



A trend of Medical Negligence in Laser Therapy in the Capital City: A Nine-Year Survey

Somayeh Jahani- Sherafat¹, Zahra Razzaghi¹, Seyed Amirhossein Mahdavi², Mehdi Forouzesh², Mohammad Ali Emam Hadi³, Mohammad Rostami-Nejad⁴, Mostafa Rezaei Tavirani⁵, Mohammadreza Razzaghi^{1*}

¹Laser Application in Medical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran

²Legal Medicine Research Center, Iranian Legal Medicine Organization, Tehran, Iran

³Department of Forensic Medicine, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

⁴Gastroenterology and Liver Diseases Research Center, Research Institute for Gastroenterology and Liver Diseases, Shahid Beheshti University of Medical Sciences, Tehran, Iran

⁵Proteomics Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran

*Correspondence to

Mohammadreza Razzaghi, Laser Application in Medical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.
Email: morazzaghi@gmail.com

Received: March 16, 2022

Accepted: June 11, 2022

Published online July 2, 2022



Abstract

Introduction: The purpose of the present study is to investigate the common causes of injuries, claims, and decisions related to laser therapy medical malpractice during a nine-year survey.

Methods: The legal documents in the Coroner's Office of Forensic Medicine were investigated in a national database from 2012 to 2020 in Tehran, Iran. The frequency and nature of the cases, including the year of litigation, the location and certificate of the provider, the injury sustained, and the cause of legal action and judgment were collected.

Results: Three hundred and eighty-three cases related to injury from laser therapy were registered in the coroner's Office of Forensic Medicine during the study period. The incidence of litigation related to laser surgery showed an increasing trend, with a peak occurrence in 2020. Laser hair removal was the most common (51.2%) litigated procedure. General practice operators (48%) recorded the highest rate of laser-related medical complaints. Lack of skill was the most common reason for failure. Among 383 cases with public decisions, 62.4% of them were fault liability in paid judgment.

Conclusion: Medical claims related to laser application are increasing. However, as it is clear, the growth of laser technology and the increasing demand for lasers in medical science require more surveillance to avoid probable injuries and improve patient safety, especially surveillance of the physicians who work outside the scope of their specialty.

Keywords: Malpractice; Laser therapy; Forensic medicine.

Introduction

Medical malpractice is a serious problem in any healthcare system and causes physical and mental harm and a financial burden on patients.¹ Despite the variation of medical litigation systems in different countries, there are the same standards for the health care providers.² Four elements, including responsibility, Violation of responsibility, causation, and harm, have been considered for the description and survey of medical negligence.³ According to these four elements, medical malpractice occurs when the physician or a member of the healthcare system takes responsibility for treating the patient, but the function does not accord with the standard methods.⁴ Studies have shown that the rate of patients' legal complaints in the world has been rising recently.⁵ This steady rise has several reasons, including population increase, people's awareness of their rights, complex technologies used in medicine, lack of proper justification for possible side effects of remedies, patients' increased expectations of treatment outcomes, lack of

disciplinary actions, and so on.^{4,6,7}

Today, laser devices ('Laser' is the abbreviation of Light Amplification by Stimulated Emission Radiation) have brought about a revolution in health care systems and are an integral part of medicine.⁸ Laser surgery has increased enormously with regard to various applications in medical or paramedical procedures in the past 2 decades, including general surgeries (e.g. gynecology, urology, and neurosurgery), dentistry, orthopedics, and dermatology in particular.⁹ Because of more attention to beauty and aesthetics in the world, the use of lasers has increased rapidly in the cosmetic industry.¹⁰ Furthermore, depilation by lasers is the most popular method in dermatology and aesthetics; removal of pigmented lesions, tattoo removal, treatment of vascular lesions, and facial rejuvenation are also common among several other programs in dermatology.¹¹

One of the advantages of laser application in surgeries is minimal damage to tissues, resulting in diminishing blood loss, pain, and wound infection and achieving

better ulcer healing.¹² However, laser surgeries are not risk-free for human health.

