RECOMMENDATIONS: *CLINICAL PRACTICE GUIDELINE*

Use of Vital Pulp Therapies in Primary Teeth 2024

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Abstract: ***Purpose:*** *The purpose of this study was to present an evidence-based guideline for primary teeth with deep caries or trauma requiring vital pulp therapies (VPT).* ***Methods:*** *A systematic review/meta-analysis on vital primary teeth resulting from trauma or caries was conducted using GRADE to assess the certainty of evidence for clinical recommendations. A decision tree was provided for choosing VPTs.* ***Results:*** *No articles on trauma VPT were found. For VPT in primary teeth with deep caries, indirect pulp treatment (IPT) or pulpotomy using the calcium silicate cement (mineral trioxide aggregate [MTA] or Biodentine®) show increased success over using direct pulp capping (DPC) and other pulpotomies. Different liners do not affect IPT success (high certainty) or DPC capping agents' success (very low certainty) after 24 months. It is strongly recommended, with high certainty from 24-month data, that calcium silicate cement pulpotomy is preferred over formocresol, ferric sulfate, zinc oxide eugenol pulpotomy, and other pulpotomies. Using selective caries removal and IPT for deep caries is strongly recommended with moderate certainty over complete and stepwise removal. Statistically, this results in significantly fewer pulp exposures. No caries removal and Hall technique crown may be used when indicated (moderate certainty at 24 months). For vital primary incisors with deep caries, pulpotomy was significantly better statistically than pulpectomy. Teeth diagnosed with/without reversible pulpitis pain showed comparable success after 12 months of treatment by IPT or calcium silicate cement pulpotomy. The following had little or no significant effect on MTA pulpotomy success: coronal pulp removal methods; irrigation solution; method to control hemorrhage; base over MTA; treatment in one or two visits; anterior or posterior teeth.* ***Conclusions:*** *Indirect pulp treatment or calcium silicate cement pulpotomy is likely to increase vital pulp therapy success over other VPTs such as direct pulp capping and other pulpotomies after 24 months (moderate certainty).* *(Pediatr Dent 2024;46(1):13-26) Received May 15, 2023 | Last Revision September 12, 2023 | Accepted September 12, 2023*

KEYWORDS: PULPOTOMY; IPT; PULP CAPPING; CARIES

Plain language summary

Purpose. This guideline document supersedes the 2017 clinical practice guideline termed "Use of vital pulp therapies in primary teeth with deep caries lesions" and the vital primary tooth treatment part of the American Academy of Pediatric Dentistry's (**AAPD**) Reference Manual, Best Practices section listed as "Pulp Therapy for Primary and Immature Permanent Teeth."

Deep decay (caries) in a primary (baby) tooth may cause the pulp (nerve) inside the vital tooth to be inflamed. A normal pulp exhibits no or little inflammation in part of the coronal pulp, and the tooth is asymptomatic. Reversible pulpitis is the next stage of pulp inflammation. The tooth may exhibit pain from eating for five to 10 minutes, but the inflammation can be reversed to a normal state with treatment. Irreversible pulpitis is a further stage of pulp inflammation in a primary tooth that signifies the coronal and/or root canal pulp tissue cannot return to a normal pulp state. Necrosis of the pulp in a primary tooth signifies that the coronal and radicular pulp tissue (in one or more root canals) is no longer vital and the tooth may exhibit similar signs and symptoms as irreversible pulpitis. Treatment options for irreversibly inflamed or necrotic primary teeth are covered in another AAPD guideline termed "Use of Nonvital Pulp Therapies in Primary Teeth."

The purpose of the present guideline is to make clinical vital pulp therapy (**VPT**) recommendations for primary teeth affected by caries where the pulp is normal or has reversible pulpitis.

Methods. The authors, working with the AAPD, systematically reviewed all the dental literature, up to July 2022, about vital (normal pulp and reversible pulpitis) primary tooth pulp treatments. This systematic review (**SR**) used 299 articles published between 1977 and 2022 that included randomized and nonrandomized controlled trials as well as studies done in laboratories, which are termed *in vitro* studies. The authors defined treatment success as the child having no pain or clinical infection signs, symptoms, or radiographs showing no signs of pathology. The systematic review provided data from which the clinical recommendations were derived together with the level of certainty and strength of evidence for each recommendation. A decision tree figure was developed from the evidence-based recommendations to aid in the choice of pulp therapies.

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GLOSSARY of TERMS and ABBREVIATIONS

95% CI: 95 percent confidence interval.
AAPD: American Academy of Pediatric Dentistry.
ABS: is Ankaferd blood stopper, a pulpotomy agent.
Alternate 3Mix used in LSTR is an antibiotic modification of traditional 3Mix in which tetracycline/minocycline is replaced by another antibiotic such as clindamycin.
Calcium silicate cement materials evaluated for vital pulp treatment in this guideline refer only to mineral trioxide aggregate (MTA) and Biodentine®. Calcium silicate cement is a bioceramic material.
Biodentine® is the brand name of a pulpotomy material made by Septodont which is a calcium silicate type material.
CH: calcium hydroxide pulpotomy.
Chemical caries removal (chemo-mechanical) refers to the use of chemicals (Papacarie® or Carisolv®) to soften the carious dentin followed by its removal by mechanical hand methods.
Complete removal of deep decay is a nonselective technique for the removal of all decay (caries) with burs or hand instruments until the tooth structure feels hard.
DPC (direct pulp cap) in primary teeth is done to pinpoint one-mm pulp exposures after caries removal and is treated with a material intended to maintain the pulp's vitality and is sealed with a filling or crown to minimize microleakage.
FC: formocresol pulpotomy.
FS: ferric sulfate pulpotomy.
GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) provides a framework for specifying health care questions, choosing outcomes of interest and rating their certainty by evaluating the available evidence, and bringing together the evidence with considerations of values and preferences of patients and society to arrive at recommendations.
Hall technique (HT) is treatment for a decayed tooth where no decay removal is done and a preformed metal crown is placed to minimize microleakage and stop the progression of dental caries.
I^2 statistic is a measurement of inconsistency of the data included in the meta-analysis.
Indirect pulp treatment (IPT) leaves the deepest decay after selective caries removal to prevent pulp exposure and seals the decay with a material or crown to minimize microleakage and stop caries progression.
Iodoform refers to either Vitapex (Neo Dental International Inc, Burnaby, British Columbia, Canada) or Metapex (Meta Biomed LTD, Cheongju-si, Chungcheongbuk-do, South Korea) root canal filler, two identical proprietary brands containing an iodoform and calcium hydroxide.
Irreversible pulpitis is a stage of pulp inflammation in a primary tooth that signifies the coronal and/or root canal pulp tissue cannot return to a healthy pulp state. The tooth may exhibit a history of sharp, unprovoked, lingering pain (including nocturnal pain) and could be associated with any one or more of the following clinical or radiographic findings: periodontal ligament widening; radiographic furcation; or periapical radiolucency. Diagnosis of irreversible pulpitis cannot be based solely on pulpal bleeding that cannot be controlled within five minutes.
Lasers are laser pulpotomies.
LSTR (lesion sterilization tissue repair) is a procedure for necrotic primary teeth that usually requires no instrumentation of the root canals or filling of the canals but instead includes the placement of an antibiotic mixture in the pulp chamber to disinfect the root canals.
mm: millimeter.
MTA is mineral trioxide aggregate pulpotomy which is a calcium silicate-type material similar to Portland cement. MTA causes gray discoloration of the tooth, but newer calcium silicate cement materials try to overcome that disadvantage.
NaOCl (sodium hypochlorite) or common household bleach is normally used in one to five percent concentration for a sodium hypochlorite pulpotomy or pulpal irrigation agent.
NNT (number needed to treat) is the estimate of the number of teeth needed to be treated with one method to prevent one failure if treated by the alternate method. A low NNT number, such as 10 or less, indicates the alternate treatment may be preferred.
Nonrestorable primary tooth is a tooth where the root(s) and or crown have extensive resorption or destruction from caries or trauma, or the tooth has a very poor prognosis and is not considered a candidate for pulp therapy or restoration.

