Risk Management for Oral Health Programs and HRSA’s FTCA Program

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Main Sections

- BPHC Quality Strategy
- What is Risk Management?
- Top Potential Risk Areas for Health Center Oral Health Programs
- Common Types of Record Keeping Errors
- Federal Tort Claims Act (FTCA)
- Case Study
Learning Objectives

✓ Introduce BPHC’s Quality Strategy
✓ Define risk management and the role it plays in providing primary oral health care
✓ Understand and identify common risks involved in providing primary oral health care and how to prevent them
✓ Familiarize ourselves with the Federal Tort Claims Act (FTCA) Program
✓ Understand how to respond to and address malpractice claims
## BPHC Quality Strategy

### Strategy Implementation

1. Programs/Policies
2. Funding
3. Technical Assistance
4. Data/Information
5. Partnerships/Collaboration

### Priorities & Goals

1. Implementation of QA/QI Systems
   - All Health Centers fully implement their QA/QI plans
2. Adoption and Meaningful Use of EHRs
   - All Health Centers implement EHRs across all sites & providers
3. Patient Centered Medical Home Recognition
   - All Health Centers receive PCMH recognition
4. Improving Clinical Outcomes
   - All Health Centers meet/exceed HP2020 goals on at least one UDS clinical measure
5. Workforce/Team-Based Care
   - All Health Centers are employers/providers of choice and support team-based care
What is Risk Management?

• **Risk Management** is the identification, assessment, and prioritization of risks, and the application of resources to minimize, monitor, and control the probability or impact of adverse events.

• Clinical and administrative activities undertaken to identify, evaluate, prevent, and control the risk of injury to patients, staff, visitors, volunteers, and others to reduce the risk of loss to the organization.
Adverse Event

- An undesired outcome or occurrence, not expected within the normal course of care or treatment, disease process, condition of the patient, or delivery of services
Risk Assessment

- Activities undertaken to identify potential risks and unsafe conditions inherent in the organization or within targeted systems or processes
Risk Analysis

- Determination of the causes, potential probability, and potential harm of an identified risk and alternatives for dealing with the risk
- An example of risk analysis is root-cause analysis
Risk management is important consideration for Health Centers striving to provide high quality health care services that result in improved patient outcomes.

Successful risk management involves developing and implementing systems that minimize the probability of adverse events in all aspects of providing care.
Standard of Care

• That degree of care and skill which is expected of a reasonably competent provider acting in the same or similar circumstances (*Blair vs. Eblen*)

• Can change over time based on emerging clinical practice, prevailing knowledge and court case precedent
Definition of *Tort*

- *Tort* is a wrong that involves a breach of duty owed to someone else, that causes injury. The person who suffers injury is entitled to receive compensation for damages from the person or people responsible.

- In health care/dentistry the most common tort liability is negligence or malpractice.
Elements to Establish Negligence

- A duty to render care must be shown (standard of care)
- A breach of that duty must have occurred
- The patient must have suffered some damages
- Damages were caused in fact and proximately caused by the breach of duty
1. Lack of Informed Consent
2. Failure to Diagnose
3. Lack of a Comprehensive Exam
4. Failure to Follow-Up On Emergency Cases
5. Treatment of The Wrong Tooth/Wrong Site
6. Surgical Complications
7. Unsatisfactory Removable Dental Prostheses
8. Lack of/or Inadequate Treatment Plan
9. Failure to Complete Procedures
10. Inappropriate or Unnecessary Procedures
1. Lack of Informed Consent

The American Medical Association defines informed consent as “the process of communication between a patient and a physician that results in the patient’s authorization or agreement to undergo a specific medical intervention”
Six elements of informed consent…

- Diagnosis and proposed treatment
- Alternative treatments available
- The risks of that treatment
- The benefits of the proposed treatment
- The prognosis of the proposed treatment
- The cost of the proposed treatment

All six parts should be explained to patient (by the provider) and they must agree to all six parts for consent to be complete.
2. Failure to Diagnose

- Periodontal disease status, documentation of pocket depth is insufficient
- Early signs of oral cancer lesions – persistent lesions that last longer than a week should be biopsied
- Radiographic anomalies
- Other common conditions such as cracked tooth syndrome, orthodontic conditions, TMD, and endodontic pathosis
- Failure to refer patient to a medical provider or social services (suspected child abuse or child neglect)
3. Lack of a Thorough Exam

- Medical history
- Oral hygiene status
- Evaluation of occlusion
- Soft tissue/oral cancer evaluation
- Periodontal exam and charting
- Hard tissue examination and charting

