언택트 시대의 연하장애 디지털 헬스케어

서울대학교병원 재활의학과
이우형

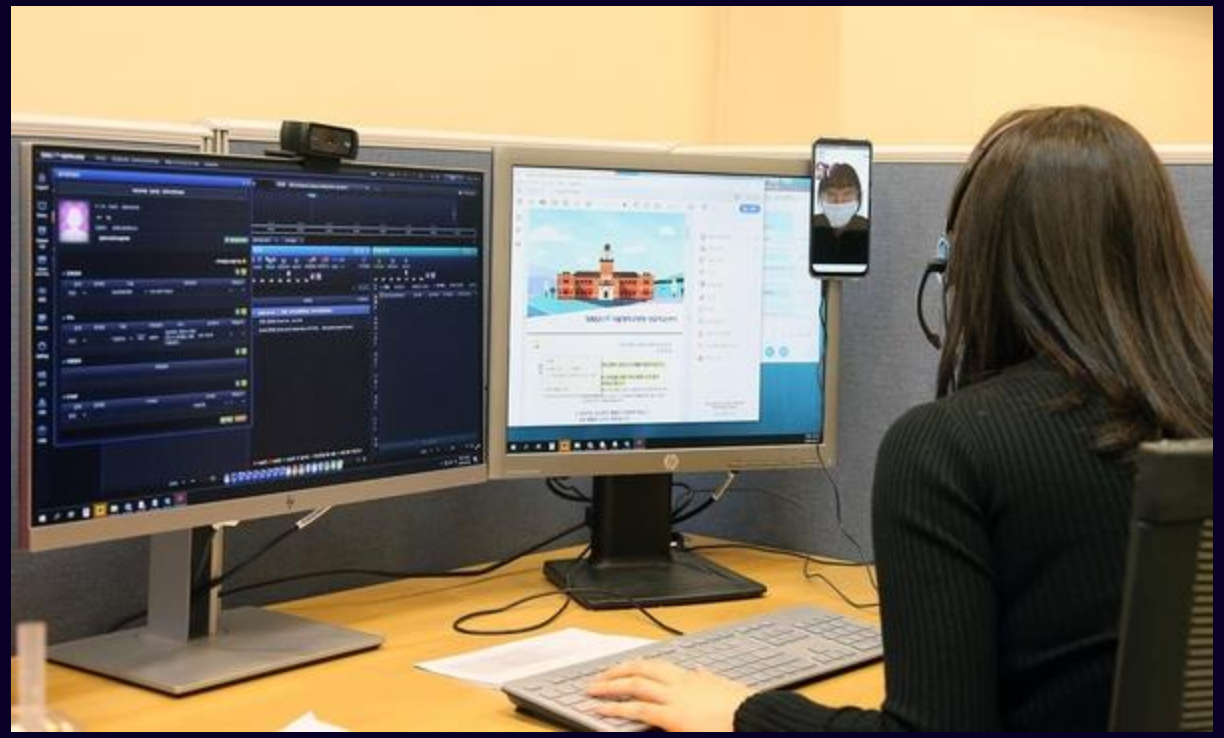
Contents

- What is digital health?
  - Spectrum
  - Categories
- Digital health in dysphagia
- Issues in digital health

COVID-19 era

Medicircle (2020.3.13)

Medicine in COVID-19 era



Non-Face-to-Face medical care

https://biz.chosun.com/site/data/html_dir/2020/06/25/2020062501534.html

Non-Face-to-Face medical care

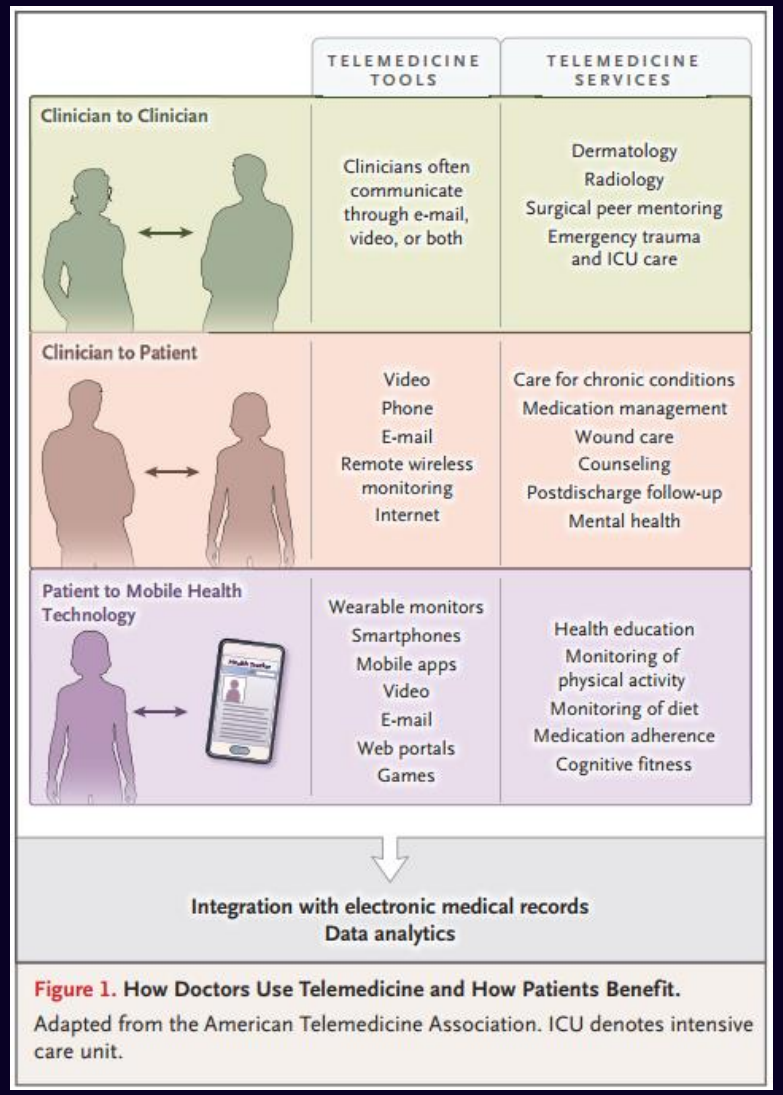


Figure 1. How Doctors Use Telemedicine and How Patients Benefit.

Adapted from the American Telemedicine Association. ICU denotes intensive care unit.

Telehealth, NEJM (2017)

In rehabilitation medicine …

Physical therapy

Occupational therapy

Swallowing therapy

Conventional dysphagia evaluation and treatment

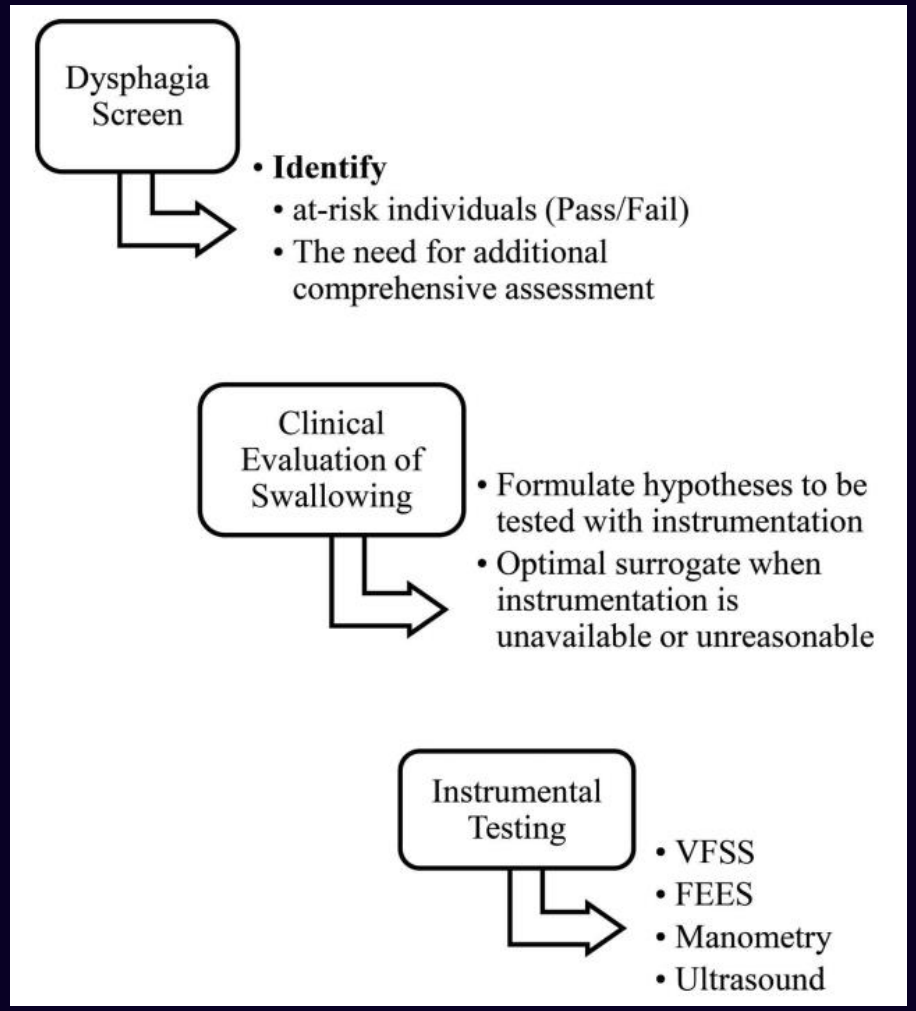


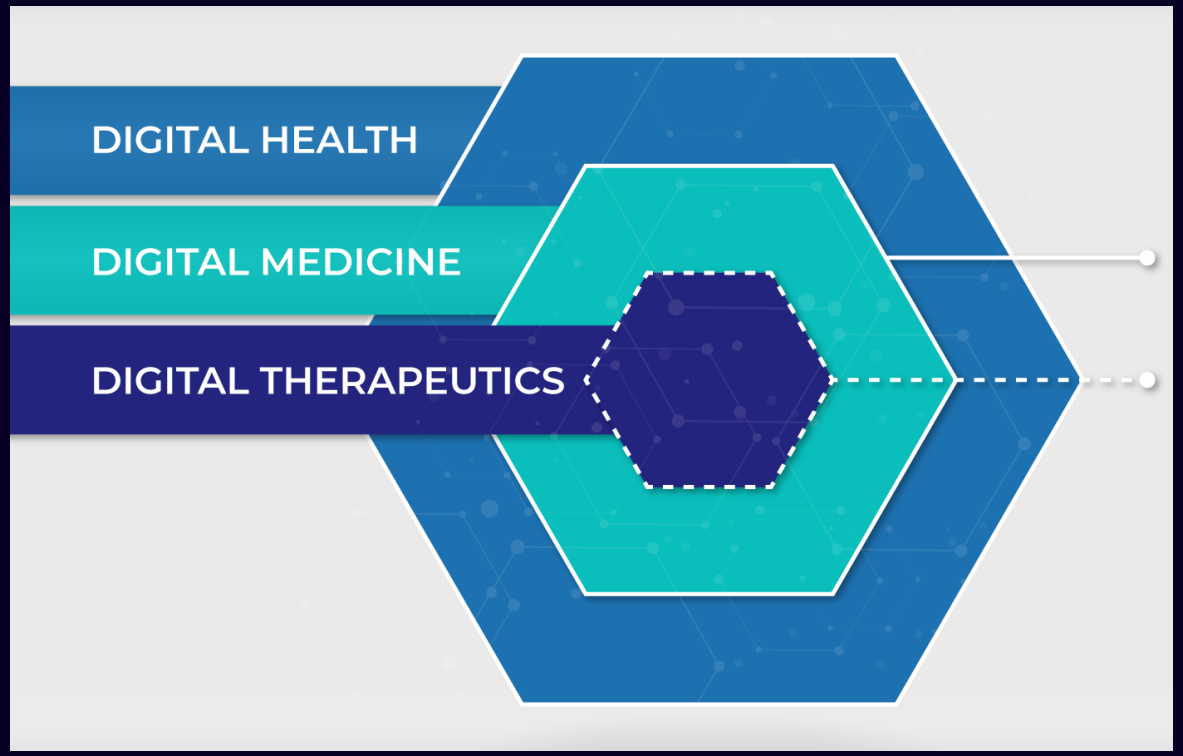
TABLE 18.4 Options for the Treatment of Dysphagia

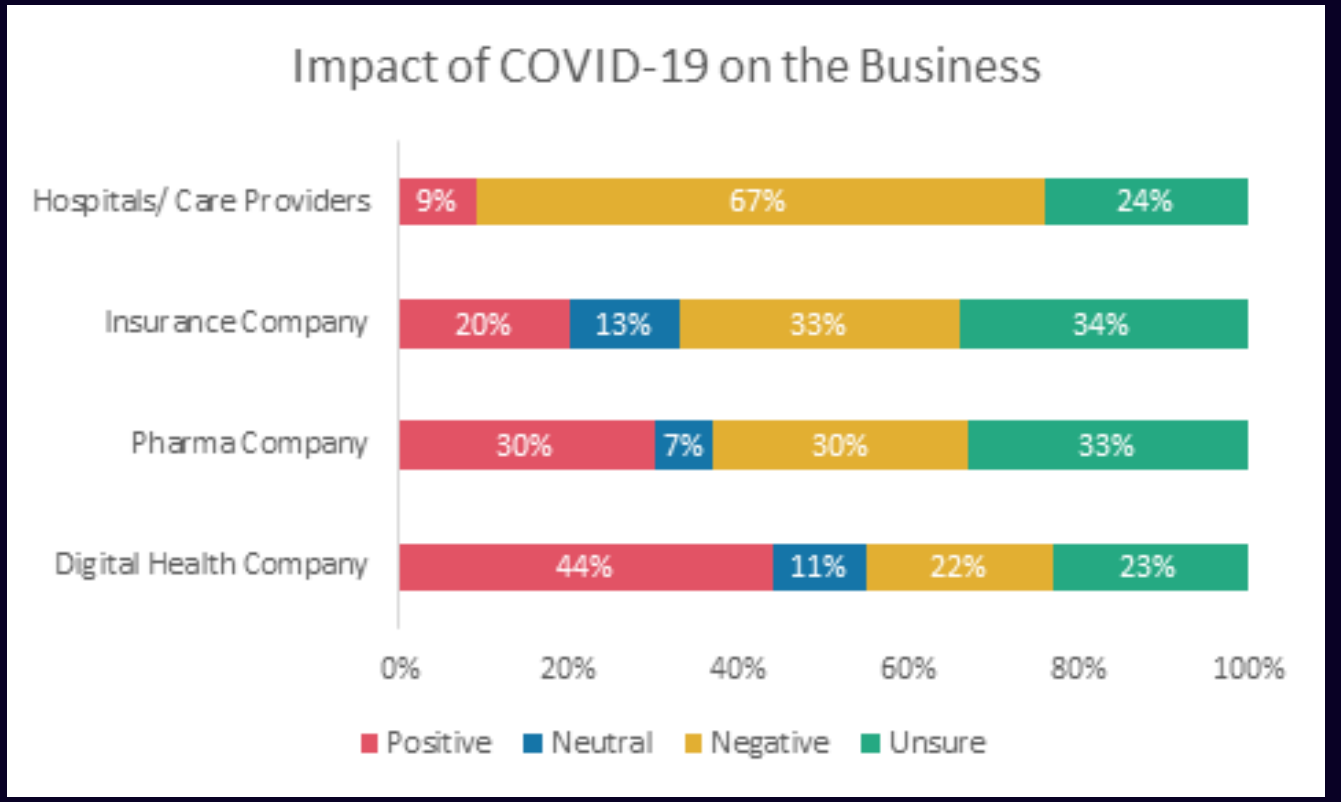
Compensatory treatments
Postural adjustments
Diet modification
Change of eating habits
Feeding strategies
Rehabilitative treatments
Strengthening exercises
Range-of-motion exercises
Sensory enhancement
Surgical treatments
Correction of structural abnormalities
Treatment of vocal cord paralysis
Cricopharyngeal myotomy or UES dilatation[a]
Gastrostomy (most often percutaneous)
Therapies under evaluation
Transcranial magnetic stimulation
Implantable neuroprosthesis

[a]Only indicated in cases of isolated cricopharyngeal muscle dysfunction, in which this muscle and the UES fail to relax upon swallowing (can be seen as part of the lateral medullary syndrome).
Abbreviation: UES, upper esophageal sphincter.

