Design for a Cluster-Randomized Trial of an AI-derived Clinical Decision Support Tool for Surgical Transfusion

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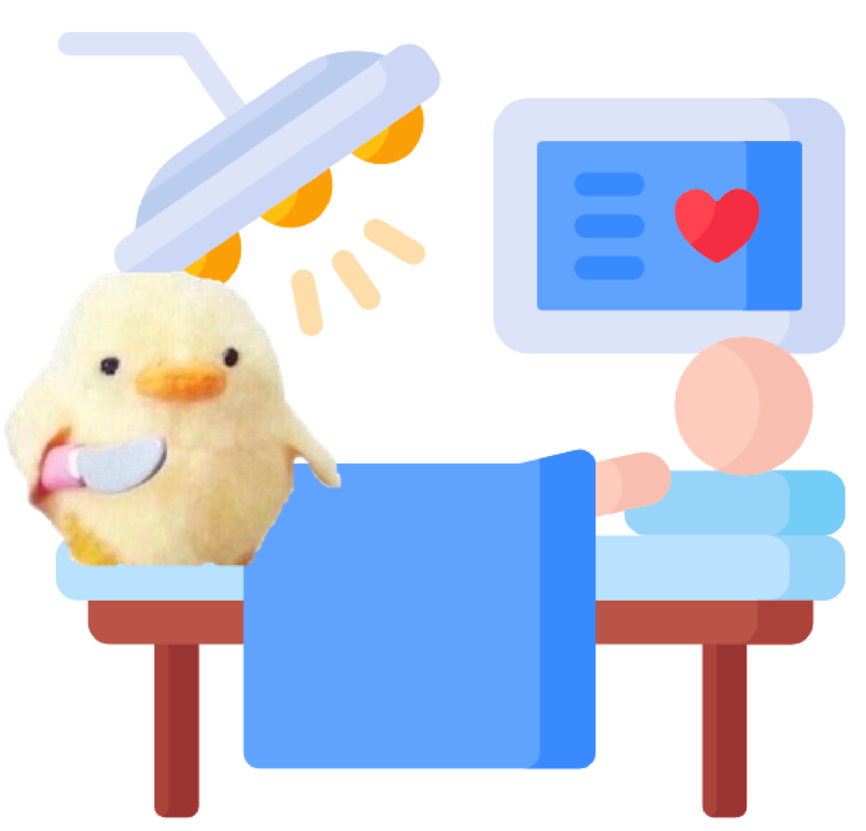
Introduction

Preoperative preparation for transfusion is

Important for patient safety



Preparation process:

1. Identify patient's blood type (~1h)
2. Find compatible unit (min–hours)
3. Deliver unit to OR (15–30min)

Frequently over-utilized

>50% have presurgical blood orders

<5% require blood during surgery

$1 billion

RBC waste

Current standard - MSBOS

Procedure	Routine blood order
Open heart surgery	T&S, crossmatch 4 units
Total hip replacement	T&S only
Lap. cholecystectomy	Emergency release blood

Our proposal - personalized transfusion risk estimation

Planned procedure → MSBOS → Standard preoperative blood orders

Planned procedure + Patient demographics + Patient comorbidities + Preoperative laboratory values → S-PATH → Personalized blood orders

