Reporting Standard for *in vivo* Neural Interface Research (RSNIR) to Accelerate Interoperability, Clinical Integration, and Commercialization of NeuroTechnologies

IEEE Systems, Man, & Cybernetics Conference 2019
Workshop on Standardization of Neural Interface Research
Sun, Oct 6, 2019

Zach McKinney
Working Group Chair, WG P2794, IEEE Standards Association,
Member, IEEE Engineering in Medicine & Biology Society (EMBS)
Post-Doctoral Fellow, The BioRobotics Institute, Scuola Superiore Sant’Anna (Pisa)
Workshop Overview

I. [11:00-12:45] Presentations: 10-12 minutes + 2-3 minutes Q&A each
   - Zach McKinney (Scuola Superiore Sant’Anna, Pisa)
   - Sumit Soman (Centre for Development of Advanced Computing (IN))
   - Rodolfo Fiorini (Polytechnic University of Milan)
   - Carole Carey (C3-Carey Consultants; IEEE EMBS Standards Committee)
   - Luigi Bianchi (University of Rome, Tor Vergata)
   - Jorge Cardoso (iMM Lisboa)
   - Jean-Louis Divoux (AIMD)

II. [12:45-13:00] Panel Discussion & Q&A
   - Needs & use cases for neurotechnology standards
   - Current barriers to development & adoption of neurotech standards
   - Strategies for accelerating neurotech stds development & adoption
Some Questions to Consider…

• Which actors, phases, and aspects of the neurotech research should standards aim to address?
  ➢ Specific needs and use cases for neurotech standards?

• What aspects of neurotech system/study design must be clearly reported to make the corresponding literature thoroughly interpretable and reproducible?

• What are the key barriers to standards development and adoption?

• What strategies can accelerate stds development & adoption?
  ➢ Individual and organization-level
  ➢ Regulatory & Infrastructural Level
Overview (Objectives)

• WHY Standardize?
  ➢ Rationale for standardization of neural interface research *reporting*

• WHAT to Standardize (next)?
  ➢ Intro and scope of IEEE Working Group P2794 (RSNIR)

• WHO Are we?
  ➢ WG P2794 membership and constitution

• HOW are we doing it?
  ➢ WG Strategy and Segmentation
  ➢ Current & Upcoming Activity
  ➢ *Input: How can you contribute?*
WHY Standardize?

…what’s the need? … what’s the value?

→ to enable INTEGRATION!

1. Interoperability (Functional Integration)
   - Ecosystem of “plug & play” devices and systems
   - Functional/integrative neuroscience
   - Multimodal rehabilitation

2. Assimilation (Information Integration)
   - Personalized & evidence-based medicine
   - Systems neuroscience & multimodal rehab

3. Translation (Clinical & Commercial Integration)
   - Demonstration of value via rigorous validation and reporting
Innovative Research & Development Process

Knowledge

Hypothesis

Experimental Design → Execution

Engineering Innovation

Data Analysis & Interpretation

REPORTING (Publication)

Commercial Device Development

Clinical Practice

(Scientific Impact + Funding)

IEEE WG P2794: Reporting Standard for in vivo Neural Interface Research (RSNIR)
WHY Standardize Reporting?

→ High-quality, high-impact publications are a primary de facto objective for neurotechnology researchers

→ Rigorous experimentation and reporting is the way to validate, communicate, and translate the value of neurotechnology
  
  - To scientific reviewers
  - To funding agencies
  - To (medical) device regulators
  - To healthcare payers
  - To device users (doctors, clinicians, patients)

→ Therefore, reporting standards can establish a broad incentive scheme for both neurotech researchers and device developers
  
  - For researchers: via scientific publication review
  - For commercial developers: via regulatory body review
Intro: IEEE Working Group P2794: Reporting Standards for *in vivo* Neural Interface Research (RSNIR)

- **WG P2794 Officers**
  
  - **Chair:** Zach McKinney – Scuola Superiore Sant’Anna  
    (z.mckinney@ieee.org)
  
  - **Vice Chairs:** Dennis McBride – NeuroRx, Source America  
    Calvin Eiber – University of Melbourne
  
  - **Secretary:** Yu Yuan – Senses Global Labs & Ventures

- **Sponsoring Committee Representative:**
  
  - Carole Carey – C3-Carey Consultants, EMB/Std’s Com

- **IEEE Support Staff**
  
  - Tom Thompson
WG P2794 Affiliation

• **Sponsoring Society & Committee:** IEEE Engineering in Medicine & Biology Society/Standards Committee (EMB/Stds Com)

