Dental Pilot Projects Program: Technical Assistance in Adverse Event Reporting Requirements

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Webinar

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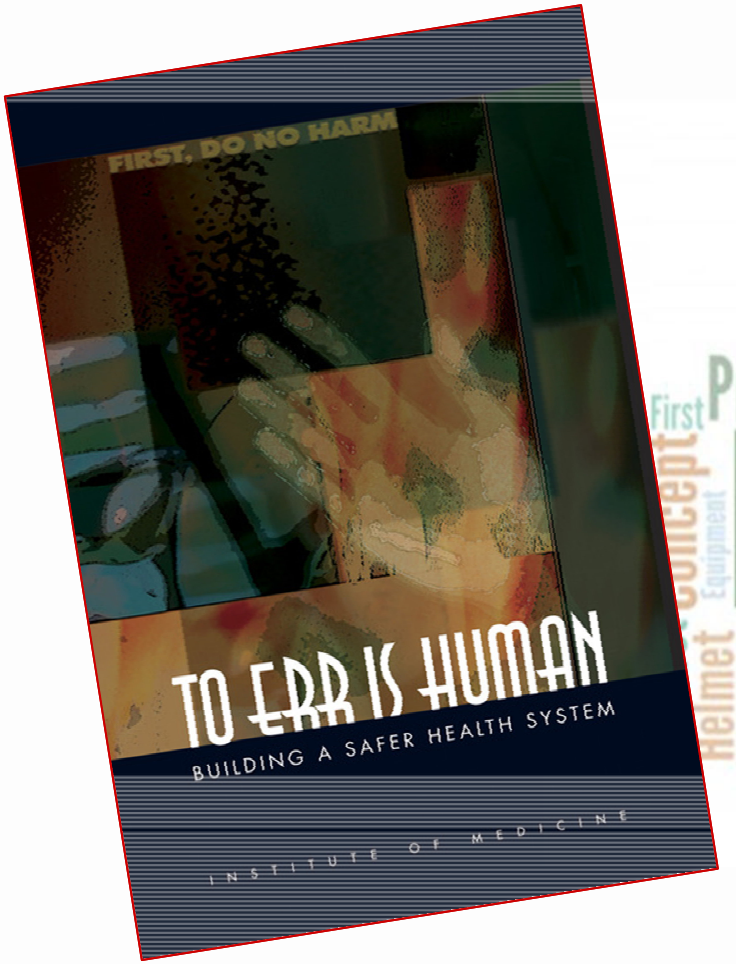
Oregon Health Authority

Oral Health Program
Public Health Division

Dental Pilot Projects Program: Technical Assistance in Adverse Event Reporting Requirements

- Recognize differences in Adverse Events(AE) and Quality of Care
- Understand Adverse Event Reporting Requirements for Dental Pilot Projects
  - Identify **when** to report AE and **where** to report


FIRST, DO NO HARM
TO ERR IS HUMAN
BUILDING A SAFER HEALTH SYSTEM
INSTITUTE OF MEDICINE


PATIENT SAFETY
Work
Caution
Risk
Safe
Protect
Sign
Secure
Danger
Rules
Helmet
Equipment
Life
Prevention
Industrial
Careful
First
Job
Health
Concept

What is an Adverse Event (AE)?

- Adverse events are incidents of "**physical harm** that are due to treatment within a timeframe relevant to the clinical scenario"
  - The goal is to identify the Adverse Event (AE).
  - It is not relevant to determine or assign fault or blame to recognize that an Adverse Event (AE) occurred.

Example: Patient moved and explorer fell into a patient's eye.
An AE occurred

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Adverse Events vs Quality of Care

- Past confusion between Adverse Events and Quality of Care concerns in pilot projects

- Adverse Event system is objective
- Purpose of Adverse Event system is to allow standardization using a defined process to determine if an AE occurred and the severity of AE
- Objective system = less ambiguity for the program and projects, provides clarification, less misinterpretation of information

Adverse Events vs Quality of Care

Examples of Dental Adverse Events

- Painful dry socket
- Perforation of tooth due to endodontic treatment
- Pain following extraction/RCT without proper pain management
- Wrong tooth extraction
- RCT on wrong tooth
- Paresthesia following a dental procedure
- Death due to overdose of anesthesia
- Tissue necrosis due to bleaching or rubber dam clamp
- Allergic reactions to dental materials
- Laceration of lip/tongue/cheek during dental procedure

Adverse Events vs Quality of Care

Poor Quality of Care

- Chart Omissions/inadequate documentation
- Poor or no images
- Bad margins, overhangs that do not cause ST damage
- Porous material
- Non-retentive restorations
- Open contacts
- Caries remains
- Heroic Dentistry (dentistry that has poor prognosis for longevity)
- Errors

Adverse Events (AE
of Car

AE's are when a patient is physically harmed…

Yes!…so we need an objective system to determine the severity of the AE…

It's confusing to say an AE occurred without context! This is good for everyone! We need to define when a serious AE happened vs mild-temporary AE! Big differences between the two!

"DEVELOPING A PATIENT SAFETY SYSTEM FOR DENTISTRY"

AHRQ Agency for Healthcare Research and Quality

US Department of Health & Human Services - NIH

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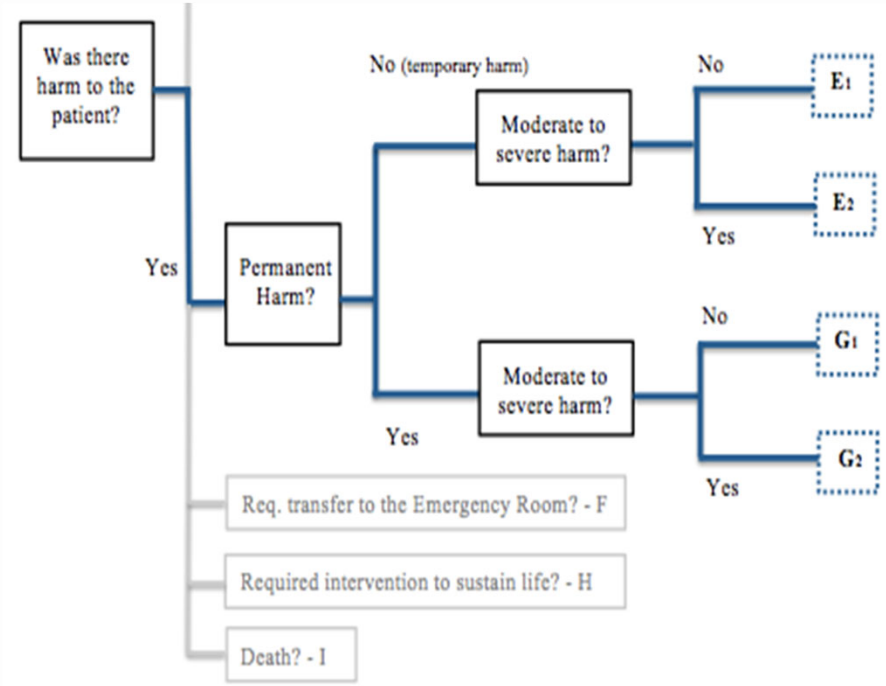
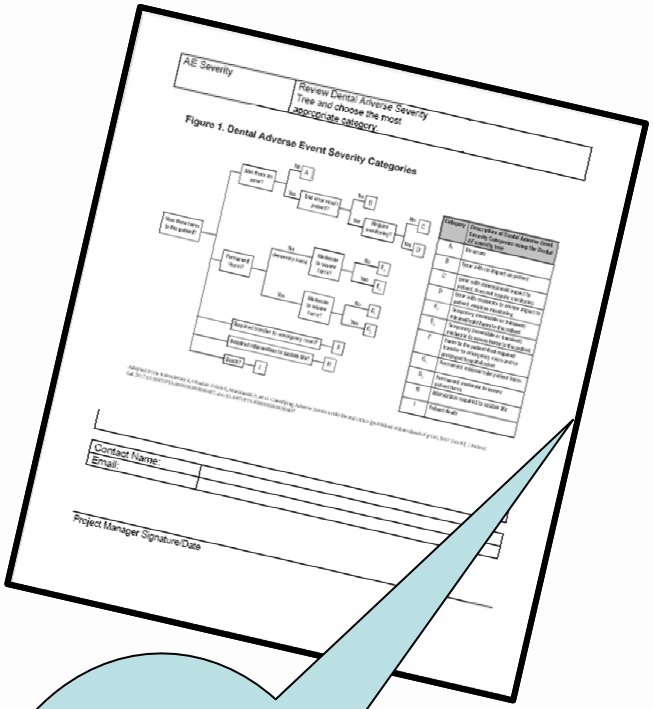
Severity Tree





