



Essentials for Childhood **POLICY GUIDE**



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Introduction

Public health leaders and their partners can make the greatest impact on population health by focusing on early childhood. As several decades of research show, early childhood experiences and environments profoundly influence health and well-being throughout a person's life.¹ Healthy brain development from an early age creates the building blocks for educational achievement, economic productivity, responsible citizenship, positive parenting, and lifelong health and well-being.

State and territorial health departments can take steps to promote safe, stable, and nurturing relationships and environments for children and ensure a foundation for health into the next generation. Evidence-based programs and services that address specific needs have greater impact when they are coupled with policies that help working families, such as those that provide economic support, expand access to quality early care and education, and promote family-friendly workplaces. This resource presents an overview of the state health department's role in informing policy and lays out several policy options for states and other partners to consider when working to create the context for healthy children and families.

Policy Options to Promote Safe, Stable, and Nurturing Relationships and Environments

The following policy options, divided into three categories, reflect the best available evidence for what works to promote safe, stable, and nurturing relationships and environments, ones that prevent child abuse and neglect and reduce risk factors for child abuse and neglect (e.g., parental stress or parental mental health).

Economic Supports to Families

Policies that increase economic self-sufficiency for lower income families and streamline complicated application processes for public assistance programs may reduce parental stress associated with child abuse and neglect.² Policies that promote access to affordable, high-quality childcare enable parents to work and support a family and help ensure that all children feel safe and comfortable in their surroundings as they learn, play, and grow.

- Minimum wage
- Earned Income Tax Credits and Child Tax Credits
- TANF benefits
- Child support pass-through
- Enrollment in federal nutrition safety net programs
- Housing assistance programs
- Childcare access



Quality Care and Education Early in Life

Policies that promote high-quality early childhood programs and services that are designed to meet the needs of children and families can help ensure that every environment provides learning opportunities for young children, whether at home, in childcare, or other preschool settings.

- Early Head Start
- High-quality preschool education

Policies to Support Working Families

Policies that provide employees with the flexibility to spend time away from work caring for a child or other family member without the worry of losing their jobs or income encourage both stronger family bonds and increased productivity when employees return to work.³

- Paid leave: family, parental, and medical leave
- Paid sick leave

Impacts of Early Childhood Experiences and Environments

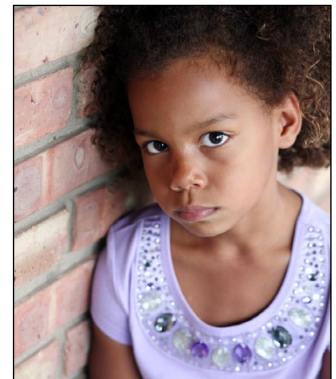
Health is shaped by a number of determinants, including environmental and social exposures, education and economic opportunities, health behaviors, access to and quality of healthcare, and genetics. The health outcomes of young children are particularly affected by early life experiences. Early experiences, especially within the first three years of life, transform the architecture of the brain.⁴ Having consistent, stable, reciprocal interactions with caring people at home and in the community are important for building a strong foundation for future health and wellness.

Adverse Childhood Experiences (ACEs)

Some children are exposed to conditions or events that are so severe and persistent that they produce toxic stress responses that damage the brain's developing architecture. Adverse childhood experiences (ACEs) are incidents that harm social, cognitive, and emotional functioning and dramatically upset the safe, nurturing environments children need to thrive. As the number of ACEs increases so does the risk for asthma, depression, smoking, diabetes, and a number of other negative health and well-being outcomes across a lifespan.⁵

Adverse childhood experiences include:

- | | | |
|---|--|--|
| <ul style="list-style-type: none">• Emotional abuse• Physical abuse• Sexual abuse | <ul style="list-style-type: none">• Emotional neglect• Physical neglect | <ul style="list-style-type: none">• Mother treated violently• Household substance abuse• Household mental illness• Parental separation or divorce• Incarcerated household member |
|---|--|--|



Early exposure to these traumas become programmed into the physiological system and can lead to difficulties in learning, memory, and self-regulation. Since cognitive, emotional, and social capacities are closely intertwined, children who are abused or neglected early in life can develop an exaggerated stress response that, over time, weakens the body's defense system against diseases and other health problems.⁶

Experiencing abuse or neglect as children can negatively affect how adults develop parenting skills. Adults who encountered ACEs at an early age are at higher risk for experiencing mental health issues, substance abuse, and intimate partner violence themselves⁷, all of which can diminish the quality of the parent-child relationship. Many parents may not recognize how early trauma can affect their parenting and their reactions to stressful situations. Helping parents and caregivers understand how ACEs and trauma affect health, relationships, and parenting is an important step in preventing ACEs from becoming part of an intergenerational cycle.

Many states are collecting information about ACEs through the Behavioral Risk Factor Surveillance System (BRFSS).⁸ BRFSS is an annual, state-based telephone survey that collects data on general demographics, health status, health behaviors, risks for chronic diseases and injuries, and access to healthcare. Since 2009, 32 states and the District of Columbia have added a module to the survey consisting of 11 questions related to ACEs to measure cumulative childhood stress in a large, representative sample of adults.⁹

Data from the BRFSS surveys show that roughly two-thirds of adults have experienced at least one ACE, creating a sense of urgency around understanding trauma and its effects on brain development. ACEs data has been used by health departments, national organizations, advocacy groups, and others to inform public policy and primary prevention efforts, as well as to educate the public and specific sectors about the prevalence of ACEs in states and communities. State health officials and their partners are often called to inform and educate the public, policymakers, and others about the scientific evidence related to the impact of policy on health outcomes. In doing so, they frequently use data, including ACEs data, to communicate with decisionmakers and partners about the potential effects of a policy intervention on a public health issue.

CDC'S ESSENTIALS FOR CHILDHOOD

To prevent child abuse and neglect and improve short- and long-term health, CDC promotes safe, stable, and nurturing relationships and environments for all children. The [Essentials for Childhood](#) framework proposes steps communities can consider to promote the types of relationships and environments that help children grow to be healthy and productive adults. The framework is organized around four goals and related steps to promote safe, stable, and nurturing relationships and environments for children and families.¹⁰

Four Goal Areas:

- #1:** Raise Awareness and Commitment to Promote Safe, Stable, Nurturing Relationships and Environments and Prevent Child Maltreatment
- #2:** Use Data to Inform Actions
- #3:** Create the Context for Healthy Children and Families through Norms Change and Programs
- #4:** Create the Context for Healthy Children and Families through Policies

A wide range of policies are important for promoting children's health, especially policies that prevent child abuse and neglect from happening in the first place. This supplement explores Goal #4 in-depth, with a menu of policy options that support strong families and communities.



Role of the State Health Department and Partners in Informing Policy

Policy approaches can shape the social environments in which children grow up in ways conducive to better health and well-being. There is no one-size-fits-all approach to informing policy. In addition, effective policies are not the sole responsibility of any one agency or group. They result from collaboration among many different types of partners at the federal, state, and local levels. State agencies, county and city governments, businesses, healthcare professionals, school administrators, childcare providers, community- and faith-based organizations, and individual families, youth, and community members are all essential partners in advancing policy.

A comprehensive policy agenda encourages better linkages across sectors to address the health and developmental needs of young children, particularly among children with special needs and low-income families. State health departments can exercise their authority as regulators, conveners, and educators to inform smart policies that facilitate coordination and engagement across multiple sectors, including education, labor, agriculture, human services, housing, public safety, parks and recreation, and child welfare. An increasing number of private partners, such as businesses, faith-based and civic organizations, primary healthcare providers, universities, foundations, cultural arts centers, and sports clubs and athletic associations, are also coming together in the interest of supporting safe, stable, and nurturing relationships and environments.

Many states are already integrating what is known about the health impacts of early childhood experiences into cross-cutting policy efforts.^{11,12}

Policy: Organizational, Regulatory, and Legislative

CDC defines “policy” as a law, regulation, procedure, administrative action, incentive, or voluntary practice of governments and other institutions. There are different types of policies and each plays an important role in improving the public’s health, including the following:

- **Organizational policies** (also known as internal policies) – rules or practices established within an agency or organization.
- **Regulatory policies** – rules, guidelines, principles, or methods created by government agencies with regulation authority for products or services (government agencies receive authorization to make regulations through state laws).
- **Legislative policies** – laws or ordinances.

State health departments participate in all aspects of the policy change process, which includes:

- **Problem identification** – analyze and communicate challenges and obstacles.
- **Policy analysis** – identify possible interventions.
- **Strategy and policy development** – prioritize interventions.
- **Policy enactment** – provide evidence as requested by decisionmakers.
- **Policy implementation** – support implementation through education, training, technical assistance, and guidance.

For more detailed information on the policy process, see: [The State Health Department’s Role in the Policy Process: A Tool for State Health Department Injury and Violence Prevention Programs](#).



Examples of State Initiatives


Connecticut's Two-Generation Approach

In 2015, Connecticut passed a provision in the state budget establishing what it calls a “two-generational” school readiness and workforce development pilot program¹³ to foster family economic self-sufficiency in low-income families. The program delivers early education and workforce services concurrently across generations (i.e., parent and child or caregiver). Six pilot communities located in New Haven, Greater Hartford, Norwalk, Meriden, Colchester, and Bridgeport are beginning to coordinate children’s school readiness and academic achievement services with parents’ job readiness and support services. State and local governments are working together to align funding, programming, and other systems so that community-based programs can more easily provide these and other types of two-generation services.

To oversee the program, the legislation (PA 15-5, Section 401) established an interagency workgroup co-chaired by two leaders representing the appropriations and human services committees and managed by the Connecticut Commission on Children. The interagency workgroup is comprised of commissioners of the departments of social services, early childhood, education, housing, transportation, public health, labor, and corrections, as well as the chief court administrator, nonprofit and philanthropic organizations, and other business and academic professionals.

Oregon's Child Fatality Review Teams

The Oregon Health Authority and the Department of Human Services bring together child fatality review teams from across the state to identify trends and work together on prevention strategies.¹⁴ A major focus of this work is on increasing family stability and child safety by strengthening the integration of mental health and addiction, housing, and employment services and other systems.



While federal funds cannot be used to lobby at the federal, state, or local level, these prohibitions do not prevent state health departments from participating in the policy process. Importantly, health departments can educate elected officials and the public about evidence-based policy options that will improve health outcomes. Partnerships are vital throughout the process, from collecting data to policy development to implementation.

Anti-lobbying Restrictions for CDC Grantees

Language included in Section 503 of Division F, Title V, of the FY 12 Consolidated Appropriations Act reinforces and expands statutory and other provisions governing the use of appropriated funds by CDC and its grantees for advocacy, lobbying, and related activities.

What is prohibited?

No appropriated federal funds can be used by CDC grantees for grassroots lobbying activity directed at inducing members of the public to contact their elected representatives to urge support of, or opposition to, proposed or pending legislation or appropriations or any regulation, administrative action, or order issued by the executive branch of any federal, state or local government.

What is allowed?

State and local agencies funded by CDC are permitted to work directly on policy-related matters across their equivalent branches of state or local government. This derives from language in Section 503 permitting communications through a normal and recognized executive-legislative relationship, and permitting a grantee to participate in policymaking and administrative processes within the executive branch of their state or local government, if within these boundaries:

Allowable activities using CDC appropriated funding include:

- Educating the public on personal health behaviors and choices.
- Research on policy alternatives and their impact.
- Working with other agencies within the executive branch of their state or local governments on policy approaches and on implementation of policies.
- Educating the public on health issues and their public health consequences.
- Educating the public on the evidence associated with potential policy solutions to health issues.
- Working with their own state or local government’s legislative body on policy approaches to health issues, as part of normal executive-legislative relationships.
- Development of model laws, templates, and menu of options, which could include various state and local laws that serve as models.

These joint efforts in Oregon have resulted in:

- A coordinated child fatality data collection and reporting system that uses surveillance data from outside the child welfare system.
- Improved partnerships with drug and alcohol treatment providers and efforts to expand family-based treatment.
- Co-location of domestic violence advocates in the state's child welfare and self-sufficiency offices. After working with an advocate, clients were more likely to access services provided by the health department's offices.

Minnesota's Prenatal to Three Policy Framework

In Minnesota, the Children's Cabinet, which includes commissioners of the departments of health, education, and human services, charged the Minnesota Department of Health with developing a statewide policy framework that addresses the health of children beginning with prenatal mothers through age three. The framework focuses on outcomes for children and families in five key areas: prenatal health, general health, education, well-being, and service area coordination for children from before birth to age three. During the initial planning phases, the department of health convened a workgroup to identify potential outcomes across these key areas, as well as metrics to determine success. The second phase involved building partnerships with external stakeholders to identify policy recommendations to promote healthy development and early learning, and raise awareness of the importance of infant and toddler development. Minnesota is continuing to build community capacity for reducing health inequities and promoting safe, stable, and nurturing relationships and environments, as well as social and economic security for pregnant and parenting families with very young children.¹⁵

New Jersey's Centralized Intake System

In New Jersey, a centralized intake system helps families access services, such as home visiting, pediatric and adult primary care, and social services, all through a single entry point.¹⁶ The model began with a focus on linking infants and pregnant women to the state's home visiting programs and has since expanded, with intake hubs in every county that provide referrals and linkages to other programs, including Head Start and Early Head Start and high-quality childcare centers. Central intake is part of a larger interagency collaboration across four state departments—health, children and families, human services, and education—to build a comprehensive pregnancy to age 8 early learning plan for New Jersey.



Policy Options to Promote Safe, Stable, and Nurturing Relationships and Environments

Research shows that the domains of child development are interconnected. As our understanding of these connections and their collective influence continues to evolve, states can explore policy options that are most likely to have a positive impact on the first years of a child's life. The following policy options represent strategies to prevent and reduce risk factors for child abuse and neglect.

Economic Supports to Families

Poverty makes it harder for parents to meet a child's most basic needs, including food, shelter, and medical care. Economic hardship also creates significant stress and can lead to changes in parental mental health, caregiving behaviors, or family dynamics. Research shows that children living in families with limited economic resources are at greater risk for abuse and neglect than children from higher socioeconomic groups.¹⁷ Children in low socioeconomic status households experience some type of abuse or neglect at more than five times the rate of other children.¹⁸

The adverse health effects of low family income also accumulate over time. Children from poorer families often enter adulthood with worse overall health, which affects their future earnings ability and keeps their socioeconomic status low.^{19,20} Many states have used county-level data to show that average life expectancy varies considerably across different zip codes. Areas where residents have a shorter life expectancy are often characterized by much higher rates of poverty and lower family incomes.²¹

Policy options to support more stable, economically secure families are discussed below.

Minimum Wage

■ OVERVIEW

One way to improve economic sufficiency is to consider policies that directly address low-wage workers and low family income. Proposals to raise the minimum wage have gained momentum among policy-makers as a strategy to address widening income inequality. States and some local government entities, such as cities and counties, have the authority to set their own minimum wages above the federal level. Currently, 29 states and the District of Columbia have minimum wages above the federal minimum wage of \$7.25 per hour.²² Fourteen states have tied increases in pay to the Consumer Price Index to ensure the minimum wage will keep pace with increases in the cost of living. One adult working full-time at the minimum wage with two children earns roughly \$14,500 a year, well below the 2015 U.S. poverty threshold of \$19,096 for a family of this size. Childcare is virtually out of reach for many workers who earn minimum wage to support their families, since full-time care for children up to age four in childcare centers in the United States averages roughly \$9,500 per year.

A recent study in the American Journal of Public Health found that a higher minimum wage may yield significant health benefits and that increasing the minimum wage could be a potential strategy for addressing health disparities. The study examined community-level income and mortality data from New York City between 2008 and 2012 to estimate the impact of a minimum wage of \$15 per hour over a five-year period. The analysis suggests that a \$15 minimum wage would reduce premature deaths in New York City by as many as 5,500 deaths over five years.²³

Although the relationship between income and health has been well-documented, there are studies^{24,25} to support positions on both sides of the minimum wage debate. Research on the employment effects of minimum wage increases, for example, has yielded mixed findings.²⁶ Increasing the minimum wage has

proven to be a divisive issue. Proponents of minimum wage increases consider it a moral imperative to achieve greater fairness and believe it will stimulate the economy. Opponents say increases will cost businesses too much, leading to increased prices and fewer jobs.

■ ROLE OF THE HEALTH DEPARTMENT

State health officials can educate policymakers on the well-established health consequences associated with poverty. They can also stay informed about efforts to study how poverty rates change in states where the minimum wage is increased, and ultimately how it affects health in those states. Participating in an exchange of ideas with policymakers around this issue serves as an opportunity for health departments to explore the feasibility of other approaches, complementary to raising the minimum wage, which may also benefit low-wage workers, such as policies to ensure paid sick time, more consistent work schedules, and protections against wage theft. State health departments may also consider conducting health impact assessments (HIAs) to quantify the impact of changes to the minimum wage on mortality and other health outcomes.

■ SELECTED STATE EXAMPLES

In 2014, the **Health Officers Association of California** and Human Impact Partners conducted a rapid health analysis using the California Health Interview Survey to assess a legislative proposal to raise the state's minimum wage. The analysis found that raising the minimum wage to \$13 per hour would result in almost 400 fewer premature deaths annually among working-age Californians.²⁷ In April 2016, California's governor signed Senate Bill 3 into law, increasing the minimum wage to \$15 per hour by 2022 and indexed thereafter annually for inflation.

A similar analysis found that for San Francisco families, increasing the minimum wage to \$11 per hour would result in a 22 percent decrease in the risk of early childbirth and a greater likelihood of completing high school. San Francisco approved a ballot initiative that will raise the minimum wage to \$15 by 2018. The city's current minimum wage of \$12.25 has been in effect since May 1, 2015.

Earned Income Tax Credit (EITC) and Child Tax Credit (CTC)

■ OVERVIEW

The Earned Income Tax Credit (EITC) both provides income support and incentivizes work. The EITC is explicitly tied to work—an individual or family without earned income is not eligible for the credit. Because it increases after-tax wages for some workers, the EITC creates incentive for individuals to enter the workforce. Under the federal EITC, families with two children receive a 40 percent subsidy to their earnings up to a maximum of \$5,548, which phases out as incomes rise. The gradual phase-out keeps families from abruptly losing the credit and reinforces the incentive to keep working and earning more. The Child Tax Credit (CTC) provides a similar benefit, giving families a \$1,000 credit for each child under 17 to help offset the costs of raising a child.

Twenty-six states and the District of Columbia supplement the federal credit by offering a state EITC, but the amount provided varies dramatically by state. In California, the EITC is equal to 85 percent of the federal EITC (for families and individuals with wage income below \$7,000 to \$14,000) and in a few states it is worth 30 percent or more. In other states, however, the state EITC is worth less than 10 percent of the federal credit.²⁸



Research shows that EITCs can contribute to improvements in children's health, academic performance, and future earnings.²⁹ Increased income may allow the family to purchase more nutritious foods, seek preventive medical and dental care, and improve the safety of their home environment.

The EITC is an important component of state and federal efforts to reduce poverty. Poverty during pregnancy can have lasting effects on child health and cognitive development. One study found that \$1,000 in income from the EITC was associated with a 6.8 percent to 10.8 percent decrease in rates of low birth weight for single mothers with a high school education or less and up to a 15 percent decrease in low birth weight in high-poverty neighborhoods.³⁰ The Child Tax Credit was significantly associated with decreases in maternal depression³¹, a risk factor for child physical abuse and neglect.³²

■ ROLE OF THE HEALTH DEPARTMENT

States can support outreach efforts to maximize the number of families taking advantage of the credit, regardless of whether the state has an EITC that piggybacks on the federal EITC credit or not. Due to the way the EITC is calculated and claimed, administrative costs are minimal and as a result, in some states, there is no single agency charged by statute to promote public awareness of the credit or its eligibility requirements. To assist low-income individuals who may qualify for, but be unaware of, the credit, state health departments can provide public education and free tax preparation services to help families claim financial assistance. Informational materials can be included with public assistance checks, tax forms, and utility bills, or advertisements can be placed on public transportation. State health departments can also take steps to ensure that licensed childcare providers, home visiting programs, community health workers, and other professionals who serve low-income working families can offer clear and concise information about how to claim the EITC.

■ SELECTED STATE EXAMPLES

The **Texas Workforce Commission** and local workforce development boards assist TANF recipients who become employed to apply for the federal EITC.³³ **Washington's Department of Social and Health Services** created a toll-free hotline to provide eligibility information and referrals to tax providers. The **Virginia Department of Social Services** mailed and called potential EITC-eligible recipients to encourage them to claim the EITC. The department spent roughly \$42,000 on outreach via mailings and phone calls, resulting in a \$2.4 million increase in EITC benefits claimed.³⁴

TANF Benefits

■ OVERVIEW

Temporary Assistance for Needy Families (TANF) provides income assistance and wage supplements, childcare, education and job training, early childhood home visiting programs, transportation, and other services to help low-income families with children. TANF benefits are funded through block grants to states, and each state has some flexibility in determining how it implements the program. TANF plays an important role in the range of income supports for low-income families because it is the only widely available source of cash assistance, usually a benefit paid monthly to help meet a family's ongoing basic needs.

A family's eligibility for TANF and the amount of cash assistance they receive depend on the state. States that set higher TANF benefits, allow longer lifetime limits, and eliminate family caps have documented decreases in the number of children in foster care.³⁵ Nine states and the District of Columbia raised TANF benefit levels between July 1, 2014 and July 1, 2015.³⁶

In addition, TANF connects families to other services that support positive long-term health outcomes for both children and parents, including health and nutrition programs, early childhood education, and quality employment and training opportunities.

■ ROLE OF THE HEALTH DEPARTMENT

State health departments can work with TANF agencies to both coordinate and serve as active partners in statewide, tribal, regional, and local efforts to promote family economic security. Many families are eligible for TANF benefits but do not receive them due to a lack of knowledge about their eligibility or the difficulty of the application processes. Online tools designed to streamline multiple benefit applications have been developed in states, including Colorado and California, where child welfare and income support specialists are co-located in one office, creating a single point of entry for accessing services. States can also support the co-location of parent and child services by sponsoring a job skills class in a childcare center, for example, making it easier for families to access both services.

■ SELECTED STATE EXAMPLES

Washington created a private-public partnership called Thrive Washington to better allow evidence-based home visiting programs to serve TANF families. Several types of funds, including state TANF and federal Maternal, Infant, and Early Childhood Home Visiting block grant funds, as well as private donations, are being used to provide TANF families with slots in home visiting programs, focusing on pregnant women and families with infants. The home visiting model bring a whole-family lens to working with TANF clients and supporting parents in their role as caregivers. Partners in this work include the Department of Early Learning, the Department of Social and Health Services, and the Department of Commerce. Thrive Washington also sits on Washington's *Essentials for Childhood* Steering Committee.

In **North Carolina**, the Division of Social Services, Economic and Family Services, which houses NC Work First, the state's TANF program, partnered with the North Carolina Office of Early Learning to improve collaboration between Head Start and Early Head Start programs and programs that administer TANF and work with TANF families. With funding from the state's Head Start program, the two agencies issued a competitive grant to incentivize partnerships between local Head Start and Early Head Start programs and county social services offices. As a result, more children of TANF participants accessed Head Start or Early Head Start slots through referrals from NC Work First.³⁷



Child Support Pass-Through

■ OVERVIEW

Consistent emotional and financial support from both parents benefits children's well-being. The child support system is meant to mediate the potentially negative consequences that children living apart from one of their parents experience by requiring noncustodial parents to contribute financially to their upbringing.

Under federal law, families receiving TANF benefits assign their rights to child support payments to the state in order to keep receiving income assistance under TANF. When a state collects child support on behalf of a TANF recipient, the state is permitted to keep the money to recoup its own costs or to allow some or all of the child support payment to be "passed through" to the custodial parent. Pass-through programs encourage noncustodial parents to pay child support because they know their money will directly benefit their children.³⁸

States can also disregard some or all of the child support payment when calculating the recipient's monthly TANF benefits; otherwise, benefits can be reduced dollar-for-dollar depending on the amount of child support received. Pass-through and disregarded dollar amounts vary by state. In recent years, states have experimented with child support pass-through policies, and currently about half of states allow some portion of the child support payments to pass-through to the families.

Child support payments can make a difference in the financial security of single parents and their children, as well as reduce the risk of child abuse and neglect. A recent study showed that a pass-through policy allowing 100 percent of child support to reach custodial parents is associated with a 10 percent decrease in child abuse and neglect reports.³⁹

■ ROLE OF THE HEALTH DEPARTMENT

Each state designates an agency to implement child support enforcement (CSE) efforts, such as the department of health, department of revenue, or the attorney general's office. TANF and CSE programs often serve an overlapping population and both systems share a common mission of ensuring the well-being of children and families. States can promote cross-training between TANF and CSE staff so they better understand each other's program goals, services, and policies and to recognize their shared objectives in supporting families. States can also support improved coordination across all programs and organizations involved in CSE, including legislators, courts, local and state bar associations, district and state attorneys, local child support directors, local law enforcement officials, and family and child support advocacy groups.

■ SELECTED STATE EXAMPLES

Research demonstrates that child support pass-through and disregard policies benefit both states and families. In **Wisconsin**, where all child support collected by the state is passed through to families receiving TANF cash assistance and disregarded as income, a widely-studied demonstration project showed that:⁴⁰

- Fathers were more likely to pay child support and make higher payments.
- Rates of paternity establishment increased.
- Overall costs for increased collections and distribution were relatively small, with a cost savings to the state.⁴¹

In addition, because many noncustodial parents have a limited ability to pay due to unemployment or other barriers to finding or maintaining a job, states are working to establish income-based child support orders. Determining child support payment based on income helps parents pay their child support more regularly over time. To address these underlying issues, states have implemented work-oriented

programs for unemployed noncustodial parents who are behind on their child support payments. As of February 2014, at least 30 states and the District of Columbia have work-oriented programs that serve noncustodial parents.⁴² Georgia, Maryland, and North Dakota have statewide programs.

North Dakota's Parental Responsibility Initiative for the Development of Employment (PRIDE) program provides case management, skills training, and job placement services to help noncustodial parents find employment.⁴³ Referrals to the program come from the court system and child support workers. PRIDE was expanded statewide in 2009 and is a collaborative effort involving Job Service North Dakota (the designated state workforce agency), the courts, and the Department of Human Services' regional human service centers, TANF, and child support enforcement programs.

In 2006, the **District of Columbia** used a Section 1115 Medicaid demonstration waiver to test a service delivery change to increase the number of child support orders by improving collaboration between the Department of Human Services' Child Support Services Division (CSSD) and the TANF agency. Three CSSD intake workers were colocated at one TANF office, so that clients could complete their child support interviews—the first step in establishing a child support order—on the same visit. By colocating staff, the project streamlined the child support order establishment process and increased child support payments to TANF families over time. There was limited interagency collaboration prior to this demonstration project but, because of the overlap in clients and their goals, as well as the potential for child support to contribute meaningfully to low-income families' resources, collaboration between the agencies yielded many benefits.⁴⁴

Enrollment in Federal Nutrition Safety Net Programs

■ OVERVIEW

Nutrition influences health at every stage of life, and many families living in poverty do not have access to healthy foods. Part of creating a nurturing environment is having adequate food. Household food insecurity has been associated with maternal depression, and family stress can undermine children's well-being.⁴⁵ Health problems associated with hunger and malnutrition can have permanent, negative effects on a child's immune system, cardiovascular system, and developing brain. Participation in federal nutrition safety net programs, such as the Supplemental Nutrition Assistance Program (SNAP) and the Supplemental Nutrition Program for Women, Infants, and Children (WIC), provides vital nutrition and health benefits to low-income families to ensure that young children have what they need for healthy development.

SNAP is designed primarily to assist eligible low-income households by providing monthly benefits that can be used to purchase food. To increase SNAP participants' access to fresh fruits and vegetables, states have created incentive programs to allow people to use Electronic Benefits Transfer cards and redeem benefits at farmers' markets and other fresh produce retailers.

WIC provides nutrient-rich foods, healthcare and social services referrals to low-income women, infants, and children, along with breastfeeding promotion and support. Breastfeeding has been shown to reduce the risk of child maltreatment.⁴⁶

Receiving WIC or SNAP benefits is associated with fewer child maltreatment reports.⁴⁷ Additionally, children who receive WIC and SNAP benefits experience lower levels of food insecurity.⁴⁸ While not directly aimed at preventing abuse and neglect, participation in programs such as SNAP and WIC, which offer a range of services and supports, may enhance protective factors, alleviate financial stress, and help caregivers meet their children's needs during critical developmental stages.

■ ROLE OF THE HEALTH DEPARTMENT

States play a critical role in maximizing the effectiveness of the federal nutrition safety net. Through a variety of policy options, states have the ability to adapt SNAP and WIC programs to meet the needs of their low-income populations.

WIC's funding is discretionary, and state agencies use formula grants to operate the program through local WIC agencies and clinics. While federal WIC guidelines provide a framework for delivering nutrition education programs, state and local agencies have significant flexibility to design programs that are culturally appropriate and responsive to the needs of their clients.

In 2014, about three-quarters of households receiving SNAP benefits also had at least one member enrolled in health insurance coverage through Medicaid or the Children's Health Insurance Program.⁴⁹ As states are implementing new eligibility systems and policies under the Affordable Care Act, this overlap presents an important opportunity to reduce duplication of effort and retain eligible families in these programs. States can use SNAP data to determine Medicaid eligibility without requiring eligible participants to complete a new application and submit supporting documentation to prove their income. In this way, states can simplify the application and eligibility determination processes and coordinate their renewal policies to improve administration, customer service, and program participation.

Similarly, the process of demonstrating eligibility for WIC can be time-consuming and complicated. States often use adjunctive eligibility to simplify the WIC application process. Under adjunctive eligibility, applicants who show proof of participation in SNAP, TANF, or Medicaid are automatically considered income-eligible for WIC.



Because WIC is often housed within state health departments, there is a natural bridge to other public health programs. State health departments can coordinate program operations and foster positive relationships with community partners and other entities that interface with clients, including childcare centers, shelters and food pantries, faith-based organizations, and educational institutions that train nurses and dietitians. Some states have designated WIC "referral days," where the WIC clinic might temporarily suspend services or change its hours of operation to allow local agency staff to physically visit other community partners to learn about other programs so that they, in turn, can make better referrals.

■ SELECTED STATE EXAMPLES

To better understand the referral process in WIC clinics, the **Maryland Department of Health and Mental Hygiene's** Office of Population Improvement started a quality improvement project to learn more about how clients were referred to, or educated about, lead testing, immunizations, smoking cessation, and comprehensive women's healthcare services.⁵⁰ WIC staff make referrals in these four areas, to either the local health department or to community health partners. Each month, more than 10,000 of these public health service referrals are given to Maryland WIC clients statewide with no systematic process of determining or tracking those who ultimately participate in or receive a service to which they were referred. WIC offices and other public health entities had very limited data-sharing capabilities. This project helped not only connect WIC clients to these services, it made the referral process more effective.

Maryland tested several strategies over a period of 10 months to identify ways to help ensure that WIC clients received the services to which they were referred. Health department staff conducted site visits of all the WIC clinics located in Prince George's and Montgomery counties and met with local health department coordinators to map out the procedures and steps taken at each stage of the referral process to identify the root causes of some of the issues within each process that could be made more effective or efficient.

The quality improvement team found that referral rates to family planning services were very low, in part because WIC staff are not trained on comprehensive women's issues. To address this educational gap, the team developed a module in partnership with the health department's maternal and child health program and the WIC training staff. The partnership focused on domestic violence prevention and response, smoking cessation, postpartum depression, and contraception methods. Of all pilot WIC clinic staff, 100 percent completed the module on comprehensive women's health and reported that they felt more comfortable talking with clients about family planning and postpartum depression. As a result, the state WIC program plans to standardize and implement this comprehensive women's health training module statewide.

Housing Assistance Programs

OVERVIEW

A safe, stable, nurturing environment for children starts with secure and affordable housing. Housing is considered an important social determinant of physical and mental health. High-quality, stable housing has been linked with improved health, educational, and economic outcomes.⁵¹ Without affordable housing options, families are often forced into substandard living arrangements, which puts them at risk for lead exposure, asthma, and unintentional injury.

Impoverished communities often lack the businesses, employment opportunities, and other institutional resources that help families thrive. Concentrated poverty limits opportunities for people living in these communities, and social disadvantage perpetuates a cycle of crime, health, and education problems. Without social cohesion, limited neighborhood resources can exacerbate stress. Affordable housing programs are a platform for helping families become self-sufficient.

Housing assistance reduces homelessness,⁵² homelessness increases the likelihood that a child will be placed with relatives or in foster care.⁵³ Housing voucher programs may reduce child abuse and neglect by decreasing children's exposure to crime and violence, and by allowing families to rent properties in safer, more stable, and higher opportunity neighborhoods.⁵⁴

ROLE OF THE HEALTH DEPARTMENT

Some state and local governments offer housing assistance programs for low-income families and individuals who qualify for, but do not receive, federal rental assistance programs.

The most common housing assistance programs include:

- Housing vouchers that allow people to live in private rental housing.
- Public housing, which consists of affordable housing developments managed by public housing authorities.
- Project-based rental assistance, which contracts with private building owners to make apartments affordable.

Linking housing to health, education, workforce programs, and other supportive and case management services may improve outcomes for low-income families and children. State health departments can work with public housing agencies to explore colocating or coordinating health, behavioral health, and



safety and wellness services with housing. State Medicaid agencies can leverage funds to test innovative strategies for bringing housing and Medicaid-reimbursed services together, since homelessness is a major driver of healthcare costs among vulnerable populations.

Racial and economic segregation affects how different groups of people access educational, transportation, healthcare, and employment resources. Opportunity mapping uses a variety of data sources to reveal patterns of segregation and can help policymakers understand how these trends influence access to services that promote economic and physical well-being. State health departments can use local data from public housing authorities, education and transportation agencies, and nonprofit organizations to supplement the U.S. Department of Housing and Urban Development's national data sources to create a more relevant, meaningful picture of local conditions that represent what is actually happening. States can conduct an opportunity mapping analysis and study a variety of different indicators to create an opportunity index for each community in a selected county, for example.

State health departments can also make housing voucher programs easier for families to navigate. Sometimes families who rely on housing vouchers can face discriminatory practices among landlords who refuse to allow voucher holders to rent from their properties, either to circumvent the administrative requirements of the program or because of negative stereotypes of families who participate in a voucher program. States can raise awareness about housing discrimination and enact local laws to prohibit property owners' discrimination against families who use housing vouchers.

■ SELECTED STATE EXAMPLES

In 2012, **New York** used a Section 1115 Medicaid demonstration waiver to overhaul its Medicaid system, and later, in 2014, the state was awarded a Centers for Medicaid and Medicare Services (CMS) State Innovation Model grant to help support its planning and implementation efforts. Part of a larger Medicaid redesign effort, one of the state's priorities under the Supportive Housing Initiative⁵⁵ is expanding supportive housing units and providing rental subsidies for high-risk homeless and unstably housed Medicaid recipients. Supportive housing dovetails with other interventions, providing subsidies for housing providers to offer supportive services to high-risk patients, including older adults and persons living with HIV. Supportive housing providers in New York can use Medicaid funds to expand the supply of permanent supportive housing in the state and better address the health needs of homeless and other individuals. These efforts are coordinated across a variety of state agencies, including the Office of Addiction Services and Supports, the Office of People with Developmental Disabilities, the Office of Mental Health, and the AIDS Institute.

In December 2015, CMS approved a five-year renewal of **California's** Section 1115 Medicaid Waiver, Medi-Cal 2020. Included in the waiver was the Whole Person Care pilot program⁵⁶, a new initiative that allows participating counties to test local strategies to better coordinate physical health, behavioral health, and social services for Medicaid beneficiaries who are high users of multiple healthcare systems

and have poor health outcomes. One of the project's main goals is to improve integration among county agencies, housing authorities, health plans, providers, and other entities within the participating counties so that they can develop an infrastructure that will ensure local collaboration to identify and secure housing for people with medical needs who are experiencing, or are at risk of, homelessness.

