



## Selected Conference Papers

## The German national consensus on wound documentation and outcomes: Rationale, working programme and current status

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## ABSTRACT

Chronic wounds are of high socio-economic importance. Accurate and efficient treatment includes the use of outcomes measures in clinical care and in research. To date, consented standards for documentation of chronic wounds, agreements on interpretation of wound outcomes and harmonisation about standardised goal setting in wound treatment are lacking.

**Objective:** (1) To establish a national German consensus group for the definition of standards in outcomes measurement of chronic wounds, (2) to agree on recommendations for practice and research based on a continuous decision process, including implementation of the standards.

**Methods:** The national consensus group includes delegates from the German scientific medical societies involved in health care for chronic wounds, the national boards on nursing, and the chairs of regional wound networks. Moreover, the roof organisations of the German health insurances, the German ministry of health and further single wound experts were invited. The consensus work is based on a structured decision process.

**Results:** The consensus group consists of 58 representatives and co-representatives of 26 societies and organisations. Since 2012, in the regular bi-annual meetings a Delphi-based workflow has been followed starting with standards for documentation and outcomes measurement in patients with leg ulcers. Additionally, web-based decision processes are conducted and the results are presented for finalisation in the face-to-face meetings. The following application areas of particular interests were defined: clinical routine, health services research, clinical research, and health economics. In the meantime, 245 single decisions have been approved.

**Conclusions:** Based on a national joint process involving medical societies, nursing groups, German sickness funds and health politics, a continuous decision process on standards for outcomes measurement and interpretation could be established. The Delphi based decision processes showed high levels of participations, thus providing a valid and robust set of standards. First results are in process of approval by the societies.

## 1. Background

Chronic wounds are challenging medical conditions imposing great burden to the patients, the society and the payers [1]. Medical complexity is caused by the large variation in pathophysiological conditions, clinical features and comorbidities [2].

Patients greatly experience marked reductions of quality of life [3–7], substantial cumulative life course impairment [8] and widely unmet needs from treatment [9]. The socio-economic impact of chronic wounds is considerably high. Annual average costs per patient are high, reaching 8500 euros for venous leg ulcers [10] and about 10,000 euros for arterial ulcers [11] in Germany. Driving factor of the overall costs is the great number of patients with chronic wounds in the society. Based on data from the statutory health insurances, a 0.1%

incidence and a 0.9% prevalence [12] of chronic wounds in Germany are assumed. Countrywide, about 900,000 patients with chronic wounds undergo active treatment. The quality of health care is characterised by large variations concerning the quality. Good quality is predicted by involvement of wound specialists in the treatment process [13]. Finally, achievement of substantial health-related quality of life is a major goal in wound care [14].

Accurate and efficient treatment demands the use of outcomes measures both in clinical care and in research. Health care can further be optimised by defining treatment goals over time. Standardised sets of wound documentation and outcomes parameters facilitate wound care in clinical routine. Specific criteria for the interpretation of results and definitions of clinically meaningful outcomes are needed. To date, no such systematic standards have been published and

