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ORIGINAL RESEARCH

Correlation Between Malpractice Litigation and Legislation Reform in Taiwan Over a 30-Year Period

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Background: The annual medical litigation rate has increased yearly since 1987 in Taiwan. Policy makers keep going medical legislation reforms. The effectiveness of legislation reforms to reduce malpractice litigation risk is uncertain.

Objective: To determine whether medical legislation reform helps reduce the risk of medical litigation.

Design, Setting, and Participants: This retrospective study used national data obtained from Ministry of Health and Welfare in Taiwan. The period analyzed was from 1987 to 2018. The annual medical litigation rate was determined, types of medical negligence litigation were compared, medical appraisal results were summarized, and the importance of medical legislation was identified.

Interventions: After legislation reform vs before legislation reform.

Measurements: The main outcome showed trends in medical dispute assessments over time by adjusting for the general population (per 1, 000, 000 people). We established 2004 and 2012 as the 2 cut-points for further analysis of medical appraisal results due to legislation reform.

Results: With legislation reforms, the annual medical litigation rate decreased from 26.68 cases per million people in 2012 to 16.41 cases per million people in 2018. The annual medical litigation rate declined by approximately 38% from 2012 to 2018. Medical appraisal results were malpractice cases in 22.1% before Medical Care Act (2004 Reform) compared with 18.8% from 2004 to 2012 (odds ratio [OR], 0.82; 95% CI, 0.727–0.924; p=0.001), and 6.4% after mediation system introduced in 2012 (odds ratio [OR], 0.243; 95% CI, 0.205–0.288; p<0.001).

Conclusion: Medical legislation reform has reduced the risk of malpractice litigation over time.

Keywords: medical malpractice, medical legislation reform, health policy

Introduction

During the COVID-19 pandemic, public health systems have played a crucial role in numerous countries and indicated a nation's capacity to respond to outbreaks, protect high-risk populations, limit community spread, and provide vaccines or other novel therapeutic approaches.[1–5] The National Health Insurance system, a single-payer insurance system that covers virtually the entire population of Taiwan, has covered the provision of medical services since 1995.[6,7] Numerous patients have received advanced medical services from the public health system since its establishment.

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However, although people may focus on the public health system, they may neglect the efforts of medical staff. When conducting medical procedures, medical staff members are undoubtedly exposed to the risk of malpractice litigation. Therefore, medical legislation reforms regarding such litigation risk play an essential role in the public health system.

Medical disputes require respect for patient autonomy and are associated with the individual nature of the patient–physician relationship.[8–10] Even taking into patients' emotions and idiosyncrasies, medical malpractice claims by patients remain high. The number of medical disputes is increasing daily. Regarding medical malpractice, Taiwan and the United States are different in the law evaluation circumstance. In the case law system country such as United States, the cost of malpractice insurance has skyrocketed in some specialties and geographic areas because of a medical liability crisis.[11,12] The constant threat of litigation also drives many physicians to adopt a defensive medicine strategy, which entails performing extraneous and often inappropriate procedures.[13–17] In defensive medicine, responses are undertaken primarily to avoid liability rather than to benefit the patient. Under medical liability crisis, defensive medicine is more than before. Because of such changes, medical legislation reform is necessary to avoid the collapse of the medical system. When the Medical Care Act was enacted in 1986 in Taiwan, the legal provisions for medical malpractice in Medical Care Act was not clearly stipulated. No-fault liability and fault liability were ambiguous at that time. In 2004, Medical Care Act (2004 Reform) excluded the application of no-fault liability and established the standards for medical negligence. In 2012, policy makers proposed the Medical Malpractice Resolution and Compensation Act (draft) as the alternative dispute resolution (ADR) system for medical litigations.

In this article, we analyze the correlation between malpractice litigation and medical legislation reform in Taiwan over a 30-year period. This analysis provides evidence and information to policy makers so that the government can continue to reform medical legislation and improve the public health system.

Methods

Medical Review Committee Assessment Report Review

The medical dispute analysis detailed herein was based on public statistical data provided by the official Medical Review Committee (MRC) of the Ministry of Health and Welfare in Taiwan. Observational studies regarding medical disputes were analyzed according to the year of completion to investigate trends in assessment reports over time during the study period. Data were collected for the period of 1987 to 2018. The analysis was based on 3 major topics: medical dispute litigation type, medical appraisal results, and the annual medical litigation rate.

