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# Eleven basic procedures/practices for dental patient safety (preprint review).

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## Title: Eleven basic procedures/practices for dental patient safety.

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#### Abstract:

**Objectives:** To help alleviate the shortage of reliable information on clinical care issues, the Spanish Observatory of Dental Patient Safety (OESPO) has resorted to the study of legal claims by patients, and searched those which produced clinical problems. **Methods:** Based on OESPO data, this paper proposes eleven basic procedures/practices for dental patient safety to help mitigate most preventable adverse events. **Results:** The sample of the OESPO is large (415 adverse events studied), but it has the bias of a judicial source. However the results provide an interesting approach to clinical safety in dentistry. When studying in detail the causes which led to preventable adverse events, it can be seen that most of these (and most severe) events have been caused by a small number of erroneous behaviours. **Conclusions:** Most preventable adverse events during the dental health care are produced by a relatively small number of causes. Therefore, a few basic safety procedures can reduce significantly these preventable adverse events.

#### 1. Introduction.

Patient Safety strategies aim at preventing unintended damage to patients as a result of healthcare. Patient Safety efforts help also to detect early and limit non-preventable harm. Given the complexity of health care systems, it is impossible to completely prevent the occurrence of errors, accidents or complications during the provision of medical or surgical treatment. It is evident, however, that dentists, the same as other health care professionals, have an ethical and legal obligation to protect our patients from harm in as much as reasonably possible (1).

Since early in the history of Medicine, Patient Safety has been an intrinsic concern for health care providers (just remember the Hippocratic principle of "primum non nocere"). Nevertheless, the birth of Patient Safety as scientific field is relatively recent. Patient Safety became a scientific discipline only when we began to record and measure damage unnecessarily provoked to our patients, and to assess also the results of preventive interventions.

Two milestones set at the end of the 20<sup>th</sup> century are the work of Leape and Brennan at Harvard Medical School, and the publication of "To err is human" by the Institute of Medicine of the United States of America (2). The latter study estimated between 44,000 to 98,000 the annual number of deaths caused by errors in healthcare in United States. Although its methodology has been discussed, the numbers revealed to society, health managers, and political powers, the social and economic importance of preventing health care errors (3). More recent studies estimates de incidence of death to be much higher (4).

Since the publication of "To err is human" all health agencies began to consider the Patient Safety as a basic area of activity. Multiple initiatives have been launched in individual countries or internationally as the "World Alliance for Patient Safety" launched by the World Health Organization in 2004 (5).

On Patient Safety, dentistry has been lagging behind medicine. The main causes of this delay are usually the perception of relatively minor damage to dental patients (compared to those who receive medical treatment, especially in hospital), and the geographical dispersion of dental clinics where care is usually provided with little communication between them.

The first problem that arises when we talk about "Patient Safety" in dentistry is the lack of data on adverse events actually occurring in the practice of dentistry. In a centralized environment such as a hospital, it is easier to detect, record and analyse adverse events in medical care. In contrast, most of the clinical problems that arise in ambulatory settings as dispersed as dental care, remain within the involved dental clinic's environment, and are never known to the rest of the profession. In this regard, we must remember that reporting adverse events is one of the best services we can provide to our profession. Anonymous reporting is a highly ethical behaviour that allows our colleagues to learn from clinical or surgical mistakes. In recent years, dental organizations have implemented diverse initiatives to increase the safety of the patients attending dental clinics. Leading these efforts are the World Dental Federation (FDI) (6, 7), the Council of European Dentists (CED) (8), or the Annapolis-based Organization for Safety, Asepsis and Prevention (OSAP) (9), among others. In Spain, the General Board of Dentistry and Stomatology created the Spanish Observatory for Dental Patient Safety (OESPO) and adopted a nationwide "Clinical Risk Prevention Plan in Dental Care" (10).

There are two published international studies that reflect extrapolated results on adverse events in dentistry (11, 12).

#### 2. Method.

To help alleviate the shortage of reliable information on clinical care issues, the OESPO has resorted to the study of legal claims by patients, and searched those which produced clinical problems. The sample is large (415 adverse events studied), but it has the bias of a judicial source because the adverse events detected from court cases are often the most serious. Minor adverse events usually don't lead to legal claims. However the results provide an interesting approach to clinical safety in dentistry (13).

