# BIG issues

Evaluation of the effects of granting legal authority to Dutch Nurse Practitioners and Physician Assistants to independently perform reserved medical procedures

**Daisy De Bruijn-Geraets**

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# Chapter 1

## General introduction

## Background

Similar to most industrialized countries, the Netherlands are facing a growing imbalance between healthcare demand and supply, which puts pressure on the nation's goal to ensure broad access to high quality and affordable healthcare.

Key determinants of the increasing healthcare demand are a high population growth and rapidly changing demographics. Over the past 25 years the Dutch population has grown by 13.5% to more than 17 million. [1] In addition, people are living much longer, as death toll falls from major diseases. The average life expectancy at birth has risen from 80.1 in 1990 to 83.1 years in 2016 for women and from 72.7 to 79.9 years for men. [2] These extra years of life are not often spent in good health. In 2016, only 40.8 and 46.8 years of the average life expectancy respectively in women and men are without chronic conditions. [2] Chronic conditions are not only common among elderly, but are increasingly observed in all age groups, mostly as a consequence of an unhealthy lifestyle: 10.1% of the Dutch population is obese, 12.4% is a heavy drinker and 23.2% is smoker (2010-2013). [3] Chronic conditions have now replaced acute diseases as major cause of illness, disability and death and account for most of the healthcare expenditures. [4, 5] By its nature, chronic care is prolonged and when personalized (including control, clinical care, self-management support, education and adherence policies), very labour-intensive. [6, 7]

Furthermore, technical advances in medicine can also have an upward effect on healthcare demand, especially when a new technology supplements existing treatment. [8] With the rise of technology, patient's expectations also change. Patients seeking for treatment are exposed to a constant flow of new services they expect to have access to, preferably without delays.

The ever-increasing caseload of the growing, older, sicker, and more demanding population inevitably leads to an increasing need for healthcare providers. It is calculated that, to respond to the increasing healthcare demand, 400.000 additional health professionals over 15 years, are needed in Dutch healthcare. [9] However, during the last 25 years the number of live born children has fallen by a quarter and is expected to decrease further. [10] This is referred to as dejuvenation. As a consequence of both aging and dejuvenation, the "grey pressure", i.e. that is, the ratio between the elderly to the working population (65+ as % of 20-65), is expected to double in the next 25 years to 50.9%. [11]

Though additional health professionals are needed, fewer people are available to meet the growing demand for healthcare. Strategies to decrease the demand for healthcare focus on health education and prevention of diseases. [12, 13] Strategies to increase the workforce focus on recruitment and retainment of care providers, efficient use of care providers time supported by technologies and telemedicine tools, and relevant here, on optimal, efficient use of skills and competences. [12, 13] For example, 70%-80% of the physicians are over-qualified for some of their tasks. [13] For over 20 years, an international strategy for achieving an efficient use of skills, and above capacity problems, is task shifting. [14]

**Task Shifting**

Task shifting refers to the structural redistribution of tasks between various professions with the aim to efficiently use their competences and overall capacity. [14, 15] Differently and shorter trained professionals take over tasks from the higher educated, whilst maintaining or increasing quality of care for patients. [14]

In fact, this is one of the four forms of task shifting, namely (vertical) substitution. Substitution concerns the transfer of tasks with associated authorities between types of professions. [16] Whereas vertical substitution comprises the substitution of tasks to professionals with a lower educational level, horizontal substitution refers to substitution of tasks to professionals with a comparable educational level (e.g. from general practitioner to internist). Another form of task shifting is delegation. In this case, the performance of tasks is transferred to less educated health professionals, but the authorities stay with the person delegating the task(s). Direct supervision of a physician with the possibility to intervene is at all times required. [16] In this context, the term “extended arm structure” (in Dutch: verlengde arm-constructie) is often used, but this is in fact no longer legally correct. The final form of task shifting is role enhancement; this involves the extension of tasks and skills without crossing professional domains, and innovation, where a new type of professional is introduced. [16]

Next to the intended efficient use of resources and equal or improved quality of care, possible additional beneficial factors of task shifting are improved access to and continuity of care [17], providing an interprofessional skill mix in chronic disease management again resulting in improved quality of care [18, 19], limiting the escalation of costs in healthcare [20, 21], ensuring a sustainable workforce of physicians [22, 23], and advancing the careers of health professionals.

A major step towards enabling task shifting was the development of new professions, properly equipped and capable of taking over tasks of physicians. Two of those professions are the nurse practitioner (NP) and the physician assistant (PA).

**Nurse practitioners and physician assistants**

Since the early years of this century, NPs and PAs are active in Dutch healthcare and nowadays, over 3.000 NPs and 1.000 PAs are employed in hospitals, general practitioners' practices, mental healthcare institutions, rehabilitation centres, nursing homes and other healthcare facilities. [24]

NPs are nurses with higher professional education (Bachelor of Nursing), who have followed the 2-year dual study Master Advanced Nursing Practice (MANP). Currently, there are five graduation profiles (specialisms): acute care, chronic care, intensive care, mental care and preventive care but it is expected that after an ongoing evaluation, this classification will not be maintained. A PA holds a diploma of Master Physician Assistant (MPA). To be admitted to the 2.5-year dual MPA study, a nursing or paramedical pre-education at higher professional level is required. The MANP program is offered by nine universities of Applied Science, the MPA program by five. All 14 master study programmes are accredited by the NVAO (The Accreditation Organisation of the Netherlands and Flanders). To meet a growing need for task shifting, the total number of traineeships rose by 75% in 2013 to 700. [25]

After graduation, NPs must register in the specialist register (in Dutch: Register Specialismen Verpleegkunde) and the register of the Individual Health Care Professions Act (IHCP register, in Dutch: BIG register) to call themselves "verpleegkundig specialist". In 2009, this legally protected title officially replaced the previously used nurse practitioner title, but in international literature (and this manuscript), there still is mention of the term NP. Both professions are deployed to take over tasks from physicians. Whereas PAs clearly operate in the medical domain, NPs combine "care" and "cure" and are found at the cutting edge of the nursing and medical domain. PAs take over tasks for all patient groups within a medical specialism, NPs work with a well-defined group of patients. [26, 27] This involves both tasks in (in)direct patient care like consultations, visits, case management and file-keeping, as well as not patient related tasks like development of integrated care, quality improvement programmes and protocols; training of other healthcare providers and management tasks. [28] Generally, NPs spend more time on the latter, compared to PAs. [28]

In direct patient care, within the agreed working domain, NPs and PAs independently come to a (differential) diagnosis based on self-initiated anamnesis, physical and/or psychiatric examination and additional diagnostics and apply evidence-based interventions. [28-30] Both professions can form an individual independent treatment relationship with a patient and can under certain conditions act as the responsible care provider. [28] If in doubt, they can call upon a physician (in case of a PA, a supervisor) to seek for advice. However, in performing certain medical procedures, NP's and PA's autonomy as well as their optimal use (and thus task shifting) is hampered by the legal obligation to obtain a physician's consent to this. In daily practice, this stringent authorising requirement is experienced as obstructive. To offset this situation, the Dutch Ministry of Health has taken measures to relax the requirements, through amending the Individual Health Care Professions Act (IHCP Act, in Dutch: Wet op de Beroepen in de Individuele Gezondheidszorg (Wet BIG)).

**IHCP Act**

The IHCP Act, made executive in 1997, seeks to monitor and promote the quality of professional health practice and to ensure patient safety, by providing regulations for healthcare professions.

One of the instruments is title protection for certain healthcare professionals. Eight principal professions are included under Article 3: physicians, dentists, midwives, pharmacists, nurses, physiotherapists, clinical psychologists and psychotherapists. Practitioners of these professions are eligible to enter the IHCP register when they meet the legal educational requirements governing their profession. Registration gives the right to use the professional title. The title of NP (in Dutch: verpleegkundig specialist) is legally regulated in accordance with article 14, in which all specialist professions are regulated. Registration in the IHCP register is regulated in Article 3 because of the nursing background. Contrary to the NP function, the PA function is not included in the IHCP register. The National Association of Physician Assistants (NAPA) has therefore opened up a separate quality register. [31] In 2013, 85% of the PAs are registered in this non-compulsory register. [32] Titles of other professions such as dieticians, occupational therapists and radio diagnostic technicians are protected through Article 34, where educational requirements and area of competence are also defined. However, they do not have to enter a register.

Another quality instrument is medical disciplinary law. All Article 3 professions are subject to disciplinary jurisdiction. Direct stakeholders (including patients and the Healthcare Inspectorate) can file complaints, when suffering damage caused by injury (or death) due to the actions of (Article 3) professionals.

Finally, the IHCP Act has defined certain medical procedures which pose major unacceptable risks if performed incorrectly, so that they are reserved to certain health professions. These so-called reserved procedures consist of 14 clusters of procedures and are stated in article 36 of the IHCP Act. These reserved procedures are (*Italic* in Dutch):

- Artificial insemination *(kunstmatige fertilisatie);*
- Cardioversion *(cardioversie);*
- Catheterisation *(katheterisatie);*
- Defibrillation *(defibrillatie*);
- Electroconvulsive therapy *(electroconvulsieve therapie);*
- Endoscopy *(endoscopie);*
- General anaesthetic *(narcose);*
- Injection *(injectie);*
- Lithotripsy *(steenvergruizing);*
- Obstetric procedures *(verloskundige handelingen);*
- Prescribing *(voorschrijven)* (also controlled by the Medicines Act);
- Procedures involved in the use of radioactive substances and ionising radiation *(het gebruik van radioactive stoffen en ioniserende straling);*
- Punctures *(puncties);*
- Surgical procedures *(heelkundige handelingen).*

The IHCP Act (Article 36) distinguishes between health professionals who have direct authorisations (i.e. physicians, dentists and midwives) to indicate, perform and delegate reserved procedures within their field of expertise and those who may, under certain conditions, perform the procedures on the orders of those with direct authorisation. The purchaser must verify if the contractor is competent to perform the procedures correctly. The contractor, in turn, must consider him/herself competent and act according to the instructions of the purchaser (Article 35). Supervision and intervention must be possible in cases where this is reasonably required (Article 38). In emergency situations, the reserved procedures regulations

are not applicable. If the reserved procedures regulations are not adhered to, involved professionals are punishable by law.

In the 2009 report 'Reserved procedures hold against the light' (in Dutch: 'Voorbehouden handelingen tegen het licht'), the reserved procedures regulation was evaluated from the need to advance task shifting and it was concluded that the authorisation requirements lack the necessary flexibility. [33] It was recommended to include an experiment article in the IHCP Act, giving professions the opportunity to independently perform certain reserved procedures. This principle is further developed in Article 36a, which merely dictates that new professions and associated reserved procedures have to be set in separate Orders in Council. Orders in Council are valid for a period of 5 years and subject of evaluation. In the experimental period, Article 36a professions have a legally based, protected title, cannot enter the IHPC register and are subject to disciplinary jurisdiction with limited measures.

The proposed legalisation was approved in November 2011. The first new Orders in Council have become effective in January 2012 and relate to NPs and PAs. [34, 35]

**Independent rights for NP and PA**

Through the Orders in Council, NPs and PAs have been granted independent rights to indicate, perform and delegate the reserved procedures catheterisation, cardioversion, defibrillation, endoscopy, injection, puncture and simple surgical procedures, and to indicate and perform prescribing prescription-only medicines. The bounds of authority are determined by the education, the area of competence and the own competence. The expanded authority is also restricted to medical procedures of limited complexity, routinely by nature and subject to manageable risks. Besides that, NPs and PAs must work according to guidelines which also contain cooperation agreements with other disciplines. PAs have independent rights for all above procedures. The authority of NPs is specified by specialism (Table 1.1). NPs Acute care and NPs Intensive care have the same independent rights as PAs. The same applies to NPs chronic care, except for cardioversions and defibrillations. NPs Preventive care have the lowest expanded authority, they can independently inject and prescribe, NPs Mental care can also independently perform punctures and defibrillations.

**Table 1.1** Independent rights for NPs and PAs by reserved procedures

| | Catheterisations | Cardioversions | Defibrillations | Endoscopies | Injections | Prescribing | Punctures | Small surgical procedures |
|---|---|---|---|---|---|---|---|---|
| NP Acute care | x | x | x | x | x | x | x | x |
| NP Chronic care | x | - | - | x | x | x | x | x |
| NP Mental care | - | - | x | - | x | x | x | - |
| NP Intensive care | x | x | x | x | x | x | x | x |
| NP preventive care | - | - | - | - | x | x | - | - |
| PA | x | x | x | x | x | x | x | x |

x = independent rights

\- = no independent rights

**International comparison of NPs/PAs independent practice on processes and outcomes**

It is estimated that in approximately 70 countries some form of NP/APN roles exists or is being explored. [36] In the USA, NPs have a presence in 50 states. The PA profession is not yet as widespread as its NP counterpart. Following USA, PA programs are offered in Afghanistan, Australia, Canada, Germany, Ghana, India, the Netherlands, Saudi Arabia, Scotland, South Africa, United Kingdom and Taiwan. [37] Besides, several countries like Ireland, Rwanda and Thailand are utilizing US trained PAs in pilot programs. [37] Notwithstanding, a lack of clarity and consistency on their roles exists, most probably because NPs and PAs work in a broad range of settings, from primary care to secondary care and from major hospitals to ambulatory care facilities. This is seen within and between countries. [37-47]

The scope of practice for NPs varies by country from full practice authority, i.e. fully independent practice without any contribution of a physician, to restricted practice requiring physician oversight on all care provided by a NP. [48-50] The variation in practice authority tends to be reflected in the closely linked prescriptive authority. In Australia, Canada, Finland, Ireland, Netherlands, New Zealand, Norway, South Africa, Sweden, United Kingdom and USA, (advanced) nurses are legally authorized to prescribe. [51-55] Again, the prescription authority varies greatly from one country to the next, ranging from fully independent prescription with an extensive formulary to prescription under the supervision of a physician with a limited formulary. [52-58] Little is however known about PA regulations and authorities. The

legal status of PAs is often not yet resolved, resulting in limited authorities. [59] The common denominator seems to be that PAs, as physician extenders, work under supervision of physicians and rarely practice independently. [50, 60-64] Full PA prescriptive authority has been introduced in Australia and the Netherlands. [61] In the USA, the cradle of PAs, all but one state allow PAs to prescribe any controlled substances, six states only grant PAs partial prescriptive authority. [63]

The independent performance of medical procedures by NPs and PAs as part of practice authority is rarely specified in regulations. In literature, various illustrations of, to a greater or lesser extent, independent performance of medical procedures can be found in different settings in Australia, United Kingdom, and USA, like abdominal drainage, biopsy, bronchoscopy, cardioversion, chest tube insertion or removal, endoscopy, fine-needle aspiration, placement of (pulmonary) arterial or (peripherally) central catheter, placement of extra ventricular drain, intravitreal/joint/carpal tunnel injection, lumbar puncture, paracentesis, sedation/anaesthesia**,** thoracentesis, removal of intracranial pressure monitor, and thoracotomy. [61, 64-74]

There is a growing, though insufficient, body of evidence, based on systematic reviews, showing that NPs provide quality of care at least equivalent to physicians with respect to clinical outcomes, satisfaction, treatment adherence, patient safety, and use of specialist care. [74-84] There are some indications, based on observational studies, that PAs can have a similar or favourable effect on continuity for patients and hospital staff, lengths of stay, patient satisfaction, adverse events, readmissions and mortality compared to physicians. [84-88] Regarding efficiency aspects, no conclusive scientific evidence is available yet, because of a limited number of studies with contradictory results and methodological weaknesses; all recommending that further research is required. [74-77, 81, 87, 89] Moreover, a direct comparison between studies on quality of care or efficiency aspects is hampered by the fact that studies fail to take account of NPs/PAs degree of independence (from complete independence to working under supervision), nor any changes thereto over time.

Therefore, high-quality studies are needed measuring the causal effects of changed NP's/PA's independent practice on processes and outcomes of healthcare.

**Mixed methods**

Currently, there is a strong movement towards the use of both quantitative and qualitative data in establishing causal relationships. [90-94] Qualitative data are especially important for exploration and providing in-depth understanding of the causal chain with a broad focus on the context. Quantitative methods are important for confirmation of the hypothesis and for generalizing findings with a narrow focus on potential causal explanations. [90] Where both quantitative and qualitative methods are used in one study, this is referred to as a mixed methods study. [95] The main benefit of a mixed methods design is the possibility of triangulation. Triangulation facilitates validation of data through combination, integration and cross verification of multiple approaches (data sources, methods and theories) to examine the same phenomenon. [96]

With a mixed methods design, applying triangulation of quantitative and qualitative methods, it is therefore deemed most opportune to evaluate the causal effects of independent practice on processes and outcomes of care.

**This thesis**

As referred above, the Orders in Council for NPs and PAs working in Dutch healthcare are valid for a period of 5 years and are subject of evaluation. This thesis describes this national evaluation, as commissioned by the Dutch Ministry of HWS. The objective of the evaluation was to systematically evaluate the effects of granting independent rights to NPs and PAs on the processes and outcomes of care. This evaluation study aims to support the Ministry in the policy making and decision forming process regarding the continuation or otherwise of the independent rights of NPs and PAs, as formulated in the Orders of Council. In addition, as this is the first evaluation study within this context, it offers a model for evaluation in other countries as well as data for cross national comparison.

The full set of findings stemming from this evaluation have been described in the report “voorBIGhouden” and were presented to the Minister of Health, Welfare and Sport in November 2015. [97] This thesis contains the main study’s findings.

Chapter 2 in this thesis, describes the protocol of the evaluation, characterised by an innovative mixed methods design with triangulation. Structures, processes and outcomes are selected from evidence-based frameworks and models. The various subjects of the evaluation have been addressed in Chapters 3, 4 and 5.

In Chapter 3 attention is paid to the theme “safety”. Disciplinary rulings can give some information about the circumstances under which the quality of care was at stake in an individual case. For this purpose, disciplinary rulings against NPs and PAs, performing the previously mentioned reserved procedures, are analysed. In addition, important quality and safety elements when indicating and performing these reserved procedures are examined by retrospectively analysing disciplinary rulings against all health care providers. This offers a general picture of the factors to be taken into account when developing legislation on independent authorities.

In the evaluation many themes are subject of investigation. In Chapter 4, a hierarchy of these themes (in this chapter referred to as requirements) is established and described. This is to facilitate informed decision making on whether the temporary authorities of NPs and PAs should be continued

Chapter 5 shows the effects of the law amendment on NP’s and PA’s practice authority.

Finally, in Chapter 6 we summarize the main findings as described in the chapters, considering some important strengths and limitations. Then, we elaborate on the current legal framework being task-shifting proof or not. The chapter closes with recommendations for policy makers, healthcare practice and future research.

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# Chapter 2

## Evaluating newly acquired authority of Nurse Practitioners and Physician Assistants for reserved medical procedures in the Netherlands: a study protocol

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## Abstract

**Aim**

The study protocol is designed to evaluate the effects of granting independent authorisation for medical procedures to nurse practitioners and physician assistants on processes and outcomes of healthcare.

**Background**

Recent (temporarily) enacted legislation in Dutch healthcare authorises nurse practitioners and physician assistants to indicate and perform specified medical procedures, i.e. catheterisation, cardioversion, defibrillation, endoscopy, injection, puncture, prescribing simple surgical procedures, independently. Formerly, these procedures were exclusively reserved to physicians, dentists and midwifes.

**Design**

A triangulation mixed method design is used to collect quantitative (surveys) and qualitative (interviews) data.

**Methods**

Outcomes are selected from evidence-based frameworks and models for assessing the impact of advanced nursing on quality of healthcare. Data are collected in various manners. Surveys are structured around the domains: I) quality of care; II) costs; III) healthcare resource use and IV) patient centeredness. Focus group and expert interviews aim to ascertain facilitators and barriers to the implementation process. Data are collected before the amendment of the law, 1 and 2.5 years thereafter.
Groups of patients, nurse practitioners, physician assistants, supervising physicians and policy makers all participate in this national study. The study is supported by a grant from the Dutch Ministry of Health, Welfare and Sport in March 2011. Ethical approval was obtained in July 2011.

**Conclusion**

This study will provide information about the effects of granting independent authorisation for medical procedures to nurse practitioners and physician assistants on processes and outcomes of healthcare. Study findings aim to support policy makers and other stakeholders in making related decisions. The study design enables a cross-national comparative analysis.

## Introduction

Enhancing the role of allied healthcare professionals, such as nurse practitioners (NPs) and physician assistants (PAs), is often cited as a solution to improve the balance between the increasing demand for care and the decreasing supply of medical healthcare professionals. [1, 2] Possible additional beneficial factors of NPs and PAs are improving access to and continuity of care [3], providing an interprofessional skill mix in chronic disease management resulting in improved quality of care [4], limiting escalating costs in healthcare [5, 6], ensuring sustainable workforce of physicians [7] and advancing the careers of allied health professionals. The NP and PA professions originate from the USA in the mid-1960s, followed by the UK in the 1990s. In both countries, the introduction of these professions was mainly determined to address physician shortages. After the turn of the century, there has been an expansion of both professions in most Western European and Anglo-Saxon countries. [8]

Although their number and influence increase, the evidence that the contribution of these non-physicians leads to healthcare (cost) efficiency is rather weak. A systematic review showed conflicting results. [9] Moreover, the included studies in this review were all conducted in the US and the UK and many were more than 10 years old. Generalizing results to other countries, with different healthcare systems and where the implementation of NPs and PAs is in the full throes of development, is extremely hard. Given the widespread and growing interest for NPs and PAs, the need for up to date, high quality research in other countries than the US and UK, enabling cross-country comparison, is evident.

### Background

In the Netherlands, the first NPs and PAs made their appearance in 2001 and 2004, respectively. Both introductions were driven by task reallocation in distinctive domains (Council for Public Health and Health Care, 2002). NPs focus on broadening activities in the medical domain within selected groups of patients and simultaneously on deepening activities in the nursing domain. PAs focus on broadening and deepening activities in the medical domain, within their medical specialty. Both professions work at a master's degree level.

More recently, the Dutch Ministry of Health, Welfare and Sport has taken two measures which allow NPs and PAs to reach their full potential. First, the capacity of the joint NP and PA training places is structurally expanded with 75% to 700 places

in 2013. Second, by broadening national legislation a more efficient usage of NPs and PAs is supported. Until recently the Dutch Individual Health Care Professions Act (IHCP Act, in Dutch Wet BIG) ruled that the performance of specified medical procedures, so-called reserved procedures, was reserved to health professionals who have direct authorisations within their field of expertise (i.e. physicians, dentists and midwifes) and to those who may, under certain conditions, perform the procedure on the orders of those with direct authorisation. In daily practice however, the stringent authorising requirement is experienced as particularly obstructive by NPs and PAs and therefore hampers optimal task reallocation as well as optimal use of NPs and PAs.

Due to the addition of section 36a in the IHCP Act in March 2011, a (temporally) legal basis has come into existence where new professions can be granted rights to independently perform reserved procedures. The new professions and the specific reserved procedures should be established in separate Orders in Council. The first Orders in Council (January 2012) relate to NPs and PAs. Defined procedures are: catheterisation, cardioversion, defibrillation, endoscopy, injection, puncture, prescribing prescription-only medicines and simple surgical procedures. These Orders in Council are valid for a period of 5 years and subject of evaluation.

## The study

### Aims

This protocol describes a study which aims to systematically evaluate the effects of granting independent rights to NPs and PAs on the processes and outcomes of care, with regard to each reserved procedure within the framework of the Dutch IHCP Act. The research questions of this study are: to what extent do processes and outcomes of care change after acquirement of the above-mentioned independent rights and, if changes occur, for which reserved procedures is this the case?

### Collaborating organizations

The study is commissioned by the Dutch Ministry of Health, Welfare and Sport (March 2011) and supported by the professional organisations Nurses and Carers Netherlands department for nurse practitioners (NCN NP, in Dutch V&VN VS), National Association of Physician Assistants (NAPA) and the Royal Dutch Medical Association (RDMA, in Dutch KNMG).

**Design**

This study has a mixed method design [10] with concurrent phasing of a quantitative and a qualitative part, both of equal importance (triangulation) to increase the validity and credibility of the evaluation. [11]

To measure changes in processes and outcomes, quantitative data will be collected by means of an one group, pretest and posttest design [12, 13] with three measurements: before the Orders in Council came into force, 1 and 2.5 years thereafter. Qualitative data will be collected through semi-structured in-depth expert interviews and focus group interviews up to 1 year after the law amendment. The emphasis here lays on exploration of existing barriers and facilitators that affect the performance of NPs and PAs in performing reserved procedures.

**Quantitative research**

*Framework*

The quantitative part of the study is based on the conceptual framework of Sidani and Irvine [14], initially developed for evaluating the NP role in acute care (Figure 2.1).

This framework is based on a wider framework for advanced nurses [15] complemented by Donabedian's model for assessing healthcare quality based on structures, processes and outcomes. [16] The framework with minor adaptions has been applied before, by Dierick-van Dale *et al*. in a study on the value of NPs in Dutch general practices. [17]

The major propositions of this model are [16]:

- the effects of structures on processes represent the influence of patients' variables, NP characteristics and organizational variables on the different roles of NPs;
- the effects of structures on outcomes are mainly limited by patient characteristics, such as the severity of illness;
- the NP roles affect the outcomes in terms of quality of care and costs.

It is presumed that the model can be widened for evaluating NP roles as well as PA roles, regardless of the setting they work in. Following from this, the quantitative part of our study is structured around four domains: quality of care, costs, use of care professionals and patient centred care. Table 2.1 shows the domains with the subdomains and their operationalization into outcome measures.

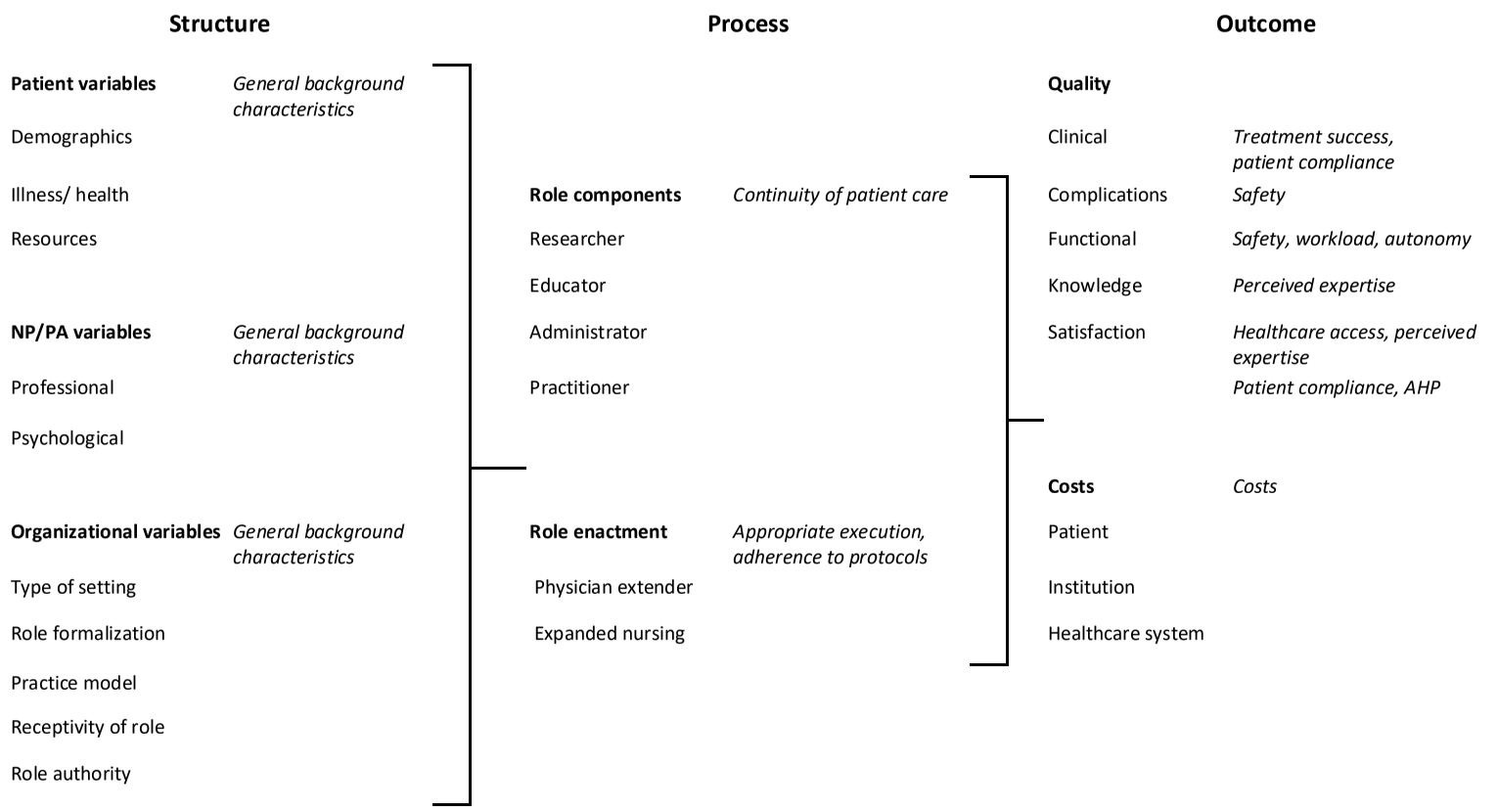


**Figure 2.1** Framework for evaluation and measurement outcomes

**Table 2.1** Domains with the subdomains and the operationalization into outcome measures

| Subdomain | Level | Operationalization | Number of questions |
|---|---|---|---|
| | | *Quality of Care* | |
| Appropriate execution | Caregiver | Monthly performance of specified reserved procedures and authorisation mode. For prescribing medicines: distinction between new, refill and change in dosage prescriptions; name and dosage of the drug, for injections: distinction between joints, tendon sheaths and keloids; administration of sclerotherapy; administration of local anaesthetics; intramuscular, intravenous, subcutaneous and intracardiac injections and also name and dosage of the drug | 61 |
| Adherence to protocols | Caregiver | Presence, contents an enforcement of protocols [18] | 7 |
| Safety | Caregiver | Establishment of competence [19], availability of supervising physicians, satisfaction about this, frequency and mode of consultations, review of prescribing [18] and delegation of reserved procedures to other health professionals | 18 |
| Workload | Caregiver | Subjective: McCranie's job satisfaction scale [20, 21], 10 points satisfaction score; 5-point Likert scale on workload [22] and hectic work.<br>Objective: number and duration of patient contacts, distribution of total working hours [17], number overtime hours, number of workdays | 26, 7 |
| Autonomy | Caregiver | 5-point Likert scale on extent of controlling the own work [22] | 10 |
| Healthcare access | Patient | 10-points score on satisfaction with the perceived treatment, recurrence to same care giver, preference for NP/PA or physician | 3 |
| Treatment success | Patient | Subjective: contribution of perceived treatment to health, for surgical procedures: Global Perceived Effect [23], for prescribing medicines: presence of and adaption to adverse events | 4 |
| Patient compliance | Patient | Satisfaction about comprehensibility of advice, instructions and treatment prognosis. For prescribing medicines: Satisfaction with Information about Medicines Scale (SIMS) [24] | 10 |
| Safety | Patient | Perceived complications | 4 |
| | | *Costs* | |
| - | Caregiver | Duration specific reserved procedure included consultation and process time, number and duration of inter collegial consultation (to be linked to hourly tariff) | 61 |
| | | *Utilization of care* | |
| Continuity of patient care | Patient | Contact frequencies between patient and health professionals involved in the care and treatment process, split up into care setting; patient satisfaction about time until follow-up appointment and consultation time | 6 |
| Perceived expertise | Patient | Satisfaction about perceived expertise | 3 |
| | | *Patient centred care* | |
| - | Patient | Satisfaction about waiting time, treatment by NP/PA, for surgical procedures: pain control, AHP | 4 |
| | | *General background characteristics* | |
| - | Caregiver | Job title, specialism, age, gender, education, years of experience, care setting and presence of collaborating physicians | |
| - | Patient | Gender, age, ethnicity, education composition household, EuroQol-5D [25] | |

*Survey*

Three different questionnaires, one for patients, one for NPs/PAs and one for supervising physicians, are developed to collect general background characteristics (i.e. age, gender, job title, specialism, years of experience and care setting) and data regarding: adherence to protocols, safety, workload, autonomy, healthcare access, patient compliance, continuity of patient care and quality of healthcare. Furthermore, the caregiver questionnaires address questions related to the practices in the execution of reserved procedures. A list of 61 specified reserved procedures is presented (Figure 2.2) and participants are asked to estimate the monthly performance, if appropriate to report whose authorisation is required, if consultation with a supervisor is needed and the procedure of the given orders (authorisation method). To determine cost effectiveness, the (additional) contact frequency between PA or NP and patient, the number of peer-reviewed consultations with a physician that are needed, the amount of extra time as a result of not having direct authorisation are linked to provisions of services and hourly tariffs.

