An Overview of Pediatric Preventive Health Care in the United States

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ABOUT US

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EXECUTIVE SUMMARY

Keeping children healthy is a crucial element of a sustainable world; pediatric preventive care ensures that children and adolescents grow into healthy and productive adults. Pediatric preventive care, however, has challenges. Recommendations for pediatric preventive health care require frequent re-evaluation to ensure that children benefit from ever-evolving clinical research and advances in medical science. Groups that evaluate pediatric health policy follow a rigorous review process that requires a substantial evidence base, including data on long-term benefits and harms of a given service or intervention. Pediatric research, irrespective of disease area, can be notoriously difficult because it requires a large investment of time and resources to build the required evidence base effectively.

In this paper, the Milken Institute Center for Strategic Philanthropy (CSP) explores how philanthropic funders can help advance pediatric preventative care. We explore the development of pediatric policies and the scientific evidence that feeds those policies. This paper does not focus on a specific disease. Instead, the information and recommendations provide a foundation for any pediatric condition that might benefit from preventive care.

Philanthropists who support biomedical research are passionate about research and care; often, first-hand experience drives their passion. This personal knowledge, along with a strategic focus, can catalyze change. This report aims to inform and galvanize the philanthropic community to support robust science that can inform policy change. We outline four areas for philanthropic investment that support the science and advocacy necessary to accelerate change in pediatric preventive care:

- funding long-term scientific research studies,
- funding cost/benefit analyses,
- supporting voluntary health organizations, and
- supporting patient advocacy groups.

The right strategies, resources, and investment in these areas can result in robust pediatric preventive health processes, policy review, and implementation. In the long term, attention to these areas will lead to transformative care and save many lives.

PEDIATRIC PREVENTIVE HEALTH CARE

Preventive care remains the most effective way to improve health outcomes and reduce costs to individuals and insurers. Evidence-based preventive health care enables medical professionals to intervene early to delay or prevent disease. Pediatric preventive care focuses on promoting physical, mental, and social well-being for children so that they grow into healthy, productive adults. Infants, children, and adolescents undergo physical and developmental changes at a more rapid rate than adults, which presents many opportunities to offer preventive services (Willis 2015). Such services include well-child visits with a health-care provider, immunizations, screening tests and assessments, and age-appropriate counseling and guidance for patients and families.

TABLE 1: PREVENTIVE SERVICES OFFERED IN CHILDHOOD AND ADOLESCENCE

AGE	SERVICE	REASON
Newborn/Infancy	Newborn screening and hearing screening	Detect chronic and genetic conditions
Childhood	Screening for chronic disease risk factors	Minimize progression to lifetime disease
Adolescence	Reproductive health and high-risk behavior screening	Instill healthy behavior for lifelong health
All ages	Injury prevention counseling and vaccinations	Protect against acute conditions

Source: Yeung et al. (2014)

Overview

For stakeholders in pediatric health care to invest philanthropic capital effectively, they must understand the landscape of pediatric preventive health care. This landscape encompasses the organizations that create, review, and implement policy, the processes to change preventative health-care policy, and the requirements for evidence review.

In the United States, doctors, nurses, dentists, and other health-care providers typically deliver preventive care for children in clinical settings. Many screenings and immunizations occur during well-child visits. Disparities in preventive care persist, with children who are uninsured and living in underserved communities being less likely to receive services. The implementation of the Affordable Care Act (ACA) increased access to these services, with an estimated 2.8 million children gaining health-care coverage between 2010 and 2015 (Garrett and Gangopadhyaya 2016).

Organizations that determine preventive care measures have the responsibility of staying aware of current and emerging issues that impact child health in the United States. The following organizations create, review, and implement pediatric preventive health policy and services.

UNITED STATES PREVENTIVE SERVICES TASK FORCE (USPSTF)

The USPSTF is an independent, volunteer panel of medical professionals with expertise in evidence-based medicine and prevention services. Its goal is to provide evidence-based recommendations for clinical preventive care services for both children and adults. Included in the ACA list of covered services, these recommendations are adopted by public health-care systems such as Medicaid, which ensures their broad implementation within the United States.