Results. Indirect pulp treatment (**IPT**), direct pulp cap (**DPC**), and pulpotomy have high successes and can be used for the treatment of primary teeth with normal or reversible pulpitis in decayed vital primary teeth. For deeply decayed teeth, there is a high certainty of evidence supporting the success of IPT or pulpotomy using the calcium silicate cement mineral trioxide aggregate (**MTA**) or Biodentine® over 24 months. On the other hand, DPC is supported by very low certainty evidence based on 24-month data. Formocresol pulpotomy **(FC)** has significantly lower success compared to MTA pulpotomy at 24 months based on a high certainty. Better alternatives to FC pulpotomy are IPT or calcium silicate cement pulpotomy. Laser pulpotomy had lower success than FC at 12 months and could not be compared to other pulpotomy agents. Ferric sulfate pulpotomy (**FS**) had significantly lower success than MTA pulpotomy, and the decision is a conditional recommendation against the use of FS. It was conditionally recommended against using zinc oxide eugenol (**ZOE**) as the sole pulpotomy medicament given its very low success at 24 months. Sodium hypochlorite pulpotomy had 18-month results that resulted in a conditional recommendation against its use. Pulpotomies using lasers and Ankaferd Blood Stopper® (**ABS**) had only 12-month results, resulting in a lower certainty of evidence, and no recommendation was made due to no 24-month results. Calcium hydroxide (**CH**) pulpotomy is not recommended since it has significantly lower success at 24 months than MTA pulpotomy and a number needed to treat (**NNT**) of two. An NNT of two means, after performing a CH pulpotomy on two teeth, the dentist would have prevented a failure if instead MTA pulpotomy had been used.

The method of decay removal (selective, stepwise, or complete) did not significantly affect VPT success, but more pulp (nerve) exposures were found when complete caries removal was used (P<0.001; NNT equals four). An NNT of four means that, after treating four teeth with complete caries removal, the dentist would have prevented a pulp exposure if selective or stepwise caries removal had been used. The use of burs to remove caries was significantly faster (almost six minutes) than chemical caries removal using Papacarie® or Carisolv®.

IPT versus several types of pulpotomy treatments showed no significant difference in treatment success at 24 months. IPT had the highest overall 24 months success (97 percent) of all types of VPT. Therefore, a dentist can prioritize IPT with selective caries removal as a biological and cost-effective option for primary teeth with deep decay. If a pulp exposure occurs, 24-month data indicated the calcium silicate cement pulpotomies increased success over other pulpotomies and DPC (strong recommendation, moderate certainty).

IPT and calcium silicate cement pulpotomy were both effective treatments for relieving pre-operative reversible pulpitis pain in teeth. This type of pain is temporary and does not wake the child in the middle of the night. IPT and pulpotomy are not indicated for pain from a tooth with irreversible pulpitis. There were no studies found to assess DPC treatment for pre-operative reversible pulpitis pain.

For a vital primary incisor with deep decay and no irreversible pulpitis or necrosis, it is strongly recommended, with moderate certainty, to perform a pulpotomy rather than a root canal procedure. A root canal is a more technical procedure and more costly than a pulpotomy.

The method used for removing the coronal pulp tissue for a pulpotomy, the type of pulp irrigation solution, or the method of stopping the pulpal bleeding showed little effect on

GLOSSARY – CONTINUED

Normal pulp exhibits no inflammation or little inflammation in part of the coronal pulp but the tooth is asymptomatic.
NRS: nonrandomized observational study (NRSs is the plural).
Necrosis, or a necrotic pulp, in a primary tooth signifies the coronal and radicular pulp in one or more root canals is not vital (has died) and may be symptomatic or not. The tooth may exhibit any of the following: sinus tract, soft tissue pathology, or gingival swelling not associated with periodontal disease; abnormal mobility not associated with exfoliation; radiographic furcation or periapical radiolucency; and external or internal radiographic root resorption.
Pulpectomy is a root canal procedure for primary teeth with irreversible pulpitis or a necrotic (dead) pulp resulting from caries or trauma in which the root canals are instrumented with files, irrigated, and filled with a resorbable material.
Pulpotomy treatment for vital primary teeth with pulp exposures from trauma or caries is a procedure involving the removal of the entire coronal portion of the pulp (nerve) and placement of a medicament to cover the vital portion of the nerve remaining in the pulp canals. Various techniques or medicaments are used to restore the tooth with a filling or crown to minimize microleakage.
RCT: randomized clinical trial (RCTs is the plural).
Reversible pulpitis is an initial stage of pulp inflammation in a primary tooth without signs or symptoms of irreversible pulpitis or necrosis but may have provoked pain for a short duration (five to 10 minutes) from eating. The inflammation can be reversed to a healthy state with vital pulp treatment.
ROB (risk of bias) is an assessment of any deviations in a study's methods used for an intervention's results.
RR for binary outcomes, random effects were used to estimate relative risks (also termed risk ratio) expressed with a 95 percent confidence interval (95% CI).
Selective caries removal is completed in one visit, leaving the deepest caries in place, and is covered with a durable restoration.
SR2022 is the AAPD's systematic review of vital pulp therapies.
SSC: stainless-steel crown (SSCs is the plural).
Stepwise caries removal is accomplished over two patient visits. The first visit leaves the deepest caries in place and is covered with a temporary restoration. After four weeks or more, the remaining caries is removed at a second visit and the tooth is permanently restored.
Success in this guideline refers to the overall success of pulp treatment in teeth that show both clinical and radiographic success simultaneously.
The AAPD **Workgroup (WG)** consisted of dentists nominated by the AAPD to perform a systematic review and meta-analysis.
Traditional 3Mix is usually a mixture of three antibiotics (minocycline, metronidazole, and ciprofloxacin) blended in a propylene glycol base and used in LSTR treatment.
Vital pulp exists when the pulp's tissue is alive, is capable of healing, and will respond to appropriate pulp tests.
ZOE stands for a mixture of zinc oxide powder and liquid eugenol.

pulpotomy success. The materials placed over the MTA pulpotomy showed differing successes. Resin-modified glass ionomer cement (**RMGIC**) placed over MTA pulpotomy had 91 percent success compared to intermediate restorative material's (**IRM**) 97 percent success at 24 months.

For the Hall technique (**HT**), the dentist does not remove any decay but cements a steel crown over the decayed tooth. When primary teeth with deep decay over halfway into dentin were treated with the HT, results showed no significant difference in pulp vitality success at 24 months compared to complete decay removal and a filling.

Guideline

Exceptions to the guideline recommendations. Regarding exceptions to the guideline recommendations, treatment plans may have to be altered from the decision tree figure's recommendations due to a child's ability to cooperate, complex medical conditions, inability to achieve local anesthesia of the tooth, limited oral opening, severe gag reflex, facial swelling, oral pain with an unclear diagnosis, complications from prior pulp therapy, or concurrent periodontal problems. Also, parent and patient preferences, age, and cost of treatment may alter treatment decisions that may not conform to this decision tree or guideline.

Scope and purpose

The AAPD intends this guideline to replace the 2017 primary tooth vital pulp therapy guideline[1] and does not include pulp therapies for permanent teeth or nonvital primary teeth. The previous Guideline was based on a systematic review done through September 2016.[2] This guideline will aid clinicians in optimizing patient care when choosing pulp therapies for treating children with deep carious lesions in vital primary teeth. The pulp diagnosis is based on symptoms as well as clinical and radiographic signs. Carious primary teeth diagnosed with a normal pulp or reversible pulpitis are considered vital and can be treated with VPTs.[3-6] Currently, there are four VPT options for the treatment of deep dentin carious lesions approximating the pulp in vital primary teeth: (1) IPT, also known as indirect pulp cap; (2) DPC; (3) pulpotomy; and (4) pulpectomy for vital anterior teeth.[7,8]

For this guideline, the overall (combined clinical and radiographic) success of VPTs was evaluated. The influence of various diagnostic and intervention aspects of VPT, such as the presence of pre-operative pain, choice of pulp medicament/liner, caries removal technique, and pulp therapy techniques, were evaluated for the overall success of VPT.

Outcome moderators were evaluated for their effect on VPT. These included the type of pulp irrigation, hemostasis method for DPC and pulpotomy, type of base material over the pulpotomy, type and timing of final restoration, type of primary tooth, type of pulp injury, patient behavior guidance techniques, and other factors were reviewed for this guideline. Also reviewed were the adverse events such as pulpal exposure.

Statement of changes. In the AAPD's *The Reference Manual of Pediatric Dentistry*, there is a best practices section listed as "Pulp Therapy for Primary and Immature Permanent Teeth." It is periodically updated with the last revision completed in 2023.[9] In addition, the AAPD published a clinical practice guideline[1] on VPT entitled "Use of Vital Pulp Therapies in Primary Teeth with Deep Caries Lesions," which was based on a systematic review[2] published in 2017. This current guideline document supersedes the 2017 clinical practice guideline and the VPT for primary teeth part of the best practices section listed as "Pulp Therapy for Primary and Immature Permanent Teeth." It provides updated recommendations based on 2023 evidence from a systematic review and meta-analysis of the VPT for primary teeth with deep caries.[8]

Guideline development workgroup. As a part of a five-year guideline updating process, the AAPD Board of Trustees approved the formation of a workgroup (**WG**) to systematically review the current evidence and update recommendations for VPTs in primary teeth with deep carious lesions. The WG defined the Population, Interventions, Comparisons, and Outcomes (**PICO**) to be assessed and then created a comprehensive list of

relevant clinical questions, which were reviewed and approved by the WG. The WG met virtually and in-person between June 2020 to August 2023 to systematically search, select, and synthesize the best available evidence to develop evidence-based recommendations.

