Clinical Decision Support Software in ePCTs

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Session Goals

- Describe case studies from the Collaboratory and beyond illustrating challenges with clinical decision support software.
- Hear from the FDA about the newly released guidance on clinical decision support software and the associated considerations and opportunities for ePCTs.
- Hear about regulatory, ethical, and IRB considerations related to evaluation of clinical decision support tools.
- Hear about considerations related to evaluation of clinical decision support tools from the perspective of ePCT trialists.

Setting the Stage

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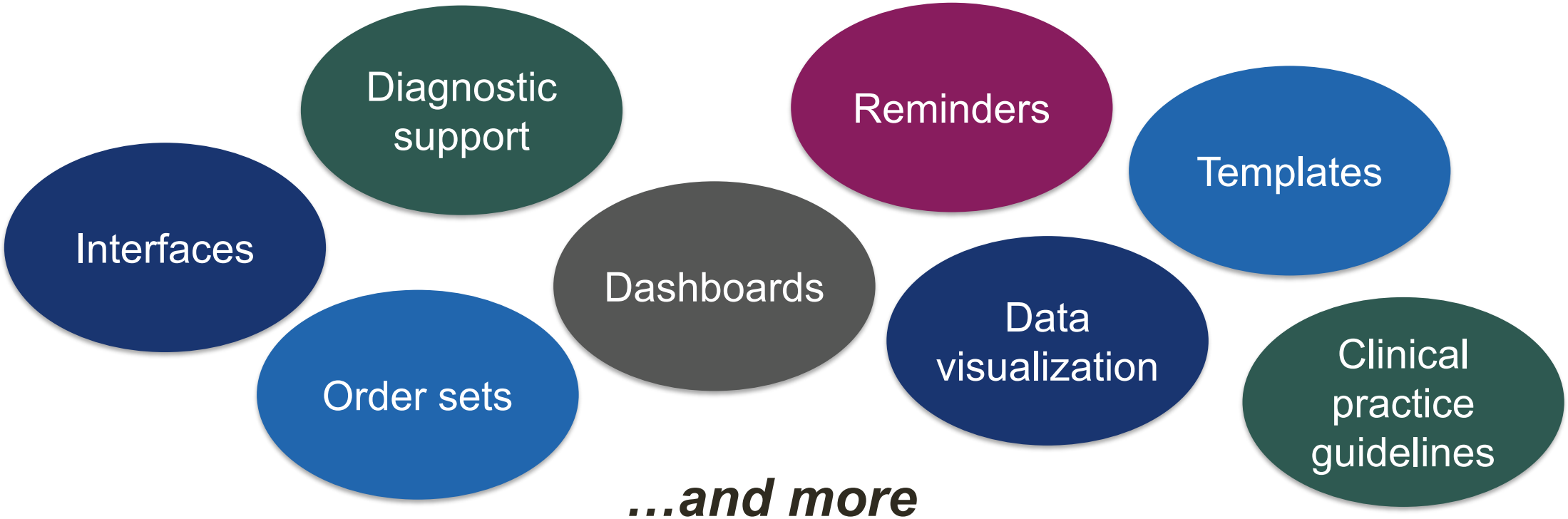
What Is Clinical Decision Support?

- A wide variety of tools all tailored to clinicians' data, information, and knowledge needs
- Provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care

AHRQ 2022

More Than Just “Alerts”



