



Dental Risk Management and Legal Concerns

FTCA University, June 2, 2017
Louisiana Primary Care Associates
3:00 – 4:15 p.m.

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Risk Assessment: what is it?

- Risk assessment is the identification, assessment, and prioritization of risks (*the effect of uncertainty*)
- It specifies information needed by providers, leaders, and staff to minimize risks for their oral health programs and next steps if an error occurs

Risk Management: what is it?

- Risk management is the identification, assessment, and prioritization of risks (*the effect of uncertainty*) and the application of resources to minimize, monitor, and control the probability or impact of adverse events
- It specifies information needed by providers, leaders, and staff to minimize risks for their oral health programs and next steps if an error occurs

Clinical Risk Assessment Indicators

Examples of use and application in clinical practice



Risk Assessment Tools

- Risk Assessment Protocols are an addition to treatment planning
- Allows diagnosis based on relative risk of dental disease, not just the presence of actual disease – Presence of CARIES ONLY
- Patients assigned to a diagnostic group after examination with treatment protocols
- Outcomes monitoring consistent with diagnostic grouping unless changed in future recall exams

Risk Assessment Indicators

- **Risk Factors vs. Protective Factors**

- Dietary habits
- Food groups – sugars, low pH/high acid levels
- Calcium intake
- Presence of enamel defects, pits, fissures, or erosion
- Fluoridated water source
- Plaque control
- Brushing and flossing frequency
- Genetics
- History of decay
- Bacterial load in oral flora
- Salivary function (buffering capacity)
- Medications (dry mouth producing)
- Presence of decay or dental restorations
- Physical/mental disabilities and limitations



Level of Risk Groupings may differ

- **Three to Four primary risk groupings**
 - Low Risk
 - Moderate Risk
 - High Risk
 - Highest “Extreme” risk based on medical modifier
 - Xerostomia – chronic dry mouth
 - Chronic Disease – diabetes, organ transplant
 - Immuno-compromised
 - Medication, e.g., bisphosphonates, psychotropic drugs, etc.

Example of a CARIES RISK ASSESSMENT FORM FOR AGE 0 TO 5 YEARS

Patient Name: _____ I.D. # _____ Age _____ Date _____
 Initial/baseline exam date _____ Recall/POE date _____

Respond to each question in sections 1, 2, and 3 with a check mark in the yes or no column	Yes	No	Notes
1. Caries Risk Indicators - Parent Interview**			
(a) Mother or primary caregiver has had active dental decay in the past 12 months			
(b) Child has recent dental restorations (see 3b below			
(c) Continual bottle use - contains fluids other than water			
(d) Child sleeps with a bottle, or nurses on demand			
(e) Frequent (greater than three times daily) between-meal snacks of sugars/cooked starch/sugared beverages			
(f) Saliva-reducing factors are present, including: 1. medications (e.g., some for asthma or hyperactivity) 2. medical (cancer treatment) or genetic factors			
(g) Child has developmental problems , Past Med Hx			
(h) Parent and/or caregiver has low SES (Socio-economic status) and/or low health literacy			
(i) No dental home/episodic dental care			



CARIES RISK ASSESSMENT FORM FOR AGE 0 TO 5 YEARS

Patient Name: _____ I.D. # _____ Age _____ Date _____
 Initial/baseline exam date _____ Recall/POE date _____

2. Protective Factors/Indicators – Parent Interview			
(a) Child lives in a fluoridated community or takes fluoride supplements by slowly dissolving or as chewable tablets			
(b) Teeth cleaned with fluoridated toothpaste (pea size) daily			
(c) Mother/caregiver has caries activity			
(d) Mother/caregiver chews/sucks xylitol chewing gum/lozenges 2-4 X daily or dissolving xylitol tablets			
(e) Child has a dental home and regular dental care			
3. Caries Risk Indicators - Clinical Examination of Child**			
(a) Obvious white spots, decalcifications, or obvious decay present on the child's teeth			
(b) Restorations placed in the last 2 years			
(c) Plaque is obvious on the teeth and/or gums bleed easily			
(d) Dental or orthodontic appliances present, fixed or removable: e.g., braces, space maintainers, obturators			
(e) Visually inadequate saliva flow - dry mouth			
**If yes to any one of 1(a), 1(b), 3(a) or 3(b) or any two of 1(c)-1(i), or 3(c)-3(e), consider performing bacterial culture on mother or caregiver and child. Use this as a baseline to follow results of antibacterial intervention.		Parent/Caregiver Date:	Child Date:
(a) Mutans streptococci (Indicate bacterial level: High, Medium, Low)			
(b) Lactobacillus species (Indicate bacterial level: High, Medium, Low)			

