Neurodevices and the European Market

Rathenau Instituut

Outline

Case study on neurodevices and the EU market:

- The trend towards neuromodulation;
- The neurodevice market: some facts and figures;
- Three devices for neuromodulation: DBS, TMS and EEG neurofeedback;
- Some regulatory and governance issues of neuromodulation devices in the EU.

Case study: part of STOA project ‘Making *Perfect* Life’.

Neuromodulation

Growing trend:

- New molecular knowledge has not yet resulted in new, effective psychopharmaceuticals;
- Drugs not always succesful (stroke);
- Regulatory pathways for medical devices are both less time consuming and less costly than new drugs.

Market for neurodevices

Market for neurodevices is part of medical devices:

Estimated worth, globally (2010): USD 305 billion

Estimated worth, Europe (2010): USD 95 billion

Estimated worth of market for neurodevices,

globally (2010): USD 4 – 4.5 billion

annual growth: 18.6%

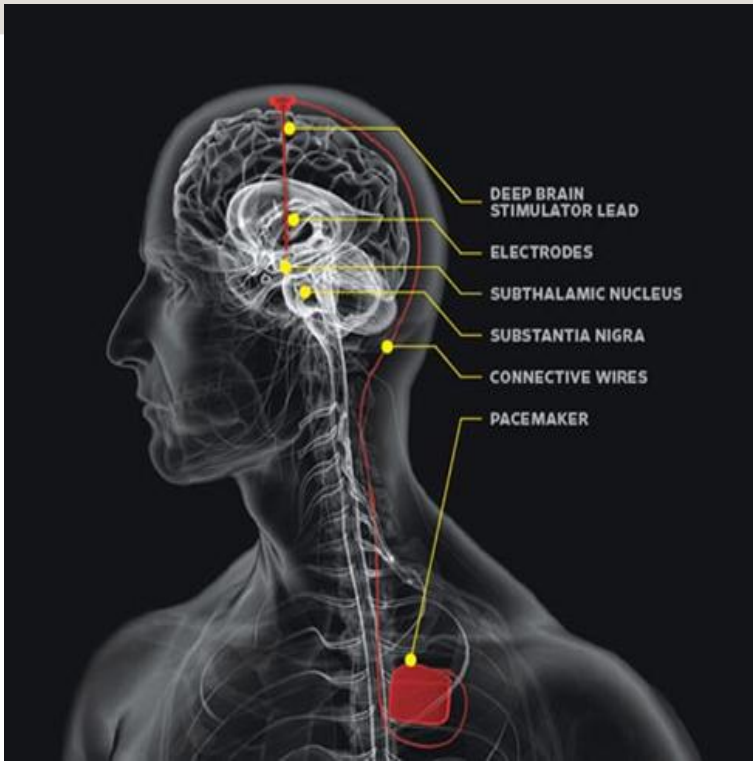
(Kalorama 2011, Sapiens 2011, INS 2011, Neuroinsights 2010)

Central question of our case study

If and how the growing market of neuromodulating devices poses new regulatory and governance challenges for the European Union with a focus on three neuromodulation technologies:

- deep brain stimulation (DBS);
- transcranial magnetic stimulation (TMS); and
- EEG neurofeedback.

Deep brain stimulation



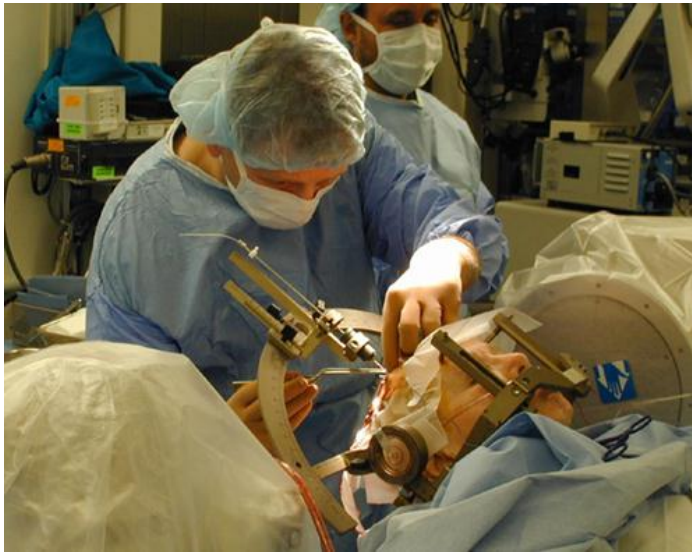
- Treatment, not a cure;
- CE marking for Parkinson's, essential tremor, dystonia, OCD, epilepsy, depression;
- 75,000 people have a DBS system (worldwide, 2011);
- 10-40% suffer from side effects.

