Chapter

Digital Health and Healthcare Quality: A Primer on the Evolving 4th Industrial Revolution

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Abstract

The inefficiencies of the healthcare sector continue to be a barrier to achieving the quadruple aim of healthcare quality improvement. The 4th Industrial Revolution has been characterized by rapid transformations due to information technology, data volume, ubiquity, and increased computer processing power. Despite all the promises and hopes of Digital health tools as a means of attaining healthcare quality, there remains many challenges and hurdles to overcome. This chapter describes the relationship between the 4th Industrial Revolution and healthcare quality as it relates to its impact on healthcare quality, applications, and challenges. Suggestions to stakeholders on ways of navigating these challenges are also discussed.

Keywords: digital health, health information technology, 4th industrial revolution, healthcare quality improvement, quadruple aim, artificial intelligence, ML, data science, patient safety

1. Introduction

1.1 Basic concepts of digital health and big data

1.1.1 Differentiating digital health from health informatics and E-health

Digital Health (DH) is an evolving multidisciplinary scientific field that seeks to monitor medical problems while also preventing new ones with the ultimate aim of improving the overall quality of health [1, 2]. These means of information technology can be applied through mobile health (mHealth), telehealth/telemedicine, activity trackers, personal wearables, and remote monitoring, and represent an interplay of the art and science of medicine to achieve overall improvement in health [2]. Due to its broad nature, DH is usually used interchangeably with health information technology (HIT).

Electronic-health or E-Health is characterized by an intersection of public health, medical informatics, the business of healthcare, information science, and health services to achieve better health for users [3]. The term comprises both technical aspects like hardware, software, and internet broadband and social elements centered on the way of thinking and networked global effect through information technology [3].

1.1.2 Sources of big data and its contemporary drivers in healthcare

Big data refers to an enormous data set existing as either structured (organized), unstructured (unorganized), or mixed [4, 5]. These characteristics have been described as the paradigm of 4 "Vs:" volume, velocity, variety, and veracity [4, 6–8]. Generally, about 2.5 quintillion bytes of data are created every day worldwide and it is rather amazing that 90% of it was created in the past 5 years [9].

Sources of big data span a wide spectrum including posts from social media sites to sensors and navigation devices. It is a big challenge to determine the amount of data generated yearly by the healthcare industry due to the complex nature of healthcare data with heterogeneous sources and structures [10]. Healthcare data sources include electronic health record data (EHR), prescription compliance and refill rate, personal activity tracking devices, laboratory data, cell phone-based geographical monitoring, and remote telemedicine monitoring. About 500 petabytes of data were generated by electronic medical records alone in 2012 and it is expected to reach 25,000 petabytes by the end of 2020 [11]. The various methods/processes of big data analysis are referred to as analytics.

Many factors are responsible for our contemporary adoption and application of big data and DH. The greatest driving force is the dynamic state of computer power relative to it cost of acquisition rightly predicted by Moore's law. It states that computer power (in terms of speed and memory storage) will double every two years at the same price. In 1956, you would have had to pay $10 million for one gigabyte of storage. In 1981, the cost of a gigabyte was $ 300,000 and by the year 2000, it had dropped to $10. In 2010, the price of storing a gigabyte of data dropped to just 10¢ [12].

Another technology-based driver is the advent of cloud computing. This is the process of utilizing remote computer networks via the internet to manage, process, store, and manipulate data rather than utilizing the local or personal computer connected to the network. This phenomenon allowed for an exponential increase in the capacity of local computers, hence serving as a driver for the "internet of things," or the interconnectivity between various devices embedded with electronics, software, and sensors. Its ability to impact all major players in the healthcare industry, including the patient, healthcare provider, healthcare regulators, payers, and vendors, has been described as the Internet of Medical Things (IoMT) [13].

Another driver of big data application and DH is the advancement in genomic medicine and gene therapy [13]. Gene mapping and sequencing is an integral part of big data as it utilizes various bioinformatics processes for interpretation and storage.

The most important factor remains the paradigm shift in the role of the patient as a "consumer" of health services. Patients seek to better manage their health by playing active roles through information gathering on the internet and especially via social media networks [14]. One in three Americans has gone online to investigate a medical condition [15]. Another important factor is the changing demographics of the aging population and prevalence of chronic diseases leading to escalating cost of healthcare. In fact, the cost of chronic diseases accounts for up to 75% of healthcare cost in the US [16].

