Guidelines in Multiple Injured Patients. The Approach of the German Trauma Registry.

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Introduction

According to the latest WHO World Health Report [1] injuries, intentional and unintentional, accounted for 16 % of the global burden of disease in 1998. Globally, injuries are responsible for one in six years lived with disability. Traffic accidents are the biggest cause of ill-health and premature death for adult men aged 15-44 world-wide. In Germany, approximately 80 million inhabitants have to sustain about 4 - 5 million accidents which are causing injuries each year (Tab. 1). In 1997 there were nearly 22,000 deaths by accidents, 80 % of them due to falls and road casualties. From the 8,500 people who were killed in traffic accidents more than two thirds were younger than 45, resulting therefore in about 12 billion (23 billion German Marks) of direct and indirect costs [2].

The lack of valid data in the field of trauma research is one of the major concerns for further investigation. Some of the reactions to this misery have resulted in the establishment of trauma registries throughout the world, by analogy to cancer registries, to gain insight into the complex facts. From this point of view the German Trauma Registry (TR) of the *Deutsche Gesellschaft für Unfallchirurgie* (DGU) (German Society for Trauma Surgery) provides a tool for valid data acquisition, and for - among other aims - the development of guidelines in the treatment of multiple injured patients.

The Trauma Registry of the German Society for Trauma Surgery (DGU)

Tab. 1: Epidemiology of Trauma in Germany. Summary View *(for details see text).*

- 4-5 million accidents in Germany per year
- 21,963 deaths by accidents:
  - 8,907 deaths by falls
  - 8,511 deaths in traffic accidents:
    - 2/3 of road casualties aged < 45 years
    - loss of > 300,000 work years
    - ≈ 12 billion direct and indirect costs

Development and Objectives

The historical roots of the German Trauma Registry (TR) date back to the late eighties, when there was a lively discussion about the value of scoring systems in clinical practice. Within the DGU a working group on 'scoring' was established, which later became the 'polytrauma' working group. The registry itself was thereafter established in 1993, and a first publication appeared in 1994 in the German journal for trauma surgery *"Der Unfallchirurg"* [3].
The objectives of the Trauma Registry and its working group are:

1. Analysis of epidemiology and categorisation of trauma patients.
2. Evaluation of diagnostics and time of diagnostics to develop guidelines.
3. Evaluation of therapy results in relation to surgical treatment.
4. Definition of criteria (quality filters) to define structural and procedural quality standards, and outcome parameters to form a basis for quality management in the care of severe trauma patients.
5. External comparison of own results with those from USA, UK, Australia, etc., using internationally accepted scoring systems (ISS, AIS, GCS, RTS, TRISS).
6. Development of an online data processing system for participating hospitals.
7. Development and testing of instruments to evaluate the long-term outcome in quality of life up to 2 years after trauma.
8. Standardised annual reports and hospital specific profiles based on plausibility-controlled data.

These points of interest reflect the existing deficiencies already mentioned before, namely the lack of valid epidemiological data, especially within the first 1-2 hours after an injury-provoking incident, which are necessary for further qualitative research on diagnostics and therapy. The results of this research should be translated into the development of guidelines in trauma care.

Outline of the German Trauma Registry

The TR is a prospective and standardised compilation of anonymous trauma patient data. For practical reasons only patients who arrive alive at hospital via the emergency room (ER) are included.. Compilation includes four different times of data acquisition:

A: Site of accident: mechanism of accident, vital parameters, neurological status, type of injury.

B: Arrival in the ER: clinical/physiological status, diagnostics, therapy.

C: Arrival in ICU: vital parameters, physiology, GCS.

D: At discharge: outcome (organ failure, death), diagnostics, operations, 90-day-lethality.

E: Follow Up (2 years): clinical outcome and quality of life (currently under development).

