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Professionalization of nursing responsibilities in wound management by academization: From an accompanying nursing to evidence-based healing-related activities

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ZUSAMMENFASSUNG

Deutschland hat ca. 3-4 Millionen Betroffene die an chronische Wunden leiden. Die häufigsten Ursachen für die Entstehung sind zivilisatorische Ursachen sowie der demographische Wandel und die damit verbundene Morbidität.

In Deutschland stellt die Versorgung von Menschen mit chronischen Wunden sowohl im stationären als auch im ambulanten Sektor eine multiprofessionelle Herausforderung dar.

Defizite ergeben sich aus fehlenden Standards. In diesem Artikel werden die verschiedenen Ebenen der Versorgung im Wundmanagement sowie ihr Übergreifen in transsektoraler, interprofessioneller sowie interdisziplinärer Form beschrieben und die typischen, immanenten Probleme er einzelnen Akteure im Wundmanagement in Deutschland beschrieben. Damit soll der Widerspruch, daß immer mehr Menschen an Wunden leiden, jedoch die Versorgung auf ganz unterschiedlichen Qualitätsebenen, jedoch insgesamt qualitativ nicht ausreichend erfolgt, erläutert und aufgelöst werden.

Komplexe und vielschichtige Interaktionen und Arbeitsabläufe prägen den medizinischen Versorgungsalltag. Medizinische Fachbereiche können nur funktionieren, wenn die Tätigen unterschiedlicher Professionen zusammenarbeiten. Eine zentrale Schnittstelle bei der Versorgung von Menschen mit chronischen Wunden, bildet hier der Arzt und die Pflegekraft.

Was in den europäischen Ländern wie Schweden, Finnland, Großbritannien aber auch in den USA längst implementiert ist, nämlich eigenverantwortliches Arbeiten im Pflegeberuf, wie z.B. im Wundmanagement oder die Therapieüberwachung von Diabetikern etc., obliegt in Deutschland immer noch der traditionellen Auffassung nach der Arzthoheit. Das Thema Übertragung ärztlicher Tätigkeiten an das Pflegepersonal ist schon seit Jahren in der Diskussion. Im Kern geht es hierbei um die Realisierung einer neuen Arbeitsteilung zwischen den Professionen Arzt und Pflege.

Die Diskussion um die Professionalisierung der Pflege ist in diesem Zusammenhang ein wichtiges Thema, dazu gehört auch die Forderung nach einer universitären Ausbildung in vollständiger Erfüllung der PISA-Kriterien. Bereits jetzt werden viele ärztliche Aufgaben von Pflegefachkräften im Wundmanagement übernommen, ohne dass sie formal oder rechtlich ausreichend abgesichert sind.

Um eine sichere und professionelle Ausübung der Tätigkeit zu gewährleisten, ist das entsprechende Wissen der Pflegepersonen über evidenzbasierte Maßnahmen im Bereich der Wundversorgung erforderlich und der rechtliche Rahmen für eine Übertragung heilkundlicher Tätigkeiten zu schaffen. In seiner Sitzung vom 20.Oktober 2011 hat der gemeinsame Bundesausschuss beschlossen, dass im Rahmen von Modellvorhaben künftig ärztliche Leistungen auf Fachkräfte der Alten- und Krankenpflege übertragen werden können. In diesem Artikel soll erörtert werden, ob der § 63 Abs 3 c SGB V eine Möglichkeit der Realisierung eines Modellvorhabens bieten kann.

ABSTRACT

In this article we want to point out why more and more people in Germany suffer from chronic wounds and what causes may underlie. Furthermore, the different levels of care in wound management and its spillover in trans-sectoral, interprofessional and interdisciplinary form will be described and the typical, inherent problems of the different partners in wound management in Germany will be mentioned.

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The discussion about the professionalization of nursing is an important topic, this includes the demand for university training, with the complete performance of the PISA criteria. Already now many medical tasks in wound management were executed by nurses, without being formally or legally assured in a sufficient way.

In order to guarantee a safe and professional pursuit of these activities it seems indispensable to extend the knowledge of the caregivers about evidence-based interventions in wound care and it is necessary to install a legal framework which offers the opportunity to assign these medical work.

We would like to work out if §63 paragraph 3 c SGB V offers the opportunity to realize a pilot project.

1. Introduction: general basic information

Wounds are as old as mankind. It is well known, that various injuries as well as chronic diseases can lead to a loss of integrity of our body shell, the skin. Healers have to face with major challenges and over the centuries the principle of the treatment of chronic wounds has changed little.

Formerly and even nowadays the systematic drying of wounds, constantly changing and poly-pragmatic treatment with topical therapies, short intervals of changing the medical dressing and last not least the misbelief, that a "breathing" wound, wound which uncovered, will heal faster, still plays a key role in the therapy of wound management.

