

### Prof. Katarzyna Wac 2021









Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra









### **Relevant Financial Relationships**

Novartis, Merck Group, Lundbeck

Google, Samsung, Quantac, HealBe, Amazfit / Huami, Withings, Intel, MigraineBuddy, AARDEX Group, Orchestral Networks, Acaster Lloyd Cons.

### Off-Label Investigational Uses NONE

### The Small Picture



### A Patient (female, 69)

Type 2 Diabetes (1992) Heart attack (2014) Hip fracture & replacement (2016)

Loves cooking Much (too much) food (carbs)



### Not the Only One





Naghavi, M., Abajobir, A. A., Abbafati, C., Abbas, K. M., Abd-Allah, F., Abera, S. F., ... & Ahmadi, A. (2017). Global, Regional, And National Age-Sex Specific Mortality For 264 Causes Of Death, 1980–2016: A Systematic Analysis For The Global Burden Of Disease Study 2016. The Lancet, 390 (10100), 1151–1210.

Mokdad, A. H., Marks, J. S., Stroup, D. F., & Gerberding, J. L. (2004). Actual Causes of Death in the United States, 2000. Jama, 291 (10), 1238-1245.

### **PROs: Self-Reported Outcomes**



### 'Behaviour marker', 'Behaviome',( Digital Biomarkers')

### If you can't measure it, you can't improve it.

William Thomson, 1st Baron Kelvin, 1824-1907

The Big Picture



### **Smartphone**

### of the time next to us



### 300′000+ health apps 200 added daily





Dey, A. K., Wac, K., Ferreira, D., Tassini, K., Hong, J. H., & Ramos, J. (2011). Getting closer: An Empirical Investigation Of The Proximity Of User To Their Smart Phones. In Proceedings of the ACM UBICOMP. Liquid State. The Rise of mHealth Apps: A market snapshot. liquid-state.com/mhealth-apps-market-snapshot (2018) The dawn of digital medicine, The Economist Group Limited, December 2020

### **Wearables**

biomedicine information technology miniaturization (incl. battery) wirelessness mobility connectivity







Wearables database vandrico.com/wearables.html (431 wearables as of 12.2.2021) Wac, K. (2018). From Quantified Self to Quality of Life, Chapter in: Digital Health: Scaling Healthcare to the World, Series: Health Informatics, Springer Nature, Dordrecht, the Netherlands. Annotated 438 wearables dataset doi.org/10.6084/m9.figshare.9702122

### **TechROs:'Digital Biomarkers'**



### **Patient Today**



### **Patient Tomorrow = Primary Point of Care**

Health care = personalized, predictive, preventative, participatory Patient = expert in own health, equipped, enabled, engaged, empowered



# Algorithms

### **FDA Approvals**



Note: Figure maps 29 Algorithms out of 72 in the online DB

72 example approvals (6 for treatment)
61: 510(k) premarket notific. (moderate risk, class II)
9: de novo pathway ('reasonable assurance of safety and effectiveness')
2: premarket approval (PMA) (high risk, class III)





Benjamens, S., Dhunnoo, P., & Meskó, B. (2020). The State Of Artificial Intelligence-Based FDA-Approved Medical Devices And Algorithms: An Online Database, NPJ digital medicine, 3(1), 1-8. Also at medicalfuturist.com/fda-approved-ai-based-algorithms



### 2016: Digital Stethoscope (510(k))

STETIC

Al: none Symptoms/ Behaviours: self-reported

> THE AMERICAN JOURNAL *of* MEDICINE.



Vasudevan, R. S., Horiuchi, Y., Torriani, F. J., Cotter, B., Maisel, S. M., Dadwal, S. S., ... & Maisel, A. S. (2020). Persistent Value of the Stethoscope in the Age of COVID-19. The American journal of medicine. Also at stethio.com



### 2019: ACR | LAB Urine Analysis Test (510(k))

### Al-Assessment

ketones, leukocytes, nitrites, glucose, protein, blood, specific gravity, bilirubin, urobilinogen, pH

Al: computer vision for color matching

Symptoms/Behaviours: none





Leddy, J., Green, J. A., Yule, C., Molecavage, J., Coresh, J., & Chang, A. R. (2019). Improving proteinuria screening with mailed smartphone urinalysis testing in previously unscreened patients with hypertension: a randomized controlled trial. BMC nephrology, 20(1), 1-7. Also at healthy.io



