

ORGAN AND TISSUE DONATION IN SOUTH AFRICA

CREATING A NATIONAL STRATEGY ROADMAP



Report from

Southern African Transplantation Society National Conference

International Society of Organ Donation and Procurement

Multidisciplinary Workshop

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Acronyms

ANZOD	Australian and New Zealand Organ Donation Registry
ABTO	Brazilian Organ Transplant Association
CBS	Canadian Blood Services
CCSSA	Critical Care Society of Southern Africa
CCDT	Canadian Council for Donation and Transplantation
CEO	Chief Executive Officer
CIHDOTT	Intra-Hospital Organ and Tissue Transplant Donation Commissions
CLOD	Clinical Lead in Organ Donation
CME	Continuing Medical Education
CMSA	Colleges of Medicine of South Africa
CNCDO	Organ Notification, Procurement and Distribution Centre
CPD	Continuing Professional Development
DBD	Donation after Brain Death
DCD	Donation after Circulatory Death
DHHS	Department of Health and Human Services
GCS	Glasgow Coma Scale
HLA	Human Leukocyte Antigen
HPCSA	Health Professions Council of South Africa
ICU	Intensive Care Unit
IRODaT	International Registry in Organ Donation and Transplantation
ISODP	International Society of Organ Donation and Procurement
IT	Information Technology
LD	Living Donor
MAC	Ministerial Advisory Committee
MEC	Member of the Executive Council
MOOC	Massive Online Open Course
MRC	Medical Research Council
NCB	National Coordinating Body
NDD	Neurological Determination of Death
NDoH	South African National Department of Health
NGO	Non-governmental Organisation
NHA	National Health Act
NHI	National Health Insurance
NHS	National Health Service
NHSBT	National Health Service Blood and Transplant
NKF	National Kidney Foundation
NORS	National Organ Retrieval Service

ODF	Organ Donation Foundation
ODO	Organ Donation Organisation
ODT	Organ Donation Taskforce
OHSC	Office of Health Standards Compliance
ONT	National Transplant Organisation
OPO	Organ Procurement Organisation
OPTN	Organ Procurement Transplant Network
OTA	Organ and Tissue Authority
OTDT	Organ and Tissue Donation and Transplantation
PHC	Primary Health Care
pmp	per million people
POPI	Protection of Personal Information
SABMR	South African Bone Marrow Registry
SANC	South African Nursing Council
SANS	South African Nephrology Society
SATIBA	South Africa Tissue Bank Association
SATS	Southern African Transplantation Society
SATCS	South African Transplant Coordinators Society
SAHCS	Southern African HIV Clinicians Society
SNOD	Specialist Nurse in Organ Donation
SNT	National Transplant System
SOP	Standard Operating Procedure
SRTR	Scientific Registry of Transplant Recipients
TELL	Transplant Education for Living Legacies
TPC	Transplant Procurement Coordinator
TTS	The Transplantation Society
UHC	Universal Health Care
UK	United Kingdom
UNOS	United Network for Organ Sharing
USA	United States of America
WHO	World Health Organization

Message from the Southern African Transplantation Society and Ministerial Advisory Committee

Organ and tissue donation has the potential to change so many lives. It is limited by the number of donors and it is our responsibility, as health care professionals, to ensure that our health care system performs as well as it possibly can.

There is room for much improvement in how we, as a health care system, approach organ and tissue donation in South Africa. This workshop report is the output of a year-long process that brought leading world experts together with local stakeholders and leaders across the field of organ and tissue donation.

High performing donation systems throughout the world have hospital processes in place to support and monitor organ and tissue donation activity. This information is used to generate public reports that hold institutions accountable for providing good end-of-life care and for treating families with compassion in their time of grief. Without referral of potential donors and a timely and considered request for consent to the family, organ donation cannot take place.

The creation of a national culture of donation and a donation system that facilitates this goal are essential to realising the full potential of donation to save and transform lives. Exploring organ donation is a marker of good end-of-life care. It is up to health care professionals to engage with the National Department of Health and our patients and their families to ensure that exploring organ and tissue donation as part of end-of-life care is a standard of practice across all institutions.

This report provides a national strategic roadmap for achieving this goal. Thank you to all who contributed to the project and we look forward to following through on the next steps in improving our South African system.

David Thomson – Executive member of Southern African Transplantation Society, Workshop convenor, Critical Care Subspecialist and Transplant Surgeon, Groote Schuur Hospital and University of Cape Town

The Southern African Transplantation Society is a professional society representing the various professionals that contribute towards organ and tissue donation and transplantation.

Albert Muranda – Ministerial Advisory Committee, Nephrologist, Steve Biko Academic Hospital, University of Pretoria

The Ministerial Advisory Committee advises the National Department of Health on dialysis and transplantation and is responsible for recommending approval of living unrelated and foreign national transplants.

Foreword by the President of the International Society of Organ Donation and Procurement

In September 2019 South African champions for organ donation, in collaboration with leaders from the International Society of Organ Donation and Procurement (ISODP), held a high-level workshop focused on creating a national strategy roadmap to improve organ donation in South Africa.

Led by ISODP Past-President Kimberly Young, Dr David Thomson from the University of Cape Town, and ISODP President Susan Gunderson, this focused two-day workshop brought together key stakeholders from health care providers, government authorities, transplant leaders and donor hospital staff to identify the barriers and opportunities for change and to develop recommendations for a national approach to establishing a comprehensive organ and tissue donation system.

Africa as a continent has many unique obstacles to overcome to improve organ donation rates and access to transplantation for its population. And while some of the pioneering work in organ transplantation originated in South Africa, most notably the world's first human heart transplant in 1967, the country remains challenged by persistently low organ donation rates (approximately 1.5 donors per million population) and poor access to transplantation for the majority of its population.

The workshop brought together international donation leaders with key stakeholders from across South Africa, with an action-oriented focus on developing a national strategy roadmap for enhancing referral and consent practices for organ and tissue donation in the South African context. With a goal of creating a culture of donation, the workshop focused on three main areas:

- Organ donation potential – optimising identification and referral
- Organ donation conversion – consent processes and improving consent rates
- Data collection of key performance indicators and dissemination of this information to promote transparency and accountability to the public.

This ISODP-sponsored workshop is part of an ongoing priority on advancing donation worldwide through professional leadership and development. This is the third in a series of targeted regional initiatives, structured to address unique and specific challenges in the region. Previous successful programmes conducted in Saudi Arabia and China launched structural change and systematic and sustained growth in organ donation in those countries.

Susan Gunderson – President of the International Society of Organ Donation and Procurement; President and CEO, LifeSource Organ Procurement Organization, Minneapolis, USA

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The impetus for the workshop came from the International Society of Organ Donation and Procurement, the Southern African Transplantation Society and the National Department of Health (NDoH).

Contributions were received from many groups to make the workshop a success and the individuals who attended gave freely of their time and expertise.



The NDoH represented and participated in the workshop through Sister Ntebaleng Morolo and Advocate Kgorohlo Moabelo.

The NDoH derives its mandate from the National Health Act (NHA) of 2003, which requires that the NDoH provides a framework for a structured and uniform health system for South Africa. The NHA sets out the responsibilities of the three levels of government in the provision of health services. The main objective of the NDoH is to achieve a healthy life for all. The organ transplant programme in the NDoH and provincial departments of health is supported by Sister Morolo.

Ntebaleng Morolo – Deputy Director of Dialysis and Transplantation at the NDoH

RN, RM, Nephrology Nurse Specialist, BCur I et A

The first Professional Nurse at the NDoH to occupy the position of Deputy Director of Dialysis and Transplantation, Sister Morolo coordinates and supervises all non-related living donor organ transplants of South African citizens and all living donor organ transplants of non-South African citizens, including applications to place non-South African citizens on the South African deceased donor transplant list. Sister Morolo also provides general information about dialysis and transplantation to patients, the public and the media, participating in public awareness and education campaigns.

Sister Morolo assists in the formulation of policies, guidelines and regulations, and she oversees the South African Renal Registry. She is member of the Ministerial Advisory Committee on Dialysis and Transplantation and is a board member of the National Kidney Foundation of South Africa. She is a past committee member of the Renal Care Society of South Africa. Sister Morolo is the co-author of several publications on living kidney donation in South Africa and Africa.

Sister Morolo has 44 years of nursing practice, of which 26 years have been as a dialysis and transplant specialist. She is a founder member of the George Mukhari Hospital Renal Unit, in August 1983, which marked the beginning of her nephrology-nursing career. In 1993, she obtained her Certificate in Nephrology Nursing and later transferred to Charlotte Maxeke Johannesburg Hospital. Sister Morolo earned her Bachelor of Nursing in Education, Management and Community Nursing Science as an extra course from the University of Pretoria, and a Diploma in Critical Nursing specialising in Nephrology at Nelson Mandela Metropolitan University. She was appointed Live Donor Transplant Coordinator in 1997 at Charlotte Maxeke Johannesburg Hospital. Furthermore, she has worked for three years as Senior Dialysis nurse in the United Kingdom at King's College Hospital, Guy's Hospital and St Thomas' Hospital.

Advocate Kgorohlo Moabelo – Director, Legal Services at the NDoH

Advocate Moabelo was admitted as an advocate of the High Court of South Africa in 2007. He has been in public service since 2000, having worked for the Mpumalanga Department of Education and Department of Social Development, the National Department of Environmental Affairs and Tourism and the Department of Defence. Advocate Moabelo holds three law degrees, Baccalaureus Iuris (B Iuris), Bachelor of Laws (LLB) and Master of Laws (LLM). He has extensive experience in the development of policies, regulations and legislation.

“Organ and tissue donation in South Africa has the potential to help so many. This workshop and the report generated offers a framework to improve our donation system to help us improve availability of lifesaving and life-altering procedures to the population of South Africa.”

“The Department of Health has participated actively in the process and has expressed a desire in implementing the well thought through improvement strategies contained herein. Organ donation depends on many factors and no one aspect happens in isolation. As such, it is important that we all act together in achieving these goals.”

Executive summary

A strategic roadmap for improving deceased donation in South Africa was created by various role players in organ and tissue donation from across South Africa, with input from international experts.

Deceased donation was identified as the most effective area to rapidly improve access to transplantation given the room for improvement relative to the performance of other countries. This is evidenced by multiple examples of national initiatives to restructure systems, training and education, which show large improvement in outcomes with limited investment.

“It is not the fault of the population not to realise the full potential of deceased organ donation. It is a reflection of the health care system.”

Rafael Matesanz (ONT – Spain)

Seven priority areas were identified and developed during the course of a two-day workshop. The ultimate goal was to facilitate, across our health care system, a culture of donation where compassionately exploring organ and tissue donation at the end of life in all appropriate circumstances is recognised and monitored as a marker of good health care.

The priority areas identified for improvement were:

- **Optimising organ donation potential** through appropriate and timely identification, assessment and referral of potential donors
- **Optimising organ donation conversion** through best practice consent approaches and donor management
- **Standardised data collection** for ongoing quality improvement and public accountability
- **Foundational system development (National Department of Health development)** to provide leadership, guidance and coordination across the various components of the donation system
- **Legislation and policy development** to support governance and compliance with leading practices
- **Professional education and practice** to assist implementation of policy and best practice
- **Public awareness** to highlight the benefits and ensure the support of the organ donation system.

A vision of organ and tissue donation in South Africa was discussed, together with the need to create a mandate for change under an officially sanctioned and supported coordinating body that is empowered by the government to administer these activities in a publicly accountable manner. While infrastructure and expertise exist in various sectors, there is a need to better coordinate and support these activities centrally. This vision aligns well with the goal of National Health Insurance to improve access to health care resources for the whole population in an open, transparent, accountable and cost-effective manner.

Across South Africa there are various cultural and religious views on organ donation and yet no culture or religion is against helping our fellow man. As health care professionals, the life saving benefits of organ and tissue donation are beyond doubt; this priority roadmap outlines a strategy towards a substantial and dramatic increase in organ and tissue donation and the consequent benefits to the health of our nation.

“Governments are accountable for the implementation of transplantation programmes in which the opportunity to benefit is shared equitably across the population. Achieving this requires: (i) appropriate legislation, regulation and oversight, (ii) registries to monitor activities and outcomes and to ensure transparency of practices; and (iii) the optimisation of activities – consistent with competing demands on health resources – by focusing on specialist training, particularly the training of transplant coordinators and the implementation of a structured professional network that incorporates continuous training and performance assessment.”

World Health Organization



**World Health
Organization**

*“It is not up to the clinician to decide about donation,
but it is a standard of care at end-of-life to compassionately
explore the option of donation with the family.”*

Stephen Beed (ISODP President)



Chapter 1

Introduction

Opportunities for deceased organ donation are rare events, with only 1-2% of all deaths being candidates for organ recovery. Globally, persistent shortages of deceased donor organs remains one of the greatest challenges to expanding access to solid-organ transplantation for individuals with end-stage organ failure. Best care for end-stage organ failure is with transplantation as the alternative is, for most organs, death on the waiting list or years of costly dialysis for those few who are able to access it. Transplant activity in South Africa remains lower than that achieved by other countries with a comparable economic capacity.

Increased deceased donation enables exponential improvements in numbers of patients accessing transplant. This cannot happen without recognition by the treating health care professionals of the potential for donation or without consent from the next-of-kin. All families should be given the opportunity to consider the option of donation as part of optimal end-of-life bereavement care.

Deceased donation is agreed to be the foremost element of the organ and tissue transplant process in which significant improvements can be made to ensure enhanced access to transplantation for all people in South Africa. Potential organ donors are identified by clinical teams involved in their treatment and must be certified dead by the treating clinical teams independent of the transplant teams (*see Figure 1 - The critical pathway of organ and tissue donation, Appendix 1 - Critical pathway for deceased organ donation*). Donation situations are rare, high-acuity and emotional events.

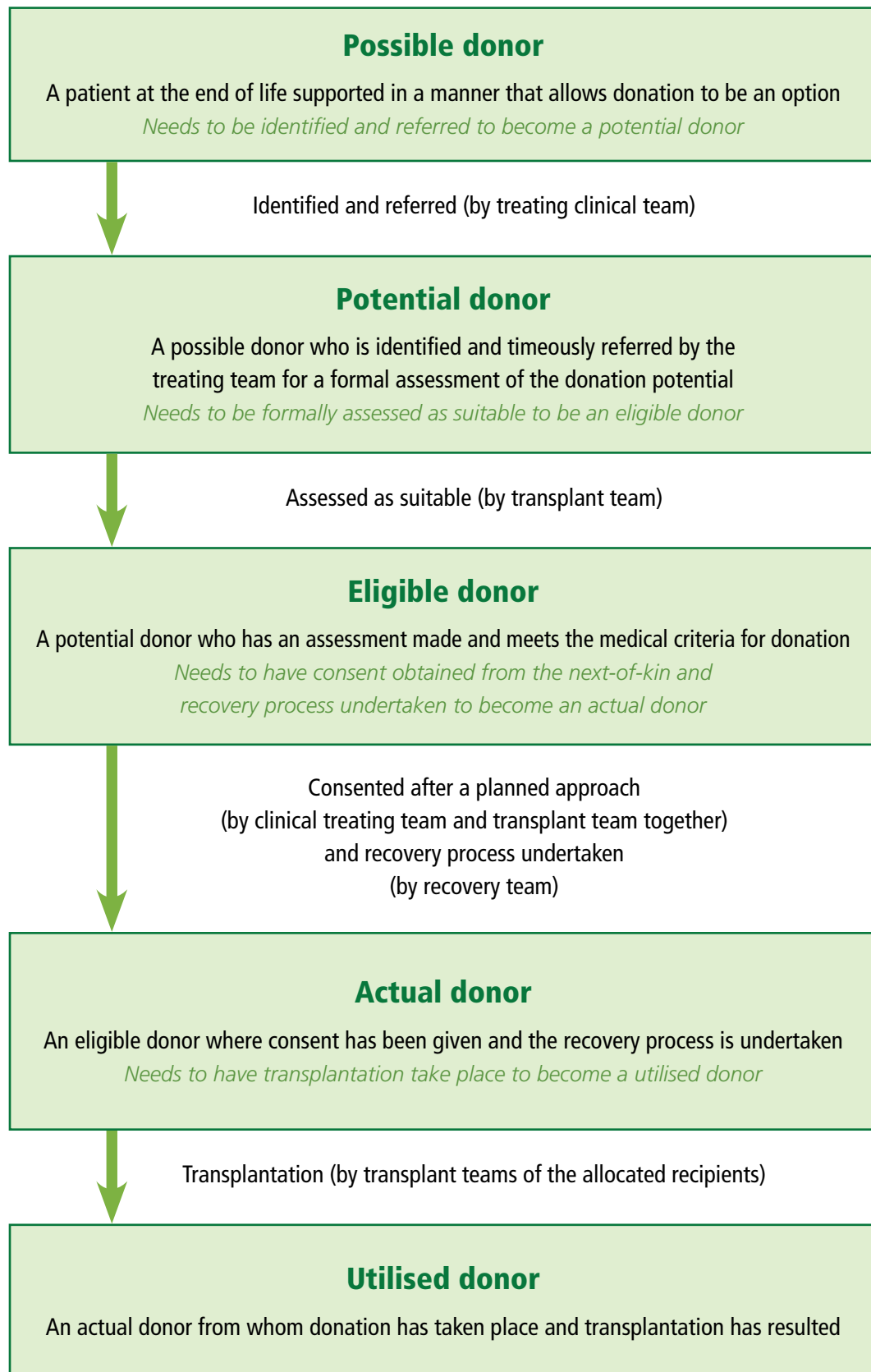


Figure 1 | The critical pathway of organ and tissue donation

Adapted from: Domínguez-Gil B, Delmonico FL, Shaheen FA, *et al.* The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transpl Int.* 2011 Apr; 24(4):373-8. doi: 10.1111/j.1432-2277.2011.01243.x. PMID: 21392129. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1432-2277.2011.01243.x>

Limited investment is required for the successful implementation of strategies that focus on maximising coordination of existing infrastructure and expertise in South Africa.

A lack of resources and, importantly, a ‘scarcity’ mindset have an impact on both the size of the potential organ donor pool and on conversion rates from obtained consent to organ recovery. Resource issues pose obstacles but are amenable to strategic intervention.^[1] As an example, highly specialised transplant units are not continually operating owing to persistently low organ donor rates^[2] despite the willingness, in general, of the South African public to donate.

A national strategy that is appropriate to the needs of the unique South African socioeconomic and health care framework is imperative to better coordinate initiatives for improved access to organ transplantation.

In considering this need, role players in organ and tissue donation and transplant from across South Africa met to develop a national strategic roadmap for improving deceased donation. A two-day workshop supported by the International Society of Organ Donation and Procurement (ISODP) and the National Department of Health (NDoH) was conducted at the Krystal Beach Hotel, Gordon’s Bay, Cape Town on the 4th and 5th September 2019, attached to the biennial Southern African Transplantation Society (SATS) meeting. The workshop programme was developed by a steering committee through a series of conference calls over a period of six months (see *Appendix 2 - Steering committee process and terms of reference*).

The core assumption of the workshop was that organ donation is reliant on the health care system to identify all potential donors, to timeously refer potential donors to the transplant team, to support the consent process, and to medically manage the donor in a manner that is optimal to facilitate organ and tissue recovery and subsequent transplantation activity.

The objectives of the workshop were to:

1. Consult with experts and key influencers on the current situation with respect to organ and tissue donation in South Africa and on how to optimise the number of consented donors
2. To review and benchmark existing practices/guidelines and policies in South Africa in relation to donor identification, referral, consent, and tissue and organ management
3. To identify factors that are supportive of, or disincentive to, optimal organ and tissue recovery including referral triggers, consent practices, cost, equipment, access to intensive care unit (ICU) and operating room, and disparate funding for state and private sector health services
4. To initiate the development of a national strategic vision 2025, with biannual reporting on the progress of related support systems necessary to implementing optimal donor referral and consent practices and optimal donor support, with a formal reassessment of the strategic vision in 2025
5. To develop a national research agenda for organ and tissue donation and consent practices in collaboration with the Medical Research Council (MRC) of South Africa
6. To disseminate the workshop findings to health care professionals, managers and administrators on a hospital, provincial and national level.

^[1] Moosa MR. The state of kidney transplantation in South Africa. *S Afr Med J* 2019 Mar 29;109(4):235-240. doi: 10.7196/SAMJ.2019.v109i4.13548. <http://www.samj.org.za/index.php/samj/article/view/12575>

^[2] Crymble K, Fabian J, Etheredge H, et al. Perceptions of nurses’ roles in end-of-life care and organ donation - imposition or obligation? *S Afr Med J* 2017 Jun 30;107(7):573-575. doi: 10.7196/SAMJ.2017.v107i7.12487. <http://www.samj.org.za/index.php/samj/article/view/11948>

Prior to the workshop, all participants completed a survey to identify priority areas for improvement within the South African organ and tissue donation system (see *Appendix 3 - Pre-workshop participant survey*). Clinicians and hospital managers interacting with transplant centres were also surveyed to identify their contextual priorities.

An independent process consultant (Strachan-Tomlinson) was employed through a grant secured from the ISODP to manage and facilitate the workshop. International experts who have helped, through outreach programmes, to effect system change in their own countries and in other countries were identified and funded by the ISODP to share their experiences and lessons learned in improving donor potential across a range of health care systems (see *Appendix 4 - International faculty*).

Four focus areas were identified by the steering committee as being key to creating a culture of donation within South Africa:

- 1. Improving organ donation potential**
Identification and referral of potential donors through the coordination of, for example, organ donation organisations and processes, hospital leadership roles, and transplant coordinator positions
- 2. Improving organ donation conversion**
Increasing consent rates of potential donors through the implementation of, for example, best practice guidance for requesting consent and donor management
- 3. Improving data collection of key performance indicators**
Enabling ongoing quality assurance, with dissemination of this information to the public in the interest of promoting transparency and accountability
- 4. Creating the governance structure and regulatory oversight necessary to the above-mentioned processes, in conjunction with the NDoH.**

The workshop was divided into two broad components. Firstly, a morning of presentations included: (i) Outlining the current South African situation from a Ministerial Advisory, an organ, and a tissue perspective; and (ii) International perspectives on similar initiatives to develop an effective national strategic priority roadmap for optimal deceased donation. Thereafter, participants (see *Appendix 5 - Workshop participants*) were divided into seven facilitated discussion groups each consisting of seven or eight people, with the aim of developing each of the priority areas identified in the pre-workshop survey. This facilitated discussion process was guided by the parameters of foundational core assumptions and key considerations, as outlined in the steering committee process and terms of reference guiding document (see *Appendix 2*).

Chapter 2

Environmental scan of the South African organ and tissue donation landscape

All centres involved in organ and tissue recovery across South Africa (see *Appendix 6 - Transplant centres and tissue banks involved in deceased donation*) were invited to participate in an environmental scan conducted to assess the current status of donation and transplant activity. The environmental scan reviewed current transplant facilities, the specialist roles working in transplantation, donor rates, data quality, and legislation and regulation in South Africa. Respondents represented 16 of 21 transplant centres in South Africa (see *Appendix 7 - Environmental scan transplant centre respondents*). The online questionnaire, consisting of 96 questions, was either organ donation-specific or tissue donation-specific (see *Appendix 8 - Environmental scan questionnaire*).

Human solid organs donated in South Africa include heart, lung, liver, kidney and pancreas. Human tissues and cells donated in South Africa include heart valves, stem cells, cornea and sclera, amnion, blood and blood-related products, skin, gametes, bone and tendon, bone marrow, femoral heads, and cord blood and tissue. Organ donors are exclusively from the hospital setting whereas human tissue donors may come from hospitals, forensic pathology services or funeral homes.

The practice of organ and tissue donation and allocation is spread across many different interest groups working within transplantation and has given rise to differing sets of practice based on local situations and varied resource investment. Although organ and tissue donation is covered by the National Health Act (NHA),^[1] there are no official guidelines and regulations emanating from or recognised and endorsed by the NDoH and there is no central coordination role played by the NDoH in promoting best practices in deceased donation. The Ministerial Advisory Committee (MAC) reviews non-related living transplants and foreign nationals requiring transplantation, both of which need Ministerial approval.

^[1] Muller E, Thomson D, McCurdie F. Transplantation in South Africa. *Transplantation* 2015 Apr; **99**(4):643-5. doi: 10.1097/TP.0000000000000712. https://journals.lww.com/transplantjournal/Fulltext/2015/04000/Transplantation_in_South_Africa.1.aspx

Guidance regarding best practice in deceased donation is provided through self-regulation by professional societies, hospital groups and transplant teams (see *Appendix 9 - Professional society guidance documents*). South African organisations and professional societies supporting organ and tissue donation (see *Appendix 10 – South African organisations supporting organ and tissue transplantation*) include:

- SATS
- South Africa Tissue Bank Association (SATiBA)
- South African Nephrology Society (SANS)
- Critical Care Society of Southern Africa (CCSA)
- Organ Donor Foundation (ODF)
- Transplant Education for Living Legacies (TELL).

2.1 Transplant facilities

Access to organ transplantation is limited in South Africa. Organ transplantation is more easily available to people in urban centres and those with the means to access private health care; both settings have greater resources, such as dialysis, and more specialists proportional to the population served that can support patients with end-organ failure. Individual transplantation centres in South Africa offer different types of transplants at different volumes, with transplant outcomes being better at high-volume centres.

Transplantation services in South Africa are confined to large urban areas in wealthier provinces. There are currently 21 transplant centres including three cornea and eye banks, one heart valve bank and one multi-tissue (bone, skin and cornea) bank (see *Figure 2 - Organ transplant centres in South Africa; Figure 3 - Tissue transplant centres in South Africa*).

There are differences in transplantation services offered between the state and the private sectors and service offerings also differ across the various transplant centres: 14 hospitals offer kidney transplantation as compared to six hospitals offering heart transplant, four hospitals offering lung transplant, four hospitals offering liver transplant, and one hospital offering pancreas transplants.

Accurate assessment of the number of treatment centres and hospitals participating in transplant activities is not possible due to the lack of centralised and mandatory reporting requirements. The Renal Registry 2016 report (see *Appendix 11 - Participating treatment centres for dialysis and transplant*) gives a representation of the number of health facilities participating in and, in the case of private facilities, earning money from the management of end-stage renal failure.^[1] Dialysis is the most easily implemented and widespread treatment for end-stage organ failure; it must be noted however that dialysis is far more expensive than a deceased donor renal transplant and that patients with end-stage kidney disease have a shorter life expectancy and a lower quality of life on dialysis. Hospitals and companies offering chronic dialysis services are not obligated or regulated to contribute towards donation and transplantation activity in a formalised manner, as they are in other countries.

Organ and tissue donation is unfortunately not addressed as a collective responsibility across all health care institutions, with responsibility for donation perceived to be that of the transplant teams. As such, there is no monitoring or accountability for the identification and referral of potential donors as part of best practice end of life care across health care institutions. National core standards and the ideal hospital framework do not include any audit mechanism of approaches for organ donation at present.

^[1] Davids MR, Jardine T, Marais N, et al. South African Renal Registry Annual Report 2016. *African Journal of Nephrology* 2018; 21(1): 61-72. <https://www.journals.ac.za/index.php/ajn/article/view/3298>

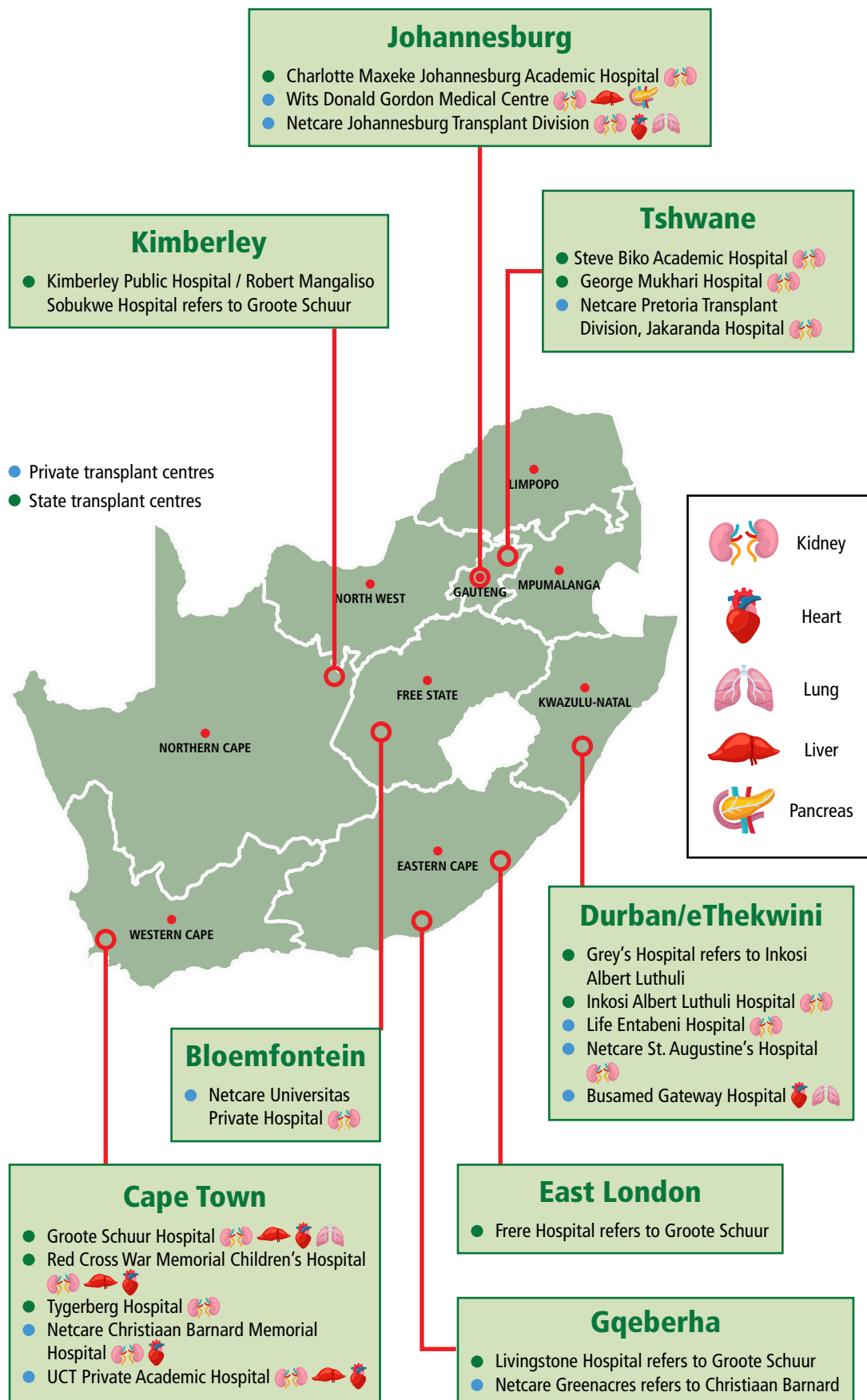


Figure 2 | Organ transplant centres in South Africa

Reflecting geographic distribution of transplant centres and organ transplant services offered

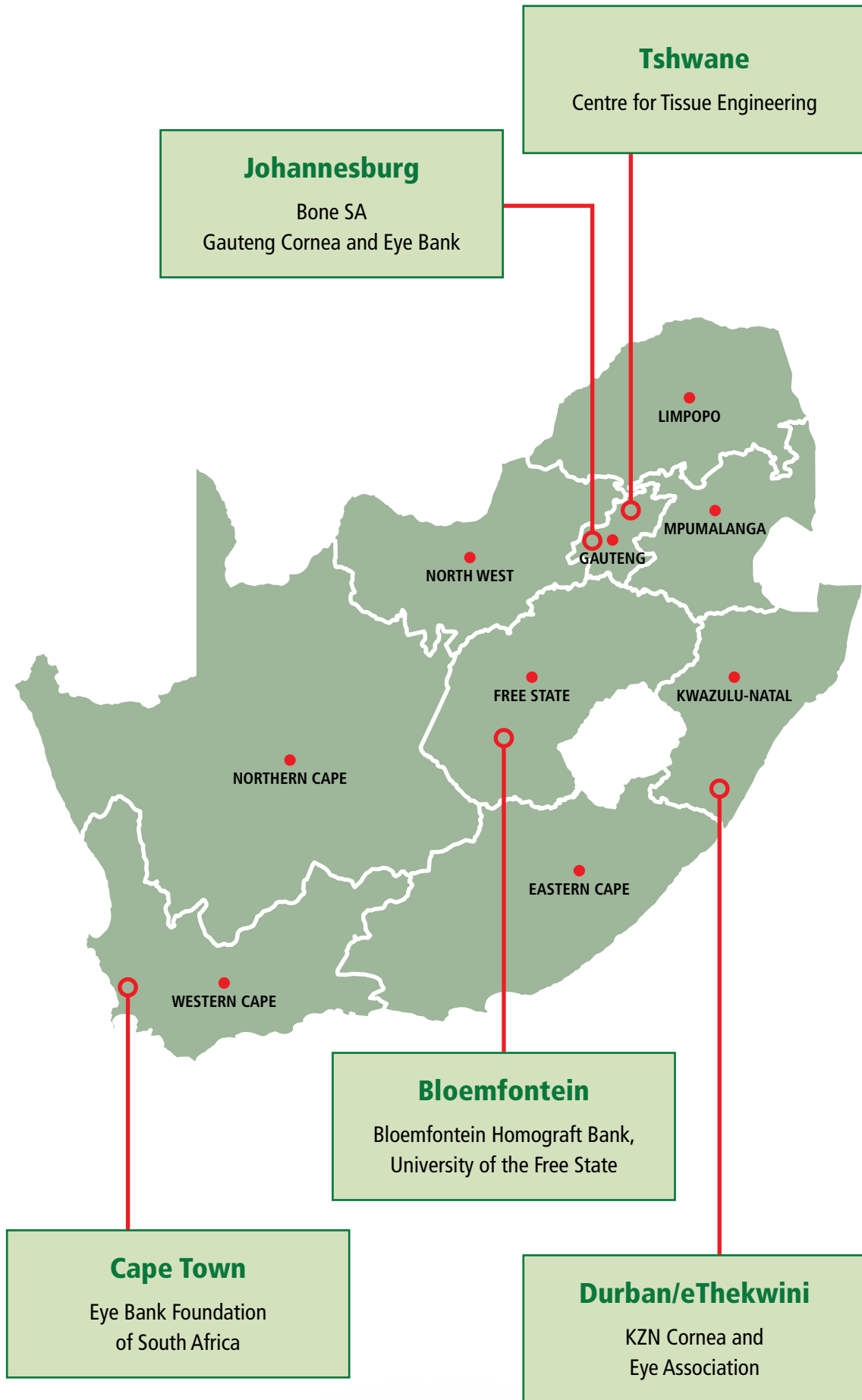


Figure 3 | Tissue transplant centres in South Africa

2.2 Specialist roles

Transplant coordinators

Transplant coordinators are critical to organ donation as they are the key point of contact between the bereaved family, the clinical team and the transplant team.^[1] The roles and responsibilities of a transplant coordinator in South Africa are not formally defined and vary between transplant centres. Scope of practice includes deceased donor procurement, education of medical staff and the public, living donor work-up, recipient work-up and listing, paired-kidney programmes, and other responsibilities such as dialysis, trauma, ICU and transplant ward work. Most transplant coordinators perform other non-transplant roles in the scope of their employment, commonly in the dialysis unit or ICU.

South Africa does not have an accredited national training programme for transplant coordinators. Existing training resources include the University of the Witwatersrand's Transplant Procurement Handbook^[2] and Organ Donation: From Death to Life,^[3] a massive online open course (MOOC) from the University of Cape Town.

Transplant coordinators are not available in many hospitals and even provinces; in this case a local untrained doctor or nurse may attempt, if a possible donor is identified, to cover all of the responsibilities of a transplant coordinator along the donation pathway. The few transplant coordinators that are available are tasked, because of limited local expertise in the donation process, with travelling to sometimes remote donor hospitals to approach grieving families, irrespective of the time of day, and to cover large distances with minimal administrative, clinical, and safety and security support. Transplant coordinators based remotely from the urban transplant centres operate in isolation, with the work being viewed as a burden and not a responsibility.

There is no national mandate to develop and implement donor identification programmes in South Africa through the appointment of a donation coordinator role in every hospital that has the capacity to participate in organ donation.^{[4][5]} Creating a broad network, throughout all state and private hospitals, of accountable health care professionals that are trained in the role of donation coordination is the backbone of all high performing donation systems around the world.

^[1] South African Medical Association. Ethical Guidelines for Organ Transplantation in South Africa. <https://www.samedical.org/cmsuploader/viewarticle/903>

^[2] Wilmans C, De Jager M. Wits Transplant Procurement Handbook: A Practical Guide to Organ Donor Procurement; 1st edition – September 2019. <http://www.dgmc.co.za/docs/Wits-Transplant-Procurement-Handbook.pdf>

^[3] Thomson D. Organ Donation: From Death to Life. <https://www.coursera.org/learn/organ-donation>

^[4] De Jager M, Wilmans C, Fabian J, *et al*. Increasing deceased organ donor numbers in Johannesburg, South Africa: 18-month results of the Wits Transplant Procurement Model. *S Afr Med J* 2019 Aug 28; **109**(9):626-631. doi: 10.7196/SAMJ.2019.v109i9.14313. <http://www.samj.org.za/index.php/samj/article/view/12701>

^[5] Crymble K, Fabian J, Etheredge H, *et al*. Perceptions of nurses' roles in end-of-life care and organ donation - imposition or obligation? *S Afr Med J* 2017 Jun 30; **107**(7):573-575. doi: 10.7196/SAMJ.2017.v107i7.12487. <http://www.samj.org.za/index.php/samj/article/view/11948>

Of the 23 organ and tissue transplant coordinators in South Africa, 11 work in the private sector and 12 work in the state sector. Most transplant coordinators are based in Gauteng (16 in Johannesburg, six in Pretoria). Eleven transplant coordinators work in Cape Town, six work in Durban and there is one transplant coordinator each working in East London, Port Elizabeth and Umtata (see *Figures 4a and 4b – Deceased donor and organ transplant activity in South Africa, 2018/2017*). The deceased donation organ procurement needs of the country in 2015 were, reportedly, serviced by 16 deceased donor transplant coordinators for a population of 56 million with an equal split between private and state sector institutions. Most of these transplant coordinators were noted to spend only 25-50% of their time on deceased donation activity.^[1]

The low number of tissue coordinators in South Africa is ascribed to financial and other constraints that include the lack of new entrants into the industry, no changes in leadership, limited funding opportunities and no new expertise. Environmental scan respondents mostly perceived tissue and eye banks to have become stagnant over the past decade.

Transplant surgeons

Of the 36 surgeons working in transplantation (20 private sector, 16 state sector), many perform other non-transplant roles in the scope of their practice or employment. Emergent from the environmental scan, 60% of participants felt that surgeon availability was a rate-limiting step to organ recovery. Transplant coordinators perceive time spent by the surgeon on deceased donation and transplant activity to be an average of 35%.

Donor champions

Donor champions, also referred to as link nurses, transplant champions or donor identifiers, are responsible for educating all new staff on organ donation, organising in-house training that is required on organ donation, functioning as the link between ICU and transplant teams, and completing the ICU death audit.

Donor champions are based in ICU and emergency departments and are not employed by transplant centres. The presence of trained referral champions in the ICU or emergency unit of hospitals is limited to a current initiative in Gauteng.

There are no accredited national training programmes to guide donor champions in the referral of possible donors and deaths to transplant coordinators, and there are no national protocols and policy that can be adhered to by all doctors and nurses along the donation pathway; standardised donor referral documentation exists only within different groups involved in transplantation. The lack of national, centralised minimum recording criteria creates difficulties in evaluating performance measurements and quality improvement markers in deceased donation.

