

# French Adult Kidney Allocation Policy Handbook

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Agence de la biomédecine

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## I. INTRODUCTION

### A. CONTEXT

The shortage of organs for transplantation always raises difficult medical and ethical questions about the process for selecting patients to be transplanted with organs from deceased donors.

Organ allocation is a complex and sensitive process, in both its conception and its implementation. No global or definitive solution exists. It differs from one country to the next depending on allocation criteria, and it changes over time due to periodic assessments of the results.

On February 3, 2015, organ allocation for adult patients awaiting kidney transplant changed substantially with the introduction of a new national score, identical for all regions in France.

This system complements the national score for pediatric patients introduced in 2011 and did not modify the existing priorities.

### B. ALLOCATION OF ORGANS

An allocation system must respond to the medical needs of patients suitably, efficiently, and equitably.

Patient prioritization at the moment of allocation is one possible solution. It is currently used at the national level, for example, for clinically urgent or highly sensitized patients.

For most patients, however, it is impossible to prioritize one group over another. Therefore, the allocation system must:

- Find a compromise between equity, efficiency, and feasibility
- Simultaneously take multiple criteria into account.

An efficient solution is to rely on a score. Thus, kidneys procured from the same donor are offered as follows:

- One through the local allocation scheme
- The other through the national allocation scheme (local recipients excluded)

### C. WHAT IS A SCORE?

A score is a calculation based on criteria for donors, recipients, and donor-recipient matching. Its objective is to classify recipients on the waiting list by priority every time a new donor is identified. A score is a decision-making tool that can be customized, simulated, and evaluated. It is an efficient allocation instrument able to achieve an objective and thus a transparent, ethical compromise that serves the interests of patients. It optimizes the allocation process according to previously established criteria.

The national score is only a part of the larger graft allocation system in France, which is organized as presented in the table below.

**Table 1: Kidney Allocation Schema for adult patients**

<p><b>A- One of the two kidney shared #</b>, and sequentially offered in priority to</p> <p><b>A1 - Urgent patients:</b> (dialysis impossibility, expert validation) <i>dialysis impossibility, expert advisory group validation</i></p> <p><b>A2 - Highly sensitized patients</b> <i>daily cPRA <math>\geq</math> 70% and peak cPRA <math>\geq</math> 85% and last serum &lt; 105 d (1)</i> <i>Blood type compatibility</i> <i>If recipient age <math>\geq</math> 50 y then age difference with donor &lt; 15 y</i></p> <p><b>Local &gt; Regional &gt; National</b></p> <p><b>A21 - Full match</b> HLA A B DR patients</p> <p><b>A22 - Acceptable mismatch program</b> eligible patients <i>Waiting time <math>\geq</math> 18 months</i> <i><math>\leq</math> 4 MM HLA A B DR and <math>\leq</math> 1 MM HLA DR and <math>\leq</math> 2 MM HLA B DR</i> <i>Each A B DR DQ HLA MM must be an acceptable antigen*</i></p> <p><b>A23 - Other highly sensitized</b> patients with <math>\leq</math> 1 MM HLA A B DR patients</p> <p><b>A3 - Sensitized patients</b> <i>daily cPRA &gt;0% and not highly sensitized (1)</i></p> <p><b>A31 - Full match</b> HLA A B DR patients</p> <p><b>A32 - Regional priorities</b> and expert advisory group validation</p> <p><b>A321 - Desensitization program</b></p> <p><b>A322 - Other sensitized</b> <i><math>\leq</math> 4 MM HLA A B DR and <math>\leq</math> 1 MM HLA DR and <math>\leq</math> 2 MM HLA B DR</i> <i>recipient age <math>\geq</math> 50 y then matching age &lt; 15 y</i></p> <p><b>A4 - If no prioritized patients:</b> allocation according to Unified national score</p> <p><b>B - Other kidney is allocated locally according to Unified national score</b> If recipient age <math>\geq</math> 50 y then age difference with donor &lt; 15 y Else nationally allocated according to Unified allocation score</p> <p>MM: mismatch</p> <p>*An antigen is considered acceptable when the bead with the highest normalized MFI for this antigen is less than 500</p> <p># except for dual kidney transplantation (donor age &gt; 65 and eDFG between 30 and 60 ml/min and vascular factors)</p>
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## D. OBJECTIVES OF THE ALLOCATION SCORE

The allocation score aims to:

- Optimize the offering of organs by allocating them more widely across the national territory
- Improve the allocation system by proposing differentiated strategies that take the recipient's age into account
- Reduce geographic disparities
- Manage medical and economic impacts.