*Analytic Hierarchy Process method*

The processes and outcomes reflected in the four domains are all relevant criteria in deciding whether to grant independent authority to NPs and PAs or not. To weigh and rank the mutual importance of these criteria, a data collection and analysis method is needed to expose the decision-making process. The Analytic Hierarchy Process (AHP) method, developed by Saaty [26], is particularly suitable for this purpose. The applications of the AHP are numerous and its value is already recognised in industrial and governmental settings and is expanding in healthcare. [27] Key step in the AHP method is to structure hierarchy by identifying criteria and sub-criteria relevant for the decision-making process. The relative importance of five criteria is investigated (Table 2.2).

Weights of criteria are achieved by 26 pairwise comparisons between (sub, sub-sub) criteria with each other at each level. Preferences are recorded on a 9-point ordinal scale, ranging from 1 (indicating equal importance of the two criteria) - 9 (extremely greater importance of one criterion over the other).

The AHP method is integrated in the questionnaires. For patients, the questions are simplified, an extensive explanation of terms is given and the preference scale is reduced to a 5-point scale. In total, 25 NPs and PAs filled in both the patient version and the questionnaire for caregivers. Data are compared to validate the results.

| **Response categories authorisation method:** | | | | | | |
|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** |
| On **order** of a **physician**, according to a **protocol** | On **written order** of a **physician** | On **oral order** of a **physician** | On **own initiative**, **with consultation** of a physician | On **own initiative, without consultation** of a physician | On **own initiative**, **delegation** to: …… | Other, namely: …… |

| **Catheterisation** | **Number of procedures per month** | **Authorisation method (1-7)** | **Duration of a single procedure (minutes)** |
|---|---|---|---|
| ❒ Bladder catheterisation of men or women | | | |
| ❒ Bladder rinse with an already placed catheter | | | |
| ❒ Insertion of an intratracheal catheter | | | |
| ❒ Insertion of a duodenal catheter | | | |
| ❒ Insertion of a peripheral infusion | | | |
| ❒ Insertion of a gastric catheter | | | |
| ❒ Insertion of a suprapubic catheter | | | |
| ❒ Tube feeding with an already placed catheter | | | |
| ❒ Administration of medication via infusion | | | |
| ❒ Oral-nasal tracheal extubating | | | |
| ❒ Oral-nasal suctioning | | | |
| ❒ Replacement of a suprapubic catheter | | | |
| ❒ Other, namely …… | | | |
| **Cardioversion or defibrillation in case of** | **Number of procedures per month** | **Authorisation method (1-7)** | **Duration of a single procedure (minutes)** |
| ❒ Atrial fibrillation | | | |
| ❒ Ventricular fibrillation | | | |
| ❒ Other, namely: …… | | | |

**Figure 2.2** Part of the caregiver questionnaire addressing the practices in execution of reserved procedures. (Which reserved procedure do you perform *(several answers possible)?* If applicable, how often a month do you perform this procedure and what is the authorisation method (1-7). How long does it take in minutes to perform this procedure, consultation time and order process time included?)

**Table 2.2** Domains in the AHP-model

| |
|---|
| **A Results of procedures:** |
| A1 Health improvement, right diagnosis |
| A2 Complications |
| A3 Patient satisfaction |
| A31 Procedure time |
| A32 Communication |
| A33 Waiting period until next appointment |
| A34 Waiting period in waiting room |
| **B Competency health professional:** |
| B1 Education |
| B2 Experience |
| **C Risks of treatment:** |
| C1 Complexity |
| C2 Types of patients |
| C3 Types of procedures |
| **D Costs** |
| **E Organizational characteristics:** |
| E1 Collaboration with physician |
| E11 Consultation |
| E12 Authority |
| E2 Protocols: |
| E21 Clarity tasks, authorities, responsibilities |
| E22 Establishment procedures, patients, |

*Participants*

Quantitative data are collected from NPs, PAs, patients and physicians. A purposive sample is drawn with no formal sample size calculation. With purposive sampling, participants are selected according to the needs of the study and some characteristics of a population. In this way, the study remains feasible and manageable. [28]

The inclusion criteria are:

- NPs: graduated, entered in the national NP register and working in the Netherlands with no restrictions on settings;
- PAs: graduated and working in the Netherlands with no restrictions on settings;
- Patients: sufficient knowledge of the Dutch language, having experienced a reserved procedure by a NP or PA and no active psychotic or serious cognitive

disorder. For children under the age of 12 years, parents will complete the questionnaire;

- Physicians: collaborating with a NP and/or PA.

*Data collection*

We aim at inviting all registered NPs (1146) and graduated PAs (284) working in the Netherlands at the time of pretest measurement. Potential participants are identified by the NCN NP and the NAPA in two different ways. The NCN NP invites their members to subscribe for study participation. The NAPA has notified their members about the ongoing study and has provided names of all potential PAs to the research team. PAs are subsequently invited by the research team to participate in the study. Every NP and PA is asked to invite five patients and two supervising physicians for participation.

*Data analysis*

Data analysis will be conducted for NPs and PAs separately, because of their different roles in healthcare. Distributions will be tested for normality with the Kolmogorov-Smirnov test and by visually inspecting the histograms.

For continuous variables, means with the corresponding standard deviations will be calculated and in case of non-normality, medians and interquartile ranges. For categorical variables, frequencies and the distribution in percentages will be presented. For the estimations of the monthly performance (caregivers), means and standard deviations will also be calculated, irrespective of a possible non-normal distribution since even rare outliers may be of special interest in a very heterogeneous population.

At a patient's level, a T-test for dependent samples (Mann-Whitney in case of non-normality) will be used to determine if there is a significant difference between pre- and posttest data. The ANCOVA model will be applied to correct the results for confounding factors.

At a caregiver's level, mixed-effects models will be used. All tests will be performed two-sided with a p-value lower than 0.05 considered as statistically significant.

With respect to the AHP method, weights will be calculated according to the 'Eigenvector method' [29], based on the matrices of the pairwise comparisons. Furthermore, the consistency ratio (CR), as a measure of how consistent the judgements have been relative to large samples of purely random judgements, will be calculated. With high CRs the judgements are considered as random. The CR has

a threshold of 0.2 that should not be exceeded. [30] Results will be randomly verified by Team Expert Choice software version 10 (outsourced). Finally, geometric means for patients and health professionals will be computed. To evaluate if there is a significant difference between groups (NPs, PAs, physicians and patients) and measurement moments (pre-post) a T-test for independent, respectively dependent, samples (Mann-Whitney in case of non-normality) will be performed. Use will be made of SPSS software version 18.0.

**Qualitative research**

*Model*

As a result of the amendment, a process of implementation of changed authorities as to reserved procedures, has started. To ascertain facilitators and barriers in this process, the implementation model of Grol *et al*. [31] is applied. Factors that can affect the process of implementation are categorized in: individual factors related to health professionals and patients (f.i. knowledge, appraisal of own competence, patients' preference); social (degree of autonomy, functioning of teams), organisational (organisational structure, available resources) and societal factors (repayment system, legislation).

*Expert*

According to Meuser & Nagel [32], an expert is either a person who is responsible for the development, implementation or control of solutions/ strategies/ policies or a person who has privileged access to information about groups of persons or decision-making processes.

*Participants expert interviews*

In the present study, 60 representatives of all parties involved (stakeholders): professional associations, management of organizations and training institutes as well as a selection of care professionals in daily practice (case studies) will be interviewed using semi-structured interviews. The objective of these interviews is to identify barriers and facilitators that are relevant for the performance of reserved procedures by NPs and PAs. The interviews will be conducted either per phone or face to face, depending on the preference of the experts. Interviews are audiotaped, and an abstract is sent to the participating expert for verification in order to increase reliability.

*Focus groups*

A focus group is a carefully planned discussion designed to obtain perceptions on a defined area of interest in a permissive, non-threatening environment. [33]

*Participants focus group interviews*

In this study, the focus groups are assembled based on the nature of the reserved procedures. Besides two 'prescribing medicines' focus groups, there are six groups related to 'technical reserved procedures' where NPs, PAs and physicians who perform catheterisations, cardioversions, defibrillations, endoscopies, injections, punctures or surgical procedures are represented, with the widest setting as possible. Furthermore, two patient focus groups will take place.

*Data analysis*

For qualitative data the editing analysis style will be applied, where various data will be documented, and meaningful items categorized according to the model of Grol. [31] In this categorization scheme patterns and structures will be searched for, using NVIVO 10 software.

Answers to open-ended survey questions will also be entered into NVIVO software. The qualitative text data will be transformed in quantitative data by using content analysis to identify themes for each question. Each theme will be coded and themes will then be counted.

**Triangulation**

In the triangulation approach (Figure 2.3), quantitative (QUAN) as well as qualitative (QUAL) data are collected and will be converged during the interpretation of the results, where the data transformation model and the validating quantitative data model [34] will be applied. In the first model, qualitative data (interviews and open-ended survey questions) will be quantified (QUAL→ QUAN) and quantitative data (close-ended survey questions) will also be converted into a narrative statement (QUAN→ QUAL). In the second model QUAL results will be correlated with QUAN results to validate the results. Both QUAN and QUAL data will be combined to create new variables.

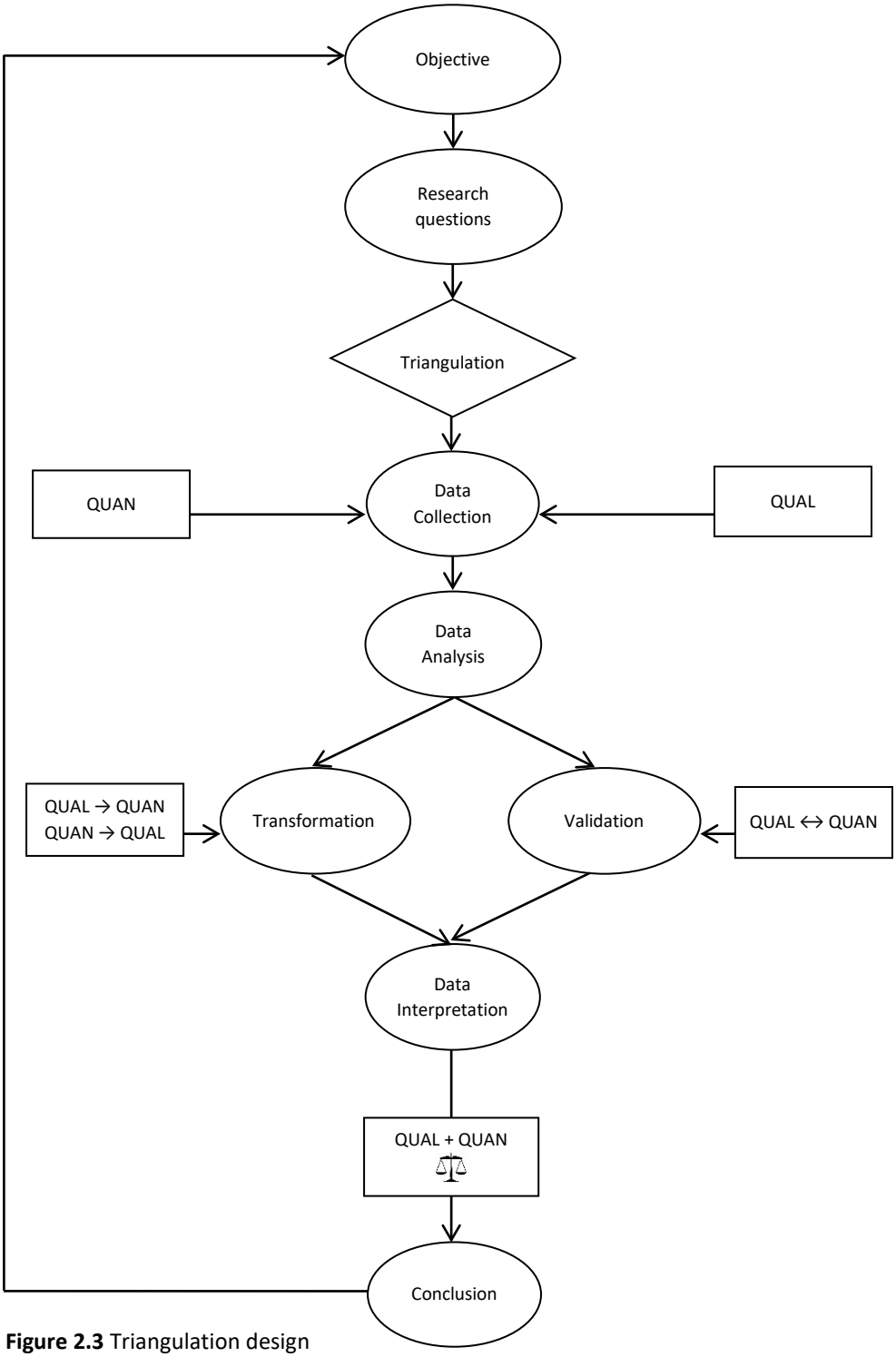


**Figure 2.3** Triangulation design

**Timetable**

The study is scheduled to last 48 months, including data-analysis and the writing of a report. In the pretest period (start up to month 9), the law amendment takes place and the survey will take place. In the posttest period (month 10 up to month 30) the survey measurement will be repeated. In addition, expert interviews as well as focus group interviews are scheduled.

**Ethical considerations**

Ethical approval has been given by a University Medical Ethics Committee in July 2011. The study was considered an evaluation of daily practice. No further approval was required. All participants will be assured that data will be handled confidentially and cannot lead to any identification. Oral informed consent will be obtained from every interview participant for the use of the data for scientific research including publication of the study findings.

## Discussion

This study investigates the effects of newly acquired authority of NPs and PAs for reserved procedures on the processes and outcomes of care as a result of recent legislation in the Netherlands. It uses a comprehensive study design, with a broad scope of triangulation, which is regarded a prerequisite to contribute to international research on the contribution of NPs and PAs to quality of healthcare. In international publications, the focus of expansion of authority for reserved procedures performed by non-physicians, lays solely on prescribing of medicines by nurses. [35, 36]

In 2012, nurses in 12 European and Anglo-Saxon countries, including (in chronological order) several states in the USA, Canada, Sweden, the UK, Australia, New Zealand, Ireland, Finland, the Netherlands and Spain, are allowed to prescribe medicines. Authority in these countries varies from prescribing independently to prescribing only under strict conditions and the supervision of physicians. In most countries, nurse prescribing is limited to defined categories of nurses, especially NPs. [37] Latter *et al*. [38] concluded that nurse prescribing has been evaluated positively, but that the evidence is still weak due to methodological limitations and limited scopes of the included studies. This conclusion has been confirmed in two more recent reviews on nurse prescribing. [36, 39] To date there is still need for robust research regarding the effects of nurse prescribing on patient and health services outcomes more specific, on financial consequences.

To our knowledge, high quality studies on prescribing authority for PAs are only conducted in the US, where PAs have prescribing authority in most states. [40]
The strength of our study is its wide scope of triangulation. Quantitative data are gathered on four domains (quality of care, costs, use of care professionals and patient centred care) and on three levels (PA/NP, physician and patient). Qualitative data on facilitators and barriers of the implementation process will be obtained by combining results of expert- and focus group interviews. This will allow us to assess outcomes within the context of the implementation of the new authority, taking the underlying mechanisms, according to the Contexts, Mechanisms and Outcomes model, into account. [41] For extrapolation to other contexts, it is not only important to state whether an implementation has succeeded but also to establish why it works, for whom and under what circumstances. Furthermore, all chosen outcomes are embedded in a proven framework [14] and model [31], which will enable cross national comparisons.
Finally, the direct involvement of all relevant parties in the design and execution of the study will create a broad support among participants.

## Limitations

Nevertheless, some methodological comments have to be made. The first relates to the one-group pretest posttest design. As the amendment affects the entire country, selection of a control group is impossible and even unethical. A historical control group is no option given that all data have to be collected prospectively. Also, it is reasonable to assume that results will get contaminated when intervention and control groups come into contact with each other [42], which would be the case here. However, internal invalidity may be limited through the applied design. Problems can occur with history (events other than the treatment may influence the treatment effect), maturation (subjects change over the course of the experiment), testing (a pretest can affect subjects' performance on a posttest), instrumentation (changes in the instrument in time) and selection-maturation interaction (subject-related variables and time-related variables may interact). [43]
Furthermore, is it almost impossible to include a fixed sample of patients in the applied design. Patients with acute problems cannot be followed up as health complaints may resolve during the time. In patients with chronic diseases or patients in primary care, new complaints may raise, but in these groups, the problem may be

solved by empanelment, by which each patient is linked to a specific care giver. However, in majority patients in the pretest group are not the same patients as in the posttest group and a comparison on an individual level cannot be made.
Third, notwithstanding the request to NPs and PAs to make no constraints in the selection of patients, we cannot exclude selection bias.

## Validity and reliability

In response to above limitations we anticipate to reduce the threat to the internal validity of our study by applying the triangulation mixed methodology and the mixed-effects model analysis. With regard to the possible different composition of the patient groups during pretest and posttest measurements, a comparison on group level will be made if important demographic characteristics are consistent in both groups. By comparing overall patient characteristics with data of similar research, we aim to respond to the potential paucity of generalizability.

## Conclusion

This study on the effects of granting independent rights to NPs and PAs concerning reserved medical procedures, firstly addresses the need of informing national policy-makers about the impact of the Orders in Council. The results will also contribute to the field of international research on the contribution of NPs and PAs to healthcare. At the time of the submission of this article, the pretest of the study has been completed. We expect the final results of the study to be available at the end of 2015.

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# Chapter 3

## A retrospective study on elements of quality and safety of care when indicating and performing reserved medical procedures in the Netherlands

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## Abstract

In order to determine elements that guarantee patient safety when performing medical procedures, we analysed disciplinary rulings against physicians and some nurses. We found that 24.6% of the well-founded complaints were about the stage in which the medical procedure is initiated (indicating) and 22.2% about the actual performance of the procedure. Based on these findings we can conclude that the indication of a medical procedure is as important as the actual performance. Although Dutch law assumes that a professional should be competent on both moments, it is not explicitly determined. In order to guarantee patient safety, the importance of this stage should be emphasized in the legal framework and be emphasized in training of the competence of the professionals. This is particularly important when drafting legislation on task shifting.

## Introduction

In order to maintain a high standard of care every European Union (EU) member state has to secure patient safety issues. [1, 2] Especially since professional healthcare workers have free movement within the EU, based on the EU Directive on professional qualifications. [3, 4] This Directive provides a system for recognition of professional experience and promotes automatic recognition of professional experience across the EU. Every member state has to convert the Directive into national law.

In the Netherlands the Individual Healthcare Professions Act (IHCP Act, in Dutch: Wet op de Beroepen in de Individuele Gezondheidszorg) seeks to monitor and promote the quality of professional care by providing regulations for healthcare professions. The act took effect in 1997 and regulated what was common practice in the medical profession in that time. However, since 1997 daily practice has changed, not least through the introduction of task shifting. Task shifting allows medical professionals other than physicians, like physician assistants and nurse practitioners, to perform medical procedures on their own authority. The legal framework for performing medical procedures however did not change much. This framework consists of only a few basic rules that focus on the competence to perform a medical procedure. Given the history of the law this can be explained. Physicians are considered competent to decide if a certain medical intervention is needed (indication) and to assess if he or she is competent to perform the specific medical procedure (performance).

The question is, if this legal framework provides sufficient protection for patients when new medical professionals are introduced in the IHCP Act. [5] The Dutch Parliament discussed this issue and introduced several additional legal requirements for conducting medical procedures by physician assistants and nurse practitioners. In the following section we elaborate on these requirements. These additional requirements, however, concern the performance of medical procedures and to a lesser extent on the indication.

We believe that both aspects (indication and performance) are important to guarantee quality of care and patient safety. We wanted to see if this assumption is correct. International literature is inconclusive, the majority of existing studies on quality and safety focus on the overall care process and not on the individual health professional. [6-9]

By retrospectively examining disciplinary rulings we aimed to identify determinants of safety and quality of care during the indication and performance of reserved procedures on the individual level. Disciplinary rulings can give some information about the circumstances under which the quality of care was at stake in an individual case. By analysing these situations, we wanted to see if indeed the indication stage is as important as the performance stage. We analysed well-founded disciplinary rulings against professionals that performed reserved procedures.
In this article we first describe the legal background in The Netherlands in more detail. Then we take a closer look at the analysis of the disciplinary rulings. We then discuss the results and we come to conclusions.

**Legal Background in the Netherlands**

The starting point of the Dutch legislation is that, within certain boundaries, (according to Art. 96 IHCP Act, it is forbidden to cause damage or a significant risk of harm when performing medical procedures within healthcare) all professionals are allowed to perform medical procedures. To secure patient safety the Dutch IHCP Act however distinguishes fourteen (groups of) medical procedures that may only be carried out by professionals indicated by law. These so-called *reserved procedures* are deemed to pose a considerable risk to the health of the patient if performed by anyone who is not qualified. For example: surgical procedures, injections, punctures and prescribing medication. Only physicians, dentists and midwives are authorized by law to perform specified reserved procedures on their own authority. The only requirement imposed by the law is that the physician, dentist or midwife, must be competent to perform the specific procedure. Although the law does not explicitly mention it, this implies the competence to initiate a medical procedure (indicating) and the competence to actually perform the procedure (the performance). Other medical professionals are allowed to perform reserved procedures, if they consider themselves competent and if the procedure is commissioned by a physician. In this situation the physician does initiate (indicate) the procedure while the other professional does perform the actual procedure. As stated before the act described the everyday practice at that time.

*Introduction of task shifting*

In 2012 the IHCP Act has been changed to enable experiments with task shifting to selected professionals during an experimental pilot of 5 years. Moreover, this change in regulation has been introduced to stimulate task shifting from physicians to nurse

practitioners (NP, in Dutch: verpleegkundig specialist) and physician assistants (PA). According to the Dutch Government, task shifting is one of the strategies to address the growing demand for care whilst ensuring the accessibility and affordability of healthcare. Consequently, since the turn of the century task shifting has been subject of scientific evaluation. [10-16] Based on the new IHCP Act, NPs and PAs are allowed to perform certain reserved procedures on their own authority and thus based on their own indication and without being commissioned by a physician. An order from a physician is no longer required. There are however some additional requirements. The expanded authority is restricted to medical procedures of limited complexity, routine in nature and subject to manageable risks and includes catheterisation, defibrillation, elective cardioversion, puncture, injection, endoscopy, small surgical procedures and prescribing. In addition, the NP and PA are only authorized to perform the procedure if he or she is, in fact, competent to perform the specific procedure. This last requirement is, as we pointed out in the previous paragraph, the basic rule for all professionals that are allowed to perform reserved procedures on their own authority.

*Disciplinary law*

In the IHCP Act, medical disciplinary law is used as an instrument to guarantee the quality of professional practice. Unlike criminal law enforcement, disciplinary law is an instrument to assurance the quality of care and not a punitive instrument. Direct stakeholders (including patients and the Healthcare Inspectorate) can file complaints against medical professionals. The disciplinary system is also applicable, to the PA and the NP, there are only a few relevant rulings yet.

## Methods

### Study design and search strategy

This is a retrospective study of disciplinary verdicts in Dutch disciplinary law cases. Anonymous verdicts are available for public record via a government website. [17] Our study covered all fully closed disciplinary verdicts between 2010 and 2015, related to complaints by the Health Inspectorate and individual patients.

### Selection strategy

Two researchers (DDB and EM) have independently screened abstracts of verdicts for potential eligibility. The final selection has been based on full text evaluation.

Discrepancy has been resolved by consensus after full text review. Cases have been included if they met the following inclusion criteria: i) complaints are against individual healthcare providers and ii) in the complaints one or more of the reserved procedures catheterisation, defibrillation, elective cardioversion, puncture, injection, endoscopy, small surgical procedures and prescribing are mentioned. Complaints against dentists have been excluded because we only want to draw conclusions about performing procedures in the medical domain and not the dental care domain. Cases that were brought before the regional disciplinary board and in appeal to the central disciplinary board have been counted as one case.

**Data extraction**

All eligible cases have been independently reviewed by DDB and DVM and with a self-developed predesigned form, information to identify case number, the disciplinary board involved, number of appeals, type of accused professional, type of reserved procedure, date and nature of the verdict (well-founded or unfounded), the sanctions (warning, reprimand, fine, (conditional) suspension of the entry in the IHCP-register, partial withdrawal of the right to practice the profession concerned, striking off the entry in the IHCP register) has been extracted. Subsequently complaints were categorized into domains and themes. Complaints have been classified into four domains (Indication, Performance, Information and Reporting) and 38 empirical themes. Per domain and theme, the distribution of complaints was determined.

**Data analysis**

Data have been extracted and compiled into an Excel spreadsheet [18] and imported in SPSS. [19] For the dichotomous thematic outcomes, frequencies and percentages have been determined. Chi-square test ($\chi^2$) with calculation of phi coefficients ($\varphi$) has been used to evaluate associations between mutual *domains* and themes, between distinct *domains* and themes and the nature of the verdicts. P-value has been assessed with Fisher's Exact Test with a significance level ($\alpha$) of 0.05, where absolute $\varphi$ values of 0-0.3 indicate a weak or no association between two variables, 0.3-0.7 a moderately strong association, and >0.7 a strong association. [20]

## Results

In the period from January 2010 until January 2015, we have found a total of 4.369 complaints that were dealt with and published by the disciplinary boards. The annual number of published complaints in this period gradually increase from 803 in 2010 to 970 in 2014. The screening of abstracts for the presence of the reserved procedures catheterisation, cardioversion, puncture, injection, endoscopy, small surgical procedures and prescribing yield 460 results. The percentage of verdicts involving reserved procedures increase from 7% in 2010 to 15% in 2014. Three quarters of all verdicts (76%) refer to complaints about prescribing, 9% about injections, 9% about surgical procedures, 6% about catheterisations, 2% about endoscopies, 1% about punctures and 1 complaint is about cardioversion/ defibrillation. Of all complaints related to reserved procedures, 1 complaint is directed against a NP, none against a PA, 7% against nurses and 93% against physicians. One quarter of the complaints address the mental health sector (data not in table).

Complaints have been divided into four empirical domains, namely A: The *Indication* stage including diagnostics and the decision to perform a specific procedure; B: the actual *Performance* of the procedure; C: the *Information*/communication about (the procedure as part of) the treatment and D: the *Reporting* about the procedure. Subsequently, 38 empirical themes have been drafted within the four domains. Some themes are generally formulated (e.g. A1: Incomplete diagnostics/no complementary tests, B1: Performance without adherence to standards), others are specific to prescribing (e.g. B2: Administration of incorrect dosage medication, C3: Information about medication). Multiple complaint components are subdivided in several themes.

The distribution of *domains* and themes in the complaints is presented in Table 3.1. Almost half of the complaints (42%) relates to *Indication*, 37% to *Performance*, 13% to *Information* and 7% to *Reporting*. Within the domain *Indication*, most complaints (17%) concern diagnostics (8% Incomplete diagnostics, 8% Wrong diagnosis previous to treatment/prescribing, 1% Diagnostics without adherence to standards) and the choice of treatment/medication (14%). In the domain *Performance*, complaints are equally distributed across the different themes, with the highest rates of Performance without adherence to standards (6%) and Forced pharmacotherapy/ treatment (6%).

**Table 3.1** Distribution of themes in (well-founded) complaints

| ***DOMAIN*/theme** | **% Total complaints N=460** | **% Well-founded N=102** |
|---|---|---|
| ***A Indication*** | 42.4 | 24.6 |
| A1 Incomplete diagnostics/no complementary tests | 7.7 | 30.1 |
| A2 Diagnostics without adherence to standards | 1.2 | 72.7 |
| A3 Wrong diagnosis previous to treatment/prescribing | 7.8 | 29.7 |
| A4 Choice of treatment/medication | 14.2 | 24.4 |
| A5Discontinuation or no initiation of pharmacotherapy | 4.5 | 11.6 |
| A6Treatment/pharmacotherapy despite contraindication | 2.1 | 26.3 |
| A7 Prescription/authorization without seeing patient | 0.9 | 33.3 |
| A8 Adoption of previously established indication | 0.7 | 28.6 |
| A9 Refusal to repeat prescriptions | 0.1 | 0.0 |
| A10 Prescription of incorrect dosage medication | 3.1 | 34.5 |
| ***B Performance*** | 37.3 | 22.2 |
| B1 Performance without adherence to standards | 5.7 | 33.3 |
| B2 Administration of incorrect dosage medication | 0.9 | 11.1 |
| B3 Method of administration | 0.5 | 20.0 |
| B4 No consent parents (in case of children) | 2.0 | 5.3 |
| B5 Forced pharmacotherapy/ treatment | 5.5 | 1.9 |
| B6 Unnecessarily prolonged pharmacotherapy | 0.9 | 44.4 |
| B7 No guidance medication | 1.5 | 57.1 |
| B8 Absence of after-care | 3.6 | 35.3 |
| B9 Absence of monitoring | 0.8 | 50.0 |
| B10 No consensus about trial treatments | 0.6 | 33.3 |
| B11 Medication policy | 2.2 | 14.3 |
| B12 No fitting treatment plan | 1.3 | 8.3 |
| B13 False identification of side effects | 1.6 | 20.0 |
| B14 Insufficient medication titration | 1.6 | 27.7 |
| B15 Delayed treatment | 1.3 | 8.3 |
| B16 Insufficient supervision | 1.7 | 25.0 |
| B17 Unauthorized performance | 0.6 | 100.0 |
| B18 Performance without expertise/competence | 1.6 | 28.6 |
| B19 No adequate assignment to perform | 0.7 | 14.3 |
| B20 Absence of peer consultation | 0.7 | 14.3 |
| B21 Poor practice management | 0.9 | 33.3 |
| B22 Inadequate pain relief during procedure | 0.9 | 44.4 |
| ***C Information*** | 12.9 | 26.0 |
| C1 Information about risks | 2.4 | 22.7 |
| C2 Information about treatment | 5.3 | 28.6 |
| C3 Information about medication | 3.1 | 24.1 |
| C4 General communication | 2.1 | 25.0 |
| ***D Reporting*** | 7.4 | 28.6 |
| D1 Content of Patient File | 6.1 | 31.1 |
| D2 Access to Patient File | 1.4 | 15.4 |
| ***Total*** | 100.0 | 22.4 |

Within the domain *Information* people especially complain about the Information about the treatment (5%), and within the domain *Reporting* most complaints are about the Content of the Patient File (6%). When we take the verdict of the judge into account (Table 3.1), about a quarter (22%) of all complaints has been judged well-founded, the distribution of well-founded complaints is approximately equal for all domains (*Indication* 25%, *Performance* 22%, *Information* 26% and *Reporting* 29%). Between mutual *domains*/themes, 56 statistically significant, mostly weak (φ <0.3), associations were found (data not in table). Two associations proved to be moderately strong, namely the association between the *domains: Indication-Performance* (χ2 (df=1, n=456) =50.095, p=0.000, φ=-0.331) and between the themes Method of administration and No adequate assignment to perform (χ2 (df=1, n=456) =49, 485, p=0.002, φ =-0.329).

