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Lung Transplants in South Africa: Why not a Prescribed Minimum Benefit?

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Abstract

This commentary critically discusses the legal position concerning the payment for lung transplants in South Africa. The Department of Health compiles a list of prescribed minimum benefits that must be covered by medical schemes in the private sector. However, lung transplants are not currently listed as a prescribed medical benefit option for lung disease in the private sector. This is despite the fact that lung transplants are increasingly becoming a regular medical practice. As a result, medical aid schemes are under no duty to cover the cost of lung transplants. This dilemma may be ascribed to the Department of Health's oversight in complying with legislative prescripts that require that the list of prescribed minimum benefits be reviewed at least every second year. This legal vacuum regarding lung transplants has dire consequences for patients in the private sector. This commentary explores the legal requirements regarding prescribed minimum benefits, concluding with recommendations to remedy the existing situation.

Keywords: lung transplants; diagnosis; treatment; care costs; prescribed minimum benefits; private sector; medical aid schemes

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1 INTRODUCTION

The first lung transplant was performed in 1963 in Mississippi in the United States of America.[1] South Africa did the first lung transplant thirty years later in 1993. Milpark Hospital in Gauteng is the only multi-disciplinary Lung Transplant Unit in the private sector in South Africa.[2] In 2017, the Groote Schuur Hospital in the Western Cape became the only public hospital performing lung transplants.[3] Despite the fact that the Groote Schuur Hospital performs lung transplants in the public health sector, South Africa does not have a formal lung transplant programme.[4]

Currently, a lung transplant is not an approved option in the "Diagnosis and Treatment" pair, listed as a Prescribed Minimum Benefit (PMB) under the heading "Respiratory System", as promulgated by the government in Annexure A of the Regulations in terms of the Medical Schemes Act.[5]

The purpose of this commentary is to indicate the current legal position of lung transplants in South Africa, as well as to highlight the legislative oversight that has occurred as a result of the South African government's failure to follow legislative prescripts. This failure has caused confusion in the lung transplant context, specifically in the private sector. Furthermore, it is our contention that the government's current approach to lung transplants displays indifference and a lack of commitment to South African patients urgently requiring lung transplants. This comment will only briefly explain the legal framework generally governing transplantations in South Africa, as this has already extensively been discussed elsewhere.[6] The focus will be mainly on the issue that a lifesaving "transplant" is not indicated as a treatment option for problems with the respiratory system in the PMB list, yet the procedure has been done in the public sector since 2017. Before the relevant pieces of legislation are discussed, a brief background on lung transplantations is necessary.

2 LUNG TRANSPLANTS

Lung transplant experimentations began in the 1950s using animals, largely dogs.[7] It only "became an accepted and successful therapy for patients with end-stage lung disease", following the introduction of cyclosporine, a calcineurin inhibitor, used as an immunosuppressant medication in organ transplants to prevent rejection.[8] Lung transplants are the last of the solid organ transplants to gain traction as a viable treatment for organ failure.[9] Other solid organs

1 Hardy "The First Lung Transplant in Man (1963) and the First Heart Transplant in Man (1964)" 1999 *Transplantation Proceedings* 25–29; Williams "Lung Transplantation in South Africa" 2016 *Transplant News* 2–4.

2 Williams 2016 *Transplant News* 4.

3 Hyman "Groote Schuur Transplant Programme Breathes Again" 2017 *Times Live* https://www.timeslive.co.za/news/south-africa/2017-12-14-groote-schuur-transplant-programme- breathes-again/ (accessed 15-04-2020).

4 Calligaro, Brink, Williams, Geldenhuys, Sussman and Pennel "Lung Transplantation in South Africa: Indications, Outcomes and Disease-specific Referral Guidelines" 2018 *Afr J Thoracic Crit Care Med* 121 https://hdl.handle.net/10520/EJC-11820e08fc (accessed 14-10-2021). See also Williams 2016 *Transplant News* 2–7.

5 Medical Schemes Act 131 of 1998. Regulations. Government Notice 1262 of 20 October 1999.

6 Slabbert and Venter "Autonomy in Organ Donation v Family Consent: A South African Legislative Context" 2019 *De Jure* 458–467. http://dx.doi.org/10.17159/2225-7160/2019/v52a24 (accessed 14-10-2021); Slabbert "The Law as an Obstacle in Solid Organ Donations and Transplantations" 2018 *THRHR* 70-84; Slabbert an Venter "Routine Referrals: A Possible Solution for Transplantation Shortages" 2017 *S Afr J Bioethics Law* 15–19.

