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AI technologies and their application in health care settings

Prof. Farah Magrabi

IMDRF/GMTA Joint Workshop

12 September 2022

Digital health, the promise of AI

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"Medical artificial intelligence is primarily concerned with the construction of AI programs that perform diagnosis and make therapy recommendations."

Clancy and Shortliffe, 1984

Now

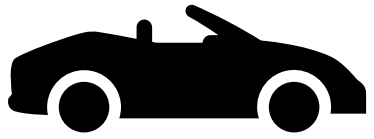
Supporting decisions:

- diagnosis
- prescribing
- alerts and reminders
- therapy critiquing and planning
- information retrieval
- image recognition and interpretation

Coiera E (2015) 3rd Ed. Guide to HI

Automation in driving

	SAE LEVEL 0™	SAE LEVEL 1™	SAE LEVEL 2™	SAE LEVEL 3™	SAE LEVEL 4™	SAE LEVEL 5™
human What does the human in the driver's seat have to do?	**You are driving** whenever these driver support features are engaged – even if your feet are off the pedals and you are not steering			**You are not driving** when these automated driving features are engaged – even if you are seated in "the driver's seat"		
	You must constantly supervise these support features; you must steer, brake or accelerate as needed to maintain safety			When the feature requests, you must drive	These automated driving features will not require you to take over driving	
machine What do these features do?	**These are driver support features**			**These are automated driving features**		
	These features are limited to providing warnings and momentary assistance	These features provide steering **OR** brake/ acceleration support to the driver	These features provide steering **AND** brake/ acceleration support to the driver	These features can drive the vehicle under limited conditions and will not operate unless all required conditions are met		This feature can drive the vehicle under all conditions
Example Features	• automatic emergency braking • blind spot warning • lane departure warning	• lane centering **OR** • adaptive cruise control	• lane centering **AND** • adaptive cruise control at the same time	• traffic jam chauffeur	• local driverless taxi • pedals/ steering wheel may or may not be installed	• same as level 4, but feature can drive everywhere in all conditions



Human information processing

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sensory processing → perception/ working memory → decision-making → response selection

Automating stages of human information processing (Parasuraman et al. 2000)

Automation of human information processing

sensory processing	perception/ working memory	decision-making	response selection
information acquisition	information analysis	decision selection	action implementation

Automating stages of human information processing (Parasuraman et al. 2000)

Open access Original research

BMJ Health & Care Informatics

How machine learning is embedded to support clinician decision making: an analysis of FDA-approved medical devices

David Lyell, Enrico Coiera, Jessica Chen, Parina Shah, Farah Magrabi

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To cite: Lyell D, Coiera E, Chen J, *et al*. How machine learning is embedded to support clinician decision making: an analysis of FDA-approved medical devices. *BMJ Health Care Inform* 2021;**28**:e100301. doi:10.1136/bmjhci-2020-100301

► Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bmjhci-2020-100301).

Received 07 December 2020
Revised 10 February 2021
Accepted 02 March 2021

ABSTRACT

Objective To examine how and to what extent medical devices using machine learning (ML) support clinician decision making.

Methods We searched for medical devices that were (1) approved by the US Food and Drug Administration (FDA) up till February 2020; (2) intended for use by clinicians; (3) in clinical tasks or decisions and (4) used ML. Descriptive information about the clinical task, device task, device input and output, and ML method were extracted. The stage of human information processing automated by ML-based devices and level of autonomy were assessed.

Results Of 137 candidates, 59 FDA approvals for 49 unique devices were included. Most approvals (n=51) were since 2018. Devices commonly assisted with diagnostic (n=35) and triage (n=10) tasks. Twenty-three devices were assistive, providing decision support but left clinicians to make important decisions including diagnosis. Twelve automated the provision of information (autonomous information), such as quantification of heart ejection fraction, while 14 automatically provided task decisions like triaging the reading of scans according to suspected

