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Policy Brief No. 060

Crossover kidney donation in Germany

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July 2024 www.econtribute.de

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Funding by the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation) under Germany's Excellence Strategy – EXC 2126/1-390838866 is gratefully acknowledged.

Crossover kidney donation in Germany

Statement on the “Entwurf eines Dritten Gesetzes zur Änderung des Transplantationsgesetzes – Novellierung der Regelungen zur Lebendorganspende und weitere Änderungen”

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21 May 2024, Update 17 July 2024

Deutsche Zusammenfassung[2]

Das Hauptziel der Überkreuzspende ist es, die medizinische Unverträglichkeit zwischen Spender und Empfänger durch einen Organaustausch zu überwinden und dadurch die Zahl der Nierentransplantationen zu erhöhen. International hat sich dabei eine Reihe von Best Practices etabliert, auf die sich unsere Stellungnahme und Empfehlungen stützen.

Das Bundesministerium für Gesundheit in Deutschland hat einen "Entwurf eines Dritten Gesetzes zur Änderung des Transplantationsgesetzes - Novellierung der Regelungen zur Lebendorganspende und weitere Änderungen" vorgelegt, um ein Nierentauschprogramm einzuführen und neue Varianten der Lebendnierenspende in Deutschland zu ermöglichen. Dies ist ein bedeutender Fortschritt bei der Bewältigung der Herausforderungen des Organmangels und der Verbesserung der Ergebnisse sowohl für viele Spender als auch für Patienten mit Nierenerkrankungen. Wir begrüßen insbesondere die Aufnahme von Varianten der Überkreuzspende (3-Wege-Tausch, nicht-gerichtete Spende) und die verpflichtende Teilnahme der Transplantationszentren an einem zentralen Überkreuzspendesystem in dem Gesetzentwurf und begründen in dieser Stellungnahme, warum dies wichtige Elemente eines effektiven Nierenaustauschsystems sind (Abschnitt 2).

Wir sprechen zwei wichtige Empfehlungen für Anpassungen des Gesetzentwurfs aus, die beide im Einklang mit internationalen Best Practices für Nierenaustauschsysteme stehen und beide die Effektivität des Systems zugunsten der Patienten und Spender signifikant erhöhen können.

Erstens sollte kompatiblen Spender-Empfänger-Paaren die Teilnahme am Tauschsystem ermöglicht werden. Obwohl diese Paare auch direkt transplantiert werden könnten, kann ihre Teilnahme nicht nur die Gesamtzahl der Transplantationen für kompatible Paare deutlich erhöhen und die Warteliste verkürzen (Simulationen deuten darauf hin, dass die Einbeziehung kompatibler Paare in die Überkreuzspende die Zahl der

[1] Contact: ockenfels@uni-koeln.de. We thank in particular David Manlove, and Itai Ashlagi, Ágnes Cseh, Thomas Gutmann, Christine Kurschat, William Pettersson, Alvin Roth and other collaborators across various disciplines for helpful exchanges and comments. Support from the German Science Foundation through the Excellence Strategy grant EXC 2126/1 390838866 is gratefully acknowledged.

[2] Ockenfels et al. (2024) enthält eine ausführliche Fassung der Analyse und Empfehlungen in deutscher Sprache.

Nierentransplantationen um bis zu 160 % erhöhen könnte), sondern es ist häufig auch möglich, dem Empfänger des kompatiblen Paares durch den Überkreuztausch eine Niere von höherer Qualität zuzuweisen (Abschnitt 3).

Zweitens sollte die nicht-gerichtete (anonyme) Spende bevorzugt für die Initiierung von Tauschketten genutzt werden, während die derzeitigen Bestimmungen des Gesetzentwurfs die Nutzung der nicht-gerichteten Spende faktisch in erster Linie für die unmittelbare Zuteilung mit der bestmöglichen Gewebeverträglichkeit auf der Warteliste vorsehen. Tauschketten ermöglichen regelmäßig mehr und qualitativ hochwertigere Transplantationen als die direkte Zuteilung der nicht-gerichteten Spende (Abschnitt 4).

Wir weisen auch auf einige Unklarheiten oder mögliche Fehler im Gesetzentwurf bezüglich der Gleichzeitigkeit von Transplantationen, des Ausschlusses von Lebertransplantationen und der Kostenschätzungen hin.

Zusammenfassend haben die vorgeschlagenen Änderungen ein enormes Potenzial, die Effektivität des geplanten Nierentauschprogramms in Deutschland zu steigern und vielen weiteren Patienten eine lebensrettende Transplantation zu ermöglichen. Allerdings geht der Gesetzentwurf in einigen spezifischen Details der Regelungen zur Allokation von Nierenlebendspenden zu weit. Diese Regeln entsprechen außerdem nicht der Best Practice in anderen Ländern. Konkret: Wenn es kompatiblen Paaren und nicht-gerichteten Spendern nicht oder nur erschwert möglich ist, an den neu ermöglichten Varianten der Überkreuzspende teilzunehmen, geht der große Wert, den die Nierenlebendspende im Gesamtsystem entfalten kann, verloren und es werden Chancen vertan, die Situation aller Patienten, einschließlich der Patienten auf der Warteliste, zu verbessern.

Die Erarbeitung detaillierter Empfehlungen zu den Allokationskriterien sollte unseres Erachtens - wie bei der postmortalen Spende - an eine Expertenkommission delegiert werden, die über ethische, rechtliche und praktische Expertise und Erfahrung mit den Nierenaustauschsystemen unserer europäischen Nachbarn und darüber hinaus verfügt.

Wir hoffen, mit unserer Stellungnahme einen Beitrag zur bestmöglichen Ausgestaltung der Reform leisten zu können.

English Summary

The primary goal of living crossover kidney donation is to overcome medical incompatibility between donor and recipient through organ exchange and thereby increase the number of kidney transplants. Internationally, a number of best practices have been established on which our statement and recommendations are based.

The Federal Ministry of Health in Germany presented an “Entwurf eines Dritten Gesetzes zur Änderung des Transplantationsgesetzes – Novellierung der Regelungen zur Lebendorganspende und weitere Änderungen” to introduce a kidney exchange program and allow new variants of living kidney donations in Germany. This represents significant progress in addressing the challenges of organ shortage and improving outcomes both for many donors and for patients with end-stage renal disease. We particularly welcome the inclusion of variants of crossover-donation (3-way exchange, non-directed donation) and the mandatory participation of transplant centers in a centralized crossover-donation system in the proposed bill and demonstrate below that these are important elements of an effective system (Section 2).

We make two important recommendations for adjustments to the bill, both of which are consistent with international best practices for kidney exchange systems.

First, compatible donor-recipient pairs should be allowed to participate in the exchange system. Although these pairs could perform a transplant directly, their participation can not only significantly increase the total number of transplants and shorten the waiting list (simulations suggest that the inclusion of compatible pairs could increase the number of kidney transplants through exchange by up to 160%), it is also often possible to allocate a higher quality kidney (younger donor, better tissue compatibility) to the recipient of the compatible pair through exchange (Section 3).

Second, while the current provisions of the proposed bill imply the use of non-directed (anonymous) donations primarily for immediate matches with the best possible tissue compatibility on the waiting list, non-directed donations should preferably be used to initiate chains of exchanges. Kidney chains allow for more and higher quality transplants than direct allocation of the initial donation (Section 4).

