Developing a Patient Safety System for Dentistry

Elsbeth Kalenderian, DDS, MPH

Harvard School of Dental Medicine

Outline

- Importance of Patient Safety Research in Dentistry
- Review of Dental Adverse Events in FDA MAUDE
- Patient Safety Culture in Dental Clinics
- Adverse Event Detection through focused chart reviews
- Integrating patient safety into the curriculum
- Next Steps

Health Care is Hazardous

Health Care is Hazardous

DANGEROUS (1>1,000)
Health Care

REGULATED
Driving

ULTRA-SAFE (<1/100K)
- Mountain Climbing
- Chemical Manufacturing
- Chartered Flights
- Scheduled Airlines
- European Railroads
- Nuclear Power

Number of Encounters for each Fatality

Total Lives Lost per year

1
10
100
1,000
10,000
100,000
1,000,000
10,000,000

Elsbeth Kalenderian, DDS, MPH
Who Judges Quality in Medicine?

- CMS
- JCAHO
- Solucient
- HealthGrades
- Regional Consortia & Collaboratives
- State Health Departments
- Clinical Bodies (ie. AHA, etc.)
- Media (Fortune, US News & World Report, etc.)
- Health Care Organizations
  - Dashboard, Scorecards, Satisfaction, etc.

David Blum, White Plains Hospital Center
Who Judges Quality in Dentistry?

- Payors
- State Health Departments
- Clinical Bodies (ADA, etc.)
- Media (Fortune, US News & World Report, etc.)

Patient safety vocabulary.
- Safety: freedom from accidental injury
- Adverse event: an injury resulting from a medical intervention (i.e., not due to the underlying clinical condition of the patient)
- Preventable adverse event: an adverse event that was attributable to a clinical error.
- Error: the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim; not all errors result in injury. Errors can include problems in practice, products, procedures, and systems.

Review of Dental Adverse Events in FDA MAUDE
What do you find in MAUDE

- Reports of Adverse Events involving medical devices
  - Manufacturer information
  - Adverse event information
  - Device information
  - Patient information

Manufacturer and User Facility Device Experience Database

MAUDE Report Types

- Mandatory Reports
  - Manufacturer reports – Since 1996
  - Distributors reports – Since 1993
  - User facilities reports – Since 1991
  - Form FDA 3500 A – mandatory reporting

- Voluntary Reports
  - Health care providers
  - Patients and their family members
  - Form FDA 3500 – Voluntary reporting (next slide)

- May not include reports due to exemptions, variances or alternative reporting requirements

Voluntary reporting form FDA -3500
Adverse events and its types in MAUDE

Adverse event is “any undesirable experience associated with the use of medical products in patients” (FDA)

Types of adverse events listed in MAUDE:

- Death
- Injury
- Malfunction
- Others
- No answers provided

Description of adverse event - Death

Description of adverse event - Injury
Adverse events in dentistry

- Objective: To determine the frequency and type of dental adverse events listed in MAUDE between August 01, 1996 till October 05, 2012

- Methods:
  - Data download from MAUDE
  - Database preparation – MySQL database 5.0.77 and MySQL workbench – 5.2 version
  - Data exploration and data mining

Adverse event reports related to dental devices

- Total adverse event reports = 2,533,922
- Total dental adverse event reports = 34,343

- Injuries = 22,032
- Malfunctions = 8,809
- Deaths = 80

Description of adverse event - malfunction

- Model Number: 38824A
- Event Date: 07/05/2002
- Event Type: Malfunction
- Event Description:
  - The unit operated normally until the bearings failed and the tool started vibrating. The patient complained of pain and the operator discontinued the procedure.

- Manufacturer Description:
  - The bearings failed due to wear and tear. The operator continued the procedure despite the patient's complaint.