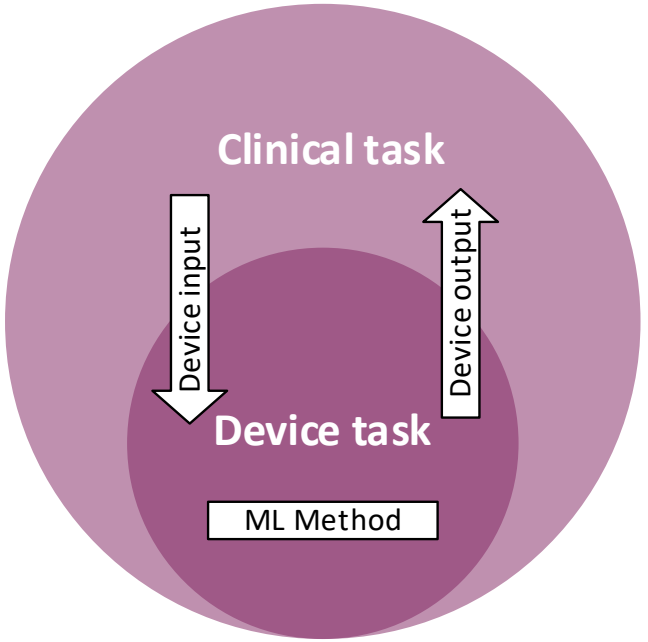
Summary

What is already known?

- Machine learning (ML)-based clinical decision support (CDS) operates within a human–technology system.
- Clinician interaction with CDS influences how they make decisions affecting care delivery and patient safety.
- Little is known about how emerging ML-based CDS supports clinician decision making.

What does this paper add?

- ML-based CDS approved by the FDA typically provide clinicians with decisions or information to support their decision making.
- Most demonstrate limited autonomy, requiring clinicians to confirm information provided by CDS and to be responsible for decisions.
- We demonstrate methods to examine how ML-based CDS are used by clinicians in the real world.



ML Medical Devices (n=49)

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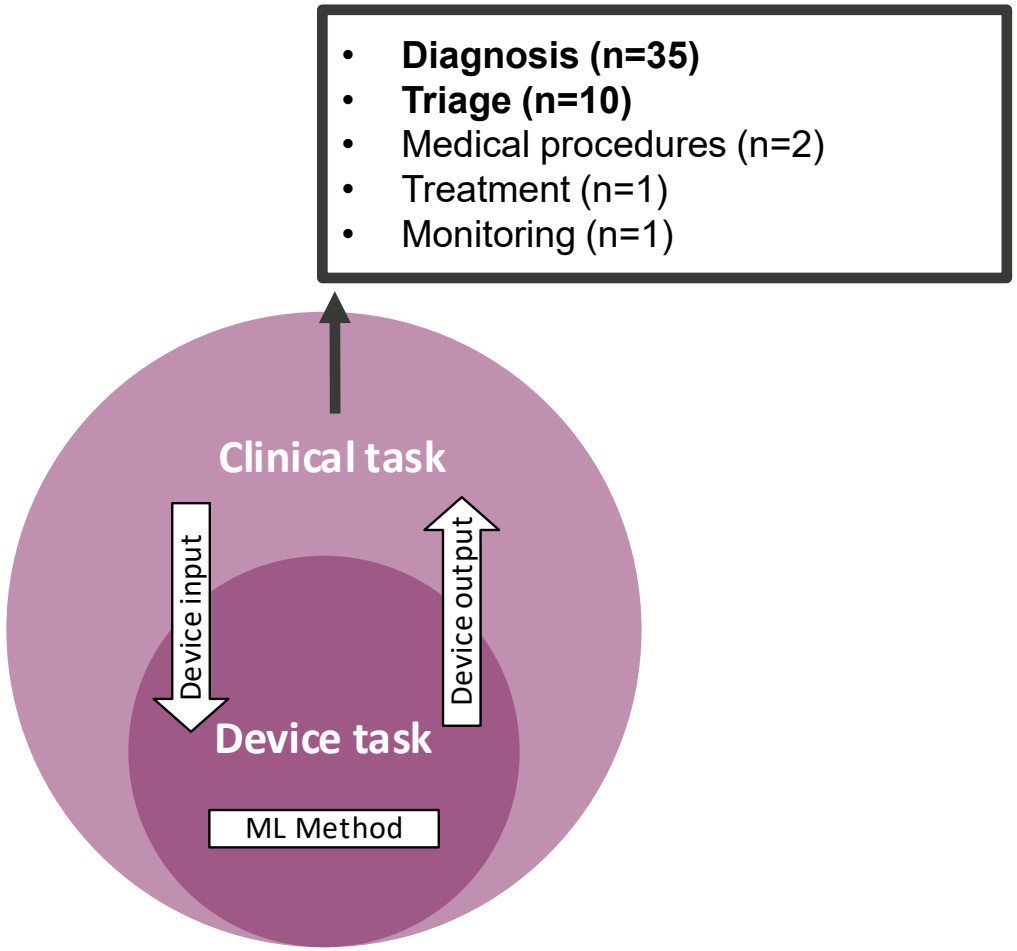
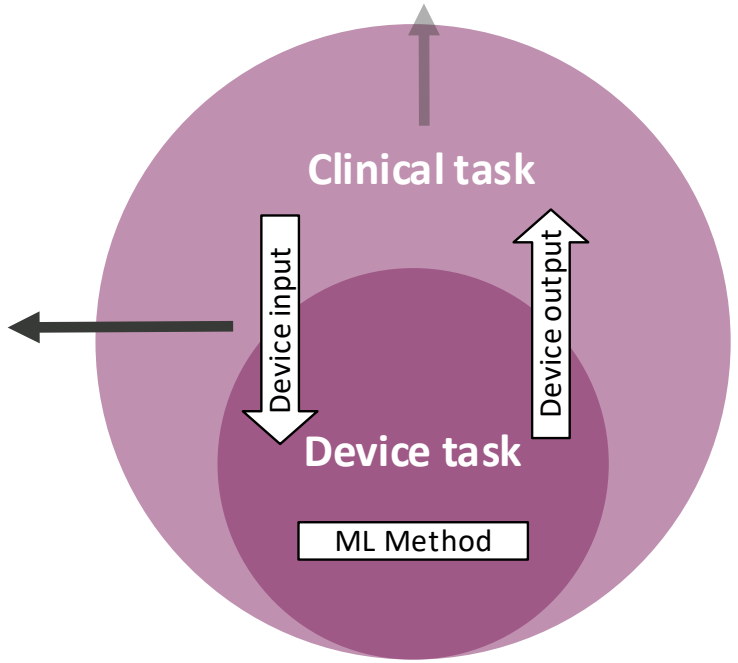


