Audit Methodologies in Pandemic Clinic Alert: What is the Real Assurance for the Patient?

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This paper analyzes the factors that explain the increased use of special reports by hospital facility auditors, such as the formalization of the clinical pandemic template Covid-19, wondering if they look like evaluation studies. It examines their training as well as their impact as well as the institutional use implicit in the performance audit. From an anthropological perspective, the audit could traditionally be considered as "Rituals of Verification", recognizing the procedure and the evaluation have social effects, in public management. In addition, auditing practices may often seem "trivial, inevitable part of a bureaucratic process", but taken together and over time, they are probably part of a distinct cultural artifact. Like the audit, the performance assessment function is to allow for accountability, but there is also an emphasis on collective learning. The audit is therefore an essential part of the assessment in hospital management, contributing to the realization of financial responsibility, guaranteed the institutional legitimacy of the managerial decision-making system.

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Keywords: Clinical Audit, Clinical Governance, Infections on a Global Scale Covid-19, Special Reports and Health Investigations.

First submission: 24/05/2021, accepted: 10/09/2021

S O M M A R I O

1. Introduction

The topic of performance management in clinical audit is particular relevant in the private sector as well as in the public sector. The relevance of the efficiency and, as a consequence, the interest about the performance management in the public sector, has been highlighted by the New Public Management. Starting from 1980', public organizations started to put more attention to the performance management and evaluation. In the performance management literature, the debate about the topic of performance measurement and evaluation is particular glowing, and we can find many different ways to define it. Neely *et al.* (1995, p. 9), comment that: "Performance measurement is a topic often discussed but rarely defined".
These were:

- "Performance measurement can be defined as the process of quantify-

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

ing the efficiency and effectiveness of action."
- "A performance measure can be defined as a metric used to quantify the efficiency and/or effectiveness of action."
- "A performance measurement system can be defined as the set of metrics used to quantify both the efficiency and effectiveness of actions."

The problem is that defining performance is extremely complex and, with specific reference to the previous definition, the limit is that it doesn't labeled the concept of performance measurement in the literature and in practice. Starting from the definition, it is possible to underline some fundamental features of performance, which explain the complexity of this concept (Guthrie & English, 1997; Van Dooren, Bouckaer & Halligan, 2010): the subjectivity and the multidimensionality within the concept of performance (Ricci & Civitillo, 2016). The subjectivity is connected to the fact that every level of performance depends on a combination of different variables: actors involved, policies and programs. The multidimensionality of performance in public sector refers to the need for a methodology characterized by an integration of economic variables with technical indicators, strategic and operative needs. Despite these critical aspects, it is fundamental to underline the main role of the measurement of performance in clinical audit.

The reasons that justify the activation of a clinical audit can be numerous: patient complaints, occurrence of adverse events such as the case of COVID-19 (de Nichilo, 2021), performance with inadequate results, publication of new guidelines; however, the "bet" is that in the future, the awareness that auditing is an irreplaceable part of professional practice will mature among professionals.

The success of the clinical audit depends on an accurate and technically rigorous design, on the involvement of all interested parties, including the strategic direction and on an adequate and widespread dissemination of the results and improvement actions identified, in order to promote professional growth and the transfer of national and international experiences.

The Italian Ministry of Health, in line with international guidelines on improving the quality of the services provided and in accordance with the principles of clinical governance, has developed a system of procedures on clinical audit, in which the method is presented, described in didactic form, but rigorous, in order to spread its use among health professionals (Al-Assaf, 1992).

This research work is the result of the consolidated and fruitful collaboration between the Italian Ministry of Health and the Italian representative bodies of health professionals. In fact, the collaboration with the National Federation of Orders of Surgeons and Dentists (NFOSD), the National Federation of Nursing Colleges (NFNC) and the Federation of Italian Pharmacists Orders (FIPO) has made it possible to create documents and training courses on the topic of quality and care safety, such as the Safe course, the Pharmaceutical care safety course and the Root Cause Analysis (RCA) course (ANAES, 2003).

