

Evidence-based Recommendations for the Use of Sealants

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ABSTRACT

In traditional research, the “level of significance” refers to the probability value used to reject the null hypothesis. In evidence-based research, a similar term, “the level of evidence” refers to the quality of the published report that is analyzed critically in the context of a systematic review.¹ A systematic review, the principal research tool of evidence-based dentistry, is distinct from a classical narrative literature review in that it is focused to examine the strengths and weaknesses of the research methodology, design and data analysis of each report included in the review. A systematic review is very clearly defined, and sets out to find what evidence there is for prescribing a particular intervention for a given patient. Evidence-based recommendations are grounded on systematic reviews, and the evaluation of systematic reviews in a given domain of dentistry is critical for the successful implementation of evidence-based dental practice.

In the context of sealants, the evidence indicates that the intervention is effective in preventing dental decay on the molars and premolars of susceptible children and adolescents (Level of evidence: II-1). The preventive effect for second-generation sealants ranges from 33 percent to 71 percent. The median preventive effect is higher when sealants are reapplied, compared to a single application, because sealant effectiveness decreases over time. The majority of studies have focused on molars, and fewer studies have examined the preventive effect of sealants on premolars.

In this paper, the authors have developed evidence-based recommendations for the use of sealants by discussing the level of evidence and, when applicable, the number needed to treat (NNT) and the prevented fraction (PF), two fundamental criteria in evidence-based dental practice.²

The American Dental Association defines evidence-based dentistry as the process of incorporating the best available evidence from the entire body of available research into clinical decision-making. The intent of evidence-based dental practice is to optimize the specific treatment intervention to fit best the needs and desires of each individual patient. To actualize evidence-based dentistry, it is essential to develop and characterize fundamental standards for the evaluation of the “best available” research, which can be achieved utilizing the levels of evidence.¹ Here, the authors discuss critically the available evidence for the use of sealants in the development of evidence-based recommendation for clinical practice.

Taken together, the evidence suggests that once a tooth has erupted into the mouth and is free from gingival tissue, a sealant should be placed on that tooth as soon as possible (and up to four years). Because children receive their permanent molars and premolars during specific developmental periods, sealant placement between the ages of 6



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to 8 and 10 to 13 years would likely yield the most cost-effective program (Level of evidence: II-1).³ Limited data suggests that molars are the most susceptible to attack within two to four years of eruption. However, the pits and fissures of molars remain susceptible to primary decay into adolescence and adulthood (Level: II-2).⁴ If risk assessment does not deem an individual to be at risk for caries, the practitioner may observe the patient over time and place sealants when the risk for caries becomes more apparent. The authors attempted to examine the number needed to treat (NNT) and the prevented fraction (PF) of sealants for differences in underlying caries risk.²

Methods

*PICO Question:*³

I. How great of a reduction in caries do pit and fissure sealants achieve, compared to identical populations without sealants in both molars and premolars?

II. In what age groups are sealants most effective in reducing caries based on the parameters of a) cost, b) number needed to treat (NNT) for various caries rates, and c) prevented fraction (PF)?

Protocol

In order to answer these questions, the Medline and Cochrane databases were searched to locate review articles using the keywords “pit and fissure sealants” and “pit and fissure sealant effectiveness.” MeSH headings “cost-effectiveness,” “age,” and “preventive effect” were also used to locate articles. Abstracts were examined to identify systematic review articles on the topic. Eight review articles were selected and provide the basis for the analysis described below. Reference lists of the selected review articles were examined for additional studies that would assist in answering the proposed questions. Key oral health reports were also reviewed.^{4,7}

Studies were evaluated in accordance

with the “scale for evaluating evidence and making recommendations” Tables 4 and 5.⁸ Although split-mouth randomized control trials (RCT) could potentially be evaluated as Level I evidence, in this paper they are classified as Level II-I evidence because of inherent biases in these designs. Since the inclusion of children into a split-mouth design generally requires at least one pair of caries-free molars, a caries-active child would be excluded. Therefore, not all children

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have the same chance of being selected for participation. Moreover, the longer the period of time after the tooth has erupted into the mouth, the higher the likelihood that a high-risk child would be excluded from the study.⁹

