The identification and validation of process and outcome indicators: reflections on the experience of the Agency for the Italian Regional Health System (ASSR)

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Summary

Objectives. To identify, experiment and validate a set of process and outcome indicators, based on administrative data, for measuring, comparing, and improving quality of hospital performance within a research project coordinated by the ASSR and developed with the collaboration of six Italian regions.

Materials and Methods. Bibliographical search, in Medline and Internet, to collect Italian and foreign experiences. Field evaluation of quality of data routinely collected, sample evaluations of completeness and quality of clinical records, computations of indicators identified by the Agency for Healthcare Research and Quality (AHRQ).

Results. Definition of a minimal set of sustainable, evidence-based, first- and second-level indicators. Adaptation of AHRQ SAS-software to Italian "Hospital Admission Records" (SDO). Production, validation, and implementation of dedicated software in ASP language.

Conclusions. Evidence-based outcome indicators of hospital performances are applied worldwide. The Diagnosis-Related Groups (DRGs) and the All Patient Refined DRG (APR-DRG) classification systems, based on administrative data, can be used for the risk stratification of patients, and to control for confounding variables. Indicators are suitable for quality screening and monitoring purposes. More research has to be done before indicators can be used in ranking, by quality, health providers, and in offering consumers advice to help them make the best choices. Given the complexity and intricacy of an increasingly specialised and fragmented system of healthcare for treating chronic diseases, through a sequence of acute episodes, indicators of continuity of care, taking into account health life events and the healthcare network, are needed, calling for new concepts and new methods (event history analysis, net analysis).

KEY WORDS: *indicators, conceptual framework, health system outcome indicators, healthcare evaluation.*

Introduction

Quality of healthcare delivery is a topic of major concern. Articles examining findings regarding shortcomings in care or differences between areas and institutions have become more and more frequent. Efforts to improve quality of care measurement, developing appropriate quality indicators, have increased in the current literature, with particular attention being paid to the methodological aspects and the conceptual framework (1, 2).

The purpose of our project was to define and to experiment a set of indicators to raise questions about the quality of healthcare across Italian regions, indicators that should be used for investigating differences: why they exist, and what can be done to reduce them.

One common reason why estimates based on indicators of health system performance can differ is the variability of the quality of data, be it in the collecting, analysing, or reporting stage. Therefore the study also aimed to evaluate the quality of data collected in different areas.

Since 1995, when DRGs (Diagnosis-Related Groups) were introduced for billing purposes in Italy, interest in evaluating the efficiency and effectiveness of the national health service, using process and outcome indicators, has increased. This development has led to the availability of information useful for appraising the effectiveness of health service performance and the quality of its "products". The evaluation process, which involved mainly hospitals, started from the classic indicators, like average length of stay, saturation index, or index of turnover, highlighting efficiency, and ended with a more complete appraisal of quality in terms of outcomes (3, 4).

Using the DRGs classification system for risk stratification of patients, it was possible to compute risk-adjusted outcome indicators. Several studies have stressed the importance of adjusting for severity of illness when comparing quality of healthcare between hospitals (case-mix bias). Since hospital statistics on inpatient episodes do not include detailed data on clinical severity, it becomes mandatory to standardise for primary diagnosis and to use measures of comorbidity, based on discharge diagnoses.

The Agency for the Italian Regional Health System (ASSR) research resulted in the raising of methodological issues and the production of software to ensure implementation of the quality evaluation tools, based on routinely collected data, in all healthcare services (regional agencies, local health authorities, healthcare providers).

This availability of information met the requirements for appraising healthcare quality, in spite of concern that the pressing need to reduce health service costs carried the risk of a deterioration of the quality of the services. The need of providers to purchase good quality services in a market context, together with the consumers' increasing sense of their right to good quality healthcare, also boosted interest in quality evaluation.

Various national and regional rules have recently introduced numerous indicators, mainly aimed at shedding light on economic aspects such as costs, charac-teristics of the offer, accessibility, and organisational aspects of the services. Few indicators were designed to appraise service effectiveness in terms of outcomes. Besides, while many institutional initiatives set out measure health activities, very few have aimed to evaluate the accuracy, reliability, and sustainability of the indicators.

Since 2002, the ASSR has been tackling the problem of the definition of a set of such indicators and, in collaboration with six Italian regions, designed a study financed by the Italian Ministry of Health aimed at identifying experiences and validating a set of indicators. The role of the academic component of the research group was to help develop the methodological aspects, particularly taking into account the potential confounders in comparing entities' performances.