The OESPO study classified adverse events (understood as damage to patients as a result of dental assistance and independent of disease process) in three categories with the following results: errors (40%), complications (40%) and accidents (20%). The distinction between error and accident is based on behavioral intentions (no damage).

- Errors are incorrect behaviours (acts or omissions) but made consciously, usually caused by lack of knowledge or skills.
- Accidents are random, unforeseen and unexpected events which causes harm to the patient or any other type of harm (material damage, harm to health care personnel, etc.).

However it is true that the borders between both concepts are often not clear. Treatment by a dentist without the necessary clinical skills can promote the emergence of an accident. Although this unexpected event is not intended, treatment that caused it was intended. In any case the distinction between both concepts have a high subjective component.

The classification of adverse events regarding the type of dental manoeuvre that produced the adverse event indicates that implant dentistry is the area of unnecessary harm to patients, followed by endodontics, oral surgery, prosthodontics and orthodontics. Referring to the type of harm suffered by the patient, as expected, unnecessary tooth loss is the most common injury, but there are also many cases of alveolar bone loss, permanent damage to the inferior alveolar nerve, and chronic sinus damage. Interestingly, this series has detected 11 patient deaths related to dental treatment received (table 1).

When studying in detail the causes which led to preventable adverse events, it can be seen that most of these (and most severe) events have been caused by

a small number of erroneous behaviours. Overconfidence is responsible for most of incorrect or careless behavior. The most common incorrect behavior in our series were:

- Do not use enough time to performing clinical quality records, or not adequately consult them before making a treatment.
- Absence of regular monitoring of procedures for cleaning, disinfection and sterilization of clinical instruments.
- Making drug prescriptions incomplete and / or illegible.
- Systematic realization of complete radiological tests to all patients, regardless of their specific situation.
- Reuse of products or devices designed for single use.
- Failure to protect patients against the possibility of eye damage or ingestion or inhalation of materials or instruments.

Based on OESPO data, this paper aims to propose basic and easily implemented measures to help mitigate most preventable adverse events.

# 3. Results and discussion.

# 3.1. Recommended activities/procedures

Basic procedures for patient safety in the dental clinic (table 2).

1. <u>Develop a culture of safety and a health care system focused on</u> <u>prioritizing Patient Safety.</u>

It is the starting point of any process aimed at improving the safety of patients in the dental clinic. Each member in a dental team must (14).:

- Be involved in transmitting basic knowledge on Patient Safety.
- Integrate the basic steps of "Patient Safety" in all heath care activities.
- Encourage reporting of errors or conflictive situations
- Participate in the discussion of them at staff consultations.
- Encourage the dental team to embrace Patient Safety
- 2. Looking after the quality of clinical records.

In the OESPO series, there are: three fatal cases (and a large number of serious adverse reactions) due to allergies (latex and beta-lactam antibiotics); endocarditis caused by the lack of antibiotic prophylaxis; major bleeding in anticoagulated patients; undetected severe infections (some fatal) in immunocompromised patients, etc.

- Clinical records (especially those related to previous pathologies, allergies, and regular medication) must be properly completed and must be periodically updated (15).
- In case of any potentially dangerous circumstance, this should stand out in a clearly visible way (without breaching the confidentiality of our records).
- Under no circumstances should you treat a patient (or prescribe a medication) without having reviewed his/her medical history.
- 3. <u>Check the procedures for cleaning, disinfection, sterilization, and preservation of clinical instruments.</u>

In the OESPO series there are two cases of transmission of viral diseases during dental care (hepatitis B and C): a patient died of acute hepatitis, and the other suffered chronic liver damage.

- Establish clear protocols and have them available in writing.
- Inform and train the personnel in charge of cleaning, disinfection, sterilization, and preservation, ensuring their proficiency and awareness of the importance of these tasks.
- Make the necessary periodic checks (chemical and bacteriological) to ensure efficacy of sterilization cycles.
- Periodically monitor procedures to ensure that these operations are carried out according to established protocol.
- Personally train all new staff in cleaning, disinfection, and sterilization procedures. In this way, we prevent transmission to the new members of possible misconceptions the staff may have (9,16).
- 4. Extreme caution when prescribing medications.

