

Ethical Quandaries of Direct-to-Consumer Neurotechnology

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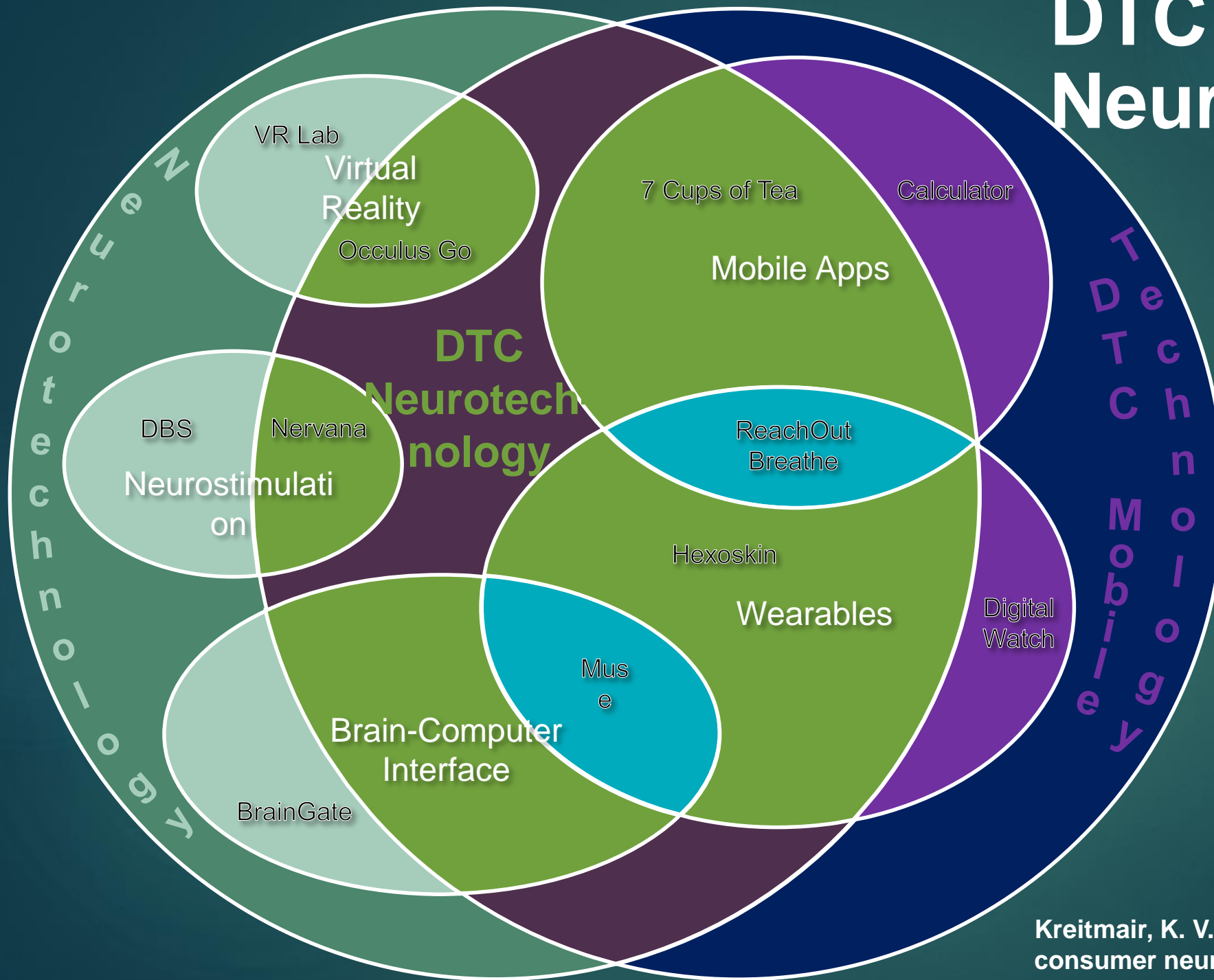
ETHICS GRAND ROUNDS – UT SOUTHWESTERN MEDICAL CENTER

