Communication

Equity or Two-Tier Care? A ROB-2 / CONSORT / STROBE Lens of “Paint SDF-and-Go” ECC Models

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Equity or Two-Tier Care? A ROB-2 / CONSORT / STROBE Lens of "Paint SDF-and-Go" ECC Models

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Abstract

Early childhood caries (ECC) is routinely described as a complex, multifactorial disease shaped by biofilm ecology, host susceptibility, diet, behavior, and social context. Yet, a growing strand of public-health messaging and implementation practice increasingly treats ECC as a one-step problem solvable by a topical "magic paint" (most prominently silver diamine fluoride, SDF) and deliverable by non-dental or minimally trained providers. This commentary argues that the **core contradiction**—declaring ECC polycausal while operationalizing it as monocausal—drives a harmful *evidence-to-policy drift*: research designs favor short-term, easily marketable surrogate endpoints (e.g., "arrest" defined partly by SDF-induced black staining) and implementation strategies shift diagnosis and management to underprepared personnel without robust guardrails. Using a journal-style critical lens anchored in **ROB-2**, **CONSORT**, and **STROBE** principles, I examine recent Canadian work frequently cited to justify "paint-and-go" approaches, including open-label randomized trials of SDF application intervals and microbiome-focused substudies, and I integrate the delegation axis through the Canadian Caries Risk Assessment Tool (CCRAT) and its embedding into primary care workflows. While SDF and non-dental screening can be valuable *adjuncts* in a continuum of care, overselling them as substitutes for dentist-led diagnosis, pulpal assessment, and definitive rehabilitation risks institutionalizing a two-tier standard for children—especially for Indigenous and remote communities. I conclude with concrete research and policy guardrails: comparator-driven trials, multilevel modeling, lesion-specific sampling where mechanistic claims are made, patient-centered outcomes, defined referral timelines, and a dental-home–anchored pathway that treats SDF as a bridge—not a destination.

Keywords: early childhood caries; silver diamine fluoride; SDF; caries risk assessment; CCRAT; Indigenous health; implementation science; risk of bias; CONSORT; ROB-2; STROBE

1. Introduction: When "Complex Disease" Becomes a Slogan

ECC is not a single lesion; it is a systemic disease manifesting in teeth. Its trajectory is shaped by biofilm ecology and microbial community structure, host factors (including genetics and taste pathways), behaviors (especially sugar exposure and hygiene), and structural determinants such as access, poverty, and rurality. [2,23,24] A recent integrative analysis combining taste genetics with plaque microbiome data illustrates this point with unusual clarity: predictive performance improves when host, microbiome, and social variables are modeled together—precisely the opposite of what "single-intervention" narratives imply. [1]

The paradox in today's pediatric oral health discourse is therefore not scientific—it is *operational*: we endorse complexity rhetorically, then design systems that behave as if ECC were a one-variable equation. That operational contradiction is now being normalized through two coupled moves:

1. **Therapeutic simplification**: "paint-and-go" caries control, in which a topical agent (often SDF) is framed as a near-cure endpoint rather than an interim measure.
2. **Workforce simplification**: shifting screening, risk assessment, and sometimes intervention to non-dental providers using brief tools (e.g., CCRAT), despite documented training gaps and weak system integration.

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This commentary does not argue against SDF, nor against medical–dental collaboration. It argues against **category errors**: substituting a medication for a care pathway and substituting a checklist for diagnosis.

2. Oversimplification of ECC—"Magic-bullet" Paints as a Substitute for Care

SDF is a useful material. It is also an unusually easy material to oversell.

The "magic paint" storyline typically goes like this: ECC is widespread; access is limited; therefore, we should prioritize high-throughput approaches—"lift the lip," score risk, paint SDF, and move on. That storyline becomes institutionally seductive when success is measured by endpoints that are (a) easy to collect in community settings, (b) quick to improve, and (c) visually dramatic.

But what looks like success in a spreadsheet can be failure in a child's life. "Arrest" does not automatically mean restored function, restored esthetics, restored sleep, restored nutrition, or restored development. And it does not replace pulpal diagnosis.

Systematically, the risk is not that SDF exists. The risk is that SDF becomes **the ceiling** instead of the **floor**—particularly for children already assigned, by geography or inequity, to limited options.

