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# Data to Information to Decisions – how can Statistical Graphics support Clinical Quality Evaluation in Hospitals?

Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen?

An overview and practical application, taking the Mortality Rate in Hospitals for Community-Acquired Pneumonia as an example

Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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## Foreword

Germany has a long tradition of quality assurance and quality management involving the collection, evaluation and presentation of quality-related statistics. The accent on the indispensable process of analysis and evaluation in a hospital manager's own department or healthcare institution, leading as a consequence to processes of change being initiated on a fact-based basis, has taken much of a back seat to date.

Given the current health policy scenario, a definite change has occurred in how the relevance of quality issues is viewed. Quality and transparency with regard to the standard of care provided have gained considerably in importance, which is highly likely to increase even more. As a consequence, this means that quality-oriented management – with the corresponding strategies, measures and reference data in place to control performance processes – has also gained in significance. On the other hand, it is all the more important to apply adequate tools to support quality assessment and evaluation procedures. If the top managers of a healthcare institution are increasingly more actively involved in quality development, they must be sure that the "right things" are being assessed and interpreted.

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This paper is based on this very scenario: modern, quality-oriented management backed by the relevant accumulated data. Based on routine data related to hospital treatment, the paper explains in detail how biometric analyses are carried out and how the results are plotted into a graphic chart, taking key quality data as an example. The graphic representation discussed in the paper includes a quality control chart that has received too little attention to date, the barely known cumulative sum (CUSUM) method, as well as variable life adjusted displays (VLAD) – the latter having never before been mentioned in a German publication. This method is being further developed and expanded to include secondary diagnoses which may initially complicate the big picture, and thus lends itself to being "tailor-made", in the best sense of the word, for any hospital.

The focus lies on the relevance of the action taken, however: by applying the appropriate sensitivity and specificity it should be possible to translate "statistical significance" into "clinical relevance". The intention is not only to draw attention – as rightly criticised in particular in the quality assurance methods imposed upon us as a result of specific health policies – to negative features or abnormalities, but also to emphasize especially positive outcomes which deserve to be pointed out, such as a run of good performance, or learning from best practice.

Based on the above, the paper outlines in clear terms what is required today to carry out an analysis and evaluation of a quality-oriented management team and to put measures into place in order to improve the quality of the respective hospital – which we (far too) seldom see or hear of as having been implemented at this level of consistency:

A quality-oriented corporate policy with clearly defined quality-related goals and targets and quality monitoring implemented on a regular basis forms the starting point when it comes to demonstrating quality and maintaining transparency inside and outside the company, and serves to support consistent quality improvement and the long-term success of the company.

The author therefore not only presents the methods and instruments inherent to the statistical representation of quality indicators, but paves the way towards a new level of quality in the field of hospital management. Rating: Highly recommended reading.

**Dr. phil. Brigitte Sens** 

Chairperson of the Gesellschaft für Qualitätsmanagement in der Gesundheitsversorgung e.V. (GQMG) Association for Quality Management in Health Care

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## Summary

The evaluation of the quality of clinical processes is one of the major performance criteria required of (clinical) leadership. If effective decisions are to be made within this context, the data collected must be analysed and transformed to information.

Statistical graphics such as timelines, control charts, funnel plots, cumulative sum (CUSUM) and variable life adjusted display (VLAD) charts can effectively support "datainformation-decision" transformation, as we were able to show from the data collected from two hospitals on community-acquired pneumonia.

Should further analysis of the data be required, then this should be planned and carried out with purpose and precision – as is the case with clinical diagnostics. To this end we recommend applying the analysis pyramid method (Mohammed et al. 2004). Besides collecting and analysing process-relevant data, we recommend conferring morbidity and mortality rates and executing a process audit as further measures for delivering important information relevant to quality evaluation, prevention and quality planning.

The procedure described supports (clinical) leadership in the evaluation of clinical processes with respect to process and outcome quality, the knowledge of which is a prerequisite for the evaluation of efficiency.

#### Keywords

Quality, Quality Evaluation, Quality Improvement, Clinical Leadership, Community-Aquired Pneumonia, Risk Adjustment, Timeline, Control Chart, Funnel Plot, Cumulative Sum (CUSUM), Variable Life Adjusted Display (VLAD), EN 15224

#### Please note

Figures can be found on page  $\underline{33}$  ff. Tables can be found on page 56 ff.

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## Introduction

### Objective

The paper will provide an overview of statistical graphics and define how they can be applied in practice to support clinical quality assessment and related decision-making in hospitals.

### **Preliminary remark**

Adequate patient care in compliance with current medical research and the best available practice is an elementary component of the quality policy practised by the CLINO-TEL Hospital Group. This understanding is maintained and promoted by continually striving for improvement. To this end, we investigate the causes in order to elicit the facts which will enable us to make the correct decisions. By dealing openly with quality data, we encourage and practise a high level of internal and external transparency.

Through the application of quality management instruments we have been working on assuring and improving quality since 1999. Process audits provide suggestions as to location decisions and recommendations for improvement, and run checks on what has been implemented. Outcome quality is especially significant, which is why we measure it and make the relevant data available so it can be evaluated and action taken accordingly. In this context, we attach great importance to it being possible to integrate the outcome estimates into corporate management so that they can support a continuing benchmarking process. We rate "Quality Assurance based on Routine Data", which we have been practising in earnest since 2003, especially highly. Over the years we have systematically researched what display formats are available and examined their applicability in the data-based control of clinical processes. This has given rise to a self-contained tool kit which supports chronological monitoring as well as "comparing with others". This overall approach is not intended as an end in itself, but to enable staff to apply control procedures and continuous improvement processes in an ongoing effort to work on the quality and safety aspects inherent to clinical treatment. The procedure is based on audited, promptly available routine data. The focus in this paper is not on the data management process, however, but rather on how routine data is translated into clinically relevant information and can thus support data-based decision-making.

The paper is designed, on the one hand, to serve as a basis for the many persons responsible for clinical processes in the hospitals that are members of the CLINOTEL Hospital Group who use these instruments regularly and thus now have the opportunity to learn more about the benefits these methods offer. On the other hand, it is intended to spark discussion beyond the confines of our association on the best methods for monitoring and comparing clinical treatment processes on the basis of key data.

"Comparing is the end of happiness and the begin of discontent." Søren Kierkegaard

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#### How the paper is structured

The following section (Background) comprises an introduction to the quality of clinical processes, paying particular attention to "efficiency". Building on this, the paper will elaborate on the different steps that can lead to relevant, issue-related decision-making.

The chapter "Basics" will include a brief description of the term "routine data". This will be followed by an explanation of the data set derived from the evaluations and graphics, followed by the definition of the term "hospital mortality rate (HMR)" and information on the significance and application of "risk adjustment".

All graphics (charts, graphs and diagrams) subsequently used constitute data gathered on mortality rates of in-patients with community-acquired pneumonia. This has the advantage that the different potentials of the individual graphics can be especially well interpreted.

In the section entitled "Non-risk-adjusted hospital mortality rates" the scope of possible interpretations of the graphics is explained and the derived recommendations listed. The so-called analysis pyramid is presented as a concept for evaluating clinical processes:

- bar chart
- excursus: analysis of clinical processes
- timeline
- control chart
- cumulative sum (CUSUM)

The ensuing section also addresses the scope of possible interpretations of graphics and lists the derived recommendations – in this case the depiction of "risk-adjusted hospital mortality rates":

- bar chart (observed versus expected)
- bar chart (risk-adjusted HMR)
- timeline
- funnel plot
- variable life adjusted display (VLAD)

In the final section CUSUM and VLAD are reviewed together. The paper concludes with an overall view of the results and consequences.

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## Background

Clinical processes form the basis for all the work and activities related to the hospital environment. They comprise the main type of services provided, and give rise to clinical diagnostics and therapies with the goal of meeting the requirements of patients to an appropriate extent. The degree to which these requirements are met is generally described by the term "quality". In order to be able to measure and control the quality of clinical processes, a set of quality criteria, as stipulated in the relatively new DIN EN 15224:2012-12 (DIN EN 15224 2012), is needed.

One of these criteria is "effectiveness" which is defined in DIN EN 15224 as follows: "In comparison with cases where medical examinations or treatment is not carried out, the provision of healthcare by qualified medical personnel increases, to a reasonable extent, the probability of an expected positive outcome" (translation provided by the author). "Effectiveness", therefore, focusses on outcomes and results and is thus consistent with the concept of "outcome quality".

Effectiveness and outcome quality are notably influenced by appropriate and correct patient care which is scientifically verified and based on best knowledge and best practice. This observation is already an explanation of the need for clinical processes whose risks are under control and avoidable damage is reduced to the minimum possible element of risk.

A further quality criterion quoted in DIN EN 15224 is "efficiency", which is defined in this document as "the best possible ratio between the outcomes achieved and the dedicated resources" (translation provided by the author). Efficiency therefore applies to both the medical and economic aspect of clinical processes in that it reveals the ratio of the achieved outcomes to the dedicated resources.

The correlation of outcome quality and costs, as well as (avoidable) costs for (avoidable) undesired outcomes has already been explicated in detail in a former paper (Becker et al. 2006).

The management of a hospital, or its respective medical business units, should first and foremost be aligned to quality with a special emphasis on effectiveness and/or outcome quality.

A certain degree of operationalisation of "management" can also be derived from DIN EN 15224. This can be found in the DIN standard under "The fundamentals of quality management".

In context with the afore-mentioned remarks, the fundamental quoted in the standard as "an issue-related approach to making decisions" is especially significant, given that "effective decisions are based on the analysis of data and information" (translation provided by the author). The sequence of words used in the title of this paper "data – information – decisions" is derived from this very statement.

Appropriate data therefore form the basis for issue-related decision-making, because it is this data that determines how the response is organised. The relevant data on clinical processes and their outcomes can be extracted from routine data, for example (to be elaborated on in the following section).

Data per se have no value. They only receive a value in the course of the first transformation stage (**Fig. 1**), whereby a specific piece of recorded data is given a meaning through a qualified member of hospital staff. The data then becomes "information". Bateson understands a "specific piece of elementary information" as the "difference that makes a difference" (Bateson 1972, page 582), and thus draws our attention to a question it is absolutely imperative that we ask, the answer to which is the starting point for decision-making. Typical questions arising in the execution of (clinical) leadership are:

- "In the case of patients with community-acquired pneumonia, does a deviation of 1% in the hospital mortality rate when considering comparative data represent a difference that makes a difference and therefore requires action?"
- "When the monthly hospital mortality rate of patients with community-acquired pneumonia in my unit fluctuates between 8% and 12%, can that be considered to

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be a random variation or is it a case of a difference that makes a difference and therefore requires action?"

In the course of the next transformation stage a specific piece of information is again given a meaning through a qualified member of hospital staff and a decision can be made.

The transformation process described here, with its focus on a significant difference, is designed to enable issuerelated decisions to be made that only lead to intervention when this is really required. It is about – as is inherent to all clinical processes – determining an indication – the pro or contra of taking specific steps in order to improve quality.

If there is actually no necessity to take action (for example because the above-mentioned fluctuations only refer to random monthly variations in the data), financial and staff resources may be spent that are then missing somewhere else.

In addition, this may also lead to other negative effects: staff motivation might be undermined when they realise that the action taken does not lead to the desired changes of the data (in this case with regard to hospital mortality rates).

The significance of specific data can be clarified best when demonstrated with the aid of graphics.

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## **Basic information**

At this stage, a number of points will be elucidated which are crucial for acquiring an understanding of the statements, explanations and comments contained in the paper:

## **Routine data**

In the healthcare sector, the term "routine data" is either understood as clinical data (for example anaesthesiological data in the context of a risk assessment/anaesthetisation or basic documentation in psychiatric units) or as administrative data (for example pursuant to §21 in the Hospital Remuneration Law). This paper is concerned with administrative routine data in hospitals, hereinafter abbreviated to "routine data". Further statements, explanations and comments on the term, or with regard to basic information on the topic and examples of how routine data can be applied are contained in papers by Benchimol et al. (2011), Becker (2012), and Becker et al. (2005; 2012a; 2012b; 2013).

### Data

The data set used as a basis for the graphics and charts contained in this paper comprises case data of 1,809,643 discharged in-patients from the years 2010 to 2012 as per the definition laid down in §21 in the Hospital Remuneration Law, provided to CLINOTEL Headquarters by the members of the hospital group.

Non-sensitive personal data is submitted cumulatively on a monthly basis over the year, starting with 1st January. This has the advantage that in the course of the year amendments and adjustments can be implemented for example as a consequence of the outcomes of comprehensive coding checks (Becker et al. 2003). The data is stored and processed in an ORACLE<sup>®</sup> database (Oracle Corporation, California, USA).

The data presented in the following graphics on HMR are derived from 24,689 in-patients (age  $\geq$ 18 years) with community-acquired pneumonia in the years 2010 to 2012.

The graphics are part of the monthly evaluations carried out for the members of our hospital group, and given that the data is submitted on a monthly basis over the year, starting with 1st January, the underlying number of cases grows accordingly from month to month.

## Hospital mortality rate (HMR)

This term refers to the number of deaths caused by a specific illness in relation to the number of patients. The socalled in-hospital case fatality rate or hospital mortality rate records all those patients who die of a specific disease or as a result of a specific therapy while in hospital. In general: the percentage of patients suffering from a particular illness who die as a result: "case mortality rate" (with reference to Kreienbrock et al. 2012, page 32). When the term hospital mortality rate is used in the course of this paper, the author is referring to HMR of patients with community-acquired pneumonia.