Low Risk

- No previous caries history or lesions
- No restorations or previous history of fillings
- Good oral hygiene with good dietary habits, fluoride intake, and salivary functions
- Protective factors outweigh risk factors

Moderate Risk

- No signs of visible active decay
- May have restorations as evidence of previous caries history
- Lacking in one or more protective factors such as good oral hygiene, dietary habits, fluoride intake, etc.
- *Higher potential for developing caries at some future point if unaddressed*

High Risk

- Currently has dental caries and/or evidence of cavitated lesions
- Previous history of restorations
- Lacking in two or more protective factors such as good oral hygiene, access to fluoridated water and toothpaste, and dietary habits, which place patients at risk
- Large enamel pits and defects

Extreme High Risk

- Has special needs that pre-disposes toward caries development
- Hypo salivary function
- Dry mouth – lack of acid buffering capability
- Active caries and/or multiple restorations present
- Chronic disease condition that lowers immunity or worsens oral condition

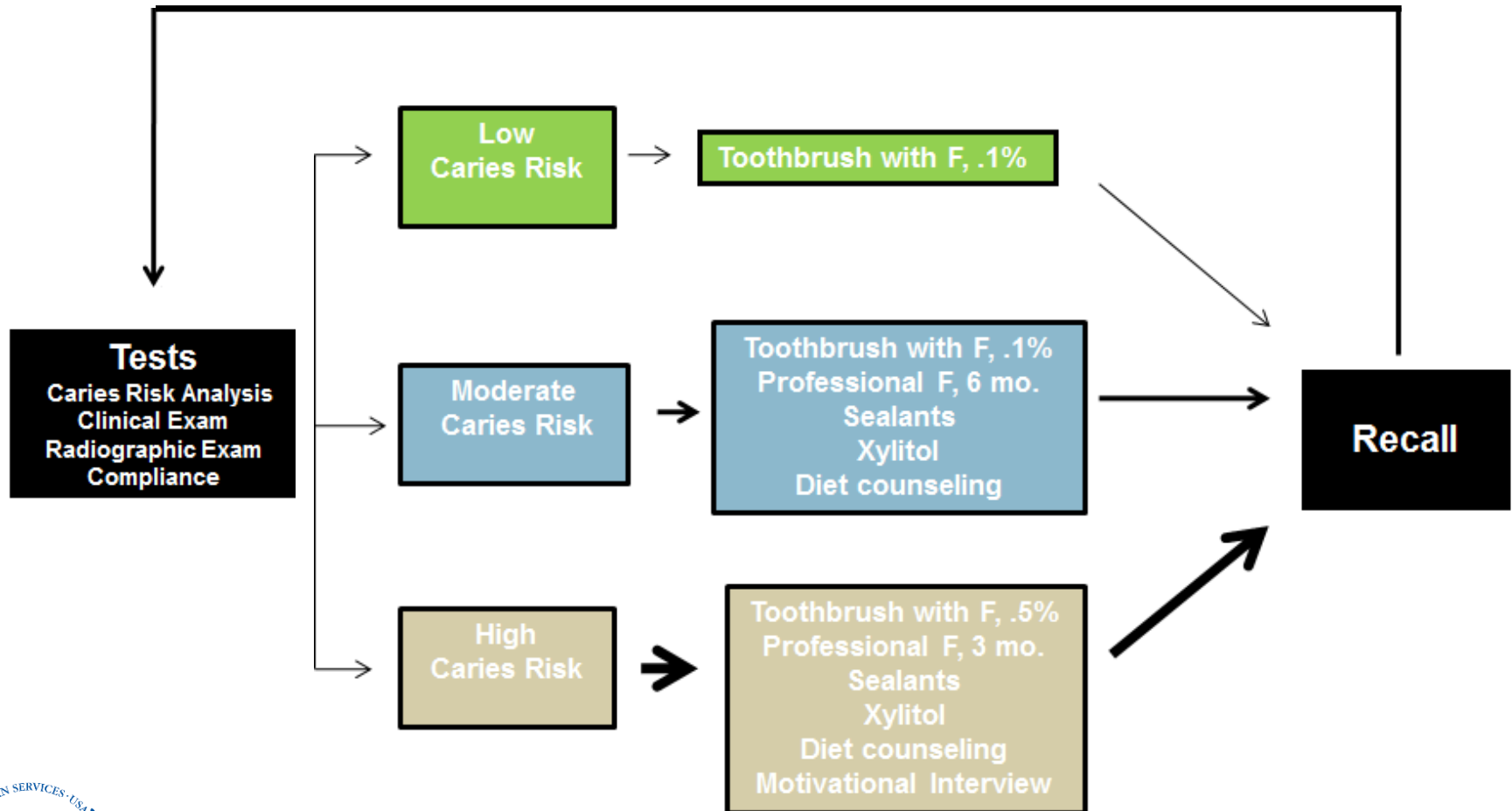
Extreme High Risk Modifiers

- With an Extreme Caries Risk Diagnosis, it is recommended that a medical consultation be sought
- Many of these cases will be jointly managed with a primary care provider
- Diagnostic coding can be used to monitor caries risk status
- Good introduction for dentists to learn diagnostic coding and applications

Example of Modified Treatment Based on Risks

- **Moderate, High, Extreme Risk**
- **Potential Prescription Therapies Recommended:**
 - Chlorhexidine rinses
 - Rx high fluoride toothpaste
 - Baking soda or calcium phosphate paste
 - Xylitol 6-10 grams daily (chewing gum, lozenge)
 - Fluoride Varnish 1-3 initial applications
 - Risk – related recall scheduled from 3 to 6 months

CAMBRA Protocol Active Surveillance (>6 years old)



Example of a Caries Protocol for a >6 Year-Old

	Diagnostic	Fluoride	Sealants	Diet Counseling	Restorative
Low Risk	<ul style="list-style-type: none"> Recall every year Radiographs every two years 	<ul style="list-style-type: none"> Twice daily brushing with F 	No	No	Surveillance