“A provider’s first line of defense is thoroughly documenting a patient’s history. If it is not on the record, you have not done it… You have to document everything, not just what you are going to do.” David Rosenstein, D.M.D., M.P.H.
4. Failure to Follow-Up On Emergencies

- Calling patients 24 to 48 hours after a surgical procedure is considered a best practice for quality care

- An effective strategy used by providers is a pre-printed follow-up form on the chart
5. Treatment of the Wrong Tooth/Wrong Site (ways to avoid this)

- Ensure there is a documented diagnosis
- Informed consent process is completed the day of the procedure
- Verification of procedure by the patient, surgical assistant, and oral surgeon

This 3-step process is known as *Time-Out* period

- The purpose of Time-Out is to conduct a final assessment that the correct patient, and procedure are identified.
6. Surgical Complications

- The only way to completely avoid surgical complications is to never perform any surgical procedures
- Eventually all providers will encounter surgical complications
- The best way to manage these risks is to discuss them with the patient before the procedure is started and include these discussions in the informed consent documentation
7. Unsatisfactory Removable Dental Prostheses

- Patients often have unrealistic expectations about dental removable prostheses, and the provider needs to determine the patient’s expectations before starting.

- Patient satisfaction increases when providers set expectations of what removable dental prostheses can and cannot accomplish in practical and understandable terms and explain all limiting factors that govern these appliances.
Common Risk Areas (Cont’d)

Unsatisfactory Removable Dental Prostheses Outcomes

• Providers must remind patients that dentures are not a substitute for teeth, they are a substitute for **NO teeth**

• Providers are responsible for educating patients on new technologies and treatment modalities such as dental implants which may improve prostheses’ function, even if the patient cannot afford them or they are not part of the Health Center’s Scope of Service
8. Lack of/or Inadequate Treatment Plan

- Treatment Planning – the process of formulating a rational sequence of treatment steps to eliminate disease and restore efficient, comfortable, esthetic masticatory function to a patient

- Providers are responsible for presenting and discussing the treatment plan with the patient, and to document it in the patient’s record
8. Lack of Treatment Plan (Cont’d)

• A comprehensive treatment plan addresses the problem list and aims at providing maximum comfort, function, and esthetics.

• It is prioritized according to urgency, addresses chief complaint, follows a common sense approach, and uses professionally accepted terminology.
9. Failure to Complete Procedures

- Treatment started is sometimes not completed for a variety of reasons.
- Patients may believe the absence of pain means further treatment is unnecessary.
- Providers are responsible to ensure patients follow the proposed treatment plan once initiated.
- Providers should develop a system that tracks patient’s care once they leave the health center.
10. Inappropriate or Unnecessary Procedures

- Unnecessary endodontic treatment, excessive bleaching are common examples.

- Even replacing functioning alloy restorations with composites – in these cases the provider must be cautious if patient believes the alloy restorations are the source of ongoing medical problems. If restorations are replaced and the medical condition does not improve, patient may find fault with dental treatment.
1. Treatment plan or changes to it, not documented
2. Health history not clearly documented or updated regularly
3. Informed consent and/or informed refusal not documented
4. Subjective complaints and/or objective findings not documented
5. Assessment (diagnosis) not documented
6. Treatment rendered not clearly documented

7. Post operative instructions and/or patient education not documented

8. Premedication and post operative prescriptions given not documented

9. Telephone conversation with patient are not documented

10. Illegible documentation (paper records) and lack of, or illegible signatures (paper records)
Dentists working at CHCs are in many instances the only dental provider in the community; we know patients will experience financial hardship if referred to a specialist.

We must remember, however, our first duty is to safeguard the patient’s health. Therefore, we should not try to perform procedures beyond our level of competency and experience in order to “help” the patient.
Informed Refusal

- Ideally, we should have a standard refusal form and have patients sign it whenever they refuse treatment.
- Sometimes refusal stems from lack of understanding. It is our duty to explain the rationale for the procedure or treatment, emphasizing probable consequences of the refusal.
- Refusal form should state in lay terms the consequences of refusing treatment.
- Dentist must document in record patient’s verbalization of understanding.
• Patient’s wellbeing comes first and everything else is second

• Providers should:
  • Remain calm and seek immediate assistance from their colleagues or help from an appropriate, evidence-based source
  • Stop the procedure, admit what is clear, and document everything in the chart.
  • Acknowledge what happened, take care of the patient personally or through referral, and strive to be a better dentist by learning from that process.
What to do (Cont’d)

• Involve the Health Center Risk Manager, QA Department, HC Management and Clinical Leadership, and the Center’s attorney

• Do not:
  • Become defensive
  • Blame the patient
  • Alter the record
• The **Federal Tort Claims Act** (FTCA) is the federal legislation that allows parties claiming to have been injured by negligent actions of employees of the United States to file claims against the federal government for the harm they suffered.