## E. ALLOCATION CRITERIA

Allocation criteria to be taken into account when calculating a score:

Equity criteria:

- Waiting time
- Dialysis time
- Difficulty in accessing transplantation, to prevent exclusion of recipients with rare HLA

Effectiveness criteria:

- Donor-recipient HLA matching, a criterion that determines long-term results for kidney transplants
- Immunization risk that affects the prospects of a second transplant in cases of graft loss

Finally, there are criteria that take into account both effectiveness and feasibility:

- Age matching, which enables the longest possible graft functioning time appropriate to the recipient's life expectancy
- Road distance in minutes between procurement and transplant centers.

## F. OPERATING PROCEDURE

### 1) Progressive score variation depending on recipient's age

Kidney score calculation varies according to the recipient's age. For young adult recipients, for example, the score aims to maximize donor-recipient HLA matching even if it means longer transport time between procurement and transplant centers. For elderly candidates, on the other hand, the HLA match aims to be as acceptable as possible, but attention is focused more on organs procured in the geographical vicinity of the transplant center.

## 2) Kidney offer at the local and national levels

Kidneys from the same donor are offered:

- One at the local level to the patient with the highest score, unless no candidate meets the 20-year maximum donor-recipient age difference requirement
- The other, at the national level (local teams excluded) to the candidate with the highest score, taking geographic distance into account.

Kidney allocation scores concern only organs from donors after brainstem death (DBD). They are not currently used for organs from donors after circulatory death (Maastricht I, II and III).

## G. GEOGRAPHICAL MODEL

The geographical model considers logistic constraints and aims to minimize the potential impact of cold ischemia time during transport.

It associates the distance between the procurement and transplant centers with the priority level of each patient on the active waiting list at the moment of the kidney offer. It also provides the most equitable access to kidney transplants by reducing waiting list disparities between candidates from the Paris metropolitan area (Ile-de France) and other regions.

The REIN<sup>1</sup> registry shows that the cumulative incidence rate of candidates of all age groups registered on the waiting list at the start of dialysis or receiving a pre-emptive transplant reaches 20% in Ile-de-France, compared with 10% in other regions. One year after the start of renal replacement therapy, this rate reaches 40% in Ile-de-France and 20% in other regions. Given that the procurement activity in Ile-de-France is not proportional to these high registration rates, this region's candidates accrue on the waiting list, which results in longer waiting times compared to other regions.

However, if we focus our interest on the equity of access to kidney transplant in general, we notice that waiting time on transplant lists is a criterion that can be biased due to divergent registration practices. On the other hand, if we take into consideration a more general criterion, such as the length of the interval between the start of renal replacement therapy and transplant, we observe that candidates from Ile-de-France have an access to kidney transplants equal to those from other regions.

Simulations have shown it is sufficient to include candidates from Ile-de-France every fifth time a kidney is retrieved from a donor outside the region to counterbalance the disparities.

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<sup>1</sup> REIN : Réseau Epidémiologique et Information en Néphrologie – Renal Epidemiological and Information Network

## II. KIDNEY SCORE CALCULATION

The **Unified allocation score (UAS)** considers<sup>2</sup>:

- The score without distance (Score noD), which focuses on medical aspects, and
- The geographical model (GM), which takes the geographical allocation criteria into account.

$$\text{UAS} = \text{Score noD} \times \text{GM}$$

The score without distance (Score noD) is a result of:

- The score without age difference (Score no $\Delta$ age) and
- A function  $F(\Delta\text{age})$  of age difference between the donor and the recipient

$$\text{Score noD} = \text{Score}_{\text{no}\Delta\text{age}} \times F(\Delta\text{age})$$

The **Unified allocation score (UAS)** requires a 3-step calculation:

- A. **Score without age difference (Score no $\Delta$ age) calculation**
- B. **Score without distance (Score noD) calculation**
- C. **Unified allocation score (UAS) calculation**

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<sup>2</sup> Audry, B., Savoye, E., Pastural, M., Bayer, F., Legeai, C., Macher, M. A., ... & Jacquelinet, C. (2022). The New French Kidney Allocation System for Donations after Brain Death: Rationale, Implementation, and Evaluation. American Journal of Transplantation.

