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ORIGINAL ARTICLE **Open Access**

Material Vigilance and Proper Use of Implantable Medical Devices: Tracking the Traceability of Dental Implants in Healthcare Institutions.

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Abstract:
Introduction: Material vigilance is implemented to ensure the safety of patients and users of medical devices. The traceability of dental implants (MDIs) is regulated and must meet various healthcare, financial, and proper use objectives. The goal is to assess the traceability of implants in healthcare facilities and evaluate the practices of professionals regarding this activity to ensure the proper use of MDIs.
Materials & Methods: An investigation was conducted in 26 public and private institutions using an open questionnaire. The questionnaire included information on dental implant traceability at the internal pharmacy (PUI), surgical odontology service, patient medical records, and information provided to the patient. The questionnaire was made available online using Google Forms to automatically collect the results. The data were analyzed using Jamovi 2.3.18, and the results are presented in percentages and averages.
Results & Discussions: A total of 60 responses were obtained, including 15 (25%) from public healthcare institutions, 32 (53.4%) from dental clinics, and 13 (21.6%) from private healthcare institutions. It was observed that dental implant identification is almost exhaustive, with a traceability percentage of 87% at the PUI. 85% of dentists use computer software, and 5% use a sharing tool with the PUI. 94% of dentists maintain patient records, while 6% of implanted MDIs do not have traceability. 65% of healthcare professionals confirmed that they provide documents to patients, while 35% do not provide patient records. This study demonstrates the importance of computerizing the MDI circuit. The use of software to record and preserve all health and financial traceability information, as well as the acquisition of automatic barcode readers, is now a prerequisite for implementing traceability in healthcare facilities. Traceability ensures the quality and safety of implantable medical devices, enables prompt detection of issues, and facilitates necessary corrective measures.
Conclusion: The traceability of dental implants is a significant

public health issue. Material vigilance and traceability are two essential elements for ensuring the safety and quality of implantable medical devices. Manufacturers and regulatory authorities are working together to establish effective surveillance and traceability systems to guarantee the safety of patients and users of medical devices.

Keywords: Material Vigilance, Traceability, Dental Implant, Regulation.

Introduction

Material vigilance is the system for monitoring and managing incidents related to medical devices after they are placed on the market. It is a process that aims to collect, analyze, and evaluate information regarding adverse effects, incidents, and risks associated with the use of medical devices. Implantable medical devices are a specific category of medical devices that require close surveillance due to their usage. This surveillance is regulated by material vigilance provisions (Article 23 of Law No. 84-12), which require that each medical device be traceable throughout the entire process, from manufacturing to implantation, including storage within the relevant healthcare facilities. The traceability of medical devices serves various objectives, such as ensuring safety, financial management, and proper use [1, 2].

Public confidence in the healthcare system has recently been shaken by significant health scandals, such as the issues with Poly Implant Prothèse (PIP) breast implants and non-compliance with Ceraver orthopedic implants, underscoring the importance of ensuring the quality of traceability for implantable medical devices (IMDs) [3].

Like all implantable medical devices, dental implants are subject to traceability regulations. From procurement by hospitals to placement in patients, implants must be tracked [4].

The purpose of this survey is to assess the state of traceability of dental implants in healthcare facilities in the city of Rabat, through the use of a standardized questionnaire.

The questionnaire allows for a greater number of responses as it is easily distributable, anonymous, and relatively short. Thus, the obtained results will be more representative.

The questionnaire is intended for healthcare professionals in healthcare facilities (public and private) in the city of Rabat who use implantable medical devices (dental implants) subject to sanitary traceability rules.

In the Rabat region, 26 facilities were contacted to respond to this questionnaire, including 5 public institutions, 15 private dental clinics, and 6 private healthcare institutions.

Materials & Methods:

1. Questionnaire Development:

To assess the quality of the sanitary traceability of dental implants, a questionnaire was developed. It was designed to distinguish different levels of sanitary traceability: traceability by the internal pharmacy (PUI) or by the person in charge of ordering/stock management for institutions without a PUI (first section), traceability by the surgical odontology service (second section), traceability in the patient's medical records (third section) [5,6]. A fourth section was dedicated to the traceability of information provided to the patient [7, 8].

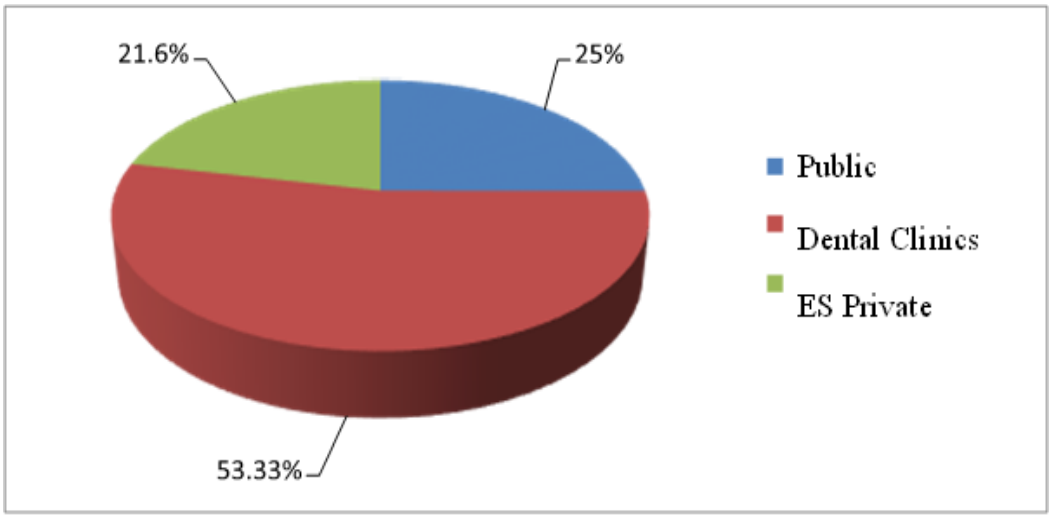
2. Distribution:

The questionnaire was distributed to healthcare professionals in the relevant institutions. Additionally, it was made available online using Google Forms to automatically collect real-time results, which were then analyzed and presented

using Jamovi 2.3.18, with results reported in percentages and averages [9].

Results:

A total of 60 responses were obtained, with 15 (25%) from public healthcare institutions, 32 (53.33%) from dental clinics, and 13 (21.6%) from private healthcare institutions.

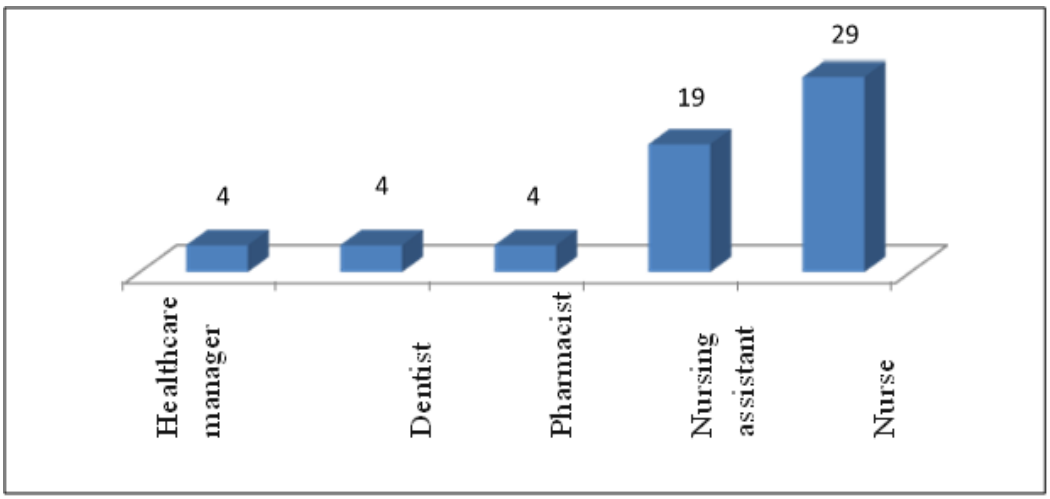


Graph 1: Type of Responding Institutions

The statistical analysis is based on 60 questionnaires.

First, let's delve into the results of the questionnaire.

The characteristics of the surveyed professionals are presented in Graph 1.

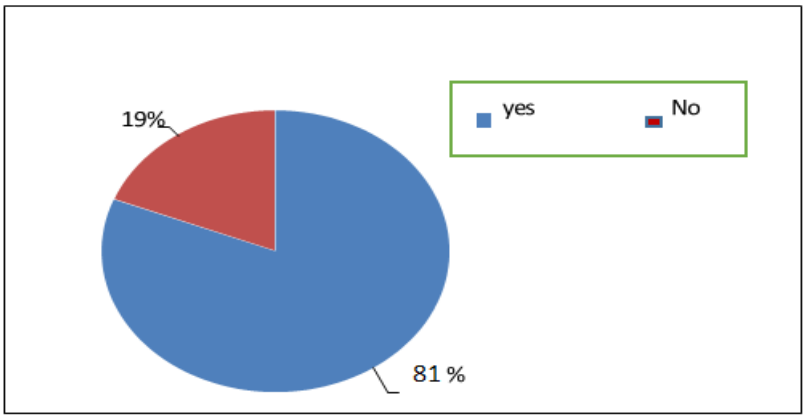


Graph 2: Characteristics of the surveyed professionals.

Traceability by the Pharmacy for Internal Use (PUI):

a. Existence of a procedure for traceability of dental implants used by PUI: - 81% of healthcare professionals reported having a procedure for the traceability of dental implants used by the Pharmacy for Internal Use (PUI).

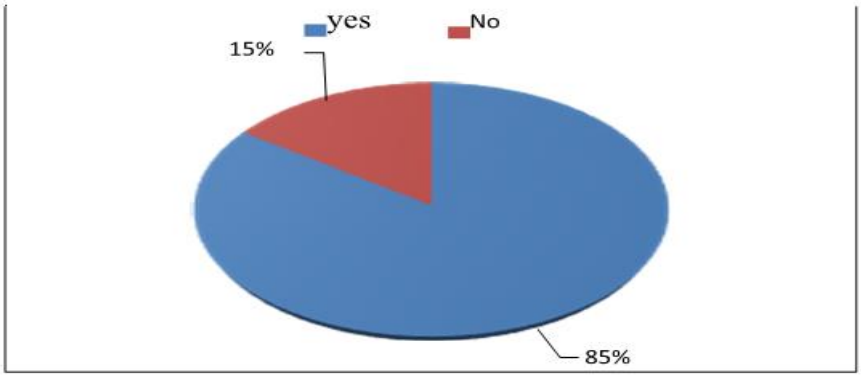
- 19% of healthcare professionals stated that they do not have any procedure regarding the traceability of dental implants used by the PUI.