Moderate Risk child engaged	<ul style="list-style-type: none"> Recall every six mo. Radiographs yearly 	<ul style="list-style-type: none"> Twice daily brushing with F Fluoride supplements* Prof. topical F every 6 mo. 	Yes	<ul style="list-style-type: none"> Yes xylitol 	<ul style="list-style-type: none"> Active surveillance Restore cavitated or enlarging lesions
Moderate Risk child not engaged	<ul style="list-style-type: none"> Recall every six mo. Radiographs yearly 	<ul style="list-style-type: none"> Twice daily brushing with F Prof. topical F every 6 mo. 	Yes	<ul style="list-style-type: none"> Limit expectations xylitol 	<ul style="list-style-type: none"> Active surveillance Restore cavitated or enlarging lesions
High Risk child engaged	<ul style="list-style-type: none"> Recall every three mo. Radiographs, six mo. 	<ul style="list-style-type: none"> Brushing with high potency F gel Fluoride supplements* Prof. topical F every 3 mo. 	Yes	<ul style="list-style-type: none"> Yes Xylitol 	<ul style="list-style-type: none"> Active surveillance Restore cavitated or enlarging lesions
High Risk child not engaged	<ul style="list-style-type: none"> Recall every three mo. Radiographs, six mo. 	<ul style="list-style-type: none"> Brushing with high potency F gel Prof. topical F every 3 mo. 	Yes	<ul style="list-style-type: none"> Limit expectations xylitol 	<ul style="list-style-type: none"> Restore, incipient, cavitated and enlarging lesions

* Need to consider fluoride levels in drinking water

CAMBRA - Reference

- Jenson, I et.al., “Clinical Protocols for Caries Risk Management by Risk Assessment.” CDA Journal Vol. 35, No 10
- Ramos-Gomez, FJ. Et.al., “Caries Risk Assessment Appropriate for the Age 1 Visit (Infants and Toddlers) CDA Journal. Vol. 35, No 10

Operational Risk Management Indicators

General Guidelines



Components of Risk Assessment and Management Planning: *Know the Regulations!*

- **Regulatory Requirements (examples)**

- Health Insurance Portability and Accountability Act (HIPAA), American Disabilities Act (ADA), Culturally and Linguistically Appropriate Services (CLAS), Federal Tort Claim Act (FTCA), Occupational Safety and Health Administration (OSHA), The National Institute for Occupational Safety and Health (NIOSH) ...most are applied health center wide, but may have dental specific applications

