

## **Diagnosing in the Home:**

### **The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Diagnostics and Therapeutics Outside of Traditional Clinical Settings**

#### **Call for Abstracts**

**Spring 2022**

The [Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics](#) at Harvard Law School is pleased to announce plans for our 2022 annual conference: “Diagnosing in the Home: The Ethical, Legal, and Regulatory Challenges and Opportunities of Digital Diagnostics and Therapeutics Outside of Traditional Clinical Settings.” The conference is organized in collaboration with [Julia Adler-Milstein](#), Professor of Medicine and Director of the Center for Clinical Informatics and Improvement Research at University of California San Francisco, and [Daniel Kramer](#), Assistant Professor of Medicine at Beth Israel Deaconess Medical Center.

#### **Conference Description**

Even prior to the COVID-19 pandemic, health care delivery was already shifting away from the clinic and into the home, utilizing telehealth, wearable sensors, ambient surveillance, and other products. The COVID-19 pandemic has shown the value of when “health care comes home.” Trends such as facilitating aging at home for seniors, keeping patients out of the clinic as much as possible, and telehealth have only been accelerated by the pandemic. For example, telehealth made up 50% of all physician visits in mid-April 2020 in response to the pandemic, and continues to grow far past pre-pandemic rates.

We are currently in a unique position to reflect on the 2020-21 explosion of at-home digital health care and to think through the ethical and legal challenges and opportunities of this shift, finally leaving the 20th century focus on the clinic and the hospital for a more modern model. Patients will increasingly interact with digital products from the start of their care, using wearable sensors to monitor changes in temperature or blood pressure, conducting home or self-directed testing before virtually meeting with a physician for a diagnosis, and then using smart pills to document their adherence to the prescribed treatment. Some of these products may be direct to consumer while others will be designed to be integrated into the existing health care system. Some medical care may be relatively easier to translate from the clinic to the home due to factors, such as pre-existing clinician/patient relationships. Other services, such as diagnostics, may prove more complicated to shift into the home.

This conference will engage with the vision for a 21<sup>st</sup> century health care system that embraces the potential of at-home digital products to support diagnoses, improve care, encourage caregivers, maximize pandemic resilience, and allow individuals to stay within the home when preferable. We welcome contributions that explore the ethical and/or legal questions raised by both direct to consumer and health system integrated technologies. Preference will be given to contributions that engage with regulatory considerations, such as the governance of protected health information or the involvement of the FDA. Similarly, preference will be given to contributions that focus on diagnostics rather than therapeutics. Contributions that focus on wellness products that do not go to the diagnosis or treatment

of health conditions will be outside the scope of this conference. Overall, this conference and subsequent book project will consider the ethical, sociological, regulatory, and legal challenges and opportunities that we will face in the coming decade that are presented by the implementation of digital products that support clinical diagnosis and/or treatment in patients' homes.

### **Call for Abstracts**

We seek papers that offer innovative conceptualizations and advance inventive approaches. Abstracts should focus on the fresh contributions the presentation will make, including sketches of the supporting arguments. The abstract should include (but not be limited to) a paragraph summarizing the issue that will be addressed and challenges to its resolution. Successful abstracts will explicitly address how the proposed presentation will address the ethical and/or legal challenges presented in the evolution of health care out of the clinic and into the home, especially in the context of diagnostics.

We welcome submissions on both broad conceptual questions and more specific policy issues related to the implementation of diagnostic and therapeutic at home digital technologies. Potential topics include:

- Access and Equity Concerns
  - If at-home digital health care requires a smartphone or other device as a prerequisite to use, to what extent will disparities in access to those technologies lead to disparities in health outcomes?
  - What regulatory changes can be made to utilize value-based care and other alternative payments to better promote equitable access to at-home digital health care technologies?
  - How can diagnostic at-home digital health care technologies bridge or worsen existing inequalities in access to health care?
- Social Interconnectedness Challenges
  - How will the patient-provider relationship evolve if the two parties are never physically in the same space?
  - What are the ethical and legal implications of physicians having access to vast amounts of patient data that they cannot review in detail? How will the standards of care shift with the explosion of at-home patient generated data?
  - With the placement of health diagnostics in households that often contain more than just the patient, how should we re-evaluate the role of caregivers, family, and housemates in the medical relationship?
- Patient Privacy Regulatory Questions

