GOOD EVIDENCE MATTERS

GEMs of the Week

SPOTLIGHT

Keep Calm & Beta-Block On

Thriving After Agina
Quality of Life Following CT vs Invasive Angiography

PROM and the Primip
Oxytocin vs Oral Misoprostol for Induction

Relax into Pain Relief, Cyclobenzaprine for Fibromyalgia

Sleeping Better by Moving Forward
Evaluating the Safety and Efficacy of MRAs in OSA Management

How the COVID-19 Pandemic Reshaped and Impacted Preventive Care for Young Children

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Keep Calm and Beta-Block On

Beta-Blockers After Myocardial Infarction in Patients Without Heart Failure

Munkhaugen J, Kristensen AMD, Halvorsen S, et al. Beta-Blockers after Myocardial Infarction in Patients without Heart Failure. *N Engl J Med*. 2025;393(19):1901-1911. doi:10.1056/NEJMoa2505985

KEY TAKEAWAY: Beta-blocker therapy reduces the incidence of death from major adverse cardiovascular events (MACE) in patients with a history of myocardial infarction (MI) and a preserved or mildly reduced left ventricular ejection fraction (LVEF).

STUDY DESIGN: Combined superiority trial with open-label and blinded end-point evaluation, randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: A prior contemporary trial (REBOOT) had found no benefit for beta-blockers in patients with preserved LVEF. However, according to the American College of Cardiology (ACC) and the American Heart Association (AHA), current Guideline-Directed Medical Therapy (GDMT) recommends the use of beta-blockers after an MI. This study helps provide evidence to support beta-blocker therapy after MI in patients without evidence of heart failure (HF).

PATIENTS: Post MI patients without HF or mildly reduced LVEF

INTERVENTION: Beta blocker therapy

CONTROL: No beta blocker therapy

PRIMARY OUTCOME: Composite death from any cause or MACE

Secondary Outcome: Individual components of the primary outcome

METHODS (BRIEF DESCRIPTION):

- Combined BETAMI-DANBLOCK superiority trial with PROBE design (Prospective, Randomized, Open-label, Blinded End-point evaluation).
- The study was conducted in Denmark and Norway between the years 2018 and 2024.
- The patient population included were those who had MI and a LVEF of at least 40%.
- In a 1:1 ratio, patients were to receive long-term beta-blocker therapy within 14 days after the cardiovascular event or no beta-blocker therapy.
- The primary outcome measured death from any cause or major adverse cardiovascular events, defined as MI, unplanned coronary revascularization, ischemic stroke, HF, or malignant ventricular arrhythmias.
- The secondary outcomes measured the impact of beta blocker therapy in each individual MACE component.

INTERVENTION (# IN THE GROUP): 2,783

COMPARISON (# IN THE GROUP): 2,791

FOLLOW-UP PERIOD: Median 3.5 years

RESULTS:

Primary Outcome –

- Beta-blocker therapy reduced the composite of death from any cause or MACE compared to no beta-blockers (14% vs 16%, respectively; hazard ratio [HR] 0.75; 95% CI, 0.75–0.98).

Secondary Outcome –

- Beta-blockers reduced the occurrence of new MI compared to no beta-blockers (5.0% vs 6.7%, respectively; HR 0.73; 95% CI, 0.59–0.92).
- There was no statistically significant difference in the rates of unplanned coronary revascularization, ischemic stroke, HF, or malignant ventricular arrhythmias between beta-blocker and no beta-blocker.

LIMITATIONS:

- Open trial that may have included bias
- Metoprolol was the main beta-blocker utilized in 95% of the intervention group.
- At six months patients were adherent to their assigned groups, unknown for remaining time or time in respect to primary end point.

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Thriving After Angina: Quality of Life Following CT vs Invasive Angiography

Health Status Outcomes After Computed Tomography or Invasive Coronary Angiography for Stable Chest Pain: A Prespecified Secondary Analysis of the DISCHARGE Randomized Clinical Trial

DISCHARGE Trial Group, Rieckmann N, Neumann K, et al. Health Status Outcomes After Computed Tomography or Invasive Coronary Angiography for Stable Chest Pain: A Prespecified Secondary Analysis of the DISCHARGE Randomized Clinical Trial. *JAMA Cardiol*. 2025;10(7):728-739. doi:10.1001/jamacardio.2025.0992

KEY TAKEAWAY: Patients with stable chest pain undergoing computed tomography (CT) compared to invasive coronary angiography (ICA) have similar long-term improvements in health-related quality of life and angina among patients with stable chest pain.