…and more

There is no definitive or comprehensive list of what can constitute CDS

ONC 2014

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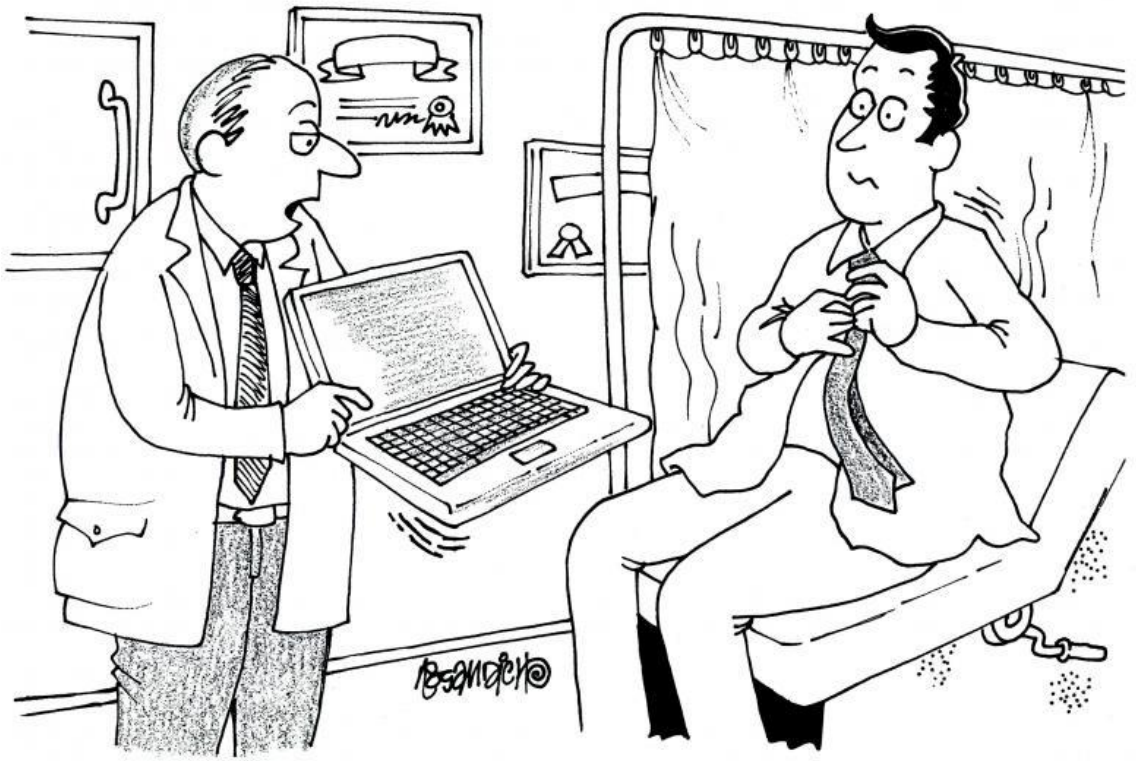
Why Clinical Decision Support?

- Potential to:
  - Increase quality of care
  - Enhance health outcomes
  - Avoid errors and adverse events
  - Improve efficiency
  - Reduce costs
  - Enhance provider and patient satisfaction

