Institute *for* Healthcare Improvement

Using Machine Learning to Improve Patient Safety

in the Home or Remote Setting for Adults

Innovation Report
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This IHI innovation project was conducted from July to September 2022.

IHI's innovation process seeks to research innovative ideas, assess their potential for advancing quality improvement, and bring them to action. The process includes time-bound learning cycles (30, 60, or 90 days) to scan for innovative practices, test theories and new models, and synthesize the findings (in the form of the summary Innovation Report).

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Executive Summary

Health care systems are interested in investing in technology that can improve the quality and safety of care for patients and clinicians. Machine learning presents an opportunity to do this, yet available products often do not function as expected or needed. Furthermore, health care systems are frequently more focused on leveraging resources to develop and support home care practices and processes, such as remote patient monitoring or telehealth, rather than implementing predicitive analytics and machine learning technologies in either the home or hospital settings.

The primary aim of the innovation project described in this report was to assess the use of predictive analytics, specifically machine learning, to improve patient safety through emerging and existing approaches to predict risk, such as technologies and decision support tools. Specific attention was given to how predictive analytics and machine learning can assist in monitoring patient deterioration in the home setting for adults ages 18 and older.

This report discusses key reasons why efforts to develop and implement new predictive analytic technologies in health care encounter numerous barriers such as complications of data mining and protection, daily workflow and a lack of interoperability, concerns about accuracy, workforce burden and lack of relevant expertise, and related health equity issues like biased data. Recommendations to address these barriers and other safety considerations are also presented, including the need for a clear purpose for new technologies, an emphasis on daily workflow and interoperability, and the development of quality and safety guardrails to support the development and integration of machine learning tools or remote patient monitoring systems.

Intent and Aim

The intent of this Institute for Healthcare Improvement (IHI) 90-day innovation project (conducted from July to September 2022) was to assess the use of predictive analytics, specifically machine learning, to improve patient safety through emerging and existing approaches to predict risk, such as technologies and decision support tools. Specific attention was given to how predictive analytics and machine learning can assist in monitoring patient deterioration in the home setting for adults (ages 18 and older), inclusive of acute and chronic illnesses and conditions. The project also focused on identifying where racial/ethnic disparities exist and opportunities to reduce those.

This IHI 90-day innovation project included these activities:

- Scan health care journals and leading health care magazines to identify the current state of machine learning in health care and care in the home setting, including remote patient monitoring, to improve safety.
- Interviews with individuals from organizations that have experience in the topic area to ascertain current use of or interest in implementing machine learning tools to improve safety:

- Amazon Web Services, Non-Profit Healthcare
- Bellin Health Systems
- Coastal Medical
- Hackensack Meridian Health
- Jefferson Health
- John Hopkins University, School of Medicine
- Medically Home
- MemorialCare
- Northwell Health
- Rush University Medical Center
- Sirio2 Healthcare Innovations
- University of California, San Fransisco
- West Health Institute
- VitalConnect

Background

Artificial intelligence (AI) technology holds great promise in health care, but adoption has been slow due to four major barriers: algorithmic limitation, data access limitation, regulatory barriers, and misaligned incentives.[1] Although forms of AI-like machine learning and deep learning have made progress in image-intense fields like radiology, currently in other health care sectors the promise of AI is greater than the available products.

This innovation project focuses on AI in health care, specifically machine learning. Machine learning is conceptualized using Beam and Kohane's description that machine learning lies on a spectrum which is scalable based on relative human-to-machine effort. Less human effort equates to a form of machine learning higher on the spectrum (e.g., convolutional neural networks and generative adversarial networks) and more human effort is placed lower on the spectrum (e.g., human decision-making and regression analysis).[2] Although machine learning toward the higher end of the spectrum relies less on human input, it still requires enormous amounts of data and transparency issues are documented with the "black box" (i.e., complex machine learning models that are not straightforwardly interpretable to humans).