MAY 10TH, 2022

Outline

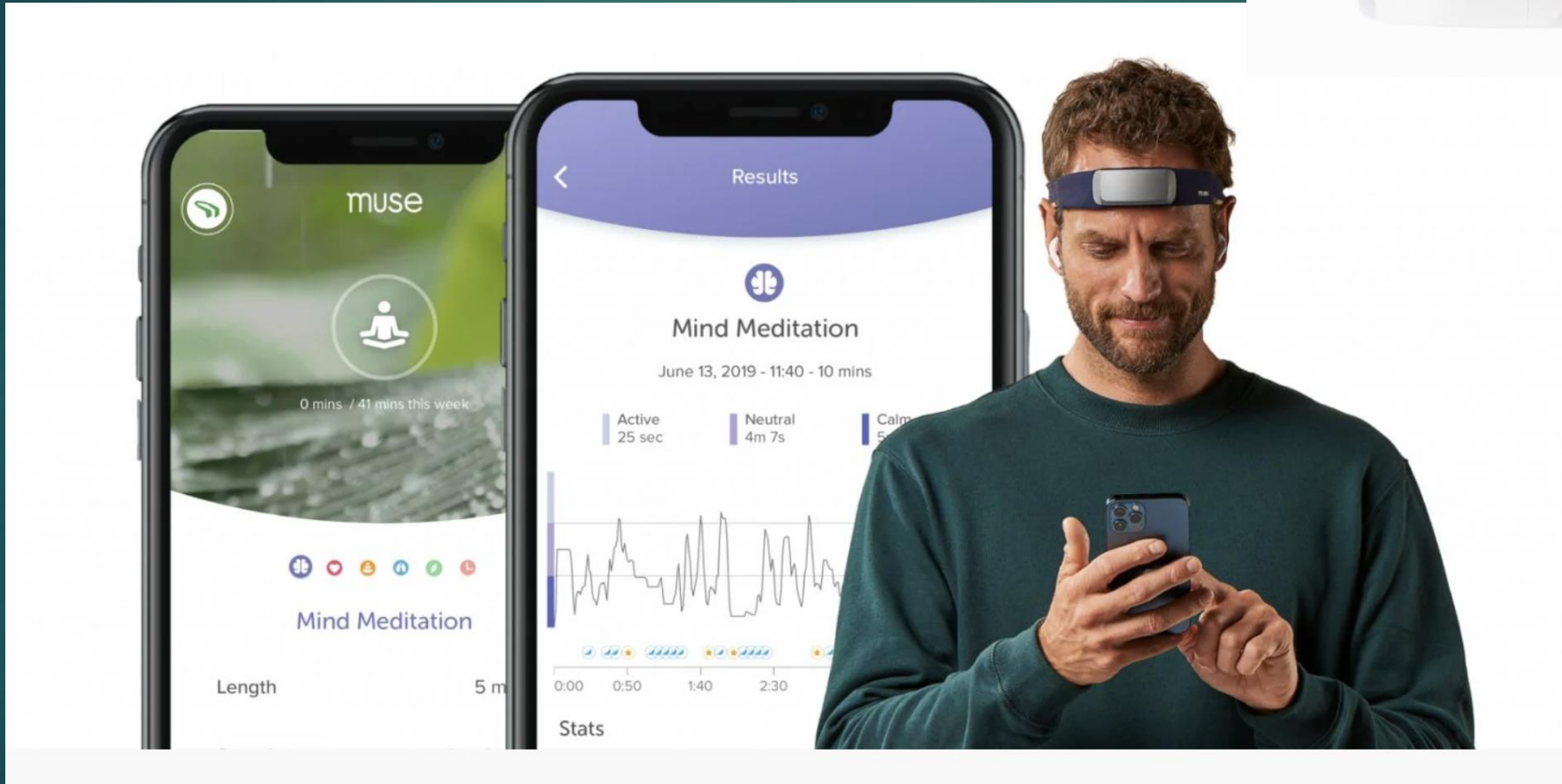
- ▶ DTC neurotechnology background
- ▶ Two sets of ethical issues
 - ▶ 'Easy' ethical issues
 - ▶ 'Hard' ethical issues
- ▶ A closer look at empowerment
- ▶ Conclusion

