July - December 2023 Volume 32 Issue 2
PRINT ISSN: 2277-1867
ONLINE ISSN: 2277-8853

JOURNAL OF FORENSIC MEDICINE SCIENCE AND LAW

Official Publication of Medicolegal Association of Maharashtra

MULTISPECIALITY, MULTIDISCIPLINARY, NATIONAL
PEER REVIEWED, OPEN ACCESS, MLAM (SOCIETY) JOURNAL
Indexed with Scopus (Elsevier) & Index Copernicus (Poland)

Editorial Office Address
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.

JOURNAL OF FORENSIC MEDICINE SCIENCE AND LAW
(Official Publication of Medicolegal Association of Maharashtra)
Email.id: mlameditor@gmail.com

PRINT ISSN: 2277-1867
ONLINE ISSN: 2277-8853

Original Research Article

Identifying Areas for Development of the Law of Practicing Healthcare Professionals in Saudi Arabia: A Medicolegal Committee-Based Survey Study

Abdulaziz Althunayan[a], Mana Almuhaideb[a], Meshari A. Alzahrani[b*], Raed Almannie[a]
[a]Urology Division, Department of Surgery, College of Medicine, King Saud University and King Saud University Medical City, Riyadh, Saudi Arabia. [b]Department of Urology, College of Medicine, Majmaah University, Al-Majmaah, 11952, Saudi Arabia.

Article Info

Received on: 12.11.2023
Accepted on: 20.12.2023

Key words
Malpractice,
Law,
Healthcare workers.

Abstract

Introduction: Malpractice lawsuits are considered a significant problem globally. In Saudi Arabia, the number of lawsuits increased by 242% since 2001. The Law of Practicing Healthcare Professions (LPHP) was introduced by the Ministry of Health (MOH) in 2005. The LPHP has some deficiencies in some regulations. These deficiencies are left for interpretation by the judge and the medicolegal committee. An example of such deficiencies is off-label prescriptions regulation. **Methods:** This is a cross-sectional study. A self-designed questionnaire was sent by email to all medicolegal panels' physician members. The first part of the survey focused on demographics. The second part focused on members' observation, opinions, and recommendations concerning LPHP and off-label medications prescription. Most of the respondents agree that implementing LPHP knowledge assessment in training and licensing will decrease the number of litigations. **Results:** 62 members out of 109 responded to the survey (56.8%). Most of the respondents agree that some physicians are liable only because they lack knowledge of the rules. 58% of the respondents (58.1%) agree that physicians should disclose if the medication is used as off-label. 38.8% of medicolegal panels' members believe that physicians should be held liable for any adverse event due to off-label medication use. **Conclusion:** It is clear from the responses that LPHP requires further elaboration. This will most likely improve healthcare for both the patient and the physician. Further objective research in the field of medicolegal litigation in Saudi Arabia is warranted.

1. Introduction

Malpractice lawsuits are considered a significant problem globally. In Saudi Arabia, the number of lawsuits increased by 242% since 2001.[1] Despite that over 50% of medical malpractice law-

How to cite this article: Althunayan A, Almuhaideb M, Alzahrani MA, Almannie R. Identifying Areas for Development of the Law of Practicing Healthcare Professionals in Saudi Arabia: A Medicolegal Committee-Based Survey Study. J For Med Sci Law 2023;32(2):43-50.

***Corresponding author:** Meshari A. Alzahrani, Department of Urology, College of Medicine, Majmaah University, Al-Majmaah, 11952, Saudi Arabia. Email: ma.alzahrani@mu.edu.sa

suits rule in favor of physicians, healthcare professionals lose substantial time, money, and utilize personal resources to resolve such litigations. In the United States, the estimated annual cost of malpractice litigations is 2%–3% of healthcare spending, which is around 60 billion USD.[2] The American Medical Association states that one-third of physicians will be sued, at least once in their career.[3] Thus, every physician is at risk of a lawsuit. The risk and cost of litigations in Saudi Arabia have not been established.