Page 2 on Adverse Event Form

Kalenderian, E., Obadan-Udoh, E., Maramaldi, P., Etolue, J., Yansane, A., Stewart, D., & ... Walji, M. F. (2017). Classifying Adverse Events in the Dental Office. Journal of Patient Safety.

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Adverse Event Reporting Process

Adverse Events may be categorized by severity in relation to **patient harm**.

- Adverse Events or Suspected Adverse Events that classified as **E1:** Temporary (reversible or transient minimal/mild harm to the patient) must be reported in the **Quarterly Progress Reports.**
- Adverse Events or Suspected Adverse Events that classified as **E2 or greater,** must be reported to OHA **the day they occur** or **are found** to have occurred.

Category	Description of Dental Adverse Event Severity Categories using the Dental AE severity tree
A	No errors
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C	Error with minimal/mild impact to patient; does not require monitoring
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E	Temporary (reversible or transient) minimal/mild harm to the patient
E_2	Temporary (reversible or transient) moderate to severe harm to the patient
F	Harm to the patient that required transfer to emergency room and/or prolonged hospitalization
G_1	Permanent minimal/mild patient harm
G_2	Permanent moderate to severe patient harm
H	Intervention required to sustain life
I	Patient death

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Quarterly Reporting

- Report Adverse Events (AE) **E1** in the quarterly reports.
- Provide a description of each Adverse Event determined during the current reporting period to the Oregon Health Authority.
- See "Quarterly Progress Reporting Requirements" document from OHA.

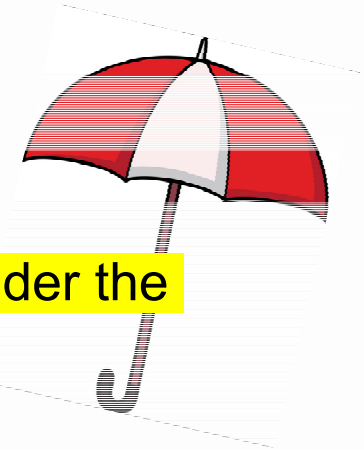
E1: Temporary (reversible or transient minimal/mild harm to the patient)

Goal is to identify Adverse Events

- Not blame patients, providers, etc.
- Ultimate goal is improve patient safety

Improve Patient Safety!

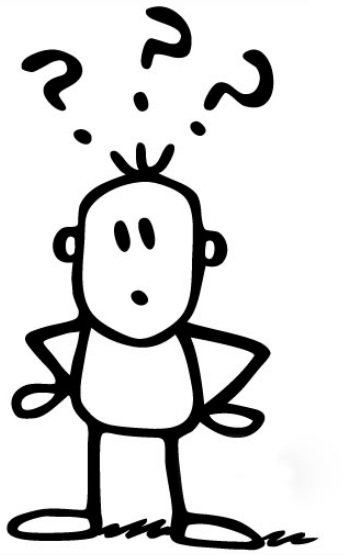
Adverse Event Reporting Process



- **Report** Adverse Event's that occur for patient's treated under the **umbrella** of the Dental Pilot Project Program

- Administrative Rules 333-010-0760 require reporting of Adverse Events
  - E1 on quarterly report
  - E2 or greater on Adverse Event Reporting Form

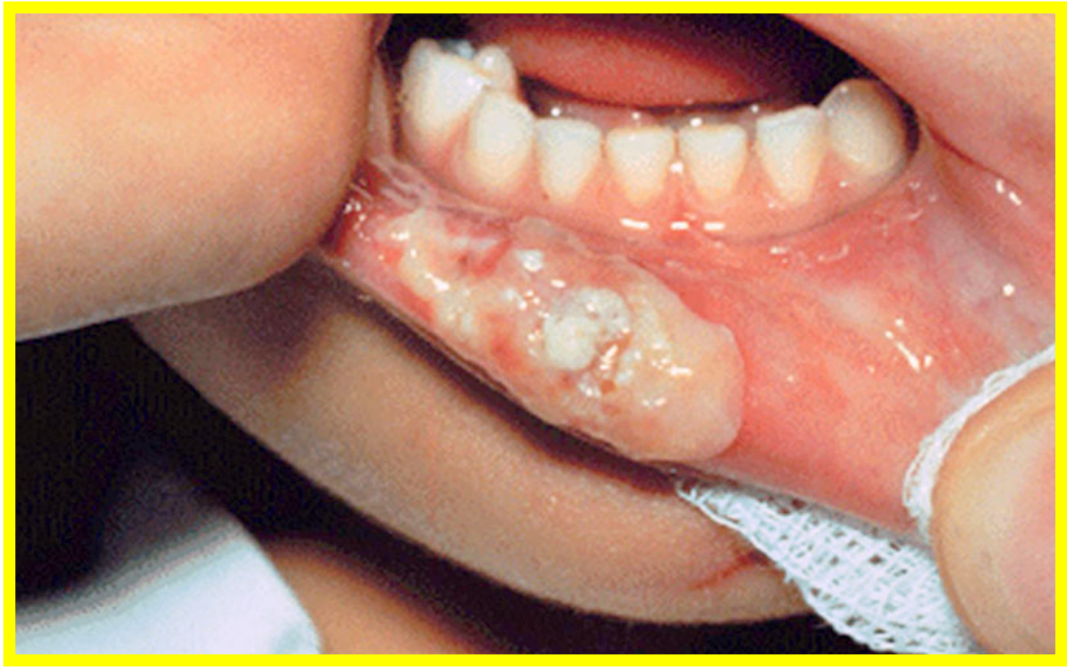
Adverse Event Reporting Process



Examples

Scenario

Clinic Scenario: Patient is an 6 year old child. Patient receives dental treatment involving local anesthesia of the inferior alveolar nerve. Patient tolerates procedure well. Parents call the next day and report that the child has bitten their lip while they were numb. Diagnosed as ulceration of lip due to lip biting.



