Medical Autonomy and the Use of Clinical Practice Guidelines in Lawsuits

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ABSTRACT

Clinical Practice Guidelines (CPGs) to promote evidence-based medicine (EBM) are rapidly proliferating in the realm of healthcare. Since CPGs are arranged in a way that makes standard healthcare practices easily understandable, they are often used in medical lawsuits to specify physicians' faults that deviate from medical standards. The medical community, however, is strongly opposed to this application of CPGs outside of their intended use while being critical of legal practitioners employing them as a tool to interfere with medical autonomy. There have been various attempts, such as the Obstetric Compensation System for Cerebral Palsy, the Medical Accident Investigation System and Medical Alternative Dispute Resolutions, to avoid legal intervention for medical accidents and use litigation to resolve medical disputes. Yet, the number of submissions by healthcare professionals through the Medical Accident Investigation System has been much smaller than expected, which shows that this approach (leaving investigation and resolution to autonomous action by healthcare professionals) is inadequate as a response to medical accidents and disputes. The conclusion, then, is that medical lawsuits are indeed a necessary process for objectively verifying facts and arriving at resolutions through third parties. That legal professionals in the course of litigation use CPGs, which have consensus in the medical community, actually becomes a way of supporting autonomy in the realm of healthcare. CPGs are a link between medicine and law and therefore a portal for starting dialogue.

A. Significance of Clinical Practice Guidelines

Medical research is advancing rapidly and the volume of healthcare-related information continues to grow unabated. Meanwhile, scientific EBM is being called for in clinical practice. It is extremely challenging for each physician in practice to master voluminous amounts of medical information and to implement care based upon it.

Consequently, each field has created explanatory documents with Q&A sections and flow charts that systematically aggregate, categorise and evaluate the medical knowledge of each group of specialists and present it in user-friendly formats provided to each point of care.

These explanatory documents are CPGs, and they have recently spread to healthcare

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sites in many medical fields. In Japan, the reliability of CPGs has been backed up by the Japan Council for Quality Health Care, which the Ministry of Health, Labour and Welfare has entrusted to assess, vet and publicise CPGs. This effort goes by the project title, 'Medical Information Network Distribution Service (MINDS)' and has released numerous CPGs online.[1)]

MINDS defines these guidelines as follows:

'Documents expressing recommendations that are viewed as optimal to support decision making by patients and health care professionals after systematic review of evidence and comprehensive evaluation of medical practices with a high degree of importance in clinical settings, and proper weighing of the balance between benefits and drawbacks'.[2)]

'The guidelines include recommendations compiled using systematic methods based on scientific evidence, and they may serve the decision making process by patients and healthcare professionals'.[3)]

This definition is nearly identical to that used in the United States.[4)]

Considering the level of evidence and the consensus among specialists, CPGs specify a recommendation level of 3, 4 or 5. The following are examples of recommendation levels:

A: Scientific evidence is robust, and the practice is strongly recommended.
B: Scientific evidence exists, and the practice is recommended.
C1: Although scientific evidence does not exist, the practice is recommended.
C2: Scientific evidence does not exist, and the practice is not recommended.
D: Scientific evidence showing lack of efficacy or presence of harm exists, and the practice is not recommended.

B. The Development and Role of Clinical Practice Guidelines

In the U.S., CPGs came into use in the 1950s, and with the spread of EBM in the 1980s, their use rapidly became recommended.

The following general points can be made about the role of CPGs.

1. They are a scientific means to assess the efficacy and safety of medical practices.

1) Minds Website, (Sept. 17, 2017) https://minds.jcqhc.or.jp/

2) Tsuguya FUKUI & Naoto YAMAGUCHI, Minds Shinryo Guidelinge Sakusei no Tebiki [Minds Handbook for Making Clinical Practice Guidelines] 2014 3, (2014) .

3) Minds Website "about Clinical Practice Guideline".