Different performance indicators have been proposed for the comparison of the quality of healthcare provided by health authorities, because: 'Data and facts are not like pebbles on a beach, waiting to be picked up and collected. They can only be perceived and measured through an underlying theoretical and conceptual framework, which defines relevant facts, and distinguishes them from background noise' (5).

Indeed, many authors have been developing conceptual frameworks for monitoring, measuring, and managing the performance of the health systems, to ensure effectiveness, equity, efficiency, and quality. Health systems are expected to achieve and manage results in line with established objectives and quality standards. A famous statement attributed to Florence Nightingale captures the performance-quality-management relationship: 'The ultimate goal is to manage quality. But you cannot manage it until you have a way to measure it' (6).

This implies that the indicators must capture a variety of health and health system-related trends and factors, requiring first of all an operational definition of quality, since they are in essence a quantitative measure of quality. Various stakeholders in the health sector hope that performance indicators will provide meaningful data for making decisions, steering health systems, and selecting good health providers.

The aims of the ASSR project were:

– to define the concepts underlying the performance framework for health systems;
– to explore the effectiveness of different entities from various regions;

– to see how and in what context the resultant performance data can be used to drive improvement.

The starting point is: what concepts, or dimensions, of quality of healthcare should be measured, and how, in principle, should they be measured?

On the question of what dimensions of quality to measure, it was decided to follow the conceptual frameworks already developed in a number of countries.

On the question of how, in principle, quality should be measured, we decided that the indicator set should contain both process and outcome measures.

Moreover, the selection of indicators should be driven by three main criteria:

– the relevance of what is being measured;
– the scientific soundness of the measurement;
– the feasibility or minimum cost of obtaining data.

It was envisaged that the indicators ultimately recommended for inclusion in the set would be scientifically sound, important at clinical and policy level, and based on routinely collected data. It was also envisaged that the indicators would not enable any judgement to be made on the overall performance of health providers. They should be used only for investigating differences, should these exist (screening purpose), and for suggesting what can be done to reduce the existing differences.

The project was divided into different phases.

Identification of indicators

The identification of the indicators resulted from a selection process based on scientific and institutional documentation that included the following steps:

a) bibliographical search in MEDLINE;
b) a review of international experiences (mainly web-based);
c) a review of national experiences (in the regions taking part in the project).

The bibliographical search produced certainly biased results, due to the selection of documents coming mainly from the English-speaking world. However, the impact of this bias is likely to be modest, in relation to the development of the hospital indicators, given that in the context of in-hospital activities, optimal procedures do not differ from one health system to another. The impact of this sort of selection

bias would, instead, be more important in relation to the evaluation of out-of-hospital health activities, where the differences among health systems certainly have a greater impact. In this case the bibliographical search was completed with exploration of the grey zone in the web, the aim being to discover important local experiences.

In particular, evidence was collected on different critical aspects, namely:

a) Defining case selection criteria. In the literature it is reported that errors in case identification can invalidate the outcome indicators (7). This is certainly the main cause of lack of validity of the quality evaluation when this is used as a means of comparison of different institutional entities.

b) Choosing risk adjustment procedures. To control for confounders, different patient classification approaches are available, used to consider the clinical complexity, influencing both length of stay in hospital (costs) and clinical outcome. The various classification systems are more or less oriented towards one of the two aims, evaluating costs or evaluating severity of disease. In any case, they can be used in order to generate an acceptable number of predictive variables (each with a limited number of categories) to be included in models of multiple, linear or logistic regression (8-13).

c) Using administrative databases. The bibliographical review revealed that outcome research based on administrative databases has been characterised by two periods: an optimistic one, lasting from 1970 until 1990, during which a multitude of studies used databases for outcome research (14, 15), and a sceptical one, starting with the publication of a document (16) by the Office of Assessment Technology (1994) that criticised the use of the database for effectiveness evaluation. Currently a critical attitude prevails, with indicators derived from administrative data seen to play a limited role in "screening" and monitoring (17).

d) Using original clinical records. A huge body of literature favours the use of this informative instrument to compute process indicators, oriented towards the practice of evidence-based medicine. Indicators of this sort certainly play a complementary role in evaluating hospital quality of care and they are useful for interpreting the results of outcome indicators, based on administrative data (11).

