KIDNEY TRANSPLANT CANDIDATE GUIDELINES

Germaine Wong
School of Public Health,
University of Sydney,
Westmead Hospital, NSW Australia
DISCLOSURES

• None
OUTLINE OF THE TALK

• Equitable access to transplantation
• Purpose of the guidelines
• Specific focus:
  1. Age criteria
  2. Co-morbidities – cardiovascular disease, diabetes and cancer,
  3. Adherence
Transplantation saves lives

![Graph showing incremental gains in life years after transplant for different categories of patients.]

- Incremental gains in a 20 yr old
- Incremental gains in a 60 yr old
- Incremental gains in a 60 yr old with cardiovascular disease
- Incremental gains in a 60 yr old with diabetes
- Incremental gains in a 60 yr old who had a stroke
- Incremental gains in an obese 60 yr old
- Incremental gains in a 60 yr old smoker

Comparative Survival and Economic Benefits of Deceased Donor Kidney Transplantation and Dialysis in People with Varying Ages and Co-Morbidities

Germaine Wong1,2,*, Kirsten Howard3, Jeremy R. Chapman3, Steven Chadban3, Nicholas Cross3, Allison Tong1, Angela C. Webster1,2,*1, Jonathan C. Craig1,1

*Corresponding authors

1Melbourne School of Population and Global Health, University of Melbourne, Melbourne, Victoria, Australia
2Kidney Disease Improving Global Outcomes (KDIGO), Denver, Colorado, USA
3University of Queensland, Brisbane, Queensland, Australia

PLoS ONE | www.plosone.org
And cost savings – despite comorbidities

In highly selected group of patients!
Disparities in access to transplantation

**Age**

![Transplant rate of dialysed patients 2016](chart1)

*2017 ANZDATA Annual Report, Figure 7.4.1*

**Ethnicity**

![Transplant rate of dialysed patients 2007-2016](chart2)

*2017 ANZDATA Annual Report, Figure 7.5.1*
Disparities to listing

Obesity and gender-biased access to deceased donor kidney transplantation

Maleeka Ladhani1,2,3, Jonathan C. Craig2,4 and Germaine Wong1,2,5

KDIGO

Obese women

Predictors of waitlisting
Australia 2007-2014

Underweight
Normal weight
Overweight

Predictors of waitlisting
Australia 2007-2014

Underweight
Normal weight
Overweight

KDIGO

Older
Indigenous
Comorbidities
Geography

Steven J. Chadban, BMed, PhD,1 Curie Ahn, MD, PhD,2 David A. Axelrod, MD, MBA,3 Bethany J. Foster, MD, MSCE,4 Bertram L. Kasiskie, MD,5 Vijay Kher, MD, DM,6 Deepali Kumar, MD, MSc,7 Rainer Oberbauer, MD, PhD,8 Julio Pascual, MD, PhD,9 Helen L. Pilmore, MD,10 James R. Rodrigue, PhD,11 Dorry L. Segal, MD, PhD,12 Neil S. Shearm, BSc, PhD,13 Kathryn J. Tinkham, MD, MS,14 Gemaine Wong, MD, PhD,15 Ethan M. Balk, MD, MPH,16 Craig E. Gordon, MD, MS,17 Amy Earley, BS,17 Valerie Rofeberg, ScM,18 and Gregory A. Knoll, MD, MSc19

Transplantation ■ April 2020 ■ Volume 104 ■ Number 4

Working Group
Co-Chairs: Steve Chadban and Greg Knoll
Evidence review team led by Ethan Balk
RATIONALE FOR CLINICAL PRACTICE GUIDELINES

• Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances

• Potential to improve the quality, delivery and process of care with the ultimate objective of improving overall patient outcomes.

• Guidelines summarize the current medical knowledge, weigh the benefits and harms of diagnostic procedures and treatments, and give specific recommendations based on this information.

