Perception of Medical Personnel on Informed Consent for Research Participation in Phramongkutklao Hospital and Phramongkutklao College of Medicine

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Objective: *To evaluate the perception of medical personnel and medical cadets toward informed consent obtained from potential research participants.*
Material and Method: *The authors conducted a study using self-administered questionnaires which included questions about perception on informed consent regarding its objectives, investigator's role, vulnerable subjects, family involvement and children's assent. The answer for each question was graded into 5 scales.*
Results: *A selection of 380, 30.5%, 37.6% and 31.8% of 669 were attending staff, residents, and medical cadets, respectively. A total of 85.5% agreed that informed consent in therapeutic trials should be obtained by their own doctors. A total of 75.3% agreed that the primary objective of informed consent was to protect investigators from lawsuits. A total of 60.8% agreed that participant spouses had to be involved in the informed consent process. A total of 79.5% agreed that permission from children was necessary in research conducted in children.*
Conclusion: *The role of investigators in therapeutic clinical trial, primary objectives of informed consent, and role of spouse were misunderstood among medical personnel and medical cadets. Education on research ethics should concentrate on these issues.*

Keywords: *Perception, Informed consent, Research participant, Medical personnel*

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At present, research has become an important tool of professional medicine since it provides new knowledge and benefits both patients and society[1]. To conduct proper research, investigators have to comply with ethical standards which aim to protect the rights, safety and well being of each research participant[2]. The principles of research ethics include respect to persons, provided benefits and justice to research participants[1-3]. Respect to person is implied through the process of obtaining informed consent. The investigators have to give adequate information and allow the potential research subjects to make the decision freely without coercion or undue influence[2].

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Empirical research has suggested that subjects often have a poor understanding of a research study's intended purpose or of their rights as participants[4]. However, the extent to which problems with informed consent are identified by medical personnel study is unclear, as is how these personnel act to rectify these problems[4,5]. Although several stakeholders are involved in clinical research including investigators, research nurses, study coordinators, and research assistants little research has been performed to determine how any of these stakeholders view the effectiveness of the informed consent process[4,6,7].

To further explore these issues, the authors conducted a survey to determine perceptions regarding the informed consent process. Phramongkutklao Hospital and Phramongkutklao College of Medicine

are specialized facilities that promote clinical research by conducting both inpatient and outpatient studies. Residents, fellows and 5th-6th year medical cadets at Phramongkutklao Hospital and Phramongkutklao College of Medicine perform research protocols and monitor research participants at the bedside and in the community. Because residents, fellows and 5th-6th year medical cadets have frequent contact with numerous participants involved in study protocols of various types, they represent a unique and well-qualified group to survey regarding the informed consent process.

Material and Method

The present study included medical personnel such as medical instructors, residents, fellows and 5th-6th year medical cadets in Phramongkutklao Hospital and Phramongkutklao College of Medicine. For medical students, the authors chose to evaluate the 5th and 6th year medical cadets since they had experience in community research during their 3rd and 4th year of medical education. The members of the ethics committee, or retired medical personnel were excluded. The present study was reviewed by the Royal Thai Army Medical Department Ethics Committee and the survey instrument was initially developed using content suggested from an expert in research ethics. The questionnaire was pilot-tested for comprehension and appropriateness with 25 target personnel. The authors subsequently removed, added and clarified questions. The final survey included 27 items aimed to determine the investigators' understanding on many aspects of informed consent including the objectives, roles, and the respect to participants' decisions. Additionally, the authors evaluated their perceptions on obtaining informed consent from participants in the community and from vulnerable subjects. The answers used a five-point Likert scale ("completely agree", "agree", "equivocal", "disagree", "completely disagree"). This article focuses specifically on the questions regarding informed consent. The questionnaire was then adjusted before sending the final version to the target population. Informed consent was obtained before completing the questionnaire. The responses to each question were analyzed independently using descriptive statistics. A comparison of the answers among groups was analyzed using Chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

The sample included 669 potential subjects at Phramongkutklao Hospital and Phramongkutklao College of Medicine. Of this sample size 279, 265 and 125 were attending staff, residents or fellows and 5th or 6th year medical cadets, respectively. A total of 380 (56.80%) returned the questionnaire. A total of 116 (30.5%), 143 (37.6%) and 121 (31.9%) were attending staff, residents or fellows and medical cadets, respectively. The rate of response to the questionnaire was 116 (41.5%) in attending staff, 143 (53.9%) in residents or fellows and 121 (96.8%) in medical cadets. A total of 276 (71.6%) were male, and 184 (48.4%) had attended training courses on research ethics. A total of 125 (32.9%) had experience in conducting research and obtaining informed consent from human subjects (Table 1).