7 Hardy 1999 *Transplantation Proceedings* 25.

8 Calligaro *et al* 2018 *Afr J Thoracic Crit Care Med* 121.

9 *Ibid.*

that are transplanted include the kidneys, the heart, the liver, and the pancreas. According to Calligaro *et al*, the reasons for the late acceptance of lung transplants as a cure for respiratory failure are threefold: first, "lung procurement rates from deceased donors are much lower than for other organs", which "is probably due to the lung's vulnerability to events arising prior or after brain death of the donor" is established.[10] Second, a "longer and more intensive period of immunosuppression is required for lung transplants than for other solid organ transplants".[11] Finally, "infectious complications are major contributors to morbidity and mortality in lung transplant recipients".[12]

Lung transplants are indicated for "patients with chronic lung diseases who are clinically deteriorating"[13] despite other interventions, such as ventilation. In other words, the patient should be ill enough "to need the transplant, but not so disabled that he or she would not survive the procedure".[14] For someone to benefit from a lung transplant the lung disease they are suffering from "should be severe enough to make survival without a transplant beyond 2 years unlikely".[15] Lung transplants involve one (single transplant) or both lungs (double transplant). A bilateral sequential lung transplant is the transplant of both lungs, done one at a time. The latter type is preferred in all patients, as "the greater postoperative lung function provides more reserve for posttransplant complications and, in turn, is associated with better survival."[16] The need for lung transplants has also been exacerbated by the COVID-19 pandemic. Recent research, published in Lancet Respiratory Medicine,[17] recommends lung transplants by extracorporeal membrane oxygenation (ECMO) for patients with COVID-19-associated acute respiratory syndrome (ARDS). Lung transplants have been performed on COVID-19 survivors with irreversible lung damage across the globe. In the United States alone, by November 2021, already 238 patients have received lung transplants due to COVID-19.[18] South Africa's first lung transplant for a COVID-19 patient, in fact, the first transplant of its kind on a COVID-19 patient on the continent, was carried out in April 2021.[19]

Patients waiting for a lung transplant in South Africa are desperate to find a donor. Donor rates in South Africa are extremely low, particularly if there is a need to wait for a brain-dead donor.[20] In South Africa, since 2009, only 65 adult lung transplants have been performed, with 13 in

10 *Ibid.* See also the Regulations Regarding the General Control of Human Tissue, Blood, Blood Products and Gametes. Government Notice R180 in *Government Gazette* 35099 of 2 March 2012, s 9 for how to determine brain death.

11 Calligaro *et al* 2018 *Afr J Thoracic Crit Care Med* 121.

12 *Ibid*.

13 *Ibid*.

14 *Ibid*.

15 Williams 2016 *Transplant News* 2.

16 Calligaro *et al* 2018 *Afr J Thoracic Crit Care Med* 121.

17 Bharat *et al* "Early Outcomes after Lung Transplantation for Severe COVID-19: a Series of the First Consecutive Cases from Four Countries" 2021 *Lancet Respiratory Medicine* 487–498. https://doi.org/10.1016/S2213-2600(21)00077-1

18 Statistics provided by United Network for Organ Sharing (UNOS). See Keridan "Once Rare, Lung Transplants for COVID-19 Patients are Rising Quickly" *Weekend Edition Sunday* (28 November 2021). https://www.npr.org/2021/11/28/1058988220/once-rare-lung-transplant-for-covid-19-patients-are-rising-quickly (accessed 2022-02-18).

19 Dipa "SA's First Covid-19 Patient to Receive a Lung Transplant is Excited to spend Easter Weekend with Newborn Daughter" *Saturday Star* (3 April 2021) https://www.iol.co.za/saturday-star/news/sas-first-covid-19-patient-to-receive-a-lung-transplant-is-excited-to-spend-easter-weekend-with-newborn-daughter-6992ff9c-3ca4-4c08-8182-7980ef88b238 (accessed 16-08-2022).