4) Marilyn J.Field & Kathleen N. Lohr (eds.) Clinical Practice Guidelines: Directions for a New Program 8 (1990) ("PRACTICE GUIDELINES are systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances.").

2. They help maintain the quality and safety of medical practices.
3. They show treatment for broad-based disease beyond the boundaries of specific specialties.
4. They highlight standard practices, support training and spread knowledge and techniques.
5. They help prevent overmedication and facilitate the provision of effective health care.
6. They help share information with patients and support joint-decision making with medical professionals.
7. To the extent that CPGs are adhered to, the physician (in principle) will not be held liable for negative outcomes.[5)]

In Japan, the then Ministry of Health and Welfare requested 12 academic associations to create CPGs in 1999, after which they came to be formally incorporated into healthcare. As of September 17, 2017, 231 CPGs have been published on the MINDS website.

Healthcare that relies on physician knowledge and experience, hospital facilities and regional medical conventions frequently invites disparity between individual physicians, facilities and locations. In a 2011 survey of 559 physicians employed in clinics, 55.1% answered yes to the question, '*Do you think there are large differences among facilities and physicians with regard to treatment and diagnosis methods?*' In particular, 81.8% of physicians in their 30s (or younger) answered yes, and 71% in their 40s answered yes.[6)] The survey also found that physicians believe that some carry out '*treatment approaches that are self-righteous and startling to others*', that '*costly healthcare with weak scientific grounding is being implemented*' and that '*many medical conventions and practices do not have a scientific basis*'.[7)]

Consequently, distributing CPGs with information on the most effective approaches is not only beneficial for healthcare professionals and patients but also helpful for society in reducing wasteful healthcare.

C. Usage of Clinical Practice Guidelines in Lawsuits

CPGs are actively used in medical lawsuits in Japan and practically in almost every

5) Maxwell J. Mehlman, Medical Practice Guidelines as Malpractice Safe Harbors: Illusion or Deceit? 40 (2) J.Law.Med Ethics 286, 291 (2012), Shunji FURUKAWA, Chiryo Guideline no Hoteki Igi [Legal Meanings of Clinical Practice Guidelines] 37 Gastroenerology 337, 337 (2003).

6) Narumi EGUCHI, Nichijoshinryo Igakujoho Shushu to Nichijoshinryo no Genjo nikansuru Chosa [The Survey about the Collection of Medical Information and Current Situation of Daily Clinical Practice] 248 Working Paper issued by Japan Medical Association Research Institute 21 (2011).

7) Tetsu KONDO, Gan Shinryo Guideline ga Rinshogenba ni Ataeta Eikyo: Hajimeni [Effect of Cancer Clinical Practice Guidelines to the Practice: Introduction], 108(5), Journal of Japan Surgical Society 236, 236 (2007).

case CPGs are submitted as evidence when they are available.

Regarding their emphasis on CPGs, judges presiding over medical lawsuits have commented:[8)]

'They are valuable and deserving of reference; in medical lawsuits in which CPGs are not referenced, it could potentially lead to an insufficient or inappropriate fact finding with regard to medical knowledge'.

Courts usually recognise practices that follow CPGs as being standard practice if the CPGs are written by reliable groups of experts, such as academic societies, and then distributed among specialists. In actual medical lawsuits, the practice is that a plaintiff asserts and brings evidence of medical conduct that deviates from the standard in the CPGs, after which the court references the CPGs and certifies that they represent standard practice, which in turn is followed by a judgement on whether a deviation (i.e., fault) has occurred with regard to the specific medical conduct in question.

In cases where medical conduct departs from CPGs, the court requests that the healthcare professional(s) explain the reason for such a departure, and if no rational reason is forthcoming, the court tends to recognise that fault has occurred.

Pharmaceutical product package inserts also function in a manner that is similar to CPGs. With regard to pharmaceutical package inserts, the Supreme Court judged on January 23, 1998:[9)]

'In physician use of pharmaceutical products, should the physician cause a medical accident due to not following the warnings and precautions detailed in product inserts, and should no compelling rational reason exist for this failure, it should be presumed that said physician is at fault'.