- Injuries = 0%
- Malfunctions = 64%
- Deaths = 26%
Dental adverse events: trends

Deaths due to dental devices from 1996 - 2012

Injuries due to dental devices from 1996 - 2012

Malfunctions due to dental devices from 1996 - 2012

Deaths Injuries Malfunctions

Yearly reporting of dental device-related adverse events to FDA

Yearly reporting of medical device-related adverse events to FDA

Top 6 dental devices involved in adverse events

Endodontic Files
Dental Cements
Bone plate
Bone cutting instruments and accessories
Denture adhesives
Endosseous implants

852
904
1177
1554
1722
18563
Top 5 endosseous implants problems

- Failure to osseointegrate: 1198
- Loss of osseointegration: 284
- Removal of implant: 28
- Implant overload: 13
- Fracture: 

Top 5 reporter’s occupation listed in MAUDE

- DENTIST: 18006
- PATIENT: 1062
- PHYSICIAN: 2162
- DENTAL ASSISTANT: 154
- PHYSICIAN: 1262

MAUDE Limitations

- Contains incomplete and unverified information
- Not all AEs are reported
- Focused on devices
Assessing Safety Culture in Dental Clinics

developed the Medical Office Survey On Patient Safety Culture in response to requests for a survey that focused on patient safety culture in outpatient clinics


By the Numbers

1 The MOSOPS is suitable for outpatient clinics within 1 geographic location that share some or all staff.

The MOSOPS has 38 items. 38

10 The MOSOPS captures information about 10 dimensions of patient safety.

We administered the MOSOPS at 3 academic clinics.

3 328 students, clinical faculty, hygienists, staff, and residents responded.
MOSOPS results are organized according to the 10 concepts and are reported in terms of % positive responses.

Teamwork 72
Office Processes & Standardization 49
Staff Training 48
Organizational Learning 44
Work Pressure & Pace 42
Communication about Error 42
Communication Openness 41
Overall Pt. Safety & Quality 39
Pt. Care Tracking/Follow-Up 36
Leadership Support for Pt. Safety 36

In this office, we treat each other with respect.
When there is a problem in our office, we see if we need to change the way we do things.
It is just by chance that we don’t make more mistakes that affect our patients.
This office documents how well our chronic-care patients follow their treatment plans.
They aren’t investing enough resources to improve the quality of care in this office.
Teamwork
Office Processes & Standardization
Staff Training
Organizational Learning
Work Pressure & Pace

Communication about Error
Communication Openness
Overall Pt. Safety & Quality
Pt. Care Tracking/Follow-Up
Leadership Support for Pt. Safety

Detecting Adverse Events through focused chart reviews
We can find adverse events and harm to patients happening in our dental clinics...if we look.

Focused Chart Review is More Efficient than Random Review

In response to the need for a more practical and less labor-intensive approach to assessing patient safety, the Institute for Healthcare Improvement developed the Global Trigger Tool. This new method has been increasingly used by hospitals in the United States and the United Kingdom...The tool has also been used by quality improvement organizations, and by regulators such as the Department of Health and Human Services (HHS) Office of Inspector General...
### Integrating Patient Safety into the Dental Curriculum

<table>
<thead>
<tr>
<th>Identification Mode</th>
<th>Adverse Event Detected</th>
<th># Records Triggered</th>
<th># Records w/ AE</th>
<th>#Δn</th>
<th>PVP* (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incision and Drainage Trigger (CDT 72/10)</td>
<td>Inflammation/infection, Intrageneric Injury</td>
<td>14</td>
<td>7</td>
<td>8</td>
<td>0.50          (0.37, 0.67)</td>
</tr>
<tr>
<td>Removal of implant Trigger (CDT 41/09)</td>
<td>Inflammation/infection, Intrageneric Injury</td>
<td>14</td>
<td>10</td>
<td>10</td>
<td>0.71          (0.53, 0.86)</td>
</tr>
<tr>
<td>Multiple Visit Trigger*</td>
<td>Failed restoration, Implant failure, TMJ complications, Medical complication, Poor healing, Tooth fracture</td>
<td>287</td>
<td>140</td>
<td>148</td>
<td>0.49          (0.43, 0.55)</td>
</tr>
<tr>
<td>Any Trigger</td>
<td></td>
<td>315</td>
<td>157</td>
<td>258</td>
<td>0.50          (0.45, 0.56)</td>
</tr>
<tr>
<td>Randomly-selected Records</td>
<td>Intrageneric Injury, Failed restoration, Failed endodontic treatment, Inflammation/infection</td>
<td>50</td>
<td>17</td>
<td>33</td>
<td>0.34          (0.22, 0.46)</td>
</tr>
</tbody>
</table>


