ORGAN ALLOCATION WORKSHOP

SATS National Conference

11th November 2022

DISCLOSURES

- I think we have a long way to go with our systems
- All systems need to be continually adapting
- There is a degree of distrust in our system
- We need to create confidence of the referring doctors and public in our systems

DISPARITY

HISTORIC

And current

TRANSPARENCY

Accountability

BODY TO COORDINATE THIS

ALLOCATION AS A STARTING POINT

- Allocation we are doing
- We all know these things – we practice them – and have systems
- But there is not a public record of our systems
- Publishing them is needed
  - Various forums for this
  - Peer-review offers a robust check
- We will be putting a statement of how we are going to periodically review them as a community going forward

Dreizehn Tage lang bangte
[illegible] an diesem Bett.
Der dreizehnte Tag war der
Höhepunkt im zweiten Leben
von Louis Washkansky. Bei
der Visite drückte er Professor
Barnard die Hand; denn es ging
ihm heute besonders gut.
Er hatte mit London und mit
Australien telefoniert,
und der Bürgermeister von
Kapstadt kam zu Besuch.
Am Abend begann die Krise.

CHIEF RABB
EXPRESSES
SORROW

Professor Chris Barnard (above), the lean, tanned and friendly heart surgeon, and leader of the 30-strong team which carried out the heart transplant operation that stunned and thrilled the world, photographed during a Press conference at which he gave details of how the operation was performed. Professor Barnard's leadership of the

. . . the girl who made it possible

ON the left is 23-year-old Denise Ann Darvall, a bank clerk whose tragic death after a road accident near Groote Schuur Hospital led to the operation taking place.

Miss Darvall and her family were on their way to visit friends and had stopped to buy a cake before the accident, which also took the life of her mother, occurred.

By a strangely ironic co-incidence, the wife of the man who was to receive Miss Darvall's heart, passed the scene of the accident after she had visited her husband, who lay dying in hospital from a heart complaint.

The historic picture on the right shows Dr. Louis Washkansky soon after he had been given a new heart at Groote Schuur Hospital. With him is one of the team of dedicated nurses who maintained an intensive round-the-clock vigil on their patient.

The smile
around

WE ARE CREATING A PEER REVIEWED PUBLICATION

SOUTH AFRICAN MEDICAL JOURNAL

- Various article types
  - Research
  - Editorials
  - Review article
  - Guidelines
  - In practice
  - CME
  - Case studies

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  - Guidelines
  - In practice
  - CME
  - Case studies

IN PRACTICE

- Guideline word limit: 2 000 - 3 000 words
- In practice articles are those that draw attention to specific issues of clinical, economic or political interest regarding medicine and healthcare in southern Africa. They are assigned to a topic:
    - Clinical practice
    - Issues in medicine
    - Issues in public health
    - Healthcare delivery

IN PRACTICE

- Position statement
- Delphi process makes this inclusive and gives multiple opportunities for feedback
- Not an AGREE II process
  - Not with GRADE criteria
- Rather than each sentence getting consensus we would like have paragraphs, sections, tables and flow diagrams collated to then put out for consensus assessment

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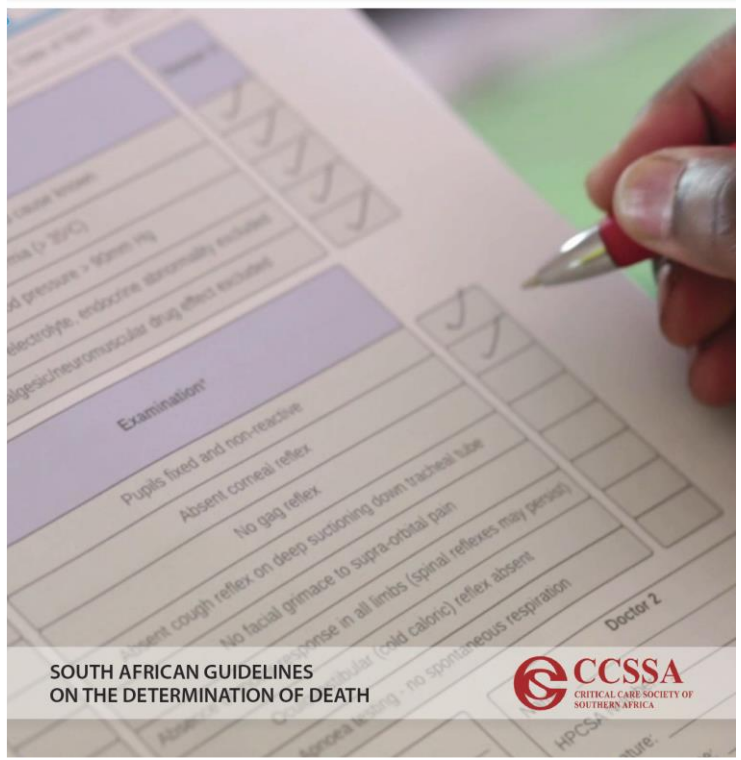
SAJCC
SOUTHERN AFRICAN JOURNAL OF CRITICAL CARE
March 2021 Vol. 37 No. 1 (Part 2)



