

Implementation of Patient-Centric Informed Consent -Intervention by a Third-party in the IC Process-

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Over the last fifteen years, "Informed Consent (IC)" has been rapidly established as a rule for clinical settings in Japan. However, behind its establishment exists the serious problem that IC is conducted without a sound understanding by involved parties of its real purpose. This fact is confirmed by a number of inadequate IC cases in which patients are suffering due to unreasonable losses. Alternatively, an opposing argument states that the majority of medical professionals are faced with extreme time constraints that are causing them to understate IC. Under the circumstances, the fact remains that the medical front is becoming more and more diversified and complex. Consequently, if the above issues are not fundamentally reviewed at an early stage then IC will continue to be conducted based on false practices. This study initially examines two cases of IC in which the patients fell victim to a misguided approach to IC. Following this, the study underlines the necessity of the "intervention by a third party in the IC process", so to ensure that patient-centric IC will be implemented in a completely unbiased manner.

Key words:

Informed consent (IC)

Intervention by third-party in IC

Patient-centric IC

IC Mediator / IC Supporter

IC validation by third party

Introduction

The basis of Informed Consent (IC) is autonomy; this basis originates from the momentum towards civil-rights movements within the U.S.⁽¹⁾⁽²⁾. This idea then became the cornerstone of IC doctrine, and it was the reservoir of medical malpractice lawsuits that shaped Euro-American IC history. However, as it was, the Western idea of IC was not unacceptable for use in Japan. Circa 1990 saw a growing debate around IC in Japan, and a unique method of IC was created to accommodate the thought processes and common practices that had long taken root on Japanese soil; to implement IC on the basis of a trusting relationship between a medical professional and a patient⁽¹⁾⁽³⁾. However, we often receive reports that IC had been implemented before a trusting relationship was developed, or before any effort to form a trusting relationship was made. In such cases, patients came to suffer from unreasonable losses. This indicates that although IC has established itself as a rule, the preconditions regarding IC are not necessarily well understood throughout the medical profession. This study cites the following two cases and extracts the problems and possible causes from them: the first case involved a patient consenting to the consultation of an IC-based team that was organized by the primary doctor, but this was not executed due to a lapse in communication among the team members. The other case saw a doctor failing to abide by some IC preconditions due to time constraints. Based on the examination of the results of these two IC cases, this study discusses whether the "intervention by a third party in the IC process" is applicable, while also deriving some practical solutions for the implementation of patient-centric IC.

Methods

The interview survey was conducted between March 2011 and June 2014 on patients and medical professionals. From the results of the interview survey, the following two cases were selected as the subjects of this study^(*1):

- A case in which the primary doctor promised the patient that an IC-based team would consult with her regarding her treatment, the patient consented to this but the IC-based team medicine never worked well due to a communication lapse among the team members that ultimately caused the patient to suffer unreasonable losses.
- A case in which the primary doctor failed to abide by the preconditions of IC because he was under too much pressure from time constraints due to a large number of patients waiting for his examination. The patient, when told to get hospitalization at a later date, tried to consult the doctor regarding any future risks but was refused on the grounds of time constraints. The patient came to experience a feeling of displeasure due to mistrust in the doctor, suffered from many stressful days and finally her chronic diabetes also worsened during the time to her hospitalization.

In scrutinizing these two IC cases, the below steps were executed:

<1> Evaluate whether all of the preconditions of IC (Table 1) were followed during the IC process, and locate which items were not complied with.

<2> Study the possible causes of the non-compliance.

<3>Based on the results from point <1> and <2>, study the applicability of the "intervention by a third party in the IC process"^(*2).

On the basis of the results from points <1> to <3>, this study suggests some potential methods for the implementation of patient-centric IC through the intervention by a third party.

(*1) All the names of facilities and parties involved in the IC cases were remained anonymous for the protection of personal information. The author obtained advance approval for publication from each party involved.

(*2) The author suggested in the previous study⁽⁴⁾ the availability of the "intervention by third party in IC process".