## A. SCORE WITHOUT AGE DIFFERENCE (SCORE noΔage) CALCULATION

The score without age difference (Score noΔ age) takes into account the following 5 parameters:

1. **Dialysis duration (DD)**
2. **Waiting time on waiting list (WT)**
3. **HLA matching (A, B, DR, DQ)**
4. **Matched donor potential (MDP)**
5. **Recipient's age (AgeR)**

The score without age difference ranges from 0 to 1050.

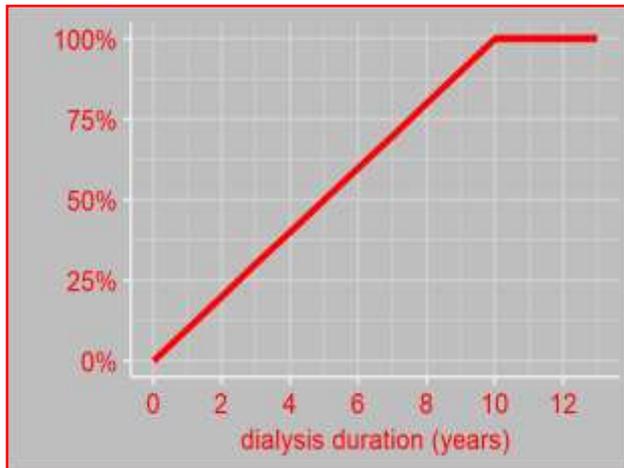
*Figure 1: Score without age difference calculation*

$$\begin{aligned}
 \text{Score no}\Delta\text{Age [0 - 1050]} = & \\
 & 100 \times f_1(\text{DD}) + 200 \times f_2(\text{WT, DD}) \\
 & + [100 \times f_3(\text{A,B}) + 400 \times f_4(\text{DR}) \\
 & + 100 \times f_4(\text{DQ}) + 150 \times f_5(\text{MDP})] \\
 & \times f_6(\text{AgeR}, 45, 75) \\
 & + 750 \times f_7(\text{AgeR}, 75, 100)
 \end{aligned}$$

## 1. Dialysis duration

Dialysis duration (**DD**) is taken into consideration in an increasing linear manner between 0 and 10 years. The maximum dialysis score is reached after 10 years.

Figure 2: Score without age difference and with dialysis duration (DD)



**Score noΔage [0 - 1050] =**

$$\begin{aligned}
 & 100 \times f_1(\mathbf{DD}) + 200 \times f_2(\text{WT}, \mathbf{DD}) \\
 & + [100 \times f_3(\text{A}, \text{B}) + 400 \times f_4(\text{DR}) \\
 & + 100 \times f_4(\text{DQ}) + 150 \times f_7(\text{MDP})] \\
 & \quad \times f_5(\text{AgeR}, 45, 75) \\
 & + 750 \times f_6(\text{AgeR}, 75, 100)
 \end{aligned}$$

The dialysis duration (**DD**) is calculated:

- For dialysis patients awaiting their first transplant:
  - date of start of dialysis
- For dialysis patients awaiting a retransplant:
  - date of return to dialysis (date of graft failure)
- For patients not undergoing a dialysis (preemptive registration), dialysis duration equals zero.

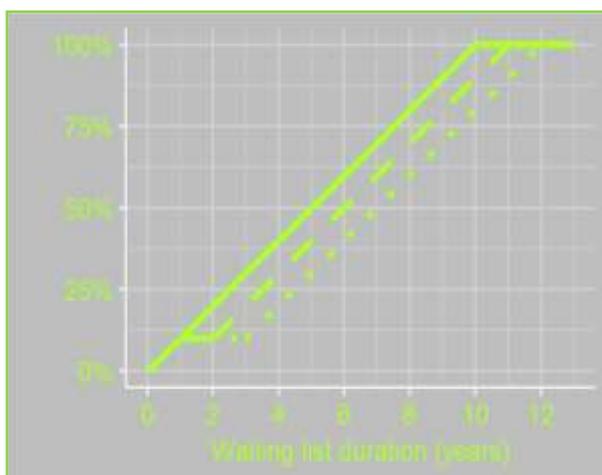
## 2. Waiting time on the national waiting list

Points attributed for the waiting time (**WT**) on the national waiting list depend on whether or not the patient is undergoing dialysis.