20 National Health Act 61 of 2003, s 1: "death" means "brain death"; Regulations Regarding the General Control of Human Tissue, Blood, Blood Products and Gametes. Government Notice R180 in *Government Gazette* 35099 of 2 March 2012, s 9.

2019 involving adult patients only.[21] This translates to approximately eight transplants per year, whilst the demand is much higher.

3 LEGAL FRAMEWORK RELATING TO ORGAN TRANSPLANTS IN SOUTH AFRICA

Organ transplants are regulated by the National Health Act 61 of 2003 (NHA) and the regulations in terms of the Act. Chapter 8 of the NHA specifically addresses organ donations and transplantations using tissue from both living and deceased donors. Since this note focuses on lung transplants, only those sections from the NHA relevant to deceased donors will be discussed.

According to section 62 of the NHA, any person who is competent to make a will (16 years and older) may, in a will or in a document signed by them and at least two competent witnesses (14 years and older), or in an oral statement made in front of two witnesses, donate their organs to be used after their death. If no such document exists, the next of kin will be asked for consent before organs are removed from the deceased. Section 62(2) established the prescribed order in which consent should be sought from the next of kin, namely the spouse, partner, major child, parent, guardian, major brother, or major sister of the deceased. South Africa follows an opt-in system of consent, which means that consent must be given either by the deceased before they died or by a family member after the death of a person. If there is a difference of opinion among the next of kin concerning the permission for the procurement of organs from a deceased, no organs will be removed.

Jurisdictions, such as Belgium, Wales, and Spain follow a different process, referred to as an opt-out system, which means every citizen in these countries is by default an organ donor, unless they register an objection to being an organ donor with the State.[22] The adoption of an opt-out system in South Africa may well address the organ shortage, however, educating all South Africans on the intricacies of organ donation in order to ensure that the system cannot be viewed as coercive, is a time-intensive exercise that will unlikely be implemented in the short term.

After the death of a family member, it is standard protocol in hospitals in South Africa to approach the next of kin for consent to the donation of organs and tissue. Because of this routine approach the next of kin may technically *veto* that deceased family member's original wish or intention to be an organ donor after their death.[23] Sadly, the low number of organ donors in South Africa means that there are simply insufficient persons consenting to the procurement of usable organs after death. Moreover, the current process of organ procurement in South Africa fails nearly to secure enough transplantable organs to meet the growing demand for organs. The need for transplantable lungs is no exception.

4 PRESCRIBED MINIMUM BENEFITS

The Medical Schemes Act and the regulations in terms of the Act, do not address the issue of organ transplants and by implication lung transplants directly. But section 29(1)(o) of the

21 Organ Donor Foundation. Statistics. https://www.odf.org.za/info-and-faq-s/statistics.html (accessed 14-10-2021). See also Muller "Organ Donation and Transplantation in South Africa" 2013 *Continuing Medical Education* http://www.cmej.org.za/index.php/cmej/rt/printerFriendly/2764/3004 (accessed 19-05-2021).

22 See Slabbert 2018 *THRHR* 81(1) 70.

23 See Slabbert and Venter 2019 *De Jure* 458–467.

Medical Schemes Act states that medical aid funds *must* pay PMBs, the section reads as follows:

> 29. Matters for which rules shall provide –
>
> (1) The Registrar shall not register a medical scheme under section 24, and no medical scheme shall carry on any business, unless provision is made in its rules for the following matters:
>
> (o) The scope and level of minimum benefits that are to be available to beneficiaries as may be prescribed.

In other words, all medical aid funds in South Africa *must* pay for the treatment a patient receives if the treatment is on the PMB list. Section 67 of the Act authorises the Minister of Health, after consultation with the Council of Medical Schemes, to make regulations concerning specific issues as well as the PMB list. The Regulations to the Medical Schemes Act was promulgated in 1999. The Regulations in Chapter 3, titled "Contributions and Benefits", section 7 "Definitions", define "prescribe minimum benefits" as:

> the benefits contemplated in section 29(1)(o) of the Act, and consist of the provision of the diagnosis, treatment and care costs of –
>
> (a) the Diagnosis and Treatment Pairs listed in Annexure A, subject to any limitations specified in Annexure A;

In 2003 these Regulations were amended, followed by a minor amendment in 2020 to make provisions for COVID-19 cases.[24] The explanatory note to Annexure A (list of PMBs) of the Regulations states the following:

> The objective of specifying a set of Prescribed Minimum Benefits within these regulations are two-fold:
>
> (i) To avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilization of public hospitals
>
> (ii) To encourage improved efficiency in the allocation of Private and Public health care resources.