Childcare Access

OVERVIEW

Providing high-quality childcare can be one of the biggest challenges for families with young children, yet it is essential to giving their children a strong start. Quality childcare allows parents to work or go to school while also providing young children with the early educational and developmental opportunities they need to be ready to learn and succeed. For parents to take advantage of other vocational training programs or classes intended to help lift them out of poverty by entering the workforce, they first need access to childcare. Quality childcare is an essential support for working families, but, without subsidies, it can be prohibitively expensive.

Childcare subsidies help parents enter and remain in the workforce so that they may provide financially for their families. Parents receiving childcare subsidies tend to choose better quality⁵⁷ and more stable childcare.⁵⁸ Research suggests that state policies improving access to subsidized childcare are associated with decreased child abuse and neglect rates.⁵⁹

The Child Care and Development Block Grant (CCDBG) is the major federal childcare assistance program that provides childcare assistance for low-income families so they can work or participate in education and training. States contribute matching resources for a portion of the CCDBG block grant funding they receive. Although states have different childcare subsidy policies, practices, financing approaches, and administrative structures, they typically use the grants to subsidize childcare for low-income working families, administered through vouchers or certificates, which can be used by parents for the care provider or program of their choice. The vouchers pay part of the fee based on a sliding scale.

The CCDBG was reauthorized in November 2014 with several new measures aimed at improving the continuity and quality of childcare. The CCDBG reauthorization sets out a number of policy changes designed to reduce barriers for families trying to access and maintain childcare assistance. It includes several statutory changes and defines requirements related to the health and safety of childcare settings, improved transparency of information for consumers and providers, new family-friendly eligibility parameters, and quality improvement efforts. As states are developing childcare plans in response to new federal rules, there is a critical opportunity to consider how these programs support both child development and address a broader set of family needs, either directly or by helping parents access other types of services.

ROLE OF THE HEALTH DEPARTMENT

States operate their childcare subsidy programs by creating policies that set income eligibility limits, waitlists, copayments and fees, and provider reimbursement rates. Coordination across state agencies is necessary to ensure that the childcare subsidy program is being administered alongside other state quality improvement initiatives and early childhood systems. While parents always have the option to receive a voucher to use with a childcare provider of their choice, states may also establish direct contracts with providers. In continuing to emphasize quality, above minimum childcare licensing standards, states can require that providers, as a condition of receiving a direct contract, meet national accreditation standards or higher levels of a state quality rating and improvement system (QRIS).



Regardless of whether they are the lead agency for administering the CCDBG, state health departments can conduct outreach to potentially eligible families who participate in programs such as TANF or WIC. Additionally, by creating and maintaining an active, centralized waitlist to illustrate the need for subsidies, particularly in underserved areas, or communities with high levels of poverty or unemployment, states can also make the case for additional resources to support access to childcare for low-income working families.

Many families receiving childcare assistance are also eligible for other benefits and services, but these programs often have separate and cumbersome eligibility and renewal requirements, which can make it difficult for families to stay actively enrolled in all of the programs that are integral to supporting their child's health and well-being. States are increasingly aligning eligibility criteria and other policies across Medicaid, SNAP, and childcare assistance to reduce duplication and more effectively connect families to the services provided through these programs.

■ SELECTED STATE EXAMPLES

In **New Hampshire**, eligibility is coordinated across SNAP, Medicaid, childcare, and TANF, with state offices using a single application for all four programs and aligning documentation and verification practices across programs.⁶⁰ Families receive 12-month eligibility for childcare, and when they receive multiple benefits, the period of time until the family must verify their eligibility again is the same across SNAP, TANF, and Medicaid. The state also created an online portal to allow families to apply for and track multiple benefits, including childcare.

In **Oregon**, the Department of Human Services recommends a budget for establishing subsidy policies. Directed by the legislature, the department implemented policy changes in 2007 by substantially increasing the maximum rates paid to providers, decreasing parents' copays, increasing income eligibility, and increasing the length of time between required redeterminations of eligibility. More recently, in July 2015, the legislature passed HB 2015, making additional reforms to Oregon's childcare subsidy program. It creates financial incentives for families and childcare providers to use the state's QRIS. Families who voluntarily choose a QRIS childcare provider get a reduced copay, and providers with a 3-, 4- or 5-star rating through Oregon's QRIS receive a monthly incentive payment on top of their set reimbursement rate.⁶¹

Quality Care and Education Early in Life

Quality early education programs can positively influence a child's approach to learning and promote social, emotional, physical, cognitive, and language development. Children who have access to high-quality early care and education experiences tend to have better outcomes across these developmental domains.⁶² In addition to addressing children's early learning needs, comprehensive early education programs also engage parents, creating a network of support that centers on strong children, families, and communities and better outcomes.

Policy strategies to promote quality care and education early in life are discussed below.

Early Head Start

■ OVERVIEW

Early Head Start provides early, continuous child development and family support services to low-income infants and toddlers and their families, and also to pregnant women and their families. The primary goal of the program is to support child development, but it has also shown positive impacts on parenting and family well-being.⁶³ Early Head Start has the potential to serve as a hub for a variety of services for the most vulnerable children and families. It is delivered through several program options, including programs that are center-based, home-based, or a combination of the two.

Children in the very young age group served by Early Head Start are in a critical period where nurturing environments are especially important, and adverse experiences can be especially harmful. The focus that Early Head Start places on increasing positive parenting and decreasing corporal punishment might play a role in reducing child abuse and neglect. Parents of children who participate in the program are more likely to enroll them in other early childhood education programs, such as Head Start or state pre-K classes.⁶⁴

In May 2013, data collection and analyses were completed on a joint project between the Early Head Start Research and Evaluation Project, the Administration for Children and Families (ACF) and the CDC to examine child protective service reports among Early Head Start research participants. For the study, researchers matched data on child protective services reports from seven pilot sites. The data show that children in Early Head Start had significantly fewer child welfare encounters between the ages of five and nine years than children in the control group. Additional findings suggest that the program may be effective in reducing child physical and sexual abuse among low-income children.⁶⁵

■ ROLE OF THE HEALTH DEPARTMENT

While the federal Office of Head Start administers the program by awarding grants directly to local grantees across the county, state health departments can consider how to better integrate Early Head Start with other state early childhood services to prioritize healthy child development and learning. States can work with local grantees to help coordinate training and technical assistance, use resources efficiently, and provide guidance on continuous quality improvement. For example, states may have existing networks of public health nurses or home visiting staff who can collaborate and provide additional training and professional development for Early Head Start providers. In lieu of providing direct services, states can use their expertise to improve both the quality of and access to the program and childcare programs, and help create the infrastructure and management systems to support young children and families.

Because state agencies often have administrative and fiduciary responsibility to oversee childcare licensing and subsidy funds, food assistance programs, state pre-kindergarten programs, and early childhood home visiting grants, they can help connect Early Head Start providers with other systems and services

that touch the same families. States can commit to helping local agencies with less organizational capacity use data and information systems to help track longitudinal trends and health outcomes among children and families served by these programs.

■ SELECTED STATE EXAMPLES

In 2014, Congress appropriated \$500 million for Early Head Start-Child Care Partnerships (EHS-CCP)⁶⁶ to expand high-quality, comprehensive early learning opportunities for young children through greater coordination of childcare and Early Head Start services and, at the same time, create a continuum of care from birth through kindergarten. By layering funding, the program integrates Early Head Start comprehensive services and resources into traditional childcare and family care environments, (i.e., by combining existing childcare operating subsidies with Early Head Start funds for both comprehensive and individual child services).

Alabama, California, Delaware, Georgia, Pennsylvania, the District of Columbia, and the Northern Mariana Islands received state-level EHS-CCP grants.



Alabama's Department of Human Resources is partnering with other state agencies and existing Head Start programs to better align state and local early learning system efforts. For example, the department created a memorandum of understanding with the Alabama Department of Health to coordinate healthcare for all families participating in the EHS-CCP initiative statewide. The state's childcare subsidy program is also aligning its eligibility policies with EHS-CCP to streamline the process and better meet the needs of families who are eligible and receiving services through both programs. A state-level Parent Policy Council also serves as an advisory body to the EHS-CCP program.⁶⁷

High-quality Preschool Education

■ OVERVIEW

High-quality preschool education, including pre-kindergarten and Head Start, is increasingly seen as laying a solid foundation for children to acquire school readiness skills and be exposed to rich learning opportunities that promote brain development, healthy behaviors, and relationships with peers and adults. Children who attend high-quality preschool programs are more likely to arrive at kindergarten with social-emotional skills and academic experiences that put them on a path for success. States often prioritize or target enrollment to those children and families living in poverty. Still, only 41 percent of four-year-olds nationwide are enrolled in publicly funded preschool programs, like pre-k and Head Start.⁶⁸

Pre-k and Head Start program models differ in several ways. Head Start is a comprehensive child development program that provides children with preschool education, health screenings and examinations, nutritious meals, and opportunities to develop social-emotional skills. Head Start programs work with families to ensure they have the means to obtain health insurance, services for children with disabilities, adequate housing, and job training. Pre-k programs are funded locally and designed for children ages 3 or 4 to provide one or two years of education prior to kindergarten. These programs focus on children's pre-academic skills to prepare children to enter a school environment. Pre-k programs often operate in conjunction with public school districts, whereas Head Start contracts with local agencies to provide early education and social services for low-income families. Head Start is similar to pre-k, but it serves a broader age group (from newborns to 5-year-olds), as well as pregnant women.

■ ROLE OF THE HEALTH DEPARTMENT

Consistent, meaningful family engagement is an important component of preschool and all early childhood programs that promote children’s development, learning, and wellness, and states play an important role in setting the foundation for effective family engagement. Increased participation in these programs by family members and other caregivers in these programs has been linked to stronger social and emotional skills among young children, and reductions in child maltreatment⁶⁹ and youth violence.⁷⁰ State health departments can work to ensure that family engagement is integrated across early



childhood and education agencies and programs by adopting a unified vision that will enable the state to better coordinate its efforts, and by supporting partnerships with community-based organizations and employers who are in a position to strengthen outreach efforts to parents.

States implement and operate pre-k programs in many different ways and, while access to pre-k is important, the quality of programs is paramount to delivering long-term, positive benefits. Many states are working to establish statewide quality systems for pre-k, and implement policies to ensure continuous improvements and high standards. Quality rating and improvement systems (QRIS) are a major initiative in many states that can be used to align standards and address transi-

tions for infant and toddler development to ensure a continuum of early learning.⁷¹

It lays out quality standards for programs and practitioners, infrastructure to meet these standards, monitoring and accountability systems, plans for ongoing financial assistance that is tied to meeting quality standards, and engagement and outreach strategies.

Through QRIS, states establish tiers of early care and education program quality and programs voluntarily participate in order to receive a quality rating. QRIS is a common framework that creates and links standards across the early childhood system, including childcare, Head Start and Early Head Start, and pre-k. Leveraging QRIS, state health departments might, for example, request that participating providers conduct a systematic assessment of their policies and practices related to referrals for family support services, or they might simply include information on child abuse and neglect prevention in the set of materials and resources that programs participating in QRIS receive.

Collaboration between Head Start and state pre-K programs requires strong partnerships and often involves revisiting how to establish or improve relationships among state and regional education agencies, school superintendents, Head Start providers, teachers, and parents. Federal and state government officials can model collaboration and encourage school districts and Head Start grantees to work together to identify and overcome the barriers that exist. States can explore intergovernmental agreements that would spell out regional, state, and local level strategies for improving the integration of education and services along the early childhood continuum.

■ SELECTED STATE EXAMPLES

Oregon is taking steps to increase equitable access to high-quality learning experiences for all young children and promote family engagement. Members of Oregon’s philanthropic community, and ardent supporters of family engagement and parent education programs, launched the Oregon Parenting Education Collaborative, which has brought Parenting Hubs to nearly every county in the state. The collaborative provides parent workshops, family events, classes, and home visiting services. In 2013, Oregon restructured its early childhood programs, moving several agencies into the Department of Education to form the Oregon Early Learning System.⁷²

Inspired by the Parenting Hubs, the state also created Early Learning Hubs, which began operating in 2013, to coordinate and foster collaborations across sectors that serve children and families. All 16 hubs across the state share common goals, including making families a central part of the state's Early Learning System. While Parenting Hubs serve a universal population, Early Learning Hubs target underserved families and children in the state—yet both are focused on integrated approaches that promote children's kindergarten readiness by teaching and building positive parenting skills. Communities are responsible for identifying the backbone organizations that will support the work of each hub. As a result, hubs have many different kinds of partners serving as their backbone organizations, including education service districts, county governments, community colleges, coordinated care organizations, and non-profits such as the United Way.

In the 2015 legislative session, the Oregon Legislature enacted HB 3380 creating Preschool Promise, a new, mixed delivery preschool model that recognizes that early learning happens in a variety of settings, giving families the ability to choose the preschool setting that works best for them and their child, such as elementary schools, Head Start programs, licensed center- and home-based childcare programs, and community-based organizations.⁷³ Hubs also are working to align their services with the coordinated care organizations that are being established in the state, with some of the organizations providing additional funding to expand parent education and support to families and children in their region.

HB 3380 directs the Early Learning Hubs to coordinate and contract with local preschool providers in the hub's service area to bring new and expanded preschool opportunities throughout Oregon.

Policies to Support Working Families

The way that families live and work has changed. Increasing numbers of children are growing up in single-parent homes or households in which both parents work. Public and private sector family-friendly policies allow working parents to more easily balance family and work priorities and help them earn a living without compromising their ability to give the emotional and developmental support children need in their early, formative years. Family-friendly policies can also help alleviate poverty by making it possible for more people to remain in the workforce.

Policy strategies to support parents and positive parenting are discussed below.

Paid Leave: Family, Parental, and Medical Leave

■ OVERVIEW

Paid leave is time away from work that helps people take care of important life events without jeopardizing their economic security. While paid leave is a relatively common benefit employers provide employees, only 12 percent of private sector workers have access to paid parental and family leave benefits through their employer.⁷⁴

Paid family leave is particularly important for low-income workers, who are often less able to bounce back from a significant loss of income when they need to take leave from work when they have a new child, experience a personal medical emergency, or have a family member who is ill. The high cost of infant care is prohibitive for many families and often forces parents, typically new mothers, to leave the workforce, which can have profound consequences on their lifetime earnings.⁷⁵

There is evidence linking paid leave to better maternal and child health outcomes. Using paid leave following the birth of a child is associated with mothers and fathers taking longer periods of leave, which results in strengthened parental bonding over a child's life, with long-term benefits for brain development and overall well-being. Paid family and medical leave programs can have a positive effect on the financial and physical health of working families, and are associated with reductions in parental

depression and stress,⁷⁶ both of which are risk factors for child physical abuse and neglect.⁷⁷ Paid family leave to care for a newborn has also been associated with reductions in abusive head trauma (i.e., shaken baby syndrome).⁷⁸

There is no national law in the United States that provides paid leave to employees to care for their families. Although the Family and Medical Leave Act (FMLA) mandates that companies provide leave, the law does not require that it be paid. Therefore, unpaid leave is most common, while paid parental leave (beyond paid sick or vacation days) is limited. Without paid family or medical leave, families often cobble together shorter leaves using bits and pieces of earned vacation or sick time.

There are several types of paid leave policies, including:⁷⁹

- Parental leave for mothers (maternity leave) and fathers (paternity leave) for bonding with a new child after birth, adoption, or foster placement.
- Family leave for parents taking care of a child with a serious health condition, or for workers who need to care for ill or disabled adult family members, such as their spouse, parents, or adult children.
- Medical leave for workers with a serious health condition needing time for self-care, including medical leave for women around pregnancy and childbirth.



The federal Family and Medical Leave Act (FMLA) allows people to take up to 12 weeks of unpaid medical, parental, or family leave with the legal right to return to their jobs, but roughly 40 percent of American workers are not eligible for the FMLA benefits because they work for smaller businesses or have not been employed long enough to be eligible.⁸⁰

Several state legislatures are considering bills to establish paid leave programs to build upon the FMLA. California, New Jersey, and Rhode Island have created insurance programs that provide paid family and medical leave to workers. In April 2016, New York became the fourth state with paid family leave, which will go into effect in 2018. Under these state laws, employees continue to receive a portion of their wages while

they are on leave.⁸¹ Other states are adding on to the FMLA's unpaid leave benefits by adopting statutory provisions that expand the definition of family, for example, or apply the law to smaller businesses.

■ ROLE OF THE HEALTH DEPARTMENT

One of the biggest challenges for states that want to implement paid family leave programs is the absence of appropriate, cost-effective state-level financing or administrative structures needed to run these programs. California, New Jersey, and Rhode Island implemented paid family leave programs on top of pre-existing temporary disability insurance programs. While they provide a solid infrastructure for building on paid leave programs, only five states have disability insurance programs.

State health officials can work with partners at the state department of labor and with legislators to explore alternative financing structures, such as looking at existing unemployment and workers' compensation programs, which are often financed through employee or employer payroll taxes, to determine if this method of tax collection could be used to generate enough revenue to fund a new paid leave program in the state.

In states that have paid family leave, state health departments can partner with other agencies, coalitions, and local businesses to disseminate accurate, clear, and comprehensive information about available leave options. To encourage low-income working families to use paid leave benefits, states can work with healthcare professionals who interact with pregnant women and parents of young children, including pediatricians and community health workers, to pass information on to their patients. States can urge

leadership and staff at other organizations that interact with families, such as childcare providers, daycare centers, Head Start programs, WIC offices, and schools, to also provide information to their clients.

State health departments can also support data collection efforts to better illustrate who has access to paid leave benefits and where disparities in access may exist. Expanding data collection and producing annual reports can help educate policymakers and increase public awareness, particularly among low-income workers. Finally, states can formally recognize champions in the business community who are educating their employees about paid leave and encouraging them to take advantage of the benefits that paid leave offers. Commending businesses that actively support their employees demonstrates a commitment to moving toward a broader culture of family-friendly business practices.

■ SELECTED STATE EXAMPLES

By the time it is fully phased-in, **New York State's** paid family leave law will make virtually all employees in the state eligible for 12 weeks of paid leave to care for an infant or a family member with a serious health condition, or to relieve family difficulties when a spouse, domestic partner, child or parent is called to active military service. The law, enacted earlier this year as part of the state budget, will provide job-protected paid family leave to workers in New York regardless of the size of their employer.

New Jersey's Family Leave Insurance (FLI) program is funded through an employee payroll tax and provides up to six weeks of paid leave to bond with a new child or care for a sick family member. Benefits are paid at two-thirds of the worker's average wage, up to a maximum weekly benefit of \$615 in 2016. To make information about paid family leave more accessible, state lawmakers passed a law in January 2016 requiring the New Jersey Department of Labor and Workforce Development to create a one-stop website containing information for the public about paid and unpaid leave benefits available to New Jersey workers. The department also provides an online filing option for individuals wishing to claim paid leave benefits, allowing them to submit required documents online, rather than by mail or fax.

In addition, a yearlong, qualitative study involving low-income parents in New Jersey found that, on average, working mothers who took time off using paid leave reported breastfeeding for one month longer, compared to those who did not use paid leave.⁸²

Paid Sick Leave

■ OVERVIEW

More than 80 percent of low-wage workers do not have paid sick days.⁸³ There are also racial and ethnic disparities in access to paid sick leave. In a survey of a nationally representative sample of U.S. adults, black and Spanish-speaking Hispanic workers were found to be more vulnerable to H1N1 transmission than whites because of a lack of paid sick leave, reliance on public transportation, and fewer options for childcare separate from other children.⁸⁴

Earned, paid sick leave helps working families take time off to recuperate from illness or seek medical care without putting their economic security at risk. Unlike paid family and medical leave, paid sick leave is designed for short-term illnesses or injuries and to support preventive healthcare. Access to paid sick leave promotes public health by reducing the spread of illness.⁸⁵ By allowing employees to seek care during regular business hours, it also reduces healthcare costs by curbing unnecessary visits to the emergency department.⁸⁶ Lastly, paid sick leave supports child and family well-being by helping parents meet their caregiving responsibilities.

There are no federal laws that require employers to provide paid sick leave for their employees. All states provide paid sick leave to at least some state employees, and the federal government provides 13 paid sick days that employees to care for themselves or their families.



In the United States, California, Connecticut, Massachusetts, Oregon, Vermont, and the District of Columbia currently have laws that require employers to provide paid sick leave benefits, along with 26 cities and one county.⁸⁷ As more states and jurisdictions consider similar legislation, there is a growing body of evidence demonstrating that providing access to paid sick leave has positive outcomes for businesses, local economies, and public health.

■ ROLE OF THE HEALTH DEPARTMENT

Nationally, several cities and states have performed health impact assessments (HIAs) on paid sick leave policies, and have developed case studies to describe the implementation of paid sick leave policies. State health departments have an opportunity to lead or serve as experts and key contributors to HIAs. Health departments have access to data sources, such as hospital discharge data, that could be used to monitor indicators associated with paid sick leave over time in order to study whether these policy changes can be linked directly to health outcomes. Health departments could also consider adding a question about paid sick leave to the Behavioral Risk Factor Surveillance System and perform an analysis on access to paid sick leave and preventive care services.

Since there are disparities in access to paid sick leave in the U.S., particularly with respect to socio-economic status, states can take steps to ensure that policies are thoughtfully crafted and implemented to help create systems and cultures that are inclusive of all workers, including a strong communication plan to help spread awareness about the policy. Health departments can play a role in supporting such public information campaigns and in reviewing the results of periodic surveys of employers to assess the impact on small businesses and on families.

■ SELECTED STATE EXAMPLES

In 2016, **Vermont's** governor signed House Bill 187 into law, enacting a statewide paid sick leave law. The requirements will be phased-in starting in January 2017, when Vermont employers must allow employees to accrue and use at least 24 hours (or three days) of earned sick time in a 12-month period. For more than 10 years, getting a paid sick leave law had been a priority for the Vermont Paid Sick Days Coalition, as well as other advocacy groups and grassroots supporters of child health and welfare, workforce and civil rights reform, and domestic violence prevention. Over the years, the coalition worked with Vermont lawmakers, businesses, and the public to educate stakeholders, hear and address concerns, and collect stories about the urgent need for paid sick leave from communities across the state.

The Vermont Department of Health and key stakeholders conducted a health impact assessment to study the possible effects of a statewide paid sick leave policy that was re-introduced during the 2015 legislative session.⁸⁸ A year earlier, having committed to pursuing a Health in All Policies approach to policy development, the department considered several topics for an HIA, but chose paid sick leave because the legislative proposal made it immediately relevant and it had widespread health and health equity implications. Health department staff with HIA experience volunteered to lead the paid sick leave HIA and invited a group of stakeholders to help complete the assessment, including the Vermont Commission on Women, as well as representatives from childcare centers, schools, hospices, trade organizations, and the restaurant industry. Other partners included the Vermont Medical Society, the Vermont Department of Labor, the Lake Champlain Regional Chamber of Commerce, and the Vermont Health Care Association.

Results from the HIA indicated that a paid sick leave law in Vermont would significantly increase access to paid sick leave among low-wage, part-time workers, and employees of small businesses. While empirical evidence demonstrated the link between the availability of paid sick leave and preventable hospitalizations, Vermont data showed that approximately \$6 million in healthcare costs could be saved if implementing a paid sick leave policy reduced avoidable hospitalizations by 10 percent.

State health departments can use HIAs on paid sick leave and other policy proposals as tools to engage the public health and business leaders on issues that affect not only the economy, but also the health and prosperity of individual workers, families, and communities.

Conclusion

Preventing child abuse and neglect is a public health imperative to help all children reach their potential. Adverse experiences in early childhood are associated with poor health and mental health outcomes in children and families, and these negative effects can last a lifetime. Federal, state, and local governments, communities, early childhood professionals, businesses, parents, and other stakeholders share in the responsibility of ensuring child and family well-being. Research has shown what children and their families need to thrive today and into adulthood, at home, in school, at work, and in the community. Because child abuse and neglect affects entire communities, multiple sectors—including medical and behavioral health, law enforcement, judicial, businesses and employers, social services, and nonprofit agencies—need to be involved in systematically implementing policies and services that best meet the needs of children and their families. Policies that help families meet their basic needs and access supportive services in the community can ease the stress that sometimes gives rise to child abuse and neglect. As the examples provided in this guide demonstrate, state health departments and other partners are well-positioned to align programs and policies to link parents to economic resources, such as job training and social services, and create access points for healthcare, childcare subsidies, and other benefits.

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Preventing Injuries and Violence

AN UPDATED GUIDE FOR STATE AND TERRITORIAL
HEALTH OFFICIALS





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Foreword – To Our Members

Injuries and violence affect everyone, regardless of race, sex, or economic status. More Americans die in the first half of life from violence and injuries, including motor vehicle crashes, falls, and homicides, than from any other cause, including cancer, HIV, and influenza. Each year, more than 3 million people are hospitalized, 27 million people are treated in emergency departments and released, and more than 192,000 people die as a result of unintentional and violence-related injuries.¹

In 2013, the total cost of injuries and violence in the United States was \$671 billion.²

Injuries and violence are also responsible for lost years of productive life when one considers the millions of people who survive injuries each year with resulting persistent, lifelong challenges that ultimately affect their health, including physical pain, disability, and emotional and financial problems. The United States needs effective prevention strategies in order to lift the immense health and societal burden of injuries and violence and create a society where people can live to their full potential.

Extensive research shows that a science-based approach is an effective way to prevent injuries: injuries are no longer simply considered “accidents,” because there are identified risk and protective factors that make them preventable. In addition, comprehensive approaches involving policy implementation, environmental changes, and education are necessary in order to effectively prevent injuries.

Similarly, violence can no longer be viewed as solely a “police or criminal justice problem.” The communities people live in can both protect them from violence or increase their risk of violence. We’ve learned that efforts to prevent all forms of violence must address social, emotional, and behavioral elements, as well as family and community environments.

The field of injury and violence prevention has seen remarkable progress. Many important medical, scientific, and public health advances in recent years were made possible by credible science, strong leadership, and committed partners.

State and territorial health departments have an opportunity to improve health and strengthen prevention efforts by integrating health into the work of other sectors. By helping agencies incorporate what is known about injury and violence prevention strategies into effective policies, together we can help ensure the health and safety of individuals, families, and communities nationwide.



Preventing Injuries Through Policy Change

State health departments are frequently called upon to support different types of policy initiatives, including organizational, regulatory, and legislative policies. From child safety to occupational health to traffic laws, we're all familiar with injury prevention policies. But how do you determine the best policy approach for your jurisdiction?

Equipped with a comprehensive understanding of both the burden of injuries in their states and where the opportunities for positive change lie, state health departments can focus their efforts on pursuing the most needed, evidence-based injury prevention policies. Partnerships, such as those with public safety officials, healthcare providers, transportation officials, social services, businesses, and faith-based organizations can help identify and build support for policy, regulatory, and programmatic strategies for preventing and reducing injuries.

When surveying the context of injury prevention in your state, include assessments of potential champions and potential barriers. What have other states experienced? Ask and resolve as many tough questions as you can before determining your course and taking action:

- *How feasible is it to implement this strategy in your state?*
- *Are there resources available to implement it or political will to support it?*
- *Are local communities prepared for the strategy? Will they support it?*
- *Does the strategy address health inequities?*
- *How will the strategy influence the environmental, social, and economic conditions that impact health?*

Many factors influence a policy intervention's effectiveness, such as public awareness and compliance and adequate financial and other resources to support the policy's implementation (e.g., enforcement capacity, education and training, and availability of programs to support and enhance the policy).

Public policies—even those grounded in seemingly popular, scientifically-supported principles—are frequently met with challenges. However, the likelihood of facing challenges doesn't make a public health problem any less worthy of becoming a top priority. It is important to consider your state's priorities and resources along with evidence of the potential solution's effectiveness. Involving a broad group of stakeholders, including local data and subject matter experts and members of the community you want to serve, can help you select the most optimal strategy for your state.

An excellent way to start planning a policy strategy is by contacting the division in your state health department that oversees and administers injury and violence prevention programs. Injury prevention coalitions or networks can also be key collaborators, as many states already have planning groups that engage communities in injury and violence prevention efforts. ASTHO partners with affiliate organization Safe States Alliance, which is the only national nonprofit organization representing state-level injury and violence prevention professionals.

State health departments participate in all of the following aspects of the policy change process:

- Identifying problems or issues.
- Identifying appropriate policy solutions:
 - » Identifying and describing policy options.
 - » Assessing policy options.
 - » Prioritizing policy options.
- Developing strategies for further adoption of policy solutions.

Progress in Injury and Violence Prevention

Over the last several years, injury and violence prevention has become an increasingly integral part of the national public health dialogue. Injury and violence prevention goals fit nicely with other public health priorities, including maternal and child health, the built environment, transportation, and healthy communities. Injury prevention is a priority for CDC, which provides significant resources for researching, translating, disseminating, and evaluating interventions that work.



It stands as an indication of progress that injury and violence prevention is being incorporated into large, cross-sector initiatives to improve population health. For example, the [National Prevention Strategy](#) was developed through the Affordable Care Act and is a blueprint for federal agencies to work across sectors to address health and safety. “Injury and Violence Free Living,” a chapter within the National Prevention Strategy, presents strategies being used across the transportation, justice, health, education, and many other sectors to address injuries and violence. Other chapters within the overall strategy also address injuries and violence, and this has provided an increasing opportunity for cross-agency and cross-departmental collaboration around shared health and safety goals.

Violence prevention collaborative efforts have included work with the U.S. Department of Justice, which has aligned resources and strategies to prevent youth violence (instead of just responding to violence) by increasing positive opportunities for young people. Today, violence is recognized as a major public health problem. These collaborative efforts have also assisted in the development of uniform definitions for topics such as child maltreatment, sexual violence, and suicide in order to improve data collection.

Priorities in Injury and Violence Prevention: An Overview

Policy interventions are important and effective community and societal level strategies for improving the public’s health. ASTHO is releasing this new guide as an update to its 2011 report [Spotting Injury and Violence Prevention on Your Radar Screen: Creating a Legacy in Public Health--A Guide for State and Territorial Health Officials](#). It includes new data and state examples that can be used to affect policy to prevent injuries and violence.

This document will discuss strategies to:

- Assess community needs surrounding injury and violence prevention priority areas and related data.
- Increase the use of evidence-based injury and violence prevention interventions statewide.
- Strengthen state and community level infrastructure, partnerships, and competencies for injury and violence prevention.
- Improve the capabilities of states, local coalitions, and formal alliances to support policies that prevent injuries and violence.

In 2015, CDC’s National Center for Injury Prevention and Control revisited its focus areas and potential opportunities for growth, considering several factors including capability for impact, scalability, external support, and existing evidence-based interventions.

Two issues remain CDC-wide priorities and will continue to be top priorities for the injury center:

- [Motor vehicle injuries](#)
- [Prescription drug overdose](#)

In addition, the injury center identified several areas for increased growth and development:

- [Child abuse and neglect](#)
- [Older adult falls](#)
- [Sexual violence](#)
- [Youth sports concussions and traumatic brain injury](#)

These areas present immediate opportunities for state health officials to begin to reduce the burden of injuries and violence in their states. Within each of these six topic areas, we'll examine what works and identify approaches that states can take to keep people safe, healthy, and productive.

SECTION I. Motor Vehicle Injuries

BACKGROUND

Each year, motor vehicle crashes claim the lives of more than 32,000 people in the United States. More than 2.5 million Americans went to the emergency department and nearly 200,000 were then hospitalized for crash injuries in 2012.³

The economic cost of motor vehicle crashes is estimated at \$242 billion—or roughly \$784 for every person living in the United States—a figure that takes into account lost productivity, property damage, and costs associated with medical care, legal fees, emergency services, and insurance.⁴

Many environmental, behavioral, and medical factors have contributed to declining motor vehicle crash death rates, including technological changes and engineering efforts that improved the safety of vehicles and highways. Federal transportation laws require each state to develop a strategic highway safety plan that focuses the efforts of all state agencies and partners on the highest priority traffic safety needs statewide. Although many lives have been saved due to these advances, individuals who survive crashes may still experience physical pain, disability, and emotional impacts that greatly reduce the quality of their lives.

Fortunately, thanks to decades of research, programs, evaluation, and changes in governmental policies, today we have a much greater understanding of who is most at risk of being involved in crashes and what strategies work to help keep drivers, passengers, bicyclists, motorcyclists, and pedestrians safe.

CREATING A CULTURE OF SAFETY

Although motor vehicle crashes clearly have a health impact on individuals and society, traffic safety has often been considered an issue for the transportation sector. However, CDC has been working with transportation safety as a public health issue for more than 20 years. Collaboration between traffic safety and public health has been successful in framing motor vehicle injuries in the context of other preventable causes of death and disease and in influencing the notion of a “culture of safety.”



Policy changes are most effective when they take place within a culture of safety, which state health departments can help create by working with state department of transportation and state highway safety offices, law enforcement, advocates, and community partners to support programs, raise awareness, and change the behaviors that contribute to reducing motor vehicle-related injuries. Health departments can help educate the community about the importance and effectiveness of the laws and their enforcement.

MOTOR VEHICLE INJURY PREVENTION: A WINNABLE BATTLE

Motor vehicle injury prevention is recognized as one of CDC's Winnable Battles.⁵ Each Winnable Battle priority has a clear set of targets and a method to track and measure progress. The Winnable Battle targets also support related federal priorities and initiatives, such as Healthy People 2020.

Winnable Battles-Related Healthy People 2020 Objectives: Motor Vehicle Safety⁶

IVP 13.1 Reduce motor vehicle crash-related deaths

2020 Target: 12.4 deaths per 100,000 population

Baseline: 13.8 deaths per 100,000 population (2007)

IVP 14 Reduce nonfatal motor vehicle crash-related injuries

2020 Target: 694.3 nonfatal injuries per 100,000 population

Baseline: 771.4 nonfatal injuries per 100,000 population (2008)

KEY STRATEGIES

There are several types of prevention strategies and policies that states may consider to reduce motor vehicle crash injuries and death.

Strategy #1: Reduce injuries and deaths in motor vehicle crashes by increasing the use of seat belts and child safety seats and booster seats.

Strategy #2: Protect teen drivers with comprehensive graduated driver licensing systems and parental monitoring.

Strategy #3: Reduce alcohol-impaired driving with evidence-based prevention strategies, such as ignition interlock programs.

Each of these strategies is discussed in the following sections.

Strategy #1: Reduce injuries and deaths in motor vehicle crashes by increasing the use of seat belts and child safety seats and booster seats.

The strategies presented below are effective for increasing seat belt, car seat, and booster seat use. They are recommended by [The Community Guide](#) or have been demonstrated to be effective in reviews conducted by the National Highway Traffic Safety Administration.⁷ In 2013, the Obama administration released [Countermeasures That Work: A Highway Safety Countermeasure Guide for State Highway Safety Offices](#), which helps select effective, science-based traffic safety countermeasures for major highway safety problem areas.



(1) Seat Belts

Seat belts reduce serious crash-related injuries and deaths by approximately half. In 2013, seat belts saved an estimated 12,584 lives among passenger vehicle occupants ages 5 and older. The national seat belt use rate in 2013 was 87 percent, up slightly from 86 percent in 2012.⁸ However, among those who died in motor vehicle crashes, nearly half were not buckled up.

Primary enforcement laws have been shown to do more to increase seat belt use and reduce deaths than secondary enforcement laws. States that switch from secondary to primary seat belt enforcement laws have increased their rates of seat belt use after primary enforcement laws went into effect.

A 2015 study published in the *Annals of Internal Medicine* compared motor vehicle-related fatality rates among persons age 10 or older between 2001-2010 in states with primary seat belt laws and in states with secondary laws. The fatality rate was 17 percent lower in states with primary seat belt laws.⁹ Another study published in *The Journal of Safety Research* found that primary enforcement covering all seating positions is an effective intervention that can be employed to increase seat belt use and, in turn, prevent motor vehicle injuries to rear-seated occupants.¹⁰

The most comprehensive policies are primary seat belt laws that cover all occupants regardless of where they are sitting in the vehicle.

