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Health information technology:Fallacies and Sober realities – Redux A homage to Bentzi Karsh and Robert Wears

Patricia A. Abbott [a,b], Matthew B. Weinger [c,d,*]

[a] Department of Systems, Populations and Leadership, USA
[b] Department of Leadership, Analytics, & Innovation, University of Michigan, School of Nursing, USA
[c] Departments of Anesthesiology, Biomedical Informatics, and Medical Education, Vanderbilt University School of Medicine, USA
[d] Geriatric Research Education and clinical Center, VA Tennessee Valley Healthcare System, USA

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ABSTRACT

Since the publication of "Health Information Technology: Fallacies and Sober Realities" in 2010, health information technology (HIT) has become nearly ubiquitous in US healthcare facilities. Yet, HIT has yet to achieve its putative benefits of higher quality, safer, and lower cost care. There has been variable but largely marginal progress at addressing the 12 HIT fallacies delineated in the original paper. Here, we revisit several of the original fallacies and add five new ones. These fallacies must be understood and addressed by all stakeholders for HIT to be a positive force in achieving the high value healthcare system the nation deserves. Foundational cognitive and human factors engineering research and development continue to be essential to HIT development, deployment, and use.

1. Introduction

Concerned about the current state of usability and safety of health information technology (HIT) in 2010, four experts came together to author a scholarly commentary entitled "Health Information Technology: Fallacies and Sober Realities" (Karsh et al., 2010). The paper was widely read (e.g., it has been cited by our peers over 300 times). Nevertheless, nearly a decade, we continue to face numerous challenges to the efficacious and meaningful use of HIT envisioned by the HITECH Act of 2009 (Burde, 2011). While HIT has produced improvements in some aspects of patient care, many of the issues we raised in 2010 regarding the impact of HIT on patient safety and care quality have intensified. The unintended consequences of new technologies, increased regulation, and continued integration of HIT into all aspects of healthcare has generated new areas of concern that must also be addressed. The prevailing sentiment before 2010, that electronic health records (EHRs) would help us to reach the "promised land" of remarkable transformation of health care with appreciable cost savings and improved user experience, has not yet transpired as predicted (Hochman, 2018). In addition, EHR use is now proposed to be a significant contributor to clinician burnout that is seriously jeopardizing the well-being of our healthcare workforce (Ommaya et al., 2018; Department of Health Human Services Department of the National Coordinator for Health IT, 2018; Reaction Data, 2017).

Even more unimaginable upon the publication of the original paper was that we would find ourselves today without the wise counsel and joyful presence of either Bentzi Karsh or Robert Wears, half of the original authors. Dr. Bentzi Karsh passed away prematurely at age 40 in 2012, leaving a large void in the scientific world of systems engineering and patient safety and an even-larger hole in the hearts of his many mentees and colleagues. The loss of Dr. Bob Wears in the summer of 2017 was another unexpected blow to the worlds of patient safety and Emergency Medicine. We honor them both in this revision.

2. The original paper

The original paper (Karsh et al., 2010) posited that the impact of HIT on the costs and quality of care were being impeded by a series of misguided beliefs or "fallacies" in regards to how users interact with technology. These misconceptions pervaded the HIT development and implementation processes thereby jeopardizing HIT efficacy and safety. Twelve fallacies were delineated (Table 1), each of which was linked to

* Corresponding author. Center for Research and Innovation in Systems Safety, Vanderbilt University Medical Center, Medical Arts Building, Suite 732, 1211 21st Ave N, Nashville, TN, 37212, USA.
E-mail addresses: pabbott@med.umich.edu (P.A. Abbott), Matt.Weinger@VUMC.org (M.B. Weinger).

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Table 1
The original 12 fallacies.

Fallacy	Brief Description	Current Status
Risk Free	Safety risks associated with HIT are minor and easily managed	**Remains:** Numerous studies have demonstrated the complex and multifactorial web of safety threats associated with HIT. These risks are context dependent and management challenges continue to intensify. (Hochman, 2018; Fry and Schulte, 2019; Ratwani et al., 2018c)
Not a Device	HIT can be safely created and deployed without substantive regulatory oversight	**Remains:** Regulatory imperatives have emerged as a necessity to temper information blocking, to reduce HIT burden, and to address safety concerns. (Ratwani et al., 2018; Hochman et al., 2019; Adler-Milstein and Pfeifer, 2017; Sittig et al., 2018b)
Bad Apple	When HIT is used 'incorrectly' or errors occur in its use, the end user (i.e., clinicians) is at fault	**Remains (but moderating):** Studies demonstrating the consequences of usage in ways that developer did not anticipate are shifting the focus to better design for safety and usability rather than user blame. (Fry and Schulte, 2019; Ratwani et al., 2018c; Adler-Milstein, 2017; Tolley et al., 2018)
Learned Intermediary	HIT risks are minimized because there is always a knowledgeable clinician to intervene before the patient is harmed, therefore vendors are "held harmless".	**Changing**: See paper for details
Use Equals Success	If HIT is used then it must be usable	**Changing**: See paper for details
Messy Desk	Clinical work is too messy and HIT should 'rationalize' it into something that is neat and linear	**Remains (but moderating):** Chaos and complexity are normal artifacts of the human condition. This fallacy persists, although awareness of the increasing complexity is rising. (Blijleven et al., 2017; Varpio et al., 2015; Alliance, 2017)
Father Knows Best	HIT has been designed by healthcare administrators to achieve the objectives they desire; thus end users are at their mercy in terms of tasks and workflow[a]	**Changing**: See paper for details.
Field of Dreams	If you provide HIT to clinicians, they will use it gladly and as the designer intended	**Remains (but moderating):** Increasing attention to clinician burnout related to EHR use has altered the discussion and efforts to address this are underway. (Linzer et al., 2017; Poghosyan et al., 2010; Dzau et al., 2018)
Sit-Stay (truth)	HIT can only do what its (human) designers tell it to do	**Remains:** Numerous studies have demonstrated the effects of HIT-induced errors and resulting workarounds. While there is greater attention on UCD, the problem remains considerable. (Ratwani et al., 2018b, 2018c; Wright et al., 2018a; Tolley et al., 2018)
One Size Fits All	One system (e.g., EHR) can be designed and deployed that provides optimal support for all users	**Remains (but moderating):** Heightened awareness of this fallacy is accelerating the importance of UCD and APIs. However, challenges remain. (Varpio et al., 2015; Clynch and Kellett, 2015)
Computerized Means Paperless	Deploying comprehensive HIT means that users won't need to use paper	**Remains (but decreasing):** Practical experience with the realities of the current healthcare environment have tempered this fallacy over time. (Department of Health Human Services Department of the National Coordinator for Health IT, 2018; Dyrbye et al., 2017) Advanced technologies should *someday* eliminate the need for paper.
Healthcare is Special	Healthcare is unique (special); neither other industries nor non-medical experts will be able to help us	**Remains (but moderating):** Belief that HIT can be developed/customized without intense end-user involvement and in the absence of HFE/SE expertise continues to result in markedly decreased usability. The insufficiency of fragmented "fixes" is giving rise to more systems-oriented approaches. (Ratwani et al., 2018c)

