# Artificial Intelligence in Medicine: The Need to Translate From Basic Science to Clinical Value

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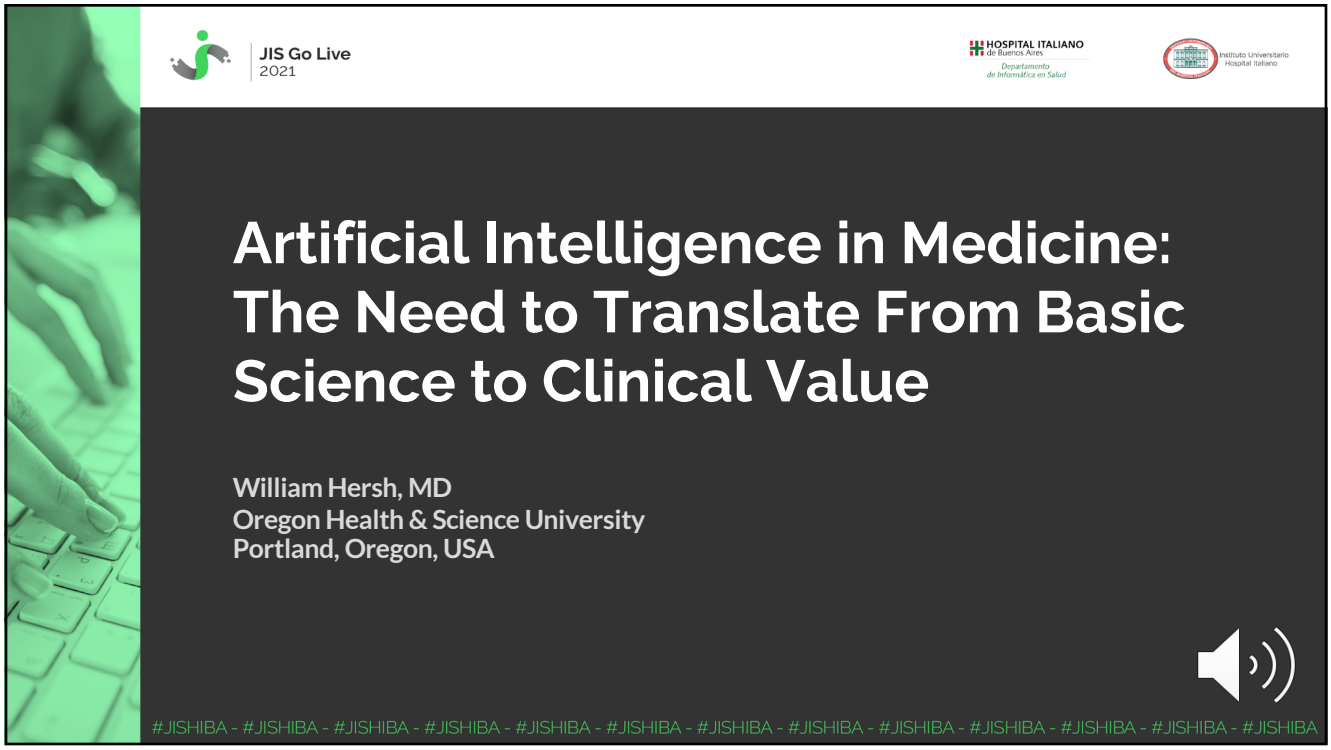
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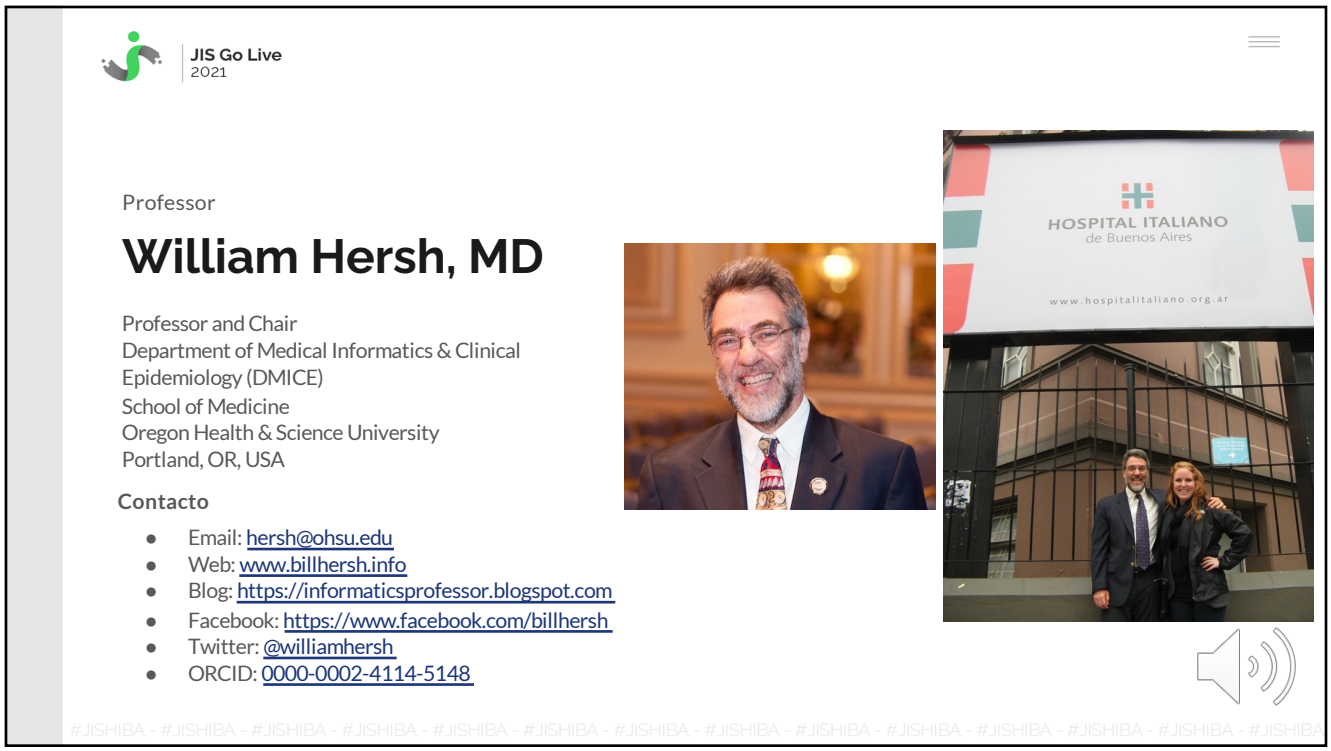
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# Outline

