“Patients’ Needs”

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Not patients, consumers

- People-first. ‘Nothing about us without us’
  - Drawn from recent community presentations

- Introductory: not BCI or modularity specific, but relevant

- People are getting on with their lives. Becoming a research subject/patient again has big implications
  - Advocate/funder comment at the end

This document presents our Disability Action Plan.
Ability/disability concepts, language

World Health Organization “ICF”
International Classification of Function, Disability and Health

- Used to frame discussion of abilities, burden of disability
- Trial outcomes must address **clinically meaningful changes**
Burdens on consumers

1. **Habilitation** – staying healthy, return to work, school…
2. **Trials** – becoming a *subject* in any kind of study
   - Becoming fully informed before consenting
     - Investigating and understanding options/invasiveness
     - Pre-training, conditioning surgery (e.g., tendon transfer?)
     - Effector equipment costs (exoskeleton, prosthetic)
   - BCI *and/or staged module* implant surgery/recovery (?)
   - Training, assessment &/or follow-up
3. **Using the BCI** – back in one’s real life(?)
   - Time: don/doff(?), reprogramming, training
   - Aesthetics: independence; longevity, battery life
   - What other activities (or medical options) does it limit?
   - *When will it leave the lab? Increase my independence?*
Consumers are eager for implementation

PRAXIS, April 2016 (Jen French & Kim Anderson-Erisman)

• “’If you think education is expensive, try ignorance’… And try disability!”
• “Can you convince me? Can you involve me?”
• “Researchers are stuffing the interventional pipeline at entry… only a trickle comes out. I’ve had my implanted standing system for 17 years and it is still experimental.”

NIH rehabilitation meeting: Same Sky Project participants

• Want: app-support on our phones; invisibility; automaticity; executive function/reminders; interoperability
• Kids don’t want to stand out unless they choose to make a fashion statement (e.g., LiveScribe pen)
Consumer input: prosthetic arm users

DARPA Haptics Meeting – Neuroprosthetics

• It has to WORK, be dependable, be durable
• It should be part of one’s own body
  – “Suddenly I was right-handed again”
• High cognitive demand is a no-go
  – “I won’t use it if it slows me down”
• Once you have the functional improvement – you want to improve on it, not lose it
  – Need to be able to depend on it to work smoothly
  – Must work in the real world better than alternatives

The list goes on, but included a willingness to test early generation tech, hoping to help improve end-products and ultimately benefit from those
Design advice

• Tech should be integrated into living life, adaptive, personalized, and updatable
  – Last two are particularly relevant to modularity

• Closed loop, implanted systems
  – Intuitive patient controller/interfaces are evolving rapidly
  – Acceptance will be higher if not waiting for next great thing

• Assess unmet needs (wisdom of Tim Denison)
  – “It’s about making people’s lives easier – ‘not built by engineers for engineers’”
    • “Ask: what simpler alternatives are there?”
    • Perfect is the enemy of the good – delays cost the consumer
  – “Don’t just listen to what they say, watch what they do”
    • Ongoing tests in people and every day use will drive design
Risks consumers care about

- What function will I lose? For how long?
- What if I lose control, fall (cost of errors)?
- Can I walk and chew gum (attention burden)?
- Sufficient walking speed, endurance
  - Can you really leave the wheelchair behind? Would you?
- Risk of progressive musculoskeletal strain? (overuse)?

Consider how adding BCI helps or hinders this consumer
  - Tim again: “Need system-level risk analysis”
Targets and priorities

Priorities

• Wireless, unobtrusive
  – Risk-tolerance for implanted devices varies
  – Depends on what function could be lost; is MRI still possible?

• Personalized
  – Improve whatever level of arm/hand function is left
  – Did upper / lower motor neurons survive? Sensory tracts?

• Can’t use grip without reach or step w/o stable trunk
  – These functions probably require interacting modules, with system-wide consideration of control-burden on user

• Once one function is restored, we will want more
  – Ditto for system upgrades, replacement
  – Requires modular designs, coordinated prescription
The up-side: willingness to contribute

- Burdens are balanced by motivation/altruism
  - *Modularity, standardization could speed approval, allow use of relevant data from early trials/technologies*
  - Need agreement (and funds) to support long-term follow-up. What assessment is needed? What continued tech support?

- It is **unethical** to unnecessarily duplicate human testing
  - *Standards for comparability of data as well as components are needed at research, regulatory and payer levels*
    - **The more standardized, shared and referenced the data are, the more value to all**
    - Use appropriate outcome measures, common data elements/structure

_Not accepting safety, durability, etc. from like-device trials and across relevant disabilities is a loss to everyone involved_
Two-way communication

Keep in touch with consumer needs
- We want to be kept informed of outcomes and progress
- Newly injured want to know lay-of-the land, honest assessment of the options
- All want to know what’s taking so long

Communicate across disciplines
- *Does modularity enhance portability to other disorders?*
- *What key safety issues are different between populations?*

Use the information
- Include Patient Reported Outcomes
- Engage therapists early
- Prioritize: user-friendly, independent use
Funding / advocacy goals and needs

• Want to accelerate and target, not replace gov’t support
  – Funders like Neilsen Foundation are not disorder agnostic –
    endowment came from a C3 quad
  – Willing to collaborate, but if it’s approved for a different disorder
    will there be motivation/requirement to deploy it in “my” disorder?

• We can rally community to support recruitment, ensure honest messaging
  – Prioritize leveraging data, sharing progress, building consensus

• Altruism wears thin
  – Science-for-knowledge-sake
  – Coolest tech – not the goal
  – Push to implement in the real world
Thank you!