Previously the complexities of wound healing and the formation of many wounds were not yet known. Today tags are at the forefront, such as cost pressure, multi-professional cooperation, lack of evidence-based knowledge on the effects of dressing materials, unified strategies in the treatment of people with chronic wounds.

Chronic wounds that are considered mainly in this article lead to a considerable reduction of quality of life. They are usually based on malnutrition of the tissue on the basis of disturbed microcirculation. Different diseases cause poorly or not healing trophic defects. They all have some in common, these wounds can be healed permanently if the responsible factors, i.e. circulatory disorders, of this disorder can be removed.

2. Positioning, situation in Germany, the concerned person

More and more people in Germany suffer from chronic wounds, experts figure a number of 3–4 million people.

The medical and technical progress, the change of life condition as well as Life Extension found a change of the spectrum of diseases in our world, in our society. So the effects of chronic wounds get more importance in epidemiological, individual, social–political as well as economic resort of healthcare service.

2.1. Considering the permanent increase of concerned persons, some examples of causal relations will be given

Between 1998 and nowadays, the number of obese people in Germany with a body mass index (BMI) of over 30 has obviously risen. The number of obese people has risen by almost a 5th in today 23.3% of men and 23.9% of women. Obese people (obesity) because of their body mass may suffer of different illness in their lifetime. Diabetes and its consequences are very serious in this group of obese people. It is estimated that in Germany there are about 6 million people with diabetes. According to the International Diabetes Federation (IDF) men and women are almost equally affected, in the group of 60–79 years old persons there is the highest rate (26).

The scientists from the RKI (Robert Koch Institute) in Berlin estimate that nearly 2% of the population suffer from not diagnosed diabetes (27).

They think that in some cases diabetes mellitus type 2 is diagnosed after its emergence only 10 years later. At diagnosis vascular effects that are followed by complications such as heart attack, stroke and kidney failure [1]. Further complications include diabetic foot problems, which are referred as "diabetic syndromes concerning the feet" ("Diabetic Podopathie" according to Chantelau) activities. Ulceration of the foot is the worst consequence. A large amount of patients suffer from a foot lesion in different phases during their illness.

Between 0.8 and 10% of all patients with diabetes mellitus get a foot ulcer. The yearly rate of new cases comes to 2.5–5.9%. Some of these diabetic foot ulceration do not heal and in the worst case they lead to minor or major amputations. Germany is compared to other European countries in the upper section with more than 60,000 amputations p.a. Approx. 70% of all amputations are executed to patients with diabetes mellitus [2].

2.2. Effect on morbidity in old age

The relationship between age and health is controversial, as there is both empirical evidence of an improvement in health of older people as well as an expansion of morbidity.

The aging of the people is not necessarily linked to disease, but an age-related increase in chronic diseases is noted. Characteristic here is the simultaneous presence of several chronic diseases, known as multimorbidity [3].

Therefore, old multi-morbid people suffer accordingly frequent from chronic diseases such as diabetes mellitus, chronic venous insufficiency, or PAD, which can lead to chronic wounds.

Pressure ulcers (bedsores) are another serious complication of multimorbidity and immobility in high age. Studies have found that in the outpatient treatment facility for more than 30% of clients in nursing and retirement homes and even more than 50% of residents have an increased risk of pressure sores (Hamburg project "quality comparison in the prevention of tissue"). Due to the aging population and the rising life expectancy, increase in chronic diseases can be expected with a further increase in pressure ulcer cases [4].

Whatever the underlying cause is, people with chronic wounds represent a complex supply problem. The individual factors of persons affected, such as the living situation, the personal experience of pain, wound odours, causal underlying disease, wound healing relevant comorbidities, etc. could result in defects in wound healing, because of a lack of therapeutic progress and, as a consequence in a significant decrease in the quality of life of those affected. Thus, many of these patients suffer for years with different therapeutic trials behind. Besides the social drama in every single case, the supply of problem wounds is associated with enormous care and expense. The wound care needs of patients posed by the sore- and treatment-related restrictions on the daily lives of those affected. Any chronic wound involves limitations of independence and social life of the patients.

Already 50 years ago, the first "modern dressings" were published on the market. Since that it has been scientifically proven that the creation of a moist wound environment by use of occlusive dressings, the healing time is shortened. But in Germany a maximum of about 20% of wound patients are adequately funded.

