



Safety, security, and responsibility: Managing incidental findings, adverse events, and privacy concerns in the use of commercial neurodevices



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BACKGROUND

Ethical concerns about privacy, incidental findings, and adverse events arise with the use of neurowearables. These concerns are in juxtaposition with claims of benefit in the \$12.2B dollar neurotechnology industry.

OBJECTIVE

Characterize industry pathways and policies for managing incidental findings and adverse events [1,2].

METHODS



- Semi-structured interviews.
- Conventional qualitative methods validated for reproducibility.

ACKNOWLEDGEMENTS



RESULTS

12 company representatives: 8 from recording device companies (e.g., EEG); 3 from stimulating device companies (e.g., tDCS); 1 from a company whose device does both (e.g., EEG+tDCS)

Few instances of incidental findings (n=1); few pathways to manage them (n=7)

Considerable interest

*It sparks particularly strong **debate** ... (Interview 1)*

Management Strategies:

- Formal strategies for managing incidental findings (n=0)
- Customer service processes (e.g., call centres, apps) used to respond to issues, including adverse events (n=10)

*Should we [...] suggest they go see their doctor because there's some **abnormal patterns** ... We're actually in the process of trying to make that decision... (Interview 9)*

Table 1: Major Themes Pertaining to Neuroprivacy (Adapted from [2]).

Data collection and management	The much bigger problem [than incidental findings] is the privacy problem [...] how do you reassure your users that their data is protected ... (Interview 6)
Ethics principles	... privacy is paramount and you're developing this with the end user's rights and autonomy as a guiding principle. (Interview 6)
Exceptionalism of brain data	[...] people are a little more personal about brain data ... (Interview 1)
International standards, policies, and laws	... privacy legislation in different jurisdictions has never kept up with technology. (Interview 12)

RECOMMENDATIONS FOR INDUSTRY

- Minimize data collection and increase data security.
- Standardize and make explicit incidental health finding and adverse event management procedures.
- Encourage regulatory standards about neurotechnologies for health and wellness.
- Support better harmonized international privacy standards.

CONCLUSION

Potential benefits of neurowearables will be challenged by risks of nondisclosure of findings of possible medical significance and violations of personal privacy if regulatory guidelines remain elusive and globally disjointed.

REFERENCES

- [1] Minielly et al., In: Bard & Hildt, *Ethical Dimensions of Commercial and DIY Neurotechnologies* (Elsevier 2020)
- [2] Minielly et al., *iScience* (2020)