Medical Dispute Litigation Type and Medical Appraisal Results

Taiwan has a statutory law system like Japan and Germany, so some medical disputes will undergo criminal proceedings that may be different from case law countries. In Taiwan, medical dispute litigation types are mainly divided into civil and criminal cases. According to the MRC statistics, medical appraisal results can be divided into "negligence," "possible negligence," "no negligence," "unable to identify," "not a medical dispute," and "other." "No negligence" cases can also be referred to as "no-fault" cases, signifying that the medical staff exercised due care while conducting a medical procedure. However, "negligence" cases and "possible negligence" cases indicate that medical personnel did not meet the standard duty of care. "Unable to identify" cases indicate that the medical appraisers may have conflicting opinions regarding the case. "Other" indicates that the cases were revoked, withdrawn, or lacked clinical data.

Trends Over Time Adjusted for the General Population

The population of Taiwan has gradually increased since 1987. Data on the total population were based on statistics from Taiwan's Ministry of the Interior. On the basis of the annual medical litigation rate, we further analyzed trends in medical dispute assessments over time by adjusting for the general population (per $1,000,000$ people).

Statistical Analysis

Medical dispute assessments were analyzed according to the year of completion and the result of the medical appraisal. The major reform of Medical Care Act (2004 Reform) is in Paragraph 2, Article 82. It revealed that "Medical care institutions and their medical personnel who harm patients in the execution of practice, whether deliberate or by accident, shall be responsible for compensation."

The legal element is based on the negligence standard which excluded the application of no-fault liability at that time. In addition, the ADR system focuses on strengthening the mediation mechanism and quickly resolving disputes before going to the malpractice litigation. Because of the Medical Care Act (2004 Reform) and the ADR system introduced in 2012, we established 2004 and 2012 as the two cut-points for further analysis. Data were analyzed using SPSS version 27.0 (IBM).

Results

From 1987 to 2018, the MRC completed a total of 11 ,162 assessment reports, 10, 737 of which involved medical malpractice, with the remaining 425 not involving medical malpractice. More criminal cases than civil cases were reported, and the total number of cases increased yearly from 1987. The number of medical disputes, whether civil or criminal, peaked in 2012 and subsequently began to decline (Figure 1). Over the years, criminal litigation accounted for 82.5% and civil litigation accounted for 17.5% of all medical litigation cases (Table 1). On average, the percentage of criminal cases was approximately 4.7 times higher than that of civil cases.

Excluding "not a medical dispute" revealed that the annual medical litigation rate decreased slightly from 19.44 cases per million people in 2004 to 16.38 cases per million people in 2005. However, the rate increased from 17.97 cases per million people in 2006 to 20.36 cases per million people in 2008, surpassing the previous high of 20.08 cases per million people in 2003, and continued to increase slightly until 2012 (Table 1).

According to judicial data, the annual medical litigation rate increased from 6.69 cases per million people in 1987 to a peak of 26.68 cases per million people in 2012 and subsequently began to decline (Figure 2). The annual medical litigation rate in 2012 was approximately 3.99 times higher than that in 1987. With medical legislation reforms such as the establishment of legal elements in Medical Care Act (2004 Reform) and mediation system (2012), the annual medical litigation rate decreased from 26.68 cases per million people in 2012 to 16.41 cases per million people in 2018. The annual medical litigation rate declined by approximately 38% from 2012 to 2018. During this 30-year period, the annual medical litigation rate was approximately 14.82 cases per million people per year.

