Institute *for* Healthcare Improvement

Innovation Project Final Report:
Using predictive analytics to improve patient safety: workflow solutions and emerging approaches
Wave 64, July to September 2022

Project Type:
(Highlight one in bold)

90-day Innovation Project: **A full wave to scan, test, and document recommendations in a formal deliverable**	*30-day Innovation Project:* A short project to scan, provide research assistance, or design an expert meeting

Executive Summary: *Please summarize the following project details, in brief (~1 paragraph): Project aim; problem the project is trying to solve; research process (including which regions were covered during scanning); and key findings*

Healthcare 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 meet the promise. This cycle found that most healthcare systems were interested in machine learning tools, but that existing tools did not function as expected or needed. Furthermore, systems often were more focused on developing home care practices and processes such as remote patient monitoring or telehealth. Roadmaps to develop and implement new predictive analytic technologies encountered 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 AI-related expertise, and related health-equity issues (i.e., biased data). Recommendations to address these barriers and other safety considerations include 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.

Team:

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Intent & Aim:

In this wave, the innovation team further built upon IHI's continued commitment to patient safety by focusing on the use of predictive analytics in improving 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 (18 and older) inclusive of acute and chronic illnesses and conditions. The team identified where there are racial/ethnic disparities and identified opportunities to reduce those.

Background:

Artificial intelligence (AI) technology holds great promise in healthcare, but its adoption is lacking. As Goldfarb and Teodoridis (2022), this lack of adoption can be attributed 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, at this moment, the promise of AI is greater than the available product in other healthcare sectors.

Building upon previous innovation waves' work on predicting and mitigating risk and cost, such as high-risk and high-cost patients and populations (Wave 26, High-Risk High-Cost) as well as quality improvements role in improving digital health technologies implementation (Wave 59, Tech Implementation and Quality Improvement), this project focuses on AI in healthcare, specifically machine learning. Machine learning is conceptualized following Beam and Kohane's description, that machine learning lies on a spectrum which is scalable based upon 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 towards the higher end of the spectrum relies less on human input, it still does require enormous amounts of data and transparency issues are documented with the "black box".

This project extends previous innovation work to address the use of predictive modeling and analytics for patient care and safety and care in the home setting, specifically questioning how deterioration in the home can be better identified and mitigated as well as used to improve the quality of care through predictive analytic models for adults with attention to workflow solutions

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[1] Goldfarb A, Teodoridis F. Why Is AI Adoption in Health Care Lagging? Brookings; 2022. https://www.brookings.edu/research/why-is-ai-adoption-in-health-care-lagging/

[2] Beam AL, Kohane IS. Big Data and Machine Learning in Health Care. JAMA. 2018;319(13):1317. doi:10.1001/jama.2017.18391

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 clinician and health care staff's ability to provide accurate and timely care for patients, particularly identifying patients at risk of worsening or deteriorating health conditions, including populations of all ages, as well as ageing populations and those living with long-term condition(s). To this end, predictive risk models can be useful for predicting any events that meet the four criteria discussed by Nuffield Trust in their 2011 report on choosing a predictive risk model in England. Those criteria include when an event is: (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: those with chronic or long-term conditions or illness and the elderly. Each group tends to be affected by multimorbidity and polypharmacy with high levels of care, risk, and cost and are a patient population likely to benefit from home or remote care such as telehealth to improve the quality of care and life.5 While this project is inclusive of these two specific patient populations, it will assess how predictive analytics can improve patient safety and care for an adult population.

Table 1. on Defining Key Terms

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. This procedure performs pattern recognition using large sets of data. Throughout this report, it will refer to machine learning algorithms

[3] Lewis G, Curry N, Bardsley M. Choosing a Predictive Risk Model: A Guide for Commissioners in England. Nuffield Trust; 2011:1-12.

[4] Lewis G, Curry N, Bardsley M. *Choosing a Predictive Risk Model: A Guide for Commissioners in England*. Nuffield Trust; 2011:1-12.