Tremor and other hyperkinemtic movements (2017)

Digital health





Global Survey, MRFR Analysis (2019)

	DIGITAL HEALTH	DIGITAL MEDICINE	DIGITAL THERAPEUTICS
DEFINITION	Digital health includes technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science and clinical operations.	Digital medicine includes evidence-based software and/or hardware products that measure and/or intervene in the service of human health.[1]	Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.[2]
CLINICAL EVIDENCE	Typically do not require clinical evidence.	Clinical evidence is required for all digital medicine products.	Clinical evidence and real world outcomes are required for all DTx products.
REGULATORY OVERSIGHT	These products do not meet the regulatory definition of a medical device[3] and do not require regulatory oversight.	Requirements for regulatory oversight vary. Digital medicine products that are classified as medical devices require clearance or approval. Digital medicine products used as a tool to develop other drugs, devices, or medical products require regulatory acceptance by the appropriate review division.	DTx products must be reviewed and cleared or certified by regulatory bodies as required to support product claims of risk, efficacy, and intended use.

1 https://www.dimesociety.org/index.php/defining-digital-medicine
2 https://www.dtxalliance.org/dtxproducts/
3 It is important to check with local regulatory requirements in each jurisdiction the product is manufactured, registered, or used in.

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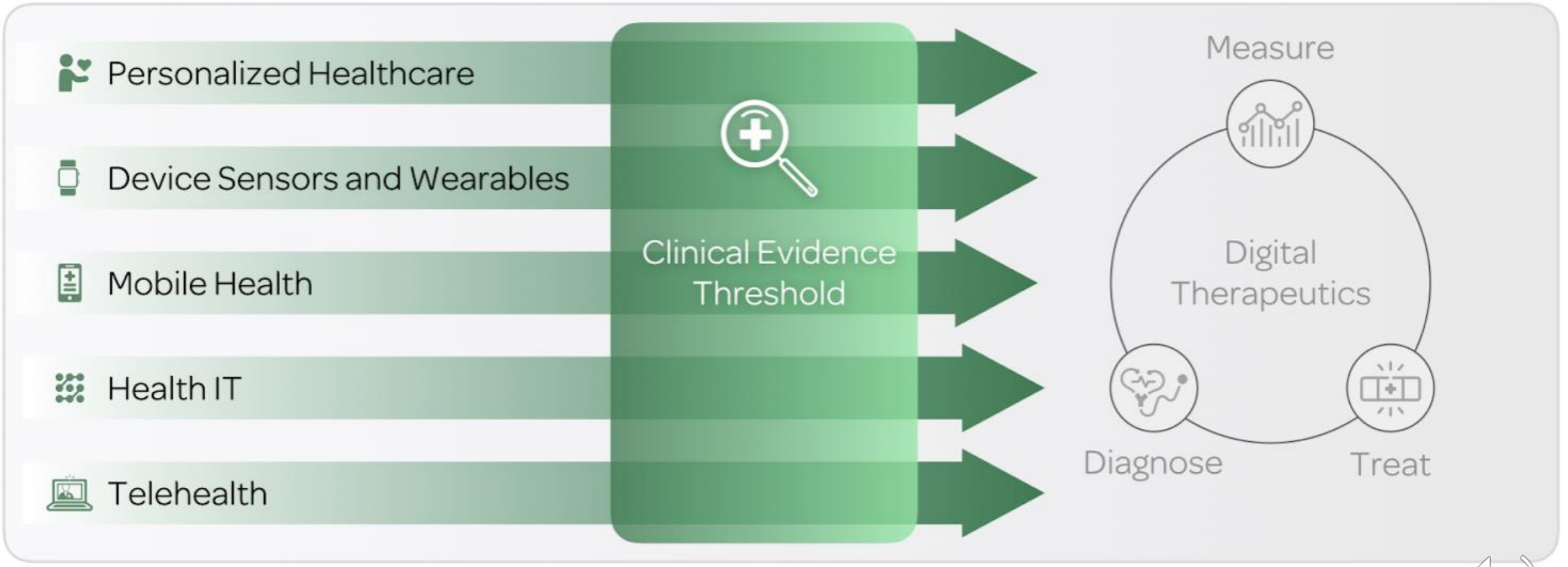
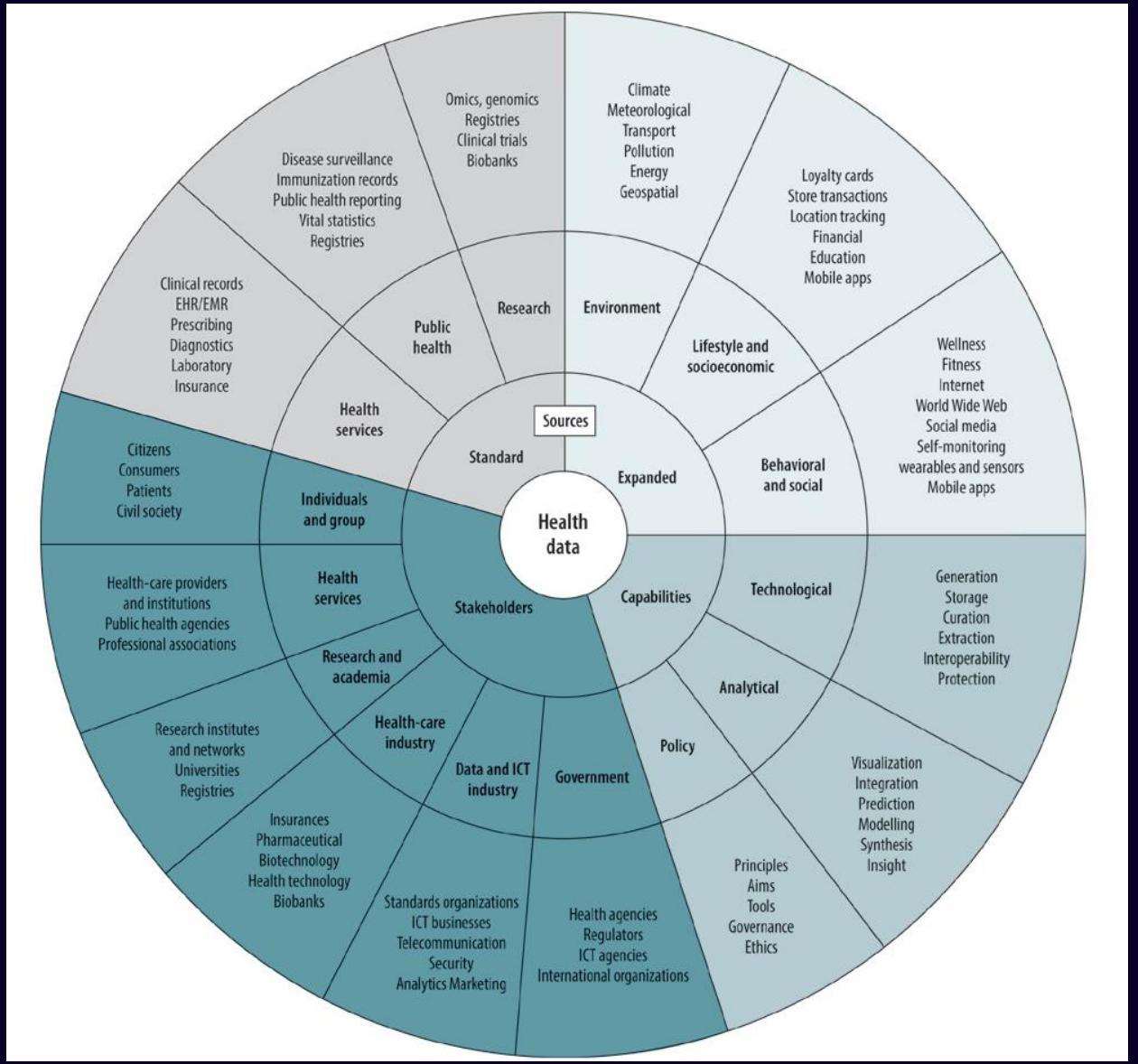
Categories of digital health



(1) Data



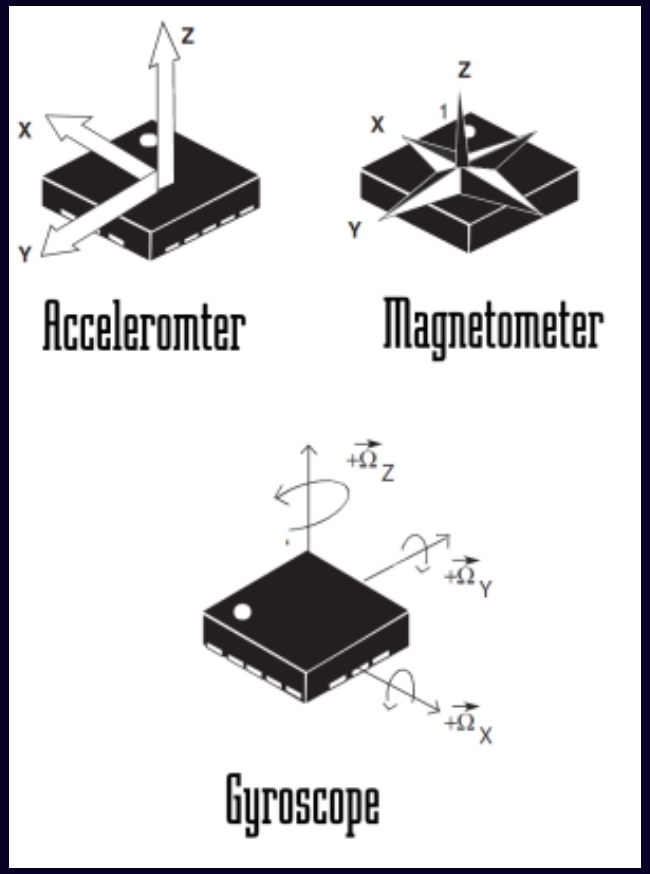
Policy implications of big data in the health sector, Bulletin of the World Health Organization (2018)

(2) Device

Samsung smartphone

Apple watch

Beddit, sleep tracker



Xiaomi Mi Scale

FreeStyle Libre, glucose monitoring

(3) Machine learning

- **How machine learning can augment the work of clinicians?**
  - Prognosis
  - Diagnosis
  - Treatment
  - Clinician workflow
  - Expanding the availability of clinical expertise

Machine learning in medicine, NEJM (2018)

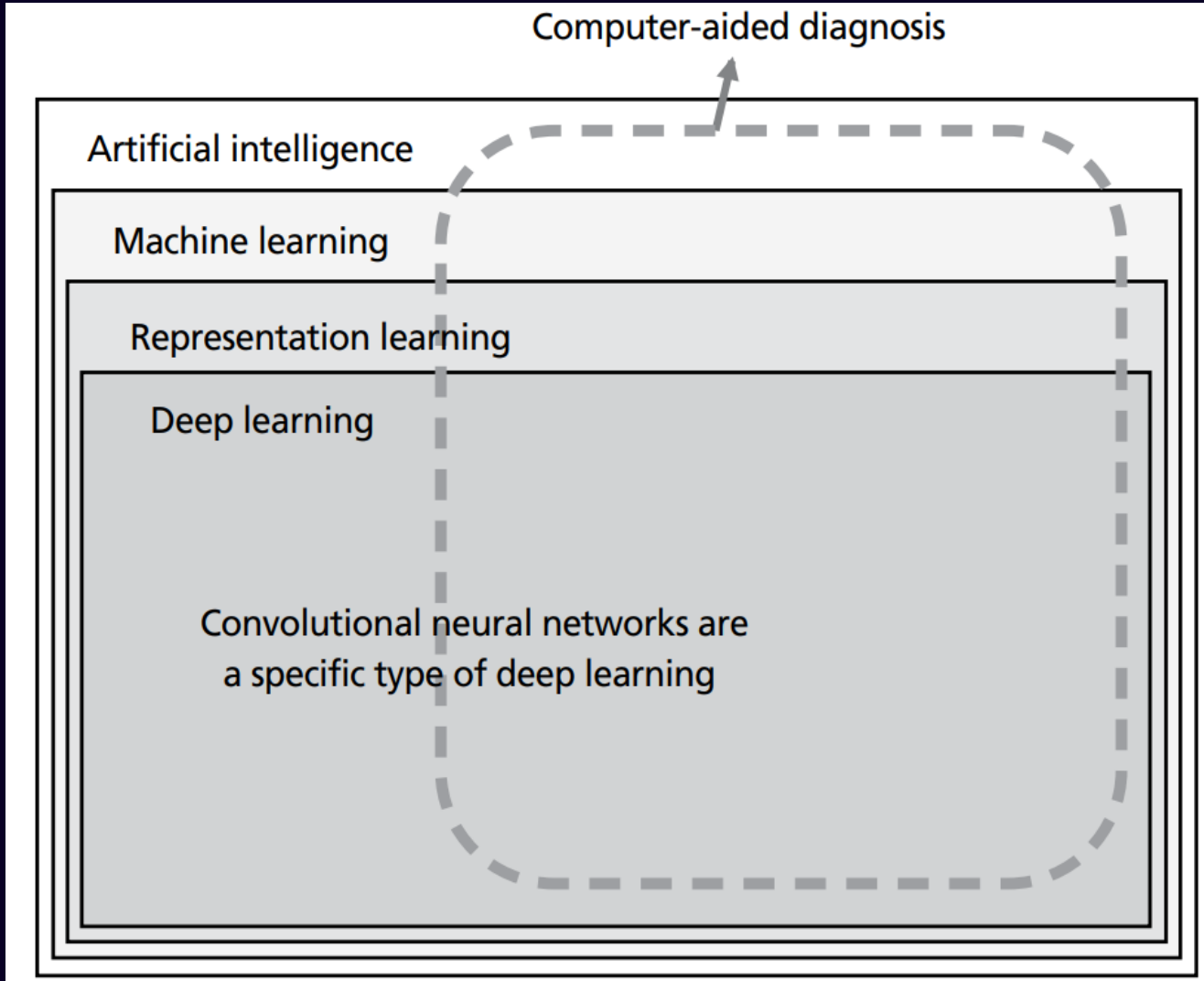


Figure 1. Hierarchy of artificial intelligence-related terms.

