Frugal Medical Technology – Your Health in Your Hands

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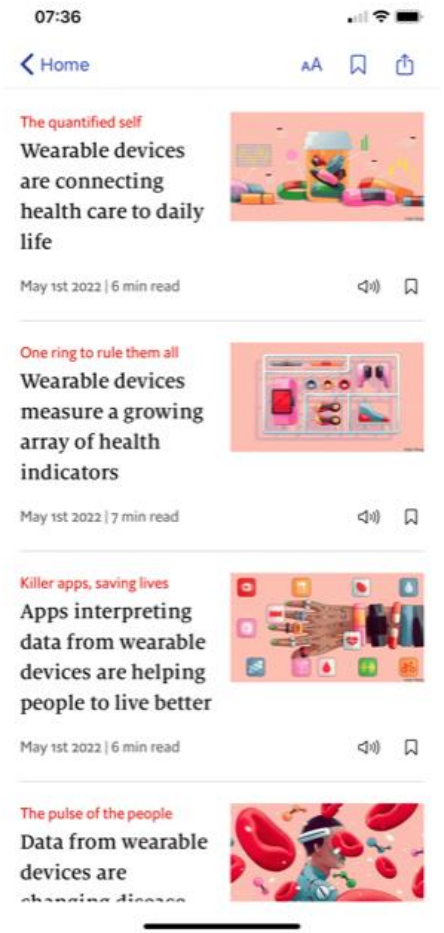
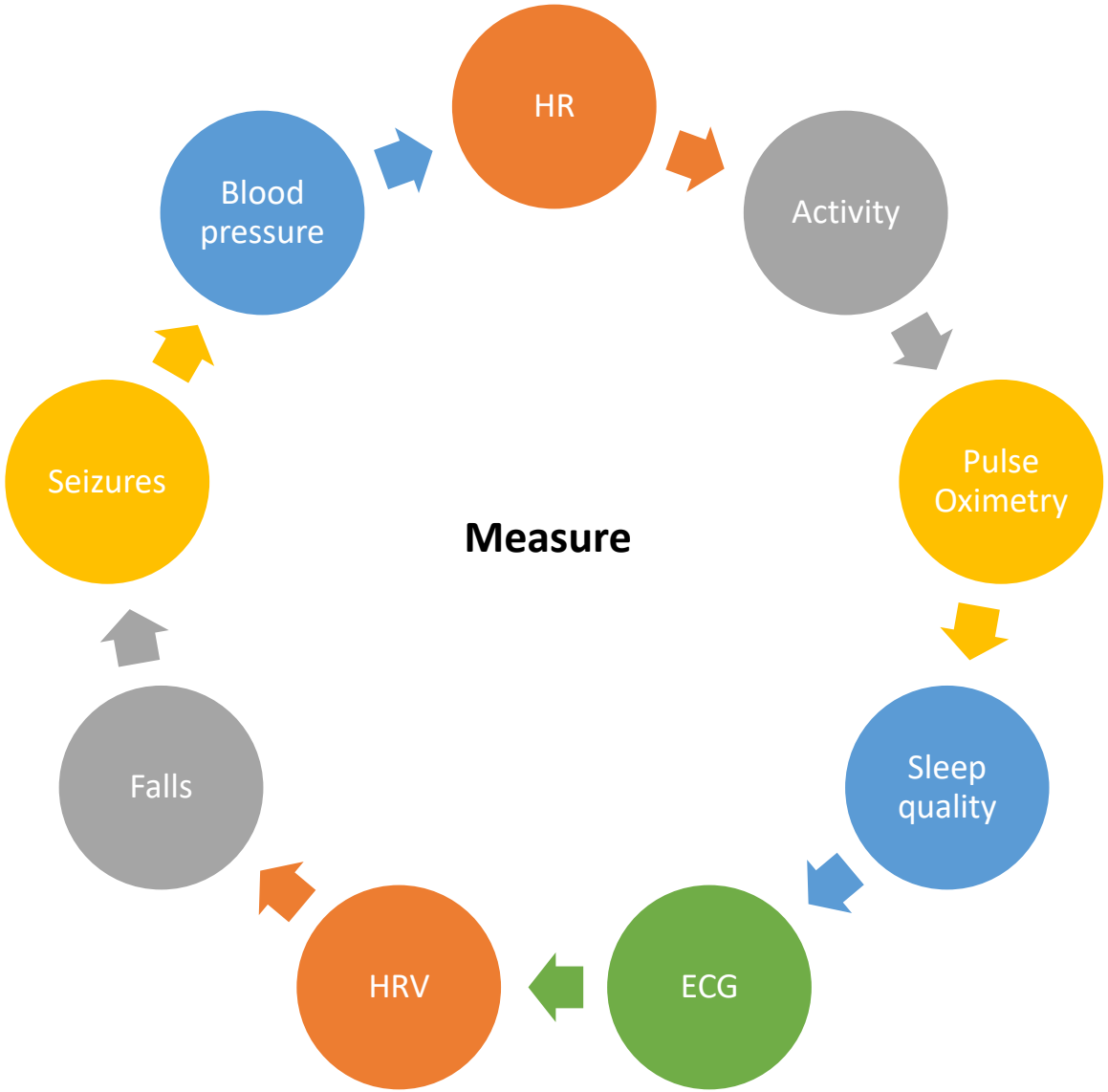
The World of Frugal Health Technology



