When a device that later disintegrates is fitted to a patient during surgery, who is responsible for the consequences? What health professionals and hospitals need to know

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Consider the following hypothetical scenario: A patient suffering constant abdominal pain is referred to State Hospital A from her local clinic after not responding to simple analgesics for chronic pelvic pain associated with irregular menstruation. The doctors at State Hospital A discover that she has a suspicion of adenomyosis. She gives written informed consent for a hysterectomy. During routine postoperative check-ups she reports no alleviation of the pelvic pain, urinary frequency along with burning on micturition and a persistent vaginal discharge. Preoperatively, she was not told that the surgeons had inserted a surgical mesh to prevent vault prolapse. She is given antibiotics and further simple analgesia. As her symptoms do not improve she self-refers to State Hospital B. She is informed that she needs a CAT scan. However, the hospital's scanner has been out of order for three years. She is advised to go to State Hospital C, where the scanner works, but is not given a referral note. She is told by Hospital C that the doctors are too busy to see her, and as she does not have an appointment, and is not an emergency case she should go back to Hospital A. She does not want to go back to Hospital A, as during her last visit there, nursing staff accused her of being a nuisance and escorted her off the premises. She approaches Private Hospital D, where her abdomen and pelvis are scanned. The scan shows the surgical mesh inside her pelvis which had disintegrated. She is told that it is too risky to remove all the fragments, but that some could be removed at a cost - which she could not afford. The surgeon refers her back to State Hospital A with a referral note and copy of the CAT scan report.

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Consider the following hypothetical scenario:

Mrs AB 42 years old is referred to a state hospital from her local clinic. She has a normal Pap smear and has not responded to simple analgesia for chronic pelvic pain, which is associated with irregular menstruation. Having completed her family, she is in a monogamous relationship and has chosen a barrier method for contraception. After further history taking, examination, assessment and investigation at State Hospital A, the doctors suspect adenomyosis. She is counselled on the findings and treatment options available to her. After considering her options, she opts for surgical treatment and is subsequently admitted for an elective hysterectomy. Mrs AB provided written informed consent for the hysterectomy, which was duly performed, she had a satisfactory postoperative course and was subsequently discharged in a satisfactory condition. After the hysterectomy Mrs AB followed up at Hospital A for a routine post-operative checkup. She reported no alleviation of the pelvic pain, new onset of urinary frequency with burning during micturition and a persistent vaginal discharge. During the follow-up assessment, the reviewing doctor found in her hospital records that, in addition to the hysterectomy, a surgical mesh had been inserted to prevent vault prolapse—a procedure not disclosed to her beforehand. Hospital A did not conduct further investigations into the new onset-symptoms; instead, she was prescribed a course of antibiotics and simple analgesics and given a follow-up date. After completing the short course of treatment without any symptom improvement, Mrs AB chose not to return to Hospital A and instead sought a second opinion at another state hospital ("Hospital B"). Mrs AB recounts her history and current symptoms to clinicians at Hospital B. After assessment, examination and an inconclusive pelvic ultrasound, she is informed that she needs to undergo a computed tomography (CT) scan of the abdomen and pelvis for further investigation. However, this specialised investigation cannot be done because the scanner has been out of service for 3 years. The clinicians suggest she go to State Hospital C, where a functioning scanner is available, but they do not provide her with a referral letter or scan booking request form. Following this advice, Mrs AB goes to the outpatient department of Hospital C, requesting to be booked for a CT scan. The nursing staff, however, refuse to refer her to a doctor for consultation and assessment, because the doctors are too busy and the fact that she does not have an appointment or an emergency indication to be seen *ad hoc*. She is then told to go back to Hospital A, where the original procedure was conducted.