ONC 2014

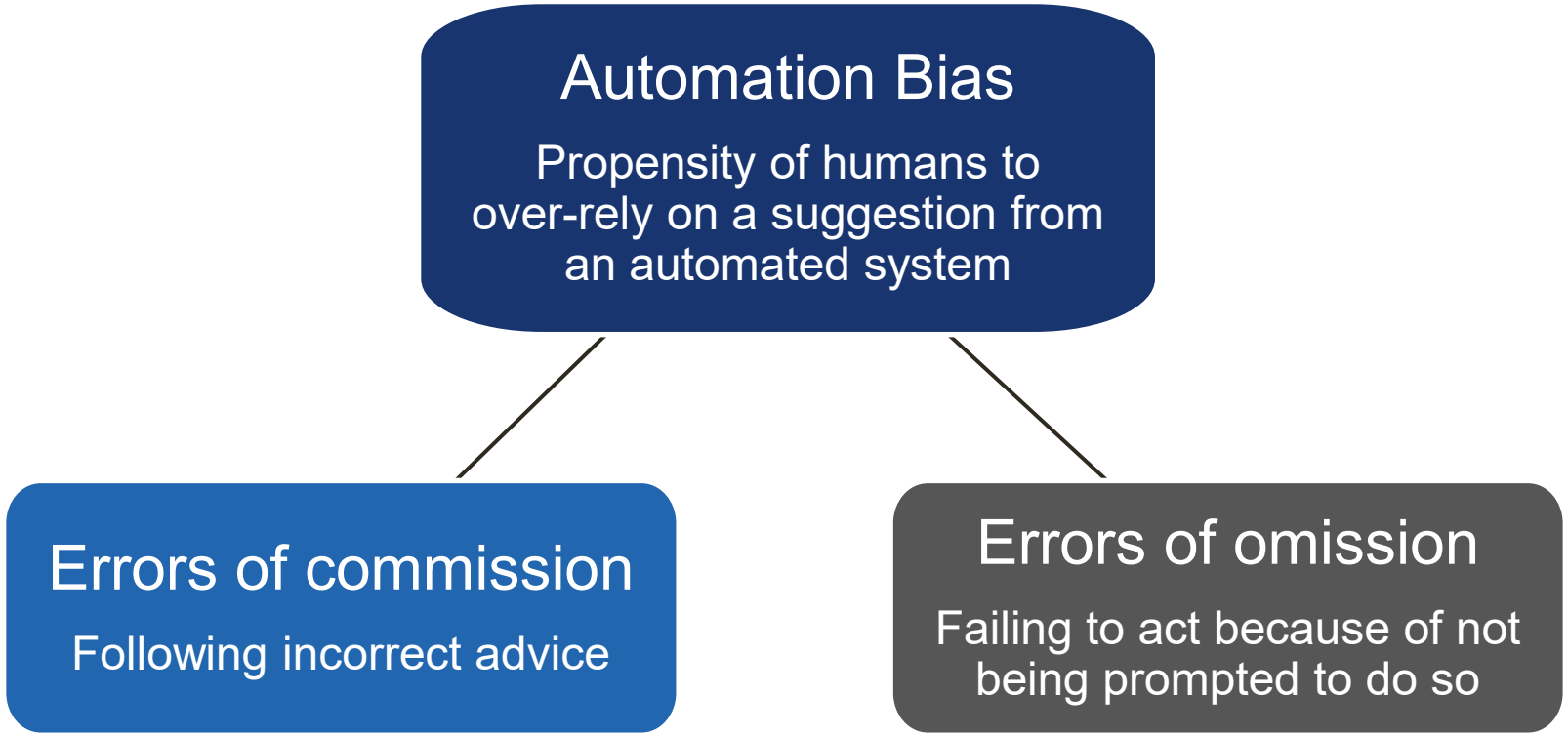
What CDS is NOT

Replacement for clinician judgment



"If you want a second opinion, I'll ask my computer."