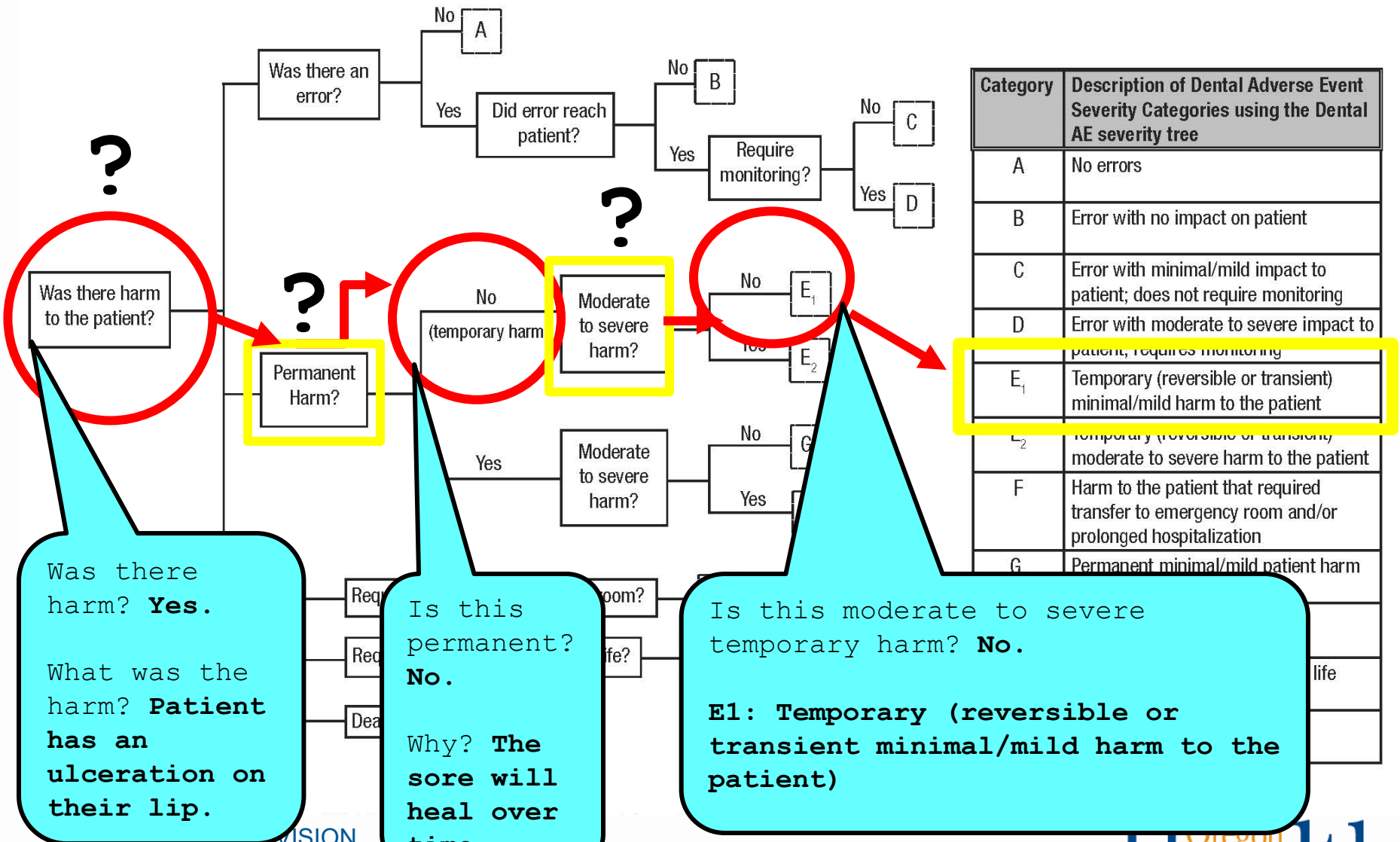
Traumatic Ulcer of Right Lower Lip

Source: Lip biting in pediatric dental patients following dental local anesthesia: a case report, J Pediatr Nurs. Author manuscript; available in PMC 2009 Dec 1.


BLAME

Adverse Event Reporting Process

Is this an Adverse Event?



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I	Patient death

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Adverse Events or Suspected Adverse Events that are determined to be an E1 must be reported on the Quarterly Report.

E1: Temporary (reversible or transient minimal/mild harm to the patient)

Questions

Adverse Event Reporting Process

Next Example

Scenario

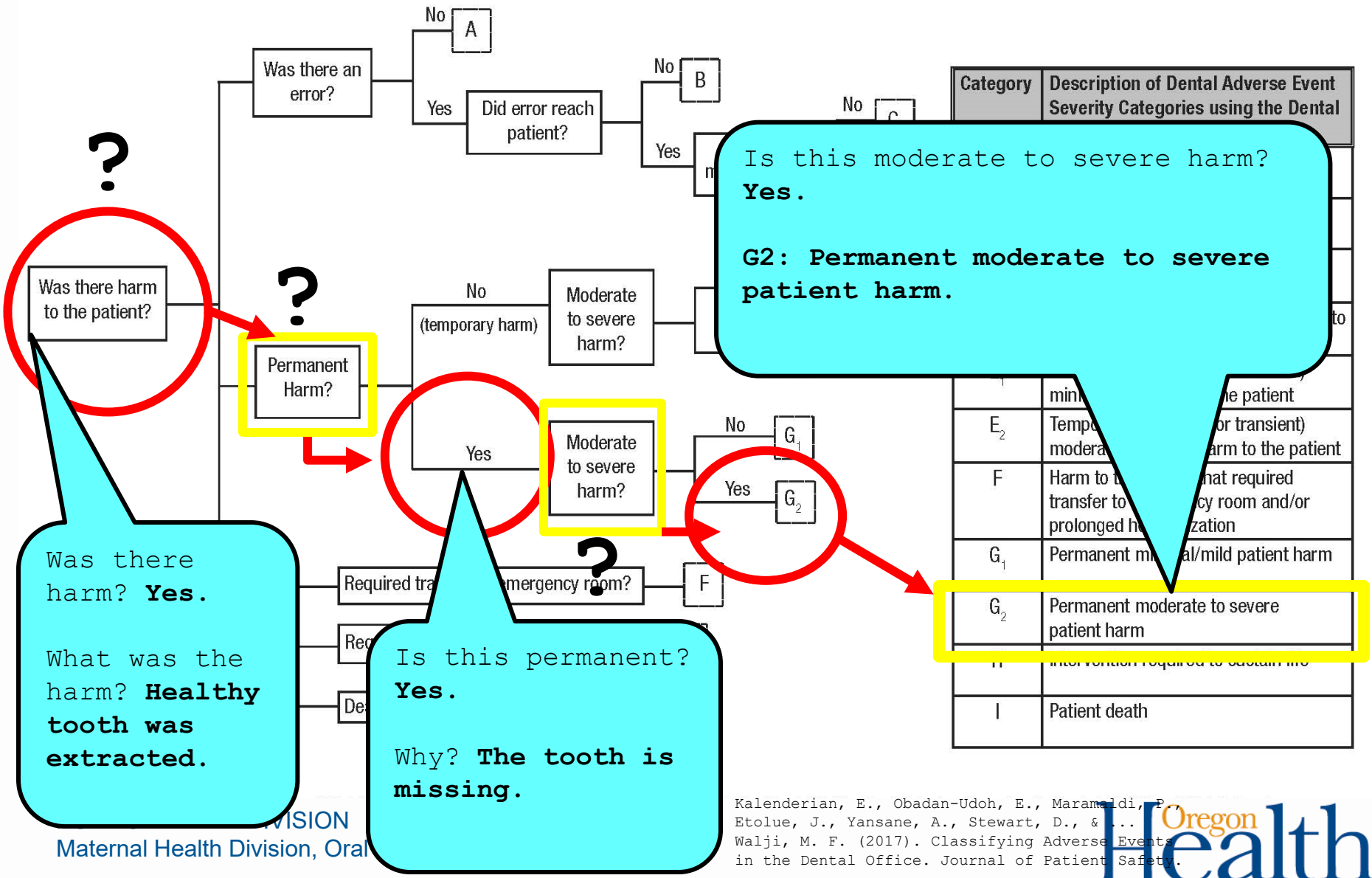
Clinic Scenario: Patient is a 25 year old female. Patient was treatment planned to have #18 extracted. Provider extracted #19. Wrong tooth was extracted.