• At the same times, guidelines should provide relevant information about the scientific evidence-base supporting these recommendations.
KDIGO NOMENCLATURE AND DESCRIPTION FOR GRADING GUIDELINE RECOMMENDATIONS

- The strength of the recommendation is indicated as **Level 1 or 2 or not graded**
- The quality of the supporting evidence is shown as **A, B, C or D**

<table>
<thead>
<tr>
<th>GRADE</th>
<th>Patients</th>
<th>Clinicians</th>
<th>Policy</th>
</tr>
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<tbody>
<tr>
<td>Level 1</td>
<td><strong>We recommend</strong></td>
<td>Most people would want the recommended course of action and only a few would not.</td>
<td>Most patients should receive the recommended course of action</td>
</tr>
<tr>
<td>Level 2</td>
<td><strong>We suggest</strong></td>
<td>Majority of people would want the recommended course of action but many would also not</td>
<td>Different choices for different patients. Important to consider patient’s values and preferences</td>
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</table>
# KDIGO Nomenclature and Description for Grading Guideline Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Quality of Evidence</th>
<th>Meaning</th>
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<tr>
<td>A</td>
<td>High</td>
<td>We are absolutely confident that the true effect lies close to the estimate of the effect.</td>
</tr>
<tr>
<td>B</td>
<td>Moderate</td>
<td>The true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.</td>
</tr>
<tr>
<td>C</td>
<td>Low</td>
<td>The true effect may be substantially different from the estimate of effect.</td>
</tr>
<tr>
<td>D</td>
<td>Very low</td>
<td>The estimate of effect is very uncertain, and often will be far from the truth.</td>
</tr>
</tbody>
</table>
SCOPE of the guideline

• Access
• Age
• Adherence
  • Psychosocial factors
  • Paediatric issues
• Smoking
• Surgical issues including obesity
• Diabetes
• Infections
• Cardiovascular disease
• Cancer
• Causes of kidney failure

• Pulmonary disease
• Peripheral vascular disease
• Gastrointestinal and liver disease
• Haematological disorder
• Bone and mineral metabolism
• Immunological assessment
Age criteria
Age criteria

Risk Factors for Early Graft Failure and Death After Kidney Transplantation in Recipients Older Than 70 Years

Increase in the transplantation rate of older patients in France

*n*KDIGO

Similar patterns are observed in the US
Risk factors for early graft failure and death after kidney transplantation in recipients older than 70 years

Study Population
171 patients receiving a kidney transplant over 4y period
Mean age: 73.3 ± 2.5 years

Patient & Graft Survival
- 1y: Patient Survival 90.1%, Graft Survival 82.6%
- 3y: Patient Survival 82.5%, Graft Survival 78.7%
- 5y: Patient Survival 68.1%, Graft Survival 75.4%

Risk factors for death or graft failure during the first year post-transplant
- Risk Factor: OR (95% CI)
  - Arrhythmia: 2.26 (1.08-4.80)
  - LVEF <56%: 2.38 (1.18-4.83)
  - HLA Antibodies: 2.10 (1.04-4.20)
  - Deceased CV Donor: 5.18 (1.22-22.2)
  - Acute Rejection: 2.77 (1.20-6.30)

CONCLUSION:
In kidney transplant recipients older than 70, cardiac evaluation and immunosuppression optimization seem to be crucial to improve short-term patient and graft survival.
Australian Data

Causes of death in patients over age 65 years
Australian data

Risk factors of death in older transplant recipients

<table>
<thead>
<tr>
<th></th>
<th>HR (95% CI)</th>
<th>P value</th>
<th></th>
<th>HR (95% CI)</th>
<th>P value</th>
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<tr>
<td>PD vs HD</td>
<td>1.71 (1.17 - 2.51)</td>
<td>0.01</td>
<td></td>
<td>1.69 (1.13 - 2.55)</td>
<td>0.01</td>
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<tr>
<td>Cardiovascular disease</td>
<td>1.47 (1.03 - 2.11)</td>
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<td>1.59 (1.08 - 2.35)</td>
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<tr>
<td>Cerebrovascular disease</td>
<td>1.99 (1.26 - 3.16)</td>
<td>&lt;0.01</td>
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<td>-</td>
<td>-</td>
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<tr>
<td>Donor age (per year)</td>
<td>1.02 (1.01 - 1.03)</td>
<td>&lt;0.01</td>
<td></td>
<td>1.02 (1.00 - 1.03)</td>
<td>0.02</td>
</tr>
<tr>
<td>Ischaemia time (per hour)</td>
<td>1.06 (1.03 - 1.09)</td>
<td>&lt;0.001</td>
<td></td>
<td>1.05 (1.02 - 1.09)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Delayed graft function</td>
<td>1.64 (1.13 - 2.39)</td>
<td>0.01</td>
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<td>-</td>
<td>-</td>
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</tbody>
</table>
How do frail people do with a kidney transplant evaluation?