[5] Wallace E, Stuart E, Vaughan N, Bennett K, Fahey T, Smith SM. Risk Prediction Models to Predict Emergency Hospital Admission in Community-dwelling Adults: A Systematic Review. *Medical Care*. 2014;52(8):751-765. doi:10.1097/MLR.0000000000000171.

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 ML 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 modeling, 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

Methods:

The first phase of this 90-day wave consisted of scanning healthcare journals and leading healthcare magazines to identify the current state of machine learning in healthcare as well as care in the home setting, including remote patient monitoring. The second phase consisted of key informant interviews. See Table 2 for the list of organizations that took part in the interviews.

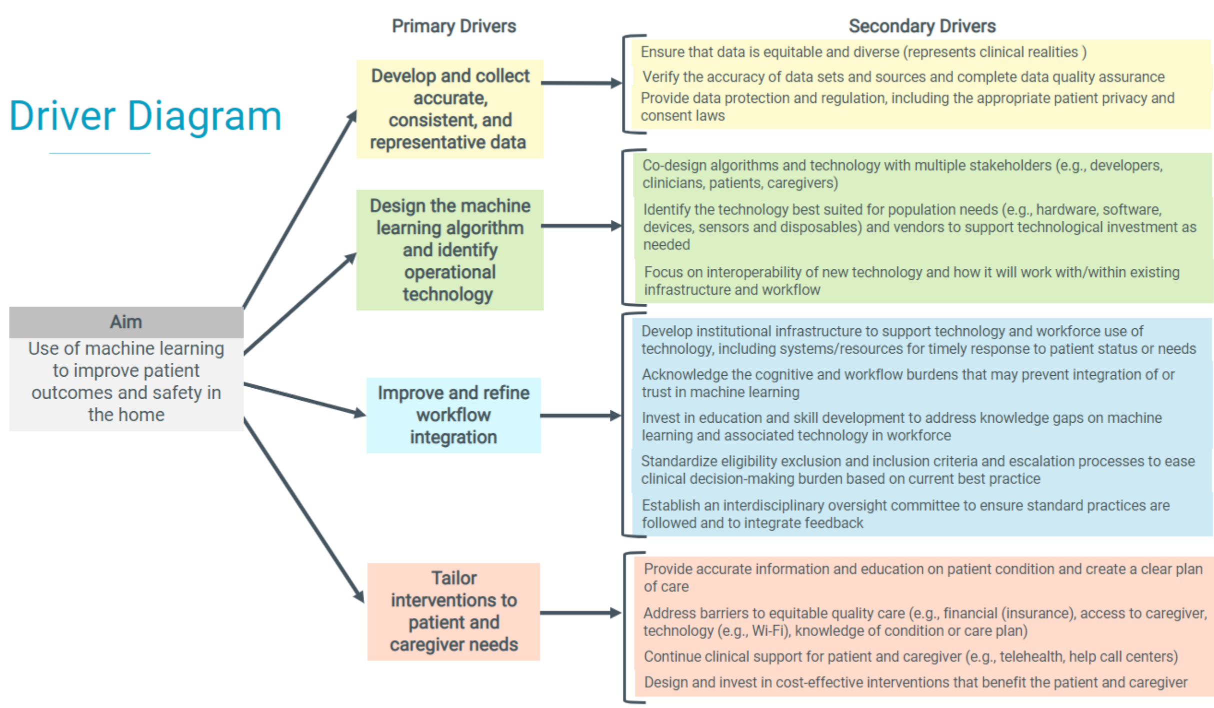
Table 2. Key Informant Interviews: List of Organizations

AWS
Bellin
Coastal Medical
ConnectiveRX
Hackensack Meridian Health
Jefferson Health
John Hopkins
Medically Home

Medtronic
Memorial Care
Northwell
Rush University
University of California, San Fransisco
West Health
VitalConnect

Results:

Our findings have been systemized into a clear driver diagram detailing how machine learning can be integrated into healthcare in the home or remote setting, with an emphasis on improving patient outcomes and safety. The following sections will expand upon the evidence supporting each primary and secondary driver.



a. Develop and collect accurate, consistent, and representative data

Beginning with accurate, consistent, and representative data is a necessary component for developing machine learning in healthcare since data is used as a training set for machine learning models. That is machine-learning-based algorithms development, particularly deep learning models, rely heavily upon 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 (see Table 1). Because of this, beginning with accurate, consistent, and representative data can increase the effectiveness and accuracy of machine learning outputs, while also working to mitigate bias that may be introduced to the model due to biased data.