This judgement strongly recognised the normative status of such inserts. Physicians, however, have stated that they attribute more weight to CPGs, which represent expert consensus, as opposed to product inserts, which are explanatory material addressing product usage and created by pharmaceutical companies. Consequently, it can also be argued that if CPGs are not followed, and there is no compelling rational reason for it, the presumption of fault is valid.

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8) Kentaro NISHIZAWA, Iryo Sosho no Jitsumu [Practice of Medical Lawsuits] 190 (Yuzuru TAKAHASHI eds., 2013).

9) Sup. Ct. (Jan. 23, 1998) 50(1) Minshu 1, 1571 Hanreijiho 57, 914 Hanreitaimuzu 106.

D. Opposition from the Medical Community

The conventional idea regarding the use of CPGs is as follows: healthcare professionals (1) use them with patients before or in the process of care (2) to reach decisions on diagnoses and treatments (3). In contrast, the practice has arisen whereby legal professionals (1) use CPGs after care has been administered (2) to reach judgements on legal responsibility (3). Legal professionals using CPGs in this manner outside of their intended application have met with strong opposition from the medical community.

In a physician survey, 27% of respondents (94 out of 338) said CPGs can be '*abused in medical lawsuits*',[10] 38% of private practice physicians and 33% of institutional physicians said they '*think lawsuits will increase due to the presence of CPGs*'.[11] Hence, it appears that a considerable number of physicians feel that CPGs promote lawsuits and are abused in the course of litigation.

One of the CPGs even states the following clearly:

'The content of this guideline is not to be evidence in medical lawsuits'.[12]

Furthermore, it has been reported that in some cases, CPG writers consider risk of lawsuits when they make policy judgements, sometimes going so far as to lower the levels of recommendations.[13]

There seems to be strong professional pride among physicians at the heart of their disdain for legal intervention. While physicians may not think that medical malpractice exists at all, it seems that they want to respond to this autonomously within their profession.

This professional pride seems to exist based on physicians' defensive attitudes. The profession has a keen sense of crisis that its autonomy may be impaired by external legal intervention, and there is a strong sentiment that CPGs should not become tools for such intervention.

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10) Shinryo Guideline wo kiru [Diagnosis the Clinical Practice Guidelines] Nikkei Medical April, 2008, at 62.

11) Shigeki ARII, Gan Shinryo Guideline ga Rinshogenba ni Ataeta Eikyo: Kangan [Effect of Cancer Clinical Practice Guidelines to the Practice: Cancer of Liver], 108(5) Journal of Japan Surgical Society 263, 265 (2007).

12) Japan Gastroenterological Edoscopy Society & Japan Gastric Cancer Association, ESD/EMR Guideline for Gastric Cancer, Introduction (2014).

13) Rinshogenba niokeru Shinryo Guideline no Katsuyo to sono Hoteki Ichizuke [Utilization of Clinical Practice Guidelines and its legal Characterization] Distributed Material at Minds Forum (Nihon Ishi Kaikan [Japan Medical Association' Hall] Feb 2014.

E. Avoiding Litigation of Medical Disputes

The medical community and the Ministry of Health, Labour and Welfare are moving toward non-litigious approaches that avoid the resolution of medical disputes through lawsuits. Evidence of this is seen in the creation of the Japan Council for Quality Health Care's Obstetric Compensation System for Cerebral Palsy (2009) and the Japan Medical Safety Research Organization's Medical Accident Investigation System (2015). In addition, where individual regions have medical Alternative Dispute Resolution (ADR), physicians cooperate with these although the medical community is not necessarily the lead agent.

