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ARTICLE

Predictive Solutions in Learning Health Systems: The Critical Need to Systematize Implementation of Prediction to Action to Intervention

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The growth in the use of predictive models in health care continues as health systems adopt electronic health records and gain access to real-time digitized clinical data. Although health systems often have substantial experience in quality improvement related to care interventions, they have limited experience in implementing predictive models as part of the care process. University of Wisconsin (UW) Health's goal was to systematize the process of selecting, validating, implementing, and evaluating a predictive solution to maximize the potential benefits and minimize the potential harms of using predictive models to guide actions and care interventions in learning health systems. The authors describe an approach to implementing predictive solutions that adapts the widely used Find-Organize-Clarify-Understand-Select–Plan-Do-Check-Act framework. This process can be used to bring together quality improvement teams and data analytics staff in leading a common process for organizational change and in supporting clinicians in adopting predictive solutions.

The use of predictive models in health care has the potential to grow rapidly as health systems adopt electronic health records (EHRs) and gain access to real-time digitized clinical data.[1] Widespread use of predictive models to guide evidence-based care interventions could transform the U.S. health care system by using data to predict and prevent poor clinical outcomes,[2] provide targeted care,[3] and lower costs,[1] thereby moving toward the paradigm of a learning health system.[4,5] Yet the application of predictive models in clinical practice to guide care interventions is challenging and remains limited, with ad hoc implementation strategies that vary from system to system.[2,6] The best predictive model will ultimately have little impact if it does not lead to widespread action and intervention. The potential of predictive models will only be realized if health systems integrate them into workflows in which they have the potential to provide actionable insights.[7] This prediction-to-action-to-intervention combination represents a predictive solution.

Although health systems often have substantial experience in quality improvement related to care interventions, they have limited experience in implementing predictive models as part of the care process.[8-10] As a result, health systems experience challenges in implementing predictive solutions, including issues related to planning, deployment, and cultural adoption (including clinician resistance); data availability and access; refinement, validation, monitoring, updating, and governance of the predictive model; cost, funding, and resource allocation; ethical issues (including equity and fairness); and care intervention–related issues such as case finding, patient follow-up, and the limited availability of evidence-based interventions easily adapted to local settings and populations.[11-16] There are several guidance documents to support the development and assessment of predictive models themselves,[17,18] but there is little systematic guidance on addressing the challenges to implementing complete predictive solutions that guide actions and care interventions within health systems. The literature on addressing these challenges is scattered, and tools to systematize implementation are often focused on either quality improvement or data analytics concerns alone. An implementation framework for predictive solutions that addresses the spectrum from prediction to action to intervention would support a common process for organizational change.

Our goal was to systematize the process of selecting, validating, implementing, and evaluating a predictive solution to maximize the potential benefits and minimize the potential harms of using predictive models to guide actions and care interventions. We describe an approach to implementing predictive solutions that adapts the widely used Find-Organize-Clarify-Understand-Select (FOCUS)–Plan-Do-Check-Act (PDCA) framework.[19,20] An extensive toolkit and workbook to guide health systems are available at HIPxChange,[21] along with detailed examples and templates related to a case study of early identification of severe sepsis within an inpatient setting at the University of Wisconsin health system (UW Health). HIPxChange is a Web portal that disseminates evidence-based health improvement programs, tools, and other materials for free to the public and is sponsored by the University of Wisconsin-Madison Health Innovation Program, the Institute for Clinical and Translational Research, and the Wisconsin Partnership Program.

Case Example: Sepsis

Implementing predictive models to enhance sepsis detection and management is increasingly a health system priority.[8] In the fall of 2017, UW Health was ready to expand to the inpatient setting sepsis work that had been developed in the ED. The Severe Sepsis and Septic Shock Early Management Bundle (SEP-1) U.S. Centers for Medicare & Medicaid Services core measure compliance rates were below the organizational expectation, and reducing hospital-acquired infections was part of the strategic plan. The quality, safety, and innovation (QSI) department was asked to manage an initiative expanding the concepts of early recognition and response to the inpatient setting. At the time, there was no standard process for how clinicians identified patients on the sepsis continuum or a consistent workflow for treating those patients.

