ORIGINAL ARTICLE

The ELPAT living organ donor Psychosocial Assessment Tool (EPAT): from 'what' to 'how' of psychosocial screening – a pilot study

Emma K. Massey[1] (iD), Lotte Timmerman[1], Sohal Y. Ismail[2], Nathalie Duerinckx[3,4], Alice Lopes[5], Hannah Maple[6] (iD), Inês Mega[7], Christina Papachristou[8] & Fabienne Dobbels[3], On behalf of the ELPAT Psychosocial Care for Living Donors and Recipients Working Group

1 Department of Internal Medicine, Erasmus Medical Centre, Rotterdam, The Netherlands

2 Department of Psychiatry, Erasmus Medical Centre, Rotterdam, the Netherlands

3 Department of Public Health and Primary Care, Academic Centre for Nursing and Midwifery, KU Leuven - University of Leuven, Leuven, Belgium

4 Heart Transplant Program, Department of Cardiovascular Sciences, University Hospitals of Leuven, Leuven, Belgium

5 Psychiatry and Health Psychology Unit, Centro Hospitalar do Porto, Porto, Portugal

6 Guy's and St Thomas' NHS Foundation Trust and King's College London, London, UK

7 Hepato-Biliar-Pancreatic and Transplantation Center, Hospital Curry Cabral, Lisbon, Portugal

8 Department for Psychosomatic Medicine, Charité-Universitäts-smedizin Berlin, Berlin, Germany

Correspondence
Emma K. Massey, Internal Medicine, Section Nephrology & Transplantation, Erasmus Medical Centre, Room NA-510, PO Box 2040, 3000 CA Rotterdam, The Netherlands.
Tel.: +31 10 70 32442;
fax: +31 (0)10 703 40 94;
e-mail: e.massey@erasmusmc.nl

SUMMARY

Thorough psychosocial screening of donor candidates is required in order to minimize potential negative consequences and to strive for optimal safety within living donation programmes. We aimed to develop an evidence-based tool to standardize the psychosocial screening process. Key concepts of psychosocial screening [1] were used to structure our tool: motivation and decision-making, personal resources, psychopathology, social resources, ethical and legal factors and information and risk processing. We (i) discussed how each item per concept could be measured, (ii) reviewed and rated available validated tools, (iii) where necessary developed new items, (iv) assessed content validity and (v) pilot-tested the new items. The resulting ELPAT living organ donor Psychosocial Assessment Tool (EPAT) consists of a selection of validated questionnaires (28 items in total), a semi-structured interview (43 questions) and a Red Flag Checklist. We outline optimal procedures and conditions for implementing this tool. The EPAT and user manual are available from the authors. Use of this tool will standardize the psychosocial screening procedure ensuring that no psychosocial issues are overlooked and ensure that comparable selection criteria are used and facilitate generation of comparable psychosocial data on living donor candidates.

Introduction

One option to alleviate the shortage of kidneys and livers for transplantation is living donation. The advantages of receiving an organ from a living donor compared to one from a deceased donor are manifold. There is a reduction in waiting time and in the case of pre-emptive transplantation, avoidance of dialysis, which further minimizes the negative impact on the recipient's quality of life and physical condition. Due to the extensive medical workup undertaken by living donors, the organ is known to have come from someone who is healthy and free from disease. This means that the organ is in optimal condition and, due to a planned operation, both the warm and cold ischaemic times are kept to a minimum. These factors all contribute to superior outcomes when compared to recipients of deceased donor organs [1,2].

Over the past decades, there has been an exponential growth in living donation programmes; kidney donation in particular. Initially, donors and recipients were genetically related, such as parents and siblings ('specified donors') [3]. This has gradually expanded to include genetically unrelated donors, such as partners and friends ('specified donors'), and those who donate to an unrelated and unknown person ('unspecified living donors') [4,5].

The current evidence indicates that when living donors are appropriately screened and selected, long-term physical and psychological morbidity is limited, and there is no impact on life span [6–14]. Recent studies in living kidney donors have shown that there may be a small increased relative risk of end-stage renal failure when compared to matched healthy nondonors, however, the absolute risk remains low [15,16]. Living *liver* donation is a more risky procedure for the donor than living *kidney* donation [17]. However, health-related quality of life has been shown to recover to baseline after liver donation and be higher than general population norm scores [18], as is the case with kidney donors [9]. Furthermore, among liver and kidney donors, interpersonal relationships appear to remain the same or improve after donation [7] and the majority of donors do not regret their decision [19].