Search strategy and evidence inclusion criteria. It was decided a priori to use the findings of the AAPD's systematic review and meta-analyses[8] on VPTs as the evidence of this guideline recommendations. The WG used the SR's multiple literature searches in PubMed®/MEDLINE, Embase®, Cochrane Library (WileyOnline; Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Cochrane Methodology Register), and Dissertations and Theses-Global databases to identify randomized controlled trials (**RCTs**), non-randomized studies (**NRSs**), and systematic reviews addressing peripheral issues not covered by the review, such as patient preferences and impact of cost. The title, abstract, and full-text review of studies were reviewed independently by pairs of WG members. The assigned members extracted data and performed the risk of bias assessment (**ROB**), meta-analyses, and certainty of evidence.

Assessment of evidence. Several pertinent outcomes, such as the clinical, radiographic, and overall success of VPT, the success of caries removal approaches, reduction in microbial load, adverse events, and toxicity, were assessed. The certainty of the evidence was assessed using the Grade of Recommendation Assessment, Development, and Evaluation (**GRADE**) approach. The GRADE approach recognizes the certainty of evidence as high, moderate, low, and very low[10] based on serious or very serious issues, including the risk of bias, imprecision, inconsistency, indirectness of evidence, and publication bias. The WG evaluated and obtained consensus on the certainty of evidence for each studied outcome. The WG also discussed the available research on values and preferences to reach an agreement on the importance of various outcomes, which was then factored into the evidence-to-decision framework to formulate clinical recommendations. Weaknesses of this guideline are inherent to the limitations found in the SR upon which this guideline is based.[8] Limitations include failure to review non-English language studies other than those in Spanish, Portuguese, and Chinese, and the recommendations are based on combined data from studies of different ROBs.

Formulation of recommendations and certainty. This clinical practice guideline provides recommendations for VPTs in primary teeth. The NNT number gives the clinician an estimate of how much better one treatment is compared to an alternate method. The WG determined a low NNT number (such as 10 or less) indicates the preferred treatment. To formulate the recommendations, the WG used an evidence-to-decision framework that compared criteria such as priority of the problem, certainty in the evidence, balance between desirable and undesirable consequences, patients' values and preferences, acceptability, and feasibility.

The clinical question(s) were subjected to the clinical practice guideline development process following the AGREE II tool.[11] The strength of each recommendation was assessed to be either strong or conditional, which presented different implications for patients, clinicians, and policy (Table 1). The recommendations for this guideline were formulated via teleconferences, in-person meetings, and online forum discussions with members of the WG. The WG members discussed all recommendations and issues surrounding the topic under review, and all significant topics such as recommendations were discussed and, if needed, voted upon to obtain consensus.

Understanding the recommendations. The evidence-based recommendations aim to help clinicians, patients/parents, and policy makers make decisions on the use of various VPT interventions for the treatment of primary teeth with deep caries in a dental office. The interpretations of what the strength of recommendations means in this guideline are listed in Table 2. These recommendations do not replace clinical judgment. A strong recommendation in favor of an intervention implies the WG is confident that the desired benefits of the intervention outweigh any undesirable effects and means in most situations clinicians should follow the suggested intervention. A strong recommendation against the intervention implies the WG is confident that

Table 1. GRADE INTERPRETATION OF STRENGTH OF RECOMMENDATIONS

Implications	Strong recommendations	Conditional recommendations
For patients	Most individuals in this situation would want the recommended course of action and only a small proportion would not.	The majority of individuals in this situation would want the suggested course of action, but many would not.
For clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Recognize that different choices will be appropriate for different patients and that you must help each patient arrive at a management decision consistent with her or his values and preferences. Decision aids may well be useful in helping individuals make decisions consistent with their values and preferences. Clinicians should expect to spend more time with patients when working toward a decision.
For policy makers	The recommendation can be adapted as policy in most situations including for the use as performance indicators.	Policymaking will require substantial debates and the involvement of many stakeholders. Policies are also more likely to vary between regions. Performance indicators would have to focus on the fact that adequate deliberation about the management options has taken place.
Grade certainty in the evidence		
High	Very confident that the true effect lies close to that of the estimate of the effect.	
Moderate	Moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect.	
Low	Confidence in the effect estimate is limited.	
Very low	Very little confidence in the effect estimate.	

the undesired effects of the intervention outweigh any potential benefits and, in most situations, clinicians should not choose that intervention. A conditional recommendation in favor indicates that there is uncertainty in the positive effects outweighing the negative results. This means the WG recognized the clinician may want to follow a course of treatment while being aware there are other more successful treatment choices for the individual patient. A conditional recommendation against implies there is confidence that the undesired effects of the intervention likely outweigh any potential benefits. This means the WG concluded there are other recommendations the clinician and patient should consider. Table 3 shows a summary of the recommendations included in this guideline, and the strength and certainty of evidence for each recommendation. The previously published AAPD evidence-based decision tree on pulp therapies in primary teeth was updated in this guideline to aid clinical practitioners (Figure).

A recommendation statement with "must" or "shall" indicates treatment is an essential or mandatory obligation; a recommendation with "should" indicates the recommended treatment is highly desirable, and a recommendation with "may" or "could" indicates freedom or choice to follow a suggested alternative.

External review. The recommendations drafted by the WG were shared with outside stakeholders (see disclosure for complete list). In addition, it was sent to members of the AAPD Council on Clinical Affairs, the Council on Scientific Affairs, and the Evidence-Based Dentistry Committee. Revisions were made by the WG based on the feedback received, and, lastly, the final version of the recommendations was produced.

Table 2. INTERPRETATION OF STRENGTH OF RECOMMENDATIONS

Implications	Strong recommendations in favor	Strong recommendations against	Conditional recommendations in favor	Conditional recommendations against
For patients	There is confidence the desired benefits of the intervention outweigh any undesirable effects.	There is confidence the undesired effects of the intervention clearly outweigh any potential benefits.	There is uncertainty about the positive effects outweighing the negative results.	There is confidence that the undesired effects of the intervention likely outweigh any potential benefits.
For clinicians	Clinicians should follow the suggested recommendation.	In most situations, clinicians should not choose that intervention.	The clinician may want to follow a course of treatment while being aware there are other more successful treatment choices for the individual patient.	A conditional recommendation against means the workgroup concluded there are other recommendations the clinician and patient should consider.

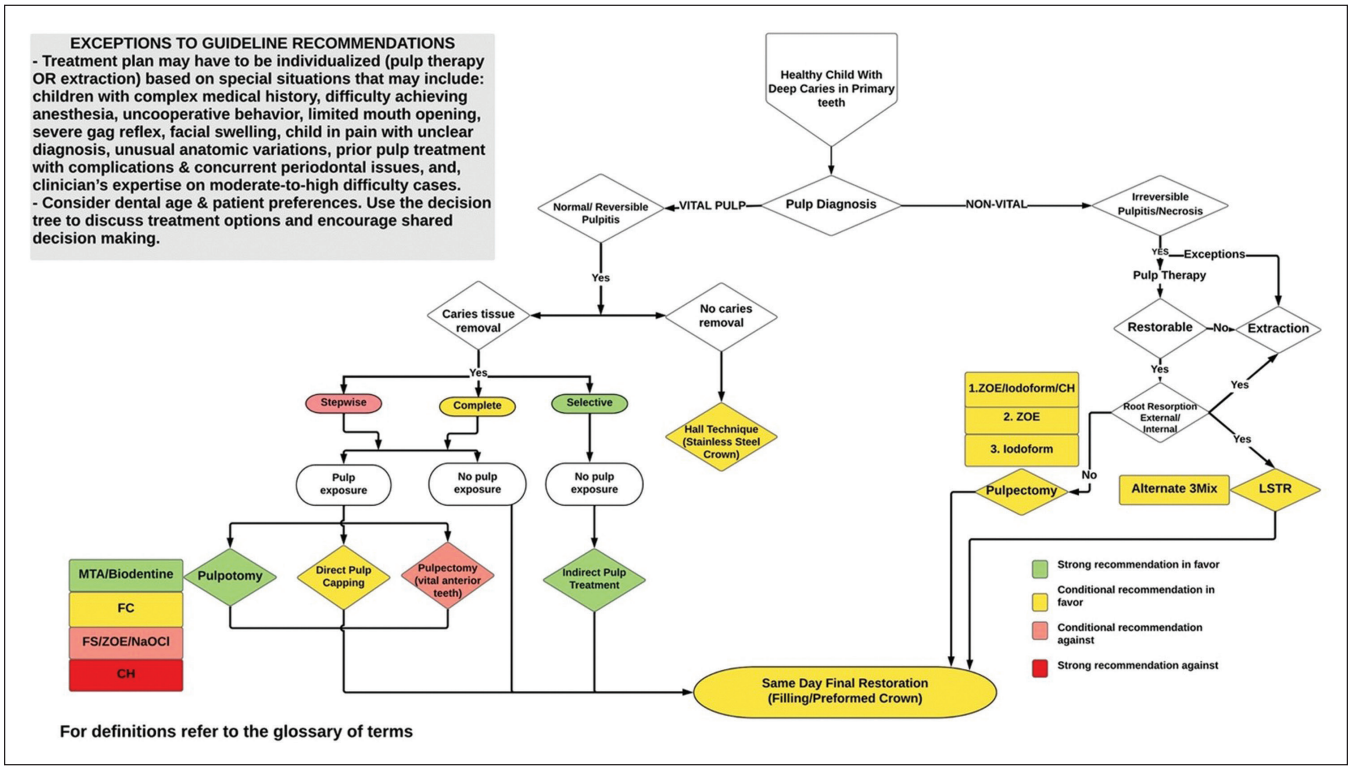

Figure. Guideline decision tree recommendations.