This following section will further detail what is meant by accurate, consistent, and representative data and why these components are crucial to the functionality of machine learning in healthcare. First, data's accuracy is dependent on the desired outcome. So, discussions of data accuracy focus upon whether the relevant factors are being collected based upon the purpose of the machine learning model. So, not only does machine learning rely upon large training data sets to ensure accurate outcomes, but it also relies upon that accuracy of the 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 medical records or aggregate data from data warehouses or third-party sources. Incomplete and inaccurate data weakens the accuracy of training sets, therefore decreasing the validity of the output. Finally, 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, BIPOC or low SES patients. 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]

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 clinical realities. This includes establishing patient privacy and consent policy and procedures, which can be integrated through IRB 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]

b. Design the machine learning algorithm and identify operational technology

While machine learning is not new to healthcare, interviews have 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 healthcare 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 healthcare, 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. And, 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.

To do so, it is highly recommended that multiple stakeholders be involved in designing the algorithm to set a clear direction for the model as well as ensure that the output produced is clinically useful, patient centered, and safe.[6,7] Within this work, collaboration is key. Involving members of the 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.

The long-term usefulness of the algorithm is based upon 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 require pulse oximetry, blood pressure and temperature monitoring, and scales as well as software to transport and interpret the data such as RPM

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[6] Reyna MA, Nsoesie EO, Clifford GD. Rethinking Algorithm Performance Metrics for Artificial Intelligence in Diagnostic Medicine. *JAMA*. 2022;328(4):329. doi:10.1001/jama.2022.10561

[7] Watson J, Hutyra CA, Clancy SM, et al. Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: what can we learn from US academic medical centers? *JAMIA Open*. 2020;3(2):167-172. doi:10.1093/jamiaopen/ooz046

[8] Reyna MA, Nsoesie EO, Clifford GD. Rethinking Algorithm Performance Metrics for Artificial Intelligence in Diagnostic Medicine. *JAMA*. 2022;328(4):329. doi:10.1001/jama.2022.10561

software.[9,10] As algorithms and technologies are developed, the end-user should be considered (e.g., the patient entering data and the clinician interpreting the data).

Here, vendor relationships and investments should be highlighted. For many systems interviewed, vendors played an important role in the developing and implementing machine learning tools in the hospital and home setting. As stated earlier, vendors can support healthcare 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] As noted in interviews, though, this support should be understood as a partnership based upon mutual trust and co-designed aims for technology and tools. Singh et al. (2020) emphasizes collaboration and transparency as the cornerstones of a successful vendor partnership.[12] Authors further advise that healthcare systems be thorough in their review of vendors and their products due to the lack of established AI suppliers in healthcare as products may lack interoperability with existing platforms or have narrow applicability due to existing regulations. 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

[9] Coffey JD, Christopherson LA, Glasgow AE, et al. Implementation of a multisite, interdisciplinary remote patient monitoring program for ambulatory management of patients with COVID-19. npj Digit Med. 2021;4(1):123. doi:10.1038/s41746-021-00490-9

[10] Pronovost PJ, Cole MD, Hughes RM. Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit. *JAMA*. 2022;327(12):1125. doi:10.1001/jama.2022.2040

[11] Watson J, Hutyra CA, Clancy SM, et al. Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: what can we learn from US academic medical centers? JAMIA Open. 2020;3(2):167-172. doi:10.1093/jamiaopen/ooz046

[12] Singh RP, Hom GL, Abramoff MD, Campbell JP, Chiang MF, on behalf of the AAO Task Force on Artificial Intelligence. Current Challenges and Barriers to Real-World Artificial Intelligence Adoption for the Healthcare System, Provider, and the Patient. Trans Vis Sci Tech. 2020;9(2):45. doi:10.1167/tvst.9.2.45

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]