3. What the Evidence Actually Supports About SDF (and What It Doesn't)

A high-quality synthesis of the SDF literature emphasizes a recurring reality: evidence across outcomes and regimens is heterogeneous, and many conclusions—especially about prevention, long-term durability, and comparative effectiveness—remain uncertain or of low certainty depending on the outcome and study design. [5,25]

Professional guidance also frames SDF as a **topical, non-restorative management** option with well-known trade-offs (notably black staining) and the practical need for **ongoing follow-up** rather than a single-application "cure." [6–8]

The scientific and ethical problem arises when these realities are translated into messaging that implies:

- "One paint cures ECC," or
- "Arrest is equivalent to treatment completion," or
- "Diagnosis and pulpal assessment can be bypassed because access is hard."

That translation is not an evidence-based leap. It is an evidence-based *collapse*.

A recurring pattern in the Canadian SDF implementation narrative—especially across work emerging from the same Manitoba/Winnipeg trial network led by Schroth and colleagues—is that a narrow clinical question (does SDF harden lesions at a short horizon?) is bundled with a broader policy payload (therefore SDF can substitute for comprehensive care; therefore frequency protocols should be standardized and scalable; therefore quality-of-life and microbiome substudies "de-risk" the model). These are not the same claims. When presented as a single package, acceptable constraints for a pragmatic trial become unacceptable as a basis for scope expansion and "paint-and-go" delivery at the population scale. [3,4,33,34]

4. Evidence Appraisal I: The Canadian SDF-Interval Open-Label RCT—When Pragmatic Becomes Permissive

A recent Canadian open-label, parallel-group randomized clinical trial compared SDF application intervals in preschool children with cavitated lesions, who were treated with **38% SDF plus 5% NaF varnish** at two initial visits, spaced 1, 4, or 6 months apart. The trial reports higher short-term arrest in the shorter-interval arms. [4]

Interval questions are important—but they are not new. Outside Canada, large kindergarten-based RCTs have tested annual vs semiannual SDF regimens (and different concentrations) over longer follow-up, showing that frequency effects exist but are context-dependent and intertwined with staining and acceptability. [26,29] High-level syntheses still emphasize heterogeneity and

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limited certainty for many regimen questions beyond short horizons. [5,25] Against that backdrop, a short-horizon open-label interval study should be interpreted as provisional operational data—not as a mandate for "more frequent paint" at the population scale.

4.1. CONSORT Lens: What the Trial Asks vs. What the System Hears

On its own terms, the trial asks an operational question: Does *earlier re-application increase early "arrest" in community clinics?* That is a legitimate pragmatic question.

The problem is what happens next—how this narrow operational result becomes broadcast as a generalizable justification for "paint more often" programs and delegated delivery, while ECC remains uncontrolled at scale.

This is where **CONSORT** is not a reporting bureaucracy; it is a boundary against overinterpretation. CONSORT exists to keep what a trial *shows* from being inflated into what it *means.* [19,21]

4.2. ROB-2 Lens: Domain-Level Concerns that Weaken Causal Confidence

Using **ROB-2** domains as a structured framework, several risk-of-bias concerns arise. [18]

(A) Bias in measurement of the outcome (detection/incorporation bias):

"Arrest" is commonly defined by tactile hardness and color change—yet black staining is an expected SDF effect. When outcome criteria include a treatment signature, open-label assessment becomes vulnerable to incorporation bias. In related work from the same trial network, lesions were "deemed arrested if found to be black and hard," illustrating exactly how treatment imprint can become outcome proof. Because outcome assessment is visual–tactile and unblinded, the risk is not theoretical; it is designed into the measurement process. [3,4]

(B) Deviations from intended interventions/performance bias:

Open-label designs in community settings can alter behaviors (e.g., provider counseling, caregiver expectations, hygiene changes), and those shifts can confound short-term outcomes—especially when no robust behavioral/dietary measurement is built into the design.

(C) Analysis unit problems (pseudo-replication risk):

When hundreds of lesions are analyzed within dozens of children, lesion-level analyses require multilevel methods to avoid inflated precision. In the microbiome RCT linked to this program, lesion counts and arrests are reported, along with group comparisons, underscoring the importance of explicitly modeling clustering rather than assuming independence.

(D) Missing outcome / limited follow-up:

Short follow-up captures early surface hardening, but not **tooth survival**, reactivation, pulpal progression, fracture, or later need for OR-based rehabilitation—the outcomes that matter most for children and systems.

4.3. The Deeper Issue: Surrogate Endpoints Become Policy Currency

The trial's most consequential output may not be its clinical finding; it may be its *marketable metric*. "Arrest rate at final visit" is a high-throughput number that institutions can deploy quickly. But it is not the same as:

- disease control,
- functional rehabilitation,
- quality of life,
- or equity in comprehensive care.