Mention is not an endorsement, these are simply examples of products on the market!



Remind

Teach

Encourage

Coach

Who cares about all that data?

- Subscription platforms or Seizure Alert e.g. Empatica Embrace 2 alert to caregiver;
- Falls alert on Apple Watch – direct alert to caregiver/emergency services;
- Patient – seeing their own trends;
- Healthcare providers – at review only, early days;
- If you don’t pay for a monitoring service, you will not get one.

Is the real power in the analysis of data from wearables, healthcare provider review and personal account of well-being?

Medical Device or Lifestyle Assistant?

Medical Device

- CE –marked showing conformance with MDD or MDR;
  - Clinical validation;
  - Makes a health claim.
- Meets relevant standards for Medical Devices.

Lifestyle Assistant

- Provides a guide which the user might find helpful:
  - Activity;
  - Medication reminder;
  - It may carry out a health function but it’s not validated – so its up to the user – managed by disclaimer.

Some Examples *(not endorsements)*

	HR	Sleep*	Pulse Oximetry	ECG	BP	HRV	Activity	Fall	Acceler-ometer & Gyroscope	Electro-dermal activity
Empatica Embrace 2	yes	yes	no	no	no	no	no	yes	yes	yes
Apple watch 7	yes	yes	yes**	yes	no	yes	yes	yes	yes	no
Fitbit Sense	yes	yes	Yes (night)	yes		yes	yes	no	yes	no
Withings ScanWatch	yes	yes	yes	yes		no	yes	no	yes	no
Samsung Galaxy Watch 4	yes	yes	Yes**	yes	yes	yes	yes	no	yes	no
Oura Ring	yes	yes	no	no	no	yes	no	no	no	no

* No standardized measure of sleep

** Does not conform to Medical Devices Directive/Medical Device Regulations

Examples: Oximetry from Manufacturer's Websites (accessed 2 May 2022)

- Withings Scan Watch
  - "Clinically validated Oxygen saturation level (SpO2)"
- Apple Watch series 7
  - "Blood Oxygen app measurements are not intended for medical use, including self-diagnosis or consultation with a doctor, and are only designed for general fitness and wellness purposes."
- Samsung Galaxy Watch 4
  - "Blood oxygen is for fitness and wellness purposes only and not intended for use in detection, diagnosis, treatment of any medical condition or disease. The measurements are for your personal reference only. Please consult a qualified medical healthcare professional for advice."

About the Medical Devices Directive (MDD)/Regulations (MDR)

- MDD: effective 1993 to May 2021;
- MDR: effective 2021 (3 year transition period);

It is a medical device which does what it claims to do (and the claim is medical), when used according to instructions for use.

CE Mark

China Export

In Europe – must have CE mark. FDA is irrelevant.

Standards – Safety and Performance

Many standards for Medical devices, health informatics and software are developed by the following International Standards Organization (ISO) Technical Committees (TC):

- ISO TC 210 – Quality management and corresponding general aspects for medical devices
- ISO TC 215 – Health informatics
- IEC TC 62 – Electrical equipment in Medical practice

Harmonised Standards (assumed in MDR)

Some standards apply to all types of medical devices irrespective of the type of device or level of risk and these are known as “Horizontal standards”.

- *I.S. EN ISO 13485 – Medical Devices – Quality management systems – requirements for regulatory purposes*
- *I.S EN ISO 14971 – Medical devices – Application of risk management to medical devices.*
- Some other horizontal standards include:
- *ISO 20417 – Medical devices – Information supplied by the manufacturer.*
- *ISO 15223-1 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.*
- *I.S. EN ISO 10993-1:2020 – Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process.*
- *I.S EN 14155 – Clinical investigation of medical devices for human subjects – Good clinical practice.*

Software and Medical Device Standards (ref)

The IEC 60601 series of standards address safety and essential performance for medical electrical equipment and covers hardware, components and software used in healthcare facilities, homes and emergency situations. Some specific standards addressing software and health and wellness apps and security are listed below:

- *IEC 82304-1:2016 – Health software – Part 1: General requirements for product safety.*
- *IEC 80001-1:2021 – Safety effectiveness and security in the implementation and use of connected medical devices or connected health software – Part 1 Application of risk management.*
- *IEC 62304:2006 – Medical device software – software life cycle processes*
- *ISO TS 82304-2:2021– Health software – Part 2: Health and wellness apps – quality and reliability.*
- IT Security and safety are also issues to consider when looking at digital healthcare. The IEC 81001 series address this with *IEC 81001-5-1:2021 Health software and health IT systems safety, effectiveness and security Part 5-1: Security – activities in the product life cycle* recently published.

