ORIGINAL ARTICLES



Medico-legal aspects of pathology – current dilemmas regarding confidentiality and disclosure

Mahomed A Dada, David J McQuoid-Mason

This article deals with confidentiality and disclosure in the practice of pathology in South Africa. The recent bringing into force of the National Health Act¹ and the proposed implementation of the *International Classification of Diseases* (*ICD-10*) codes^{2,3} as well as the furore regarding the accuracy of HIV-related mortality statistics emanating from death certificates has focused the spotlight on ethical and legal problems with regard to confidentiality.

Medical confidentiality is a duty cast upon a medical practitioner/health care provider (HCP) to keep secret any information, whether relating to a patient's ailment or otherwise, obtained directly or indirectly by the practitioner as a result of the doctor-patient relationship.

Confidentiality is governed by the ethical rules of the profession and the law. The ethical rules are based on the principles of autonomy and the duty not to harm patients. Rule 20 of the Health Professions Council of South Africa (HPCSA) Ethical Code⁴ makes it ethical misconduct to breach confidentiality '...except with the express consent of the patient or, in the case of a minor under the age of 14 years, with the written consent of his or her parent or guardian, or in the case of a deceased patient, with the written consent of his or her next-of-kin or the executor of his or her estate.' The rule has recently been amplified by Ethical Rules 24 - 26 of the HPCSA.⁵

Legally, the confidentiality of patient information is prescribed in the Constitution, statute law and in the common law. Section 14 of the Constitution specifically protects people from unwanted and unnecessary disclosures of information. Section 14 of the new National Health Act (NHA) has specific provisions regarding confidentiality, and the common law has recognised an action for invasion of privacy for many years. All these privacy provisions have to be measured against the right of access to information in the Constitution and the Promotion of Access to Information Act.

The National Health Act1

Section 13 of the NHA provides that a person in charge of a health establishment must ensure that a health record is created and maintained for every user of health services.

Bioethics, Medical Law and Research Ethics, University of KwaZulu-Natal, Durban, and Division of Anatomical Pathology, University of Cape Town

Mahomed A Dada, MB ChB, MMed (For Path), DOM, MMed (Anat Path), FCForPath (SA)

Howard College School of Law, University of KwaZulu-Natal, Durban David J McQuoid-Mason, BComm, LLB, LLM, PhD

Corresponding author: Mahomed A Dada (dadam@pathcare.co.za)

Section 14 of the Act provides that *all* information concerning a user (patient) including information relating to his/her health status, treatment or stay in a health establishment is confidential. Subject to certain exceptions, no person may disclose any of the above information unless: (*i*) the user consents to the disclosure in writing; (*ii*) a court order or any law requires such disclosure; or (*iii*) non-disclosure of the information represents a serious threat to public health.

The NHA imposes a duty on persons in charge of health establishments to set up control measures to prevent unauthorised access to health records (S17). For example, where electronic health records are kept, proper security measures must be taken to ensure that access is strictly limited to authorised persons. Failure by persons in charge of health establishments to comply with the NHA will result in the commission of an offence and liability on conviction to a fine or imprisonment, or both.

The Act defines a 'health establishment' as a public or private facility at which any health service is provided. A health establishment may vary from the rooms of a solo practitioner to a large state or private hospital (Section 1).

The provisions of the NHA with regard to access to records are in line with the Constitution⁶ and the Promotion of Access to Information Act.⁸ Section 15 of the NHA provides that a health worker or HCP who has access to the health records may disclose such records to any other person or establishment for any legitimate purpose where it is in the interests of the user (patient).

Section 16 of the NHA provides for access to health records by HCPs. An HCP may examine a user's health record with the latter's consent for the purposes of treatment, study, teaching or research. In the case of study, teaching or research, consent must also be obtained from the relevant head of the health establishment and health research ethics committee. Section 16 (2) goes on to say that if the study, teaching or research does not involve the identity of the user concerned, it is not necessary to obtain the latter's consent or that of the head of the health establishment or that of the relevant health research ethics committee. This provision appears to fly in the face of general research ethical principles. For ethical reasons, researchers would be advised to follow their research ethics guidelines rather than the Statute.

The right of patients to access information about themselves

The NHA provides that every HCP must inform a user or patient of his/her health status except in circumstances where



875



ORIGINAL ARTICLES

there is substantial evidence that such disclosure would be contrary to the user's best interest (S6 (1) (a)) – so-called 'therapeutic privilege'. This provision must be read with Sections 30 and 60 of the Promotion of Access to Information Act, whereby a HCP must provide any person older than 16 years with an copy, abstract or direct access to his or her own records on request. Where necessary the HCP must arrange for counselling or other appropriate measures before making disclosure where such disclosure may cause serious harm to the user's physical or mental health.

