
**GUIDELINE: PRIORITY SETTING APPROACH IN
THE SELECTION OF PATIENTS IN THE PUBLIC
SECTOR WITH END-STAGE KIDNEY FAILURE
FOR RENAL REPLACEMENT TREATMENT IN
THE WESTERN CAPE PROVINCE**

Prepared by the Renal Services Task Team, under guidance of Prof M R Moosa
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Executive Summary

Renal dialysis is lifesaving treatment that has revolutionized the management of end-stage kidney failure (ESKF). Together with kidney transplantation it has given a new lease on life to many millions around the world. The major obstacle to the widespread use of this treatment, which has to be offered lifelong, is its high cost. Because of this, access to treatment for patients in the public sector has to be governed and a rationing model has been endorsed. Patients are prioritized in 3 categories. Patients in Category 1 must be offered treatment, those in Category 2 would be treated only if resources allowed. All patients in these two categories must be suitable for transplantation. Category 3 patients would only be offered conservative treatment. The patients would be categorized based on a combination of social but predominantly medical factors. The ethical principle of utilitarianism was invoked and the selection criteria based mainly on evidence and social factors but also on the experience of senior clinicians working in the Western Cape environment. The mechanics of the selection process and communication with the patient/family are detailed. An appeals mechanism and audit process are recommended.

Preamble

Renal dialysis for the treatment of patients with end-stage kidney failure (ESKF) is one of the truly amazing therapeutic discoveries of modern medicine whose success has undoubtedly surpassed the wildest expectations of its early protagonists. Dialysis is capable of keeping patients alive and well for many years (even decades) - patients who are otherwise doomed to die. Patients often return to their communities to lead very productive lives. The success of dialysis has led to unprecedented demand for treatment. Treatment is however, very expensive and the question often raised is whether the use of enormous resources for the benefit of a relatively small number of ESKF patients in the face of other pressing health demands is the best way to use scarce health Rands. Worldwide the need for dialysis is escalating (16) and the discrepancy between the demand for renal services and its actual delivery is increasing despite the annual 7% increase in the maintenance population (13).

Western Cape Situation

The true incidence of ESKF in the Western Cape is unknown. Estimates of the incidence in other developing countries range between 150 and 450 per million population (pmp) per annum (3,15). With a population of 5 million the number of new

ESKF patients in the Western Cape that potentially require treatment *each year* is therefore between 750 and 2250. A realistic estimate for the Western Cape is an incidence of 250 pmp per annum giving a total 1250 new patients. The Provincial Administration serves 80% of the Western Cape population which means that the demand for treatment is for **1000** new patients per annum. The number of patients currently receiving dialysis in the public sector in the Western Cape is approximately 250. Approximately 100 patients are successfully transplanted annually and the mortality rate in dialysed patients is 10%. Therefore each year **125** new patients can be accommodated. It is therefore clear that currently we are meeting only 12.5% of the dialysis need in the public sector. The shortfall is therefore between 625 - 2125 patients annually based on an incidence ranging between 150 - 450 pmp. If these patient numbers are translated into the number of “dialysis stations” (assuming that a single “station” services a maximum of 6 patients) then the shortfall in the public sector is **104 - 354 “stations” per annum.**

The major barrier to accessing dialysis is the high cost of the procedure. Currently, the annual cost of treating an ESKF patient with dialysis is conservatively estimated at R100 000. Because of this, access to dialysis treatment has had to be restricted ever since it was introduced in the Western Cape (18). Expansion of the programme is limited by lack of facilities; however, an even greater limitation is the shortage of professional dialysis skills – technical, nursing, medical and surgical. Another major challenge has been the declining number of dialysis patients being transplanted (18).

The Provincial Government has made renal replacement treatment available since the 1970s. Because of the limitation of physical and especially human resources, it is not possible to treat all ESKF patients who are in need. In order to ensure equity and the optimal use of scarce resources a priority setting process has been established based on the National Department of Health guidelines.

Basis of selection

Kidney transplantation is the most cost-effective form of renal replacement, promises the best quality of life and has the best survival rate. All patients accepted for renal replacement therapy **must** therefore **be** eventually **suitable for transplantation.**

Secondly, the allocation of the scarce resource must be done in such a way as to maximize the benefit that the society will eventually derive from such an allocation (utilitarianism). In the case of kidneys, the organs must be allocated to potential recipients in a fair and equitable fashion that does not discriminate against any candidate deemed suitable for transplantation. Thirdly, once transplanted, patients should be capable of reliably taking care of themselves and their grafts to ensure the optimal survival of the organ.