If the patient is not under dialysis after one year of waiting time, points attributed to this function are frozen to limit the number of preemptive registrations.

Waiting time (**WT**) on the national waiting list is taken into consideration, increasing linearly between 0 and 10 years when calculating the score without age difference. After 10 years on the waiting list, the maximum number of points attributed to this criterion is attained. Waiting time is calculated from the current date to the date of registration.

*Figure 3: Score without age difference and with waiting time (WT)*



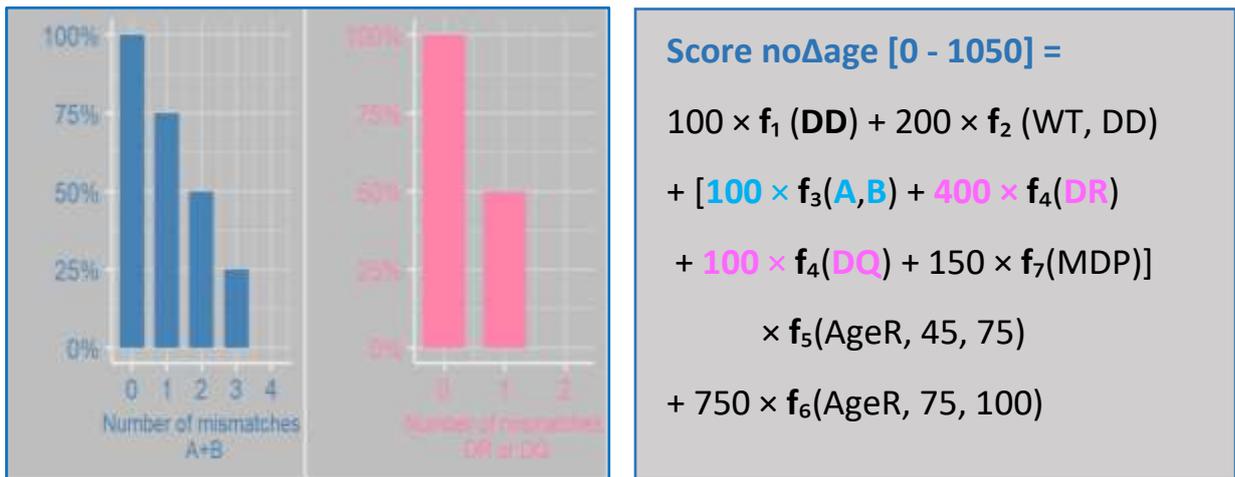
**Score noΔage [0 - 1050] =**

$$\begin{aligned}
 &100 \times f_1(\text{DD}) + 200 \times f_2(\text{WT}, \text{DD}) \\
 &+ [100 \times f_3(\text{A,B}) + 400 \times f_4(\text{DR}) \\
 &+ 100 \times f_4(\text{DQ}) + 150 \times f_7(\text{MDP})] \\
 &\quad \times f_5(\text{AgeR}, 45, 75) \\
 &+ 750 \times f_6(\text{AgeR}, 75, 100)
 \end{aligned}$$

### 3. HLA matching

HLA matching between the donor and the recipient is also included in the calculation of the score without age difference. The points allotted decrease as the number of HLA **A**, **B**, **DR**, and **DQ** mismatches increases.