[a] This is a variant of Grudin's Law, one form of which is: "When those who benefit from a technology are not those who do the work, then the technology is likely to fail or be subverted" (Grudin J. Computer-supported cooperative work: history and focus. IEEE Computer, 1994; 27:19e27).

fundamental misalignments of HIT "use-as-designed" and the reality of increasingly complex and interconnected clinical environments. Unfortunately, many of these fallacies currently remain unresolved, and the situation is further compounded by various changes that are spawning a new generation of sober realities.

The 2010 paper issued a call for further contextual research of HIT by interdisciplinary teams of clinicians, informaticians, human factors and systems engineers (HFE/SE), user experience designers (UX), and vendors – making the point that it would take concerted effort by diverse teams to realize the benefits of HIT. We believed that the incorporation of cognitive and human factors expertise into HIT development and implementation was critical. The original authors warned that business as usual would only serve to worsen existing issues. In addition, we stated that "understanding what would help people in their complex work is not as simple as asking them what they want" (Karsh et al., 2010) (p. 620) highlighting the need for fundamental changes in how commercial HIT was developed and deployed.

The 2010 paper made three overarching recommendations: 1) Gain a much deeper understanding of how clinical work is actually done using human factors engineering and related methods; 2) Alter the policy and practical focus from revenue capture and achieving 'meaningful use' (as measured by discrete functionality or clinical activities) to supporting end users' ability to effectively and efficiently achieve better health; and 3) Substantially increase the involvement in HIT design and implementation of front-line users as well as experts in interaction design, HFE/SE, cognitive science, and related disciplines. In keeping with the mood in 2010 when the magnitude of the change introduced by HITECH had many up in arms, the original paper made it clear that we were not Luddites advocating a halt to the ongoing HIT development. Rather, the paper was a plea for changes to existing HIT-related policies, systems, and processes to enhance design and dissemination to achieve safer, more effective, and more efficient healthcare (Karsh et al., 2010).

In revisiting and updating this paper, we assert that many aspects of our three overarching recommendations have not been sufficiently addressed. While there has been appreciably more published on HIT usability (Carayon et al., 2015; Ashton, 2018; Ratwani et al., 2015a; Sittig et al., 2018a), poorly designed and unsafe HIT continues to be developed and deployed, with clinician dissatisfaction escalating (Hochman, 2018; Koppel, 2018; Friedberg et al., 2014; Slight et al., 2015). That said, we are encouraged by the recent attention being paid to usability and the burden of EHRs on clinicians emerging from the Office of the National Coordinator for Health IT (ONC) (Department of Health Human Services Department of the National Coordinator for Health IT, 2018), the National Academy of Medicine (Institute of Medicine, 2015), the Electronic Health Record Association (EHRA) (EHRA, 2017), the National Quality Forum (NQF) (National Quality Forum, 2017) and from various authors (Hochman, 2018; Koppel, 2018; Hill et al., 2013; Jones et al., 2012; Blumenthal, 2018; Ratwani et al., 2018).

In 2010, it seems we were naively optimistic. Expectations that the changes necessary to improve HIT would occur as the field matured did not materialize, and worsening HIT usability continues to impede the achievement of the Triple Aim (Barnett, 2017). In the ensuing decade, the Triple Aim has now morphed into the Quadruple Aim, where "care of the patient requires care of the provider" (Bodenheimer and Sinsky, 2014) pointing to the importance of professional well-being on the delivery of high-quality care. Therefore, in 2019, we shift our perspective to one of realistic optimism (Grant, 2011), cautiously hopeful of favorable outcomes, but with increased emphasis on the complexity of the work ahead and recognizing the challenges of activating all major stakeholders to achieve the desired goals. Unfortunately, we do not have the luxury of waiting another decade to make HIT safe, usable and efficient.

3. What has changed?

In the decade since publication of the first article, many aspects of healthcare have changed. Here we provide a high-level overview of several issues we believe are most relevant to HIT and that have contributed to the new fallacies described later in this paper.

3.1 The push to improve value in care has accelerated with an increasing emphasis on achieving *better quality*. HIT *should* play a critical role in this important societal goal.[1] As currently implemented, value-based care initiatives tie payment in part to achievement of specific clinical quality metrics, and commercial EHRs have purportedly been designed to capture the data necessary to generate these metrics. However, for the front-line clinician, this has manifested as increased EHR 'reminders' and checklists to provide, and then to document, the provision of discrete care activities (e.g., diabetic foot examinations, pneumococcal vaccines, etc.). In theory, automated reminders and documentation support will facilitate adherence to best practices and better quality. Paradoxically, many current HIT-based efforts to foster higher quality has adversely affected workflow, reduced efficiency, and may adversely affect care safety and quality. The processes of documenting, abstracting, measuring, and benchmarking 'quality' can be a major distraction to achieving it (Ratwani et al., 2018b; Parsons, 2012; Kandel et al., 2012; Haas et al., 2015; Krist et al., 2014). We call this as the "tyranny of quality (measurement)".

