Promoting Transparency – A Developer's Perspective

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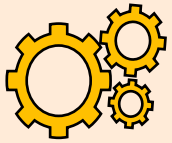
Transparency in AI-Device Performance

AI-devices should be developed and validated with data representative of their intended use, including variation in:

Intended Use Patient Population

Intended User

Reflected in Product Claims and "Labeling"



Data Inputs

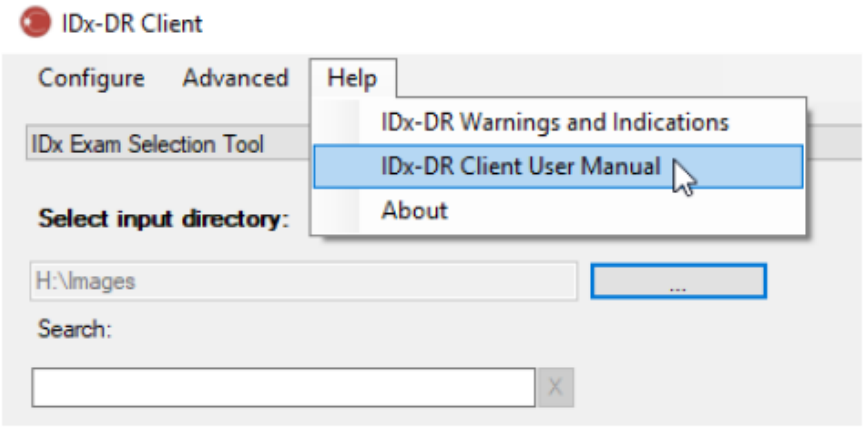
Intended Use Environment

Important Considerations for the Promotion of AI-Device Transparency

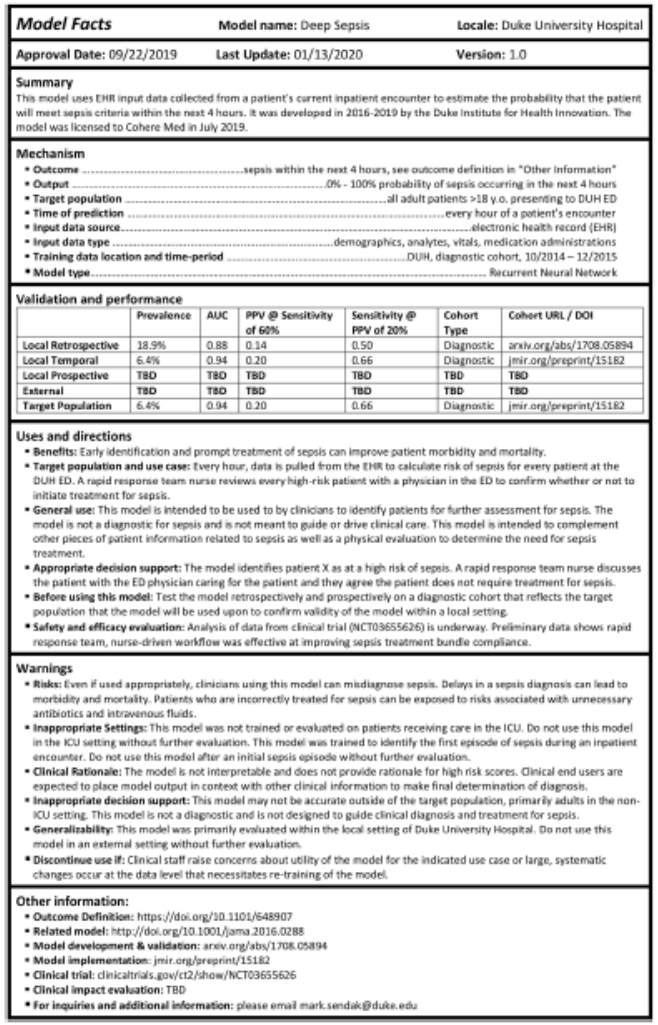
- *Labeling requirements for medical devices (21 CFR Part 801) and in vitro diagnostic devices (21 CFR Part 809) support transparency.*
- *Applying human factors and usability engineering during all stages of development is critical for ensuring safety, effectiveness, and transparency in relation to AI-devices.*
- *Summary information should be provided to users when it is not possible to provide comprehensive details (e.g., training an algorithm using federated learning).*
- *Explainability can enhance transparency should be considered in the context of the overall risk-benefit profile of the AI-device.*

An Intuitive User Interface Promotes Transparency

Source: *Lindsey, R. et al. (2018) Deep neural network improves fracture detection by clinicians. PNAS. 115(45):11591-11596.*



Source: *IDx-DR Client User Manual, Software Version 2; 2018-11-30.*



Model Facts | **Model name:** Deep Sepsis | **Locale:** Duke University Hospital

Approval Date: 09/22/2019 | **Last Update:** 01/13/2020 | **Version:** 1.0

Summary

This model uses EHR input data collected from a patient's current inpatient encounter to estimate the probability that the patient will meet sepsis criteria within the next 4 hours. It was developed in 2016-2019 by the Duke Institute for Health Innovation. The model was licensed to Cohere Med in July 2019.