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"According to the initiative Chronic wounds (ICW) in Germany only one in five chronic wound is provided properly." (23)

3. Why are the persons affected cared for on quite a different level?

The care of people with chronic wounds in Germany, both in inpatient and outpatient sector, is a multi-professional process (problem). Due to the complexity of wound treatment in connection with serious underlying diseases such as diabetes and diseases of the blood vessels as the PAD or CVI and also hygienically demanding topics (e.g. role of recurrent infections, frequent infections with multidrug-resistant bacteria such as MRSA), the requirements for the doctors are very large. It frequently occurs after a hospitalization for discontinuity in the follow-up and lack of communication between the different sectors. The consequences are stationary recovery; there is a so-called revolving door effect, which goes together with high costs.

But working together, whether interdisciplinary or inter-professionally, is a difficult challenge. Deficits in that result from lack of standards and information, lack of communication, due to lack of holistic approaches, as well as not enough interdisciplinary collaboration.

Risse writes in this connection that the supply of the diabetic foot is not a problem in technical or medical terms, but a huge field of organizational difficulties in interdisciplinary cooperation.

He describes four perspectives that influence the treatment process: the somatological – interactive – organizational–technical and the epistemological, philosophical perspective. He comes to the conclusion that all detailed knowledge exists but that supply fails at a regular fair treatment because of intractable psychopathologic problems (psychopathology of therapists). It also fails because of missing structures of interdisciplinary courses of action because the cooperation of rational egoist does not work [5].

4. Care

Wound management is primarily a medical activity that is delegated to care. The care of those affected by professionals today is indeed considered as uniformly important and valuable, but it is limited by only very small autonomous actions and may only cost a relatively low price.

Wound management is a very complicated and complex task requiring a high level of knowledge and practical skills, thus general nursing expertise ranges are not enough here. Care suffers from a lack of nurses. In addition, only a few of them have a specialization.

The German Network for Quality Development in Nursing (DNQP) published expert standards for the care of patients with chronic wounds in cooperation with the German care-advice. Hence, all care institution is obliged to implement these standards of care and to educate nurses in wound management.

Sometimes not enough further educated professionals have to treat patients with wounds because of organizational reasons, e.g. itinerary planning.

In Germany, the structural conditions and cost pressures strongly influence the quality of wound care.

Looking at the price development of outpatient care services, the economic features of the maintenance services are still at a level of developing countries. In remuneration for patient care service for a bandage change, which is €10.86 on average in Germany (as of 2006), wound care in the outpatient setting is economically deficient and investment in training and specialization are virtually impossible.

"In determining the nationwide average dressing package with a pressure ulcer grade III (according to Seiler) an average of the AOK amount of refund was formed (in accordance with self-report 2006). Prices range from €6.77 by AOK Thuringia to €18.30 by AOK Hamburg and result in a national average price of 10.86 €/Federations". [6]

Despite or perhaps because of that, these problems and challenges seem to develop into a number of motivational aspects. There is a tendency for the training and further training will be utilized to meet the new challenges in wound management in everyday work as well as the professional and political changes.

Wound management not only includes application of wound dressings, but it is also a very complex area of responsibility. Professionals must inter alia have a good knowledge about anatomy, pathophysiological processes, as well as differentiated knowledge of wound dressings and good social and communication skills. The term wound management seems initially a somewhat strange formulation, but if one considers the work of a wound manager, it becomes clear that wound manager control multi-professional events. The core tasks, such as the recognition and support of the cause of wound diagnostics, wound-related complaints of patients and their relief or the selection of dressing materials and psychosocial care make clear why the term "management" is quite fair.

As already described, the wound care is primarily a medical activity, but often it seems as if the knowledge of nurses in wound management is often be higher than that of doctors. Gradually numbers are known, how many nurses and doctors participate in appropriate training. These numbers are confirmed by internal data by Academy ZWM Kammerlander. According to that 1026 people have attended a basic course in wound management in the period between 2006 and 2010. A total of 551 people is further qualified as a certified wound manager ZWM® and only 32 of them were related doctors (28).

Nevertheless, as Panfil says, experts often complain the poor quality of supply of people with chronic wounds, especially in nursing homes and in ambulatory care. According to experts, the certified courses such as sore or wound specialist managers express a strong commitment of qualified nurses, will not suffice. The call for specialization in academic nursing education in specific clinical areas of action is getting louder [7].

4.1. Payors

The system-dependent structure of the statutory health insurance knows indeed some supply improvements as explicitly trained professionals, wound concepts or wound treatment centers, these innovations are welcome – but these professionals are still not adequately remunerated.

Therefore highly skilled professionals have to get financed by the sale of dressing materials in order to realize wound care centers or concepts. According to experts' opinion, a significant cost reduction could be reached by specialization and interdisciplinary cooperation on the basis of expert standards and guidelines.