Many publications can be found on preventing litigations with a focus on multiple aspects including patient care, diagnosis, referral, communication, documentation, physician's skills, and other aspects.[2,4-6] Keeping in mind that improving patients' safety should always be a priority when considering methods to reduce liability.[7] But some of the medicolegal issues do not impact patient safety and are related to the laws of the country of practice. For example, posting a clinical photo on social media could be allowed with a patient's consent in the USA but not in Saudi Arabia. Adherence to the laws of the country or state where physicians are practicing and providing the standard clinical practice could potentially reduce healthcare personnel liability.[8,9]

The Law of Practicing Healthcare Professions (**LPHP**) was introduced by the Ministry of Health (MOH) in 2005. LPHP regulates multiple aspects including licensing healthcare professionals, medicolegal committees, the process of litigation, and obligations toward healthcare facilities and patients.[10] Currently, healthcare providers are not required to review or know LPHP to get licensed to practice in Saudi Arabia. Not knowing the law could have an impact on the liability of physicians. This impact could be higher than anticipated because the majority of physicians in Saudi Arabia are foreigners.[11]

The LPHP has some deficiencies in some regulations. These deficiencies are left for interpretation by the judge and the medicolegal committee. This may lead to variability in decisions between different medicolegal committees. An example of such deficiencies is off-label prescriptions regulation. Off-label drug use is defined as administering medications for indications or using a dosage or dosage form, that has not been approved. Off-label use occurs in all specialties. However, it may be more common in areas of medicine in which the patient population is less likely to be included in clinical trials (e.g., pediatric, pregnant, or psychiatric patients).[12] Off-label medication use was reported to be up to 30% of the patients.[13, 14] If off-label prescribing was prohibited, various new therapies and evidence would not be presented and accessible for physicians worldwide.[12]

We aim to assess the observations and recommendations of the medicolegal committees' members concerning the impact of mandating LPHP training as a requirement to be licensed to practice in Saudi Arabia. The second aim is to assess the presence of any variability in interpreting the law by medicolegal committees' members, regarding off-label medication use, as an example of LPHP deficiencies.

2. Materials and methods

Study Design

This was a cross-sectional quantitative study during September 2020. A list of the members of the medicolegal committees in Saudi Arabia was obtained from the MOH. Each medicolegal committee, also known as a medical-sharia panel, consists of a judge and 3 physicians. The purpose of the panel is to trial malpractice lawsuits on weekly basis. An electronic survey was sent by email to all physicians who are members of these committees.

Survey Content

The electronic survey was constructed using Google Forms (Google Form, Mountain View, CA, USA). The survey questions were formulated by a member of the medicolegal committee and then revised by two other members to ensure content validity. The survey included two sections: demographic data and a self-designed questionnaire. The demographic data included age, number of years serving in the medicolegal panel, number of cases reviewed per year, and specialty (medical, surgical, or dentistry). The second section collected data regarding members' observation, opinions, and recommendations concerning LPHP and off-label medications prescription. Table 1 lists all items of the questionnaire.

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

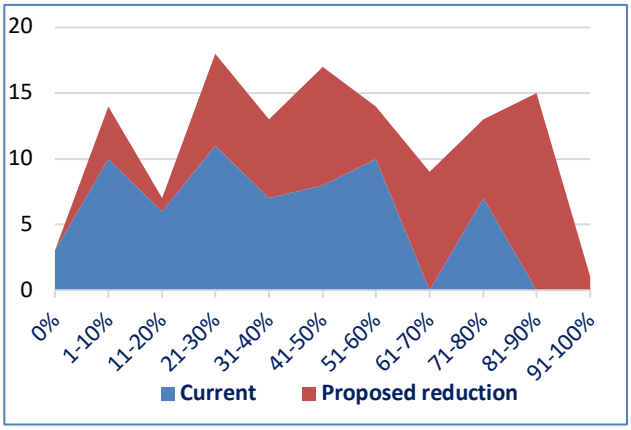
Approval from the MOH was obtained on the 6th of July 2020. No number was allocated for this project's ethical review. Electronic consent was obtained from each respondent before beginning the survey.

3. Results

Demographic data

Out of 109 medicolegal members, 62 responded to the survey (response rate = 56.8%). The mean age of respondents was 49.8 years (*SD* = 8.60); the mean number of years serving in the panel was 12.3 years (*SD* = 10.96); over 75% of the respondents had reviewed over 50 cases per year; and the respondents specialized in surgery were (62.9%), other medical specialties (29%), and dentistry (8.1%).

Figure 1: Current observed status and the proposed reduction in medical litigations after the implementation of LPHP. Y-axis represents the number of responses.



