Non-dispensing clinical pharmacists in general practice

Training, implementation and clinical effects

Ankie Hazen

NON-DISPENSING CLINICAL PHARMACISTS IN GENERAL PRACTICE:

training, implementation and clinical effects

Ankie Cornelia Maria Hazen

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NON-DISPENSING CLINICAL PHARMACISTS IN GENERAL PRACTICE:

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De apotheker-farmacotherapeut in de huisartsenpraktijk: training, implementatie en klinische effecten

(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de rector magnificus, prof.dr. G.J. van der Zwaan, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op maandag 29 januari 2018 des middags te 2.30 uur

door

Ankie Cornelia Maria Hazen
geboren op 6 april 1983 te Bergen op Zoom

Promotoren:	Prof. dr. M.L. Bouvy
	Prof. dr. N.J. de Wit
	Prof. dr. A.A. de Bont
Copromotor:	Dr. D.L.M. Zwart

It's only after you've stepped outside your comfort zone
that you begin to change, grow, and transform.

Roy T. Bennett

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Chapter 1

GENERAL INTRODUCTION

Present pharmaceutical care is suboptimal

The inappropriate use of medication often leads to adverse events and hospitalisations.[1–3] In the Netherlands, every year almost 50.000 patients are admitted to hospital due to medication therapy problems.[3] In the United States, more than 1.900.000 adverse events occur each year of which approximately 180.000 are potentially life threatening or fatal.[4] Many medication-related hospital admissions are potentially preventable.[1,2,4] The problem is expected to increase in near future. With the aging of the population, more patients with multimorbidity and polypharmacy will add to the complexity of pharmaceutical care. This will increase the risk of medication-related morbidity and mortality. This risk is broadly acknowledged as a major health care problem which is presently inadequately addressed.

As the vast majority of medication prescriptions is either initiated or repeated in general practice, primary care is the key entrance for safe and high quality pharmaceutical care. Pharmacists, who are trained as 'medication experts' should take the lead in implementing safe and effective use of medication. Currently, pharmacists are hampered to take that role, due to several factors. Community pharmacists are able to spent limited time on cognitive pharmacy services, such as performing clinical medication reviews, because facilitating timely dispensing of medication demands too much of their time and effort.[5] Moreover, pharmacists are traditionally trained with a product centered focus, indicating an insufficient patient-centered approach and a lack of clinical reasoning skills. The reimbursement of pharmacy services is another major hurdle. Pharmacists are primarily reimbursed by fee-for-dispensing and receive limited reimbursement for cognitive services. Also, collaboration with general practitioners (GPs) is often suboptimal, as GPs and pharmacists have different responsibilities, backgrounds and working processes. Limited access to patient medical records further restricts pharmacists, ability to optimally contribute to the quality of pharmaceutical care.[6]

To address the problem of medication-related harm and to meet the rising demand for care, the expertise of pharmacists could be made optimal when further integrated in primary care.[7] A patient-centered, clinically trained pharmacist integrated in a general practice team may be able to improve the safe and effective use of medication.

Paradigm shift: pharmacist as clinical care provider in primary health care teams

Although over the years the role of pharmacists has shifted from compounding and dispensing of medication towards the provision of pharmaceutical care,[5,8] they should further develop as clinical care provider. Combining clinical skills with medication knowledge offers opportunities to take integral responsibility for the pharmaceutical care provided in primary care. Expanding the pharmacists' clinical role is expected to increase patient safety and the clinical outcomes of pharmacotherapy.[9] However, expanding the pharmacists' role requires a major paradigm shift in both the positioning of pharmacists in primary care, as well as in the training that is required for more specific clinical tasks.

Integrating a non-dispensing pharmacist (NDP) in general practice is an option to expand the pharmacists' clinical role and might contribute favorably to the outcomes of pharmaceutical care.[10] An NDP will not be distracted by logistics, human resource management and other managerial tasks. This will enable the NDP to work fulltime on the improvement of pharmacotherapy. With appropriate training to learn to work at the clinical side of primary care, an NDP will provide patient-centered care and will therefore be better aligned with the GP. This will foster mutual trust and respect and will help to build interprofessional working relationships.[11]

NDPs in primary care: international context

Embedding NDPs in general practice is a new approach in the Netherlands, but has already been studied and implemented in several countries. However, the degree of integration of NDPs in general practice in different countries varies as do the specific tasks and responsibilities of NDPs.

In the United States, several models of patient-centered multidisciplinary team-based care have been developed, such as Patient-Centered Medical Home (PCMH)-practices. In these practices, NDPs are fully integrated and provide different medication therapy management services, mainly for patients with chronic conditions and polypharmacy.[12–16] A systematic review and meta-analysis that included 298 studies conducted in the United States reported favorable effects of pharmacist-provided patient care across various patient outcomes, health care settings, and disease states.[17]

In Canada, the PCMH-model was adopted and implemented as the Family Health Team. Research that has contributed to the development of integrated NDPs in general practice in Canada are the SMART and IMPACT trial.[18,19] Currently, there are over 300 pharmacists working within an integrated primary care setting in urban areas of Canada, in which pharmacists take on increasingly prominent roles as members of the health care team.[20]

In the UK, several trials on pharmacist-led services in general practice have been conducted.[21,22] Currently, 500 NDPs (also called 'primary care pharmacists') are embedded in GP practices to conduct a range of clinical, educative and administrative services.[23,24] The National Health Services' strategy is to enable a greater clinical role for pharmacists. This is highlighted by the vision of the Scottish Government to develop pharmacist-independent prescribers.[25] Also, the General Practice Forward view for Scotland supports further integration of NDPs in general practice, enabling 2.000 NDPs to work in general practice by 2020.[26]

In Australia, the government-funded Home Medicine Review and Residential Medication Management Review services provided by pharmacists are in place, although pharmacists are still seen as underutilized professionals in primary health care. There is growing support to further expand their role through the so called "GP super clinics program" in which pharmacist services are integrated in general practice.[27] Two

Australian studies are performed in general practice and highlight the effectiveness of pharmacist consultations.[28,29]

New proposed model of pharmaceutical care: fully integrated NDPs

Although research indicated that NDP-provided services generally improve pharmaceutical care and consequently the effectiveness and safety of pharmacotherapy, the evidence of improvement on clinical outcomes has not been established.[10] There is a lack of adequately powered multicenter intervention studies with sufficient follow-up. Therefore, the Pharmacotherapy Optimization through Integration of a Non-dispensing pharmacist in a primary care Team (POINT) study is developed. The original program theory of the study is described in box 1.

The POINT study investigated a complex intervention of fully integrated NDPs in general practice and was based upon the patient-centered approach of delivering medication therapy management services.[5] This patient-centered approach entails delivering a broad range of multifaceted services completely separate from the dispensing process. In addition, the POINT study was inspired by the Canadian IMPACT practice model which incorporated a multilevel approach.[19] Hence, NDPs intervened both at patient and at practice level. The activities of NDPs at patient level included clinical medication reviews for patients with polypharmacy, medication reconciliation for patients discharged from hospital and patient consultations about specific drug therapy problems. The services provided

- The NDP is located in general practice
  Assumption: pharmacists who work in general practice can easily contact the GPs. Daily face-to-face contact between the pharmacists and the GP will improve mutual understanding and will foster trust which will ultimately improve medication effectiveness and safety.
- The NDP gets access to medical data and shares patients information with the GP
  Assumption: shared patient records will optimize pharmaceutical care.
- The NDP does not dispense medication and gets a fixed income to provide pharmaceutical care.
  Assumption: the NDP does not need to focus on dispensing and logistics as the primary business model.
- The NDP participates in a clinical pharmacy training program
  Assumption: the NDP will develop as patient-centered care provider able to work on the clinical side of primary care.

Box 1. Program theory of the POINT study

by the NPDs were available for all patients in the general practice, however the NDPs focused upon care for high-risk patients (being aged 65 years or older and using five or more chronic medications). The activities of NDPs at practice level included educating team members in pharmacotherapy, the implementation of targeted pharmaceutical care programs and the optimization of care processes around repeat prescribing, clinical care paths and administrative efficiencies. The clinical impact of NDPs will be measured in a non-randomized controlled intervention study.

Given the complexity of the intervention, it is relevant to not focus merely on the clinical outcomes, but also to understand the operational aspects of the intervention in detail. In other words, to understand how clinical integration of NDPs impacts medication therapy management. An increased understanding of these aspects will result in transferable knowledge for the future optimization and implementation of the intervention.

Also, it is important to learn from stakeholder perspectives. Yet, introducing new roles into existing healthcare teams can put professional boundaries under pressure.[30] Integrating NDPs in general practice will be an incremental process in which well-known barriers and facilitators can be expected.[11] In such a process, understanding of existing consensus and controversies amongst stakeholders about integration of NDPs in general practice is key. Literature on this topic is lacking.

The POINT study was designed to obtain a full perspective on this new model of pharmaceutical care. To do so, the newly developed training, the processes of integration and the clinical effectiveness was investigated by using a variety of quantitative, mixed and qualitative methods.

Training and professional identity

Pre-graduate pharmacy education is already evolving from product centered to patient-centered. Worldwide, there is a reorientation of pharmacy curricula to train pharmacists to be able to work in a patient-centered manner, to adapt to clinically focused roles within a team of healthcare professionals.[8,31] In the Netherlands, we see a similar trend. The Dutch '2016 Pharmacist Competency Framework' defines the learning outcomes for pharmacists graduating from Dutch universities, who intend to work in a community or hospital pharmacy.[32] The pharmacist's core competence is defined as Pharmaceutical Expertise, including the delivery of clinically appropriate pharmacotherapy.

Still it is likely that academic training does not fully prepare pharmacists to work as a clinical pharmaceutical care provider (NDP) in general practice teams. Pharmacists need additional training in patient consultation, clinical reasoning and decision making. In addition, pharmacists need to learn how to efficiently collaborate with GPs, how to develop and maintain their professional identity and how to strategically position themselves within the clinic.[33] NDPs may encounter barriers during the process of integration in general practice due to a lack of role clarity, uncertainty about their level of responsibility and the unfamiliarity with the roles of other team members.[11] Only a few advanced training

programs exist, for example the UK program "Developing Clinical Pharmacists In General Practice".[34] As part of the POINT intervention study, a Clinical Pharmacy Training Program was developed, to support the pharmacists in both the challenges and potential of their professional role transition from community pharmacy to general practice.

Objective of this thesis

The objective of this thesis is to develop, implement and evaluate the integration of NDPs in general practice, with the aim to improve outcomes of pharmaceutical care by transferring pharmacists from the community pharmacy to the general practice. This thesis mainly focused upon the professional development of pharmacists, including the integration and training of NDPs who work according to the POINT practice model. A separate thesis will approach NDP-care from a general practice perspective. Both theses will evaluate the clinical effect of the intervention.
The general objective of this thesis is threefold.

1. To study the background and process of integrating NDPs in general practice;
2. To develop and evaluate the educational program for NDPs and their professional identity formation;
3. To evaluate the clinical effectiveness of this NDP based model compared to current models of pharmaceutical care.

Outline

In *Chapter 2* we report three studies about the integration processes of NDPs in general practice. First, a review of the literature about the impact of the degree of integration of NDPs in general practice on health outcomes. Second, the debate amongst stakeholders on this new role for pharmacists to uncover the controversy and consensus of integrating NDPs in the general practice. Third, the process of clinical integration of NDPs to understand the operational aspects of this complex intervention.

In *Chapter 3* we report two studies about the newly developed Clinical Pharmacy Training Program. First, the design and general findings of this program. Second, the professional identity formation of NDPs through the learning concepts of boundary crossing.

In *Chapter 4* we report three studies about the safety and clinical effectiveness of NDP-care. First, the study protocol of the controlled intervention study. Second, the impact of the NDPs on drug therapy problems and to which extent these problems are actually solved. Third, the effect of NDP-care on medication-related hospitalisations (Figure 1).

In conclusion, the research is discussed in *Chapter 5* and summarized in English and Dutch in *Chapter 6*.

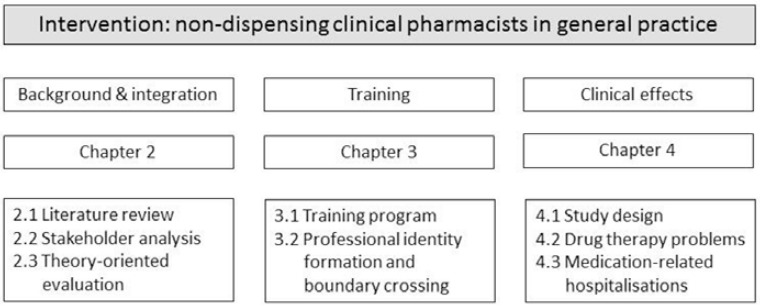

Figure 1. Outline of the thesis

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Chapter 2

BACKGROUND AND PROCESSES OF INTEGRATION

2.1

The degree of integration of non-dispensing pharmacists in primary care practice and the impact on health outcomes: a systematic review

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ABSTRACT

Background

A non-dispensing pharmacist conducts clinical pharmacy services aimed at optimizing patients individual pharmacotherapy. Embedding a non-dispensing pharmacist in primary care practice enables collaboration, probably enhancing patient care. The degree of integration of non-dispensing pharmacists into multidisciplinary health care teams varies strongly between settings. The degree of integration may be a determinant for its success.

Objectives

This study investigates how the degree of integration of a non-dispensing pharmacist impacts medication related health outcomes in primary care.

Methods

In this literature review we searched two electronic databases and the reference list of published literature reviews for studies about clinical pharmacy services performed by non-dispensing pharmacists physically co-located in primary care practice. We assessed the degree of integration via key dimensions of integration based on the conceptual framework of Walshe and Smith. We included English language studies of any design that had a control group or baseline comparison published from 1966 to June 2016. Descriptive statistics were used to correlate the degree of integration to health outcomes. The analysis was stratified for disease-specific and patient-centered clinical pharmacy services.

Results

Eighty-nine health outcomes in 60 comparative studies contributed to the analysis. The accumulated evidence from these studies shows no impact of the degree of integration of non-dispensing pharmacists on health outcomes. For disease specific clinical pharmacy services the percentage of improved health outcomes for none, partial and fully integrated NDPs is respectively 75%, 63% and 59%. For patient-centered clinical pharmacy services the percentage of improved health outcomes for none, partial and fully integrated NDPs is respectively 55%, 57% and 70%.

Conclusions

Full integration adds value to patient-centered clinical pharmacy services, but not to disease-specific clinical pharmacy services. To obtain maximum benefits of clinical pharmacy services for patients with multiple medications and comorbidities, full integration of non-dispensing pharmacists should be promoted.

INTRODUCTION

The aging of the population results in increasingly complex medication-related needs.[1] To sustain the economic viability of health care the majority of elderly patients should be treated in primary care. To incorporate specific pharmaceutical expertise, some primary care practices have embedded a non-dispensing pharmacist (NDP, also: clinical pharmacist or clinical pharmacy specialist).

NDPs in primary care practice conduct clinical pharmacy services (CPS) that primarily focus on chronic disease management. CPS are usually multifaceted, including medication therapy reviews, counselling and medication education. These services can be aimed at patients with a specific chronic condition such as diabetes, cardiovascular disease or COPD ("disease-specific CPS"), or at a more heterogeneous group of patients at risk of drug related problems, such as patients with multimorbidity and polypharmacy ("patient-centered CPS"). Disease-specific CPS focusses on evidence-based protocolled care, while patient-centered CPS entails a more non-standardized and holistic approach.[2]

Some NDPs are fully integrated into the health care team,[3,4] whereas others only temporarily provide a specific CPS.5 Common opinion is that integrated care for patients with chronic conditions may improve patient outcomes.[6–8] CPS have been shown to positively affect surrogate outcomes, such as blood pressure, glycemic control and lipid goal attainment.[9–13] Evidence of the effect of CPS on clinical endpoints, such as mortality, hospitalizations and health related quality of life, is less clear probably due to very heterogeneously defined CPS as well as strongly differing study settings.

Both aspects are features of the degree of integration of the NDP who delivers the CPS. The degree of integration of NDPs into the health care team may be a determinant for its success, but this association has never been properly assessed. Therefore, we conducted a systematic review to investigate how the degree of integration of an NDP impacts health outcomes in primary care.

METHODS

The protocol of this systematic review has been published in the PROSPERO register. The registration number is: CRD42016017506.[15]

Search strategy

We searched PubMed and Embase from 1966 to June 2016. A trained librarian, in consultation with researchers, developed a search strategy (Appendix Table 1). Also, we manually searched the reference list of systematic reviews and background articles about clinical pharmacy interventions in primary care for additional citations.

Potentially relevant studies were identified by two reviewers (AH and LB) based on predetermined inclusion criteria in a two-step procedure: 1) title and abstract, 2) screening of the full text. In case disagreement about inclusion could not be resolved by discussion

What is already known about this subject

- Co-location of a non-dispensing pharmacist in primary care practice probably enhances integrated patient care;
- The degree of integration of non-dispensing pharmacists into multidisciplinary health care teams varies between settings.

What this study adds

- This study shows the relative value of integration of clinical pharmacy services in primary care;
- Full integration may not improve the outcomes of disease-specific clinical pharmacy services in primary care;
- Full integration may improve outcomes of patient-centred clinical pharmacy services, however requires additional research.

between the two reviewers, a third reviewer (AB or MB) was consulted to reach consensus. We used the PRISMA checklist to conduct and report the systematic literature review.[16]

Study selection

Both US and non-US comparative studies of any design that had a control group or baseline comparison were included if they met the following criteria:
The intervention

1. comprised at least one key component of a chronic disease management service aimed at individual ambulatory patients;
2. was conducted by an NDP who had a regular and ongoing relationship with the primary care practice and was at least part-time physically present and at that time not involved in work related to community pharmacy;
3. measured a relevant clinical or patient reported health outcome or a proxy of a relevant health outcome (e.g. improvement of medication errors).

Studies were excluded if the intervention was delivered in a specialty or off-site clinic without collaboration with the general practitioner (GP), or if it was a pilot of an already included study or a secondary analysis. Also, unpublished studies and studies published in languages other than English were not taken into account for analysis.

Dependant variable: degree of integration

Our main focus was the degree of integration of NDPs, which we assessed via key dimensions of integration from the conceptual framework of Walshe and Smith[17]: organizational,

informational, clinical, functional, financial and normative integration (table 1). The financial integration could not be taken into account as most interventions were project funded studies. The key dimensions were scored dichotomous (yes/no). A positive score on zero to two dimensions of integration was defined as "no integration". A positive score on three or four dimensions of integration was defined as "partial integration" and a positive score on all five dimensions was defined as "full integration". Prescriptive authority was taken into account to assess clinical integration, see table 3.

Primary outcome: health outcomes

The primary outcomes of the intervention were either real clinical health outcomes, such as mortality, or surrogate clinical health outcomes, such as HbA1c, lipids and blood pressure. In addition to clinical health outcomes, we included patient reported health outcomes, such as health related quality of life and proxies of health outcomes, such as quality of care performance indicators.

Data collection process

Other extracted data included the duration of the intervention, study size, primary outcomes, specification of the CPS (disease-specific or patient-centered) and the number of involved practices and NDPs.

Table 1. Key dimensions of integrated care for chronic disease management,[17] tailored to the setting of a non-dispensing pharmacist in primary care practice

Organizational:	Organizational design and governance arrangements
	Measurable element: an umbrella organization or network, or NDP has permanent position within primary care practice
Informational:	Shared access of clinical information systems
	Measurable element: GP and NDP work with integrated clinical information systems
Clinical:	Delivery of rational and continuous clinical care to patients
	Measurable elements: multiprofessional teams, NDP performs patient counselling and follow-up, face-to-face communication between GP and NDP, patient directed activities outside the scope of the intervention, prescribing authority of the NDP
Functional:	Supportive administrative and functional elements
	Measurable element: shared education or administrative support by primary care practice staff
Financial:	Financial arrangements and payment system
	Measurable element: n/a
Normative:	Shared vision, goals and values
	Measurable element: collaboratively designed protocols with shared goals and visions of the pharmaceutical intervention

The primary outcomes of the intervention were categorized as either "positive", "negative" or "no effect". A positive outcome was defined as a statistically significant difference (p value < 0.05) compared to the control group or baseline. A negative outcome being the opposite and no effect as no statistically significant difference between intervention and control group or baseline.

Two authors independently extracted the data and one author cross-checked all extracted data. Differences were resolved in discussion. In case of dissensus, a third researcher was consulted. If we were unable to score the dimensions of integration – despite contacting the corresponding author for additional information and verifying complementary study protocols - the study was excluded for synthesis.

Quality assessment

We used the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool to assess: selection bias, study design, confounders, data collection methods, withdrawals and drop-outs. Given the nature of the included studies, blinding of the participants and outcome assessors was generally not possible. Therefore, this criterion was not included in the quality assessment. Two authors independently assessed each study and resolved disagreement by consensus or by consulting a third reviewer.

Data synthesis

The included studies were heterogeneous regarding the type of CPS, enrolled participants, number of practices, involved NDPs and measured health outcomes. Therefore, it was inappropriate to perform statistical aggregation of findings. To investigate how the degree of integration of an NDP impacts health outcomes we plotted the number of improved primary outcomes against the total number of assessed primary outcomes. We stratified the analysis for disease-specific CPS and patient-centered CPS.

RESULTS

Ninety studies were included for data extraction (Figure 1). For thirty studies we were unable to determine the degree of integration of the NDP and were excluded (Appendix Table 2a/b). We grouped studies by type of CPS: disease-specific CPS (n=43) and patient-centered CPS (n=17).

Summary of included studies

The included studies consisted of 35 RCTs, 12 two group cohort studies and 13 one group cohort studies. The median of the study population was 140 patients (interquartile range 76-321). The duration of the interventions ranged from 1 to 60 months. The median of the number of involved practices and NDPs was 1 (interquartile range 1-6) and 2 (interquartile range 1-4), respectively. The majority of the studies were performed in the United Stated of America (USA) (n=43) (Tables 2a and 2b).

Methodological quality

The methodological quality was high in 18 studies (30%), moderate in 34 studies (57%) and low in 8 studies (13%). 35 studies (58%) had a strong design, with described randomization processes. Eight studies (13%) had a high participation rate and were very likely to be representative to the target population. Forty studies (67%) controlled for at least 80% of relevant confounders and 48 studies (80%) used valid and reliable data collection tools. 29 studies (48%) had a follow-up rate of at least 80% (table 3).

Synthesis of results

We assessed 89 health outcomes in 60 comparative studies: 54 clinical health outcomes (mainly surrogate health outcomes such as blood pressure or HbA1c), 12 patient reported health outcomes, such as HRQoL and 23 proxies of health outcomes, such as medication errors. CPS conducted by NDPs showed a significant positive effect on 62% (55/89) of assessed health outcomes. The other 34 health outcomes showed no statistically significant difference compared to control group or baseline. None of the included studies measured a negative impact on health outcomes. The effect of CPS on surrogate clinical health

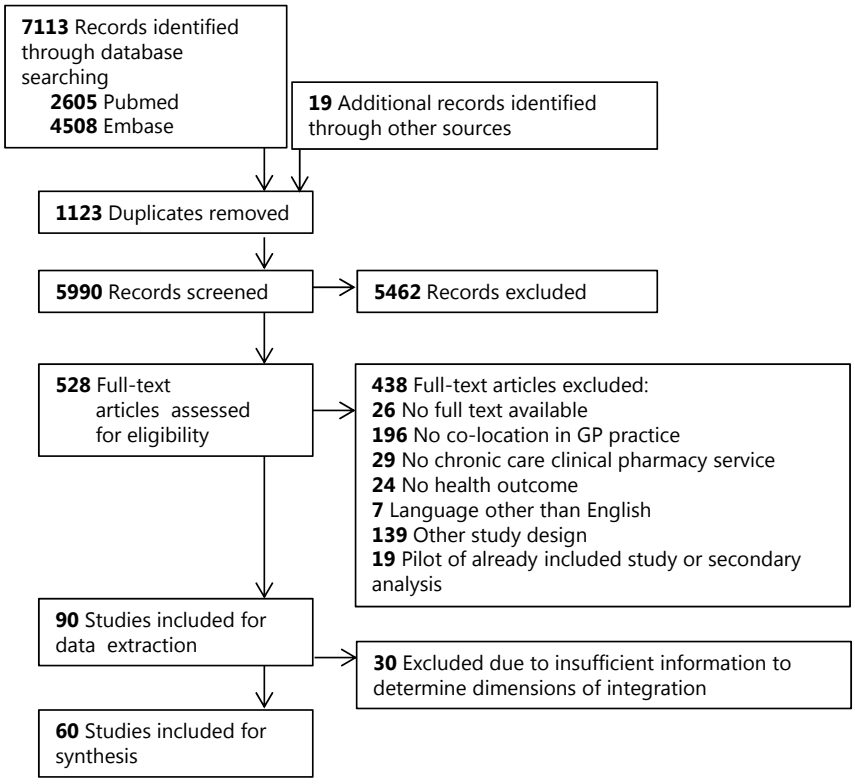

Figure 1. Flowchart of the study selection

Table 2a. Study characteristics of disease-specific clinical pharmacy services (n=43)

Author (year)	Country	No. intervention practices/No. NDPs	Duration intervention (months)	No. patients in intervention group
Diabetes (n=16)				
Choe (2005)[18]	USA	1/1	24	41
Coast-Senior (1998)[19]	USA	2/4	3-11	23
Heisler (2012)[4]	UK	5/11	14	1797
Henry (2013)[20]	USA	1/2	3	93
Ip (2013)[21]	USA	1/1	12	147
Irons (2002)[22]	USA	1/2	32	87
Jameson (2010)[23]	USA	13/1	12	52
McAdam-Marx (2015)[24]	USA	10/3	48	303
McCord (2006)[25]	USA	1/1	4	316
McFarland (2012)[26]	USA	4/3	6	36
Mourão (2012)[27]	Brazil	6/2	6	50
Rothman (2005)[28]	USA	1/3	12	112
Salvo (2012)[29]	USA	1/1	18	69
Scott (2006)[30]	USA	1/1	9	76
Shane-McWorther (2005)[31]	USA	1/1	36	176
Simpson (2011)[32]	Canada	5/2	12	131
Hypertension (n=11)				
Bex (2011)[33]	USA	4/6	18	573
Bogden (1998)[34]	USA	1/1	6	49
Borenstein (2003)[35]	USA	1/1	12	98
Carter (2008)[36]	USA	5/2	9	101
Hirsch (2014)[37]	USA	1/2	9	166
Hunt (2008)[38]	USA	9/5	12	230
Magid (2013)[39]	USA	10/≥10	6	175
Margolis (2013)[40]	USA	16/8	18	228
Mehos (2000)[41]	USA	1/1	6	18
O'Neill (2014)[42]	USA	1/1	1	63
Wong (2013)[43]	Hong Kong	1/?	6	92
Dyslipidaemia (n=5)				
Billups (2005)[44]	USA	16/16-48	12	5550
Bogden (1997)[5]	USA	1/1	6	47
Smith (2013)[45]	USA	2/1	?	213
Straka (2005)[46]	USA	2/2	6	359
Tahaineh (2011)[47]	Jordan	1/1	6	73

Dimension of integration					
Organizational	Informational	Clinical[a]	Functional	Normative	Primary outcomes (effect)
Yes	Yes	Yes	Yes	Yes	HbA1C (+)
Yes	Yes	Yes	Yes	Yes	Glycemic control (+)
Yes	Yes	Yes	Yes	Yes	BP (0)
Yes	Yes	Yes	Yes	Yes	Guideline adherence (0), HbA1C (+)
Yes	Yes	Yes	Yes	Yes	Baseline changes in HbA1c, LDL-C and BP (+) and goal attainment (+), 10-year CVRR(+)
Yes	No	Yes	No	Yes	Glycemic control (0)
No	Yes	No	Yes	Yes	HbA1c (0)
Yes	Yes	Yes	No	Yes	Glycemic control (+)
Yes	Yes	Yes	Yes	Yes	HbA1c (+), BP (0), lipids (+)
Yes	No	Yes	Yes	Yes	HbA1c (0)
No	No	No	No	No	HbA1c (0)
Yes	Yes	Yes	Yes	Yes	HbA1c (+),LDL-C (0), BP (+)
Yes	Yes	Yes	Yes	Yes	HbA1c (+)
No	Yes	Yes	Yes	Yes	HbA1c (+)
Yes	Yes	Yes	Yes	Yes	HbA1c (0), lipids (0), BP (0)
Yes	Yes	Yes	Yes	No	BP (+)
Yes	Yes	Yes	Yes	Yes	BP (+)
No	Yes	No	No	No	BP (+)
No	Yes	No	Yes	Yes	BP (+)
Yes	Yes	Yes	Yes	Yes	BP (+)
No	Yes	Yes	Yes	Yes	BP (+)
Yes	Yes	Yes	Yes	Yes	BP (+)
Yes	Yes	Yes	Yes	Yes	BP (+)
Yes	Yes	Yes	Yes	Yes	BP (+)
No	No	No	No	No	BP (+)
Yes	Yes	Yes	Yes	Yes	BP (+)
No	No	No	No	No	BP (0)
Yes	Yes	No	No	Yes	LDL-C (+)
No	Yes	No	No	No	LDL-C (+)
Yes	Yes	Yes	Yes	Yes	Lipid profile
No	Yes	Yes	No	Yes	LDL-C (+)
No	No	No	No	Yes	LDL-C (+)

Table 2a. (continued)

Author (year)	Country	No. intervention practices/No. NDPs	Duration intervention (months)	No. patients in intervention group
Metabolic syndrome (n=1)				
Hammad (2011)[48]	Jordan	6/2	6	112
Heart failure (n=1)				
Lowrie (2012)[49]	UK	174/27	60	1090
Depression (n=3)				
Adler (2004)[50]	USA	9/5	6	268
Capoccia (2004)[51]	USA	1/2	12	41
Finley (2003)[52]	USA	1/?	6	75
Osteoporosis (n=1)				
Hall (2009)[53]	USA	1/4	?	22
Cardiovascular disease (n=1)				
Evans (2010)[54]	Canada	1/1	6	176
Diabetes + hypertension (n=2)				
Edelman (2010)[55]	USA	2/2	12	133
Neto (2011)[56]	Brazil	1/4	36	97
Diabetes and/or dyslipidaemia (n=1)				
Hetro (2015)[57]	USA	1/?	6	61
Diabetes, hypertension, dyslipidaemia or asthma (n=1)				
Koenigsfeld (2012)[58]	USA	3/3	13	131+427+299+27

(+) positive effect, (0) no effect, BP Blood Pressure, CVRR Cardiovascular Risk Reduction, DM Diabetes Mellitus, HbA1c glycosylated haemoglobin, LDL-C low-density lipoprotein cholesterol. A: see Appendix Table 3 for specification

outcomes and proxies of health outcomes was high: 67% (36/54) and 78% (18/23) of these outcomes improved. Patient reported health outcomes were less frequently reported (n=12) and showed improvement in one trial.

We related the dimensions of integration to the degree of integration. We found 14 studies (23%) in which the NDPs were not or minimally integrated into the health care team (positive score on 0-2 dimensions of integration). 71% (n=10) of NDPs had shared access to patient medical records (informational integration). Yet, integration on all other

Dimension of integration					
Organizational	Informational	Clinical[a]	Functional	Normative	Primary outcomes (effect)
Yes	Yes	No	No	No	Metabolic syndrome status (+)
No	Yes	Yes	No	No	Composite of death or hospital admission for worsening heart failure (0)
No	Yes	Yes	Yes	No	Antidepressant use rate (+). depressions severity (0)
Yes	Yes	Yes	Yes	Yes	Depression symptoms (0)
Yes	Yes	Yes	Yes	Yes	Adherence to antidepressant (+), patient satisfaction (+), clinical and functional severity (0)
Yes	Yes	Yes	No	Yes	Compliance with treatment guidelines (+)
No	Yes	Yes	No	Yes	10 year CVR (0)
Yes	Yes	Yes	Yes	No	BP (+),HbA1C (0)
Yes	Yes	Yes	Yes	Yes	10 year CVR (+)
Yes	Yes	Yes	Yes	Yes	HbA1C (+), LDL-C (0), BMI (0)
Yes	Yes	Yes	Yes	Yes	Achieving goal levels for DM (0), hypertension (+) and % on asthma controller medication (0)

dimensions was low: organizational 14% (n=2), normative 14% (n=2), functional 7% (n=1) and clinical 7% (n=1).

We identified 19 studies (32%) in which the NDPs were partially integrated (positive score on 3-4 dimensions of integration). All but one (95%) had shared access to patient medical records. Integration on the clinical, functional and normative dimension was 68% (n=13) and 47% (n=9) of NDPs were permanently employed within the practice or worked within an umbrella organization or network (organizational integration).

Table 2b. Study characteristics of patient-centered clinical pharmacy services (n=17)

Author (year)	Country	No. practices/ No. NDPs	Duration intervention (months)	Study size intervention group (patients)
Avery (2012)[59]	UK	72/?	12	3812
Berdine (2012)[60]	USA	1/1	36	200
Carter (2001)[61]	USA	9/51	12	523
Davis (2007)[62]	USA	6/12	5	79
Freeman (2013)[63]	Australia	1/1	0-12	314
Galt (1998)[64]	USA	1/1	12	336
Hanlon (1996)[65]	USA	1/1	12	105
Hogg (2009)[66]	Canada	1/1	12-18	121
Isetts (2006)[67]	USA	6/7	12	285
Isetts (2008)[68]	USA	6/7	12	256
Krska (2001)[69]	UK	?/?	3	168
Lenander (2014)[70]	Sweden	1/1	12	107
Pindolia (2009)[71]	USA	1/7	24	520
Roth (2013)[72]	USA	1/2	6	64
Sellors (2003)[73]	Canada	24/12	5	431
Tan (2014)[74]	Australia	2/2	6	82
Zermansky (2001)[75]	UK	4/1	12	581

(+) positive effect, (0) no effect, ADE Adverse Drug Events, BMI Body Mass Index, BP Blood pressure, CDM Chronic Disease Management, HbA1c glycosylated haemoglobin, HRQoL Health Related Quality of Life, LDL-C low-density lipoprotein cholesterol, MAI Medication Appropriateness Index, MRP Medication Related Problem, PCI Pharmaceutical Care Issues, QoC Quality of Care. a: see Appendix Table 3for specification

We found 27 studies (45%) in which the NDPs were fully integrated within the primary care practice (positive score on 5 dimensions of integration). This involved permanent employment within the organization, or an umbrella organization or network, shared information systems, shared education or administrative support and a profound clinical role with shared goals and visions, such as a collaborative practice agreement to enhance cooperation in the delivery of CPS.

For each level of integration (none-partial-full), we plotted the number of improved primary outcomes against the total number of assessed primary outcomes (Figure 2). The accumulated evidence from these studies suggests that there is no impact of the degree of integration of NDPs on health outcomes. The percentage of improved health outcomes

Dimension of integration					Primary outcome(s) (effect)
Organizational	Informational	Clinical[a]	Functional	Normative	
No	Yes	No	No	No	Three prescribing appropriateness indicators (+)
Yes	Yes	Yes	Yes	Yes	Lipids (+), HbA1c (0) and BMI (+)
Yes	Yes	Yes	Yes	No	Patient satisfaction (0), HRQoL (0)
Yes	Yes	No	Yes	No	MAI (+)
Yes	Yes	Yes	Yes	Yes	Uptake of recommendations from medication review (+)
Yes	Yes	Yes	Yes	Yes	Reduction in use of unessential medications (+)
No	Yes	No	No	No	MAI (+), HRQoL (0), ADE (0)
Yes	Yes	Yes	Yes	Yes	QoC for CDM (+)
Yes	Yes	Yes	Yes	Yes	Patients' perceptions of care (0), HRQoL (0)
Yes	Yes	Yes	Yes	Yes	Quality-of-care performance measures for hypertension and cholesterol (+)
No	Yes	No	Yes	No	Resolved PCI (+), HRQoL (0)
No	Yes	No	Yes	Yes	Resolved MRPs (0), No. of medications (+)
Yes	Yes	No	No	No	Improvement on clinical outcome rules (0)
No	Yes	No	No	Yes	Resolved MRPs (+)
No	Yes	No	No	No	No. of daily doses (0)
No	Yes	Yes	Yes	No	Resolved MRPs (+)
No	Yes	No	Yes	Yes	No. of changes to repeat prescription changes (+)

for none, partial and fully integrated NDPs is respectively 63% (based on 19 assessed health outcomes within 14 different studies), 61% (based on 23 assessed health outcomes within 19 different studies) and 62% (based on 47 assessed health outcomes within 27 different studies). Also, after stratifying the health outcomes into clinical, patient reported and proxies of health outcomes, no association can be identified between the degree of integration of NDPs and an improvement on health outcomes.