The verdict well-founded was statistically significantly but weakly associated with four themes. These include: Diagnostics without adherence to standards (χ2 (df=1, n=456)=16.462, p=0.000, φ=0.190), No guidance medication (χ2 (df=1, n=456)=10.058, p=0.004, φ=0.149), Forced pharmacotherapy/ treatment (χ2 (df=1, n=456)=14.129, p=0.000, φ=0.176), and Unauthorized performance (χ2 (df=1, n=456)=14.005, p=0.002, φ=0.175) (data not in table).

## Discussion

In this study we looked at disciplinary rulings in order to identify elements regarding the safety and quality of care during indication and performance of reserved procedures by medical professionals in the Netherlands. We divided the rulings into groups: complaints about the stage in which the reserved procedure was indicated and the stage that the reserved procedure was performed. Of all complaints against individual healthcare professionals about a reserved procedure, 42% was about the *Indication* stage and 37% about the *Performance* of the procedures. In the *Indication* stage, most complaints were related to the diagnosis of the procedure. In our study, 22% of the complaints were well-founded. This is above average in the Netherlands, where 14-17% of all complaints submitted to a disciplinary board are well-founded. [21] Of the well-founded cases 25% are related to the *Indication* stage and 22% to the *Performance* of the reserved procedure. The moderately strong negative association between complaints in the *domains: Indication and Performance*

indicates that while there is a complaint in the *Indication* domain, it is more likely that there is no complaint in the *Performance* domain and vice versa.

So, in short, we found that the well-founded complaints about reserves procedures were almost equally divided between the indication stage and the actual performance of the procedure. Based on this outcome we cautiously could say that when something goes wrong when performing a reserved procedure, it is as often in the indication stage as in the performance stage. This outcome points out that the indication stage plays an important role when performing medical procedures. Although not explicitly stated in the law, the authority to perform reserved procedures includes both the indication and the performance itself. Consequently, the number of complaints is about equally divided between both stages. The outcome of our study does however highlight the importance of both stages.

In recent years, there has been a debate about whether diagnosing a medical procedure, as part of the Indication stage, should become a distinct reserved procedure. [22] The outcome of this debate is that diagnosing (as part of the indication stage) should not (yet) be marked in the law as a separate reserved procedure, mostly because it is not possible to exactly define the outlines of the diagnosing stage. [23] Considering the results of our study the discussion on this topic holds high societal and scientific relevance. Since in most cases legislation tends to follow practise with a certain delay in time, continuous evaluation and quality improvement is necessary.

This is especially important when tasks are shifted from one to another professional. The legal conditions for task shifting intend to ensure quality and safety of care. It is striking that in The Netherlands additional requirements were deemed necessary to guarantee patient safety when shifting tasks to NP and PA (only procedures of limited complexity, routine in nature and subject to manageable risks). But these requirements all monitor the performance of the procedure. No extra requirements were thought necessary for the indication of the procedure. This means that only the basic rule remains: the professional should consider himself competent to indicate and perform the procedure. This is remarkable because the professionals are already familiar with performing the procedures if a physician commissioned it but are not familiar to do the indication themselves. If the legal conditions for task shifting are really intending to ensure quality and safety of care, it was to be expected that these additional conditions also focus on the part of the procedure that is new to the NP and PA, i.e. the indication. For example, by explicating that the professional is only

competent to perform a specific reserved procedure if indicating the procedure was part of his education or the competence was acquired by another professional training. Indicating a medical reserved procedure should be an explicit part of the training of the competences of professionals.

*What does our study say?*

In our study we looked at disciplinary rulings. Although we used a scientific approach, we realize that it is difficult to draw hard conclusions from our results. The strength of this study however is that the results are based on a total of 460 complaints. The sample size seems sufficiently large to yield valid results. More research should be done to further examine the impact of the Indication stage on safety and quality of care. We realize that there are also some limitations to our study. We should take into account that most complaints were about prescribing medication (76%) and less on the other procedures. This may have influenced the findings because, of all reserved procedures, prescribing is about the indication and not so much about the actual performance. On the other hand, in various countries the redistribution of authority starts with prescribing. [24] We should also take into account that one quarter of the disciplinary rulings we looked at concerns the mental health sector. Many medical treatments in this sector include (forced) medication. This is also a sector where patients are more likely to file a complaint against a professional. [25] We only studied the reserved procedures that are included in the current task shifting discussion in the Netherlands. We did therefore not include the following reserved procedures: obstetric procedures, narcosis, handling radioactive materials and x-rays, electroconvulsive therapy, External Shock Wave Lithotripsy. We expect however that for these procedures, also the indication will be as important as the performance.

*International comparison*

To the best of our knowledge, this is the first retrospective study of disciplinary rulings to examine determinants of quality of care during the indication and performance of reserved procedures. It is therefore impossible to compare our findings with those from other studies. Further, the system of disciplinary proceedings differs from country to country within the EU. [26] The same goes for the authority to perform medical procedures. In most European countries only physicians are qualified to independently perform medical procedures. Other healthcare providers work under their supervision. The Netherlands seems to be on

the forefront of EU countries with respect to allocating the authority to perform medical procedures to other healthcare providers, including the NP and PA. In the United Kingdom similar experience is build up among nurse led clinics. [27-30] Finland, Ireland, Norway, Sweden, Spain and the UK have implemented nurse prescribing. [24, 31-34] The corresponding authority, however, varies from completely independent prescribing with a comprehensive formulary to prescribing with strict requirements, under the supervision of a physician and a limited formulary.

Only two other relevant studies were identified, also from the Netherlands. Gevers et al. [35] discussed the authority to perform reserved procedures and emphasised that the authority includes the performance of the procedure and the indication. The empirical study by Hout [26] looked at the Dutch disciplinary system for healthcare, however without specifically paying attention to complaints about reserved procedures.

## Conclusion and recommendations

The results of this study support our hypothesis that the indication of a medical procedure is as important as the actual performance. Although Dutch law assumes that a professional should be competent on both moments, it is not explicitly determined. In order to guarantee patient safety, the importance of this stage should be emphasized in the legal framework, for example by explicating that the professional is only competent to perform a specific reserved procedure if indicating the procedure was part of his education or the competence was acquired by another professional training. Indicating a medical reserved procedure should also be emphasized in the (training of the) competencies in the basic training of the professionals. This is particularly important when drafting legislation on task shifting. Considering the results of our study the discussion on this topic holds high societal and scientific relevance. Since in most cases legislation tends to follow practise with a certain delay in time, continuous evaluation and quality improvement is necessary.

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# Chapter 4

## Supporting political decision making on authorities of Nurse Practitioners and Physician Assistants for reserved medical procedures: an application of the analytical hierarchy process method from the perspective of patients and health care providers

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## Abstract

**Background**

At the political level of healthcare decision making patients are rarely, if ever, actively involved. During a temporary (2012-2017) legislative pilot-project, where nurse practitioners (NPs) and physician assistants (PAs) were granted authorities for certain medical reserved procedures, patients, NPs, PAs and physicians were consulted to support the Ministry. The aim of this study was to establish a weighted hierarchy of requirements that affect political decision-making on whether the temporary authorities should be continued.

**Methods**

The Analytic Hierarchy Process (AHP) method was used to rank the requirements. Requirements were translated in a decision tree with 3 levels containing 23 (sub-) criteria with main criteria being: quality of care, competence of the care provider, risks, costs, and organizational aspects. AHP was built into a paper questionnaire and distributed among a purposive sample of patients, NPs, PAs, and physicians. Individual weights, consistency ratios and group means were calculated, according to the 'Eigenvector method'. Background characteristics were determined for in- and excluded respondents separately and differences were statistically analysed.

**Results**

In total, 150 patients, 226 NPs, 142 PAs, and 238 physicians filled in the questionnaire. All four groups considered quality of care and the competence of the care provider as most important decision requirements. The percentage of included respondents differed among the individual levels and criteria. Most exclusions were found in the highest, most abstractly formulated level. Compared to care providers, patients rated the alternatives in all pairwise equations significantly more of equal importance.

**Conclusions**

This study is the first to report about the involvement of patients in the process of political decision making. In determining which requirements are important in political decision-making, both patients and care providers, supported by the AHP method, can be successfully involved. Quality of care and the competence of the care provider are deemed to be the most important requirements for NPs and PAs to perform reserved procedures.

## Background

While the importance of patient involvement in healthcare decision-making is widely recognized, it is not as self-evident at different levels. Where decisions affect their personal health, patients are particularly engaged. For example, shared decision making is increasingly accepted in medical practices. [1-3] When it comes to policy making at the population level, patients are involved in the development of patient information material, patient-reported outcome measures, clinical guidelines and in reimbursement decision-making. [4-8] In doing so, patients generally provide their opinions or feedback to decision-makers rather than submitting research evidence on patient preferences. [9] At the highest level of healthcare decision making (i.e. political) in respect of rules and regulations, patients are rarely, if ever, actively involved. In the present study, it is at the political level where we collected research evidence on patients' view to support healthcare decision making.

To ensure patient safety, the Dutch Individual Health Care Professions Act (IHCP Act, in Dutch: Wet op de Beroepen in de Individuele Gezondheidszorg), has defined certain medical procedures which pose unacceptable risks to a patient's health when performed by incompetent healthcare professionals. Until 2012, the performance of these procedures was reserved to physicians, dentists and midwifes. By means of an amendment, followed by two Orders in Council, NPs and PAs have been enabled to indicate, perform and delegate specified reserved procedures (in this case catheterisation, cardioversion, defibrillation, endoscopy, injection, puncture, prescribing prescription-only medicines and simple surgical procedures) independently. The Orders in Councils are valid for a period of 5 years and are subject of evaluation. [10, 11] To grant full practice authority to NPs and PAs, firm requirements are attached. Full authority is restricted to procedures of limited complexity, routinely by nature and subject to manageable risks. Besides, NPs and PAs must work according to guidelines which also contain cooperation agreements with physicians and must be competent to perform the procedures. Further, quality of care must be guaranteed.

The current study is part of a larger evaluation commissioned by the Dutch Ministry of Health, Welfare and Sport (HWS) to facilitate the Ministry in deciding whether temporary authorities of NPs and PAs for reserved medical procedures should be continued. At the start of the study we anticipated a diverse impact of the legislation on the evaluated processes and outcomes and that requirements for full practice

authority could be met to a greater or lesser extent. To support informed decision making, it is important to determine a hierarchy in those processes, outcomes and requirements and patients may rank some higher than others.
The Analytic Hierarchy Process (AHP) method is particularly suitable for weighing and ranking criteria based on importance. The AHP method was originally developed by Saaty [12, 13] for application in the marketing sector. Dolan et al. implemented the method in healthcare in the late 80s and since then its use is expanding in this context. [14] The AHP-method is relatively easy in use and offers the possibility to check whether the user has been consistent in the performance. In healthcare, the AHP method has been applied for management decisions, shared decision-making between patients and clinicians, development of clinical practice guidelines and national healthcare policy. [14-17] However, the AHP studies focusing on governmental policy never included patients. This is where the current study adds to what is known.

## Objective

The aim of this study (as part of the larger study described above) was to establish a weighted hierarchy of requirements that affect political decision-making on whether temporary authorities of NPs and PAs for reserved medical procedures should be continued, as determined by patients, NPs, PAs and physicians.

## Methods

The study was funded by a grant from the Dutch Ministry of HWS in March 2011 and was supported by the professional organizations Nurses and Caretakers Netherlands department for nurse practitioners (NCN NP, in Dutch V&VN VS), National Association of Physician Assistants (NAPA) and the Royal Dutch Medical Association (RDMA, in Dutch KNMG). Ethical approval was given by the Maastricht University Medical Ethics Committee in July 2011. The study was conducted between March 2011 and August 2015.
The rationale and design of the entire study are described in detail elsewhere. [18] In the remainder of this paragraph the details of this study are highlighted.

### Data collection

The study populations consisted of a purposive sample of patients, NPs, PAs, and physicians. All eligible NPs and PAs were invited by the NCN NP and NAPA to take

part in the study. [19] Every participating NP and PA invited five patients and two supervising physicians for participation. The inclusion criteria were:

- NPs: graduated, entered in the national NP register and working in the Netherlands with no restrictions on settings;
- PAs: graduated and working in the Netherlands with no restrictions on settings;
- Patients: sufficient knowledge of the Dutch language, having experienced a reserved procedure by a NP or PA and no active psychotic or serious cognitive disorder. For children under the age of 12 years, parents were asked to complete the questionnaire;
- Physicians: collaborating with a NP and/or PA.

The AHP method was used to weigh the importance of the decision requirements. It was integrated in three main questionnaires for patients, NPs/PAs, and physicians at two measure moments (T0: 3 months before the law amendment and T1: 1.5 years thereafter). Where respondents completely filled in both questionnaires, T0 data were used. In these questionnaires, also data about general background characteristics such as age, gender, specialism (NP, PA and physician) and education (patient) were collected. For the care providers, the questionnaire was available both in an online or offline paper version, for patients in an offline paper version only.

**AHP**

The AHP method comprises three key steps, namely Problem structuring, Evaluation and Calculation. [16, 20]

*Problem Structuring*

The problem that is subject for decision making (objective) can be structured by dividing it into criteria.

Criteria and underlying sub criteria were sourced from the conceptual framework of Sidani and Irvine [18, 21, 22], from the conditions as formulated in the legislation underlying the independent rights [10, 11], and from the literature (Figure 4.1).

First criterion was A Quality of care (effectiveness) [18, 21, 22], composed into A1 Clinical quality, A2 No complications, and A3 Patient satisfaction. Sub-criteria with regard to Patient satisfaction were (satisfaction on) A31 Procedural time, A32 Communication [23], A33 Appointment wait-time [24] and A34 wait-time in the

waiting room [25]. Second criterion was B Competence of the care provider [10, 11], divided in B1 Training and B2 Experience.

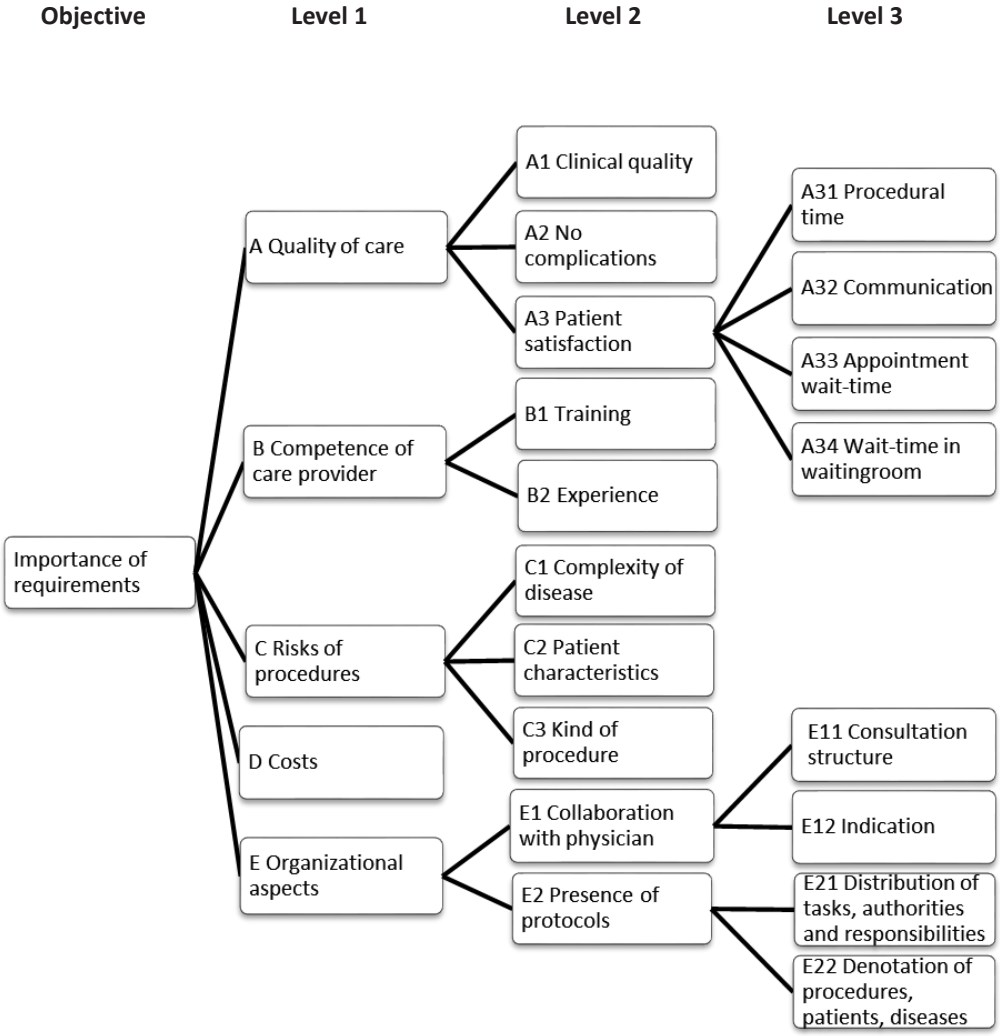


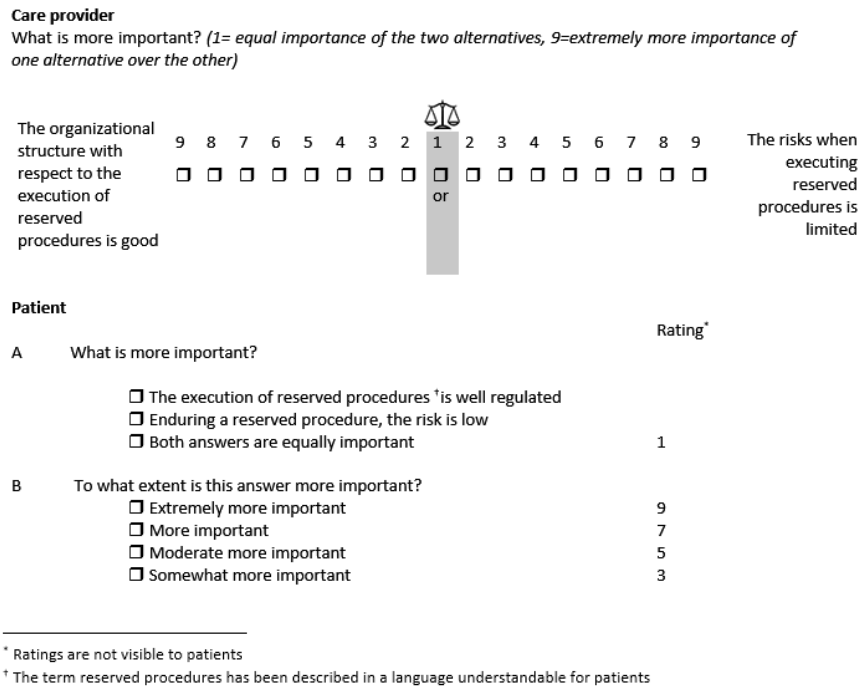

**Figure 4.1** AHP structure with criteria (level 1: A to D) and sub criteria (level 2 and 3)

The third criterion C Risks [10, 11] was based on C1 Complexity of the disease, C2 Patient characteristics and C3 Kind of procedure. Criterion D Costs (efficiency) [18, 21, 22] had no sub criteria unlike the last criterion, E Organizational aspects [18, 21, 22] namely: E1 Collaboration with a physician [10, 11] and E2 Presence of protocols

[10, 11]. The sub-criteria in E2 Protocols were E21 Distribution of tasks, authorities and responsibilities or E22 Denotation of procedures, patients, diseases.

*Evaluation*

Subsequently, criteria were weighed (evaluated) through a full factorial design: weights of criteria and their underlying sub criteria were obtained by all possible (i.e.26) pairwise comparisons between (sub-)criteria at all levels (Figure 4.2). In the questionnaire for care providers, preferences were recorded on a 9-point ordinal scale, ranging from 1 (indicating equal importance of the two alternatives) to 9 (extremely more importance of one criterion over the other). For patients, the questions and explanations of terms were simplified. Moreover, the questions were divided in two parts. In the first part, patients were asked whether one criterion was more important than the other. In the second part, patients were asked to state the extent of the difference in importance in a reduced 5-point scale. [26, 27] The AHP method for patients was pretested among 15 patients for understandability and assessed as more than satisfactory.



**Care provider**

What is more important? *(1= equal importance of the two alternatives, 9=extremely more importance of one alternative over the other)*

| | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| The organizational structure with respect to the execution of reserved procedures is good | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ or | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ | ❒ | The risks when executing reserved procedures is limited |

**Patient**

| | | Rating* |
|---|---|---|
| A | What is more important? | |
| | ❒ The execution of reserved procedures †is well regulated | |
| | ❒ Enduring a reserved procedure, the risk is low | |
| | ❒ Both answers are equally important | 1 |
| B | To what extent is this answer more important? | |
| | ❒ Extremely more important | 9 |
| | ❒ More important | 7 |
| | ❒ Moderate more important | 5 |
| | ❒ Somewhat more important | 3 |

* Ratings are not visible to patients

† The term reserved procedures has been described in a language understandable for patients

**Figure 4.2** Comparison of patient and care provider questionnaire

To avoid response bias, due to a preference for one (left/right) side of the scale, all sub-criteria within one level were evenly distributed among the left/right place. The order of the pairwise comparisons within one level were determined randomly. The questionnaire started with comparisons between criteria within level 1 (Figure 4.2), followed by criteria within level 2 and 3.

The consistency ratio (CR), a measure for consistency of judgments relative to large samples of purely random judgments, was calculated. If CR equals 0 then that means that the judgments are perfectly consistent and high CRs were considered judgments at random. The CR had a prevailing threshold of 0.2 that should not be exceeded. [12, 28]

Weights were separately calculated per individual and thereafter group means were determined per criterion. Prior to determining means, participants with inconsistent judgments (CR>0.2) were excluded from the analysis of the specific criterion and respondents who did not prefer any alternative at all in all 26 pairwise equations were excluded from all analyses. [12, 28] Where respondents completely filled in both questionnaires, T0 data were used.

An additional validity analysis was conducted to test the robustness of the weights in the applied method, where separately extreme values (respondents with mean weights ±5sd), or respondents which could attenuate results (respondents with >50% no priority in all pairwise equations) or respondents with just moderate consistent judgments (respondents with 0.1<CR<0.2) were excluded.

*Calculation of weights and priorities (statistical analysis)*

For each (sub-)criterion, *local* weights per respondent and CRs were calculated in Excel 2010 [29] according to the 'Eigenvector method'. [14] Results were randomly verified by Expert Choice software version 10 (delegated to experience expert). [30] These individual *local* weights and CRs were imported in SPSS version 22 [31] and *local* group means were calculated. Subsequently, global weights were calculated as the product of all *local* weights from level 3, through level 2, to level 1 (Figure 4.1).

Of all in- and excluded respondents the mean age (standard deviation (sd)) and gender (number male, percentage (%)) were noted, just as education characteristics of patients. These characteristics were based on the International Standard Classification of Education (ISCED) 2011 levels [32] and compressed to 3 categories, namely "low" (ISCED 2011 levels 0: less than primary education, 1: primary education, 2: lower secondary education), "middle" (ISCED 2011 levels 3: upper secondary education, 4: post-secondary non-tertiary education, 5: short-cycle

tertiary education) and "high" (ISCED 2011 levels 6: Bachelor's or equivalent level, 7: Master's or equivalent level, 8: doctoral or equivalent level). To determine if there was a significant difference between in- and excluded respondents in age, the Mann-Whitney U test was used, differences in gender and education level were assessed with the Chi square test (Fisher's Exact Test). All tests were performed two-sided with a p-value lower than 0.05 considered as statistically significant.

## Results

The questionnaires were filled in by 150 patients, 226 NPs, 142 PAs and 238 physicians. The percentage of included respondents differed among the individual levels/criteria. Most *ex*clusions were found in level 1 ABCD ranging from 34.5% for PAs and physicians to 52.7% for patients; most *in*clusions were found in level 2 A ranging from 82.0% for patients to 91.5% for PAs. Moreover, compared to other levels, pairwise comparisons in level 1 ABCD were rated statistically significantly more often of equal importance (Table 4.1). Excluded physicians in levels 1 and 3A were statistically significantly older than included physicians (mean age (sd) respectively 48.9 (9.7) versus 45.5 (8.2) and 49.8 (8.5) versus 45.9 (8.8)), whereas excluded patients in level 2C statistically significantly more male than included patients (59.0% versus 39.6%).

Compared to care providers, patients rated both alternatives in the 26 pairwise equations statistically significantly more often of equal importance (mean counts of no preference (sd) patients 7.8 (3.7) versus NPs 2.3 (2.6), PAs (3.0 (2.6)) and physicians (4.6 (3.4)) and physicians statistically significantly more than both NPs and PAs (data not in table). In addition, 13 patients did not prefer any criteria at all in the pairwise equations, against 0 NPs, PAs and physicians.

In Table 4.2 the global and *local* [23] weights of the requirements by category respondents and measurement moments are presented. Global and *local* weight are very much in line between the two measurement moments, with small differences from 0.00 to 0.08, and one deviating *local* weight for patients' level 3 E11, consultation structure (global (*local*) weight T0: 0.09 (0.77), T1: 0.10 (0.08)). Also, the ranking of the requirements is to a large extent similar between the different categories of respondents.

**Table 4.1** Characteristics of respondents included and excluded from the data-analysis

| Characteristic per level | | NPs | | PAs | | Physicians | | Patients | |
|---|---|---|---|---|---|---|---|---|---|
| | | Included | Excluded | Included | Excluded | Included | Excluded | Included | Excluded |
| **Level 1: ABCD** | | | | | | | | | |
| (n (%)) | | 122 (54.0) | 104 (46.0) | 93 (65.5) | 49 (34.5) | 156 (65.5) | 82 (34.5) | 71 (47.3) | 79 (52.7) |
| Age (mean, sd) | | 45.8 (7.9) | 46.3 (8.2) | 42.1 (8.1) | 43.6 (9.9) | 45.5 (8.2)* | 48.9 (9.7)* | 53.0 (15.7) | 57.2 (15.8) |
| Man (n (%)) | | 41 (33.6) | 25 (24.0) | 33 (35.5) | 25 (51.0) | 49 (59.8) | 92 (59.0) | 31 (43.7) | 36 (45.6) |
| Education | Low | - | - | - | - | - | - | 20 (28.2) | 17 (21.5) |
| (n (%)) | Middle | - | - | - | - | - | - | 35 (49.3) | 35 (44.3) |
| | High | - | - | - | - | - | - | 16 (22.5) | 27 (34.2) |
| **Level 2: A** | | | | | | | | | |
| (n (%)) | | 203 (89.9) | 23 (10.1) | 130 (91.5) | 12 (8.5) | 211 (88.7) | 27 (11.3) | 123 (82.0) | 27 (18.0) |
| Age (mean, sd) | | 45.9 (8.0) | 46.8 (8.2) | 42.3 (8.7) | 46.8 (8.8) | 46.3 (8.9) | 49.4 (8.6) | 55.1 (16.6) | 56.3 (12.3) |
| Man (n (%)) | | 57 (28.1) | 9 (39.1) | 50 (38.5) | 8 (66.7) | 128 (60.7) | 13 (48.1) | 54 (43.9) | 13 (48.1) |
| | Low | - | - | - | - | - | - | 33 (26.8) | 4 (14.8) |
| | Middle | - | - | - | - | - | - | 57 (46.3) | 13 (48.1) |
| | High | - | - | - | - | - | - | 33 (36.8) | 10 (37.0) |
| **Level 2: C** | | | | | | | | | |
| (n (%)) | | 174 (77.0) | 52 (23.0) | 111 (78.2) | 31 (21.8) | 207 (87.0) | 31 (13.0) | 119 (79.3) | 31 (20.7) |
| Age (mean, sd) | | 46.0 (8.3) | 46.0 (7.1) | 42.6 (8.6) | 42.7 (9.5) | 46.8 (9.0) | 45.9 (8.5) | 55.7 (16.4) | 53.5 (13.6) |
| Man (n (%)) | | 40 (23.0)** | 26 (50.0)** | 48 (43.5) | 10 (32.3) | 124 (59.9) | 17 (54.8) | 56 (47.1) | 11 (35.5) |
| Education | Low | - | - | - | - | - | - | 29 (24.4) | 8 (25.8) |
| (n (%)) | Middle | - | - | - | - | - | - | 54 (45.4) | 15 (51.6) |
| | High | - | - | - | - | - | - | 36 (30.3) | 7 (22.6) |

| Characteristic per level | | NPs | | PAs | | Physicians | | Patients | |
|---|---|---|---|---|---|---|---|---|---|
| | | Included | Excluded | Included | Excluded | Included | Excluded | Included | Excluded |
| **Level 3: A3** | | | | | | | | | |
| (n (%)) | | 153 (67.7) | 73 (32.3) | 112 (78.9) | 30 (21.1) | 189 (79.4) | 49 (20.6) | 111 (74.0) | 39 (26.0) |
| Age (mean, sd) | | 45.4 (8.1) | 47.2 (7.9) | 42.7 (8.4) | 42.5 (10.3) | 45.9 (8.8)* | 49.8 (8.5)* | 54.6 (16.2) | 57.2 (15.0) |
| Man (n (%)) | | 39 (25.5) | 27 (37.5) | 49 (43.8) | 9 (30.0) | 114 (60.3) | 27 (55.1) | 44 (39.6)** | 23 (59.0)** |
| Education (n (%)) | Low | - | - | - | - | - | - | 28 (25.2) | 9 (23.1) |
| | Middle | - | - | - | - | - | - | 50 (45.0) | 20 (51.3) |
| | High | - | - | - | - | - | - | 33 (29.7) | 10 (25.6) |
| **Total population (and Level 2: B, E; Level 3: E1, E2)** | | | | | | | | | |
| (n (%)) | | 226 (100.0) | - | 142 (100.0) | - | 238 (100.0) | - | 137 (91.3) | 13 (8.7) |
| Age (mean, sd) | | 46.0 (8.0) | - | 42.6 (8.8) | - | 46.7 (8.9) | - | 55.0 (16.2) | 58.1 (12.2) |
| Man (n (%)) | | 66 (29.2) | - | 58 (40.8) | - | 141 (59.2) | - | 59 (43.1) | 8 (61.5) |
| Education (n (%)) | Low | - | - | - | - | - | - | 34 (24.8) | 3 (23.1) |
| | Middle | - | - | - | - | - | - | 64 (46.7) | 6 (46.2) |
| | High | - | - | - | - | - | - | 39 (28.5) | 4 (30.8) |

* =Mann Whitney U test, p<0.05, **= Chi square test, Fisher ‘s Exact Test, p<0.05

