# Evidence-Based Clinical Practice

# 3

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## 3.1 A Translational Research Model

A translational research model has been developed. The model is called patient-to-PC and PC-to-patient and integrates clinical practice and research and demonstrates a dynamic process ensuring an evidence-based practice as shown in Fig. 3.1. PC is the abbreviation for ‘personal computer’.

The model is inspired by a research programme at the Sainte-Anne Hospital in Paris, France (http://www.ch-sainte-anne.fr/), also referred to as the Brain hospital owing to its dual expertise in psychiatry and neurosciences. At the Brain hospital, major scientific discoveries have been made, and some of the researchers have even won the Nobel Prize. They ascribe these achievements to their dual expertise and to the fact that they perform translational research. Their translational research model bench-to-bedside and bedside-to-bench inspired the present research programme.

The patient is the focus for nursing. It can be the patient in a bed at the hospital but also in all other settings, such as the outpatient clinic. The patient is the place of practicing nursing. Nursing research could be done in different setting, but the most common setting for nursing research is by the computer, working with data at a PC.

In the patient-to-PC and PC-to-patient model, we see the integration between nursing and research. Nurses meet patients in a variety of settings, and often clinical question arise, e.g., how best to guide a patient to prevent urinary tracts infections? Which bandage to use for this specific wound? These clinical questions need to be answered for nursing practice to be firmly based on evidence. Four elements are

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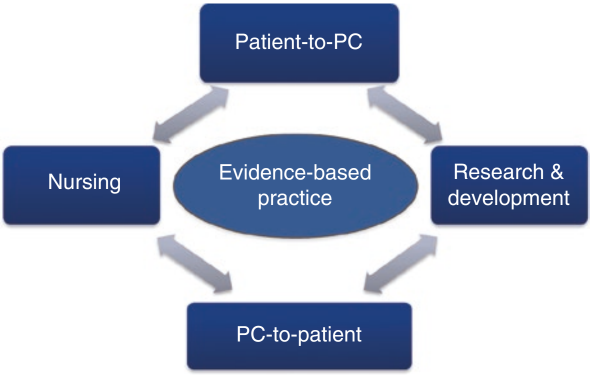


**Fig. 3.1** Patient-to-PC and PC-to-patient

important in answering questions like these, research, clinical experiences, patient preferences and clinical resources [1]. If no research is immediately available, the researcher must search for such knowledge, using a PC to identify research conducted and published internationally, or she must conduct the research herself. In the translational research model, this is the *patient-to-PC* avenue. To start a research project based on questions arising from the patient's condition ensures that the research is useful and connected to clinical practice, seeking to answer a question raised rooted in a wish to ensure the best care for the patient; furthermore, it solves a real problem in clinical practice. The other avenue in translational research, *PC-to-Patient*, is equally important. Using much time in front of the PC and producing evidence published in papers with high impact factor that has not been implemented in clinical practice is wasteful from a patient, and clinical practice perspective as implementation of research should be part of the research process in nursing. When the research question is rooted in a clinical question asked by a nurse during her interaction with a patient, it is easier to implement the answer the research brings forth. Thus, the interaction between the clinical setting and the research setting must be close all the way along, and it should be more like an iterative process than a one circle process. The following six recommendations have been made for enhancing the integration of research and practice: (1) anticipate and address likely barriers to dissemination; (2) appreciate and integrate multiple types of evidence; (3) adopt research designs such as practical clinical and behavioural trials and multiple baseline across settings that address concerns of clinicians and policy-makers; (4) conduct broader evaluations that include multiple outcomes, address generalisability, and report on contextual factors; (5) design multilevel programmes using systems and social/ecological models that attend to 'connectedness' and integration across programme components and levels; (6) do not expect a programme to work perfectly initially, but plan for adaptation and refinement to fit local condition and emerging issues [2]. The 'Brain hospital' in Paris did not only focus on the translational research model but also on their expertise. Therefore, clinical practice needs to have a research programme focusing on the clinical expertise that is required by the patients and conduct proper nursing.