Most of the recommendations are based on evidence but also important is the experience of the practicing clinicians working in the public sector.

Prioritisation Policy:

All patients in whom the diagnosis of end-stage or advanced chronic kidney disease is made will undergo formal assessment. This process will stream patients into 3 groups:

- Category 1. Patients with this priority rating **must** be accommodated on the dialysis and transplant programme. Resources will always be found to treat these patients.¹
- Category 2. Patients with this priority rating will be accommodated on the programme only **if resources allow**, with priority to the category 2 patients waiting the longest and who have the best chance of good outcomes.

Of overriding importance, is that patients in Categories 1 and 2 **must** be suitable for kidney transplantation.

- Category 3. Patients in Category 3 will be offered optimal **conservative** treatment, are not eligible for Categories 1 or 2 and will *not* be offered renal replacement therapy.

If there is uncertainty about the diagnosis of end-stage kidney disease, patients who present for dialysis will be treated until a firm diagnosis of irreversible kidney failure is made. Patients will then undergo formal assessment and if a patient is excluded by any category 3 factor, or fails to meet criteria for selection to category 2, dialysis must be withdrawn. Prior to withdrawal, a patient and/or family will be given advance notice and offered a short period of time in which to find another facility, if possible. Withdrawal will be done as humanely and sensitively as possible. Following withdrawal, the patient will not be abandoned, and will at all times be provided

¹ In practice these patients currently account for 10-20% of all patients accepted for the programme

optimal conservative treatment, although it will no longer be possible to offer dialysis and renal replacement therapy.²

Category 1:

Patients in this category are considered to potentially have the best possible outcome and would derive maximum benefit with the lowest risk of treatment failure. In addition to meeting the relevant requirements of Category 2 (and not been excluded by any Category 3 factor), a patient in this category must be assessed against, and meet the following constellation of factors:

- Age \leq 50 years;
- BMI less than 30 kg/m²;³
- HIV negative;
- Hepatitis B Surface Antigen (HBsAG) negative.⁴

These factors, taken together and considering the patient's overall medical condition, will guide the decision on selecting patients for Category 1.

Category 2:

Patients in this category may be eligible for treatment provided resources allow. The following factors improve a patient's chances of being offered treatment:

Social Factors

- Good home circumstances (including access to storage space, running water, sanitation and electricity), needed to succeed with dialysis and transplantation;⁵
- The patient is well-motivated and has access to a good social support system required to do well on dialysis and transplantation, and
- Proximity to and/or evidence of financial means or other capability to regularly arrange transport to a renal unit as frequently as this may be needed (the unit is unable to pay for or provide such transport).

² Withdrawal in this case is necessary to make the dialysis slot available for a patient in Category 2 who is eligible for a transplant and in need of dialysis in order to survive.

³ Body mass index (BMI) is a measure of obesity. It is the W/Ht^2 where W is weight and Ht is height.

⁴ Hepatitis B is a serious virus infection that is highly infectious and potentially lethal.

⁵ Peritoneal dialysis is precluded as a treatment option, restricting patients to haemodialysis which is limited. For peritoneal dialysis to be successful access to running water, electricity and sanitation are important but not essential.

The following factors, taken together, reduce the chances of being offered treatment:

Medical Factors

- Above age 50 years;
- BMI 30-35 kg/m² (8);
- Hypertension with severe left ventricular dysfunction or other severe target organ damage;
- HBsAg/HCV positive with no cirrhosis⁶ (7,9,14,25);
- Smoking⁷ (5,24);
- Diabetes mellitus (20);
- HIV⁺ patients whose CD4 count \geq 200/ml, have an undetectable viral load and, if on antiretroviral (ARV) treatment, demonstrated good adherence and clinical response within 6 months (22);
- First presentation with ESKF requiring urgent dialysis⁸ (4,11);
- Comorbid disease e.g. stable ischaemic heart disease (2,6,10);
- Previous kidney transplant.⁹

These factors, taken together and considering the patient's overall medical condition, will guide the decision on offering treatment but no single factor will automatically exclude patients from treatment. The extent to which patients have properties that resemble those of category one patients, the greater the likelihood that they will be accepted; conversely the greater the number of unfavourable factors the lower chances of acceptance.

Category 3

Kidneys are a very scarce resource and should be allocated to patients who will derive most benefit from the transplant. Any condition or circumstance which compromises the medium-long term survival of a patient or the graft will exclude the patient from transplantation and selection for Category 2 or Category 1.