3.2 *Reimbursement* for the delivery of patient care necessitates increasingly detailed 'coding' of care activities performed and associated 'compliance' documentation. The inevitable escalation of payment-related bureaucratic requirements has been compounded by the recent implementation of ICD-10, the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD) which has more than five times as many unique codes (68,000 vs. 13,000) as its predecessor (ICD-9). The EHR has been designed to optimize reimbursement through discretized documentation (e.g., checklists or drop-down selections), constraints, and forcing functions. This design increases the conduct of revenue-generating activities and the auditable documentation to support it. However, similar to the tyranny of quality measurement, the use of these systems during patient care has increased documentation burden, disrupted workflow and decision making, and lead to undesirable workarounds (Blijleven et al., 2017). Studies have demonstrated that diversion of clinical attention can substantially degrade clinician-patient interaction, patient engagement, and patient satisfaction (Burde, 2011; Hochman, 2018; Carayon et al., 2015; Street et al., 2018; Asan et al., 2014; Babbott et al., 2014; Cohen et al., 2018).

3.3 Current HIT use is associated with clinician burnout (Babbott et al., 2014; Dyrbye et al., 2017). Computerization of clinical processes, especially but not exclusively related to documentation and coding, have substantially impaired the efficiency of front-line clinicians, increased "screen time" time (including appreciable after-hours HIT use by physicians) (Arndt et al., 2017; Gregory et al., 2017; Sinsky et al., 2016), and degraded the clinical work environment (Linzer et al., 2017). HIT has emerged as a significant contributor to the "epidemic" of clinician burnout, which is associated with worse clinician well-being (e.g., mental health issues, early retirement), diminished care quality and safety, patient dissatisfaction, and other poor organizational outcomes (higher costs, staff turnover) (Cohen et al., 2018; Wachter, 2015; Adler-Milstein and Jha, 2017).

3.4 A key putative benefit of HIT is the ability to access data about prior care independent of where that care was delivered. However, HIT interoperability remains elusive and in many areas of the US, it is not any easier to exchange data than it was 10 years ago (Hochman et al., 2019). Among the many reasons for this failure include the slow adoption of national data standards, unnecessarily variable and sometimes ill-conceived customization of vendor systems by healthcare entities, and the occurrence of both inadvertent and intentional 'information blocking' that prevents the free flow of data across systems (Adler-Milstein and Pfeifer, 2017). The proliferation of competing Health Information Exchange (HIE) initiatives, originally hailed as a way to appropriately access and securely share patients' vital medical *information* electronically, has fostered confusion and resistance. Vendors and health systems have been unwilling to participate in HIE initiatives, in part to discourage competition and enhance revenue (Ratwani et al., 2018; Adler-Milstein and Pfeifer, 2017). David Blumenthal, the second ONC Director, said that asking health leaders to exchange data is like "asking Amazon to share data with Walmart." (Fry and Schulte, 2019) (para #84)

3.5 Despite the large investment as a result of the HITECH Act of 2009, the amount of Level 1 evidence related to EHRs remains scant. Therefore, the current state of the literature does not provide sufficient rigorous evidence to judge the wide scale impact of the HITECH investment and its effect on safety, quality and cost. While it is acknowledged that randomized studies of EHR use or functionality can be extremely challenging, it is vital that pragmatic clinical trials are conducted to generate the high-quality evidence needed. Without evidence to the contrary, the massive expenditures on health IT give rise to questions of worth (Hochman, 2018; O'Neill Hayes, 2015; Wachter, 2015).

3.6 There has been increasing growth of clinical decision support and modern artificial intelligence (AI) methods in healthcare. The results are already promising but the enthusiasm and practical application may be out-pacing our understanding of the human factors and contextual factors influencing the success of these powerful new tools. Like other types of automation implemented in any complex domain, usability, safety, and transparency will be critical for AI to achieve its true potential.

These six issues, while present to some degree at the time of the original paper, are increasing in prominence. Care complexity has increased, accompanied by marked increases in regulatory oversight, yet EHRs remain "primitive in design, construction and applicability given their cost and life-critical role" (Koppel, 2018)(pg. 831) We believe it is time to give greater national attention to the policies,

[1] Most experts would agree that HITECH facilitated the ability to collect patient and practice data on a national level thereby addressing a number of societal goals including the conduct of large scale pragmatic clinical trials. Of course, if the EHRs are not usable, the data being gathered may not be of sufficiently high quality for some uses. Moreover, there remain issues of data standardization and interoperability.

Table 2
Five New Fallacies (described more thoroughly in the paper).

Fallacy	Brief Description
Discrete Data are King	If the [clinical/quality/administrative] data are in the EHR, they are correct and will be correctly used.
Certifiably Safe & Usable	We must already have safe and usable HIT, after all, it's been UCD certified!
Computer-based Decision Support (CDS) = Be the best	A variant and refinement of the Father Knows Best Fallacy; Presenting "evidence-based" data (via HIT) about what to do for an individual patient in the clinical context will improve the care of that patient (see Table 3 for the Sober Reality).
Not my Circus, Not my Monkeys	The responsibility for safe and usable EHRs belongs to someone else, leading to blame, denial, deferral and a failure to address the systemic nature of the problem.
Standardization is Impossible	Rejecting the notion, promulgated by vendors, organizations, and clinicians that their system, situation, or product is special and that standardizing (e.g., UI attributes across vendor products or specific clinical workflow) is impossible. Wise standardization & flexibility can (and should) co-exist.

regulations, and processes of HIT design, configuration and implementation.

4. Revisiting the original fallacies

Since the publication of the original paper, the dangers of increasingly complex and sub-optimally designed HIT have exacerbated. Numerous design and implementation issues identified nine years ago have not been addressed in substantive ways. In this update, we revisit the original 12 fallacies (see Table 1). However, due to space constraints, the status of only three of the original fallacies that have changed most significantly over time are discussed in detail below. We then suggest five new fallacies (Table 2) that have emerged in the ensuing years.

