ELSI of neurotechnology
Aims of today

• Introduce you to Ethical, Legal & Societal Implications of BCI
  – General ELSI intro
  – BCI & sense of agency

• Not:
  – To tell you ‘how it is’
  – To tell you ‘to be good’

• Instead:
  – Show you some issues to think about
  – Help you think about (some of) them
  – Stimulate you to talk about (some of) them
  – Increase your awareness

• Consider this talk as a kind of guided museum tour
  – Showing you some issues worthy of attention
  – Not telling you what is good or bad
Neuroethics & ELSI

• “a discipline that aligns the exploration and discovery of neurobiological knowledge with human value systems”. (Illes, 2007, p.537)

• Henry Greely:
  – “Personally, I find ‘neuroethics’ less than ideal as a description for this field. It focuses entirely on ‘ethics’ and ignores the legal and social issues that may be quite important.” (Minn. Journal for Science & Technology, 2006, 7(2), p.602)

• Investigation of the Ethical, Legal and Social Implications that may arise from neuroscientific research and its applications
  – Sometimes Societal instead of Social
  – Sometimes Issues instead of Implications
ELSI’s outlook

• Constructively alert
  – Not just raising problems and worries
  – Use ELSI to communicate with (potential) stakeholders about the possible, desirable, avoidable
  – Use ELSI to possibly improve (potential applications of) neurotechnology

• Listen, Analyze, Inform, Ask
Discussing ELSI

Organization

Aim and role

The WODC aims to make a professional contribution to development and evaluation of justice policy set by the Netherlands Ministry of Security and Justice.

WODC (the Dutch abbreviation for Wetenschappelijk Onderzoek en Documentatiecentrum, in English: Research and Documentation Centre) can best be characterised as an international criminal justice knowledge centre. "Excellence" and "customer-orientation" are the organisation's guiding principles. Its major output is knowledge for the benefit of policy development.
Workshops

Team 9: Urgent issues

Dear team members,

We would like you to work toward the following ‘product’:
1. Consider Figure 4 (from Nijboer et al. 2011). Which of these issues need to be settled in the field of brain-computer interfacing within the given timeframe?
2. Which issues should be added to the list and why?
3. Who should address these issues?
4. How can we implement this?

One team member should present your findings in the 2 minutes. Thank you!
Team 10: Personal experience in (applied) neuroscience

Dear team members,

Maybe we have given you one of the most difficult assignments: introspection.

We would like you to work toward the following ‘product’:

1. Can you recall experiencing (or being close to) ethically or legally difficult situations in your own research or work?
2. Can you as a group, without identifying names or institutes, give some examples?
3. Can you indicate how the difficulties were dealt with?
4. Can you indicate how, in your view, the difficulties should have been dealt with?

One team member should present your findings in the 2 minutes. Thank you!
Challenges for neurotechnology

- Clinical issues
  - (1) obtaining informed consent
  - (2) risk/benefit analysis
  - (3) shared responsibility of teams
  - (4) the consequences for quality of life (patient, family)
  - (5) side-effects
  - (6) therapeutic applications & their limits

- Responsibility and privacy
  - (7) personal responsibility and liability (intention and agency)
  - (8) issues concerning personality and personhood
  - (9) mind-reading, privacy and data protection
  - (10) mind-control

- Societal acceptance
  - (11) questions of research ethics
  - (12) selective enhancement and social stratification
  - (13) communication to the media.
Typical ELSI questions

• What is possible?
  – What is currently possible (applications)
  – What will be possible in the near future (current research with applications in next 5-10 years)
  – What could ‘ultimately’ become possible (long term prospects)

• What is desirable?
  – Clinical applications
  – Healthy users

• What should be avoided
  – Clinical applications
  – Healthy users

• What should be regulated, by whom and how?
  – Policy makers (governmental)
  – Legal institutions
  – Scientific experts/organizations (selfregulation)
  – Nongovernmental organizations
  – Patient groups
  – General public
  – Other stakeholders?
Survey among 145 BCI researchers in 2010

- Terminology, expected marketability, informed consent, risk-benefit, team responsibility, quality of life, liability, personal identity, media communication
A simple question?

Fig. 2 The percentage of people who did (orange) or did not (blue) consider the listed example as a BCI or who did not know (purple bar).

Please indicate whether or not you think that the examples we list below can be referred to as a BCI or tell us if you don’t know.