Mrs AB is unwilling to return to Hospital A, as previous visits only resulted in ineffective treatment. On her last visit, when she reported the persistent symptoms, the nursing staff dismissed her complaints,

saying she was being a nuisance. At the request of the medical team, the security escorted her off the premises when she insisted and demanded assistance and a CT scan. Mrs AB then sought care at a private hospital ("Hospital D") as a cash-paying client, where a doctor arranged for a CT scan of her abdomen and pelvis. The results showed she had surgical mesh inside her pelvis, which had disintegrated and could be the cause of her symptoms. The surgeon explained the potential benefits and risks of removing the mesh fragments, noting that the primary benefit would be removing the piece that had eroded into her bladder and vaginal vault, which was likely causing her symptoms. However, the estimated procedure cost exceeded ZAR100 000, which she could not accept or afford. The surgeon provided her with a referral note and a copy of the CT scan report, advising her to return to State Hospital A for further assistance.

The above scenario raises several ethical and medico-legal issues, such as: What is the root cause of the liability subsequent to the complications following the mesh insertion? Was proper informed consent obtained at Hospital A before her surgery? Did the medical and nursing staff at the state hospitals act legally and ethically? Was she provided adequate access to healthcare by the state hospitals and the private hospital? With whom does that liability lie—Hospital A, B, C or D, the Department of Health or the mesh manufacturer? Does she need to prove negligence on the part of the doctors and hospitals regarding the defective mesh? Must she also prove negligence by the manufacturers in making and supplying the defective mesh?

To address these questions, the following legal and ethical frameworks must be considered: (a) The Constitution[1] and the National Health Act[2]; (b) the Consumer Protection Act[3]; (c) the Nursing Act[4]; (d) the South African Nursing Council Rules setting out the acts or omissions in respect of which the Council may take disciplinary steps[5]; the Health Professions Act[6] (HPCSA); (e) the HPCSA Ethical Rules of Professional Conduct[7]; (f) the Common Law[8] and (g) the Apportionment of Damages Act.[9]

It is trite that while a statutory breach or breach of a regulation under a statute may, in itself, constitute a crime if specified within the statute, in civil cases such a breach serves only as evidence of a wrongful act or omission. A breach of ethical rules of conduct is not in itself a crime but may be used as evidence of a failure to act as a reasonably competent health practitioner would under similar circumstances. Such breaches can lead to disciplinary investigations or hearings by the relevant professional bodies.

1. The Constitution and the National Health Act – informed consent

In terms of the Constitution,[1] everyone has the right to freedom and security of the person (section 12(1)) and the right to bodily and psychological integrity (section 12(2)), which includes the right to security in and control over their body (section (12 (2)(b)). The National Health Act[2] provides that patients may not be treated without their consent (section 7(1)), and must be informed of the 'range of diagnostic procedures and treatment options generally available' and 'the benefits, risks and consequences generally associated with each option' (section 6 (1)).

In the hypothetical case of Mrs AB, she consented only to a hysterectomy and was not informed that she may be fitted with a surgical mesh if her pelvic wall needed support and preventive measures against possible vault prolapse. Thus, she was not given sufficient information to provide informed consent because she was not told about the possible need for a surgical mesh and the risks involved with its insertion. Accordingly, the surgeons at Hospital A were guilty of assaulting the patient by intentionally fitting her with a mesh without her knowledge. The patient would succeed in her action against the surgeons, and in an action against Hospital A – based on the hospital's vicarious liability for the failure of the surgeons employed by it to obtain proper expressed informed consent in writing.

The Constitution and National Health Act – the right of access to healthcare

The South African Constitution[1] (the Constitution) provides everyone with the right of access to healthcare (section 27) and requires the State to uphold these human rights (section 7(2)). The National Health Act[2] (NHA) covers the constitutional right of access to healthcare in both the public and private sectors. This implies that private hospitals must provide healthcare to everyone who can afford their services, without discrimination on unconstitutional grounds. In emergencies, however, private hospitals must stabilise patients who cannot afford their fees before referring them to state hospitals.

In this hypothetical case, Hospital A initially provided the patient with the right of access to medical care by undertaking the hysterectomy and fitting her with the surgical mesh – albeit complications arose from the mesh, which she had not consented to, as she was only informed about the hysterectomy. Hospital B could argue that they did the right thing by referring her to Hospital C, which had a functioning scanner, and that interim treatment could not proceed until the scan was done. Hospital C could contend that it provided her access to healthcare by referring her back to State Hospital A, which had performed the original procedure, especially if no treatment could be administered to alleviate the root cause of her symptoms—the complication from the mesh insertion.

