

Review and Position Statement: Transition between different renal replacement modalities: Gaps in knowledge and care: the INTEGRATED Research initiative.

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Abstract:	Patients with end stage kidney disease (ESKD) have different options to replace the function of their failing kidneys. The "integrated care" model considers treatment pathways rather than individual RRT techniques. In such a paradigm, the most optimal strategy to plan and enact transitions between the different modalities is very relevant, but so far, only limited data on transitions have been published. Perspectives of patients, caregivers and health professionals on the process of transitioning are even less well documented. Available literature suggests that poor coordination causes significant morbidity and mortality. This review briefly provides background, development and scope of the INTErnational Group Research Assessing Transition Effects in Dialysis (INTEGRATED) initiative. We summarize the literature on the transition between different RRT modalities. Further, we present an international research plan to quantify the epidemiology and to assess the qualitative aspects of transition between different modalities.

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Review and Position Statement:

Transition between different renal replacement modalities: Gaps in knowledge

and care: the INTEGRATED Research initiative.

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Abstract:

Patients with end stage kidney disease (ESKD) have different options to replace the function of their failing kidneys. The "integrated care" model considers treatment pathways rather than individual RRT techniques. In such a paradigm, the most optimal strategy to plan and enact transitions between the different modalities is very relevant, but so far, only limited data on transitions have been published. Perspectives of patients, caregivers and health professionals on the process of transitioning are even less well documented. Available literature suggests that poor coordination causes significant morbidity and mortality.

This review briefly provides background, development and scope of the INTErnational Group Research Assessing Transition Effects in Dialysis (INTEGRATED) initiative. We summarize the literature on the transition between different RRT modalities. Further, we present an international research plan to quantify the epidemiology and to assess the qualitative aspects of transition between different modalities.

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Introduction

Patients with end stage kidney disease (ESKD) have different options to replace the function of their failing kidneys. Over the years, the search for the most optimal renal replacement therapy (RRT) has progressively been replaced by the understanding that most patients will use different modalities at different time points of their disease¹⁻⁴. This model has been coined as "integrated care" because it intends to consider treatment pathways rather than individual RRT techniques². The concept of integrated care has, however, been interpreted differently in different settings. In its original format, it involved the initiation of peritoneal dialysis (PD) followed by a timely switch to in-centre hemodialvsis (CHD)¹. In some parts of the world, this PD-first strategy was even implemented as a policy⁵⁻⁸. There is evidence to support this strategy has advantages both in terms of survival^{1,5,9-13} as for cost optimisation^{8,14}. Progressively, it was realized that RRT modalities that should be made available within an integrated care program should not be restricted to PD and CHD, but should also include home based HD¹⁵⁻¹⁷, satellite HD, conservative care and the different modalities of transplantation. In such a paradigm, new questions become relevant, such as sequence and timing of different modalities, and the most optimal strategy to plan and enact transitions between the different modalities. To date, only limited data on the epidemiology of transitions have been published. There is also general lack of knowledge on the incidences and outcomes of transitions between the different modalities, and even more so of the underlying driving factors. Perspectives of patients, caregivers and health professionals on the process of transitioning are even less well documented. Available literature suggests that at present, transition between the different modalities is poorly coordinated, causing significant morbidity and mortality¹⁸.

The objective of this review is to briefly provide background, development and scope of the INTErnational Group Research Assessing Transition Effects in Dialysis (INTEGRATED) initiative. We will summarize in a narrative way the present literature on the transition between different RRT modalities. Further, we intend to present an international research plan to quantify the epidemiology and to assess the qualitative aspects of transition between different modalities. As the transitioning between home-

based PD to in-centre HD is one of the most frequently encountered transitions, we will use this transition as a template to describe the methodology that will also be used to analyse the other transitions possible between the different RRT modalities. The group decided not to elaborate in first line on the start of renal replacement therapy, the most frequent transition as it was judged that already plenty data on this transition have been accumulated over the last decade, and that therefore, further research on this topic was not a priority.^{19,20}.