https://www.ncbi.nlm.nih.gov/pubmed/28546594


BLAME

Adverse Event Reporting Process

Is this an Adverse Event?



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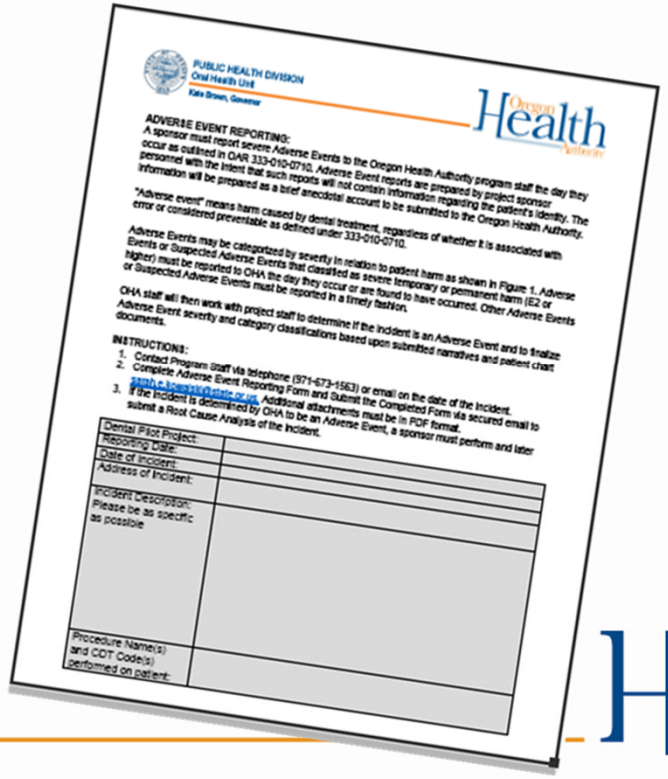
Adverse Events or Suspected Adverse Events that are determined to be an **E2 or greater** must be reported on the **Adverse Event Reporting Form**.


PUBLIC HEALTH DIVISION
Oral Health Unit
Kate Brown, Governor

Oregon Health Authority

ADVERSE EVENT REPORTING:
A sponsor must report severe Adverse Events to the Oregon Health Authority program staff the day they occur as outlined in OAR 333-010-0710. Adverse Event reports are prepared by project sponsor personnel with the intent that such reports will not contain information regarding the patient's identity. The information will be prepared as a brief anecdotal account to be submitted to the Oregon Health Authority.

"Adverse event" means harm caused by dental treatment, regardless of whether it is associated with error or considered preventable as defined under 333-010-0710.

Adverse Events may be categorized by severity in relation to patient harm as shown in Figure 1. Adverse Events or Suspected Adverse Events that classified as severe temporary or permanent harm (E2 or higher) must be reported to OHA the day they occur or are found to have occurred. Other Adverse Events or Suspected Adverse Events must be reported in a timely fashion.

OHA staff will then work with project staff to determine if the incident is an Adverse Event and to finalize Adverse Event severity and category classifications based upon submitted narratives and patient chart documents.

INSTRUCTIONS:
1. Contact Program Staff via telephone (971-673-1563) or email on the date of the incident.
2. Complete Adverse Event Reporting Form and Submit the Completed Form via secured email to [redacted]. Additional attachments must be in PDF format.
3. If the incident is determined by OHA to be an Adverse Event, a sponsor must perform and later submit a Root Cause Analysis of the incident.

Dental Pilot Project:	
Reporting Date:	
Date of Incident:	
Address of Incident:	
Incident Description: Please be as specific as possible	
Procedure Name(s) and CDT Code(s) performed on patient:	

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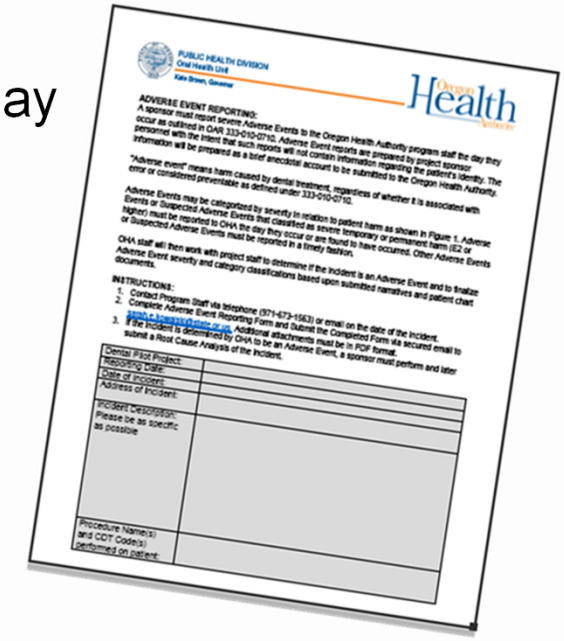
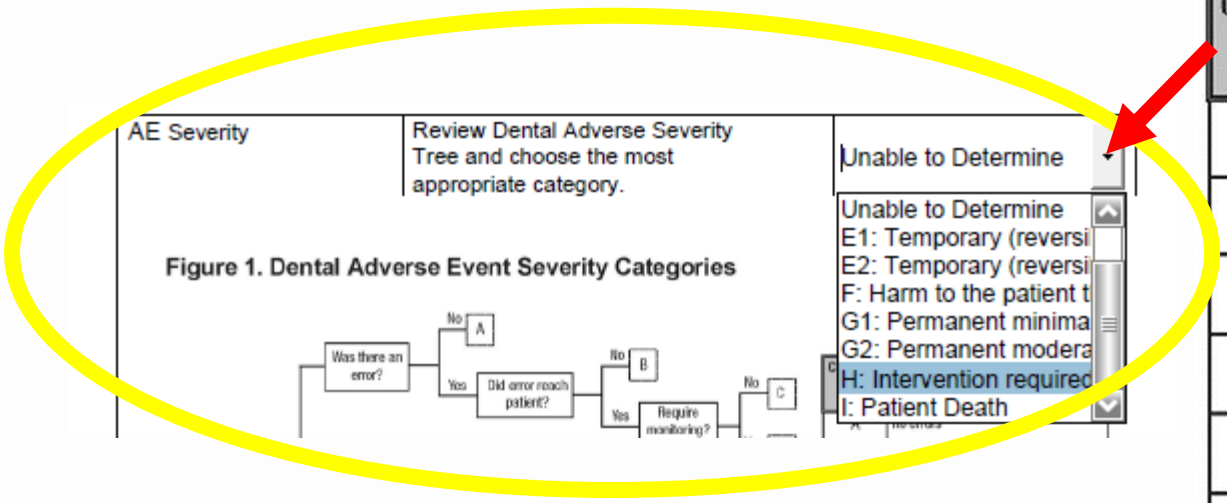
Adverse Event Reporting Process