Building on previous IHI innovation work to address the use of predictive modeling and analytics to improve patient safety and care in the home setting, this innovation project had a particular focus on using predictive analytics models in the home care setting to better identify and mitigate patient deterioration as well as to improve the quality of care for adults, with specific attention to workflow solutions and emerging approaches. With interest in and the necessity for care beyond the hospital setting, the potential for providing quality care in the home relies on clinicians' and health care staff's ability to provide accurate, timely care for patients and identify patients at risk of worsening or deteriorating health conditions, particularly for aging populations and individuals living with long-term condition(s).

To this end, predictive risk models can be useful for predicting any events that meet four criteria discussed by Nuffield Trust in their 2011 report on choosing a predictive risk model in England:

1) undesirable to the patient, 2) significant to the health services (usually cost), 3) preventable, and 4) recorded in routine administrative data.[3] Research on predictive analytics emphasizes the final criteria since administrative and clinical datasets may have greater predictability than self-reported questionnaires, while being easily accessible to health care workers and using standardized coding and recording schemes.[4,5]

As discussed above, predictive risk models in the home and remote care setting often focus on two populations: older adults and those with chronic or long-term conditions or illness. Both groups tend to be affected by multimorbidity and polypharmacy with high levels of care, risk, and cost; both patient populations are therefore likely to benefit from home or remote care such as telehealth to improve the quality of care and life.[5] While this innovation project was inclusive of these two specific patient populations, it specifically assessed how predictive analytics can improve patient safety and care for adults ages 18 and older.

Key terms used in this report are defined in Table 1 below.