Graph 3: Existence of a procedure for the traceability of dental implants used by PUI:

b. Existence of dedicated software(s) for ensuring the sanitary traceability of dental implants:

- 85% of healthcare professionals stated that they have dedicated software for the traceability of dental implants, while 15% do not have such software (Graph 3).



Graph 4: Existence of dedicated software for dental implant traceability.

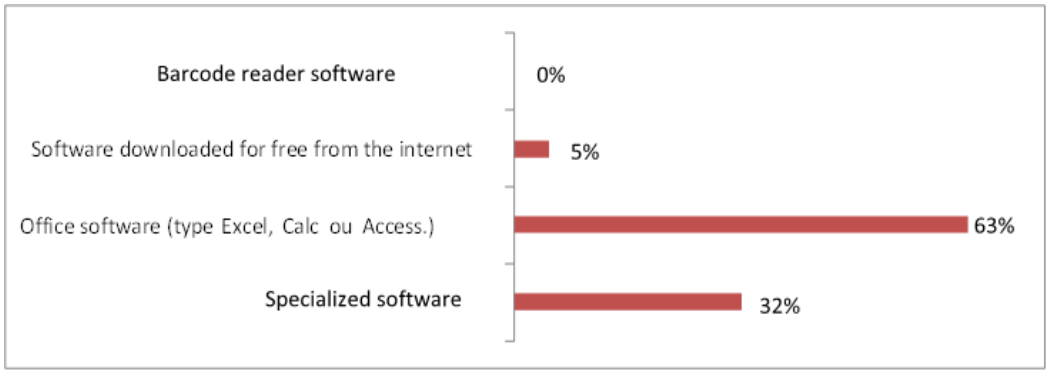
c. Type of software used to ensure traceability of dental implants:

- 63% of professionals reported using office software for traceability.

- 32% of professionals reported using specialized software for traceability.

- Only 5% of professionals mentioned using software downloaded for free from the internet.

- 0% reported using barcode reader software (Graph 4).

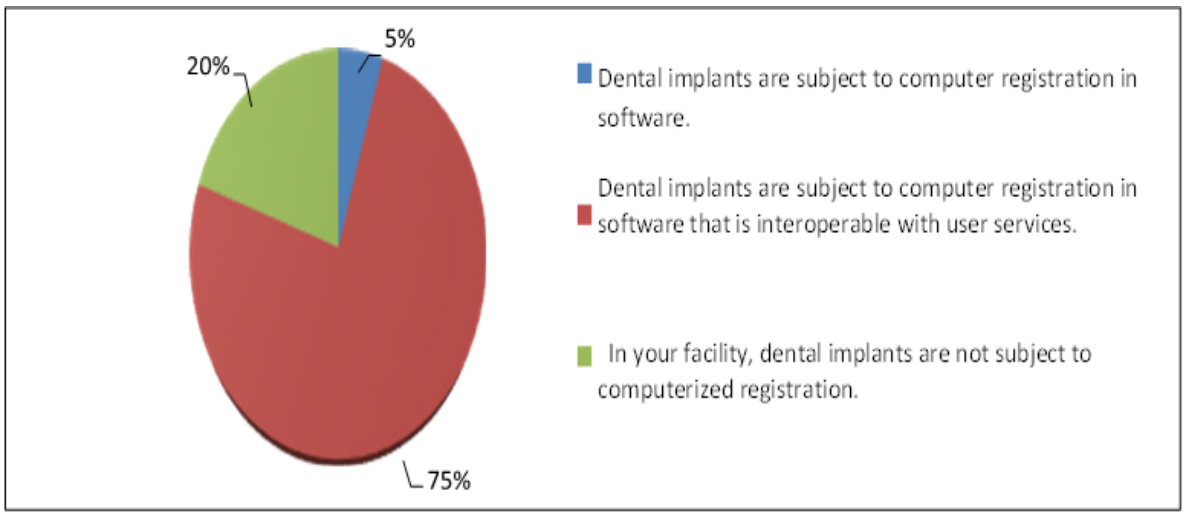


Graph 5 : Type of software used.

d. Interoperability of information systems for the traceability of dental implants:

Recording of information related to dental implants by the Pharmacy Unit for Internal Use (PUI): During RECEIVING and DELIVERY to user services. This section aims to assess whether an establishment is capable of knowing "which dental implants are present in the healthcare facility? and which dental implants have been delivered to the dental services? And with what "speed" (Computerized vs. paper-based).