We also point out some ambiguities or potential errors in the bill regarding the simultaneity of operations, the exclusion of liver transplants, and cost estimates.

Overall, the proposed changes have enormous potential to increase the effectiveness of the planned kidney exchange programs in Germany and to enable many more patients with renal insufficiency to receive a life-saving transplant. We hope that our paper will contribute to the best possible design of the reform.

Contents

1 Introduction: Best practices in kidney exchange

The Federal Ministry of Health in Germany presented an “Entwurf eines Dritten Gesetzes zur Änderung des Transplantationsgesetzes – Novellierung der Regelungen zur Lebendorganspende und weitere Änderungen” to introduce a kidney exchange program and allow new variants of living kidney donations in Germany. This represents significant progress in addressing the challenges of organ shortage and improving outcomes both for many donors and for patients with end-stage renal disease (Kübler and Ockenfels 2020).

The medical prerequisites for living donor kidney transplantation are ABO blood group compatibility and the absence of pre-formed antibodies in the recipient against the donor's HLA tissue (HLA compatibility). Thus, a willing donor may be medically incompatible with his or her matched recipient. The primary goal of a kidney exchange system is to eliminate this medical incompatibility for many recipients through donor exchange. For each incompatible pair that participates in a kidney exchange, the donor becomes eligible to donate, increasing the supply of living donor kidneys by one.

The following best practices are among the most important lessons learned from two decades of scientific analysis and practical experience worldwide (e.g., Biró et al. 2019):

1) Variants of simple 2-way exchanges, such as chains of kidney exchanges initiated by anonymous non-directed kidney donations and 3-way exchanges, can significantly increase the number of recipients who can receive a kidney transplant through crossover-living kidney donation.

2) A single centralized kidney exchange system can considerably benefit more recipients than fragmented kidney exchanges at the hospital level.

3) Including compatible pairs in the crossover-living kidney donation pool can significantly increase the number of recipients with incompatible donors who can receive a transplant (and thereby shorten the waiting list), while also providing benefits to recipients of the compatible pairs.

4) Integrating non-directed donors in the kidney exchange pool can significantly increase the number of recipients with incompatible donors who can receive a transplant.

Many of the best practices are reflected in the proposed bill. In particular, points 1) and 2) in our list above are well addressed.

1.1 Variants of 2-way kidney exchange

Regarding point 1), the proposed bill allows for variants of simple kidney exchanges. 3-way exchanges can increase the number of transplants from crossover-donation by around 20% when compared to only 2-way exchanges (Roth, Sönmez, and Ünver 2007). Simulations conducted for Germany, based on experience and data from the UK, suggest that, indeed, allowing three-way exchange and anonymous non-directed donation can increase the number of transplants in Germany quite substantially (we refer to Ashlagi et al. 2024 for the details). Similarly, in the US, a large proportion of the benefits of kidney exchanges come from non-directed donor chains. Agarwal et al. (2019, p. 4031) find that "*Initially, cycles were*

the most common type of transaction, but chains became more important over time, and today they facilitate majority of transplants in some programs such as National Kidney Registry."

One reason for the effectiveness of these variants of kidney exchanges is that they increase the number of possible matches in the system, as more complex exchanges allow for more flexibility dealing with a greater variety of blood group and antibody mismatches between donor and recipient. As a result, the likelihood of finding compatible matches increases.

As an example of why 3-way exchanges improve upon 2-way exchanges, consider three pairs (as shown in Figure 1 below): P_1 with a blood-type A recipient and a blood-type B donor, denoted as A-B, P_2 with blood types B-A, and P_3 with a sensitized blood-type A recipient and blood-type A donor, or sensitized A-A. Suppose the sensitized recipient of P_3 is HLA-compatible with the donor of P_2. A 2-way exchange would require the recipient of P_1 of blood type A to receive from the donor of P_2 of blood type A and, in return, the donor of P_1 of blood type B to donate to the recipient of P_1 of blood type B in an (A-B, B-A) 2-way exchange. On the other hand, a 3-way exchange with P_1's donor donating to P_2's recipient, P_2's donor donating to P_3's recipient, and in return, P_3's donor donating to P_1's recipient would benefit all three recipients.

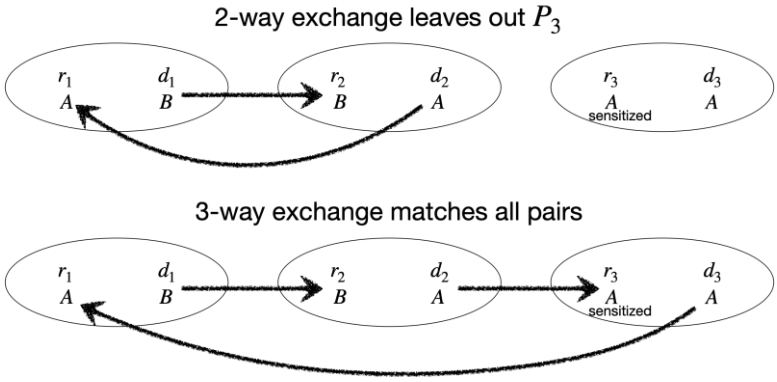

Figure 1: How 3-way exchanges improve upon 2-way exchanges

In other cases, it may not be even feasible to organize any 2-way exchanges, while a 3-way exchange would provide transplants to all three pairs. Consider the pairs P_1 (sensitized A-O), P_2 (O-B), and P_3 (B-A). Suppose the recipient of P_1 is HLA-compatible with the donor of P_3, then observe that there is no feasible 2-way exchange. However, a (sensitized A-O, O-B, B-A) 3-way exchange can be organized, saving all three lives among the three pairs (see Figure 2).

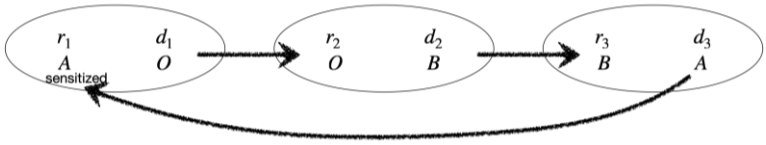

Figure 2: A 3-way exchange when 2-way exchanges are not feasible

As an example of how a non-directed donation improves upon 2-way exchanges, consider the blood-type B donor of a new pair P_1 with a sensitized blood-type A recipient. This donor is compatible with the blood-type B recipient of a pair P_2 with a blood-type A donor. However, a 2-way exchange is not feasible as the donor of pair P_2 is HLA-incompatible with

the recipient of pair P_1. On the other hand, introducing a non-directed donor of blood type A who can donate to the recipient of pair P_1 could initiate a chain. The donor of P_1 then donates to the recipient of pair P_2. Moreover, P_2's donor can return a blood-type A kidney to a recipient on the deceased-donor waiting list. In this scenario, a successful transplant chain is created even when a direct 2-way exchange is not feasible, benefiting the two recipients, in addition to a deceased-donor list candidate. This expands the potential matches significantly, leveraging the non-directed donor to enable transplants for patients who might otherwise remain unmatched (see Figure 3).