Deep brain stimulation II

Socio-technical practice:

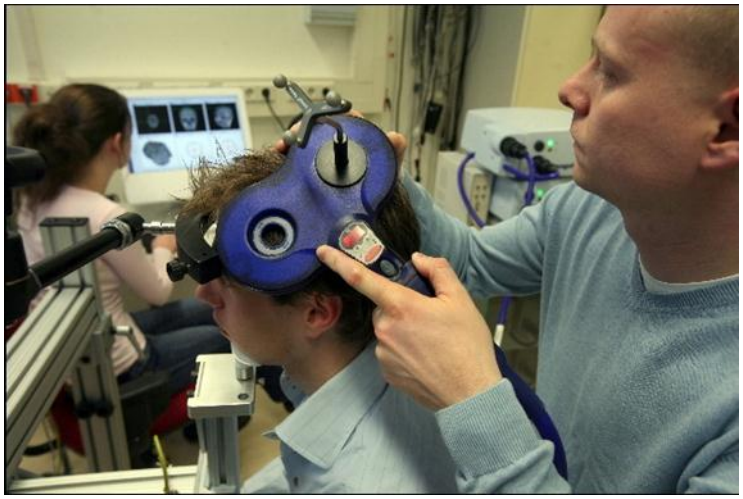
- In clinical practice since 1997;
- Offered in hospitals only;
- Shift from neurological

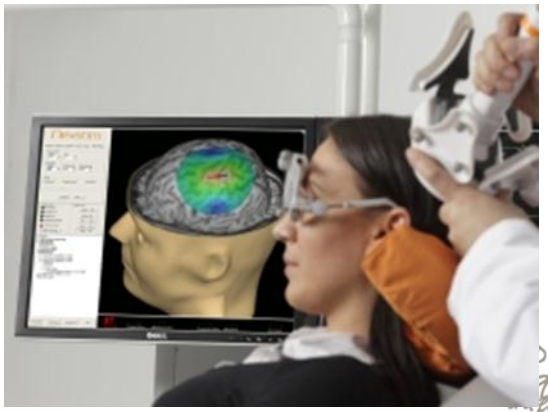
  to psychiatric indications;
- Reimbursement differs per EU country;
- No practice of non-medical use.



Transcranial magnetic stimulation

- Research, diagnostics and therapy;
- Therapy for severe depression;
- Experimental: mania, bipolar disease, panic disorder, schizofrenia, PTSD, addiction, and many more;
- Side-effects: relatively safe, unless in case of unskilled use.





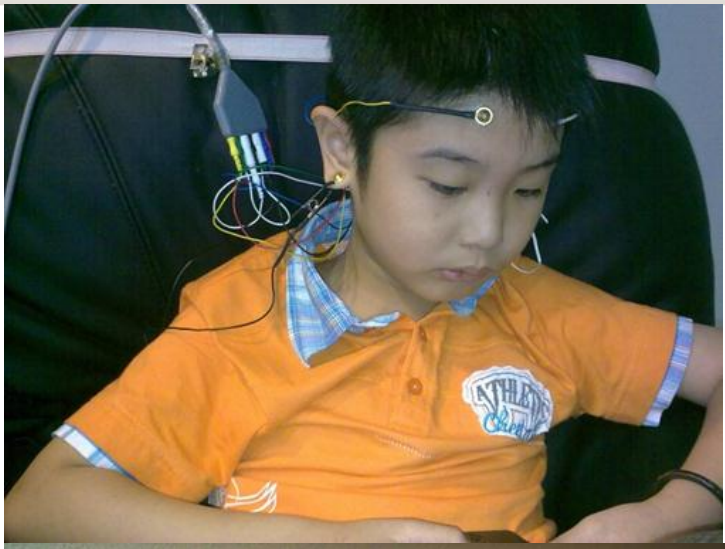
Transcranial magnetic stimulation II

Socio-technical practice:

- Established technology for diagnostics since 1985;
- Research and therapy upcoming;
- Therapy mostly offered in commercial private clinics;
- Not reimbursed for therapy in most EU countries;
- Non-medical use under investigation (i.e. enhancing sensory, motor and cognitive functions).

EEG neurofeedback

- EEG imaging technology assisted mental training
- Therapy for ADHD (efficacy not clear)
- Experimental: epilepsy, autism, learning disabilities, insomnia, and many others;
- Side-effects: relatively safe, unless in case of unskilled use.



