Predictive DSI - Intervention Risk Management Practices

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Summary of Epic's Predictive DSI Intervention Risk Management Practices

To assess, mitigate, and monitor risk associated with Predictive Decision Support Interventions (Predictive DSIs) that we supply as part of Epic software, we've implemented the practices outlined in this document.

We develop software to support healthcare organizations, which means our software is used in healthcare practices and can have an impact on patients and their care. Accordingly, our ISO-certified quality management system includes processes to analyze, mitigate, and govern risk. Each Predictive DSI that we release is developed using the same intervention risk management (IRM) practices that applies to all Epic software development. When analyzing risk and determining suitable risk mitigations, we consider the complexity of development and the context in which the software will be used. When we provide Predictive DSI based on third-party research, we review and consider use case risk, complexity, and any validation already performed by that third-party.

Risk Analysis

Epic identifies and addresses potential risks and adverse impacts as part of our standard design and testing process, with increased scrutiny during Predictive DSI development and implementation based on the specific characteristics of the intended use case. Throughout this process, we consider factors such as:

- Complexity
- Intervention inputs (such as sensitive demographics)
- Intervention outputs and intended use case and users
- Decisions and potential actions that the Predictive DSI is intended to inform
- Whether the intervention was developed by Epic or is based on third-party research
- Proximity to workflows at high risk for health equity impact
- Potential human or technical failure points

Our analysis considers the following characteristics of Predictive DSIs with an appropriate depth of analysis proportional to the factors above: validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy.

For example, for high-risk, high-workflow-complexity, Epic-developed Predictive DSIs, like clinical predictive models, we may use the following processes to analyze these characteristics:

- *Validity:* Clinical Predictive DSIs are validated by appropriate clinical experts, including both Epic employees and members of the Epic community. We also release validation tools that allow health systems to evaluate the performance of a Predictive DSI on their own data.

- *Reliability:* We work with organizations as they implement models to provide oversight during local model configuration. We use industry-standard data science methodologies to define the most important data inputs during training, and we inspect configuration of model inputs during validation to provide reliable model output. To monitor the performance of live models, we provide monitoring tools for organizations to detect feature drift and identify issues with model configuration and execution.
- *Robustness:* We provide clear guidance on appropriate configuration for the intended use of each Predictive DSI. Prior to full implementation, we provide model validation tools for organizations to track whether model performance meets expectations when applied to their specific data sets. Additionally, we provide monitoring tools to help organizations track whether model performance continues to meet expectations over time.
- *Fairness:* Our validation tools can stratify model performance by cohorts to assess health equity across demographic groups. In some cases, cohort definitions can be customized, and cohorts can be combined to enable intersectional analyses. During the development and validation of a Predictive DSI, project teams perform additional cohort analysis to investigate potential domain-specific biases as needed.
- *Intelligibility:* We provide in-system documentation and in-workflow visual aids, cues, and notification text to help users understand the factors considered in a Predictive DSI. As defined by standard Epic development processes, development teams engage experts in user experience design to help design the integration of a Predictive DSI into relevant workflows.
- *Safety, Security, and Privacy:* We have both proactive and reactive processes in place to prevent safety, security, and privacy issues and address any incidents that occur. Many Predictive DSI are run with data from an organization's local instance of Epic; cloud-based models run on Epic's secure cloud platform that uses industry standard security and encryption practices. We work with each organization to establish protocols for assessing and escalating potential clinical risks or concerns to us. After investigating potential risks and concerns, we publish any significant findings to all organizations using the relevant Predictive DSI.

Risk Mitigation

Epic mitigates and minimizes risks through software design, information provided to users (including source attribute information covering the IRM practices for each Predictive DSI), and workflow considerations.

During the development processes: We follow and enforce standard testing and project management processes that are designed to prevent and mitigate risk. These processes include a design that is reviewed and approved by expert stakeholders, code and in-system review and testing of Predictive DSI workflows, and ongoing processes for finding and reporting issues.

Post-Market Surveillance of Predictive DSI development: We collect feedback from organizations about their experience with Epic software on an ongoing basis. This may include—but is not limited to—

support visits, development team immersion, regular interactions from staff assigned to each healthcare organization, and review of local intervention configuration and performance. Epic development staff also consider intervention validity and fairness as part of ongoing development changes and regression testing.

If potential issues are identified through this surveillance, the issues are documented discretely. Then our structured triage process facilitates evaluation of the impact and frequency of an issue and takes proportional action to mitigate risk and correct the identified issues. We conduct additional review if an identified issue has a potentially high impact, such as clinical risk, security vulnerability, or financial risk. Concurrently, we notify users about impactful or frequent issues. Then, as appropriate, staff review root causes and identify preventative actions to implement beneficial process changes to avoid similar issues in the future.

Governance

Epic's quality policy is summarized in items one and two in Epic's Software Development Principles: "First, do no harm. Remember the fundamentals: software must work."

Our Predictive DSI development follows an evolving governance process, which is anchored on Epic's Principles of Thoughtful Machine Learning: *Do Good, Have Clear Intent, Be Accountable, Scrutinize Bias, and Protect Privacy.* Development teams evaluate potential risks during project scoping and follow guidelines so that Predictive DSIs receive the appropriate level of review during development, prior to release, and during initial adoption. Throughout this process, escalation paths are well-defined to promptly address any issues discovered. Before any Predictive DSI is approved for release, the risk analysis and mitigation approach is reviewed and validated by expert stakeholders. Predictive models developed by Epic are monitored and evaluated quarterly or semi-annually, to determine prioritization for enhancements and possible deprecation.

If data is used to develop a Predictive DSI, we apply standards for data retrieval, management, and access based on the sensitivity of the data, prioritizing security and privacy at each step, and we assess the proposed use of the data for appropriateness via the risk management practices defined above. When Patient Health Information or other sensitive data is needed to ensure the quality of a Predictive DSI, we limit the breadth and the volume of the data collected and remove or obfuscate unnecessary identifiers that increase the sensitivity of the data (such as, unique identifiers or demographic information of patients) when feasible.

After data is retrieved, we apply strict standards for the storage, access, and retention of that data. This is in addition to Epic's regular and recurring security and privacy training for employees and the protections and controls put in place by data usage agreements between Epic and members of the Epic community. Data does not leave Epic's network unless, as permitted by said data usage agreements with members of the Epic community, it is sent to Predictive DSI tools that are hosted by a third party with whom Epic has robust data usage agreements.

To minimize the transfer of sensitive data, some Epic community members might grant a small group of Epic employees access to a subset of their data so that Epic can develop and validate Predictive DSIs. In this scenario, data does not leave the community member's network, and the community member retains total control over the storage of the data and Epic's access to it. This approach is used whenever feasible, constrained by the available data elements and the characteristics of the community member's patient population—such as whether the community member has a sufficiently diverse patient population to yield useful fairness analysis.

Continual Improvement of Products and Intervention Risk Management Process

We regularly assess the processes that support our quality management system and the results from our software development lifecycle, in order to determine the effectiveness of these processes and identify areas for improvement. We seek and encourage feedback from executives, operations analysts, and users on our products, their usability, and their effectiveness. We also engage with academics, experts, and other stakeholders to seek feedback on our products and practices. We make iterative improvements to reflect new information as we become aware of it. This document reflects Epic's internal intervention risk management practices as of October 24, 2024.

If you have any feedback or ideas, please contact us at predict@epic.com.