ML Medical Devices (n=49)

- **Diagnosis (n=35)**
- **Triage (n=10)**
- Medical procedures (n=2)
- Treatment (n=1)
- Monitoring (n=1)

Image data (n=42)
- CT (n=15)
- MRI (n=10)
- X-ray (n=5)
- Digital breast tomosynthesis (n=3)
- Digital mammography (n=3)
- Echocardiography (n=3)
- Fluoroscopy (n=1)
- Fundus imaging (n=1)
- OCT (n=1)
- PET (n=1)
- Ultrasound (n=1)

Signal data (n=7)
- EKG (n=3)
- Phonocardiography (n=2)
- Polysomnography (n=1)
- Blood glucose & insulin pump (n=1)
- Biometric data (n=1)



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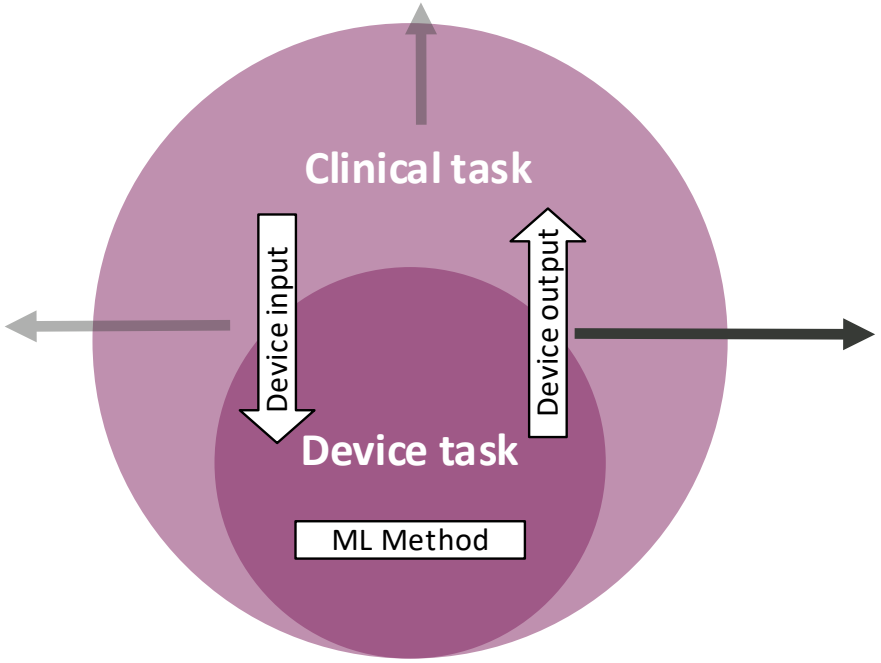

