Standards for Neurotechnologies and Brain Machine Interface

Workshop at the Int. BCI meeting in Graz- Sept. 16 2019

Ricardo Chavarriaga (Organizer),
IEEE Standards WG on standards for BMI, Switzerland

Graeme Moffat,
Graeme Moffat, Chief Scientist & VP Ethics, Blueberry Technologies, Senior Fellow, U of Toronto

Zach McKinney,
Chair WG IEEE P2794™, Reporting In-Vivo Neural Interface research

Rupert Ortner,
g.Tec Medical Engineering GmbH, Austria

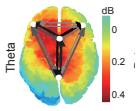
Lt. Kelliann Wachrathit,
Neuromodulation and Physical Medicine Devices , FDA, USA

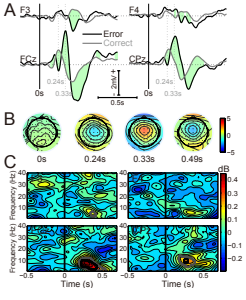
Emil Hewage,
Founder BIOS Health Ltd, UK

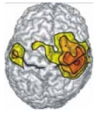
Luigi Bianchi,
Chair WG IEEE P2731™, Unified Terminology for BCI

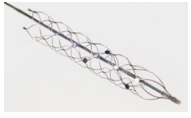
Carole Carey,
Chair IEEE EMB Standards committee.