This work is part of this process, which develops the various phases of a clinical audit and offers healthcare profession-

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

als an opportunity to engage, with expert professionals, in a method aimed at improving the quality of care, acquiring knowledge and skills, promoting the culture of quality and safety and creating a climate of trust among professionals (Baker & Fraser, 1997).
In view of the advantages offered, its application should be encouraged at local, regional and national level through the methods deemed most suitable such as training, also in the field and inclusion in the budget objectives (Mendez & Bactler, 2011). It is therefore desirable that the Italian Regions and P.A. include, among the guidelines to be provided to the General Managers of the healthcare structures and to the institutional representatives of the healthcare professions, the systematic and continuous use of the clinical audit in order to develop the ability to evaluate, innovate and respond, compared to a reality in con-

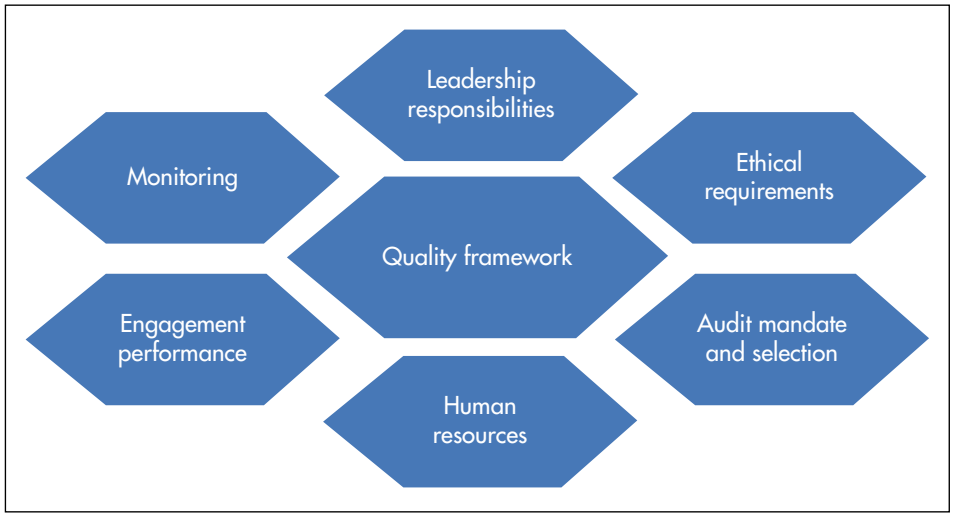

Figure 1
Clinical Assurance Organization Setting
Source: Our Elaboration

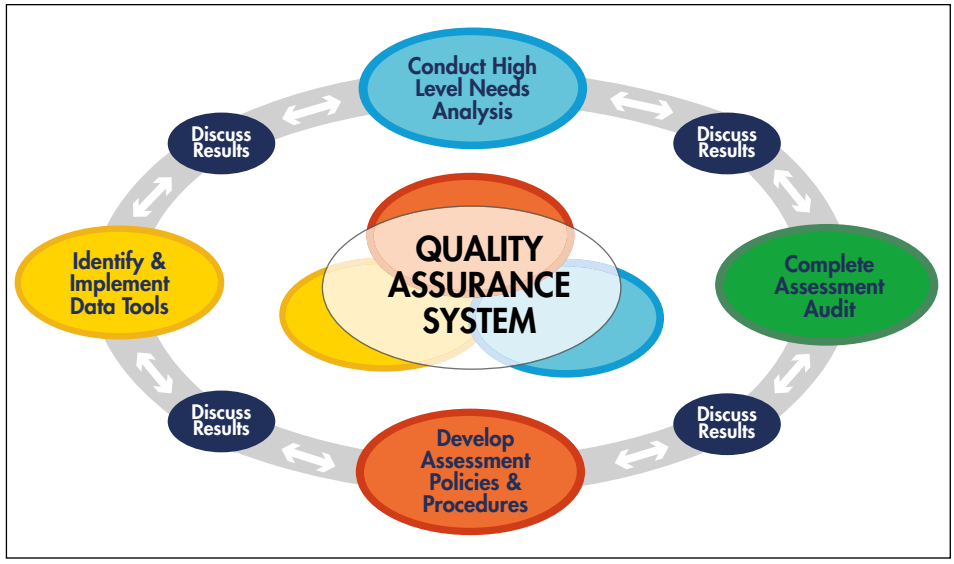

Figure 2
Role of team member
Source: Our Elaboration

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

tinuous change, to the expectations of patients and professionals (Geddes della Filicaia, 2008). The clinical audit is universally recognized as an important tool of "Clinical Governance" and its continuous and systematic use must be promoted in all areas of the National Healthcare Services NHS (1999) as it represents one of the most appropriate methods for assessing the degree of adherence of the activity clinical practice to best available practices and ensure high standards of care (Grol & Wensing, 1995).

