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Title page

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Introduction

Clinical pharmacy has been shown to have a positive impact on the optimization of therapeutic care, through activities such as prescription review and medication reconciliation (1, 2). Prescription review consists in an analysis and optimization of drug prescriptions based on patients' laboratory and medical data, therapeutic objectives, and guidelines. Medication reconciliation is a standardized process based on an exhaustive medication history retrieved from multiple sources; its purpose is to identify and justify any discrepancies between historical and current prescriptions and to share complete information between healthcare professionals (3). The optimization of therapeutic care by clinical pharmacy activities improves the quality and security of care: it reduces the risks of adverse event (AE) and adverse drug event (ADE), such as hospital readmission or emergency department visits (3, 4).

Structuring the patient care pathways is also an interesting strategy to improve the quality, security, and continuity of care especially regarding transitions of care, such as in-out hospitalization and transfer between hospital units. It consists of formalizing partnerships, practices, and protocols between medical healthcare providers and between paramedical healthcare providers. In this way, clinical pharmacists must be positioned as drug experts in the care pathways in order to optimize therapeutic care (9, 10). This is why integrating clinical pharmacy activities into a dynamic model as care pathway is encouraged by the American college of clinical pharmacy (4) and the French clinical pharmacy society (*Société Française de Pharmacie Clinique*) (8). So far, few teams have integrated clinical pharmacy activities into care pathways (1). Recent experiences were mostly focused on the in-out hospitalization

transition of care especially using medication reconciliation (5, 9, 10). To our knowledge, none of them have described their methodological development.

In the strained actual economic context, all clinical pharmacy activities cannot be achieved for all patients of all care pathways. Therefore, patient prioritization strategies must be defined. Actual strategies identify patients at high risk(s) of adverse drug event (ADE), or adverse drug reaction (ADR), or medication errors (ME), and to guide appropriate clinical pharmacy activities (5). To our knowledge, none of those strategies used the identification of adverse event (AE) risks by a pluriprofessional team (11). So multiple tools are designed based on the identification of ADE, ADR or ME strategies but none of those were executed regarding the global care pathway (11).

Therefore, the “5P project” (*Patient personalized clinical pharmacy program integrated into care pathway*) is proposed. Its objective is to develop programs of clinical pharmacy activities into 4 care pathways regarding AE risks and evaluate it in terms of feasibility, security of care (ME), patient satisfaction, and costs.

The aim of the present study was to present the methodological development of patient personalized clinical pharmacy programs integrated into two care pathways (orthogeriatric and pediatric kidney transplantation) by two methodologies used a *a priori* AE risk management approaches.

Methods

The proposed development integrated the identification of the clinical pharmacy activities required, the patients who need them, and the risky steps of the care pathway. For that purpose, two methods using qualitative study design were used as *a priori* AE risk management approaches: the Delphi method (12) and the inductive approach analysis of semi-directed interviews (IAASDI) (14). Were considered only AE risks where pharmacists can have potential clinical impact.

The predetermined topics were the following: AE risks, their influencing factors (AE risk factors), the steps of the care pathway and the clinical pharmacy activities (i.e. prescription review, medication reconciliation, admission interview, discharge interview, targeted pharmaceutical informative interview about specific treatment, educative interview, and primary care actors transmissions).

We considered “AE risk” as the possibility of an event occur (i.e. intra-hospital mortality, infections, hemorrhagic events,...) and “AE risk factors” (patient-related, medication-related, or care organization-related) as the characteristics that increased the probability of such events to occur.

Medical and paramedical healthcare direct care providers (physicians, pharmacists, nursing managers and nurses) working in either of the concerned care pathways – “orthogeriatric” (OG) and “pediatric kidney transplantation” (PKT) - were invited to participate.

Regarding results, the 5P study group’s point of view was taken into account to decide about: 1/ Patient prioritization and targeting steps; 2/ The personalized clinical pharmacy program integrated into the care pathway.

Delphi method

The Delphi method allows to confront expert point of views on a specific subject (12). The items are predetermined and most of the time are listed in a survey that needs to be iterative: it takes place necessary in several rounds, at least two. During the first round, participants respond to the survey without knowledge of other participants' answers. In the following rounds, each participant can keep or change their answers with knowledge of other participants' answers. This allows to tend towards a consensus (13).