STUDY DESIGN: Multicenter, nonblinded, randomized control trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: ICA has traditionally been the standard test for patients with chest pain, though CT is a less invasive alternative. This study aimed to determine whether CT and ICA differ in long-term effects on patient-centered outcomes.

PATIENTS: Adults with stable chest pain

INTERVENTION: Coronary CT

CONTROL: ICA

PRIMARY OUTCOME: Health related quality of life

Secondary Outcome: Angina burden, anxiety, depression

METHODS (BRIEF DESCRIPTION):

- Patients were recruited from 26 centers in 16 European countries and randomized 1:1 to CT or ICA.
- Inclusion criteria included adults with stable chest pain and intermediate pretest probability of CAD.
- Health-related quality of life was measured using the EQ-5D-VAS. Scores range from 0–100, with higher scores indicating greater quality of life. Health-related quality of life was also measured using the SF-12 physical and mental component scores. Scores range from 0–100, with higher scores indicating greater physical and mental health.
- Angina was assessed using the Seattle Angina Questionnaire and Canadian Cardiovascular Society grading.
- Depression and anxiety were measured using the Hospital Anxiety and Depression Scale (HADS). Scores range from 0–21, with higher scores indicating more severe depression and anxiety symptoms.

INTERVENTION (# IN THE GROUP): 1,808

COMPARISON (# IN THE GROUP): 1,753

FOLLOW-UP PERIOD: Median 3.5 years

RESULTS:

Primary Outcome –

- Both CT and ICA groups had significant similar within-group improvements using the EQ-5D-VAS with no significant between-group differences.
  - CT (mean change 4.0; 95% CI, 3.1–4.9)
  - ICA (mean change 4.6; 95% CI, 3.6–5.6).
- These improvements were similarly maintained on the SF-12 physical component summary with no significant between-group differences.
  - CT (mean change 1.8; 95% CI, 1.2–2.3)
  - ICA (mean change 2.0; 95% CI, 1.5–2.6).

Secondary Outcome –

- CT and ICA yielded similar angina prevalence with nonsignificant between-group differences.
- Both CT and ICA groups had similar significant within-group improvements using the HADS-Anxiety scores, with no significant between-group differences.
  - CT (mean change 0.8; 95% CI, –1.0 to –0.6)
  - ICA (mean change –0.9; 95% CI, –1.2 to –0.7)

LIMITATIONS:

- Lack of blinding
- 99% of participants were White Europeans.
- The low prevalence of major adverse cardiovascular outcomes may have reduced the ability to detect a meaningful difference CT and ICA.
- There was a notable absence of survey responses at 3.5 years, and the imputed data assumes these data absences are random, which may not be the case.

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PROM and the Primip: Oxytocin vs Oral Misoprostol for Induction

Oxytocin vs Oral Misoprostol for PROM Induction in Nulliparas with Unfavorable Cervix: A Randomized Trial

Bender WR, Mccoy JA, Levine LD. Oxytocin vs Oral Misoprostol for PROM Induction in Nulliparas with Unfavorable Cervix: A Randomized Trial. *Am J Obstet Gynecol MFM*. 2024;6(8):101414. doi:10.1016/j.ajogmf.2024.101414

KEY TAKEAWAY: Oral misoprostol does not significantly decrease time from induction to delivery compared to intravenous (IV) oxytocin in nulliparous patients >36 weeks with prelabor rupture of membranes (PROM) and an unfavorable cervix.

STUDY DESIGN: Nonblinded, randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to study being underpowered)

BRIEF BACKGROUND INFORMATION: PROM occurs in 8% of term pregnancies, and delay from PROM to labor has an increased risk of intraamniotic infection (IAI). Current gold standard of induction following PROM is IV oxytocin, even if the patient has an unfavorable cervix, as vaginal misoprostol has increased risk of chorioamnionitis and neonatal intensive care unit (NICU) admissions. This study, in contrast, explored if there is benefit in giving oral misoprostol in patients who would typically benefit from cervical ripening as opposed to using the standard of IV oxytocin.

