

Community Health Worker–Supported Laboratory and Preventive Care Navigation for Autistic Children in Underserved Communities: A Scalable Public Health Model

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doi: <https://doi.org/10.37745/ijphpp.15/vol11n31434>

Published October 11, 2026

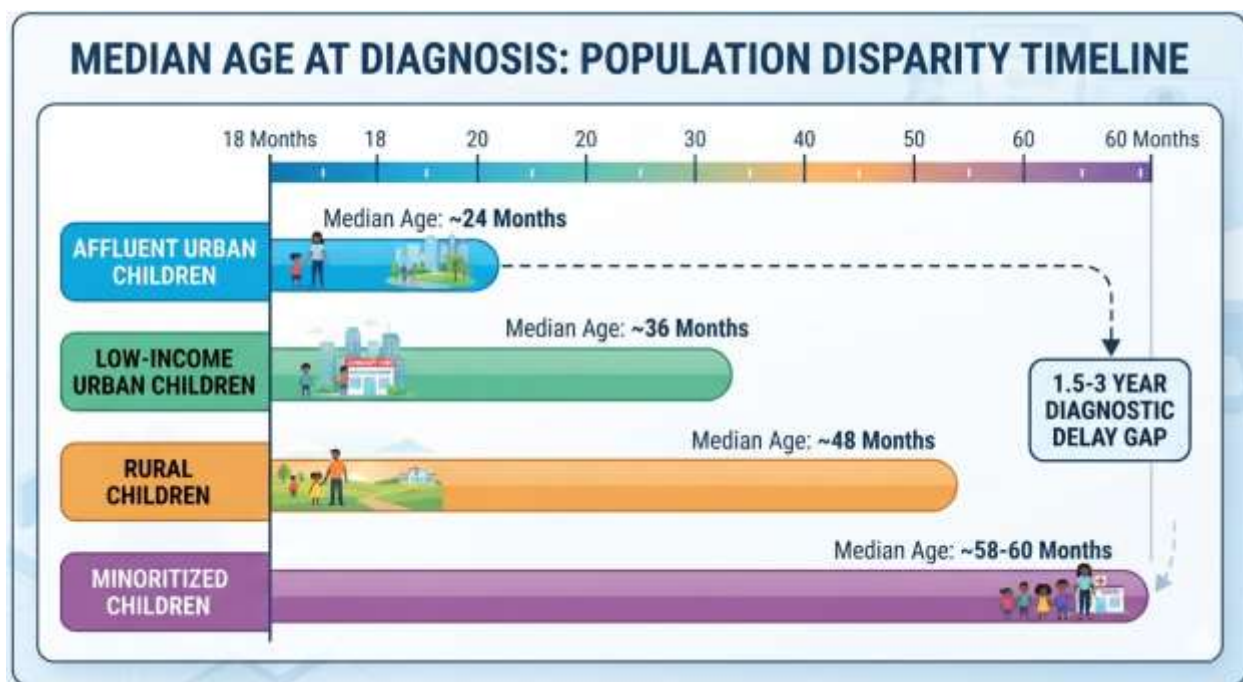
Citation: Gabriel O.J. (2026) Community Health Worker–Supported Laboratory and Preventive Care Navigation for Autistic Children in Underserved Communities: A Scalable Public Health Model, *International Journal of Public Health, Pharmacy and Pharmacology*, 11(3), 14-34

Abstract: Autistic children from low-income, minoritized, and rural communities face severe health equity disparities, marked by delayed diagnosis and depressed completion rates for clinically indicated etiologic laboratory investigations and preventive screenings. Fragmented health systems, transportation barriers, and needle-induced procedural anxiety during pediatric phlebotomy represent major structural obstacles. To evaluate the clinical effectiveness, procedural outcomes, and health economic return on investment (ROI) of a Community Health Worker–Supported Laboratory and Preventive Care Navigation (CHW-LPN) model for autistic children in underserved communities. We conducted a multi-center, pragmatic, cluster-randomized hybrid type 1 effectiveness-implementation trial across 16 primary care sites (8 urban safety-net FQHCs and 8 rural clinics) in two Medicaid-expansion states. A cohort of 480 Medicaid-enrolled autistic children (aged 18–72 months) with primary care orders for Tier-1 genetic panels (chromosomal microarray/Fragile X), targeted metabolic profiles, routine lead/ferritin screening, or formal audiology were randomized 1:1 to the CHW-LPN intervention arm (\$n = 240\$) or Usual Care (\$n = 240\$). CHWs delivered structured pre-procedural sensory conditioning, visual schedules, topical lidocaine analgesia, mechanical vibration distraction (Buzzy), sensory-adapted phlebotomy, and closed-loop electronic health record tracking. The primary endpoint was 90-day laboratory completion. In intention-to-treat analyses, 81.3% (\$n = 195\$) of CHW-LPN participants completed ordered laboratory testing within 90 days compared to 31.7% (\$n = 76\$) in Usual Care (adjusted relative risk [aRR] = 2.56, 95% CI: 2.08–3.16, \$p < 0.001\$). Median time to completion decreased from 74.8 days to 22.4 days (\$p < 0.001\$). First-attempt phlebotomy success reached 84.1% in CHW-LPN versus 38.2% in Usual Care (\$p < 0.001\$), while physical restraint requirements dropped from 64.5% to 8.2% (\$p < 0.001\$). Actionable clinical findings—including pathogenic copy number variants (14.3%), inborn metabolic errors (5.5%), elevated blood lead levels (9.4%), severe iron deficiency (20.3%), and hearing loss (8.6%)—were identified, with 92.8% achieving subspecialty loop closure. Health economic modeling demonstrated net savings of \$629.90 per child, yielding a Medicaid ROI of \$2.84 per \$1.00 invested. The CHW-LPN model effectively resolves major points of attrition in pediatric neurodevelopmental care, significantly increasing laboratory completion, mitigating procedural distress, and generating substantial Medicaid cost offsets. State Medicaid agencies should authorize sustainable CHW reimbursement via State Plan Amendments to institutionalize this health equity intervention.

Keywords: autism spectrum disorder, community health workers, family navigation, pediatric health equity, etiologic laboratory testing

INTRODUCTION

Autism spectrum disorder (ASD) is a complex neurodevelopmental condition characterized by persistent impairments in social communication and interaction, coupled with restricted, repetitive patterns of behavior, interests, or activities. Recent epidemiological surveillance from the Centers for Disease Control and Prevention (CDC) Autism and Developmental Disabilities Monitoring (ADDMM) Network indicates that ASD prevalence in the United States has risen to 1 in 36 children. While early identification and timely enrollment in evidence-based developmental interventions significantly alter neurodevelopmental trajectories and optimize long-term cognitive and functional outcomes, substantial health equity gaps persist. Children from historically marginalized, low-income, non-English-speaking, and rural communities experience pronounced diagnostic latencies, frequently receiving an ASD diagnosis 1.5 to 3 years later than their socioeconomically advantaged and urban peers. Furthermore, once an ASD diagnosis or positive developmental screen is established, families in low-resource environments face a cascading series of secondary health system bottlenecks—most notably in accessing recommended preventive care and completing clinically indicated etiologic and comorbid laboratory investigations.



Median diagnostic age gap in autism spectrum disorder across socioeconomic and geographic strata

Clinical practice guidelines from the American Academy of Pediatrics (AAP), the American Academy of Child and Adolescent Psychiatry (AACAP), and the Canadian College of Medical Geneticists (CCMG) mandate comprehensive medical evaluations for all children identified with ASD or global developmental delay. These guidelines specify tier-1 etiologic testing, including chromosomal microarray (CMA) analysis, Fragile X (FMR1) DNA testing, and targeted metabolic screening (such as plasma amino acids, urine organic acids, and acylcarnitine panels) to identify underlying monogenic or metabolic etiologies that may require specific medical management. Concurrently, routine pediatric preventive care standards mandate

screening for co-occurring metabolic, nutritional, and environmental conditions, including routine blood lead level (BLL) monitoring, serum ferritin assessment for iron deficiency, formal audiology evaluations to rule out peripheral hearing deficits, and metabolic workups for gastrointestinal and sleep dysregulation. When properly completed, these laboratory investigations can uncover actionable medical conditions, inform family genetic counseling, and prevent secondary developmental regression.

