BIOETHICS AND PROFESSIONALISM IN MEDICAL CARE, EDUCATION, RESEARCH FOR THE 21ST CENTURY RESOLVING ETHICAL DILEMMA

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I. INTRODUCTION

1. WHO (Blumenthal and Boelen, 1994)

“Teaching ethical issues should be integral and compulsory part of medical education, and taught throughout the process of education in undergraduate and postgraduate programs. For this purpose, all medical school should establish a department of ethics, and have an adequate number of qualified teachers.

Medical ethics education or bioethics teaching as a part of teaching professionalism
2. **WFME (2003 and 2012)**

   “WFME promote the highest scientific and ethical standards in medical education, and be implemented in CBC (Competence Based Curriculum), in a continuum process from basic, postgraduate and CPD (Continuing Professional Development)


   Bioethics Core Curriculum eg. Syllabus Ethics Education Programme


   “All health professionals in all country to be educated to mobilize knowledge and engage in critical reasoning and ethical conduct, so that they are competent to participate in patient and population-centered health system as a member and or leader of locally responsive and globally connected team”.
5. UUPK/ Acts on Medical Education in Indonesia, No. 20, 2013
Stated that:
All medical schools in Indonesia have to teach or train their students of:

1) Basic medical sciences
2) Clinical sciences
3) Bioethics and health humanities
4) Community medicine and public health
5) Medical education
6. Currently, for 21st Century in our world, we have, more or less:
  • 2420 schools of medicine
  • 467 schools of public health
  • Uncountable schools of nursing and midwifery, etc

All of higher education using CBC, and knowledge, skills and attitude to be achieved by all professionals on their graduation.

Some question that also should be appropriately responded, such as:
  a. What is ethics, biomedical ethics, bioethics, global bioethics, and the new sense of biothics?
  b. What is really humanities and medical humanities?
  c. What is professionalism?
  d. Are we professional medical doctors? Are we professional educators, researchers, practitioners?
### 7. Four Reformation of (Medical) Education (Fig. 1)

<table>
<thead>
<tr>
<th>Century</th>
<th>Generation</th>
<th>Reformation</th>
<th>Objective/ Process</th>
<th>Output</th>
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<td>Informative</td>
<td>Information/ lecture</td>
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<td>• Curriculum</td>
<td>• Practice</td>
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<td>• Learning</td>
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<td>II</td>
<td>Formative</td>
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<td>Transformative</td>
<td>Idem II</td>
<td>AGENT OF CHANGE</td>
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<td>• Leadership</td>
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<td>• Learning</td>
<td>• Management</td>
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<td>• New sense of bioethics</td>
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<td>IV</td>
<td>New Transformative</td>
<td>New sense of bioethics</td>
<td>INSPIRING LEADER/ PERSON</td>
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<td>Tolerance on transdisciplinary attitude</td>
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(Nicolescu B, 1997; Frenk et al, 2010; Sastrowijoto S, 2011)
II. SOME CLARIFICATION

1. Ethics:
   A study of general nature of moral choice to be made by a person; moral philosophy.

   **Ethical principles** (Belmont Reports, 1979 – USA)
   1) Respect for **person**
   2) Beneficene
   3) Justice

2. Bioethical Ethics (Beauchamp and Childress 1979)
   1) Respect for **autonomy**
   2) Non maleficence
   3) Beneficence
   4) Justice
3. Bioethics

1) **Bioethics** is a new discipline which combines biological knowledge and human values system, bridge between the science and the humanities, help humanities to survive and sustain, and improve the civilized world.

   (Potter, 1971)

2) **Bioethics**
   
The study of ethical and moral implication of new biological discoveries and biomedical advances as in the field of genetic engineering and drug research

   (Soukhanov et al, 1996)
3) **Bioethics** is **multidisciplinary** subjects of philosophy, theology, history, law, sociology, anthropology and divers health professionals, multicultural of their local and national wisdom.

   (Khusfh, 2004)

4) **Bioethics** is a study of **multidisciplinary** subject closed related to science and technology, politics, economics, social, humanities, education, cultures, religions, pluralism and globalization.

   Position of developed countries and the advantaged group population are stronger and stronger, exploring natural resources, employing the diadvantaged, without sharing benefits appropriately

   (Nazim, _____)

5) **Bioethics** is a study of **interdisciplinary** subjects of biology, medicine, health, ethics, philosophy, law, sociology, economics, politics, anthropology, culture, language, and art, is studying human behavior.