## **Risk adjustment**

One goal of the data analysis is to compare the specific treatment outcomes in different medical healthcare institutions in order to discover what room for improvement there is in the reviewed hospitals. When carrying out such comparisons patient-related risk factors which the hospital has no influence over can play a decisive role and result in the effect that different treatment outcomes are achieved in spite of the fact that the work performed or services provided are of the same quality.

Demographic features such as the age or gender of the patients, or factors related to specific illnesses, such as the degree of severity of the illness or comorbidities, can also impact the treatment outcome of the respective hospital. That is to say: a hospital with a majority of older and multimorbid patients will inevitably be rated as below average if compared with a healthcare institution with younger, stronger patients who are more likely to recover faster – irrespective of the quality of the patient care provided.

If such relevant risk factors are not taken into account when comparing outcomes, this can lead to unfair comparisons and false conclusions. In order to be able to de-

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cide whether there are really any differences in the patient care provided, the same baseline conditions must be established for all the healthcare institutions with respect to the outcomes under comparison. A risk-adjusted approach is therefore essential if the goal is to achieve a fair comparison.

This is where risk adjustment comes into play: through the use of appropriate statistical methods differences within the entire patient spectrum can be balanced and adjusted. The objective is to ensure that comparisons made between hospitals are conducted fairly so that differences in the outcomes truly reflect differences in the quality of patient care and are not due to dissimilar patient structures. Risk adjustment is therefore crucial for data that represent treatment outcomes.

The risk-adjusted data used in this paper are based on a model developed by us, which has not yet been published and was calculated using so-called multiple logistical regression. Multiple logistical regression is a standard form of analysis used in statistics to determine the impact of different factors on an issue in which the dependent variable is binary (for example "patient died: yes/no"). Thus by using this model it is possible to calculate the expected probability of the predicted outcome (for example death in hospital) for any patient, taking into account his/her individual risk profile.

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## Non-risk-adjusted hospital mortality rate

### Bar chart

Non-risk-adjusted HMR data (raw data) based on routine data can be plotted and depicted in different ways. One option is to create a bar chart as shown in **Fig. 2**. Such bar charts form part of our hospital group's standard monthly evaluations.

What is illustrated here is the non-risk-adjusted HMR data provided by the respective hospitals (black bars) as well as the overall value of all healthcare institutions in the hospital group (grey bar). In our evaluations the individual bars are labelled with the names of the hospitals. For reasons of anonymity they have been omitted in this paper.

**Fig. 2** shows the outcomes of the year 2012. The diagram refers to the evaluation of the data set as of 31.12.2012.

For an individual hospital, for example the hospitals marked A and B, the question may be asked as to whether the values of 12.0% or 20.7%, respectively – correspond with the hospitals' expectations (for example a pre-defined value). This, of course, presumes that such a value has been prospectively formulated, which would be expected of quality-oriented clinical leadership. When formulating the expected value it is possible to extract data from specialist literature, guidelines, external quality assurance sources or other hospitals.

These values can then also be drawn upon when formulating a target value for an improvement process.

Attention should be paid to the fact that the sources drawn upon are very likely to be using different data sets and definitions. Already, it is clear that conducting comparative quality assessment can be an extremely complex task. It should not be regarded as an exact science, since there are a number of impassabilities that need to be taken into account. The above statements give rise to the first recommendation:

The hospital management and/or the clinical leadership should define target values prospectively for the process und outcome quality of defined patient groups.

The overall value of all healthcare institutions in the hospital group (grey bar/13.6%) provides an initial "helpline", which, in our experience, is intuitively applied by the users in that it divides the bar chart into two parts "to the left and to the right of the average group value".

It is therefore understandable when (clinical) leaders declare their objective as being "to the right of the CLINO-TEL value".

At first glance, this would appear to be a good thing, since it is based on the robust division "to the left and to the right of the average group value". It is only when you take a closer look that you realise what this really implies. It is not as positive as you think, since the hospitals "to the right of the CLINOTEL value" show rates of 5.8% to 13.3%. It would make sense to define one's objective as being "to the right of the CLINOTEL value" when a hospital participating in this evaluation programme for the first time (for example on joining the hospital group) indicates a value above the CLINOTEL value of 13.6%.

A value of  $\leq 13.6\%$  might be defined as a tendency and a first step towards improvement, but should subsequently be substituted by a concrete numerical value.

In the other group we also find different values that settle somewhere between 13.6% and 20.7%. One of the first arguments to be raised when such data is discussed is the severity of the illness (in this case pneumonia) plus the comorbidity of the patients. What we have here, in fact, is an explanatory model showing the continuous correlation between disease severity/comorbidity on the one hand and case fatality rates in hospitals on the other. Higher hospital mortality rates can thus be explained by the higher proportion of patients with "severe" pneumonia and increased morbidity. It is absolutely legitimate to follow this clinically traceable explanatory model to start

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with, but we must not forget to ask whether the respective clinic actually disposes over data on disease severity and/ or comorbidity. Without such data the above explanatory model remains purely hypothetical. Nothing can be verified and no evidence can be drawn upon as a basis to warrant an issue-related, that is to say educated, decision.

It would also be conceivable that all clinics "to the left of the CLINOTEL value" quote data related to the most severely ill and complex patient population, which again raises the question as to whether the varying values in this group (13.6% to 20.7%) only represent random variations. The explanatory model is also problematic in that in our experience also hospitals "to the right of the CLI-NOTEL value" imply they are also responsible for a severely ill and complex patient population.

A further objective in the efforts to improve quality may, of course, also be a shift within the regions "to the left and right of the CLINOTEL value". The respective hospital management or (clinical) leadership is accountable for determining the exact value.

The CLINOTEL value of 13.6% is calculated based on the average of all data received from the hospitals in the CLI-NOTEL Hospital Group. It is thus to be understood as a "self-referential" value that lies above the external quality assessment (EQS) value quoted for assessment year 2011 at 12.7% covering all patients (whether or not it has been documented that a specific therapy was stopped) (EQS 2011). Given the varying data sets and assessment procedures applied, it cannot be determined at this stage, whether the difference between 12.7% and 13.6% is a difference that makes a difference and we therefore also regard the EQS value merely as a further aid to quality assessment.

The EQS value is represented in the diagram by the horizontal grey line and divides the results into two groups: "above and below the EQS value". Any statement or comments resulting from discussion on this data do not differ from those mentioned above. The bar chart is therefore a good way of graphically representing the HMR and comparing these with orientation values (other hospitals, CLINOTEL value, data extracted from specialist literature and from external sources).

In spite of the fact that we are dealing with varying data sets, as mentioned above, it is possible to derive the following recommendations from the relatively simple bar chart presented here:

Hospitals whose mortality rate is above orientation values and/or their own defined targets, should be subjected to further analyses to determine where the causes lie and have these verified. The goal should be to come to a decision as to whether an improvement in the hospital mortality rate is deemed possible and can thus be targeted through the application of appropriate means.

Should the hospital mortality rate be below the orientation values and/or their own defined targets, it should be considered whether a further improvement is deemed possible and can thus be targeted through the application of appropriate means.

### Excursus: analysis of clinical processes

A concept that has proven to be extremely practical and useful for the analysis of the structural, process and outcome quality of clinical processes is the analysis pyramid Method (Mohammed et al. 2004; Duckett et al. 2007) which is shown in **Fig. 3**.

It is clear to the viewer that the lowest section of the pyramid forms the basis for quality assessment and thus also for educated, issue-related decision-making, since insufficient or poor quality data can quickly lead to misinterpretations (**Fig. 4**). The previously formulated recommendations have therefore been supplemented as follows:

Irrespective of the hospital mortality rate itself and how it relates to an orientation value and/ or the hospital's pre-defined target, the quality of the data should always be recognised as correct. Should this not be the case, the data must be verified.

The second level as shown in **Fig. 4** is a call to analyse patient characteristics which again must be displayed in the form of correct data.

Taking our example of pneumonia as a basis, when verifying data and patient characteristics special attention would need to be paid to the parameters laid down in the EQS system for dividing patients into risk categories (the so-called CRB-65 score) which can be represented reliably using routine data (age and ventilation required). Hospitals A and B both display the proportion of patients at an age of  $\geq$ 65 years as being 77%. In hospital A 4.4% of the patients were ventilated for at least 25 hours and in hospital B 6.3%, respectively.

Specialist literature also offers a substantial amount of information with respect to clinical risk factors which are codable in the form of secondary diagnoses (for example, Fine et al. 1997; Bratzler et al. 2011).

Level 3 addresses structures and resources which can impact outcome quality. This is, of course, an important point, and DIN EN 15224 also requires that the healthcare organizations identify and procure the necessary resources to enable all requirements to be met. Resources also include aspects such as infrastructure and the work environment.

Levels 4 (Process of care) and 5 (Staff) are elaborated on in **Fig. 5.** The care process takes place within the environment formed by the given structures and resources. It is influenced by both these aspects and must therefore be regarded in this context. It is especially important to know whether the care process can be regarded as scientifically proven (evidence-based) and is founded on best knowledge (scientific findings) and best practice as required by DIN EN 15224. Has the best possible knowledge – in this case the guidelines applicable to pneumonia (Leitlinie Pneumonie 2009) – been adopted by the hospital, and is it being effectively applied to patients? Does "Transfer Research Into Practice (TRIP)" work in this case?

Clinical processes involve human resources and the questions formulated for Level 5 are of elementary importance for the quality of a process. DIN EN 15224 consequently requires: "Staff whose activities impact fulfilling the requirements in providing services as healthcare providers must dispose over the competences to perform the work they do: educational qualifications, training, skills and experience" (translation provided by the author).

It should also be noted that medical staff is occupied within the environment formed by the given structures and resources and other organisational factors affecting the clinical processes.

The statements and comments made hitherto also apply for all diagrams and graphics to be discussed hereafter, and naturally not only with regard to hospital mortality rates, but also for other parameters (for example hospitalacquired infections) and patient groups.

At this point, there are two further recommendations to be made:

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An analysis of the hospital mortality rate should accordingly take the interdependency of clinical processes with other (clinical) processes, as well as any potential parameters that may impact these processes, into account.

It is expressly recommended to conduct the analysis of the hospital mortality rate in a standardised fashion using a defined procedure which is compatible with the clinical reality of the care processes. For this, we expressly recommend using the analysis pyramid (pyramid model for investigating hospital performance).

## Timelines

A further way of representing non-risk-adjusted hospital mortality rate data is via a so-called timeline.

A timeline is a chronological sequence of data (observations). Even if the word timeline implies that the sequence is inherently linked to "time", a sequence of data or observations can also result from other criteria such as a case number from 1 to x, allocated according to date and time of discharge. Under such circumstances the case number would then again be regarded as a temporal criterion.

Since the timeline in our example is amended monthly, it serves to assess the current month or a period of time based on historical data, that is to say data from that specific period.

**Fig. 6** shows the non-risk-adjusted HMR data provided by hospital A for the years 2010 to 2012 with a total of 1,295 cases. Besides the monthly hospital mortality rates, the graph also shows a correlation line. By this we mean a line that aligns as well as possible to the individual points marked on the graph, or correlates the points as well as possible, thus depicting the line of best-fit to the data points. The correlation line indicates whether the data will adopt a particular trend in the course of time, which is why we also refer to it as the "trend line".

The example at hand shows that the trend line in January 2010 starts at around 16% and ends in December 2012 with a value of around 12%. From this we can read that the non-risk-adjusted rate has decreased over time. This corresponds to the total values recorded on an annual basis, which are not shown here, which amount to 15.2%, 15.9% and 12.0% respectively for the years 2010/2011/2012 for hospital A. These three values show very clearly that the trend line does indeed represent a trend that developed over a specific period of time and that it is generally falling. While the total annual values from 2010 to 2011 initially start with a rise in cases, a substantial decline is recorded from 2011 to 2012.

Furthermore, we can identify that the individual data points clearly deviate from the trend line now and then. In order to be able to interpret how well the trend line fits to the individual data points or, in other words, how reliable the conclusion is that there actually is a trend, the correlation factor (r) quoted can be helpful. With regard to the correlation factor r (according to Hüsler & Zimmermann 2006, page 192; Muche et al. 2005, page 55):

- It is a value between -1 and +1.
- A positive value shows a rising trend line, a negative value a declining one.
- Zero values indicate that the trend line shows no usable fit.
- The better the fit, the nearer the r-value to +1 (rising trend line) or -1 (declining trend line).
- A trend line with a good fit has an r-value of  $\geq 0.7$ .

In this case the trend line has an r-value of −0.2 and does not give an indication of a good fit, which is not surprising given the extent to which the values are fluctuating. Fluctuating values naturally make it very difficult to structure and map out quality assessment. If the trend line were to fall or rise significantly and indicate good fit (for example r≥0.7), it would be far simpler to interpret the statistics. In reality we are seldom confronted with such definite or clear-cut trends.

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The basic question that arises when considering and interpreting such trends is: "Are the fluctuations the result of random variations or do they comprise variations that are not random but need to be assessed as positive or negative from a medical quality standpoint?"