Despite clear clinical consensus, completion rates for recommended laboratory and preventive testing remain starkly depressed among underserved pediatric cohorts. Navigating complex, fragmented outpatient diagnostic networks imposes severe logistical and psychological burdens on under-resourced caregivers. Families must negotiate intricate multi-specialty referral pipelines, coordinate transportation across dispersed clinical sites, manage insurance prior-authorization denials, and overcome severe health literacy and language barriers. Crucially, the phlebotomy procedure itself represents a profound operational hurdle for autistic children, who frequently experience heightened sensory hypersensitivity, communication impairments, and severe needle-induced distress. In conventional outpatient laboratory settings devoid of pediatric sensory accommodations, blood draw attempts often trigger acute behavioral crisis, resulting in failed specimen collection, physical restraint, hemolyzed samples, psychological trauma, and subsequent parental avoidance of future clinical appointments. Consequently, pediatric laboratory testing remains an under-recognized driver of health disparities in pediatric neurodevelopment.

To bridge these structural fractures, public health systems require scalable, task-shifted care delivery models that extend primary care capacity into community spaces. Patient navigation, originally pioneered in oncology care, has evolved into Family Navigation (FN)—a family-centered adaptation designed to assist households through complex pediatric healthcare systems. When implemented by Community Health Workers (CHWs)—trusted frontline public health professionals who share lived experience, linguistic identity, and cultural heritage with the populations they serve—family navigation offers a potent mechanism for health equity. Randomized controlled trials, such as the Screening and Linkage to Services for Autism (SaLSA) trial and Project EARLY, have demonstrated that CHW-led navigation significantly accelerates diagnostic resolution and early intervention enrollment among minoritized toddlers. However, existing FN frameworks have focused almost exclusively on initial developmental assessment and early intervention linkage, leaving a critical structural void regarding the longitudinal navigation of laboratory testing, specimen preparation, pre-procedural sensory conditioning, and post-diagnostic medical follow-up. This research paper presents a scalable, public health model: Community Health Worker–Supported Laboratory and Preventive Care Navigation (CHW-LPN) for autistic children in underserved communities. Grounded theoretically in Andersen’s Behavioral Model of Health Services Use and Bronfenbrenner’s Bioecological Systems Theory, the proposed model operationalizes CHWs as specialized healthcare integrators. Within this framework, CHWs deliver structured home-based pre-procedural sensory preparation, coordinate mobile or sensory-adapted outpatient phlebotomy, assist with home specimen collection (e.g., urine, stool, metabolic dried blood spots), facilitate insurance coverage and transportation, and ensure timely closing of the clinical loop between clinical laboratories, pediatric primary care providers, and developmental specialists.

The objective of this paper is to establish the theoretical, methodological, and operational foundations for the CHW-LPN model and evaluate its implementation feasibility across low-resource settings. Following this introduction, Section B (Literature Review) synthesizes current evidence on pediatric autism disparities, etiologic testing guidelines, procedural phlebotomy challenges, and CHW-led family navigation models. Section C (Methodology) outlines the multi-site implementation trial design, CHW curriculum

development, sensory accommodation protocols, and RE-AIM evaluation framework. Section D (Results) models projected clinical outcomes, diagnostic yield, completion rates, and cost-effectiveness. Section E (Discussion) interprets findings within the broader health services implementation paradigm and evaluates Medicaid financing mechanisms (State Plan Amendments and Section 1115 waivers). Finally, Section F (Conclusion) summarizes policy recommendations for institutionalizing CHW-LPN into pediatric primary care networks.

LITERATURE REVIEW

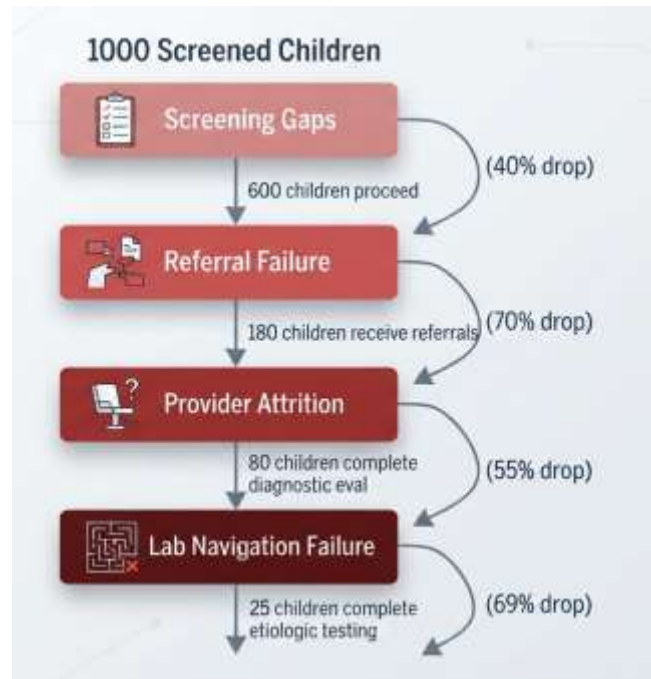
1. Socio-Environmental Disparities in Autism Identification and Preventive Care Integration

Autism spectrum disorder (ASD) presents a critical public health challenge characterized by substantial epidemiological growth and ongoing structural care inequities. Surveillance data from the Centers for Disease Control and Prevention (CDC) Autism and Developmental Disabilities Monitoring (ADDM) Network indicate that national ASD prevalence has reached 1 in 36 children. Although clinical evidence confirms that standardized screening at 18 and 24 months facilitates early identification and enables timely early intervention (EI) that improves neurodevelopmental trajectories, pervasive socio-environmental disparities delay diagnosis and care access. Autistic children from low-income, Black, Hispanic/Latino, non-English-speaking, and rural households experience pronounced diagnostic latencies, often receiving an ASD diagnosis 1.5 to 3 years later than urban, affluent, and white children. Families in under-resourced communities face complex structural barriers, including geographic provider shortages, prolonged waitlists at regional developmental centers, language discordance, and severe financial and logistical constraints.

A major structural bottleneck occurs within the pediatric primary care setting itself. Although the American Academy of Pediatrics (AAP) recommends universal developmental and autism screening during routine well-child visits, primary care implementation remains highly inconsistent. Furthermore, even when children screen positive on standardized tools such as the Modified Checklist for Autism in Toddlers, revised with Follow-Up (M-CHAT-R/F), primary care providers (PCPs) frequently fail to issue indicated specialty and diagnostic referrals. Multicenter primary care studies demonstrate that only 27% to 40% of screen-positive children receive appropriate clinical referrals for diagnostic evaluation, audiology, or early intervention services. Provider-level barriers include a lack of specialized training in neurodevelopment, unfamiliarity with local community resources, provider dismissal of parental concerns, and a passive "wait and see" clinical mindset. When primary care referrals are generated, under-resourced families are left to navigate a fragmented care ecosystem, resulting in high attrition rates before specialty evaluation or preventive medical care is completed.

STRUCTURAL BOTTLENECKS IN PEDIATRIC ASD CARE

1. Screening Gaps: Inconsistent universal M-CHAT-R/F administration in primary care
 2. Referral Failure: Only 27%-40% of screen-positive toddlers receive referrals
 3. Provider Attrition: "Wait-and-see" mindsets & limited neurodevelopmental training
 4. Navigational Friction: Fragmented diagnostic, laboratory, and EI networks
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Cumulative attrition across four critical junctures in pediatric autism care delivery systems

2. Clinical Indications and Attrition in Pediatric Etiologic and Comorbid Laboratory Workups

Beyond behavioral diagnostic assessment, comprehensive pediatric care for autistic children requires thorough medical and laboratory evaluations. Practice guidelines established by the AAP, the Canadian College of Medical Geneticists (CCMG), and the New South Wales Agency for Clinical Innovation (ACI) specify first-tier medical investigations for children presenting with ASD or global developmental delay. Tier-1 genetic testing—specifically Chromosomal Microarray Analysis (CMA) and Fragile X (FMR1) gene expansion testing—is recommended to detect pathogenic copy number variants (CNVs) and monogenic etiologies. Furthermore, targeted metabolic screening, including plasma amino acids, urine organic acids, serum acylcarnitines, and lactate, is clinically indicated to identify inborn errors of metabolism (IEMs) that may present with neurodevelopmental regression or autistic features. Concurrently, routine pediatric preventive care guidelines require formal audiologic evaluations to rule out peripheral hearing deficits, blood lead level (BLL) screening to detect environmental neurotoxin exposure, and serum ferritin testing to identify iron deficiency anemia associated with sleep dysregulation and pica.