   (Callahan, 2004)
6) **Bioethics/ Global Bioethics**

Global bioethics has two basic ideas:

a. **Global Bioethics** is the ethics or the voice of those who relatively powerless or voiceless and who suffer most from global injustice and inequities, the poor or the disadvantaged, the concept of social investment.

b. **Global Bioethics** is the implementation of bioethics in the global era of freedom autonomy, individualism, liberalism, capitalism (free market based on the concept of capital investment), corporatization and commercialization of health or medical care, research and education.

(Widdow, 2011)

e.g:

- Climate change
- Trafficking
- Child labour
- Scarce resources
- To buy a body part
- Immigration
- etc
The New Sense of Bioethics

Is a study of transdisciplinary subjects of biology, medicine, health, ethics, philosophy, law, sociology, economics, politics, anthropology, culture, language, and art, and is studying of human behavior to having a new tolerance to **transdisciplinary** attitude.

(Sastrowijoto S, et al, 2014)

The New Sense of Bioethics

1. Belief in God or Faith
2. Respect for others
3. Beneficence
4. Non maleficence
5. Social justice for all

Based on the concept of

- Social investment
- Benefits for the disadvantaged
- To balance capital and social investment
4. Mono, Multi, Inter, Transdisciplines (subjects) (Nicolescu B, 1999) (Fig. 2)

1).

Mono Multi Inter Trans

2) Monodisciplinary Research
   Multidisciplinary
   Interdisciplinary
   Transdisciplinary

   Used ONE methods
   Used the same/ ONE methods between the disciplines
   Transfer the method to the other discipline
   At once the discipline accross the different discipline and beyond all discipline
5. **Humanities** is those branches of knowledges, such as philosophy, literatures, art, etc. that are concerned with human thought and cultures.

   (Soukhanov et al, 1996)

**Medical humanities** is an understanding the human experiences of health and illness, and also a study of exploring ethical issues in clinical practice.

   (Moore A, 1977)
III. PROFESSIONALISM

1. In 2009, School of Medicine, UGM arranged a workshop professionalism to develop the CORE components/attributes of professionalism and the challenges that have to be avoided. The result could be learned from following table (Fig. 3)

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<tr>
<th>Professionalism</th>
<th>Challenges</th>
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<td>1) Altruism and advocacy</td>
<td>1) Abuse of power</td>
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<td>2) Respect, responsibility and accountability</td>
<td>2) Breach confidentiality</td>
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<td>3) Honor, honesty and integrity</td>
<td>3) Arrogance &amp; greedy</td>
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<tr>
<td>4) Life long learning and limit of knowledge</td>
<td>4) Conflict of interest</td>
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<td>5) Effective communication</td>
<td>5) Lying &amp; Freud</td>
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<td>6) Leadership and management</td>
<td>6) Discrimination</td>
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<td>7) Etc</td>
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(Kansas Univ., 2001; Sastrowijoto el al, 2009)
2. The graduates could demonstrate their cognitive and psychomotor to express one self attitude in communication with patient/family, colleagues, society and community, integratedly and could be assessed with appropriate observable components. They also could be a leader or member of health care team.

3. Professionalism move from individual person to institution. Professionalism should be inculcated within medical school with complete integration of a culture of professionalism involving staff, faculty, students and residents

(WHO, 1994; Passi et al, 2010)
IV. BIOETHICS AND PROFESSIONALISM IN MEDICAL CARE/ SERVICES, EDUCATION, RESEARCH for the 21st Century

1. Bioethics – HELP (Humanities, Ethics, Legal, Professional) in Medical CARE:
   1) General Principles of clinical ethics
      (Forrow et al, 1999)
   2) Four Box Approach/ Methods
      (Jonsen et al, 2010)
   3) Resolving ethical dilemma for clinicians
      (Bernard Lo, 2009)
1) **Clinical Ethics** (Forrow et al, 1999), some principles in medical care should be conducted:

   a. **Fundamental Principles:**
      A clinical intervention is justified if and only if the expected benefits outweigh the expected burdens from the perspective of patient.

   b. **Share decision making:**
      a). Paternalistic, b) complete patient autonomy, or c) share decision making.

   c. **Rules/ medico legal perspective:**
      Competent or incompetent patients or **surrogate decision maker** (parent, community leader, local regulation/ tradition)

   d. **Some cases and judicial guidance:**
      DNR/ hydration, ECT/ antipsychotic medicine, Jehovah’s winesses, and “living will”.
e. Keep in mind:
That **good decision** requires **good data** seek **win-win** solution and be creative think about who should decide as well as what decision is the best.

