The Healthtech Declaration

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Healthcare technology—sometimes called "healthtech" or "healthsec"—is enmeshed with security and privacy via usability, performance, and cost-effectiveness issues. It is multidisciplinary, distributed, and complex—and it also involves many competing stakeholders and interests. To address the problems that arise in such a multifaceted field—comprised of physicians, IT professionals, management information specialists, computer scientists, medical informaticists, and epidemiologists, to name a few—the Healthtech Declaration was initiated at the most recent USENIX Summit on Information Technologies for Health (*Healthtech 2015*) held in Washington, DC. This Healthtech Declaration includes an easy-to-use—and easy-to-cite—checklist of key issues that anyone proposing a solution must consider (see "The Healthtech Declaration Checklist" sidebar). In this article, we provide the context and motivation for the declaration.

What Is Healthtech?

The healthtech field unites technological, primarily computer-based, solutions to healthcare. It aims to improve health with safe, secure, and appropriate technology use in four broad areas:

- Healthcare delivered by professionals in complex environments (for instance, hospitals, ambulatory practices, and ambulances).

Hospital IT systems and electronic health records (EHRs) are the main examples in this area.
- Healthcare managed by patients (for instance, for ambulatory patients with chronic diseases). Examples include handheld blood glucometers for diabetics and home dialysis.
- Healthcare in geographically distributed contexts (such as telemedicine, disaster relief, and less industrialized healthcare). This might include networked medical facilities, use of the Internet to send medical images, or use of many systems to connect patient data.
- Wellness (for instance, fitness monitoring). Examples include devices and apps for measuring activity, and weight.

The first three areas focus on professional users, patients as users, and resource limitations. The fourth area avoids the sometimes uncertain regulatory environments associated with clinical healthcare. Some technologies, like medical apps, apply to all four areas.

Note that healthtech covers devices for large organizational systems, as well as interoperability between those systems, including:

- devices, both external and implanted, that constantly measure patients' pulse, oxygen use, carbon dioxide, or respiratory rate;
- devices that examine the patient, for instance, MRIs, x-rays, and sonograms;

- devices that control the flow of medications and liquids into the patient, for instance, "smart pumps";
- laboratory equipment and devices that process measurements of blood, gases, cells, and so on—all of which must be reported to an EHR;
- software for sending prescriptions to pharmacies; and
- pharmacy IT systems, including warning systems for incompatible drugs.

Why Does Healthtech Need a Declaration?

Healthtech solutions almost never operate in isolation. They must work successfully in and connect to other environments, including human cultures, organizational protocols, odd physical environments, and multiple existing computer systems as well as contend with external and internal hackers—all while involving human users performing complex, sometimes competing tasks, often with time constraints.

Loss of situational awareness—often called *tunnel vision*—is a recognized problem among people who perform demanding tasks. For instance, surgeons might become unaware of a patient's vital signs while performing a complicated procedure. Similarly, when we do research, write papers, design or write programs, or referee papers or funding proposals, we get tunnel vision. Tunnel vision isn't necessarily due to unprofessionalism, but rather is an unavoidable consequence of a task's high demands—we must focus on these hard tasks and exclude distractions. For our purposes, we define tunnel vision as a narrowing of attention as a natural consequence of intensely dedicated professionals focusing on a specific task and being blinded to the larger field of issues around them.

The healthtech discipline's complexity limits our situational awareness. Literally without thinking

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The Healthtech Declaration Checklist

1. Healthtech is the interdisciplinary field that combines security, privacy, safety, human factors, computer science, health IT and healthcare and related disciplines.
2. Healthtech addresses real and vexing problems affecting healthcare worldwide that have defeated single-disciplinary approaches, products and research.
3. Solutions cannot be found in just individual disciplinary advances. What may seem like self-evident, obvious or simple solutions in each discipline separately (particularly to experts in those individual fields) are not sufficient to solve the vexing problems of healthtech. We must not evaluate healthtech ideas through the lens of any single discipline, where things might seem much easier and even solved.
4. While consumer IT is developing fast, we should not evaluate healthtech ideas only through the lens of "consumerism" (our personal experience) where solutions may be personally exciting and promising but of misleading value to healthcare.
5. Progress relies on interdisciplinary awareness and multidisciplinary collaboration. Progress must be made on many fronts, and progress in one area does not mean progress in another is not also worthwhile.
6. More rigorous research needs funding and doing. We note that while the overall view is that healthtech is a vexing problem, there are very few papers reporting problems. This success bias of the literature is well-known and is problematic for an area that must overcome problems. The bias is assisted by software vendors with significant vested interests and by enthusiasts who honestly seek solutions to healthcare's myriad problems.
7. The promise of IT, security, safety and improvement will be achieved on a foundation of rigorous research rather than by uncritical pursuit of the latest IT. Research requires an open approach, without concealing faults, without excessive "hold harmless" clauses, without nondisclosure clauses, and without other limitations.
8. Translating healthtech innovations and research into improved healthcare and health outcomes will require regulatory change and other cultural shifts, informed by rigorous evidence.

