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Department of Forensic Medicine & Toxicology, Third Floor, Library Building, Seth G S Medical College & KEM Hospital, Parel, Mumbai, Maharashtra, India. Pin-400 012. Email id: mlameditor@gmail.com Phone: 022-24107620 Mobile No. +91-9423016325.

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Original Research Article

What is Considered Enough in Disclosure of Adverse Events? A Cross Sectional Study of Medicolegal Panel Members

Raed Almannie[a*]
[a]Associate professor, Urology division, College of Medicine, King Saud University, King Saud University, Riyadh, Saudi Arabia. 11451.

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Medicolegal Committee, Informed Consent, Saudi Arabia.

Abstract

Objective: To assess the current understanding and practice of the medicolegal committees' members in Saudi Arabia in regard to the disclosure of adverse event of medical and surgical treatment. And to assess their opinion and recommendations concerning the reasonable amount of information needed for an adequate discloser of adverse events. **Methods:** A cross-sectional quantitative study conducted in September 2020 by sending an electronic survey to physicians working in medicolegal committees' in Saudi Arabia. The survey's content was formulated by a member of the medicolegal committee and content validation was reviewed by two other members. **Results:** 62 out of 108 medicolegal members responded to the survey (57.4% response rate). Most of the respondents believe that all surgical adverse events should be disclosed to the patient 38 (61.3%), and most respondents 24 (38.7%) either agree or strongly agree with the statement "The physician should be held liable for any surgical adverse event not discussed with the patient". **Conclusion:** Our findings show subjectivity in interpreting the law by medicolegal committees' members in regard to informed consent and the sufficient amount needed for disclosure for adverse events. We recommend policy makers to create a model that protect the patient rights and respect his autonomy and, in the other hand, decrease the physician liability.

1. Introduction

Informed consent (IC) is the process where the patient authorizes the health practitioner to initiate medical or surgical treatment, after discussion in regard to the benefit, risk and alternatives of the proposed treatment.[1] The conditions that should be part of any IC are: disclosure, comprehension, voluntary choice and authorization.[2] Violating any of these conditions is a violation to patient legal right and might subject the physician to medical litigation.

A significant number of studies revealed gaps between the real practice of IC and the anticipated IC based on its theoretical construct.[2-5] One of these challenges is how much information should be disclosed to the patient in regard to the proposed medical or surgical treatment.

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***Corresponding author:** Dr Raed Almannie, Associate professor, Urology division, College of Medicine, King Saud University, King Saud University, Riyadh 11451. Email: ralmannie@ksu.edu.sa Orchid: 0000-0002-4417-0154
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To avoid litigations, health practitioner should provide adequate information to the patient to be able to reach an informed decision. But IC codes and laws do not indicate the extent of information that should be provided.[6]Deficient disclosure is a violation to the patient autonomy, as the patient is deprived of information to make the right choice. While detailed disclosure has its limitations due to physician time constrains, increasing side effects to the patient, suboptimal treatment and increase rate of withdraw.[7-11]

IC deficiencies is one of the most common causes of physician's liability. The common understanding that IC is optimal if a patient signs is misleading and not protective in case of a law suit. Instead, IC is a process of providing the patient with adequate information relevant to his condition and ends up with the patient's approval to undergo treatment. The process of IC requires time and excellent communication skills.[12] However, clinical practice revealed some factors that negatively influenced the process of IC including: prolonged duties, increased patients numbers with lack of time, lack of quality audit, inadequate training of medical professionals, and insufficient legal regulations.[13-15]

In Saudi Arabia, the Law of Practicing Healthcare Professions (LPHP) was released in 2005.[16] The law contains many articles that regulate the following: Licensing, Duties, Professional liability and the process of investigation and trial. Later patient Bill of right and responsibilities was released.[17] In 2019, the ministry of health published the guidelines of informed consent.[18] In the law, bill and guidelines nothing mentioned about the amount of information sufficient for informed consent. We aim to assess the opinion and recommendations of the medicolegal committees' members in Saudi Arabia concerning the reasonable amount of information needed for an adequate discloser of adverse events. And to assess their current understanding and practice in the committee in regard to the adverse event disclosure of medical and surgical treatment.

2. Materials And Methods

Study Design

This was a cross-sectional quantitative study conducted in September 2020. Study sample were physicians working as consultants for the medico-legal committees in Saudi Arabia. All medical lawsuit in Saudi Arabia are trialed by medico-legal committee. Each committee consist of three physicians of different specialties and one judge. Physician working in these committees are the most expert physicians in medical litigation, thereby their opinion is highly respected. They meet weekly to trial 5-10 medical lawsuit. A total of 36 medicolegal committee was included. The database was obtained from the ministry of health. An electronic survey was sent to all physician-members of these committees.