South African guidelines on the determination of death

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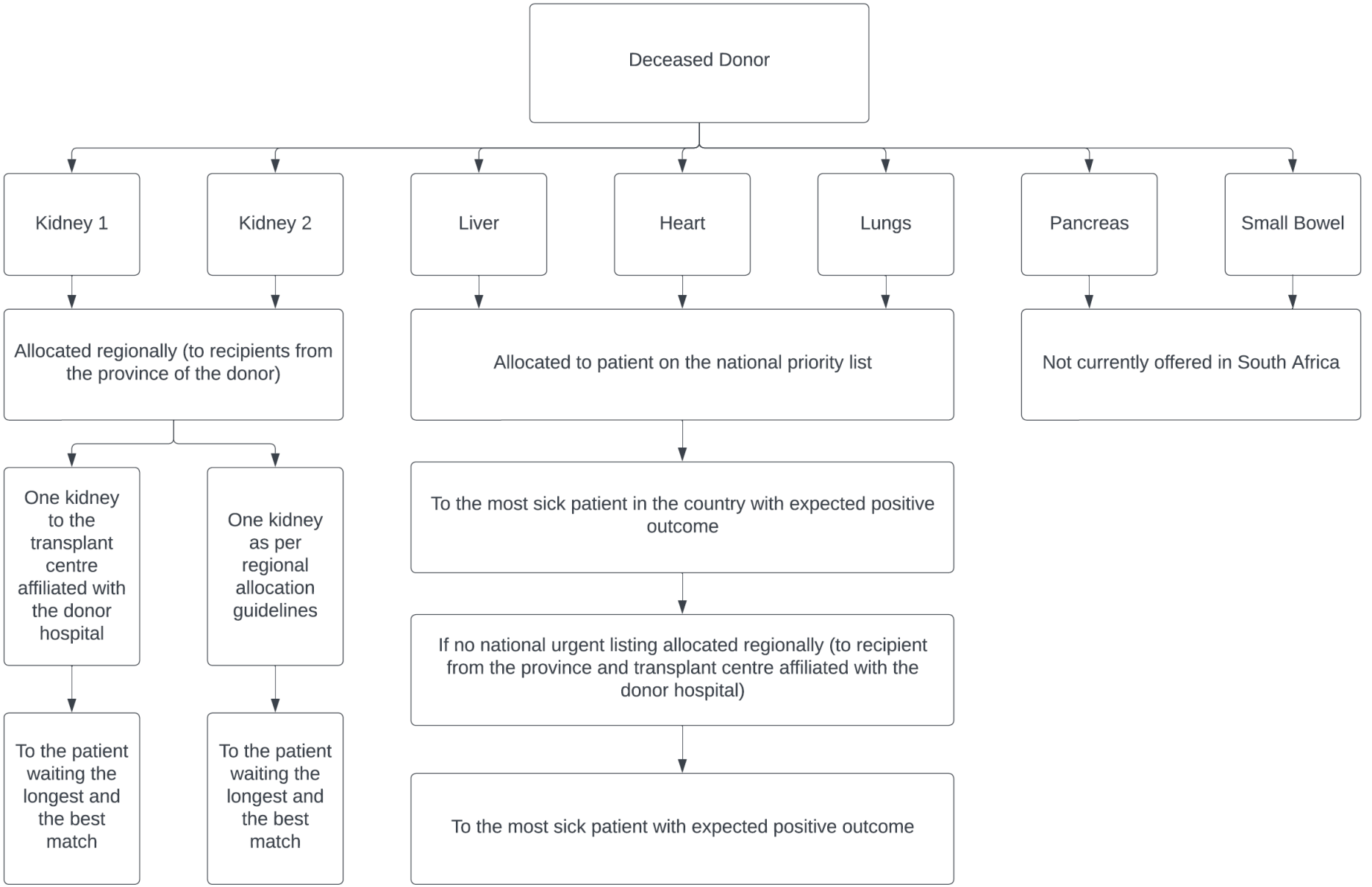
Death is a medical occurrence that has social, legal, religious and cultural consequences requiring common clinical standards for its diagnosis and legal regulation. This document compiled by the Critical Care Society of Southern Africa outlines the core standards for determination of death in the hospital 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



Allocation is done within blood groups (for all non-urgent transplants) and requires a negative crossmatch to ensure no immediate rejection of the organ in the recipient. Paediatric donors are preferentially allocated to paediatric recipeints.

AUTHORSHIP

This is a big group

Steering committee and writing group currently:

- David Thomson, Hloni Bookholane
- Can take on more gladly

Expert panel

- On behalf of: "South African Transplantation Society Organ Allocation Working Group"
- ICMJE (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html)

ICMJE - AUTHOR

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
- We will include people who couldn't make it here by including them electronically in the Delphi process

THERE ARE OTHER ARTICLES HERE

- Editorial: How do we make hospitals accountable for end of life practices?
- Case Studies / CME:
  - Allocation of multi-visceral organ
  - Donation after circulatory death allocation process to minimize cold ischaemic time
  - Acceptance process of an increased risk organ
  - Safeguards against organ trafficking
  - Ethics of giving an organ to a higher risk recipient than the average waiting list

CORRECT IF WE ARE WRONG

Or missing something

ABSTRACT

A transparent and equitable organ allocation system for all organs is an essential component of the national resource of altruistically donated organs. Organ allocation principles and practices strive to ensure fairness and benefit in accessing the life saving benefits of transplantation through equitable and just processes. Public and health professional support of the donation system is essential to improve donor referrals and consent rates. Despite the world leading role South Africa has played and continues to play in transplantation there are no openly published organ allocation guidelines in South Africa. The aim of this paper is to describe current South African practices in the allocation and the ethical rationale underlying these processes.