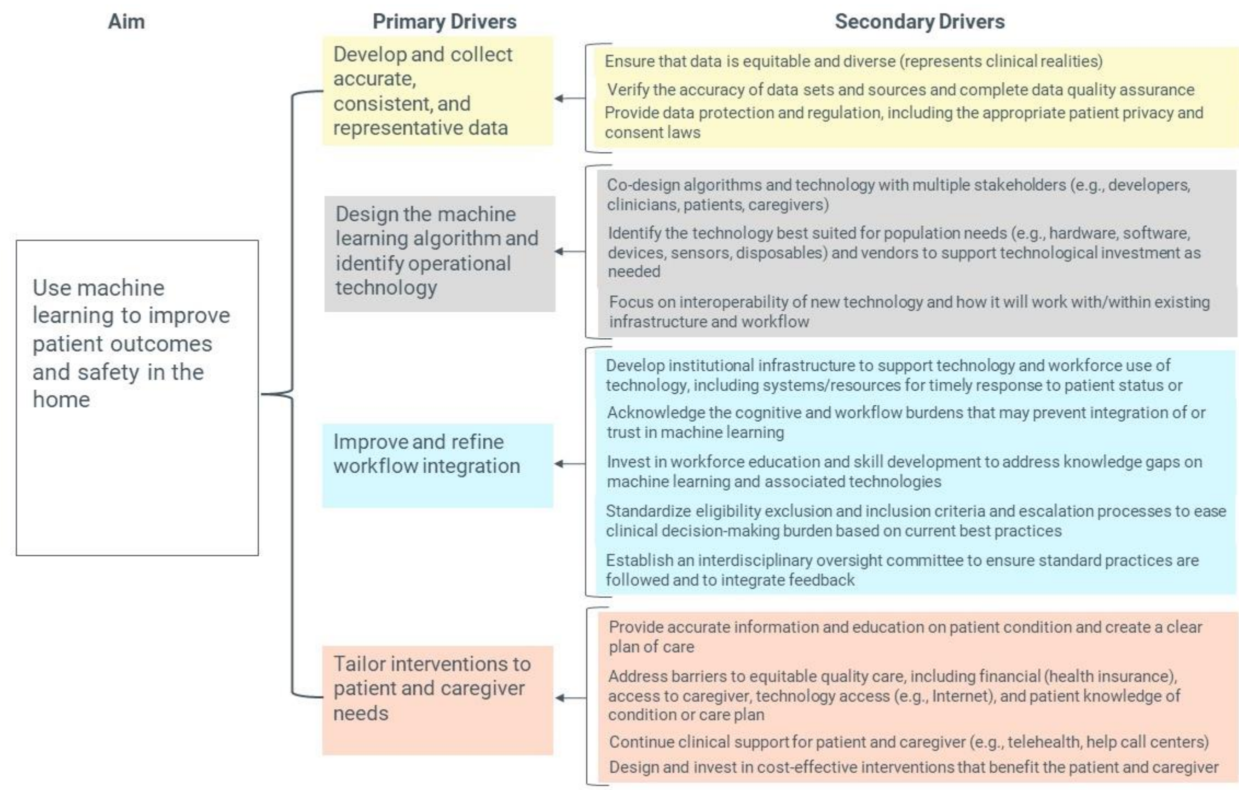
Table 1. Key Terms and Definitions

Term	Definition
Algorithm	A procedure used for solving a problem or performing a computation; in machine learning, this is a procedure that runs data to create a model and performs pattern recognition using large sets of data Throughout this report, this term refers to machine learning algorithms.
Artificial intelligence (AI)	A field of developing computers and robots that are capable of behaving in ways that both mimic and go beyond human capabilities
“Black box”	Shorthand for machine learning models that are sufficiently complex that they are not straightforwardly interpretable to humans
Machine learning (ML)	A branch of AI that focuses on the use of data and algorithms to imitate the way that humans learn, gradually improving model accuracy
Predictive analytics	A branch of advanced analytics that makes predictions about future outcomes using historical data combined with statistical modelling, data mining techniques, and machine learning
Remote patient monitoring (RPM)	Monitoring patients’ physiological measurements (such as blood pressure, weight, or blood glucose levels) outside hospital conditions by means of technology

Results of the 90-Day Innovation Project

As noted above, this project focused specific attention on the use of predictive analytics and machine learning to improve patient outcomes and safety in the home for adults (ages 18 and older). Findings from the 90-day innovation project are organized into a driver diagram (see Figure 1) detailing how machine learning can be integrated specifically into health care in the home or remote setting, with an emphasis on improving patient outcomes and safety.

Figure 1. Driver Diagram: Using Machine Learning to Improve Patient Outcomes and Safety in the Home or Remote Setting for Adults



The section that follows expands on the rationale and evidence supporting the four primary drivers and related secondary drivers depicted in the driver diagram.

Develop and Collect Accurate, Consistent, and Representative Data

Machine-learning-based algorithms development, particularly deep learning models, rely heavily on large data inputs to produce clinically useful and valid results. While this is a natural extension of a traditional statistical model, the increasing capacity of machine learning to produce results independent of human interactions creates the potential for knowledge gaps, such as the lack of transparency attributed to the "black box." Because of this, beginning with accurate, consistent, and representative data can increase the effectiveness and accuracy of machine learning outputs, while also mitigating biased data that may be introduced to the model.

The secondary drivers that support accurate, consistent, and representative data are described in more detail below.

- **Ensure that data is equitable and diverse**
  The necessity of representative data reaffirms the need for diverse population representation in data and datasets to mitigate biased or poor outcomes for underrepresented populations such as Black, Indigenous, and people of color (BIPOC) or individuals with low socioeconomic status. Data sources and sets can be diversified through the expansion of data elements, oversampling minority or marginalized populations using methods like Synthetic Minority Oversampling Technique (SMOTE), and the use of secondary methods such as Medicare Bayesian Improved Surname Geocoding (MBISG), which was developed to address data incompleteness in Medicare records pertaining to race and ethnicity.[1,2,3]
- **Verify the accuracy of data sets and sources and complete data quality assurance**
  Data accuracy is dependent on the desired outcome, thus data accuracy focuses on whether the relevant factors are being collected based on the purpose of the machine learning model. Machine learning relies on both large training data sets to ensure accurate outcomes and the accuracy of data within the training set. Accuracy can further be promoted through the performance of data quality assurance, which involves identifying and eliminating anomalies. Consistent data, then, responds to the need for complete, accurate, and standardized medical information and physiologic signals, such as completed and standard electronic health records or aggregate data from data warehouses or third-party sources. Incomplete and inaccurate data weakens the accuracy of training sets, thereby decreasing the validity of the output.
- **Provide data protection and regulation, including the appropriate patient privacy and consent laws**
  Since a machine learning algorithm is only as accurate and useful as the data source teaching it, it is imperative to develop and maintain complete, accurate, and equitable data sources and training sets that reflect realities of clinical care. This includes establishing patient privacy and consent policy and procedures, which can be integrated through Institutional Review Board approval for model testing.[4] Proper privacy protections in accordance with HIPPA and other existing privacy laws must be considered when collecting data, particularly from electronic health record systems.[5]