^[1] Muller E, Thomson D, McCurdie F. Transplantation in South Africa. *Transplantation* 2015 Apr; **99**(4):643-5. doi: 10.1097/TP.0000000000000712. https://journals.lww.com/transplantjournal/Fulltext/2015/04000/Transplantation_in_South_Africa.1.aspx



Transplant Statistics

2018

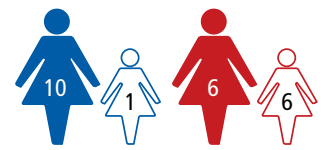
**Deceased donation
and transplantation
activity**

National deceased donation statistics (2018)

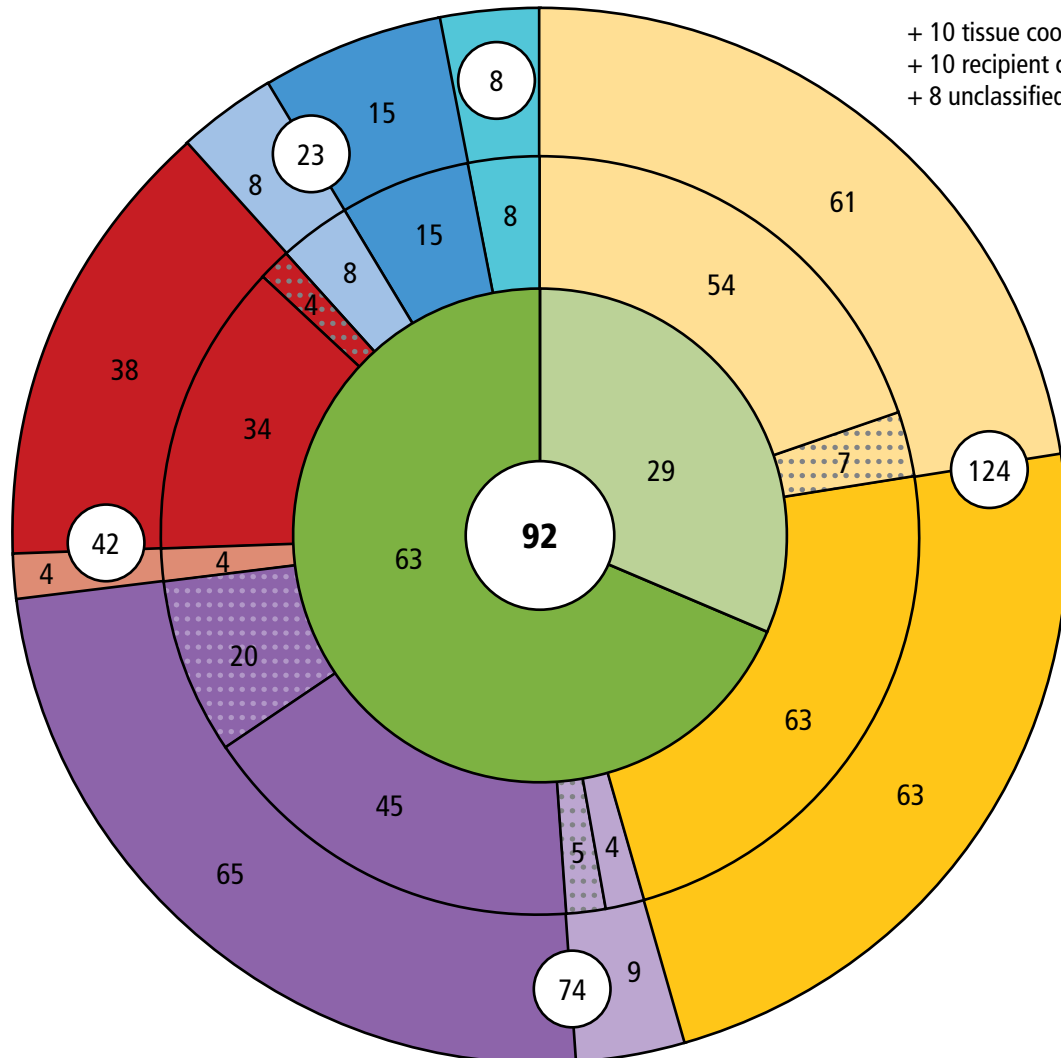
Population 59 622 350

Donors pmp 1.62

Annual deaths 446 544*



+ 10 tissue coordinators
+ 10 recipient coordinators
+ 8 unclassified coordinators

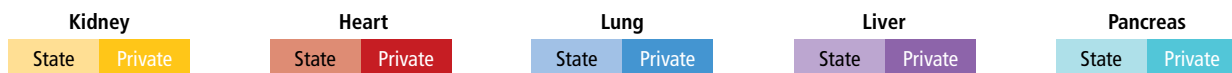


* 17 213 unspecified deaths

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

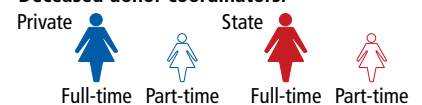


Figure 4a | Deceased donor and organ transplant activity in South Africa, 2018

Populations data from <https://www.southafricanmi.com/population-density-map.html>

Death data from Department of Statistics South Africa, Mortality and causes of death in South Africa: Findings from death notification 2017.

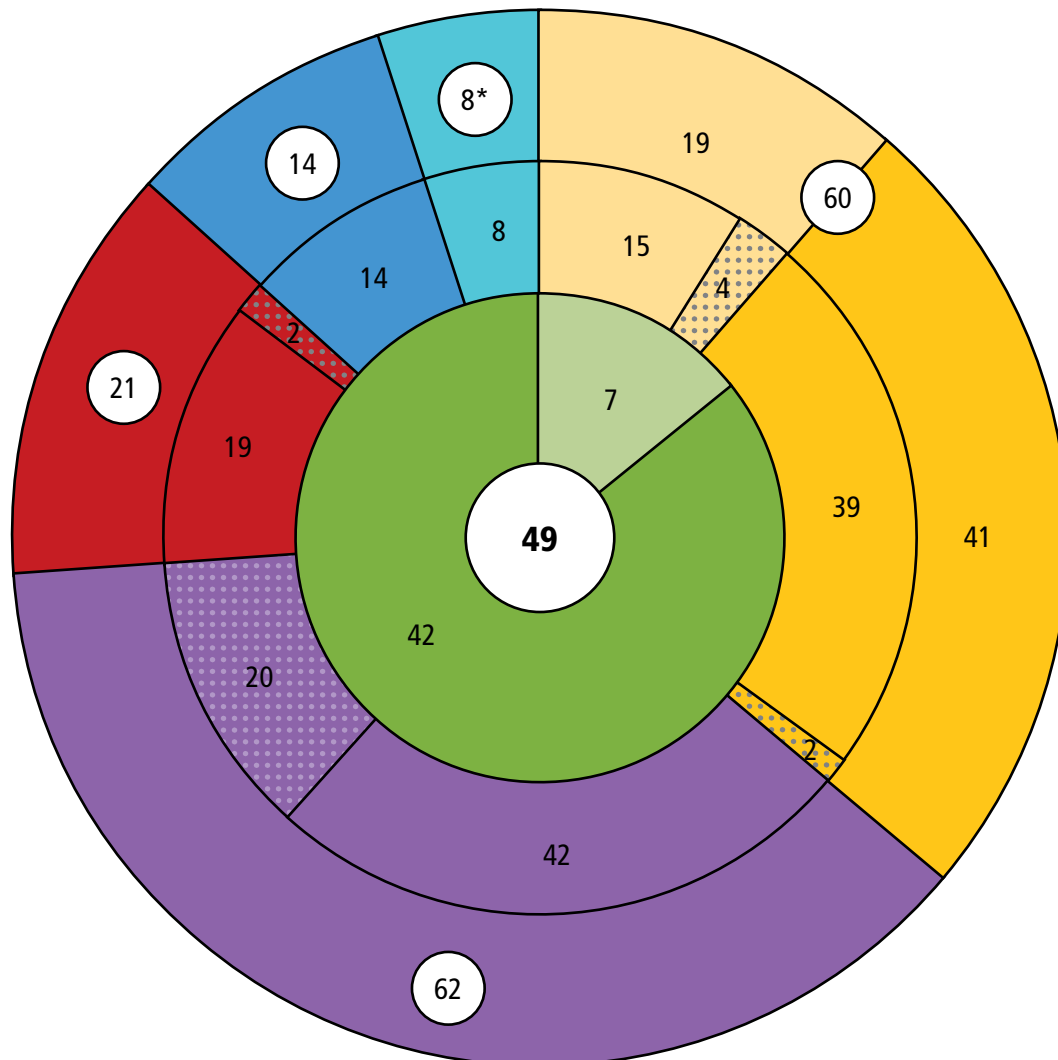
<http://www.statssa.gov.za/publications/P03093/P030932017.pdf>

Gauteng deceased donation statistics (2018)

Population 15 488 137

Donors pmp 3.33

Annual deaths 92 523

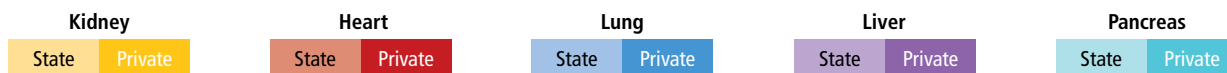


* All simultaneous kidney-pancreas transplants

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



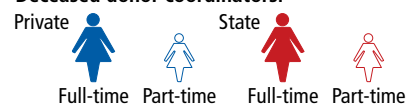
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

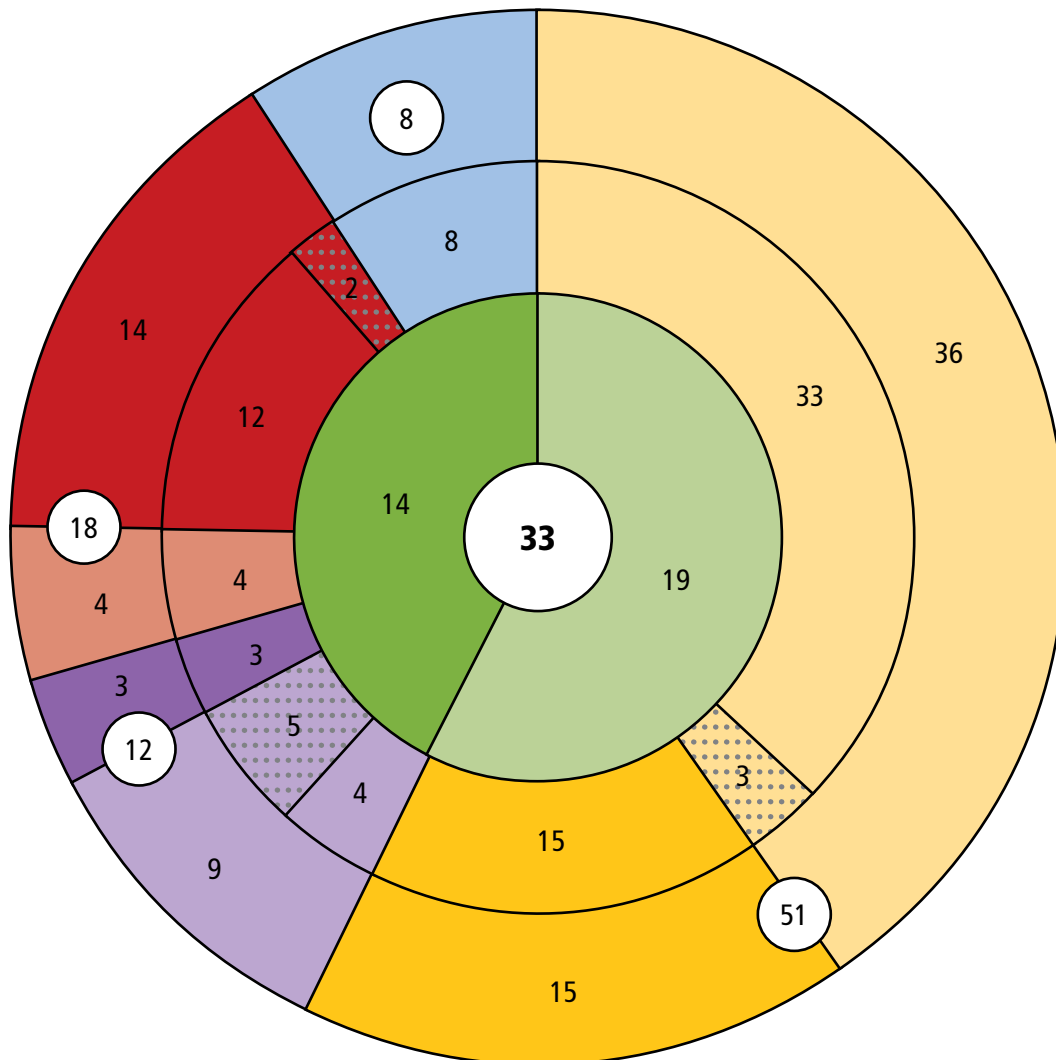
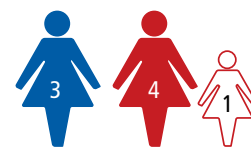


Western Cape deceased donation statistics (2018)

Population 7 005 741

Donors pmp 4.98

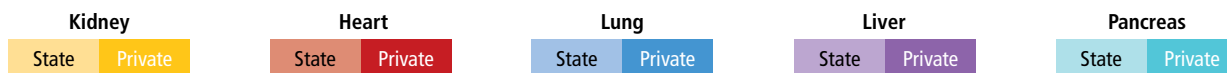
Annual deaths 45 715



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

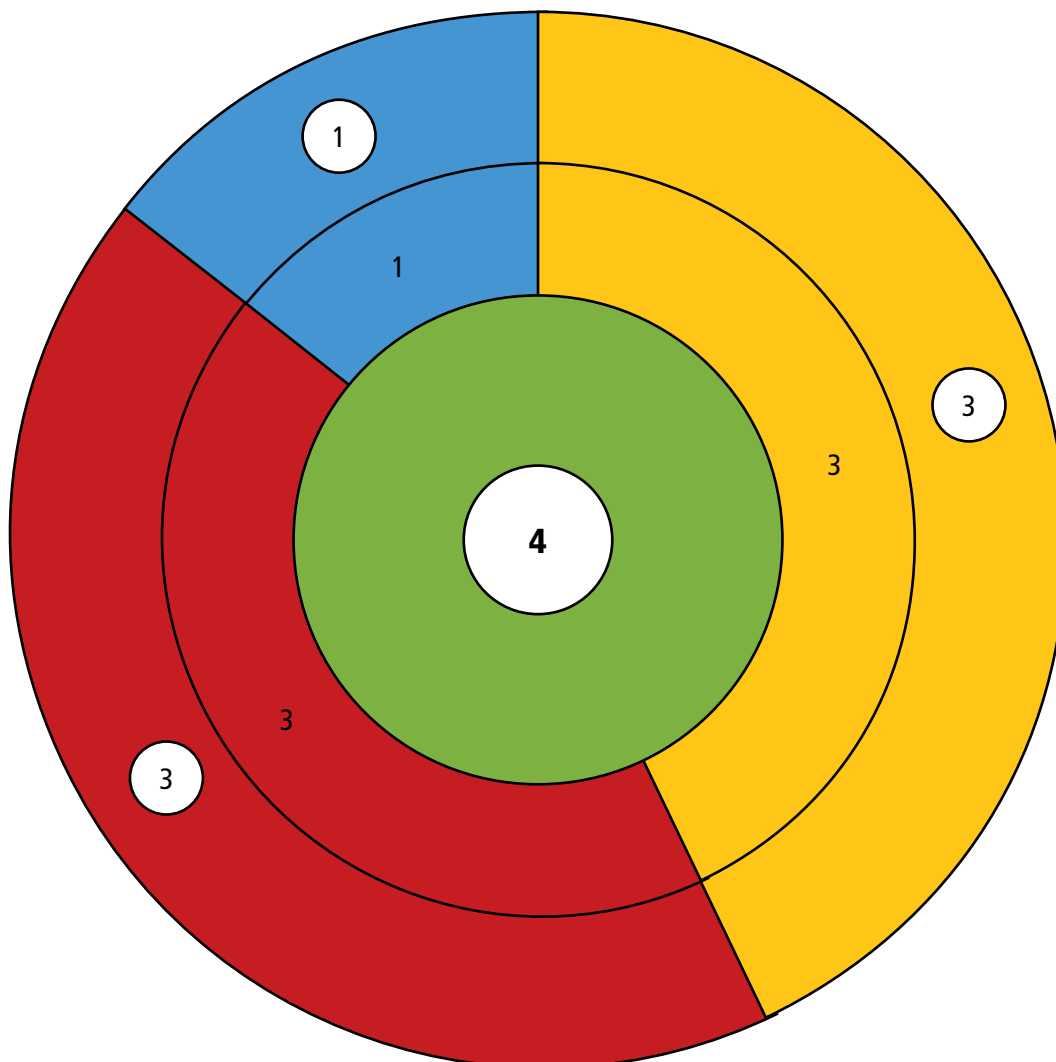
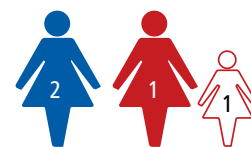


KwaZulu-Natal deceased donation statistics (2018)

Population 11 531 628

Donors pmp 0.35

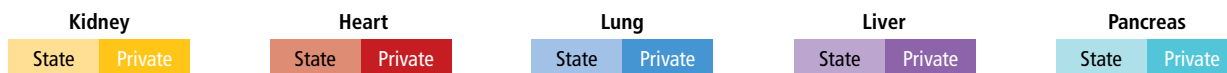
Annual deaths 76 605



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



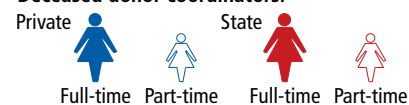
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

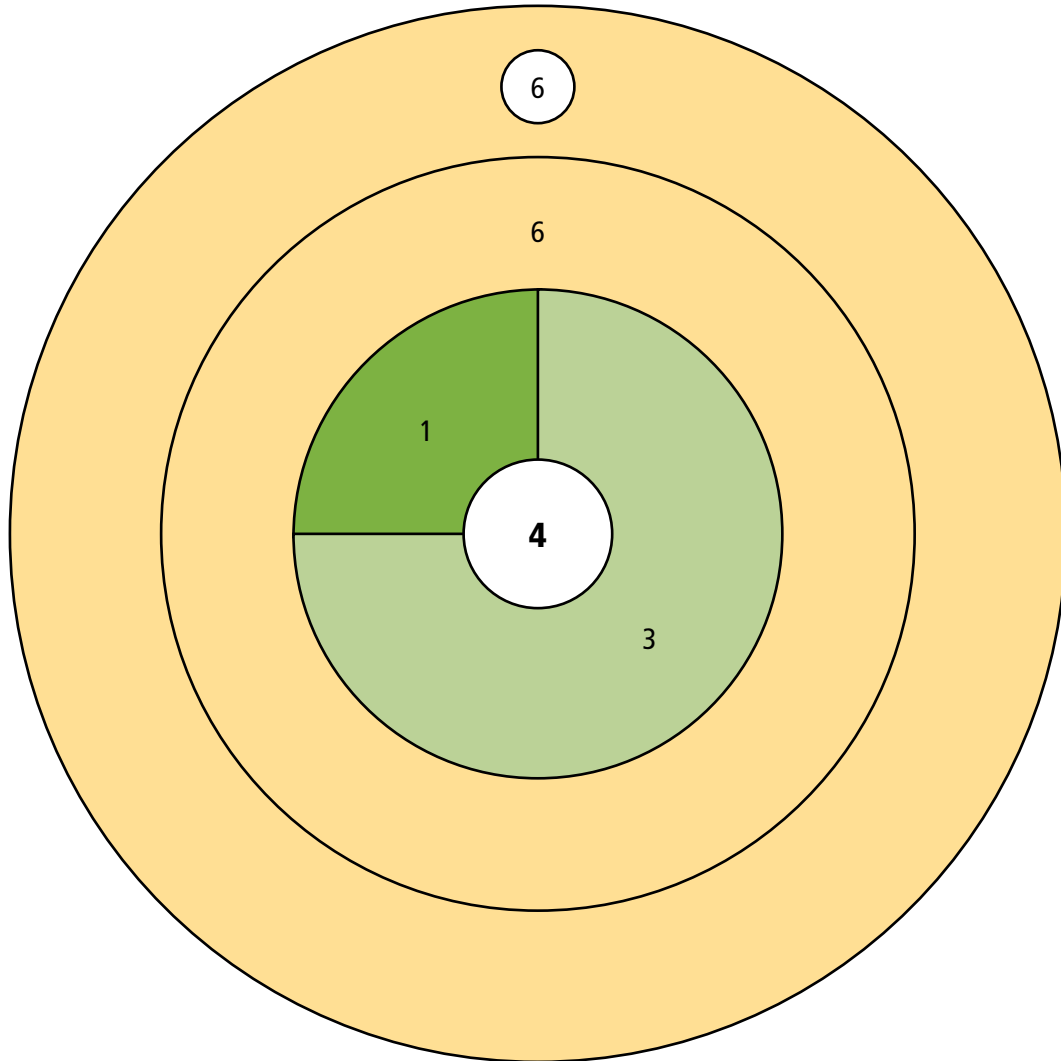
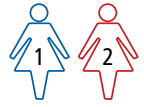


Eastern Cape deceased donation statistics (2018)

Population 6 734 001

Donors pmp 0.61

Annual deaths 65 162

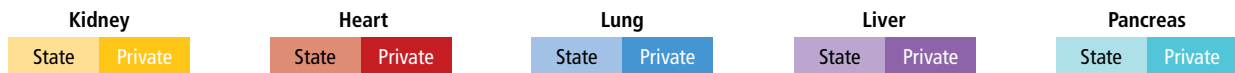


Deceased donor kidney transplants performed in the Western Cape

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

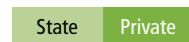
Outer ring: reflects total number of transplants for each organ type



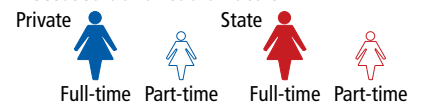
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



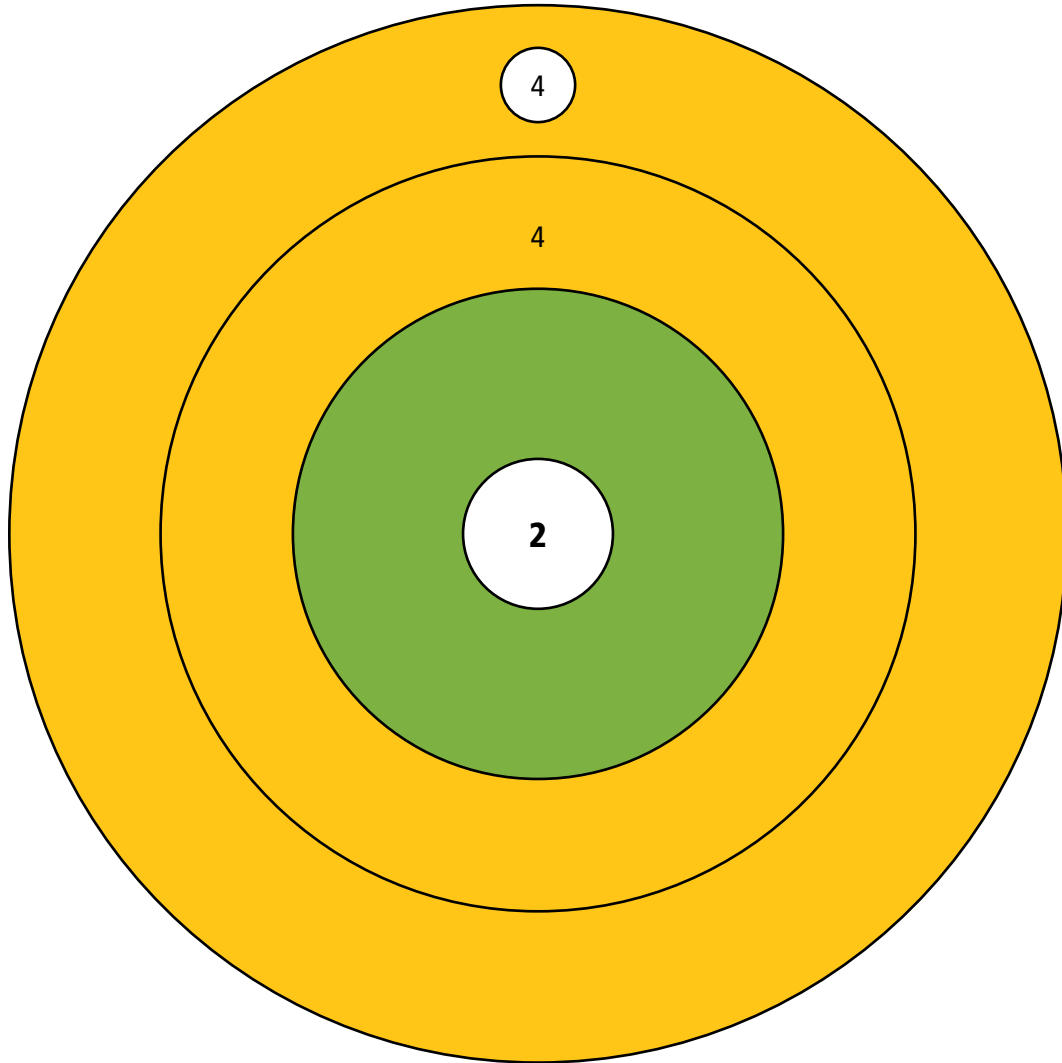
Free State deceased donation statistics (2018)

Population 2 928 903

Donors pmp 0.68

Annual deaths 31 208

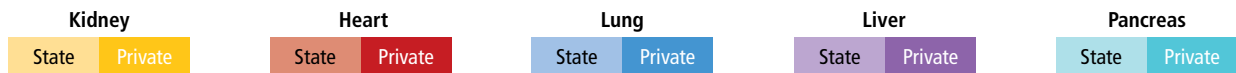
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

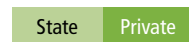
Outer ring: reflects total number of transplants for each organ type



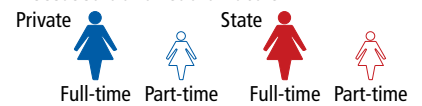
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

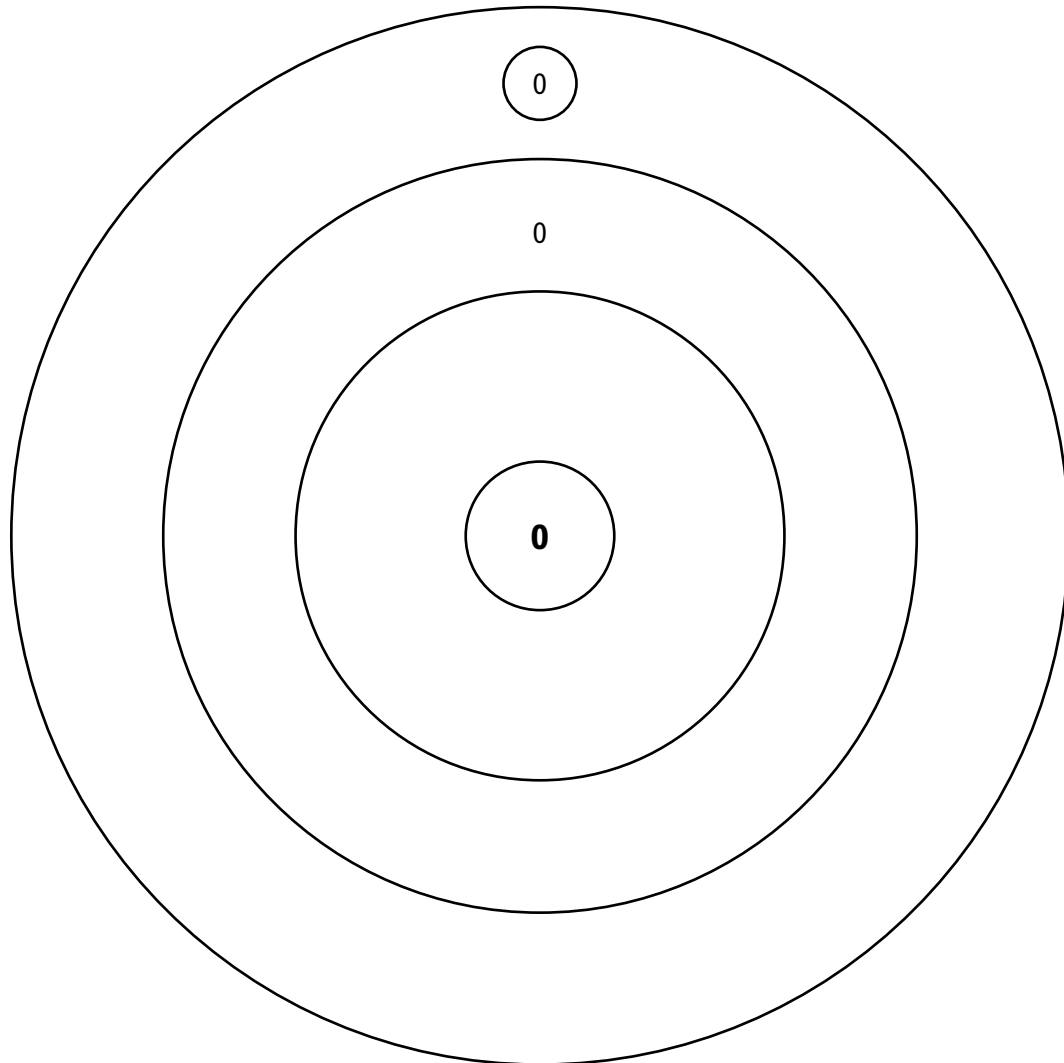


Northern Cape deceased donation statistics (2018)

Population 1 292 786

Donors pmp 0.00

Annual deaths 12 638

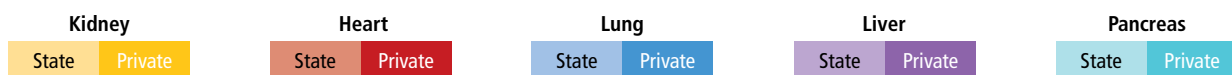


Deceased donor kidney transplants performed in the Western Cape

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



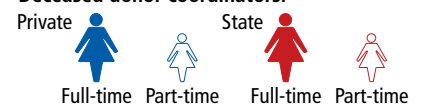
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



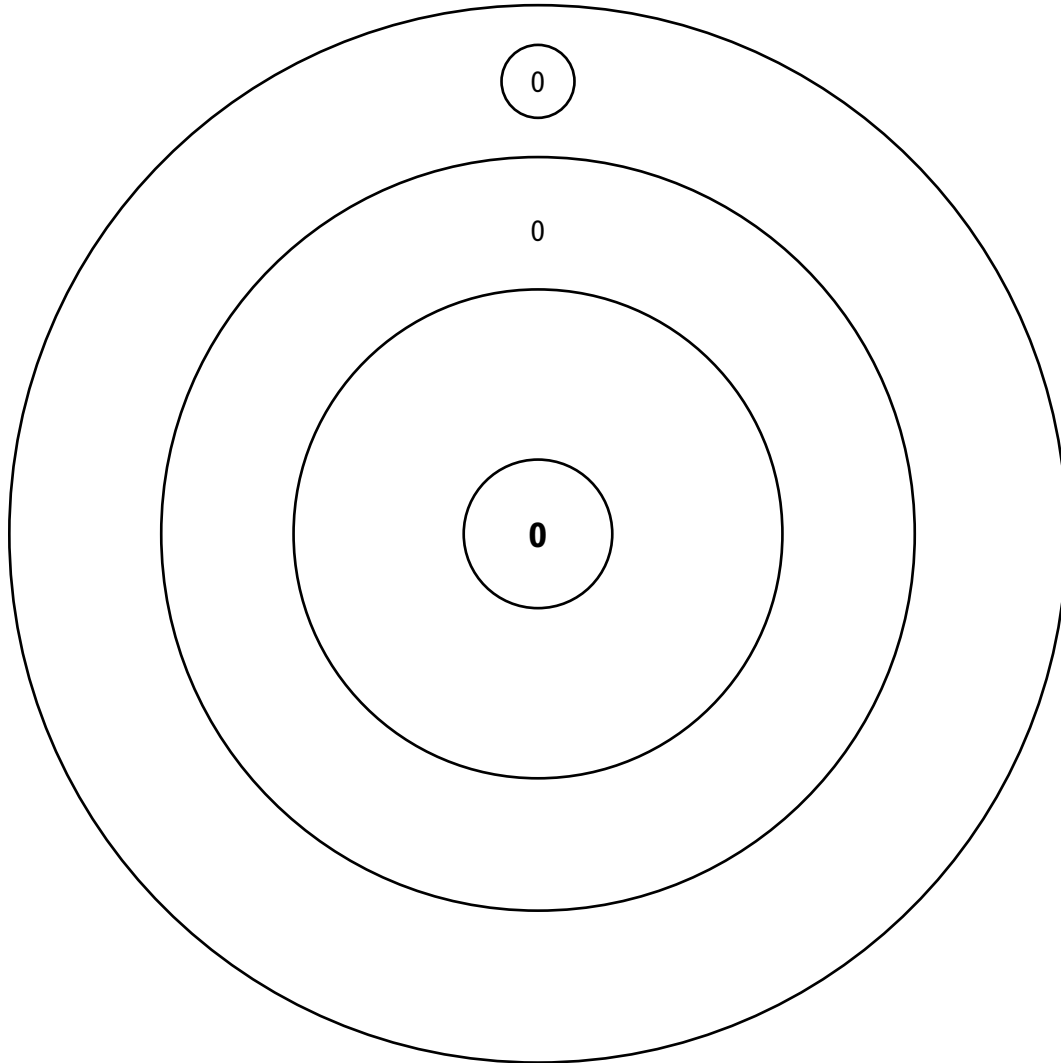
Mpumalanga deceased donation statistics (2018)

Population 4 679 786

Donors pmp 0.00

Annual deaths 29 300

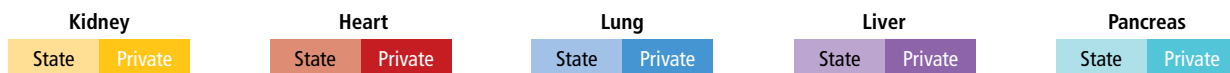
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

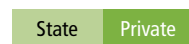
Outer ring: reflects total number of transplants for each organ type



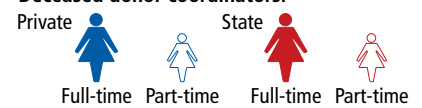
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



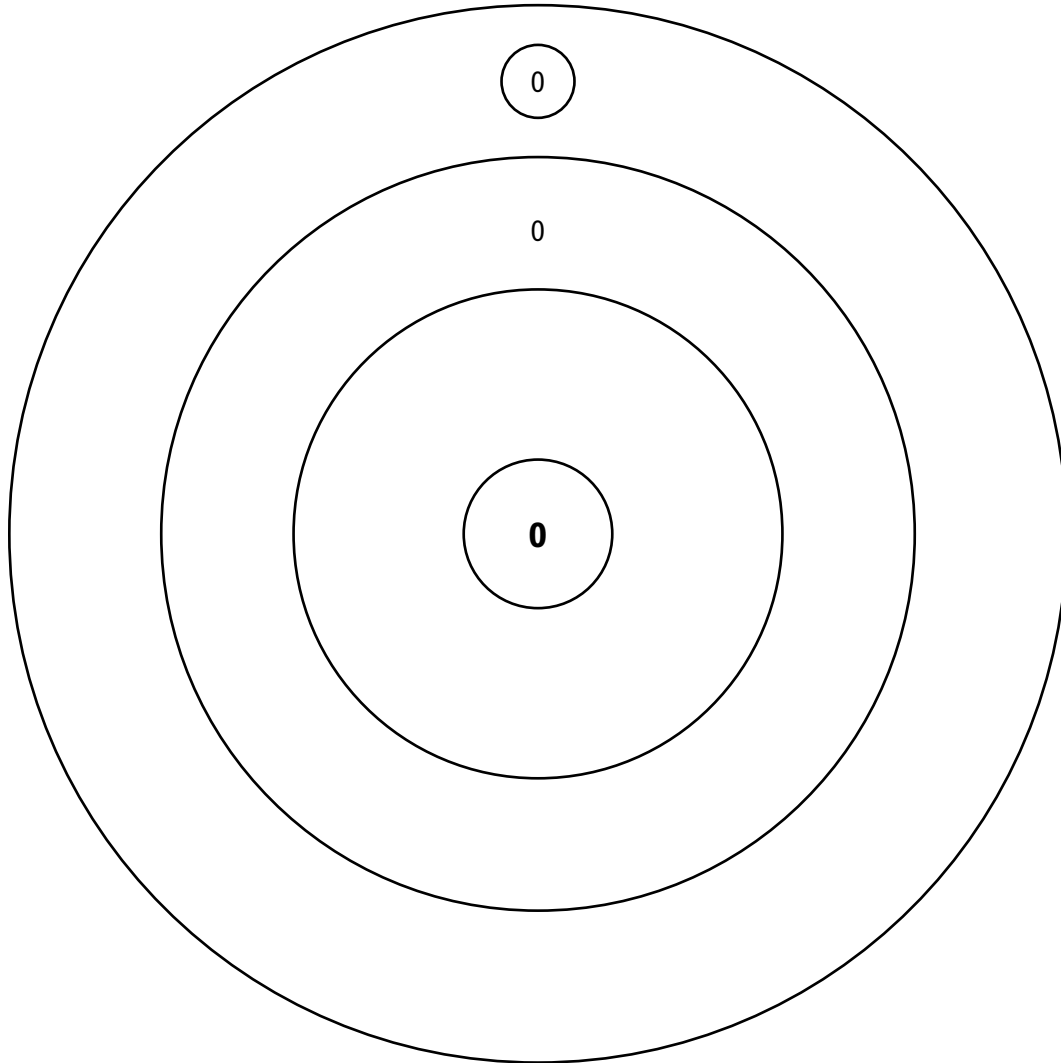
North West deceased donation statistics (2018)

Population 4 108 816

Donors pmp 0.00

Annual deaths 32 473

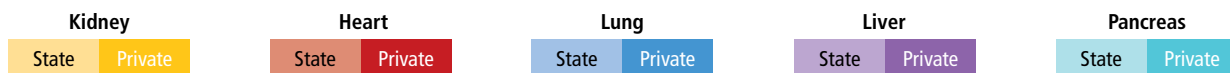
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



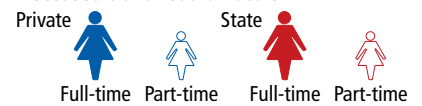
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