Table 3. Quality assessment of included studies

Author (year)	Selection bias	Study design	Confounders	Data collection	Drop-outs	Global
Adler (2004)[50]	Weak	Strong	Strong	Strong	Strong	Moderate
Avery (2012)[59]	Weak	Strong	Weak	Strong	Strong	Weak
Berdine (2012)[60]	Moderate	Moderate	Weak	Strong	Weak	Weak
Bex (2011)[33]	Moderate	Moderate	Weak	Strong	Moderate	Moderate
Billups (2005)[44]	Moderate	Moderate	Weak	Strong	Strong	Moderate
Bogden (1997)[5]	Moderate	Strong	Strong	Strong	Strong	Strong
Bogden (1998)[34]	Moderate	Strong	Strong	Strong	Strong	Strong
Borenstein (2003)[35]	Weak	Strong	Moderate	Strong	Strong	Moderate
Capoccia (2004)[51]	Moderate	Strong	Strong	Moderate	Strong	Strong
Carter (2001)[61]	Moderate	Strong	Weak	Strong	Weak	Weak
Carter (2008)[36]	Weak	Strong	Strong	Strong	Moderate	Moderate
Choe (2005)[18]	Strong	Strong	Strong	Moderate	Moderate	Strong
Coast-Senior (1998)[19]	Moderate	Weak	Weak	Moderate	Strong	Weak
Davis (2007)[62]	Strong	Moderate	Weak	Strong	Moderate	Moderate
Edelman (2010)[55]	Weak	Strong	Strong	Strong	Strong	Moderate
Evans (2010)[54]	Moderate	Strong	Strong	Strong	Strong	Strong
Finley (2003)[52]	Moderate	Strong	Strong	Strong	Weak	Moderate
Freeman (2013)[63]	Strong	Moderate	Weak	Moderate	Moderate	Moderate
Galt (1998)[64]	Weak	Moderate	Weak	Moderate	Weak	Weak
Hall (2009)[53]	Moderate	Moderate	Strong	Strong	Weak	Moderate
Hammad (2011)[48]	Strong	Strong	Strong	Strong	Strong	Strong
Hanlon (1996)[65]	Strong	Strong	Strong	Moderate	Strong	Strong
Heisler (2012)[4]	Moderate	Strong	Strong	Strong	Weak	Moderate
Henry (2013)[20]	Moderate	Moderate	Weak	Weak	Moderate	Weak
Hetro (2015)[57]	Moderate	Moderate	Weak	Strong	Moderate	Moderate
Hirsch (2014)[37]	Weak	Strong	Strong	Strong	Strong	Moderate
Hogg (2009)[66]	Moderate	Strong	Strong	Moderate	Strong	Strong
Hunt (2008)[38]	Weak	Strong	Strong	Strong	Weak	Weak
Ip (2013)[21]	Moderate	Moderate	Strong	Strong	Moderate	Moderate
Irons (2002)[22]	Moderate	Moderate	Strong	Strong	Moderate	Moderate
Isetts (2006)[67]	Weak	Moderate	Moderate	Strong	Moderate	Moderate
Isetts (2008)[68]	Moderate	Moderate	Strong	Strong	Weak	Moderate
Jameson (2010)[23]	Weak	Strong	Strong	Strong	Strong	Moderate
Koenigsfeld (2012)[58]	Moderate	Moderate	Weak	Strong	Moderate	Moderate
Krska (2001)[69]	Moderate	Strong	Strong	Moderate	Strong	Strong
Lenander (2014)[70]	Moderate	Strong	Strong	Weak	Moderate	Moderate
Lowrie (2012)[49]	Weak	Strong	Strong	Strong	Strong	Moderate
Magid (2013)[39]	Moderate	Strong	Strong	Strong	Strong	Strong
Margolis (2013)[40]	Moderate	Strong	Weak	Strong	Strong	Moderate
McAdam-Marx (2015)[24]	Moderate	Moderate	Strong	Strong	Moderate	Moderate
McCord (2006)[25]	Moderate	Moderate	Weak	Strong	Moderate	Moderate

Table 3. (continued)

Author (year)	Selection bias	Study design	Confounders	Data collection	Drop-outs	Global
McFarland (2012)[26]	Moderate	Moderate	Strong	Strong	Moderate	Moderate
Mehos (2000)[41]	Moderate	Strong	Strong	Strong	Strong	Strong
Mourão (2012)[27]	Strong	Strong	Strong	Strong	Moderate	Strong
Neto (2011)[56]	Moderate	Strong	Strong	Strong	Strong	Strong
O'Neill (2014)[42]	Moderate	Weak	Strong	Strong	Moderate	Moderate
Pindolia (2009)[71]	Weak	Moderate	Weak	Strong	Moderate	Weak
Roth (2013)[72]	Moderate	Moderate	Strong	Strong	Strong	Moderate
Rothman (2005)[28]	Moderate	Strong	Strong	Strong	Strong	Strong
Salvo (2012)[29]	Moderate	Moderate	Weak	Strong	Moderate	Moderate
Scott (2006)[30]	Moderate	Strong	Strong	Strong	Strong	Strong
Sellors (2003)[73]	Moderate	Strong	Strong	Strong	Strong	Strong
Shane-McWorther (2005)[31]	Moderate	Moderate	Weak	Strong	Moderate	Moderate
Simpson (2011)[32]	Weak	Strong	Strong	Strong	Strong	Moderate
Smith (2013)[45]	Moderate	Moderate	Strong	Strong	Moderate	Moderate
Straka (2005)[46]	Strong	Strong	Strong	Strong	Strong	Strong
Tahaineh (2011)[47]	Strong	Strong	Weak	Strong	Moderate	Moderate
Tan (2014)[74]	Moderate	Moderate	Strong	Moderate	Moderate	Moderate
Wong (2013)[43]	Moderate	Strong	Strong	Strong	Strong	Strong
Zermansky (2001)[75]	Weak	Strong	Strong	Moderate	Strong	Moderate
Sum weak	**14 (23%)**	**2 (3%)**	**18 (30%)**	**2 (3%)**	**8 (13%)**	**8 (13%)**
Sum moderate	**38 (63%)**	**23 (38%)**	**2 (3%)**	**10 (17%)**	**23 (38%)**	**34 (57%)**
Sum strong	**8 (13%)**	**35 (58%)**	**40 (67%)**	**48 (80%)**	**29 (48%)**	**18 (30%)**

Stratification of the results according to type of CPS

We included 43 studies about disease-specific CPS, in which 61 health outcomes, mainly surrogate clinical health outcomes (n=51) were assessed, of which 67% showed a significant positive effect. Five patient reported health outcomes and five proxies of health outcomes were reported, of which 20% (n=1) and 60% (n=3) showed improvement, respectively. Within this subgroup of CPS services, we found 8 studies (19%) in which the NDPs were not or minimally integrated into the health care team, 14 studies (33%) in which the NDPs were partially integrated and 21 studies (49%) in which the NDPs were fully integrated within the primary care team. For disease-specific CPS the percentage of improved health outcomes in studies with not, partial and fully integrated NDPs is respectively 75%, 63% and 59%. Our data suggest a negative association between integration and improvement on health outcomes for disease-specific CPS (Figure 2).

We included 17 studies about patient-centered CPS and assessed 28 health outcomes, mainly proxies of health outcomes (n=18) of which 83% showed a significant positive effect. In total, 7 patient reported health outcomes were reported of which none showed

Table 4. The impact of the degree on integration of NDPs on health outcomes in primary care.

	All outcomes (n=89)		
	No integration	Partial integration	Full Integration
Clinical health outcomes			
Death or hospitalization	0/1 (1090)		
Surrogate clinical health outcomes			
HbA1c	1/1 (50)	2/6 (687)	8/11 (1369)
Lipids	2/2 (120)	2/2 (5909)	4/7 (1225)
BP	2/3 (159)	4/4 (430)	7/11 (4198)
BMI			1/2 (261)
Metabolic syndrome status	1/1 (112)		
Cardiovascular risk reduction		0/1 (176)	2/2 (244)
Subtotal	6/8 (75%)	8/13 (62%)	22/33 (68%)
Patient reported health outcomes			
HRQoL	0/2 (273)	0/1 (523)	0/2 (453)
Patient satisfaction, perceptions of care	0/1 (105)	0/1 (523)	1/2 (360)
Depression severity		0/1 (268)	0/2 (116)
Subtotal	0/3 (0%)	0/3 (0%)	1/6 (17%)
Proxies of health outcomes			
Adherence rate		1/1 (268)	1/1 (75)
Reduction of (unwanted) medications	0/1 (431)	2/2 (688)	1/1 (336)
Medication errors, pharmaceutical care issues, prescribing appropriateness	6/7 (12.293)	3/4 (290)	3/5 (753)
Uptake of recommendations from MR			1/1 (314)
Subtotal	6/8 (67%)	6/7 (86%)	6/8 (75%)
Total	**12/19 (63%)**	**14/23 (61%)**	**29/47 (62%)**

BP Blood pressure, BMI Body Mass Index, HbA1c glycosylated haemoglobin, HRQoL Health Related Quality of Life, MR Medication Review.

For each health outcome, the number of studies that demonstrated significant improvement is divided by the total number of assessed studies. Since studies can include more than one primary outcome, the total number of assessed outcomes (89) exceeds the total number of included studies (60). The numbers in parentheses reflect the accumulated number of intervention patients in studies assessing the specific health outcome.

improvement. A small number of surrogate clinical health outcomes was reported (n=3) and 2 were positively affected by the NDP provided services. We found 6 studies (35%) in which the NDPs were not or minimally integrated into the health care team, 5 studies (29%) in which the NDPs were partially integrated and 6 studies (35%) in which the NDPs were fully integrated within the primary care team. For patient-centered CPS the percentage

No. of improved outcomes / no. of assessed outcomes (no.of intervention patients)					
Disease-specific CPS (no. of assessed outcomes: 61)			Patient-centered CPS (no. of assessed outcomes: 28)		
No integration	Partial integration	Full integration	No integration	Partial integration	Full integration
0/1 (1090)					
1/1 (50)	2/6 (687)	8/10 (1169)			0/1 (200)
2/2 (120)	2/2 (5909)	3/6 (1025)			1/1 (200)
2/3 (159)	4/4 (430)	7/11 (4198)			
		0/1 (61)			1/1 (200)
1/1 (112)					
	0/1 (176)	2/2 (244)			
6/8 (75%)	8/13 (62%)	20/30 (67%)			2/3 (67%)
		0/1 (168)	0/2 (273)	0/1 (523)	0/1 (285)
		1/1 (75)	0/1 (105)	0/1 (523)	0/1 (285)
	0/1 (268)	0/2 (116)			
	0/1 (0%)	1/4 (25%)	0/3 (0%)	0/2 (0%)	0/2 (0%)
	1/1 (268)	1/1 (75)			
			0/1 (431)	2/2 (688)	1/1 (336)
	1/1 (22)	0/2 (120)	6/7 (12.293)	2/3 (268)	3/3 (633)
					1/1 (314)
	2/2 (100%)	1/3 (33%)	6/8 (75%)	4/5 (80%)	5/5 (100%)
6/8 (75%)	**10/16 (63%)**	**22/37 (59%)**	**6/11 (55%)**	**4/7 (57%)**	**7/10 (70%)**

of improved health outcomes in studies with not, partial and fully integrated NDPs is respectively 55%, 57% and 70%. Therefore, our data suggest a positive association between integration and improvement on health outcomes for patient-centered CPS (Figure 2).

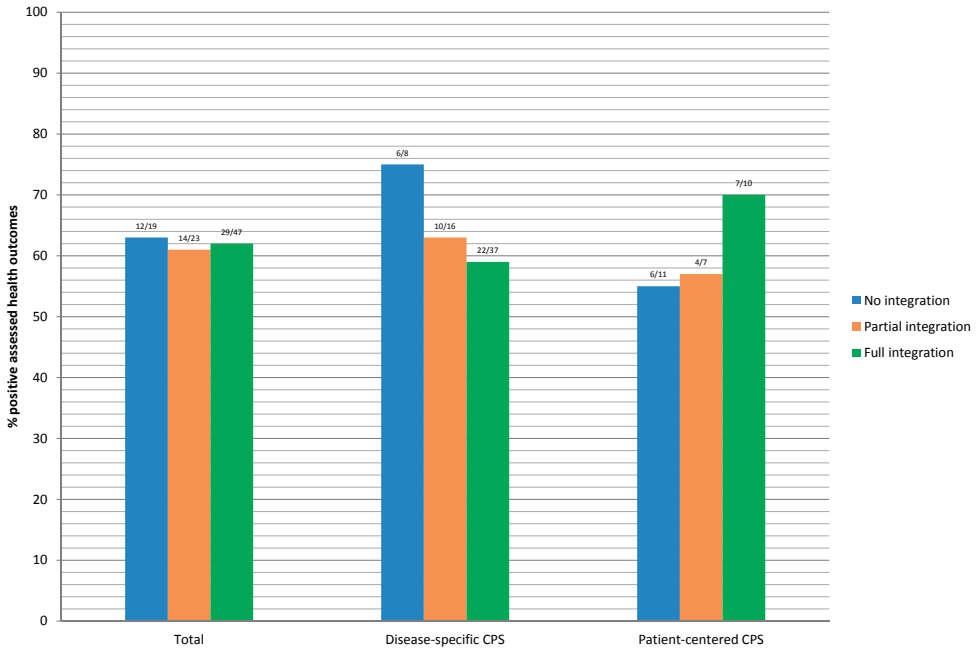

Figure 2. Outcomes by degree of integration of NDPs on health outcomes in primary care. CPS Clinical Pharmacy Service.
For each category of integration the total number of significant improved outcomes is divided by the total number of assessed outcomes. The results are also stratified by disease-specific CPS and patient-centered CPS.

DISCUSSION

We evaluated the impact of the degree of integration of NDPs on health outcomes in primary care. Although we found that the degree of integration of NDPs did not impact health outcomes in the overall group, subgroup analysis suggests that full integration of an NDP may be especially relevant for patient-centered CPS.

An explanation of why full integration of an NDP is more relevant for patient-centered interventions than disease-specific interventions is provided by Weick.[76] Integration enables NDPs to manage interruptions in the care trajectory of an individual patient. Being in close relation with both GPs and patients, NDPs can pick up the small clues that signal lapses in the care trajectory. The degree of integration showed a trend towards a negative association with the health outcomes of disease-specific CPS. The diseases-specific CPS included in this study were based upon a set protocol. These standardized care trajectories are less prone to errors and allowing for variety may not have an added value. Reliability – defined as compliance to the protocols – seems to be more effective.[77]

Almost all studies reported surrogate health outcomes rather than clinical endpoints such as hospitalization or mortality. Disease-specific CPS mainly described surrogate

clinical health outcomes (e.g. HbA1c, lipids and blood pressure), while patient-centered CPS often used process outcomes (e.g. quality of care performance indicators) to measure the effect of the intervention. Also, we found a low impact of CPS on health related quality of life.[51,61,65,67,69] The effects of a multifaceted quality improvement service often do not extend as far as to health related quality of life.[78]

Fully integrated NDPs are permanently employed or work within a network or umbrella organization (organizational integration), they usually have shared access to clinical information systems (informational integration), work in multiprofessional teams with face-to-face collaboration with the GP (clinical integration), have shared education and/or support staff for administrative functions (functional integration) and share a vision on patient care with clinicians (normative integration). Clinical integration into a multidisciplinary primary care team provides greater opportunities for both formal and informal communication, probably enhancing patient care.[63] Also, expanding the clinical role of the NDP by allocating prescribing privileges might be beneficial.[79] Within disease-specific CPS, more than half of the NDPs were authorized to make medication changes within a defined scope of practice. Within patient-centered CPS, only 2 studies showed NDPs with prescribing authority. In these kind of services, with a more holistic approach to pharmaceutical care, prescribing authority would entail the whole spectrum of medications. The current absence of prescribing authority might have restricted the impact of the CPS on health outcomes.

CPS performed in isolation may negatively influence the quality of care.[80] There is one systematic review that described the effectiveness of NDPs co-located in primary care practice.[9] The importance of follow-up and face-to-face communication with the patient's GP (clinical integration) is highlighted. Other available studies described the effectiveness of CPS in different outpatient settings.[10–14] This study is the first to unravel the association between the extent of NDP integration in clinical care and drug related health outcomes.

Limitations

This review has a number of limitations. Similar to most literature reviews, there might have been publication bias. Also, CPS can like all cognitive interventions be subject to the Hawthorne-effect. The Hawthorne-effect might, at least partly, explain the absence of any negative health outcome in the included studies. The interventions and outcomes assessed in this review were heterogeneous. Also, we were unable to assess the impact of health care systems on the degree of integration of NDPs and on the success of the provided services. Moreover, the study population, duration of the intervention, number of practices and involved NDPs differed widely, limiting our options to assess the independent effect of integration and to pool data. The problem of heterogeneity in clinical pharmacy intervention studies has been previously addressed.[9,12,14,81–83] Hence, we cannot draw too strong conclusions about the impact of integration – as reflected by the wording we choose. Lastly, the positive association we found between the degree of integration and the effect of

patient-centered CPS was based upon a limited number of studies (n=17). Random effects cannot be ruled out. Additional research is required when new studies about integrated clinical pharmacy services in primary care become available.

Implications

This study has several implications for practitioners and policy-makers. Integration on *all* dimensions for *all* types of chronic disease management services performed by NDPs in primary care practice may not be necessary. Integration on *all* dimensions should be promoted for individually tailored, i.e. patient-centered CPS.

CONCLUSION

To obtain maximum benefits of CPS for patients with multiple medications and comorbidities, full integration of NDPs should be stimulated.

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APPENDIX

Table 1. Search strategies for Pubmed and Embase

Pubmed search June 2016	Embase search June 2016
("pharmacist"[Title/Abstract] OR "pharmacists"[Title/Abstract] OR "pharmaceutical service"[Title/Abstract] OR "pharmaceutical services"[Title/Abstract] OR "pharmacy"[Title/Abstract] OR "pharmacists"[MeSH Terms] OR "pharmaceutical services"[MeSH Terms])	pharmacist:ti,ab OR pharmacists:ti,ab OR pharmacy:ti,ab OR 'pharmaceutical service':ti,ab OR 'pharmaceutical services':ti,ab OR 'pharmacist'/exp OR 'pharmacy'/exp
("family practice"[Title/Abstract] OR "general practitioner"[Title/Abstract] OR "primary care"[Title/Abstract] OR "general practitioners"[Title/Abstract] OR "general practice"[Title/Abstract] OR "family physician"[Title/Abstract] OR "physicians, family"[MeSH Terms] OR "family practice"[MeSH Terms] OR "general practitioners"[MeSH Terms] OR "general practice"[MeSH Terms])	'family practice':ti,ab OR 'general practitioner':ti,ab OR 'general practitioners':ti,ab OR 'general practice':ti,ab OR 'community dwelling':ti,ab OR 'family physician':ti,ab OR 'community dwelling':ti,ab OR 'ambulatory patient':ti,ab OR 'ambulatory elderly':ti,ab OR 'ambulatory patients':ti,ab OR 'primary care':ti,ab OR 'general practice'/exp OR 'general practitioner'/exp
("patient care"[Title/Abstract]) OR "interprofessional relation"[Title/Abstract] OR "interprofessional relations"[Title/Abstract] OR "cooperation"[Title/Abstract] OR "collaboration"[Title/Abstract] OR "consultation"[Title/Abstract] OR "referral"[Title/Abstract] OR "refer"[Title/Abstract] OR "home medicines review"[Title/Abstract] OR "medication review"[Title/Abstract] OR "medication reviews"[Title/Abstract] OR "communitydwelling"[Title/Abstract] OR "ambulatory patient"[Title/Abstract] OR "ambulatory elderly"[Title/Abstract] OR "ambulatory patients"[Title/Abstract] OR "pharmaceutical care"[Title/Abstract] OR "drug utilization review"[Title/Abstract] OR patient care[MeSH Terms] OR interprofessional relations[MeSH Terms]OR cooperative behaviour[MeSH Terms]OR counseling[MeSH Terms]OR professional role[MeSH Terms] OR (referral and consultation[MeSH Terms] OR "drug utilization review"[MeSH Terms] OR "review"[Title/Abstract])	'patient care':ti,ab OR 'interprofessional relation':ti,ab OR 'interprofessional relations':ti,ab OR cooperation:ti,ab OR collaboration:ti,ab OR consultation:ti,ab OR referral:ti,ab OR refer:ti,ab OR 'home medicines review':ti,ab OR 'medication review':ti,ab OR 'medication reviews':ti,ab OR review:ti,ab OR 'pharmaceutical care':ti,ab OR 'drug utilization review':ti,ab OR 'patient care'/exp OR 'patient referral'/exp

Table 2a. excluded studies with disease-specific CPS

	Dimension of integration				
Author (year)	Organizational	Informational	Clinical	Functional	Normative
Anaya (2008)[84]	No	Yes	Yes	N/A	Yes
Barnes (2014)[85]	Yes	Yes	No	N/A	N/A
Bruhn (2013)[86]	Yes	Yes	Yes	N/A	N/A
Carter (2015)[87]	Yes	Yes	Yes	No	N/A
Chung (2014)[88]	Yes	Yes	N/A	N/A	Yes
Cording (2002)[89]	Yes	Yes	N/A	Yes	Yes
Duran-Parrondo (2011)[90]	No	N/A	Yes	N/A	Yes
Erickson (1997)[91]	Yes	Yes	No	N/A	No
Gums (2014)[92]	Yes	Yes	Yes	No	N/A
Gums (2015)[93]	Yes	Yes	Yes	No	N/A
Jacobs (2012)[94]	No	Yes	No	N/A	No
Jamieson (2010)[95]	No	Yes	N/A	N/A	N/A
Johnson (2010)[96]	No	N/A	N/A	N/A	N/A
Kelly Hester (2000)[97]	No	N/A	N/A	No	No
Monte (2009)[98]	No	N/A	No	Yes	N/A
Shane-McWorther (2015)[99]	N/A	No	N/A	No	Yes
Solomon (1998)[100]	Yes	N/A	No	N/A	N/A
Stading (2009)[101]	Yes	Yes	N/A	N/A	N/A
Thumar (2014)[102]	No	Yes	No	Yes	N/A
Tobari (2010)[103]	Yes	Yes	No	N/A	N/A
Trompeter (2009)[104]	No	Yes	N/A	Yes	N/A
Villa (2009)[105]	N/A	N/A	N/A	N/A	N/A

Table 2b. excluded studies with patient-centered CPS

	Dimension of integration				
Author (year)	Organizational	Informational	Clinical	Functional	Normative
Hamley (1997)[106]	Yes	N/A	N/A	N/A	N/A
Harris (2009)[107]	Yes	Yes	No	N/A	N/A
Jameson (1995)[108]	N/A	N/A	No	N/A	N/A
Jameson (2001)[109]	N/A	Yes	No	N/A	N/A
Laucka (1996)[110]	No	Yes	No	N/A	N/A
Lowe (2000)[111]	No	No	No	N/A	N/A
Morrison (2015)[112]	No	Yes	No	N/A	Yes
Taylor (2003)[113]	No	Yes	No	N/A	N/A

Table 3. Clinical integration based upon six measurable elements.

Ref.	Patient counselling by NDP	Follow-up by NDP	Face-to-face communication GP and NDP	Multiprofessional collaboration (≥3 care providers)	Other patient directed activities outside scope of intervention	Prescribing authority
Adler (2004)[50]	Yes	Yes	Yes	Yes	Yes	No
Avery (2012)[59]	No	Yes	Yes	No	No	No
Berdine (2012)[60]	Yes	Yes	Yes	No	Yes	Yes
Bex (2011)[33]	Yes	Yes	Yes	Yes	Yes	No
Billups (2005)[44]	No	Yes	No	No	Yes	No
Bogden (1997)[5]	Yes	No	No	No	No	No
Bogden (1998)[34]	Yes	No	Yes	No	No	No
Borenstein (2003)[35]	Yes	Yes	No	No	No	No
Capoccia (2004)[51]	Yes	Yes	Yes	Yes	Yes	Yes
Carter (2001)[61]	Yes	Yes	Yes	Yes	Yes	Yes
Carter (2008)[36]	Yes	Yes	Yes	Yes	Yes	No
Choe (2005)[18]	Yes	Yes	Yes	Yes	Yes	No
Coast-Senior (1998)[19]	Yes	Yes	Yes	Yes	Yes	Yes
Davis (2007)[62]	Yes	Yes	No	No	Yes	No
Edelman (2010)[55]	Yes	Yes	Yes	Yes	Yes	No
Evans (2010)[54]	Yes	Yes	Yes	No	Yes	No
Finley (2003)[52]	Yes	Yes	Yes	Yes	Yes	Yes
Freeman (2013)[63]	Yes	No	Yes	Yes	Yes	No
Galt (1998)[64]	Yes	Yes	Yes	Yes	Yes	No
Hall (2009)[53]	Yes	Yes	No	Yes	No	Yes
Hammad (2011)[48]	Yes	Yes	Yes	No	No	No
Hanlon (1996)[65]	Yes	No	Yes	No	No	No
Heisler (2012)[4]	Yes	Yes	Yes	Yes	Yes	Yes
Henry (2013)[20]	Yes	Yes	Yes	Yes	Yes	No

Table 3. (continued)

Ref.	Patient counselling by NDP	Follow-up by NDP	Face-to-face communication GP and NDP	Multiprofessional collaboration (≥3 care providers)	Other patient directed activities outside scope of intervention	Prescribing authority
Hetro (2015)[57]	Yes	Yes	Yes	Yes	Yes	Yes
Hirsch (2014)[37]	Yes	Yes	Yes	No	No	Yes
Hogg (2009)[66]	Yes	Yes	Yes	Yes	Yes	No
Hunt (2008)[38]	Yes	Yes	Yes	No	No	Yes
Ip (2013)[21]	Yes	Yes	Yes	Yes	Yes	Yes
Irons (2002)[22]	Yes	Yes	No	No	Yes	Yes
Isetts (2006)[67]	Yes	Yes	Yes	Yes	No	No
Isetts (2008)[68]	Yes	Yes	Yes	Yes	Yes	No
Jameson (2010)[23]	Yes	Yes	Yes	No	No	No
Koenigsfeld (2012)[58]	Yes	Yes	Yes	No	Yes	No
Krska (2001)[69]	Yes	Yes	No	Yes	No	No
Lenander (2014)[70]	Yes	No	Yes	Yes	No	No
Lowrie (2012)[49]	Yes	Yes	Yes	Yes	No	Yes
Magid (2013)[39]	Yes	Yes	No	Yes	Yes	Yes
Margolis (2013)[40]	Yes	Yes	No	Yes	Yes	Yes
McAdam-Marx (2015)[24]	Yes	Yes	Yes	Yes	No	Yes
McCord (2006)[25]	Yes	Yes	Yes	Yes	Yes	Yes
McFarland (2012)[26]	No	Yes	No	Yes	No	Yes
Mehos (2000)[41]	Yes	Yes	No	No	No	No
Mourão (2012)[27]	Yes	Yes	No	No	No	Yes
Neto (2011)[56]	Yes	Yes	Yes	Yes	Yes	No
O'Neill (2014)[42]	Yes	Yes	Yes	Yes	Yes	Yes
Pindolia (2009)[71]	Yes	Yes	Yes	No	No	No
Roth (2013)[72]	Yes	Yes	Yes	No	No	No
Rothman (2005)[28]	Yes	Yes	Yes	Yes	No	Yes

Table 3. (continued)

Ref.	Patient counselling by NDP	Follow-up by NDP	Face-to-face communication GP and NDP	Multiprofessional collaboration (≥3 care providers)	Other patient directed activities outside scope of intervention	Prescribing authority
Salvo (2012)[29]	Yes	Yes	No	Yes	Yes	Yes
Scott (2006)[30]	Yes	Yes	No	Yes	No	Yes
Sellors (2003)[73]	Yes	Yes	Yes	No	No	No
Shane-McWorther (2005)[31]	Yes	Yes	No	Yes	Yes	No
Simpson (2011)[32]	Yes	Yes	Yes	Yes	No	No
Smith (2013)[45]	Yes	Yes	Yes	Yes	Yes	Yes
Straka (2005)[46]	Yes	Yes	Yes	No	No	Yes
Tahaineh (2011)[47]	Yes	Yes	No	No	Yes	No
Tan (2014)[74]	Yes	No	Yes	Yes	Yes	No
Wong (2013)[43]	Yes	No	No	No	No	No
Zermansky (2001)[75]	Yes	Yes	Yes	No	No	No

The NDP was considered clinical integrated when the result on ≥ four elements was positive ("Yes").

2.2

Controversy and consensus on a clinical pharmacist in primary care in the Netherlands: a Q study

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ABSTRACT

Background

Controversy about the introduction of a non-dispensing pharmacist in primary care practice hampers implementation.

Objective

The aim of this study is to systematically map the debate on this new role for pharmacists amongst all stakeholders to uncover and understand the controversy and consensus.

Setting

Primary health care in the Netherlands.

Method

Q methodology. 163 participants rank-ordered statements on issues concerning the integration of a non-dispensing pharmacist in primary care practice.

Main outcome measure

Stakeholder perspectives on the role of the non-dispensing pharmacist and pharmaceutical care in primary care.

Results

This study identified the consensus on various features of the non-dispensing pharmacist role as well as the financial, organisational and collaborative aspects of integrating a non-dispensing pharmacist in primary care practice. Q factor analysis revealed four perspectives: "the independent community pharmacist", "the independent clinical pharmacist", "the dependent clinical pharmacist" and "the medication therapy management specialist". These four perspectives show controversies to do with the level of professional independency of the non-dispensing pharmacist and the level of innovation of task performance.

Conclusion

Despite the fact that introducing new professional roles in healthcare can lead to controversy, the results of this Q study show the potential of a non-dispensing pharmacist as a pharmaceutical care provider and the willingness for interprofessional collaboration. The results from the POINT intervention study in the Netherlands will be an important next step in resolving current controversies.

Impact on practice

- Most professionals recognize the need for more integration of pharmaceutical care into daily primary care practice.
- General practitioners and community pharmacists regard the introduction of the non-dispensing pharmacist as a possible route to integrate pharmaceutical care into practice.
- Most primary care professionals agree that pharmacist should be an integral part of the primary care team, offering consultations to vulnerable patients with polypharmacy.
- Although further separation of pharmaceutical care and drug dispensing is considered as the key paradigm shift, there is discussion about the best way to implement this.

INTRODUCTION

Co-locating a non-dispensing pharmacist (NDP) in primary care practice, including shared use of patients' medical records, is expected to improve interprofessional collaboration and communication and thus effective patient-centred medication management services.[1] However, controversy about this new role for pharmacists is hampering implementation. Different perceptions have led to significant barriers preventing pharmacists from expanding their roles as pharmaceutical care providers. The barriers include lack of mandate, legitimacy, effectiveness and readiness to embrace change.[2] Currently, NDPs have been integrated successfully in primary care practice in only a limited number of health care settings, mainly in Great Britain, the United States, and Canada.[3-5]

Interprofessionality is an essential feature of healthcare development,[6] reflected in the willingness to work in interprofessional teams.[7] Yet, introducing new roles in healthcare practices puts professional boundaries under pressure.[8] New roles lead to the substitution of labour, including reallocation of resources and control. Consequently, it has an impact on dominance and authority, fed by the implicit wish to maintain established arrangements for healthcare delivery and by scepticism about the feasibility and effectiveness of related professionals working jointly.[6]

Despite the identified positive attitude to team-based work, attempts to introduce the NDP to primary care practice have led to debate, as evidenced by several qualitative studies on stakeholder experiences with NDPs in primary care practices.[9-10]

Aim of the study

In this Q- study we systematically map the debate on the introduction of NDPs in primary care practice amongst all involved stakeholders to uncover and understand the controversy and consensus.

Ethical approval

This Q study is part of the POINT project, which aims to evaluate the effect of integration of an NDP in general practice with regard to the quality and safety of pharmacotherapy.[11] This project is exempted of formal medical-ethical approval by the Medical Ethical Committee University Medical Centre Utrecht (METC protocol number 13-432C).

METHOD

Research design

Q methodology[12] was used to disclose different viewpoints on the value and position of the NDP in primary healthcare. The Q method is a robust and hybrid qualitative–quantitative technique that provides a basis for the systematic study of subjectivity and accentuates shared understanding.[13] A Q study consists of three steps: construction of the Q set, performing Q sorting and analysis of obtained data.[14-15]

Step 1 Constructing the Q set

The first step is the collection of statements broadly covering the debate on the subject at hand. In Q methodological terms this is called "the concourse".[14-15] The concourse on integration of an NDP in primary care was based on the literature and collected from six interviews with pharmaceutical and medical experts. From this concourse we drew a subset of 116 statements. Since careful consideration of the context is helpful to a better understanding of the debate on NDP integration, we deliberately added a number of general statements on improving pharmaceutical care in primary care. The subset of 116 statements was stripped of double and comparable statements and condensed to a Q set of 37 statements (Table 1). The statements were evaluated by a group of experts who were both pharmacists, general practitioners and researchers with experience in Q methodological studies. They refined the statement set to improve readability and clarity. Next, statements were assessed and sorted by a small group of general practitioners (GP) and pharmacists. Finally, statements were again refined and improved. The result was the final Q set which was considered representative for the issues raised on integrating an NDP in primary care. Quoted statements were originally phrased in Dutch.

Step 2 Performing Q sorting

For Q sorting, respondents considered to have a clear and distinct viewpoint were selected. In this study, they were community, clinical and hospital pharmacists and GPs with varying levels of work experience, located in both rural and urban settings; other pharmaceutical and medical experts; health care insurers; policy makers; practice nurses and patients. Members of the research team approached a convenience sample of respondents for Q sorting online or in person . Q sorting in personal interviews was done by two researchers (AH and AW). Q sorting started by sorting the 37 statements into three categories: 'agree,' 'neutral' or 'disagree.' Next, respondents were asked to place the statements in a Q sorting table (Figure 1). Respondents were requested to adhere to the Q sorting table, in order to gradually force them to take position on the statements. Q methodology combines statement-sorting and interviews to unravel different perspectives. Therefore, respondents were asked to comment on the four statements at the extreme ends (-3 being disagree most and +3 being agree most). FlashQ© was used as an online Q sorting programme.[16]

Step 3 Analysis of obtained data

The final step in Q methodology is by-person factor analysis in order to identify significant correlation between individuals, expressed as factors with common viewpoints and preferences.[14] In this study, obtained Q sorts were analysed using PQMethod 2.35.[17] By-person factor analysis with centroid factor extraction and varimax rotation was conducted with the aim to obtain a clear pattern of relationships between the factors.[15] Since more than the theoretically required minimum of 40-60 respondents was included, it was decided to increase significance.[15,18] As a result, Q sorts that loaded significantly on one

Table 1. Q set of 37 statements and idealized Q sort for the four factors representing perceptions of integration of an NDP in primary care clinics

Statements	Factor A	Factor B	Factor C	Factor D
1. With the introduction of a NDP confusion arises about whom the patient can ask questions related to medication	-1*	0	0*	0
2. The GP wishes to minimize the number of other healthcare providers in general practice	-1	0*	-2*	-1
3. **The NDP poses a risk to patient safety due to the resulting formation of an additional link between prescription and delivery**	**-2**	**-1**	**-3**	**-2**
4. The patient has more confidence in the NDP than in the community pharmacist	0	-1*	1	1
5. The community pharmacist is insufficiently informed about the pharmacotherapy of the individual patient	1*	-2*	0	-1
6. **The NDP improves adherence**	**2**	**1**	**2**	**1**
7. A community pharmacists' primary concern includes the financial status of the pharmacy business	-2	-1	0*	-2
8. **The health insurance company pays too little for pharmaceutical care**	**2**	**2***	**1**	**1**
9. A fee for practice costs for community pharmacists is essential to enable delivery of pharmaceutical care	1	2*	1	-1*
10. **Earmarked funding for pharmaceutical care in general practice should be initiated**	**1**	**1**	**2**	**1**
11. The NDP loses its independent position as healthcare provider as an employee of a general practice	-2	0	-1	0
12. GP care will be unnecessarily expensive by nationwide introduction of a NDP	-2*	0	0	-1
13. The GP has insufficient knowledge of medication	1	1	-1*	2
14. The tasks of the NDP and the community pharmacist are different	1	0*	1	1
15. The knowledge of the NDP about clinical pharmacology is essential in general practice	3*	1	1	1
16. **Shared training in the GP's and pharmacist's educational programmes improves pharmaceutical care**	**1**	**2**	**3**	**1**
17. To improve pharmaceutical care, the community pharmacist needs to give advice about the choice of medication	0	2*	0	0
18. **The added value of the NDP is the care of the individual patient**	**1**	**1**	**2**	**3**

Table 1. (Continued)

Statements	Factor A	Factor B	Factor C	Factor D
19. Medication reviews should take place in general practice	0	-2*	1*	0
20. **Access to medical records is an essential prerequisite for pharmaceutical care**	**3**	**3***	**2**	**2**
21. **The GP and NDP share a common goal in the pharmacotherapy of the patient**	**2**	**3**	**3**	**2**
22. Information on medication provided to the patient by the community pharmacist does not sufficiently reflect the GP's advices	0*	-1	0	2*
23. The inferior position of the pharmacist relative to the GP impedes medication safety	0	0*	-2*	-1
24. The NDP will take on the fun part of the community pharmacist's work	-1*	0	0	0
25. Without proactive identification of patients with potential drug therapy problems, the NDP has no added value	0	1*	-1	3*
26. The advice on pharmacotherapy and the dispensing of the medication should be separated	0	-2*	0*	0
27. The community pharmacist is not skilled to perform a patient consultation	0	-3*	0	0
28. To enable a successful collaboration it is necessary that GP and NDP are working in the same organisation	2*	0	0	0
29. **The NDP is doing work that can be done more adequately by a practice nurse**	**-3**	**-2***	**-3**	**-3**
30. The logistics in the community pharmacy can be coordinated more adequately by someone with a bachelor's degree	0	0	0	0
31. The education of the patient about their medication use should be linked to the dispensing of the medication	-1	1*	-1	-2*
32. The pharmaceutical care (including the dispensing of the medication) can best be accommodated at a general practice	0	-3*	-1	-1
33. The community pharmacist should focus solely on counselling on pharmacotherapy	-1	-1	-1	0
34. The NDP must be an independent prescriber	0*	0*	-2	-3
35. A general practice with 10,000 patients is too small to employ a full-time NDP	-1*	0	-1*	0
36. A NDP cannot be employed at a community pharmacy due to conflict of interest	-1	-1*	1*	-1
37. **The NDP takes on too many tasks of the GP**	**-3**	**-1**	**-2**	**-2**

'-3' indicates that the factor on (weighted) average disagrees most with that statement.
'3' indicates that the factor on (weighted) average agrees most with that statement.
* distinguishing statements ($p<0.01$), consensus statements: bold, neutral statements (neglected in final results): grey.