During her visits to Hospital A to voice her concerns, the patient was effectively denied access to healthcare. She received ineffective treatment without any investigation into the cause of her ongoing symptoms, and during her last visit, she was removed from the hospital premises by security guards for being a 'nuisance' when she demanded assistance.

In contrast, Hospital D did provide her with access to healthcare by assessing her condition and conducting a CT scan. They informed her that the mesh had disintegrated and protruded into her bladder and vaginal vault. Apart from removing the protruding mesh fragment, the risks outweighed the benefits in attempting to remove the mesh fragments. Hospital D also acted appropriately by informing her of the composite cost of the operation, which she could not afford, and by referring her back to State Hospital A with a referral note, given that they could not offer her interim treatment.

2. The Consumer Protection Act

The Consumer Protection Act[3] imposes a modified form of strict liability on providers of defective specialist services and manufacturers of goods that cause injury to patients or injuries that result in the death of patients (section 61(1)). In such cases, the harmed person only has to show that the providers supplied or installed defective goods. There is no requirement for the harmed person to prove negligence on the part of the service provider (section 61(1)). Providers of such goods cannot escape liability unless they can prove that it would have

been unreasonable to expect them to test the goods beforehand (section 61(4)).

In the hypothetical case of Mrs AB, she needs to prove that the surgeons in Hospital A fitted the mesh and that the mesh was defective; she does not have to prove that they acted negligently during the procedure. The strict liability by the Consumer Protection Act is modified, allowing the surgeons to escape liability if it can be shown that it would have been unreasonable to expect them to discover the defects in the mesh, given their role as surgeons. However, this defence would not hold if it can be shown that it was common knowledge among surgeons that such meshes were often defective at the time or if a recall notice had been issued by the manufacturers that was ignored by Hospital A's employees or procurement team. Moreover, while it is not routine practice to fit a surgical mesh after a hysterectomy to prevent prolapse, the surgeons had both an ethical and legal obligation to inform the patient about the possible risks involved and to obtain her consent before fitting the mesh.

3. The Nursing Act and rules setting out the acts or omissions in respect of which the Council may take disciplinary steps

The Nursing Act[4] establishes the South African Nursing Council (SANC) (section 2), which has promulgated rules outlining the acts or omissions in respect of which the Council may take disciplinary steps[5] (sub-rule 3). One of the SANC's objectives is to 'uphold and maintain professional and ethical standards within nursing' (section 3(e)). Thus, the SANC Rules state that the acts or omissions regarding professional and ethical standards for which the Council can take disciplinary steps against a registered nurse include a wilful or negligent omission to perform duties in diagnosing, treating, caring for, prescribing, collaborating, referring, coordinating and advocating for patients, as permitted by their professional scope (sub-rule 3). These acts or omissions include 'determining the health status of the patient and the physiological responses of the body to disease conditions, trauma and stress' and 'the correct administration of treatment, medication and care' (sub-rule 4).

In the hypothetical scenario, the nurses at State Hospital A did not uphold and maintain professional and ethical standards. They did not adequately assess the patient's health status or her physiological responses related to her symptoms, opting instead to provide ineffective treatment when she complained, Additionally, they did not advocate for her with the attending doctor and instead called security guards to remove her for being a 'nuisance'.

In contrast, the nurses at State Hospital B acted appropriately by referring her to Hospital C, which had a functioning scanner, especially since they could not provide any interim treatment to alleviate Mrs AB's symptoms until the CT scan was done. The administrators at Hospital C could potentially be held liable for any harm suffered by patients as a result of the 3-year delay in repairing the scanner, which could be deemed negligent or a case of maladministration.

The nurses at State Hospital C could argue that they upheld the professional standards required by the Council by issuing the patient with a referral note and referring her back to State Hospital A, where her surgical procedure was performed, especially if they were unable to administer any treatment to alleviate her condition.