Model code publicly available here

Model Development and Validation

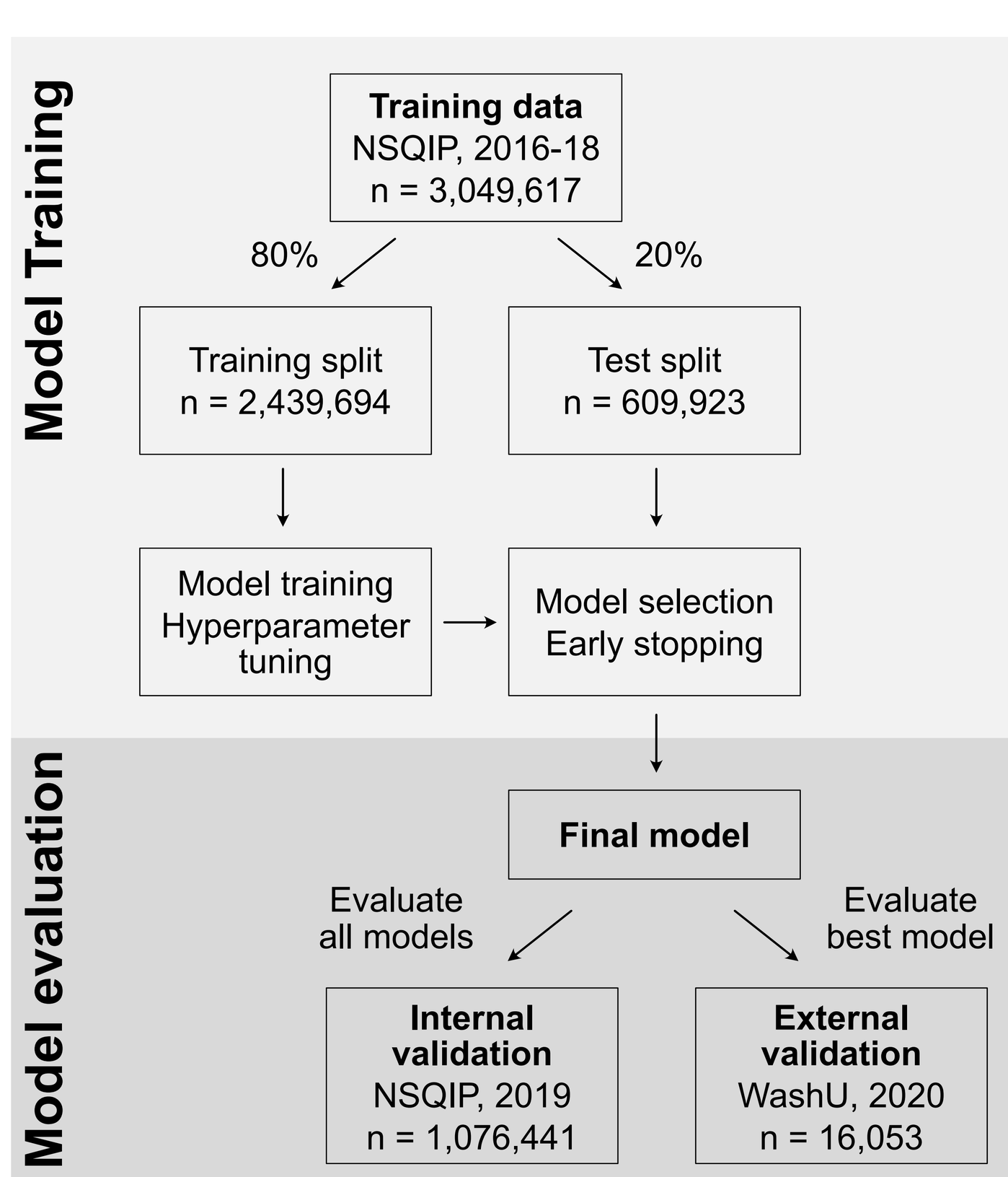
Training data: National Surgical Quality Improvement Program (NSQIP), 2016-2018

Internal validation: NSQIP 2019

External validation: WashU 2020

Input variables: Age, weight, height, sex, HTN, DM, COPD, CHF, smoking, dialysis, Hct, Plt, INR, PTT, Cr, Na, albumin, bilirubin, elective surgery, procedure-specific transfusion rate