QUESTIONS

Comments

METHODS

- An expert panel was constituted, reviewed current practice and compiled a position statement on organ allocation in South Africa, using a modified Delphi process.

PANEL RECRUITMENT

- Expert panel members were recruited through the South African Transplantation Society (SATS), as experts in donation and transplantation care representing a broad range of health care practitioners (doctors, nursing, administrators, National Department of Health and allied health). Family and community engagement was sought and included. Informed consent was given by the expert panel with acknowledgement that they would be identifiable in the publication (Appendix 1 - 3).

- We will do the electronic forms at the end of this section
- We will ask you to submit contact details of experts who you feel should be part of the process but aren’t yet

DRAFTING

- Key components of current principles and practices regarding organ allocation in South Africa were drafted at an initial in person meeting of stakeholders at the South African Transplant Society National Conference in November 2022. During three rounds of a modified Delphi process 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.

MODIFICATION PROCESS

- Participants were invited to suggest additional points for inclusion in each round using free-text responses. The writing committee summarised the responses and the available evidence and formulated a draft position statement that was circulated to SATS members, relevant professional societies and National Department of Health for comment over three months. All questions and feedback from this process were then reviewed with the steering committee with the document submitted for external review and endorsement. All expert panel members approved the final document for publication.
-

UPDATING OF THE POSITION STATEMENT

- A review period of 2 years was set after publication of this document, unless an earlier revision is required due to change in practice or legislative changes.