PATIENTS: Nulliparas women ≥18 years old who are ≥36 weeks pregnant with PROM and unfavorable cervix

INTERVENTION: Oral misoprostol

CONTROL: IV oxytocin

PRIMARY OUTCOME: Time from induction of labor (IOL) to delivery

Secondary Outcome: Time from induction to vaginal delivery, rate of cesarean delivery, patient satisfaction, maternal and neonatal morbidity, and rate of suspected IAI

METHODS (BRIEF DESCRIPTION):

- Patients were recruited from a single institution (Hospital of the University of Pennsylvania).
- All patients were nulliparous women who were ≥18 years old with a single gestation of ≥36 weeks gestational age (WGA) with an unfavorable cervix as determined by the Bishop score.
- The Bishop score is a standardized scoring system which helps assess likelihood of a vaginal delivery.
  - Cervical dilation, effacement, station, cervical consistency, cervical position are considered.
  - A Bishop score of less than <8 is considered unfavorable and was used for this study.
- Patient's for this study also required a cervical dilation ≤2 cm. However, if group B streptococcus (GBS) status was unknown, the patients were excluded.
- Exclusion criteria for this study included subjective reporting of contractions or contractions noted on monitor with cervical change without intervention, contractions >3 times per 10 minutes averaged over 30 minutes, contraindications to vaginal birth or misoprostol, fetal demise, or congenital anomalies.
- Patients were randomly assigned 1:1 to the oral misoprostol or IV oxytocin group.
- Patients receiving oral misoprostol received 50 mcg every four hours to a maximum of six doses or until an obstetrics provider determined cervical ripening was no longer indicated.
- Patients receiving IV oxytocin were done per the hospital's protocol which starts with oxytocin at 2 mU which can then be increased every 15 minutes as indicated until regular uterine contractions. While there is no maximum amount of time a person could receive oxytocin, the maximum dose noted was 40 mU of oxytocin.
- The primary outcome was measured in the number of hours from induction of labor to delivery regardless of the mode of delivery.
- Secondary outcomes were measured using the following:
  - IOL to vaginal delivery was also measured in hours.
  - Cesarean section rate was measured, regardless of if it was for a fetal or labor indication.
  - Rates of suspected IAI were measured if the clinical diagnosis was met (maternal fever [≥100.4^{o}F] plus 1 or more of the following: maternal leukocytosis, purulent cervical discharge, or maternal or fetal tachycardia).

- Patient satisfaction was measured using the Birth Satisfaction Scale-Revised (BSS-R), which included three measured domains: Quality of care provision, stress experienced during labor, and personal attributes. Scores range from 10–50, with higher scores indicating increased satisfaction by the patient.
- Maternal and neonatal morbidity was measured in percentage/number of participants in each group who had adverse events following delivery.

INTERVENTION (# IN THE GROUP): 52
COMPARISON (# IN THE GROUP): 56

FOLLOW-UP PERIOD:

- Primary Outcome: From time of induction to delivery
- Maternal morbidity: Up to four weeks post-partum

RESULTS:

Primary Outcome –

- Oral misoprostol did not significantly affect induction of labor to time of delivery compared to IV oxytocin (18 vs 15 hours, respectively; *P*=.06).
- When stratified into subgroups, oxytocin decreased the time from IOL to delivery compared to oral misoprostol in obese population (BMI >30) (17 vs 22 hours, respectively; *P*=.04).

Secondary Outcome –

- Oral misoprostol did not significantly affect time to delivery, rate of Cesarean section, neonatal morbidity, maternal morbidity, and rate of suspected IAI compared to IV oxytocin.
- IV oxytocin increased patient satisfaction for personal attributes compared to oral misoprostol (4.8 vs 3.8, respectively; *P*=.04).
- There was no significant difference in the quality of care or stress experienced during labor between IV oxytocin and oral misoprostol.

LIMITATIONS:

- By nature of the study, patients were unable to be blinded to the intervention
- The study occurred at a single location, which may make this study not representative of the general population.
- Study was underpowered at 66% due to small sample size
- Only tested 50 mcg of misoprostol, as opposed to varying doses, which could have potentially affected outcome and delivery time.

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Relax into Pain Relief, Cyclobenzaprine for Fibromyalgia

Efficacy and Safety of Sublingual Cyclobenzaprine for the Treatment of Fibromyalgia: Results from a Randomized, Double-Blind, Placebo-Controlled Trial

Lederman S, Arnold LM, Vaughn B, Kelley M, Sullivan GM. Efficacy and Safety of Sublingual Cyclobenzaprine for the Treatment of Fibromyalgia: Results from a Randomized, Double-Blind, Placebo-Controlled Trial. *Arthritis Care Res (Hoboken)*. 2023;75(11):2359-2368. doi:10.1002/acr.25142

KEY TAKEAWAY: Sublingual cyclobenzaprine reduces daily pain, was safe and well tolerated, for patients with fibromyalgia.