The list of PMBs, compiled by the Department of Health, should reflect changes in medical treatment, technology, and medical practice, in order to remain current and relevant. Consequently, the Department should monitor the impact, effectiveness, and appropriateness of the PMB provisions. According to Annexure A, a review of the PMB list shall thus "be conducted at least *every two years* by the Department that will involve the Council for Medical Schemes, stakeholders, Provincial health departments and consumer representatives" [authors' emphasis]. These reviews shall provide recommendations for the revision of the Regulations and Annexure A on the basis of –

> **(i) inconsistencies or flaws in the current regulations;**
>
> (ii) the cost-effectiveness of health technologies or interventions;
>
> (iii) consistency with developments in health policy; and the impact on medical scheme viability and its affordability to Members. [Authors' emphasis]

So, the Department of Health is obliged to review Annexure A of the Regulations at least every

24 Medical Schemes Act 131 of 1998. Government Notice 44103 of 29 January 2021.

two years. Unfortunately, and without explanation, the review has not been done for quite some time. The Regulations in Chapter 3, section 8, "Prescribed Minimum Benefits" furthermore provide as follows:

> (1) Subject to the provisions of this regulation, any benefit option that is offered by a medical scheme must pay in full without co-payment or the use of deductibles, the diagnosis, treatment and care costs of the prescribed minimum benefit conditions. [Authors' emphasis]

The Explanatory notes and definitions to Annexure A in section (2) state as follows:

> Where **the treatment component of a category in Annexure A is stated in general terms** (i.e. "medical management" or "surgical management") **[authors' note: as is the case with lung illnesses]** it should be interpreted as referring to prevailing hospital-based medical or surgical diagnostic and treatment practice for the prescribed condition. Where significant differences exist between Public and Private sector practices, the interpretation of the Prescribed Minimum Benefits should follow the predominant Public Hospital practice **[authors' note: lung transplants are being performed in the public sector since 2017]** as outlined in the relevant provincial or national public hospital clinical protocols, where these exist. Where clinical protocols do not exist, disputes should be settled by consultation with provincial health authorities to ascertain prevailing practice. The following interventions shall however be excluded from the generic medical/surgical management categories unless otherwise specified:
>
> (vi) Organ transplantation **[authors' note: no specification excluding lungs]**.

Annexure A's reference in section 5 to solid organ transplants states that: "[t]he PMBs Annexure A includes solid organ transplants (liver, kidney and heart) only *where these are provided by public hospitals* in accordance with public sector protocols and subject to public sector waiting lists" [authors' emphasis]. In other words, according to the current PMB list, transplants of the liver, kidneys, and heart should be paid as a PMB by medical aid funds. Lung transplants are not included, and we ask the question, why?

5 LUNG TRANSPLANTS NOT A PMB?

If the PMB list had been reviewed at least every second year, as is required by the Regulations, "transplantation" could have been included as a treatment option for respiratory system problems (lung illnesses) in the PMB list. We regard this omission as a serious oversight on the part of the Department of Health, which affects patients waiting for a lung transplant. Aside from the fact that the Department of Health should review the PMB list at least every two years, lung transplants have been performed in the public sector since 2017. Once a procedure is conducted in the public sector, as we explain above, the regulations require that the procedure be placed on the PMB list so that private patients' medical schemes could cover these procedures.

PMBs include "treatment and care costs", but because the Regulations (Annexure A) were not updated as directed by the Regulations, there is currently no option on the PMB list for a "transplant" indicated for the treatment of a lung disease. Again, had it been updated as from 2017 (the time when the lung transplants started to be carried out in the public sector) patients in the private sector in need of a lung transplant would have benefitted.

