The Rise of Digital Health and Innovation Centers at Academic Medical Centers: Time for a New Industry Relationship Paradigm

Ravi N. Shah, MD, MBA; Jodie Nghiem, BS/BA; Megan L. Ranney, MD, MPH

First coined in 2000, the term digital health originally referred to leveraging the internet to improve medical content, connectivity, and commerce. Since then, it has come to encompass everything from mobile health to wearables to telemedicine to personalized medicine. It is promoted as having the potential to revolutionize the diagnosis and treatment of disease, the experience of health care, and the advancement of population health. Private-sector investment in digital health has grown quickly, from $2.1 billion in 2013 to $14.1 billion in 2020. In parallel, an increasing proportion of patients are gravitating toward digitally augmented health care tools. In a 2018 survey, 89% of consumers reported adopting at least 1 digital health tool, and in early 2020, health care systems rapidly adopted new digital services to manage the COVID-19 pandemic.

Academic medical centers (AMCs) developed technology transfer offices with the goal of participating in commercialization of intellectual property developed in universities. Digital health is rarely patentable, and as such, AMCs are beginning to create dedicated centers for digital health development, validation, and commercialization. The Brown-Lifespan Center for Digital Health, Brigham Digital Innovation Hub, and Stanford Medicine Center for Digital Health are examples offering services such as grant writing, research design, clinical validation, product piloting, and ad hoc faculty consultation. Some centers offer additional services; for example, Johns Hopkins HealthCare Solutions sells digital tools developed in house, and UCHealth CARE Innovation Center offers investments opportunities. The University of California, San Francisco’s SOLVE Health Tech focuses on innovation serving vulnerable populations. Collaborators include companies in digital health, health insurance, health care services, pharmaceuticals, technology, and venture capital. These collaborations offer AMCs the opportunity to bring evidence-based practices and quality thought leadership to digital health innovations in the real world while simultaneously generating new revenue streams. Although these new centers are exciting, they are not without risk, and the discussions involved are often uncomfortable or unfamiliar to clinician-scientists. In this Insight, we address key considerations for AMCs partnering with digital health companies to ensure successful collaboration.

Key Considerations for AMC Digital Health Collaborations

Effective industry relationships allow AMCs to harness their expertise to move the field of digital health forward in a meaningful way while maintaining their independence. First and foremost, AMCs working to develop such partnerships must deeply consider if the solutions offered truly address a real clinical need among patients or clinicians. For-profit companies developing health care technology are motivated to maximize profit, so it is up to AMCs to ensure that collaborations are ultimately aimed at solving a problem for patients or clinicians.

Initial contracting should also cover questions of intellectual property, branding, research integrity, and conflicts of interest. The contract should specify who will own intellectual property generated from the relationship and under what conditions the digital health company can cobrand with the AMC. Partnering with a digital health company may be construed as an indirect endorsement of a product, so AMCs need to clarify the parameters around marketing the partnership from the outset. In research partnerships, AMCs should retain the right to publish outcomes research.
no matter the results. Conflicts of interest should be disclosed publicly on an ongoing basis and in any publications to promote transparency.

Regulations such as the Anti-Kickback Statute and Stark Law prohibit clinicians from financially benefiting from clinical referrals. The Physician Payments Sunshine Act requires transparency from physicians regarding their financial ties to industry partners. AMC digital health centers must comply with these laws even as they seek to be compensated for their time and intellectual contributions in partnerships with digital health companies. Numerous appropriate financial models for such collaborations exist, ranging from a consulting fee paid to an institution, which compensates AMC faculty and staff for their time while minimizing conflict of interest, to equity arrangements, a particularly popular model for startups. Special considerations must be taken to weigh whether AMCs can remain objective if they take an equity stake in a company sponsoring its research. Preferential pricing is another common model, in which AMCs receive discounts on products they help develop or receive the products they help beta test for free. Other compensation options include licensing/royalties, sponsored research agreements, and external funding sources (eg, Small Business Innovation Research/Small Business Technology Transfer grants, foundations), each of which has its own benefits and pitfalls.

AMCs must ensure that patient privacy is held to the highest standard in both technology and internal processes. The data in electronic health records have monetary value to companies. Under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, AMCs may not hand over identifiable patient data to third parties without meeting all of the Privacy Rule's applicable conditions. However, few rules cover digital health companies' sharing and selling of their patient data, and ample exposés describe blatant HIPAA concerns, among even large digital health companies. AMCs must do their due diligence in evaluating any potential partner's internal privacy practices prior to partnership.

Sharing deidentified patient data is a gray area. Data sharing practices must be patient centered, meaning they should maximally benefit the patients whose data they are leveraging. Deidentified patient data may inform development of lifesaving digital therapeutics that could ultimately benefit patients with minimal risk; however, patients have prevailed in legal challenges to AMCs for sharing data with technology companies without consent.6 We encourage AMCs to develop processes that allow patients to opt out of sharing deidentified data and to ensure internal oversight of any deidentification processes. Finally, AMCs need to involve their chief privacy officers and general counsel before engaging in partnerships that share their data.

The rise of digital health innovation in health care has transformed patient and clinician expectations of the health care experience. AMCs can and should play a role in this innovation to ensure that clinical quality standards are met and evidence-based research is developed to better understand these changes. Doing so will require a new paradigm of private-sector partnerships beyond traditional technology transfer models. Critical steps to achieve this goal include laying out specific terms for intellectual property, branding, and publishing; managing conflicts of interest; developing best practices for data sharing; and considering current regulations in formulating compensation models. Innovation in partnership models will be required to support innovation in health care itself.
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REFERENCES