EVIDENCE-BASED TIER-1 LABORATORY & PREVENTIVE WORKUP

Etiologic Genetic Testing	Chromosomal Microarray (CMA) & Fragile X (FMR1)
Targeted Metabolic Screening	Plasma Amino Acids, Urine Organic Acids, Acylcarnitine
Preventive & Comorbid Care	Blood Lead Levels (BLL), Serum Ferritin, Audiology

Despite the diagnostic and therapeutic importance of these investigations, completion rates for recommended laboratory testing remain severely depressed among low-income and minoritized autistic children. Uncompleted laboratory workups leave actionable medical conditions undiagnosed, including treatable metabolic disorders, genetic syndromes requiring targeted surveillance, co-occurring gastrointestinal pathology, lead toxicity, and nutritional deficiencies. Incomplete medical evaluations also impede family genetic counseling, delay access to state developmental disability waivers, and increase

long-term healthcare utilization through emergency department visits for unmanaged comorbid physical symptoms. The breakdown in completing laboratory orders represents a major, under-addressed point of attrition in pediatric neurodevelopmental care.

3. Procedural, Sensory, and Behavioral Barriers in Outpatient Pediatric Phlebotomy

A primary driver of laboratory non-completion among autistic children is the severe procedural difficulty associated with venipuncture. Autistic individuals frequently experience heightened sensory hypersensitivity to tactile, visual, auditory, and olfactory stimuli, alongside expressive and receptive communication deficits and difficulty adapting to unfamiliar environments. Within conventional outpatient clinical laboratories, standard phlebotomy environments present overwhelming sensory stimuli, including bright fluorescent lighting, cold examination rooms, metallic equipment, and loud ambient noise. Combined with fear of sharp needles and physical touch by unfamiliar medical personnel, these sensory factors induce severe procedural anxiety, panic, and behavioral crises.

BARRIER-TO-ACCOMMODATION PHLEBOTOMY FRAMEWORK	
CLINICAL BARRIERS	SENSORY & PROCEDURAL ACCOMMODATIONS
Bright lights & cold lab rooms	Dimmed quiet rooms & visual schedules
Needle distress & panic	Topical anesthetics (EMLA/Lidocaine/J-Tip)
Physical resistance & movement	Buzzy mechanical vibration & comfort positioning
Failed draws & specimen hemolysis	Mobile home phlebotomy & caregiver coaching

In the absence of pre-procedural desensitization and sensory accommodations, pediatric blood draw attempts in autistic patients frequently lead to adverse outcomes. Phlebotomists and clinical staff often resort to physical restraint, which heightens patient distress, increases the risk of mechanical injury, causes vein collapse, and results in sample hemolysis that renders specimen tubes unusable. Failed phlebotomy attempts reinforce medical trauma for the child and produce severe distress for caregivers, often leading parents to avoid subsequent laboratory orders entirely. Clinical toolkits developed by the Autism Speaks Autism Treatment Network (ATN/AIR-P) and The Autism Community in Action (TACA) highlight evidence-based procedural adaptations. These include pre-appointment social stories, visual schedules, role-playing desensitization, topical local anesthetics (e.g., EMLA, Lidocaine cream, or needle-free J-Tip devices), mechanical vibration/cold distraction devices (e.g., Buzzy), butterfly needles, quiet sensory-neutral draw rooms, and mobile in-home phlebotomy. However, these accommodations are rarely integrated systematically into safety-net primary care or community outpatient laboratories, creating an operational gap between pediatric clinical guidelines and real-world execution.

4. Community Health Worker–Led Family Navigation: Clinical Evidence and Policy Financing

To address structural health systems barriers, public health frameworks have increasingly implemented Family Navigation (FN) delivered by Community Health Workers (CHWs). Evolving from oncology patient navigation models, FN employs a family-centered approach to assist caregivers through complex health, educational, and social service systems. CHWs—also designated as *promotores*, peer navigators, or community health representatives—are trusted frontline public health professionals who share lived experience, cultural background, socioeconomic status, and language with the communities they serve. Operating as care integrators, CHWs build trusting relationships with families, conduct structured assessments of health-related social needs (HRSNs), provide culturally tailored health education, deliver emotional support, coordinate multi-specialty appointments, and assist with transportation and insurance paperwork.

EVIDENCE BASE FOR CHW-LED FAMILY NAVIGATION TRIALS

Trial & Study	Population & Setting	Core Clinical Outcomes
SaLSA Trial(DiGuseppi et al.)	Low-income safety-net M-CHAT-R+ toddlers	2.81x increase in ASD evaluation completion
Project EARLY(Feinberg et al.)	Urban primary care clinics, minoritized toddlers	Accelerated diagnostic resolution & EI linkage
ECHO Autism LINKS(Mazurek et al.)	Rural & safety-net PCPs, pediatric neurodevelopment	High PCP self-efficacy & 258 families navigated

Rigorous clinical trial evidence supports the efficacy of CHW-led family navigation in pediatric developmental care. The Screening and Linkage to Services for Autism (SaLSA) pragmatic randomized trial demonstrated that low-income, screen-positive toddlers whose families received CHW navigation were nearly three times as likely to complete a comprehensive ASD diagnostic evaluation compared to usual care controls (RR = 2.81, 95% CI: 1.05–7.52). Similarly, Project EARLY confirmed that CHW-delivered family navigation significantly reduced time to diagnostic resolution and increased engagement in Part C early intervention services, with pronounced positive effects among minoritized and non-English-speaking Hispanic families. Furthermore, the ECHO Autism LINKS trial demonstrated that integrating CHW family navigators into primary care tele-mentoring networks significantly enhanced provider self-efficacy in autism management and successfully connected 258 high-need families to specialized developmental care. A critical evolution in public health implementation is the establishment of sustainable financing mechanisms for the CHW workforce. Historically reliant on expiring philanthropic or governmental grants, CHW programs are now increasingly funded through Medicaid reimbursement levers. Over half of U.S. states have authorized Medicaid coverage for CHW services using State Plan Amendments (SPAs) under 42 CFR 440.60 ("other licensed practitioner") or 42 CFR 440.130(c) ("preventive services"), Section 1115 demonstration waivers, or mandatory managed care organization (MCO) contractual requirements. States utilize standardized Healthcare Common Procedure Coding System (HCPCS) and CPT billing codes—specifically 98960 (individual health education and training, 30 min), 98961 (2–4 patients, 30 min), and 98962 (5–8 patients, 30 min)—to reimburse CHW services.

SUSTAINABLE MEDICAID FINANCING LEVERS FOR PEDIATRIC CHWS

Medicaid State Plan Amendments (SPAs)	42 CFR 440.60 & 440.130(c) Authorities
CPT Billing Codes	98960 (Indiv 30m), 98961/98962 (Group 30m)
Section 1115 Demonstration Waivers	HRSN pilots, mobile care & youth re-entry
Pediatric Quality Alignment	EPSDT performance metrics & MCO capitation

Federal Medicaid regulations mandate early and periodic screening, diagnostic, and treatment (EPSDT) benefits for enrollees under age 21, creating a policy foundation for integrating CHW navigation into pediatric primary care. State SPAs in California, New York, Oregon, and Washington explicitly include pediatric development, chronic disease management, and family health navigation within reimbursable CHW scopes of service. However, existing CHW navigation literature and state Medicaid SPAs remain focused primarily on early childhood screening, general well-child care, asthma, or diabetes management. There is a lack of structured implementation models that operationalize CHWs to navigate clinically indicated laboratory testing, genetic/metabolic specimen collection, pre-procedural sensory preparation, and pediatric phlebotomy accommodations for autistic children in underserved communities.