Design the Machine Learning Algorithm and Identify Operational Technology

While machine learning is not new to health care, individuals that IHI interviewed indicated that health systems still generally lack the needed infrastructure and skill set for the development and implementation of machine learning. Because of this, vendors seek to fill this gap and are developing proprietary tools.

This lack of progress within health care can be partially attributed to the growing complexity of machine learning as it becomes less human dependent as well as the lack of ML–AI competent workers currently in health care, which can place a greater reliance on vendors and external expertise. This emerging independence and flexibility are, in part, what allows machine learning models to accurately function without human intervention, but issues such as a lack of clarity or transparency on how the output was reached create tension within health care. Due to this lack of transparency, it is necessary for those designing and implementing algorithms and machine learning to do so with forethought to ensure accuracy, usability, and sustainability.

The secondary drivers that support designing the algorithm and identifying technology are described in more detail below.

- **Co-design algorithms and technology with multiple stakeholders (e.g., developers, clinicians, patients, caregivers)**
  It is highly recommended to involve multiple stakeholders in designing the algorithm, to establish a clear direction for the model as well as ensure that the output is clinically useful, patient centered, and safe.[6,7] Within this work, collaboration is key. Involving members of the health care workforce can ensure the output is relevant and complementary to existing clinical utility and daily workflow.[8] Interdisciplinary collaboration can mitigate common issues with machine learning such as the "black box" and lack of transparency.

- **Identify the technology for population needs (e.g., hardware, software, devices, sensors, disposables) and vendors to support technological investment as needed**
  The long-term usefulness of the algorithm is based on continuous, available data on the patient. In the home setting, user-friendly technology to monitor metrics are needed such as vital signs technologies that include pulse oximetry, blood pressure and temperature monitoring, and scales as well as software to transport and interpret the data such as remote patient monitoring software.[9,10] End users need to be considered as algorithms and technologies are developed (e.g., the patient entering data, the clinician interpreting the data).

  Here, vendor relationships and investments should be highlighted. For many of the health systems that IHI interviewed, vendors played an important role in developing and implementing machine learning tools in the hospital and home setting. As stated earlier, vendors can support health care systems by bridging technological, infrastructural, and workforce gaps (e.g., provide additional workforce such as data scientists and 24/7 nursing call centers for remote care), while lowering the financial burden of predictive modeling and machine learning models.[11] This type of support from vendors, however, needs to be understood as a partnership based on mutual trust and co-designed aims for technology and tools. Singh and colleagues emphasize collaboration and transparency as the cornerstones of a successful vendor partnership.[12]

- **Focus on interoperability of new technology and how it will work with/within existing infrastructure and workflow**
  Singh and colleagues also advise health care systems to be thorough in their review of vendors and their products due to the lack of established AI suppliers in health care since products may lack interoperability with existing platforms or have narrow applicability due to existing regulations.[12] Regulations on patient privacy and data sharing may also hamper data accrual and quality, so business associate agreements on data liability and ownership should be pursued for each individual partnership. This need for partnership agreements and guidelines for navigating regulations could become more pertinent as the Food and Drug Administration (FDA) recently announced new guidance on clinical decision support (CDS) devices, stating that some AI tools should be regulated as medical devices, which is part of the FDA's oversight of CDS software intended for health care professionals.[13,14]