DTC Neurotechnology



Kreitmair, K. V. (2019). Dimensions of ethical direct-to-consumer neurotechnologies. *AJOB neuroscience* 10(4), 152-166.

Brain-Computer Interface



[Choosemuse.com](https://choosemuse.com)

Neurostimulator

LIFTiD
Neurostimulator



Source: getlift.com

Virtual Reality



Source: metaquest.com



* smartphone not included

Source: mindcotine.com

Mental Health Apps



7 Cups: Online Therapy & Chat 12+

Stress & Depression Counseling

[7 Cups of Tea](#)

Designed for iPad

★★★★★ 4.7 • 8.8K Ratings

Free · Offers In-App Purchases

[View in Mac App Store ↗](#)

[Apps.apple.com](https://apps.apple.com)

Wearables

Pavlok 2



TIME

BBC

LATE NIGHT WITH JIMMY FALLON

The New York Times

STEVE HARVEY MORNING SHOW

GOOD MORNING AMERICA

CBS NEWS

SHARK TANK

npr

YAHOO! TECH

2015 WINNER - ELECTRONICS

\$777,400 FUNDED WITH INDIEGOGO

2015 tech/motion TIMMY AWARDS

TOP 0.1% BOLT

pavlok.com

‘Easy’ ethical issues

- ▶ Safety
- ▶ Privacy
- ▶ Transparency

Safety

- ▶ Example: tDCS device
- ▶ Marketed as increasing focus and alertness; improving cognition; relieving symptoms of anxiety and depression; and combatting cravings.
- ▶ Risks: unintended areas may be affected, enhancing one area might hurt another, effects may be longer-lasting than expected, tDCS may impair working memory, and that tDCS cause skin burns.

Research Article | [Open Access](#) | [Published: 18 August 2015](#)

“Unfocus” on *foc.us*: commercial tDCS headset impairs working memory

[Laura Steenbergen](#) ✉, [Roberta Sellaro](#), [Bernhard Hommel](#), [Ulman Lindenberger](#), [Simone Kühn](#) & [Lorenza S. Colzato](#)

[Experimental Brain Research](#) **234**, 637–643 (2016) | [Cite this article](#)

12k Accesses | **44** Citations | **198** Altmetric | [Metrics](#)

Annals of
NEUROLOGY

An Official Journal of
the American Neurological
Association and the
Child Neurology Society



AMERICAN
NEUROLOGICAL
ASSOCIATION



Editorial

An open letter concerning do-it-yourself users of transcranial direct current stimulation

Rachel Wurzman PhD, Roy H. Hamilton MD, MS, Alvaro Pascual-Leone MD, PhD, Michael D. Fox MD, PhD

First published: 23 May 2016 | <https://doi.org/10.1002/ana.24689> | Citations: 58



Source: getlift.com

Regulation?

- ▶ DTC neurotechnologies not classified as medical devices by the FDA.
- ▶ ‘General wellness products’.
- ▶ With medical devices, medical benefits are weighed against risks.
- ▶ With general wellness products, no such assessment is made.
- ▶ No ‘medical benefits’ recognized.