LPHP Implementation

Most of the respondents (67.7%) agree with the statement, "some physicians are liable only because they lack knowledge of the rules and not because of error in planning or executing treatment". Based on the respondents' observations, the average percentage of litigations due to lack of knowledge of the rules is 38.5% **(Figure 1)**.

Most respondents either agree (24.2%) or strongly agree (53.2%) with the statement "Implementing the Law of Practicing Healthcare Professions in training and licensing will reduce physician liability". An average of 61% reduction is expected to occur in litigations after implementation **(Figure 1)**. 67.7% believe that LPHP knowledge assessment should be implemented in both residency training and licensing. Responses to the questionnaire are presented in **Table 1a & 1b**.

Table 1a: Responses to questionnaire items

Question	Responses:	n (%)
If a malpractice lawsuit was trialed by multiple medical-sharea panels, it will have the same verdict every time.	Strongly Agree Agree Neutral Disagree Strongly Disagree	10 (16.1%) 16 (25.8%) 20 (32.3%) 11 (17.7) 5 (8.1%)
Some physicians are liable ONLY because they lack the knowledge of the rules and NOT because of errors in planning or executing the treatment.	True False	42 (67.7%) 20 (32.3%)
How much percentage of the cases you examine fall in the previous category?	0% 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%	3 (4.8%) 10 (16.1%) 6 (9.7%) 11 (17.7%) 7 (11.3%) 8 (12.9%) 10 (16.1%) 0 (0%) 7 (11.3%) 0 (0%) 0 (0%)
Implementing the "Law of Practicing Healthcare Professions" in training and licensing will reduce physician liability.	Strongly Agree Agree Neutral Disagree Strongly Disagree	33 (53.2%) 15 (24.2%) 8 (12.9%) 2 (3.2%) 4 (6.5%)
How much reduction of physician liability do you anticipate if this type of training is implemented?	0% 1-10% 11-20% 21-30% 31-40% 41-50% 51-60% 61-70% 71-80% 81-90% 91-100%	0 (0%) 4 (6.5%) 1 (1.6%) 7 (11.3%) 6 (9.7%) 9 (14.5%) 4 (6.5%) 9 (14.5%) 6 (9.7%) 15 (24.2%) 1 (1.6%)
Where do you believe the implementation of the "Law of Practicing Healthcare	Licensing Residency training Both	3 (4.8%) 17 (27.4%) 42 (67.7%)

Professions" will be most useful?		
The physician should be held liable for any adverse event due to off-label medication use.	Strongly Agree Agree Neutral Disagree Strongly Disagree	12 (19.4%) 12 (19.4%) 10 (16.1%) 6 (9.7%) 22 (35.5%)
The physician should disclose if the medication is used as off-label.	Strongly Agree Agree Neutral Disagree Strongly Disagree	22 (35.5%) 14 (22.6%) 11 (17.7%) 6 (9.7%) 9 (14.5%)
The "Law of Practicing Healthcare Professions" needs further elaboration on off-label prescriptions.	Strongly Agree Agree Neutral Disagree Strongly Disagree	32 (51.6%) 13 (21%) 10 (16.1%) 1 (1.6%) 6 (9.7%)