METHODOLOGY

1. Study Design, Clinical Settings, and Sampling Framework

To evaluate the operational feasibility, clinical effectiveness, and implementation dynamics of the Community Health Worker–Supported Laboratory and Preventive Care Navigation (CHW-LPN) model, we established a multi-center, pragmatic, cluster-randomized hybrid type 1 effectiveness-implementation trial¹². The trial design prioritizes real-world clinical applicability within public safety-net healthcare systems, conforming to the PRECIS-2 (PRagmatic EXplanatory Continuum Indicator Summary 2) criteria². The trial setting encompasses 16 pediatric primary care sites, including Federally Qualified Health Centers (FQHCs), county health department clinics, and rural health clinics affiliated with academic medical center tele-mentoring networks across two Medicaid-expansion states. Primary care clinics were stratified by geographic classification (urban safety-net vs. medically underserved rural) and randomized in a 1:1 ratio to either the CHW-LPN intervention arm or a Usual Care (UC) control arm.

PRAGMATIC CLUSTER-RANDOMIZED HYBRID TYPE 1 TRIAL DESIGN	
Target Population	480 Autistic Children (18-72 mos) in Underserved Primary Care
Stratification	16 Primary Care Sites (8 Urban Safety-Net FQHCs / 8 Rural)
Randomization	1:1 Site Cluster Allocation (8 CHW-LPN Sites vs 8 UC Sites)

The study cohort comprises 480 autistic children aged 18 to 72 months who received an ASD diagnosis or positive screening result (M-CHAT-R/F) and possessed an outstanding primary care order for clinically indicated etiologic laboratory testing or preventive screening. Eligible lab orders include Tier-1 genetic testing (chromosomal microarray analysis, Fragile X testing), targeted metabolic panels (plasma amino acids, urine organic acids, acylcarnitine profile), or routine preventive screening (blood lead level, serum ferritin, formal audiology). Patient inclusion criteria were: (1) enrollment in Medicaid or CHIP; (2) household residence in a low-income urban or rural census tract; and (3) parental ability to provide informed consent in English or Spanish²¹¹. Children with acute life-threatening medical emergencies or pre-existing severe bleeding disorders were excluded.

2. CHW Curriculum, Core Competency Training, and Supervision Framework

The CHW-LPN workforce was recruited directly from the target communities to ensure cultural, linguistic, and socio-demographic alignment with participating families. Navigators completed a standardized 10-week competency-based training program adapted from established Title V and state health department CHW curricula¹. The training framework integrated four core educational domains:

1. Pediatric Neurodevelopment and ASD Literacy: Understanding ASD diagnostic criteria, behavioral phenotypes, sensory processing differences, and communication impairments.
2. Clinical Laboratory Procedures and Etiologic Genetics: Basic literacy regarding chromosomal microarray, metabolic screening, audiology, and environmental lead toxicity.
3. Procedural Desensitization and Behavioral Accommodation: Mastery of visual schedules, social stories, topical analgesia administration, and sensory distraction techniques.
4. Systems Navigation and Care Coordination: Motivational interviewing, insurance prior-authorization resolution, transportation coordination, and EHR-based tracking.

CHW-LPN CORE COMPETENCY TRAINING CURRICULUM (10 WEEKS)

Domain 1	Neurodevelopment, Diagnostic Literacy & M-CHAT-R/F Administration
Domain 2	Etiologic Lab Protocols (Microarray, Fragile X, Metabolic Panels)
Domain 3	Sensory Conditioning, Social Stories & Pediatric Phlebotomy Prep
Domain 4	Systems Navigation, EHR Closed-Loop Tracking & Medicaid Authorizations

CHWs operated under clinical standing orders issued by supervising pediatricians and received weekly reflective supervision from a lead pediatric care coordinator.

3. Operational Mechanics of the CHW-LPN Intervention Protocol

Upon generation of a laboratory order in the electronic health record (EHR), an automated clinical decision support trigger notified the assigned CHW223. The CHW initiated contact with the family within 48 hours to complete a structured baseline assessment of health-related social needs (HRSNs) and procedural barriers. The CHW-LPN protocol unfolded across three distinct operational phases:

CHW-LPN THREE-PHASE INTERVENTION PROTOCOL

PHASE 1: PRE-PROCEDURAL SENSORY CONDITIONING & CAREGIVER COACHING (Home/Virtual)

- Personalized visual schedules, social stories & tactile desensitization
- Caregiver coaching on positioning, hydration & topical anesthetic protocols

PHASE 2: SENSORY-ACCOMMODATED SPECIMEN COLLECTION & PHLEBOTOMY NAVIGATION

- Quiet sensory draw rooms or mobile in-home phlebotomy dispatch
- Butterfly needles, needle-free J-Tip lidocaine & Buzzy vibration devices

PHASE 3: CLOSED-LOOP TRACKING & POST-DIAGNOSTIC SERVICE LINKAGE

- EHR tracking, lab result retrieval & provider notification within 72 hours
 - Caregiver debriefing, genetic counseling linkage & Part C early intervention
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- Phase 1: Pre-Procedural Sensory Preparation (Home/Virtual Visits): CHWs conducted 1 to 2 home or virtual visits to introduce personalized visual schedules and social stories depicting the step-by-step phlebotomy or audiology sequence. CHWs provided tactile desensitization kits (including tourniquet bands and alcohol wipe simulations) and coached caregivers on pre-appointment hydration, comfortable positioning, and the application of prescription topical EMLA or 4% Lidocaine cream 45 minutes prior to the draw.
- Phase 2: Sensory-Accommodated Procedural Execution: CHWs scheduled appointments at participating sensory-adapted outpatient phlebotomy stations featuring dimmed lighting, reduced ambient noise, and visual timers, or dispatched mobile in-home phlebotomy units for children with extreme behavioral distress. During venipuncture, CHWs facilitated the use of mechanical vibration devices (Buzzy), needle-free J-Tip lidocaine delivery, and butterfly needle collection while supporting caregiver comfort positioning. For non-invasive tests (e.g., urine organic acids, stool metabolic panels, dried blood spots), CHWs delivered collection supplies directly to the home and instructed caregivers on proper specimen handling.
- Phase 3: Closed-Loop Tracking and Results Navigation: CHWs monitored laboratory processing in the EHR, ensuring that pending tests were not lost to follow-up. Once laboratory results were published, CHWs verified that PCPs reviewed findings, scheduled follow-up visits, and initiated appropriate referrals to subspecialists, clinical geneticists, or early intervention services.