Apps and Standards and Validation

Most of the devices depend on an App.

Some apps are made for other manufacturer’s wearables.

Many apps communicate with Apple Health Kit.

A dynamic world – need to critically and regularly review the literature.

Software/apps may in themselves be a medical device and therefore must conform to the Medical Device Regulations.

Advantages & Disadvantages of Wearables

- Advantages of Wearables
  - Always on
  - Bigger picture
  - Closest to real world
  - Person-specific base-line
  - Depends on the wearer

- Disadvantages of Wearables
  - Who monitors the data?
  - Who cares about the data?
  - How meaningful is the data?
  - Who calibrates (if necessary)?
  - Understanding of the technology;
  - Selecting the right device;
  - Not part of the patient's hospital record.

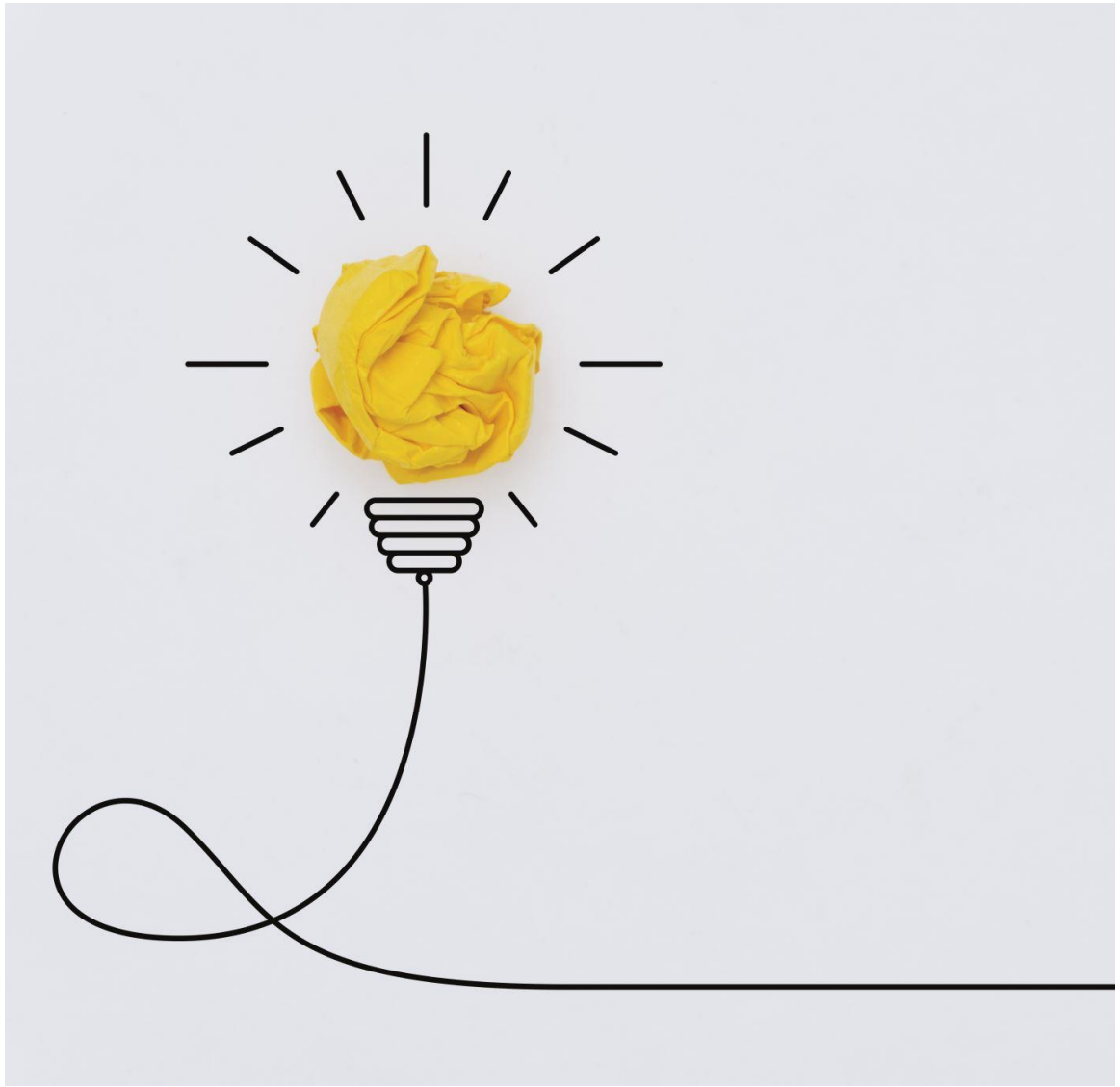
Real World Considerations

- Battery life (18 hours to 30 days);
- Clinical validation;