Outcome variable: Red cell transfusion on the day of surgery



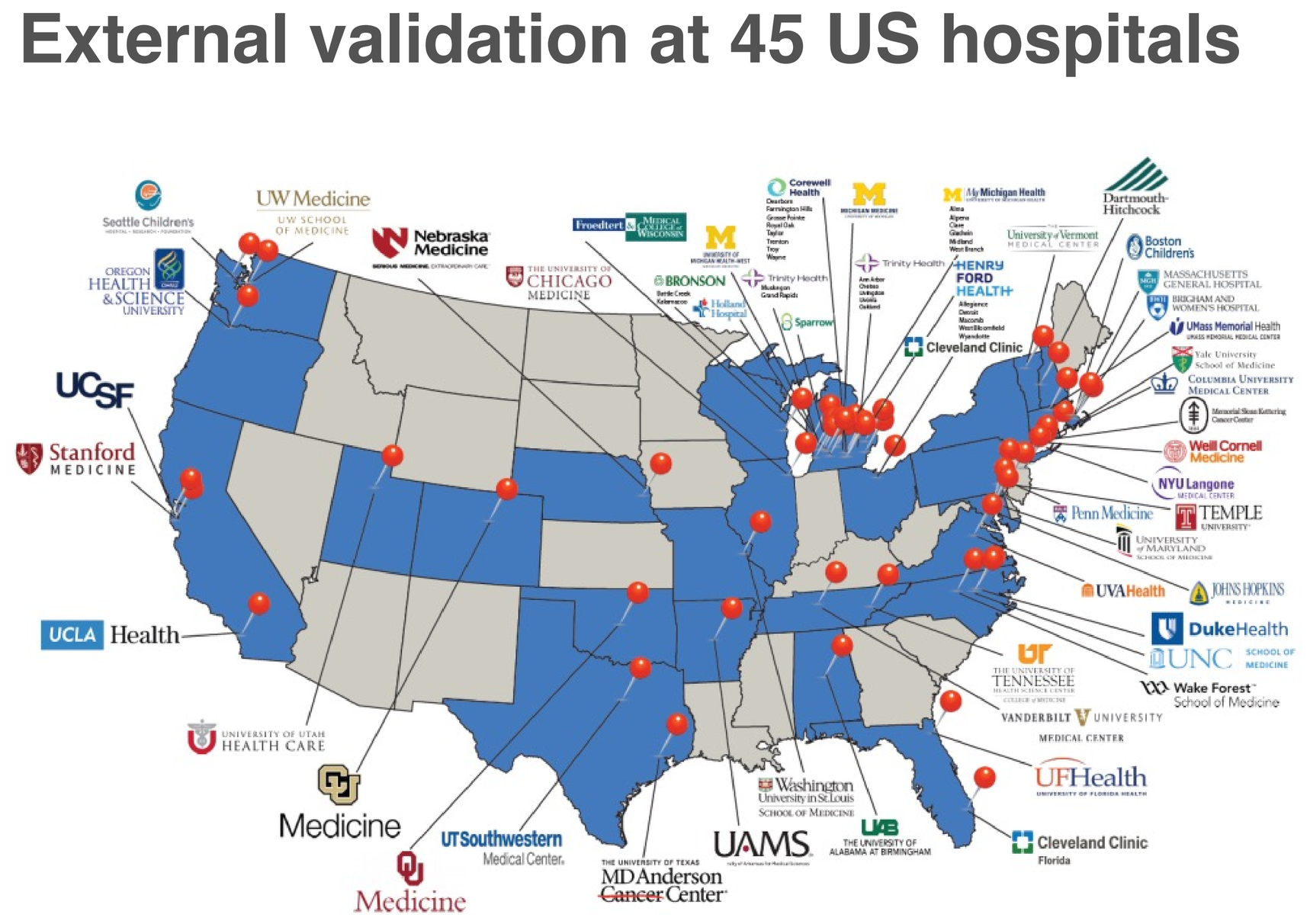
Internal validation (NSQIP)

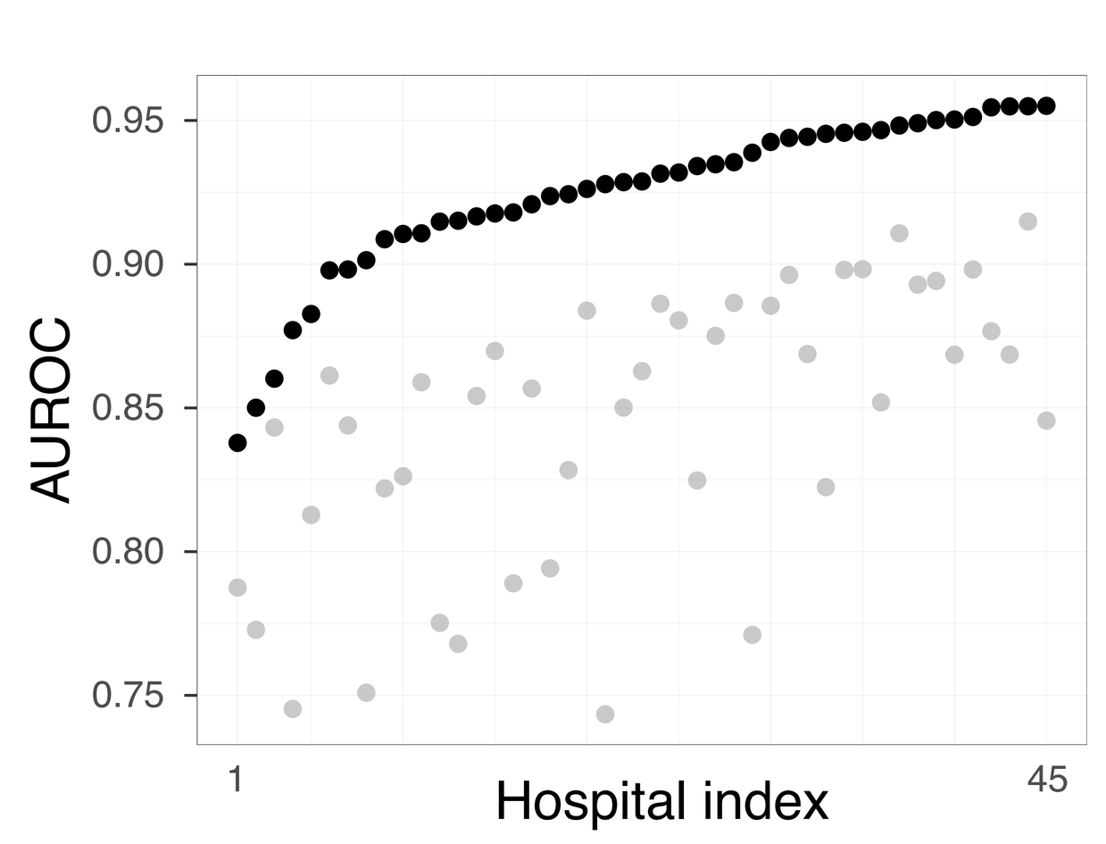
Model	AUROC	Sensitivity	% T/S
MSBOS	0.888	0.970	57%
S-PATH	0.924	0.963	36%