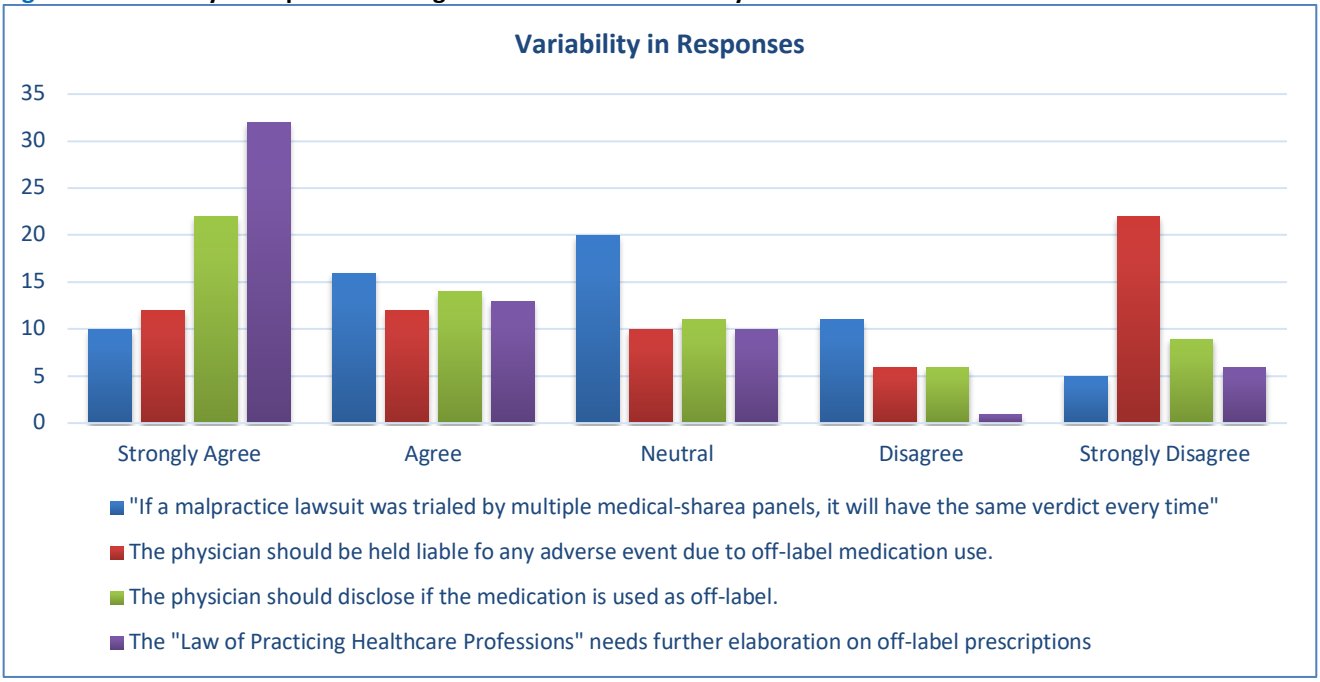
Off-Label Medication Use

Most of the respondents (58.1%) agree that physicians should disclose if the medication is used as off-label. 38.8% of medicolegal panels' members believe that physicians should be held liable for any adverse event due to off-label medication use. 72.6% agree that LPHP requires further elaboration on off-label prescriptions. As for the suggested laws, 58.1% recommended that physicians should disclose the off-label prescriptions, 48.4% recommended that physicians are only held liable if an approved alternative is available with equal efficacy, and 33.9%

Table 1b: Responses to questionnaire items

In regard to off-label medications, which of the following suggested laws is considered practical, respects patient autonomy, and reduces physician liability?	The disclosure that the medication is off-label is not needed	14 (22.6%)
	The disclosure that the medication is off-label is needed	36 (58.1%)
	The physician is liable if the indication is scientifically not supported	21 (33.9%)
	The physician is liable if an approved alternative is available with an equal efficacy	30 (48.4%)
	The physician is not liable and these medications can be used freely	5 (8.1%)

Figure 2: Variability in responses among certain items in the survey



recommended that physicians are held liable if the indication is not scientifically supported.

When asked about which of the presented laws regulating off-label prescription are practical, respect patient autonomy and reduce physician liability, the most frequent answer was the need for disclosure (58.1%), followed by liability if an approved alternative is available with an equal efficacy (46.8%), liability if the indication is not supported scientifically (33.9%), disclosure not needed (22.6%), no liability and prescription can be offered freely (8.1%). Only 41.9% of respondents either agree or strongly agree with the item stating that the same malpractice lawsuit if reviewed by multiple medico-legal panels will result in the same verdict.

Variability in responses among medicolegal committees' members

To assess the variability of responses to items pertaining to off-label use and reproducibility of the verdicts of the survey, 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 2** 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 off-label prescriptions".

Comparison between surgical and other medical specialties

The surgical and medical specialties groups were compared using both independent samples *t*-tests and Mann-Whitney *U* tests (Table 2). Moreover, a Chi-square test of independence was also performed. Medicolegal members from the medical specialty group (M = 3.94, SD = 1.21) agreed with the statement that physicians should be liable for any adverse event when using medications off-label statistically significantly higher than their surgical counterparts (M = 2.31, SD = 1.45). Other items didn't show any significant difference responses between medical and surgical specialties as shown in **Table 2.**

Table 2: Comparison between medical and surgical specialties.