A case illustrating the consequences of this legislative vacuum is this of Mrs X. When lung transplants started in the public sector, a female patient with a long history of chronic obstructive pulmonary disease and respiratory disability developed severe airflow limitations. She was using oxygen at home. Despite maximal medical therapy with antibiotics, steroids, and bronchodilators, her short-term prognosis was assessed as being very guarded, and she was referred for a lung transplant as a therapy of last resort. She was referred to the Groote

Schuur Hospital for a life-saving lung transplant.[25] Although a private healthcare member, she was admitted to the Groote Schuur Hospital. Her medical scheme indicated they would fund the transplant from their organ transplant benefit. This benefit also covers immune suppressive medication, post-transplant biopsies and scans as well as pre-transplantation radiology and pathology. The scheme does *not* cover post-transplantation monitoring and care.[26] After the operation, the medical scheme settled the costs of the lung transplant but refused to cover the post-operation care. Upon querying this decision, the medical scheme informed the patient that a lung transplant was not a PMB, and they were therefore not responsible for the costs. They were technically correct as we argued above, but it seems unfair for them to cover the costs of the operation and then to stick pedantically to the PMB list and refuse to pay for post-operative costs.

We argue that diagnosis, treatment, and care costs are inseparably connected to each other. A diagnosis that requires treatment is futile if further post-operation care is denied after treatment has commenced. As observed above, the oversight of listing lung transplants in this list is the result of the fact that the Regulations were not updated in accordance with the legal requirement.

A 2012 publication of the Council for Medical Schemes, *CMScript*, refers in its fifth issue in an article, entitled, "Member of a Medical Scheme? Know your Guaranteed Benefits" to solid organs including heart, liver and kidneys only. It is widely accepted in the transplant community that solid organs include the heart, liver, kidneys, lungs, and pancreas.[27] The same article confirms that "solid organ transplants" as described are a listed PMB and that these include "post-operative care and follow-up of both recipient and living donor".[15] Moreover, the section on the "Care of Recipients", extends the treatment to include:

> • consultations with relevant clinicians, including psychotherapists and professionals on the transplant team;
>
> • rehabilitation by a physiotherapist and/or occupational therapist;
>
> • radiology tests to assess the functionality of the organ;
>
> • pathological tests to monitor potential complications due to the transplant (this includes a test to diagnose complications after the immunosuppressive drugs that must be taken after a transplant, have been taken);
>
> • a lifetime's supply of immunosuppressive drugs (which prevent the rejection of the transplanted organ/s)
>
> • a lifetime's supply of medicines to prevent and/or alleviate the side effects associated with immunosuppressive therapy; and
>
> • pain treatment.[15]

The section on "Funding Donor Organs" and "Recipients" addresses the cost issue relating to these transplants:

> Organ donation is a prescribed minimum benefit (PMB) and your medical scheme must therefore cover in full all the costs associated with the pre-surgery evaluation, the surgery

25 Letter dated 16 July 2019 from Dr Calligaro, the patient's treating physician, to the MSC (CMS 72349) [on file with the authors].

26 *Ibid*.

27 Black, Termanini, Aguirre *et al* "Solid Organ Transplantation in the 21st Century" 2018 *Ann Transl Med.* 409. http://dx.doi.org/10.21037/atm.2018.09.68

itself, in-hospital care, and lifetime care, as per Regulations 8 of the Medical Schemes Act.[15]

Thus, the relevant medical scheme that refused to cover the lung patient's post-operative care or medication, relied strictly on the wording of the Act and the Regulations to justify their decision. Although aligned with the PMB list, their decision is problematic in our view, as the consequence of the government's omission to update the Regulations timeously has befallen the unfortunate lung patient. It would be reasonable, having regard to considerations of public and legal policy, not to impose these liabilities on the patient for the government's omission.

The organ transplant process consists of the diagnosis, treatment, and aftercare. The question arising is why a medical scheme agrees to cover the diagnosis and the treatment (the transplant) but refuses to fund the post-operative care. One may argue that by covering the costs for the treatment, they tacitly or by implication accepted (or should expect) the post-operative care as well, yet they denied covering this responsibility. Their refusal is irrational and has placed the patient in a dismal position. She is worse off than before, not to mention the huge financial burden that she will need to carry regarding the post-operative care.

6 CONCLUSION

The National Department of Health and the Council for Medical Schemes should take note of this untenable situation so that the list of PMBs be amended to include a lung transplant as a treatment option for certain lung illnesses. In the meantime, it is our view that the State should be held responsible for the post-operative care of the lung recipient as their official and legal documents are outdated. This is also borne out by the fact that the government has introduced and paid for lung transplants in the public sector to date.