- **Quantification (n=13)**
- **Triage notification (n=10)**
- Case level finding of disease (n=6)
- Identify features of disease (n=6)
- Clinical grades (n=5)
- Enhanced images (n=4)
- Automatic coding of features (n=2)
- Automatic control of devices (n=2)
- Treatment recommendations (n=1)

ML Medical Devices (n=49)

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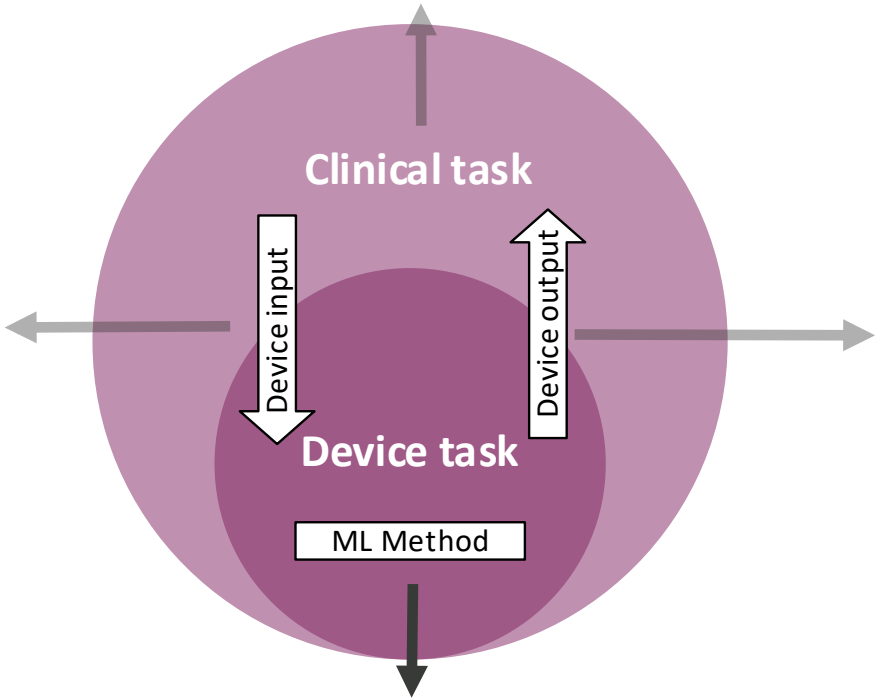

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- Artificial intelligence (n=15)
- Machine learning (n=14)
- Deep learning (n=11)
- Convolutional neural network (n=6)
- Neural network (n=1)
- Deep neural network (n=1)
- Deep convolutional neural network (n=1)