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
Implementing the "Law of Practicing Healthcare Professions" in training and licensing will reduce physician liability.	-0.14	.892
The physician should be held liable for any adverse event due to off-label medication use.	144.00	< .001
The physician should disclose if the medication is used as off-label.	320.00	.581
The "Law of Practicing Healthcare Professions" needs further elaboration on off-label prescriptions.	-0.35	.726

Comparisons based on demographics

The relationships between questionnaire items and demographics (age, number of years in the panel, number of cases) were tested by correlation analysis. **Table 3** shows that age is a statistically significant variable. The older the medicolegal panel member, the more likely they were to deal with malpractice cases that occur due to lack of knowledge of the rules (r_s = 0.28).

Table 3: Correlation analysis between demographic data and questionnaire items

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
How much percentage of the cases you examine fall in the previous category?	.28*	.11	-.02
Implementing the "Law of Practicing Healthcare Professions" in training and licensing will reduce physician liability.	-.08	-.17	.18
How much reduction of physician liability do you anticipate if this type of training is implemented?	.23	.12	-.08
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

4. Discussion

Medical malpractice combined with adverse events is a major cause of morbidity and mortality worldwide. The World Health Organization (WHO) estimates that 4 in 10 patients globally are harmed during primary and outpatient care and 80% of such harm is preventable.[15] This could explain the global increase in medical litigations. In Saudi Arabia, efforts to improve patient care and safety include the establishment of the Saudi patient safety center[16], the Saudi central board for accreditation of healthcare institutions[17], and the LPHP. Improving patient safety doesn't necessarily decrease physician liability.

The LPHP was introduced in 2005 through a royal decree and has undergone minor modifications since then. Many of the articles within the LPHP are consistent with universal standards of practice such as informed consent, autonomy, and the reporting of infectious diseases. However, some articles are not universal, for example, prohibition of publishing procedures in social networks for advertising, even with the patient's consent.[10] Thus, certain provisions of the law may subject physicians to increased liability due to a lack of knowledge of the law, despite practicing the best patient safety measures. In addition, LPHP is not detailed and probably has some deficiencies which are left for the legal committees to interpret. This may increase subjectivity and lead to different verdicts among similar cases. Physician

members of the medicolegal committees in Saudi Arabia are among the most highly respected professionals in the field of medical litigations. Their observations and opinion are valued highly, especially in the absence of detailed research on malpractice lawsuits in Saudi Arabia.

Most of the surveyed medicolegal committee members (67.7%) agree that some physicians are liable only because they lack the knowledge of the rules and not because of errors in planning or executing a treatment. Between 29% and 39% of the cases are observed to be due to the lack of physician knowledge of the LPHP rules and not due to errors in the planning or execution of treatment. Respondents expect an average of 61% reduction in medical litigations after the implementation of LPHP knowledge assessment in both licensing and training. According to the MOH, 66.6% of physicians in Saudi Arabia are foreigners.[11] Given the high number of foreign physicians, the probability of foreign physicians being unaware of local laws is more likely. In general, physicians and other healthcare professionals should familiarize themselves with the laws of the country of practice. And such a percentage should only add to the importance of implementing knowledge assessment in hopes of reaching the optimal healthcare environment for both the patient and the physician. Mandating an introduction to LPHP assessment during physician training and licensing may be cost-effective by minimizing reviewing unnecessary cases and reducing physician liability. To the best of our knowledge, there are no published data demonstrating changes in medical litigations after implementing knowledge assessments of the law. We recommend more research into quantifying the cost of medical litigations due to a lack of knowledge of the policies and rules in addition to implementing knowledge assessment.

In our study, we aimed to assess off-label prescription as an example of LPHP deficiency and to illustrate the variability in responses among medicolegal committees' members, which will impact their decisions. Rates of off-label use are variable and may be affected by the specialty itself and country of practice. In a review by Bavdekar and Gogtay across Germany, the United Kingdom, Ireland, Germany, Israel, Australia, and some of the European countries, the off-label drug use varied from 10.8 to 66.0%. The magnitude of off-label use varied according to the level of health care, subspecialty, and certain patient characteristics.[18] In Saudi Arabia, few studies regarding off-label medication were published and all were related to the pediatric population. Albeit, off-label medication use was reported to be up to 30% of the patients.[13,14]

In a study including 46,021 patients who received off-label medications, 3484 experienced adverse events, demonstrating a higher rate of adverse events compared to on-label use (19.7 vs 12.5 per 100,000).[19] In our study, 38.8% of medicolegal panels members believe that physicians should be held liable for any adverse event due to off-label medication use. In the United States, the FDA and AMA state that physicians are at liberty to prescribe approved drugs for any scientifically supported use, whether on- or off-label.[20] To minimize liability, physicians should prescribe medications only for indications that they believe and can argue are in the best interest of their patients.

