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QUALITY OF CARE BETWEEN DONABEDIAN MODEL AND ISO9001V2008

Abstract: *The Healthcare institutions, like every organization offering a product or service, must meet the requirements of its customer “Patient” by being sensitive to his needs and his requests. Therefore, it was necessary that this system adopts the culture of measurement and implements an evaluation process in order to improve the quality of care and the services delivered to the “Patient”.*

The objective of this paper consists in studying the compatibility between the DONABEDIAN model “specific model to healthcare institutions” and the ISO9001v2008 model “generic model applicable to all types of organizations”. First of all, the paper explains the approach of each model to the assessment and improvement of quality, then it presents the different correspondences between the two models, and at the end it shows the conformity rate of DONABEDIAN model indicators to the ISO9001v2008 model.

This study aims to demonstrate the potentiality of DONABEDIAN model, considered as a reference in the field of healthcare quality, to be adapted with the ISO9001v2008 model, requiring the implementation of “Quality Management System” based on the principle of continuous quality improvement.

Keywords: *ISO 9001v, 2008, DONABEDIAN Model, Quality of care, quality of service, continuous quality improvement, Healthcare institution*

1. Introduction

ISO 9001v2008 is an International standard which specifies the required elements to establish a Quality Management System and to improve it continuously. It is designed to help organizations satisfying their customers by offering to them a high quality product or service.

ISO 9001v2008 was essentially adopted by Industries; nevertheless it is a generic

standard which applies to all kinds of organizations: public administrations, tourism and education.

In Healthcare, this standard could be the starting point towards Quality Management (Heuvel, 2006), taking into consideration all the challenges that healthcare institutions have to face due to their poorly designed processes (Bell, 2010).

The concept of Healthcare quality was defined by Avedis DONABEDIAN in his model: Structure-Process-Outcomes. This Model was universally accepted and has been widely used in the literature especially

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for the development of quality standards.

In a global context where ISO 9001V2008 is considered as a qualifying tool for competitiveness in the International market and for customer satisfaction, how could ISO9001v2008 help a Healthcare institution satisfying its customers (Patients) and improving its processes' performance? What would be the contribution of this generic standard to a model used specifically in healthcare such as the DONABEDIAN Model?

This study aims to identify the specific organizational and technical requirements with which should comply health institutions in order to provide high quality of care and services to their customers "Patients".

2. Material and methods

1) Background:

The ISO 9001 standard has been the subject of several studies of compatibility and comparisons with other models designed for different areas:

- A study of the relationship between ISO 9001 and six sigma (Mouse, 2004) demonstrated the complementarity between them and the contribution of the six sigma to ISO 9001.
- A study of the possibility of implementing QMS "Quality Management System" in presence of SMS "Safety Management System" adopted by shipping companies (EL Ayadi *et al.*, 2007). This study demonstrated the similarity between the requirements of the two models which facilitates the ISO 9001 certification.
- A study of compatibility between ISO 9001 and the method named "Automaîtrise" (Sebaai and Lamrini, 2009) showed that the implementation of this method contributes to the success of ISO 9001 implementation and its sustainability.
- A comparative study between ISO 9000 certification and the certification of

Home care structures (Benbachouch *et al.*, 2009) to demonstrate the similarities and differences between the two types of certification.

- A study of compatibility between ISO 9001v2008 and a specific quality standard for higher education such as the Code of Practice of Quality Assurance Agency for Higher Education. (El Abbadi *et al.*, 2011).

On the basis of the important results of the studies of compatibility between ISO 9001 and other models adopted in different fields, we considered that the confrontation between a healthcare specific model (the DONABEDIAN Model) and a generic model designed for all types of institutions (ISO 9001 v 2008), would reveal the opportunities, presented by both of the Models, to improve the quality of care and services in healthcare Institutions taking into consideration their specific requirements and characteristics.

2) Models overview

a) The ISO 9001v2008 Standard

(Lamprecht, 1992; Mullan, 2001)

ISO 9001 was prepared by Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC2, Quality Systems. This edition was prepared in order to complement the ISO 9004:2000: "Managing for the sustained success of an organization -- A quality management approach". It clarifies some points of the previous edition (ISO9001v2000) and enhances the compatibility with ISO 14001:2004: "Environmental management systems - Requirements with guidance for use".