**Table 4.2** Mean global and *local* [23] weights of the requirements by category respondents and measurement moments

| | Requirements | NPs | | PAs | | Physicians | | Patients | |
|---|---|---|---|---|---|---|---|---|---|
| | | T0 | T1 | T0 | T1 | T0 | T1 | T0 | T1 |
| **A** | **Quality of care** | **0.28** | **0.28** | **0.31** | **0.32** | **0.32** | **0.32** | **0.25** | **0.24** |
| | | ***0.28 (0.13)*** | ***0.28 (0.13)*** | ***0.31 (0.10)*** | ***0.32 (0.11)*** | ***0.32 (0.12)*** | ***0.32 (0.11)*** | ***0.25 (0.08)*** | ***0.24 (0.08)*** |
| A1 | Clinical quality | 0.13 | 0.12 | 0.16 | 0.17 | 0.15 | 0.13 | 0.14 | 0.12 |
| | | *0.46 (0.20)* | *0.44 (0.21)* | *0.53 (0.17)* | *0.53 (0.18)* | *0.48 (0.18)* | *0.41 (0.20)* | *0.56 (0.18)* | *0.50 (0.17)* |
| A2 | No complications | 0.09 | 0.09 | 0.08 | 0.08 | 0.10 | 0.11 | 0.05 | 0.06 |
| | | *0.31 (0.19)* | *0.31 (0.21)* | *0.25 (0.17)* | *0.26 (0.13)* | *0.31 (0.17)* | *0.35 (0.20)* | *0.18 (0.13)* | *0.26 (0.15)* |
| A3 | Patient satisfaction | 0.06 | 0.07 | 0.07 | 0.07 | 0.07 | 0.07 | 0.07 | 0.06 |
| | | *0.23 (0.18)* | *0.25 (0.20)* | *0.22 (0.16)* | *0.21 (0.13)* | *0.21 (0.15)* | *0.23 (0.18)* | *0.26 (0.17)* | *0.25 (0.14)* |
| A31 | Procedural time | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 |
| | | *0.27 (0.06)* | *0.26 (0.07)* | *0.29 (0.08)* | *0.26 (0.06)* | *0.27 (0.08)* | *0.29 (0.10)* | *0.34 (0.09)* | *0.34 (0.09)* |
| A32 | Communication | 0.03 | 0.04 | 0.03 | 0.03 | 0.03 | 0.03 | 0.02 | 0.02 |
| | | *0.50 (0.11)* | *0.51 (0.10)* | *0.47 (0.12)* | *0.49 (0.10)* | *0.46 (0.13)* | *0.46 (0.11)* | *0.38 (0.09)* | *0.35 (0.10)* |
| A33 | Appointment wait-time | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| | | *0.13 (0.07)* | *0.13 (0.05)* | *0.13 (0.07)* | *0.12 (0.06)* | *0.16 (0.09)* | *0.14 (0.07)* | *0.21 (0.11)* | *0.22 (0.10)* |
| A34 | Wait-time in waiting room | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.00 | 0.01 |
| | | *0.10 (0.05)* | *0.10 (0.06)* | *0.11 (0.05)* | *0.12 (0.07)* | *0.11 (0.05)* | *0.11 (0.07)* | *0.07 (0.06)* | *0.10 (0.10)* |
| **B** | **Competence of care provider** | **0.33** | **0.35** | **0.36** | **0.32** | **0.31** | **0.32** | **0.28** | **0.26** |
| | | ***0.33 (0.12)*** | ***0.35 (0.12)*** | ***0.36 (0.10)*** | ***0.32 (0.11)*** | ***0.31 (0.10)*** | ***0.32 (0.11)*** | ***0.28 (0.16)*** | ***0.26 (0.08)*** |
| B1 | Training | 0.12 | 0.13 | 0.10 | 0.11 | 0.11 | 0.13 | 0.11 | 0.12 |
| | | *0.35 (0.26)* | *0.38 (0.27)* | *0.27 (0.20)* | *0.33 (0.26)* | *0.36 (0.25)* | *0.40 (0.27)* | *0.40 (0.22)* | *0.45 (0.22)* |
| B2 | Experience | 0.21 | 0.22 | 0.26 | 0.21 | 0.20 | 0.19 | 0.17 | 0.14 |
| | | *0.65 (0.26)* | *0.62 (0.27)* | 0.73 (0.20) | 0.67 (0.26) | *0.64 (0.24)* | *0.60 (0.27)* | *0.60 (0.22)* | *0.55 (0.22)* |

| | Requirements | NPs | | PAs | | Physicians | | Patients | |
|---|---|---|---|---|---|---|---|---|---|
| | | T0 | T1 | T0 | T1 | T0 | T1 | T0 | T1 |
| **C** | **Risks of procedures** | **0.15** | **0.13** | **0.13** | **0.13** | **0.17** | **0.15** | **0.20** | **0.21** |
| | | ***0.15 (0.12)*** | ***0.13 (0.09)*** | ***0.13 (0.09)*** | ***0.13 (0.07)*** | ***0.17 (0.12)*** | ***0.15 (0.10)*** | ***0.20 (0.11)*** | ***0.21 (0.09)*** |
| C1 | Complexity of disease | 0.04 | 0.04 | 0.04 | 0.03 | 0.05 | 0.04 | 0.06 | 0.07 |
| | | *0.26 (0.15)* | *0.27 (0.13)* | 0.29 (0.16) | 0.26 (0.13) | 0.28 (0.14) | 0.27 (0.13) | 0.32 (0.21) | 0.31 (0.14) |
| C2 | Patient characteristics | 0.04 | 0.04 | 0.03 | 0.04 | 0.04 | 0.04 | 0.07 | 0.08 |
| | | *0.27 (0.17)* | *0.31 (0.17)* | *0.26 (0.17)* | *0.28 (0.17)* | *0.27 (0.19)* | *0.25 (0.18)* | *0.36 (0.22)* | *0.40 (0.19)* |
| C3 | Kind of procedure | 0.07 | 0.05 | 0.06 | 0.06 | 0.08 | 0.07 | 0.06 | 0.06 |
| | | *0.47 (0.21)* | *0.42 (0.21)* | *0.45 (0.21)* | *0.46 (0.20)* | *0.45 (0.20)* | *0.48 (0.19)* | *0.32 (0.24)* | *0.29 (0.22)* |
| **D** | **Costs** | **0.10** | **0.13** | **0.08** | **0.11** | **0.07** | **0.07** | **0.12** | **0.10** |
| | | ***0.10 (0.07)*** | ***0.13 (0.08)*** | ***0.08 (0.05)*** | ***0.11 (0.07)*** | ***0.07 (0.05)*** | ***0.07 (0.06)*** | ***0.12 (0.10)*** | ***0.10 (0.11)*** |
| **E** | **Organizational aspects** | **0.13** | **0.12** | **0.11** | **0.12** | **0.13** | **0.14** | **0.15** | **0.20** |
| | | ***0.13 (0.07)*** | ***0.12 (0.06)*** | ***0.11 (0.05)*** | ***0.12 (0.10)*** | ***0.13 (0.07)*** | ***0.14 (0.07)*** | ***0.15 (0.10)*** | ***0.20 (0.09)*** |
| E1 | Collaboration with physician | 0.06 | 0.06 | *0.05* | *0.06* | *0.06* | *0.08* | 0.12 | 0.14 |
| | | 0.44 (0.33) | *0.50 (0.30)* | *0.47 (0.30)* | *0.49 (0.29)* | *0.47 (0.30)* | *0.55 (0.29)* | *0.79 (0.16)* | *0.72 (0.23)* |
| E11 | Consultation structure | 0.05 | 0.05 | 0.04 | 0.05 | 0.04 | 0.05 | *0.09* | *0.10* |
| | | *0.80 (0.17)* | *0.82 (0.12)* | *0.80 (0.13)* | *0.83 (0.08)* | *0.70 (0.24)* | *0.68 (0.26)* | *0.77 (0.20)* | *0.68 (0.26)* |
| E12 | Indication | 0.01 | 0.01 | 0.01 | 0.01 | 0.02 | 0.02 | 0.03 | 0.05 |
| | | *0.20 (0.17)* | *0.18 (0.12)* | *0.20 (0.13)* | *0.17 (0.08)* | *0.30 (0.24)* | *0.32 (0.26)* | *0.23 (0.20)* | *0.32 (0.26)* |
| E2 | Presence of protocols | 0.07 | 0.06 | 0.06 | 0.06 | 0.07 | 0.06 | 0.03 | 0.06 |
| | | *0.56 (0.33)* | *0.50 (0.30)* | 0.53 (0.30) | *0.51 (0.29)* | *0.53 (0.30)* | *0.45 (0.29)* | *0.21 (0.16)* | *0.28 (0.18)* |
| E21 | Distribution of tasks, authorities. responsibilities | 0.04 | 0.03 | 0.03 | *0.04* | *0.04* | 0.04 | 0.02 | 0.03 |
| | | *0.54 (0.32)* | *0.50 (0.31)* | *0.55 (0.29)* | *0.59 (0.27)* | *0.53 (0.28)* | *0.56 (0.29)* | *0.62 (0.25)* | *0.55 (0.27)* |
| E22 | Denotation of procedures, patients, diseases | 0.04 | 0.03 | 0.03 | 0.03 | 0.03 | 0.03 | 0.01 | 0.03 |
| | | *0.46 (0.32)* | *0.50 (0.31)* | *0.45 (0.29)* | *0.41 (0.27)* | *0.47 (0.28)* | *0.44 (0.29)* | *0.38 (0.25)* | *0.45 (0.27)* |

T0 = 3 months before the law amendment, T1 = 1.5 years after the law amendment, sd = standard deviation

In establishing a weighted hierarchy of requirements that affect the political decision-making on whether above mentioned temporary authorities should be continued, all respondents considered A Quality of care (global weights 0.24-0.32) and B Competence of the care provider (global weights (0.26-0.36) as most important in Level 1. Costs were considered as least important requirement by all respondents (global weight 0.07-0.10). The highest overall global weight was applied to B2 Experience of the care provider (within B competence of the care provider, global weights 0.14-0.21). The requirement that a physician always indicates the reserved procedure (E12) was found only marginally important (global weights 0.01-0.05) according to physicians (as well as NPs, PAs and patients). Within this context, appointment waiting time and wait-time in the waiting room was of low priority according to patients (global weights 0.00-0.01).
Exclusions of extreme values, or respondents which could attenuate results, or exclusion of respondents with just moderate consistent judgments did not change the result as for the order of the criteria neither the magnitude of order (Table 4.3).

## Discussion

In this study, we assessed the relative importance of a hierarchy of requirements, that can affect the political decision-making on whether temporary authorities of NPs and PAs for reserved medical procedures in Dutch healthcare should be continued. This hierarchy of requirements was weighted with the AHP method by patients, NPs, PAs, and physicians. Our results show that quality of care and the competence of the care provider were the most important requirements. Quality of care could be mainly ascribed to health improvement/ correct diagnosis (not subdivided) compared to patient satisfaction and the absence of complications. The competence of care providers mainly concerned their experience. Costs and organizational aspects (collaboration with a physician or the presence of protocols) were considered to be the least important requirements. The *values* of all requirements have also been determined and translated to degrees of fulfilment (yes, partly, not). Values and degrees of fulfilment are presented in order of priority (AHP results) to the Ministry of HWS for informed decision-making. All this is published in the final report. [33]

**Table 4.3** Validity analysis of global weights (sd) of the requirements by category respondents

| | Requirements | A Quality of care | B Competence of care provider | C Risks of procedures | D Costs | E Organizational aspects |
|---|---|---|---|---|---|---|
| **NP** | Total (T0+T1) | 0.28 (0.13) | 0.33 (0.12) | 0.14 (0.11) | 0.11 (0.08) | 0.13 (0.07) |
| | Exclusion of cases with mean ±5sd | 0.28 (0.13) | 0.33 (0.12) | 0.14 (0.11) | 0.11 (0.08) | 0.13 (0.07) |
| | Exclusion of cases with CR<0.1 | 0.29 (0.13) | 0.32 (0.11) | 0.15 (0.10) | 0.11 (0.07) | 0.13 (0.07) |
| | Exclusion of cases with >50% no priority in all pairwise equations | 0.29 (0.12) | 0.35 (0.12) | 0.13 (0.10) | 0.12 (0.07) | 0.12 (0.06) |
| **PA** | Total (T0+T1) | 0.31 (0.11) | 0.35 (0.11) | 0.13 (0.08) | 0.09 (0.06) | 0.12 (0.07) |
| | Exclusion of cases with mean ±5sd | 0.32 (0.11) | 0.35 (0.10) | 0.13 (0.08) | 0.09 (0.06) | 0.11 (0.05) |
| | Exclusion of cases with CR<0.1 | 0.31 (0.10) | 0.34 (0.10) | 0.13 (0.08) | 0.10 (0.06) | 0.11 (0.08) |
| | Exclusion of cases with >50% no priority in all pairwise equations | 0.32 (0.11) | 0.35 (0.11) | 0.13 (0.08) | 0.09 (0.05) | 0.12 (0.08) |
| **Physician** | Total (T0+T1) | 0.32 (0.12) | 0.31 (0.11) | 0.16 (0.11) | 0.07 (0.05) | 0.13 (0.07) |
| | Exclusion of cases with mean ±5sd | 0.33 (0.11) | 0.32 (0.11) | 0.15 (0.09) | 0.07 (0.04) | 0.14 (0.07) |
| | Exclusion of cases with CR<0.1 | 0.32 (0.11) | 0.31 (0.10) | 0.16 (0.10) | 0.07 (0.05) | 0.13 (0.07) |
| | Exclusion of cases with >50% no priority in all pairwise equations | 0.31 (0.11) | 0.32 (0.11) | 0.16 (0.11) | 0.07 (0.05) | 0.13 (0.07) |
| **Patient** | Total (T0+T1) | 0.24 (0.09) | 0.27 (0.13) | 0.20 (0.09) | 0.11 (0.11) | 0.18 (0.09) |
| | Exclusion of cases with mean ±5sd | 0.24 (0.09) | 0.27 (0.13) | 0.20 (0.09) | 0.11 (0.11) | 0.18 (0.09) |
| | Exclusion of cases with CR<0.1 | 0.24 (0.08) | 0.26 (0.13) | 0.21 (0.09) | 0.11 (0.11) | 0.18 (0.09) |
| | Exclusion of cases with >50% no priority in all pairwise equations | 0.24 (0.09) | 0.27 (0.13) | 0.20 (0.10) | 0.11 (0.12) | 0.18 (0.10) |

T0 = 3 months before the law amendment, T1 = 1.5 years after the law amendment, sd = standard deviation, CR = consistency ratio

When weighting the hierarchy of requirements/criteria, patients showed comparable results with care providers; the order of the requirement was the same and so was the magnitude of the weights. Yet, compared to care providers, patients rated both alternatives in all pairwise equations statistically significantly more often to be of equal importance.

One explanation can be found in the way of presenting the questions. Patients' questions are divided in two parts (sequential method). In the first part patients were asked whether one criterion was more important than the other, or that there was no difference in importance (3 options). Only in the second part, patients were asked to state the extent of the difference in importance. This in contrast to the care providers' questions; in the same question (concurrent method) care providers had to prioritize and rate the (difference of) importance, where equal importance was

just 1 out of 17 options. The sequential method was used before [34], while validation with the concurrent method was never done before. Comparison of our ´no preference´ rate with those of concurrent methods in literature is, unfortunately, not possible because 'no preference' rates are rarely presented. Another obvious explanation can be that patients do not have clear preferences for one criterion. Complexity of the AHP method as rationale for the high 'no preference' rate among patients seems unlikely, given the large number of AHP studies with patients. Already in 1995, Dolan concluded that patients are capable of using the AHP method. It seems that he difficulty relates to the specific contents rather than the applied method. Further research on the use of the sequential method can contribute to more robust results. [35]

In this study, the AHP method proved to be robust; exclusions of extreme values, or respondents which could attenuate results, or respondents with just moderate consistent judgments did not change the results as for the order of the criteria neither the magnitude of weights. However, we observed variation in the number of excluded respondents, based on inconsistency. Most exclusions were found in level 1 with five abstractly formulated criteria, followed by level 3 A with three concretely formulated criteria and level 2 A and C, both with three rather abstractly formulated criteria. As CR could not be calculated for the other levels containing only two criteria, exclusion based on inconsistency did not apply in this case. The number of exclusions may depend on the number of criteria (more likely to be inconsistent), but also on the way of formulating (abstract-concrete) and the presenting order of the levels. In our questionnaire, we presented the higher-level comparisons first (top down). To gain familiarity with the details of the higher levels (abstract), Saaty [36] suggested to present the lower level comparisons first (bottom-up), but Webber et al. [37] did not find strong consistent order effects. Here too, more research is required for providing clarity.

Strengths of our study are the large sample size and the robust results, that are particularly novel to this area of research. A limitation is that order-effect bias cannot be ruled out. The order of the pairwise comparisons within one level were determined randomly, the levels, on the other hand, where in numeric order (randomly ordered criteria in level 1 followed by randomly ordered criteria in level 2 etcetera). A major limitation of our study is the modest generalizability of the identified order of the requirements, which are tailored to the Dutch setting. However, this article is also intended to describe the innovative approach of indirect

involvement of patients in the process of political decision making. Notwithstanding, there are still gaps in the knowledge base of AHP that need to be filled.

## Conclusion

In determining which factors are important in political decision-making, both care providers and patients can be successfully involved, as followed from applying the robust AHP method. Quality of care (health improvement or a correct diagnose) and the competence of the care provider are deemed the most important requirements to perform reserved medical procedures in Dutch healthcare.

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# Chapter 5

## A national mixed methods evaluation of the effects of removing legal barriers to full practice authority of Dutch Nurse Practitioners and Physician Assistants

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## Abstract

**Objective**

To evaluate the effects of granting legal full practice authority (FPA) to nurse practitioners (NPs) and physician assistants (PAs) regarding the performance of specified reserved medical procedures and to support governmental decision-making.

**Design**

Nationwide mixed methods design with triangulation of quantitative (Pre-posttest design) and qualitative data (expert interviews and focus groups).

**Methods**

Surveys focused on the performance of the procedures (monthly number, authorisation mode, consultations and procedural time) and legal cross compliance requirements (adherence to protocols, competence). Interviews focused on competence, knowledge, skills, responsibilities, routine behaviour, NP/PA role, acceptance, organisational structure, collaboration, consultation, NP/PA positioning, adherence to protocols, and resources. Data collection took place between 2011 and 2015.

**Results**

Quantitative data included 1251 NPs, 798 PAs and 504 physicians. Besides, expert interviews with 33 healthcare providers and 28 key stakeholders, and five focus groups (31 healthcare providers) were held.

After obtaining FPA, the proportion of NPs and PAs performing reserved procedures increased from 77% to 85% and from 86% to 93% respectively; the proportion of procedures performed on own authority increased from 63% to 76% for NPs and from 67% to 71% for PAs. The mean number of monthly contacts between NPs/PAs and physicians about procedures decreased (from 81 to 49 and from 107 to 54 respectively), as did the mean duration in minutes (from 9.9 to 8.6 and from 8.8 to 7.4 respectively). Utilization of FPA was dependent on the setting, as scepticism of physicians and medical boards hampered full implementation. Legal cross compliance requirements were mostly fulfilled.

**Conclusions**

Informal practice was legalised. The opportunities to independently perform catheterisations, injections, prescribing, punctures and small surgical procedures were highly utilized. Care processes were organized more efficiently, services were performed by the most appropriate healthcare provider and conditions were met. This led to the recommendation to continue with FPA.

**Strengths and limitations of this study**

- This is the first study to systematically evaluate the effects of introducing legal full practice authority (FPA) on processes and outcomes of care.
- This study offers a novel mixed methods approach for evaluation as well as data for cross-national comparison.
- The use of a mixed methods design with triangulation provides a comprehensive insight into a complex, sensitive subject.
- The limitations of this study, mostly anticipated by triangulation, include a moderate participation rate and the restraints of causal interference in the One Group Pre-posttest design with quantitative data.
- The novel survey tool was not tested for reliability and validity.

## Introduction

Despite task shifting being a common strategy for healthcare reform in many countries, its regulation does not keep pace. Task shifting concerns the redistribution of tasks among health workforce teams. It is no longer exclusively applied to anticipate health workers shortage, specifically physicians, although the benefits it has on the quality of healthcare have been recognized. [1-4] In particular, nurse practitioners (NPs) and physician assistants (PAs) are well qualified healthcare providers, who can comply with the requirements of healthcare reform, but practising to the full extent of their education and training (full practice authority: FPA) is often hampered by (the absence of) regulation. [5-7] In a review on task shifting from physicians to advanced nurses in five western countries, three levels of regulations have been distinguished: national regulation, decentralized regulation and unregulated, setting-dependent governance. [8] Both level and content of the regulation varied by country. Authority to prescribe medication was regulated by law in all countries, but the level of independence varied. The authors concluded that regulation for task shifting can either act as a potential barrier (when restrictive in nature) or be enabling (when up-to-date with educational competencies). Hence, for task shifting to be effective, regulation is decisive.

In the Netherlands, the Ministry of Health, Welfare and Sports (HWS) has adopted national task shifting policy. One measure to advance task shifting is to grant FPA to NPs and PAs. The number of registered NPs and PAs at present is over 3.000 [9] and 950 [10] respectively, most being employed in general and academic hospitals, general practitioner practices, mental healthcare institutions and nursing homes. [11] Both NPs and PAs work at a master's degree level. NPs work in medical and nursing domains, often with a specific group of patients. PAs only work in the medical domain. This involves both tasks in (in)direct patient care like consultations, visits, case management and file-keeping, as well as not patient-related tasks like development of integrated care, quality improvement programmes and protocols; training of other care providers and management tasks. In direct patient care, within the agreed working domain, NPs and PAs independently come to a (differential) diagnosis based on self-initiated anamnesis, physical and/or psychiatric examination and additional diagnostics and apply evidence-based interventions. [12,13]

In doing so, NPs/PAs autonomy (and thus optimal use of their competencies) was hampered by a legally required physician's consent to perform certain medical

procedures, as described in the Individual Health Care Professions Act (IHCP Act, in Dutch Wet BIG). In this law, the performing of specified medical procedures, termed reserved procedures, is reserved for defined healthcare professionals. By means of an amendment, followed by two Orders in Council in 2012, NPs and PAs have been legally authorized to independently indicate, execute and delegate the following reserved procedures: catheterisation, cardioversion, defibrillation, endoscopy, injection, puncture, prescribing prescription-only medicines and simple surgical procedures, creating truly FPA. NPs and PAs must be competent to perform these procedures and work according to guidelines containing cooperation agreements with physicians (i.e. protocols) including the range of prescriptive authority, a formulary may be added. The Orders in Council are valid for a period of 5 years and are subject to evaluation. Commissioned by the Ministry of HWS, we carried out this evaluation to support decision-making regarding continuation of the temporary practice authorities of NPs and PAs.

## Objective

We aimed to systematically evaluate the effects of granting FPA to NPs and PAs on the processes and outcomes of care. Due to the elimination of required consent, we hypothesized that NPs/PAs would perform more procedures on their own authority and that procedure times would become shorter overall. Furthermore, we expected legal cross compliance requirements would be met.

## Methods

The study protocol, including a comprehensive description of the methods, has been published elsewhere. [14] The study meets the STROBE [15] and COREQ [16] criteria for reporting quantitative and qualitative study results.

### Design

This study utilized a mixed methods design with a concurrent triangulation strategy (Table 5.1). Quantitative (surveys) and qualitative (interviews and focus groups) data were collected, analysed and interpreted in the same timeframe, and were considered of equal importance. [17-20] Quantitative data were collected according to a One Group Pre-posttest design with three time points: before the

**Table 5.1** Triangulation of structure, process and outcome measures

| **STRUCTURES** | |
|---|---|
| **Quantitative data** | ***Qualitative data*** |
| **NP/PA, physician background characteristics**<br>Job title, specialism, age, gender, education, years of experience. | ***NP/PA, physician background characteristics***<br>*Job title, specialism, gender.* |
| **Organisation background characteristics**<br>Type organisation, specialism, urbanisation level. | ***Organisation background characteristics***<br>*Type organisation, specialism.* |
| **Collaboration**<br>Presence of collaborating physicians, availability of supervising physicians, satisfaction (5-point Likert) about this. | ***Collaboration*** |
| | ***Positioning NP/PA*** |
| | ***Resources*** |
| **PROCESSES** | |
| **Quantitative data** | ***Qualitative data*** |
| **Adherence to protocols**<br>presence, contents and enforcement of protocols [26] | ***Adherence to protocols*** |
| **Consultation**<br>Frequency and mode of consultations [26] and sufficiency of this. | ***Consultation*** |
| **Competence**<br>Appraisal of competence [27] | ***Competence*** |
| | ***Role*** |
| | ***Routine behaviour*** |
| | ***Knowledge/skills*** |
| | ***Acceptance*** |
| **OUTCOMES** | |
| **Quantitative data** | ***Qualitative data*** |
| **Appropriate performance**<br>Monthly performance of specified reserved procedures and authorisation mode. For prescribing medicines: distinction between new, refill and change in dosage prescriptions; name and dosage of the drug. For injections: distinction between joints, tendon sheaths and keloids; administration of sclerotherapy; administration of local anaesthetics; intramuscular, intravenous, subcutaneous and intracardiac injections and name and dosage of the drug. | ***Responsibilities*** |
| **Costs**<br>Duration specific reserved procedure included consultation and process time, number and duration of inter collegial consultation. | |

amended law (T0) and one (T1) and two and a half years (T2) post-amendment. As the amendment affects the entire country, selection of a control group was impossible. Both methods were based on existing theoretical frameworks. The quantitative piece was based on the Nursing Role Effectiveness framework of Sidani and Irvine [21-23] combined with Donabedian's model [24] for assessing healthcare quality and proposing specific relationships between structures, processes and outcomes. The qualitative piece was based on the implementation model of Grol et al. [25] Factors that could affect the implementation process were categorized as individual health professionals' characteristics and social, organisational and societal components conforming to the model.

Triangulation was carried out according to the transformation model [18], in which qualitative data were quantified and quantitative data were converted into a narrative.

**Participants and recruitment**

We collected quantitative data (Figure 5.1) from a purposive sample of registered NPs and graduated PAs working in the Netherlands. Professional organizations, applied universities with NP/PA programs and national NP/PA congress committees, all assisted in data collection by means of newsletters, websites and direct contact. Every NP/PA was asked to invite two collaborating physicians for participation. Qualitative data were collected through semi-structured expert interviews and focus groups. Supported by the above organisations and facilities, we recruited NPs/PAs, physicians (as case studies) and stakeholders (including management staff across all levels in various settings, professional medical organisations, professional trainers, the Health Care Inspectorate, and Netherlands Institute for Accreditation in Healthcare) for expert interviews, taking into account the broad distribution of health organization types and medical specialisations, as well as geographical coverage. Case studies across the country were also invited to focus group meetings.

**Data collection**

For the quantitative data collection at T0, T1, T2 (Table 5.1), three different web- and paper-based questionnaires were used. [14] The first questionnaire, the Quickscan, consisted of five short questions and directed a maximal response. NPs and PAs could register the reserved procedures (main group) they had performed at a given time, complemented with the type of care organisation and medical specialism.

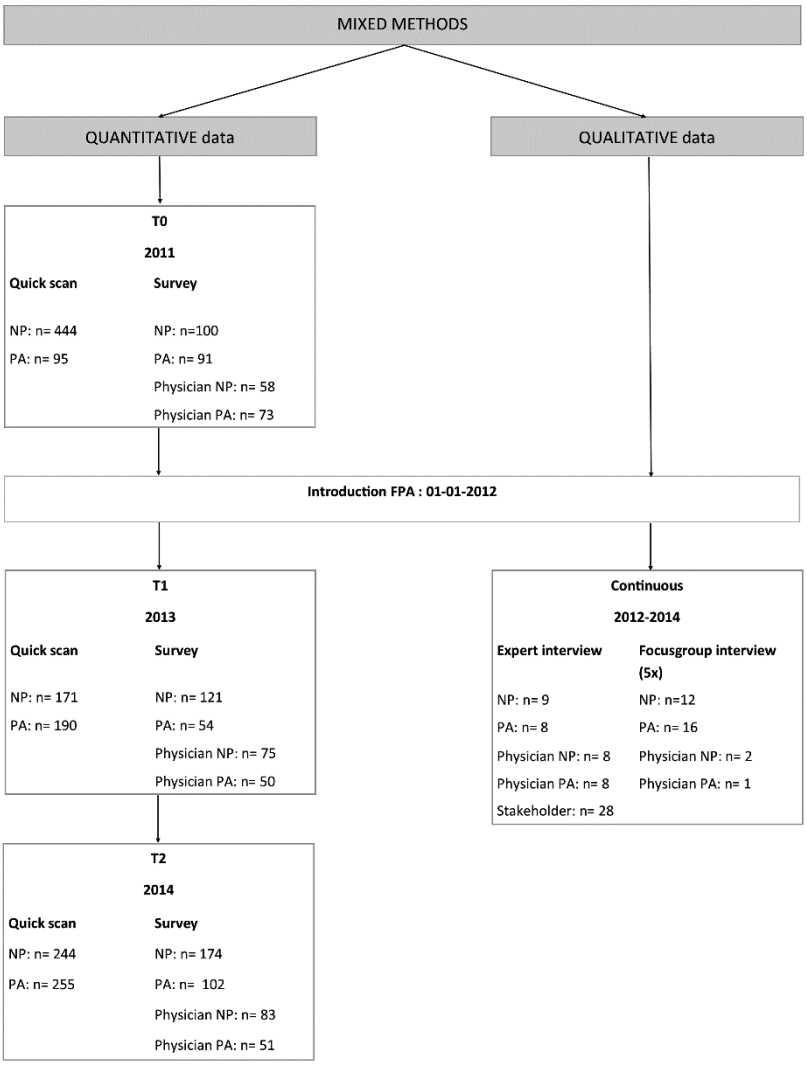


**Figure legend:**

NP: nurse practitioner PA: physician assistant
physician NP: physician collaborating with a NP physician PA: physician collaborating with a PA
stakeholders: management staff across all levels in various settings, professional (medical) organisations, professional trainers, pharmacies in various settings, GP out-of-office service, the Health Care Inspectorate, Netherlands Institute for Accreditation in Healthcare, Health insurance companies

**Figure 5.1** Study flow

By means of the NP/PA and physician questionnaires (Table 5.1), data were collected on the estimated number of procedures performed monthly (including whose authorisation was required and whether consultation with a physician was needed) and the procedure time needed (including consultation/assignment time). Background characteristics (i.e. age, gender, job title, specialism, years of experience and care setting) and the legal cross compliance requirements adherence to protocols [26] and competence [27] were also asked.

Expert interviews and focus groups were all directed by interview guides, that were developed in consultation with the study advisory board based on the implementation model (Table 5.1). [25] Expert interviews were conducted by author DDB. YvE moderated the focus group interviews, with DDB and MBB acting as observers. The independent interviewers had ample previous experience in conducting interviews. Prior to the interviews, the interviewers introduced themselves (stating their personal goals) and informed the participants about the general objectives of both the study and interview. Afterwards, an oral provisional summary was provided. The expert interview guide was pilot-tested over three interviews. After each quantitative data time point and analysis, the interview protocol was reviewed and refined. At first, open questions were raised about the main factors of the implementation model. A check list of derived key elements was kept. When the conversation did not elicit responses about these elements, direct questions were asked. The one-on-one interviews were conducted in person (or by phone) at a time and location that was convenient for the interviewee. Interviews lasted approximately 20-40 minutes for case studies and 45-60 minutes for stakeholders.

In the focus group guide, four central themes were drawn up to elicit multiple perspectives: the situation in which NPs/PAs performed reserved procedures, facilitators and barriers for that situation and preconditions for FPA. The themes were also compared with the factors in the implementation model [25] and unanticipated or vague elements were brought up later by the observers who made extensive field notes. All participants completed a written form providing demographic information. The focus group interviews (2 hours each) were conducted at four different meeting centres across the Netherlands.

The expert interviews and focus groups were digitally recorded and transcribed verbatim. The researchers checked the transcriptions and abstracts were sent to the participants for verification (i.e. member check).

**Statistical analysis**

Quantitative data analysis was performed using SPSS software version 22. [28] T1 was considered to be a mid-term evaluation (values are presented but not tested). For continuous variables, means with the corresponding 95% confidence interval (CI) were calculated and in case of non-normality (determined with the Kolmogorov-Smirnov normality test), medians and interquartile ranges were used. For the number and duration of monthly performed procedures, extreme values (>5 standard deviations from the mean) were excluded. Before determining the mean monthly performance for the main groups of reserved procedures (e.g. catheterisation), numbers from the separate procedures (e.g. bladder catheterisation) were added up for each respondent. The original plan was to perform longitudinal group analyses. [14] However, as the composition of the groups at time points strongly diverged (only 12% of the NPs/PAs completed the surveys at each time point, 66% at a single one), the Mann-Whitney test was instead used to test for differences between T0 and T2. For categorical variables, frequencies and percentages were calculated and the chi square test (with 1 degree of freedom) was used to test for differences between T0 and T2. Tests were performed at both group and subgroup levels for participants taking part in T0 and T2. Only group data are presented, although differences for subgroup data are discussed in the main text. All tests were performed two-sided with a p-value of >0.05.