⁶ Patients with HBsAg infection especially with cirrhosis have a poorer prognosis following transplantation because immunosuppression stimulates viral replication. Patients are also at risk of developing liver-related complications as well as an increased risk of sepsis.

⁷ Smokers have a 10% poorer graft survival rate compared to non-smokers and quantitatively do as poorly as patients with diabetes.

⁸ Patients presenting with advanced disease and requiring emergency dialysis have a significantly poorer outcome than patients started on treatment electively.

⁹ This is both in the interest of fairness to eligible patients who as yet have received no graft and because subsequent grafts have poorer overall survival compared to primary grafts.

Any **one** of the following factors excludes patients:

- Renal transplantation is contraindicated or carries unacceptable risks;
- AIDS or HIV infection other than HIV+ patients with the medical characteristics described in category 2;¹⁰
- Age \geq 60 years;¹¹ (17,23)
- Active substance abuse or dependency; (21)
- Morbid obesity (BMI \geq 35 kg/m²);¹² (1,8,12)
- HBeAg positive or cirrhosis; (7)
- Diabetes mellitus and aged >50 years; (5)
- Active, uncontrollable malignancy with short life expectancy;
- Advanced, irreversible progressive disease of vital organs such as:
 - cardiac, cerebrovascular or peripheral vascular disease
 - liver disease
 - lung disease
 - unresponsive infections
- Psychological Exclusion Criteria
 - Any form of serious mental illness or incapacity which, as shown by psychiatric and medical examination, would preclude the patient and/or family or available support group from successfully managing the patient, considering his/her impairment, through dialysis, a transplant, and extended follow up care;
- Habitual Non-Adherence
 - Patients with habitual non-adherence to any medical treatment.

¹⁰ Up to now patients who were HIV positive were only offered conservative treatment because the experience with renal transplantation in these patients was limited and antiretroviral therapy has only recently become widely available in public sector. New evidence and our anecdotal experience suggest that these patients can be successfully transplanted provided certain strict conditions are fulfilled (see above in section on Category 2). Renal transplantation must be considered an experimental procedure in these patients who should be appropriately consented.

¹¹ Evidence shows that after 5 years elderly patients have more than twice the risk of dying with functioning grafts mainly due to sepsis and cardiovascular disease. Although some data indicates that, under certain circumstances, elderly patients do as well as, or even better, on dialysis than some younger patients, the goal of the renal replacement programme is to provide kidney transplantation to as many patients as possible who will potentially achieve the best outcomes measured by increased life expectancy generally offered by younger transplant candidates. In addition, dialysis units in the public sector have limited access to expensive immunosuppressive agents which could reduce the morbidity associated with conventional agents in the elderly. Results in South African transplant units confirm the inferior survival of older patients after transplantation (17).

¹² Obese patients have significantly poorer outcomes compared to non-obese patients. This includes greater risk of acute rejection and chronic allograft nephropathy.

Re-evaluation of transplanted patients whose grafts fail

All transplanted patients whose grafts fail will be re-evaluated for re-admission to the programme in the same way as new patients are and, if they fail criteria for inclusion in Category 1 or Category 2, or are excluded by a factor in Category 3, further renal replacement treatment will not be offered. A patient and/or family will be given advance notice of the decision and offered a short period of time in which to find another facility, if possible. Withdrawal from the programme will be done as humanely and sensitively as possible. Following withdrawal, the patient will not be abandoned, and will at all times be provided optimal conservative treatment, although it will no longer be possible to offer dialysis and renal replacement therapy.¹³

2. MECHANICS OF THE SELECTION PROCESS AND COMPOSITION OF THE SELECTION COMMITTEE

Prior to the Selection Committee meeting every patient should be assessed by the social worker who will prepare a written report that will tabled at the meeting. At the interview, the patient should be informed of the reason for the interview and the decision of the Committee should be conveyed to the patient by the doctor caring for the patient as soon as possible in terms that he/she will understand. The patient/family should be informed of the reasons for the denial of treatment. The meeting must be scheduled to allow as many role-players as possible to attend. The meeting will be chaired by the most senior nephrologist and the decisions minuted with reasons.¹⁴ An attendance register must be signed by all attendees. The meeting should be attended by at least the following:

- a) Nephrologist,
- b) Doctor in charge of the case, and
- c) Social worker.

In addition to the above, if available, a second nephrologist, professional Renal Unit staff representative(s), and the responsible medical superintendent (or delegated representative) should be added to the committee.