Background, aims and scope of the INTEGRATED initiative

Based on personal initiative, and supported by an unrestricted research grant (Baxter Global Grant Progam), the INTEGRATED initiative group was established to set up international research on aspects of transitioning between the different RRT modalities. This initiative was founded in response to a shared perception that there were big gaps in knowledge and data on this important part of RRT care.

The core group convened in Paris to define the scope and the relevant topics to be explored within this initiative. Participants (see supplementary document) were each asked to prepare 3 questions they considered as most relevant with regard to transitioning, and send them before the meeting to the coordinating team. These questions were pooled and duplicates removed (table 1).

During different chaired group sessions using a modified nominal group technique, different themes for research were distilled from these proposed questions:

- a/ barriers/facilitators to successful transition;
- b/ understanding of integrated care flow path;
- c/ optimizing outcomes of transitions;
- d/ impact of planned vs unplanned transitions;
- e/ experiences, perceptions and beliefs of patients and healthcare workers on transitioning.

Building on these themes, the INTEGRATED group considered that there was a need to create two different work streams to better understand transitioning, and to support development of strategies to improve outcomes. First, there was a perceived need for

quantitative methodology to explore the epidemiology of transitions by mining national and international registries to gain insight into the outcomes and associated factors of transitioning. Second, using qualitative methodology, to explore the perspectives of patients, relatives and health care professionals was deemed to be of high importance to improve understanding of the needs, facilitators and barriers to successful transition, and to determine outcomes that could be used to evaluate success of transitioning programs. It was appreciated that for some topics, a mixed methods approach would be most suited. Last, it was correctly suggested during the process that it would be very appropriate and useful to include the patient voice also in steering the research questions. Patient representation in the INTEGRATED group, either through individual patients, or through organisations representing patients, will be actively explored.

Quantitative analysis: Background and Rationale

As stated above, the INTEGRATED group elected to first explore the epidemiology, predictors and outcomes of transition from PD to in-center HD. This specific transition was targeted, as this is one of the most common transitional periods during RRT. Yet, little quantitative data are available on the transitioning from PD to CHD with regards to incidence, driving factors, risk factors, and especially outcomes in terms of mortality and morbidity. Overall, technique failure is a universal reality of PD and its high attrition rate translates into the globally low prevalence of PD internationally ²¹. In many countries, less than 50% of patients will have remained on PD two to three years after PD initiation, with a high proportion being transferred to HD ²²⁻²⁹.

There appear to be two stages in the PD to CHD transition: one early in the first three to six months after the start of PD, and one later on^{23,24,26,30,31}. Risk factors may vary according to the length of PD duration with, for instance, higher involvement of catheter-related dysfunction in the early period transition^{24,31}. In a US cohort, 22% of incident patients transitioned to CHD within the first 3 months, the majority of them on a central venous catheter³². Several patient-related factors such as gender, race, body mass index, diabetes, social deprivation, number of peritonitis episodes, education level and PD catheter dysfunction have been associated with higher risk of PD technique failure ^{23,24,33-37}. Nonetheless, these factors poorly correlate with the large variability of technique failure across different centres and countries and centre-related characteristics such as centre size, proportion of patients treated with PD and centre compliance with phosphate targets are emerging as important predictors of PD technique failure hazard ^{22,38-41}.

Moreover, the scant available data on PD to CHD transition teach important lessons, and seem to challenge some existing prejudices. For example, a recent analysis of United States Renal Data Systems (USRDS) data regarding the evolution of the incidence of transitioning from PD to CHD over the years seems to contradict the assertion that a higher PD incidence will result in more technique failure (Sukul and al. unpublished data). Indeed, whereas the PD to CHD transition rate remained stable, mortality decreased over the years, supporting the notion that expanding PD programs can improve outcomes. A similar finding was found in a Canadian study with a decrease

in mortality but mostly stable risk of technique failure throughout the years ²⁷. In contrast, other studies have shown an improvement in technique failure in recent compared to earlier PD cohorts⁴¹⁻⁴³