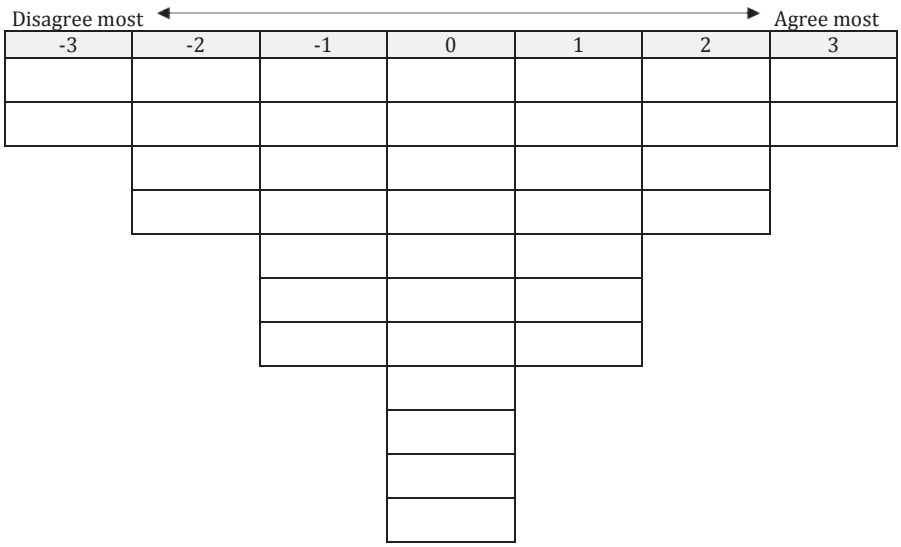

Figure 1. Q sorting table

factor (with $p<0.01$) were included in the analysis. For each factor solution an idealized Q sort was computed. This idealized Q sort represents how a person with a 100% loading on that factor would have ranked the 37 statements.[14,15]

The content of the factors was examined by reviewing the characterising, distinguishing and consensus statements. Characterising statements are the statements that a factor most (rating +2 or +3) or least (rating -2 or -3) agrees with. The characterising statements are a first peek into the content of a factor. Distinguishing statements are the statements on which factors have different opinions. These statements highlight the differences between factors. Consensus statements are the statements with which all factors (dis)agree. These statements uncover the common viewpoints between factors.[14,15] Statistical characteristics of the different factor solutions were evaluated.

RESULTS

A total of 163 participants performed Q sorting: 125 online (77%) and 38 in person (23%). Respondents had an average of 17 years of work experience in healthcare (Table 2). Q analysis of the Q sorts supported a maximum of five factors. Content and statistical characteristics were examined for three-, four- and five-factor solutions. The four-factor solution was selected as the desirable solution, based on statistical characteristics, defining statements and written and verbal comments provided by the respondents defining the factors during Q sorting. These four factors explained 53% of the total variance in the Q sorts (Table 3).

The next section presents quotations of comments made by respondents (italics). The figures in parentheses, preceded by "s", correspond to statement numbers in Table 1.

Table 2. Baseline characteristics participants

Characteristic	Number
Total number of respondents	163
Female	50% (n=82)
Age, mean (range)	45 years (24-77)
Total years of experience in healthcare, mean (range)	17 years (0-42)
Medical and/or pharmaceutical positions	**Percentage (n)**
Pharmacy	28% (60)
Community pharmacist	18% (37)
Non-dispensing pharmacist	4% (9)
Hospital pharmacist	3% (7)
Pharmacist trainee	3% (7)
General practice	16% (35)
General practitioner	11% (24)
General practitioner trainee	3% (7)
Practice nurse	2% (4)
Other medical and/or pharmaceutical expert	34% (71)
Teacher or professor	49% (35)
Medical advisor	17% (12)
Medical doctor (no GP)	14% (10)
Researcher	8% (6)
Employee of research and medication safety institute	7% (5)
Employee health insurance company	4% (3)
Policy maker	13% (28)
Pharmacy or medical student	5% (11)
Patient	2% (5)

Note: Some participants fulfil multiple positions (e.g. a part-time GP also working part-time as policy maker). As a result 163 participants fulfil 211 positions.

Table 3. Factor characteristics

		Factor			
Characteristic		A	B	C	D
Number of defining variables		27	50	20	8
Explained variance (%)		15	18	11	9
(cumulative %)			33	44	53
Correlation between factors	B	0.59			
	C	0.68	0.46		
	D	0.68	0.55	0.69	

Similarities between factors

All participants shared the same opinion of many statements (Figure 2).

First, all participants in either factor A, B, C or D believe that an NDP improves adherence (s6), should focus on individual patient care (s18) and does not take over too many tasks of the GP (s37). Second, it is thought evident that the work of an NDP could not be done by a practice nurse (s29). According to some respondents, the pharmaceutical knowledge of the practice nurse is "*nowhere near as extensive as the NDP's.*" However, some participants suggested that the practice nurse could support the NDPs in the follow-up of some care issues.

Third, all factors emphasize that health insurance companies pay too little for pharmaceutical care (s8) and that there should be funding earmarked for pharmaceutical care (s10):

"*Pharmaceutical care is variable and hard to quantify. So it's challenging for health insurance companies to develop a good reimbursement system.*" This leads to "*low quality patient consultations and medication reviews.*" And "*since reimbursement is insufficient, evaluation and follow-up are neglected. Also, quality projects are initiated, but not embedded.*"

Fourth, access to medical records is thought a prerequisite for pharmaceutical care (s20). Numerous participants commented that especially knowledge of (contra-)indications and the results of lab tests are important in providing safe pharmaceutical care. Respondents also stressed the importance of access to medical data: "*Without access to medical records it's impossible to properly assess the quality of pharmacotherapy and to develop a pharmaceutical care plan tailored to the needs of individual patients.*"

Fifth, another organisational aspect which all factors agree with unanimously is that NDP integration does not pose a risk to patient safety, despite it creating an additional link between prescription and delivery (s3).

Finally, clearly GP and NDP share a common goal in the pharmacotherapy of the patient (s21): "*[Providing good patient care] is indisputable. […] Everything else (costs, practical implementation etc.) is secondary.*" Moreover, all respondents agree that pharmaceutical care would be improved by shared training in GP and pharmacist educational programmes (s16).

Differences between factors

Despite the large number of statements on which all participants shared the same opinion, controversies between the four factors are identified (figure 2).

Factor A: "independent clinical pharmacist"

Participants aligned with factor A, one third of whom were medical or pharmaceutical experts (Table 4), seem to fully support NDP integration in general practice. Working in the same organisation is considered necessary to enable successful collaboration between GP and NDP (s28). "*The GP and NDP will share the same vision and principles when they*

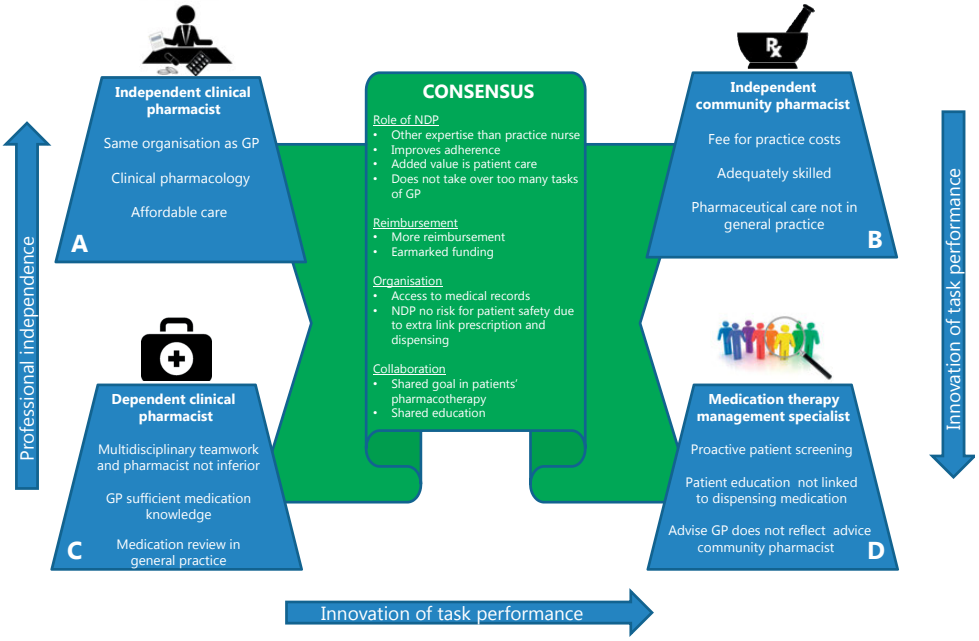

Figure 2. Four factors covering the debate on NDP integration in general practice.

work in one organisation. Integrating an NDP stimulates close collaboration and this will result in unambiguous pharmaceutical care for the patient." Since the community pharmacist is not fully informed of the details of the pharmacotherapy of the individual patient (s5), an NDP can provide better pharmaceutical care.

Specifically the knowledge about clinical pharmacology that an NDP brings into general practice is regarded as added value (s15). When it comes to complicated patients , the importance of the knowledge of the NDP in primary care is emphasised:

"*The unique combination of an NDP's knowledge of medication and clinical experience enables them to tailor the pharmacotherapy to the needs of the individual patient. This is particularly important with multimorbidity and polypharmacy, when patients really can't be treated according to the guideline for one specific disease or condition.*"

Introducing a new care provider in general practice might confuse patients as to whom they should address questions related to medication (s1). Nevertheless, factor A does not identify this as a problem: "*When a clinical pharmacist takes care of a patient, they establish a relationship which makes it natural for the patient to consult them about their pharmaceutical care issues.*" Participants disagree with the statement that an NDP loses their independent position as healthcare provider as an employee of a general practice (s11): "*The clinical pharmacist's professional integrity will not be influenced by the organisational framework of the workplace.*" "*An NDP has its own expertise and independency.*" However, participants commented that it will take some time to adjust to this new role of a pharmacist.

Respondents loading on this factor disagree with the statement that the NDP takes on too many tasks of the GP (s37). "*The NDP doesn't take over too much of the pharmaceutical care, but enhances it by working together with the GP.*"

Participants of factor A show confidence in a nationwide introduction of this new pharmacists' role. This is underlined by the statement that NDP introduction will not make primary care unnecessarily expensive (s12): "Healthcare *costs might be reduced by preventing adverse effects, overprescribing and medication-related hospital admissions*."

Factor B: "independent community pharmacist"

Participants aligned with factor B, over forty percent of whom were community pharmacists (Table 4), insist that the community pharmacist should be the leading independent pharmaceutical care provider, with sufficient financial reimbursement as a prerequisite to perform this role. The participants agree with the statement that a fee for practice costs is necessary to deliver pharmaceutical care (s9): "*Improper reimbursement for pharmaceutical care results in hasty dispensing [pharmaceutical activities performed in a short amount of time] resulting in low quality pharmaceutical care and inadequate follow-up.*" The participants aligning with this factor disagree that a community pharmacists is unable to perform pharmaceutical care. This is reflected by their disagreement on: the community pharmacist is insufficiently informed about the patients' individual pharmacotherapy (s5) and the community pharmacist is not skilled enough to perform patient consultation (s27). They said, "*patient consultation is the most important part of our job*" and *"during our training, and in the community pharmacy, it's crucial to have good communication skills otherwise you can't do your job as a (community) pharmacist.*"

These participants share the opinion that a community pharmacist should advise on the choice of medication (s17):

"*Nowadays medication is an important part of therapy. The [up-to-date] pharmaceutical knowledge of a community pharmacist is more extensive than the GP's knowledge. A community pharmacist can, with this knowledge, increase adherence, efficiency and medication safety by giving advice on the choice of medication.*"

Moreover, these participants disagree with the statement that the patient has more confidence in the NDP than in the community pharmacist (s4). They strongly disagree with the statement that pharmaceutical care can best be accommodated at a general practice (s32) and that clinical medication reviews should take place in the GP practice (s19): "*Medication reviews can also take place in community pharmacy. It's not really a matter of where the reviews are done, what's important is that they are done. Medication reviews should be done in collaboration with the prescriber and the patient.*" Therefore, an NDP can also be stationed at a community pharmacy; a potential conflict of interest, due to both consulting on medication and selling it is thought unlikely (s36). Dissimilar to the other factors (A, C and D), participants of factor B strongly support linking dispensing medication and both patient education and giving advice on pharmacotherapy (s31, s26). These statements illustrate the wish to keep general practice and community pharmacy separate. "*Dispensing*

medication involves more than a GP can handle. GPs have only a limited amount of time per patient. They have little time to give advice on medication, let alone take care of the dispensing."

Factor C: "dependent clinical pharmacist"

The theme of this factor is pharmaceutical care improvement, managed primarily by GPs, with a supporting role for the NDP to join the team as a dependent pharmaceutical care provider. Sixty-five percent of the participants defining this factor were GPs or GP trainees (Table 4).

Unlike the other factors (A, B and D), participants in factor C believe that the GP has enough knowledge of medication (s13): "*In general, no major accidents happen due to the GP's pharmacotherapeutic choices. Over the past years, the GP's knowledge has increased.*" However, GPs are considered to be open to having more healthcare providers in their practice and encourage multidisciplinary teamwork (s2): "*The support from other caregivers is very nice, since a doctor can't know it all.*" In line with this multidisciplinary approach, participants aligning with this factor are open to having an NDP in their practice and debate the statement that a pharmacist has an inferior position which could impede medication safety (s23): "*A pharmacist is not inferior. Collaborating on conducting safe practice together is the main issue.*" Medication safety is not thought endangered by inequality in positions but "*a lack of collaboration or organisational flaws*" are considered the most likely cause of medication safety problems.

Those aligning with this factor are the only respondents who agree with the statement that an NDP cannot be employed at a community pharmacy due to a conflict of interest (s36). They agree with the statement that the patient has more confidence in the NDP than in the community pharmacist (s4): "*Patients associate general practice with good quality of care. They prefer to discuss their care issues with healthcare providers who are physically present in general practice.*" Therefore, clinical medication reviews should be organised in general practice (s19): "*The GP is the centre point of primary care. That's why it's logical to do medication reviews in general practice*" and "*the access to medical records in general practice facilitates medication reviews.*" Pharmaceutical care provision can be performed in close collaboration with an NDP but in contrast to the respondents aligning with factors A and B, respondents on factor C disagree with the statement that an NDP should be an independent prescriber (s34): "*A pharmacist is not a medical doctor.*"

Factor D: "medication therapy management specialist"

Factor D supports the idea of integrating an NDP in primary care and shows similarities with factors A and C, although this vision of the added value of an NDP includes managerial expertise. Also, this factor shows some mistrust in the ability of community pharmacists to provide good pharmaceutical care. Participants defining this factor are a heterogeneous group of GPs, hospital pharmacists, policy makers and other medical and/or pharmaceutical experts (Table 4).

The added value of an NDP is made tangible by their proactive task to screen patients with potential drug therapy problems (s25): "*An NDP can intervene before medicines are prescribed, while intervening afterwards is inconvenient, time-consuming and confuses the patient.*" A GP who worked with an NDP stated: "*In our practice, the NDP's particular expertise to proactively identify high-risk patients resulted in improved patient safety.*" Besides this preventive approach, factor D is most outspoken about the individual patient care an NDP should deliver (s18). Also, they are most distinct about the NDP not being an independent prescriber (s34): "*Prescribing and monitoring medication have to be separate at all times*" and "*the GP will lose control over patient care if multiple healthcare professionals are allowed to prescribe medication independently" and "the pharmacist has not enough (clinical) knowledge about a patient.*" Despite the latter, the GP conceded their insufficient knowledge of medication (s13): "*GPs get very little schooling on medication.*"

This factor suggests that educating patients on their pharmacotherapy can be separated from dispensing medication (s31). Moreover, it was stated that the information on medication given by the community pharmacist to the patient does not reflect the GP's advice well enough (s22): "*Unfortunately, patients are often confused by the different advice in the community pharmacy.*" Also, participants aligning with this factor disagree on the statement that a fee for practice costs for community pharmacists is essential to enable delivery of pharmaceutical care (s9). This implies that this factor does not necessarily support the development of community pharmacists as pharmaceutical care providers. On the other hand, participants aligning with factor D acknowledge that a community pharmacists' primary concern is not the financial status of the pharmacy business (s7), which suggests the possibility of another primary concern, for instance pharmaceutical care.

Table 4. Defining participants

Expertise	Factor A (n=27) Percentage (n)	Factor B (n=50) Percentage (n)	Factor C (n=20) Percentage (n)	Factor D (n=8) Percentage (n)
Community pharmacist	11 (3)	44 (22)		
Non-dispensing pharmacist	19 (5)	2 (1)		
Hospital pharmacist	7 (2)	2 (1)		25 (n=2)
Pharmacist trainee		12 (6)		
General practitioner	4 (1)	4 (2)	45 (9)	25 (n=2)
General practitioner trainee	4 (1)		20 (4)	
Practice nurse	4 (1)		5 (1)	
Other medical and/or pharmaceutical expert	33 (9)	18 (9)	20 (4)	25 (n=2)
Policy maker	7 (2)	8 (4)		25 (n=2)
Pharmacy or medical student	11 (3)	10 (5)	5 (1)	
Patient			5 (1)	

DISCUSSION

We systematically mapped the debate amongst stakeholders on introducing an NDP in primary care practice and revealed four perspectives: "the independent community pharmacist" (Factor B), "the independent clinical pharmacist" (Factor A), "the dependent clinical pharmacist" (Factor C) and "the medication therapy management specialist" (Factor D).

Factors A, C and D favour NDP integration in primary care practice. The main contrast between factors A and C concerns the level of professional independence, which is an eminent point of debate when introducing new roles into current practice. Fournier says that the construction of boundaries and the creation of an independent area of knowledge is crucial to professional development.[19] In accordance with this, factor A supports the integration of an NDP as an "independent clinical pharmacist" based upon the clinical knowledge that an NDP brings into practice and the benefits of working within the same organisation. This creates interprofessional trusting relationships and integrates work processes, thereby improving quality and continuity of individual patient care. Despite the restricted clinical, economic and political autonomy of pharmacists described by Edmunds,[20] factor A highlights development in the process of reprofessionalisation of pharmacy.

In contrast to factor A, factor C stresses the role of an NDP in general practice as a "dependent clinical pharmacist" within a multidisciplinary team of healthcare professionals, with drug monitoring and not drug prescription as the primary task. This perspective accentuates the GPs' wish to maintain professional dominance, triggered by external threats of their privileged position (8). Also, it is acknowledged that GPs are hesitant about the clinical roles of medication management performed by community pharmacists.[2] This hesitance towards community pharmacists might have influenced their perception of the level of independence that an NDP in primary care practice should attain.

Factor D is distinct about the innovation level of tasks performed by NDPs. Supporters of this factor promote a new model of care: an NDP as a "medication therapy management specialist" who focuses on proactive screening (and treating) of patients with potential drug therapy problems, thereby integrating managerial expertise and values into the professional work. It involves population-focused preventive care, which is important in an era with a large ageing population, to prevent avoidable chronic diseases and unnecessary medical expense.[21]

While factors A, C and D favour NDP integration in primary care practice, factor B see pharmaceutical care provision improved by maintaining and expanding the traditional roles of community pharmacists. The respondents aligning with factor B underline the essential role of community pharmacists as leading pharmaceutical care providers.[22] According to the respondents of factor B, pharmaceutical care, including dispensing medication, should definitely not be accommodated in general practice. Factor B wishes to enhance the level of independence of community pharmacists in the context of treating individual patients to

legitimate their role as pharmaceutical care professionals.[20] They see clear boundaries and the creation of an independent area of knowledge crucial to the professional development of the pharmacist.[19]

Although these four perspectives are distinct, we identified a relatively large overlap between them. There was consensus on the potential of the NDP as a pharmaceutical care provider. Moreover, all respondents in this Q study were consistent in their view on financial, organisational and collaborative issues such as more funding for pharmaceutical care improvements, better access to medical records for pharmacists, shared education for GPs and pharmacists, and shared responsibility for the outcome of pharmacotherapy. This high level of consensus demonstrates a willingness for interprofessional collaboration and a positive attitude towards different aspects of an NDP integrated in primary care practice.

A strength of this study is that it included participants with a large variety of medical and pharmaceutical experience. This makes it likely that it represents all the different viewpoints on the NDP in Dutch general practice. No indications for missing topics were found in the evaluation by the expert group and pilot study. Also, this study is part of the POINT study, a large multicentre intervention study on NDPs in Dutch primary care practice[11] and the results of this Q study will contribute to further development of the intervention.

This study does have limitations. Firstly, nothing can be said about the prevalence of the four factors amongst pharmacists, GPs and external stakeholders in the wider population since Q methodology is not designed for this purpose. Secondly, for pragmatic reasons the majority of the respondents ranked the Q set electronically, including computer-based interviews instead of personal interviews. In-person interviews enable the researcher to better understand and interpret the results. However, we identified no apparent differences in reliability or validity of these two methods of administration.[23]

Since all stakeholders underline the potential benefit of an NDP as pharmaceutical care provider, we need to reflect upon the financial aspects of these services. As said, all stakeholders agree that more and earmarked funding is needed to improve pharmaceutical care. In the POINT study that we are currently evaluating, the NDP services were funded via a temporary grant.[11] A sustainable model of reimbursement for the services performed by NDPs is needed. The employer could than either be community pharmacies or GP practices. A community pharmacy fee finance model, however, is less feasible because this model is based on dispensing of medication. The relatively small fees for pharmaceutical services obstruct employment of an NDP in community pharmacies. Implementation through the GP fee finance model is feasible, but limited to groups of collaborating GP practices. Implementation of the NDP would probably be optimal if dedicated additional funding from the insurance company. Whether and how an NDP can be employed in other health care systems heavily depends on the local situation. Hence, it would be relevant to replicate this study in a country with a different health care system.

It is important to define the scope of practice of NDPs in comparison to both the community and clinical pharmacists. The NDP is the clinical pharmacist in primary

care. While earlier initiatives to bring hospital clinical pharmacists in primary care failed, the NDP provides an alternative role. NDP services will add especially to the quality of pharmaceutical care of specific subgroups of individual patients, such as elderly patients and those with polypharmacy. The community pharmacist will – in addition to dispensing medication and medication surveillance – provide pharmaceutical care connected to the pharmaceutical product to less complex patients. In contrast to the UK and the US, neither community pharmacists, clinical pharmacists nor NDPs can prescribe drugs in the Netherlands. In the current study prescribing by pharmacists was not seen a priority for an NDP.

CONCLUSION

Despite the fact that introducing new professional roles in healthcare can be controversial, this Q study identified a consensus on various features of the NDP role, as well as on financial, organisational and collaborative aspects of NDP integration in primary care practices. This shows the potential of an NDP as a pharmaceutical care provider and the willingness for interprofessional collaboration. The main identified controversies concern the NDP's level of professional independence and the level of innovation of task performance. The results from the POINT intervention study will be an important next step in resolving current controversies.

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2.3

How clinical integration of pharmacists in general practice has impact on medication management: a theory-oriented evaluation

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ABSTRACT

Background

Data on medication-related hospital admissions suggest that there is an opportunity for improved pharmaceutical care. Hence, concerns about medication-related hospital admissions is a driver to extend and integrate the role of community pharmacists in general practice.

Aim

The aim of this paper is to give a systematic description of 1) what integrating a non-dispensing pharmacist (NDP) in general practice entails and 2) how this integrated care model is expected to contribute to patients' medication management.

Methods

Based on ethnographic data collected by NDPs in general practices in the Netherlands, we conducted a theory evaluation.

Results

The impact of the NDP providing integrated care can be explained by 1) the specific expertise NDPs bring into general practice, which results into patient-centered solutions, 2) the integration of quality management into clinical work which results in pharmaceutical care projects, and 3) the reconciliation of possible tensions caused by overlapping tasks with practice nurses, which results in a distinct patient population.

Conclusion

Clinical integrated NDPs in general practice can provide maximum support to patients' medication management. NDPs can use their pharmaceutical expertise in clinical practice to find customized solutions for individual patients. As NDPs integrate quality management work into clinical work they can develop a distinct patient population that optimally benefit from their services.

INTRODUCTION

Data on medication-related unplanned admissions suggest that there is ample opportunity to improve pharmaceutical care. A systematic review reported that 7.1% of unplanned admissions were medication-related of which 59% were considered preventable.[3] The Dutch prospective multi-center study of Hospital Admissions Related to Medication (HARM) reported similar results with 5.6% of unplanned admissions being medication-related, of which nearly half were considered preventable.[4] The number of medication-related hospital admissions increases up to 10.4% within the aging population.[5]

Pharmacists can play a vital role to address the problem of medication-related harm. In recent years, we have seen a profound change in the role of community pharmacists. Their role has shifted from compounding and dispensing medications to providing integrated pharmaceutical care.[6,7] The concept of pharmaceutical care emphasizes the pharmacists' responsibility to pursue the best possible patient outcomes of medication therapy.[8] The implementation of pharmaceutical care may be hampered by traditional activities of pharmacists. Embedding non-dispensing pharmacists (NDPs, also called clinical pharmacists, practice pharmacists) in general practice enables pharmacists not to be distracted from logistics but to primarily contribute to the quality of pharmaceutical care.

NDP-led services improve the quality of medications' use and are increasingly implemented in the United States, Canada, Australia and the United Kingdom.[9–12] The evidence for the benefits of this new role of pharmacists on real clinical endpoints such as mortality or medication-related hospitalisations is unknown.[13] The POINT study group conducted a controlled intervention study, comparing clinical outcomes between NDP-led care and current models of pharmaceutical care delivery in the Netherlands. NDP-led care is new in the Netherlands. Therefore, the POINT practice model incorporated key elements of the Canadian IMPACT model of NDP-care and assured alignment to the prevailing vision of pharmaceutical care provision.[1,2] For a period of 15 months, ten NDPs - all with previous work experience in community pharmacy - were posted in ten general practices.[14] Concurrently, the NDPs participated in an extensive Clinical Pharmacy Training Program to be prepared to work at the clinical side of primary care.[15]

The introduction of NDP-led care is considered a complex intervention. However, measuring the effectiveness of such a complex intervention is challenging. Hence, for optimal interpretation of the data, i.e. whether and how NDP-led care improves medication safety, we needed to describe the operational aspects of the intervention in detail. In addition, we needed to describe how the NPDs' role has been implemented in general practice.[16] In particular, we wanted to describe the characteristics of the care setting, that could support or hamper optimal integration of the NDPs. Therefore, the aim of this paper was to give a systematic description of what is entailed in integrating an NDP as a member of the primary care team and how the integration could contribute to patients' medication management. We focused on clinical integration, i.e. collaboration between the NDP and other professionals in the clinical care delivery process.

BACKGROUND

In the Netherlands, pharmaceutical care in primary care is currently provided by community pharmacists. The typical Dutch community pharmacy serves approximately 9,000 patients with one or two community pharmacists and eight pharmacy technicians delivering medication and health-related products. Dutch community pharmacists focus on counselling and dispensing of prescription medication. The majority of Over-The-Counter medication, food supplements and cosmetics are distributed through so called drugstores. In addition to dispensing fees, health care authorities have introduced a limited number of fees for cognitive services. In addition, community pharmacists can receive a higher dispensing fee if they score better on a selection of quality of care indicators.

General practice care in the Netherlands is increasingly organized in group practices. These group practices are at their turn increasingly located in community health centers together with community pharmacists, nurses and other health care providers. On average three to five general practitioners (GPs) with an extensive auxiliary staff provide primary care to 6,000–10,000 patients. GPs are paid by capitation (60%) and fee for service (40%), mainly consultations of ten minutes each. GPs receive bonus funding from insurance companies to meet the predefined quality of care indicators. Most GPs employ nurses specialized in chronic illnesses such as diabetes, cardiovascular disease and chronic obstructive pulmonary disease, and mental health staff addressing psychosocial problems. In addition to nurses, GPs employ practice assistants who do most of the triage, practice administration, and simple procedures.

In contrast to community pharmacists, NDPs in the study worked in the clinical setting of the GP practice. They had a fixed income, access to medical records and did not dispense medication. As described in the study protocol,[14] the NDPs performed:

- clinical medication reviews for patients with polypharmacy;
- medication reconciliation for patients discharged from the hospital;
- patient consultations about specific medication-therapy problems;
- targeted pharmaceutical care programs.

The intervention was designed with a specific set of assumptions about how an NDP would reduce medication-related hospital admissions. First, as a team member of a general practice, the NDP can easily contact the GP. Daily personal contact between the NDP and GP can improve mutual understanding and fosters trust. Second, the NDPs will have access to the medical records of patients to support pharmaceutical care provision.[17–19] In addition, shared records facilitate communication between NDPs and GPs. The GP can trace what the NDP does. Third, as the NDP does not dispense, the work of the NDPs is purely clinically focused, consisting of clinical medication reviews, consultations for medication related questions and targeted pharmaceutical care programs to systematically improve the quality of prescribing. As in all clinical practice the NDP's work is problem-

based and patient-centered, presuming that it starts with individual or population-based problem identification and subsequently targets the problem in a patient-centered way.

METHODS

We reconstructed the program theory of the integration of NDPs in general practice.[20] A program theory is a systematic description of what an intervention entails, how its elements link to the intended outcomes and how the intervention interacts with the context.[16]

Data collection

We trained the nine NDPs to do participative observations. These consisted of observing and describing any professional encounter during their work, e.g. conversations at lunchtime meetings on pharmaceutical care, the questions that GPs asked them during work, the reflections of the practice nurses and the practice assistants to their work and the role of managerial expertise in their work. The focus of the observations was defined upon both what is known about the introduction of new professional roles as well as upon the results of the first observations. Based upon what is known about new roles, we asked NDPs to observe how their work interacted with and possibly conflicted with the work of the GPs, the practice nurses and the practice assistants. Therefore, we asked the NDPs to observe the daily work of GPs, practice nurses and practice assistants. We asked them in particular to make notes about daily organization of the work in the practice and the interactions between assistants, nurses and GPs. In addition, we asked the NDPs to record how they spend their time. The researchers and the NDPs had monthly meetings in which they jointly analyzed the ethnographic data.

Analysis

Two researchers (AdB and AH) performed an inductive qualitative analysis of the notes. This analysis enabled a systematic identification of the pharmaceutical expertise that matters in general practices. The analysis centered on the differences and commonalities between the 10 NDPs and the ten general practices. We presented a selection of excerpts to the NDPs. We asked the NDPs to identify - independently from our analyses - the differences and commonalities between the excerpts. The joint analyses of the observation data resulted in a further specification of the observation, such as questions asked and skills for quality management.

RESULTS

The right expertise

In the first four weeks**,** we asked the NDPs to make notes of the questions GPs asked them. These questions provided insight in which NDP's expertise was relevant for GPs. In the first months of the study, the GPs asked the NDPs questions on medication therapy.

GPs appreciated concise and practical answers to these questions. After a couple of months, the GPs started sharing more complex cases with the NDPs. They appreciated alternative solutions for patients with more complex medication related problems. In the next paragraphs, we classified the questions for expertise in three categories. We illustrated the differences with similar cases.

Category 1. Questions where the NDP had to mobilize pharmaceutical evidence on the spot. The questions were short and relatively uncomplicated and knowledge of the patient's context was not essential. For example, a GP asked the NDP how to switch from the antidepressant citalopram to fluoxetine, since citalopram was not effective. The NDP gave direct advice and the GP informed the patient. In this case, the GP had already decided on the choice of medication therapy and only needed specific information about the best way to switch from one medication to the other.

Category 2. Questions, in which patient context needed to be taken into account for an optimal decision. In a similar case as in the first example, the GP asked which alternative medication therapy the NDP would recommend for a patient who was non-responsive to citalopram, i.e. advice on how to switch. The NDP asked additional questions about the indications for citalopram (anxiety disorder), whether the patient experienced any side effects and whether alternative medication therapies had already been tried. The NDP decided to check the patient's medical record to find further information on co-morbidity and current medication use. Based on this, the NDP gave the GP advice on switching medication therapy and the GP contacted the patient.

Category 3. High-complex questions, in which patient counseling was essential. Again we took a similar case to allow for comparison. The GP asked the NDP if and how he should stop citalopram for a patient with anxiety disorder. The NDP decided to invite the patient for counseling to discuss current medication-related needs, usage and experience with the medication (efficacy and side effects), concerns, potential complaints and the patient's wish to stop the medication therapy. The NDP suggested a tailored scheme to stop citalopram and the NDP monitored the patient during the process of stopping.

Distinct patient population

Based upon the observations of the work of practice nurses, we analyzed how both the NDPs and the nurses reconciled interprofessional tensions over responsibilities and domain discussions. We reconstructed two strategies. The first strategy is to support the nurses in - what they call - difficult cases. NDPs take over the provision of pharmaceutical care to those patients who either did not fit well in the protocol or who used a medication that could be potentially dangerous. This strategy aimed to ease the work of the nurses. The following example was presented as a success by an NDP in her new role.

"*The nurse told me (the NDP) that she had failed in the pharmaceutical care of a patient. She was very happy that I had taken over the complex care of this patient. After three consultations, which resulted in adjusting antihypertensive medication, extra lab monitoring,*

stopping amitriptyline and starting vitamin B12, the patient was referred back to the nurse. I explained the medication changes to the nurse. The nurse said she appreciated our efficient collaboration and the insights into medication therapy. She added that she liked it that I (NDP) was so approachable." (field notes of the NDP)

The second strategy that we reconstructed was the identification of new patients. Based on specific observation of who initiated a patient consultation, we learned that the NDPs invited 69% of the patients for consultation. The GP initiated 13% of the consultations, other health care providers such as nurse practitioners initiated 7% and the patient initiated 11%. Hence, the NDPs do not seem to compete with nurses because the NDPs take up their own roles and identify their own distinct patient population.

Time competent

We also asked NDPs to assess the effectiveness of the time spend on clinical medication reviews. In the first months, the NDPs were instructed to book a one-hour slot with patients for a clinical medication review. This hour would allow the NDP to study the whole patient record and especially a patient's medication history. We asked the NDPs to note questions and comments on the one hour time slot. The GPs objected to a consultation of 60 minutes, and suggested a maximum of 20 minutes. They regarded the required duration of the consultation as a matter of competency and experience. An experienced GP can deal with single questions in time slots of ten minutes and can deal with multiple questions in 20 minutes (double consultation fee). Yet, the NDPs – in response to this observations - stressed that they needed more than an hour to discuss multiple problems, assess data, to contact other caregivers and make a sound clinical judgment. They compared their role with the role of a geriatric specialist, who can spend three hours on one patient. As an NDP explained: *"we try to unravel the puzzle, that takes time. But that is our strength. The GPs in my practice are positive about the work that I do for patients.*" (field notes of the NDP)

In addition, we asked the NDPs to register the length of their consultations. In our intervention, the time spent on a clinical medication review was neither ten minutes nor three hours. A clinical medication review consisted on average of an intake consultation of 30 to 60 minutes in the patient's home or in the general practice, followed by two to three short follow-up meetings in the patient's home, by telephone or in the general practice.

Clinical quality management

We asked the NDPs to introduce medication therapy quality management into their practice. As community pharmacists, the NDPs were already trained in quality management. We asked the NDPs to observe which clinical skills were relevant for quality management in general practices. One particular skill became prominent in the analysis of the different quality projects that the NDPs started. This skill was to invite patients to the clinic for medication management. *"It is not easy to ask a patient to come to the clinic for a medication review. Some patients are not inclined to come. They are content with the medication they*

use." (field notes of the NDP). Patients tended not to come to the practice when they were invited to change or discontinue their medication therapy.

Rather than discussing whether medication should be stopped or changed, the NDP needed to start the consultation by discussing symptoms that might bother patients and then assess their needs regarding these symptoms. A good example was a quality management project that all NDPs performed on the use of alpha-blockers for lower urinary tract symptoms. The NDPs selected patients from the general practice who were prescribed medication for lower urinary tract symptoms and invited them to evaluate their medication use. By discussing symptoms and the effect of medication therapy, the NDPs experienced that the patients were more likely to discuss their medication-related needs, identify medication related problems and actually change their medication use.

DISCUSSION

NDPs in general practice take up an active role as care provider by being integrated in the clinical decision–making process. NDPs bring specific pharmaceutical expertise into general practice. They can mobilize pharmaceutical evidence on the spot to improve patients' medication management. They offer tailored solutions for the problems of individual patients. Thereby NDPs integrate quality management work into clinical work which results in the implementation of pharmaceutical care projects. Via comprehensive medication therapy management services, they support patients in the safe and effective use of medication.

The evidence on pharmacist-led services for patients with a specific condition or specific medication is convincing.[9,13,21] However, patients at risk of medication-related problems often have multiple conditions and polypharmacy and require a comprehensive medication therapy management approach. The fundament of the POINT practice model was that comprehensive services can best be provided by pharmacists as integrated members of the multidisciplinary health care team. Based on studies in North-America, Australia, New Zeeland and the United Kingdom[1,9,12,13,22–25] we know of considerable variety in the specific services that NDPs performed, their degree of (clinical) integration in the practice and the way that they were trained. In our program we assumed that the expertise of pharmacists can be made optimum use, when they are fully integrated in the primary care team,[26] and when they have full responsibility for pharmaceutical care. Hence, the practice model had a patient-centered and multilevel approach in which NDPs provided comprehensive medication therapy management services.