The observer may initially be inclined to draw upon the average EQS value (12.7%, see above) from the year 2012 for the corresponding section in **Fig. 6**. This is not particularly helpful, since the data points in this case would also fluctuate around the orientation value. It should also be noted that by orientation value we mean the total annual value covering all the cases and hospitals evaluated in the EQS under this diagnosis. It would be substantially more helpful to be able to view the monthly values we do not have at our disposal, which may also turn out to be variable.

Identifiable variations in hospital mortality rates can also be influenced by deviating case numbers. In **Fig. 7** the respective case numbers (fatalities/in total) are indicated for the marked extreme values. With a median of 5 in 35 patients dying over the space of time from 2010 to 2012, it can be determined that the extreme values below the trend line indicate a low number of fatalities among patients when compared with the median. In addition, in month 2011-01 the case number is far above the average of 35. The extreme values below the trend line show an inverse image with lower case numbers and in two months (2011-05 and 2011-07) the number of fatalities is also above a median of 5.

Of course, it makes sense to pose the question with regard to the case numbers. Be warned, however, that fluctuating case numbers alone do not provide the basis for an adequate explanatory model. NB: numbers can render profound complexity dangerously simple!

A further aid to answering the question: "Are the fluctuations related to differences that make a difference?" is provided in **Fig. 8**. Here one can view the monthly values for all cases recorded by the hospital group (24,689 in total). In addition, the 95% confidence interval (95% CI, Altman et al. 2000; Bender & Lange 2007; du Prel et al. 2009) is calculated for the CLINOTEL values. The 95% CI is useful when answering the above question in that the following rule of thumb can be applied: If a value related to my hospital is outside the 95% CI of the CLINOTEL values, as a rule this points to the difference as being statistically significant.

Please note that this difference is the result of comparing the hospital values with the CLINOTEL values. A different reference parameter may produce a different result, as will be seen in the following.

Awareness should be raised for recognising series, defined here as being at least three data points above or below the 95% CI.

The following has been formulated for hospital A: the trend line declines in the course of 2010 to 2012 and is practically completely within the 95% CI of the CLINO-TEL values. Individual data points, or several data points, lie outside the 95% CI. These require further analysis. Hospital B data is shown in **Fig. 9**. The extreme values in the months 2012-06 and 2012-11 are immediately evident. The case numbers in these months differ significantly from the median values of the deceased persons (5), and the case number (35) of the CLINOTEL values, respectively: they constitute 11/20 in June and 9/15 in November. Particularly striking are the series of data points that lie on the upper limit, for example above the 95% CI (2011-09 to 2012-04, highlighted in the graph).

With a small adjustment, the trend line shows a rise of around 13% to around 21% (r = 0.2).

What we see here, therefore, is a rising trend line which lies above the 95% CI of the CLINOTEL values in broad sections. In conjunction with the extreme values referred to above, plus the fact that we have a series of such values in this case, further analysis is strongly recommended.

If it is to take into account the complexity of the clinical processes behind the data recorded, such an analysis will naturally go beyond a mere examination of the case numbers.

As a consequence, the analysis pyramid method can also be applied in this case.

At this point, further recommendations can be made:

It is advisable to monitor hospital mortality rates at regular intervals with the aid of timelines.

The hospital data depicted in the timeline should be supplemented by a trend line that encompasses the entire observation period and/or individual time segments (years, for example).

The case numbers inherent to the individual data points should be available in order to be able to evaluate what impact they have had on the data points.

The data relevant to a comparison group, including the inherent case numbers and the confidence interval, should also be depicted in the timeline.

The comparative reference data should be depicted in the breakdown of the hospital data, on a monthly basis, if possible.

Hospital data that lie outside the confidence interval of the comparison group should be subjected to closer analysis in a standardised fashion using a defined procedure. This naturally also applies when the hospital data lie below the confidence interval – illustration of good practice.

The recommendation to carry out a closer analysis of the data applies in particular when deviating data occur in series.

## **Control chart**

As was already seen with timelines, the continuous representation and interpretation of data (in this case: non-adjusted hospital mortality rates) helps in the overall quality assessment process which in turn is designed to lead to appropriate decisions being made at management level. Control charts can be used for this purpose. For many they are a good option because they can be calculated and depicted without using a statistics program. Control charts, like timelines, are able to depict risk-adjusted data.

In the literature available there are a number of papers and books which describe the basic principles of control charts and how they are applied in the healthcare sector; for example Cook et al. (2008), Duclos et al. (2009), Hart et al. (2003), Henderson et al. (2008), Kottner & Hauss (2013), Mohammed et al. (2008), Mohammed & Worthington (2013), Noyez (2009), Perla et al. (2011), Poelaert et al. (2007), Tennant et al. 2007, Winkel & Zhang (2007) and Woodall (2006).

A special mention should be made here with regard to the work conducted by Mohammed et al. in the year 2013, in which the authors identify problems and solutions relevant to the application of control charts for very large amounts of data. Such problems arise when using routine data, which explains the explicit reference to this paper.

The basic principles of control charts are contained in a review by Kottner & Hauss (2013): all empirically determined data are influenced by systematic and random errors. One way of handling random variation in comparing hospital performance data adequately is to apply Statistical Process Control (SPC). This theory maintains that variations occur in practically all processes, products and results/outcomes. There are no two examples of work performed and no two products on the market that are one hundred per cent identical. The issues SPC aims to address are: "How much variation can naturally be expected within stable processes (common cause variation)? When do processes and outcomes show signs of increased variation, which, based on existing data, can no longer be explained as common cause (special cause variation)?

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Winkel & Zhang (2007, page 12) put it in precise terms: "Statistical control is a concept fundamental to the theory of control charts. It is based on a distinction between two types of variation: one resulting from unavoidable causes, which one cannot identify (random variation), and one resulting from causes, which may be identified (assignable causes of variation). A process in which sample values vary due to random causes alone is said to be in a state of statistical control. Additional variation caused by assignable causes may occur. If this is the case, the process is said to be out of statistical control. Since the causes may be identified, it is often possible to regulate and control them so that the process may be brought back into a state of statistical control".

A variation that cannot be readily identified on the basis of the data (also referred to as a "signal") might be contingent to deviations from the recommendations laid down in the German Pneumonia Guidelines 2009 (Leitlinie Pneumonie 2009), for example.

The term "control chart" was coined in the 1920s by Walter A. Shewhart. Using this statistical method, it is possible to compare data over a period of time and thus compile a comparison of one's own performance data (according to Kottner & Hauss 2013). No comparison is made with data from other hospitals.

Different control charts can be applied depending on the parameters to be considered. In this paper the so-called p-chart will be presented in more detail, (see **Fig. 10**).

The known monthly hospital mortality rates in hospital A and the arithmetic average of all data points are plotted in the chart. In addition, so-called upper and lower warning limits and upper and lower control limits are also charted. By convention the warning limits are located  $\pm 2$  standard deviations and the control limits  $\pm 3$  standard deviations from the arithmetic average. An exact description of the calculations can be found in the Kottner & Hauss (2013) review.

A process is described as stable when practically all the data points are located within the control limits which have been determined as being appropriate, given that – statistically speaking – in stable processes only 0.27% of the data points are wrongly plotted outside the control limits. This means that only one in 370 data points would be wrongly classified as "signal".

The data from hospital A points to the process as being statistically considered stable. In chronological sequence none of the data points are beyond the warning or control limits. Even the data points described in the previous paragraph as extreme values (highlighted) are not considered to require further attention.

At this point in time, the significance of the comparison data becomes evident: in the case of the timeline, we used the CLINOTEL values, in this case the arithmetic average (relative frequency) of the hospital itself (self-referential). The warning and control limits are calculated in relation to this arithmetic mean.

There are some other rules that apply to the interpretation of data that, according to Mohammed et al. (2008), are also considered as "signals" which point to non-random variation in the process:

- eight (some authors prefer seven) coherent data points on one side of the midline (shift)
- two of three consecutive data points located beyond a warning limit
- a "run" of eight (some authors prefer seven) consecutive data points that form a continuously rising or falling line (trend)

Hospital A showed no negative scores on any of these conditions, which is an outcome worth aspiring to.

The process may be considered to be "in a state of control", but it is nevertheless advisable to check how the data rate in comparison to a representative set of comparative data. From our point of view it makes sense to apply the timeline method described above in combination with control charts.

That said, the following still applies: even processes classified statistically as being "in control" should also always be examined from a clinical perspective. This guar-

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antees that we are able to recognise distinct data fluctuations as an indication of good or poor practice when they are located within the warning or control limits.

The data from hospital B are shown in **Fig. 11**: the extreme values already highlighted in the timeline are clear "signals", since they exceed the upper control limit. The critical series of data points in the timeline (2011-09 to 2012-04) does not represent a "signal" in the control chart, however. This again shows the advantage of the combination of both methods, since we would also use the timeline as grounds for continuing our analysis in this area.

Two further "signals" that already stood out in the timeline can be seen in the months 2010-04 and 2011-08 – in this case it would be interesting to find out which factors taken from the analysis pyramid can explain these "signals" in sense of best practice. What was different in these two months and also in the months 2012-06 and 2012-11? What has changed? What was done differently in the other months? What should we be doing more of – and what should we avoid doing in the future?

The control chart is a highly manageable and accessible method for regular data monitoring. Since it does not require any external comparative data, it is ideal as a statistical method in hospitals which are not organised in a hospital group. Calculation and graphic representation do not require any specialist knowledge or statistical software. Since the basic principles of control charts are described well in available literature (Kottner & Hauss 2013), control charts can be created in practice at reasonable expense.

#### Recommendations

Regular monitoring of the hospital-related hospital mortality rates should be carried out with the aid of control charts.

Rules should be defined to facilitate determining what a "signal" is and what it is not.

"Signals" should be subjected to closer analysis in a standardised fashion using a defined procedure.

Even processes classified statistically as being "in a state of control" should also always be examined from a clinical perspective. This is especially applicable when there is evidence of data fluctuations which are either clinically not explicable or – in the case of pre-defined specified values – not acceptable. Never confuse statistical significance with clinical relevance.

It is advisable to use control charts in combination with the timeline method.

The task for (clinical) leadership should be understood as securing an appropriate level of variability through the application of different processes.

## Cumulative sum (CUSUM)

The "cumulative sum (CUSUM)" method was introduced in England around 60 years ago as a means of industrial quality control and applied in 1994 for the first time for the quality monitoring of cardiac surgery (Grunkemeier et al. 2003).

In his review Noyez (2009) gives an overview of methods that are applicable for "performance monitoring" in the healthcare sector. He also provides an overview of the various types of CUSUM control charts:

- cumulative failure chart
- standard non-risk-adjusted CUSUM chart
- risk-adjusted CUSUM chart (also referred to as CRAM, VLAD)

The "Cumulative failure chart" is the simplest form of CUSUM: it depicts the cumulative sum of results (for example death, bleeding complication).

The "standard non-risk-adjusted CUSUM chart" is used in conjunction with constant expected values (for example a complication rate). This means that there are no calculated expected values available for individual patients (for example for hospital mortality). This is the case for many issues that require being subjected to quality control and quality evaluation, which is why CUSUM charts fulfil an important function.

The "risk-adjusted CUSUM chart" is a graphic representation of cumulative sums of expected minus observed death rates (or specific complications). It should be pointed out at this point that the literature available describing this chart is actually quite confusing, given that different authors use different terms for "risk-adjusted CUSUM chart": Poloniecki et al. (1998) refer to the chart as "Cumulative risk-adjusted mortality (CRAM)". Lovegrove et al. (1997) published a report on the further development of the cumulative sum method introducing the term "Variable life adjusted display (VLAD)" (according to Grunkemeier et al. 2003; Noyez 2009).

To avoid further confusion, in this paper the term VLAD is used for the portrayal of cumulative sums of risk-adjusted data. This section focusses on an explanation of CUSUM. VLAD will be elaborated on later in the paper. If a constant expected value is being sought for the application of CUSUM for a specific issue, there are a number of sources worth looking into. For example:

- external quality assurance
- registers of scientific associations
- hospital groups
- hospital associations
- specialized literature
- medical guidelines
- hospital data

In our example, the hospital mortality rate as quoted in the results of external quality assurance sources from the year 2011 (12.7%) is used as the constant expected value. The data calculated for the CUSUM chart shown in **Fig. 12** is described in more detail in **Tab. 1**:

The 432 patients are numbered chronologically in ascending order according to the date on which they were discharged (column: Patient).

The expected hospital mortality rate (0.127) is plotted for each patient in column E with the respective observed result (survived: o/died: 1, column: O).

Thereafter, the difference of E – O is calculated for each patient. The following logic applies:

Patient 1 did not die. Thus, 0.127 (0.127 – 0) "lives were saved", or in other words: "0.127 fewer patients died than expected".

Patient 5 died. Thus 0.873 (0.127 - 1) "lives were lost", or in other words: "0.873 more patients died than expected". The CUSUM column contains the cumulative sums of the individual differences (columns: E - O): adding the values of patient 1 (0.127) + patient 2 (0.127) results in the CU-SUM value of 0.254). This is continued consistently up to the result for patient 432, concluding with 2.864.

On reviewing these values, it becomes evident that the constant expected value leads to a "life saved" being plotted mathematically with 0.127 in the CUSUM chart, whereas a "life lost" results in a deduction of 0.873.