- Definitions
- Results
- Challenges



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# Artificial intelligence and machine learning

- Artificial intelligence (AI) is ability of computers to perform tasks normally associated with human intelligence
- Modern AI has been greatly advanced by machine learning (ML), which is ability of computer programs to learn without being explicitly programmed
- ML has been advanced by new algorithms, enhanced computer processing abilities, and availability of large and diverse quantities of data
    - Most important has been deep learning (DL), involving use of multi-layered neural networks
- Don't need to understand math or theory to understand use or evaluate clinical benefit



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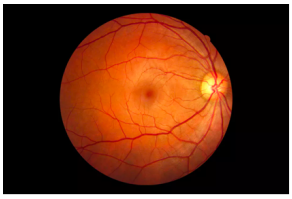
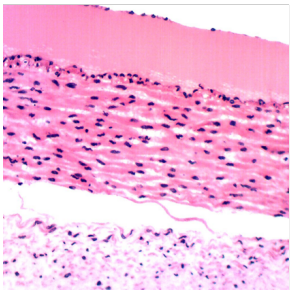
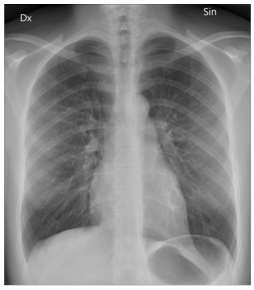
# Most success has come from image classification