  Vendors are not the only path to successfully developing or implementing these models. Some health care systems may prefer to develop their own algorithms and clinical support tools.[15]

Improve and Refine Workflow Integration

For machine learning and remote monitoring to be successfully developed and implemented, workforce and workflow concerns must be addressed, including a lack of institutional infrastructure to support the development and implementation of new decision-making tools, the need to recognize and mitigate existing clinical burden, knowledge gaps in the workforce, interdisciplinary oversight, and the ability to ensure timely support and response to patient needs wherever they are receiving care, including in the home. These concerns encompass the three major barriers noted by Gray and colleagues that impede organizations in implementing artificial intelligence: lack of governance structures and processes, resource constraints, and cultural unreadiness.[16]

The secondary drivers that support improving and refining workflow integration are described in more detail below.

- **Develop institutional infrastructure to support technology and workforce use of technology, including systems/resources for timely response to patient status or needs**
  To address these concerns and barriers and to support clinicians in practicing at the top of their license, health care systems need to ensure that they have the necessary infrastructure to support design, implementation, and refinement of machine-learning-based interventions. As Buck and colleagues noted in their attempts to maximize remote patient monitoring efforts during the COVID-19 pandemic, existing infrastructure was leveraged to rapidly scale their programs, including national communications, training, resource management, and equipment distribution infrastructure.[17] Being infrastructurally prepared for new technological implementations can ease the execution burden on the workforce, increasing overall institutional readiness.

- **Acknowledge the cognitive and workflow burdens that may prevent integration of or trust in machine learning**
  In IHI's interviews, many health care systems noted existing struggles to meet current patient needs and volume, attributed in part to staffing shortages, which place more strain on the workforce. Before addressing workforce burden due to the implementation and maintenance of new machine learning tools, consider how to alleviate existing burdens on the workforce, particularly given staffing shortages, burnout, and turnover, as well as existing workflow issues such as documentation and administrative tasks that prevent clinicians from working at the top of their license.[18]

- **Invest in workforce education and skill development to address knowledge gaps on machine learning and associated technologies**
  The workforce burden may be eased through investment in education and skill development to bridge the knowledge gap on artificial intelligence and machine learning in health care. For design and implementation to be successful, develop an AI-competent workforce via medical education curricula for students as well as professional development and workforce continuing education. Additionally, ensure that the workforce is not only AI-competent, but also has knowledge and skills to care for patients in remote locations such as the home. Education-related investments for remote care can include supporting information processing (e.g., daily patient submitted vitals), training on telemedicine devices or platforms and basic troubleshooting, and establishing and recognizing failure modes and mitigating risks in the remote care setting. Each of these investments in education must consider other burdens that prevent the workforce from engaging in professional development and continuing education such as time constraints and cognitive strain. An alternate pathway gleaned from IHI interviews is creating a new workforce skilled in data science and technology to shoulder the implementation and maintenance of new technology.

- **Standardize eligibility exclusion and inclusion criteria and escalation processes to ease clinical decision-making burden based on current best practices**
  There is a need to develop and implement a standardized set of best practices and eligibility criteria, as well as an oversight body for the implementation and use of new technologies and technology-based protocols, to ease the burden of clinical decision-making and provide clinical guidance and platforms for feedback and system improvement. Lack of standardization and interruption of workflows were identified as barriers to health care's adoption of AI and use of remote monitoring.[19,20,21] Therefore, while machine learning provides an opportunity to improve patient health outcomes, it often fails to follow or establish best practices, warranting the need for standardization to better understand the accuracy of machine learning models and support trust-building between the workforce and new technologies.[22,23]

- **Establish an interdisciplinary oversight committee to ensure standard practices are followed and to integrate feedback**
  Developing appropriate governance such as an oversight committee can provide mechanisms to resolve conflicts, prioritize diverse varieties of projects, improve

accountability, and ensure continued funding for machine learning tools and technologies.