4.1. Use equals success fallacy

This fallacy emphasized that equating increased use of HIT as an indicator of system success was erroneous. HIT use that is perfunctory or *pro forma* and/or does not directly support users' goals are not accurate indicators of success. Complex workarounds and the associated keystroke compensations that are often necessary to complete a given task may more appropriately indicate that the HIT fails to address users' needs. In 2010 we also made the point that selective *lack of use* should not be a proxy for a determination of system failure or modular malfunction. Ignoring reminders for certain patients or populations, for example, may be clinically appropriate.

Sober Reality: Interestingly, the points made in 2010 regarding usage as a measure of success continue to resonate deeply and disturbingly in 2019. The use of EHRs has continued to increase, evidenced by high profile reports of system adoption (Adler-Milstein and Jha, 2017; Patel et al., 2013; Department of Health & Human Services Office of the National Coordinator, 2018). A closer examination of the literature, however, shows that the increased use of EHRs is largely unrelated to improving the work of clinicians or contributing to more effective and safer health care but rather to the mandates of healthcare financing and regulation (Blumenthal, 2018). Recent studies show that excessive time spent to meet documentation requirements, looking for data in complex and over-crowded EHR displays, using EHRs that do not match real-world clinical workflow, and dealing with low value and fragmented data continue to plague the entire care team (Jones et al., 2012; Ratwani et al., 2018b; Poghosyan et al., 2010; Weinger and Gaba, 2014). The increased use and adoption of EHRs may actually be a perverse contributor to interference in the patient-provider relationship (Hill et al., 2013), clinician burnout (Slight et al., 2015; Dyrbye et al., 2017; Linzer et al., 2017), and professional dissatisfaction (Carayon et al., 2015; Cohen et al., 2018; Wachter, 2015; Friedberg et al., 2014) rather than an indicator of "success". Thankfully, attention is beginning to shift to these "unintended consequences" of sub-optimal HIT but it is disturbing to see how potent this fallacy remains a decade later.

4.2. Learned intermediary fallacy

This fallacy rests upon the belief that HIT risks are negligible because the human alone ultimately makes the decision and humans can be counted on to "detect and overcome any fallibility or contributing factor of the product" (Karsh et al., 2010). (pg. 406) We pointed out in 2010 that this fallacy creates an odd paradox in that systems designed to error check now require oversight by the end-user with the system developers "held harmless" (Ratwani et al., 2018). Apparently, system vendors and institutional 'builders" still do not fully appreciate the impact of information presentation (e.g., aspects of interface design such as placement, color, and fonts) and use effort on clinical decision-making. At the time of the original paper, we gave the benefit of the doubt to these stakeholders but the expectation was that usable HIT would emerge over the subsequent decade as the necessary science and expertise was woven into HIT development and implementation – this has thus far largely failed to occur.

Sober Reality: The time to give the benefit of the doubt to vendors and those who configure HIT (often at the institutional level) has lapsed. Strong evidence exists regarding the risks associated with sub-par HIT usability and its impact on various dimensions of patient safety, usability, and efficacy – yet the issues continue to plague current systems.

In 2014, the ONC funded the creation of the SAFER guides (updated in 2017) to help health systems conduct proactive risk assessment of EHR safety-related policies, processes, procedures, and configurations (Sheber, 2018). The slow pace of industry compliance with these best practices is disturbing. In a recent report, Sittig and colleagues studied 11 certified EHRs across 8 organizations and found that only 25 of the 140 of the SAFER recommendations were fully implemented (Sittig et al., 2018a; Sheber, 2018). It is acknowledged that SAFER was designed to provide guidelines at a system level without providing the specificity and measurement criteria with which each recommendation could be explicitly assessed. In response, Dhillon-Chattha et al. (Dhillon-Chattha et al., 2018) generated a list of 642 detailed features that should be considered at a more individual level prior to implementation. We agree with Koppel (2018), that the magnitude of Dhillon-Chattha's list highlights: 1) the many design improvements still needed in vendors' foundational systems and 2) the daunting task for purchasing organizations to create and implement safe systems. Importantly, fixing this issue is not *solely* the responsibility of the vendor community. In-house builders who configure or "build" the EHR to their local requirements are major contributors to inefficient HIT user interfaces, safety and security problems, and other unintended consequences. (Emergency Care Research Institute (ECRI), 2013; Ratwani et al., 2018c).

The essential fact is that *design matters*. Human behavior is measurably influenced by order of item presentation, color saliency, ease of use, data availability, and the amount of effort that must be expended to achieve a goal. The current proliferation of increasingly difficult, error inducing, and time-consuming HIT indicates that the deep design imperatives have not been addressed. Embedded research, informed by HFE/SE professionals, is critical for HIT to reach its promised state. Finally, it is difficult to see how the safety of certified EHRs can be assured when ONC-endorsed safety guides are disregarded, and vendors are able to avoid liability for inadequate design via constraints on end-user disclosure of HIT issues and hold harmless clauses (Fry and Schulte, 2019). As occurred with medical device regulations 20 years ago,

HIT-related use errors (not user errors) must become a shared obligation of all stakeholders but with the vendors taking primary responsibility (Weinger et al., 2011).

4.3. Father Knows Best fallacy

As the primary benefits of HIT use accrue to entities upstream from direct patient care at the expense of those who shoulder the burden, frustration builds. We pointed out in the 2010 paper that insulating those who design or configure HIT from the negative aspects of real-world use (Grudin's Law) perpetuates the problem. This remains true today.

Sober Reality: The Father Knows Best Fallacy will continue to be perpetuated as long as the focus of EHRs is on the needs of billing and compliance departments, regulators, and administrators at the expense of clinicians and patients. The numerous consequences of clinicians shouldering much of the poor usability of EHRs have been noted earlier. Clinicians further perceive that the EHR data that they painfully entered into the EHR is largely unavailable to them, which further disheartens and frustrates those who understand the value of data in transforming care (Cohen et al., 2018).