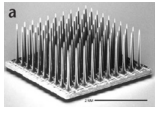
Decoding/processing

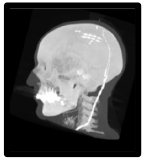








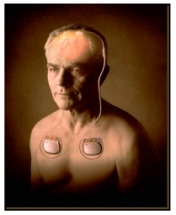




Sensing/Acquisition

AR/VR

Sensory feedback



Neurostimulation

Exo-skeletons

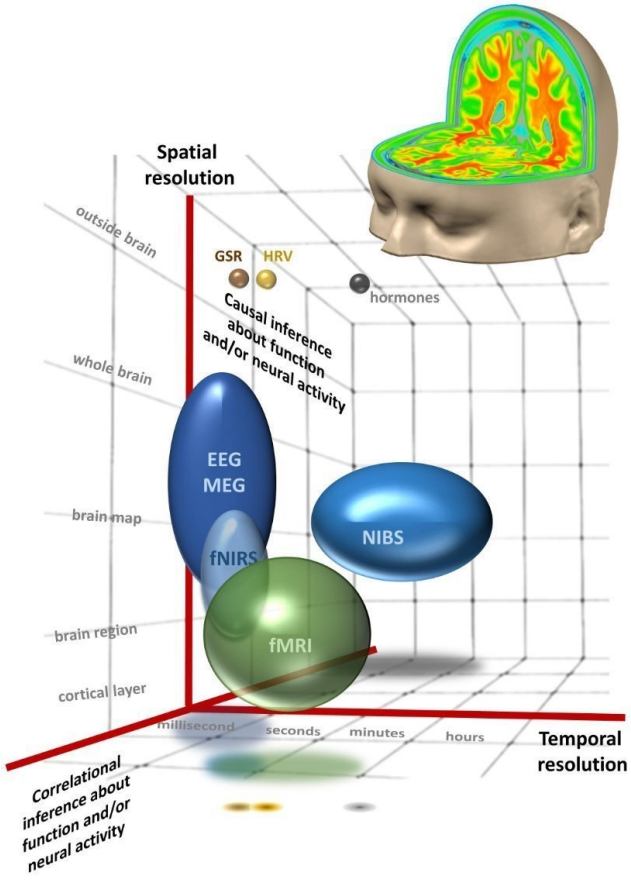
Rehabilitation

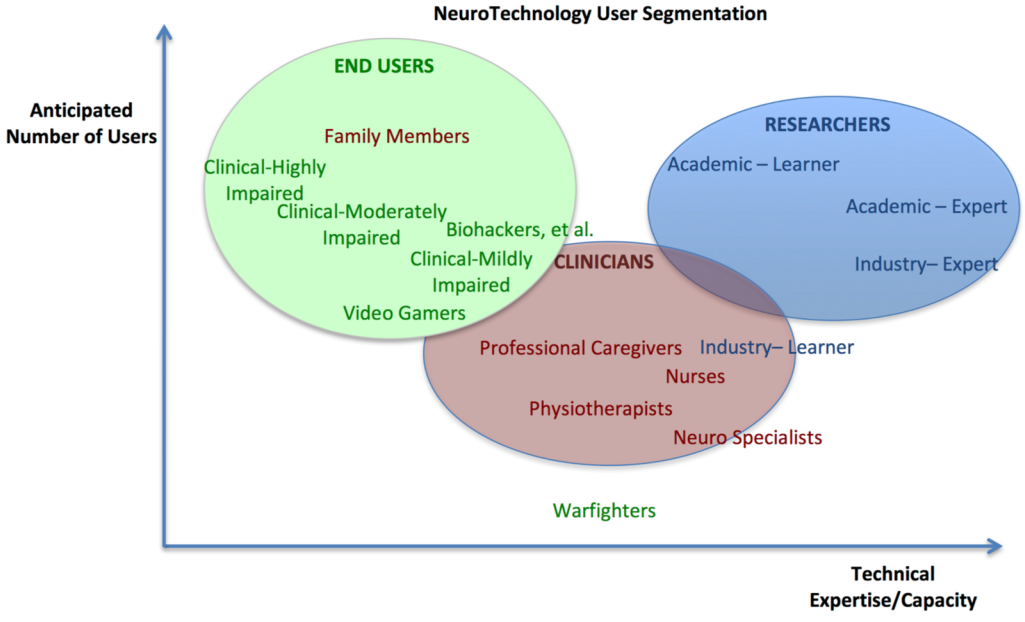
Gaming

Data storing/sharing

Automotive

Neurotechnologies: A tale of diversity





Neurotechnologies are part of a growing ecosystem…

- It comprises **clinical** and **consumer** applications
  - Researchers, developers and innovators can exploit synergies between them. Consumer applications can drive down prices also for clinical applications

- BCIs are composed of multiple sub-systems for:

  data acquisition | processing | actuation | feedback

- Interoperability becomes crucial while fulfilling requirements for

  reliability | safety | communication |

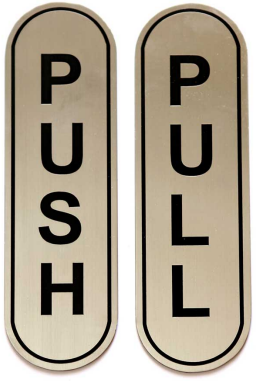
  | regulatory processes | biocompatibility | privacy

… needs for **standards** in the field

Standards: a tool for scientific rigorousity and responsible innovation

Tackling challenging societal problems
(mental health, aging population)

Dynamic rapid innovation,
economic sustainability



Threats of misuse (intended/unintended)
Data use, social inequality, neuroethics

Ensure safety, efficiency

These concerns are **common among multiple emerging technologies** (Big data, IoT, AI)

Change towards a framework of prospective standards**. Let standards evolve** alongside with technology

Standardization process is **not only a matter of the industry**. Rapid development requires them to be considered at the research stage

Not all ideas are ripe for commercialization, ready to be standardized. But late is too late

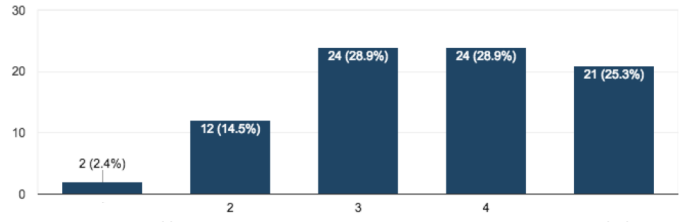
Continuum between community guidelines, good practices and technical standards

Survey on Standardisation

Online survey May-Aug 2018 (N=83) https://goo.gl/forms/kUAihLfO98H3mJHB2.