Anonymity is considered a mandatory prerequisite and guaranteed for the participating hospitals. The registry is open for every hospital or trauma department in Germany and German-speaking countries (Austria, Switzerland, etc.). During congresses and meetings of the German Society for Trauma Surgery (DGU), hospitals are invited to participate in the Trauma Registry of the DGU. Clinics which are interested in participation receive a set of basic information about the TR, the forms necessary for a prospective and online documentation of their polytrauma patients, including a manual. After completion, the data sheets are sent either to one of the documentation centres or to the headquarters, where the forms are entered in a database after validation checks. During data entry a first step

of plausibility control is imposed. A second step of plausibility control takes place after the separate databases are put together to build the master file. Subsequently, the data are analysed and a quality report is prepared on a yearly basis for each participating clinic, accompanied by a conference with representatives of the clinics.
Since 1997, the documentation headquarters in Cologne, documentation centres in Celle and Essen, and their staff - documentation secretaries, a psychologist, and a public health expert as biometrician - are supported by a grant of the Deutsche Forschungsgemeinschaft (DFG).
From five core clinics in 1993, more than 70 hospitals from Germany, Austria and Switzerland participate actively in the registry today. In the last period of analysis the TR included 2,069 patients, currently reaching more than 3500 cases.

Quality Management

Philosophy of Total Quality Management

For several years industry has been searching for new standards. Therefore, among others, the concept of Total Quality Management (TQM) was introduced. In Germany this effort was taken over by setting new standards (e.g., ISO 9000f. certification) based on TQM procedures. Medicine and surgery also have taken up the concept of TQM, adapting it to their needs [4 , 5 , 6].
The need to secure quality in the medical profession is not only an up-to-date topic but a consequence of medical care in itself. And so it is the duty of every medical care researcher and supplier to become aware of and consciously register apparent deficiencies which result in "complications" during patient treatment. For patients, securing quality in medical care means a correct diagnosis in good time, to heal or ease the disease, and *to avoid harm of therapeutic concepts*. Physicians must recognise quality-securing measures as a tool of self-control and a keen perception of problems. Hospital managers and health insurers will also profit from quality-securing measures as capabilities and quality of care will guarantee the optimal use of resources and avoid unnecessary services. With respect to Germany, participation in quality-improving and securing measures are obligatory by law nowadays (§§ 112, 115b, and 137 SGB V) for hospitals and rehabilitation clinics. As a consequence of German political reforms (GRG 1998, GSG 1992) a vast multitude of guidelines has developed in recent years, all of which aim at a quality- controlled health care system.
So, what is quality? In the medical world the term "quality" is usually defined in a pragmatic manner: Medical quality is the difference between what *could have been* achieved by medical treatment and what *was* achieved for a given patient. So, there is no definition of the quality of a doctor's action, but only a definition of quality with respect to a certain medical aim, which should be achieved in an individual patient. Quality of care can be differentiated threefold into structural, procedural and outcome quality. Structural quality here is used in the sense of characteristics of hospitals and care givers (e.g., staff qualification, in-house organisational structure, etc.). The term procedural quality refers to components of the encounter between health care providers and patients (e.g., diagnostic or therapy prescribed, etc.). Especially during this step physicians may be proactive in a way to improve quality. Finally, quality of outcome should be measurable in terms of patient improvement or decline (e.g., complication rate, quality of life, etc.). Within different disciplines indicators of quality are proposed by consensus conferences or multicentre studies.
In general, quality control programs or TQM, as mentioned above, consist of five elements:

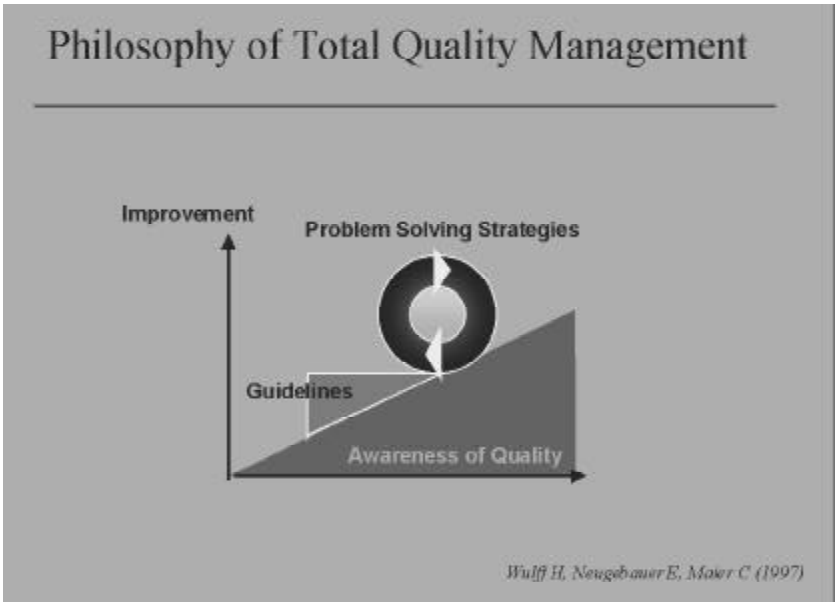

Fig. 1: Philosophy of Total Quality Management (TQM) *(for details see text).*

(1) documentation of the present situation, (2) analysis of the given situation, (3) application of problem- solving strategies to the analysed situation, (4) implementation of measures for improvement, and (5) a continuous check of the intended improvement using the means of documentation and analysis repeatedly (Fig. 1). TQM additionally not only includes the quality of performance, but also consumer satisfaction (here meaning patients *and* staff), and cost-benefit-relation for given treatments.

Methods of Quality Management in Surgery

The methods in use for TQM in surgical research differ only in discipline- specific adaptations from those used in industry. They are based on well- defined audit filters, the TRISS methodology, and comparison with reference values. Feed-back to participating hospitals, at least one per year, is obligatory.

Concept of Audit Filters:

In 1990 the American College of Surgeons (ACS) established their concept of audit filters [7]. They defined criteria for 22 audit filters in surgery, which have to be applied and afterwards are evaluated for selected criteria. Costs of criteria application were also considered. An intermediate balance check led to the selection of useful (specific) criteria, which were continuously re-evaluated. The resulting quality improvement leads to the establishment of standards or guidelines, in the manner of evidence-based medicine (EBM).

DGU Audit Filters

Having in mind the ACS criteria the Munich group of Nast-Kolb revised them for the German situation [8, 9]. In the DGU Trauma Registry we include eight audit filters (selection criteria in brackets):

1. Time from accident to hospital (ISS > 15)

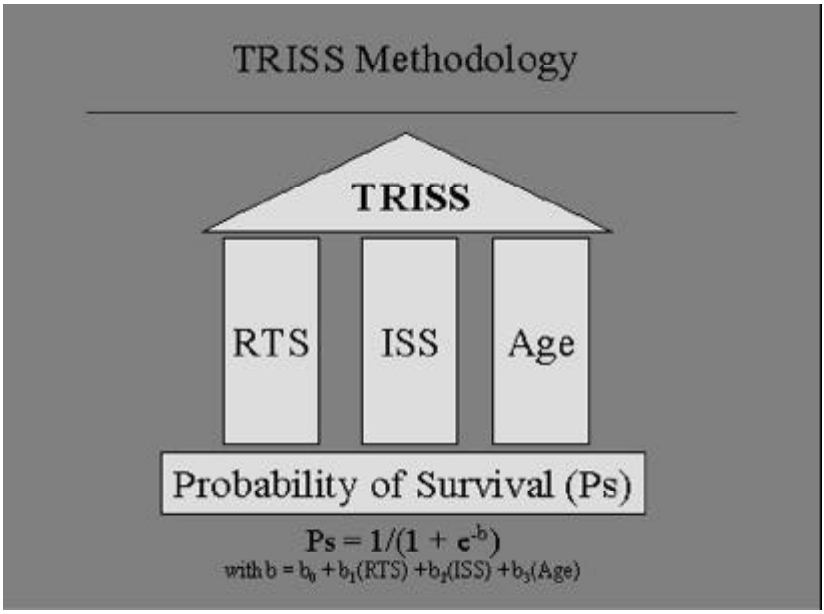

Fig. 2: The TRISS Methodology *(for details see text).*

2. Pre-clinical intubation rate (thorax trauma, AIS ³ 3)
3. Pre-clinical intubation rate (severe head injury, GCS < 9)
4. Time until X-ray of thorax (blunt trauma, ISS > 15)
5. Time until X-ray of pelvis (blunt trauma, ISS > 15)
6. Time until sonography (ISS > 15)
7. Time until cCT in severe head injuries (GCS < 9)
8. Difference of ISS between arrival in the emergency room and release from hospital

By applying these audit filters to our data it is possible to identify at least some of the factors which might account for an explanation of different "hospital outcomes". Whether these filters are the correct ones, we do not know yet. We have to show that by reaching optimised values patient outcome improves.