Full integration and full responsibility requires training in clinical reasoning and consultation skills.[27,28] NDPs need to make evidence-based decisions, which means combining their knowledge of medication with their clinical experience, balancing with the context and the needs of the patient.[29] The distinction between evidence and expertise is hereby relevant.[30] Evidence is objective facts that can be transferred from one domain to the other – such as the active mechanism of a pharmaceutical, its benefits for a defined

patient population and its possible side effects. Expertise is the professional ability to make judgments within a specific context,[31] such as the decision to deviate from a prescription guideline or to suggest a non-pharmaceutical solution.[32] Expertise is recognized within the relations between the NDPs, nurses and GPs in which it is appreciated and made credible. It is therefore that tailored pharmaceutical solutions for the problems of individual patients depends upon clinical integration of NDPs in general practice.

Despite full integration, NDPs have a distinct role in general practice thanks to their experience in quality management and their ability to apply this in the clinical setting of the general practice.[33] With their focus on medication management and their experience in quality improvement projects for patient populations at risk, they integrate managerial skills in professional skills. In fact, NDPs embed pharmaceutical care in quality management strategies, structures and routines.[33] It is the integration of managerial expertise and values into the professional work of a clinician that explains the impact of the NDPs on patients' medication management.

The implications of this study for the development of pharmaceutical care are the following. First, NPDs will not substitute care presently provided by GPs or nurses. They will provide a complementary skill set to GPs. Second, NDPs can and need to take the time to let patient change or stop medications. Structured follow-up is key to provide valuable support in patients' medication management.

Conclusion

Clinical integrated NDPs in general practice can provide maximum support to patients' medication management. The integration of NDPs in general practice allows NDPs to mobilize pharmaceutical evidence on the spot and to gain credibility for customized advice on what to do for a particular patient given their specific context. As NDPs integrate managerial expertise with professional skills, they can focus on distinct groups of patients to optimize the patients' medication management.

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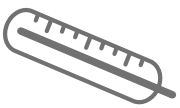
Chapter 3

TRAINING AND PROFESSIONAL IDENTITY

3.1

Design of a 15-month interprofessional workplace learning program to expand the added value of clinical pharmacists in primary care



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ABSTRACT

Background and purpose

Clinical pharmacists who work in general practice settings bring an improvement to patient care and outcomes. Postgraduate training for an independent clinical role does not often occur in the primary health care setting. When it does, the design of the curriculum is infrequently based on interprofessional workplace learning principles and it does not always integrate practical experience with classroom based learning activities. This could lead to situations where clinical pharmacists are insufficiently trained to apply clinical reasoning skills and direct patient care in the general practice setting.

Educational activity and setting

A program was designed, including competencies and learning objectives, based on results from focus group interviews with stakeholder and the literature on interprofessional workplace learning. Ten participants were selected for a pilot run of the program and were asked several times for their opinion about the program.

Findings

A 15-month training program was offered to pharmacists who became clinical pharmacists with the responsibility to perform patient consultations in general practice. The program was based on interprofessional workplace learning principles and facilitated the participants' skill in connecting the evidence, the patients' perspective and their own professional perspective. The ten participating pharmacists were satisfied with the program.

Discussion

The training program provided increased opportunities to clinical pharmacists to add value in general practice. The training program enabled pharmacists to advance their skills in direct patient care and to improve the alignment between different professionals in the primary care domain.

BACKGROUND AND PURPOSE

The role of pharmacists is changing and there is a shift from 'dispensing pharmacy' to providing pharmaceutical care.[1] Such developments lead to a demand for more clinical pharmacists in order to support the move away from dispensing activities.[2] Clinical pharmacists in contrast with dispensing pharmacists are required to assume clinically focused roles, work in a patient centred manner, within a team of healthcare professionals.[2]

Hence, a large diversity of educational programs is offered within formal graduate, post-graduate and specialization programs, that lead to a range of job titles such as Advanced Practice Pharmacist and Clinical Pharmacist Practitioner.[3] Many of these programs train participants to be able to assume the role of clinical pharmacists on the ward in a hospital environment, with single exceptions, for example, the program "Developing Clinical Pharmacists In General Practice" in the United Kingdom (UK).[4] In a few countries, for example, Canada, Unites States and the UK, the role of the clinical pharmacist in primary care settings exists.[3,5,6,7,8] But in many other countries, clinical pharmacists work within their community pharmacy rather than at the workplace of the general practice.[9,10,11] A case has been made that states that clinical pharmacists should be located within general practice on a full-time basis in order to achieve an improvement in patient care.[6]

A few advanced training programs exist for pharmacists who intend on working within the general practice setting, for example, medication therapy management services through consultations with patients. The development of the programs and the establishment of clinical training sites does not always happen in tandem, thereby making theoretic course content less cohesive with clinical practice.[3] Dual training in general practice is essential in order to prepare pharmacists for the new role which requires the acquisition of specific competencies and skills in addition to knowledge.[12] For example, general practitioners (GP) take a more longitudinal perspective on patient care and on monitoring patients in time than physicians working in a hospital environment. Clinical pharmacists aspiring to work in general practice therefore need exposure to this manner of working and reasoning in order to participate as an effective team member.[13, 14.] Also, the role of clinical pharmacists in general practice is complicated given that in some countries, controversies prevail concerning their independence and tasks.[15] Without training, presumed advantages of clinical pharmacists probably do not sufficiently materialize, for example in the Netherlands where pharmacists follow graduate training with a focus on pharmaceutical product knowledge and have limited training on patient-centered communication,[16] clinical reasoning or interprofessional collaboration.

The presence of clinical pharmacists within general practices has been nonexistent in the Netherlands until recently, but the need for such a new professional role has been acknowledged,[17] as was the necessity to train these professionals.[13] Therefore, we have developed a 15-month program for pharmacists aspiring to become clinical pharmacists. The program is characterized by a dual track comprised of classroom meetings and simultaneous practice experience. This design assisted professionals to learn in an

interprofessional manner in the workplace, through co-location of pharmacists within the general practice. Furthermore, a clear connection to a classroom setting was provided where participants could reflect on experiences and practice new skills.[18, 19]

This program was not a certificate, nor a training involving different internships but a dual program where pharmacists learn to perform fully integrated pharmaceutical care in one specific general practice from the inception of their training program. One of the important assumptions in the design of this workplace learning program has been the demand for good interprofessional collaboration between diverse healthcare professionals. Interprofessional collaboration was felt neccessary for successful integration of clinical pharmacists in general practice.[14] Acquiring such collaboration skills calls for a training program that offers ample opportunities for interprofessional learning.[20, 21] In line with the argument presented by Fox and Reeves, we anticipated that sufficient attention for interprofessional competencies is closely related to patient-centered care because the patient benefits from a better alignment between different professionals.[22]

Within the literature on the role of clinical- as well as community pharmacists the need for improved communication with patients and their involvement in decision making has been identified.[23] Professionals, even those who had worked as a pharmacist in a community pharmacy, needed new skills to achieve partnership with patients to become trusted partners of patients. [24] Therefore, during the classroom meetings, the participants learned to work with a structured communication model for consultations, the Cambridge Calgary model, which has been widely used in postgraduate specialty training for general practitioners (see Table 1).[25] This communication model describes the process of an effective interview and assisted pharmacists in conducting consultations with patients within the general practice setting.

Again, the learning of participants was facilitated through a blend between the formal classroom and the general practice setting. First, they theoretically learnt about the model then they applied it during their days in the general practice and finally they reflected on their progress during later classroom meetings.

The objective of this article is to describe the design of the training program and discuss some general findings from the evaluation of this program. Elsewhere will be reported on how the program has been studied within a trial design, studying whether medication-related hospitalizations are prevented as a result of the clinical medication reviews carried out by the clinical pharmacists, and on how interprofessional learning occurs between clinical pharmacists and GPs.[17]

EDUCATIONAL ACTIVITY AND SETTING

Context

In the Netherlands, 1981 community pharmacies were employing 2929 pharmacists in 2015,[26] and 5045 general practices were employing 9418 GPs.[27] The need for the introduction of clinical pharmacists in the Netherlands was based on the finding that a small percentage

Table 1. The tasks in the Cambridge Calgary Model

1. Initiating the session
2. Rapport building
3. Information gathering
4. Information giving and planning
5. Closing the session

(5,6%) of all hospital admissions had been related to clinical medication errors and on the observation that implementation of clinical medication reviews, anticipated to prevent these errors, has been slow.[17] In the Netherlands, people are listed with a GP who is their point of entry to health care. The GP coordinates access to specialized care. Specialists and hospital care can only be accessed through a referral from the GP. Dutch GPs often work in group practices or manage(s) a practice which is not affiliated with a hospital in the same manner in which outpatient clinics in the US and other countries are. Pharmacists regularly work in community pharmacies, which are also independent of hospitals, or in hospital pharmacies but until recently not in general practices. In our program, the participants each worked in a general practice in the city of Utrecht. The clinical pharmacists did not progress to different clinical sites but started at one particular site from the beginning of the program. The clinical pharmacists were educated as community pharmacists at Dutch universities in a 6-year graduate curriculum (3 years Bachelor plus 3 years Master) and obtained their Pharmacy Degree.

Pedagogy

The pedagogy in the program was developed on the basis of workplace learning where learning activities during the classroom meetings focused on skills (such as consultation skills) and knowledge that these professionals could apply in the general practice. In addition, participants had to reflect during the classroom meetings upon their experiences in general practice while establishing their new role. Workplace learning is a particularly suitable frame of reference for interprofessional learning, between clinical pharmacists and GPs,[28] and it is important to note that incorporation of interprofessional training in a monodisciplinary curriculum is often difficult.[21]

Our purpose was to create a safe and optimal learning environment with an emphasis on the group development, introducing a buddy system and scheduling sessions to practice mindfulness in the classroom. Mindfulness, in the words of Lovell (2015, p.653) is "to be adaptive, and to be able to face unfamiliar situations with assurance."[29] In the challenging task of developing a new professional role for themselves, in an environment where they could be seen as outsiders, explicit attention to their well-being was considered essential. Moreover, in a group of 10 students, participants were offered affordances for intense learning and identity development.[30]

For the duration of the training program, participants were given tools to communicate with other members of the group which supported the informal learning process, for example, a WhatsApp group.[14] The formal education offered in the classroom was based on The Ten Steps of van Merriënboer which is an approach that supports complex learning.[31] It ensures that tasks are of increasing difficulty in time. Such an increase in difficulty reflects the actual work of clinical pharmacists who are faced with increasingly complex cases given the move of health care from hospital to primary care.[32]

Design

First, we determined what this new role in the in the Dutch healthcare system, a non-dispensing clinical pharmacist, should be which was done through consultation with five experts. These experts were from within the field of clinical pharmacy and teaching, related to two different Dutch universities. Besides, a group of GP-educators from the University Medical Center Utrecht was consulted, and a study was carried out in two general practices with a clinical pharmacist. Next, inspired by clinical pharmacy courses in the US, Canada, and Europe, (even though their focus was different) and the CanMeds framework,[33] we formulated competencies. From the competencies, we developed learning objectives (see

Duration (hours)	Activity
1.5	Guided group reflection[a] about the experiences, new skills and the development of the role of the non-dispensing pharmacists in practice.
1.5	Video-based consultation training[b]
0.5	Mindfullness[c]
2	Clinical reasoning with pharmaceutical knowledge by means of patient cases.
0.5	Formulating short-term objectives with a plan of action
0.5	Explanation of the new practice assignments

[a] Based upon the importance of ongoing self-reflection in the process of the development of a professional.[30]
[b] Based upon the Calgary-Cambridge Guide,[25] adapted to pharmaceutical care
[c] Mainly in group meditation guided by the supervisor of the program or by a sound recording.[29]

Box 1. Format of the classroom meetings

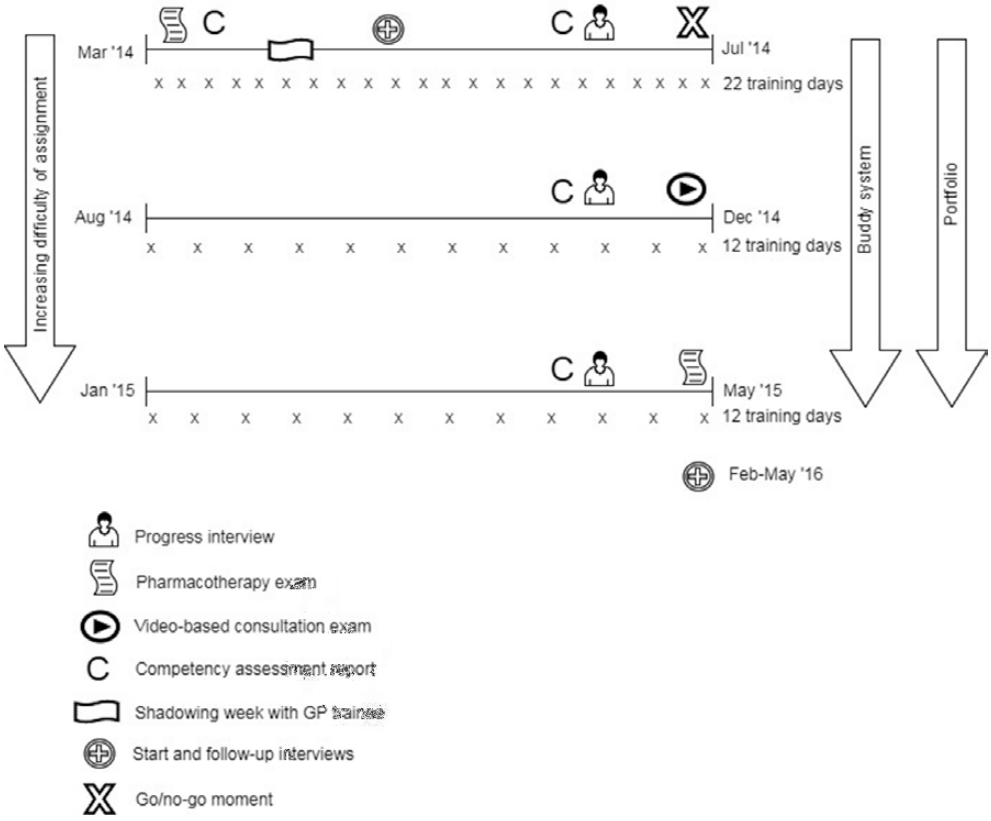

Figure 1. Timeline training program

Table 2). The objectives were discussed by an expert group of pharmacy practitioners who were experienced in pharmacy teaching and education development.

We developed the actual program (Figure 1) in close partnership with the academic department for general practice specialty training, in which patient-centeredness was at the core. During the design process, we could build on the knowledge and expertise on how GP trainees were educated on this essential learning objective of the program. Specific training and workplace activities were developed according to the learning objectives (Table 2). The content of the classroom meetings is summarized in Box 1 (format of classroom meetings).

In our pilot for the program, ten clinical pharmacists took part (see Table 3). The small number of participants was primarily for organizational reasons: the training has been embedded in a larger study.[11] The aim of the larger study was to investigate a primary outcome measure, being whether the deployment of clinical pharmacists located within general practice has an effect on the number of medication-related hospitalizations. Participation of more clinical pharmacists was not necessary for this trial.

Classroom meetings had been scheduled between their days in practice. Based on the ideas laid out by Kolb,[34] formal training provided opportunities for reflection on their experiences; such reflection led to conclusions which were subsequently used to test out different behavior in new situations. During the classroom meetings, the clinical pharmacists honed their clinical pharmacy skills through analyzing medication plans, seeking the literature for additional evidence for the changes they proposed and discussing their interventions with their peers and developed a pharmaceutical care plan (PhC-Plan). At the workplace, participants discussed the PhC-Plans with patients and with GPs during tutorial dialogues, which are bilateral discussions to learn together. From these discussions and dialogues, the participants learned more about the three aspects of evidence-based medicine: the evidence, the patient's preferences and the expertise of the professional.[35,36]

Reflecting on experience

Participants performed patient consultations, including PhC-Plans, within the general practice. At the beginning of the program, participants were made familiar with a consultation model based on the Calgary-Cambridge Guide,[25] adapted to pharmaceutical care because consultations were about medication-related issues only. With permission, participants video-recorded at least 20 of their patient consultations and at least 5 of their tutorial dialogues with (one of) their supervising general practitioner. During their peer group meetings, participants reflected on their experiences. The videos were first used for individual reflection and next for discussions in the classroom with fellow participants and supervisors.

Increasing difficulty of assignment

The program was designed to facilitate the growth of the participants.[16] At the beginning of the program, participants learned and practiced in the classroom four days per week, whilst working in the GP practice one day a week. At the end they spent only one day in the classroom every other week and the rest of the time they learned at the workplace. Initially, the clinical pharmacists had to present their plan to the GP before commencing patient treatment. However, in time, they only discussed the complex cases with the GP prior to treatment and reported on all other cases subsequent to treatment. At the outset of the program, participants presented simple cases about pharmacotherapy, but in time they presented complex cases and showcased how they took a more holistic approach. This encompassed taking into account medication issues and also elements the patients' perspective and experience on the medication and its effect. For example, the first assignment involved pharmacotherapy optimization of anticholinergic medicines in patients who used a maximum of five chronic medications (simple case) and the second assignment had the same topic but in complex patients, for example, patients who used more than ten chronic medications or were resistant to medication changes. The increasing difficulty of the case-based assignments offered the possibility to learn about different aspects of

Table 2. Learning objectives of the program and overview of the content of the training program

Learning objective	Training activities in classroom meeting	Workplace activities
1. Communication: communicating with individual patients to understand their expectations, experiences, and purpose about pharmacotherapy and to obtain an adequate medication history as well as present-day medication use.	Reflecting on videos of consultations with patient and of general practitioner (GP) meetings	Consulting on patients and participating in informal feedback sessions with GP (tutorial dialogues, a bilateral discussion to learn together) Following three chronically ill patients longitudinally
2. Identification of drug therapy problems (DTPs): identification and prioritization of individual DTPs, in accordance with the guidelines for pharmacotherapy and based on the understanding and information from learning objective one and on information of other practitioners in the health domain.	Listening to presentations of medical and pharmaceutical experts Discussing patient cases with peers	Consulting on patients with increasing complexity and receiving online peer feedback
3. Developing pharmaceutical care plans (PhC-Plans): formulate, implement, monitor and evaluate PhC-Plans, and adjust when necessary, for individual patients.	Plenary patient case discussions about the PhC-Plans	Formulating, implementing, monitoring and evaluating PhC-Plans with increasing complexity
4. Quality control: take responsibility for processes related to medication and pharmacotherapy within general practice. Take responsibility for the definition, monitoring, and adjustment of local drug formularies based on maximal effectivity, patient safety, patient satisfaction, and efficacy.	Developing quality improvement plans	Implementing procedures to streamline processes around repeat prescribing and to proactively screen and treat patients at risk of medication errors
5. Education: enhance the professionalism, and develop and implement professional knowledge of professionals who prescribe and other practitioners on pharmacotherapy.	Giving presentations and receiving peer feedback	Teaching GPs and other members of the health care team on pharmacotherapy

PhC-Plans pharmaceutical care plans; DTPs drug therapy problems; GP general practitioner

Table 3. Characteristics of participants in the program

Gender female, number (%)	8 (80)
Age at start of the training program, mean (range)	29 (25-38)
25-30	7
>30	3
Years since MSc Pharmacy	
<1	3
<5	5
5-10	2
Practice site experience	
Community	10
Hospital	0
Other	2

MSc Master of Science

pharmaceutical care, such as consultation skills and knowledge. This helped the clinical pharmacists to develop towards complete responsibility for complex patients in practice.

Interprofessional learning

At the general practice, where participants were located for an increasing number of days per week, they had opportunities for interprofessional learning with GPs and with GP trainees. Interprofessional learning was supported through reflection assignments about their experiences which were discussed in their classroom meetings with their peers and their supervisors. Informal conversations during the program and focus groups with the GPs that hosted the clinical pharmacists confirmed that a program designed around workplace learning helped the entire general practice to learn from the clinical pharmacists.

Supervision

The number of supervisors for the formal training days was based on the format of the Dutch GP training program, including one supervisor with extensive practice experience in clinical pharmacy in primary care practice (AL) and one psychologist (SV) who already was a qualified teacher within the GP training program. The clinical pharmacy supervisor had experience in higher education teaching but her experience in supervising one specific group of students over a longer period of time was limited. Therefore, a GP-supervisor (DZ) provided mentorship to the clinical pharmacist supervisor, to assist the clinical pharmacist supervisor in her learning process. Since the program was designed to foster interprofessional learning, we deliberately asked this GP-supervisor - with extensive experience in teaching (associate professor and head of student education of the graduate GP training at University Medical Center Utrecht) - to educate the clinical pharmacist trainees, yet, on a less regular basis than the clinical pharmacist supervisor. The fourth

supervisor, a professor of sociology of care innovations, guided the clinical pharmacist trainees in the process of role development and integration in the general practice. She provided four educational plenary sessions in the classroom and was available throughout the program for individual feedback sessions.

Assessment

Within the program diverse assessment methods were administered, most of them formative: to help participants improve learning. The participants received feedback from supervisors and peers on videos of patient consultations with a rubric that is also used within postgraduate GP training. Feedback was also given on their discussions with the supervising GP at the workplace. All assignments were incorporated in a portfolio, in addition to reflection reports and self-assessments on the desired competencies. Summative assessments were a written pharmacotherapy exam and oral examinations with a supervisor. Seven competencies were structurally assessed during the training program (start, month 4-11-15), based upon an adjusted version of a competency assessment instrument for the Dutch GP training program in combination with individual reflection reports and a personal development plan. A score of each competency needed to be >4 in order to achieve completion of the program. Whether the scores were sufficient or not, was evaluated during a formal go-no go moment.

Delivery of the program

In the spring of 2014, an advertisement for participation in the program was published online and in print. All pharmacists who wished to participate had to apply for this program, regardless of their number of working years in community pharmacy. After rating the application letters, two rounds of face-to-face interviews were conducted to select participants. The following criteria were used during this formal application process in order to select the top applicants: motivation, vision, pharmacotherapy knowledge, empathy, independence, decisiveness and flexibility. In addition, they had to give examples of how they mastered different skills, such as communication, collaboration, critical reflection, feedback and organizing skills. Ten participants were selected from 75 applicants.

The course was run for 15 months starting in September 2014 at the University Medical Center Utrecht. It was done in close collaboration with the 10 general practices (including 10 000 patients each) located in the Utrecht area that hosted the ten clinical pharmacist-trainees. These non-dispensing clinical pharmacist trainees performed patient consultations, including PhC-Plans, and shared responsibility for the pharmaceutical care provided in practice.

Data collection

Three months after the commencement of the program, semi-structured start interviews were conducted with the participants and the four supervisors to get an impression of the development and the needs of the students. At the end of the program, a follow up

interview was conducted with each participant. The results of this qualitative study have been used to develop the program further, and to adjust when necessary. In addition, each participant wrote a self-reflection report in which they evaluated the program at month 4, 11 and 15.

3.1 FINDINGS

In Table 3 the characteristics of the participants are summarized. Reflections on experience, using the video recordings made of consultations and tutorial dialogues with GPs, were primarily about new skills, such as conducting patient consultations, and about the uptake and development of their new role as non-dispensing clinical pharmacists. In a progress report, one of the participants reflected on this '*I have learned a lot from reflecting on video recordings, and I appreciate the feedback I receive from the group. I try to incorporate such feedback in the following consultations. I do think I learn this competency especially through sharing with the group.*" To help them connect their clinical reasoning with pharmaceutical knowledge, each participant wrote about the steps in their reasoning process about the patient cases in regular assignments. At the end of each assignment, participants formulated their short-term objectives with a plan of action on which they could reflect later on in the program, to finalize the reflection cycle.[34]

Continuous evaluation of the program by the supervisors who were responsible for the classroom meetings resulted in more focus on the transference of knowledge. After five months an informal group evaluation meeting about the supervisors and the educational design resulted in only minor improvements and adaptations to the design. One of the participants answered, when asked what would have happened when they would have started to work in a GP practice without the training program, "*I would have struggled I guess, and then I think I would have been very uncomfortable in the first weeks.*" [SG, start interview] At the end of the program, participants still thought that the program was meaningful for them. In the interview at the end of the program, one of the participants remarked: "*I think we became inspired by the classroom meetings, and these gave us a kind of energy 'ok, let's do this for real'.*" [PH] and another participant wrote in her final progress report "*Now, I notice that, compared to a year ago, I use communication skills and apply them in my professional behavior. I do think more about it, and as a result, I achieve more. The design of the program ensured that I learned a lot.*" [BP, progress report 3] Most GPs were also satisfied with the program. One GP indicated that it had been a steep learning curve, but she had been impressed by the new knowledge the clinical pharmacist provided "*She knows so much. How many mistakes she has found in our documentation, not small mistakes but major ones.*"

Of the ten participating pharmacists nine met the objectives and acquired the competencies. The one participant who did not complete the program was diagnosed using the assessment system that was in place, include ago-no go decision by the supervisors. Participants in the program indicated that experiences with actual patients, and learning

through (group) reflection on those experiences, had been meaningful for them. As one of the participants wrote down is his progress report: "*The group reflection in the classroom helps me a lot to grow toward becoming a professional. A very simple intervention did help a lot, I wrote down each week what I would like to discuss during those meetings. Moreover, as a result, I found out; I reflected a lot more on my work already.*" [PH, progress report] Or, as one of the participants stated in the follow up interview:"*The group reflection was very useful for me […] when someone shared information about a general practitioner who was not cooperative, or who did not understand the added value of a clinical pharmacist, being cross. It made me think 'how do you deal with such situations?' That could be useful if you encounter such situations yourself.*" [VM, follow up interview]

From the fact that the tools provided in our program, such as electronic learning system and dedicated social media accounts (WhatsApp), were actively used by participants in which they discussed cases and logistics of the program, we concluded that participants have been able to build an active learning community in time.

DISCUSSION

The program was aimed at educating clinical pharmacists for proficiency in practicing pharmaceutical care within a general practice setting where they are tasked with the responsible provision of pharmacotherapy for the purpose of achieving definite outcomes that improve a patient's quality of life. The emphasis was placed on clinical reasoning and practicing in a patient-centered manner. After the program, the clinical pharmacist trainees considered themselves more able to define and respond to the patients' needs and to communicate effectively with other healthcare providers.

We propose that our program provided good preparation for pharmacists to deliver direct pharmaceutical care because our dual design was based on interprofessional workplace learning principles. Consultation skills, clinical reasoning skills, and interprofessional collaboration skills need to be trained in actual clinical practice.[3] In designing our program in close collaboration with GPs and, especially at the beginning of the program, getting them involved in the development of the new program, provided the GPs with the opportunity to become more familiar with the role of clinical pharmacists. A challenging aspect of our program was the lack of role models in the workplace. This arose from the fact that the clinical pharmacists were the first cohort located within general practices in the Netherlands. As a result, they had to define and create their role in the practice, in close collaboration with the other healthcare professionals. The processes of alignment associated with a new role caused tensions that could be considered unique learning opportunities.[37] To this end, the group supervisors explicitly addressed role expansion and innovation in healthcare during the peer group meetings.

A further challenge was that only one supervisor within the program was a clinical pharmacist herself because the role of the clinical pharmacist is extremely rare in the Netherlands. The supervisors within the general practice were able to discuss patient-

centered communication and clinical reasoning with the pharmacists, but they could not give feedback on clinical pharmacy competencies. In our program, we provided this feedback during the classroom meetings and individual consultations with the one clinical pharmacist who was involved. In future, we expect that this challenge will diminish given that the participants who had the opportunity to continue working as a clinical pharmacist (n=5) could be a role model for future participants.

A limitation of our paper is its focus on the Dutch healthcare system, where the integration of the clinical pharmacist in the primary care setting is in an infant stage. However, based on our knowledge about other educational programs elsewhere, we consider the didactic design of our course to be relevant in other countries as well.

SUMMARY

We consider the design of the training program for clinical pharmacists to be relevant for others because it is typically designed for the general practice setting and it is grounded in educational theory. At present, an updated version of the program is being planned in which more than ten participants will be trained. This will allow for more quantitative evaluation measures. The creation of job opportunities for graduates is a future consideration, given that the role is still new and relatively unknown within the Netherlands. Participants found the program beneficial for their future role as clinical pharmacist. A novel design based on principles derived from the theory of workplace learning seems to be a useful method to prepare pharmacists better for their new role within general practice, which is expected to improve patient care.

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3.2

Learning through boundary crossing: professional identity formation of clinical pharmacists in general practice

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ABSTRACT

Purpose

To unravel boundary crossing as it relates to developing professional identity formation in pharmacists transitioning from a community pharmacy to working as non-dispensing clinical pharmacists in general practice, with the aim of optimizing their education.

Method

A multiple case study, including interviews, peer feedback and individual reflection, that collected data from eight clinical pharmacists working in general practice. These pharmacists acted – without a role model in the workplace – as pharmaceutical care providers in general practices during a 15-month training program. In within-case and cross-case analysis, data were examined through the lens of professional identity formation and boundary crossing.

Results

Analysis of data collected during and after the training program revealed that the clinical pharmacists who applied the learning mechanisms of reflection and transformation developed a strong, patient care-oriented professional identity. Some clinical pharmacists, who learned mainly through the mechanism of identification, did not integrate the new role into their professional identity. They felt that their workplace provided limited opportunities for reflection and transformation. Learning with peers on formal training days was seen as highly valuable for developing a professional identity formation; it counterbalanced the lack of a role model in the workplace.

Conclusions

This is the first study to explore professional identity formation in the transition from community pharmacist to clinical pharmacist in general practice. Reflective, on-the-job training, permitting transformative, boundary-crossing learning with peers, supports the development of a professional identity formation that is oriented to the provision of practice-based pharmaceutical care.

INTRODUCTION

Professional identity formation is essential in the education of health professionals.[1] A strong professional identity empowers individuals to act confidently[2] and is associated with career commitment and workplace satisfaction.[2,3] Professional identity formation should be an educational goal for the health professions, a view that is reflected by the recommendation to amend Miller's learning pyramid with "being" as the highest level of aspiration.[1,4,5]

Ample literature highlights the importance of professional identity formation in physicians,[2–4,6,7] but there are hardly any studies on pharmacists.[8] Earlier research deals primarily with their roles.[9–12] However, knowledge about professional identity formation in pharmacists is timely, given their transition from being dispensers of pharmaceuticals to clinical pharmaceutical care providers. Especially relevant in this context is to study identity formation in clinical pharmacists who are training in settings where no role models are in place. Such was the case in this study, where clinical pharmacists were trained in general practice teams of physicians and nurses delivering primary medical and preventive care in the community. The presence of a role model has been identified as a key facilitator in the process of professional identity formation.[8,13]

We define professional identity as the individual thinking, acting and feeling like a clinical pharmacist. It relates to what they find important and what they are enthusiastic or get upset about.[4,14] During the process of professional identity formation, clinical pharmacists seek to integrate their various new roles and diverse experiences into a coherent self-image.[7] The transition involves learning through boundary crossing so that individuals learn how to make experiences meaningful.[15] Learning through boundary crossing occurs when the professional works together with other professionals who differ in norms, views, beliefs and manners.[16] Boundaries can be perceived as barriers, leading to a discontinuity in (inter)action, but also as opportunities for learning and drivers for change and development in the ongoing process of identity formation.[17]

In this study, we evaluated the learning process of ten traditionally trained pharmacists in the Netherlands who participated in a 15-month training program, which alternated between formal training in the classroom and workplace learning. In this practice-based training program the pharmacists lacked a role model in the workplace, but the learning concept provided opportunities for learning across boundaries. To unravel professional identity formation, we adopted four learning mechanisms:[17] *identification* is the awareness of the differences between the current practice of general practitioners (GPs) and community pharmacists and can lead to defining the new practice of the clinical pharmacist in primary care. The learning potential of *reflection* resides in the possibility to learn through the eyes of others and can lead to an expanded set of perspectives or adjusted behavior. *Transformation* is a fundamental change in the way of thinking or acting and can result in a new and integrated practice. *Coordination* is aimed at aligning with the GP and can result in the development of procedure and routines, such as adjusted communication between the clinical pharmacist and the GP.

It is important to understand how clinical pharmacists develop their professional identity through crossing the boundary in interaction with GPs. Increased understanding will help to optimize the training program. In addition, changes in the Dutch healthcare system have created many new roles, such as physician assistant and nurse practitioner,[18] who also need to work in settings without existing role models. Better understanding of how to integrate new roles into professional identities in such settings may enhance the performance of new professionals.[19]

METHOD

Study design

Since our research was exploratory and observational we took a multiple case study approach,[20] which allowed us to assess each clinical pharmacist in great detail. We obtained ethical approval from the national educational review board, and all participants provided their written consent.

Setting and participants

The study took place during a new Clinical Pharmacy Training Program designed as a mix of workplace learning and formal classroom sessions. [21] Ten clinical pharmacists (trainees) participated in the 15-month program. Since one pharmacist withdrew from the program and one trainee was also the principal researcher of this study, we included data from only eight participants. These participants, two male and six female, aged 24–39 years, had previously worked in community pharmacy for 1–12 years. During the training program, they all worked in general practice and took integral responsibility for medication therapy management. They were the first fully integrated primary care clinical pharmacists in the Netherlands.

Data collection

We collected data throughout the training program. Following the organizing principles of the multiple case study we collected four data sources for each participant: 1) a transcript of a semi-structured interview, conducted within the first three months of the program (March–May 2014); 2) reports of weekly peer feedback sessions (PFS report); 3) individual reports reflecting on competency development in months 4, 10 and 15 of the program; and 4) a transcript of a semi-structured interview conducted one year after the program ended (Feb–May 2016). These data sources were analyzed through the lens of professional identity (inductive approach) and boundary crossing (deductive approach).

Both face-to-face interviews used a semi-structured format to allow for open exploration of predefined themes. [22] (See Appendices 1 and 2 for the interview guides). The interviews lasted 45–60 minutes. The first round of interviews was conducted by a physician or a sixth-year medical student (LB, TL). We asked participants to reflect upon the development of

their professional identity and their perceptions of their learning processes (e.g. during the formal training days).

The first round of interviews were evaluative, aimed at improving the design of the training program. In the second round we were looking for in-depth knowledge about professional identity and therefore the psychologist-supervisor of the training group (SV), who had been involved in both supervising the weekly peer sessions and consultation training, conducted the interviews. An experienced interviewer, the psychologist had a well-established relationship with the participants and created a safe environment that permitted thorough exploration.

We used 'video-stimulated recall' (VSR) to facilitate reflection on the topics.[23] For each participant, 4–8 video recordings of patient case discussions with their GP were available. Two researchers (SV, EdG) independently selected discussion fragments from these video recordings throughout the training period. The selected fragments contained boundary-crossing conversations about, for example, conflicting perspectives on patient treatment, task reallocation and changing responsibilities. The final selection of fragments was made in consensus with a third researcher (AH). On average, three video fragments per participant were played during the interviews, which were audiotaped and transcribed verbatim.

Data analysis

We coded the data within the analytical framework of professional identity and boundary crossing,[7,15,17,24,25] allowing both inductive and deductive approaches, and tailored descriptions to the context. We used the codes 'identification', 'coordination', 'reflection' and 'transformation' to identify the participant's learning mechanisms (see Table 1). We explored how boundary-crossing experiences explained the participants' professional identity formation. After (re)reading the data, we identified episodes in which the participants used value-laden terms that reflected how they felt about their experiences in general practice. These episodes contained five characteristics that qualified their professional identity, namely 'anticipator', 'broker', 'clinician', 'expert' and 'professional' (see Table 2). Fragments were coded when the participants mentioned the importance of being an anticipator, broker, clinician, expert, or professional, rather than performing a specific role.

Two researchers (AH, EdG), each with a different professional background, independently coded the first two transcripts. An analytical framework was developed in iterative meetings to compare and define codes. Given the likely influence of the training program on professional identity formation of the participants, we coded the data for perceptions of both workplace and training program.

One researcher (AH) applied the analytical framework to the entire data set using a qualitative data analysis software program (NVivo, version 11,QSR International). To enable within-case and cross-case synthesis[26] we organized the data for each participant and for each theme in a framework matrix. We performed investigator triangulation;

investigators from different disciplines (pharmaceutical, educational and medical sciences) analyzed the data (AH, EdG, DZ).

We maintained a detailed audit trail, including notes from team meetings, any adjustments to coding definitions and serial versions of the coded data. An external evaluator (SM) assessed the quality of the research by auditing the visibility, comprehensibility and acceptability of the data and decisions made during the process. [27]

RESULTS

We collected a total of 45 data sources. From those we coded data referring to professional identity (418 data points), boundary-crossing learning mechanisms (355 data points), perceptions of the workplace (226 data points) and perceptions of the training days (118 data points). Tables 1 and 2 provide an overview of the definitions used, with sample quotations. Below we describe the themes and provide further representative extracts. To each quote, we added an indicator for each clinical pharmacist (CP1–CP8) and followed this by denoting the data source (I1, I2, CR and PFS report) to indicate the data from the first interview, the second interview, the competency report and the peer session report, respectively.