## 3.2 A Research Programme Integrating Evidence into Clinical Practice: An Example

The specific clinical practice to be addressed in this example is that of renal care where care is provided for patients with chronic kidney disease. Whether patients receive dialysis treatment or not, they will experience disease-specific symptoms that influence their life and activities of daily living. Evidence shows that patients with chronic kidney disease report up to 20 symptoms affecting their life [3]. The care for these patients therefore needs to focus on symptom management, mainly symptoms of uraemia which arise because urea accumulates in the blood. In the field of renal care, the purpose of nursing is to alleviate or manage uraemia symptoms, which is the focus in clinical practice and hence also the field of research. Uraemia care research resorts to a combination of natural and human science. Transplantation, dialysis and conservative care are the most effective treatments available [4] (Fig. 3.2).

Research into uraemia symptoms is sparse, and knowledge of how to manage these symptoms is limited. Furthermore, uraemia symptoms are underrecognized and not well managed in routine renal practice although they are the most important predictor of reduced quality of life among people with chronic kidney disease [3]. Consequently, this research programme answers to a need both in the field of research and in clinical practice. The current research programme is designed in line with the transitional approach to research. In the next section, we will illustrate how a research project in renal care based on the translational research model and the research programme for renal care was designed.

## 3.3 Shared Decision-Making and Dialysis Choice

The project used the method of complex intervention. A complex intervention is defined as:

> Activities that contain a number of component parts with the potential for interactions between them which, when applied to the intended target population, produce a range of possible and variable outcomes [5].

Most health services are complex interventions, but only few of the components of the intervention are reported. Knowledge about the components of a complex intervention is crucial for understanding the effect of the intervention and then the reason for implementing the intervention and how to replicate the intervention [6]. The method was developed by the Medical Research Council in the UK, and the most recent guideline presents an iterative model for developing and evaluating a complex intervention using the five phases: (1) developing an intervention, (2) piloting and feasibility, (3) evaluating an intervention, (4) reporting and (5) implementation [7]. The iterative process is between phase 1, 2, 3 and phase 5, whereas phase 4, the reporting, is a part of all the phases.

**Fig. 3.2** The renal care research programme

The description of the project ‘shared decision-making and dialysis choice’ is structured by phase 1 to phase 45 of the model, including a short introduction on the dialysis choice and a description of the intervention. There the focus is on the development phase, which is how the research project is initiated in clinical practice by the patients and how new knowledge is created in front of the PC through reflection, systematic literature search and analysis of data. The focus is also on the evaluation phase, which is how to evaluate an intervention in clinical practice generating data for the research project but also generating data to ensure a safe pathway for the patient and to develop clinical practice.

### 3.3.1 Dialysis Choice

When patients are in a need of dialysis, they have two options:

1. Haemodialysis, which is cleaning the patients' blood through a filter via a machine
2. Peritoneal dialysis, which is cleaning the blood using the peritoneum as a filter

Patients may be able to perform both dialysis modes on their own or with help from a healthcare professional. Evidence on how to guide the patient's decision-making concerning choice of dialysis is inconclusive. International and national guidelines therefore recommend involving the patient in the decision to choose the dialysis mode most suitable for him or her. Nevertheless, studies show that patients are not sufficiently involved in this specific decision-making process [8–10].

### 3.3.2 The Development Process

The key factors in the development process of a complex intervention are identifying the evidence base, identifying the theory and modelling process and outcomes [7]. One paper states how to optimize the development process for complex intervention to increase value and reduce waste. The way to optimize the development process is consistent with the transitional research model, patient-to-PC and PC-to-patient. The development process must be based on knowledge regarding the causal mechanisms and interactions within the intended clinical context and have to fit daily practice and to be beneficial for the end-user, which in this case is both the patient and the healthcare professional [11].

