




› Future of healthcare: Digital Biomarkers

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Leiden Drug Development Conference 2022

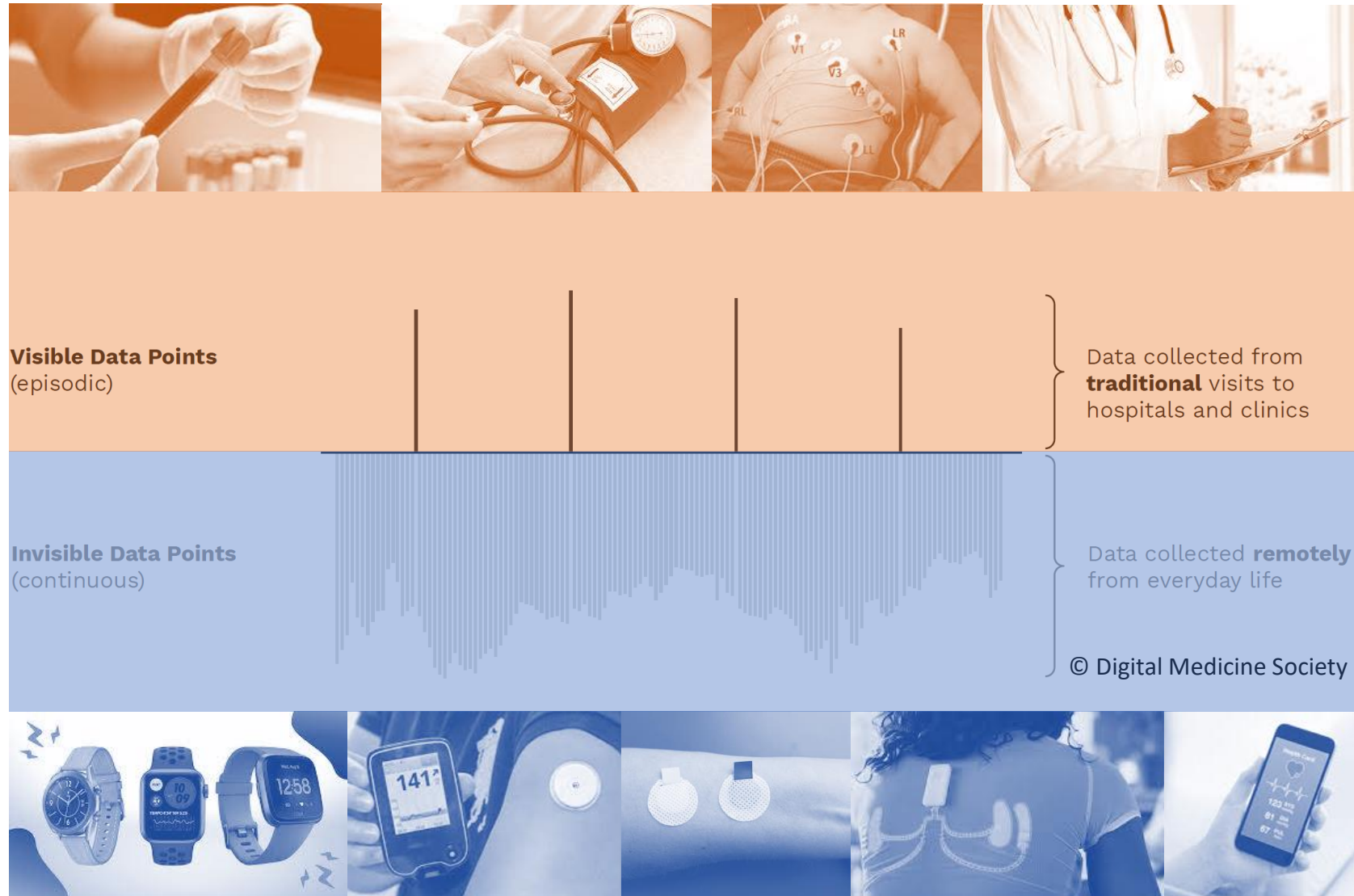
A hand is holding a wooden bowl filled with various fruits, including a green apple, an orange, a banana, a red apple, and a bunch of dark grapes. A stethoscope with a blue tube is resting on the bowl, with its chest piece placed on the green apple. The background is a light-colored wooden surface. A semi-transparent white banner with rounded corners is overlaid on the bottom half of the image, containing the text.