The editing analysis style [29] was used for qualitative data and was carried out with NVIVO 10 software. [30] The authors DDB and MBB independently (re-)read the transcripts for an overall impression and identified patterns inside the categorization scheme, which was composed of the factors from the implementation model. [25] For each pattern, search terms were selected, and a code book was drafted through an iterative consensus process. After independent coding of several initial transcripts, the code book was refined and used to guide the analysis of the remaining transcripts. Three reviewers (DDB, MBB and EM (research assistant)) independently applied the codebook and expanded it as the analysis proceeded. They continually met and reviewed findings. The authors YvE and HV reviewed and discussed the findings. Since we aimed to cover a broad scope, data saturation (the ability to obtain additional new information) [31] of the interviews was attained only in the final stage of the interview series.

**Ethics statement**

Ethical approval was given by the Maastricht University Medical Ethics Committee in July 2011. The study was considered an evaluation of daily practice and hence not subject to

the Medical Research Involving Human Subjects Act. All participants were assured that data were handled confidentially and could not lead to their identification. Interviewees were also informed that they could terminate the interview at any time. Oral informed consent to use data collected for scientific research (including publication of the study findings) was obtained from every interviewee.

**Patient and Public Involvement**

Data were collected from patients regarding continuity of patient care, treatment success, patient compliance, perceived expertise, patient centred care, safety, healthcare access, preferences and satisfaction. In doing so, patients were invited to fill out surveys and to participate in interviews. The findings from the perspective of patients will be published in a separate scientific paper, whereas all study findings, including those from patients, have been published in a Dutch study report that is publicly available at https://www.rijksoverheid.nl/documenten/rapporten/ 2015/ 11/11/voor-bighouden. During a national conference about skill mix later this year, patient representatives will be invited to share their feedback on the study findings.

## Results

In accordance with the triangulation framework, quantitative and qualitative results are not presented separately. To distinguish between them, quantitative results are presented in regular font and *qualitative results in italic font*. In case of significant quantitative trends between values at T0 and T2, both values are presented in the text separated by an arrow (T0→T2), otherwise only values at T2 are presented. For each (*qualitative*) topic, the most supporting and appealing citation (*Qx*) is presented in Table 5.2. The study flow is presented in Figure 5.1. In total 544/292/418 NPs, 186/244/357 PAs and 131/125/134 physicians filled in the questionnaires at T0/T1/T2; 9 NPs, 8 PAs, 16 physicians and 28 stakeholders were individually interviewed and 12 NPs, 16 PAs and 3 physicians attended the five focus group meetings.

**Table 5.2** Quotes per topic

| *Number quote* | *Topic* | *Quote* |
|---|---|---|
| *Q1* | *Implementation* | *"That is the next step, that for several departments those protocols have been prepared. We are proposing this to divisional directors and psychiatrists, so they know how we want to implement this and also to give them insight into our competence. This is so that they are aware of how we work." (NP)* |
| *Q2* | *Collaboration* | *"We stated within our team of nurse practitioners, that within the institution one has to collaborate with psychiatrists. That one does not just go at it alone. We have said: we want to provide openness and draft protocols together." (NP mental health)* |
| *Q3* | *Positioning NP/PA* | *"Show us what the NPs/PAs can do! In fact, what do they add? What is the actual added value, how do they make this visible and how can we make sound agreements?" (stakeholder)* |
| *Q4* | *Resources* | *"If you don't allow NPs to open a DBC*, you won't know whether care will ultimately become cheaper." (stakeholder)*<br>**DBC (in Dutch Diagnose Behandeling Combinatie) is a hospital funding model based on fixed prices for a combination of diagnosis and treatment* |
| *Q5* | *Adherence to protocols* | *"Psychiatrists within the institution refuse to give NPs an opportunity to develop good protocols, leaving them bound hand and foot." (NP)* |
| *Q6* | *Consultation* | *"We talk with each other every day. Every two weeks there are formal consultations with the entire team. But in the workplace, there is daily consultation. During consultation hours, we are physically next to each other, you know. So, in this aspect, there are very short lines of communication." (physician)* |
| *Q7* | *Competence* | *"When is someone competent? In the centre, we deal flexibly with this. This is necessary when you have 4 NPs walking around. It also means that when they do ask for consultation, it should run quite smoothly. If they really should prescribe drugs and they believe themselves incompetent, they should consult us, so we can give them the background they need." (physician)* |
| *Q8* | *Role* | *"What is NP's/PA's role within the medical team? I think, best to describe is being part of it." (physician)* |
| *Q9* | *Routine behaviour* | *"If it concerns nonstandard drugs, we will then write it down. The prescription must be seen by neonatologist within 24 hours. When in doubt, or whatever else, I let someone watch." (NP)* |
| *Q10* | *Knowledge* | *"Pharmacotherapy is a skill in itself. Final responsibility sometimes covers knowledge of additional medical subjects, of which they have no expertise." (physician)* |
| *Q11* | | *"It is just that we need to ensure that all of the specific knowledge will be used. But it is also reflected in the internship supervisor's assessments, of course I see them too, and I notice that they all are satisfied with the quality of knowledge, as I personally am on a day to day basis" (physician)* |

| Number quote | Topic | Quote |
|---|---|---|
| Q12 | | "What is not yet properly regulated is that we don't have a real budget for refresher courses. It is extremely important for them to receive further training. As with the specialist, who creates a budget through collective labour agreements. Unfortunately, this is not yet possible for the PA. The interesting conferences and symposia are naturally always abroad, which means that they have to travel abroad, but simply don't have the money." (PA) |
| Q13 | Acceptance | "The advantages are increasingly being recognized by everyone. Furthermore, being the constant of the outpatient clinical team, they take over several responsibilities. We work there about one day every two weeks. They work there every day and therefore they overhear more such as problems doctors' assistants face in their work. They recognize them more quickly than we do, which means that problems can be resolved more rapidly. Besides, because they work there every day and know a great deal, outpatient clinic staff occasionally ask them what the standard approach is. There was support, but now this is completely broad. No one has any doubts." (physician) |
| Q14 | | "This led to quite some issues with some people. Not so much a defined profession, but the hierarchy that has arisen due to a long-time employment of certain colleagues. People like healthcare psychologists cannot abide a nurse practitioner with a different approach for the activities. Not so much a discipline, but personal views, I guess. Some psychologists are very excited while others say, 'what on earth are you doing.'" (NP) |
| Q15 | | "Of course, nurses like to work with more permanent people, which make it possible to build up experience and expertise with each other." (PA) |
| Q16 | | "How the organisation handles it, that is what I do not find entirely satisfactory. I must say that I am the second NP in our hospital. How do they deal with the talks we have held with the organisation? Do they respond and set up things more often in consultation with you? It is a real pioneering role, you know, together with my colleagues. So yes, organisational awareness is required. I must make things known, to set up by myself, to organise by myself. The initiative comes from ourselves, rather than the organisation. It is a pity. It is partly unfamiliarity, also with the role, and inadequately being informed or involved. I think it comes from both sides, which is unfortunate." (NP) |
| Q17 | | "The NPs are very credible care providers for patients, if patients have confidence in NPs knowledge, which is certainly present, and NPs demonstrate they know their boundaries. Nurse's accessibility and communication make them a credible care provider for patients. Naturally, from time to time patients should be seen by a physician. But very often they return to the NP, as soon as possible." (physician) |
| Q18 | | "They are struggling with the problem, that they want to see that we are authorized, that we have a quality register, that we are registered, that they can check whether we are allowed as we say. Contacts should be established with pharmacists in primary care to present the legislative amendment. Many people do not know we are allowed to prescribe, which is often the problem." (PA) |
| Q19 | | "What makes it very difficult is that the insurers within the psychiatry, the mental healthcare, currently indicate that they do not recognise NPs as primary practitioners. They extremely prohibit us from treating." (NP) |
| Q20 | Responsibilities | "Yes, this is more of a learning process. As it is getting better and I can agree with their proposals, I increasingly let them go. Not before, regardless any amendment. Sure, that amendment makes it easier, but it must be justified." (physician) |

| *Number quote* | *Topic* | *Quote* |
|---|---|---|
| *Q21* | *Legislation* | *"The letters of the law do not allow me to order chest photos, CT-scans or anything with radiation. This is hard to grasp in reserved procedures. Because that is also related to radiation, captured in another law. PA's daily work is hampered by the absence of a reserved procedure on ordering radiation sources." (PA)* |
| *Q22* | | *"No, it is not yet complete. It is also quite difficult. When is it completed? It may well be that procedures are included you think that this should not be the case since in practice it turns out to be relatively rare. I can certainly imagine that many procedures will be added. In practice, procedures, not yet known nationally, are increasingly allocated. It is hard to say the list is complete. I guess that is not possible. In this stage, considerable variation may develop. Over time, this will further develop and at a given time you have your profile." (stakeholder)* |

**Implementation**

At T2, FPA was achieved for 83.5% of the NPs and 86.3% of the PAs (data not in table). *Reasons for not achieving FPA included physician reluctance, lack of approval by management and/or in-process implementation. NPs and PAs went through several key steps to achieve FPA. These included making individual agreements with physicians, assembling working groups within the organisation, making (group) agreements with pharmacists, writing protocols, submitting protocols to management (Q1), arranging access to (digital) patient files, widely informing the organisation and training.*

**STRUCTURES**

**Background characteristics**

Quantitative demographic data and work-related details of the participants are presented in Table 5.3. The results showed no statistically significant differences over time for age, gender, prior education or NP specialisation.

**Collaboration/collaboration**

The number of physicians with whom NPs and PAs collaborated did not change after the introduction of FPA (data not in table). Over half of the PAs (T2: 55.9%) worked in collaboration with >6 physicians and about one third (T2: 32.4%) in collaboration with 3-6 physicians. NPs worked in slightly smaller teams: equal proportions worked in a collaboration with 3-6 physicians (T2: 37.4%) and >6 physicians (T2: 37.4%). A small percentage of NPs (T2: 1.7%; those who worked in an ambulance setting) did not collaborate with any physicians. *All NPs/PAs and physicians emphasized the importance of collaboration with each other (Q2).*

***Positioning NP/PA***

*The positioning and visibility of the NP/PA was associated with the implementation of FPA, but FPA was also used to achieve better positioning. Higher management and external stakeholders asked for evidence of the added value provided by NPs/PAs (Q3).*

***Resources***

*Funding of NPs/PAs varied. They were employed by the organisation, but also by associations of physicians. Registration of their operations was not transparent, although the necessity was recognized by the directorate. Clear registration was considered indispensable to establish the cost-effectiveness of using NPs/PAs (Q4).*

**Table 5.3** General background characteristics of the respondents in the surveys at T0, T1 and T2

| **NP** | **T0** | **T1** | **T2** |
|---|---|---|---|
| Number included | 100 | 121 | 174 |
| Age (*mean, 95% CI)* | 45.8 (44.3-47.4) | 46.3 (44.8-47.8) | 46.6 (45.3-47.8) |
| Gender *(n man, % man)* | 31 (31.0) | 30 (24.8) | 48 (27.4 |
| Years of experience (*mean, 95% CI*) | 4.3 (3.5-5.1) | 5.9 (5.2-6.6) | 5.6 (5.0-6.1)* |
| Prior education *(n, %)* | | | |
| Nurse anaesthetist | 3 (3.0) | 0 (0.0) | 2 (1.1) |
| Occupational therapist | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Physiotherapist | 0 (0.0) | 0 (0.0) | 1 (0.6) |
| Nurse with higher professional education | 38 (39.2) | 50 (41.7) | 83 (47.7) |
| In-service training | 53 (54.6) | 66 (55.0) | 81 (46.6) |
| Medical imaging technologist | 1 (1.0) | 0 (0.0) | 0 (0.0) |
| Nurse with secondary vocational education | 3 (3.1) | 3 (2.5) | 3 (1.7) |
| Surgical assistant | 0 (0.0) | 1 (0.8) | 0 (0.0) |
| Dietician | 0 (0.0) | 0 (0.0) | 2 (1.1) |
| Specialism NP *(n, %)* | | | |
| Acute healthcare | 7 (7.1) | 10 (8.4) | 15 (8.8) |
| Chronic healthcare | 17 (17.3) | 28 (23.5) | 36 (21.1) |
| Mental healthcare | 25 (25.5) | 27 (22.7) | 47 (27.5) |
| Intensive healthcare | 49 (50.0) | 53 (44.5) | 72 (42.1) |
| Preventive healthcare | 1 (1.0) | 2 (1.7) | 2 (1.2) |
| **PA** | **T0** | **T1** | **T2** |
| Number included | 91 | 54 | 102 |
| Age (*mean, 95% CI)* | 42.7 (41.0-44.4) | 43.5 (41.1-45.8) | 41.6 (39.7-43.6) |
| Gender *(n man, % man)* | 34 (37.4) | 24 (35.8) | 36 (35.3) |
| Years of experience (*mean, 95% CI*) | 4.1 (3.6-4.5) | 4.9 (4.3-5.6) | 4.4 (3.8-4.9) |
| Prior education *(n, %)* | | | |
| Nurse anaesthetist | 10 (11.2) | 3 (4.5) | 6 (5.9) |
| Occupational therapist | 1 (1.1) | 3 (4.5) | 3 (2.9) |
| Physiotherapist | 20 (22.5) | 13 (19.4) | 19 (18.6) |
| Nurse with higher professional education | 21 (23.6) | 23 (34.3) | 24 (23.5) |
| In-service training | 21 (23.6) | 11 (16.4) | 14 (13.7) |
| Medical imaging technologist | 6 (6.7) | 3 (4.5) | 12 (11.8) |
| Nurse with secondary vocational education | 4 (4.5) | 2 (3.0) | 1 (1.0) |
| Surgical assistant | 7 (7.7) | 4 (6.0) | 11 (10.8) |
| Dietician | 2 (2.2) | 0 (0.0) | 4 (3.9) |
| **Physician collaborating with a NP** | **T0** | **T1** | **T2** |
| Number included | 58 | 75 | 83 |
| Age (*mean, 95% CI)* | 47.2 (44.8-49.5) | 46.5 (44.4-48.7) | 46.9 (44.9-48.9) |
| Gender *(n man, % man)* | 33 (55.9) | 44 (55.7) | 41 (47.1) |
| Years of experience (*median, IQR*) | 11.8 (9.5-14.0) | 12.3 (10.2-14.3) | 12.3 (10.5-14.1) |
| **Physician collaborating with a PA** | **T0** | **T1** | **T2** |
| Number included | 73 | 50 | 51 |
| Age (*mean, 95% CI)* | 47.9 (46.1-49.8) | 46.7 (44.0-49.4) | 45.5 (43.3-47.7) |
| Gender *(n man, % man)* | 52 (70.3) | 35 (68.6) | 24 (47.1)** |
| Years of experience (*median, IQR*) | 12.3 (10.5-14.2) | 12.0 (9.6-14.3) | 11.5 (9.2-13.8) |

* Mann-Whitney test between T0 and T2, $p<0.05$

** Chi square test (df=1) between T0 and T2, $p<0.05$

**PROCESSES**

**Adherence to protocols/*Adherence to protocols***

*Almost every interviewed NP/PA worked according to (national) guidelines and under clear work instructions. Cooperation agreements with physicians as part of the protocols were occasionally drafted.* Written protocols were still not present in all settings (Table 5.4, T2: NPs: 15.2%, PAs: 23.7%). If present, they often failed to be completely satisfactory (T2: NP 44.4%, PA 36.2%). Deficiencies mainly concerned the distribution of tasks (T2: NP 21.9%, PA 14.7%) and responsibilities (T2: NP 22.6%, PA 10.6%). *This was not due to ambiguities, but to lack of formally recording the mutual agreements. About half of the NPs/PAs indicated that protocol development was still in process; but some stated that the process was restrained (Q5) since physicians wanted to maintain overall responsibility.* For about half of the NPs and a third of the PAs the protocols were personalized and recorded (Table 5.4, T2: NP 57.4%, PA 36.7%). Of those with personalized protocols, less than half (T2: NP 43.0%, PA 38.5%) were checked for adherence.

**Table 5.4** Adherence to protocols

| | NP | | | PA | | |
|---|---|---|---|---|---|---|
| n (%) | **T0** | **T1** | **T2** | **T0** | **T1** | **T2** |
| General written protocols present | 31 (70.5) | 97 (81.5) | 145 (84.8) | 16 (66.7) | 44 (68.8) | 74 (76.3)) |
| Completely satisfying | 15 (55.6) | 51 (56.7) | 81 (58.3) | 10 (66.7) | 21 (51.2) | 44 (63.8) |
| Partly satisfying | 11 (40.7) | 37 (41.1) | 54 (38.8) | 5 (33.3) | 18 (43.9) | 24 (43.8) |
| Not satisfying | 1 (3.7) | 2 (2.2) | 4 (2.9) | 0 (0.0) | 2 (4.9) | 1 (1.4) |
| Ambiguities about | | | | | | |
| Work instructions | 2 (8.3) | 6 (5.0) | 9 (6.0) | 0 (0.0) | 7 (11.1) | 4 (4.7) |
| Distribution of tasks | 1 (4.2) | 14 (11.7) | 34 (21.9)* | 0 (0.0) | 5 (7.9) | 14 (14.7) |
| Distribution of responsibilities | 8 (33.3) | 12 (10.0) | 35 (22.6)* | 1 (7.1) | 8 (12.7) | 10 (10.6) |
| Personalized protocols present, Including: | 19 (42.2) | 67 (57.3) | 89 (57.4) | 11 (42.3) | 23 (37.7) | 33 (36.7) |
| Specified reserved procedures allowed to perform on own | 11 (61.1) | 45 (38.5) | 70 (55.6) | 8 (72.2) | 13 (22.4) | 28 (38.4)* |
| Specified patient groups, allowed to treat on own | 10 (55.6) | 41 (35.0) | 57 (41.0) | 5 (45.5) | 7 (12.1) | 19 (23.8)* |
| Specified medication, allowed to prescribe on own authority | 9 (50.0) | 49 (41.9) | 81 (58.3) | 4 (36.4) | 12 (20.7) | 29 (36.3) |
| Method to assess competence | 3 (16.7) | 13 (11.1) | 29 (20.9) | 1 (9.1) | 9 (15.5) | 4 (5.0) |
| Distribution of responsibilities | 2 (11.1) | 16 (13.7) | 25 (18.0) | 2 (18.2) | 6 (10.3) | 8 (10.0) |
| Adherence to personalized protocols examined | 11 (55.0) | 24 (36.9) | 43 (43.0) | 5 (45.5) | 15 (57.7) | 15 (38.5) |

* Chi square test (df=1) between T0 and T2, p<0.05

**Consultation/*Consultation***

Availability of physicians for consultation, if needed by the NP/PA, was considered good (Table 5.5, T2: NP 63.3%, PA 79.2%) and thus NPs/PAs were satisfied (T2: NP 91.6%, PA 95.0%). The frequency of the consultation varied. Two trends between T0→T2 were statistically significant: more NPs/PAs consulted physicians more than once a day (NP: 11.9%→25.1%, PA: 29.2%→52.0%) and fewer NPs only consulted them once a day (33.3%→18.1%). One third of the NPs that consulted physicians monthly worked in an acute setting. The consultation was mainly face-to-face or by phone. *Ad hoc consultation was always possible, but structural consultations about less acute issues were hard to schedule and in-depth conversations were not always possible. Most NPs/PAs had structural work meetings, the frequency of which were highly dependent on the setting (Q6). In hospitals NPs/PAs participated in multidisciplinary meetings, which physicians sometimes considered as a threat.*

**Table 5.5** Consultation

| | NP | | | PA | | |
|---|---|---|---|---|---|---|
| | **T0** | **T1** | **T2** | **T0** | **T1** | **T2** |
| How often is a physician available for consultation when you perform a reserved procedure? | | | | | | |
| Seldom | 2 (5.0) | 6 (5.3) | 6 (3.6) | 0 (0.0) | 3 (4.8) | 2 (2.1) |
| Sometimes | 1 (2.5) | 4 (3.5) | 17 (10.2) | 2 (8.3) | 1 (1.6) | 3 (3.1) |
| Often | 10 (25.0) | 31 (27.2) | 38 (22.9) | 8 (33.3) | 12 (19.0) | 15 (15.6) |
| As needed | 27 (67.5) | 73 (64.0) | 105 (63.3) | 14 (58.3) | 47 (74.6) | 76 (79.2) |
| How satisfied are you with the availability? | | | | | | |
| Very satisfied | 22 (48.9) | 40 (36.0) | 57 (34.1) | 14 (58.3) | 34 (54.0) | 57 (57.6) |
| Satisfied | 20 (44.4) | 60 (54.1) | 96 (57.5) | 9 (37.5) | 27 (42.9) | 37 (37.4) |
| Less satisfied | 2 (4.4) | 10 (9.0) | 9 (5.4) | 1 (4.2) | 2 (3.2) | 3 (3.0) |
| Dissatisfied | 1 (2.2) | 1 (0.9) | 5 (3.0) | 0 (0.0) | 0 (0.0) | 2 (2.0) |
| Very dissatisfied | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| How often do you consult a physician on individual patients? | | | | | | |
| More than 1x/day | 5 (11.9) | 45 (38.5) | 43 (25.1)* | 7 (29.2) | 31 (47.7) | 52 (52.0) |
| 1x/day | 14 (33.3) | 13 (11.1) | 31 (18.1)* | 10 (41.7) | 10 (15.4) | 18 (18.0)* |
| More than 1x/week | 13 (33.3) | 35 (29.9) | 61 (35.7) | 3 (12.5) | 20 (30.8) | 19 (19.0) |
| 1x/week | 9 (21.4) | 22 (18.8) | 28 (16.4) | 2 (8.3) | 4 (6.2) | 10 (10.0) |
| 1x/month | 0 (0.0) | 2 (1.7) | 8 (4.7) | 2 (8.3) | 0 (0.0) | 1 (1.0) |
| In what form is this consultation? (multiple answers possible) | | | | | | |
| Face to face | 42 (42.4) | 117 (96.7) | 159 (92.4)* | 23 (25.6) | 63 (94.0) | 96 (96.0)* |
| By telephone | 23 (23.1) | 75 (62.0) | 104 (60.5)* | 15 (16.7) | 40 (59.7) | 56 (56.0)* |
| By e-mail | 17 (17.2) | 53 (43.8) | 66 (38.4)* | 6 (6.7) | 14 (20.9) | 22 (21.8)* |
| Do you think the available time for consultation is sufficient? | | | | | | |
| Yes | 40 (93.0) | 111 (91.7) | 152 (91.0) | 24 (92.3) | 64 (97.0) | 99 (98.0) |
| No | 3 (7.0) | 10 (8.3) | 15 (9.0) | 2 (7.7) | 2 (3.0) | 2 (2.0) |

* Chi square test (df=1) between T0 and T2, $p<0.05$

**Competence/ *Competence***

Significantly more NPs and PAs replied affirmatively to most response categories with methods to assess their competence for reserved procedures. At T2 compared to T0 (data not in table): more NPs and PAs assessed their competence, above all, based on patient characteristics (NP 27.0%→68.8%, PA 18.4%→65.3%) next to the specific procedure (NP 26.0%→27.1%, PA 23.0%→44.6%) and the education/training (NP 13.0%→28.8%, PA 9.3%→35.6%). An increase was observed in tendency for physicians to issue certificates of competence and/or endorsements (NP 11.0%→26.5%, PA 2.3%→27.7%). Small percentages NPs/PAs left the assessment of their competence to the responsibility of the physicians (T2: NP 7.7%, PA 6.9%). Physicians usually assessed this competence based on their training (T2: physician NP 34.3%, physician PA 26.9%) or left the assessment to the NP/PA themselves (T2: physician NP 33.3%, physician PA 28.8%). Significantly less physicians assessed the competence of NPs based on the specific procedure (physician NP 47.5%→23.0%). *Interviews showed that physicians had a growing confidence in NPs/PAs to guard their own boundaries (Q7).* Before the amendment, half of the NPs reported that the physicians checked their prescriptions, whereas after the amendment this went down to just a quarter (data not in table; 47.1%→22.5%). For PAs, there was no shift: before and after the amendment, a quarter of the prescriptions were checked (T2: 24.7%). The percentages NPs/PAs asking for physician consent afterwards decreased significantly (NP 98.2%→29.1%, PA 52.9%→30.6%).

***Role***

*All NPs/PAs had an integrated role in the treatment team (Q8). Following the amendment, the role of some NPs/PAs had changed to be more autonomous and, in many cases, they became seen as role models*.

***Routine behaviour***

*Some reserved procedures could not be performed routinely. To maintain expertise some NPs/PAs regularly worked in a different setting. When prescribing nonstandard medication or medication for patients with multi-morbidity, most NPs/PAs consulted a physician or had the prescription checked afterwards (Q9).*

***Knowledge/skills***

Most NPs and PAs judged their knowledge to independently prescribe as sufficient (data not in table; T2: NP 79.9%, PA 76.1%), which did not change significantly over

time. *NPs/PAs reported that because of the limited prescription formulary, their knowledge was good enough.* Alike, physicians stated that NPs/PAs had an adequate level of pharmacotherapy knowledge, however a small proportion disagreed (T2: physician NP 9.1%, physician PA 14.5%) *and explained that sometimes broader knowledge of other medical specialisations was essential (Q10).*

*Interviews showed that NPs/PAs and physicians agreed that NPs/PAs knowledge was the most important requirement for FPA, which was generally perceived as adequate (Q11). To maintain knowledge, on-going training occurred in different ways: internal training (strongly setting dependent), visiting (inter-)national conventions/symposia and attending courses. Lack of adequate funding was often a limiting factor (Q12) and caused problems with obtaining accreditation points. The restricted accredited training services also hindered the gathering of these points.* However, most NPs/PAs indicated they were ultimately able to submit a sufficient amount of accreditation points to the National Accreditation Registry governing their profession (data not in table; T2: NP 85.7%, PA 78.6%).

NPs/PAs skills to perform reserved procedures were rated as excellent (data not in table; T2: NP 83.6%, PA 90.7%, physician NP 78.5%; physician PA 87.8%).

***Acceptance***

*The acceptance of NPs/PAs could be divided into:*

- *Closely collaborating physicians: Interviewed NPs/PAs were well accepted by those physicians. The introduction of the NP/PA was most often initiated by a single physician and after initial scepticism the role was widely supported by associated physicians. Good positioning was considered to be facilitating (Q13);*
- *Other physicians: The acceptance by other physicians varied. The more ignorant physicians were of NPs/PAs role, the weaker their support. NPs/PAs talked about the process of gaining confidence as slow going and there remained scepticism among physicians. The level of support for prescription authority was strongly dependent of the type of medication (Q14);*
- *Nurses: Nurses supported NPs/PAs for being a consistent and (often) having a nursing background (Q15);*
- *Management: The lowest management levels widely accepted NPs/PAs. The extent of support from the highest levels was strongly dependent on the*

*setting being "NP/PA-minded", which led to differences in policy, guidelines and agreements (Q16);*

- *Patients: Physicians and NPs/PAs pointed out that patients strongly accepted NPs/PAs for their accessibility and continuity. Most patients could not tell the difference between NPs/PAs and physicians (Q17);*
- *Pharmacists: Pharmacists contributed to the implementation of FPA when quality was guaranteed and clear agreements were made. The provision of a formal approval of a physician added value (Q18);*
- *Health insurance companies: In mental healthcare the proper functioning of NPs was hindered by their lack of recognition as primary caregivers, which subsequently caused invoice problems (Q19).*

**OUTCOMES**

**Appropriate performance**

Most NPs, PAs and physicians agreed that implementation of FPA led to improvement in healthcare for particular groups of patients (data not in table; T2: NP 88.7%, PA 84.6%; physician NP 66.6%, physician PA 61.2%). *When asked for clarification, they said NPs and PAs provided continuity and could work on quality improvement, previously the responsibility of rotating trainee doctors.*

The proportion of NPs/PAs performing (indicating, executing, delegating) a reserved procedure (Quickscan, Table 5.6) increased during the measurement period T0→T2 for all procedures (except for cardioversion and endoscopy by PAs). Increases were statistically significant for catheterisations performed by PAs (25.3%→26.7%), prescriptions by NPs and PAs (NP 55.2%→72.5%, PA 57.9%→81.6%), and small surgical procedures by NPs and PAs (NP 22.3%→31.0%, PA 37.9%→52.9%). Trends for mean (95% CI) number of monthly performed procedures were less coherent. There were significant increases in PA injections (19.8 (13.3-26.2)→37.2 (27.5-47.6)), punctures (9.5 (5.7-13.3)→19.6 (12.5-26.8)) and small surgical procedures (15.5 (9.3-20.9)→30.0 (22.8-38.3)).

Compared to T0, NPs/PAs performed all procedures at T2 more autonomously and without consulting a physician.

The proportion of procedures performed on authorisation of NPs significantly increased for prescribing (65.7%→74.5%) and small surgical procedures (62.7%→88.7%). As for prescribing, no differences in authorisation mode between new and repeat prescriptions emerged.