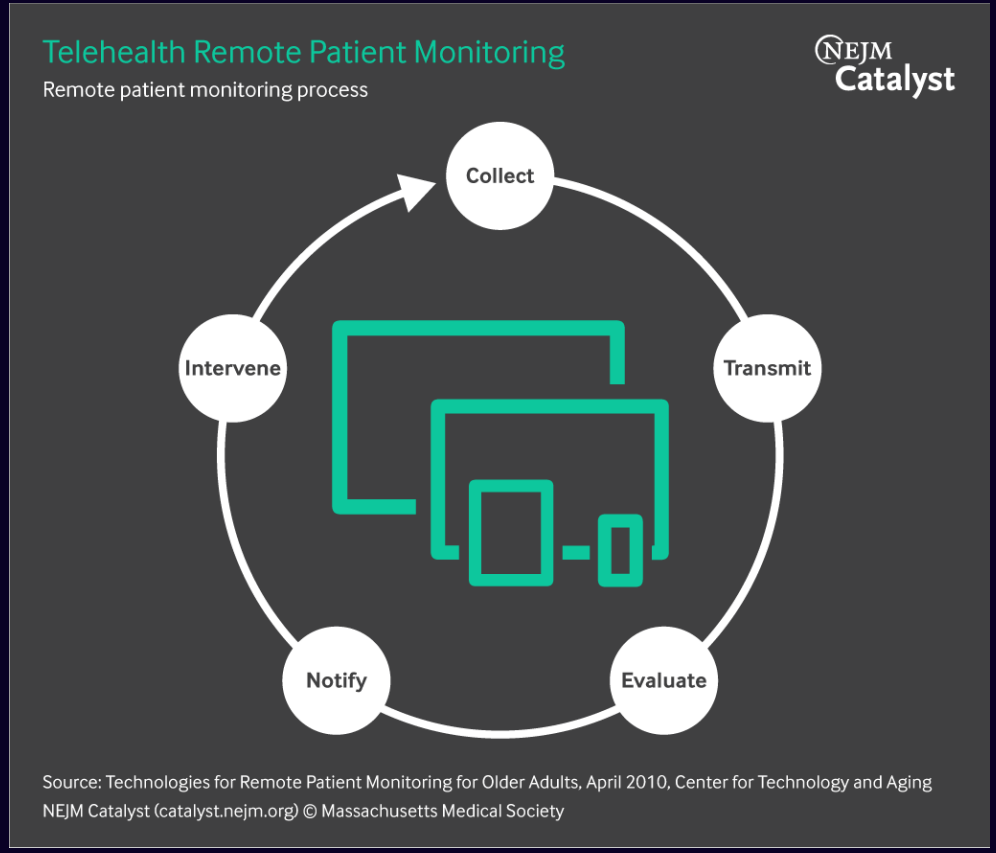
Principles for evaluating the clinical implementation of novel digital healthcare devices, JKMA (2018)

(4) Telemedicine

- What is telemedicine?
  - The remote diagnosis and treatment of patients by means of tele-communications technology

- Telemedicine encompasses the use of technologies and tele-communication systems to administer healthcare to patients who are geographically separated from providers

- Tele-monitoring ~ Tele-surgery



What is telehealth?, NEJM (2018)

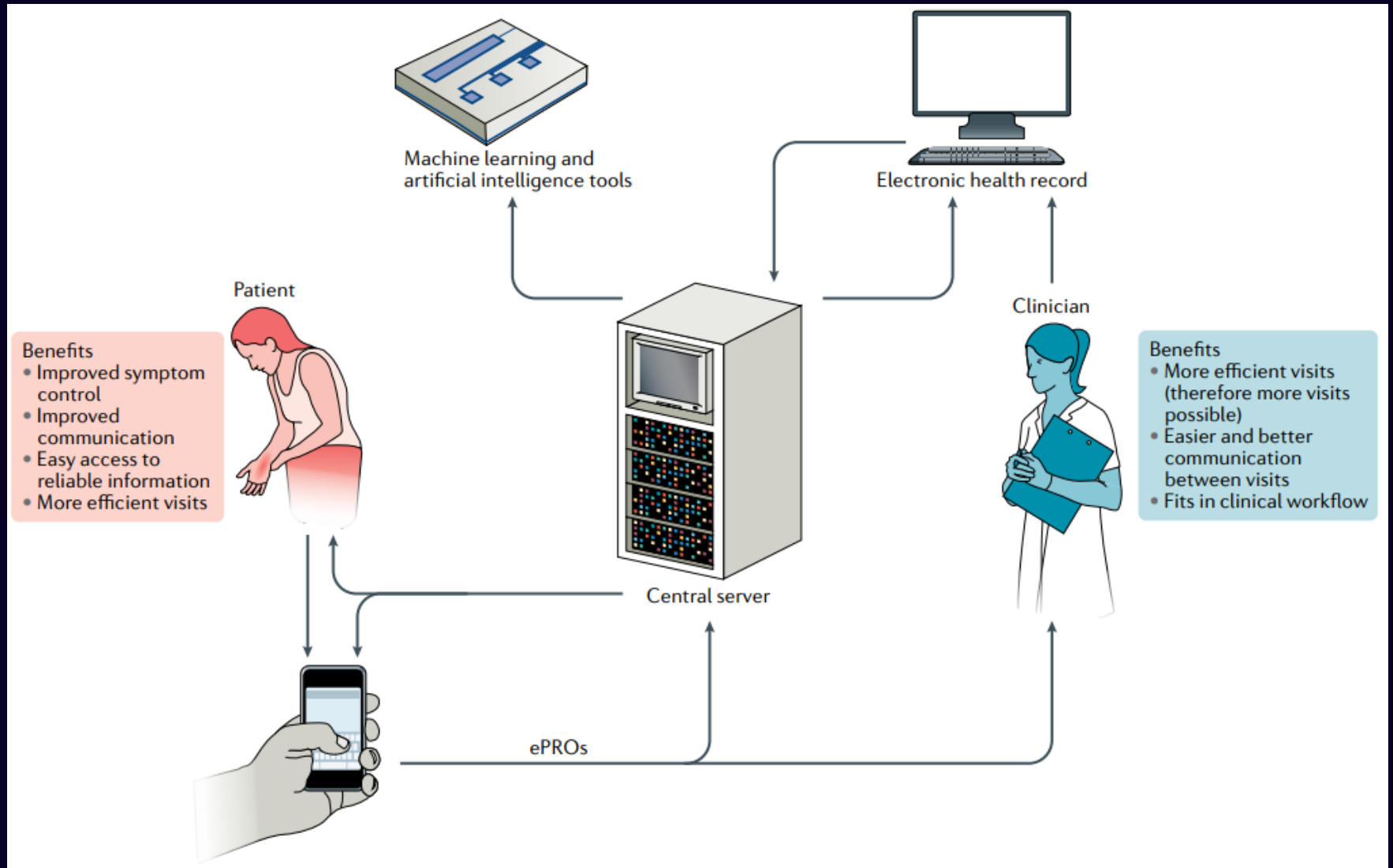


Fig. 2 | **Integrated system of digital health technologies in a possible future rheumatology clinic.** Patients will use smartphone apps with or without voice-enabling capacity to report symptoms to their clinicians. Their symptoms may be reported as electronic patient-reported outcomes (ePROs) through the electronic health record (EHR). The information from the EHR and other data sources will be integrated in a centralized and secure server environment. Machine learning and artificial intelligence algorithms will be running against the data to assist clinicians with diagnosis, prognosis, treatment selection and monitoring.

Digital health technologies: opportunities and challenges in rheumatology, Nature reviews Rheumatology (2020)

「한시적 비대면 진료 허용방안」 안내

○ 코로나바이러스감염증-19 중앙사고수습본부-32695(2020.12.14)호와 관련, 「감염병의 예방 및 관리에 관한 법률」(국무회의 의결, 12.8) 및 2020년 제4차 감염병관리위원회 심의·의결에 따라, 코로나19 감염병 위기대응 심각단계시 「한시적 비대면 진료 허용방안」을 마련하고, 붙임과 같이 공고합니다.

◈ '**코로나19 감염병 위기대응 심각단계**의 위기경보 발령 **기간**' 동안

○ **의사의 판단**에 따라 **안전성 확보가 가능한 경우 환자**가 의료기관을 직접 방문하지 않고도 **비대면 진료**를 받을 수 있도록 **한시적으로 허용**

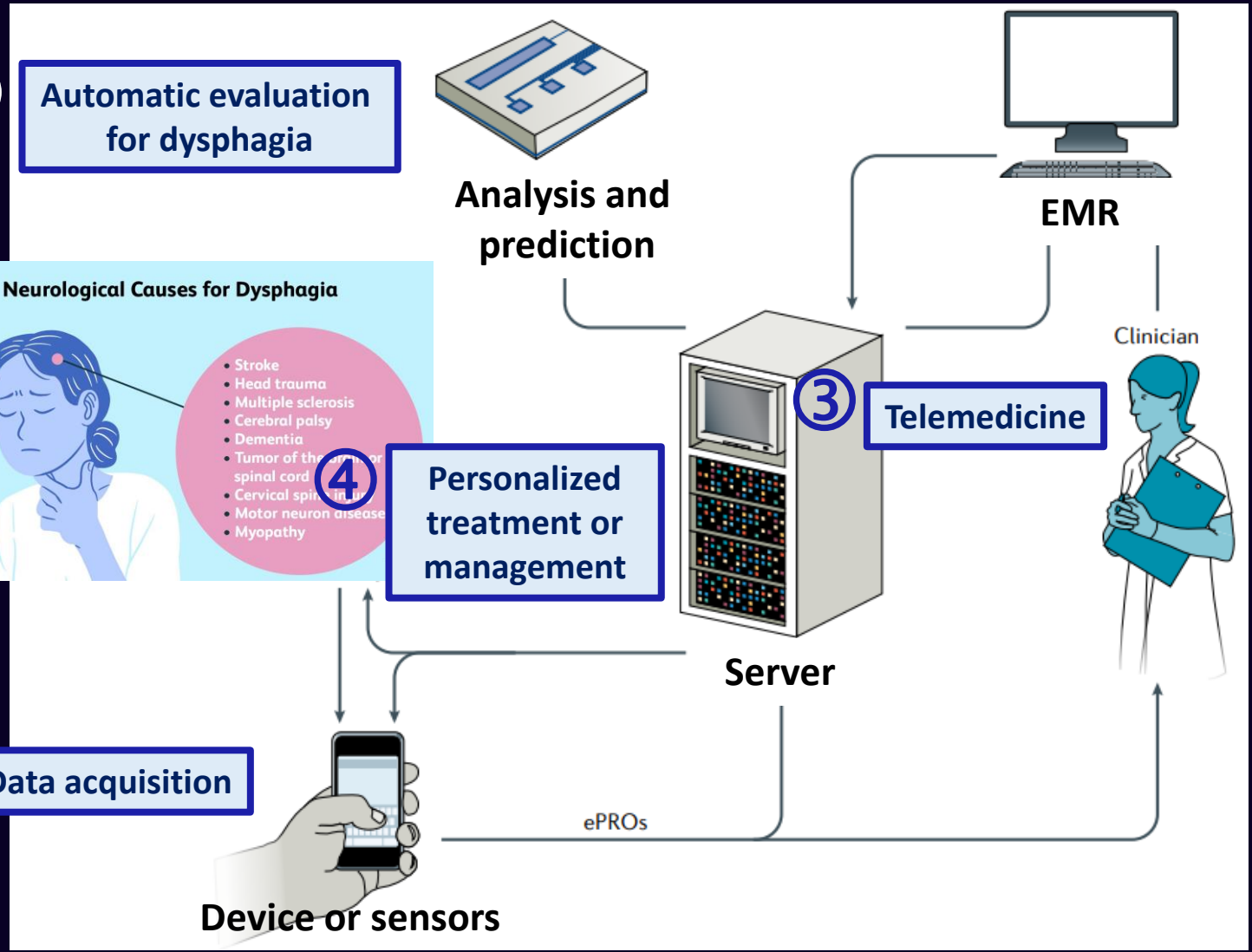
◇ **(적용 기간) 코로나 19 감염병 위기대응 심각 단계**의 위기경보 발령 **기간**(「감염병의 예방 및 관리에 관한 법률」 제49조의3 공포 시행일('20.12.15)부터 적용)

