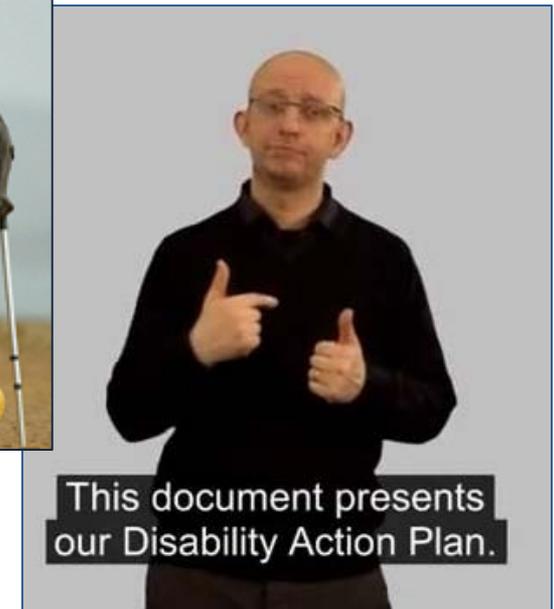


“Patients’ Needs”

Naomi Kleitman, PhD
Craig H. Neilsen Foundation

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

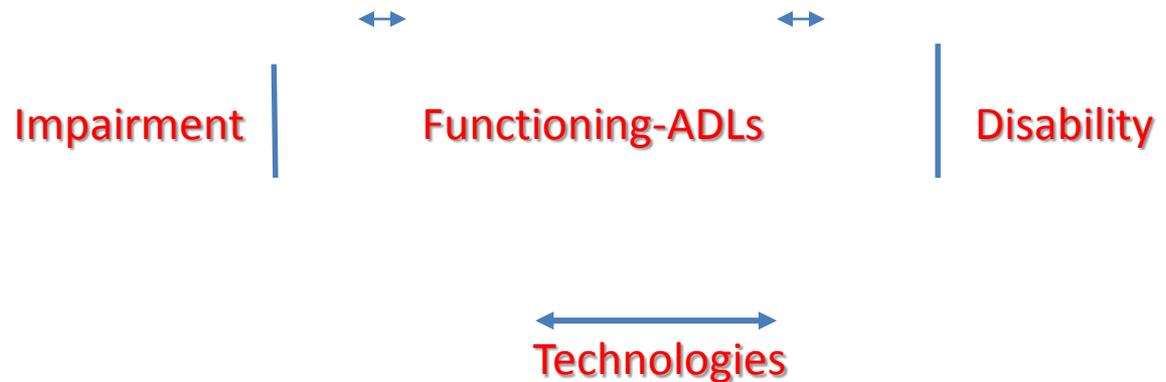


Ability/disability concepts, language

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.”

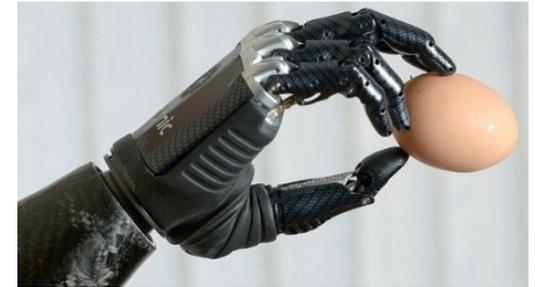
NIH rehabilitation meeting: Same Sky Project participants

- 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

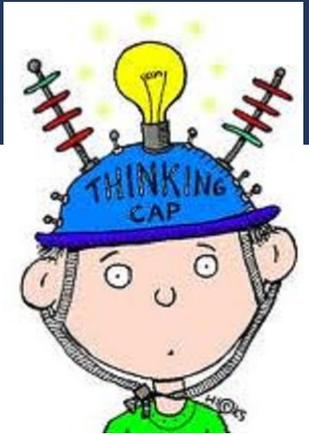
- What function will I lose? For how long?
- What if I lose control, fall (cost of errors)?
- Can I walk and chew gum (attention burden)?
- Sufficient walking speed, endurance
 - Can you really leave the wheelchair behind? Would you?
- Risk of progressive musculoskeletal strain? (overuse)?

Consider how adding BCI helps or hinders this consumer

– *Tim again: “Need system-level risk analysis”*



Targets and priorities



Priorities

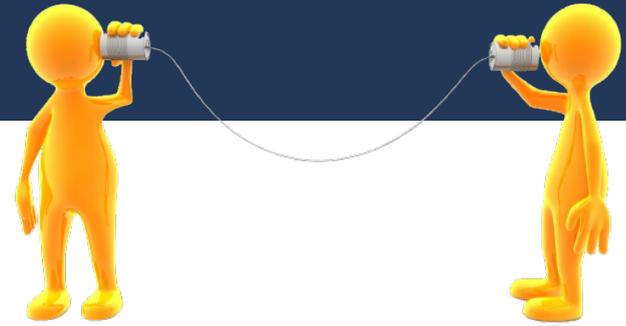
- Wireless, unobtrusive
 - Risk-tolerance for implanted devices varies
 - Depends on what function could be lost; is MRI still possible?
- Personalized
 - Improve whatever level of arm/hand function is left
 - Did upper / lower motor neurons survive? Sensory tracts?
- Can't use grip without reach or 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~~
 - ~~Cooler tech~~ – *not the goal*
 - *Push to implement in the real world*



Thank you!

