Exploration of Instruction for use and General Information Displayed on Dental Material and Device Labels/Packages

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Abstract-The regulatory agency (including FDA) regulates the marketing approval, licensing and clearance of OTC products (including dental material) to ensure product safety and effectiveness. The agency further extends its regulation to labelling and promotion of the product. Dentistry is the branch of medicine that is involved in the study, diagnosis, prevention, and treatment of diseases, disorders and conditions of the oral cavity. Although the practice of dentistry is governed by State law and regulations but dentist and patient must be aware of safety of the product. This can be achieved by proper labelling practice that can protect patients from adverse errors. Based on the data obtained, a unique packaging standardization checklist was developed. An exploratory cross sectional study was performed using various search engines and websites to access the laws and regulations existing pertaining to dental materials packaging. This study considered 16 brands of dental material instruments for analysis. Analysis was performed using the direct observation checklist. Conclusion: This study found lower rate of adherence to the guidelines, thus indicating insufficient information being disclosed to the consumers. The general labelling provisions for dental devices and the elements of comprehensive reprocessing instructions as per FDA Guidance Document need to be added on the labels.

1. INTRODUCTION

Regulatory Bodies the FDA assesses the safety and effectiveness of medical products. Furthermore, the agency is in charge of regulating the marketing, clearance, and licencing of pharmaceutical, over-the-counter, and biological goods in the United States.

1. The FDA has regulatory legal authority over medical product labelling and promotion. Promotion of the manufacturer's product includes any written, oral, video, or other actions that add to the product's sales growth
2. Based on scientific facts, manufacturers determine the proper product claims before submitting their application to the FDA.
3. The FDA does not control the practice of dentistry or medicine. Dentists and physicians, known as the "Practise of Medicine Exception," may prescribe or administer lawfully marketed medication for an off-label indication.
4. The Exploration of Instruction for Use must be studied for the "Adequate instructions for usage" to be included on the label. This means that the instructions must be followed in order for a layperson to use the product safely and for its intended purposes. The goal of "sufficient directions for use" is to relieve dental professionals of having to follow extensive instructions; nonetheless, the labelling must still include information regarding the conditions under which the dental material can be properly used. .(1)

2. OBJECTIVE

This study was designed with the following goals:

- To investigate existing rules and legislation relevant to specifications and standards, if any, for the display of information on dental materials and devices packages, and

- To conduct a legal analysis of the information included in/on dental material packs (2)

3. REGULATION FOR DENTAL MATERIAL AND DENTAL DEVICES

- Dental material labelling takes into consideration the regulations, recommendations, and standards. Within the FDA, regulations are based on the Code of Federal Regulations (CFR). Recommendations are based on current thinking and research, as well as standards such as ISO (International Organisations for Standardisation) and EMA (European Medicines Agency). Because many of the products are available worldwide, international standards are used.
- Labelling requirements exist for dental materials and devices. There are broad labelling rules and regulations for the minimum requirements for all devices under 21 CFR Part 801. Minimum requirements include the manufacturer's, packer's, or distributor's name and location; definitions; the intended use of the material; directions for use; (no) misleading statements; prominence of required label statements and use of symbols in labelling; a Spanish-language version; and the format of dates provided.
- "Adequate directions for use" must be included on the label. This refers to the guidelines that laypeople can follow to use a material safely and for its intended uses. The goal of "adequate directions for use" is to make sure that procedures are clear and simple for dental team members who are handling instrument processing. However, substances that have an Rx statement. (3)

4. GENERAL RULES FOR HANDLING DENTAL MATERIALS

- A dental hygienist must be informed about the composition, application, physical qualities, and manipulation skills of popular dental products. This will improve office efficiency, material economy, and patient care quality. Based on this knowledge, a few general principles should be followed to assure success when manipulating and applying these dental materials.

I.Follow the Manufacturer’s Directions

A. It is critical to read, comprehend, and follow the instructions that come with dental supplies. One should not only read the instructions but also understand why each step is executed in the manner specified.

B. Office personnel should save copies of instructions for office materials. These copies should be retained in a file, hard copy, or digital format. As a result, if the instructions for a kit are misplaced, a duplicate will be easily available. Most manufactures provide instructions online.

C. Before using a new item in a clinical setting, practise using it at least once after purchasing it. Examine the new product's "feel" and see how it stacks up against competing offerings.

D. Keep the supplies in a cool, dry area. Refrigeration increases several materials' shelf lives. On the other hand, if materials are cool, some will gel or mixes will separate. For proper storage, according to the manufacturer's instructions.

II.Mixing and Setting Times

A. To time key phases like etching, mixing, and setting, use a clock with a second hand or one that shows seconds. Both the clinic and the lab are affected by this.

B. The mouth is a warming place. Materials, therefore, are set more quickly in the mouth than on a countertop or instrument tray. A substance is placed in the mouth if it is placed on the instrument tray. Materials that are set through cooling, like impression compound, and materials that are triggered by light are exceptions to this rule. The moisture in the mouth also has the effect of speeding up the setting of some materials. (4)

5. MATERIALS AND METHODS

- A cross sectional study was designed and conducted for a period of from 10 Oct to 12 Oct 2022. The data collection was done over a period of 3 days. I Visited a wholesale distributor with permission from a letter head and during my visit, the distributor gave me a general overview of the major dental material merchants in Nagpur.
- Based on the data gathered, a direct observation checklist was created to assess the legal features of the packaging found on dental goods. The checklist was created using FDA. For the

purposes of documenting the checklist and presenting the findings, the rules for dental materials and devices were further classified as physical and chemical qualities, chemical composition, minimal tests addressed, preventive measures, waste disposal, and health hazards [Table 1] & [Table 2].