ISO 9001v2008 specifies requirements for a Quality Management System in an organization which:

- a) Needs to demonstrate its ability to consistently provide product that meets customer's needs and comply with applicable statutory and regulatory requirements.

b) Aims to increase customer satisfaction through efficient application of the system, including processes for continuous improvement of the system and to insure compliance with customer and applicable statutory and regulatory requirements.

ISO 9001v2008 has 8 clauses, the first three clauses are introductive and the last five clauses are presented as below:

- Clause 4: Quality Management System.
- Clause 5: Management Responsibility.

- Clause 6: Resource Management.
- Clause 7: Product Realization.
- Clause 8: Measurement, analysis and improvement.

This International Standard promotes the adoption of a process approach and applies the methodology known as PDCA “Plan, Do, Check, Act”.

The model of process-based quality management system proposed by the ISO9001v2008 is presented in Figure 1.

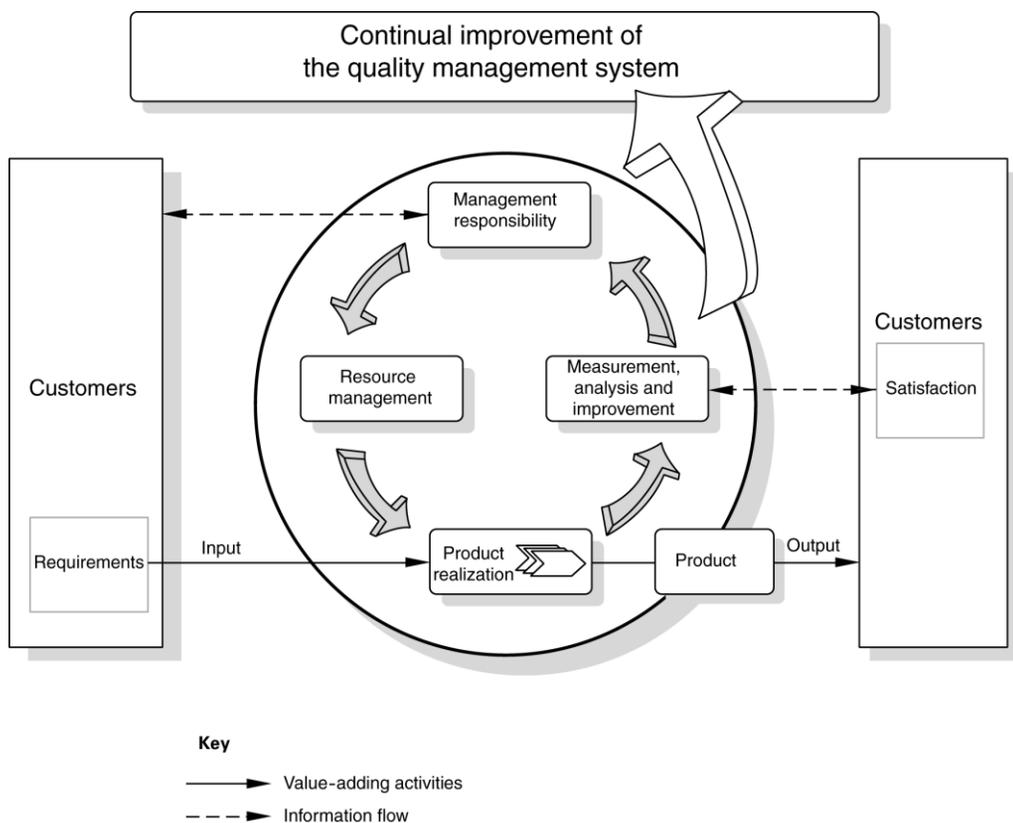


Figure 1. Model of a process-based Quality Management System (Mullan, 2001)

Since ISO 9001v2008 is a generic standard which is not specific to health care institutions, we used the IWA 1 v 2005: Systems Quality management - Guidelines for process improvements in health services organizations. The ISO International Organization for Standardization” published

this document as an International Workshop Agreement “IWA 1” at a workshop organized by different organizations. The IWA1v2005 is the second edition of IWA 1 which cancels and replaces the first edition (IWA 1v 2001). The IWA 1:2005 helped us to understand the characteristics of the

implementation of a QMS “Quality Management System” in a healthcare Institution and made the correspondence between the Model of ISO9001v2008 and the DONABEDIAN model easier (International Workshop Agreement, 2005).

b) DONABEDIAN Model:

The model proposed by Avedis DONABEDIAN has been a widely accepted method to design the main dimensions of healthcare quality (Bureau régional de l’Europe de l’organisation Mondiale de la santé, 1998; Kelley and Hurst, 2006; Mullan, 2001).