Couchoud et al⁴⁴ developed a mathematical model based on data from the Renal Epidemiology and Information Network (REIN) registry to improve understanding of the complexity of the RRT modality landscape. This model can help policy makers to estimate effects at society level to stimulate or not certain RRT options⁴⁴. While predictors of PD technique failure and transition to HD have been assessed in a number of studies, guality data on the clinical outcomes following transfer from PD to incentre HD are still scarce. This is different from the HD-to-PD transition, where transfer to PD was associated with an increased risk of death and technique failure^{1,45-47}. In a retrospective single centre study, the switch to hemodialysis did not adversely affect patient outcomes provided the patients survived the first 60 days.²⁹ However, exclusion of events during this first 60 days limits the relevance of this study, as it is potentially the highest risk period for patients transitioning between dialysis modalities ¹⁹. A Spanish study reported that patients who started on PD with subsequent transfer to HD had a higher crude survival than those who started on HD, although no adjustment for confounding was performed⁴⁸. A single-center US study reported a 6-month and 12month survival of 92% and 85%, respectively, in a cohort of 120 patients⁴⁹. In an Australia and New Zealand study including 4781 incident PD patients, those transferred to HD with a central venous catheter (CVC) at transfer had a higher mortality than patients initiated on HD with an arteriovenous fistula or graft²⁶. In a French multicenter study evaluating 60 PD patients with a transfer to HD, unplanned transition was a risk factor for hospitalization at time of transition¹⁸. Temporary or permanent transfer to HD was not associated with a significant difference in survival in Australian PD patients with peritonitis⁵⁰. Finally, an ANZDATA study showed that patients transferred from PD to home HD had a similar survival than those directly initiated on HHD¹⁵. Overall, most studies evaluating the outcomes of transition between PD and incentre HD are of limited quality because of single-centre design, lack of adjustment for significant variables and poor generalizability of the results.

Quantitative Analysis: collaboration among international registries

As indicated above, a key component of this INTEGRATED initiative is the close collaboration among investigators from various international registries to: (1) help facilitate analyses to be carried out in a nearly identical fashion by each registry, and (2) describe overall rates and outcomes across participating registries, and how these vary across registries. This international collaboration also serves as a means to foster different perspectives and broader considerations in framing INTEGRATED analyses than may occur from only one registry with the goal of study findings to be pertinent for addressing key issues relevant to different international perspectives. Currently, the registries which have closely collaborated in developing the quantitative INTEGRATED study include the Australian and New Zealand Dialysis and Transplant (ANZDATA) Registry (www.anzdata.org.au), United States Renal Data System (USRDS; www.usrds.org), Canadian Organ Replacement Register (CORR; www.cihi.ca/en/canadian-organ-replacement-register), and the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Registry (www.era-edta-reg.org) consisting of 31 registries from 17 European countries. Data from the international Dialysis Outcomes and Practice Patterns Study (DOPPS) Program are also being planned for use in future INTEGRATED investigations, and with the ability to collect specific new data that may not be collected by registries if helpful for future INTEGRATED studies. Sharing of analytic research plans and sharing of programming code (as needed by registry participants) have greatly aided the goal of utilizing the same definitions for study outcomes, predictors, and other key variables, what inclusion and exclusion criteria are used in defining the study cohort within each registry, and for carrying out analyses in a similar fashion by each registry. This first phase of the INTEGRATED initiative has been limited thus far to the above registries as a means to work out and harmonize the processes of carrying out such a large international collaboration and demonstrate the ability to be successful in this endeavour. However, one goal of INTEGRATED is to ultimately have even broader international involvement once success has been demonstrated in these initial two projects since the findings from other registries will be very important and provide valuable perspectives regarding the outcomes pertinent to this INTEGRATED

initiative⁵¹. Other research groups and registries are invited to contact us and join INTEGRATED.

Quantitative Analysis: research proposal

Given that more than 1/3 of patients will experience a transition to another RRT modality, particularly to facility-based conventional haemodialysis (CHD)^{25,27-29,42,52}, within the first 3 years on PD, a better understanding of morbidity and mortality associated with this transition is critically important for the care of patients with end-stage kidney disease (ESKD).