Evaluation: TRISS Methodology

The TRISS methodology is a statistical method to translate scores, age, and type of trauma to a probability of survival (Fig. 2). The resulting probability of survival (Ps) for an individual patient corresponds to the logistic regression result of the independent variables RTS, ISS, and patient's age. The logistic regression coefficients are based on the data of 80.000 patients from MTOS (Major Trauma Outcome Study).

External Comparison

Another statistical procedure, the z-statistics, provides the external standard for outcome comparison between two subsets of a population (Fig. 3). It is the calculus of the difference of observed vs. estimated number of deaths (or survivors) based on the baseline norm, which is the MTOS population [10 , 11]. The graph shows the outcome of participating hos-

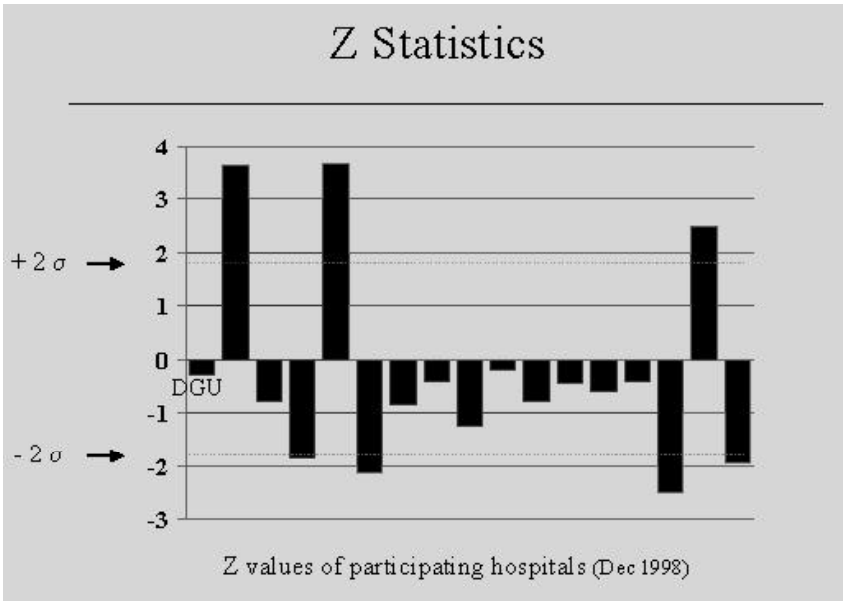

Fig. 3: Results of the z-statistics *(for details see text).*

pitals and the DGU sample in its entirety. E.g., the clinics A and B differ significantly in their outcome, so they may serve as examples for what accounts for a positive (B) or negative (A) outcome. This case analysis is going to be discussed elsewhere [12].

Feed Back

For the participating hospitals in the German Trauma Registry it is possible to check their status individually according to the transmitted results. This feed back is given in an annual report which includes a description of the patients (demography, injury severity, etc.), some aspects of treatment (intubation rate, operations, length of stay, etc.) and treatment results (lethality, continuing treatment, etc.). A separate chapter is dedicated to the quality management of the hospital (inter-hospital comparison).

Summary

The approach of the German Trauma Registry in the development of guidelines in multiple-injured patients is based on elements of quality -control methods and Total Quality Management (TQM) procedures. Differences in outcome and process quality between hospitals are detected by application of carefully developed audit filters and the use of valuable biometrics, combined with an external standard (MTOS). In this way problematic areas are identified. This enables the postulation of optimal values for guidelines.

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