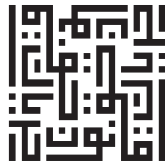


Executive Summary

Development of a Comprehensive Legal System for Investigation of Medical Errors

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Executive Summary

Development of a Comprehensive Legal System for Investigation of Medical Errors

It is equally important for doctors and health professionals to investigate the causes of medical errors as it is for the patients affected and their families. A serious and exhaustive investigation of a medical error is vital for patients to re-assure them that those who have caused harm will be subjected to proper legal accountability.

A number of legal procedures currently exist for the investigation of medical errors, and there is consensus that such cases must be investigated vigorously and those responsible held accountable. This consensus on the accountability of medical staff needs to be reflected in the relevant legal procedures established by the state, and via procedures that conform to the standards for a fair trial stipulated in international law and in the Palestinian National Authority (PNA) Basic Law of 2002. The fundamental principle that all are equal before the law must also be taken into account; this includes equality between the two parties in accountability for medical errors.

If the PNA is to demonstrate respect for and commitment to human rights, particularly the right to health, and hold those who violate this right accountable, it must ensure that all citizens have equal rights and duties as stipulated in the relevant laws, regulations and procedures and that penalties are imposed on them in a just manner. Equality cannot be achieved as long as different laws are applicable to health professionals in the West Bank compared with the Gaza Strip, and also between private and public health workers.

Many countries apply different laws relating to criminal or civil accountability. For example, Palestine has the Palestinian Penal Procedures Law (2001) and the Palestinian Civil and Commercial Trials Assets Law (2001). However, the lack of clear disciplinary procedures for accountability for many health professionals, especially those working in the private sector, makes it necessary to consider the enactment of a law on procedures for administrative trials in cases involving medical errors.

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Several items of national legislation were reviewed as part of this report, particularly the PNA Basic Law of 2002 and its amendments; the Palestinian Law of Public Health No 20 of 2004; the Palestinian Civil Service Law No 4 of 1998 and its amendments; and the Palestinian Civil Service Law executive by-laws of 2005 with amendments. Other legislation reviewed included the Jordanian laws that remain in effect in the West Bank, such as the Jordanian Doctors' Syndicate Law No 14 of 1954 and its amendments; the Jordanian Dentists' Syndicate Law No 11 of 1956 and its amendments; the Jordanian Pharmacists' Syndicate Law No 10 of 1957 with its amendments; and the Palestinian Cabinet's Law of Complaint Regulations No 6 of 2009. Also of relevance are the British Mandate laws that are still in effect in the Gaza Strip, such as the British Mandate Doctors' Law No 58 of 1947, Section 110 of the British Mandate Pharmacists' Law (1921) with its amendments, and the British Mandate Dentists' Law No 1 (1945) with its amendments.

Relevant legislation in the Arab world was also reviewed: The Emirates Federal Law No 10 (2008) on medical liability with its bylaws; the Saudi Health Practitioners Law (1426 H.) together with its bylaws (1427 H.); the Libyan Law No 17 (1986) on medical liability; the Libyan Civil Service Law No 55 (1976) with its amendments; the Iraqi Civil Servants Discipline Law (1991) with its amendments; draft Jordanian laws on medical liability (2009 and 2010); and the Egyptian Draft Law on Medical Liability (2011).

The report with its important annexes aims to open discussion on the administrative investigation of medical errors with the purpose of devising fair optimal strategies to be pursued with all groups of health professionals involved in any stage of the delivery of medical treatment to the patient.

The report also aims to promote the implementation of both official and unofficial steps that will result in more effective procedures when investigating cases of medical error in which more than one party has been involved in health service delivery: the doctor, pharmacist, nurse, laboratory, medical equipment. This would eliminate the need to wait for the enactment of a comprehensive law on medical liability that would include the formation of a technical committee to investigate cases of medical error and compensation mechanisms.

The report consists of two topics: The first is dedicated to discussion of national and Arab legal frameworks for investigating medical errors. The Palestinian legal system lacks a single common legal mechanism to govern the work undertaken by committees investigating medical errors. The procedures adopted in the public health sector differ from those adopted by the private health sector. Furthermore, the non-governmental and private health sectors in the West Bank and Gaza Strip also adopt different procedures. These differences are the result

of the diverse legal systems governing the health sector. Although the PNA has adopted legislation and policies to develop and consolidate legislation applicable to the health sector, its efforts have fallen short of holding health professionals found to have been negligent in the performance of their duties administratively accountable.

The review is based on six themes covering the legal framework for national legislation to hold health professionals administratively accountable in light of relevant experiences in the Arab world. The first theme, the general framework, addresses topics related to the legal form of provisions for administrative investigations of medical errors and the principle of confidentiality. The second theme addresses disciplinary penalties. The third theme tackles the organizational framework of the committee tasked with investigating medical errors, including its formation, terms of reference, the qualifications of committee members, how committee investigations are recorded and the response of the committee chairman or member(s). The fourth theme outlines the committee's operational procedures: the method of submitting complaints, procedures for investigating medical errors administratively and the cross-examination of witnesses before the committee. The fifth theme addresses appeals against the decisions of the investigation committee or disciplinary council. The sixth theme covers the final provisions for a legal system, such as financial recompense for committee members and the implementation of the disciplinary council's decisions by the Ministry and the public prosecution.