**Table 5.6** Appropriate performance of separate reserved procedures

| | NP | | | PA | | |
|---|---|---|---|---|---|---|
| | **T0** | **T1** | **T2** | **T0** | **T1** | **T2** |
| **Cardioversion/defibrillation**[1] | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 23 (5.2) | 1 (0.6) | 15 (6.1) | 12 (12.6) | 16 (8.4) | 27 (10.6) |
| **Catheterisation** | | | | | | |
| N (%) NPs/PAs, performing the procedure | 69 (15.5) | 29 (17.0) | 53 (21.7)[3] | 24 (25.3) | 33 (17.4) | 68 (26.7) |
| Mean (95% CI) number of monthly performed procedures by NP/PA | 16.2 (10.3-22.1) | 14.0 (9.4-18.7) | 23.0 (15.6-30.3) | 15.2 (10.0-20.5) | 19.0 (11.3-26.6) | 23.0 (15.7-30.5) |
| % procedures performed on authorisation of NP/PA | 65.3 | 75.5 | 81.9 | 81.2 | 83.9 | 78.5 |
| + without consultation | 43.0 | 57.1 | 65.6 | 56.5 | 75.8 | 65.2 |
| ++ delegation to other care provider | 1.7 | 21.8 | 34.4[3] | 0.0 | 42.5 | 33.7[3] |
| Mean (95% CI) duration of a single performed procedure by NP/PA (min.)[2] | 13.4 (11.9-15.0) | 11.6 (10.1-13.1) | 9.2 (8.1-10.2)[4] | 10.3 (8.9-11.7) | 8.3 (7.1-9.4) | 7.2 (6.2-8.2)[4] |
| Mean (95% CI) number of monthly contacts physicians-NP/PA about the procedure[5] | 23.3 (9.8-36.7) | 15.0 (7.4-22.7) | 12.0 (2.0-22.0) | 25.7 (15.5-35.9) | 33.6 (13.7-53.6) | 16.0 (2.9-29.1) |
| % contacts on physician's assignment of the procedure to the NP/PA[5] | 69.1 | 52.2 | 70.6 | 56.0 | 57.4 | 62.5 |
| Mean (95% CI) physician's assignment time (min)[5] | 3.3 (1.0-5.0) | 6.6 (2.5-10.0) | 8.2 (6.1-10.0)[4] | 3.2 (1.3-4.6) | 6.1 (4.3-10.0) | 7.9 (4.9-9.4)[4] |
| **Endoscopy**[1] | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 9 (2.0) | 6 (3.5) | 9 (3.7) | 8 (8.4) | 14 (7.4) | 21 (8.2) |
| **Injection** | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 208 (46.8) | 75 (43.9) | 124 (50.8) | 64 (67.4) | 132 (69.5) | 178 (69.8) |
| Mean (95% CI) number of monthly performed procedures by NP/PA | 18.3 (10.4-26.2) | 24.4 (14.0-34.2) | 25.2 (17.0-33.5) | 19.8 (13.3-26.2) | 26.6 (15.7-36.9) | 37.2 (27.5-47.6)[4] |
| % procedures performed on authorisation of NP/PA | 54.0 | 64.4 | 68.7 | 66.7 | 76.7 | 79.6 |
| + without consultation | 30.7 | 42.5 | 47.2 | 38.7) | 54.7 | 56.5 |
| ++ delegation to other care provider | 0.7 | 13.1 | 19.4[3] | 0.5 | 16.9 | 14.8[3] |

| | NP | | | PA | | |
|---|---|---|---|---|---|---|
| | T0 | T1 | T2 | T0 | T1 | T2 |
| Mean (95% CI) duration of a single performed procedure by NP/PA (min.)[2] | 7.8 (6.7-8.8) | 6.3 (5.4-7.2) | 7.4 (6.5-8.3) | 7.3 (6.4-8.3) | 6.2 (5.3-7.0) | 5.6 (4.7-6.4)[4] |
| Mean (95% CI) number of monthly contacts physicians-NP/PA about the procedure[5] | 18.1 (10.5-25.6) | 15.3 (8.5-22.2) | 15.5 (6.9-24.2) | 19.1 (11.7-26.5) | 21.4 (8.1-34.7) | 29.5 (8.6-50.4) |
| % contacts on physician's assignment of the procedure to the NP/PA[5] | 80.6 | 60.5 | 50.0[3] | 52.4 | 60.8 | 47.7 |
| Mean (95% CI) physician's assignment time (min)[5] | 2.6 (0.5-5.0) | 4.8 (4.4-5.0) | 7.1 (5.1-15.0)[4] | 2.6 (1.7-3.0) | 2.5 (1.3-3.5) | 6.3 (5.6-10.3)[4] |
| **Prescribing** | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 245 (55.2) | 134 (78.4) | 177 (72.5)[3] | 55 (57.9) | 148 (77.9) | 208 (81.6)[3] |
| Mean (95% CI) number of monthly performed procedures by NP/PA | 52.7 (41.2-64.1) | 46.2 (37.7-54.8) | 49.5 (42.5-56.5) | 74.7 (59.6-89.8) | 87.3 (66.1-108.5) | 76.8 (62.7-89.8) |
| % procedures performed on authorisation of NP/PA | 65.7 | 75.7 | 74.5[3] | 66.5 | 79.6 | 67.1 |
| + without consultation | 27.3 | 51.6 | 51.0[3] | 35.8 | 52.1 | 45.6[3] |
| ++ delegation to other care provider | 1.6 | 3.9 | 5.0[3] | 0.0 | 9.3 | 2.9[3] |
| Mean (95% CI) duration of a single performed procedure by NP/PA (min.)[2] | 7.2 (6.5-7.9) | 6.3 (5.6-6.9) | 7.2 (6.7-7.6) | 4.3 (3.8-4.7) | 4.5 (4.0-5.0) | 3.5 (3.3-3.8) |
| Mean (95% CI) number of monthly contacts physicians-NP/PA about the procedure[5] | 70.9 (46.3-95.5) | 58.0 (40.2-75.9) | 46.8 (30.1-63.5) | 74.6 (54.5-94.6) | 64.6 (41.2-88.1) | 57.2 (37.5-76.9) |
| % contacts on physician's assignment of the procedure to the NP/PA[5] | 53.5 | 57.2 | 31.4[3] | 54.1 | 47.7 | 54.6 |
| Mean (95% CI) physician's assignment time (min)[5] | 4.1 (1.0-5.0) | 4.6 (4.2-5.0) | 4.1 (3.9-4.3) | 2.2 (1.8-2.5) | 3.2 (2.7-3.9) | 3.6 (3.3-3.8)[4] |
| **Puncture** | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 88 (19.8) | 32 (18.7) | 51 (20.9) | 41 (43.2) | 102 (53.7) | 135 (52.9) |
| Mean (95% CI) number of monthly performed procedures by NP/PA | 14.7 (8.9-20.5) | 11.8 (5.7-17.0) | 11.8 (7.5-15.8) | 9.5 (5.7-13.3) | 18.2 (11.8-24.6) | 19.6 (12.5-26.8)[4] |
| % procedures performed on authorisation of NP/PA | 55.8 | 64.9 | 74.1 | 72.0 | 69.4 | 70.8 |
| + without consultation | 32.6 | 43.2 | 46.9 | 45.3 | 51.8 | 47.2 |
| ++ delegation to other care provider | 0.0 | 2.7 | 16.0[3] | 0.0 | 18.8 | 14.6[3] |

| | NP | | | PA | | |
|---|---|---|---|---|---|---|
| | T0 | T1 | T2 | T0 | T1 | T2 |
| Mean (95% CI) duration of a single performed procedure by NP/PA (min.)[2] | 13.5 (10.9-16.0) | 11.1 (7.8-14.4) | 13.0 (10.1-15.8) | 11.1 (9.3-13.0) | 11.3 (9.2-13.3) | 11.0 (8.4-13.6) |
| Mean (95% CI) number of monthly contacts physicians-NP/PA about the procedure[5] | 26.9 (14.9-38.9) | 10.2 (2.7-17.6) | 6.9 (2.2-11.5)[4] | 13.9 (9.6-18.1) | 11.1 (2.6-19.6) | 6.3 (3.7-8.9)[4] |
| % contacts on physician's assignment of the procedure to the NP/PA[5] | 78.6 | 56.5 | 28.6[3] | 64.3 | 53.3 | 67.7 |
| Mean (95% CI) physician's assignment time (min)[5] | 3.9 (0.5-5.0) | 14.3 (5.0-10.4) | 10.5 (7.3-17.5)[4] | 2.5 (1.3-5.0) | 4.2 (1.0-7.8) | 9.2 (5.3-13.5)[4] |
| **Small surgical procedure** | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 99 (22.3) | 41 (24.0) | 76 (31.1)[3] | 36 (37.9) | 88 (46.3) | 135 (52.9)[3] |
| Mean (95% CI) number of monthly performed procedures by NP/PA | 10.5 (7.1-13.9) | 11.8 (6.5-17.0) | 15.1 (9.0-21.2) | 15.5 (9.3-20.9) | 17.0 (10.6-23.4) | 30.0 (22.8-38.3)[4] |
| % procedures performed on authorisation of NP/PA | 62.7 | 82.8 | 88.7[3] | 60.9 | 72.4 | 68.2 |
| + without consultation | 40.0 | 64.4 | 68.1[3] | 32.4 | 45.9 | 47.0 |
| ++ delegation to other care provider | 1.8 | 2.3 | 15.7[3] | 0.0 | 11.0 | 10.3[3] |
| Mean (95% CI) duration of a single performed procedure by NP/PA (min.)[2] | 16.0 (13.8-18.3) | 14.5 (12.1-16.8) | 13.6 (12.1-15.1) | 16.0 (13.8-18.2) | 13.8 (12.3-15.3) | 13.9 (12.6-15.3) |
| Mean (95% CI) number of monthly contacts physicians-NP/PA about the procedure[5] | 20.1 (7.5-32.7) | 17.1 (8.1-26.1) | 19.3 (8.5-30.1) | 30.9 (20.0-41.8) | 7.9 (3.9-12.0) | 14.1 (8.7-19.5)[4] |
| % contacts on physician's assignment of the procedure to the NP/PA[5] | 70.7 | 48.7 | 47.1[3] | 53.8 | 61.5 | 47.4 |
| Mean (95% CI) physician's assignment time (min)[5] | 4.6 (1.0-5.0) | 5.0 (3.9-8.2) | 6.9 (4.8-8.8) | 6.4 (1.3-7.8) | 8.0 (2.9-6.8) | 10.5 (8.0-15.0)[4] |
| **Total of above procedures** | | | | | | |
| N (%) NPs/PAs, performing the procedure (Quickscan) | 341 (76.6) | 152 (88.9) | 207 (84.8)[3] | 82 (86.3) | 178 (93.7) | 236 (92.5) |
| Mean (95% CI) number of monthly performed procedures by NP/PA | 80.5 (64.6-96.3) | 71.8 (58.2-85.3) | 77.4 (65.7-89.2) | 119.8 (97.6-142.1) | 141.6 (106.8-176.4) | 133.2 (111.7-154.8) |
| % procedures performed on authorisation of NP/PA | 63.0 | 74.3 | 76.1[3] | 66.7 | 77.1 | 71.1 |
| + without consultation | 31.9 | 51.9 | 54.2[3] | 38.4 | 55.2 | 50.8[3] |
| ++ delegation to other care provider | 1.7 | 7.5 | 13.0[3] | 0.1 | 17.9 | 12.4[3] |

| | NP | | | PA | | |
|---|---|---|---|---|---|---|
| | **T0** | **T1** | **T2** | **T0** | **T1** | **T2** |
| Mean (95% CI) duration of a single performed procedure by NP/PA (min.)[2] | 9.9 (9.3-10.5) | 8.1 (7.5-8.6) | 8.6 (8.2-9.0)[4] | 8.8 (8.1-9.4) | 8.1 (7.6-8.7) | 7.4 (6.9-7.8)[4] |
| Mean (95% CI) number of monthly contacts physicians-NP/PA about the procedure[5] | 81.2 (58.2-104.3) | 60.7 (44.7-76.7) | 49.1 (35.1-63.0) | 107.2 (82.9-131.5) | 67.5 (48.7-86.3) | 53.9 (38.6-69.3)[4] |
| % contacts on physician's assignment of the procedure to the NP/PA[5] | 64.8 | 56.2 | 41.5[3] | 55.4 | 55.6 | 54.7 |
| Mean (95% CI) physician's assignment time (min)[5] | 3.8 (1.0-5.0) | 6.3 (2.0-10.0) | 5.9 (1.6-10.0)[4] | 3.5 (0.5-5.0) | 4.3 (1.0-5.0) | 6.6 (2.0-10.0)[4] |

[1]= lack of data about the mean (95% CI) number of monthly performed procedures by NP/PA; % procedures performed on authorisation of NP/PA; mean (95% CI) duration of a single performed procedure by NP/PA; mean (95% CI) number of physician noted contacts with NP/PA about the procedure and % physician noted contacts on an assignment of the procedure to the NP/PA

[2]= including consultation or assignment time

[3]= statistically significant difference between T0-T2 ($X^2(1)$ $p<0.05$)

[4]= statistically significant difference between T0-T2 (MW $p<0.05$)

[5]= physician's perspective

The proportion of procedures performed on authorisation of NPs/PAs without consultation with a physician also significantly increased for prescribing (NP 27.3%→51.0%, PA 35.8%→45.6%) and small surgical procedures performed by NPs (40.0%→68.1%). At the same time, the proportion of all procedures delegated to another care provider significantly increased (NP 1.7% →13.0%, PA 0.1%→12.4%).
The mean (95% CI) contact between physicians and NPs/PAs regarding procedures (from the perspective of the physician) significantly decreased for puncture (NP 26.9 (14.9-38.9) →6.9 (2.2-11.5), PA 13.9 (9.6-18.1)→6.3 (3.7-8.9)) and for all procedures performed by PAs (107.2 (82.9-131.5)→53.9 (38.6-69.3)). Mean contact also decreased for all other procedures (except injection), however none met statistical significance.
For all procedures, the contact between physicians and NPs changed over time. Significantly less contact was made to assign procedures to the NP (64.8%→41.5%) and more contact was made for consultations requested by the NP. The proportion of assignments did not change for PAs. Furthermore, the proportion of assignments to NPs significantly decreased for all specific procedures, with the exception of catheterisation.
From the perspective of physicians, the overall mean (95% CI) assignment time significantly increased (physician NP 3.8 (1.0-5.0)→5.9 (1.6-10.0) minutes; physician PA 3.5 (0.5-5.0)→6.6 (2.0-10.0) minutes). Increases were also observed for all separate procedures except for prescribing performed by NPs.
Above measures could not be determined for cardioversion/defibrillation or endoscopy due to a lack of data.

***Responsibilities***

*A few NPs/PAs reported that the amendment was not a tipping point for the way they performed a reserved procedure. For most NPs/PAs, autonomy increased for the range of reserved procedures they were allowed to (independently) perform and they were less rigorously checked. A learning curve was mentioned often (Q20).*

**Efficiency**

The mean duration (95% CI) of the all procedures in minutes (Table 5.3), including consultation or assignment time, significantly decreased over the time points (NP 9.9 (9.3-10.5)→8.6 (8.2-9.0), PA 8.8 (8.1-9.4)→7.4 (6.9-7.8)), just like some of the specific procedures, namely catheterisation (NP 13.4 (11.9-15.0)→9.1 (8.1-10.2), PA 10.3 (8.9-11.7)→7.2 (6.2-8.2)) and injections performed by PAs (7.3 (6.4-8.3)→5.6 (4.7-6.4)).
Nearly every NP/PA and physician opined, during all measurements, that health care for certain groups of patients became more efficient after granting FPA for specific

reserved procedures (data not in table, T2: NP 96.4%, PA 94.8%, physician NP 80.4%; physician PA 83.9%).

In answer to the question whether physicians noticed a change in contact with patients following the introduction of NPs/PAs, only a minority controverted (Table 5.7; T2: physician NP 23.9%, physician PA 13.5%). Half of the physicians collaborating with a NP (56.8%) and a quarter of the physicians collaborating with a PA (28.8%) saw patients with more complex medical needs. Moreover, a quarter of physicians reported they saw less patients (physician NP 26.1%, physician PA 26.9%) and another quarter (those collaborating with a PA) also reported they performed fewer medical procedures (25.0%). About one in six physicians reported that patient contact lasted longer.

**Table 5.7** Change in patient contacts after introduction of NP/PA

| Do you notice a change in your patient contact with the advent of the NP or PA (multiple answers possible)? *n (%)* | **T2**<br>**Physician NP** | **T2**<br>**Physician PA** |
|---|---|---|
| No | 21 (23.9) | 7 (13.5) |
| Yes, | | |
| I see more patients | 4 (4.5) | 6 (11.5) |
| I see less patients | 23 (26.1) | 14 (26.9) |
| I see more patients with complex problems | 50 (56.8) | 15 (28.8) |
| I perform more medical procedures | 3 (3.4) | 0 (0.0) |
| I perform fewer medical procedures | 10 (11.4) | 13 (25.0) |
| I perform more complex medical procedures | 11 (12.5) | 5 (9.6) |
| My patient contacts last longer | 13 (14.8) | 7 (13.5) |

**Legislation**

The amended law was persistently considered to be an improvement over previous regulation (data not in table; T2: NP 94.0%, PA 95.7%, physician NP 78.8%, physician PA 70.9%) and in line with daily practice (NP T2: 79.9%; PA T2: 72.2%; physician NP T2: 83.8%; physician PA T2: 70.8%). Yet, a reasonable percentage of care providers indicated that the list of reserved procedures did not go far enough, though this did significantly decrease over time (NP 17.7%→9.5%; PA 31.8%→21.6%; physician NP 29.7%→7.2%; physician PA 37.3%→15.2%). *Specific procedures mentioned to be lacking included ascites tapping, determination of death and performing/ordering radiotherapy (Q21). It was also said that the described list should be regularly re-evaluated as to whether it corresponds to daily practice (Q22).*

## Discussion

In Dutch health reform policy, task shifting has been prioritised in the form of granting FPA to NPs and PAs, specifically for the performance of cardioversion/defibrillation, catheterisation, endoscopy, injections, prescribing, puncture and small surgical procedures. FPA's introduction was accompanied by a nationwide evaluation of its effects on the processes and outcomes of care for purposes of further decision-making. The present article includes a basic section of the evaluation study.

FPA's legalization was driven by the need of the professional field. [32, 33] In our study, this need was clearly reflected in the initial presence of informal practice and further exploitation of the legal possibilities. Prior to the introduction of FPA, most NPs/PAs frequently performed reserved procedures on their own authority. After the introduction, the proportion of NPs/PAs performing reserved procedures increased, as did autonomous performance.

The implementation of FPA was found to be strongly dependent on the setting, as was already shown for prescriptive authority. [34] Scepticism of physicians and medical boards hampered the full implementation, especially in areas of mental health, which was demonstrated prior to the introduction of FPA. [35] This barrier has also emerged in other countries where restrictions that limit a more fully practicing authority were addressed. [7, 36-41] The main objection to FPA is also reflected in the present study: following an extensive clinical education, physicians are better trained at managing patients with complex health problems. [14, 42]

Three quarters of the studied reserved procedures were performed on the NPs/PAs own authority. For about a quarter of those procedures, consultation with a physician was needed. The observed need for consultation might have been due to a sense of uncertainty, emphasising the necessity of a collaborative relationship with a physician. Consultation might also have been necessary when additional rules and limitations had been imposed. [34] Indeed, there was a growing trend to set out specified conditions (e.g. type of procedures, patient groups to treat independently) in protocols. Restriction of NP activities to a narrower scope of practice than legally authorised has been seen in other studies. [43-45]

The mean number of contacts between physicians and NPs/PAs about a procedure decreased over time with FPA, as did the overall procedural time. However, the mean physician's assignment time increased. A plausible explanation for this might

have been the shift in the physician's patient population towards fewer patients that had more complex health problems. Assigning a reserved procedure to a NP/PA subsequently required more instruction. Also, NPs/PAs treated most of their patients independently. Physicians were only consulted when the NP/PA was in doubt, which also resulted in longer consultation time. Literature has confirmed the existence of such a patient shift, where physicians tend to have older patients with a greater number of comorbidities or severity of illness. [46] However, more research on this patient-shifting hypothesis is needed. Furthermore, to test the hypothesis around cost-effectiveness of FPA, more and broader research on (additional) operations (e.g. ordering diagnostic imaging and pathology, and prescribing patterns) is needed because the effect of FPA on total healthcare spending is inconclusive.

A first proxy to efficient granting of FPA can be found in the mean duration for NPs/PAs to perform a procedure. This duration decreased due to elimination of dispensable assignment time and, to a lesser extent, consultation time with physicians. One of the presumed benefits of FPA is removing delays in care when a physician authorisation is needed prior to initiation of medications or diagnostic testing. [47] Saving time for both NPs/PAs and physicians may result in more time for patient care, thereby improving access to care. [42] To our knowledge, the present study is the first to account for time in this regard.

As access to care improves, utilization will run in parallel. Although prices could decrease for NP/PA services, the number of services provided may increase, raising overall costs of healthcare. [42, 48] For example, US granting NPs independent prescriptive authority had higher rates of prescriptions filled and higher prescription costs, leading to higher overall costs. [46] At the time of this evaluation NP's/PA's operations were registered in the name of the supervising physician or department instead of the individual NP/PA. This has since been adjusted. [49-51]

Legal cross compliance requirements were mainly fulfilled. The most important requirement was the NP's/PA's competency. NPs/PAs were very conscious of the boundaries of their competency, usually based on the actual situation, and on the individual patient associated with the specific reserved procedure. After the introduction of FPA, physicians left the assessment of NP's/PA's competency more and more to the NPs/PAs themselves. Physicians began to provide slightly more certificates of competence to, and regular assessment for, NPs/PAs. An insufficient budget for training sometimes obstructed maintenance of knowledge and therefore competency. Another cross-compliance requirement included the consultation

structure for the performance of reserved procedures. NPs/PAs were very satisfied with the consultation structure and physician's availability for consultation. Lastly, NPs/PAs performed reserved procedures according to (national) guidelines and extracted (and personalized) protocols. The protocols sometimes showed deficiencies in recording local cooperation agreements, like the distribution of tasks and responsibilities.

According to the study protocol [14], workload and the perspective of patients (4th questionnaire): continuity of patient care, treatment success, patient compliance, perceived expertise, patient centred care, safety, healthcare access, in addition to patient preference and satisfaction in the patient interviews, were the subjects of evaluation. These are elaborated on elsewhere due to the extensiveness of results.

Despite their ability to provide diverse health services independently, NPs worldwide are constrained from doing so because of restrictive state laws and regulations. [3, 7, 38, 52-57] Little is known about PA regulations and authorities. The legal status of PAs is often not resolved, resulting in limited authority. [57] The common denominator seems to be that PAs, as physician extenders, work under supervision of physicians and rarely practice (or prescribe) independently. [53, 57-61] As a result, there is a great lack of studies measuring the effectiveness of fully independent practices, as also seen above. This is reinforced by the fact that research isolating the effects of NP/PA from a whole healthcare chain on various outcomes is limited. Most studies on the role of NP/PA address quality of care and there is a growing body of evidence, based on systematic reviews, that NPs provide care at least equivalent to that of physicians in terms of health status, satisfaction, treatment adherence, patient risk and use of specialists. [2, 62-66] However, systematic reviews do not distinguish between degrees of independence, nor any changes thereto over time. For PAs, no conclusive scientific evidence is available at all. Nevertheless, internationally there are some indications that easing scope-of practice regulations can increase quality of care. Traczynski and Udalova [67], in a study on healthcare utilization and health outcomes, concluded that US states without restrictive NP regulations scored better on patient-reported available time, listening to concerns and understandable explanations. Furthermore, they saw an increase in annual check-ups and a long-term reduction in avoidable emergency room visits after gaining NP independence. Similar studies within the Dutch setting are advisably.

The independent performance of medical procedures by NPs and PAs as part of practice authority is rarely specified in regulations. In literature, various illustrations

of, to a greater or lesser extent, independent performance of medical procedures can be found in different settings in Australia, England, and US. These procedures include abdominal drainage, biopsy, bronchoscopy, cardioversion, chest tube insertion or removal, endoscopy, fine-needle aspiration, placement of (pulmonary) arterial or (peripherally) central catheter, placement of extra ventricular drain, intravitreal/joint/carpal tunnel injection, lumbar puncture, paracentesis, sedation/anaesthesia**,** thoracentesis, removal of intracranial pressure monitor, and thoracostomy. [58, 61, 68-78] Here too, more research is needed.

## Strengths and weaknesses of the study

A key strength of this study is the mixed-methods and triangulation approach. The introduction of FPA, a complex and delicate intervention, asked for an evaluation from multiple perspectives in a broad range of areas. Quantitative data alone might not cover the full picture, as it neither illuminated how or why FPA was implemented (or not), nor enabled contextualising. Multi-faceted triangulation was used to minimize bias. We applied not only (mixed) methods triangulation to reduce single method bias, but also data triangulation through various data sources, including time (three time points), participant (NPs/PAs, physicians, patients, stakeholders) and site (organizational setting, geographical coverage). Investigator triangulation, combining multiple interviewers and data analysts, supported by a solid interview guide and codebook, and peer review of the findings, was used along with theory triangulation (two theoretical frameworks) to further reduce bias. This approach empowered us to overcome moderate survey participation and provided a reliable and representative picture of the effectiveness and efficiency of FPA for NPs/PAs.

Another strength of this study is its potential for cross-country comparison. The frameworks used for both quantitative and qualitative data are internationally accepted and applied. Besides, the study design captures not only the impact of the regulation on generic outcomes but also the underlying mechanism and their association.

There are, nonetheless, some limitations of this research which require consideration. First, only a small proportion (12%) of the NPs/PAs, and hence also physicians, completed the surveys at all time points. Observed differences between T0 and T2 in those population-level results could be attributed to differences in group composition. However, longitudinal sub-analysis of the individuals completing

all surveys, showed equal (i.e. not statistically significant due to insufficient statistical power) trends. Moreover, these trends were confirmed by qualitative data. Second, according to the traditional positivist/empiricist approach of demonstrating causality, the used One Group pre-posttest design has its shortcomings. Over the past decade, new more advanced causality models were developed, all reflecting three key criteria: the cause precedes the effect, there is a certain relationship between cause and effect, and other plausible alternatives are eliminated. [79] With the mixed method design we approached all criteria. The quantitative methods were used to establish a relationship between the cause and effect, before the amendment and thereafter. Qualitative data were used to describe the processes after the amendment and to eliminate other plausible alternatives. A third limitation of this study is related to external validity. The survey sample of collaborating physicians did not reflect the total population of physicians. It was considered important to include only those physicians who had experience in working with NPs/PAs. However, formal points of view of professional organisations, representing all physicians, were expressed in expert interviews. Finally, the novel survey tool was not tested for reliability and validity. However, the survey tool was based on validated instruments and there were no indications for issues regarding reliability and validity.

## Conclusion and policy implication

The study showed that for some NPs/PAs informal practice was legalised by the law amendment enabling FPA, whereas others were encouraged to further develop their role. New opportunities for NPs/PAs to independently indicate, perform and delegate catheterisations, injections, prescriptions, punctures and small surgical procedures were highly exploited. Notwithstanding, for elective cardioversion/defibrillation and endoscopy, lack of data did not allow for any conclusions. Care processes were organized more efficiently, and care was provided by the most appropriate healthcare provider. These study findings support the policy initiative to improve the effectiveness of care delivery by granting FPA to NPs and PAs. Hence, our advice is to turn this temporary policy initiative into a definite one.

FOOTNOTES

**Contributors**

DDB, MBB, YvE and HV significantly participated in the conception and design of the study and the interpretation of the data. DDB and MBB conducted the interviews, collected the data and were responsible for the statistical analyses. BE provided input for the cost-study. DDB wrote the first and subsequent drafts of the paper, all (DDB. MBB, YvE, BE, CD and HV) contributed to editing and refining. All authors read and approved the final manuscript.

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**Competing interests**

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work.

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**Ethics Approval**

Ethical approval for this study was obtained from the Maastricht Medical Ethics Committee in July 2011 (reference number METC 11-5-045).

**Data sharing statement**

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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# Chapter 6

## General discussion

## Introduction

To improve quality of care by means of task shifting, the Dutch Ministry of Health, Welfare and Sports (HWS) fundamentally changed the Individual Health Care Professions Act (IHCP Act, Wet BIG) in 2012. By this legal change, new additional healthcare providers, other than physicians, midwives and dentists are, during a pilot period of five years, allowed to independently perform legally regulated medical procedures that entail considerable health risks, the so-called reserved procedures. The IHCP Act prescribes that such task shifting is evaluated.

The first healthcare providers to fall under this regulation, were Nurse Practitioners (NPs) and Physician Assistants (PAs). Commissioned by the Ministry of HWS, we carried out an evaluation to support decision-making regarding continuation of the temporary authorities of NPs and PAs, resulting in the Dutch report "voorBIGhouden". [1] The overall aim of the study was to systematically evaluate the effects of granting independent rights to NPs and PAs regarding the performance of specified reserved medical procedures (in *chapter 5* also referred to as full practice authority (FPA)), on the processes and outcomes of care. The evaluation did not aim to compare and contrast NPs and PAs. This dissertation contains the main findings of the evaluation that are published in international literature. The separate findings together with its strengths and limitations have been addressed in the previous chapters. This chapter presents an overview of the main findings, a more general reflection and discussion of the current legal framework in relation to task shifting and closes with recommendations and an overall conclusion.

## Summary of the main findings

The implementation of independent rights to NPs and PAs, regarding eight totally different procedures (each also a catch-all term including a multitude of procedures), in very different settings (general and academic hospitals, general practitioner practices, mental healthcare institutions and nursing homes) and even more different medical specialities with their own identities, can truly be called a complex intervention. The evaluation of such a complex intervention requires a comprehensive design.

As presented in ***chapter 2***, we used a triangulation mixed method design to collect both quantitative (surveys) and qualitative (expert interviews and focus groups) data. Separate surveys for NPs/PAs, collaborating physicians and patients were

structured around the domains quality of care, healthcare resource use, costs and patient centeredness. Outcomes were selected from evidence-based frameworks for assessing the impact of advanced nursing on quality of healthcare. [2-4] Data were collected according to a One Group Pre-posttest design with three time points: before the amended law (T0), one year (T1) and two and a half years (T2) post-amendment.

Focus group and expert interviews aimed to ascertain facilitators and barriers to the implementation process and were structured following the implementation model of Grol. [5] Expert interviews and focus groups were held with NPs/PAs, physicians and other stakeholders (including management staff across all levels in various settings, professional medical organisations, professional trainers, the Healthcare Inspectorate, and the Netherlands Institute for Accreditation in Healthcare).

The study design applied was one of the strengths of the evaluation. Quantitative data alone might not cover the full picture, as it neither illuminated how the independent rights were implemented (or not), nor enabled contextualising (see also the "Reflection and debate" section). This necessitated qualitative data collection. Multiple perspectives in a broad range of areas could therefore be accounted for. Besides, the triangulation of quantitative and qualitative data enabled us to minimize bias. The choice of internationally recognized, generic outcomes has the potential to facilitate cross-national comparative analysis. As it is the first study to evaluate the implementation of independent rights, the novel mixed methods approach may serve as a valuable guide for other studies.

Patient safety must not be put at risk by granting independent rights regarding reserved procedures to new groups of health professionals and was therefore an important element of the evaluation. Patient safety is defined as the (almost) absence of (the risk of) patient harm (physical/mental) that is caused by not acting according to the professional standard of healthcare providers and/or failure of the health system. [6] Retrospective analysis of disciplinary rulings can give an indication whether patient safety was at risk at any time, due to inadequate professional acting. Disciplinary jurisdiction, as established in the IHCP Act, aims to promote and monitor the quality of professional practice and thus to protect the patient. Disciplinary jurisdiction also applied to NPs and PAs during the period of experimentation.

As described in ***chapter 3***, we screened all disciplinary verdicts between 2010 and 2015, whether one or more of the reserved procedures catheterisation, defibrillation, elective cardioversion, puncture, injection, endoscopy, small surgical

procedures and prescribing were mentioned in the complaints against individual healthcare providers.

The screening of a total of 4.369 complaints yielded 460 hits. Three quarters of all verdicts referred to complaints about prescribing. A small proportion (<10%) related to injections, surgical procedures and catheterisations. Endoscopies, punctures and cardioversion/defibrillation were only occasionally mentioned in the complaints. Of all complaints related to reserved procedures, the majority (93%) was directed to physicians, a small proportion (7%) against nurses, *one complaint against a NP* and *none against a PA*.

To gain insight into the specific elements of the complaints and corresponding verdicts, complaints were classified into four empirical domains, namely the *Indication* stage including diagnostics and the decision to perform a specific procedure; the actual *Performance* of the procedure; the *Information*/communication about (the procedure as part of) the treatment and the *Reporting* about the procedure. Subsequently, 38 empirical themes have been drafted within the four domains. Most complaints (both well and ill-founded) were more or less equally related to the indication (mainly attributed to diagnostics and the choice of treatment/medication) and the performance, and only to a limited extent to the information and reporting.

It turned out that there was little jurisprudence of disciplinary verdicts over the past years regarding reserved procedures performed by NPs/PAs. This was in line with our expectations, as NPs/PAs worked under supervision of a physician before the legislative change and the period thereafter was relatively short. Indicating a medical procedure is just as important as the performance of the procedure itself. This should be emphasized in training the competences of professionals. Moreover, this should, more than already done, manifest itself in the legal conditions for task shifting (see also the “Reflection and debate” section). It should be noted that most complaints were about prescribing medication and less on other procedures. This might have influenced the findings since, of all reserved procedures, prescribing is about the indication and not so much about the actual performance.