External validation (WashU)

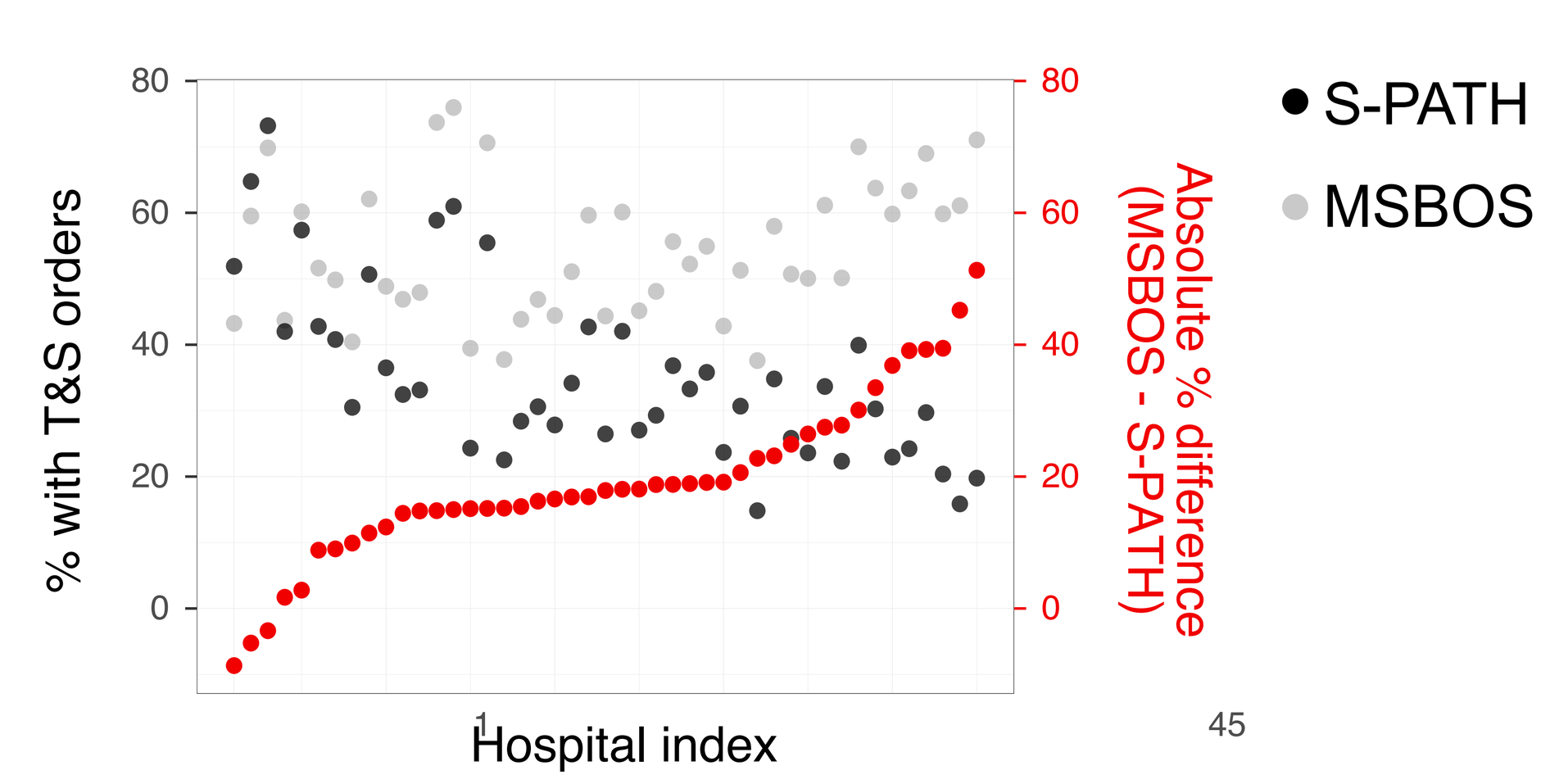
Model	AUROC	Sensitivity	% T/S
MSBOS	0.908	0.957	46%
S-PATH	0.939	0.959	31%