- Cursor control based on self-regulation of slow...
- Orthosis control based on the self-regulation...
- Fatigue monitor for drivers in a car based...
- Offline alertness tool to assess workers
- Adaptation of avatar to emotion of user...
- EEG lie detector
- Deep brain stimulator
- Image detection; whether a recently presented...
- Retinal implant
- Neuromarketing; classification of brain responses...
- Remote controlled rat

Legend:
- Orange: This is a BCI
- Blue: This is NOT a BCI
- Purple: I don’t know
Fig. 4 An overview of when respondents think certain BCI issues should be settled. From top to bottom bar: ‘a certification process to determine that the product is adequate for a BCI’, ‘a regular journal devoted solely to BCI research’, ‘a certification process to determine that a BCI scientist is qualified to work with patients’, ‘ethical guidelines specific to BCI research and BCI use’ and ‘a standard definition of what a BCI is’
What’s in a name?

• BCI dilution
  – “The rapidly developing tendency to expand the conventional definition of BCI to include that group’s interests”
    e.g. include passive monitoring systems, or relying on facial muscle signals
    “The term BCI runs the risk of being diluted into meaninglessness.”

• BCI exaggeration
  – “The tendency to make unrealistic claims about what BCIs can do, or could do with a few years of funding”

Asilomar survey

- Half or more than half of the respondents identified 4 elements as crucial (in order of importance);

A BCI
1) must detect brain activity directly (without using signals from peripheral nerves or muscles) (83.8% of the respondents).

2) provides feedback in realtime, or neartime (71.1% of the respondents).

3) must classify brain activity (60.6% of the respondents).

4) provides feedback to the user that reflects whether s/he successfully attained a goal (50.0% of the respondents).
What is BCI *use*?

1. BCIs for healthy users
2. BCIs as assistive technology, which provides compensation for loss of motor function (e.g. BCI-controlled communication program or wheelchair)
3. BCI-controlled prostheses, which restore motor function by replacing a paralyzed limb by a prosthesis (e.g. a BCI-controlled robotic arm or leg)
4. BCIs as therapy tools, which help people with psychological/neurological disorders to directly use feedback of their brain activity for training/recovery purposes (e.g. neurofeedback of sensorimotor rhythms may promote brain recovery after stroke, neurofeedback of slow cortical potentials may help improve attention).
A note on ethical aspects of BCI

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2009 Special Issue

ARTICLE INFO

Article history:
Received 30 September 2008
Received in revised form 26 June 2009
Accepted 27 June 2009

Keywords:
BCI
Ethics
Locked-in syndrome
Communication
Informed consent

ABSTRACT

This paper focuses on ethical aspects of BCI, as a research and a clinical tool, that are challenging for practitioners currently working in the field. Specifically, the difficulties involved in acquiring informed consent from locked-in patients are investigated, in combination with an analysis of the shared moral responsibility in BCI teams, and the complications encountered in establishing effective communication with media.

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• Locked-in patients, informed consent, team responsibility & communication with the media
Locked-in syndrome (LIS)

- Classical
  - lack of voluntary motor control except for vertical eye movements, combined with consciousness
- Incomplete
  - remnants of voluntary motion other than vertical eye movements
- Complete
  - a total lack of voluntary motor control, including all eye movements, with consciousness
  - invasive BCI’s with better signal quality than non-invasive
    Significantly higher risks involved
Medical Ethics

• Autonomy
  – The right for an individual to make his or her own choice.

• Beneficence
  – The principle of acting with the best interest of the other in mind.

• Non-maleficence
  – The principle of above all, do no harm.

• Justice
  – Ensure fairness and equality among individuals.
Team 1: Case scenario Jane

Dear team members,

We would like you to work toward the following ‘product’:

1) Please identify the main ethical, legal or societal (ELSI) issues that need to be discussed regarding the case scenario about Jane (taken from Vlek et al. 2012).

2) Keep in mind different perspectives, such as a) what information needs to be presented to the person and/or family and/or legal representative in order to make an informed consent decision, b) how would one communicate the possibilities and difficulties involved in such a case to the public media?

3) What information would you need additionally to form an opinion about this case? In other words, what information is missing in the scenario below?

4) What would you recommend in this case scenario? What are the do’s, don’ts?

5) What kind of research project is needed to address these ELSI issues?

Try to summarize the team’s major findings. One team member should present this plenary in 2 minutes. Thank you!