### Preventice AliveCor

### 2012, 2014, 2017, ...: Cardiology (510(k))

### Al-Assessment

- continuous ECG (RootiCare)
- atrial fibrillation (BodyGuardian, AliveCor 6-leads)
- physical activity
- Al: detect AF episodes

Symptoms/Behaviours: self-reported



www.rooticare.com

Teplitzky, B., McRoberts, M., Mehta, P. Ghanbari, H. Real world performance of atrial fibrillation detection from wearable patch ECG monitoring using deep learning. Poster presented at Heart Rhythm 40th Scientific Sessions May 8-11, 2019, San Francisco, CA. Heart Rhythm Journal, Vol. 16(5), S1 - S712, S-P002-197. Also at <u>preventicesolutions.com/hcp/body-guardian-heart</u>

Sugrue, A., & Asirvatham, S. J. (2018). Highlights from Heart Rhythm 2018: Innovative Techniques. The Journal of Innovations in Cardiac Rhythm Management, 9(9), 3330. Also at alivecor.com







**Caption Health** 

### 2019: Cardiac Ultrasound Imaging (de novo)



### Al-Assessment

cardiac sonographer skills

Al: computer vision for image acquisition and optimization, image analysis





Schneider, M., Bartko, P., Geller, W., Dannenberg, V., König, A., Binder, C., ... & Binder, T. (2020). A machine learning algorithm supports ultrasound-naïve novices in the acquisition of diagnostic echocardiography loops and provides accurate estimation of LVEF. The International Journal of Cardiovascular Imaging, 1-10. Also at captionhealth.com

### empatica **{>**

### 2018: Wearable for Seizure Monitoring (510(k))

### Al-Assessment

- Electrodermal Activity (EDA)
- physical activity
- Al: Detect tonic-clonic seizures
- Symptoms/Behaviours: self-reported







Meritam, P., Ryvlin, P., & Beniczky, S. (2018). User-based evaluation of applicability and usability of a wearable accelerometer device for detecting bilateral tonic-clonic seizures: A field study. Epilepsia, 59, 48-52. Also at empatica.com

### **NKILI** 2020: Gaming for Children with ADHD (de novo)

### Al-Assessment

- attention
- movements, game insights (goals)

### Al: Adapt interaction pattern

attention, impulsivity, working memory, goal management, spatial navigation, memory, and planning and organization

### Symptoms/Behaviours: self-reported









Kollins, S. H., DeLoss, D. J., Cañadas, E., Lutz, J., Findling, R. L., Keefe, R. S., ... & Faraone, S. V. (2020). A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): a randomised controlled trial. The Lancet Digital Health, 2(4), e168-e178. Also at akilinteractive.com



### 2019: Opioid Use Disorder (510(k))

### Al-Assessment

- patterns of craving
- patterns of triggers

Al: none

Symptoms/Behaviours: self-reported



Insights





Velez, F. F., Colman, S., Kauffman, L., Ruetsch, C., & Anastassopoulos, K. (2020). Real-world reduction in healthcare resource utilization following treatment of opioid use disorder with reSET-0, a novel prescription digital therapeutic. Expert Review of Pharmacoeconomics & Outcomes Research, 1-8. Also at peartherapeutics.com

### 2018: Managing Type 1 Diabetes (de novo)

Al-Assessment: behavioural patterns Al: insulin dose adjustment

every 3 weeks

Symptoms/Behaviours: self-reported glucose and insulin, activity, carbs







dreame

diabetes a



Nimri, R., Oron, T., Muller, I., Kraljevic, I., Alonso, M. M., Keskinen, P., ... & Phillip, M. (2020). Adjustment of Insulin Pump Settings in Type 1 Diabetes Management: Advisor Pro Device Compared to Physicians' Recommendations. Journal of Diabetes Science and Technology, 1932296820965561. Also at dreamed-diabetes.com

### Apps & Wearables

Harvard Business Review

#### Want to See the Future of Digital Health Tools? Look to Germany.

by Ariel D. Stern, Henrik Matthies, Julia Hagen, Jan B. Brönneke, and Jörg F. Debatin