- **Clinical (examples)**

- CDC Infection Control Guidelines
- State Licensing Regulatory Standards of Care
- ADA Principles of Ethical Standard and Conduct
- The Joint Commission (TJC formerly JCAHO) or other ambulatory certification authority



Ethical Practices in Risk Management

1. Patient autonomy (self-governance)
2. Nonmaleficence (do no harm)
3. Beneficence (do good)
4. Justice (fairness)
5. Veracity (truthfulness)

Patient Rights and Responsibilities

- Language interpretation
- Confidentiality
- Patient grievances
- Release of information
- Bill of rights and responsibilities
- Handling of suspected child abuse cases



Clinical Care Guidelines

- Emergent dental infections
- Opioid prescribing
- Storing of medications in the clinic
- Antibiotic premedication for the prevention of
- Prosthetic joint infections
- Hypertension screening and referral
- Management of patients taking anticoagulants
- Prevention and management of dental caries
- Prescribing of dental radiographs
- Intervals for routine dental exam and prophylaxis
- Periodontal screening and therapy
- Oral cancer screening
- Biopsies/tissue specimen management
- Dental equipment maintenance and repairs
- Behavior management



Top 10 Potential Risk Areas for Health Center Oral Health Programs

1. Lack of informed consent
2. Failure to diagnose
3. Lack of a thorough exam
4. Failure to follow up on emergencies
5. Treatment of the wrong tooth
6. Surgical complications
7. Removable prosthetics
8. Lack of/inadequate treatment plan
9. Incomplete treatment
10. Inappropriate procedures



15 Types of Errors in Record Keeping

1. Treatment plan is not documented
2. Health history not clearly documented or updated regularly
3. Informed consent not documented
4. Informed refusal not documented
5. Assessment of patient is incompletely documented
6. Words, symbols, or abbreviations are ambiguous
7. Telephone conversation with patient not documented
8. Treatment rendered not clearly documented
9. Subjective complaints not documented



15 Types of Errors in Record Keeping

- 10. Objective findings incompletely documented
- 11. Post operative instructions and patient verbalization of understanding not documented
- 12. Patient education not documented
- 13. Premedication and post operative prescriptions given not documented
- 14. Illegible documentation (paper records)
- 15. Lack of signatures or illegible signatures (paper records)



Necessary Conditions for Malpractice to Have Occurred

- There was a duty of the provider to the patient to conform to standard conduct or a standard of care established by the profession or by law
- There was a breach of that duty by the provider, whereby the provider failed to conform to the accepted standard of conduct or care
- There were actual damages to the patient in the form of bodily harm, either permanent or temporary
- Causation can be established; that is, the damage must have resulted from the breach of duty, either in fact or by proximate cause
- Proximate cause is a legal concept based on foreseeability of harm when a duty is breached (e.g., one can foresee that failure to use a rubber dam when performing endodontics can result in the aspiration of a dropped file)

Patient Management as a Risk Management Tool

- Spend enough time talking with and listening to your patients. Make sure each patient's treatment expectations are realistic
- Encourage your patients to ask questions and become active participants in decisions regarding their health care
- Make every effort to eliminate excessive waiting time for patients in the office. This is one of the major criticisms by patients
- Monitor staff courtesy; discourteous staff may be costly to attracting/retaining patients
- Maintain a clean and pleasant office. The physical condition of the office may be perceived as an indication of the staff's feeling toward patients
- Maintain patient confidentiality



Patient Management as a Risk Management Tool (Cont.)

- Don't neglect a patient's complaints. Even if you feel the complaints are not significant, a word of reassurance to the patient may be all s/he needs
- Remember that most patients will not necessarily evaluate their care by its technical quality, but by the quality of their relationship with those who provide the care
- The same courtesy that is extended in face-to-face contact should also be extended in telephone conversations with patients; calls should be returned in a timely fashion
- Inform patients of fees and costs
- Never underestimate the effect of good patient relations on a patient's decision to sue

Reducing Malpractice Risk

- Provide conscientious dental care
- Encourage and support continuing dental education for employees
- Make clear and legible entries in the health record
- Bring the patient into the decision-making process through informed consent
- Have peer review and analysis of adverse events that occur in the clinic
- Discipline repeat offenders by reducing their privileges or by dismissal
- Place an emphasis on establishing a good rapport with patients
- Use a Patient's Bill of Rights and Responsibilities, written in lay language the patient can understand and provided in pamphlet form and as a poster prominently displayed in the health facility

Establish Incident Report Protocols

- **Examples of reportable incidents**

- Error in the care of patients (e.g., errors in administration of medications, treatments)
- Slips or falls in the clinic or on clinic grounds
- Development of conditions seemingly unrelated to the condition for which the patient was treated
- Adverse or suspected adverse reactions to a procedure or medication

What to do if a Patient Files a Claim?