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about it, we lose sight of the critical need to consider outside perspectives. As authors, this might mean that we miss relevant context; as referees, it might mean that we criticize others who aren't pursuing the particular perspective we are devoted to.

A widely known example of tunnel vision in healthtech systems is developers routinely ignoring security issues. Hackings and breaks in healthtech systems are reported regularly. Tunnel vision explains this: it is very difficult to get healthtech to work at all; securing it is yet another step and sometimes gets overlooked.

Another simple indicator of tunnel vision is people's use of the word "just" when offering solutions. For

example, we "just" need interoperable systems, we "just" need big data, or we "just" need the latest IT. Any use of the word "just" suggests that the complexity of the emergent interdisciplinary problems is being ignored.

A common but unhelpful solution to healthtech problems is "just" having people learn human factors. Certainly, many IT systems fail to reach their potential because of human factor problems. But "just" telling vendors, developers, and programmers about human factors merely adds to their workload, introduces unfamiliar elements, and increases the likelihood of tunnel vision. Building a usable, secure, and safe system requires an understanding of how people interact

with computers that cannot "just be added on" bit by bit after the software is created. The program's very structure, and its interactions with other systems, affects how people visualize and interact with the data.

To mitigate tunnel vision, it's important to have an effective multidisciplinary team. In addition, the checklist is a particularly successful solution to tunnel vision. Good checklists spell out different steps, questions, or even points of view, forcing people to systematically consider other issues to widen their tunnel vision. In particular, if checklists are based on research, the issues they point out are both critical and effective. (See *The Checklist Manifesto* for an enthusiastic and powerful justification of checklists.[1]) The Healthtech Declaration can be used as a checklist: Are we—vendors, system designers, researchers, and reviewers—covering all perspectives fairly? If not, who can help?

The Gap between Promise and Reality

Computers play a leading role in the improvement and sustainability of healthcare. Yet current computers (embedded and other systems, such as implants and bedside devices) are often overly complicated, vulnerable, and insecure. They induce user errors and continually go obsolete.

In many countries, major initiatives to increase the use of computerization in healthcare have not delivered promised improvements in efficiencies and effectiveness. The UK's effort at installing EHRs for all citizens resulted in a £12.7 billion loss—one of the earliest well-known disasters. However, even that is eclipsed by the US$30 billion incentive to US healthcare IT firms that resulted in $3 trillion worth of IT investments generally regarded as user hostile and non-interoperative. Healthtech remains one of the world's vexing problems precisely because it is complex and tangled and it has repeatedly resisted best efforts internationally. The gap between healthtech's promise and reality is tragic, costing lives and health.

Sometimes it is easy to dismiss or underplay this gap because, in many areas of life, computers are getting better, faster, smaller, and more desirable. However, although modern IT might be good for us as consumers, we cannot yet answer whether and how it might benefit healthcare. Very few rigorous studies or experiments have been undertaken thus far.

As consumers, we can and often do ignore problems—we can have a cup of coffee while our mobile phone reboots or recharges. If we think our phone is slow, we can dream of buying a better one. If there is no Internet, we can do something else. In healthtech, these are not acceptable options.

Moreover, healthcare computers and the software they run aren't used in isolation but rather as part of complex, linked systems. These systems are often beyond the scope originally envisioned by the authors of each individual component comprising the system and are therefore prone to unforeseen errors. Complexity and failure modes grow quickly. Such systems' emergent properties cannot be understood by studying individual components in isolation—another form of tunnel vision.

Healthtech is a complex area tackling an urgent, vexing international problem. The problem is complex, but healthtech *as a discipline* need not become vexing! This Healthtech Declaration helps reduce the discipline's potential problems by clarifying the factors and the range of issues that can, separately or collectively, contribute to success. The declaration can be referenced by authors (of papers, theses, proposals, and so on) and freely used by referees.

We welcome feedback and will work toward an update in due course. ■

Reference

1. A. Gawande, *The Checklist Manifesto: How to Get Things Right*, Profile Books, 2011.

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