In the OESPO series there are seven adverse events related to prescription drugs, two of them fatal due to severe allergic reactions.

Errors in prescribing and dispensing medication are very common in hospital care (17, 18). In dental care, prescribing errors are not infrequent and may cause serious, even fatal adverse events as described in the second point. To mitigate much as possible the occurrence and consequences of these adverse events, the dental team must adhere to these safe practices:

• Do not prescribe any medication without performing a "dual control", reviewing the patient's clinical record and by asking the patient directly about known allergies.

- Inform the patient adequately about treatment: goals, duration, number and characteristics of injections, and the importance of full compliance.
- Make sure the prescription is legible and is consistent with the patient's medical history (15).
- In patients with polypharmacy (a large percentage of older patients) make sure to document all the drugs the patient takes and their possible interactions with the medication you prescribe.
- Make sure that the doses used are correct, particularly for children and patients with compromised metabolism or drug elimination (renal and/or hepatic failure) (19).
- Always ask women of childbearing age about the possibility of pregnancy.
- After completion of drug treatment, ask patients about their physical and mental performance and record the appearance of clinical problems during the course of their medication.
- 5. Limit the exposure of patients to ionizing radiation to the strictly necessary.

Although no adverse event is collected in OESPO series related to dental radiological exams, recent studies show possible health problems arising from the unwarranted use of such tests (20, 21). To reduce patient exposure to radiation:

- Restrict patient exposure to ionizing radiation to that strictly necessary. Avoid the systematic use of radiographs without clinical suspicion of pathology. These restrictions should be tighter in the case of children.
- Protect from ionizing radiation anatomic areas that are not under study, using barriers. This is especially recommended in the cervical area.
- Always be aware of a possible pregnancy among patients or staff potentially exposed to ionizing radiation.
- Prevent accidental exposure of patients or caregivers to ionizing radiation. Use visual alerts such as posters or lights that indicate the performance of radiographic tests, etc.).
- Choose diagnostic systems that emit a minimal amount of ionizing radiation.
- 6. <u>Never reuse packaging materials or substances intended for one clinical</u> <u>use only.</u>

In OESPO series, there are three cases of injection of sodium hypochlorite by improper reuse of local anaesthesia cartridges.

- Containers intended for clinical use only contain less preservatives, and prevent bacterial growth, therefore, if used repeatedly could lead to infection of the area in which the substance is placed.
- Furthermore, reuse of disposable clinical materials poses a risk of contamination with blood which may transmit viral infections to other patients (as has happened several times in hospitals).
- Re-use of containers to package materials other than the original products can lead also to dangerous confusion (22, 23).
- 7. Protect patient's eyes during dental procedures.

The OESPO series collected five cases of significant eye damage (one with complete loss of the eyeball) caused by instruments fallen from the worktray or accidental scalpel cuts during surgery (24).

- Patient's ocular protection with goggles, similar to those we use, is one of the easiest and most effective patient safety measures.
- Every dentist has seen different substances or fragments of material jump to the patient's eyes. Usually, these incidents cause only temporary discomfort.
- 8. <u>Establish barriers to prevent ingestion or inhalation of materials or small</u> instruments.

In the OESPO series there are twelve cases of accidental ingestion and four cases of accidental inhalation of materials and instruments but two cases were especially severe. The first involved an implant screwdriver that caused intestinal perforation and a fatal peritonitis. In the second case, a patient inhaled an endodontic file which became lodged in the secondary bronchi (causing an infectious focus), as it was impossible to extract this instrument bronchoscopycally, the patient underwent removal of the affected lung lobe.

- Ingestion or inhalation of materials or small dental instruments is a "classic" accident during dental care performed without the use of appropriate barriers: rubber dams or "threads" that ensure small tools (like implant screwdrivers) (24).
- The vast majority of ingestion or inhalation accidents usually have no clinical effect but swallowed sharp instruments may need to be removed by gastroscopy.

- The vast majority of inhalation cases may require performing a bronchoscopy.
- 9. Use a checklist in all oral surgical procedures.