Results and Inferences

Sealants and the Best Available Evidence

The evidence is strong that pit and fissure sealants placed on the occlusal surfaces of permanent teeth do prevent caries among susceptible children and adolescents (Level II-I). However, there is little evidence on sealant efficacy among adults. The classic meta-analysis by Llodra examined the effectiveness of autopolymerized pit and fissure sealants in preventing caries.¹⁰ A search of the MEDLINE database from January 1975 to December 1990 was conducted to locate studies on sealant effectiveness. To be included into the meta-analysis, studies had to contain original data, examine sealants as the sole preventive

intervention, be published in English, Spanish, or French, and include data which could be used to derive PF. All studies used a half-mouth design (Level II-I). Publication bias was considered analytically. Results were stratified by sealant type, length of follow-up, tooth treated, water fluoridation, and operator. Reports on visible light sealants were excluded because the PF could be not calculated. The final analysis included results from a single application of autopolymerized sealants. Eighty-one percent of studies examined sealant efficacy for the first molars. Pooled data from Llodra’s meta-analysis yielded a PF among the exposed group of 71 percent (CI⁹⁵: 69, 72) among children 5 to 13 years old.⁴

As part of an independent review, a nonfederal task force conducted a systematic review to evaluate the effectiveness, applicability, and cost-effectiveness of school-based and school-linked sealant programs. School-based programs are carried out in schools, while school-linked programs can be conducted in schools, private dental practices, and clinic settings. In general, these delivery programs target children at risk for caries based on their eligibility for free- and reduced-price lunch services throughout second to sixth grades. Experts have recommended that school-based and school-linked sealant programs target the first and second permanent molars of high-risk children.⁴

Ten out of 37 studies were retained for the final analysis on the effectiveness of school-based and school-linked sealant delivery programs in preventing caries (Level II-I, 2). The primary reasons for exclusion were insufficient data for quality scoring, limitations in execution or design, and lack of an appropriate effect measure. Seven studies reported on the effect of using sealant bisphenolglycidyl methacrylate (bis-GMA) as the only preventive intervention, and three reported using both bis-GMA sealants in

combination with other caries-preventive interventions.

The authors abstracted 22 estimates from the 10 studies that compared the caries experience of children who received sealants through a school-based or -linked program with children who did not. Exposure to a school-based or school-linked sealant program was associated with a median decrease in caries of 60 percent (range, 5 percent to 93 percent). School-based programs had a higher median effect (65 percent, range 23 percent to 93 percent) when compared to school-linked sealant delivery programs (37 percent, range 5 percent to 93 percent). Programs that provided sealant reapplication showed a higher median effect (65 percent vs. 35 percent).

The task force assessed the applicability of these findings to a variety of circumstances. The evidence encompassed studies that varied by time, place, population, the number of times sealant was applied to the same tooth surface, and duration of follow-up between sealant-caries status. The studies spanned from 1970 to the 1990s and included children and adolescents six to 17 years old from the United States, Guam, United Kingdom, Australia, Spain, Thailand, and Columbia. The effect size for studies in the United States (four studies) were similar to studies conducted outside of the country (six studies). The task force concluded that the findings should “apply broadly to populations of school-age children in a variety of school settings.”¹¹

Locker et al. cited Llodra et al. PF of 71 percent, and agreed with others that there was good evidence to support that sealants do prevent pit and fissure caries among susceptible children and adolescents (assuming the sealant is retained) (Level II-I).^{3,10,12,13}

On the other hand, in their meta-analysis, Majare et al. found the evidence limited for assessing the caries-preventive effect in first molars and

incomplete for assessing the preventive effect on primary molars, premolars and second molars (Level II-I, 2).⁹ The sample included children age five to 14. Potential factors which might modify the effectiveness of pit and fissure sealants were also examined. Criteria for inclusion into their analysis were stricter than those used by Llodra et al.¹⁰

Of 113 studies assessed by Majare et al., nine met their criteria and were retained for the final analysis.⁹ None of the studies were classified as strong evi-

THE AUTHORS CONCLUDED THAT THE LITERATURE WAS INSUFFICIENT TO EXAMINE HOW SEALANT EFFECTIVENESS VARIES IN LOW-RISK VERSUS HIGH-RISK POPULATIONS.

dence; two were evaluated as moderate, and 11 as limited evidence (c.f., Majare et al., Table 5).⁹ Eight studies were used for the pooled estimate effect because they all used resin-based materials and a single application on permanent first molars. All but one study included in the pooled estimate were evaluated by Majare as limited evidence. Three studies yielded nonsignificant results.¹⁴⁻¹⁶

For single applications, the relative risk ranged from 4 percent to 54 percent, and for repeated applications, the reduction in caries ranged from 69 percent to 93 percent. The pooled estimate for subjects with a single application of resin sealants on permanent first molars (compared to those without) showed a relative risk reduction (RR) of 33 percent (RR, 0.67 CI⁹⁵: 0.55, 0.83). The test of heterogeneity was highly significant at $p < 0.001$, so the assumption that the studies were taken from the same population was rejected. The authors concluded that the literature was insufficient to examine how sealant effectiveness varies in low-risk versus high-risk populations.

