

Evaluation of the Effectiveness of Health Care Services: One of the Foundations of Patient Safety

La evaluación de la efectividad de los servicios de salud, uno de los sustentos de la seguridad del paciente

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The provision of quality health care services and work oriented toward patient safety constitute a current demand in medical care. As part of this provision, it is important to understand how effective the procedures or health care services received are. Achieving patient safety is the responsibility of institutions and work teams, and it is systemic rather than individual.¹

Articles have been published on determining the effectiveness of health care services.²⁻⁵ Some of them analyze a before-and-after scenario following the implementation of the evaluated procedure or strategy; however, very few assess effectiveness as the result of measuring indicators, which can even be formulated and expressed as a percentage value.⁶

There is growing interest in determining effectiveness in healthcare; however, there is a need to strengthen the research culture in this area, as such studies involve complex research resources and mixed paradigms (quantitative and qualitative).⁷

The concepts of efficacy, efficiency, and effectiveness are well established. In a Colombian publication on research tools, these concepts are clearly defined as follows:⁸

Efficacy: the degree to which the objectives and goals of a plan are achieved; that is, how much of the expected results were attained. Efficacy involves focusing efforts on the activities and processes that must be carried out to meet the established objectives.

Efficiency: the achievement of an objective at the lowest possible unit cost. It implies optimal use of available resources to achieve the desired outcomes.

Effectiveness: this concept encompasses both efficacy and efficiency; that is, achieving planned results at the most reasonable cost. It implies doing the right things accurately and without wasting time or resources.

Regarding effectiveness in healthcare, this concept ultimately refers to the degree to which an intervention, service, process, procedure, diagnostic test, or treatment produces the desired outcome; hence the importance of its evaluation. The concept of effectiveness also

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includes the appropriateness of care delivery, insofar as it is delivered to individuals who may benefit from it. Additionally, it requires the selection of measurable indicators representing priority areas for improvement in specific population groups, with defined cutoff values depending on the aspect being evaluated.⁶

An indicator is an observable qualitative or quantitative expression that allows the description of characteristics, behaviors, or phenomena of reality through the evolution of a variable or the establishment of relationships between variables. Indicators serve to simplify information, measure and establish reference values, and communicate changes or variations relative to an initial situation.⁹

Methods for evaluating the quality of health-care can be applied to three basic elements of the system: structure, process, and outcomes, from which corresponding indicators are derived. Structural indicators measure the quality of the setting in which services are provided and the state of the resources available; process indicators directly or indirectly measure the quality of activities carried out during patient care; and outcome indicators measure effectiveness, determining the level of success achieved in the patient, that is, whether the intended results of care were achieved.¹⁰

There are indicators used by health care systems worldwide that are common and generalizable¹¹. However, certain specific procedures, interventions, or strategies require evaluation for which no predefined indicators exist; these must be constructed, which is often a complex process involving both qualitative and quantitative methods. Among qualitative methods, expert opinion and consensus—along with measures of agreement and variance—are prominent, as well as focus groups and brainstorming. Quantitative methods include mathematical formulas, percentages, Pareto diagrams or other prioritization methods, and the determination of standards and cutoff points, often based on percentile distributions. To compare both approaches is essential.^{9,10}

Generally, structural and process indicators are already assumed in these studies and are not required to determine effectiveness. However, outcome indicators are essential and may require classification according to the process being evaluated. For example, in the case of a surgical technique for reconstructing the anterior chest wall following significant tissue loss due to infection or tumor excision, indicators should be classified into: clinical outcome measures; anatomical outcome or secure closure; functional outcome; lethality; cosmetic outcome (referring to aesthetic appearance and

the absence of major deformities); and any other deemed relevant.

