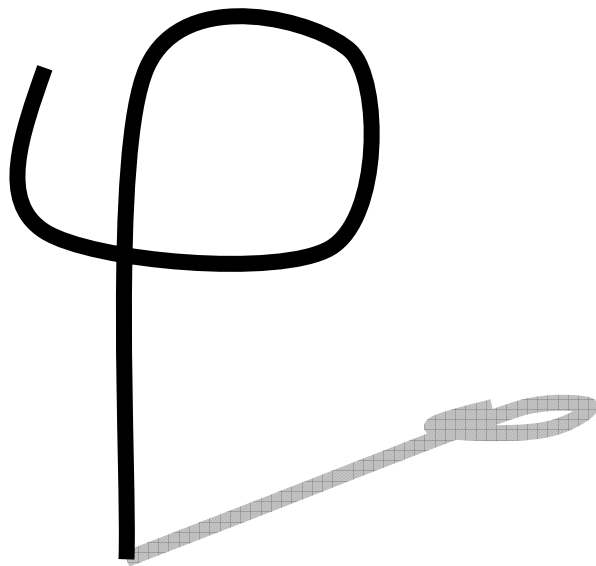


**R.Schiffer**



**Indicators of clinical use in digitized  
biometrics**

## **Introduction**

The use and development of tools and methodologies capable of making measurable and documentable the methods adopted by professionals, in the context of health organizations, in dealing with care problems and health results obtained, date back to the mid-1800s - early 1900s with the first significant examples of evaluation of the results obtained from care practices.

Since then, many things have changed and not only in terms of the techniques and methodologies used for the analysis of clinical outcomes. The latter have become particularly complex and refined, thanks to the substantial contributions offered by statistics and epidemiology.

The evaluation of clinical performance has found its own formal conceptual framework.

It has assumed a systemic character, becoming a fundamental element for the functioning of the health system. It represents an essential part of the connective tissue that supports the relationships and relationships between the different parts of the health system.

The evaluation action is now an integral part of the development, development and implementation of health policies. The concrete forms of accountability relationships are based on it (having to account for one's own decisions and actions) that characterize a healthcare system. The general principles and characteristics in the evaluation of clinical performance.

The dimensions of health care that contribute to defining the quality of a biometrics laboratory can be:

- accessibility: ease with which patients access the laboratory necessary for their disability
- continuity: degree of coordination and integration between services and operators involved in the management of certain categories of patients
- efficacy: ability of a health intervention to obtain the desired clinical results
- efficiency: ability to obtain the desired clinical results with the minimum use of resources
- clinical appropriateness: use of an application, effective indicators in patients who can actually benefit from it due to their disability
- organizational appropriateness: delivery of a type of instrumental assessment (stabilometry, baropodometry, three-dimensional reconstruction of the vertebral column, etc.) in an appropriate and congruent organizational context, for the quantity of resources used, with the complexity characteristics of the intervention provided and with those patient clinics.
- safety: provision of assistance in organizational contexts that minimize the conditions of risk or danger for patients and operators
- timeliness: delivery of an intervention in a time appropriate to the patient's disability
- centrality of the patient: ability to take into account, in defining the therapeutic pathways, the expectations and preferences of the patient and his family members, respecting his culture, his decision-making autonomy and his dignity.
- development of human resources: ability to maintain and develop the skills of professionals, offering opportunities for continuous learning and training, in an environment suited to maintaining the satisfaction of professionals for the working context in which they operate.

The instrumental assessment should be based on reference standards, i.e. measurable performance values that indicate the quality of care to be achieved on the basis of the best evidence or, where not available, on the basis of expert opinion.

## **Evaluation criteria**

The evaluation criteria must faithfully reflect the available scientific knowledge, since they must represent the reference parameter against which to compare current clinical practice.

The traditional classification distinguishes: structure, process and outcome criteria.

*Structural criteria:* these are criteria referring to the availability of technical, organizational and structural resources necessary for an appropriate performance of the instrumental evaluation. This class also includes the requirements that refer to the skills of professionals and their degree of integration and coordination.

For example, one of the characteristics of a movement analysis laboratory is the sharing of the procedures established and shared by those who work in this area. The frequency with which meetings are organized in which the critical issues and the results obtained are discussed.

*Process criteria:* refer to the actions or decisions taken by clinical operators, such as prescriptions for orthoses or aids, medical or surgical therapies, diagnostic investigations. A typical process criterion is represented, for example, by the proportion of patients with flat feet of the 3rd degree who access surgical treatment.

*Outcome criteria:* typically refer to the response obtained from a treatment, the state of health, patient satisfaction. An example of an outcome criterion could be the statement that the metatarsalgia that persists in flat feet in patients who have been prescribed an orthotic should not exceed 2%.