2. Methodology

The research looks at the way organizational performance is defined and measured by Italian healthcare organizations. The data collection methods include document analysis and semi-structured interviews with key informants. To investigate the ways in which the healthcare organizations define organizational performance and measure it, we performed an in-depth analysis of the content of the documents prepared by a sample of Italian public healthcare organizations.
Content analysis is a research method that "classifies textual material, reducing it to more relevant, manageable bits of data" (Weber, 1990, p. 5). In particular, we used an inductive approach, starting with data and then creating specific categories that can explain the general phenomena. The qualitative data were organized with the process of "open coding" according to which notes and headings were written in the text while reading it. Only after this analysis were the categories created. The analyzed documents include the following: the evaluation system, the performance plan, and the performance report. Each of these documents has specific functions, and it is important to consider all of them in the analysis. The evaluation system sets the guidelines by which performance at both individual and organizational levels is measured and evaluated. The performance plan shows what performance dimensions, objectives, and indicators have been selected, consistent with the evaluation model defined by the system. The performance report provides evidence of the results achieved and of the way the performance measurement process worked.
The "Clinical Audit Charter" is presented below, a decalogue in which the key aspects for the appropriate "road map" of the audit are focused (Power, 2015).

1. General framework (Figure 1).
It specifies the general lines of the clinical audit, the objectives, the challenges, the risks, the areas and the action plan in the process of improving the quality of the structure (Benjamin, 2008).

2. Decision-making power (Figure 3).
The operating margins and the decisions to be taken are defined and must be validated by the company management (Bovenga, 2008).

3. Role of team members (Figure 2).
The role and responsibilities of the leader and each member of the group and the relationships within the group are defined (Bowie, McCoy, McKay & Lough, 2005).

4. Conduct of the clinical audit (Table 4).
The participatory management method is defined, based on the mobilization of skills, on the trust and responsibility of each one (Bowie & Pringle, 2008).

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

5. Monitoring (Table 4).
The timing, tools and methods of monitoring are programmed by the leader in collaboration with the group (Burnett & Winyard, 1998).

6. Accessibility of information (Table 4).
The information necessary for carrying out the pre-established activities is made available to the members of the group, according to defined methods (Buttery, Walshe & Rumsey, 1995).

7. Confidentiality (Table 1).
Anyone involved in the audit must be aware of the confidentiality rules according to current legislation (Chassin, Brook, Part RE, Keesey, Fink & Kosecoff, 1986).

8. Communication (Table 2).
Communication is structured both within and outside the group. Internal communication must encourage participation, adherence to activities and motivation of professionals (Coles, 1989).

9. The resources (Table 3).
The necessary resources are material (spaces and tools) and human. It is necessary to inform the management and the heads of the departments/ departments about the participants and the time commitment required (Cinotti & Cartabellotta, 2000).

10. The rules of behavior (Table 4).
The activities must be carried out according to specific behavioral requirements and in compliance with the requests (compliance with deadlines, adherence to the corporate mission, conflicts of interest) (Collins, Lewis, Flynn, Emmans, Myers & Wilson, 2005).

Current data mainly provide information on outcomes, while process information is rather scarce and not very reliable and, since process indicators are the most frequently used in clinical audit, it is necessary to pay particular attention to the interpretation of quantitative data, especially when comparing different structures (benchmarking).
Quantitative data can also be collected ad hoc, using both the prospective and retrospective approach, while keeping in mind the limits of both types of study.
In the event of insufficient quantitative data, especially for the choice of process indicators, it may be useful to resort to qualitative assessments. This can be advantageous to highlight, through the narration of the professionals with respect to their experience, the dimension of the gap between the practice and the standard, as well as the critical issues with respect to organizational problems. For this purpose, detection tools such as short questionnaires can be used, to be administered to all the professionals involved, including those who are not part of the working group.
The systematization of the collection of quantitative data must be carried out with the help of tables that show the source (e.g. SDO, CEDAP, Cancer Registry, etc.) alongside each criterion identified and the corresponding numerical data.
With regard to qualitative data, obtained through short questionnaires and interviews or investigation with professionals, the collection and systematization of these must be carried out with the help of grids, or matrices that report the formulation of each criterion drawn up in the affirmative and the answer. This is very often binary (yes / no, present / absent), but it can also be in the form of free text. In addition, a space must be provided for any comments and annotations.