Boundary-crossing learning to integrate roles into professional identity

We found that five participants (out of eight) who were able to learn through reflection and transformation developed a strong professional identity. Becoming aware of the GP's perspective enabled the clinical pharmacists to develop their clinical reasoning and take on a patient-centered approach (clinician), to efficiently apply knowledge about pharmacotherapy and pharmacology (expert) and to take responsibility for the pharmacotherapy of the individual patient (professional). They seemed to have integrated their new clinical role in such way that it became a structural part of their thinking and reasoning. We found that these participants strongly emphasized being patient-centered. As one participant said: *"Patient consultations are so gratifying. Like [one I had] yesterday [with] a woman who felt misunderstood by her family, friends and caregivers. She wanted to cut down her opiate use. I could help her by asking questions and giving advice. That made her so happy. It was great to see."* [CP8–I1] Two of the five clinical pharmacists who were able to learn through reflection and transformation also developed the professional identity of a broker, expressed by their drive to improve patient care through bridging the differences between the general practice and community pharmacy. One pharmacist developed the professional identity of an anticipator, since being pro-active was considered "*an essential part of my professional identity as a clinical pharmacist*". [CP5–I2].

The learning potential of shifting from the community pharmacy context to the general practice context is clearly voiced by one of the clinical pharmacists: "*We never learned or saw what a drug actually does to a patient because the GP always did that part.*" [CP3–I2] For one participant, working in general practice transformed her as a professional: "*I'm*

really not like you [community pharmacists] *anymore*." [CP3–I1] For example, relating how she had discussed a patient's case with a community pharmacist, she explained: *"She* [community pharmacist] *totally ignored the patient's demand for care. I mean, you're the one dealing with the patient, so how can you give that advice?*" [CP3–PFS report] This illustrates her profound change into becoming a patient care-oriented professional.

Table 1. Boundary-crossing learning mechanisms: definitions and quotes, based on Akkerman et al.[17]

	Definition	Quote
Identification	The participant defines and is aware of differences between their practice and the practice of the GP or community pharmacist, which leads to the demarcation of practices and legitimating coexistence.	*My point was that no one should be afraid that a clinical pharmacist would take on the GP's job, since a clinical pharmacist would not feel comfortable in that role. [*CP1–I2]
Coordination	The participant describes how to overcome the boundary and align themselves with the GP. For example, by talking about the connections and trying to improve the structure of inter-professional collaboration, setting procedures or routines to implement the new activities of the clinical pharmacist.	*... during the learning process I began talking more like a GP – presenting information far more compactly, just the information I need, followed by a recommendation.* [CP4–I2]
Reflection	The participant explicates a new, broader set of views by including the perspectives of the GPs and community pharmacists.	*GPs look at it differently. I was used to focusing on the medication side of things while they think mainly about the diagnosis, the patient's complaint. So my way of thinking really changed. I began thinking in terms of the complaint and tried to help patients like that. And since I had daily talks with the GPs, I heard their way of reasoning. That was how I learned clinical reasoning.* [CP6-I2]
Transformation	The participant describes a fundamental change in their way of thinking or acting and develops a clear vision of the new practice, which then gets embedded in the general practice.	*The fact that I am a real part of the team, that I know how to talk with patients and how to coach them, that I've found a working mode for general practice.* [CP8–I2]

Table 2. Professional identity: definitions and quotes

Professional identity	Definition	Quote
Clinician	Patient-centeredness; providing clinical care to patients, or being concerned about the impact of medication on a patient's health.	*I ask lots of questions and the patients answer sweetly but that doesn't mean you really know what they really want. That's an active process, something you do together with the patient and I really had to learn to double check that. [...] What does the patient find most important? You won't find the answer to that in the medication lists or in the GP's medical record.* [CP7-I2]
Expert	Being knowledgeable about clinical pharmacology and pharmacotherapy.	*I am showing off my expertise, sort of taking charge of my position – this is my domain, this is what I know about, so here my view counts for something.* [CP5–I2]
Professional	Feeling responsible for the patients' pharmacotherapy and capable of making decisions independently.	*[Becoming aware of the GP's domain and my own domain] went hand in hand with the increase in responsibility, or at least the increase in responsibility that I felt. As a clinical pharmacist you are always responsible for the patient, even when only dispensing. But during the study we made recommendations for pharmacotherapy, we didn't just suggest it to the GP but carried it out too.* [CP7–I2].
Anticipator	Being pro–active, which involves signaling and anticipating medication safety problems that might otherwise go unnoticed or might lead to harm in future.	*I provide pro-active care. And that is an essential part of my work, of that identity. […] In the general practice where I work, it is assumed that the assumption is that if a patient has a complaint, they will see the GP and the GP will respond. Meanwhile, I see patients who have no idea that they even have a problem, or maybe they do know but haven't yet gone to the GP.* [CP5–I2]
Broker	Being an intermediary to improve patient care or care processes, for example between GP and community pharmacist.	*Community pharmacists also acknowledge the added value of my work. Our tasks are extensions and complete each other. I try to build bridges and improve the collaboration between general practice and community pharmacy. An essential part of that is learning about and understanding each other's work.* [CP3–competency report]

Role playing

The other three participants learned mainly through identification – merely defining the differences between their personal context and the context of the GP or community pharmacist – and did not demonstrate learning through reflection or transformation. Our data suggest that these three did not develop a strong professional identity as a clinician, but mainly acted the part. For example, one pharmacist described patient encounters in clinical practice as: "*Patient consultations take a long time, they're exhausting and don't lead to concrete action.*" [CP1–PFS report]. This pharmacist added: "*Patient care is not what drives me. I feel that it compromises the quality of my work. I'm less enthusiastic, less connected to the group* [peers]. *[…] However, last week was fine. I could do a lot of minor medication interventions. That felt good.*" [CP4–PFS report]. The focus seemed to be on *doing*, i.e. changing medication in individual patients, rather than on *being*, i.e. behavior arising from a sincere natural interest in the individual patient.

Role playing vs. professional identity: perception of the workplace

Three participants, who experienced limited learning potential across the boundaries in terms of reflection and transformation and mainly acted their roles, perceived their workplace as unsupportive and had problems demarcating their professional domains and the level of responsibility and independency. One participant explained: "*The GP is also actively engaged in pharmacotherapy. He likes to be in control. I find that difficult.*" [CP2–PFS report] This pharmacist felt that the GP did not want to share the responsibility for the patients' pharmacotherapy and was of the opinion that the pharmacist was "*overstepping her authority*" [CP4–PFS report]. Consequently, the pharmacist tried to align better with the GP by discussing this issue and making arrangements to constructively improve collaboration. Given that the clinical pharmacist focused on coordination during her work in the general practice, this seemed to limit the learning potential of crossing the boundary in terms of reflection and transformation.

The five clinical pharmacists with clear (re)shaping of their professional identity experienced their workplace as supportive, and potential interference from the domains of either profession did not lead to significant conflict. They felt the GPs were open to critical reflection and dialogue and therefore did not use coordination to solve conflicts, but to structurally improve the inter-professional collaboration, applying patient-centered communication: "*An important point was to formulate pharmacotherapeutic advice for the GP. I've noticed that the consultations with the GP often provide a good structure for this. Sometimes, the GP appreciates additional patient information. I try to give this after I have given the advice and then I repeat the recommendation.*" [CP3–competency report]. They also coordinated to creating procedures and routines to clarify tasks and responsibilities: "So *I started a project to monitor and – if possible – stop the chronic use of gastroprotective medication. I deliberately screened the first eligible patients together with the GP to figure out my tasks and responsibilities in this project. First of all, I selected the patient.and then we*

discussed who would do the patient consultations. And [then I asked the GP] if I do it, shall I reduce the dosage or will you do it?. And shall I do the follow-up, or will you?" [CP5-I2]

Role playing vs. professional identity: perception of the formal training

All participants regarded formal training – a combination of feedback sessions and training in consultations and clinical reasoning with their group of peers – as relevant to their professional identity formation, particularly in relation to their identity as a professional clinician. One clinical pharmacist stated: "*If I hadn't had the training and you'd put me in this general practice here as a community pharmacist, I wouldn't have been any good at establishing the relationship you need with patients to contribute to their pharmacotherapy*." [CP5PH–I2] Concerning the identity of a professional, another clinical pharmacist explained: "*The biggest development was [learning] to cope with feeling responsible for the patient. [I think] reflection in the peer feedback sessions was a prerequisite to learning. It's important to focus on certain processes that you go through and the feedback sessions forced you to put them into words*." [CP7–I2].

Since the clinical pharmacists were pioneers in the provision of pharmaceutical care in Dutch general practices, they had no role model to follow as their example. One participant said: "What *I find hard is that you have come up with it all on your own, you really have to be your own driving force. […] I find that hard to do alone*." [CP7–PFS report]. They felt that the formal training days compensated for the lack of a role model. One participant stated: "*The training was a great help to get me through the day. It gave me the handhold I needed to do things. And if I hadn't had that, then I would have felt that I had to do it all by myself. Besides , you wouldn't have heard things from your colleagues [other clinical pharmacists], and yes, I'd have found that really hard. I don't know what would have happened then*." [CP6–I1]

The cross-case analysis led us to conclude that the impact of the formal training days on professional identity formation is of great value, particularly for participants who encountered a less cooperative workplace. When the opportunity to learn across boundaries in the workplace is perceived to be limited, formal training days seems essential for learning about professional identity.

DISCUSSION

Analyzing the experience of participants in a training program for general practice-based clinical pharmacists in the Netherlands, we identified boundary-crossing learning mechanisms necessary for professional identity formation. We found that pharmacists who able to learn through *reflection* and *transformation* – both in the workplace and in their peer group – developed a strong multi-dimensional professional identity which includes such aspects as being a clinician, an expert, a professional, a broker and an anticipator. Pharmacists who learned mainly through *identification* and *coordination*, attempting to overcome frictions, developed less of a professional identity and performed the role of a clinician.

All participating pharmacists had to adopt the new clinical role and learn how to incorporate it in their identity. Through learning at the boundary, in interaction with GPs, they developed into patient-centered clinical care providers (clinician), anticipated on medication-related safety issues (anticipator), took responsibility for the patient's pharmacotherapy (professional) and built bridges between general practice and community pharmacy (broker). They were all knowledgeable about clinical pharmacology and pharmacotherapy (expert). Some clinical pharmacists were able to incorporate the new roles into their identity, others were not. Incorporating a new role into identity is challenging[28] as professionals are emotionally attached to a role, seeing it as 'part of who they are'.[29,30] Our data suggest that some participants became more emotionally attached to their new role and were better able to integrate it in their professional identity.

To explain this result we first looked into the concept of *identity dissonance:* 'Integrating new professional identities is an easy process for people whose personal identities are consonant with their new professional role, but traumatic for those whose personal identities are dissonant with it'.[2] Likewise, we hypothesized that professional identity formation is easier for participants whose professional identity is already aligned with that of the clinical pharmacist. In our study, the participants varied strongly in amount of work experience. Some had already developed a strong identity in their previous jobs in community pharmacy. In contrast to what might be expected from the concept of identity dissonance, the participants with more experience in community pharmacy did not have more problems in adopting their new role compared to those who had recently obtained their pharmacy degree. Therefore, identity dissonance alone does not explain the differences.

Another possible explanation for the degree of role integration and professional identity formation is the direct work environment.[14] The workplace can be a constraining factor when it is perceived as competitive, lacking in trust or when the new roles for the clinical pharmacists are not valued or accepted. A general practice which values and accepts the new roles for the clinical pharmacist probably enhances the process of role incorporation.[28] Our study shows that trainees experienced difficulties in role integration if they perceived their workplace as unsupportive and there were disagreements about the demarcations of their professional domain. The clinical pharmacists who did not manage to cope with these disagreements more or less role-played in their daily practice. However, those who were able to align with the GP to overcome the professional boundaries (learning mechanism *coordination*) began working from a new professional identity.

Another relevant aspect of the study concerns learning in settings without a role model. Since the wider literature on professional identity of physicians highlights the importance of socialization and role modelling, we expected that it could be challenging for clinical pharmacists to develop their professional identity in general practice without a role model present.[5,31–33] Innovative settings with no role models present limit opportunities for learning through socialization. Our results suggest that the professional identity of the clinical pharmacists develops in part through socialization with GPs, most notably

the aspect of being a clinician. However, to develop a new multi-dimensional identity, peer feedback and reflective discussions with of peers are also important. The learning mechanisms of boundary crossing stress the horizontal dimension of learning occurring in groups of peers and might be specifically relevant to participants who experience their workplace as unsupportive.[24] In the current era of healthcare transformation and emerging new roles, an experiential training design that allows professionals to learn in dialogue with peers and other health care professionals may secure the learning process.

This study has limitations. During the interviews, we asked participants about their perspectives and behaviour in specific situations and professional identity formation. The concept of professional identity might be prone to different interpretations between the participants. Nevertheless, in the safe interview environment the participants were able to ask questions in return to clarify the concept if needed. Also, the principal researcher (AH) participated in the training program and had previous work experience in community pharmacy. To prevent us from projecting our own experiences on the interpretation of the data, we had regular meetings with the study team and openly discussed and challenged our researchers' perspectives and assumptions. Furthermore, the perspective of the principal researcher contributed to practice-relevant interpretations of the findings. Also, identities are not fixed or static, neither a single construct.[4,13] They are subject to a constant process of transformation and considered a combination of multiple personal and social identities.[13] Hence, the findings of our study should not be considered definitive, but should be seen as a continuing process of (re)shaping of identity. Finally, our study is strongly bound to the Dutch context, where clinical pharmacists working in general practice is a new profession.

In conclusion, this study unravels the learning mechanisms involved in developing professional identity in clinical pharmacists. Pharmacists who make the transition from community pharmacy to general practice need to develop a strong professional identity as a patient-focused, clinical pharmaceutical care provider. A training program that provides opportunities for reflective and transformative learning – both in the workplace and among peers – contributes to professional identity formation.

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APPENDIX 1

Interview guide interview 1

Expectations of the workplace and formal training program

- What were your expectations of the function when you started?
- What did you hope for?
- What were the things you thought that would be easy or difficult in practice?
- Did or do you have any doubts?
- What do you expect to learn during the formal training program?
- What do you think you will do differently at the end of formal training program?

First experiences at the workplace and formal training program

- What are your experiences at the workplace so far?
- What do you like best/least?
- What do you find easy/hard?
- What are your thoughts about the patient consultations? What do you find difficult/easy?
- What are your experiences of the training program so far?
- Can you describe a strength and a limitation of the training program?
- What can be improved in the training program?

Perception and ideas of the new function

- What is for you the added value of your work in general practice?
- Which qualities are required to function effectively as a clinical pharmacist in general practice?
- How do you perceive your new role compared to the GP?
- What are the differences between your work in general practice and community pharmacy?
- How do you think this function will develop in future?
- What are the (dis)advantages of working as a clinical pharmacist in general practice?

Impact of formal training program on performance in practice

- What effect does the training program have on your performance and behavior in the general practice?
- How does the training program contribute to the quality of care in the general practice?
- What do you think that would have happened if you would had not participated in the formal training program? What do you think went wrong/right?

APPENDIX 2

Interview guide video stimulated recall interview (interview 2)

Questions related to each video fragment

- Considering your professional identity, what happens in this video fragment?
- What do you notice? Also related to your (non) verbal communication with the GP?
- How do you consider your performance in this fragment?
- How is that different compared to your way of acting as a community pharmacist?
- How did your performance develop during the period that you worked in the general practice?

Learning at the boundary

- What did you need from the GP to successfully fulfill your new function in practice?
- How did the interaction with the GP contributed to your professional identity development?
- How did other (learning)activities contribute to your professional identity development?

Professional identity

- What is for you essential of your professional identity as a clinical pharmacist in general practice?
- How is this different compared to your previous work as a community pharmacist?
- How do you introduce yourself to others?
- If you had to grade the development of your professional identity during this training program, what grade would you give? Why?

Chapter 4

CLINICAL EFFECTIVENESS

4.1

Design of the POINT study: Pharmacotherapy Optimisation through Integration of a Non-dispensing pharmacist in a primary care Team (POINT)

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ABSTRACT

Background

In the Netherlands, 5.6% of acute hospital admissions are medication-related. Almost half of these admissions are potentially preventable. Reviewing medication in patients at risk in primary care might prevent these hospital admissions. At present, implementation of medication reviews in primary care is suboptimal: pharmacists lack access to patient information, pharmacists are short of clinical knowledge and skills, and working processes of pharmacists (focus on dispensing) and general practitioners (focus on clinical practice) match poorly. Integration of the pharmacist in the primary health care team might improve pharmaceutical care outcomes.

Aim

To evaluate the effect of integration of a non-dispensing pharmacist in general practice on the safety of pharmacotherapy in the Netherlands.

Methods

The POINT study is a non-randomised controlled intervention study with pre-post comparison in an integrated primary care setting. We compare three different models of pharmaceutical care provision in primary care: 1) a non-dispensing pharmacist as an integral member of a primary care team, 2) a pharmacist in a community pharmacy with a predefined training in performing medication reviews and 3) a pharmacist in a community pharmacy (care as usual). In all models, GPs remain accountable for individual medication prescription. In the first model, ten non-dispensing clinical pharmacists are posted in ten primary care practices (including 5 – 10 000 patients each) for a period of 15 months. These non-dispensing pharmacists perform patient consultations, including medication reviews, and share responsibility for the pharmaceutical care provided in the practice. The two other groups consist of ten primary care practices with collaborating pharmacists. The main outcome measurement is the number of medication-related hospital admissions during follow-up. Secondary outcome measurements are potential medication errors, drug burden index and costs. Parallel to this study, a qualitative study is conducted to evaluate the feasibility of introducing a NDP in general practice.

Discussion

As the POINT study is a large-scale intervention study, it should provide evidence as to whether integration of a non-dispensing clinical pharmacist in primary care will result in safer pharmacotherapy. The qualitative study also generates knowledge on the optimal implementation of this model in primary care. Results are expected in 2016.

Trial registration number

NTR4389, The Netherlands National Trial Register, 07-01-2014.

BACKGROUND

Adverse drug events account for 5,6% of acute hospital admissions in the Netherlands. Almost half of these admissions are potentially preventable.[1] Older age, polypharmacy, multimorbidity, impaired cognition and impaired renal function have been identified as risk factors for these preventable medication-related hospital admissions (HARMs).[1] Given the ageing of the population, the population at risk will grow in near future. Hence, new strategies are needed to improve the effectiveness and safety of pharmacotherapy in clinical practice and to prevent these hospital admissions.

As most of the pharmacotherapy is initiated in general practice, its quality may be primarily improved by structural reviewing patients' medication in primary care. So far, the results of studies on the effectiveness of medication reviews have been inconclusive: several studies reported a positive effect on the number of drug therapy problems,[2–7] but no effect on morbidity, mortality or quality of life was found.

Several difficulties hamper the implementation of medication reviews in primary care[8–10] and may have contributed to the inconclusiveness of these results. First of all, as community pharmacists get no or an insufficient fee for performing medication reviews, a financial incentive is lacking. However, this does not seem to be the only problem. Another important difficulty in the implementation is the lack of information: community pharmacists do not have access to routine patient records. Consequently, performing proper medication reviews is often impeded, as not all available information can be taken into account. Third, pharmacists lack clinical pharmacology knowledge and clinical reasoning skills, for pharmaceutical training and practice are historically drug product oriented instead of patient oriented. Community pharmacists' tasks mainly concern the organisation and monitoring of logistic processes (e.g. dispensing the right medication in the right dose to the right patient); community pharmacists perform little to no direct pharmaceutical patient care. As a result, pharmacists have sparse experience in clinical pharmacotherapy. Fourth, in the present system pharmacists and general practitioners (GPs) have different responsibilities, backgrounds and working processes, resulting in inadequate collaboration.[11] Fifth, the present way of practicing of both GPs and pharmacists is mainly reactive,while the pharmaceutical care process requires a proactive approach. Finally, there is a misfit between time-consuming nature of performing medication reviews and the current workload of both GPs and pharmacists.

Implementation of a non-dispensing pharmacist (NDP) in primary care teams might address these implementation problems and improve outcomes of pharmaceutical care. The NDP – as a healthcare team member – would have access to patient records and the required clinical information. The lack of clinical knowledge and skills of the pharmacist could be overcome by a training in clinical pharmacy. Collaboration with the GP is expected to improve, because the NDP is positioned into the clinical practice and is a full member of the primary care team, with the GP as head of the team. Furthermore, as the NDP's scope alters from drug product oriented to patient oriented, the professional perspective

will collide better with that of the GP.[12,13] Finally, this change in scope relieves the NDP of his responsibility for the dispensing process, and enables the NDP to work fulltime on the improvement of pharmacotherapy.

This model of integrated pharmaceutical care has already been studied in Canada,[14,15] Australia[16] and the United States of America.[17] It was found that the model has the potential to address many of the barriers to effective pharmaceutical care in the ways described above, thereby optimising medication use and hence leading to better healthcare outcomes.[14,16] In Canada, physicians recognised many interprofessional benefits by working with a pharmacist directly integrated into their practice. Also, benefits of improved education were described.[14] The Australian study reported a significant reduction in medication-related problems after intervention by the pharmacists, and a significant improvement of adherence to the medication regimen.[16] In the USA, both GPs and patients perceived qualitative benefits from the pharmacotherapy consultations.[17]

However, the ultimate benefit of this model for patients, namely the prevention of HARMs, has not been demonstrated yet. Therefore, we designed the Pharmacotherapy Optimisation through Integration of a Non-dispensing pharmacist in a primary care Team (POINT) study, in which we assess, amongst others, the effect of a non-dispensing pharmacist on medication-related hospital admissions.

METHODS

Design

The POINT study is a non-randomised, controlled intervention study with pre-post comparison (see Table 1 for a time schedule of the POINT study). Three different models of pharmaceutical care provision in primary care will be compared:

- *Group A (intervention group)*: a GP practice with a non-dispensing pharmacist based in the practice as an integral member of the primary healthcare team;
- *Group B (control group 1)*: 'upgraded' care as usual: a GP practice collaborating with a dispensing pharmacist based in a community pharmacy in the traditional way, with the pharmacist having had a predefined, certified additional training in reviewing medication,
- *Group C (control group 2)*: care as usual: a GP practice collaborating with a dispensing pharmacist based in a community pharmacy in the traditional way.

A flowchart of the study design is shown in figure 1. Concurrently, a qualitative implementation study is performed. The protocol was peer-reviewed by the funding organisation.

Setting

The project is implemented within primary care practices from the Julius General Practitioners Network (University Medical Centre Utrecht) and the Academic Network of

Table 1. Time schedule of the POINT study

Period	Dates
Pre intervention period (1 year)	1st of January 2013 – 31st of December 2013
Start-up period, prior to intervention period (3 months)	1st of March 2014 – 31st of May 2014
Intervention period (1 year)	1st of June 2014 – 31st of May 2015

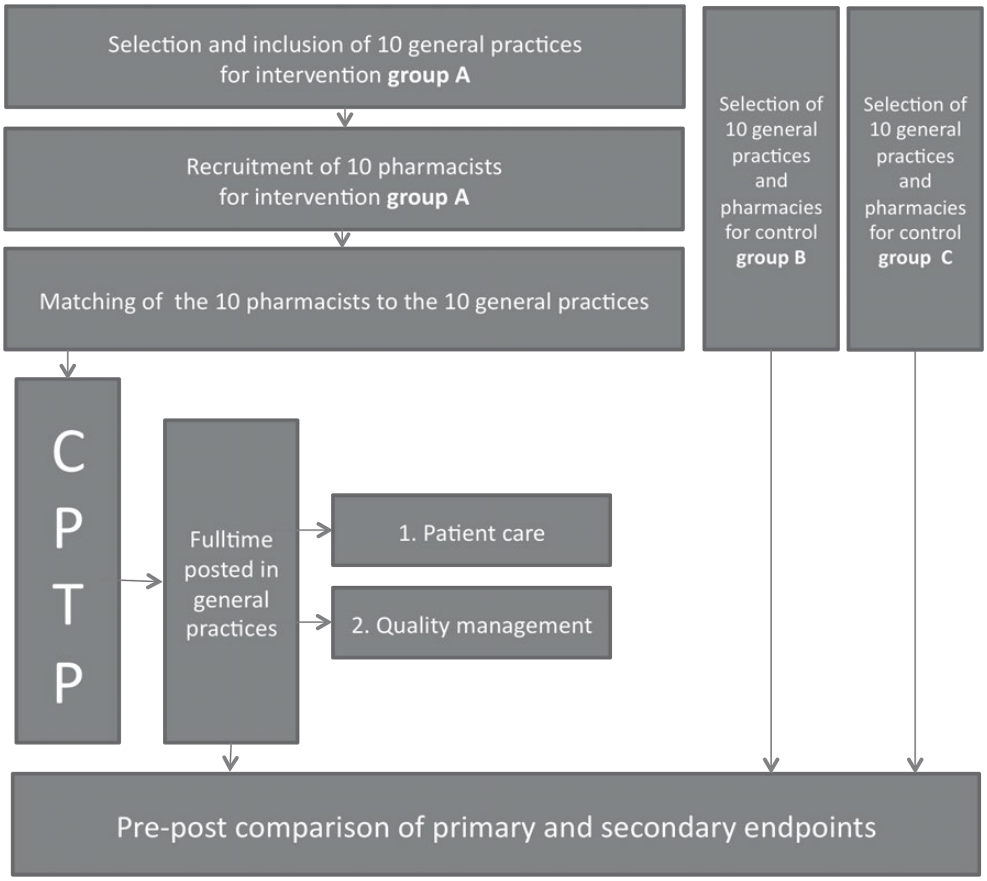

Figure 1. Flowchart of the study design. CPTP Clinical Pharmacy Training Program (newly developed for the intervention)

General Practitioners (VU University Medical Centre Amsterdam). These networks consist of more than 200 collaborating general practices.

Group A: selecting GPs, non-dispensing pharmacists and matching both

General practices from the above mentioned networks are all pro-actively invited to participate in the POINT study. Ten general practices are selected, based on the following

criteria: willingness of the GPs to participate in the project; willingness of the GPs to cooperate in the development and evaluation of the role of the NDP; minimum of 5000 registered patients; availability of an office for a NDP, with access to the GP information system; minimum of one practice nurse working on disease management programs for chronic conditions such as chronic obstructive pulmonary disease, diabetes, cardiovascular disease or mental health; healthcare centre accredited by the Dutch College of General Practitioners (NHG).[18] The research collaboration is formalised in a collaboration agreement.

Ten non-dispensing pharmacists are employed, using a structured application procedure. All participating pharmacists have a master degree in pharmacy (PharmD) and preferably have working experience in providing pharmaceutical care to individual patients. Furthermore, in the selection procedure communication and collaboration skills, as well as pharmacotherapy knowledge, empathy, self-reflection skills and innovative attitude are emphasized.

Subsequently, each NDP is posted in one of the ten selected primary care centres in Utrecht or Amsterdam regions. The NDPs work full time and exclusively in the general practices, for a period of 15 months. The introduction of such a new role in a healthcare practice is complicated and faces a variety of challenges.[14] For example, pharmacists need to be trained to fulfil their new tasks, both pharmacists and GPs have to collaborate closely and GPs have to explore the complementary role of the NDP. Therefore, the first three months are used as a start-up period before actually starting the intervention period.

Group B and C: selecting GPs and collaborating pharmacists

For both group B and C, ten general practices and collaborating pharmacies are selected from the above-mentioned networks as well. Criteria for participation are comparable to those concerning the size of the practices, described for group A. In addition, characteristics of patients of practices in groups B and C were matched as far as possible with group A, considering age distribution and socioeconomic status. Subsequently, practices and collaborating pharmacies are assigned to group B or C, depending upon whether the collaborating pharmacists have completed a certified training program on performing medication reviews in the Netherlands,[19,20] or not, respectively. See Figure 2.

Intervention

To improve the safety of pharmacotherapy within the general practice, the intervention in group A by the NDPs aims at two levels: individual patient consultation and quality management on an organisational level. Herewith, the NDPs are responsible for the medication management and pharmaceutical care provided in the general practice. The NDPs perform complementary work and do not take over tasks of the GP nor the community pharmacist.

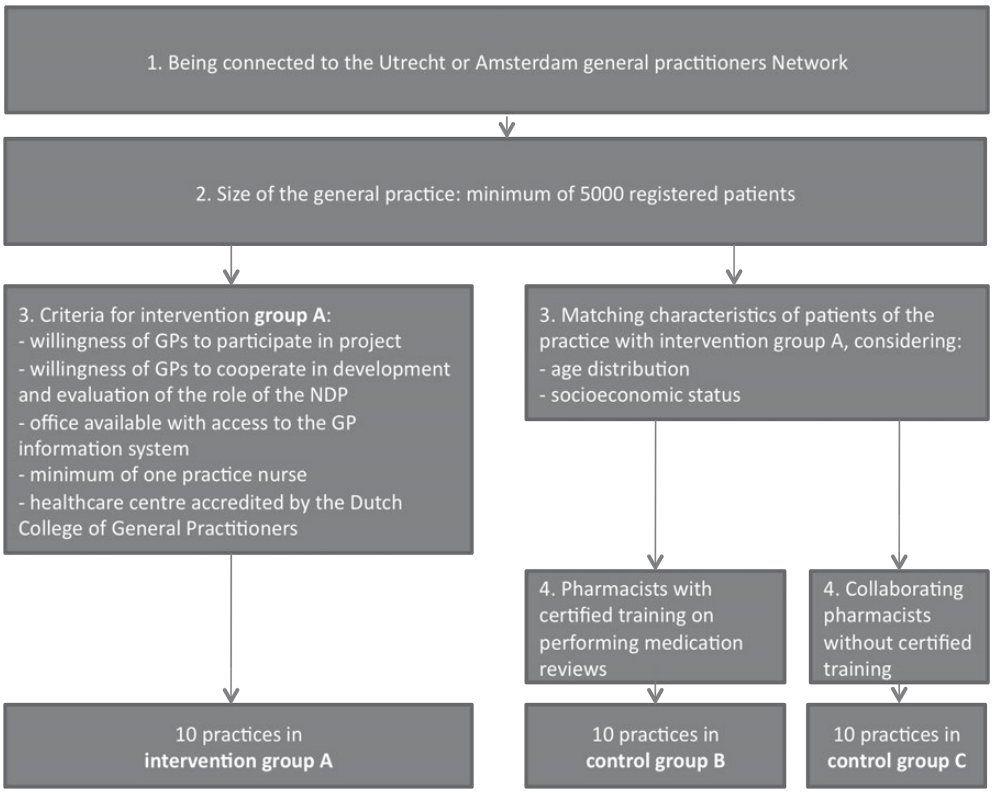

Figure 2. Overview of the selection criteria for general practices for group A, B and C

Individual patient consultation

The patient care process consists of an assessment of the patient's drug-related needs, a care plan to meet the specific needs of the patient, and a follow-up evaluation to determine the impact of the decisions made and actions taken. In practice, the NDP provides pharmaceutical patient care for patients who are considered to be at risk of adverse drug events, such as HARMs. These patients, mostly of older age, with mulitmorbidity and polypharmacy (chronic use of five or more medicines),[1] are either pro-actively invited by the NDP or referred by the GP to discuss and review their medication. Also, patients can make an appointment for a medication assessment at their own request. During the first consultation, which is preferably a home visit, the NDP will work on a therapeutic relationship and interviews the patient to gather information on the patient's experiences with and believes about medication, in order to assess his or her drug-related needs. Questions concern the goal of therapy for the patient, the current and past medication history, adherence to the medication regimen and patient reported medication issues. Afterwards, the NDP integrates the patient reported experiences and believes with the medical status to determine whether there are potential drug therapy problems. If necessary, the NDP

provides recommendations for optimisation of pharmacotherapy to the GP: suggestions to stop, start or switch medication, to adjust dosages, or for actions to improve adherence. These recommendations result in a documented individual pharmaceutical care plan, as part of the patient's medical record. The implementation of recommendations is monitored by the NDP. Follow-up contacts can be conducted as a home visit, a practice visit or by telephone.

Furthermore, the NDP covers other aspects of pharmaceutical patient care, such as individual consultations for specific drug therapy problems or questions, and medication reconciliation in patients discharged from hospital.

All patient level interventions involve ongoing on-location collaboration with the healthcare team – being GP, practice nurses, assistants and the community pharmacists. The NDP is available at the GP practice and has daily formal and informal meetings with the GP in order to establish individual pharmaceutical care plans and to report on plans in progress. All members of the healthcare team can easily approach the NDP with questions about medication and patients' pharmacotherapy.

Quality management

The NDP aims to improve medication safety on an organisational level, through optimisation of processes within the practice around repeat prescribing, clinical care paths, administrative efficiencies and identification of common medication errors. The NDP is looking for possible optimisation options in medication regimens, such as monitoring renal function and electrolytes with indicated pharmacotherapy, tapering the chronic use of protonpump inhibitors, and optimising antibiotic prescribing. Hereby, the NDP organises targeted programs to improve the quality of pharmaceutical care in the practice. Also, the NDP provides education of patients and professionals involved.

Training program group A

To train the NDPs for their new role, a specialised Clinical Pharmacy Training Program (CPTP) is developed, based on workplace learning and the Canadian Medical Education Directions for Specialists (CanMEDS) Roles.[21] The CPTP started with a six-day training workshop, an internship in a nursing home and assignments in practice. Pleanary education days are gradually decreased and days in the general practice gradually increased, ending with full time practice work with weekly education days at the university. Key elements of the training are consultation and communication skills, clinical reasoning, clinical pharmacotherapy and being reflective in practice. NDPs are trained to use a patient centred approach in providing care, instead of a drug product centred approach. Barriers to implementation are discussed and ongoing support is provided through structural intervision sessions and a mentorship and buddy program.[22]

Outcomes and measurements

Primary outcome: medication-related hospital admissions (HARMs)

The primary outcome is the number of medication-related hospital admissions (HARMs) in the high-risk population. HARMs are defined as hospitalisations related to adverse drug events. To identify these medication-related hospital admissions, two pharmacists with clinical experience will independently assess each hospitalisation that occurred in the study population during follow-up, using discharge information combined with the medical and medication history. They will assess the causal relationship between the suspected medicine and the reason for hospitalisation, according to an adjusted version of the algorithm by Kramer et al.[23] In this version, three questions need to be answered (in contrast to six questions in the original algorithm): whether the reason for admission is known to be an adverse event of the suspected medicine, whether alternative causes can explain the relationship between the suspected medicine and the adverse event, and whether a plausible time relationship exists between the adverse event and the start of medication administration (or the occurrence of the medication error). On the basis of the answers, causality is classified as "possible," "probable," or "unlikely." Cases with an assessment of unlikely will be excluded.

Secondary outcomes

Potential medication errors

The percentage of patients with potential medication errors will be measured.[24] These potential medication errors mainly concern prescription errors, such as under- and overprescribing and dosis errors. Other potential medication errors might be due to medication that is not or insufficiently effective, or to inadequate monitoring of the effects of the therapy. Also administration errors, such as non-adherence problems, will be measured as potential medication errors. A complete list of included potential medication errors can be found in Table 2.

Drug burden index

The drug burden index will be calculated for every patient. This drug burden index measures exposure to anticholinergic and sedative medication, and is associated with poorer physical and cognitive performance in older people.[25] Hence, the drug burden index can be seen as a proxy of drug therapy risk and medication safety.

Costs

A cost analysis will be performed, based upon reimbursement data from databases of a Dutch major health insurance company. Direct medical costs, such as for medication, hospital care, specialist care, diagnostic tests and other healthcare-related costs will be included.

Table 2. Overview of outcomes, measurements and data sources.

Outcomes	Measurement	Data sources
Primary outcome		
Frequency of HARMs	Number of HARMs	DL, MH, MED
Secondary outcomes		
Potential medication errors	% patients with:	
	· medication not indicated	MED/MR
	· underprescribing	MED/MR
	· dosing error (too low or too high)	MED/MR
	· therapeutic duplication medication	MED/MR
	· medication contra-indicated	MED/MR
	· drug-drug interactions	MED/MR
	· medication not effective	MED/MR
	· inadequately monitored therapy	MED/MR
	· administration errors (e.g. non-adherence)	MED/MR
Drug burden index	Drug burden of medications with sedative and/or anticholinergic effects	MR
Costs	Medication costs and healthcare-related costs	Database of insurance company

HARM Hospital Admission Related to Medication, DL Discharge Letter, MH Medical History (with ICPC codes for diagnoses), MED Medication records (including ATC code, dose and strength), MR Medical records (including laboratory markers and measurements such as blood pressure, pulse and body mass index)

Data collection

Data of all patients in groups A, B and C are accessible through the routine health care databases of the Julius General Practitioners Network (Utrecht) and the Academic Network of General Practitioners (Amsterdam). After the intervention period (see Table 1), key data will be extracted anonymously from the electronic medical records in the general practices of both the pre- and post-intervention period, through standard procedures and existing algorithms. These data (see Table 2) are combined with reimbursement data from the major healthcare insurance company in the Utrecht and Amsterdam region, obtaining 40-55% of the reimbursement data of the region. No data will be obtained directly from patients.

Confounding factors

To be able to control for possible confounding, characteristics of the involved general practices and pharmacies in each group will be collected, using a questionnaire. Additional information will be gathered about pharmaceutical care provision, the medication review protocol used, the setting of the pharmacy and the general practice, the collaboration between the pharmacy and the general practice and agreements on pharmaceutical care provision.

Analyses and statistical method

All primary and secondary outcomes will be compared in pre-post analyses and between groups comparisons will be conducted. Descriptive statistics will be calculated for the baseline characteristics according to data of the overall population in group A, B and C, as well as for the high-risk patients. The effect on the primary outcome will be tested with logistic multilevel analysis. The potential medication errors, drug burden index and costs will be tested with mixed effect models. Baseline characteristics can be integrated into the mixed effect models to control for confounding.

Sample size calculation

With an expected prevalence of 4,5% HARMs in 12 months within the high-risk population,[8] we expect an effect of 50 percent reduction of HARMs.[8] To show a statistically significant difference between the intervention group A and control group C, we include ten practices, with a total of 45.000 patients, in each group. As 6,4% of patients in an average GP practice is part of the high-risk elderly population,[26] this means that in each arm at least 2850 high-risk patients are included. This is based on an alpha of 0,05 and a power (1-beta) of 0,8.