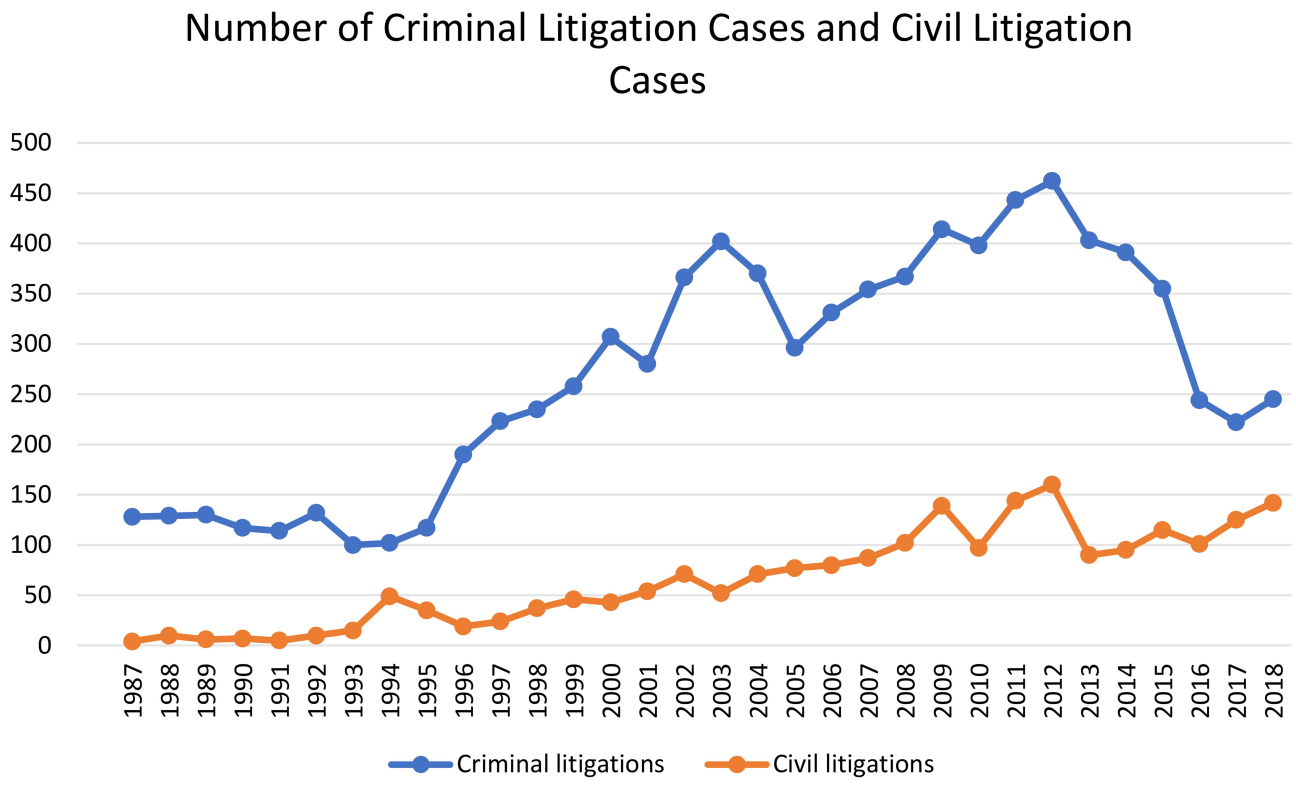

Figure 1 Number of Criminal and Civil Litigation Cases in Medical Disputes. The type of medical dispute litigation can mainly be divided into civil and criminal claims. The number of criminal litigation cases was higher than that of civil litigation cases.

Table 1 Types of Medical Dispute Litigation and Rates of Annual Medical Litigation