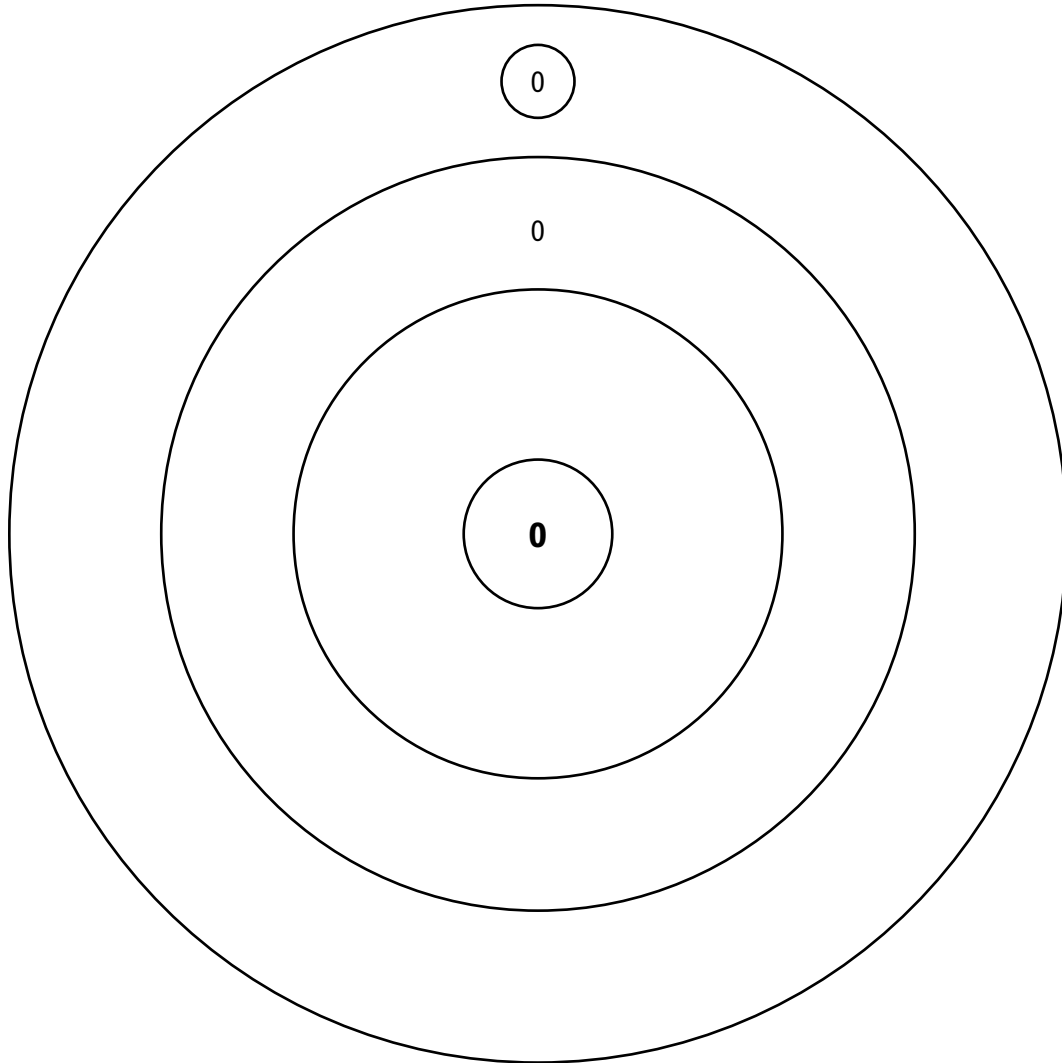
Limpopo deceased donation statistics (2018)

Population 5 852 553

Donors pmp 0.00

Annual deaths 43 707

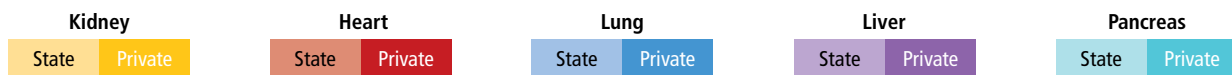
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



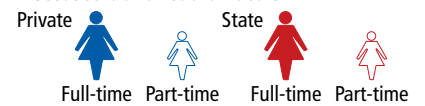
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:





Transplant Statistics

2017

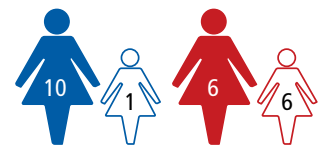
**Deceased donation
and transplantation
activity**

National deceased donation statistics (2017)

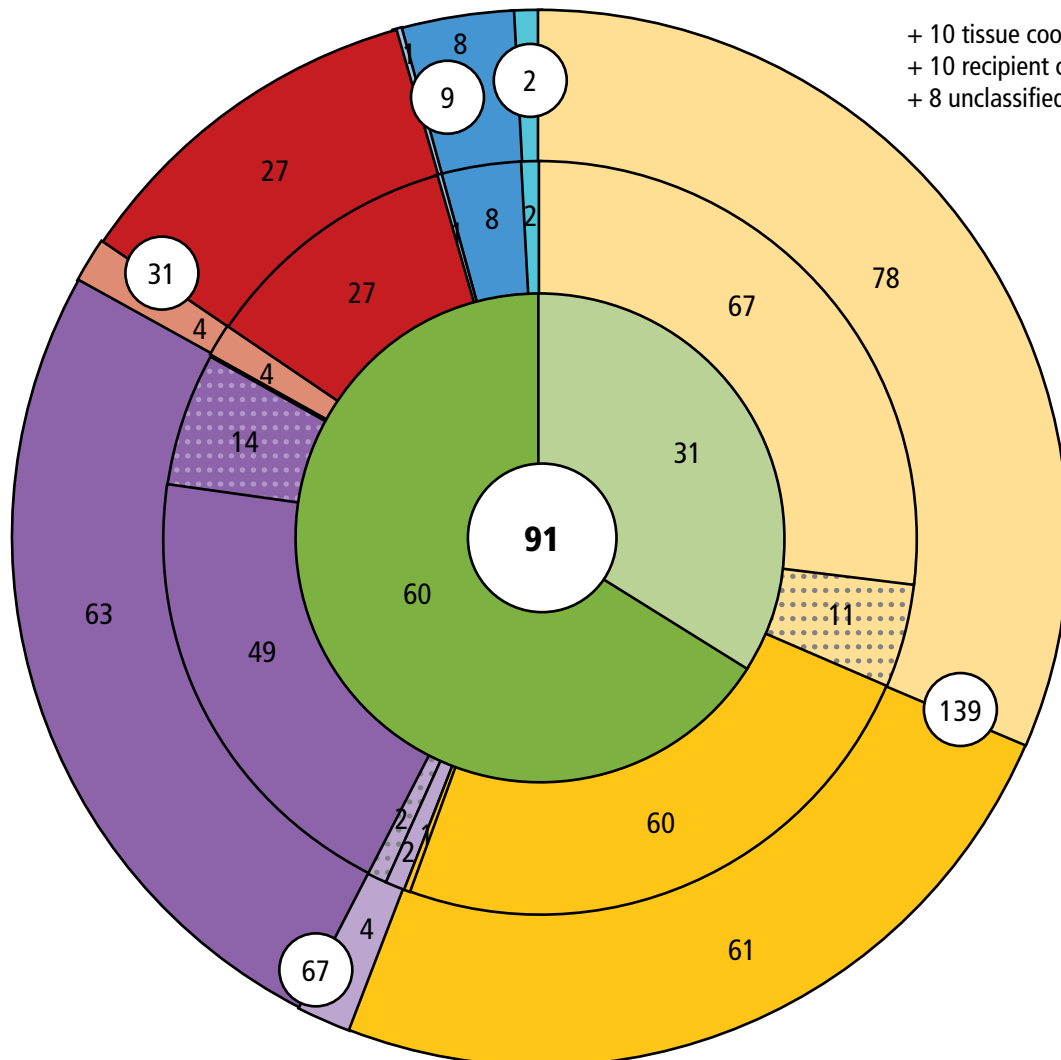
Population 59 622 350

Donors pmp 1.60

Annual deaths 446 544*



+ 10 tissue coordinators
 + 10 recipient coordinators
 + 8 unclassified coordinators

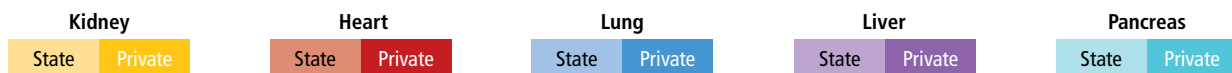


* 17 213 unspecified deaths

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

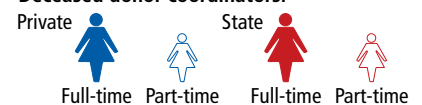


Figure 4b | Deceased donor and organ transplant activity in South Africa, 2017

Populations data from <https://www.southafricanmi.com/population-density-map.html>

Death data from Department of Statistics South Africa, Mortality and causes of death in South Africa: Findings from death notification 2017.

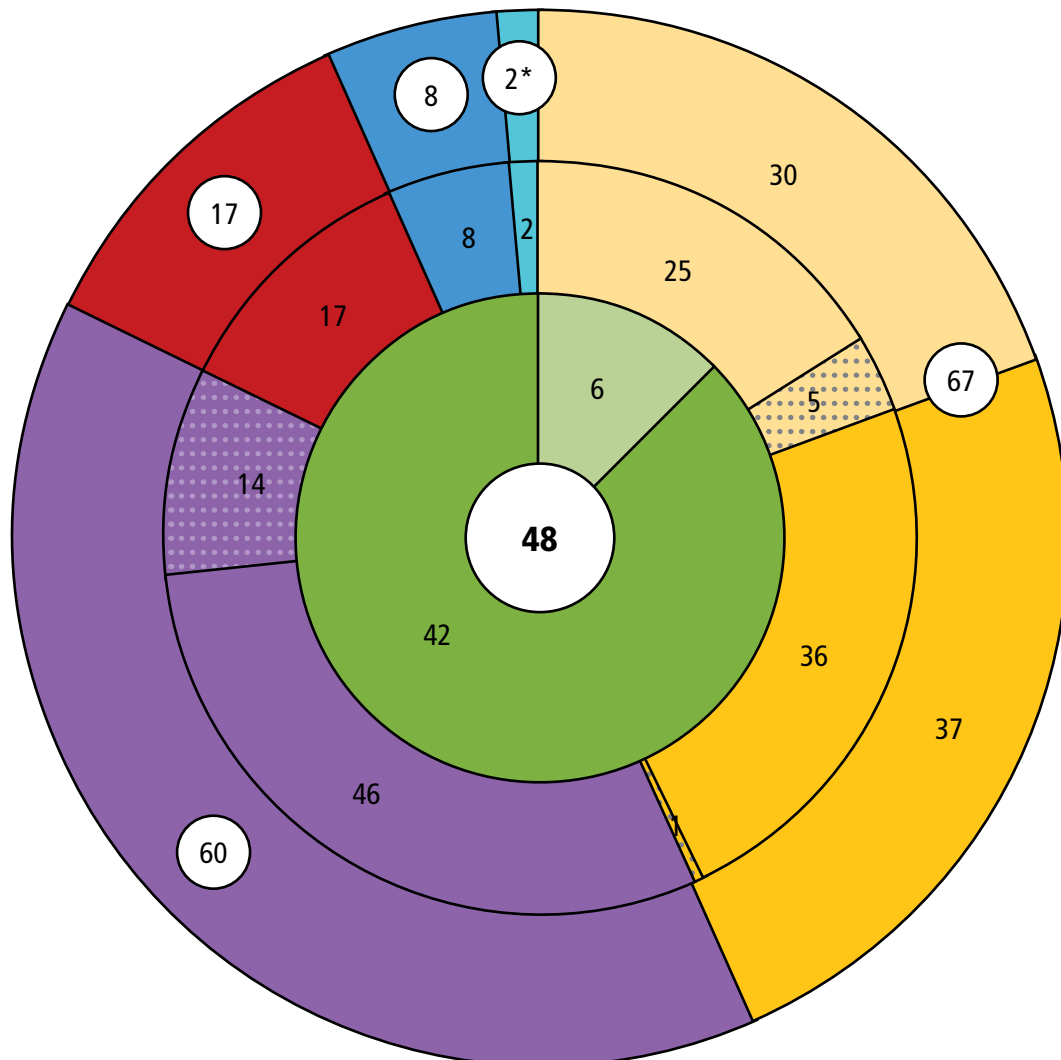
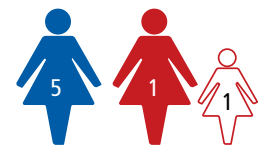
<http://www.statssa.gov.za/publications/P03093/P030932017.pdf>

Gauteng deceased donation statistics (2017)

Population 15 488 137

Donors pmp 3.26

Annual deaths 92 523

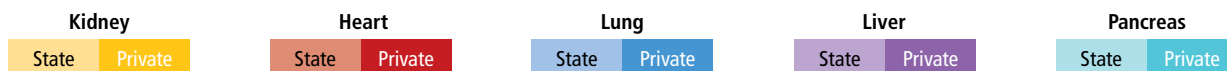


* All simultaneous kidney-pancreas transplants

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



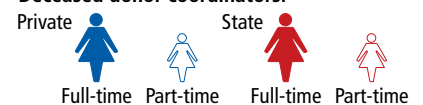
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

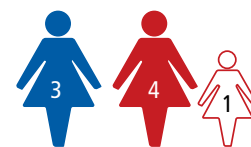


Western Cape deceased donation statistics (2017)

Population 7 005 741

Donors pmp 4.22

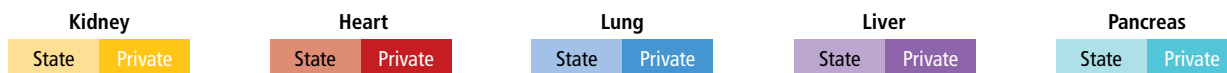
Annual deaths 45 715



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

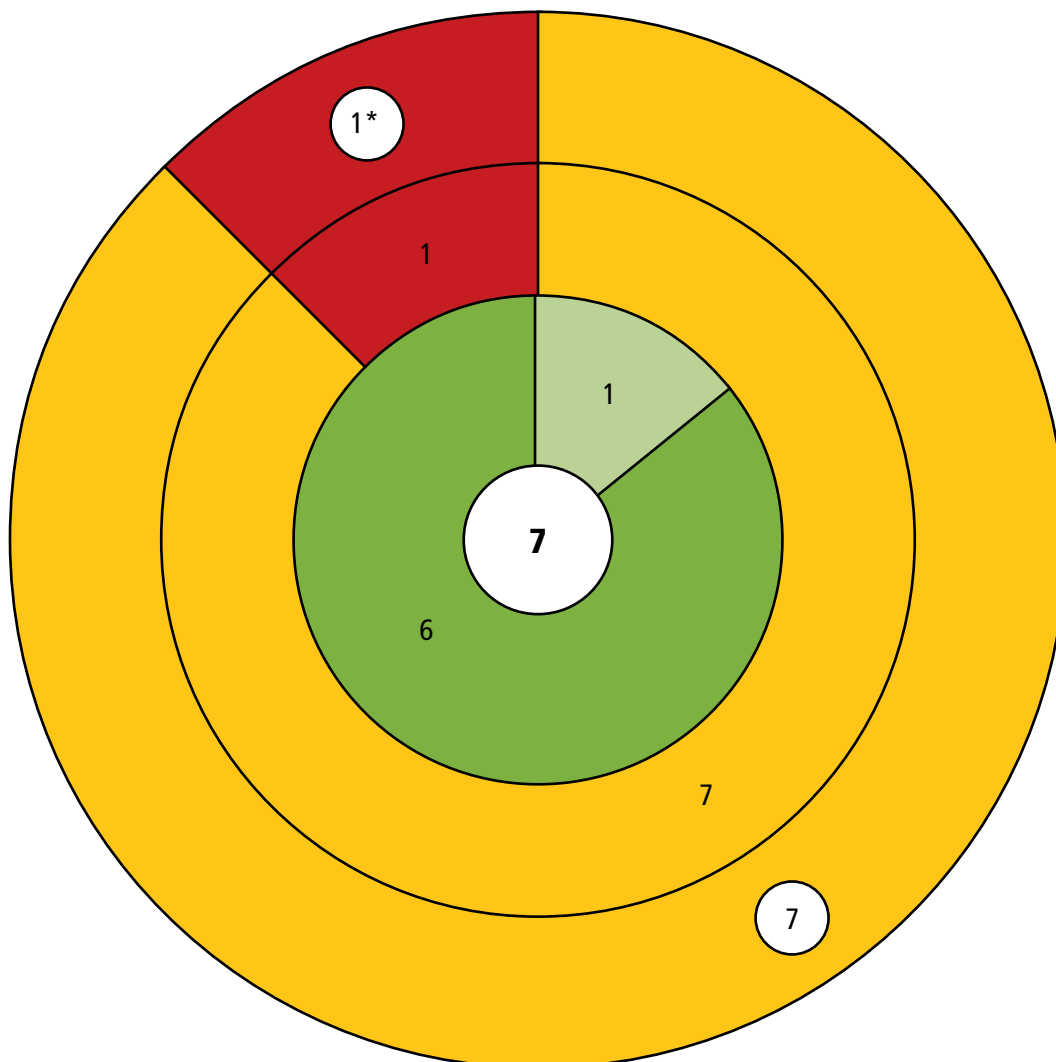
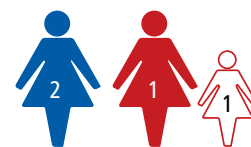


KwaZulu-Natal deceased donation statistics (2017)

Population 11 531 628

Donors pmp 0.61

Annual deaths 76 605

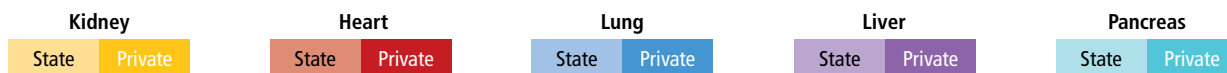


* Plus one heart-lung transplant in the private sector

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



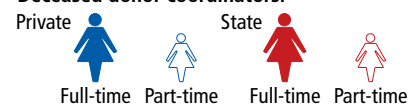
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

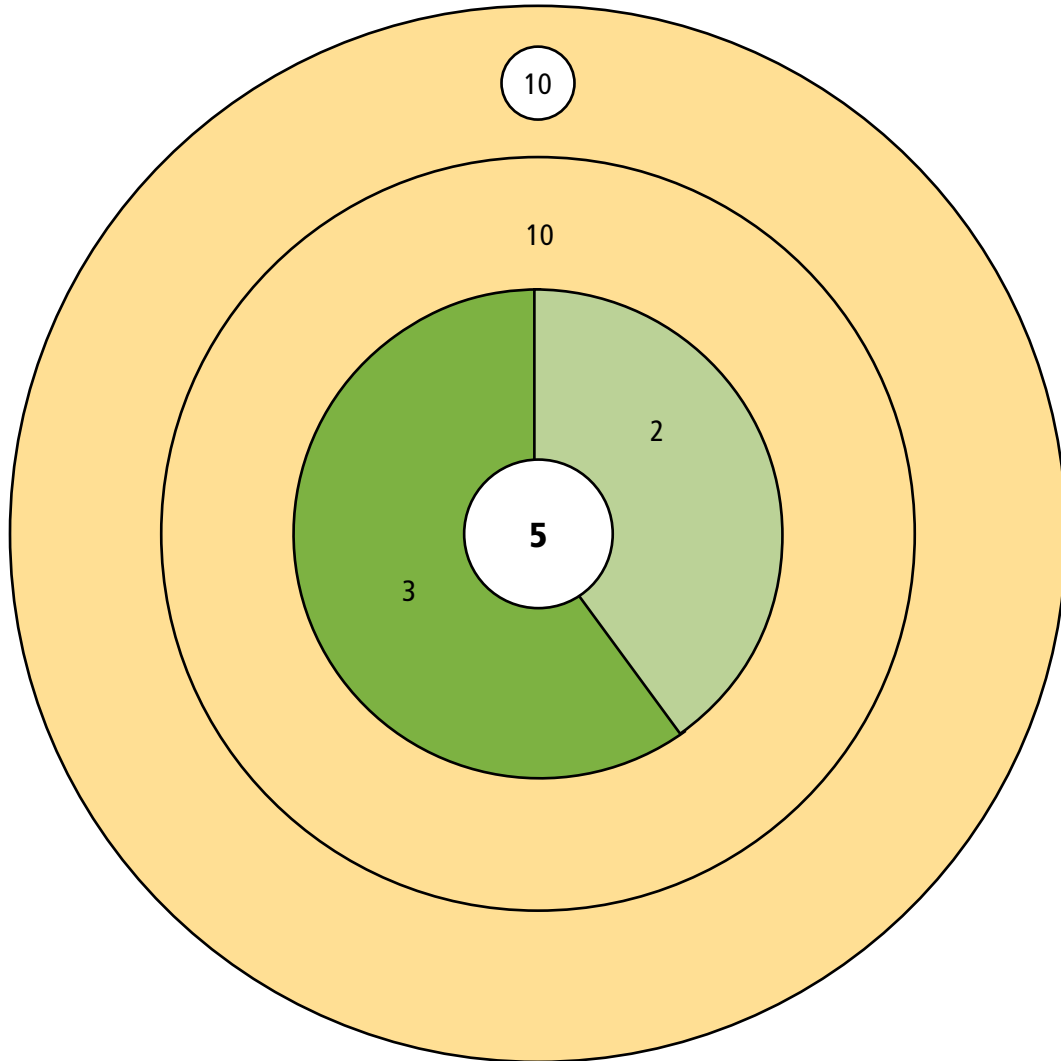
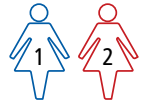


Eastern Cape deceased donation statistics (2017)

Population 6 734 001

Donors pmp 0.76

Annual deaths 65 162

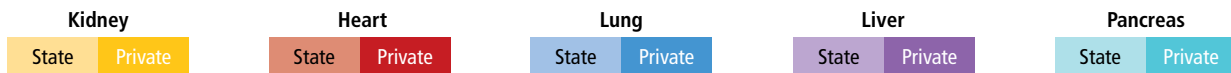


Deceased donor kidney transplants performed in the Western Cape

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



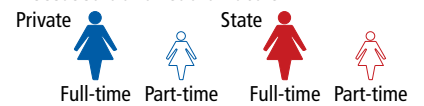
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



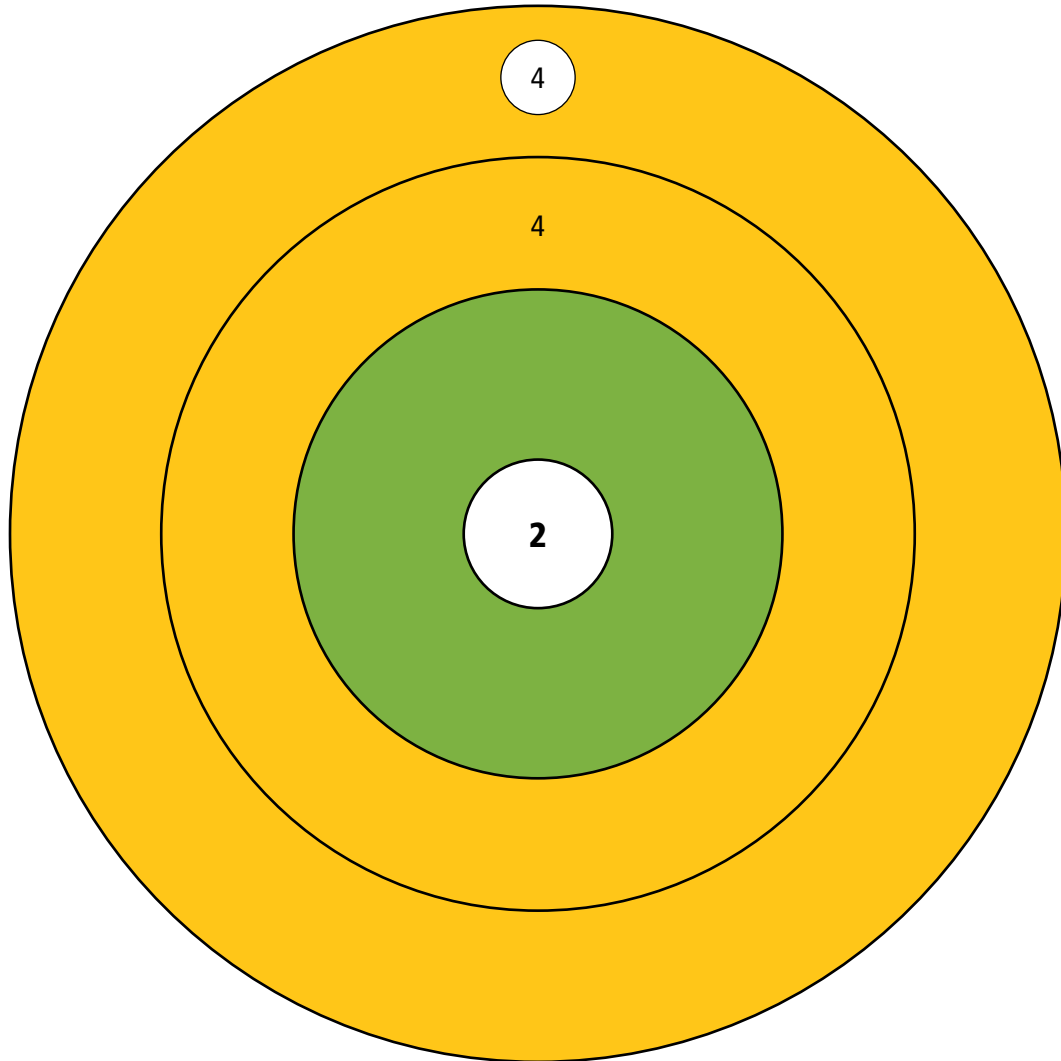
Free State deceased donation statistics (2017)

Population 2 928 903

Donors pmp 0.68

Annual deaths 31 208

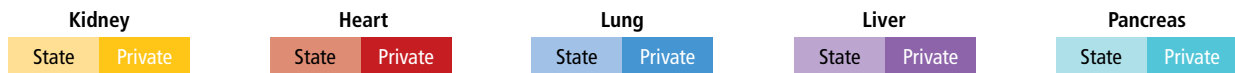
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

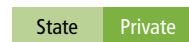
Outer ring: reflects total number of transplants for each organ type



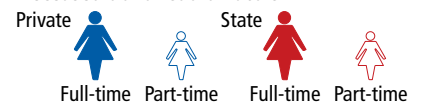
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:

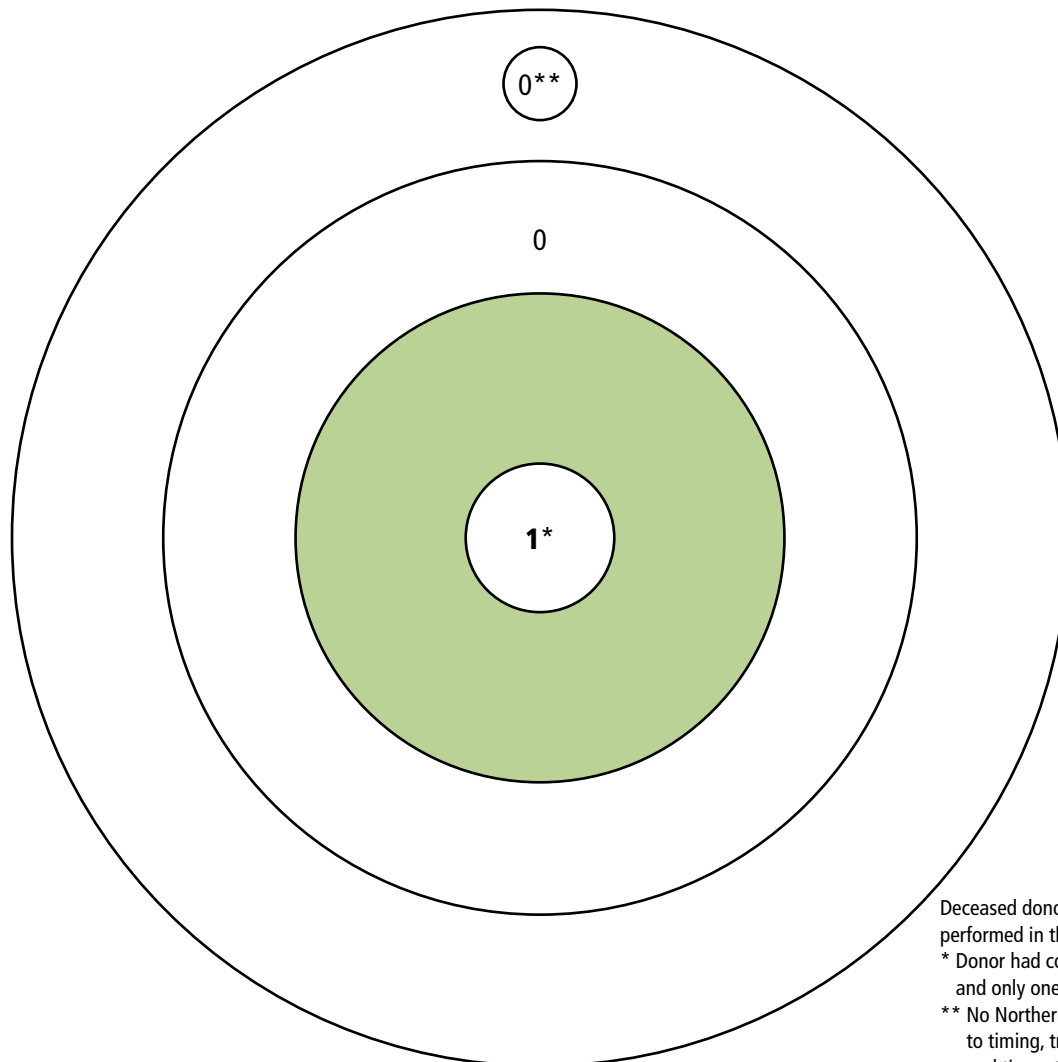


Northern Cape deceased donation statistics (2017)

Population 1 292 786

Donors pmp 0.81

Annual deaths 12 638

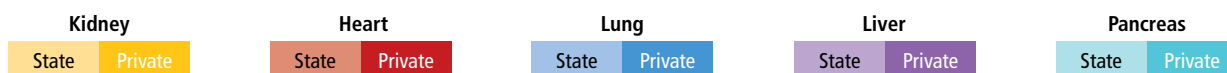


Deceased donor kidney transplants performed in the Western Cape
 * Donor had congenital anomaly and only one kidney
 ** No Northern Cape recipient due to timing, transport limitations and tissue typing, transport logistics; allocated to a Western Cape recipient

See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



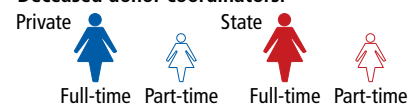
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



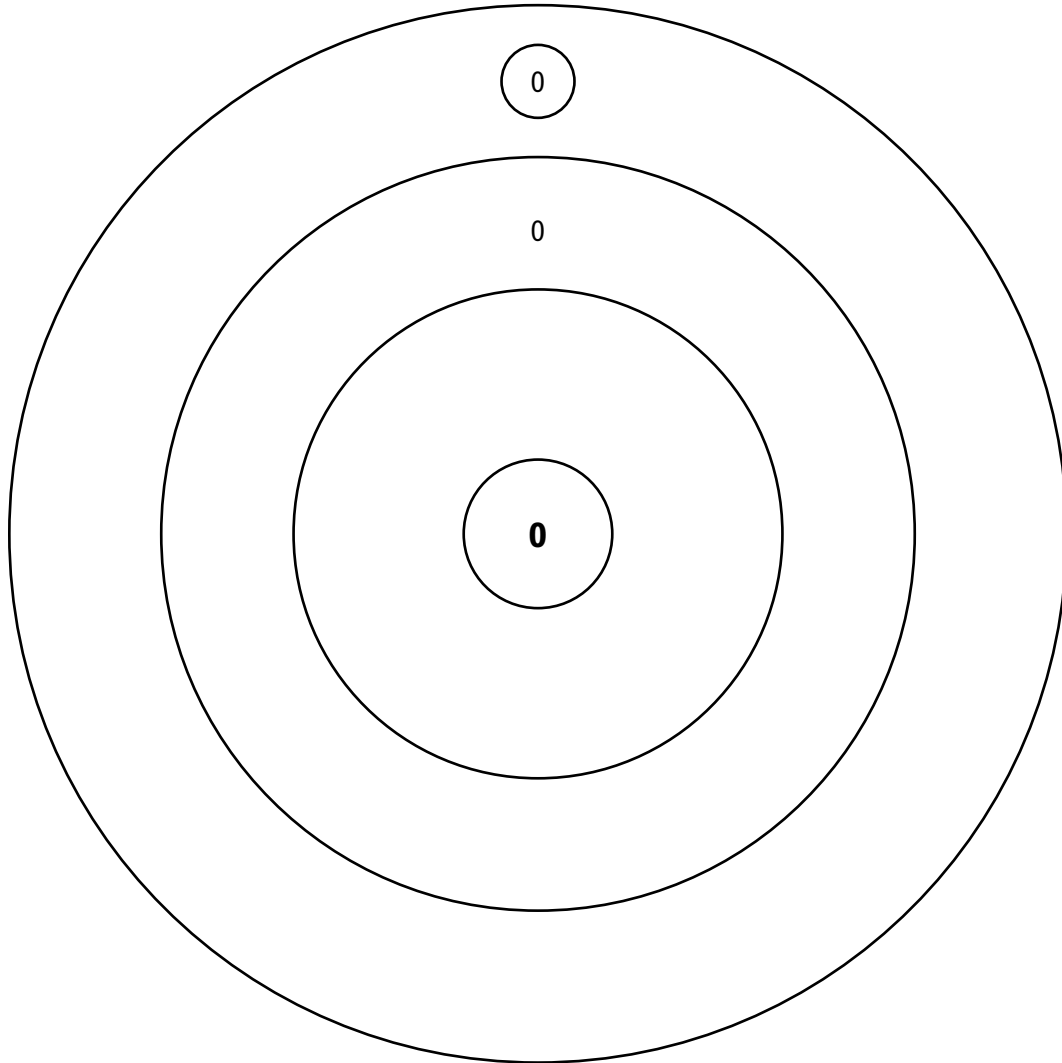
Mpumalanga deceased donation statistics (2017)

Population 4 679 786

Donors pmp 0.00

Annual deaths 29 300

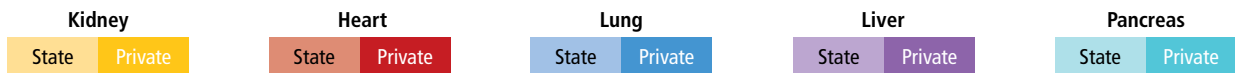
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

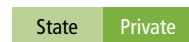
Outer ring: reflects total number of transplants for each organ type



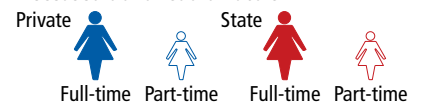
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



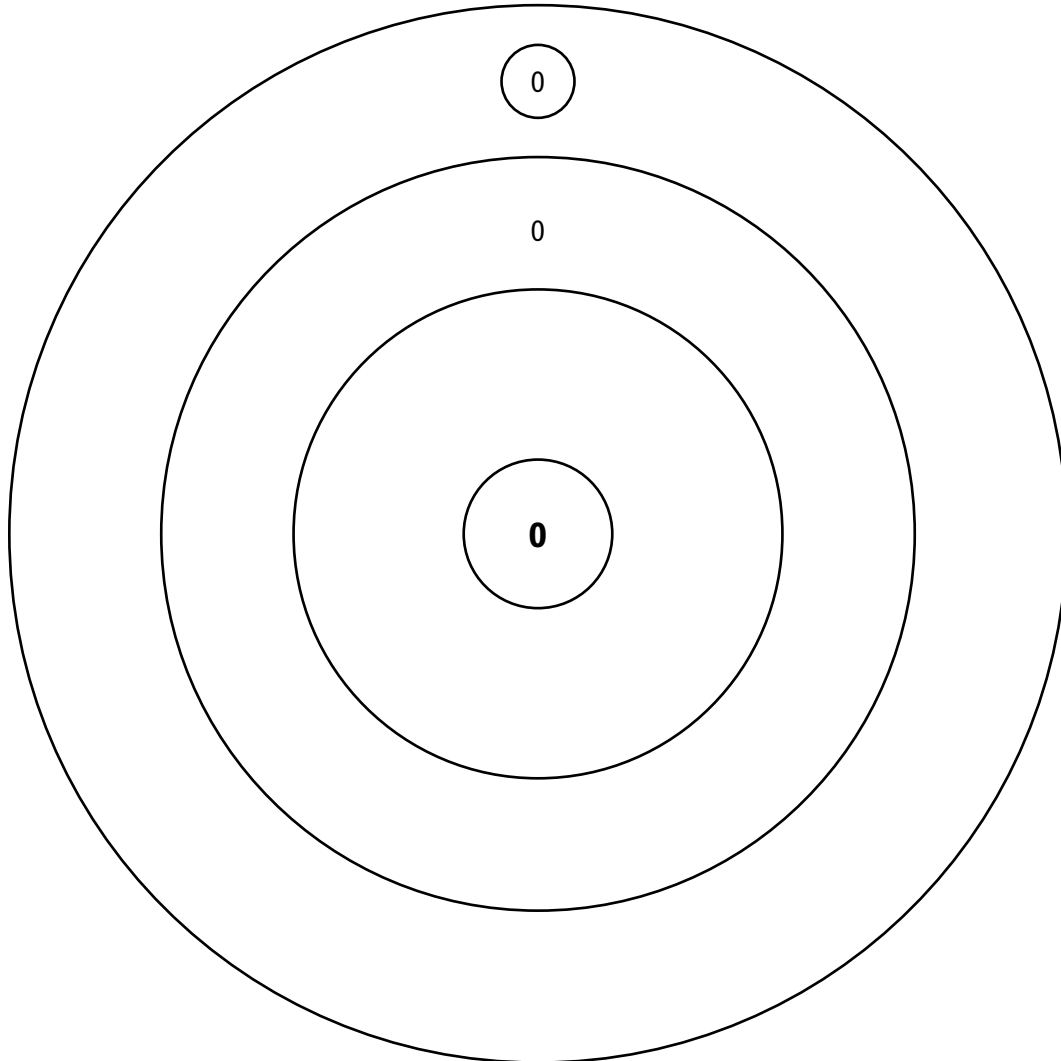
North West deceased donation statistics (2017)

Population 4 108 816

Donors pmp 0.00

Annual deaths 32 473

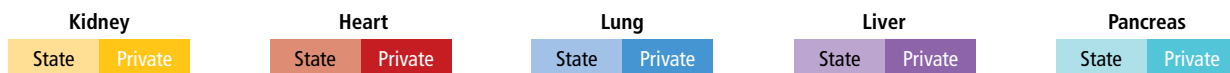
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



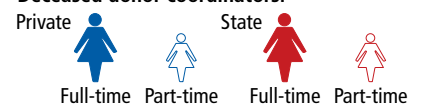
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



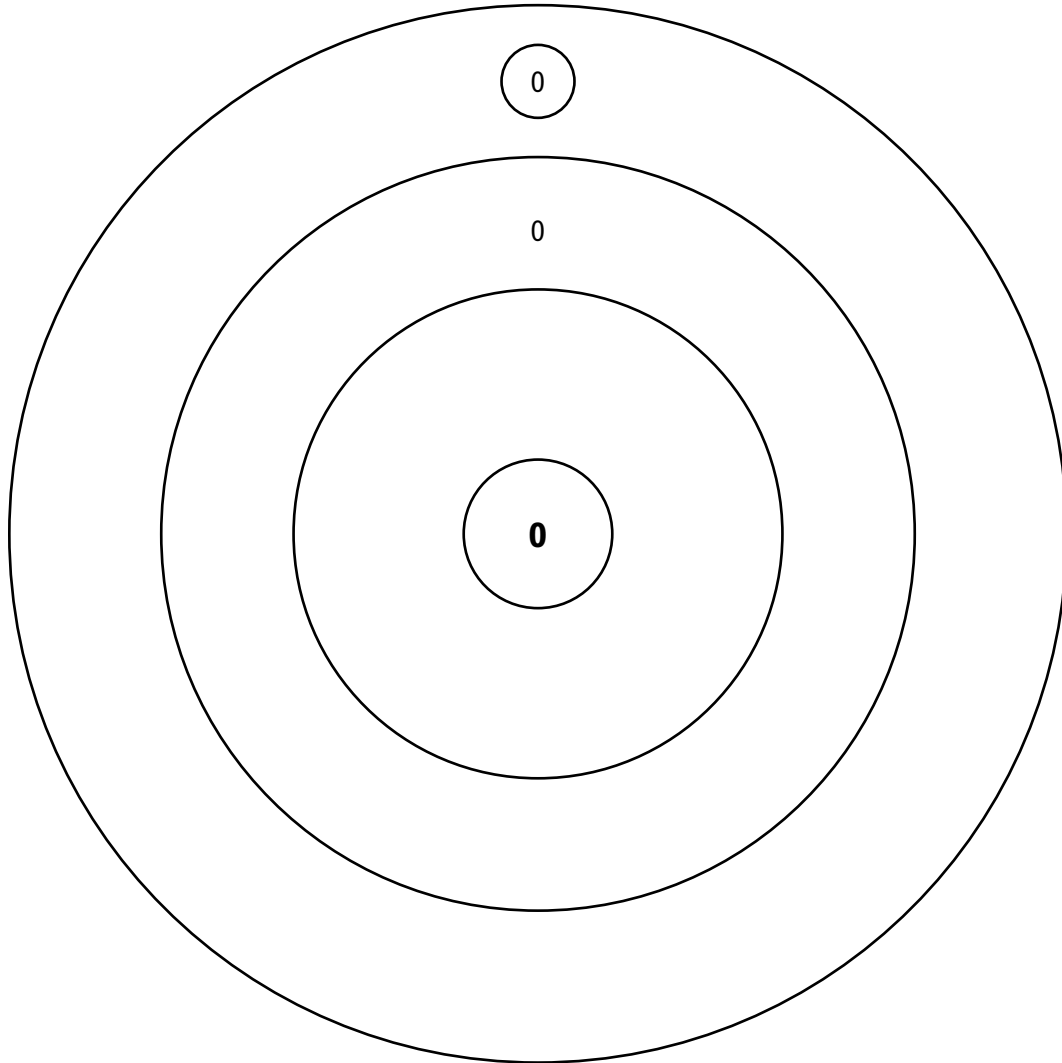
Limpopo deceased donation statistics (2017)

Population 5 852 553

Donors pmp 0.00

Annual deaths 43 707

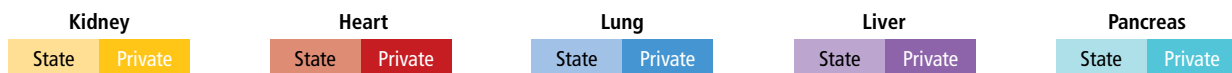
No transplant coordinators



See Appendix 12: Deceased donor and organ transplant activity: South Africa 2017/2018

KEY

Outer ring: reflects total number of transplants for each organ type



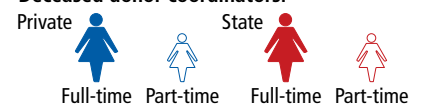
Middle ring: reflects number of adult and paediatric transplants for each organ type



Inside circle: reflects total number of deceased donors



Deceased donor coordinators:



2.3 Donor referral and consent

An average of five potential donor referrals were made per month in South Africa in the year preceding the environmental scan, with a range of 20 per month to two per year arising from different transplant centres (see *Figures 4a and 4b - Deceased donor and organ transplant activity in South Africa, 2018/2017; Appendix 12 - Deceased donor and organ transplant activity: South Africa 2017/2018*). Consent rates were not reported. Donor identification and referral policies varied markedly and were at the discretion of the treating teams, with no oversight of referral practices. Despite low numbers of deceased donation (multiple organs can be donated by a single deceased donor) these donors accounted for 100% of heart, lung, and pancreas transplants, 84% of liver transplants and 54% of kidney transplants.