At the Department of Renal Medicine at Aarhus University Hospital in Denmark, some patient cases were identified where it looked like that the patients were not involved in the decision-making process regarding dialysis choice, and questions arose if the 'right decisions' were made. The managers of the department chose to investigate this clinical problem further. They used the method of 'shadowing' to explore specific patient pathways as they appeared from the patient's perspective. These observations showed that the pathway for decision-making of dialysis choice in the department was inconsistent. No changes were made, but the management team wanted to investigate this problem further, and the manager invited the department's clinical nurse specialist to elaborate the problem further. The aim of this study was to gather information about how patients experienced involvement in the decision concerning the choice of dialysis modality just after they had made the decision and before starting dialysis. This study, which was published in 2015, also encompassed a literature review about patient involvement and dialysis choice [12]. The findings of this study showed that patients felt appropriately involved in decision-making, even though there was a variation in the extent to which they wished to

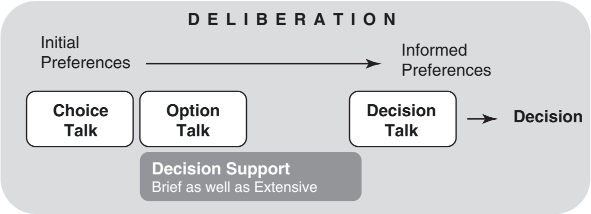


**Fig. 3.3** Shared decision-making: a model for clinical practice

be involved. Information, dialogue and advice increased the feeling of being involved. Information, dialogue and advice correspond with the method of shared decision-making, and the department therefore wanted to improve the patient pathway in relation to dialysis choice using the method of shared decision-making [12]. Through a literature search regarding shared decision-making, a model for shared decision-making in clinical practice' was identified [13] (Fig. 3.3).

Through three talks, a *choice talk*, an *option talk* and a *decision talk*, as described in the model [13], the patient is supported in making a decision not based on initial preferences but based on informed preferences. The patient is supported in the decision-making process by *decision coaching* performed by the healthcare professionals and by decision aids [13]. In the present case, an intervention was described based on the shared decision-making model and including a decision aid. Using decision aids is new in Denmark. Very few decision aids have been developed and none for dialysis choice. A systematic literature search was made regarding decision aids and dialysis choice including both scientific and the grey literature and international networks in renal care were used to identify interventions regarding decision aids and dialysis choice. Nine decision aids were identified, and of these only five have been used as part of an intervention, and only four have been evaluated [14]. None of the interventions targeted both the patients and the healthcare professionals. Implementing shared decision-making into clinical practice seems to be very difficult according to the latest Cochrane review in the area [15]. In the present case and based on the findings in the review [14], it was decided to develop a decision aid intervention targeting both the patient and the professional, which would improve the implementation of shared decision-making.

The decision aid intervention, 'dialysis choice', was developed using International Patient Decision Aids Standards (IPDAS) for the developing process [16]. The IPDAS describes a need for involving patients and users in the development process. One group of patients and healthcare professionals developed the decision aid, and another group of patients and healthcare professionals gave feedback during the process. Involving both a group of patients and a group of healthcare professionals enhanced the commitment in both groups [17]. The development process of the intervention has been published [14], and the decision aid has been assessed both internal and external by the IPDAS criteria. Also, the decision aid is published on the international webpage for decision aids (https://decisionaid.ohri.ca/).

### 3.3.3 The Intervention Shared Decision-Making and Dialysis Choice

The intervention, shared decision-making and dialysis choice (SDM-DC), consists of three meetings and is integrated into the patients' pathway. See Fig. 3.4 for an illustration of the intervention.

The first meeting is the *choice talk*, making sure that the patient knows about the options available. The patient receives the decision aid, called 'dialysis choice', consisting of all the tools, to bring home after this first meeting. During this first meeting, two tools are in use: the decision map and the overview of symptoms. The second meeting is the *option talk*, providing more detailed information about the options. During this meeting, one tool offering an overview of options and two videos with patients at home managing either peritoneal dialysis or home haemodialysis are used. The development of this tool was inspired by some of the identified decision aids for dialysis choice and is based on (a) the knowledge gained from the literature study with a focus on involvement and dialysis choice [14] and (b) interviews with patients before and after starting dialysis [12]. The overview of options is supported by several questions frequently asked by patients. For each dialysis mode, answers are based on a combination of evidence and practice-based knowledge. The third meeting is the *decision talk* supporting the considered preferences and deciding what is best. One tool, the 'Ottawa Personal Decision Guide' [18], is used for this meeting. This guide has been translated and culturally adapted to the Danish population [19]. The patient receives the tool at the second meeting. The tool consists of some reflecting questions, and the patient answers these questions together with his relative before the third meeting.