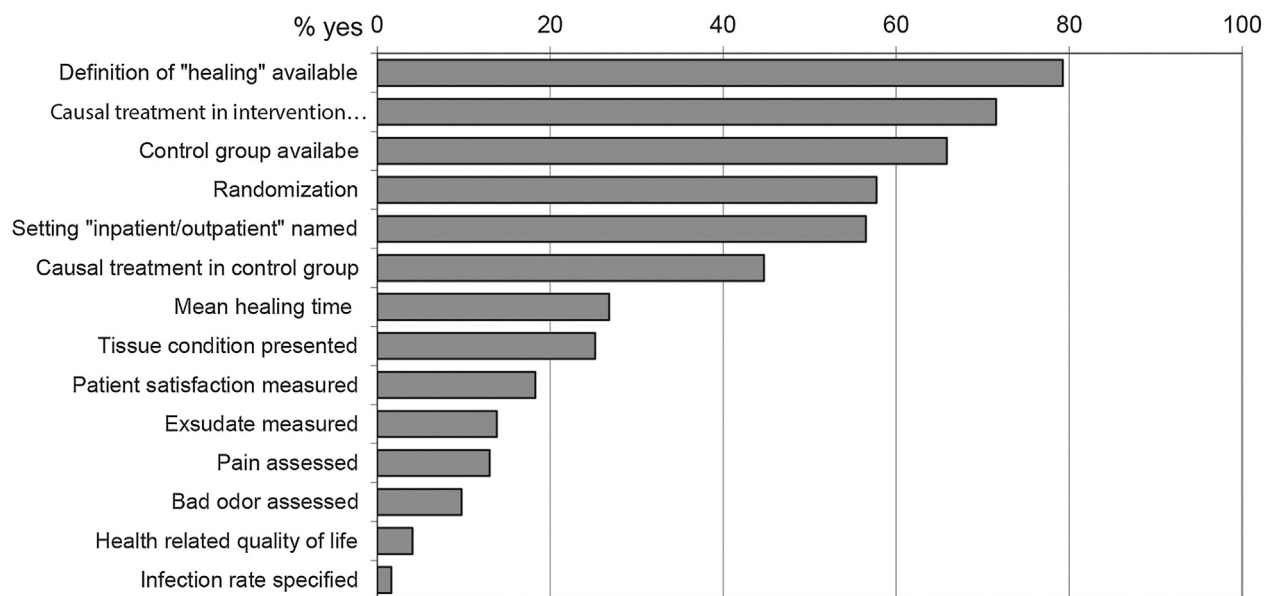


Fig. 1. Shortcomings of clinical trials on chronic wounds with regard to reportings (percentage of publications; adapted from Heyer et al. [17]).

consented in Germany compared to most other countries. In fact, there still is rather a lack of consensus on the documentation and measurement of chronic wounds. Furthermore, no harmonisation on standardised goal setting in wound treatment is still missing.

In order to establish standards for wound outcomes measurement and interpretation, a German national consensus group was started in 2012. This group included representatives from the national medical scientific societies associated with chronic wound care. Moreover, members of regional wound networks, as well as decision-makers and experts from various professional and institutional fields were invited.

The present manuscript presents the processes and structures of the national consensus group, the quality standards and the prioritised topics of work.

A first comprehensive analysis was conducted by a European Wound Management Association (EWMA) task force on wound outcomes [15].

### 1.1. Chronic wound evaluation

While the proper design of wound healing studies is essential for the outcomes measurements, even the trials included in the meta-analysis by Palfreyman et al. [16] markedly lacked of information and scientific vigour for essentials like blinding, power calculation and comparability of baselines between the comparators. The same findings were reported by Heyer et al. [17] (Fig. 1). In this more extended meta-analysis, only less than 5% of publications showed a satisfying design and reporting of outcomes measures.

## 2. Objectives

The project was started (1) in order to establish a national German consensus group for the definition of standards in outcomes measurement and interpretation of chronic wounds, (2) to agree on recommendations for practice and research based on a continuous decision process, including implementation of the standards.

## 3. Methods

Initiated by the German Centers for Health Services Research in Dermatology (CVderm) and in Vascular Diseases (CVvasc), this national consensus group includes delegates from the German scientific medical societies involved in health care for chronic wounds, the national boards on nursing and the chairs of regional wound networks [18]. Moreover, the roof organisations of the German health insurance companies, the Federal Ministry of Health and further single wound experts were invited.

### 3.1. Set-up of the national consensus group

The consensus group was initiated by members of different wound healing societies involved in health services research for chronic wounds in Germany. Coordinated by the German Centers for Health Services Research and Dermatology (CVderm) and in Vascular Diseases (CVvasc), the major medical societies involved in health care for wounds were identified and invited for collaboration. Moreover, the German sickness fund organisations and the major German wound care networks as well as the German conference for nursing standards were approached. Overall, 28 different parties were invited for the first meeting. At this meeting, a charter and procedural standards for the group process were established and consented. The delegates elected the chairpersons and the moderator of the meetings. They also decided on the frequency of meetings and the communication between the decision circles.

### 3.2. Formal decision process

The consensus work is based on a structured decision process coordinated by a trained moderator. All processes are regulated in the charter approved by all delegates. The decision process was initiated with a group discussion in the first face-to-face meeting and formally continued by web-based Delphi rounds. The list of topics and the choice of indications was prepared by the steering group and extended to the working group in the next meeting.

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