> *The potential of predictive models will only be realized if health systems integrate them into workflows in which they have the potential to provide actionable insights. This prediction-to-action-to-intervention combination represents a predictive solution.*"

The initial goal of the initiative was to build a standard process and workflow that included clinical decision support and predictive algorithms to drive the recognition and bundle treatment of these patients. QSI selected the widely used FOCUS-PDCA framework to structure the process and achieve the project goal. A set of working groups was established to tackle the different aspects of the project, including data and dashboards, nursing workflow, physician workflow, pharmacy support, and education. The workgroups met over the span of a year to determine the appropriate components for the process, design workflows, build tools, and assess the trade-offs (e.g., feasibility, acceptability, effectiveness, cost/benefit, and sustainability) of working with a predictive model. UW Health determined that they would start with a sepsis predictive model that was already built into the electronic medical record. The predictive model was coupled with a nursing best practice alert (BPA) and screen for suspected infection: if the nurse accepted the BPA and ordered a lactate (indicating that the patient screened positive), a physician BPA was triggered automatically, supporting alerts via a paging system to an offsite critical care unit for remote surveillance of positive patients and to review compliance to the SEP-1 bundle for treatment. Adaptations were made on the basis of lessons learned, with any component proven to be ineffective abandoned.

UW Health piloted the new workflows and model in three inpatient units with preliminary outcomes for a 2-month period. The primary outcomes for the pilot were related to decision support. We evaluated, via a survey, actions taken in response to the BPAs (including lactate orders, because a serum lactate level greater than 2 mmol/L indicates a high risk of septic shock)[22] as well as the perceived value of the predictive solution to clinicians. Outcomes of this 2-month pilot study indicated that the model and associated workflows were feasible and acceptable. Specifically, the nursing BPA was triggered 844 times, with 30% of alerts screening positive and resulting in 271 physician BPAs. There were 45 new lactate orders based on the BPA, of which 11 had serum lactate levels higher than 2 mmol/L (serum lactate had already been ordered in 34 cases, and treatment was already in progress in 63 cases). The perceived value of the predictive solution was based on a survey of 167 clinicians before and 67 clinicians after the completion of the pilot. After the pilot, 94% of clinicians strongly agreed or agreed that "I am able to identify when a patient is at risk of developing sepsis" compared with 82% before the pilot. Similarly, after the pilot, 83% of clinicians strongly agreed or agreed that "standardized interventions are provided," compared with 52% before the pilot.

The FOCUS–PDCA Framework

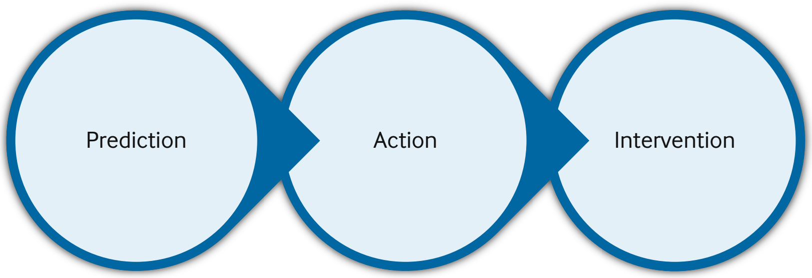
The FOCUS-PDCA model is a well-established quality improvement methodology that represents the five phases of Find-Organize-Clarify-Understand-Select, followed by Plan-Do-Check-Act cycles that allow for iterative improvement.[20] In general, this model systematizes the process of implementation by placing a solution in the right workstream/workflow in clinical practice to ensure clinical and operational value, to enable assessing and addressing challenges proactively, to establish that all elements or actions are achieving the desired outcome, and to allow for systematic review to reduce variability and further improve performance.[23] The model is familiar to health system quality improvement staff and has been used widely for quality improvement within health systems.[19] However, the implementation of a predictive solution brings its own unique set of challenges related to the integration of large-scale and often real-time digital data into clinical practice.

