EBM-Based Clinical Practice Guidelines

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Introduction

The need for clinical practice guidelines that are grounded in evidence-based medicine (EBM) is a subject that has recently come under debate in various quarters. It goes without saying that this does not mean that the physicians of this country have been diagnosing and treating patients without evidence to date. Every medical institution and every physician collects and accumulates a variety of evidence, which they then evaluate before feeding it back into characteristic settings. Decisions on the policies (guidelines) of an individual institution or physician are made as the need arises and are then used as the basis for diagnosing and treating patients. There is no need for this process to be altered in the future.

Healthcare is first and foremost a highly individualized practice and the individual predicaments and value decisions of patients cannot be eliminated no matter what form guidelines may take. Nonetheless, the necessity of creating clinical practice guidelines that are founded in EBM as a way of maintaining and improving the quality of healthcare is widely recognized.

This article examines and elucidates a number of issues relating to the work that is being done by the nation and by the Ministry of Health, Labor and Welfare in connection with EBM-based clinical practice guidelines and the measures being taken by the Japan Medical Association (JMA), and simultaneously puts forward the opinions of the latter Association.

Study Group on the Positioning of Medical Technology Assessment (former Ministry of Health and Welfare)

Medical technology assessment as a technique for improving the quality of medical practice and patient services has been attracting attention in a number of countries, and it became clear that Japan would also need to investigate the introduction of this type of assessment. Bearing this situation in mind, in December 1996, the then Ministry of Health and Welfare (currently the Ministry of Health, Labor and Welfare) established the “Study Group on the Positioning of Medical Technology Assessment”. Akihiko Koike, then executive member of the Japan Medical Association, participated in the investigations of the study.
group on behalf of the Association.

In June 1997, the study group finalized a report, which can be summarized as follows:
1. A definition of medical technology assessment
2. The position of medical technology assessment and related areas
3. The current status of medical technology assessment
4. The utilization of medical technology assessment in Japan
5. The need to tackle the promotion of medical technology assessment

Having received this report, the then Ministry of Health and Welfare established the “Study Group on the Promotion of Medical Technology Assessment” in June 1998 with the aim of investigating specific promotion measures for medical technology assessment.

Study Group on the Promotion of Medical Technology Assessment (former Ministry of Health and Welfare)

Takashi Aoyagi, an executive board member of the Japan Medical Association, participated in the investigations of this study group on behalf of the Association.

It is significant that one of the stated objectives of establishing this study group was that “Realizing evidence-based medicine (EBM) is crucial to the effective utilization of limited medical resources and to improving the quality of medical practice and patient services . . . ”. In fact, the discussions that were conducted by this study group converged on matters relating to EBM.

Generally speaking, the practice of EBM is conducted in four stages. The sequence is as listed below.
1. Clinical questions concerning a particular patient are elicited.
2. A search for literature that deals with these questions is undertaken.
3. The reliability of the literature obtained is appraised.
4. The appropriateness of applying the results from the literature to the patient is evaluated.

Clinical practice guidelines grounded in EBM are designed to enhance the efficiency of this process and to support physicians in diagnosing and treating patients. Based on these perspectives, the study group issued a report in March 1999, which is summarized as follows.
1. Promote EBM
2. Create medical (clinical practice) guidelines
3. Systemize activities towards comprehensive promotion
4. Promote clinical research and obtain the understanding and cooperation of the general public
5. Ascertain the necessity for an information network

Bureaucratic Initiative in the Creation of Clinical Practice Guidelines

Having received the suggestions of the “Study Group on the Promotion of Medical Technology Assessment”, plans were laid for the compilation of clinical practice guidelines to be undertaken as a bureaucratic initiative led by the then Ministry of Health and Welfare. The Ministry’s scientific research funds were to be utilized to support the creation of “Clinical Practice Guidelines” for individual diseases by various medical societies. In fiscal 1999, guidelines were compiled for among others, hypertension, bronchial asthma, myocardial infarction, and prostatic hyperplasia. This was followed, in fiscal 2000, by the provision of national support in the formation of guidelines for gastric ulcer, cerebral infarction, cataracts, low back pain, chronic rheumatoid arthritis, subarachnoid hemorrhage, and allergic rhinitis (hay fever).