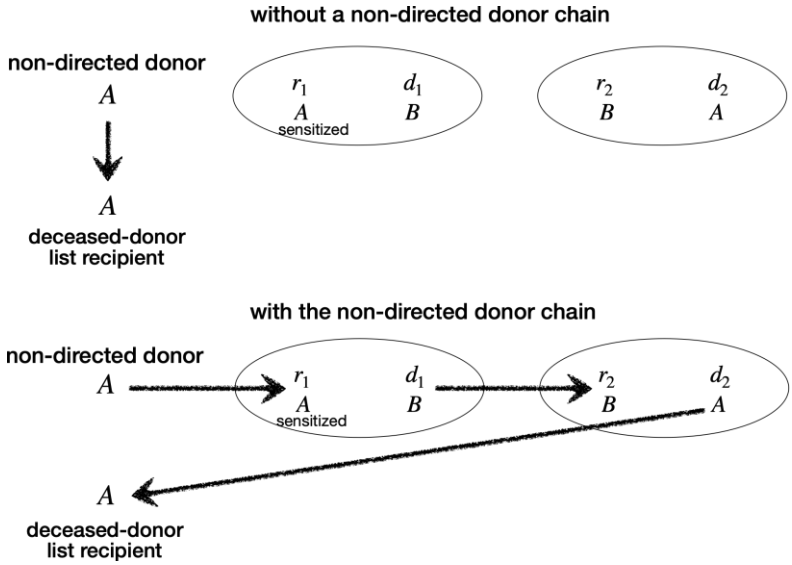

Figure 3: How a non-directed donor chain improves upon 2-way exchanges

Based on such insights, the flexibility to allow for variants of simple 2-way exchanges is an important feature of the proposed bill.

1.2 Centralized kidney exchange

Regarding point 2) of our list of best practices, the proposed bill makes it mandatory for hospitals to submit all donor-patient pairs and anonymous, non-directed donors to a centralized kidney exchange system. There are indeed many advantages to centralized matching. Centralized programs can use sophisticated algorithms to optimize matches across a wide range of donor-recipient pairs. This can significantly increase the number of matches and successful transplants, as well as the opportunity for highly sensitized recipients as well as patients with minority ethnic backgrounds to be matched, compared to decentralized, fragmented matching within individual hospitals. In a centralized setting, organs are allocated to those most in need and most compatible (as determined by the KEP), thus improving overall transplant success rates. A centralized KEP can also be designed to ensure equitable access to transplantation regardless of a recipient's location, socioeconomic status, or hospital affiliation. Similarly, centralization allows for the implementation of uniform standards and protocols that enhance the safety, ethical integrity, anonymity, and quality of the exchange process (we provide more details in Ashlagi et al. 2024).

However, without regulation, an efficient centralized system is unlikely to emerge 'by itself'. Establishing an efficient KEP requires substantial initial investment and maintenance (Cseh et al. 2024), and more importantly, hospitals may choose not to fully participate by withholding

some donor-recipient pairs for internal matching, as this could temporarily increase the number of transplants within their own facility in the short term at the expense of the national system. Indeed, this challenge has been recognized in other countries (Roth 2008), is well understood and documented in the literature (Sönmez and Ünver 2013, Ashlagi and Roth 2014), and is shown by simulation results to be also a potential challenge in Germany (Ashlagi et al. 2024).

As an example, consider four recipient-donor pairs, P_1 with a mildly sensitized, blood-type A recipient and a blood-type O donor, P_2 with recipient-donor types O-A, P_3 with types B-A, and P_4 with types O-B. Suppose recipients of P_1 and P_2 are patients in Hospital X, while the rest are Hospital Y's patients. If both hospitals cooperate and submit all pairs to the centralized system, three transplants are possible through a 3-way exchange for P_1, P_4, and P_3 (see the top part of Figure 4). However, if Hospital X withholds its pairs for internal matching, it can match the recipients of both P_1 and P_2 through a 2-way exchange instead of only one, but Hospital Y receives none (see the bottom part of Figure 4).

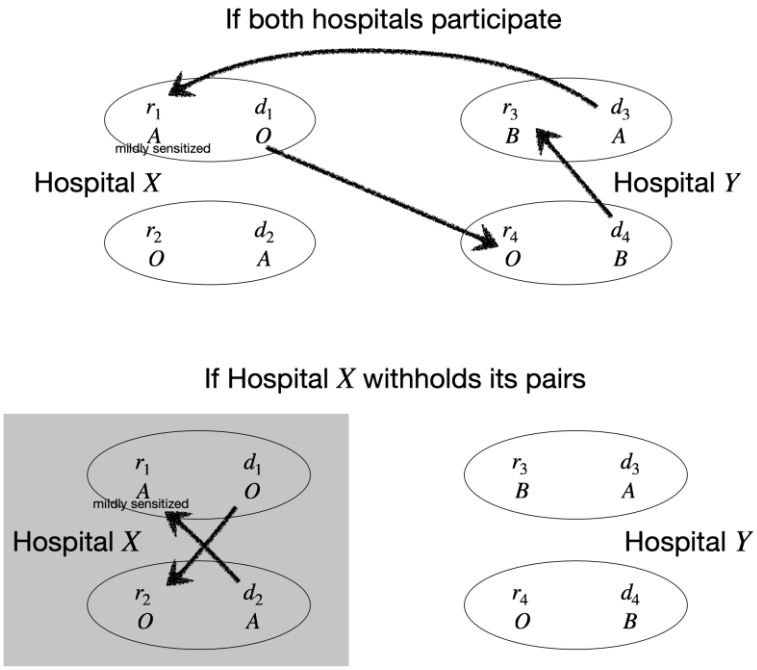

Figure 4: Centralized versus fragmented kidney exchange system

Based on such insights, the obligation for hospitals to submit all pairs to the central program is an important feature of the proposed bill. [3]

1.3 Room for improvement

However, there are other provisions in the bill that could negate many of the large benefits of points 1) and 2). These are related to our points 3) and 4) in our list of best practices above, where in our opinion the proposed bill can be significantly improved, with a potentially large impact on the number of transplants possible, even by making rather small changes in the regulation of matching.

[3] There can be similar challenges for cross-border kidney exchanges, as they also emerge in some of the kidney exchange programs in Europe (Druzsin et al. 2024).

In Section 2, we argue that allowing compatible donor-patients to participate in kidney exchanges will often result in more and higher quality transplants, including for the patient of the compatible pair. Therefore, in line with best practice elsewhere, we strongly recommend that compatible pairs should not be denied the benefit of kidney exchange. We explain why compatible pairs will often want to participate in the exchange, and how this will also benefit other patients, including those on the waiting list.

In principle, the proposed bill allows variants of kidney exchange like chains of donations initiated by a non-directed donation and 3-way exchanges. However, as we explain in Section 3, overly specific regulations about the feasible matching procedure would prevent the important advantages of these variants. In particular, the current version of the proposed bill would result in non-directed donor kidneys typically going to recipients on the deceased donor waiting list. This means giving up additional living donor kidneys that would otherwise become available because of the non-directed donor kidney that might start a donation chain. In fact, this rule would exclude matches that would otherwise benefit all patients. Therefore, in line with best practice elsewhere, we strongly recommend that "best match" should not be evaluated too narrowly in terms of an immediately achievable outcome, but should also consider the number and quality of transplants that can be achieved when the donation is "optimally" used in the kidney exchange system, including when it can initiate a chain of donations.