4.2. Academization and professionalization in the context of nursery

The discussion about professionalization in nursing is an important subject in Germany, it includes the demand of academic education in full compliance with the PISA criteria. The terms of academization and professionalization run through the discussion about wound management in Germany like a golden thread.

As part of academization, nursing structural conditions have been created to generate nursing knowledge and nursing science at

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colleges and universities, as well as sophisticated and ambitious knowledge of experts.

Characteristics of profession are a high degree of professional organization (professional association), personal and functional freedom of legal arrangement, as well as a proper professional ethic.

The typical professions are e.g. physicians, notaries, lawyers, and theologians. Characteristic of these professions is their prerogative of interpretation in their key process.

Physicians have got this prerogative of interpretation in diagnostics and therapy, even in a juridical conflict a medical referee has got this prerogative of interpretation. Similar to this fact the prerogative of interpretation for theologians considering the religious righteousness is as firmly established as the prerogative of interpretation for the jurists giving the definition of right and wrong [8].

4.3. Is nursing a profession?

The Medical Director of the University Hospital Hamburg-Eppendorf, Professor Jörg Debatin, has depicted the following picture of the nursing sector.

The highest potential in healthcare is the do gooder, highly motivated, poorly paid – a trifle annoyed because his work will not sufficiently appreciated.

The traditional meaning that describes care as housework even as various nursing care has already disappeared. A new legal framework, demographic change and the recommendation of the Advisory Council have pushed the process of professionalization. These days we consider a broad agreement that nursing profession is to be regarded as a modern and high-qualified task. The center stage is creating a scientific base that implements the concept of evidence-based practice. Compared to other countries, caring in Germany is in the reorientation since about 30 years, so the process of professionalization has just started [9].

For the progress of professionalization, it is important to submit the progression of higher academic degrees in the functional areas such as teaching and management, as well as the expansion and development of specialized, evidence-based competence. Another key criterion is the ruling of responsibility in operational procedures and by association the development of autonomy of the profession (professional activity). The "scientification" of a professional's own "body of knowledge" and with that the formation of a proper professional identity are important aspects for the development of a nursing profession [10].

Despite all the care taken in setting the course we have to realize that professionalization has not yet ore even modestly reached the professional practice. As compared to international standards we cannot ignore the accumulated needs of professionalization of nursing. Foreign observers of the German nursing landscape let us know, that the chief difficulty in developing the nursing profession is that nursing persons develop an institutional identity but no professional identity. This professional identity is not imparted by using the professional authority of socialization such as education, training or study. The professional group of care in Germany is still seen as a group of medical assistant career with a minor autonomous radius of operation and prescientific reasoned decisions. So it is often disvalued as a semi-profession working heavily dependent from physicians. It is significant that at the beginning of an act of care, there is always the physician who is responsible in (who decides) assessment, prescription and at the end of medical service of the insurances (Medizinischer Dienst der Krankenkassen, MDK) in medical assessment Regardless of how physician and nursing work in a cooperative way, finally the physician decides on the prescription of services [8].

These structures are patronized by the medical lobby, they like to see the academization confined to functional areas (Administration and Management) and they honorably mention the German education system that still considers nursing persons as "medical assistants". So their profession is even ranked as a lower priority health discipline. A further handicap in the process professionalization is that care is not a full-fledged discipline and that expert knowledge is only in a lesser extent generated and legitimated in education, training, study and research, so that it is necessary to rely on foreign expertise. Oral tradition and myths such as the healing potency of tannins and zinc paste to chronic wounds, or "iron and blow-dry" is "good for the circulation of the skin" or statements like, "we've always done it, we never have done it different …", serve as a legitimation and reasoning of nursing actions.

Important elements of a profession are missing. Lorenz describes that in Germany, like in Austria, the only state in the EU, has not installed the protection of practice of a profession but only a protection of professional titles. That is to say, not everyone may be called nurse, occupational health nurse, geriatric nurse, but everybody can do it in Germany [8].

4.4. Facts from the context described above

More and more people in Germany suffer from chronic wounds caused by unhealthy lifestyles and by demographic changes. As a consequence, chronic wounds become more important in epidemiological, individual, social, political, and healthcare economics.

In Germany the care of people with chronic wounds, both inpatient and outpatient sector, is a multi-professional process. Approximately 70% of wound patients are not adequately supplied.

Wound management in Germany is still largely unorganized. While there exist connective structures (Academy ZWM KWFI, ICW, DGfW), they work more or less against each other or at its best next to each other, rather than with each other.

Most physicians lack from specific knowledge, since the doctor's basic and specialist training is neither taught in study nor in specialist training in the form of bandages, wound management doctrine of indications and case management.