In a Cochrane systematic review, Ahovuo-Saloranta et al. evaluated the caries preventive effect of resin-based pit and fissure sealants and glass ionomer sealants among subjects under 20 years old.¹⁷ Studies included in the analysis were either randomized or quasi-randomized control trials with at least 12 months duration (Level II-1). Of 297 reports, 16 met Ahovuo-Saloranta et al. criterion. Of the 16 eligible studies, eight were retained for the final analysis, one parallel group design, and seven split-mouth designs. Five of seven split-mouth designs provided data on sealant versus a control group; two studies reported the difference between resin sealants and glass ionomer. The parallel design study compared resin sealant with a control group, glass ionomer with a control group, and resin sealant with glass ionomer. Incidence of caries was expressed as caries or no caries on the occlusal surfaces of permanent molars. Caries was defined as dentin, and enamel lesions were considered sound surfaces.¹⁷

The mean sample of children was 230 with approximately 300 tooth pairs. The parallel group study included 752 children in total. The combined analysis included children five to 13 years old from the United States, Australia, Columbia, Thailand, and the Syrian Arab Republic. Three studies were included in the meta-analysis for 12, 24 and 36 months, and two studies in the 48- to 54-month meta-analysis.¹⁷

The results comparing second-generation resin sealant with no sealant at follow-up months 12, 24, 36 were highly significant in support of the preventive effect of sealants to prevent decay. Compared to the control group, the reduction in caries rates among the sealant group ranged from 86 percent at 12 months to 57 percent at 48 to 54 months. The 24-month parallel group study found that among 12 to 13 year olds, there was significantly more caries in the control group with DFS = 0.65

(CI⁹⁵ 0.47, 0.83). Retention rates were considered good across all studies.¹⁷

Since few studies report the baseline caries prevalence in the population, it was not possible to examine the relationship between sealant effectiveness and baseline caries risk. Ahovuo-Saloranta et al. concluded that although sealants are shown as effective in caries prevention, it is impossible to infer the magnitude at each level of caries risk. Clinicians should consider local factors and follow specified guidelines for sealant placement.¹⁷

Tooth surface and type are important factors that influence levels of caries attack, and the pits and fissures of first and second molars are at highest risk.^{3,18,19} Sealant application to the occlusal surfaces of first molars yielded the highest percentage of caries-free teeth for the least amount of resources.¹⁸ Brown noted these findings are understandable because permanent first molars are at greatest risk of attack, and have the highest sealant retention rates.¹⁸ However, Rozier concluded that “for the purposes of sealant use decisions, the evidence suggests that first and second molars are at equal risk of caries for pit and fissure caries, and together are at the highest risk of any tooth types.”¹⁹

As discussed by Soderholm, epidemiologic studies suggest that targeting the first and second molars of children would reach 85 percent of all surfaces expected to develop caries.²⁰ By including premolars into a sealant program, 99 percent of tooth surfaces among schoolchildren expected to develop caries would be reached. Therefore, Soderholm suggested that including premolars in a sealant program would improve the outcome by only 14 percent, but would require significantly more resources. Including only first and second molars (and not premolars) into sealant delivery programs would yield the most cost-effective program. Additionally, he stated “If limited resources are available, targeted education about dental disease should have a

higher priority than placing preventive sealants on low-risk patients.” However, to adequately assess these issues, randomized control trials in populations with varying caries rates are needed.²⁰

Of interest is a recent analysis of more than 500,000 children, which found an 85 percent reduction in overall restoration rates among children ages of seven to 15 with pit and fissure sealants compared to children without. This study was unique in that it used an outcome measure of “restorations on all surfaces,”

EPIDEMIOLOGIC STUDIES SUGGEST THAT TARGETING THE FIRST AND SECOND MOLARS OF CHILDREN WOULD REACH 85 PERCENT OF ALL SURFACES EXPECTED TO DEVELOP CARIES.