f. Question:
On what are the important:
- **Fact** (history, diagnosis, interventions, family/ patient choice)
- **Values** (patient/ family, team, institutions, third parties, etc); conflicts (what values?) possible courses of action; decision and justifications (compare, choose, improve that choice)
- **Further reflection** (preventive ethics)
g. Ethical disagreement:
about fact, values, follow up, and where decision authority lies.

h. Preventive ethics:
with establish a trust worthy partnership with patient/ family; and communicate early, often and realistic about goals and endpoint.

i. Some cases:
informed consent, end of life issues, physician assisted dying, organ donation, truth telling, confidentiality, interaction with peers, disability, interaction with supervisor, conflict of interest mistake/error/ malpractive, sex/ abortion, gift, language differences, money/ managed care, etc
2) **Four Box Approach/ Methods (Jonsen et al, 2010) (Fig. 4)**

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<tr>
<th>MEDICAL INDICATION</th>
<th>PATIENT/ FAM. PREFERENCES</th>
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<td><strong>Principles of beneficence &amp; non maleficence</strong></td>
<td><strong>Principles of respect for other/ autonomy</strong></td>
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<td>1. Medical problems?</td>
<td>1. Good informed consent, understood?</td>
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<td>2. Goal of treatment?</td>
<td>2. Mentally capable, legally competent?</td>
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<td>3. Circumstances, medical treatment, non indicated?</td>
<td>3. Preferences of patients/ family stating</td>
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<td>5. Benefited by medicine and nursing care, harm can be avoided?</td>
<td>5. Appropriate surrogate</td>
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<td>6. Patient unwilling to medicine, treatment?</td>
<td>6. Patient unwilling to medicine, treatment?</td>
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<th>QUALITY OF LIFE</th>
<th>CONTEXTUAL FEATURES</th>
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<td><strong>Principles of beneficence, non maleficence &amp; respect autonomy</strong></td>
<td><strong>Principles of Justice &amp; Fairness</strong></td>
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<tr>
<td>1. Medical treatment – physic, mental, social, deficit?</td>
<td>1. Conflict of interest?</td>
</tr>
<tr>
<td>2. Quality of life, before and after?</td>
<td>2. Fairness preferences?</td>
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<tr>
<td>9. PH issues?</td>
<td>9. PH issues?</td>
</tr>
</tbody>
</table>

1. Diagnosis
2. Treatment
3. Prognosis

1. Before
2. During
3. After

1. Patient
2. Family
3. Team

1. Support system
2. Cost availability
3. Special circumstance

(Jonsen, et al, 2010)
3) Resolving Ethical Dilemmas (Bernard Lo, 2019)

- Grew from such perplexing or difficult cases
- Currently patients can obtain genomic information, cross cultural medicine on disclosing diagnosis, end of life care, surrogate decision making, etc.

- Ethical issues in surgery
  Several ethical guidelines are particularly silent in surgery:
  a. Acting in the patient’s best interest
  b. Informed consent – discloser of alternative because
     • A major bodily invasion
     • Dramatically alter patient’s body image, sense of self, etc
     • Learning procedural skills
     • Individual surgeon – responsible for outcome of surgery
1. **Questions**
   - What level of statistical/experience evidence to support futility?
   - Who decide whether an intervention is futile, physician or patient?
   - What process should be used to disagreement, between patient/surrogate and clinical team?

2. **Questions**
   - The success of treatment (1 – 3 – 6)%? Should be continued?
   - The contextual features, too high price, minimal benefit, will be continued?
   - What level of EBP to support aggressive treatment
2. Bioethics HELP (Humanities, Ethics, Legal, Professional) in EDUCATION:

In discussing the ethics in medical education, in this case the ethics could be developed to bioethics and HELP approach could be implemented.