According to CDC, to increase seat belt use among adults, states can:¹¹

- Make sure that police and state troopers enforce all seat belt laws. Consider steeper penalties, like higher fines. Excessively low penalties may have little effect.
- Support seat belt laws with visible police presence and awareness campaigns for the public. Studies show that publicized enforcement campaigns such as “Click It or Ticket” can help sustain high levels of compliance over time.
- Educate the public to make seat belt use a social norm.

As of October 2015:¹²

- Thirty-four states, Washington, D.C., American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands have primary seat belt laws for front seat occupants.
- Fifteen states have secondary laws. In many of these states, the law is primary for younger drivers and passengers.
- Twenty-eight states, Washington, D.C., Guam, and the Northern Mariana Islands have laws requiring belt use for all rear seat passengers. The law is primary in 17 of these states, Washington, D.C., Guam, and the Northern Mariana Islands.

In some states, there is substantial opposition to changing a secondary law to a primary belt use law. Some opponents claim that primary laws impinge on individual rights and provide opportunities for law enforcement to single out certain groups on the basis of race. However, studies that have examined this issue have found no evidence of racial profiling with respect to primary belt laws.^{13, 14} States have also added anti-harassment language to their primary seat belt laws to reduce the risk of differential enforcement.^{15, 16}

Rhode Island's Primary Seat Belt Law

Rhode Island enacted a primary seat belt law in June 2011. Although the initial law had a two-year sunset provision, it was made permanent in 2013 with a \$40 fine for offenders. The 2014 seat belt use rate for Rhode Island was 87.4 percent for drivers and passengers combined.¹⁷ These rates have fluctuated over time, but have shown an overall upward trend in seat belt use. The largest increase (from 77.5 percent in 2012 to 85.6 percent in 2013) was likely due to the law becoming permanent and the presence of enforcement-based messaging around the state.¹⁸

Enactment of the law made Rhode Island eligible for an additional \$3.7 million in federal funding for incentive grants to increase seat belt use. Rhode Island has increased statewide awareness of the law through media campaigns and committed one million dollars to support minority community education on seat belt use.

(2) Child Passenger Safety

Any restraint is better than none at all, but when correctly used child restraints provide the best protection in a crash until children are large enough for adult seat belts to fit properly.¹⁹ Buckling children in age- and size-appropriate car seats, booster seats, and seat belts reduces serious and fatal injuries.²⁰ Child restraints also reduce fatalities in passenger cars by 71 percent for infants younger than 1 and by 54 percent for children 1 to 4 years old.²¹

In 2011, the American Academy of Pediatrics released its updated child passenger safety recommendations, which call for children to remain in rear-facing child safety seats until they reach age 2 or until they outgrow the height and weight limits determined by the manufacturer of their rear-facing child safety seat. Although intended to educate parents on the best practices to protect their children from death or injury while traveling in a vehicle, these recommendations also provide guidance to state policymakers.²²

Today, all states and territories have child passenger safety laws, although requirements of the laws vary widely. State laws and regulations generally use a child's age, height, and weight to determine whether a car seat, booster seat, or seat belt should be used.

Child passenger restraint laws that increase the age for car seat or booster seat use result in more children being buckled up. Among five states that increased the required car seat or booster seat age to 7 or 8 years, car seat and booster seat use tripled, and deaths and serious injuries decreased by 17 percent.²³

Many state child restraint laws contain gaps in coverage or provide exemptions that allow children to go unrestrained in certain circumstances. For example, even when states have laws covering older children, many of them fail to distinguish child passengers in need of rear-facing infant seats from those who should use booster seats.

States can support child passenger restraint laws that require car seat or booster seat use for children ages 8 and under or until seat belts fit properly (lap belt lays across upper thighs and shoulder belt lays across the shoulder, not the neck or face).²⁴

As of October 2015:²⁵

- All states and territories require child safety seats for infants and children fitting specific criteria, but requirements vary based on age, weight, and height.
- Forty-eight states, Washington, D.C., and Puerto Rico require booster seats or other appropriate devices for children who have outgrown their child safety seats but are still too small to use an adult seat belt safely.
- Three states (California, New Jersey, and Oklahoma) require that children younger than 2 years of age be in a rear-facing child seat.
- Five states (California, Florida, Louisiana, New Jersey, and New York) have seat belt requirements for school buses.

States can take several approaches to keep costs reasonable and help parents obtain restraints. States can also support car seat and booster seat give-away programs that include education for parents or caregivers.

California's "Who's Got Car Seats?" and Vehicle Occupant Safety Program

California's child passenger safety laws require all children under 8 years old to be buckled in a car seat or booster seat in the rear seat of the vehicle and all children under 16 years old to be in a car seat, booster seat, or vehicular seat belt properly restrained. For each child who is not properly secured, drivers can be fined more than \$475 (minimum fine is \$100) and get a point on their driving records.²⁶

The funds from the fines collected under this law are allocated such that 60 percent (and up to 85 percent) goes to local health departments for community education and assistance programs. There is a child passenger safety coordinator in each California county health department who works directly with the court systems, hospitals, law enforcement, and other local agencies and oversees the transfer of funds into the program.

When state or local law enforcement issue child passenger safety citations, the courts have the option to refer drivers to violator education programs, community programs that include education on the proper installation and use of child passenger restraint systems for children of all ages. These programs are managed and supported by the California Department of Public Health's (CDPH) Vehicle Occupant Safety Program (VOSP), which works closely with local health departments, hospitals, community agencies, child care providers, law enforcement, municipal court systems, and other state and local agencies to develop child passenger safety educational programs and offer low cost or loaner car seats for low-income families. VOSP developed violator education program curriculum guidelines to enhance standardization of these programs statewide.

In 2013, California amended its law to require that public or private hospitals, clinics, or birthing centers provide parents or caregivers with information on current child passenger safety state laws, the use of proper child restraints, and transportation of children in the rear seats.

CDPH maintains a list of "Who's Got Car Seats?" which is mandated in statute to be updated annually and posted to the VOSP website. It shows a list of child passenger safety programs and services by county and whether the county has a violator education program. This information is provided to local courts, birthing centers, community child health and disability prevention programs, county clinics, prenatal clinics, agency locations for the Special Supplemental Nutrition Program for Women, Infants, and Children, county hospitals, and the public.²⁷

Strategy #2: *Protect teen drivers with comprehensive graduated driver licensing systems and parental monitoring.*

Teen Drivers

Motor vehicle crashes are the leading cause of death for U.S. teenagers.²⁸ The risk of motor vehicle crashes is higher among 16 to 19-year-olds than among any other age group, and that risk is highest during the first year that a teen has his or her license. Young drivers tend to overestimate their driving abilities and underestimate the dangers on the road. Immaturity leads to speeding and other risky habits, and inexperience means that teen drivers often don't recognize or know how to respond to hazards.²⁹

Graduated licensing helps new teenage drivers gain skills under low-risk conditions.³⁰ Graduated driver licensing (GDL) programs grant driving privileges in three stages: a supervised learner's period, an intermediate license (after passing a road test) that limits driving in high-risk situations except under supervision, and a license with full privileges.

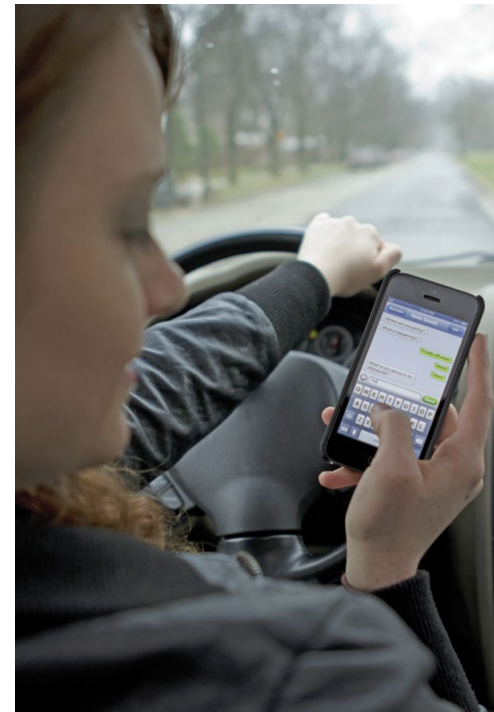
There is no national GDL system, and state laws vary. Research indicates that more comprehensive GDL systems prevent more crashes and save more lives than less comprehensive GDL systems. On the basis of this evidence, research funded by the National Institutes of Health found that the most effective legislation had at least five of the following seven key elements:³¹

- Minimum age of 16 years for a learner's permit.
- Mandatory waiting period of at least six months before a driver can apply for an intermediate license.
- Requirement for 50 to 100 hours of supervised driving before testing for an intermediate license.
- Minimum age of 17 years for an intermediate license.
- Restrictions on nighttime driving.
- Limit on the number of teenage passengers allowed in the car.
- Minimum age of 18 years for licensure with full privileges.

Some states have applied additional restrictions on young drivers, including:

- Cell phone use bans.
- Texting bans.
- Seat belt requirements.
- Zero tolerance for driving under the influence of drugs or alcohol.
- Stronger penalties for offenses that occur during the intermediate licensing stage.
- Minimum standards for driver education.

An online calculator developed by the Insurance Institute for Highway Safety shows how much each state could reduce the fatal crash rate for teens if it adopted the strongest policies in five GDL components, including permit age, practice driving hours, license age, and restrictions on night driving and teen passengers.³²



CDC's [Parents Are the Key](#) campaign helps parents, pediatricians, and communities keep teen drivers safe on the road.³³

As of October 2015, states mitigate these risks in the following ways:³⁴

- **Cell Phones and Texting:** 38 states and Washington, D.C. ban all cell phone use by novice drivers.
- **Nighttime Driving Restriction:** 48 states and Washington, D.C. restrict nighttime driving during the intermediate licensing stage.
- **Passenger Restriction:** 46 states and Washington, D.C. restrict the number of allowed passengers during the intermediate licensing stage.
- **Novice Driver Decal:** New Jersey is the only state with a measure requiring individuals younger than 21 without full-privilege licenses to display a decal on their vehicle identifying them as new drivers.

The Parents Are the Key campaign identifies the eight major risks affecting teen drivers as:

- Driver inexperience.
- Driving with teen passengers.
- Nighttime driving.
- Not using seat belts.
- Distracted driving.
- Drowsy driving.
- Reckless driving.
- Impaired driving.

Nebraska's Driver Education Program Results in Fewer Crashes

In Nebraska, driver education appears to be an important tool within the context of GDL, reducing crashes and violations for teen drivers in their first two years of driving.³⁵ Nebraska has a modified three-stage GDL system where a teen can apply for a provisional operators permit following the one-year learner's permit stage. To apply for the provisional operators permit, the teen must either complete a Department of Motor Vehicles-approved driver education safety course and pass written and driving tests obtain a 50-hour Certification Form log signed by a parent, guardian, or licensed driver who is at least 21 years old.

The Nebraska Prevention Center for Alcohol and Drug Abuse received a grant from the Office of Highway Safety to study Nebraska teen drivers from 2003-2010. The study found that teens who participated in the driver education program had significantly fewer overall crashes, crashes involving injuries or fatalities, traffic violations, and DUIs in both the first and second year of driving than teens who obtained their provisional license by completing 50 hours of adult supervised driving.³⁶ Driver education appears to enhance the effectiveness of GDL as a complementary strategy, and state policies might consider how to strengthen educational requirements within the GDL environment.

Utah's Teen Driving Task Force

The Utah Department of Health's Injury Prevention Program, with support from CDC's Core Violence and Injury Prevention Program, analyzed 20 years of data on motor vehicle crashes and found a decrease in teen crash fatalities over the last 20 years, with a 61 percent decrease occurring after the 1998 passing of a GDL policy.³⁷

According to a statewide randomized survey, 56 percent of adults in Utah were not aware of nighttime driving restrictions for teen drivers, and 21 percent were not aware of passenger restrictions. A further review of Utah's in-school teen driver education program, overseen by the Utah Office of Education, found that the driver education curriculum was outdated and lacked parental involvement despite national recommendations to the contrary.

Through the Utah Teen Driving Task Force, the Utah Department of Health worked closely with the Office of Education to rewrite Utah's driver education curriculum so that it is now based on evidence, informed by local data, supported by local and national resources, and includes parent classes. The Utah Department of Health also contracted with local health departments and trained staff at each to collaborate with the Zero Fatalities Program and their high school driver education instructors to teach parent classes throughout the state on teen driving and passenger restrictions.

Strategy #3: *Reduce alcohol-impaired driving with evidence-based prevention strategies, such as ignition interlock programs.*

Impaired Driving

In 2013, more than 10,000 people died in alcohol-impaired driving crashes in the United States—one every 51 minutes.³⁸ Alcohol impairment accounts for nearly one-third (31%) of all traffic-related deaths in the United States. Strategies for reducing alcohol-impaired driving, as well as the associated injuries and deaths, may include legislation and policy approaches, sobriety checkpoints, and school-based programs.

Ignition interlocks, when appropriately used, reduce repeat offenses for driving while intoxicated (DWI) by approximately 70 percent, resulting in increased safety for everyone on the road.³⁹ All states have enacted legislation requiring or permitting the use of breath alcohol ignition interlock devices to prevent alcohol-impaired driving. An ignition interlock is a device connected to a vehicle's ignition that prevents the vehicle from starting unless the driver blows into the interlock and has a blood alcohol concentration (BAC) below a pre-set low limit, usually .02 BAC.

Impaired driving is often linked to a bigger problem: alcohol misuse and abuse. Data collected by the interlock can provide substance abuse treatment providers with information regarding the person's consumption and behavior, which helps support better treatment outcomes. Costs associated with interlock devices are usually paid by the offenders and average \$3-4 per day in addition to the average initial installation charge of approximately \$70-90 and additional monthly fees to download and report the interlock data.⁴⁰ One challenge that state programs face is that some offenders cannot afford the fees associated with an interlock sanction.

How can states increase ignition interlock use?

CDC and the National Highway Traffic Safety Administration collaborated on an evaluation conducted by the Preusser Research Group and managed by the Governors Highway Safety Association that aimed to provide information and best practices to states for ignition interlock programs. The evaluation looked at key features of interlock programs and use of interlocks in 28 states from 2006–2011.⁴¹

States may consider using the following eight program keys to strengthen state alcohol ignition interlock programs. Implementing just one of these program keys is likely to increase interlock use, and implementing multiple program keys is associated with even higher increases in interlock use.

Eight Program Keys for Strong State Alcohol Ignition Interlock Programs

Program Key	Characteristics of a Strong Program Key	Example
Require or incentivize use.	Requirement or strong incentive to install interlocks.	A law covering all offenders with significant reduction of hard license suspension period if interlock is installed.
Levy strong penalties.	Strong, swift, and appropriate penalties.	Extension of interlock time, home monitoring, or jail time if refuse to install, fail breath test, or tamper or otherwise circumvent interlock.
Monitor interlocks to ensure proper use.	Careful monitoring to assure interlocks are installed and used as intended.	Random checks by DMV, probation, or treatment centers to ensure offender has installed and is using an interlock.
Implement uniformly across state.	Uniform and consistent implementation, statewide.	All agencies report data regularly in compatible format, using uniform definitions of violations in same time frame.
Coordinate across agencies.	Close coordination and communication across all agencies.	Regular communication with representatives from all interlock program involved agencies.
Educate stakeholders about the program.	Regular training or education for all interlock agency staff and management.	Regular trainings between interlock program managers, law enforcement, vendors, DMV, and court staff.
Provide adequate resources.	Adequate staff and funding resources.	Designated interlock program manager and staff, and financial assistance for offenders.
Use data for action.	Excellent data records (including level of offense, BAC level at time of arrest, number of prior arrests, installation and removal dates, and violations).	Combined annual data on offenders available from all agencies to monitor offenders, report violators, and evaluate program effectiveness.

SECTION II. Prescription Drug Overdose

BACKGROUND

The misuse and abuse of prescription drugs in the United States is widespread and the impact it has on states and communities is troubling. From 1999 to 2013, the amount of prescription opioids prescribed and sold in the United States nearly quadrupled, and overdose deaths quadrupled in lockstep.⁴² In the United States, drug poisoning has now surpassed motor vehicle crashes as the leading cause of injury death. These deaths are attributable largely to an increase in overdoses involving prescribed controlled substances, especially opioid analgesics.⁴³

Opioids have a role in treating some types of pain, but the misuse and abuse of these drugs is a serious public health concern. Although recent data suggests that nonmedical use of prescription opioids among adults ages 18-64 years has decreased, the prevalence of prescription opioid use disorders increased, as did the number of “highly frequent” users, or individuals with 200 days or more of nonmedical opioid use in the past year.⁴⁴

Using multiple drugs, such as alcohol and sedatives, can increase overdose risk. Studies have shown a strong relationship between inappropriate opioid prescribing and negative health outcomes. Higher daily doses (as calculated by the morphine milligram equivalent dose per day, generally >100 morphine milligram equivalent per day) have been associated with misuse, emergency department visits, and overdoses.^{45,46} Now, growing evidence suggests that people who misuse prescription opioids are shifting to heroin, which is cheaper and, in some communities, easier to obtain. Heroin deaths are increasing sharply, with the number of fatal overdoses tripling since 2010.⁴⁷

Prescription drug abuse is costly for communities, leading to increased healthcare costs and greater risk of homelessness, incarceration, placement of children into foster homes, drug exposed pregnancies, and early death. Comprehensive strategies must take into account the complex interplay of factors and social determinants of health that are driving this epidemic. Some people who misuse prescription drugs believe that these substances are safer than illicit drugs because they are monitored and distributed through the healthcare system. This misperception may contribute to individuals, particularly youths, initiating first-time nonmedical use of prescription drugs.

In the same way that public health officials would approach other disease outbreaks, reversing the trend in prescription drug overdoses requires a comprehensive approach. To be most effective, this approach should be multidisciplinary, with strategies that include prevention and education, surveillance and monitoring with tools such as prescription drug monitoring programs (PDMPs), diversion control through law enforcement and licensure efforts, and a focus on treatment and recovery.



KEY STRATEGIES

As states continue to explore policy options to address prescription drug abuse and misuse, it will be crucial to ensure a focus on prevention as well as treatment. It is important to think about (1) establishing systems to monitor the prevalence of prescription drug abuse and to use data to ensure coordinated policies and programs across key agencies, and (2) using data-driven approaches to eliminate or reduce the impact of prescription drug misuse and abuse.

At the policy or regulatory level, states can:

- Enhance surveillance and monitoring through PDMPs to improve prescribing, inform clinical practice, and protect at-risk patients.
- Promote clinical practice tools that support clinicians in preventing unintended dangerous or inappropriate use of prescription drugs.
- Use oversight approaches to prevent multiple provider episodes (“doctor shopping”), pain clinic operation, and other prescriber practices outside of accepted medical standards.
- Improve access to overdose prevention tools such as naloxone, a medication designed to counter the effects of opioid overdose, as well as to drug abuse treatment and rehabilitation.

State health departments can continue to provide leadership and support efforts to prevent prescription drug overdose by:

- Conducting surveillance and monitoring to identify individuals at highest risk of prescription misuse or overdose.
- Communicating with policy and decisionmakers regarding the overall burden of prescription drug overdoses within the state and policy strategies for preventing overdose and death.
- Raising awareness among the general public regarding the prescription drug overdose epidemic and steps that individuals can take to prevent addiction and overdose.
- Developing and disseminating clinical support tools to strengthen practices and prevent dangerous prescribing, while assuring access to legitimate pain management.
- Monitoring, evaluating, and sharing results of actions taken to reduce prescription drug overdoses.

Prescription Drug Monitoring Programs

PDMPs can serve both public health and public safety objectives in a collaborative manner. Appropriately prescribing and dispensing controlled substances can reduce their diversion and abuse, and law enforcement efforts to limit drug diversion can protect public health. This is similar to the collaborative efforts between public health and law enforcement to reduce motor vehicle-related injuries and deaths.

Primary areas in which PDMPs can be used to meet public health objectives include:

- **Education:** Providing information on prescribing trends and raising general awareness of the prescription drug abuse epidemic.
- **Epidemiological Surveillance:** Using PDMP data to understand prescribing trends and the prevalence of controlled substance use statewide and by county, region, or city.
- **Prevention:** Enabling healthcare providers to avoid prescribing duplicate therapies and creating deterrents to drug diversion.
- **Early Intervention:** Detecting patients at risk of drug abuse at initial stages of drug-seeking behavior.

Using state PDMPs is a valuable way to enhance patient care when prescribing and dispensing controlled substances. States have many different models of administrative oversight, specific drugs targeted for monitoring, methods of data collection, and levels of information sharing. Although PDMP best practices and recommendations have not been firmly established nationwide, many states are moving forward with a set of promising strategies and implementing core program elements, including:⁴⁸

- **Universal Use:** Prescribers use PDMP each time they prescribe opioids and other controlled substances.
- **Real-Time:** PDMP reduces the prescription drug data transmission time between dispensers and PDMPs, with the goal of real-time access (i.e., under five minutes).
- **Actively Managed:** Agencies are using PDMP data for public health surveillance and to send proactive reports to authorized users to protect patients at the highest risk. The system is linked in a way that allows for comprehensive interstate data sharing.
- **Easy to Use Available Access:** PDMPs are easy to use and integrated into the clinical workflow, which eliminates practical, bureaucratic, and legal barriers to prescription drug information sharing.



Prescribing Guidelines

Improving the way opioids are prescribed through clinical practice guidelines can promote safe, effective treatment while reducing opioid-related abuse and overdose. Prescribing practices that may be addressed through guidelines include: determining when to initiate or continue opioids for chronic pain outside of end-of-life care; adjusting opioid selection, dosage, duration, follow-up, and discontinuation; and assessing the risk and addressing the harms of opioid use.⁴⁹

Prescribing guidelines can present different treatment approaches for acute and chronic pain; assess potential abuse risk before prescribing; help prescribers develop “contracts” that clarify pain

management expectations, goals, and responsibilities for patients and prescribers; and encourage use of the lowest effective dose of pain medication for the shortest possible duration.⁵⁰

Pain prevention, assessment, and treatment is a challenge for both health providers and systems. Professional organizations, states, and federal agencies, including the American Academy of Pain Medicine, the Washington Agency Medical Directors Group, and the U.S. Department of Veteran Affairs, have all developed guidelines on opioid prescribing.^{51,52,53} Addressing inappropriate prescribing through guidelines can potentially disrupt the cycle of opioid pain medication misuse and abuse that contribute to the overdose epidemic.

Regulatory Action – Pain Clinics and Oversight

Many states have increased their enforcement efforts in order to curb prescription drug abuse. State medical boards are typically composed of physician and public members who are often appointed by the governor. Some boards are independent, exercising all licensing and disciplinary powers, while others are part of a larger state agency, such as the state health department, which may act as an advisory body. Regulatory actions can also help change behaviors among both providers and patients. Because states have the ability to regulate healthcare practices and monitor prescriptions, many of the critical policy levers exist at the state level.

A state's policy response should include coordination among many agencies and stakeholders with interests or responsibilities related to prescription opioid use, including health departments, insurance and workers' compensation bureaus, boards or agencies that regulate and license pharmacists and prescribing physicians, law enforcement, and other governmental entities that may play a role monitoring and enforcing policies.

To understand the legal authority needed to address inappropriate prescribing, doctor shopping, and "pill mills," states should review the existing statutes, rules, and relevant policies of non-government agencies, such as medical professional societies, that address opioid prescribing. A balanced approach is also important. States should be aware of unintended or potentially harmful consequences associated with establishing new standards of practice or changing the statutory and regulatory requirements for pain management clinics.

Many jurisdictions have developed interagency task forces to specifically address opioid abuse. One example of interagency collaboration is the Agency Medical Directors' Group (AMDG) in Washington state. AMDG was responsible for the development of the **Opioid Dosing Guideline for Chronic Non-Cancer Pain** (originally published in 2007) which was intended as an educational pilot to address how opioids were used to treat chronic pain. AMDG included medical directors of five Washington state agencies: Corrections, Health, Health Care Authority, Labor and Industries, and the state's Medicaid program. Boards and commissions that set practice standards reviewed the guideline, and the workgroup also received input from others in state government and the medical and scientific community.

Use of the AMDG Guideline, along with other robust statewide efforts, resulted in a 29 percent decrease in prescription opioid-related deaths between 2008 and 2013. Hospitalizations for prescription opioid overdose also decreased 29 percent between 2011 and 2013. The guidelines have since been evaluated and updated (in 2010 and 2015) to reflect current medical evidence and trends in opioid prescribing patterns.

Texas' Closed Formulary

Formularies can influence prescribing practices by requiring physicians to obtain authorization to prescribe non-formulary drugs, like benzodiazepines and some opioids that are often used inappropriately, by certifying that the drugs are medically necessary to treat the injured patient. Some states have also implemented closed formularies for prescription drugs in an effort to control overutilization of expensive opioid medications. Closed formularies, such as those in Ohio, Texas, and Washington state, allow a limited list of covered medications for workers' compensation claims. In 2014, Oklahoma's Workers' Compensation Commission established a formulary under "emergency rules."

Texas adopted one of the nation's first workers' compensation pharmacy closed formularies in September 2011. It took time to get the program up and running: Texas started the process in 2005 by passing HB 7, which created the Division of Workers' Compensation (DWC) within the Texas Department of Insurance and authorized a closed formulary for prescription medications. After establishing the necessary regulatory infrastructure and developing treatment guidelines, the state is beginning to see results. In August 2014, DWC reported that under the closed formulary, the total number of claims receiving not-recommended "N" drugs (drugs that are not appropriate for first-line therapy) was reduced by 65 percent between 2010 and 2011.

The closed formulary has also significantly reduced prescription drug costs in the Texas workers' compensation system and impacted prescribing patterns for Texas physicians treating workers' compensation claims. The frequency of all opioid prescriptions was reduced by 11 percent and the frequency of "N" drug opioids was reduced by 64 percent between 2010 and 2011. Although more medications now require pre-authorization as a result of the closed formulary, DWC has worked on its administrative processes to improve communication and care coordination between insurance carriers and prescribing physicians, which has resulted in fewer consumer disputes since the formulary took effect.

Overall, total pharmacy costs for 2011 were reduced by approximately \$6 million when compared to 2010 claims. These cost reductions were even more significant for "N" drugs, which saw reductions of up to 82 percent.⁵⁴

Overdose Prevention

States are pursuing a number of strategies to reduce and prevent fatal opioid overdose. Naloxone, an opioid antagonist medication used to treat overdose, is an important part of a continuum of substance abuse services that includes prevention and intervention efforts, access to treatment, and recovery support services.

Improving access to emergency intervention—and, in particular, naloxone—has shown to be effective in reducing negative consequences associated with drug use. There have been efforts at both the federal and state levels to ensure naloxone availability, but access and cost barriers remain: the price of intranasal naloxone more than doubled in the second half of 2014. More than half of states have passed laws expanding naloxone access and offer some level of immunity from prosecution for seeking help for someone during an overdose occurrence. Because a large number of overdose deaths involve pharmaceuticals, it is critical that appropriate overdose response services are available in conjunction with protection from prosecution in emergency help-seeking situations.

In 2014, New York equipped 19,500 police officers with naloxone to combat overdoses across the state.⁵⁵ The U.S. Office of the Attorney General recommends that federal law enforcement agencies train personnel who may interact with opioid overdose victims and equip them with naloxone. Citing the Network for Public Health Law, state and local public health officials, regulatory boards, and other stakeholders are considering many legal and policy questions regarding overdose prevention, such as:⁵⁶

- What are the emerging best practices regarding “Good Samaritan” drug overdose laws?
- Are there liability concerns related to police officers administering naloxone?
- Are nurse practitioners in my state permitted to write naloxone prescriptions?
- What are the rules governing pharmacist collaborative practice agreements for naloxone?

Early evidence indicates that efforts to prescribe and dispense naloxone have been successful. According to a report published by the Harm Reduction Coalition, by June 2014, at least 644 local, community-based opioid overdose prevention programs in the United States provided naloxone to laypeople, including drug users, their friends and family, and service providers who had the potential to witness an overdose. More than 26,463 drug overdose reversals using naloxone were reported between 1996 and June 2014.⁵⁷

Vermont’s Care Alliance for Opioid Addiction

Vermont has taken a multipronged approach to addressing opioid addiction that includes multiple community partners, regional prevention efforts, drug take-back programs, recovery services at 11 recovery centers across the state, and naloxone kit distribution to prevent overdose deaths. In 2013, the Vermont Legislature tasked the Vermont Department of Health with developing and administering a statewide pilot program for distributing the naloxone kits.

The [Care Alliance for Opioid Addiction](#) is at the heart of Vermont’s comprehensive treatment system, responsible for regional centers (hubs) that provide intensive addiction treatment to patients and consultation support to medical providers (spokes) treating patients in the general practice community.⁵⁸ Because patients treated in the hubs and their families may have contact with people at high risk of overdose, the hubs are uniquely positioned to enroll people in the program and provide training and intervention resources. By January 2015, the state health agency had distributed 2,385 overdose rescue kits to the pilot sites. More than 1,400 have been dispensed to patients and family members, and more than 100 kits have been used to save lives.⁵⁹

SECTION III. Preventing Child Abuse and Neglect

BACKGROUND

Child maltreatment is a significant public health problem that requires a multifaceted approach across healthcare, education, child welfare, and juvenile justice. Child maltreatment and other adverse childhood experiences (ACEs) are non-specific risk factors for multiple diseases and conditions. Adversity in childhood also contributes to multigenerational illnesses and disparities. Because children who experience maltreatment

CDC has classified four common types of abuse:

- Physical abuse
- Sexual abuse
- Emotional abuse
- Neglect



are more likely to endure persistent and negative health outcomes later in life, it is critical to address the broader social and economic causes of child maltreatment through prevention-focused efforts. Effective prevention strategies can help stop child abuse and neglect before it happens.

Preventing child maltreatment requires a two-pronged approach: behavior change at the individual level, and at the same time, a focus on creating healthy relationships between families and neighbors, supporting community involvement, and promoting policies and societal norms to create safe, stable, and nurturing environments.

Brain development is shaped by different biological, psychological, social, and environmental factors, and traumatic experiences in early childhood are correlated with changes in brain physiology and functioning. When children feel safe and nurtured, their brains can focus on learning instead of focusing solely on survival-oriented tasks. Prolonged, chronic stress in early childhood can set children on a lower learning and achievement trajectory, adversely impacting an entire country's social and economic development in the long run.

States can take several steps now to ensure a foundation for healthy families in the next generation. When combined with policies that allow for equal access for all for families and communities, evidence-based programs and services can have a very broad impact.

Findings from the Adverse Childhood Experiences Study

Research shows that the long-term effects of ACEs are reflected in adults' health status and behavior. The [Adverse Childhood Experiences study](#), conducted by CDC and Kaiser Permanente's Health Appraisal Clinic in San Diego, is a multi-year, large-scale research study exploring the associations between childhood adversity and later-life health and wellbeing. Between August 1995 and October 1997, more than 17,000 enrollees in Kaiser Permanente's HMO completed a survey with questions related to categories of adverse childhood experiences, including experiencing abuse (emotional, physical, and sexual) and neglect (emotional or physical), witnessing domestic violence, and growing up with substance abuse, mentally illness, parental discord, or crime in the home.⁶⁰

The study confirmed widespread prevalence of childhood trauma: almost two-thirds of study participants reported at least one adverse childhood experience, and many reported having three or more. The CDC-Kaiser study uses the ACE score, a total count of the number of ACEs reported by each respondent, to assess the total amount of stress during childhood. As the number of ACEs increases, so does a person's risk for many serious physical and behavioral health problems, including chronic disease, depression, alcoholism, drug abuse, smoking, severe obesity, risky sexual behavior, poor anger control, and attempted suicide.⁶¹

ACEs have an impact on individual health and well-being in adolescence and adulthood, including physical and mental health, substance abuse, healthcare utilization, psychotropic medication use, and autoimmune diseases. There have been numerous studies to suggest that people who are involved in service systems, such as child welfare, criminal justice, and Medicaid, show even higher rates of trauma and exposure to multiple traumatic experiences. The CDC-Kaiser study illustrates how the cumulative stress of ACEs can be a powerful determinate of the public's health and a major driver of physical and behavioral health costs.

Data from Alaska suggest that 40.6 percent of the state's adult Medicaid enrollment is linked back to ACEs, which means that in 2012, approximately \$350 million of adult Medicaid (age 20 or older) costs in Alaska could have been prevented if ACEs were eliminated.⁶² In another example highlighting the staggering costs associated with ACEs, Maine spends more than \$3 billion dollars annually on ACEs-related outcomes, not counting lost work productivity. The state estimates that more than \$500 million of this estimate is attributed to people who have four or more ACEs.⁶³

States may consider the following opportunities and resources to prevent ACEs:

Collect state – and county-level data on ACEs prevalence. More than 20 states currently collect information about ACEs by adding related questions to their Behavioral Risk Factor Surveillance Survey.

- Use data to examine the relationship between ACEs and other systems that impact the lives of children, including child welfare and juvenile justice.
- Designate funds to continue the collection, analysis, and dissemination of state ACEs data.
- Compile a statewide inventory of community ACEs prevention initiatives to use as a strategic tool to inform decision making and move from awareness to action.

Increase awareness about ACEs and their impact on health and wellness.

- Develop and share information about ACEs and their connections to specific health outcomes.
- Talk with other state agencies about the health, social, and economic benefits of reducing and preventing ACEs.
- Engage community members through ACEs and resilience trainings, public forums, community task forces, focus groups, and other facilitated conversations.

Increase access to healthcare, including mental health services.

- Study the regional distribution of mental health providers.
- Explore methods for improving reimbursement rates.
- Utilize telemedicine.
- Developing integrated models for behavioral healthcare (e.g., co-location of services).
- Work with primary care providers to screen for ACEs.

Support efforts to prevent and treat ACEs.

- Expand and evaluate programs that increase healthy family relationships, improve parenting behaviors, and decrease rates of child abuse and neglect.
- Increase the use of trauma-informed practices by social service agencies through training and technical assistance.

KEY STRATEGIES

Prevention Approaches

Assuring safe, stable, nurturing relationships and environments for children can have a positive impact on health and well-being and develop skills to help children reach their full potential. Entry points to influencing child development are situated in multiple sectors, including health and nutrition, education, and social services, and can be directed toward pregnant women, young children, and parents and caregivers.



Prevention programs that address the needs of children and their families include:

- Home visiting programs.
- Parental skill-building and social support programs.
- Intimate partner violence prevention.
- Teen pregnancy prevention programs and support programs for parenting teens.
- Mental health treatment programs.
- Substance abuse treatment programs for parents.

Policy Approaches

Social and economic policies can affect poverty, unemployment, and housing. It is clear that investments in early childhood are needed for children to reach their full potential. For example, policies can help ensure more equitable opportunities for families, resulting in better outcomes for education, health, and economic productivity. More specifically, policies can help families access various services and community supports to make sure that they have the resources they need so that their children can be healthy and thrive.

“Family-friendly” workplaces, for example, can help support healthier communities. Family-friendly policies make it possible for employees to more easily balance family and work in order to fulfill both their family and work obligations.⁶⁴ Policies such as flexible parental leave allow parents to participate in their children’s lives, and having more time with their children helps parents and caregivers form positive bonds and relationships. These practices also produce societal benefits, because family-friendly policies lead to better outcomes for children and more stable families who have time to contribute to their communities.⁶⁵

State health departments can help employers understand organizational family-friendly policy options and how to implement them. Health departments can also encourage more businesses to adopt these policies by working with employers who have implemented family-friendly programs and tapping them as spokespersons to talk to wider audiences about how these policies have benefited both them and their employees.