In particular, the process and outcome criteria are of relevance in the evaluation of clinical performance.

The criteria for evaluating clinical performance are the explanation of the methods of instrumental evaluation that should be carried out in specific clinical circumstances and / or for certain categories of patients. A practical example of an evaluation criterion could be: "Morton-type podalgia patients, evaluated with baropodometry, should undergo conservative treatment through the use of orthotics or physical or surgical therapy? Do patients with movement disorder, for example M. di Parkinson who undergo stabilometry and gait analysis, have to undergo instrumental control (analysis of indicators) after neuromotor rehabilitation treatment?"

This recalls the link between guidelines and quality assessment of digitized biometric instrumental analysis.

Accurate guidelines would constitute an explanation of forecasting criteria, applicable not only to guide future clinical behaviors, but also, retrospectively, to evaluate the rules of care provided to individuals or groups of patients.

The criteria of instrumental value should refer to measurable / quantifiable aspects and therefore translatable into indicators (quali-quantitative) which represent the measure of the degree of disability, then distinguishable from the indicators of structure, process and outcome.

### **Assessment criteria requirements**

- Reflect the available scientific knowledge acquired (evidence-based)
- Be shared (for example transposed by guidelines)
- Be relevant to the welfare aspects that you intend to evaluate

Be translatable into indicators that meet the following characteristics:

- measurable in a reproducible way (inter and intra detectors)
- accurate, that is, detected in ways that ensure that the indicator actually measures the phenomenon that was intended to be assessed, with a sensitivity and specificity that correctly discriminates between good and bad quality assistance, minimizing false positives and false negatives;

- sensitive to change, that is, able to detect changes in the phenomenon measured over time and in space (ie between different subjects);
- easy to understand
- simple and inexpensive to detect

### **Definition of indicators**

The indicators should respond to some essential requirements that connote their validity from the tools that allowed their detection.

The indicator must discriminate between false positives and false negatives. There is a conceptual and operational link between evaluation criteria, performance indicators and guidelines. As illustrated in the figure, corresponding evaluation criteria and performance indicators can derive from the recommendations contained in the guidelines.

The guidelines define the recommended clinical behaviors and therefore an address for the clinical decisions that will have to be adopted in specific circumstances, the corresponding evaluation criteria represent the retrospective application of these recommendations in the evaluation of the therapeutic processes actually provided to individual patients.

In this sense, performance indicators represent the measurement of the frequency with which the evaluation criteria were actually applied to a sample of patients.

The link between guidelines, evaluation criteria and performance indicators is further described by the example below.

**Tab. 1** Control of the improvement of the half-step length in parkinson patients: guidelines, evaluation criteria and performance indicators.

<p><b>Guidelines:</b> the patient with M. di Parkinson should be evaluated and subjected to the measurement of the length of the half-step before the neuromotor rehabilitation treatment and at the end of the treatment</p> <p><b>Evaluation criterion:</b> The patient was evaluated before treatment and at the end of the rehabilitation treatment</p> <p><b>Indicator:</b> increase, decrease, no change in the length of the half-step</p>
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Adapted from "Training manual for clinical governance: monitoring of clinical performance, December 2012" Ministry of Health DEPARTMENT OF THE NATIONAL HEALTH SERVICE PROGRAMMING AND ORDERING DIRECTORATE-GENERAL FOR HEALTH PLANNING Office III ex DG.PROG.

### **The choice of indicators**

Deciding which indicators to use, i.e. choosing what to measure and how, is a critical aspect, since the measures of the indicators must make it possible to formulate an explicit judgment on the quality of the assistance provided.

Therefore, in choosing the indicators, the following considerations should be kept in mind:

#### **• number of indicators**

The adoption of too limited a number of indicators exposes the risk of offering an excessively simplified reading of a reality such as that of the quality of movement analysis which which, as multidimensional, is complex and articulated. On the other hand, an excessively large number of indicators exposes the risk of creating confusion and making the analysis and critical reading of disability much more complex.

To allow a synthetic reading of the quality, so-called composite indicators are used today, which represent a synthesis of different measures. However, composite indicators pose particularly complex conceptual and statistical problems and can hamper, rather than facilitate, interpretation.

Therefore, there is no criterion that allows to define, a priori, what is the "right number" of indicators to be adopted, but from time to time, a critical reflection will be needed that identifies the appropriate number of measures, chosen among those endowed of the technical requirements of validity previously stated, functional to describe the dimensions of the quality deemed of interest.

#### • **type of indicators**

Among the classes of indicators are mainly those of process and outcome to be called into question in the context of the evaluation of clinical performance.