As a **physician-educator**, Society of Teaching and Learning Higher Education (STHLE) included medical teacher, developed Nine Principles in University Teaching. These principle consisted of

1) Content competent
2) Pedagogical competent
3) Dealing with sensitive topic
4) Student development
5) Dual relationship
6) Confidentiality
7) Respect for colleagues
8) Valid assessment for students
9) Respect for institution

(Murray et al, 1996).
• Medical Education Conference, 15-17 May 2002 AAMC (Association of American Medical Colleges), NBME (National Board of Medical Examiness) Baltimore US, “Embedding Professionalism in Medical Education, Assessment as a Tool for Implementation”

• World Medical Students Association:
  “….We are being asked to be professional medical students in an unprofessional environment. Faculty should be subject to the same criteria for assessment as students and residents”.
  (AAMC and NBME, 2002)
• Transdisciplinary Approach in Health Education
  1. Lectures
  2. Practices (laboratory/ basic, clinics, community)
  3. PBL – SGD, innovations
  4. Leadership and management
  5. Inspiring medical teachers (role models)

• Out put
  1. Medical doctors, specialist; experts, professionals
  2. Managers, leaders (agent of changes)
  3. Role models, inspirators
• Lecture
  1. Team, teching, transdisciplinary approach
  2. Tutorial, small group discussions
  3. Patient and population, health centers/ system (academic hospital center/ system) – AHS/ C
• Student assessment in CBC program based on student’s competences in their Cognitive (C), Psychomotor (P), and Affective (A) domains:

```
C   P   A
```

Quality development
Basic standard
Under standard

A: Affective/Attitude
S: Skills
K: Knowledge

This concept could be implemented to improve the professionalism of students, faculties and administrators.

(Soenarto Sastrowijoto, 2006)
• Structure of Medical Education Organization

Undergraduate

Dokter

Spesialis

Konsultan

CPD

Praktisi

Spesialistik

Peneliti

Praktisi

Umum

Doctor/ PhD

Post Doc

Master

Dokter Layanan Primer

CPD
• **Bioethics Education**

  Should be in a continuum process, from undergraduate, graduate, postgraduate and CPD programs
• Teaching Learning in Bioethics with Media (Dale, ____)

![Diagram showing a pyramid with the following levels from top to bottom: Lambang kata, Lambang Visual, Rekaman dan radio, Gambar diam, Gambar hidup, Televisi, Pameran, Karya wisata, Demonstrasi, Dramatisasi (Bermain Peran), Pengalaman Tiruan/ model simulasi, Pengalaman langsung.]

Abstract

Concret
1. Words symbol: textbook, handout, study guide, newsletter
2. Visual symbol: bioethics specific picture
3. Radio and records: caset theory of bioethics
4. Motionless picture: foto
5. Motion picture: film of bioethics
6. Television program: selling organs, kidney
7. Exhibition: foto, clipping, newspapers
8. Field trip: visit cancer centers
9. Demonstration: direct telling bad news
10. Drama: patients, role model
11. Model simulation: eg. In informed consent
12. Direct experience: direct experiences in health care

(Dale, _____)
A Continuum process of bioethics teaching in medical education (Undergraduate, Graduate, Postgraduate, Continuing Professional Development)

(SoenartoSastrowijoto, 2006)
Five issues in developing medical professionalism in the future doctors (Passi et al, 2010) (Fig. 6)

<table>
<thead>
<tr>
<th>Curriculum Design</th>
<th>Student Selection</th>
<th>Teaching Learning Methods</th>
<th>Role Modeling</th>
<th>Assessment Methods</th>
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<td>29</td>
<td>9</td>
<td>40</td>
<td>19</td>
<td>37</td>
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- Professionalism in medicine is an extraordinarily complex phenomenon, in a complex social system

(Passi et al, 2010)
- Some medical student’s view on health professional for the 21st Century (Striegler et al, 2010):
  1) Student agreed on knowledge, skills and attitude to be achieved by all doctors on graduation day
  2) Necessity of involving students with the entire process, from developing of the curriculum and in the evaluation of the program
  3) Student from low income countries have to benefits from such initiatives
  4) Interprofessional forum, should being togather (medicine, nursery, pharmacy, and allied health professional)
  5) Students of all health professionals, all countries get envolved in joint planning mechanism.
Assessment methods in Medical Ethics or of Professional Behavior.

1. Passi et al (2010), A systematic review. There are some methods in assessing medical professionalism:
   1) Peer assessment
   2) Direct observation
   3) Patient evaluation
   4) OSCE
   5) Standardized patient assessment
   6) Standard evaluation forum
   7) Self evaluation
   8) Educational portfolios
   9) Team work exercise
   11) Attendance records
   12) Video tape Analysis
   13) Single best answer multiple choice, situational judgment test
Conclusion:
1) No single instrument for measuring all aspects of professionalism.
2) The importance of multidimensional approach – summative and formative assessment, in the curriculum.
3) Different clinical setting, may use different assessment methods should be chosen appropriately.