The merit of non-litigious approaches to medical disputes is that (1) causal investigation, (2) recurrence prevention, (3) compensation for loss and (4) satisfactory dispute resolution can be more swiftly achieved by leveraging specialised expertise in a scheme that differs from that of pursuing legal responsibility. However, since non-litigious approaches are used as ex post evaluations of medical conduct, they do not obviate the need for CPGs. To be sure, in such approaches, CPGs are actually referenced as criteria for judging clinical appropriateness. Although legal professionals participate in the Obstetric Compensation System for Cerebral Palsy and Medical Accident Investigation System, these processes are mainly led by healthcare professionals. Thus, they differ from lawsuits and fall within the borders of medical autonomy. Therefore, opposition to this type of usage of CPGs is less prevalent.

While the annual number of cases of unexpected deaths of patients and stillbirths related to medical conduct, which is the target of the Medical Accident Investigation System, was estimated to be between 1,300 and 2,000 before the system started, only approximately 350 cases were actually reported and investigated. It indicates that entrusting the response to medical accidents to autonomous action within the field is not sufficient to solve the problem.

Consequently, while there is a trend toward non-litigious approaches, legal intervention in healthcare neither can, nor should, be excluded entirely. Medical lawsuits serve the function of legally establishing medical standards, constructing normative approaches and providing feedback to the medical community and to society. CPGs are very useful when medical lawsuits play that role. Insofar as CPGs are based on medical evidence, they are clearly beneficial as court evidence. CPGs from the outset can be used in lawsuits not only by plaintiffs but also by defendants proving that treatment has been administered following guidelines, and in fact, there are many actual examples of such usage.

F. The Impact of Lawsuits and Legal Professionals on CPGs

Legal professionals not only utilize CPGs; in some cases, they also influence CPGs.

For example, lawsuits and judgements can spur the creation of CPGs. And, judgements can function as prior regulations for subsequent healthcare. Apparent examples are the impact that lawsuits and judgements have had on CPG formulation with regard to ethical and social problems such as blood transfusions for Jehovah's Witnesses,[14] utility of assisted reproduction technologies[15] and disclosure of diagnoses to cancer patients.[16]

In addition, when CPGs have not been formulated due to insufficient accumulation of medical knowledge, there are instances where a lawsuit has been the impetus for creating or revising CPGs. With regard to cerebral haemorrhage in pregnant mothers during labour, the 2010 Osaka District Court's judgement of the Oyodo Hospital[17] case garnered sufficient attention to lead to the addition of details on distinguishing eclampsia and stroke in the 2014 version of the CPG for Obstetrics.[18] Although the court dismissed the case, it appears that the lawsuit instigated a revision of the CPG.

In other examples, legal professionals have had a direct impact on the formulation of CPGs. In the U.S., the participation of legal professionals in the process of drafting CPGs has become preferable to ensure the removal of inexact wording from CPGs and to provide for fairness and transparency in healthcare.[19] In Japan as well, legal professionals take part in writing CPGs that deal with the ethics such as organ transplants, terminal treatment and so forth. Since only having attorneys involved representing medical parties can lead to guidelines slanted toward avoiding legal risk, the involvement of attorneys representing patients and legal scholars is most likely a necessity as well.

G. Respecting Medical Autonomy

As shown, the utilisation of CPGs has the dual facets of exercising non-legal, prior control over conduct within the medical community and exercising legal, ex post control from outside the medical community. While the conventional use of CPGs has been the former, attempts to exclude the latter have had meagre success. More to the point, it is constructive to recognise the use of CPGs as a tool for bridging the gap between medicine and law.

If the reason for the medical community's opposition to legal intervention is a reaction