Although the work of formulating the guidelines was being conducted by medical societies, the fact that the source of the funding (costs) was the country (government) created a number of problems. The societies were saying that the guidelines had been created by them, whilst at the national level, the government was saying...
that the guidelines had been created by it. This made it difficult to aver that regional healthcare settings and the circumstances of patients were being considered, meaning that the guidelines took on a “top-down” approach, and there was even a risk that they would be detrimental to the content of regional healthcare.

In addition, the Ministry of Health and Welfare’s budget allocation for fiscal 2000 included plans to establish databases for the literature relating to EBM and clinical practice guidelines within government facilities, and the management of EBM to be undertaken by the government. As might be expected, such unequivocal plans were indicated to be problematic even within the parliament, and the plans were withdrawn.

Clinical Practice Guidelines Information Center Project Committee (The Japan Medical Association)

In response to these movements, the Japan Medical Association exerted its influence over the Japanese Association of Medical Sciences (JAMS) and various hospital associations, overseeing the inauguration of a project committee targeting the establishment of a private-sector based “Clinical Practice Guidelines Information Center (tentative name)” that would be led by the Japan Medical Association. The deliberations of this committee yielded a number of conclusions.

1) The biggest problem is sifting through vast amounts of data for useful information that is in line with EBM and this is what underpins the formulation of appropriate clinical practice guidelines.

2) The clinical guidelines created by individual medical societies and others, on the basis of selected data or data obtained from original research, need to undergo a second evaluation. Appraising and judging whether or not the guidelines are objective and measure up to clinical results and achievements in this country is a major responsibility. It is a task that will require the recruitment of suitable human resources, including clinical physicians, clinical epidemiologists, and statisticians, and in which the Japan Medical Association must take a primary role.

3) Even after such assessments have been completed, the objective of clinical practice guidelines, even published guidelines, is ultimately to provide a source of reference. The guidelines should not impose any restrictions on the practice of physicians.

4) Clinical practice guidelines are not designed to be used by physicians only; their contents should also be shared with the patients who are on the receiving end of medical treatment.

5) Once a set of clinical practice guidelines has been created, continuous review that incorporates the feedback of opinions from practicing physicians and patients will be essential.

As a starter, the project committee is currently engaged in formulating standards for the creation of clinical practice guidelines (i.e. guidelines for guidelines).
and medical students require?

2. **On specific measures for the required information services**
   
   (1) How should the accumulation and processing of medical literature and guidelines be undertaken?
   
   (2) How should statistical evaluations relating to individual topics be undertaken?
   
   (3) On the operation of information services
      
      (a) What should be done regarding the contents of systems that should be disclosed?
      
      (b) How should the accumulation of useful data be undertaken?
      
      (c) How should the systemization of accumulated data be undertaken?
      
      (d) How should systemized data be presented?

3. **On the division of roles between the private and public sector in relation to information services**
   
   (1) What type of system should be put in place to move forward with the information services?
   
   (2) What role should the government take?
   
   (3) What role should the private sector take?
   
   (4) What support should the government extend to the private sector in its role?

**Clinical Practice Guidelines Information Centers in Various Countries**

An examination of one of the materials produced by this study group, which deals with organizations that are similar to clinical practice guidelines information centers in five countries, their establishing bodies, the types of databases available, and the bodies responsible for their administration, yielded the information shown in Table 1.