STUDY DESIGN: Phase III, double-blind, multicenter, randomized, placebo-controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to lack of generalizability)

BRIEF BACKGROUND INFORMATION: Patients with fibromyalgia experience symptoms that include chronic multi-site pain, fatigue, disturbed sleep, and cognitive impairment. The FDA has approved pregabalin, duloxetine, and milnacipran for treatment of fibromyalgia, however many patients often report poor symptom control. This study aimed to evaluate the efficacy and safety of once-nightly sublingual cyclobenzaprine in reducing pain in patients with fibromyalgia.

PATIENTS: Adults 18–65 years old diagnosed with primary fibromyalgia

INTERVENTION: Nightly 5.6 mg sublingual cyclobenzaprine

CONTROL: Placebo tablet

PRIMARY OUTCOME: Change in weekly average of daily pain from baseline to week 14

Secondary Outcome: Perception of health, function, impact, sleep and fatigue

METHODS (BRIEF DESCRIPTION):

- This was a 14-week trial of TNX-102 (low dose sublingual cyclobenzaprine) taken nightly for treatment of fibromyalgia.
- Patients 18–65 years old with diagnosis of primary fibromyalgia according to 2016 diagnostic criteria were included in the study. Criteria include generalized pain, symptoms duration for >3 months, widespread pain index ≥7 and symptom severity score of ≥5, or widespread pain index between four and six and symptom severity score ≥9, and no other disorder that can explain pain.
- Patients with a medical or psychiatric condition that could affect their ability to participate in the trial, or unwilling or unable to withdraw from prohibited medications (duloxetine, milnacipran, pregabalin, gabapentin, tricyclic antidepressants, trazodone, opioids, naltrexone, benzodiazepine and other formulations of cyclobenzaprine) were excluded from the study.
- The study consisted of a 35-day screening period, which included a 28-day medication washout (excluded medications), followed by a seven-day baseline period prior to randomization.
- Patients were randomized 1:1 to receive TNX-102 SL 5.6 mg or matching placebo tablets.
- Patients completed a daily electronic diary from screening through week 14.
    - Average pain severity over the previous 24-hour period was obtained using an 11-point numeric rating scale (NRS). Scores range from 0–10, with higher scores indicating worse pain.
    - Quality of sleep for the prior night was obtained using an 11-point NRS. Scores range from 0–10, with higher scores indicating worse sleep.
- Patients visited the study center at screening (baseline), and at two, six, 10, and 14 weeks.
- At the two-, six-, 10- and 14-week visits patients completed the Patient's Global Impression of Change (PGIC) questionnaire, the Revised Fibromyalgia Impact Questionnaire (FIQR) and the Patient-Reported Outcomes Measurement Information System (PROMIS) questionnaire for sleep disturbance and fatigue.
    - The PGIC gauges patient assessment of change in their overall condition on a seven-point scale. A score of one indicating "very much improved," four indicating "no change," and seven indicating "very much worse."
    - The FIQR questionnaire is comprised of 21 questions framed in the context of the last seven days using the NRS scale to assess

function, symptoms and overall impact. Scores range from 0–10, with higher scores indicating worse pain.
    - PROMIS assess patient-reported outcomes across chronic conditions.
        - The sleep instrument focuses on perceptions of sleep quality, restorative sleep, difficulty getting to sleep and satisfaction with sleep.
        - The fatigue instrument focuses on the experience of intensity, frequency and duration of symptoms, in addition to its impact on physical, mental and social activities.
        - Scores range from 1–5, indicating not at all (1), a little bit (2), somewhat (3), quite a bit (4) and very much (5).