Survey Content

An electronic survey was constructed using Google Forms (Google Form, Mountain View, CA, USA). The survey's content was formulated by a member of the medicolegal committee and content validation was reviewed by two other members. The questionnaire consists of two sections. The first section contains demographic information including: age, sex, specialty, number of years working with the medicolegal committee and the number of cases trialed per year. The second section contain questions focusing on the participants' opinions and recommendations regarding adverse events disclosure for medications and surgical procedures. This section focused on how much disclosure is enough, liability of physicians in cases of non-disclosed adverse event, and suggested changes to the law. A detailed list of the questionnaire items is shown in (**Table 1-4**).

Statistical Analysis

Statistical analysis was performed using SPSS version 23 (IBM Corp. Released 2015. Version 23.0. Armonk, NY: IBM Corp). All demographic frequencies were calculated and the responses to all questionnaire items were analyzed. We compared the responses of medical and surgical respondents; dentists were excluded due to the low number of respondents. Because the data for some variables did not have a normal distribution and the assumption of variance homogeneity was violated for some of the variables, both independent samples *t*-tests and Mann-Whitney *U* tests were computed. We used Kolmogorov-Smirnov and Shapiro-Wilk to assess the normality of responses to certain survey items. A Chi-square test for independence was performed to test the associations between specialty and specific responses to the questionnaire. Correlation analyses were performed to compare responses based on demographics (age, years of experience, and the number of cases reviewed per year). We also tested for relationships between questionnaire items and demographics. Spearman's *rho* coefficients were calculated due to the non-normality of the data. A p-

value of less than 0.05 was determined to be significant.

Ethical Considerations: We obtained approval from the ministry of health to contact panel members and conduct the study. Also, institutional review board approval was granted. An electronic approval from each participant was obtained prior to beginning the survey.

Table 1. Responses to questionnaire items regarding surgical adverse events

Question	Responses				n (%)
For surgical procedures, what adverse events should be discussed with the patient prior to surgery?	All adverse events				38 (61.3%)
	All adverse events except ones that occur in < 1%				13 (21%)
	All adverse events except very rare ones				8 (12.9%)
	All adverse events except ones that occur in < 2%				0 (0%)
	All adverse events except ones that occur in < 5%				3 (4.8%)
The physician should be held liable for any surgical adverse event not discussed with the patient.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	15 (24.2%)	9 (14.5%)	19 (30.6%)	9 (14.5%)	10 (16.1%)

Table 2. Responses to questionnaire items regarding medications adverse events

Question	Responses				n (%)
For medications, what adverse events should be discussed with the patient prior to administering the medication?	All adverse events				24 (38.7%)
	All adverse events except very rare ones				21 (33.9%)
	All adverse events except ones that occur in < 1%				4 (6.5%)
	All adverse events except ones that occur in < 2%				3 (4.8%)
	All adverse events except ones that occur in < 5%				8 (12.9%)
	All adverse events except ones that occur in < 10%				2 (3.2%)
The physician should be held liable for any medication adverse event not discussed with the patient.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	8 (12.9%)	10(16.1%)	18 (29%)	12(19.4%)	14 (22.6%)
In cases of adverse events secondary to medications, physicians are liable because the consent is usually verbal, and the disclosure is not documented	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	16(25.8%)	12(19.4%)	16(25.8%)	10(16.1%)	8(12.9%)

Table 3. Responses to questionnaire items of suggested regulations in disclosure of adverse events

Question	Responses	n (%)
Which of the following suggested laws (regarding medical adverse events) do you consider practical, respects patient autonomy, and reduces physician liability?	All adverse events in the label have to be discussed	25(40.3%)
	All adverse events in the label have to be discussed except very rare adverse events	18(29%)
	All adverse events in the label have to be discussed except events that occur in < 2%	6(9.7%)
	All adverse events in the label have to be discussed except events that occur in < 5%	9(14.5%)
	All adverse events in the label have to be discussed except events that occur in < 10%	4(6.5%)
Which of the following suggested laws (regarding surgical procedures adverse events) do you consider practical, respects patient autonomy, and reduces physician liability?	All adverse events have to be discussed	24(38.7%)
	All adverse events have to be discussed except very rare adverse events	17(27.4%)
	All adverse events have to be discussed except adverse events that occur < 2 %	5(8.1%)
	All adverse events have to be discussed except adverse events that occur < 5 %	3(4.8%)
	All surgical adverse events should be provided in the consent form	13(21%)