Clinicians are not the only end-users who suffer from the Father Knows Best fallacy. The quest for clinical revenue and evidence of meeting numerous reporting requirements (e.g., quality metrics) affects the lives of untold data abstractors, data analysts, and quality improvement personnel who spend inordinate amounts of time trying to wrangle EHR data of questionable value (Haas et al., 2015; Chan et al., 2010). Extracting the data from EHRs necessary to meet reporting requirements and to inform quality initiatives is difficult, expensive, time consuming, and error prone (Parsons, 2012; Krist et al., 2014). Stakeholders frustratingly report an inability to customize EHR-derived quality measure reports without the use of expensive consultants or costly system upgrades (Hochman, 2018; Jones et al., 2012) Thus, many believe that the effort required to meet these largely administrative demands is a major impediment to the innovation necessary to achieve more clinically efficacious HIT (Slight et al., 2015; Office of the National Coordinator for Health IT, 2018).

While the complexity of clinical care and the regulations that surround it will continue to grow, the primary function of the EHR must be to support safe, high quality clinical care. Documentation is broken and must be improved by collaborative multidisciplinary teams that include clinicians and HFE/SE's. "Getting rid of the stupid stuff" (Ashton, 2018) (e.g., pointless tasks imposed by faulty EHR design or organizational decisions) appears to be an area where we could achieve quick wins. At the same time, in the current fee-for-service environment that underpins our healthcare industry, we cannot ignore that EHRs are necessary to generate clinical revenue (Blumenthal, 2018). Such complexity mandates that those who develop, configure, and implement EHRs work intimately with all representative users and integrate bona-fide user--centered design (UCD, also called human-centered design). A systematic approach to solving this complex conundrum is fundamental.

Such efforts will require that the *pro forma* UCD processes currently used by most vendors to achieve ONC certification be substantially upgraded to meet best practices across other high consequence industries. We and others also believe that simple reliance on a "certified" EHR to assure a level of design adequacy is misguided (; Holmgren et al., 2018). Improving EHRs will require changing the fundamental priorities governing their design from blunt-end (i.e., administrative, billing, compliance) to sharp-end (care quality and safety) goals. As articulated by Blumenthal (2018), this will probably require "moving away from fee-for-service payments toward risk-sharing by providers and, ultimately, some form of prospective compensation. Until then, optimizing the usability and value of EHRs will be an uphill struggle." (p.8).

But we cannot sit back and wait for fundamental changes in US payment models to drive HIT improvements. Our patients and society would be best served by the tightening of federal oversight of HIT (e.g., ONC EHR certification criteria and processes) and by providing additional education to the vendor community as well as to healthcare organizations that purchase, configure and deploy their systems. This is not dissimilar to the changes required in the late 1990s when the FDA instituted human factors engineering requirements for the medical device industry to address safety and other problems (Weinger et al., 2011).

Fundamentally, Grudin's law is still being ignored, resulting in burdensome systems that embed error and inefficiency into care processes and contribute to worse rather than better clinician and patient outcomes. To change this worrisome trajectory will require a strengthening of federal regulations, a redistribution of the costs of using the EHR, and the benefits accrued from them (from the end-user's perspective), enhanced compliance with best practices (e.g., the SAFER guides and others), and rigorous application of UCD. Our original call for collaborative HIT design still stands; "Pilots did not improve aviation safety nor did nuclear power operators improve nuclear safety by themselves. Rather they worked closely with experts in cognitive, social, and physical performance and safety to improve safety" (Karsh et al., 2010)(pg. 621) We continue to call for a rapprochement to bridge the gaps that exist between those who develop and/or configure HIT, those who develop regulations and policies and those who must use HIT on the front lines.

5. The new fallacies

New concerns have arisen in the last decade. As in the original paper, we believe that these new fallacies must be acknowledged and addressed if the promises of HIT are to be fully realized.

5.1. The domination of discrete data fallacy

Discrete data entered into HIT by end-users are widely used to run the healthcare business, both locally and nationally. There continues to be a pervasive belief by those not on the sharp-end that "if the [clinical/quality/administrative] data have been entered into the system, they are likely to be correct and patient care will improve." Further, it appears to be believed that simple aggregations of structured data (e.g., into notes) is sufficient for effective clinical use.

Sober Reality: The (sometimes fervent) belief in the reliability and accuracy of digital (and especially quantal) data is problematic in several ways. From a human factors perspective, perhaps the most pertinent fact is that poor usability predisposes to improper, incorrect, and ineffective use. Thus, frustrated and harried clinicians will focus on taking care of the patient in front of them and, more generally, getting their clinical work accomplished in the most expedient way possible. Unless relevant to these priorities, entry of "required" data elements in the EHR is haphazard and prone to workarounds. Further, when a data element is considered by supervisors or organizational leadership to be "critical" (e.g., for payment or compliance) then that data is more likely to be documented, but not necessarily with full veracity. To tie several points we've made together, particularly for quantal data used to assess individual (or organizational) performance such as reported quality measures, the clerical burden is high, the data are likely to be flawed, and there is limited evidence that EHR-documented compliance with many quality metrics is actually associated with higher quality of care (Cohen et al., 2018; Randall et al., 2018).

In addition to the focus on mandatory entry of billing, compliance, and quality metric data, there is an increasing emphasis on all clinical data being "structured" to better support risk adjustment, data mining, clinical decision support (CDS), etc. The result is that the patient encounter is distilled into a long list of discrete and disconnected data elements that actually makes it more difficult to tell what is happening to the patient (i.e., the "patient story"). Clinicians use the patient story as a cognitive scaffold which informs their understanding of the patient's condition and guides decision making and team communication.

Modern EHRs are largely devoid of narrative text; such stories are discouraged by the clerical burden of discrete data entry, the inefficiencies of poor usability, and by admonishments that "if it isn't coded data we can't use it". Narrative text that does exist in EHRs is commonly divided by professional discipline (e.g., nurses notes, doctors notes, progress notes, etc.) (Hripcsak et al., 2011) This fragmentation of narrative notes and the focus on objective discretized facts engendered by current HIT design increases the cognitive load, makes deep understanding of patient condition more difficult, and impedes interprofessional communication (Varpio et al., 2015; Clynch and Kellett, 2015; Cortese et al., 2015). Again, design dictates use. We agree with Varpio et al. that, "Being reliant on EHRs means that clinicians' care decisions are increasingly influenced, for good or for ill, by the EHRs they use."(62) (pg. 1025).