14) Sup. Ct. (Feb. 29, 2000) 54(2) Minshu 582, 1710 Hanreijiho 97, 1031 Hanreitaimuzu 158.
15) Sup. Ct. (Mar. 23, 2007) 61(2) Minshu 619, 1767 Hanreijiho 36, 1239 Hanreitaimuzu 120.
16) Sup. Ct. (Apr. 25, 1995) 49(4) Minshu 1163, 1530 Hanreijiho 53, 877 Hanreitaimuzu 171. Sup. Ct. (Sept. 24, 2002) 1803 Hanreijiho 28, 1106 Hanreitaimuzu 87.
17) Osaka Dist. Ct. (Mar. 1, 2010) 2079 Hanreijiho 67, 1323 Hanreitaimuzu 87.
18) Japan Society of Obstetrics and Gynecology & Japan Association of Obstetricians and Gynecologists, Sanfujinka Shinryo Guideline 2014 [Guideline for Obstetrical Practice in Japan 2014] 173 (2014).
19) Sachihiko IIJIMA, Iryo niokeru Kokyoteki Kettei: Guideline toiu Seido no Joken to Kanousei [Public Decision Making in Medicine: Condition and Possibility of the System of Clinical Practice Guidelines] 138-139 (2016).

to external infringement upon professional autonomy, it is misplaced. Legal judgements based on CPGs actually respect medical autonomy.

Shigeaki Tanaka has commented that minimal legal regulations on healthcare serve to improve physician–patient relationships through professional ethics and self-monitoring on the side of the physician and awareness of cooperation on the side of the patient. Consequently, he argues that medical logics need to be incorporated into legal procedures.[20)]

CPGs are the optimal tool for effecting this incorporation of medical logics into legal procedures. Legal professionals posit standards, apply facts to those standards and reach a conclusion. When they solve medical disputes, CPGs are utilised when positing standards for proper medical conduct by physicians in the situations in question and a conclusion is reached by applying the specific medical conduct to those standards. Where application is problematic, the opinions of medical experts are utilised in the form of court-appointed experts, expert witnesses and expert advisers. This is evidence of respect for medical autonomy from legal professionals both in positing and application of standards. CPGs give physicians the opportunity to participate in establishing precedents.

Thus, use of CPGs in medical lawsuits should actually be welcomed by physicians. Utilising CPGs in trials demonstrates legal parties' respect and consideration for medical autonomy. CPGs fulfil the role of protecting the autonomy of the medical community from legal logics.

H. Summary: CPGs are a Key Link between Medicine and Law

In contrast to the impressions of physicians, CPGs can be expected to reduce lawsuits. Because if physicians follow CPGs, they are less susceptible to being culpable. And CPGs also serve as foundational material for communication with patients and help facilitate resolutions in out-of-court settlements and ADRs.

In the 2011 CPG for obstetrics, the introduction stated:[21)]

‘We believe that drafting well-made guidelines increases the safety of obstetrics care by standardising treatments, while also helping prevent the implementation of deviant treatment that leads to trouble and lawsuits’.

This statement illustrates expectations of fewer troubles and litigation brought by the

20) Shigeaki TANAKA, Iryo to Ho no Sougo Rikai no tameni [For Mutual Understanding between Medicine and Law] , in Ho eno Shiza Tenkan wo Mezashite [Change of the Viewpoint; Toward Law] 167-168 (2005).

21) Japan Society of Obstetrics and Gynecology & Japan Association of Obstetricians and Gynecologists, Sanfujinka Shinryo Guideline 2011 [Guideline for Obstetrical Practice in Japan 2011] 1 (2011).

CPG. In fact, in the 2014 revised version of the CPG, the introduction extols positive results, stating:[22)]

'This guideline has been thoroughly distributed among members, thereby leading to a drastic reduction in medical lawsuits related to obstetrics care'.

The number of medical lawsuits in Japan peaked in 2004 at 1,110 new cases and has been on a downward trend in recent years. If one factor behind this decrease has been to improve medical safety through the spread of CPGs, they have achieved their original objective. The awareness that implementing treatment that deviates from CPGs without a rational basis leads to losing a lawsuit will provide further support for the spread of guidelines.