EEG neurofeedback II

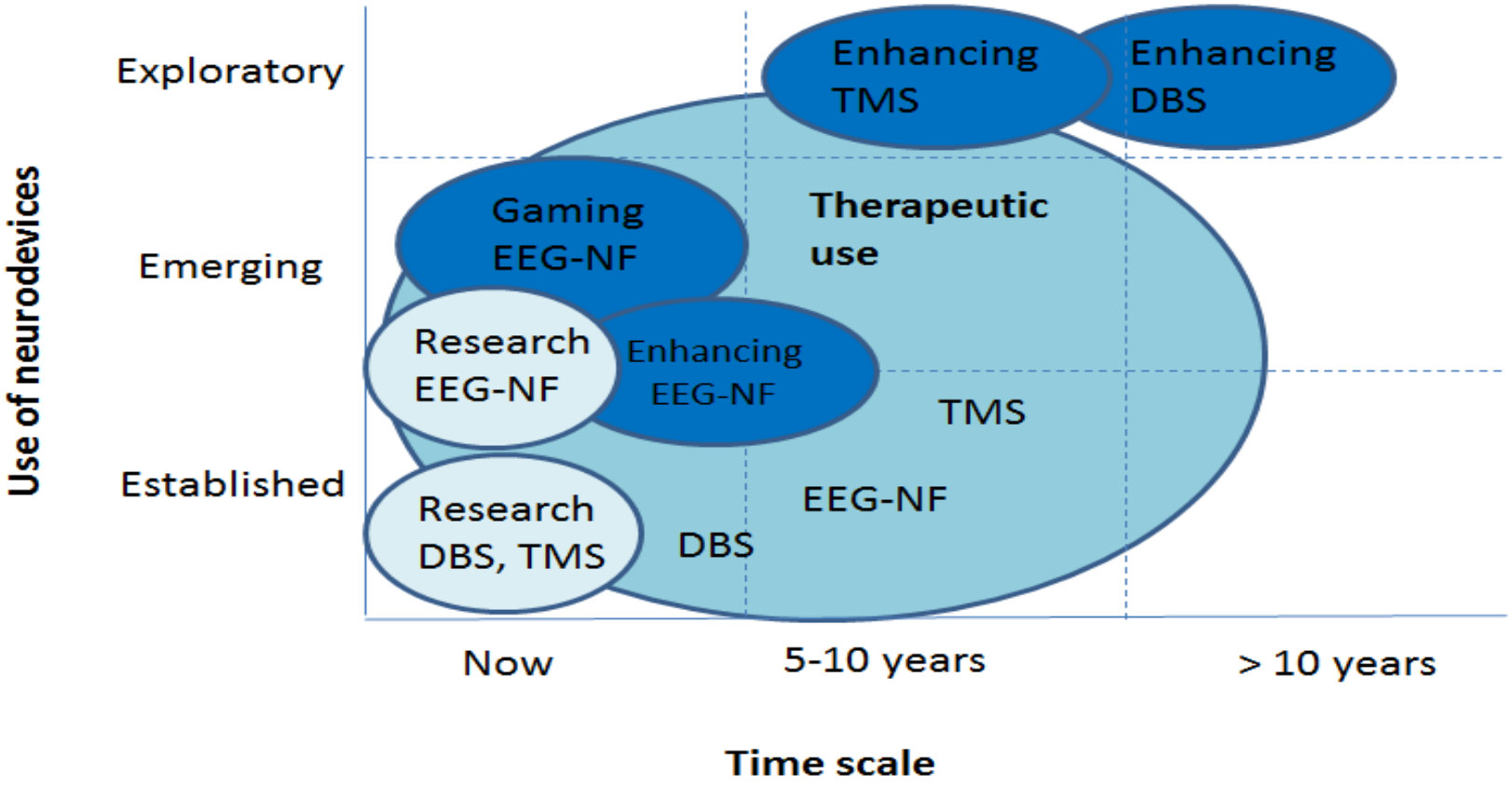
MINDMEDIA
NEURO AND BIOFEEDBACK SYSTEMS

Socio-technical practice:

- Existing practice since 1960s, as an ‘alternative therapy’;
- Offered in commercial private clinics;
- Not reimbursed in most EU countries;
- From clinic to lab;
- CE mark?
- Non-medical use: enhancement of cognitive, sports, artistic performance and gaming.

Thought Technology Ltd.

Timescale of neuromodulation practices



EU regulatory framework medical devices

- Medical Device Directive and Active Implantable Medical Device Directive:
  - concerned with safety of users (doctors and patients) and harmonizing requirements for bringing medical devices on the market to promote trade;
- CE mark affixed when in accordance with EU regulation for market entry;
- Different classification and regulatory routes to get a device CE marked:
  - Difficult to retrieve → no public accessible database.