How motivated you are in participating in the development of standards for BMI/Neurotechnologies?

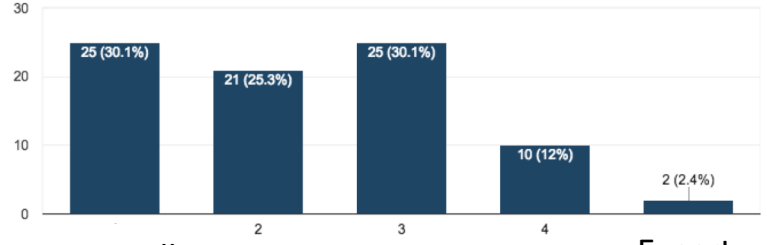
83 responses



Not at all — Highly interested

How familiar are you with the process for developing a standard?

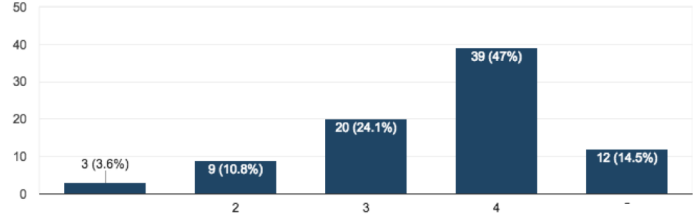
83 responses



Not at all — Expert

Do you think of standardisation as more of a hindrance or promoter in the development of new technologies?

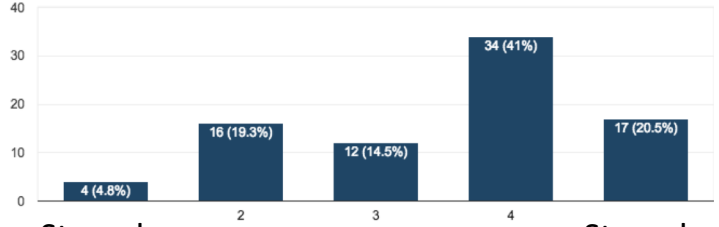
83 responses



Strong hindrance — Strong promoter

Do you think health-oriented consumer products should follow similar standards as clinical products