Utilisation of donation after circulatory death (DCD) has the potential of improving organ availability in South Africa.^[1] South Africa lags behind the international community in using more organ donors after circulatory death, with only one unit in South Africa practicing DCD. In order for DCD to take place, treating clinicians need to be consistent in end-of-life care practices and should consult early with transplant centres for a formal assessment of donation potential prior to death certification. Early and pragmatic assessment of the clinical situation allows for more time to be spent with the family discussing end-of-life care options. Many countries have instituted clinical triggers for when such an assessment of organ donation potential should be made in order to inform discussions with the family (see *Table 1 – NHS Blood and Transplant recommendations: Timely identification and referral of potential organ donors*).^[2]

Table 1. NHS Blood and Transplant recommendations: Timely identification and referral of potential organ donors^[2]

Recommends that hospital staff initiate discussions with a specialist nurse for organ donation (SNOD) when one of the following criteria are met:

- Defined clinical trigger factors in patients who have had a catastrophic brain injury, namely:
 - » The absence of one or more cranial nerve reflexes and
 - » A Glasgow Coma Scale (GCS) score of four or less that is not explained by sedation
 - unless there is a clear reason why the above clinical triggers are not met (for example because of sedation)
 - » Or a decision has been made to perform brainstem death tests, whichever is the earlier.
- The intention to withdraw life-sustaining treatment in patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death.

^[1] Muller E, Thomson D, McCurdie F. Transplantation in South Africa. *Transplantation* 2015 Apr; **99**(4): 643-5. doi: 10.1097/TP.0000000000000712. https://journals.lww.com/transplantjournal/Fulltext/2015/04000/Transplantation_in_South_Africa.1.aspx

^[2] NHS Blood and Transplant. Timely identification and referral of potential organ donors. <https://nhsbt.dbe.blob.core.windows.net/umbaco-assets-corp/1337/timely-identification-and-referral-of-potential-organ-donors-nhsbt.pdf>

Barriers to referral of potential donors

Barriers to referral of potential donors at hospital level include:

- Misunderstandings of the transplant process on the part of those frontline health care professionals that are responsible for identifying potential donors
- An unwillingness by frontline health care professionals to have difficult conversations with families about death and to refer timeously to transplant coordinators so that a trained requestor can ask for consent
- A lack of resources and/or willingness to support the donor while the family is counselled
- The lack of a formal death referral system which is essential for monitoring of referrals and to performing quality improvement measures.^{[1][2]}

The pending Protection of Personal Information (POPI) Act presents a further barrier to the referral of potential donors as it has given rise to a reluctance by hospital groups to proactively support donation referrals, a reluctance on the part of the funeral industry to share family contact details with tissue coordinators, and a refusal to share information by most forensic pathology service facilities. It seems no longer to be an accepted and appropriate course of action to refer potential donors in order that transplant teams can make an informed approach for consent.

Barriers to consent

Whereas sensitivities around human tissue related to cultural traditions and beliefs and issues of literacy and language may represent a barrier to consent or may limit understanding of requests for consent, many systemic issues create further barriers to organ and tissue consent:

- Lack of widespread training of health care professionals in best practice recommendations for managing the grieving process and for making the donation request
- Overcrowded and busy health care units
- Variations in who is responsible for raising the organ donation discussion with the family
- Level of knowledge of the person making the approach regarding the prognosis of the potential donor
- Importantly, appropriate timing of handover from the treating team to the transplant team.^[3]

Cultural engagement and public support for organ donation needs to be targeted to ensure all of society is engaged with and empowered to make informed decisions about donation. Donation needs to be incorporated into new cultural and religious practices and discourse in order to not be seen as a counter to these, and to help create widespread support for donation across society.

^[1] De Jager M, Wilmans C, Fabian J, *et al.* Increasing deceased organ donor numbers in Johannesburg, South Africa: 18-month results of the Wits Transplant Procurement Model. *S Afr Med J* 2019 Aug 28; **109**(9): 626-631. doi: 10.7196/SAMJ.2019.v109i9.14313. <http://www.samj.org.za/index.php/samj/article/view/12701>

^[2] Moosa MR. The state of kidney transplantation in South Africa. *S Afr Med J* 2019 Mar 29; **109**(4): 235-240. doi: 10.7196/SAMJ.2019.v109i4.13548. <http://www.samj.org.za/index.php/samj/article/view/12575>

^[3] Bookholane H, Michaelides A, Prins L, *et al.* Factors influencing consent rates of deceased organ donation in Western Cape Province, South Africa. *South African Medical Journal* 2020; **110**(3): 204-209. <http://www.samj.org.za/index.php/samj/article/view/12857>

2.4 Data

Organ donation

In South Africa there are no publicly available routinely published data on waiting list numbers or outcomes or transplant activity for both organs and tissues; this data should be a national resource and prerogative. The Renal Registry currently provides the best data on dialysis in South Africa; this data, however, is limited and sub-optimal in reporting on the long-term outcomes of kidney transplantation. The Organ Donor Foundation Registry only represents an expression by an individual of their intent to donate and these registries are not available to consent requestors, as families are always approached for consent in all cases where there is a potential donor.

The kidney transplant rate in South Africa was 4.5 per million people (pmp) in 2016, with availability and activity differing between provinces as well as between state and private sectors. Of renal replacement therapy patients, kidney transplant occurred in 28.1% (n = 893) in the state sector and 7.5% (n = 532) of patients in the private sector.^[1] This discrepancy in transplant rates must be assessed in the context of state sector dialysis rationing of 68 pmp compared with the private sector having 798 dialysis patients pmp.

Deceased donation data from the Western Cape during the period 1 May 2017 to 1 May 2018 reflects a consent rate of 23% (n = 74) in the state sector, with 70% of referrals originating from emergency units, and a private sector consent rate of 55% (n = 9) with the private sector having a much lower referral rate of potential donors. Of donor referrals in both state and private sectors, 70% required immediate fluid resuscitation with 1 litre of intravenous fluid; a reflection that the potential donors were probably not being proactively supported at the time of their referral.^[2]

Tissue and eye donation

There is no formal South African national registry for tissue and eye donation. Tissues have a long shelf-life, they are preserved differently from organs, and are made available across the entire country. The potential for tissue and eye donation is also greater than that for organ donation as the potential donor does not have to be on mechanical ventilation at the end of their life. Irrespective of these considerations, South Africa has a very low number of tissue and eye donors, and low consent rates have impacted on access of patients to therapies based on these gifts.

Between the years 2002/2003 and 2016, cornea donor numbers declined by 86.9% (see *Figure 5 - Cornea donation in South Africa, 1998-2018*). In 2016, 3 000 patients nationwide needed corneal transplant and only 150 local corneas were transplanted; in 2017, 1 800 corneas were imported at a total cost of R55.8 million. Other tissue donation data shows that bone and tendon donors have declined by 59.2% over a similar period (see *Figure 6 - Bone tissue donation in South Africa, 1995-2018*); although 27 000 allografts were delivered, there was still a 21% shortfall on the need. Heart valve donation has declined by 72.3% (see *Figure 7 - Heart valve donation in South Africa, 2000-2018*).

^[1] Davids MR, Jardine T, Marais N, et al. South African Renal Registry Annual Report 2016. *African Journal of Nephrology* 2018; 21(1): 61-72. <https://www.journals.ac.za/index.php/ajn/article/view/3298>

^[2] Bookholane H, Michaelides A, Prins L, et al. Factors influencing consent rates of deceased organ donation in Western Cape Province, South Africa. *South African Medical Journal* 2020; 110(3), 204-209. <http://www.samj.org.za/index.php/samj/article/view/12857>

Reasons for declining tissue supply are ascribed to a major decrease in the referral of potential tissue donors and to a decrease in the consent rate. The decrease in referrals occurred at the same time as a change of responsibility for government mortuaries, in 2006, from the South African Police Service to the Forensic Pathology Services under the NDoH, with major alterations of the referral pathway on death affecting the potential for tissue donation. Stigma related to HIV and AIDS has also resulted in a societal shift in attitudes towards greater confidentiality of patient medical records and this, coupled with negative media publicity in 2005 regarding tissue donation from mortuaries, has also resulted in fewer next-of-kin consenting to donate tissues.

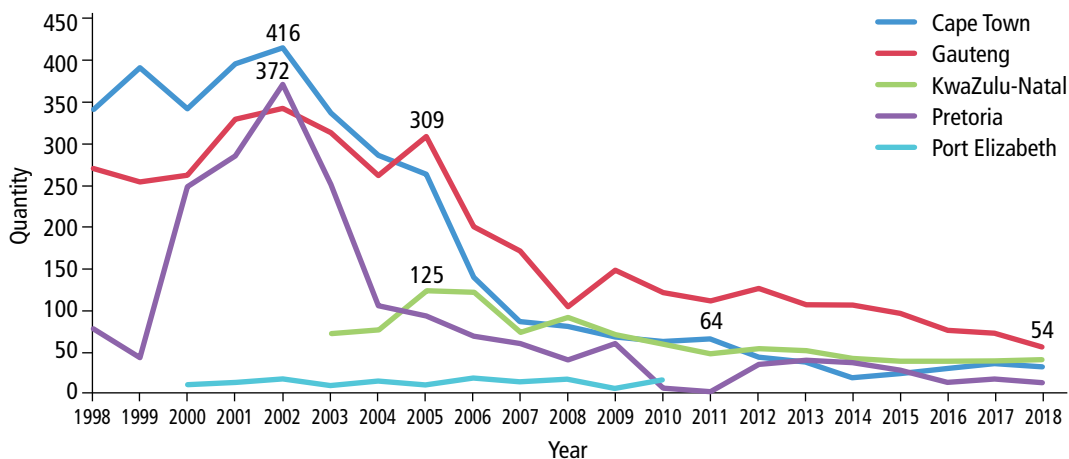


Figure 5 | Cornea donation in South Africa, 1998–2018

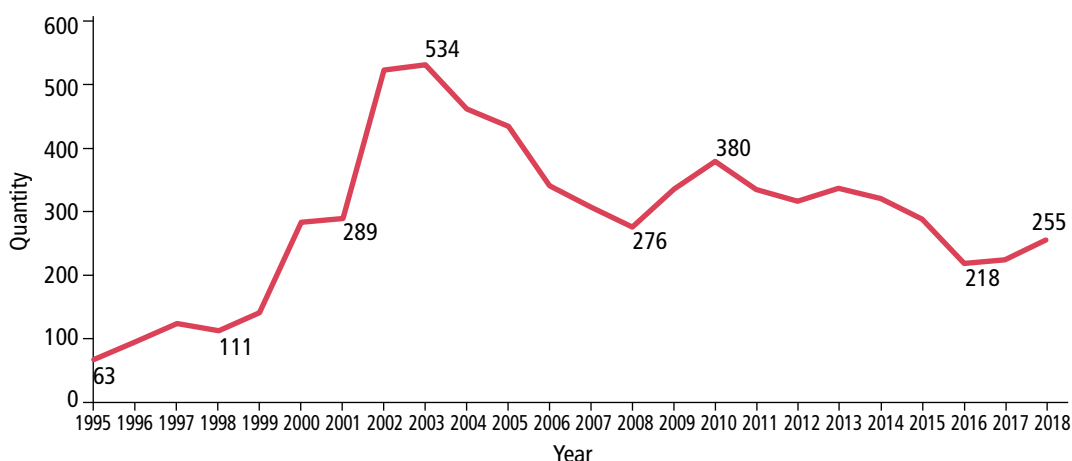


Figure 6 | Bone tissue donation in South Africa, 1995–2018

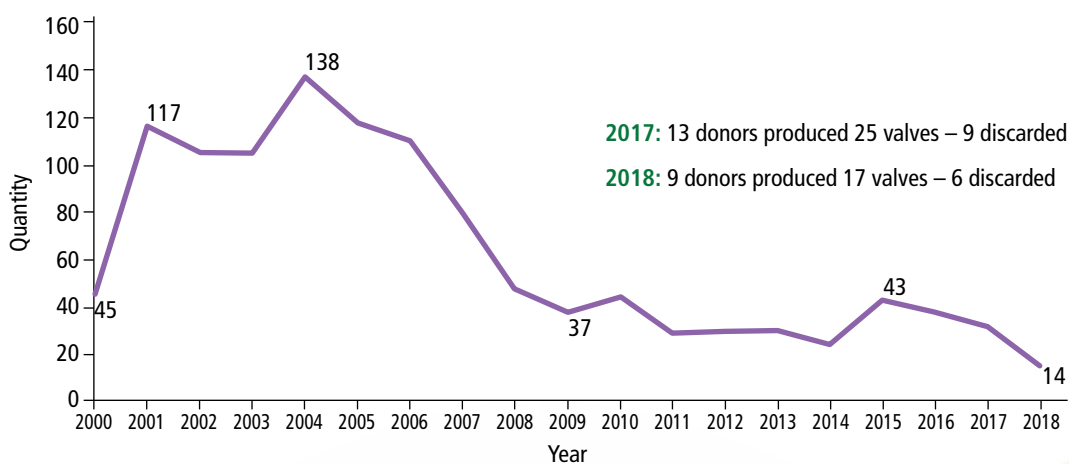


Figure 7 | Heart valve donation in South Africa, 2000–2018

2.5 Legislation and regulation in South Africa

The South African NDoH has officially endorsed the principles of the Declaration of Istanbul (see *Appendix 13*) wherein organ trafficking and transplant tourism are expressly prohibited. Chapter 8 of the NHA is the official legislation governing organ and tissue donation in South Africa.^[1]

Objectives of human tissue legislation in South Africa include, but are not limited to:

- Protecting the individual from harmful and unethical practices,
- Respecting the individual's autonomy - their right to determine how to use their own organs/tissues/cells,
- Make provision for all South Africans,
- Allow South Africans to benefit from the advances in medical science, and
- Not be unduly restrictive - to enable basic and clinical research and biotechnological innovation.

A further joint initiative between governments and professional organisations is the Resolution of Madrid (2010) which calls for all countries to strive towards self-sufficiency, both by increasing organ donation activity and by efforts to reduce the burden of end-stage organ failure. The Madrid Resolution urges:

1. National capacity management (such as an appropriate healthcare infrastructure and workforce);
2. National regulatory control (through adequate legislation for declaration of death, consent, organ procurement, fair and transparent allocation and penalties for organ trafficking and commercialisation); and
3. National authorities to lead normative change so that all levels of society share a collective responsibility for donation after death, contributing to the common good of transplantation for all.

Currently there is no legislation that clarifies the role of clinicians and nurses in end-of-life care and organ donation, or hospital standards in this regard. There are currently no regulations in South Africa specifically for transplantation, cell and gene therapy, and biobanks. Redundancy of some existing human tissue regulations and overlap of other regulations provide challenges, and definitions are not harmonised between different regulations or the NHA.

Human tissue regulations (see *Appendix 14 – South African legislation*) and policy documents are not complete and there are no official human tissue guidelines or standards that have been endorsed by the NDoH. The definition of human tissue differs between the NHA and regulations relating to tissue banks. NHA Act No. 61 of 2003 defines human tissue 'and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete'. Regulations relating to tissue banks (No. R.182 of 2010) define human tissue as a functional group of cells, used collectively to indicate both cells and tissues. A tissue bank is defined as an organisation, institution or person that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals for transplantation purposes.

^[1] McQuoid-Mason D. Human tissue and organ transplant provisions: Chapter 8 of the National Health Act and its Regulations, in effect from March 2012 – what doctors must know. *S Afr Med J* 2012; **102**(9): 733-735. DOI:10.7196/SAMJ.6047 <http://www.samj.org.za/index.php/samj/article/view/6047/4414>

Payment for human tissue services is regulated by the NHA Section 60 - Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes. Remuneration for tissue banks in South Africa are based on cost recovery. There are no public stem cell banks in South Africa, private banks operate on a for-profit basis. Many gamete banks form part of specific *in vitro* fertilisation facilities. In organ donation, there is no central fund to support recovery for organ procurement costs.

In terms of payment to donors, human tissue and organ donation is altruistic. For stem cell banks, donors are not remunerated but payment is required for storage and use is limited to the individual or close family. Gamete donors are remunerated and there is a question as to whether this is limited to costs related to the donation.

Chapter 3

International perspectives

There is an opportunity to build upon lessons previously learned by other nations when developing a South African-specific solution to maximise deceased donation and to improve the standard offering of end-of-life care by the health care system. There is no comparator country perfectly matched with the South African context against which to benchmark South African performance in organ and tissue donation. There are, however, countries that are realising consistent improvements in organ and tissue donation which have some similarities with South African circumstances (see *Table 2 - Global Observatory on Donation and Transplantation - Deceased donor rates 2007-2017*).

Table 2. Global Observatory on Donation and Transplantation - Deceased donor rates pmp, 2007-2017^[1]

Country	Population	Deceased donation rate 2007	Deceased donation rate 2017	Change in donor rate over 10 years
Australia	24.5 million	9.61	20.82	+11.21
Brazil	209.3 million	5.48	16.34	+10.86
Canada	36.7 million	14.70	21.90	+7.20
South Africa	56.7 million	1.30	1.60	+0.30
Spain	47.05 million	35.55	47.05	+12.50
United Kingdom	66.2 million	13.22	22.54	+9.32
United States	324.5 million	26.60	31.70	+5.10

^[1] WHO-ONT. Data of the WHO-ONT Global Observatory on Donation and Transplantation. <http://www.transplant-observatory.org/>: World Health Organization and Organizacion Nacional de Trasplantes.

In relation to the South African context, Brazil has a similar economy and donor consent system; the United Kingdom (UK) has a relatively low ICU bed to population ratio with many donors coming from emergency units, and a hospital-based system of coordinators; Australia and Canada have very large distances between hospitals and transplant centres, and operate within a federal system of provinces; and the United States of America (USA) has a similar health expenditure per capita as compared to the private sector in South Africa, with a very diverse culture and population. Globally, Spain is the highest performing country in organ and tissue donation, using a particular model of centrally coordinated authority with a focus on trained transplant coordinators in all hospitals with an ICU.

Strategic priorities that have contributed to successful efforts in improving organ and tissue donation rates in these countries fall within various jurisdictions:

- Legal/ethical framework
- Clinical governance
- System quality (audit, evaluate, measure clinical performance)
- National coordinating body (NCB)
- Improve donor identification and referral rates (by treating doctors/nurses)
- Expansion of donor pool - donation and brain death (DBD) and donation after circulatory death (DCD)
- Improvements in consent rates (conversion from potential to actual donors) – DBD, DCD
- Clinical triggers to define the time point where the transplant team is consulted to assess the potential for donation in end-of-life care (see *Table 1 – NICE recommendations: Timely identification and referral of potential organ donors*)
- In-hospital donation specialist expertise
- Professional education for effective requesting
- Financial support – NCB, hospitals, support services
- Media strategy, public engagement, intent registry
- Leading practices, professional society engagement, faith/cultural involvement
- System improvements – information technology (IT), registries, quality assurance, accreditation, data, human leukocyte antigen (HLA) matching, family support.

“What I believe has made the biggest difference in the United Kingdom was the genius, even if not fully realised at the time, of making donation a local concern. In the old UK there were 18 coordinator teams, in the new one there are 190 local donation teams, all thinking about organ donation in their hospital. What makes a local donation team? You do - the organ donation triumvirate of CLOD (clinical lead for organ donation - physician), SNOD (specialist nurse for organ donation) and Chair (hospital management), supported by a well-represented and active hospital donation committee.”

Dale Gardiner - National Clinical Lead for Organ Donation, UK



Blood and Transplant

3.1 International organisations supporting organ donation and transplantation

Global organisations

The Transplantation Society (TTS)

TTS is a non-profit, non-governmental organisation providing global leadership in transplantation. The core mission of TTS is the development of the science and clinical practice, scientific communication, continuing education and guidance on the ethical practice of organ and tissue donation and transplantation.

International Society of Organ Donation and Procurement (ISODP)

The ISODP is the sole global professional organisation focused exclusively on developing deceased donation programmes through societal attitudes and legislative requirements, perfecting the process of donation and procurement, ways of expanding the donor pool, measures to minimise donor organ injury, the development and facilitation of educational programmes, and ethical matters related to organ and tissue donation and procurement. An official section of the TTS, the ISODP Congresses have been held every other year in numerous geographic regions of the world to highlight organ donation and transplantation, with intent to share best practices and improve organ donation for that country. The Congress usually attracts 500 to 700 participants.

Australia

Organ and Tissue Donation and Transplantation Authority (OTA)

The OTA, established in 2009, is an independent statutory agency within the Australian Government Health portfolio and works with states and territories, clinicians, the community sector and the general public. The objectives of the OTA are to increase the capability and capacity within the health system to maximise donation rates and to raise community awareness and stakeholder engagement across Australia to promote organ and tissue donation. The OTA leads the implementation of the Australian Government's National Reform Agenda, in collaboration with state and territory Medical Directors and DonateLife agencies (one in each state and territory) which are comprised of a network of hospital, medical and nurse specialists in organ and tissue donation. The OTA operates under the *Australian Organ and Tissue Donation and Transplantation Authority Act of 2008*.

Brazil

National Transplant System (SNT)

The SNT, established in 1997, is a federal entity that plans, organises, coordinates and controls all transplantation operations and strategy nationwide.

Brazilian Organ Transplantation Association (ABTO)

The ABTO oversees the organ donation and transplant process nationwide and in each Brazilian state.

Canada

Canadian Blood Services (CBS)

The Canadian Council for Donation and Transplantation (CCDT), created in 2001, functioned as an advisory body in support of efforts to coordinate federal, provincial and territorial activities relating to organ donation and transplantation. The CCDT conducted extensive consultations on standards and clinical practice guidelines to maximise organ donation potential. The CCDT's functions were transferred to the CBS in 2007.

India

Multi Organ Harvesting Aid Network (MOHAN) Foundation

The MOHAN Foundation is a registered not-for-profit, non-governmental charity organisation that works in the field of deceased organ donation and transplantation.

Spain

National Transplant Organisation (ONT)

The ONT is under the stewardship of the Spanish Ministry of Health and is charged with developing competencies related to the provision and clinical utilisation of organs, tissues and cells. To date the ONT has trained 16 000 health care workers. The essential mission of the ONT is to promote and facilitate donation and transplantation of organs, tissues and cells; it also guarantees more appropriate and correct distribution of all transplantation activity according to technical knowledge and equity principles. After the creation of the ONT in 1989, Spain increased deceased donation from 14 donors pmp to 35.1 in 2005, 35.3 in 2011, 40.2 in 2015 and 46.9 donors pmp in 2017.

United Kingdom

National Health Service Blood and Transplant (NHSBT)

NHSBT is an executive non-departmental public body of the UK's Department of Health and Social Care. The remit of the NHSBT is to provide a reliable and efficient supply of blood, organs and associated services to the NHS. It was established in 2005 to take over the responsibilities of two separate NHS agencies: UK Transplant, now renamed Organ Donation and Transplantation (ODT) and the National Blood Service. The NHSBT manages the NHS Organ Donor Register and the National Transplant Register.

Hospital Donation Committees

Hospital donation committees are chaired by hospital management and are comprised of hospital role players who manage potential donors - a local physician tasked with being Clinical Lead for Organ Donation (CLOD) and nurses working as Specialist Nurses for Organ Donation (SNODs).

United States of America

United Network for Organ Sharing (UNOS)

UNOS is a non-profit scientific and educational organisation, with 394 employees and 500 volunteers, that administers the Organ Procurement and Transplantation Network. The role of UNOS is:

- Managing the national transplant waiting list, matching donors to recipients
- Maintaining the database that contains all organ transplant data for every transplant event that occurs in the US
- Bringing together members to develop policies that make the best use of the limited supply of organs and to give all patients a fair chance at receiving the organ they need, regardless of age, sex, ethnicity, religion, lifestyle or financial/social status
- Monitoring every organ match to ensure organ allocation policies are followed
- Providing assistance to patients, family members and friends
- Educating transplant professionals about their important role in the donation and transplant processes
- Educating the public about the importance of organ donation.

Organ Procurement and Transplantation Network (OPTN)

The OPTN is a non-governmental entity administered by the UNOS. The OPTN approves new transplant centres and programmes, operates organ sharing systems, manages waiting lists and the national database, sets allocation policies for deceased donors, maintains data on all living and deceased donors and transplants, and monitors compliance with organ allocation and other policies. The OPTN is comprised of 24 committees, each with a director and membership of over ten experts in the clinical field, that address issues of concern in the transplant community. The organisation strives to be transparent, evidence-based, and to work collaboratively to increase the number of transplants and access to transplants, as well as to improve patient outcomes and to promote safety.

Organ Procurement Organisations (OPOs)

OPOs are non-profit organisations that are responsible for the evaluation and procurement of deceased donor organs for organ transplantation. There are 58 such organisations in the USA; each OPO is a member of the OPTN and is responsible for organ procurement in a specific region. The individual OPOs represent the frontline of organ and tissue procurement, having direct contact with the hospital and the family of the recently deceased donor. Once the OPO receives the consent of the decedent's family, it links to UNOS to identify the best candidates for the available organs and coordinates with the surgical teams for each organ recipient. A typical OPO is comprised of 150 staff to cover a population of 11 million, excluding surgical teams.

Scientific Registry of Transplant Recipients (SRTR)

The SRTR strives to be a trusted resource for epidemiological data and statistical analyses regarding the status of solid organ transplantation and the transplantation system in the USA, intended for use by the public, the Department of Health and Human Services (DHHS), the OPTN/UNOS, transplant programmes, OPOs, transplant candidates, transplant recipients, living donors, and donor families. The SRTR, with a complement of 44 staff, is highly regulated by both the federal government and voluntary accredited organisations for organ, tissue and eye donation, offering very robust data reporting on transplant centre activity and OPO performance. This data is available to the public online.

3.2 Australia

Since 2009, the number of deceased organ donors in Australia has more than doubled and the number of transplant recipients has increased by 93%.

Key strategies that have been implemented include:

- The establishment of the Australian and New Zealand Organ Donation (ANZOD) Registry that collects and records data on all organ donors after death, as well as a wide range of statistics that relate to organ donation
- The establishment of the DonatLife network of donation specialists in hospitals across Australia
- Provision of international best practice clinical training, to intensive care and critical care specialists, in the conduct of the donation conversation that is both respectful and responsive to the needs of each family
- Enhanced reporting and auditing of organ and tissue donation practice that is embedded across the hospitals in the DonatLife network
- Implementation of a nationally consistent public education campaign, including awareness of the importance of family discussion
- Facilitation of optimal matching of donor organs to transplant recipients through the activities of OrganMatch.

Australia operates an opt-in or explicit/required consent organ donation system whereby an individual expresses their intention to become a donor.

3.3 Brazil

Brazil currently ranks second among all countries with regard to the total number of transplants performed. It has the highest level of public funding, 95% of transplants in the country are funded by the state health care system.

A single state transplant waiting list model with a single recipient registry ensures fair, free and universal access to available organs. The recipient registry consists of state lists classified by different organ types, with organ distribution following order of registration and compatibility between donors and recipients. Unused organs are made available to the national listing.

Implementation of the organ recovery logistics and organ allocation are handled by Organ Notification, Procurement and Distribution Centres (CNCDOs). State transplant centres are responsible for managing lists of potential recipients, receipt of brain death notifications and the organisation of organ logistics and distribution in their operating areas.

OPOs and Intra-Hospital Organ and Tissue Transplant Donation Commissions (CIHDOTTs) assist the CNCDOs. The establishment of these CIHDOTTs is mandatory in hospitals with more than 80 beds, among other criteria. The OPOs work mainly at the regional level, organising donor procurement logistics, whereas the CIHDOTTs work under organ donation assistance protocols in health care establishments. When there are no CIHDOTTs in place, the OPOs accumulate the functions inherent to the Intra-Hospital Commissions.

Although Brazil has the largest public system of organ transplants in the world, there are stark disparities in access to transplantation services both within and across Brazil's regions. Factors that have negatively affected patient access include inadequate funding, poor health care infrastructure, unequal distribution of national transplantation centres and geographic distance, insufficient human resources, precarious information systems used in state transplant coordination offices, and the lack of communication protocols related to organ procurement and donation.

Upon initiation, the SNT adopted an opt-out system for organ donation; this resulted in major denial with the majority opting "no" due to lack of general public information. Currently, organ and tissue donation is still based on family authorisation.

3.4 Canada

The Canadian system emphasises transplant champions in frontline health care teams and has had an enormous influence on donation outcomes, with significant growth trends in deceased donation over the past decade.

The *Safety of Human Cells, Tissues and Organs for Transplantation Regulations* (2007) standardise the screening and testing of potential donors and are described as reflecting the best practices in place across Canada. Organ donor coordinators are trained to identify potential donors and approach families for consent. The organ donor physicians are trained to improve donation practices, support donor care, and facilitate education and awareness, all in collaboration with the coordinators and the health care facility.

Mandatory referral requires that Canadian health care professionals report all brain deaths, cardiac deaths (if occurring in a hospital equipped to follow the candidate as a potential organ donor), or imminent deaths to their local OPO. A national registry contains information about donors and recipients to improve efficiency in identifying compatible recipients.

Professional education is a key component of successful Canadian programmes and includes:

- Organ and Tissue Donation and Transplantation (OTDT) system overview
- Clinical triggers – Identifying potential organ donors
- Donor management
- Process for referring potential donors
- Inclusion and exclusion criteria
- How to conduct neurological determination of death (NDD)
- How to conduct DCD
- Paediatric NDD
- Paediatric DCD
- Ancillary tests for NDD
- Best practice in consent discussions
- Legal and ethical considerations in deceased organ donation
- Surgical DCD process
- Hospital donor procurement role
- High risk donors
- Donor coordinator role in transportation.

All Canadian provinces and territories have historically elected opt-in systems for organ donation. However, as of 18 January 2021, those people of Nova Scotia who are eligible donors and who have not registered to be a donor or have not opted out are legally considered as having consented to donating their organs and tissues after death, referred to as presumed/deemed consent.

3.5 Spain

Globally, Spain has progressively reached the highest rate of organ donation. This success has been attributed to factors including presumed consent, the presence of a central coordinating authority, the presence of transplant coordinators in every ICU, in-built quality assurance systems, and the creation of a culture of routine donation through media education, an outreach system and an open telephone channel for queries from the general public.

The ONT is in charge of official reports in the field of organ donation and transplantation and guarantees the complete equity and transparency of the system, thereby assuring best use. On a national scale, the ONT oversees organ sharing and management of waiting lists, arranges for transplant teams and organ transport, maintains the official statistics on organ donation and transplantation activity, and keeps interested groups informed. The ONT is also concerned with training programmes and research in the field of organ donation and transplantation.

Orientation of organ recovery around transplant coordinators in every ICU and the systematisation of donor identification and organ recovery have been key to improved donation. A physician acts as coordinator and a team of trained people from the hospital itself performs organ procurement activities, for which the hospital is reimbursed. Effective audits of hospital deaths ensure the quality of the process. The efficacy of the Spanish model has now been demonstrated across a diverse range of countries and is considered to be the international reference standard.

3.6 United Kingdom

Improvements in deceased donation since 2008 arise from recommendations made by the ODT to establish a coherent UK-wide framework for deceased donation. This framework is supported by all health administrations and representatives of all relevant professional societies and Royal Colleges, and has led to major changes in the structuring of organ donation in the UK. Most notably, the centrally employed workforce is made up of trained SNODs, a UK-wide network of CLODs, and a National Organ Retrieval Service (NORS) that ensures there are fully staffed retrieval teams who are available 24/7 to retrieve donated organs from any hospital within the UK.

The SNODs spend more than 60% of their time in the hospitals they support, covering four main areas of work:

- Approaching families about donation
- Managing and coordinating the donation and offering process
- Hospital development through supporting the clinical lead and Donation Committee in improving hospital processes
- Carrying out the potential donor audit.

A large increase in donation has resulted after mandated Regional Collaboratives were created to oversee the Donation Committees of each hospital, which are accountable for the donation activity occurring under their watch. Regional Collaboratives bring together intensive care consultants, SNODs, CLODs, Chairs of Donation Committees, retrieval surgeons and recipient coordinators to share innovative best practice and to work out how to overcome local obstacles. Led by the Regional Clinical Lead and Regional Manager, these Collaboratives review audit data, share learning, provide support to people leading change in hospitals and drive improvement.

The increase seen in the number of donors between 2008 and 2013 was almost entirely due to expansion of DCD programmes. Additionally, significant improvements have been made to end-of-life care standards and practices to ensure that a patient's wish to donate is met.

Of note, in 2020 English law changed to an opt-out system where all adults in England are considered to have agreed to be an organ donor when they die unless they have recorded a decision not to donate or are in one of the excluded groups.

3.7 United States of America

The USA has shown a significant growth trend in deceased donation over the past 20 years for both DBD and DCD, with DCD currently constituting 20% of deceased donations. **Key success factors contributing to improved donation in the US are a coordinated national system - “the shortage of organs is a national issue” - with a strong regulatory framework.**

Federal bodies drive all procurement and transplant work. The USA model is OPO-centric, focused on professional donation teams with defined professional roles to address organ donation. A broad scope of services that are the responsibility of an OPO includes:

- Donor family support
- Clinical support and management of organ donors
- Professional education
- Public education
- Tissue donation
- Research.

The success of this system relies on collaboration between the donor hospital, the OPO and the transplant centre. **It is a federal regulation to notify an OPO of all imminent and actual deaths; this regulation allows the OPO to assess organ and tissue donation potential and respond on-site within one hour of referral, where they work closely with the hospital team to set up the donation conversation and to ensure that it happens at the best time and under the best format.** The advantage of this regulation is that there is no reliance on a physician or nurse champion/referral link and therefore fewer opportunities are missed because the same process is followed with every imminent death. Tracking, reporting and analysis of multiple components of performance are used for regulatory monitoring and performance improvement monitoring at OPO level, at hospital level and at transplant centre level.

Key to success with donor hospitals is support for nursing leadership, engaged physician champions and leadership that is invested in outcomes, with donation integrated into the fabric of the hospital. A major focus of the OPO educational and awareness efforts is the multidisciplinary hospital donation committee that meets on a monthly basis in order to set goals, discuss activity and performance improvement, set policy, and recognise success. The hospital donation committee is comprised of a senior hospital administrator, a physician leader, nurse leader, care staff and the OPO.

Organ and tissue donation in the US is opt-in; once included on the public donor registry, this decision is registered on the driver's licence.

Chapter 4

Vision and outcomes for improving deceased donation

4.1 Vision

Vision statements that were supported by all workshop participants were:

“Giving hope to all through transparent, accountable and ethical organ and tissue donation in South Africa”

“Meaningful end-of-life possibilities through a culture of organ donation in South Africa”

4.2 A charter for systemic change

A mandate is required for a national organisational entity representative of all stakeholders to empower the vision and priorities identified in the workshop.

Such a mandate outlines current challenges and priorities, outlines the required scope of work to be accomplished and related boundaries, and suggests key activities and outcomes.

Function and core competencies of a charter for systemic change

- Mechanism to represent and liaise with all stakeholders, and advise the Minister of Health and Health MECs
- Assist in creating a national policy for solid organ and tissue donation and transplantation
- Create national standard operating procedures (SOPs) to ensure all potential donors are timeously identified and referred
- Establish a mandatory death reporting system with the aim of allowing quality assurance in end-of-life care practices, thereby increasing the potential of organ and tissue donors
- Establish, administer and regulate a standardised fully inclusive national waiting list for all organs and tissue, with up-to-date recipient and donor information
- Implement, coordinate and regulate a national organ allocation policy, procurement activities and quality assurance
- Establish accreditation standards and mechanisms to audit hospital units, tissue banks and transplant coordinators
- Establish and administer a mechanism for transporting transplant teams and organs on a cost recovery basis
- Establish a mandatory transplant curriculum for medical professionals at undergraduate, postgraduate and sub-specialist level
- Standardise key messages for public awareness education, with regular transparent reporting on donation and transplant activities.

Beneficiaries and target populations

If created as a national organizational entity such a charter would be held accountable to:

- The people of South Africa through the NDoH and NHI
- Transplant centres
- Tissue banks
- NDoH hospitals and clinics
- Private hospital groups
- Health care funders (medical aid)
- Hospital managers and CEOs
- Trauma, emergency (including paramedic) and ICU medical professionals
- Transplant advocates/ambassadors and coordinators
- Other medical professionals (neurology, surgery, anaesthesia, palliative care including counsellors/psychologists, forensic pathology)

- Medical and nursing universities and colleges
- Journalists and the media
- General public (including religious and cultural interest groups).

Transparency and accountability

It is integral that such a mandated national organisational entity is transparently accountable to patients and to the public. Several considerations can ensure that this goal is attained:

- Members of the entity must be diverse, reputable and representative of all stakeholders, and appointed for a fixed term under a clear governance structure
- Regular (quarterly/biannual/annual) publishing, in the public domain, of annual general meeting/congress minutes and key performance indicators
- Reporting mechanism for feedback to all hospital managers and CEOs and to the MECs for Health on performance management and death referral audits
- Public awareness projects on the role of the national organisational entity.