CDC’s [Essentials for Childhood](#) initiative proposes a menu of strategies that communities can consider to promote the types of relationships and environments that help children become healthy and productive citizens.⁶⁶

Generally speaking, state health departments may find it useful to develop agency policies or regulatory recommendations that serve to:

- Require joint planning, implementation, and data sharing among child and family serving systems.
- Codify relationships between state agencies to ensure data exchange and resource commitment.

State policymakers are also seeing an increase in ACEs-related legislation. Several recent legislative activities are summarized below.

◆ [California ACR 155](#)

This legislation, passed in August 2014, encourages statewide policies to reduce children's exposure to ACEs and stress. California is the second state to pass a resolution on ACEs. It is modeled after a Wisconsin resolution that encourages state policymakers to consider the impact of early childhood adversity on long-term health.

◆ [Wisconsin SJR 59](#)

This legislation, passed in January 2015, notes that "Policy decisions enacted by the Wisconsin state legislature will take into account the principles of early childhood brain development and will, whenever possible, consider the concepts of toxic stress, early adversity, and buffering relationships, and note the role of early intervention and investment in early childhood years as important strategies."

◆ [Vermont H 596](#)

When an original version of this bill, H 762, was first introduced, there were seven provisions in the bill proposing that an ACEs questionnaire be used by Vermont Blueprint for Health providers (as part of Vermont's statewide health services model) to expand ACEs screening and educate healthcare providers on ACEs and trauma-informed care. Although the bill initially failed on the last day of the legislative session in May 2014, the Vermont General Assembly then passed a broad healthcare reform bill (H 596) that contains several ACEs-focused measures, including a mandate for the Director of the Vermont Blueprint for Health to review the evidence base on the relationship between ACEs and population health and recommend whether ACEs-informed medical practice should be integrated into Blueprint practices and community health teams. This report was finalized in January 2015 and presented to the Vermont General Assembly.

◆ [Washington HB 1965](#)

Washington state passed this legislation in 2011 to identify and promote innovative strategies to prevent or reduce ACEs and form public-private partnerships to support these efforts. It established a statutory definition of ACEs and codified the state's commitment to incorporating ACEs in state policy. In accordance with the law, the Washington State ACEs Public-Private Initiative was launched and is currently conducting a two-year retrospective evaluation of community-level work in five communities: North Central Washington (Wenatchee), Okanogan, Skagit, Walla Walla, and Whatcom.

Essentials for Childhood offers several examples of the types of policies states may consider to support children and families. By targeting multiple settings where children grow up, these policy strategies can help ensure access to essential services that address family-specific needs.

- Provide needed flexibility at work, such as paid time off (family and sick leave, including paid time off after the birth of a child).
- Align eligibility and recertification dates for benefits packages (e.g., income supports and housing assistance and nutrition programs).
- Expand accessibility to high-quality, affordable child care and early education.
- Establish affordable housing and housing protections for poor and low-income families.
- Provide protections against predatory lending practices.

SECTION IV. Older Adult Falls

BACKGROUND

Falls are not an inevitable part of aging, but they can have a significant impact on health-related quality of life and function among older adults. One out of every three adults aged 65 or older falls each year, making falls a leading cause of injury deaths, hospitalizations, and emergency department visits for this age group.⁶⁷ People who fall once are two to three times more likely to fall again. On average, the hospitalization cost for a fall injury is more than \$35,000.⁶⁸ Falls cost an estimated \$34 billion in healthcare spending annually and are considered a risk factor for needing long-term care services at home or entering a nursing facility.⁶⁹ With such costs projected to reach \$67.7 billion by 2020, public health officials, aging services, and housing authorities have a shared interest in reducing falls among older adults.

Many people who fall, even if they are not injured, develop a fear of falling. As a result, they may self-limit their activities and social engagements, which affects physical fitness and mobility and can contribute to depression, social isolation, and feelings of helplessness. Given the aging population, developing and implementing cost-effective programs to prevent falls is vitally important in order to limit the burden of fall-related injuries over the next several decades.

Research on preventing older adult falls and injuries has identified important and modifiable risk factors, including muscle weakness, gait and balance problems, psychoactive medication use, poor vision, and environmental hazards. There are several types of interventions that, if implemented on a large scale, can prevent a significant number of falls and fall-related injuries, including: group exercise programs (e.g., Tai Chi), home-based exercise programs (e.g., Otago), and home safety modifications (e.g., installing non-slip rubber mats or additional lighting), combined with behavioral changes recommended by an occupational therapist.



CDC's third edition of the [*Compendium of Effective Fall Interventions*](#) describes single interventions that address a specific fall risk factor (e.g., treating gait and balance issues with physical therapy). In total, the compendium discusses 29 single interventions (15 exercise interventions, four home modification interventions, and 10 clinical interventions) and 12 multifaceted interventions, which address multiple risk factors.

A cost-benefit analysis shows that community-based fall interventions generate a positive return on investment (ROI):⁷⁰

- Otago Exercise Program costs \$339.15 per participant, has an average expected benefit of \$768.33, and an ROI of 127 percent for each dollar invested when the intervention is targeted to persons age 80 and older.
- Tai Chi: Moving for Better Balance costs \$104.02 per participant, has an average expected benefit of \$633.90, and an ROI of 509 percent for each dollar invested.
- The Stepping On program costs \$211.38 per participant, has an average expected benefit of \$345.75, and an ROI of 64 percent for each dollar invested.



Fall Risk Assessments

Awareness of individual risk is also an important factor in falls prevention. In addition, healthcare providers play an important role in screening for and assessing their older adult patients' fall risk. The challenge for providers is to make older people aware of their potential risk of falling without causing distress or denial of a problem. Therefore, a self-assessment can be a good tool. Reviewing the patient's self-assessment provides useful information about what he or she believes to be the cause of any falls, and prompts a discussion about his or her priorities.⁷¹

There are also a number of suggested clinical interventions to reduce falls. For example, providers can review medications and stop, reduce, or alter drugs that increase a patient's fall risk. They can recommend daily vitamin D supplements and refer to community based fall prevention programs. A fall risk assessment is a covered benefit in Medicare's Annual Wellness Visit.

CDC has a multi-pronged approach to better engage and partner with the medical community in order to integrate falls screening, assessments, and interventions into the clinical setting.

CDC's **STEADI (Stopping Elderly Accidents, Deaths, & Injuries)** toolkit is a comprehensive resource based on the American and British Geriatrics Societies clinical practice guidelines for fall prevention. The STEADI toolkit helps primary care physicians and other healthcare providers incorporate fall screening, assessment, and management into their clinical practice. The toolkit includes basic information about falls, case studies, conversation starters, and standardized gait and balance assessment tests (with instructional videos). There is also a free continuing education course available to train providers on how to implement STEADI practice.

If they adopt STEADI, providers in New York state, Colorado, and Oregon are now eligible to earn part IV Maintenance of Certification credits through the American Board of Family Medicine and American Board of Internal Medicine. CDC estimates that if 5,000 healthcare providers adopt STEADI, over a five-year period it could lead to as many as:

- 6 million additional screened patients.
- 1 million prevented falls.
- \$3.5 billion in saved direct medical costs.

Broome County, New York and United Health Services Health System – STEADI in Primary Care

The New York State Health Department worked with the United Health Services (UHS) Medical Group, located in Broome County, New York, to implement CDC's STEADI toolkit and optimize the UHS electronic health records (EHR) system to integrate fall risk screening as a standard component of the primary care visit. The Broome County Health Department conducted a community health assessment and found that the county's rates of deaths and emergency department visits due to older adult falls were higher compared with the state's overall rates. Based on this data and the aging demographics of the region, the state health department selected Broome County to receive funding for the STEADI pilot.

When the pilot began in 2012, the team first needed to figure out how to fit the STEADI algorithm into the workflow of the clinician and the office. There was no screening tool built into the EHR at the time, so IT administrators at UHS added fall risk screening questions and built them directly into the nurses' intake form. As a result, during the intake process, if a patient answers "yes" to any of the screening questions, an alert will now appear on the screen prompting the nurse to perform a timed "up and go" walking test. If the patient demonstrates an increased fall risk, the nurse records this information in the EHR system. The EHR then generates information that is sent to the physician, including educational materials and potential interventions to consider, such as community-based exercise and balance programs and vitamin D supplementation. Medication reconciliation also takes place during the nursing intake.

In the final step of the visit, the physician will perform a targeted assessment, develop a care plan, and make appropriate referrals. In Broome County, patients are given information about the "In Balance" program offered by the UHS Home Care home health agency, which assigns them a physical therapist and uses a customized approach to help them regain strength and balance. Patients may also be referred to Tai Chi, offered by the YMCA, or the Stepping On program run by Independence Awareness and the Broome County Health Department, in partnership with the Office for Aging.

EHR customization was considered an important attribute and key to the success of this program. It also allows UHS providers to track and monitor the "date of last fall risk assessment" to identify patients that have not been screened in the past year. Future plans include recruiting care coordinators to collect follow-up data and establish hand-offs between patients and local resources and services.

KEY STRATEGIES

Preventing Older Adult Falls: State Approaches

In order to have an effective and sustainable falls prevention statewide initiative, it is essential to have strong, committed partners at the leadership level between the department of health, the state agency on aging, and coalitions at the state and local levels. In July 2015, the National Council on Aging released the [2015 National Falls Prevention Action Plan](#), which builds on a version originally released in 2005. The updated plan includes 12 broad goals, 40 strategies, and more than 240 action steps focused on increasing physical mobility, improving medication management, enhancing home and environmental safety, increasing public awareness and education, and funding and expanding falls risk screening, assessment, and interventions to prevent falls.⁷²

Led by the National Council on Aging, the Falls Free initiative is a national effort that is largely focused on connecting coalition members with other state and regional chapters and helping states promote effective strategies to address falls, including regulatory and policy changes. The Falls Free State Coalition Workgroup includes members from 42 states. This group created the State Policy Toolkit for Advancing Falls Prevention, which includes a dashboard of selected indicators.⁷³

Included in the toolkit are recommendations for building relationships with policymakers to ensure that state health departments are seen as “go to” authorities on pending policy and regulatory changes to prevent falls and avoid potentially negative or unanticipated outcomes of policy decisions. Bringing greater awareness about the impact of older adult falls to the legislature is an important step in planning for legislative policy initiatives, as is data that reflects trends over time to inform policy decisions. Accurate and consistent data collection is essential to making the case for falls prevention and planning efforts to address areas of high injury rates and gaps in service.

State Examples:

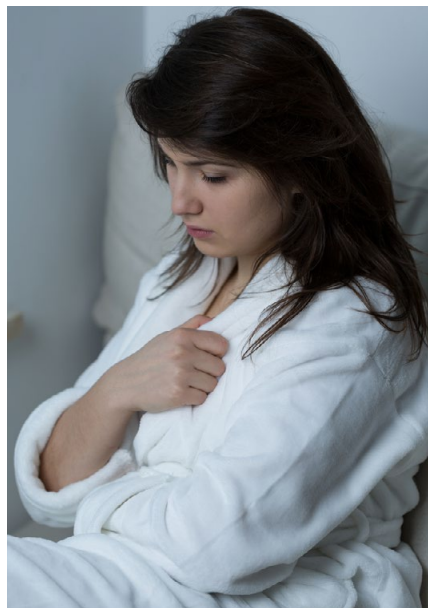
- Arizona launched the Arizona State Healthy Aging Strategic Plan, which includes strategies for falls prevention.
- The Georgia Falls Prevention Coalition worked with the Physical Therapy Association of Georgia and Mercer University to bring together physical therapist volunteers to conduct STEADI assessments.
- In Hawaii, Tai Chi for Health became a permanent part of Kaiser Permanente, Kauai Parks and Recreation, and Catholic Charities.
- The Southern Nevada Health District health educator gave a separate presentation in Spanish about senior falls prevention and the STEADI assessment for fall risk at a meeting of the Latin Chamber of Commerce.
- Ohio partnered with the Ohio Pharmacy Association to conduct fall risk screenings and collaborated with a large grocery store chain to conduct medication reviews for adults 65 years and older.
- Vermont worked with the Governor’s Commission on Successful Aging Health Care Reform subcommittee to submit key findings and make recommendations for the creation of a State Plan on Falls Prevention.


SECTION V. Preventing Sexual Violence

BACKGROUND

Sexual violence refers to any sexual activity where consent is not obtained or freely given. There are many types of sexual violence, including forced intercourse, sexual contact, and touching, as well as harassment, exploitation, and threats. Sexual violence perpetration is a product of multiple, interrelated factors that affect the individual, that person’s relationships, the community, and the broader cultural and social environment.⁷⁴

Efforts to prevent sexual violence on college campuses have intensified in recent years. One in five women has been a victim of completed or attempted sexual assault while in college. Although it happens less often, men can also be victims of sexual violence. Sexual assaults on





college campuses are widely under-reported. Despite the prevalence of campus sexual assaults, approximately 40 percent of colleges and universities reported not investigating a single sexual assault in the previous five years.⁷⁵

Campus sexual violence remains a legislative priority at the state and federal level. Over the last several decades, policymakers have put in place legislation that increases campus accountability for addressing sexual violence. The Campus Sexual Violence Elimination (SaVE) Act was enacted in March 2013 when the Violence Against Women Act was reauthorized, and included in the bill were amendments to the Clery Act. The SaVE Act expands the scope of the Clery Act, and as a result, most higher education institutions, including community colleges and vocational schools, are now held to more reporting, response, and prevention education requirements around rape, domestic violence, dating violence, sexual assault, and stalking.

The SaVE Act also establishes collaboration between HHS and the U.S. Departments of Justice and Education to collect and disseminate best practices for preventing and responding to domestic violence, dating violence, sexual assault, and stalking. Health departments can help inform prevention programs and policies in university systems as they work to address the issue and their new prevention and response efforts now mandated through the Campus SaVE Act.

Comprehensive approaches to violence need to address risk and protection at all levels, not just at the individual level. Individuals who experience one form of violence are more likely to experience other forms of violence, be at higher risk for behaving violently, and commit other forms of violence. Understanding how different forms of violence are linked to one another is paramount to developing effective policies, programs, and tools.

The work that health departments do to prevent sexual violence overlaps with the efforts of many other agencies and partners working to reduce other kinds of violence and improve community health. Protective factors, such as economic stability, healthy families, and access to education all help prevent child maltreatment, suicide, sexual violence, and community violence by providing an environment where violence is less likely to occur.

Minnesota's Sexual Violence Prevention Plan

In 2013, the Minnesota Legislature directed the Minnesota Department of Health to prepare a report on its activities to prevent sexual violence, including coordination of existing state programs and services that address the root causes of sexual violence.⁷⁶ The Minnesota Department of Health Sexual Violence Prevention Program and members of the Sexual Violence Prevention Advisory team surveyed community partners and interviewed 26 state agency representatives from 11 different departments to gather information about current prevention activities, gaps in activities, and opportunities for improvement at the legislative and agency level. They found that opportunities to strengthen sexual violence prevention efforts exist at multiple levels, including:

Legislative:

- Appoint representatives from the house, senate, and the judicial branches to serve on a sexual violence prevention advisory board.
- Support comprehensive health education programs and policies because they increase protective factors for sexual violence.
- Authorize agencies to conduct statewide crime victim surveys to collect accurate and timely data on victimization.
- Authorize agencies to conduct statewide student surveys to collect data on sexual violence and dating violence in youth.

State Agency:

- Appoint agency staff to serve on sexual violence prevention advisory board.
- Implement and evaluate data and best practices for preventing sexual violence.
- Ensure that proposed policy and practice changes include the voices, opinions, and needs of populations who are disproportionately affected by sexual violence.
- Work with the state's education, child welfare, mental health, public health, healthcare, substance abuse, juvenile justice, corrections, and public safety systems to increase awareness of the impact of trauma, ACEs, and sexual violence.

Community Organizations:

- Provide culturally responsive training on sexual violence prevention for all staff who serve children and youth, including school personnel, law enforcement, and other professionals.
- Increase prevention programming targeted at preschool aged children and other populations who are at higher risk of being victimized.
- Offer community programs on parenting, responsible fatherhood, conflict resolution, and home visiting.
- Increase collaboration between community organizations and effective sex offender treatment programs.

KEY STRATEGIES

Safe Dates and Shifting Boundaries: Primary Prevention Programs

In 2012, CDC conducted a systematic review of 140 studies examining the effectiveness of primary prevention strategies for sexual violence perpetration in order to summarize the best available research evidence for public health practitioners. Currently, there are only two primary prevention strategies that have demonstrated significant reductions in sexual violence behaviors in a rigorous outcome evaluation design: *Safe Dates* and *Shifting Boundaries*.



Intended for male and female eighth and ninth grade students, [Safe Dates](#) is a universal prevention program to prevent emotional, physical, and sexual abuse in adolescent dating relationships. According to one study, four years after receiving the program, students in the intervention group were significantly less likely to be victims or perpetrators of sexual violence involving a dating partner.

[Shifting Boundaries](#) is a 6-10 week school-based dating violence prevention strategy for middle school students that includes six classroom sessions and addresses policy and safety concerns in schools through the use of temporary restraining orders, a poster campaign to increase awareness of dating violence, and “hotspot” mapping to identify unsafe areas of the school for increased monitoring by faculty or school security personnel.

While the classroom curriculum alone was not effective in reducing rates of sexual violence, the school-wide intervention was effective alone or in combination with the classroom instruction. At a six-month follow-up, the school-wide intervention showed reductions in sexual harassment, peer sexual violence and victimization, and dating violence.

Despite significant knowledge gaps, research shows that comprehensive, evidence-based sexual violence prevention plans that address risk and protective factors at the community or organization level have the greatest potential for population-level impact. The research is not definitive, but lessons learned from other prevention efforts, such as alcohol regulation and policy, may impart some potential opportunities for looking at community-level factors as they may contribute to sexual violence. Although alcohol-related policies do not address the root causes of sexual violence perpetration, research has shown that there is a strong relationship between excessive alcohol consumption and sexual violence.^{77,78,79} As part of a more comprehensive strategy, policies affecting the cost (e.g., pricing strategies or increased taxes) and availability of alcohol (e.g., campus alcohol bans or outlet density) may represent way of modifying risk factors at the community-level to prevent sexual assault.



Rape Prevention and Education Program

CDC currently provides funding to all 50 states, Washington, D.C., Puerto Rico, and four U.S. territories through the Rape Prevention and Education Program (RPE), which was established through passage of the Violence Against Women Act in 1994. States are permitted to use their RPE grant funds in a variety of ways to help prevent sexual violence, and program activities are guided by a set of prevention principles that include:⁸⁰

- Preventing first-time perpetration and victimization.
- Reducing modifiable risk factors while enhancing protective factors associated with sexual violence perpetration and victimization.
- Using the best available evidence when planning, implementing, and evaluating prevention programs.
- Incorporating behavior and social change theories into prevention programs.
- Using population-based surveillance to inform program decisions and monitor trends.
- Evaluating prevention efforts and using the results to improve future program plans.

RPE's focus on primary prevention has enabled a focus on "upstream" thinking and stronger partnerships. The funds have bridged connections, for example, between rape crisis centers—which have a long history of advocacy and experience providing critical services to victims of sexual violence—and public health, which has advanced the science-based conceptual models essential to our understanding of how such violence can be prevented in the first place.

Additional research is needed to understand the impacts of prevention strategies on sexual violence behaviors. However, states can make progress by incorporating the following key concepts into the cycle of program planning and evaluation:

- Using data to better understand sexual violence.
- Developing comprehensive prevention plans that include policy, structural, and social norm components.
- Selecting prevention strategies based on best practices and available evidence.
- Evaluating strategies that are implemented.
- Sharing lessons learned.

State health agencies also have a responsibility to assess their state investments in violence prevention and convene partners for strategic planning. To support sexual violence prevention efforts more broadly, state health departments may also:

- Review and recommend health department positions on proposed legislation.
- Develop health department testimony on proposed legislation.
- Provide information on the effectiveness of existing state or local policies.
- Use surveillance data to inform policymakers.
- Identify model legislation, policies, or ordinances.

Kentucky's RPE State Initiatives—From EMPOWER to Green Dot⁸¹

CDC launched the EMPOWER Program in 2005 as a capacity building demonstration project. The EMPOWER Program provided additional funding, technical assistance, and training to a subset of states receiving RPE funding. As part of the project, Kentucky organized the State Capacity Building Team (SCBT) steering committee, including members from the state sexual violence coalition and the Kentucky Cabinet for Health and Family Services. SCBT was responsible for assembling the state prevention team, whose task was to create a statewide sexual violence prevention plan.

Recognizing the importance of having local communities involved in the planning process, a committee of representatives from each of Kentucky's 13 regional rape crisis centers came together to work with the state prevention team. This partnership ultimately led to the decision to select one pilot program to implement in all of Kentucky's rape crisis centers in order to evaluate its effectiveness in preventing sexual violence.

In preparing to take on the project, a significant amount of time was spent developing a shared definition and understanding of primary prevention. Working with CDC and the other five states in the EMPOWER collaborative, Kentucky found that the best way to help people understand what primary prevention means was to think about it in terms of goals, activities, and strategies that aim to stop violence *before* it occurs. SCBT used a public health approach and the socioecological model as a way of ensuring community, regional, and state participation in the prevention planning and implementation process.

The program selected was called "Green Dot," a bystander primary prevention program first developed in 2006 and designed to reduce the risk of perpetration of all types of sexual and dating violence in high schools and colleges. It teaches students how to identify situations that could lead to an act of violence and shows them how to intervene safely and effectively. In the [Green Dot](#) approach, by promoting social norms that are not accepting of violence, students are shown how to intervene when faced with a situation that may result in an assault, particularly when alcohol or drugs are involved. Early success of Green Dot on the University of Kentucky college campus was a strong determinant in the state deciding to adapt and evaluate Green Dot in the high school setting.

In 2009, CDC awarded a five-year, \$2 million cooperative research agreement to the University of Kentucky and its partners, the Kentucky Association of Sexual Assault Programs, Inc. and the rape crisis centers that provide services across the state, to conduct a randomized control trial in 26 Kentucky high schools. Half of the schools were assigned to receive the Green Dot intervention to test how effectively the program increased active bystanding behaviors and decreased rates of violence victimization and perpetration over time.

In September 2014, preliminary findings found a greater than 50 percent reduction in the self-reported frequency of sexual violence perpetration by students at schools that received the Green Dot training. In schools that did not receive the training, there was a slight increase in self-reports.

While more rigorous evaluation on various prevention approaches is needed to determine what works to reduce sexual violence at the population level, Kentucky's approach offers the field valuable insight for building a program that addresses a broad range of risk and protective factors for sexual violence.

SECTION VI. Youth Sports Concussions and Traumatic Brain Injury

BACKGROUND

Traumatic brain injuries are sometimes described as a “silent epidemic.” In recent years, sports- and recreation-related traumatic brain injury (TBI) has been increasingly recognized as a significant collective public health concern affecting people of all ages in the United States. Based on data from the National Electronic Injury Surveillance System-All Injury Program, sports- and recreation-related traumatic brain injuries alone caused more than 3 million emergency department visits between 2001 and 2012, and approximately 70 percent of those were reported among persons ages 0 to 19 years. However, there are many more sports and recreation-related TBIs that are not treated in a hospital or emergency department.⁸² While most people recover from TBI, others can experience lifelong disability or death.

Repeated TBIs can have prolonged and long-term effects. Children and adolescents who sustain a TBI can experience lasting physical impairments, lowered cognitive and academic skills, and changes in behavior, socialization, and adaptive functioning. Because of the considerable increase in the number of TBI-related emergency department visits over recent years, it is important to monitor these yearly trends to identify the groups at highest risk as well as describe the most common causes of TBI. States are identifying policy approaches that protect young athletes in an effort to make sports safer while making sure that everyone has an opportunity to benefit from sports and physical activity.

As part of the Injury Center’s Core Violence and Injury Prevention Program, several states are focusing on TBI prevention:

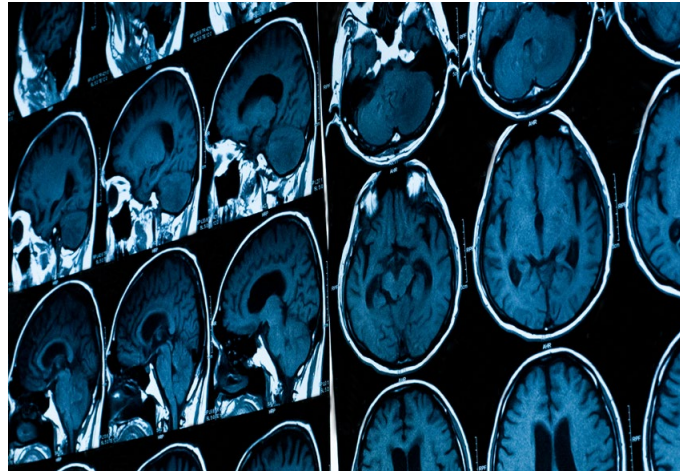
- **Massachusetts and Nebraska** are monitoring and supporting implementation of recently-passed sports concussion laws.
- **Oklahoma** is educating residents about sports-related TBI among individuals under 25.
- **Minnesota** is establishing a statewide surveillance system for tracking high school student-athletes who sustain concussions.
- **Ohio** is focusing on bicycle helmet use and sports related concussions in middle and high schools and recreational leagues.
- **Hawaii** is focused on improving helmet use when riding a motorcycle or motorized scooter.



TBI Surveillance and Data Needs

In November 2014, President Obama signed the Traumatic Brain Injury Reauthorization Act of 2014, which allowed for continued appropriations to HHS through fiscal year 2019 for TBI programs carried out by federal agencies. First enacted in 1996, this is the third reauthorization of the bill, which strengthens CDC’s ability to conduct TBI surveillance, prevention, and education. The law also supports NIH research activities and state grant programs and directs the HHS secretary to develop a plan to improve the coordination of federal activities, including a review of current interagency efforts.

At the federal level, a significant area of focus moving forward will be related to opportunities to build a national TBI surveillance system to better determine the incidence of sports- and recreation-related concussions, as recommended by the National Academy of Medicine (Institute of Medicine). Current data sources are insufficient and could be improved to inform decisionmaking on prevention initiatives, research needs, and education priorities. A more comprehensive national surveillance system that allows for an examination of trends would help guide states' prevention programs.



KEY STRATEGIES

Return to Play

Since 2009, there have been several federal legislative efforts related to youth sports concussions, including bills that support funding for states to collect data on the incidence and prevalence of youth sports concussions, adopt and implement return to play guidelines, and implement pre-season baseline and post-injury testing youth athletes.

Being cleared to participate in competitive or recreational activities by a qualified medical professional, especially for youth athletes, is important to avoid re-injury, prolonged recovery, or permanent neurological and psychological deficits. States can implement strategies to help improve early TBI detection, prevention, and treatment, and to help increase the adoption of “return to play” protocols. Policy approaches may be appropriate to ensure that people who have sustained concussions have recovered thoroughly before fully participating in sports or other activities.

Washington was the first state to pass a “modern day” youth sports TBI law in 2009, which focused on improving the recognition and understanding of concussion in sports, removing athletes suspected of sustaining a concussion, and requiring those athletes to receive clearance before returning to play. Texas had similar legislation in place in 2007, but it only applied if the athlete lost consciousness. In 2015, all 50 states and Washington D.C. had some form of youth sports-related TBI law that contained provisions about when an athlete may return to a sport or activity.⁸³ Fewer than 10 states, the [Network for Public Health Law](#) reports, have laws that address “return to learn,” or the concept of returning to the classroom or school environment following a concussion.

State laws should identify a specific entity, such as the board of education, that is responsible for implementing training and education provisions regarding TBI. In Massachusetts, Missouri, New York, and Pennsylvania, the legislative language directs health departments to develop concussion training programs. Be sure to verify with your state laws to determine who is responsible for developing and implementing these programs in your state.

In 2015, the Oregon School Activities Association became the first state high school activities association in the United States to require coaches to enroll in USA Football’s Heads Up Football program, and in 2008, it became the first state high school activities association to prohibit same day return to play for athletes with

a suspected concussion.^{84,85} USA Football's Heads Up Football program includes training on concussion diagnosis and management, based on CDC's HEADS UP initiative.

CDC HEADS UP Concussion Training

CDC's HEADS UP training offers information about concussion and other serious brain injury to coaches, parents, school and health professionals, and athletes. The HEADS UP campaign provides important information on preventing, recognizing, and responding to a concussion, and celebrated its 10th anniversary in 2013.

HEADS UP's accomplishments include:

- More than 215 million media impressions through print media and TV public service announcements.
- Close to 40 million social media impressions.
- More than 22,000 Facebook fans, and growing.
- More than 6 million distributed print materials.
- Completed online trainings for more than 3 million coaches.
- More than 50 HEADS UP products developed.
- More than 85 organizations signed on as participating organizations.

In fiscal year 2015, the HEADS UP campaign aimed to expand efforts to evaluate the public health impact of the campaign and build momentum for research and efforts focused on changing social norms around concussion.


Many laws that address youth sports concussions have similar provisions. States can consider this set of questions from the [Robert Wood Johnson Foundation Public Health Law Research](#) program to think about where some of these variations might exist in state laws:⁸⁶

Does your state's law...

- Specifically address youth sports TBIs?
- Require a student athlete with a suspected TBI to be removed from play?
- Require parents to be notified of their child's suspected or diagnosed TBI?
- Specify requirements for when an athlete may return to play?
- Require additional mandatory TBI-specific training for coaches?
- Explicitly require distribution of some form of TBI or concussion information sheet?
- Require that a TBI information sheet be distributed at least annually to parents of athletes or student athletes?
- Explicitly address liability and, if so, does it identify who may or may not be liable for failure to comply with the law?



Additional research is emerging related to how youth sports concussion laws are being implemented, as well as factors that promote or impede implementation and ways to determine the level of compliance in each community or school district.



CDC evaluated the implementation of concussion legislation in Washington state and Massachusetts by interviewing stakeholders at both the state level (health departments and statewide interscholastic athletic associations) and at the school level (athletic directors and coaches). The case study identified challenges and successes that would help inform implementation in other states, including the following factors:⁸⁷

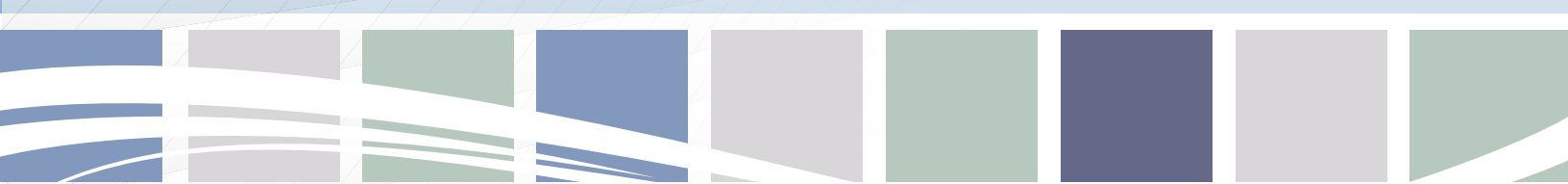
- A need for involvement of a range of stakeholders in the planning process in order to identify barriers and improve outreach and education.
- The importance of developing a comprehensive and specific implementation plan to ensure that the original intent of the law is executed.
- Consideration of a broad approach to injury prevention, such as combining the return to play protocols for concussion with those for other sports-related injuries.
- A need to work with recreational leagues to whom the state law does not apply by sharing access to educational materials and resources.
- The importance of identifying requirements for continuing education on youth sports concussions.
- The value of educating teachers about concussion symptoms and emphasizing “return to learn” principles.

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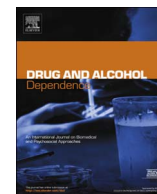
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Full length article

Smoking-related outcomes and associations with tobacco-free policy in addiction treatment, 2015–2016

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ABSTRACT

Objective: This study assessed changes in smoking-related outcomes in two cross-sectional samples of clients enrolled in addiction treatment and whether tobacco-free grounds policies were associated with smoking-related outcomes.

Method: Clients in 25 programs were surveyed in 2015 (N = 1176) and 2016 (N = 1055). The samples were compared on smoking prevalence, cigarettes per day (CPD), thinking of quitting, past year quit attempts, staff and clients smoking together, attitudes towards quitting, and tobacco-related services. Second, programs with (n = 6) and without (n = 17) tobacco-free grounds at both time points were compared on smoking-related outcomes. Last, we examined changes in these measures for two programs that adopted tobacco-free grounds between 2015 and 2016.

Results: There was one difference across years, such that the mean score for the tobacco Program Service scale increased from 2.37 to 2.48 (p = 0.043, effect size = 0.02). In programs with tobacco-free grounds policies, compared to those without, both CPD and the rate of staff and clients smoking together were significantly lower. In the two programs where tobacco-free grounds were implemented during study years, client smoking prevalence decreased (92.5% v. 67.6%, p = 0.005), the rate of staff and clients smoking together decreased (35.6% v. 4.2%, p = 0.031), mean CPD decreased (10.62 v. 8.24, p < 0.001) and mean tobacco services received by clients increased (2.08 v. 3.05, p < 0.001).

Conclusion: Addiction treatment programs, and agencies responsible for licensing, regulating and funding these programs, should implement tobacco-free grounds policies.

1. Introduction

The Centers for Disease Control and Prevention (CDC) recently reported that cigarette smoking among adults in the United States (U.S.) had decreased from 20.9% in 2005–15.1% in 2015 (Jamal et al., 2016). During this time, smoking prevalence decreased in every age group, in every racial/ethnic group, in nearly all educational attainment groups, and in all Census Regions. Although some have commented that decrease in U.S. smoking prevalence has slowed or stopped (King et al., 2011; Mendez and Warner, 2004), Jamal et al. (2016) report a statistically significant decrease from 16.8% in 2014–15.1% in 2015.

As smoking prevalence declines overall, smoking in subgroups becomes increasingly important in terms of tobacco control, health disparities (Okuyemi et al., 2015) and social justice (Heaton and Nelson, 2004). Compared to 15.1% in the general population, smoking prevalence was 40.6% among persons with serious psychological distress

(Jamal et al., 2016), a category that combines a number of risk groups. Smoking prevalence is 25% for persons with anxiety disorders, 30% for those with depressive disorders (Grant et al., 2004), and 50–80% for those with schizophrenia (Prochaska et al., 2008; Schroeder, 2009). Lasser et al. (2000) estimated that 44% of all cigarettes smoked in the U.S. were consumed by persons with mental health diagnoses, and Higgins et al. (2016) estimated that 14% of all U.S. smokers are persons with drug and/or alcohol abuse problems.

A review of smoking prevalence in U.S. addiction treatment programs, from 1987 to 2009, found a median annual smoking prevalence of 76.3% (Gudyish et al., 2011a). Among all admissions to addiction treatment in New York State, annual smoking rates ranged from 69.5% in 2007–71.2% in 2012 (Gudyish et al., 2015). A 2015 survey of persons enrolled in 24 addiction treatment programs reported a smoking rate of 77.9% (Gudyish et al., 2016b). These studies show no observable decrease in smoking prevalence among persons enrolled in addiction

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treatment, from 1987 to 2015, and highlight the need for innovative approaches to smoking in this population.

There are, however, reasons to expect that smoking could decrease among those enrolled in addiction treatment. First is the continuing decline in population smoking prevalence (Jamal et al., 2016). Second, access to tobacco cessation services should be expanding, based on U.S. mental health parity legislation (Garcia, 2010), because the 2010 Affordable Care Act (ACA) was expected to increase the numbers of persons who receive addiction treatment (Buck, 2011), and because the ACA required coverage of smoking cessation intervention. Third, the 2009 Family Smoking Prevention and Tobacco Control Act placed regulatory authority over tobacco products into the hands of the Food and Drug Administration (FDA), with the mandate to protect public health (National Institutes of Health, 2012).