5.2. *"Certifiably safe and usable" fallacy*

The Centers for Medicare and Medicaid (CMS) EHR Incentive Programs launched in 2010 required the use of "certified" EHR systems as a qualifying condition for receipt of incentive payments. Concomitantly, the ONC began a program in which EHR vendors could voluntarily submit their systems to be certified. The current UCD certification process relies on vendor self-reporting of their development processes and usability test data, independent testing laboratories, and authorized certification bodies. According to the ONC, (Office of the National Coordinator for Health IT) this "provides assurance to purchasers and other users that a system meets the technological capability, functionality, and security requirements adopted by HHS." (para. #1) The EHR certification process allowed organizations to attest to their use, thereby facilitating the collection of the CMS EHR incentive payments. A general assumption was that a certified EHR implied that a robust level of usability, quality and safety was "baked in".

Sober Reality: Studies show considerable variation in the quality of certified EHRs, and much of this variance directly affects safety, usability, and interoperability (Sittig et al., 2018a; , Ratwani et al., 2018; Holmgren et al., 2018). Compliance with accepted best-practice UCD is similarly variable and often weak, particularly with regard to the use of recurrent rigorous functional usability testing with representative users. To this point, in a study of DHHS provided EHR certification reports Ratwani et al. found that only about one-third of EHR vendors used UCD in any significant way (Ratwani et al., 2015c).

Thankfully, the call for an increase in the amount of Federal oversight and rigor of usability in the EHR certification process has been steadily growing (Holmgren et al., 2018; Adler-Milstein, 2017). The August 2018 request for information (RFI) by the ONC in the Federal Register (Department of Health Human Services Department of the National Coordinator for Health IT, 2018) clearly acknowledges that current federal policies and procedures to assure usable HIT have been ineffective.[2] The RFI asks for perspectives on end-user ratings of usability rather than vendor self-report as part of the HIT certification process. These developments are welcomed as a step forward in accurately assessing the usability of certified EHR products.

The responsibility for usable and safe EHRs cannot lie solely with the vendor community, however. The criteria used to certify EHR safety and usability does not address customizations that occur after purchase or during implementation into the clinical environment (Trusts, 2018). While the underlying design of the foundational EHR system creates substantial constraints, an appreciable amount of the variability in usability and safety appears to be related to healthcare organization's customization decisions (Ratwani et al., 2018c). The impact of such variation on the quality and safety of the deployed system should not be surprising. Many healthcare organizations are ill-prepared to properly configure and deploy a comprehensive EHR using established UCD principles. Even large health care entities do not typically have the resources or experienced staff to do the extensive planning, preparatory research, iterative development and testing, user training and implementation refinement essential to deploy such a complex technology.

Governmental agencies and other entities have been developing guidelines and protocols to address usability in EHRs (Trusts, 2018; National Institutes of Standards and nology; Department of Health and Human Services Office of National Coordinator for Health IT, 2014). For example, the Association for the Advancement of Medical Instrumentation (AAMI) launched its HIT Standards Initiative in 2015 (Association for Advancement of Medical Instrumentation (AAMI), 2016). Over the last 4 years, vendors, human factors professionals and clinicians have been developing three consensus national standards that will address HIT risk management processes (AAMI/HIT 1000), HIT quality system principles and processes (AAMI/HIT, 2000), and HIT usability engineering processes (not yet named). The first part of AAMI/HIT 1000 detailing general principles, was released for review in 2018 (Association for the Advancement of Medical Instrumentation (AAMI), 2016). Developing and widely disseminating best practices consensus standards is a reasonable first step and parallels the path the medical device industry embarked on more than 20 years ago to achieve robust UCD throughout every product's life-cycle. Yet the development of national standards that are recognized by all stakeholders (and especially government regulators) is only one component of the needed systemic solution to a complex problem.

5.3. *"CDS → Be the best" fallacy*

As mentioned earlier, a putative benefit of HIT is the ability to deliver the latest in evidence-based guidance to the responsible clinician at the point of care whereby such Computer-based Clinical Decision Support (CDS) could substantially improve care quality, safety, and cost. Numerous studies point to the *potential* value of properly designed and implemented CDS yet results to date in terms of improved care delivery are mixed, particularly with commercial systems and for meaningful patient outcomes (Moja et al., 2014). Those at the blunt end still make the fallacious assumption that delivering the 'right thing to do" (or alerting to not do the wrong thing) to the clinician via HIT will lead to the "right thing" being done. Then, when the CDS does not yield the expected results, the Bad Apple Fallacy is invoked, placing blame on the end-user (see Table 1).

Sober Reality. There are many reasons why CDS alone is unlikely to be a panacea for healthcare's historically poor compliance with the latest medical evidence and established guidelines (Bonetti et al., 2009). Here, we will focus on our issues specific to HIT that we have synthesized and enumerated in Table 3. In fact, substantial fault almost certainly lies in the CDS itself (Miller et al., 2018) rather than the actions of the end-user. Starting with the often dubious assumption that the clinical evidence is sufficiently robust to produce correct and actionable clinical recommendations, effective CDS is dependent on correctly: 1) translating the current evidence into computer algorithms; 2) obtaining the required inputs (i.e., clinical & operational data) in a timely fashion; and 3) presenting the resulting recommendations to the clinician in a way that optimizes the likelihood that the clinician will act (when appropriate). (Wright et al., 2018a).

Relative to our focus on HF/SE and UCD, the CDS' user interface is often poorly conceived, constrained by the existing HIT infrastructure, triggered at the wrong time in the clinical workflow, or necessitates too much effort by the clinician to make its use worthwhile in the moment (Miller et al., 2015). The inability of the CDS in current EHRs to conform to UCD best practice and to integrate seamlessly into clinical workflows contributes to user frustration and avoidance. When the CDS triggers repeatedly with recommendations that are irrelevant or of questionable validity, the clinician begins to ignore the CDS – a significant and well publicized problem with medication-related (e.g., drug-drug

[2] The RFI also acknowledges the slow progress to date toward effective data interconnectivity and interoperability.