Table 1 Preconditions of IC

| | |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Essential steps for IC⁽⁵⁾⁽⁶⁾ | 1) Medical professional provides patient with therapeutic info including alternative |
| | 2) Medical professional repeats the step 1) until patient fully understands it and answers to all questions from patient |
| | 3) Medical professional gives patient a chance to contemplate all of therapeutic info provided and goes into it in more detail with patient if necessary |
| | 4) Patient makes a decision whether or not to accept/reject therapy suggested, on a basis of his/her own values, environmental factors, and so on |
| | 5) Medical professional and patient share decision-making and confirm agreement |
| Semi-essential steps for IC⁽²⁾⁽⁹⁾ | a) When the patient rejects all the suggestions, the medical professional provides patient with another alternative |
| | b) According to circumstances, above five steps 1) to 5) are to be repeated |
| Items to tell patient⁽⁷⁾⁽⁸⁾⁽⁹⁾ | i) Disease name and state |
| | ii) About treatment: purpose, efficacy, precautions, concrete contents, post-treatment, possible complications, possible risks, occurrence frequency of complications/risks |
| | iii) About alternative treatment: purpose, efficacy, precautions, concrete contents, post-treatment, possible complications, possible risks, occurrence frequency of complications/risks |
| | iv) Possible undesirable consequence when proposed treatment is not executed |

Results

1. Examination of IC Cases

For the selected two IC cases, the problems were extracted in confirmation of compliance with the preconditions (see Table 1), and then the possible causes of non-compliance were discussed.

1.1 IC Case-1

- Time of implementation: February, 2012
- Place of implementation: middle-sized Hospital A located in B city, C prefecture
- Interviewee: Patient Ms. D (80s) and Nurse E (Internal Medicine)

Case overview

Ms. D, who had experienced a sharp pain in her leg, visited the surgery of Hospital A, received a diagnosis of “acute bacterial cellulitis” and was told to get hospitalized by the primary doctor. Also the primary doctor explained to her that the IC-based team medicine would be conducted during the hospitalization by the team consist of staffs from the internal medicine, the surgical, the pharmaceutical department and the nutritionists office. Ms. D, a serious Type 1 diabetic, fully understood his explanation and gave written informed consent, which appeared that the IC process was done properly between Ms. D and the primary doctor. In fact, however, the IC-based team medicine promised by the primary doctor did not work well due to a conflict between the internal medicine and the surgical over the timing of when to stop the antibiotic administration. This conflict last for a week during which Ms. D and her family were continuously bombarded with contradictory information. On the day 10 in the hospital, the antibiotic administration was discontinued, and when another two weeks lapsed, Ms. D’s symptoms went negative. Nurse E, a member of the team, was sure that the antibiotic administration should not have been discontinued that early. She went through the ethical dilemma caused by the fact the team medicine did not work well as promised, but the circumstances did not allow her to ostensibly refute the treatment policy decided by the team leader. Instead, Nurse E dared to apply the antibiotic cream to the affected part of Ms. D at her own discretion, which dramatically cured her symptoms. Though Ms. D and her family were very grateful to Nurse E for her courageous action, they strongly requested the general manager of Hospital A to re-examine the entire course of treatment including the IC process. However, this request was flatly rejected by the chief nurse, and Ms. D had no choice but to move away to another hospital.

[Problems / Possible Causes]

The following problems were extracted from the IC Case-1:

1. The IC-based team medicine that had been promised by the primary doctor upon the consent was not properly given to Ms. D.
2. Nurse E, as a team member, faced with an ethical dilemma caused by the fact that the IC-based team medicine was not given as promised, but the circumstances did not allow her to refute the treatment policy decided by the team leader.
3. Despite the request from Ms. D’s family to the hospital general manager that the entire course of treatment including the IC process be reviewed, the chief nurse flatly rejected the request only at her own discretion without forwarding it to in-house concerned personnel.

The possible causes of these problems were as follows:

- The nature of IC or team medicine was not fully recognized by medical professionals in the team. Or some problems, such as insufficiency of lectures, may have existed with medical curriculums on IC, medical communication, and/or team medicine that they had taken at school.
 - The medical professionals in the team neglected their obligation to make efforts to implement IC^(*3) due to lack of sense of medical ethics.
 - A supposedly impermissible hierarchy structure in the team made the communication within the team difficult.
 - An outdated, false medical paternalism remained in Hospital A.
- (*3) In the amendment of Medical Service Act (1997), the obligation of doctors to make efforts to implement IC was clearly specified⁽⁵⁾.