Mechanism

- **Outcome** ..... sepsis within the next 4 hours, see outcome definition in "Other Information"
- **Output** ..... 0% - 100% probability of sepsis occurring in the next 4 hours
- **Target population** ..... all adult patients >18 y.o. presenting to DUH ED
- **Time of prediction** ..... every hour of a patient's encounter
- **Input data source** ..... electronic health record (EHR)
- **Input data type** ..... demographics, analytes, vitals, medication administrations
- **Training data location and time-period** ..... DUH, diagnostic cohort, 10/2014 – 12/2015
- **Model type** ..... Recurrent Neural Network

Validation and performance

	Prevalence	AUC	PPV @ Sensitivity of 60%	Sensitivity @ PPV of 20%	Cohort Type	Cohort URL / DOI
Local Retrospective	18.9%	0.88	0.14	0.50	Diagnostic	arxiv.org/abs/1708.05894
Local Temporal	6.4%	0.94	0.20	0.66	Diagnostic	jmir.org/preprint/15182
Local Prospective	TBD	TBD	TBD	TBD	TBD	TBD
External	TBD	TBD	TBD	TBD	TBD	TBD
Target Population	6.4%	0.94	0.20	0.66	Diagnostic	jmir.org/preprint/15182

Uses and directions

- **Benefits:** Early identification and prompt treatment of sepsis can improve patient morbidity and mortality.
- **Target population and use case:** Every hour, data is pulled from the EHR to calculate risk of sepsis for every patient at the DUH ED. A rapid response team nurse reviews every high-risk patient with a physician in the ED to confirm whether or not to initiate treatment for sepsis.
- **General use:** This model is intended to be used to by clinicians to identify patients for further assessment for sepsis. The model is not a diagnostic for sepsis and is not meant to guide or drive clinical care. This model is intended to complement other pieces of patient information related to sepsis as well as a physical evaluation to determine the need for sepsis treatment.
- **Appropriate decision support:** The model identifies patient X as at a high risk of sepsis. A rapid response team nurse discusses the patient with the ED physician caring for the patient and they agree the patient does not require treatment for sepsis.
- **Before using this model:** Test the model retrospectively and prospectively on a diagnostic cohort that reflects the target population that the model will be used upon to confirm validity of the model within a local setting.
- **Safety and efficacy evaluation:** Analysis of data from clinical trial (NCT03655626) is underway. Preliminary data shows rapid response team, nurse-driven workflow was effective at improving sepsis treatment bundle compliance.

Warnings

- **Risks:** Even if used appropriately, clinicians using this model can misdiagnose sepsis. Delays in a sepsis diagnosis can lead to morbidity and mortality. Patients who are incorrectly treated for sepsis can be exposed to risks associated with unnecessary antibiotics and intravenous fluids.
- **Inappropriate Settings:** This model was not trained or evaluated on patients receiving care in the ICU. Do not use this model in the ICU setting without further evaluation. This model was trained to identify the first episode of sepsis during an inpatient encounter. Do not use this model after an initial sepsis episode without further evaluation.
- **Clinical Rationale:** The model is not interpretable and does not provide rationale for high risk scores. Clinical end users are expected to place model output in context with other clinical information to make final determination of diagnosis.
- **Inappropriate decision support:** This model may not be accurate outside of the target population, primarily adults in the non-ICU setting. This model is not a diagnostic and is not designed to guide clinical diagnosis and treatment for sepsis.
- **Generalizability:** This model was primarily evaluated within the local setting of Duke University Hospital. Do not use this model in an external setting without further evaluation.
- **Discontinue use if:** Clinical staff raise concerns about utility of the model for the indicated use case or large, systematic changes occur at the data level that necessitates re-training of the model.

Other information:

- **Outcome Definition:** https://doi.org/10.1101/648907
- **Related model:** http://doi.org/10.1001/jama.2016.0288
- **Model development & validation:** arxiv.org/abs/1708.05894
- **Model implementation:** jmir.org/preprint/15182
- **Clinical trial:** clinicaltrials.gov/ct2/show/NCT03655626
- **Clinical impact evaluation:** TBD
- **For inquiries and additional information:** please email mark.sendak@duke.edu

Source: *Sendak, MP et al. (2020) Presenting machine learning model information to clinical end users with model facts labels. npj Digital Medicine. 3:41.*

Predetermined Change Control Plans Benefit Patient and Public Health and Should Address Change Transparency

Predetermined Change Control Plan (PCCP)*

- Describes the device update strategy to ensure continued safety and effectiveness post deployment
- An *essential* mechanism for deploying significant changes for AI-devices in a safe and effective manner
  1) Ensures patients and healthcare professionals will receive timely and innovative updates in a safe and effective manner
  2) Enables the iterative nature of AI-devices
  3) Optimizes Agency resources

A PCCP should describe how software changes will be transparent to users

- *Rationale for the software update*
- *Description of changes in product claims*
- *Description of changes in performance*
- *Review of instructions for use*

*Source: *Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD),* US Food and Drug Administration.

Doing now what patients need next