The addiction treatment field has also noted the high rates of smoking among clients (Guydish et al., 2011a), the excess tobacco-related mortality in this population (Bandiera et al., 2015; Hser et al., 1994; Hurt et al., 1996), and the impact of smoking cessation on other treatment outcomes (McKelvey et al., 2017; Prochaska et al., 2004; Thurgood et al., 2016). Some have called for tobacco policies in state-level treatment systems (Krauth and Apollonio, 2015), and some states have implemented such policies, including tobacco-free grounds. (Brown et al., 2012; Drach et al., 2012; Williams et al., 2005).

Tobacco-free grounds policies include complete smoking bans on all program grounds (CDC, 2015), and may offer a policy approach to epidemic smoking in addiction treatment. Workplace smoking bans increase smoking cessation and reduce cigarette consumption (Bauer et al., 2005; Fichtenberg and Glantz, 2002), and complete bans reduce smoking more than partial bans (Tabuchi et al., 2016). Around one third of U.S. addiction treatment facilities had smoking bans on program property (Muilenburg et al., 2016; Shi and Cummins, 2015; Substance Abuse and Mental Health Services Administration, 2017) and 7 states required comprehensive indoor and outdoor smoking bans in treatment programs (National Association of State Alcohol and Drug Abuse Directors, 2010). One review of mental health and addiction treatment centers found that smoking restrictions had little effect on clients quitting smoking (el-Guebaly et al., 2002). However, pre-post assessments of the New York State tobacco-free grounds policy found that client smoking prevalence decreased significantly from 69.4% to 62.8% (Guydish et al., 2012), and that screening for smoking and use of cessation services increased post policy (Brown et al., 2012). Eby and Laschober (2013) found greater clinician support for smoking cessation in New York programs, compared to programs in other states that had not implemented tobacco-free grounds policies. Staff smoking prevalence and client cigarette consumption declined, and client attitudes toward quitting were more positive five years after policy implementation (Pagano et al., 2016a). Apart from New York State studies, Knudsen et al. (2010) found that programs with tobacco-free grounds policies reported lower smoking prevalence among counselors than those with indoor-only policies, and Richey et al. (2017) found that tobacco-free grounds implementation was not accompanied by a decrease in client census.

The current paper asks, first, whether any changes in smoking behavior were observed among clients enrolled in addiction treatment programs from 2015 to 2016 and, second, whether tobacco-free grounds policies were associated with differences in smoking-related measures.

2. Methods

2.1. Sampling design

We recruited a random sample of addiction treatment programs through the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) in 2013. We first identified CTN-affiliated programs meeting these inclusion criteria: publicly-funded, had at least 60 active

clients, and the program director would designate a staff liaison to coordinate with the research team. From 48 programs meeting these criteria, 33 were randomly selected and contacted. Six programs were no longer eligible, two declined, and one was not needed to meet recruitment goals. The remaining 24 programs were located in 14 states (CA, CT, FL, HI, NC, NY, OH, OR, PA, SC, SD, TX, WV, VA). Sampling design, program selection, and program recruitment, procedures were previously reported (Guydish et al., 2016b). One program was added to the sample in 2015, because it was transitioning to a tobacco free grounds policy and offered an opportunity to observe any changes associated with policy implementation. The current paper uses data from all 25 programs, including 7 outpatient, 11 residential, and 7 methadone programs.

2.2. Participants and procedures

Each program was site visited in 2014, 2015, and 2016. Cross-sectional and anonymous surveys were expected to represent independent samples, but some respondents in 2015 said they remembered taking the survey before. In 2016 all participants were asked whether they had taken the survey previously, enabling removal of any likely repeating cases. Data presented here are from site visits made to each program in 2015 and 2016, with repeating cases removed to support independence of the samples. The mean time between site visits to the same program, from 2015 to 2016, was 321.3 days (SD = 6.7).

Two research team members visited each clinic at each visit, and logistics of each visit were coordinated with the program liaison designated by the program director. In residential programs, participants were recruited into multiple time slots throughout the day, while in methadone programs, clients were recruited during morning dosing hours. Clients in outpatient programs were recruited either before or after group counseling sessions. Both smokers and non-smokers were eligible to participate if they had been in treatment for at least 10 days and if they were physically present in the program on the day of the site visit. The 10 day time in treatment criterion ensured that clients had time to become aware of program tobacco policies. These procedures yielded a systematic sample in outpatient and methadone programs, where clients visit daily or weekly, and yielded a census sample in residential programs where clients reside on a daily basis.

The research team explained the study to all clients who expressed interest to participate, and completed informed consent procedures. No information was recorded for those uninterested in the survey, and all those who completed the consent process also completed the survey. Participants completed surveys using iPads. The number of participants surveyed in each site ranged from 31 to 55, with a median of 50. Client respondents received a \$20 gift card, and each program received a \$2000 incentive after each site visit. Following the site visit, the director of each program was interviewed by phone concerning tobacco-related policies and services. Additional details concerning client surveys and director interviews are reported elsewhere (Guydish et al., 2016b; Pagano et al., 2016b). Study procedures were approved by the University of California, San Francisco, Institutional Review Board.

2.3. Measures

2.3.1. Client demographic characteristics and use of tobacco products

Clients reported age, gender, highest education level achieved, race/ethnicity, and type of program where they were recruited (outpatient, residential, methadone). The study was funded by the FDA Center for Tobacco Products, in part, to better understand use of tobacco products, so questions included the use of cigarettes, electronic cigarettes (e-cigarettes), smokeless tobacco, and cigars, and use of more than one tobacco product.

2.3.2. Smoking-related outcome measures

Participants were asked whether they were current smokers, defined

as having smoked more than 100 cigarettes in their lifetime and also self-identifying as current smokers at the time of the survey. All participants were asked, “Do staff and clients ever smoke together,” and the proportion reporting “yes” was used as a measure of organizational climate with respect to smoking. Current smokers reported number of cigarettes smoked per day (CPD). Current smokers were asked “Are you seriously thinking of quitting smoking?” an item used to measure stage of change for readiness to quit smoking (DiClemente et al., 1991). For analyses, responses were dichotomized into whether or not the participant was thinking of quitting in the next 30 days. Current smokers also reported whether they had made a quit attempt lasting at least 24 h in the past year.

Respondents also completed the Smoking Knowledge, Attitudes and Services (S-KAS) survey (Gudyish et al., 2011b). In this analysis we used the Attitude (8 items) and Program Service (8 items) subscales. Attitude items ask, for example, whether clients in the program want to quit smoking, whether the program prioritizes counseling for smoking cessation, and whether the client is aware of community smoking cessation resources. Program Service items ask, for example, whether the current program had provided the client with educational material about quitting smoking, whether quitting smoking is a requirement of the program, and whether the risks of smoking were discussed with the client. All items are scored from 1 to 5, and a higher scale score (the mean of the item scores) reflects more positive attitudes toward smoking cessation, or receipt of more tobacco cessation services in the current treatment program. Prior research demonstrated acceptable reliability ($\alpha = 0.75$) for the Attitude scale and high reliability ($\alpha = 0.82$) for the Program Service scale (Gudyish et al., 2011b).

2.3.3. Program tobacco policy

Following each site visit the program director was interviewed concerning tobacco policies in their clinic, and interviews were transcribed (Pagano et al., 2016b). After the first director interview, two raters independently read the interviews to assess whether a clinic did (1) or did not (0) have a tobacco-free grounds policy, defined as a ban on indoor and outdoor smoking with no designated smoking areas. Inter-rater reliability was good ($\kappa = 0.73$), and disagreements on policy status were resolved through discussing with a third rater. In one case where the presence of tobacco-free grounds was still uncertain, the program director was contacted for confirmation.

Among the 6 addiction treatment programs with a tobacco-free grounds policy during all survey periods, four programs explicitly extended the ban to include electronic cigarettes and two programs explicitly prohibited staff and clients from smoking together. Two program directors said there were consequences for staff or clients smoking on grounds, while the remaining four directors reported no specific consequences for breaking the ban. None of the programs prohibited clients from smoking when they were not on program grounds. Among the two programs that adopted a tobacco-free grounds policy after the initial survey, one prohibited staff from showing evidence of smoking, and both had established consequences for both staff and clients who smoke on program grounds.

2.4. Data analysis

Across all programs, the total sample size was 1176 in 2015 and 1202 in 2016. In 2016, however, 147 cases said they took the survey previously ($n = 109$), were unsure ($n = 34$), or were missing data for this item ($n = 4$). Of the 147 cases, 60% were from methadone programs, 22% were from outpatient programs, and 18% were from residential programs. Because all responses were anonymous, it was not possible to use a model accounting for non-independence of some observations. Therefore, these 147 cases were dropped from analysis. Included in analyses were 1176 cases in 2015 and 1055 cases in 2016.

We first compared samples across the two waves, using Pearson's chi-square test for categorical variables and the *t*-test for continuous

variables, on demographic characteristics, treatment type, and use of each tobacco product. This was to indicate whether the two samples differed in ways that should be adjusted in later analyses. Second, we compared the two samples on each of the 7 smoking-related outcomes using regression models, adjusting for treatment type (outpatient, residential, methadone) which was significantly different across two samples at the univariate analyses. The regression models also controlled for nesting of clients within program. This was to assess the level of change on each outcome from 2015 to 2016.

As there were few differences on smoking-related outcomes over time, we collapsed across waves and compared outcomes for clients in programs with ($n = 6$) and without ($n = 17$) tobacco-free grounds. Tobacco free-grounds status (yes/no) was consistent over time for 23 programs, but 2 programs adopted tobacco-free grounds policies between 2015 and 2016. Consequently, the comparison of smoking-related outcomes by policy status included only the 23 programs where tobacco-free policy status was the same at both time points. Moreover, policy status was confounded with program type, such that 1 of 9 residential programs, 1 of 7 outpatient programs, and 4 of 7 methadone programs had tobacco free grounds at both times. To minimize potential confounding, we compared smoking-related outcomes by policy status within each program type. While demographic variables showed no difference across waves for the total sample (see Table 1), they were often associated with outcomes when analyzing policy status within

Table 1

Demographic characteristics and use of tobacco products among persons enrolled in 25 addiction treatment programs over time.

	Mean (SD) or n (%)		p value (2016 vs. 2015)
	2015 (N = 1176)	2016 (N = 1055)	
Age	38.5 (11.87)	37.9 (11.83)	0.212
Gender			0.487
Male	604 (51.4%)	519 (49.2%)	
Female	566 (48.1%)	527 (50.0%)	
Other	6 (0.5%)	8 (0.8%)	
Education			0.531
< HS	256 (21.8%)	222 (21.1%)	
HS/GED	401 (34.2%)	384 (36.5%)	
> HS	516 (44.0%)	447 (42.5%)	
Race			0.927
Hispanic	160 (13.6%)	152 (14.4%)	
Black/African American	200 (17.0%)	165 (15.6%)	
White	658 (56.0%)	587 (55.6%)	
American Indian/Alaska	53 (4.5%)	54 (5.1%)	
Asian/Pacific Islander	26 (2.2%)	24 (2.3%)	
Other	79 (6.7%)	73 (6.9%)	
Treatment type			0.034
Outpatient	345 (29.3%)	307 (29.1%)	
Residential	479 (40.7%)	479 (45.4%)	
Methadone	352 (29.9%)	269 (25.5%)	
Weekly Use of Tobacco Products ^{a,b}			
Cigarettes	910 (77.4%)	811 (76.9%)	0.775
E-cigarettes	187 (16.1%)	165 (15.7%)	0.829
Smokeless Tobacco	94 (8.1%)	60 (5.7%)	0.031
Little Filtered Cigars	76 (6.5%)	86 (8.2%)	0.135
Cigars	43 (3.7%)	36 (3.4%)	0.749
Weekly use of at least one product	964 (82.0%)	872 (82.7%)	0.674
Multiple Product Use ^a			0.424
No product	212 (18.0%)	183 (17.3%)	
One product only	687 (58.4%)	644 (61.0%)	
Multiple products	277 (23.6%)	228 (21.6%)	

^a Self-report use of tobacco products at least weekly in the past 30 days.

^b Percentages add to more than 100% due to multiple product use.

each program type. Consequently, analyses comparing policy and non-policy programs controlled for analyses adjusted for age, gender, education, and race/ethnicity, and for nesting of clients within program.

For the two programs that changed their tobacco-free grounds policy status from 2015 to 2016, we compared each of the smoking-related outcomes in 2015 (pre-policy) and 2016 (post-policy). These analyses also controlled for demographic characteristics and for nesting.

3. Results

3.1. Smoking behavior among clients enrolled in addiction treatment programs, 2015–2016

Clients recruited in 2015 had a mean age of 38.5 (SD = 11.87), nearly half were women (48.1%), and 44% had some education beyond high school (Table 1). The 2015 sample was 56% White, 17% African American, 13.6% Hispanic, 4.5% American Indian or Alaska Native, and 2.2% Asian/Pacific Islander. Participants were recruited from outpatient (29.3%), methadone (29.9%), and residential (40.7%) programs. Most (77.4%) smoked cigarettes at least weekly, 82% used at least one tobacco product on a weekly basis, and 23.6% used more than one tobacco product. These characteristics did not differ between the 2015 and 2016 samples, except that there were fewer methadone participants ($p = 0.034$) and fewer smokeless tobacco users in 2016 ($p = 0.031$).

Table 2 shows means or proportions for the 7 selected smoking-related outcomes, at each wave. Comparisons adjusted for program type and for nesting of participants within program. In the 2015 sample, most respondents were current smokers (77.4%), nearly one-third (32.3%) reported that staff and clients smoked together in their program, and mean CPD was 13.04. Among current smokers, 25.6% were thinking of quitting in the next 30 days, and 50.5% had made a quit attempt in the past year. In the context of a 5 point scale where 5 reflects positive attitudes about quitting or receipt of more tobacco services, mean scores were 3.09 for the S-KAS Attitude scale and 2.37 for the Program Service scale. There was a single significant difference across years, such that the S-KAS Program Service scale increased from 2015 to 2016 ($p = 0.043$). The effect size for this difference (0.02) can be interpreted in light of Cohen (1988), which considers effect sizes at or below 0.2 to represent “small” effects.

3.2. Association of tobacco free grounds policy with smoking-related outcomes

As there was only one significant difference in the analysis of smoking outcomes across waves, we collapsed waves and compared each outcome for programs that did and did not have a tobacco free grounds policy in place. For these analyses, we used a subset of 23

Table 2
Tobacco outcomes over time for 25 programs.

	Adjusted Mean/Proportion ^a		p value ^a
	2015	2016	
	(N = 1176)	(N = 1055)	
Client smoking prevalence	77.4%	76.9%	0.828
Staff and clients smoking together	32.3%	28.5%	0.269
Cigarettes per Day (CPD)	13.04	13.04	0.996
Thinking of quitting in the next 30 days	25.6%	25.5%	0.969
Any quit attempts in past year	50.5%	50.5%	0.982
Client S-KAS attitude	3.09	3.11	0.539
Client S-KAS program service	2.37	2.48	0.043

^a Adjusted for program type; and for nesting participants within program.

Table 3
Tobacco outcomes between programs with and without tobacco-free grounds for 23 programs

	Adjusted mean/proportion ^a		p value ^a
	Policy program	No policy program	
Residential			
Client smoking prevalence	89.9%	82.3%	0.014
Staff and client smoking together	27.0%	50.6%	0.005
Cigarettes per day (CPD)	9.7	11.0	0.009
Thinking of quitting in the next 30 days	40.4%	27.4%	0.009
Any quit attempts past year	55.5%	56.0%	0.810
Client S-KAS attitude	3.29	3.05	0.268
Client S-KAS program service	3.01	2.25	0.276
Outpatient			
Client smoking prevalence	48.8%	70.5%	< 0.001
Staff and client smoking together	6.4%	23.4%	< 0.001
Cigarettes per day (CPD)	9.1	11.5	< 0.001
Thinking of quitting in the next 30 days	25.3%	25.6%	0.861
Any quit attempts past year	67.9%	57.2%	< 0.001
Client S-KAS attitude	3.31	3.15	0.318
Client S-KAS program service	2.78	2.37	0.387
Methadone			
Client smoking prevalence	84.1%	81.2%	0.365
Staff and client smoking together	21.2%	47.7%	0.004
Cigarettes per day (CPD)	12.3	13.6	0.045
Thinking of quitting in the next 30 days	21.4%	22.0%	0.820
Any quit attempts past year	49.2%	42.8%	0.299
Client S-KAS attitude	3.10	3.13	0.775
Client S-KAS program service	2.54	2.53	0.931

^a Adjusted for age, gender, race and education; and controlled for nesting participants within program.

programs where the policy was the same at both waves, and removed 2 programs that shifted from having no policy in 2015 to having a policy in 2016. Because policy status was confounded with program type, comparisons shown in Table 3 were performed within program type. Models shown in Table 3 adjusted for age, gender, race/ethnicity, and education, and controlled for nesting of clients within program.

Two significant findings were consistent across all three program types. First, the proportion of respondents reporting that staff and clients smoked together in their program was lower in programs with tobacco-free grounds policies compared to programs without such policies. Second, mean CPD was lower in programs with tobacco-free grounds policies compared to those without. Smoking prevalence was inconsistently associated with program policy status. In residential programs smoking prevalence was higher in the tobacco-free grounds program, compared to others without the policies, and in outpatient programs smoking prevalence was lower in the tobacco free-grounds policy program. Two associations were specific to program type. The residential program with a policy had more clients thinking of quitting in the next month compared to programs without (40.4% v. 27.4%, $p = 0.009$), and the outpatient program with a policy had more clients making a quit attempt in the past year compared to programs without (67.9% v. 57.2%, $p < 0.001$).

3.3. Analysis of change in smoking-related outcomes pre-post tobacco free grounds policy

Two residential programs adopted tobacco-free grounds policies between survey data collection in 2015 and 2016. For these programs combined, Table 4 shows adjusted means and proportions for smoking-

Table 4
Tobacco outcomes pre- and post-policy implementation for 2 programs.

	Adjusted mean/proportion ^a		p value ^a
	Pre-policy	Post-policy	
Client smoking prevalence	92.5%	67.6%	0.005
Staff and client smoking together	35.6%	4.2%	0.031
Cigarettes per day (CPD)	10.62	8.24	<0.001
Thinking of quitting in the next 30 days	26.9%	31.6%	0.058
Any quit attempts past year	38.5%	52.1%	0.155
Client S-KAS attitude	3.08	3.07	0.925
Client S-KAS program service	2.08	3.05	<0.001

^a Adjusted for age, gender, race and education; and controlled for nesting participants within program.

related outcomes before and after policy implementation, adjusting for demographic variables and controlling for nesting within program. Five of the seven outcomes show significant difference from pre to post-policy, and all differences are in the direction of improved outcomes following implementation of tobacco-free grounds.

4. Discussion

In 25 addiction treatment programs, and comparing annual cross-sectional samples of clients recruited in 2015 and 2016, we observed no difference over time for smoking prevalence, staff and clients smoking together, and CPD, or for the rates of thinking of quitting, making quit attempts. We saw no difference over time for client attitudes toward quitting smoking, and a small increase for program services related to tobacco. While there is a continuing decline in smoking in the U.S. general population in recent years (Jamal et al., 2016), we observe no such decline in persons enrolled in addiction treatment. Together with previous reports, these findings suggest no decrease in smoking prevalence among persons enrolled in publicly-funded addiction treatment from 1987 through 2016 (Guydish et al., 2016a; Guydish et al., 2011a; Guydish et al., 2015).

The finding of little or no change over time for most tobacco-related measures suggests that public health, tobacco control, and addiction treatment efforts to address tobacco use have limited impact in this population so far. Innovative approaches are necessary to address smoking in this population, and possibly in other populations where smoking remains prevalent. These may include regulating the amount of nicotine in cigarettes to reduce addictiveness (Benowitz and Henningfield, 2013), eliminating menthol flavoring, which appears to be associated with greater nicotine addiction and more difficulty in quitting (Benowitz and Samet, 2011; Foulds et al., 2010; Keeler et al., 2016) or, acceptable in Europe but not in the U.S., using e-cigarettes as a harm reduction strategy (Hartmann-Boyce et al., 2016).

Compared to programs with no such policy, those having tobacco-free grounds recorded lower rates of staff and clients smoking together and lower CPD across all treatment types. Thinking of quitting smoking was associated with tobacco free grounds in residential programs, while making a past year quit attempt was associated with tobacco-free grounds in outpatient programs. Smoking prevalence was higher in the residential program with tobacco-free policies, and lower in the outpatient program having such a policy. It is possible that the single residential program that already implemented tobacco free grounds by the time of the first data collection did so partly in response to a high rate of smoking among clients. In two residential treatment programs where tobacco-free grounds policies were implemented between 2015 and 2016, analysis of smoking-related outcomes showed significantly decreased smoking behavior and increased receipt of tobacco-related services post policy.

These findings suggest the potential for tobacco-free grounds policies to impact smoking-related outcomes in addiction treatment

programs. These findings are consistent with studies of workplace smoking bans (Bauer et al., 2005; Fichtenberg and Glantz, 2002), and with studies reporting on the New York State tobacco-free initiative implemented in addiction treatment programs (Brown et al., 2012). Tobacco free grounds policies have been widely implemented in other healthcare settings, including primary care clinics, hospitals, and psychiatric facilities (American Hospital Association, 2017; American Nonsmokers' Rights Foundation, 2017). As tobacco-free grounds have been implemented in about one-third of addiction treatment facilities (Muilenburg et al., 2016; Shi and Cummins, 2015; Substance Abuse and Mental Health Services Administration, 2017), there seems little argument about feasibility of implementation. In addiction treatment settings, where smoking is epidemic, such policies have the advantage of providing a consistent message concerning all drug use, including tobacco use, and that the program is concerned with client health beyond drug use (Knapp et al., 1993). Moreover, use of tobacco-free grounds does not require lengthy rule setting and comment periods of federal regulatory actions, and does not carry current controversy of use of e-cigarettes. Implementation of tobacco free grounds policies offers an immediate, low cost and actionable strategy for addressing tobacco use in addiction treatment programs, and supports a program environment where client smoking can be addressed more effectively by, for example, reducing or eliminating the negative practice of staff and clients smoking together (Guydish et al., 2017).

One limitation is that we did not examine how well the tobacco-free grounds policies were followed or enforced. Differences in implementation, enforcement, and compliance of tobacco-free grounds policies is an important area for future research. Other study limitations include limited generalizability, as programs participating in this research were drawn from the NIDA CTN and some differences between CTN and non-CTN programs have been reported (Ducharme and Roman, 2009; Susukida et al., 2016). The programs in this study were publicly-funded, which is true for two-thirds of addiction treatment programs in the U.S. (Mark et al., 2007), but do not represent privately funded programs or those operated by large healthcare providers such as Kaiser. Clients within each program were recruited using census or convenience procedures, and may not fully represent all clients in the selected programs. Findings reported are based on cross-sectional analyses and do not permit causal attribution.

4.1. Conclusion

Findings reported from a large sample of clients drawn from a national sample of addiction treatment programs indicate first, little change over time in smoking prevalence or other smoking-related measures in this population and second, support the use of tobacco-free grounds policies as a strategy to address smoking in these settings. We recommend that the Center for Substance Abuse Treatment require tobacco-free grounds policies as a condition for block grant and capacity expansion funding to addiction treatment programs, that state agencies concerned with regulation and licensing of addiction treatment programs require adoption of tobacco-free grounds and that, even in the absence of any future mandate, addiction treatment programs implement tobacco-free grounds as a way to reduce health risks for both program staff and clients.

Role of funding source

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Contributors

Joseph Guydish conceived the study, had oversight of all implementation and analysis and drafted the paper. Deborah Yip executed data collection, developed literature review, drafted sections of the manuscript, and interpreted qualitative data regarding program policies. Thao Le managed data, conducted analyses presented, and contributed to data interpretation. Noah Gubner executed data collection and contributed to literature review and data interpretation. Kevin Delucchi provided consulting on the analysis plan, statistical methods, and data interpretation. Paul Roman contributed to development of program sampling procedures, drew the sample of programs using data previously collected by his research team, and commented on the manuscript. All authors have read and approved of the submission of this manuscript to *Drug and Alcohol Dependence*.

Conflict of interest

No conflict declared.

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Original investigation

Tobacco Smoking, Nicotine Dependence, and Patterns of Prescription Opioid Misuse: Results From a Nationally Representative Sample

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Abstract

Introduction: The misuse of prescription opioid medications is a growing public health crisis. Given evidence of complex nicotine-opioid interactions, and initial support for the role of smoking status as a risk factor for prescription opioid misuse, a more detailed analysis of how current and historical patterns of smoking may influence misuse of prescription opioids is warranted.

Methods: The current study is the first to test whether varying levels of current/historical smoking (current daily, current intermittent, former daily, never) and indices of smoking heaviness/nicotine dependence may be associated with greater likelihood of past-year prescription opioid misuse in the general population. Data were derived from the National Survey on Drug Use and Health ($N = 24,348$).

Results: Consistent with hypotheses, after accounting for sociodemographic factors and major depressive/alcohol use disorders, both daily and intermittent smokers were greater than 3 times more likely to report past-year nonmedical prescription opioid use than were never smokers. In addition, daily smokers were observed to be nearly 5 times more likely, and intermittent smokers were nearly 3 times more likely, to have met past-year abuse/dependence criteria, relative to never smokers. Results further revealed positive associations between various indices of smoking heaviness/nicotine dependence and opioid medication misuse, and these findings remained largely consistent when analyses were stratified by gender.

Conclusions: These findings indicate that smokers are not a homogeneous group with regard to risk for opioid misuse, and support the utility of comprehensive smoking assessment in the context of opioid-based treatment/tapering.

Introduction

The misuse of prescription opioid medications is a growing public health crisis that warrants greater empirical attention.¹ Although the term misuse may comprise a variety of aberrant behaviors, the current study focuses on nonmedical use (i.e., use for the feeling or experience, or use without a prescription) and diagnostic criteria for

abuse/dependence (e.g., evidence of impaired functioning, tolerance, withdrawal). Factors that have been shown to confer heightened risk for prescription opioid misuse include the presence of chronic pain and co-occurring substance use/mood disorders.^{2,3} Despite evidence of unique nicotine-opioid interactions,⁴ surprisingly little research has examined tobacco smoking as a risk factor for the misuse of

prescribed opioids, and we are not aware of any studies that examined whether varying levels of tobacco consumption/dependence or having successfully quit smoking may confer differential risk for these outcomes.

There are several pathways by which unique nicotine-opioid interactions may confer greater risk for prescription opioid misuse. First, chronic nicotine exposure may result in dysregulation of the endogenous opioid system, leading to greater pain and cross-tolerance to prescription opioids.⁴ There is also evidence that nicotine may sensitize the neural system to enhance the rewarding properties of opioid medications,⁵ which is consistent with incentive-sensitization theories of addiction.^{6,7} Although there is initial evidence that smoking may be associated with nonmedical use of prescribed opioids,⁸⁻¹⁰ each of these studies utilized fairly “crude measures of smoking” (Skurtveit, Furu, Selmer, Handal, and Tverdal¹¹, p. 893) over the past year (i.e., any vs. none) that were included along with numerous other factors in large statistical models. While this approach has utility in the identification of risk factors that warrant further empirical scrutiny, such narrow classifications infer homogeneity and may obscure important differences both within current smokers (e.g., as a function of daily cigarette consumption or age at smoking onset) and between current smokers, those who previously smoked but quit, and never smokers. Indeed, evidence of substantive differences between heavy and light or intermittent smokers (e.g., smoking motives; Shiffman, Dunbar, Scholl, and Tindle¹²) underscores the need to conduct research among samples that represent a spectrum of smoking patterns (i.e., smoking frequency, intensity, and duration; Fagan and Rigotti¹³).

Considering the societal and economic costs associated with an escalating prescription opioid epidemic,¹⁴ additional studies designed to explicate patterns of misuse in the general population are sorely needed.¹ Evidence of complex nicotine-opioid interactions, along with initial support for the role of smoking status in the prediction of prescription opioid misuse, warrants a more detailed analysis of how current and historical patterns of smoking may influence these outcomes. Indeed, we are aware of only one population-based study that examined relations between nicotine dependence and misuse of prescribed opioids,¹⁵ though these analyses were limited to lifetime diagnostic criteria, and failed to account for co-occurring mood and substance use disorders. Additional support for a more detailed examination of smoking characteristics in relation to prescription opioid misuse can be derived from studies that found heavier smokers (relative to lighter and never smokers) used analgesic medications more frequently¹⁶ and held a greater number of opioid prescriptions.^{11,17} We are not, however, aware of any previous studies that tested associations between varying levels of tobacco smoking and prescription opioid misuse outcomes.

The main goal of the current study was to assess the extent to which varying levels of current and historical nicotine/tobacco exposure (i.e., current daily vs. current intermittent vs. former daily vs. never smoking) may be differentially associated with past-year opioid misuse, after accounting for relevant sociodemographic characteristics and the presence of past-year major depression and alcohol use disorders. A second goal was to examine indices of smoking heaviness/nicotine dependence in relation to past-year opioid misuse among our nationally representative sample of current daily smokers. Specifically, we hypothesized that the greatest likelihood for both nonmedical use and abuse/dependence on prescribed opioids would be observed among current daily smokers, followed by intermittent and former smokers, relative to never smokers. We further

hypothesized that, among current daily smokers, greater cigarette consumption, higher nicotine dependence scores, and earlier age at initiation of smoking would each be positively associated with past-year opioid misuse outcomes. Finally, consistent with previous research,^{8,10} we examined each of these outcomes stratified by gender.

Methods

Data Source

Data were derived from the 2009 National Survey on Drug Use and Health (NSDUH). The NSDUH is a nationally representative survey of persons age 12 and older who reside in the United States (total $N = 68,700$). Recruitment, sampling, and interviewing procedures have been previously described.¹⁸ The current analyses were restricted to data obtained from adult respondents who were classified as current daily, current intermittent, former daily, or never smokers ($N = 24,348$).

Measures

Nonmedical Prescription Opioid Use

Nonmedical prescription opioid use was defined by either use without holding a prescription, or for the experience/feeling that it produced. Respondents viewed a card with pictures and names of prescription pain relievers, and were asked to indicate (yes/no) whether they had used each in a nonmedical fashion over the past year. Medication names provided on the card corresponded with pictures of the capsules/tablets, such that pictures of brand name medications were labeled with the registered brand name (e.g., OxyContin® or Percocet®), and pictures of generic medications were labeled with the name of the medication (e.g., morphine, codeine). Respondents who endorsed nonmedical use of at least one prescription opioid were considered positive for past-year nonmedical opioid use.

Prescription Opioid Abuse/Dependence

Past-year prescription opioid abuse and dependence were assessed using Diagnostic and Statistical Manual criteria (DSM-IV).¹⁹ Given that prior research has typically combined abuse/dependence,^{8,9} and that DSM-V criteria no longer distinguishes abuse from dependence,²⁰ we utilized a composite variable provided by NSDUH that represents the presence or absence of past-year opioid abuse/dependence.

Smoking Status

Lifetime smoking status was first screened with a single item (“Have you ever smoked part or all of a cigarette?”). A response of “yes” prompted additional questions regarding frequency of smoking, number of cigarettes smoked per day, and age at smoking onset. Responses were used to calculate a composite smoking status variable as follows: current daily smokers (smoked every day for the past 30 days), former daily smokers (prior daily smoking but no smoking in the past year), intermittent smokers (smoked 4–27 days of the past month and never smoked daily; Shiffman et al.¹²), and never smokers (never smoked all or part of a cigarette).

Number of Cigarettes Smoked per Day

Respondents who endorsed past-month smoking were asked: “On the days you smoked cigarettes during the past 30 days, how many cigarettes did you smoke per day, on average?” Responses were coded by the NSDUH into a categorical item representing fewer

than 6, 6–15, 16–25, or 26 or more. Consistent with prior research that utilized 15 cigarettes per day (cpd) as a cut-off to delineate light from moderate/heavy smokers,^{21,22} cpd was dichotomized (≤ 15 or > 15).

Nicotine Dependence

Nicotine dependence was assessed using an item from the Fagerström Test of Nicotine Dependence that asked smokers to indicate how soon after waking they have their first cigarette of the day.²³ Time to first cigarette is considered a valid measure of physiological dependence on nicotine/tobacco,²⁴ and has been related to biochemical markers of tobacco use (i.e., cotinine; Muscat, Stellman, Caraballo, and Richie²⁵) and smoking cessation outcomes.²⁶ Consistent with prior research,^{25,27} responses were dichotomized as being indicative of either high (i.e., smoking within 30 min of waking) or low (i.e., smoking more than 30 min after waking) dependence.

Age of Smoking Onset

Respondents were asked: “How old were you the first time you smoked part or all of a cigarette?” Responses were coded by the NSDUH into a categorical item representing age of onset at 14 years or younger, 15–17 years, 18 years or older, or nonusers.

Sociodemographic Characteristics and Psychiatric Comorbidity

Previous research indicates that several factors may be relevant to smoking-opioid use relations, including various sociodemographic characteristics and co-occurring depression and alcohol use disorders.^{8,9,28,29} Therefore, from an a priori basis, all analyses statistically-controlled for age, marital status, education, employment status, gender, race/ethnicity, past-year major depressive episode (MDE), and past-year alcohol use disorder (AUD). Past-year MDE and AUD were diagnosed according to DSM-IV criteria.¹⁹

Data Analytic Plan

Analyses were conducted in SAS 9.4 using PROC SURVEYLOGISTIC, and utilized weights provided by NSDUH.¹⁸ First, we constructed a set of logistic regression models with smoking status entered as the fixed factor, and past-year nonmedical prescription opioid use and past-year prescription opioid abuse/dependence entered as the respective dependent variables. We then constructed a second set of logistic regression models to test associations between indices of nicotine dependence (i.e., age at initiation of smoking, nicotine dependence scores, and number of cigarettes smoked per day) and past-year nonmedical opioid use and abuse/dependence, among our subsample of current daily smokers ($n = 6,922$). Analyses included never smokers as the reference group. To test whether the smoking variables were uniquely associated with nonmedical prescription opioid use and abuse/dependence, above-and-beyond the variance attributed to other relevant factors, all regression models controlled for sociodemographic characteristics, MDE, and AUD. Consistent with prior research that utilized data derived from the NSDUH, we then conducted separate logistic regression models, stratified by gender, to determine whether associations were consistent across males and females.^{8,10}

Results

Sample Characteristics

Of the adult respondents meeting criteria for one of the smoking categories ($N = 24,348$), 24.1% were categorized as current daily

smokers, 25.9% as former daily smokers, 3.5% as intermittent smokers, and 46.5% as never smokers. As seen in Table 1, slightly more than half of all respondents were male (52.5%), married (53.9%), and currently employed (61.3%). Nearly 70% of the sample identified as non-Hispanic White, and greater than 80% had graduated from high school. Consistent with previous research derived from nationally representative surveys, 4.3% of all respondents endorsed past-year nonmedical prescription opioid use (e.g., 4.5%–5.1%; Back et al.⁸; Becker et al.⁹), 0.7% met criteria for past-year opioid abuse/dependence (e.g., 0.7%; Back et al.⁸), and 6.5% met criteria for a past-year major depressive episode (e.g., 6.7%; Kessler, Chiu, Demler, Merikangas, and Walters³⁰).

Associations Between Current/Historical Smoking Status and Prescription Opioid Misuse

Past-Year Nonmedical Prescription Opioid Use

As hypothesized, among the total sample, both daily ($AOR = 3.79$, 95% $CI = 3.00$ – 4.79 , $p < .001$) and intermittent smokers ($AOR = 3.12$, 95% $CI = 2.32$ – 4.18 , $p < .001$) were over three times more likely than never smokers to have endorsed past-year nonmedical prescription opioid use (Table 2). No differences were observed between former and never smokers ($p = .44$). A similar pattern of results was observed when analyses were stratified by gender, such that both daily and intermittent ($ps < .001$), but not former ($ps > .44$) smoking were associated with a greater likelihood of past-year nonmedical use of prescription opioids among both men and women (Table 3).