External validation at 45 US hospitals





Median AUROC
0.925 (IQR 0.908 - 0.955)



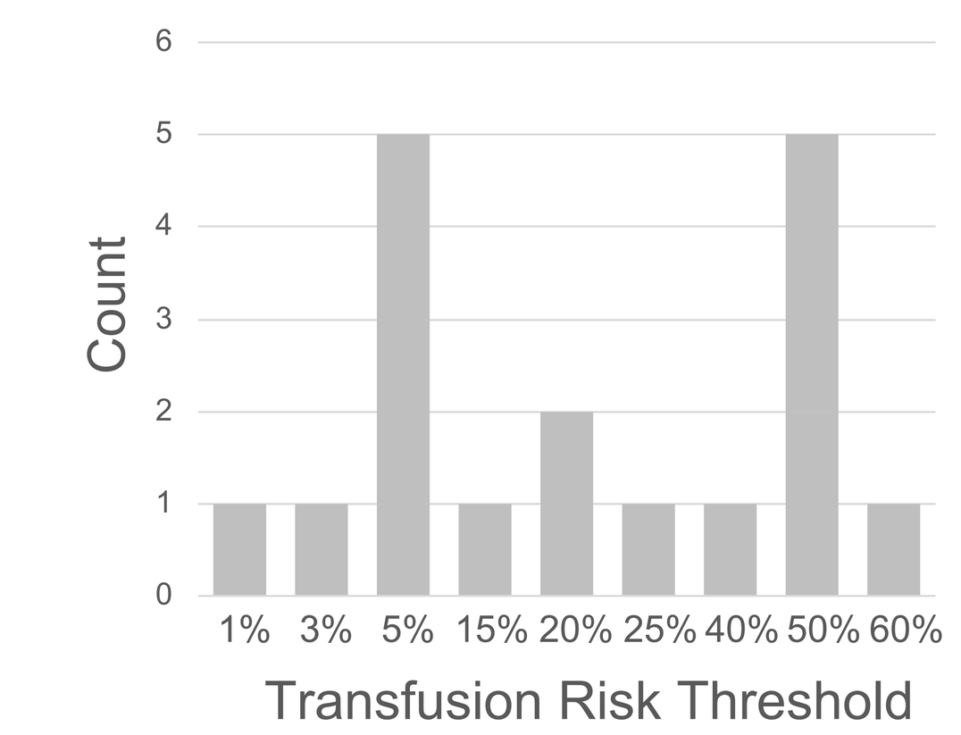
Median Absolute Δ (% T/S)
17.3 (IQR 14.7 - 26.7)