- AE E2 or greater must be reported to OHA the day they occur or are found to have occurred
  - Dental Pilot Project Name:
  - Reporting Date:
  - Date of Incident:
  - Address or Location of Incident:
  - Incident Description:
  - Procedure Name(s) and CDT Code(s) performed on patient:



PUBLIC HEALTH DIVISION
Maternal Health Division, Oral Health Program

Adverse Event Reporting Process



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I	Patient death

- **Technical Assistance**: OHA staff will work with project staff, if requested, to determine if the incident is an Adverse Event and to finalize Adverse Event severity and category classifications based upon submitted narratives and patient chart documents.

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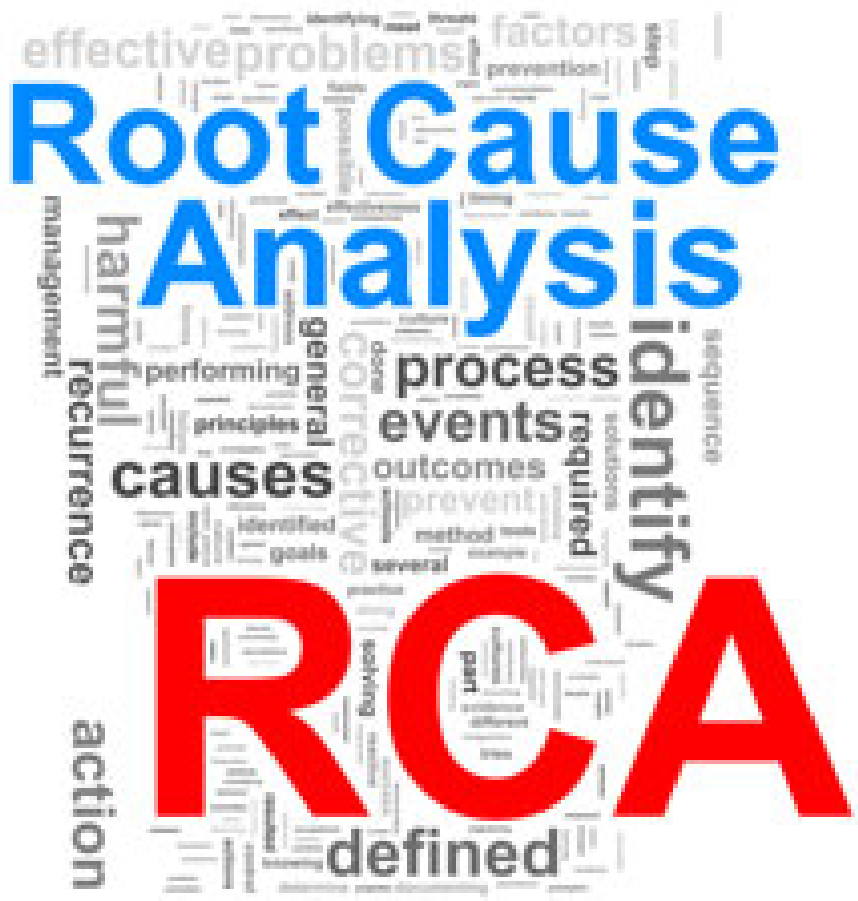
- If the incident is determined by OHA to be an Adverse Event **E2 or greater,** a sponsor must perform and later submit a Root Cause Analysis of the incident.



Root Cause Analysis

- Goal is to identify gaps in systems or processes
- Improve patient safety
- Prevent reoccurrence

Example RCA Findings:

- Miscommunication between clinics
- Different teeth numbering systems
- Incorrectly mounted radiographs

Wrong tooth extraction: Root cause analysis

Oren Peleg, DMD[1]/Navot Givot, DMD[1,2]/Tali Halamish-Shani, LLB[3]/Shlomo Taicher, DMD[1]

Objective: Errors made by clinicians in dental practice require changes in the original planning of patient management. The purpose of this study was to analyze events that led to wrong tooth extraction. **Method and Materials:** A total of 54 insurance claims for wrong tooth extractions were reported and evaluated by Medical Consultants International from 1993 to 2004. Data were collected and analyzed according to parameters regarding the clinician who performed the procedure, the nature of the referral for extraction, the demographics of the patient, the venue in which the extraction took place, the reason for the error, and the nature of the insurance claim. **Results:** General practitioners performed 72% of the extractions, 48% of the referring clinicians were orthodontists, 74% of the errors were made during extraction, and 77% of the errors were made in polyclinics. **Conclusions:** Errors during treatment and poor communication among clinicians led to extraction of the wrong tooth. This can be avoided by greater caution on the part of the extracting clinician when following the treatment plan. Guidelines toward this end are recommended. (Quintessence Int 2010;41:869–872)

Key words: tooth extraction, treatment error, wrong tooth extraction

Tooth extraction is a common procedure in dental practice, making it all the more curious how rarely wrong tooth extraction is mentioned in the literature and the fact that its incidence is unknown. Given that medical errors in general tend to be underreported,[1] it seems reasonable to assume that the known figures on wrong tooth extraction are lower than actually is the case, as well. Numerous extractions are performed based on a referral from another clinician, without the operator's being acquainted with the patient and the referring clinician's overall treatment plan. This gap could result in the need for taking corrective measures should an error occur, an event that could be expensive and certainly aggravating to both the patient and the clinician.

In 2005, the ADA Council on Members Insurance and Retirement Programs conducted a survey on the frequency, severity, and causes of dental malpractice claims reported between 1999 and 2003. Fifteen of the leading dental professional liability insurers across the country participated, which together insured nearly 104,600 licensed dentists. In the report of the results, the ADA published that statistics on dental malpractice claims are available only from the insurance companies that underwrite dental professional liability insurance.[2] But these companies do not publicly disclose the data they collect, most likely for competitive reasons. In the survey, the definition of "incidence" of professional liability claims was the total number of reported claims divided by the total number of the company's dentist policyholders, and a "claim" was defined as an occurrence in which a patient demanded damages from the insured company. The survey revealed that 4.8% of the allegations involved in paid claims were due to treatment of

"Wrong Tooth Extraction: Root Cause Analysis"

Questions

Adverse Event Reporting Process

Next Example

Scenario

Clinic Scenario:
Patient presents for treatment on #30.
Patient is incorrectly anesthetized on the opposite side, left lower quadrant.