As noted, the overall study intended to evaluate the impact of granting independent rights to NPs and PAs regarding defined reserved procedures on processes and outcomes. Obviously, processes and outcomes were important components of the evaluation, but also the extent to which the legal conditions were met. But what to decide on continuation, if some processes and outcomes would demonstrate satisfactory results, but others did not? Or what if all legal conditions would be

satisfactory, but effectiveness (in terms of processes and outcomes) could not (yet) be demonstrated? For informed decision making it was crucial to know what processes, outcomes and legal conditions were perceived more important than others. The aim of the study described in ***chapter 4*** was therefore to establish a weighted hierarchy of decision requirements that could affect political decision-making on whether the temporary authorities should be continued. This hierarchy was determined by patients, NPs, PAs, and physicians, the most important key actors in the working field, by means of the Analytic Hierarchy Process (AHP) method. This is an innovative approach, as the involvement of patients in AHP studies focusing on governmental policy has never taken place.

In the AHP method all relevant requirements are pairwise compared, wherein respondents indicate which of the two requirements is most important and rate this relative importance, by which weights of importance can be calculated. In our study, the main criteria quality of care, competence of the healthcare provider, risks, costs and organizational aspects, were subdivided into 23 sub-criteria. All possible pairwise equations were integrated in the questionnaires for patients, NPs/PAs and physicians.

In total, 150 patients, 226 NPs, 142 PAs, and 238 physicians filled out the AHP questions. All four groups considered quality of care and the competence of the healthcare provider (particularly the experience of the care provider) as most important decision requirements, costs were considered as least important requirement. Patients showed comparable results with healthcare providers; the order of the requirements was similar and so was the order of magnitude of the weights. Yet, compared to healthcare providers, patients rated both alternatives in all pairwise equations statistically significant more often to be of equal importance (no preference). Explanations could be found in the different way of presenting the questions to patients compared to healthcare providers and unfamiliarity with the specific content of the questions.

We used the established order as follows: the detailed results of all decision requirements were also determined in the overall study (*chapter 5*) and translated to degrees of fulfilment (yes, partly, not). Results and degrees of fulfilment were presented in order of priority (AHP results) to the Ministry of HWS for informed decision-making. All this was published in the final report. [1] Since the decision requirements are tailored to the Dutch setting, the identified order cannot easily be generalised to other countries. However, this study was also intended to describe

the innovative approach of indirect involvement of patients in the process of political decision making.

In determining which factors are important in political decision-making, both healthcare providers and patients can be successfully involved. Quality of care and the competence of the healthcare provider are deemed the most important requirements to perform reserved medical procedures in Dutch healthcare.

In ***chapter 5***, the main results of the evaluation study are described. In total 544/292/418 NPs, 186/244/355 PAs and 131/125/134 physicians filled in the questionnaires at T0/T1/T2; 9 NPs, 8 PAs, 16 physicians and 28 stakeholders were individually interviewed and 12 NPs, 16 PAs and 3 physicians attended the five focus group meetings.

*Effectiveness* - Even before the law amendment enabling Full Practice Authority (FPA), most NPs and PAs performed reserved procedures, with high frequency and regularly on own authorisation. Post-FPA the proportions NPs and PAs performing reserved procedures and the independence in this, further increased for most reserved procedures. Post-FPA, three-quarters of the reserved procedures under investigation were independently indicated and performed. For about a quarter of those procedures, consultation with a physician was needed. Independent prescribing was not limited to repeat prescriptions, but also included change of dosage and new prescriptions. However, one out of five prescriptions was checked afterwards. With regards to elective cardioversion/defibrillation and endoscopy, no reliable results could be obtained due to a limited response rate to these limited executed procedures. These reserved procedures are subsequently evaluated in a follow-up research described in the report “voorBIGhouden 2”. [7] Ultimately, FPA was achieved for 83% of the NPs and 86% of the PAs. Utilization of FPA was dependent on the setting, as scepticism of physicians and medical boards (especially in mental healthcare) hampered full implementation.

*Context*- Main precondition for FPA is the competence of the NP/PA. NPs/PAs were very aware of the limits of their competence and mainly assessed their competence for reserved procedures based on the individual patient and the specific procedure, and their education/training. Post-FPA, physicians left the assessment of the competence more and more to the NP/PA themselves because of their confidence in the comprehensive training. Besides, there was an increase in tendency for physicians to issue certificates of competence and/or endorsements. Lack of

adequate funding was sometimes a limiting factor for maintaining knowledge and -accordingly- competence and caused problems with obtaining accreditation points.
NPs/PAs and physicians emphasized the importance of collaboration with each other. The number of physicians with whom NPs and PAs collaborated, did not change after the introduction of FPA. A small percentage of NPs, who all worked in an ambulance setting, did not collaborate with any physician when performing reserved procedures.
NPs/PAs worked according to (national) guidelines and clear work instructions. Cooperation agreements with physicians, as part of the protocols, were often not adequately addressed. Written protocols were still not present in all settings. If present, they often failed to be completely satisfactory. Deficiencies mainly concerned the distribution of tasks and responsibilities, usually the result of not formally recording the mutual agreements.
Availability of physicians for consultation, if needed by the NP/PA, was considered good and thus NPs/PAs were satisfied about this situation. The frequency of such consultation varied. NPs/PAs (independent rights) were well accepted by closely collaborating physicians, nurses and patients, but less accepted by other physicians. The more ignorant of the NP/PA role, the weaker their support. This also applied to higher management levels, which was reflected in the existence of specific policy on NPs/PAs. Following the acceptance, the positioning and visibility of the NP/PA within the organisation played a role in implementing FPA. Good positioning and visibility led to optimal implementation of FPA, but FPA was also used to achieve better positioning.
*Efficiency*- The time required to perform reserved procedures, including assignment and consultation time, as a first proxy for efficiency, decreased post-FPA. This time gain seemed to derive from reduction of assignments and consultations, being confirmed by the growing independence mentioned earlier, but also by an observed decrease in the number of monthly contacts between NPs/PAs and physicians about reserved procedures. However, the nature of these contacts changed. Pre-FPA, the contacts were mostly assignments to NPs/PAs by the physician, post-FPA they were NPs/PAs consulting the physician. Moreover, the duration of the contacts increased for almost all reserved procedures. This might be due to a patient shift induced by task shifting, one quarter of the physicians saw less patients, as well as more patients with more complex problems. In such cases, assignments to NPs/PAs to perform a reserved procedure could demand more explanation. Besides, NPs/PAs treated most

patients independently and only in case of doubt, from NP's/PA's perspective in complex situations, consulted a physician. This also might result in longer contact duration.

Another proxy for efficiency was the increase in the number of delegations of low complexity procedures by NPs/PAs to other, often cheaper, health professionals. Pre-FPA, delegation was rare; post-FPA, over one in ten reserved procedures were delegated. Prescribing was only sporadically delegated (if so it was to specialists in training).

Linking time gains and salary costs was insufficient to draw firm conclusions regarding cost-effectiveness. This would require more insights into patient flows and information on additional costs, for example diagnostic costs, at the macro level. This was however not measurable in the course of the evaluation, because NPs/PAs could not register operations under their own name.

Key strengths of the evaluation were the mixed-methods and triangulation approach (*see also chapter 1 and the Reflection and debate section*) and its potential for cross country comparison. Main limitations included a variable composition of respondents at the three measure points, the pre-posttest design potentially limiting causal inference and the selected group of physicians with reduced generalizability. These limitations could largely be addressed by the triangulation mixed-methods design.

The evaluation study showed that for some NPs/PAs informal practice was legalised by the law amendment enabling FPA, whereas others were encouraged to further develop their role. New opportunities for NPs/PAs to independently indicate, perform and delegate catheterisations, injections, prescriptions, punctures and small surgical procedures were highly exploited, which collectively have proven the political measure to be effective. Notwithstanding, for elective cardioversion/defibrillation and endoscopy, lack of data did not allow for any conclusions. Care processes were organized more efficiently and care was provided by the most appropriate healthcare provider. Only indications for the cost-effectiveness could be made, since at the time of the evaluation, NP/PA cost recording and declaration, required for a traditional assessment, were not transparent. The study revealed that all legal conditions were met and no negative side effects occurred. These study findings supported the policy initiative to improve the effectiveness of care delivery by granting FPA to NPs and PAs. Hence, our main recommendation was to turn the temporary policy initiative into a definite one.

**Deviations from and supplements to the study protocol**

Like almost any study executed in real world setting, this evaluation has (minor) deviations from and supplements to the study protocol. Some had not been covered in the previous chapters.

The most notable supplement is the use of the 'Quickscan". Soon after the distribution of the questionnaires at T0, the first data showed that mainly NPs/PAs whose duties required that they performed reserved procedures and who thus had an interest in the continuation of the independent rights, filled in the questionnaire. This was confirmed by email contacts and it affected the accurate and reliable determination of the proportion NPs/PAs performing a reserved procedure. To collect information on the total population of NPs/PAs an additional questionnaire was developed, the Quickscan. This Quickscan was kept as short as possible to achieve maximum response. In 5 questions NPs/PAs were asked about the reserved procedures they performed, together with NP specialism and setting. It was explicitly mentioned that also NPs/PAs who did not perform reserved procedures should complete the Quickscan. The Quickscan was wider distributed. It was included in the gift bag of the national NP/PA congresses, so that participants could complete it on location. The results allowed to calculate the precise proportion NPs/PAs performing a reserved procedure.

Furthermore, a more comprehensive recruitment of respondents was used than was described in the study protocol *(Chapter 2)*. According to the study protocol both professional organisations had a different strategy to facilitate the recruitment: "The NCN NP invites their members to subscribe for study participation. The NAPA has notified their members about the ongoing study and has provided names of all potential PAs to the research team. PAs are subsequently invited by the research team to participate." Despite various reminders, the initial response was minimal and needed further actions. Universities of applied Sciences with NP/PA programs were asked to support the recruitment, as they did by approaching their alumni through mail, newsletters and information on their websites. As mentioned, the Quickscan was distributed at national NP/PA congresses, where also additional recruitment for other parts of the evaluation took place.

By using the Quickscan and a more comprehensive recruitment, bias could be minimized and results better generalised.

## Reflection and debate: is the current legal framework task shifting-proof?

By adding an experimental article in the IHCP Act, a first step was made towards *authority* shifting between health professionals, in addition to *task* shifting. The study shows that this political measure was effective. However, during the evaluation, some legal challenges were encountered.

**Indication**

At the time of introduction, the IHCP Act regulated what was common practice: physicians decided if and what medical intervention was needed and left parts of the performance to other health professionals, who s/he considered as competent. It is therefore not surprising that the regulation of the reserved procedures focuses on the performance. The text in the Act literally states: "Authorised to perform (in Dutch "verrichten") …. are…." With the progress of task-shifting, daily practice however changed. Other health professionals than physicians had, because of their training, the competence not only to perform a reserved procedure but also to decide upon the necessity thereof, i.e. to indicate. This was acknowledged and for the first time, the concept "independently authorised" was explicitly referenced in the Orders in Council of the NPs and PAs, which was translated to the authority to independently perform and indicate reserved procedures. [8, 9] The meaning and scope of the concept indication is, however, nowhere explained. Moreover, the conditions attached to the independent authority still focus on performance: the authority is restricted to procedures of limited complexity, routine in nature and subject to manageable risks, and one must be competent to perform the procedure. Paradoxically, for the indication no conditions have been set, whereas this was the main novelty, since NPs and PAs were often already highly experienced in performing the procedure. Besides, interviewed physicians held the opinion that the difficulty did not lie in the performance ("everyone can learn this trick") but in the indication phase, in which different actions must be taken, depending on the situation, which culminates in a decision to perform a procedure or treatment.

For the concept indication, distinctive definitions exist. The simplest definitions, like "a suggestion or direction as to the treatment of a disease, derived from the symptoms observed", only relate to the most appropriate choice for a procedure/treatment. [10] More elaborated definitions also relate to other

subsequent actions such as diagnostics: "the facts, opinions, and interpretations about the patient's physical and/or psychological condition that provide a reasonable basis for diagnostic and therapeutic activities aiming to realize the overall goals of medicine: prevention, cure, and care of illness and injury."[11]

In practice, the absence of a uniform well-documented definition, leads also to different interpretations, as we have noticed during our research. The authority to indicate varied from the establishment of the most appropriate procedure/treatment in *already diagnose*d patients (often by a physician) to the establishment of the most appropriate procedure/treatment in *self-diagnosed* patients. The heart of the problem seems to be the diagnostic process. The establishment of the most appropriate procedure/treatment is largely according to a proven protocol. On the other hand, diagnosing (including requesting and evaluating additional examinations) requires more competences. In the competence profiles of the Master Advanced Nursing Practice (MANP) and Master Physician Assistant (MPA) studies, diagnosing is one of the key competences. [12, 13] Here too, there is a significant lack of clarity about the term “diagnosis” as stated by the Council for Public Health and Health Care (in Dutch: Gezondheidsraad en Raad voor Volksgezondheid en Zorg (RVZ)) in background studies on medical diagnosis [14]: “the” diagnosis does not exist. Because of the absence of a clear definition, diagnosing was not designated as a separate reserved procedure. [15] Given the many disciplinary complaints relating to the indication stage, including diagnostics (*chapter 3*), it is questionable whether this is acceptable or sustainable.

This shortcoming could be tackled by making diagnosing an integral part of the indication process and thus its definition. However, respiratory, diabetes and oncology nurses recently received prescriptive authority for a limited number of medicines. [16] In the concerning Order in Council, the concept indication is not explicitly included, but when prescribing, authority applies particularly to the indication rather than the performance (i.e. writing out the prescription). One of the conditions linked to specialized nurses’ prescriptive authority is that a physician has already diagnosed the patient.

To improve task-shifting regulations, a uniform definition of the concept indication is essential. Diagnosing should not be included herein, but rather be appointed as reserved procedure.

**Phrasing of the legal framework**

The IHCP Act is a framework law, in which only main lines are indicated. In separate Orders in Council the outlines are further elaborated. [17] The advantage is that not all details *need to be* regulated by law; regarding task shifting the disadvantage can be that not all details *are* regulated by law.

The IHCP Act contains widely formulated, or open standards such as the individual healthcare professional should deliver responsible care (Article 40). The individual is supported in his efforts by the care providing organisation, which, in turn, is obliged to provide the right conditions for the delivery of responsible care under the Healthcare Facilities Quality Act, also a framework law.

The meaning and the concrete interpretation of the open standards are not laid down in the law(s) but are specifically left to the work field with a high degree of self-regulation. This gives NPs and PAs room to further elaborate with physicians, at a local level. We see, however, a large variation in the extent to which the independent authority is implemented across settings. Scepticism of both physicians and medical boards sometimes hampered full implementation, especially in areas of mental health.

Often, this is prompted by the criteria for professional acting, set by the scientific or professional associations reflecting their interpretation of the open standards. These criteria can be established in field norms, guidelines, recommendations, covenants and codes of conduct. [18] In practice, however, NPs and PAs are hardly being involved in this process of standardization and therefore their actions also not defined in the texts. This may be related to unfamiliarity with the NP/PA profession, but also to guarding the interest of their own members. For example, in a positioning document the board of the Workgroup Intervention Cardiology states that there is no place for NPs/ PAs in heart catheterisation. It is argued that the procedure is not routinely nor low complex and the risk of perforation is considerable. [19] The workgroup also claims that quality of care must be assured through concentration of activities to a limited number of healthcare professionals, i.e. cardiologists. Also, capacity problems with the training of cardiologists play an important role here. The document also states that a cardiologist should act as first practitioner and is responsible for being in control of cardioversions carried out by him/herself or by the NP/PA.

The independent authority is also restricted regarding cytostatics prescriptions as can been seen in a field standard drawn up by Dutch Association of Hospital

Pharmacists, Netherlands Association for Medical Education and the and the Dutch Oncology Nursing Society [20] and a multidisciplinary standardization report. [21] The prescription of cytostatics is reserved for physicians and not yet for NPs/PAs.
In addition, there is a discrepancy regarding task shifting in laws and regulations. The IHCP amendment enables NPs/PAs to independently perform endoscopies. However, the guidelines for the population screening for colorectal cancer (established by a national public body) authorise only physicians to perform screening GE endoscopies. [22]
Nevertheless, the advantages of a not rigorous formulation outweigh the disadvantages. Guiding principle for the deployment of the NP/PA must be the local need, which strongly varies across settings and over time. This cannot be completely captured by a detailed law.
A partnership of all parties involved, should decide on the concrete details of task shifting. Simultaneously it must be monitored that interests other than effectiveness and efficiency of care affect this process and hamper task shifting.

**(Non-)reserved procedures**

As described in the introduction, the IHCP Act has defined certain medical procedures that pose significant risks to life or health of individuals, so that they may only be performed by authorized healthcare providers, i.e. reserved procedures. In addition, there are also procedures that entail considerable health risks (high risk procedures), that are not explicitly included in the law. Examples include modification of an external pacemaker, administration of blood(products), seclusion of psychiatric patients and psychotherapy. Many of these procedures are also subject of task-shifting and patient safety should also be adequately ensured as with the reserved procedures.
The classification into reserved and non-reserved seems to be somewhat arbitrary and ambiguous. In the report 'Reserved procedures hold against the light' (in Dutch: 'Voorbehouden handelingen tegen het licht'), it is concluded that the list of reserved procedures does have its drawbacks. [15] The necessity to designate certain procedures as reserved, is questioned because the probability of incompetent performance is rather small, as with lithotripsy. [15] In contrast, some procedures should be considered as reserved. For example, the Dutch Society for Dermatology and Venereology makes a case for including laser and flashlight therapy in the list of reserved procedures, given the damage which may occur from incompetent use. [23,

24] The now former Minister of HWS shares this view and intends to adapt the IHCP Act. [25]. As a final example, insertion of a feeding tube is a reserved procedure; the administration of nutrition by this tube is not, though the risks are of the same order. [26] Prior to administration, the position of the tube should be checked. This requires a competence similar to insertion of the tube.

All this is also reflected in our findings, for many the dividing line was not clear and the further subdivision of reserved procedures not known.

Even though a procedure is not specified in law, risks ought to be managed and reduced. Health professionals are expected to act with due care. The Council IHCP has recommended to apply the same level of diligence regarding high risk procedures as for reserved procedures. [27] This means, that the same legal requirements can be used. Here too, the procedure must be carried out by order of a physician or another independent authorized health professional. Concepts as competence and training are applicable as well. According to the IHCP Act, individual institutions can designate high risk procedures themselves. Under the Care Institutions Quality Act, institutions are obliged to supply sound care of good quality. Healthcare quality policy should also comprise the supply and performance of both reserved as non-reserved high-risk procedures. In practice, many institutions have indeed adopted similar or comparable arrangements for non-reserved high-risk procedures as for reserved. [15]

The regulation of the non-reserved procedures seems sufficient, although ongoing attention needs to be paid to the topicality of the assigned reserved procedures. Also here, as with the reserved procedures, interests other than effectiveness and efficiency of care may not affect the decision-making process. [15] In this case, the voice of NPs/PAs can be less strong, because they are not within their (legal) rights.

**Evaluation**

The independent rights for NPs/PAs have been followed by independent rights for technical physicians (in Dutch: technisch geneeskundigen) and Allied Medical Healthcare professionals (in Dutch: Bachelor Medisch Hulpverleners). [28, 29] All granted rights are of temporary nature and are explicitly subject of evaluation as defined in the Orders in Council. The research questions and variables to measure are consistent in all three orders. The Ministry formulated their assignment as follows: is granting independent authority effective and efficient; thus, to what extent does it contribute to more effective and efficient care? The defined variables

are quality of care (safety, patient centeredness, access to care); effectiveness, efficiency and continuity of care. The aim is straightforward and clear, but also somewhat conservative as explained in more detail below.

Firstly, policy evaluation traditionally focuses on effectiveness ("does it work?") and efficiency (using minimum resources while being effective). By using such a focus, it remains unclear whether a new policy approach failed or was poorly implemented, in the occasion that it shows ineffective. The level of implementation is depending on the local situation, i.e. context, expressed by how well information about the policy innovation is supplied, whether the local organization decides to adopt the policy and how well the innovation has been executed during implementation. [30] The final outcomes therefore are highly depending on the level of implementation and hence also on the context. Moreover, if an innovation ultimately "does work" in one setting, it does not guarantee success in other settings, suggesting that many innovations themselves are also context-dependent. [31]

Secondly, by focussing too narrowly on effectiveness and efficiency, not measured unintended effects are wrongly not included in the deliberations. Unintended effects can be both positive and negative. An innovation may be effective and efficient, but negative unintended effects or the risks of this, should not overshadow the positive effects. [32] In any situation, i.e. context, it is necessary to establish whether costs (efficiency) and all effects (effectiveness and unintended effects) are properly in balance with each other. [32]

Thirdly, policy makers overestimate the evidence of causality generated by traditional policy evaluation. They want to know the extent to which the policy innovation causes changes in the defined variables between initial situation and final situation, or between settings with and without the implemented policy innovation. With traditional policy evaluation, it is difficult to demonstrate any causal relationship. The most that can be concluded is a correlation between the policy innovation and the changes, because changes may also be caused by external contextual factors. However, the plausibility of causality can be increased by identifying and controlling for the effect of such contextual confounders.

Lastly, if the policy innovation proves to be effective and efficient during the experimental period, sustainability of these outcomes over time should be monitored. This can only be done with on-going evaluation within time and changing contexts. [33]

Context runs like a scarlet thread through above arguments. Context interacts, influences, modifies, facilitates or constrains the innovation and its implementation and effectiveness. [34] Awareness of the importance of context is increasing. However, the science of assessing or measuring contextual factors is not yet fully mature and (the impact of) contextual factors are hardly described in evaluation literature. [34-36]. This can be partly explained by the study designs used. Standard quantitative research methodologies do not allow exploration of contextual factors. In contrast, qualitative research does enable contextualising. In line with this, the Health Council of the Netherlands has recently recommended to make greater use of qualitative and mixed-methods designs to obtain "responsive research" (responding to social tasks and leading to innovation of healthcare and prevention). [37] A mixed methods design with both integrated methodologies can make a significant contribution to achieve clarity on effectivenes and efficiency in a wider context. All of the above points call for a broader evaluation of context-specifically effectiveness, efficiency and sustainability.

In general terms, we may conclude that, for now, the legal framework is suitable for task and associated authority shifting. There are areas of attention that need to be addressed, such as the definition and range of indication (diagnosis), the topicality of the assigned reserved procedures, the local interpretation of the independent rights and the requirements for evaluation.

## Recommendations

In the light of the above we have set out a series of recommendations for policy makers and healthcare practice as well as research recommendations.

**Recommendation for policy makers**

The most important recommendation for the Minister of HWS was to make NPs/PAs independent authorities as for catheterisations, small surgical procedures, injections, punctures and prescribing, permanent. This recommendation has in fact already been followed by the Minister and on 12 September 2017 the legislative proposal was approved by the Lower Chamber of the Parliament and rubber-stamped on 3 October 2017 by the Upper Chamber. [38] Besides, the independent rights as for endoscopy, elective cardioversion and defibrillation were adopted simultaneously, after positive findings in a separate follow-up evaluation. [7] The proposal and subsequent approval responded also to the recommendation to

include PAs in the IHCP Act as an Article 3 profession. Another recommendation, which retains all its relevance, is that in regulations and legislations, greater attention should be paid to the definition and range of the concept indication. There is also the need, stipulated in a recommendation to the Minister too, to monitor whether the appointment of (non-)reserved procedures still meet the needs in day-to-day practice.

**Recommendations for healthcare practice**

The amendment has removed the main barrier to independently perform reserved procedures. At the local level, new barriers arise, which may ultimately hamper the process of task shifting. The precise details of the authorities should first and foremost, locally be established in cooperation between physician and NP/PA. The same applies for non-reserved procedures. If, however, it is decided to make agreements more nationwide, legislation should be the guiding principle.

The presence of protocols is fundamental for the delineation of NPs/PAs independent authorities. Not only work instructions should be included, bus also cooperation agreements with the division of tasks and responsibilities, which is underexposed so far.

Positioning and visibility is important for the embedding of the professional groups. This cannot be regarded as a task for NPs/PAs alone, but as a joint responsibility of employers, professional organisations and insurance companies.

**Research recommendations**

The impact of task shifting with NPs/PAs on processes and outcomes of healthcare, will always remain a challenging topic for research. This is first of all because most NPs/PAs still work in an arrangement with physicians as responsible care providers, who are consequently considered to be overall responsible for various processes and outcomes. Isolating the impact of NPs/PAs from this whole healthcare chain will often be impossible. If possible, new professional roles are often introduced in new health services, which makes it difficult to differentiate clearly between effects attributed to the new role and to the new health services. [39] Furthermore, it is necessary to monitor effects over time. It seems likely that benefits are only tangible in the longer term, as new professionals become familiar with the new tasks. [39] NPs/PAs roles are not yet fully implemented for such a long time. It is not, therefore, surprising that internationally, there is a great lack of studies on (cost)effectiveness of NPs/PAs as described in the general introduction (International comparison of

NPs/PAs independent practice on processes and outcomes). Some systematic reviews on this topic also indicate that included studies have contradictory results, especially where it concerns costs, and show methodological shortcomings. [40-43] Furthermore, all systematic reviews do not distinguish between degrees of independence, nor any changes thereto over time. It is likely that the extent of independence somehow affects the effects. For costs, the picture is identical. Arrangements where NPs/PAs work under supervision and thus an additional physician is needed, are placed at a cost and time disadvantage compared to independently working NPs/PAs. It is clear that more research is needed on the (cost)effectiveness of NPs/PAs, while taking into account the extent of independence, also in the long term.

As mentioned, research on task-shifting has its methodological shortcomings. The study described in this thesis can be regarded as an innovative encouraging concept, which must be perfected to a more "realistic evaluation" approach. A promising theoretical framework for evaluation, anticipating to the urgent need to include the context in policy evaluations next to the traditional (cost) effectiveness, is the 'realist evaluation', developed by Pawson and Tilley. [44] This framwork seeks to understand the interactions between intervention, variations in context and underlying mechanisms of change, by anwering the questions "what works, how, for whom, to what extent, in what respects, in what circumstances and over what duration?' rather than to answer the question 'does it work?'. [44] The application of realistic evaluation for task-shifting should further be explored.

In the study described in this thesis, we have shown a time gain post-FPA, derived from the reduction of assignments and consultations, which can be seen as a first proxy for efficiency. Saving time for both NPs/PAs and physicians may result in more time for patient care, thereby improving access to care. [45] As access to care improves, utilization will run in parallel. Although prices could decrease for NP/PA services, the number of services provided may increase, raising overall costs of healthcare. [45, 46] At the time of this evaluation NP's/PA's operations were registered in the name of the supervising physician or department instead of the individual NP/PA. This has since been adjusted. [47-49] On January the first 2015, the Dutch Healthcare Authority (in Dutch: Nederlandse Zorgautoriteit) has reviewed the accounting and declaration rules, which make NPs/PAs operations more transparent. This enables to study cost-effectiveness of task-shifting and

independent practices. In doing so, account should be taken of the observed patient-shift among physicians, i.e. physicians mostly see patients with complex needs.
Many different parties are involved in task-shifting. The opinion of one expert group regarding this complex subject is too often underexposed: the patient. This also applies to political decision-making, patients are so far never being directly involved. In the present study, the AHP method clearly demonstrated its usefulness to involve patients in political decision-making, but this should be confirmed in future research. A point for attention should be the rationale of the high "no preference" rate of patients. This point should also be addressed in all AHP studies with patients.
It turned out that there was little jurisprudence of disciplinary verdicts over the past years regarding reserved procedures performed by NPs/PAs, as NPs/PAs worked under supervision of a physician before the law change and the period thereafter was relatively short. On-going monitoring of the disciplinary verdicts can provide insight in the circumstances in which patient safety is put at risk as a result of task-shifting.

## Overall conclusion

In view of the results of the study presented in this thesis, the law amendment enabling FPA for NPs/PAs, has proved effective for catheterisations, small surgical procedures, injections, punctures and prescribing. The study also shows that all legal conditions were met and no negative side effects occurred. Care processes were organized more efficiently and care was provided by the most appropriate healthcare provider. With this, the law amendment seems to be cost-effective. Firm conclusions about the cost-effectiveness, however, require greater insight in cost recording and declarations. To further optimise task-shifting, attention should be paid to the definition and range of indication (diagnosis), the topicality of the assigned reserved procedures, the local interpretation of the independent rights, the presence of protocols, the positioning of the healthcare professionals and the requirements for evaluation. The current study can internationally contribute to the knowledge about the impact of (independent practices) of NPs/PAs on processes and outcomes of healthcare.
Based on this thesis, the main recommendation was to turn the temporary policy initiative into a definite one. This has become practice.

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# Samenvatting

## Samenvatting


**Hoofdstuk 1. Introductie**

De Nederlandse gezondheidszorg wordt de laatste decennia geconfronteerd met een sterk toenemende en veranderende zorgvraag alsook een afnemend zorgaanbod. Eén van de oplossingsrichtingen voor deze onbalans is taakherschikking. Door taken structureel te herverdelen tussen zorgverleners wordt beoogd de aanwezige zorgcapaciteit zo efficiënt mogelijk te benutten. Het ministerie van Volksgezondheid, Welzijn en Sport (VWS) heeft taakherschikking als speerpunt in haar beleid opgenomen. Om optimale taakherschikking mogelijk te maken, is de Wet op de Beroepen in de Individuele Gezondheidszorg (Wet BIG) gewijzigd. Hiermee is het voor zorgverleners, anders dan artsen, mogelijk geworden om tijdelijk bepaalde voorbehouden handelingen zelfstandig uit te voeren. Met het van kracht gaan van twee Algemene Maatregelen van Bestuur (AMvB) per 1 januari 2012, is aan verpleegkundig specialisten (VSen) en physician assistants (PAs) als eerste groep zorgverleners een zelfstandige bevoegdheid toegekend en wel voor de handelingen: katheterisatie, defibrillatie, electieve cardioversie, endoscopie, heelkundige handelingen, injecties, puncties en het voorschrijven van geneesmiddelen die uitsluitend op recept verkrijgbaar zijn. VSen en PAs zijn op masterniveau opgeleid om zelfstandig een breed scala van taken van artsen te kunnen overnemen. Bij de uitvoering van deze taken, voorafgaand aan het van kracht gaan van de AMvB's, werden ze belemmerd in hun zelfstandigheid, doordat ze genoemde handelingen alleen in opdracht van een arts mochten uitvoeren.

Aan het tijdelijk experiment was een studie gekoppeld die de effecten van het toekennen van een zelfstandige bevoegdheid aan VSen en PAs evalueerde om besluitvorming door het ministerie van VWS over het toekennen van de zelfstandige bevoegdheid te ondersteunen.

Alle resultaten van de evaluatie naar het toekennen van de tijdelijke bevoegdheid aan VSen en PAs zijn beschreven in het rapport "voorBIGhouden", dat aan de minister van VWS in november 2015 is overhandigd. [1] Dit proefschrift beschrijft de kernpunten van de evaluatie.

**Hoofdstuk 2. Het studieprotocol**

In de evaluatie werd gebruik gemaakt van een *mixed methods design* met triangulatie van kwantitatieve (vragenlijsten) en kwalitatieve data (expertinterviews

en focusgroep interviews). De separate vragenlijsten voor VSen/PAs, artsen met wie VSen/PAs samenwerken en patiënten, waren opgebouwd rondom de domeinen effectiviteit, doelmatigheid, inzet van beroepsbeoefenaren en patiëntgerichtheid. Uitkomstmaten waren gebaseerd op conceptuele kaders voor evaluatie van de impact van de VS op de kwaliteit van zorg. [2-4] Data werden verzameld volgens een *One Group Pre-posttest design* met drie meetmomenten: vóór de wetswijziging (T0), 1 jaar (T1) en 2.5 jaar (T2) na de wetswijziging.