This is the first mechanism of evidence-to-policy drift: **surrogates become substitutes**.

4.4. Frequency Is not a Scheduling Detail; It Is the Policy Payload

In the Canadian interval RCT and its linked publications, frequency is treated as a technical tweak—1 vs 4 vs 6 months. In practice, frequency determines staffing, budgets, recall systems, and

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the probability that children will ever reach definitive care. When frequency decisions are based on short-term visual–tactile endpoints that are partly treatment-signatured (black and hard), systems can be nudged to repeat the surrogate rather than complete care. [4]

Established trials in other settings have compared annual vs semiannual SDF regimens with larger samples and longer follow-up, showing that more frequent application can increase arrest but also increases visible staining—an outcome that interacts with parental acceptance and tooth location. [26,29] This is why syntheses and guidelines continue to emphasize heterogeneity, shared decision-making, and follow-up rather than turning any one regimen into a universal policy mandate. [5,6,8,25]

4.5. SDF and Quality of Life: Why Reassurance Is not Resolution

Quality of life is not a decorative endpoint; it is the lived-experience domain in which pain, function, appearance, caregiver distress, and stigma are integrated. OHRQoL is multidimensional, and measurement choices (instrument, timing, domain-level analysis) shape what a study can legitimately claim. [28] In preschool populations, ECOHIS is widely used, but it was designed to capture both child and family impacts—meaning "improvement" can reflect changes in caregiver stress or access to care even when the child's daily functioning domain remains unchanged. [27]

Within the same Canadian trial ecosystem, a JCDA pilot combined SDF with fluoride varnish and explored OHRQoL, but its design and sample size limit causal inference. [33] More recently, an OHRQoL analysis from the interval RCT reported improvements in total ECOHIS scores after treatment, driven largely by family domains, with no ECOHIS differences between frequency groups. [34] These findings are clinically interesting—but they do not close the ethical question. A null difference between regimens is not the same as "no cost," especially when esthetic staining is unevenly acceptable (posterior vs. anterior) and context dependent. [29]

The broader OHRQoL evidence base to date suggests that SDF is not clearly worse than alternative non-surgical approaches on measured OHRQoL, but the literature is limited, heterogeneous, and often underpowered for the social and esthetic domains most relevant to children and families. [30] For policy, the guardrail is simple: treat PROM evidence as complementary (and pre-specify it), not as a moral license to replace comprehensive care with a surrogate endpoint.

5. Evidence Appraisal II: The "Bacteriome/Mycobiome" RCT—Mechanistic Language Without Mechanistic Sampling

A randomized clinical trial examining microbiome changes under different SDF regimens recruited 45 children, treated 195 lesions with SDF plus NaF varnish, and sampled supragingival plaque at each visit. Importantly, plaque was collected by scrubbing **all available tooth surfaces** with a sterile interdental brush; the authors also state that samples were **not site-specific** and therefore could not localize changes to treated lesions. [3]

5.1. CONSORT Framing: "Adheres to CONSORT" is not the Same as "Answers the Claimed Question."

The study explicitly states adherence to CONSORT and describes open-label methods and non-blinded personnel.

But the key scientific question is not whether the protocol is described, but whether the **sampling frame** matches the **inference frame**. [19]

If the implied claim is lesion-level ecological transformation, then lesion-level sampling is not optional. Sampling the whole mouth and then attributing shifts to lesion-level intervention is classic ecological inference drift. Contemporary reporting guidelines for human microbiome research (STORMS) explicitly emphasize transparent sampling frames, processing pipelines, and analytic reproducibility—especially when mechanistic language is used to justify clinical simplification. [31] Lesion-site studies of SDF-treated caries illustrate why these matters: overall diversity may appear stable while species-level shifts differ between active and arrested lesions. [32]

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5.2. Core Methodological Contradictions

(A) Non–site-specific sampling undermines lesion-level inference

The study's methods specify interdental-brush sampling across all available tooth surfaces, and its discussion acknowledges the limitation that the microbiome data cannot be localized to the carious lesion site.

That single point collapses many mechanistic interpretations into hypothesis-generating observations. [3]

(B) Small sample size + attrition in mycobiome pipelines

The trial reports the loss of samples due to low read counts and their removal for paired analysis (including multiple excluded fungal samples).

In 'omics work with high dimensionality, these losses matter: they amplify instability, especially when paired with multiple-testing burdens and flexible analytic choices. [3]

(C) No true control group for attribution

All groups receive SDF plus NaF varnish, so observed changes reflect a combined regimen over time rather than isolating SDF's contribution.