A minority of donors nevertheless report negative outcomes. More specifically, postdonation depressive or anxiety symptoms have been reported in 5–23% and 6–14% of cases, respectively [7]. Six percent to 22% report finding the surgery/postoperative period stressful [7]. Concerns/worries include living with one kidney, complications of nephrectomy, insult to own health, future kidney problems and needing a transplant themselves in the future, medical costs and loss of income, acquisition of insurance and recipient outcomes [7]. Family conflicts, disappointment, deterioration in body image, feeling ignored, a lack of appreciation, sadness or loss have also been reported [7,20–24]. Medical complications experienced by the recipient or donor have been shown to be predictive of an increase in psychological symptoms 1 year after kidney donation [25]. One study reported that in cases when the graft failed or the recipient died, 8% experienced suicidal ideations [26]. In living liver donors, a recent study identified five groups of donors with varying psychosocial outcomes, of which one (31%) reported reduced physical and socio-economic outcomes and only limited psychological benefit [27]. In summary, although living donation is generally a safe procedure from a psychosocial perspective, a proportion of living kidney and liver donors also experience negative consequences. Hence, transplant professionals have a duty of care to screen, evaluate and provide after-care for living organ donors.

In order to minimize these potential negative consequences and to strive for better safety outcomes within living donation programmes, thorough psychosocial screening of donor candidates is required. To date, many psychosocial screening guidelines and protocols have been produced for specified [28–37] and unspecified liver and kidney donors [4,5,38–43]. There is, however, no broadly accepted 'gold standard', and the content and process of psychosocial screening have been shown to differ between centres and countries. Guidelines published on the psychosocial evaluation of living donors mainly originate from the United States, are very broad and tend to list only topics of *what* needs to be addressed, whilst concrete recommendations on *how* screening should be performed are missing [35].

Consequently, the interpretation of these guidelines varies substantially, leading to large differences in screening practices and differential treatment of potential donors. Specifically, the criteria used to screen living donors in clinical practice varies extensively [32]. Although 60% of centres seem to perform routine psychosocial screening by a psychologist or psychiatrist [44], less than 50% of them use standardized protocols and/or validated tools [32]. Similarly, process-related factors are under-reported in the currently available guidelines, protocols and programme descriptions [32]. Whilst most medical guidelines provide an overview of specific clinical or laboratory tests that should be performed to describe the medical profile of a prospective donor and their associated cut-off values, the current

psychosocial guidelines do not recommend which tools or tests should be used to carry out standardized and comparable psychosocial screening of living donors. Moreover, some European centres only perform an in-depth psychosocial screening for unspecified (anonymous) donors [44].

One recent development in this field is the development of the Living Donor Assessment Tool (LDAT) [45]. This useful tool is the only one currently available that outlines how screening should be conducted in practice. The LDAT provides guidance on donation-specific issues; however, it does not integrate validated measures on generic constructs such as depression and anxiety which are essential components of psychosocial screening. Furthermore, not all areas pertinent to living donor screening are included in the LDAT, such as health literacy and resilience.

The main aim of this paper was therefore to present the development of the ELPAT living organ donor Psychosocial Assessment Tool (EPAT) and associated procedures for implementation. We present a complete package that can be used as an initial psychosocial screening of living donor candidates to identify candidates that require further assessment and/or support during the donation process.

Tool development

Collaborators

This project was conducted by the members of ELPAT. ELPAT is a European Platform on the Ethical, Legal and Psychosocial Aspects of organ Transplantation and is a subdivision of the European Society for Organ Transplantation (ESOT). The core collaborators in this project were from the working group 'Psychosocial care for living donors and recipients' ($n = 9$). Collaborators were psychologists ($n = 7$: FD, EM, LT, IM, SI and CP), a surgeon ($n = 1$, HM), a psychiatrist (AL) and a transplant clinical nurse specialist ($n = 1$, ND) working in Belgium, Germany, the Netherlands, Portugal and the United Kingdom.

Procedure

First, we conducted a systematic review which highlighted the lack of agreement regarding which criteria to use in psychosocial screening of living kidney or liver donors [32]. One hundred and ninety-seven unique screening criteria were reported over all the studies reviewed. We concluded that donor screening criteria

vary extensively across protocols. This review also highlighted that there was little consensus regarding the definition of what 'psychosocial' means within the context of donor screening. The study by Ismail *et al.*[46] brought clarity to this issue by clustering the 197 psychosocial screening criteria reported by Duerinckx *et al.* using a rigorous concept mapping methodology. These criteria were rated on importance in differentiating between high- and low-risk candidates and how commonly the criteria were applied in current clinical practice. Analyses of these ratings resulted in six clusters of screening criteria representing the most important and commonly used criteria: (i) motivation and decision-making; (ii) personal resources; (iii) psychopathology; (iv) social resources; (v) ethical and legal factors; and (vi) information and risk processing. These six key concepts of psychosocial screening were used as a basis to structure our tool. To translate the concepts into practical tools for implementation, we discussed how each item could be measured, by whom and under which conditions. For some concepts, such as depressive symptoms, validated instruments already existed. For donation-specific items, validated instruments were often not available, and therefore, development of interview questions was necessary.