Table 3
Potential issues with computer-based clinical decision support (CDS) *.

Issue	Brief Description
Problems with the underlying data	The data elements that triggered the specific CDS are wrong, corrupt, incomplete, etc.
Problems with the "rules" that generate the recommendations	The rules or algorithms that translate the data input into the recommendations are flawed.
• Rules inconsistent with actual available evidence	The resulting recommendations are inconsistent with the available evidence because of flaws in the design or implementation of the rules or algorithms
• Rules incorrectly manage missing or fuzzy data	The rules do not correctly account for missing or ambiguous data inputs. This could be due to flaws in the HIT or in the clarity/completeness of the evidence-base.
• Recommendations are based on inconclusive or incomplete evidence	The available evidence is incomplete or ambiguous, or has not been distilled into a form that permits effective CDS.
There are problems with semantics and taxonomy	The ability to generate the correct recommendations is impaired by problems with definitions, relationships between variables, or other semantic or ontological issues.
Rules not triggered due to incomplete data or delayed documentation	Necessary inputs to CDS rules fail to be entered by the end-users due to work pressures or incorrect matching to workflow.
CDS user interface (UI) is poorly designed or implemented	The CDS UI cannot be successfully navigated by the end-user in the context of use. This is a common cause of failure to comply with CDS in HIT and is often due to insufficient HFE/SE involvement.
• Clinician doesn't see CDS or it is unavailable when needed	The CDS is hidden (sometimes in plain sight) to users during their routine work with the HIT.
• Clinician is unable or unwilling to enter necessary data	Many CDS require clinician input (or at least validation) of data needed by the algorithms. Clinicians may be unwilling or unable to enter these data in the required format.
• Clinician can't successfully navigate CDS to get recommendations	The user cannot figure out how to use the CDS, eventually getting frustrated and doing anything to make it go away.
• CDS is too time-consuming	The demands of the CDS exceed the time or patience of the user, often due to problems with usability. Users then question value.
• Clinician ignores CDS so as to deal with more immediate or higher priority task	Clinicians' interactions with HIT are goal oriented and usually very specific tasks are trying to be completed under time pressure. The CDS is viewed as an interruption or distraction. "Hard stops", an important safety feature, also run the risk of creating reflexive behaviors and frustration - leading to avoidance and workarounds.
Recommendations are inappropriate or wrong for this patient at the time of triggering	The clinician receives and perceives the CDS but chooses to ignore the recommendation.
• Recommendations are incorrect or irrelevant to this patient	The recommendations may apply to some patients but do not apply to this patient.
• Clinician does not agree with the recommendations	The clinician does not agree with, or is skeptical of, the underlying evidence.
• Recommendations are correct but not at this time or under these circumstances	The clinician's priorities and constraints for managing this patient in this encounter are inconsistent with complying with the CDS recommendations.
• CDS has been annoying and/or not useful frequently enough that the user now ignores it	Also called 'reminder fatigue' or 'cry wolf syndrome', here the recommendations are correct and applicable to this patient but the CDS has been so frequently wrong, disruptive, time consuming and/or annoying that the clinician uses an established workaround to avoid or short-circuit the CDS.

Although developed independently, interested readers may find synergistic information in the following references (Wright et al., 2009, 2018a, 2018b; Finlayson et al., 2019; Sittig et al., 2008).

interaction) alerts (Wright et al., 2018a; Xie et al., 2014; Tolley et al., 2018). Finally, as CDS becomes more reliant on models derived from deep machine learning, skepticism arises regarding the generalizability of the model, biases (inadvertent and intentional), and the potential impact of autonomous or "self-correcting" algorithms on clinical decisions (Finlayson et al., 2019). Greater acceptance and use of CDS will require much better understanding of, for example, how clinical decisions are actually made in the work context, how clinicians adapt CDS use into workflow, and cognitive aspects that affect CDS use. The success of HIT-delivered decision support is most likely to be achieved when CDS is studied, designed and implemented with the active involvement of HFE/SE professionals.

5.4. *"Not my circus, not my monkeys" fallacy*

The current situation has engendered appreciable finger pointing. EHR vendors blame local health IT configurations and end-users for safety issues that emerge upon implementation. Numerous stakeholders blame the federal government for failure to enforce regulations, while others blame vendors for producing sub-optimal EHRs in the first place. Policy makers blame providers for failing to 'get with the program' with regards to pay for performance and quality. The government blames developers for inhibiting interoperability, while others cite deliberate information blocking and lack of transparency on the part of vendors (Ratwani et al., 2018; Adler-Milstein and Pfeifer, 2017; Sittig et al., 2018b). The point is that all of the stakeholders have some responsibility for the current state of affairs. It *is* our circus and those *are* our monkeys.

Sober Reality. Collectively, we all need to step up and work together. The tension between standardizing care (i.e. evidence based practice) and individualizing it (i.e. personalized medicine) will continue to challenge the clinical enterprise (Mannion and Exworthy, 2017). The solutions will require the substantive collaboration between all relevant stakeholders, particularly "those who can contribute unique and important expertise" (Karsh et al., 2010). (pg. 621) It may also require that a new way of sharing risk, removing the protective shield that has shifted risk away from vendors while also acknowledging the contributions of healthcare organizations to the overall situation (Fry and Schulte, 2019).

Belmont has advocated for "shared responsibility in the design, implementation, and use of health IT among involved stakeholders through contractual allocation of responsibility to ensure that the party who has the most control over the factors giving rise to a particular health IT patient safety risk takes appropriate steps to prevent and mitigate risk, with corresponding liability for damages apportioned accordingly." (Belmont, 2017) (pg. 111) Such shared responsibility would reduce many of the bottlenecks to improving EHR safety such as hold harmless clauses, the learned intermediary doctrine, vendor indemnification, and contract-enforced gag orders that prevent end-users from sharing EHR-related safety concerns. We agree with Sitting and colleagues (Sittig et al., 2018b), it is an opportune time to develop and embrace shared responsibility principles to encourage safe and usable EHRs.