Finally, Section 4 discusses some minor ambiguities or potential errors in the proposed bill regarding liver donation, simultaneity of operations, and cost estimates.

2 Allow compatible pairs to participate in kidney exchange

The proposed bill strictly restricts participation to kidney exchange system to incompatible pairs, as e.g. stated on p. 62 of the proposed bill:

"*Die Teilnahme als Paar kompatibler Organspenderinnen oder -spender und Organempfängerinnen oder -empfänger an einer Überkreuzlebendnierenspende ist dagegen nicht vorgesehen, da bei diesen Paaren eine Organlebendspende immunologisch möglich wäre. Es besteht daher keine Notwendigkeit, auch für diese Paare die Überkreuzlebendnierenspende zu ermöglichen*."

[Translation by DeepL: "Participation as a pair of compatible organ donors and organ recipients in a crossover living kidney donation, on the other hand, is not envisaged, as a living organ donation would be immunologically possible in these pairs. There is therefore no need to enable cross-living kidney donation for these couples as well."]

It is argued that since recipients of compatible pairs can receive a transplant directly from their respective co-registered donors, their participation in kidney exchange is not necessary. However, kidney exchange programs in other countries often allow the participation of compatible recipients and donors (Kübler and Ockenfels 2000) – and they do so for compelling reasons.

For one, there will be often cases, in which *everyone can be made better off* by including compatible pairs: The patient in the compatible pair can often receive a higher-quality kidney

by participating in the kidney exchange, the exchange would make it possible for an additional donor-patient pair to have a transplant and this would then reduce the length of the waiting list.

Consider an example with many unsensitized or poorly sensitized type O recipients and type A donors, as shown in Figure 5. Suppose there is also a compatible pair P0 with an unsensitized or poorly sensitized blood type A recipient and a blood type O donor, such that the donor of P0, who is 40 years old, has 4 HLA mismatches with the recipient. P0 can now participate in a 2-way exchange with any of the O-A pairs in the exchange pool instead of receiving a direct transplant from his co-registered donor. Since there are many O-A pairs, one or more of the donors in these pairs may be a better match for P0's recipient than his or her co-registered donor. In fact, as seen in Figure 5, P3, P8, and P10 each have younger donors who have a better tissue antigen match with P0's recipient than P0's donor. Better tissue match in terms of fewer HLA mismatches and younger donor age are some of the known indicators of long-term transplant success. Among these three pairs, P3 has the best donor for P0's recipient. Therefore, a 2-way exchange between P0 and P3 will not only provide a better kidney for P0's recipient, but will also be beneficial for P3's recipient.

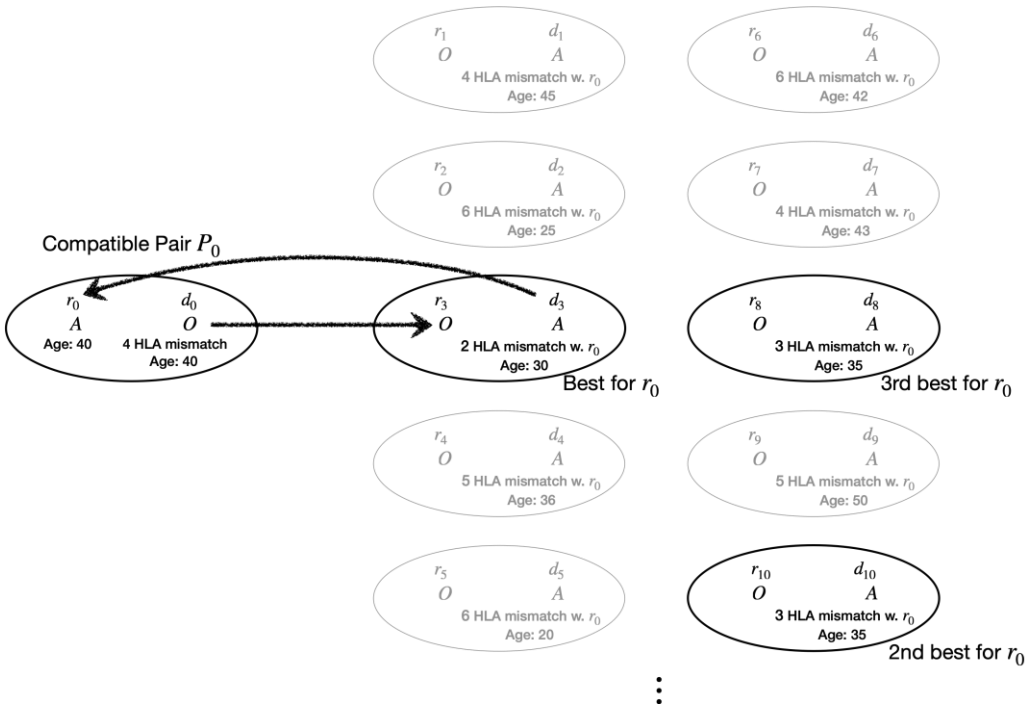

Figure 5. A recipient with a compatible donor can find a better match via kidney exchange.

Consider another example in Figure 6 with many O-A pairs that have unsensitized recipients. In addition, there are three A-B pairs with unsensitized or poorly sensitized recipients. If a compatible B-O pair P0 with an unsensitized recipient becomes available and P0's donor is not a good match for P0's recipient, one of the donors from the three A-B pairs may be a better match. Now, a (B-O, O-A, A-B) 3-way exchange that benefits the recipients of two incompatible pairs and provides a better donor for P0's recipient is feasible, as shown in Figure 6.

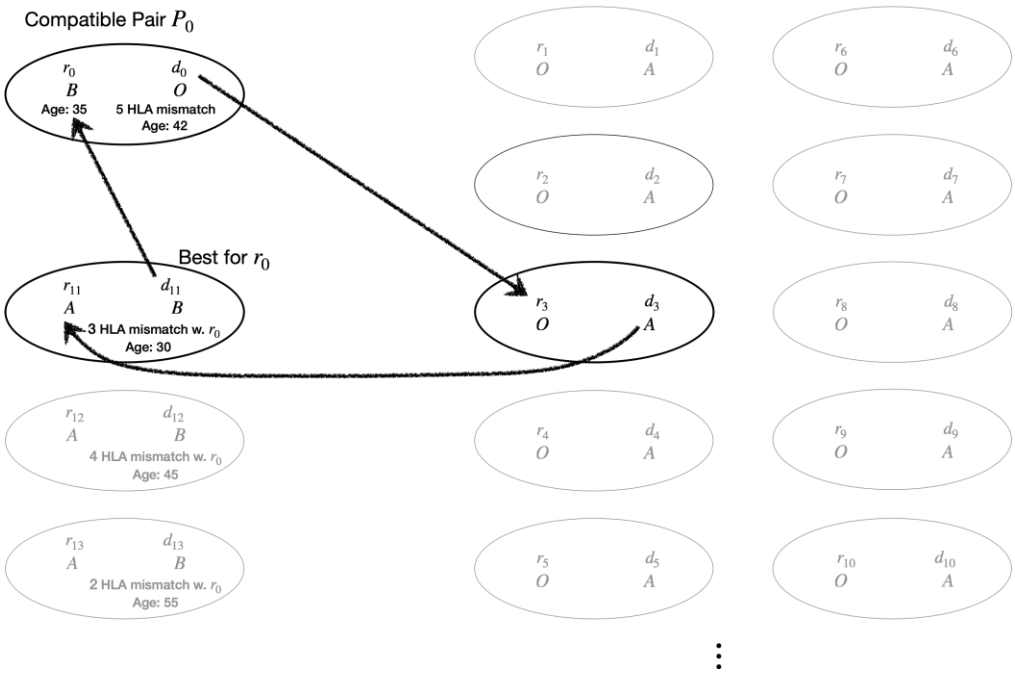

Figure 6. An exchange with one compatible and two incompatible pairs benefiting all recipients