Abbreviations in figure: CH=Calcium hydroxide (pulpotomy); FS=Ferric sulfate (pulpotomy); LSTR=Lesion sterilization tissue repair; MTA=Mineral trioxide aggregate (pulpotomy); NaOCl=Sodium hypochlorite (pulpotomy); ZO=Zinc oxide; ZOE=Zinc oxide eugenol (liquid form).

Recommendations for VPTs in primary teeth with deep caries

Question1. Which is the most reliable method to diagnose pulp vitality in primary teeth?

Recommendation: There is insufficient evidence to make a recommendation on methods used to accurately diagnose the pulp's vitality in primary teeth with deep caries. The clinician should use clinical signs and symptoms as well as radiographic evidence to rule out irreversible pulpitis and necrosis.

Table 3. AMERICAN ACADEMY OF PEDIATRIC DENTISTRY RECOMMENDATIONS FOR VITAL PULP THERAPIES IN PRIMARY TEETH WITH DEEP CARIES

Summary of Recommendation Findings are After Methods		Strength of recommendation	Certainty of evidence
The American Academy of Pediatric Dentistry (AAPD) Workgroup used the Population, Intervention, Control, and Outcome (PICO) formulation to develop the following clinical questions.			
Vital pulp therapies (VPTs): Pre-operative pain and diagnosis			
Question #1	*Which is the most reliable method to diagnose pulp vitality in primary teeth?*		
Recommendation:	There is insufficient evidence to make a recommendation on methods used to accurately diagnose the pulp's vitality in primary teeth with deep caries. The clinician should use clinical signs and symptoms as well as radiographic evidence to rule out irreversible pulpitis and necrosis.		
Question #2	*Does the presence of pre-operative (reversible pulpitis) pain influence VPT success?*		
Recommendation:	For primary teeth with pre-operative pain from deep caries, indirect pulp treatment (IPT) and calcium silicate cement pulpotomy may be preferred over direct pulp capping (DPC).	Conditional	Very low certainty at 12 months
Choice of VPT			
Question #3	*In vital primary teeth requiring pulp therapy due to deep carious lesions, which VPT (IPT, DPC, partial pulpotomy, pulpotomy) has better success?*		
Recommendation	For pulp therapy in vital primary teeth with deep carious lesions, the use of IPT or calcium silicate cement pulpotomy is likely to increase success and is preferred over other VPTs such as DPC and other pulpotomy medicaments.[1-3]	Strong	Moderate certainty at 24 months
Choice pulp therapy medicament/techniques			
Question #4	*For indirect pulp therapy (IPT), does the choice of medicament/liner affect success?*		
Recommendation:	For vital primary teeth with deep carious lesions treated with IPT, the type of medicament does not affect the success of treatment.	Strong	High certainty at 24 months
Question #5	*For direct pulp capping (DPC), does the choice of medicament affect success?*		
Recommendation:	For vital primary teeth with deep carious lesions treated with DPC, the type of medicament used does not affect treatment success, but the evidence is very uncertain.	Conditional	Very low certainty at 24 months
Question #6	*For pulpotomy, does the technique and choice of medicament affect success?*		
Recommendation:	For vital primary teeth with deep carious lesions treated with pulpotomy, the use of calcium silicate cement pulpotomies increases success and is recommended over the use of other pulpotomy medicaments/techniques.	Strong	High certainty at 24 months
Question #7	*In the instance of pulp exposure, which pulp treatment is better for a carious vital primary incisor: a pulpotomy or a pulpectomy?*		
Recommendation:	For vital primary incisors with carious exposures, pulpotomy is likely to increase success compared to pulpectomy.	Strong	Moderate certainty at 12 months
VPT: Caries removal techniques			
Question #8a	*Which caries removal method is recommended for deep caries requiring VPT?*		
Recommendation	For primary teeth with deep caries requiring VPT, selective caries removal and IPT is recommended over nonselective (complete) or stepwise caries removal.	Strong	Moderate at 24 months
Question #8b	*Which caries removal method is recommended for deep caries to prevent pulp exposures?*		
Recommendation	For primary teeth with deep caries requiring caries removal, selective caries removal is recommended to avoid pulp exposures.	Strong	High at 24 months
Question #8c	*How does the no caries removal approach Hall technique (HT) affect VPT success?*		
Recommendation	For primary teeth with deep caries requiring VPT, no caries removal (HT) had comparable results to selective/complete caries removal and may be used when indicated.	Conditional	Moderate certainty at 24 months
Question #9	*Which approach is preferred for caries removal, bur or chemo-mechanical (i.e., Papacarie® or Carisolv®)?*		
Recommendation:	For caries removal during VPT, the use of a bur is likely faster (almost 6 minutes) compared to a chemo-mechanical technique. Both chemo-mechanical and bur removal of caries are effective in the reduction of cariogenic bacterial load. It is suggested that clinicians choose the approach (bur versus chemo-mechanical) based on their clinical expertise and patient cooperation.	Conditional	Low certainty

Summary of findings: The SR[8] found conflicting evidence on pulpal blood color, plus conflicting histologic evidence showing pulpotomy not indicated in teeth that received pulpotomy, and electric or cold tests that accurately diagnose the primary tooth's pulp vitality.

Question 2. Does the presence of pre-operative (reversible pulpitis) pain influence VPT success?

Recommendation: For primary teeth with pre-operative pain from deep caries, IPT and calcium silicate cement pulpotomy may be preferred over DPC (conditional, very low certainty at 12 months).

Table 3. CONTINUED

Pulpotomy technique/visits			
Question #10	***Which is the preferred isolation method when doing vital pulp therapy (VPT)?***		
Recommendation:	There are no studies that directly compared the use of a rubber dam or other isolation methods on VPT success. The studies that were reviewed used rubber dams for VPTs. If one expects to obtain the reported success, it is recommended to use a rubber dam as the standard of care.		
Question #11	***Does the method of coronal pulp removal affect mineral trioxide aggregate (MTA) pulpotomy success?***		
Recommendation:	The practitioner may remove the coronal pulp for MTA pulpotomy with a manual technique (spoon/curette), bur, or both instruments without altering MTA pulpotomy success, but the evidence is very uncertain.	Conditional	Very low certainty at 12 months
Question #12	***Does the type of coronal pulp irrigation affect MTA pulpotomy success?***		
Recommendation:	The type of pulp irrigation (anti-microbial or water/saline) does not seem to affect MTA pulpotomy success, but the evidence is very uncertain. Clinicians may choose to use water/saline or sodium hypochlorite over the use of chlorhexidine based on their clinical expertise and chlorhexidine's potential safety concerns.	Conditional	Very low certainty at 12 months
Question #13	***When stopping pulpal bleeding for an MTA pulpotomy, does the use of a water-/saline-moistened pellet, saline only, or a dry cotton pellet improve success?***		
Recommendation:	A practitioner may use a water-/saline-moistened cotton pellet, saline irrigation, or a dry cotton pellet for MTA pulpotomy to control hemorrhage without altering the success rate, but the evidence is uncertain.	Conditional	Very low certainty at 12 months
Question #14	***For MTA pulpotomy, does the type of base over the pulpotomy affect MTA pulpotomy success?***		
Recommendation:	The use of an intermediate restorative material (IRM) or a resin-modified glass ionomer cement (RMGIC) over an MTA pulpotomy does not seem to alter MTA pulpotomy success.	Conditional	Low certainty at 24 months
Question #15a	***What is the effect on MTA pulpotomy success if done in one or two visits?***		
Recommendation:	MTA pulpotomy is likely to have similar success if performed in one or two visits, but the evidence is very uncertain. Based on patient compliance, additional costs, and resources needed, one appointment visit may be preferred.	Conditional	Very low certainty at 12 months
Question #15b	***What is the effect on pulpotomy success if the final restoration is placed on the same day or a different date?***		
Recommendation:	Calcium silicate cement pulpotomy or formocresol pulpotomy's final restoration can be placed on the same day or a different date without affecting success. Based on patient compliance, additional costs, and resources needed, placing the final restoration on the same day as the pulpotomy may be preferred.	Conditional	Moderate certainty at 24 months
Question #15c	***What is the effect of the type of final restoration on MTA pulpotomy success?***		
Recommendation:	This type of restoration does not influence the success of MTA pulpotomy. The clinician may choose to use a preformed crown, composite, amalgam, or RMGIC restoration based on clinical expertise and shared decision-making.	Conditional	Very low certainty at 12 months
VPT moderator: Tooth type/caries location/patient behavior/trauma			
Question #16	***Is pulpotomy equally successful in anterior versus posterior teeth?***		
Recommendation:	The success rate of pulpotomy is not likely to differ for anterior versus posterior teeth.	Conditional	Very low certainty at 12 months
Question #17	***What is the success of VPT in teeth affected by trauma?***		
Recommendation:	There are no studies, and indirect data is inadequate on using VPT on primary teeth after trauma.		
Question #18	***In vital primary teeth requiring pulp therapy, does caries location or patient behavior influence VPT treatment success?***		
Recommendations:	The location of caries (occlusal or occlusal-proximal) is not likely to influence the success of VPT, but the evidence is very uncertain.	Conditional	Very low certainty at 12 months
	Behavior guidance using tell-show-do with or without nitrous oxide utilization and their effect on VPT success could not be determined.	No strength of recommendation	No certainty of recommendation