**Figure 4: Score without age difference and with the number of HLA A, B, DR, and DQ mismatches**

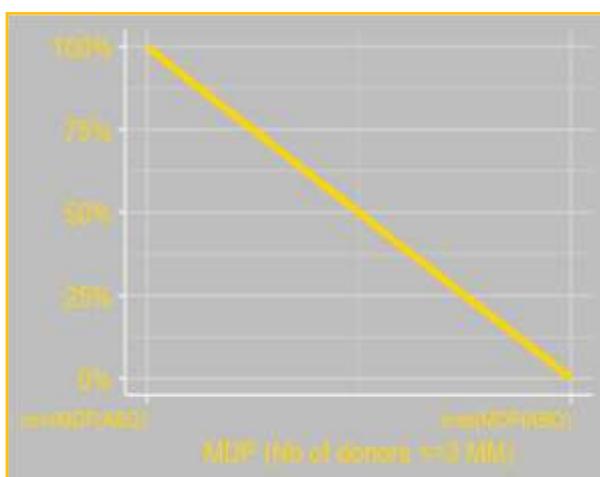


#### 4. Matched donor potential

Matched donor potential (**MDP**) is taken into consideration in an increasing linear manner between 0 and 10 years when calculating the score without age difference. **MDP** represents the number of donors in France over the past 5 years (calculated nightly) from whom at least one kidney was retrieved and transplanted, in the recipient's ABO group, with whom the recipient would have had at most three HLA A, B, and DR mismatches (after the exclusion of HLA-incompatible donors, based on HLA specificities entered into the CRISTAL recipient database, in case of sensitization).

**MDP** varies between 0 and the maximum MDP for patients waiting for the blood group in question.

Figure 5: Score without age difference and with matched donor potential (MDP)



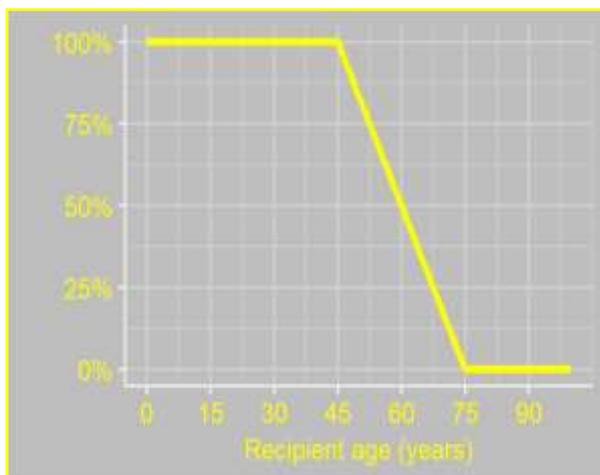
Score no $\Delta$ Age [0 - 1050] =

$$\begin{aligned}
 &100 \times f_1(\text{DD}) + 200 \times f_2(\text{WT, DD}) \\
 &+ [100 \times f_3(\text{A,B}) + 400 \times f_4(\text{DR}) \\
 &+ 100 \times f_4(\text{DQ}) + 150 \times f_7(\text{MDP})] \\
 &\quad \times f_5(\text{AgeR, 45, 75}) \\
 &+ 750 \times f_6(\text{AgeR, 75, 100})
 \end{aligned}$$

## 5. Recipient's age

Calculation of the score without age difference includes an interaction between the matching functions of HLA and MDP with the candidate's age, to enable allotment of the maximum number of points to young candidates. For candidates aged 45 and over, the number of points progressively decreases and is no longer taken into account for those aged more than 75 years.

**Figure 6: Score without age difference, with HLA matching and candidate's age (AgeR)**

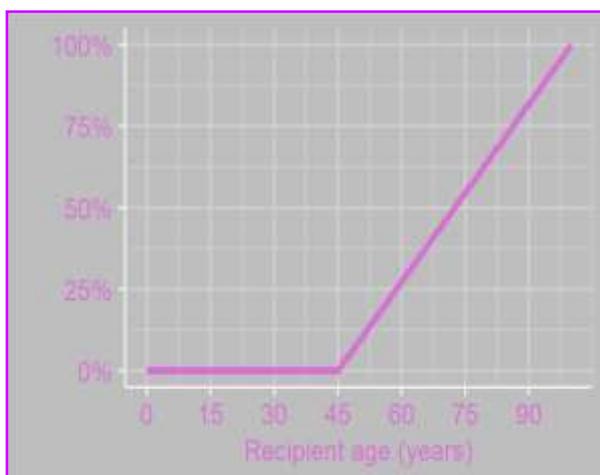


**Score noΔAge [0 - 1050] =**

$$\begin{aligned}
 &100 \times f_1(\text{DD}) + 200 \times f_2(\text{WT, DD}) \\
 &+ [100 \times f_3(\text{A,B}) + 400 \times f_4(\text{DR}) \\
 &+ 100 \times f_4(\text{DQ}) + 150 \times f_7(\text{MDP})] \\
 &\quad \times f_5(\text{AgeR}, 45, 75) \\
 &+ 750 \times f_6(\text{AgeR}, 75, 100)
 \end{aligned}$$

To compensate for the points allotted to HLA matching and MDP for young patients, the score takes the age of candidates over 45 into account by increasing linearly with age.