Successful implementation of predictive solutions requires that predictions (e.g., the outputs from a predictive model) be tied to actions (e.g., alerts within the EHR and provider response to alerts) that lead to interventions (e.g., changes in preventive, curative, or symptomatic care) (Figure 1).

FIGURE 1

Process for Implementing Predictive Solutions

The process for implementing predictive solutions requires that predictions (e.g., the outputs from a predictive model) be tied to actions (e.g., alerts within the electronic health record [EHR] and provider response to alerts) that lead to interventions (e.g., changes in preventive, curative, or symptomatic care).



Source: The authors.

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FOCUS-PDCA has several advantages for implementing predictive solutions. First, by integrating predictive solutions within a health system's existing quality improvement process, it reduces the isolation of predictive modeling and advanced data analytics from quality improvement within a health system. For example, staff might perceive that predictive models are "magic devices that can spin data into gold"[24] without recognizing the commonalities with quality improvement and its challenges. Similarly, data analytics staff may have robust quantitative skills but lack the familiarity with quality improvement methodology, thereby limiting their ability to achieve successful organizational change. Second, the use of FOCUS-PDCA ensures that the evaluation of predictive solutions is multifaceted and not limited to assessing only the predictive model. Specifically, while FOCUS-PDCA prompts systematic evaluation of the predictive model itself (e.g., precision, positive predictive value [PPV], and C-statistic), it also prompts evaluation of the actions (e.g., number of alerts, provider responses to the alerts, and provider experience of the alerts) and of the interventions (e.g., effectiveness in improving patient outcomes and number needed to treat [NNT]).[25]

Table 1. FOCUS Process for Selecting and Validating Predictive Solutions

	Questions
Find a process	Is there a clear written statement of the problem that will be addressed and the impact on patients?
	Is there an organizational priority/reason for developing a predictive solution for this purpose?
	Are there alternatives to predictive solutions that should be considered to address the problem?
	Is the population defined, including those who are excluded?
	Are there definitions of the expected outcome(s) and time frame(s)?
	Is there a primary metric that this predictive solution is trying to change?
	What are the operational/workflow metrics that you expect to change or monitor?
Organize the team	Is there executive sponsorship for the development of this predictive solution?
	Are there clinician champions for the development?
	Who are the stakeholders for the development and use?
	Are the individuals who will implement the predictive solution in the system known?
	Is there a process or committee for signing off on the predictive solution and its implementation?
	Are the individuals who need to see the outputs from the predictive model known?
	Has the evaluation team been determined?
	Should patients or other stakeholders be involved in development?
Clarify current knowledge	What are the current mental model and related workflows for implementing actions?
	What actions are taken on the basis of the current mental model?
	What is the intervention or program associated with the current mental model?
	What is the definition of the patients who do and do not have actions taken?
	Are there interventions for patients who do not have actions triggered?
	Can possible adverse actions associated with the current mental model use be identified?
	What is the outcome that is being targeted for impact by the current mental model?
Understand process variation	When is the current mental model not used?
	What other actions are taken that do not rely on the current mental model?
	What other interventions or programs are used that do not rely on the current mental model?
	Who are the patients who do not experience the current mental model?
	Are there possible adverse actions when the current mental model is not used?
	When the current mental model is not used, is this likely to worsen/change disparities in care delivery?
	Are other outcomes more important when the current mental model is not used?
	Is there potential to extend the predictive solution to other populations?
	Is there potential to extend the predictive model to other interventions?
	Is the predictive solution for use only within your local health system?
	How could use of a predictive solution worsen/change disparities in care delivery?
Select a predictive solution	Is the population that the existing predictive model(s) was developed on similar to your local population?
	Is the outcome that was used to develop the existing predictive model(s) similar to your desired outcome?
	How will use of the predictive solution fit within the existing workflow and EHR build?
	What is the location for display of predictive model outputs (e.g., header, BPAs, lists, reports, and registry)?
	What criteria are most important for model selection (e.g., positive predictive value and C-statistic) and are they acceptable?
	Will the input variables be transparent (i.e., will the fields that go into the predictive model be displayed)?
	Was there external validation of the existing predictive model(s) (e.g., separate site)?
	Will the model be internally validated on the health system's population?
	Are there high risks to patients or high costs to the system of misclassification?