Can digital health drive the transition from sickcare to health focused care?



Remote patient monitoring
Early disease diagnosis
Lifestyle medicine

A paradigm shift of measurement



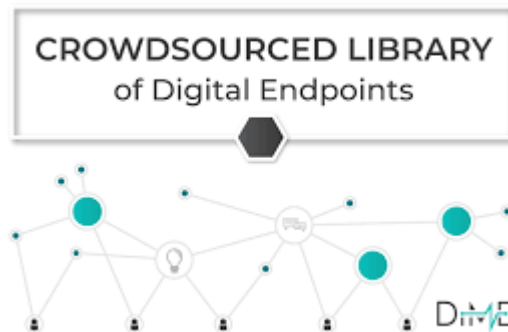
Digital biomarkers

An emerging phenomenon and a need

Forbes

The Future Of Medicine: Fighting
Deadly Diseases With Smart
Devices And Digital Biomarkers

- Library of Digital Endpoints includes
147 clinical trials on >75 conditions
 - Diabetes
 - Parkinson's Disease
 - Heart Failure



Applications

Accelerate clinical research



- Internal decision making (phase I/II)
- Patient stratification (phase I/II/III)
- Patient recruitment (phase I/II/III)
- RWE collection (phase IV)
- Decentralize clinical trials

Power public health



- Screening and surveillance
- Health technology assessment
- Comparative studies

Enhance healthcare



- Triage and early detection
- Clinical decision support
- Remote patient monitoring
- Companion diagnostics
- Education and self-management
- Prevention and health promotion