Adverse Event Reporting Process

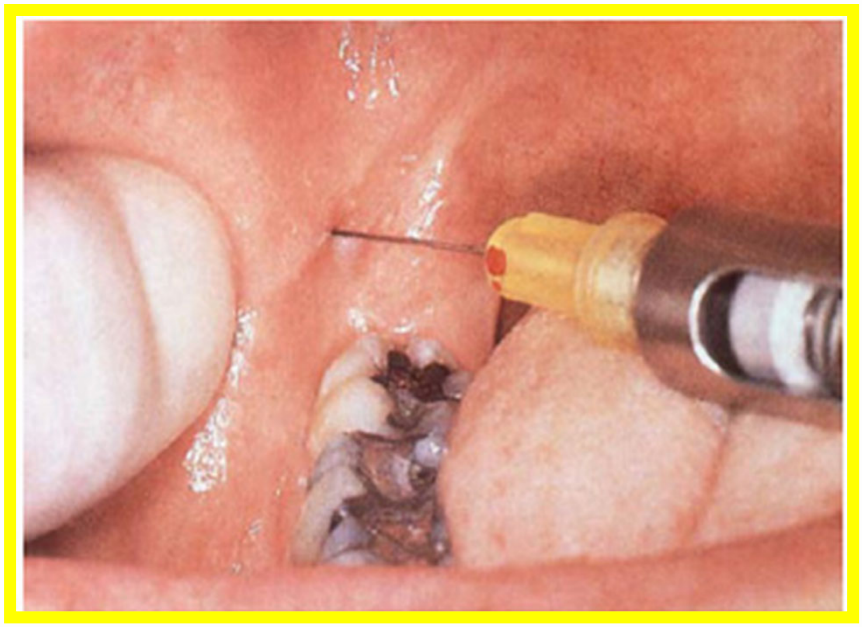
Is this an Adverse Event?

? **Was there physical harm?** NO

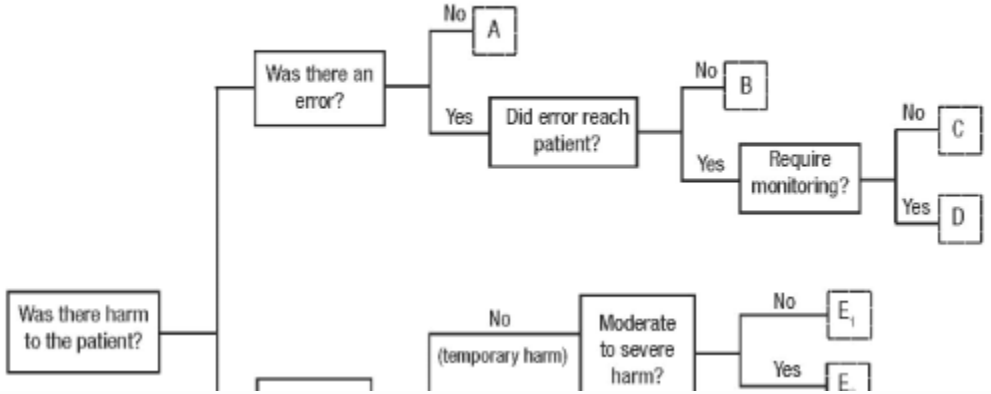
Why? Anesthetizing the wrong site is an **error, not an AE unless harm occurs**

What are errors?

- Errors are unintended incidents that did not cause physical harm
- Example: anesthetizing the wrong side



Errors



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- If **no harm** to patient you **do not need** to report errors to OHA as Adverse Events
- Quarterly Progress Reports and patient safety concerns, errors could be reported here if a patient safety concern is found

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Questions

Adverse Event Reporting Process

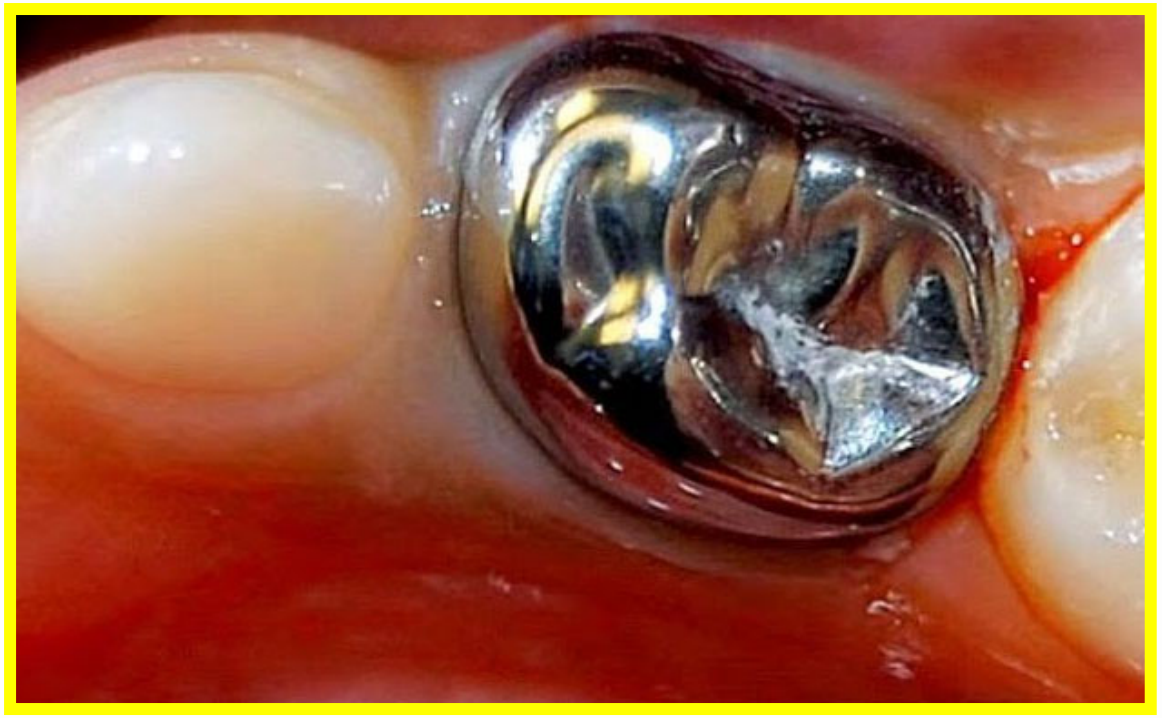
Next Example

Scenario

Clinic Scenario: Patient is 7 year old child. Provider places a stainless steel crown on #I.

Patient returns two months later complaining of tenderness around the crown.

Upon examination, excess cement is found and removed. Tissues are irritated.