Early studies

- Diabetic retinopathy (DR) (Gulshan, 2016; Ting, 2017)
- Histology of cancer (Benjordi, 2017) and metastases (Veta, 2019)
- Tuberculosis (Lakhani, 2017) and pneumonia (Rajpurkar, 2018)
- Skin cancer (Esteva, 2017; Haenssle, 2018; Tschandi, 2019)

State of the art (Esteva, 2021)



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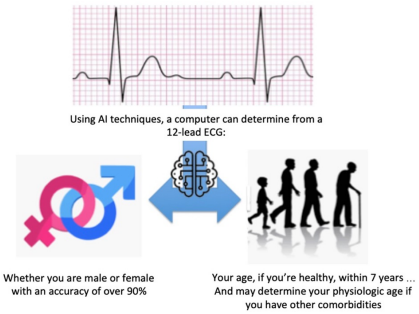
# Other successes in clinical prediction

- Length of stay, mortality, readmission, and diagnosis at two large medical centers (Rajkomar, 2018)
- Age and sex determination from retinal images (Poplin, 2018) or ECG (Attia, 2019)
- Early risk of chronic kidney disease in patients with diabetes (Ravizza, 2019)
- Dementia from EHR data up to two years before clinical diagnosis (Wang, 2019)
- Prediction models for mechanical ventilation, renal replacement therapy, and readmission in COVID-19 (Rodriguez, 2021)



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# What is the evidence for the benefit of AI?

- Best evidence for interventions (treatment or prevention) comes from randomized controlled trials (RCTs)
  - Ideally RCTs that are well-conducted, generalizable, and well-reported
- There are other clinical questions that can be answered by AI
  - Diagnosis – can AI methods improve ability to diagnose disease?
  - Harm – can AI identify harms from environment, medical care, etc.?
  - Prognosis – can AI inform the prognosis of health and disease?
- Ultimately, however, AI interventions must be demonstrated experimentally to benefit patients, clinicians, and populations
  - Some instances when RCTs are infeasible so observational studies may be justified



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# Systematic review of clinical interventions

- Zhou, Q., Chen, Z.-H., Cao, Y.-H., Peng, S., 2021. Clinical impact and quality of randomized controlled trials involving interventions evaluating artificial intelligence prediction tools: a systematic review. *NPJ Digit Med* 4, 154. https://doi.org/10.1038/s41746-021-00524-2
- Review of all randomized controlled trials (RCTs) using
  - Traditional statistical (TS) – mostly regression
  - Machine learning (ML) – all but deep learning
  - Deep learning (DL) – neural networks
- Found use for
  - Assistive treatment decisions
  - Assistive diagnosis
  - Risk stratification



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Identified 65 RCTs with following characteristics

- 61.5% positive results
- Variety of disease categories – cancer, other chronic disease, acute disease, and primary care
- Types of algorithms – TS > ML > DL
- Predictive tool function – assistive treatment decisions > assistive diagnosis > risk stratification

Some concerns of bias in studies

- One-third no sample size estimation
- Three-fourths no masking (open-label)
- Majority did not reference CONSORT, use intent-to-treat analysis, or provide study protocol

- Caveat: number of positive studies does not necessarily indicate general superiority of methods