Table 4. Responses to questionnaire items regarding inconsistency of verdicts and the need of training to healthcare providers

Question	Responses				
If a malpractice lawsuit was trialed by multiple medicolegal committees, it will have the same verdict every time.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	10(16.1%)	16(25.8%)	20(32.3%)	1 (17.7%)	5(8.1%)
The "Law of Practicing Healthcare Professions" needs further elaboration on what is necessary to disclose to patients in regard to adverse events.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	34(54.8%)	14(22.6%)	10(16.1%)	4(6.5%)	0(0%)

Table 5. Comparison between medical and surgical groups – t-test and Mann-Whitney U test

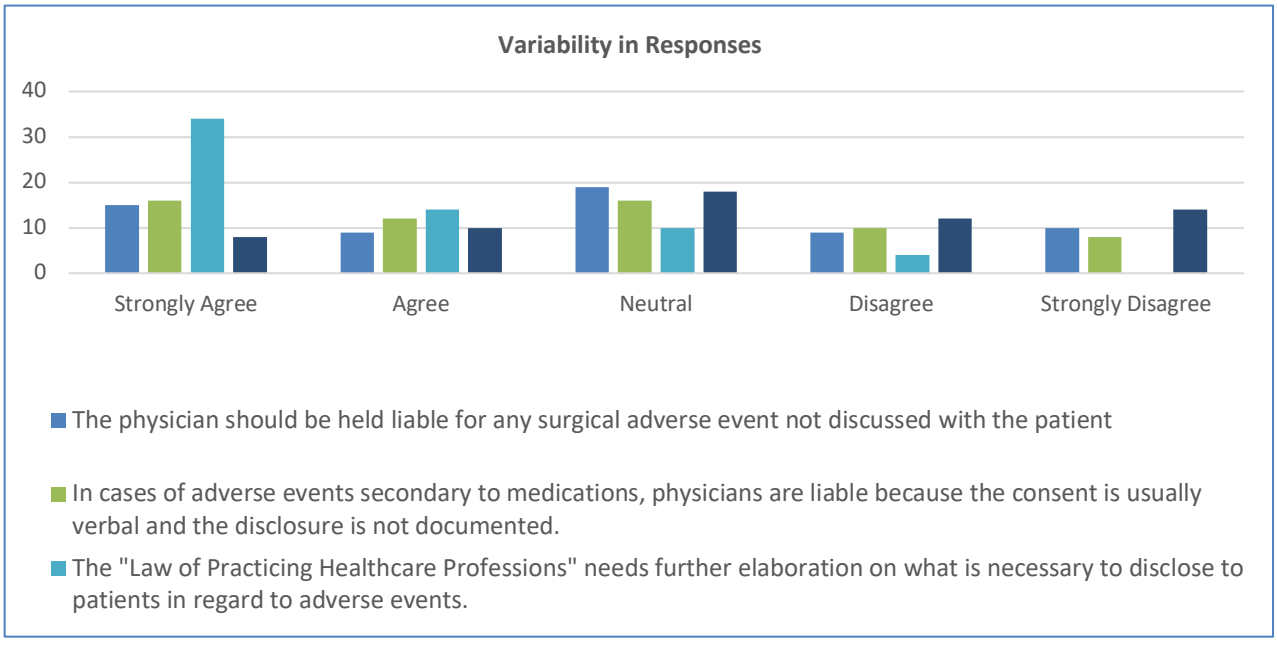
Question	t/U	p
If a malpractice lawsuit was trialed by multiple medical-sharea panels, it will have the same verdict every time.	0.93	.358
How much percentage of the cases you examine fall in the previous category?	0.27	.792
The physician should be held liable for any surgical adverse event not discussed with the patient.	1.27	.210
The physician should be held liable for any medication adverse event not discussed with the patient.	1.30	.198
In cases of adverse events secondary to medications, physicians are liable because the consent is usually verbal and the disclosure is not documented.	1.08	.287

Table 6: Correlation analysis based on demographics

Question	Age	Years	Cases
If a malpractice lawsuit was trialed by multiple medical-sharea panels, it will have the same verdict every time.	-.10	.24	.19
The physician should be held liable for any surgical adverse event not discussed with the patient.	.10	.04	**.30***
The physician should be held liable for any medication adverse event not discussed with the patient.	.00	.04	.24
In cases of adverse events secondary to medications, physicians are liable because the consent is usually verbal and the disclosure is not documented.	.10	.01	-.19
The physician should be held liable for any adverse event due to off-label medication use.	-.25	.00	.00
The physician should disclose if the medication is used as off-label.	-.03	-.02	-.20
The "Law of Practicing Healthcare Professions" needs further elaboration on off-label prescriptions.	.09	-.07	-.23