Tailor Interventions to Patient and Caregiver Needs

While machine learning in health care aims to improve patient safety, outcomes, and quality of life, patients themselves may be neglected in considerations for how to use machine learning to adapt care, especially in the home or remote care setting. Failing to engage patients in this work can negate the impact of machine learning in health care, particularly in the home setting. Therefore, tailoring machine-learning-based interventions, specifically remote monitoring, to patient as well as caregiver needs can further improve the quality of care and usability of interventions.

Research on remote care during the COVID-19 pandemic identified the potential for remote monitoring to increase safety for patients and reduce hospitalizations, patient deaths, and cost per patient.[24] Research on in-home monitoring for those with chronic conditions such as COPD and asthma found that for "patients with chronic disease, remote monitoring increased their disease-specific knowledge, triggered earlier clinical assessment and treatment, improved self-management and shared decision-making."[25,26] Furthermore, remote monitoring and telemedicine can decrease patient and workforce burden while increasing patients' comfort and recovery, the latter specifically noted for patients in postoperative recovery from cardiac surgery.[27]

The secondary drivers that support tailoring interventions to patient and caregiver needs are described in more detail below.

- **Provide accurate information and education on patient condition and create a clear plan of care**
  Patient engagement with remote home monitoring services is influenced by patient factors such as health and knowledge, support from family, friends and staff, availability of and ease of use of source technologies, informational and material resources, and service factors.[28] Education on the appropriate knowledge of the patient's condition, technology for remote monitoring, and escalation processes helps most patients engage with services, yet is a barrier for those who indicate problems with understanding the information (e.g., how equipment works, how to complete daily tasks, or escalation of care procedures).[28]
- **Address barriers to equitable quality care, including financial (health insurance), access to caregiver, technology access (e.g., Internet), and patient knowledge of condition or care plan**
  While the provision of accurate information and education on the patients' condition and health plan can increase patients' comfort and ability to participate in remote monitoring, barriers (knowledge, environmental, financial) to machine learning and/or remote monitoring interventions must be considered and addressed.

  The safety of the home, in particular, needs to be considered on an individual basis: Can patients safely and accurately apply and troubleshoot technology? Is the infrastructure of the home safe and functional? Can remote monitoring technology safely function in the home space? Are there other members of the household and, if so, will any person function as a caregiver? Is there a backup power source for technology in the event of power failure? Are patients and family care partners able to accurately teach back how to apply and use related technology and respond in the event of a technology failure or emergency? Are language translators available for patients who require such services? Are there hazards in the home that present a risk to patients, caregivers, or the health care workforce, including weapons?

As noted in both the literature and in IHI interviews, access to wireless Internet connectivity for remote monitoring technology is a primary need and concern. Remote patient monitoring often relies on the household's connectivity (e.g., access to a smartphone and WiFi). Without that infrastructure, the ability for a care team to safely monitor a patient in the home setting diminishes.

Financial barriers may also prevent the use of machine learning models or remote patient monitoring in the home care setting due to the lack of insurance coverage in the United States; Medicare, Medicaid, and most private payers do not cover hospital care delivered at home and have restrictions for telemedicine.[29] Although these gaps in insurance coverage shrunk during the pandemic due to Centers for Medicare & Medicaid Services (CMS) blanket waivers for telemedicine, they still pose a challenge to encouraging patients and providers to engage in home care and remote patient monitoring.