- The checklist excluded brand, indications, methods of use, consistency, and patient approval as independent parameters. The characteristics of unsatisfactory, satisfactory, and lack of information were not clear from the prior literature; the investigator for the study was calibrated for the use of the checklist as the absence and presence of recommendations were recorded in the study instrument.
- The main dental material merchants in Nagpur city were located online. All commercially registered enterprises in the city that sell dental products were visited in search of the various brands and types of dental materials included in the research. Each dealer was asked for permission, and the identity of the institution was kept hidden. Registered dealers were contacted in order to survey 20 different brands of dental materials and devices of unsatisfactory, satisfactory, and lack of information were not clear from the prior literature, the investigator for the study calibrated the use of the checklist by recording the absence and presence of guidelines in the study instrument.
- I visited a wholesale distributor with permission from a letterhead, and during my visit, the distributor gave me a general overview of the major dental material merchants in Nagpur. All commercially registered enterprises in the city that sell dental products were searched for the different brands and types of dental materials included in the study. Each dealer was asked to consent, and the identity of the institution was kept confidential. The registered dealers were contacted for a study of 16 brands of dental materials.(2)

6.IMPLEMENTATION

Before using a device in your organisation, review the IFU. Make sure the dental team is aware of the device's intended usage, including whether it is single-use, multiple-use (on a single patient), or reusable (and potentially reprocessed and used on additional patients). Devices may be marked by manufacturers as:

1. Reusable sterile products are intended to be reprocessed after each use, whereas non-sterile devices are intended to be processed both before and after each use.
2. A non-sterile, single-use product that is given with the intent of being processed before use Consider the preparation of clinical impressions, equipment, and other materials for safe laboratory usage.
3. Consider the processing of clinical impressions, appliances, and other things for safe laboratory handling and patient delivery. Finally, check packing and containers for safe storage and handling. The dental staff should specifically evaluate the IFU for dental burs and endo files. These devices should be clearly labelled to identify whether they are given pre-sterile and whether they are meant to be single-use or reusable.
4. Before the appliances are packaged and sterilised, a visual inspection may be used to find any wavering bioburden, dried dental materials, damaged or cracked instruments, and so on. Remaining bioburden or dental debris may prevent the device from being sterilised because the sterilant won't be able to penetrate it and reach all of the device's surfaces.(3)

DENTAL PRODUCTS WITH THE LIST OF INGREDIENTS
Table no.1

Name of Products	1 Zinc oxide Cement	2 Acrylic Repair	3 Mercury	4 Acid Fixes	5 Alginate Impression	6 Lidocaine	7 Camphore Monochoro phenol	8 Sodium Hypochorit e
Indication	✓	✓	✓	✓	✓	X	✓	✓
Method of uses	✓	✓	✓	✓	✓	✓	✓	X
Category	✓	X	✓	X	X	X	X	✓

Class	X	X	X	X	X	X	X	X
Name of company	✓	✓	✓	✓	X	X	✓	✓
Chemical Composition	✓	✓	X	X	X	✓	✓	X
Physical & Chemical	X	X	X	✓	X	X	X	X
Precaution yes/no	X	✓	✓	✓	✓	✓	✓	X
Trademark	X	X	X	✓	✓	✓	X	X
Price		✓	✓	✓	✓	✓	✓	✓
Use	✓	✓	✓	✓	✓	X	✓	✓
Brand	✓	✓	✓	✓	✓	✓	✓	✓

Table no.2

11 Etch Bonding Agent	12 EDTA Gel	13 Smart Etch	14 Lidocaine	15 F D Fixer	16 D D Developer	17 y-Dens impression	18 Ceramics Denture
✓	✓	✓	✓	X	X	X	X
X	✓	X	X	X	✓	X	X
X	✓	✓	X	✓	X	X	✓
X	X	X	X	X	X	X	X
X	✓	✓	✓	✓	X	X	X
X	X	✓	✓	X	X	✓	✓
X	X	✓	X	X	X	X	✓
X	X	X	X	X	✓	X	X
X	✓	✓	X	✓	✓	X	X
X	X	X	✓	X	X	X	✓
✓	✓	✓	✓	✓	✓	✓	✓

7.CONCLUTION & RESULT

- Exploration of Instruction for Use entails studying current law and using it to settle disputes in comparable circumstances. Not only do instructions present information for promoting the use of dental products by consumers, but they also demonstrate ways to prevent workplace dangers and preoperative errors.
- The current exploratory research sparked the need for recommendations that, if feasible, adhere to the most recent standards, as inadequate and out-of-date legislation permits the sale of subpar and dangerous goods. The findings showed a lack of adherence to the established standards, thus standard organisations should make it mandatory for manufacturers to follow their recommendations. (2)(3)
- The study improves the scope to include all dental products marketed by various companies. This study's finding of a lower rate of guideline compliance shows that customers are not receiving enough information. The general labelling rules for dental materials, as well as the components of full reprocessing instructions as per the FDA Guidance Document, must be included on the labels. (3)

REFERENCE

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