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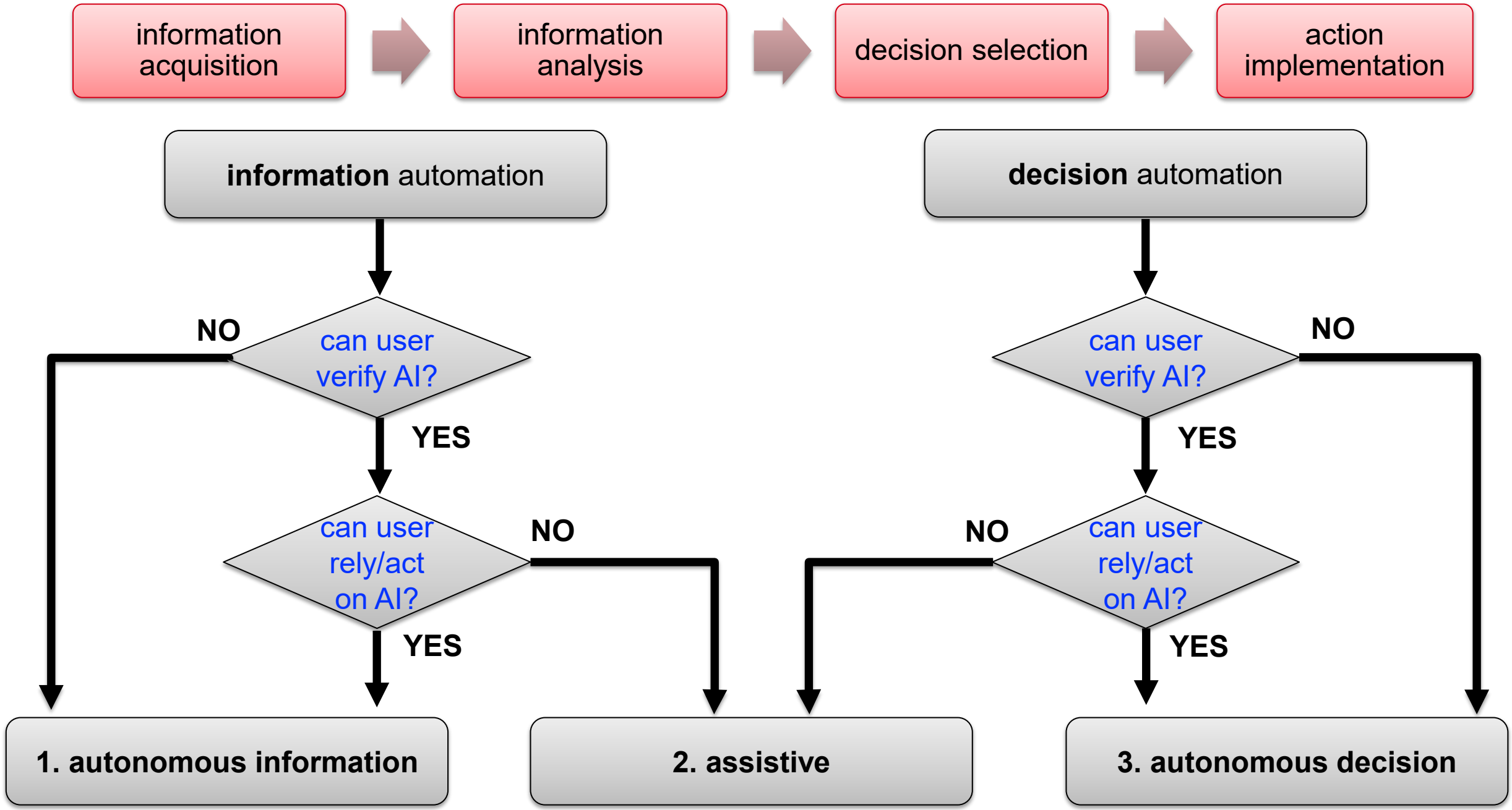
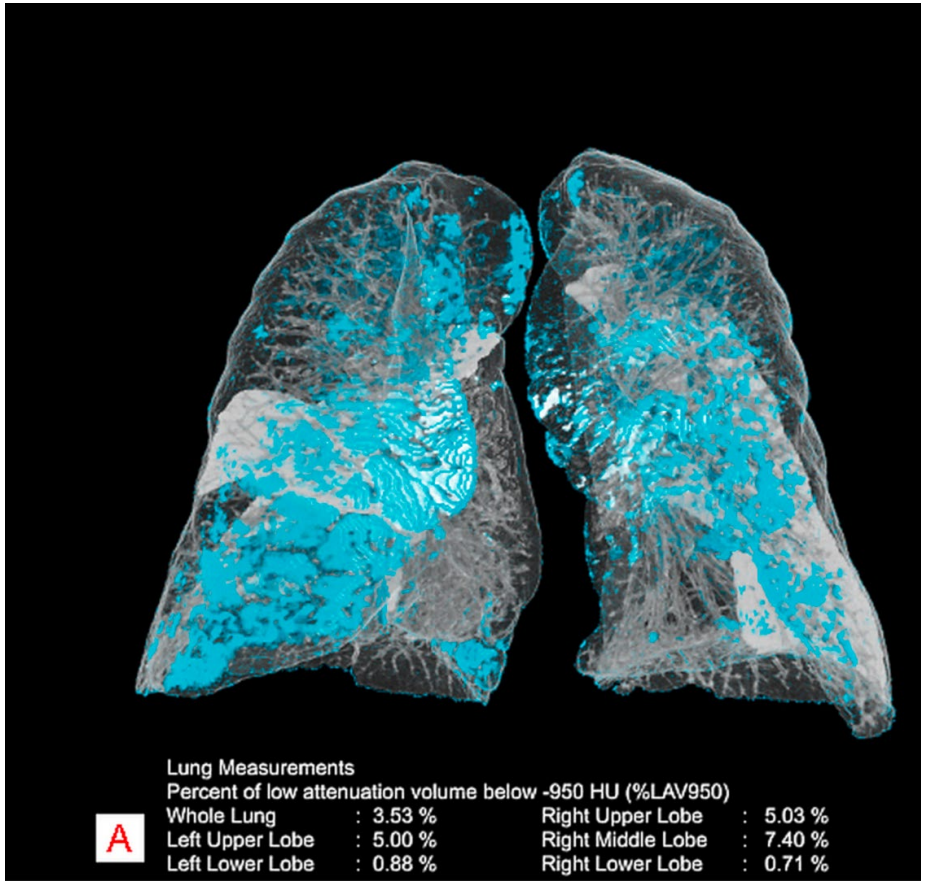
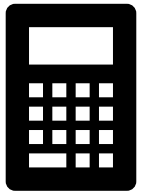
Level of autonomy


information acquisition
information analysis
decision selection
action implementation
information automation
decision automation
can user verify AI?
NO
YES
can user rely/act on AI?
NO
YES
can user verify AI?
NO
YES
can user rely/act on AI?
NO
YES
1. autonomous information
2. assistive
3. autonomous decision