At the time of this report's publication, CMS blanket waivers, including telemedicine, are still available. However, in IHI interviews, health care systems and providers acknowledged that the temporary nature of these blanket waivers complicate their ability to plan for and deliver long-term care that relies on the accessibility of remote care or care in the home setting (e.g., telehealth). These waivers were originally issued in response to COVID-19, citing section 1135 of the Social Security Act. But recent updates to the COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers state that, unless otherwise noted, waivers will be terminated at the end of the COVID-19 public health emergency.[30] Although no end date is provided in the updated document, CMS does have a publicly available roadmap for navigating the end of the COVID-19 public health emergency and termination of emergency waivers.[31]

- **Continue clinical support for patient and caregiver (e.g., telehealth, help call centers)**
  Even with a focus on remote monitoring interventions in the home setting, it is necessary to continue clinical support from providers and staff to balance "against concerns about losing interpersonal contact, and the additional personal responsibility of remote monitoring."[32] Clinical staff support is reassuring for patients and caregivers. One study identified support from staff helped patients engage in services and assisted patients and caregivers in understanding information, obtaining and using equipment appropriately, and escalating care.[33]

- **Design and invest in cost-effective interventions that benefit the patient and caregiver**
  It is necessary for any interventions related to machine learning and/or in the home

setting to be cost-effective for both the health care system and patient, while maintaining or improving patient safety and quality of care. Notably, research on care in the home setting such as remote patient monitoring and Hospital at Home have been found to lower costs.[34,35] For example, one randomized control trial of an older adult care intervention found that the intervention group had a 31 percent lower annualized inpatient cost, attributed to the cost of inpatient encounters, highlighting the potential impact of telehealth-based population health management programs.[36]

Further Considerations

Current State of Predictive Analytics (AI–ML) in Health Care Systems

Most of the health care systems that IHI interviewed were in the preliminary stages of developing or pursuing a digital roadmap to implement machine learning technologies, often developed through an internal committee structure to prioritize health care system goals related to digital health care. Committees were often interdisciplinary, including executive leadership such as chief strategy officers and chief information officers, although the deep engagement of safety and quality professionals was variable.

Although health systems expressed strong interest in and support for harnessing the benefits of newer technologies, the pandemic dislodged systems' previous plans and shifted to an increase in remote care. Not only had interest shifted to developing and sustaining remote care and telehealth, but many systems also shared that the promise of machine learning technologies had exceeded available products. For example, a study found that one sepsis predictive model had "poor discrimination and calibration in predicting the onset of sepsis at the hospitalization level," which furthered existing alarm fatigue and failed to perform more effectively than clinicians.[37,38] Health systems that IHI interviewed echoed this assessment, disclosing struggles with effectively implementing the tool. Due to project time constraints, IHI did not complete a comprehensive review or survey of this specific tool, or other predictive analytic or AI technologies, and thus cannot make a definitive statement on clinical accuracy or usefulness. In the recently released FDA statement, this is one such technology that may now be subject to regulatory review.[39]

Other barriers to the development and implementation of effective machine learning models in health care systems include challenges with data collection and processing and workforce issues. Health care systems possess substantial amounts of valuable data, yet these data often remain underutilized due to shortages of expertise in the workforce (e.g., data scientists), a lack of data integration and management, and cost. Solutions to these issues include vendor partnerships to provide expertise and additional workforce, internal development of data capacity (i.e., expand internal data workforce, upgrade technological infrastructure, integrate data collection with electronic health records), and data sharing agreements.

However, as noted previously, health systems' current aims tend to focus on pandemic recovery and improvements and on home care such as remote patient monitoring and implementation of programs such as Hospital at Home. While development and implementation of machine learning technologies and interventions are being explored, they are not widely employed and, when employed, have not performed to industry standards.

Safety Considerations

Since this innovation project had a specific focus on safety — for the patient, caregiver, and health care workforce — IHI considered the safety concerns and unintended consequences of predictive analytics and machine learning, both in the home and acute setting. Five selected safety considerations identified in our literature scan and interviews are discussed below. These five considerations are in addition to and expand on previous safety issues discussed within the driver diagram, but do not present a comprehensive review of all potential factors.

Alarm Fatigue

Alarm fatigue due to false positives is a well-documented safety concern. Machine learning tools and interventions introduce the challenge of configuring and calibrating alarms to the correct sensitivity. To strike the right balance when implementing this technology (over-triggering vs. under-alerting), consider which alerts should be sent, how to optimize alert accuracy, who should receive alerts, and when and how to send them.[40] This issue was highlighted in IHI interviews when discussing implementation of the predictive sepsis model and remote patient monitoring. Notable safety concerns include missed alerts due to alarm fatigue or improper calibration of alarm sensitivity.