**Fried Physical Frailty Score**
- Unintentional weight loss
- Grip strength
- Walking speed
- Exhaustion
- Activity level

**Getting Listed**
- Frail: 0.62
- 95% CI: 0.56-0.69
- Not Frail: 1.0
- ref

**If listed, getting Transplanted**
- Frail: 0.68
- 95% CI: 0.58-0.81
- Not Frail: 1.0
- ref

**Conclusions**
Frailty is associated with lower chance of getting listed for a kidney transplant and subsequently a lower chance of actually getting a kidney transplant.

Age criteria

- Do not exclude patients from kidney transplantation because of age alone, but rather consider the context of other comorbidities, including frailty, that may impact on outcomes about the suitability of kidney transplantation (ungraded)
Shared-decision making process for older transplant candidates

• Expected survival on dialysis
• Expected quality of life on dialysis
• Expected survival with a functioning graft
• Post-transplant expectations
• Balancing the risk of over vs. under immunosuppression
Diabetes and Cardiovascular disease
Diabetes and CVD

Figure 3

Kidney transplant recipients: first MACE or cardiac mortality

<table>
<thead>
<tr>
<th>Incidence rates per 1000 person-years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes + vascular disease</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Vascular disease</td>
</tr>
<tr>
<td>No disease</td>
</tr>
</tbody>
</table>

- **7-years**
  - 31.1 (25.5-37.6)
  - 30.2 (24.3-37.2)
  - 10.0 (7.8-12.5)

- **5-years**
  - 39.8 (23.8-36.8)
  - 25.8 (19.9-32.9)
  - 10.0 (7.7-12.9)

- **3-years**
  - 29.3 (22.3-38.0)
  - 21.3 (15.1-29.3)
  - 7.5 (5.1-10.6)

Lim WH et al manuscript submitted. Incidence rates of major adverse cardiovascular events (MACE) and cardiac mortality of kidney transplant recipients using data from linked administrative healthcare databases from Ontario, Canada (2005-2014, follow-up until 2018).
Risk of MACE on the waiting list and after transplantation

Issues to consider during work-up for diabetic patients

• We recommend that candidates with type 1 or type 2 DM be considered for kidney transplantation (1B)

• We suggest that asymptomatic candidates at high risk for coronary artery disease (e.g. diabetes, previous CAD or with poor functional capacity) undergo non-invasive CAD screening (2C)

• We recommend that asymptomatic candidates with known CAD not be revascularized exclusively to reduce perioperative cardiac events (1B)

• Diabetes associated with higher risk of wound complications (not graded)
Screening for CVD in high-risk transplant candidates

• WHO criteria
• Condition must be an important health problem
• Condition should be a recognizable latent or early symptomatic stage
• Natural history of the condition, including development from latent to declared disease, should be adequately understood
• An accepted treatment for patients with recognized disease
• Suitable test or examination that has a high level of accuracy
• Acceptable to the population
• Cost-effectiveness of the screening program
• Screening should be a continuing process
Screening for CVD in high-risk transplant candidates

- WHO criteria
- Condition must be an important health problem \(\text{Yes}\)
- Condition should be a recognizable latent or early symptomatic stage
- Natural history of the condition should be adequately understood
- An accepted treatment for patients with recognized disease
- Suitable test or examination that has a high level of accuracy
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Uncertain
Evidence

Cardiac Outcomes After Screening for Asymptomatic Coronary Artery Disease in Patients With Type 2 Diabetes

The DIAD Study: A Randomized Controlled Trial

Figure 1. Flow of Study Participants
Evidence

Does not appear to have any benefits from routine screening in asymptomatic diabetic patients.

But this trial exclude patients with kidney disease !!!
Eagerly await for the results of the CARSK trial

**CARSK** stands for the *Canadian–Australasian Randomised Trial for Screening Kidney Transplant Recipients for Coronary Artery Disease.*
# Accuracy of the screening tests

## Cardiac Testing for Coronary Artery Disease in Potential Kidney Transplant Recipients: A Systematic Review of Test Accuracy Studies

Louis W. Wang, MM(ClinEpi)(Hons),¹ Magid A. Fahim, MD,² Andrew Hayen, PhD,¹
Ruth L. Mitchell, MA(Inf),³ Stephen W. Lord, DM,⁴ Laura A. Baines, MD,⁵
Jonathan C. Craig, PhD,¹,³ and Angela C. Webster, PhD¹,³,⁶