This therefore means that the CUSUM chart is influenced more strongly by the constant expected value resulting from deceased patients rather than from patients surviv-

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ing an illness. The explanations and comments on VLAD will address this attribute in more detail.

In the total outcome for hospital A in the year 2012 around three fewer patients died than expected. This outcome is not surprising, given that it was evident in **Fig. 2** that the value of 12.0% from hospital A lay below the orientation value provided by external quality assurance sources.

It is already clear that the CUSUM chart makes a substantial contribution towards translating "statistical significance" into "clinical relevance". The special advantage of this method is that every data point corresponds to the line of one patient only, and that any unexpected plotting in the CUSUM chart can be assigned to the respective patient and specific periods of time. Such specific periods of time are readily identifiable in **Fig. 12** on the x-axis, which is marked with the names of the months and shows that different case numbers have been plotted over the different periods of time.

For assistance in interpreting the individual sections of the CUSUM chart, please refer to the respective explanations on VLAD contained in this paper.

**Fig. 12** shows two additional limits, an upper and a lower one. Noyez (2009) explains how these limits are calculated, which is why we will not go into any detail here. We would only like to comment on the benchmarks required for the calculation of the limits:

The calculation of the limits as presented by Noyez (2009) requires an "accepted failure rate" and an "unaccepted failure rate" to be determined. These values define the area within which one would speak of an accepted quality as per the requirements laid down by the (clinical) leadership of a hospital or hospital department. This area would then be applied in the "Data to information" transformation stage (**Fig. 1**). It thus becomes clear that determining target values, or target areas, as a basis for quality assessment is one of the essential tasks assigned to (clinical) leadership.

In **Fig. 12** we have defined 12.7% and 19.1% as the "accepted failure rate" and "unaccepted failure rate", respectively, whereby the 19.1% corresponds to a 1.5 increase in the "accepted failure rate".

In the appendix to this paper you will find a file which shows how a CUSUM chart is calculated.

The limits serve to answer the question as to whether the shape of the curve (for example fluctuations in the curve/ continuously rising or falling curve over a given space of time) is consistent with "normal variation" or whether it is an indication of a positive or negative abnormality ("signal").

In the case of hospital A we can see from Fig. 12 that the CUSUM curve fluctuates and the limits are exceeded in March and October.

The CUSUM chart from hospital B (Fig. 13) likewise shows phases where the curve fluctuates. The important difference to hospital A is the fact that at the end of the year the CUSUM chart concludes negatively (–19) and that the CUSUM chart exceeds the lower limit several times in the course of the year. The first "signal" occurs in March and the question as to the causes and possible action could only have been raised at the latest with the occurrence of the "signal" in May.

Reference to the underlying case can be made at any time by means of the individual data points. This is one of the most important features of the CUSUM method. Further explanations and comments will be found later in this paper when we refer to VLAD in more detail.

At this point one can sum up by saying that the CUSUM method does not depict the in-house mortality rate as the target parameter of our observations as a percentage but as a life gained or lost at a specific point in time since the defined commencement date (in this case, the beginning of the year). The CUSUM method is thus able to represent the impact of interventions in a clearly legible fashion.

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Recommendations

Monitoring of the observed and expected hospital mortality rates should be carried out regularly with the aid of CUSUM charts.

Every "signal" should give rise to further in-depth analysis.

Trends without "signals" should be subjected to further in-depth analysis.

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## Risk-adjusted hospital mortality rate

### Bar chart (observed versus expected)

**Fig. 2** shows a bar chart with plotted non-risk-adjusted hospital mortality rate data. Here we are referring to "observed" hospital mortality rate (OHMR). The observed rates are also depicted in **Fig. 14** (again a bar chart) and supplemented by the expected rates calculated for the respective hospitals. The expected rate (EHMR) is depicted as a filled grey diamond with the corresponding 95% CI. This evaluation is also made available to our hospitals on a monthly basis.

The hospitals marked with an "x" have too low case numbers to enable expected values to be calculated. A quality assessment that takes expected values into account should therefore not be carried out in these cases (criteria according to Ash et al. 2003, pages 305/312).

The observed values for hospitals A and B have already been commented on above.

The expected value for hospital mortality is calculated for each case. This is conducted using a statistical model that was calculated using the above-mentioned multiple logistical regression analysis method. The expected HMR calculated for a patient undergoing treatment increases with the number of so-called risk factors pertaining to the patient. These may be: primary diagnosis pneumonia through pseudomonads or aspiration pneumonia, old age, simultaneously occurring malign illness, condition following a stroke, left-sided heart failure (stage NYHA IV), chronic kidney disease in stage IV.

One can say: the older the patient and the more risk factors manifested, the higher the calculated expected hospital mortality rate.

For the monthly evaluations the expected values of all concluded in-patient cases of pneumonia are accumulated and the resulting value then depicted as a filled grey diamond with the corresponding 95% CI.

Even if all hospitals are represented in the chart, the goal is not to stage a comparison in the sense of: who is providing the best quality?

This display format enables the comparison of the observed and expected values of a hospital. We are again talking about a "self-referential" process whereby each individual hospital can retrieve significant information applicable to its own situation.

When considering the expected values of the different hospitals, the question may arise as to why the expected value of one department deviates (appreciably) from that of another department, although the observer knows both departments and presumes that the risk structure for pneumonia patients in both departments hardly differs, if at all. That is the advantage of being part of a hospital group: it is possible to also acquire information on the frequency of risk factors for pneumonia patients in the associated hospitals. The CLINOTEL Group ensures this, given that this data is made available to member hospitals every month.

The expected value is based on risk factors and these are in turn, with the exception of age, coded by secondary diagnoses. This gives rise to the "documentation – coding – expected value" sequence and should there be any doubts as to the quality of the data, reference should be made to levels 1 and 2 in the analysis pyramid (**Fig. 4**) and the relevant questions asked.

The confidence intervals indicated for the expected values enable conclusions to be made as to the statistical significance of the outcome. Should a confidence interval not contain the observed value (bar chart), this as a rule points to the difference as being "statistically significant". In hospital A this is indeed the case (OHMR < EHMR) and

if fewer pneumonia patients die than expected, this outcome is also classified as being clinically relevant. This, of course, does not answer the questions as to what lies behind this outcome (for example: Is it due to overcoding, which has resulted in a wrongly defined high expected mortality rate? Are the clinical diagnostics and therapy in line with the Pneumonia Guidelines?).

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The width of the confidence interval depends on the extent of the random sampling and standard deviations in the groups under review. A large control sample leads to "more confidence", and thus to a narrow confidence interval. A broad confidence interval derives from a small control sample (see the hospitals marked wih an "x"). The greater the statistical spread of the values, the more uncertain or vague the conclusion will be – and the broader the confidence interval. A broad statistical spread can, of course, also be an indication of high variability within the coding process, in which case reference should be made to levels 1 and 2 in the analysis pyramid and an investigation conducted accordingly.

The advantage of confidence intervals is that results are immediately indicated at data measurement level. Confidence intervals provide information on statistical significance as well as on the trend and impact of the effect.

This means that they also enable decisions to be made as to the clinical relevance of the outcomes. Moreover, in the case of pre-determined probability of error, the variability of the data and the case number of the control sample under review are included in the width of the confidence interval.

For further reading on confidence intervals we recommend the reviews by Bender & Lange (2007) and du Prel et al. (2009), which have been quoted here.

For hospital B we can read OHMR > EHMR, which also requires questions to be asked with regard to the coding and/or treatment applied: is it due to undercoding, which has resulted in expected values that are far too low? Is the therapy not in line with the Pneumonia Guidelines?

For hospital C we can read: OHMR < EHMR, whereby OHMR drops into the lower confidence interval. Further analysis is urgently required in this case. For hospital D the plotted value marginally skims the lower confidence interval and for hospital E it is a case of a "near miss". We would recommend that the (clinical) leadership of both hospitals conduct an analysis.

The chart indicates a number of approaches which can be helpful for quality assessment processes. In our experience this is not sufficient on its own, because it always depends on who is reading the chart and what experience or expectations they have. Comments often heard in practice are:

- "OHMR ≤ EHMR" is an outcome that meets the expectations of the hospital managers perfectly and naturally infers a course of action or strategy that is in line with best evidence and clinical practice.
- If the outcome is "OHMR > EHMR", this may well be solely due to the coding or to insufficient and unrealistic statistical processes. A hospital may be treating the most severely ill patients but cannot plot their data correctly using the means available.

It is important that the following points are communicated to the target group directly interested in a specific evaluation. This applies especially to users with a limited knowledge of statistics:

Statistic processes do not claim to depict the absolute truth. This is not possible, because the results are quite simply always affected by a certain probability of error and depend on how well formulated the questionnaire is, and of course on the quality of the ensuing data.

The calculation of an expected risk-adjusted HMR is a prognostic rather than a diagnostic process. Any plotted data that appears to be out of the ordinary is a sign that further in-depth analysis is required. This is the diagnostic part of quality assessment.

We recommend the following:

Monitoring of the observed and expected riskadjusted hospital mortality rates should be carried out regularly.

The confidence interval should be quoted for the respective expected and observed values.

Should an observed value exceed the confidence interval, this should be read as a "signal" and a sign that further in-depth analysis is required.

If risk-adjusted data is used as a basis for quality assessment, data should also be available on the case numbers and the frequency of risk factors in the respective hospital and comparison group as an aid to interpretation.

Furthermore, information on the statistical quality of the process applied to address risk adjustment should be available, so that this can be taken into account in the course of the quality assessment programme.

## Bar chart (risk-adjusted HMR)

The bar chart is another form of representing data pertaining to risk-adjusted hospital mortality rates (**Fig. 15**): to calculate this for the individual hospitals the ratio of observed/expected (%) is multiplied by the case fatality rate (%) observed throughout the group. The computed value describes the result that would be achievable for every hospital if all hospitals had been treating patients with the same disease severity. The outcomes for all the hospitals can thus be immediately compared with one another (Ash et al. 2003, page 306).

It is evident that hospital B no longer shows the highest value and that hospital A has moved further to the right. This is due to the characteristics of the observed and expected values and requires no further elaboration at this point.

Both clinics have obviously benefited from the process. Hospital B also records the highest values in this area, however.

### Timeline

Timelines can also be used to represent risk-adjusted hospital mortality rates, as shown for hospitals A and B in **Fig. 16** and **17**.

When these timelines are compared with those related to non-risk-adjusted data (Fig. 8, 9) there are clear differences: for hospital A there are now 5 data points plotted above the confidence interval of the comparative value, in Fig. 8 there were 12. The number of data points plotted below the confidence interval of the comparative value is now also higher (14 versus 11).

Hospital B also shows fewer "signals": before there were 15 data points plotted above the confidence interval of the comparative value (**Fig. 9**), now there are only 11. The number of data points below the confidence interval of the comparative value remains unchanged.

With respect to the potential questions that may arise and further analysis that may be required, the statements and comments mentioned above apply. Recommendations are formulated as follows:

Monitoring of the risk-adjusted hospital mortality rates should be carried out regularly, since this process allows the hospitals to be directly compared and indications of good practice identified.

Monitoring of the risk-adjusted hospital mortality rates should be carried out regularly with the aid of timelines.

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### Funnel plot

Basic information on funnel plots can be found under Spiegelhalter (2005) and Lack & Gerhardinger (2009). Mayer et al. (2010) demonstrate the differences between conventional graphics (for example bar charts, caterpillar diagrams) and funnel plots, taking as an example a radical cystectomy (data provided by the National Health Service from the years 2000 to 2006). Becker & Eissler (2013) use funnel plots to represent risk-adjusted primary caesarean section rates.

A funnel plot is a graphical aid for institutional comparisons, in which an estimate of an underlying quantity is plotted against an interpretable measure of its precision. Control limits form a funnel around the target outcome, in close analogy to standard Shewhart control charts (Spiegelhalter 2005). Funnel plots enable the appropriate representation of data and simultaneously take case numbers into account. They serve as a visual aid to detecting bias.

The funnel plot in **Fig. 18** contains two so-called funnel limits which are calculated around the arithmetic mean (horizontal grey line) and correspond to confidence intervals. Presuming that rates deviating from the mean are purely coincidental, there is a 95% likelihood that they will lie within the inner limit and a 99.8% likelihood that they will lie within the outer limit (Bragg et al. 2010).

It is clearly visible that as the case number increases the limits are more closely spaced.

To ensure the anonymisation of data, we forgo plotting the case volume on the x-axis. This process is also used in a modified form by the British Healthcare Commission, for example (quoted in Lack & Gerhardinger 2009).

All in all, we can say the result displayed in the funnel plot is good, since only one clinic exceeds an upper limit (in this case the 95% limit). Since hospitals are as a rule reproached for "too high" fatality rates, the graph is initially dedicated to healthcare institutions approaching the upper limits (encircled). One clinic is plotted as being on the 95% limit and one as between the upper limits. In both these cases it would be advisable to conduct a further analysis of the outcomes.

But we also see evidence of best practice, since there are two clinics plotted as lying on the lower 95% limit (see arrows). Their respective outcomes can therefore not be construed as being randomly low.

In both cases, reference should again be made to levels 1 and 2 in the analysis pyramid and an investigation conducted accordingly.

In view of the outcomes recorded hitherto and the comparatively high case number, hospital A lies, as expected, below the average and close to the lower 95% limit.