In the light of the Promotion of Access to Information Act and the user's constitutional right of access to information (Section 32),6 it is recommended that pathology laboratories give results to users on request with a 'warning' about the dangers of self-interpretation of laboratory test result in isolation from the medical history and clinical examination. The HPCSA is in favour of an approach that treatment decisions should be in consultation with the family practitioner or specialist, based on the full medical history of the patient and not on the basis of a single test result.

Access to medical records by minors and their parents

Where the patient is under 16 years of age, the parent or legal guardian should make the application for access to the patient's records. However, no HCP shall make information available to a parent or legal guardian regarding a user who is older than 14 years, but under the age of 16 years, without written authorisation from that patient. Currently, 14 years is the age at which children may independently consent to medical treatment.⁹

An exception to the above is implied in the Choice on Termination of Pregnancy Act¹⁰ which states that a termination of pregnancy may be conducted on a person of any age without her parent or guardian's consent. The corollary of this implies that information about the termination of pregnancy may not be divulged to any party, except the patient herself, regardless of the age of the patient.

Disclosure of patient information

As mentioned previously, disclosure of information on a patient, including by pathology laboratories, should be done only with the patient's consent. In situations where disclosure may be made without the consent of the patient, the HCP should first attempt to persuade the patient to give such consent.

Circumstances where it would be legally justifiable for an HCP to disclose information on a patient without the latter's consent are where: (*i*) there is a statutory duty to disclose (e.g. in the case of 'notifiable diseases'¹¹ and in cases of suspected child abuse¹²); (*ii*) a court orders disclosure (e.g. in custody

disputes);¹³ (*iii*) there is a moral, legal or social duty to disclose (e.g. a referring HCP or member of a treatment team); (*iv*) there is an endangered third party (e.g. spouse or partner of an HIV-positive patient);^{14,15} or (*v*) the HCP needs to make disclosure in order to protect him- or herself during legal or disciplinary hearings.

Remedies for breach of confidentiality

A breach of confidentiality may result in a civil action for invasion of privacy,¹⁶ defamation or breach of contract.¹⁷ In the case of a civil claim or 'delict', the matter is between private individuals and bodies and is compensated by an award of money called 'damages'. For negligent breaches of confidentiality only damages for actual loss (e.g. present and future medical expenses, loss of present and future earnings, etc.), and some 'general' damages (e.g. pain and suffering, loss of amenities of life, etc.) may be recovered. In cases of intentional breaches of confidentiality sentimental damages may be recovered in addition to the above.

Furthermore, the HPCSA may investigate a charge of improper or disgraceful conduct.¹⁸

Confidentiality in pathology

In the practice of pathology the following may have access to laboratory results: patients, the referring HCP, insurance companies, medical schemes and managed care organisations, and administrators involved in public institutions providing for compensation for occupational injuries and disease¹⁹ and road accidents.²⁰

The rules regarding confidentiality in the medical profession also apply to pathologists.²¹ Pathology results should be confidential and only released in terms of the above principles. Disclosure of information obtained from a pathology examination to persons not entitled to receive such information amounts to breach of confidentiality, and may result in legal action.

All laboratory test results should be considered confidential information, no matter how they are transmitted – electronically or otherwise. A records management strategy should be drawn up to ensure that all records (administrative as well as medical) are properly controlled, readily accessible and available for use, eventually archived or otherwise disposed of.²²

Pathologists must make sure that the results they send out are received by the person who has a moral, social or legal right to receive the information.²¹ Pathologists may also be vicariously liable for the action of their staff if there is uncontrolled disclosure of patient information. The training of staff, as well as the development of standing order protocols, is mandatory not only for medico-legal and ethical reasons, but also for laboratory accreditation.

876

ORIGINAL ARTICLES



In pathology, current dilemmas are the release of ICD-10 codes to medical aid schemes and the accurate completion of death certification in cases of death as associated with HIV/AIDS.