“Jane”

Jane is a 46-year-old housewife who has had the neurodegenerative disease ALS for 10 years. She lives at home and has a full-time staff of caregivers. Since the onset of locked-in syndrome 1 year ago, she has not been able to communicate in any way. She has a legal representative who enrolled her in tests with noninvasive brain-computer interfaces. The researchers using noninvasive BCI say they can see that Jane is making an effort but that they are unable to reliably decode Jane’s brain activity. Jane’s husband, who is eager to communicate with his wife again, has read about invasive BCIs in the media and would like to try this method. He asks the BCI team whether his wife could be considered for brain surgery.
### Opinions on informed consent

Table 3: Overview of statements regarding the informed consent process. Columns 2 to 5 show the percentage of respondents (dis)agreeing (with the extent indicated in the column) to the different statements. The last column (response count) indicates how many respondents scored the statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Disagree completely</th>
<th>Mostly disagree</th>
<th>I don’t know</th>
<th>Mostly agree</th>
<th>Agree completely</th>
<th>Response count</th>
</tr>
</thead>
<tbody>
<tr>
<td>People who cannot communicate in any way should <em>not</em> be included in BCI studies even if their legal representative agrees with their participation</td>
<td>33.3</td>
<td>42.4</td>
<td>12.5</td>
<td>9.7</td>
<td>2.1</td>
<td>144</td>
</tr>
<tr>
<td>Obtaining an informed consent from a locked-in patient should be video-taped</td>
<td>4.2</td>
<td>9.0</td>
<td>31.9</td>
<td>34.7</td>
<td>20.1</td>
<td>144</td>
</tr>
<tr>
<td>A BCI expert is the suited person to inform the locked-in patients about the BCI studies, the risks and the benefits</td>
<td>4.9</td>
<td>18.8</td>
<td>13.2</td>
<td>49.3</td>
<td>13.9</td>
<td>144</td>
</tr>
<tr>
<td>A medical expert is the suited person to inform the locked-in patients about the BCI studies, the risks and the benefits</td>
<td>2.1</td>
<td>17.6</td>
<td>14.8</td>
<td>59.2</td>
<td>6.3</td>
<td>142</td>
</tr>
<tr>
<td>If a patient has no means to communicate but the legal representative of a patient asks for a BCI intervention then an attempt should be made to provide him or her with a BCI</td>
<td>0</td>
<td>8.4</td>
<td>17.5</td>
<td>53.8</td>
<td>20.3</td>
<td>143</td>
</tr>
<tr>
<td>If a patient has no means to communicate, and the legal representative does not agree to a BCI intervention, you should still attempt to provide a BCI</td>
<td>37.8</td>
<td>29.4</td>
<td>21</td>
<td>8.4</td>
<td>3.5</td>
<td>143</td>
</tr>
</tbody>
</table>
Informed consent

• In medicine
  – Assuring that fully informed patients are able to fully participate in decisions about their healthcare

• Involving
  – the nature of the decision procedure
  – reasonable alternatives to the proposed intervention
  – the relevant risks, benefits and uncertainties related to each alternative
  – assessment of the understanding of the patient
  – certainty about the acceptance of the intervention by the patient

• Additional elements concerning research in clinical cases
  – purpose & duration of research
  – research procedures
  – confidentiality of records
Deciding on using BCI

• Hildt (2008, p. 135)
  – "Only those uses in which considerable benefit can reasonably be expected and in which the expected benefits clearly outweigh the risks can be considered acceptable."

• However, risk-benefit calculation is not easily applicable
  – expectations may be (too) high, due to media exaggeration
  – the scientific community has not yet established a reasonable expectancy of a considerate benefit of BCIs
  – risks are multi-faceted (infections, cumbersome training, household privacy)
  – people who are (on the verge of) being completely locked-in may seem to have little choice
Team responsibility

• Interdisciplinarity of BCI teams (mathematicians, computer scientists, psychologists, neuroscientists, physicians, etc.)

• Teamwork can lead to fragmentation in the understanding of the overall picture

• Not just knowledge about, or perspectives on, but also responsibility for the effects of BCI can become unclear due to teamwork

• The scientist with the most encompassing perspective may not be the one actually communicating with the patient or family
Table 5  Overview of statements regarding team responsibility. Columns 2 to 5 show the percentage of respondents (dis)agreeing (with the extent indicated in the column) to the different statements. The last column (response count) indicates how many respondents scored the statement.