Year	Criminal Litigations	Criminal (%)	Civil Litigations	Civil (%)	Medical Litigations	Others	Total	Total Population	The Medical Litigation Rates (Per Million People)
1987	128	97	4	3	132	13	145	19,725,010	6.69
1988	129	92.8	10	7.2	139	24	163	19,954,397	6.97
1989	130	95.6	6	4.4	136	14	150	20,156,587	6.75
1990	117	94.4	7	5.6	124	3	127	20,401,305	6.08
1991	114	95.8	5	4.2	119	9	128	20,605,831	5.78
1992	132	93	10	7	142	23	165	20,802,622	6.83
1993	100	87	15	13	115	25	140	20,995,416	5.48
1994	102	67.5	49	32.5	151	40	191	21,177,874	7.13
1995	117	77	35	23	152	42	194	21,357,431	7.12
1996	190	90.9	19	9.1	209	25	234	21,525,433	9.71
1997	223	90.3	24	9.7	247	13	260	21,742,815	11.36
1998	235	86.4	37	13.6	272	15	287	21,928,591	12.40
1999	258	84.9	46	15.1	304	28	332	22,092,387	13.76
2000	307	87.7	43	12.3	350	33	383	22,276,672	15.71
2001	280	83.8	54	16.2	334	32	366	22,405,568	14.91
2002	366	83.8	71	16.2	437	19	456	22,520,776	19.4
2003	402	88.5	52	11.5	454	11	465	22,604,550	20.08
2004	370	83.9	71	16.1	441	9	450	22,689,122	19.44
2005	296	79.4	77	20.6	373	3	376	22,770,383	16.38
2006	331	80.5	80	19.5	411	7	418	22,876,527	17.97
2007	354	80.3	87	19.7	441	3	444	22,958,360	19.21
2008	367	78.3	102	21.7	469	3	472	23,037,031	20.36
2009	414	74.9	139	25.1	553	3	556	23,119,772	23.92
2010	398	80.4	97	19.6	495	1	496	23,162,123	21.37
2011	443	75.5	144	24.5	587	1	588	23,224,912	25.27
2012	462	74.3	160	25.7	622	1	623	23,315,822	26.68
2013	403	81.7	90	18.3	493	3	496	23,373,517	21.09
2014	391	80.5	95	19.5	486	1	487	23,433,753	20.74
2015	355	75.5	115	24.5	470	4	474	23,492,074	20.01
2016	244	70.7	101	29.3	345	6	351	23,539,816	14.66
2017	222	64	125	36	347	7	354	23,571,227	14.72
2018	245	63.3	142	36.7	387	4	391	23,588,932	16.41
Average		82.5		17.5					14.82

In Taiwan, medical appraisal results are mainly used by a judge as a reference during the evaluation of evidence. For medical litigation, we focused on three groups: "negligence," "possible negligence," and "no negligence/no-fault." The "negligence" and "possible negligence" cases were combined into the "malpractice" cases and compared with the "no negligence/no-fault" cases. Notably, "no-fault" cases were more frequent than "negligence" and "possible negligence" cases (Figure 3). "No-fault" cases accounted for approximately 68.1% of all MRC reports, and "negligence" and "possible negligence" cases accounted for approximately 15.3% of all MRC reports (Table 2). The percentage of "no-fault" cases was approximately 4.5 times higher than that of "negligence" and "possible negligence" cases.

We used the Medical Care Act (2004 Reform) as a cut-point for analyzing medical appraisal results. We then further compared the "malpractice" cases ("negligence" and "possible negligence" cases) and the "no-fault" cases. Before Medical Care Act (2004 Reform), 22.1% of medical appraisals (751 cases) were "malpractice" cases, whereas from 2004 to 2012, 18.8% of medical appraisals (609 cases) were "malpractice" cases (OR, 0.82; 95% CI, 0.727–0.924; p=0.001) (Table 2). The percentage decreased, and Medical Care Act (2004 Reform) significantly affected medical appraisal results.

Evidently, the rate of annual medical lawsuits peaked in 2012. The total number of malpractice cases in Taiwan