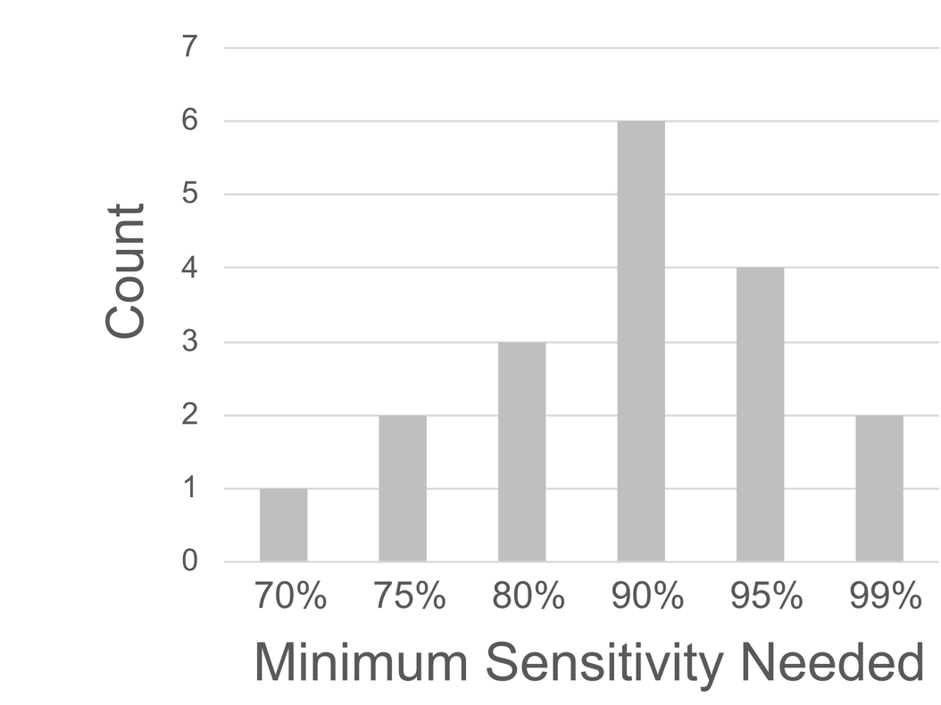
Human-Centered Design

29 stakeholders

- Surgeons
- Anesthesiologists, CRNAs
- Preop Clinic NPs
- Transfusion Medicine

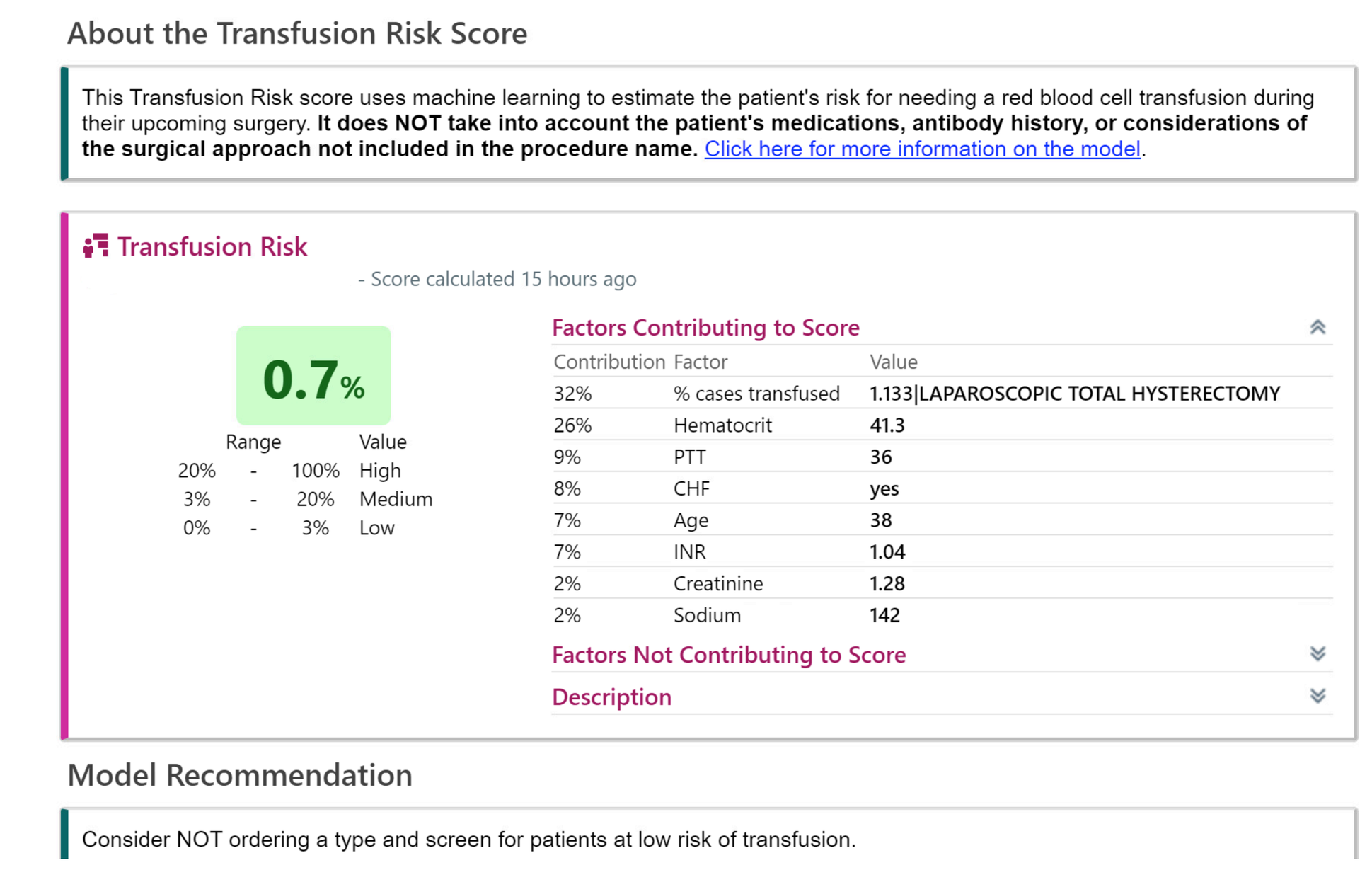
Interviews Identify needs, tasks → **Design workshop** Needs ▶ Design / **Iterative Prototyping** / **Scenario Evaluations** Test the design