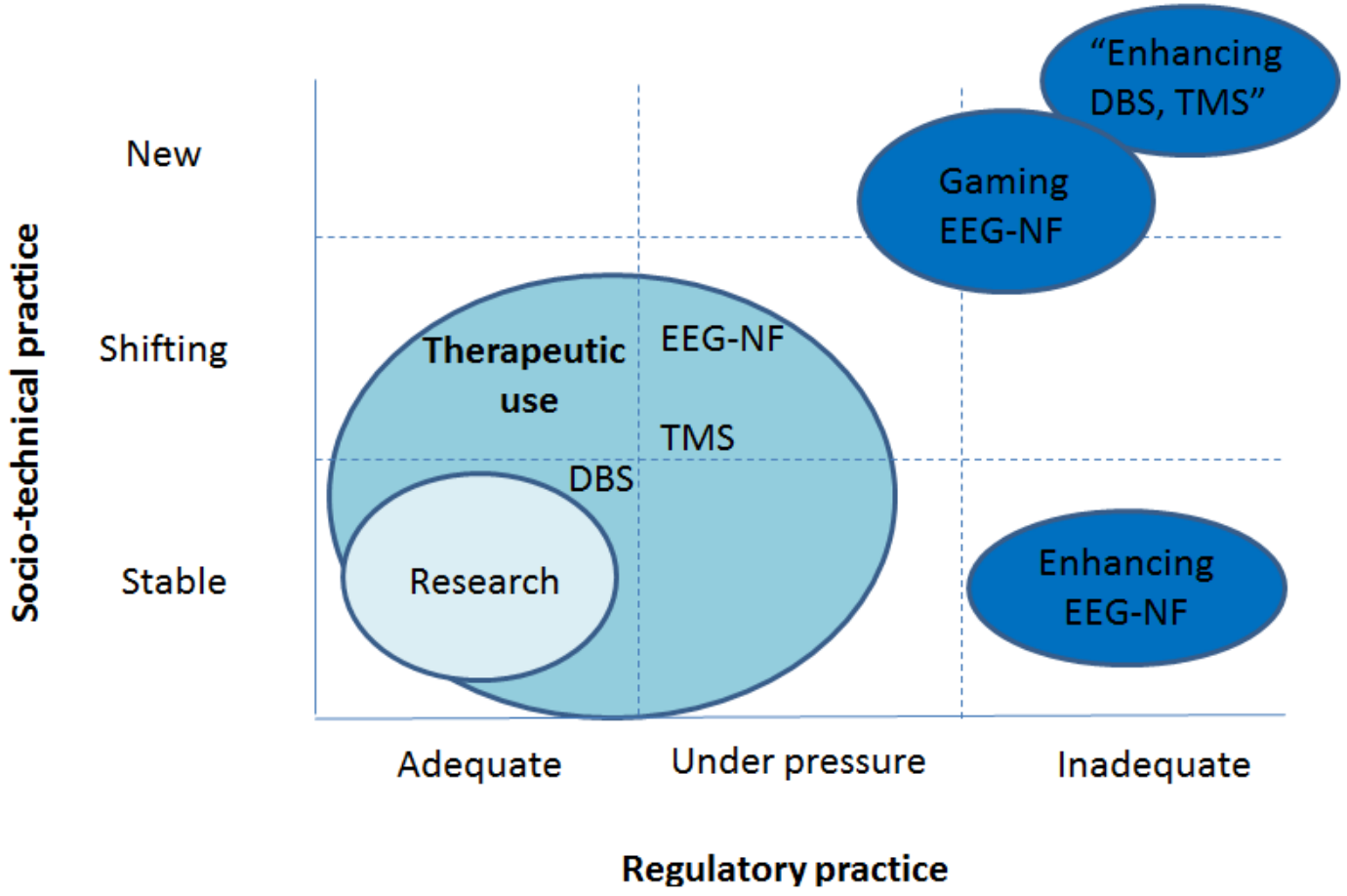
Regulatory issues

- Regalutory vacuum:
  - Intended use;
  - Bypassing medical devices regulation via non-medical intended use:
    - EEG neurofeedback devices intended for relaxation, or
    - EEG neurofeedback (or similar) devices used for gaming.

Regulatory issues

- Governance vacuum:
  - Reimbursment;
  - Certification of end-users;
  - Standardisation of treatment protocols.

Socio-technical and regulatory practices in neuromodulation



Finally

- This case-study is part of the STOA project ‘Making *Perfect* Life’, available via: http://www.europarl.europa.eu/stoa/
  http://www.rathenau.nl/

- We would like to thank Thomas van Zoest and Ellen Moors.

- Contact us?
  - Ira van Keulen: i.vankeulen@rathenau.nl
  - Mirjam Schuijff: m.schuijff@rathenau.nl

- More on ‘Making *Perfect* Life’ on Friday, in the Emerging Technologies session!