Diversion of Resources

The diversion of resources, inclusive of system funds and clinician time, is also pertinent since both remote patient care and machine learning care are resource-intensive endeavors that may not be beneficial to the patient. For example, if a new predictive analytic model is poorly integrated into existing electronic health records, clinicians may spend more time on documentation, deliberation, and troubleshooting, decreasing the time spent on patient care. This decrease in attentive patient care could lead to a reduction in the quality of care received, thereby creating a safety issue.

Complications with Data Presentation and Interpretation

The ways in which data are presented and interpreted can impact a clinician's decision making and may thus impact safety. Two primary concerns for data presentation and interpretation are introduced with machine learning tools and interventions:

- **Mistrust:** A clinician's lack of trust for machine learning outputs could create complications in care (i.e., the "black box"). Even if the technology is accurate, mistrust could undermine adoption of machine learning tools.
- **Overreliance:** Alternatively, clinicians could become too reliant on machine learning tools.[41] Machine learning could become a collective medical mind with authority, which would undermine individual clinical experience and critical thinking, allowing machine learning to bypass its role as a support tool.[42]

Both lack of trust and overreliance on support tools could create safety issues by potentially undermining the quality of care that patients receive. Another data-related complication is poor adherence to medical documentation such as not reviewing a patient's active medications, which may carry over unused medications in the electronic health record and possibly lead to a safety issue.

Lack of Patient and Caregiver Education

For remotely monitored patients, safety issues may arise if patients and caregivers are not properly educated on the patient's condition, care plan, or escalation pathways. For example, patients required to enter vital signs as a part of their remote monitoring care plan must be able to correctly use the devices (e.g., pulse oximeter) to obtain accurate readings and understand how to relay that information to providers (e.g., navigating an application on a tablet or smartphone). Patient safety or quality of care concerns may arise if they are unable to accurately and efficiently communicate this information. For patients with visual, hearing, cognitive, and/or motor skills deficits, their ability to safely and accurately use remote monitoring technology may be impacted.

Sustainability

Sustainability refers to the ability to continue providing a quality care service with machine learning technology and remote patient monitoring. While each has its benefits, health care systems must ensure that the implementation of interventions and technologies is feasible and supportable in the long term. Safety concerns may arise should a patient's care be reliant on a technology-based program or product that is discontinued, and this may also negatively impact the patient's quality of care and life.

Despite these and other safety considerations, remote monitoring and machine learning present opportunities to understand and identify patient deterioration and improve timeliness of care, enabling the development of more successful interventions to increase patient quality of care and life. Health care systems must consider these safety concerns, however, in their efforts to develop and implement these types of interventions or tools in order to provide a high quality of care and life for patients, clinicians, and caregivers.

Conclusion

Considerable thought has been given to the development and implementation of machine learning and remote patient monitoring in health care. Big data and new technologies hold promise in improving the quality of care and safety for patients, caregivers, and clinicians, but barriers to effective implementation and integration remain.

To safely advance these types of technology-based tools in health care, IHI provides the guidance and recommendations that follow.

- **A clear purpose for new technologies or interventions:** Each new tool or intervention that is introduced needs to enhance the patient–provider experience, while maintaining or improving safety and quality of care.

- **An emphasis on daily workflow when implementing new technologies or interventions:** Lack of interoperability or added work for clinicians and other health care staff prevent safe and quality care from being provided and exacerbates existing workforce burden.
- **Quality and safety guardrails:** Health care systems must consider how to design, implement, and sustain new technologies while ensuring and improving the quality and safety of care for patients, caregivers, and the workforce. This includes the meaningful engagement of quality and safety professionals as well as systems and human factors expertise in the planning and operationalization of such efforts.

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