Structural requirements to fulfil this national mandate for systemic change

Structural requirements that are integral to systemic change include:

- Steering committee incorporating members of SATS, SATiBA and the NDoH MAC
- Full-time administrators
- Part-time experts for education and training, curriculum development and the regular updating of these
- Legislative and regulatory structure to support organ donation referral links to transplant teams, with transplant ambassadors in every hospital
- The creation of a national OPO, with a centralised database, that administers the allocation of organs and tissue – NDoH as custodian.

Chapter 5

Strategic priorities and action plan for improving deceased donation

Seven key strategic priorities have been identified as describing the major areas of responsibilities and commitments that are required to improve South African organ and tissue donation:

- Organ donation potential (identification and referral)
- Organ donation conversion (consent practices and rates)
- Data collection
- Foundational system development
- Legislation and policy
- Professional education and practice
- Public awareness.

For successful outcomes, these key strategic priorities require collaboration between and among health care professionals, stakeholders, patients and their families, and also requires a societal dialogue. Foundational system development is the priority that has the potential to coordinate and assist with developing the other aspects of the strategic roadmap.

5.1 Organ donation potential: Identification and referral

Goals

- a) To create an enforced and functioning 24-hour central referring system (call centre) with well-defined points of entry for professionals working in:
 - Hospitals - all units - for organ and tissue donation
 - Post-hospital - undertakers, forensic mortuaries - for tissue donation
- b) To ensure a commensurate network of well-trained transplant coordinator teams across the state and private sector, with no hospital excluded
- c) To increase eligible donor approach rates to 80% through SOPs and training for:
 - Donor identification and referral criteria
 - Death certification
 - Death notification
 - Referral pathways.

Action plan

Central death notification system with appropriate referral system (NDoH custodian)

Requirements:

- Integration with current hospital and mortuary accreditation schemes (Office of Health Standards Compliance (OHSC)) and national core standards/ideal hospital framework
- Professional society and NDoH review and support of guidelines and coordination of standardisation across institutions
- A call centre to process and record all referrals centrally
- IT setup and maintenance of the reporting system.

Pre-existing and established resources:

- Current data sources and reporting mechanisms within the NDoH are very limited and poor
- SATS, with the assistance of the ODF, collects basic statistics annually but with no audit ability or mandate; these data are reported to the WHO Global Observatory on Transplantation
- Current hospital SOP systems
- OHSC.

Training in donor identification and referral

Requirements:

- Physician training – ensure competency in death determination, family counselling and end of life care/management
- Ongoing exposure of health care professionals to organ and tissue donation training programmes – undergraduate (universities/colleges), postgraduate continuing professional development (CPD) platforms
- Training/accreditation for competence in timely and comprehensive end-of-life discussions
- Public awareness campaigns – schools, medical professionals
- Funding
- Expertise for curriculum development and training
- Collaboration between the National Departments of Health and Education.

Pre-existing and established resources:

- South African-created online education course – Organ Donation: From Death to Life
<https://www.coursera.org/learn/organ-donation>
- Universities and Colleges, continuing medical education (CME) platforms
- Wits Transplant Procurement Handbook
<http://www.dgmc.co.za/docs/Wits-Transplant-Procurement-Handbook.pdf>

5.2 Organ donation conversion: Consent practices and rates

Goals

- a) Define a pathway from potential donor identification to consent outcome
- b) Identify quality improvement markers along this donor identification-consent pathway
- c) Implement monitoring and evaluation of quality improvement markers for this
- d) Develop evidence-based guidelines to improve consent practices and conversion rates, supported by all stakeholders
- e) Develop a transplant ambassador programme, to ensure a transplant champion is present in every hospital.

Action plan

Obtain consensus on the data variables required to meet South African needs in quality improvement of the consent process

Requirements:

- Definition of the organ donor pathway, in the South African context, from identification to consent
- Delphi consensus - of donation and transplant professionals in the field - with a mandate to create data variables and implement such data collection
- Study coordinator based at NDoH to record and audit (monitoring and evaluation) the statistics.

Pre-existing and established resources:

- Collaborative relationships exist between various stakeholders.

Develop a South African database on quality improvement markers of the consent process

Requirements:

- Database administration (data manager)
- Legal advice on data protection.

Pre-existing and established resources:

- Guidance from international database models
- TTS Data Harmonization Committee is an international body assisting with national registry data standards
- Pre-existing national systems inform the development of a South African system
- Published research studies.

Develop evidence-based guidelines to improve consent practices and conversion rates, supported by all stakeholders

Requirements:

- Consensus/support by all stakeholders.

Pre-existing and established resources:

- *Appendix 15 - South African guidelines on the determination of death*^[1]
- Southern African HIV Clinicians Society (SAHCS) guidelines for solid organ transplantation in HIV.^[2]

Develop a national transplant ambassador training programme

Requirements:

- Curriculum development and development of formal qualification
- A mentoring network affiliated to the training programme, that includes considerations of burnout prevention/intervention/management.

Pre-existing and established resources:

- Mentorship of transplant coordinators, employed in the role, with in-service training
- Online training course: <https://www.coursera.org/learn/organ-donation>
- Local training initiatives led by transplant coordinators and transplant centres.

^[1] Thomson D, Joubert I, De Vasconcellos A, *et al.* South African guidelines on the determination of death. *SAMJ/SAJCC* April 2021, Vol. 111, No. 4 (Part 2). <http://www.samj.org.za/index.php/samj/article/view/13264/9746>

^[2] Nel J, Conradie F, Botha J, *et al.* Southern African HIV Clinicians Society guidelines for solid organ transplantation in human immunodeficiency virus: An evidence-based framework for human immunodeficiency virus-positive donors and recipients. *Southern African Journal of HIV Medicine* 2020; 21(1), 8 pages. doi:<https://doi.org/10.4102/sajhivmed.v21i1.1133> <https://sajhivmed.org.za/index.php/hivmed/article/view/1133/2027>

5.3 Data collection

Goals

- a) To determine priority data collection areas and to describe these data points required for a centralised database with the NDoH as custodian
- b) That all state and private hospitals submit standardised, accurate death and potential donor data, mandatory to hospital accreditation with the NDoH
- c) That all transplant centres submit data on organ allocation and outcomes
- d) To regularly publish accurate audited data to ensure equity and transparency in organ allocation and transplant outcomes
- e) That South Africa contributes reliably to the International Registry in Organ Donation and Transplantation (IRODaT) and the WHO Global Observatory for Donation and Transplantation.

Action plan

Assess and compile data collection methods, criteria and programmes appropriate to the South African setting

Requirements:

- Collaboration between stakeholders.

Pre-existing and established resources:

- Established Renal Registry
- Established Bone Marrow Registry
- SATS data collection 2017/2018
- Private hospital data (e.g. Netcare)
- Collaboration with international affiliations - TTS, ISODP, WHO Global Observatory.

NDoH mandatory directive for standardised data collection as part of hospital accreditation

Requirements:

- MAC to engage with NDoH - previous attempts related to hospital accreditation have been stalled due to data asymmetry, technical difficulties and cost
- Administrative support (data capture) from NDoH and private hospitals
- Oversight management of data collection.

Pre-existing and established resources:

- Established administrative staff in state and private sector hospitals.

Standardised auditing of data collected

Requirements:

- Electronic platform
- Information manager/data scientist.

Pre-existing and established resources:

- There is currently no existing/established standardised audit of national data
- There is no national or provincial collation of the various waiting lists for organ transplants.

5.4 Foundational system development – National Organisation

Goals

- To implement an NDoH policy, transplant regulations and SOPs for organ and tissue donation that is 'National Health Insurance (NHI)-ready'
- To establish and run a transparent real-time database of quality outcomes and processes
- To increase donations from 1.6 to 3 pmp by 2025
- To have a public awareness campaign affiliated to the launch of the database
- Ensure transplant is an examination-based exit requirement for all undergraduate doctors and nurses.

Action plan

Creation of an interim decision-making National Coordinating Body (NCB)

Requirements:

- Collaboration and cooperation between SATS, SATiBA, NDoH, SATCS, CCSSA, Neurosurgery, ODF, Trauma Society for the creation of national guidelines and SOPs for transplant
- Definition of leadership positions required – portfolios with frame of reference/scope of practice
- Running costs (initially to be covered by SATS, SATiBA and other stakeholders).

Pre-existing and established resources:

- Pre-existing private-state sector collaboration in certain areas
- Goodwill and receptivity of nursing staff and CCSSA
- Established relationship/links between SATS and SATiBA.

Transparent database with established parameters

Requirements:

- NDoH mandate
- Governance structure
- Funding.

Pre-existing and established resources:

- SATS and SATiBA contain all the relevant role players to inform on parameters.

Accreditation of transplant centres

Requirements:

- NDoH mandate
- Involvement of all transplant specialities.

Pre-existing and established resources:

- SATS and SATiBA contain all the relevant role players to inform on parameters.

NCB-managed relations on integration of training programmes into existing undergraduate curricula and establishment as a mandatory exit criterion

Requirements:

- Cooperation of University Deans, the Colleges of Medicine of South Africa (CMSA), the South African Nursing Council (SANC) and the Health Professions Council of South Africa (HPCSA).

Pre-existing and established resources:

- Established collaboration between academic institutions.

5.5 Legislation and policy

Goals

- a) Capacitation of a funded, well functioning support system within the NDoH that has a focus on organ and tissue donation and transplantation (including dialysis services)
- b) A national registry comprising waiting lists, donor registry, patient information; available to the public to ensure distributive justice
- c) Collaboration between all professional bodies/stakeholders and the organ donation support structures within the NDoH
- d) Identification of legislative gaps to be addressed by professional society and NDoH collaboration
- e) Accreditation of units involved with dialysis, tissue/organ donation and transplantation services
- f) To undertake a health economics analysis to inform on current expenditure of dialysis/bridging programmes vs tissue donation and transplantation implementation.

Action plan

Environmental scan and assessment of existing legislative framework by stakeholders

Requirements:

- Funding (IT, consultants, administrative support)
- Collaboration of all stakeholders.

Pre-existing and established resources

- Parliament, NDoH.

Extension of National Registry for Organ and Tissue Transplantation and Donation (NDoH custodian)

Requirements:

- Collection and collation of existing data to illustrate the need for a national registry
- Funding (IT development and support structures, data capturers, real-time data oversight/management)
- Standardisation of SOPs and informed consent forms
- Mandatory hospital and morgue death reporting.

Pre-existing and established resources:

- Bone Marrow Registry, Renal Registry, private hospital registry (Netcare)
- Existing governance structure for listing and allocation.

MAC to lobby for establishment of Organ/tissue Donor Transplantation Council to inform NDoH on all issues

Requirements:

- Funding for expansion of MAC roles and subcommittees.

Pre-existing and established resources:

- Pre-existing MAC.

Identification of legislative gaps

Requirements:

- MAC task teams comprised of appropriate role players for each area, e.g. Critical Care Society consultation for deceased donation, cardiac transplantation professionals for heart allocation, etc.

Pre-existing and established resources:

- MAC.

Accreditation of units involved with dialysis, tissue/organ donation and transplantation services

Requirements:

- NDoH coordination, publication of regulations.

Pre-existing and established resources:

- NDoH.

Health economics analysis

Requirements:

- NDoH to direct the form and manner of such analysis
- MAC to provide guidance.

Pre-existing and established resources:

- Research infrastructures at universities
- NDoH economics analysts.

5.6 Professional education and practice

Goals

- a) To increase the number of health care professionals and transplant coordinators in South Africa
- b) To improve the standard of transplant education for health care professionals and transplant coordinators in South Africa
- c) To improve access to transplant education for health care professionals and transplant coordinators in South Africa.

Action plan

Clinical/professional education curriculum development, update and facilitation

Requirements:

- Standardised clinical education module to target undergraduate clinical training programmes for doctors, nurses and paramedics
- Engagement with Deans/Heads of Department of University and College medical faculties, and hospital managers and CEOs to ensure access to inclusive and appropriate training
- Clinical expertise for regular update of online training courses and other transplant coordinator training initiatives
- Accreditation of training courses and trainers
- Standardised clinical education curricula to target postgraduate clinical training programmes for doctors, nurses and paramedics working in/with emergency departments and ICUs
- Creation of higher qualification in the field of organ donation: e.g. Postgraduate diploma
- Standardised professional education for transplant coordinators and transplant links
- Use of South African electronic training resources - massive open online courses (MOOCs)
- Training handbooks
- CPD/CME courses focused on aspects of organ donation.

Pre-existing and established resources:

- A pre-existing MOOC, <https://www.coursera.org/learn/organ-donation>, can easily be integrated into curricula of Universities and Colleges at minimal cost
- Established clinical education structures and curricula
- Transplant coordinator mentorship/in-service training.

Transplant links (doctors and nurses) on every shift in every hospital

Requirements:

- Mandatory policy standardised across state and private sector hospitals with reporting
- Education of transplant links on every shift in every hospital; biannual training mandatory; performance indicator in job description.

Pre-existing and established resources:

- Hospital shift leaders, operational managers.

Standardising and implementing national policies in the state and private sectors

Requirements:

- Stakeholder collaboration to create standardised national policy documents.

Pre-existing and established resources:

- Stakeholders in private and government sectors have various SOPs
- Pre-existing standards and guidelines from national (*See Appendix 9 - Professional society guidance documents*) and international stakeholders.

5.7 Public awareness

Goals

- a) Increased visibility and transparency on transplant activities to improve public trust and participation
- b) Increased visibility to political stakeholders to lobby for change
- c) To attain a transparent and consistent national message from societal leadership – government, private, religious and traditional/cultural – accessible and understandable to all cultural and language groupings
- d) Ongoing unprompted ‘good news’ media engagement with transplant ambassadors within the media.

Action plan

More effective linkage of transplant units, tissue banks and other NGO stakeholders with the public

Requirements:

- A standardised approach to managing the interactions between public relations officers of hospitals, tissue banks and NGOs
- Key messages to be coordinated and common to all stakeholders.

Pre-existing and established resources:

- Numerous reputable NGOs (ODF, TELL etc)
- Passionate and well-trained health care professionals and transplant coordinators.

Coordinated marketing strategy across all stakeholders

Requirements:

- Funding
- Professional marketing management
- Corporate involvement
- Consistent public honouring of donor families, if they are willing; and using their stories for messaging content.

Pre-existing and established resources:

- Numerous reputable NGOs that are well-branded and run successful marketing campaigns.

Access to funding

Requirements:

- Lobbying for funding – with a need to specify a Rand value required per project basis
- Fundraising.

Pre-existing and established resources:

- NDoH
- NGOs
- Hospital groups.

Incorporation of transplant awareness into end-of-life care planning and funeral planning

Requirements:

- Engagement with palliative care workers and neurologists
- Incorporation into guidelines on end-of-life care planning
- Engagement with general medical professionals (CME platforms – ethics CPD; specialist society congresses/meetings, newsletters and websites)
- Transplant ambassador training programme.

Pre-existing and established resources:

- Clinical guidelines – Hospice Palliative Care Association
- National Policy Framework and Strategy on Palliative Care 2017-2022.
<http://www.health.gov.za/wp-content/uploads/2020/11/NationalPolicyFrameworkandStrategyonPalliativeCare20172022.pdf>

Chapter 6

Alignment with National Health Insurance

There is a clear alignment with what the national government is striving to achieve with NHI and the strategic principles underpinning effective organ and tissue donation and transplant as outlined in this document.

Phase 1 of the NHI piloted various health system strengthening interventions at the primary health care (PHC) level at pilot sites around the country. The current state of organ donation and transplantation is in definite need of system strengthening and could demonstrably be shown to benefit from such in line with the aims of the NHI.

Specifically, deceased donation is an opportunity where central efforts such as the OHSC could help to create a culture of organ donation across all health care institutions in South Africa and ensure that appropriate quality assurance and improvement mechanisms are in place for end-of-life care.

“The NHI is a health financing system that is designed to pool funds to provide access to quality affordable personal health services for all South Africans based on their health needs, irrespective of their socioeconomic status. NHI is intended to ensure that the use of health services does not result in financial hardship for individuals and their families. NHI seeks to realise universal health coverage for all South Africans. This means that every South African will have a right to access comprehensive healthcare services free of charge at the point of use at accredited health facilities such as clinics, hospitals and private health practitioners. This will be done using an NHI card. The services will be delivered closest to where people live or work.”

It is important to note that feedback on Phase I of the NHI^[1] reported that: “Overall, the implementation of the pilot interventions had mixed success across the pilot districts. Where successful, we identified a few common factors: strong political will, adequate human and financial resources for implementation, good coordination and communication, and good monitoring systems put in place at the time of implementation. However, the interventions also faced a number of challenges and, to varying degrees, these factors hindered their success: inadequate planning, lack of resources, inconsistent communication, a lack of coordination where necessary and insufficient mechanisms to monitor progress to ensure course correction.”

^[1] Evaluation of Phase 1 implementation of interventions in the National Health Insurance (NHI) pilot districts in South Africa. NDOH10/2017-2018 Final Evaluation Report July 2019. https://www.hst.org.za/publications/NonHST%20Publications/nhi_evaluation_report_final_14%2007%202019.pdf

“The evaluation findings highlighted the importance of strong leadership and good governance in order to drive a successful and effective health system. There are four main components of governance which are critical for the successful implementation of NHI: clarity of vision, setting appropriate priorities, performance management and accountability. In many interventions, the presence of strong champions who held the vision of NHI, and of that specific programme, ensured that there was robust implementation. However, this was not evident in some of the interventions. In many cases managers implemented the interventions in silos and seemed to lose the overall objective of the NHI process, which was to improve access to and the quality of services at facilities.”

“Some performance management structures were put into place during implementation but there was not always an adequate amount of upward feedback. Overall there was insufficient monitoring, and course correction was insufficient in some interventions. Finally, the organisational culture within some parts of the department is perceived by staff to be overly bureaucratic. The culture is often not supportive of problem solving and leaves little room for creativity or innovation. There is also little recourse for consequences of poor performance, a lack of accountability and insufficient use of data to monitor progress. Likewise, there is little incentive for high performance and to encourage staff to produce high quality data. There is a need to strengthen health system governance during NHI phase 2, otherwise there is the potential for new interventions to continue to have varied implementation success across the country.”

The lack of clarity of vision is noted by the NHI pilot evaluation report as a continual challenge from district level upwards. This strategic roadmap has highlighted those improvements to deceased donation practices and systems around the country that can be effected with a very clear vision and outcomes markers.

The need for NHI within organ transplantation in South Africa

As with other health care services in South Africa, organ transplantation is inequitably distributed, skewed towards service provision in the country's better-resourced private sector. The inequities in transplantation, specifically the differences in transplant rates between the medically insured and the uninsured and urban-rural discrepancies, are an indictment on distributive justice in South Africa.^[1] However, the private health care system is also grossly underperforming in deceased donation.

A standardised system of organ donation would allow donors to come from all walks of life and all hospitals, both private and state, where a patient can be mechanically ventilated, and from anywhere in the country, to contribute the life saving gift of an organ being given to another person. The structural change and standardisation of processes that comes with a single strategic coordinator can thus have wide-reaching positive impacts on organ donation.

Organ donation and transplantation allows state tertiary facilities to demonstrate their academic position, retain and enhance skill and capacity in the state sector, and ensure the sustainability and quality of their multidisciplinary training programmes. Conversely, private sector facilities would be incentivised to leverage their agility and capital to service previously uninsured populations away from major metropolitan areas, in economically inactive communities.

^[1] Moosa MR. The state of kidney transplantation in South Africa. *S Afr Med J* 2019 Mar 29; **109**(4): 235-240. doi: 10.7196/SAMJ.2019.v109i4.13548. <http://www.samj.org.za/index.php/samj/article/view/12575>

The NHI thus represents an opportunity to strengthen the capacity of the country to increase rates of transplantation in the population, to improve the standardisation, transparency and efficiency of organ allocation, and to allow for the measurement and improvement of the quality of transplantation services.

A core political goal of universal health coverage (UHC) is to engender social solidarity. This aligns perfectly with organ donation and transplantation. The cultivation of a new national social contract and a culture of donation would increase the efficiency of organ donation from donors to recipients as required. Under such a transparent and national system, public value would be maximised.

NHI structure

The NHI will impose a system of financial arrangements and quality controls on all health care providers in South Africa, with the aim of attaining UHC. The WHO defines UHC as a state in which: *'All people and communities can use the promotive, preventive, curative, rehabilitative and palliative health care services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.'*

A universal right to health care implies distributive justice. However, in practice, access to and quality of health care are directly proportional to socioeconomic status, thus quality of health care is adversely affected in a resource-poor setting (the 'Inverse Care' Law). South Africa is thus moving towards UHC in an effort to enhance equitable, affordable access to quality health care for the entire population.

There are three dimensions to consider when moving towards UHC:

- Minimising the direct costs of health care services
- Maximising the health care services covered
- Maximising the proportion of the population covered.

Funds for the NHI will be derived from mandatory payroll, income and value-added taxes. Once this revenue has been collected, it will be channelled to a centralised NHI Fund. This pooling of funds enables national pooling of risk between low- and high-income groups, as well as sick and healthy persons. The fund will act as a single payer for all health care services, both state and private, in the country. The presence of a legislated single strategic purchaser will allow government to dictate price and quality controls to all providers of health care in the country.

The benefits covered under the NHI Fund will be integrated gradually, as revenue allows. Benefits will be determined by a committee of the fund. Packages will focus first on preventative and primary health care before inclusion of tertiary and academic services.

All health care providers will have to be accredited by the OHSC in order to invoice the NHI for services rendered. This will require facilities to pass accreditation audits performed on a regular basis by the OHSC.

Preventative health care is likely to be incentivised by capitation payment models at primary care level, whereas tertiary academic services will likely be carried out on a fee-for-service basis (Health Market Inquiry). Accurate service activity, health outcomes and costing information will be crucial to enable accurate invoicing to the NHI Fund. State and private facilities will be incentivised to compete for service based on quality and efficiency of care and will be able to recapitalise monies received to improve capacity and quality of services rendered.

Making organ donation NHI-ready

In order to participate effectively in the NHI, organ transplantation in South Africa will require a framework of standardised, well-coordinated processes in a transparent system with measurable outcomes. Thus, the development of a system of NHI is an opportunity for the transplant community to integrate donor and recipient processes, standardise policies nationally, and improve the measurement of waiting times, organ transplantation and outcomes. An integrated, transparent system will enable continuous quality improvement in all facilities which conduct organ transplants.

It is imperative that organ donation and transplantation gains public and role player support by engaging with the NDoH and industry and across the state-private sector divide to formulate legislation, regulations and standards of care, to build joint transplant targets for the country and to improve the collection of service and financial data in preparation for the monumental change and opportunity which NHI presents. There is an opportunity for the NHI roll-out to be tasked with facilitating this improvement in organ donation. It has been proven repeatedly around the world that improved central coordination results in substantive improvements. Organ donation and transplantation volume, quality and value can be dramatically improved over the coming decades in South Africa with the support of the resources of the NHI, and this is potentially a poster child for what NHI success could mean.

Chapter 7

Cost-effective interventions for addressing the deceased donor shortage

National improvement strategies from across the world regarding access to transplantation have seen the largest return on investment when focused on health care system interventions to improve deceased donation. System improvements are relatively low-cost for a return of a large increase in donor numbers.

While public education is required, it has not been demonstrated to result in wholesale improvements in transplant numbers; rather, the greatest benefit has been yielded from strategies that focus on health care system improvement.^[1]

A model such as the UK potential donor audit of DBD enables identification of where donor attrition occurs (not formally tested for brain death, medical contraindication to donation, family not approached about donation, consent refused, unable to procure), and targeting these areas for systemic improvement would increase donations.

High performing systems focus on 'Every Donor Every Time' organ and tissue pathways with integration into hospital and professional standards, thereby creating local accountability for donation training, practice and monitoring.

Common aspects to high performing donation systems are:

- Death audits/medical record review (mandatory reporting of missed donation opportunities)
- National consistency in clinical referral criteria/triggers underpinned by accountability tools and structures
- Information/data contribute to and are the foundation of evidence-based medicine and practice guidelines
- Professional education and training

^[1] Domínguez-Gil B, Delmonico FL, Shaheen FA, *et al.* The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transpl Int.* 2011 Apr; **24**(4): 373-8. doi: 10.1111/j.1432-2277.2011.01243.x. PMID: 21392129. <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1432-2277.2011.01243.x>

- Implementation of national leading practices regarding NDD/DCD national guidelines, donor management and consent conversation at end-of-life
- System-wide donation-specialised personnel including dedicated organ donation organisation (ODO) administrative leadership, medical directors for organ donation, donation coordinators and donation-focused physicians
- Availability of timely performance data and data transparency that is crucial to driving success
- Adequate ICU/hospital capacity
- Adequate funding
- Legislation regarding required referral
- Public education and awareness
- Intent to donate (online registries)
- Continuous quality improvement and research.

National data reported annually should, at minimum, reflect:

- Total population
- Total deaths
- Deaths in hospital
- Potential donors
- Requested donors
- Consented donors
- Actual donors
- Transplant recipients
- Organ transplant procedures
- Organs transplanted.

Measuring hospital performance should include:

- Total deaths
- In-hospital deaths
- Potential cornea donors
- Cornea recovered
- Potential tissue donors
- Tissue donors recovered
- Potential organ donors
- Organ donors recovered.

The core processes for optimum clinical care at end-of-life include timely referral, patient evaluation, family support and effective family approach. Ensuring hospital staff are adequately trained for end-of-life patient management includes understanding all of the opportunities for donation and support throughout the grieving process. Embedding this practice into the culture of the institution is key to a high donation rate and can be achieved by ensuring that there is allocation of defined roles at all institutions where donors may come from.

Key drivers of organ donation/recovery/ procurement organisation success are:

- Professionalisation
- Training and education
- Performance improvement
- Mandatory death reporting
- Legislative and regulatory support
- Specialised roles
- Donor registration
- Collaboration with transplant centres
- Data driven processes.

Chapter 8

Surveillance – monitoring, evaluation and research

Discussions by workshop participants on the primary considerations of monitoring, evaluation and research centred around funding and who is actually going to do the research. Not that much money is immediately readily available, but how much money is actually needed? In research, a 'scarcity' mindset may be a hindrance as the primary need is for human resources who have the time to do the research without having to focus on other roles.

Creative solutions that can contribute to organ and tissue donation research needs include:

- Approaching Heads of Department and registrar groups from various disciplines (public health, internal medicine, emergency medicine) with a specific research question and associated aims
- Approaching international research partners and residency programmes with research for MSc and PhD students
- Approaching university faculties outside of the health sciences (humanities, social sciences), posing research questions that are non-health science related.

Important areas of necessary future research topics that were discussed among workshop participants included the legal aspect and gap analysis; foundational system and data collection; referral and consent; procurement; and public awareness.

8.1 Research questions – Legal aspects and gap analysis

- Review of the POPI Act and Section 15 of the NHA and their interplay with regards to sharing patient information to tissue banks.
- Perceptions of practicing clinicians and nurses related to the interpretations of the POPI Act.

8.2 Research questions – Foundational system and data collection

- A donation database
This primary research point is also the largest of all of the studies that need to be undertaken and is a multidisciplinary (all stakeholders) foundational necessity to improving organ and tissue donation systems.
Delphi on feasibility, acceptability, adaptation and approval of database data metrics in the South African setting, combining existing data metrics used in local fragment databases with established international databases
Part 1: Donor referral and conversion
Part 2: Recipient outcomes post-transplant.
- Identifying the potential pool of organ donors
A retrospective chart review of all deaths in a health care facility (without pre-existing mandatory reporting of deaths to transplant coordinator) and assessing clinical notes to ascertain if they meet criteria for referral (tissue and solid organ)
Pilot study: Mandatory reporting of all deaths to tissue bank/transplant coordinator
Phase 1: Tertiary
Phase 2: Regional/District hospital.
- Registrars and consultants (multiple disciplines) knowledge of brain death testing.
- Registrars (multiple disciplines) ability to perform brain death testing correctly with a checklist in a simulated environment.
- Are specialist/critical care nurses/trauma-trained nurses able to be trained to perform brainstem death testing safely?
Train/test/simulation
Processes and regulations, and how this affects resource limited facilities.
- Surveying clinicians on perceived obstacles for referring potential donors.

8.3 Research questions – Referral and consent

- Development of a standardised consent form – consensus process.
- Linguistics-based study related to how coordinators take consent.
- Development of a detailed video educational resource for clinicians on breaking bad news regarding brain death and devastating brain injury
Including role-play scenarios and troubleshooting for common difficulties encountered by clinicians.
- Development of a detailed video educational resource for donor family consenting
Including role-play scenarios and troubleshooting for common difficulties encountered by coordinators.
- Descriptive study on donor conversion rates across the country
Only possible once a donation database has been established.
- Development of video communication tools in alternate languages
Particularly useful for rural or distant sites where access for coordinators is difficult.
- The potential of AI electronic patient record guidance to give prompts for referral
Automatic triggers on the electronic register of patient documentation
?Artificial Intelligence consenting?
- Tissue referral
Development of communication guide on telephonic consenting - 'scripting for success'.
- Reporting on unsuccessful solid organ consent, are the family subsequently referred after cardiac death for re-counselling for tissue donation?
- Mapping silos
Perceptions of nurses and doctors in referring deceased/palliative patients for tissue donation in comparison to solid organ donation.

8.4 Research questions – Procurement

- What are the factors that affect procurement after consent has been given?
- Qualitative interview exploration of experiences of referring clinicians after 'first-time referrals'
Identifying areas for improvement.
- Is surgeon availability a limiting factor in procurement?
Exploratory study.
- What is the role of *ex-vivo* organ perfusion after consent is obtained in a low/medium resource setting?
- Qualitative interviews with donor families regarding the referral, consent, procurement, post-procurement process
Identifying areas for improvement.

8.5 Research questions – Public awareness

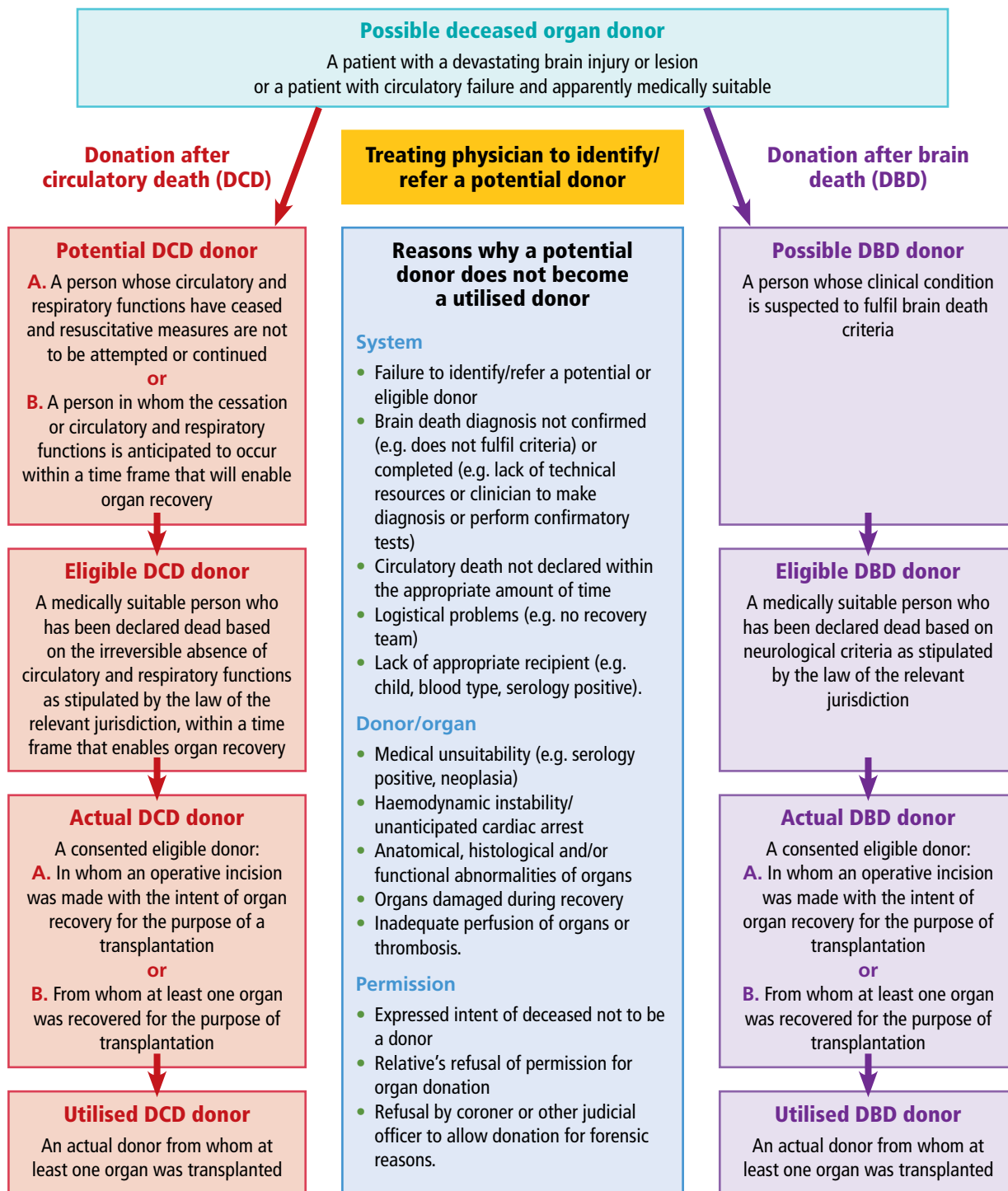
- Investigating best techniques for increasing public awareness; family, religious, community and traditional leaders and opinion moulders. This research needs to be broken into multiple research questions/studies that engages with humanities and social science research.

The background features a vibrant green color palette. On the left side, there are several overlapping, semi-transparent, wavy ribbons that create a sense of movement and depth. The rest of the background is filled with a pattern of small, light green dots arranged in a regular grid, which fades out towards the left edge.

Appendices

Appendix 1

Critical pathways for deceased organ donation



* The "dead donor rule" must be respected. That is, patients may only become donors after death, and the recovery of organs must not cause a donor's death

Domínguez-Gil B, Delmonico FL, Shaheen FA, *et al.* (2011). The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transplant International*; 24(4): 373-378.

<https://onlinelibrary.wiley.com/doi/full/10.1111/j.1432-2277.2011.01243.x>

Appendix 2

Steering committee process and terms of reference

Organ Donation and Transplantation in South Africa: Creating a National Strategy Roadmap

Process Terms of Reference

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Introduction¹

A process terms of reference (PTR) is a conceptual framework describing eight key elements involved in process designs such as strategic planning, issues analysis, action research, team development, etc. These 8 elements are:

1. **Current situation:** This section introduces the circumstances and context in which a process exists. It helps to reveal the meaning of a process in relationship to its setting, key stakeholders, and contributing factors.
2. **Developing a focus:** This section describes four main aspects of an initiative: purpose, objectives, outputs, and outcomes. It is a clear, engaging and exact description of what you intend to do in a process.
3. **Stakeholder collaboration:** Stakeholders are individuals, groups, and organizations with a significant vested interest in the purpose, objectives and outcomes of a process.
4. **Core assumptions:** These are the agreed-upon ‘givens’ or decisions that provide a common starting point for reflection, discussion, and decision-making. They are “off the table” for the purposes of the process.
5. **Key considerations:** Every process has important circumstances, data, reflections, and concerns that need to be taken into account because of their potential impact on the success of an initiative. These key considerations are revisited (‘on the table’) throughout the process.
6. **Work Plan:** A work plan outlines the key phases in an initiative and what will be accomplished in each phase, including the main activities in sequence. The work plan section includes a process overview, title and outline for each phase, main action items for each phase, main deliverables for each phase, and estimated resources. (The work plan for this project is a separate document.)
7. **Governance:** the best process governance structures are simple, efficient, and elegant. They support stakeholders in working together to provide oversight complete tasks, manage issues, and make decisions.
8. **Supportive Documents:** The essential documents required to support a process depend on its scope, purpose, objectives, outputs and outcomes. Some initiatives require extensive information, including comprehensive literature reviews, scientific and legal evidence, surveys and interviews for decision-making purposes. Other initiatives may be focused more on stakeholders and participants bringing their experience, expertise, and opinions to the table.

Completing a PTR is required to anchor a process; it clarifies and shapes the conceptual heart of an initiative and the relationships, roles and responsibilities required to make it successful. As such, it can be a powerful tool for upstream prevention.

A PTR is a living document: it needs to be revisited throughout a project, e.g., to keep it updated and confirm changes in scope, stakeholders, etc. as a project evolves.

¹ Strachan, Dorothy and Tomlinson, Paul. *Process Design: Making it Work*, A Practical Guide to What to do When and How for Facilitators, Consultants, Managers and Coaches. San Francisco, CA: Jossey-Bass, Business & Management Series, 2008, pp 97-98.

Current Situation

- This workshop is happening prior to and feeding into the biennial South African Transplant Congress sponsored by the South African Transplantation Society, and the South African Tissue Bank Association which is focused on changing and improving South Africa's Transplant Future.
 - Cape Town, where the 2019 conference is being held is one of the major transplant centres in South Africa.
- Estimates of organ donation (deceased donors) for South Africa are 1.4 per million - extremely low in comparison to other countries ⁽²⁾. Due to lack of a national data registry this estimate is inferred from statistics for deceased donor kidneys.
- Infrastructure reports and related data to support a donation culture in South Africa is limited or non-existent, with various institutions and role players keeping local statistics and none being collected centrally on a national level.
 - Data points required for quality improvement in organ donation include, for example, hours invested by donor coordinators, how much donor awareness activity is happening across the country, how many intensive care beds are in place, definition of transplant services, definition of a donor and how many there are for specific organs.
 - Students currently doing research on organ donation in the Western Cape are finding that the consent rate among poorer populations is 20% while in the private sector it is 50%. The referral rate is higher in the government sector than in the private sector: in a one-year period in the poorer population there were 80 referrals and 18 consented.
- There are significant discrepancies in health care services in South Africa: 70% of physicians provide services to 16% of the population, leaving the remaining 30% of physicians to care for 84% of the population. ⁽³⁾
- One centre has an active donation after circulatory death programme.
- Reporting on organ donation in South Africa is voluntary. Legislation and consensus-based leading practice guidelines are lacking and are required to bring rigour to consent and donation practices across the country.
- The role of race, religion and culture in organ donation in a society as diverse as South Africa and with our history must be sensitively considered.
- Rising dialysis costs and challenges in expanding access to dialysis in South Africa support the need for enhanced organ donation and consent practices. ⁽⁴⁾
- Transplantation is done in four of South Africa's nine provinces. In 2011 the majority of transplantation activity is in the Western Cape (35%) and Gauteng (40%). The other two provinces offering transplantation are Kwa-Zulu Natal (8%) and the Free State (3%). Kwa-Zulu Natal previously performed 25% of South Africa's transplants prior to prosecutions in the private sector related to

² The deceased organ donor rate in Canada in 2017 (including Quebec) was 21.9 donors per million population, an increase of 51% since 2008. The living donor rate was 14.6 donors per million population, a decrease of 11% since 2008. Deceased donor rates in Australia are 20.7 per million population and in the United Kingdom (23.1 per million population). (<https://www.cihi.ca/en/organ-replacement-in-canada-corr-annual-statistics-2018>) After a recent initial investment Saudi Arabia is reported to be at approximately 9 donors per million.