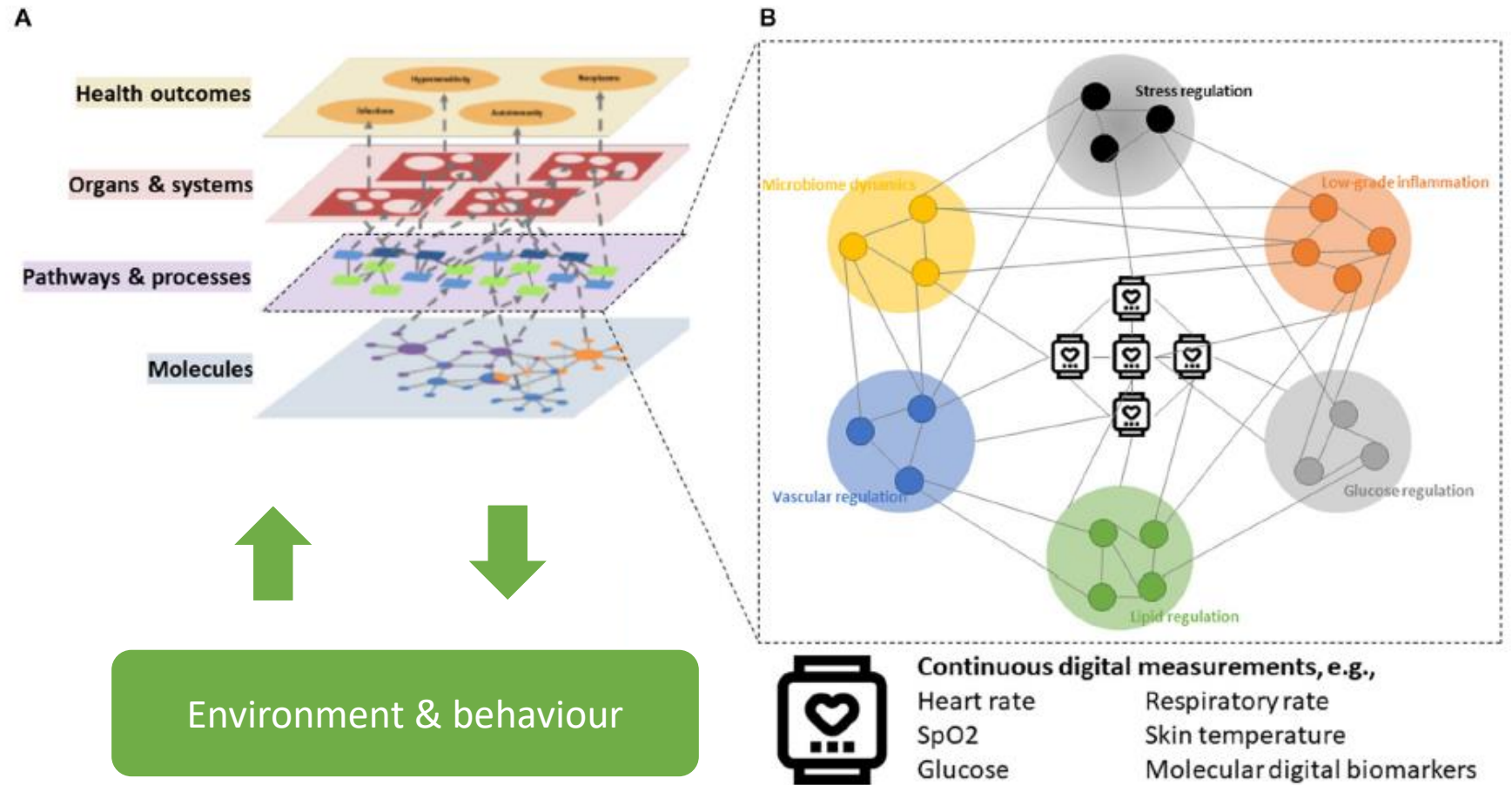
Digital biomarkers

Digital biomarkers/
endpoints
(e.g., activity count, gait)

Indirect digital
biomarkers
(e.g., glycemic variability,
heart rate variability)

Direct digital
biomarkers
(e.g., heart rate, sweat
glucose, cortisol)

Contextual digital
biomarkers
(e.g., physical activity,
diet)