Determining effectiveness requires research in health care systems and services. These studies focus on analyzing decision-making processes, planning, utilization of health care services, and quality improvement. They are essential for assessing safety, efficacy, effectiveness, and cost analyses to achieve better outcomes. Typically, they are conducted prior to the implementation of processes and evaluate their potential effectiveness, accessibility, and infrastructure costs.^{12,13}

However, health technology assessment (HTA) studies are particularly valuable, as they determine the effectiveness of procedures, interventions, or healthcare processes after implementation, enabling the establishment of recommendations to improve quality and patient safety. These studies involve evaluating safety and efficacy, especially in terms of the presence or absence of adverse events, complications, and lethality. HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different stages of its life cycle. When patients are informed in advance about the effectiveness of a procedure or intervention, they can provide informed consent without hesitation.^{14,15}

The term technology refers to medications, procedures, devices, or medical equipment. The evaluation of procedures as a form of soft technology is particularly complex, both in the construction of indicators and in comparison with alternatives addressing the same health problem.^{14,15}

To initiate research leading to evaluation, a PICO question (Population, Intervention, Comparator, Outcome) must be formulated, guiding evidence search and assessment.¹⁵

The most common types of studies used to evaluate different health technologies are: randomized clinical trials, analytical cohort studies or case-control studies, experimental studies, and meta-analyses.¹⁵

As part of effectiveness assessment, safety, efficacy, utility, and impact are also evaluated. A technology can be assessed at different stages: experimental (before implementation), development (pilot implementation), application or generalization (after full implementation), and decline (when becoming obsolete and potentially replaceable). In many of these phases, expert judgment is used; they may also be carried out through clinical trials, descriptive or analytical observational studies.

The determination of the effectiveness of surgical procedures or techniques is particularly

challenging and often controversial. In principle, any technique that has been described and introduced into practice is assumed to have undergone prior evaluation and proven effective for treating the condition it was designed to address. However, new techniques are often developed and described, whose effectiveness must be established through comparative evaluation, whenever ethically permissible. Some techniques undergo modifications, improvements, or refinements, and users need to be informed of their effectiveness; it is the responsibility of their developers to demonstrate and justify it.

Nevertheless, direct comparison with other techniques is not always feasible. In some cases, there are no reference standards, or the technique is merely an alternative, or it is not ethical to expose a group of individuals to both techniques for comparison. Furthermore, certain modifications are intended to expand the applicability of a procedure to patients who do not meet the criteria for existing techniques. For these reasons, the development of specific indicators tailored to the surgical procedure, along with the calculation of effectiveness expressed as a percentage, represents the most appropriate approach.

The recommended formula is:¹⁶

$$\text{Effectiveness (\%)} = \frac{\text{positive indicators} \cdot 100}{\text{total number of indicators}}$$

The total number of indicators includes all those calculated according to expected outcomes.

In surgical techniques, indicators typically include complications, adverse events, lethality, hospital stay, anatomical results, functional outcomes, and cosmetic outcomes, among others. These indicators are determined according to the specific characteristics of the procedure, the anatomical structure involved, the target patient population, and, when applicable, the equipment used, infrastructure, and associated costs.

Positive indicators are defined as those observed in more than 75% of patients; that is, those achieving the expected outcome in over 75% of the sample. Exceptions include lethality, the presence of complications, and length of hospital stay, for which lower values indicate a favorable result. In general, these thresholds correspond to the 75th percentile, which is commonly used as the cutoff value.

Thus, the sum of positive indicators multiplied by 100 and divided by the total number of evaluated indicators, yields a percentage expressing the effectiveness of the procedure under assessment.

A procedure, intervention, health care service, or health care process with high effectiveness ($\geq 75\%$) provides a foundation for patient safety in clinical care. Evaluations equal to or greater than 75% are considered adequate. However, depending on the aspect being assessed, other standards may be applied at the discretion of experts.¹⁶

Patient safety is defined as the deliberate effort to prevent harm caused by healthcare itself. It is an essential condition for the performance of any clinical activity.¹⁷

Patient safety is defined as the absence of preventable harm to patients and the reduction, to an acceptable minimum, of the risk of causing them unnecessary harm during the provision of care.¹⁸

Among the most important aspects of patient safety is the reporting and understanding of the incidence of adverse events. In the development of indicators to assess the effectiveness of a procedure, process, or intervention, particular emphasis is placed on the presence or absence of adverse events, as previously noted. These include complications, adverse reactions, and mortality; therefore, the assessment of effectiveness inherently incorporates patient safety considerations and represents a critical step in harm prevention.

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