Belemmerende en bevorderende factoren voor het implementatieproces werden via focusgroepen en expertinterviews (met VSen/PAs, artsen en andere stakeholders, zoals management op verschillende niveaus, beroepsverenigingen, opleiders, IGZ en NIAZ) in kaart gebracht en ingedeeld volgens het implementatiemodel van Grol. [5]

Het design van de studie geldt als een van de sterktes van de evaluatie. Met uitsluitend kwantitatieve data zou geen volledig beeld worden verkregen en zou niet duidelijk zijn of en hoe de zelfstandige bevoegdheid was geïmplementeerd. Daarnaast zou contextualisering niet mogelijk zijn. Dit vereiste kwalitatieve data vanuit meerdere perspectieven op uiteenlopende gebieden. Door triangulatie werd bias geminimaliseerd. Door gebruik te maken van internationaal erkende generieke uitkomstmaten is het mogelijk een vergelijkende analyse tussen landen te maken. Omdat dit de eerste studie is die de invoering van een zelfstandige bevoegdheid op nationaal niveau evalueert, kan de nieuwe *mixed methods* benadering als leidraad dienen voor andere studies.

**Hoofdstuk 3. Tuchtrecht**

Patiëntveiligheid mag nooit in het geding komen doordat nieuwe groepen zorgverleners een zelfstandige bevoegdheid krijgen voor een aantal voorbehouden handelingen. Veiligheid was dan ook een belangrijk onderdeel van de evaluatie. Met behulp van tuchtrechtuitspraken kan inzicht worden gekregen in die situaties waar risico's bestaan voor de patiëntveiligheid als gevolg van ontoereikend professioneel handelen. Het tuchtrecht, zoals vastgelegd in de Wet BIG, heeft als doel de kwaliteit van de beroepsuitoefening te bevorderen en te bewaken. Tijdens de experimenteerperiode was het tuchtrecht ook van toepassing op VSen en PAs.

Alle tuchtrechtuitspraken tegen individuele zorgverleners tussen 2010 en 2015 werden gescreend op aanwezigheid van bovengenoemde voorbehouden handelingen. Van de in totaal 4369 klachten, bevatten 460 klachten één of meerdere

voorbehouden handelingen. Drie kwart van deze klachten had betrekking op voorschrijven, een klein percentage (<10%) op injecties, heelkundige handelingen en katheterisaties. Endoscopieën, puncties en cardioversies/defibrillaties werden slechts sporadisch genoemd in de klachten. Het overgrote deel van de klachten met voorbehouden handelingen (93%) was gericht tegen artsen, een klein gedeelte (7%) tegen verpleegkundigen, 1 klacht tegen een VS en géén tegen een PA.

Om inzicht te krijgen in de specifieke aspecten van de klachten en bijbehorende uitspraken, werden de uitspraken in vier empirische domeinen ingedeeld: de indicatiestelling (inclusief diagnostiek en het besluit om een specifieke voorbehouden handeling wel/niet uit te voeren); de daadwerkelijke uitvoering van de handeling; de informatie/communicatie over (de handeling als onderdeel van) de behandeling; en de rapportage van de procedure. Binnen deze domeinen werden in totaal 38 empirische thema's geformuleerd.

De meeste klachten (zowel gegrond als niet-gegrond) hadden betrekking op de indicatiestelling (42%), met name diagnostiek en de keuze voor een behandeling/geneesmiddel, en de uitvoering (37%) en slechts in beperkte mate op de informatie en rapportage.

Kanttekening hierbij was dat de meeste klachten betrekking hadden op voorschrijven. Dit kan de resultaten beïnvloed hebben, omdat van alle voorbehouden handelingen het bij voorschrijven juist over de indicatiestelling gaat en niet zo zeer over de daadwerkelijke uitvoering.

Er bleek weinig jurisprudentie op het gebied van tuchtrecht over voorbehouden handelingen verricht door VSen/PAs. Dit lag in de lijn der verwachtingen aangezien VSen/PAs vóór de wetswijziging onder supervisie van een arts werkten en de periode na de wetswijziging relatief kort was.

Het indiceren van een medische handeling is net zo belangrijk als de uitvoering van de handeling. Dit dient te worden benadrukt in de opleiding van de zorgverleners. Daarnaast zou dit nog meer dan nu tot uitdrukking moeten komen in de wettelijke bepalingen.

**Hoofdstuk 4. Rangorde van beslissingscriteria**

Zoals eerder aangegeven, werd het effect van het toekennen van een zelfstandige bevoegdheid aan VSen en PAs, voor een aantal vastgelegde voorbehouden handelingen, op verschillende proces- en uitkomstmaten geëvalueerd. Daarnaast is gekeken naar de mate waarin aan de wettelijke voorwaarden is voldaan. Maar hoe

te beslissen over continuering van de zelfstandige bevoegdheid als enkele proces- en uitkomstmaten bevredigende resultaten laten zien, maar andere niet? Of als aan alle wettelijke voorwaarden is voldaan, maar effectiviteit (met betrekking tot proces- en uitkomstmaten) (nog) niet kan worden aangetoond? Voor geïnformeerde besluitvorming is het essentieel om te weten welke maten en wettelijke voorwaarden belangrijker worden geacht dan andere. Via de Analytic Hierarchy Process (AHP) methode werd een gewogen rangorde bepaald van de criteria die van belang zijn bij de politieke besluitvorming over prolongatie van de zelfstandige bevoegdheid. Deze rangorde werd bepaald door patiënten, VSen, PAs en artsen; de belangrijkste partijen in het werkveld. Dit is een vernieuwende aanpak, omdat patiënten nooit eerder betrokken zijn geweest in AHP-studies gericht op regeringsbeleid.

De AHP-methode berust op het steeds paarsgewijs vergelijken van alle relevant geachte criteria. Op basis van de cijfers die respondenten toekennen aan het criterium dat zij het belangrijkste vinden, worden wegingsfactoren berekend. De toegepaste hoofdcriteria kwaliteit van zorg, bekwaamheid van de zorgverlener, risico's, kosten en organisatorische aspecten, waren onderverdeeld in 23 sub-criteria. Alle mogelijke paarsgewijze vergelijkingen waren opgenomen in de vragenlijsten voor patiënten, VSen/PAs en artsen.

In totaal hadden 150 patiënten, 226 VSen, 142 PAs en 238 artsen de AHP-vragen ingevuld. Alle groepen respondenten beoordeelden kwaliteit van zorg en de bekwaamheid van de zorgverlener (met name diens ervaring) als belangrijkste beslissingscriteria. Kosten werden als minst belangrijke criterium gezien. Patiënten hadden vergelijkbare resultaten als de zorgverleners, zowel wat betreft de rangorde als de grootte van de wegingsfactoren. Echter, zij beoordeelden de beide criteria in alle paarsgewijze vergelijkingen significant meer als even belangrijk, in vergelijking met zorgverleners. Verklaringen hiervoor kunnen gezocht worden in een andere formulering van de vragen in de patiënten vragenlijst of onbekendheid met de specifieke inhoud van de vragen.

De bepaalde rangorde werd in het eindrapport van de evaluatie [1] gekoppeld aan de resultaten van alle beslissingscriteria (de meeste beschreven in hoofdstuk 5). Resultaten werden ingedeeld op basis van de mate waarin het doel verwezenlijkt werd (ja, gedeeltelijk, niet) en op volgorde van belangrijkheid (AHP-resultaten) aan het ministerie van VWS gepresenteerd voor verdere besluitvorming. Omdat de beslissingscriteria toegespitst waren op de Nederlandse setting, kan de bepaalde

volgorde niet zonder meer gegeneraliseerd worden naar andere landen. Dit geldt wel voor de innovatieve benadering om patiënten indirect te betrekking bij het proces van politieke besluitvorming.
Bij het bepalen welke criteria belangrijk zijn voor politieke besluitvorming, kunnen zowel zorgverleners als patiënten met succes betrokken worden. Kwaliteit van zorg en de bekwaamheid van de zorgverleners worden als belangrijkste criteria gezien bij het uitvoeren van voorbehouden handelingen in de Nederlandse gezondheidszorg.

**Hoofdstuk 5. Effecten van de invoering van de zelfstandige bevoegdheid**
In totaal hadden 544/292/418 VSen, 186/244/355 PAs en 131/125/134 artsen de vragenlijsten bij T0/T1/T2 ingevuld; 9 VSen, 8 PAs, 16 artsen en 28 stakeholders waren individueel geïnterviewd en 12 VSen, 16 PAs en 3 artsen hadden deelgenomen aan een focusgroep bijeenkomst.

*Effectiviteit*
Vóór de wetswijziging werden voorbehouden handelingen door de meerderheid van de VSen en PAs verricht met grote frequentie alsook veelal op eigen indicatie. Na de wetswijziging namen de percentages VSen en PAs die voorbehouden handelingen uitvoerden en de zelfstandigheid hierbij nog verder toe voor de meeste voorbehouden handelingen. Drie kwart van de onderzochte voorbehouden handelingen werd tijdens T2 door de VS/PA zelfstandig uitgevoerd. Over één kwart van de zelfstandig uitgevoerde handelingen was nog overleg nodig met een arts. Bij het voorschrijven van geneesmiddelen was geen verschil waarneembaar tussen herhaalrecepten, recepten met veranderingen van dosering en nieuwe recepten. Wel werd één op de vijf recepten achteraf gecontroleerd door een arts. Ten aanzien van electieve cardioversies/defibrillaties en endoscopieën werden door de geringe respons bij deze (weinig uitgevoerde) voorbehouden handelingen, geen betrouwbare resultaten verkregen (deze voorbehouden handelingen werden in een vervolgonderzoek geëvalueerd en beschreven in het rapport “voorBIGhouden 2”). [6] Uiteindelijk bleek de zelfstandige bevoegdheid bij 83% van de VSen en 86% van de PAs te zijn geïmplementeerd. De mate van implementatie was afhankelijk van de setting, omdat artsen en medische raden (met name in de GGZ) hier vaak sceptisch tegenover konden staan.

*Efficiëntie*

De tijd die VSen en PAs voor het uitvoeren van een handeling nodig hadden, inclusief overlegtijd of tijd om een opdracht van een arts te verwerken (als een eerste indicatie voor efficiëntie), was voor bijna alle voorbehouden handelingen na de wetswijziging afgenomen. De tijdwinst leek het gevolg te zijn van de afname van opdrachtverstrekkingen door en overleggen met artsen. Dit werd bevestigd door de toenemende zelfstandigheid bij de indicatiestelling (zie boven), maar ook door de afname van het aantal contacten tussen VSen/PAs en artsen over voorbehouden handelingen. Vóór de wetswijzing bestonden de contactmomenten tussen arts en VS/PA voornamelijk uit opdracht-verstrekkingen door de arts, na de wetswijziging voornamelijk uit overleg na indicatiestelling door de VS/PA. De gemiddelde duur van het contact was echter toegenomen voor bijna alle voorbehouden handelingen. Dit kan het gevolg zijn van verschuiving binnen de patiëntenpopulatie als gevolg van taakherschikking in zijn algemeenheid. Immers, één kwart van de artsen zag een kleiner aantal patiënten, alsook relatief meer patiënten met complexe problematiek. Opdrachtverstrekking aan een VS/PA om een voorbehouden handeling uit te voeren, vereist dan meer uitleg. Daarnaast behandelt de VS/PA de meeste patiënten zelfstandig en overlegt alleen bij twijfel, vanuit VS/PA-perspectief, over complexe situaties, hetgeen ook resulteert in een langere overlegtijd.

Een andere indicator voor een doelmatige zorg was de toename van het aantal delegaties van laagcomplexe handelingen door VSen/PAs naar andere zorgverleners, met vaak lagere salariskosten. Vóór de wetswijzing werden voorbehouden handelingen slechts sporadisch gedelegeerd; na de wetswijziging werd een tiende van de voorbehouden handelingen gedelegeerd. Het voorschrijven van geneesmiddelen werd slechts sporadisch gedelegeerd en wel naar artsen in opleiding.

Het koppelen van tijdwinst aan salariskosten is onvoldoende om harde conclusies te trekken over doelmatigheid. Hiervoor is inzicht in patiëntenstromen en aanvullende kosten op macroniveau nodig, zoals kosten voor diagnostiek. Dit bleek tijdens de evaluatie niet inzichtelijk, omdat VSen/PAs niet onder hun eigen naam hun verrichtingen konden registreren.

*Context*

Belangrijkste randvoorwaarde voor het zelfstandig kunnen uitvoeren van voorbehouden handelingen is dat de VS/PA hiertoe bekwaam is. VSen/PAs waren zich bewust van de grenzen van hun bekwaamheid. Bekwaamheid werd door VSen

en PAs voornamelijk bepaald op grond van de concrete situatie, de combinatie van de individuele patiënt en de specifieke handeling, en hun opleiding. Artsen lieten na de wetswijziging het bepalen van de bekwaamheid steeds meer over aan de VSen/PAs, omdat ze vertrouwen hadden in de opleiding. Daarnaast was een lichte stijging waar te nemen in het opstellen van bekwaamheidsverklaringen. Het niet hebben van een eigen toereikend scholingsbudget bleek soms een knelpunt voor het op peil houden van kennis en dus bekwaamheid, en konden onvoldoende accreditatiepunten aan het kwaliteitsregister overlegd worden.

VSen/PAs en artsen benadrukten het belang om met elkaar samen te werken. Het aantal artsen met wie VSen/PAs samenwerkten, veranderde niet na de wetswijziging. Een klein percentage VSen, werkzaam in de ambulance setting, werkte helemaal niet samen met een arts.

VSen/PAs werkten volgens (landelijke) richtlijnen en duidelijke werkinstructies. Het vastleggen van samenwerkingsovereenkomsten met artsen, als onderdeel van protocollair werken, verdiende meer aandacht. Schriftelijke protocollen waren niet overal aanwezig en ook niet tot volle tevredenheid. Er bestonden met name lacunes in de verantwoordelijkheidsverdeling en taakverdeling, meestal omdat de onderlinge afspraken niet goed waren vastgelegd.

Artsen waren, indien nodig, goed beschikbaar voor overleg, dit tot tevredenheid van de VS/PA. De frequentie van overleg varieerde per setting. Het draagvlak voor de (zelfstandige bevoegdheid van de) VS/PA was groot bij artsen met wie werd samengewerkt, bij verpleegkundigen en patiënten, maar wisselend bij andere artsen: hoe onbekender met de functie, hoe kleiner het draagvlak. Dit was ook het geval voor de hogere managementlagen in de organisaties, wat tot uiting kwam in het al dan niet aanwezig zijn van een specifiek beleid ten aanzien van VSen/PAs.

In het verlengde van draagvlak speelde de positionering en zichtbaarheid van de VS en PA binnen de organisatie een rol bij de implementatie van de zelfstandige bevoegdheid. Een goede positionering en zichtbaarheid zorgden voor een optimale implementatie, aan de andere kant werd de zelfstandige bevoegdheid ook gebruikt voor een betere positionering.

De evaluatie maakte duidelijk dat de ingevoerde wetswijziging voor een deel van de VSen en PAs een legalisering was van werkwijzen in de dagelijkse praktijk en voor anderen perspectief had geboden hun functie verder te ontwikkelen. De mogelijkheden die de wetswijziging had geschapen om katheterisaties, heelkundige handelingen, injecties en puncties te kunnen indiceren, uitvoeren en delegeren en

het voorschrijven van UR-geneesmiddelen te kunnen indiceren en uitvoeren, waren door VSen en PAs in hoge mate benut, waardoor de maatregel effectief was voor deze handelingen. Voor electieve cardioversie, defibrillatie en endoscopie konden geen conclusies worden getrokken door gebrek aan voldoende gegevens. Zorgprocessen met voorbehouden handelingen waren efficiënter ingericht en de zorg werd door de hiertoe geschikte professional uitgevoerd, hetgeen indicatoren zijn voor doelmatige zorg. Kostenbepaling in het kader van doelmatigheid was niet mogelijk, omdat ten tijde van het onderzoek de kostenregistratie en het declaratieverkeer voor VSen en PAs niet inzichtelijk waren. Uit het onderzoek was verder gebleken dat aan alle in de wet vastgelegde randvoorwaarden was voldaan en dat geen negatieve bijeffecten waren opgetreden als gevolg van de wetswijziging. Deze bevindingen steunden het beleidsinitiatief om de effectiviteit van de zorg te verbeteren door het toekennen van een zelfstandige bevoegdheid aan VSen/PAs. De belangrijkste aanbeveling was dan ook om de tijdelijke bevoegdheid om te zetten in een definitieve.

**Hoofdstuk 6. Algemene discussie**

Tenslotte worden in de algemene discussie de belangrijkste bevindingen uit het proefschrift samengevat en wordt gereflecteerd op de geschiktheid van de huidige wet- en regelgeving voor taakherschikking. Tevens worden aanbevelingen gedaan voor beleidsmedewerkers, het werkveld, en toekomstig onderzoek.

Dit proefschrift laat zien dat de wettelijke regeling waardoor VSen en PAs een zelfstandige bevoegdheid hebben gekregen effectief is gebleken voor katheterisatie, heelkundige handelingen, injectie, punctie en het voorschrijven van geneesmiddelen die uitsluitend op recept verkrijgbaar zijn. De evaluatie laat ook zien dat aan alle wettelijke voorwaarden is voldaan en dat er geen negatieve bij effecten zijn opgetreden. Zorgprocessen werden efficiënter ingericht en de zorg werd geleverd door de meest geschikte zorgverlener. De maatregel lijkt daarmee doelmatig, echter harde conclusies ten aanzien hiervan kunnen pas getrokken worden als meer inzicht wordt verkregen in de kostenregistratie en het declaratieverkeer.

In de huidige wet- en regelgeving is een aantal aandachtspunten ten aanzien van taakherschikking te benoemen.

Door de wetswijziging kunnen zorgverleners nieuwe bevoegdheden krijgen voor het zelfstandig indiceren, uitvoeren en delegeren van voorbehouden handelingen. De grootste verandering betreft het mogen indiceren van de handelingen. De focus van

wet- en regelgeving ligt echter nog steeds op de uitvoering. De voorwaarden voor de wettelijke zelfstandige bevoegdheid zijn uitsluitend gericht op de uitvoering en een definitie en de reikwijdte van het begrip indiceren ontbreken.

De Wet BIG is een kaderwet, waarin alleen hoofdpunten worden vastgelegd. De interpretatie wordt aan het veld overgelaten, met een hoge mate van zelfregulatie. Bij de toekenning van de zelfstandige bevoegdheid aan VSen/PAs, is echter een grote variatie in de implementatiegraad van de zelfstandige bevoegdheid te zien. Vaak is dit gevoed door de standaarden die zijn opgesteld door wetenschappelijke of beroepsverenigingen. Echter, het niet strikt formuleren van details in wet- en regelgeving weegt ruimschoots op tegen dit nadeel omdat de lokale behoefte altijd leidend moet zijn bij taakherschikking. De lokale behoefte kan per setting verschillen en veranderen in de tijd, wat niet kan worden vastgelegd in een gedetailleerde wettekst. De uitwerking van de details moet derhalve worden overgelaten aan de lokale partijen. Wel moet ervoor gezorgd worden dat geen andere belangen dan effectiviteit en doelmatigheid van de zorg hier invloed op hebben en taakherschikking niet belemmerd wordt.

Een zelfstandige bevoegdheid kan alleen worden toegekend met betrekking tot voorbehouden handelingen. Daarnaast worden ook de indicering en uitvoering van risicovolle handelingen overgedragen naar andere zorgverleners. De scheidslijn tussen voorbehouden handelingen en risicovolle handelingen is echter (flinter)dun, de indeling in de categorie soms arbitrair. In wet- en regelgeving is voor de indicatie en uitvoering van de risicovolle handelingen niets vastgelegd. In de praktijk blijken organisaties gelijksoortige afspraken te maken voor risicovolle handelingen als voor voorbehouden handelingen, op basis van de Kwaliteitswet Zorginstellingen. Aanpassing van de Wet BIG in het kader van taakherschikking van risicovolle handelingen is daarom vooralsnog niet nodig.

Het toekennen van een wettelijke tijdelijke zelfstandige bevoegdheid is gekoppeld aan een evaluatie met expliciete onderzoeksvragen: is het effectief en doelmatig om een zelfstandige bevoegdheid toe te kennen aan de betreffende zorgverlener? Deze vragen zijn gestoeld op traditionele beleidsevaluatie en gaan voorbij aan de context waarin de interventie plaatsvindt, de mate van implementatie en het effect over de tijd. De evaluatie dient breder getrokken te worden naar een evaluatie van context-specifieke effectiviteit, doelmatigheid en duurzaamheid. *Een mixed methods design* is hiervoor uitermate geschikt.

Om verdere taakherschikking mogelijk te maken, moet meer aandacht worden besteed aan de definitie en reikwijdte van het begrip indicatiestelling (en diagnose), de actualiteit van de toegekende voorbehouden handelingen, de lokale interpretatie van de zelfstandige bevoegdheid, aanwezigheid van protocollen, de positionering van de zorgverleners, en de voorwaarden voor evaluatie. Onderhavige studie kan ook internationaal bijdragen aan de kennis over de effecten van een zelfstandige bevoegdheid voor VSen en PAs op proces- en uitkomstmaten in de gezondheidszorg. De belangrijkste aanbeveling was dan ook om de tijdelijke bevoegdheid om te zetten in een definitieve. Dit is in de Nederlandse gezondheidszorg inmiddels een feit.

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# Valorisation

Changing legislation is not an everyday policy measure. This takes place only in special circumstances. By changing the IHCP Act, the Dutch government responded to a clear need of "the work field". The independent rights were granted, however, on a temporary basis and would only be permanently enshrined in case of a positive evaluation. It is beyond doubt that the findings of the evaluation have an impact not only on "the work field" but also on other stakeholders. However, to become valuable, findings must be well communicated.

The process of value creation from knowledge by making it available and suitable for economic and social exploitation and to translate this knowledge into products, services, processes and new business is known as valorisation (National Valorisation Committee, 2011). This definition particularly applies to technological innovations. Practice-oriented research mainly focuses on creating value for society. The extent to which research findings are taken up and used is closely linked to the way practice has been involved. Knowledge must be exchanged not only at the end but also during the research period. This is a continuous process of informing each other and adjusting its exchange strategies.

This chapter reflects on the relevance of the findings of the evaluation, as described in this dissertation, for the different stakeholders, as well as the actions already taken or that must be taken to disseminate the findings.

**Nurse practitioners (NPs) and physician assistants (PAs)**

Nowadays, over 3.000 NPs and 1.000 PAs are working in the Netherlands. [1] These health professionals have been specifically trained to take over tasks from physicians. Being independently authorised to perform certain medical reserved procedures, is then essential. The legally required, physician's consent was seen by NPs and PAs as a bothersome burden to perform their tasks optimally. The granted independent rights were welcomed with open arms. Besides, the independent rights strengthen NPs'/PAs' position within Dutch healthcare by making them distinctive from other non-medical professions. Not continuing these rights could limit their added value and thus undermine the reason for their existence.

The importance of the evaluation was acknowledged by the national umbrella professional associations, Nurses and Carers Netherlands department for nurse practitioners (NCN NP, in Dutch V&VN VS) and National Association of Physician Assistants (NAPA), respectively. Both associations fully cooperated with the research to increase its response rate and thereby its reliability. Both associations took part

in the evaluation's guidance committee set up by the Ministry of Health, Welfare and Sport (HWS) in order to provide advice and therefore to secure acceptance among their members. The members, in turn, were informed about the study at the annual congresses, in newsletters and other media. During the congresses, researchers were also present to answer questions and to pick up signals which were relevant for the evaluation. After completion of the evaluation, the associations informed their members of the outcomes and conclusions on their own websites [2, 3] and via social media (Facebook and Twitter) [4-6] and posted the final report `voorBIGhouden` to download on their websites. [7]

VoorBIGhouden was also used in a working conference for 2ndyear MANP students, co-organised by NCN NP. In order to prepare the subject independent rights, students had to go through the report. [8]

Interim and overall results are presented to NPs and PAs during multiple national annual conferences and internationally during the 10th ICN NP/APN Conference 2018 by the PhD Candidate and during CAPA ACAM 2017 by the president of the NAPA.

**Physicians**

Physicians, working in close collaboration with NPs and PAs, were pre-amendment responsible for the complete care pathway, including the performance of reserved procedures by NPs and PAs. Post-amendment NPs and PAs themselves were responsible for their own part of the care pathway and were, therefore, disciplinarily accountable. Physicians formerly organised care processes in such a way that supervision and intervention were always ensured. In practice, this meant that parallel consultation hours were held and patients were discussed before or afterwards. Post-amendment, this was no longer needed since physician's legal position had been changed. Furthermore, NPs and PAs introduction caused a shift in the physician's patient population towards fewer patients but with more complex health problems. This process was improved by NPs'/PAs' independent rights. Care processes were adjusted such that physicians had more time for those patients. A negative evaluation could (partly) offset all above effects and lead to rearrangement of care processes.

Despite initial scepticism regarding NPs'/PAs' independent rights because of a lack of clear conditions [9], the Royal Dutch Medical Association (RDMA, in Dutch KNMG) also took part in the evaluation's guidance committee and the underlying

associations had actively recruited physicians for participation in the study. A notice about the findings of the evaluations was placed in the Dutch physician's trade journal "Medisch Contact". [10]

**Policy makers**

The findings of the evaluation were of the utmost importance for the ministry of HWS, as commissioner. Task shifting is one of the key points of Ministry of HWS's policy to combat the gap between healthcare demand and supply. A successful experiment not only has an effect on nation's policy toward NPs and PAs but also toward new professions eligible for task shifting such as technical physicians (in Dutch: technisch geneeskundigen) and Allied Medical Healthcare professionals (in Dutch: Bachelor Medisch Hulpverleners). The latter two evaluations are yet to be presented to the Parliament.

During the entire evaluation period, a representative of the Ministry was a member of the guidance committee. In this way, barriers known at the time, could be addressed more rapidly, as it was the case with the lack of transparency in costing and invoices on NPs'/PAs' operations.

The importance of the evaluation has been highlighted by the decision of the Minister to receive the final report in person (Figure 1). The minister communicated, based on the report, that task shifting was successful and that she would adopt the recommendations. [11] The subsequent legislative proposal was approved by the Lower Chamber of the Parliament and rubber-stamped on 3 October 2017 by the Upper Chamber. [12]


**Figure 1:** Delivery of the report voorBIGhouden to Minister Schippers

By now, the report is also broader used in policy documents, such as in the 2016 Advisory Committee's Plan (in Dutch: Capaciteitsplan 2016), where the Advisory Committee on Medical Manpower Planning (in Dutch: Capaciteitsorgaan) provided intake recommendations for the healthcare sections and government on workforce capacity. [13] Or, in the consensus document 'Task shifting in Rehabilitation Medicine', where recommendations with regard to the registration of cooperation agreements were met. [14]

The results of the evaluation have recently been presented at a national conference on task shifting to an audience of Dutch policy makers, health care professionals and patients (Taakherschikking in de Nederlandse gezondheidszorg: de experimenteerfase voorbij [15]); to trainers of universities of applied sciences with a MANP and/or MPA education and advisory bodies of several hospitals.

**Researchers**

The Dutch Advisory Council on Health Research recommended in 2007 that studies initiated by University Medical Centres, should connect to public health and health care issues and should lead to innovation of healthcare and prevention. [16] To achieve this, the Health Council of the Netherlands recommended in 2016, instead of the established quantitative research designs, to use designs that are better adapted to real-world problems faced during daily practice, like qualitative and mixed-methods designs. [17] The evaluation presented in this dissertation satisfies both conditions and could serve as an example.

The current evaluation can internationally contribute to the knowledge about the impact of (independent practices) of NPs/PAs on processes and outcomes of healthcare. As discussed in Chapter 1, there is a strong need for up to date, high quality research in other countries than the US and UK, enabling cross-country comparison. Research on task-shifting has its methodological shortcomings. The evaluation described in this dissertation can be regarded as an innovative encouraging framework, which should be optimised. Most scientific results of the evaluation are published in peer-reviewed international journals.

What remains to be accomplished is to write articles about patients' perspective and NPs/PAs workload (data are available) and to present the findings and the used design/methods to researchers internationally.

The relevance of the study and the extent to which findings were communicated can be best summarised in Figure 2. In this figure the number of online search results are given for the report “voorBIGhouden” and the minister’s response: “Task shifting is successful” (“Taakherschikking is succesvol”).

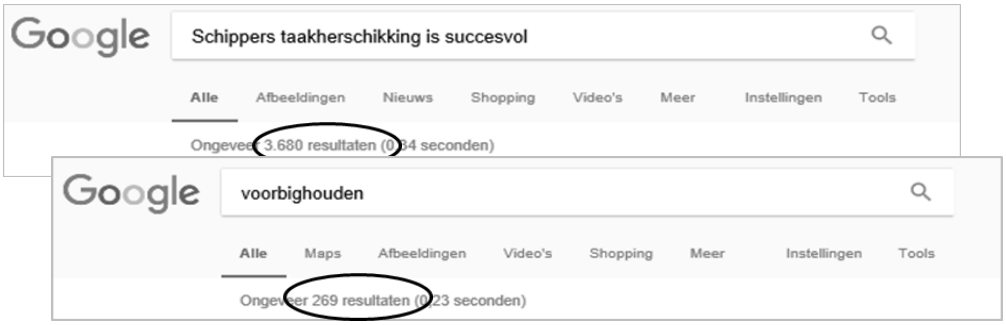


**Figure 2:** Number of online search results per key words (September 2018)

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# Curriculum Vitae

Daisy De Bruijn-Geraets was born on January 24th, 1964 in Heerlen, the Netherlands. After graduating from secondary school (Gymnasium, 1982) at the Bisschoppelijk College in Sittard she obtained an applied university degree on biochemistry at the Zuidlimburgse Laboratoriumschool Sittard in 1986. Following her training, she accepted the position of analyst at the Tissue Typing laboratory in the Maastricht University Medical Centre (MUMC+), where she specialised in DNA techniques, especially sequencing. Soon after, she was promoted to leading analyst. As a mother of four, she wanted to work part-time and decided to switch her career and joined in 1999 the department of Patient & Care in the MUMC+.

Since then, she was involved in several studies in the field of integrated care and task allocation as a research assistant and in later stages as a researcher. In 2009, she combined this work with the part-time study Epidemiology at the Maastricht University. She received her master's degree in 2011, after finishing her thesis about Acrylamide and risk of colorectal cancer with specific mutations in key genes.

In the period 2011 to 2016, she was appointed as a researcher for the study, that resulted in this thesis, on the independent rights of Nurse Practitioners and Physician Assistants for some reserved procedures. This study was commissioned by the Dutch Ministry of Health, Welfare and Sport and was carried out at the department of Clinical Epidemiology and Medical Technology Assessment (CEMTA, a section of Patient & Care) in the MUMC+ in collaboration with CAPHRI Care and Public Health Research Institute, Department Health Services Research of Maastricht University. This was followed up by a study, commissioned by the professional organisations Nurses and Carers Netherlands department for nurse practitioners and National Association of Physician Assistants, specifically focusing on NPs' and PAs' independent rights for the reserved procedures cardioversion/defibrillation and endoscopy.

Currently, she works as a healthcare scientist at CEMTA where she is developing a new programme in realist evaluation. Furthermore, she is involved as a researcher in an evaluation on the independent rights of Allied Medical Healthcare professionals (in Dutch: Bachelor Medisch Hulpverleners). She is also an advisory member of the "College Specialismen Verpleegkunde".

# List of publications

**Publications related to his thesis**

*International publications*

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**Wet BIG Artikel 36a:**

1. Bij algemene maatregel van bestuur kan in afwijking van artikel 36 van deze wet en van artikel 1, eerste lid, onderdeel pp, van de Geneesmiddelenwet bij wijze van experiment worden bepaald, dat voor een termijn van maximaal vijf jaar een bij de maatregel omschreven categorie van beroepsbeoefenaren, die werkzaam is op het gebied van de individuele gezondheidszorg en die met goed gevolg een bij de maatregel aangewezen opleiding met betrekking tot de aan te wijzen voorbehouden handeling heeft afgerond, wordt aangewezen als zijnde bevoegd tot het verrichten van in die maatregel aangewezen handelingen.
2. […]