Table 1. FOCUS Process for Selecting and Validating Predictive Solutions (*Continued*)

	Questions
	Is there any evidence that the existing predictive model(s) could change or worsen disparities?
	What are the criteria or known factors for choosing among options such as free vs. buy vs. build?
	Is the existing predictive model(s) available in your EHR or from an external vendor?
	Are there legal or licensing issues related to use of the existing predictive model(s)?
	Are the data sources and fields needed for scoring the existing predictive model(s) available?
	What would be the strategy for dealing with missing data sources and/or fields?
	Are thresholds and actions recommended for the existing predictive model(s)?
	What will be the thresholds for action for the existing predictive model, along with the associated actions?
	Is information other than or in addition to a predictive model needed to support decisions about interventions?
	Are the existing interventions within your system effective?
	Can the existing interventions within your system be scaled to accommodate more patients?
	Are interventions similar to those in your system recommended for the existing predictive model(s)?
	Is staff bandwidth available to implement an existing or new predictive model and/or interventions?

FOCUS = Find-Organize-Clarify-Understand-Select, EHR = electronic health record, BPA = best practice alert. Systemizing the process of selecting and validating a predictive solution using the FOCUS process includes questions for quality improvement teams and data analytics staff to consider. Source: The authors.

The FOCUS Process for Selecting and Validating Predictive Solutions

The FOCUS process ensures that the right problem is identified for improvement, the right team is organized to address the problem, the current process and interventions are well documented, variations in process leading to underperformance are understood, and the right combination of a predictive model, actions, and interventions is selected.[19] Framed as questions for quality improvement teams and data analytics staff to consider, Table 1 systematizes the process of selecting and validating a predictive solution using the FOCUS process. Incorporating evidence into this process by, for example, selecting a validated predictive model also addresses a key element of becoming a learning health system.[26]

Here is a look at the elements of the FOCUS model, how they function, and related learnings from this case example.

Find a Process

The initial step of a FOCUS-PDCA involves finding a process to improve. It includes an initial identification of the problem and a description of how solving this problem aligns with any strategic or organizational goals. It should confirm that the problem being proposed is appropriate for a predictive solution and that the predictive solution will be supported and resourced, including resources for a new build within the EHR. In most cases, health systems will not develop new predictive models, but validation/recalibration in a new setting is almost always necessary. This highlights the value the predictive solution can provide to the patients, clinicians, and organization.

The organizational priority of the problem will likely determine the extent of resources dedicated. Identifying the action and intervention associated with a predictive model early in its development cycle is crucial to allocating resources only to models with the potential to impact patient care. A critical step is documenting in an aim statement the primary metric that the organization would like to change, and in what direction; this step aids in identifying the appropriate solution and how to evaluate it. Identifying the population of interest helps to understand exactly how that population is important to the organization.

> *"The use of FOCUS-PDCA ensures that the evaluation of predictive solutions is multifaceted and not limited to assessing only the predictive model."*

Learnings from Case Example

Assessing the current organizational culture toward innovation and readiness for change is essential for developing the process to address the problem and whether a predictive solution is appropriate. Initially, we moved too quickly toward a predictive modeling solution, without considering provider comfort with or knowledge of predictive models, leading to some provider resistance. We learned that it is critical to describe the purpose of the model more extensively with providers prior to implementation (i.e., detailed information on the problem it addresses, target population, expected outcomes, and operational/workflow changes). We discovered that clinicians would ask to see the results of clinical trials supporting a particular model. In the absence of that gold-standard approach to ensuring that an intervention is effective, the FOCUS-PDCA process allowed us to take on the burden of proof in an efficient manner, quickly deploying, testing, and evaluating a predictive solution on our own patients. We could then see if it had met clinician-defined metrics for acceptance and continued spread and, if it was not acceptable, quickly revise the solution and redeploy.