Table 1. Rates of responding to the questionnaire categorized by academic status

Status	n	Responders (%)
Attending staff	279	116 (41.5)
Residents or fellows	265	143 (53.9)
5th or 6th year medical cadets	125	121 (96.8)
Total	669	380 (56.8)

Of the respondents, 90%-97.9% understood the goals of obtaining informed consent to show respect to human subjects and to protect the rights, safety and well being of research participants. A large number, 75.3% agreed that the objective of informed consent was to protect investigators from lawsuits. Of the sample 92.2% to 97.9% understood that the investigators had to allow the potential participants to make their decisions freely without coercion or undue influence (Table 2).

Of the respondents, 85.5% agreed that the process of informed consent was an agreement between the researcher and potential research participants. It was understood by 88.4% of them that informed consent from patients in therapeutic trials had to be obtained by physicians. Of the sample, 11.8% agreed that the informed consent process impaired the physician-patient relationship (Table 3).

Of the respondents, 60.7% reported that besides obtaining informed consent from individual participants, investigators should also ask their spouses for permission. The findings showed 94.2% agreed that the research in children aged less than 18 years and in mental/cognitive incompetent subjects required informed consent from parents or legal guardians. In addition to informed consent from parents or legal guardians, 79.5% and 37.9% of them

Table 2. Responses of the questions on the ethical principles

Statements	Agreement (%)		
	Attending staff (n = 116)	Resident/fellow (n = 143)	Medical cadet (n = 121)
Obtaining informed consent is to show respect to the research participants	98.3 (114)	97.9 (140)	97.5 (118)
The objective of informed consent is to protect rights, safety and well being of research participants	89.7 (104)	92.3 (132)	87.6 (106)
The objective of informed consent is to protect investigators from lawsuits	72.4 (84)	80.4 (115)	71.9 (87)
Investigators should allow the potential subjects to make decision freely without coercion	98.4 (114)	97.2 (139)	98.3 (119)
Investigators should allow potential subjects to make decision freely without undue influence	92.2 (107)	97.9 (140)	95.9 (116)

Table 3. Responses of the questions on investigator and physician roles

Statements	Agreement (%)		
	Attending staff (n = 116)	Resident/fellow (n = 143)	Medical cadet (n = 121)
Informed consent is the agreement between researchers and potential research participants*	88.8 (103)	79.7 (114)	89.3 (108)
Physicians should obtain informed consent from their patients	85.3 (99)	81.1 (116)	100.0 (121)
Informed consent process affects the physician-patient relationship	8.6 (10)	14.0 (20)	12.4 (15)

* p-value < 0.01

responded that investigators should ask for affirmation from children and mental/cognitive incompetent subjects, respectively (Table 4). Interestingly, a statistically significant difference was found between the responses from pediatricians and those who were not (p-value = 0.01). Of those who were not pediatricians, 79.5% responded that investigators should ask children for their affirmation. Where as only 61.7% of pediatricians accepted that concept.

Discussion

The current study is the first survey to assess the understanding of medical personnel at Phramongkutklao Hospital and Phramongkutklao College of Medicine about informed consent for participating in research. Although research ethics is integrated into the training courses of clinical epidemiology and research for medical personnel, only half of them replied that they attended the courses. Moreover, only one-third of them noted that they had experience in obtaining informed consent from research participants. These findings indicate that the education on research ethics, especially informed consent procedure, should be emphasized along with the effort to establish an appropriate research atmosphere in the authors' institution.

Most of the medical personnel agreed with the principles of informed consent. They also agreed with the goal of informed consent to protect the rights, safety and well being of research participants. Of the sample, 75% also understood that the objective of informed consent was to protect the investigators from lawsuits. This perception needs to be addressed since the participant's signature in the consent doesn't waive his/her legal rights or release the investigator from liability for negligence.