³ <https://www.neim.org/doi/pdf/10.1056/NEJM1405012?>

⁴ [Healthcare \(Basel\)](#). 2017 Sep; 5(3): 38. Published online 2017 Jul 31. doi: [10.3390/healthcare5030038](https://doi.org/10.3390/healthcare5030038)

organ trafficking. Transplants in Kwa-Zulu Natal subsequently dropped to <1% of South Africa’s total by 2010. ⁽⁵⁾

- Resource issues pose obstacles but are amenable to strategic intervention, and include logistic constraints including a paucity of transplant coordinators, limited access to operating theatres, scarcity of intensive care beds. ⁽⁶⁾
- Possible strategies for increasing organ donation and transplantation in a developing country such as South Africa have been proposed but without implementation strategies. ⁷
- “A recent report identified nurses as healthcare workers who should be empowered to play a much greater role in the identification and referral of donors in SA.” ⁽⁸⁾
- “Deceased donation relies heavily on these transplant coordinators of which there are currently 22 in a country of 52 million.” ⁽⁹⁾
- Several commitments in the *South African Declaration on Chronic Kidney Disease* to “reducing the risks of kidney disease and improve access to affordable renal replacement treatment of high quality to the majority of our population” relate to this workshop. *NOTE: The following are adapted to relate to all organ donation and transplantation.*
 - Promote organ donation among the public.
 - Educate and train health care workers about transplantation.
 - Increase funding and improve resource utilization, i.e., progressively increase state funding to improve access to treatment; explore funding models including PPI within the context of the NHI.
 - Review human resource issues, i.e., develop a comprehensive HR needs plan; develop strategy for staff training, recruitment and retention; look at alternative staffing models (e.g., using midlevel workers); develop innovative ways to increase public sector posts.
 - Promote transplantation, i.e., increase deceased donation; promote preemptive transplantation, increase availability of donors through registry; support infrastructure development; drive for organ donation (e.g., through required referral); promote donor registration; improve patient education and adherence.
 - Maintain standards, i.e., Have compulsory licensing of units; have appropriate QA mechanisms in place; adhere to SARS minimum core standards; address the special needs of children prioritizing transplant in children; report to a SA organ donation registry
 - Identify key areas for research, i.e., strengthen and broaden the scope of the South African Renal registry; promote research into the epidemiology and other aspects of chronic kidney disease in South Africa
 - Foster collaborations between various stakeholders. ⁽¹⁰⁾

⁵ D. Thomson, E. Muller, F. McCurdie, D. Kahn. South African Organ Transplantation 1991 – 2011: A twenty-one year review of transplantation in a developing country.

⁶ Scribante J, Bhagwanjee S. National audit of critical care resources in South Africa – transfer of critically ill patients. *S Afr Med J* 2007;97(12):1323-1326.

⁷ Moosa, MR. The state of Kidney transplantation in South Africa. *South African Medical Journal*: April 2019, Vol 109, No 4 p 238.

⁸ Crymble K, Fabian J, Etheredge H, Gaylard P. Perceptions of nurses’ roles in end-of-life care and organ donation – imposition or obligation? *S Afr J Med* 2017;107(7):573-575 <https://doi.org/10.7196/SAMJ.2017.v107i7.12487>

⁹ Elmi Muller, David Thomson, Fiona McCurdie. Transplantation in South Africa. *Transplantation*. April 2015, vol 99, #4. P. 643.

¹⁰ South African Declaration on Chronic Kidney Disease. March 25-26 2015.

Focus

Purpose

Optimal referral, consent practices and donor support rely on the health care system to identify donors, refer to the transplant team, support the consent process and optimally manage the donor to allow organ and tissue recovery to take place. The purpose of this meeting is to develop a national strategy for enhancing referral and consent practices for organ and tissue donation in the South African context.

This workshop will focus on three main areas essential to creating a culture of donation:

- a. Improving organ donation potential – identification and referral, e.g., organ donation organizations and processes, hospital leadership roles, transplant coordinator positions
- b. Improving organ donation conversion – consent processes and rates, development of a toolkit for evolving the consent process, country consent practices
- c. Improving data collection of key performance indicators and dissemination of this information to promote transparency and accountability to the public.

Objectives

1. To consult with experts and key influencers on the current situation in South Africa with respect to organ donation and how to optimize the number of consented donors
2. To review and benchmark existing practices/guidelines and policies in South Africa in relation to donor identification, referral, consent and organ management.
Countries identified for comparison: Spain, Brazil, Canada, United States, UK, Thailand, Malaysia.
3. To identify supports and disincentives affecting optimal organ recovery including referral triggers, consent practices, cost, equipment, access to ICU and OR, disparate funding for public and private sector health services
4. To initiate the development of a national strategic vision 2025, with a biannual report on progress and a formal reassessment in 2025 of the road map created and progress of required related systems in support of implementing optimal donor referral and consent practices and donor support.
5. To develop a national research agenda for organ donation and consent practices in collaboration with the Medical Research Council of South Africa
6. To disseminate the workshop findings-to health-care professionals, managers, administrators on a hospital, provincial and national level.

Immediate Outcomes

- Initiation and/or enhancement of collaborative relationships among health professionals, NGOs and the public in relation to organ donation in South Africa
- A draft implementation strategy for enhanced national organ donation, referral and consent practices in South Africa
- Data collection strategy to monitor organ donation, referral, consent practices and transplant activity.
- Initiation of a national research agenda for organ donation and consent practices.

Longer term Outcomes

- Consistent and transparent organ donation and referral practices in South Africa; transplant coordinators linked into local and national organ donation systems

- Increased confidence among health professionals and the public in South African organ donation, consent and referral practices
- Enhanced health services research opportunities in organ donation, referral and consent practices
- Focused action to address gaps in infrastructure support at local, provincial and national levels.

Stakeholders

- National Department of Health
- [Southern African Transplantation Society](#)
- South African National Tissue Bank Association
- [Health Professionals Council of South Africa](#)
- The Organ Donation Foundation of South Africa
- National Kidney Foundation
- Council for Health Services Accreditation in South Africa
- Council for Medical Schemes
- South African Transplant Coordinators Society
- National Ministry Advisory Committee (Nephrology)
- Critical Care Society of South Africa

Core Assumptions

These conclusions are the agreed-upon 'givens' or decisions that provide a common starting point for reflection, discussion, and decision-making. They outline the scope of discussions and are accepted as reality for the purposes of this workshop.

- This workshop will address deceased donation of organs, tissues and eyes not living donation.
- All families should be given the opportunity to consider the option of donation as part of optimal end-of-life bereavement care.
- A high performing national donation system in South Africa would have significant benefits for patients, i.e., more available organs, tissues and eyes; standardized consent practices in support of ethical donation.
- There is and will continue to be a shortage of deceased and living organs for transplantation. There is and will continue to be increasing demand for transplantable deceased and living donors. Increasing living donation is beyond the scope of this workshop.
- South African health professionals and the public will increasingly demand to know how organs are allocated to patients on a waitlist. Transparency and fairness are important and ethical aspects of donation.
- Equitable access to organ transplantation regardless of ethno-cultural identities and socio-economic circumstances are important with heightened sensitivity about discrimination.
- South African policies and approaches are required for sound decision-making. Consistent approaches and accountabilities utilized across the country are beneficial to patients.
- South Africa's organ donation system serves the entire population and aims to be inclusive and fair, based on transparency and accountability.
- As the South African Ministry of Health, the Southern African Transplantation Society, the Southern African Renal Society and the International Society of Organ Donation and Procurement have officially endorsed the principles of the Declaration of Istanbul, organ trafficking and transplant tourism are expressly prohibited and institutions should safeguards and increased vigilance required given the potential for exploitation of the vulnerable.
- The act of organ donation should be financially neutral and neither the donors or their families should lose or gain financially as result of the donation. Payment of funeral costs of donor family are therefore not an ethical solution to address the shortage of organ from deceased donors.
- In the current context of sustained low deceased donor consent rates and low levels of public awareness and understanding of organ donation, no evidence exists to support an assumption of majority presumed consent.

Key Considerations

Every process has important circumstances, data, reflections, and concerns that need to be taken into account because of their potential impact on the success of an initiative. These key considerations are revisited ('on the table') throughout the process.

- In South Africa private and public health systems exist in parallel. The public system serves the vast majority of the population, but is chronically underfunded and understaffed. The wealthiest 20% of the population use the private system and are far better served.
- Transplantation in SA has shifted from primarily the public sector to the private sector.
- There are nine provinces in South Africa with only a few having transplant services.
- With increasing urbanization the issue of migration (in all forms) of health personnel has become a critical factor in the debate about social justice in health, especially access and equity in the provision of health services. ([WHO 2015](#))

Work Plan

Deliverables	Timeline
a. Scheduled touch points with steering committee/client and others designated by them as required: average 2-3 per month. Timelines to be determined; includes assistance with agendas/facilitation.	Mar-October 2019
b. Review supportive documentation and develop a draft Process Terms of Reference (PTR) in collaboration with the steering committee.	Mar/Apr 2019
c. Assist with the review of workshop/planning materials: steering committee to initiate document development and provide oversight.	Mar-Sept 2019
d. Develop and administer a brief survey of meeting participants (max 3 questions on what works and what needs to be addressed) and prepare a report to serve as a foundation document for the process. In collaboration with the core planning group and the Steering Committee (i.e., Maryn Reyneke to do report), contribute to an interview-based environmental scan outlining the current situation on deceased donation in South Africa.	May 2019
e. Forum design (0.5 day) and facilitation (2 days) including detailed agenda development, worksheets, collaboration with steering committee, proposed report outline, etc. Client to provide note-takers/report-writers; effort includes briefing of same.	Sept 2019
f. Review of post-forum materials and facilitation of a post-forum steering committee meeting agenda to support follow-up work/ knowledge mobilization; develop hindsight reflections and discuss report outline (including process overview and meeting outcomes).	Sept-Oct 2019
g. Review draft forum report (est. 3 drafts) in collaboration with the steering committee. Client to provide related data, graphics and publication strategy.	Oct-Nov 2019

Project Governance

The primary clients for this contract are Dr. David Thomson, Chair South African Organ Donation and Transplantation (ODT) steering committee and national conference, and Kim Young, representative of the International Society for Organ Donation and Procurement (ISODP). Dorothy Strachan is the primary contact for Strachan-Tomlinson (ST) with responsibility for designing and facilitating the workshop. She works closely with Mike Tomlinson, Senior Associate at ST, who will provide support on pre-workshop consultation as required.

Secondary clients are members of the proposed workshop steering committee as follows.

International

- Susan Gunderson, President ISODP; CEO LifeSource OPO, USA
- Howard Nathan, Treasurer ISODP; President and CEO Gift of Life Donor Programme, Philadelphia USA
- Kimberly Young, Past President ISODP

Local Transplant Professionals

- David Thomson, Workshop Chair, Consultant Surgeon Transplant Unit and Critical Care Subspecialist
- Albert Muranda, Steve Biko Academic, Ministerial Advisory Committee
- Ntebaleng Morolo - National Department of Health
- Anja Meyer, Transplant Coordinator at Charlotte Maxeke Hospital, Chairwoman of South African Transplant Coordinators Society
- Maryn Reyneke, Executive Director, Declaration of Istanbul Custodian Group.
- Elmi Muller, Transplant Surgeon at Groote Schuur Hospital, Head of Department of Surgery at Cape Town University, Vice-President of The Transplantation Society
- Elmin Steyn, Transplant Surgeon at Christiaan Barnard Memorial Hospital, Head of Department of Surgery at Stellenbosch University, HPCSA Board Member
- Shrikant Peters, Medical Superintendent Groote Schuur Hospital Wits Donald Gordon Medical Centre
- Ziyanda Mgugudo-Sello, Public Health Department, University of Cape Town

Other potential members:

- Prominent public figure who has benefited from transplant e.g., government official, journalist.
- Other prominent leaders in health or related areas who need to be engaged to mobilize this plan, e.g., NGOs, high profile people, faith leadership, health charities, palliative care personnel.

Supportive Information

Document	Status	Who
1. Process Terms of Reference	Draft	ST
2. Glossary and Acronyms		
3. Chronology (1 page) leading up to the workshop		
4. Pre-meeting survey results		DT
5. Meeting agenda, detailed design, worksheets		DS
6. “Transplantation in South Africa” (Journal of Transplantation)		
7. Renal Summit declaration		
8. Presentation at TTS San Francisco conference on SA transplant statistics		
9. Report on organ and tissue donation in SA		
10. Report from Hospital groups on organ donation systems		
11. National government report on organ donation oversight		
12. SA Organ and Tissue Donation Legislation: Critical Review and SWOT		
13. Ethical considerations on a roadmap for organ and tissue donation		
14. NGO reports in support of organ donation systems		
15.		
16.		

Appendix 3

Pre-workshop participant survey

To: Workshop Participants

Re: Workshop: Organ and Tissue Donation in South Africa – Creating a National Strategy Roadmap

Thank you for accepting our invitation to participate in this workshop to determine priority areas for action related to developing a National Strategy Roadmap for Deceased Organ Donation to be held in Cape Town, South Africa on 4th-6th September 2019.

A key workshop objective involves consulting with meeting participants beforehand regarding their priorities with respect to this strategy. To do this, the planning committee is working with the International Society for Organ Donation and Procurement and a process consultant from [Strachan-Tomlinson](#) (ST).

It should take you about 10 minutes to complete this survey. Please be candid – we need open, thoughtful, and constructive information to ensure a solid information base for this work. An ST associate will synthesise your confidential responses into an anonymous report for use during the workshop. Please submit your completed survey 21 August 2019.

Here is your link to the survey: [INSERT LINK]. As this link is uniquely tied to this survey and your e-mail address, please do not forward this message. If you have any questions about the survey please feel free to contact Mike Tomlinson: <mike@strachan-tomlinson.com>.

Thank you in advance for your time and effort on this important project!

Dr David Thomson, Workshop Chair

Pre-workshop survey questions

1. In what capacity/role do you support organ donation? (*Insert checklist including "other"*)
2. How does your employer/organisation support a culture of organ donation in South Africa?
3. From your perspective what are the two or three most pressing needs to improve deceased organ and tissue donation in South Africa? (You can consider your answer along the following lines: Imagine that it is three years from today and the organ donation numbers in South Africa have tripled. What do you see going on that is different than today?)
4. What are the top two solution(s) you would propose to effect change in the areas you have identified? For each solution how can you/your institution support this change?
5. What documents do you think participants should receive before the meeting to support discussion by all present?
6. What is your advice for the facilitator of this meeting to ensure that it is both productive and enjoyable?

Reconciliation of participant responses

Public and professional education and awareness

- Consistent national message
- Health charities, spiritual leaders
- Education strategies at multiple levels with a focus on the benefits of donation, e.g., primary, secondary schools, university
- Media engagement: marketing campaign
- Cultural and religious barriers, traditional healers
- Health professionals training and education.

Legislation/policy

- Intent to donate/presumed consent/opt-in/opt-out
- National Registry
- NDoH support
- Political will to increase donation rates
- Transparent donor and allocation policies (fair and equal access to organs).

Organ donation potential: identification and referral

- Potential donor identification at point of entry (emergency department, critical care)
- Timely and appropriate referrals (clinical referrals), training to increase referrals
- Required referral (e.g., Canada) for optimising donation potential using all resources, i.e., NDD, DCD
- Donation as a standard of care in critical care and hospital practices.

Data collection

- Clean and concise: limited number of priority measurements
- Required reporting
- Transparent allocation policies.

Foundational system development

- National Coordinating Body
- Roles and responsibilities (governance)
- Resources to support healthy system
- Improved collaboration between stakeholders on an ongoing, regular basis to identify and resolve issues
- Implement an overseeing body not just for organs, but also to govern tissue banks and champion their needs.

Organ donation conversion: consent practices and rates

- Opt-in/opt-out
- Medical education: doctors and nurses re how to approach families
- Conversion rates.

Appendix 4

Transplant centres and tissue banks involved in deceased donation

Transplant centres

Busamed Gateway
Charlotte Maxeke Johannesburg Academic Hospital
Frere Hospital
George Mukhari Hospital
Grey's Hospital
Groote Schuur Hospital
Inkosi Albert Luthuli Hospital
Kimberley Public Hospital/Robert Mangaliso Sobukwe Hospital
Life Entabeni Hospital
Livingstone Hospital
Netcare Universitas Private Hospital
Netcare Christiaan Barnard Memorial Hospital
Netcare Greenacres
Netcare Johannesburg Transplant Division
Netcare Pretoria Transplant Division, Jakaranda Hospital
Netcare St. Augustine's Hospital
Red Cross War Memorial Children's Hospital
Steve Biko Academic Hospital
Tygerberg Hospital
UCT Private Academic Hospital
Wits Donald Gordon Medical Centre

Tissue banks

Bone SA
Bloemfontein Homograft Bank, University of the Free State
Centre for Tissue Engineering
Eye Bank Foundation of South Africa
Gauteng Cornea and Eye Bank
KZN Cornea and Eye Association

Appendix 5

International faculty

Kimberly Young

Past-President ISODP

Ms Young has a history of accomplishments in the OTDT field, including contributions at the programme, provincial, national and international levels. As CEO of the former Canadian Council for Donation and Report on the OTDT Ethics Consultation, Ms Young led the development of several pivotal leading practice and policy reports which resulted in improvements in patient care and system organisation. Her commitment to collaborative leadership is key in building relationships with governments, programmes and stakeholders leading to the development and implementation of innovative improvements in OTDT across Canada and the world.

Professor Stephen Beed

Education Coordinator, Department of Critical Care Education Committee

Medical Advisor, Legacy of Life Nova Scotia Organ and Tissue Donation Programme

Professor Beed has completed postgraduate training focused on Adult Critical Care Medicine plus Thoracic and Cardiovascular Anaesthesia. His current clinical focus is in the ICU. Professor Beed is the current President (2019-2021) of the ISODP. He has served as the Medical Advisor for the Nova Scotia Organ and Tissue Donation Programme since its inception in 2006, also serving as the Clinical Lead for the new presumed-consent legislation that has passed in Nova Scotia, and was National Chair of the Deceased Donation Advisory Committee (2008-2018). Professor Beed is also a member of the Organ Donation and Transplantation Expert Advisory Committee through CBS.

Susan Gunderson

President ISODP

President and CEO, LifeSource, Minneapolis, USA

Ms Gunderson both established and directed the LifeSource OPO for three states, being accountable for all leadership, operational, and policy aspects of the organisation responsible for human organ recovery leading to transplantation. She has developed the LifeSource OPO to be national leader in donation activity in the United States. Ms Gunderson has significant experience in national and international OPO and transplant activities, legislative initiatives, and public relations.

Howard Nathan*

*President and CEO, Gift of Life Donor Programme, USA
President, Transplant Foundation*

Considered a leading world authority on organ and tissue donation, Mr Nathan has contributed greatly to the overall science of organ transplantation and the knowledge of professionals working in this field worldwide. A renowned speaker and the author of hundreds of scientific publications on organ procurement, transplantation, and related subjects, Mr Nathan's contributions have greatly enhanced the level of patient care and family services available across the United States. He has been a mentor to colleagues in more than 15 countries and has held leadership roles on numerous boards including UNOS, the Association of Organ Procurement Organizations, DonateLife America and the ISODP, among others.

** Unfortunately, Howard Nathan was unable to attend the workshop due to health reasons, having participated actively in the pre-workshop steering committee meetings and supplying slides for presentation of international perspectives on leading practices.*

Appendix 6

Workshop participants

Ms Shirley Claasen, Transplant Coordinator - Tygerberg Hospital - Western Cape

Prof Stephen Beed, International Society of Organ Donation and Procurement - Head of Department of Critical Care - Dalhousie University - Canada

Dr Greg Calligaro, Pulmonologist and Intensivist - Groote Schuur Hospital - Western Cape

Ms Lucille Claassen, Transplant Coordinator - Livingstone Hospital - Eastern Cape

Ms Shirley Coetzee, Transplant Coordinator - Tygerberg Hospital - Western Cape

Ms Lizette Cooke, Transplant Coordinator - Regional Manager - Netcare - Johannesburg

Mrs Marlize De Jager, Transplant Coordinator - Wits Donald Gordon Mediclinic - Johannesburg

Mrs Ntebaleng Morolo, National Department of Health - Deputy Director of Dialysis and Transplantation

Ms Carol du Plessis, Transplant Coordinator - Netcare - Free State

Mr Fanie du Toit, NGO - National Kidney Foundation

Ms Reka Dulandas, Transplant Coordinator - Netcare - Kwa-Zulu Natal

Dr Katya Evans, Emergency Medicine Consultant - Mitchell's Plain District Hospital - Western Cape

Ms Margaret Fourie, Transplant Coordinator - Netcare - Cape Town - Western Cape

Ms Babalwa Gili, Transplant Coordinator - Red Cross Children's Hospital - Western Cape

Ms Cindy Goldie, Unit Manager - Busamed - Gateway Private Hospital - Kwa-Zulu Natal

Mrs Susan Gunderson, International Society of Organ Donation and Procurement - CEO - Lifesource - USA

Mr Raymond Hartle, Journalist - Heart Transplant Recipient

Dr Roland Hollhumer, Ophthalmologist - Johannesburg

Ms Louise Human, Transplant Coordinator - Netcare - Western Cape

Mr Tobie Kleinhans Le Roux, Social Worker - Netcare - Western Cape

Ms Zibuyile Koloane, Transplant Coordinator - Inkosi Albert Luthuli

- Mrs Sarita Mans**, Tissue Bank - Bone SA
- Ms Thandeka Matunjwa**, Transplant Coordinator - Netcare - Durban
- Ms Fiona McCurdie**, Transplant Coordinator - Groote Schuur Hospital - Western Cape
- Ms Anja Meyer**, Transplant Coordinator - Charlotte Maxeke Hospital - Johannesburg
- Ms Alexia Michaelides**, Regional Manager - Transplant - Netcare - Western Cape
- Mr Kgorohlo Moabelo**, Advocate - National Department of Health
- Prof Rafique Moosa**, National Department of Health - Ministerial Advisory Committee
- Head of Department - Medicine - Stellenbosch University
- Mrs Michelle Narayan**, Tissue Bank - Bone SA
- Ms Simangele Ndimu**, Transplant Coordinator - Netcare - Johannesburg
- Mrs Samantha Nicholls**, NGO - Organ Donor Foundation - Executive Director
- Ms Annette Otto**, Regional Manager Transplant - Pretoria and Bloemfontein
- Ms Gail Peggs**, Transplant Coordinator - Netcare - Johannesburg
- Prof Michael Pepper**, South Africa Tissue Bank Association - Chairperson and President
- University of Pretoria
- Ms Lettie Prins**, Transplant Coordinator - Netcare - Western Cape
- Ms Maryn Reyneke-de Kock**, Transplant Coordinator - Executive Director, Declaration
of Istanbul Custodian Group
- Prof Magda Slabbert**, University of South Africa - Pretoria - Medical Law
- Dr Debbie Southwood**, Critical Care Society of Southern Africa - Livingstone Hospital -
Eastern Cape
- Mr Luke Steenkamp**, Transplant Coordinator - Groote Schuur Hospital - Western Cape
- Mrs Ana Sterrenberg**, Tissue Bank - Bone SA
- Ms Jacqui Stewart**, Council for Health Service Accreditation of Southern Africa - CEO
- Mr Marais Steyn**, Tissue Procurement Supervisor - Centre for Tissue Engineering -
Tshwane University of Technology
- Dr Otto Thaning**, Cardiothoracic Surgeon - Netcare - Cape Town - Chairperson - NGO -
Organ Donor Foundation
- Mrs Carol Tonnesen**, Eye Bank - Kwa-Zulu Natal
- Ms Bonnie Venter**, Steve Biko Centre for Bioethics - University of Witwatersrand -
Director - NGO - Transplant Education for Living Legacies
- Mrs Sandra Venter**, South Africa Tissue Bank Association - Vice-President - Centre for
Tissue Engineering

Ms Irene van Schalkwyk, Western Cape Blood Services

Ms Michelle Vermuelen, Western Cape Blood Services

Dr Shrikant Peters, Medical Superintendent - Groote Schuur Hospital - Western Cape

Dr Ziyanda Mgugudo-Sello, Public Health Registrar - University of Cape Town - Western Cape

Dr Jenna Piercy, Critical Care Society of Southern Africa - Intensivist - Groote Schuur Hospital - University of Cape Town - Western Cape

Dr Tinus du Toit, South African Transplant Society - Board Member - Transplant Surgeon - Groote Schuur Hospital - University of Cape Town - Western Cape

Prof Elmin Steyn, Health Professions Council of South Africa - Board Member - Head of Department of Surgery - Tygerberg Hospital - University of Stellenbosch

Prof Elmi Muller, South African Transplant Society - Past President - Head of Division of General Surgery - Groote Schuur Hospital - University of Cape Town - Western Cape

Ms Glenda Hardy, Medical writer

Dr Norbert Welkovich, Critical Care Society of South Africa - Intensivist - Unitas Hospital - Pretoria

Dr Albert Muranda, National Department of Health - Ministerial Advisory Committee - Steve Biko

Dr David Thomson, Critical Care Society of Southern Africa - Intensivist and Transplant Surgeon - Groote Schuur Hospital - University of Cape Town - Western Cape

Prof Mignon McCulloch, President of International Paediatric Transplantation Association - Head of Transplant - Red Cross Children's Hospital - Western Cape

Ms Glenda Richards, Life Healthcare - Vincent Pallotti Hospital - Western Cape

Mrs Dorothy Strachan, Meeting facilitator - Strachan-Tomlinson and Associates

Ms Kimberly Young, International Society of Organ Donation and Procurement - Past President

Appendix 7

Environmental scan transplant centre respondents

Transplant centres responding to environmental scan

Charlotte Maxeke Johannesburg Academic Hospital

Frere Hospital

Grey's Hospital

Groote Schuur Hospital

Inkosi Albert Luthuli Hospital

Kimberley Public Hospital/Robert Mangaliso Sobukwe Hospital

Livingstone Hospital

Netcare Universitas Private Hospital

Netcare Christiaan Barnard Memorial Hospital

Netcare Greenacres

Netcare Johannesburg Transplant Division

Netcare Pretoria Transplant Division, Jakaranda Hospital

Netcare St. Augustine's Hospital

Red Cross War Memorial Children's Hospital

Tygerberg Hospital

UCT Private Academic Hospital

Wits Donald Gordon Medical Centre

Transplant centres that did not participate in environmental scan

Busamed Gateway

George Mukhari Hospital

Life Entabeni Hospital

Tissue banks responding to environmental scan

Bloemfontein Homograft Bank, University of the Free State

Centre for Tissue Engineering

Eye Bank Foundation of South Africa

Tissue banks that did not participate in environmental scan

Gauteng Cornea and Eye Bank

KZN Cornea and Eye Association

Bone SA

Appendix 8

Environmental scan questionnaire



Environmental Scan - ISODP - Improving Deceased Donation Workshop General

1. Name and surname of information provider

2. What is the full name of your transplant centre or institution?

3. Which of the following functions does your centre or institution provide? Check all that apply.

- General
- Donor Identification
- Donor Referral
- Donor Management
- Donor Family Follow Up
- Professional Education
- Public Awareness

Comments

4. 3. What is the primary healthcare sector in which your center or institution function?

- Public
- Private

If some work done in the other sector please specify split in patient load in percentage:

5. Does your center or institution perform some services in another sector from time to time? Eg. Shared private/public deceased donor call list. Please elaborate.

6. What geographical area do you cover for transplants? (Renal, Liver, Heart, Lung)
eg. Tygerberg - Metro East drainage area of Western Cape - state sector, no liver, heart, lung

Renal	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
Liver	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
Heart	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
Lung	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>

7. What geographical area and sector do you service as primary contact for donor referrals?

Renal	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
Liver	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
Heart	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>
Lung	<div style="background-color: #cccccc; height: 20px; width: 100%;"></div>

8. Are you the only service for the areas and sectors you service? Yes/No Please explain.

9. How many hospitals do your deceased donor coordinators manage donors in? Could you supply a list please.

Within these hospitals how many ventilated beds are there - give a best estimate per hospital please - include emergency department ventilators if referrals come from this area at that hospital

[Redacted text area]

10. Do the majority of your referrals come from the emergency unit or ICU?

- Emergency units
- ICUs

What is the split in terms of a percentage?

[Redacted text area]

11. How many transplant coordinators support deceased donation for your transplant centre?

[Redacted text area]

12. How many of these coordinators are full-time on deceased donation?

[Redacted text area]

13. For those coordinators not full-time on deceased donation please specify % time spent on deceased donation activity per person. (eg. No 1. = 50%, No 2. = 75%)

[Redacted text area]

14. What other roles do transplant coordinators fill at your institution?

[Redacted]

15. How many surgeons support deceased donation from your transplant centre?

[Redacted]

16. For each surgeon please specify the % time spent on transplant work and other surgery?
(eg. No. 1 = 25%)

[Redacted]

17. Is surgeon availability ever a rate limiting step for organ recovery by your centre?

- Yes - everytime
- Yes - sometimes (often)
- Yes - sometimes (very rarely)
- Never

Comments

[Redacted]

18. How many administrative staff support deceased organ donation in your centre? (Please elaborate on their functions)

[Redacted]

19. How many donor referrals does your centre receive per month (average out over the last year)?

[Redacted]

20. Are donor referrals increasing or decreasing over last 5 years?

- Increasing
- Stagnant
- Decreasing
- Unknown

21. How many consented donors do you have per month? (average out over the last year)

22. Does your center record consent rate as an outcome metric?

- Yes
- No

Comment on any processes to review this trend

23. If Yes - What was the consent rate (as a percentage of referrals) over last 12 months?

24. Are consent rates increasing or decreasing over last 5 years?

- Increasing
- Stagnant
- Decreasing
- Unknown

25. What qualifications do your transplant coordinators have? (Number with ICU qualification and number with international diploma)

[Redacted]

26. Do you practice donation after circulatory death? Yes/No

- Yes
- No

27. If yes, how often does a consented DCD donor result in organs procured? (eg. 75% of the time we end up procuring organs) - if unknown please state

[Redacted]

28. If yes do you have a SOP (Standard operating procedure / protocol) for DCD? Yes/No. If yes, please share.

- Yes
- No

29. If a patient is GCS 2T with one or two brain stem reflexes preserved would you:

- Continue to support in case there is progression to brain death? (For how long?)
- Consider donation after circulatory death
- Not consider organ donation?
- Comment

[Redacted]

30. Are there Link Nurses / Donor Identifiers / Donor Champions in the hospitals you support whom you can count on to identify donors in the ICU or EU?

Yes

No

Please elaborate

[Redacted text area]

31. If yes, how are these supporters acknowledged?

[Redacted text area]

32. If yes, what training do these supporters have?

[Redacted text area]

33. How many hours per month do you spend on donor identification education in ICUs and EU in your referral areas?

[Redacted text area]

34. Do you have a separate budget to support organ donation activities of your institution?

[Redacted text area]

35. Do you have a separate budget for organ transplantation in your institution?

Yes

No

Comments

[Redacted text area]

36. How many full-time equivalent staff are dedicated to donation or donation care per month? Is this estimate based on recorded data or a general perception?



Environmental Scan - ISODP - Improving Deceased Donation Workshop

Donor Identification

37. What are the total number of deaths in the potential deceased donor procurement area you serve per month?

38. What number of deaths are on mechanical ventilation or after planned withdrawal of ventilation per month?

39. What number of deaths are assessed for tissue and eye donation per month?

40. What triggers are used for referral to the transplant team? (Insert options including “other”)

- | | |
|--|--|
| <input type="checkbox"/> GCS 2T not explained by sedation | <input type="checkbox"/> Decision to perform brain death testing |
| <input type="checkbox"/> GCS 3T not explained by sedation | <input type="checkbox"/> Brain death testing declared |
| <input type="checkbox"/> GCS 4T not explained by sedation | <input type="checkbox"/> Circulatory death declared |
| <input type="checkbox"/> Planned withdrawal of ventilation | |
| <input type="checkbox"/> Other (please specify) | |

41. Is it a struggle to use intensive care resources for potential donors? Please comment.

- Yes
- No
- Sometimes
- Please comment (if sometimes give a % of how often it is an issue)

42. Are ventilated beds often fully occupied at a donor institution? If yes, please indicate % time that bed availability is at capacity. Is this estimate based on recorded data or a general perception?

43. How would you describe the overall reception to continuing management of potential donors in your setting? (Insert list, e.g., positive, supportive, hesitant, obstructive, etc.)

Overwhelmingly positive	Supportive	Hesitant	Obstructive	Hostile
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments

44. Do you have a brain death certification checklist? Yes/No. If yes, please share.

- Yes
- No

Note if there is a checklist to share

45. Do doctors perform brain death examinations independently or simultaneously?

- Independently (Seperately)
- Concurrently (At the same time/together)
- Depends on the doctors

46. Are there delays in performing brain death testing? Please explain causes.

47. Who is consulted if the referring team is unsure on an aspect of the certification process?

48. What if the procedure if the family refuses the diagnosis of brain death - can treatment be maintained indefinitely?

- Yes
- No

Comment

49. How is circulatory death determined in your institution?

50. Is there a protocol for determination of circulatory/cardiac/cardiorespiratory death you use? If so please share.

- Yes
- No

51. Do you have a policy for donation after circulatory death? If so please share.

Yes

No

52. What referral triggers are used to assess patients for possible donation after circulatory death?

[Redacted text area]

53. Is donation after circulatory death considered a possibility for increasing the donor pool markedly?

Yes

No

Comments

[Redacted text area]



Environmental Scan - ISODP - Improving Deceased Donation Workshop

Donor referral

54. Who does the referral for donors?

- Doctor
- Nurse
- Allied health
- Transplant coordinator identifies

Comment

55. Within your institution do you refer all deaths (those within criteria) that occur in your unit or hospital to a tissue / eye team?

- Yes
- No

Comment

56. Do you record all referrals made from your ICUs / emergency units in your procurement area?

Yes

No

Comment

57. Do you have a policy for referral of deceased donors into your system? (eg. Triggers for referral) Yes/No. If yes, please share.

Yes

No

Comments

58. What information is routinely documented at the end of life?

Consideration of organ donation (when appropriate)

How death was determined

Other

Consideration of tissue donation

Results of any consent request

Comments

59. Do you provide training on deceased donation to other healthcare providers? Yes/No If yes, who?

Yes

No

Elaborate?

[Redacted text box]

60. What performance measures are recorded about donor referral, consent rates, organ utilization?

[Redacted text box]



Environmental Scan - ISODP - Improving Deceased Donation Workshop Consent

61. Who usually first brings up the possibility for organ donation?



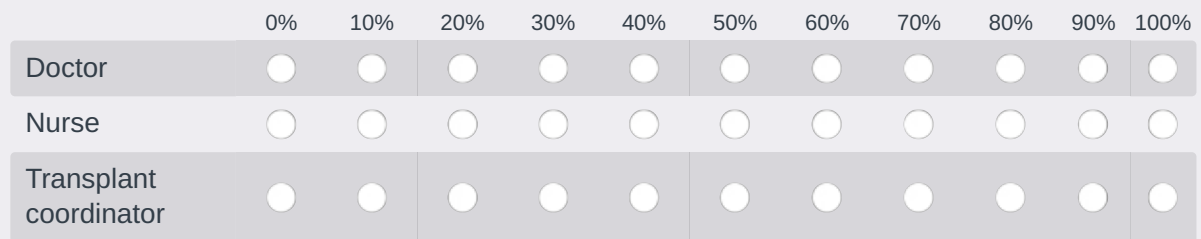
Why this split?

62. Who usually first brings up the possibility for tissue donation?

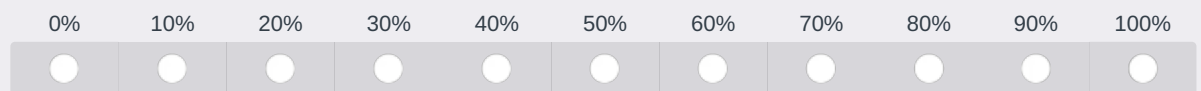


Why this split?

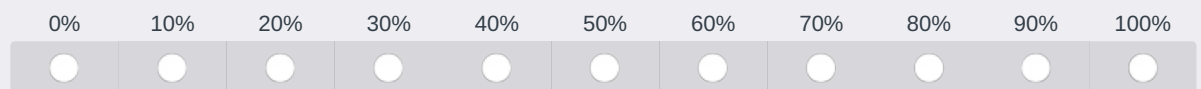
63. Who requests consent from the family?



64. How often does a family not have family members contactable within time that allows for an approach for organ donation?



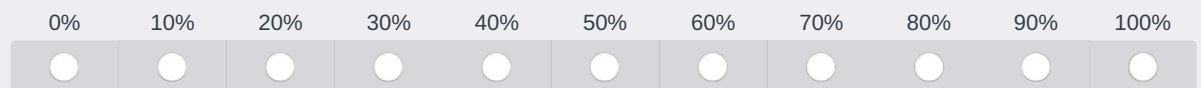
65. Do you record every referral (telephonic) your unit receives/makes?



Explain

66. How, where and what is the minimum information recorded on referrals? Could you please supply a blank copy of the documentation you record on referrals.

67. How frequently is a referral inappropriate?



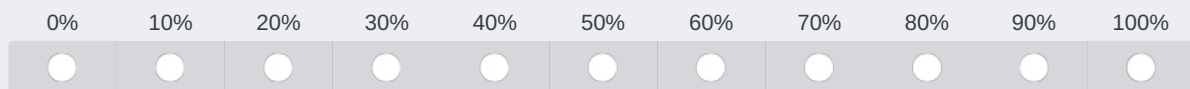
What are the most common reasons?

68. Are all deaths referred to you? Yes/No Please explain.

- Yes
- No
- Commonet on whether its: All hospital deaths? / All ICU deaths? / Only deaths assessed by the treating doctor as potential donors?

69. What additional resources would you/your unit require to be able to manage an “all deaths referral” policy?

70. How frequently is the wrong team contacted? Is this estimate based on accurately recorded data or a general perception?



Accurately recorded data or general impression?

71. How do you facilitate a referral to the appropriate team?

72. Do you ever “pick up” potential donors that have not been officially referred to you by the primary caring team? How might this happen? Please provide a very brief sketch or possible scenarios.

73. Do you experience a resistance to refer from primary caring teams? If so, how and why?

74. Do your forensic pathologists support deceased donation?

Overwhelmingly positive	Supportive	Hesitant	Obstructive	Hostile
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Have they ever denied a case going forward? Why?

75. Do hospital managers you deal with support deceased donation?

Overwhelmingly positive	Supportive	Hesitant	Obstructive	Hostile
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments?

76. Is hospital management adequately informed about the process or is additional information needed?

- Yes
- No

Comment



Environmental Scan - ISODP - Improving Deceased Donation Workshop Donor Management

77. Do you have a donor management protocol?

- Yes
- No

If yes please share. If no, please explain why not.

78. In the case of an unstable donor, who is the managing physician responsible for interventions? (Provide checklist including “other”)

- Referring clinician
- Transplant coordinator on their own
- Transplant coordinator supervisor
- Receiving Cardiac surgeon
- Receiving Lung surgeon
- Receiving liver surgeon
- Receiving nephrologist
- Other

Other / Comments

79. If there are competing organ systems impacted by your institution’s donor management strategy who is responsible for the management strategy? (Provide checklist including “other”).

- Referring clinician
- Transplant coordinator on their own
- Transplant coordinator supervisor
- Receiving Cardiac surgeon
- Receiving Lung surgeon
- Receiving liver surgeon
- Receiving nephrologist
- Other

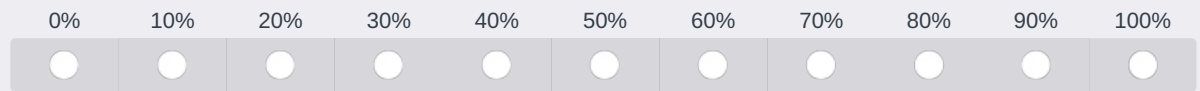
Other / Comments

80. What monitoring is considered necessary for a stable multi-organ donor?

- | | |
|--|---|
| <input type="checkbox"/> Non-invasive BP | <input type="checkbox"/> End tidal CO2 |
| <input type="checkbox"/> Intra-arterial line | <input type="checkbox"/> Cardiac output monitor |
| <input type="checkbox"/> ECG trace | |

Comment

81. How often does a consented brain dead donor collapse haemodynamically prior to donation?



Accurately recorded data or general impression?



Environmental Scan - ISODP - Improving Deceased Donation Workshop

Donor Family Follow-Up

82. Do you support donor families in any way after donation (letters, funding, other?) Yes/No.

Yes

No

If yes, please indicate how. Please share SOP if one exists. If no, please explain.