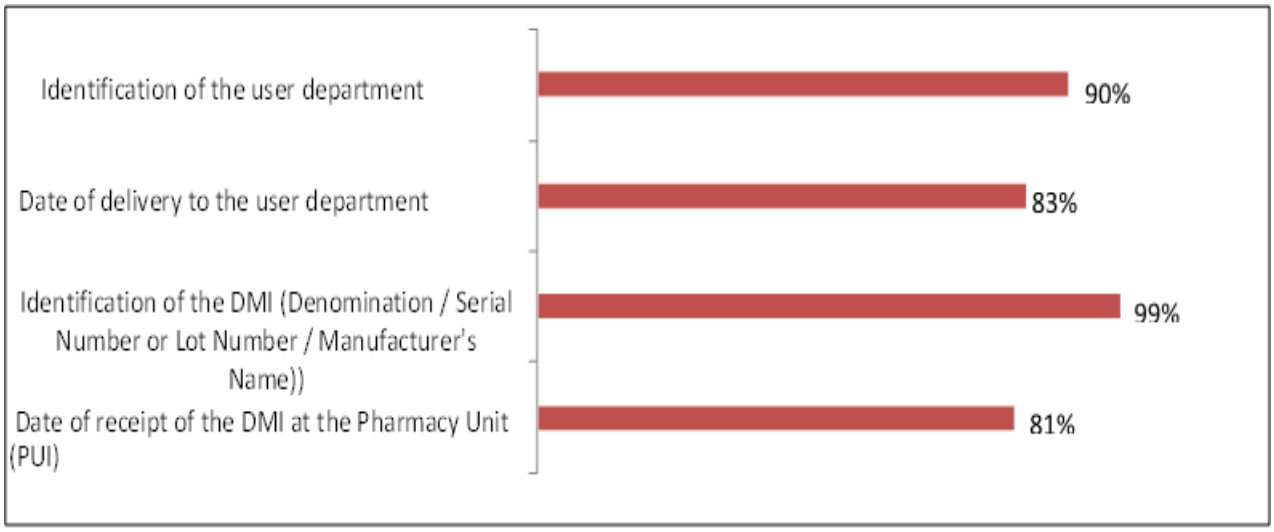
- 75% of healthcare professionals confirmed that dental implants are recorded electronically in a software that is non-interoperable with the user services. Only 5% use an interoperable tool with user services, while 20% stated that the recording is non-computerized.



Graph 6: Interoperability of information systems for the traceability of dental implants.

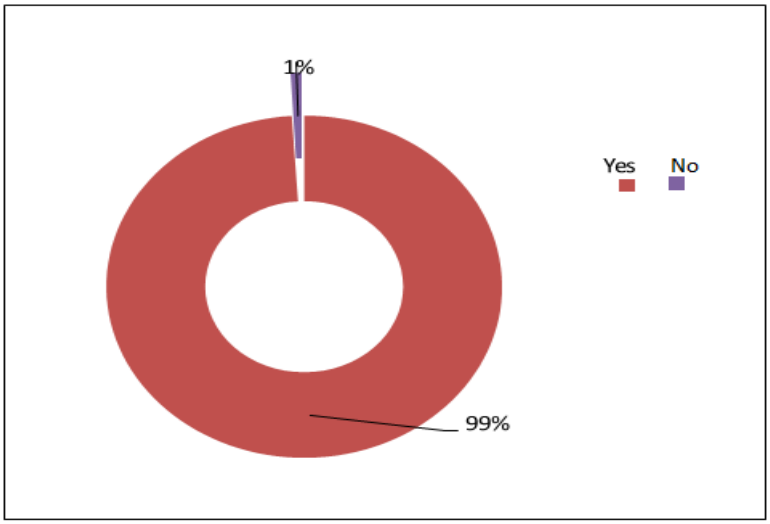
The type of information recorded by the PUI:

- 99% of professionals stated that the identification of the medical device DMI of PUI (manufacturer or authorized representative name, lot number, and device denomination) is almost always found at the PUI. The user department is known in 90% of cases, and the date of delivery of the medical device to the user department is known in 83% of cases. The date of receipt at the PUI is recorded in 81% of cases.



Graph 7 : Type of information recorded by the PUI:

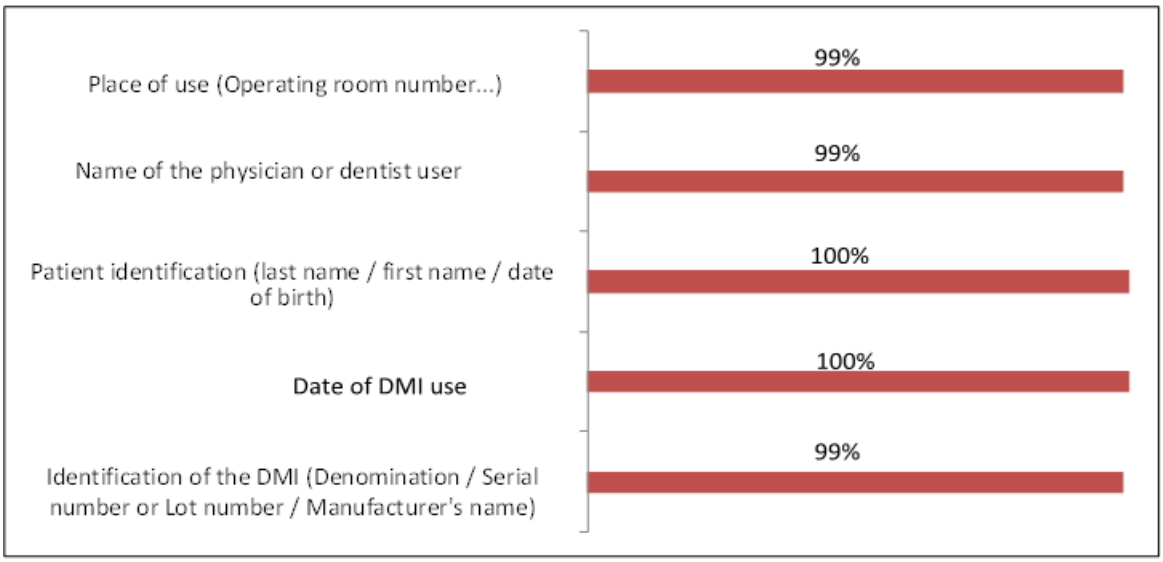
✓ **Traceability by the user department:** 99% of healthcare professionals reported having a person responsible for the traceability of dental implants, while 1% does not (Graph 7)



Graph 8: Existence of a person in charge of the traceability of dental implants within the dental department.

