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Dilemmas and possibilities in the development of Science of Improvement projects involving the use of Artificial Intelligence in Healthcare

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Introduction: In recent years, there has been great interest in Artificial Intelligence (AI) applications in healthcare. However, the issues related to AI's implementation, ethical use, and safety are not consensual and have not yet been adequately addressed.(1)

Objective: Report the experience of the Einstein Network for Critically Ill Patients, focusing on the dilemmas and possible paths for the use of Science of Improvement (SI) tools in the study of potential applications of AI in healthcare (specifically, in the management of severe patients or those at risk of clinical deterioration).

Methods: Report of the experience and presentation of insights based on a prospective observational study (Proof of Concept) conducted from February 2022 to June 2023 in the Semi-Intensive Unit of the *Hospital Israelita Albert Einstein Hospital* (HIAE), as part of the Improvement Advisor Course from the Institute for Healthcare Improvement (IHI).

Results: In phase 1, data was collected from the monitoring center, while in parallel, an AI algorithm, previously trained with retrospective data, was also fed (without contact with the healthcare team). After assessing the non- inferiority of the algorithm compared to the monitoring center, phase 2 (POC), which involved creating a user interface for physicians and actual use, was authorized.

Considering the Improvement Model (IM) of IHI aims to bring established evidence to clinical practice, it could seem inappropriate to be used with AI for early detection of clinical deterioration in a Semi-Intensive Unit due to the lack of scientific evidence. This report is based on international guidelines for evaluating AI solutions in healthcare1. The rational and ethical incorporation of AI in healthcare should follow similar stages as those for new medications in Phase I, II, and III studies. The proposed rationale for using the IM to support the early validation of AI on a small scale, should focus on three key areas.

I. Adoption
II. Patient safety
III. User experience
IV. Patient safety is the most important factor among the three, following the established framework for Phase I studies and adhering to the Bioethical principle of Non-Maleficence. Various variables were carefully selected to ensure balance and optimize processes. Since it was a quality improvement project, no specific protocols were recommended to the physicians.

Tools and concepts like Psychology of Change, Process Mapping, Value Stream Mapping, early involvement of frontline "Gemba" visits, and the Plan-Do-Study-Act (PDSA) cycles were valuable in guiding initial AI tests. Exploring more specific techniques for Quality Improvement Through Planned Experimentation in the future could be beneficial.[2]

Conclusion: The experience report showed that using SI tools in a project integrating AI to redesign an early detection process for clinical deterioration in the Semi-Intensive Unit is feasible and beneficial.

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