# KIDNEY ADVISORY GROUP
# JULY 2023
# INTERNATIONAL (TRANSNATIONAL) COLLABORATION IN KIDNEY EXCHANGE PROGRAMMES WITH DONOR-RECIPIENT INVOLVEMENT: PROPOSED APPROACH FOR THE UK

## 1. BACKGROUND

The UK Living Kidney Sharing Scheme (UKLKSS) is one of the largest and most innovative programmes in Europe and has benefited from on-going continuous improvement since it was established in 2007.[1] To date, more than 1750 patients have been transplanted through the UKLKSS. However, some highly sensitised patients still wait many months/years in the scheme without a suitable donor being identified.

NHSBT has represented the UK within the European Network of Collaboration in Kidney Exchange Programmes (ENCKEP) in which the options for how countries may collaborate in transnational kidney exchange programmes (KEPs) are described[1]. Through this work, other countries within Europe have expressed interest in collaborating with the UK as part of a transnational KEP.

Using the ENCKEP proposed models for collaboration, this paper outlines a proposal for how international collaboration in KEPs could be established between the UK and other European countries. This is consistent with the ambitions for developing the UKLKSS within the 'Organ Donation and Transplantation 2030: Meeting the Need' strategy.[2]

## 2. WHAT ARE THE BENEFITS OF INTERNATIONAL COLLABORATION IN KEPs?

Countries may choose to collaborate to create a viable KEP by increasing the size and diversity (HLA type and ABO blood groups) of the donor-recipient pool and/or, within an existing national KEP, to maximise transplant opportunities for the benefit of all patients who are waiting for a transplant.

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[1] Building Kidney Exchange Programmes in Europe- An Overview of Exchange Practice and Activities. Biró P, Haase-Kromwijk B, Andersson T, Ásgeirsson EI, Baltesová T, Boletis I, Bolotinha C, Bond G, Böhmig G, Burnapp L, Cechlárová K, Di Ciaccio P, Fronek J, Hadaya K, Hemke A, Jacquelinet C, Johnson R, Kieszek R, Kuypers D, Leishman R, Macher MA, Manlove D, Menoudakou G, Salonen M, Smeulders B, Sparacino V, Spieksma F, de la Oliva Valentín Muñoz M, Wilson N, Vd Klundert J; ENCKEP COST Action, Transplantation. 2018 Sep 21

[2] Organ Donation and Transplantation 2030: Meeting the Need https://www.odt.nhs.uk/odt-structures-and-standards/key-strategies/meeting-the-need-2030/

The UK is more self-sufficient than many countries in KEP with the success of the UKLKSS, partly because of pool size and innovation but, also due to other contributing factors including

- Commitment from the clinical community
- Willingness of recipient and donor pairs to participate in the scheme
- A high proportion of non-directed altruistic donors (NDADs) initiating transplant chains
- Responsibility and administration of the scheme through NHSBT
- Partnership between NHSBT and Glasgow University for the development of the matching algorithm
- The proportion of identified transplants that proceed to donation

However, there are risks of errors associated with the UKLKSS because of its size and complexity. These materialised in 2019-2020 in critical incidents in two successive matching runs, prompting the digital transformation of the manual, paper-based processes that underpin the registration and inclusion of donors and recipients within the scheme.

The benefit to patients in the UK through international collaboration with other national KEPs must be balanced against the possible risks that could occur by introducing additional complexity into the UKLKSS. Any additional risks need to be considered in the context of plans to develop the UK scheme in the coming years but, also in the current climate: any effort to increase legitimate transplantation and deter risky behaviours to seek an illicit transplant should not be dismissed.

## 3. HOW COULD WE DO IT?

Tables 1 and 2 show the various models identified by the ENCKEP network for transnational collaboration. Option 3 is the preferred option for the UK, giving patients here the opportunity to participate in another national scheme and for patients from other countries to participate in the UK scheme. In comparison with options 1 and 2, the complexity of this arrangement is proportionate to the benefit that may be realised for individual patients. An additional option for NDADs is also presented in table 1, which would be beneficial for UK patients and feasible to accommodate.

Although some national frameworks are more flexible than others, given that countries within the European Union (EU) all have legal frameworks and ethical policies that support living donation, collaboration within the EU rather than further afield is likely to be the preferred starting point. The limitation to this approach is the lack of diversity in the HLA pool across the

countries of Europe. However, from a practical perspective, including travel and logistics, working within the EU reduces the complexity, minimising the risk of negative consequences.