Delphi method: survey conception and data collection

The survey was elaborated by a clinical pharmacist (DH) based on bibliographic research and validated by a pluri-professional group (geriatricans and clinical pharmacists). For each AE risk identified, the survey contained the following questions: 1) "What is the priority of this risk?"; 2) "In which step(s) of the care pathway was this risk considered as of high-priority?"; 3) "What clinical pharmacy activities could prevent this risk?"; 4) "What risk factors are major?". Answer modalities were documented on a 5-point Likert scale from 1 "not priority at all" or "not majority at all" to 5 "very priority" or "very majority", except for clinical pharmacy activities-related questions for which a binary answer (yes/no) was expected. Participants were free to add risks, care pathway steps, risk factors or clinical pharmacy activities.

Two rounds of survey were realized.

Delphi method: data analysis

Data analysis was performed using EXCEL by a clinical pharmacist (DH). An analysis by risk, and then a global analysis were defined *a priori*. If a risk obtained more than 40% of "not priority at all" (1 on the 1-5 scale) or "not priority" (2 on the 1-5 scale) answers, it was excluded from the analysis.

Analysis by risk: Care pathway steps that obtained more than 70% of “very priority” or “very majority” (5 on the 1-5 scale) and “priority” or “majority” (4 on the 1-5 scale) answers were retained. For each retained risk, the risk factors that obtained more than 15% of “very priority” answers and more than 25% on average of 5 “very priority” or “very majority” (5 on the 1-5 scale) and “priority” or “majority” (4 on the 1-5 scale) answers were retained. If less than 3 risk factors were retained using these 2 criteria, the risk factors that obtained more than 15% of “priority” or “majority” (4 on the 1-5 scale) answers were retained as well. For each risk, activities that obtained more than 25% of positive answers were retained.

Global analysis: the 3 retained steps of care pathway were the ones for which at least 4 risks were identified. Regarding these risks, influencing factors and clinical pharmacy activities required at each step were pinpointed. Also, risk factors were used to identify patients in need of these activities.

Inductive approach analysis of semi-directed interviews (IAASDI)

IAASDI allowed to explore the participants’ points of view of participants on a specific subject (14). An interview guide allowed to conduct the interviews (15) with the same predetermined topics previously mentioned.

IAASDI: interview guide conception and data collection

Prior to participant inclusion, the guide was designed for interviews by a clinical pharmacist (JM). It was then validated by a group of clinical pharmacists (DH, JM, MB). Semi-structured interviews were prospectively conducted by a clinical pharmacist (JM) who has been trained in methodology.

Healthcare providers were invited to participate in the interview during their working hours. The interviews were conducted at the hospital, in a private setting and were audiotaped.

IAASDI: data analysis

Audiotapes were manually transcribed without rephrasing the content (JM). This material was analyzed manually by a 3 steps “inductive content analysis” method (14-16), conducted by two clinical pharmacists (JM and DH). Firstly the raw text was read; secondly each analyst identified specific text segments for each predetermined categories: AE risk, AE risk-factors and clinical pharmacy activities. This identification method was itself divided in two steps: a vertical identification was made, by analyzing the interviews one by one and focusing on the recurrences and contradictions, then a horizontal identification was made, by comparing similarities, differences and oppositions between the categories (16). Finally, both analysts pooled their analyses and resolved differences in opinion until a consensus was obtained. There was no intercoding calcul.

A complementary bibliographic research allows to add AE risks, their influencing factors and the clinical pharmacy activities to prevent these risks.

Selected care pathways for development of clinical pharmacy programs

The “orthogeriatric” (OG) care pathway manages patients, aged of 75 years old or more, who suffer for hip fracture. The care pathway includes the following steps: emergency care, pre-operative care, operative room, post-operative care, rehabilitation care, home. The healthcare providers of the OG pathway belong to different specialties: emergency, reanimation, clinical pharmacy, kinesitherapy, nursing, surgery, and geriatrics. The Delphi method was chosen to elaborate the clinical pharmacy program in this care pathway because it includes several professions and because of the important number of healthcare providers involved.

The “pediatric kidney transplantation” (PKT) care pathway manages patients for kidney transplantation, aged from 0 to 18 years old. This care pathway includes the following steps: pre-transplant assessment, transplant hospitalization (month 0, M0), short-term post-

transplant (M+1), middle-term post-transplant (M+3), long-term post-transplant (M+6). The healthcare providers in the PKT pathway are mainly pediatricians working in kidney unit for at least 5 years, clinical pharmacists and nurses. The IAASDI method was chosen to elaborate the clinical pharmacy program in this care pathway because of the mono-specialty character and because of the low number of healthcare providers involved.