◇ **(적용 범위) 유·무선 전화, 화상통신**을 활용한 **상담 및 처방**

* 진료의 질을 보장하기 위하여 문자메시지, 메신저만을 이용한 진료는 불가

[보건복지부 공고 제2020-889호]

Digital health in dysphagia



Image(VFSS) + Machine learning

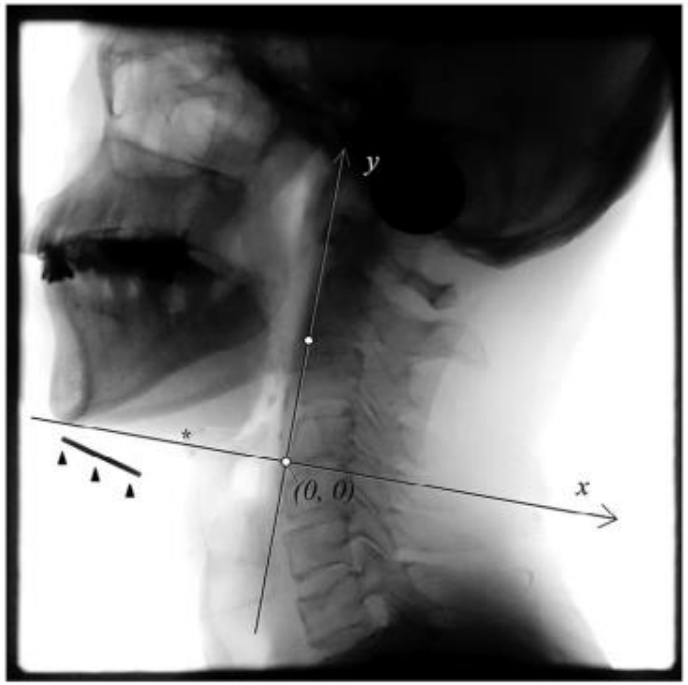
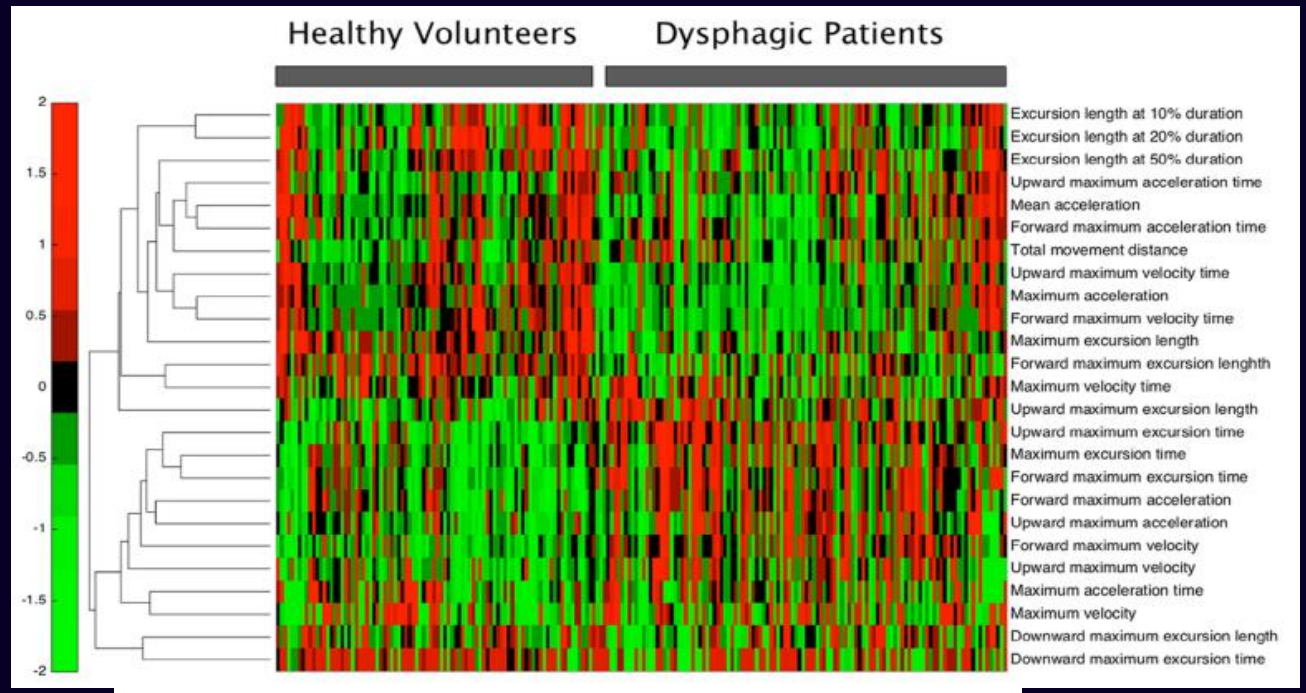
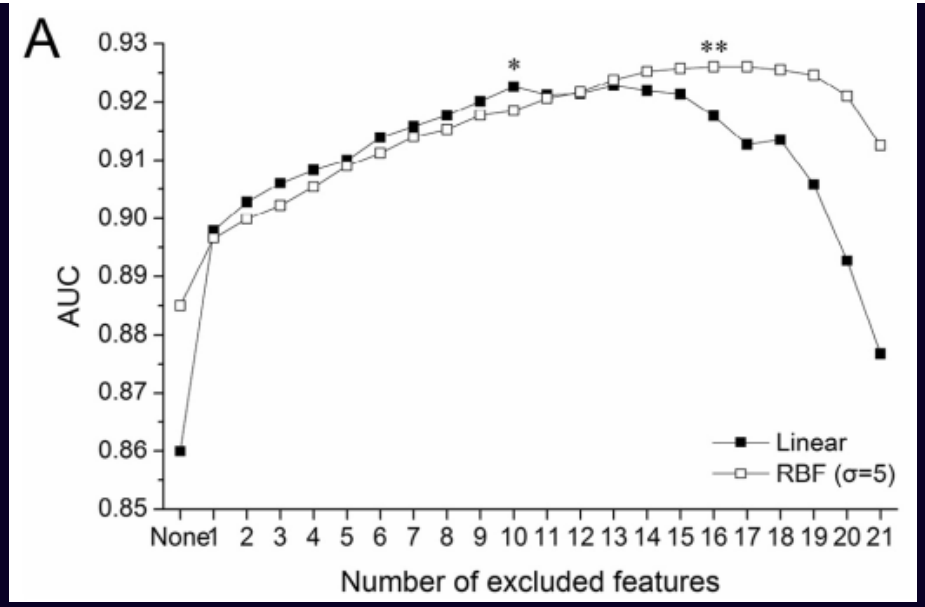


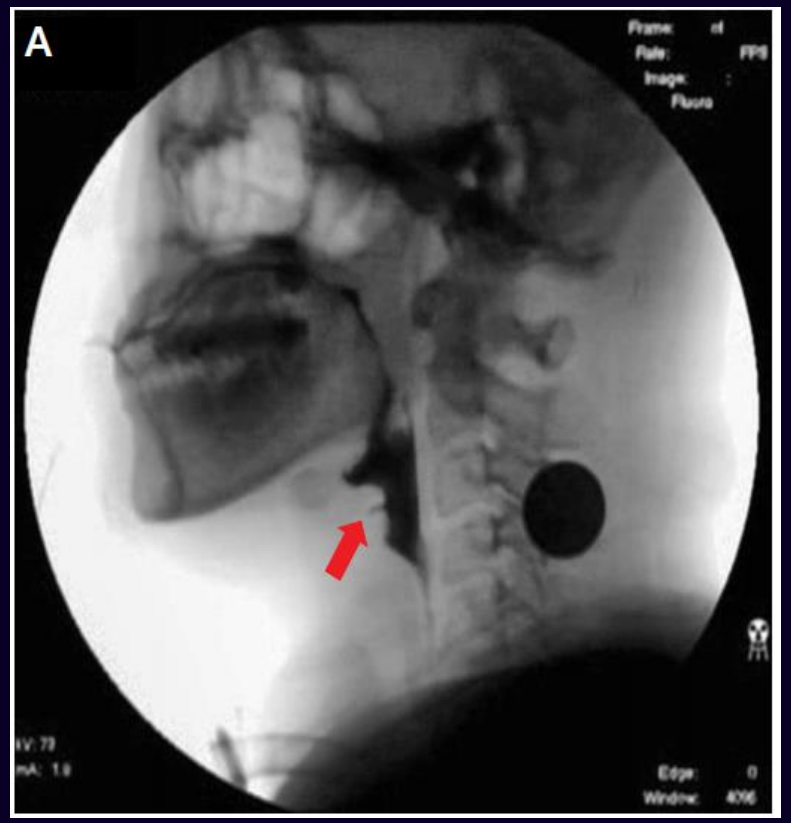
Fig. 2 – The axes for kinematic analysis of videofluoroscopic images. The Y-axis was set to a line connecting the anterior edges of C4 and C2 lower endplates, and then a line perpendicular to the Y-axis at C4's lower endplate constitutes the X-axis. A radio-opaque disc was attached under the chin (arrowheads) to measure distance of movement. Asterisk (*) indicates the anterosuperior end of hyoid bone.





Computer-assisted detection of swallowing difficulty, Comput Methods Programs Biomed (2016)

Image (VFSS) + Machine learning



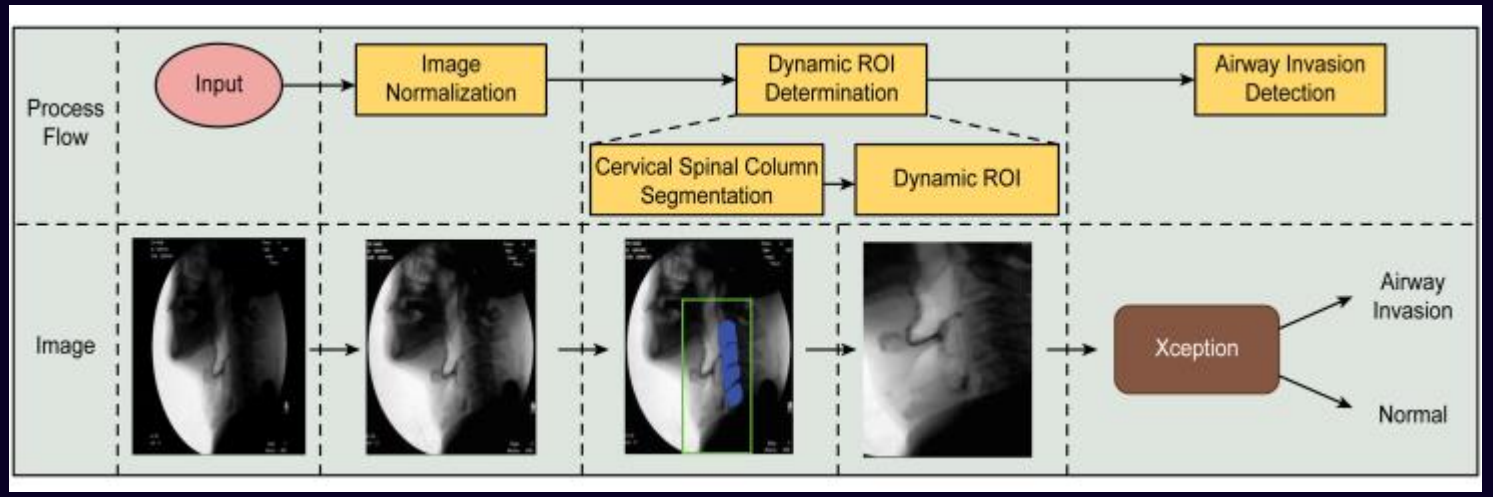


Table 3. Performance per frame for classifying airway invasion.

Accuracy	Recall	Precision	Specificity	NPV	F1-Score
97.2%	74.2%	59.1%	98.0%	99.0%	0.658

Table 4. Performance for classifying complete videos containing image frames with airway invasion.

Accuracy	Recall	Precision	Specificity	NPV
93.2% (167/179)	91.2% (52/57)	88.1% (52/59)	94.2% (115/122)	95.8% (115/120)

Automatic Detection of Airway Invasion from Videofluoroscopy via Deep Learning Technology, Applied sciences (2020)

IMU sensor (accelerometer) & microphone

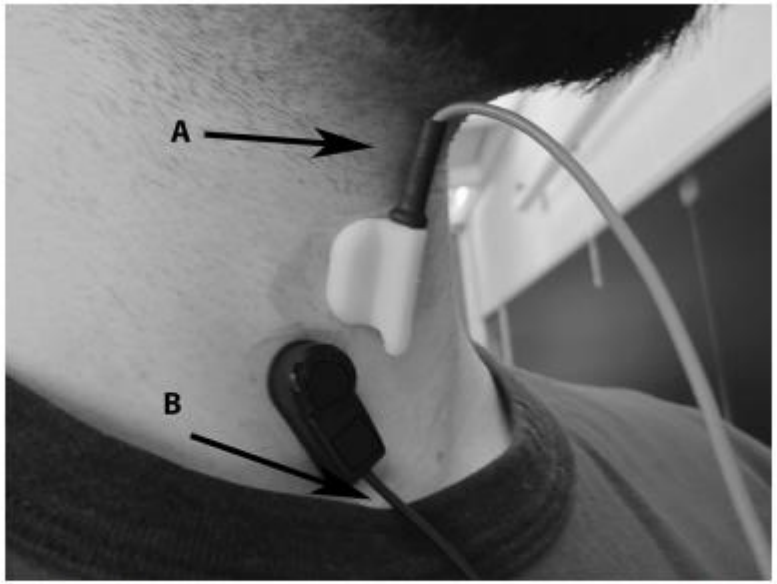


Fig. 1 Transducer mounting locations. Location of recording devices during data collection. A: Thyroid cartilage B: top of the suprasternal notch For reference, the microphone (lower device) is approximately 10 × 30 mm and the accelerometer (upper device) is aligned with the centre axis of the neck. This figure has been previously published by BioMed Central in [41]

Table 6 Statistically significant features (healthy vs non-healthy thin swallows)

Feature	A–P	S–I	Sound
Skewness	$p << 0.001$	$p << 0.001$	$p << 0.001$
Kurtosis	$p << 0.001$	$p << 0.001$	$p << 0.001$
Entropy rate	$p << 0.001$	$p << 0.001$	$p << 0.001$
L–Z complexity	$p << 0.001$	$p << 0.001$	$p << 0.001$
Peak frequency	$p << 0.001$	$p << 0.001$	$p << 0.001$
Center frequency	$p << 0.001$	$p << 0.001$	$p << 0.001$
Bandwidth	$p << 0.001$	$p << 0.001$	$p << 0.001$
Wavelet entropy	$p << 0.001$	$p << 0.001$	$p << 0.001$