**Figure 7: Score without age difference, with HLA matching and age of candidates <45 (AgeR)**



**Score noΔAge [0 - 1050] =**

$$\begin{aligned}
 &100 \times f_1(\text{DD}) + 200 \times f_2(\text{WT, DD}) \\
 &+ [100 \times f_3(\text{A,B}) + 400 \times f_4(\text{DR}) \\
 &+ 100 \times f_4(\text{DQ}) + 150 \times f_7(\text{MDP})] \\
 &\quad \times f_5(\text{AgeR}, 45, 75) \\
 &+ 750 \times f_6(\text{AgeR}, 75, 100)
 \end{aligned}$$

## B. SCORE WITHOUT DISTANCE (SCORE noD) CALCULATION

The score without distance (Score noD) calculation takes into account the interaction between the score without age difference (Score no $\Delta$ age) and a function  $F(\Delta$ age) of age difference between the donor and the recipient:

$$\text{Score noD} = \text{Score no}\Delta\text{age} \times F(\Delta\text{age})$$

To calculate the age difference between the donor and the candidate function  $F(\Delta$ age), age matching is asymmetrical to avoid insofar as possible a match between a candidate who is more than 5 years older than the donor. Conversely, matching a donor with a younger candidate is authorized more easily.

This approach facilitates securing young donors for young patients as much as possible and helps to maintain more favorable donor-patient matching.

For the same reasons, a filter blocking a proposal of a donor 20 years older than a candidate has been put in place. This filter introduces a score equal to 0 in such cases.

This filter is the only exception to offering a kidney to a local team: the offer is not made in the rare cases in which no patient on the waiting list is less than 20 years younger than the donor.

### C. UNIFIED ALLOCATION SCORE

The unified allocation score (**UAS**) erases geographical/administrative borders and creates a more flexible geographical model by creating an interaction between the priority level assigned by the score and the distance between the procurement and transplant sites.

**Unified Allocation Score = Score noD x GM**

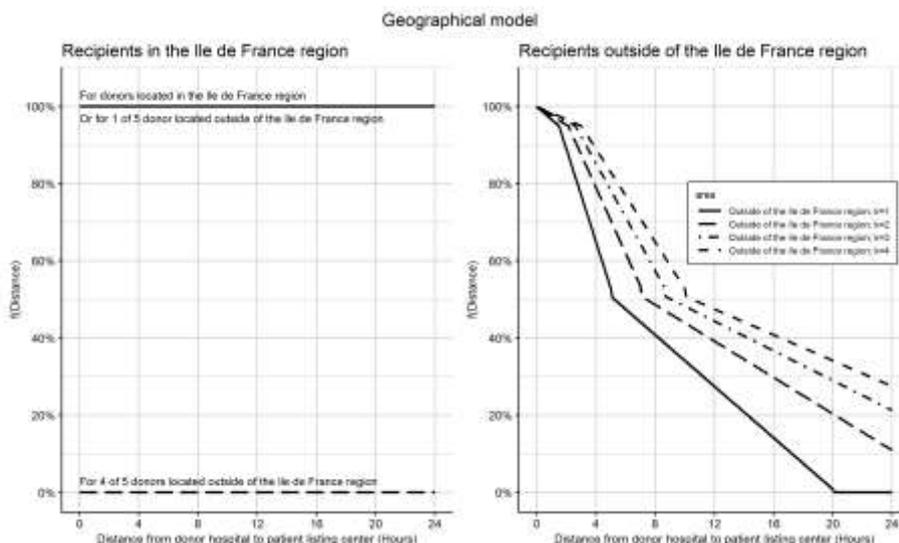
The geographical model (GM) of the kidney allocation score depends on:

- The region in which the donor’s organs are procured
- The region in which the recipient’s transplant team is situated.