Past-Year Prescription Opioid Abuse/Dependence

As hypothesized, among the total sample, daily smokers were nearly five times more likely ($AOR = 4.82$, 95% $CI = 2.46$ – 9.43 , $p < .001$), and intermittent smokers were nearly three times more likely ($AOR = 2.96$, 95% $CI = 1.13$ – 7.78 , $p = .03$), to have met criteria for past-year abuse/dependence, relative to never smokers. We did not observe any differences between former and never smokers ($p = .39$). When analyses were stratified by gender, results indicated that both male and female current daily smokers (relative to never-smokers) were more likely to have met criteria for past-year abuse/dependence ($ps < .01$). Among females only, former daily smokers were also more likely to have met criteria for opioid abuse/dependence in the past-year ($p = .008$), relative to never smokers.

Associations Between Indices of Smoking Heaviness/Nicotine Dependence and Prescription Opioid Misuse Among Current Daily Smokers

Past-Year Nonmedical Prescription Opioid Use

As hypothesized, among the total sample, current daily smokers who reported smoking onset prior to age 14 were more than twice as likely to have endorsed past-year nonmedical use of prescribed opioids ($AOR = 2.32$, 95% $CI = 1.56$ – 3.44 , $p < .001$), relative to those who began smoking after age 18. A similar pattern of results was observed when analyses were stratified by gender, such that smoking onset prior to age 14 was associated with an increased likelihood of past-year opioid misuse among both males and females ($ps < .01$). Results also indicated that smoking greater than 16 cpd (vs. ≤ 15 cpd) was associated with an increased likelihood of past-year nonmedical opioid use among females ($AOR = 1.79$, 95% $CI = 1.27$ – 2.53 , $p = .001$), but not in the total sample or among males ($ps > .08$). Finally, no associations were observed between nicotine dependence

Table 1. Sample Demographics by Smoking Status

	Total sample N (%)	Current daily smokers, n (%)	Former smokers, n (%)	Intermittent smokers, n (%)	Never smokers, n (%)
Past-year nonmedical opioid use					
Yes	1,812 (4.3)	1,132 (10.5)	125 (1.8)	217 (11.5)	338 (1.9)
No	22,536 (95.7)	5,790 (89.5)	3,516 (98.2)	1,206 (88.5)	12,024 (98.1)
Past-year opioid abuse or dependence					
Yes	338 (0.7)	265 (2.1)	14 (0.3)	23 (1.6)	36 (0.2)
No	24,010 (99.3)	6,657 (97.9)	3,627 (99.7)	1,400 (98.4)	12,326 (99.8)
Past-year MDE					
Yes	1,877 (6.5)	834 (11.0)	254 (6.2)	114 (8.9)	675 (4.2)
No	22,271 (94.5)	6,017 (89.0)	3,375 (93.8)	1,296 (91.1)	11,583 (95.8)
Past-year AUD					
Yes	2,427 (6.7)	1,306 (13.7)	234 (4.9)	364 (22.0)	523 (3.0)
No	21,921 (93.3)	5,616 (86.3)	3,407 (95.1)	1,059 (78.0)	11,839 (97.0)
Age					
18–29	13,473 (20.4)	3,956 (24.6)	719 (5.3)	1,156 (51.5)	7,642 (24.4)
30–49	6,888 (34.9)	2,187 (42.1)	1,389 (27.9)	224 (34.5)	3,088 (35.2)
50+	3,987 (44.6)	779 (33.4)	1,533 (66.9)	43 (14.0)	1,632 (40.4)
Sex					
Female	11,109 (47.5)	3,535 (51.1)	1,785 (45.0)	581 (38.8)	7,338 (59.9)
Male	13,239 (52.5)	3,387 (48.9)	1,856 (55.0)	842 (61.2)	5,024 (40.1)
Race/ethnicity					
White	15,161 (67.5)	5,221 (79.4)	2,870 (82.8)	735 (48.8)	6,335 (54.2)
Black	3,265 (12.0)	597 (9.3)	225 (6.5)	250 (19.2)	2,193 (16.0)
Hispanic	3,729 (13.6)	545 (7.7)	322 (7.2)	315 (25.7)	2,547 (19.2)
Other	2,193 (6.9)	559 (3.6)	224 (3.4)	123 (6.3)	1,287 (10.6)
Marital status					
Married	8,553 (53.9)	1,973 (41.5)	2,219 (67.8)	186 (27.0)	4,175 (54.5)
Unmarried	15,795 (46.1)	4,949 (58.5)	1,422 (32.2)	1,237 (73.0)	8,187 (45.5)
Education					
Less than high school	4,649 (17.5)	1,742 (21.9)	527 (13.6)	279 (18.6)	2,101 (17.4)
At least high school	19,699 (82.5)	5,180 (78.1)	3,114 (86.4)	1,144 (81.4)	10,261 (82.6)
Employment					
Employed	15,662 (61.3)	4,439 (64.6)	2,361 (56.8)	959 (69.2)	7,903 (61.5)
Not employed	8,686 (38.7)	2,483 (35.4)	1,280 (43.2)	464 (30.8)	4,459 (38.5)

Note. Results are reported as unweighted N and weighted percentages. AUD = alcohol use disorder; MDE = major depressive episode.

scores and past-year nonmedical prescription opioid use in the total sample or when analyses were stratified by gender ($ps > .08$).

Past-Year Prescription Opioid Abuse/Dependence

Also as hypothesized, current daily smokers who scored high (relative to low) on the nicotine dependence item were more than twice as likely to have met past-year prescription opioid abuse/dependence criteria in the total sample ($AOR = 2.51$, 95% $CI = 1.57$ – 4.00 , $p < .001$), and among both males and females ($ps < .01$). Current daily smokers who reported smoking greater than 16 cpd (relative to those who smoked ≤ 15 cpd) were also more likely to have met diagnostic criteria for past-year prescription opioid abuse/dependence in the total sample ($AOR = 1.96$, 95% $CI = 1.21$ – 3.17 , $p = .006$) and among females ($p = .007$). Finally, we observed no association between age of smoking onset and past-year prescription opioid abuse/dependence in the total sample or when analyses were stratified by gender ($ps > .08$).

Discussion

Despite initial evidence that tobacco smoking may confer increased risk for the nonmedical use of prescribed opioids,^{8–10} and increasing awareness of unique nicotine-opioid interactions,⁴ we are not

aware of any previous studies that examined the extent to which varying levels of current and historical nicotine/tobacco exposure may be differentially associated with likelihood of past-year prescription opioid misuse. Consistent with hypotheses, these data revealed that both daily and intermittent smokers were greater than three times more likely than never smokers to have engaged in nonmedical use of prescribed opioids over the past year. These data further revealed that, relative to never smokers, daily smokers were nearly five times more likely, and intermittent smokers were nearly three times more likely, to have met diagnostic criteria for past-year prescription opioid abuse/dependence, even after accounting for relevant sociodemographic characteristics and the presence of past-year major depressive/alcohol use disorders. The pattern of results observed among the total sample remained largely consistent when analyses were stratified by gender, which suggests that varying levels of tobacco smoking are associated with prescription opioid misuse among both males and females. To our knowledge, this is the first population-based study to observe an association between positive smoking status and increased likelihood for prescription opioid abuse/dependence.

It is also noteworthy that, among females only, former daily smokers were more likely to have met criteria for past-year prescription opioid abuse/dependence, relative to never smokers. Thus, for

Table 2. Past-Year Nonmedical Opioid Use and Abuse/Dependence Among Respondents Aged 18 and Older

	Past-year nonmedical opioid use			Past-year opioid abuse/dependence		
	AOR	95% CI	<i>p</i> value	AOR	95% CI	<i>p</i> value
Smoking status						
Never smoker	ref					
Current daily smoker	3.79	3.00–4.79	<.001	4.82	2.46–9.43	<.001
Former daily smoker	1.18	0.81–1.72	.39	1.46	0.59–3.64	.42
Intermittent smoker	3.12	2.32–4.18	<.001	2.96	1.13–7.78	.03
Past-year MDE						
No	ref					
Yes	2.44	1.88–3.17	<.001	3.55	2.33–5.43	<.001
Past-year AUD						
No	ref					
Yes	2.81	2.26–3.50	<.001	3.54	2.34–5.36	<.001
Age						
18–29	ref					
30–49	0.43	0.41–0.60	<.001	0.63	0.41–0.97	.04
50+	0.23	0.16–0.32	<.001	0.21	0.11–0.42	<.001
Sex						
Female	ref					
Male	1.31	1.09–1.57	.004	1.45	0.98–2.14	.06
Race/ethnicity						
White	ref					
Black	0.43	0.30–0.61	<.001	0.16	0.07–0.33	<.001
Hispanic	0.58	0.44–0.77	.001	0.66	0.33–1.31	.23
Other	0.82	0.50–1.33	.41	0.74	0.18–3.04	.67
Marital status						
Unmarried	ref					
Married	0.68	0.55–0.84	<.001	0.69	0.43–1.10	.12
Education						
<High school	ref					
≥High school	0.86	0.69–1.07	.17	0.66	0.42–1.04	.07
Employment						
Employed	ref					
Unemployed	1.22	1.01–1.48	.04	1.86	1.26–2.75	.002

Note. AOR = adjusted odds ratio; AUD = alcohol use disorder; MDE = major depressive episode.

women in our sample, successful smoking cessation was not associated with a reduced likelihood of opioid abuse/dependence. Within the total sample and among males, we observed no differences in prescription opioid misuse between former and never smokers. Whereas this null finding might be interpreted to suggest that successful quitting may reduce liability for misuse of prescribed opioids, it is equally plausible that these former smokers may have been less dependent on both nicotine and opioid medications in the first place.

Consistent with the notion that tobacco and prescription opioid dependence may covary, the current results also revealed positive associations between several indices of nicotine dependence and likelihood of past-year opioid medication misuse. As hypothesized, in the total sample, current daily smokers who initiated tobacco use prior to age 14 (compared to after age 18) were more than twice as likely to have endorsed past-year nonmedical use of prescribed opioids. In addition, those who either reported smoking greater than 15 cpd or scored high (relative to low) on a measure of nicotine dependence were approximately two times more likely to have met criteria for past-year prescription opioid abuse/dependence. Interestingly, when analyses were stratified by gender, results indicated that smoking greater than 15 cpd was associated with increased likelihood of both past-year prescription opioid nonmedical use and abuse/dependence among females only. These results suggest that, particularly among

females, greater levels of cigarette consumption may be an important factor to consider in assessment of prescription opioid misuse.

Prescription opioid misuse is a growing public health crisis. In 2010, there were greater than 22,000 prescription drug overdose deaths, and 75% involved opioid pain medications.³¹ Unfortunately, the identification of factors that reliably and accurately predict prescription opioid misuse has proven to be an empirical and clinical challenge.³ For example, challenges in this area include both the identification of misuse among those who hold prescriptions for opioid medications, and the identification of nonmedical opioid use among those who obtain the medications without a prescription (e.g., purchased illegally). Results of the current study extend previous findings that current smoking may be associated with increased utilization of prescription opioids,^{11,17} by indicating that heavier, more nicotine-dependent smokers may be at greater risk to misuse opioid medications than lighter, less-nicotine dependent smokers.

There are several mechanistic pathways by which tobacco smoking may be associated with the onset and maintenance of prescription opioid misuse. First, chronic nicotine exposure may result in dysregulation of the endogenous opioid system, leading to greater pain and cross-tolerance to opioid medications.⁴ As such, smokers tend to require greater doses of analgesic medications,^{32,33} and we suspect that greater pain, cross-tolerance to

Table 3. Associations Between Smoking Variables and Prescription Opioid Misuse Stratified by Gender

	Male			Female		
	AOR	95% CI	<i>p</i> value	AOR	95% CI	<i>p</i> value
Outcome variable: past-year nonmedical prescription opioid use						
Smoking status						
Never	ref			ref		
Daily	4.33	2.96–6.36	<.001	3.28	2.48–4.38	<.001
Former	1.17	0.65–2.12	.60	1.20	0.75–1.91	.44
Intermittent	3.53	2.32–5.37	<.001	2.81	1.78–4.41	<.001
Age of smoking onset						
>18 years	ref			ref		
15–17 years	1.14	0.67–1.94	.63	1.93	0.98–3.81	.06
<14 years	2.17	1.32–3.57	.002	2.46	1.29–4.70	.006
CPD						
≤15	ref			ref		
>15	0.98	0.69–1.40	.92	1.79	1.27–2.53	.001
Nicotine dependence						
Low	ref			ref		
High	1.18	0.86–1.62	.32	1.27	0.89–1.81	.18
Outcome variable: past-year prescription opioid abuse/dependence						
Smoking status						
Never	ref			ref		
Daily	3.26	1.35–7.88	.009	8.46	3.94–18.18	<.001
Former	0.64	0.16–2.59	.06	4.07	1.44–11.50	.008
Intermittent	3.10	0.96–10.06	.53	1.74	0.49–6.27	.39
Age of smoking onset						
>18 years	ref			ref		
15–17 years	1.60	0.61–4.18	.34	0.60	0.13–2.76	.67
<14 years	2.19	0.91–5.21	.08	1.35	0.33–5.50	.52
CPD						
≤15	ref			ref		
>15	1.86	0.87–3.97	.11	2.28	1.26–4.13	.007
Nicotine dependence						
Low	ref			ref		
High	2.62	1.29–5.31	.007	2.50	1.32–4.75	.005

Note. Individual logistic regression models were constructed for each respective smoking variable. Age of smoking onset, cpd, and nicotine dependence were tested only among respondents who endorsed current daily smoking. AOR = adjusted odds ratio, after controlling for past-year major depressive episode, past-year alcohol use disorder, age, race/ethnicity, marital status, education, and employment; CPD = cigarettes per day.

opioid medications, and diminished pain relief could motivate escalation of opioid consumption among smokers. There is also some evidence from animal models that exposure to nicotine may enhance the rewarding/reinforcing properties of prescription opioids.⁵ Reward and reinforcement processes are well-represented in theories of addiction,³⁴ and according to Incentive Sensitization Theory, repeated drug administration may not only render the neural system hypersensitive to the effects of that drug, but can also produce cross-sensitization to other substances.⁶ Indeed, the rewarding effects of both nicotine and opioid medications are thought to be partially mediated by the dopaminergic system, and there is some evidence that chronic nicotine exposure may sensitize the dopaminergic system to opioid-based medications.⁵ Thus, over time, tobacco smokers may become sensitized to enhanced reward/reinforcement from prescription opioids, which could in turn contribute to opioid misuse among smokers. Finally, it has been suggested that associations between smoking and prescription opioid misuse may covary as a function of co-occurring risk factors such as depression and other substance use.² However, in the current study, associations between smoking status/heaviness and prescription opioid misuse persisted after controlling for past-year major depressive and alcohol use disorders.

The current findings may have clinical relevance for smokers with chronic pain who are maintained on opioid therapy, as they have been shown to report more severe pain and to require greater doses of opioid analgesics, relative to nonsmokers.^{32,33} Treatment-seeking pain patients who endorse smoking to cope with pain have evinced greater reliance on opioid medications,³⁵ and smokers (compared to nonsmokers) may be less likely to complete pain treatment that requires opioid tapering.³⁶ In addition, there is some evidence that smoking behavior may be influenced by consumption of prescription opioids,³⁷ and persons who use opioid medications for pain management may be more likely to smoke tobacco.³⁸ Collectively, these data are consistent with a recently proposed reciprocal model of pain and smoking (for review, see Ditre, Brandon, Zale, and Meagher³⁹), which posited that chronic pain, continued smoking, and the use/misuse of prescription opioids may interact to maintain pain and impede smoking cessation.

Strengths of the current study include use of a large and nationally representative sample, multilevel analysis of current and historical smoking patterns, and the utilization of established diagnostic criteria for past-year prescription opioid abuse/dependence. Several limitations also bear noting. First, these cross-sectional data preclude causal inferences and cannot establish temporal precedence with

regard to smoking onset/cessation and the use/misuse of prescribed opioids. Second, smoking status was not biochemically verified, and though former smokers reported being abstinent for at least one year, the exact duration since quitting was not known. Third, given that chronic pain was not assessed in the NSDUH, these findings may not generalize to all smokers with chronic pain who have received prescriptions for opioid medications. However, chronic pain and smoking are highly comorbid,³⁹ and these data may be representative of a broader segment of the smoking population that is likely to have experienced pain. These findings may also be representative of the broader population of persons who misuse prescription opioids, including those who use these medications without holding a prescription.

In summary, results of the current study indicate that “current smokers” are not necessarily a homogenous group with regard to likelihood of past-year opioid medication misuse, and that indices of nicotine dependence and smoking heaviness may have utility in differentiating misuse liability among current smokers. These results also suggest that the likelihood of prescription opioid misuse may not be elevated among males who successfully abstained from tobacco smoking. However, among females, former daily smokers were more likely to have met criteria for opioid abuse/dependence, which underscores the importance of a detailed smoking assessment that includes both current and historical tobacco use. Indeed, these data support the utility of more comprehensive assessment of smoking in clinical pain treatment settings, and in the context of studies that examine interrelations between pain reporting and the self-administration of prescribed opioids. These data also contribute to an emerging literature that may ultimately explicate potentially unique and reciprocal relations between tobacco smoking and the misuse of prescription opioid medications. Future research should examine whether smokers maintained on opioid therapy develop tolerance more quickly than nonsmokers, and whether smoking independently predicts use of opioids for its rewarding properties. Future research would also benefit from testing real-time associations between tobacco smoking and the consumption/perceived utility of opioid medications, perhaps using ecological momentary assessment.⁴⁰ Additional research may also benefit from examining relevant cognitive constructs that could help to explain the co-occurring use of both nicotine and prescription opioids (e.g., distress tolerance, impulsivity, and delay discounting). Finally, it would be interesting to examine prospective relations between smoking cessation/relapse, pain severity, and the consumption/perceived efficacy of prescription opioids.

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Declaration of Interests

None declared.

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Association Between Smoking Behavior and Cognitive Functioning in Patients With Psychosis, Siblings, and Healthy Control Subjects: Results From a Prospective 6-Year Follow-Up Study

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Objective: The high prevalence of smoking and cognitive deficits in schizophrenia patients is well known, but findings regarding the association between the two are contradictory, and longitudinal studies are lacking. The authors sought to examine the multi-cross-sectional association between smoking behavior and performance in specific cognitive domains and the longitudinal association between change in smoking behavior and change in cognitive functioning in a large prospective study.

Method: The authors conducted a cohort study of patients with nonaffective psychosis (N=1,094), their siblings (N=1,047), and healthy control subjects (N=579). At baseline and at 3- and 6-year follow-ups, smoking behavior was assessed with the Composite International Diagnostic Interview and cognitive functioning with a test battery. Multivariate linear mixed-effects regression analyses were conducted to assess associations between smoking and cognitive domains while adjusting for variation in demographic factors, psychopathology, medication, and substance use. Bonferroni correction for multiple testing was applied.

Results: At baseline, 66.6% of the patients smoked, compared with 38.3% of the siblings and 25.2% of the control subjects. Significant multi-cross-sectional associations were found between smoking and lower processing speed in the patient and control groups compared with the nonsmoking patient group (estimate=−2.38, SE=0.84) and the nonsmoking control group (estimate=−3.13, SE=1.06). In siblings, smoking was significantly associated with lower performance in working memory and reasoning and problem solving compared with nonsmoking. Also, the number of cigarettes smoked per day was negatively associated with these domains. Patients, but not siblings and control subjects, who quit smoking showed a significant improvement in processing speed (estimate=4.90, SE=1.73).

Conclusions: The study findings indicate that smoking is associated with poorer cognitive performance in patients, their siblings, and healthy control subjects compared with nonsmoking. Smoking cessation may improve processing speed in patients.

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Tobacco use is an undisputed risk factor for increased mortality in both the general population and psychiatric patients. A meta-analysis (1) showed that smoking is three times more prevalent among schizophrenia patients than in the general population, and adults with schizophrenia are almost 10 times more likely to die from chronic obstructive pulmonary disease compared with the general population (standardized mortality ratio=9.9, 95% CI=9.6–10.2) (2). Although tobacco use has declined in the general population in recent decades, smoking prevalence among patients with psychosis is still high.

Cognitive deficits also occur frequently in patients with psychosis (3). The severity and range of the affected cognitive

domains in patients vary widely (4). Cognitive domains are influenced by various underlying pharmacological mechanisms, and nicotine is known to enhance attention in patients and in the general population (5, 6). The short-term effects of nicotine have been studied intensively in patients with schizophrenia, given that the nicotinic acetylcholine receptor (nAChR) system that is implicated in cognitive functioning appears to be dysregulated in these patients (7, 8). Preclinical evidence has shown that nicotine affects several neurotransmitter systems, including acetylcholine, dopamine, glutamate, and γ -aminobutyric acid (GABA), and patients with psychotic disorders may experience short-term

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cognitive benefits from nicotine administration (5). However, the most recent reviews on this topic showed that nicotine or nAChR-based treatments do not enhance cognition in patients with schizophrenia (9).

The long-term effects of smoking on cognitive functioning have been studied more extensively in the general population than in patients. A meta-analysis that included prospective studies with at least 12 months of follow-up (10) showed that elderly smokers in the general population are at a higher risk of cognitive decline than nonsmokers. In a large cohort study (N=10,308), similar results were found for middle-aged smokers compared with nonsmokers. In addition, the risk of poor cognition was lower among people who had stopped smoking compared with current smokers (11). Longitudinal research on the association between long-term smoking and cognition in patients with psychotic disorders, however, is scarce. Cross-sectional studies have found contradictory results (12–14). The largest of these studies (14) used a composite measure of cognitive performance to assess the effect of current smoking compared with past or never smoking in patients with severe mental illness (including 400 patients with schizophrenia). Current smokers performed on a lower level overall, but results were not reported for specific cognitive domains. This is unfortunate, because among patients with psychosis, the severity and range of affected cognitive domains are generally heterogeneous (3, 15). Moreover, a review on chronic smoking in the general population showed that cognitive domains may be differentially affected by smoking (16).

Longitudinal evidence regarding the associations between smoking and specific cognitive functions in patients with psychosis is lacking. Moreover, it is unknown whether these associations differ in patients with psychosis compared with healthy subjects and individuals who have high vulnerability to psychosis but do not have illness-related confounders (unaffected siblings).

In this study, we examined 1) the cross-sectional association between current smoking behavior and performance in specific cognitive domains and 2) the longitudinal association between smoking behavior and cognitive functioning, as well as changes in these parameters, in a large prospective study that included patients with psychotic disorders, unaffected relatives (siblings), and healthy control subjects. We hypothesized that smoking is associated with reduced cognitive functioning compared with not smoking and that smoking cessation is associated with partial cognitive recovery in all groups.

METHOD

Population and Study Design

This study was performed within the naturalistic multicenter Genetic Risk and Outcome of Psychosis (GROUP) cohort study. The full sample consisted of 1,119 patients with a diagnosis within the nonaffective psychotic spectrum, 1,059 unaffected siblings, and 586 unrelated healthy control subjects. The study procedures and inclusion and exclusion criteria for participants have been described in detail

elsewhere (17). Patients diagnosed as having a nonaffective psychotic disorder according to DSM-IV criteria were recruited by clinicians from four university study sites and their surrounding mental health care facilities in the Netherlands and Belgium (18). Trained investigators conducted clinical interviews with patients and applied rating instruments. All patients, unaffected siblings, and healthy control subjects were invited to take part in a baseline assessment and in follow-up assessments 3 and 6 years after enrollment. We analyzed all individuals for whom complete data were available for the baseline measurement of smoking in the past 12 months. The study was approved by the Medical Ethics Committee of the Academic Medical Center of Utrecht. Written informed consent was obtained from participants before they were enrolled in the study. Release 5.00 of the GROUP database was used for the analyses.

Smoking details. The shortened version of the Composite International Diagnostic Interview (CIDI) (19) was used to assess the quality, severity, and course of tobacco use during the past year. A special Substance Abuse Module (CIDI-SAM) covers tobacco in considerable detail, and this instrument was found to be reliable in a cross-cultural trial (20). Participants were defined as smokers if they smoked daily during 1 month or more in the past 12 months. Data were also collected on number of cigarettes smoked per day in the period of most severe smoking in the past 12 months.

Cognitive measures. All participants were assessed with a cognitive task battery that assessed cognitive domains comparable to those defined in the MATRICS Consensus Cognitive Battery, as described in detail previously (3, 17). Different subtests of the WAIS-III (21) were used to assess global cognitive functioning and to measure, specifically, the domains of processing speed (digit-symbol coding task), working memory (arithmetic), and reasoning and problem solving (block design task). A word learning task (the Auditory Verbal Learning Test [22]) assessed verbal learning with outcome parameters of immediate recall (15-word list, three learning trials) and retention rate after 20 minutes. The Continuous Performance Test (23) was administered to test the domain of attention/vigilance, for which the accuracy score and mean reaction time were used. The tests were administered in a fixed order. Total testing time was approximately 2 hours. A break was scheduled in the testing in case of fatigue; smokers received no special instructions regarding their smoking behavior and possibly smoked during this break.

Assessment of covariates. Based on the well-known association with cognition and in line with previous studies (12, 14), the following confounders were selected a priori: age, gender, years of education, cannabis use, antipsychotic medication use, and severity of psychopathology. Years of education was determined at each assessment. Cannabis use was assessed with urinalysis; urine was screened for the presence of cannabis with a 50 ng/mL THC cutoff in order to infer a detection window of 1 month. Data on antipsychotic

medication use (yes/no) were collected at each assessment. Severity of psychopathology in patients was determined with the Positive and Negative Syndrome Scale (PANSS) (24). Sub-clinical symptoms in siblings and control subjects were assessed with the Community Assessment of Psychic Experiences (25).

Statistical Analysis

Student *t* tests, Pearson chi-square tests, and one-way analysis of variance were used to compare baseline differences in demographic characteristics and clinical outcomes between smokers and nonsmokers in patients, unaffected siblings, and healthy control subjects. To illustrate the baseline difference in cognitive performance, one cognitive score per domain was standardized to a *z*-score, using the values of the nonsmoking control subjects as reference. Next, we used R, version 3.3.2 (26), and the lme4 package (27) to perform linear mixed-effects analyses of the relationship between cognitive measures and smoking status over a period of 6 years. Visual inspection of residual plots revealed no obvious deviations from homoscedasticity or normality, with the exception of the accuracy score on the Continuous Performance Test. Linear mixed models were applied to the raw scores and raw change scores for each cognitive domain. In all analyses, *p* values were calculated by the Kenward-Roger approach, using the pbkrtest package in R (28), which has been shown to produce the most acceptable type I error rates in mixed-effects models (29). Given the seven outcomes in five independent cognitive tasks, we used Bonferroni correction to minimize the risk of type I errors, and thus the two-tailed significance threshold was set at 0.007 (0.05/7).

To answer the multi-cross-sectional research questions, we entered into the model, as fixed effects, smoking status during the past 12 months, time, and all confounders selected a priori. As random effects, we added intercepts for subjects and by-subject random slopes for the effect of time. Each variable was added in a forward approach, and the Akaike information criterion was used to compare model fit. A lower Akaike information criterion estimate for the model after adding the covariates indicates a better model fit. Post hoc linear mixed-model analyses were conducted if a significant difference was found between smokers and nonsmokers for a specific task. To specifically investigate the association of cognition with smoking severity, we then entered the number of cigarettes per day instead of smoking status and subsequently entered the same fixed and random effects as stated above.

To answer the research questions concerning the effect of change in smoking behavior, we determined change in smoking status at 3-year follow-up compared with baseline and at 6-year follow-up compared with 3-year follow-up. In a similar fashion, a change score was calculated for each period for number of cigarettes per day and raw scores for each cognitive task. Next, we used linear mixed models with the same a priori covariates to explore differences in change scores of cognitive performance between subjects who quit smoking, those who started smoking, and those whose smoking status did not change. The same set of fixed and

random effects as used to answer the first research question were entered. If a significant result was found, we conducted post hoc analyses to examine the relationship between change in number of cigarettes per day and cognitive performance with the same set of fixed and random effects.

RESULTS

Study Sample Characteristics

In total, we analyzed data from 1,094 patients with a non-affective psychosis, 1,047 siblings, and 579 control subjects at baseline. The demographic and clinical characteristics of smokers and nonsmokers are presented in Table 1. A total of 717 (65.5%) patients were diagnosed as having schizophrenia (DSM-IV codes 295.1, 295.2, 295.3, 295.6, and 295.9). Baseline smoking rates were significantly higher in patients compared with siblings and compared with healthy control subjects (66.6%, 38.3%, and 25.2%, respectively; $\chi^2=312.49$, $p<0.001$). Patients who smoked also used significantly more cigarettes per day (mean=17.8, SD=8.6) than did smoking siblings (mean=13.1, SD=9.1) or control subjects (mean=12.0, SD=7.7) ($F=60.28$, $p<0.001$). Smoking patients, siblings, and control subjects showed significant differences in various demographic characteristics and in the presence and severity of psychopathology compared with nonsmokers (Table 1). Unadjusted baseline cognitive scores were lowest in the patient group and highest in the nonsmoking control group (Figure 1).

Multi-Cross-Sectional Association Between Smoking and Cognitive Performance

To explore the overall association between smoking status and cognitive outcomes over 6 years, we used data from 916 patients, 947 siblings, and 552 control subjects (Table 2; see also section 1 in the online supplement). Data on cognitive performance scores were missing for a maximum of 179 patients, 100 siblings, and 27 control subjects. In patients, mixed-effects analyses revealed a significant negative association between smoking and score on the digit-symbol coding task (estimate=−2.38, SE=0.84, $p=0.005$). Post hoc analysis (see section 2 in the online supplement) revealed a similar negative association between number of cigarettes per day and score on the digit-symbol coding task (estimate=−0.10, SE=0.03, $p=0.002$). In siblings, significant negative associations were found between smoking and score on the arithmetic task and the block design task (Table 2). Post hoc analyses also showed negative associations between number of cigarettes per day and score on the block design task (estimate=−0.13, SE=0.04, $p=0.002$). In control subjects, we found a significant negative association between smoking and score on the digit-symbol coding task (Table 2). Finally, analyses yielded a negative association between number of cigarettes per day and score on the digit-symbol coding task (estimate=−0.25, SE=0.07, $p=0.001$). We did not find significant associations between smoking status and performance on the Auditory Verbal Learning Test and the Continuous Performance Test in any of the three groups.

TABLE 1. Baseline Characteristics of Smoking and Nonsmoking Patients With Psychosis, Siblings, and Healthy Control Subjects

Characteristic ^a	Patients (N=1,094)					Siblings (N=1,047)					Control Subjects (N=579)				
	Smoking (N=729)		Nonsmoking (N=365)		p	Smoking (N=401)		Nonsmoking (N=646)		p	Smoking (N=146)		Nonsmoking (N=433)		p
	Mean	SD	Mean	SD		Mean	SD	Mean	SD		Mean	SD	Mean	SD	
Age (years)	26.8	6.9	29.2	9.5	<0.001	27.5	8.1	28.08	8.38	0.242	26.93	9.9	30.75	10.8	0.253
Education (years)	12.0	3.7	13.2	3.9	<0.001	12.8	3.9	13.92	3.97	<0.001	14.17	3.0	14.62	9.4	0.158
PANSS scores															
Positive subscale	1.9	0.8	1.7	0.7	<0.001										
Negative subscale	2.0	0.9	1.9	0.8	0.059										
General subscale	1.8	0.5	1.7	0.5	<0.001										
CAPE scores															
Positive symptoms						0.2	0.2	0.2	0.2	0.012	0.2	0.2	0.18	0.2	0.031
Negative symptoms						0.6	0.5	0.5	0.4	<0.001	0.5	0.3	0.5	0.3	0.042
Depressive symptoms						0.7	0.4	0.6	0.4	0.001	0.6	0.4	0.6	0.3	0.039
Cigarettes per day	17.8	8.6	0.0	0.0		13.1	9.1	0.0	0.0		12.0	7.7	0	0.0	
Duration of illness	4.2	3.8	4.4	4.4	0.345										
	N	%	N	%	p	N	%	N	%	p	N	%	N	%	p
Male	603	82.7	230	63.0	<0.001	189	49.4	281	43.5	0.063	73	50.3	193	44.5	0.219
Positive test for cannabis	147	23.0	7	2.2	<0.001	62	17.5	11	1.9	<0.001	19	13.7	8	1.9	<0.001
Antipsychotic drug use	615	95.1	300	92.6	0.121										

^a CAPE=Community Assessment of Psychic Experiences; PANSS=Positive and Negative Syndrome Scale.

Prospective Association Between Change in Smoking Behavior and Cognitive Performance

Overall, patients, siblings, and control subjects showed significantly better performance on most cognitive tasks during follow-up (see sections 3 and 4 in the online supplement). We found that smoking behavior remained unchanged in most individuals from one assessment to the next (patients, 89.6%; siblings, 86.1%; control subjects, 90.7%). Over time, however, more individuals quit smoking (patients, 6.7%; siblings, 7.8%; control subjects, 5.4%) than started smoking (patients, 3.7%; siblings, 6.1%; control subjects, 3.9%).

We found a significant positive association between smoking cessation and change scores on the digit-symbol coding task (estimate=4.90, SE=1.73, $p=0.005$), indicating that processing speed improved in patients who quit smoking compared with patients who did not change their smoking behavior (see section 3 in the online supplement). This association was not found in siblings and control subjects. No significant associations were found between smoking initiation and changes in cognitive functions in any of the groups (see section 3 in the online supplement). In the patient group, post hoc analyses revealed a significant negative association between change in number of cigarettes per day and change in score on the digit-symbol coding task (estimate=−0.18, SE=0.05, $p=0.001$).

DISCUSSION

As in most other studies, the prevalence of smoking and the number of cigarettes smoked per day were much higher among patients with psychotic disorders than among unaffected siblings and control subjects. Consistent with our hypothesis, smoking was associated with lower performance

in cognitive functions (e.g., processing speed, working memory, and reasoning and problem solving) in all groups—patients, unaffected siblings, and control subjects. In addition, a dose-response relationship was found for the multi-cross-sectional association of number of cigarettes per day with processing speed and reasoning and problem solving. Notably, we found a positive association between smoking cessation and processing speed only in the patient group. These findings provide new insights on the relationship between smoking behavior and cognitive functioning in patients with psychotic disorders, suggesting that smoking cessation or reduced smoking may improve processing speed in this population.

Multi-Cross-Sectional Association Between Smoking and Cognitive Performance

Previous studies on smoking and cognition in patients with psychotic disorders have reported contradictory findings. Our results are in line with the largest cross-sectional study so far, which reported reduced functioning in smoking patients compared with nonsmoking patients with psychotic disorders, based on a cognitive composite score in a total of 400 patients (14). In two other cross-sectional studies (12, 30) that included patients with first-episode psychosis (N=304 and N=159), no differences were found between smokers and nonsmokers on specific cognitive tasks. One small study (13) found an advantage of smoking (N=32) compared with nonsmoking (N=15) for verbal memory outcomes in patients with schizophrenia. However, research in patients with psychotic disorders has varied in sample characteristics, with differences in illness duration, sample size, and adjustment for covariates. Our study also adds relevant findings from analyses of number of cigarettes smoked per day, showing a dose-response relationship between number of cigarettes

and impairments in processing speed in patients and control subjects, and in reasoning and problem solving in siblings.