Table 4. Responses of the questions on vulnerable participants

Statements	Agreement (%)				
	Total	Attending staff (n = 116)	Resident/fellow (n = 143)	Medical cadet (n = 121)	p-value
Besides obtaining informed consent from the individual participant, investigators have to ask for the spouse's permission*	231 (60.7)	63.8 (74)	76.2 (109)	39.7 (48)	<0.001
For research in children, investigators have to obtain informed consent from parents or legal guardians	358 (94.2)	97.4 (113)	92.3 (132)	93.4 (113)	0.55
Besides the informed consent from parents, investigators should also ask children for affirmation	302 (79.5)	75.0 (87)	77.6 (111)	86.0 (104)	0.13
For research in subjects with mental/cognitive incompetence, investigators have to obtain informed consent from legal guardians*	358 (94.2)	98.3 (114)	88.8 (127)	96.7 (117)	0.11
Besides the informed consent from legal guardians, investigators should also ask the affirmation from mental/cognitive incompetent subjects	144 (37.9)	29.3 (34)	39.2 (56)	44.6 (54)	0.02

* p-value < 0.05

For therapeutic trials, most personnel (85%) showed confusion between the roles of investigators and physicians. In such research, the physician should be particularly cautious if the subject is in a dependent physician-patient relationship since the subjects may consent under duress or from the assumption that the research will help them[8,9]. Based on the Declaration of Helsinki, informed consent should be obtained by a well-informed physician who is not engaged in the investigation and completely independent of this relationship[3]. Some personnel believed that informed consent affected the ensuing physician-patient relationship[9]. Taylor's survey study of 170 specialists in breast cancers revealed that physicians perceived a loss of individual decision-making power and believed that their professional "self" was not compatible with the informed consent regulations[4]. Therefore, the investigator should realize the differences between the roles of investigator and physician when dealing with therapeutic trial research involving human subjects[10]. More than half of the samples noted that besides informed consent obtained from the individual participants, permission from their spouses was also required. This response is similar to Zhai's study in China which showed the cultural effect on attitude and perception[5]. Most Chinese people believe the decision had to be made not only by the individual but also by family members. Thus, the investigators have to be aware of culture issues, especially when conducting multi-centered and multi-national research. Basically, the subjects should be encouraged to discuss with their spouses and family members before making decisions. However, the majority were unaware the spouse's opinion cannot override the subject's decision.

Most personnel agreed it was necessary to ask for permission from parents or legal guardian of children and mental/cognitive incompetent subjects. A large number, 75% agreed it was proper to ask children for their affirmation, but only one-third agreed to ask subjects with mental/cognitive incompetence. Children and subjects with mental/cognitive incompetence cannot give or refuse consent by themselves[1,6,9]. In addition they may be especially prone to giving consent under duress. Thus, they are vulnerable and need special protection. The investigator must obtain informed consent from their parents or legal guardian. When vulnerable subjects are able to give assent or affirmation of agreement to participate in the study, the investigator should respect their decision and also obtain the assent[10]. Interestingly, a lower percentage of pediatricians agreed with the concept of assent in children. The reason is probably due to their more complete understanding of children, and more correctly estimate the children's capabilities[9,10]. The

appropriate age of children for assent may vary depending on culture, maturity of the children and type of research.

In summary, most medical personnel of Phramongkutklao Hospital and Phramongkutklao College of Medicine understood the concept of informed consent. However, some aspects need to be clarified and emphasized, i.e. the roles of investigators in therapeutic trials, the ultimate goal of obtaining informed consent and assent in vulnerable subjects. The training of research ethics, especially the informed consent process, should be implemented to assure the accomplishment of sound and ethical research.

References

1. Beauchamp TL, Childress JF. Respect for autonomy. In: Beauchamp TL, Childress JF, editors. Principles of biomedical ethics. 5th ed. New York: Oxford University Press; 2001: 57-112.
2. International Conference on Harmonization (ICH) Guidances [homepage on the Internet]. 2005 [cited 2005 Feb 20]. Available from: http://www.fda.gov/cber/guidelines.htm
3. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2000; 284: 3043-5.
4. Taylor KM, Shapiro M, Soskolne CL, Margolese RG. Physician response to informed consent regulations for randomized clinical trials. Cancer 1987; 60: 1415-22.
5. Zhai X. Informed consent in medical research involving human subjects in China. In: Song SY, Koo YM, Macer DRJ, editors. Asian bioethics in the 21st century. Christchurch, New Zealand: Eubios Ethics Institute; 2003: 4-5.
6. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? JAMA 2000; 283: 2701-11.
7. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. Lancet 2001; 358: 1772-7.
8. Howard JM, DeMets D. How informed is informed consent? The BHAT experience. Control Clin Trials 1981; 2: 287-303.
9. Levine RJ. Ethics and regulation of clinical research. Baltimore, MD: Urban & Schwartzenberg; 1981.
10. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. Washington, DC: US Government Printing Office; 1979.