INTERVENTION (# IN THE GROUP): 248

COMPARISON (# IN THE GROUP): 255

FOLLOW-UP PERIOD: 14 weeks

RESULTS:

Primary Outcome –

- Low dose sublingual cyclobenzaprine reduced daily pain compared to placebo at 14 weeks.
    - Low dose sublingual cyclobenzaprine (least squares [LS] mean difference –1.9; 95% CI, –2.1 to –1.7)
    - Placebo (LS mean difference –1.5; 95% CI, –1.7 to –1.3)

Secondary Outcome –

- There was no difference in patient perception of health with time between low dose sublingual cyclobenzaprine and placebo.
- Low dose sublingual cyclobenzaprine improved symptom scores compared to placebo at 14 weeks (LS mean difference –4.3; 95% CI, –7.4 to –1.2).
- Low dose sublingual cyclobenzaprine improved function scores compared to placebo at 14 weeks (LS mean difference –4.4; 95% CI, –7.7 to –1.0).
- Low dose sublingual cyclobenzaprine improved impact scores compared to placebo at 14 weeks (LS mean difference –1.4; 95% CI, –2.3 to –0.5).
- Low dose sublingual cyclobenzaprine improved sleep scores compared to placebo at 14 weeks (LS mean difference –2.9; 95% CI, –4.5 to –1.3).
- Low dose sublingual cyclobenzaprine improved fatigue scores compared to placebo at 14 weeks (LS mean difference –1.8; 95% CI, –3.3 to –0.3).

LIMITATIONS:

- 95% of the study population was female which likely underrepresents real-world population and thus generalizability.
- Fibromyalgia symptoms could have been affected by the allowed use of analgesics (NSAIDs), sleep aids (antihistamines), or antidepressants (SSRIs) in some patients.
- The trial occurred during the COVID-19 pandemic which could have reduced patient access to regular medical care.

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Sleeping Better by Moving Forward: Evaluating the Safety and Efficacy of MRAs in OSA Management

An Analysis of Adverse Events Associated with Mandibular Repositioning Appliances (MRA)- Study of the FDA Manufacturer and User Facility Device Experience (MAUDE) Database

Al Khouri T, Halasa I, Medarov BI. An analysis of adverse events associated with Mandibular Repositioning Appliances (MRA)- study of the FDA Manufacturer and User Facility Device Experience (MAUDE) database. *Respir Med*. 2025;248:108342. doi:10.1016/j.rmed.2025.108342

KEY TAKEAWAY: Reported events from the MAUDE database suggest that mandibular repositioning appliance (MRA) use may be associated with allergic reactions, broken appliance parts, and temporomandibular joint (TMJ) problems.

STUDY DESIGN: Retrospective review

LEVEL OF EVIDENCE: STEP 4 (downgraded due to quality of data in manufacturers database)

BRIEF BACKGROUND INFORMATION: Obstructive sleep apnea (OSA) is associated with numerous adverse health outcomes. Although continuous positive airway pressure (CPAP) therapy has proven effective, many patients struggle to maintain adherence due to discomfort. As a result, MRAs have gained popularity as an alternative treatment. However, limited evidence exists regarding their safety and efficacy. This study therefore aims to identify common complications associated with MRA use.

PATIENTS: Adults diagnosed with OSA

INTERVENTION: MRA

CONTROL: None

PRIMARY OUTCOME: Adverse events

METHODS (BRIEF DESCRIPTION):

- Retrospective search of the FDA MAUDE database from 2015–2025 was complete.
- Inclusion criteria included studies adverse events related to anti-snoring devices in patients with OSA.
- Exclusion criteria included pillar implants, tongue base suspension, elevoplasty, and duplicate reports.
- The intervention assessed mandibular responsitioning device use.
- There was no control group.
- The primary outcome measured the number of adverse events associated with MRA use which were grouped into the following seven categories: Allergic reactions, broken parts, loose screws, dental issues, ill-fitted appliances, TMJ problems, and miscellaneous.

INTERVENTION (# IN THE GROUP): 517

COMPARISON (# IN THE GROUP): Not applicable

FOLLOW-UP PERIOD: Not applicable

RESULTS:

Primary Outcome –

- Allergic reactions were the most reported adverse event (40% of total events). Swelling and erythema were the most reported symptoms.
- Broken parts were the second most common adverse event (39% of total incidents). 3.3% of these cases resulted in harmful outcomes such as aspiration, swallowing, or choking.
- TMJ was reported in only 2.9% of cases.

LIMITATIONS:

- MAUDE database did not review reports or check whether duplicate entries were submitted thus making data less reliable.
- Researchers were unable to distinguish between true allergic reactions and mechanical trauma caused by MRAs.
- Reports lacked a detailed classification of adverse events other than death or injury.
- Reports were made on a voluntary basis which may mean that events were underreported.