DONABEDIAN has defined a conceptual and multidimensional framework of Healthcare quality which is frequently used (Jlassi *et al.*, 2007). He has assumed that the measurement of Healthcare quality should be based on three components: Structure, Process and Outcomes (Ammenwerth *et al.*, 2007; Bahrami *et al.*, Jlassi *et al.*, 2007; Kelley and Hurst, 2006; Kunkel *et al.*, 2007) and that each component has a direct influence on the next one: (Committee on Redesigning Health Insurance Performance Measures, Payment, and Performance Improvement Programs, 2006).



Figure 2. DONABEDIAN Model (Committee on Redesigning Health Insurance Performance Measures, Payment, and Performance Improvement Programs, 2006)

1) Structure: (Rjeb, 2003; DONABEDIAN, 1997; The National Roundtable on Health Care Quality, 1999; Garnerin, 2001)

The Component “Structure” refers to relatively static characteristics of the personnel who provides care and of the settings where the care is delivered. These characteristics include for:

- Personnel: education, training, experience and certification.
- The settings where the care is provided: the adequacy of the facility’s staffing, equipment, safety devices, and overall organization.

2) Process: (Rjeb, 2003; DONABEDIAN, 1997; The National Roundtable on Health Care Quality, 1999; Garnerin, 2001)

The Component “Process” denotes all the activities taking place during the delivery of care to the patients (diagnosis, prescription...). It concerns the way in which care is delivered according to two

further aspects:

- The technical aspect: it refers to the application of current medical science and technology in an attempt to maximize the balance between benefits and risks. This aspect concerns the timeliness and accuracy of diagnosis, the appropriateness of therapy, complications and incidents that may occur during treatment and coordination between the various stages of the care delivery and between different disciplines involved (The National Roundtable on Health Care Quality, 1999; Ransom *et al.*, 2005)
- The Interpersonal aspect related to the clinician-patient relationship: it refers to the rules and standards regulating all human interactions, to the ethical standards specific to health and to the patients expectations (information, answering questions, asking about their preferences, involvement in taking decisions) (The National Roundtable on Health Care Quality, 1999; Ransom *et al.*, 2005). The Interpersonal

relationship is also important because it affects the technical performance (DONABEDIAN, 1988).

When evaluating the quality of care and services in Health Institution in terms of Process, it is useful to distinguish two aspects on which quality can vary: (Ransom *et al.*, 2005):

- Appropriateness: which refers to whether the right actions were taken.
- Skill: that is, how well actions were carried out.

3) Outcomes: (Agence Nationale d'Accréditation et d'Evaluation en santé, 2002; Rjeb, 2005; DONABEDIAN, 1997; The National Roundtable on Health Care Quality, 1999; Garnerin, 2001)

Quality of care can be assessed in terms of Outcome measures, which seek to capture whether the goals of care were achieved (Ransom *et al.*, 2005). It includes apart from the health-status indicators, other indicators

related to the cost of care and Patient satisfaction.

In fact, Health-status Indicators are divided into:

- Indicators of intermediate outcomes: which refer to the activity and quality of the process steps such as : the rate of operating site infection, immunization rate, percentage of unplanned readmission, the failure rate.
- Indicators of final outcomes: which refer to the to the effect of the provision of care in terms of health (quality of life, disability, death, complications...), and the presence of good events or absence of bad events expressed in terms of quality of life, and in clinical and physiological terms.

The measuring Indicators of the DONABEDIAN model components are listed in the Table 1: (Bureau régional de l'Europe de l'organisation Mondiale de la santé, 1998).