The principle of delegation by physicians to nursing slows the process of professionalization of nursing and has implications for the provision of care and support. Additionally, it characterizes the professional image of nursing.

Wound management is a very complicated area of responsibility, so general nursing expertise is not enough here. Care suffers from a lack of nurses and even nurses without further education, as well as from the missing of reimbursement of the additional services provided.

Care is in a process of professionalization, but lacks features of typical professionalism.

One of the causes for an inadequate wound treatment includes the limited autonomy of nurses in comparison to the medical profession in their instructions remit "wound care".

To strengthen care, motivating, efficient academic trainings and the establishment of programs are necessary. In addition, a framework should be developed in order to create a legal basis for the further development of an advanced nursing practice.

5. Does § 63 SGB V provide a way for the professionalization of nursing profession?

Already, many medical tasks are undertaken by nurses in wound management, without being formally or legally adequately protected. This article is to be considered whether and what conditions must be created to provide the appropriate knowledge about evidence-based interventions in the field of wound care, as

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Table 1
The internal structure of the Directive to § 63 paragraph 3 c SGB V.

General part (A)	Special part (B)
Legal foundations of transmission	Naming activities (catalog of activities)
Provisions for autonomous medical care Provisions Recommendations regarding the content of the demonstration projects	Qualifying minimum requirements of the individual activities: • Five plug diagnosis related power complex (diseases) • Procedure-related single activities

well as the legal framework for the transfer Heilkundlicher activities, ensuring a safe and professional pursuit of the business is assured.

"At its meeting of 20 October 2011, the Federal Joint Committee has decided that, as part of pilot projects in future medical benefits to qualified employees of the sick and elderly care can be transferred. Specifically, it has to be understood that this is not only the delegation of medical services, but their "substitution". Substitution of medical services by a non-medical service (non-"doctor" service) means health professionals as opposed to the entire delegation transmission of medical and legal responsibility for the proper conduct while they remain with a delegation to the doctor." (24)

A principled approach could be the § 63 SGB V 3c, this creates the conditions for pilot projects to launch. Consequently, specialized nurses organized cooperation could after diagnosis of the attending physician to take certain medical activities. Nurses should assess the model independently care needs, get execution and regulation expertise in bandages and nursing aids, undertake specific assignments/transfers and prescribe to patients with chronic illnesses in definable frame medicines must.

What in European countries such as Sweden, Finland, Great Britain and also in the U.S. was implemented long ago, namely autonomous work in the nursing profession, such as in wound management or therapy monitoring for diabetics, etc., in Germany is always up not traditional to the doctor's sovereignty. The theme of transmission of medical activities to the nursing staff has many years of discussion. In essence, this is the realization of a new division of labor between the professions, doctors and nursing that the requirements of an increasingly complex health and care events, lack of job satisfaction, complexity of medical progress, demographic change and its impact on the nursing staff, changing pursuits, from patients existing regional shortfalls, to be fair.

§ 63 SGB V 3c prepares a chance for national pilot projects. This development is back on a recommendation of the Advisory Council on the Assessment of increase in health care. It suggested in the report of 2007, "Cooperation and Responsibility" before the entrenchment of a model clause for stronger involvement of non-physician health professionals in health care. Under the Nursing Further Development Act dated 28.05.2008, the structural evolution of the long-term care, the legislature followed and has instructed the Federal Joint Committee, in a policy set the ACTIVITIES in which a transfer of medicine onto nursing professionals. After three years of intensive work, the Federal Joint Committee (G-BA) at its meeting on 20 October 2011 presented the first draft of the policy available via the transfer of defined medical services to nursing professionals as part of pilot projects. On 21/03/2012 again this modified policy pursuant to § 63 para 3c Book V was declared legally. An independent and autonomous exercise of medicine by the health and medical care, the pediatric care and the nursing profession is the goal. Later in the pilot project will be launched by health insurance, which is the transfer of medical services and which are due to a training specially qualified. Chief pilot projects are temporary [11].

Analysis of the policy of § 63 para 3c SGB V The policy is divided into two parts, a general text part (A) and a special section (B). Part A sets, as part of the general legal principles, the transmission of healing professionals on the elderly and the sick, as well as the content and scope of the independent practice of medicine. Further, Part A includes provisions to binding regulatory components of the model plan and recommendations to additional contents of the demonstration projects. Part B designates, as a special part, the single transferable medical activities, which underlie pilot project pursuant to § 63 para 3c SGB V and allow a transfer of independent medical exercises to members of the profession of the old and the sick to. The directive prescribes to the individual activities, what qualifications have to be purchased to medical activities of professionals in the sick and elderly care so that medical care can be provided (Table 1).

5.1. General part (A)

§ 1 describes the legal basis and the subject matter of section 1 Directive.