December 02, 2020





Digitalen Gesundheitsanwendungen (DiGA) Registry

Low Risk (class I or class IIa medical devices)

Evidence (12 m): safety, functionality, quality, data, protection/ security, care effect (SGB V, §(2): (i) medical benefit (i.e., therapeutic effect) or (ii) procedural/structural health care improvement

### 10 apps (17 Feb 2021)

- 7: provisionally approved
- 3: permanently approved

migraine mild depressive episode intracerebral hemorrhage cerebral transient ischemia and related syndromes non-organic insomnia other depressive episodes moderate depressive episodes obesity bilateral coxarthrosis due to dysplasia SOCial phobias agoraphobia with panic disorder agoraphobia with panic disorder episodic paroxysmal anxiety other primary coxarthrosis generalized anxiety disorder tinnitus aurium primary coxarthrosis bilateral multiple sclerosis

Bundesinstitut für Arzneimittel und Medizinprodukte

acute treatments of migraine attacks personalized motivational and knowledge coaching personalized adjustable exercises digital headache diary COGNIUVE behavioural therapy for insomnia



Gerke, S., Stern, A. D., & Minssen, T. (2020). Germany's digital health reforms in the COVID-19 era: lessons and opportunities for other countries. NPJ digital medicine, 3(1), 1-6. Digitalen Gesundheitsanwendungen (DiGA) Registry, diga.bfarm.de/de/verzeichnis, 2021



### **M-sense Migräne: Migraine** (provisional)

Il Sketch

0

### Al-Assessment

behavioural patterns

Al: attack classification

Symptoms/Behaviours: self-reported attacks

Use: as needed, for life (?)

N BMC

The Journal of Headache and Pain





Roesch, A., Dahlem, M. A., Neeb, L., & Kurth, T. (2020). Validation of an algorithm for automated classification of migraine and tension-type headache attacks in an electronic headache diary. The Journal of Headache and Pain, 21(1), 1-10. Also at m-sense.de



### Rehappy: Aftercare of Stroke Patients (provisional)

### Al-Assessment

behavioural patterns incl. rehabilitation

Al: none

Symptoms/Behaviours: self-reported + wearable

Use: 12 weeks





### Zanadio: Obesity (provisional)

Al-Assessment

behavioural patterns

Al: none

Symptoms/Behaviours: self-reported exercise and diet wearable, smart scale

Use: as needed, for life (?)

aidhere.de



Withings Body Pulse HR Band







i at 49 Pausieren	22:42 Heute	€ 51%)
-	<b>1</b>	-
Katze & Kuh	1	~
$2 \times 20$ Sek.		
Kurze Plank	<b>1)</b>	-

### Invirto

### Invirto: Anxiety, Panic Disorder, Social Phobia

(provisional)

- Cognitive Behavioural Therapy Exposure Therapy
- Al-Assessment: none

Al: none

Symptoms/Behaviours: self-reported Use: 8 weeks





### **Crowdsourcing Data** 'Together, we are powerful

Bertalan Meskó, MD, PhD, Top 6 Crowdsourcing Examples In Digital Health tmfinstitute.org



### 2000: Help to Find a Vaccine

Aggregated, crowdsourced synchronized computational resources Running simulations to find potential drug candidates For cancer, ALS, Parkinson's, COVID-19, ...





### 2004: Find me a Treatment

750000+ patients with 2,800+ conditions are sharing about their symptoms and how they manage them.



JOURNAL OF MEDICAL INTERNET RESEARCH

**Original Paper** 

Wicks, P., Massagli, M., Frost, J., Brownstein, C., Okun, S., Vaughan, T., ... & Heywood, J. (2010). Sharing health data for better outcomes on PatientsLikeMe. Journal of medical Internet research, 12(2), e19. Also at: patientslikeme.com Also for practitioners: Figure 1 Medical Case Sharing figure1.com and for individuals wanting to donate their datasets: openhumans.org



figure

James et al

### **2021: Design for My Needs**

Young Onset Parkinson's disease: Jimmy Choi (44, since 27)



Also project careables.org

### 2015: Extreme DIY Treatment

T1DM: Dana Lewis (since age of 14)

- 2015: Open Artificial Pancreas System
  - Feb 2021: 2211 active users
- FDA Approvals & Actions
  - 2016: Artificial pancreas (Medtronics)