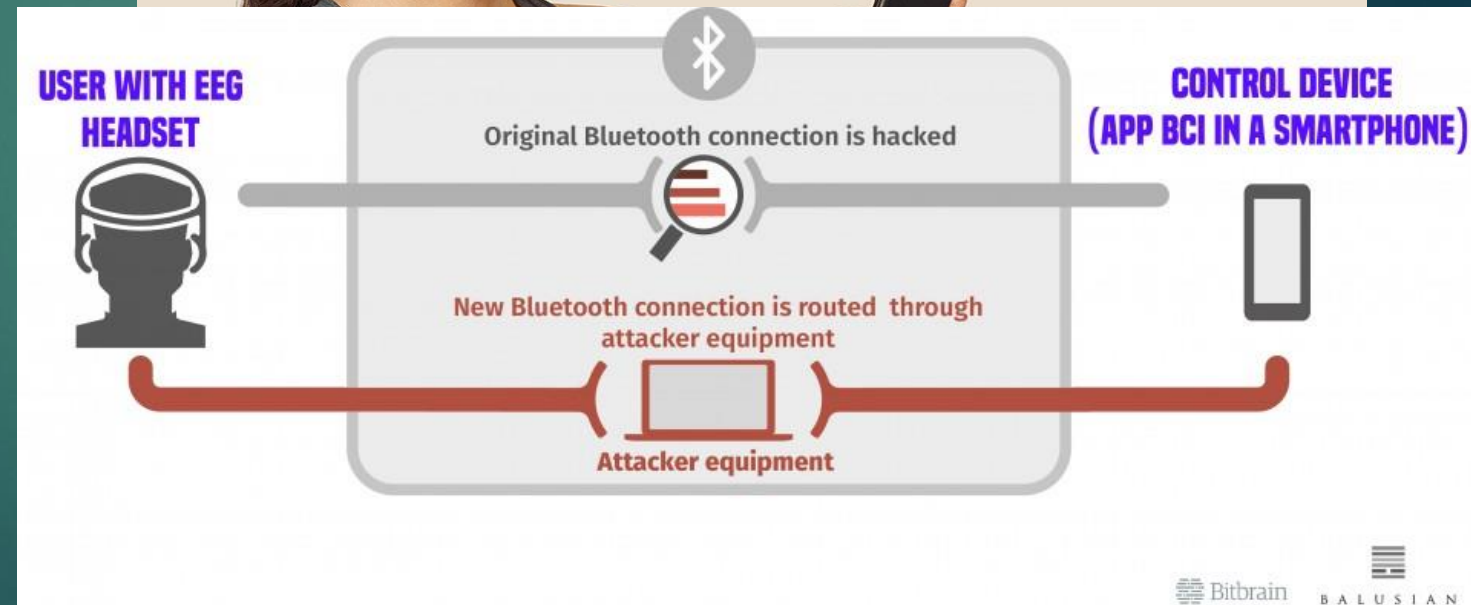
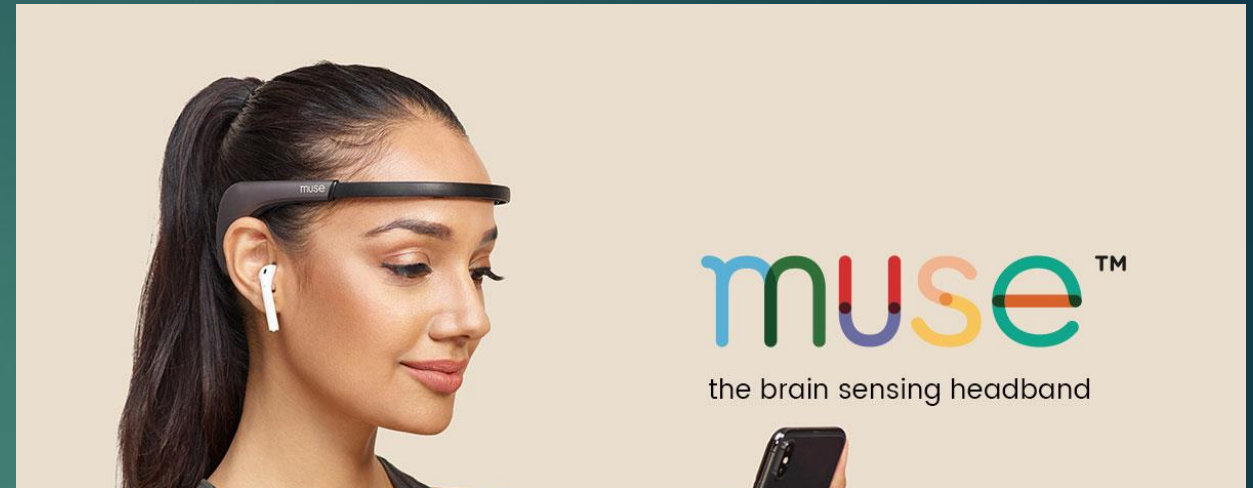
Docket No: FDA-2014-N-1039; 09/27/2019