2. Assessment methods: (Suvillian C and Arnold L, 2009)
   1) Summative form:
      indicate whether learners and faculty have met professional standards.
   2) Formative form:
      a continual striving to guide individual’s professional development.
   3) Comprehensive form:
      covering attitude, skills, knowledge (ASK) appropriate to the stages of a medical career.
Many kind of tools/ instruments, could be incorporated quantitative and or qualitative approach, with its fundamental components of communication and ethics, and central principles of excellence, humanism, accountability and altruism.

**Tools or instruments**

1) Standardized clinical encounter (OSCE)
2) High-fidelity simulation
3) Portfolio
4) Observations by faculty – learners
5) Critical incident reports and longitudinal observation
6) Multisource assessment or 360 degree evaluation
7) Self assessment, starting point
8) Peer assessment
9) Other(s)
• A specific approach to **assessing faculty’s professionalism:**
  1) Routine instructor evaluation of professionalism.
  2) Assessing professionalism of practicing physicians by patients/parents appropriate instrument can also be applied to faculty.
  3) The same issues for medical teacher and researchers, in assessing their professionalism.

1) Good patient care does not only depend on professionals’ adequate knowledge and skills, it also requires adequate professional behavior.

2) Professional behavior should be incorporated into undergraduate curriculum

3) Designing an educational and assessment framework for professional behavior, that could be implemented in all the collaborating schools.

4) Individual universities ample room to tailor the professional behavior program to local conditions and requirements.
Assessment of Professional Behavior

1) **Focus on observable behavior** and reflection on that behavior, appropriate with the educational setting.

2) **Longitudinal assessment** by different judges is required, with a clear definition (un-ambiguous) of the final objective.

3) At least **two assessment per year** by four to six of different, independent judges.

4) **Careful documentation and record keeping** is the essence in the assessment.

5) **Access to student files** should be only be granted to a limited group of persons.

6) A **negative judgment cannot be compensated by positive results** on the other aspects of other clinical competence (knowledge and skills)

7) A **negative judgment** should be accompanied by **feedback** and remediation.
A Blue Print to Assess Professionalism: Result of a Systematic Review. Academic Medicine, Vol. 84, No.5/ May. 84: 551-558

1) Professionalism is multidimensional, so a combination of assessment tools is required.

2) Nine clusters of assessment tools were identified
   a. Observed clinical encounters
   b. Collated views of coworkers
   c. Records of incidents of unprofessionalism
   d. Critical incident reports
   e. Simulations
   f. Paper-based tests
   g. Patients’ opinion
   h. Global view of supervisor
   i. Self administered rating scales
3) Attribute that require more development in their measurement are:
   a. Reflective
   b. Advocacy
   c. Life long learning
   d. Dealing with uncertainty
   e. Balancing availability to others with care for oneself
   f. Seeking and responding to result of an audit.
UGM Experience (Fig. 7)

• UGM implemented the concept of teaching medical ethics in a continuum process, from undergrad – graduated – post grad CPD (Continuing Professional Development)

A Continuum process of bioethics teaching in medical education (Basic, Postgraduate, Continuing Professional Development) (SoenartoSastrowijoto, 2006)
• Student assessment in CBC program based on student’s competences in their Cognitive (C), Psychomotor (P), and Affective (A) domains: (Fig. 8)

A: Affective/ Attitude
S: Skills
K: Knowledge

(Soenarto Sastrowijoto, 2006)
Teaching Learning Medical Ethics (Fig. 9)

HELP approach curriculum/ learning.

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<th>H – Humanities</th>
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<tr>
<td>E – Ethics</td>
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<td>L – Law</td>
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<tr>
<td>P - Professionalism</td>
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OUT PUT (Standards)
TEACHER/LECTURER

TEACH CONTENT MATERIAL

TEACHING METHODS:
- LECTURE
- SMALL GROUP DISCUSSION
- CASES BASED
- ETC

STUDENT

KNOWLEDGE OF MEDICAL ETHICS

APPLICATION OF MEDICAL ETHICS

FORMATIVE ASSESSMENT

SUMMATIVE ASSESSMENT
**OUTPUT (Fig. 11)**

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**PROFESSIONAL**
TUTORIAL TOOL (Fig. 12)

The Student Professional Behavior Assessment in Tutorial

<table>
<thead>
<tr>
<th>1st Meeting</th>
<th>Block:</th>
<th>Group:</th>
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<tr>
<td>Scenario Week:</td>
<td>☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6</td>
<td>Tutor’s Name:</td>
</tr>
<tr>
<td>Day</td>
<td>☐ Monday ☐ Tuesday ☐ Wednesday</td>
<td>Tutor’s signature:</td>
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<tr>
<td>☐ Thursday ☐ Friday ☐ Saturday</td>
<td></td>
<td></td>
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<tr>
<td>Date/Time</td>
<td>... - ........ - 201.../........... - ........ WIB</td>
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Please fill in with ✓ to the most likely answer.