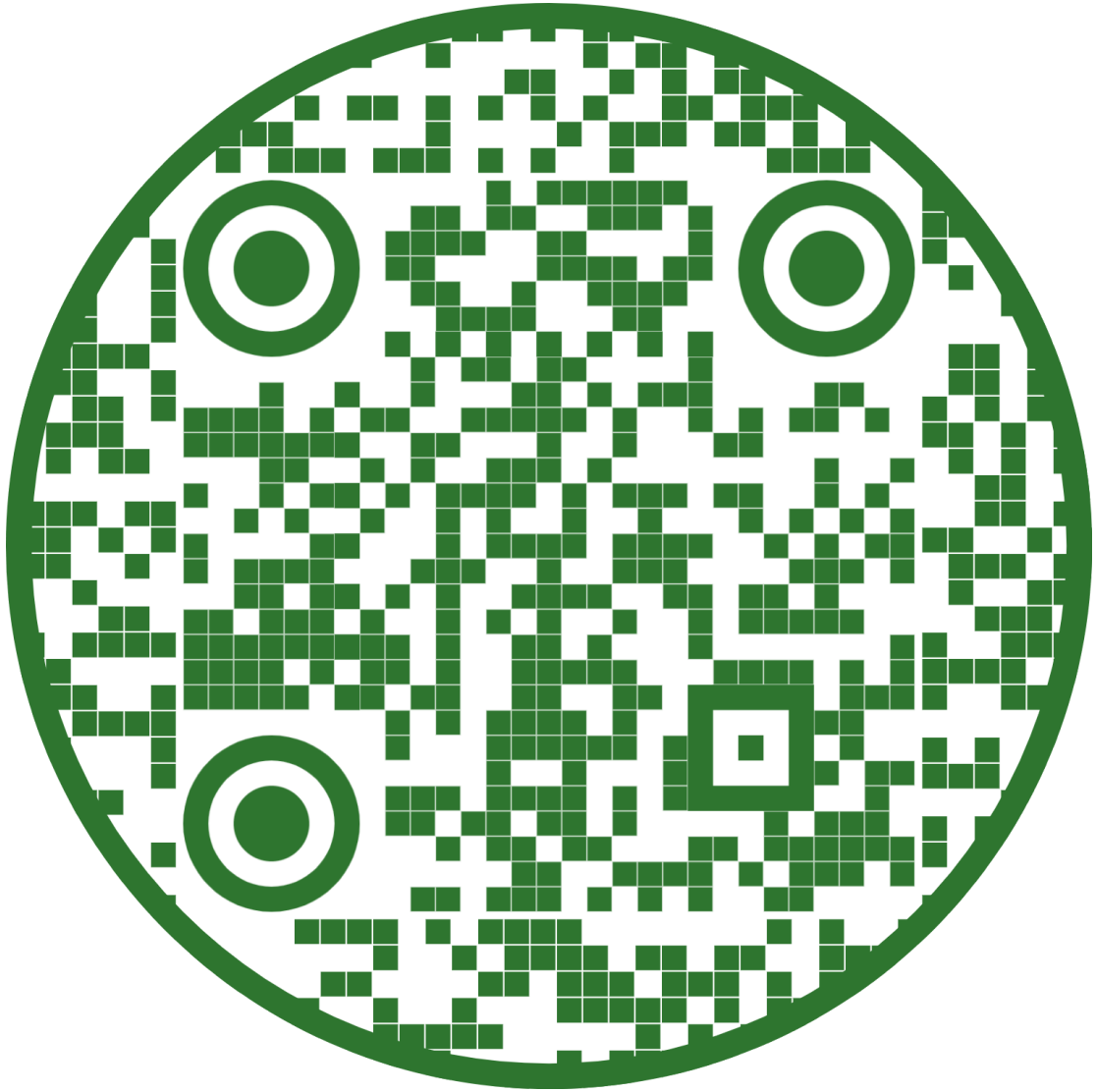
QUESTIONS

Comments

INFORMATION SHEET AND CONSENT

PARTICIPANT DETAILS

HTTPS://ORCID.ORG/



NOW LOOK AROUND

EXPERT PANEL RECRUITMENT

THE RUNNING OF TODAY

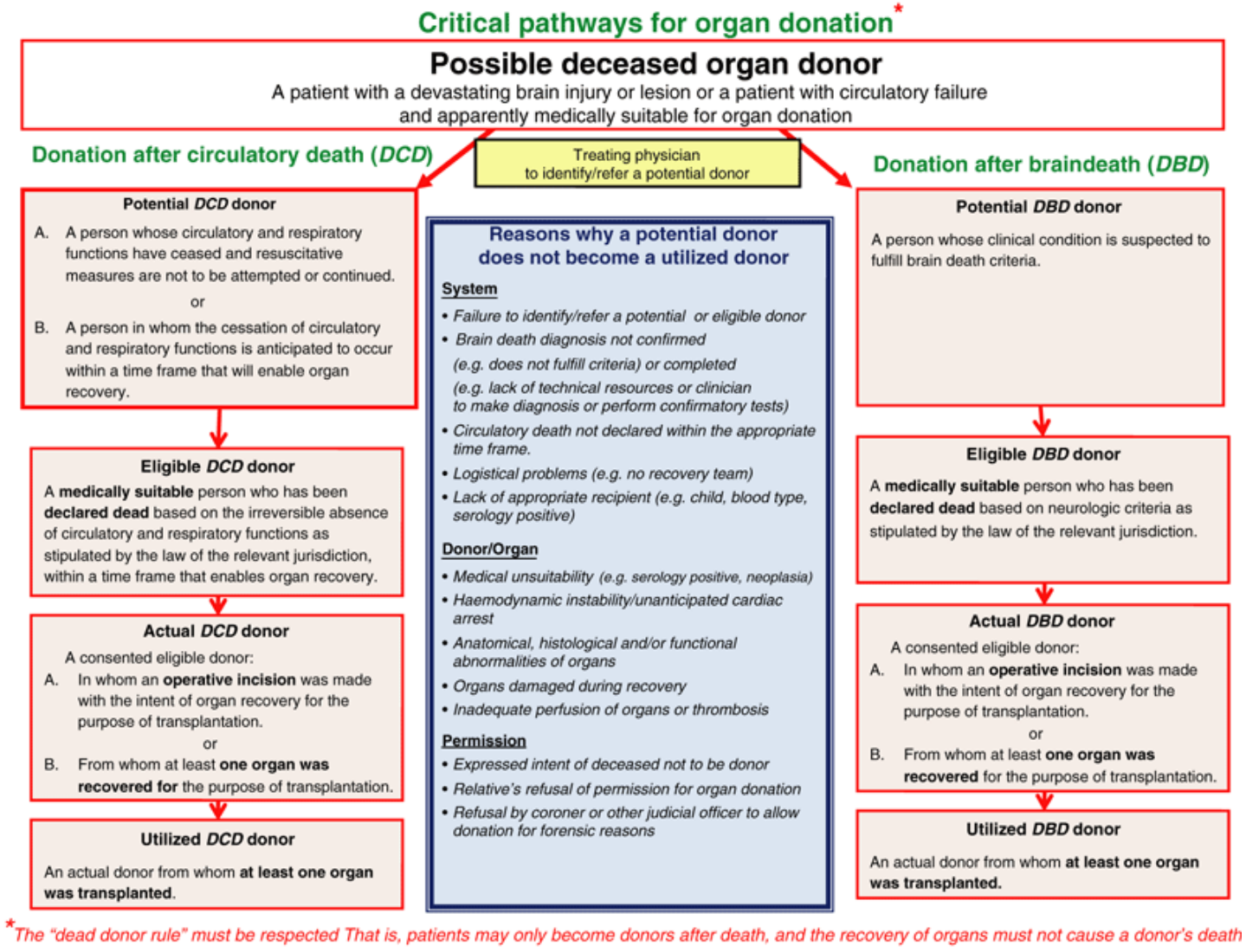
- We are going to go through a series of topics for discussion
  - They may be completed sentences or paragraphs
  - They may be topics
- There are slam dunk statements
- And statements very definitely needing reworking / SA context applied

WHAT ARE WE ALLOCATING

- Organs may be retrieved from deceased or living donors. Deceased donation may occur after circulatory death (DCD) or brain death (DBD). Living organ donation is usually directed, but non-directed altruistic donation also occurs. In practice, living donation mainly involves kidneys but donation of other organs such as liver and lung may occasionally occur. Domino transplants are of living-donor organs that are removed for clinical reasons but may be suitable for another patient.
- All donations from deceased donors must be unconditional although donor families may request allocation to a close family member or friend if clinically suitable.

DEFINITIONS

- **Deceased donor** is a donor certified dead by two doctors, one with more than 5 years experience and both not involved with the transplant teams by either neurological criteria (brain death) or circulatory criteria (circulatory death) where the next of kin has consented to donation.