For the reasons listed in the section I-G, when a graft retrieved in a region other than the Ile-de-France (Paris metropolitan area) is offered according to the national score, patients from Ile-de-France are eligible every fifth offer. In the absence of a candidate from this region, the graft is offered to patients from other areas based on the geographical model (see table below). When a patient from Ile-de-France is eligible, distance is not taken into account, as the distance between the procurement and transplant center is considered to be the same for all teams in the region. When the donor is situated in other regions, the distance is again not considered to compensate for the disparities affecting the patients from the Paris metropolitan area.

Moreover, we also have models differentiated according to a transplant team’s coefficient to take into account the specificities of teams from border and coastal zones. This coefficient aims to provide an identical procurement zone that depends on travel possibilities of transplant teams: cities in the center of France (e.g., Angers) versus border (e.g., Strasbourg) or coastal (e.g., Brest) cities.

**Figure 8: Geographical model**



The distance is provided by the CRISTAL database: it is the distance by road calculated in minutes and taking the topography into consideration.

If the procurement site is associated with a transplant team's procurement network, one of the two kidney grafts is allocated on the local level according to the national allocation score, with the possibility of exemption requiring a written justification that must be submitted to Regulation and Assistance Service within 48 hours.

When a patient from a local team is eligible for national or local priority, the kidney graft for transplant allocated to the patient is the local graft.

If the local transplant team refuses the graft or the site is not associated with a transplant team's procurement network, the kidney is then allocated according to the same procedure as the second graft.

In the absence of a national, interregional, or protocol-defined interregional or local priority, the second kidney graft is allocated according to the kidney score without any possibility of exemption.

The CRISTAL database edits a two-part potential allocation list:

- The first part includes the first five<sup>3</sup> candidates on the local list according to their score. Normally, the graft is allocated to the first ranked candidate with a negative cross-match. Any exemption requires a written justification that must be submitted to the *Agence de la biomédecine* within 48 hours.
- The second part establishes a national list of the first 10<sup>4</sup> recipients according to their score, at least two of whom are "not immunized". The transplant team is informed and required to confirm that the patient has no contraindication or any other kind of impediment. The National Organ Allocation Service then attributes the graft to the first patient with a negative cross-match.

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<sup>3</sup> This list can contain up to 20 patients

<sup>4</sup> This list can contain up to 20 patients

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**Table 1: Kidney Allocation Schema for adult patients .....4**

### III. APPENDICES

#### A. APPENDIX I: CALCULATION OF DONOR-RECIPIENT AGE DIFFERENCE

$$\Delta\text{Age} = \text{If}(\text{AgeR} - \text{AgeD} > 5; 100; \text{abs}(\text{AgeR} - \text{AgeD}))$$