Dysphagia and its efects on swallowing sounds and vibrations in adults, BioMed Eng OnLine (2018)

Microphone + Machine learning

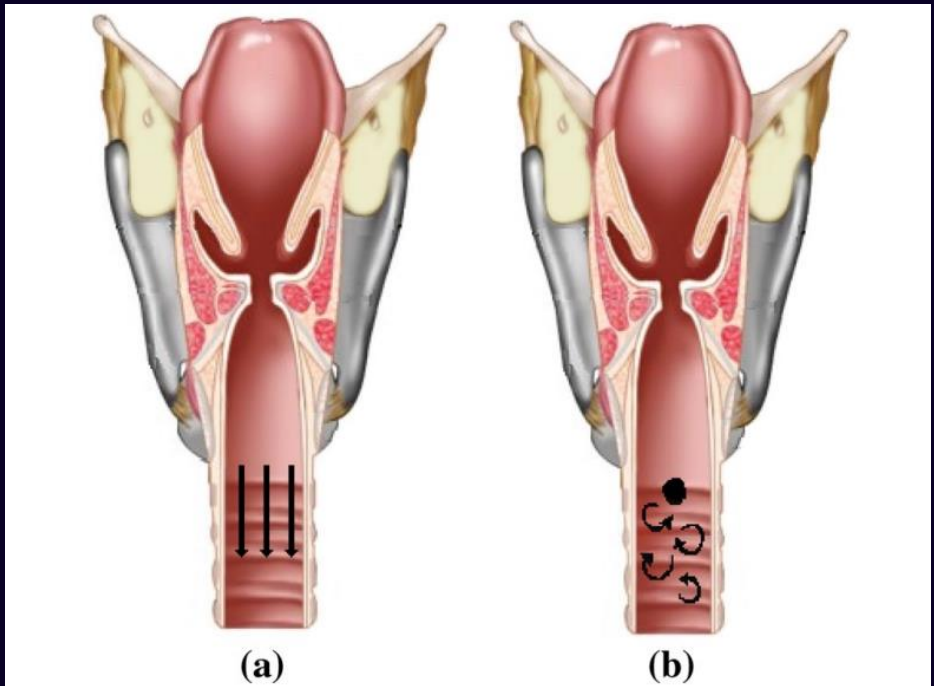
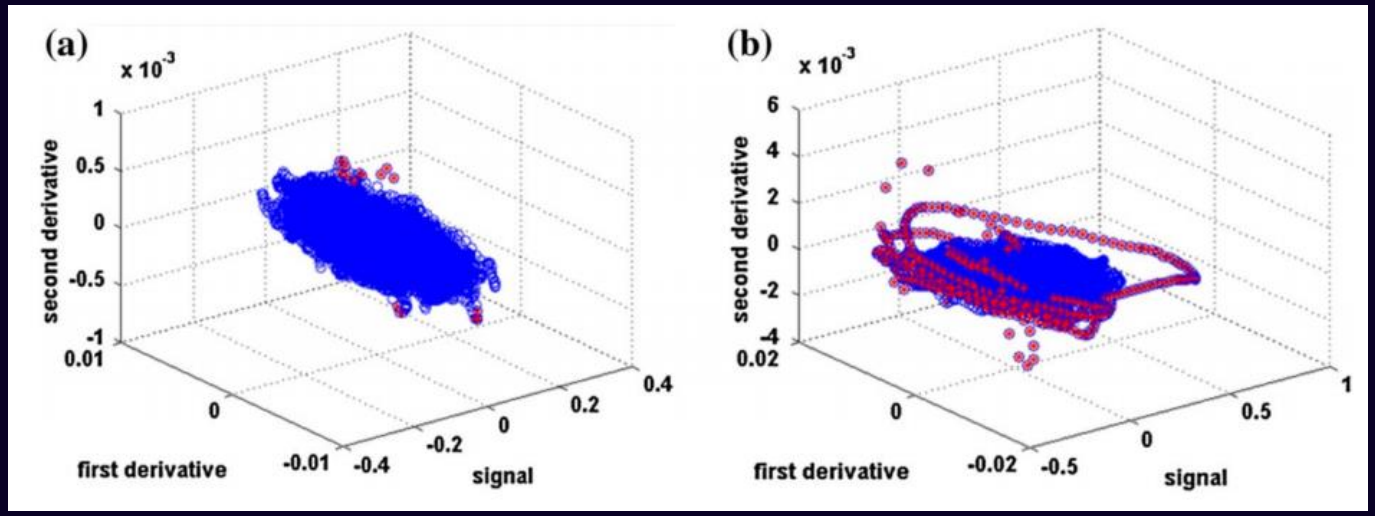
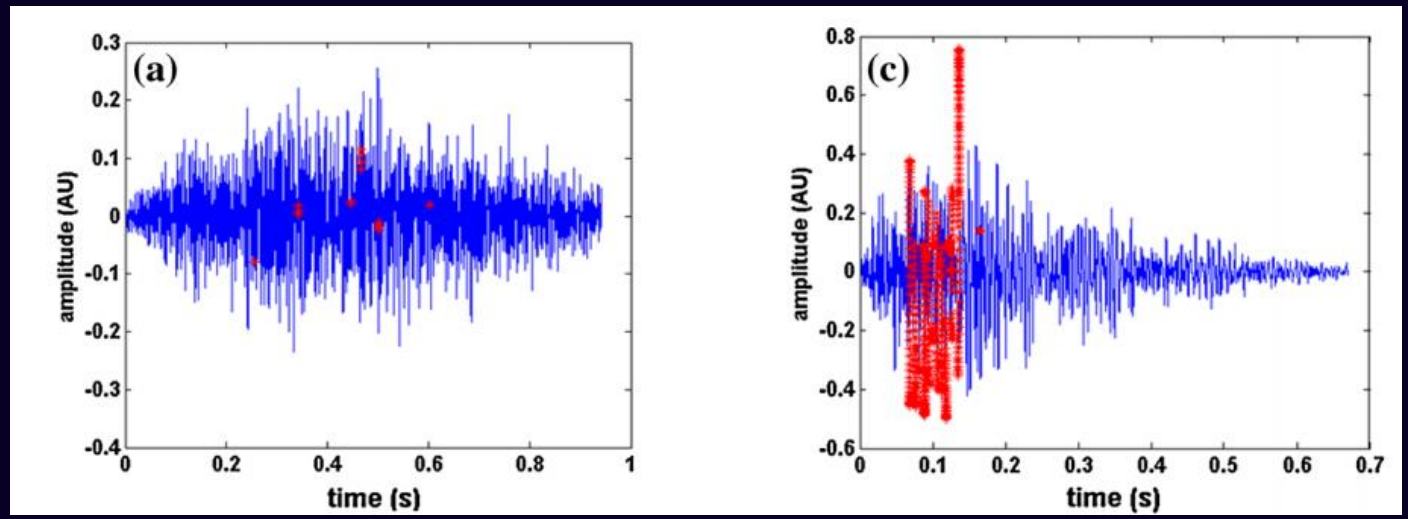


Fig. 1 The pattern of airflow in **a** a clear trachea and **b** a trachea with a food particle in it

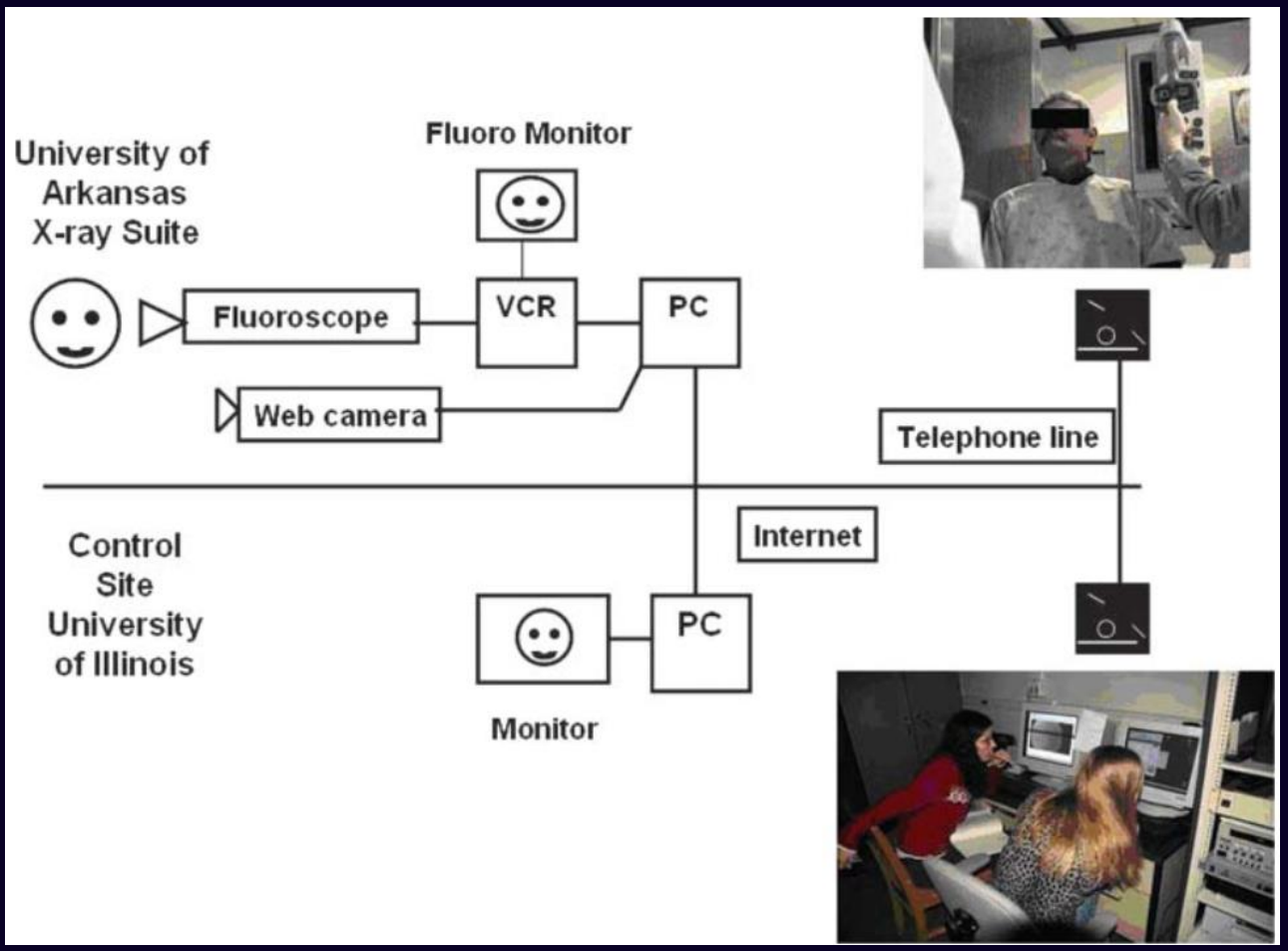




91 % sensitivity and 85 % specificity
in detection of patients with severe aspiration

Noninvasive and automatic diagnosis of patients at high risk of swallowing aspiration, Med Biol Eng Comput (2014)