CRITICAL PATHWAY FOR ORGAN DONATION

Possible donor

A patient at the end of life supported in a manner that allows donation to be an option

Needs to be identified and referred to become a potential donor

Identified and referred (by treating clinical team)

Potential donor

A possible donor who is identified and timeously referred by the treating team for a formal assessment of the donation potential

Needs to be formally assessed as suitable to be an eligible donor

Assessed as suitable (by transplant team)

Eligible donor

A potential donor who has an assessment made and meets the medical criteria for donation

Needs to have consent obtained from the next-of-kin and recovery process undertaken to become an actual donor

Consented after a planned approach
(by clinical treating team and transplant team together)
and recovery process undertaken
(by recovery team)

Actual donor

An eligible donor where consent has been given and the recovery process is undertaken

Needs to have transplantation take place to become a utilised donor

Transplantation (by transplant teams of the allocated recipients)

Utilised donor

An actual donor from whom donation has taken place and transplantation has resulted

DEFINITIONS

- **Adult donor** age equal to or greater than 18 years at the time of death
- **Paediatric donor** age less than 18 years of age at the time of death
- **Living altruistic non-directed donor:** a healthy individual who chooses to donate an organ
- anonymously to someone not known to them
- **Domino donor:** An individual who has an organ removed as a component of medical treatment and who receives a replacement organ. The organ that was removed is transplanted into another person.

DEFINITIONS

- **Selection criteria:** the criteria that is applied to determine if an individual is to be placed on the waiting list for an organ.
- **Allocation:** the process that is applied when an organ becomes available for transplantation
- **Equity:** that all patients with similar clinical characteristics on the waiting list have equal probability of receiving an organ from a deceased donor
- **Utility:** allocation of an organ to the individual with the greatest number of life-years following the transplant
- **Benefit:** allocation of an organ to the individual who is clinically assessed as having the greatest increase in life-years gained (comparing survival with and without transplantation)

QUESTIONS

Comments

STANDARD LISTING CRITERIA

Kidneys

Heart

Lung

Liver

WORD COUNT

- These can be done as supplemental appendices
- We can stress in the text it always an MDT involved
- Not enough time or space to go into these now? (What time is it)

APPEALS PROCESS FOR NON-SELECTION TO THE WAITING LIST

DISCUSSION

ABSOLUTE CONTRAINDICATIONS (GENERAL)

- Not all patients who meet criteria for transplantation are suitable for a variety of reasons. Patients need full evaluation by a discussion at an MDT meeting. Some contraindications are absolute, and others are relative. The team needs to take a balanced decision based on need and avoiding futility.
-

CONTRAINDICATIONS

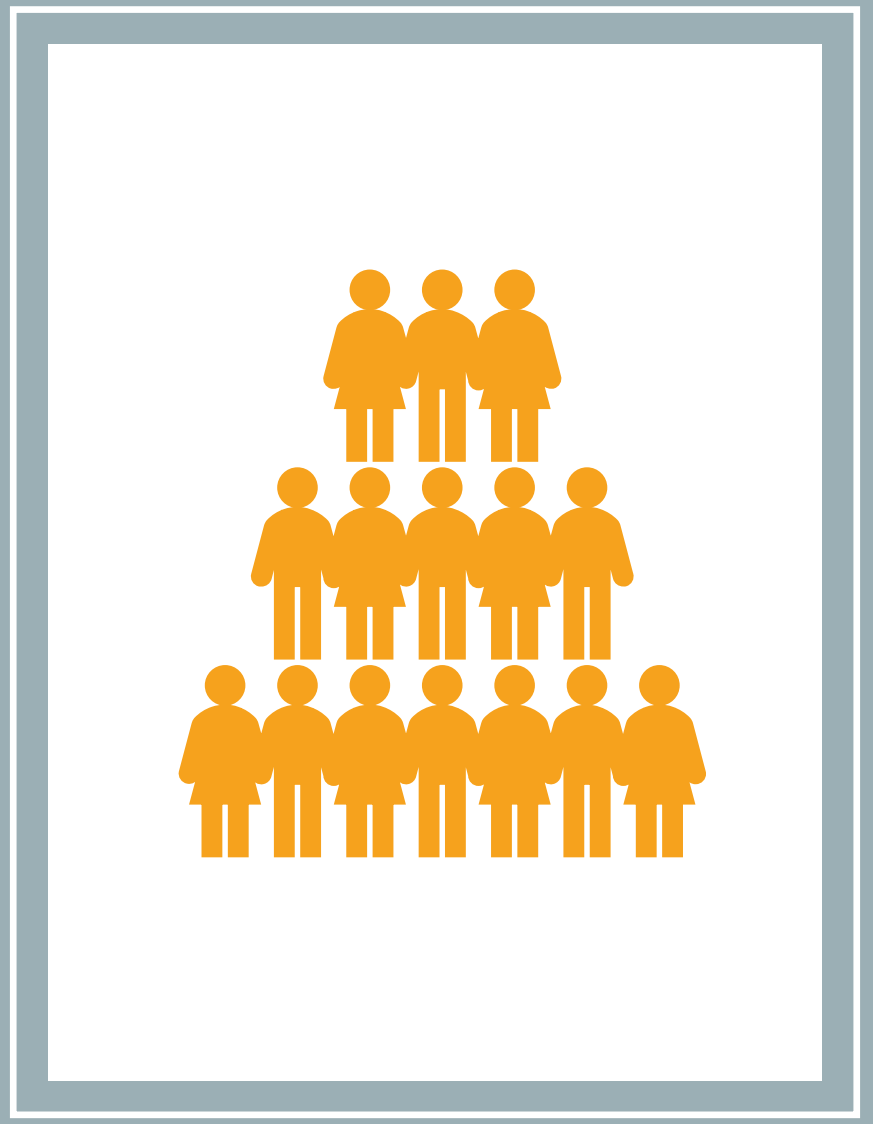
- Solid organ and haematological malignancies within 5 years of listing for transplantation with the exception of cutaneous squamous and basal cell tumours and selected paediatric malignancies

