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Technical Report No. 1089

Track and Trace for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

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AMERICAN DENTAL ASSOCIATION TECHNICAL REPORT NO. 1089 FOR TRACK AND TRACE OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P's)

EXECUTIVE SUMMAY

(This Executive Summary does not form a part of American Dental Association Technical Report No. 1089 for Track and Trace of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's)).

Though FDA's Current Good Tissue Practice regulations requires manufacturers to use methods and controls to prevent the transmission of communicable disease by human cells, tissues, and cellular and tissue-based Products (HCT/P's), dental facilities that obtain HCT/Ps for implantation do not fall under the regulatory jurisdiction of the FDA and are not bound by these requirements. This has created a gap in the tracking of tissue implants from a donor all the way to the recipient. This capability, though not currently mandated, is necessary to facilitate the investigation of suspected or actual transmission of communicable disease and the provision of appropriate and timely corrective action.

Public health concerns are prompting regulators to consider proposals for action. Proposed regulations by the Centers for Medicare and Medicaid Services (CMS) and The Office of the National Coordinator (ONC) for Health Information Technology may soon require that certified Electronic Health Record (EHR) systems accommodate the collection of unique device identifier (UDI) information by providers.

This technical report defines inventory management requirements in dental practices for HCT/Ps to ensure traceability from the donor to the recipient and the recipient to the donor. Its intent is also to facilitate reporting of potential adverse reactions, including disease transmission, to all parties involved in processing the HCT/P. This technical report should be used in conjunction with ADA Technical Report No. 1081, *Track and Trace for Implantable Devices and Biologics Regulated as Medical Devices.*

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The Council on Dental Practice of the American Dental Association has approved American Dental Association Technical Report No. 1089 for Track and Trace of Human Cells, Tissues, and Cellular and Tissue-Based Products. Working Groups of the ADA Standards Committee on Dental Informatics (SCDI) formulate this and other specifications and technical reports for the application of information technology and other electronic technologies to dentistry's clinical and administrative operations. The ADA SCDI has representation from appropriate interests in the United States in the standardization of information technology and other electronic technologies used in dental practice. The ADA SCDI confirmed approval of ADA Technical Report No. 1089 on July 12, 2016.

The ADA Standards Committee on Dental Informatics thanks the members of Working Group 11.8 on Track and Trace for Implantable Devices and the organizations with which they were affiliated at the time the specification was developed:

Mohamednazir Harunani (chairman), Academy of General Dentistry, private practice, Rockford, IL;
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Craig Ratner, individual representative, Staten Island, NY;
Larry Stigall, American Association of Oral and Maxillofacial Surgeons, individual representative, Boone, NC; and
Leslie Tompkins Steen, US FDA Center for Devices and Radiological Health, Silver Spring, MD.

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FOREWORD

(This Foreword does not form a part of American Dental Association Technical Report No. 1089 for Track and Trace of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's)).

In 1992, there was interest in the standardization of clinical information systems related to electronic technology in the dental environment. After evaluating current informatics activities, a Task Group of the ANSI Accredited Standards Committee MD156 (ASC MD156) was created by the ADA to initiate the development of technical reports, guidelines, and standards on electronic technologies used in dental practice. In 1999, the ADA established the ADA Standards Committee on Dental Informatics (SCDI). The ADA SCDI is currently the group that reviews and approves proposed American National Standards (ANSI approved) and technical reports developed by the standards committee's working groups. The ADA became an ANSI accredited standards organization in 2000.

The scope of the ADA SCDI is:

> *"The ADA SCDI shall develop informatics standards, specifications, technical reports and guidelines and interact with other entities involved in the development of health informatics standards aimed at implementation across the dental profession."*

This technical report was prepared by SCDI Working Group 11.8 on Track and Trace of Biological Implantable Devices. The SCDI Working Group chairman is Mohamednazir Harunani. SCDI Working Group 11.8 prepared this report at the request of Mark Diehl, chairman of the SCDI Subcommittee on Clinical Informatics.

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SUMMARY

The US Food and Drug Administration (FDA), the American Association of Tissue Banks (AATB), and state regulations require that processors assign each donor a unique donor identifier (donor ID). They further require that tissue processers establish a system for tracking HCT/Ps from a donor to a consignee and/or end user facility and tracing from the consignee and/or end user facility to donor. To accomplish this, tissue processors are required assign each individual HCT/P product a distinct identification code.[1] This distinct identification code facilitates the linkage between HCT/Ps and a donor.

Relevant professional organizations provide guidelines to support a track and trace system for HCT/Ps, including the AATB, Association of perioperative Registered Nurses (AORN), and The Joint Commission. Surprisingly, few regulations or standards require consignees/end user facilities, such as dental practices, to track HCT/P use to the recipient.

SCOPE

This technical report defines inventory management requirements in dental practices for HCT/Ps to ensure traceability from the donor to the recipient and the recipient to the donor. Its intent is also to facilitate reporting of potential adverse reactions, including disease transmission, to all parties involved in processing the HCT/P. This technical report should be used in conjunction with ADA SCDI TR 1081, Track and Trace for Implantable Devices and Biologics, which addresses HCT/P's regulated as medical devices which are covered under the FDA's Unique Device Identifier (UDI) final rule.

BACKGROUND

In 2015, the ADA SCDI approved TR 1081, Track and Trace for Implantable Devices and Biologics, which addressed the FDAs recent UDI rule and offered expertise, guidance and best practices on implementing automatic identification and data capture technologies and their application in dentistry. The effort was led by Dr. M. Harunani, Chairman, SCDI WG 11.8.

Industry continues to be faced with additional challenges when it comes to other products used in dental practice not covered by the FDA's UDI rule, including many HCT/Ps. The positive impact of TR 1081 on facilitating track and trace of dental devices, coupled with petitions from stakeholders concerned with track and trace for HCT/Ps, encouraged ADA-SCDI WG 11.8 to develop this additional technical report to offer expertise, guidance and best practices on implementing automatic identification and data capture technologies and their application in dentistry for human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely as "361 products," (i.e. products regulated by FDA only under 21 CFR 1271 and Section 361 of the Public Health Services (PHS) Act). Such products, which are not covered under the FDA's UDI rule, are generally referred to as 361 HCT/Ps.

Though information standards have been developed specifically to address the tracking requirements of biologics, the ability to track and trace HCT/Ps from a donor to a recipient is a serious, ongoing public health concern largely hindered by a lack of an appropriate mechanism by which to collect, store and share HCT/P data for public health, clinical use and research purposes. Efforts to address the issue through federal regulatory and legislative efforts have largely fallen flat, but remain ongoing priorities for the Department of Health and Human Services, Department of Veteran's Affairs, the Department of Defense and other organizations.

In April 2015, Dr. Gregory Zeller, Chair of the ADA SCDI, made a presentation before the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), which provides advice to the Secretary of Health and Human Services (HHS) and to the Assistant Secretary for Health, on a range of policy issues and on the work of the ADA SCDI to address track and trace of HCT/Ps within the dental industry through standards development. While developed primarily for dental practices, ADA SCDI Technical Reports No. 1081 and 1089 are scalable to other healthcare settings, including hospitals, ambulatory surgical centers (ASCs) and other medical treatment

[1] § 1271.290(c). http://www.gpo.gov/fdsys/pkg/CFR-2007-title21-vol8/pdf/CFR-2007-title21-vol8-sec1271-290.pdf