The intervention is provided by a nurse, appointed as a dialysis coordinator and very experienced in renal care. The dialysis coordinators deliver the intervention based on tailoring the intervention to the patient's needs and using three different communication skills: mirroring [20], active listening [21] and value clarification [22].

### 3.3.4 Pilot Test

The key factors in the feasibility and piloting are testing the procedures, estimating recruitment and retention and determining sample size [7]. The aim of the pilot testing was to investigate the feasibility and acceptability of the intervention

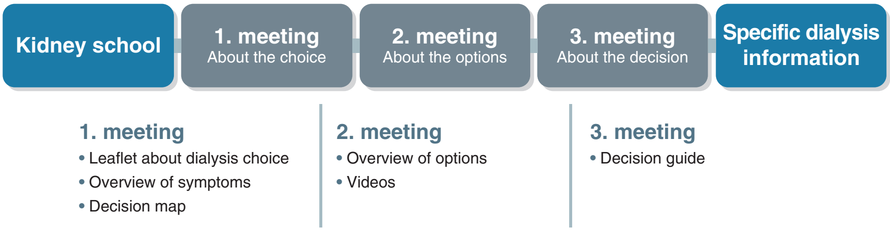


**Fig. 3.4** The intervention, SDM-DC

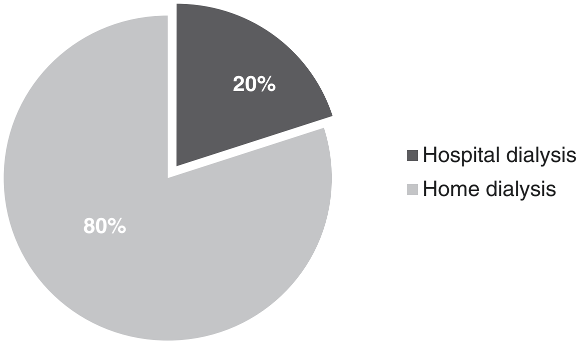
and the methods used for evaluation. From August 2015 to September 2016, 137 patients took part in a pilot test of the intervention. All adult patients with chronic kidney disease referred to the department during the study period were offered the intervention. Different methods were used in the pilot testing, which has been published [14]. The following will feature some of the highlights from the pilot test. The share decision-making questionnaire was used to measure if the decision was based on shared decision-making [23]. The questionnaire consists of nine statements. The patients were asked to rate each statement on a 6-point Likert scale from zero indicating 'completely disagree' to five indicating 'completely agree'. The findings showed that for all nine items, an average score of 4.0 was obtained, reflecting that the patients strongly agreed that the intervention was based on shared decision-making. The statement 'the dialysis coordinator and I selected a dialysis treatment option together' obtained the lowest score at 3.6. The patients who gave a low score for this item had all written the same comment: 'I made the decision myself'. Furthermore, the Decision Quality Measurement instrument [24] was used to measure the quality of the decision. The questionnaire consisted of six knowledge statements about dialysis choice and six readiness statements about being ready to make a decision. The patients were asked to answer each statement by 'yes', 'no' or 'unsure'. An average was calculated for the knowledge statements for the patients choosing the right answer. The patients answered an average of 87% of the knowledge questions correctly. An average was made for the readiness statements for patient choosing 'yes' for each statement. An average at 78% of the readiness questions was scored as a 'yes' by the patients. 'I can imagine what it would be like to live with each options' obtained the lowest score.

The patients' choice of dialysis mode was also measured (Fig. 3.5). Eighty percent of the patient chose either peritoneal dialysis or home haemodialysis. Twenty percent chose dialysis at the hospital.

Not all of the 137 patients had started dialysis yet; but of those who had started dialysis ($n = 56$), 91% of the patients received the treatment they had chosen. A total of 73% had started dialysis at home.

A register study was performed investigating the number of patients starting home dialysis versus hospital dialysis before and after implementing the intervention.