• **Outgrowth of IEEE Industry Connections Activity IC17-007:**
  **NeuroTechnologies for Brain-Machine Interfaces (NT-BMI)**
  o Scope of NT-BMI: provide summary & gap analysis of BMI landscape w. respect to standardization, as precursor for further BMI standardization
  o WG conception at BMI Standardization Workshop, BCI Society Meeting, May 24, 2018 -- Asilomar, CA (Chaired by NT-BMI Leadership)

• **Additional Active Working Groups** originating from NT-BMI
  o P2731 – Standard for Unified Terminology for Brain-Computer Interfaces
  o P2725.1 – Standard for Microwave Medical Imaging Device Safety
IEEE WG P2794: Reporting Standard for *in vivo* Neural Interface Research (RSNIR)

- **WG Roster:** 53 Total Participants
  - 37 Members (25 Voting, 12 Non-Voting)
  - 13 Observers + 3 IEEE Staff

- **Distribution of WG Participant Affiliations:**
  (participants may list more than one affiliation type)

  ![Bar Chart]

  - Academic (or non-profit) Research Lab: 36
  - Commercial Entity: 14
  - Standardization Organization: 6
  - Neural Interface End User: 5
  - Other: 4
  - Scientific Publication: 4
  - Private Foundation or Advocacy Group: 2
  - Healthcare Provider: 2
  - Open-Source Platform Provider: 2
  - Regulatory Body: 2
  - Public Funding Agency: 1

→ *Seeking to increase neurotechnology stakeholder diversity!*
AIMS OF STANDARDIZATION of neural interface research reporting:

1. **Primary (direct):** Improve the transparency, reproducibility, and mega/meta-analyzability of *in vivo* neural interface research (*human and animal*)

2. **Secondary (indirect):** Facilitate convergence towards rigorous standard experimental methodologies, outcome measures, and easily aggregated neural data representation structures (file formats, etc.)

3. **Tertiary (downstream):** Promote increased interoperability and clinical capability in the field of neurotechnology

[Reference: IEEE Project Authorization Request (PAR) 2794, §5.4 – Purpose]
Working Group Scope: Reporting Standard

Official Scope, defined by IEEE Project Authorization Request (PAR) 2794:

“This Standard defines the essential characteristics and parameters of in vivo neural interface research studies (including clinical trials) to be reported in peer-reviewed scientific and clinical literature, including both minimum reporting standards and best-practice guidelines.”

NOT Included in Scope (… potential downstream effects…)

• Specification of Neural Interface system design features, configurations, or performance parameters
• Explicit requirements on experimental methodology
• Use of specific neurodata file formats and data structures
Challenge #1: How to Define “Neural Interface” (NIx), as addressed by our Standard?

- not a currently recognized standard term — **could be interpreted to include:**
  - Brain-Computer Interfaces: EEG, ECoG, Intracortical Arrays
  - Peripheral Nerve Interfaces: invasive, non-invasive
  - Neuroimaging: fMRI, fNIRS, MEG, optogenetics
  - Indirect Neural Modalities: electromyography (EMG), electrooculography (EOG), etc.
  - *Neuromodulation*: DBS, spinal cord stimulation, peripheral nerve stimulation, focused ultrasound… FES??
Neural Interface Taxonomy: *Multi-Dimensional*!

\[ \{ \text{NI} \} \text{ The set of all neural interfaces} \]
Challenge #1: How to Define “Neural Interface” (NIx), as addressed by our Standard?

- Fundamental Balance (Tension) between:

1. **Specificity**: Want to create a standard with enough technological specificity to be useful to neurotech researchers & developers; AND

2. **Breadth**: Want to create a Standard that serves as a framework enabling coherent communication between experts (engineers, researchers, clinicians, etc.) in diverse fields of expertise!

- “Looking for a system to describe and manage complexity”
WG P2794 – Scope of Standardization

Challenge #1: How to Define “Neural Interface” (NIx), as addressed by our Standard?

→ Working Solution: distinguish between 2 (3) different domains of scope:

1. The **Physical Interface (Technological) Scope**: the set of all technologies to which our Standard may apply

2. The **Application Scope**: The set of all (research) uses of NIx technology to which our Standard may applies

3. (TBD…) **Epistemological (Informational) Scope**: The set of all aspects of NIx research to which our Standard applies
WG P2794 – Scope of Standardization

Physical Interface (Technological) Scope – As defined thus far by WG:

- **Definitively Include:** “systems that record or modulate *biological signals directly in neural tissue*”

- **Potentially Include:** “systems that record or modulate *biological signals of neurological origin*” (including EMG, EOG, etc.)

- **Exclude:** systems measuring *motor output* (e.g. IMUs, eye tracking, MoCap) that don’t directly measure *biosignals*
WG P2794 – Scope of Standardization

(Potential) Epistemological Scope (*to be refined…*):

- Experimental methodology and outcome measures
- Recording configurations and parameters
- Cognitive aspects & ontology
- Signal processing, neurodata feature extraction, and standard file formats
- Data analysis and statistical analysis methods
- Data aggregability and shareability
- Data security?
- NeuroEthics?
QUESTION relating to Epistemological Scope:

To what extent can and should the reporting requirements and guidelines established by our Standard be formulated to influence experimental methodology and NIx system design/performance themselves?