1. AI provides information for humans to use in decision-making

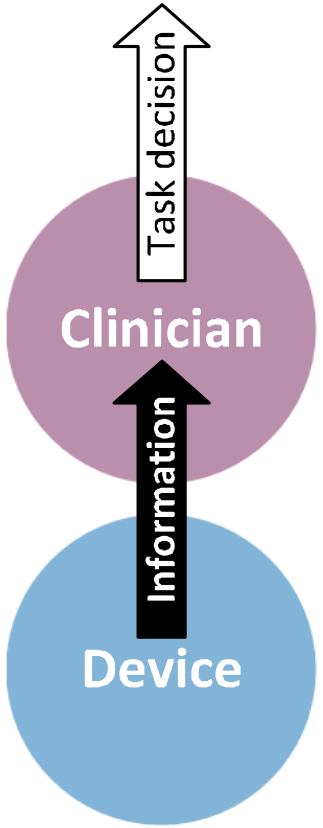


AI-Rad *(Siemens Medical Solutions)*



Quantification of
- lung volume
- lung lobes
- specified lung lesions

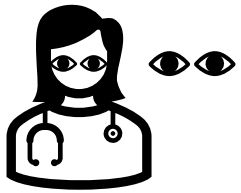
Autonomous Information



n = 12

2. AI assists human decisions

Cardiologs *(Cardiologs Technologies)*

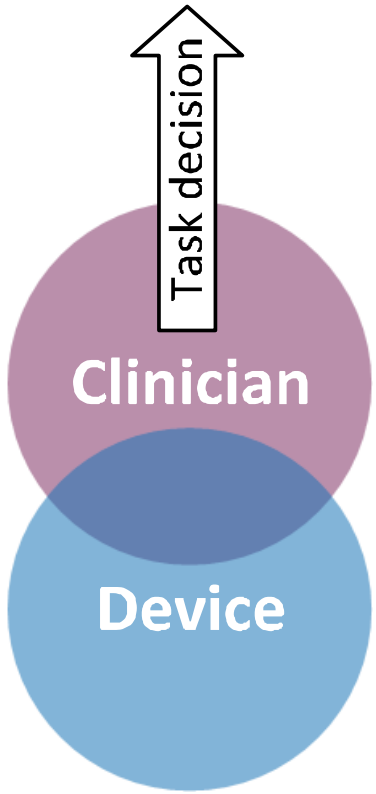


Identification of abnormal cardiac rhythms

"Clinicians must not use the [AI] generated output as the primary interpretation."