83. Do you facilitate donor family and recipient meetings? Yes/No

Yes

No

If yes, please indicate how this happens. Please share SOP if one exists. If no, please state reasons briefly.

84. What feedback is provided to other centres about organs received? How is it delivered? Recorded? Is there a standard feedback protocol? Yes/No. If yes, please share.



Environmental Scan - ISODP - Improving Deceased Donation Workshop Public Awareness and Education

85. What medical education on organ and tissue donation does your centre provide? To whom?
How many hours is spent on this per month?

86. What public awareness on organ and tissue donation does your centre provide? To whom?
How many hours is spent on this per month?

87. Do you have a marketing strategy to support organ donation?

Yes

No

Comments



Environmental Scan - ISODP - Improving Deceased Donation Workshop Organ Allocation

88. What process do you follow for organ allocation? Please share protocol(s) for kidneys, livers, lungs, hearts and combined organ transplants.

89. How are allocation disputes resolved? And recorded?

90. What transplant outcome measures are recorded?

91. How are outcomes assessed?

92. Are outcomes reported to / reviewed by anyone else or another centre or body?



Environmental Scan - ISODP - Improving Deceased Donation Workshop Tissue Banks

93. What criteria do tissue banks have regarding donor referral after death. Please share criteria that you use. (Age, Time periods, Cause of death)

94. In your experience how many units need to be contacted if everything is donated from a tissue and eye point of view? (Please list centres)

95. In your experience is this referral process standardized across all units in SA?

96. What % of tissue and eye donors come from multi-organ donors?

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Comments

Appendix 9

Professional society guidance documents

Area	Professional body	Guidelines
Transplantation	Southern African Transplantation Society (SATS)	<p>Previous work on accreditation of transplant centres and allocation criteria has been done. Not published on a formal forum and differs between the provinces. No mandate or involvement in the MAC</p> <ul style="list-style-type: none"> • http://www.sats.org.za
Assisted reproductive technology	Southern African Society of Reproductive Medicine and Gynaecological Endoscopy (SASREG)	<p>Yes. Has various guidelines on embryo transfers, egg donation agencies, ethics and good practice in <i>in vitro</i> fertilisation (IVF) laboratories</p> <ul style="list-style-type: none"> • https://sasreg.co.za/ • https://sasreg.co.za/downloads/Embryo-Transfer-Guidelines.pdf • https://sasreg.co.za/downloads/Guidelines-for-Egg-Donation-Agencies.pdf • https://sasreg.co.za/downloads/Egg-Donation-Eshre-Executive-Summary.pdf • https://sasreg.co.za/downloads/IVFGuidelines.pdf
Blood and blood products	National Blood Committee (not in operation since 2008)	<p>Yes, guidelines not available on website. Western Cape Blood Transfusion Service and South African National Blood Service have international accreditation for their processes</p> <ul style="list-style-type: none"> • https://www.wcbs.org.za/ • https://sanbs.org.za/
Cell-based therapy	South African Stem Cell Transplantation Society (SASCTS)	<p>Yes, guidelines not available on website</p> <ul style="list-style-type: none"> • https://sascets.org.za/
Genetic services	Southern African Society of Human Genetics (SAHGS)	<p>Yes</p> <ul style="list-style-type: none"> • http://www.sashg.org/documents.htm

Tissue banks	South African Tissue Bank Association (SATIBA)	Yes <ul style="list-style-type: none"> • http://www.satiba.org.za/index.php • http://www.satiba.org.za/resources-standards.php • http://www.satiba.org.za/resources-legislation.php
Forensic pathology and medicine	National Forensic Pathology Services Committee	Yes, guidelines not publicly available No website
	National Clinical Forensic Committee	In progress
Consent and ethics	Health Professionals Council of South Africa (HPCSA)	Yes, in a series of booklets. No inclusion of organ donation in any of the booklets including those on ethics, consent, patient confidentiality or palliative care <ul style="list-style-type: none"> • https://www.hpcs.co.za/?contentId=79
	South African Medical Association (SAMA)	Ethical guidelines for organ transplantation in South Africa <ul style="list-style-type: none"> • https://www.samedical.org/cmsuploader/viewarticle/903
Death determination guidelines	Critical Care Society of Southern Africa (CCSSA)	Yes. Guidelines on the medical standards for determination of death <ul style="list-style-type: none"> • https://criticalcare.org.za/ • http://www.samj.org.za/index.php/samj/article/view/13264/9746
Solid organ transplantation in HIV	Southern African HIV Clinicians Society (SAHCS)	Yes <ul style="list-style-type: none"> • https://sajhivmed.org.za/index.php/hivmed/article/view/1133/2027

Appendix 10

South African organisations supporting tissue and organ transplantation

Southern African Transplantation Society (SATS)

“... to advance the science of transplantation and to facilitate contact between those interested in transplantation and related subjects.”

SATS is a professional body of health care professionals working in the field of transplantation, with a mission to:

- Eradicate boundaries
- Promote equal access to transplantation
- Define standards of care
- Champion organ donation.

The SATS furthermore educates health care professionals, public and patients, and acts as a link between the NDoH, transplant centres, regulatory and legal partners.

<https://www.sats.org.za/>

South African Tissue Bank Association (SATiBA)

The SATiBA, established in 2015, is a not-for-profit organisation functioning as an industry representative body that serves a lobbying function, the drafting of guidelines and capacity building. Although the NHA definition of human tissues explicitly excludes stem cells and gametes, there are currently no existing organisations overseeing matters regarding stem cell and gamete tissue banking as the industry in South Africa is relatively small with limited resources. SATiBA has taken on the role of inclusivity for stem cells and gametes, as this creates an opportunity to increase awareness and surveillance among members, including self-regulation and limited oversight, with a code of practice, a code of conduct and ethics committee.

<https://www.satiba.org.za/>

South African Nephrology Society (SANS)

The SANS is a non-profit organisation established to:

- Promote the profession of nephrology
- Facilitate co-operation and contact between all interested parties in the field of nephrology and related subjects
- Provide guidelines for the optimal care of renal patients.

<http://sa-renalsociety.org/>

Critical Care Society of Southern Africa (CCSSA)

The Critical Care Society of Southern Africa (CCSSA) is a non-profit organisation dedicated to delivering appropriate, quality care to the critically ill. Founded in 1970, the CCSSA represents doctors, nurses and allied health practitioners working in the field of critical care medicine. The CCSSA provides professional development; research; guidelines; protocols; accreditation; training; conferences and seminars to its members. Patient advocacy is an integral focus of the Society and to this end, information and resources are made available to patients and their families on all aspects of critical care and ICU. The CCSSA is administered by volunteers from the professional community.

<https://criticalcare.org.za/>

Ministerial Advisory Committee (MAC) on Transplantation

The MAC on Transplantation was first formed in 1998 and is composed of 10 members, all experts in their field and including an ethicist, appointed by the Minister of Health for a period of 5 years. The MAC is currently chaired by Professor MR Moosa, a nephrologist practicing at Tygerberg University Hospital. The MAC on Transplantation provides high level strategic advice to the Minister of Health. The terms of reference for this committee are not publicly available at present and there is no supporting website. The process of selection of members to represent the donation and transplant community is at the discretion of the Minister of Health.

The main functions of the MAC currently entail:

- Provide advice to the Minister of Health on transplantation operations involving unrelated donors and recipients, as well as non-South African citizens
- Provide recommendations on living organ transplantation operations between donor and recipient from other countries for the Minister of Health's approval or disapproval
- Provide recommendations to place or not to place non-South African citizens on the South African transplant waiting list for the Minister of Health's approval or disapproval.

Organ Donor Foundation (ODF)

The ODF, a non-profit organisation that is subject to the provisions of the NHA No. 61 of 2003, has the following objectives:

- Promote awareness of life-saving solid organ transplants
- Promote awareness of tissue and life-enhancing transplants.

The ODF's objective is not to be responsible for, or directly involved in any medical-related processes, treatments, organ procurement or organ allocation.

In fulfilling its objectives, the ODF has the following aims (without limitation):

- To educate the public about organ and tissue donation
- To engender a greater willingness amongst members of the public to donate their organs and tissue
- To significantly increase the number of members of the public registered as organ and tissue donors with the ODF, and to record these registered organ/tissue donors on an easily accessible registry/database which will be used as a means of measuring the success of organ and tissue donor awareness drives
- To assist medical professionals and stakeholders responsible for donor identification by helping with financial assistance towards organ donor and tissue referral programmes and workshops, such assistance shall be provided at the Board's sole discretion and only if it is financially viable for the ODF to do so
- Where possible, the Board, acting in its sole discretion, shall assist in advocating the challenges of organ transport and delivery and to increase the number of possible transport and delivery incidences that are required, and to do all such things as are consistent with the foregoing objectives and aims.

<https://www.odf.org.za/>

Transplant Education for Living Legacies (TELL)

"Because the most important part of organ and tissue donation, is conversation."

TELL was created in 2018 with heart for hearts (and other organs). Two of the three founders and directors are lung transplant recipients, which not only gave them a second chance at life, but also put them in the unique position to make a difference in the transplant community. Through years of collective experience in the field, TELL have identified various hurdles to organ transplantation in South Africa. The issues range from legal, to social, to stigmas and stereotypes. It is the mission of TELL to solve as many of these problems as possible, so that we can end the waiting list, together.

<https://tell.org.za/>

Appendix 11

Participating treatment centres for dialysis and transplant^[1]

National (261)

State (30)

Private (231)

Western Cape (38)

State (5)

George Hospital • Groote Schuur Hospital • Red Cross War Memorial Children's Hospital • Tygerberg Hospital • Worcester Hospital.

Private (33)

Athlone Kidney and Dialysis Centre (FMC) • B. Braun Avitum: Cape Gate, Mossel Bay, Oudtshoorn, Worcester • Cape Town Kidney and Dialysis Centre (FMC) • George Kidney and Dialysis Centre (FMC) • Hermanus Kidney and Dialysis Centre (FMC) • Khayelitsha Kidney and Dialysis Centre (FMC) • Life Vincent Pallotti Hospital • Life Vincent Pallotti Hospital Paediatrics • MRC: Gatesville HD, Gatesville PD, Mitchells Plain, Tokai, Blaauwberg, Cape Town CBD, Cape Town PD, George, Goodwood, Kuils River, Paarl, Plumstead, Vredenburg • Paardevlei Kidney and Dialysis Centre • Panorama Kidney and Dialysis Centre (FMC) • Rondebosch Dialysis Clinic • Stellenbosch Kidney and Dialysis Centre (FMC) • UCT Kidney and Dialysis Centre (FMC) • UCT Private Academic Hospital • Winelands Kidney and Dialysis Centre (FMC) • Worcester Kidney and Dialysis Centre (FMC).

FMC: Fresenius Medical Care; LRC: Lenmed Renal Care;
MRC: Melomed Renal Care; NRC: National Renal Care

^[1] Davids MR, Jardine T, Marais N, et al. South African Renal Registry Annual Report 2016. *African Journal of Nephrology* 2018; 21(1): 61-72. <https://www.journals.ac.za/index.php/ajn/article/view/3298>

Gauteng (74)

State (7)

Charlotte Maxeke Johannesburg Academic Hospital • Chris Hani Baragwanath Hospital • Dr George Mukhari Hospital • Helen Joseph Hospital • Leratong Hospital • Sebokeng Hospital • Steve Biko Academic Hospital.

Private (67)

Arcadia Kidney and Dialysis Centre (FMC) • Atteridgeville Kidney and Dialysis Centre (FMC) • B. Braun Avitum: Lakeview Benoni, Pretoria Kloof, Pretoria Urology Hospital, Sandton, Vanderbijlpark Emfuleni, Vereeniging Midvaal • Carletonville Kidney and Dialysis Centre (FMC) • Edison Hammanskraal Centre • Groenkloof Kidney and Dialysis Centre (FMC) • Harmelia Kidney and Dialysis Centre (FMC) • Izinso Dialysis: Garankuwa, Soshanguve, Soweto • Kempton Kidney and Dialysis Centre (FMC) • Lanika Nursing Home and Dialysis Centre • Lenasia Kidney and Dialysis Centre (FMC) • Lesedi Kidney and Dialysis Centre (FMC) • Life: Bedford Gardens Hospital, Carstenhof Hospital, Fourways Hospital, The Glynwood Hospital • LRC Lenasia Lenmed • LRC Lenasia South Daxina • Mabika Renal Solutions • Midstream Kidney and Dialysis Centre (FMC) • Morningside Children's Kidney Treatment Centre • Morningside Kidney and Dialysis Centre (FMC) • Morula Kidney and Dialysis Centre (FMC) • Naledi Kidney and Dialysis Centre (FMC) • Netcare Transplant Centre: Garden City Hospital, Jakaranda Hospital, Milpark Hospital • NRC: Akasia, Alberton, Arcadia, Johannesburg PD, Krugersdorp, Linksfield, Lyttleton, Mayfair, Montana, Mulbarton, Olivedale, Parktown West, Pretoria East, Pretoria PD, Rynfield, Sebokeng, Sedibeng, Sunninghill, Sunward Park, Waterfall • Pretoria Kidney and Dialysis Centre (FMC) • Randfontein Kidney and Dialysis Centre (FMC) • Randfontein Private Hospital Dialysis Unit • RCH Zamokuhle (NRC) • Renalworx Dialysis Centre Wilgers • Tshepo-Themba Kidney and Dialysis Centre (FMC) • Tshwane Kidney and Dialysis Centre (FMC) • Vaal Kidney and Dialysis Centre (FMC) • Vosloorus Kidney and Dialysis Centre (Clinix) • Waverley Kidney and Dialysis Centre (FMC) • Westrand Kidney and Dialysis Centre (FMC) • Wits Donald Gordon Kidney and Dialysis Centre (FMC) • Wits Donald Gordon Medical Centre Transplant Division.

KwaZulu-Natal (66)

State (5)

Addington Hospital • Greys Hospital • Inkosi Albert Luthuli Hospital • King Edward VIII Hospital • Ngwelezana Hospital.

Private (61)

B. Braun Avitum: Dundee, Durdoc, Ethekwini, Howick, Newcastle, Pietermaritzburg, Scottburgh, Vryheid • Chatsworth Kidney and Dialysis Centre (FMC) • Coastal Nephrology Centre: Greytown, Nongoma, Ulundi • Durban Kidney and Dialysis Centre (FMC) • Ekuphileni Renal Centre Manguzi • Empangeni Kidney and Dialysis Centre (FMC) • Ethekwini Kidney and Dialysis Centre (FMC) • Hibiscus Kidney and Dialysis Centre (FMC) • Kokstad Kidney and Dialysis Centre (FMC) • Kwazulu Dialysis: Shifa Renal Unity, Umlazi Megacity Renal Unit, Westville Renal Unit • Life: Chatsmed Hospital, Empangeni Hospital, Entabeni Hospital, Hilton Hospital, Mount Edgecombe Hospital • Merediac: Durban, Pinetown • Mount Edgecombe DCG • Mount Edgecombe Kidney and Dialysis Centre (FMC) • Netcare Transplant Centre St Augustine's Hospital • Newcastle Kidney and Dialysis Centre (FMC) • NRC: Athlone, Ballito, Berea, Chatsworth,

Durban PD, Gateway, Greyville, Hillcrest, Ladysmith, Margate, Pietermaritzburg CBD, Pietermaritzburg PD, Pinetown, Richards Bay, Umhlanga • Pinetown Kidney and Dialysis Centre (FMC) • Regional Renal Services: Harding, Ixopo • Renal Care Team: Durdoc, Kwamashu, Pinetown • Richards Bay Kidney and Dialysis Centre (FMC) • Sparks Renal Unit • Stanger Kidney and Dialysis Centre (FMC) • Ultra Kidney Care Isipingo • Umhlanga Kidney and Dialysis Centre (FMC) • Verulam Dialysis Centre • Victoria Kidney and Dialysis Centre (FMC) • Vryheid Kidney and Dialysis Centre (FMC).

Eastern Cape (21)

State (3)

Frere Hospital • Livingstone Hospital • Nelson Mandela Academic Hospital.

Private (18)

Jeffreys Bay Kidney and Dialysis Centre (FMC) • Life Mercantile Hospital • Living Waters Dialysis Aliwal North • NRC: Butterworth, East London HD, East London PD, King Williamstown, Kwadwesi, Mdantasane, Mthatha, Port Elizabeth HD, Port Elizabeth PD, Queenstown, Uitenhage • Port Elizabeth Kidney and Dialysis Centre (FMC) • Regional Renal Services: Lusikisiki, Matatiele, Mthatha.

Northern Cape (5)

State (1)

Kimberley Hospital.

Private (4)

B. Braun Avitum: Kimberley, Upington • North West Dialysis Hartswater • RCH Kimberley (NRC).

Free State (19)

State (6)

Boitumelo Regional Hospital • Bongani Regional Hospital • Dihlabeng Regional Hospital • Mofumahadi Manapo Mopeli Hospital • Pelonomi Regional Hospital • Universitas Academic Hospital.

Private (13)

B. Braun Avitum: Bethlehem, Bloemfontein, Welkom • Bloemfontein Kidney and Dialysis Centre (FMC) • Graham and Kolff Renal Therapy ThabaNchu • Life Rosepark Hospital • Living Waters Dialysis Hospital • NRC: Bloemfontein HD, Bloemfontein PD, Kroonstad, Pelonomi • Sasolburg Kidney and Dialysis Centre (FMC) • Universitas Private Hospital.

Limpopo (13)

State (0)

None.

Private (13)

B. Braun Avitum: Louis Trichardt, Mokopane, Polokwane, Tzaneen • Chantel van Rooyen Bela-Bela • Edison Giyani Centre • Edison Thohoyandou Centre • Hope Renal Care and Dialysis • NRC: Polokwane, Venda • Phalaborwa Kidney and Dialysis Centre (FMC) • Polokwane Kidney and Dialysis Centre (FMC) • Thohoyandou Kidney and Dialysis Centre (FMC).

Mpumalanga (11)

State (0)

None.

Private (11)

B. Braun Avitum: Ermelo, Nelspruit, Trichardt, Witbank • Emalahleni Kidney and Dialysis Centre (FMC) • Hazyview Dialysis Centre • Highveld Nephrology Centre • Life Midmed Hospital • Middelburg Kidney and Dialysis Centre (FMC) • Mpumalanga Kidney and Dialysis Centre (FMC) • NRC Nelspruit.

North West (14)

State (3)

Job Shimankana Tabane Hospital • Klerksdorp Hospital • Mafikeng Hospital.

Private (11)

B. Braun Avitum Vryburg • Brits Kidney and Dialysis Centre (FMC) • Izinso Dialysis Mafikeng • Mafikeng Kidney and Dialysis Centre (FMC) • North West Dialysis: Klerksdorp, Lichtenburg, Viljoenskroon • NRC Rustenburg • Potchefstroom Kidney and Dialysis Centre (FMC) • Rustenburg Kidney and Dialysis Centre (FMC) • Zeerust Renal Unit.

Appendix 12

Deceased donor and organ transplant activity: South Africa 2017/2018

SATS audit

Table 3. National deceased donor and transplant activity 2018 (2017) Population 56 720 000			
	Total	Adult	Paediatric
Deceased donors	92 (91)	84 (82)	8 (9)
State	29 (31)	27 (27)	2 (4)
Private	63 (60)	57 (55)	6 (5)
Donors per million population	1.62 (1.60)		
Kidney transplants	124 (139)	115 (127)	9 (12)
State	61 (78)	54 (67)	7 (11)
Private	63 (61)	61 (60)	2 (1)
Liver transplants	74 (67)	49 (51)	25 (16)
State	9 (4)	4 (2)	5 (2)
Private	65 (63)	45 (49)	20 (14)
Pancreas transplants	8* (2)	8 (2)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	8 (2)	8 (2)	0 (0)
Heart transplants	42 (31)	38 (31)	4 (0)
State	4 (4)	4 (4)	0 (0)
Private	38 (27)	34 (27)	4 (0)
Lung transplants	23 (9)	23 (9)	0 (0)
State	8 (1)	8 (1)	0 (0)
Private	15 (8)	15 (8)	0 (0)
Heart-Lung transplants	0 (1)	0 (1)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	0 (1)	0 (1)	0 (0)
Total organ transplants from deceased donors	271 (249)		
State	82 (87)		
Private	189 (162)		

*All simultaneous kidney-pancreas transplants

Table 4. Western Cape deceased donor and transplant activity 2018 (2017)			
Population 6 621 100			
	Total	Adult	Paediatric
Deceased donors	33 (28)	(25)	(3)
State	19 (21)	17 (18)	2 (3)
Private	14 (7)	13 (7)	1 (0)
Donors per million population	4.98 (4.22)		
Kidney transplants	51 (51)	48 (45)	3 (6)
State	36 (38)	33 (32)	3 (6)
Private	15 (13)	15 (13)	0 (0)
Liver transplants	12 (7)	7 (5)	5 (2)
State	9 (4)	4 (2)	5 (2)
Private	3 (3)	3 (3)	0 (0)
Pancreas transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Heart transplants	18 (13)	16 (13)	2 (0)
State	4 (4)	4 (4)	0 (0)
Private	14 (9)	12 (9)	2 (0)
Lung transplants	8 (1)	8 (1)	0 (0)
State	8 (1)	8 (1)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Heart-Lung transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Total organ transplants from deceased donors	89 (72)		
State	57 (47)		
Private	32 (25)		

Table 5. Eastern Cape deceased donor and transplant activity 2018 (2017)			
Population 6 522 700			
	Total	Adult	Paediatric
Deceased donors	4 (5)	4 (5)	0 (0)
State	3 (2)	3 (2)	0 (0)
Private	1 (3)	1 (3)	0 (0)
Donors per million population	0.61 (0.76)		
Kidney transplants	6 (10)	6 (10)	0 (0)
State	6 (10)	6 (10)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Liver transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Pancreas transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Heart transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Lung transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Heart-Lung transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	0 (0)	0 (0)	0 (0)
Total organ transplants from deceased donors	6 (10)		
State	6 (10)		
Private	0 (0)		

Table 6. Gauteng deceased donor and transplant activity 2018 (2017)			
Population 14 717 000			
	Total	Adult	Paediatric
Deceased donors	49 (48)	45 (43)	4 (5)
State	7 (6)	7 (5)	0 (1)
Private	42 (42)	38 (38)	4 (4)
Donors per million population	3.33 (3.26)		
Kidney transplants	60 (67)	54 (61)	6 (6)
State	19 (30)	15 (25)	4 (5)
Private	41 (37)	39 (36)	2 (1)
Liver transplants	62 (60)	42 (46)	20 (14)
State	0 (0)	0 (0)	0 (0)
Private	62 (60)	42 (46)	20 (14)
Pancreas transplants	8* (2)	8 (2)	0 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	8 (2)	8 (2)	0 (0)
Heart transplants	21 (17)	19 (17)	2 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	21 (17)	19 (17)	2 (0)
Lung transplants	14 (8)	14 (8)	0 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	14 (8)	14 (8)	0 (0)
Heart-Lung transplants	0 (0)	0 (0)	0 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	0 (0)	0 (0)	0 (0)
Total organ transplants from deceased donors	165 (154)		
State	19 (30)		
Private	146 (124)		
*All simultaneous kidney-pancreas transplants			

Table 7. KwaZulu-Natal deceased donor and transplant activity 2018 (2017)			
Population 11 384 700			
	Total	Adult	Paediatric
Deceased donors	4 (7)	4 (6)	0 (1)
State	0 (1)	0 (1)	0 (0)
Private	4 (6)	4 (5)	0 (1)
Donors per million population	0.35 (0.61)		
Kidney transplants	3 (7)	3 (7)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	3 (7)	3 (7)	0 (0)
Liver transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Pancreas transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Heart transplants	3 (1)	3 (1)	0 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	3 (1)	3 (1)	0 (0)
Lung transplants	1 (0)	1 (0)	0 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	1 (0)	1 (0)	0 (0)
Heart-Lung transplants	0 (1)	0 (1)	0 (0)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	0 (1)	0 (1)	0 (0)
Total organ transplants from deceased donors	7 (9)		
State	0 (0)		
Private	7 (9)		

Table 8. Northern Cape deceased donor and transplant activity 2018 (2017)			
Population 1 225 600			
	Total	Adult	Paediatric
Deceased donors	0 (1)	0 (1)	0 (0)
State	0 (1)	0 (1)	0 (0)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Donors per million population	0.00 (0.81)		
Kidney transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Liver transplants	0 (0)	0 (0)	0 (0)
State	0 (0)	0 (0)	0 (0)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Pancreas transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Heart transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Lung transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Heart-Lung transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	0 (N/A)	0 (N/A)	0 (N/A)
Private	N/A (N/A)	N/A (N/A)	N/A (N/A)
Total organ transplants from deceased donors	0 (N/A)		
State	0 (N/A)		
Private	N/A (N/A)		

Table 9. Free State deceased donor and transplant activity 2018 (2017)			
Population 2 954 300			
	Total	Adult	Paediatric
Deceased donors	2 (2)	1 (2)	1 (0)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	2 (2)	1 (2)	1 (0)
Donors per million population	0.68 (0.68)		
Kidney transplants	4 (4)	4 (4)	0 (0)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	4 (4)	4 (4)	0 (0)
Liver transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Pancreas transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Heart transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Lung transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Heart-Lung transplants	0 (N/A)	0 (N/A)	0 (N/A)
State	N/A (N/A)	N/A (N/A)	N/A (N/A)
Private	0 (N/A)	0 (N/A)	0 (N/A)
Total organ transplants from deceased donors	4 (4)		
State	N/A (N/A)		
Private	4 (4)		

Appendix 13

The Declaration of Istanbul on organ trafficking and transplant tourism (2018 Edition)



The **DECLARATION** of **ISTANBUL**
on **ORGAN TRAFFICKING** and **TRANSPLANT TOURISM**



THE DECLARATION OF ISTANBUL ON ORGAN TRAFFICKING AND TRANSPLANT TOURISM (2018 Edition)

Preamble

Organ transplantation, one of the greatest medical success stories of the twentieth century, has prolonged and improved the lives of hundreds of thousands of patients worldwide. Countless acts of generosity by organ donors and their families, as well as the many important scientific and clinical advances achieved by dedicated health professionals, have made transplantation not only a life-saving therapy but a symbol of human solidarity. Yet these accomplishments have been tarnished by numerous instances of organ trafficking, of trafficking in persons for the purpose of organ removal, and of patients who travel abroad to purchase organs from poor and vulnerable people. In 2007 it was estimated that up to 10% of transplants worldwide involved such practices [1].

To address the urgent and growing problems posed by these unethical activities, the Transplantation Society (TTS) and the International Society of Nephrology (ISN) convened a Summit Meeting in Istanbul in April 2008. 151 participants—representatives of scientific and medical bodies, government officials, social scientists, and ethicists—reached consensus on the Declaration of Istanbul [2], which has been subsequently endorsed by more than 135 national and international medical societies and governmental bodies involved in organ transplantation.

The Declaration of Istanbul expresses the determination of donation and transplant professionals and their colleagues in related fields that the benefits of transplantation be maximized and shared equitably with those in need, without reliance on unethical and exploitative practices that have harmed poor and powerless persons around the world. It aims to provide ethical guidance for professionals and policymakers who share this goal. The Declaration thus complements efforts by professional societies, national health authorities, and inter-governmental organizations such as the World Health Organisation [3], the United Nations [4,5], and the Council of Europe [6-8] to support the development of ethical programs for organ donation and transplantation, and to prevent organ trafficking and transplant tourism. These efforts have contributed to the considerable progress made in countries around the world since 2008.

In 2010 TTS and ISN created the Declaration of Istanbul Custodian Group (DICG) to disseminate the Declaration and to respond to new challenges in organ trafficking and transplant tourism. Between February 2018 and May 2018, the DICG carried out a wide-ranging consultation, open to all interested parties, to update the Declaration in response to clinical, legal and social developments in the field. The results of the consultation process were presented, reviewed, and adopted as set forth in this document in Madrid in July 2018 during the International Congress of TTS.

The Declaration should be read as a whole and each principle should be applied in light of all the other principles which are equally important. The accompanying Commentary Paper explains and elaborates the text of the Declaration and suggests strategies for implementation.

Definitions

The following terms have specified meanings in the context of this document.

Organ trafficking consists of any of the following activities:

- (a) removing organs from living or deceased donors without valid consent or authorisation or in exchange for financial gain or comparable advantage to the donor and/or a third person;
- (b) any transportation, manipulation, transplantation or other use of such organs;
- (c) offering any undue advantage to, or requesting the same by, a healthcare professional, public official, or employee of a private sector entity to facilitate or perform such removal or use;
- (d) soliciting or recruiting donors or recipients, where carried out for financial gain or comparable advantage; or
- (e) attempting to commit, or aiding or abetting the commission of, any of these acts.¹

Trafficking in persons for the purpose of organ removal is the recruitment, transportation, transfer, harbouring, or receipt of persons, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, of deception, of the abuse of power or of a position of vulnerability, or of the giving or receiving of payments or benefits to achieve the consent of a person having control over another person, for the purpose of the removal of organs.²

In the context of this Declaration, the term **resident** denotes a person who makes their life within a country, whether or not as a citizen; the term **non-resident** denotes all persons who are not residents, including those who travel to, and then reside temporarily within, a country for the purpose of obtaining a transplant.

Travel for transplantation is the movement of persons across jurisdictional³ borders for transplantation purposes. Travel for transplantation becomes **transplant tourism**, and thus unethical, if it involves trafficking in persons for the purpose of organ removal or trafficking in human organs, or if the resources (organs, professionals and

¹ This definition is derived from the Council of Europe *Convention against Trafficking in Human Organs* (2015). [8]

² This definition is derived from the *Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, Supplementing the United Nations Convention against Transnational Organized Crime* (2000).[4] The Protocol provides that 'consent' of a victim of trafficking in persons shall be irrelevant where any of the means set forth in the definition have been used.

³ In the context of this Declaration, the term jurisdiction encompasses not only nations but also states, provinces, other formally defined areas within countries, and regional or other supra-national legal entities with the authority to regulate organ donation and transplantation.

transplant centres) devoted to providing transplants to non-resident patients undermine the country's ability to provide transplant services for its own population.

Self-sufficiency in organ donation and transplantation means meeting the transplant needs of a country by use of donation and transplant services provided within the country and organs donated by its residents, or by equitably sharing resources with other countries or jurisdictions.

Financial neutrality in organ donation means that donors and their families neither lose nor gain financially as a result of donation.

Principles

1. Governments should develop and implement ethically and clinically sound programs for the prevention and treatment of organ failure, consistent with meeting the overall healthcare needs of their populations.
2. The optimal care of organ donors and transplant recipients should be a primary goal of transplant policies and programs.
3. Trafficking in human organs and trafficking in persons for the purpose of organ removal should be prohibited and criminalized.
4. Organ donation should be a financially neutral act.
5. Each country or jurisdiction should develop and implement legislation and regulations to govern the recovery of organs from deceased and living donors and the practice of transplantation, consistent with international standards.
6. Designated authorities in each jurisdiction should oversee and be accountable for organ donation, allocation and transplantation practices to ensure standardization, traceability, transparency, quality, safety, fairness and public trust.
7. All residents of a country should have equitable access to donation and transplant services and to organs procured from deceased donors.
8. Organs for transplantation should be equitably allocated within countries or jurisdictions, in conformity with objective, non-discriminatory, externally justified and transparent rules, guided by clinical criteria and ethical norms.
9. Health professionals and healthcare institutions should assist in preventing and addressing organ trafficking, trafficking in persons for the purpose of organ removal, and transplant tourism.
10. Governments and health professionals should implement strategies to discourage and prevent the residents of their country from engaging in transplant tourism.

11. Countries should strive to achieve self-sufficiency in organ donation and transplantation.

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Appendix 14

South African legislation

Acts relevant to human tissue

- National Health Act No. 61 of 2003 (Box 2), which replaced the Human Tissue Act No. 65 of 1983
- Medicines and Related Substances Control Act No. 101 of 1965 (Medicines Act)
- Protection of Personal Information Act No. 4 of 2013
- Genetically Modified Organisms Act No. 15 of 1997
- Consumer Protection Act No. 68 of 2008
- Children’s Act No. 38 of 2005
- Inquest Act No. 58 of 1959.

National Health Act Chapter 8

- Blood and blood products
- Assisted reproductive technology
- Cell-based therapy
- Transplantation
- DNA and genetic services
- Tissue banks
- Examination, allocation and disposal of human bodies and tissues.

Regulations

Published in Government Gazette no. 35099 on 02 March 2012

- No. R. 175 - Regulations relating to artificial fertilisation of persons; GG 35099 pages 3-21
- No. R. 176 - Regulations regarding rendering of clinical forensic medicine services; GG 35099 pages 22-30
- No. R. 177 - Regulations relating to the use of human biological material; GG 35099 pages 31-38
- No. R. 179 - Regulations relating to blood and blood products; GG 35099 pages 62-74
- No. R. 180 - Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes; GG 35099 pages 75-96
- No. R. 181 - Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue, zygotes and gametes; GG 35099 pages 97-124
- No. R. 182 - Regulations relating to tissue banks; GG 35099 pages 125-141
- No. R. 183 - Regulations relating to stem cell banks; GG 35099 pages 142-158.

NHA Section 60 – Payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes

- (1) No person, except—
 - (a) a hospital or an institution contemplated in section 58 (1) (a), a person or an institution contemplated in section 63 and an authorised institution or, in the case of tissue or gametes imported or exported in the manner provided for in the regulations, the importer or exporter concerned, may receive payment in respect of the acquisition, supply, importation or export of any tissue or gamete for or to another person for any of the purposes contemplated in section 56 or 64;
 - (b) a person or an institution contemplated in section 63 or an authorised institution, may receive any payment in respect of the importation, export or acquisition for the supply to another person of blood or a blood product.
- (2) The amount of payment contemplated in subsection (1) may not exceed an amount which is reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, gamete, blood or blood product in question.
- (3) This section does not prevent a health care provider registered with a statutory health professional council from receiving remuneration for any professional service rendered by him or her.

Appendix 15

South African guidelines on the determination of death

South African guidelines on the determination of death

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Death is a medical occurrence that has social, legal, religious and cultural consequences requiring common clinical standards for its diagnosis and legal regulation. This document compiled by the Critical Care Society of Southern Africa outlines the core standards for determination of death in the hospital context. It aligns with the latest evidence-based research and international guidelines and is applicable to the South African context and legal system. The aim is to provide clear medical standards for healthcare providers to follow in the determination of death, thereby promoting safe practices and high-quality care through the use of uniform standards. Adherence to such guidelines will provide assurance to medical staff, patients, their families and the South African public that the determination of death is always undertaken with diligence, integrity, respect and compassion, and is in accordance with accepted medical standards and latest scientific evidence. The consensus guidelines were compiled using the AGREE II checklist with an 18-member expert panel participating in a three-round modified Delphi process. Checklists and advice sheets were created to assist with application of these guidelines in the clinical environment (<https://criticalcare.org.za/resource/death-determination-checklists/>).

Key points

- Brain death and circulatory death are the accepted terms for defining death in the hospital context.
- Death determination is a clinical diagnosis which can be made with complete certainty provided that all preconditions are met.
- The determination of death in children is held to the same standard as in adults but cannot be diagnosed in children <36 weeks' corrected gestation.
- Brain-death testing while on extra-corporeal membrane oxygenation is outlined.
- Recommendations are given on handling family requests for accommodation and on consideration of the potential for organ donation.
- The use of a checklist combined with a rigorous testing process, comprehensive documentation and adequate counselling of the family are core tenets of death determination. This is a standard of practice to which all clinicians should adhere in end-of-life care.

S Afr Med J 2021;111(4b):367-380. <https://doi.org/10.7196/SAMJ.2021.v111i4b.15200> | *South Afr J Crit Care* 2021;37(1b):41-55. <https://doi.org/10.7196/SAJCC.2021v37i1b.466>

Death is a medical occurrence that has social, legal, religious and cultural consequences requiring common clinical standards for its diagnosis and legal regulation.^[1] There is no documented case of a person who fulfils the preconditions and criteria for brain death ever subsequently developing any return of brain function.^[2,3]

Clear medical standards for death certification augment the quality and rigor of death determination.^[4-6] Currently there are no clinical guidelines on death determination in South Africa (SA), with clinicians using available international guidelines, which vary markedly and are not always applicable to the SA context.^[7-10] The World Federation

of Societies of Intensive and Critical Care Medicine (WFSICCM) recently published a document, based on current literature, aiming to standardise terminology and establish minimum testing standards across the world.^[5] In order to be applicable over a range of legal jurisdictions, some sections of this document are necessarily broad, making application to the local context challenging. There is therefore a need to align the WFSICCM document with the SA context and legal system, and to provide clear guidance to SA practitioners and the public.

The aims of this document are to provide guidelines for healthcare providers for the testing process, and to answer key questions that commonly arise when medical professionals are called upon to determine death in SA. The objectives are to:

- provide clear medical standards for healthcare providers in the determination of death, in order to promote safe practice and avoid diagnostic errors in the determination of death
- provide assurance to patients, their families and the SA public that determination of death is undertaken with diligence, integrity, respect and compassion and in accordance with accepted medical standards and societal expectations
- create a checklist for brain death and circulatory death determination.

Methods

An expert panel was constituted and reviewed current evidence and compiled consensus-based recommendations for the minimum standards required for death determination, applicable in the SA context, using a modified Delphi process. All statements in this guideline are considered strong recommendations. In cases where evidence is less strong, the term ‘suggested’ is used to indicate a lower level of evidence. Statements are intentionally similar to international documents in the interests of commonality of approach. Recommendations are aligned with the best interests of patients and their families.

Panel recruitment

Expert panel members were recruited through the Critical Care Society of Southern Africa (CCSSA) as experts in the field of death determination and end-of-life care representing a broad range of disciplines within critical care (neurosurgery, paediatrics, obstetrics and gynaecology, surgery, anaesthesiology, nursing, ethics). Informed consent was given by the expert panel with acknowledgement that they would be identifiable in the publication (Appendix 1 - 3: <http://samj.org.za/public/sup/15200-1.pdf>). The study methodology was approved by the University of Cape Town Human Research Ethics Committee (HREC 476/2019).

Delphi process

A literature search of Pubmed, Web of Science, SCOPUS and the grey literature was conducted by the steering committee of the expert panel and a professional librarian to identify national and professional society guidelines in death determination, and their supporting evidence, for review (<http://samj.org.za/public/sup/15200-2.pdf>). A modified Delphi approach was used with adherence to the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument to compile the guidelines.^[11]

Key questions related to current principles and practice regarding death certification were drafted by the meeting steering committee. During three rounds of a modified Delphi process^[12] using SurveyMonkey (SVMK Inc., USA), a web-based application, the expert panel progressively modified, deleted or added questions and components. Participants were asked to rate agreement with each component between 1 and 9 on a Likert scale, with 1 - 3 being ‘not important’, 3 - 6 being ‘important but not critical’ and 7 - 9 being

‘critically important’, or state if they were unable to comment. This scale is recommended by the Grading of Recommendations Assessment, Development and Evaluation working group.^[11,13] Participants were invited to suggest additional questions for consideration for the round table in each round using free-text responses. Although five to 10 experts are considered adequate for content validation, we used 18 to ensure a broadly representative group.^[14]

Precise terminology was reviewed and finalised in order to improve clarity in death determination discussions and debate. We defined consensus for the Delphi *a priori* based on guidance in *The COMET Handbook*.^[15] For inclusion in the consensus outcome statement (COS), outcomes required at least 70% of participants in each stakeholder group to score the outcome as critically important and <15% to score the outcome as not important. Outcomes excluded from the COS required at least 70% of participants in each stakeholder group to score the outcome as not important and <15% to score the outcome as ‘critical’. If outcomes did not meet either criterion, they were presented at the round-table for discussion. The expert panel members summarised the responses and the available evidence and formulated draft recommendations that were presented and discussed at a face-to-face round table meeting prior to the CCSSA national conference in Cape Town, SA, in 2019. The results were presented at a plenary meeting of the conference.