The significance of the case number related calculation of the limit becomes evident when you consider hospital B, which lies within the 95% limit. From our point of view there is no contradiction to the values ascertained based on the observed and expected and the risk-adjusted hospital mortality rates, given that the value for this hospital is plotted very close to the upper 95% limit. From the point of view of a (clinical) management, we would assess this finding in the funnel plot as endorsing values determined hitherto, and conduct a further analysis of the clinical process.

Areas with differing rates and similar case volume ("outcome clusters", encircled in dotted turquoise lines) give rise to the question as to what impact structures and treatment processes in the clinics concerned may have on the risk-adjusted hospital mortality rate. Such issues can in turn be a reason for benchmarking the structures underlying the clinical process.

In their paper, Dimick et al. (2004) showed that it is fundamental to consider the case volume when evaluating outcomes. The funnel plot illustrated here demonstrates

that clinics with lower case numbers show substantially larger spreads of values before they come anywhere near the limits and become "alarming". At this juncture, it does not really matter whether we are dealing with nonadjusted or adjusted values.

If the goal is to generate a serious representation of the relevant data, however, these circumstances should not be regarded as a chance for "small case numbers" or even "small clinics" to avoid being subjected to internal or external quality assessment. It is quite natural for the spread of values to be case volume related, and this of course may lead to a completely different view which claims that lower case volumes actually complicate data assessment to a large extent. This is because it is very difficult to determine trends or effects of transformation processes and data can only be assessed with a relatively high degree of uncertainty. This therefore means that clinics with higher case volumes are – at least from a statistical standpoint – in a favourable situation when it comes to data and quality assessment.

#### Recommendations

The graphic representation of risk-adjusted hospital mortality rates should be conducted using funnel plots and taking case numbers into account.

Should outcome clusters be identified, the clinics affected are advised to conduct a further analysis and consider introducing benchmarking.

## Variable life adjusted display (VLAD)

VLAD is a method which is not widely used, as a research in PubMed (US National Library of Medicine, National Institutes of Health) shows: a search for "variable life adjusted display" or "VLAD" via the fields marked "title" and "abstract" will yield 68 results, but none of them from Germanspeaking countries (status 30.05.2013). This paper is thus most likely the first to be written on the application of this method in a journal which is also to be published in German.

The following authors provide a good overview of the fundamentals of this method and how to apply it: Andrianopoulos et al. (2012), Coory et al. (2008), Duckett et al. (2007), Flaatten (2005), Fusco et al. (2012), Grunkemeier et al. (2003), Guest et al. (2012), Noyez (2009), Pagel et al. (2012), Pagel et al. (2013), Roberts et al. (2012), Sherlaw-Johnson et al. (2000), Sherlaw-Johnson (2005), Tan et al. (2005) and Winkel & Zhang (2007).

Ideas on how and when to apply this method can be found on websites hosted by certain Australian states such as Queensland and Victoria (this is especially interesting, since they include VLAD in conjunction with the analysis pyramid). The respective web addresses are listed in the bibliography.

As a graph representing cumulative outcome quality, VLAD is based on the "cumulative sum (CUSUM)" method which has been described above.

The data for the VLAD graph (**Fig. 19**) was calculated for hospital A as follows (**Tab. 2**): the 432 patients are numbered chronologically in ascending order according to the date on which they were discharged (column headed Patient). The expected mortality is calculated for each patient using the above-mentioned statistical model (column E) with the observed outcome (survived/died, column O) plotted in.

The difference [E - O] is then calculated for each patient – in principle as per the CUSUM method:

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- The expected value for patient 1 was calculated as 0.146. The patient did not die and thus 0.146 (0.146 - 0) "lives were saved", or in other words: "0.146 fewer patients died than expected".
- The expected value for patient 5 was calculated as 0.253 and since the patient died the conclusion is: "0.747 lives were lost" or "0.747 more patients died than expected".

In the column headed VLAD, the individual differences (column E - O) are then added together: adding the values of patient 1 (0.146) + patient 2 (0.218) results in a VLAD value of 0.364. This is continued cumulatively up to and including patient 432, with a final result of 20.883. For hospital A this therefore means that in the year 2012 approximately 21 fewer patients died than expected. This was to be anticipated given that in **Fig. 14** it was evident that the observed value was below the 95% CI of the expected value.

The following example explains some of the different effects arising from the survival or death of patients with high or low expected mortality rates:

If a patient with a low expected value (0.1) survives, this will only lead to a slight increase of the VLAD by 0.1 (0.1 – 0). If this patient does not survive, the value entered for the case will be recorded as -0.9 in the VLAD (0.1 – 1). In the case of a patient with a high expected mortality, for example 0.8, the outcome is quite different. If the patient survives, the VLAD increases by 0.8 (0.8 – 0). If the patient dies, the graph will drop by 0.2 (0.8 – 1).

This therefore means: the most marked increases in the VLAD are caused by patients with a high expected value surviving, and the most marked drops by patients with a low expected value dying.

The graph depicted in **Fig. 20** in accordance with Pagel et al. (2013) shows these VLAD characteristics with the aid of two enlarged sections taken from **Fig. 19**.

VLAD graphs are also extremely useful for those looking to translate "statistical significance" into "clinical relevance". Here, too, each data point along the curve corresponds to a patient, thus allowing abnormal (or even alarming) sections of the VLAD to be allocated to the respective patients and thus also to periods of time.

Such periods of time are evident in **Fig. 19** along the x-axis, which is marked with the names of the months and shows that there are different case volumes plotted for the different periods of time.

From January to mid-February the VLAD rises, only to drop around mid-March. At this point in time, cumulatively speaking (!), exactly the number of patients died as was expected.

From mid-March onwards, the VLAD shows a practically continuously rising curve, which naturally gives rise to the question as to whether this rise will eventually become "striking" in the positive sense. The evidence of such a "run of good performance" (Sherlaw-Johnson 2005) is naturally important, since it may provide an indication of good practice. Again questions arise: "What was different during this period? What did we do especially well, which could be done more in future?" Equally important is the acknowledgement of a "run of bad performance" (Sherlaw-Johnson 2005), since this may develop into a qualitatively insufficient process.

In addition, **Fig. 21** displays two limits, an upper and a lower limit. Both limits are composed of data points which are calculated according to a complex procedure for the current VLAD value. The calculation of the limits has been explained in detail by a number of competent authors, which is why we will not go into more depth here (for example Andrianopoulos et al. 2012; Coory et al. 2008; Grunkemeier et al. 2003; Sherlaw-Johnson et al. 2000; Sherlaw-Johnson 2005; Spiegelhalter et al. 2003; Steiner et al. 2000).

In the appendix to this paper you will find a file which shows how a VLAD graph is calculated. The limits are calculated as described in the papers by Andrianopoulos et al. (2012) and Coory et al. (2008).

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The limits serve to answer the question as to whether the above-quoted "runs" are indications of positive or negative abnormalities which are, statistically speaking, striking and can thus be interpreted as "signals".

If limits are calculated for this purpose, they should be triggering as few wrongly positive and wrongly negative "signals" as possible. At the same time, it should be possible to identify correctly positive "signals" as early as possible, and to trigger wrongly positive "signals" as seldom as possible (Coory et al. 2008).

In their publication Coory et al. (2008) report on the calculation of three limits, which stand for a 30%, 50% or 75% increase or decrease in the relative risk, respectively. In our example the upper limit is set at a 30% decrease and the lower limit at a 30% increase in the relative risk. Applying these limits is the earliest possible way to identify positive "signals".

The VLAD value for patient 223 (end of May, first arrow) is higher than the corresponding value of the upper limit. It can thus be interpreted as a positive "signal". It indicates that at this point in time cumulatively more patients survived than expected. This conclusion is based on the following data: of the 223 patients 27 died, whereby the expected value is/was 36. If 30% more patients had actually died, this would have been 35 (27 + (27 x 0.3)). The calculated value (for example 30% above the observed value) is thus still below the expected value (36) – we can say this is a positive "signal" leading to a "run of good performance".

As soon as a "signal" is identified, a limit needs to be "reset", which means that the limit has to be re-calculated and the process can recommence to identify a further 30% decrease or increase in the relative risk.

This is the case for patient 340 (beginning of October, second arrow) – a second "good run" has been identified. The limit is re-calculated after the first "signal", now from patient 224 onwards. For patients 224 to 340, the observed value is 11 and the expected value 21. Again, the observed value with a 30% increase (11 + (11 x 0.3)) is at 14.3 below the expected value (in this case: 21). Again, a positive "signal" has been identified.

**Fig. 22** shows the VLAD graph for hospital B. On a cumulative basis five more patients died than expected, as based on the risk adjustment. Yet this does not give rise to a "signal" for a "bad run". This is because before a drop in the VLAD there is always a marked increase. In this case the VLAD is not an indication of long-term trends. What we see is a jagged curve.

By patient 139 at the latest (mid-June) one would intuitively expect a negative "signal" to be triggered. However, the subsequent calculation confirms that this does not occur – and rightly so: 30 patients have died, and the expected value was 25. Since we are now focussing on the lower limit, the following question is likely to arise: was the lower limit under-run by at least 30%? This is not the case, since – given that 30 patients died – the observed value is still lower than the expected value which has increased by 30% (25 + (25 x 0.3)).

There are three sections marked in the graph, the beginning and end of which are in relation to the well defined low points on the VLAD. With the aid of a statistical process it is possible to look more closely at these three sections and investigate whether the observed (O) and expected (E) case fatality rate differ in a statistically significant way (p<0.05) (for this purpose the statistical software from STATA<sup>®</sup> StataCorp LP, Texas, USA, version 12.1 and the command "smyrby" were used). No significant difference was identified in any of the three sections.

Of course, this does not mean that the downward trends shown in the VLAD graph cannot or should not be further analysed.

Duckett et al. (2007) expressly point out: "VLADs do not provide definitive answers about the quality of care. They are used to develop ideas about why variations in reported outcomes occur and suggest possible solutions, be they ways of improving data quality, improving case mix adjustment, or implementing system changes to improve quality of care".

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A further development of the VLAD method is presented by Pagel et al. (2013). This adds more applications whereby individual data points – which correspond to individual cases – are highlighted in different colours. We have adopted this idea in the development of the VLAD for the CLINOTEL Hospital Group. This is explained in **Fig. 23**, taking hospital A as an example. This graph basically shows what is already contained in **Fig. 21**, with two differences: there are no months marked in on the x-axis but rather data on case numbers, which enables the case numbers to be allocated approximately to data point sections.

The especially innovative feature of this graph is that it allows different colours to be used for the data points. The colours are coded as follows:

- A green data point indicates that the upper limit was reached, or that a patient who ranked highly in the individual risk-adjusted mortality, actually survived. The calculation is performed using the statistical model mentioned above. In this case, we use the 95% percentile as the threshold value. In our data, this starts with the value 0.46.
- A data point is highlighted in red when the lower limit has been reached, or when a patient with a low expected values, has died. In this case the threshold value is 0.015, which is the equivalent of a 5% percentile.
- Given that we have access to the patients' routine data, we are able to examine the secondary diagnoses of the patients for adverse events, which may be available in the form of coded secondary diagnoses. If there is one or perhaps even several medical events plotted in the graph, the data point is highlighted in orange.

As of 2014, all members of the CLINOTEL Hospital Group will be sent a copy of the table together with the quality assessment evaluations based on routine data (**Tab. 5**). The table shows which event applies to which patient. The table provides a wide range of information on the different cases: the first column (headed serial no.) contains the respective number of the data point in the VLAD graph. The next columns contain the case number of the patient (not shown here) and the dates and times when the patient was admitted and discharged (likewise not displayed in this paper).

The column headed "expected" shows the calculated expected value for the hospital mortality rate for a specific patient, followed by the observed outcome.

The column headed "VLAD" contains the VLAD value related to the data point, followed by the inherent upper and lower limit values.

The events explained above can be seen in the last column.

For the sake of completeness, it should be mentioned that highlighting data points can naturally also be applied when using the CUSUM method.

With regard to VLAD one can say in summary that VLAD does not represent our target value (for example the hospital mortality rate) as a percentage, but as the number of lives saved or lost at a given point in time. VLAD graphs are thus able to depict the impact of interventions extremely vividly.

#### Recommendations

Monitoring of the observed and expected riskadjusted hospital mortality rates should be carried out regularly with the aid of VLAD.

Every "signal" should give rise to further in-depth analysis.

Trends without "signals" should be subjected to further in-depth analysis.

## General overview of CUSUM and VLAD

Both CUSUM and VLAD make a substantial contribution towards translating "statistical significance" into "clinical relevance".

Besides their common traits there are a number of differences which arise in the main from the varying expected values: whereas CUSUM uses constant expected values, VLAD graphs plot patient-related, risk-adjusted expected values. The resulting differences between the CUSUM and VLAD values are explained again here with reference to **Tab. 1** and **2**:

Calculating the difference [E - O] for patient 2 results in distinctly different values, that is to say 0.127 (CUSUM) versus 0.218 (VLAD). The values recorded for patient 5 are -0.873 (CUSUM) versus -0.747.

As a consequence: if the expected value calculated for an individual patient (VLAD) is greater than the constant (CUSUM), the resulting value [E - O] for the VLAD will thus be greater.

Vice versa: the expected VLAD value < CUSUM will result in the VLAD value [E – O] being smaller.