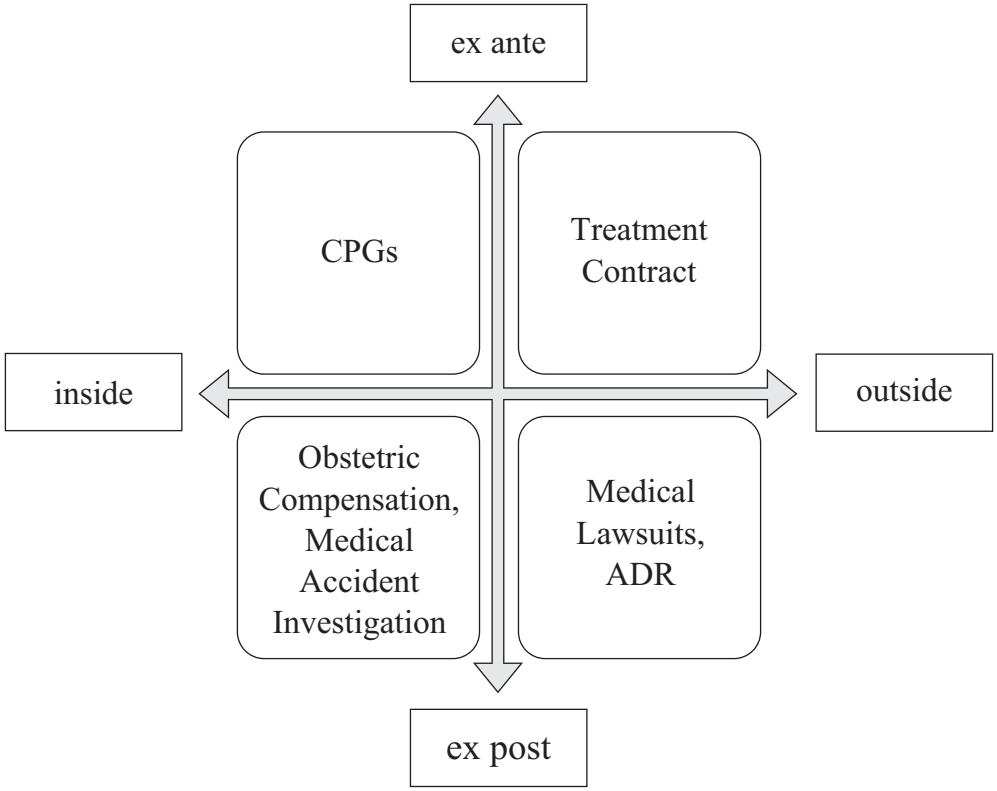
Moreover, incorporating guidelines in treatment contracts will establish 'soft' (non-binding) prior regulations based on physician–patient agreement. This directly corresponds to the objective of CPGs to '*support decision making for patients and physicians*'. In this context, if an unsatisfactory result occurs from carrying out treatment based on a decision reached by mutual agreement, the patient should be more accepting of the situation and less likely to pursue a lawsuit, while if a lawsuit were to come about, the court will likely pass a judgement that emphasises the treatment contract. Consequently, treatment based on contracts incorporating CPGs will mitigate the risk of trouble with patients and unexpected legal judgements.

Last, I would like to graphically summarise the relationship among CPGs, healthcare regulations, investigations and redress.

While CPGs are prior, internal regulations, they are also an overarching tool tying together the four quadrants in the diagram. In other words, even with accident investigations and the Obstetric Compensation System for Cerebral Palsy, which is an internal, ex post investigation system, CPGs are seen as standards. In treatment contracts, which align patients and physicians before care is administered, incorporating the content of CPGs provides support for decision making. CPGs also serve as evidence for judgements of legal fault (or non-fault) in medical lawsuits and ADRs providing ex post dispute resolution and redress.

CPGs are a link that connects medicine and law and can be considered to be a launch pad for dialogue.

22) Japan Society of Obstetrics and Gynecology & Japan Association of Obstetricians and Gynecologists, Sanfujinka Shinryo Guideline 2014 [Guideline for Obstetrical Practice in Japan 2014] 1 (2014).


ex ante
CPGs
Treatment Contract
inside
outside
Obstetric Compensation, Medical Accident Investigation
Medical Lawsuits, ADR
ex post