Summary of findings: The SR[8] in sFigure 10b evaluated calcium silicate cement pulpotomy success after 12 months in 11 studies that included patients without preoperative pain and four studies where teeth with reversible pulpitis pain were included. The indirect comparison forest plot in the SR showed studies having teeth without pain had a success rate of 95 percent and studies including teeth with pain had a 99 percent success rate after 12 months. The forest plot showed no significant difference (P=0.07). The quality of the evidence on this result was assessed as very low due to serious inconsistency (I^2 equals 58 percent), and the findings were indirect evidence.

The effect of preoperative reversible pulpitis pain on the success of IPT was also investigated in the SR. The pulpal success for IPT with 12 to 48 months follow-up from 12 studies including teeth without a history of pain was calculated as 96 percent. The 11 IPT studies that included teeth with transient or elicited reversible pulpitis pain had 12 to 24 months follow-up. Their calculated success rate was 94 percent. The certainty of the evidence for these results was assessed as very low due to serious inconsistency, and the findings were indirect evidence. There was not sufficient evidence to assess the effect of preoperative pain on the success of DPC; there were DPC studies on teeth without a history of any pain but none that included teeth with pain.

IPT success was directly compared with pulpotomy success in four studies in the SR that included teeth with transient or reversible pulpitis. The cumulative success rate for IPT over 12 months was 91 percent versus 96 percent for pulpotomy. This result also indicated that IPT and pulpotomy are both effective in relieving preoperative transient or reversible pulpitis pain.

Question 3. In vital primary teeth requiring pulp therapy due to deep carious lesions, which VPT (IPT, DPC, pulpotomy) has better success?

Recommendation: For pulp therapy in vital primary teeth with deep carious lesions, the use of IPT or calcium silicate cement pulpotomy is likely to increase success and is preferred over other VPTs such as DPC and other pulpotomy medicaments (strong, moderate certainty at 24 months).

Summary of findings: The SR[8] evaluated 12- and 24-month IPT to pulpotomy studies. The SR prepared a meta-analysis in sFigure 6a using three RCT studies[6,12,13] at 12 months, and there was no significant difference between IPT and pulpotomy success (Risk Ratio [**RR**] equals 1.08, 95 percent confidence interval [**95% CI**] equals 0.89 to 1.31). The SR[8] reported in Figure 6 that a meta-analysis was done at 24 months using two RCT studies[13,14] after 24 months showing no significant difference between IPT and pulpotomy success in the meta-analysis and an NNT of 34 (RR equals 0.97; 95% CI equals 0.91 to 1.03). The certainty of the evidence for this result was high, according to GRADE at 24 months, because all certainty criteria were judged to be not serious.

Remarks: Nine IPT studies with different follow-ups were compared to pulpotomy methods with different follow-ups in the SR.[8] It was reported that IPT had 94.2 percent, 96.7 percent, and 96.4 percent success at 12, 24, and greater than 34 months. Pulpotomy had 91.2 percent, 94.6 percent, and 93.9 percent success at 12, 24, and greater than 34 months. There were only two 12-month studies in the SR that compared DPC with CH to IPT. The study designs were Nonrandomized Observational Study (**NRS**) or case series, and their ROB was rated as having some concerns and high. The success data of DPC success at 12 months was 70 percent while IPT's success was 96.5 percent. The certainty of the evidence for this result was very low, according to the GRADE at 12 months, due to serious imprecision and very serious indirectness of the evidence. IPT is the least expensive VPT for the dentist to perform. However, if DPC and pulpotomy were utilized, NeoMTA and IRM bases had lower costs in the SR[8] (conditional, very low certainty). The SR[8] also evaluated cost estimates from an *in vitro* article for bioactive cement pulpotomies.[14] Calcium silicate dioxide type cement (two-mm layer) and IRM powder liquid base had the lowest mean cost (3.5 times less) per tooth for single-tooth pulpotomy versus using other calcium silicate cement and a base of Ketac Molar. When multiple pulpotomies were to be performed at the same visit, Biodentine® was ranked as the lowest mean cost per tooth.

Question 4. For indirect pulp therapy (IPT), does the choice of medicament/liner affect success?

Recommendation: For vital primary teeth with deep carious lesions treated with IPT, the type of medicament does not affect the success of treatment (strong, high certainty at 24 months).

Summary of findings: The SR[8] reported in Figure 2 and sFigure 1b 24-month and 48-month direct comparison forest plot for IPT success using calcium hydroxide liners versus alternate bonding agent liners. The 24-month meta-analysis was done using three RCT studies[3,4,15] and showed that there was no significant difference between calcium hydroxide liners versus bonding agent liners success (RR equals 1.00 (95% CI equals 0.96 to 1.03; P=0.79) and an NNT of 22 (sFigure 1b[8]). The certainty of the evidence for this result was high, according to GRADE at 24 months, because all certainty criteria were judged not serious. A meta-analysis at 48 months showed no significant difference between calcium hydroxide liners versus alternate bonding agent liners success in the meta-analyses at 48 months (RR equals 0.87; 95% CI equals 0.71 to 1.06; P=0.16). The certainty of the evidence was low, according to GRADE at 48 months, due to very serious sample size imprecision.

Remarks: The 24-month IPT overall calculated success rate was 97 percent when alternate and CH liner successes were combined. At 48 months, there was a small sample size (N equals 82) and the IPT overall success rate decreased to 84 percent.

Question 5. For direct pulp capping (DPC), does the choice of medicament affect success?

Recmmendation: For vital primary teeth with deep carious lesions treated with DPC, the type of medicament used does not affect treatment success, but the evidence is very uncertain (conditional, very low certainty at 24 months).

Summary of findings: The SR[8] reported a 24-month direct comparison meta-analysis for DPC success using calcium hydroxide liners versus alternate capping agents (Prime and Bond, Xeno III, MTA). The SR reported in sFigure 2 using three RCT studies[16-18] involving only occlusal lesions with a normal pulp. At 24 months, these three studies showed no significant difference between calcium hydroxide liners versus alternate capping agents in the meta-analyses (RR equals 1.04; 95% CI equals 0.89 to 1.21; P=0.65). A second meta-analysis involving four studies in the SR's Figure 3 with all lesion types also showed no significant difference for the various pulp capping agents (RR equals 1.10; 95% CI equals 0.94 to 1.30; P=0.24). The certainty of the evidence was very low, according to GRADE at 24 months, due to the very serious inconsistency in both meta-analyses.

Question 6. For pulpotomy, does the technique and choice of medicament affect success?

Recommendation: For vital primary teeth with deep carious lesions treated with pulpotomy, the use of calcium silicate cement pulpotomies increases success and is recommended over the use of other pulpotomy medicaments/techniques (strong, high certainty at 24 months).

Summary of findings: (Calcium silicate cement pulpotomies) The SR[8] reported that a 24-month direct comparison forest plot in Figure 4 evaluated MTA versus Biodentine® pulpotomy success studies. The meta-analysis at 24 months showed there was no significant difference between MTA versus Biodentine® success (RR equals 1.04 95% CI equals 0.96 to 1.11; *P*= 0.34; NNT equals 28). The certainty of the evidence for this result was high, according to GRADE at 24 months, due to direct comparison, and all the certainty criteria were judged not serious.