As underlying modifying factors might be related to geographical or organisational factors, an international approach to the analysis is warranted. The INTEGRATED initiative postulates that the period (weeks before to months after) around transitioning between RRT modalities is associated with heightened risk of morbidity (including impaired quality of life) and mortality as compared with other time points in the RRT journey. This risk then gradually decreases to reach the baseline rate of the new modality. This 'maximal risk period' will differ for each type of RRT transition (e.g. PD to HD versus transplant to PD). Determining this risk evolution over time is essential to benchmark transition success. We further postulate that specific patient, centre and state/country-related factors are associated with successful vs unsuccessful RRT transitioning. Knowing these specific risk factors is essential to adjust for underlying differences in case-mix and to allow benchmarking between centres/regions. Furthermore, knowledge of these underlying factors might reveal modifiable risk factors, thereby allowing improvement of the process of care and thus outcomes.

To test these hypotheses, the INTEGRATED initiative will leverage available renal registries (USRDS, CORR, ANZDATA, DOPPS and ERA-EDTA registry and others willing to join in the future) with the following specific aims:

A. To identify the incidence, predictors, risk factors, and outcomes of transitions between PD to CHD.

B. To compare crude and adjusted death rates, morbidities and risk factors in the early (<3, <6 months) and late (> 6 months) period following a transition from PD to CHD.

C. To analyse on a worldwide/regional basis which parts of the renal replacement portfolio are actually made available to patients at the centre level. This is an important question, as availability of different modalities is a prerequisite for free patient choice and for timely and appropriate transition. The question will be explored by a systematic analysis at country/regional level of how care is organised at centre level.

A statistical analysis plan has been agreed between the registries participating in the INTEGRATED research collaborative.

The first major challenge was to agree on what exactly constituted a transition from PD to CHD. Whilst most registries do not have a specific definition for transition⁵³, it was agreed within the INTEGRATED initiative that transfer from PD to CHD for a period of 30 consecutive days or longer would constitute a transition, as per the standardized definition proposed by the ANZDATA Registry⁵⁴. Similar reasoning will be used later on for transitions between other RRT modalities. Sensitivity analyses will also be performed using alternative definitions of 60, 90 and 180 days.

Studies will include all patients with ESKD who commenced RRT between 1 January 2000 and 31 December 2014, and initiated PD for at least 1 day within 180 days of RRT commencement. The rate of first transition from PD to CHD will be expressed as number per 100 patient-years and the patient- and centre-level characteristics associated with transition will be evaluated using a Cox proportional hazards with shared frailty model. Patient-level characteristics will include age, gender, race, body mass index, smoking status, diabetes, cardiovascular disease, peripheral vascular disease, cerebrovascular disease, initial PD modality and initial RRT modality. Centre-level characteristics will, as a minimum, include centre size (calculated as mean number of incident PD patients at the centre), PD proportion (proportion of all dialysis patients at centre treated with PD), automated PD (APD) versus CAPD use (proportion of centre PD patients exposed to APD at least once), transplant centre status (defined as whether

or not at least one kidney transplant was performed in the same hospital as the PD centre) and type of centre (public/private/University/urban/rural/remote)⁵⁵. PD commencement era will also be included as a fixed effect covariate in the final model to adjust for era effect. Results will be presented for countries and regions to ascertain potential regional variability. For Japan, a separate analysis for patients transitioning from PD to hybrid PD/HD combination could be considered.

The primary outcome of the quantitative analysis will be mortality following transition. Time from PD->CHD transition to all-cause mortality will be assessed using a Cox proportional hazards model with multi-level, mixed effects analyses being performed to take into account data clustering on dialysis centre and/or region/country. Data will be censored at the time of transplantation, any subsequent RRT transition, recovery of renal function or the end of follow-up. Competing risks analyses will also be undertaken. Mortality rate will further be evaluated in a count model at different time points after transition, presented as weekly (1-7, 8-14, 15-21, 22-28 days, etc.) or monthly (30, 60, 90 days, etc.) mortality rates.

Sensitivity analyses will be undertaken, including: 1) with and without censoring the follow-up at time of a subsequent modality change and/or transplantation; 2) with restriction of the cohort to patients without hospitalization at the time of transition (as a marker of an acute medical event); and, 3) including only the first RRT transition during the RRT journey (i.e. only 1 transition per patient allowed), 4) a planned subgroup analysis in a cohort of patients who, at start of RRT, have a predicted survival of more than 5 years. This specific patient group is most likely to undergo a transition, and the impact of transition (positive and negative) is therefore likely to be higher in this specific subgroup than in patients with an intrinsically limited life expectancy.