ความเห็นของบุคลากรในโรงพยาบาลพระมงกุฎเกล้าและวิทยาลัยแพทยศาสตร์พระมงกุฎเกล้าต่อการให้ความยินยอมโดยได้รับข้อมูลของอาสาสมัครที่เข้าร่วมในโครงการวิจัย

เดชวิจิตร์ สุวรรณภักดี, แสงแข ชำนาญวนกิจ, สุธี พานิชกุล

วัตถุประสงค์: *เพื่อศึกษาความเห็นของแพทย์บุคลากรทางการแพทย์ และนักเรียนแพทย์ทหาร ต่อการให้ความยินยอมโดยการให้ข้อมูลของอาสาสมัครที่เข้าร่วมในการวิจัย*

วัสดุและวิธีการ: *สร้างแบบสอบถามฉบับสมบูรณ์ ซึ่งเป็นแบบสอบถามชนิดให้ตอบเอง โดยรายละเอียดของแบบสอบถาม แบ่งเป็น การประเมินความเข้าใจเกี่ยวกับบทบาทของผู้วิจัยต่อการขอความยินยอม, วัตถุประสงค์ของการขอความยินยอม, การเคารพในการตัดสินใจเข้าร่วมการศึกษาของอาสาสมัคร, การขอความยินยอมในชุมชน, การขอความยินยอมในอาสาสมัครที่เป็นเด็ก, การขอความยินยอมในอาสาสมัครที่เป็นบุคคลอ่อนแอหรือทุพพลภาพ แบ่งระดับการประเมินความคิดเห็นเป็น 5 ระดับ คือ เห็นด้วยอย่างยิ่ง, เห็นด้วย, ไม่แน่ใจ, ไม่เห็นด้วย, ไม่เห็นด้วยอย่างยิ่ง*

ผลการศึกษา: *จากผู้เข้าร่วมการศึกษา 380 ราย เป็นอาจารย์ ร้อยละ 30.5 แพทย์ประจำบ้านและแพทย์ประจำบ้านต่อยอด ร้อยละ 37.6 และนักเรียนแพทย์ทหาร ร้อยละ 31.8 ผลการตอบแบบสอบถามเกี่ยวกับคำถาม การขอความยินยอมจากอาสาสมัครที่เป็นผู้ป่วยในการเข้าร่วมการวิจัยที่เกี่ยวข้องกับการรักษาควรทำโดยแพทย์ที่รักษาผู้ป่วยรายนั้น พบว่า ตอบเห็นด้วย ร้อยละ 85.5 และไม่มีความแตกต่างในระหว่างกลุ่มบุคลากร ความเห็นเกี่ยวกับคำถามการขอความยินยอมจากอาสาสมัครที่เข้าร่วมการวิจัยมีวัตถุประสงค์เพื่อป้องกันผู้วิจัยจากการฟ้องร้อง พบว่าตอบเห็นด้วย ร้อยละ 75.3 กรณีที่อาสาสมัครมีสามีหรือภรรยานอกเหนือจากการลงนามให้ความยินยอมจากอาสาสมัครต้องได้รับอนุญาตจากสามีหรือภรรยาด้วย ตอบเห็นด้วย ร้อยละ 60.8 การเข้าร่วมการวิจัยของเด็กหรืออาสาสมัครที่อายุน้อยกว่า18 ปี นอกเหนือจากการลงนามให้ความยินยอมจากบิดามารดาแล้ว ต้องได้รับความยินยอมจากเด็กด้วย พบว่า ตอบเห็นด้วย ร้อยละ 79.5*

สรุป: *บุคลากรส่วนใหญ่ของโรงพยาบาลพระมงกุฎเกล้าและวิทยาลัยแพทยศาสตร์พระมงกุฎเกล้า ยังมีความรู้และความเข้าใจที่คลาดเคลื่อนในเรื่องของบทบาทของผู้วิจัยต่ออาสาสมัครที่เป็นผู้ป่วย วัตถุประสงค์หลักของการขอความยินยอมจากอาสาสมัครในการเข้าร่วมการวิจัย และต้องได้รับอนุญาตจากสามีหรือภรรยาอาสาสมัครนอกเหนือจากการลงนามให้ความยินยอมจากอาสาสมัครแล้ว ดังนั้นการอบรมความรู้ ด้านจริยธรรมของการทำวิจัยในคนจึงควรมุ่งเน้นที่ประเด็นดังกล่าว เพื่อสร้างทัศนคติที่ถูกต้องต่อไป*