✓ **The type of information recorded by the user service:**

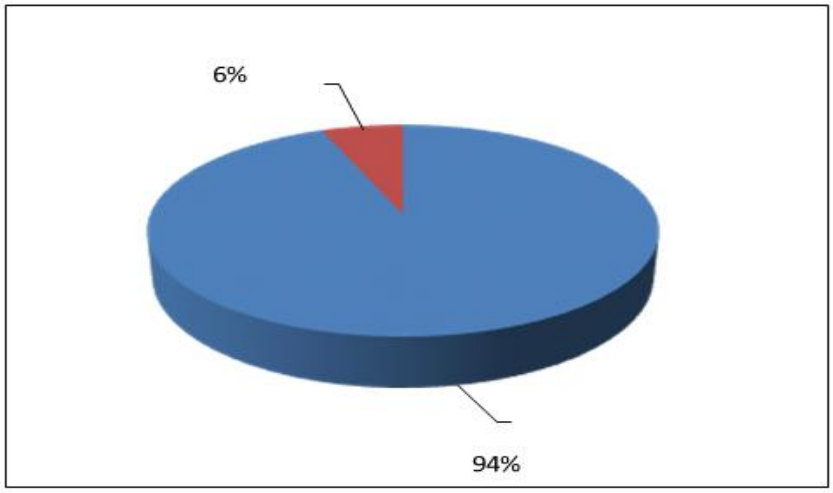
-100% of healthcare professionals stated that the date of use is systematically identified, as well as the identification of the patient to whom the dental implant was implanted. The name of the physician or dentist user is recorded in 99% of cases. The location of use and the identification of the dental implant are recorded in 99% of cases.



Graph 9: Type of information recorded by the dental service.

✓ **Traceability in the patient's record:**

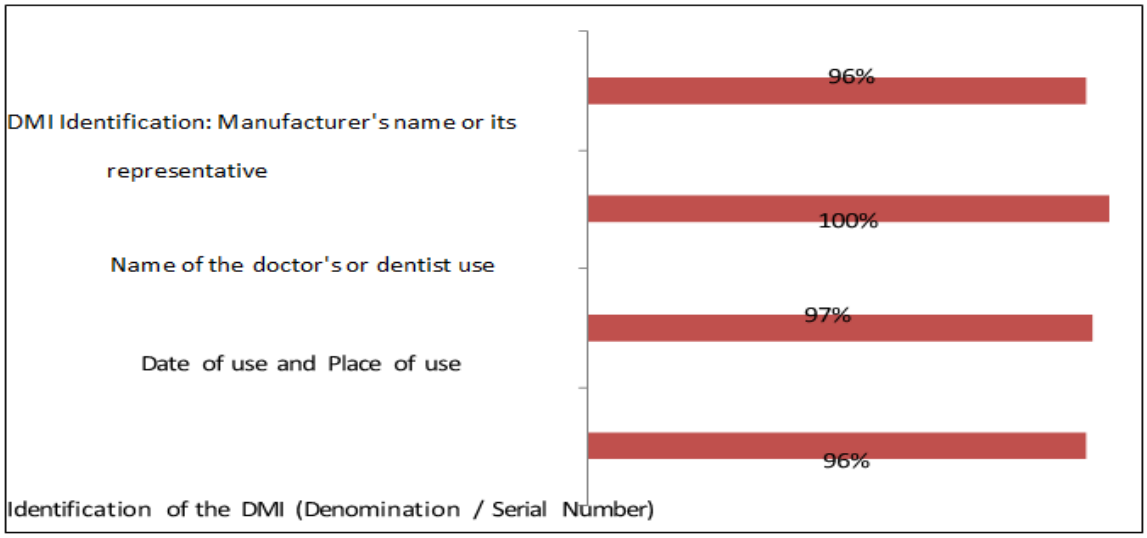
- 94% of healthcare professionals reported that they have the patient's record, while 6% do not.



Graph 10: Existence of a patient record (paper/electronic).

✓ **The type of information recorded in the patient record:**

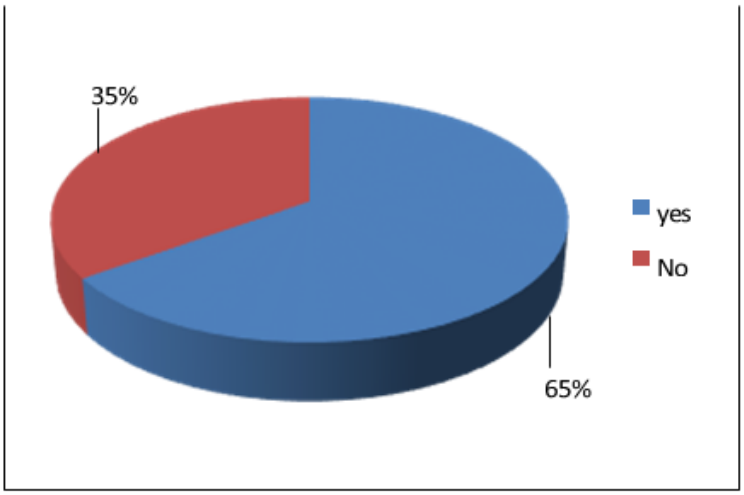
- 96% of healthcare professionals confirmed that the designation of the DMI (Dental Medical Device) and its serial number or lot number are found in the patient records. The manufacturer or representative's name is found in 95% of cases, the date of DMI implantation is traced in 97% of cases, and the name of the physician or dentist user is present in 100% of the records.