which included smooth surface caries rather than only looking at pit and fissure caries. These data indicated that sealants can confer protective effects on smooth surfaces, even though the sealant was not applied to that area. The authors proposed that limiting the favored niches for growth of caries causing bacteria in pit and fissure surfaces through sealant placement may lead to a change in the bacterial growth patterns on the teeth, thus reducing overall caries rates. This study utilized a retrospective cohort study design in an insured population with continuous eligibility for the Delta Dental insurance plan (Level II-b).²¹

Effectiveness of Sealants as a Function of the Patient's Age

According to Brown and Selwitz, the declining rates of caries experienced by most segments of the population, slower rates of disease progression, and disproportionate impact of caries among low-income and minority groups have enormous implications for sealant programs.¹⁸ Since caries rates have declined (overall), and disease progression has

slowed, cavitation appears to manifest later in the course of the caries process. This suggests that the accepted standard: that sealants should be placed as soon as possible once the tooth has erupted and is free from gingival tissue (and up to four years), may not hold true as individuals remain at-risk for caries into adolescence and adulthood (Level II-I).³

This is contrary to the belief that teeth are only susceptible to decay for a few years after eruption, and if a tooth does not develop a carious lesion within several years, it will remain caries-free.¹⁸ While molars are most susceptible to attack within two to four years of eruption, the pits and fissures of molars remain susceptible to primary decay into adolescence and adulthood.^{4,22} Thus, the risk for primary caries in the pit and fissures of molars can continue across the life span.^{3,4,18}

In one of the few studies including young adults, Arthur and Swango reported that an “appreciable amount” of pit and fissure decay occurred in subjects during the ages of 17 to 25, and suggested that the selective application of sealants to susceptible tooth surfaces could prevent disease.²³ Two studies reported a relatively constant rate of caries attack over time on the molars of schoolchildren between the ages of 5 to 15.^{24,25} Thus, it was noted by Brown and Selwitz that the post-eruptive age of a tooth should “not be the major criterion of whether a tooth should be sealed.” Rather, it is the “conditional probability of developing caries in a sound surface given the number of years after eruption.”¹⁸ Nevertheless, several comprehensive literature reviews have concluded that sealants should be placed shortly after eruption, but can be applied across a wide range of ages.^{3,12}

Solderholm noted that sealant retention rates are higher among older children compared to younger children.²⁰ In his analysis, he argued that sealant application may be delayed until the child is older and caries risk can be more

easily determined. He suggested that “by accepting this approach, sealants become restorative materials rather than preventive materials shifting the time spent on traditional restorative methods, to time spent restoring incipient lesions would improve cost-effectiveness by reducing unnecessary sealant use” (by only treating individuals who are truly at risk for caries). He also noted that by delaying sealant placement until a child is older, it would be easier to keep the tooth dry, which would improve sealant retention, a primary ingredient of sealant effectiveness. However, this argument assumes in part, that sealants placed in younger children are not correctly done. There is no evidence to support that sealant retention rates for permanent molars differ between younger and older children when the procedure is correctly done.²⁰

In contrast, Weintraub found it cost-effective when children received sealants before the age of 8, especially among children with previous caries experience (Level II-2).²⁶ This large retrospective cohort study included children living in North Carolina between the ages of 5 to 13 who were enrolled in Medicaid around the time of first molar eruption (between the ages of 5 and 7). To estimate sealant effectiveness among children with various levels of caries risk, data on caries-related services were examined. The service variable enabled the stratification of subjects based on caries risk (low-, middle-, and high-risk). Demographic factors, geographic characteristics, and sealant status were accounted for using multivariate analysis.²⁶

Among low-risk children (66 percent of sample), sealants were effective in reducing the likelihood of a restoration in the sealed molars for up to four years, but sealants did not save cost expenditures within the eight-year follow-up period. For children classified as middle- and high-risk, sealants substantially lowered the odds of having a restoration for six and seven years,

respectively. Restoration rates for high-risk children peaked at eight years old for unsealed teeth, and at nine years for sealed teeth (18 percent vs. 8 percent). The age when sealants had their greatest effect was eight years old, but both sealant effectiveness and restoration rates declined after this time. The effect on the level of expenditures was greatest for high-risk children at nine years, but declined over subsequent years as sealant effectiveness decreased. Expenditure savings for high-risk chil-