Indeed, the participation of compatible pairs can significantly increase the number of recipients who receive a transplant through the system. Based on US data, Sönmez, Ünver, and Yenmez (2020) estimates that this policy can potentially increase the number of kidney exchange transplants by as much as 160%. The most successful single-center kidney exchange system in the world in San Antonio-US (discussed below) and the most successful single-center liver exchange system in the world in Malatya-Turkey (discussed below) both owe their efficiency in large part to the inclusion of compatible pairs. Relevant data can also be found at the US National Kidney Registry that publishes and reports outcomes for compatible pairs (Chipman et al. 2021; see also the results on their website and Weng et al. 2017).

Why does participation of compatible pairs in kidney exchange significantly increase the efficacy of the system? According to Wikipedia, 41% of the German population is blood-type O, 43% of the population is blood-type A, 11% of the population is blood-type B, and 5% of the population is blood-type AB. Consider a recipient with a blood-type A who has a donor of blood-type O. Since they are blood-type compatible, unless they are HLA incompatible (somewhere around 20% possibility for an average pair), this pair is medically compatible. Therefore, under the proposed bill, they are ineligible to participate in kidney exchange. This means there will rarely be a blood-type A recipient in the kidney exchange system with a blood-type O donor.

Similarly, consider a scenario where the blood types of the recipient and donor are reversed. In this case, the patient is blood-type O and the donor is blood-type A. For this pair, and any pair in the same situation, kidney exchange is the only way to receive a living-donor transplantation. Therefore, under the proposed bill, one can expect several times more blood-type O patients with blood-type A donors in the system than blood-type A patients with blood-type O donors – perhaps 5 times more depending on the prevalence of HLA

incompatibility. As a result, at most 20% of blood-type O patients with blood-type A donors can receive transplants through kidney exchange.

Similarly, the following types of pairs will be at a severe disadvantage under a kidney exchange system which limits participation to incompatible pairs:

- Blood-type O patients with blood-type A donors
- Blood-type O patients with blood-type B donors
- Blood-type O patients with blood-type AB donors
- Blood-type A patients with blood-type AB donors
- Blood-type B patients with blood-type AB donors

Consequently, it is essential for many patients to include compatible patient-donor pairs in the system with blood-type A/B/AB (i.e., A or B or AB) patients with blood-type O donors, as well as blood-type AB patients with blood-type A/B donors. For each such pair included in the kidney exchange system, at least one (and in some cases more) recipients with incompatible donors will be able to receive a transplant. This is why inclusion of all such pairs would increase the number of kidney exchange transplants by 160% in the US.

Not only would the participation of compatible pairs increase the number of transplants, but there is also reason to believe that compatible pairs often want to participate. One reason is the prospect of a higher-quality kidney for the patient.

Moreover, a compatible pair may want to help other less fortunate patients, in particular (but not only) if they can be ensured that they do not receive a graft of inferior quality. Indeed, with non-directed donors, altruism is already an accepted donor motive in the proposed bill, even without the possibility of an exchange that would benefit the donor's loved ones. So, there appears to be no reason to deny such voluntary and altruistic participation in kidney exchange to compatible pairs.

We note that it is also possible to consider – perhaps in the future, after an evaluation of the new policy – implementing policies that further promote the kidney exchange of compatible pairs and that have been discussed in the literature or implemented in the field. Examples include:

1. ***Providing patients of compatible pairs with kidneys from younger donors*** (Bingaman et. al, 2012, 2018): The Methodist San Antonio system is the largest single-center kidney exchange system in the world. They achieved this status by both including compatible pairs in the system, and also using subtype-type A2 kidneys. Participating compatible pairs were provided kidneys from younger donors. Bingaman et al. (2018) summarize the importance of compatible pairs in the system for the time window from March 2008 to October 2017: *"51 compatible pair donors were utilized of which 48 donors (94%) were blood type O or A2, and 3 donors (6%) were blood type A1. Compatible pairs participated in a total of 155 KPD transplants. All compatible pair recipients received kidneys from younger donors."* The 51 compatible pairs helped 104 additional transplants to patients with incompatible donors.

2. ***Providing patients of compatible pairs with kidneys with better HLA matches***: National Kidney Registry, the largest multi-hospital kidney exchange system recently started using a

sophisticated "eplet matching" system to attract compatible pairs in kidney exchange by providing them kidneys with better tissue-type match. Additional details are available on the following website: https://www.kidneyregistry.org/for-patients/finding-the-best-kidney-match/.

3. ***A related scheme in living-donor liver transplantation***: While it is not directly related to kidney exchange, it is illustrative to present some statistics from the largest liver exchange system in the world managed by Sönmez and Ünver at Liver Transplant Institute at Inonu University, Malatya-Turkey. In 2023, the system facilitated 64 liver exchange transplants, accounting for 27.7% of the Institute's 231 living-donor liver transplants. Among the pairs who participated in liver exchange, 45 were incompatible—18 due to blood-type incompatibility, 18 due to small graft size, and 9 due to large graft size. The remaining 19 were compatible pairs. Without the participation of the compatible pairs, the Institute would not have been able to conduct 45 of the 231 liver transplants in 2023, specifically for patients with incompatible donors. As a result, the system led to a 24.2% increase in living-donor liver transplantation volume in 2023 (Yilmaz et al., 2024; Sönmez and Ünver, 2024, Section 3).

4. ***Kidney Exchange including compatible pairs and priority points*** (Sönmez, Ünver, and Yenmez, 2020): An average living-donor kidney transplant lasts 20 years. One idea to help compatible pairs with the above configurations is for recipients to receive some priority points on the deceased donor kidney waitlist in the future in case they need a repeat transplant. Under both the current law and the proposed bill, such priority points for living donors are already accepted.[4] The logic for compatible pairs is not much different. For example, when a blood-type A patient with a blood-type O donor participates in kidney exchange even though they are medically compatible, they strictly increase the supply of living donor kidneys by at least one by enabling donors of incompatible pairs to feasibly donate. Consequently, they also reduce the number of patients on the deceased-donor waitlist. In return, in the future, the patient receives priority points in the deceased-donor waitlist for one time if it becomes necessary.

Sönmez, Ünver, and Yenmez (2020) show that this policy not only increases the welfare of all patient subgroups, but it also reduces the wait times between patients of different blood types. This happens because this approach especially benefits hard-to-match patients with blood-type O. In many countries (e.g., the US), deceased-donor (post-mortem) kidney waitlists and crossover-living kidney donation systems are administered by different entities, making such an "institutionalized" incentive scheme more difficult to implement. In this regard, the proposed bill presents an excellent opportunity for a potential national German crossover-living kidney donation system since it could be managed through the same institution as the German deceased-donor waitlist.