- **If a claim is filed against a provider/Health Center**
 - Remain calm, do not panic or become defensive
 - Do not argue with the patient or his/her representative
 - Do not change anything on the patient record
 - Follow the steps determined by HRSA for FTCA-covered programs seen at
<https://bphc.hrsa.gov/ftca/claimsfiling/healthcenterclaims.html>
 - Consult with an attorney and follow the advice given



Joint Commission Protocols for Dental Clinics

https://www.jointcommission.org/standards_information/up.aspx



Risk Assessment: The Joint Commission, HRSA BPHC - PCER Monitoring Expectations

Environment of Care

The organization manages risks related to hazardous material and waste (Standard EC 02.02.01/EPs 3, 4, 5, 7)

- **Instrument Cleaning:**

- Maintain sharps containers in a manner that reduces risk of exposure
- Label basins containing instrument cleaning solution
- Include the expiration date or information related to the diluted cleaning solution

- **Radiation Concern:**

- Follow organization's policy on the wearing of dosimeters and testing/inspecting of lead aprons

- **Eye Wash Station:**

- Ensure accurate labeling of faucets and water temperature



The Joint Commission: HRSA BPHC Monitoring Expectations

The organization inspects, tests, and maintains medical equipment (Standard EC 02.04.03/EPs 1, 3, 4)

- **Before Initial Use of Equipment:**
 - Test and document safety and function of dental equipment
 - Educate/train staff on the use of dental sterilizers per guidelines
- **Inspect Equipment Identified on Inventory:**
 - Tag all equipment (e.g., curing light, amalgamator)
 - Tag and document equipment for annual maintenance inspection
 - Document evidence of preventive maintenance

The Joint Commission: HRSA BPHC Monitoring Expectations

- **Conducts Performance Tests on Sterilizers (general performance testing):**
 - Establish sterilizer policy that follows the recommendations of the manufacturer or state and review with staff
 - Perform correct use of biological testing media, fully document all details on dental sterilizers' spore tests, and validate the accuracy of tests using controls
 - Educate/train dental staff on how to perform, read, and retest biological testing
 - Record all information and avoid gaps in spore testing logs
 - Ensure any outside laboratory's spore tests reports are timely and accurate
 - Provide appropriate in-use/non-expired supply levels needed for sterilizer tests



The Joint Commission: HRSA BPHC Monitoring Expectations

Human Resources

The organization verifies staff qualifications (Standard HR 01.02.05/EP 1)

- For care providers required to be licensed, certified, or registered that do not practice independently (e.g., dental hygienists, dental assistants), primary source verify their license, registration, or certification at time of hire and renewal
- Verify evidence of education (e.g., dental hygiene school)



The Joint Commission: HRSA BPHC Monitoring Expectations

The organization grants initial, renewed, or revised clinical privileges to individuals who are permitted by law and the organization to practice independently (licensed independent practitioners – LIPs) (Standard HR 02.01.03/EPs 3, 5, 10, 16, 21, 24, 25)

- **Primary Source Verification:**
 - Before granting initial, renewed, or revised privileges and at the time of licensure expiration, primary source verify licensed independent practitioners (e.g., dentist) for:
 - training
 - licensure
- **Privileges Requirements for LIPs:**
 - Ensure there is a written statement that no health problems exist that could affect a dentist's ability to perform their requested privileges
 - Query the National Practitioner Data Bank
 - Renew privileges every 2 years
 - Provide written list and limit scope of practice to initial/revised privileges



The Joint Commission: HRSA BPHC Monitoring Expectations

Infection Prevention and Control

The organization implements infection prevention and control activities (Standard IC 02.01.01/EP 2)

- **Use standard precautions, including personal protective equipment**
 - When cleaning instruments, use gowns, eye protection, and puncture-resistant gloves

The organization reduces the risk of infections associated with medical equipment, devices, and supplies (Standard IC 02.02.01/EPs 1, 2, 4)

- **Cleaning and disinfecting:**
 - Follow manufacturer's recommended frequency when cleaning and performing low-level disinfection of dental supplies and devices
 - Follow manufacturer's recommended contact time for surface disinfection of operatories between patients



The Joint Commission: HRSA BPHC Monitoring Expectations

Infection and Prevention Control (Cont.)