DH innovations have shown some promising results as a means of achieving efficient and cost effective care without compromising quality of care [17]. The mandate from regulators to shift from a volume- to value-based reimbursement model is a testament to the fact that the shift to reward quality, efficiency, and collaborative care is here to stay [18]. The incentive for hospitals to adopt meaningful use of digital technology due to the Health Information Technology for Economic and Clinical Health (HITECH) act, enacted as part of the American Recovery and Reinvestment Act of 2009 [19], resulted in widespread adoption of electronic health records system in the US.

1.2 Practical applications of data science in DH: traditional techniques, artificial intelligence, and machine learning

Data is the foundation of DH. Data science is the term used to describe the scientific study of the creation, validation, and transformation of data to create meaning [20]. It is composed of multiple disciplines like statistics, mathematics, and computer science (**Figure 1**). Data science is an overarching field that underlies many DH innovations like artificial intelligence (AI), machine learning (ML), deep learning, reinforcement learning, and data mining (**Figure 2**) [21].

ML is a sub-discipline of AI that uses algorithms to identify patterns in data, as such giving computers the ability to learn without being explicitly programmed to create predictive models based on training data and validated on test data.

Data mining refers to the discovery of patterns in large data sets with methods at the intersection of unsupervised learning, traditional statistics, and database systems [22]. Predictive analytics involves learning from historic data to predict likely future outcomes with an expressed degree of certainty. Clinical decision support (CDS) programs are systems set up to augment clinicians in their day-to-day complex decision-making processes [23].

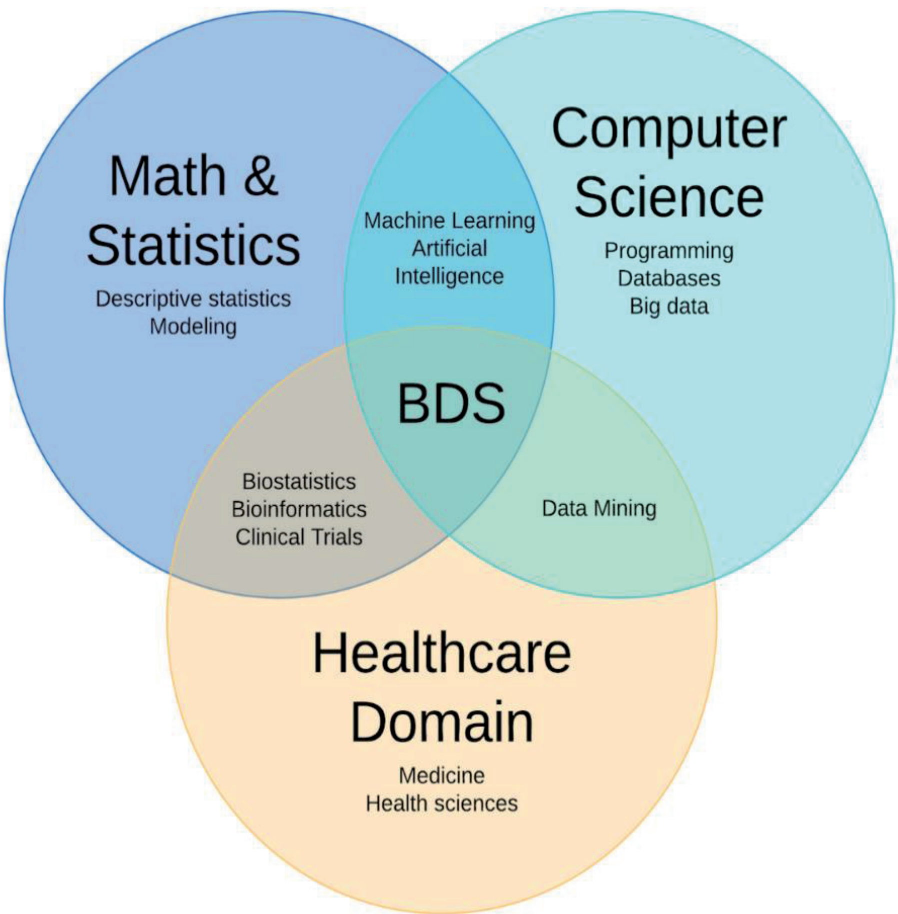

Figure 1.
Data science as a multidisciplinary field of study. Diagram reprinted with permission from Robert (Bob) Hoyt, MD, FACP, FAMIA, ABPM-CI.