These findings naturally have an impact on the graphics. We will first take a closer look at the CUSUM chart (**Fig. 12**) and the VLAD graph (**Fig. 21**) for hospital A:

CUSUM and VLAD both show a positive cumulative final outcome, and yet the value as plotted in CUSUM (+3) is clearly below that for the VLAD (+21). This difference is the result of the impact of the expected values described above, namely fixed versus individually calculated values and should therefore not lead to false conclusions. The cumulative final outcome is thus likely to be positive, that is to say: more patients survived than expected. And both methods display this. Both graphics reveal rising and falling curves. Both graphs indicate that the upper limits have been exceeded. The lower limit is only reached in the CUSUM chart.

Hospital B shows the tendency towards identical findings in both the CUSUM (Fig. 13) and the VLAD graph (Fig. 22).

The cumulative final outcome is recorded in the CUSUM chart as –19, which is clearly below the value recorded in the VLAD (–5). Whereas the VLAD does not give rise to a "signal", CUSUM definitely does. The above explanations also apply for these findings. Adding to that is, of course, the fact that the higher hospital mortality rate recorded for hospital B (20.7% versus CLINOTEL 13.6%/hospital A 12.0%) has a considerable impact given the relatively high number of cases with negative [E – O] values (0.127 – 1 = –0.873).

With respect to the relevant aspects, both methods in principle enable consistent conclusions to be made, which means we have an instrument at our disposal which can be applied across the entire spectrum for riskadjusted and non-risk-adjusted expected values.

The particular advantage of this method is that every data point corresponds to the line of one patient only and thus any unexpected plottings in the chart can be assigned to the respective patient and specific periods of time.

On the Government of Victoria's website they sum this up very nicely:

"A key strength ... is that each episode of care has an impact on the chart. That is, every patient outcome moves the line up or down according to the outcome of their stay."

Victorian Government Website

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## **Overview of the results**

The findings resulting from the analysis of the charts and graphs for hospitals A and B are summarised in **Tab. 3** and **4**.

If we had to decide which of the two hospitals we would advise to undertake a further analysis of the clinical process for the "diagnosis and treatment of community-acquired pneumonia", we would opt for hospital B.

In the funnel plot the value for the hospital is well above average, but only just within the inner limit and the riskadjusted hospital mortality rate is far to the left of the CLINOTEL value.

The timelines, control chart, CUSUM chart and VLAD graph also show significant abnormalities. Here it is a question of whether there is still a chance of positively impacting the ratio of observed to expected numbers of fatality cases in future. In other words, could deaths have been avoided in the past, and what can we learn for the future?

In addition, we would ask hospital A to investigate whether there are signs of best practice in the care process which can be communicated to other hospitals. A further question would be to determine whether amendments to clinical processes (for example interventions) were implemented during the observation period.

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## Conclusion

Statistical graphics can effectively support "data – information – decision" transformation, as we were able to show from the data collected from two hospitals.

This involves a complex process, which in turn reflects the complexity of clinical processes. Attempts to reduce this complexity have not proved to be productive. Many observers may find it charming to reduce the quality of a care process, a medical department or even an entire hospital to traffic light colours, thumbs up or down, or a series of stars. However, one cannot seriously expect that such ratings will promote sustainable improvements of care quality.

The prime prerequisite for initiating a change in a care process is the professional quality of the staff involved. This begins with the "data – information – decision" sequence and becomes mission critical when the changes are realised and maintained as standard practice. It is not only the problem – in this case deviating from an evidence-based guideline – that is maintained through repetitive operational measures. The solution, too, must be revealed and manifested in new, observable and repetitive operational measures.

This requires a lot of energy which people are only prepared to invest in on a long-term basis if the complexity of the work they perform and the conditions under which they do so are acknowledged.

If the solution does not take the form of a repetitive operational measure, it will not last long. This is the effect described in practice when external consultants come up with a solution, install it, and withdraw. Since in such cases it is often about the consultant's solution and not the solution of those directly involved in the care process, metaphorically speaking the consultant takes the solution away with him when he leaves and the process returns to its accustomed state. Goeschel (2011) and Dixon-Woods et al. (2011) provide a good overview of the success factors that determine successful clinically relevant change processes. Further analysis – as well as the clinical diagnosis – should be carefully planned and conducted in a targetoriented fashion. We recommend using the aforementioned analysis pyramid.

Besides collecting and analysing process relevant data we recommend two further measures which in our experience can deliver important findings with regard to quality evaluation, prevention and quality planning and should be mentioned in the context of this paper. Another point that speaks in favour of these measures is that – in contrast to a peer review, for example – they can be conducted by one hospital alone:

A morbidity and mortality conference can be staged at some time during the year to allow time to reflect on the care process. The staging of such a conference might be triggered by the detection of a "signal" in the Variable Life Adjusted Display (VLAD). If the morbidity and mortality conference follows a defined course of action and fulfils further quality criteria, "signal cases" can lead to a qualified discussion throughout the entire therapeutic team. This is the best chance of pinpointing unstable actions and system factors and learning from them (Becker 2013a).

A so-called process audit is especially helpful in the case of defined clinical care processes, since this allows an audit to be carried out in line with patients' pathways. Internal audits of this kind (DIN EN 15224) can be conducted on a real-time basis (for example in response to abnormalities occurring in the control chart or VLAD) or as a component of a prospective internal audit programme.

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The clinical process for the "diagnosis and treatment of community-acquired pneumonia" thus makes for a prime example since it can be easily measured using routine data and there are evidence-based guidelines available (Leitlinie Pneumonie 2009). With the aid of the guidelines critical control points in the care process can be pinpointed and monitored, and systematically audited. These may be: premature risk stratification, indication for primary admission to the intensive care unit, appropriate diagnostic strategy, initiation of antibiotic therapy, etc. In the ideal case, the data will correspond with the critical control points in the care process.

Conducted in this manner, the process audit can be both the trigger and the consequence of the "data – information – decision" sequence.

The procedure described supports (clinical) leadership in the evaluation of clinical processes with respect to process and outcome quality, the knowledge of which is a prerequisite for the evaluation of efficiency. The combination of different statistical graphics for analysis purposes is of special value since it enables data to be considered in the course of the year and further analyses carried out accordingly. Decisions on interventions to be made in the clinical process can therefore be made in good time and not only after a long observation period. From the point of view of the patient the time gained can indeed make a difference that makes difference.

We have shown that an issue-related, and thus relevant, approach to effective decision-making is possible. Returning to Søren Kierkegaard's quote at the beginning of this paper, we can therefore optimistically amend it to:

"Comparing is the end of discontent and the begin of satisfaction."

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# Figures

#### Fig. 1:

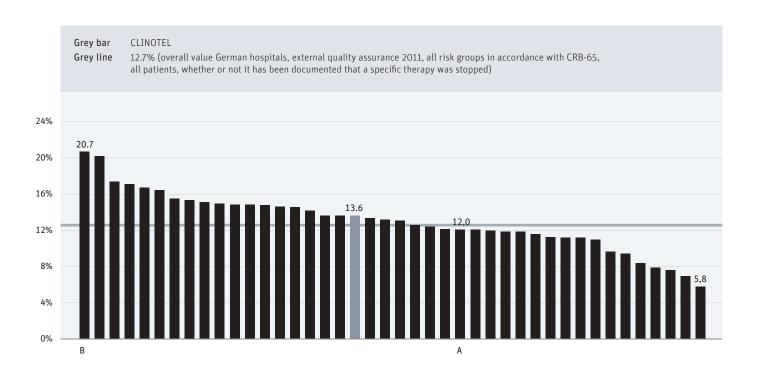
Data to information to decisions

Data	$\rightarrow$	Information	$\rightarrow$	Decision
Mortality rate Complications 	Meaning	Adequate? Actual ≥ Target value? Actual < Target value? 	Meaning	"No intervention" "Need for improvement" Investigations Analyses Dialogue Projects 

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#### Fig. 2:

Hospital mortality rate (%) for community-acquired pneumonia: bar chart Data 2012 | 10,379 patients

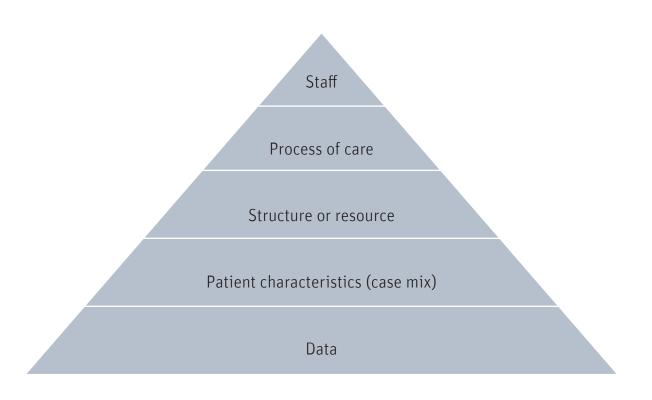


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#### Fig. 3:

Pyramid model for investigating hospital performance pursuant to Mohammed et al. 2004



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#### Fig. 4:

Pyramid model for investigating hospital performance pursuant to Mohammed et al. 2004

#### Level 1: Data

- Was the data coded correctly?
- Was the primary diagnosis indicated correctly?
- Were all secondary diagnoses coded correctly (qualitatively and quantitatively; also in the case of patients who died prematurely)?
- Were any changes made in the key or the coding guidelines and were these correctly implemented?
- Were any changes made in the coding practice?
- Is the clinical documentation clear, complete and consistent?
- Were definitions applied correctly?
- Is the data complete?

#### Level 2: Patient characteristics (case mix)

- Are there any factors related to patients that may affect the outcome quality and are not taken into account in the course of risk adjustment?
- Were any changes made in conjunction with the admission/discharge of patients (diagnosis, procedures ...)?
- Patients with the status "Do not resuscitate" (impacts the outcome quality, but cannot be coded and therefore does not appear in the risk adjustment). In such cases relevant secondary diagnoses may no longer be coded for risk adjustment.

#### Level 3: Structure or resource

- Were any changes made to the existing structures and resources available which might impact outcome quality or risk adjustment?
- Are there any capacity bottlenecks that affect ORs, ITS, functional sections etc.?
- Changes in procedures (guidelines, SOPs etc.) and how these are communicated, or staff is trained to adopt them?
- Introduction of new procedures?

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#### Fig. 5:

Pyramid model for investigating hospital performance pursuant to Mohammed et al. 2004

#### Level 4: Process of care

- Were any changes made in the field of care processes which could impact outcome quality or risk adjustment?
- Were any changes made in conjunction with the admission/discharge of patients, or moving patients to a different ward (diagnosis, procedures ...)?
- Changes or new guidelines?
- Application of new equipment, medication etc.?
- Differences in shifts, weekdays, holiday periods?

# Level 5: Staff

- Were any changes made to staffing which could impact outcome quality or risk adjustment?
- Quantitatively (personnel working within one area)?
- Qualitatively (competences, skills, staff mix)?
- Loss of staff which has a significant impact on processes and outcome quality?
- Changes in team structures?

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#### Fig. 6:

Hospital mortality rate (%) for community-acquired pneumonia: timeline Hospital A | data 2010 to 2012 | 1,295 patients

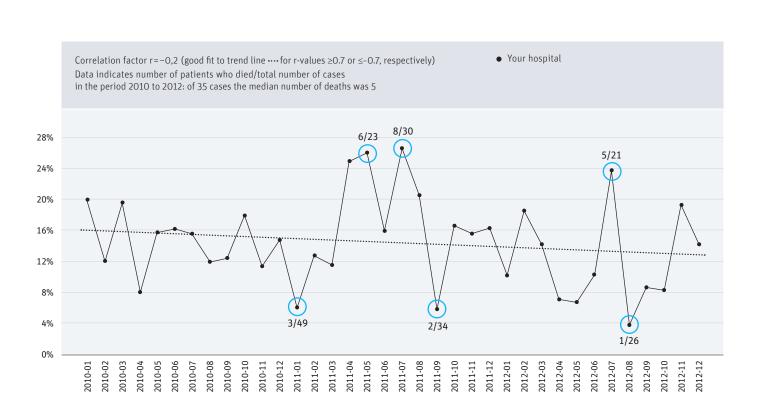


Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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#### Fig. 7:

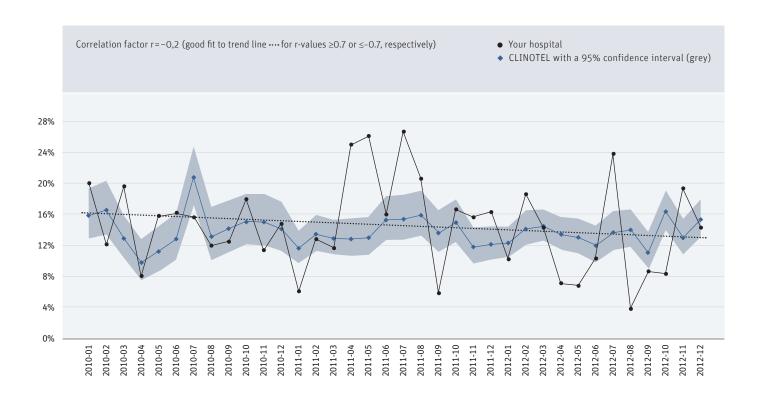
Hospital mortality rate (%) for community-acquired pneumonia: timeline Hospital A | data 2010 to 2012 | 1,295 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Journal