<table>
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<tr>
<th>Student’s Name:</th>
<th>*</th>
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<tbody>
<tr>
<td>Student’s Number:</td>
<td></td>
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</tbody>
</table>

Present on time | ☐ Yes ☐ No Late ___min
Dress appropriately to the faculty rules | ☐ Yes ☐ No
Bring Tutorial book | ☐ Yes ☐ No

Agree / Disagree
Student’s signature:
Already read the scenario | ☐ Yes ☐ No
Show own note of the scenario | ☐ Yes ☐ No

At the End of Tutorial Session

General Impression of the Learning Process

- Passive
- Reactive
- Active
- Proactive

Bold ☐ is better in each group

General Impression to the Team Work

Disturbing | ☐ Yes ☐ No

Write the constructive feedback to him/her (if necessary):

Note for NOT DRESSING appropriately to the faculty rules:

*Fill in with: L- as Leader; S- as Scribe

Please turn over if more space needed
TUTORIAL TOOL (Fig. 13)
ASSESSMENT POINTS CONT’

• **EMPHATY**
  • Point to assess: How the students respect each other and respect their tutors due to discussion?

• **SINCERE**
  • Can’t be assessed yet in undergraduate, should be assessed later in next grades

• **SOCIAL RESPONSIBILITY**
  • Can’t be assessed yet in undergraduate, should be assessed later in next grades

• **INTEGRITY**
  • Can’t be assessed yet in undergraduate, should be assessed later in next grades
ASSESSMENT POINTS CONT’

• OBEDIENCE
  • POINT TO ASSES: HOW DISCIPLINE ARE THE STUDENTS? ARE THEY COME ON TIME AND DRESS APPROPRIATE?

• NOBLE
  • POINT TO ASSES: HOW STUDENTS FIND THEIR OWN RESOURCES AND THEN THEY FORMULATE, ANALYZES, AND DELIVER MATERIAL BY THEMSELVES, NO PLAGIARISM.

• ALTRUIST
  • CAN’T BE ASSESSED YET IN UNDERGRADUATE, SHOULD BE ASSES LATER IN NEXT GRADUES

• LIFE LONG LEARNER
  • POINT TO ASSES: HOW STUDENTS SHOW THEIR PREPAREDNESS FOR THE DISCUSSION.
RESULT (Fig. 14)

Professional Behaviour Assessment Result for Batch 2009 (International and Regular)

<table>
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<th>years</th>
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Hasil & Interpretasi??
3. Bioethics HELP (Humanities, Ethics, Legal, Professional) in RESEARCH:

1. Some questions should be discussed related to potential collaboration of clinical research, clinical trials, and translational research with industries, in an ABCFG partnership principles.
   1) Ethics and regulatory challenges in RCT?
   2) The behavior of clinical investigators and the sponsors related to conflicts of interest
   3) Ethics is local (?) engaging cross cultural variations in the ethics of clinical research and clinical trials.
   5) What should we do for the best of the developing countries and developed countries, particularly for the disadvantaged group of population?
   6) How to manage seriously the ABCFG partnership to minimize potential conflict of financial and other issues interest among them?
2. In carrying out a clinical trials and translational research, physician-researcher has to fairly treat the patients/research participants and the sponsors. Various issues in collaborative clinical trials and translational research with industries (pharmaceutical and others) and universities or research institutions: the owner of specimen, data equipments, intellectual property rights; MTA: authorships; royalties; etc. All should be agreed before the studies will be started, based on the idea of the New Sense of Bioethics (Sastrowijoto S, 2012)

3. In managing the ABCFG partnership in clinical trials and translational research to minimize the potential conflicts of interest, HELP approach could be implemented, based on the New Sense of Bioethics concept.
Abad - 20:

- Ilmuwan-ilmuwan Dasar (Biomedical Scientists) dan tokoh-tokoh laboratorium – memandang rendah (scorn) – kegiatan-kegiatan klinik adalah tidak ilmiah.
- Para klinisi menolak penelitian-penelitian laboratorik tidak praktis, tidak cocok dengan kondisi-kondisi klinis.
  → ● Translational research
  ● Clinical trials
  ● Transdisciplinary attitude
• **Three basic sciences**
  1. Biomedical sciences
  2. Clinical epidemiology and biostat.
  3. Bioethics, management and leadership

• What are clinical research, translational research, clinical trials, translational ethics, translational medicine and translational education?