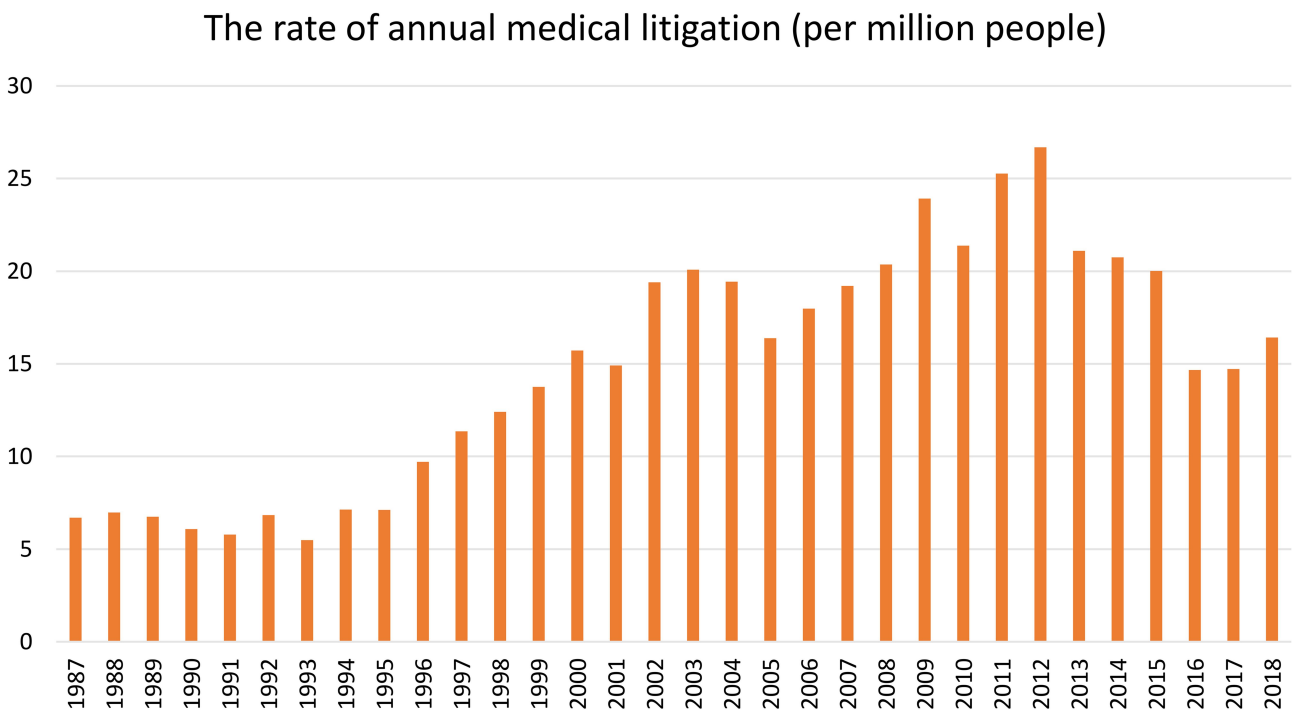

Figure 2 Trend in annual medical litigation rate. This figure displays the trend in the annual medical litigation rate (per million people) from 1987 to 2018.