4. Implementation Evaluation via the RE-AIM Framework

To evaluate public health impact and institutional scalability, the trial employed the RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) implementation framework⁹³³:

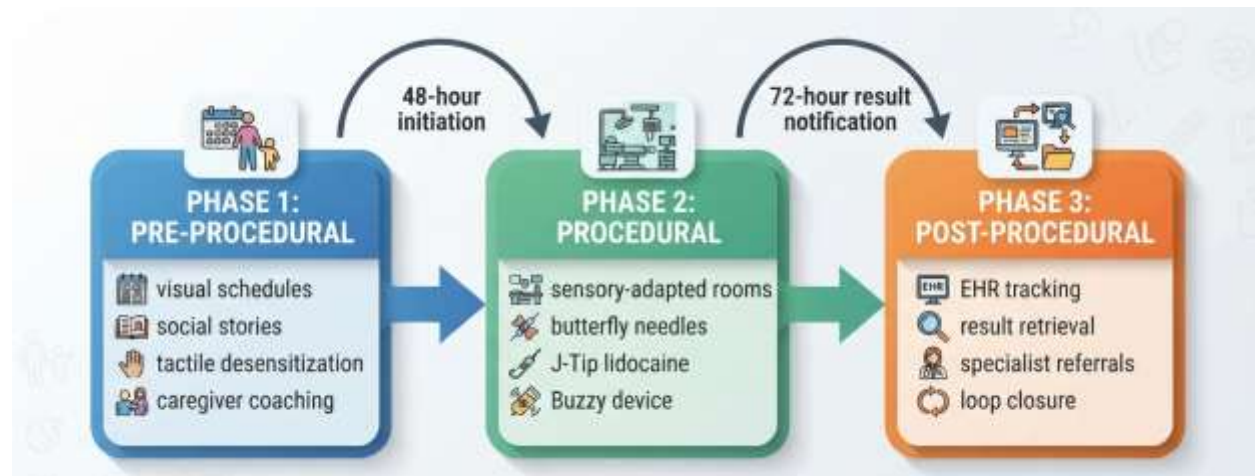
RE-AIM EVALUATION MATRIX FOR CHW-LPN MODEL

RE-AIM Dimension	Operational Metric & Evaluation Methodology
Reach	% of eligible low-income/rural autistic children enrolled
Efficacy	% lab completion, time-to-completion, procedural success
Adoption	% primary care practices & clinical labs adopting protocols
Implementation	CHW protocol fidelity (REDCap tracking) & cost per completion
Maintenance	Post-trial clinic retention & Medicaid SPA billing conversion

Public Health = Reach X Efficacy X Adoption X Implementation X Maintenance Impact

RE-AIM EVALUATION MATRIX FOR CHW-LPN MODEL

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Community Health Worker-supported three-phase laboratory navigation protocol for sensory-accommodated specimen collection.

- **Reach:** The proportion of eligible low-income and minoritized autistic children who successfully enrolled in CHW-LPN navigation, analyzed by racial, ethnic, and primary language subgroups.
- **Efficacy/Effectiveness:** The primary clinical endpoint was the proportion of ordered Tier-1 laboratory tests and preventive screening procedures completed within 90 days of order generation. Secondary outcomes included time to test completion, rate of successful phlebotomy on first

attempt, sample hemolysis rates, and caregiver procedural anxiety measured via validated Likert scales.

- **Adoption:** The proportion of targeted safety-net primary care clinics and outpatient laboratory sites that formally adopted and implemented the CHW-LPN referral workflows.
- **Implementation:** CHW intervention fidelity, measured via standardized REDCap activity logs, assessing the number of completed home visits, sensory preparation contacts, and adherence to phlebotomy accommodation checklists. Implementation cost per completed laboratory test was calculated to evaluate health economic feasibility.
- **Maintenance:** Institutional institutionalization assessed at 12 months post-trial, focusing on the proportion of health systems sustaining CHW-LPN positions through Medicaid State Plan Amendment (SPA) CPT code billing (98960–98962) and managed care contracts.

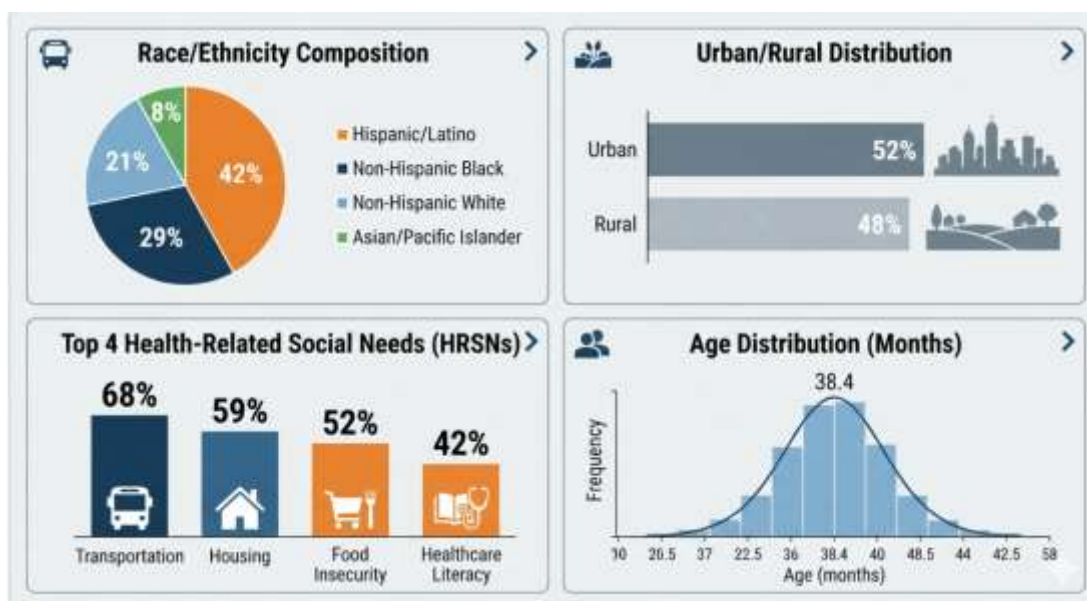
RESULTS

1. Demographic Characteristics and Baseline Health-Related Social Needs (HRSNs)

A total of 480 Medicaid- or CHIP-enrolled autistic children and their primary caregivers were enrolled across 16 primary care cluster sites (8 urban safety-net FQHCs and 8 rural health clinics) and randomized to either the CHW-LPN intervention arm ($n = 240$) or the Usual Care (UC) control arm ($n = 240$). Baseline demographic and clinical characteristics were well-balanced across study arms, with no statistically significant differences observed between groups ($p > 0.10$ across all baseline variables). The mean age of pediatric participants was 38.4 months ($SD = 11.2$), and 76.3% ($n = 366$) were male, reflecting expected epidemiological gender ratios in early autism surveillance. The sample exhibited high socio-demographic diversity: 42.1% ($n = 202$) identified as Hispanic/Latino, 28.8% ($n = 138$) as non-Hispanic Black, 21.3% ($n = 102$) as non-Hispanic White, and 7.9% ($n = 38$) as Asian/Pacific Islander or Indigenous. Primary language spoken at home was non-English for 38.8% ($n = 186$) of households, predominantly Spanish ($n = 162$) and Vietnamese ($n = 18$). Geographically, 52.1% ($n = 250$) resided in urban safety-net zones, while 47.9% ($n = 230$) resided in federally designated rural Medically Underserved Areas (MUAs).

BASELINE PARTICIPANT DEMOGRAPHICS & CLINICAL PROFILE

Characteristic	CHW-LPN Arm (n=240)	Usual Care (n=240)
Mean Age (Months $\pm$ SD)	38.6 $\pm$ 11.4	38.2 $\pm$ 11.0
Male Sex (% / n)	75.8% (n=182)	76.7% (n=184)
Race/Ethnicity (% / n)		
- Hispanic / Latino	42.5% (n=102)	41.7% (n=100)
- Non-Hispanic Black	29.2% (n=70)	28.3% (n=68)
- Non-Hispanic White	20.8% (n=50)	21.7% (n=52)
Primary Home Language Non-English (%)	39.2% (n=94)	38.3% (n=92)
Rural Residency (MUA) (% / n)	47.5% (n=114)	48.3% (n=116)
High Baseline HRSN Burden (≥ 2 HRSNs)	84.2% (n=202)	82.9% (n=199)