Table 1. Quality of care Indicators (Bureau régional de l'Europe de l'organisation Mondiale de la santé, 1998)

Structure Indicators	Process Indicators	Outcomes Indicators
Financial Resources	Preventive care	Health Status
Personnel	Diagnosis	Outcomes of delivered and preventive care
Equipments	Therapeutic care	Patients well-being
Facilities	Rehabilitation	Patient Satisfaction
Information system	Information and Instruction of the patient	Good use of resources

1) Study of compatibility between the ISO 9001v2008 and the DONABEDIAN model

The study of compatibility consists on:

- Corresponding between the components of the DONABEDIAN model and the requirements of ISO 9001v2008 clauses.
- Calculating the conformity rate of DONABEDIAN model to ISO 9001v2008 by using the method named "SAMI" based on four levels of

evaluation (S: Satisfactory, A: Acceptable, M: Medium, and I: Insufficient) (El Ayadi, 2007).

a) Correspondence between the two models: DONABEDIAN and ISO 9001v2008

The Correspondence between the two models is based on the comparison between measuring indicators of the DONABEDIAN model components with the requirements of

ISO 9001v2008 clauses.
Some changes have been introduced to the table 1 “Quality of care Indicators” in order

to facilitate the graphical representation in the correspondence Table 2.

Table 2. Classification of Quality of care Indicators

S	Structure Indicators	P	Process Indicators	R	Outcomes Indicators
S.1	Financial Resources	P.1	Preventive care	R.1	Health Status
S.2	Personnel	P.2	Diagnosis	R.2	Outcomes of delivered and preventive care
S.3	Equipments	P.3	Therapeutic care	R.3	Patients well-being
S.4	Facilities	P.4	Rehabilitation	R.4	Patient Satisfaction
S.5	Information system	P.5	Information and Instruction of the patient	R.5	Good use of resources

b) Calculation of compliance DONABEDIAN to ISO 9001v2008

The conformity rate of DONABEDIAN model components to ISO 9001v2008 clauses was calculated by using the method

named “SAMI” (Table 3). This method consists on classifying the observations into four levels of evaluation: S: Satisfactory, A: Acceptable, M: Medium, and I: Insufficient. (El Ayadi, 2007).

Table 3. Evaluation by SAMI method (El Ayadi, 2007)

	Appreciation	Note	Definition and justification
Non-Significant difference felt by the customer.	Satisfactory (Conformity)	4	Good Control of Quality Management elements. -No differences. -Adequate Formalism
	Acceptable (Observation)	3	-Good control of Quality Management elements. -Discrepancy of Formalism leading to minor differences
Significant difference felt by the customer	Medium (Minor non-conformity)	2	-Some mistakes in controlling quality management elements. -Risk of difference with limited consequences.
	Insufficient (Major non conformity)	1	-Out of control: Major differences leading to serious consequences at the customer level

The average conformity rate is calculated according to the following formula:

$$100 * \left(\frac{\sum N_i}{\sum N_{mi}} \right)$$

with:

N_i : The total score of the clause.

N_{mi} : the maximum score of the clause.

Example of calculation: We'll suppose that the Clause 4 has 14 Key concepts which are according to the diagnosis distributed as below: 5 concepts are "Conformities", 4 concepts are "Observations", 3 concepts are "Minor non-conformities" and 2 are "major non-conformity".

The total score of the clause is $\sum Ni = (5 \times 4) + (4 \times 3) + (3 \times 2) + (2 \times 1) = 40$.

The conformity rate of this clause is calculated by dividing the obtained score $\sum Ni = 40$ by the maximum score of the clause $\sum Nmi = 56$ [14 (key concepts) \times 4 (note for conformity) = 56].

So the average conformity rate is $= (100 \times 40) / 56 = 71.42\%$.

Results:

1) Correspondence between DONABEDIAN model indicators and the requirements of ISO 9001v2008

The study of DONABEDIAN Model Indicators and the ISO 9001v2008 requirements permitted to establish the correspondence between the two models and the results are represented in table 4. The presence of correspondence between DONABEDIAN Model and ISO 9001v2008 is indicated by a gray Box, and the absence of correspondence is indicated by a white box.

According to the correspondence between the two models: DONABEDIAN model and ISO 9001 v 2008, it was noted that:

- All measuring indicators of the DONABEDIAN model have correspondents in ISO9001v2008.
- All requirements given in the ISO 9001v2008 clauses below have no correspondents in the DONABEDIAN Model:
 - 5.1 "Management Commitment".
 - 5.6 "Management Review".
 - 7.6 "Control of monitoring equipment and measurement"
 - 8.5 "Improvement".