Graph 11: Type of information recorded in the patient's file.

✓ **Document provided to the patient:**

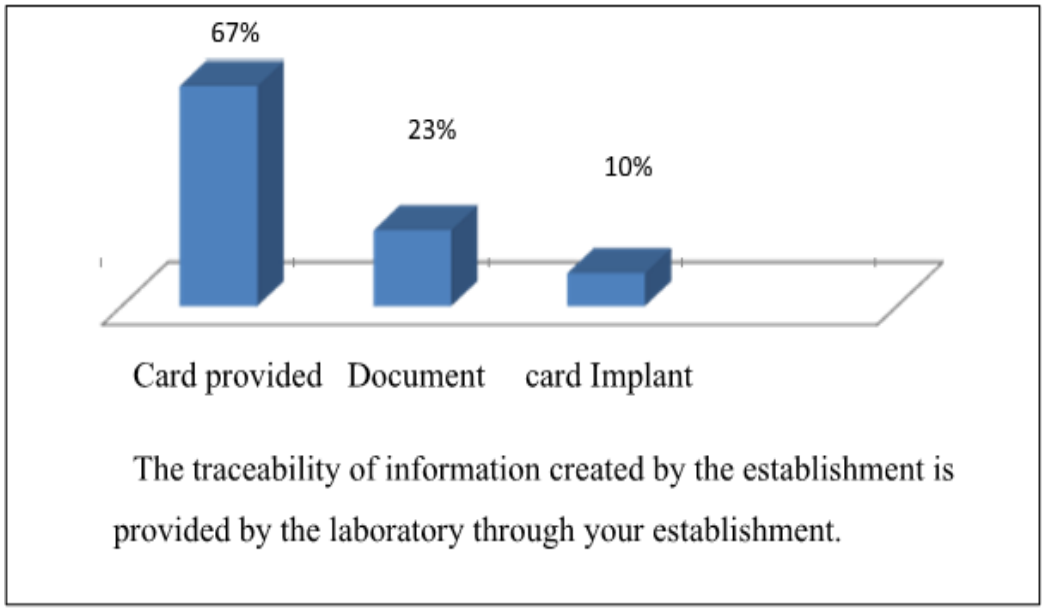
- 65% of healthcare professionals confirmed that they provide the document to the patient, while 35% stated that the traceability document is not provided to the patient.



Graph 12: Existence of a document provided to the patient.

✓ **Types of documents provided to patients:**

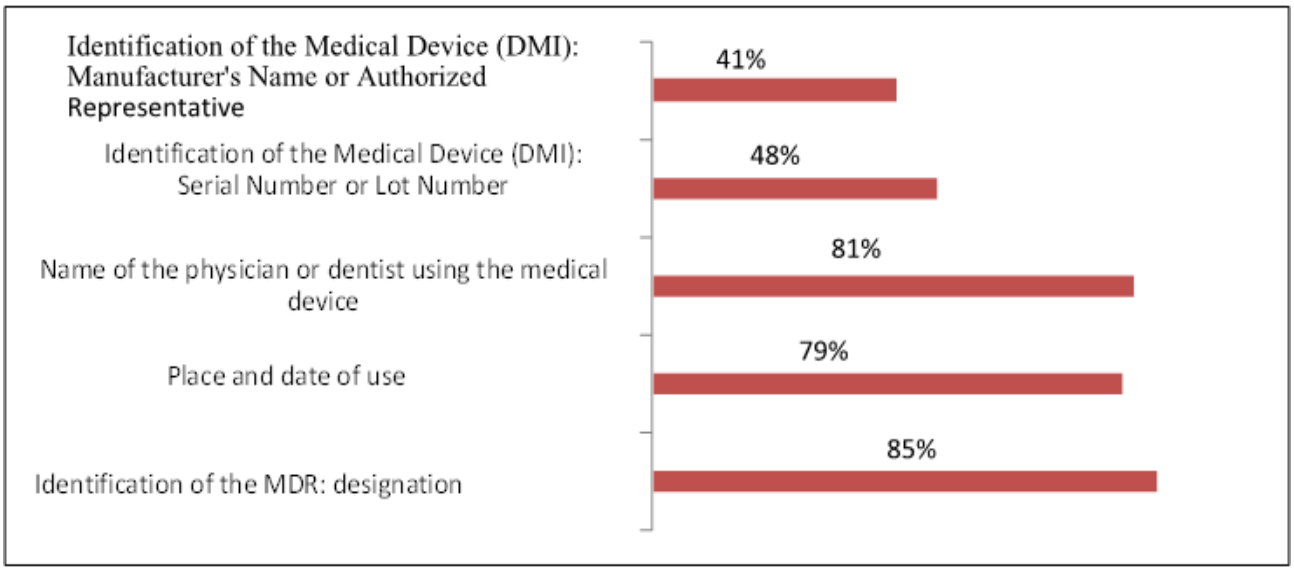
- 67% of healthcare professionals confirmed that establishments provide patients with a card produced by the laboratory. Additionally, 23% provide a document provided by the establishment, and 10% provide an implant card created by the establishment**.**



Graph 13: Support used for the document provided to the patient.