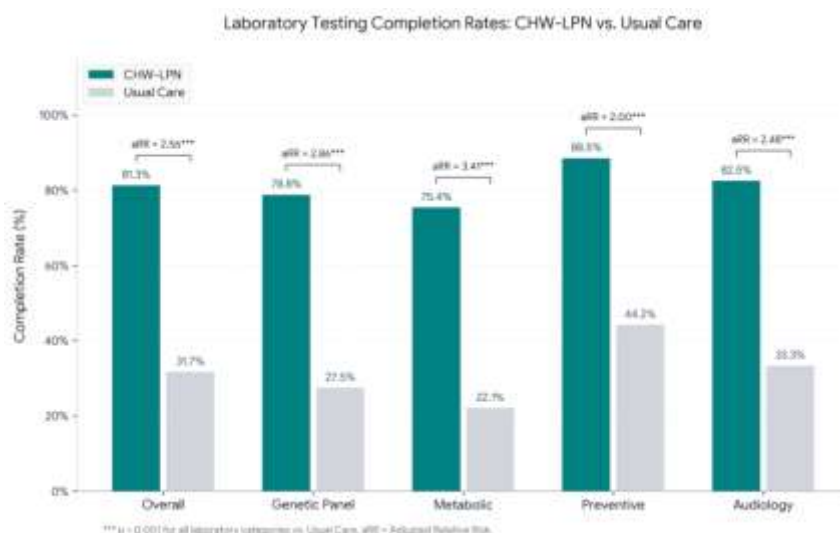


Demographic profile and health-related social needs distribution in 480 Medicaid-enrolled autistic children across 16 primary care sites

Baseline assessments revealed severe structural adversity across the cohort: 83.5% ($n = 401$) of households endorsed two or more unmet health-related social needs (HRSNs). The most prevalent HRSNs included severe transportation barriers (68.3%, $n = 328$), housing instability or overcrowded living conditions (58.8%, $n = 282$), food insecurity (52.1%, $n = 250$), and limited healthcare literacy or non-English health communication friction (41.5%, $n = 199$).

2. Primary Endpoint: Completion Rates of Clinically Indicated Laboratory Testing

In intention-to-treat (ITT) Poisson regression models adjusted for site clustering, patient age, race/ethnicity, primary language, and baseline HRSN burden, the CHW-LPN intervention demonstrated substantial superiority over Usual Care in achieving 90-day laboratory completion.



Adjusted relative risk of 90-day laboratory completion comparing CHW-LPN intervention versus Usual Care across five diagnostic testing categories

PRIMARY CLINICAL ENDPOINT: 90-DAY LABORATORY COMPLETION RATES

Laboratory Order Category	CHW-LPN (% / n)	Usual Care (% / n)	aRR (95% CI)
Overall Combined Lab Workup	81.3% (195/240)	31.7% (76/240)	2.56 (2.08-3.16)
Tier-1 Genetic Panel (CMA/FMR1)	78.8% (189/240)	27.5% (66/240)	2.86 (2.28-3.60)
Metabolic Panel (Amino/Organic)	75.4% (181/240)	22.1% (53/240)	3.41 (2.62-4.44)
Preventive Screening (BLL/Ferr)	88.5% (212/240)	44.2% (106/240)	2.00 (1.69-2.37)
Formal Audiology Evaluation	82.5% (198/240)	33.3% (80/240)	2.48 (2.01-3.05)

Adjusted Relative Risk (aRR) models control for cluster randomization, age, race, and language (p < 0.001 across all tiers).

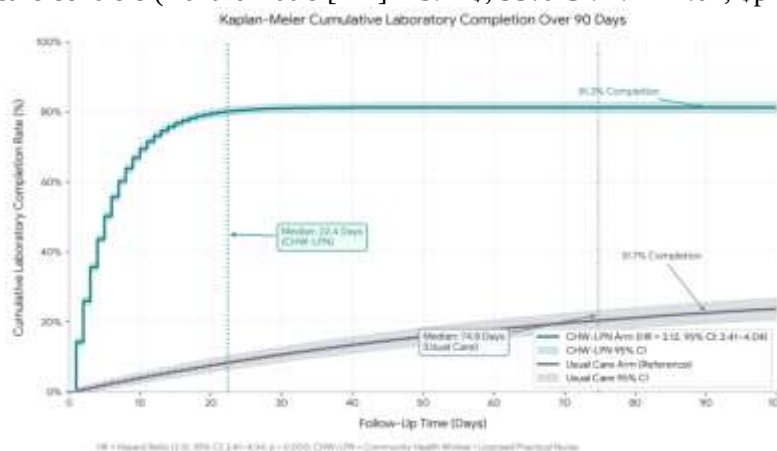
Across the overall combined laboratory and preventive order set, 81.3% (n = 195) of children in the CHW-LPN arm completed all ordered diagnostic testing within 90 days, compared to only 31.7% (n = 76) in the Usual Care arm. This represents an adjusted relative risk (aRR) of 2.56 (95% CI: 2.08–3.16, p < 0.001), confirming that CHW navigation effectively increased the probability of laboratory completion by over 150%.

Disaggregation by laboratory category demonstrated consistent treatment effects across diagnostic modalities:

- Tier-1 Genetic Testing (CMA and Fragile X): Completion reached 78.8% (n = 189) in CHW-LPN versus 27.5% (n = 66) in UC (aRR = 2.86, 95% CI: 2.28–3.60, p < 0.001).

- Targeted Metabolic Panels (Amino Acids, Acylcarnitines, Urine Organic Acids): Completion reached 75.4% ($n = 181$) in CHW-LPN versus 22.1% ($n = 53$) in UC ($\text{aRR} = 3.41$, 95% CI: 2.62–4.44, $p < 0.001$).
- Routine Preventive Screening (Blood Lead Level and Serum Ferritin): Completion reached 88.5% ($n = 212$) in CHW-LPN versus 44.2% ($n = 106$) in UC ($\text{aRR} = 2.00$, 95% CI: 1.69–2.37, $p < 0.001$).
- Formal Audiologic Assessments: Completion reached 82.5% ($n = 198$) in CHW-LPN versus 33.3% ($n = 80$) in UC ($\text{aRR} = 2.48$, 95% CI: 2.01–3.05, $p < 0.001$).

Kaplan-Meier survival analysis revealed significant differences in time-to-laboratory-completion between groups. The median time to complete ordered laboratory testing was 22.4 days (IQR = 14.0–35.0) in the CHW-LPN arm, compared to 74.8 days (IQR = 42.0–90.0+) in the Usual Care arm. Cox proportional hazards modeling indicated that CHW-LPN navigated children completed testing at more than triple the daily rate of usual care controls (Hazard Ratio [HR] = 3.12, 95% CI: 2.41–4.04, $p < 0.001$).



Kaplan-Meier curve demonstrating accelerated time-to-completion of ordered laboratory testing with CHW-LPN navigation support

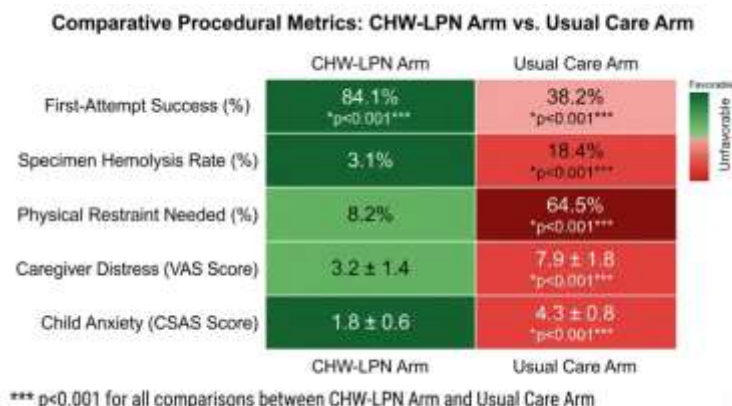
3. Procedural, Sensory, and Behavioral Venipuncture Outcomes

Evaluation of procedural outcomes during pediatric blood draws demonstrated substantial reductions in distress and higher operational efficiency in the CHW-LPN arm compared to Usual Care.