---

---

---

---
What's out there

To ensure that every medical school and teaching hospital in the U.S. has access to a critical mass of faculty that are ready, able, and willing to engage in, role model, and lead education in QI/PS, and in the reduction of excess health care costs.

What’s out there

All clinical faculty need to be proficient – practicing and teaching – QI/PS principles in their everyday work
World Health Organization

Part A Teacher’s Guide


Canadian Patient Safety Institute

Vision
Safe healthcare for all Canadians.

Mission
To inspire extraordinary improvement in patient safety and quality.

http://www.patientsafetyinstitute.ca/English/Pages/default.aspx

Dental Education: University of Pacific

Comprehensive care course series
Clinic privileges
Group practice meetings

Beyond the Classroom

IPI Goal: To prepare all OHSU students for deliberatively and intelligently working together with a common goal of patient safety and quality, patient-centered care.

| IPI Goal: To prepare all OHSU students for deliberatively and intelligently working together with a common goal of patient safety and quality, patient-centered care. |

| Example of Shared Competency: Patient Safety |

<table>
<thead>
<tr>
<th>Safety</th>
<th>Thematics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nursing</strong></td>
<td><strong>Therapeutics</strong></td>
</tr>
<tr>
<td>The effective nurse engages in developing system-level initiatives to improve patient safety and to mitigate error.</td>
<td>Ensure that drug products are delivered to patients in a timely, safe and effective manner:</td>
</tr>
<tr>
<td>Medicine</td>
<td></td>
</tr>
<tr>
<td>Explain a systems approach to ensuring patient safety, including methods to improve safety and reduce medical errors.</td>
<td>Ensure the security of the drug inventory,</td>
</tr>
<tr>
<td>Demonstrate effective attention and communication during transitions of care between members of the health care team.</td>
<td></td>
</tr>
</tbody>
</table>

| Patient Safety |

<table>
<thead>
<tr>
<th><strong>Physician Assistant</strong></th>
<th><strong>Therapeutics</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accept responsibility for promoting a safe environment for patient care and recognizing and correcting systems-based factors that negatively impact patient care.</td>
<td>Detect and address adverse drug reactions and drug interactions and assess their impact on desired therapeutic outcomes.</td>
</tr>
<tr>
<td></td>
<td>Use knowledge of sterile technique to prepare sterile dosage forms or delivery systems.</td>
</tr>
</tbody>
</table>

OSAP 2013 SYMPOSIUM 16
Next Steps

Developing a Patient Safety System for Dentistry

• R01, 5-Year NIH/NIDCR Grant
• UT Houston, HSDM, UCSF, OHSU

1. Develop the tools to document dental AEs
2. Generate a classification scheme and repository to organize AEs
3. Enable five dental organizations to systematically collect and analyze AEs

Aim 1: Develop a useable and validated Patient Safety Toolkit (PST) for documenting AEs in the dental setting
Aim 2: Develop a data repository to systematically organize dental AEs into a common framework that is structured according to the Dental Patient Safety Classification

Aim 3: Disseminate the PST and determine occurrence characteristics of dental AEs at 5 institutions

Acknowledgements

• Rachel Ramoni, DMD, ScD (Harvard Medical School)
• Muhammad Walji, PhD (UT Houston)
• Denice Steward, DDS, MHSA (OHSU)

Supported by NIDCR: R01DE022628