General Wellness: Policy for Low Risk Devices Guidance for Industry and Food and Drug Administration Staff

*A general wellness product, for the purposes of this guidance, has (1) an intended use that relates to maintaining or **encouraging a general state of health** or a healthy activity, or (2) an intended use that relates the role of healthy lifestyle with helping to **reduce the risk** or impact of **certain chronic diseases or conditions** and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.*

Privacy

- ▶ Cybersecurity threats
- ▶ Example: EEG BCIs
- ▶ Hackers can intercept EEG data and/or establish unauthorized Bluetooth connections.
- ▶ Hacked data is valuable, e.g., \$5 for credit card information or \$250 per medical record (Trustwave 2018).



Privacy

[Nature](#) 551, 159–163 (2017)

Four ethical priorities for neurotechnologies and AI

Artificial intelligence and brain–computer interfaces must respect and preserve people’s privacy, identity, agency and equality, say **Rafael Yuste**, **Sara Goering** and colleagues.

- ▶ Companies need regulation
- ▶ Brain data increasingly sensitive and revealing.
- ▶ Can be integrated with host information – digital phenotyping
- ▶ Data uses might include insurance, educational settings, “social credit” systems.
- ▶ Cognitive liberty.

RESEARCH

Open Access

Towards new human rights in the age of neuroscience and neurotechnology



Marcello Ienca^{1*}  and Roberto Andorno²

Transparency

- ▶ Efficacy?
- ▶ Tension between designation as not a medical device and requirement of full validation.
- ▶ Lack of regulation is problematic.
- ▶ Majority of efficacy claims made by DTC EEG and tDCS companies are unsubstantiated, rely on testimonials, unrelated general scientific concepts, or unpublished, non-peer-reviewed in-house R&D (Coates McCall et al, 2019).
- ▶ Autonomy requires truthful information.

[Published: April 2007](#)

Commercializing cognitive neurotechnology—the ethical terrain

[Margaret L Eaton](#) & [Judy Illes](#)

[Nature Biotechnology](#) **25**, 393–397 (2007) | [Cite this article](#)

2154 Accesses | **39** Citations | **9** Altmetric | [Metrics](#)

Neuron

CellPress

Volume 102, Issue 4, 22 May 2019, Pages 728–731

NeuroView

Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies

Iris Coates McCall¹, Chloe Lau¹, Nicole Minielly¹, Judy Illes¹  

‘Hard’ ethical issues

- ▶ Psychological continuity (Ienca and Adorno, 2017)
- ▶ Agency and identity (Yuste, Goering, et al, 2017)
- ▶ Existential authenticity (Kreitmair, 2019)
- ▶ ‘Empowerment’

[illegible]

Elon Musk's Neuralink to empower human brains with AI

by Kartik Singh | Jul 26, 2019 | AI, Data Science | 0 comments



dimensionless.com



Empower People With Health Tech And Health



With more health data such as ECG and blood oxygen available on our wrists, devices such as the Apple Watch allow users to keep close tabs on their health.