<table>
<thead>
<tr>
<th>Test</th>
<th>No. of Studies</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>DOR (95% CI)</th>
<th>AUC</th>
<th>Variance of Random Effects of log(DOR)</th>
<th>P for Difference In Accuracy <strong>a</strong></th>
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<tbody>
<tr>
<td>MPS</td>
<td>7</td>
<td>0.69 (0.48-0.85)</td>
<td>0.77 (0.59-0.89)</td>
<td>7.68 (1.99-29.67)</td>
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<td>0.2763</td>
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<td>DSE</td>
<td>11</td>
<td>0.80 (0.64-0.90)</td>
<td>0.89 (0.79-0.94)</td>
<td>30.98 (10.66-90.03)</td>
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<td>0.2224</td>
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</table>

**Overall Results (all studies)**

<table>
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<tbody>
<tr>
<td>MPS</td>
<td>6</td>
<td>0.68 (0.43-0.85)</td>
<td>0.80 (0.60-0.91)</td>
<td>8.15 (1.58-42.00)</td>
<td>0.81</td>
<td>0.3487</td>
</tr>
<tr>
<td>DSE</td>
<td>8</td>
<td>0.78 (0.59-0.90)</td>
<td>0.87 (0.75-0.94)</td>
<td>24.40 (7.19-82.78)</td>
<td>0.90</td>
<td>0.2492</td>
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**Only Studies With Reference Standard Threshold ≥70% Coronary Artery Stenosis**

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<td>0.80 (0.60-0.91)</td>
<td>8.15 (2.56-25.93)</td>
<td>0.81</td>
<td>0.3487</td>
</tr>
<tr>
<td>DSE</td>
<td>9</td>
<td>0.74 (0.52-0.88)</td>
<td>0.88 (0.74-0.95)</td>
<td>20.41 (6.46-64.50)</td>
<td>0.89</td>
<td>0.2571</td>
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</tbody>
</table>

**Only Studies in Which Partial Verification Was Avoided**

<table>
<thead>
<tr>
<th>Test</th>
<th>No. of Studies</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
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<td>0.90</td>
<td>0.2492</td>
</tr>
</tbody>
</table>
Managing Coronary Disease in Advanced Kidney Disease

**OPEN-LABEL RANDOMIZED, CONTROLLED TRIAL**

**777 Patients** with stable coronary disease and advanced CKD

**Invasive Strategy**
- 123 (N=388)
- Adjusted HR 1.01; 95% CI, 0.79–1.29; P=0.95
- No difference in Seattle Angina Questionnaire summary score
- Invasive treatment did not reduce the rate of death or nonfatal MI or improve angina-related health status

**Conservative Care**
- 129 (N=389)
- Medical therapy

S. Bangalore et al. 10.1056/NEJMoal915925
Limitations and applicability in transplant candidates

• Not really applicable to our candidates
• Early deaths from CVD occur in the peri-operative periods
• Transplantation surgery is complex
• Hemodynamic changes
• Blood loss and other factors may potentially influence the outcomes
Cancer
# Potential Candidate with a Prior Cancer

- Recommendations/suggested waiting times from various clinical practice guidelines
- Based on largely observational data on cancer recurrence rates

<table>
<thead>
<tr>
<th>TYPE</th>
<th>STAGE</th>
<th>AST</th>
<th>CART</th>
<th>EURAD</th>
<th>OBT</th>
<th>ERPG</th>
<th>MUCCH</th>
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<td>Large or Invasive</td>
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<td>Bladder cancer</td>
<td>In-situ or non-invasive papilloma</td>
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<td>Stage 3-4 (advanced/invasive)</td>
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<td>Colorectal Cancer (c)</td>
<td>Duke A or B1</td>
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<td>Duke D</td>
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<tr>
<td></td>
<td>Patients with a history of colorectal cancer</td>
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<td>Uterine Cancer</td>
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<td>Wilms Tumour</td>
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</table>

*Recommendation:
- 0 years
- Minimum 2 years
- 2-6 years
- Minimum 5 years
- Contraindicated
- No recommendation (or insufficient evidence)

*Batabyal et al., 2012 Transplantation*
**Prior Cancer and Overall Survival Post-Transplant**

**Norwegian Study**
- Policy of 1 year waiting period (except NMSC and prostate cancer)
- Matched analysis comparing with and without Hx of cancer
- No difference in overall and graft survival