The process measures directly measure the assistance provided to the patient and are therefore a more direct and immediate indicator of what has actually been done. They generally have a greater sensitivity to change, being representative of clinical decisions taken in the management of specific categories of patients. In addition, they are generally easier to assign, as they make it clear which professional or which team is responsible for the measured activity and pose the problem of risk adjustment in less relevant terms than it does for outcome results. On the other hand, they have the disadvantage of requiring information that is often difficult to retrieve for their collection, if not directly using the medical record.

The outcome indicators have the undoubted merit of directly highlighting the results obtained, and are typically represented by the mortality resulting from specific procedures.

The attribution may not be simple, especially in those circumstances in which the clinical outcome of a service can be legitimately attributed not only to those who physically performed it, but to a set of services that contribute to the identification and selection of patients.

Their application is problematic in contexts where mortality is not an appropriate result indicator and where the effects of health interventions have an expected impact not so much or not only on the vital state, but above all on other relevant aspects, such as for example functional recovery (prognosis quoad valetudinem) or other dimensions related to quality of life, whose routine and systematic detection is more difficult than ever. In this regard it is interesting, for its potential developments, the English experience of detection of PROMs (patient reported outcome measures), outcome measures detected through questionnaires administered to patients before and after the execution of specific surgical interventions whose quality is not it is detectable in terms of mortality, but rather for their impact on quality of life aspects, such as hip replacement operations. As noted in the experimentation conducted in England, their application presupposes the consolidation in the clinical contexts of robust organizational skills capable of bearing the burdens of a systematic collection of data of this type.

### **Indicators**

The indicators are variable concerning the object to be observed. They allow the formulation of a judgment. They can be selected based on hypotheses, values, objectives set and used to describe, evaluate and predict.

They must be useful for reading, interpreting reality. Facilitating forecasts, planning treatments, making diagnoses, making decisions. Their quality (relevance, specificity, sensitivity, ease of detection, decision-making utility) is related to the context in which they are used.

Variables are entities that can assume different values both from a quantitative and qualitative point of view. The term value indicates a constitutive character of a style, which in our case must be not very similar to the subjective estimate, but must confer precise meaning and function. Quality concerning aspects of reality, arouses classifications, various judgments on intrinsic or extrinsic characteristics of the object under study.

A quantitative value can be expressed directly from an integer or not.

A qualitative value allows to detect aspects of reality that have intrinsic or extrinsic characteristics and that rise to constitutive characters of a style, meaning, function and are subject to subjective estimate.

We can distinguish dependent variables (whose value depends on the effects of other variables) from independent variables (which cause an effect on another, called employee).

In summary, an indicator is a synthetic measure, generally expressed in quantitative form, coinciding with a variable or composed of several variables, capable of summarizing the trend of the phenomenon to which it refers. The indicator is not the phenomenon, but represents and summarizes the behavior of the most complex phenomenon that we need to monitor and evaluate.

In allowing an evaluation judgment, through the indicators we can reach the clinic of:

- **over time assessments.** The so-called time series or remote controls over time of various parameters such as the length of the step, the distance between the steps, the time of support or double support
- **cross section assessments.** As happens for example in benchmarking where there is a comparison with good practices
- **conformity assessment,** with respect to a defined objective, for example the control of a footbed in which the values of the surface and load are assessed with and without the aid.

The two main dimensions of evaluation are effectiveness and efficiency.

External efficacy is understood as the relationship between products (output: biometric examination reports and therapeutic indications) and results (outcome or remote controls), so evaluating external efficacy means analyzing the consequences of therapeutic prescription on the problem intervention or disability.

In external effectiveness, the outcome indicators are the measures related to the modification of the behavior of the beneficiaries. For example, in the case of balance disorders, the number of subjects who have agreed to perform the exercises daily to prevent the degree of instability

The impact indicators instead measure how much the activities performed in the physiotherapy gym have actually influenced the modification of the imbalance, for example the reduction in the number of falls in the subject.

Internal effectiveness is understood as the relationship between products (output: how many exams I have done in a certain period of time) and promoters' objectives (waiting lists, improvement of the health of patients).

The indicators of internal efficacy and / or of project realization refer to the rules for transforming inputs into outputs, and therefore to the direct effects of the biometrics laboratory interventions on the patient's disability.

Therefore efficacy as a product indicator is given by the number of diagnoses carried out which lead to a result indicator, i.e. the number of patients who have used the stick, or the Coldivilla spring, or the orthotics and lead as an impact indicator to a reduction of disability.

Efficiency, on the other hand, is the relationship between resources used (inputs, appropriate type of tests) and products (outputs, exact clinical diagnoses), so its evaluation implies an analysis of the technical-production process and the management of production factors.

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