The literature demonstrates that combining fluoride modalities can alter arrest outcomes compared with SDF alone, underscoring the need for a proper comparator structure. [3,9]

(D) Outcome definition loops back into bias

In this microbiome RCT, lesions were "deemed arrested if found to be black and hard," and personnel were not blinded.

That is not a fatal flaw for pragmatic care delivery, but it is a serious limitation when arrest is used as a hard endpoint to justify expanded delegation. [3,18]

5.3. The Interpretive leap: Microbiome "Noise" Used as a Mechanistic Defense for Simplified Care

The more subtle problem is rhetorical: microbiome language can be used to create an aura of mechanistic depth around an intervention model that is, clinically, shallow. If a study cannot localize its sampling to the treated lesion, then "microbiome shift" should be framed as **exploratory ecology**, not as proof that a paint-and-pray pathway is biologically sufficient.

Related methodological concerns have also been raised in correspondence responding to the trial's microbiome claims, underscoring that these issues are visible to readers outside the original study team. [22]

6. The Delegation Axis: CCRAT, Primary Care Integration, and the Risks of Shifting Diagnosis Without Infrastructure

The "magic paint" movement does not travel alone. It is increasingly coupled with **risk tools** that enable non-dental providers to identify high-risk children and trigger preventive actions within medical workflows.

6.1. CCRAT: What It Is and What It can Realistically do

The Canadian Caries Risk Assessment Tool (CCRAT) was designed for **non-dental primary care providers** and embedded in early childhood records (e.g., well-child frameworks).

As an adjunct to screening, this can be valuable—*if* the downstream pathway exists. [11–13]

But the tool's validation data also matters. A pilot validation study in dental clinics reports **high sensitivity (~87%) but modest specificity (~43%)** for predicting new cavitated lesions, meaning many children will be flagged "high risk" who may not progress as predicted.

That is not a condemnation—it is what many screening tools look like. The danger is using a low-specificity screen to justify large-scale delegated management without a robust referral-and-treatment system. [10]

6.2. STROBE Lens: What Is Missing When Validation Becomes Advocacy

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STROBE is not a ritual; it is a demand for transparent limits in observational inference.

In the CCRAT validation study, several features constrain generalizability and causal interpretation: [20]

- validation occurred in **dental clinics** with a dentist examiner, not in real-world primary care settings where the tool is intended to operate;
- The examiner was reportedly **not blinded** to CCRAT items during assessment.
- and performance metrics derived from high-risk clinic populations may not transport cleanly into Indigenous, rural, or structurally different contexts.

This is where the "delegation without deliberation" risk becomes concrete: a tool validated under one set of conditions can be rhetorically repurposed to justify scope shifts under very different conditions.

6.3. Implementation Reality Check: Training Gaps and Workflow Barriers Are not Minor Details

Two recent strands of evidence deepen the concern:

(A) Training-needs evidence (Frontiers, 2025):

Non-dental professionals value CRA tools and find them feasible, but many report limited formal preparation and emphasize the need for culturally appropriate, hands-on education before engaging competently. [14]

(B) Qualitative implementation evidence in Indigenous pediatric primary care (BMC, 2025):

Healthcare providers describe structural barriers and a critical communication problem: some parents interpret preventive actions (e.g., fluoride varnish) as equivalent to "dental care," which can delay definitive dental visits. [15]

If screening and varnish become psychologically coded as completion, then "integration" becomes a paradox: it can expand contact while inadvertently extending time-to-treatment.

6.4. The Ethical Trap: Two-Tier Dentistry Disguised as Equity

It is easy to claim equity while lowering the standard. True equity expands **access to the full spectrum of care**, not access to a reduced menu.

If CCRAT flags risk but the system cannot deliver timely pediatric dental care, then risk identification becomes a bureaucratic loop: children are labeled, not treated.

7. Research-to-Policy Drift: How the Field Ends Up Supporting Simplification With Weak Evidence

Across these SDF and CCRAT streams, the same drift pattern appears:

1. Choose outcomes that are easy to measure (arrest at a short horizon).
2. Use designs that are pragmatic but bias-vulnerable (open-label + subjective endpoints).
3. Avoid comparators that would force real clinical choices (no Hall/ART/restorative arms when feasible).
4. Translate a limited result into a broad claim ("This can be done by anyone, anywhere, as a substitute for care").