In light of the long-term goal to enact a law on medical liability, the second topic addressed is the aspirations for a Palestinian legal system applicable to cases of medical error. Official and unofficial authorities need to work together to realize this goal. Reference is made to models that could be adopted by Palestine to develop its legal system in this area based on relevant experiences in the Arab world.

The study outlines the existing legal procedures to investigate medical errors and describes the recommendations proposed by the committee in the 2012 report on medical errors, particularly the workshop held by the Coalition for Accountability and Integrity (AMAN) in May 2013 on accountability in such cases. The study presents relevant approaches, including the institutionalization of the work undertaken by investigation committees, the formation of the committees, operational procedures, reporting lines and preparation in a manner that ensures impartiality, competence and effectiveness. The study emphasizes the need for compulsory insurance against medical errors and the establishment of a compensation fund that would offer a fundamental guarantee of compensation for patients subjected to medical errors that are not the result of error, oversight or negligence by medical staff. It highlights the need to adopt an inte-

grated system to document medical errors committed in the healthcare sector, whether under the control of the Health Ministry or the Doctors' Syndicate, with the purpose of taking into account lessons learned. It also highlights the need for intervention to ensure that relevant legislation is updated to define medical errors and identify channels of accountability, committees, and work mechanisms and procedures. The study advocates compulsory medical error insurance and discusses possible alternative methods of resolving conflicts arising from medical errors, such as amicable settlement.

The study notes the proposals submitted by AMAN on the possibility of taking advantage of Article 83 of the Palestinian Law of Public Health No 20 of 2004. This authorizes the competent authorities to approve an executive by-law that would define the work of the medical error investigation committee. The proposal ensures that the Health Ministry would retain its political role as the primary party responsible for the realization of the right to health in the PNA territories, while maintaining the professional role of the Doctors' Syndicate on the following basis:

- *A group of 50 Palestinian doctors shall be selected every three or four years as experts to form the nucleus of the medical error investigation committees.*
- *The group of experts shall be selected by the Minister of Health based on consultation between the Health Ministry and the Doctors' Syndicate. The selection of the experts should be on the basis of half of their number from the public sector and the other half from the private sector. They should have a proven track record of experience (a number of years in their field of specialization, for example).*
- *A Board of Directors shall be formed for the group of experts as follows: the Health Minister or Deputy Minister shall be appointed as the Chairman; the President or Deputy President of the Doctors' Syndicate as Deputy Chairman; and five members of the Board of Directors shall be selected from the group of experts for a term of two years.*
- *The Board of Directors shall have a secretariat in any or both of the Health Ministry and the Doctors' Syndicate. The secretariat shall be tasked with organizing the administrative work to be undertaken by the Board of Directors, receipt of complaints from patients and documenting medical errors in accordance with due process.*
- *The secretariat shall submit complaints to the Board of Directors, which will decide whether to accept or reject them.*
- *If a complaint is accepted, the Board of Directors shall select three doctors*

from the group of experts to form an investigation committee. The committee members shall be nominated based on the nature of the complaint and the position of the person against whom the complaint has been submitted; the committee's chairperson shall be determined by a decision of the Board of Directors.

- *The investigation committee shall submit its reports and recommendations to the Board of Directors, which has the power to take the decision it deems fit.*
- *If the Board of Directors decides that a medical error has been committed, the patient shall be entitled to obtain compensation from the Medical Errors Fund, to be established under legislation that determines the fund's management, expenses and revenues. The fund's revenues may be generated from financial contributions by doctors and the Health Ministry, as well as from contributions made by private hospitals on behalf of their health professionals. Pending the establishment of the fund, compulsory insurance shall be introduced as a guarantee of compensation for patients.*

The committee pointed out that, in order to realize these proposals, Palestine must catch up with the experiences of various Arab and foreign states in enacting independent laws for accountability for medical errors. That step is currently hampered by a dysfunctional Legislative Council incapable of debating and approving draft laws on medical liability, particularly the formation of medical error investigation committees and the provision of civil compensation for damages suffered by patients due to medical errors. Nevertheless, it is not acceptable that we fail to devise the solutions necessary to reduce cases of death and disability that still occur at private and public hospitals, in particular by pursuing pertinent and vital legislative procedures. Pending the enactment of an independent law on medical liability that would address all the relevant issues, we propose the following:

A: Medical error investigation committees

- A special system should be put in place for medical error investigation committees. The system should provide for selection procedures for these committees and their operational protocols based on the details outlined in the AMAN proposal. Article 83 of the Palestinian Law of Public Health makes it contingent on the cabinet to enact the procedures and executive by-laws necessary for the law to be implemented. These by-laws should include provisions on how to deal with complaints lodged by citizens under Article 60 of the Palestinian Law on Public Health, which grants patients the right to lodge a complaint against a health institution or health professional.