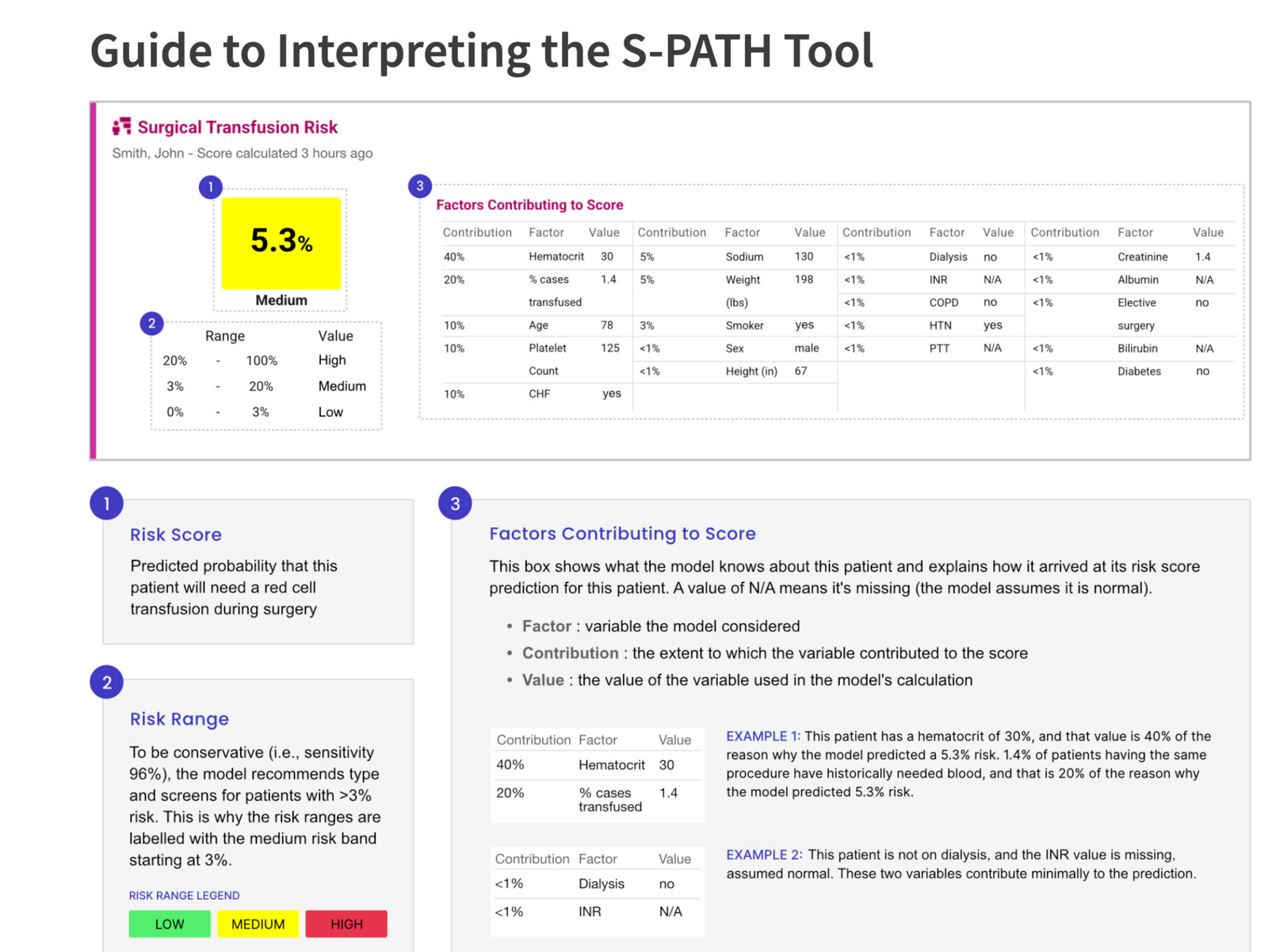




Key lessons

- Communicating sensitivity is hard
- Simpler display is better
- Web resource links can be useful
- People ignore BPAs