**Table 1.** General characteristics of the 65 randomized controlled trials.

| Variables | Levels | Total (*n* = 65) |
|---|---|---|
| Results (%) | Negative | 25 (38.5) |
| | Positive | 40 (61.5) |
| Duration of study (*n*[a] = 59, months, median [IQR]) | | 12 [6, 24] |
| Sample size (median [IQR]) | | 435 [192, 999] |
| Sample size estimation (%) | Larger or equal than expected | 37 (56.9) |
| | Less than expected | 7 (10.8) |
| | Not performed | 21 (32.3) |
| Publication year (%) | 2010–2015 | 21 (32.3) |
| | 2016–2020 | 44 (67.7) |
| Study design (%) | RCT superiority (individualized) | 48 (73.8) |
| | RCT superiority with crossover (individualized) | 1 (1.5) |
| | RCT non-inferiority (individualized) | 2 (3.1) |
| | Clustered RCT superiority (clustered) | 7 (10.8) |
| | Stepped-wedge design (clustered) | 7 (10.8) |
| Allocation ratio (%) | 1:1 parallel | 55 (84.6) |
| | Others | 10 (15.4) |
| Masking (%) | Open-label | 49 (75.4) |
| | Single-blinded | 12 (18.5) |
| | Double-blinded | 4 (6.2) |
| Centers (%) | Single | 33 (50.8) |
| | Multi | 32 (49.2) |
| Disease category (%) | Cancer | 11 (16.9) |
| | Chronic disease not included cancer | 18 (27.7) |
| | Acute disease | 19 (29.2) |
| | Primary care | 9 (13.8) |
| | Others | 8 (12.3) |
| Types of algorithms (%) | Traditional statistical model | 37 (56.9) |
| | Machine learning | 17 (26.2) |
| | Deep learning | 11 (16.9) |
| Prediction tools function (%) | Assistive treatment decision | 35 (53.8) |
| | Assistive diagnosis | 16 (24.6) |
| | Risk stratification | 12 (18.5) |
| | Others | 2 (3.1) |
| Referenced CONSORT (%) | No | 47 (72.3) |
| | Yes | 18 (27.7) |
| Intent-to-treat analysis (%) | No | 39 (60.0) |
| | Yes | 26 (40.0) |
| Study protocol available | No | 49 (75.4) |
| | Yes | 16 (24.6) |
| Model development (%) | No | 7 (10.8) |
| | Yes—independent publication | 49 (75.4) |
| | Yes—published in the same article with RCT | 9 (13.8) |
| Internal validation (%) | No | 23 (35.4) |
| | Yes | 42 (64.6) |
| External validation (%) | No | 25 (38.5) |
| | Yes | 40 (61.5) |
| AUC in model development (*n*[a] = 21, median [IQR]) | | 0.81 [0.75, 0.91] |
| AUC in internal validation (*n*[a] = 18, median [IQR]) | | 0.83 [0.7, 0.91] |
| AUC in external validation (*n*[a] = 26, median [IQR]) | | 0.74 [0.75, 0.77] |

*IQR* interquartile range, *AUC* area under the receiver operating characteristic curve.
[a]Available numbers used for description



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Characteristics by tool type varied

- Model input – clinical quantitative data for TS/ML, images for DL, little use of natural language
- Disease category – varied for TS, chronic disease for ML, cancer for DL
- Tool function – risk stratification and treatment for TS, treatment for ML, diagnosis for DL
- Results – mixed for TS, more positive for ML/DL