Although there are strict controls on the manufacturing and licensing of laser devices, there is a lack of comprehensive surveillance of laser operators' training, physicians' supervision, and the place where laser services are provided, to improve patient safety.¹³

Therefore, given the increasing use of laser technology in medicine, a lack of surveillance, and a rising incidence of medical errors, related complaints in laser surgeries are expected. In addition, medical malpractice in laser service recipients and consequently indemnity payments will increase. Identification and analysis of common risk factors and errors could aid to prevent an increase in laser-related malpractice injuries.

In Iran, medical malpractice complaints are referred to the coroner's Office of Forensic Medicine, in which the patients' complaints are checked and a decision about negligence or innocence and financial penalties are made. Given this, the aim of this study was to investigate the laser-related medical malpractice data referred to the coroner's Office of Forensic Medicine in Tehran between 2012 and 2020 in Tehran, Iran.

Materials and Methods

Data Extraction

In this retrospective descriptive study, we readopted the legal documents in the coroner's Office of Forensic Medicine in Tehran by using the keyword 'laser' from 2012 to 2020. Documents within this office are registered and include legal cases, jury judgship and summaries, and court documents. Concerning ethical criteria, no names including the name of the plaintiff, doctor or medical center were included in the questionnaire survey.

Data Synthesis

This search identified 383 cases concerning injuries resulting from laser surgery. All forensic complaint cases that had used laser technology in the treatment process from 2012 to 2020 were included in this study. Duplicate

files and files registered before 2012 were excluded from the study.

Laser-medical litigation files were surveyed and analyzed in terms of the year of action, the location, provider's demographic data including degrees or certificates, as well as subspecialty practice, the nature of the procedure including alleged injuries sustained, the cause of action, the verdict, and indemnity payments.

The data were analyzed by descriptive statistics, using IBM SPSS Statistics software version 24.

Results

The mean age of the plaintiffs was 37.3 ± 13.07 years and 70% of them were female. Out of 383 investigated cases, 204 (53.3 %) underwent laser therapy in private clinics, 32 (8.4%) in public hospitals, 110 (28.7%) in offices, 34 (8.9%) in private hospitals, and 3 (0.8%) in beauty salons. 228 laser treatment procedures that led to complaints were performed by male operators (59.5%) (physician and non-physician operators).

Figure 1 shows the increasing trend of complaints over the given period. The highest complaints occurred in 2020 (22.19%). The dermatologic complaints were the first reason for legal malpractice complaints each year. Subsequently, ophthalmologic complaints were more prevalent each year. Although there are strict controls on the manufacturing and licensing of laser devices, there is a lack of comprehensive surveillance of laser operators' training, physicians' supervision, and the place where laser services are provided, to improve patient safety.

Table 1 shows the specialties of the operators or supervisors of laser treatment separately for skin treatment. The most common complaint of laser surgery was related to 274 cases (71.5%) in dermatology, which are listed separately from other treatments in Table 2.

The injuries and the reason for complaining about the laser treatment procedure in these people are shown in Table 3.

The vote of two hundred and 46 (64.2%) cases of 383 medical malpractice files was a failure and led to paid

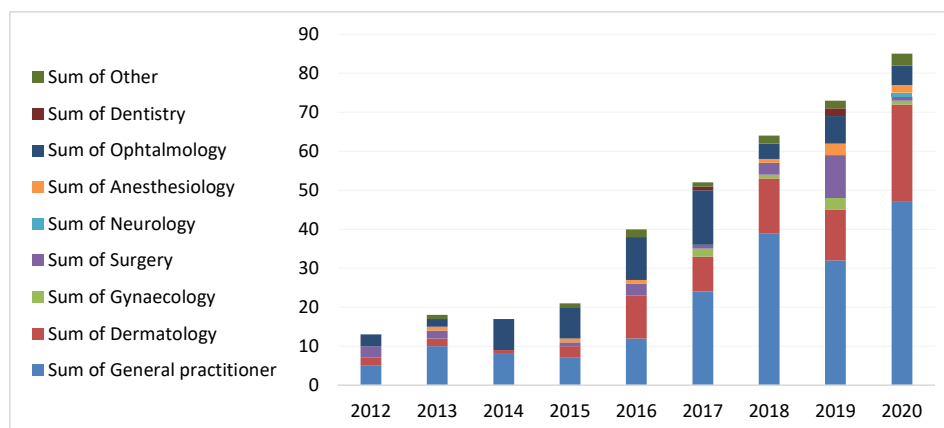


Figure 1. Distribution of Cases by Frequency in Each Year and Medical Field.