5.5. *Standardization is impossible fallacy*

In our original paper, we described the "one size fits all" fallacy and asserted that it was important to customize and optimize the HIT to fit the end-users' needs (still true). We also pointed out that different end-users (e.g., nurses vs. physicians) will need different informatics tools to do their jobs most effectively (also still true). Now, we argue that clinicians, vendors and builders have gone too far in avoiding standardization, often using the arguments that it is unwanted, too difficult,

unnecessary, and will stifle innovation. While we are not advocating for dogmatic standardization, the degree of variability in user experiences with HIT, even by the same user in different parts of a single hospital, has become substantial and dangerous.

Sober Reality: In 2019, we believe that where the net benefit of standardization will outweigh the costs, then we must strive to standardize. Conversely, where customization is important or standardization is costly, then flexibility is important and should be maintained. Standardization (or one-size fits all) makes less sense when, for example, developing UI elements for different user groups that do substantively different tasks and who do not have to share work. In contrast, we believe that HIT standardization is critical for terminology (i.e., data taxonomy and definitions), data sharing protocols, in the conduct of UCD, and in the reporting and sharing of HIT-related safety events. We also advocate for standardization across all products of task-critical user interface elements that support safety critical actions (e.g., medication ordering). An argument could also be made for standardizing other aspects of the UI such as the patient header (to reduce the risk of wrong patient errors). This, in our opinion, is a situation where the potential benefits of 'innovation' and the need for 'branding' are outweighed by patient safety considerations.

Another example of beneficial standardization is in particular areas of clinical workflow. HIT design shapes workflow and thus can enforce workflow standardization (e.g. chemotherapy can only be ordered by qualified clinicians and must be signed off by the oncology pharmacist before dispensing). In fact, because of the risks of errors, in oncology, workflow around both chemo- and radio-therapy electronic ordering and administration are often highly standardized. In these examples, the safety-critical aspect of the process supersedes individual preferences, and standardization supports safety. At the other end of the spectrum, there are many reasons for practice variation and this will require flexibility to match workflow and support individual clinicians in their decision-making. For example, clinical guidelines are just that – guidelines, not mandates, and we are not advocating for a "remaking of the Procrustean bed" (Mannion and Exworthy, 2017). The autonomy of the clinician in using appropriate clinical judgement must be supported, not thwarted, by HIT (Lagnato, 2016).

In regards to standardization related to processes intended to achieve better safety and usability, UCD has been proven to be reliable, useful, and achievable (Wiklund and Wilcox, 2005). HFE/SE and UCD are widely used for both technology and processes across all high-risk industries such as aviation, nuclear power, military acquisition, and medical devices (Weinger et al., 2011, 2013; Vredenburg et al., 2002; Stanney et al., 2010). These well-validated standard practices can and should be applied to the development of any HIT deployed in safety-critical environments.

6. A future vision

As we think about our vision of the future of HIT, we believe that humans have a relationship with their technology and the best technology enables humans to achieve their goals more effectively, efficiently, safely, and with greater satisfaction. With this framing, our vision is that in 2030, most information technology will be essentially invisible to clinicians and patients in the same way that the technology in other modern affordances like refrigerators and elevators are today. For diagnostic tools, the HIT would provide useful, timely, non-disruptive, advice. For therapeutic tools, the HIT would easily elicit users' needs or goals and then be a seamless extension of the clinician, patient, or caregiver. Importantly, clinical documentation as well as 'back-end' functions of the EHR (i.e., quality measures, billing, compliance, etc.) would happen in the background as a natural consequence of a health encounter. Even for experienced clinicians, the HIT could function as a mentor or coach thereby facilitating life-long learning and mastery. Digitized data that derives from encounters with the healthcare system (and its complex web of affiliated stakeholders) that is accessible and transferrable, will facilitate the continuity of safe and efficient care. Finally, we also envision systematic policy and regulatory change that is based on the understanding of the root causes of sub-optimal HIT, and the impact it has on patient safety, professional well-being, and inefficiency.

Achieving such a vision will not only require continued advances (such as natural language processing, deep machine learning and data driven personalization of care), but a much greater systematic approach to HFE/SE and UCD (Association for Advancement of Medical Instrumentation (AAMI), 2016; Stanney et al., 2010; Tippey and Weinger, 2017).

7. Conclusion

Since the publication of our original commentary in 2010, health information technology (HIT) has become nearly ubiquitous in US healthcare facilities. The three recommendations made in 2010 of: 1) using UCD and human factors engineering to gain a deeper understanding of how clinical work is done; 2) shifting the focus of EHR use from that of revenue capture and compliance to one of end-user and workflow support; and 3) increasing the engagement of front-line users in HIT design and implementation, have failed to be systematically and fundamentally addressed. The promised land of HIT envisioned in 2010 has yet to be reached, and the road to 21st century healthcare envisioned by the HITECH Act in 2009 has become a complex morass with numerous negative unintended consequences. While some might say we have arrived at our deserved destination, we believe that the glass remains half-full and all is not lost.

Similar to the early stages of commercial aviation, where risks were high and the limitations of human performance were being reached, the understanding of the importance of aligning human requirements in the design of complex technology resulted in a commonplace and very safe modes of transportation (Karsh et al., 2010). This pattern of safety-critical computing been followed for other complex, high-risk industries and should be systematically applied to healthcare. We still believe, as we did in 2010, that, "foundational cognitive and human factors engineering research and development are essential to better inform HIT development, deployment, and use"(Karsh et al., 2010).

We acknowledge that even with much greater oversight, guidelines, standards, and regulation, it will never be possible to totally engineer error out of HIT. Achieving the Quadruple Aim will require significant investment of attention and resources from all relevant stakeholders. However, a failure to act on the systematic usability and safety challenges that continue to plague HIT is a dangerous game. Bentzi and Bob would expect better of us.

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