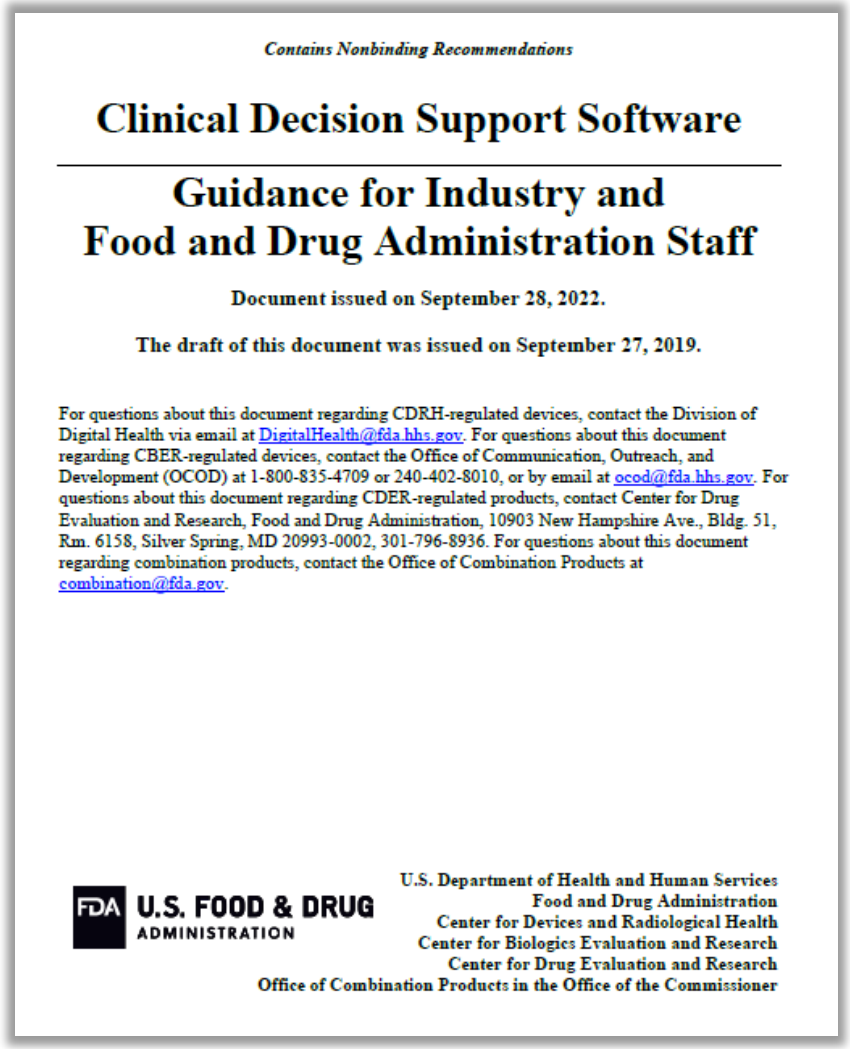
Potential Pitfalls Include



Ethical Issues

- CDS tools are based on data from patients records in the EHR
  - Data may not be representative of the population:
    - those who are underserved or lack access to care are excluded
  - Patients represented in clinical trials predominantly White and have a high socioeconomic status
  - Using these data in CDS tools may perpetuate health inequities

Regulatory Complexities



Contains Nonbinding Recommendations

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

The draft of this document was issued on September 27, 2019.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health via email at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

This guidance presents the Agency's current thinking on which CDS software functions are **excluded from the definition of device**

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Collaboratory Examples

Project	CDS Use	Goal
EMBED	Intervention User-centered computerized clinical decision support tool	Improve rates of buprenorphine initiation for patients with opioid use disorder treated in the emergency department
INSPIRE	Part of Intervention Predictive algorithm integrated into the computerized provider order entry system	Reduce prescribing of unnecessary extended-spectrum antibiotics while maintaining good clinical outcomes
NOHARM	Intervention EHR-embedded tools to aid shared decision-making about pain management	Reduce postoperative opioid use while improving pain and function
PRIM-ER	Supporting the Intervention Alert intended to help emergency department providers identify patients who could be candidates for palliative care	Reduce healthcare utilization and improve survival

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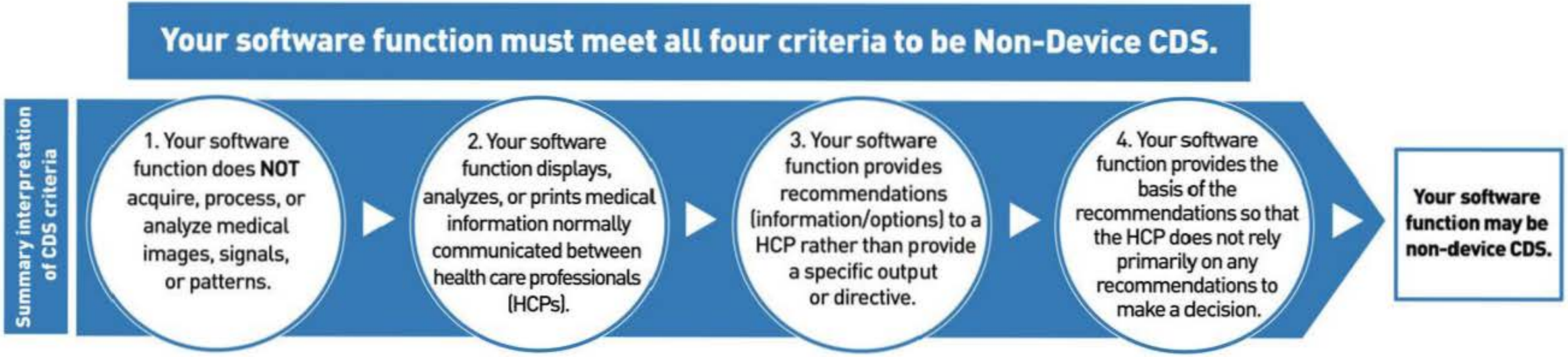
INSPIRE