- Some requirements given in the ISO 9001v2008 clauses below have no correspondents in the DONABEDIAN model:

- 5.5 "Responsibility and Authority": The requirements of 5.5.2 "Management Representative" and 5.5.3 "Internal Communication" have no correspondents in the DONABEDIAN Model.

2) Conformity rate of DONABEDIAN Model to ISO 9001v2008:

The calculation of Conformity rate of DONABEDIAN Model to ISO9001v2008 consisted on assessing each measuring Indicator of the DONABEDIAN model components, against each requirement of the ISO 9001v2008 Clauses by using the method "SAMI".

Conformity rates of the DONABEDIAN model to ISO9001v2008 clauses are represented in the Figure 3 below:

- 72.82% of the requirements given in the clause 4: "Quality Management system" of ISO 9001v2008 were met by DONABEDIAN Model.
- 50% of the requirements given in clause 5: "Management's Responsibility" of ISO 9001v2008 were met by DONABEDIAN Model.
- 95.83% of the requirements given in clause 6: "Resource Management" were met by DONABEDIAN Model.
- 57.69% of the requirements given in clause 7: "Product Realization" of ISO 9001v2008 were met by DONABEDIAN Model.
- 71.05% of the requirements given in clause 8: "Measurement, Analysis and Improvement" of the ISO 9001v2008 were met by the DONABEDIAN Model.

The average conformity rate of the DONABEDIAN model to ISO 9001 v 2008 is 61.90%.

Table 3. Correspondence between components of DONABEDIAN Model and ISO9001v2008 clauses

	Structure Indicators					Process Indicators					Outcomes Indicators					
	S1	S2	S3	S4	S5	P1	P2	P3	P4	P5	R1	R2	R3	R4	R5	
4. Quality Management System	General requirements															
	Documentation requirements															
5. Management responsibility	Management commitment															
	Customer Focus															
	Quality Policy															
	Planning															
	Responsibility, authority and communication															
6. Resource management	Management review															
	Provision of resources															
	Human resources															
	Infrastructure															
	Work environment															
7. Product realization	Planning of product realization															
	Customer related processes															
	Design and development															
	Purchasing															
	Production and service provision															
8. Measurement, analysis and improvement	Control of monitoring and measuring equipment															
	General															
	Monitoring and measurement															
	Control of nonconforming product															
	Analysis of Data															
Improvement																

ISO 9001v2008

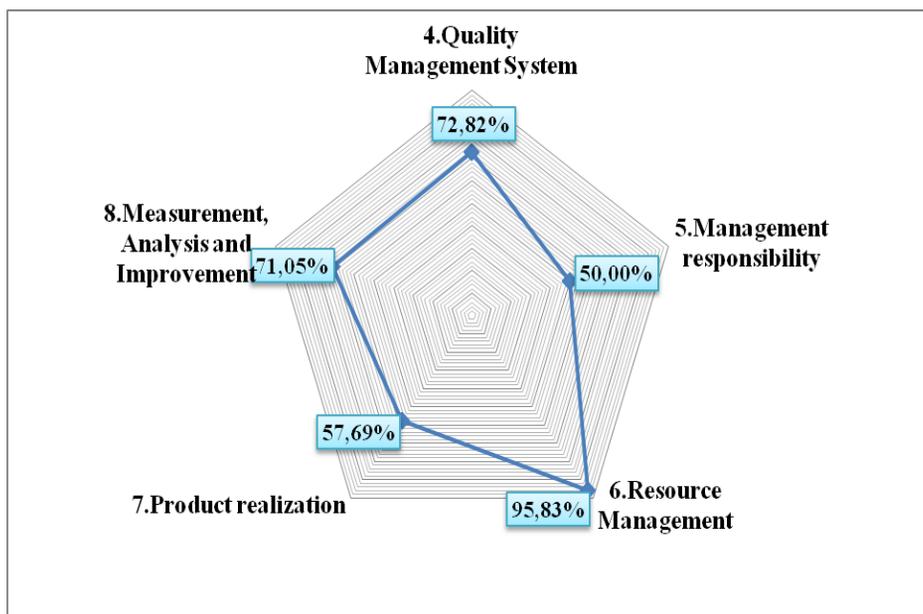


Figure 3. Conformity rate of the DONABEDIAN model to ISO9001v2008 clauses

4. Discussion

Our study was carried out in order to analyze the points of resemblance and discrepancy between the DONABEDIAN model and the ISO 9001v2008 Model. We have evaluated the correspondence between the two models and then calculated the conformity rate of the DONABEDIAN model to ISO9001v2008 model by using the method named “SAMI”. The objective of this analysis consisted in identifying the specific organizational and technical requirements with which health institutions should comply in order to provide high quality of care and services to their customers “Patients”.