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dren occurred as early as seven years old, but the observed effect of sealant effectiveness dissipated these savings in subsequent years. Weintraub concluded that although sealants were effective overall, the savings to the Medicaid program from 1984 to 1992 for placing sealants in high-risk children (22 percent) were not adequate to offset the cost of placing sealants in the first permanent molars of all Medicaid-eligible children who received them. No conclusions can be made about cost-effectiveness beyond the time of the follow-up period. But, a similar study found increasing cost-benefit ratios over time (Level II-2).²⁷ It may be noteworthy that although this was a Medicaid population (and assumed to be at high-risk for caries); the overall disease burden was fairly low. A sealant program would be more cost-effective in a population with a higher underlying caries risk.^{19,27}

Weintraub specifically examined the effectiveness of sealants among high-risk children and adolescents (Level II-I, 2).¹³ Outcome measures included percent sealant retention, caries rates,

changes in salivary mutans streptococci levels, cost-effectiveness, or cost-benefit analyses. Nine studies were randomized, half-mouth designs, and seven were cohort studies. Four split-mouth studies excluded children with no previous caries history or restricted the sample to children with caries. Five of the studies included a mixture of potentially low- and high-risk children. Studies varied across sealant type, application technique, age groups, selection criteria, sample size, and study duration.¹³

Retention began high, and declined over time regardless of risk status. Results showed that sealants are “more effective from a cost and time perspective if placed on high-risk rather than low-risk children, though it may take several years for savings to accrue.”¹³ It is widely accepted that limiting sealant application to high-risk children/teeth/sites is critical for achieving cost-effectiveness in any sealant program.^{3,4,12,19,27} Although many studies use prior caries history or current caries status as an indicator of risk, ideal risk assessment should identify high-risk children before clinical caries is detectable.¹³

Bader examined the efficacy of caries preventive methods in high-risk individuals.²⁸ The study population included caries-active or high caries-risk children and adults, which was defined as any combination of decayed, filled and/or missing primary and/or permanent surface or tooth scores. He noted a number of limitations within the literature including the lack of studies including adult subjects, inconsistency in the identification of caries-active and at-risk subjects, and study design weaknesses. The literature focuses heavily on the permanent teeth of children and adolescents. Bader concluded that it is unknown whether the results from studies on children are applicable to adult populations with the same underlying caries risk.²⁸

As demonstrated by Ahovuo-Saloranta et al. and Majare et al., few studies have

reported the baseline caries risk. Therefore, it was not possible to examine the NNT for the various caries rates.^{17,9}

In 2001, Rozier updated Llodra et al. meta-analysis with a review of the preventive effects of pit and fissure sealants in the permanent teeth of children and adolescents.^{12,10} Rozier presented the treatment effect as two measures: the NNT and the prevented fraction (PF). The pooled estimate for the caries preventive effect of sealants revealed that sealing 28 tooth surfaces would avert one DMFS in a low-risk patient. The mean PF ranged from 62 percent to 92 percent. These estimates were based on an annual increment of decay-affected pit and fissure-tooth surfaces of 50 per 1,000, or 5 percent per year. The American Dental Association, Canadian Medical Association, and expert opinion have all recommended that sealants be used selectively for high-risk individuals in clinical settings.¹² Clinical data suggest that sealants have a greater benefit when placed on teeth with incipient decay or in molars of individuals with a history of caries experience (Level III). If the underlying disease burden is low (i.e. there is less disease to prevent) within a population, the procedure will be more costly per surface of caries prevented, unless susceptible individuals and/or surfaces can be identified. In a population with a greater disease burden, one would expect the NNT to decrease. Balanced randomized control studies are needed to assess sealant effectiveness in light of individual caries risk.

Relevance to Clinical Decision-making

Sealants are effective in preventing dental decay on the molars and premolars of susceptible children and adolescents (Level II-1). The preventive effect for second-generation sealants ranges from 33 percent to 71 percent. However, new data shows a decrease in caries rates of 85 percent, and indicates that sealants may confer protective effects to smooth surfaces, as well as pit and fis-

sure surfaces.²¹ The median preventive effect is higher when sealants are reapplied, compared to a single application. This is because sealant effectiveness decreases over time. The majority of studies have focused on molars; while fewer studies have examined the preventive effect of sealants on premolars.