(MTA versus FC): The SR[8] reported in sFigure 4b a 24-month direct comparison forest plot using nine RCT studies for pulpotomy success for MTA versus FC. The meta-analysis showed a significant difference between MTA versus FC success (RR equals 1.07; 95% CI equals 1.01 to 1.13; *P*=0.02; NNT equals 15). MTA pulpotomy success (94 percent) was significantly higher than FC success (86 percent) in the nine directly compared studies. The certainty of the evidence for this result was high, according to the GRADE at 24 months, due to a direct comparison, and all certainty criteria were not serious (conditional for FC use, high certainty at 24 months).

(MTA versus FS): The SR[8] reported in sFigure 4a on three RCT[19-21] 24-month studies in a direct comparison forest plot for pulpotomy success using MTA versus FS. The meta-analysis showed there was significantly better success using MTA over FS (RR equals 1.27; 95% CI equals 1.02 to 1.59; *P*=0.03; NNT equals five). An NNT of five means that, after 24 months, one failure would be prevented after every fifth tooth using MTA pulpotomies instead of FS pulpotomies. The certainty of the evidence for this result was low, according to the GRADE at 24 months, due to serious inconsistency and imprecision. FS pulpotomy was conditionally recommended against use (conditional, low certainty at 24 months).

(MTA versus CH): The SR[8] reported in sFigure 4c 24-month results in a direct comparison forest plot for pulpotomy success using RCT articles for MTA versus CH. The meta-analysis showed there was a significant difference strongly favoring MTA versus CH pulpotomy success (RR equals 2.33; 95% CI equals 1.78 to 3.05; *P*<0.00001; NNT equals two). The certainty of the evidence for this result was moderate due to serious sample size imprecision. The recommendation was strongly against the use of CH pulpotomy (strong, moderate certainty at 24 months).

(Laser versus FC): The SR[8] reported in sFigure 7d on 12-month results in a direct comparison forest plot for pulpotomy success using RCT studies for laser versus FC. The meta-analysis showed that, after 12 months, there was no significant difference between laser and FC pulpotomy (RR equals 1.04; 95% CI equals 0.98 to 1.10; *P*=0.18; NNT equals 20). No recommendation was made for laser pulpotomy due to no 24-month data.

(ABS): ABS pulpotomy was reported in the SR[8] sFigure 7e(a) and 7e(b) only in 12-month RCT studies. FC versus ABS pulpotomy at 12 months only had 43 teeth in each arm of the forest plot, and the meta-analysis was not significantly different (*P*=0.72). FS verses ABS pulpotomy had 48 teeth and showed no significant difference at 12 months (*P*=0.58). No recommendation for ABS pulpotomy was made due to the small sample sizes and only 12-month data.

*(Sodium hypochlorite [**NaOCl**] and ZOE pulpotomy):* The SR[8] reported in sFigure 7b an 18-month direct comparison forest plot for pulpotomy success using NaOCL versus FC. The NaOCl pulpotomy success rate forest plot at 18 months was significantly less than FC pulpotomy (RR equals 1.18; 95% CI equals 1.01 to 1.37; *P*=0.03; NNT of seven). However, this meta-analysis only included two studies, with one having a high ROB. NaOCL versus FS pulpotomy after 12 months was not significantly different (*P*=0.88). NaOCL pulpotomy was given a conditionally against recommendation for use (conditional, very low certainty at 18 months).

The SR[8] reported ZOE used as the sole pulpotomy medicament was studied in only one RCT. [21] The results showed MTA pulpotomy had significantly better success (96 percent) than ZOE (68 percent) after 24 months (*P*=0.02). There was one prospective NRS and one prospective case series with 12- and 24-month results for ZOE pulpotomy. Combining these three studies' results showed that ZOE pulpotomy success at 24 months was 65 percent. ZOE as the sole pulpotomy medicament was given a conditionally against recommendation for use (conditional, very low certainty at 24 months).

Network analysis of pulpotomy agents after 24 months: The objective of a network meta-analysis is to combine both direct and indirect evidence across all studies. The network meta-analysis also ranks the effectiveness of the studied interventions. The SR[8] reported a 24-month network analysis of four pulpotomy medicaments' success (sFigure 7f[b]). This analysis ranked MTA first, Biodentine® second, FC third, and worst was FS. Regarding the cumulative probability percentages of rankings, MTA was not significantly different than Biodentine® but was significantly better than FC and FS.

Question 7. In the instance of pulp exposure, which pulp treatment is better for a carious vital primary incisor, a pulpotomy or a pulpectomy?

Recommendation: For vital primary incisors with carious exposures, pulpotomy is likely to increase success compared to pulpectomy (strong, moderate certainty at 12 months).

Summary of findings: The SR[8] evaluated 12-month pulpotomy success, shown in SR Figure 7, for carious vital anterior teeth in comparison to a pulpectomy treatment in two RCTs. One study[7] evaluated FC pulpotomy versus Vitapex pulpectomy while the other[22] evaluated ferric sulfate plus MTA pulpotomy versus ZOE pulpectomy. The 12-month forest plot favored pulpotomy over the use of pulpectomy in vital primary incisors (RR equals 1.21; 95% CI equals 1.07 to 1.37; *P*=0.002; NNT equals seven). This NNT means that, after 12 months, one failure would be prevented after every seven anterior teeth by using pulpotomy instead of pulpectomy. The certainty of this result was assessed as moderate due to serious imprecisions in the sample size for pulpectomy. The WG determined the recommendation as strong for pulpotomy due to patient values/resources, including lower cost, more time efficient, and easier to perform in comparison to pulpectomy.

Remarks: No studies were found comparing IPT to pulpotomy for primary incisors. Limited data are available for studies longer than 12 months for anterior teeth. The SR[8] reported data after 18 months in one study,[22] with an MTA pulpotomy success rate of 87 percent (67 out of 77) versus a pulpectomy success rate of 75 percent (46 out of 61; *P*=0.11). The SR

reported a retrospective study without a comparison group. Its success rate for ZOE vital pulpectomies in incisors at 18 months was reported as 76 percent (79 out of 104). Pulpotomy was compared to pulpectomy for vital primary incisors at 24 months in one other study.[23] Due to large amounts of dropouts and study design, few pulpal treatment evaluations were reported at 24 months.

Question 8a. Which caries removal method is recommended for deep caries requiring VPT?

Recommendation: 8a. For primary teeth with deep caries requiring VPT, selective caries removal and IPT are recommended over nonselective (complete) or stepwise caries removal (strong, moderate certainty at 24 months).

Question 8b. Which caries removal method is recommended for deep caries to prevent pulp exposures?

Recommendation: 8b. For primary teeth with deep caries requiring caries removal, selective caries removal is recommended to avoid pulp exposures (strong, high certainty at 24 months).

Summary of findings 8a, 8b: The SR[8] reported that IPT had the highest overall success of all the VPTs and selective caries removal used in Figure 2 studies. The liner had no significant effect on success (P=0.79). The certainty of evidence was moderate based on the data's serious imprecision. Selective caries removal is done in one patient visit while stepwise involves two visits, and a child is subjected to additional local anesthesia. The indirect comparison meta-analysis reported in SR sFigure 8 of IPT done using selective versus complete caries removal showed no significant difference in success (P=0.91) after 12 to 33 months. The certainty of evidence was moderate based on the selective versus complete caries removal data's serious indirectness. As shown in SR sFigure 9b, fewer pulp exposures were noted after selective versus complete caries removal in the SR[8] (P= 0.04).

Four RCT studies shown in sFigure 9a in the SR[8] studied selective, stepwise, and complete caries removal, and the incidence of pulp exposures was statistically evaluated in the SR. The meta-analysis evaluated the incidence of exposures after combined selective and stepwise caries removal (4.5 percent) versus the incidence of exposures after complete caries removal (19.3 percent). The results shown in SR sFigure 9a strongly favored selective/stepwise over complete caries removal to decrease the incidence of pulp exposures with an NNT of six (RR equals 3.73; 95% CI equals 1.89 to 7.38; P<0.001). The certainty of the evidence for this result was high because all certainty criteria were judged to be not serious. There were three RCTs[13,24,25] cited in the SR[8] reporting IPT studies done with one visit selective versus complete caries removal. The 12- to 33-month indirect meta-analysis that calculated success using only the RCT studies showed no significant difference (P= 0.91) in pulpal success between selective caries removal (97 percent; 95% CI equals 0.93 to 0.99) and complete (97 percent; 95% CI equals 0.94 to 0.99). The one-visit selective IPT approach to minimize pulp exposures and the resulting high success would be preferred.

Question 8c. How does the no caries removal approach hall technique (HT) affect VPT success?

Recommendation: 8c. For primary teeth with deep caries requiring VPT, no caries removal (HT) had comparable results to selective/complete caries removal and may be used when indicated (conditional, moderate certainty at 24 months).

