A Risk Assessment and Mitigation Approach to Ethically Addressing and Guiding Use of Emergent Neurotechnologies

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Domains of Use

- **Clinical**
  - Medical
    - Neurology/Neurosurgery
    - Psychiatry
    - Rehabilitation
    - Pain Medicine/Anesthesiology

- **Para-clinical**
  - Occupational
    - Training
    - Performance
  - Military
    - Operator Optimization
    - Intelligence

- **Public**
  - Educational
  - Wellness
  - Lifestyle (Communications)
  - “Entertainment” (Gaming)
The Good, the Bad, ....and the Ugly

- **Good**
  - Diagnose and cure/treat neuro-psychiatric disease
  - Facilitate/improve neuro-cognitive functions
  - Improve quality of life

- **Bad**
  - Misunderstood application
  - Inapt use
  - Distributional asymmetries

- **Ugly**
  - Intentional mis-use (of information and capabilities)
  - Neglect of analysis, precaution, preparation
Neuroethico-legal Issues & Risks

Technology-focal
- Intersecting unknowns
- Capabilities, limitations
- Validity, viability of use
- Runaway and Wexelblatt effects

Social
- Inviolability of “mind”/“cognitive liberty”
  - “Reading minds”
- Autonomy: “Mind control”
- Awareness, understanding, consent
- Treatment/protection/enhancement
- Justice: Provision/access
- Informed Consent
- Dual-use
Neuromodulation Superspeedway

- Multiple lanes
- Multiple entries
- Rapid pace
- Competitive
- Big Prizes
- Not without risks...
ON-RAMP

Operational Neuroethical Risk Assessment and Mitigation Paradigm (from Giordano, 2015; 2016 ©)

6-R Approach

- Responsibility
- Realistic Assessment: of the neurotechnology
- Research: evaluating use/effects-in-practice
- Responsiveness: to burdens and deleterious effects
- Revisions: in technology and marketing
- Regulation: insure rigor in development and claims

Poses key questions

Framed within defined parameters
Preparatory Neuroethics Paradigm

Any Consideration of Using Neuroscience and Neurotechnology (neuroS/T) Should be Informed by...

6-W Questions:

- **What** neuroS/T are available for current use?
- **Why** is neuroS/T considered or advocated for use?
- **Who** will receive neuroS/T?
- **When** will neuroS/T be considered (algorithm/protocol)?
- **Where** will neuroS/T be administered (e.g.-hospital; clinic, school; worksite; home)?
- **Which** mechanisms will be in place for ongoing provision of services/resources?
Preparatory Neuroethics Paradigm

As Framed by...

6-C Considerations:

- *Capacities* and limitations of the neuroS/T
- *Consequences* incurred by neuroS/T on recipients, families, and society in the short, intermediate, and long-term
- *Character* of the research and recipient (e.g., patterns of cognition, emotion, and behavior) affected by neuroS/T
- *Contexts* of need and value that influence use of neuroS/T
- *Continuity* of research and clinical care
- *Consent* through provision most information possible
Audits

1. NeuroS/T
2. Neuroethics
3. Medico-social Views/Expectations of Both
4. Regulations and Policies
Que será...

• Use-in-practice *will* incur unanticipated/deleterious effects
• Does NOT necessarily proscribe use
• DOES obligate need for:
  – Rigorous monitoring
  – Continuing R/D
  – Clinical engagement
  – Revisable guidelines/regs
  – Neuroethical guidance
Moving forward...
Take Home Messages

Reflection, insight and prudence must be the stepping stone for all future acts of inquiry, invention and intervention...

“Measure twice, cut once”, for all too often, there is no turning back.
Additional Information


Contact

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