Van den Brink et al, Front. Dig. Health, 2021

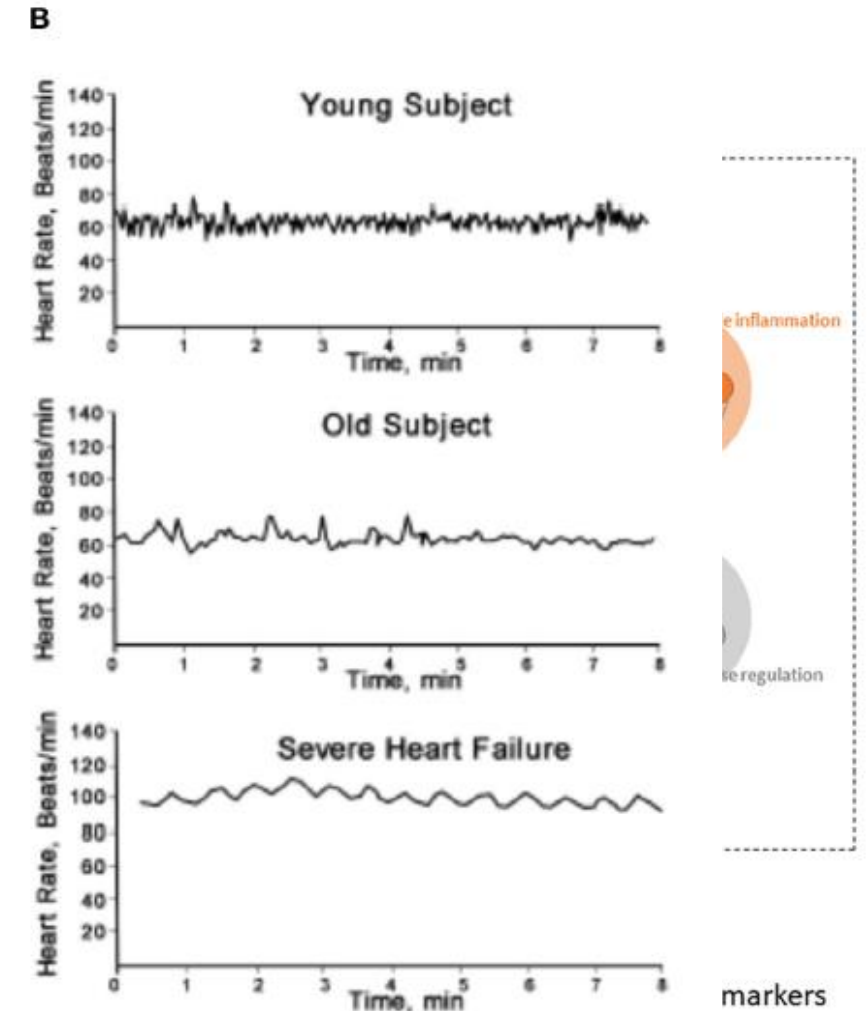
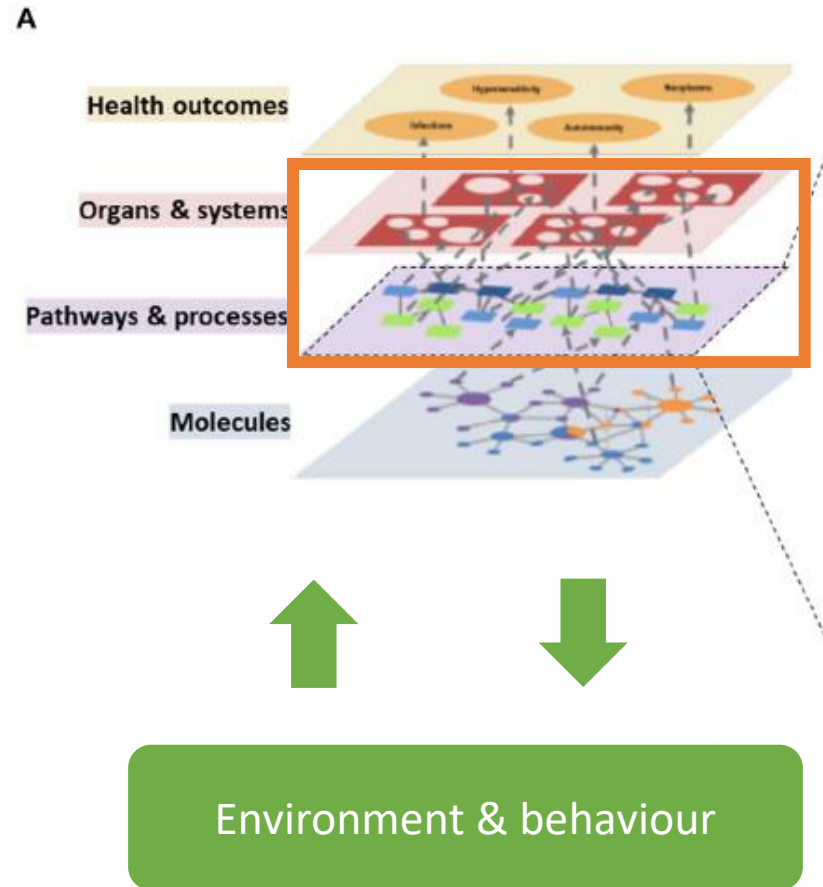
Digital biomarkers

Digital biomarkers/
endpoints
(e.g., activity count, gait)

Digital resilience
biomarkers
(e.g., glycemic variability,
heart rate variability)

Direct digital
biomarkers
(e.g., heart rate, sweat
glucose, cortisol)