Ethics

Data collection through audio recording, for analysis and archiving has been performed in conformity with the “*Méthodologie de Référence004*” of the *commission nationale de l’informatique et des libertés* (CNIL, French national commission of information technology and freedom) on May 1st 2019, agreement number 18-314. The ethics committee of the concerned hospital approved this research on February 26th 2019.

Results

Delphi method and IAASDI, were conducted in a multi-site teaching hospital, respectively on « orthogeriatric » (OG) and « pediatric kidney transplantation » (PKT) care pathways.

Delphi method – orthogeriatric care pathway

Based on bibliographic research, 11 AE risks were present in the survey before the 1st round: intra-hospital mortality, acute confusion and cognitive alterations, infections (including osteoarticular), cardiovascular complications, thromboembolic complications, loss of medication information, pains, kidney complications, fall fractures, acute urine retention, and post-hospital mortality.

None of the 11 risks initially present in the survey were excluded. The participants added two risks (post-operative anemia and functional decline-institutionalization) and the risk factors associated. No clinical pharmacy activities has been added.

From April 1st to May 8th 2019, Delphi method has been realized in two rounds. A total of 9 physicians (6 geriatricians, 2 surgeons, and 1 emergency physician) and 8 pharmacists answered to the 1st round. For the 2nd round, 4 physicians (3 geriatricians and 1 emergency physician) and 4 pharmacists change their answers. No paramedical healthcare provider answered to either the 1st or 2nd round of the Delphi method.

Steps retained as priority were the post-operative step (for 10 risks among 13) and the rehabilitation care step (for 4 risks among 13), 12 risk factors were retained for the post-operative step and 5 for the rehabilitation care step. The pinpointed clinical pharmacy activities were prescription review and medication reconciliation at post-operative care step, and prescription review and targeted pharmaceutical informative interview about oral anticoagulants at rehabilitation care step.

Thus, regarding the results, 5P study group validated:

1/ Patients were prioritized for OG care pathway by the presence of at least 2 criteria among the following 4 criteria: age > 90 years old, cardiovascular diseases, prescribed potentially inappropriate medication for elderly patients (17), and obesity or diabetes. The physician and/or pharmacist can always prioritize the patients without those criteria, as long as this decision is justified in writing.

The targeting steps were post-operative care and rehabilitation care.

2/ The personalized clinical pharmacy program integrated into OG care pathway, presented in Figure 1.

IAASDI – pediatric kidney transplantation care pathway

From 31st of July to 3th of October 2019, 9 semi-directed interviews were conducted. All 4 pediatricians, 2 pharmacists, and 3 nurses answered one interview. The average duration of the interview was 19 ± 4.9 min.

The two main AE risks identified were graft rejection and infection. The risk factors associated to those two risks were: non-optimal medication adherence, non-optimal adaptation of immunosuppressive therapy doses, lack of information or a misinformation, and bad hygiene. Some participants defined “non-optimal medication adherence” as a risk and thus introduced the associated risk factors: adolescence period, familial environment with low socioeconomic level and/or parents not involved in the medical care, ADR, taste of medication (especially for young children), and non-adapted galenic form. The care pathway steps identified at highest risk were pre-transplant assessment, transplant hospitalization (M0), short-term post-transplant (M+1), middle-term post-transplant (M+3), long-term post-transplant (M+6), and pediatric-adult care transition. The educative interview was evocated by

participants, who mentioned the importance of adapting the message to the time when it is delivered.

Thus, regarding the results, 5P study group validated:

1/ Given the annual volume expected for the PKT care pathway (about 30 patients per year) no prioritization of patients is necessary: all the activities of the program will be carried out for all patients.

The targeting steps are pre-transplantation, immediate post-operative step, and post-transplantation.

2/ The personalized clinical pharmacy program integrated into PKT care pathway is presented in Figure 2. It takes into account the time when the message is delivered to adapt it.

Discussion

The present study described effective development of clinical pharmacy programs integrated into patient care pathway, based on AE risk management approach. This originality is at the same time to use AE risk management for prioritization patients and also to integrate clinical pharmacy activities into a dynamic model which is care pathways.