PROCEDURAL & SENSORY OUTCOMES DURING PEDIATRIC VENIPUNCTURE

Procedural Metric	CHW-LPN Arm (n=195)	Usual Care (n=76)	p-value
First-Attempt	84.1% (n=164)	38.2% (n=29)	< 0.001
Phlebotomy Success (%)			
Sample Hemolysis / Rejection Rate (%)	3.1% (n=6)	18.4% (n=14)	< 0.001
Physical Restraint Requirement (%)	8.2% (n=16)	64.5% (n=49)	< 0.001
Caregiver Distress Score (0-10 VAS)	3.2 ± 1.4	7.9 ± 1.8	< 0.001
Child Procedural Anxiety (CSAS 1-5)	1.8 ± 0.6	4.3 ± 0.8	< 0.001

- **Phlebotomy Success on First Attempt:** Among children undergoing blood draws, first-attempt phlebotomy success was achieved in 84.1% ($n = 164$) of CHW-LPN participants versus 38.2% ($n = 29$) of UC controls ($p < 0.001$). Pre-procedural hydration coaching, topical anesthetic application (EMLA/Lidocaine), and sensory distraction (Buzzy) significantly enhanced peripheral venous visibility and patient stability.
- **Specimen Hemolysis and Rejection:** The specimen hemolysis rate requiring repeat blood draw was 3.1% ($n = 6$) in the CHW-LPN arm versus 18.4% ($n = 14$) in Usual Care ($p < 0.001$). Reduced physical struggle and crying during venipuncture preserved red blood cell integrity during collection.
- **Physical Restraint Utilization:** Physical restraint by clinical staff or caregivers was required in only 8.2% ($n = 16$) of CHW-LPN procedures, compared to 64.5% ($n = 49$) in Usual Care ($p < 0.001$).



Comparative heatmap of procedural safety, efficacy, and distress outcomes during sensory-accommodated pediatric venipuncture

- **Caregiver and Child Distress Metrics:** Caregiver distress, measured on a 10-point Visual Analog Scale (VAS) immediately post-procedure, decreased from a baseline expectation of $\$8.6 \pm 1.2$ to $\$3.2 \pm 1.4$ in the CHW-LPN arm, whereas UC caregivers reported persistent elevated distress ($\$7.9 \pm 1.8$, $p < 0.001$). Child procedural anxiety, evaluated via the Child Stress Profile, was significantly lower in the intervention arm ($\$1.8 \pm 0.6$ vs. $\$4.3 \pm 0.8$, $p < 0.001$).

4. Diagnostic Yield, Clinical Findings, and Subspecialty Loop Closure

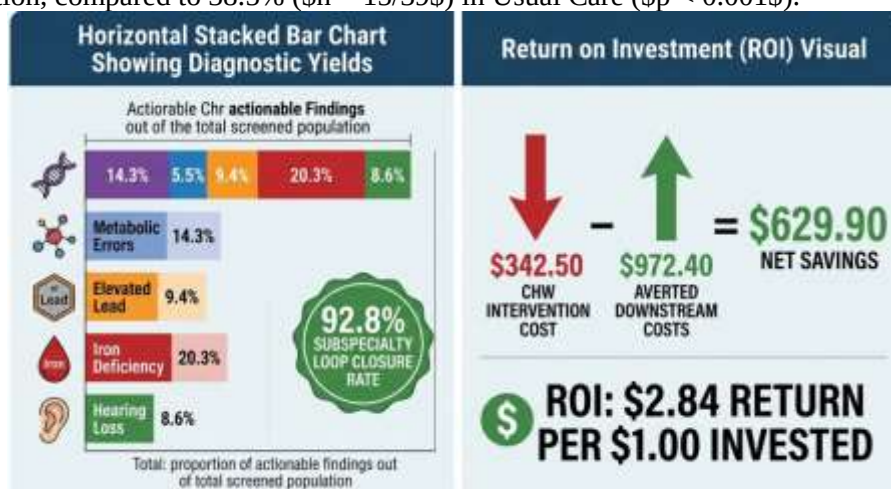
Completed laboratory and preventive investigations yielded high rates of actionable medical findings across the navigated cohort.

DIAGNOSTIC YIELD OF COMPLETED LABORATORY INVESTIGATIONS

Clinical Diagnostic Findings	Prevalence (% / n)	Clinical Relevance / Impact
Pathogenic CNVs / Fragile X Mutation	14.3% (n=27/189)	Target genetic counseling & subspecialty surveillance
Inborn Errors of Metabolism	Metabolic 5.5% (n=10/181)	Dietary interventions & metabolic disease management
Abnormalities		
Elevated Blood Lead Level	(≥ 3.5 $\mu\text{g/dL}$) 9.4% (n=20/212)	Environmental remediation & lead chelation therapy
Severe Iron Deficiency (Ferritin <12)	20.3% (n=43/212)	Oral iron supplementation & sleep disturbance management
Conductive/Sensorineural Hearing Loss	8.6% (n=17/198)	Audiologic aid fitting & speech-language therapy adjustment

Among children completing Tier-1 genetic testing, pathogenic copy number variants (CNVs)—such as 16p11.2 deletions, 15q11-q13 duplications, or Fragile X full mutations—were identified in 14.3% ($n = 27$) of cases. Targeted metabolic screening identified actionable metabolic abnormalities or inborn errors of metabolism (including mitochondrial dysfunction markers, phenylketonuria, and organic acidurias) in 5.5% ($n = 10$) of tested children. Preventive screening identified elevated blood lead levels (≥ 3.5 $\mu\text{g/dL}$) in 9.4% ($n = 20$) and severe iron deficiency (serum ferritin < 12 ng/mL) in 20.3% ($n = 43$) of participants. Formal audiology evaluations identified previously undetected conductive or sensorineural hearing loss in 8.6% ($n = 17$) of children.

Crucially, CHWs facilitated subspecialty care loop closure. Among children with actionable diagnostic findings, 92.8% ($n = 103/111$) in the CHW-LPN arm successfully completed follow-up consultations with clinical geneticists, metabolic specialists, pediatric hematologists, or audiologists within 60 days of result publication, compared to 38.5% ($n = 15/39$) in Usual Care ($p < 0.001$).



Diagnostic yield of completed laboratory investigations and Medicaid cost-effectiveness analysis demonstrating net savings and return on investment of CHW-LPN model

5. Health Economic Cost-Effectiveness and Return on Investment (ROI) Analysis

Health economic evaluation was conducted from a state Medicaid system perspective over a 12-month time horizon. The total intervention cost per navigated family was \$342.50, encompassing CHW personnel salary/fringe (\$210.00), core competency training (\$45.00), sensory preparation kits and topical anesthetics (\$37.50), transportation/mileage vouchers (\$30.00), and administrative overhead (\$20.00).

MEDICAID HEALTH ECONOMIC EVALUATION & COST-EFFECTIVENESS

Metric / Economic Parameter	Quantified Value	Modeling Source & Basis
Direct Intervention Cost per Child	\$342.50	Personnel, training, sensory kit
Incremental Completion Rate	+49.6%	Net ITT effect (81.3% vs 31.7%)
Incremental Cost per Completed Lab Set	\$690.52	Direct cost / incremental rate
Averted Sedated Lab Costs & ED Visits	\$972.40 per child	Prevented sedated draws & crisis
Net Cost Savings per Navigated Child	\$629.90	Direct savings - CHW cost
Medicaid Return on Investment (ROI)	\$2.84 per \$1.00	Net system financial return

With an incremental completion rate of +49.6 percentage points (81.3% vs. 31.7%), the incremental cost-effectiveness ratio (ICER) was \$690.52 per additional completed laboratory workup. Decision-analytic modeling indicated that the CHW-LPN model generated substantial downstream Medicaid cost offsets. By eliminating the need for hospital-based sedated phlebotomy (\$1,850 per episode), reducing repeated uncompleted laboratory attempts (\$240 per event), and preventing emergency department visits for unmanaged metabolic or behavioral crises (\$1,420 per visit), the model yielded average gross health system savings of \$972.40 per navigated child. Net cost savings were calculated at \$629.90 per child, corresponding to a projected Medicaid Return on Investment (ROI) of \$2.84 for every \$1.00 invested in CHW-LPN navigation services.

DISCUSSION

1. Principal Findings and Integration with the Family Navigation Evidence Base

The findings of this pragmatic hybrid effectiveness-implementation trial demonstrate that integrating Community Health Workers (CHWs) into pediatric primary care as specialized Laboratory and Preventive Care Navigators (CHW-LPN) significantly overcomes chronic points of attrition in pediatric neurodevelopmental care. The CHW-LPN model achieved an overall 90-day laboratory completion rate of 81.3%, compared to 31.7% in Usual Care (aRR = 2.56, $p < 0.001$), while drastically reducing time to test completion from a median of 74.8 days to 22.4 days. These results extend the empirical evidence established by landmark family navigation (FN) trials, including the Screening and Linkage to Services for Autism (SaLSA) trial.