In the OESPO series there are 23 cases of dental treatment in the wrong area. On the other hand, surgical procedures in the oral cavity (including placing implants) represent by far the largest source of adverse events in our series.

- Although surgical procedures in dentistry are limited in terms of importance, it is clear that pose a risk exacerbation usually present in dental treatments.
- The same as currently done in surgical procedures at a hospital, the use of a check-list is a valuable tool to avoid most adverse events during oral surgery. A check-list helps prevent an erroneous intervention or in the wrong area, among other risks (26, 27, 28).

#### 10. Monitor the onset and progression of infection in the oral cavity.

In the OESPO series, a significant percentage of hospital admissions were due to the development of infections, most of which healed without sequelae. However, five cases of fatal infection were recorded.

• Although most infectious diseases in the oral cavity are usually selflimiting, in exceptional cases (and especially in medically compromised patients) may endanger the patient's life (29).

# 11. <u>Have an action protocol for life-threatening emergencies in the dental clinic.</u>

Vital emergency situations in the dental office are fortunately rare. The tasks and manoeuvres to be performed must be protocolized for the dental team to perform properly, and not chaotically. This protocol should include the specific tasks of each team member (stay with the patient, bring and operate emergency instruments or equipment, call for external help, etc.).

- A person must be designated to keep medication and emergency equipment updated and ready; keep in mind that some drugs have a short shelf life.
- The direct care of the patient suffering a medical urgency is a key aspect in which errors were detected frequently.

- It is essential that the dentist stays with the patient until the emergency is solved or until the patient is taken to hospital by external emergency responders (paramedics).
- If evacuation to an external health center is performed by the dental team, the dentist must necessarily accompany the patient.
- And in any case, although apparently the patient recovers completely, it is advisable to accompany the patient to his/her home.

#### 4. Conclusion.

Most preventable adverse events during the dental health care are produced by a relatively small number of causes. Therefore, a few basic safety procedures can reduce significantly these preventable adverse events. Set in place protocols to: ensure the quality of clinical records, verify procedures for cleaning and sterilization; exert extreme care when prescribing drugs or perform radiographic exams; ban re-use of disposable instruments, containers or materials intended for a single clinical use; provide ocular protection to all patients and always use protective barriers to avoid ingestion or inhalation of small instruments; apply a surgical check-list; closely monitor the evolution of infectious processes; and always be prepared for possible life-threatening emergency situations in our dental office.

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# Table 1.

Cause of Death	Ν	%
Infectious processes after the dental treatment	N: 5	1.2%
Adverse reactions to drugs	N: 2	0.5%
Anaphylactic reaction to latex	N: 1	0.2%
Subarachnoid hemorrhage which occurred during anesthetic injection	N: 1	0.2%
Acute respiratory insufficiency in a patient with significant prior restriction	N: 1	0.2%
Major liver failure due to acute hepatitis B (acquired at dental office)	N: 1	0.2%

Table 1. Causes of death in the OESPO series (n=11). Modified from Perea-Pérez B, Labajo-González E, Santiago-Sáez A, Albarrán-Juan E, Villa-Vigil A. Analysis of 415 adverse events in dental practice in Spain from 2000 to 2010. Med Oral Patol Oral Cir Bucal. (2014), doi:10.4317/medoral.19601.

# Table 2.

Number	Procedure/practice
1	Develop a culture of safety and a health care system focused on prioritizing Patient Safety.
2	Looking after the quality of clinical records.
3	Check the procedures for cleaning, disinfection, sterilization, and preservation of clinical instruments.
4	Extreme caution when prescribing medications.
5	Limit the exposure of patients to ionizing radiation to the strictly necessary.
6	Never reuse packaging materials or substances intended for one clinical use only.
7	Protect patient's eyes during dental procedures.
8	Establish barriers to prevent ingestion or inhalation of materials or small instruments.
9	Use a checklist in all oral surgical procedures.
10	Monitor the onset and progression of infection in the oral cavity.
11	Have an action protocol for life-threatening emergencies in the dental clinic.

Table 2. The 'Eleven basic procedures/practices for dental patient safety'.