The following three points were confirmed as being basic concepts for the development of EBM databases in this country. (1) The need to ensure comprehensiveness, currency, objectivity, impartiality, and transparency. (2) The need to ensure free-access, including that by patients. (3) The need to ensure a secure financial base. It was also established that a number of additional points need to be considered, namely, (1) the necessity of promptly

<table>
<thead>
<tr>
<th>Country</th>
<th>Establishing Body</th>
<th>Available Databases</th>
<th>Administrative Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>National Library of Medicine (NLM)</td>
<td>Healthcare information for the general public</td>
<td>Agency for Healthcare Research and Quality (AHRQ)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical Practice Guidelines</td>
<td>National Guidelines Clearinghouse™ (NGC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medline</td>
<td>American Medical Association (AMA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical trials, etc.</td>
<td>American Association of Health Plans (AAHP)</td>
</tr>
<tr>
<td>Canada</td>
<td>Canadian Medical Association (CMA)</td>
<td>Clinical Practice Guidelines only</td>
<td>Canadian Medical Association (CMA)</td>
</tr>
<tr>
<td>Germany</td>
<td>Agency for Quality in Medicine (AQM)</td>
<td>Clinical Practice Guidelines only</td>
<td>German Medical Association (GMA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>National Association of Statutory Health Insurance Physicians (NASHIP)</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Guidelines Group (NZGG)</td>
<td>Clinical Practice Guidelines only</td>
<td>National Health Committee (NHC)</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>National Electronic Library for Health</td>
<td>Clinical Practice Guidelines</td>
<td>National Health Service (NHS)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Knowledge management technologies</td>
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<tr>
<td></td>
<td></td>
<td>Information media, etc.</td>
<td></td>
</tr>
</tbody>
</table>
developing the necessary systems for EBM, starting with databases, (2) the necessity of gaining respect for guaranteed academic impartiality, and to eliminate any unnecessary intervention by the administration, etc.

These considerations gave rise to three plans pertaining to the form that the body responsible for administering EBM databases in Japan should take, which were submitted by the study committee (Table 2).

### The Japan Council for Quality Health Care

The result of the investigations outlined above was the decision to commission the “Japan Council for Quality Health Care”, currently a public-service corporation, to organize the EBM databases in this country.

The main reason for entrusting this task to the Japan Council for Quality Health Care was that the council is a neutral public-service corporation. However, at the same time, a number of other reasons were advanced including the fact that the “Assessments of the Quality of Health Care in Hospitals” that are currently being undertaken by the council also represents one facet of the “Medical Technology Assessments” that instigated the current problem, and are, moreover, closely related to “EBM-based Clinical Practice Guidelines”. In addition, the collection of medical information for inclusion in EBM databases can also be utilized in future assessments of the quality of health care in hospitals, and conversely, the medical information obtained from the hospitals that are subject to functional appraisal will be useful as evidence from clinical settings, in reviewing the EBM-based clinical practice guidelines.

In response to the proposed commission, the Japan Council for Quality Health Care held a hearing in December 2001, which resulted in their decision to accept the commission. Accordingly, as one of its projects, the council was requested to begin organizing EBM databases as of April 2002.

This represents one direction, which has been hammered out after long years of deliberations, however, this important project has still only just begun and there is no doubt that numerous problems lie ahead. This is a matter of great consequence to the Japan Medical Association and we intend to keep close tabs on this important project to ensure that it develops along the right tracks.

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**Table 2**

<table>
<thead>
<tr>
<th>Administrative Body</th>
<th>Financing</th>
<th>Points for consideration</th>
</tr>
</thead>
<tbody>
<tr>
<td>JMA’s Clinical Practice Guidelines Information Center Plan</td>
<td>Japan Medical Association</td>
<td>Japan Medical Association</td>
</tr>
<tr>
<td>A neutral institution</td>
<td>Case assuming an existing public-service corporation Treasury subsidy + private sector expenditure</td>
<td>*Treasury subsidies to public-service corporations are likely to be shelved, thus there is a problem of securing operating costs</td>
</tr>
<tr>
<td></td>
<td>Case assuming the establishment of a new public-service corporation Treasury subsidy + private sector expenditure</td>
<td>*As above *Establishing a new nonprofit corporation is highly problematic</td>
</tr>
<tr>
<td>Publicly-funded, privately operated</td>
<td>Established by the government, operated by the private sector Private sector commission using public funds</td>
<td>*Will government involvement intensify to the point of excess?</td>
</tr>
</tbody>
</table>
I would now like to present two problems that I perceive in connection with the practice of EBM.