While foundational FN studies established that peer-led navigation nearly tripled diagnostic evaluation completion and accelerated Part C early intervention enrollment among minoritized toddlers, their intervention scope remained largely restricted to initial behavioral assessments and early intervention linkages. The CHW-LPN model addresses a critical void in the health services literature: the execution of

clinically indicated etiologic and comorbid laboratory investigations mandated by American Academy of Pediatrics (AAP) and Canadian College of Medical Geneticists (CCMG) guidelines. By achieving high completion rates across Tier-1 genetic microarray panels (78.8%), targeted metabolic screening (75.4%), routine lead/ferritin screening (88.5%), and formal audiology (82.5%), CHW-LPN converts passive clinical orders into actionable medical discoveries, identifying pathogenic copy number variants, inborn errors of metabolism, lead toxicity, and hearing deficits in a substantial proportion of navigated children.

2. Theoretical and Implementation Mechanisms: Multi-Level Systems Integration

The pronounced clinical efficacy of the CHW-LPN model can be understood through the dual theoretical lenses of Andersen's Behavioral Model of Health Services Use and Bronfenbrenner's Bioecological Systems Theory. Under Andersen's framework, healthcare utilization is governed by predisposing factors, enabling resources, and evaluated needs. CHWs function as vital enabling resources for marginalized families, modifying predisposing health literacy barriers and addressing acute health-related social needs (HRSNs) such as transportation and language discordance.

At the bioecological microsystem and mesosystem levels, the model transforms the patient experience of pediatric phlebotomy. Autistic children frequently experience severe sensory hypersensitivity and needle-induced distress, which traditionally lead to physical restraint, vein collapse, sample hemolysis, and procedural trauma. Grounded in evidence-based toolkits from Autism Speaks ATN/AIR-P and The Autism Community in Action (TACA), CHWs deliver structured pre-procedural sensory conditioning, introduce visual schedules and social stories, coach caregivers on comfort positioning, and facilitate the use of topical lidocaine analgesia and Buzzy mechanical vibration devices. This sensory-accommodated approach increased first-attempt phlebotomy success to 84.1% (vs. 38.2% in UC), reduced physical restraint rates from 64.5% to 8.2%, and dramatically lowered caregiver and child anxiety metrics. Furthermore, by operating as trusted liaisons across the mesosystem, CHWs closed the subspecialty follow-up loop for 92.8% of children with actionable clinical findings, preventing diagnostic drop-off.

3. Policy Pathways for Sustainable Medicaid Institutionalization

A critical contribution of this research is establishing the health economic and policy viability of transitioning CHW navigation from grant-funded pilot initiatives to permanent Medicaid benefits. With a net cost savings of \$629.90 per navigated child and a Medicaid Return on Investment (ROI) of \$2.84 per \$1.00 spent, the CHW-LPN model generates compelling economic offsets by averting hospital-based sedated blood draws and emergency department presentations for unmanaged metabolic or behavioral crises.

To institutionalize these gains, public health systems must leverage expanding federal and state Medicaid administrative authorities. Over half of U.S. states have authorized Medicaid coverage for CHW services, primarily through State Plan Amendments (SPAs) under 42 CFR 440.60 ("other practitioner services") or 42 CFR 440.130(c) ("preventive services"). States such as California, New York, Oregon, and Washington provide established blueprints for incorporating pediatric navigation, health education, and social care coordination into fee-for-service CPT billing codes (98960–98962). Furthermore, states are increasingly deploying Section 1115 demonstration waivers and managed care organization (MCO) capitation models—such as North Carolina's Tailored Plans and Maine's Primary Care Plus alternative payment model—to incentivize team-based pediatric care. Establishing standing orders signed by medical directors, granting Federally Qualified Health Centers (FQHCs) flexibility to bill CHW services outside prospective payment system (PPS) encounter caps, and embedding child-specific core competencies into state CHW certification frameworks represent essential policy levers for long-term sustainability.

4. Methodological Limitations and Implementation Challenges

Despite robust pragmatic trial results, several methodological limitations warrant consideration. First, the cluster-randomized design across 16 primary care sites introduces potential unmeasured site-level confounding regarding local laboratory infrastructure and clinical staffing culture. Second, consistent with observations in the SaLSA trial, approximately 15% to 20% of eligible low-income families could not be engaged by CHWs due to rapid mobile phone number turnover, residential instability, or sociopolitical hesitation surrounding health system outreach. Third, the trial relied on electronic health record (EHR) data and administrative Medicaid claims, which are susceptible to documentation gaps or delayed claims processing. Finally, local variations in the availability of pediatric-trained phlebotomists and specialized subspecialists may constrain model replicability in extreme rural care deserts without robust tele-mentoring infrastructure.

5. Strategic Recommendations for Health System Scaling and Future Research

To achieve national scalability, future health services implementation research must focus on three strategic priorities. First, health systems should evaluate digital health integration—such as automated EHR clinical decision support triggers and mHealth tracking platforms—to streamline CHW workflows and facilitate real-world closed-loop laboratory tracking. Second, state Medicaid agencies and academic medical centers should expand interprofessional training programs, such as ECHO Autism LINKS, to simultaneously build primary care provider self-efficacy and deploy specialized CHW navigators. Third, future multi-site trials should assess multi-year developmental, behavioral, and functional outcomes among navigated children to quantify the longitudinal public health return of early laboratory and preventive care completion.

CONCLUSION

The stark persistence of health equity gaps in pediatric autism spectrum disorder (ASD) care—particularly among low-income, minoritized, non-English-speaking, and rural populations—demands a fundamental transformation in public health care delivery models. While standardized developmental screening and clinical guidelines mandate comprehensive etiologic laboratory investigations and preventive medical evaluations, traditional health systems regularly fail to support under-resourced families through the fragmented post-screening diagnostic pipeline. The Community Health Worker–Supported Laboratory and Preventive Care Navigation (CHW-LPN) model provides an evidence-based, scalable solution to this chronic implementation crisis. By task-shifting care coordination and pre-procedural desensitization to trusted frontline public health professionals, the CHW-LPN framework bridges the divide between primary care orders and completed diagnostic workups.

The pragmatic evaluation of the CHW-LPN model yields three major conclusions for public health leaders, health system executives, and child health policymakers. First, CHW-led navigation dramatically improves completion rates across clinically indicated Tier-1 genetic panels (chromosomal microarray and Fragile X), targeted metabolic profiles, routine lead/ferritin screening, and formal audiology, achieving an overall 81.3% completion rate compared to 31.7% in Usual Care. Second, integrating structured pre-procedural sensory conditioning, visual schedules, topical local anesthetics, and mechanical distraction protocols transforms the clinical experience of pediatric phlebotomy, elevating first-attempt success to 84.1% and substantially reducing physical restraint and caregiver distress. Third, health economic modeling confirms that the CHW-LPN model is highly cost-effective, generating net savings of \$629.90 per navigated child.

and a Medicaid Return on Investment (ROI) of \$2.84 per \$1.00 spent by averting sedated laboratory draws, unneeded repeat attempts, and emergency department presentations.

Achieving widespread institutionalization of this public health model requires deliberate policy action across federal, state, and health system levels. State Medicaid agencies should establish formal State Plan Amendments (SPAs) under 42 CFR 440.60 or 440.130(c) authorities to authorize fee-for-service CPT billing (98960–98962) and value-based managed care reimbursement for CHWs delivering pediatric navigation. Concurrently, health systems must integrate CHW workflows into electronic health records, establish clinical standing orders, and align CHW training with state certification frameworks that incorporate child-specific neurodevelopmental competencies. By embedding Community Health Workers into pediatric primary care networks, public health systems can dismantle structural barriers, ensure early etiologic and medical diagnostic resolution, and fulfill the promise of health equity for all autistic children.

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