Organize the Team

Organizing a team that knows the process involves identifying and engaging the right people in the organization to be included in the project, with leadership from quality and safety, clinical operations, and data analytics, as well as senior organizational leaders where appropriate. Predictive solutions will require extensive analytical, technical, clinical, and operational perspectives to be successful. Identifying the appropriate stakeholders will assist in obtaining additional resources to select the appropriate solution. The appropriate governance process should also be defined, including necessary leaders or committees for approval and prioritization of development work, approval of models prior to implementation, and making decisions on the basis of postimplementation monitoring data.

Learnings from Case Example

Identifying the appropriate stakeholders, as well as setting the right scope and number of people for the steering teams, supports key decision-making to move the implementation of the predictive solution forward. Initially, we created a steering committee with 25 people, which worked extremely well for initial engagement. We learned, however, that when key decisions were required to move forward, the steering committee was too large and diverse to make consensus decisions. We addressed this challenge by developing a smaller team of key decision-makers who drafted proposals for implementation steps to bring to the steering committee for decisions. We also learned that multiple working teams/workgroups were needed to support the work and that the list of stakeholders would expand over time as the problem and solutions are further detailed.

Clarify Current Knowledge

Clarifying current knowledge of the process (and strategies that are being used to address the problem) supports the development of a solution that is both feasible and aligned with your local context. This includes documentation of the current mental model and workflows (including current use of data and whether clinicians are informally using any clinical prediction rules) and understanding variation and why variation exists (looking at the gap between current performance/process and desired performance/process). It helps to ensure that the predictive solution becomes integrated into the relevant clinical and operational workflows and that it is addressing the root problem.

Learnings from Case Example

Evaluating the current mental model and workflows for implementing actions is time consuming and requires working with stakeholders to understand how data are collected and assumptions made by the team while executing the workflow. We learned at the onset of the implementation of the sepsis predictive model that there was no standard way that clinicians were recognizing and treating patients with severe sepsis. We addressed this challenge by capturing many different mental models to interpret and document the processes. Understanding how providers are currently predicting the outcome was important to designing workflows, even though it meant capturing many different mental models.

Understand Process Variation

Understanding the causes of process variation uncovers the factors contributing to the problem of interest, including clinician differences in their preferred use of information from a predictive model (e.g., different clinician thresholds for action and different types of actions). It generates an effective solution that links predictions to actions and interventions that will be sustainable within the local context. Scalability should also be assessed, such as extending the predictive solution to other populations beyond the initial population or extending the predictive model to other interventions within the same population. The potential for a predictive solution to worsen or change disparities in care delivery should also be assessed.[27]

Learnings from Case Example

Conducting an in-depth assessment of the current process provides knowledge of when the current workflow/model is and is not used and which interventions/actions are taken that do not rely on the workflow/model. This assessment can identify reasons why the current workflow/model is not recognizing and treating the problem (i.e., organizational/cultural barriers) and can provide an opportunity to make adjustments. We learned that we did not do a deep enough assessment of the reasons why the current process for recognizing and treating sepsis was lacking. We addressed this challenge later in the project by making adjustments once we had a clearer understanding of the organizational and cultural barriers. An example of a barrier was the concern that "modelers" would create algorithms that may not be clinically relevant or may be potentially misleading. We mitigated this risk by bringing on a medical director and forming algorithm workgroups for each model that consisted of clinical subject matter experts who could provide endorsements for the model.

> *"Understanding how providers are currently predicting the outcome was important to designing workflows, even though it meant capturing many different mental models."*