**EBM Evidence**

The concept of practicing medicine based on evidence is one that is not open to debate. The following are proposals that have been put forward for classifying the quality of that evidence.

Classifying the quality of evidence (United States Preventive Services Task Force)

I: Randomized controlled trials

II-1: Epidemiological (nonrandomized) controlled trials

II-2: Cohort studies and case-controlled studies

II-3: Longitudinal studies, non case-controlled studies

III: Opinions of leading medical authorities, epidemiological statements

In other words, enormous emphasis is placed on evidence that is based on epidemiological processes. However, whilst acknowledging the significance of evidence, it is possible to conceive a number of slight problems with this approach.

One example can be found in the report mentioned earlier that was issued by the Study Group on the Promotion of Medical Technology Assessment. The report gave prominence to the necessity of promoting EBM and stated that “In order to generate a scientific basis [for EBM] it is necessary to convert current pathophysiologically-focused studies into research that resembles randomized controlled trials that target patients”. I believe that this statement is erroneous. “Converting” medical research that is “pathophysiologically-focused” into “research based on randomized controlled trials” is not plausible in the field of medicine. If by this they mean the introduction of “research based on randomized controlled trials” that are grounded on “pathophysiological research” then that is understandable, but I am utterly opposed to “converting” the latter into the former.

As another example, in 2001 “A” tablets were approved as an analgesic agent for migraines. The results of the clinical trial with this drug, which employed the double-blinding method, was a headache improvement rate of 48.6% for the placebo group \((n = 70)\) and 71.5% for the “A-treated” group \((n = 70)\), or a significant difference, which was used to demonstrate that the drug “is fast-acting and has superior efficacy in the relief of pain from migraine headaches”, and it was approved as a new agent. However, put simply, the results of the trial were equivalent to efficacy in 5 patients out of 10 in the placebo group and 7 out of 10 in the “A-treated” group. Undeniably, this evidence is from a high quality randomized controlled trial and the difference is statistically significant, nevertheless, there are elements that are unsatisfactory. Five of the 10 patients who took “A” tablets actually experienced headache relief as a result of the placebo effect, thus it is conceivable that the headache was alleviated by “A” tablets in only 2 patients.

Evidence, as it is understood within the framework of current medical knowledge, is not that infallible. The report by the Ministry of Health, Labor and Welfare starts by interpreting EBM as being “healthcare that is based on scientific grounds”; somewhere along the line, however, this becomes simply, “healthcare that is reliably based”. I would even go so far as to suggest that it might be more fittingly interpreted as “healthcare that is based on the highly unreliable grounds of the scope of current knowledge”.

**Conclusion — The Professional Freedom of Physicians**

I believe the view that physicians implement self-serving treatment, that this is a professional freedom granted to doctors, and that physicians are free to use their discretion, is wrong.
Although at the same time, I am also against the opinion that physicians must follow guidelines to the letter when treating their patients. In the long run, the purpose of the guidelines is to furnish a source of reference. Individual medical institutions and physicians must determine the advisability of adopting the guidelines, and even assuming that there are some physicians who do not follow said guidelines, such physicians should not immediately be labeled as “wrong”. In particular, under no circumstances should the guidelines be used as screening criteria for the healthcare services provided under the health insurance system.

On the other hand, the professional freedom of physicians should be considered to be an obligation, not a right. Physicians have an obligation to conscientiously and judiciously provide their patients with the best available healthcare, which should be based on evidence they themselves have judged. This is the discretion that physicians exercise, or their professional freedom. It is imperative that physicians do not wave aside this obligation in the face of pressure from outside. It is the patients who have the right to be provided with the best available medical treatment based on professional freedom.