- Predictive CDS to promote guideline concordant prescribing of broad spectrum antibiotics
- Clearly fit criteria for 1, 2, and 3
- IRB discussed criteria 4, and determined the intervention to be part of a larger package of clinician education
- Resolution: Not a device

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Case Example: Surgery

- You are pre-op for a surgical procedure.
- You check-in into the pre-op clinic.
  - Your information is automatically integrated, and you are directed by the computer to go to 1 of 3 doors:
    - Low, medium and high risk
    - Behind each door includes limited to extensive tests based on risk

brendantheraven, superawesomevectors

Is this a device?

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Case Example: Intra-operative

- You have your surgery.
- Your data are automatically integrated (pre & intra-op). and the surgeon is directed by the computer to do 1 of 3 things for closing the wound:
  - Simple sutures, special covering or a closed- incision wound vacuum

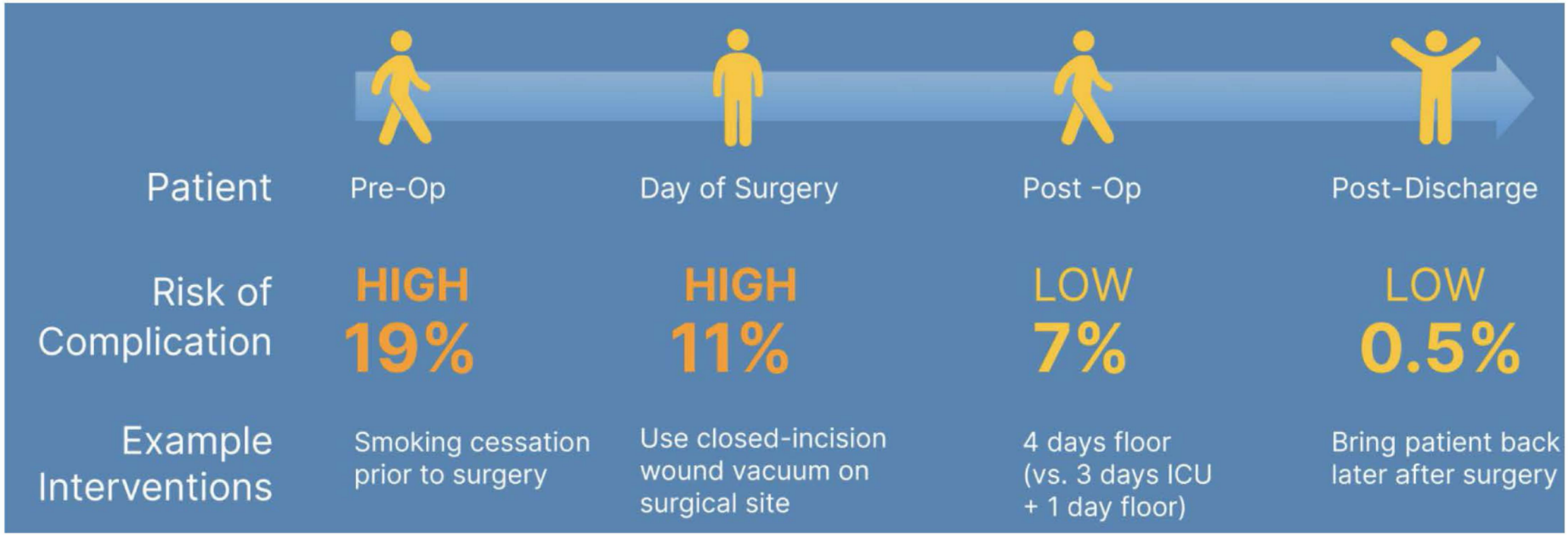
Is this a device?

Case Example: Post-operative

- You are recovering postoperatively.
- Your data are automatically integrated (pre, intra-op and post-op) and your 30-day risk for readmission is computed.
- The team is ready to discharge you and schedules you for follow-up based on your readmission risk:
  - 7 days, 21 days or sends you back to your primary care.

Is this a device?

Now imagine….
Can computers improve quality of care vs random thoughts?



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Thank You!

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