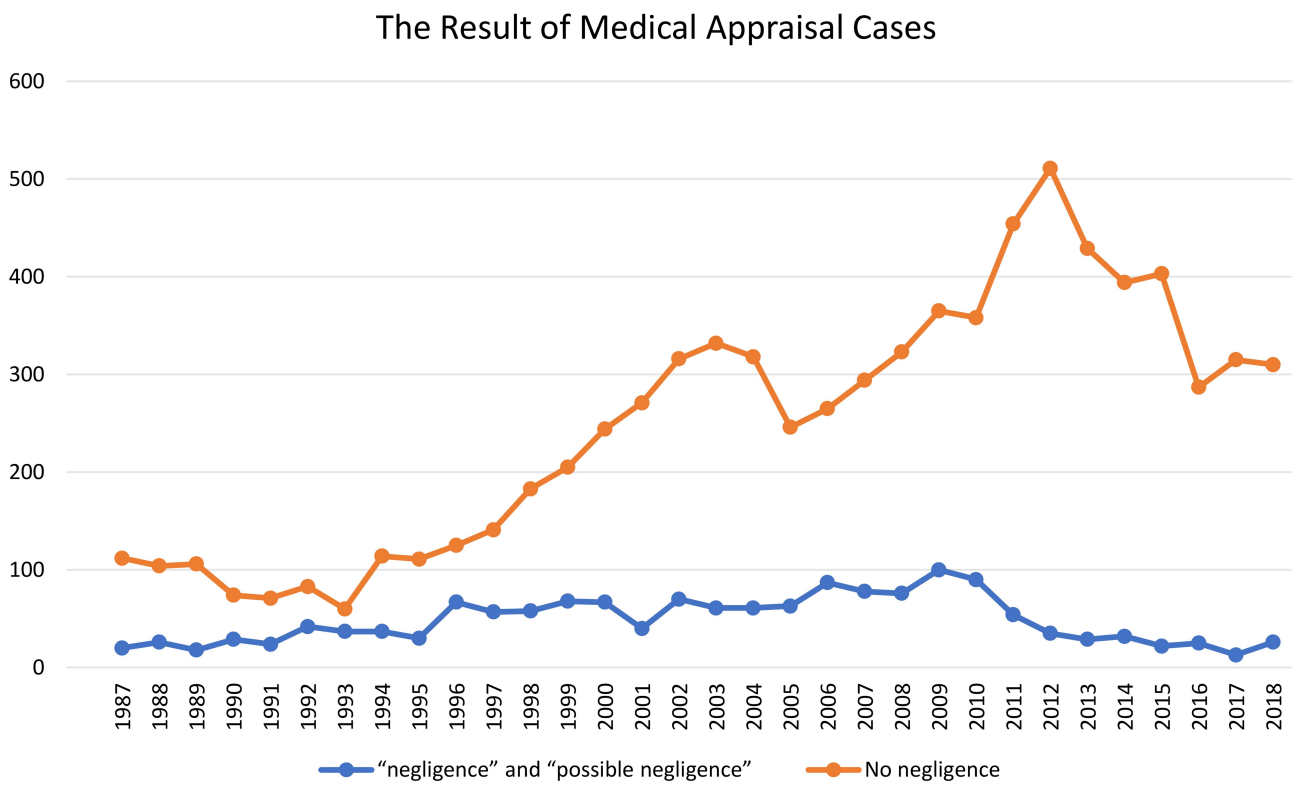

Figure 3 Results of medical appraisal. The number of "no-fault" cases was higher than that of "negligence" and "possible negligence" cases.

reached 622 that year, and the annual medical litigation rate reached 26.68 cases per million people in 2012. The Medical Malpractice Resolution and Compensation Act (draft) introduced the ADR system at that time for resolving such problems. Additionally, with the encouragement of the government, medical care institutions also began to

Table 2 Results of Medical Review Committee Reports

Year	Negligence	Possible Negligence	"Negligence" and "Possible Negligence"	"Negligence" and "Possible Negligence" (%)	No Negligence	No Negligence (%)	Unable to Identify	Not a Medical Dispute	Others	Total
1987	8	12	20	13.8	112	77.2	0	0	13	145
1988	14	12	26	16.0	104	63.8	1	2	30	163
1989	7	11	18	12	106	70.7	2	0	24	150
1990	16	13	29	22.8	74	58.3	7	0	17	127
1991	6	18	24	18.8	71	55.5	1	1	31	128
1992	21	21	42	25.5	83	50.3	6	0	34	165
1993	27	10	37	26.4	60	42.9	4	0	39	140
1994	34	3	37	19.4	114	59.7	15	10	15	191
1995	24	6	30	15.5	111	57.2	24	12	17	194
1996	52	15	67	28.6	125	53.4	22	9	11	234
1997	40	17	57	21.9	141	54.2	27	30	5	260
1998	43	15	58	20.2	183	63.8	22	18	6	287
1999	59	9	68	20.5	205	61.7	26	31	2	332
2000	40	27	67	17.5	244	63.7	30	33	9	383
2001	24	16	40	10.9	271	74.0	17	30	8	366
2002	37	33	70	15.4	316	69.3	30	34	6	456
2003	34	27	61	13.1	332	71.4	33	15	24	465
Before Medical Care Act (2004 Reform)			**751 (22.1%)**		**2652 (77.9%)**		**1 [Reference]**			
2004	25	36	61	13.6	318	70.7	24	26	21	450
2005	28	35	63	16.8	246	65.4	42	9	16	376
2006	54	33	87	20.8	265	63.4	43	10	13	418
2007	68	10	78	17.6	294	66.2	45	17	10	444
2008	59	17	76	16.1	323	68.4	43	17	13	472
2009	65	35	100	18.0	365	65.6	46	29	16	556
2010	37	53	90	18.1	358	72.2	24	12	12	496
2011	28	26	54	9.2	454	77.2	46	24	10	588
2004~2012			**609 (18.8%)**		**2623 (81.2%)**		**Odds Ratio, 0.82; 95% CI, 0.727–0.924 (P=0.001)**			
2012	18	17	35	5.6	511	82.0	39	21	17	623
2013	21	8	29	5.8	429	86.5	27	5	6	496
2014	20	12	32	6.6	394	80.9	35	14	12	487
2015	13	9	22	4.6	403	85.0	30	15	4	474
2016	12	13	25	7.1	287	81.8	21	7	11	351

2017	9	4	13	3.7	315	89.0	18	2	6	354	
2018	23	3	26	6.6	310	79.3	13	1	41*	391	
After ADR introduced (2012)			**182 (6.4%)**		**2649 (93.6%)**		**Odds Ratio, 0.243; 95% CI, 0.205–0.288 (p<0.001)**				
Average				15.3		68.1					

Notes: Data were derived from the official Medical Review Committee of Ministry of Health and Welfare in Taiwan. *Includes 38 medical appraisal cases not yet completed.

establish internal mediation systems to resolve medical disputes.