The majority of studies regarding sealant effectiveness involve a mix of children and adolescents. Rather than focusing on discrete age groups, the literature tends to classify individuals based on

THE UNDERLYING CARIES RISK OF THE POPULATION REMAINS THE MOST IMPORTANT CONSIDERATION FOR DETERMINING COST-EFFECTIVENESS OF SEALANT PROGRAMS.

their risk for caries. For the most part, caries risk was assessed by a child's previous or existing caries experience, the presence or absence of deep pit and fissure grooves, and demographic factors. That being said, age is still considered one component of risk. The evidence suggests that once a tooth has erupted into the mouth and is free from gingival tissue, a sealant should be placed on that tooth as soon as possible (and up to four years). Because children receive their permanent molars and premolars during specific developmental periods, sealant placement between the ages of six to eight, and 10 to 13 years would likely yield the most cost-effective program (Level II-1).³ Limited data suggests that molars are the most susceptible to attack within two to four years of eruption. However, the pits and fissures of molars remain susceptible to primary decay into adolescence and adulthood (Level II-2).⁴ If risk assessment does not deem an individual to be at risk for caries, the practitioner may observe the patient over time and place sealants when the risk for caries becomes more apparent (Level II-2).

Few studies have reported the baseline caries rate in the population. At this time, it is not possible to examine the NNT for various caries rates. Rozier reported a NNT of 28, but noted that this number reflects data from a low-risk population.¹² He concluded "estimates for the NNT suggest that the effects of sealants are low in patients who are at reduced risk for dental caries." If the underlying disease burden is low (i.e., there is less disease to prevent) within a population, the procedure will be more costly per surface of caries prevented, unless susceptible individuals and/or surfaces can be identified. In a population with a greater disease burden, one would expect the NNT to decrease.

In conclusion, data from balanced randomized control trials provide critical and timely new information. However, the underlying caries risk of the population remains the most important consideration for determining cost-effectiveness of sealant programs.

Appendices

1. Standards have been established for rating the level of evidence based on the nature of the study (e.g., fundamental vs. clinical), and of the design (e.g., observational vs. clinical trial) (c.f., *Journal of Evidence-Based Dental Practice*, and 2).

2. Systematic reviews of randomized controlled trials provide the highest level of evidence of efficacy of treatments, though in other circumstances, like adverse events, randomized trials may not always provide the best evidence. Systematic examination of the research evidence generates information that can be used to quantify the number of patients needed to treat (NNT) to obtain the beneficial outcome of the intervention, or to avoid the undesired side effect. NNT is considered to be a good measure of the absolute risk, an estimate of the average number of patients that the dentist would need to treat in order to have one additional event occur. NNT

refers in fact to the number of individuals or surfaces needed to treat per year to prevent one carious event.^{5,6}

The prevented fraction represents the proportion of disease occurrence in a population averted due to a protective risk factor or a clinical intervention. PF is not equivalent to the absolute, but rather directly measures the impact of the treatment intervention. PF refers quantitatively to the proportional reduction in dental caries between experimental and control, expressed as a percentage: $PF = \frac{I_0 - I_1}{I_1}$, where I_1 is the incidence of dental caries in the group treated with pit and fissure sealants, and I_0 is the incidence of dental caries in the control group.³

3. Systematic reviews are research endeavors that follow the scientific process. They start with the research question, "PICO," for "population of patients to be examined," "interventions to be evaluated," "evaluation by means of a comparison of the treatment interventions under study," and "outcome under scrutiny."

4. The data of a systematic review are generally analyzed by two principal techniques. Acceptable sampling analysis provides the investigator with a quantification of the strength and the weaknesses with respect to the methodology, design and data analysis aspects of each report included in the systematic review. Meta-analysis is an overarching statistical analysis of the level of significance of the reports in the systematic review. A meta-analysis is a summary estimate of the effects, reported as rates, relative risks or odds ratio, in each report. It requires that every report included in the meta-analysis have similar methods, design, and data analysis, lest the comparison across reports be spurious. A fixed-model meta-analysis is one whose conclusions apply stringently and only to the reports examined. A random model meta-analysis refers to one whose conclusions were derived presumably from a random sample of reports in a given domain, and which

may apply to the entire population of such reports. Whereas the acceptable sampling analysis is grounded on an analysis of variance approach, with the applicable parametric statistical inferences, meta-analysis are typically based on a chi-square analysis (either Mantel-Haenzel in the case of strict stratification, or Peto for looser stratification designs), with the associated limitations in parametric inferences.^{2,29} **CDA**

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