Validated questionnaires

We searched the literature for appropriate validated instruments and held brainstorm sessions to list potentially relevant measures. Reviews in which psychometric properties of instruments were assessed informed our choice whether or not to include these instruments in our own evaluation [47, 48]. An initial selection of instruments was made per cluster. These were rated on a standardized form by two independent raters on the following aspects: addresses the psychosocial criterion under investigation, previous use in the liver or kidney transplant setting, number of items, length of time to complete, availability in multiple languages, training requirements to administer, availability of a handbook, copyright and costs of use. Psychometric properties were also evaluated as follows: sensitivity, specificity, criterion validity, construct validity and reliability. Criteria described by Vandenbroeck *et al.* and Kimberlin *et al.* were used [49, 50]. Table 1 shows the questionnaires evaluated per domain and a summary of the pros and cons per instrument. We considered those measures with under 10 items as brief. A process of review and discussion took place to come to a consensus on the most appropriate measures (2012–2017). In order to

Table 1. Validated questionnaires considered for inclusion in the EPAT screening tool.

Measure evaluated	Inclusion/ exclusion	Considerations: positive	Considerations: negative
Motivation and decision-making			
Simmons Ambivalence Scale (SAS) [51]	Excluded	Addresses the criterion under investigation, used in transplant setting.	Manual not widely available, copyright @ Roberta G. Simmons, languages not known, interview deemed more appropriate.
Personal resources			
The Brief Resilience Scale (BRS) [52]	Included	Addresses the criterion under investigation (i.e. resilience), brief (6 items), satisfactory psychometric properties, no training required, no copyright, free access.	Not used in transplant setting, no handbook available, available in few languages (English, Chinese).
The Connor-Davidson Resilience Scale (CD-RISC) [53]	Excluded	Addresses the criterion under investigation, handbook available (via website), available in many languages, no training required, brief version available, satisfactory psychometric properties.	Not used in transplant setting, length (25 items), permission for use required from author.
The Resilience Scale for Adults (RSA) [54]	Excluded	Addresses the criterion under investigation, available in many languages, satisfactory psychometric properties.	Length (33 items), not used in transplant setting, training requirements not found, no handbook available, copyright required.
Living Donor Expectations Questionnaire (LDEQ) [55]	Excluded	Used in transplant setting, no copyright, no training required.	Measures expectations rather than resilience, length (42 items), no handbook, available in few languages, limited testing of psychometric properties.
The Marlowe-Crowne Social Desirability Scale (MCS) [56]	Excluded	Addresses the criterion under investigation, brief versions available, used in transplant setting, available in many languages, no copyright.	Length (33 items), face validity questionable.
Balanced Inventory of Desirable Responding (BIDR) [57]	Excluded	Addresses the criterion under investigation, handbook available, available in many languages, no copyright, no training required.	Length (40 items), not used in transplant setting.
Social Desirability Scale-17 (SDS-17) [58]	Excluded	Training not required, no copyright, satisfactory psychometric properties.	Not used in transplant setting, length (17 items), no handbook available.
Psychopathology			
Patient Health Questionnaire-9 & -2 (PHQ-9 and PHQ-2) [59,60]	Included	Addresses the criterion under investigation (i.e. depressive symptoms), very brief versions available, used in transplant setting, handbook available, self-administration, available in many languages, satisfactory psychometric properties. Available from www.phqscreeners.com.	Copyright @ Pfizer (subject to terms but free to use).
General Anxiety Disorder Questionnaire (GAD-7 and GAD-2) [61]	Included	Addresses the criterion under investigation (i.e. anxiety symptoms), very brief versions available, used in transplant setting, handbook available, self-administration, available in many languages, satisfactory psychometric properties.	Copyright @ Pfizer (subject to terms but free to use).
Hospital Anxiety and Depression Scale (HADS) [62]	Excluded	Addresses the levels of anxiety and depression that a patient with physical health condition is experiencing, used in the transplant setting, available in many languages, satisfactory psychometric properties.	Length (14 items), Copyright© GL Assessment.

Table 1. Continued.