#### Fig. 8:

Hospital mortality rate (%) for community-acquired pneumonia: timeline Hospital A | data 2010 to 2012 | 1,295 patients

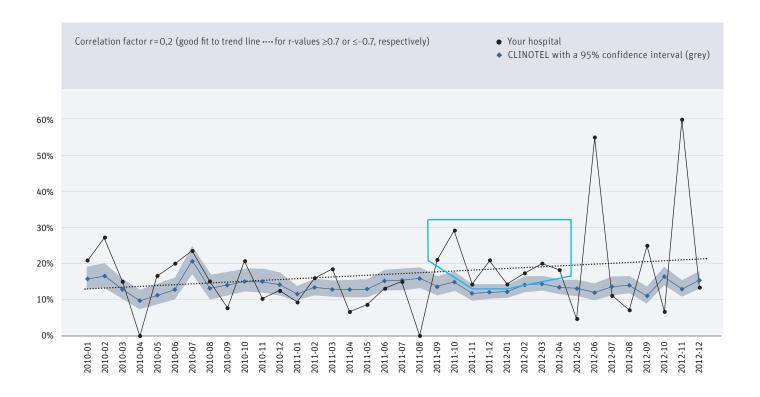


Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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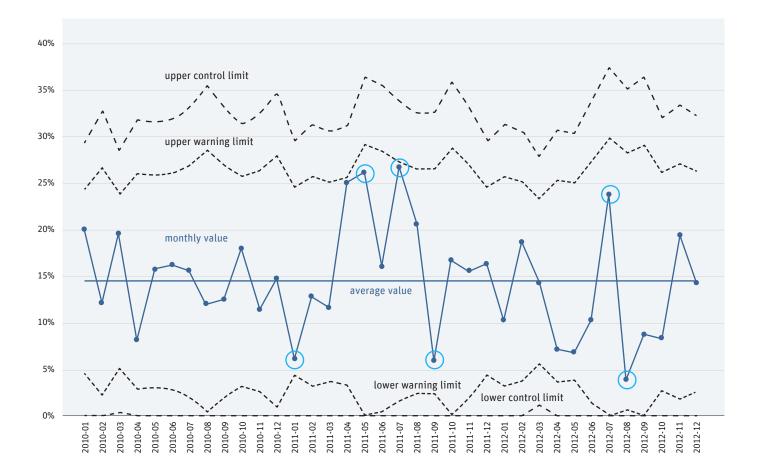
#### Fig. 9:

Hospital mortality rate (%) for community-acquired pneumonia: timeline Hospital B | data 2010 to 2012 | 786 patients



#### Fig. 10:

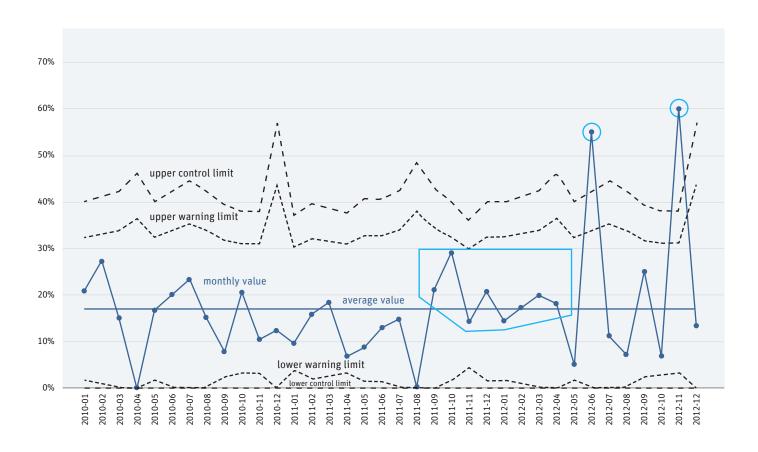
Hospital mortality rate (%) for community-acquired pneumonia: p-control chart Hospital A | data 2010 to 2012 | 1,295 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Journal

#### Fig. 11:

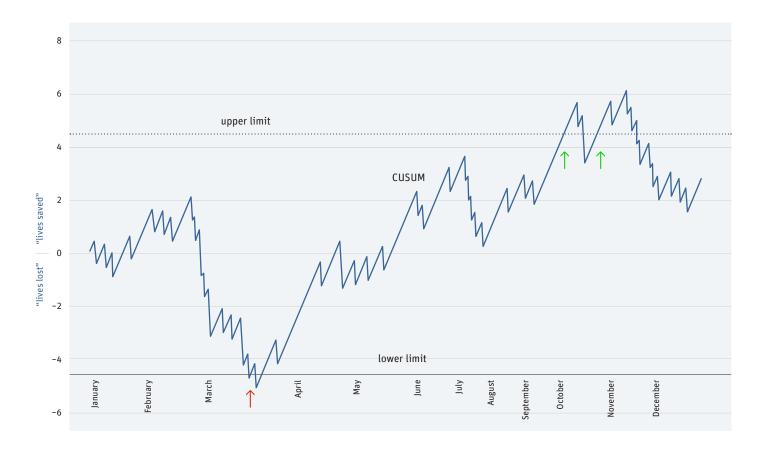
Hospital mortality rate (%) for community-acquired pneumonia: p-control chart Hospital B | data 2010 to 2012 | 786 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Journal

#### Fig. 12:

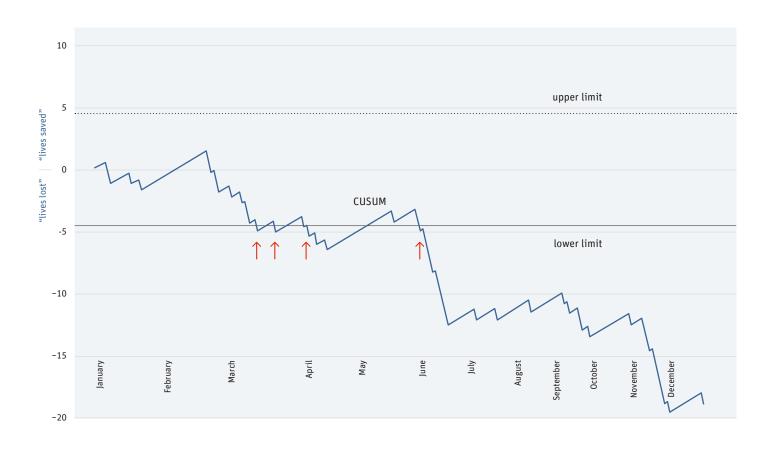
Hospital mortality rate for community-acquired pneumonia: cumulative sum (CUSUM) Hospital A | data 2012 | 432 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Journal

#### Fig. 13:

Hospital mortality rate for community-acquired pneumonia: cumulative sum (CUSUM) Hospital B | data 2012 | 237 patients

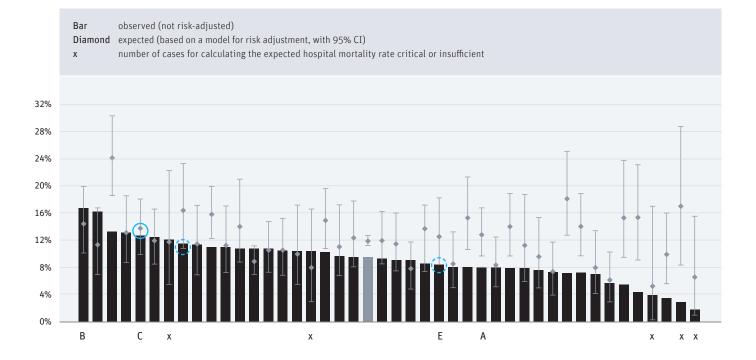


Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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#### Fig. 14:

Observed and expected hospital mortality rate (%) for community-acquired pneumonia Data 2012 | 10,379 patients

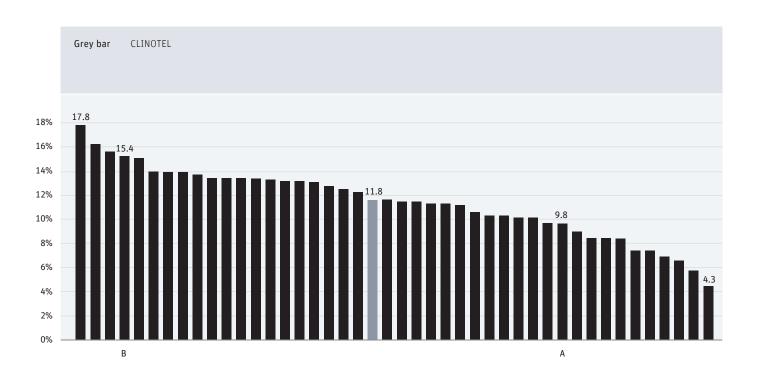


Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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#### Fig. 15:

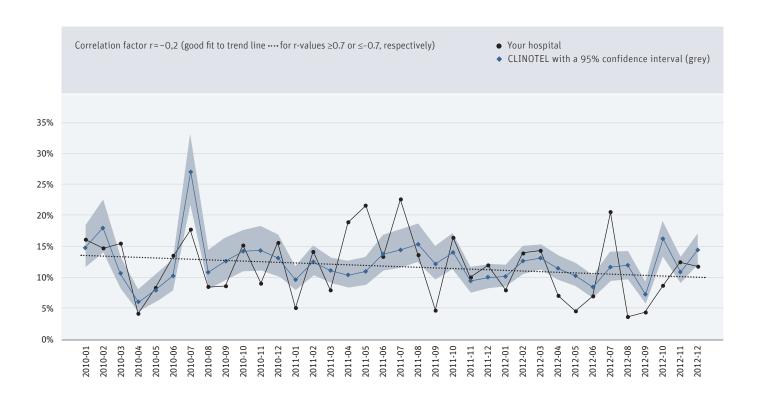
Risk-adjusted hospital mortality rate (%) for community-acquired pneumonia Data | 2012 | 10,379 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Iournal

#### Fig. 16:

Risk-adjusted hospital mortality rate (%) for community-acquired pneumonia: timeline Hospital A | data 2010 to 2012 | 1,295 patients



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 Community-Acquired Pneumonia as an example

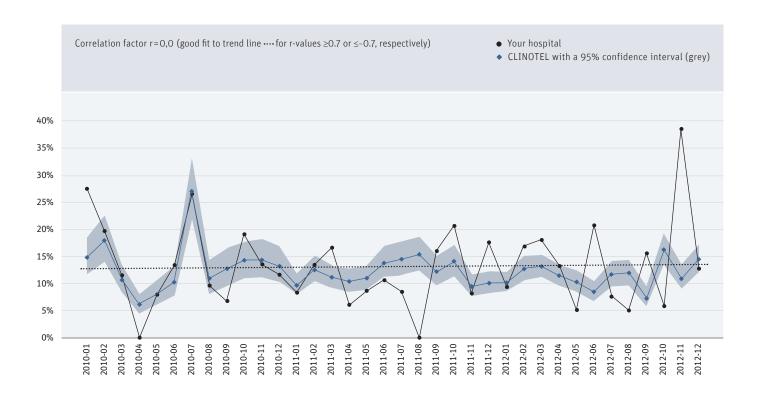
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#### Fig. 17:

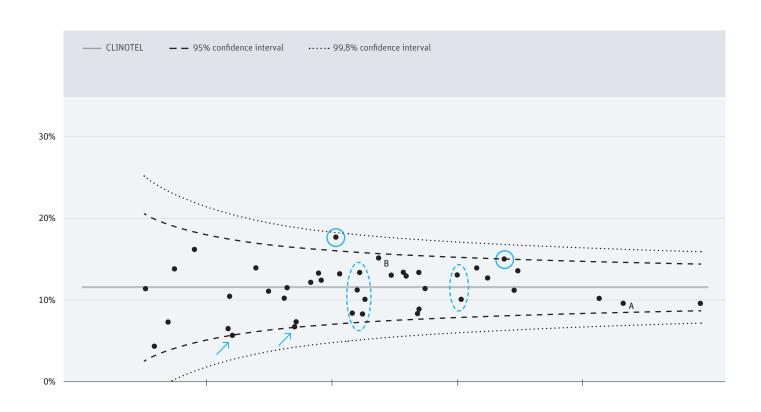
Risk-adjusted hospital mortality rate (%) for community-acquired pneumonia: timeline Hospital B | data collected 2010 to 2012 | 786 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Journal

#### Fig. 18:

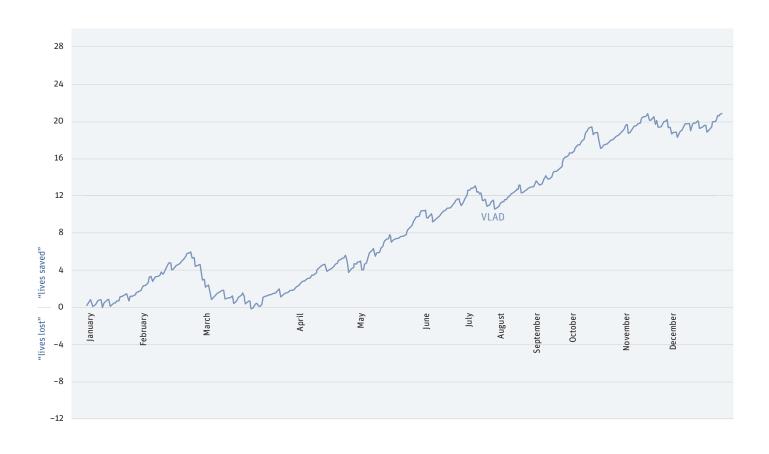
Risk-adjusted hospital mortality rate (%) for community-acquired pneumonia: funnel plot Data 2012 | 10,379 patients