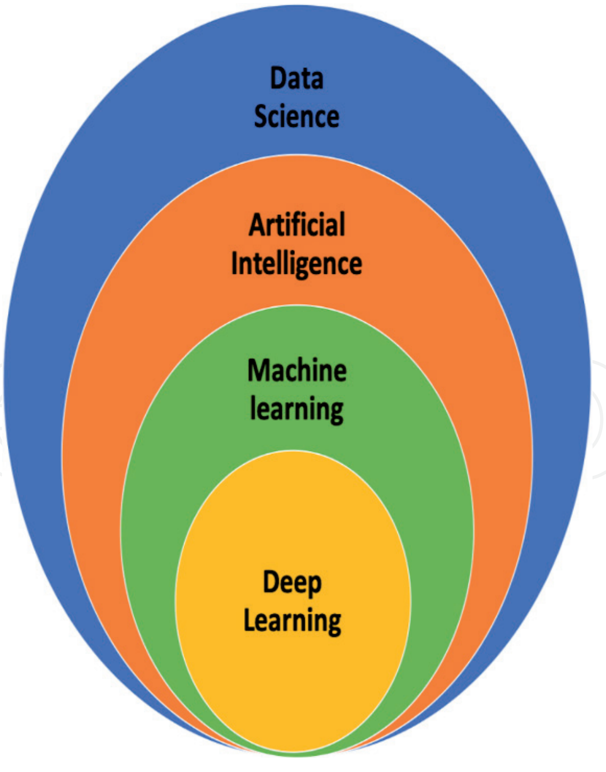

Figure 2.
Relationship between data science, artificial intelligence, and machine learning. Diagram reprinted with permission from Robert (Bob) Hoyt, MD, FACP, FAMIA, ABPM-CI.

1.3 DH's relationship with the healthcare value equation

All the factors driving DH and HIT are geared towards a paradigm shift from our present state of "sick care" to "high value healthcare" [24]. Healthcare value definition is rather challenging because of its complex ecosystem with many different stakeholders and their associated conflicting goals and expectations [25].

Nevertheless, the meaning which most stakeholders can relate to is the concept of value in healthcare as outcome (rate of quality outcome) per cost needed to achieve a result [26]. It is represented mathematically as quality/cost and is the extent to which our health interventions achieve desired health outcomes that are consistent with evidence-based knowledge [27]. Essentially, it is healthcare which is cost effective and efficient, safe, patient-centered, and equitable, with the aim of achieving the best outcome in terms of morbidity and mortality [28, 29].

Patient safety on the other hand is the foundation of quality care. The Institute of Medicine (IOM) believes that health quality is indistinguishable from Patient safety [30, 31]. I will define patient safety as a system of care delivery that prevents errors built on a culture that learns from previous mistakes. In simple terms, it is a system that functions to avoid harm to patients [32]. And healthcare quality will be analyzed in the context of the quadruple aim of quality improvement [33].

The quadruple aim is a compass to optimizing health system performance which is made up of four components: improving health outcome and experience of care, improving population health, improving healthcare cost, and improving staff engagement.

To overcome the inefficiencies of the healthcare sector in the US, healthcare organizations are encouraged to adopt methodologies like the lean or six sigma methodology that has a track record of optimizing systems in other sectors. Lean methodology involves processes put in place to reduce waste in every procedure, process, and task based on an ongoing system of improvement and learning, and focuses on eliminating waste by avoiding efforts that do not add value to the patient

[34]. Six sigma, on the other hand, is a metric-driven system used to reduce medical errors, defects, and variations in output by applying the following: design, measure, analyze, improve, and control (DMAIC) [35].

Examples of successful applications include reducing time to life saving procedure like door-to-balloon time in cardiac catherization, unnecessary antibiotics prescriptions, turnaround time for pathology reports, and clinic wait times, and streamlining electronic payment for vendors [35, 36]. Optimized symptoms that run efficiently can maximize the output of DH technologies [37].

The US spends up to 17.6% of its GDP on healthcare which is far more than that of all the other developed nations combined at 9%. Despite this amount of spending, the US ranks poorly in the World Health Organization's ranking of health system performance [38]. The public health improvement goals of the quadruple aim correspond with the goal of contemporary medicine which involves the need to achieve cost-efficient quality health through participatory and personalized medicine, ultimately ensuring optimum predictive and preventive medicine [37].