• Related to **ABCFG partnership**, how to manage the potential **conflicts of financial and other issues of interest** among them?
  When clinical trials need **DMC, DSMB, CIC**? Who ought to develop/ set up?
In Clinical Trials:

• Physician – researchers have to serve two masters, the need and demand of patients/families and interest of the sponsors (ABCFG).

• The **quality and standards** of clinical research should be seriously considered:

  1) Ethical and regulatory aspects of health research: Scandals and tragedies on medical/health research; involving human and animal participants; Certain population: women, children, captive population (students, soldiers, prisoners, impairments, etc); Genetics and stem cell studies, biobank, stored materials.

  2) Collaborative studies: interceters, intercountries – regional and international, with varies agreements: **MTA**; owners of **specimen stored materials**; **data**; **equipment**; **products**; intellectual property rights, sharing benefits, sharing publications, **marketing** of products – all have to be agreed before the study will be started.
3) Informed consent, 
4) Scientific misconduct, 
5) Conflicts of interest, 
6) DMC, DSMB, and or CIC development, 
7) Research participants selection & recruitment, 
8) Research involving human, animal, plants, and microbes, 
9) Writing report, 
10) Ethics in clinical trials, their rights and autonomy, 
11) Conflicts of interest in ABCFG partnership.

• All steps of research procedures ought to be based on the basic moral principles and new sense of bioethics, considering the above 11 points. (*Schuster, 2005; Ludbrook et al, 2005*)
Clinical Research Includes:

1) Basic **patient-oriented** research (mechanistic studies)
2) Applied **patient-oriented** research (studies of disease management)-the purposes of the textbook.
3) **Translational research** (a type of patient-oriented research)

A clinical research includes any scientific investigation in which the unit analysis is the person.
(Fig. 15) Interaction and interrelationships among clinical research, basic research and clinical practice activities, diagnostic, and therapeutic studies: A Health Services Research (HSR) (Shuster, 2005; Ludbrook, et all, 2005)
ABCFG – PARTNERSHIP

• Collaborations/ Partnership
  ✓ National, regional, global; institutional
  ✓ Inter centers/ Inter countries/ trans centers
  ✓ A – B – C – F – G partnership
Some issues have to be considered

1. The Ethical & Regulatory Standards
2. Respect for others
   1) Research participants (human, animal)
   2) Stakeholders/partners (A-B-C-F-G)
   3) Law and regulations

ABCFG
A (Academician/ University)
B (Business)
C (Community)
F (Foundation)
G (Government)

Varies agreement should be developed before the studies will be started:

1) MTA (Material Transfer Agreement)
2) The owner of specimen, data, intellectual property rights, products/models, marketing, etc agreement, including stored materials/biobanks, royalties, etc
3) Authorship-PI, co PI: acknowledgement report/writing/publication agreement
4) Conflict of interest in A-B-C-F-G partnership
5) Vulnerable research participants: children, women, prisoners, soldiers, students, impairment
6) DMC, DSMB, CIC development/ set up
7) Human research participant selection (informed consent)
8) IRB approvals
• Universities activities need team approach (internal and external) in education, research, and services.

• A – B – C – F – G partnership is an important team approach.

• Individual researchers, universities and industries have to learn about the management of conflicts of interest and creatively collaboration (Park & Disis, 2004).
• The **strategy** how and what the **triggers** to manage potential conflict of interest should be learnt.
  ✓ Strategy in simply to prohibit personnel financial interest in research.
  ✓ Seek to ensure the integrity of research and guarantee public scrutiny and access, and protect human participants.
  ✓ Give the sponsor the right to control publication.
  ✓ The potential to compromise and independence in design, conduct, publication or compensation for personal service, equity or other ownership interest, royalties, intellectual property rights, consulting incomes scientific advisory board *(Park and Disis, 2004).*
- Translational ethics helps navigate the ethical ramifications of technological and scientific advances – will increasingly challenge the corporate – oriented health care system in the new millennium (Kagarise and Sheldon, 2010).
AUTHORSHIPS

Who will be included in authorship? Who will be PI and Co Pis? Student could be as PI?