- Unstable critical clinical condition (such as active septicaemia, shock, unstable condition on mechanical ventilation or extra-corporeal membrane oxygenation)

DELISTING (LIVER)

- Tumour rupture occurred α-fetoprotein (AFP) greater than 1,000 iu/ml
- A single tumour >7 cm diameter, more than 5 tumours, between 2 to 5 tumours any one >3 cm diameter or a single tumour >5 cm and ≤7 cm diameter and evidence of tumour progression within a 6-month time period, all judged by USS or CT scan, radiological evidence of vascular invasion, extra-hepatic tumour spread. Tumour size will be assessed by serial scanning 3-monthly using the scan, which demonstrates the largest diameter
- Failure of adherence with guidelines relating to alcoholic liver disease and illicit drug use
- The development of comorbidities sufficient to impact on expected 50% probability of survival at 5 years

HOW MANY TIERS TO ALLOCATION CRITERIA?



PRIORITY LISTING CRITERIA

Kidneys

Heart

Lung

Liver

ORGAN SPECIFIC URGENT LISTING PROCESS

Renal urgent listing criteria (Western Cape):

Inadequate dialysis, poor access/dialysis options
Children severely impaired growth and development on dialysis
Committee who reviews the case: extra 50 points allocated

Review of their outcomes at a combined provincial meeting
Committee is a member of each transplant centre and a vascular access surgeon

HEART ALLOCATION

- **Heart Allocation** (transcribed from Position Statement and Guidelines; Thoracic Transplants; Priority Listing Heart Transplant Patients; Revised 7 May 2012)
- **1.1 Objective:**
- To ensure that all transplant centres referring organs for transplantation are aware of patients listed for urgent transplantation through the utilisation of a National Urgent Waiting List.
-

HEART

- Patients meeting the urgent criteria (see below) will be placed on a National Urgent Waiting List.
- Patients must be reassessed weekly for meeting urgent criteria and must be relisted every Monday before the close of business with the responsible person,
- Please note that any patient not relisted on a Monday will be delisted and considered not to have met the criteria

  .
- The responsible Coordinator will complete the "Urgent Notification Sheet* and forward it to the list coordinator as prescribed,
- The person responsible for coordination of the list will maintain a database of all listed patients and the outcome of the listing.

DATA

- The data will include:
  - Transplant center and Coordinator listing
  - Date and time of listing
  - Patient name and surname
  - Age
  - Height, weight and chest sizes
  - Blood group
  - Criteria for listing indicated
  - Outcome
- The date of first listing will determine order of priority or as discussed between transplant surgeons or panel.

FOR DISCUSSION

- Pro-forma document for each organs
- Outside review
  - Beforehand only for renal?
- Outcome follow-up
  - What outcome?
  - By who and how often?

USE OF PATIENT INFORMATION

POPIA Act, compliance
Patient consents to share information
- what if they don’t?
- we need a required baseline to inform our allocation
Protection of the information
Sharing platform of the information
Follow-up
Standard waitlist metrics to be reported monthly by each centre.
Priority list metrics to be reported monthly.

PATIENT CONTACT AND INFORMATION

It is the patient's responsibility to make him/herself available to be contacted by the transplant centre at any time. This is discussed with the transplant coordinator. Patients are requested to inform the transplant centre of any changes in their circumstances, for example:

- If they become unwell
- If they are admitted to hospital
- Any changes in medication
- Travel

Reliable contact numbers for the patient and next of kin (a combination of landlines and mobile phone numbers is preferable)

During the waiting period the transplant centre will maintain contact with the patient and his/her family to offer support, information and guidance according to their needs. Patients on the waiting list will be reviewed as clinically indicated.

CONSENT FROM THE RECIPIENT

- Transplantation of any organ is associated with risk and it is the responsibility of the transplant team to ensure that the potential transplant recipient understands and accepts the risks associated with organ transplantation as well as the benefits. Obtaining informed consent is a process which involves the whole multi-disciplinary team.
- We need to add something for extended criteria, increased risk donors?
-

PATIENT PREFERENCES IN DONOR SELECTION

- All elective liver patients should state their preference, at the point of waitlisting or subsequent follow-up, for donor type (e.g. would the recipient consider a liver offer from a donor after circulatory death or a split liver) and donor virology (e.g. would the recipient consider a liver offer from a donor with an Hep b, C or HIV positive test result).
-

DISCUSSION

METRICS TO EVALUATE ORGAN ALLOCATION

- Effectiveness
- Equity
- Efficiency
- Costs and resources
- Donor rates
- Transparency and objectivity
- Patient reported outcomes

EFFECTIVENESS

- The number and proportion of donor organs that are utilized for transplantation is one specific measure of effectiveness.
- Another could be the successful transplantation of the organs i.e., the technical success of the operation.
- Clinical measures such as graft and patient survival, quality of life, and rate of complications.
- There are many potential impediments, responsible providers, and dynamic factors that may affect these metrics, but when compared with other systems or in relation to past performance, these may give direct evaluation of the system.