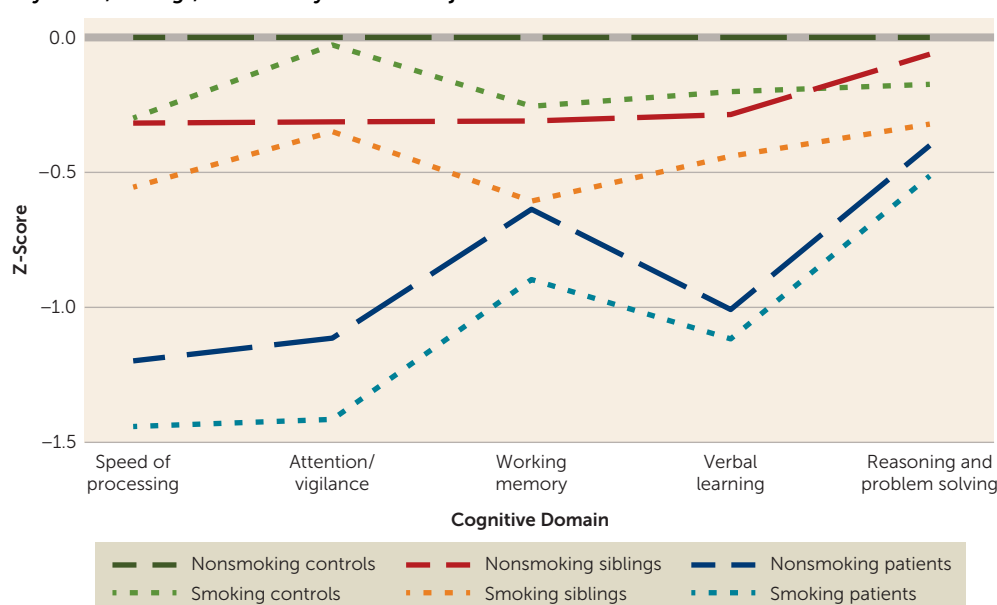
Because cognitive tasks that assess working memory and problem solving also impose a time limit, processing speed could represent a core cognitive symptom that is negatively associated with smoking. This hypothesis is consistent with the already mentioned negative association between smoking and a cognitive composite score in patients with psychotic disorders (14) and with previous studies showing that overall cognitive performance in patients with schizophrenia can be explained by one component or a single factor based on five domains (31, 32). Although we did not test this in the present study, the lower performance in processing speed in smoking patients could represent worse cognitive performance overall. Finally, in studies in the general population, chronic cigarette smoking has repeatedly been found to be associated with lower cognitive functioning in multiple domains beyond processing speed (16, 33). Large studies, including the present study, point to a negative association between smoking and cognitive functioning for both patients and individuals without psychosis.

Lower cognitive performance in smokers probably reflects a multifactorial etiology, with a large number of directly cytotoxic compounds from cigarettes (e.g., carbon monoxide, polycyclic aromatic hydrocarbons) causing adverse effects in the brain (16). Despite the large body of evidence regarding smoking and general health problems, studies concurrently assessing cognitive, neurobiological, and genetic factors in relation to chronic smoking are still scarce. A review of this issue in the general population (16) that summarized a limited number of studies stated that chronic smoking is related to globally decreased brain perfusion, an abnormal increase in global brain atrophy, and structural and biochemical abnormalities in the anterior frontal region, subcortical nuclei, and commissural white matter.

Prospective Association Between Change in Smoking Behavior and Cognitive Performance

A study on the short-term effects of nonsmoking on cognitive performance in 26 patients with schizophrenia (34) found no significant effect on any cognitive task after 3 weeks of smoking abstinence. To our knowledge, the present study is the first to find a significant positive association between

FIGURE 1. Baseline Z-Scores for Cognitive Domains in Smoking and Nonsmoking Patients With Psychosis, Siblings, and Healthy Control Subjects



smoking cessation and processing speed in patients with psychotic disorders. We have not found any studies on the association between sustained tobacco abstinence and cognitive performance in patients with psychosis. A meta-analysis of abstinence from various kinds of substances, but not tobacco, found that abstinence generally results in partial cognitive recovery (35). There are currently no published studies in patients or the general population that evaluated whether this positive association can be explained by neurobiological processes, such as brain plasticity (e.g., capacity to change in response to smoking cessation) and perfusion rates. Nevertheless, the accumulating evidence concerning the neurotoxic effect of persistent smoking is substantial. In the general population, it has been found repeatedly that former smokers showed less cognitive decline than those who continued smoking in later life (11, 36). Moreover, more lifetime years of smoking has been found to be related to poorer performance on measures of cognitive efficiency, processing speed, and visuospatial skills (33). Research relating measures of cognitive function to neurobiological integrity is therefore needed to understand whether or to what extent the harm of smoking is reversible in patients with psychotic disorders.

Strengths and Limitations

The main strengths of this study are the large sample size, the presence of two comparison groups, and the prospective long-term nature of the study, with follow-up assessments after 3 and 6 years. The study also has some limitations. First, given the observational design, no definite causal conclusions can be drawn, since reverse causation cannot be ruled out (e.g., patients who show improvement in cognitive performance also stop smoking). Second, and related to the first limitation, this study focused on spontaneous changes in

TABLE 2. Results of Linear Mixed Models Regarding the Multi-Cross-Sectional Association Between Smokers and Neurocognitive Tasks in Study of Smoking and Nonsmoking Patients With Psychosis, Siblings, and Healthy Control Subjects

Effect	Patients				Siblings				Control subjects			
	Estimate	SE	p	N	Estimate	SE	p	N	Estimate	SE	p	N
Processing speed, WAIS digit-symbol coding task (0–133)												
Intercept	69.75	1.34	<0.001	928	77.86	0.76	<0.001	966	80.27	0.95	<0.001	562
Smoking	–2.38	0.84	0.005 ^a		–1.04	0.65	0.113		–3.13	1.06	0.003 ^a	
Attention/vigilance, Continuous Performance Test, accuracy (0–100)												
Intercept	98.90	0.39	<0.001	916	99.34	0.17	<0.001	947	99.63	0.08	<0.001	552
Smoking	0.03	22	0.874		0.00	0.13	0.971		–0.01	0.11	0.905	
Attention/vigilance, Continuous Performance Test, mean reaction time												
Intercept	434.35	7.40	<0.001	916	404.46	4.10	<0.001	947	413.97	5.28	<0.001	552
Smoking	–3.03	4.69	0.521		2.14	3.91	0.586		–2.47	5.89	0.678	
Working memory, WAIS, arithmetic task (0–22)												
Intercept	14.07	0.41	<0.001	930	15.68	0.22	<0.001	967	16.59	0.28	<0.001	562
Smoking	–0.59	0.26	0.022		–0.60	0.20	0.003 ^a		–0.39	0.30	0.119	
Verbal learning, Auditory Verbal Learning Test, immediate recall (0–45)												
Intercept	25.21	0.54	<0.001	929	26.56	0.29	<0.001	965	27.39	0.35	<0.001	561
Smoking	0.07	0.34	0.827		–0.38	0.28	0.176		–0.78	0.40	0.076	
Verbal learning, Auditory Verbal Learning Test, delayed recall (0–45)												
Intercept	8.54	0.25	<0.001	926	9.12	0.13	<0.001	966	9.06	0.17	<0.001	559
Smoking	0.05	0.16	0.750		–0.26	0.13	0.043		0.01	0.20	0.946	
Reasoning and problem solving, WAIS, block design task (0–68)												
Intercept	44.95	1.18	<0.001	929	47.61	0.74	<0.001	967	47.32	0.93	<0.001	562
Smoking	–1.66	0.79	0.037		–1.73	0.61	0.005 ^a		–1.92	0.94	0.044	

^a Statistically significant at a Bonferroni-corrected p threshold of 0.007.

smoking status and their relation to cognitive functions. Lower cognitive functioning is a known vulnerability for relapse of substance abuse (37), and patients who quit smoking could therefore represent a subgroup that had a larger increase in cognitive performance than those who did not change their smoking behavior. Third, information about exposure to smoking was limited. Observation points within the GROUP study have a 3-year interval, and participants were interviewed regarding their smoking behavior only over the 12 months before each assessment. Smoking history (i.e., number of pack-years) was not assessed, and this barred correction for length of exposure. This is of interest because a greater number of lifetime years of smoking has been found to be related to poorer performance on measures of cognitive efficiency, processing speed, and visuospatial skills (36). Fourth, no data were available on blood levels of cotinine or carbon monoxide. However, in a systematic review and meta-analysis about the validity of self-reported smoking behavior (38), interviewer-administered questionnaires, such as the CIDI-SAM, which was used in this study, were shown to produce accurate data. Fifth, GROUP patients represent a relatively high-functioning cohort, probably with higher cognitive performance than average patients with psychosis, which limits the generalizability of our findings. Finally, a minor limitation was the use of accuracy scores from the Continuous Performance Test to assess sustained vigilance. This measure showed ceiling effects, not reacting to transformation. By also including the mean reaction time scores from the Continuous Performance Test, we aimed to bypass assessment of nondiscriminating values.

Implications

We found substantially higher smoking rates in patients with psychotic disorders compared with unaffected siblings and control subjects, and lower cognitive performance in several domains in smokers compared with nonsmokers, irrespective of their illness or vulnerability status. Two main hypotheses have been proposed to explain the high smoking rates in patients with schizophrenia: the self-medication hypothesis and the shared-vulnerability hypothesis (7). The self-medication hypothesis postulates that patients often smoke to alleviate clinical symptoms, such as cognitive impairments. This theory is criticized by researchers who believe that shared genetic and shared environmental factors together with neurological deficits make individuals with schizophrenia more vulnerable to tobacco use and nicotine dependence (39, 40). Our prospective results on the cognitive effects of changes in smoking status in patients with non-affective psychosis do not support the self-medication hypothesis. This is illustrated by our finding that smoking in patients with psychotic disorders is associated with impairment in domains similar to those observed in smoking nonpatients (after correcting for crucial confounders such as variation in psychopathology) and the fact that patients who quit smoking showed a significant improvement in processing speed. Moreover, our finding that smoking is more prevalent in both patients and unaffected siblings of patients (i.e., siblings without illness-related confounders) compared with healthy control subjects points to the presence of shared genetic or environmental factors that increase the risk of both smoking and psychosis. Still, patients often report that

they smoke because of a need for stimulation and activation (41). We argue that more psychoeducation about the potential long-term negative effects of smoking on cognitive performance is necessary. The results of our study further underline the importance of smoking cessation treatment to increase cognitive, mental, and somatic health in patients with psychosis.

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RESEARCH ARTICLE

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Smoking cessation in severe mental ill health: what works? an updated systematic review and meta-analysis

Emily Peckham^{1*} , Sally Brabyn¹, Liz Cook¹, Garry Tew² and Simon Gilbody¹

Abstract

Background: People with severe mental ill health are more likely to smoke than those in the general population. It is therefore important that effective smoking cessation strategies are used to help people with severe mental ill health to stop smoking. This study aims to assess the effectiveness and cost –effectiveness of smoking cessation and reduction strategies in adults with severe mental ill health in both inpatient and outpatient settings.

Methods: This is an update of a previous systematic review. Electronic databases were searched during September 2016 for randomised controlled trials comparing smoking cessation interventions to each other, usual care, or placebo. Data was extracted on biochemically-verified, self-reported smoking cessation (primary outcome), as well as on smoking reduction, body weight, psychiatric symptom, and adverse events (secondary outcomes).

Results: We included 26 trials of pharmacological and/or behavioural interventions. Eight trials comparing bupropion to placebo were pooled showing that bupropion improved quit rates significantly in the medium and long term but not the short term (short term RR = 6.42 95% CI 0.82–50.07; medium term RR = 2.93 95% CI 1.61–5.34; long term RR = 3.04 95% CI 1.10–8.42). Five trials comparing varenicline to placebo showed that the addition of varenicline improved quit rates significantly in the medium term (RR = 4.13 95% CI 1.36–12.53). The results from five trials of specialised smoking cessation programmes were pooled and showed no evidence of benefit in the medium (RR = 1.32 95% CI 0.85–2.06) or long term (RR = 1.33 95% CI 0.85–2.08). There was insufficient data to allowing pooling for all time points for varenicline and trials of specialist smoking cessation programmes. Trials suggest few adverse events although safety data were not always reported. Only one pilot study reported cost effectiveness data.

Conclusions: Bupropion and varenicline, which have been shown to be effective in the general population, also work for people with severe mental ill health and their use in patients with stable psychiatric conditions. Despite good evidence for the effectiveness of smoking cessation interventions for people with severe mental ill health, the percentage of people with severe mental ill health who smoke remains higher than that for the general population.

Keywords: Severe mental ill health, Smoking cessation, Nicotine replacement therapy, Varenicline, Behavioural intervention, Bupropion

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Background

The physical health of people with severe mental ill health (SMI) is poor, with people with a diagnosis of SMI dying 20–25 years earlier than those in the general population [1]. Smoking is one of the most important modifiable risk factors that contributes to this excess mortality [2]. People with SMI tend to smoke more heavily and extract more nicotine from cigarettes than smokers without mental health problems [3], and up to 70% of people with SMI smoke [4].

Whilst the percentage of people who smoke in the general population has been steadily declining, the percentage of people with SMI who smoke has not seen a similar decline [5]. Despite this, when questioned, the percentage of people with SMI who are interested in cutting down or quitting smoking is similar to that of the general population [6]. In 2010 a systematic review was conducted to establish the clinical and cost effectiveness of smoking cessation and reduction strategies for people with SMI to determine the most successful strategies such as the use of pharmacotherapy (e.g. nicotine replacement therapy, varenicline, bupropion) or behavioural interventions [7]. In the United Kingdom, following the publication of guidance issued by the National Institute of Health and Care Excellence (NICE) Guidance PH 48 in 2013 [8], a number of mental health trusts have decided to go smoke free and encourage people with SMI to give up or cut down on their smoking. We have therefore decided to update the 2010 review with the additional inclusion of e-cigarettes as a smoking cessation strategy to provide up to date information on the most effective and cost-effective strategies to help people with SMI cut down or quit smoking.

Objectives

To assess the effectiveness and cost-effectiveness of smoking cessation and reduction strategies in adults with severe mental ill health.

Methods

Search strategy

The protocol for this review has been registered on the PROSPERO register of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015029455).

An electronic search strategy based on that used in our previous review, combining search terms for severe mental ill health, smoking cessation and randomised controlled trials, adapted from terms developed by the Cochrane groups for schizophrenia and tobacco addiction was used to search the following database for potentially relevant studies: MEDLINE (PubMed), EMBASE, PsycINFO, CINAHL, Health Management Information Consortium (HMIC) and CENTRAL.

The search strategy was limited to the inception year of each database until September 2016. An example of the search strategy is shown in an additional word file (see Additional file 1).

Searching other resources.

Reference lists of all identified studies and existing reviews were checked for additional potentially relevant studies.

Inclusion criteria

Types of studies

Randomised controlled trials (RCTs), including cluster-randomised controlled trials, that assess the effects of smoking cessation and reduction interventions in people with severe mental ill health were included. Studies conducted in any country and in either in-patient or out patient settings were eligible for inclusion. Studies that are not published in English were excluded.

Types of participants

Participants were adults aged 18 years and above who had been diagnosed with SMI. We defined SMI as schizophrenia or other psychotic disorders, bipolar disorder and depression with psychotic features. We have not included personality disorder, severe anxiety disorder, post traumatic stress disorder (PTSD), major depression or autism in this review. We have based this classification on diagnoses that would typically be included on a UK primary care SMI register [9]. Diagnosis needed to be made by using International Classification of Disease (ICD10 F20–29 and F30–31) or Diagnostic and Statistical Manual (DSM IV 295.x, 296.x and 297.x) criteria.

Studies involving participants who had a problem with substance abuse (other than nicotine addiction) without any other mental disorder, or whose participants had learning disability, dementia, other neurocognitive disorders or terminal illness were not included in this review.

Types of interventions

Trials of all types of smoking cessation and reduction strategies, (behavioural or pharmacological as monotherapy or in combination) compared to each other, placebo, usual care or to no intervention were included, including trials of very brief advice. Behavioural interventions include on-to-one programmes, group programmes, and telephone counselling. Pharmacotherapy includes products licensed for smoking cessation e.g. nicotine replacement therapy (NRT), varenicline, nortriptyline, and bupropion. Trials in which electronic cigarettes ('e-cigarettes') have been used as a smoking cessation aid were also included. Studies looking at 'implementation of a smoke-free environment' as an intervention were excluded. Behavioral interventions were classed as 'group' or 'individual' therapy.

Types of outcome measure

The primary outcome measure was biochemically verified self-reported smoking cessation. Accepted methods of biochemical verification were expired carbon monoxide (CO level of <10 ppm (p.p.m.), salivary cotinine <15 ng/ml, urinary cotinine <50 ng/ml or serum cotinine <15 ng/ml. All follow-up times were included and categorised as short-term quit if less than or up to four weeks, mid term quit for up to six months, and long-term quit if longer than six months. Participants lost to follow up were treated as 'still smokers'.

The secondary outcomes were:

1. Smoking reduction; as no acceptable standard exists for its measurement, any measure was acceptable as long as it was verified by biochemical assay
2. Change in body weight
3. Change in psychiatric symptoms (any validated symptom scale)
4. Adverse events

Selection of included studies and data extraction

Two authors independently screened 10% of the titles and abstracts of publications identified by the search strategy. Results from this initial screening were compared to check the level of agreement between the two authors over which studies should proceed to full text screening. Both authors were in agreement over which texts should proceed to full text screening therefore one author continued to screen the remaining studies. All studies that were not applicable according to our inclusion criteria were discarded. The full text of the remaining references was obtained.

Two authors independently decided whether the studies meet the inclusion criteria with any disagreements resolved through discussion with a third author.

Data extraction

Two authors independently extracted data from the included studies. Any disagreements were resolved through discussion with a third author where necessary.

Any missing data, relating to the primary outcome only, was sought by contacting the Investigators and/or corresponding authors of primary studies.

Assessment of risk of bias in included studies

The methodological quality of included trials was assessed independently by two reviewers using the Cochrane's tool for assessing risk of bias, [10] which assesses the following domains:

1. Sequence generation (selection bias)
2. Allocation concealment (selection bias)
3. Blinding of participants and personnel (performance bias)
4. Blinding of outcome assessment (detection bias);

5. Incomplete outcome data (attrition bias)
6. Selective outcome reporting (reporting bias)
7. Other potential sources of bias

Each of the domains was scored as 'high', 'low' or 'unclear' risk of bias, following criteria outlined in Chapter 8 of the Cochrane Handbook for Systematic Reviews of Interventions [10].

Data synthesis

A narrative overview of study design features, study populations, outcomes, risk of bias and study results is given.

For smoking cessation data, we present risk ratios with 95% confidence intervals as per our previous review [7]. Where interventions and comparisons were sufficiently similar we conducted a meta-analysis using RevMan (version 5.3, *Review Manager (RevMan) [Computer program]. Version 5.3. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014*). We performed standard pairwise meta-analysis for every comparison that contained at least two studies and used a random-effects model if studies were statistically heterogeneous as measured by I^2 ($I^2 \geq 50\%$); otherwise we used a fixed-effect model. Absolute quit rate was taken as the proportion of participants who met criteria for abstinence out of the number randomised to that group.

Unit of analysis issues

The unit of analysis was the individual.

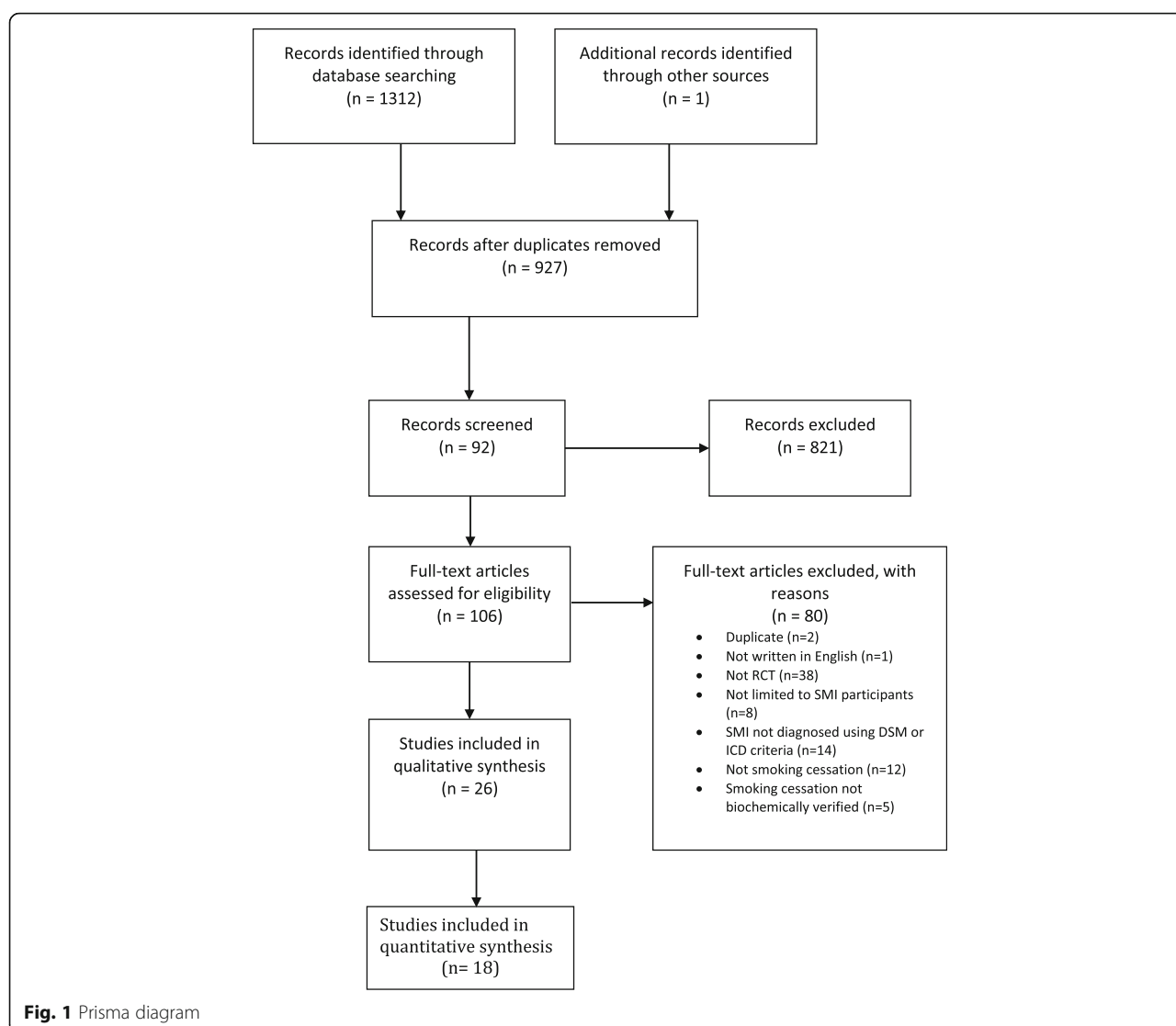
Results

Of the 1312 records identified 106 full texts were screened (Fig. 1). Of these 28 (based on 26 studies) involving 1978 participants met the inclusion criteria [11–38]; 18 more studies than in our previous review. The reasons for ineligibility are shown in Fig. 1, with the most common reason being that the study was not a randomised controlled trial.

Study characteristics

Study characteristics are given in Table 1. No cluster RCTs were identified in this review. The sample size of the studies ranged from five participants [22, 37] to 298 participants [18]. The majority of the studies recruited participants who were outpatients ($n = 20$), one study recruited solely from an inpatient setting [29], and one study recruited from a mixture of inpatients and outpatients [35] the remaining 4 studies did not clearly state whether the participants were inpatients or outpatients.

Sixteen of the studies were conducted in the United States, two in Australia, one in Taiwan, one in England one in the United States, Israel and China and one in the United States and Canada. In four studies the country was not clearly stated.



The majority of the studies recruited participants with schizophrenia or schizoaffective disorder ($n = 21$), with three studies recruiting participants with bipolar disorder, and two studies included participants with schizophrenia, schizoaffective disorder or bipolar disorder. In eight of the studies it was a study requirement that the participants had stable symptoms, in three studies it was a requirement that participants were on a stable dose of medication and in six studies it was a requirement that participants has stable symptoms and were on a stable dose of medication. Nine studies did not state whether the participants were clinically stable or were on a stable dose of medication.

In just over half of the studies the participants had expressed a willingness to quit smoking ($n = 12$), in one study participants were excluded if they were planning on quitting in the next 30 days [36] and in the remaining 12 studies participants' views on quitting were not stated. No

study stated that it was recruiting participants with no interest in quitting smoking.

Nine of the studies used an intention to treat analysis, one used a per protocol analysis [36] and 16 studies did not report whether or not they used an intention to treat analysis.

Description of the interventions

The included studies covered a range of interventions (Table 1). Nine studies explored the effects of the prescription of bupropion, six studies the prescription of varenicline and one study the prescription of nicotine replacement therapy (NRT). The varenicline studies all followed a standard dosing schedule whereas the dose in the bupropion studies ranged from 150 mg once per day to 150 mg twice per day. Five studies explored the effects of a specialist smoking cessation programme for people with

Table 1 Study characteristics

Study/design	Population	Interventions	Smoking abstinence outcomes	Secondary outcomes
Complex interventions				
Baker 2006 [18, 38] (including data from Baker 2010) RCT	298 clinically stable adult outpatients with ICD diagnosis of psychotic disorder who expressed an interest in quitting smoking and smoke ≥ 15 cigarettes per day. Australia 52% male, ethnicity not stated.	1. Individual motivational interviewing/CBT 2. Usual care Intervention consisted of 8 \times 1 hour sessions of manualised motivational interviewing and CBT over 10 weeks.	Continuous abstinence self report verified by expired CO < 10 ppm at 3, 6, 12 months and 4 years 7 day point prevalence smoking abstinence verified by expired CO < 10 ppm at 3, 6, 12 months and 4 years	Change in psychiatric symptoms (BDI, BPRS, SF-12, STAI)
Baker 2015 [32] RCT	235 adult outpatients who expressed an interest in quitting smoking with ICD diagnosis of psychotic disorder and Smoking ≥ 15 cigarettes per day and with stable symptoms. Australia 59% male, 84% Australian born.	1. Healthy lifestyle intervention (individual) 2. Telephone intervention Healthy lifestyle intervention consisted of manualised motivational interviewing and CBT delivered as a single 90 min sessions followed by 7 \times 1 h sessions weekly then 3 fortnightly 1 h sessions then monthly 1 hour sessions for 6 months. The telephone intervention consisted of 1 face to face meeting followed by up to 16 \times 10 minute manualised telephone sessions	7 day point prevalence smoking abstinence verified by expired CO < 10 ppm at 15 weeks and 12 months verified by expired CO measure Number of cigarettes per day FTND	Change in psychiatric symptoms (BBPS-24, BDI, SF-12 mental component)
George 2000 [12] RCT	45 participants with DSM IV schizophrenia or schizoaffective disorder with a FTND score of ≥ 5 United States 67% male, 62% white.	1. ALA group programme + NRT patch 2. Specialised group programme + NRT patch *21 mg for 6 weeks then 14 mg for 2 weeks then 7mg for 2 weeks ALA group consisted of 3 weekly 60 min manualised sessions of group counselling Specialised programme consisted of 3 weeks of 1 h motivational enhancement then 7 weeks 1 h of psychoeducation. All manualised	7 day point prevalence abstinence at week 10, and 26 verified by expired CO < 10 ppm. Continuous abstinence in last 4 weeks of treatment	Change in psychiatric symptoms (AIMS, BDI, PANSS, WEPS)
Gilbody 2015 [33] RCT	97 adult outpatients with DSM IV schizophrenia, schizoaffective disorder or bipolar disorder who expressed a desire to cut down or quit smoking and smoked ≥ 10 cigarettes per day. England 60% male, 87% white.	1. Bespoke intervention 2. Usual care Intervention consisted of 8-10 \times 30 min manualised sessions tailored to the participants needs.	Smoking cessation at 12 months (CO ≤ 10 ppm) FTND Number of cigarettes per day	Change in psychiatric symptoms (SF-12, PHQ-9)
Smith 2015 [34] RCT	33 outpatients with DSM IV schizophrenia or schizoaffective disorder 73% male, 30% white.	1. 5 sessions of transcranial direct current stimulation 2. 5 sessions of sham treatment	Self report number of cigarettes smoked and expired CO 1 week after final treatment session Urges to smoke	PANSS and PSYCHRATS hallucination scale
Steinberg 2003 [15] RCT	78 outpatients with DSM IV schizophrenia or schizoaffective disorder smoking ≥ 10 cigarettes per day United States 68% male, 77% white.	1. Motivational interviewing (individual) 2. Psychoeducational intervention (individual) 3. Control Motivational interviewing consisted of 1 \times 40 minute session.	Expired CO at 1 week and 1 month Number of cigarettes per day Heaviness of smoking Contemplation ladder FTND Importance of quitting Confidence in ability to quit	

Table 1 Study characteristics (*Continued*)

Steinberg 2016 [36] RCT	98 outpatients with DSM IV schizophrenia, schizoaffective disorder or Bipolar I 46% male, 61% white.	Psychoeducation consisted of 1 x 40 minute session Control consisted of 1 5 min session. 1. Motivation interviewing 1 x 45 min personalised session 2. Interactive education 1 x 45 min non personalised session Motivational interviewing 1 45 min session manualised. Interactive education consisted of 1 x 45 min manualised session	Expired CO at 1 month Motivation to quit	
Williams 2010 [23] RCT	100 adult outpatients with DSM IV schizophrenia or schizoaffective disorder who Smoke ≥ 10 cigarettes per day and were willing to try and quit smoking. United States 64% male, 66% white.	1. Treatment of nicotine addiction in schizophrenia + nicotine patch (individual) 2. Medication management + nicotine patch 3. (individual) *21 mg for 12 weeks and 14 mg for 4 weeks TANS consisted of 24 x 45 min sessions over 26 weeks of manualised motivational interviewing. MM consisted of 9 x 20 min sessions of manualised active education.	7 day point prevalence abstinence at 3, 6 and 12 months verified by expired CO <10 ppm. Continuous abstinence at 3 months.	Change in psychiatric symptoms (BDI, PANSS)
Wing 2012 [28] RCT	15 DSM-IV schizophrenia or schizoaffective disorder, smoking ≥ 10 cigarettes per day for 3 years or more with expired CO ≥ 10 ppm and FTND score ≥ 4 and motivated to quit within the next month. Ethnicity and gender not reported.	1. Trans cranial magnetic stimulation + weekly group therapy and nicotine patch (21 mg) 2. Sham + weekly group therapy and nicotine patch (21 mg)	Weekly (for 10 weeks) Smoking self report verified by expired CO. Tiffany questionnaire for smoking urges	Change in psychiatric symptoms (PANSS) Adverse events
Bupropion studies				
Evins 2001 [13, 16] (including data from Evins 2004) RCT	19 DSM IV schizophrenia outpatients on a stable dose of antipsychotic medication for at least 4 weeks who smoke at least half a pack of cigarettes per day and express a wish to quit smoking United States 61% male, 89% white.	1. Bupropion (150 mg per day) + CBT Quit Smoking Group 2. Placebo + CBT Quit Smoking group	7 day point prevalence abstinence verified by expired CO < 9 ppm or serum cotinine <14 ng/ml at 12 and 24 weeks and 2 years Significant smoking reduction at 12, 24 weeks and 2 years defined by $\geq 30\%$ reduction in expired CO and $\geq 50\%$ reduction in number of cigarettes per day	Change in psychiatric symptoms (BPRS, SANS, Ham-D, AIMS, Hillside Akathisia Scale, SAS)
Evins 2005 [17] RCT	19 DSM-IV schizophrenia or schizoaffective disorder outpatients and smokes 10 cigarettes per day with stable symptoms and on a stable dose of antipsychotic for >30 days HAM-D score ≤ 20 and willing to set a quit date within 4 weeks. United states	1. Bupropion (150 mg) + behavioural therapy intervention 2. Placebo + behavioural therapy intervention	7 day point prevalence abstinence at week 4, 12 and 24 verified by expired CO <9 ppm. 4 week continuous abstinence at week 24 Number of cigarettes smoked per day	Change in psychiatric symptoms (SANS, Ham-D, Ham-A, PANSS, SAS, Barnes akathisia scale) Adverse events

Table 1 Study characteristics (Continued)

Evins 2007 [19] RCT	68% male, ethnicity not reported. 51 adult outpatients DSM-IV Schizophrenia, capacity to consent, smokes 10 cigarettes per day with stable symptoms and on a stable dose of antipsychotic for 30 days and willing to set a quit date within 4 weeks United States 57% male, ethnicity not reported.	1. Bupropion (150 mg 1 x daily 7 days then 150 mg 2x daily thereafter) + transdermal nicotine patch, nicotine polacrilex gum and CBT 2. Placebo + transdermal nicotine patch, nicotine polacrilex gum and CBT then 7 mg/d 4 weeks, 21 mg/d 2 weeks then 7 mg/d 2 weeks 2 mg as needed up to 18 mg/d	7 day point prevalence abstinence at week 12, 24 and 52 verified by expired CO <8 ppm. 4 week continuous abstinence at week 8, 12, 24 and 52.	Change in psychiatric symptoms (SANS, Ham-D, STAI, PANSS)
Fatemi 2013 [30] RCT	24 clinically stable DSM-IV schizophrenia or schizoaffective disorder, smoking ≥ 10 cigarettes per day expressing a motivation to quit or reduce smoking. United States Ethnicity and gender not reported.	1. Bupropion + antismoking counselling 2. Varenicline + antismoking counselling 3. Placebo + antismoking counselling	Self report abstinence verified by CO Serum and urine levels of nicotine and cotinine	Change in psychiatric symptoms (BPRS, SAPS, SANS, BDI, CSSRS, WISDM, MNWS) Adverse events
George 2002 [14] RCT	32 clinically stable adult outpatients on a stable dose of medication with DSM IV schizophrenia or schizoaffective disorder smoking ≥ 10 cigarettes per day with expired CO > 10 ppm, plasma cotinine >150 ng/ml and scored ≥ 5 on FTND and ≥ 3 on an assessment measure of self-reported motivation indicating a strong desire to quit smoking. US 56% male, 63% white.	1. Bupropion (150 mg 2x day) + specialised schizophrenia smoking cessation program 2. Placebo + specialised schizophrenia smoking cessation program	7 day point prevalence abstinence at week 10, and 36 verified by expired CO <10 ppm. Tiffany questionnaire for smoking urges	Change in psychiatric symptoms (AIMS, BDI, PANSS, WEPS)
George 2008 [21] RCT	58 clinically stable outpatients with DSM IV schizophrenia or schizoaffective disorder on a stable dose of antipsychotic medication and smoking ≥ 10 cigarettes per day with expired CO > 10 ppm and scored ≥ 7 on the contemplation ladder United States 60% male, 48% white.	1. Bupropion + manualised group behavioural therapy + NRT patch (21 mg) 2. Placebo + manualised group behavioural therapy NRT patch (21 mg) 150 mg per day days 1–3 and 150 mg 2 x day thereafter	7 day point prevalence abstinence at week 10, and 26 verified by expired CO <10 ppm. 4 week continuous abstinence at week 10.	Change in psychiatric symptoms (BDI, PANSS) Adverse events
Weinberger 2008 [22] RCT	5 clinically stable DSM-IV Bipolar disorder I outpatients smoking ≥ 10 cigarettes per day with expired CO ≥ 10 ppm United States 40% male, 100% white.	1. Bupropion + manualised group behavioural therapy 2. Placebo + manualised group behavioural therapy (Days 1–3 75 mg 1 x day, days 4–7 150 mg 1 x day and 150 mg 2x day thereafter)	Abstinence at 10 weeks verified by expired CO <10 ppm.	Change in psychiatric symptoms (YMRS, BDI, Ham-D) Adverse events
Weiner 2012 [25] RCT	41 clinically stable adult outpatients with DSM IV schizophrenia or schizoaffective disorder who Smoke ≥ 10 and scored $\geq x$ on FTND United States 79% male, 72% white.	1. Bupropion + group support programme 2. Placebo + group support programme (Days 1–3 150 mg 1 x day and 150 mg 2x day thereafter)	Complete abstinence at 15 weeks defined by expired CO < 10 ppm at last 4 study visits. Complete abstinence at 6 months and 12 months self-report verified by CO < 10 ppm	Change in psychiatric symptoms (BPRS, SANS, SAS) Adverse events