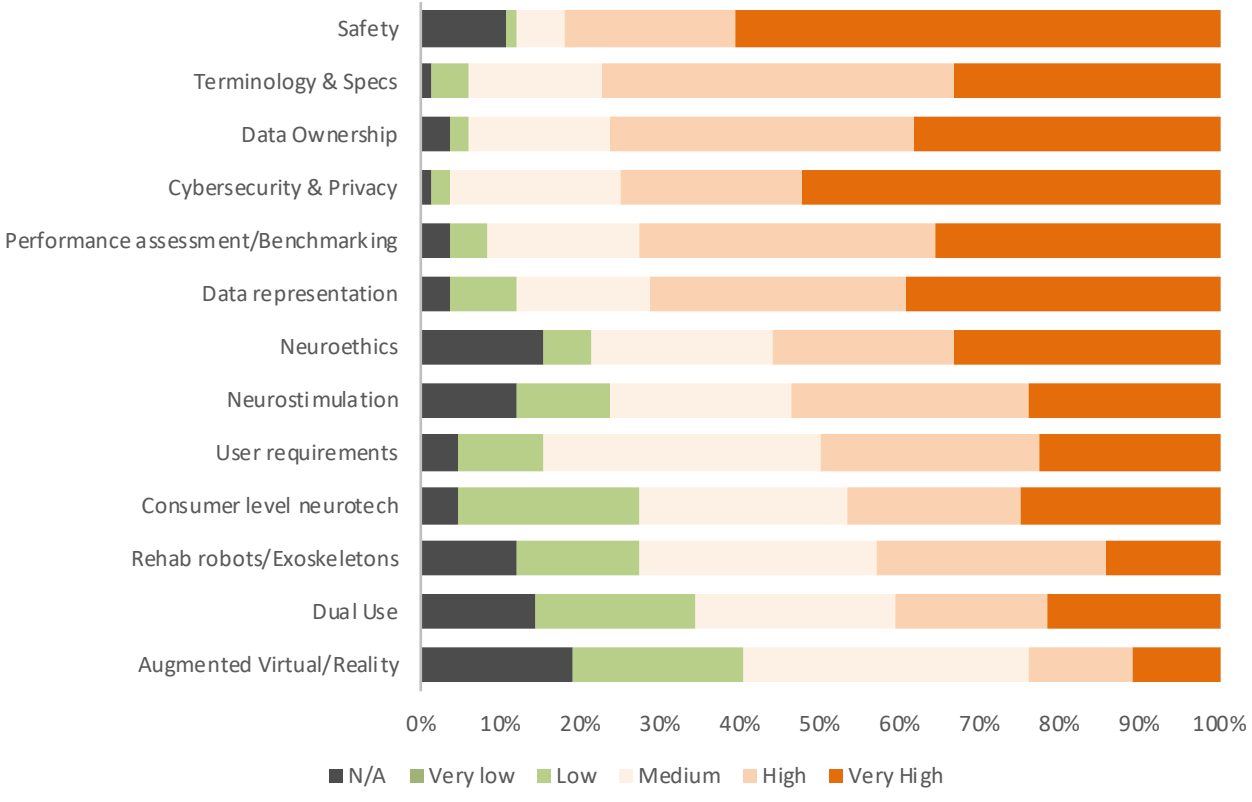
83 responses



Strongly disagree — Strongly agree

Standardisation Priorities - Survey

Online survey May-Aug 2018 (N=83) https://goo.gl/forms/kUAihLfO98H3mJHB2.



Status and priorities

	Sensor Technology	End-Effectors	Data management	User requirements	Performance Assessment
Current situation	Established standards for electromagnetic safety, biocompatibility	Electrical/Mechanical safety Standard for lexicon for prosthetics Ongoing development on wearable robotics	Community driven standards EEG consumer devices	Human factors Medical design device control	Community driven standards and good practice Benchmarking efforts (case-by-case)
Standardisation Priorities	Interoperability	Terminology Communication Shared control	Cybersecurity/Privacy Interoperability between data management platforms Meta data Closed-loop data	User needs healthy and less severely affected patients User needs (beyond direct user. e.g., caregivers, familiy) Benchmarking of user needs fulfilling	Closed-loop evaluation Assessment of clinical use

10h00-10h10	Welcome and introduction
10h10-10h25	**Status and priorities for BCI standardisation** *Ricardo Chavarriaga*, Chair IEEE Standards working group on neurotechnologies
10h25-10h40	**Creating open standards for commercialisation** *Emil Hewage*, Founder BIOS Health Ltd, UK
10h40-10h55	**Five current challenges for BCI standards** *Rupert Ortner*, g.Tec Medical Engineering GmBH, Austria
10h55-11h10	**Standardisation of neural interface reporting** *Zach McKinney*, Chair WG IEEE P2794™
11h10-11h30	Panel discussion and floor questions
11h30-11h45	**Developing a Standard Unified Terminology for Brain-Computer Interfaces** *Luigi Bianchi*, Chair WG IEEE P2731™
11h45-12h00	**Standards for consumer-oriented neurotechnology (Temptative title)** *Graeme Moffat*, Chief Scientist & VP Ethics, Blueberry Technologies, Munk School of Public Policy, U Toronto
12h00-12h15	**FDA draft guidelines implanted BCIs** *Lt. Kelliann Wachrathit*, Neuromodulation and Physical Medicine Devices , FDA, USA
12h15-12h45	Panel discussion and floor questions
12h45-13h00	**Developing standards: Procedures and how to participate** *Carole Carey*, Chair IEEE EMB Standards committee.
13h00-13h45	Group discussion
13h45-14h00	Wrap-up and conclusions

Industry Connections Activity
Neuro technologies for Brain-Machine Interfacing

Please contact Ricardo Chavarriaga for more information

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