Measure evaluated	Inclusion/exclusion	Considerations: positive	Considerations: negative
Brief Symptom Inventory (BSI-18) [63]	Excluded	Addresses the criterion under investigation, used in transplant setting, handbook available, self-administration, available in multiple languages, satisfactory psychometric properties.	Copyright @Pearson. Longer than alternative measures.
Brief Psychiatric Rating Scale-extended (BPRS-E) [64]	Excluded	Addresses the criterion under investigation, used in transplant setting, handbook available, available in many languages, no copyright, satisfactory psychometric properties.	Length (24 items).
Standardized Assessment of Personality-Abbreviated Scale (SAPAS-SR) [65]	Included	Addresses the criterion under investigation (i.e. personality), brief (8 items), self-administration, no copyright, available in some languages (English, Dutch, German), satisfactory psychometric properties.	Not used in transplant setting, no handbook available.
IOWA Personality Disorder Screen (IPDS) [66]	Excluded	Addresses the criterion under investigation, self-administration, relatively brief (11 items), administration and scoring guidelines available, available in some languages (English, Dutch, Norwegian), satisfactory psychometric properties.	Not used in transplant setting, copyright @University of Iowa.
Modified MMSE (3MS) [67]	Excluded	Addresses the criterion under investigation, used in transplant setting, handbook available, satisfactory psychometric properties.	Training required, length (15 items), copyright @ Teng & Chui (1987), available in few languages (English, French).
Addenbrooke's Cognitive Examination-III (ACE-III) [68]	Excluded	Detects suspected dementia and mild cognitive impairments, used among chronic kidney disease patients, available in some languages (English, Spanish, Thai), satisfactory psychometric properties, free access with registration, copyright held by John Hodges, short version available (MINI-ACE)[69].	For patients over 60 years old and/or those with a pre-existing illness, length, training required (available online).
Montreal Cognitive Assessment (MoCA) [70]	Excluded	Addresses the criterion under investigation, used in transplant setting, handbook available, available in many languages, satisfactory psychometric properties, free access with registration via www.mocatest.org.	Training required, length (16 items), copyright @ Z. Nasreddine.
Social resources			
ENRICHD Social Support Inventory (ESSI) [71]	Included	Measures perceived social support, brief (five items), satisfactory psychometric properties, no copyright, self-administered, training not required.	Manual not available, not used in the transplant setting.
Social Provisions Scale (SPS) [72]	Excluded	No training required, no copyright.	Items on perceived support only. Length (24 items), not used in a transplant setting, availability of manual unclear, questionable reliability.
Inventory of Socially Supportive Behaviors (ISSB) [73]	Excluded	Items on frequency of support received, satisfactory psychometric properties, used in transplant setting, short form available, manual available, no training required, no copyright.	Length (40 items) did not sufficiently address the psychosocial criterion under investigation (no consideration of deficiencies in social interactions).
Personal Resources Questionnaire (PRQ) [74]	Excluded	Satisfactory psychometric properties, used in transplant setting.	Length (11 items with many subitems), manual not available, appears complex (depends on living situation of the person).

Table 1. Continued.

Measure evaluated	Inclusion/exclusion	Considerations: positive	Considerations: negative
Medical Outcomes Social Support Scale – Tangible Support (MOSS-TS) subscale [75]	Included	Addresses the criterion under investigation (i.e. tangible support), used in transplantation, manual available, brief, no training required, available in multiple languages, no copyright, satisfactory psychometric properties, available at www.rand.org.	
Information and risk processing			
MacArthur Competence Assessment Tool – Treatment (MacCAT-T) [76]	Excluded	Addresses the criterion under investigation, used in transplant setting, handbook available, satisfactory psychometric properties.	Training required, length (15–20 min), copyright required.
Hopemont Capacity Assessment Interview (HCAI) [77]	Excluded	Addresses the criterion under investigation, handbook available.	Not used in transplant setting, length (30–60 min), training required, copyright required, available in few languages, limited testing of psychometric properties.
Capacity to Consent to Treatment Instrument (CCTI) [78]	Excluded	Addresses the criterion under investigation, satisfactory psychometric properties.	Not used in transplant setting, length (20–25 min), training required, copyright unclear, available in few languages.
Newest vital signs (NVS) [79]	Excluded	Addresses the criterion under investigation, used in transplant setting, brief (six items), available in multiple languages (English, Spanish, Dutch, Turkish), handbook available, satisfactory psychometric properties, available at www.pfizerhealthliteracy.com.	Some training required, relevance of an ice-cream label to healthcare setting questioned.
Test of Functional Health Literacy in Adults (TOFHLA) [80]	Excluded	Addresses the criterion under investigation, used in transplant setting, handbook available, satisfactory psychometric properties.	Length of original version (67 items), short form available (40 items), training required, copyright required, available in few languages (Spanish, English).
Health literacy item [81,82]	Included	Addresses the criterion under investigation (i.e. health literacy), used in transplant setting, brief (one or three items), good internal consistency, evidence for predictive validity of a single item.	Availability in few languages.
Rotterdam Renal Replacement Knowledge Test (R3K-T) [83]	Excluded	Addresses the criterion under investigation, used in transplant setting, self-administered, no copyright, available in multiple languages.	No handbook available, length (21 items).

minimize barriers to using the tool and maximize quality, priority was given to measures that were easy to access and implement in practice (e.g. no copyright or fees) and those that had strong psychometric properties. When multiple measures of equal quality were available, the briefest measure was chosen for pragmatic reasons and to limit burden.

During this process, we considered including a social desirability measure in the personal resources domain. However, consensus was achieved that it was not appropriate for the purpose of donor screening and that donor candidates might question the relevance of this type of question in this context. Social desirability can be assessed in a second phase if deemed necessary, in which case the Social Desirability Scale-17 (SDS-17) is recommended. Similarly, when considering the content of the psychopathology domain, we considered assessing cognitive impairment. However, again we felt that this should be assessed only upon indication, in which case the Addenbrooke's Cognitive Examination-III (ACE-III) appears to be an accurate measure of this construct [84].