The last component of the quadruple aim is provider satisfaction and engagement. Healthcare quality can hardly be achieved without an engaged healthcare workforce. Burnout involves a state of emotional exhaustion (with or without physical fatigue) and powerlessness to change the status quo [39–41]. Up to 60% of healthcare providers experience one or more symptoms of burnout in the US [42, 43] and suicide rate amongst physicians in the US is higher than those of the general population [39]. Multiple factors are responsible for burnout which include high data and information volumes and changes in the healthcare model including a shift from volume- to value-based care [40].

Even cutting-edge EHR functionalities involving AI/ML for predictive clinical decision support are potential sources for provider dissatisfaction and burnout due to lack of regulation mandated user-centered design approach in their product development [44, 45].

1.4 The 4th industrial revolution and its peculiarities

The 4th Industrial Revolution is philosophical and ideological construct by the world economic forum which postulates on how digital, physical, and biological technology have uniquely combined together in our contemporary world creating new opportunities and challenges [41].

The first Industrial Revolution was powered by steam in the 18th century, the 2nd powered by electricity in the 19th century, and the 3rd in the 20th century powered by technology [46]. Although the 4th Industrial Revolution is considered by many as a direct extension of the 3rd, the 4th differs due to the unprecedented volume and velocity of data in addition to enhanced global interconnectivity [47].

To reap the potential benefits in the 4th Industrial Revolution, it is imperative for the healthcare sector to adopt practices like the agile methodology with the ability to "fail fast" while learning quickly in an iterative manner to achieve the desired state of healthcare quality [48].

1.5 Literature research strategy

The peer reviewed articles reviewed for this chapter were obtained from a broad literature search performed in PubMed, and Google scholar. Search terms included; "4th industrial revolution", "digital health" "quality improvement", "Digital health and patient safety", "applications of digital health for healthcare quality", "Digital health security", "Regulation of digital health". Due to the relative novelty of digital health and the 4th industrial revolution, other sources of relevant information like digital health magazines, quality improvement magazines and health informatics websites were also refer referenced.

2. Contemporary applications of HIT and DH In the context of healthcare quality improvement

The full potential of DH remains unquantifiable at this juncture mainly because of a shortage of well-conducted evaluation studies showing evidence of value added by new tools, especially those involving AI/ML [49, 50]. The rapid acceleration of DH methods and overall geometric advancement is such that any novel technology is almost outdated upon arrival. Despite all these setbacks in the application of DH, there have been some notable applications which have shown some promising results.

2.1 Individual healthcare maintenance

Remote patient monitoring involves patient data collection by appropriate providers with data either patient reported or automatically collected via apps, sensors, and any other specific gadget (glucose meters, blood pressure cuffs, or scales). This produces a vast amount of real-time data which is usually beyond the analytic capacity of the healthcare provider, creating an excellent scenario for predictive analysis of the data using ML and similar tools [51, 52].

ML analysis of bidirectional remote monitoring and EHR data has potential to provide great insights on the overall quality of individual patient care [51]. Remote monitoring has successfully been applied to diseases like congestive heart failure management (resulting in a 30% reduction in admission) [44] and diabetes management (resulting in better glycemic control compared to standard of care) [53].

2.2 Direct patient care and patient safety

Utilizing standardized risk scores and predictive analysis, some organizations have been able to predict patients that are likely to be readmitted to the hospital within 30 days after discharge [54]. Apart from the mortality benefits to the patients, the institution is also able to benefit financially as they avoid significant penalties associated with readmissions imposed by Medicare under the Medicare's Hospital Readmissions Reduction Program (HRRP) [55].

Algorithms that predict the likelihood of hospitalized patients to develop acute kidney injury during their index hospital stay have been successfully developed as well [56]. Additionally, significant reduction in sepsis mortality by algorithms leveraging the patient's data in the EHR to predict severe sepsis have also been achieved [57].

An algorithm developed using EHR data was able to predict suicide risk in individuals better than traditional clinical methods [45]. Predictive analytics tools continue to demonstrate their role in the overall reduction of in-hospital adverse events [58].

The use of CDS in antibiotics choice has been shown to significantly increase antibacterial susceptibility, thereby reducing the need for broad-spectrum antibacterial agents and the risk of antibiotic resistance [59].