Summary of findings 8c: The 24-month data from three studies[26-28] was analyzed in the SR[8] for the effect of different methods of caries removal on pulp vitality based on the success of the VPT treatment. The no caries removal groups had HT crowns placed and only the data with caries greater than 50 percent into dentin was included for study. The SR[8] meta-analysis shown in Figure 5 revealed the HT group was not significantly different from the selective/complete caries removal groups in maintaining pulp vitality (RR equals 1.09; 95% CI equals 0.93 to 1.27; P=0.29). The certainty of the evidence for this result was moderate, according to GRADE at 24 months, due to serious inconsistency. A subgroup meta-analysis directly compared the complete caries group versus HT group at 24 months (sFigure 5, from SR[8]). The result showed no significant difference in maintaining pulp vitality between HT crowns versus doing complete caries removal and a filling in teeth with caries greater than 50 percent into dentin (RR equals 1.16; 95% CI equals 0.95 to 1.41; P=0.14). The certainty of the evidence for this result was very low due to serious inconsistency and serious sample size imprecision.

Remarks: The outcomes of VPT according to the SR[8] were not affected by caries removal methods. Selective/stepwise caries removal is favored over complete removal in preventing pulp exposure. HT is as effective as complete caries removal and a filling in maintaining pulp vitality. A retrospective clinical study noted in the SR[8] studied the costs of complete caries removal plus a pulpotomy restored with conventional restorations versus HT crowns and IPT. An evaluation of 836 teeth showed the cost of the former technique was significantly different (P<0.001), approximately $57.82 more expensive, than using HT and IPT. In addition, the HT does not require local anesthesia. These factors can be beneficial to patients and guardians when a patient's health status or level of cooperation is marginal. While one-visit selective caries removal and two-visit stepwise caries removal have similar success for IPT, the increased cost and chair time for performing stepwise may make it a less desirable choice for practitioners and patients. When choosing a caries removal technique, clinicians should take into consideration their clinical expertise, patient health, and cooperation levels as well as parental values and preferences.

Question 9. Which approach is preferred for caries removal, bur or chemo-mechanical (i.e., Papacarie® or Carisolv®)?

Recommendation: For caries removal during VPT, the use of a bur is likely faster (almost six minutes) compared to a chemo-mechanical technique. Both chemo-mechanical and bur removal of caries are effective in the reduction of cariogenic bacterial load. It is suggested that clinicians choose the approach (bur versus chemo-mechanical) based on their clinical expertise and patient cooperation (conditional, low certainty).

Summary of findings: No studies were reported in the SR[8] comparing caries excavation methods to vital pulp treatment success. The SR evaluated in sFigure 11a the speed of caries removal using a bur versus chemo-mechanical techniques using only low ROB studies. The meta-analysis showed that using a bur was significantly faster (P<0.001) by almost six minutes than the chemical method. The certainty of the evidence for this comparison was assessed as low because of serious inconsistency and imprecision.

One *ex-vivo* RCT[29] compared the reduction of colony-forming units in dentin using Carisolv®, Papacarie®, and manual excavation before and after caries removal. The three excavation methods equally reduced *Streptococcus mutans* and lactobacilli

counts after caries excavation. Another study[30] compared Carisolv® to bur caries removal with microbial counts from pre- and post-excavation dentin samples in 21 children. Both methods produced a statistically significant reduction in the total viable bacterial count and the viable count of lactobacilli. Another *ex vivo* study reported that Papacarie® was significantly more effective in reducing the residual cariogenic bacteria in dentin compared to Carisolv® and manual excavation. No meta-analysis could be done due to the heterogeneity of the studies.

Question 10. Which is the preferred isolation method when doing VPT?

Recommendation: There are no studies with low or unclear ROB that directly compared the use of a rubber dam or other isolation methods on VPT success. The studies that were reviewed used rubber dams for VPTs. If one expects to obtain the reported success, it is recommended to use a rubber dam as the standard of care.

Summary of findings: The vast majority of reviewed studies in the SR[8] involving VPT in primary teeth used rubber dam isolation and only a few used cotton-rolls. Rubber dam is used worldwide and is considered the "gold standard" for VPT procedures preventing field contamination from blood, saliva, and other contaminants.

Question 11. Does the method of coronal pulp removal affect mineral trioxide aggregate (MTA) pulpotomy success?

Recommendation: The practitioner may remove the coronal pulp for MTA pulpotomy with a manual technique (spoon/curette), bur, or both instruments without altering MTA pulpotomy success, but the evidence is very uncertain (conditional, very low certainty at 12 months).

Summary of findings: In the SR[8] shown in sFigure 10d was a meta-analysis that evaluated MTA pulpotomy success from studies where pulp removal was done either with manual methods (curette or spoon excavator), low speed burs, or combined methods (both bur and manual) after a 12-month follow-up. The reported overall success was 96 percent for the manual method, 95 percent for burs, and 98 percent for combined bur and manual methods. This meta-analysis showed no significant difference (P=0.91) in pulpotomy success for the method of pulp tissue removal. The certainty of the evidence for this result was very low at 12 months because of the serious inconsistency and very serious indirectness of the data.

Question 12. Does the type of coronal pulp irrigation affect MTA pulpotomy success?

Recommendation: The type of pulp irrigation (anti-microbial or water/saline) does not seem to affect MTA pulpotomy success, but the evidence is very uncertain. Clinicians may choose to use water/saline or sodium hypochlorite over the use of chlorhexidine based on their clinical expertise and chlorhexidine's potential safety concerns (conditional, very low certainty at 12 months).

Summary of findings: In sFigure 12, the SR[8] evaluated the effect of saline/water irrigation on MTA pulpotomy success, compared to NaOCl, and chlorhexidine irrigation. All studies had low ROB with 12 months follow-up. An indirect comparison meta-analysis was done showing saline/water had 96 percent success, NaOCl 96 percent, and chlorhexidine 90 percent for MTA pulpotomy with no significant differences observed (P=0.24). The certainty of the evidence for this comparison after 12 months was assessed as very low because of serious inconsistency and very serious indirectness in the forest plot after 12 months of follow-up.

Remarks: The Centers for Disease Control and Prevention (**CDC**) has posted alerts on multiple outbreaks of nontuberculous mycobacteria infections in children who received pulpotomies. These infections were potentially caused by water lines infected with high levels of bacteria, so the CDC recommends disinfecting dental water lines.[31] There is evidence to suggest that aqueous solution of 0.2% chlorhexidine can generate detectable *para*-chloroaniline, which is found to be carcinogenic in animal studies.[32,33] Given their higher effectiveness and lower toxicity concerns, water/saline or NaOCl may be preferred over chlorhexidine. Proper care and rubber dam isolation should be used to prevent accidental spillage when NaOCl is used.

Question 13. When stopping pulpal bleeding for an MTA pulpotomy, does the use of a water-/saline-moistened pellet, saline only, or a dry cotton pellet improve success?

Recommendation: A practitioner may use a water/saline-moistened cotton pellet, saline irrigation, or a dry cotton pellet for MTA pulpotomy to control hemorrhage without altering the success rate, but the evidence is very uncertain (conditional, very low certainty at 12 months).

Summary of findings: In sFigure 13, the SR[8] evaluated the effect of different methods of achieving hemostasis on MTA pulpotomy success at 12 months follow-up in studies with low ROB. The studies that used a water-/saline-moistened pellet had a 95 percent success rate, those using saline irrigation had 100 percent success, and the studies using dry cotton pellet had 99 percent success. The saline irrigation performed significantly better, followed by dry pellet and water/saline pellet *(P*=0.03) but was affected by sample size imbalance. Since the overall success among the groups was 95 to 100 percent, the consensus was that all could be utilized. The certainty of the evidence for the result was assessed as very low due to serious ROB and inconsistency and the very serious indirectness of the data.

Question 14. For MTA pulpotomy, does the type of base over the pulpotomy affect MTA pulpotomy success?

Recommendation: Use of intermediate restorative material (IRM) or a resin-modified glass ionomer cement (RMGIC) over an MTA pulpotomy does not seem to alter MTA pulpotomy success (conditional, low certainty at 24 months).

Summary of findings: The SR,[8] shown in its sFigures 15a and 15b, evaluated 12- and 24-month MTA pulpotomy success where IRM or RMGIC bases were used over the MTA pulpotomy. The 24-month indirect comparison forest plot evaluated 12 studies having IRM base after MTA pulpotomy verses five using RMGIC base. The MTA pulpotomy success was significantly better *(P*=0.049) using IRM (97 percent) versus RMGIC (91 percent). The certainty of the evidence for this result was low, at 24 months, due to very serious indirectness.