- **Requirements for sterilizing dental equipment, devices, and supplies (also see Environment of Care):**
 - Include dental areas in an organization's sterilization policy
 - Establish methods by which patients can be identified in cases of sterilization failure and instruments can be retested if there is a previous failed test
 - Pack sterile instruments to avoid perforations
 - Use different personal protective equipment (PPE) for patient care versus sterilization areas
- **Storing dental equipment, devices, and supplies:**
 - Establish and follow a monitoring protocol for separating expired instruments/supplies from sterilized instruments/supplies (e.g., sutures, composite tip, fluoride, preparation pulp liners and varnishes, restorative materials, indicator strips, disinfection cleaners)



The Joint Commission: HRSA BPHC Monitoring Expectations

Leadership

The organization has policies and procedures that guide and support patient care, treatment, or services (Standard LD 04.01.07/EP 2)

- **Manages the implementation of policies and procedures:**
 - Ensure that policies and procedure used for dental services are consistent with the organization's policy and procedures (e.g., patient health history requirements for oral surgery procedures) and are communicated to all staff
 - Ensure that patient consent forms used for dental services are part of an organization's policies and procedures

The Joint Commission: HRSA BPHC Monitoring Expectations

Medication Management

The organization safely stores medications (Standard MM 03.01.01/EP 6, 8)

- **Medication security:**
 - Prevent unauthorized individuals from obtaining medications, consistent with law and regulation recommendations, including mobile dental carts or emergency kits
 - Include dental in the periodic inspection of dental medication storage areas
- **Expired, damaged, and/or contaminated medications storage:**
 - Separate common expired dental medications (e.g., local and topical anesthetics, temporary bonding adhesive, items in emergency cart/kit)



The Joint Commission: HRSA BPHC Monitoring Expectations

Provision of Care, Treatment, and Services

*The organization assesses and manages the patient's pain
(Standard PC 01.02.07/EP 1)*

- **Comprehensive Pain Assessment:**
 - Ensure pain assessment for dental patients is consistent with organization's policy
 - When indicated, refer or conduct a comprehensive pain assessment and document in the patient's record
 - Educate/train dental staff on pain policy (e.g., scale to use)

The Joint Commission: HRSA BPHC Monitoring Expectations

Rights and Responsibilities of the Individuals

The organization honors the patient's rights to give or withhold informed consent (Standard RI 01.03.01/EP 13)

- **Informed Consent Policy and Procedures:**
 - Ensure the patient dental consent form:
 - documents that the patient was informed of benefits, risks, or alternatives
 - includes minors
 - covers both the procedure and any sedation required
 - is used with each new dated procedure
 - is complete with organization required information (e.g., tooth number)
 - Document that the patient dental consent form was completed



The Joint Commission: HRSA BPHC Monitoring Expectations

Universal Protocol (part of National Patient Safety Goals)

The procedure site is marked (NPSG UP.01.02.01/EPs 2&5)

- Mark the procedure site before the procedure is performed, and if possible, with the patient involved....have a written alternate process in place...when impractical to mark the site (e.g., extractions).
 - Consider use of the dental diagram or x-ray as the alternative process
 - Involve the patient whenever possible

The Joint Commission: HRSA BPHC Monitoring Expectations

A time-out is performed before the invasive procedure (NPSG UP 01.03.01/EPs 1,2,4,5)

- **Conduct and Document a Time-Out:**
 - Educate/train dental staff on the organization's policy assuring that all components (correct patient, site, and procedure) of the time-out are conducted
 - The time-out must include all staff members present and involved
 - Document that the time-out was conducted prior to the procedure



Disclaimer

We ask you to please keep in mind that this conference is not the appropriate place to discuss detailed case specific aspects of unresolved claims or litigation. Likewise, risk management information provided in this conference is not to be considered legal advice and, as with any information provided by is intended as guidance to be used consistent with the internal needs of your organization. This information is not to be viewed as required by ECRI Institute, KEPRO or HRSA. Any detailed fact specific health center issues should be addressed to the FTCA helpline and all questions regarding pending legal cases should be directed to your own organization's private attorneys.



Questions?

BPHC Helpdesk:

1-877-974-BPHC (2742)

<https://www.hrsa.gov/about/contact/bphc.aspx>