Table 1. Subspecialty Certificates of Laser Operators and Supervisors by Skin Treatment Scope

Physician Subspecialty	Total Complaints No. (%)	Complaints in Laser Skin Treatment Scope No. (% in Each Scope)
General practitioners	183 (47.8)	184 (67.15)
Ophthalmologists	62 (16.2)	0 (0)
Dermatologists	53 (13.8)	53 (19.3)
General surgeons	25 (6.5)	2 (0.72)
Obstetrics and gynecologists	9 (2.3)	4 (1.45)
Anesthetists	9 (2.3)	-
Dentists	3 (1.05)	2 (0.72)
Urologists	1 (0.3)	-
Neurologists	1 (0.3)	-
other	11 (2.8)	3 (1.1)
Non-physicians	26 (6.7)	26 (9.5)
Total	383 (100)	274 (100)

Table 2. Laser Procedures Performed in Forensic lawsuits

Procedures	No. (%)
Hair removal	196 (51.2)
Pigment disorder	24 (6.3)
Scar	15 (3.9)
Lipolysis	15 (3.9)
Rejuvenation	13 (3.4)
Tattoo removal	12 (3.1)
Vascular	4 (1.1)
Eye disorder*	63 (16.4)
Related to pain**	18 (4.7)
Hemorrhoid	8 (2.1)
Other	15 (3.9)
Total	383 (100)

*The legal complaints related to the application of lasers in eye surgery include cataracts, laser in situ keratomileusis (LASIK), intraocular lens implants, etc.

**The legal complaints related to the application of lasers in pain were in discopathy, cord spinal pain, etc.

Table 3. Injuries Sustained by the Laser Therapy Procedure

Injury	No. (%)
Burns	112 (29.2)
Burns and pigmentation	57 (14.9)
Burns and scars	38 (9.9)
Pigmentation	40 (10.4)
Ulcerations	2 (0.5)
Erythema	1 (0.3)
Diminished quality of life	4 (1)
Eye and vision problems	60 (15.7)
Physical suffering	16 (4.2)
Emotional distress	11 (2.9)
Infection	8 (2.1)
Death	4 (1)
other	30 (7.8)

indemnity, and 128 (33.4%) cases were innocence. Nine (2.3%) forensic cases had been closed without any vote during the present investigation.

The mean of failure in dermatological treatment showed a high rate with 74.45% (204/274 dermatology files), but in other fields, it showed a lower percentage; for example, ophthalmologic legal failure included just 22.6 % (14/62 ophthalmology files) of the legal failure of the files.

In dermatology scope, 67.15% of the failure votes were done by general practitioners, 19.3% by dermatologists, and 13.55% by other physicians with unrelated disciplines (Table 1).

In the failure vote, lack of skill 153(62.2%) was the highest reason of legal causes of action proven to be medical malpractice, and after that, negligence 29(11.8%) and improper treatment 64 (26%), respectively.

Discussion

In this study, we investigated the distribution and frequency of medical malpractice related to laser application in Tehran, Iran, between 2012 and 2020.

During this period, the Legal Medicine Organization and Medical Council in Tehran received 383 laser-related litigations. The distribution of cases by frequency showed growing annual increases. Other studies showed a growing trend of complaints about laser-related litigation, especially in the field of dermatology and the cosmetic industry.¹³ Although laser technology and laser applications have made significant progress in medical sciences during the last decade, it can be considered that laser complaints have increased in accordance with total forensic complaints in the world.^{10,14} Growth of patients' awareness of their legal rights, no necessity for licenses, no actual supervision of laser service centers, and untrained operators could be the additional motives for increasing complaints.^{13,15,16}

Consistent with previous studies, more than 90% of legal claims were made in private centers (including offices, clinics, and hospitals). Several studies showed that private medical centers have higher medical malpractice in comparison with the public health system.^{2,15} Ong et al compared legal claims in dermatological practice in the National Health Service (NHS) and private centers in England and reported that the highest percentage of legal claims (34%) in private centers belonged to laser treatment, whereas just 7% of legal claims in the NHS were related to laser therapy. This result could be explained by several considerations such as accurate supervisory coordination in the national health system, the higher rate of laser application in private clinics, especially in aesthetic dermatology procedures, and lack of accurate monitoring of operators and laser devices by specialist supervisors.^{2,15} Although this must be considered, therapeutic process charges in private centers are higher

than those in national health systems; therefore, the level of expectations and demands in patients is higher than that in the NHS.