Overall, we strongly recommend not to deny compatible donor-patient pairs voluntary participation in crossover kidney donations – and indeed to inform compatible pairs about why this might be a reasonable choice to them.

[4] Other models are conceivable. The National Kidney Registry (largest program in the US) uses a voucher program https://www.kidneyregistry.org/for-centers/voucher-program/.

3 Match for the greatest medical benefit

We agree with the proposed bill that matching organ donors and patients should be designed to reach the greatest medical benefit. In our opinion, however, some of the regulations are diametral to this goal and at odds with international best practice in kidney exchange. Indeed, those regulations would very severely limit the potentially large benefits of non-directed donations and 3-way exchanges in Germany (Cseh et al. 2024).

3.1 Kidney exchange and quality of match

The proposed bill mandates that a kidney in an exchange be placed with the recipient who is the best match according to the current state of medical science, as, e.g., described on p. 17 of the proposed bill.

"Kommen für die Übertragung einer Niere mehrere Empfänger anderer inkompatibler Organspendepaare in Betracht, ist die Niere an den Empfänger zu vermitteln, der nach dem Stand der Erkenntnisse der medizinischen Wissenschaft, insbesondere nach Erfolgsaussicht und Dringlichkeit, die beste Übereinstimmung aufweist."

[DeepL translation: "If several recipients of other incompatible organ donation pairs are considered for the transfer of a kidney, the kidney is to be placed with the recipient who is the best match according to the current state of medical science, in particular with regard to the likelihood of success and urgency."]

This narrow definition of "best match", however, ignores the 'system value' of a donation, and thus potentially excludes the utilization of three-way or larger cycle exchanges, which can often significantly increase the total number of transplants. Such exchanges allow more patients to receive compatible kidneys even when a direct best match is not available within their pair.

For instance, in the example in Figure 1, suppose among the three pairs, P_1 with recipient-donor blood types A-B, P_2 with blood types B-A, and P_3 with blood types A-A, the recipient of P_3 is very highly sensitized with very few possibilities of ever finding a compatible donor. On the other hand, the donor of P_2 is compatible with him or her. Yet, suppose that the best recipient for the kidney of P_2's donor is P_1's donor because this recipient is young and has a kidney graft with the highest chance of long-term transplant success. Therefore, instead of the 3-way exchange matching all three pairs as (A-B, B-A, sensitized A-A) depicted in Figure 1, the 2-way exchange (in the same figure) with pairs P_1 and P_2 will be conducted according to the current draft of the bill. This not only leads to a reduction in the number of recipients receiving a transplant, but also the recipient of P_3 losing one of the very few chances that he or she will ever receive a kidney transplant. As a result, the drafted regulation may create an unfair outcome for a highly sensitized recipient, even though it was feasible to match all three pairs.

Thus, we strongly recommend optimizing the "weighted" number of successful transplants across the system by allowing more flexible matching criteria that can be further studied to find the desired tradeoff between the number of transplants, quality, and fairness, though possibly not providing the "best match" for individual cases. Our recommendation here is consistent with the main prioritization criterion in 8 out of 10 major kidney crossover-donation programs in Europe and the US mentioned in Biró et al. (2021) and Sönmez and Ünver (2024), which maximize the number of transplants first and consider other criteria secondary, while the other 2 use a more nuanced approach exploiting the tradeoff between

number, quality, and prioritization of certain patients or exchanges.[5] We further elaborate on our recommendation in the next subsection.

3.2 Including Non-Directed Donors

The proposed bill emphasizes the possibility of non-directed donations, and in principle allows their participation in crossover-living donor pool. However, according to the proposed bill, the kidney of a donor of a non-directed anonymous kidney donation may only be placed with a recipient of an incompatible organ donation pair if the kidney is not a better match with a patient on the waiting list, as, e.g. stated on page 63 of the proposed bill:

"*Eine nicht gerichtete anonyme Nierenspende kann danach grundsätzlich zu-gunsten einer Empfängerin oder eines Empfängers eines inkompatiblen Organspende-paars im Rahmen einer Überkreuzlebendnierenspende oder zugunsten einer Patientin oder eines Patienten in der Warteliste nach Maßgabe des § 12 Absatz 3a – neu – erfolgen. Eine Patientin oder ein Patient in der Warteliste wird aber nur dann berücksichtigt, wenn zum Zeitpunkt der Vermittlung nach § 12 Absatz 3a Satz 5 – neu – zwischen der in die Warteliste aufgenommenen Patientin oder dem in die Warteliste aufgenommenen Patienten und der Spenderin oder dem Spender eine bessere Übereinstimmung besteht. Durch diese Regelung wird sichergestellt, dass eine nicht gerichtete anonyme Nierenspende immer an die Patientin oder den Patienten vermittelt wird, bei der oder dem aufgrund der besten immunologischen Übereinstimmung, insbesondere der Gewebemerkmale, die höchste Erfolgsaussicht der Transplantation besteht. Auf diese Weise kann eine selbstlose, freiwillige Spende einer Spenderin oder eines Spenders medizinisch den größten Nutzen bewirken*."

[DeepL translation] "A non-directed anonymous kidney donation can then generally be made in favor of a recipient of an incompatible organ donor couple in the context of a living kidney donation or in favor of a patient on the waiting list in accordance with Section 12 (3a) - new. However, a patient on the waiting list will only be considered if there is a better match between the patient included on the waiting list and the donor at the time of placement in accordance with Section 12 (3a) sentence 5 - new. This provision ensures that a non-directed anonymous kidney donation is always referred to the patient with the best immunological match, particularly in terms of tissue characteristics, and who has the best chance of a successful transplant. In this way, a selfless, voluntary donation from a donor can provide the greatest medical benefit."

However, there will be almost always a better 'immediate' match on the waiting list, so non-directed donations are unlikely to be included in kidney exchange. This is a concern.

When a deceased-donor kidney is assigned to a recipient, it is reasonable to allocate it to the recipient in the deceased-donor waitlist who has the best match. After all, the decision has no effect on the supply of transplant kidneys beyond utilizing the specific deceased-donor kidney in question. However, allocating kidneys from non-directed donors to recipients in the deceased-donor waitlist requires more careful consideration, because it would mean giving up additional living-donor kidneys which become available due to the non-directed donor's kidney. Indeed, it could exclude other matches that otherwise make all patients better off.

As an example, suppose a kidney from a non-directed donor is offered to a pair in the kidney exchange pool, such that it enables at least one additional living donor to donate an even better-quality kidney to the pool, which could either generate an additional living donor as

[5] Also, the OPTN-UNOS Kidney Paired Donation Program, run by the US federal government contractor UNOS and the successor of one of these mentioned programs, has a weighted optimization policy, which considers a tradeoff between the number of transplants and certain quality, priority, and fairness metrics for especially highly sensitized recipients, developed over the years (https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf, Section 13 Page 263).

part of the chain or donated to a patient in the deceased-donor waitlist. Therefore, inclusion of non-directed donors to kidney exchange, would not only allow additional transplantations, but it also allows higher-quality kidneys to be donated to the patients. That is, even if there is a better 'immediate' match for the non-directed donor kidney in the deceased-donor list in terms of some objective function (maximizing expected life gain, maximizing the smallest remaining life, etc.), in all likelihood some of the additional kidneys that would be generated through non-directed donor chains may result in better matches.