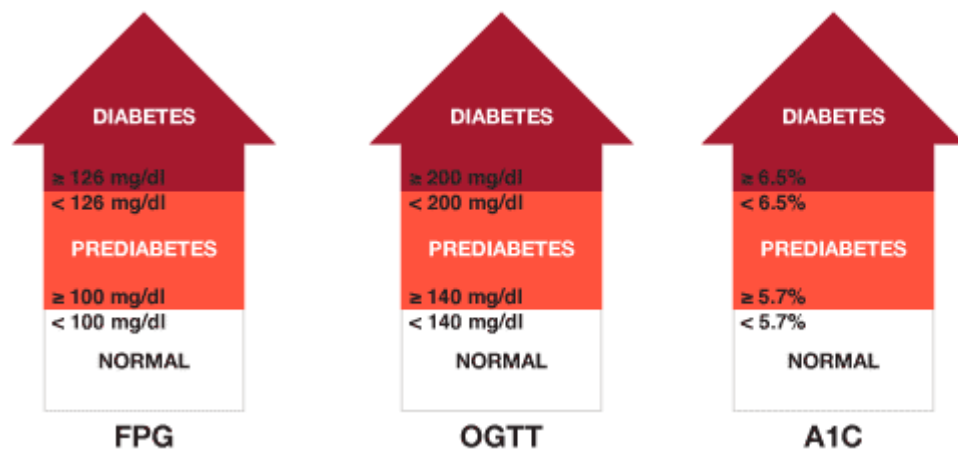
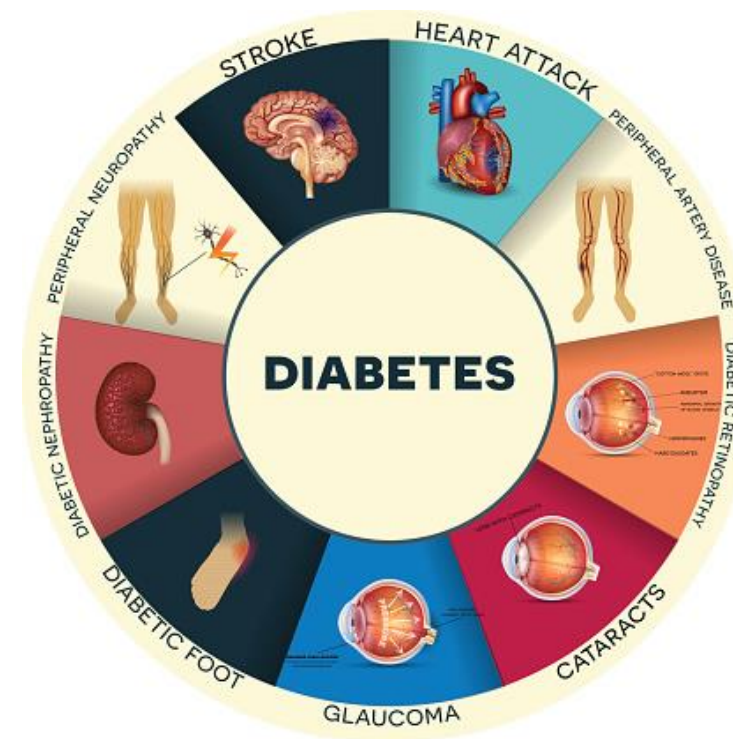
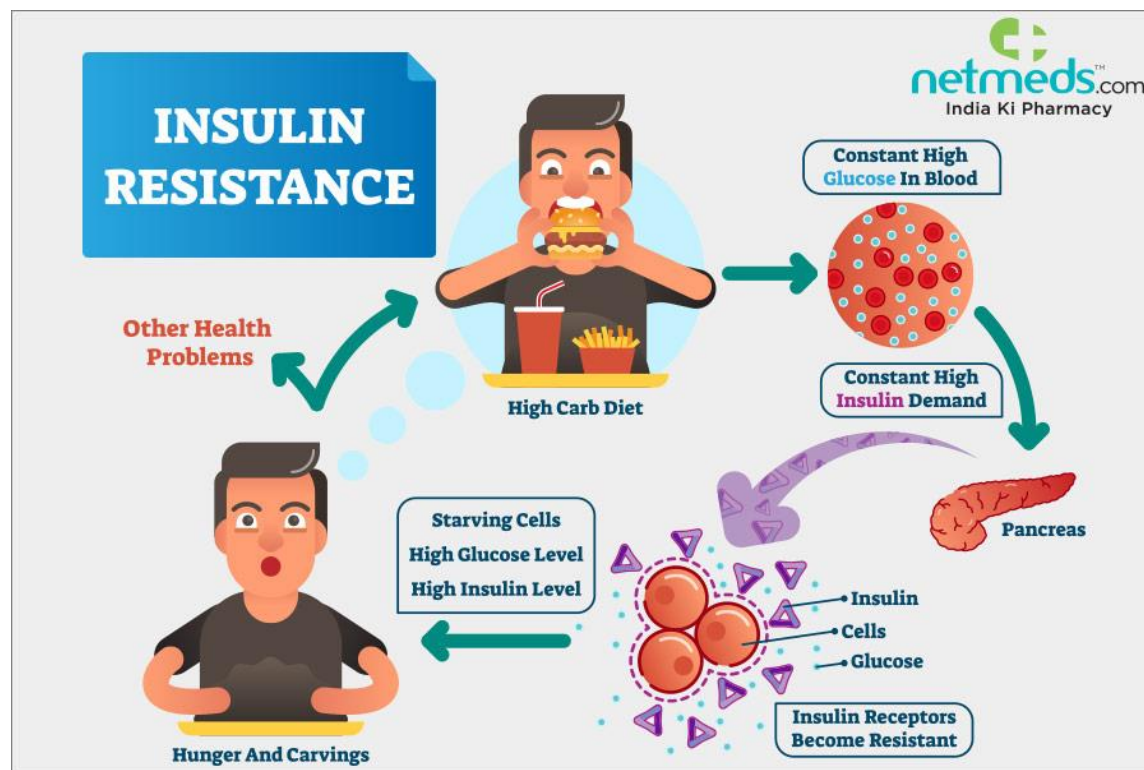
Contextual digital
biomarkers
(e.g., physical activity,
diet)