EQUITY

There are many challenges with maintaining equity for all potential patient groups and even more broadly determining what dimensions of patient characteristics should be considered for evaluating equity in the system of organ allocation [19]. Moreover, there may be an important distinction between disparities in access to care versus differences, which the latter may be considered medically appropriate differential rates of access to transplantation. Certainly, one measure of equity incorporates the distribution of donor organs as compared to the number of patients in need. This is commonly measured based on patient groups that are placed on a waiting list for a donor offer. However, it is also appropriate to consider the broader population of patients that have end-organ failure but have not necessarily been placed on a waiting list that may also be as important as there are many known barriers to access to waiting lists, and the duration of waiting times may independently dissuade expeditious placement on deceased donor waiting lists in certain populations.

COSTS AND RESOURCES

- The costs and resources required to procure, allocate, transplant, and care for transplant candidates and recipients may all be affected by the system of organ allocation.
- A system that can achieve other metrics of allocation quality that can minimize costs may reallocate scarce limited healthcare resources to other aspects of care delivery.

DONOR RATES

A focus of the effects of organ allocation has been directed at measuring the impact of donor placement following procurement of organs for the purpose of transplantation. However, there may be many downstream effects of an effective (or ineffective) process of organ allocation. For example, a system that is particularly inefficient may dissuade prospective identification of donors or innovation toward developing systems to adapt to increased numbers of available donor Donor rates may also be a reflection of public trust or coordination with hospital providers and services that may be encouraged or discouraged by prior processes of organ allocation. As organ allocation is affected and incorporates multiple providers and processes of care, a holistic approach toward assessing quality that includes the identification and consent of viable donors may be important.s.

TRANSPARENCY AND OBJECTIVITY

- One of the important aspects of allocation policy is transparency of the algorithms and rationale of the process that govern donor organ distribution. As donor organs are limited, multiple stakeholders including patients must be empowered to inform potential life altering decision-making based on established criteria.
- Despite the complexities of organ allocation, efforts to disseminate the most salient features of allocation systems to decision-makers including patients is a vitally important component of existing and changing policies.

PATIENT REPORTED OUTCOMES

- The ultimate purpose of organ allocation policy is to facilitate the distribution of the donor organs to patients with significant need and potential benefit based on organ failure. As such, comprehensive assessment of the impact of policies governing organ distribution should include satisfaction, quality of life, and perception of patients, donors, and donor families. This may extend beyond the population of patients directly impacted by end-organ disease, as the perceptions of our national systems of organ allocation from the general public are also salient toward understanding the trust and connotations associated with the field of transplantation.
-

QUALITY OF LIFE

- Using quality of life benefit as opposed to survival benefit changes the way allocation algorithms should be designed to prioritize patients. Age, performance status, metabolic status (in particular sarcopenia, obesity, and diabetes) and comorbidities may become much more important than organ dysfunctions in allocating according to this principle.

METRICS TO MEASURE

- Metrics reflecting proposed policy changes, including numbers of patients listed, deaths on the waiting list, risk of death on the waiting list reflected in medical urgency metrics such as MELD, numbers of transplants or transplant rates, numbers of organs recovered for transplant but not transplanted (also known as ‘discards’), and post-transplant deaths and graft failures.

- Constant vigilance regarding the effectiveness of the process and maximizing the quality of the system is of the utmost importance.

DISCUSSION

DONOR QUALITY

- Paediatric liver: Less than 18 years of age
- Splittable liver:
  - < 51 years
  - BMI < 26
  - < 4 days in ICU
  - ALT / AST < 3 x normal
- Normal liver:
  - Any other liver ≤ 65 years
- Extended criteria donor (Defined by the responsible surgeon on call)
  - DCD
  - Donor > 65 years

DONOR QUALITY

- Kidneys from donors aged 4 years and under 365 days (before their 5th birthday) will be retrieved and offered en bloc (but may be split if appropriate) while kidneys from donors aged 5 years and over will be retrieved and transplanted singly wherever possible.
- Kidneys will not be offered from donors under 1 month old, including neonates.

PAYBACK SYSTEMS

- After utilizing a referred organ for a Status 1 patient as defined above, the receiving unit will be obligated to "Pay Back" an organ to the referring unit. This will be on a 1 for 1 basis.
- The receiving centre has to do the pay back with the first available AB0 blood group identical liver of the same quality as the liver received, or better.
- Offered only once or 3 times?
- UK rotates between centres in sequence

DISCUSSION

DISPARITY

PAEDIATRIC

- In addition to the survival and quality of life benefits enjoyed by transplant recipients at any age, children with end-stage organ failure have a time-limited opportunity for growth and development and may suffer life-long consequences if not transplanted expeditiously. As a result, pediatric candidates have the potential to receive unique benefits from transplantation that will positively affect their lives as children and later, as adults.
-

PAEDIATRIC

- Paediatric candidates also experience barriers to transplantation as a result of their small size and developing anatomy. In addition to the universal issue of donor scarcity, availability of organs is further restricted to pediatric patients requiring size-matched organs. For this reason, children on the waiting list may need to have ready access to a particular subset of organs for which anatomical compatibility will allow transplantation.
-