Medical aid funds and managed care organisations

Prospective members of medical aid funds and managed care organisations (MCOs) are required to sign a general release form on enrolment in the plan. These forms authorise the release of medical information to the funders. However, patients may not be aware that funders request data on disease and tests such as laboratory request forms and *ICD-10* codes. *ICD-10* is the World Health Organization (WHO)'s *International Classification of Diseases*, 10th revision, and was adopted by the national Department of Health in 1996. The Medical Schemes Act² requires that all health service providers should include a diagnostic code in their claim form. The Council of Medical Schemes has made it obligatory to include an ICD code in claims in order for payment to be made to health providers.³

It is recommended that before forwarding medical records to a medical aid funder, MCO, utilisation review programme or other health programme, doctors, pathologists, hospitals, and others should obtain a signed copy of the patient's consent to release of their medical records.

Death certificates

There is general agreement that vital statistics derived from properly completed death certificates are of great value to public health experts and the government. However, the accuracy of death certificates is poor for the following reasons:

- 1. Failure to understand the difference between cause of death and mechanism of death. Many HIV/AIDS cases are underdiagnosed because of lack of understanding of the primary versus the immediate cause of death.
- 2. There is lack of understanding of the importance of properly completing the death certificate using the *ICD-10* guidelines. Many deaths are simply diagnosed as 'undetermined natural cause' or 'unspecified natural cause'.
- 3. There is pressure from the family or community to omit certain causes of death from the death certificate (e.g. HIV/AIDS).

4. Genuine concerns about the confidentiality of page 2 of the BI-1663 as there are many instances of breach of confidentiality by Home Affairs officials. For more details about this problem refer to the article by Dhai *et al.*²³

Conclusion

Respect for patient confidentiality is an important ethical and legal principle protected by the Constitution and the common law. The rules regarding confidentiality in the doctor-patient relationship also apply to the patient-pathologist relationship. The Constitution, the Promotion of Access to Information Act and the new National Health Act allow patients to have access to their medical records, but in the case of pathology test results patients should be warned to discuss these with their doctors.

Insurance companies, medical aid funds and managed care organisations may only receive information on patients where the latter have expressly or implicitly consented to such disclosure.

References

- 1. Act 61 of 2003.
- 2. Regulation 5 (f) of the Medical Schemes Act, Act 131 of 1998
- 3. Council of Medical Schemes. Circular 46 of 2004 91/10/20040.
- Rule 20, Ethical Rules of the Health Professions Council of South Africa. Available from: http://www.hpcsa.co.za/legalmed/ethical.html (last accessed 11 July 2005).
- Booklet 1: General Ethical Guidelines for Doctors and Dentists. Pretoria: Medical and Dental Professions Board of the Health Professions Council of South Africa, 2003.
- 6. Constitution of the Republic of South Africa Act 108 of 1996.
- 7. Janse van Vuuren v Kruger 1993 (4) SA 842 (AD).
- 8. Promotion of Access to Information Act No. 2 of 2000.
- 9. Child Care Act No. 74 of 1983 s 39(4).
- 10. Choice on Termination of Pregnancy Act 92 of 1996 s 5(3)
- 11. Health Act No. 63 of 1977 s 47.
- 12. Child Care Act No. 74 of 1983 s 42
- $13. \quad \textit{Botha v Botha} \ 1972 \ (2) \ SA \ 559 \ (N).$
- As was stated in an American case: 'The protective privilege ends where the public peril begins' (Tarasoff v. Regents of the University of California (1976) Cal S Ct, 17 Cal Rep 3rd series 425).
- 15. SAMDC Bulletin 1989; September, 6: 2.
- 16. Janse van Vuuren v Kruger 1993 (4) SA 842 (AD).
- Dada MA, McQuoid-Mason DJ, eds. Introduction to Medico-Legal Practice. Durban: Butterworths, 2001: 450.
- 18. Health Professions Act 56 of 1974 s 42.
- 19. Compensation for Occupational Injuries and Diseases Act, Act 130 of 1993.
- 20. Road Accident Fund, Act 56 of 1996.
- Cf Nebbeling v Van Drimmelen Laboratorium 2004 WLD (Case no. 11 307/00, 18/3/2004) (unreported).
- 22. For more details refer to Guidelines on Medical Records by the Medical and Dental Professions Board of the HPCSA and by the Royal College of Pathologists see Royal College of Pathologists, Marks and Spencer Publications Unit. The Retention and Storage of Pathological Records and Archives. London: Royal College of Pathologists, 1995.
- 23. Dhai A, Dada MA, Kirk GM, McQuoid-Mason DJ. Confidentiality a dying wish? S Afr Med J 2001; 91: 123-127.

Accepted 12 July 2005.

