided as to whether a remote consultation with the treating physician is sufficient in the absence of interaction between the consulting physician and the patient, I am unable to find a case in which a doctor-patient relationship has been found in the absence of engagement by the physician on a specific patient’s case (i.e., review of a specific patient’s films or record). Given this case law, it is unlikely that a physician who participates in the design or development of a mobile health product for use by the general public, rather than by her own patients, would be subject to professional malpractice liability. Development of an app for use by patients within a particular physician group practice or network might be considered a gray area, but liability remains unlikely in the absence of the defendant’s exercise of medical judgement with respect to an identifiable patient, as opposed to a general patient population.

**Liability for providing medical services without forming a doctor-patient relationship**

Although malpractice liability for developer-physicians is unlikely in the absence of a doctor-patient relationship, it is worth noting that there are several telemedicine cases in which medical boards have taken disciplinary action against physicians who performed medical services—especially prescription writing—without forming a doctor-patient relationship. In *Jones v. North Dakota State Board of Medical Examiners-Investigative Panel B*, 691 N.W.2d 251 (N.D. 2005), for example, Dr. Jones worked for an online prescription service, providing prescriptions for non-narcotic medications (mostly erectile dysfunction drugs) to individuals who filled out the company’s online survey. Jones reviewed the survey responses, directly calling the individuals when necessary to ask additional questions, which he rarely did. The state board revoked the doctor’s license for writing prescriptions without establishing a doctor-patient relationship and Dr. Jones appealed, arguing he did not violate the state medical statute. The court upheld the board’s findings, holding that writing approximately seventy-two prescriptions per hour (extrapolating from Dr. Jones’ testimony) made it impossible for him to spend sufficient time evaluating a patient’s medical needs sufficient to establish a doctor-patient relationship. Similarly, in *Golob v. Arizona Medical Bd. of State*, 176 P.3d 703 (Ariz. Ct. App. 2008), the state medical board censured and suspended Dr. Golob for providing prescriptions to individuals through an online prescription service without forming a doctor-patient relationship. Individuals filled out an online form and paid a fee for the questionnaire to be reviewed by the physician. In
some cases, the individuals would answer questions over the phone, but operators working for the company, rather than the physician, would ask the questions; Dr. Golob purportedly “directed” the operators to ask the questions. The court upheld the board’s decision, finding that these acts did not establish a doctor-patient relationship. These cases suggest that developer-physicians could face professional disciplinary action, which is akin to malpractice liability, but distinct. Notably, disciplinary action would be a concern even if no identifiable patients have been harmed by the defendant physician’s negligence.

**Malpractice Liability for Health Professionals who Rely on Mobile Health Products for Patient Care**

Health professionals who use mobile health technologies directly in the context of patient care could be held liable for malpractice if a patient is harmed. Conversely, a health professional who declines to make use of data provided by a patient via mobile health technology (which is likely to be overwhelming in its volume) could be held liable if she misses important information, delaying diagnosis and harming the patient. But in either case, the physician will only be held liable if she fails to exercise sound professional judgement in the use of mobile health technologies.

The customary standard of care adopted by courts to adjudicate the breach element of malpractice claims requires that physicians exercise “the degree of skill and care that a physician must use in diagnosing a condition is that which would be exercised by competent practitioners in the defendant doctors’ field of medicine…. Negligence may not be inferred from a bad result. Our law says that a physician is not an insurer of health, and a physician is not required to guarantee results. He undertakes only to meet the standard of skill possessed generally by others practicing in his field under similar circumstances.”

If a physician’s use or non-use of a mobile health product reflects reasonable medical judgement, then she or he is unlikely to be held liable, even if the product malfunctions or is poorly designed or if key information buried in masses of irrelevant data is missed. In a case of misuse, a court might consider whether the physician should have known how to use the technology properly or should have refrained from using it if she was not sufficiently informed regarding its proper use. In the case of product malfunction, the question would be whether the physician knew or had reason to know that the product was defective, poorly designed, or otherwise prone to malfunction. In the case of non-use of patient data provided via mobile health products, the question would be whether a reasonably competent physician could have and would have taken hours to sort the wheat from the chaff.

It is worth noting that in about half of jurisdictions, the standard of care is defined differently for informed consent claims. If the basis of a claim by an injured patient is that the physician failed to inform him adequately of the risks associated with the use of a mobile health product, courts in about half of jurisdiction adopt a patient-centered, rather than a doctor-centered, standard of care. In these courts, “the patient’s right of self-decision shapes the boundaries of the duty to reveal…. Thus the test for determining whether a particular peril must be divulged is its materiality to the patient’s decision: all risks potentially affecting the decision must be unmasked. And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.”

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the courts would ask whether information about mobile health products that the defendant-physician failed to provide would have been material to a reasonable patient’s decision about whether to consent to treatment.