Moreover, even if a better quality match with the waiting list patients cannot always be guaranteed, if "best match" is narrowly defined as in the proposed bill, those with good immunological properties on the waiting list sometimes will receive only slightly better organs at the cost of (highly sensitized) patients who might otherwise have no chance to be matched, which does not necessarily seem to be the ethically and medically reasonable choice.

More generally, when a kidney from a non-directed donor is assigned to a recipient in the deceased-donor waitlist, just as a deceased-donor kidney, it does not affect the supply of transplant kidneys beyond utilizing the specific non-directed donor's kidney in question. In contrast, when a kidney from a non-directed donor is utilized in the crossover-living donor pool, it enables additional (potentially several) donors who are incompatible with their co-registered recipients to also donate through non-directed donor chains, thus increasing the supply of transplant kidneys beyond the gift of the non-directed donor (see Figure 7 which expands the example in Figure 3). That is, utilizing the kidney of a non-directed donor in the kidney exchange system 'amplifies' the effect of the gift. This amplifying effect is indeed one of the reasons why donation from non-directed donors increased in the US after mid-2000s.

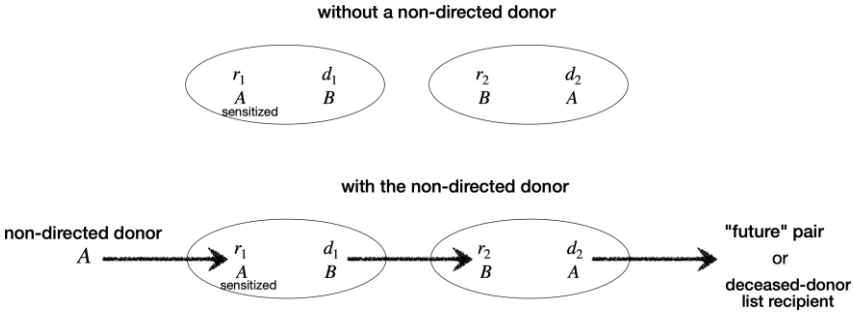

Figure 7. Amplification of non-directed donations

Therefore, the statement in the proposed bill "*In this way, a selfless, voluntary donation from a donor can provide the greatest medical benefit."* is not accurate. To provide the greatest medical benefit, the selfless gift of a non-directed donor should most often (but not necessarily always) be utilized to further increase the supply of living-donor kidneys through non-directed donor chains.

The allocation of post-mortem donated kidneys in Germany is controlled by a highly specialized algorithm managed by Eurotransplant. The specific algorithms and criteria for organ allocation are not laid down directly in the law, but in the guidelines of the German Medical Association and in coordination with Eurotransplant (see, e.g., Bundesärztekammer 2021, de Rosner et al. 2022, de Boer et al. 2024). These guidelines are based on medical and

ethical standards that are developed by expert committees and are regularly reviewed and adapted. The Federal Ministry of Health then approves these recommendations.

Accordingly, we recommend less *ex ante* regulation by the proposed bill regarding matching of non-directed donations and donations from (compatible and incompatible) donor-kidney, and rather delegate the preparation of recommendations regarding the matching criteria to an expert commission with ethical, legal and practical expertise and experience with the kidney exchange systems of our European neighbors and beyond. The goal is to develop matching algorithms according to best international practices, taking legal and ethical considerations into account, and to prevent unintended consequences as described above.

4 Three ambiguities or errors

4.1 Simultaneity of operations

There appears to be a somewhat unclear requirement involving preferably ("möglichst") simultaneity of all kidney removals in chains enabled by non-directed donors. The proposed bill states that (p. 72):

"*Bei einer Überkreuzlebendnierenspende, unabhängig davon, ob sie zwischen inkompatiblen Organspendepaaren oder unter Beteiligung einer nicht gerichteten anonymen Nierenspende erfolgt, besteht immer ein immanentes Risiko des Transplantatverlustes oder die Gefahr eines nicht vorhersehbaren anderen Umstandes, der eine erfolgreiche Übertragung der Niere verhindert. Um dieses Risiko möglichst auf alle betroffenen Organspenderinnen und -spender und Organempfängerinnen oder -empfänger gleichmäßig zu verteilen, sollen die Organentnahmen möglichst zeitgleich erfolgen*."

[DeepL translation: "In the case of a cross-living kidney donation, regardless of whether it takes place between incompatible organ donor pairs or with the participation of a non-directed anonymous kidney donor, there is always an inherent risk of transplant loss or the danger of an unforeseeable other circumstance that prevents a successful transfer of the kidney. In order to distribute this risk as evenly as possible among all affected organ donors and recipients, the organs should be removed as simultaneously as possible."]

The "simultaneity" of operations is a best practice worldwide for cyclic (e.g., 2-way or 3-way) donor exchanges between pairs in the cross-living donor pool, but not for chains initiated by non-directed donors (Roth et al. 2006). For example, in a 2-way exchange involving pairs X and Y, if the donor of pair X becomes unavailable after their co-registered patient in pair X receives a kidney from the donor in pair Y, the recipient in pair Y "loses" their willing donor without receiving a kidney, thus causing great harm. That is why simultaneity is important in these donor exchanges. For chains initiated by non-directed donors, however, the same logic does not apply. That is because, starting with the recipient who receives the kidney of a non-directed donor, each recipient in the non-directed donor chain can receive a kidney before their co-registered donor donates their kidney. With this sequence of transplants, there is no risk of harm to any recipient, even if some donor changes their mind and fails to donate after their recipient receives a transplant. The donor of the "next" recipient in the chain (who is still waiting for a kidney) has not yet donated a kidney, and thus the pair remain available to be matched on a future occasion.

In the US, such chains are called never-ending altruistic donor chains. It became one of the main ways kidney exchanges are performed in some kidney exchange programs including

National Kidney Registry which is the largest multi-center kidney exchange program in the world.

On the contrary, requiring simultaneity for non-directed donor chains limits the number of incompatible pairs who can benefit from the gift of non-directed donor (due to logistical considerations), and thus also limiting the supply of living donor kidneys in the system.

Summing up, we strongly recommend that the anonymous gift of a non-directed donor can and should almost always be utilized to further increase the supply of living-donor kidneys through non-directed donor chains. Moreover, we recommend clarifying that the simultaneity requirement does not hold for chains of kidney donations initiated by anonymous non-directed donors.

4.2 Exclusion of liver from crossover-living liver donation system

In addition to 608 living-donor kidney transplants performed in Germany in 2023, there have been 52 living-donor liver transplants. Thus, while the potential number of recipients from crossover-donor liver transplantation system may be a fraction of those from crossover-donor kidney transplantation, as many as 10-15 recipients annually may still benefit from inclusion of liver to the proposed bill.