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

Figure 3
Risk Assessment Matrix
Source: Our Elaboration

RISK MATRIX				
IMPACT	HIGH	MEDIUM Significant	HIGH Significant	HIGH Significant
	MEDIUM	LOW Not significant	MEDIUM Significant	HIGH Significant
	LOW	LOW Not significant	LOW Not significant	MEDIUM Significant
		LOW	MEDIUM	HIGH
	LIKELIHOOD			

The data collected during the audit can therefore be available in three different forms: "tick-box", or box in which to click to select the object, free or numerical text.
The grids must be accompanied by a guide to compilation and it may be appropriate, in advance, an adequate preparation of those who have responsibility for data collection; in addition, during the collection, it is necessary to verify the completeness of the compilation of the grid and its completeness in order to make any changes.

3. Results

Below is a case study relating to the verification of COVID-19 swabs (tampon) from April to May of 2020 in a Italian hospitals group in Lombardy region (Milan) consisting in a investigation of twenty structures (Babu, 2001). Suppose we want to check a sample of debt for swabs whose total balance is equal to 1,426,000 euros and that we have an investigation size of 100,000 euros. Based on our knowledge, we have judged the average inherent risk (IR = 65%) and, based on the internal control tests, we have decided to rely on "MEDIUM" internal control (= average control risk CR = 65%) in relation to the existence claim. We also carried out comparative analysis procedures (so-called analytical review), believing that there are no anomalous deviations in the balances relating to the debts on the pads and therefore justified as a "SOFT" risk by other verification procedures (DR_1 = 25%). By solving the formula DR_2 = AR / (IR * CR * DR_1), a 47% risk of detection from other procedures is obtained, therefore the confidence level is equal to 53% (1-47%) to which it corresponds, as seen above, a confidence factor of 0.75 (Baatz, 1992). For convenience we report the counts for thousand euros.

Table 1 – Confidence level standard parameters

Confidence level	Confidence factor
50%	0.7
55%	0.8
60%	0.9
65%	1.1
70%	1.2
75%	1.4
80%	1.6
85%	1.9
90%	2.3
95%	3

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

The monetary selection interval will be equal to:
Performance Materiality / Confidence Factor = 100 / 0.75 = 134.2
The sample size will be equal to:
Population / Monetary range = 1,426.00 / 134.2 = 11
The first element chosen on a random basis is 111 thousand euros, the next one corresponds to the balance containing the cumulative amount of 245.21 thousand euros (= 111 + 134.2), the third corresponds to the balance containing the cumulative amount of 379.43 thousand euros (= 245.21 + 134.2) is so on until all 11 elements have been selected.

Performance Materiality ("PM")	100
Audit Risk ("AR")	5%
Inherent Risk ("IR")	65% MEDIUM
Control Risk ("CR")	65% MEDIUM
Detection Risk Comparative analysis ("DR_1")	25% SOFT
Detection Risk Other validity procedures ("DR_2")	47%
Overall Confidence	53%
Confidence factor	0.75
Selection range ("I")	134.21
Random Start	111.00
Swabs Debt Balance (Population)	1,426.00
Sample size = (Population / I)	11

The use of statistical sampling methods allows errors to be projected on the overall value of the population from which the sample was extracted, in order to estimate the likely error on the aforementioned population.
We take the sample selected in the previous example and assume that we have found the following differentials between book value and ascertained value, for three hospitals structures.
Once the error has been projected on the entire population, it will be possi-

Table 2 – Error analysis: quali-quantitative evidence of clinical sampling

Hospital	Accounting value	Ascertained value	Delta	Error %
Alpha	69	40	–29	–42%
Beta	89	65	–24	–27%
Gamma	49	54	5	10.2%

Sum of error	–59%	Good	8
Sum% Error / Sample size	–5.34%	Bad	3
		Total Sampled	11
Projected error = –5.34% * Population	–76.2	No Sampled	9

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

Table 3 – Risk Assessment Matrix

Analysis of the effectiveness of the tampon.

	No damage	Slight damage	Average damage	Serious damage	Death
Frequent				1	1
Likely					1
Occasional	5	1	1		
Remote	1				

	Acceptable risk – monitoring operations
	Low risk – programming operations
	Medium risk – emergency operations
	High risk – emergency operations

ble to formulate a statistical conclusion on the entire population. In particular, if the probable error is lower than the acceptable error level, the account or the set of accounts can be considered correct; if, on the other hand, the probable error is higher than the acceptable error level, the account or the set of accounts must be considered incorrect. In our case the projected error is less than materiality and therefore we can conclude that the account under investigation is not materially incorrect.

4. Conclusion

This paper aims to provide an analysis of the organizational performance in Italian public health care sector in COVID-19 pandemic alert. In particular, this analysis started from the

Table 4 – Scale for estimating the probability of COVID-19 occurrence and severity of the damage. Source: Italian Ministry of Health in first quarterly of 2020

Clinic Audit Alert Issues Matrix for Covid-19.