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- The group of experts proposed by AMAN should be composed of experts from diverse medical and health sectors, including pharmacists, dentists, anesthesiologists, nurses, lab technicians and other health professionals, as stipulated in Article 1 of the Palestinian Law of Public Health. It should also include administrative officers from various health institutions.
- Sound legal and constitutional parameters should be observed in the establishment or abolition of public institutions to reduce the negative consequences to an individual's right to an optimal level of health services. This factor is especially important in view of the fact that AMAN's proposal calls for the formation of a Board of Directors for the group of experts, and a Board of Directors can only be formed if the expert group is a legal entity. According to the constitutional text of Article 69 of the PNA Basic Law, the establishment or abolition of public institutions falls within the sphere of the cabinet's powers.

B: Insurance

For the investigation committee to investigate medical errors successfully as proposed, the issue of insurance against liability resulting from medical errors needs to be addressed.

1. The Palestinian Insurance Law No 20 of 2005

Although the Palestinian Insurance Law No 20 of 2005 lacks any legal provisions making medical error insurance compulsory, it does provide a relevant set of provisions. Pending the enactment of an independent law on medical liability that would include insurance, these provisions should be examined to assess to what extent they could be relied on to impose compulsory insurance for civil liability against the risk of medical errors. The text reads as follows:

- Article 3 of this law provides: “(1) Insurance shall involve the following categories . . . F- Insurance against accidents and civil liability, insurance against occupational risks, and J- other insurances.” It also provides: “(2) The cabinet shall issue the regulations necessary to address other categories of insurance” This implies that the cabinet is authorized by law to draw up the regulations for other forms of insurance such as civil liability insurance resulting from medical errors.
- Article 6 of the law provides: “The authority (Palestine Capital Market Authority) may exercise the following powers following the decision of the Board of Directors: . . . (7) The necessary regulations or by-laws shall be de-

vised for the imposition and definition of the general terms and provisions of compulsory insurance against specific risks, and its conditions, general provisions and limits of liability shall be determined." This means that the Palestine Capital Market Authority is authorized by law to draft statutes and regulations for the imposition of compulsory insurance against specific risks, including the risk of civil liability arising from medical errors, for approval by the cabinet as provided for in Article 3.

- Article 42 of this law provides: "The insurer shall be liable for the losses and damages caused by persons for whom the insured bears civil liability regardless of the nature and gravity of the errors committed by such persons. The insurer should also be liable for losses and damages caused by objects and animals kept by the insured." This article clarifies the nature of insurer-insured relations in regard to liability for losses caused by risks that are the subject of insurance.

C: Palestinian Law of Public Health No 20 of 2004

Pending the enactment of a law on medical liability, amendments may be required to articles in the Palestinian Law of Public Health of 2004 relating to the licensing of non-governmental health institutions and to make medical liability insurance a compulsory condition for licensing non-governmental hospitals and health institutions.

In conclusion, the study noted that patients could not be protected against medical errors that put their lives at risk unless they have access to forms of compensation that ensure that those who cause harm are punished via administrative, criminal and civil procedures and the damages sustained by patients are redressed.

To ensure that procedures for investigating medical errors in the Palestinian Territory are applied uniformly and fairly to all health professionals, whether employed in the private or non-governmental health sectors in the West Bank or Gaza Strip, the authorities need to establish an appropriate legal framework with comprehensive, uniform and written operational procedures for the investigation of medical errors across all sectors. Relevant Palestinian legislation, particularly the Palestinian Law of Public Health, the Law of Insurance, the Penal Procedures Code and the Palestinian Civil and Commercial Court Law, must be taken into account as vital keys in the formulation of a system to investigate medical errors.

Within certain limitations, it is crucial that the findings of administrative and pe-

nal investigations into medical errors are published in the media as a public deterrent in the form of an administrative penalty. This would contribute to improving the quality of health services provided to all people and would increase public confidence in the health sector. It would also ensure uniformity between the various public, private and non-governmental health sectors in terms of administrative penalties, the procedures for investigating medical errors and the bodies selected for this purpose.

Pending the enactment of a comprehensive law for the investigation of medical errors in the State of Palestine, all official authorities must take substantial and convincing steps towards holding health professionals accountable for the medical errors they commit. In addition, relevant legislative provisions, particularly those in the Palestinian Law of Public Health and the Law of Insurance, must be put into effect.

In conclusion, the report includes five annexes. Annex one addresses the Saudi Health Professions Practice System issued in Decree No 59 of 2011. Annex two addresses the amended Iraqi Civil Servants Discipline Law No 14 (1991). Annex three presents a list of non-governmental and official institutions that provide assistance to victims of medical errors. Annex four outlines articles related to the compensation fund for survivors of traffic accidents provided in the Palestinian Law of Insurance No 20 of 2005. Annex five presents the invitation made by AMAN for participation in a workshop on the formation of committees tasked with investigating medical errors and the draft recommendations proposed in that workshop.