Secondary outcomes will include cause-specific mortality (cardiovascular, infectious, dialysis withdrawal, etc.), hospitalization, and predictors of successful transition (i.e. being alive 30 days after transition).

We will also describe the proportion of PD patients who undergo a transition to in-centre HD within a given year as well as switches to all of the following outcomes:

- Death/withdrawal from dialysis without transfer to CHD
- Death/withdrawal from dialysis after having switched to CHD for <30 days
- Transition to transplant
- Transition to home hemodialysis (defined as home HD for >30 consecutive days)
- Recovery of kidney function or loss-to-follow-up (which is quite low)

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Qualitative approach: general considerations of "change processes":

Transitioning from one therapy to another can be seen as a specific application of the change process occurring in the business world. Change is a gradual process, with well defined, distinct steps all with their specific properties, opportunities and pitfalls. Typically, the different steps can be distinguished as *current situation*, the *letting go* stage (grieving), the new beginning stage and the new situation. The nature, appreciation and perception of these different phases will impact on the final result and acceptance of the new situation (figure 2). For example, it could be hypothesized that a patient who is doing very well on PD, but needs to transfer to in-centre HD because of a perforated diverticulitis, will not have had very much opportunity to reflect on the prospect of leaving PD and starting HD, and will therefore perceive this transition as a "loss", whereas a patient who is on PD for many years, with an increasingly complex regimen due to decreasing residual renal function, will potentially see a transfer to HD as a relief from a burden. It can thus be hypothesized that a better understanding of the emotions and perceptions of the patient in this context can help the health care provider to support the patient in a more tailored way, which will result in an improved outcome. In general, a successful change will require that there is an awareness of the need to change, a tendency to *support* the change, sufficient *knowledge* on what the change will look like, and the *willingness and capacity* to implement the change. Applied to renal replacement therapies, this implies that patients should be made aware from the beginning that a transfer might be needed at some point, what can be underlying reasons/motivations to do so, and what are the alternative options: in short, patients should be informed from the start, and empowered to sustain the transition. Sufficient health care professionals with suitable competences should be made available to support the patients in the transitioning process. Most people have an inherent tendency to object to change. This can reveal itself as an inclination to try to block off or deny the change (passive objection), or by blaming others for the incurred problems or even by aggressive behaviour (active objection). Such aggressive behaviour can be directed towards family and carers, to health care professionals, but also to the disease

or the patient him/herself. It is important to recognize and clarify this feeling of revolt to avoid escalation and conflict.

More positive coping strategies are to explore the advantages of the new situation, and how eventual problems can be turned into opportunities. In most situations, it is important to avoid framing the new situation as good by framing the old situation as bad or poor. Most patients will indeed have felt comfortable with the old situation, and presenting it as poor might damage credibility and thrust. Emotions underlying this objection or resistance to change are *loss of control*, *uncertainty* over the future, *surprise*, perception of *failure*, *fear to fail* in the new situation, and the fear that this change might be just a *first step in a downward cascade*. In the case of transitioning between different renal replacement modalities, the current change might often dredge up previous experiences of the disease process. Again, it is of importance to present already early on that transition is part of a (planned) process.

Qualitative analysis: what is already known on transitioning in renal replacement therapy

There are little or no data on qualitative evaluations of transitioning between the different RRT modalities. A Pubmed search using combinations of MeSH terms "qualitative research", "peritoneal" dialysis", "treatment failure" yielded 131papers, but only two of those directly or indirectly related to transitioning between home-based therapies and centre-based renal replacement therapies. In a qualitative analysis of modality selection for home-based therapies, different themes were identified⁵⁶. *Optimizing survival* was one of the considerations when making a modality choice. Consequently, it can be expected that providing evidence to the patient that a transitioning will not jeopardize outcomes, or might even at that specific time point improve survival, will be determinant for how patients perceive the transitioning process. In this regard, the work of the quantitative part of INTEGRATED is essential. *Sustaining relationships* and *minimizing lifestyle disruption* were also identified as important themes in modality selection for home-based therapies. It can be expected that a transfer to a centre-based treatment modality will have a negative impact on these aspects, and will accordingly contribute to a negative perception of the patient and caregivers. *Lacking*