Image (VFSS) + Telemedicine



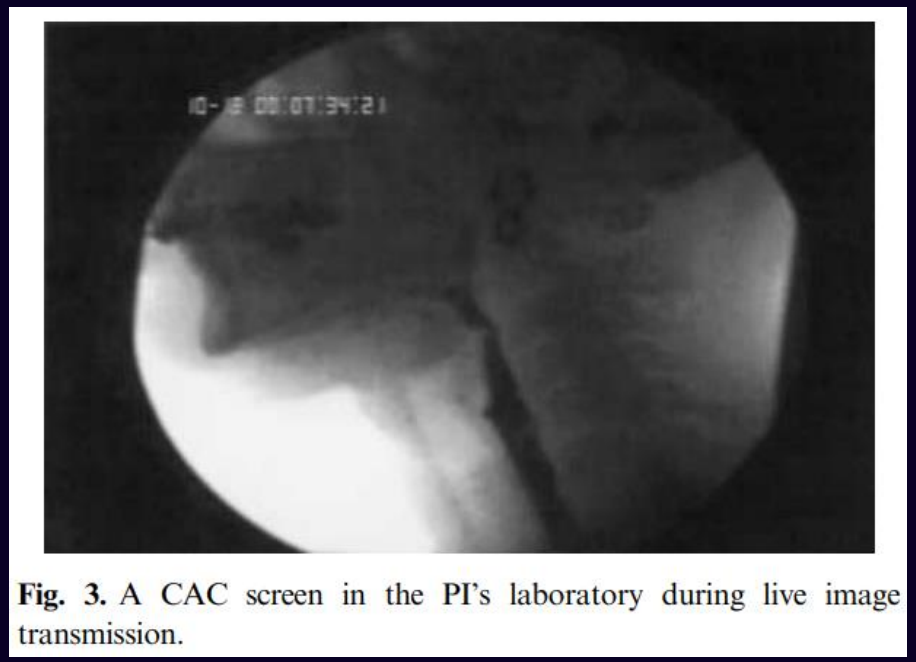


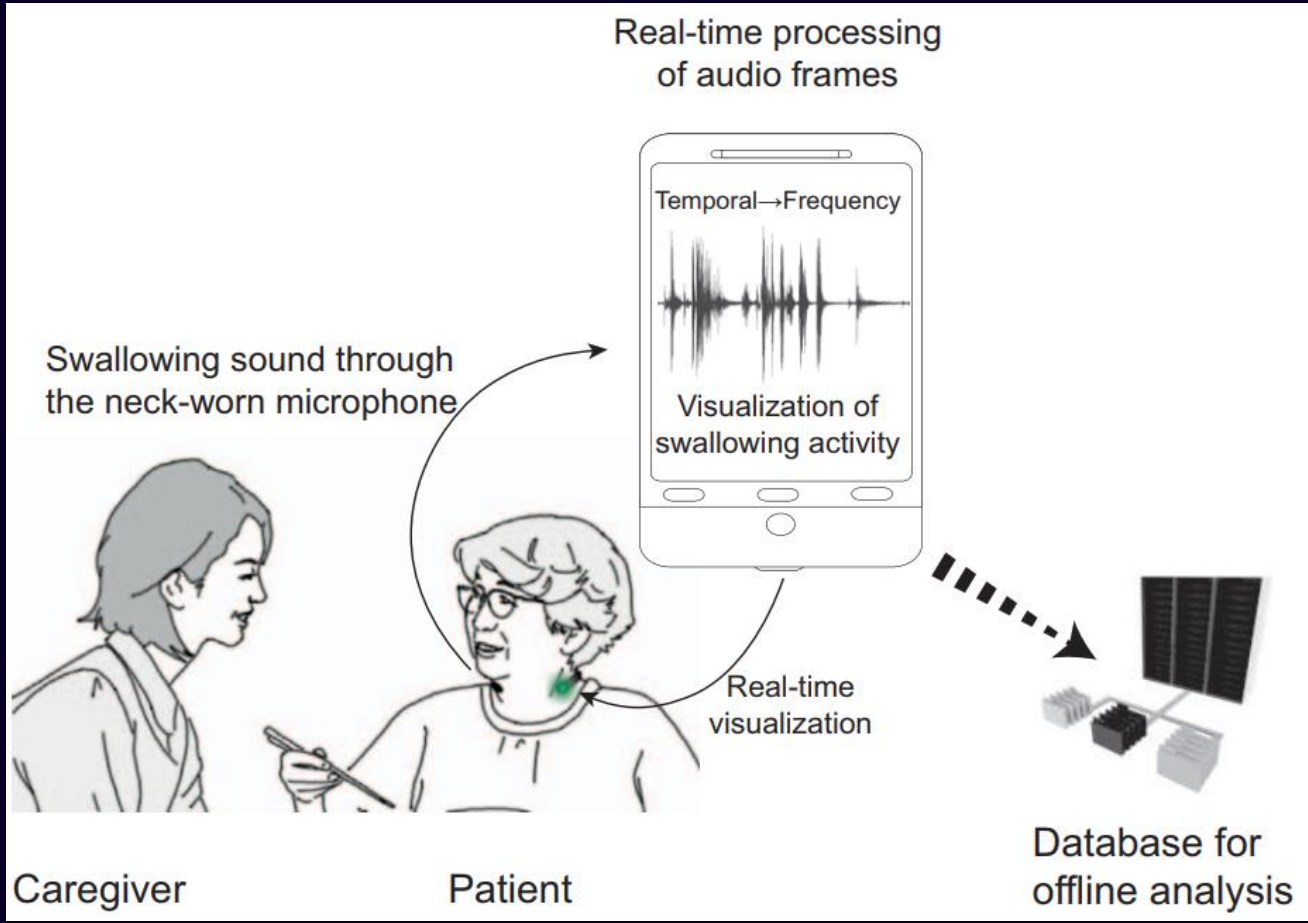
Fig. 3. A CAC screen in the PI's laboratory during live image transmission.

Table 2. Recommendation groups, number of discrepancies/disagreements, percentage of agreement, and 95% confidence intervals (CIs) for the percentage of agreement.

Recommendation group	Number of discrepancies/disagreements	% agreement	95% CI for the percentage of agreement	
			Upper bound	Lower bound
Reducing or eliminating oral intake	7/32	78.1	0.89	0.61
Altering meal habits	10/32	68.8	0.82	0.51
Medication administration method	1/32	96.9	1.00	0.84
Control bolus viscosity	6/32	81.2	0.91	0.65
Postural adjustments	5/32	84.4	0.93	0.68
Laryngeal closure maneuvers and exercises	4/32	87.5	0.95	0.72
Strengthening and ROM exercises and maneuvers	2/32	93.7	0.98	0.80
Sensory enhancement	0/32	100	1.00	0.89
Referral to physicians	6/32	81.2	0.91	0.65

Teledynamic evaluation of oropharyngeal swallowing, JSLHR (2011)

Microphone & Smartphone + Telemedicine



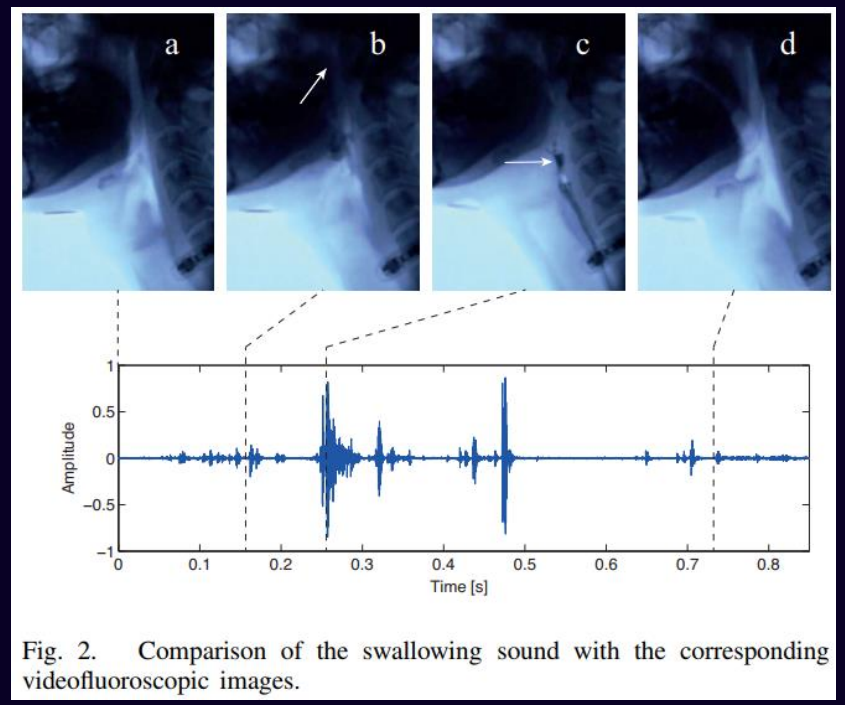
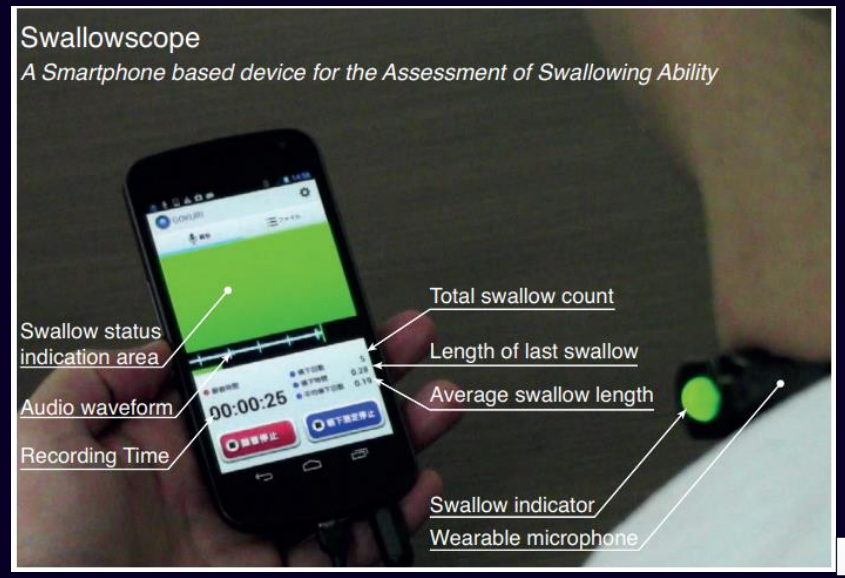


Fig. 2. Comparison of the swallowing sound with the corresponding videofluoroscopic images.



Swallowscope: A Smartphone based device for the Assessment of Swallowing Ability, IEEE-EMBS International Conference on Biomedical and Health Informatics (2014)

Image + Machine learning + Personalized treatment + Telemedicine

Action Sequence	Common Errors	System Requirement (sysreq)
		1. Detect nearby face in view of camera (determine when to initiate monitoring)
Sit in upright position	Head/trunk misaligned	2. Estimate head/trunk alignment
Sip liquid/spoon in food	Swallow before tuck	3. Track cup/utensil movement toward and into mouth.
Tuck chin to chest	Forget to perform tuck Incomplete tuck Swallow mid-tuck	4. Estimate head/angle to torso in sagittal plane
Swallow in that position	Raise head during swallow	5. Detect swallow (timing and omission errors)
Raise the head	Swallow post tuck	

Table 1. Chin Tuck Actions and Errors

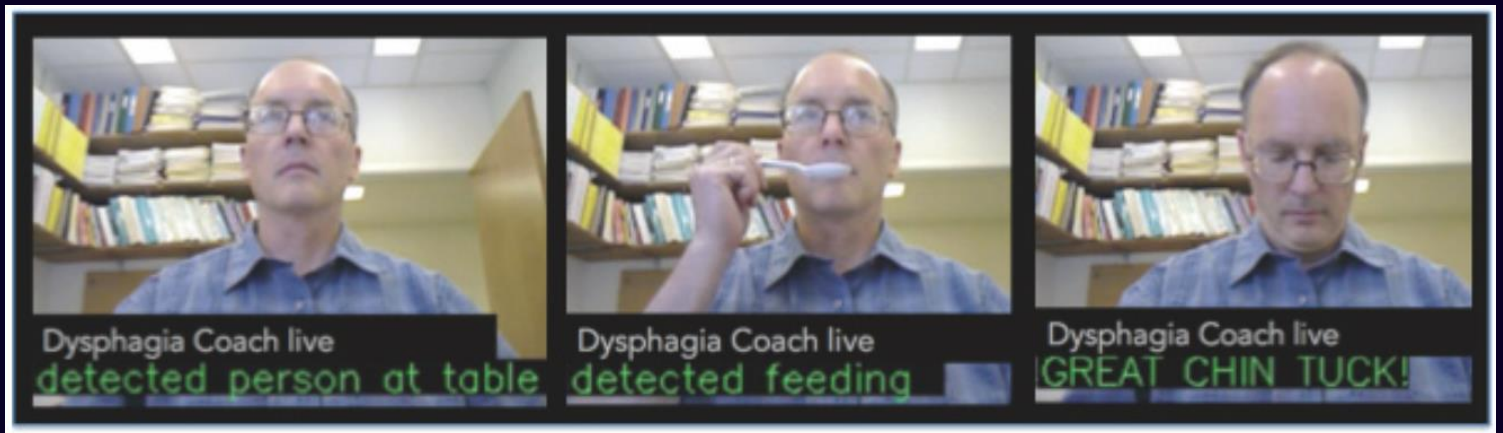
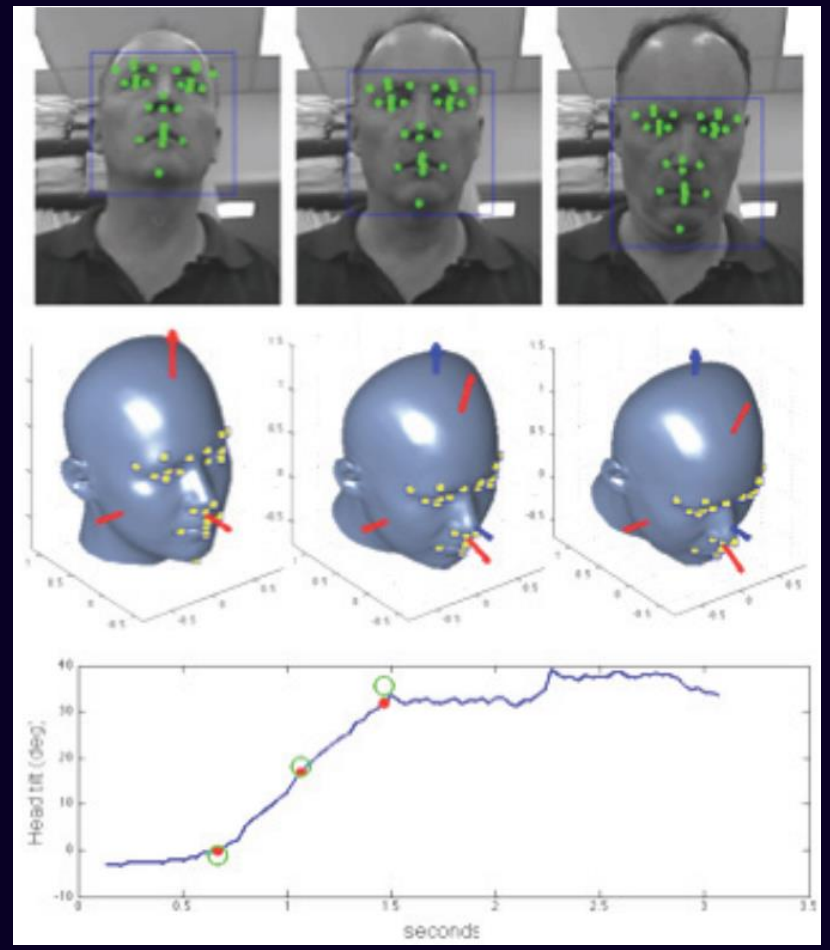


Figure 1. Dysphagia Coach prototype showing detection of user and feedback on a chin tuck maneuver.