*p < .05

Figure 1. Variability in responses among certain items in the survey



3. Results

Demographic data

The questioner was sent to 108 members of 36 medico-legal committee. 62 medicolegal members responded to the survey (57.4% response rate). All responses were complete and were included in the study. Mean age was 49.84 years (*SD* = 8.60). Mean number of years serving in the panel was 12.34 years (*SD* = 10.96). With regard to number of lawsuits per year, the most frequent answer was 91-100 lawsuits per year (22.6%), followed by 0-10 lawsuits per year (11.3%) and >210 lawsuits per year (11.3%). Most of the respondents (62.9%) were from surgical specialties, followed by medical specialties (29%), and finally dentistry (8.1%).

Surgical adverse events

Most of the respondents believe that all surgical adverse events should be disclosed to the patient 38 (61.3%), and 13 (21%) believe that disclosure should be done except for rare adverse events. 24 (38.7%) respondents either agree or strongly agree with the statement "The physician should be held liable for any surgical adverse event not discussed with the patient", and only 19 (30.6%) respondents either disagree or strongly disagree with the same statement (**Table1**). When asked about the suggested laws regulating disclosure of surgical adverse events that are considered practical, respects patient autonomy, and reduces physician liability: the most frequent law suggested was "All adverse events have to be discussed" 24 (38.7%), followed by *"All surgical adverse events should be provided in the consent form"* 13 (21%). Responses to the questionnaire are presented in (**Table 3**).

Medication adverse events

Most of the responded believe that all medications adverse events should be disclosed to the patient 24 (38.7%), and 21 (33.9%) believe that disclosure should be done except for rare adverse events. 18 (29%) respondents either agree or strongly agree with the statement "The physician should be held liable for any medication adverse event not discussed with the patient", and 26 (42%) respondents either disagree or strongly disagree with the same statement (**Table2**). When asked about the suggested laws regulating disclosure of medication adverse events that are considered practical, respects patient autonomy, and reduces physician liability: the most frequent law suggested was "All adverse events have to be discussed" 25 (40.3%). Most responders 28 (45.2%) either agree or strongly agree with the statement "In cases of adverse events secondary to medications, physicians are liable because the consent is usually verbal, and the disclosure is not documented". Responses to the questionnaire are presented in (**Table 3**).

Variability in responses among medicolegal committees' members

To assess the variability of responses, we conducted both Kolmogorov-Smirnov and Shapiro-Wilk tests to quantify normality of distribution. Both normality tests revealed statistically significant results showing all responses to be not normally distributed. **Figure 1** represents the responses to tested items, with a clear presentation of non-normally distributed data. Moreover, we assessed the skewness of data in each item. All responses were not skewed Except for the statement "The Law of Practicing Healthcare Professions needs further elaboration on what is necessary to disclose to patients in regard to adverse events".

Comparison between surgical and other medical specialties

Firstly, comparisons between medical and surgical groups were conducted (since there were only five dentistry participants, they were excluded from this analysis). Due to non-normality of the data as well as violations of variance homogeneity for some of the variables, both independent samples *t*-test and Mann-Whitney *U* test were computed. Results are shown in (**Table 5**). A Chi-square test of independence was also performed and did not result in statistically significant results.

Comparisons based on demographics

A correlation analysis was performed as well to test for a relationship between questionnaire items and demographics (age, number of years in the panel, number of cases). Spearman's *rho* coefficients were calculated due to non-normality of the data. Results are shown in (**Table 6**). The more cases the respondent had, the stronger they agreed with a statement that physician should be held liable for surgical adverse effects not discussed with the patient. All other comparisons were not statistically significant.

4. Discussion

The adequate disclosure of adverse events of a treatment is considered a challenge to physicians.[19] According to the doctrine of IC, adequate information should be provided to the patient in order to reach an informed decision. It will be practical for physician to know what they need to disclose, to fulfil their ethical

duty and avoid litigations. Unfortunately, laws and regulations do not specify in details the amount of information that is needed to be disclosed.[6] Although it seems reasonable to mandate disclosure of all adverse events for surgical procedures, this does not apply to medical treatment. Is it realistic to disclose all adverse effects in the print of a medication, even if the rate is one in 100000 or even less? This might lead to tremendous decrease to the efficiency of the healthcare system and probably will increase treatment waiting time and cost.[8]