Most of the respondents (58.1%) agree that physicians should disclose if the medication is used off-label. However, it should be noted that such disclosure could frighten patients and lead to refusal of treatment and unforeseen consequences.[21] In the US, no court decision has mandated that a physician must disclose, through an informed consent process, the off-label use of a drug.[22] In Saudi Arabia, although it is a common practice, LPHP does not regulate its use. Another potential drawback to disclosure is that doctors would be burdened by focusing on reading more governmental materials and the approval status of each drug rather than focusing on patient care.[23] Physicians' fear of facing litigations in the event of off-label use may introduce an environment of uncertainty to physicians and possibly enforcing the practice of defensive medicine, without providing the proper "off-label" treatment. Defensive medicine will subsequently increase the cost of patient care.[21]

72.6% of respondents agreed that LPHP requires further elaboration about off-label medication use. The optimal situation in regulating off-label use of medications is to provide a legal system and policies that are practical, respect patient autonomy, provide room for scientific development and reduce physician liability. In the setting of such a high percentage agreeing that LPHP requires further elaboration on off-label use, we asked our study members to pick recommended laws that will provide more clarity. Most of the respondents recommended

that physicians should disclose that the medication is off-label (58.1%), the physician should be liable if an approved alternative is available with equal efficacy (48.4%), and physicians are liable if the indication is not scientifically supported (33.9%). On the other hand, only a few respondents stated that disclosure that the medication is off-label is not needed and physicians are not liable in such cases.

In a perfect world, all medications would have solid scientific support. However, this is not always true. Off-label use of medication is an integral part of contemporary medicine and the scientific cycle and providing space for physicians to prescribe such medications will assist in providing such an environment.[24] We recommend that policymakers and physicians introduce policies and laws that provide a culture of utmost freedom of using medications off-label and minimizing patients' safety compromises. Such a culture will hopefully propel research and innovation, maintain optimal patient care, and regulate clinical practice without increasing liability.

Moreover, we assessed the variability of responses among medicolegal members, regarding off-label prescription, using normality tests and skewness. We noticed a high variability in the responses of medicolegal panels' members. Such variability reflects the necessity of elaboration and standardization of LPHP, as deficiencies in the law will create room for subjective rulings and inequality between different lawsuits. This finding was emphasized by the fact that only 41.9% of respondents agree that the same malpractice lawsuit would result in the same verdict if it was reviewed by multiple medico-legal panels. Disagreement among professionals is common and occurs in up to 30% of physicians.[21] In a study that reviewed 20 years of medical malpractice claims, it has been suggested that providing jurors with scientific material in a comprehensible manner could improve the consistency of verdicts in malpractice cases.[25] Variability among verdicts is inevitable, but further efforts should be done to minimize it. We suggest standardizing LPHP articles, making them more comprehensive, and consulting specialists in each field to provide an expert's opinion.

5. Conclusion

We recommend further elaboration in LPHP based on the need and difficulties faced by medicolegal committees. In addition, we recommend the implementation of LPHP in training and licensing to establish higher adherence to Saudi Arabia's law. Further objective research in the field of medicolegal litigation in Saudi Arabia is needed.

Acknowledgement

The authors thank the Deanship of Scientific Research and RSSU at King Saud University for their technical support. The authors would like to extend their gratitude to the MOH represented by the secretary-general of the medicolegal committees, Malek Alshabanat for permitting the use of the data. In addition to, Abdulrahman Almusharaf and Maher Ayesh for their contribution in providing the data and approval.

Statement of Ethics

Approval to conduct this paper was obtained from the Ministry of Health. Written electronic consent was obtained from participants prior to beginning the survey.

Conflict of Interest Statement

The authors have no conflicts of interest to declare

Funding Source

No source of funding was used to conduct this paper

Author Contribution

MA: Data collection, Data analysis, Manuscript preparation and editing.

RA: Conception, Ethical Approval, Manuscript Review.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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