One of the considerable findings in the present study is about service providers. In this regard, general practitioners received the highest percentage of medical malpractice claims, and dermatologists, non-physicians, and general surgeons are in the next ranks (Table 1). During the last decade, litigation against practice physicians performing cutaneous laser procedures has shown intense growth, especially in private health centers.¹⁷ It seems this negligence is due to financial gain and has significant implications for the safety of patients undergoing laser therapy. Therefore, more disciplinary actions and supervision are essential for private clinics in the cosmetic and skin care scope of laser therapy.

The mean age of legal claimants in the present study was 37.3 years, but studies have shown elderly patients have higher legal claims in comparison with young people.¹⁸⁻²⁰ This difference could be because of applicants for laser therapy. The highest medical malpractice claims in this investigation belonged to dermatology and cosmetic services, and the young and middle-aged women demanded dermatological laser therapy; therefore, the mean age was less than total claims in medical malpractice, although the mean age in ophthalmology was higher than that in other fields, and these differences refer to the target group in any medical specialty.

This study is compatible with previous studies, and it demonstrated that the hair removal laser was the major reason for laser-related legal claims.^{13,15} There has been explosive growth in the application of hair removal lasers since Theodore Maiman developed lasers for destroying hair follicles in 1960.²¹ Now laser hair removal is the most commonly performed laser technique in the world.²² The highest demand for laser hair removal has been from young females, and consequently, the highest complications in the laser technique have been shown in this group.²³ The common side effects after laser hair removal are superficial burns, pigmentary changes, and scars.^{24,25} These complications have usually been caused by untrained operators.²³ Most laser hair removal complications are preventable if physicians know the skin-related side effects of procedures to correctly treat patients and justify them for necessary care after laser therapy. This point should be considered that laser application to hair removal is a fast, safe, and effective treatment if it is carried out by a physician who knows the type of skin, probable skin-related side effects, and laser applications.²⁶

The death case is another noticeable point in the current study. The causes of death for three cases who died in this investigation have been associated with negligence in mole removal by a laser. Mole removal without attention to features and appearance of moles

and possibly additional tests and pathologic examination (malignance/benign) may cause a delay in malignancy diagnosis and treatment, leading to patients' death. Malignant moles are serious diseases, and the delay in diagnosis makes a bad prognosis. Early detection and treatment are vital for patients' survival.²⁷ The ophthalmology legal claim has the second rate (16.2%) of legal malpractice claims after the dermatology legal claim in the current study. Laser advances in ophthalmology are one of the most important medical applications of lasers in medical science.²⁸ Ophthalmology legal claims are common cases of medico-legal complaints because of their straight effects on a patient's lifestyle.²⁹ Lasers in ophthalmology have several applications such as laser vision surgery or LASIK [for the correction of nearsightedness, farsightedness, or astigmatism], cataract surgery, intraocular lens exchange, trabeculoplasty, and so on.³⁰⁻³² LASIK and cataract surgery are the first causes of ophthalmology legal claims in the present study. As the results showed, only 22.6% of the legal claims in the ophthalmology section were in favor of the plaintiffs and the acquitted.

In this survey, 9 (2.3%) of the laser-related medical claims are about anesthesiology. Anesthesiologists in this study used laser devices to reduce pain in the spinal cord. Nevertheless, their activities caused a delay in necessary surgery, leading to consequent injuries because of a delay in treatment. Accordingly, a large number of complaints are avoidable with correct examination and sufficient explanation about side effects, real results, and complications after surgery.³³

Conclusion

Lack of skill and improper treatment are the two important reasons for laser-related legal claims. Experience and knowledge of the technical aspects of laser devices are essential factors in the application of lasers in medical science, so training fluent operators and monitoring their performance are vital for utilizing lasers in medicine. One of the important causes of medical claims refers to no justification and perfect interaction between physicians and patients. Raising expectations in the use of laser devices can be one of the reasons for patients' dissatisfaction and complaints. Physicians should explain the risk of probabilistic subsequent complications and possible benefits, understand patients' concerns about the application of lasers, and manage patient expectations about the treatment before each decision.