Time constrain is not the only limitation of full disclosure, a large number of studies have shown that detailed disclosure might have additional disadvantages leading to higher incidence of experiencing the side effect and withdraw from the treatment.[20-22] In one study on aspirin (n=555), the group that was informed about the gastrointestinal side effects developed these symptoms sixth-fold higher than the group not told about these side effect.[21] Another study on finasteride (n=120) revealed, the group that was informed about the sexual side effects developed those side effects three-fold higher than the control group.[20] This phenomenon is called nocebo effect and it can be harmful. Moreover, the information given to patients can shape the adverse events that they will experience, in a study with two placebo groups: one placebo acupuncture and placebo pill, showed that the development of side effect in each group was dependent on the information given.[23] Even word choice can influence the rate of occurrence of side effects. For example, using the word cool sensation instead of pain can reduce the rate of pain development after starting treatment.[24]

Nocebo effect is believed to be the result of the patient's anxiety and negative expectations.[25] It has many consequences including: psychological distress, excess costs, decrease compliance, increased clinical visits, and increase the medications prescribed to treat the nocebo response.[8] It was also found that changing medication due to side effect can result in more complications and less suboptimal disease control.[7,26] In 1995, the estimated hospital cost associated with drug adverse events was 76.6 billion dollars and the estimated emergency department cost was 17 million for the same reason.[27]

Our study was done on physicians who are working with the medicolegal committee. Their job is to provide consultation in each medical lawsuit and they are considered the most expert physician in medical litigations, their opinion could alter the judgment of any case. We assessed their opinion in regard to the amount of disclosure of adverse events for surgical or medical treatment and the liability in case of the occurrence of an adverse event. We found their responses to be variable and not normally distributed (Table1-3) and (figure 1). This finding has to conclusions: first conclusion, the law in regard to amount of disclosure is subjective, and it relay on the members interpretation of the law and their personal opinion. Second conclusion, in case of a litigation due to adverse events, there may be different verdicts for the same case depending on the medicolegal member involved.

Another dilemma, is the appropriate type of consent needed to avoid liability. For surgical procedures, the consent is usually written and the authorization is clear, but for medication the consent is usually verbal except for certain medications.[19] The magnitude of these dilemma can be observed if there is a litigation due to a medication adverse events with the patient denying the disclosure. In this situation, what will prove the occurrence of disclosure and prevent physician unnecessary litigation. In our study, the responses to our question "In cases of adverse events secondary to medications, physicians are liable because the consent is usually verbal, and the disclosure is not documented" showed that (45.2%) of medicolegal committee member either agree or strongly agree with this statement. This high agreement validates the importance of having a clear laws and regulations to avoid unnecessary liability.

When we asked the medicolegal members "Which of the following suggested laws do you consider practical, respects patient autonomy, and reduces physician liability?" there responses were not randomly distributed and not homogenous, which substantiate the lack of objectivity in IC. For surgical adverse events disclosure, most of the member (38.7%) believe all adverse events should be disclosed, while (27.4%) believe that disclosure should be done except for very rare adverse events. Only (21%) believe that all adverse events should be documented in the consent form. For medications adverse events disclosure, surprisingly, most of the members (40.3%) believe that all adverse events described in the medication label should be disclosed. All answers were not normally distributed and skewed which indicate that our question need to be addressed by policy makers.

Some models have been developed to resolve the limitations of the current IC theoretical construct including: the reasonable patient standard, the subjective standard, and the reasonable physician standard.[1] But these methods are subjective and does not resolve the question "how much adverse event disclosure is enough". We found that the responses of the medicolegal members were not normally distributed and not skewed, which prove the subjectivity of the model adapted by members. This fact might affect the verdict of a certain lawsuit depending on the opinion of the member and not due to a clear law statement. This was also shown by the question "If a malpractice lawsuit was trialed by multiple medicolegal committees, it will have the same verdict every time", only 41.9% of members either agree or strongly agree to this statement. The only response which was normally distributed was "The Law of Practicing Healthcare Professions needs further elaboration on what is necessary to disclose to patients in regard to adverse events", this finding corporate the previous findings which emphasis on the subjectivity and lack of objectivity. So practically, IC is the process where the physician provides sufficient information in order for him to make an informed decision.[28] But what is the information that is considered enough and will achieve the following goals: Respect patient autonomy, Not violating patient rights, Avoid harm to patient, Not paralyze the health system and Protect physician from litigations. Thus, to achieve these goals a model has to be developed and the information given to the patient has to be tailored. Also, implementing technology is also suggested to achieve the ethical goals of IC.[29-32]

5. Conclusion

Our findings show subjectivity in interpreting the law in regard to IC. We recommend policy makers to create a model that protect the patient rights and respect his autonomy and, in the other hand, decrease the physician liability.

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