4. The Health Professions Act and Professional Rules of Conduct for the Health Professions

The Health Professions Act[6] establishes the Health Professions Council of South Africa (HPCSA) (section 2(1)), which has introduced Professional Rules of Conduct for the Health Professions.[7] The Professional Rules of Conduct of the HPCSA clearly state that a practitioner must at all times:

Act in the best interests of his or her patients (rule 27A).

Likewise, the HPCSA General Ethical Guidelines for the Health Professions[8] emphasise that health practitioners should:

Always regard concern for the best interests or well-being of their patients as their primary professional duty (para 5.1.1);

Respond appropriately to protect patients from any risk or harm (para 5.1.9);

Act quickly to protect patients from risk due to any reason (para 7.1); Report violations and seek redress in circumstances where they have a good or persuasive reason to believe that the rights of patients are being violated (paras 7.2 and 10.1.1).

Health practitioners, whether employed in the private or public sector, are bound by the same ethical and professional rules. In the hypothetical case, the surgeons at State Hospital A failed in their ethical duty to prioritise the interests and wellbeing of the patient when fitting the mesh without her knowledge and consent, including the possibility of experimental insertion if warranted. They also neglected to respond appropriately to protect her from risk or harm by failing to provide a follow-up remedial evaluation of her new symptoms. Instead of assisting her in seeking redress, they allowed her to be turned away and escorted off the hospital premises.

As previously mentioned, the staff at State Hospital B could argue that they acted correctly by referring her to State Hospital C, which had a working scanner - provided there was no interim treatment they could provide. Likewise, the staff at State Hospital C could argue that they prioritised her interests when they referred her back to Hospital A when they could not provide interim treatment.

Private Hospital D acted appropriately by arranging the scan and informing her about the necessary definitive surgical procedure, provided they could not administer any interim treatment to alleviate her condition. The practitioner at Hospital D did not deem it beneficial to undertake a high-risk operation to remove the mesh fragments and duly communicated this assessment along with the associated costs to the patient. Furthermore, the practitioner at Hospital D acted correctly by referring her back to the state hospital that initially operated on her, to evaluate Mrs AB and plan for the removal of the foreign body (the mesh) responsible for her symptomatology.

5. The Common Law

The Common Law impacts health law in the areas of contract, delict and criminal law.[8] In Common Law, the relationship between a doctor and a patient is contractual,[9] meaning it is based on an agreement where one party offers a service and the other accepts it.[8] For instance, patients consent to treatment from specific practitioners or hospitals, who in turn agree to provide care in accordance with accepted medical standards. A delict, on the other hand, refers to a breach of a legal duty to not harm others, independent of any

contractual relationship.[8] For example, if an unconscious patient is brought to a hospital, a surrogate may consent to treatment or, in emergencies where contacting a surrogate is not feasible, treatment may proceed without consent. The conduct of the doctors and hospitals will be judged by the court according to the reasonable standard of medical care imposed by the law of delict on doctors and hospitals.[10] Breaches of contracts and delicts are civil wrongs against individuals, making the wrongdoers liable to compensate the injured person.[8] In civil cases, the injured party must prove, 'on a balance of probabilities', that the wrongdoer negligently or intentionally caused or contributed to the injury.[8] 'Negligence' is a failure to act as a reasonable person or practitioner ought to have acted if he or she would have foreseen the risk of injury to another in the relevant circumstances. 'Intention' is the direction of the will of the person concerned to commit an act or omission, which he or she knows is unlawful.[8]

A crime is a wrong against the State for which the wrongdoer may be punished.[9] In a criminal case, the State must prove 'beyond a reasonable doubt' that the wrongdoer intentionally or negligently committed the wrongful act or omission that caused injury to the victim of the crime.[8] Sometimes, an act or omission may qualify as both a crime and a civil wrong. For instance, if a person assaults another person, the wrongdoer can be punished by the State (e.g. fined or imprisoned), while the victim can pursue a separate civil action for damages.[8] In a civil action, the injured party has a choice: they may sue based on an intentional omission or on negligence. Proving negligence may be easier than proving intentional omission. If suing for an intentional act, the injured party may claim both sentimental damages (to address emotional harm) and damages for pain, suffering and actual financial loss. If suing for negligence, only damages for pain, suffering and actual financial loss are recoverable.[8] Actual financial loss can be calculated by adding up the expenses connected to the injury, such as loss of present and future income, cost of present and future medical bills and other measurable present and future expenses.[8]