- The word “author” is derived from the Latin word auctor, meaning “creator, originato”. The word “authority” comes from the same root. In more modern thinking, the term “intellectual property” is a central issue.

- In discussing who is or are the author(s) and contributor(s), we are better to define the role of authors and contributors. (ICJME, 2015, International Committee on Medical Journal Editors)
The ICMJE recommends that authorship be based on the following four (4) criteria:

- Substantial contributions to the conception or design of the work: or acquisition, analysis, or interpretation of data for the work, and
- Drafting the work or revising it critically for important intellectual content; and
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
All those designated as author should meet all four criteria for authorship, those who do not meet all four criteria should be acknowledged.

All people named as authors meet all four criteria, and it is not the role of journal editors to determine who qualifies or does not qualify for authorship.

If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not journal editor, should be asked to investigate.
The corresponding author is the one individual who take primary responsibility for communication with the journal during the manuscript submission, peer review, and publications process, and typically ensures that all the journals administrative requirement, such as providing of authorship, ethics committee approval, clinical trial registration documentation and gathering conflict of interest forms and statements, are properly completed, although these duties may be delegated to one or more co authors, etc.

The ICMJE recommended that editors send copies to all listed authors. (2015)
Medline will list the names of individual group members who are authors or who are collaborator, sometime called non author contributor.
Non Author Contributor

Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. The acknowledgement could individually or together as a group under a single heading, eg. “clinical investigator” or “participating investigator”.

In defining the role of authors and contributor(s) should always keep up to date.
SUMMARY/ ABSTRACT

• Professionalism of an institution such as School of Medicine have to be improved continuously through the improvement of each individual person (students, resident, administrative staff and faculty members), for the 21st Century. The role of Bioethics and HELP (Humanities, Ethics, Law and Professionalism) in medical health service, research and education as an important and compulsory part concept that have to be implemented at each institution.

• Partnership among disciplines in health (medicine, nursing, nutrition, and the allied health disciplines) should be developed based on the new tolerance on transdisciplinary attitude is an essential part of partnership.

• Various issues of professionalism should be discussed seriously, and in the School of Medicine will be supported by Professional Behavior Committee of the schools.

• Institutional, national, regional, and international ABCFG-Partnership based on the new spirit of ”New Sense of Bioethics” should be improved
V. REFERENCES

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• Belmont Report, 1979


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• WMFE, 2003. Basic Medical Education, WMFE Global Standards for Quality Improvement. WMFE Office: Univ. of Copenhagen, Denmark.
I. The basic norm in:

- Rukun (harmonious)
  1. Conflict prevention
  2. Social harmony
  3. Togetherness
  4. Love

- Hormat (respect)
II. Three attributes (sifat) of Javanesese Bioethics

1. Sikap yang tepat / Attitude: appropriate attitude

1) Temen (honest)
2) Prasojo (modesty)
3) Teposeliro (empathy)

- Memperlakukan orang lain seperti kita sendiri ingin diperlakukan
- Mengenal diri sendiri dan mengenal diri sendiri dan mengenal orang lain

Berbudi Luhur (Virtue)
Menyinarkan kehadiran Allah dalam diri manusia dan lingkungan
2. **Tindakan yang tepat** / **Action**: appropriate action

*Sepi in pamrih rame ing gawe* (hardworking spirit, no conflict of interest) – *hamemangku hayuning bawono*

3. **Tempat yang tepat** / **Place**: appropriate place

*Dunia yang selaras* (The harmonious world) – *dunia yang indah dan tidak dirusak*
III. Tatanan hidup orang Jawa yang ingin dicapai/ level, rank
“Toto titi tentrem kerto raharjo” (prosperity in peaceful system)
IV. Tri rita krana (Three beautiful condition)

1. Jawa

1) Golong giling (keselarasan dengan sesama makhluk ciptaanNya/ harmony with others)
2) Hamemayu hayuning bawono (keselarasan dengan alam/ harmony with nature)
3) Manunggaling kawulo Gusti (keselarasan dengan Sang Pencipta/ harmony with Creator)
2. **Bali**

Tiga (3) cara menuju kebahagiaan, tradisi masyarakat Ubud:

Mambangun harmonisasi hubungan dengan:

1. Tuhan (vertikal)
2. Alam (lingkungan)
3. Sesama manusia dan makhluk hidup lain (horizontal)

Secara berimbang!