e) Managing the clinical risk (hospital care adverse events and disease complications). This is an interesting development in health information system application. Preventable adverse events are a leading cause of death in USA. They exceed the number attributable to motor vehicle accidents, breast cancer or AIDS. To tackle such an epidemic, we need incidence measurements and identification of determinants (18). In this context there has been an unexpected development of the capacity to measure the phenomena using administrative data (19, 20). In this context, too, knowledge of the organisational and institutional setting is necessary in order to take corrective action: in the absence of this knowledge, information on adverse events can be misleading and produce highly undesired effects.

f) Presenting results. The debate on this issue is mainly focused on using confidence intervals and the procedures for calculating them, on choosing reference standards, on using control charts, and on interpreting the outcome-volumes relationship (21-23). The treatment of random variability is critical, considering that a quality indicator is currently computed as a complement of random variability and of variability explained by covariates considered in the regression model (24-26).

Considering the evidence on quality indicators in the literature, the following selection criteria for the indicators to be used in the project have been defined:
– "Evidence-based": giving priority to the indicators demonstrated to provide information on effectiveness.
– Based on a sound rationale and an algorithmic definition for data extraction and computation.
– Availability of the computation software, in order to guarantee their implementation by the units involved in the project.
– Availability of a severity score system for dealing with differences in the importance of cases admitted by different entities (to deal with the case-mix problem).
– Flexibility: taking into account the possibility of modifying the structure of the indicators over time.
– Continuously supported and evaluated by an accredited official health agency.

Following these criteria, the set of indicators of the Agency for Healthcare Research and Quality (AHRQ: http://www.qualityindicators.ahrq.gov) was chosen as main the reference (first-level indicators). These indicators are completely based on administrative data, are used for the screening of quality problems and for the monitoring of activities, and are supported for maintenance purposes by the Agency. A second-level set of indicators was also defined, based on more informative sources, mainly original clinical records, following the Joint Commission on Accreditation of Healthcare Organisations (JCAHCO) model, suggested by the Centres for Medicare & Medicaid Services (CMS, formerly HCFA).

Data validation

a) Quality control of the data extracted from the Hospital Discharge Records (SDO). Every region sends data on in-hospital admissions to the Ministry of the Health using a uniform format (SDO), but in practice the quality of these data is highly heterogeneous, necessitating correction or integration of data by the regional database managers. The check of quality of data was done:
– by applying an automatic control for coding errors (a procedure aimed at giving the probability of each kind of error as a consequence of the variability of the coding procedure among regions and hospitals);
– by extracting and evaluating a random sample of clinical records, to estimate coding errors directly.
b) A random sample of clinical records was also used for extracting data in order to compute the second-level indicators, with the aim of analysing clinical procedures (process indicators) for validating first-level indicators and as a means of clinical risk management.
c) A sample control of the completeness and the quality of clinical records in different regions and hospitals was also performed.

Computation of indicators

The AHRQ website gives free access to three software packages that, after adaptation to the format of the Italian SDO, make it possible to calculate three kinds of indicators: Inpatient Quality Indicators (IQIs), based on mortality for given clinical conditions, post-surgery mortality, volumes of activity, ap-

propriateness indicators; Patient Safety Indicators (PSIs), designed to measure the quality of care involved in preventing adverse events; Preventive Quality Indicators (PQIs), useful for evaluating outpatient quality of care, and mainly involved in preventing undue hospital admissions o re-admissions. The AHRQ software requires the availability of licensed software (SAS or SPSS), but, as a product of the research, a translation of the software into ASP language has been done. Recently AHRQ, too, has developed a specific set of indicators oriented for paediatric procedures and new software operating in the Windows operating system, using a reduced patient classification system and a specific predictive model.

Validation of indicators

The first-level indicators are defined by ICD9-CM codes. The analysis of the frequency distributions of the codes effectively used made it possible to carry out an empirical validation and to describe the variability among regions and among hospitals within regions. The usual outcome indicators, based mainly on mortality (post-operative mortality), volumes of activity, and appropriateness, proved to be robust to coding problems; instead, the sensitivity of the indicators oriented towards clinical risk evaluation (disease complications and adverse events) depended on the local context. They were found to be more informative only in the context of a more structured and complex risk management organisation.
A further validation was done based on clinicians' expertise, asking specialist panels to evaluate the first- and second-level indicators in terms of face and construct validity.