Select the Predictive Solution

This step guides the process of selecting the most effective predictive solution. The selection process will determine whether an existing predictive model would be acceptable or whether a new model needs to be developed. It will also help identify whether the existing interventions are sufficient or whether a new intervention needs to be developed. If a new predictive model or intervention is being developed, this will be incorporated into the planning portion of the PDCA cycle for design, along with operational and evaluation design. The selection process should determine the necessary trade-offs required for any given predictive solution. For example, for any predictive model, there are potential risks caused by misclassification (false negatives) and the possibility that the model could worsen existing health disparities. Recent questions of model fairness have raised important issues about model implementation, because many existing validated models may not have been tested for bias in subpopulations.[27] Subpopulation analysis focusing on potentially affected groups is critical to ensure that predictive solutions not only achieve benefit, but also do so equitably without creating or exacerbating health disparities.[28] Costs to the health system can also be significant if false positives lead to the enrollment of patients into expensive interventions with no benefit. For example, to allocate an expensive intervention, PPV will be more important than the C-statistic in evaluating model performance. Using an impactability or benefit model to minimize false positives may be appropriate in this scenario.[10,14,29]

To ensure applicability to the local population, models may need to be recalibrated and internally validated by a health system. If an estimation of the effectiveness of the proposed intervention is available, this information can be combined with model performance characteristics to estimate relevant metrics such as NNT for the entire predictive solution.[25,30] Note that decisions about acceptability for performance characteristics depend on the clinical scenario and the actions that a prediction model might inform. The selection process must also incorporate metrics such as the intervention effectiveness, the data availability, and the available bandwidth of staff for reviewing the predictive model output on a regular basis. This will influence whether the chosen model will be free, built, or purchased.

Learnings from Case Example

Participants in such a process may feel pressure to implement the perfect solution. To mitigate this pressure, team members should recognize that there may be multiple solutions identified and that tools can be developed in phases throughout the duration of the project. We learned that the BPAs that originally accompanied the sepsis predictive model had language that was confusing to the bedside teams; therefore, the language had to be adjusted. Cost is another important consideration when selecting a predictive solution. Solutions that are the most effective often require a large amount of work. The sponsors of the project will have to determine what level of work is appropriate for the resources allocated to the project and if there is staff available to implement a predictive model. For example, development of a new predictive model is a resource-intensive task, and many health systems may prefer to implement existing models with validation/recalibration.

PDCA Cycles for Implementing and Evaluating Predictive Solutions

PDCA cycles are a systematic process for launching changes — in this case, implementing the predictive solution, tracking the impact, and adjusting to continually improve the solution.[19] The first PDCA cycle is typically a small pilot or proof-of-concept prior to broader implementation of the predictive solution, but multiple PDCA cycles are common. Documentation of PDCA cycles is important to support local learning and to enhance the likelihood of transferring successes to the next setting. Table 2 systematizes the process of implementing and evaluating a predictive solution using PDCA cycles. This ensures that the health system collects and learns from its own data, another key element in becoming a learning health system.[31]

Here is a look at the PDCA cycle, how the components function, and related learnings from this case example.

Plan Implementation and Evaluation

The planning phase is focused on identifying the objective, questions, and expectations, as well as developing a plan to conduct the PDCA cycle (who, when, and where) and obtaining organizational signoff on the plan. Specifically, the plan includes implementation of the predictive model, the development of a system to support actions based on the model, and expansion or enhancement of the interventions linked to actions. A careful design process in the planning phase is critical to ensure the implementation of a complete predictive solution. Unfortunately, there are numerous examples in the literature of technically successful models with impactful interventions achieving poor uptake by clinicians.[32]