In the hypothetical case we presented, the doctors who fitted the mesh without the patient's consent could be charged with the crime of assault, although the State may decline to prosecute for policy reasons, suggesting instead that the patient pursue civil damages. For the crime of assault, the State will have to prove that the doctors intentionally withheld information about the mesh and were aware of the wrongfulness of their omission. In a civil action, the patient could base her claim on either an intentional or negligent omission. If she sues on the basis of an intentional act or omission she can claim both sentimental damages for her hurt feelings, as well as for pain and suffering and actual financial loss. If she sues for negligence she can only recover for pain and suffering and actual financial loss.[8]

6. The Apportionment of Damages Act

The Apportionment of Damages Act[7] provides for joint wrongdoers to be sued together during court proceedings and enables the court to apportion damages among them (section 2(1)). An application for apportionment of damages may be made by the injured party or by any joint wrongdoer (section 2(2)).

In the hypothetical case, the surgeons at Hospital A were at fault for not obtaining informed consent before fitting the surgical mesh during the hysterectomy and for failing to assist the patient when she returned with complaints. The administrators at Hospital B could be held liable if their failures to fix the scanner—owing to administrative lapses such as not renewing a service agreement timeously—led to harm for any patient. Similarly, the hospital staff could be held at fault for not examining her to see if they could provide her with interim assistance. Additionally, staff at Hospital C could be faulted if they did not examine her to see if there was any interim assistance they could provide before sending her back to Hospital A. The Department of Health could therefore be held liable vicariously for any negligent or intentionally wrongful actions by staff at Hospitals A, B and C, provided the patient can prove that each instance of staff conduct contributed to her injury. If so, the fault of the various staff members at Hospitals A, B and C could be apportioned between them as joint wrongdoers in terms of the Apportionment of Damages Act.[7]

In the hypothetical case, the surgeons at Private Hospital D appropriately performed a CT scan, diagnosed the mesh disintegration and informed the patient of the risk and cost associated with removal surgery. They also referred her back to State Hospital A with a referral note for the doctors, which was in accordance with good medical practice. However, the practitioner should have offered to assist the patient with any interim emergency care that was possible, before referring her to a state hospital. If the doctors were independent practitioners there would be no vicarious liability for Hospital D. As in the case of the State hospitals, to join the private hospital staff members as joint wrongdoers, the patient would have to prove that the omission by them was negligent and had caused or contributed to the injury suffered (e.g. if there was a need for her to have emergency care).

Conclusion

This article describes a hypothetical case involving a patient who was fitted with surgical mesh without her consent. It explores her potential for recovering damages and achieving justice under a range of South African legal frameworks including the Constitution, the National Health Act, the Consumer Protection Act, the Nursing Act, the SANC Rules setting out the acts or omissions in respect of which the Council may take disciplinary steps, the HPCSA, the HPCSA Ethical Rules of Professional Conduct, the Common Law and the Apportionment of Damages Act.

The scenario seeks to remind and illustrate to healthcare professionals the need to be cautious when obtaining informed consent, and when faced with patients who subsequently suffer harm arising from the consequences of medical procedures or operations. The failure to appropriately handle and deal with the issues raised by the patient may lead to a breach of several statutes, the regulations under them or the common law, which could lead to claims for damages, as well as disciplinary investigations and hearings under the relevant professional rules of conduct. While patients cannot pursue multiple simultaneous actions for damages based on each relevant statute, regulations under them or the common law, their lawyers can use those statutes or common law principles that make it easier for the patients to prove the liability of the health professionals and hospitals concerned. They can also bring alternative actions under the different statutes or the common law in case they fail under the category chosen.

All health professionals registered with their respective professional bodies are bound by their specific ethical and professional rules and codes of conduct and should adhere to the provided guidance when rendering patient care including the process of obtaining informed consent.

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