In § 1 Paragraph 2 the Federal Joint Committee determines a catalog of medical activities on nursing and elderly care exercises that can be transferred to autonomous exercise of medicine, unless they are qualified in § 4 Section 7 of the respective professional licensing law (Nursing Act or elder care law). In addition, using rules for the regulation and guidelines for pilot projects follow [11].

5.1.1. § 2 Autonomous medical exercise

§ 2 reflects the fact that only medical activities within the framework of the Directive can be transferred so far. Doing so, the medicine will be exercised autonomously and responsibly by the nurses within the range prescribed by the Directive framework. The exercise is to follow the logic of the "acceptance" of technical, economic and legal responsibility. The doctor is not responsible for the activities transferred. The transfer of the medical profession is not directly on the pilot project, but only indirectly via the doctor. The doctor is the decision-making powers reserved to whether and to what extent the autonomous exercise of medicine is medically necessary by making the transferred medical job responsibilities. The medical transfer is thus led to the doctor.

5.1.2. § 3 Bindings and limits of the autonomous medical exercise

Time before that, but after that editorial, § 3 determines that the diagnosis and the indications are subject exclusively to the medical subject. The medical intervention by qualified nurse requires medical diagnosis and indication to be forwarded to the nurse. The diagnosis and indications are communicated to the nurses well documented. Any therapeutic intervention is always tied to the medical diagnosis and indication. The transfer of the physician implies the always subject to correct treating. These diagnoses can change, reduce or withdraw transmissions. This must be documented in constitutive relation to the nurse. Mirroring, the nurses must feedback information, changes and limitations of the need for the medical side instantly [11].

5.1.3. § 4 Requirements for regulation

A performance so far underlying to physicians, such as the prescribing of medicines and medical aids is part of the model project that was recorded by explicitly trained professionals as a portable medical activity. Thus, for example, in the context of

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model projects the nurse can prescribe bandage shoes or podiatric services for patients with diabetic foot ulcers.

5.1.4. § 5 Control components of the demonstration projects and

5.1.5. § 6 Recommendations to further regulatory components of the demonstration projects

Commitments and recommendations are also given onto the activities of demarcation to all parties in a model project. For example, the model project control components include the necessary technical, human and organizational requirements for the independent exercise of the delegated medical practice. And the regulations required for communication and cooperation policies and procedures for the development of standardized clinical pathways so action processes [12].

5.2. Special section (B)

In Part B (special part) of the Guidelines the catalog of activities is concretized within which the pilot project will be carried out. The catalog of activities includes a mixture of diagnosis-related power complexes (diseases) and procedure-related single activities (Table 2).

5.3. Diagnosis-related section

In the first section of Part B of the "special part", a collection of diagnostic related activities for communicable healing activity on four conditions is explicitly referred to:

- diabetes mellitus types 1 and 2,
- chronic wounds,
- dementia (not palliative), and
- hypertension (excluding pregnancy).

The example of the diagnosis "chronic leg ulcer wounds" the transferable healing activities are divided into: assessment, diagnostics development, planning of initializing interventions, treatment path algorithm, implementation of the treatment plan (wound management) (Table 3).

The second section of Part B of the Directive is the activity catalog which defines the procedure as related single activities, e.g.

- infusion therapy/injections,
- stoma,
- tracheostoma management,
- load and supply feeding tube,
- insert and monitor a transurethral bladder catheter,
- nutrition and excretion,
- pain management,
- respiratory therapy,
- patient management, and
- case management and transition management that can be conducted in various diseases.

Table 2
Contents of the special section B.

Naming activities (catalog of activities)
Special section (B) Qualifying minimum requirements of the individual activities: • Five plug diagnosis related power complex (diseases) • Procedure-related single activities

A condition for the execution of healing activities by specialized nurses is in addition to the existence of a medical diagnosis and indications, which can be made in the naming of activities from the catalog of activities, each of the transmission (launch) by the doctor. The transfer of medical activity to the nurse can only work in the frame of the pilot project and certain medical activities defined in § 63, including all responsibilities. This can be done e.g. by transfer, regulation, or in any other form. The catalog of activities refers basically equally apply to the outpatient as well as on the stationary area, taking in the outpatient area includes certain activities also have the power to prescribe medical aids and to initiate further diagnostic or therapeutic activities by the panel physician. The regulation of details and opportunities in arrangement lie in the decision of the contracting parties under the pilot project [12].

6. Interpretation §63 Abs. 3c SGB V

Sophisticated interactions and complex workflows characterize the daily routine of medical care. Medical faculties can only function properly if people of different professions cooperate. An important point of intersection in caring sick people is the doctor's and nurse's work. There are various models of the division of medical responsibilities.