Previous attempts to analyse the potential benefit for long-waiting patients (>1 year) in the UK with The Netherlands (NL) KEPs was difficult to model due to the information governance requirements for information sharing in the NL. However, the UK has many years' experience working successfully with the Republic of Ireland (RoI) to facilitate living donation in the UKLKSS for Irish Citizens through UK centres that can be applied to future collaborations.

Given the above, any arrangement with an individual country in which the exchange of donor and recipient information and organs is involved, would require a Memorandum of Understanding (MoU) between the participating countries to underpin clinical practice. An MoU would include:

- Legal and ethical considerations for both countries (e.g; established legal framework and safeguarding (donor and recipient); permitted donor-recipient relationships; country specific criteria; referral to a centre within the partner country; reciprocity between countries)
- Proposed model of international collaboration (from table 1)
- Acceptance criteria for recipients joining (may vary according to collaborating country limitations but e.g. recipients who have waited 1 year or more in their national scheme)
- Logistical arrangements (e.g.; organs or patients travel; transport and traceability; UK centre involvement; inclusion in more than one national KEP)
- Scheme administration (e.g. governance arrangements and sharing of patient identifiable information; criteria for donor-recipient registration and inclusion; completeness of data; inclusion in LivingPath)

**Table 1: Potential Options for International (Transnational) KEPs- (ENCKEP)**

| Collaborative Model | Detail | Strengths and Limitations | Benefit to UK? |
|---|---|---|---|
| **Option 1**<br><br>**Merged pool** | In which two or more national KEPs join to create a single pool | Best suited to emerging/small/medium national KEPs<br><br>Risks likely to outweigh benefit in large, mature national KEPs | UK pool likely to contribute more kidneys than received<br><br>May increase non-proceeding transplants due to logistical delays |
| **Option 2**<br><br>**Consecutive pool** | In which national KEPs continue to operate but difficult to match donor-recipient pairs from different countries can subsequently join to form an additional pool | Suitable for any size KEP; national KEP runs to usual schedule followed by international collaboration<br><br>Only includes unmatched pairs in national KEP- chances of matching very low due to high sensitisation[3]<br><br>Clinical/logistical complexity likely to outweigh benefits for larger KEPs[3] | Unattractive option for UK due to low conversion rate in international pool and logistical complexity<br><br>Maybe a future consideration for the UK |
| **Option 3**<br><br>**Outside registration** | In which individual recipients from countries with or without a KEP can join another country's national KEP pool with their donor/s | Suitable for all KEPs<br><br>Offers patient choice by exposing them to a whole national KEP<br><br>Number of potential matches limited in comparison with merged pool but complexity proportionate to risk | Offers patient choice at minimal risk to other patients<br><br>Offers reciprocity to other countries<br><br>Logistically manageable - non-UK donors could be registered with complex considerations |
| **Additional Option** | In which people who wish to donate to an unknown recipient may | Suitable for all KEPs, legal frameworks permitting | Feasible in the UK with minimal risk to other patients |

[3] Spain and Italy take the lead in the first international cross kidney transplant in southern Europe, https://www.lamoncloa.gob.es/lang/en/gobierno/news/Paginas/2018/20180808transplant.aspx August 2018

| **Non-directed anonymous donation** | donate to a recipient on the waiting list or into a national KEP in another country if they do not have access to this in their country of origin | Maximises opportunities for patients in the KEP and on the transplant list if NDADs are utilised in a KEP<br><br>Facilitates donors' wish to donate but perpetuates inequity of access to transplantation or patients who live in countries where NDADs are not permitted | Some logistical complexities to overcome/agree within MoU |
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**Table 2: Summary: application of collaborative KEP models by national programme size**

| | **Programme Characteristics** | | |
|---|---|---|---|
| **KEP Model** | None<br>Emerging | Small<br>Medium | Large |
| **Merged Pool** | √ | √ | |
| **Consecutive Pool** | | √ | √ |
| **Outside registration** | √ | √ | √ |
| **Non-directed anonymous donation** | √ | √ | √ |

## 4. WHAT IS KIDNEY ADVISORY GROUP (KAG) ASKED TO DO?

KAG members are asked to approve the following recommendations:

1. To facilitate international collaboration between the UK and other EU countries to improve transplant opportunities for long-waiting patients in the UKLKSS
2. Endorse option 3 (registration of individual pairs in another national KEP) as the preferred starting point for UK – EU transnational collaboration in KEPs

Subject to approval, a MoU template will be drafted and brought back to the next meeting of KAG for approval.

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