| Variables | Levels | TS (*n* = 37) | ML (*n* = 17) | DL (*n* = 11) | *P* value |
|---|---|---|---|---|---|
| Duration of study (*n* = 59, months, median [IQR]) | | 17 [8, 32] | 7 [4, 19] | 6 [4, 9] | 0.005 |
| Sample size (median [IQR]) | | 435 [194, 999] | 258 [90, 537] | 700 [548, 994] | 0.122 |
| Clinical settings (%) | Outpatients | 19 (51.4) | 6 (35.3) | 1 (9.1) | 0.015 |
| | Inpatients | 17 (45.9) | 8 (47.1) | 10 (90.9) | |
| | Home | 1 (2.7) | 3 (17.6) | 0 (0.0) | |
| Publication year (%) | 2010–2015 | 14 (37.8) | 7 (41.2) | 0 (0.0) | 0.041 |
| | 2016–2020 | 23 (62.2) | 10 (58.8) | 11 (100.0) | |
| Model input (%) | Clinical quantitative data | 36 (97.3) | 16 (94.1) | 0 (0.0) | <0.001 |
| | Images or videos | 1 (2.7) | 0 (0.0) | 10 (90.9) | |
| | Natural language | 0 (0.0) | 1 (5.9) | 1 (9.1) | |
| Disease category (%) | Cancer | 2 (5.4) | 0 (0.0) | 9 (81.8) | <0.001 |
| | Chronic disease | 4 (10.8) | 13 (76.5) | 1 (9.1) | |
| | Acute disease | 16 (43.2) | 2 (11.8) | 1 (9.1) | |
| | Primary care | 9 (24.3) | 0 (0.0) | 0 (0.0) | |
| | Others | 6 (16.2) | 2 (11.8) | 0 (0.0) | |
| Prediction tools function (%) | Assistive diagnosis | 3 (8.1) | 2 (11.8) | 11 (100.0) | <0.001 |
| | Risk stratification | 11 (29.7) | 1 (5.9) | 0 (0.0) | |
| | Assistive treatment decision | 22 (59.5) | 13 (76.5) | 0 (0.0) | |
| | Others | 1 (2.7) | 1 (5.9) | 0 (0.0) | |
| Results (%) | Negative | 18 (48.6) | 5 (29.4) | 2 (18.2) | 0.136 |
| | Positive | 19 (51.4) | 12 (70.6) | 9 (81.8) | 0.044 (*P* for trend) |



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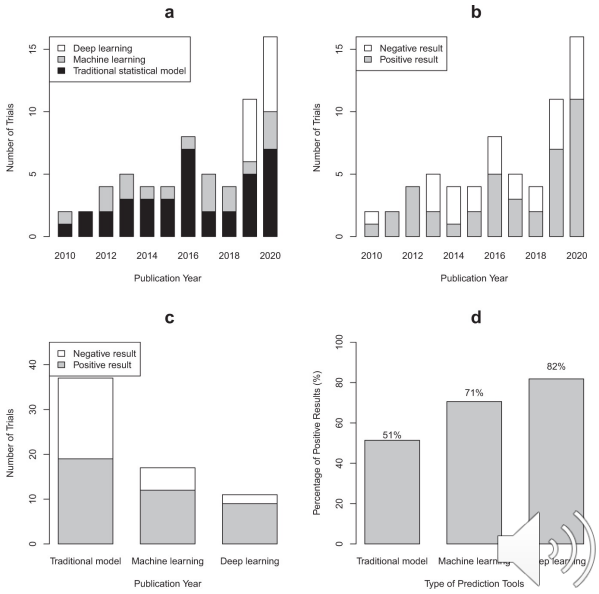
By publication year
- Increasing per year
- Increasing DL per year

By tool type, more positive for DL > ML > TS



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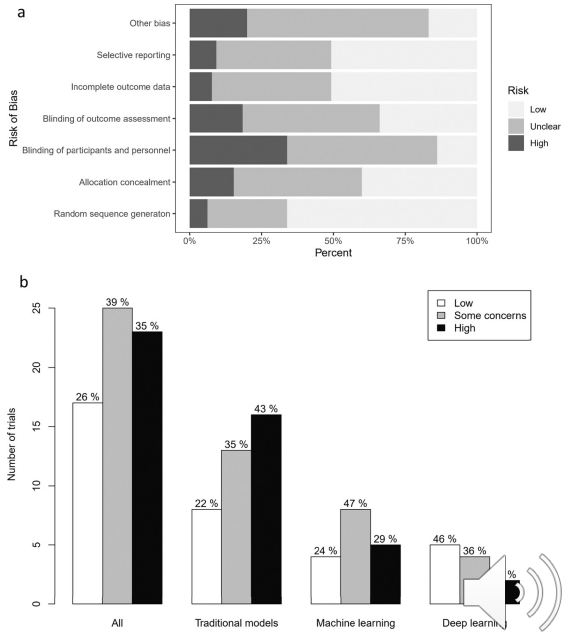
Only 17 of 65 trials with low risk of bias