No persons unconnected with the case should be present unless invited by the Chair. All proceedings and decisions must be documented and will be communicated only

¹³ Withdrawal in this case is necessary to make the dialysis slot available for a patient in Category 2 who is eligible for a transplant and in need of dialysis in order to survive.

¹⁴ It is recommended that the instrument developed for this policy be used along with other procedural matters determined by the committee.

on a need to know basis. All documentation must be treated confidentially and stored for a minimum period of 5 years.

3. APPEALS PROCEDURE

If the patient/family is dissatisfied with the decision and requests further review, the case should be referred to the relevant superintendent who may request that the case be re-considered at the next meeting of the committee. If the decision remains unchanged and the patient/family so requests, the medical superintendent must convene a committee of persons unconnected with the first decision to independently review the case. The second committee should consist of a senior nephrologist, social worker and medical superintendent, all without any prior connection with the case to be reviewed, from another public hospital's renal unit (with a transplant programme). The social report, all relevant medical data, and the reasons for decision by the first committee must be tabled. An opportunity will be afforded to the patient (or representative) to make representations to the review committee. The first selection committee and the patient should be informed of the decision of the review committee as soon as possible.

4. AUDIT, CONTROL AND REVIEW MECHANISMS

The purpose of audit is to ensure that the Selection Committee is functioning appropriately. The audit will monitor if the set of guidelines is being followed by the Committee, that the correct protocols are being followed by the Committee, that the composition of the Committee is representative, that decisions are properly conveyed to the patients, and that the Appeals process is functioning correctly. The assessment process and guidelines should be reviewed in 24 months to ensure that equity and justice prevails. The public should be informed by the Western Cape Department of Health that access to dialysis and transplantation is limited and the public should have access to these guidelines.

The following audit structures are recommended.

- Inter-hospital audit on *ad hoc* basis (senior nephrologist of one unit audits the other)
- Independent hospital manager (or nominee)
- Chair of the Hospital Board (or nominee)
- Ethicist

Audits should be done at least yearly and be conducted independently by separate structures. All records to be saved and available for review by auditor on request. It will be the responsibility of the head of the unit and the superintendent to ensure that audits are performed as recommended.

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Committee: M R Moosa (Chair), B Rayner, M R Davids, J Nel, Z Barday, C Swanepoel.

Ethical and legal advice and guidance: S. R. Benatar and T. Fleischer

Department of Health approval: _____

APPENDIX

Important notes from policy drafter for reviewing authorities:

1. 10 Year escalation plan

The recommendation of the team setting the guidelines is that the Province, at the same time as implementing this policy, increases the quantum of renal services. The suggestion is to allow for an 8% escalation per annum in the number of patients accommodated on the programme in the first year. This can be escalated by an additional 2-4 % in the subsequent years. In comparison with other countries with a similar GDP, we have a very small number of patients on treatment. The escalation should be accompanied by an escalation in support staff (including surgeons), and other resources

2. Disadvantaging of Black and other disadvantaged patients

Based on data in the cited article, the use of these or similar guidelines will result in certain groups being disadvantaged. Blacks and other disadvantaged groups of patients, who represent a majority of patients served by public sector facilities, are more likely to fail the criteria for admission to Category 2. The disadvantaging of certain groups remains a recognized consequence of rationing treatment (18). Hospitals and units, as well as Provincial authorities, who adopt, approve and implement these guidelines, must therefore be prepared to support their use on medical, ethical and legal grounds.

3. Withdrawal of treatment

The current policy applies only to new patients being considered for renal replacement treatment. A vexing issue that challenges nephrologists practicing in the public sector is the management of patients whose medical and/or social circumstances change substantially enough to render them category 3 patients and thus unsuitable for renal replacement treatment. The current practice in the Western Cape is to re-evaluate all transplanted patients whose grafts fail. We recommend that this practice continue. The re-evaluation of failed transplant patients will follow the same format as the primary evaluation. In practice patients who are no longer transplantable form a sizeable proportion of the dialysis cohort. If dialysis were withdrawn from these patients, other patients who are

eligible for transplants would potentially be given the opportunity to be treated. On the other hand, moral and pragmatic considerations make the task of withdrawing treatment from these patients very difficult. It is recommended that the working group continue to study the unique challenges raised by these patients, taking into consideration the practical, moral and legal considerations, as well as the sensitivities of the relevant stakeholders. Further revisions to the policy to address this issue will be submitted after canvassing various options and trying to achieve consensus.

M. R. Moosa

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