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#### Fig. 19:

Hospital mortality rate for community-acquired pneumonia: variable life adjusted display (VLAD) Hospital A | data 2012 | 432 patients



 Data to Information to Decisions – how can Statistical Graphics support Clinical Quality Evaluation
 Review

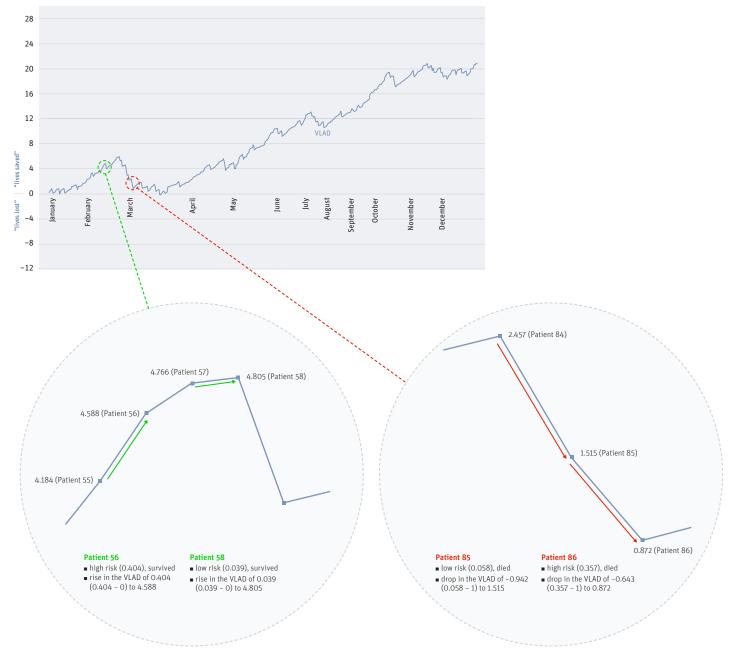
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# Fig. 20: Enlarged details of two sections explaining the characteristics of VLAD graphs

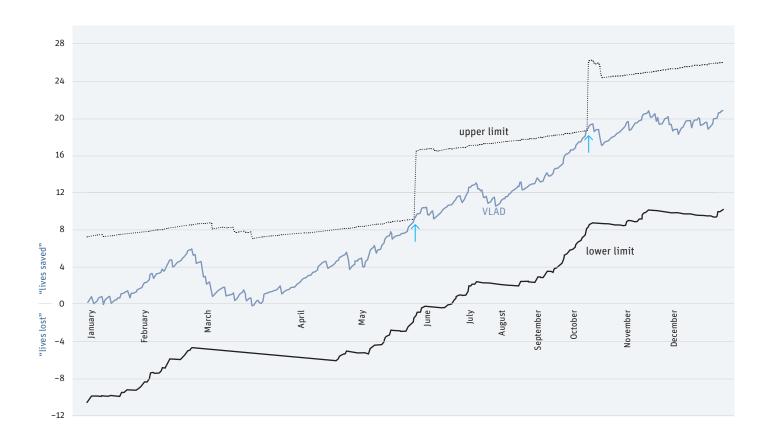
Hospital mortality rate for community-acquired pneumonia: variable life adjusted display (VLAD) Hospital A  $\,|\,$  data 2012  $\,|\,$  432 patients



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#### Fig. 21:

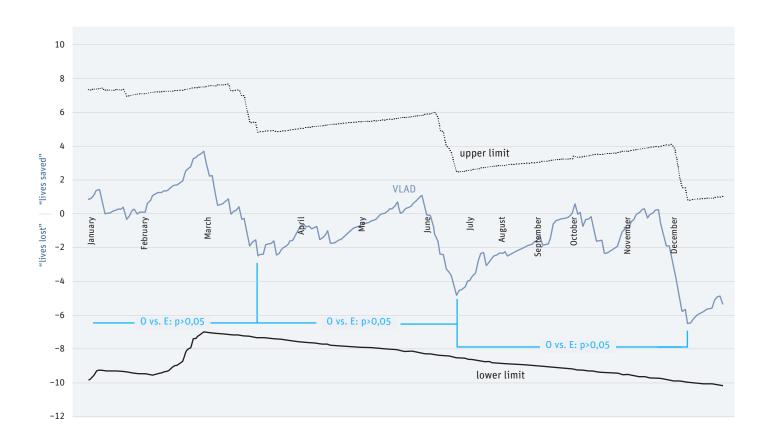
Hospital mortality rate for community-acquired pneumonia: variable life adjusted display (VLAD) Hospital A | data 2012 | 432 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie CLINOTEL-Journal

#### Fig. 22:

Hospital mortality rate for community-acquired pneumonia: variable life adjusted display (VLAD) Hospital B | data 2012 | 237 patients

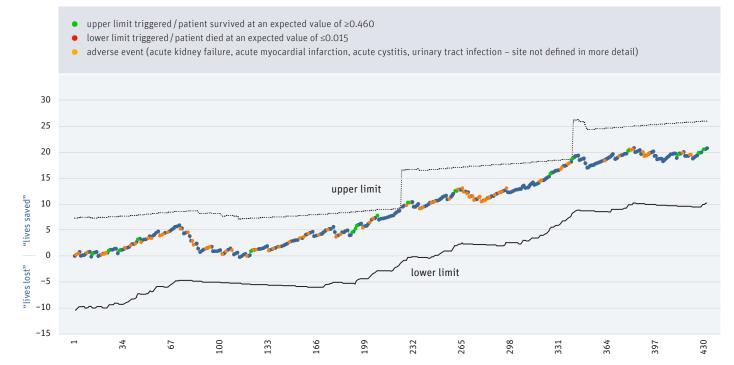


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 Fig. 23: Further development of the variable life adjusted display (VLAD) method according to Pagel et al. (2013) Hospital A | data 2012 | 432 patients



Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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# Tables

## Tab. 1:

CUSUM calculation (Hospital A | data 2012 | 432 patients)

Patient	E	0	E – 0	CUSUM		
1	0.127	0	0.127	0.127		
2	0.127	0	0.127	0.254		
3	0.127	0	0.127	0.381		
4	0.127	0	0.127	0.508		
5	0.127	1	-0.873	-0.365		
6	0.127	0	0.127	-0.238		
7	0.127	0	0.127	-0.111		
8	0.127	0	0.127	0.016		
9	0.127	0	0.127	0.143		
10	0.127	0	0.127	0.270		
:	:	:	:	:		
:	:	:	:	:		
430	0.127	0	0.127	2.610		
431	0.127	0	0.127	2.737		
432	0.127	0	0.127	2.864		
E	E expected mortality rate (in this case: value taken from external quality assurance data 12.7% in 2011)					
0	observed value: pa	itient die	ed, yes (1) no (	0)		

CUSUM cumulative sum of E – O values (for patient no. 1, CUSUM = E – O)

Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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## Tab. 2:

VLAD calculation (Hospital A | data 2012 | 432 patients)

Patient	E	0	E – 0	VLAD	
1	0.146	0	0.146	0.146	
2	0.218	0	0.218	0.364	
3	0.255	0	0.255	0.619	
4	0.257	0	0.257	0.876	
5	0.253	1	-0.747	0.129	
6	0.045	0	0.045	0.174	
7	0.074	0	0.074	0.248	
8	0.211	0	0.211	0.459	
9	0.242	0	0.242	0.701	
10	0.090	0	0.090	0.791	
:	:	:	:	:	
:	:	:	:	:	
430	0.008	0	0.008	20.649	
431	0.136	0	0.136	20.785	
432	0.098	0	0.098	20.883	
E	expected mortality rate, calculated for each patient individually				
0	observed value: patient died, yes (1) no (0)				

0	observed value: patient died, yes (1) no
VLAD	cumulative sum of the E – O values

(for patient no. 1, VLAD = E - O)

Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

# Tab. 3:

Summary of results: non-risk-adjusted data

Chart	Hospital A	Hospital B
Bar chart (2)		
position in relation to group value	•	
position in relation to external value	▼	•
Timeline (6–9)		
trend line: curve	falling	rising
trend line: fit	unsatisfactory	unsatisfactory
case numbers influential	yes	yes
value(s) > 95% CI	yes	yes
value(s) < 95% CI	yes	yes
trend line: within 95% CI	yes (a)	no (b)
series > 95% CI	no	yes
series < 95% CI	yes	no
p-control chart (10–11)		
value(s) > upper warning limit	no	yes
value(s) > upper control limit	no	yes
value(s) < upper warning limit	no	yes
value(s) < upper control limit	no	yes
signal: shift	no	no
signal: two of three	no	no
signal: trend	no	no
Cumulative sum (CUSUM) [12–13]		
lives saved	yes	no
lives lost	no	yes
signal(s): upper limit	yes	no
signal(s): lower limit	yes	yes
good run, no signal	yes	yes
bad run, no signal	yes	yes

Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

#### Tab. 4:

Summary of results: risk-adjusted data

Chart	Hospital A	Hospital B
Bar chart: observed versus expected (14)		
observed ≤ expected	yes	no
observed < expected 95% CI	yes	no
observed > expected	no	yes
observed > expected 95% CI	no	no
Bar chart: risk-adjusted hospital mortality rate (15)		
position in relation to group value	•	
position in relation to external value	(a)	(a)
·		
Timeline (16–17)		
value(s) > 95% CI	yes	yes
value(s) < 95% CI	yes	yes
trend line: within 95% CI	no (b)	no (b)
series > 95% CI	no	yes
series < 95% CI	yes	yes
Funnel plot (18)		
value(s) > upper 99.8% limit	no	no
value(s) > upper 95% limit	no	no
value(s) < lower 95% limit	no	no
value(s) < lower 99.8% limit	no	no
Variable life adjusted display (VLAD) (19–22)		
lives saved	yes	no
lives lost	no	yes
signal(s): upper limit	yes	no
signal(s): lower limit	no	no
good run, no signal	yes	yes
bad run, no signal	yes	yes

Von Daten zu Informationen zu Entscheidungen – wie können statistische Grafiken die klinische Qualitätsbewertung im Krankenhaus unterstützen? Eine Übersicht und praktische Anwendung am Beispiel der Krankenhaussterblichkeit bei ambulant erworbener Pneumonie

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#### Tab. 5:

Table of cases (extract) Hospital A | data 2012 | 432 patients

 0.071	n	17.503			
		11.303	18.579	6.831	
0.060	n	17.563	18.588	6.891	
0.305	n	17.868	18.624	7.196	urinary tract infection, site not otherwise specified
0.131	n	17.999	18.643	7.327	urinary tract infection, site not otherwise specified
0.197	n	18.196	18.669	7.524	
0.719	n	18.915	18.707	8.243	survived at an expected value of ≥0,46
					upper limit
					acute myocardial infarction
0.123	n	19.038	26.222	8.366	
0.278	n	19.316	26.256	8.644	
0.080	n	19.396	26.268	8.724	
0.083	n	19.479	26.280	8.807	
0.172	у	18.651	25.941	8.787	
	0.131 0.197 0.719 0.123 0.278 0.080 0.083	0.131 n 0.197 n 0.719 n 0.719 n 0.123 n 0.278 n 0.080 n 0.083 n	0.131       n       17.999         0.197       n       18.196         0.719       n       18.915         0.719       n       18.915         0.123       n       19.038         0.278       n       19.316         0.080       n       19.396         0.083       n       19.479	0.131       n       17.999       18.643         0.197       n       18.196       18.669         0.719       n       18.915       18.707         0.123       n       19.038       26.222         0.278       n       19.316       26.256         0.080       n       19.396       26.268         0.083       n       19.479       26.280	0.131       n       17.999       18.643       7.327         0.197       n       18.196       18.669       7.524         0.719       n       18.915       18.707       8.243         0.123       n       19.038       26.222       8.366         0.278       n       19.316       26.256       8.644         0.080       n       19.396       26.268       8.724

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# Manuscript data

# **Conflict of interests**

The author hereby declares that there is no conflict of interest related to this article.

He is the managing director the CLINOTEL Hospital Group which is a non-profit organisation. In this capacity he represents the company vis-à-vis the following institutions and professional associations: Aktionsbündnis Patientensicherheit e.V. (German Coalition for Patient Safety), Gesellschaft für Qualitätsmanagement in der Gesundheitsversorgung e.V. (Association for Quality Management in Health Care), Deutsche Gesellschaft für Qualität e.V. (German Society for Quality), European Foundation for Quality Management, International Society for Quality in Health Care, Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e.V. (German Society for Medical Informatics, Biometry and Epidemiology), Verband der Krankenhausdirektoren Deutschlands e.V. (Association of Hospital Directors in Germany) und Bundesverband Pflegemanagement e.V. (Association of Nursing Managment).

Professor Becker is a personal member of the "Medizinische Informatik" Certification Committee of the Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e.V. (German Society for Medical Informatics, Biometry and Epidemiology) and a Fellow of the International Society for Quality in Health Care.

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