Considering the complexity of cancers, the vast amount of knowledge released daily, and expansion of treatment options, the incorporation of genomic data in treatment modality all make it very challenging for clinical oncologist to choose the best personalized therapy [47]. CDS in oncology have shown some potential with assisting clinicians to navigate the challenges inherent in treatment modalities and have performed similar to multidisciplinary tumor boards [60].

The risk of failure in predictive analytics and CDS can result in significant patient harm, hence why mitigation of risk and human oversight is still an essential part of their deployment.

2.3 Healthcare operations: payment, billing, and scheduling

Predictive analytics have been used to accurately identify patients likely to skip appointments without advanced notice [61]. Additionally, they have been successfully used to anticipate peak and low utilization periods by mining previous utilization data [62]. This knowledge assists leadership in planning for changes in volume so they are ready with corresponding resources required to navigate changes in volume. Other proven applications of AI/ML include automation of invoice processing, correct coding for reimbursement, and processing of insurance denials and claims [51].

2.4 Public health essentials

The optimal state of public health of a nation should emphasize predictive and preventive care in addition to easy and equitable access to healthcare to improve overall mortality and morbidity. While the US health system falls short of these public health essentials in comparison to other developed nations, DH application has shown some promising outcomes [57].

2.5 Predictive and preventive medicine

Individual risk for developing chronic disease can be ascertained with a high degree of certainty. Integrative genetic profile has been applied successfully to determine high risk of diabetes mellitus type 2 in an individual who did not have common risk factors like obesity and family history [63].

Direct-to-consumer genetic testing for risk factors of diseases are also gaining traction with commercialized proteomic analysis testing kit for diseases like Alzheimer's disease [53]. Utilizing proteomic analysis of specific blood proteins was able to a determine if a lung nodule was benign with 90 percent accuracy during screening [64].

Similar DH based programs can assist with opioid epidemics as they have been proven to result in a 30% reduction in statewide opioid prescriptions [65–67]. Another promising application involves the development of opioid abuse risk profiles of patients using ML model and EHR data to predict patients who are prone to future abuse and overdosage [68].

2.6 Improving health access

The healthcare provider shortage coupled with the increasing aging population are factors that exacerbate healthcare access and inequity across the nation [54]. This shortage of healthcare providers and lack of access to health is worse in rural areas where 65% of non-metropolitan counties lack psychiatrists and 45% are without psychotherapists [55]. Telemedicine has shown strong evidence as a means of increasing access to mental healthcare in rural areas by providing effective treatment for mental health conditions, improving medication adherence, and effective follow up and continuity of care [69]. AI-powered chat bots can be used for initial triage based on symptoms and an expert engine can determine type and nature of visit necessary (either a virtual check-in or a face-to-face visit).

2.7 Regulations and oversight

The US Government's 21st Century Cure Act prioritized improvement in HIT, including interoperability, patient access to their health records, and improved regulatory oversight for DH [56]. As part of the Cures Act, the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) has adopted analytics methodologies like "in silico" testing. This is particularly important in diseases where the smaller patient sample sizes is often a limitation of their clinical trials [70].

3. Not all that glitters is gold: challenges and shortcomings of HIT and DH utilization to achieve the quadruple aim of quality improvement

Despite the excitement which comes from the potential of DH for quality improvement, challenges exist. Not considering these challenges is akin to chasing "shiny objects" with potential for negative and adverse consequences both in the short and long term.

3.1 Overall HIT challenges across DH and big data

3.1.1 Lack of interoperability

Interoperability is the ability of different information systems to access, exchange, and cooperatively use data in a coordinated manner, within and across organizational and regional boundaries, to provide timely and seamless portability of information for optimal healthcare [57]. The healthcare data ecosystem in the US is highly fragmented with different EHR systems as a repository of patient data. These disparate EHR systems are not connected and as such their lack of interoperability is a huge set back and operational burden to DH implementation for patient safety.

3.1.2 Lack of consensus standard for evaluation and monitoring

The lack of consensus evaluation standards in DH is also a barrier to determining the value added [71]. The world of biomedical sciences is accustomed to the traditional randomized control trials as a gold standard for evaluation. Unfortunately, this is not always a practical option for most DH applications due to variation in input data and a lack of stability of deliverables needed to quantify outcomes in RCT [72]. Although various evaluation framework exists across the industry, no consensus standards have been generally accepted across board [73]. Thus, we have no standardized method of determining the effectiveness of the over 300,000 medical apps available [71].