Deepa Narwani | Nov 08, 2021

Empowerment

- ▶ Claim: Like all digital, mobile, health technologies, DTC neurotechnology *empowers* users to adopt healthier habits, take responsibility for their health, become more productive and relaxed. This technology empowers physical and psychological self-improvement.

Empowerment

- ▶ Empowerment is a state a person is in with respect to a certain situation, in which five things are true of her:
 - 1) Knowledge
 - 2) Control
 - 3) Responsibility
 - 4) Availability of Good Choices
 - 5) Healthy Desires

$\text{Empowerment}_{(\text{state})} \neq \text{Empowerment}_{(\text{self-perception})}$

Empowerment

Availability of Good Options

Must have access to good options.

Knowledge

Must have knowledge about relevant possibilities.

Healthy Attitudes / Desires

Must be motivated by healthy attitudes and desires.

Control

Must have the ability to bring about an outcome.

Responsibility

Must be responsible for the outcomes one chooses to bring about.

Empowerment_(state) Definition

- ▶ An individual possesses empowerment_(state) with respect to a certain situation, if there are *good options available* to her, she has *knowledge* of these options, she has *healthy desires* with respect to these options, she has *control* over which of these options to bring about, and she is *responsible* for the respective action or actions.

Knowledge



SCIENCE

18 JANUARY 2019 • VOL 363 ISSUE 6424

Oversight of direct-to-consumer neurotechnologies

Efficacy of products is far from clear

By Anna Wexler¹ and Peter B. Reiner²

Neuron

CellPress

Volume 102, Issue 4, 22 May 2019, Pages 728-731

NeuroView

Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies

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choos

Control



pavlok.com

Neurosky



Neuron

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Responsibility

- ▶ Being responsible means being praise- and blameworthy.
- ▶ Two options:
 - ▶ Something about the use of DTC neurotechnology makes the user more praise- and blameworthy.
 - ▶ The decision to use DTC neurotechnology in the first place is praise- or blameworthy.

Responsibility – Option 1 (Within Use)

- ▶ Example: Automatic calorie-tracker
- ▶ Horace is obese and wants to lose weight by cutting calories. He buys and uses the GoBe wearable.
- ▶ Question: Assume Horace is successful in cutting calories. Is Horace's calorie-cutting behavior more praiseworthy if it happens in the setting of GoBe use rather than via another method?
- ▶ No.



Responsibility – Option 1 (Within Use)

- ▶ Question: Assume Horace is *not* successful in cutting calories. Is Horace's calorie-cutting behavior more blameworthy if it happens in the setting of GoBe use rather than via another method?
- ▶ Perhaps, Horace is more blameworthy because he has improved tools and “no more excuses”. “He just lacks willpower.”
- ▶ No! Obesity is complex phenomenon, largely driven by genetics, environmental factors, and psychological adversity.



Responsibility – Option 2 (Decision to Use)

Original Research



Health professionals' attitudes to patients' use of wearable technology

Digital Health
Volume 5: 1–6
© The Author(s) 2019
DOI: 10.1177/2055207619845544
journals.sagepub.com/home/dhj
SAGE

Angus Watt¹, Katherine Swainston¹ and Gemma Wilson²

“[S]ome participants generally felt that patients do not take enough responsibility of their own health and ‘rely on everyone to sort out the problem’” (p. 3).

Responsibility – Option 2 (Decision to Use)

Original Research



Digital Health
Volume 2, No. 1, 2019

Health professionals' responsibility of wearable technology

Angus Watt¹, Katherine Swainston

“[S]ome participants questioned the responsibility of their role in the problem” (p. 3).