Van den Brink et al, Front. Dig. Health, 2021



Digital resilience biomarkers in (pre)diabetes



Digital resilience biomarkers in (pre)diabetes

- Time in range (TIR) and glucose management indicator (GMI) over 14 days
 - Surrogate for HbA1C in glycemic control
 - Risk marker for microvascular complications
 - Support self-management



AGP Report: Continuous Glucose Monitoring

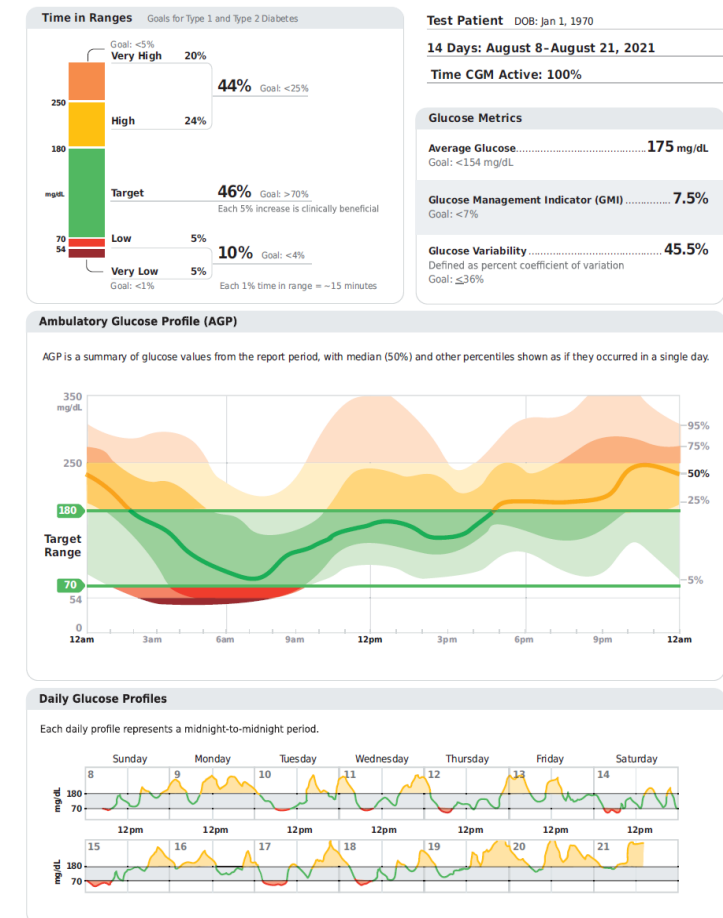


Figure 6.1—Key points included in standard ambulatory glucose profile (AGP) report. Reprinted from Holt et al. (33).