A Prototype Intelligent Assistant to Help Dysphagia Patients Eat Safely At Home, AAAI Conference on Artificial Intelligence (2016)

Image + Personalized treatment + Telemedicine

Lee Silverman Voice Treatment (LSVT)

REPORTED SPEECH CHANGES [23]	REPORTED PHYSIOLOGICAL CHANGES [23]	REPORTED & HYPOTHESED SWALLOW/COUGH CHANGES
Articulatory precision	Articulatory movements	Lingual function [28]
Speech intelligibility		
	Vocal tract configuration	Tongue base strength [28]
Prosodic inflection		
Resonance	Laryngeal & supralaryngeal movements	Pharyngeal timing & strength [28,50*]
Voice quality	Vocal fold adduction Laryngeal muscle activity & synergy	Airway closure [28,50*]
Loudness	Respiratory drive	Expiratory cough [47-50*]

*Changes seen with forced expiratory exercises (EMST)

Web camera

Face-to-face interaction

LSVT education
Personal relationship
Homework tasks

A clinician certified in LSVT

Delivering the Lee Silverman Voice Treatment (LSVT) by web camera: A feasibility study, International Journal of Language & Communication Disorders (2008)

Personalized management + Machine learning

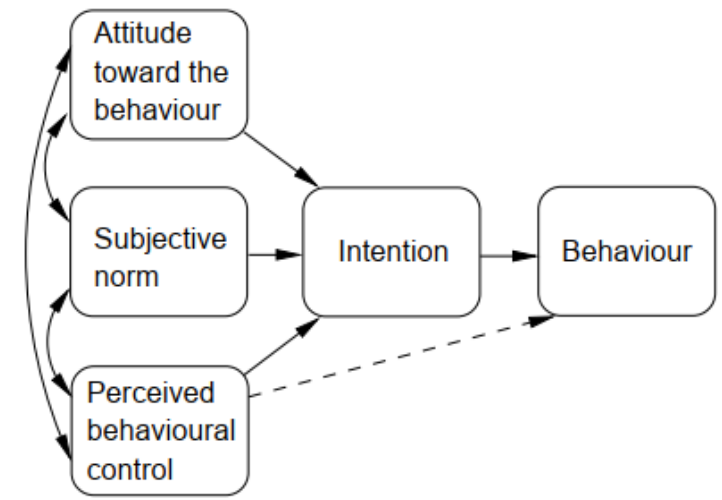


Figure 1: Theory of planned behaviour

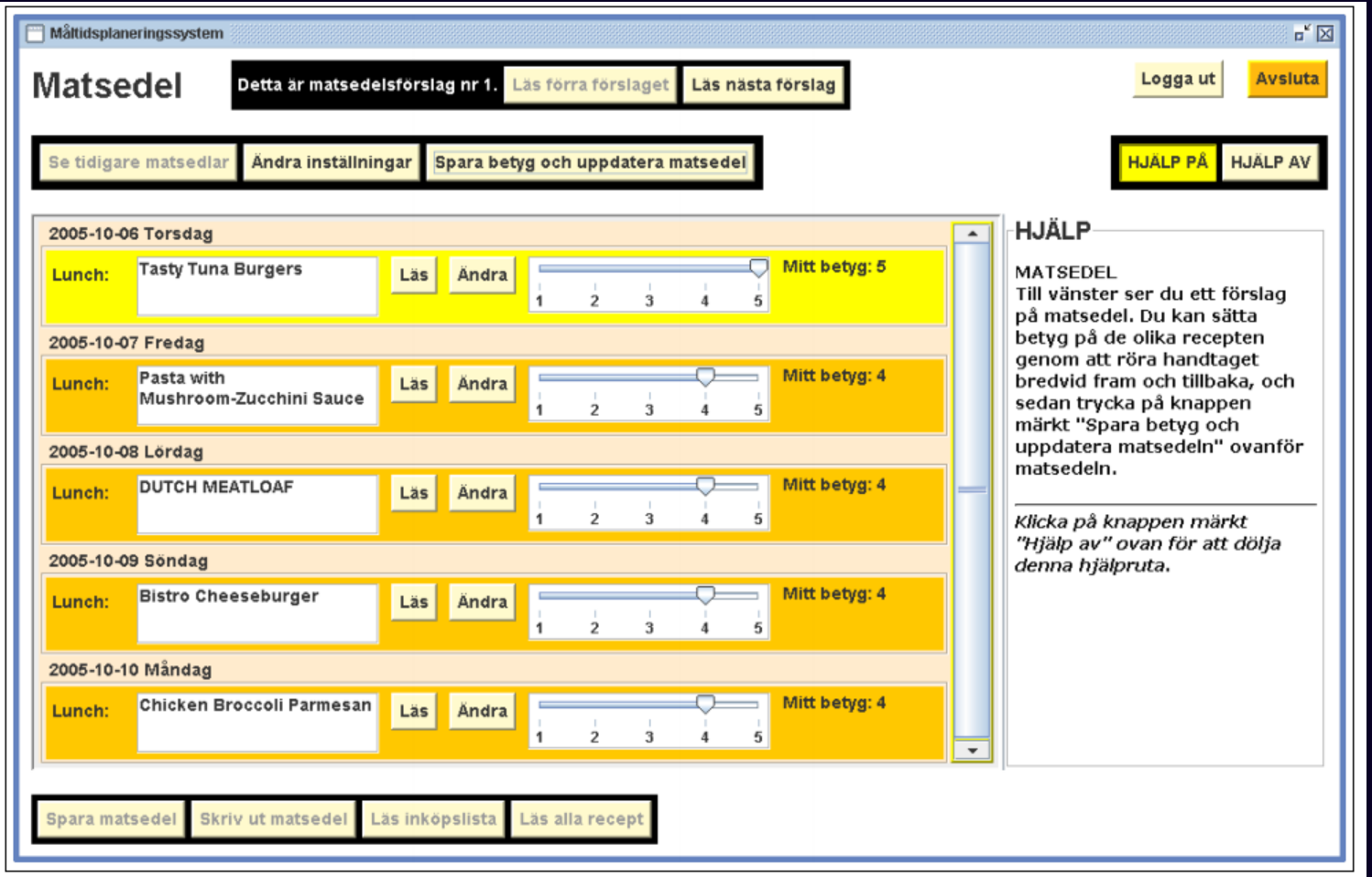


Figure 3: Meal planning system output: a recommended meal plan

Dealing with Malnutrition: A Meal Planning System for Elderly, AAAI (2006)

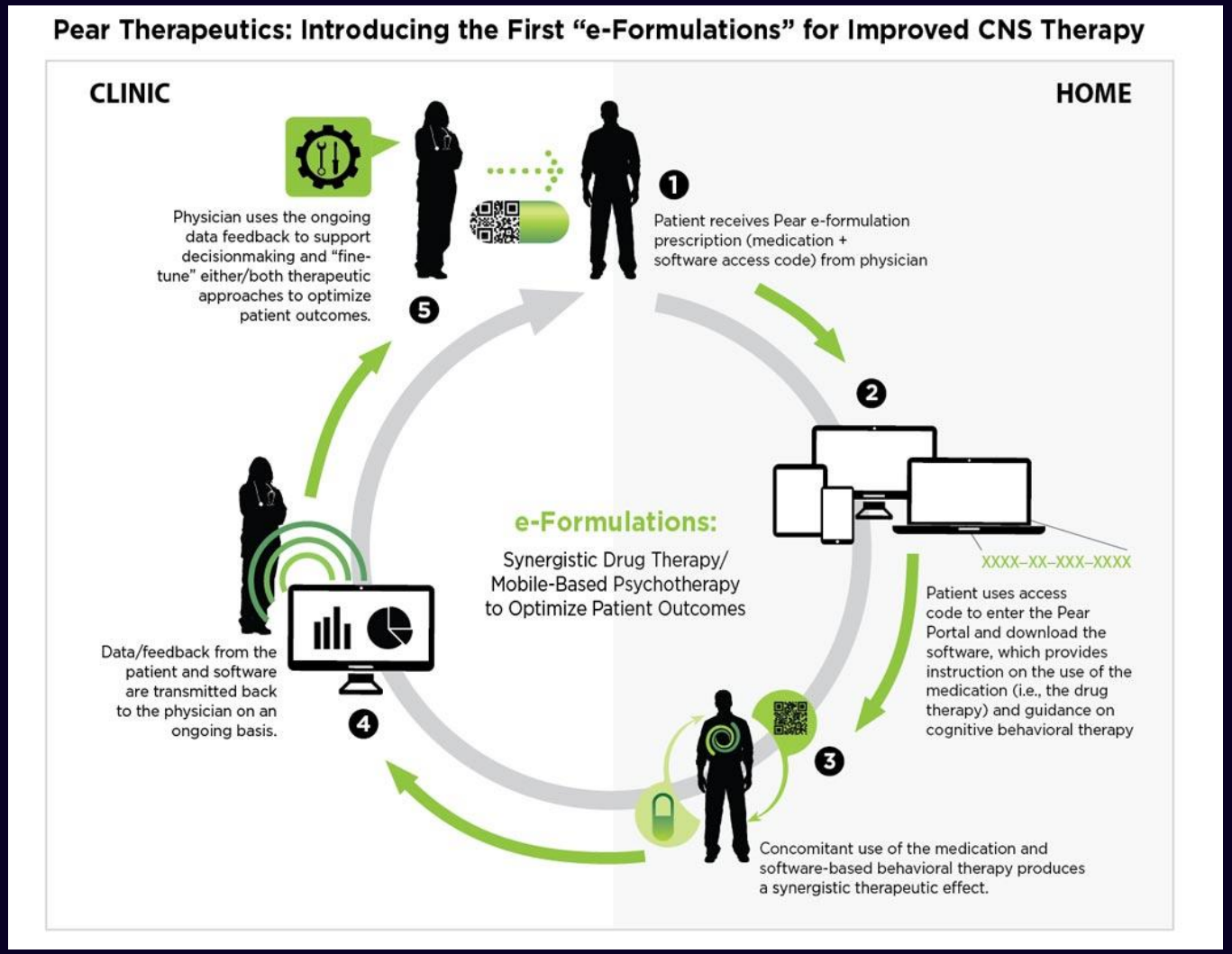
Wellness device vs. Medical device

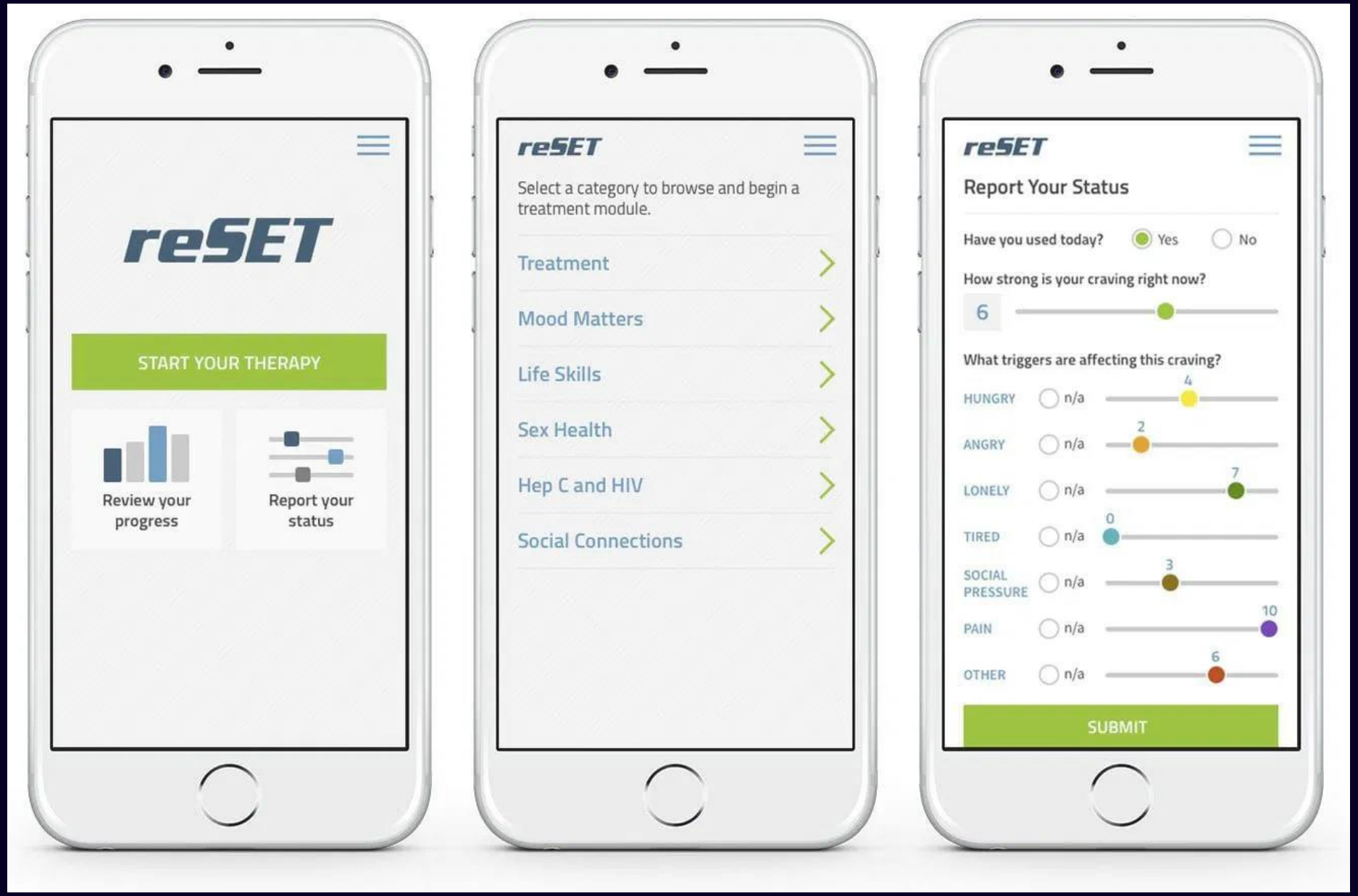
- **Wellness device**
  - 일상적 건강관리용
  - 만성질환자 건강관리용

- **Medical device**
  - 질병을 진단, 치료, 경감, 처치 또는 예방할 목적으로 사용하는 제품
  - 상해 또는 장애를 진단, 치료, 경감 또는 보정할 목적으로 사용하는 제품
  - 구조 또는 기능을 검사 대체 또는 변형할 목적으로 사용하는 제품
  - 임신을 조절할 목적으로 사용하는 제품