1.2 IC Case-2

- Time of implementation: June, 2014
- Place of implementation: Medical University Hospital F (Ophthalmology) located in G city, H prefecture
- Interviewee: Patient Ms. J (70s)

Case Overview

Ms. J visited the ophthalmology department of Medical University Hospital F, one of the nation's leading medical university hospitals. There, she received a diagnosis of "band keratopathy", and was told by the primary doctor to get hospitalized at a later date for the laser surgery. IC was implemented with Ms. J mainly on the surgery and hospitalization but not on the future risks. The amount of time spent for IC was only five or six minutes. When Ms. J asked the primary doctor about the future risks, he replied that she might need the corneal transplantation, because her serious diabetes would prevent the regenerating epithelium from stabilizing. He told her to read the IC briefing papers at home and then sign them if agreeable. Startled to hear the term of "transplantation", Ms. J tried to acquire more detailed explanation, but the primary doctor, under the time pressure, only suggested that he would talk on it when it really happened. Ms. J, for fear that the primary doctor would be offended by further questions, gave up trying to get more information out of him. Ms. J came to experience a feeling of displeasure due to mistrust and a loss of confidence in the doctor, suffered from many stressful days and finally her chronic diabetes worsened showing a sharp rise in her blood sugar during the time to hospitalization. The laser surgery itself succeeded. However, being frustrated by the behavior of the primary doctor shown during the pre-hospital IC process, Ms. J quit Hospital F and moved to another local eye clinic.

[Problems / Possible Causes]

The following problems were extracted from the IC Case-2:

1. Judging from the fact that the primary doctor told Ms. J to read the IC briefing papers and sign them at home, most of “Essential steps for IC” 1) to 6) were not properly performed by the primary doctor.
2. In general, the declaration of intention by the patient whether to accept/reject the proposed treatment becomes possible only when she/he is given the full explanation including on future risks from the doctor. In this case, however, the primary doctor left out the explanation about the future risks associated with corneal transplantation on ground of the time constraint. That is, the “Essential steps for IC” 1) to 6) were not well performed, and not all of the “Items to tell the patient” were informed to the patient by the primary doctor.
3. Judging from the fact that Ms. J came to feel a sense of displeasure with the primary doctor and spent stressful days, and then her chronic diabetes worsened during the time to hospitalization, an invisible pressure by the primary doctor had a bad influence on her QOL.

And, the possible causes of these problems were as follows:

- The nature of IC was not fully recognized by the primary doctor. Or some problems, such as insufficiency of lectures, may have existed with medical curriculums on IC and/or medical communication that he had taken at school.
- The primary doctor neglected his obligation to make efforts to implement IC due to lack of sense of medical ethics.
- The time constraint that the primary doctor was facing was caused by the manpower shortage. This issue could have been treated earlier as a matter of human resources by the hospital management.
- The primary doctor implicitly brought Ms. J an invisible overpowering pressure due to distorted medical paternalism.

1.3 Summary

This study so far has addressed the two IC cases, and extracted problems / possible causes from each case. Tables 2 and Table 3 respectively summarize the results from the examination of IC case-1 and IC case-2.

Table 2 IC Case-1: Problems/possible causes of IC done under team medicine

| <i>Classification of problems</i> | <i>Possible causes</i> |
|---------------------------------------------------------|-------------------------------------------------------------------------------|
| Poor understanding of nature of IC | A problem with medical education on IC, lack of ethical sense |
| Non-performance or negligence of essential steps for IC | Lack of ethical sense, non-performance of obligation to make efforts to do IC |

| | |
|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Poor understanding of nature of IC-based team medicine | A problem with medical education on IC-based team medicine, lack of ethical sense, lack of experience in team medicine |
| Existence of hierarchy in team medicine | Surviving distorted medical paternalism within a medical facility, a problem with medical education on team medicine, lack of experience in team medicine |
| Conflict over the treatment policy between the inner medicine and the surgical | A problem with medical education on team medicine, surviving distorted medical paternalism |
| Tendency toward medical paternalism | Surviving distorted medical paternalism within a medical facility |

Table 3 IC Case-2 : Problems/possible causes of IC done under time constraint

| <i>Classification of problems</i> | <i>Possible causes</i> |
|---------------------------------------------------------|-------------------------------------------------------------------------------|
| Poor understanding of nature of IC | A problem with medical education, lack of ethical sense |
| Non-performance or negligence of essential steps for IC | Lack of ethical sense, non-performance of obligation to make efforts to do IC |
| Unable to spend enough time on IC | Shortage of manpower |
| Invisible pressure by doctor | Surviving distorted medical paternalism within a medical facility |

Judging by the contents of these two tables, most of the problems in the IC process were typically related to a sense of right or wrong in the medical facilities or medical professionals:

- Whether or not the nature of IC is correctly recognized.
- Whether or not "Essential steps/Semi-essential steps for IC" are valued.
- Whether or not a sense of professional ethics have been developed.
- Whether or not the distorted practice of medical paternalism has been overcome.