**Fig. 3.5** Patient's choice of dialysis mode ($n = 137$)



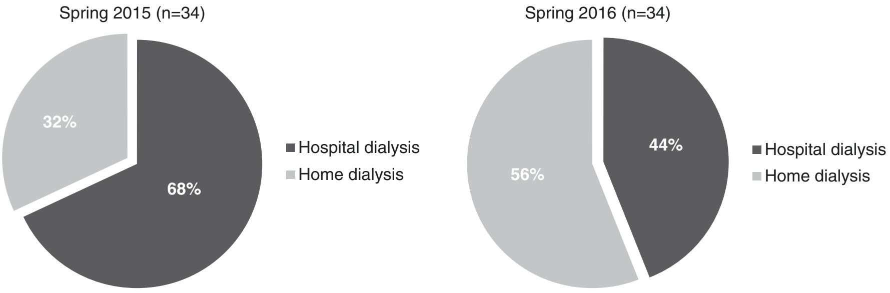


**Fig. 3.6** Patients starting home dialysis versus hospital dialysis

Figure 3.6 illustrates how the intervention influenced the number of patient starting dialysis at home.

The first pie chart shows that before the intervention, 32% of the patients in our department started dialysis at home. The second pie chart shows that after the intervention 56% of the patients in the department started dialysis at home. The intervention reflects an increased number of patients starting dialysis at home, and it is statistic significant (chi $p = 0.05$). The conclusion of the pilot testing was that an intervention based on shared decision-making supported by decision aids seemed to increase the number of patients starting dialysis at home. Both the intervention and the methods used for evaluation were found feasible and acceptable by the patients. Further research is needed to gain insight into the patients' experiences of involvement and the implications for their choice of dialysis mode. This is the focus in the evaluation study which is currently taking place.

The development process and the pilot testing were part of a larger implementation programme for *user involvement* launched by the hospital in the same period. The aim of this user involvement programme was to test the development and implementation of two methods for patient involvement in a larger scale at Aarhus University Hospital and, thereafter, to develop and disseminate generic tool boxes with open access to a variety of material with tips and tricks to be used by any hospital or other health institution in Denmark [25]. Eighteen departments from Aarhus University Hospital participated in the user involvement programme and used either the method 'shared decision-making' or the method 'patient-led care' (similar to self-management support and individual care planning) [26]. The Department of Renal Medicine chose to be a part of the *user involvement programme* because it neatly suited the wish to use *shared decision-making* to improve the patient pathway for dialysis choice. When considering participation in a larger programme of user involvement, both some advantages and disadvantages were noted. The advantages were networking with other professionals working with shared decision-making and an access to further knowledge on shared decision-making. Furthermore, being part of a larger programme highlighted the local *shared decision-making project* by increasing attention from the hospital CEOs and even CEOs on a regional and national level. The disadvantages, however, could be a threat of losing ownership because the local project became a part of something bigger and thereby may be not perceived by the department managers and staff as something useful and important in the care for patients.

## 3.4 Evaluation and First Results

The key factors in an evaluation are assessing effectiveness, understanding change process and assessing cost-effectiveness [7]. The aim of the evaluation study was to investigate if the intervention SDM-DC influences how the patients (1) experience to be involved in the choice of dialysis modality, (2) take care of life with chronic kidney disease and (3) are involved in their own care and treatment. The aim was also to investigate if SDM-DC influences the number of patient choosing dialysis at home and maintains this decision. It was decided not to include cost-effectiveness in this evaluation because the focus was patients undergoing suitable treatment and not on the delivery of the most cost-effective healthcare service.

The evaluation of the SDM-DC intervention is conducted using five different studies, which are currently taking place at four different hospitals including Holstebro, Hillerød, Sønderborg and Aarhus and in collaboration with the Danish Kidney Foundation. The four different hospitals cover three different regions in Denmark. Aarhus University Hospital has initiated the intervention and has the chairing position. The SDM-DC intervention and the methods for evaluation were only changed slightly after the pilot testing. Some words in the decision aid were changed. Although the healthcare professionals from the three other hospitals were part neither of the development process nor the pilot testing, they were able to take part in the evaluation study and implement the intervention at their hospital and in their departments. The involved staff were all invited to comment on the intervention and suggest changes, and only some minor changes were made, like a way to qualify the decision aid. The main evaluation study ran from 1 October 2016 to the end of May 2018. In total, 300 patients were planned to be included for the intervention. Both qualitative (study I and II) and quantitative (study III, IV and V) methods for outcome and process evaluation of the SDM-DC intervention are used. The study numbers have been chosen randomly, and there is no hierarchy between the studies. Data collection and data analysis have been conducted simultaneously between the studies, though study II is followed by study I. The data from study III has been used in the data collection for study I.