It should be noted that vendors are not the only path to successfully developing or implementing these models. Some healthcare systems may prefer to develop their own algorithms and clinical support tools.[15]

c. Improve and refine workflow integration

For machine learning and remote monitoring to be successfully developed and implemented, workforce and workflow concerns must be addressed. These concerns include: 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 et al. (2022) that impeded organizational to implement artificial intelligence: the lack of governance structures and processes, resource constraints, and cultural unreadiness.[16]

To address these concerns and barriers and to support clinicians in practicing at the top of their license, healthcare systems should ensure that they have the needed infrastructure to support design, implementation, and refinement of machine-learning-based interventions. As Buck et al. (2021) 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

[13] Kennedy S. FDA Releases Guidance on AI-Driven Clinical Decision Support Tools. HealthITAnalytics. Published September 29, 2022. https://healthitanalytics.com/news/fda-releases-guidance-on-ai-driven-clinical-decision-support-tools

[14] Food and Drug Administration. Guidance for Industry and Food and Drug Administration Staff. Food and Drug Administration; 2022:1-26. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

[15] Watson J, Hutyra CA, Clancy SM, et al. Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: what can we learn from US academic medical centers? JAMIA Open. 2020;3(2):167-172. doi:10.1093/jamiaopen/ooz046

[16] Gray K, Slavotinek J, Dimaguila GL, Choo D. Artificial Intelligence Education for the Health Workforce: Expert Survey of Approaches and Needs. JMIR Med Educ. 2022;8(2):e35223. doi:10.2196/35223

infrastructure.[17] Being infrastructurally prepared for new technological implementations can ease the execution burden placed upon the workforce, increasing overall institutional readiness.

Before addressing workforce burden due to the implantation of new machine learning tools, consideration should be given for existing burdens placed upon 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] As discussed in interviews, many healthcare systems are struggling to meet current patient needs and volume which can be, in part, attributed to staffing shortages, which place more strain upon the current workforce. Therefore, the implementation and maintenance of new models and technologies should consider how to both alleviate this burden as well as preventing further burdens.

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 healthcare. For design and implantation to be successful, an AI-competent workforce should be developed through the curriculum within medical education for students as well as professional development and continuing education for the workforce.[19,20,21] Additionally, there is the need to ensure that the workforce is not only AI-competent, but also that they can care for patients in remote locations. Here, education-related investments for remote can include supporting the processing of information (e.g., daily patient submitted vitals), training on how to use telemedicine devices or platforms and basic troubleshooting and establishing and recognizing failure modes and mitigating risk 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

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[17] Buck C, Kobb R, Sandreth R, et al. Maximizing VA Remote Patient Monitoring During the COVID-19 Response. *TMT*. Published online July 30, 2021. doi:10.30953/tmt.v6.281

[18] Coffey JD, Christopherson LA, Glasgow AE, et al. Implementation of a multisite, interdisciplinary remote patient monitoring program for ambulatory management of patients with COVID-19. *npj Digit Med*. 2021;4(1):123. doi:10.1038/s41746-021-00490-9

[19] Amarasingham R, Patzer RE, Huesch M, Nguyen NQ, Xie B. Implementing Electronic Health Care Predictive Analytics: Considerations And Challenges. Health Affairs. 2014;33(7):1148-1154. doi:10.1377/hlthaff.2014.0352

[20] Gray K, Slavotinek J, Dimaguila GL, Choo D. Artificial Intelligence Education for the Health Workforce: Expert Survey of Approaches and Needs. *JMIR Med Educ*. 2022;8(2):e35223. doi:10.2196/35223

[21] Watson J, Hutyra CA, Clancy SM, et al. Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: what can we learn from US academic medical centers? *JAMIA Open*. 2020;3(2):167-172. doi:10.1093/jamiaopen/ooz046

pathway provided in interviews recommends creating a new workforce skilled in data science and technology to shoulder the implementation and maintenance of new technology.