responsibility for final decision resides with clinician

Assistive

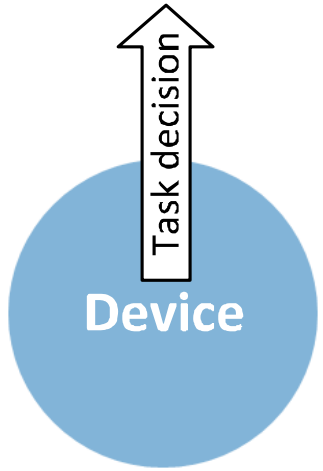


n = 23

3. AI decides in place of human expert

IDx-DR *(Idx LLC)*

Autonomous Decision



n = 14

Safely integrating AI into clinical workflow

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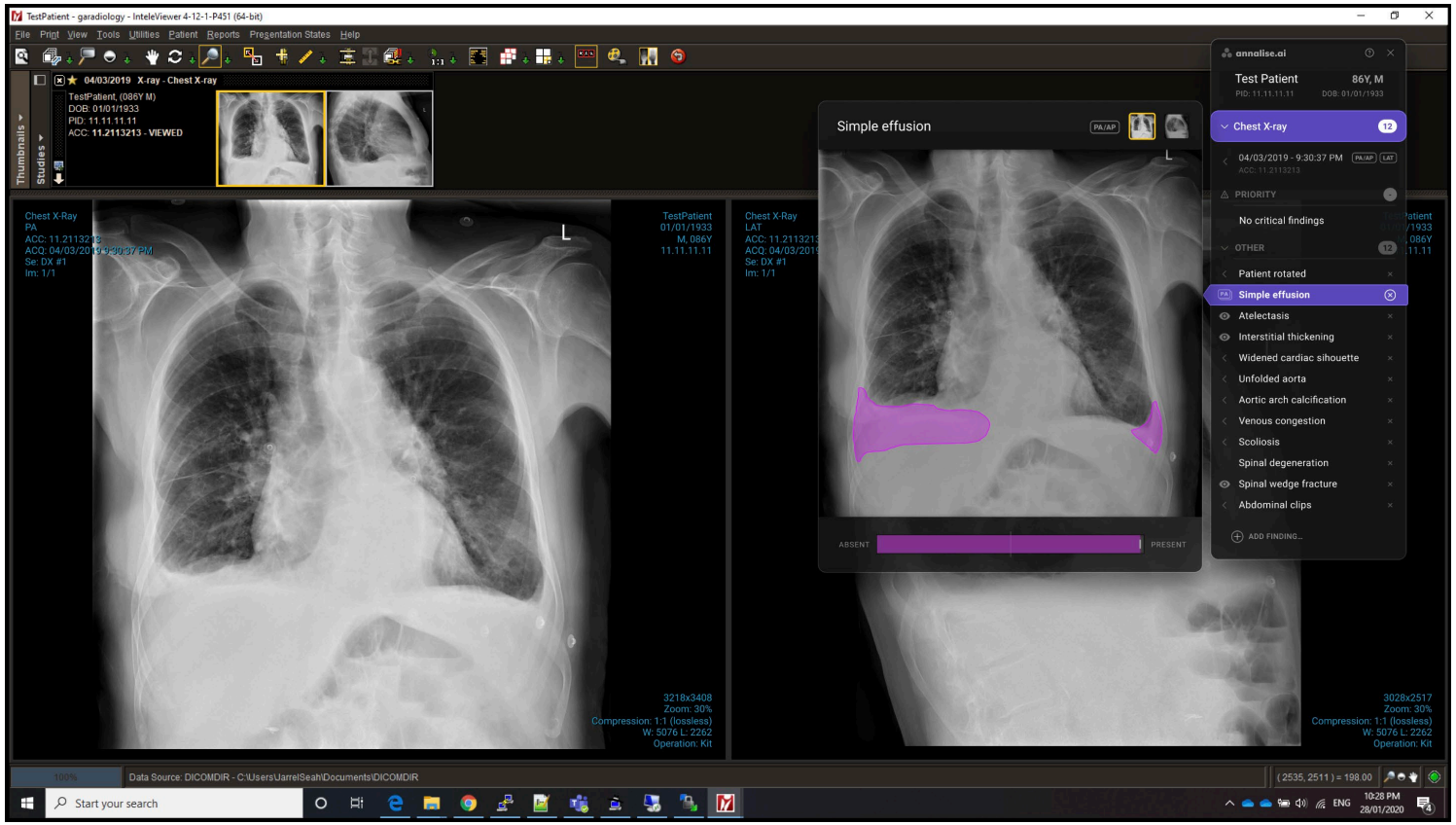

annalise.ai

Class 1 medical device

CXR AI findings + **Clinical context** → **Diagnoses** → **Management** → **Disposition**

The Last mile: Coiera JMIR 2019

Summary

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- Framework to classify AI/ML-based clinical decision support by **level of autonomy**

- Current systems:
  - provide information
  - assist humans to make decisions
  - provide decisions