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Adverse Event Reporting Process

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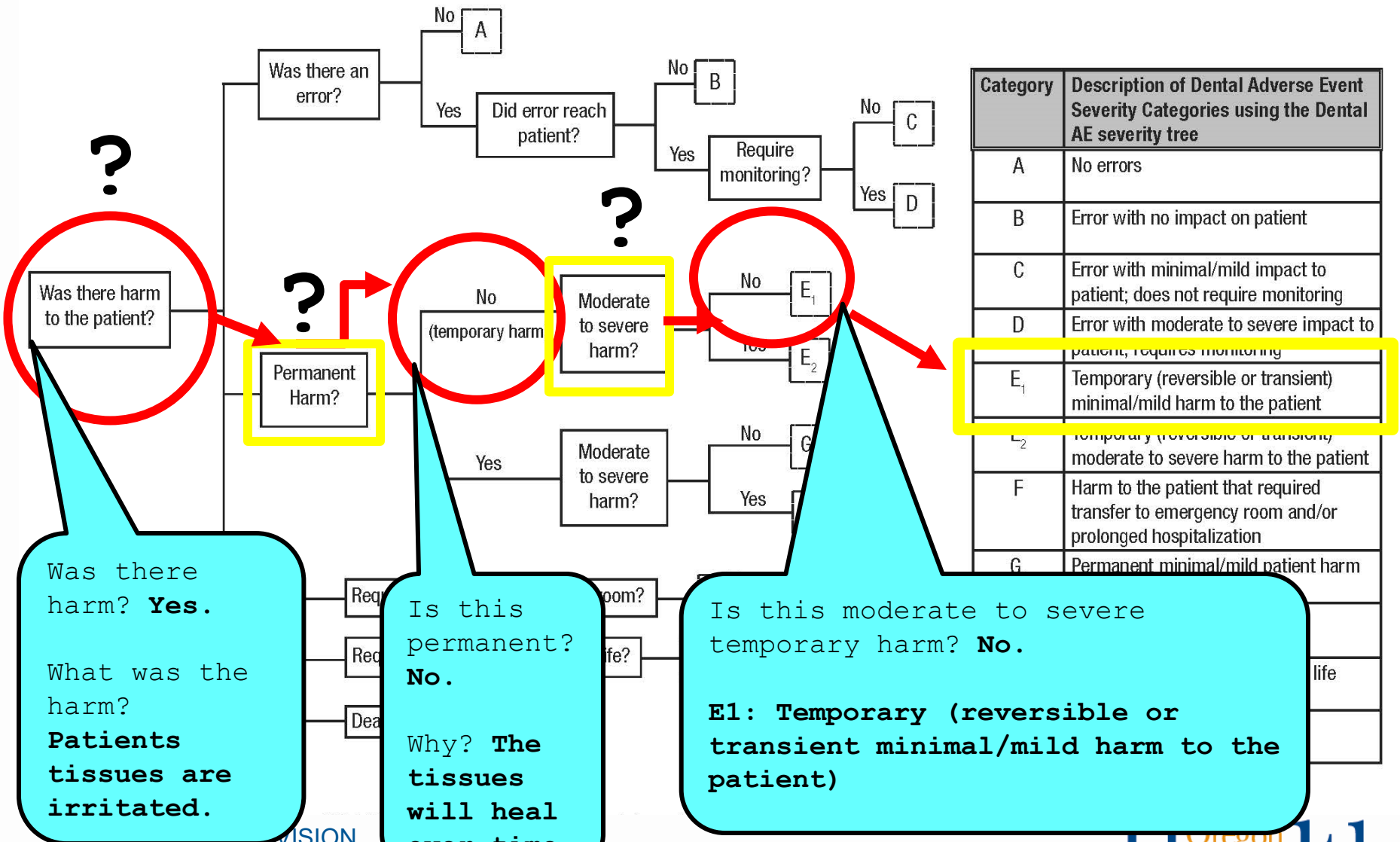

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Adverse Events or Suspected Adverse Events that are determined to be an E1 must be reported on the Quarterly Report.

E1: Temporary (reversible or transient minimal/mild harm to the patient)

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Questions

Adverse Event Reporting Process

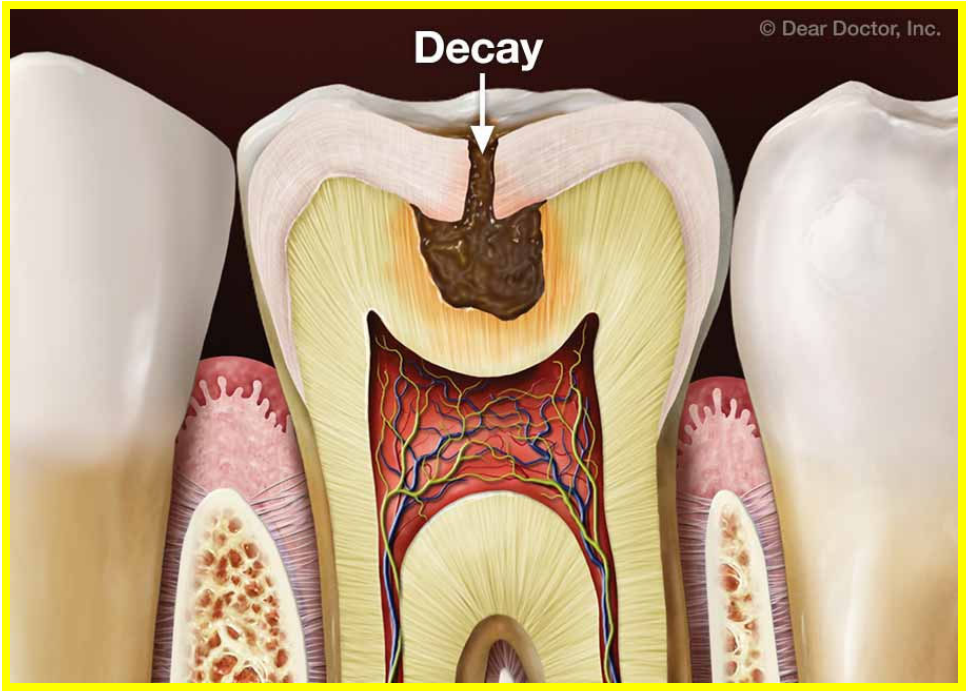
Next Example

Scenario

Clinic Scenario: Patient is 20 year old female. Patient refuses local anesthetic. Provider completes restoration on #30. Patient returns six months later complaining of sensitivity.

Radiograph is taken.

Decay was not completely removed during first restoration.

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Adverse Event Reporting Process

Is this an Adverse Event?