Trial Design

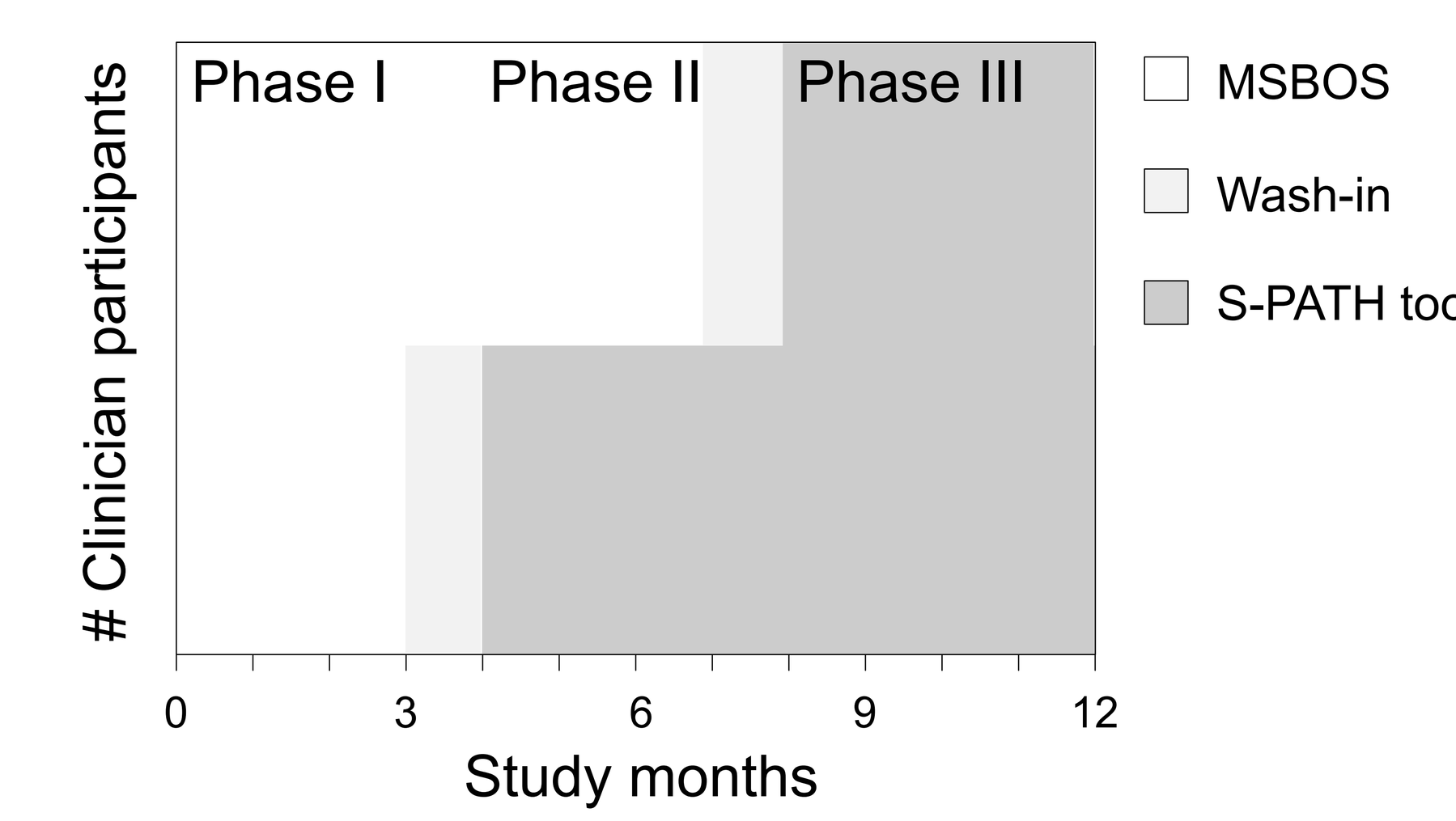
Setting: Preoperative assessment clinic

Participants:

- Clinicians (NP, intern physician)
- Patients randomized by clinician assigned

Inclusion: Patients with predictions

Exclusion: Patients with red cell alloantibodies



Phase I: Usual care / everyone uses MSBOS

Phase II: Half gain access to S-PATH tool

Phase III: Everyone has access to S-PATH

Recruitment and training plan:

Present to NP group
- Discuss blood management and transfusion risk
- Discuss how to evaluate machine learning models
- Discuss SPATH development
- Recruit participants

+ CME

→ **Individual / small group training**
- Go over tool with example scenarios
- Quiz to evaluate understanding
- Score usability (SUS)
- Score acceptability and trust

+ CME

→ **Feedback / Reinforcing training**
- Provide concerns / comments on tool
- Receive training in additional areas as needed

+ CME

Outcomes

1' : Frequency of T/S orders at preop clinic

2' : Frequency of T/S orders by surgery start
Frequency of transfusion without a T/S by surgery start
Frequency of transfusion

Safety : Emergency release blood use
Transfusion reaction

Implementation outcomes

- Frequency of viewing the tool
- Clinician-level acceptance of tool recommendations

Semi-structured exit interviews

- Barriers and facilitators to tool use
- Score acceptability and trust

Soliciting feedback!

- Survey instruments to measure acceptability and trust
- Suggestions for other implementation outcomes
- Ideas for evaluating the quality of training
- How to modify the trial if implementation outcomes are poor

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