Under either the patient-centered or physician-centered standard of care, malpractice doctrine obligates physicians to take reasonable steps to inform themselves regarding the limitations of the resources available to them and adjust their conduct accordingly. For example, in *Hall v. Hilburn*, 466 So. 2d 856 (Miss. 1985), the defendant doctor argued that the nursing staff provided by the hospital were incompetent. The court found that the defendant was obligated to adjust his conduct in light of what he knew or should have known about the competence of nursing staff—declining to rely on their independent judgment if he knew them to be incompetent. Another case from the same court, *Boyd v. Lynch*, 493 So.2d 1315 (Miss. 1986), illustrates the importance of the reasonableness standard as applied to a physician’s reliance on available resources. Although an expert witness suggested that a doctor should generally work with a nurse for at least six months before justifiably relying on that nurse to independently assess patients, the state supreme court affirmed a directed verdict for the defendant, finding that, under the circumstances, the doctor’s reliance on the independent assessment of a nurse he’d known for only one month was insufficient to show that the defendant had breached the standard of care for general practitioner physicians. Similarly, in *Forsberg v. Edward Hosp. and Health Servs.*, 906 N.E.2d 729 (Ill. App. Ct. 2009), another state court found that the defendant doctor reasonably relied on nurses who were responsible for collecting surgical sponges during a surgery. In *Pacheo v. Ames*, 69 P.3d 324 (Wash. 2003), however, the court found that, under the circumstances, the defendant oral surgeon unreasonably relied on a referring dentist’s handwritten notation on an x-ray, resulting in a procedure performed on the wrong side of the patient’s mouth. The relevant inquiry, then, is whether the defendant physician’s reliance on any given resource (be it a nurse, a medical record, or a device) was reasonable under the circumstances.

By implication, if, for example, a physician using a “connector” product misreads a patient scan on a mobile device due to poor lighting conditions, the appropriate question for purposes of the physician’s malpractice liability is whether she conformed to the prevailing standard of care and exercised reasonable medical judgement under the circumstances. This is not much different from a situation where a physician misreads a scan at a time when she is experiencing blurry vision—should she have realized that conditions were inadequate and adjusted her conduct appropriately? Was it reasonable for her to rely on her vision, which she knew to be compromised? Similarly, if a physician relies on an informer or educator product in the course of researching a patient’s condition, that is not fundamentally different from relying on a print publication. Would a reasonably prudent physician have known that the product was unreliable? If a physician relies on a “replicator” product to serve as a stethoscope, or an “automator” product to determine the appropriate dose of anesthesia and that product is poorly designed or malfunctions, the question will be whether the physician’s reliance on the product reflects sound professional judgment in light of what she knew or should have known about it. Did the physician take reasonable steps to inform herself of the limitations of the product? The standard of care is typically quite forgiving, holding doctors liable in situations where the dangers of the defendant’s approach were widely known among peer physicians or should have
been evident to her under the circumstances, but generally not requiring that physicians take extraordinary steps to exhaustively research every technology or resource on which they rely.

The adoption of a new technology may introduce some uncertainty as to what physicians know or should know about the design and appropriate use of that technology. Like any other treatment innovation, the customary standard of care for malpractice—which boils down to what other physicians in good standing would have done under the circumstances—can lead to liability concerns acting as a drag on adoption of innovative approaches. Doing things “the old way” can appear safer from a liability standpoint, but that is true only up to an ill-defined tipping point at which the innovation becomes the prevailing standard of care. In any case, the basic inquiry is the same; there is no need for the development of new mHealth-specific doctrines.

**Malpractice Liability for Health Professionals who Recommend that Patients Use Mobile Health Products**

Health professionals who recommend the use of mobile health technologies to their patients, without using them directly, could similarly be held liable if the recommendation to use mHealth products for the purposes of patient self-care does not reflect sound professional judgement or deviates from the prevailing standard of care. Again, this is not fundamentally different from low-tech scenarios. If a physician recommends that a patient use a logger and tracker physical fitness app, she must take reasonable steps to inform herself regarding the regimen that the app will urge the patient to adopt and must apply sound medical judgement to determine whether that regimen is appropriate in light of the patient’s condition. There are probably more permutations, and perhaps more unknowables, in this scenario, compared to a physician recommending that a patient start a particular exercise regimen such as P90X, because the app is personalized and may allow for nearly endless permutations. This problem is amplified if we are talking about a pediatrician recommending that parents use a customizer product that amounts to an all-in-one diagnostic tool before calling the doctor. It would be harder for a physician to evaluate all of the possible recommendations of a customizer app than to read a book that gives basic advice on whether to call a pediatrician or take a child to the emergency room based on particular symptoms. But again, the basic doctrinal approach—what should the physician have known about the product she was recommending or prescribing? What, if any warnings or instructions regarding self-care should the physician have conveyed to the patient?—remains the same.

**Conclusion**

Physicians and other health professionals are accustomed to adapting as new technologies and methods are introduced, which are often modified with practice. New technology often introduces uncertainty as to what physicians know or should know about its appropriate use. As with any other treatment innovation, the customary standard of care for malpractice can chill or accelerate adoption of new approaches. Doing things “the old way” can appear safer from a liability standpoint. But that is true only up to an ill-defined tipping point at which the innovation becomes the prevailing standard of care. Malpractice liability for physicians who participate in the design of, rely on, or recommend and prescribe mobile health products does not

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raise novel legal issues. However, existing legal doctrines will likely influence the development and adoption of mobile health products by health professionals.