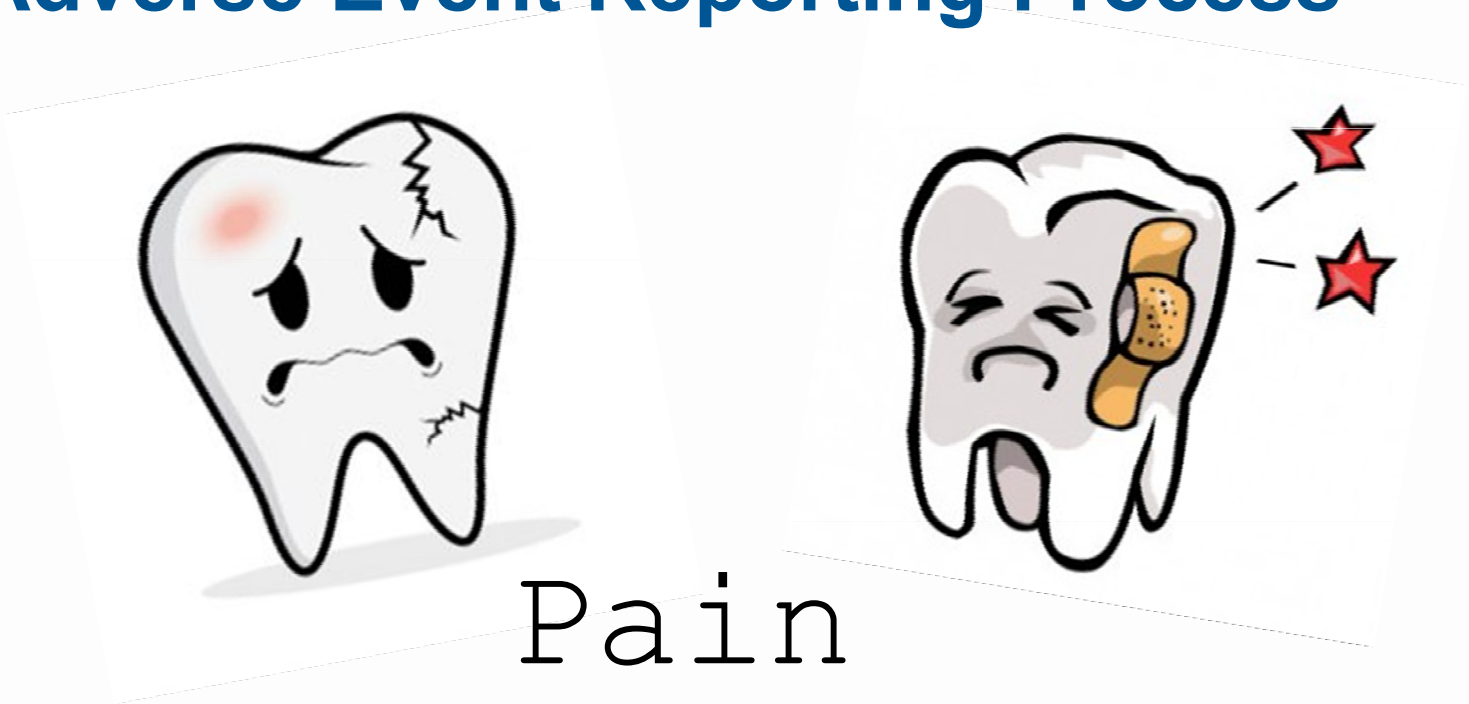
Was there physical harm?

NO

Why? Patient already had decay, the provider did not cause the decay. The lack of complete removal is a poor quality of care issue.

Questions

Adverse Event Reporting Process



Pain

Pain can be expected; if the pain is slight, manageable or temporary, then **no harm** has occurred. **No Adverse Event**

Pain Scale

Scale of 1-10

- 1-3 = Slight pain = No Harm (expected or considered commonly occurring within the standard of care)
- 4-6 = Moderate pain = E1
- 7-10 = Severe pain = E2

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Pain

- In the absence of a pain scale, if the pain is described as
- “Can’t sleep, Killing me, throbbing, stabbing, jabbing, pounding, pulsing it is an AE =E2
- If the patient goes in for an emergency dental visit for pain it is an AE = E2
- If a representative calls with the complaint and requests and Rx for pain management, it is an AE = E2

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Questions

Specific Questions Submitted to OHA

Specific Questions Submitted

Question: There is minimal to moderate damage to adjacent teeth while removing decay. What should this be classified as?

First questions is always…

YES

Then we determine the severity of the AE using the AE system

Specific Questions Submitted

Question: There is minimal to moderate damage to adjacent teeth while removing decay. What should this be classified as?

Review the clinical scenario

If the tooth can be minimally smoothed such that the contact is favorable and treated with fluoride until it remineralizes, then it's E-2. The harm was moderate/severe enough that it requires an intervention to compensate.

If adjacent tooth severely damaged, definitely requires a restoration, this severity of the AE will be either G1 or G2, depending on degree of damage, etc.

Specific Questions Submitted

Question: There is soft tissue trauma from removing supragingival calculus. What should this be classified as?

First questions is always…

Maybe

Review clinic scenario to determine

Specific Questions Submitted

Question: There is soft tissue trauma from removing supragingival calculus. What should this be classified as?

Review the clinical scenario

It is within the normal course of treatment to have bleeding, irritation, etc. when scaling. If a provider has incorrectly adapted the scaler or curette to the tooth, trauma beyond the normal expected course of treatment would be considered an E1, temporary mild harm.

If a papilla is lopped off and then it's "G" as the result would be flattened architecture.

Specific Questions Submitted

Question: There is a small cut of tongue during prepping of tooth structure. What should this be classified as?

First questions is always…

Yes

Review clinic scenario to determine AE severity

Specific Questions Submitted

Question: There is a small cut of tongue during prepping of tooth structure. What should this be classified as?

Review the clinical scenario

It is within the normal course of treatment to have bleeding, irritation, etc. when completing restorative procedures around the tooth. It is not part of the normal expected course of treatment to have a cut on the tongue. A cut on a tongue would be considered an E1, temporary mild harm.

Specific Questions Submitted

Question: There is a soft tissue trauma during polishing of restoration? What should this be classified as?

First questions is always…

Maybe

Review clinic scenario to determine AE severity

Specific Questions Submitted

Question: There is a soft tissue trauma during polishing of restoration? What should this be classified as?

Review the clinical scenario

It is within the normal course of treatment to have bleeding, etc. when polishing a restoration. If tissues are frail, inflamed, etc. bleeding is common during the normal course of treatment. It depends on the clinical scenario – has a section of soft tissue been removed? If it is beyond the normal expected course of treatment then it would be considered an E1, temporary mild harm. Will tissue grow back? Is papilla removed? Then G1. Depends on scenario.

Dental Pilot Projects Program: Technical Assistance in Adverse Event Reporting Requirements

- Recognize differences in Adverse Events and Quality of Care
- Understand Adverse Event Reporting Requirements
  - Identify **when** to report AE and **where** to report

Questions

OHA

Technical Assistance

Sources

- Kalenderian E, Walji M, Tavares A, Ramoni R. An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. Journal Of The American Dental Association (1939) [serial online]. July 2013;144(7):808-814. Available from: MEDLINE Complete, Ipswich, MA. Accessed July 26, 2017.

- Kalenderian, E., Walji, M. F., Tavares, A., & Ramoni, R. B. (2013). An adverse event trigger tool in dentistry: a new methodology for measuring harm in the dental office. Journal Of The American Dental Association (1939), 144(7), 808- 814.

- Kalenderian, E., Obadan-Udoh, E., Maramaldi, P., Etolue, J., Yansane, A., Stewart, D., & ... Walji, M. F. (2017). Classifying Adverse Events in the Dental Office. Journal of Patient Safety.

- Annotated Event Reporting Bibliography Handout

Thank you!