Qualitative study

In order to assess the feasibility of introducing a NDP in general practice, parallel to the POINT study qualitative data hereon is systematically collected. Semi-structured interviews with participating GPs and NDPs are conducted, and their views are described.

Patients who are seen by a NDP are asked about their perceptions and experiences, using anonymised questionnaires. Hereby, conditions that hinder or facilitate the introduction of a NDP in general practice in the Netherlands may be identified.

Privacy and informed consent / Ethical approval

Based on the Dutch law for patient data protection, this study was exempt of formal medical-ethical approval by the Medical Ethical Committee University Medical Centre Utrecht. (METC protocol number 13-432C)

DISCUSSION

The POINT study aims to improve safety of pharmacotherapy in primary care, by introducing a non-dispensing pharmacist as a member of the primary care team in the Netherlands. This intervention aims to improve pharmaceutical care at both patient level and organisational level. Therefore, it may be more effective than a singular intervention, such as current medication reviews. A comparison will be made with two existing models of pharmaceutical care provision in primary care. This comparison will demonstrate whether the introduction of the NDP is more effective in improving the quality and safety of pharmacotherapy than existing care models.

Several methodological challenges were faced during the design of the POINT study.

Choice for the design

Despite the fact that a randomised controlled trial is the preferred design to evaluate the effect of an intervention, we thoughtfully chose to use a non-randomised model. In our opinion, willingness of all participating parties to improve pharmaceutical patient care is a key condition for the implementation of this intervention to succeed. This has been recognised before, during the implementation of a pharmacist in primary care in Canada.[14] Therefore, general practices participating in the intervention group of this study are selected instead of randomly allocated to one of three research arms.

This selection, of course, has disadvantages. Once proven effective, the broad implementation of this new function might be challenging because of the high standards we set for participating practices in this study. In addition, selection of motivated general practices might mask the effect of the intervention. As these practices are motivated to improve pharmaceutical care, standard pharmaceutical care might be better than average beforehand, leaving little room for improvement. By including pre-post analyses, we attempt to obviate this problem.

Composition of the intervention

The introduction of the NDP is considered a complex intervention. This is for intervening at different care levels, as well as for integrating a new professional into the primary

work processes, which requires redistribution of tasks and responsibilities around pharmacotherapeutic care. Although the tasks of the NDP are predefined, the actual implementation in the individual GP practices cannot be protocolled: in order to increase the likelihood of a successful implementation of the intervention, the intervention has to be aligned to the needs of each participating centre. Consequently, the actual implementation of the intervention itself may be heterogeneous. This can blur quantitative measurements. Therefore, parallel to this study, we conduct a qualitative study as described earlier. With this study, we will list facilitators and barriers to the implementation process, in order to assess the feasibility of introducing a NDP in a complex healthcare setting in daily practice.

Development of the clinical pharmacy training program

The clinical pharmacy training program (CPTP) has been newly developed for the POINT study and has neither been validated nor accredited. As the CPTP is developed by experts in the field of education, based on the theoretical frameworks of Vermunt, Kolb and Merrienboer[27–29] and as it is embedded in the department of vocational training for general practice, it is expected to be an adequate postgraduate training for the NDPs. Within the context of the POINT intervention study, the program is evaluated and attuned on a structural basis.

Choice of the primary outcome measurement

In the context of 'primum non nocere'[30] the prime aim of this study is to improve the safety of pharmacotherapy. Therefore, we chose reduction of medication-related hospital admissions (HARMs), being a severe adverse drug event, as primary outcome. This choice is, however, challenging in several aspects.

First, the incidence of HARMs in primary care is low. Although 5.6% of acute hospital admissions are related to medication,[1] this accounts for only about 3.4 medication-related hospital admissions per GP on a yearly basis – which means around 12-16 HARMs per participating practice in this study. In addition, we do have a limited follow-up period of only one year. However, our sample size calculation is based upon the occurrence of HARMs in a large group, so we expect this problem to be adequately addressed. Last, measuring HARMs is challenging for quite detailed data have to be obtained in order to determine HARMs. Causality assessments in the POINT study will be based upon information of discharge letters, which is limited information. However, using this amount of information to determine HARMs has been done before.[31] Also, we do have experience from previous studies[1,26] and will use a validated method to identify the primary outcome parameter.

Availability of data for secondary outcome measurements

To correctly measure and analyse the secondary outcomes, the required data need to be properly documented in the GPs' information systems. Due to the heterogeneous study setting we are dependent on the diverse working methods of the participating healthcare

providers. As this possible loss of information will show equally in each research arm, we expect this will not influence our study results.

The cost evaluation performed in this study will yield an insight in the direct medical costs of each model of pharmaceutical care provision in primary care. For this evaluation, a subgroup of patients will be analysed, as data of the insurance company will not be available for all patients. A full economic evaluation including a societal costs and economic modelling is outside the scope of this research project.

CONCLUSION

This study will provide information as to whether the integration of a non-dispensing pharmacist in primary care will improve medication safety compared to current care models.

Acknowledgements

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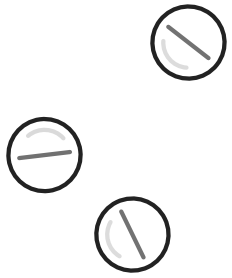
4.2

Non-dispensing pharmacists' actions and solutions of drug therapy problems among elderly polypharmacy patients in primary care



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ABSTRACT

Objective

This study aims to describe the number and type of drug therapy problems (DTPs) identified by non-dispensing pharmacists (NDPs) integrated in general practice, and the proportion of DTPs that they solved.

Method

An observational study, conducted in nine general practices in the Netherlands between June 2014 and June 2015. The NDPs conducted clinical medication reviews of elderly patients with polypharmacy (use of ≥ 5 chronic medications). On three pre-set dates, the NDPs collected data of the last ten patients who completed all stages of the clinical medication review. Outcomes were the type and number of DTPs, the extent to which recommendations were implemented and the percentage of DTPs that were eventually solved. Interventions were divided as either preventive (aimed at following prophylactic guidelines) or corrective (aimed at active patient problems).

Results

In total, 1292 DTPs were identified among 270 patients, with a median of 5 (IQR 3) DTPs per patient, mainly related to overtreatment (24%) and undertreatment (21%). The NDPs most frequently recommended to stop medication (31%). Overall, 83% of the proposed recommendations were implemented; 57% were preventive and 35% were corrective interventions (8% could not be assessed). Almost two third (64%) of the corrective interventions actually solved the DTP.

Conclusion

Non-dispensing pharmacists integrated in general practice identified a large number of DTPs, and successfully implemented a proportionally high number of recommendations that actually solved the majority of DTPs.

Key Points

- Non-dispensing pharmacists in general practice identify a high number of drug therapy problems;
- Non-dispensing pharmacists implement a very high proportion of recommendations aiming to solve these problems;
- Non-dispensing pharmacists actually solve a high proportion of drug therapy related problems.

INTRODUCTION

Drug therapy problems (DTPs), defined as an event or circumstance that actually or potentially interferes with an optimum outcome of medication therapy for a specific patient,[1] are associated with drug-related morbidity and mortality.[2–4] In the Netherlands in 2013, 48.779 acute hospitalizations of elderly patients were related to medication, of which half were potentially preventable.[5] Poor communication between health care professionals can contribute to DTPs, highlighting the need for better collaboration between general practitioners (GPs) and pharmacists to improve pharmaceutical care.[2,3,6]

Since most of the pharmacotherapy is either initiated or repeated in general practice, systematic implementation of clinical medication reviews in primary care is recommended to timely identify and solve DTPs.[7–9] A clinical medication review is defined as a structured critical assessment of the patient's medication by pharmacist, GP and the patient, aiming to optimize medication effect and to prevent adverse events.[8,10]

Although clinical medication reviews are demonstrated to be effective in identifying DTPs, there is conflicting evidence regarding their effectiveness to solve them.[9,11–15] This can partly be explained by the extensiveness of performed medication reviews, ranging from a superficial 'medication use review' to a full 'clinical medication review'[12] and partly by the relatively poor implementation of recommendations resulting from clinical medication reviews.[9,16–19] Several barriers have been identified for the low uptake of these recommendations, such as geographical distance between pharmacists and GPs, poor interprofessional communication and limited access for pharmacists to patients' medical records.[20]

Non-dispensing pharmacists (NDPs) integrated in general practice can help to overcome these barriers.[21] Various models with different levels of integrated pharmaceutical care have been studied in the United Kingdom,[22,23] North America[24–27] and Australia[28,29], showing that integration of an NDP generally increases the implementation rate of recommendations during the process of clinical medication review.[18,28] However, it is unknown whether the better uptake of these recommendations actually solve the DTPs. In a large multicenter study we studied the impact of NDPs on DTPs in primary care, aiming to evaluate the extent to which DTPs were detected and actually solved.

METHOD

Design

An observational study was conducted in the Netherlands between June 2014 and May 2015 at nine primary care practices with NDPs and GP's providing integrated care. The study was part of the POINT intervention study, which aimed to evaluate the effect of integration of NDPs in general practices on the quality and safety of pharmacotherapy.[30]

Setting and participants

The participating general practices were multidisciplinary health care centers in both urban and suburban settings, with five to nine (part-time) GPs employed and a total number of registered patients varying between 3700 and 11700 per general practice. Nine NDPs participated in this study; two male and seven female, aged between 24-39 years, all obtained their Pharmacy Degree at Dutch universities. Their work experience in community pharmacy varied between 1-12 years. The NDPs participated in a 15-month Clinical Pharmacy Training Program to advance their consultation and interprofessional collaboration skills. The design and findings of this training program are described elsewhere.[31] The NDPs had their own consultation room in the practice and had full access to the patient's medical record

Intervention: clinical medication reviews

The NDPs' main focus was conducting clinical medication reviews among patients considered to be at risk of adverse drug events: elderly patients (age ≥ 65 years) with polypharmacy (use of ≥ 5 chronic medications).

The medication review started with a semi-structured interview with the patient in which the NDP identified the patient's experiences, needs and concerns about medication. These were integrated with the medical records to determine potential DTPs. In the next step of the clinical medication review the NDP developed a pharmaceutical care plan in collaboration with the patient and the GP, including recommendations to stop, start or switch medication, to adjust dosages, or to improve adherence to medication. The recommendations were implemented and monitored, mainly by the NDP.

Data Collection

During three data collection weeks, in July 2014, December 2014 and May 2015, each of nine NDPs completed an online data form about the last ten patients who completed all stages of the clinical medication review (total 270 patients). The data form gathered detailed information about the type and number of DTPs, type of medication, the extent of implementation of the proposed recommendations and the number of DTPs that were solved. Recommendations were categorized in preventive interventions (aimed at following prophylactic guidelines) or corrective interventions (aimed at active patient problems, such as side effects) (Box 1). Also, information was collected about the reasons why recommendations were not implemented and about the number of follow-up consultations with the NDP required to implement recommendations. Data were coded based upon the Systematic Tool to Reduce Inappropriate Prescribing.[7] To ensure consistency and accuracy of coding, all data were manually checked by a research assistant and discrepancies were resolved by the principal investigator of this study (AH).

For the patients of data collection week two and three (n=180), the pharmaceutical care plan, patient's medical history, laboratory results and consultation notes from the patients'

electronic medical records were available for follow-up. This additional information was used to verify if DTPs were actually solved.

Outcomes

Outcomes were (1) the percentage of recommendations that were implemented and (2) the percentage and type of DTPs that were solved. Recommendations were marked into either preventive or corrective interventions. A recommendation was considered implemented when the GP endorsed the recommendation personally, or after approval by the NDP or practice nurse. A DTP was considered solved when an active problem no longer existed or when a potential problem was successfully anticipated on (Box 1).

Analyses

Analyses were performed using SPSS for Windows Version 21.0 to calculate baseline characteristics and outcomes on the number of DTPs, proposed recommendations, the extent of implemented recommendations and the extent of solved DTPs. Results were presented as means (with standard deviation, SD) and median (with interquartile range, IQR).

	PREVENTIVE INTERVENTION	CORRECTIVE INTERVENTION
Patient case	Patient, 73 years, with a history of atrial fibrillation and hypertension, CHADS-VASc score* 3, uses acetylsalicylic acid.	Patient, 81 years, uses metoprolol, has frequent nightmares.
DTP	Possible ineffective medication	Possible side effect
Recommendation	Switch of acetylsalicylic acid to vitamin K antagonist	Tapering the dose of metoprolol from 200mg to 100 mg, while monitoring blood pressure
Implemented	Yes	Yes
DTP solved	Yes: treated according to guidelines	Yes, nightmares disappeared

* The CHADS-VASc score is used to determine whether anticoagulant treatment is required.32
DTP Drug Therapy Problem

Box 1. Examples of preventive and corrective interventions

Ethical approval and patient confidentiality

The POINT project was exempted of formal medical-ethical approval by the Medical Ethical Committee University Medical Centre Utrecht (METC protocol number 13-432C). All data were anonymized by the NDP to protect patient's privacy.

RESULTS

The mean age of patients was 74 years and 61% was female. The median number of chronic medication and comorbidities was 8 (IQR 5) and 6 (IQR 3), respectively. The patients had a median of 2 follow up contacts with the NDP (IQR 2). (Table 1)

During the reviews 1292 DTPs were identified, with a median of 5 (IQR 3) per patient (mean 4.8). Overtreatment (24%), undertreatment (21%) and side effects (16%) were most frequently reported. Interaction and or contra-indication was only limited reported (2%). (Table 2)

The DTPs concerned 194 different drugs within 75 different drug classes.[33] The most frequently involved drug classes were proton-pump inhibitors (7%), lipid modifying agents (4%), vitamin D (4%), calcium (4%) and antithrombotic agents (4%). The most frequently involved medication in overtreatment were proton-pump inhibitors (19%), antithrombotic agents (6%) and diuretics (4%). Medication related to undertreatment were vitamin D (15%), calcium (15%) and lipid modifying agents (7%). Side effect were most frequently reported for lipid modifying agents (7%), beta blocking agents (7%) and ACE inhibitors (6%). (Table 3)

Table 1. Patient Demographics

	Patients (n=270)
Gender*, n (%)	
Male	70 (39)
Female	110 (61)
Unknown	90
Age, mean (SD)	74 (10)
Chronic medication,* median (IQR)	8 (5)
Comorbidities,* median (IQR)	6 (3)
Follow up contacts with NDP, median (IQR)	2 (2)
DTPs	
Median (IQR)	5 (3)
Mean (SD)	4.8 (1.9)
Range	1-12

* Based upon information from medical records and pharmaceutical care plan in data collection weeks two and three

n number, SD standard deviation, IQR interquartile range, DTP drug therapy problem, NDP non-dispensing pharmacist.

Table 2. Drug therapy problems

	N=1292 (%)
Overtreatment	309 (24)
Undertreatment	274 (21)
Side effect	213 (16)
Medication not effective	145 (11)
Sub-optimal medication use*	125 (10)
Additional monitoring required†	125 (10)
Incorrect dose	73 (6)
Interaction or contra-indication	28 (2)

* Including non-adherence, sub-optimal moment or way of taking medication, sub-optimal dosage-form of medication

† laboratory tests, routine physical examination, routine visits

Table 3. Medication related to the drug therapy problems

ATC-class	Medication related to all DTPs (n=1292)	N (%)†
A02B	Medication for peptic ulcer and GORD	91 (7)
C10A	Lipid modifying agents	57 (4)
A11C	Vitamin D	56 (4)
A12A	Calcium	53 (4)
B01A	Antithrombotic agents	45 (4)
	Medication related to overtreatment (n=308)	
A02B	Medication for peptic ulcer and GORD	58 (19)
B01A	Antithrombotic agents	18 (6)
C03C	High-ceiling diuretics	13 (4)
N06A	Antidepressants	12 (4)
N05C	Hypnotics and sedatives	9 (3)
	Medication related to undertreatment (n=274)	
A11C	Vitamin D	42 (15)
A12A	Calcium	40 (15)
C10A	Lipid modifying agents	19 (7)
N02B	Other analgesics and antipyretics	17 (6)
A02B	Medication for peptic ulcer and GORD	8 (3)
	Medication related to side effects (n=212)	
C10A	Lipid modifying agents	14 (7)
C07A	Beta blocking agents	14 (7)
C09A	ACE inhibitors	13 (6)
C08C	Selective Calcium channel blockers	12 (6)
N06A	Antidepressants	10 (5)

* Data on related medication is missing for 70 patients in data collection week one due to a technical error in the online questionnaire

† Percentages within the associated DTP category

ACE angiotensin Converted enzyme, ATC-class anatomical therapeutic chemical class,[33] DTP drug therapy problem, GORD gastro-oesophageal reflux disease

Stopping of medication (31%) was the most frequently proposed recommendation, followed by starting medication (17%) and switching to another medication (12%). In total, 83% of all recommendations were implemented by either the NDP (80%), GP (5%), practice nurse (3%), specialist (1%) or combined by different health care providers (11%). The main reason that prevented implementation of the recommendation was a rejection by the patient (40%), mainly related to the advice to stop the use of proton-pump inhibitors, antidepressants, anxiolytics or analgesics. (Table 4 and 5)

In total, in 78% of the DTPs the implementation of the recommendations actually solved the DTP. After stratifying the implemented recommendations (n=1070), we identified 601 preventive interventions (56%) in 259 patients. Almost all preventive interventions were considered solved (91%). We identified 382 corrective interventions (36%) in 182 patients. Sixty-four percent of the corrective interventions solved the patient problem. In 76% of patients (n=139), at least one patient problem was solved. Patient problems related to taking medication, for example due to swallowing issues, were most successfully solved (91%). Stopping medication to solve an active patient problem, such as a side-effect was successful in 40% of patients (Table 4). Due to a technical issue in the data forms, we had insufficient information of 87 implemented interventions (8%) to correctly stratify into either a preventive or corrective intervention.

DISCUSSION

This study shows that an NDP-led service actually solves the majority of identified DTPs. NDPs are very effective in performing medication reviews: not only do they identify a high number of problems but they also manage to solve DTPs through optimal implementation of their recommendations.

Earlier research of NDP-led services only reported proxy outcomes, such as the extent of implementation of proposed recommendations.[28,29] The results on implementation rates of recommendations are in line with those of earlier studies on clinical medication review performed by NDPs in primary care practice.[25,28,29,34] Most studies evaluating community pharmacist-led clinical medication reviews showed lower compliance rates with recommendations.[16–19,28,35,36] Improved collaboration between pharmacists and GPs, access to patient medical records and opportunities for face-to-face communication are possible explanations for the higher implementation rates in integrated primary care clinics.[18,28]

Overtreatment and undertreatment were - in line with previous studies - the most frequently identified DTPs, accounting for almost half of all DTPs (45%). [17,19,36–39] In other studies, non-adherence and drug selection problems were also frequently reported. [17,19,28,29,40] DTPs because of drug-drug or drug disease interactions were rare, which is probably a reflection of the widespread use of automated clinical risk management systems both in primary care and community pharmacy. [41]

Due to the high prevalence of overtreatment, we found a high rate of recommendations to stop medication. In other studies the need for additional therapy was the most common recommendation. [28,29,42] Inappropriate drug use and overdiagnosis is associated with

Table 4. Implementation of recommendations and drug therapy problems that were solved, stratified by preventive and corrective interventions

	Recommendation	Total, n (%)	Recommendation implemented, n (%)	DTP solved, n (%)
All interventions	Stop medication	407 (32)	318 (78)	237 (75)
	Start medication	224 (17)	189 (84)	177 (94)
	Switch medication	155 (12)	117 (75)	75 (64)
	Change medication use	96 (7)	90 (94)	76 (84)
	Adjust medication dose	163 (13)	129 (79)	101 (78)
	Advice/education	81 (6)	71 (88)	36 (51)
	Provide monitoring	136 (11)	126 (93)	104 (83)
	Refer to healthcare professional	30 (2)	30 (100)	24 (80)
	Total	1292 (100)*	1070 (83)	830 (78)+
Preventive interventions	Stop medication	270 (21)	212 (79)	198 (93)
	Start medication	177 (14)	150 (85)	148 (99)
	Switch medication	60 (5)	41 (68)	34 (83)
	Change medication use	22 (2)	18 (82)	14 (78)
	Adjust medication dose	87 (7)	69 (79)	67 (97)
	Advice/education	28 (2)	25 (89)	11 (44)
	Provide monitoring	88 (7)	79 (90)	71 (90)
	Refer to healthcare professional	7 (1)	7 (100)	5 (71)
	Total	739 (57)	601 (81)	548 (91)
Corrective interventions	Stop medication	122 (9)	94 (77)	38 (40)
	Start medication	42 (3)	36 (86)	28 (78)
	Switch medication	76 (6)	62 (82)	39 (63)
	Change medication use	59 (5)	57 (97)	52 (91)
	Adjust medication dose	59 (5)	46 (78)	24 (52)
	Advice/education	37 (3)	33 (89)	23 (70)
	Provide monitoring	34 (3)	33 (97)	22 (67)
	Refer to healthcare professional	21 (2)	21 (100)	18 (86)
	Total	450 (35)	382 (85)	244 (64)

* in 87 cases insufficient information to categorize the intervention into either preventive or corrective interventions
+ 11 DTPs were partially solved DTP Drug Therapy Problem

adverse drug events and acute hospitalization and has even resulted in the development of an evidence-based deprescribing process. [43,44] This reflects the current emphasis on deprescribing in primary care.

However, the process of deprescribing (i.e. to stop medication) should not be underestimated; it often needs extensive education and monitoring of the patient, taking into account the motivation, concerns and expectations of the patient. Also, intervening in the prescribing cascade requires a holistic approach, careful monitoring and tailored adjustments when necessary. An NDP, trained to consult patients and to make clinical sound decisions can fulfill this role.

Table 5. Reasons for not implementing recommendations

Reasons	N (%)
Patient disagreed	89 (40)
Consensus between GP, NDP and patient	41 (18)
GP disagreed	37 (17)
Specialist disagreed	15 (7)
Deliberate deviation by GP or specialist	19 (8)
DTP already solved	10 (5)
Practice nurse disagrees	3 (1)
Missing	10 (4)
Total	224

GP general practitioner, NDP non-dispensing pharmacist, DTP drug therapy problem

Although the majority of recommendations were implemented, patients sometimes did not follow the advice to stop medication. We identified anxiety as a main reason to decline a recommendation, particular related to medication that has an immediate effect, or because patients believe that drugs are essential for their well-being, such as antidepressants, anxiolytics, analgesics and proton-pump inhibitors. Patients were afraid to experience former symptoms after stopping the medication or were concerned about their health. These barriers need to be carefully addressed, for example during follow-up consultations.[45]

This study has limitations. First, the observational study design, which lacks a control group, may have compromised the validity of the conclusions and might limit extrapolation. Nevertheless, we think the multicenter study design, the random sampling of patients and the real-life setting allows for conclusions with a more than local impact. Second, the outcomes were primarily based upon self-report by the NDPs. This might have resulted in social desirable answers. However, the research team manually checked the self-reports with the patient's medication list and consultation notes from the patients' electronic medical records. Third, the extent to which DTPs were solved was mainly based upon patient's self-report. This often did not include validated tools, such as Visual Analogue Scaling to measure the intensity of pain across a continuum. With our data sources we were still able to assess whether the DTP was totally, partially or not solved.

CONCLUSIONS

Non-dispensing pharmacists in general practice are effective in the successful conduct of medication reviews among elderly patients at risk. Implementation of NDPs could substantially contribute to optimizing pharmacotherapy and drug safety.

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4.3

Effects of non-dispensing pharmacists integrated in general practice on medication-related hospitalisations: results of the POINT study

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ABSTRACT

Objective

To evaluate the effect of a non-dispensing pharmacist (NDP) integrated in general practice on medication-related hospitalisations.

Design

A multicentre pragmatic controlled intervention study with pre-post comparison (2013 versus June 2014 - May 2015) comparing NDP-led care (intervention) with two current models of pharmaceutical care delivery (usual care and usual care plus).

Setting

Twenty-five general practices in the Netherlands.

Participants

Patients at risk of medication problems, defined as being aged 65 years or older and using five or more chronic medications.

Intervention

Ten specially trained NDPs were employed in general practices to take integral responsibility for the pharmaceutical care. They provided a broad range of medication therapy management services both on patient level (e.g. clinical medication review) and practice level (e.g. quality improvement projects).

Main outcome measure

Medication-related hospitalisations in the high-risk population.

Results

Overall, 822 possible medication-related hospitalisations were identified among 11.281 high-risk patients during the intervention period. After adjustment for baseline number of medication-related hospitalisations, clustering and potential confounders the mean risk of medication-related hospitalisations in the intervention period was 4.4% in the intervention group, 6.5% in the usual care group and 4.0% in the usual care plus group. The adjusted relative risk of medication-related hospitalisations in the intervention group compared to usual care was 0.68 (0.57 to 0.82) and 1.05 (0.73 to 1.52) compared to the usual care plus group.

Conclusion

In general practices with an integrated NDP, the risk of medication-related hospitalisations is lower compared to usual care.

Trial registration number

NTR-4389, The Netherlands National Trial Register.

What is already known

- Elderly patients with polypharmacy are at risk of medication-related morbidity and mortality;
- Non-dispensing pharmacists integrated in general practice are reported to improve safety and effectiveness of pharmacotherapy in single diseases and proxy endpoints.

What this study adds

- This study demonstrates a lower risk on medication-related hospitalisations in patients with NDP-led care compared to usual care;
- To optimise the quality of pharmacotherapy, pharmaceutical care needs to be fully integrated in primary care.

Box 1. What this paper adds

INTRODUCTION

With the aging of the population the number of patients with comorbidities and polypharmacy increases.[1] Those elderly patients are especially prone to unsafe and ineffective pharmacotherapy, leading to adverse events and hospitalisations. In the Netherlands, 10.4% of acute hospitalisations in elderly patients in 2013 was related to medication and almost half of these hospitalisations was potentially preventable.[2]

Pharmacists can have an important contribution to safe and effective pharmacotherapy, although at present they do not optimally fulfil this role. Several barriers are identified: pharmacists lack access to patient medical records, they are insufficiently trained in clinical reasoning, pharmacists and general practitioners (GPs) often collaborate inadequately and they both lack time to provide pharmaceutical care.[3,4] Full integration of a clinical or non-dispensing pharmacist (NDP) in the primary care team could help to overcome these barriers.

Internationally, the role of pharmacists is developing from mainly medication dispensing towards providing pharmaceutical care in a clinical context.[5] In this new role, the 'clinical pharmacist' takes overall responsibility for the patient's pharmacotherapy in close collaboration with the treating physician.[6] This new pharmaceutical care provision includes different pharmacist-led services, such as performing clinical medication reviews, conducting quality improvement projects, holding individual consultations for specific drug therapy problems and educating team members in pharmacotherapy.

Medication therapy management provided by NDPs in general practice is demonstrated to reduce the number of drug therapy problems and improves intermediate outcomes, such as blood pressure, cholesterol and blood glucose.[7] So far, evidence on the effectiveness in terms of clinical outcomes such as morbidity or mortality is lacking. We conducted the POINT study (Pharmacotherapy Optimization through Integration of a Non-dispensing pharmacist in a primary care Team),[8] to assess the effect of integration of an NDP in general practice on medication-related hospitalisations.

METHODS

Design

A multicentre non-randomised controlled intervention study with pre-post comparison was conducted between January 2013 and June 2015, comparing pharmaceutical care by an NDP as integral member of the primary care team (intervention group) with two current models of pharmaceutical care (control groups). For a detailed description of the study design, see the study protocol.[8]

Setting

This study was conducted in general practice in the Netherlands. Participating practices were affiliated to one of three research networks: Julius General Practitioners Network (University Medical Centre Utrecht), healthcare network Almere (Zorggroep Almere)

and the Registration Network of General Practitioners Associated with Leiden University (RNUH-LEO).[9–11]

Participating practices

For the intervention group, we included practices that were explicitly willing to host an NDP. These practices had to meet the following additional criteria: availability of a consultation room for the NDP, access to the GPs' electronic medical records, a minimum of 5.000 registered patients and at least one practice nurse working on chronic disease management programs.

For the control groups, we included practices that matched the characteristics of those in the intervention group, except for the presence of an NDP.

The intervention group: NDP-led care

Ten NDPs (all PharmD) were embedded in ten general practices in the intervention group, on a full time basis. Contemporary, they participated in a newly developed Clinical Pharmacy Training Program based on interprofessional workplace learning.[12]

The NDPs were given integral responsibility for the pharmaceutical care in the practice, with a main focus on 'high-risk patients': patients aged 65 years or older and using five or more chronic medications (see Box 1). Non-dispensing pharmacists performed clinical medication reviews for patients with polypharmacy, medication reconciliation for patients discharged from the hospital and provided individual patient consultations to solve specific drug therapy problems. Patients were either invited by the NDPs, referred by the GPs or could consult on their own request. On practice level, the NDPs organised quality improvement projects to systematically identify and treat patients at risk of medication errors, and educated team members on optimal pharmacotherapy.

Patients considered at high-risk of adverse drug events were defined as:

1. being 65 years or older at the end of the intervention period (first of June, 2015), and
2. with polypharmacy, defined as the chronic use (more than three prescriptions per year) of at least five medications (different at the anatomical therapeutic chemical (ATC)-3 level), either in the pre and/or the intervention year. Dermatologicals (ATC-D) were excluded for the calculation of the total number of chronic used medications.[48]

Box 2. Definition of high-risk patients

The control groups: usual care and usual care plus

The usual care group consisted of general practices where pharmaceutical care was provided in the traditional way, i.e in collaboration with community pharmacists. In the usual care plus group pharmaceutical care was provided in collaboration with community pharmacists who had completed a national certified training in performing medication reviews.[13,14]

Data collection

Data were collected between 2013 and 2015. The intervention period started on 1 June 2014 and ended on 31 May 2015. Three months prior to the intervention period NDPs already started working in the practices. These months were considered necessary to prepare their activities and to integrate in the practice team;[15] no data were collected in these months. The period between 1 January 2013 and 31 December 2013 served as baseline period.[8] For outcome measurements we only included high-risk patients in both periods (see Box 1).

Patient characteristics, such as patients' medical history, medication records and laboratory results were extracted anonymously from the GPs' electronic medical records. The number of chronic conditions was based on a standardized morbidity index list[16] and a national prevalence list[17] of chronic diseases and multimorbidity. Data on acute, unplanned hospitalisations in above described periods were collected by research assistants. They visited participating practices to collect anonymised discharge letters of acute hospitalisations.

Primary outcome

The primary outcome was the number of possible medication-related hospitalisations. Only acute admissions were included as planned admissions are rarely related to medication.[18]

Measurements

We performed a case-by-case assessment based on a modified version of the algorithm by Kramer et al.,[19] to identify possible medication-related hospitalisations. We applied the following procedure, in which all assessors were blinded for the corresponding study groups:

STEP 1: a medical doctor or a senior medical Master student determined whether the reason(s) for admission could be related to a known side-effect of the used medication. Side-effects with an incidence of at least 1 percent according to Dutch standard reference sources[20–22] and side-effects explicitly described in the discharge letter were included for further assessment.

STEP 2: An expert duo, consisting of a medical doctor (JP, VS) and a clinical pharmacist (AH, PH, SH, MB) assessed whether the hospitalisations selected in step 1 were 'possibly' or 'unlikely' medication-related. For this assessment, two elements were taken into account: whether alternative causes (other than the suspected medication) explained the reason for admission, such as a pre-existing clinical condition; and the time relationship between

the potential side effect and the start of medication administration. Admissions that were beyond the scope of the NDPs were excluded, such as admissions in patients treated for malignancies, post-transplantation, patients on renal dialysis and psychiatric admissions.

STEP 3. Results of step 1 and 2 were compared. In case of disagreement, consensus meetings with consulting of an experienced GP or clinical pharmacist (DZ, AL) were arranged. Differences were resolved in discussion.

STEP 4. Of all cases excluded in step 1, ten percent was double checked by a medical doctor (VS) and a clinical pharmacist (AH). In case of disagreement about the exclusion, the case was reassessed. According to a pre-set protocol, all excluded cases would be reassessed in case the percentage of disagreement exceeded 10%.

Patient involvement

The intervention was pre-tested in two non-participating general practices in the Netherlands. Feedback regarding the medication therapy management services that were provided was collected from high-risk patients. We developed our study together with the Dutch national patient federation,[23] the elderly association (UnieKBO),[24] the chronic care counsil (CG-raad),[25] and the Patient Academy[26] , and used input from a patient focus group.

Sample size

We assumed the annual prevalence of medication-related hospitalisations in the high-risk population to be 4.5%.[27] We expected a 50% reduction of medication-related hospitalisations.[27] To demonstrate a statistically significant difference between the intervention and control groups at least 2.850 high-risk patients needed to be present in each study group. As the high-risk population comprises 6.4% of an average general practice in the Netherlands, 45.000 patients needed to be present in each study group.[28] Assuming an average practice size of 5.000 patients, we aimed to include ten practices per study group. This was based on an alpha of 0.05 and a power (1-beta) of 0.8.[8]

Data analysis

The primary outcome was analysed with a log-binomial mixed model in order to report the comparison between the intervention and control groups as adjusted relative risks.[29,30] As these models often have convergence problems, we used Poisson regression combined with robust (i.e. Hubert/White's) standard errors. All models included a random intercept to adjust for clustering at practice level and a residual (i.e. generalized estimating equations type) covariance matrix for patients with multiple medication-related hospitalisations. The intervention effect was assessed with the interaction between study group and study period. We adjusted for patients age, sex, number of chronic medications used and number of comorbidities at the year of hospitalisation. On practice level, we adjusted for the degree of urbanization and socioeconomic status.

In a sensitivity analysis, we excluded those types of medication-related hospitalisations that were previously not used in research of medication-related hospitalisations (fever/infection/inflammation) because of an unclear or weak association between medication and hospitalisation.

All analyses were performed with SAS, Version 9.4 (ref SAS institute, NC) and IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY).

Role of the Funding Source

A research grant was obtained from the Netherlands Organization for Health Research and Development (grant agreement number 80-833600-98-10206). Implementation of NDPs was financed by an unconditional grant of the Foundation Achmea Healthcare, a Dutch health insurance company (project number Z456). Both study sponsors had no role in the design of the study, data collection, analysis, interpretation of the data or writing of the report; nor in the decision to submit the manuscript for publication.

Ethical considerations

The Medical Ethical Committee of the University Medical Centre Utrecht waived formal medical-ethical assessment (METC protocol number 13-432C).

RESULTS

Study practices

Ten NDPs were embedded in ten general practices in the intervention group. One NDP was unable to develop the required competencies to provide integrated pharmaceutical care and withdrew from the study. This resulted in nine intervention practices with an embedded NDP. For the usual care and usual care plus groups, we approached approximately 125 general practices and selected ten and six participating practices, respectively.

The practices in the three study arms did not differ concerning being multidisciplinary health centres, accreditation, GP training site and urbanisation. (Table 1)

The mean proportion of high-risk patients per practice was highest in the usual care plus group: 7.4% compared to 5.6% and 6.4% in the intervention and usual care groups. The mean socioeconomic status of patients was higher in the intervention practices (0.9) than in the control practices (0.6). (Table 1)

The median number of medication reviews in the intervention group in 2013 was 28 per practice, compared to 54 in the usual care group and 13 in the usual care plus group. No information on the quality of medication reviews was available. Almost all practices had a high standard of quality of pharmacotherapy audit meetings.[31,32]

Patients

A total of 11.928 high-risk patients was included in the analysis. Of 647 patients (5.4%) only baseline data were available, as they deregistered from the participating practices

Table 1. Practice and patient characteristics at baseline

		INTERVENTION group (9 practices)	USUAL CARE group (10 practices)	USUAL CARE PLUS group (6 practices)
PRACTICE	Practice size, mean ± SD (range)			
	Patients ≥18 years	7750 ± 3077 (3727-11962)	6157 ± 1629 (3563-9760)	8516 ± 3077 (3727-15637)
	High-risk patients	431 ± 178 (101-667)	394 ± 164 (230-707)	632 ± 381 (256-1119)
	Setting and organization			
	Degree of urbanization[1], mean ± SD (range)	1.8±1.1 (1-4)	2.1±0.7 (1-3)	2.2±0.8 (1-3)
	Socioeconomic status[2], mean ± SD (range)	0.9± 1.0 (-1.2-2.2)	0.6± 0.9 (-2.1-1.7)	0.6± 0.5 (0-1.2)
	Health care centre, n (%)	7 (78)	7 (70)	3 (50)
	GP training practice, n (%)	8 (89)	7 (70)	4 (67)
	Indoor pharmacy, n (%)	6 (67)	6 (60)	4 (67)
	Collaborating pharmacies, mean± SD (range)	1 ± 1 (1-4)	2 ± 1 (1-4)	2 ± 2 (1-5)
PATIENT	High-risk patients, n	3879	3941	3791
	Male sex, n (%)	1702 (44)	1759 (45)	1693 (45)
	Age, mean ± SD	75 ± 8	75 ± 8	75 ± 8
	Patients <75 years, n (%)	2070 (53)	1909 (48)	1893 (50)
	Patients 75-85 years, n (%)	1318 (34)	1415 (36)	1298 (34)
	Patients > 85 years, n (%)	490 (13)	621 (16)	600 (16)
	Chronic medications, median (IQR)	6 (2)	6 (3)	6 (3)
	Comorbidities,[3] median (IQR)	4 (3)	4 (3)	5 (4)

n number; SD Standard Deviation; GP General practitioner; IQR Inter Quartile Range.