decisional power was an element that favoured a choice for centre-based therapies. Accordingly, it can be expected that patients who initially opt for a home-based treatment tend to be more independent and prefer to make their own choices. Not having a choice, for example, because of a medical contra-indication to continue the home-based treatment, might have a strong negative impact for these patients. Life participation seems to be superior for patients with a kidney transplant vs dialysis, but apparently, there are few differences between patients on hemodialysis and peritoneal dialysis. These results were consistent throughout study periods, across diverse populations, and among the subset of studies that performed appropriate adjustments for potential confounding factors⁵⁷. However, these were all cross-sectional studies, and there might thus be bias by indication. It can therefore not be automatically derived that a transitioning from PD to CHD will not impact on the perceived life participation, especially when this transitioning is abrupt or forced (lack of choice). In that regard, it will be of interest to compare experiences, feelings and attitudes of patients immediately after transitioning as compared to after some months on the new modality. If there is truly no difference in life participation between PD and CHD, it can be hypothesized that once people accommodate to CHD, their perception of life participation will go up again to what it was before the transitioning (accommodation/adaptation).

Qualitative approach: proposal for qualitative research on transitioning

Transitioning from one modality to another can have an enormous impact on the wellbeing and lifestyle of patients and their caregivers. Little is known regarding what factors make patients' transition and their caregivers experiences successful, stressful or even unsuccessful. Moreover, data are lacking on how patients and their caregivers perceive such a transition, what their ideas and emotions are, and how they cope with them. Furthermore, transitioning can also have an impact on the health care professionals involved in this process, whereas at the same time, a variety of emotions, perceptions, motivations and beliefs of health care professionals might drive, delay or impede transitioning, leading to patients not receiving the treatment that best suits their needs at a given moment. It has so far not been explored which mechanisms drive the emotions, perceptions and eventually behaviours of patients and health care workers in relation to the transitioning. Understanding these mechanisms is a first essential and important step to improve care processes in this regard.

It can be hypothesized that, besides the medical outcome of the transition itself, other factors will influence whether patients experience their transition as successful or not. Understanding these associated factors and the emotions, perceptions and mechanisms linked to them might also be relevant to improve the approach and management of transitioning. Therefore, the qualitative part of the INTEGRATED project intends to explore and analyse patients', caregivers' and health professionals' perspectives and experiences and the underlying mechanisms thereof of transitions between the different renal replacement therapy modalities.

We will first focus on the transition from self-managed (home based) to healthcare worker managed (centre-based) treatments. At a later stage, we will also explore transitions from failed transplant back to RRT. We hypothesize that this qualitative research might help to understand and explore options for how clinical practice might need to change so that patients' and caregivers' experiences of transition are optimised.

We will use different strategies:

1/ Qualitative semi-structured interviews of patients who actually went through a transition. We are interested to know experiences and perceptions of aspects related to the transitioning process, and what these mean to patients and their caregivers. We also intend to find out how patients and their caregivers cope with this transitioning, and how renal units can support them through it. We hypothesize that finding out which factors made this transition to be perceived as successful or not should help renal units to improve care to patients and provide better support when treatments might need to be changed. Next to open questions, we will also specifically explore themes associated with change in treatment reported in the literature if they were not brought up spontaneously as a theme by the patient him/herself: the role and timing of information, the prediction of need for transition and discussion of alternative options, the role of exposure to peers and the impact of social support.

We will use a purposive sampling aiming at an equal distribution of patients with medically successful and unsuccessful transitions, from different socio-economic backgrounds, age and gender. Patients will be included until saturation. Patients will be selected from different regions (Belgium, UK, Canada and Australia). Transcripts of individual interviews will be checked for accuracy and imported into a qualitative data management program to facilitate data management. Textual data from the interview transcripts will be analysed inductively, using an interpretive approach of qualitative description. Transcripts will be coded for emergent themes and patterns, and constant comparison will be employed in order to identify similarities and differences within and across patients.