All questions and feedback from this meeting were then reviewed with the steering committee. The combined consensus statement and proposed guideline were circulated to all society members for comment over three months. All expert panel members approved the final document for publication. The guidelines were then submitted for external review and endorsement by other South African professional medical societies (Table 1).

Updating of the guidelines

A review period of five years was set after publication of this document, the review to be undertaken by the guideline development group of the CCSSA, unless an earlier revision is mandated by emerging high-quality medical evidence or legislative changes.

South African guidelines on the determination of death

1. General statements

Death is the clinical point of irreversible loss of the capacity for consciousness and the irreversible loss of the capacity to breathe.^[16]

Death is determined by either neurological or circulatory criteria and must be made in accordance with accepted medical standards.^[1]

Table 1. List of endorsing societies

Trauma Society of Southern Africa
The Association of Surgeons of South Africa
Radiology Society of South Africa
Southern African Transplantation Society
Islamic Medical Association
South African Medical Association
Resuscitation Council of South Africa
South African Thoracic Society
Colleges of Medicine of South Africa - Committee of Critical Care
Neurological Association of South Africa
Society of Neurosurgeons of South Africa
South African Paediatric Association (Affirmation of Value)

A correctly performed clinical examination can determine the point of death with complete certainty. It is not necessary to wait for pathognomonic signs of death (hypostasis, rigor mortis, decay) to be present in the healthcare setting.^[16,17]

In cases where there are confounders affecting the clinical examination, testing should be deferred until such confounders are resolved or ancillary testing confirms the diagnosis of death.^[17]

2. Definitions

Ancillary test: an additional test that can assist with the clinical diagnosis of brain death.^[18]

Accommodation: a period of somatic support to allow for family to process the diagnosis of death.

Brain death/death by neurological criteria: the preferred term when death is determined on neurological grounds. (This is in preference to the term brain-stem death and is in alignment with the latest guidelines.)^[5]

Circulatory death/death by circulatory criteria: the preferred term when death is determined on circulatory grounds. (This is in preference to terms such as cardiac or cardiorespiratory death and is in alignment with the latest guidelines.)^[11]

Coma: the absence of wakefulness, awareness and the capacity for sensory perception and responsiveness to the external environment.^[11]

Confounder: a situation during which a diagnostic test may be unreliable. Repeat testing when the confounder is no longer present, or ancillary testing, is required to diagnose death in these settings.

Somatic support: management to support the body and organs, excluding the brain, after brain death has been confirmed.

3. Brain death

3.1 Preconditions for brain death testing

There must be an established aetiology compatible with complete and irreversible loss of all brain function prior to commencement of the determination of brain death.

Preconditions for brain-death testing to be valid are:

- a minimum temperature of 36°C^[2,5]
- a systolic blood pressure (BP) \geq 100 mmHg or a mean arterial pressure (MAP) \geq 60 mmHg (or age-appropriate haemodynamic targets in the paediatric population)
- exclusion of the influence of central nervous system (CNS) depressing drugs. This is done by at least one of the following:
 - allowing five elimination half-lives of the drug to pass before making an evaluation of brain death (taking into consideration the dose and the elimination half-life, which may be influenced by age, organ dysfunction or prior hypothermia)^[5]
 - administering an appropriate drug antagonist
 - measuring drug levels^[5]
 - performing ancillary testing in addition to a complete clinical examination if there is concern about prolonged or unknown drug elimination
- intact neuromuscular function
 - If doubt exists regarding the effects of pharmacological paralysis, a train-of-four nerve stimulator can be used. A normal response to stimulation should be observed.^[3]
- correction of severe metabolic, acid-base and endocrine derangements that could affect the examination
 - If these derangements cannot be corrected and are judged to be potentially contributing to the loss of brain function, ancillary testing must be used after a clinical examination of brain death has been completed.

3.1.1 Additional remarks: Preconditioning^[5]

Neuroimaging is recommended when available to assist with establishing an aetiology and confirming brain injury.

Neuroimaging is not required for the diagnosis of brain death where an obvious cause is known.

Drug levels should not exceed the therapeutic range and, if within a therapeutic range, not be associated with an altered level of consciousness.

Barbiturates have long and variable elimination half-lives, so blood levels should be measured and documented to be below that of clinically significant effects (<10 mg/L) or alternatively ancillary testing should be used to diagnose brain death.

If there is concern about severe alcohol intoxication being the primary cause of coma, the blood alcohol level should be shown to be <80 mg/dL.

Consensus was not achieved on a standardised observation period prior to brain-death testing. The appropriate observation period was felt to be specific to each individual case. However:

- in cases of anoxic brain injury, this observation period should be 24 hours
- in cases where therapeutic hypothermia was used, there should be a 24-hour period of normothermia prior to an examination for brain death
- in paediatrics, a cautious approach is advised, given the frequent presence of confounders in this group.

It must be possible to adequately examine the brain-stem reflexes. It must be possible to examine at least one eye and one ear and safely perform apnoea testing.^[3,5]

Apnoea testing may be precluded by severe hypoxic respiratory failure or a high cervical cord injury, in which case ancillary testing can be used after confirming that brain-stem reflexes are absent.^[3,5]

While trying to provide broad guidance on the magnitude of metabolic and endocrine disorders which are likely to influence the testing of brain-stem reflexes, it is essential to bear in mind that the most important factor is the establishment of an unequivocal cause for the individual's coma.^[17]

It is recognised that circulatory, metabolic and endocrine disturbances (e.g. hypotension, hypernatraemia, diabetes insipidus) are likely accompaniments of death as a result of cessation of brain-stem function. It is important to emphasise that these may be the effect rather than the cause of cessation of brain function and do not preclude the diagnosis of death by neurological testing.^[17]

It is recognised that:^[17]

- Sodium can cause unresponsiveness at levels <115 or >160 mmol/L.
- Serum potassium levels can cause flaccid paralysis below 1 mmol/L. Therefore, we recommend a level >3 mmol/L be confirmed.
- Profound elevation or lowering of phosphate or magnesium can be associated with severe neuromuscular weakness at levels <0.5 or >3.0 mmol/L and may need to be corrected.
- Hyperglycaemia in diabetic ketoacidosis or hyperosmolar non-ketotic coma may cause a state of unresponsiveness which mimics irreversible cessation of brain-stem function, but this state is extremely unlikely with blood glucose levels <20 mmol/L.
- Severe hypoglycaemia is associated with coma or stupor and testing of brain-stem reflexes should not be undertaken if the glucose level is <4 mmol/L. As blood glucose concentrations change rapidly in critically ill patients, a blood glucose measurement should always be made immediately prior to the testing of brain-stem reflexes.

The following endocrine conditions are extremely rare and unlikely to co-exist in the presence of known primary pathologies. If there is any clinical reason to expect these disturbances, then it is obligatory to ensure appropriate hormonal assays are undertaken.

- Myxoedema may cause a deep unresponsive coma.
- An Addisonian crisis may be associated with severe neuromuscular weakness, causing an acute ascending paralysis or encephalopathy proceeding to coma.

3.2 Braindeath testing^[3,5,17]

The testing process comprises assessment for:

1. coma
2. absence of brain-stem reflexes
3. inability to breathe.

A detailed explanation of the testing process is outlined (Table 2).

Table 2. Clinical testing for brain death – coma, brain stem reflexes, apnoea test

Clinical testing for	Test and interpretation	Cautionary remarks
1. Coma	<p><i>Test:</i> Assess both centrally and peripherally. Apply deep pressure to all of the following:</p> <ul style="list-style-type: none"> • the condyles at the level of the temporomandibular joints • the supra-orbital notch bilaterally • the sternal notch • all four extremities, via deep nail bed pressure. <p><i>Interpretation:</i> Noxious stimuli should not produce grimacing, facial muscle movement or a motor response of the limbs other than spinally mediated reflexes. Any non-spinal reflex response is incompatible with a brain death diagnosis.</p>	A multilevel assessment of motor function is important to exclude focal lesions. The clinical differentiation of spinal responses from brain-mediated motor responses requires expertise. Consultation with an experienced practitioner is recommended if the origin of a response is unclear. Alternatively, if interpretation is unclear, ancillary testing is recommended.
2. Brain-stem reflexes	<p>Testing of the brain-stem reflexes comprises examination of the cranial nerves: pupils, ocular movements, facial sensation and movement, pharyngeal and tracheal response. These are tested sequentially and bilaterally when possible. All brain-stem reflexes must be absent to determine brain death.</p>	
2.1. Pupillary light reflex – cranial nerves II and III	<p><i>Test:</i> Shine a bright light into the eye and look for a pupillary constrictor response.</p> <p><i>Interpretation:</i> There should be no pupillary response.</p>	The pupils should not be pinpoint. Pupils do not have to be fully dilated. Anticholinergic drugs such as atropine can cause pupillary dilatation. Cataract or iris surgery is not a contraindication to clinical testing.
2.2. Corneal reflex – cranial nerves V and VII	<p><i>Test:</i> Touch the corneas with soft cotton wool or gauze and examine the eyes for blinking or a withdrawal response.</p> <p><i>Interpretation:</i> No blinking or withdrawal response.</p>	Touching the sclera is not sufficient. Remove contact lenses. Examine the cornea gently as it is easily damaged.
2.3. Response to pain in the trigeminal distribution – cranial nerves V and VII	<p><i>Test:</i> Apply pain over the trigeminal distribution with deep pressure over the supra-orbital nerve bilaterally and to the condyles at the level of the temporomandibular joints.</p> <p><i>Interpretation:</i> No grimacing, facial muscle movement or motor response of the limbs other than spinally mediated reflexes.</p>	In patients with spinal cord injuries, peripheral sensation and motor function can be lost and it is essential to adequately assess response to stimuli through brainstem-mediated sensation and motor response.
2.4. Vestibulo-ocular reflex – cranial nerves III, IV, VI and VIII	<p><i>Test (cold caloric):</i> Inspect the external auditory canal with an otoscope to confirm that the eardrum is visible. If the eardrum is not visible, the canal must be cleared before testing can occur. Elevate the head to 30° to align the semi-circular canal and generate a maximal response. Flush 50 mL of ice-cold water into the ear canal using a syringe. Hold eyelids open and observe for eye movement for a minimum of 60 seconds.</p> <p><i>Interpretation:</i> No eye movement in response to the cold water; the eyes remain in the midline within the socket.</p>	Presence of a ruptured eardrum does not invalidate the test. Fractures to base of skull or petrous temporal bone may obliterate the response on the side of the fracture. Testing should not proceed on that side if there is cerebrospinal fluid (CSF), blood or brain tissue in the external auditory canal.
Vestibulo-ocular reflex – cranial nerves III, IV, VI and VIII	<p><i>Not required/recommended:</i> Testing for the oculo-cephalic (head turning/doll’s eye) reflex examines the same reflex pathways as cold caloric testing but is a sub-maximal stimulus and is not recommended. It may also aggravate a pre-existing cervical spinal injury.</p>	

...continued

Table 2. (continued) Clinical testing for brain death – coma, brain stem reflexes, apnoea test

Clinical testing for	Test and interpretation	Cautionary remarks
2.5. Gag reflex – cranial nerves IX and X	<p>Test: Stimulate the posterior pharyngeal wall, on both sides, with a tongue depressor or Yankauer suction.</p> <p>Interpretation: No gag response seen.</p>	
2.6. Cough reflex – cranial nerve X	<p>Test: Stimulate the tracheobronchial wall with a soft suction catheter.</p> <p>Interpretation: No cough response seen.</p>	The efferent limbs for this reflex are the phrenic nerve and the innervation of the thoracic and abdominal musculature. Therefore, it cannot be assessed in patients with a complete high cervical injury. ^[21]
3. Apnoea test	<p>Only proceed with the apnoea test if all above reflexes are absent. Apnoeic oxygenation is used to demonstrate lack of ventilatory drive. This involves the supply of 100% oxygen to the trachea, without providing ventilatory assistance. Through mass-movement, oxygen reaches the alveoli, allowing for transfer to the blood. In the absence of ventilation, $p_a\text{CO}_2$ rises and stimulates the brain-stem respiratory centres, causing spontaneous breathing. As the $p_a\text{CO}_2$ rises, the ventilatory centre is maximally stimulated by a $p_a\text{CO}_2 >60$ mmHg (8 kPa) and $\text{pH} <7.30$. An attempt at breathing is defined as any respiratory muscle activity that results in abdominal or chest excursions or activity of accessory respiratory muscles.</p> <p>Test: Pre-oxygenate the patient with 100% oxygen for 10 minutes to allow for elimination of nitrogen and to prevent hypoxaemia during the test. Perform a baseline blood gas measurement. Disconnect the patient from the mechanical ventilator. Supply continuous oxygen via a T-piece (preferred) or through a catheter inserted through the endotracheal tube and placed above the carina.</p> <p>Observe continuously for any spontaneous breathing. At the end of the period without mechanical ventilation, apnoea must persist in the presence of an adequate stimulus to spontaneous ventilation, i.e. an arterial $p_a\text{CO}_2 >60$ mmHg (8 kPa) and an arterial $\text{pH} <7.30$. Take an arterial blood gas to document the rise in $p_a\text{CO}_2$ and change in pH. At the end of the test, reconnect the patient to the mechanical ventilator.</p> <p>Interpretation: No breathing effort is seen at any point. Apnoea testing should be aborted if:</p> <ul style="list-style-type: none"> spontaneous respirations are witnessed during apnoea testing systolic blood pressure becomes <100 mmHg or mean arterial pressure becomes <60 mmHg despite titration of inotropes/vasopressors (age-appropriate targets for paediatrics) there is sustained desaturation below 85% an unstable arrhythmia occurs. <p>It is suggested that prior to aborting the apnoea test because of cardiorespiratory instability, an arterial blood gas (ABG) be sent for testing. If the $p_a\text{CO}_2$ target is met, the apnoea test can be considered positive (consistent with brain death).</p>	<p>Throughout the procedure, monitor the patient's SpO_2.</p> <p>An option to minimise the time required for the $p_a\text{CO}_2$ to rise to the desired level, is to adjust the minute ventilation to mild hypercarbia ($p_a\text{CO}_2 \sim 45$ mmHg (6 kPa)) before disconnecting the patient from the ventilator.</p> <p>If using a catheter, supply oxygen at 4 - 6 L/min. The diameter of the catheter must be $<70\%$ of the diameter of the endotracheal tube. When using the tracheal insufflation method, care should be taken to avoid high oxygen flows and wedging of the catheter insufflating oxygen as high intrapulmonary airway pressure may cause barotrauma.</p> <p>The period of observation to achieve an adequate threshold of stimulus of the respiratory centre is variable. Usually $p_a\text{CO}_2$ rises by ~ 3 mm Hg (0.4 kPa) for every minute of apnoea.</p> <p>If starting from normocapnia, the $p_a\text{CO}_2$ is likely to be >60 mmHg (8 kPa) after 10 minutes. If this is not the case at 10 minutes and the patient is stable, wait a further 5 minutes and repeat the arterial blood gas.</p> <p>In patients with pre-existing hypercapnia, it is recommended to wait for a $p_a\text{CO}_2$ rise >20 mmHg (2.7 kPa) above the chronic level, with a $\text{pH} <7.30$. Failure of the $p_a\text{CO}_2$ to rise is most likely due to an inappropriately high oxygen flow rate via a tracheal catheter.</p> <p>If hypoxia occurs, 1 - 2 positive pressure breaths can be given, and apnoea testing continued. Adequate pre-oxygenation and recruitment usually avoids this problem.</p>

Two doctors are required to confirm the diagnosis of brain death. One of the doctors must have more than five years' experience (since qualification as a medical practitioner). Neither doctor must be involved with a transplantation team.^[19]

Two doctors should perform the brain death testing together. If testing is done separately, there is no need for a delay between the tests; however, it is strongly advised that a single apnoea test should be done by the two doctors together.^[5,20]

3.2.1 Additional remarks: Apnoea testing

We do not recommend using a spontaneous breathing mode and remaining connected to the ventilator during apnoea testing. Performing testing in such a manner typically requires turning off the ventilator's default safety features to prevent back-up apnoea ventilation. If a patient remains connected to a mechanical ventilator, auto-triggering can give a false impression that a person is breathing spontaneously. This occurs when the ventilator is set on a spontaneous breathing mode (pressure support ventilation) and either extrinsic or intrinsic factors generate sufficient change in airflow or negative pressure that exceeds the trigger threshold, leading to a mechanically delivered breath. Extrinsic causes for auto-triggering include excessive condensation in ventilator tubing, endotracheal tube leak, chest tubes, and random artefacts or noise in the ventilator circuit, while intrinsic causes include cardiogenic oscillation, especially in a hyperdynamic cardiovascular state.^[5]

3.2.2 Additional remarks: Clinical observations

Observations compatible with a diagnosis of brain death are:^[3]

- spinal reflexes (which can be spontaneous or elicited by stimulation)^[22,23]
 - extension-pronation movements of the upper limbs
 - nonspecific flexion of the lower limbs
 - presence of deep tendon reflexes
 - plantar responses, either flexor or extensor
 - respiratory-like movements (shoulder elevation and adduction, back arching or intercostal expansion) without significant tidal volume
 - undulating toe reflex (plantar flexion of great toe, followed by brief plantar flexion sequentially of second to fifth toes)
 - Lazarus sign (bilateral arm flexion, shoulder adduction, hand raising to above the chest, and may include flexion of trunk, hips and knees)
 - head turning
- sweating, blushing, tachycardia
- normal blood pressure without the need for pharmacological support
- absence of diabetes insipidus (DI) (preserved osmolar control mechanism).

Observations incompatible with brain death are:

- decerebrate or decorticate posturing
- true extensor or flexor motor responses to painful stimuli
- witnessed seizures.

3.3 Ancillary testing

The clinical exam is considered the most sophisticated way of testing neurological function in that it deliberately delivers a stimulus to provoke central processing followed by an efferent response. All ancillary tests infer the integrity of this stimulus-integration-response arc, but do not observe it directly.^[5]

It is recommended that the clinical exam be completed to the fullest extent possible prior to conducting an ancillary test.^[5]

Making an appropriate choice of an ancillary test depends on the clinician and the clinical circumstances. The most effective method to address a confounder must be identified using an educated appraisal of the strengths and weaknesses of those tests that are readily available.^[5]

It is recommended that ancillary testing is required in the following circumstances:^[5]

- inability to complete a clinical neurological determination of death, including the apnoea test
- confounding conditions which would invalidate clinical testing that cannot be resolved
- uncertainty regarding interpretation of spinal-mediated motor reflexes
- pre-existing severe neuromuscular disorder, such as amyotrophic lateral sclerosis or a pre-existing severe sensory neuropathy.^[24,25]

Ancillary testing which establishes the absence of intracranial blood flow is the preferred method of testing where available.^[5]

- radionuclide studies
- conventional four-vessel cerebral angiography
- transcranial Doppler.

It is suggested that electrophysiological testing with an electroencephalogram (EEG) not be utilised routinely as an ancillary test, given its low specificity.^[5,26] EEG testing may, however, be preferred where craniovascular impedance has been affected by an open skull fracture, decompressive craniectomy, or an open fontanelle/suture in infants.^[5,27]

It is suggested that computed tomography angiography (CTA) and magnetic resonance angiography (MRA) which may be used in the investigation of these patients not be used in isolation to support a diagnosis of cerebro-circulatory arrest at present, pending further research into the sensitivity and specificity of these modalities.^[5,28-35]

3.3.1 Technical aspects of ancillary testing

Radionuclide/brain scintigraphy studies

To confirm brain death with radionuclide/scintigraphic techniques, the study must demonstrate absence of intracranial isotope.^[5,36-38]

- Diffusible radiopharmaceuticals (brain-specific tracers) should be used preferentially.
- Single photon emission computed tomography (SPECT) is preferred over planar imaging.
- If SPECT is not available, perfusion scintigraphy with anterior and lateral planar imaging should be used with appropriate time intervals to demonstrate static filling of the posterior fossa.

Cerebral angiography

If used as an ancillary test to confirm brain death, four-vessel cerebral angiography must demonstrate absent filling at the points where the internal carotid and vertebral arteries enter the skull base, with demonstration of patent external carotid circulation.^[39]

Transcranial doppler

Transcranial doppler testing is operator training dependent, needs specialised probes and requires that:^[40,41]

- two examinations be performed ≥ 30 minutes apart
- the examinations be performed bilaterally, anteriorly and posteriorly to include both internal carotid arteries as well as the vertebrobasilar circulation
- the exams illustrate biphasic oscillating flow and systolic spikes with reversal of flow in diastole in order to make a declaration of brain death.

Transcranial doppler testing is not validated in paediatrics^[42] and is not widely available in SA.

Electroencephalography (EEG)

If EEG testing is used, it should be used in conjunction with somatosensory and brainstem auditory evoked potentials.^[43]

EEG should be interpreted as demonstrating absence of brain activity when a 30-minute study is isoelectric above 2 microvolts with a sensitivity of 2 microvolts/mm and filter of 0.1 or 0.3 seconds and 70 Hz.^[5,44]

3.4 Paediatric considerations in brain death

A cautious approach with a low threshold for serial examinations is recommended in this population group.^[5,45]

Brain death cannot be diagnosed in neonates <36 weeks' corrected gestation.^[3,4]

Clinical assessment of brain death in neonates and the paediatric population is the same as in adults, with age-appropriate haemodynamic targets,^[46,47] except that in neonates (<4 weeks) the sucking and rooting reflex should be absent in addition to the other brain-stem reflexes.^[5]

Ancillary testing (as with adults) is not routinely required in this population group when clinical testing confirms brain death.^[45]

A T-piece should be used for oxygenation during the apnoea test in paediatric patients in preference to the tracheal insufflation method, owing to the risk of barotrauma with this method.^[5]

In patients with chronic hypoxaemia owing to cyanotic heart disease, apnoea testing should not be performed and instead an ancillary study be conducted to assist with the determination of brain death.^[5]

3.5 ECMO and brain death^[48-50]

The same fundamental principles of brain-death testing apply to patients on extracorporeal membrane oxygenation (ECMO).

The apnoea test should be performed in patients on veno-arterial (VA) or veno-venous (VV) ECMO unless unable to be completed owing to haemodynamic instability.

In VA ECMO, the flow rate may be adjusted to maintain a MAP ≥ 60 mmHg during testing.

Preoxygenation prior to apnoea testing should be done by increasing the inspired oxygen via the mechanical ventilator to 100% and to the membrane lung of the ECMO machine to 100% for 10 minutes. The sweep gas flow should be titrated to <1 L/min while maintaining oxygenation in order to allow a rise in carbon dioxide (CO₂). Apnoea must persist in the presence of an adequate stimulus to spontaneous ventilation, i.e. an arterial p_aCO₂ >60 mmHg (8 kPa) or 20 mmHg above the patient's baseline and an arterial pH <7.30. Serial blood gases may be required as achieving the rise in CO₂ may take longer to achieve than in a person without ECMO support.

3.6 Pregnancy and brain death^[51-54]

If a decision is made to offer somatic support to a brain-dead pregnant patient, it is recommended that a multidisciplinary team of intensivists, obstetricians, social workers, psychologists and neonatologists be involved.

The consent to continue providing somatic support to a brain-dead pregnant patient should be made in keeping with the HPCSA professional rules on consent.^[55] Due consideration to duration of support required, the high-risk nature of the delivery and an assessment of the home and legal circumstances needs to be conducted by a multidisciplinary team.

The fetus should be routinely monitored with at least daily heart rate checks, given that fetal health may affect decision-making.

Antenatal steroids should be administered to facilitate fetal lung maturation with preparations for delivery made between 26 and 33 weeks when fetal lung maturity is reached.

3.7 Family accommodation in brain death

While it is reasonable to provide accommodation for a finite period of time, assuming that the specific timeframe for doing so is brief, that resources allow, and that a family is informed of the timeframe in advance, accommodation ordinarily should not be provided for a period greater than 24 hours.

It is ethically and legally appropriate for the treating team to end somatic support for a body when the family has been adequately counselled on the diagnosis of death and the option of organ donation explored.

An additional clinician in the hospital can provide the family with a second opinion regarding determination of brain death if it is felt that this may assist the family in accepting the person's death.

Even in the setting of requests for accommodation, support should be discontinued if a person has been declared brain-dead and the hospital bed is required for a living patient where no other bed is available.^[5]

4. Circulatory death

4.1 Preconditions for circulatory death testing

To declare death on circulatory grounds, one of the following criteria must be met:

- it is inappropriate to attempt cardiopulmonary resuscitation
- attempts at cardiopulmonary resuscitation have failed
- treatment aimed at sustaining life has been withdrawn.

Treatment may be withdrawn because:^[56]

- it has been assessed to be of no further benefit to the patient (non-beneficial/futile) and is not in his or her best interest to continue
- it is in respect of the patient's wishes via an advanced directive to refuse life-sustaining treatment
- it is in respect of the patient's wishes as expressed by their legal surrogate decision-maker.

4.2 Circulatory death testing

The patient should be observed by the person responsible for confirming death for a minimum period of five minutes to establish that irreversible circulatory arrest has occurred.^[57]

The absence of mechanical cardiac function should be confirmed using a combination of the following:

- absence of a central pulse on palpation
- absence of heart sounds on auscultation.

In the hospital setting, clinical assessment of absent mechanical cardiac function can be supplemented by one or more of the following:

- absence of pulsatile flow using direct intra-arterial pressure monitoring
- absence of contractile activity using echocardiography.

Once mechanical cardiac function is confirmed as absent by clinical assessment, intra-arterial pressure monitoring or echocardiography, the 5-minute waiting period can begin.

Any spontaneous return of circulatory or respiratory activity during the five-minute observation period should prompt a reset of the observation period from this point.^[58]

Spontaneous return of circulatory or respiratory activity is not an indication to begin resuscitation efforts in a context where this has been determined to be inappropriate.

After the 5-minute period of continued circulatory arrest has passed, the absence of pupillary response to light and of any motor response to supra-orbital pressure should be confirmed.^[59-61] The time of death is recorded as the time at which these criteria are fulfilled.^[1]

It is inappropriate to initiate any intervention that has the potential to restore cerebral perfusion after death has been confirmed.^[3,62] In cases where organ donation after circulatory death takes place, a second doctor is required to certify the death.^[19]

5. Organ donation

End-of-life care should, as standard of care, explore the patient's wishes regarding organ and tissue donation.^[63]

The recommended time for a clinical assessment of organ donation potential (with the transplant co-ordinator) is when the treating team makes a decision to perform brain-death testing or to initiate discussions with the family to withdraw life-sustaining treatment. This allows clarification of the potential for organ and tissue donation prior to end-of-life discussions, and an informed approach for consent from the family.^[64]

Somatic support of a brain-dead patient is appropriate to allow the possibility of organ and tissue donation to be fully explored with the family.^[3]

6. Training and documentation

All doctors should be trained in the determination of death. It is recommended that a standardised checklist be used for death determination and its documentation.^[65,66]

Consultation with a medical practitioner experienced in the diagnosis of brain-death is advised in situations where the diagnosis and testing are uncertain.

All doctors training in disciplines that manage patients with severe brain injuries should receive detailed training in the preconditions for brain-death testing, clinical testing procedures, indications for and utility of ancillary testing, somatic support of the brain-dead patient, and techniques for effective counselling of families.^[5,65,67]

All phases of the brain death determination should be documented in the medical record, including:^[5,68]

- aetiology of the coma
- absence of confounders
- full details of the clinical testing performed, including apnoea testing and laboratory values
- neuroimaging results if done
- the reason for ancillary testing if performed and the findings
- time and date of death
- identity of the practitioners performing the evaluation, with their HPCSA numbers.

In cases where brain death can be determined with a neurological exam and ancillary testing is not needed, the time of death must be documented as the time the arterial p_aCO₂ reaches the target, with no spontaneous respirations seen, during the apnoea test confirmed by two doctors.^[3,5]

In cases where the doctors were not able to complete the apnoea test together, the time of death will be upon completion of the second apnoea test.^[3,5]

In cases where ancillary testing is performed, the time of death must be documented as the time that the ancillary test results are formally interpreted and documented.^[3,5]

Determination of death on the basis of circulatory criteria should be documented in the medical record, including:

- in cases where resuscitation was attempted, a record of the resuscitation attempts and the time resuscitation was stopped

- in cases where resuscitation was not attempted, the rationale
- confirmation of absent pupillary and pain response, respiratory effort and circulation after a 5-minute period
- time and date of death
- identity of the practitioner/s performing the evaluation, with their HPCSA number/s.

7. Strengths and limitations

This guidance document offers clear, pragmatic evidence-based medical guidance in the determination of death in the SA context. The provided checklists (Figs 1 - 4) offer a summary of the recommendations for clinical application. A limitation of this document is that a lack of high-quality data from large randomised clinical trials prevented the use of formal analytical techniques (GRADE, AGREE) in the literature appraisal. It is also acknowledged that these recommendations were developed without direct patient, cultural and religious input; however, the panel of experts did represent a broad range of cultural and religious viewpoints from across SA.

7.1 Applicability, barriers, facilitators and cost implications of these guidelines

Barriers to effective implementation of death determination guidelines include a lack of uptake and acceptance by both clinicians and the public as well as the challenge of ensuring cultural and religious engagement and support for the medical determination of death. The endorsement and application of these guidelines is to be formally encouraged across all healthcare disciplines. Undergraduate and postgraduate teaching should consider these guidelines as the standard of care for the determination of death in SA and incorporate them into their training programmes. Hospital policies and standard operating procedures should similarly align themselves with the guidelines to prevent differing practices across institutions, which can cause confusion among clinicians, families and the general public.^[9,69] Use of the provided checklists is expressly recommended in the guidelines to facilitate clinicians to apply them in their daily practice. Continuing professional development programmes should incorporate these guidelines in the education of practising clinicians.

Pursuing a diagnosis of brain death may entail additional resources, and the clinician must judge the appropriateness in each clinical context. The beneficial effects of organ and tissue donation to the SA public and healthcare system are large. Exploring the option of organ and tissue donation at the end of life is a standard of care that should be fully assessed and appropriately explored with all patients and their families. Folder reviews and audits of documentation completed at end of life to assess compliance with these guidelines will assist in improving standards in death determination and end-of-life care.^[70]

8. Conclusion

Death can be determined with complete certainty by medical professionals adhering to these guidelines which offer the clinician the latest evidence in best practice for determining death by either neurological or circulatory criteria. Use of the attached checklists is recommended.

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key questions and supervised the Delphi process, including the drafting and grading of recommendations; drafted the manuscript, supervised revisions to the drafts, and approved the final manuscript.

IJ, DG, FP, KDV chose the participants, developed and supervised the methodology, participated in the Delphi process and face-to-face round-table meeting, performed literature searches, participated in manuscript drafting and revisions to the drafts, and approved the final manuscript.

SM, RM, MM, BM, DB, BR, NM, GAR, NW, BL, MS, NA participated in the Delphi process and face-to-face round-table meeting, drafted and graded associated recommendations; participated in revisions to the drafts and approved the final manuscript.

IC participated in the Delphi process, drafted and graded associated recommendations; participated in revisions to the drafts and approved the final manuscript.

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BRAIN DEATH CERTIFICATION Summary Recommendations - South African Death Determination Guidelines Checklist		
Name: _____ Hospital Number: _____ Date of Birth: _____		
Doctor 1	Prerequisites	Doctor 2
	Coma, irreversible and cause known	
	Normothermia (>36°C)	
	Systolic blood pressure \geq 100 mm Hg*	
	Significant metabolic, electrolyte, endocrine abnormality excluded	
	Sedative/analgesic/neuromuscular drug effect excluded	
Examination**		
	Pupils fixed and non-reactive	
	Absent corneal reflex	
	No gag reflex	
	Absent cough reflex on deep suctioning down tracheal tube	
	No facial grimace to supra-orbital pain	
	Absence of motor response in all limbs (spinal reflexes may persist)	
	Oculovestibular (cold caloric) reflex absent	
	Apnoea testing – no spontaneous respiration	
<p style="text-align: center;">Doctor 1</p> Name: _____ HPCSA Number: _____ Signature: _____ Date and time: _____	<p style="text-align: center;">Doctor 2</p> Name: _____ HPCSA Number: _____ Signature: _____ Date and time: _____	
<p>* or mean arterial pressure \geq 60 mmHg / in paediatrics age-appropriate haemodynamic targets apply ** One doctor with more than 5 years' experience, tests may be done by both doctors simultaneously, no doctor may be involved with the transplant team</p>		

Fig. 1. Summary recommendations – Brain death certification checklist (<https://criticalcare.org.za/resource/death-determination-checklists/>).

BRAIN DEATH CLINICAL TESTING Summary Recommendations - South African Death Determination Guidelines Checklist	
Coma	Apply deep pressure to: the temporomandibular joints, the supra-orbital notch bilaterally, the sternal notch and all four extremities via deep nail bed pressure. There should be no true motor response.
Pupillary light reflex	Shine a bright light into the eye and look for a pupillary constrictor response. There should be no pupillary response.
Corneal reflex	Touch the corneas with soft cotton wool or gauze and examine the eyes for blinking or a withdrawal response. There should be no blinking or withdrawal response.
Response to pain in the trigeminal distribution	Apply pain over the trigeminal distribution, e.g. pressure over the supra-orbital nerve and to the condyles at the level of the temporomandibular joints. There should be no facial or limb movement.
Gag reflex	Stimulate the posterior pharyngeal wall, on both sides, with a tongue depressor or Yankauer suction. There should be no gag response.
Cough reflex	Stimulate the tracheobronchial wall with a soft suction catheter. There should be no cough response.
Vestibulo-ocular reflex (cold caloric)	Inspect the external auditory canal with an otoscope to confirm that the eardrum is visible. If the eardrum is not visible, the canal must be cleared before testing. Elevate the head to 30° to align the semi-circular canal and generate a maximal response. Flush 50 mL of ice-cold water into the ear canal using a syringe. Hold eyelids open and observe for eye movement for a minimum of 60 seconds. There should be no eye movement in response to the cold water; the eyes remain in the midline within the socket.
Apnoea test	See separate advice sheet.
Observations that are incompatible with a diagnosis of brain death:	
Decerebrate or decorticate posturing. True extensor or flexor motor responses. Witnessed seizures.	
Observations that are compatible with a diagnosis of brain death:	
Spinal reflexes, sweating, blushing, tachycardia, and a normal blood pressure.	

Fig. 2. Summary recommendations – Brain death clinical testing (<https://criticalcare.org.za/resource/death-determination-checklists/>).

APNOEA TESTING	
Summary Recommendations - South African Death Determination Checklist	
<p>Background:</p> <p>Only proceed with the apnoea test to confirm brain death if all other brainstem reflexes are absent and patient is haemodynamically stable (may be on inotropes).</p> <p>Two doctors should perform a single apnoea test together.</p>	<p>Interpretation:</p> <p>In cases of brain death, apnoea must be demonstrated in the presence of an adequate stimulus to spontaneous ventilation, i.e. an arterial $p_aCO_2 >60$ mmHg (8 kPa) and an arterial pH <7.30.</p> <p>In patients with pre-existing hypercapnia, it is recommended to wait for a p_aCO_2 rise of >20 mmHg (2.7 kPa) above the chronic level, with a pH <7.30.</p> <p>Attempt at breathing is defined as any respiratory muscle activity that results in abdominal or chest excursions or activity of accessory respiratory muscles.</p>
<p>Testing procedure:</p> <p>Pre-oxygenate the patient with 100 percent oxygen for 10 minutes to prevent hypoxaemia during the test.</p> <p>Perform a baseline ABG. Assess baseline CO_2 level (p_aCO_2 35 - 45 mmHg, 4.6 - 6.0 kPa).</p> <p>Disconnect the patient from the mechanical ventilator and supply continuous oxygen via a T-piece (preferred) or through a catheter inserted through the endotracheal tube and placed above the carina.*</p> <p>Observe continuously for any spontaneous breathing.</p>	<p>Duration (Target p_aCO_2)</p> <p>The period of observation to achieve an adequate threshold of stimulus of the respiratory centre is variable. Usually p_aCO_2 rises by ~ 3 mmHg (0.4 kPa) for every minute of apnoea. If starting from normocapnia, the p_aCO_2 is likely to be >60 mmHg (8 kPa) after 10 minutes.</p> <p>If this is not the case at 10 minutes and the patient is stable, wait a further 5 minutes and repeat the arterial blood gas.</p> <p>An option to minimise the time required for the p_aCO_2 to rise to the desired level, is to adjust the minute ventilation to mild hypercarbia ($p_aCO_2 \sim 45$ mmHg [6 kPa]) beforehand.</p>
<p>Halt testing if:</p> <ul style="list-style-type: none"> - Spontaneous respirations are witnessed; - Systolic blood pressure <100 mm Hg or mean arterial pressure <60 mm Hg despite titration of inotropes/vasopressors; - Sustained oxygen desaturation $<85\%$; - An unstable arrhythmia occurs. <p>It is suggested that prior to aborting the apnoea test due to cardiorespiratory instability, an arterial blood gas (ABG) be sent for testing. If the p_aCO_2 target is met, the apnoea test can be considered positive (consistent with brain death).</p>	<p>If unable to complete testing, consider:</p> <p>If hypoxia occurs 1-2 positive pressure breaths can be given, and apnoea testing continued. Adequate pre-oxygenation and recruitment usually avoids this problem.</p>

*If using a catheter through the endotracheal tube supply oxygen at 4 - 6 L/min.

Fig. 3. Summary recommendations – Apnoea testing (<https://criticalcare.org.za/resource/death-determination-checklists/>).

CIRCULATORY DEATH CERTIFICATION Summary Recommendations - South African Death Determination Guidelines Checklist									
Name: _____ Hospital Number: _____ Date of Birth: _____									
Prerequisites									
Inappropriate to attempt cardiopulmonary resuscitation or attempts at cardiopulmonary resuscitation have failed	<input type="checkbox"/>								
Intensive support (ventilation, inotropes) withdrawn at _____ (time) on _____ / _____ / _____ (date)									
Examination									
Absence of mechanical cardiac function confirmed by one of the following: - Absence of central pulse / heart sounds on auscultation - Absence of pulsatile flow on intra-arterial BP monitoring - Absence of contractile activity on echocardiography	<input type="checkbox"/>								
Patient observed for 5 minutes with no respiratory or circulatory activity seen*	<input type="checkbox"/>								
At end of 5 minutes observation period, lack of pupillary response to light and motor response to supraorbital pain confirmed	<input type="checkbox"/>								
Death certified at _____ (time) on _____ / _____ / _____ (date) by									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center; padding: 2px;">Doctor 1</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Name: _____</td> </tr> <tr> <td style="padding: 2px;">HPCSA Number: _____</td> </tr> <tr> <td style="padding: 2px;">Signature: _____</td> </tr> </tbody> </table>	Doctor 1	Name: _____	HPCSA Number: _____	Signature: _____	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center; padding: 2px;">Doctor 2 (in case of organ donation**)</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Name: _____</td> </tr> <tr> <td style="padding: 2px;">HPCSA Number: _____</td> </tr> <tr> <td style="padding: 2px;">Signature: _____</td> </tr> </tbody> </table>	Doctor 2 (in case of organ donation**)	Name: _____	HPCSA Number: _____	Signature: _____
Doctor 1									
Name: _____									
HPCSA Number: _____									
Signature: _____									
Doctor 2 (in case of organ donation**)									
Name: _____									
HPCSA Number: _____									
Signature: _____									
<p><small>*Any spontaneous return of circulatory or respiratory activity during the 5-minute observation period requires a reset of the observation period from this point</small></p> <p><small>** In cases of possible organ donation after circulatory death one doctor with more than 5 years experience, neither doctor may be involved with the transplant team.</small></p>									

Fig. 4. Summary recommendation – Circulatory death certification checklist (<https://criticalcare.org.za/resource/death-determination-checklists/>).