The result is not fraudulent science—it is *thin science over-weighted by policy ambition.*

A useful conceptual reminder comes from the caries prediction literature: risk tools and prediction models can become "risky" when treated as deterministic substitutes for clinical pathways rather than as probabilistic aids embedded in robust systems. [17,35]

8. What "Good" Looks Like: A Continuum-of-Care Model with Guardrails (Not Pedestals)

A scientifically coherent public-health strategy does not reject simplification; it disciplines it.

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8.1. Clinical Guardrails for SDF (Minimum Standard)

- **Diagnosis remains dentist-led** when treatment planning is involved, especially for cavitated lesions and pulpal risk.
- **Case selection**: SDF for appropriate lesions without signs/symptoms of pulpal involvement; explicit referral/definitive plan when deeper disease is suspected.
- **Reapplication as a protocol, not an afterthought**, aligned with guideline framing that SDF is not a one-time cure. [5–8,25]
- **Outcomes beyond "arrest"**: function, pain, sleep, feeding, parental acceptance, child-centered OHRQoL, tooth survival/time-to-failure. [27–30]

8.2. System Guardrails for CCRAT Integration (Minimum Standard)

- **CCRAT is for early identification only**, not independent diagnosis or management.
- **Mandatory referral pathways with defined timelines** for high-risk children—measured as completed visits, not referrals written.
- **Training with boundaries**: culturally safe, competency-based training for screening and counseling, coupled with explicit "stop points" that trigger dental referral.
- **Equity metrics that matter:** dental-home establishment by age one, referral completion rates, reduction in OR-based rehabilitation, and caregiver-reported outcomes—rather than isolated arrest percentages. [8,16]

9. Research Recommendations: What Future Studies Must Do to Earn the Claims They Want to Make

If we want the public and policymakers to treat ECC as a serious disease, our research must stop acting like "arrest at next visit" is the gold standard.

9.1. CONSORT Upgrades for ECC Pragmatic RCTs

- **Comparator arms that match real choices**: SDF regimen versus Hall/ART/conventional restorations where feasible, or well-defined stepped-care pathways.
- **Blinded, calibrated outcome assessment** whenever endpoints are subjective or treatment signatured. [18,19,21]
- **Multilevel models** when lesions are clustered within children—pre-specified and powered accordingly.
- **Longer horizons** with tooth survival and reactivation, not just early hardening.

9.2. 'Omics Discipline for Mechanistic Claims

- If the claim is lesion-level biology, **sample the lesion site** (and ideally, subsurface where feasible), or explicitly limit claims to overall plaque ecology. [31,32]
- Pre-register analytic pipelines and control false discovery risks transparently. [31]

9.3. STROBE Discipline for Tool Validation and Implementation Studies [20]

- Validate in the **intended setting** (primary care), with real users (non-dental providers), and measure downstream effectiveness (referral completion, treatment uptake), not merely usability.

10. Conclusion: SDF Belongs on the Shelf, Not on a Pedestal

SDF is an access tool. CCRAT is a screening tool. Neither is a replacement for pediatric dentistry.

When ECC is treated as complex in theory but simplified in practice, the system drifts toward a two-tier model: comprehensive care for children with proximity and privilege, and "paint-and-go" for children with distance and disadvantage. The tragedy is that this drift can be framed as progress.

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A science-aligned pathway is possible: dentist-led diagnosis, team-delivered prevention, structured follow-up, meaningful outcomes, and culturally safe integration that builds dental homes rather than checklists. If our data can model ECC as polycausal, our policies must stop pretending a single paint can cure it.

In the spirit of the 3R series—Rethink, Reform, and Rise—the call here is simple: rethink ECC as a polycausal disease (not a lesion); reform how we translate short-horizon surrogate evidence into policy; and rise to an ethical standard where access innovations expand care without lowering the ceiling for children who already face the highest burdens. This is the Butterfly movement at its best: small actions that compound into systems that keep children whole.

Abbreviations

AAPD – American Academy of Pediatric Dentistry

ADA – American Dental Association

ART – Atraumatic Restorative Treatment

CONSORT – Consolidated Standards of Reporting Trials

CRA – Caries Risk Assessment

CCRAT – Canadian Caries Risk Assessment Tool

ECC – Early Childhood Caries

HPCDP – Health Promotion and Chronic Disease Prevention in Canada

NaF – Sodium Fluoride

OHRQoL – Oral Health–Related Quality of Life

ROB-2 (RoB 2) – Revised Cochrane Risk of Bias Tool for Randomized Trials

SDF – Silver Diamine Fluoride

STROBE – Strengthening the Reporting of Observational Studies in Epidemiology

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