3.1.3 Lack of emphasis on DH/hit in the context of the socio-technical impact

Most stakeholders consider DH a singular fix for the inefficiencies in healthcare [74]. But, for any DH innovation to be successful, design and implementation need to be compatible with all elements of the system engineering initiative for patient safety (SEIPS) model [75]. The elements to consider in this model include consideration of persons involved and their peculiarities, available technology and tools for success, organizational culture, type of tasks, environmental layout, care and information process/flow, and patient outcomes.

This lack of overall socio-technical consideration manifests as the absence of stakeholder input in the development of new DH tools, consequently leading to poor usability of the DH tool like the EHR, which is a significant contributor to provider burnout and inefficiency [76]. Additionally, the low usability of EHR increases the cognitive load of the healthcare provider, which contributes significantly to medical error [77].

Lack of overall consideration in the context of the socio-technical landscape increases the chances of unexpected consequences like creating workarounds in the EHR with a negative impact on patient safety [78].

3.1.4 Regulatory bodies and government unable to keep up with the dynamic changes brought on by DH

Government and regulatory agencies struggle to provide a clear-cut regulatory pathway for DH tools. Restrictions and barriers to telemedicine adoption like provider portability of license to practice across state lines, geographical restrictions, and specifics about reimbursement parity still exist and have only been temporarily lifted during the 2019–2020 COVID-19 pandemic [79]. The lack of consistent regulations of proliferating medical apps prevents a high risk to patient safety [80].

3.2 Expectations and value gaps

Innovations in most healthcare organizations in the US are driven by the need to meet basic regulatory compliance metrics and financial viability (bottom line). Healthcare leadership are more concerned about the bottom line while regulators are mostly concerned about patient safety. Patients are concerned about convenience of service and safety.

3.3 Data security and data integrity

Another important issue with DH and big data is the constant threat to healthcare data integrity and security. These occur in the form of hacking, malware, unauthorized access, and data theft. In 2019, almost 41 million medical records were affected by healthcare data breaches, mostly through hacking and ransomware attacks [81]. The average cost of these breaches to affected healthcare organizations was about $6.5million [82].

3.4 Disparity in access to DH tools

Presently, resources (infrastructure, expertise, and personnel) required to utilize DH/big data are not available to all and confer a competitive advantage to those who possess them. The resulting disparity and its consequences are contrary to the outcome we seek from DH innovations. Nearly half of the world's population do not have reliable internet access. This phenomenon is well known and described in the literature as the "digital divide" [64].

3.5 Challenges peculiar to artificial intelligence and ML

3.5.1 Lack of explainability and interpretability

Explainability describes the degree of transparency and traceability of the outcome of any AI/ML model [83]. This is particularly important because of the non-linear, highly nested structure of complex algorithms, which makes us unaware of how they arrive at their conclusion or output [65]. This characteristic, described as the "black box" phenomenon, represents a huge setback in the application of AI/ML in healthcare [66]. This is mainly due to the sensitive nature of health operations and its low tolerance for lack of transparency in decision making. Thus, those who develop AI tools must involve primary stakeholders and decision makers from the beginning to assist with transparency and adoption by end users.

3.5.2 Highly dependent on data quality and quantity

Predictive analytics and model development rely heavily on not just high volume data but also high quality data. Unfortunately, most available healthcare data are unstructured and interspersed with artifacts/"noise" which increases the chances of spurious model output even in the setting of a near-perfect model [84].

3.5.3 Prone to adversarial attacks

Adversarial attacks are either targeted or non-targeted inputs uniquely engineered to cause mis-classification and fool an AI model to produce an incorrect output [67]. This tendency for adversarial attacks in medical AI applications is due to the inherent monetary incentive for fraud in healthcare as an industry with more than three trillion-dollar annual expenditure [68]. A second reason is the technical vulnerability of the models in healthcare.

3.5.4 Implicit bias propagation

In an ethnically diverse nation like the US, an excellent AI/ML output can only be achieved if the training data utilized are equally diverse. If there is no conscious effort to ensure diversity of training data, the algorithm would be propagating the conscious and subconscious bias that exists in our society [85]. An example is an algorithm developed to detect malignant melanoma.

Malignant melanoma is treatable if detected earlier and ML algorithm can aid in early detection. However, the algorithm is at risk of bias and disparity already grounded in our society due to the lack of adequate representation of people of color/darker skin tone in training data [85]. This limitation can hinder the utility of the algorithm for people of color. Presently, most ML programs like the International Skin Imaging Collaboration Project source their training dataset mostly from fair skinned populations in the US, Australia, and Europe [85].