Finally, 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 as well as provide clinical guidance and platforms for feedback and system improvement. A lack of standardization and interruption of workflow were identified as barriers to healthcare's adoption of AI and use of remote monitoring.[22,23,24] Therefore, while machine learning provides an opportunity to improve healthcare outcomes, it often fails to follow or establish best practices warranting the need for standardization to better understand model's accuracy and patient health outcomes as well as to support trust-building between the workforce and new technologies.[25,26] Furthermore, the development of appropriate governance, such as an oversight committee, can provide mechanisms to resolve conflicts, prioritize diverse varieties of projects, improve accountability, and ensure continued funding.

d. Tailor interventions to patient and caregiver needs

While the aims of machine learning in health care focus upon improvements to patient safety, outcomes, and quality of life, the patient, themselves, may be neglected in considerations for how machine learning will be adapted for care, especially in the home or remote setting. This neglect 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 patients as well as caregiver needs can further improve the quality of care and useability of interventions.

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22 Goldfarb A, Teodoridis F. *Why Is AI Adoption in Health Care Lagging?* Brookings; 2022. https://www.brookings.edu/research/why-is-ai-adoption-in-health-care-lagging/

23 Coffey JD, Christopherson LA, Glasgow AE, et al. Implementation of a multisite, interdisciplinary remote patient monitoring program for ambulatory management of patients with COVID-19. *npj Digit Med*. 2021;4(1):123. doi:10.1038/s41746-021-00490-9

24 Pronovost PJ, Cole MD, Hughes RM. Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit. JAMA. 2022;327(12):1125. doi:10.1001/jama.2022.2040

25 Sendak MP, D'arcy J, Kashyap S, et al. A Path for Translation of Machine Learning Products into Healthcare Delivery. *EMJ Innov*. Published online January 27, 2020. doi:10.33590/emjinnov/19-00172

26 Sandhu S, Lin AL, Brajer N, et al. Integrating a Machine Learning System Into Clinical Workflows: Qualitative Study. *J Med Internet Res*. 2020;22(11):e22421. doi:10.2196/22421

As research on remote care during the COVID-19 pandemic recognized, remote monitoring can increase safety for patients and reduce hospitalizations, patient deaths, and cost per patient.[27] As Walker et al. (2019) found in their research on in-home monitoring for those with chronic conditions such as COPD and asthma, "patients with chronic disease, remote monitoring increased their disease-specific knowledge, triggered earlier clinical assessment and treatment, improved self-management and shared decision-making.[28],[29] 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.[30]

Tailoring interventions includes four criteria, then, to provide accurate information and education on the patients' condition and health plan, address barriers to quality care, continue clinical support, and provide an intervention that is cost-effective. As Walton et al. (2022) identified patient engagement with remote home monitoring services was 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. Education on the appropriate knowledge of the patient's condition, technology for remote monitoring, and escalation processes helped patients engage with services (55%) while becoming a barrier for those who indicated problems with understanding the information (e.g., how equipment works, how to complete daily tasks, or escalation of care procedures).[31]

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 are present. In addition to knowledge barriers, environmental and financial barriers should also be considered for machine learning and/or remote monitoring interventions. For interventions based

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[27] Pronovost PJ, Cole MD, Hughes RM. Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit. *JAMA*. 2022;327(12):1125. doi:10.1001/jama.2022.2040

[28] Sanchez-Morillo D, Fernandez-Granero MA, Leon-Jimenez A. Use of predictive algorithms in-home monitoring of chronic obstructive pulmonary disease and asthma: A systematic review. *Chron Respir Dis*. 2016;13(3):264-283. doi:10.1177/1479972316642365

[29] Walker RC, Tong A, Howard K, Palmer SC. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. *International Journal of Medical Informatics*. 2019;124:78-85. doi:10.1016/j.ijmedinf.2019.01.013

[30] Atilgan K, Onuk BE, Köksal Coşkun P, et al. Remote patient monitoring after cardiac surgery: The utility of a novel telemedicine system. *Journal of Cardiac Surgery*. 2021;36(11):4226-4234. doi:10.1111/jocs.15962

[31] Walton H, Vindrola-Padros C, Crellin NE, et al. Patients' experiences of, and engagement with, remote home monitoring services for COVID-19 patients: A rapid mixed-methods study. Health Expectations. Published online July 7, 2022:hex.13548. doi:10.1111/hex.13548

in the home setting, the safety of the home should 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 monitoring technology safety function in the home space? Are there other members of the household and, if so, will any person function as a caregiver (e.g., family or pets)? 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 translators available for patients who require such services? Are there hazards in the home that present a risk, to patients, families, or workforce, including weapons? A continuous concern noted in literature and in interviews is wireless connectivity.