Probability of occurrence of the error mode	Probability range
Remote	Less than 0,3%
Occasional	0,3% – 7%
Likely	7% – 14%
Frequent	Above 14%

Italian Covid-19 Hospital Guideline.

No damage	The error did not result in any damage or only made it necessary to monitor the patient more closely.
Mild	The error caused temporary damage to the patient and made additional treatments or interventions necessary, or led to an extension of the hospital stay above the specific average value.
Middle	The error caused temporary damage to the patient and made it necessary to start or extend the stay.
Serious	The error either caused permanent damage to the patient or resulted in an event close to death.
Death	Death of the patient.

MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865

respect of the normative that imposes some public documents for all public organizations. The second step focus on the real way in which public health care organizations measure their organizational performance, with an in deep studies of the organizational performance systems used and the principal influencer factors. The last one wants to considerer not only the organizational performance, but also the possible connections between expenditure and performance in a particular sector as the public health care sector.
In particular, the results of the study suggest a view that performance management in the Italian Healthcare sector is poorly defined and less than effective. The reason why this happens is partially connected to a theoretical explanation: the intrinsic complexity of the healthcare sector makes a standardized performance measurement system more difficult to be defined. At the same time, the lack of a standardized performance measurement system at national level, badly influenced the measurement process and its effective.
In fact, what is emerged is that there are some cases where the systems work, but in other cases not. The presence of a standardized system should solve the problem of an over-reliance on the individual competences, and should improve the effective of all the systems.
Another interesting result which improve the relevance of the contribution of this analysis, is the almost complete absence of a connection between the variation in expenditure and the healthcare performance. This means that there are other factors that influence the healthcare performance, first of all the individual management competences.
Addressing the problem of clinical risk organically will allow to answer many important questions: how many accidents happened, how many could be avoided and were the consequence of a "human error", how many were unpredictable and inevitable?
But why do medical errors occur? The predisposing factors for the occurrence of adverse events are mainly the following: staff shortage, staff fatigue, communication errors, work-related stress, overcrowding of hospital wards, excessive workload for staff, non-application of guidelines/company procedures/protocols, deficiencies in the healthcare facility.
Healthcare facilities, especially hospitals, have long been said to be dangerous places for patients: many of them suffer from the side effects caused by the medical treatments they have undergone. Some of the iatrogenic lesions are due to errors, therefore they are potentially avoidable.
The clinical risk is precisely the possibility of suffering damage as a result of an error.
Patients and healthcare professionals need to combine their efforts to prevent adverse events, redesign care processes and make a complex system like healthcare safer for everyone.
Addressing the problem of clinical risk organically will allow you to answer many important questions: how many accidents happened, how many could be avoided and were the consequence of a "human error", how many were unpredictable and inevitable?
But why do medical errors occur? The predisposing factors for the occurrence of adverse events are mainly the following: staff shortage, staff fatigue, communication errors, work-related stress, overcrowding of hospital wards, excessive workload for staff, non-ap-

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plication of guidelines/company procedures/protocols, deficiencies in the healthcare facility.

As we have seen, the reasons that justify the activation of a clinical audit can be numerous: patient complaints, occurrence of adverse events such as the case of COVID-19, performance with inadequate results, publication of new guidelines; however the "bet" is that in the future the awareness that auditing is an irreplaceable part of professional practice will mature among professionals.

The success of the clinical audit depends on an accurate and technically rigorous design, on the involvement of all interested parties, including strategic direction and on an adequate and widespread dissemination of the results and improvement actions identified, in order to promote professional growth and the transfer of national and international experiences (de Nichilo, 2019b).

We have seen that the sampling method, if correctly applied, allows to obtain reasonable certainty that a balance sheet balance has been correctly represented without incurring the cost of verifying all the findings that make it up. Therefore sampling represents an effective and efficient tool for carrying out the statutory audit activity in the healthcare facilities where the COVID-19 virus is treated. The use of the sampling method must also be considered in other areas, such as in verifying the veracity of company data required in the report that certifies "the truthfulness of the company data and the feasibility of the emergency plan (de Nichilo, 2019a)". In any case, it will be necessary to formalize the methodology used in the work papers in order to make clear the level of investigation carried out and the scope of the conclusions reached.

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MECOSAN – ISSN 1121-6921, ISSNe 2384-8804, 2022, 121 DOI: 10.3280/mesa2022-121oa13865