This *a priori* AE risk management approach applied in these development contrasts with actual literature about patient prioritization, which when it is described, are based on the identification of ADE, ADR or ME risk (11). A more step back vision allows to consider three questions in one: Where could clinical pharmacist prevent AE risks; which risks, and by which activities. Complementarily to bibliographic research, a pluriprofessionnal team is needed with the light of their expertise, to both identify AE risks and to answer the precedent question. This AE risk management approach will allow the clinical pharmacy activities' patient prioritization to gain in relevance and efficiency. By integrating this program development into patient care pathway, this approach will gain even more in rationality in the actual economic constraint context. It positions, as required (9,10), the clinical pharmacist as one of the actor of those care pathway, the expert of their therapeutic care optimization.

From qualitative research, the two used methods have advantages and disadvantages. The Delphi method can be performed with many participants, but can be rebarbative for them as they are required to fulfill the survey minimum twice. The analysis is time-consuming because qualitative data need to be translated into quantitative data (12,13). For IAASDI, the time spent for each interview is controlled by participants, but the transcription is time-consuming and the analysis requires 2 analysts (18). In the present study, methods were chosen because of the number and diversity of HPs involved in the care pathway: Delphi

method for OG care pathway (big number and wide pluriprofessionality), IAASDI for PKT (low number and low pluriprofessionality).

The 2 developed programs of clinical pharmacy activities integrated into OG and PKT care pathways are very different, as are the AE risks and their influencing factors in those 2 different care pathways. They however share the high risks of AE at transitions of care. Leistman *et al.* have showed the positive role of pharmacists, in particular by clinical pharmacy activities, in this context of transitions of care (5,9,10). To secure these risky moments in both OG and PKT care pathways, medication reconciliations were integrated into OG care pathway in different points of transition and information transmissions were integrated into both OG and PKT care pathways at patient discharge.

In addition to developing a clinical pharmacy program integrated into patient care pathways based on AE risk management approach, these methods helped its implementation by 3 aspects. Firstly, they associate knowledge from the literature and from the healthcare provider's experiences and opinions. According to the latter, organizational factors were taken into account, which helped the implementation of clinical pharmacy activities. However, this also constitutes a limit to the reproducibility of those programs to others hospitals which may be differently organized. Secondly, professionals of different skills (nurses, physicians, and pharmacists) from different units were involved. This pluri-professionnal partnership during the development of these programs helped for the operational set-up of clinical pharmacy activities. Thirdly, the methods permitted to define and present clinical pharmacy activities to nurses and physicians, by another way than usual. It helped their integration into the daily routine of units and therefore their implementation. These three aspects were described as implementation facilitators of health interventions by Damschroder *et al.* (19).

Conclusion

Today, those 2 programs have been executed in our multi-site teaching hospital, during 8 months of data collection. The feasibility and the quality and security of therapeutic patient care (medication errors) were evaluated. Those results will provide information on whether these programs are feasible as developed, and if they secure OG and PKT care pathways. If these results are positive, these two programs could be deployed, and these methodologies could be used to develop other patient personalized clinical pharmacy programs integrated into other care pathways.

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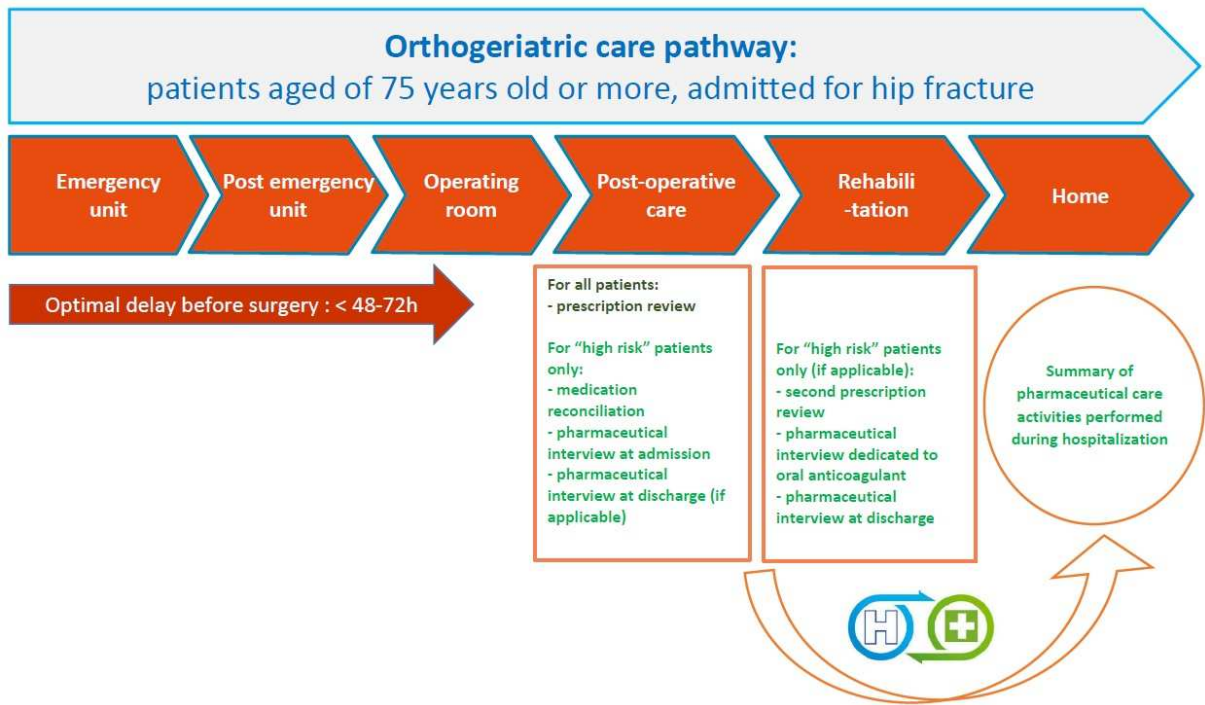