Table 2. PDCA Cycles for Implementing and Evaluating Predictive Solutions

	Questions
Plan implementation and evaluation	What is the objective of the PDCA cycle?
	What questions should be answered and what are expected outcomes for the PDCA cycle?
	Who will be responsible (i.e., what is the organizational chart) and what is the timeline for the PDCA rollout?
	Where will the predictive solution be implemented (e.g., pilot units)?
	Can the sequence of PDCA cycles be planned initially to mitigate decision fatigue?
	What is the process for organizational signoff on the PDCA cycle(s)?
	Which providers will see the predictive model outputs and/or reports/feedback?
	Are either real-time calculation and/or regular external data feeds required?
	Will providers be able to easily override the predictive model recommendation?
	What training will be required to use the predictive solution, and how will it be conducted?
	What will be the design for the evaluation (e.g., pre/post and staggered rollout) and the comparison group?
	Does the evaluation consider model performance, workflow metrics, and intervention effectiveness?
	Does the evaluation consider potential adverse effects of the predictive solution?
	New: Has the outcome for the new predictive model been validated in the health system?
	New: What criteria are most important for selection of a new predictive model and are they acceptable?
	New: Is chart review by providers needed to support face validity of the new predictive model?
	New: Are there high risks to patients or high costs to the system of misclassification?
	New: Is there any evidence that the new predictive model could change or worsen disparities?
Do the implementation	Will there be an oversight group to monitor the rollout of the predictive solution?
	What process will be used to review implementation status/metrics and early outcomes?
	Who will document problems and unexpected observations?
	How will small adjustments be made to improve interpretability, functionality, or implementation?
	Who will conduct initial data analyses?
	Is there a process for regular review of the predictive model performance?
	Will software detect improper application and underperformance of the predictive model?
	What quality assurance processes are needed to maintain fidelity to the actions and interventions?
Check the evaluation	What will be the process to develop an evaluation report for each PDCA cycle?
	Who will review the evaluation reports and who will explain the results to stakeholders?
	How many PDCA cycles are needed before impact on outcomes can be evaluated?
	Is an experienced external evaluation group available for consultation or collaboration?
	New: Is further chart review by providers needed to support face validity of the new predictive model?
Act on the results	Is the decision to adopt and scale, abandon, or complete another PDCA cycle?
	What adjustments or changes need to be made for the next cycle?

PDCA = Plan-Do-Check-Act. Systemizing the process of implementing and evaluating a predictive solution using the PDCA cycles includes questions for quality improvement teams and data analytics staff to consider. Note: *New* indicates these questions are only relevant if a new predictive model will be developed. Source: The authors.

> *Subpopulation analysis focusing on potentially affected groups is critical to ensure that predictive solutions not only achieve benefit, but also do so equitably without creating or exacerbating health disparities.*"

Beyond simply selecting the appropriate model and intervention, a workflow must be designed to provide data according to the five rights of decision support: giving the right member of the team the right information, through the right format and right channel, and at the right time in the workflow.[33] Primary considerations include (if applicable) how and where the results of the model will be displayed (including model explainability), determining thresholds for action, decisions on how providers will interact with the model, and other human factor considerations (including the ability to override), training requirements, workflow considerations, and reporting and/or feedback. Threshold recommendations for actions can be made on the basis of data analysis, expert input, and intervention capacity; in real-world scenarios, model performance at various thresholds must be balanced with operational capacity for associated interventions.[25] The planning phase also includes the design of the evaluation and development of evaluation criteria, as well as development of a new predictive model and/or a new intervention. The evaluation design should include a comparison group, and evaluation outcomes should examine performance of the predictive model, process and workflow metrics for the actions (including characteristics of patients who will and will not have actions triggered), and the effectiveness of the intervention on outcomes. Last, potential adverse consequences that might be associated with the predictive solution should be identified and considered.

Learnings from Case Example

We learned that piloting the sepsis workflow and model in an adaptive fashion was crucial to the long-term success of the sepsis project. We piloted the workflow and model in a few inpatient units to allow for testing without impacting the larger organization. The changes requested from the pilot made the model and workflow stronger and easier for the larger system to adopt. For example, there were materials developed for just-in-time training that continue to be invaluable, including scripts for nurses to communicate with physicians and quick cheat sheet rules for the model. We also reduced the complexity of the BPA logic, which was too comprehensive and attempted to identify all possible gaps. Last, we identified that clinicians could log out of the BPAs, which would show up as an "N/A" response on reports; we were not able to identify a solution, but knowing helped us interpret the data.