Other manifestations of propagated bias include: fit bits® produces inaccurate heart rate in people of color [86] and biases and mislabeling of facial recognition software with algorithm output of people of Asian descent represented as blinking facial images [69]. The risk here is the tendency to worsen all our societal ills like health disparity, inequality, gender bias, and racism, which are all hindrances to quality public health for all.

3.5.5 Unable to handle outliers/unexpected data points/events without precedence

ML algorithms are only as good as the quality of their training data set. Unexpected data points and sudden changes in pre-defined events will likely result in poor performance. This lack of initiative of the ML/AI algorithm is coupled with a lack of empathy displayed in a human-to human healthcare interaction, representing a setback for patient satisfaction.

3.5.6 Lack of consensus on disclosure of AI/ML tools in direct patient care

There exists a lot of ethical dilemmas in the application of ML tools which cannot be ignored. One of the dilemmas we face is the need for disclosure whenever ML tools are used in direct patient care [87]. In most of these applications, patients are not aware that the care from their clinician is augmented by ML algorithms even when the effectiveness of these algorithms are yet to be proven [70]. There is still no consensus amongst providers and patients alike regarding the right ethical approach to tackle this issue.

4. Separating the "wheat from the chaff:" evaluating and monitoring of HIT and DH tools for value and healthcare quality

Evaluation of DH tool/intervention is the objective and systemic assessment of a DH intervention/tool with the sole purpose of determining the efficacy, efficiency, impact, sustainability, and extent to which pre-set specific objectives are met. According to the World Health Organization, "evaluation asks whether the DH tool/project is doing the right things, while monitoring asks whether the DH tool/project is doing things right." [88]. Although monitoring and evaluation (M&E) are distinct entities, they are usually addressed simultaneously from pre-prototype/prototype stage through the pilot and demonstration/display of tool up to the stage of scale up.

4.1 Stages of monitoring and evaluation

The first stage of M&E is to identify the stage of maturity of the tool. This determination will play into the methodology/framework utilized for M&E.

After identifying the stage of maturity of tool, the next step would be to ascertain concrete baseline expectations of the tool and define appropriate claims based on stage of maturity of the DH tool. The usability of the tool is an important measure that should be evaluated in all the stages of maturity from early to late stages. It is also important to set expectations in relation to time to deliverables to guide M&E activities. A tool being developed to shorten wait time at the clinic should get input from patients about their pain points while setting M&E standards.

The next steps is to define the M&E framework to guide the process. There are well-established frameworks for M&E published in the literature; however, I favor structures that are result oriented [73, 88]. To strengthen the evaluation framework, it should be developed through a stakeholder consultative process and reviewed as needed during the life cycle of the project.

The next step is to determine who will be carrying out these M&E activities, how many resources will be required, and the time-based deliverables expected from the team in charge.

5. Navigating the challenges of HIT and DH for quality improvement: a call to action for all stakeholders

Considering the degree of rapid transformation and dynamism we are experiencing with the 4th Industrial Revolution, only organizations positioned to adapt will succeed. This adaptation requires that all stakeholders learn new skill sets as we navigate this transformation.

5.1 Stakeholder specific suggestions to navigate 4th industrial revolution

5.1.1 Government and regulatory agencies

Government regulatory oversight teams are needed to craft rules/policies to regulate broad DH principles like security, privacy/disclosures of DH tools, fairness and equity of implementation, and avoidance of bias in implementation. The regulatory rigors placed before approval of DH tools should be based on the level of risk of a DH tool in the event of failure, determined by a baseline failure mode and effect analysis.

Government mandates should ensure that DH tools maintain a well laid out process for human oversight of implementation no matter how "perfect" the tool may be.

5.1.2 Professional expert organizations

Professional organizations can assist with navigating complexities as it relates to specific requirements for M&E of DH tools developed for their subsections. Once general overall policies are established by the government or regulatory agencies to address fundamental societal issues to ensure quality and safety of DH, expert organizations can help narrow down these policies to suit their subsection of the healthcare ecosystem.