In the context of the § 63 para 3c SGB V the current debate refers especially on the relation of medical to non-medical activities, especially nursing activities.

In this context, the various forms of division of labor will be introduced.

- horizontal and vertical division of labor and
- delegation, substitution.

7. Horizontal and vertical division of labor

We speak about a horizontal division of labor exclusively in the medical range. We find it in the cooperation between physicians of different medical specialty, between doctors and legally independent working providers of medical service or between resident physicians and physicians working in a hospital.

The vertical division of labor is the range of a hierarchical order between different organization involved in treatment, among legitimate medical care provider instruction or dependent care providers. We find it when collaboration between doctors and nursing staff is not equal.

The distinction between horizontal and vertical division of labor is due to the civil liability law, considering the rules of professional conduct and is to determine the liability.

There is no direct professional legal relevance of this distinction. The distinction is however based on criteria of the profession law. Certain features qualifying the activities, i.e. the standard for medical specialist are used [13]. In the § 63 Section 3c we find the formulation that in transferring the activities the responsibility should be devolved.

The delegation is therefore a case of vertical division of labor. It describes the transmission of medical activities. Delegation defines the unilateral and arranged transfer of activities or individual tasks of physicians to the care (nursing people) keeping the possibility to cancel the transfer of activity at any moment. This means all activities rest on the physician's responsibility. The must be prescript by the physician. The nurse does not decide on "whether" but only "how", she is responsible for carrying out.

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Table 3
Contents of part B special.

Diagnosis	Transferable medical activity	Defining the scope and nature	Qualification according to § 4 Nursing Act or elder care law
3. Chronic wounds e.g. Leg Ulcer	Assessment History diagnosis	Detection of wound condition including wound size and wound infection and pathological causes and relevant monitoring parameters; deep wound swabs	Knowledge of pathophysiology, diagnosis and treatment of wounds and causative diseases (e.g. diabetes mellitus)
		Instigation of contract medical referrals for further diagnosis (including case conference)	Selection and use of assessment instruments (including Skoringskalen, old man; bank principle; URGE division; pain scale, independence analogous NBA/GDS/Barthel

As I have already described, the Federal Joint Committee has decided that, as part of pilot projects medical services can be "transferred" to specialist for geriatric nursing an health caring.

One point in this guideline is the subject of controversial discussion, they discuss whether the transfer of healing activities, in the form of substitution or delegation to the nursing staff should be realized or can be realized. The legislature has not formulated an unambiguous legal definition of future division of labor, whether it should be substitution or delegation.

The phrase "transfer an acquisition of healing activity" should probably aim to a consensus, however, this phrase defines in common language only the generic term for all forms of division of labor. The term "transfer" can apply to all forms of division of labor, as well for delegation as for substitution. This phrasing offers all possibilities to argue for or against, they can find their arguments in the article of the statue.

The National Association of Statutory Health Insurance an the Germand Medical Association for Physician favor the transfer of medical ACTIVITYS only in the sense of delegation. "The German Medical Association rejects, by considering the interests of patient safety, care quality and legal certainty, a relaxation of the doctor's reserve in medical diagnosis an therapy, however, pleads – on condition of a relevant qualification – for an exhaustion of delegation and promoting interprofessional cooperation based on existing skills" [14].

This opinion is clearly represented.

"Primum nihil nocere" (first of all: do no harm)

This ancient principle of any medical intervention must be the main idea, even in the ideas about delegation of medical activities. Patient's welfare and in consequence the effectivity of the treatment must remain in the focus of all activities in the health service, even when it is difficult in times of economic problems an lack of physicians" [15].

The leading association of statutory health advocates, however pleads for substitution. Pilot projects' could help to install other possibilities of division of work. Their aim seems to be to save money.

The Catholic Care Association welcome (in a press release), the policy of delegation of healing activities. They ask the responsible persons in the health care system, not to obstruct the progress and development of an economic and social useful decision by hierarchical ideas and by thinking of privileges. However, it is only a first step in the right direction, but it must be kept moving to guarantee that health can even be available for everyone in our solidary group. That was what Monika Pöhlmann, the first chairman of the Catholic Care eV, has declared when she had read the approval of the BMG to Directive §63c SGB V [16,19].

In addition to extensive training in nursing, students are also qualified to participate in healing activities by delegation. They learn to assist in medical tasks, and they are asked to fulfill on their own tasks, that the physician has delegated. New fields of application can be considered, not only the care, but also consultation. The interdisciplinary cooperation, that will get more important, is pointed out. Juridical specialists like Abanador and Rossbruch speak about substitution in projects, they do not speak about delegation. It is about substitution in medical activities .... Even seen by Mr Hess, president of G-BA, it is not a delegation, when they consider the medical activities [17].