*Dahle et al., 2017 Transplantation*
PRIOR CANCER AND CANCER SPECIFIC DEATH

- Higher risk of cancer-related death among those with a prior cancer

Dahle et al., 2017 Transplantation
CANCER RECURRENCE AFTER KIDNEY TRANSPLANTATION

- Systematic review of 57 studies
- Meta-analysis of 39 studies
- Overall estimated recurrence rate: 1.6 per 100 person-years
- Substantial heterogeneity between studies

Acuna et al., 2017 Transplantation Reviews
A higher risk of cancer recurrence in patients who have waited shorter than 5 years after cancer remission

Acuna et al., 2017 Transplantation Reviews

Note – high heterogeneity

Acuna et al., 2017 Transplantation Reviews

Waiting time and cancer recurrence after kidney transplantation
KDIGO RECOMMENDATIONS

• 11.2.1: We recommend that candidates with **acute malignancy be excluded** from kidney transplantation except for those with indolent and low-grade cancers such as prostate cancer (Gleason score ≤ 6), superficial non-melanoma skin cancer, and incidentally detected renal tumors (≤ 1 cm in maximum diameter) (1B)

• 11.2.2: **Timing of kidney transplantation** after potentially curative treatment for cancer is dependent on the cancer type and stage at initial diagnosis (not graded) (Table 14)

• 11.2.3: We recommend no waiting time for candidates with curatively treated (surgically or otherwise) non-metastatic basal cell and squamous cell carcinoma of the skin; melanoma in-situ; small renal cell carcinoma (< 3 cm); prostate cancer (Gleason score ≤ 6cm), carcinoma-in-situ; thyroid cancer (follicular/papillary <2 cm of low grade histology) and superficial bladder cancer (1C).

• 11.2.4: Decisions about transplantation for candidates in remission from cancer should be made collaboratively with oncologists, transplant nephrologists, patients and their caregivers (not graded)
<table>
<thead>
<tr>
<th>Condition</th>
<th>Early</th>
<th>Advanced</th>
<th>Colorectal</th>
<th>Dukes A/B</th>
<th>Duke C</th>
<th>Duke D</th>
<th>Bladder</th>
<th>Invasive</th>
<th>Incidentaloma (&lt; 3 cm)</th>
<th>Uterine</th>
<th>Localized</th>
<th>Invasive</th>
<th>Cervical</th>
<th>Localized</th>
<th>Invasive</th>
<th>Lung</th>
<th>Localized</th>
<th>Invasive</th>
<th>Testicular</th>
<th>Localized</th>
<th>Invasive</th>
<th>Melanoma</th>
<th>Localized</th>
<th>Invasive</th>
<th>Contraindicated</th>
<th>Prostate</th>
<th>Gleason ≤ 6</th>
<th>Gleason 7</th>
<th>Gleason 8-10</th>
<th>Thyroid</th>
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<tbody>
<tr>
<td>Breast</td>
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<td>Colorectal</td>
<td>At least 2 years</td>
<td>2-5 years</td>
<td>At least 5 years</td>
<td>Bladder</td>
<td>Invasive</td>
<td>No waiting time</td>
<td>Uterine</td>
<td>Localized</td>
<td>At least 2 years</td>
<td>Cervical</td>
<td>Localized</td>
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* KDIGO
CONSIDERATION FOR TRANSPLANTATION IN CANDIDATES WITH PRIOR CANCERS AND IN COMPLETE REMISSION

Patient survival rates depending on tumor type, stage given current treatment approaches

*Absolute contraindication for those with active cancers

Effects of immunosuppression on cancer outcomes including remission and recurrence rates

Estimated survival rates after transplantation if cancer recurs

Expected survival and QOL on dialysis

Expected survival with transplant and without cancer recurrence

Patient preferences and perspectives

Shared decision making between patients, caregivers, oncologists and transplant health professionals

Wait or proceed to transplantation
Adherence
KDIGO recommendations

• Assess adherence and adherence barriers pre-transplantation. Appropriate adherence-based education, counselling pre-transplant and post-transplant surveillance should be provided.

• Candidates with a history of nonadherence from kidney transplantation should not be excluded except for those with on-going, health-compromising nonadherent behaviour despite education and counselling.
Summary

• Transplant assessment is complex.
• This guideline provides recommendations for evaluation of individual aspects of a candidate’s profile such that each risk factor and comorbidity are considered.
• This guideline is intended to be global.
• The goal is to assist transplant professionals to assimilate all data relevant to an individual, consider this within their local health context, and make an overall judgment on candidacy for transplantation.
Thank you very much