Digital resilience biomarkers in (pre)diabetes



Oral Glucose Tolerance Test



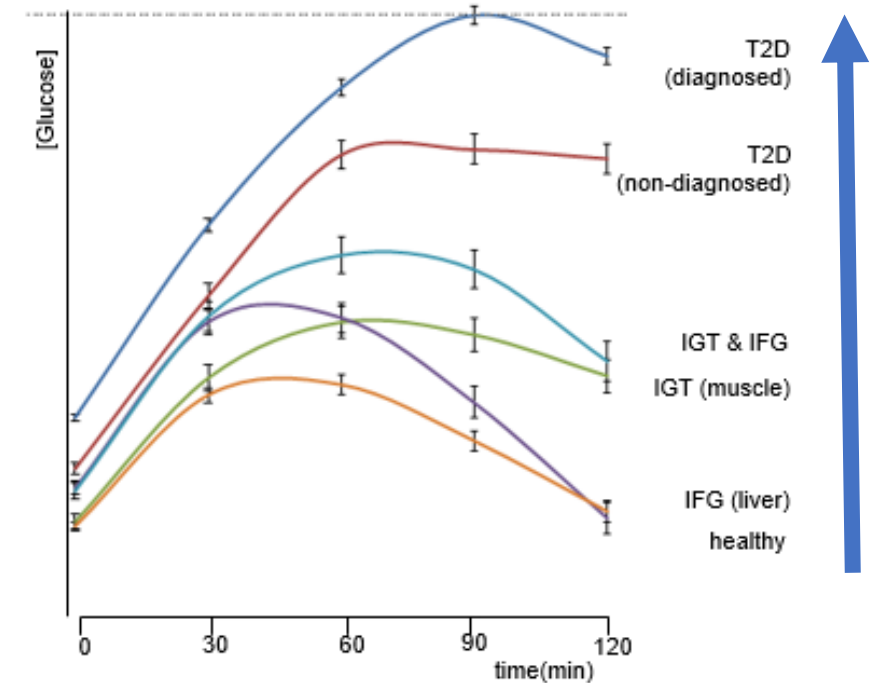
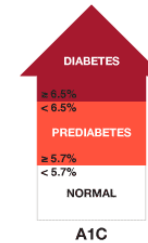
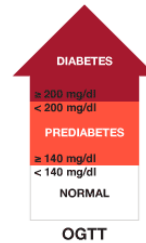
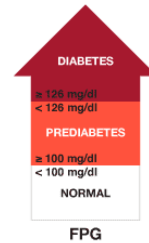
No food or drink 8 to 12 hours prior to test