Medicine, Health Care and Philosophy
<https://doi.org/10.1007/s11019-019-09900-y>

SCIENTIFIC CONTRIBUTION

Mobile health ethics and the expanding role of autonomy

Bettina Schmietow¹ · Georg Marckmann¹

© Springer Nature B.V. 2019

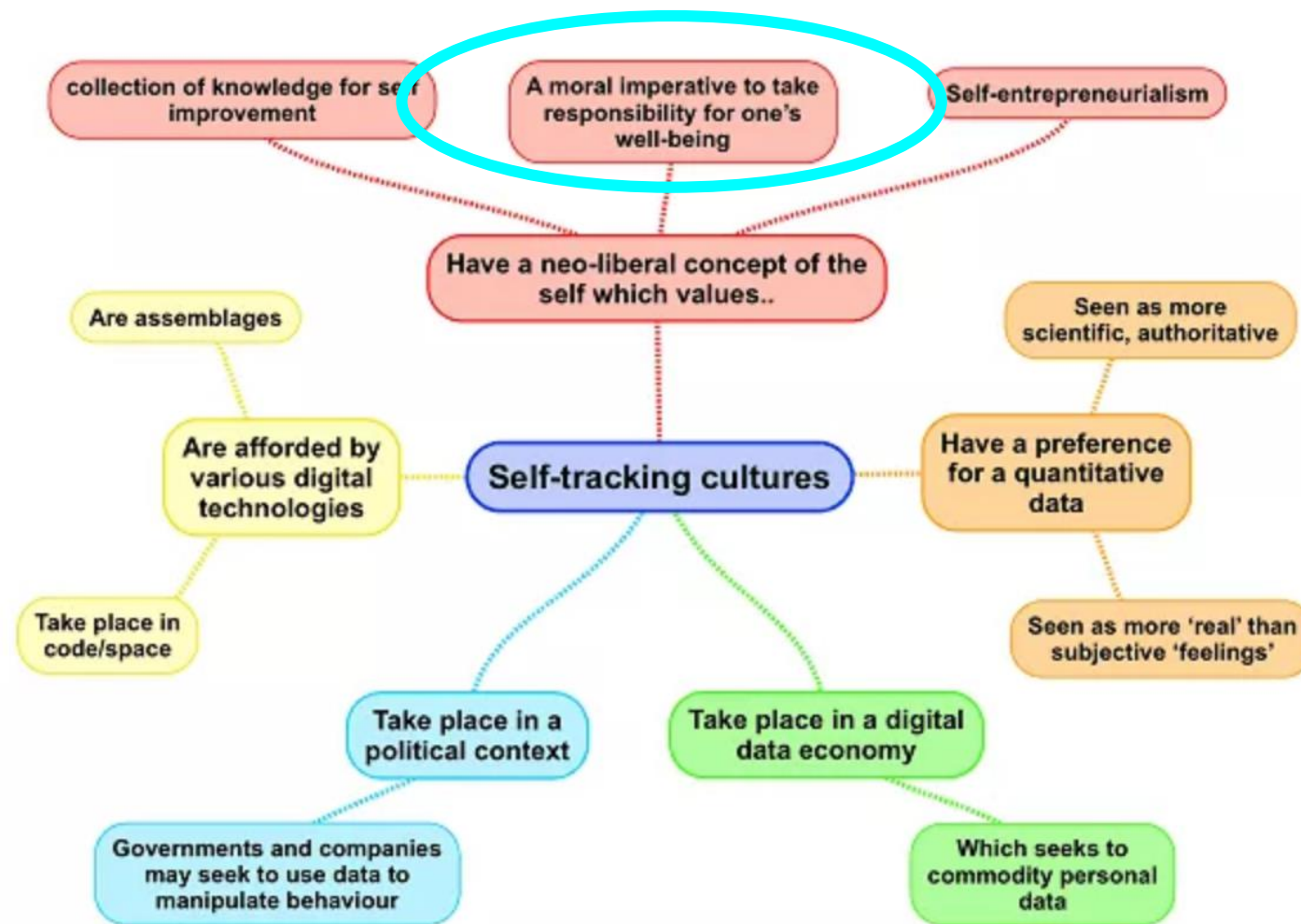
Responsibility – Option 2 (Decision to Use)