• The FTCA also provides authority for the federal government to defend against such claims.
• Amendments to the Public Health Service Act in 1992 and 1995 provide that employees at deemed Health Centers are to be treated as employees of the United States for purposes of medical malpractice. These "employees" include board members, officers, employees and certain contractors of deemed Health Centers.

• "Employees" are given malpractice protection for actions within their scope of employment, and within the scope of project of a deemed Health Center.
How the Program Works

• Who, what, when, where?
  • Who is covered - Relationship to Health Center
  • What is covered – medical malpractice
  • Where is it covered – scope of project
  • When is it covered – scope of employment
How the Program Works

- Who is covered
  - Employees – full-time or part-time
  - Officers
  - Directors
  - Governing Board members
  - Contractors (some but not all)

- Not covered - Volunteers
• Who is covered – Contractors
  • Any full time contract provider (over 32.5 hrs/week)
  • Part time contract provider of services in the fields of family practice, Ob-Gyn, general internal medicine, or general pediatrics
  • Contract must be between the deemed health center and the individual provider
  • Contracts between the deemed health center and a corporation (including Professional Corporations are not covered)
How the Program Works

• What is covered?
  
  • Medical malpractice
  
  • More specifically, medical, surgical, dental and related activities (if within the scope of employment and scope of project)
How the Program Works

• When is it covered?
  • Coverage is only for acts that are within the scope of practice of employment of the covered individual
  • No moonlighting
  • Must be acting on behalf of deemed entity
How the Program Works

• Where is it covered?
  • Only incidents that occur within the scope of project are covered (see PIN 2011-01)
  • Scope of project are the activities described in the grant application that are approved by Public Health Service via Notice of Grant Award
  • An existing scope of project can be changed by applying for a Change in Scope (CIS)
    • CIS must be done through the 330 Program and your PO. FTCA Branch does not do Changes in Scope
• How is FTCA different from my individual malpractice policy?

  • Under FTCA you do not need an individual malpractice policy

  • If you have FTCA protection, you have financial protection from a malpractice lawsuit

  • The United States government would be substituted as the defendant in any malpractice claim for your activities, which are within your scope of employment and within the scope of project of a deemed Health Center
• I am a dentist/dental hygienist. Does FTCA cover my profession?

  • Yes. FTCA malpractice protection applies to you and all other employees (and certain contractors) of appropriately deemed Health Centers

  • Dentists who are contractors (receive a 1099 from the deemed Health Center) must be full time, that is, they must work at least 32 ½ hours per week for the deemed health center. Dentists who are employees (receive a W-2 from the deemed health center) can be full- or part-time and receive FTCA coverage

  • Malpractice protection is not available for Health Center volunteers.
• I am a dental resident at a Community Health Center, do I get FTCA protection?

• Malpractice protection is not available for students or residents training in a Health Center. Malpractice protection for these individuals should be provided through a means other than FTCA.

• Heath Center dental programs participating in Residencies and other training programs must have clear contracts with the residency program defining malpractice coverage for attendings and preceptors as well as for the students/trainees.
• What is my coverage limit?

- There is no monetary limit.
- If you come under FTCA malpractice protection, the Federal Government is the defendant for claims made against your Health Center-related actions or omissions.
- FTCA settlements and judgments are the responsibility of the United States government.
- As a provider, you and your organization are responsible for the clinical outcomes related for the claim.
- FTCA coverage does not preclude provider from being reported to the NPDB in case of an adverse lawsuit outcome or a settlement.
• Plaintiff files administrative claim against the United States
• DHHS reviews claim and may deny it, pay it, or offer a settlement
• If DHHS denies claim plaintiff may file suit
• If DHHS does not act on claim within six months plaintiff may file suit
• When suit is filed case is transferred to DOJ
• DOJ may attempt to settle suit, otherwise it goes into litigation
• Plaintiffs often file suit in state court (Premature Claims)
  • What to do?
    U.S. Department of Health and Human Services
    Office of the General Counsel
    General Law Division
    330 Independence Avenue, S.W.
    Mail Stop Capitol Place
    Washington, DC  20201
    202-233-0233
    202-233-0227 (fax)