Except for the practical problems like a lack of experience in IC-based team medicine (Table 2) and an issue regarding human resources (Table 3), the matters that relate to right or wrong are easily subjectivized and should be treated in an evenhanded manner. As discussed in the previous work⁽⁴⁾, "intervention by a third party in the IC process" can provide a practical solution for the implementation of patient-centric IC. Additionally, through the mediation or observation by a third party during the IC process the following can be expected⁽¹⁰⁾: 1) a smooth communication flow is established between the parties, 2) patient comfort is enhanced, 3) the issue of "he said, she said" can be avoided, and 4) time constraints caused by a lack of manpower may possibly be reduced.

2. Intervention by Third Party in IC Process

In terms of the correct implementation of IC, there are two possible approaches that can be followed for the "intervention by a third party in the IC process". Firstly, the "IC mediator/IC supporter", and secondly, "IC validation by a third party". Concerning the "IC mediator/IC supporter", training courses have commenced in a couple of cities throughout Japan^(*). The "IC validation by a third party" was first suggested in the author's previous work⁽⁴⁾. The characteristics and present status of these approaches are described below.

2.1 Efficient Use of IC Mediator / IC Supporter

The function of the "IC mediator/IC supporter" to sit in on the IC process emerged in Japan approximately five years ago. In some medical practices, "IC mediators/IC supporters" actually participate in the IC process to support the communications between patients and doctors. Aside from having an intermediary function, the "intervention by IC mediators/IC supporters" is also effective in enabling unemotional monitoring of the IC process allowing the possibility of independent opinions being given by IC mediators/IC supporters to serve as useful references after the fact. On the other hand, the authorization given to "IC mediators/IC supporters" and the range of their activities are limited to ensure that the occurrence of misunderstandings or legal disputes are minimized. The current state of "IC mediators/IC supporters" is that: a) medical professionals, such as nurses or doctors mainly concurrently serve as IC mediators/IC supporters, b) they are only permitted to sit in on the IC process to ensure smooth communication between the patient and doctor, not to implement IC in place of the doctor⁽¹⁰⁾.

The author considers medical social workers (MSWs) to be the most appropriate personnel for the role of "IC mediators/IC supporters" because most MSWs are qualified personnel who have passed the national Certified Social Worker exam, and have excellent communication skills and experience as expert advisors at medical facilities. However, the fact is that the number of authorized MSWs remains limited, and this shortage is creating very difficult working conditions for this profession⁽¹¹⁾⁽¹²⁾. In order to successfully utilize MSWs in "intervention by a third party in the IC process", this quantitative problem should be solved as a matter of first priority.

To establish the approach of "IC mediators/IC supporters" in society, we must consider the following aspects⁽¹⁰⁾:

- Intensification of educational programs that provide medical and ethical expertise to fully qualify "IC mediators/IC supporters" in the process of intervention during the IC process.
- Establishment of an authorization system for "IC mediators/IC supporters".
- Promotion of collaborative activities with patient groups and/or citizen groups.

2.2 IC Validation by Third Party

There are a number of small-scale clinics and mid-sized hospitals without an IC monitoring body such as an institutional ethics board, however, during the interview survey the author received

a couple of case reports of IC incompletely implemented at such medical facilities. Specifically, medical professionals, including doctors, dentists and/or surgeons at private hospitals failed to abide by the preconditions of IC, or to comply with the ethical guidelines governed by the Ministry of Health, Labor and Welfare (MHLW) or academies, but in fact these instances of non-compliance have been overlooked or not seen as problems.