✓ **Content of the document provided to the patient:**

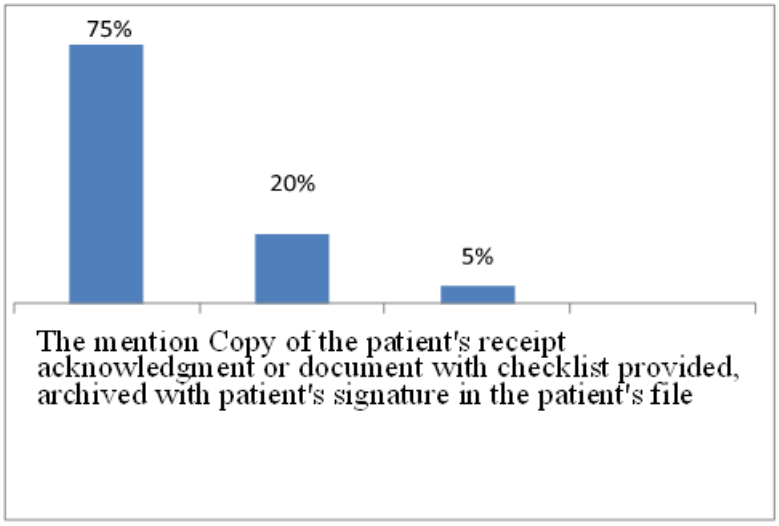
- The name of the physician or dentist user and the date of use are mentioned in 81% and 79% of the documents provided to patients, respectively. The designation of the medical device implant (DMI) is indicated in 85% of cases, but the name of the manufacturer or representative and the lot number only appear in 48% and 41% of the documents, respectively.



Graph 14: The type of information presented in the document provided to the patient

✓ **Modalities chosen for the traceability of the document provided to the patient:**

- This traceability is carried out using different modalities (Graph 14): 75% for written traceability or checklist, 20% for a photocopy of the provided document archived in the patient's file, and only 5% for the patient's signature on the traceability document.



Graph 15: Methods chosen by establishments for tracking the delivery of patient documents.

Discussion:

The field of dental implantology is complex.

Dental implants are implantable medical devices. They comply with health traceability regulations. Traceability at each stage of the implantable medical device circuit is essential. The registration of DMI the medical device at the pharmacy before dispensing to users (surgery or consultation) is a mandatory step according to regulations.

The objective of this work is to evaluate the quality of dental implant traceability carried out in healthcare facilities in the city of Rabat, through the proposal of a common questionnaire. The goal was to find all the information related to a dental implant at the Hospital Pharmacy (PUI), in the user department, within the patient's record, and on the information provided to the patient.

As a reminder, the objective of health traceability rules for implantable medical devices is to quickly identify:

- The patients for whom devices from a specific batch have been used;

- The batches from which the devices used on a patient originate.

The first point, which is the identification of patients for whom devices from a specific batch have been used, falls within the scope of downward alerts in materiovigilance. In the event of a batch recall involving an implantable medical device, the pharmacist in charge of managing the hospital pharmacy must be able to identify the patient(s) who received the implicated medical device. This traceability is achieved through the information recorded at the Hospital Pharmacy (PUI) and then supplemented by the user department.

The second point, which is the identification of batches from which the devices used on a patient originate, is possible through the registration of health traceability information in the patient's record and the provision of information to the patient regarding the implanted medical devices (including an implant card).

To address the first objective of traceability, which is to identify patients for whom devices from a specific batch have been used, it is necessary for traceability at the Hospital Pharmacy (PUI) and in the user department to be in compliance. However, the evaluated health traceability at the PUI, as assessed through the questionnaire, reaches 87% (Graph 7), while traceability in the user department is close to 100% (Graphs 8 and 9). A lack of traceability at the PUI appears to be the primary limitation identified in implementing traceability in healthcare facilities [10].

As a reminder, the information that should be recorded at the PUI includes:

- Identification of each medical device: name, serial number or lot number, manufacturer's name or their representative's name.

- Date of dispensing the medical device to the user department.

- Identification of the user department.

We observe that the identification of dental implants is almost exhaustive (name, serial number or lot number, manufacturer's name or their representative's name recorded in 99% of cases) (Graph 7). The 87% traceability rate at the PUI is explained by a lack of traceability in:

- Identifying the user department (90%) (Graph 7).

- Recording the date of dispensing to the user department (83%) (Graph 7) .

While knowing the identification of the user department and the date of dispensing the dental implant to the user department is important, recording information related to the medical device DMI (especially the lot number and its name) remains crucial for traceability.

Indeed, it is this information that will allow for almost certain identification of an implanted medical device subject to a batch recall. The systematic recording of dental implant identification at the PUI is therefore a well-managed step in the traceability process in healthcare facilities in the city of Rabat.

Finding dental implants that have been implanted and are subject to a batch recall is also dependent on traceability carried out in the user department, particularly in terms of identifying the patient who received the dental implant. This questionnaire shows that traceability of patient information (name, first name, and date of birth) is exhaustive (100% traceability). Similarly, the date of use is known in 100% of cases, and the practitioner's name in 99% of cases. Therefore, we can conclude that traceability within the user department is adequate (Graph 9).