Risk of bias high or unclear for most studies – higher for TS > ML > DL

Suboptimal use of CONSORT, sample size pre-estimation, randomization, and intent-to-treat analysis



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Characteristics of DL trials

- Of 11 RCTs, 9 evaluate assisting endoscopy – all positive results
- 2 other RCTs have negative results

**Table 2. Procedures of predictive tool interventions in the eleven randomized controlled trials involving interventions evaluating deeplearning tools**

| Reference | Conditions | Sample size | Tools for intervention | Control | Algorithms | Tool function | Tool input | Tool output | How the output being used in clinical settings | Trial primary outcomes | Gold standard | Trial findings |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Chen 2019 | Upper gastrointestinal lesions | 437 | Routine EGD examination stratified by three types with the assistance of ENDOANGEL AI system | Routine EGD examination stratified by three types without AI | DCNN (VGG-16) | Assistive diagnosis | EGD images | A virtual stomach model monitoring blind spots; timing; scoring and grading | Experts referenced AI output to make EGD examination and monitor blind spots. | Mean blind spot rate | Experts | Positive |
| Lin 2019 | Childhood cataracts | 700 | CC-cruiser web diagnosis platform | Regular ophthalmic diagnosis | DCNN (ImageNet) | Assistive diagnosis | Ocular images from slit-lamp photography | Diagnosis outcome; comprehensive evaluation; treatment recommendation | AI made diagnosis independently, and its results would be comparted with experts and not impact clinical decision making. | Accuracy of diagnosis | Experts | Negative |
| Su 2019 | Colorectal cancer | 659 | Routine colonoscopies with the assistance of an AI automatic quality control system | Routine colonoscopies | DCNN (AlexNet, ZFNet, YOLO V2) | Assistive diagnosis | Colonoscopy images | Location of colorectal polyps; timing; reminding retest and clean | Endoscopists referenced AI output to make endoscopic examination and report of polyps and adenomas. | Adenoma detection rate | Pathology | Positive |
| Wang 2019 | Colorectal cancer | 1058 | Routine colonoscopies with the assistance of an automatic polyp detection system | Routine colonoscopies | Deep learning architecture | Assistive diagnosis | Colonoscopy images | Location of polyps; alarming | Endoscopists were required to check every polyp location detected by the system and report of polyps and adenomas. | Adenoma detection rate | Pathology | Positive |
| Wu 2019 | Upper gastrointestinal lesions | 303 | Routine EGD examination with the assistance of WISENSE AI system | Routine EGD examination | DCNN (VGG-16 and DenseNet) | Assistive diagnosis | EGD images | A virtual stomach model monitoring blind spots; timing; scoring and grading; extracting frames with the highest confidence | Experts referenced AI output to make EGD examination and monitor blind spots. | Mean blind spot rate | Experts | Positive |
| Gong 2020 | Colorectal cancer | 704 | ENDOANGEL-assisted routine colonoscopy | Routine colonoscopy | DCNN and perceptual hash algorithms (VGG-16) | Assistive diagnosis | Colonoscopy images | Timing; safe, alarm, and dangerous ranges of withdrawal speed for real-time monitoring; slipping warning | Operating endoscopists referenced AI output to make endoscopic examination and report of polyps and adenomas. | Adenoma detection rate | Pathology | Positive |
| Liu 2020 | Colorectal cancer | 1026 | Routine colonoscopy with CADe assistance | Routine colonoscopy | DCNN-3D | Assistive diagnosis | Colonoscopy images | The probability of polyps in each frame; lesions alarming | Endoscopists focused mainly on the main monitor during the examination process, and a voice alarm prompted them to view the system monitor to check the location of each polyp detected by the system. | Detection rate of polyps and adenomas | Pathology | Positive |
| Luo 2020 | Colorectal cancer | 157 | AI-assisted colonoscopy | Traditional colonoscopy | CNN (YOLO) | Assistive diagnosis | Colonoscopy images | Location of polyps | Endoscopists referenced AI output to make endoscopic examination and report of polyps. | Polyp detection rate | Not reported | Positive |
| Repici 2020 | Colorectal cancer | 685 | High-definition colonoscopies with the AI-based CADe system | Routine colonoscopy | CNN | Assistive diagnosis | Colonoscopy images | Location of polys | Endoscopists referenced AI output to make endoscopic examination and report of polyps and adenomas. | Adenoma detection rate | Pathology | Positive |
| Wang 2020 | Colorectal cancer | 962 | White light colonoscopy with assistance from the CADe system | White light colonoscopy with assistance from a sham system | Deep learning architecture | Assistive diagnosis | Colonoscopy images | Location of polyps; alarming | Endoscopists were required to check every polyp location detected by the system and report of polyps and adenomas. | Adenoma detection rate | Pathology | Positive |
| Blomberg 2021 | Out-of-hospital cardiac arrest (OHCA) | 5242 | Normal protocols with alert | Normal protocols without alert | Speech recognition using deep neural networks | Assistive diagnosis | Emergency calls | OHCA Alert | Dispatchers in the intervention group were alerted when the machine learning model identified out-of-hospital cardiac arrest. | The rate of dispatcher recognition of subsequently confirmed OHCA | Danish Cardiac [illegible] | egative |