Study I: A quality interview study with 29 patients just after they participated in the SDM-DC showed that the patients experienced the decision on the dialyse modality to be their own but that both the meetings with the dialysis coordinators and the decision aid contributed to the decision-making process. The patients experienced the decision-making process to be circular and iterative (Submitted for publication). This study has not only evaluated the outcome of the intervention but also some of the processes and the fidelity of the intervention.

Study II: A qualitative study including interviews with patients from Study I after they started dialysis ($n = 12$) is currently ongoing. When the patients from study I start dialysis, another interview is conducted to explore whether they experience their choice of treatment as expected and how they handle their life with kidney disease after the intervention.

Study III: A survey study measuring shared decision-making and the decision quality (*n* = 300) is currently ongoing. All patients who have received the intervention are invited to take part and to fill in two questionnaires after they have finished the intervention. One questionnaire measures if the patients experience the intervention to be based on shared decision-making and the other measures the quality of the decision.

Study IV: A retrospective register study with a historical control group (*n* = 300/300) is conducted. The pathway for patient starting dialysis at the four different hospitals is measured. The period ran from 1 October 2016 to 31 May 2018 as an intervention group compared to the period 1 October 2013 to 31 May 2015 as a historical control group. This study is not only an evaluation study but also measures the implementation phase of the complex intervention. Furthermore, this study monitors the dissemination of the intervention, surveillance and long-term follow-up.

Study V: A quantitative study will be conducted using video observations of two interventions for each dialysis coordinator (*n* = 12). All the six dialysis coordinators who perform the intervention are observed using video recordings while they provide the intervention to two randomly selected patients. All the meetings with the patients are video recorded. Afterwards, these videos will be observed and scored by two persons using the OPTION5 [27] and DSAT10 [28] to measure if the intervention is performed like shared decision-making. The two persons, who perform the scoring, are both healthcare professionals and have a master's degree in nursing, but are not a part of the project and the clinical environment. The videos will also be observed for element of tailoring and communications skills, mirroring and active listening.

## 3.5 The Implementation Process

The three key factors in the implementation phase are monitoring the dissemination of the intervention, surveillance and long-term follow-up [7]. Some of these key factors are monitored in study IV described in the evaluation. The Normalization Process Theory described by May et al. [29] has shown how to motivate and shape the implementation process of complex interventions and affect their outcomes. This theory has four constructs: coherence, cognitive participation, collective action and reflexive monitoring. These four constructs have been strived for in different ways in the implementation process. The intervention, the SDM-DC, is a complex intervention but is made as simple as possible. The key components in the interventions are explicated, but there is no manual for the different hospitals on how to implement the intervention into their clinical pathway. Some of the departments have changed their clinical pathway for dialysis choice radically, and some have made no changes. None of the participating departments received any funding for performing the intervention but only for data collection. They had to find their own resources to conduct the interventions. A meeting with all the dialysis coordinators was held every 6 months to discuss the implementation process and the preliminary results of the evaluations. The project period ended in May 2018, and all the participating departments have decided to continue the intervention.

The leadership of this project has been directed by the translation research model. Thus, decisions in this project have taken the clinical practice into account, and the project leader has collaborated very close with patients and healthcare professionals.

## 3.6 Conclusion

This chapter has described the development of an intervention for dialysis choice based on shared decision-making. The intervention is seen as a complex intervention using the MRC-model for complex interventions for the developing, piloting and evaluating process. The patient-to-PC and PC-to-patient' model has been used to establish nursing leadership within renal care where symptoms of uraemia are the most important issues experienced by patients which nurses need to address. The chapter has demonstrated the implications of the case of renal care being nested at a university hospital where many other agendas are ongoing, some of these being initiated to support local clinical initiatives and research and development within patient involvement at the hospital. The chapter is meant to illustrate how nurse leaders must collaborate, navigate and proactively seek benefits from opportunities showing up—both inside and outside the organization.

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