The formal and the actual validity of informed consent in emergency medical studies

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1. **Informed consent**

has different connotations, when is applied in different medical situations
2. Informed consent applies to two related, but nevertheless different, settings:

- biomedical research and
- medical practice
research

experimental
  - animals
  - humans

clinical
  - therapeutical
    - clinical studies
    - clinical trials
  - non-therapeutical
    - cost-effectiveness studies
    - epidemiological studies
    - genetical studies

basic
The main goal of biomedical research is the acquisition and application of new knowledge for the benefit of individual patient and society as a whole.
Achieving this goal requires:

• excellence in scientific methodology

• honesty in data collection

• honesty in data interpretation

• realistic assessment of the implications of the findings or results
research

experimental
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- therapeutical
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basic
freedom of research

right to selfdetermination

researcher

person, patient, subject

Bauer 1987
Have the terms

- “person”
- “patient” and
- “(research) subject”

the same meaning?
PATIENTS’ RIGHTS

• protection of personal autonomy
• to be informed
• access to health care
• appropriate quality of health care
• free choice of caregiver
Principle based ethics

• beneficence,
• non maleficence,
• respect for autonomy, and
• justice

("Georgetown mantra")

Principle based ethics

• **beneficence** [balance between potential benefits and harms of participation]

• **non maleficence and justice** [vulnerable people are not to be exploited and eligible candidates who may benefit from participation are not to be excluded without reasonable cause],

• **respect for patient's/subject’s autonomy** [real informed consent],

and traditional military values

• **loyalty and respect**,  

• **courtesy and chivalry**  

Pearn, 2000
Translational ethics

- **autonomy of the patient** and
- **informed consent**

Autonomy

- **self determination** and
- **independence**

(autonomous choices [informed consent, informed refusal, informed choice] – patient is expert about his own life and psychosocial-spiritual circumstances; he contributes decision making by expressing his personal preferences, beliefs and values i.e. “personal freedom” and “freedom of choice”)

- **right to privacy and confidentiality**

(regarding all health problems)
I. Kant:  
*Autonomy* is governed by rational choices (rationality)

J. S. Mill:  
*Autonomy* means the right to self determination as long as is not harmful to others (preferences, desires)

“Captive subjects”

- service members (e.g. soldiers)
- prisoners
- students
- children
- intellectually disabled

(eg. frightened patient in ER; patient with trauma in ICU or OR; but also drug user or alcohol abused)
<table>
<thead>
<tr>
<th>Procedure</th>
<th>elective</th>
<th>emergency*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Patient</td>
<td>inf. consent</td>
<td>inf. consent</td>
</tr>
<tr>
<td>Competent Patient temporarily</td>
<td>inf. consent</td>
<td>next of kin (or LAR)</td>
</tr>
<tr>
<td>Incompetent permanently</td>
<td>LAR court decision</td>
<td>principle of necessity</td>
</tr>
</tbody>
</table>

*) - time (risk of loosing competence)
   - prognosis (risk of fatal complications, death)

LAR - Legal Authorised Representative
Legal validity of *informed consent*

1. **patients’ ability** to give consent

2. **sufficient information**

3. **appropriate form of consent**
EVERYDAY LIFE

VS

EMERGENCY SETTINGS
1. patients’ ability to give consent

- able to legal functions (age, not incapacitated)
- able to give and understand the meaning of consent (able to read, speak and understand [mentally competent and educated]; free of mental deficiency or certain psychiatric disorders).
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What about above mentioned patients with:

• traumatic brain injury (TBI) or stroke?
• trauma?
• alcohol or drug abuse?
• phase I/II hepatic encephalopathy?
2. Sufficient information

- What does it mean “sufficient”?
- Is “sufficient” equal to “understandable”?
- Is the meaning of the term “risk” the same to the physician and the patient?

For **physician** – unexpected, unfavourable events or circumstances concerned with equipment failure or unexpected patients’ reactions or adverse events.

For **patient** – fear of additional pain or suffering, health deterioration, missed diagnosis and further consequences with various complications (...”all the worst always happens to me...”) including fatal events (..”is it a risk, that I may die?”)

If you don’t agree …… you will probably die!
Providing information for *informed consent*:

- **orally**
  (discussion and asking questions improves understanding, confidence and doctor-patient relationship – if given by physician)

- **written**
  (information leaflets, sheets, booklets improve understanding if readable; ensure the same information; convenient for the patients and the staff; may be used any time)

- **video-tapes**
  (eliminate the problems of written documents’ readability; ensure reproducibility of information)
3. the form of consent

eg. in cases of emergency, trauma (incl. TBI) –

• informed consent by patient when feasible (preferably written - „short form”).
• If patient is unable to give consent
  - family or LAR (written, preferably abbreviated form).
  - consent exception by second physician.
• Repeated consent to continue when available or when prior consent has been „utilised” (consent for additional procedures etc. - always in written form [patient, next of kin, LAR])

“Valid” vs “informed” consent

Personal competence?

Valid consent?

Procedural competence?

Material competence?

Richards, Schwartz 2002; Ramcharan, Cutliffe 2001; Syse 2000;
INFORMED, VALID OR "INSTITUTIONALLY TRANSFERRED" CONSENT

some cases from real life
Case 1: **Is informed consent necessary?**

Therapeutical activity prevents functional decline and reduces mortality. Little is known about typical levels of activity among ICU patients.

**Aim:** to determine the benefits of measuring or implementing therapeutic activity (direct observation, actigraphy and turning the patient)

**Patients:** chronically, critically ill adults in ICU

Decision of the hospital Human Subject Review Board?

Informed consent

If being able - by themselves

if not - by families or LAR

Case 2: Is informed consent necessary?

The provision of nutritional support for patients in ICUs varies widely.

Hypothesis: Evidence based algorithms would improve patients outcome

Intervention: ACCEPT (algorithms for critical care enteral and parenteral therapy) in 14 hospitals; observation; enteral or parenteral nutrition

Martin CM., Doig GS., Heyland DK. et al. CMAJ 2004; 170(2): 197-204
Decision of the University Ethics Review Board?

Informed consent waived on the basis that intervention was a quality-improvement initiative.

Martin CM., Doig GS., Heyland DK. et el. CMAJ 2004; 170(2): 197-204
Case 3: Is informed consent necessary?

**Hypothesis:** Patients’ recollections of experiences in the ICU may affect their quality of life.

**Intervention:** 10 Portuguese ICUs; prospective study on experiences of 1433 adult patients 6 months after their ICU discharge; original HR-QoL and EQ-5D questionnaires send by mail with a letter containing detailed information on the aims of the study; patients completed their questionnaires at home, and returned them by mail (5 ICUs) or directly during follow-up consultation (5 ICUs).

Informed consent was obtained from all patients at the time of the follow-up visit, where applicable. Because consent was implicit in answering the questionnaire, the need for additional informed consent was waived.

Martin CM., Doig GS., Heyland DK. et al. CMAJ 2004; 170(2): 197-204
Obtaining valid informed consent for procedures or studies in emergency settings is one of the most difficult tasks for the staff.
Always try to keep the balance