The DONABEDIAN model and the 9001v2008, promote Resource Management, the measurement of performance and process effectiveness, the measurement of customers’ satisfaction and how much information they are getting. Both models aim to reduce costs while providing high quality of care and services to the “Patients” (DONABEDIAN, 2003; Ransom et al., 2005; Committee on Redesigning Health

Insurance Performance Measures, Payment, and Performance Improvement Programs, 2006).

DONABEDIAN model assumes that the component “Process” include all related activities to patient’s treatment. So, this model only defines a process which could be called "treatment-Process”, whereas ISO 9001v2008 is based on a “Process Approach" which consists in identifying all the organization’s processes, the interactions between them and ensuring their control and their management in order to produce the desired outcomes (Norme Internationale, 2008). This carving operation and configuration of processes come against the relative inconsistency or incompatibility of “classical model” of organization with health services (Blanc, 2008). It gives as major benefit: the achievement of “Improved, significant and predictable outcomes” (Blanc, 2008). Despite this discrepancy between DONABEDIAN and ISO 9001v2008 which influenced the conformity rate of DONABEDIAN model to requirements given in 4.1 “General

Requirements” of ISO9001v2008, the DONABEDIAN Model met 72.82% of the clause 4: “Quality management system” requirements. This relatively high conformity rate was achieved because the DONABEDIAN model met most of the requirements given in 4.2, “Control of documents” thanks to its measurement indicator S5: “Information Systems”.

DONABEDIAN model requires an overall organization so the health Institution works correctly, but the measuring indicators of the model’s components don’t specify any indicator to measure the contribution of management to organize work in order to ensure the quality of care and services to patients. In the model of ISO 9001 v 2008, the clause 5: “Management Responsibility” defines the adopted measures by management to demonstrate its commitment to the implementation of a QMS “Quality Management System” as well as the Continuous improvement of its efficiency. This difference between the two models explains the 50% conformity rate of DONABEDIAN Model to requirements given in clause 5: “management responsibility” of ISO 9001v2008.

The DONABEDIAN model assumes in its component “structure” that high quality of care could be delivered only if the human and material resources are allocated and if the infrastructure and work environment are adequate. ISO 9001v2008 shares the same concepts in its clause 6, “Resource Management” whose requirements are at 95.83% met by DONABEDIAN Model. However, it is worth noting that ISO 9001V2008 gives further details how all available resources should be managed to ensure the efficiency of the QMS and to achieve the ultimate goal of the organization which is the Patient satisfaction. The ISO9001v2008 adopts the principle of “Involvement of people” of all the organization’s levels and ensuring necessary resources so they could improve their performance and consequently the organization’s performance (Blanc, 2008).

This principle “involvement of people” is mentioned in the component “Process” of DONABEDIAN Model. It assumes that the delivery of care is based on two aspects: technical aspect and interpersonal aspect related to the clinician-patient relationship. This model summarizes the patient’s relationship with the healthcare institution in his relationship with the clinician staff carrying out medical activities even though the employees performing other kind of activities, such as paramedical and administrative activities, could strongly influence the quality of care and services delivered to the “Patient”. Personnel of all the health institution levels should be represented in the relationship “Patient-Institution”, because the perceived quality of care and services by the patient is the result of his interaction with all healthcare institution personnel during his journey seeking for healthcare. DONABEDIAN model indicates all the basic elements needed to ensure efficiency in providing high quality care and services to the “Patient”. The Correspondence between the two models revealed that the clause 7 “Product Realization” of ISO9001v2008, has several connections with the two components of DONABEDIAN Model: “structure” and “process”. Even though, the conformity rate of DONABEDIAN Model to this clause was only 57.69%. In fact, this rate is quite low because there are no measuring indicators in the DONABEDIAN Model that could be linked to requirements given in 7.6: “Control of monitoring and measuring equipment”. Also, there were no specific measuring indicators corresponding to requirements given in 7.3, “Product Design and Development”, Section 7.4: “Purchases” and Section 7.5, “Production and service”. The process of care delivery is highly depending on the effectiveness and relevance of the other processes such as: technical, medical-technical, support, logistics and management. Thanks to its “Process Approach” the ISO9001v2008 promotes both kinds of processes: realization