Abbreviations: AI = Artificial intelligence; DL = Tools using deep learning algorithms; ML = Tools using machine learning algorithms; CNN = Convolutionalneural networks; DCNN = Deep convolutional neural networks; CADe = Computer-aided detection; EGD = Esephagogastroduodenoscopy; OHCA = Out-of-hos[illegible]cardiac a



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# Conclusions

- AI predictive tools show great promise in improving clinical decisions for diagnosis, treatment, and risk stratification but comprehensive evidence lacking
  - Number of clinical trials assessing clinical benefit is small
  - Majority of the clinical trials have indeterminate or high risk of bias
  - Most trials of deep learning focused on endoscopic procedures
- Concerns about review
  - Missing column in Table 2 of DL interventions
    - Does not include Yao et al. 2021 – published after review done?
  - Difficult to use data in Supp Table 4 of ML interventions
    - Includes Wijnberge et al. 2020 (62) but not in ML table – considered TS?
  - No data/table for TS interventions



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## Other concerns about AI algorithms

- CDS studies rarely (0.3%) replicated (Coiera, 2021)
- AI for radiographic COVID-19 detection selects non-signal features that may be idiosyncratic (DeGrave, 2021)
- In case of using AI for screening mammography, quality of studies is poor, mostly retrospective, and mostly inferior to radiologists (Freeman, 2021)
- Almost all published prediction models for COVID-19 prognosis poorly reported and at high risk of bias (Wynant, 2020)
- Studies of CXR used for diagnosis of COVID-19 had inadequate reporting of methodology (Roberts, 2021)
- Machine learning for health compared poorly to other areas regarding reproducibility metrics, such as dataset and code accessibility (McDermott, 2021)
- Of 130 medical AI devices approved by FDA, only 4 underwent prospective evaluation and number of evaluation sites and samples often not reported (Wu, 2021)



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## Summary

- Much promise, but clinically proven benefit still mostly lacking
- Need "translation" from "basic science" of AI to "clinical value"
  - Clinically-driven applications and trials
  - Attention to patient safety and benefit and to clinician workflow
  - Robust AI and RCT methods that are replicable and generalizable
- Most conduct implementation and trials from a health equity standpoint



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