We will not use surveys of established instruments such as SF-36 or others, or patient activation measure (PAM), as these do not provide additional insights in the underlying processes.

2/ Qualitative structured interviews of health care professionals to explore which factors they believe make a transition successful or not. Preferentially, healthcare workers from different backgrounds and settings will be interviewed.

3/ Systematic literature review on 1 and 2 to identify issues, themes, topics and constructs that can be used during the interviews.

4/ Focus groups with patients who underwent a transition, patients who did not (yet) undergo a transition, and with healthcare professionals (nephrologists, nurses) to explore factors and their importance for a transition being called successful or not.
5/ Identification, prioritisation, and gaining of consensus on non-medical *outcomes* that are of importance for evaluating successful transition between dialysis modalities and the reasons for these priorities. An online Delphi approach will be used to select these non-medical outcomes for benchmarking. Patients, caregivers and health professionals will be invited to complete two rounds of the Delphi survey to reach consensus about priorities. As a list of potential outcomes will have already been generated from other phases of the INTEGRATED initiative, only two rounds will be required rather than the usual 3 rounds, whereby the first round is used to generate outcomes for use in rounds 2 and 3.

By the end of the project, a rich picture will have been developed of the range of perspectives and experiences of patients and caregivers going through treatment modality transitions. The project will also be able to demonstrate how this information can be used to develop a shared understanding amongst patients, caregivers and health professionals about how clinical practice might need to change to improve outcomes. We will also have achieved a consensus about the selection of outcomes which could be used in future studies to evaluate interventions designed to improve the experience of transitions, and will have a clear understanding about the rationale for selecting these outcomes.

Summary and conclusions

The INTEGRATED initiative is an international research collaborative that seeks to explore existing data and generate new data on the transitioning of patients between different renal replacement therapies. INTEGRATED is an open collaborative effort, so people willing to do so can join, provided they are willing to share efforts and data. Please contact us by mail in that case.

We will explore and generate both quantitative as qualitative data to better understand the process, with the intention to apply this knowledge to steer practice and improve outcomes of patients during their journey with end stage renal disease.

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Pooled Primary (pre-me	Peritoneal Dialysis International
* Selection criteria/ Medical in	dications for transitioning
 * Psychosocial barriers * What is the optimal duration 	of PD therapy?
3 * Should dialysis be started with the started with t	th PD (PD first)?
* Does PD first followed by hor	ne HD improve outcomes
* What are the predictors of su	ccessful transition
* What are the outcomes after	transitioning (mortality, morbidity, quality
 of life), immediate and longer t * What are the reasons/metivation 	erm ions for transitioning (medical, non
8 medical)	
o * impact of planned vs unplann	hed transitioning
10* impact of positive vs negative	e choice?
* How many centers organize p	lanned transitioning?
[*] Risks factors predicting trans 12* Risk factors associated with	nositive/negative outcome of
13 transitioning	
14* How to improve outcomes of	transitioning
15* How do transitions affect cos	ts/cost effectiveness of RRT?
* Does an optimal RRT flow ch	art exist (universal vs individual)?
17* Perceptions of health	
18* Place of transplantat Them	
19 * Plan	co
20 * Timir	a of transitioning
21 * Selec	tion criteria/indications for transitioning
22 *I nteg	rated care flowcharts
23 * Optin	hization of transitioning/ Barriers/facilitators
24 Patie	nt and health professional's perception, beliefs,
25	
26	
	Quantitative analysis: epidemiology
27	Quantitative analysis: epidemiology
27 28	Qualitative analysis: epidemiology Qualitative analysis: patient and health care
27 28 29	Quantitative analysis: epidemiology Qualitative analysis: patient and health care professionals perceptions, experiences, beliefs
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27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 41 42 43 44	Qualitative analysis: epidemiology Qualitative analysis: patient and health care professionals perceptions, experiences, beliefs
27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 41 42 43 44	Qualitative analysis: patient and health care professionals perceptions, experiences, beliefs
27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46	Quantitative analysis: epidemiology Qualitative analysis: patient and health care professionals perceptions, experiences, beliefs



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