Original Research

**Health professionals
of wearable**

Angus Watt¹, Katherine

“[S]ome part
responsibility
the problem”



Lupton, 2016, The Quantified Self

of autonomy

Responsibility – Option 2 (Decision to Use)

- ▶ DTC m-health technology use most common among young, wealthy, white, college-educated individuals (Chandresekaran et al, 2020).
- ▶ DTC m-health technology expensive and beyond reach for many who are interested in using it (Holko et al, 2022).
- ▶ DTC m-health technology may be less accurate or non-functional in individuals with dark skin (Colvonen et al, 2020).
- ▶ Deeming individual praiseworthy for using DTC m-health technology and/or blameworthy for not using such technology, risks exacerbating existing racial and socio-economic discrimination.

Availability of Good Options

- ▶ Efficacy
 - ▶ Cost
 - ▶ Adherence
- ▶ Safety
- ▶ Privacy

Neuron

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Owning Ethical Innovation: Claims about Commercial Wearable Brain Technologies

Iris Coates McCall ¹, Chloe Lau ¹, Nicole Minielly ¹, Judy Illes ¹  

 TECHNOLOGY TO EMPOWER PATIENTS

Why People Stick With or Abandon Wearable Devices

Article • September 14, 2017

Glenn Fox, PhD, Shaun Garland, PhD, Andrew Keibel, MD & Leslie A. Saxon, MD

University of Southern California, Center for Body Computing

Healthy Desires

- ▶ Example: Automatic calorie-tracker
- ▶ Can drive disordered eating (Linardon & Messer 2019).
- ▶ Example: Sleep tracking
- ▶ *“The patients' inferred correlation between sleep tracker data and daytime fatigue may become a perfectionistic quest for the ideal”* (Baron et al 2017).
- ▶ For the unregulated DTC neurotechnology industry, furthering healthy behavior is only valuable so far as that is aligned with their profit objective.



Case Reports

<http://dx.doi.org/10.5664/jcsm.6472>

Orthosomnia: Are Some Patients Taking the Quantified Self Too Far?

Baron KG, Abbott S, Jao N, Manalo N, Mullen R. Orthosomnia: are some patients taking the quantified self too far? *J Clin Sleep Med.* 2017;13(2):351–354.

Empowerment

- ▶ Empowerment is a state a person is in with respect to a certain situation, in which five things are true of her:
 - 1) Knowledge
 - 2) Control
 - 3) Responsibility
 - 4) Availability of Good Choices
 - 5) Healthy Desires
- ▶ Narrative of empowerment is prevalent.

Empowerment_(self-perception)

- ▶ Empowerment(self-perception) is not a state but a *perception* of oneself as powerful or potent.
- ▶ Rappaport (1987): “psychological sense of personal control or influence”.
- ▶ Definition: An individual possesses empowerment_(self-perception) with respect to a certain situation, if she perceives there to be *good options available* to her, she perceives herself to have *knowledge* of these options, she perceives herself to have *healthy desires* with respect to these options, she perceives herself to have *control* over which of these options to bring about, and she perceives herself to be *responsible* for the respective action or actions.
- ▶ It is possible to perceive oneself as possessing a feature without actually possessing it.

Upshot

- ▶ If DTC neurotechnology at least sometimes engenders not empowerment_(state) but empowerment_(self-perception), then it is important to determine how prevalent that phenomenon is. Someone who is empowered_(self-perception) but not empowered_(state) is not in a position to bring about desired behavior change, despite feeling that they should be able to. Not only can this generate unreasonable expectations detrimental to health and wellbeing, it also places the burden of change on the shoulders of seemingly empowered individuals, when in reality, the conditions necessary for individuals to affect change are not met.

Thank you

References

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