Remarks: The indirect comparison meta-analysis at 12 months showed that 30 studies employed an IRM base over the MTA pulpotomy and 12 studies used RMGIC. The forest plot of the two base materials showed no significant difference (P=0.24) for MTA pulpotomy's 12-month success. The 24-month forest plot favored IRM over RMGIC bases (P=0.049). This significant difference was due to the large sample size in sFigure 15b[8], and the WG did not feel that using an IRM or an RMGIC base at 24 months would give remarkably different results. (IRM equals 97 percent versus RMGIC equals 91 percent). Other types of pulpotomy were not evaluated for the

effect of the base material on their success because there was either insufficient data or the pulpotomy's success was much lower than MTA's success.

Question 15a. What is the effect on MTA pulpotomy success if done in one or two visits?

Recommendation: MTA pulpotomy is likely to have similar success if performed in one or two visits, but the evidence is very uncertain. Based on patient compliance, additional costs, and resources needed, a one-appointment visit may be preferred (conditional, very low certainty at 12 months).

Summary of findings: There was no meta-analysis in the SR[8] comparing one versus two visits to MTA pulpotomy success. The SR reported an indirect comparison of 64 MTA studies of various designs done in one visit, showing a mean success of 92.6 percent. This success was compared to only two MTA pulpotomy studies performed in two visits with a mean success of 94.9 percent. It was felt that the one-visit approach to pulpotomy would be preferred by the child (fewer local anesthesia applications) and the parent (one less appointment to attend and possibly cost differences). The certainty of the evidence for this result was very low, according to GRADE at 24 months, due to including high ROB studies and very serious due to the indirect comparison.

Question 15b. What is the effect on pulpotomy success if the final restoration is placed on the same day or on a different date?

Recommendation: Calcium silicate cement pulpotomy or FC pulpotomy's final restoration can be placed on the same day or a different date without affecting success. Based on patient compliance, additional costs, and resources needed, placing the final restoration on the same day of pulpotomy may be preferred (conditional, moderate certainty at 24 months).

Summary of findings: In sFigure 16a and 16b, the SR[8] reported a 12 and 24-month direct comparison forest plot for the timing of the final restoration and pulpotomy success. These meta-analyses directly compared calcium silicate cement and FC pulpotomy success for restoration the same day or days later. The 24-month meta-analysis showed no significant difference (RR equals 1.08; 95% CI equals 0.94 to 1.24; *P*=0.26) and an NNT of nine. The certainty of the evidence was moderate due to the serious sample size imprecision.

Remarks: The SR[8] 12-month comparison in forest plot, sFigure 16a reported on the final restoration done the same day or days later. This meta-analysis showed no significant difference in success (RR equals 1.00; 95 percent CI equals 0.98 to 1.02; *P*=1.00) with an NNT of 100 involving 164 teeth or more in each comparison group. The 24-month meta-analysis directly compared only calcium silicate cement, and FC pulpotomy success for restoration timing. However, this forest plot only had 55 or fewer teeth in each comparison group. The meta-analysis showed no significant difference (RR equals 1.09; 95% CI equals 0.92 to 1.30; *P*=0.30) and an NNT of nine favoring placing the restoration on the same day.

Question 15c. What is the effect of the type of final restoration on MTA pulpotomy success?

Recommendation: The type of restoration does not influence the success of an MTA pulpotomy. Clinicians may choose to use preformed crown, composite, amalgam, or RMGIC restorations based on clinical expertise and shared decision-making (conditional, very low certainty at 12 months).

Summary of findings: In the SR,[8] the type of final restoration effect on pulp treatment success could only be tabulated for 12-month data using MTA pulpotomy. The SR reported that MTA pulpotomies restored with an SSC resulted in 94 percent success, amalgam 93 percent, composite 96 percent, and RMGIC 100 percent. The certainty of the evidence for the restoration's effect on MTA pulpotomy success after 12 months was assessed as very low due to the indirect comparison and no meta-analysis evaluation.

Question 16. Is pulpotomy equally successful in anterior versus posterior teeth?

Recommendation: The success of pulpotomy is not likely to differ for anterior versus posterior teeth (conditional, very low certainty at 12 months).

Summary of findings: There was an indirect comparison meta-analysis in the SR[8] sFigure 10c comparing anterior versus posterior pulpotomy success at 12 months. Calcium silicate cement and FC pulpotomies were combined for this analysis. There was no 24-month comparison. The pulpotomy success for anterior teeth was 93 percent and for posterior teeth 93 percent, and the forest plot showed no significant difference (*P*=0.99). The certainty of the evidence for this result was very low at 12 months due to the serious inconsistency and very serious indirectness based on the indirect comparison.

Remarks: At 12 months, the SR[8] only compared calcium silicate cement and FC pulpotomy for anterior versus posterior pulpotomy success using an indirect comparison meta-analysis. These were equally successful and only included studies with no high ROB. The SR reported another retrospective study after 36 months follow-up. Anterior tooth pulpotomy success was stated as 90 percent and posterior at 96 percent. That same study's anterior IPT success was 95 percent compared to posterior IPT success of 98 percent based solely on a tooth not being extracted.

Question 17. What is the success of VPT in teeth affected by trauma?

Recommendation: There are no studies, and indirect data are inadequate on using VPT on primary teeth after trauma.

Summary of findings: This question could not be answered since there are no studies on teeth affected by trauma treated with VPT and indirect data is inadequate to establish any recommendation.

Question 18. In vital primary teeth requiring pulp therapy, does caries location or patient behavior influence VPT treatment success?

Recommendation: The location of caries (occlusal or occlusal-proximal) is not likely to influence the success of VPT, but the evidence is very uncertain (conditional, very low certainty at 12 months). Behavior guidance using tell-show-do with or without nitrous oxide utilization and their effect on VPT success could not be determined.

Summary of findings: Based on the limited information available, caries location (occlusal or proximal) did not seem to influence VPT success. There was limited information available in the SR[8] to evaluate occlusal caries versus multiple surfaces or proximal caries' effect on VPT success. There was a mixture of IPT and pulpotomy studies with only 12-month success that could be compared. An indirect forest plot was the only type of analysis possible. This meta-analysis was flawed in that the VPTs were different types, and there were very few studies in

this comparison. The SR[8] did not report on behavior guidance studies affecting pulp therapy success.

Research implications

This guideline recommends further research in primary tooth pulpal diagnosis methods. It was disappointing that the SR found insufficient evidence for methods used to accurately diagnose the pulp's vitality in primary teeth with deep caries. In addition, primary tooth pulpal diagnosis research could also include studying, use of ITR, cold and electric pulp test effectiveness in children.

At the time of this guideline's publication, a child with a primary tooth exhibiting only spontaneous pain is usually diagnosed with irreversible pulpitis. More research is needed to determine if spontaneous primary tooth pain can be treated with VPT using calcium silicate cement if hemostasis can be achieved in less than five minutes. In permanent teeth, calcium silicate cement materials have been utilized for pulpotomy in teeth with spontaneous pain but no other signs or symptoms. Studies have shown high success (78-90 percent) four to five years.[34,35] Possibly, pulpotomies would avoid extraction or pulpectomy procedures in primary teeth with only spontaneous pain.

More 24-month and longer research is needed on other calcium silicate cement materials used in VPT to evaluate if they are equal to or more effective than MTA and Biodentine®. Research is needed to identify if proximal caries versus occlusal caries differs in their VPT success. In addition, more research is needed to compare VPT's success using basic behavior guidance with nitrous oxide analgesia versus treatment with general anesthesia for the difficult-to-manage child.

The WG did not locate any studies to consider if VPT had any indications for use after trauma or in medically compromised children. These are needed avenues of research for the clinician.

This guideline endorses IPT using selective caries removal as a viable option for VPT. By definition, IPT leaves the deepest caries in place near the pulp and avoids pulp exposures and a DPC or pulpotomy. The literature will benefit from long-term studies evaluating the success of selective caries removal compared to nonselective (complete) caries removal. There is also a need for high-quality research with 24- to 36-month follow-up comparing the success of no caries removal and the HT with traditional stainless steel crowns for the management of deep carious lesions.

Other research areas include calcium silicate cement used as direct pulp capping materials; investigations on whether DPC is effective in proximal lesions; DPC versus pulpotomy using more affordable calcium silicate-based cement (in nations, the cost of calcium silicate cement materials may be a barrier to their usage); and testing of the esthetic effect of calcium silicate cement materials under tooth-colored restorations and zirconia crowns.

Conclusions

Based on the study's results, the following conclusions can be made:

1. In teeth with deep caries, indirect pulp therapy or calcium silicate cement pulpotomy is preferred over other vital pulp therapies such as direct pulp capping and other pulpotomy medicaments.
2. For teeth with pre-operative pain from deep caries, IPT and calcium silicate cement pulpotomy may be preferred over DPC.
3. For vital primary incisors with carious exposures, pulpotomy is likely to increase success compared to pulpectomy.
4. For teeth with deep caries requiring VPT, selective caries removal and IPT are recommended over stepwise caries removal or non-selective (complete).
5. The Hall technique had comparable results to selective/complete caries removal and may be used for teeth with deep caries requiring VPT.

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