and support, the one won't be effective and efficient without the other. Considering all the processes taking part in delivering care to patients as an interconnected network makes the process of care delivery more effective because it allows controlling the interfaces between processes and involves all the actors in the responsibility of delivering a care and service with high quality.

Observing the outcomes indicators of DONABEDIAN model, we notice that "patient satisfaction" (Bureau régional de l'Europe de l'organisation Mondiale de la santé, 1998) is an indicator of the quality of care and services while ISO 9001v ISO 2008 exceeds measuring the "Patient satisfaction" and adopts the principle of "Customer-Focus" which means understanding the present and future needs of the customer and strive to go beyond his expectations. However, Avedis DONABEDIAN didn't agree with this Finding and explained that the quality of care is traditionally patient-oriented (Baker, 1993).

The DONABEDIAN's triad "structure-process-outcomes" promotes the measurement, analysis and monitoring, but according to (Garnerin *et al.*, 2001) the DONABEDIAN's model doesn't explicitly describe the linkage between adequate "Structure", Good Practices "Process" and satisfactory "outcomes". Therefore, this model could be useful for assessing every component independently. It is more for assessment purpose than for Continuous Improvement. Our study of Compatibility confirms this finding since the requirements given in 8.5: "Improvement" don't have any correspondents in the DONABEDIAN Model. Our study showed that the DONABEDIAN Model has met 71.05% of requirements of Clause 8: "Measurement, Analysis and Improvement".

The DONABEDIAN Model emphasizes the importance of assessing the quality of care on the basis of the three components: "Structure, Process, and outcomes".

Certainly, this Model aims to improve the quality of care as the "Improvement" depends on "Assessment", but it doesn't explain how this assessment could lead to "improvement"? And what should be done in case of deficiencies? Whereas, the ISO 9001v2008 model is based on measuring, analyzing, in the purpose of ensuring the Continuous Improvement of quality and its sustainability.

5. Conclusion

Healthcare Institutions took up the challenge of improving the quality of care and services offered to the customers "Patients" and satisfying their requirements. Indeed, the quality of care has become a world concern and an essential criterion in the assessment of healthcare institutions performance and governments' programs of public health.

Avedis DONABEDIAN has been conscious that it is important to assess the quality of care and services offered to "Patients" in order to improve the healthcare quality. In the sixties, DONABEDIAN has introduced the principles of his model: "Structure-Process-Results". This model presents a multidimensional framework for quality of care and services in health institutions and is still considered as a reference in this field.

The ISO9001v2008 model based on the "Process approach" is an internationally-recognized tool to establish and to maintain a QMS "Quality Management System" in order to ensure continuous and sustainable quality improvement.

The study of compatibility between the DONABEDIAN Model "specific model to healthcare institutions" and the ISO9001v2008 "generic model applicable to any type of organization" helped to understand the different factors which affect the quality of care and services offered to the customers "patients". The results revealed that the DONABEDIAN model indicators have all correspondents in the ISO9001v2008 but not all the requirements

of the ISO9001v2008 have correspondents in the DONABEDIAN model.

The DONABEDIAN model is at 61.90% compliant with the ISO9001v2008. This fairly significant rate would convince health institutions, adopting DONABEDIAN model as a reference, that the implementation of "Quality Management System" needs complying with only 38.1% of the ISO9001v2008 requirements related to

clauses 5.1 "Management Commitment", 5.6 "Management Review", 5.5 "Responsibility and Authority", 7.6 "Control of monitoring equipment and measurement" and 8.5 "Improvement". Besides the ISO9001v2008 model is an appropriate tool for health Institutions which would like to go beyond the measurement and assessment of quality to achieve Continuous Quality Improvement.

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