

**First, Do Not Kill: Reordering
Human Research Principles from a
Japanese Perspective**
**首先, 不要杀人: 从一个日本人的视角
重新安排人体研究原则**

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Points of this Presentation 要点

- Making priority among human research principles. 人的研究原則優先順位
- Informed consent (IC) is a necessary but not sufficient condition. 知情同意不十分
- No-harm (nonmaleficence) must come first, IC come last. 不危害第一、知情同意最後

Points of this Presentation 要点

- Nonmaleficence is necessary not only for nontherapeutic but also for therapeutic research 治療的研究, since patient-subjects can believe in doctor-researcher 信用医生 and be desperate for innovative therapy 必死追求新規定療.
- It is researcher's duty 研究者的義務 to arrange the research protocol 計畫 according to the principles of nonmaleficence, beneficence, and justice 不危害·有利·公正, before asking informed consent to patient 知情同意以前.

Human Research Principles-- Belmont Report (1979)

- Respect for persons 尊重人
 - informed consent 知情同意
- Beneficence 有利
 - assessment of risk and benefits
危險/受益的考慮
- Justice 公正
 - selection of subjects 公平選擇受試者

Beauchamp & Childress (1979)

四原则

(For biomedical ethics in general, not only for research, and there is no priority among them)

- Respect for autonomy 尊重自主性
- Nonmaleficence (“do no harm”) 不危害
- Beneficence 有利
- Justice 公正

I take this four principles for the analysis.

Why nonmaleficence (no harm)?

The story of Nazi and Japanese doctors' medical atrocities tells that medicine can sacrifice subjects to gain scientific and technical knowledge 科学技術的知識のために受試者を犠牲にしうる.

The old medical precept “first, do no harm 不危害” has significance still in the 20th century. For example, over the half articles of the Nuremberg Code are based on the principle of nonmaleficence.

Researchers must not intend to injure, disable, or kill the subjects 不危害受試者. This is simple but the most important lesson from the Nazi and Japanese cases 最重要教訓.

Principles in the Nuremberg Code

(article 1 to 5)

1. Voluntary informed consent 自發的知情同意
(←autonomy 尊重人)
2. Beneficence to the society 有利社会(←beneficence)
3. Result anticipation by animal research 動物實驗and
on natural history 自然經過 (←nonmaleficence)
4. Avoid unnecessary suffering and injury 避不必要苦
(←nonmaleficence)
5. Avoid death or disabling injury 避死亡及殘疾
(←nonmaleficence)

Principles in the Nuremberg Code (article 6 to 10)

6. Reduce risk, never exceeding humanitarian importance of resolving the problem
(←beneficence)
7. Proper preparation and adequate facility to avoid injury, disability, or death (←nonmaleficence)
8. Scientific quality, skill, and care of experimenter
(←nonmaleficence)
9. Subject's liberty to terminate (←autonomy)
10. Experimenter's duty to terminate to avoid injury, disability, and death (←nonmaleficence)

Ends of Phases of Pharmaceutical Clinical Trial 藥物臨床試驗段階

Phase I: **Safety** 安全

← **nonmaleficence** 不危害

Phase II: **Safety** and effectiveness

← **nonmaleficence** and beneficence

Phase III: Effectiveness with comparative study

← beneficence 有利

(Phase IV: Gather information of the drug in market)

For extraordinary situation? 「異通常研究」?

There may be a reply as follows 反論可:

“The Nazi and Japanese cases were all of extraordinary nontherapeutic researches by constraint 非通常非治療的研究, totally different from ordinary medical research 異通常的研究.

In today's research respecting autonomy, subjects are all free to be informed, evaluate risk and benefits, decide to participate 今日尊重受試者自由.

Research may be of patients' interest, and patients have right to participate in researches and innovative treatments 參加研究病人的權利.”

Nonmaleficence in Today's Research

不危害必要今日的研究

But the principle of nonmaleficence is necessary even for today's ordinary research, because

1. Subjects may fully believe in researcher or doctor-researcher 受試者信用医專家. They would think that researcher does everything good for him/her, there is no harm or risk, must be good benefits, and they are fairly selected.
2. In therapeutic research, patient-subjects can be desperate for innovative therapy and set hope on it more than really it is 病人乞實驗的治療.

Nonmaleficence is a duty of researcher 不危害研究者的義務

Doctor-researcher can abuse this trust by patient-subject
濫用病人信用.

Ambitious researcher may offer high-risk experimental
procedure 野望的研究者問病人危險的實驗治療.

The desperate patient-subject would participate in it
wishing miracle recovery, if there is no effective
treatment so far 病人希望奇跡的回復、參加危險實驗
治療.

→ Informed consent is necessary, but not sufficient
condition 知情同意必要、不十分.

Keeping nonmaleficence is one of researcher's duty 不危
害研究者的義務. Researcher cannot discharge from it
by getting subject's consent 知情同意没有正当化.

Other reasons for nonmaleficence

不危害別理由

The duty of nonmaleficence comes also from the essential character of medicine.

1. Medicine must use human as means in order to accomplish its humanitarian goals of healing and alleviating 医目標善、方法惡.
2. Patients and subjects must finally trust and rely on medical professionals 病人信用医專家, since they have less knowledge and no authority to judge on medical issues 病人知識少、不可判斷.

Five Realms of Medical Ethics

醫療倫理的五領域

Medical ethics has at least five realms:

1. Therapy and treatment 治療

of individual patient 個人患者

2. Research 研究 (on subject)

3. Education 教育 (by exercise on patient 患者實習)

of medical professionals

4. Management 經營

of medical organization 醫療組織

5. Public policy 公共政策

for public health 公衆衛生 (of people 人民)

Structural Ethical Dilemmas of Medicine

医構造的倫理葛藤

The goal of medicine is healing illness and/or alleviating suffering of patients 医目標治病緩苦.
In order to achieve this humanitarian goal, medicine need effective treatment 必要証明効果.
But for proving effectiveness in human 人的効果証明, medicine must try it on human subject 必要人的研究.

Namely, medicine must take “bad” way of “using human as a means” in order to achieve “good” goals of healing and alleviating 目標善、方法惡.

Fundamental Ethical Commandment of Medicine 医根本命令

This leads to make a commandment

“Do not use person merely as means 不用人唯
道具”

(Similar to the second formula of the Moral Law
by Immanuel Kant)

become fundamental in medicine 医根本命令.

This commandment has a corollary of the
principle of respect for autonomy, but signifies
more.

Nonmaleficence is absolutely essential 不危害絕對必要

Medical researcher has power and authority to be able to use subjects as a means 醫學研究者權力權威.

Medical professionals are dominant over subjects (especially patient-subjects) in medical knowledge and authority 醫生支配病人. For in-patient 入院病人, medical professionals also administer their daily life 管理病人生活.

So, medical professionals must not abuse their power and authority 醫專家不濫用權力權威. Above all, they must not offer procedures which tend only to harm the subjects .