Drink glucose



Blood is tested two hours later



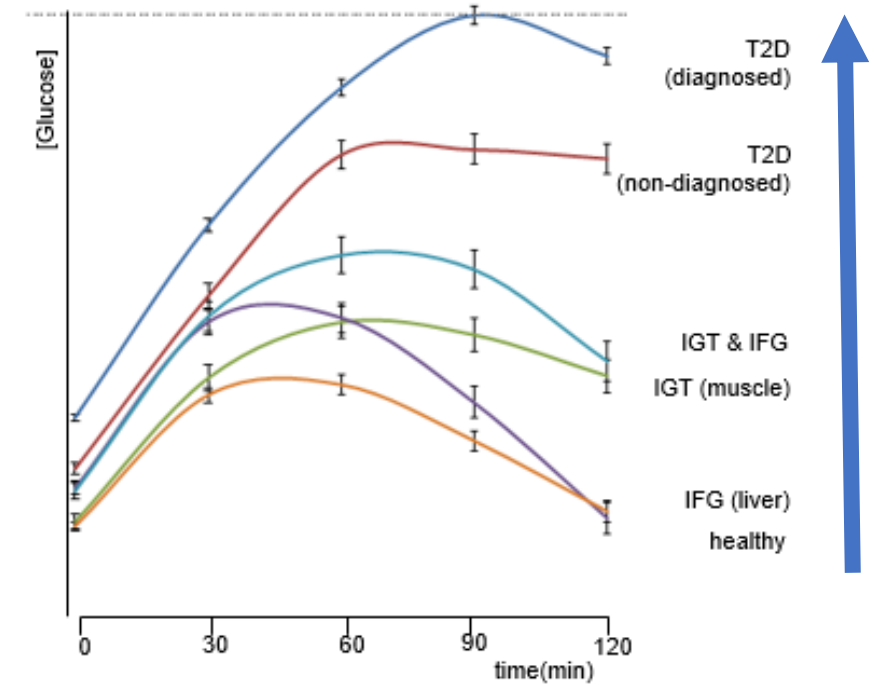
Personalized lifestyle advice

Liver IR: caloric restriction, low-fat diet

Muscle IR: exercise training, Mediterranean diet

Poor beta-cell function: caloric restriction

Digital resilience biomarkers in (pre)diabetes

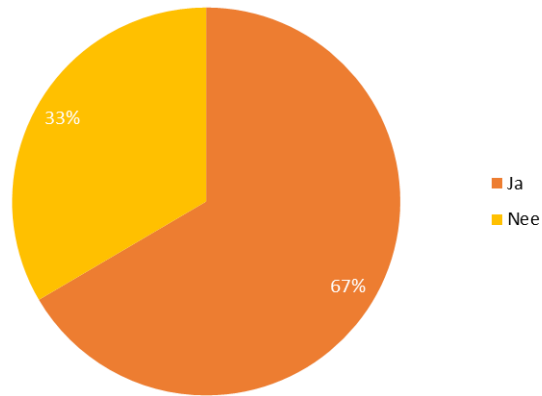




Digital biomarkers that matter to patients

Digital biomarkers that matter to patients

Do you use simple measuring devices for keeping track of your health?



Relieve doctor

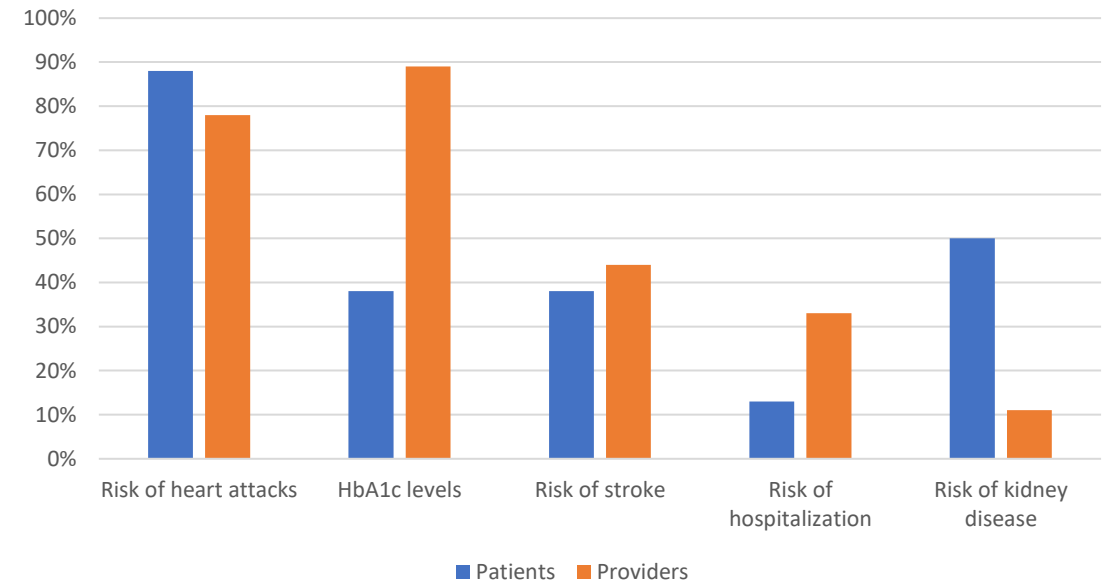
- Insight/control
- Independence

Direct result → alarm function

Adapt medication dosage

Overall well-being

Value based outcomes T2D



Neilsson L. et al, J Manag Care Specialty Pharm, 2019

Summary

- Digital biomarkers facilitate the transformation of sick-care to healthcare with accessible, remote, and continuous health measurement in everyday life
- Digital resilience biomarkers provide an opportunity for early detection of disease progression
- Integrating contextual digital biomarkers is important to support lifestyle change
- Define digital biomarkers that matter to patients



› Thank you!
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