For remote patient monitoring, much of the monitoring relies upon the households' connectivity (e.g., access to a smartphone and Wi-Fi). Without that infrastructure, the ability for a care team to monitor a patient in the home care setting safely 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 as Medicare and Medicaid services as well as most private payers do not cover for hospital care delivered at home and have restrictions for telemedicine.[32] Although these gaps in coverage shrunk during the pandemic due to CMS blanket waivers for telemedicine, they still pose a challenge to encouraging patients and providers to engage in home care and remote patient monitoring.

It should be noted that, while CMS blanket waivers, including telemedicine, are still available at the time of this report's publication, in our interviews, healthcare systems and providers acknowledged that the temporary nature of these blanket waivers complicated their ability to plan for and deliver long-term care that rely 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.[33] Note that no end date is provided in the updated document, though, CMS does have a publicly available

[32] Klein S. "Hospital at Home" Programs Improve Outcomes, Lower Costs But Face Resistance from Providers and Payers. The Commonwealth Fund. https://www.commonwealthfund.org/publications/newsletter-article/hospital-home-programs-improve-outcomes-lower-costs-face-resistance.

[33] Centers for Medicare & Medicaid Services. COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. Centers for Medicare & Medicaid Services (CMS); 2022. https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

roadmap for navigating the end of the COVID-19 public health emergency and termination of emergency waivers.[34]

Even, with a focus on 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."[35] Clinical staff support is reassuring for patients and caregivers. As Walton et al. (2022) 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.[36]

Finally, it is necessary for any interventions within the scope of the project—relating to machine learning and/or in the home setting—to be cost-effective for both the healthcare 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.[37,38] For example, Nikolova-Simons et al. (2021) found, in their randomized control trial of an older adult care intervention, the intervention group had a 31% lower annualized inpatient cost, which was attributed to the cost of inpatient encounters, highlighting the impact of telehealth-based population health management programs.[39]

e. Further considerations

34 Blum J, Blackford C, Moody-Williams J. Creating a Roadmap for the End of the COVID-19 Public Health Emergency. Published August 18, 2022. https://www.cms.gov/blog/creating-roadmap-end-covid-19-public-health-emergency

35 Walker RC, Tong A, Howard K, Palmer SC. Patient expectations and experiences of remote monitoring for chronic diseases: Systematic review and thematic synthesis of qualitative studies. *International Journal of Medical Informatics*. 2019;124:78-85. doi:10.1016/j.ijmedinf.2019.01.013

36 Walton H, Vindrola-Padros C, Crellin NE, et al. Patients' experiences of, and engagement with, remote home monitoring services for COVID-19 patients: A rapid mixed-methods study. Health Expectations. Published online July 7, 2022:hex.13548. doi:10.1111/hex.13548

37 Levine DM, Ouchi K, Blanchfield B, et al. Hospital-Level Care at Home for Acutely Ill Adults: A Randomized Controlled Trial. Ann Intern Med. 2020;172(2):77. doi:10.7326/M19-0600

38 Klein S. "Hospital at Home" Programs Improve Outcomes, Lower Costs But Face Resistance from Providers and Payers. The Commonwealth Fund. https://www.commonwealthfund.org/publications/newsletter-article/hospital-home-programs-improve-outcomes-lower-costs-face-resistance.

39 Nikolova-Simons M, Golas SB, den Buijs J op, et al. A randomized trial examining the effect of predictive analytics and tailored interventions on the cost of care. npj Digit Med. 2021;4(1):92. doi:10.1038/s41746-021-00449-w

What is the current state of predictive analytics (AI-ML) in healthcare systems?