Limitations of the Study

Our study has several limitations. The investigation into patient claims was conducted within a single city. However, we consider that laser therapy complications are comparable in other cities in Iran. Some of the claims were missing in the present investigation, and the non-

medical centers like beauty salons and gyms did not have any licenses for laser surgery and salons. Therefore, cosmetology operators are not available and responsible, and their legal claims were not registered in the coroner's Office of Forensic Medicine completely.

Acknowledgements

The authors wish to thank Dr. Ladan Jafarnejad, the Head of the coroner's Office of Forensic Medicine in Tehran, for her cooperation.

Conflict of Interests

The authors declared no conflict of interest.

Ethical Considerations

The current study was approved by the local Ethics Committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RETECH.REC.1399.1377). To consider the ethical issue, the collected data were not revealed to anyone except for the researchers; hence, patients' names were kept confidential.

Funding

The current study was financially supported by the Laser Application in Medical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran.

References

- Panagiotti M, Khan K, Keers RN, Abuzour A, Phipps D, Kontopantelis E, et al. Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. *bmj*. 2019;366. doi:10.1136/bmj.l4185
- Harbitz MB, Stensland PS, Abelsen B. Medical malpractice in Norway: frequency and distribution of disciplinary actions for medical doctors 2011–2018. *BMC Health Serv Res*. 2021;21(1):1-9. doi:10.1186/s12913-021-06334-2
- Goldberg DJ. Legal issues in laser operation. *Clinics in dermatology*. 2006;24(1):56-9.
- Raeissi P, Taheri Mirghaed M, Sepehrihan R, Afshari M, Rajabi MR. Medical malpractice in Iran: A systematic review. *Med J Islam Repub Iran*. 2019;33:110. doi: 10.34171/mjiri.33.110.
- van Dael J, Reader TW, Gillespie A, Neves AL, Darzi A, Mayer EK. Learning from complaints in healthcare: a realist review of academic literature, policy evidence and front-line insights. *BMJ Qual Saf*. 2020;29(8):684-695. doi:10.1136/bmjqs-2019-009704.
- Khara A. Descriptive Analysis of Medical Malpractice Complaints from General Surgeons in Tehran 2012–2013; a Short Report. *J Police Med*. 2016;5(1):1-6.
- Pandit MS, Pandit S. Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective. *Indian J Urol*. 2009;25(3):372-378. doi:10.4103/0970-1591.56206.
- Stylianou A, Talias MA. The 'Magic Light': A Discussion on Laser Ethics. *Sci Eng Ethics*. 2015;21(4):979-98. doi: 10.1007/s11948-014-9566-4.
- Lin J-T. Progress of medical lasers: fundamentals and applications. *Med Devices Diagn Eng*. 2016;2(10.15761).
- Gianfaldoni S, Tchernev G, Wollina U, et al. An Overview of Laser in Dermatology: The Past, the Present and ... the Future (?). *Open Access Maced J Med Sci*. 2017;5(4):526-530. doi:10.3889/oamjms.2017.130.
- Tanzi EL, Lupton JR, Alster TS. Lasers in dermatology: four decades of progress. *J Am Acad Dermatol*. 2003;49(1):1-31; quiz 31-4. doi: 10.1067/mjd.2003.582.
- Khalkhal E, Rezaei-Tavirani M, Zali MR, Akbari Z. The Evaluation of Laser Application in Surgery: A Review Article. *J Lasers Med Sci*. 2019;10(Suppl 1):S104-S111. doi: 10.15171/jlms.2019.S18.
- Jalian HR, Jalian CA, Avram MM. Common causes of injury and legal action in laser surgery. *JAMA Dermatol*. 2013;149(2):188-93. doi: 10.1001/jamadermatol.2013.1384.