Interpretation of results

The indicators adopted were risk adjusted and their computation included 95% confidence limits. The risk stratification of patients was carried out using the APR-DRG classification system. Obviously the model makes it possible, at least partially, to control for the effect of the main confounding variables, linked to the severity of disease, but not to control for the effect of classification errors, due to systematic

causes such as voluntary discharges from hospitals, in pre-terminal conditions, influencing systematically mortality comparisons among regions. The effect of this particular phenomenon was evaluated through random samples of clinical records of discharged patients within each region.
These validity considerations, together with those implied by the limits of an observational rather than an experimental approach, suggest that confidence intervals should be used just as a measure of precision, rather than as a statistical significance tool. This approach is in agreement with the use of the first-level indicators as a screening tool. In terms of monitoring, an interesting development in the field would be a greater use of control charts, describing the time trend of quality of care within each health provider.

Further developments

At the beginning the outcome research was completely oriented towards the evaluation of hospital care, because of the greater reliability of the hospital information sources, and also considering the resources devoted to hospital functioning. In this context the evaluation is easier, given that, the world over, clinicians (in theory at least) refer to the same evidence when deciding a good practice. From this point of view there must be no meaningful differences among geographical areas. The professionals involved in hospital activities all over the world share practical guidelines for the treatment and diagnosis of the same diseases. Therefore it is relatively easy to transfer a set of good practice indicators from one health system to another, with limited implementation difficulties.
The situation is different in the context of the evaluation of out-of-hospital health activities. In this case the definition of a set of indicators is subordinated to the peculiar characteristics of the various health systems, considering the priorities of each system and of each institution. A conceptual framework oriented towards the European system was defined through the European Community Health Indicators (ECHI) (1) project , supported by the European Union, which aimed to improve homogeneity between European countries' health information systems by:

- developing comparable measures in the EU public health area;
- defining a sustainable, minimum, shared set of health indicators;
- indicating priorities for the development of a European information system;
- defining guidelines for public reporting at international, national and local level;
- defining a common reference standard for health information systems;
- defining the European reference context for monitoring public health programmes.

ECHI defines the following as criteria for a good set of indicators:

- comprehensiveness: the set must be complete, including indicators for monitoring all aspects of public health quality;
- consistency: coherence of any indicator with the accepted conceptual framework;
- flexibility: to take into account the heterogeneity of European health policies and the differences between the objectives of different countries, allowing, over time, modifications to health policies;
- coherence with the indicators previously used by WHO-Europe, OECD, Eurostat and with the scientific evidence.

Given this conceptual and institutional framework, the Italian Agency (ASSR) promoted an extension of the project, also considering indicators for out-of-hospital health activities. This extended project was concluded in September 2006, and produced a minimum set of common indicators, designed to quantify inappropriate admission to hospital as a measure of lack of quality in the provision of outpatient care.

The most important methodological result of this extension was the finding that it is possible to define a common set of indicators in the description of territorial activities, as well, even though the institutional variability among regions, in Italy, is no less than that among European countries.

Two sorts of indicators have been identified: those specific to the single database (outpatient activities, drug prescriptions, vaccinations, psychiatric care), which do not present methodological problems different from those already discussed, and those that make it possible to track individual experiences of care, necessitating linkage between different databases. In the second case two different problems exist: the availability of effective record linkage instruments, and the different quality of the different databases involved.

In general it can be said that databases of good quality, mainly as far as the variable "linkage" or "blocking" is concerned, allow the use of a deterministic approach to record linkage. When these "good quality" conditions are not met, a more time-consuming, probabilistic approach to record linkage is needed.

Considering a complete individual history of care, as opposed to a single episode of care, places the question of quality evaluation in a new light, where it must be seen from the perspective of the continuity of care, implied by two apparently antithetical approaches, called "Disease Management" and "Clinical Governance". In Europe (within the United Kingdom's NHS to be precise), the concept of "Clinical Governance" was first defined as an organisational and institutional approach to continuous quality improvement, to endorse clinical excellence in healthcare. Similarly, in the US, "Disease Management" has been developed essentially to control health system costs.

Disease Management and Clinical Governance converge on one particular dimension of the continuity of care: so-called managerial continuity. Currently, the conceptual definition of continuity of care has three different, not independent, dimensions: managerial, relational, and informational (27). A further important theoretical aspect of the continuity of care approach is the application of the "network" paradigm to the healthcare system. The world-wide development of the Internet and the need to study this new entity, induced different researchers to carry out research on the web, defining a conceptual framework that can be applied whenever we have to investigate an entity defined by links and nodes, exchanging information and self-structuring.