Table 1 Study characteristics (*Continued*)

Tidey 2011 [24] RCT	57 clinically stable adult outpatients with DSM IV schizophrenia or schizoaffective disorder on a stable dose of psychoactive medication who Smoke ≥ 20 cigarettes per day and scored ≥ 6 on FTND and ≥ 4 on the contemplation ladder indicating some interest in quitting smoking United States 71% male, 75% white.	1. Contingent + Bupropion (150 mg per day days 1–3 and 150 mg 2 x day thereafter) 2. Contingent + placebo 3. Bupropion (150 mg per day days 1–3 and 150 mg 2 x day thereafter) + non-contingent 4. Placebo +non contingent Non contingent = \$25 dollar store card Contingent = \$25 store card plus bonuses	7 day point prevalence abstinence at 15 weeks verified by CO < 10 ppm FTND Cotinine in urine CO breath measure Number of cigarettes per day At weeks 1,2,3 and 4	Change in psychiatric symptoms (PANSS, UPDRS, AIMS)
Varenicline studies				
Chengappa 2014 [31] RCT	60 adult outpatients with DSM-IV bipolar disorder on a stable dose of medication. Smoking ≥ 10 cigarettes per day with expired CO ≥ 10 ppm United States Ethnicity and gender not reported.	1. Varenicline + smoking cessation counselling 2. Placebo + smoking cessation counselling 1 x 0.5 mg per day days 1–3, 0.5 mg 2x per day days 4–7 then 1 mg 2x per day thereafter	7 day point prevalence smoking abstinence verified by expired CO <10 ppm at 12 weeks and 24 weeks Continuous 4 week abstinence at 12 weeks	Change in Psychiatric symptoms (YMRS, MADRS, HARS, CGI) Adverse events
Smith 2016 [35] RCT	87 adult inpatients or outpatients with DSM IV schizophrenia or schizoaffective disorder who smoke at least 6 cigarettes per day or in the case of inpatients had flouted the smoking ban on several occasions. United States, Israel and China 85% male, 31% white.	1. Varenicline + smoking prevention counselling 2. Placebo + smoking prevention counselling 1 x 0.5 mg per day days 1–3, 0.5 mg 2x per day days 4–7 then 1 mg 2x per day thereafter	Self-reported number of cigarettes smoked per day Expired CO, cotinine levels and urges to smoke.	Change in psychiatric symptoms (PANSS, SANS, Calgary Depression Scale) Adverse events
Weiner 2011 [25] RCT	9 Clinically stable adult outpatients with DSM IV schizophrenia or schizoaffective disorder for 3 years who smoke ≥ 10 and scored ≥ 4 on FTND. United States Ethnicity and gender not reported.	1. Varenicline (1 mg 2x day) + individual smoking cessation counselling (ALA) 2. Placebo + individual smoking cessation counselling (ALA)	Smoking cessation at 12 weeks defined by expired CO < 10 at last 4 study visits. Change in CO	Change in psychiatric symptoms (BPRS) Adverse events
Williams 2012 [27] RCT	128 adult outpatients with DSM IV schizophrenia or schizoaffective disorder with stable symptoms who Smoke ≥ 15 and scored ≥ 7 on the contemplation ladder indicating a willingness to quit in the next month and with no smoking abstinence in the last 3 months United States and Canada 76% male, 59% white.	1. Varenicline 2. Placebo 1 x 0.5 mg per day days 1–3, 0.5 mg 2x per day days 4–7 then 1 mg 2x per day thereafter	7 day point prevalence abstinence at 12 and 24 weeks verified by expired CO <10 ppm. Number of cigarettes per day	Change in psychiatric symptoms (SAS, C-SSRS, CGI, PANSS) Adverse events

Table 1 Study characteristics (Continued)

Wu 2012 [37] RCT	5 psychiatrically stable DSM-IV bipolar disorder I or II on a stable dose of mood stabiliser, smoking ≥ 10 cigarettes per day. Outpatients 40% male, 100% white	1. Varenicline (1 mg 2x day) + smoking cessation counselling (group) 2. Placebo + smoking cessation counselling (group)	Smoking cessation verified by expired CO > 10 ppm at 10 weeks and 6 months	Adverse events
Nicotine Replacement Therapy (NRT) studies				
Chen 2013 [29] RCT	184 adult inpatients who were regular daily smokers with DSM-IV schizophrenia or schizoaffective disorder with stable symptoms. Taiwan 93% male, ethnicity not stated.	1. High dose NRT (31.2 mg for 4 weeks then 20.8 mg for 4 weeks) 2. Low dose NRT (20.8 mg for 8 weeks)	7 day point prevalence self report verified by expired CO < 10 ppm at 5 weeks and 8 weeks Number of cigarettes smoked per day FTND	Change in psychiatric symptoms (PANSS, SAS)
Dalak 1999 [11] RCT (within subject crossover)	19 male veteran outpatients with DSM III schizophrenia, schizoaffective disorder Smoking ≥ 20 cigarettes per day on a stable antipsychotic regime. United States 100% male, 60% white.	1. Nicotine patches (22 mg per day) 2. Placebo patches	Nicotine blood level Expired CO Cotinine blood level	Change in psychiatric symptoms (BPRS, SANS, HAM-D) Adverse events
Gallagher 2007 [20] RCT	181 stable adult outpatients with DSM-IV schizophrenia or schizoaffective disorder, smoking ≥ 10 cigarettes per day for 3 years or more with expired CO ≥ 10 ppm after 15 min smoke free. United States 52% male, 76% white.	1. Contingent reinforcement (up to \$480) 2. Contingent reinforcement (up to \$480) + NRT patch (21 mg) 3. Self-quit group	Smoking cessation at week 20 and week 36 (Cotinine ≤ 15 ng/ml or expired CO ≤ 10 ppm) FTND	Change in psychiatric symptoms (BSI)

AIMS abnormal involuntary movement scale; ALA American Lung Association; BDI Beck Depression Index; BPRS Brief Psychiatric Rating Scale; CBT cognitive behaviour therapy; CGI-S Clinical Global Impression-Severity of Illness Scale; CO carbon monoxide; C-SSRS Columbia Suicide Severity of Illness Scale; DSM Diagnosis and Statistical Manual; HAM-D Hamilton Depression Rating Scale; FTND Fagerstrom Test for Nicotine Dependence; ICD International Classification of Disease; MADRS Montgomery-Asberg Depression Scale; MNWS Minnesota Withdrawal Scale-Revised; NRT nicotine replacement therapy; PANSS: Positive and Negative Syndrome Scale; SANS Scale for Assessment of Negative Symptoms; SAS Simpson Angus Scale; SF-12 21 Item Short Form Survey on general functioning; SRP Sustained Release Preparation; p.p.m. parts per million; STAI State Trait Anxiety Inventory; UPDRS Unified Parkinson's Disease Rating Scale; WEPS Webster Extrapyramidal Movement Scale; WISDM Wisconsin Inventory of Smoking Dependence Motives; YMRS Young Mania Rating Scale

SMI and three studies investigated the effects of contingent reinforcement (i.e., providing people with cash incentives if they had remained abstinent from smoking at defined time points).

Of the nine trials (involving 306 participants in total) which explored the effects of bupropion, five tested bupropion plus group therapy versus placebo plus group therapy [13, 14, 17, 22, 26], two tested bupropion plus group therapy plus NRT versus placebo plus group therapy plus NRT [19, 21] one tested bupropion plus smoking cessation counselling versus placebo plus smoking cessation counselling [30]. The final study employed a factorial design testing contingent plus bupropion versus non-contingent plus bupropion versus contingent plus placebo versus non-contingent plus placebo [24]. Tidey did not report abstinence therefore was not included in the meta-analysis.

The addition of varenicline to a range of interventions in the control arm was tested in six trials (313 participants in total). Of these six trials, four tested varenicline plus smoking cessation counselling versus placebo plus counselling [30, 31, 35, 37], one tested varenicline plus group therapy versus placebo plus group therapy [25], and one tested varenicline versus placebo [27].

Five studies explored the effects of a smoking cessation programme designed for people with SMI (638 participants): two studies compared the smoking cessation programme to usual care [18, 33], one explored a specialist programme plus NRT versus a standard smoking programme plus NRT [12], one study compared a specialist programme with medication management [23], and one study compared motivational interviewing with personalised feedback with interactive education with no personalisation [36].

Smoking cessation counselling, whether part of the intervention being tested or part of the control arm, consisted of a range of behaviour change techniques delivered in a variety of formats e.g. face-to-face one-to-one sessions, face-to-face group sessions or one-to-one sessions delivered via telephone. It is important to note that in the trials of varenicline and bupropion, where smoking cessation counselling was delivered, the same programme was delivered in both the medication (varenicline or bupropion) arm of the trial as in the usual care arm of the trial. Therefore it is unlikely that the smoking cessation counselling component of the study had any bearing on the study results. In the majority of the trials the exact content, in terms of the behaviour change techniques employed in the smoking cessation counselling, was insufficiently described.

No studies were identified exploring the effectiveness of very brief advice or the effectiveness of electronic cigarettes.

Methodological quality

Table 2 Summarises the risk of bias in the included studies. Overall the studies were at high risk or unclear risk of bias

aside from Smith 2015 [34] and Smith 2016 [35] which were both at low risk of bias. Overall there was a lack of detail given in the descriptions of key study design features which has led to studies being deemed at an unclear risk of bias. For those studies that were assessed as having an unclear risk of bias the issue may be with the reporting as opposed to actual study conduct. The risk of bias was assessed by two reviewers and there were only few disagreements which were simply resolved by discussion until consensus was reached. Discussion with 3rd reviewer not necessary in any of the instances.

Smoking abstinence

Risk ratio (pooled) for point prevalence abstinence at short, medium and long term for studies exploring the addition of bupropion (Fig. 2), varenicline (Fig. 3) and a specialist smoking intervention for people with SMI (Fig. 4) were calculated. Funnel plots are not included in this review because we identified less than 10 studies eligible for inclusion in the meta-analyses.

Bupropion versus placebo

Eight trials that tested the addition of bupropion to a range of interventions in the control arm reported abstinence data. These studies were pooled to judge whether the addition of bupropion offered any additional benefit (Fig. 2). Pooling this data using a fixed-effects meta-analysis showed that the addition of bupropion improved quit rates significantly in the medium term and long term but not in the short term (short term RR = 6.42 95% CI 0.82–50.07; medium term RR = 2.93 95% CI 1.61–5.34; long term RR = 3.04 95% CI 1.10–8.42). The median duration of the short term comparison was four weeks, 3.5 months for the medium term comparison, and 11.75 months for the long term comparison. There was no evidence of between study heterogeneity ($I^2 = 0\%$).

Varenicline versus placebo

Five of these studies were pooled to evaluate whether the addition of varenicline offered any additional benefit (Fig. 3). Pooling this data using a fixed-effects meta-analysis showed that the addition of varenicline improved quit rates significantly in the medium term (RR = 4.13 95% CI 1.36–12.53), median time-point six months. None of these five studies gave long term quit data. There was no evidence of between study heterogeneity ($I^2 = 0\%$). Participants in these studies received varenicline for between eight and 12 weeks. Removing the monotherapy study [27] from the meta-analysis did not substantially change the results and there was no overall change in heterogeneity (RR = 3.62 95% CI 0.68–38.69).

Specialist smoking cessation programme

The results from the studies exploring smoking cessation interventions were mixed in terms of results when

Table 2 Risk of bias of included studies

	Adequate sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data addressed	Free of selective reporting	Free of other bias	Overall
Baker 2006 [18]	Unclear	High Risk	High Risk	Low Risk	Low Risk	Low Risk	Low risk	High risk
Baker 2015 [32]	Unclear	Unclear	High Risk	Low Risk	High Risk	Low Risk	Low risk	High
Chen 2013 [29]	Unclear	Unclear	Unclear	Unclear	Low Risk	Unclear	Low risk	Unclear
Chengappa 2014 [31]	Unclear	Unclear	Low Risk	Low Risk	Unclear	Low risk	Low risk	Unclear
Dalak 1999 [11]	Unclear	Unclear	Unclear	Unclear	Unclear	High risk	High risk	Unclear
Evins 2001 [13]	Unclear	Unclear	Unclear	Unclear	Low Risk	Unclear	Low risk	Unclear
Evins 2005 [17]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	High risk	Unclear
Evins 2007 [19]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Low risk	Unclear
Fatemi 2013 [30]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Gallagher 2007 [20]	Unclear	Unclear	High Risk	High Risk	High risk	Unclear	Low risk	High
George 2000 [12]	Unclear	Unclear	High Risk	Unclear	Unclear	Unclear	High risk	High
George 2002 [14]	Unclear	Unclear	Low Risk	Low Risk	Low risk	Unclear	Low risk	Unclear
George 2008 [21]	Unclear	Unclear	Unclear	Unclear	High risk	High risk	Low risk	High
Gilbody 2015 [33]	Low Risk	Low Risk	High Risk	High Risk	Low Risk	High Risk	Low risk	High
Steinberg 2003 [15]	Unclear	Unclear	High Risk	Low Risk	High Risk	Unclear	Low risk	High
Tidey 2011 [24]	High Risk	High Risk	Low Risk	Low Risk	High Risk	Unclear	High risk	High
Weinberger 2008 [22]	Unclear	Unclear	Unclear	Unclear	High Risk	Unclear	High risk	High
Weiner 2011 [25]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Weiner 2012 [26]	Unclear	Unclear	Unclear	Unclear	Low risk	Unclear	Low risk	Unclear
Williams 2010 [23]	Unclear	Unclear	High Risk	Low Risk	High Risk	Unclear	High risk	High
Williams 2012 [27]	Unclear	Unclear	Low Risk	Low Risk	Low Risk	Low Risk	Unclear	Unclear
Wing 2012 [28]	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Wu 2012 [37]		Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Steinberg 2016 [36]	Unclear	Unclear	High risk	Low risk	Low risk	Unclear	High risk	High
Smith 2015 [34]	Low risk	Low risk	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk
Smith 2016 [35]	Low risk	Low risk	Low risk	Low risk	Low risk	Low risk	Unclear	Low risk

compared to those exploring the effectiveness of smoking cessation medication. Whilst some studies reported positive findings others reported negative findings. This may be due to differences in the smoking cessation intervention being tested. It may be that some interventions or components of interventions are more effective than other smoking cessation interventions, however this cannot be certain. The setting, delivery mode and who delivers the intervention may also have some influence of the effectiveness of the intervention.

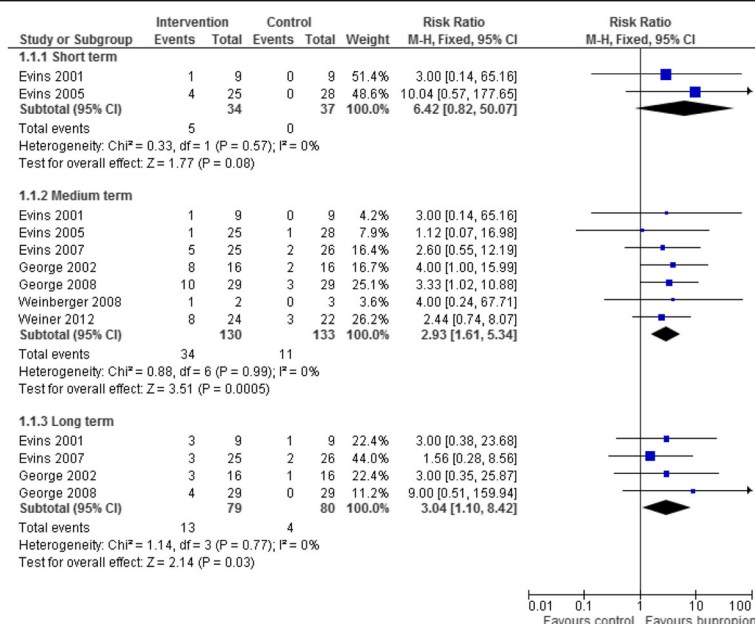
Four studies gave abstinence data, three of which gave medium term data and long term data and one gave long terms data only. These studies were pooled to assess whether a specialist programme offered any additional benefit (Fig.4). Pooling this data using a fixed-effects

meta-analysis showed that there was no evidence of benefit for the specialist smoking cessation programme in the medium term (RR = 1.32 95% CI 0.85–2.06) or in the long term (RR = 1.33 95% CI 0.85–2.08). Median duration of comparison was six months in the medium term and 12 months in the long term. None of these five studies gave short term quit data. There was no evidence of between study heterogeneity ($I^2 = 0\%$).

Secondary outcomes

Change in psychiatric symptoms

Of the included studies, 22 used one or more validated symptom scales to ascertain whether psychiatric symptoms had altered during the course of the trial (Table 3). None of the studies that tested outcomes for significance found any

**Fig. 2** Addition of bupropion

significant worsening of psychiatric symptoms in the intervention group and only one study found a significant worsening of cognitive score in the intervention group compared to placebo [17]. Therefore it does not appear that smoking cessation interventions worsened psychiatric symptoms however due to heterogeneity between the symptom scales and time points used no meta-analysis was conducted.

Only one study that included participants with bipolar disorder reported on the significance of any change in psychiatric symptoms (not significant). The rest of the studies that reported secondary outcome included participants with schizophrenia and schizoaffective disorder.

Change in BMI

Change in BMI was not routinely measured in the included studies and only two studies listed BMI as one of their outcomes [31, 33]. Of these only one study reported change in BMI therefore no meta-analysis was conducted.

Adverse events

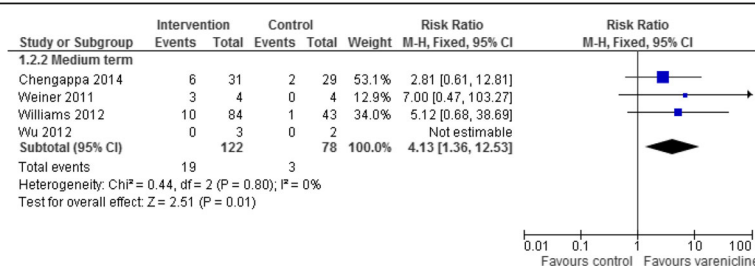
Of the included studies 14 included some reporting of adverse events (Table 3), although in four of these studies this was not fully reported. No standardised method for reporting adverse events was used and some studies differentiated between serious adverse events and adverse events whereas some did not.

Cost effectiveness

Only one study [33] set out to explore the cost-effectiveness of the intervention. This study demonstrated that it was feasible to carry out a cost-effectiveness analysis of a bespoke smoking cessation intervention compared to usual care however as it was a pilot study it was not sufficiently powered for any firm conclusions could be drawn.

Discussion

Since our previous review there has been an increase in the evidence base of smoking cessation interventions for people with SMI. Previously we identified seven studies

**Fig. 3** Addition of varenicline

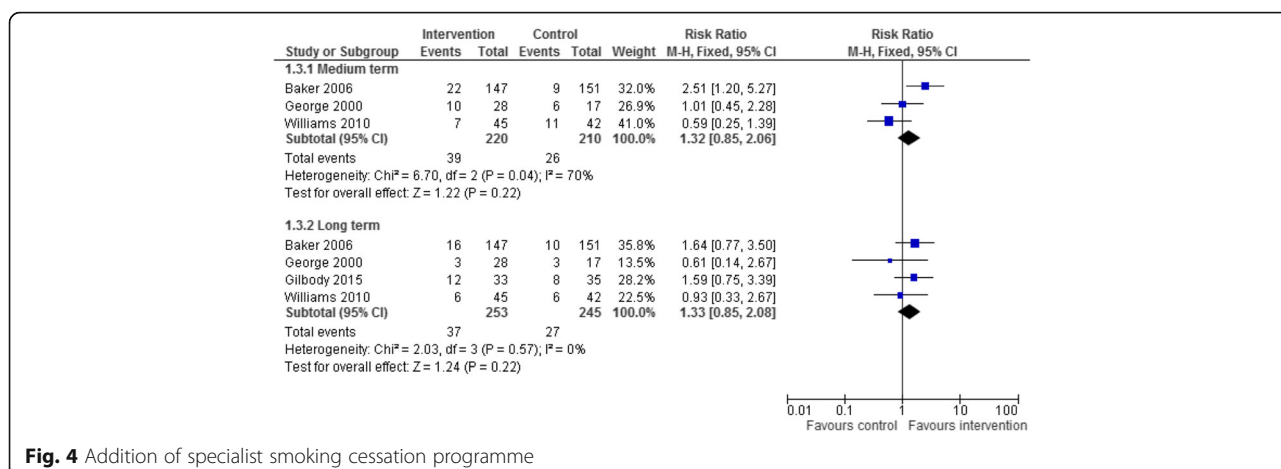


Fig. 4 Addition of specialist smoking cessation programme

meeting the inclusion criteria, in this review we have included 26 studies, 19 more than our previous review, indicating that this is a rapidly developing field. Despite the increase in the number of studies exploring the effectiveness of smoking cessation interventions for people with SMI, the studies are still generally of a small size and underpowered to detect a difference between the intervention and control. Overall studies were at high or unclear risk of bias with only two of the most recent studies being at low risk of bias [34, 35].

In line with the results of our previous review, this updated review indicates that people with SMI can quit smoking and the same interventions that work for people in the general population work for people with SMI e.g. the use of varenicline, bupropion or NRT to support a quit attempt. The addition of bupropion gives a similar risk ratio at both medium and long term to that of our previous review [7]. In our previous review we calculated an RR = 2.76 (95% CI 1.48–5.16) compared to 3.04 (95% CI 1.10–8.42) for long term point prevalence. For varenicline our review showed a slight increase in RR compared to a recent Cochrane review [39] where the RR = 2.27 (95% CI 2.02–2.55) whilst our meta-analysis gave a medium term RR of 2.93 (95% CI 1.61–5.34). A recent review of the effectiveness of varenicline in people with SMI which had slightly different inclusion criteria to our review also concluded that varenicline was clinically superior to placebo in helping people with SMI [40]. Due to the unclear or high risk of bias of 24 of the 26 included studies in our review our results need to be interpreted with some caution.

Point prevalence absolute quit rates at the final time-point for intervention groups ranged from 1.1 to 75.0%, and for control groups ranged from 0.0 to 22.9%. In addition quitting smoking did not appear to worsen participants' mental state. In terms of varenicline and bupropion our review indicates that both medications appear to be effective in the medium terms as an aid to

smoking cessation. A recent large trial comparing outcomes of people with psychiatric disorder has also found varenicline and bupropion to be effective with no increase in neuropsychiatric events [41], however this study was not eligible for inclusion in our review as the psychiatric cohort was not limited to people with SMI. The effectiveness of behavioural interventions in helping people with SMI to quit smoking is currently unclear and is the subject of on-going study [42].

We identified two studies [29, 35] that included patients in an inpatient setting, however the majority of the studies were conducted in a psychiatrically stable population and it is therefore unclear as in our previous review how far these findings are generalisable to an acutely unwell population. It is important that further studies are conducted into what works in an acutely unwell population.

The use of e-cigarettes has been increasing in recent years [43] and a Cochrane review was conducted in 2016 exploring their effectiveness as a smoking cessation aid [44]. E-cigarettes have been shown to have a similar effect on quit rate as NRT [45]. However we did not identify any RCTs that explored the use of e-cigarettes as a smoking cessation aid for people with SMI. A subgroup analysis of people who took part in the ASCEND trial was conducted analysing the results for people with mental disorders however this was not limited to SMI [46]. This subgroup analysis indicated that e-cigarettes appear to be as effective in people with mental disorders as those without mental disorders. This topic deserves further research and there is a need for future trials of electronic cigarettes as an aid to smoking cessation amongst people who use mental health services.

Only one study investigated the cost effectiveness of a smoking cessation intervention and this was a pilot study so no clear conclusions could be drawn [33]. More trials are needed with a prospective cost effectiveness analysis. In addition how an intervention may fit into existing service structures needs to be explored.

Table 3 Outcomes

	Change in BMI	Change in psychiatric symptoms	Adverse events	Quit rate (%) intervention (I) control (C)
Complex interventions				
Baker 2006 [18, 38] (including data from Baker 2010)	Not reported	Time-points: 4 months, 7 months, 13 months CDI: significantly lower score for intervention group $p < 0.001$ at all time-points BPRS: not significant at any time point SF-12 (mental): significantly lower score for intervention group $p < 0.001$ at all time-points STAI: significantly lower for intervention group $p < 0.001$ at 7 months	Not reported	4 months I: 22/147 (15.0) C: 9/151 (6.0) 7 months I: 14/147 (9.5) C: 6/151 (4.0) 13 months I: 16/147 (10.9) C: 10/151 (6.6) 4 years I: 13/147 (8.8) C: 17/151 (11.3)
Baker 2015 [32]	Not reported	Time point 3.75, 12 months BPRS, BDI, GAF, SF-12 not significant	Not reported	3 months I: 13/122(10.7) C: 13/113 (11.5) 12 months I: 8/122 (6.6) C: 7/113 (6.2)
George 2000 [12]	Not reported	Time-points: 3 months, 8.5 months AIMS, BDI, PANSS, WEPS: not significant	Not reported	3 months I: 10/28 (35.7) C: 6/17 (35.3) 8.5 months I: 3/28 (10.7) C: 3/17 (17.6)
Gilbody 2015 [33]	Change in BMI not reported. Mean BMI at baseline and 12 month reported.	Time points 1.6, 12 months PHQ-9, EQ-5D, SF-12 mental reported but not tested for significance	21 events of which 12 SAEs, 10 in intervention 2 in usual care	12 months I: 12/33 (36.3) C: 8/35 (22.9)
Smith 2015 [34]	Not reported	Time point after final session PANSS and PYCHRATS no significant differences	15 AEs in active treatment arm and 16 in sham treatment arm	Abstinence not reported
Steinberg 2003 [15]	Not reported	Not reported	Not reported	Abstinence not reported
Steinberg 2016 [36]	Not reported	Not reported	Not reported	1 month I: 8/49 (16.3) C: 5/49 (10.2)
Williams 2010 [23]	Not reported	Time-point 3 months BDI and PANSS positive and negative not significant	Not reported	3 months I: 7/45 (15.6) C: 11/42 (26.2) 6 months I: 7/45 (15.6) C: 8/43 (18.6) 12 months I: 6/45 (13.3) C: 6/43 (14.0)
Wing 2012 [28]	Not reported	No detail on secondary outcomes given	Not reported	Abstinence not reported
Bupropion studies				
Evins 2001 [13, 16] (including data from Evins 2004)		Time-points 3 months, 6 months AIMS, SANS, SAS: not significant BPRS (total): significant decrease intervention group 0–3 months ($p = 0.03$) and 3–6 months ($p = 0.02$)	No adverse events	1 months I: 3/9 (33.3) C: 1/9 (11.1) 3 months I: 1/9 (11.1) C: (0/9) (0.0) 6 months I: 1/9 (11.1) C: 0/9 (0.0) 24 months I: 2/9 (22.2) C: 2/9 (22.2)

Table 3 Outcomes (Continued)

Evins 2005 [17]	Not reported	<p>BPRS (+ve symptoms): significant decrease intervention group 0–3 months ($p = 0.03$). Not significant 3–6 m. HAM-D: significant increase for placebo group 0–3 months ($p < 0.01$). Not significant 3–6 m. HAS: not significant</p> <p>Time-points 3 months Barnes Akathisia Scale: not significant HAM-A, HAM-D, SANS, SAS, WEPS, PANSS (total): not significant PANSS (subscale): significant increase in excitement score placebo versus intervention group ($P = 0.017$) Significant decrease cognitive score intervention versus placebo ($P = 0.029$) Other subscales not significant</p>	<p>3 events requiring withdrawal, 1 in the intervention, 2 group unknown</p> <p>1 months I: 9/25 (36.0) C: 2/28 (7.0) 3 months 4/25 (16.0) C: 2/28 (0.0) 3.5 months I: 2/25 (8.0) C: 1/28 (3.6) 6 months I: 1/25 (4.0) C: 1/28 (3.6)</p>
Evins 2007 [19]	Not reported	<p>Time-points: 3 months AIMS, BDI, SANS, STAI, HAM-D, PANSS: not significant Barnes Akathisia Scale: significantly lower in intervention group ($P = 0.005$) SAS: significantly lower score in the intervention group ($P = 0.016$)</p>	<p>No SAEs</p> <p>2 months* I: 13/25 (52.0) C: 5/26 (19.2) 3 months* I: 9/25 (36.0) C: 5/26 (19.2) 6 months* I: 5/25 (20.0) C: 2/26 (7.7) 15 months* I: 3/25 (12.0) C: 2/26 (7.7) Abstinence not reported</p>
Fatemi 2013 [30]	Not reported	<p>Time point: 3 months Significant positive correlation between serum cotinine levels and BPRS total score ($p = 0.014$), BPRS +ve subscale score ($p = 0.002$), SAPS total composite score ($p = 0.02$) and SAPS delusion subscale score ($p = 0.013$)</p>	<p>Not fully reported</p>
George 2002 [14]	Not reported	<p>Time-points 2.5 months, 8.5 months AIMS, BDI, WEPS: not significant PANSS: significant decrease in intervention group for negative symptoms ($P < 0.05$; general positive subscales not significant)</p>	<p>Not reported</p> <p>2.5 months I: 8/16 (50.0) C: 2/16 (12.5) 8.5 months I: 3/16 (18.8) C: 1/16 (6.3)</p>
George 2008 [21]	Not reported	<p>Time-points: 2.5 months, 6.75 months BDI, PANSS: not significant</p>	<p>No SAEs</p> <p>2.5 months I: 10/29 (34.5) C: 3/29 (10.3) 6.75 months I: 4/29 (13.8) C: 0/29 (0.0)</p>
Weinberger 2008 [22]	Not reported	<p>No details given on secondary outcomes</p>	<p>Not fully reported</p> <p>2.5 months I: 1/2 (50.0) C: 0/3 (0.0)</p>
Weiner 2012 [26]	Not reported	<p>Time-points: 2 weeks, 1 month, 2 months and 3.5 months BPRS, SANS: not significant</p>	<p>5 SAEs in the intervention group and 2 in the placebo group</p> <p>3.5 months I: 8/24 (33.3) C: 3/22 (13.6)</p>
	Not reported	<p>Time-points 1, 2, 3, 4 weeks</p>	<p>Abstinence not reported</p>

Table 3 Outcomes (Continued)

Tidey 2011 [24]			PANSS, UPDRC ad AIMS not significant	Not fully reported incidence of specific AEs reported but not all	
Varenicline studies					
Chengappa 2014 [31]	Mean weight gain		Time-points 3, 6 months Scores for MADRS, YMRS, HARS and CGI reported but not tested for significance.	6 SAEs in the intervention group and 4 in the placebo group	3 months I: 15/31 (48.4) C: 3/29 (10.3) 6 months I: 6/31(19.4) C: 2/29 (6.9)
Smith 2016 [35]	Not reported		Time-point 8 weeks Scores for PANSS, and SANS not significant when corrected for multiple comparisons.	Comparisons made between number of AEs in both groups. Concluded that no AE involving emergent psychiatric symptoms could be attributed to varenicline.	8 weeks I: 7/42 (16.7) C: 4/45 (8.9)
Weiner 2011 [25]	Not reported		Time-points 3 months BPRS +ve items, anxiety/depression not significant	8 side effects in the intervention group 2 in the placebo group	4 months I: 3 /4 (0.75) C: 0/4 (0.0)
Williams 2012 [27]	Not reported		Time-points: 3, 6 months PANSS not significant	9 SAEs in the intervention group and 4 in the placebo group	3 months I: 16/84 (19.0) C: 2/43 (4.7) 6 months I: 10/84 (11.9) C: 1/43 (2.3)
Wu 2012 [37]	Not reported		Time-points 2.5 months Psychiatric symptoms not significantly changed	Not fully reported	2.5 months I: 1/3 (33.3) C: 0/2 (0.0) 6 months I: 0/3 (0.0) C: 0/2 (0.0)
NRT studies					
Chen 2013 [29]	Not reported		Time-points: 2 months PANSS, SAS not significant	Not reported	2 months I: 1/92 (1.1) C: 4/92 (4.3) I = high dose C = low dose
Dalak 1999 [11]	Not reported		Time-points: day 2 AIMS: significantly increased score intervention group day 2 ($p < 0.05$) BPRS, HAM-D, SANS, SAS: not significant	Assessment for signs of nicotine toxicity none reported	Abstinence not reported
Gallagher 2007 [20]	Not reported		Time points 5, 9 months BSI not significant	Not reported	5 months Ia*: 23/60 (38.3) Ib***: 25/60 (41.7) C: 3/60 (5.0) 8.5 months Ia: 22/60 (36.7) Ib: 26/60 (43.3) C: 5/60 (8.3)

Ia = contingent reinforcement * Ib = Contingent reinforcement plus NRT

Only one study reported change in body weight and this was reported as mean change in BMI [31]. Given that weight gain is associated with the prescription of antipsychotic medication [47] and the health implications of obesity it is important that weight change is recorded and reporting in clinical trials. A recent systematic review demonstrated that whilst the mean increase in body mass 12 months after stopping smoking is four to five kilograms there was a wide variation in body mass change [48] (16% of participants had a reduced mass and 13% gained more than 10 kg).

The reporting of adverse events was not standardised. In 12 of the studies included in this review no details of adverse or serious adverse events were reported. It is important that adverse events are clearly reported as per the CONSORT guidelines [49] to allow a judgment to be made as to whether or not a pharmaceutical smoking cessation aid is suitable for people with SMI.

Strengths and limitations

A limitation of this review is that it only included articles that were written in English and this could have resulted in the exclusion of potentially important studies. The fact that all the titles and abstracts were not double screened is a possible limitation however the fact that both authors who screened the initial 10% of titles and abstracts were in agreement over which studies should go forward to full text review reduces the possibility that potentially suitable studies were missed. In addition reference lists of previous reviews of smoking cessation strategies were searched. There is currently a paucity of e-cigarette research. This is a technology that is rapidly evolving and where there has been uptake in the use of e-cigarettes in advance of randomised trials being conducted. However, a strength of this review compared to our previous review is that it includes the use of e-cigarettes as a smoking cessation aid.

Due to the heterogeneity of the scales used to assess psychiatric symptoms it was not possible to conduct a detailed analysis of the results or a meta-analysis. We have therefore summarised whether or not studies found a significant change in psychiatric symptoms and concluded that no significant worsening was found on giving up smoking.

It is possible that the results of this review are at risk of publication bias. To minimise the possibility of publication bias we checked trial registries to determine whether there were any trials registered that had not been published. Funnel plots are not included in this review because we identified less than 10 studies eligible for inclusion in the meta-analyses.

Recommendations for future research

It is currently unclear what proportion of people with SMI will engage with a smoking cessation intervention and trials are needed that will explore the use of very brief advice to encourage people with SMI to seek help

with smoking. It is also recommended that the use of e-cigarettes as a smoking cessation aid for people with SMI be explored in future high quality RCTs.

Conclusions

Despite evidence for the effectiveness of smoking cessation interventions for people with SMI the percentage of people with SMI who smoke in the UK still remains higher than the percentage of people without SMI who smoke.

In addition to our previous findings regarding the effectiveness of bupropion in helping people with SMI to quit smoking there is now trial based evidence to demonstrate that varenicline appears to be effective in helping people with SMI to quit smoking.

Additional file

Additional file 1: Search strategy, Description: example search strategy. (DOCX 13 kb)

Abbreviations

BMI: body mass index; CI: confidence interval; CO: carbon monoxide; NRT: nicotine replacement therapy; RCT: randomised controlled trial; RR: risk ratio; SMI: severe mental ill health

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Availability of data and materials

All data generated or analysed during this study are included in this published article.

Authors' contributions

EP, SB, LC, GT and SG contributed to the study design. LC and SB carried out the screening. EP, GT and SG analysed the data. All authors interpreted the data, drafted the manuscript and read and approved the final manuscript.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

Professor Gilbody and Dr. Peckham are investigators for the SCIMITAR study.

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