Justification for the exclusion of kidney is given as follows in the proposed bill (p. 61)

„Für die Leber ist eine Erweiterung der Möglichkeiten einer Überkreuzlebendspende und einer nicht gerichteten anonymen Spende darüber hinaus auch nicht erforderlich. Eine wichtige Voraussetzung für eine Transplantation ist die Blutgruppenverträglichkeit sowie eine möglichst große Übereinstimmung der Gewebemerkmale (sogenanntes individuelles HLA-System (humanes Leukozyten-Antigen-System)). Diese Faktoren spielen aus immunologischer Sicht eine wesentliche Rolle bei der Feststellung, ob die Gefahr für eine Trans-plantatabstoßung gering und eine Organspende möglich ist. Der Grad der Übereinstimmung, die zwischen der Spenderin oder dem Spender und der Empfängerin oder dem Emp-fänger bestehen muss, ist bei verschiedenen Organen unterschiedlich. Bei einer Nieren-transplantation beispielsweise ist es sehr wichtig, eine weitgehende Übereinstimmung der HLA-Merkmale und damit eine möglichst gut passende Spenderin oder einen möglichst gut passenden Spender zu finden. Bei einer Lebertransplantation hingegen muss nicht auf die Übereinstimmung der HLA-Merkmale geachtet werden. Bei hochimmunisierten Nierenpatientinnen und Nierenpatienten ist es daher sehr schwierig, eine passende Nierenspenderin oder einen passenden Nierenspender zu finden. Bei einer fehlenden HLA-Inkompatibilität zwischen einem Organspendepaar, bei dem die Spenderin oder der Spender der Empfängerin oder dem Empfänger zwar spenden möchte, es aber aus immunologischen Gründen nicht kann, ist daher die Überkreuzlebendspende eine Option für eine Lebendnieren-spende. Die Zulassung einer Überkreuzlebendnierenspende erhöht die Wahrscheinlichkeit gerade bei hoch immunisierten Patientinnen und Patienten, die eine Nierentransplantation benötigen und die oftmals jahrelang in der Warteliste für eine Nierentransplantation stehen, eine passende Organspenderin oder einen passenden Organspender zu finden. Die Notwendigkeit einer Überkreuzlebendspende aus Gründen einer HLA-immunologischen In-kompatibilität besteht bei der Leberlebendspende nicht."

[DeepL translation: "For the liver, it is not necessary to extend the possibilities of cross-donation and nondirected anonymous donation. An important prerequisite for transplantation is blood group compatibility and the closest possible match of tissue characteristics (so-called individual HLA system (human leukocyte antigen system)). From an immunological point of view, these factors play a key role in determining whether the risk of transplant rejection is low and organ donation is possible. The degree of match that must exist between the donor and the recipient is different for different organs. In the case of a kidney transplant, for example, it is very important to match the HLA characteristics as closely as possible and thus find the best possible donor. In the case of a liver transplant, on the other hand, it is not necessary to match the HLA characteristics. It is therefore very difficult to find a suitable kidney donor for highly immunized kidney patients. In the absence of HLA incompatibility between a pair of organ donors, where the donor wishes to donate to the recipient but is unable to do so for

immunological reasons, crossover living donation is therefore an option for living kidney donation. The approval of a living crossover kidney donation increases the probability of finding a suitable organ donor, especially for highly immunized patients who require a kidney transplant and who are often on the waiting list for a kidney transplant for years. There is no need for a crossover living donation for reasons of HLA-immunological incompatibility in the case of living liver donation."]

It is true that HLA-incompatibility is not an important consideration for living-donor liver transplantation. However, since a living donor only gives a lobe of their liver (rather than a whole organ as in the case of kidney), there is another important consideration: Size incompatibility. An otherwise medically feasible liver graft of a donor can be too small for their co-registered donor. For example, consider a scenario in which a blood-type A recipient requiring a minimum of 800 ml of liver graft (as he weighs 100 kg) cannot receive a donation from his co-registered donor with a right liver lobe of 500 ml, although they are blood-type compatible. Suppose there is another pair with an O blood-type recipient, who has a modest minimum graft size requirement (e.g., 450 ml), and an A-blood-type donor, whose right liver lobe is relatively large (e.g., 850 ml). Then, a 2-way liver exchange between these two pairs saves both of their lives (see Figure 8).

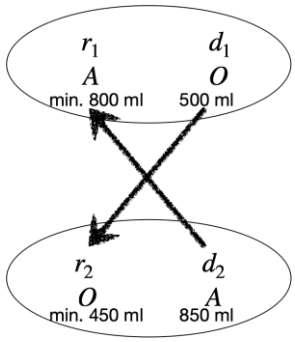

Figure 8. Liver exchange

Moreover, in case of pediatric recipients, the liver lobe from the intending donor can also be too large. In the Living-Donor Liver Transplantation Consensus Conference, Sturdevant et al. (2022) indicated that 14% of potential living liver donors are declined in the US due to size incompatibility. This number is much higher at Liver Transplant Institute at Inonu University, Malatya-Turkey where Sönmez and Ünver launched a crossover-donor liver donation system in 2022. As we indicated earlier in Section 2, the system increased the number of living-donor liver transplants by 24.2% (45 of the 231 living-donor liver transplants) in 2023.

In our opinion, a well-designed national crossover-donor liver donation system has the potential to provide similar benefits in Germany.

4.3 Correction of cost estimates

Finally, we would like to correct a cost estimate regarding the usage of KEPsoft. KEPsoft is a well-established, not-for-profit (EU-funded) software solution, based on the current state of the art of matching technology, and can be adapted in Germany as required. (None of us is associated with the software.) It is already used by several European countries and piloted by others.

On pages 48/49 of the proposed bill it is stated that KEPsoft essentially requires an investment of €530,000, of which €500,000 is for infrastructure adjustments to meet the requirements. This is not correct. While such investment costs, or more, would be expected if the software were to be developed from scratch (which we do not recommend), there are in fact no investment costs associated with KEPsoft, as well as with other professional and academically developed software. The only cost of KEPsoft would be for maintenance and is around €30,000 per year (assuming no extensive customization is required). As explained by Cseh et al. (2024):

> "Bei einer Neuentwicklung ist nach unserer Einschätzung je nach Professionalität und Erfahrung des Anbieters mit Anschaffungskosten von ca. 500.000 bis 1.000.000 Euro für Datenbank und Software zu rechnen. Davon entfallen ca. 10% auf die Datenbank, 35% auf die Benutzeroberfläche, 20% auf das HLA-Modul und 35% auf das Optimierungsmodul.
>
> Alternativ stehen Praxiserprobte und bewährte Softwarelösungen zur Verfügung, die den gegenwärtigen Stand der Wissenschaft abbilden und bei Bedarf angepasst werden können. So steht z.B. die von der EU geförderte Software KEPsoft Deutschland als EU-Land zur Verfügung. Hier entfallen die Anschaffungskosten.
>
> [...] Der personelle Aufwand für die Pflege einer entsprechenden Datenbank ist unseres Erachtens gering. Allerdings können im Laufe der Zeit Anpassungen der Software notwendig werden. Den Programmieraufwand schätzen wir bei einer kommerziellen, neu entwickelten Lösung auf ca. 80.000 Euro pro Jahr. Die Wartungs- und Unterstützungskosten für eine not-for-profit Softwarelösung wie KEPsoft liegen bei ca. 30.000 Euro pro Jahr. In diesen Kosten ist die Wartung der Datenbank enthalten."

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