Interview

In each cluster, items were generated when there was no validated measure available. We used an iterative approach of design, testing and redesign until consensus was reached within the group on content and wording, and until testing did not reveal issues warranting further revision.

First, open-ended questions were drafted per item in the cluster. The concept items were subsequently pilot-tested on 12 potential living donors in one of the collaborating transplant centres. Overall, donor candidates appreciated the opportunity to extensively discuss their thoughts on donation. These 'case-studies' were discussed within the working group which helped refine the wording of the questions, question order, layout and interpretation of the answers given.

We subsequently conducted a content validity assessment on the refined interview questions according to the principles of Polit and Beck (2007). Content validity is defined as 'the degree to which an instrument has an appropriate sample of items for the construct being measured' [85]. Typically, five or more raters are needed in the first round of content validity evaluation. We invited seven professionals who conduct living donor screening in their daily practice to rate the interview questions. These raters scored the individual items according to a 4-point Likert scale ranging from not at

all relevant (1) to highly relevant (4) in the context of psychosocial screening of donor candidates. Raters also gave explanations for their ratings in the form of open text. For each item, the content validity index on item level (I-CVI) was computed as the number of experts who gave a rating of 3 or 4, divided by the number of experts. A target of ≥0.78 indicates good item-level content validity. Content validity index on scale-level unanimous agreement (S-CVI/UA) is computed as the proportion of items for which there is unanimous agreement on relevance among experts (S-CVI/UA). Content validity index on scale-level average agreement (S-CVI/Ave) is computed as an average across I-CVI's. Targets of ≥0.80 and ≥0.90 for the 'universal agreement' (S-CVI/UA) and 'average' (S-CVI/Ave) calculation respectively indicate good scale-level content validity.

After the first round, the S-CVI/UA was 0.76 and the S-CVI/Ave was 0.89. Ten out of an original set of 41 items had a suboptimal I-CVI and were revised by the group. Some items were reformulated for enhanced clarity and precision. All feedback from the raters was discussed until a consensus was reached among the working group members. The revised items were returned to three raters (two original raters to check revisions and one new rater), which resulted in 100% item and scale-level content validity indices. Additional items were added to round off the interview and check that information was complete.

The ELPAT living organ donor Psychosocial Assessment Tool (EPAT)

The final selection of validated questionnaires chosen for inclusion in the tool and an overview of the administration properties are shown in Table 2. The final semistructured interview consists of 43 items. Below we present the chosen validated measures and summarize the interview items per cluster as reported by Ismail *et al.* [46]. To illustrate the EPAT, we present the cluster 'Psychopathology' in its entirety in Table 3. To accompany the tool, we developed a user manual and a Red Flag Checklist (see Figure 1) for use during the interview in clinical practice. Key implementation and interpretation guidelines are highlighted below. The complete EPAT package is available from the first and last authors.

Motivation and decision-making

There were no appropriate measures found to assess the concepts in this cluster. Sixteen items were included in

Table 2. Validated questionnaires included in the ELPAT living donor Psychosocial Assessment Tool (EPAT).

Measure	Concept	Cluster	Items (n)	Answer categories	Scale range	Scoring	Cut-off	Cronbach's α	Time frame	Minutes to complete
Health literacy [81,82]	Health literacy	Information and risk processing	1	1 (none of the time) to 5 (all of the time)	1–5	–	1–2 indicates inadequate health literacy	0.75	At this moment in time	<1
ESSI [71]	Social support	Social resources	5	1 (none of the time) to 5 (all of the time)	5–25	Sum	≤18	0.95	None	5
MOSS-TS [75]	Tangible support	Social resources	4	1 (none of the time) to 5 (all of the time)	1–5	Mean	No specific cut-off; higher scores reflect higher tangible support	0.92	None	2
PHQ-2 [59]	Depressive symptoms	Psychopathology	2	0 (not at all) to 3 (nearly every day)	0–6	Sum	≥3 refer for further assessment	0.78	Past 2 weeks	1
GAD-2 [61]	Anxiety symptoms	Psychopathology	2	0 (not at all) to 3 (nearly every day)	0–6	Sum	≥3 refer for further assessment	0.75	Last 2 weeks	1
SAPAS-SR [65]	Personality	Personality	8	0 (no) or 1 (yes)	0–8	Sum	≥3 YES, refer for further assessment	0.68	Most of the time	5–10 [86]
BRS [52]	Resilience	Personal resources	6	1 (strongly disagree) to 5 (strongly agree)	1–5	Mean	No specific cut-off; higher scores reflect higher ability to bounce back after stressful events	0.80–0.91	None	2–5

ESSI, ENRICHD Social Support Instrument; MOSS-TS, Medical Outcomes Social Support Scale – Tangible Support; PHQ-2, Patient Health Questionnaire-2; GAD-2, Generalized Anxiety Disorder Questionnaire; SAPAS-SR, Standardized Assessment of Personality – Abbreviated Scale; BRS, Brief Resilience Scale.