- How do we design at-home health products to reflect the importance of privacy while still utilizing the data generated by these products?
  - What are the ethical and legal expectations for the sharing of information recorded by at-home digital health devices with non-physicians, such as employers and schools?
  - What heightened legal and ethical privacy protections are needed to protect the sanctity and privacy of the home even in the context of health care?
  - What sort of access should patients have to the data generated by these technologies? Who decides what is appropriate for patients to access? Does the company or data holder have the right to limit patient access to this data?
- Role of Regulatory Agencies
    - Which institutions are best poised to regulate these technologies? To what degree are new regulatory frameworks needed (versus relying on those that exist today)? What regulatory tools are available for them to do so?

**Please note that this list is not meant to be exhaustive;** we welcome all abstracts related to the conference's central question, even if the particular topic was not specifically listed here. **Proposals should demonstrate a clear linkage to all three aspects of the conference: diagnostics; at-home digital health care; and ethical, sociological, or regulatory innovation.** Papers that focus on ethics should include substantial discussion of policy implications. Relatedly, law will be treated broadly to include governmental policy decisions more generally. Successful abstracts will propose or outline an argument/position, rather than merely stating a topic. Purely technical submissions will likely be outside the scope of this conference.

In an effort to encourage interdisciplinary and international dialogue, we welcome submissions from legal scholars and lawyers, bioethicists, philosophers, clinicians, medical researchers, disability rights advocates, public health practitioners, economists, government officials and staff, and others who have a meaningful contribution to make on this topic. We welcome philosophical and legal reflections from contributors across the world, but with preferences to contributions that are general, or United States- or European Union-focused. We welcome submissions from advocacy organizations, think tanks, and others outside academia, but emphasize that this is a scholarly conference, and abstracts/papers will be held to academic standards of argumentation and support.

**Have more questions about submitting an abstract? We will address FAQ on our blog, [Bill of Health](#).**

### **How to Participate**

If you are interested in participating, please send a 1-page abstract of the paper you would plan to present to [petrie-flom@law.harvard.edu](mailto:petrie-flom@law.harvard.edu) as soon as possible, but **not later than October 14, 2021**. If

your abstract is selected, your final paper will be due on **March 28, 2022**, and you will be assigned a presentation slot for the conference. **All presenters must provide a full final draft in order to participate. Presenters are expected to attend the conference for its full duration.** We will accept conference papers of all lengths and styles (e.g., law review, medical, philosophy, or policy journal, etc.), but presentations will be limited to 15 minutes.

We currently anticipate that the conference will be in person, on the Harvard Law School campus, in early June 2022. We will pay travel expenses for presenters who must travel to Cambridge; co-authored papers must name a single presenter. Due to COVID-19, however, we cannot guarantee that the conference will be in-person. If we are unable to host the conference in person, we will work to translate these materials into a virtual event to be held in early June 2022.

In the past, we have successfully turned several of our conferences into edited volumes (e.g., with Cambridge, MIT, Johns Hopkins, and Columbia University presses). It is possible, although not guaranteed, that conference presenters will publish their papers with us in an edited volume whose chapters will be limited to 5,000 words, including references. **All presenters should plan on contributing their submission to any subsequent volume arising from the conference and should not submit an abstract if they anticipate this will be a problem.** Previous conference participants have been able to publish their submissions in different formats in multiple venues, for example both as a short book chapter and a longer law review article. However, the version that will be used for an edited volume should not have been published previously or be planned to publish separately.

## How to Register

Registration information is available [here](#). Attendance is free and open to the public. [Register now](#) for updates on date and format, as well as the conference agenda, which will be posted to our [website](#) once abstracts have been selected.

## Questions

Please contact the Petrie-Flom Center with any questions: [petrie-flom@law.harvard.edu](mailto:petrie-flom@law.harvard.edu).

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