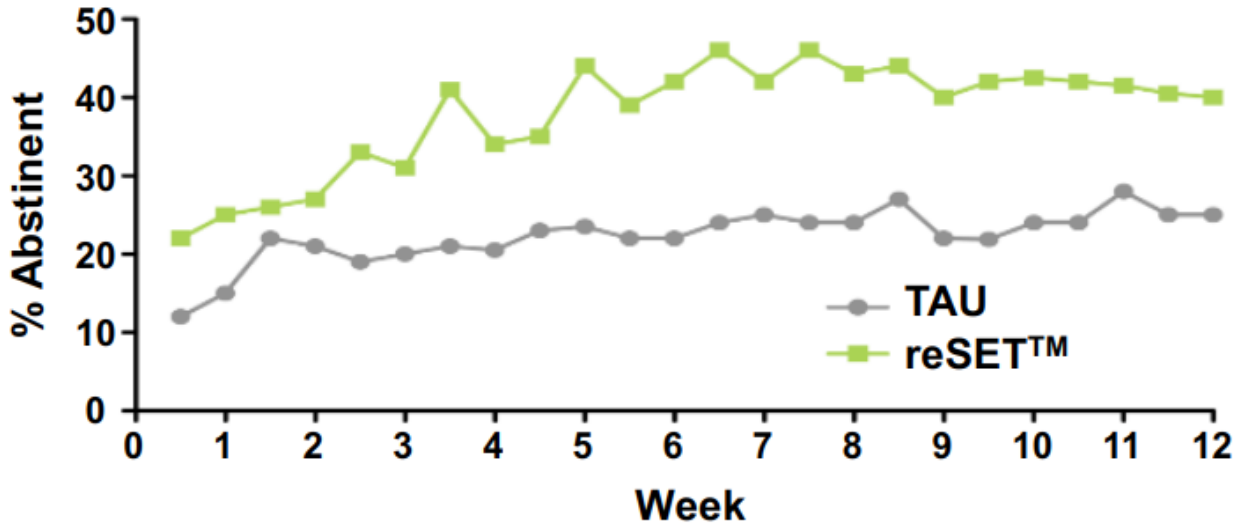
의료기기와 개인용 건강관리 웰니스 제품 판단기준 (2020)

Digital therapeutics




reSET
START YOUR THERAPY
Review your progress
Report your status
reSET
Select a category to browse and begin a treatment module.
Treatment
Mood Matters
Life Skills
Sex Health
Hep C and HIV
Social Connections
reSET
Report Your Status
Have you used today?
Yes
No
How strong is your craving right now?
6
What triggers are affecting this craving?
HUNGRY
n/a
4
ANGRY
n/a
2
LONELY
n/a
7
TIRED
n/a
0
SOCIAL PRESSURE
n/a
3
PAIN
n/a
10
OTHER
n/a
6
SUBMIT

507 patients with Substance Use Disorder at 10 nationwide treatment centers were randomized to 12 weeks of typical outpatient treatment (TAU) vs reSET® with limited clinician exposure and abstinence was measured through urine analysis and self reports[1]



Population	Time Point	reSET® (n=255)	TAU (n=252)	Odds Ratio (95% CI)	P-value*
All comers	Week 9-12	**29.7%**	**16.0%**	2.22 (1.24, 3.99)	0.0076
Non-abstinent at start	Week 9-12	**10.1%**	**3.0%**	3.59 (1.36, 9.48)	0.0099

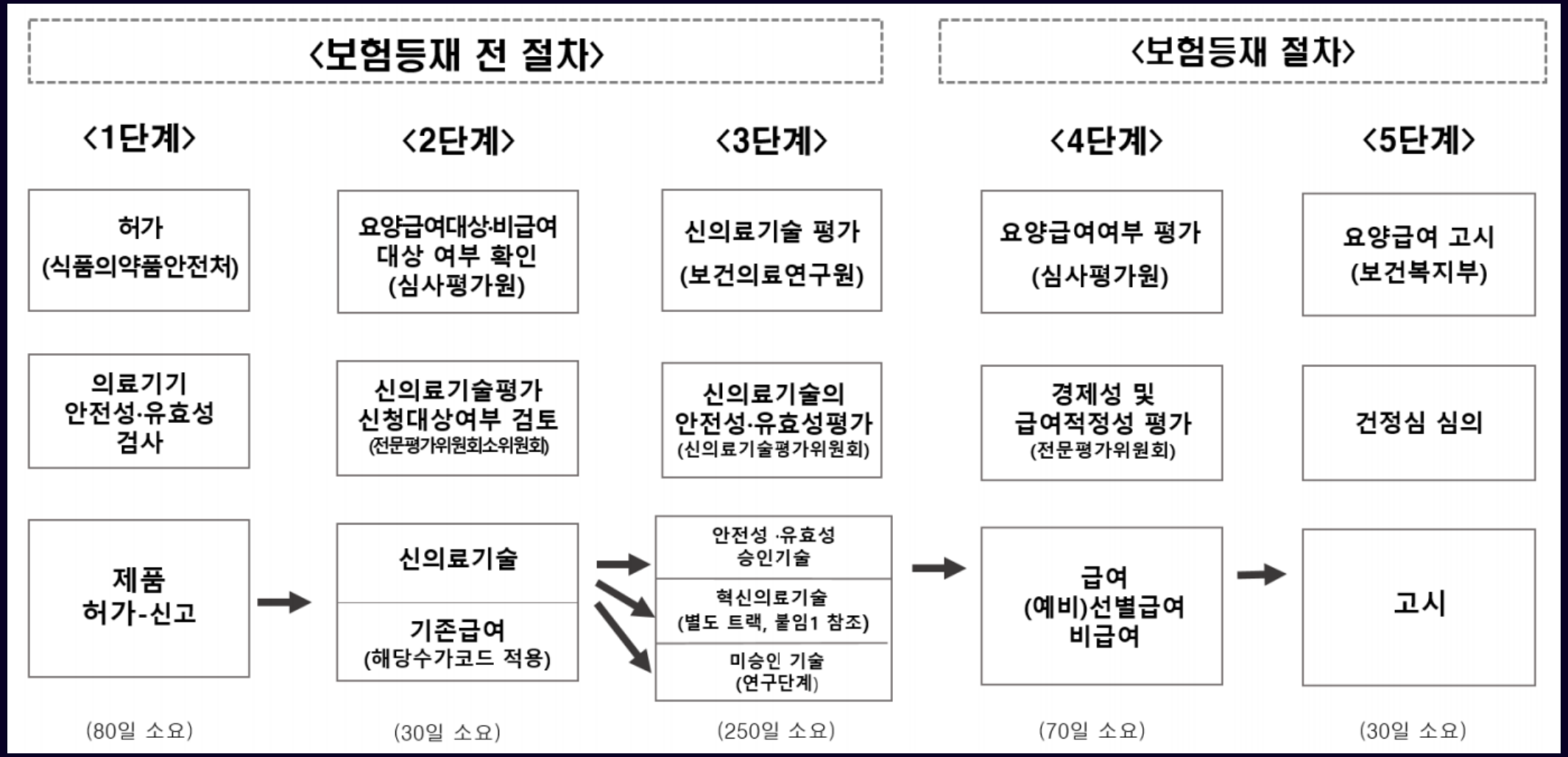
[1] Campbell et al. Am J Psychiatry. 2014.

Table 1. Sampling the Digital Therapeutics Pipeline.

Company	Product	Indication(s)	Status	Commercial partner	Investment partner
Pear Therapeutics	reSET	Substance use disorder[25,26]	Marketed	Sandoz[a][27]	Novartis
	reSET-O	Opioid use disorder[28]	Marketed	Sandoz[a]	
	Somryst	Chronic insomnia[29]	Marketed		
	Pear-004	Schizophrenia	Marketed[b] Pivotal		
	Pear-006	Multiple sclerosis	Discovery	Novartis[30]	
	Unspecified	Gastrointestinal conditions	Discovery	Ironwood Pharmaceuticals[31]	
Welldoc	Bluestar	Type I diabetes, Type II diabetes[32]	Marketed	Astellas[33]	
Akili Interactive	Endeavor	ADHD[34]	Marketed	Shionogi[35]	Amgen, Merck
	AKL-T02	Autism spectrum disorder[36]	Pilot		
	AKL-T03	Major depressive disorder	Pilot		
Nightware	Nightware	Post-traumatic stress disorder	Marketed		
Click Therapeutics	CT-152	Major depressive disorder	Pivotal	Otsuka[37]	Sanofi, Hikma
Cognoa	Autism Diagnostic	Autism spectrum disorder	Pivotal	EVERSANA	
	Autism Therapeutic	Autism spectrum disorder[38]	Feasibility		
Biofourmis	BiovitalsHF V1	Heart failure	Marketed	Novartis[39]	
	BiovitalsHF V2	Heart failure[40]	Pivotal		
	BF140	Pain[41]	Pilot	Chugai[42]	
Propeller Health	Propeller	Asthma[43], chronic obstructive pulmonary disease[44]	Marketed	AstraZeneca[45], GlaxoSmithKline, Novartis, Orion, Boehringer Ingelheim	
AppliedVR	EaseVRx	Chronic pain[46]	Efficacy		
	RelieVRx	Acute postoperative pain[47]	Efficacy		
	AnxietyVRx	Generalized anxiety	Discovery		
Happify Health	Happify	Multiple sclerosis-associated depression and anxiety	Discovery	Sanofi[48]	

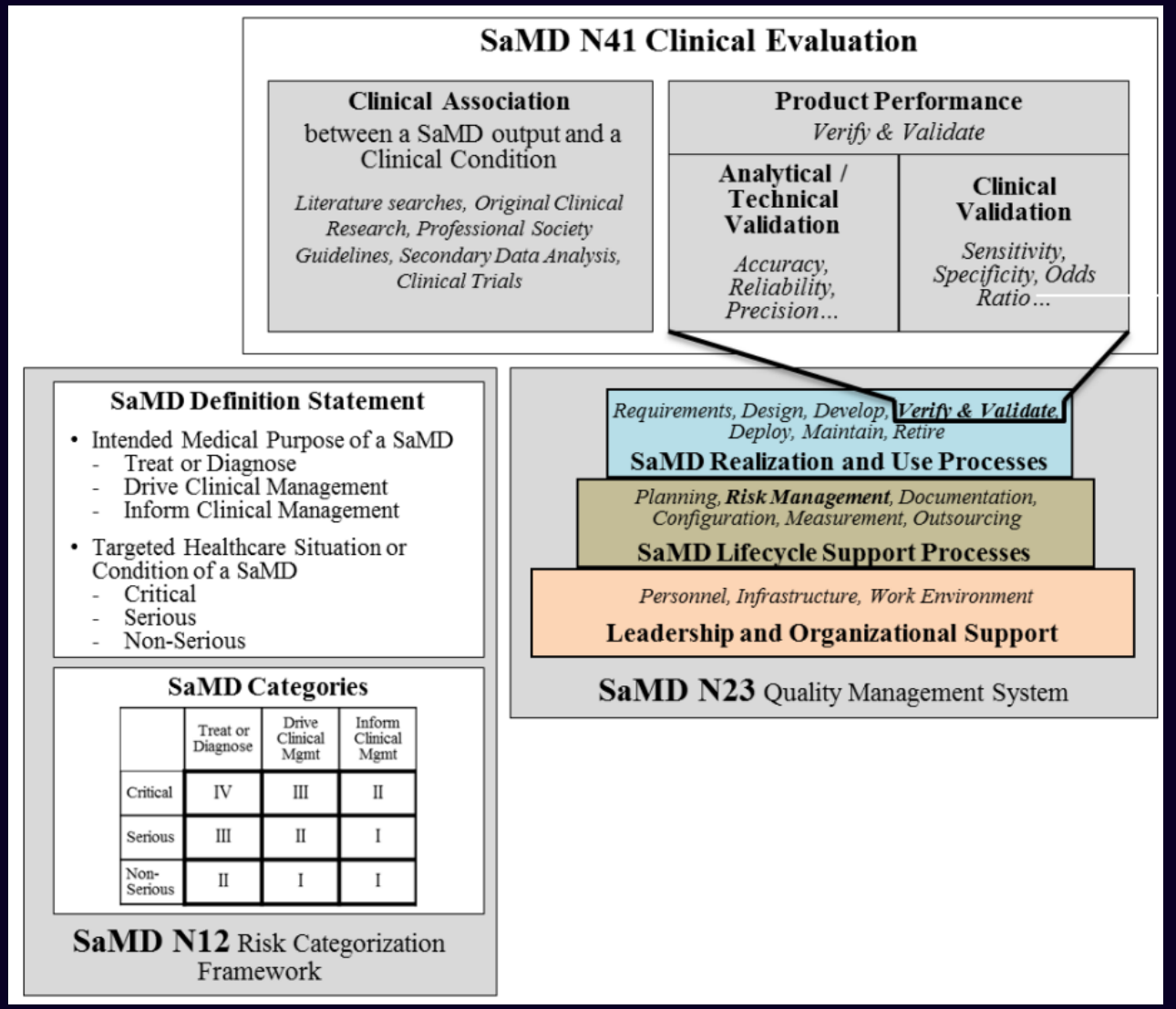
As of November 2020.
[a]Dissolved partnership.
[b]Marketed temporarily under the FDA Enforcement Policy for Digital Health Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

Process for evaluating a novel health technology



혁신적 의료기술의 요양급여 여부 평가 가이드라인 (2019)

Clinical evaluation



Software as a Medical Device (SaMD): Clinical Evaluation (2017)

Regulation


혈압
혈압을 측정하려면, 측정 버튼을 누르세요.
측정
50%
움직이거나 말하지 마세요.
이완기
119 / 77 mmHg
79 bpm
측정 결과에 따라 복용 중인 약이나 약의 용량을 임의로 변경하지 마세요. 약 복용에 대한


NEOFECT

Regulation

제34조(원격의료)

- ①의료인(의료업에 종사하는 의사・치과의사・한의사만 해당한다)은 제33조제1항에도 불구하고 컴퓨터・화상통신 등 정보통신기술을 활용하여 **먼 곳에 있는 의료인에게 의료지식이나 기술을 지원하는 원격의료(이하 "원격의료"라 한다)**를 할 수 있다.
- ㉡원격의료를 행하거나 받으려는 자는 보건복지부령으로 정하는 시설과 장비를 갖추어야 한다. <개정 2008. 2. 29., 2010. 1. 18.>
- ㉢원격의료를 하는 자(이하 "원격지의사"라 한다)는 환자를 직접 대면하여 진료하는 경우와 같은 책임을 진다.
- ④원격지의사의 원격의료에 따라 의료행위를 한 의료인이 의사・치과의사 또는 한의사(이하 "현지의사"라 한다)인 경우에는 그 의료행위에 대하여 원격지의사의 과실을 인정할 만한 명백한 근거가 없으면 환자에 대한 책임은 제3항에도 불구하고 현지의사에게 있는 것으로 본다.

Summary

- Spectrum of digital health
  - Digital health – medicine – therapeutics
- Categories of digital health
  - Data
  - Sensors
  - IT (mobile)
  - Personalized care
  - Telehealth
- Digital medicine in dysphagia
  - No commercial services
  - Usually focused on component technologies
  - Automatic evaluation based on ML
  - Data acquisition with wearable sensors
  - Telemedicine (mobile IT)
  - Personalized medicine
- Issues

Thank you