We also established 2012 as a cut-point for analyzing medical appraisal results. Before legislation reform, 22.1% of medical appraisals (751 cases) were "malpractice" cases, whereas after mediation system was introduced in 2012, 6.4% of medical appraisals (182 cases) were "malpractice" cases (OR, 0.243; 95% CI, 0.205–0.288; p<0.001) (Table 2). The percentage decreased and a significant correlation was observed between the introduction of the ADR system and medical appraisal results.

Discussion

In the current observational study, we analyzed nationwide assessment reports from the MRC and the Ministry of Health and Welfare over a 30-year period in Taiwan. We focused on three major topics: medical dispute litigation type, medical appraisal results, and the annual medical litigation rate.

As medical liability reform continues to progress, even if slowly, a better liability system that fosters progress toward safe, high-quality health care is expected to emerge.[18–20] Taiwan has a statutory law system, and thus, medical legislation reform and legal elements were highly critical in the 30-year period studied. Over the study period, 2004 and 2012 represent two crucial time points. Medical legislation reform data were based on information provided by the Legislative Yuan, the central legislative body in Taiwan. The Medical Care Act (2004 Reform) explicitly excluded the application of no-fault liability described in the Consumer Protection Act, and the essence of its legal elements is based on the negligence standard in civil law. In 2012, the Executive Yuan (Taiwan) proposed the Medical Malpractice Resolution and Compensation Act (draft) to establish an ADR system for medical malpractice. Additionally, policy makers also advocated for internal mediation systems in medical care institutions and promoted communication between medical and legal professionals. The current study revealed five major findings.

First, in medical malpractice litigation in Taiwan, more criminal cases than civil cases were reported in the 30-year period studied; this was largely due to the litigation strategies adopted by patient-plaintiffs in Taiwan. Victims tended to view using criminal proceedings as their optimal litigation strategy due to the intervention of a prosecutor. For medical staff, the mental stress of criminal liability is greater than that of civil liability. Malpractice claims also

have various effects on physicians; for instance, they may stop practicing medicine or switch to smaller practice settings.[21] Conceivably, the strategy of criminal proceedings and increasing criminal litigations prompted the Medical Care Act (2004 Reform) in Taiwan.

Second, the annual medical litigation rate was 6.69 cases per million people in 1987 and peaked at approximately 26.68 cases per million people in 2012. The annual medical litigation rate began to decrease after 2012, with the latest figure being 16.41 cases per million people as of 2018. Our study revealed that malpractice litigation has increased since the late 20th century, which is comparable with the worldwide upward trend in malpractice litigation. In the United States, the number of malpractice suits started rising in a geometric fashion, more frivolous lawsuits were filed, and malpractice insurance premiums started rising, resulting in a malpractice crisis.[22] The growth in malpractice litigation has also been noted in Asian countries such as Japan, China, and Malaysia.[23–25]

Third, the percentage of physicians who are found to have been negligent during medical practice is low according to MRC assessment reports. Even with a no-fault medical appraisal, the extended duration of litigation consumes a considerable amount of physicians' time and energy. Furthermore, resolution of malpractice claims requires time and affects physicians because of lost time and the added stress from extra work and a damaged reputation.[26–28] Therefore, medical legislation reform is imperative in the early 21st century.

Fourth, the annual medical litigation rate slightly decreased in 2004 and 2013 and declined by approximately 38% from 2012 to 2018, which corresponds to the timing of Medical Care Act (2004 Reform) and the introduction of the ADR system. This decline reveals that medical legislation reform and legal element changes can considerably influence the annual medical litigation rate. Four legal elements must be proven in medical malpractice: a professional duty owed to the patient; breach of such duty; injury caused by the breach; and resulting damages.[29,30] Breach of professional duty is the most critical legal element for courts in determining whether a physician has acted negligently in medical practice.[31] In Taiwan, the Medical Care Act was reformed and adjusted on April 9, 2004. Paragraph 2, Article 82 of the Medical Care Act (2004 Reform) established the basis for civil negligence liability in malpractice litigation. Additionally, the ADR system and other internal mediation systems were introduced in 2012. The annual medical litigation rate did not decrease in 2012 but decreased the following year possibly because policy discussion requires substantial time, and consequently, statistics cannot immediately reflect implemented changes.