Fig 1. Patient personalized clinical pharmacy program integrated into the orthogeriatric care pathway

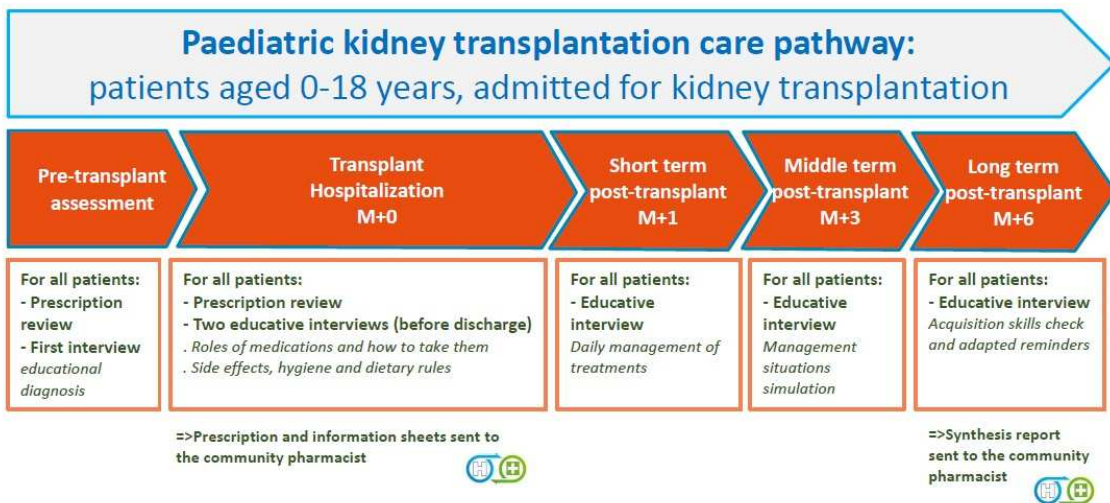


Fig 2. Patient personalized clinical pharmacy program integrated into the pediatric kidney transplantation care pathway

Steps	Delphi Method	Inductive approach analysis of semi-directed interviews
1	Survey conception	Interview guide conception
2	First round sollicitation	Interviews
3	Global & individual analysis	Retranscription of all audiotaped interviews
4	Second round sollicitation	Identification of significative segments by each analyst
5	Global analysis	Consensus between analysts

Table 1. Steps' methods

	Emergency care	Pre-operative care	Operative room	Post-operative care	Rehabilitation care	Home
Intra-hospital mortality	X		X	X		
Acute confusion and cognitive alterations	X			X		
Infections (including osteoarticulary)			X	X		
Cardiovascular complications				X		
Thromboembolic complications		X		X	X	
Loss of medication information	X					
Pains				X	X	
Kidney complications				X		
Fall fractures				X		
Acute urine retention					X	X
Post-hospital mortality						
Post-operative anemia			X	X		
Functional decline-institutionalization				X	X	

Table 2. Priority adverse event risks in the orthogeriatric care pathway