- **Last mile** of safe implementation and use needs careful attention

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Thank you

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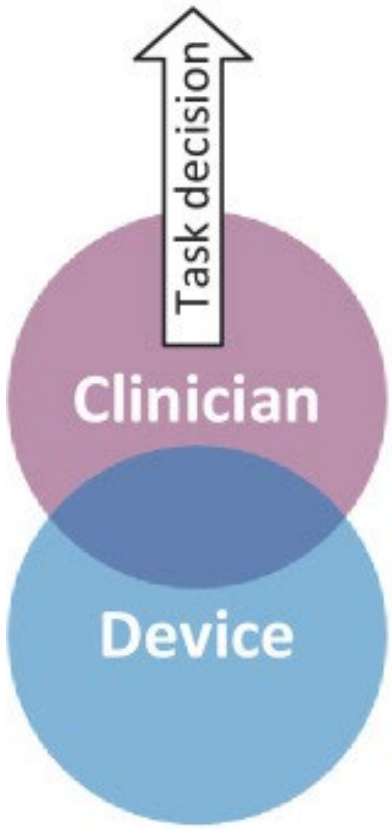
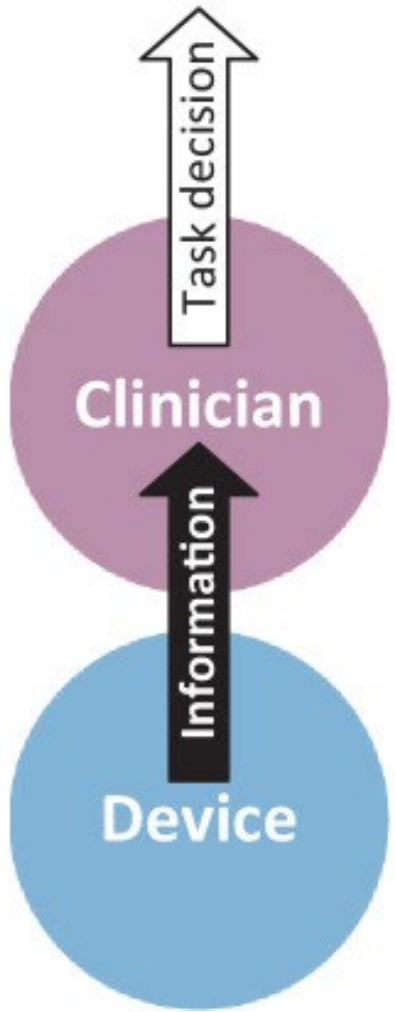
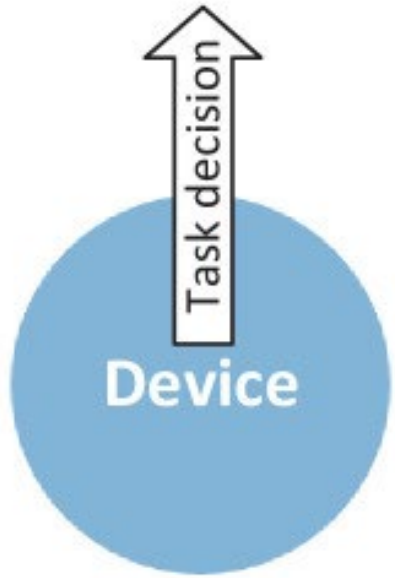
Assistive



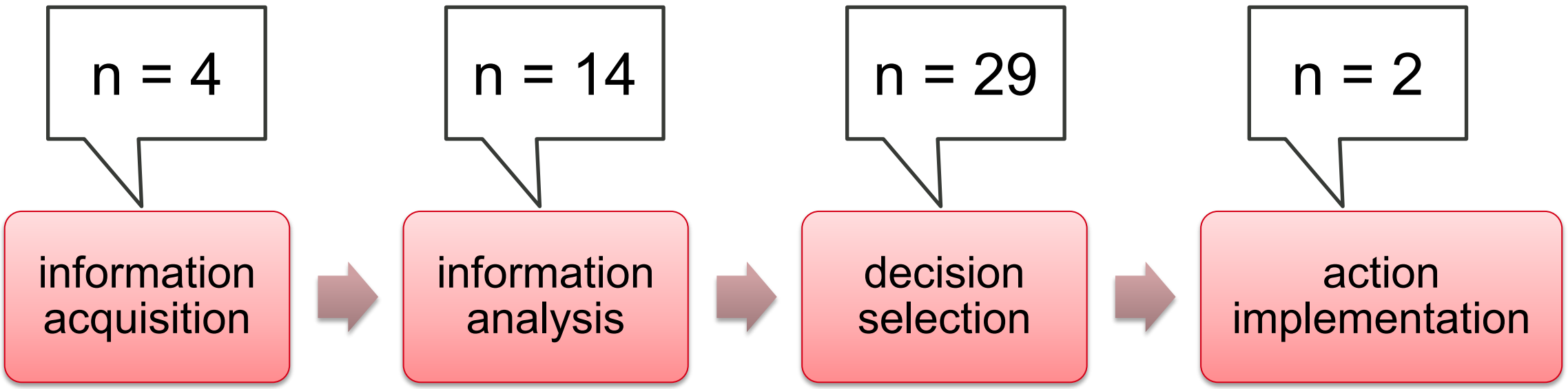
Autonomous Information



Autonomous Decision



Automation of human information processing



Automating stages of human information processing (Parasuraman et al. 2000)