

## The Most Significant Move Forward

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It is a truth universally acknowledged, that without a doubt, medical malpractice is intolerable. But with all due respect to the victims of malpractice, I am not here today to denounce mistakes. Then what? Well, while hospitals and doctors dread bad reputations, certain things with the medical world have been making it possible for them to conceal their mistakes, even fabricate. That is what I am here today to denounce. I believe that first and foremost, every case of possible medical malpractice must be secured from being buried, and to establish steps to realize this, will be the most significant breakthrough.

Medical institutions in Japan long remained infamous for their secretiveness. They had their reasons and also the means to conceal inconvenient information including malpractice, from government authorities and the people. Thus, although we know for fact that accidents and human error do not spare even hospitals, presently we can only speculate as to their actual conditions. Our best speculation so far is from a recent research, which estimated that at least 130 cases exist per hospital per year - the patients are exposed unexpectedly to threats or actual harm to their being, with or without negligence of the hospital.

Despite the secretiveness however, there have been ways to bring cases of malpractice into light. Most has been due to prosecutions from within the hospitals, or outside, such as patients themselves or patients' rights groups. Some hospitals voluntarily disclose their accident records. Nonetheless, none have yet succeeded in uncovering as many cases as practical.

How could this be? The foremost reason why the true facts of medical malpractice remain obscured is that there has never been practical legal obligations on the national level; neither for disclosure, nor for having quality management structure within the hospitals. Please think about this: how do we discuss how to reduce the number of accidents, or how to learn from past mistakes, if we lack solid numbers and clear understanding?

Now, I would like to introduce a hospital that experimented on a giant step forward, which I'd like all the hospitals in Japan to follow. It is to become qualified with a class of ISO standards, namely the "ISO 9000 series", which is an international standard for quality control. This is the idea, which I ask all of you to take home today.

Although manufacturers mostly employ ISO 9000, its guidelines for quality management can by all means be adopted to medical institutions. In which case, the "end product" would mean "to maintain or to restore the patient's health conditions". Among several attempts in Japan, both public and private, Okubo Hospital in Ibaragi prefecture became a pioneer of this system in 1998. The following is an overview of the new quality management scheme in Okubo hospital following the requirements of ISO 9000.

First, it was made so that every step of treatment of a patient, such as medication and operation, is planned out, and that every action is kept accurate record of. In addition, preserving records and reporting regularly became strict obligation for everyone, with no inconveniences small enough to escape. In other words, ISO 9000 requires the hospital to be able to predict the steps in which accidents might occur, and very importantly, allows every action to be traced back to the people responsible.

Secondly, the hospital will pool and analyze the data and share it with all personnel. Then, by making use of an internal committee, the hospital can frequently discuss and execute measures for improvement. Finally, after the hospital was qualified by an authorized ISO agent, it is semi-annually inspected by the agent. Together with the Health Department of Ibaragi prefecture to which the hospital discloses the records, they keep track of what goes on inside the hospital. Surprisingly, none of these are current requirements of the government.

After the adoption of ISO 9000, quantity of accident reports significantly increased. This should not be mistaken for increase of accidents, but it suggests rising awareness of personnel, which is due to large amount of education and shared sense of purpose that accompanies the adoption of ISO 9000. In a nutshell, within the structure of ISO 9000, to attempt to conceal malpractice becomes extremely difficult, and even if it is done, the chance is that it will be exposed.

Well, all this may sound idealistic, but not exactly. Fulfilling ISO requirements is proved in the world as one of the best ways to improve management conditions as well as corporate evaluation. Moreover, I believe adopting ISO 9000 to hospitals will work to converge many separate improvement ideas that are presently discussed.

I suggest that we create this an obligation for all hospitals in Japan, starting with about 2000 major ones. It must begin simultaneously with a preset deadline throughout the country. A nationwide network will enable us to step inside hospitals' everyday affairs, which no non-governmental body has so far achieved. Even though ethics and low morale of medical personnel may not improve immediately, without given a solid guideline for improvement, their attitudes will not even begin to change.

It is a truth, also universally acknowledged, that what makes a world of difference is to be modest enough to face your mistakes and work to improve. In order to do this, we must first make sure to uncover the mistakes. I ask for all of your support and understanding, because in all respects, what I have suggested today is sure to be the most significant and most productive move forward.