• Have health center attorney request extension of time to reply
FTCA Help Line
1-877-974-BPHC (1-877-974-2742)
9:00 AM TO 5:30 PM (ET)
Email: BPHChelpline@hrsa.gov
FTCA Website: http://www.bphc.hrsa.gov/ftca
For More Information

  http://bphc.hrsa.gov/policiesregulations/policies/pin201101.html

- **FTCA Program Assistance Letter (PAL 2012-02)**

- **FTCA FAQs**
  http://bphc.hrsa.gov/ftca/about/aboutfaqs.html
• Engar, R., AGD Impact, “Full Mouth Extractions Gone Awry,” August 2012, Vol. 40, No. 8
25 y/o female patient presented to subject dentist for consultation. She is contemplating implants or extractions as her teeth are not in good shape and she was getting married and wanted to look good for her wedding pictures. Only a panoramic radiograph was taken, no periapicals or bitewings were taken as patient claimed to have a bad gag reflex and would not allow them. Panoramic radiograph showed severely decayed (non-restorable) teeth 1-5, 13, 16, 17-19, & 32.

Initially patient claimed she could not afford implants. A Tx. plan was formulated which involved removal of all maxillary teeth and four hopeless mandibular teeth; restoration of some decayed mandibular teeth, and fabrication of a maxillary CD. Patient signed an informed consent form for the extractions and was instructed to call back to schedule the extractions.
According to the receptionist who took the call, the patient called back to make an appointment and claimed she wanted all remaining teeth removed since they all hurt, so an appointment was made for full mouth extractions. Nothing that was discussed in the phone conversation was documented in the patient’s chart and a new treatment plan was not created. No one called the prosthodontist who was making the maxillary denture.

The patient showed for the scheduled appointment and there was no reiteration of what was planned, no time out documented, and no phone call was made to verify the dentures were ready. Only a general surgical informed consent was signed and the patient was given IV sedation by a nurse anesthetist. All teeth were extracted and the patient was sent to the prosthodontist for delivery of the complete dentures.
The prosthodontist who thought he was providing the upper denture was surprised as he only had one denture to insert.

The patient’s mother was very upset and left a message for the dental office staff, asserting that the wrong teeth had been removed.

The same receptionist who claimed to have taken the call wherein the patient stated she wanted all teeth removed called the patient and left a message for her, admitting that the office staff had made a mistake. She requested that the patient returned to the dental office so she and the dentist could discuss how to remedy the situation.

The dentist tried to negotiate a settlement wherein he agreed to provide mini implants at no charge for both the upper and lower arches to stabilize the dentures and agreed to pay for the mandibular denture.
The dentist placed the implants and wrote the patient a check for $1000 to pay for the mand. denture. The dentist faced problems adapting attachments on the implants to both dentures and patient was not satisfied with the results. In a final meeting with the patient, the dentist essentially botched the follow-up discussion, and when the patient threatened to sue him he exclaimed, “Go ahead, I have the best attorneys in the state.”

Patient retained the services of a lawyer and they offered to settle for $1 million. They tried mediation but failed as the plaintiff insisted patient deserved $950K. Both sides retained expert witnesses who gave opposed opinions. Since liability was clear, it was determined the best course of action was to admit it and let the jury decide on a fair value to give the patient. Case was settled for undisclosed amount.
What Mistakes This Dentist Made

- No documentation of the alleged phone call in which the patient said she wanted all her teeth removed
- No informed consent signed authorizing the removal of all teeth
- Dentist had the receptionist leave a message admitting they had made a mistake
- No immediate call to malpractice insurance carrier to report potential problems at the time the teeth were removed
What mistakes the dentist made?
Mistakes…

• Subject dentist held preliminary negotiation with the patient without getting any coaching or advise from the malpractice insurer. He gave a check to pay for lower denture, but did not obtain a “Release of All Claims and liabilities” form from the insurer and did not have the patient sign anything.

• Dentist tried to fix upper denture, this was the prosthodontist’s responsibility.

• When he reached an impasse with the patient, the dentist told patient to go ahead and sue him.
How does this apply at a CHC?

- Procedures outlined for adverse events must be followed. You should not try to negotiate settlements or agreements with patients.

- Make sure the Standard of Care is followed while making amends to the patient.

- Do not threaten the patient or boast that you are covered under FTCA.
QUESTIONS?
THANK YOU

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