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.

**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]).**

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


**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.

**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.