[1] Using a five point scale of degree of urbanization (1=highly urbanized area, 5=rural area).[33]

[2] Data from Dutch Social and Cultural Planning Office, using status scores of zip code area of the general practice (a higher score represents a higher status).[34]

[3] Using the UK Quality and Outcomes Framework and overview of chronic diseases developed by the Dutch National Institute for Health and Environment.[16,17]

because of death (66%), moving (10%), or for unknown reason (24%). Of 317 patients who newly registered in the practices during follow-up, no baseline data were available (Figure 1). The number of patients who were deregistered or newly registered were not equally distributed between the study groups. In the intervention, usual care and usual care plus groups, 3.9%, 5.3% and 7.5% of patients were deregistered, and 1.9%, 4.2% and 2.3% of patients were newly registered, respectively.

There were no differences in mean age and gender distribution in the three study groups. The proportion of patients aged 85 years or older, however, differed: 13% in the intervention group and 16% in both control groups (Table 1). The median number of chronically used medications was 6 in all study groups and the median number of registered comorbidities was 4 in both the intervention and usual care group and 5 in the usual care plus group.

Primary outcome: medication-related hospitalisations

In the intervention period, we identified a total of 822 possible medication-related hospitalisations among 11.281 high-risk patients in the three study groups. The adjusted mean risk of medication-related hospitalisations per high-risk patient was 4.4% in the intervention group, 6.5% in the usual care group and 4.0% in the usual care plus group (see Table 2). The adjusted relative risk for medication-related hospitalisations in the intervention group was 0.68 (CI 0.57 to 0.82) compared to usual care and 1.05 (0.73-1.52) compared to usual care plus (Table 3). Of the patients with a medication-related hospitalisation, 5% had more than one medication-related hospitalisation.

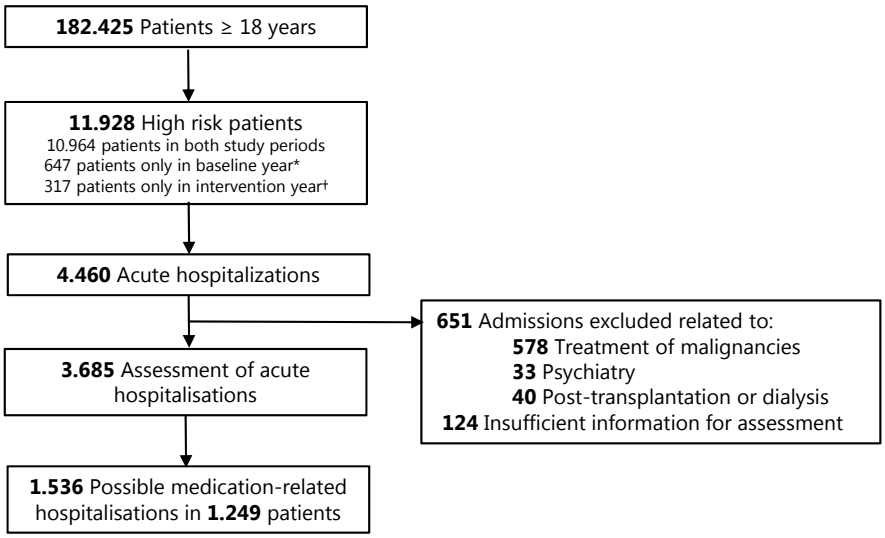

Figure 1. Flowchart of possible medication-related hospitalisations in the total study population in both study periods.

* Deregistered high-risk patients in general practice during baseline period,

† Newly registered high-risk patients in the general practice after baseline period.

The types of medication-related hospitalisations and associated medications are reported in Table 4. Most frequent hospitalisations were those related to infections, falls and bleeding. Most medication-related hospitalisations were associated with a single medication, but those related to falls and constipation were often associated with a combination of medications.

The sensitivity analysis excluding medication-related hospitalisations related to infections, showed similar adjusted relative risks of the intervention compared to usual care and usual care plus: 0.70 (CI 0.55-0.89) and 0.97 (CI 0.68-1.39), respectively.

Table 2. Absolute numbers on possible medication-related hospitalisations in high-risk patients

Study group	INTERVENTION		USUAL CARE		USUAL CARE PLUS	
Period of measurement	Baseline	Intervention	Baseline	Intervention	Baseline	Intervention
High-risk population, n	3879	3798	3941	3894	3791	3589
Acute hospitalisations, n (%)	542 (14.0)	584 (15.4)	691 (17.5)	841 (21.6)	517 (13.6)	500 (13.9)
Possible medication-related hospitalisations, n (%)	213 (5.5)	230 (6.1)	297 (7.5)	355 (9.1)	204 (5.4)	237 (6.6)
Patients with medication-related hospitalisations, n (%)	172 (4.4)	187 (4.9)	236 (6.0)	289 (7.4)	166 (4.4)	199 (5.5)

Table 3. Adjusted mean risks and relative risks of possible medication-related hospitalisations in high-risk patients, per study group†

Adjusted mean risk (%)			Relative risk (95% CI)	
	Baseline	Intervention		
Intervention group	4.6	4.4	Intervention…	
Usual care group	6.0	6.5	…vs. usual care group:	0.68 (0.57 – 0.82)
Usual care plus group	3.5	4.0	…vs. usual care plus group:	1.05 (0.73 – 1.52)

†Adjusted for the number of medication-related hospitalisations at baseline, at patient level for age, gender, number of chronic medications and comorbidities in the year of measurement (control or intervention period), at practice level for the degree of urbanization and socioeconomic status and adjusted for clustering, using a log-binomial mixed-model.

Table 4. Reason for possible medication-related hospitalisation and associated medications

Reason for admission*	N (%)	Most associated medications (n)∞
Fever/infection/inflammation (e.g. pneumonia, urinary tract infection)	407 (24)	Corticosteroids (387), immunosuppressive drugs (24), sympathicomimetics (20), opiates (10), diuretics (8), antibiotics (7)
Dizziness/collapse/hypotension/syncope†	357 (21)	Beta blockers (156), benzodiazepines (98), ACE-inhibitors (98), diuretics (83), angiotensin II receptor blockers (60), calcium channel blockers (59), antidepressants (54), nitrates (52), opiates (48)
Bleeding (non-gastro intestinal) (e.g. hematuria, epistaxis, anemia)	165 (10)	Vitamin K antagonists (103), antiplatelets (76), heparins (10)
GI complication/bleeding (e.g. ulcer, gastritis, melena)	141 (8)	Antiplatelets (88), vitamin K antagonists (71), NSAIDs (11)
Congestive heart failure	123 (7)	Diuretics (60), ACE-inhibitors (20), proton pump inhibitors (9), angiotensin II receptor blockers (9), NSAIDs (7)
Arrhythmia (e.g. bradycardia, atrial fibrillation)	85 (5)	Beta blockers (53), calcium channel blockers (37), diuretics (32), corticosteroids (14)
Renal insufficiency/electrolyte imbalance (e.g. hypokalemia, hyponatremia)	85 (5)	Beta blockers (40), antiarrhythmics (34), antidepressants (7)
Nausea/vomiting/diarrhea/gastroenteritis	61 (4)	Proton pump inhibitors (16), antibiotics (14), opiates (14), diuretics (5)
Ileus/constipation	45 (3)	Opiates (23), calcium channel blockers (20), beta blockers (13), antidepressants (8)
Chest pain	43 (2)	ACE-inhibitors (25), beta blockers (7), alpha blockers (3), antiplatelets (5)
Confusion/drowsiness/delirium	33 (2)	Opiates (13), dopaminergics (12), antidepressants (7), antiepileptics (5)
Hypoglycemia or hyperglycemia	30 (2)	Insulin (21), oral antihyperglycemics (12)

Table 4. (continued)

Reason for admission*	N (%)	Most associated medications (n)∞
Other (e.g. cardiovascular events, dehydration, intoxications)	150 (9)	Diuretics (34), corticosteroids (26), dopaminergics (13), antiplatelets (12), vitamin K antagonists (11), beta blockers (11), opiates (7), digoxin (6), ACE-inhibitors (5), antibiotics (4), antiepileptics (3)

N, n number; ACE angiotensin-converting enzyme; GI gastro intestinal; NSAID non-steroidal anti-inflammatory drug.

* In one medication-related hospitalisation (total n=1536) more than one cause could be identified (total n=1725).

∞ One medication-related hospitalisation (total n=1536) could be associated with more than one medication (total n= 2205)

† Also includes patients with a fracture following collapse.

DISCUSSION

This study demonstrates a lower risk of possible medication-related hospitalisations among high-risk patients in general practices with fully integrated NDPs compared to usual care. No difference was found between the intervention practices and usual care plus practices. These results suggest that in order to improve medication safety the current model of pharmaceutical care provision should be replaced by more advanced and integrated models, such as the NDP care model.

Differences in risk of medication-related hospitalisations have to be interpreted with caution. We found quite a large increase over time in the number of acute hospitalisations in the usual care group, compared to the other two groups (see Table 2). Even after detailed analysis of the data, we could not explain this increase. It might be related to the practice population, or simply to chance. Nonetheless, as the number of acute hospitalisations is closely related to the primary outcome, this typical increase in the usual care group might have influenced (part of) the intervention effect.

Comparison with existing literature

To our knowledge, this is the first study evaluating the effect of NDPs integrated in general practice on medication-related hospitalisations. Studies measuring the impact of NDP-led care on relevant clinical patient outcomes are sparse. Lowrie et al. reported no effect of NDP-led care on death or hospitalisation in patients with heart failure.[35] Maybe this lack of effect was due to the fact that this intervention had insufficient patient follow-up. Moreover, NDPs in this study, so-called "non-specialist pharmacists", only received a very short training.

Studies measuring the impact of NDP-led care on surrogate clinical outcomes (e.g. glycated haemoglobin, blood pressure and cholesterol levels) and the quality use of medication (e.g. appropriateness of prescribing and medication adherence) are more

frequent, and generally demonstrate positive effects.[36,37] However, heterogeneity amongst interventions complicates valid comparison of results. Studies with specific interventions and targeting specific conditions or specific medications are more likely to show positive results.[38–42] We think however that comprehensive medication therapy management is specifically needed in high-risk patients, in whom multiple medications and conditions impact each other.[43]

Measuring clinical effects of such NDP-induced medication therapy management is challenging. Full integration of NDPs in general practice seems key to enlarge effect on pharmaceutical care outcomes.[37] Also, taking integral responsibility for the provided pharmaceutical care including sufficient patient follow-up is recognised to be essential.[44,45] Furthermore, appropriate education in clinical reasoning and communication is needed.[46] Since we found an effect, we think full integration, integral responsibility and adequate education are key in improving the quality of pharmaceutical care.

Comparable results in intervention and usual care plus practices

Interestingly, outcomes in intervention and usual care plus practices did not differ. We think this is related to the characteristics of the usual care plus practices. The additional training in performing clinical medication review (the inclusion criterion for usual care plus) seemed no standalone feature but rather an element of an already highly integrated pharmaceutical care-model. There was a strong existing collaboration between GPs and community pharmacists, with joint medical information systems, regular (in)formal face-to-face meetings between GPs and pharmacists and a common focus upon medication therapy management. The main difference with intervention practices is that NDPs are formally co-located in general practices and extensively trained in clinical reasoning and communication.[12]

Strengths and limitations of the study

This study has several strengths. We covered a large patient population with in total 11.928 registered high-risk patients. The intervention was multifaceted, tailored to the needs of each general practice and performed in a real-life setting. We used a structured methodology to systematically identify possible medication-related hospitalisations (assessment by a multidisciplinary team, consensus meetings with experts and cross-checking of data) limited the risk of subjectivity in judgement.

This study also has several limitations. The fact that we chose not to randomise puts the comparison at risk of bias, even though we corrected for baseline differences. We think however, that randomisation would have put optimal performance of the NDP at risk. A second limitation concerns the sample size calculation of the study. During our study, a new study reported an increased prevalence of medication-related hospitalisations: 10.4%[2] instead of the 4.5%[27] we used in our original calculations. In addition, the original sample size calculation was not adjusted for clustering. Future research should take these

two elements into account. Third, regarding the primary outcome, the hospitalisations we identified were *possibly* medication-related, including various levels of certainty about the causality. To assess *definite* causality (if that is even possible), data including interviews with involved doctors, pharmacists and patients would have been necessary.[47] In addition, we could not measure *preventability* of the medication-related hospitalisations due to the nature of available data. Fourth, flaws in the electronic medical records extraction resulted in the omission of an unknown number of deceased patients in our database. As the number of high-risk patients is the numerator in our primary outcome, these missing data may influence the absolute risk of medication-related hospitalisations among elderly with polypharmacy. Yet, as data collection was similar in all study groups, these missing data did probably not affect the between-group comparison. Fifth, we included all high-risk patients registered in the participating practices, instead of only patients who had a clinical medication review or consultation with the NDP. This might have diluted the measured effect.

Future research

Integration seems key to improve the quality of pharmaceutical care. This may either be done by introduction of the NDP, or by developing more usual care plus practices. The latter would involve investing in existing infrastructure and collaboration, which is likely to be a time consuming and non-transparent improvement process. The integration of an NDP in general practice appeared a concrete organizational intervention with a fairly rapid implementation process. Cost-effectiveness of both models should be investigated and implementation research should be continued.

CONCLUSION

In practices with NDP-led care, we found a lower risk on medication-related hospitalisations compared to usual care. High-risk patients will benefit most from integrated pharmaceutical care. Full integration of an NDP in clinical practice, adequate training and integral responsibility are key conditions of success for this new concept of pharmaceutical care provision.

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Chapter 5

GENERAL DISCUSSION

In this thesis, we evaluated the implementation of the non-dispensing pharmacist (NDP) in general practice, and its impact on the safety and effectiveness of pharmacotherapy. This care model is an example of integrated pharmaceutical care. Currently, there is an unacceptable high prevalence of drug-related morbidity and mortality. Better integration of pharmaceutical care in clinical practice is key in reducing this problem.

In this study we unraveled the processes of integrating and implementing NDP-care (Chapter 2). We showed how NDPs developed the required clinical skills and professional expertise with an intensive training program based on interprofessional workplace learning (Chapter 3). After introducing NDP-care a lower number of medication-related hospitalizations occurred as compared to usual care (Chapter 4). Moreover, process evaluations showed that NDPs were able to effectively resolve drug therapy problems (Chapter 4).

We reason that medication therapy management (also 'clinical pharmacy services') provided by the NDPs do improve the intrinsic quality of drug therapy and supports high-risk patients to better understand their medications and better adhere to their drug regime. Consequently, the NDP improves the effectiveness of medication and reduces adverse drug events. We explain the positive results of our studies by two key elements of NDP-care: full integration in the general practice, and taking integral responsibility for the provided pharmaceutical care including adequate patient follow-up. An absolute requirement is education of NDPs in clinical reasoning and communication to develop a professional identity.

In this chapter, we will discuss the context, the results and consequences of our studies. We will focus on why and how NDP-care is effective by taking into account the relevance of professional identity formation, the scope of practice of NDPs and future opportunities for further role expansion by prescribing authority. Also, we will elaborate on the differences between NDP-care and pharmaceutical care provision in usual care and usual care plus (UCP) settings. Finally, we will provide a practical approach for successful implementation of NDP-care and discuss the next steps to enhance the development of the pharmacy profession.

The new professional identity of NDPs

It is essential that NDPs develop a professional identity, which differs substantially from the traditional model of community pharmacists (Figure 1). Our hypothesis was that the NDPs needed to become a patient-focused, clinical care provider in order to effectively take responsibility for the quality of pharmaceutical care (Chapter 3.2). We assume that this change in professional thinking and acting is crucial to improve the quality of pharmacotherapy in general practice.

The concept of professional identity formation is defined in the educationalists' domain as the incorporation of various roles and experiences, into a coherent self-image, so that these roles become a structural part of professional reasoning and acting.[1,2] Our study showed

that the transformation of NDPs expanded the traditional 'being a medication expert' with 'being a clinical professional, anticipator and broker'. In other words: the professional identity of an NDP is multidimensional. Building upon existing knowledge, this study confirmed that development of a professional identity involves the incorporation of various roles.[1] In addition to what is already known, we unraveled five different roles that are part of the NDP identity (Figure 1). Figure 1 shows similarities to the CanMEDS Competency Framework,[3] though, our model reflects the incorporation of roles into a coherent identity, instead of an overview of competencies.

Central to the identity of NDPs is being a medication **expert**. All NDPs within our program had fully incorporated the role of expert into their identity and positioned themselves likewise. However, this part of their identity could only flourish when their competency and expertise was recognized by GPs and patients. As GPs and community pharmacists generally work in separate settings with different work processes, recognizing and valuing each other's expertise is often hampered. This might limit the potential of community pharmacists to develop a position as medication expert.

A second feature of NDP identity is being a **clinician**: a patient-centered caregiver who is inherently integral responsible for the impact of medication on a patient's health. NDPs performed patient consultations on a daily basis, allowing to experience the impact of medications in patients. Often several follow-up visits were necessary to implement changes in pharmacotherapy. Thus, NDPs developed clinical expertise and a 'sense of urgency'.[4]

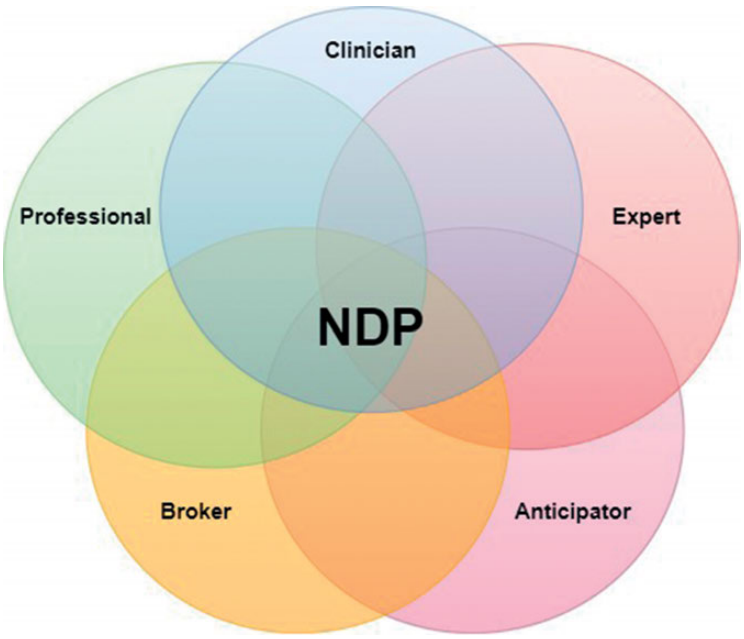

Figure 1. Five key aspects of the professional identity of NDPs

NDPs who felt less comfortable with patient care experienced difficulty in developing this clinical identity. Developing as a clinician will be challenging for community pharmacists, as they receive limited training in clinical and communication skills. Moreover community pharmacist usually focus on the dispensing process, which consumes a relatively large proportion of their time. Thus community pharmacists feel less responsibility for clinical care. Many community pharmacists actually regard themselves primarily as medication dispensers and not as patient-centered caregivers.[5] Many of these pharmacists have probably deliberately chosen to work in community pharmacy because of their personal interest in product, logistics and management. This implicates that the current pharmacy culture might be a barrier to develop more clinically oriented pharmacists.

A third feature of NDP identity, which is closely related to being a clinician, is being both responsible for the patient's pharmacotherapy and capable of making clinical decisions (defined as **professional**). Clinical decision making requires 'tolerating uncertainty, exploring probability and marginalizing danger'.[6,7] Physicians are more willing to take 'calculated' risks, compared to pharmacists who by nature are risk averse. Also, pharmacists are traditionally trained within a beta-science approach, ensuring safe dispensing of medication on a highly detailed level. So, clinical decision making reflects a major shift in thinking and acting of pharmacists. An NDP in general practice needs to make evidence-based decisions, which means combining their knowledge of medication with their clinical experience, balancing with the context and the needs of the patient.[7] By doing this, the NDPs develop a feeling of responsibility for the patient's pharmacotherapy. The importance of taking responsibility was already raised when Hepler and Strand first introduced the concept of pharmaceutical care almost thirty years ago.[8,9] Not all community pharmacists are prepared to accept calculated risks and to take on this new level of responsibility.[10] To accept responsibility for the patient's pharmacotherapy, we assume that it is vital to closely cooperate with GPs at the clinic setting (full integration) and to share experiences with peers outside the workplace (training).

A fourth feature of NDP identity is being an **anticipator**. As NDPs were full-time available in the practice, and trained in anticipating they were able to proactively detect possible medication errors and to pick up small clues that signaled lapses in the care trajectory. Anticipatory pharmaceutical care, i.e. preventive identification of patients with possible medication safety issues became a daily routine of NDP's. Of course, resolving medication safety issues that have not been experienced by the patient (yet) is a challenge, as it needs influencing patients' beliefs and behavior. Therefore, building a therapeutic relationship with the patient is essential. A majority of patients does not experience such a therapeutic relationship with their community pharmacist.[11] We think that an NDP working in the clinical setting as a health care provider, will be more successful in developing this relationship in order to anticipate on possible medication therapy problems.

The fifth feature of the NDP identity is being a **broker**. Due to different backgrounds, working processes and responsibilities, the collaboration between GPs and community

pharmacists is often suboptimal.[12] The introduction of an NDP has the potential to bridge the differences, which will improve the care process and outcome. The work of brokers is known to be complex, as it requires the ability to align different perspectives and to introduce elements of one practice into the other.[13] In our study, only a few NDPs developed into broker, because they were able to create connections and to facilitate interprofessional collaboration between community pharmacists and GPs.

In order to develop their new professional identity NDPs have to incorporate these different roles. Only being a medication expert is insufficient to successfully work in general practice as an NDP. If we want NDPs to develop this broad multidimensional identity, it is essential to explicitly focus on professional identity formation during training. Indeed, "education is about the transformation of the self into new ways of thinking and relating."[14] Medical curricula increasingly support professional identity formation of medical professionals by incorporating features of social learning theory, communities of practice, and situated learning.[15] The possibility to incorporate roles into identity can further be enhanced by interprofessional workplace learning, allowing for reflective learning. "Crossing boundaries" between NDPs and GPs provides unique learning opportunities for professional identity formation, and is a driver for change.[16,17] With appropriate training and workplace learning, NDPs will "think, act and feel"[2] as a clinical care provider. In our study, we emphasized the importance of identity formation of NDPs, but we did not study specifically which aspects of the NDP identity typically added to the quality of pharmaceutical care. This question requires further research.

Expanding the role of NDPs with prescribing authority

The clinical role and responsibilities of NDPs in the Netherlands should be further expanded by allocating prescribing privileges. Possible advantages of prescribing by NDPs are more efficient delivery of clinical pharmacy services and making better use of the skills of NDPs. Pharmacists are already authorized to prescribe in Anglo-Saxon countries such as Australia, Canada, New Zealand, the United States and the United Kingdom. Additional training is always required and prescribing is often limited to certain disease areas (e.g. heart failure, minor ailments or pulmonary drugs).[18] Most progressive is the development in Scotland, where the government aims that in 2023 all pharmacists that provide pharmaceutical care will be independent prescribers.[19]

There is an evidence base and rationale for this expanded scope of practice.[20,21] A recent Cochrane review on prescribing by non-medical staff, including 20 studies among which also pharmacist prescribers, suggested that nonmedical prescribers are as effective as medical prescribers. In addition, a meta-analysis showed a positive effect of non-medical prescribers on intermediate health outcomes (such as blood pressure and glycated hemoglobin) compared to medical prescribers.[22] The pharmacists in the included trials often performed a multifaceted health-related intervention, such as clinical medication review, with prescribing being one element of the intervention.

In the Netherlands prescribing authority is not incorporated in the 2020 pharmaceutical care vision report of the Royal Dutch Pharmacists Association.[23] Yet, the association of young community pharmacy professionals (VJA) strives to have prescribing authority for common diseases in primary care.[24] The results of our stakeholder research showed no clear opposition, nor strong support for prescribing pharmacists in the Netherlands (Chapter 2.2). The studies described in chapter 2.3 and 3.2 demonstrated that NDPs selected medications post-diagnosis, wrote prescriptions and monitored the effects of medications. Yet, the GP remained ultimately responsible for prescribing. Apparently, not having prescribing authority was not a limitation for NDPs to take up integral responsibility for the patient's pharmacotherapy: professional autonomy of the NDPs developed irrespective of having formal prescribing authority.[10]

We state that the quality of pharmaceutical care that NDPs deliver is not dependent on having prescribing authority. However, prescribing authority of NDPs is the logical consequence of further role development and clinical integration of NDPs in the primary care team. It does help to make better use of the expertise of NDPs and will contribute to a streamlined care process. Evaluation research in real-life settings can provide further information about how, why and when independent prescribing does work optimally.

NDP-care compared to current models of pharmaceutical care provision

We expect that NDP-care, which includes taking full responsibility for the pharmaceutical care in general practice by providing comprehensive medication therapy management, proactive consultations and structured follow-up of patients, would result in optimal quality of pharmaceutical care (Figure 2). Nevertheless, community pharmacists in UCP settings – the settings in which the GP collaborated with a community pharmacists who had additional training in reviewing medication - did have comparable pharmaceutical care outcomes regarding medication-related hospitalisations. UCP, which is still primarily based upon the dispensing of medication, apparently represents an already better model of pharmaceutical care compared to usual care. We think there are several explanations.

A first explanation is the *institutional setting* of the UCP settings. When comparing the practice characteristics of the intervention and UCP settings, we learned that the additional training course about clinical medication review was not a stand-alone feature but rather an expression of an already existing high collaborative and innovative background of the UCP settings. The UCP settings were all multidisciplinary health care centers, pioneering for years in establishing collaborative practice and integrated pharmaceutical care. The GPs and pharmacists had shared medical information systems and had regular (in)formal face-to-face meetings to discuss ad-hoc problems of the patient's medication, as they were mostly located in the same building. Several UCP settings integrated the repeat prescription process in the primary process of the community pharmacy. The tradition of collaboration in the UCP settings developed over a period of 10 years. The integration of the NDP, however, showed benefits of integrated pharmaceutical care on both patient and

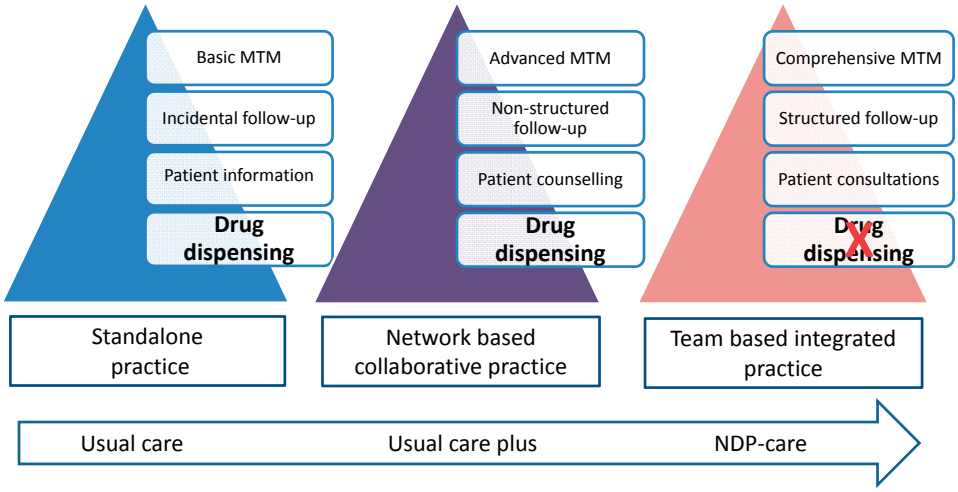

Figure 2. Professional development of pharmacists in different settings and related services. MTM Medication Therapy Management.

practice level within a period of less than two years. In other words, the introduction of an NDP in general practice has short term benefits to patient care.

A second possible explanation is related to *professional identity formation*. It may well be that the degree of integration in the UCP settings contributed to a gradual professional identity formation comparable to that of NDPs. So far, there is little academic research about professional identity formation of community pharmacists,[25] but a long learning process is probably conditional. The collaborative practices might facilitate learning: community pharmacists might have gradually started making decisions about the patient's pharmacotherapy from a clinical perspective. In contrast to NDPs, they did not have additional training in clinical reasoning. Also, the frequency of interprofessional meetings and patient consultations (not linked to dispensing of medication) is probably considerably lower compared to NDPs in general practice. Both NDPs and community pharmacists in UCP settings develop a professional identity, but do so at a different pace.

A third possible explanation of the comparable effects of NDP and UCP-care could be the *high level of care coordination* in the UCP settings. Lapses in the care trajectory may be easily identified and adequately resolved. Streamlined exchange of information, standardized quality care projects aimed at improving inappropriate prescribing and reducing error might have resulted in high quality of care, at least regarding medication related-hospitalisations. Indeed, we have an indication that pharmacists in UCP settings focused upon other processes than performing clinical medication review, highlighted by the low median number of reviews performed in 2013 (n=13, Chapter 4.3). This topic would need further research to understand the potential and the feasibility of UCP-like settings for improving pharmaceutical care.

A last explanation is the *limited follow-up time* of the study. We anticipated that the "start-up period" of NDPs to become clinically integrated in the multidisciplinary team was three months. However, NDPs experienced that they needed at least one year to become fully embedded in the decision-making process and to substantially add to the quality of pharmaceutical care. NDPs had to develop their role, participate in weekly classroom training days and build new and trusting interprofessional relationships. Presumably, the maximum effect of the NDPs was not achieved yet within the intervention year to measure a significant effect on medication-related hospitalisations compared to UCP-care. Follow-up research is recommended.

A new approach to clinical medication reviews

Performing clinical medication reviews is an essential element of the work of NDPs in general practice. Although the evidence for clinical medication review is inconclusive,[26–28] this study showed that clinical medication reviews conducted by NDPs have a different approach and may be more effective. This can be explained by the following factors.

The first factor is the *setting*. In general, the quality of medication reviews strongly varies between settings. Approaches to perform those reviews range from a superficial 'medication use review' with minimum input from GP and patient, to a full 'clinical medication review'. By definition, NDPs performed clinical medication reviews in a general practice setting with a multidisciplinary approach. NDPs were clinical practitioners and able to align with the patients' health related demands, rather than to apply standardized (e.g. STOPP/START) criteria to the patient's pharmacotherapy.

The second factor is *incentives*. The current incentives to perform clinical medication reviews in primary care are inadequate: there is currently insufficient reimbursement for this service and an obligatory target number of reviews that GPs and pharmacists must comply with. As a result, pharmacists are more likely to offer a clinical medication review to 'non-complex' patients (e.g. aged 65 years with 5 medications for a limited number of highly protocolled conditions) instead of patients who are more likely to benefit the most, namely frail elderly with complex polypharmacy. NDPs did not have such incentives as they had a fixed income and no preset target.

The third factor is *time spent on implementation of recommendations*. In traditional pharmaceutical practice the number of recommendations arising from clinical medication review that is actually implemented and the proportion of drug therapy problems that is eventually solved is often disappointing.[12] NDPs demonstrate to be able to solve the majority of drug therapy problems by getting recommendations implemented (Chapter 4.1). Although the majority of recommendations were preventive measures, NDPs solved direct patient problems as well, which are considered highly relevant to patients. Patients problems, such as side effects or concerns about adhering to medication can only be identified and solved by consulting the patient and providing follow-up. Adequate follow-up may even reduce the number of hospitalizations[29] and should be more broadly implemented in primary care to have impact on the patient's medication management.

The fourth factor is *the difficulty of stopping medications*. Stopping requires careful patient guidance and follow-up.[30,31] Reducing the number of medications may particularly reduce harm,[32] while the most common medication change arising from clinical medication review in community settings is adding medication to existing pharmacotherapy.[33–36] NDPs in our study primarily stopped or tapered down medication (Chapter 4.1).

Although we claim that NDPs can effectively perform clinical medication reviews, it still is a time-consuming and resource–intensive service. It is expected that over time, NDPs can provide more targeted and thus less time-consuming patient consultations. The first clinical medication review is most extensive and will probably result in substantial changes in the patients' pharmacotherapy. During the next clinical medication review the NDP and patient will anticipate on possible new drug therapy problems that have developed due to physiological changes of aging or due to newly diagnosed conditions. Hence, follow-up clinical medication reviews will become less resource-intensive.

In general, we think that the quality (and not the quantity) of clinical medication review can be improved in different settings. Key features are aligning to the patients' needs, providing follow-up in order to get recommendations implemented. Improving clinical outcomes will then be more successful, as is demonstrated by Malet-Larrea et. al.[37] We, however, believe that the clinical effect that we found in our study (Chapter 4.3) is not only related to the quality of clinical medication review, but by the integral approach to pharmaceutical care provision in general practice.

Requirements for successful implementation of NDPs in general practice

Successful implementation of NDP-care requires *integral responsibility* of NDPs for pharmaceutical care, primary care based *training* in clinical pharmacy and *full integration* in the primary care team. NDP-care will then provide short term benefits to patient care. All participating parties of the POINT project, (i.e. GPs, other members of the primary care team, community pharmacists, patients and the NDPs) endorsed this new practice model. Moreover, we identified a broad consensus of this new care model in our stakeholder research (Chapter 2.2). Community pharmacists are sometimes hesitant about NDP-care, but the community pharmacists who worked together with NDPs perceived NDP-care of added value. The success of the POINT practice model was also highlighted by the fact that several NDPs continued working in general practice after termination of the POINT study program.

However, broad implementation of NDP-care will be an incremental process where well-known barriers and facilitators can be expected.[38] Of course, future implementation research will provide further information about the feasibility and sustainability of this new care model. Yet, we need a practical approach to start successful implementation of NDP-care now. Hence, this paragraph provides an overview of requirements, based upon the results of our research and aligned with the recently developed guidelines about NDP integration in general practice.[39]

1. Develop a job description

A job description for NDPs will enhance the likelihood to take integral responsibility and to become fully integrated in the practice. A job description should include tasks, process agreements and integration steps.

The tasks of the NDP are the services delivered both at patient and practice level (Table 1). To prevent fragmentation of care, the tasks of the NDP need to be clearly aligned with the tasks of the practice nurses and community pharmacists. The tasks should not be restrictive, but leave room for adjustment to tailor to the practice needs. The primary care team should develop tasks in collaboration, aligned with the patient population and priorities of the team members. The priorities and needs for specific pharmaceutical care programs can be determined by mapping the practice population (most common chronic diseases, frail elderly), evaluation of previously performed pharmaceutical care projects and medication therapy challenges that the team experiences.

Process agreements involve referral procedures and frequency and planning of interprofessional consultations to discuss patient cases. Also, agreements need to be made about feedback sessions with the clinic manager or lead GP to keep expectations and preferences of collaboration aligned.

Integration steps involve participation in team meetings, social activities and joint education. A concrete example of joint education is sharing patient cases to illustrate successes. It enhances integration and is of educational value as well.

2. Define responsibility

All partners in the primary care team or organization should agree with the professional responsibility of NDPs in the team. NDPs need to be recognized as autonomous health care providers on a nonhierarchical position to GPs. A fully integrated NDP should be involved in the strategic management of the clinic, comparable to the involvement of GPs. Recognition of the professional responsibility of the NDP requires strong leadership and support from the lead GPs or management team.

Table 1. Key tasks of the NDP

	Tasks of NDP
Patient level	1. Clinical medication reviews for patients with polypharmacy; 2. Patient consultations about specific drug therapy problems; 3. Medication reconciliation for patients discharged from hospital.
Practice level	1. Implementing targeted pharmaceutical care projects on appropriate prescribing, medication use and care processes; 2. Medication management advise and education in pharmacotherapy to team members.

To operationalize the responsibility of NDPs, the primary care staff needs to agree on the scope of practice as well as on the level of actions that the NDP can undertake without seeking prior approval. Also, the boundaries ('grey area') of the NDP profession should be made explicit: is the NDP allowed to prescribe, to order and interpret laboratory results and to perform clinical examinations such as measuring blood pressure?

3. Inform patients and other professionals about the role and responsibility of the NDP

A job description, consultation room and adequate financing is of no value when patients and other professionals are uninformed about the opportunities of NDP-care. NDPs need to be positioned as pharmaceutical care providers with clinical skills. The NDP can regularly inform and update the team about their scope of practice during team meetings or individual meetings. Patients can be informed about the services offered by the NDP in various ways, such as a display in the waiting room, referral cards that practice staff can hand out to patients, publication about the NDP role in local press or on the practice website.

4. Provide office, ICT and administrative support

Minimal requirements that enable an NDP to provide pharmaceutical care in general practice are a consultation room close to the GP offices with a computer with internet access and a telephone. The shared use of patients' health records is of paramount importance for patient assessment and communication with the team. An NDP should use a pre-set and shared agenda (comparable to that of the GP) with appropriate timeslots for short consultations, intakes or home visits for clinical medication review, follow-up and telephone-consultations. Efficiency can be increased when administrative staff books patient appointments. In addition, continuity of NDP-care can be increased when NDP appointments are structurally planned before or after the periodic chronic-care appointments with the practice nurse or GP.

Manually screening and identifying patients at risk who may benefit from an NDP consultation is a time-consuming task. This process can be facilitated when these patients are automatically identified and invited for an NDP appointment by the practice assistant. Evidence-based screening tools that can be implemented in digital medical information systems are of help.

5. Provide continuous training and feedback information

The fundament of successful implementation of NDP-care is adequate training. This training should be based upon the principles of experiential learning and should include interprofessional training. Creating job opportunities for NDPs without appropriate training introduces a large risk of unsuccessful practices.