Table 3. EPAT cluster 'Psychopathology'.

Questionnaires			
The following questions are about your mood or emotions. Over the past 2 weeks, how often have you been bothered by any of the following problems?* Circle one number on each line to indicate your answer.			
	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3
Over the *last 2 weeks*, how often have you been bothered by the following problems?† Circle one number on each line to indicate your answer.				
	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	1	2	3
Not being able to stop or control worrying	0	1	2	3

Interview questions

Now I would like to talk about possible psychological issues you may have had in the past. I want to emphasize that is to help highlight any potential risks of donation so we can provide the best possible care for you and avoid any problems for you after donation.

-Have you ever experienced a phase in your life when you had psychological problems (e.g. feeling depressed or anxious, sleeping problems, drinking more or smoking more than usual or taking drugs)? If yes, how did this impact your daily functioning? *(See answers on the PHQ-2 and GAD-2 for input).*

-Have you ever received psychological or psychiatric treatment (counselling or psychopharmacologic medications)? If yes, what for and is this ongoing? *(If they are currently undergoing treatment: ask permission to contact this professional to obtain more information)*

-How often do you have problems with concentration or memory?

*The Personal Health Questionnaire-2 (PHQ-2).
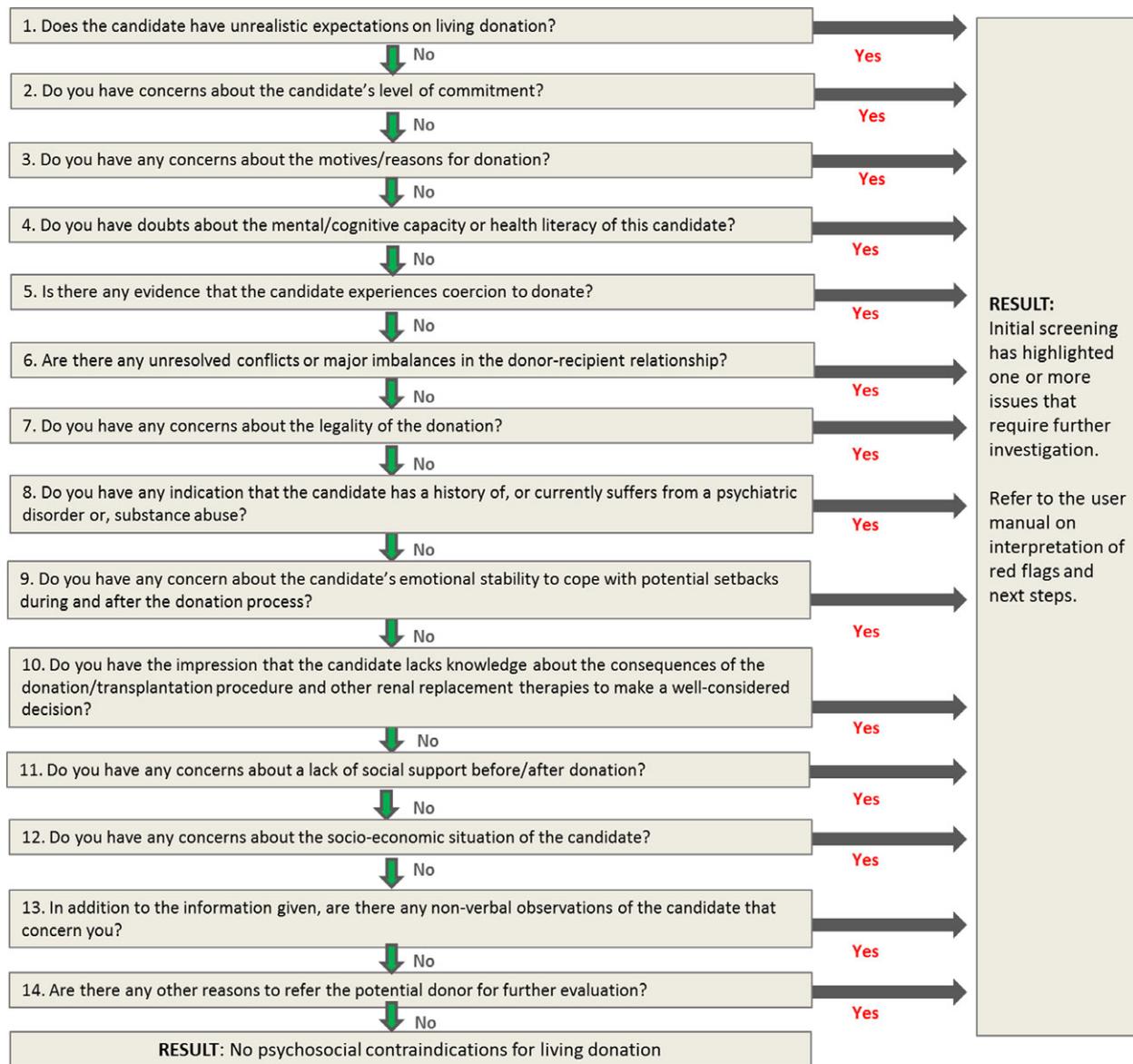
†The Generalized Anxiety Disorder Questionnaire (GAD-2).