(AgeR) = Recipient's Age

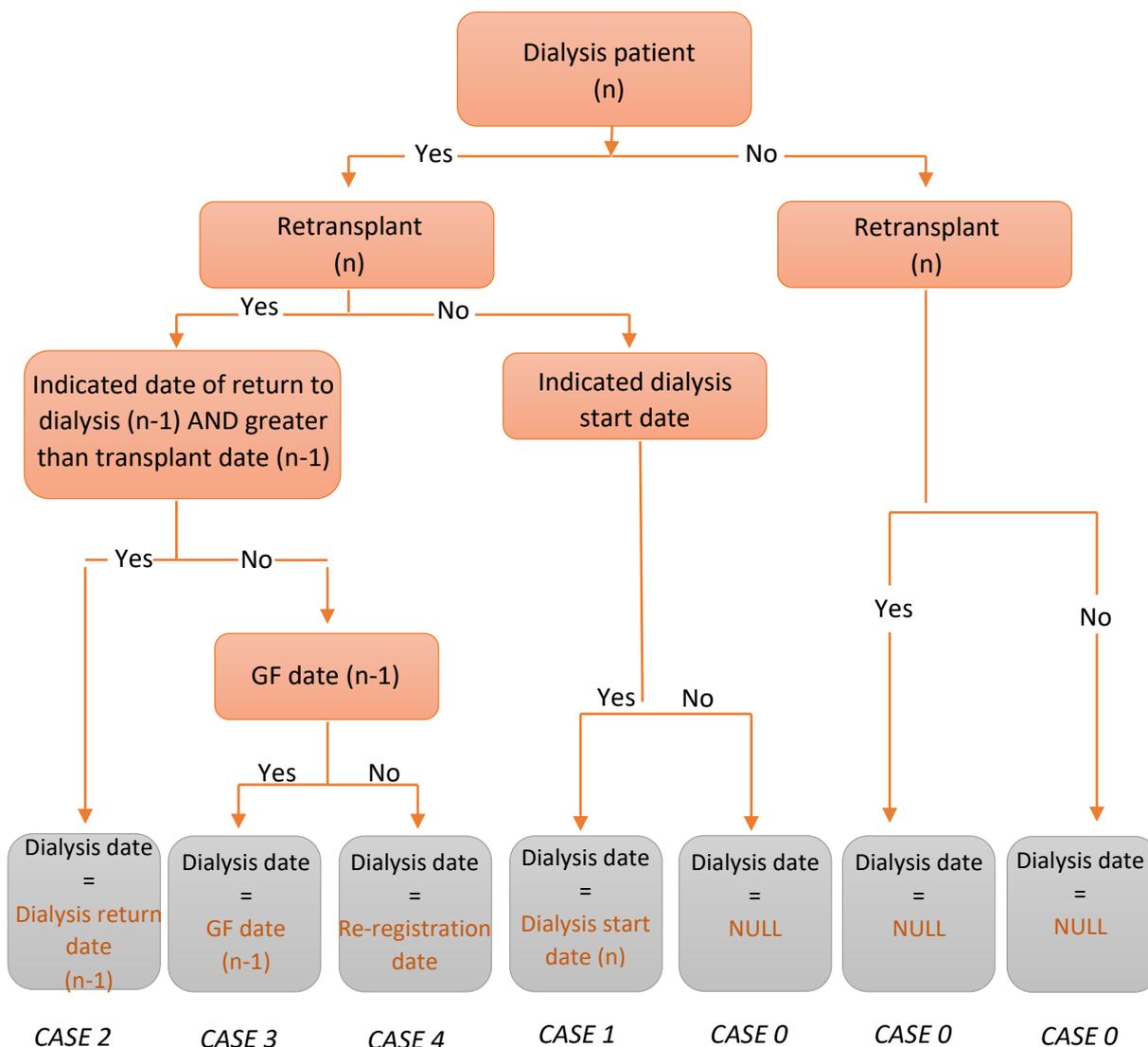
(AgeD) = Donor's Age

$$f(\Delta\text{Age}) = \frac{1}{\exp(0.02 \cdot \Delta\text{Age}^{0.85})}$$

#### B. APPENDIX II: DETAILED CALCULATION OF THE SCORE WITHOUT DISTANCE

$$\text{Score noD} = \frac{\text{Score no}\Delta\text{Age} \times \text{If}(\text{AgeR} > \text{AgeD} + 20; 0; 1)}{\exp(0.02 \cdot \Delta\text{Age}^{0.85})}$$

C. APPENDIX III: DATE OF DIALYSIS CALCULATION ALGORITHM



*(n): current file of the patient awaiting kidney transplant*  
*(n-1): previous patient file*  
*(GF): graft failure*  
*(\*) : re-registration date*

D. APPENDIX IV: INCLUSION OF THE WAITING TIME CALCULATION ALGORITHM

$$\left\{ \begin{array}{ll} f_2(\mathbf{WT}, \mathbf{DD}) = (1/120) \times (\mathbf{WT}) & \text{if } \mathbf{WT} < 120 \text{ months} \\ f_2(\mathbf{WT}, \mathbf{DD}) = 1 & \text{if } \mathbf{WT} \geq 120 \text{ months} \end{array} \right.$$

including RegistrationDate = SeniorityStatusResumption If SeniorityStatusResumption = 'O'  
 Otherwise RegistrationDate

**WTTT** = (CurrentDate – RegistrationDate)

**DDIAL** = (CurrentDate – DialysisStartDate) if undegoing dialysis

**Otherwise 0**

**WT = WTTT**            if (WTTT – DDIAL) < 12 months OR ReTR='Yes'

**WT = 12 + DDIAL**    if (WTTT – DDIAL) ≥ 12 months AND ReTR='No'

<i>(WT):</i>	<i>waiting time</i>
<i>(DD):</i>	<i>dialysis duration</i>
<i>(WTTT):</i>	<i>waiting time: calculation</i>
<i>(DDIAL):</i>	<i>dialysis duration: calculation</i>
<i>(ReTR):</i>	<i>retransplant</i>