Most of the healthcare systems interviewed were in the preliminary stages of developing or pursuing a digital roadmap (i.e., the implementation of machine learning technologies). Digital roadmaps were often developed through an internal committee structure to prioritize healthcare system goals related to digital healthcare. 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 strong interest in and support for harnessing the benefits of newer technologies was expressed, 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 also shared that the promise of machine learning technologies had exceeded the available product. For example, in their review of the EPIC Sepsis Model (ESM), Wong et al. (2021) found the ESM to have "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.[40] Systems interviewed echoed this assessment disclosing struggles effectively implementing the tool. Due to project time constraints, we did not complete a comprehensive review or survey of this specific tool and, therefore, cannot make a definitive statement on its clinical accuracy or usefulness. In the recently released FDA statement, this is one such technology that may now be subject to regulatory review.[41] See Table 3 for other predictive analytic and AI (Artificial Intelligence) tools discussed in interviews.

Other barriers to the development and implementation of effective machine learning models in healthcare systems include data collection and processing challenges and workforce issues. Healthcare systems possess substantial amounts of valuable data, yet this data remains untapped. Key reasons why this data remains underutilized include expertise shortages in the workforce (e.g., data scientists), a lack of data integration and management, and cost. Solutions to these issues include vendor partnership to provide expertise and additional workforce, internal development of data capacity (i.e., expand internal data workforce, upgrade technological

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[40] Wong et al. (2021) noted that the ESM only identified 7% of patients with sepsis missed by clinicians and failed to identify 67% of patients with sepsis.

Wong A, Otles E, Donnelly JP, et al. External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients. JAMA Intern Med. 2021;181(8):1065. doi:10.1001/jamainternmed.2021.2626

[41] Food and Drug Administration. Guidance for Industry and Food and Drug Administration Staff. Food and Drug Administration; 2022:1-26. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software

infrastructure, integrate data collection with electronic medical records), and data sharing agreements.

However, again, systems' current aims tended to focus on pandemic recovery and improvements and focus on home care such as efforts towards remote patient monitoring and implementation of programs such as Hospital at Home. So, 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.

Table 3. Predictive analytic and AI tools discussed in interviews

BlueSync	Bluetooth	Enables pacemaker to transmit data to smart device	Home/remote
EPIC Deterioration Index (EDI)	Predictive tool	Computerized clinical acuity score to predict decompensation events	Acute hospital
EPIC Sepsis Model (ESM)	Predictive tool	Generate alerts to warn clinicians of patients who may be developing sepsis	Acute hospital
Modified Early Warning Score (MEWS)	Physiological score	Assist with identifying and documenting clinical deterioration	Acute hospital, specifically surgical
Nuance DAX (Dragon Ambient eXperience)	AI-powered ambient listening	Clinical encounter documentation	Telehealth and in-person care
Phillips SmartSleep Analyzer	Scoring algorithm	Identify sleep problems in adults	Home/remote
VitalConnect Patch	Wearable biosensor	Monitors patients' vitals (8 physiological measurements) continuously in real time	Hospital or home/remote

Safety considerations

As this project was approached with a focus on safety—for the patient, care partner, and workforce—considerations for the safety concerns and unintended consequences of predictive analytics and machine learning, both in the home and acute setting, were examined. Five selected safety considerations noted in our literature scan and interviews are discussed below: alert fatigue and false positives; diversion of resources; complications with data presentation and interpretation; lack of patient and caregiver education; and sustainability concerns. Please note this expands upon previous safety issues discussed within the driver diagram and is not comprehensive, but additional.

First, alarm fatigue due to false positives is a well-documented safety concern. With the introduction of machine learning tools and interventions, the challenge of configuring and calibrating alarms to the correct sensitivity is introduced. To strike the right balance when implementing this technology (over-triggering vs. under-alerting), it should be asked what signals should be sent, how signal accuracy can be optimized, who to send them to, and when and how to send them.[42] This issue was highlighted in interviews when discussing the implementation of EMS and remote patient monitoring, respectively. Notable safety concerns included missed alerts due to alarm fatigue or improper calibration of alarm sensitivity. Second, the diversion of resources, inclusive of system funds and clinician time, is also pertinent to our topic as both remote patient care and machine learning care are resource-intensive endeavors which 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, therefore, creating a safety issue.