Despite a traceability rate of 87% at the Hospital Pharmacy (PUI), the detailed results of traceability at the PUI and in the user department allow us to qualify this compliance rate. The systematic identification of the medical device (name, manufacturer or representative, and lot number) as well as the patient receiving the medical device fulfils one of the objectives of health traceability: identifying patients for whom devices from a specific batch have been used. Therefore, patient safety is not compromised in

case of batch recall or downward alerts in materiovigilance [11].

However, the application of regulations regarding traceability of dental implants is strongly correlated with the computerization of the dental implant circuit [12,13]. According to the questionnaire, 85% of healthcare professionals reported using computer software to ensure traceability of dental implants (Graph 4), with 63% stating that they use office software such as Excel® or Access® (Graph 5). Only 5% use a single tool shared between the PUI and the user department (Graph 5).

Indeed, the use of a single tool or interoperability between software, when applicable, would improve the traceability of user department identification and the date of dispensing the medical device to the user department. Therefore, among the proposed improvements to traceability of dental implants, we can mention:

- Preferably ensure health traceability of dental implants using computer-based systems.

- Discontinue the use of office software such as Excel® or Access® for recording traceability data.

- Use a single tool shared between the PUI and the user department.

- Perform traceability at each stage of the implantable medical device circuit, including:

- At the PUI: recording the medical device during dispensing.

- In the user department: recording the patient during use.

The second objective of health traceability, which is to identify the batches from which devices used on a patient originate, is evaluated by the completeness of traceability data available in the patient's record. 94% of healthcare professionals reported having the patient's record (Graph 10). The identification of the medical device, in turn, is traced in 96% of patient records. However, for 6% of implanted dental implants, there is no health traceability in the patient's record. It is worth noting that there is a loss of traceability information at this stage.

Furthermore, the questionnaire identified that some establishments perform traceability on paper. Traceability in the operating room involves attaching traceability labels for dental implants to an operative traceability sheet. The PUI subsequently transcribes the traceability information into office software (such as Excel®) or another non-interoperable specialized software.

Manual traceability in the operating room is a source of errors, such as label omissions. Additionally, being in paper format, traceability sheets can get lost, rendering traceability in the patient's record nonexistent. Moreover, there is a risk of input and transcription errors in the traceability software, both in the user service and the Pharmacy and Medicines Unit (PUI).

Therefore, among the proposed improvements to enhance the traceability of dental implants, the following can also be mentioned:

- Utilizing barcode readers integrated with the traceability software, which eliminates the need for information transcription into the software. The recorded information becomes more reliable through scanning the code present on the implant packaging, ensuring the reliability of health traceability.

Regarding the traceability of information provided to the patient, this study has revealed weaknesses in delivering information to patients.

Not all establishments provide patients with a traceability document. Among the 26 contacted establishments, 65% of healthcare professionals confirmed that they provide the document to the patient, while 35% (Graph 12) stated that the traceability document is not provided to the patient.

Dental teams used different supports, such as patient cards provided by dental implant manufacturers. This is problematic as these supports do not always contain the mandatory regulatory information (Graph 16). The existence of different types of supports increases the number of paper sources. The institutional implant passport simplifies the choice of support and its accessibility, aiming to facilitate the delivery of information to patients by reducing the number of documents to be provided.

The goal is for all patients to leave the department with a single document containing information about the placed implant. The systematic recording of the implant passport in the computerized patient record also improves practices and ensures the preservation of traceability for placed implants, providing proof of information delivery to patients.

Finally, the financing of medical devices is also a factor that affects the health traceability of medical devices. In addition to health traceability, some medical devices, to be reimbursed in addition to the homogenous groups of stays, also require financial traceability.

Dental implants are not reimbursed in addition to the homogenous groups of stays. Moreover, they are mainly implanted in outpatient settings and thus billed to the patient.

Ultimately, the identified biases of this survey are summarized below:

- This survey was based on the experience of healthcare professionals. However, not all professionals interviewed have the same level of experience, raising questions about the credibility of each response.

- Not all targeted establishments responded to the questionnaire. Given the ongoing health crisis, it can be assumed that these establishments did not have the time to respond.

- For some establishments, traceability in the patient record is evaluated through traceability software, rather than directly within the patient record itself. Compliance in the patient medical record is likely to be overestimated.

- The traceability of information provided to the patient after treatment is difficult to interpret because the patient record rarely mentions it.

Conclusion:

Material vigilance and traceability of implantable medical devices are closely related concepts aimed at ensuring patient safety by monitoring device-related incidents and enabling their tracking throughout their journey. The tracked information allows for the identification of patients with medical devices. These measures contribute to the continuous improvement of quality of care and risk management. Each patient record should also contain health traceability information. Although mandatory since 2008, the traceability of dental implants is still not optimally implemented.

The observed health traceability in the city of Rabat remains partial; however, the identification of medical devices and patients is nearly exhaustive, which is crucial for material vigilance. This study also demonstrates the importance of computerizing the medical device circuit. Choosing software that can record and preserve all health (and possibly financial) traceability information, along with the acquisition of barcode readers, is now a prerequisite for implementing traceability in healthcare facilities.

An action plan should be developed to optimize the health traceability of dental implants. Work also needs to be done on providing patients with a document containing the necessary health traceability information.

Acknowledgment Section : There are no potential conflicts of interest to declares.

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