Finally you can say that an interpretation in terms of delegation actually contrary to the many existing projects in favor of the principle of delegation, such as the "doctor-relief, community-based, e-health-assisted, systemic intervention" AGnES stands. The delegation by the doctor to the nursing staff in the outpatient setting is a long-established practice, legal framework for the delegation are already found in § 15 Section 1, 28 Section 1 as at work law, which means that there is actually no need of legal order in terms of delegation. Therefore, you can assume that the Federal Joint Committee has been given the legal mandate to formulate a policy for the transmission of medical activities of the nursing staff in the form of substitution.

The condition to practise is to get an additional qualification in healer activity opportunity to participate in pilot projects, which must be purchased by the carer. This is to ensure that a controllable risk for the patient, in the caring activity is ensured. The Directive refers to § 4 Section 7 of Nursing Act (KrPflG). § 63, requires: that individuals, whose activities the benefits are substituted, an additional qualification (§ 4, para 7 KrPflG/AltPflG) [18].

The time-limited trial of training opportunities, the level of training in accordance with § 4 para 7 KrPflG for staff qualifications in § 63 para 3c V-to-place "Advanced Competencies" so Abanador, the conditions of qualifications are not really formulated. At least it is determined that a standard training for professional caregiver is necessary to add to an additional qualification, which can be purchased as part of a "extended training".

The directive of the G-BA sets in Part B, is to be additional activities for which they qualified. Thus, the contents seem to formally clear. To create curricula are part of the pilot project and are subject to approval of title by the Federal Ministry of Health in consultation with the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth (§ 4 para. 7 KrPflG/AltPflGdes Elderly Nursing Act).

Especially is that the design of the curricular model of the contractors responsible for projects under § 63 para 3c SGB V, so with the health insurance and their associations approved in SHI providers. That means they must develop a curriculum for obtaining the required additional qualification of the participating nurses. Suspected the consequence of this is that each model project will develop its own individual curriculum for the additional qualification.

It does not have all the skills and abilities to perform all activities of the Directive will be taught. It is quite possible to provide only a partial aspect of the additional training that

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Table 4
Steps and formal responsibilities in the context of a pilot project.

Formal designation of step	Competence
Steps of a model project	
1. § 63 Section 3c SGB V	Legislator
2. Creating the policy	Federal Joint Committee
3. Agreement of model projects	Health care providers and training centers BMG/BMFSFJ
4. Creating training plans	Health care providers and
5. Approval of the training plans	Legislator
6. Testing of model projects	
7. Evaluation of the models	Health care providers and training centers
8. If necessary, transfer into the regular health care law	Legislator

qualifies it for specific activities under the Directive. That could lead to penalties, that, like what happened with the individual departments developments of countries as may arise for the surgical or intensive care, no single qualification.

The further development of the curriculum, leaving the legislature by saying" Details are the training plans of individual schools' individual educational institutions." Individual criteria e.g. are how long the additional training is, how is the percentage of theory and how is the proportion of practice, how can these projects be paid for (Table 4).

If a pilot project is initiated, one would have first to find a training provider who can design, together with the participants a curriculum that following § 4 Section 7 KrPflG, 4 para 7 AltPflG goes beyond standard training without compromise, and involves the placement of the increased powers for healing. The Legislature determined yet another not insignificant point, even if a school has a curriculum designed for both content and time, then it must be sent to the Ministry of Health for review and approval in consultation with the Federal Ministry for Family Affairs, Senior Citizens, Women and Youth. Furthermore, the question is asked under what criteria the Curricular approved or not approved by the BGA.

When approved, a training cohort could be started. Since the training must not be compromised and already takes three years, may assume more temporal needs are necessary (e.g. one year). Only after completion of this training, can one start with a pilot project. Considering the lengthy procedure and difficult procedure of the pilot project, it is obvious that it will take several years to complete.

Since the pilot projects are initially for 10 years until implementation (conversion to the standard care) changes can be made. If this timetable is to be maintained it is unlikely that in the coming years a serious impact in the healthcare will be felt [12].

8. Conclusion

The directive of the G-BA makes testing of transmission healing activities, within the meaning of the substitution principle, possible but the necessary qualifications required for this cannot however be purchased as an additional qualification (technical training). The healing profession of nursing staff, without compromising quality, can be transferred our European neighbors who have already proven the system. However, whether an implementation of the pilot projects on the basis of § 63 SGB V Abs3c has a realistic chance, depends on many factors, not least by the acceptance of all participants. At least have some questions and points are made in this connection and must be clarified and redefined by legislature before a new project can be started.

Appendix A. Supplementary data

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