Next, complications with data presentation and interpretation can cause safety issues since the way data is presented and interpreted can impact a clinicians' decision making. Two concerns on data presentation and interpretation are introduced with machine learning tools and interventions. First, a clinician's lack of trust for machine learning outputs could create complications in care (re: black box). Even if the technology is accurate, mistrust could undermine machine learning tools adaptation. Second, some worry that the alternate scenario could occur, and clinicians could become too reliant on machine learning tools.[43] Here, 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.[44] Both a lack of trust and overreliance on support tools could create safety issues in healthcare as it could undermine the quality of care received by a patient. Other complications of data include poor adherence to medical documentation such as not reviewing a patient's active medication, which may carry over unused medications in the electronic health record, leading to a safety issue.

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42 Watson J, Hutyra CA, Clancy SM, et al. Overcoming barriers to the adoption and implementation of predictive modeling and machine learning in clinical care: what can we learn from US academic medical centers? JAMIA Open. 2020;3(2):167-172. doi:10.1093/jamiaopen/ooz046

43 Amarasingham R, Patzer RE, Huesch M, Nguyen NQ, Xie B. Implementing Electronic Health Care Predictive Analytics: Considerations And Challenges. Health Affairs. 2014;33(7):1148-1154. doi:10.1377/hlthaff.2014.0352

44 Char DS, Shah NH, Magnus D. Implementing Machine Learning in Health Care — Addressing Ethical Challenges. N Engl J Med. 2018;378(11):981-983. doi:10.1056/NEJMp1714229

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, if a patient must enter their vital signs as a part of their remote monitoring care plan, they must be able to use the devices correctly to obtain accurate vital signs (e.g., a pulse oximeter) and understand how to relay that information to their providers (e.g., navigating an application on a iPad or smartphone). If they are unable to accurately and efficiently communicate this information, this could be a patient safety and care quality concern. For patients with visual, hearing, cognitive and/or motor skills deficits, their ability to safely and accurately use of technology may be impacted. Finally, sustainability concerns for new initiatives or technologies were expressed. Sustainability refers to the ability to continue providing a quality care service concerning both machine learning technology and remote patient monitoring. While each has its benefits, healthcare systems must ensure that the implementation of interventions and technologies is feasible and supportable for the long-term. Safety concerns may be introduced should a patients' care be reliant on a program or product that is discontinued. This may also negatively impact the patient's quality of care and life.

Even with these safety considerations, remote monitoring and machine learning present opportunities to understand and identify patient deterioration and improve timeliness of care, which may allow the development of more successful interventions increasing patients' quality of care and life. But endeavors to develop and implement these types of interventions or tools take these safety concerns into consideration in order to provide a high quality of care and life for patients, clinicians, and caregivers.

Conclusions and Recommendations:

Considerable thought has been given to the development and implementation of machine learning and remote patient monitoring in healthcare. 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.

Therefore, we recommend the following:

- A clear purpose for new tools or interventions. Each introduction should enhance the provider-patient experience, while maintaining or improving safety and quality of care.
- An emphasis on daily workflow by healthcare systems when implementing new technologies or interventions. Lack of interoperability or added work for clinicians prevent safe and quality care from being provided and exacerbates existing workforce burden.
- The development and implementation of quality and safety guardrails on how to introduce new care interventions and technologies in the digital space without

compromising the quality and safety of care. 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 programs.

- IHI can act as a facilitator and convener as the healthcare systems navigate their transition into the digital space. Two specific areas where IHI may be effective are in workforce wellbeing and quality and safety standards and improvements. Existing IHI work has been conducted in these areas (e.g., Whole System Quality, National Action Plan to Advance Safety and Joy in Work) and, as a facilitator, this work can be refined and applied to how healthcare systems design, implement, and sustain new technologies while ensuring and improving the quality and safety of care for patients, caregivers, and the workforce. Previous waves and project interviews identified that guidance is needed to help effectively identify and implement machine learning technologies and tools in healthcare with a focus on safety and careful integration into workflow. As interviewees expressed interest in AI and the development and implementation of a digital roadmap, IHI could begin by initiating discussions with healthcare systems for further interaction on the topic.