- Bonetti M, Cirillo P, Musile Tanzi P, Trincherio E. An Analysis of the Number of Medical Malpractice Claims and Their Amounts. *PLoS One*. 2016;11(4):e0153362. doi: 10.1371/journal.pone.0153362.
- Ong S, Coulson IH. Legal claims in English dermatological practice. *Br J Dermatol*. 2011;164(1):217-9. doi: 10.1111/j.1365-2133.2010.10047.x.
- Svider PF, Carron MA, Zuliani GF, Eloy JA, Setzen M, Folbe AJ. Lasers and losers in the eyes of the law: liability for head and neck procedures. *JAMA Facial Plast Surg*. 2014;16(4):277-83. doi: 10.1001/jamafacial.2014.21.
- Jalian HR, Jalian CA, Avram MM. Increased risk of litigation associated with laser surgery by nonphysician operators. *JAMA Dermatol*. 2014 Apr;150(4):407-11. doi: 10.1001/jamadermatol.2013.7117.
- Caspard H, Chan AK, Walker AM. Compliance with a statin treatment in a usual-care setting: retrospective database analysis over 3 years after treatment initiation in health maintenance organization enrollees with dyslipidemia. *Clin Ther*. 2005;27(10):1639-46. doi: 10.1016/j.clinthera.2005.10.005.
- Lacasse Y, Archibald H, Ernst P, Boulet LP. Patterns and determinants of compliance with inhaled steroids in adults with asthma. *Can Respir J*. 2005;12(4):211-7. doi: 10.1155/2005/375454.
- Jin J, Sklar GE, Min Sen Oh V, Chuen Li S. Factors affecting therapeutic compliance: A review from the patient's perspective. *Ther Clin Risk Manag*. 2008;4(1):269-286. doi:10.2147/tcrm.s1458
- Alster TS. *Manual of cutaneous laser techniques*: Lippincott Williams & Wilkins; 2000.
- Surgery ASfAP. 15th Annual Cosmetic Surgery National Data Bank Statistics. American Society for Aesthetic Plastic Surgery New York; 2011.
- Vano-Galvan S, Jaen P. Complications of nonphysician-supervised laser hair removal: case report and literature review. *Can Fam Physician*. 2009;55(1):50-52.
- Patil UA, Dharmi LD. Overview of lasers. *Indian J Plast Surg*. 2008;41(Suppl):S101-S113.
- Lovgren ML, McCrae L, Drummond A. Legal claims in Scottish National Health Service dermatology departments, 2002-2013. *Clin Exp Dermatol*. 2016;41(4):436-7. doi: 10.1111/ced.12789.
- Goldberg DJ. Hair Removal. Lasers and Non-surgical Rejuvenation. 2009:69.
- Cummins DL, Cummins JM, Pantle H, Silverman MA, Leonard AL, Chanmugam A. Cutaneous malignant melanoma. *Mayo Clin Proc*. 2006;81(4):500-7. doi: 10.4065/81.4.500.
- Cordero I. Understanding and safely using ophthalmic lasers. *Community Eye Health*. 2015;28(92):76-77.
- Saha R, Kabanovski A, Klejman S, Margolin E, Buys YM. Patients' complaints involving ophthalmologists in the province of Ontario, Canada: a 5-year review. *Can J Ophthalmol*. 2020;55(3 Suppl 1):22-26. doi: 10.1016/j.jcjo.2019.08.007.
- Song J. Complications of selective laser trabeculoplasty: a review. *Clin Ophthalmol*. 2016;10:137-143. Published 2016 Jan 14. doi:10.2147/OPHTH.S84996.
- Sugar A, Rapuano CJ, Culbertson WW, Huang D, Varley GA,

- Agapitos PJ, de Luise VP, Koch DD. Laser in situ keratomileusis for myopia and astigmatism: safety and efficacy: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2002;109(1):175-87. doi: 10.1016/s0161-6420(01)00966-6.
32. Radhakrishnan S, Chen PP, Junk AK, Nouri-Mahdavi K, Chen TC. Laser Peripheral Iridotomy in Primary Angle Closure: A Report by the American Academy of Ophthalmology. *Ophthalmology*. 2018;125(7):1110-1120. doi: 10.1016/j.ophtha.2018.01.015.
33. Nuwagaba J, Olum R, Bananyiza A, Wekha G, Rutayisire M, Agaba KK, et al. Patients' Involvement in Decision-Making During Healthcare in a Developing Country: A Cross-Sectional Study. *Patient Prefer Adherence*. 2021;15:1133-1140. doi: 10.2147/PPA.S302784.