Figure 1 Red Flag Checklist to accompany the EPAT.

the interview to assess the decision-making process, motivation, the donor–recipient relationship, pressure to donate and ambivalence.

Personal resources

The concept 'resilience' was selected as it focuses on bouncing back from stress which we felt appropriate in the context of living donation. The Brief Resilience Scale (BRS) [52] was included for its strong psychometric properties and because it is the shortest of the three resilience scales recommended by these authors [47]. Four items on stressors and coping were included in the interview.

Psychopathology

The Patient Health Questionnaire-2 (PHQ-2) was included to measure depressed mood and anhedonia [59]. The purpose of the PHQ-2 is not to establish a diagnosis or to monitor depression severity, but to serve as an initial screen for core symptoms of depression. Strong psychometric properties have been described, with a sensitivity of 83% and specificity of 92% to detect depressive symptoms [48,59,87]. The Generalized Anxiety Disorder Questionnaire (GAD-2) was included to measure anxiety [61]. Similar to the PHQ-2, the purpose is to screen for symptoms of an anxiety disorder. Sensitivity and specificity to detect any anxiety

disorder are reported to be 65% and 88%, respectively [61]. The self-report version of the Standardized Assessment of Personality – Abbreviated Scale (SAPAS-SR) was included to measure symptoms of a personality disorder [65,88]. Sensitivity and specificity of detecting personality disorders have been reported to be 83% and 80%, respectively [86]. Three items were included in the interview to assess previous psychopathology, treatment and memory.

Social resources

The ENRICHD Social Support Instrument (ESSI) [71] was included to measure social support. This scale assesses structural, instrumental and emotional support. There is evidence to support its convergent and divergent validity [71] and criterion validity [89]. In addition, the Medical Outcomes Social Support Scale – Tangible Support (MOSS-TS) subscale [75] was included to measure tangible support which was not sufficiently represented in the ESSI. There is evidence for concurrent, convergent and discriminant validity as well as reliability. Nine items were included in the interview to assess support for donation, employment and the financial situation of the candidate.

Ethical and legal factors

There were no appropriate measures found to assess concepts in this cluster. Three items were included in the interview to assess the impact of donation on (future) insurability and the possibility of follow-up after donation.

Information and risk processing

A single item was included to briefly screen health literacy [81,82]. Evidence suggests that this item can accurately identify patients with limited or marginal health literacy [90,91]. Five items were included in the interview to assess understanding of the donation process and associated risks.

Closing

Three items were included in the interview to assess questions the candidate may have their commitment and awareness of their right to withdraw at any time.

Implementation and interpretation

This tool has been designed to assess all living donor candidates (kidney and liver), irrespective of the donor–recipient relationship or whether the donation is to a specified or unspecified recipient. It should be conducted after initial medical screening (e.g. blood tests and review of past medical history) and prior to embarking on full medical evaluation. It is essential that the psychosocial evaluation is conducted before making a decision about suitability to donate so that results of the psychosocial screening are included in the decision-making process by the multidisciplinary team.

The EPAT should be conducted in its entirety to ensure that the screener has a complete picture of all the issues per candidate to present to the multidisciplinary team and, if needed, for referral purposes. Depending on the case and the screener, more than one session may be necessary. Pilot testing of the entire EPAT among three donor candidates suggested that the tool takes 60–90 min to conduct depending on the number and complexity of issues raised, as well as the experience of the screener. The questionnaires should be completed prior to the interview, (ideally in the order presented in Table 2), and in the absence of third parties (e.g. the potential recipient or family members). The single item on health literacy should be administered first so that the screener can offer support in completing the questionnaires for candidates with low health literacy. The proposed order of the questionnaires is intended to present less intrusive questions on social support first, prior to more intrusive topics such as psychopathology. The interview should be conducted face-to-face with the donor candidate. In case of language issues, an independent professional interpreter should be used as opposed to a family member or somebody brought in by the family or recipient, as this may influence the interview process and introduce bias.

Ideally, psychosocial screening of living donors is conducted by a mental health professional with experience in transplant care. This is in line with the current EU directive [92] and other recommendations [93]. Should a transplant centre not have a mental health professional as part of their interdisciplinary team, this tool should only be used by other professionals within the transplant team if (i) they are supervised by a mental health professional on a case-by-case basis, and (ii) they can refer to mental health services for further evaluation of living donor candidates if needed. Training in use of the tool is also recommended (contact the authors for details).