<table>
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<th>Response count</th>
</tr>
</thead>
<tbody>
<tr>
<td>All BCI teams should have 1 common code with rules &amp; regulations for team responsibility issues</td>
<td>0.7</td>
<td>14.8</td>
<td>12</td>
<td>45.1</td>
<td>27.5</td>
<td>142</td>
</tr>
<tr>
<td>It is okay when a patient hears about the difference of opinion of various team members considering the risks and the benefits of a BCI</td>
<td>12.7</td>
<td>31</td>
<td>15.5</td>
<td>29.6</td>
<td>11.3</td>
<td>142</td>
</tr>
<tr>
<td>BCI teams should stick to one risk/benefit analysis and tell this to the patient</td>
<td>4.2</td>
<td>14.1</td>
<td>21.8</td>
<td>43.0</td>
<td>16.9</td>
<td>142</td>
</tr>
</tbody>
</table>
Some comments

• “It's very important to have one clear message. The last thing we want is the patient to become confused”

• “I do not believe that a single party can, in all situations, adequately inform the patient about all issues concerning a BCI study. In such cases, I believe it would be more appropriate for experts with complementary areas of expertise .... to inform the patient. This raises the issue of whether multiple perspectives are consistent. It is not clear to me how this can be resolved systematically”.
Learn from other interdisciplinary teams

Intensive care units (ICU)

Breen et al. 2001: staff conflicts more often than among patient family

• General lessons
  – Different areas of expertise must be integrated into a practical “service delivery” for the patient
    ensure appropriate team members are present at consent procedure
  – While at the same time “mechanisms for accountability” must be assured
    have ‘preconference’ to develop team consensus

• Specific team issues to keep attentive to
  – how teams achieve justice in the distribution of work and the credits thereby attainable
  – assign responsibility for decisions that are made, especially those that may have far-reaching consequences for participants or patients
  – ensure reasonableness in allowing participation, resolution of conflicts and reaching consensus
  – maintain honesty in communication and reporting results
Media communication

• Expectations from patients and caregivers are high, in part because of news in the media
  – Paralysed man’s mind is ‘read’ (BBCNews, 2007; ScienceDaily, 2008)
  – Towards zero training for BCI (ScienceDaily, 2008)

• Future expectations
  – The gap between the currently feasible and the potentially possible

• The (un)certainty of science
  – Researchers are aware that what is known is dwarfed by what is unknown
  – This uncertainty is not what policy makers, nor the larger society understand, seek, or value about science
  – In general, non-scientists tend to overestimate the degree of certainty attached to scientific results
Table 8  Columns 2 to 5 show the percentage of respondents (dis)agreeing (with the extent indicated in the column) to the different statements. The last column (response count) indicates how many respondents scored the statement.

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<th>Response count</th>
</tr>
</thead>
<tbody>
<tr>
<td>It is the responsibility of scientists to check whether their separation from the facts and fiction is adequately represented by journalists</td>
<td>2.1</td>
<td>9.1</td>
<td>7.7</td>
<td>51.0</td>
<td>30.1</td>
<td>143</td>
</tr>
<tr>
<td>BCI scientists should moderate their enthusiasm when speaking to the media</td>
<td>1.4</td>
<td>12.6</td>
<td>9.8</td>
<td>37.8</td>
<td>38.5</td>
<td>143</td>
</tr>
<tr>
<td>Each BCI scientist should restrict him/herself to discussing current and near-future applications of BCI instead of speculating about long-term applications</td>
<td>3.5</td>
<td>31.9</td>
<td>9.7</td>
<td>36.8</td>
<td>18.1</td>
<td>144</td>
</tr>
<tr>
<td>BCI scientists should actively speak out against inaccurate statements in the media, regardless of the source</td>
<td>0.0</td>
<td>4.2</td>
<td>9.0</td>
<td>47.2</td>
<td>39.6</td>
<td>144</td>
</tr>
</tbody>
</table>
Creating realistic expectations

• Don’t empathize with the public’s desire for certainty
  – The risk of creating false hopes and expectations

• Be aware of / feel responsible for potential misinterpretations
  – “We need to recognize that our words might be misunderstood, and that we are to some degree just as responsible for likely misunderstandings of what we say as we are for the “proper” effects of our words.” (Dennett, 2003, p. 17)

• Be explicit concerning the current limitations of BCI
  – Specify what constitute reasonable expectations concerning which (preferably nearby) point in the future
  – Refuse to engage in (or qualify explicitly as) speculations concerning anything beyond the near future or depending on breakthroughs that currently are not foreseeable
Conclusions/Suggestions

• What is a BCI exactly?

• Ethically sound informed consent from a locked-in patient requires the development of standardized procedures

• Awareness of the ethical issues regarding teamwork may help to achieve responsible team functioning

• Prudent communication with public media and watchfulness concerning how statements get represented could help to reduce unrealistic expectations

• A growing attention for the practical ethical challenges faced by scientists, clinicians, participants and patients is called for