- Privacy;
- Calibration e.g. blood pressure;
- Cost including subscription for monitoring;
- Usability (eg screen size);
- Acceptability;
- Comfort;
- Understanding;
- Operating system/platform (Android/IOS);
- Keeping a record;
- Some people do not want or like this quantification.

The value of data for a population versus for an individual.

Questions?

Actually, these are our questions to you…..



What are the barriers to optimising the value of wearable life style and medical technology?

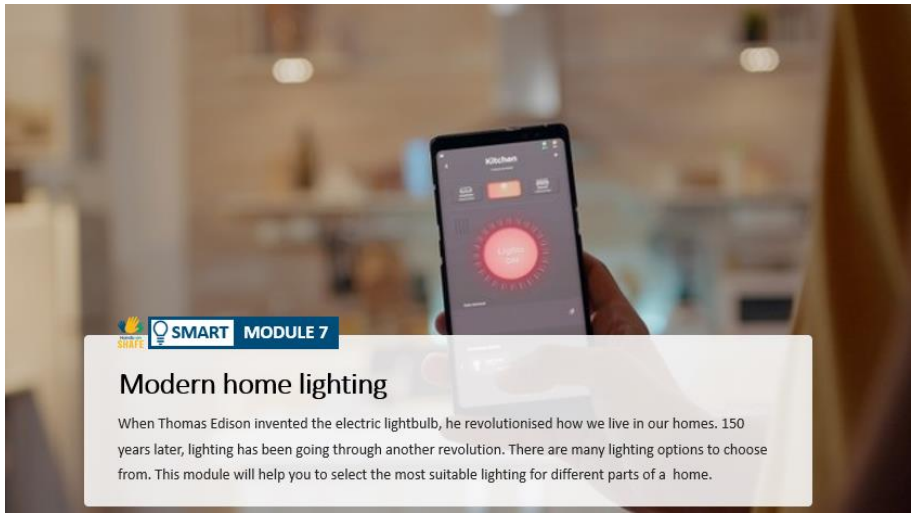
Barriers?

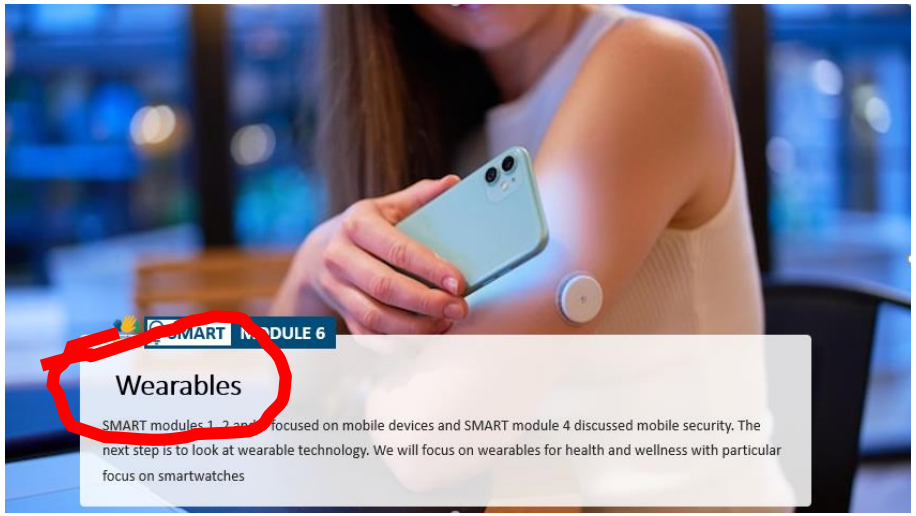
- User confusion
- Hard sell
- Digital divide
- Clinical engagement
- Health technology assessment

Addressing the digital divide

Hands-on SHAFE

“SMART” learning materials
“ECDL” for mobile devices & wearables





Informed stakeholders

Conclusion

There is huge potential

A journey still to go

There are definitely pitfalls and risks