To aid interpretation of donor candidates' answers, we developed a 14-item Red Flag Checklist (see Figure 1). This checklist is meant to aid the screener in summarizing the interview and determining the next steps. If the screener answers YES to any of the items, this would suggest that the candidate requires further assessment. If the screener is a mental health professional, he/she can further assess the red flags within the same session or organize a subsequent consultation if needed. Planning a subsequent session to further explore these issues allows the screener time to reflect, cross check information and consult other professionals. If the screener is not a mental health professional, he/she should discuss with their supervisor and, if necessary, refer the donor for a consultation with a mental health professional at this point.

Discussion

This project addressed the need for more concrete guidance in the area of psychosocial screening of living organ donors. Our aim was to translate the recommendations of 'what' should be screened into practical guidelines on 'how' to perform such a screening. This resulted in the EPAT, which consists of a combination of validated questionnaires and a semistructured interview. An accompanying Red Flag Checklist and user manual was also developed to support implementation and interpretation of the tool. The tool is designed to be a practical aid that can be implemented in daily clinical practice for the initial exploration of psychosocial issues among living donor candidates. It aims to identify donors who are at risk of developing negative psychosocial outcomes and therefore need further assessment and/or extra psychosocial support during the donation process. The EPAT is likely to be particularly useful to centres that have yet to formalize and standardize the process of psychosocial screening.

The key motives to develop the tool were to ensure safety, quality and equality in access to living donation. The EPAT may contribute to safety of the donation process by assisting screeners in the psychosocial risk analysis of living donor candidates. This in turn allows tailored selection of intervention strategies or guidance during the donation process. The tool contributes to quality by way of standardization. Use of a standardized tool ensures that no psychosocial issues are overlooked, thus, ensuring that the procedure is comprehensive. Moreover, the tool incorporates validated measures which have been shown to have strong psychometric properties to assess known constructs. The use of a

selection of validated psychological tests specifically chosen for the purpose of screening of living donors has the advantage of generating comprehensive quantitative psychosocial data on donor candidates. The results of these tests, as well as the results from the medical tests, could then be integrated in an international registry database. This would allow comparison of outcomes and monitoring of benefits and risks for the donor over time. Finally, the tool contributes to increasing equality in access to donation and transplantation as the same criteria can be applied to each candidate, so that acceptance of a donor candidate becomes less dependent on setting. As Duerinckx and colleagues described, currently transplant centres use varying criteria with varying interpretations of eligibility [32].

In clinical practice, this tool still allows room for case-by-case assessment and the clinical judgement of the screener who should preferably be a mental health professional. We feel that this is the standard of care, we should strive to attain as the sensitivity of any psychosocial screening will depend on the skill of the screener. We hope that this initiative will further highlight the clinical need for a mental health professional in multidisciplinary transplant teams and that further research will help generate an evidence base to support this. However, we are also aware that in reality not all centres have or are able to incorporate a mental health professional into their transplant team. Therefore, with an appropriate supervision and referral system in place, the EPAT can also be used by other professionals. Future research is needed to (i) translate the tool (including the validated questionnaires) into other languages, (ii) assess the validity and sensitivity of the tool to predict poorer psychosocial outcomes and to identify candidates who require additional psychosocial support. One potential drawback to implementation may be the length; therefore, this is potentially an area for improvement in the next phase. Moreover, feasibility, acceptability and synergy with the medical screening will need to be assessed.

We are aware that alternative measures could have been chosen to be incorporated into the EPAT. However, our rigorous assessment focussed on practical feasibility, whereby brevity was paramount in combination with strong psychometric properties. Such measures have two advantages: firstly, they limit the barriers to implementation by limiting the time and resource burden for both professional and donor candidate, and secondly, they are more likely to facilitate uptake of data in donor registries. Another alternative tool for living donor candidate screening is the LDAT. There is

overlap in concepts covered by the LDAT and EPAT, however, the EPAT additionally includes topics such as health literacy, resilience, coping and insurability. Moreover, the use of these tools is rather different. The EPAT includes validated measures that allow easier comparison of data, outlines which questions should be posed per domain and identifies answers that are judged to raise red flags. Due to this standardization, the EPAT is less likely to be influenced by experience or opinion of the screener. In contrast, the LDAT does not stipulate how the information should be obtained by the professional (as it is not an interview guide) but assigns a score to the various possible answers per topic, which in turn enables the interviewer to score the candidate as low, moderate or high risk.

Parallel to developing the tool, we developed a user manual that is available upon request from the first or last author. We encourage transplant centres to use the EPAT to assess living donor candidates and inform us about their experiences. Moreover, we invite centres to collaborate with us to help translate, validate and further develop the tool.

Authorship

Emma Massey, Lotte Timmerman, Sohal Ismail, Nathalie Duerinckx, Hannah Maple, Inês Mega, Christina Papachristou and Fabienne Dobbels were involved in research design, data collection, analysis and writing the manuscript. Alice Lopes was involved in analysis and writing the manuscript.

Conflict of interest

The authors declare no conflict of interest.

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