PAEDIATRIC

- The lack of availability of life-sustaining therapies while awaiting transplant further compounds the problem of donor scarcity for paediatric candidates. Technologies to manage end-stage organ failure while waiting for an appropriate organ, also known as Bridge to Transplant technologies, for paediatric patients are limited with inconclusive evidence of success. Bridge therapy for paediatric heart candidates have significant complications, which increase with the duration of technological support and can require intensive multi-disciplinary rehabilitation.
-

PAEDIATRIC

- Across the entire population of pediatric versus adult transplant recipients, pediatric transplant recipients will on average enjoy lower mortality rates due to the strong association between younger age and longer survival, despite the very young (< 2yrs of age) and adolescents having slightly worse outcomes. For recipients of any organ, children less than 18 years old have over two times the 20 year patient survival rate of adults.

DISCUSSION

WHAT ARE THE OTHER HIGH RISK GROUPS

- Highly sensitized
- Retransplant
- Priority listed patients

RETRANSPLANT

Re-transplants are only undertaken when there is evidence of irreversible graft failure and the risk of mortality from that exceeds the increased post-operative mortality after re-transplantation. Re-transplant patients are also expected to achieve a 50% probability of an acceptable survival and quality of life 5 years after transplant.

RETRANSPLANT

- Patients requiring re-transplantation will not have access to urgent listing
- Hepatic artery thrombosis

PROPORTION OF DEFINED HIGH RISK TRANSPLANTS FROM THE OVERALL VOLUME

We need to offer a full range of supports

Links to payback or rotational system

DISCUSSION

OFFERING PROCESS

- During the offering process the centre should maintain contact with the Transplant Coordinator managing the donor. If the donor is becoming increasingly unstable and continuing with the offering sequence is likely to jeopardise other solid organ retrieval, the Transplant Coordinator should discuss with the Regional Manager on call whether it would be appropriate to abort the offering sequence.
- A centre must only state that they wish to accept if, following full centre discussion, they have identified a specific patient who is suitable for the organ.

FOLLOW-UP FOR ALCOHOL / DRUG ABUSE

- Follow-up for alcohol use will be separate from and additional to the transplant follow-up and should be carried out by specialists in substance misuse. Ideally this would be the same individual/s that were involved in the initial assessment. It is anticipated that as time from the liver transplant increases, frequency of follow-up will decrease, and that shared care arrangements with alcohol services in the patient's locality will often be appropriate. The type and frequency of follow-up will depend on the patient's needs.

BACK-UP OFFERING

REALLOCATION

- If a kidney needs to be reallocated because the patient for whom the kidney has been accepted cannot subsequently receive the transplant, the following rules apply:
- If the kidney has not been dispatched to the transplant centre it will continue to be offered for prioritised patients in the usual way
- If the kidney has been dispatched to the transplant centre, it will be offered back for any urgent listed patients. If there are no suitable patients, the kidney can be kept by the centre to which the kidney has been dispatched. The centre will select the most appropriate patient from their local list.
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NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- All health care professionals and those involved in transplantation should report any instance of known or suspected clinically and ethically inappropriate non-compliance to the National Department of Health Deputy Director of Dialysis and Transplantation.

NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- The National Department of Health Deputy Director of Dialysis and Transplantation (or nominated representative in their absence or where there is a conflict of interest) will form a group of at least two external transplant clinicians (“the Compliance Group”) who will classify, investigate the incident and report the outcome within 20 working days of the initial report of those incidents where there is potential cause for concern. This group will contact the incident reporter and relevant clinicians to establish the circumstances around the non-compliance.
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NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- Incidents of non-compliance will be classified as minor or major. Minor includes inadvertent mistakes (such as resulting from a clerical error) or noncompliance mitigated by circumstances. Major includes intentional non-compliance or repeated non-compliance.
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NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- In cases of minor non-compliance and where appropriate, the relevant health care professional and institution where the incident took place will be asked to outline what actions have been taken to avoid repetition. The Minister of Health or delegated representative will review the relevant actions in the official report of the incident to determine whether modification is required.
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NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- All incidents will be reported to the clinician's Medical Line Manager, Director of Nursing and/or Chief Executive, and Provincial Head of Department as appropriate. If the clinician is employed by an institution, the clinician will be subject, if appropriate, to the institutional disciplinary procedures and outcome reported to the National Department of Health.

NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- In cases of major non-compliance further action in the case of serious professional misconduct (such as non-compliance for personal financial reward) may include reporting the incident to the appropriate regulatory body (such as the Health Professions Council of South Africa or the South African Nursing Council). In cases of criminality the case will be reported to the South African Police Service for further investigation.

NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- The healthcare license of that transplant centre may be withdrawn and/or centres may decline to allocate deceased donor organs to that transplant centre, particularly where there are concerns around patient safety. It is recognised that this would be in very exceptional circumstances.

NON COMPLIANCE TO PATIENT SELECTION AND ALLOCATION POLICIES

- Incidences of possible non-compliance should be investigated and closed within 20 working days from the initial report, assuming full cooperation from the relevant transplant centre, although it is recognised that actions arising from the incidents may take longer to implement.

DISCUSSION

FUTURE RECOMMENDATIONS

Thank you

“Organ donation is not an outcome failure but rather a positive reflection of the whole health care system and is an essential part of end-of-life care that should be provided routinely.”