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How the COVID-19 Pandemic Reshaped and Impacted Preventive Care for Young Children

Impact of the COVID-19 Era on Preventative Primary Care for Children 0–5 Years Old: A Scoping Review Protocol

Qi X, Jordan M, Mignacca I, Bayoumi I, Li P. Impact of the COVID-19 Era on Preventative Primary Care for Children 0–5 Years Old: A Scoping Review Protocol. *Syst Rev*. 2024;13(1):113. Published 2024 Apr 26. doi:10.1186/s13643-024-02507-2

KEY TAKEAWAY: The COVID-19 era significantly disrupted preventative primary care for children 0–5 years old, and this scoping review protocol outlines a systematic approach to map the extent, nature, and gaps in existing evidence particularly around missed well-child visits, immunizations, and developmental screenings to inform recovery strategies and future health system resilience for early childhood care.

STUDY DESIGN: Scoping review protocol

LEVEL OF EVIDENCE: Not available

BRIEF BACKGROUND INFORMATION: Preventative primary care in early childhood, particularly for children 0–5 years old, is critical for timely immunizations, developmental surveillance, growth monitoring, and early identification of health and social concerns. The COVID-19 pandemic substantially disrupted health care delivery worldwide through lockdowns, reduced in-person visits, caregiver hesitancy, and rapid shifts to virtual care. These disruptions raised concerns about missed well-child visits, delayed vaccinations, and widening health inequities during a formative period of child development. While emerging studies have examined aspects of these impacts, the evidence remains fragmented across settings and outcomes. This scoping review protocol was developed to systematically identify, map, and characterize the existing literature on how the COVID-19 era affected preventative primary care for young children, with the goal of identifying knowledge gaps and informing future research, policy, and post-pandemic recovery strategies.

PATIENTS: Children 0–5 years old receiving preventive primary care services (e.g., well-child visits, immunizations, developmental screening)

INTERVENTION: The COVID-19 era (pandemic-related healthcare disruptions, public health restrictions, system-level changes)

CONTROL: Pre-COVID-19 period (baseline preventive care utilization and delivery prior to pandemic onset)

PRIMARY OUTCOME: Changes in preventive primary care utilization (well-child visits, immunization rates), developmental screening and surveillance, access to primary care services, and health disparities in preventive care delivery

METHODS (BRIEF DESCRIPTION):

- The authors conducted the review by using established scoping review methodology based on the Arksey and O'Malley framework, with enhancements from Levac et al., and will report findings in accordance with PRISMA-ScR guidelines.
- A comprehensive search of electronic databases (such as MEDLINE, Embase, and CINAHL) was performed; two independent reviewers screened titles, abstracts, and full texts using predefined inclusion and exclusion criteria focused on preventive services such as well-child visits, immunizations, and developmental screening during the COVID-19 era.
- Intervention group: Children exposed to the COVID-19 era that included pandemic-related healthcare disruptions and public health measures affecting preventive primary care delivery.
- Comparison group: Children exposed to pre-COVID-19 era healthcare and primary care
- Data was extracted using standardized forms to capture study characteristics, populations, types of care disruptions, and outcomes.
    - Pre-pandemic vs pandemic well-child visit rates
    - Pre-pandemic vs pandemic immunization rates
    - Baseline vs disrupted developmental screening practices
- Findings were synthesized descriptively and thematically to identify trends, patterns, and gaps in the literature.
- As a scoping review, the study did not aim to perform a risk-of-bias assessment or meta-analysis, but rather to map the scope and nature of available evidence.

INTERVENTION (# IN THE GROUP): Not available
COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Not available

RESULTS:

Primary Outcome –

- This study will aim to map and characterize the impact of the COVID-19 pandemic on preventive primary care for children aged 0–5 years. The outcomes of interest broadly include changes in:
  - Well-child visit utilization
  - Immunization rates
  - Developmental screening and surveillance
  - Access to preventive primary care services
  - Health disparities in preventive care delivery

LIMITATIONS:

- Because this publication is a protocol (a plan for a future scoping review), it does not include results, limitations, or findings in the same way that a completed study does.
- The protocol itself does not list specific limitations of the scoping review because limitations are typically identified after completion of the review when results are analyzed. However, based on the methods outlined, likely inherent limitations include:
  - No primary data collection: The review will only summarize existing studies, so evidence is limited to what has already been published.
  - Language restriction to English studies, which may exclude relevant research published in other languages.
  - Focus on high-income countries limits generalizability of findings to low- and middle-income settings.
  - Possible heterogeneity in included study designs and outcomes, which may limit synthesis.

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