5.1.3 Payers

Payers are responsible for processing patient eligibility, enrollment, claims, and payment of healthcare services. In the US, payers exists as either governmental (Medicare/Medicaid) or private entities. A testament to the fragmented nature of the US healthcare system is the fact it has more than 900 healthcare payers as of 2020 [89]. These entities have a significant influence on how healthcare is delivered in the US based on their reimbursement schemes. As part of their basis for reimbursement of any healthcare service which has been augmented by DH, they should mandate standardized M&E of the tools to justify compensation; it is equally important to be wary of mandates that would stifle innovation.

5.1.4 Vendors

Healthcare vendors ranging from device and pharmaceutical manufacturers to core HIT and analytics developers and entrepreneurs are numerous; in fact, there are more than 370 HIT-specific vendors in the US as of 2020 [90]. Vendors also have a role to play in ensuring that DH tools do not only offer novelty but also have an in-built yardstick for evaluating their comparative effectiveness for objective assessment of their overall impact upon implementation.

5.1.5 Direct patient care organizations

Considering that these centers are the avenue for implementation of most DH tools, they must insist on implementing DH tools with a track record of adding value to patient safety and improving healthcare quality. In the event the DH tool intended for use is novel with no track record, the organization should demand a concrete basis and claims for M&E. This will assist with an objective comparison of the impact of a new tool with the status quo.

5.1.6 Healthcare providers

Healthcare providers are often laggards and usually conservative in the adoption of new tools, as consequences of failure are very high with regards to patient safety [91]. Nevertheless, the 4th Industrial Revolution permeates all sectors of healthcare and healthcare providers are directly impacted. They must actively learn how to become an information specialist and ask the right questions about a potential DH tool to be implemented [92]. Considering that they will be utilizing these tools to make important decisions about patients and their safety, it is important they are well equipped with the knowledge of how to evaluate and monitor the DH tools for optimal healthcare quality.

5.1.7 Patients and caregivers

Patients and caregivers are the ultimate intended beneficiaries of DH tools, as any failure of DH tool implemented will have an adverse consequence on their safety and quality of health [93]. In this new dispensation, they must prompt their healthcare providers to ask the right questions from the DH tools' developers. Patients and caregivers should understand that, as we progress further into the 4th Industrial Revolution, these DH tools will increasingly play an essential role in decisions about their care directly or indirectly.

6. Conclusion

The quadruple aim describes healthcare value as improved health outcomes, increase patient satisfaction, reduced costs, and healthcare provider satisfaction/fulfillment. DH tools have shown potential in improving healthcare quality and achieving the quadruple aim, such as promoting behaviors like healthy eating and smoking cessation, improving outcome in people with chronic conditions like cardiovascular diseases, and increasing health access through telemedicine and remote monitoring [72, 94].

Although there are demonstrated impact of DH tools in healthcare quality, it is still not an overall fix able to transition us from our state of sick care to optimum healthcare quality alone. Its applications and implementation are filled with many limitations presently hindering the achievement of its full potential in healthcare quality improvement. We cannot figure out how effective a tool is without a pre-defined basis on how to ascertain its effectiveness. Presently the evaluation and performance measurement in healthcare is costly, redundant, and labyrinthine [78].

DH tools are only part of the solution and not an ultimate solution. As such every DH tool implementation should be considered in the context of the overall socio-technical ecosystem. All innovations should be based on stakeholders' input right from the start of conception. No matter how effective a piece of technology is, if it is implemented in a poorly optimized system, it will likely result in failure.

Navigating the 4th Industrial Revolution requires that all stakeholders play an active role in this transition. No doubt it brings forth many possibilities for healthcare quality improvement; however, in the absence of evaluation standards and a systematic approach to its implementation, we risk being immersed in hype born out of the hope of an elusive better outcome. DH tools are key components in achieving value in healthcare, but it is not the destination and neither is it the goal, but rather a catalyst in the process of obtaining the ultimate goal of the quadruple aim.

Conflict of interest

The author declares no conflict of interest.

Appendix 1: glossary of abbreviations

Abbreviation	Meaning
DH	Digital Health
mHealth	Mobile Health
HIT	Health Information Technology
IoMT	Internet of Medical Things
HITECH	Health Information Technology for Economic and Clinical Health
ML	Machine learning
AI	Artificial Intelligence
DMAIC	Design, Measure, Analyze, Improve, and Control
GDP	Gross Domestic Product
HER	Electronic Health Record
HRRP	Medicare's Hospital Readmissions Reduction Program
CDS	Clinical Decision Support
FDA	Food and Drug Administration
M&E	Monitoring and Evaluation

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