Although there has yet been no practical developments reported, the following existing practices appear to be applicable to the "IC validation by a third party":

- Ethics consultation of HEC (Hospital Ethics Committee)⁽¹³⁾⁽¹⁴⁾
- Second opinion⁽⁵⁾

However, a majority of the institutional ethics boards at hospital and medical facilities in Japan tend to have characteristics similar to those of the IRB (Institutional Review Board) rather than the HEC⁽¹³⁾⁽¹⁴⁾. Thus, there are a handful of hospitals that have the ability to deal with IC-related problems, or conflicts as agendas for their institutional ethics boards. Furthermore, the practice of "second opinion" has not yet been established as a patient-centric approach in Japan⁽⁵⁾. According to a couple of reports that the author received during the interview survey, the requests for a second opinion were often obliquely rejected by primary doctors. Notably, in one particular case where a patient advised their doctor of their wish for a second opinion from a different hospital concerning the IC contents, the doctor was reluctant to comply and displayed a pacifying attitude in order to convince the patient not to obtain a second opinion. Additionally, with the restriction of health insurance being a negative factor, the rate of utilization of the second opinion is scarce.

2.3 Summary

Table 4 summarizes the discussions in the sections, 2.1 and 2.2.

Table 4 Advantages and Issues of Intervention by Third Party in IC Process

| | Advantages | Issues/Challenges |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| IC Mediator / IC Supporter | | |
| Training Course | Trainees, after completing the course, are adaptable as assets to promote a smooth communication for IC or to monitor the IC process in a neutral way. | Responses to legal actions, reinforcement of medical/ethical education, recognition system, collaboration with patient / citizen group |
| Utilization of MSWs | Most approximate human materials to "IC mediators / IC supporters" | Manpower shortage, improvement of working conditions |
| IC Validation by Third Party | | |
| HEC | Function of "ethics consultation" is applicable as it is. | Necessity of increase in number of HECs |

| | | |
|-----------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| Practice of Second Opinion | Function of “medical evaluation or judgment by third party” is applicable as it is. | Tendency of conciliatory attitude by doctors, non-applicability of insurance |
|-----------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------|

Discussions

On the basis of the considerations shown so far, the following points re-discuss the applicability of the "intervention by a third party in the IC process".

As shown in Table 2 and 3, the following problems were extracted from the two IC cases:

1. Poor understanding of the nature of IC/IC-based team medicine,
2. Non-performance or negligence of essential IC steps,
3. Existence of conflict / hierarchy in team medicine, and
4. Tendency towards medical paternalism

Given that the "intervention by a third party in the IC process" was applied to IC sites, these various improvements are expected: 1) a smooth flow of communication between the interested parties, 2) enhancement in patient comfort, 3) avoidance of the "he said, she said" issue, and 4) reduction of time constraints caused by manpower shortages. In other words, the "intervention by a third party in the IC process" is the essential first step in the conceptual framework for the resolution of IC-related issues.

On the other hand, the problems stated above are subject to the sense of right or wrong. In an earlier section (1.1), the author pointed out the necessity to reform the medical curriculum on IC, medical communication and/or the relationship between the patient and medical professionals so to ensure that medical personnel in training can develop a fundamental sense of ethics, patient-centric views, and understand the significance of IC.

This study has introduced two elements for the successful achievement of the "intervention by a third party process": "IC mediator/IC supporter" and "IC validation by a third party". Ensuring the availability of "IC mediators/IC supporters" has been demonstrated through the launch of relevant training courses for "IC mediators/IC supporters". For the "IC validation by a third party", given its function to monitor or evaluate post-IC processes, the HEC and/or second opinion will provide a promising outlook. On the other hand, there are various problems that remain before a solid platform for the "intervention by a third party in the IC process" can be built, as shown in Table 4. The most urgent and crucial matters that require addressing for this matter are: 1) to investigate the legal impact on "IC mediators/IC supporters", 2) to eliminate the issue of MSW's manpower shortage, and 3) to solicit a thorough understanding of the position of the "IC validation by a third party" in the HEC and/or second opinion. The author mentioned earlier that a medical society led local community group could be expected to serve as one of the elements of the "IC validation by a third party". From this viewpoint, the aim is for not only a non-participant community group to act as the IC evaluator, but to make certain that the "patient" and "medical professional" participate equally in the process so as to realize the impartial validity of "IC validation by a third party"

process. To embrace the "IC validation by a third party" process based on this thinking, it is first necessary to increase the awareness of it among medical societies and local community groups. Most importantly, whether it be a case of "intervention by a third party in the IC process" or "IC validation by a third party", all actions should be conducted based on the patient-centric view at all times.

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