- 2018: FDA Premarket approval (PMA)
  - Guardian Connect System<sup>(R)</sup>
  - Al: predicting glucose 60 min ahead
- 2019: Patient Engagement Advisory Committee







Asarani, N. A. M., Reynolds, A. N., Elbalshy, M., Burnside, M., de Bock, M., Lewis, D. M., & Wheeler, B. J. (2020). Efficacy, safety, and user experience of DIY or open-source artificial pancreas systems: a systematic review. Acta Diabetologica, 1-9. Also at <u>OpenAPS.org</u>

U IOB + 30 g carbs

### **Human Factors**

## What about the patient?



### **Human Factors**

### 'I just want my life back' (S111)



What is your current experience of Quality of Life?



What applications do you use, that support your Quality of Life?



Wac, K., Rivas, H., & Fiordelli, M. (2016). Use and misuse of mobile health information technologies for health self-management. Annals of Behavioral Medicine, 50 (Supplement 1).

Wac, K. et al., (2019). "I Try Harder": The Design Implications for Mobile Apps and Wearables Contributing to Self-Efficacy of Patients with Chronic Conditions, Frontiers in Psychology, SI: Improving Wellbeing in Patients with Chronic Conditions.

### **Human Factors**

0: Do you use technologies (smartphone/wearable) for your own health/care?

#### I don't!

I don't mix my smartphone with my health [visibly angry] It's all in here [indicating own head] I do not want a phone reminds me about my disease I have got a [fitbit as a] gift and I dropped it

#### I would...

Privacy is an issue It's complicated, I don't know how to use it, I am not a techie It's inaccurate: I have compared [fitbit] to my husband's Garmin and I was disappointed" [and have dropped it]

#### Study details

N = 200 participants (US) Affinity clustering of significant factors

### l do...



#### Batterv Too short Carry 2 batteries

Walked for free!

Emotions Keeps me entertained

I hate it when gained weight I get addicted

### Routines

For me when I need it Non-routine events most critical

, & Fiordelli, M. (2016). Use and misuse of mobile health information technologies for health self-management. Annals of Behavioral Medicine, 50 (Supplement 1).

Wac, K. et al., (2019). "I Try Harder": The Design Implications for Mobile Apps and Wearables Contributing to Self-Efficacy of Patients with Chronic Conditions, Frontiers in Psychology, SI: Improving Wellbeing in Patients with Chronic Conditions

Back to The Big Picture





### Computer is getting ready to assist, are we ready?



### Behavioural Medicine Readiness Principles



		generation	integration	loop
awareness prevention accessibility trust education (patients & clinicians) inclusion family history	clinical data biobanks data policy data privacy data access data integration transparency bias & fairness standards accountability	outcomes measurements (safety, efficary, quality, patient centricity, privacy, ongoing clinical impact) health economics role of academia role of government role of industry new research aims approvals certifications liability	care delivery organization policy system design screening counseling diagnostic treatment	economic development reimbursements partnerships role of academia ventures investments funding startups

Foundational elements (enablers):

health systems; insurance / financial models; inclusion; regulatory / government oversight; IT infrastructure; general infrastructure; social determinants



Precision Medicine Readiness Principles. Portfolio Overview Call, January 29th, 2020. Barriers from World Economic Forum weforum.org

Back to The Small Picture



### What about my Mom?



Freestyle Libre



Red: infrequent finger pricks, 3 / day

### What about my Mom?



New medication  $\rightarrow$  worse sleep...



**Exponential Technologies** 'Take Home' Messages

- Change patients (4E)
- experts in own health, equipped, enabled, engaged, empowered Change health care (4P)
- personalized, predictive, preventative, participatory

Challenges are numerous, 'systemic' approach is needed

Future focus: behaviome & digital biomarkers



Digital Health Scaling Healthcare to the World D Springer



Quality of Life Technologies Lab www.gol.unige.ch

European Network of Living Labs



Thank You

### Prof. Katarzyna Wac and the QoL Team

Quality of Life, Center for Informatics, University of Geneva, Switzerland

katarzyna.wac@unige.ch

SCIENCE

OUNDATION

COSE









Schweizerische Eidgenossenschaft Confédération suisse Confederazione Svizzera Confederaziun svizra







. \_\_\_\_ عالياً<mark>0</mark>