DECISION: Our Standard will remain officially agnostic regarding experimental methods, choice of outcome/performance measures, NIx system design, and NIx configuration parameters.

- …rather, we will simply specify the aspects of methodology and NIx system design/configuration that must be reported in 2794-compliant documents
- … prescriptive requirements will be left to the resulting scientific & neurotech community consensus, and the policy decisions of scientific publishers and device regulators.
WG P2794 – Scope of Standardization

→ **Benefits of “Design & Methods-Agnostic” Policy:**

1. **NO CONSTRAINT on Innovation**
2. Minimize barriers to adoption & adherence
3. **Improved longevity of Standard: applicability (& extensibility) to new devices and methodologies not yet in existence**
4. **Accelerate discovery & innovation via improved quality of experiments, results, and information sharing**
5. **Accelerated commercial development (via regulatory approval) via rigorous, development-aligned research practices**
   - Minimize project failures due to flawed study design or execution
   - Reduce barriers to translational research & commercial development
Challenge #2: How to segment our WG into working sub-groups?

- Sub-group segmentation would ideally (but not necessarily) reflect the organization of the final standard…

- Vertical (technology-based) vs. Horizontal (application or research aspect-based) Hierarchy?
WG Segmentation … via NIx taxonomy?

\[ \{ \text{NI} \} \text{ The set of all neural interfaces} \]
Challenge #2: How to segment our WG into working sub-groups?

- Sub-group segmentation would ideally (but not necessarily) reflect the organization of the final standard…

- **Vertical** (technology-based) vs. **Horizontal** (application or research aspect-based) **Hierarchy**?
Challenge #2: How to segment our WG into working sub-groups? ...

- **SOLUTION:** Segment WG based on distribution of member expertise

- WG Member expertise survey:
WG P2794 – Group Organization (Strategy)

Challenge #2: How to segment our WG into working sub-groups? ...

➢ **SOLUTION:** Segment WG based on distribution of member expertise
  → 6 sub-groups total: 5 technology-oriented (“vertical”) groups:
    o EEGs for BCI
    o Invasive BCIs (intracortical, ECoG, spinal)
    o Peripheral Neural Interfaces
    o Neuromodulation
    o Neuroimaging
  ...
  + **“Horizontal Integration” group**, to coordinate & harmonize others

➢ Plan to develop Standard with a **modular, layered** structure, that
  enables parallel **indexing of requirements** in a 3 domains of scope
  (tech-based, application-based, research epistemology-based)
YOUR INPUT ENcouraged!! … and thank you!

• Via direct WG Participation
  ➢ seeking to increase NeuroTech stakeholder diversity
    o scientific publishers
    o (medical) device regulators
    o … + clinicians? … end-users?

• By sharing your experience: First-hand descriptions of use cases for our Std and testimonials of its potential value to you
  ➢ How would the proposed Standard improve your NeuroTech research, development, or quality assurance capabilities?
  ➢ How has the lack of standardization in this area presented a challenge or barrier to your past efforts?
Current & Future WG Activity

• **Physical Interface-Oriented (“Vertical”) Groups**: Generate list of epistemological aspects to be reported, to make the Standard useful

• **Horizontal Integration Group**: Inventory and gap analysis of existing reporting standards, best-practice guidelines, and initiatives
  - Clinical trial and meta-analysis reporting guidelines & initiatives (CONSORT, FAIR, PRISMA, EQUATOR, etc.) re: NeuroTech specificity
  - Neurodata-specific standardization initiatives: Neurodata Without Borders, INCF, COBIDAS, Brain Imaging Data Structure (BIDS), NeuroImaging Data Model (NIDM)
  - Standard data structures & file formats – e.g. XDF, HDF5
  - Open source platforms & tools for Neurotech interoperability – e.g. OpenBCI, Lab Streaming Layer, BCI2000, OpenVIBE
  - Other NeuroTech Stds Working Groups – eg. IEEE P2731 (Unified BCI Terminology)
  - Clinical Neurophysiology Data and Electronic Health Record formats? – e.g. MEF3

➢ **… then develop our Standard to address the gaps!**
Current & Future WG Activity

• Upcoming WG-Related Events
  • Next Teleconference: Wed, Oct 23 – 15:30-17:00 CET (9:30-11:00 EDT)

    ➢ To learn more, provide input, or participate:
    ➢ RSNIR public web page: https://sagroups.ieee.org/2794/
    ➢ Direct Contact: z.mckinney@ieee.org; y.yuan@ieee.org