Fifth, we combined the medical legislation reform and medical appraisal result time points. Medical appraisal results revealed less malpractice cases after legislation reform. In the study, we established 2004 and 2012 as 2 cut-points for further analysis. Medical appraisal results were malpractice cases in 22.1% before Medical Care Act (2004 Reform) compared with 18.8% from 2004 to 2012 (Odds ratio [OR], 0.82; 95% CI, 0.727–0.924; p=0.001), and 6.4% after mediation system introduced in 2012 (Odds ratio [OR], 0.243; 95% CI, 0.205–0.288; p<0.001). This decline in malpractice cases reveals a significant correlation between medical legislation reform and medical appraisal results.

Other studies have revealed that physicians with certain high-risk specialties or other distinctive characteristics are targets of more malpractice claims.[32–35] Reducing the risk of medical litigation is highly critical. In an atmosphere with low risk of litigation, medical staff can concentrate on fighting disease, especially in the context of a pandemic such as COVID-19. Physicians should be able to understand and measure how and where they have not performed their duty.[36] In the context of medical disputes, numerous studies have focused on the details of professional duties such as the duty to inform, the duty of care, and the duty of confidentiality.[37–41] However, our observational study revealed a special finding. In addition to physicians understanding their professional duty, policy makers also play a crucial role in malpractice litigation. Legislation reform and extensive discussions have not only helped reduce the number of medical lawsuits but have also affected medical appraisal results. Consequently, a statistically significant reduction in negligence results was observed.

In the 30-year period studied, physicians in Taiwan confronted an array of immediate challenges associated with the increasing number of malpractice claims. Similar to judges in continental European countries, judges in Taiwan independently investigate the facts of a case and decide the outcome. Therefore, reforming the Medical Care Act remains a priority because it is the applicable regulation for medical malpractice. Legislation reform makes the legal elements clearer than before. This protects the rights and harmonious relationship between patients

and medical staff. Patient can also receive fair trial form judges under clear legal elements in statutory law country.

Medical legislation reform in Taiwan is consistent with international trends. Countries that use case law also appear to reform their common law of torts related to medical malpractice.[42–44] Additionally, the ADR system may be regarded as a means for resolving medical disputes, reflecting the examples of other countries.[45–48] As the rights of medical staff began to take priority, the annual medical litigation rate gradually decreased. Medical legislation reform significantly progressed toward resolving the increasing number of malpractice claims in Taiwan in the 30-year period studied.

Limitations

This study has several limitations. It was restricted to the variables and factors for which data were available, including high-risk specialties, distinctive characteristics, patient's clinical condition, patient-physician relationship and physicians perform their duty or not. Although the statistical analysis of odds ratio reveals that legislation reform plays an important role in reducing the risk of malpractice litigation, this study may be limited by differences between statutory law and case law in different countries. The results obtained can be generalized to countries with statutory law system similar to Taiwan's. Nonetheless, caution should be exercised in generalizing them to other countries with case law system.

Conclusion

According to the current observational study, the annual medical litigation rate gradually increased since 1987, and of malpractice claims, more criminal cases were filed than civil cases. After the Medical Care Act (2004 Reform) and the introduction of the ADR system, the annual medical litigation rate decreased. Among medical appraisal results, more "no negligence" cases were reported than "negligence" and "possible negligence" cases. A significant correlation was also observed between medical legislation reform and medical appraisal results. Legislation reform progress in Taiwan demonstrates that consensus in society, belief in communication, and courage to change can help establish a better health care system.

Human Participant Protection Statement

No human participant in this research.

Disclosure

All authors declare that: (i) no support, financial or otherwise, has been received from any organization that may have an interest in the submitted work; and (ii) there are no other relationships or activities that could appear to have influenced the submitted work.

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