Do the Implementation

This "do" phase involves executing the operational plan for the predictive solution, documenting problems and unexpected observations, and beginning analysis of data. This phase includes oversight, review, and making small adjustments. Quality assurance processes assess and maintain fidelity to the actions and interventions and identify the extent to which implementation of predictions, actions, and interventions is progressing as planned. Continuous management and monitoring of the predictive model, once it is in use, is necessary to ensure accurate performance and to maintain validity. Models will need continuing monitoring with model recalibration and re-engineering to account for several dynamics, including changes to the clinical characteristics of the target populations or subpopulations that impact the characteristics of the data, changes to operational processes and clinical workflows as the data generating processes, and changes to systems and technology that impact the processing and curation of the data.[34,35]

Learnings from the Case Example

We learned that we needed to be able to quickly identify when one of the features of the model was not correctly mapped because of an oversight, communicate the change back to the nurses, and provide analysis regarding the impact. We addressed this challenge by scheduling 30-minute huddles with clinicians, build teams, and analytics once per week during the initial pilot. It was difficult to keep resourcing these huddles once the solution went live, so we worked to ensure that the initial plan included an evaluation period during the pilot to help set clear expectations with the supporting teams.

Check the Evaluation

The "check" phase involves evaluating the results of predictive solution implementation by completing the data analysis, comparing data with expectations and identified metrics, and summarizing the learnings. It is helpful to create a standard process for developing an evaluation report for each PDCA cycle, including determining the review process, metrics, and who will explain the results to stakeholders. This planning is particularly helpful in the early stages when the results may be negative because of small sample sizes or short follow-up. Frequently, early PDCA cycle evaluations focus on ensuring predictive model performance and understanding changes to workflows (including actions and interventions), because longer time frames (e.g., 6–12 months) may be needed to evaluate impact on outcomes. It is important to distinguish the different questions and sources of data and who will do the checks (e.g., quality improvement staff or clinicians). If available, an experienced evaluation group can provide consultation or collaboration to maximize the amount of useful information obtained from the report and reduce the risk of bias.

> "*Cost is another important consideration when selecting a predictive solution. Solutions that are the most effective often require a large amount of work.*"

Learnings from the Case Example

We learned that when sharing data with stakeholders, it was important to present a balance of all program aspects to show the big picture. We initially provided substantial amounts of data about the model, which overweighted some of the programmatic picture and caused clinicians to lose focus on the adoption aspects of the program success. We addressed this challenge by collecting and sharing data across the program, including qualitative data, to provide a holistic view of how clinicians were interacting with the model. For example, a metric of specific interest to clinicians was whether the BPA made any difference in the course of care. To answer this, we had to identify somewhat arbitrary boundaries of which actions were being influenced by the BPA. We compiled rule-of-thumb metrics, including orders, laboratory tests, and transfers to a higher level of care, to be able to describe when the course of care was influenced, even though it was not always clear that the BPA prompted all of these actions.

Act on the Results

The "act" phase focuses on the decision to adopt and scale the predictive solution on the basis of the pilot, or abandon it, or complete another PDCA cycle. It identifies any changes or adjustments that need to be made and provides a scope for the next cycle, if any. For example, adjustments might be revising an action threshold to be more aligned with what clinicians are actually experiencing or to reflect capacity changes in the organization (e.g., loss of a key staff). At the end of the PDCA cycles, a final decision will need to be made about the process of going live and when this should occur in a stepped or all-at-once fashion.

Learnings from the Case Example

Initially, our PDCA cycles were not planned in advance, which caused a long delay between version 1 and version 2 of the solution. In addition, as we got closer to the go-live date and the team was immersed in the workflow, we generated great ideas for optimizing the model, but incorporating those changes would have delayed our go-live date even further. We learned that preplanning the periods of adjustment reduced delays and helped the program be more responsive to end-user requests.

Looking Ahead

Learning from data is a core principle of learning health systems. Because health systems have little experience with using their data to implement predictive solutions but substantial experience with quality improvement methods, we developed a systematic process for implementing a predictive solution that relies on a well-established quality improvement framework. This process can be used to bring together quality improvement teams and data analytics staff in leading a common process for organizational change. A shared understanding will maximize the potential benefits and minimize the potential harms of using predictive models to drive actions and care interventions, as well as create a common language and process to support clinicians in adopting predictive solutions. Building on our learnings from the sepsis predictive model implementation, UW Health is currently planning a clinical deterioration model and opioid misuse models, evaluating an at-home falls risk model, and implementing an X-ray Covid-19 model.

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