In the Italian national health system, the evaluation of an individual history of care, integrating different episodes of care, received by the same patient from different providers, based on an integrated informative approach, is now seen as a priority for evaluating the quality of the system as a whole. The information system can support the computation of this new sort of indicator, exploring the continuity of care as a value.

As in the case of the more traditional health indica-

tors, we have to start from a well-defined conceptual framework, including relational continuity and informational continuity with management continuity.

Relational continuity presupposes good communication between patients and providers, implying specific training in communicating within the care system. To this end there is a need for communication channels and procedures, and as far as specific indicators are concerned, we can hypothesise two different approaches to this aspect:

1) the first one based on the measurement of certain characteristics of the relations, which are decided among the subjects participating in the management of the patient, using concepts and measures defined within the general theory of networks;

2) the second one based on measuring variation of indicators of managerial continuity, after an intervention aimed at improving communication and the quality of human relations among health operators and between operators and patients.

Informational continuity has to do with the informative content of the communication among the nodes of the network. As far as this aspect of continuity of care is concerned, an interesting development is promised by the possibility of evaluating the current information flow, using automated procedures for evaluating, for informative content, the text of the traditional means of communication between professionals and means of patient-doctor communication, such as the hospital discharge letter.

The availability of electronic archives can facilitate the extraction of texts of letters, diagnostic protocols, laboratory data, and so on, that can be submitted to automated analysis. This analysis can also be used to validate the diagnosis, and to uncover adverse events and complications.

From the bibliographical review, international experiences documented on the Internet, suggest two approaches to the evaluation of text quality:

1) an "a priori" approach, based on the identification of strings of characters, meaningful in specific clinical conditions and for specific links between nodes of the care network, aimed at comparing the clinical documentation with a reference standard defined in terms of measures of "semantic distance";

2) an "empirical" approach, based on a procedure of "data mining", starting from the frequency distri-

bution analysis of specific morphemes, to be interpreted.

The continuity of care, in its managerial, informational, and relational aspects, is the focus of an ongoing project coordinated by the ASSR.

Conclusions

The ASSR experience (http://www.assr.it/monitor/supplementi/supplementi_monitor.htm) produced some results now available for all the Italian regions through the ASSR website:

– a set of process and outcome indicators, evaluating quality of hospital activities;

– software for computing first-level indicators, based on administrative databases, and for record linkage;

– a shared methodology, and common instruments, for analysing clinical records and computing second-level indicators, allowing process analysis within hospitals;

– the development and the validation of a common methodology for quality control of clinical and administrative data.

The next step calls for the identification of the specific needs of various stakeholders, interested in the different kinds of information and messages: first the Ministry of Health, regional offices, local health authorities (being responsible for planning and financing, these are more interested in efficiency); hospitals, care and research institutes, professional orders, and individual professionals (being healthcare providers, these are more interested in effectiveness, based on the best evidence); consumers, interested in receiving good quality of care.

The different messages could concern:

a) descriptions of outcome variability, useful for planning and for the economic boosting and sanctioning of providers (if it is possible to define a sensible reference standard, and if such mechanisms are shown to be useful);

b) the distance of every subject (region, hospital, professional) from the benchmark (where one exists), in order to stimulate improvement in quality;

c) the information given to customers, based on robust indicators, to favour informed choice.

A critical point that deserves particular attention is the effectiveness of the programming mechanisms

based on economic boosting and sanctioning. Health indicators, particularly those based on administrative data, are useful for screening purposes and for monitoring, but very rarely are they robust enough to be used as a basis for "rewards and punishments".

Another point that deserves attention is the information supplied to the single customer. There is, in fact, evidence in the scientific literature that such information, even if the best methods of risk adjustment are applied, can be completely misleading. Furthermore, the customers often prefer the advice of their trusted expert, like their general practitioner, and tend to ignore information structured within some system of indicators.

At present the most appropriate use of indicators is within the continuous quality improvement cycle, stimulating direct participation in the discussion of results, and involvement in their interpretation and use in order to identify critical points in health processes. At this stage, the increasing availability of data for computing every sort of indicator calls for the gathering of more evidence on the effectiveness of their different uses.

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