In order to provide continuous training and support, a post-graduate training program needs to be accredited, based upon a competency based framework for continuous

education. The already developed training program for NDPs in the Netherlands (Chapter 3.1) can be adopted to develop patient-centered practitioners who are able to make clinical decisions. In such training, NDPs learn to provide both ad-hoc evidence-based advice to GPs and to take responsibility for the patient's pharmacotherapy when it is considered complex or non-standardized. Training should also particularly aim at professional development by paying attention to reflection and critical self-awareness.[40,41] Especially a reflective practitioner is able to adequately handle complex and unpredictable problems that occur on a regular basis in primary care practice.

In addition to post-graduate NDP-training, current graduate pharmacy curricula also need to better prepare pharmacists for team based patient care in clinical practice. Indeed, post-graduate clinical pharmacy training should not be in place to 'repair the deficiencies' of graduate training. Good examples of this new education are the new Pharmacy Master at Leiden University and the revised pharmacy Master curriculum in Utrecht. The necessity of transforming pharmacy curricula to develop patient-centered practitioners is already broadly acknowledged.[42] However, there is room for improvement regarding the incorporation of interprofessional training and placements in clinical settings. Those two aspects offer unique learning opportunities to contextualize learning, allowing for a steep learning curve of pharmacist-trainees. Ideally pharmacy students should learn to perform patient consultations from year one of the Bachelor's degree. This will strongly enhance professional identity formation (i.e. acting and feeling like a pharmaceutical care provider). The pharmacy Bachelor, however, remains mostly drive by beta-sciences. The upgrade of current pharmacy graduate curricula will still make post-graduate training for NDPs necessary, as this is specifically tailored to primary care based pharmaceutical care. Opportunities for harmonization of NDP-training with current primary care or secondary care post-graduate training needs to be explored.

6. Ensure adequate financing

Although we did not perform cost-effectiveness research, a first step towards successful implementation of NDP-care is the incentive of health insurance companies to allocate appropriate budget for NDP-care. An adequate reimbursement model will improve the access to and quality of clinical pharmaceutical care. A fee-for-service model (the NDP or practice is reimbursed per service item, such as per consultation or clinical medication review) might be an obvious model, but can increase the risk of overtreatment as well. Current fee-for-service models for pharmaceutical care provision in primary care provide limited reimbursement opportunities. A more viable model of reimbursement is through capitation (the NDP or practice receives a periodical sum per registered patient, irrespective of the number of services that the NDP provides). This model would provide opportunities to expand pro-active preventive-care services and would encourage cost-effective treatments.[43] To optimize the model of capitation, the periodical sum per registered patient should be adjusted according to the frailty level of the patient population of the practice.

The quality of NDP-care – and therefore the success of the implementation process – can be further enhanced by a complementary model of pay-for-performance (the NDP or practice is reimbursed based on clinical relevant quality indicators). This model of reimbursement is in line with recent (small-scale) transformation of the GPs' reimbursement model.[44] However, the optimal reimbursement model for NDP-care needs further research.

7. Ensure national adoption of NDP-care

The implementation of NDP-care needs to be prioritized by stakeholders and policymakers. First, the professional organisations of pharmacists and GPs,[45–47] need to discuss the consequences of the results of our studies for the professional development of pharmacists, and their role in the primary care team. Support of these bodies will create the fundament for further development of NDP-care and pharmacy education. Second, policy agencies (the Ministry of Health, national Healthcare Authority)[48,49] need to stimulate the paradigm shift towards separation of pharmaceutical care and dispensing of medication by implementing NDPs in general practice. Third, the national Care Institute[50] needs to further discuss the policy conditions and the options for a sustainable model of reimbursement. Finally, health insurance companies need to allocate appropriate budget for NDP-care.

We think that these macro-level policy enhancements are key in the national adoption of NDP-care. Therefore it is important that the vision about integrated pharmaceutical care in primary care and a strategy for broad implementation of NDP-care is endorsed by the Ministry of Health, by professional organisations and insurance companies. The aim should be to maximize the contribution of NDPs to the quality of pharmaceutical care, by future positioning of NDPs as autonomous, separately funded health care professionals fully embedded in the primary care team.

High quality integrated pharmaceutical care is the future

The future role of the pharmacist is not in dispensing of medication, but in the delivery of high quality integrated pharmaceutical care. We have demonstrated that full integration of trained NDPs in general practice improves pharmaceutical care. NDPs develop a professional identity as clinical care provider and can take integral responsibility for the patient's pharmacotherapy. NDPs improve the safety and effectiveness of pharmacotherapy in primary care. Therefore, NDP-care should be further implemented in general practice.

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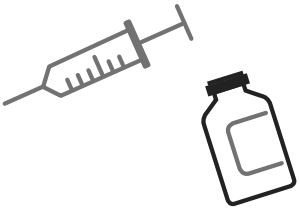
Chapter 6

APPENDIX

6.1

Summary



Medication-related morbidity and mortality is a broadly acknowledged health care problem and is currently inadequately addressed. With the aging population, this problem is expected to increase. Elderly patients often have multimorbidity and use multiple medications, adding to the complexity of pharmacotherapy.

As most pharmacotherapy is initiated or repeated in general practice, safety and effectiveness of pharmacotherapy needs to be improved in primary care. Research evidence indicates that pharmacists contribute to safe and effective pharmacotherapy. However, pharmacists in community pharmacy are often hampered to take up their role as pharmaceutical care provider. To make optimal use of the skills of pharmacists, we propose that they need to be fully integrated in primary care, as non-dispensing pharmacists (NDPs) can take integral responsibility for pharmaceutical care, without being distracted by logistics and pharmacy management. Non-dispensing pharmacists will have full access to patient's medical records. Embedding in primary care will result in better collaboration with general practitioners (GPs), and consequently, the quality of pharmacotherapy will improve. Additional clinical training is required for pharmacists to develop as patient-centered clinical care providers.

Therefore, we developed the POINT practice model (Pharmacotherapy Optimization through Integration of a Non-dispensing pharmacist in a primary care Team). The NDPs who worked within the POINT practice model provided comprehensive medication therapy management services completely separate from the dispensing process. The NDPs were fully integrated in the general practice team and intervened both at patient and practice level. This multilevel approach is expected to maximally contribute to safe and effective pharmacotherapy.

The objective of this thesis is to evaluate the training, implementation and clinical effects of NDPs in general practice. This thesis consists of three parts. **Chapter 2** describes the background and processes of integrating NDPs in general practice. **Chapter 3** presents the design of the newly developed clinical pharmacy training program for NDPs and their professional identity formation. **Chapter 4** demonstrates the clinical effectiveness of integrated NDP-care compared to current models of pharmaceutical care provision in the Netherlands.

Background and processes of integration

Chapter 2.1 presents a systematic review of studies on NDP-led services in general practice. We identified 60 studies evaluating how the degree of integration of NDPs in general practice impacts medication-related health outcomes. The level of integration (no, partial or full integration) was assessed by scoring the presence of the following five dimensions of integration of the NDP-led service: organizational, informational, clinical, functional and normative integration. The review demonstrated a positive association between the degree of integration and health outcomes, but only for broad patient-centered services. These services have a holistic and comprehensive approach compared to disease-specific services,

which are more protocolled. The results of the review suggest that full integration of NDPs will especially benefit patients with multiple medications and comorbidities.

Introducing new professional roles in healthcare, such as the NDP, can lead to controversy about the boundaries of the work domain of health care professionals. Therefore, it was considered essential to understand the consensus and controversies about integrating NDPs in general practice amongst stakeholders in the Netherlands. *Chapter 2.2* presents the results of our stakeholder research in which we used a mixed-method: Q-methodology. Based upon data of 163 stakeholders who ranked statements about the integration of NDPs in general practice, the factor analysis revealed four perspectives: "the independent community pharmacist", "the independent clinical pharmacist", "the dependent clinical pharmacist" and "the medication therapy management specialist". These four perspectives showed a consensus on various features of the NDP's role, such as involvement in individual patient care and improving medication adherence. In addition, there was consensus on different financial, organizational and collaborative aspects of integrating NDPs in general practice. Controversy exists on the level of professional independence of NDPs and the type of tasks that NDPs should perform. This Q-study demonstrates the potential of NDPs as pharmaceutical care provider and the willingness amongst stakeholders for interprofessional collaboration.

In *Chapter 2.3* we describe how clinical integration impacts medication therapy management. The aim of the study was to give a systematic description of what is entailed in integrating NDPs as member of the primary care team and how integration could contribute to patients' medication management. We conducted a theory-oriented evaluation, based on ethnographic data collected by the NDPs who participated in the POINT study. We unraveled three processes that can explain the impact of NDP-led care on patients' medication management. First, the specific expertise that NDPs bring into general practice results in customized solutions for individual patients. NDPs gained convincing and trusting interprofessional relationships in order to actively treat patients, rather than to only advise GPs about pharmacotherapy. Second, the integration of quality management into clinical work results in a systematic approach of performing pharmaceutical care. Third, the reconciliation of possible tensions caused by overlapping tasks with practice nurses results in a distinct patient population. Especially patients without standardized care trajectories optimally benefit from NDP services.

Training and professional identity

It is likely that community pharmacists are not fully prepared to work at the clinical side of primary care, let alone without a role model present in general practice. Hence, we developed a 15-month Clinical Pharmacy Training Program, which is presented in *Chapter 3.1*. The program was based upon the principles of interprofessional workplace learning and the program integrated practical experience with classroom based learning activities. The NDPs within the POINT project were trained in the pilot run and were asked

several times for their opinion on this program. The training program helped NDPs to develop the required skills and clinical expertise to work as pharmaceutical care provider. The NDPs were able to train and improve their skills in consultation, clinical reasoning and interprofessional collaboration. The training also offered support in defining and creating their new roles in general practice. In conclusion, the training program provided increased opportunities to NDPs to add value in general practice.

Although education is often aimed at gaining knowledge, competencies and skills, professional identity formation is essential for health care professionals. Professional identity formation is related to work commitment and career sustainability. The introduction of NDPs in general practice can cause tensions between the different professionals involved, but these tensions can also be considered a unique learning opportunity. This so-called "boundary crossing" between NDPs and GPs can stimulate professional identity formation. Therefore, we studied professional identity formation of ten pharmacists who moved from community pharmacy to general practice to work as NDP. *Chapter 3.2* shows the results of the multiple case study, including interviews, peer feedback and individual reflection. By using within-case and cross-case analysis, we demonstrated that NDPs who applied the learning mechanisms of reflection and transformation developed a professional identity as patient-focused, clinical pharmaceutical care provider able to take responsibility for the patient's pharmacotherapy. Some NDPs, who learned mainly through the mechanism of identification, did not integrate new roles into their professional identity. They experienced the workplace as uninviting for reflection and transformation. A training program with reflective and transformative learning – both at the workplace and among peers – contributes to professional identity formation.

Clinical effectiveness

In **Chapter 4**, we examined whether fully integrated and trained NDPs improved the safety and effectiveness of pharmacotherapy in primary care. In *Chapter 4.1* we describe the design of a controlled intervention study to compare the effect of NDPs on medication-related hospitalisations with two existing models of pharmaceutical care provision. The number of medication-related hospitalisations in the intervention practices was compared to usual care and usual care plus. In usual care plus practices, the community pharmacists had had additional training in performing clinical medication review. In this chapter, we describe the methodological decisions and challenges in order to provide evidence as to whether integration of an NDP in general practice will result in safer pharmacotherapy.

Chapter 4.2 reports the results of the observational study on the NDPs' actions and solutions of drug therapy problems among elderly polypharmacy patients. On three pre-set dates, the NDPs collected detailed information about the drug therapy problems of the last ten patients who completed all stages of clinical medication review. The NDPs identified a median of five drug therapy problems per patient. More than 80% of the recommendations to optimize the patient's pharmacotherapy were actually implemented, mostly aimed at

stopping medication (31%). NDPs' actions were either preventive (aimed at following prophylactic guidelines) or corrective (aimed at active patient problems). Almost two third (64%) of the corrective interventions actually solved the drug therapy problem. In conclusion, NDPs in general practice can identify a large number of drug therapy problems, and can successfully implement a proportionally high number of recommendations that solve the majority of drug therapy problems.

In *Chapter 4.3* we report the outcomes of the intervention study on medication-related hospitalisations. The ten specially trained NDPs provided comprehensive medication therapy management services both at patient and practice level. In this multicentre pragmatic controlled intervention study, we identified 822 possible medication-related hospitalisations among 11.281 high-risk patients during the intervention period (June 2014 - May 2015). After adjusting for the number of medication-related hospitalisations at baseline (2013), clustering and possible confounders, the mean number of medication-related hospitalisations in the intervention period was 4.4% in the intervention group, 6.5% in the usual care group and 4.0% in the usual care plus group. The relative risk of medication-related hospitalisations in the intervention group compared to usual care was 0.68 (0.57 to 0.82) and 1.05 (0.73 to 1.52) compared to the usual care plus group. We conclude that in general practices with an NDP who provides integrated pharmaceutical care, the risk of medication-related hospitalisations is lower compared to usual care. No difference was found between the intervention practices and usual care plus practices.

In **Chapter 5** (General Discussion) we discuss the context, results and consequences of our studies. We focused on the relevance of professional identity formation of NDPs, which is multidimensional and consists of the incorporation of five different roles: medication expert, clinician, professional, anticipator and broker. We reflect on the differences of role incorporation when working in community pharmacy.

The allocation of prescribing privileges would stimulate further professional development of NDPs. We argue that – despite the fact that the results of our studies did not find a strong support nor opposition about this topic - the clinical role and responsibilities of NDPs in the Netherlands should be expanded by allocating prescribing privileges. This is a logical consequence of further role development and clinical integration of NDPs in the primary care team. It does help to make better use of the expertise of NDPs and will contribute to a more efficient care process.

We explain why pharmaceutical care outcomes regarding medication-related hospitalisations did not differ in NDP and usual care plus practices. These explanations are related to the institutional setting, differences and similarities in professional identity formation, the high level of care coordination in usual care plus settings and also, the limited follow-up time of the study.

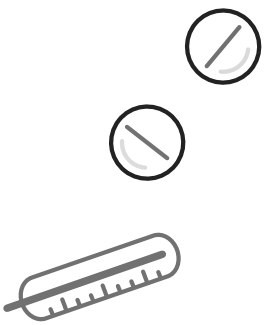
We reason that the different approach of clinical medication review performed by NDPs in general practice is possibly more effective, because of the setting, other (financial) incentives, better alignment to the patients' needs and providing follow-up.

Finally, we provide a practical approach containing seven recommendations for successful implementation of NDP-care in general practice: 1. Develop a job description, 2. Define responsibility, 3. Inform patients and other professionals about the role and responsibility of the NDP, 4. Provide office, ICT and administrative support, 5. Provide continuous training and feedback information, 6. Ensure adequate financing and 7. Ensure national adoption of NDP-care.

In conclusion, this thesis presents a series of both qualitative, quantitative and mixed-method studies about the training, implementation and clinical effects of NDPs in general practice. We have demonstrated that integration of NDPs improves pharmaceutical care and its outcomes. NDPs develop a professional identity as clinical care provider and can take integral responsibility for the patient's pharmacotherapy. NDPs improve the safety and effectiveness of pharmacotherapy in primary care. Therefore, NDP-care should be further implemented in general practice.

6.2

Samenvatting



Medicatie-gerelateerde morbiditeit en mortaliteit vormt een groot gezondheidsprobleem dat momenteel onvoldoende bestreden wordt. Met de vergrijzing van de bevolking zal dit probleem naar verwachting toenemen: oudere patiënten hebben vaak meerdere aandoeningen en gebruiken meerdere medicijnen, wat bijdraagt aan de complexiteit van farmacotherapie.

Aangezien de meeste medicatie in de huisartspraktijk wordt gestart of herhaald, kan de veiligheid en effectiviteit van farmacotherapie juist hier verbeterd worden. Uit onderzoek blijkt dat apothekers bijdragen aan veilige en effectieve farmacotherapie. Apothekers in openbare apotheken worden echter vaak belemmerd zich volledig te richten op farmaceutische patiëntenzorg. Wij verwachten dat de expertise van apothekers beter benut kan worden als ze volledig geïntegreerd in het multidisciplinaire team van de huisartsenpraktijk werken. Deze apotheker-farmacotherapeut kan dan de integrale verantwoordelijkheid nemen voor farmaceutische patiëntenzorg, zonder afgeleid te worden door logistieke of managementtaken. In de huisartsenpraktijk hebben apothekers volledige toegang tot het medische dossier van de patiënt. Verwacht wordt dat de samenwerking met huisartsen verbetert en daarmee de kwaliteit van farmacotherapie. Aanvullende training van apotheker-farmacotherapeuten op het gebied van klinische zorgverlening in de eerste lijn is een vereiste.

Daarom hebben we het POINT-model ontwikkeld (Pharmacotherapy Optimization through Integration of a Non-dispensing pharmacist in a primary care Team). De apotheker-farmacotherapeuten die binnen het POINT-model werkten hielden zich bezig met het optimaliseren van de farmacotherapie door zowel op patiënt- als op praktijkniveau extra farmaceutische zorgverlening te bieden die bijdraagt aan veilige en effectieve farmacotherapie.

Het doel van dit proefschrift is om de training, implementatie en klinische effecten van apotheker-farmacotherapeuten in de huisartspraktijk te evalueren. Dit proefschrift bestaat uit drie delen. **Hoofdstuk 2** beschrijft de achtergrond en integratie van apotheker-farmacotherapeuten in de huisartspraktijk. **Hoofdstuk 3** beschrijft het nieuw ontwikkelde trainingsprogramma voor apotheker-farmacotherapeuten en hun professionele identiteitsvorming. **Hoofdstuk 4** beschrijft de klinische effectiviteit van de interventie in vergelijking met de huidige modellen van farmaceutische zorgverlening in de eerste lijn in Nederland.

Achtergrond en processen van integratie

Hoofdstuk 2.1 beschrijft een systematische literatuurbeoordeling van 60 onderzoeken naar interventies die uitgevoerd zijn door apotheker-farmacotherapeuten in de huisartspraktijk. De literatuurstudie evalueerde hoe de mate van integratie van apotheker-farmacotherapeuten in de huisartspraktijk van invloed is op medicatie-gerelateerde gezondheidsuitkomsten. Het integratieniveau (niet, gedeeltelijk of volledig geïntegreerd) werd beoordeeld aan de hand van de volgende vijf dimensies: organisatorische, informatieve, klinische,

functionele en normatieve integratie. De literatuurstudie toonde aan dat meer integratie leidt tot betere gezondheidsresultaten, maar alleen voor de brede 'patiëntgerichte interventies'. Deze interventies hebben een holistische en uitgebreide benadering in vergelijking met 'ziekte-specifieke interventies', die meer geprotocolleerd zijn. De resultaten van het onderzoek suggereren dat volledige integratie van apotheker-farmacotherapeuten vooral gunstig is voor patiënten met meerdere aandoeningen en polyfarmacie.

Het introduceren van nieuwe professionele rollen in de gezondheidszorg, zoals de apotheker-farmacotherapeut, kan leiden tot controverse over de grenzen van het werkdomein van de diverse zorgverleners in een praktijk. Daarom vonden wij het essentieel om de consensus en controverses over de integratie van de apotheker-farmacotherapeut in de huisartspraktijk te ontrafelen en te begrijpen. *Hoofdstuk 2.2* beschrijft de resultaten van dit onderzoek waarin we een mixed-methode hebben gebruikt: Q-methodologie. Gebaseerd op gegevens van 163 belanghebbenden die stellingen rangschikten over de integratie van de apotheker-farmacotherapeut in de huisartspraktijk, kwamen we middels factoranalyse tot vier perspectieven: ''de zelfstandige openbaar apotheker'', ''de zelfstandige apotheker-farmacotherapeut'', ''de ondersteunende apotheker-farmacotherapeut '' en ''de specialist medicatie therapie-management''. Er was consensus onder de deelnemers over verschillende aspecten van de rol van de apotheker-farmacotherapeut, zoals betrokkenheid bij individuele patiëntenzorg en mogelijkheden in het verbeteren van therapietrouw. Er bestaat controverse over de mate van professionele zelfstandigheid van de apotheker-farmacotherapeut en diens taakinvulling. Deze Q-studie toont bereidheid onder belanghebbenden tot interprofessionele samenwerking.

In *Hoofdstuk 2.3* beschrijven we hoe klinische integratie het management van farmacotherapie beïnvloedt. Het doel van het onderzoek was om een systematische beschrijving te geven van wat het integreren van de apotheker-farmacotherapeut als lid van het eerstelijnsteam met zich meebrengt en hoe integratie zou kunnen bijdragen aan de management van farmacotherapie van patiënten. We hebben een theoriegerichte evaluatie uitgevoerd, gebaseerd op etnografische data die verzameld zijn door de apotheker-farmacotherapeuten die deelnamen aan het POINT-onderzoek. We beschrijven drie processen die van invloed zijn op het management van farmacotherapie door de apotheker-farmacotherapeut. Ten eerste leidt de specifieke expertise van apotheker-farmacotherapeuten in de huisartspraktijk tot oplossingen die afgestemd zijn op de individuele patiënt. Apotheker-farmacotherapeuten bouwden overtuigende en betrouwbare interprofessionele relaties op, opdat ze patiënten in de huisartsenpraktijk zelfstandig konden behandelen, in plaats van alleen huisartsen te adviseren over farmacotherapie. Ten tweede, de integratie van kwaliteitszorg in klinisch werk resulteert in het systematische inbedden van farmaceutische zorg in de praktijk. Ten derde, afstemming over de taakinvulling met praktijkverpleegkundigen leidt ertoe dat de apotheker-farmacotherapeut effectief kan worden ingezet bij patiënten zonder gestandaardiseerde zorgtrajecten.

Training en professionele identiteit

Openbaar apothekers zijn momenteel onvoldoende voorbereid om klinisch werk als apotheker-farmacotherapeut te doen, zeker omdat een rolmodel in de praktijk ontbreekt. Daarom hebben we een trainingsprogramma ontwikkeld, dat wordt beschreven in *Hoofdstuk 3.1*. Het trainingsprogramma van 15 maanden was gebaseerd op de principes van interprofessioneel werkplek leren, en integreerde praktijkervaring met plenaire opleidingsdagen. De 10 apotheker-farmacotherapeuten uit het POINT onderzoek waren de eerste die het trainingsprogramma volgden en het evalueerden. Het trainingsprogramma hielp de apotheker-farmacotherapeuten om de vereiste vaardigheden en klinische expertise te ontwikkelen, om als klinische zorgverlener te kunnen werken. De apotheker-farmacotherapeuten trainden en verbeterden hun vaardigheden op het gebied van patiënt-consultatie, klinisch redeneren en interprofessionele samenwerking. De training bood ook ondersteuning bij het definiëren en creëren van hun nieuwe rollen in de huisartspraktijk. Kortom, het trainingsprogramma bood apotheker-farmacotherapeuten mogelijkheden om van toegevoegde waarde te zijn in de huisartspraktijk.

Terwijl onderwijs zich vaak richt op het verkrijgen van kennis, competenties en vaardigheden, is de ontwikkeling van een professionele identiteit ook essentieel voor zorgverleners. Professionele identiteitsontwikkeling draagt bij aan toewijding en loopbaanduurzaamheid. De introductie van de apotheker-farmacotherapeut in de huisartspraktijk kan spanningen veroorzaken, maar biedt ook unieke leermogelijkheden. Deze "boundary crossing" leermogelijkheden tussen de apotheker-farmacotherapeut en de huisarts kan professionele identiteitsontwikkeling bevorderen. Daarom hebben we de professionele identiteitsontwikkeling bestudeerd van apothekers die de overstap maken van de openbare apotheek naar de apotheker-farmacotherapeut in de huisartspraktijk. *Hoofdstuk 3.2* beschrijft de resultaten van de meervoudige casestudy, inclusief interviews, peer-feedback en individuele reflectie. Via in-case en cross-case analyse, hebben we aangetoond dat de apotheker-farmacotherapeuten die de leermechanismen van reflectie en transformatie toepasten, een professionele identiteit ontwikkelden als patiëntgerichte, klinisch-farmaceutische zorgverlener die verantwoordelijkheid kan nemen voor de farmacotherapie van de patiënt. Sommige apotheker-farmacotherapeuten die voornamelijk leerden via het mechanisme van identificatie, integreerden geen nieuwe rollen in hun professionele identiteit. Ze ervoeren de werkplek als minder uitnodigend voor reflectie en transformatie. Een trainingsprogramma waarbij ruimte is voor reflectief en transformatief leren - zowel op de werkplek als met andere apotheker-farmacotherapeuten – draagt bij aan professionele identiteitsontwikkeling.

Klinische effectiviteit

In **Hoofdstuk 4** hebben we onderzocht of volledig geïntegreerde, getrainde apotheker-farmacotherapeuten de veiligheid en effectiviteit van farmacotherapie in de eerste lijn hebben verbeterd. In *Hoofdstuk 4.1* beschrijven we het design van de grootschalige

gecontroleerde interventiestudie die gericht is op de vergelijking van het aantal medicatie-gerelateerde ziekenhuisopnames in de interventiepraktijken en de huidige zorg in de eerste lijn. Het aantal medicatie-gerelateerde ziekenhuisopnames in de interventie praktijken werd vergeleken met de praktijken die gebruikelijke zorg verlenen en praktijken die 'plus' zorg verlenen. In de plus-praktijken hadden de openbare apothekers een landelijk gecertificeerde training gevolgd voor het uitvoeren van medicatiebeoordelingen. In dit hoofdstuk beschrijven we de methodologische beslissingen en uitdagingen om te bewijzen of integratie van een apotheker-farmacotherapeut in de huisartspraktijk zal resulteren in veiligere farmacotherapie.

Hoofdstuk 4.2 toont de resultaten van de observationele studie naar de acties en oplossingen van farmacotherapie problemen bij oudere polyfarmaciepatiënten in de eerste lijn. Op drie vooraf ingestelde datums verzamelden de apotheker-farmacotherapeuten gedetailleerde informatie over farmacotherapie problemen van de laatste tien patiënten die alle stadia van medicatiebeoordeling hadden voltooid. De apotheker-farmacotherapeuten identificeerden een mediaan van vijf farmacotherapie problemen per patiënt. Meer dan 80% van de aanbevelingen om de farmacotherapie van de patiënt te optimaliseren werd opgevolgd, meestal gericht op het stoppen van medicatie (31%). De interventies van de apotheker-farmacotherapeuten waren ofwel preventief (gericht op het volgen van profylactische richtlijnen) ofwel corrigerend (gericht op actieve patiëntproblemen). Bijna twee derde (64%) van de corrigerende interventies leidden tot het oplossen van het farmacotherapie probleem. We concluderen dat apotheker-farmacotherapeuten in de huisartspraktijk een groot aantal farmacotherapie problemen identificeren. De meeste interventies die de apotheker-farmacotherapeut voorstelt worden uitgevoerd en leiden vaak tot het oplossen van het farmacotherapie probleem.

In *Hoofdstuk 4.3* rapporteren we de resultaten van de interventiestudie naar medicatie-gerelateerde ziekenhuisopnames. De tien opgeleide apotheker-farmacotherapeuten voerden verscheidene diensten uit – zowel op patiëntniveau als op praktijkniveau – om de farmacotherapie te optimaliseren. In deze multicenter gecontroleerde interventiestudie identificeerden we 822 mogelijke medicatie-gerelateerde ziekenhuisopnames bij 11.281 hoog-risicopatiënten gedurende de interventieperiode (juni 2014 - mei 2015). Na correctie voor het aantal medicatie-gerelateerde ziekenhuisopnames op baseline (2013), clustering en mogelijke verstorende variabelen, was het gemiddeld aantal medicatie-gerelateerde ziekenhuisopnames in de interventieperiode 4,4% in de interventiegroep, 6,5% in de gebruikelijke zorg groep en 4,0% in de plus zorg groep. Het relatieve risico van medicatie-gerelateerde ziekenhuisopnames in de interventiegroep in vergelijking met gebruikelijke zorg was 0,68 (0,57 tot 0,82) en 1,05 (0,73 tot 1,52) in vergelijking met de plus groep. We concluderen dat in huisartsenpraktijken met een geïntegreerde apotheker-farmacotherapeut het risico op medicatie-gerelateerde ziekenhuisopnames lager is dan in praktijken waar gebruikelijke zorg wordt geleverd. Er werd geen verschil gevonden tussen de interventiepraktijken en de plus praktijken.

In **Hoofdstuk 5** (Algemene discussie) worden de context, resultaten en consequenties van onze onderzoeken besproken. We hebben ons gericht op de relevantie van professionele identiteitsontwikkeling van apotheker-farmacotherapeuten, die multidimensionaal is en bestaat uit de integratie van vijf verschillende rollen: medicijndeskundige, clinicus, professional, anticipator en bruggenbouwer. We reflecteren op de verschillen in het eigen maken van deze rollen tussen apotheker-farmacotherapeuten en openbaar apothekers.

Het hebben van voorschrijfbevoegdheid zou de professionalisering van de apotheker-farmacotherapeut stimuleren. We beargumenteren dat – ondanks dat dit in de resultaten van onze onderzoeken niet als belangrijk issue naar voren kwam – de klinische rol en verantwoordelijkheden van de apotheker-farmacotherapeut in Nederland moet worden uitgebreid met voorschrijfbevoegdheid. Dit is een logische vervolgstap in verdere rolontwikkeling en klinische integratie in het eerstelijnsteam. Voorschrijfbevoegdheid helpt om de expertise van apotheker-farmacotherapeuten beter te benutten en zal bijdragen aan een efficiënter zorgproces.

We hebben getracht te verklaren waarom de resultaten met betrekking tot medicatie-gerelateerde ziekenhuisopnames niet verschillen in praktijken met een apotheker-farmacotherapeut en zogenaamde plus-praktijken. Deze verklaringen hebben betrekking op de setting, verschillen in professionele identiteitsontwikkeling, de hoge mate van coördinatie van zorg in de plus-praktijken, en verklaarden we aan de hand van de beperkte follow-up tijd van het onderzoek.

We denken dat de uitvoering van medicatiebeoordelingen door apotheker-farmacotherapeuten mogelijk effectiever is door de setting waarin ze werken, andere (financiële) prikkels, betere afstemming op de behoeften van de patiënt en de mate waarin er sprake was van follow-up.

Tenslotte beschrijven we zeven praktische aanbevelingen die kunnen leiden tot succesvolle implementatie van de apotheker-farmacotherapeut in de huisartsenpraktijk: 1. Ontwikkel een functieomschrijving, 2. Definieer verantwoordelijkheid, 3. Informeer patiënten en andere zorgverleners over de rol en verantwoordelijkheden van de apotheker-farmacotherapeut, 4. Voorzie in spreekkamer, ICT en administratieve ondersteuning, 5. Maak continue training en feedback informatie beschikbaar, 6. Waarborg adequate financiering en 7. Zorg dat het zorgmodel van de apotheker-farmacotherapeut landelijk wordt aangenomen.

Samenvattend, dit proefschrift bevat zowel kwalitatieve als kwantitatieve onderzoeken over de training, implementatie en klinische effecten van de apotheker-farmacotherapeut in de huisartspraktijk. We hebben aangetoond dat dit model van geïntegreerde farmaceutische zorg de veiligheid en effectiviteit van farmacotherapie in de eerste lijn verbetert. Apotheker-farmacotherapeuten ontwikkelen een professionele identiteit als klinische zorgverlener en kunnen een integrale verantwoordelijkheid nemen voor de farmacotherapie van de patiënt. Op basis van de resultaten van de POINT-onderzoeken bevelen wij verdere integratie van de apotheker-farmacotherapeut in de huisartsenpraktijk aan.

6.3

Dankwoord

Eind 2013 begon mijn persoonlijke reis van openbaar apotheker naar apotheker-farmacotherapeut, en van onervaren onderzoeker naar gepromoveerd onderzoeker. Ook al heb ik met het afronden van mijn proefschrift deze bestemming bereikt, de reis gaat verder. Het POINT onderzoek heeft mijn enthousiasme en passie voor het vak van apotheker-farmacotherapeut, de mogelijkheden van interprofessionele samenwerking en wetenschappelijk onderzoek op dit terrein alleen maar verder aangewakkerd. Natuurlijk had ik deze bestemming niet bereikt zonder de hulp van vele anderen en ik wil jullie hier heel graag voor bedanken.

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Ankie Hazen
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List of publications

JOURNALS

Hazen ACM[Ω], Sloeserwij VM[Ω], Zwart DLM, de Bont AA, Bouvy ML, de Gier JJ, de Wit NJ, Leendertse AJ. Design of the POINT study: Pharmacotherapy Optimisation through Integration of a Non-dispensing pharmacist in a primary care Team (POINT). BMC Fam Pract. 2015 Jul 2;16:76.

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Keijsers CJ, Brouwers JR, de Wildt DJ, Custers EJ, Ten Cate OT, Hazen AC, Jansen PA. A comparison of medical and pharmacy students' knowledge and skills of pharmacology and pharmacotherapy. Br J Clin Pharmacol. 2014 Oct;78(4):781-8.

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Ω Contributed equally

PAPER PRESENTATIONS

Effects of non-dispensing pharmacists integrated in general practice on medication-related hospitalisations: results of the POINT study. Presented at the 46th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Heidelberg, Germany.

Het effect van een apotheker-farmacotherapeut in de huisartspraktijk op medicatie-gerelateerde ziekenhuisopnames [Effects of non-dispensing pharmacists integrated in general practice on medication-related hospitalisations]. Presented at the Nederlands Huisartsen Genootschap (NHG) Wetenschapsdag 2017 in Utrecht, the Netherlands.

POSTER PRESENTATIONS

The non-dispensing clinical pharmacists' needs in a clinical pharmacy training program. Presented at the 8th Pharmaceutical Care Network Europe (PCNE) working conference in Mechelen, Belgium.

Integration of a non-dispensing clinical pharmacist in primary care: design of the POINT intervention study. Presented at the 8th Pharmaceutical Care Network Europe (PCNE) working conference in Mechelen, Belgium.

Added value of the non-dispensing clinical pharmacist in primary care. Presented at the 43th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Copenhagen, Denmark.

Application procedure for non-dispensing clinical pharmacists in a primary care team. Presented at the 43th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Copenhagen, Denmark.

The non-dispensing clinical pharmacists' needs in a clinical pharmacy training program. Presented at the 43th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Copenhagen, Denmark.

Pharmacotherapy Optimization through Integration of Non-dispensing pharmacist in a primary care Team (POINT). Presented at the 43th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Copenhagen, Denmark.

A pharmacist in the GP clinic: the controversy about clinical pharmacy in primary care. Presented at the 43th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Copenhagen, Denmark.

Changing the skill mix in pharmaceutical patient care: the introduction of clinical pharmacists in general practice. Presented at the 43th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy in Copenhagen, Denmark.

BOOK CHAPTERS

Mok L, Wenning H, de Vries I. (2016) Handboek POH-GGZ. Samenwerking met de apotheker-farmacotherapeut (pp.33-34) in hoofdstuk 2 De kunst van samenwerking. Bohn Stafleu van Loghum, onderdeel van Springer Media BV. Houten, the Netherlands.

Mok L, Wenning H, de Vries I. (2016) Handboek POH-GGZ. Afbouwen antidepressiva (pp. 160-165) en Afbouwen benzodiazepinen (pp. 166-169) in hoofdstuk 6 Methode, methodiek en interventies. Bohn Stafleu van Loghum, onderdeel van Springer Media BV. Houten, the Netherlands.

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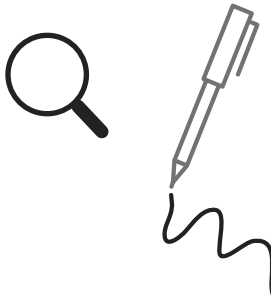
About the author



Ankie Hazen was born on April 6th 1983 in Bergen op Zoom, the Netherlands. After graduation from secondary school Gymnasium Juvenaat, she studied Dutch language and culture at Utrecht University. After obtaining her Propedeuse cum laude in 2001 she switched to study Pharmacy at the same university. She obtained her Bachelor cum laude in 2005. Before starting her Master, she was a one year full-time member of the Utrecht Pharmaceutical Student Association. In 2009, she obtained her Master in Pharmacy. As part of her master she was involved in a 6-month research internship at the School of Pharmacy in London, within the department of Practice and Policy.

She was a university teacher at the Utrecht Institute for Pharmaceutical Sciences, within the division of Pharmacoepidemiology & Clinical Pharmacology until 2013. She obtained her Qualification for Academic Teaching (Basis Kwalificatie Onderwijs) in 2011. She combined her work as university teacher with a position of out-of-hours pharmacist in Amsterdam Oost (until 2012) and community pharmacist at the Loosdrechtse Apotheek in 2013. Given her specific interest in pharmacotherapy and clinical medication review, she participated in a national certified training in performing medication reviews (Periodieke Individuele Analyse Pharmacotherapie, PIAF).

She started working as a PhD-candidate on the POINT study as described in this thesis at the Julius Center for Health Sciences and Primary care, University Medical Center Utrecht in close collaboration with Dr. Anne Leendertse. She was supervised by Prof. dr. Marcel Bouvy, Prof. dr. Niek de Wit, Prof. dr. Antoinette de Bont and Dr. Dorien Zwart. During her work as researcher, she also worked as non-dispensing pharmacist in Julius Gezondheidscentrum Vleuterweide. She participated in the 15-month dual training program about primary care based clinical pharmacy, which was newly developed within the POINT study and described in this thesis as well. Since 2017, the author is a member of the Research Committee of the European Society of Clinical Pharmacy.

Ankie lives in Utrecht with Tom and her children Felien and Max. They will move to London in February 2018 where she hopes to further continue her research and educational work on non-dispensing pharmacists in general practice.