MATERNAL AND CHILD HEALTH BUREAU (MCHB)

The MCHB, which is part of the Health Resources and Services Administration (HRSA), works to improve the health of mothers, children, and families by supporting health care and public health services—primarily through the Title V Maternal and Child Health Block Grant. This grant provides states and other jurisdictions with funds to support health-care access, preventive care services, and follow-up treatment, as well as coordinated care services for children with special health-care needs. The MCHB also provides funding for the Bright Futures initiative, which is led by the American Academy of Pediatrics ("About the Maternal and Child Health Bureau (MCHB)" 2016).

AMERICAN ACADEMY OF PEDIATRICS (AAP)

The AAP consists of pediatricians and pediatric medical and surgical subspecialists and is committed to the optimal physical, mental, and social health and well-being of all infants, children, adolescents, and young adults.

The AAP leads Bright Futures, a national health promotion and prevention initiative that HRSA funds through the MCHB. *The Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents, 4th Edition* was developed with support from HRSA/MCHB and is published by the AAP. The associated *Bright Futures/AAP Recommendations for Preventive Pediatric Health Care (Periodicity Schedule)* outlines which preventive care services, screenings, and risk assessments are to be performed at each well-child visit from birth through age 21.

The Periodicity Schedule reflects Grades A and B recommendations by the USPSTF, community-based recommendations endorsed by the Centers for Disease Control and Prevention Community Guide, and other preventive care services approved by the AAP Executive Committee and Board of Directors.

EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT (EPSDT)

EPSDT services are a Medicaid benefit that provides comprehensive and preventive health-care services for children enrolled in Medicaid. States share the responsibility for implementing the EPSDT benefit with Medicaid, which has published a set of strategy guides for states to use to improve access, utilization, and quality of care for children. EPSDT services include screenings, including vision, dental, and hearing, and diagnostic and treatment services. States are required to use periodicity schedules for delivering these services, and most use the Bright Futures Periodicity Schedule ("Early and Periodic Screening, Diagnostic, and Treatment | Medicaid" n.d.).

Changes in Pediatric Preventive Health Care

Public and private insurers look to the USPSTF and AAP to provide evidence-based recommendations for pediatric preventive care. Both organizations have a thorough and stringent process for reviewing preventive care and screening topics. To be reviewed by the USPSTF and AAP, topics must have high-quality, evidence-based data available that show long-term positive health outcomes for children. Insurers, including integrated health delivery systems, and professional societies play an important role in policy change as they identify gaps in current recommendations and develop new field- or program-specific guidelines. These initial changes in policy lead to changes in clinical practice, which will then yield additional evidence that can be assessed by organizations such as the USPSTF and AAP to affect even greater change in clinical practice.

UNITED STATES PREVENTIVE SERVICES TASK FORCE POLICY REVIEW

In its effort to develop evidence-based recommendations for clinical preventive care services for both children and adults, the USPSTF reviews the available scientific evidence for potential screening and intervention services.

Key questions posed for evidence review include the following:

- Does direct evidence show that providing the service improves health outcomes if implemented in a general primary care setting?
- Can an at-risk population and/or an increased risk population be identified?
- Are accurate (i.e., sensitive and specific) screening tests available?
- Does screening reliably lead to presymptomatic detection of disease?
- Does treatment of screening detected disease improve health outcomes, specifically mortality or morbidity?
- What harms are associated with the screening process, including risk identification, screening test, confirmatory diagnosis, and treatment?

Every year the USPSTF reviews up to two new topics in addition to current recommendations already scheduled for re-review. Any individual or group can recommend a topic for review. Topics are prioritized based on relevance to preventive primary care, the importance for public health, the potential impact of the recommendation, and the availability of new evidence that may change a current recommendation. The USPSTF and researchers from a designated Evidence-based Practice Center, which are institutions designated to review scientific literature and develop evidence reports, use the final plan to gather, review, and analyze evidence on the topic that is published in peer-reviewed journals. The members of the USPSTF then weigh the potential benefits and harms of the proposed intervention and draft a recommendation that is posted on the USPSTF website for public review and comment. During the public comment period, the draft evidence report undergoes external peer review by five content experts. The report is then finalized and published on the USPSTF website (“Procedure Manual” n.d.).

The USPSTF sets a high bar for evidence and prefers to use evidence resulting from randomized controlled clinical trials for its review. The USPSTF grades its recommendations as A, B, C, D, or I. Grades A and B indicate that the USPSTF recommends that all patients receive the service, with a substantial net benefit expected for Grade A and a moderate net benefit expected for Grade B. Grade C indicates that the service should be offered to select patients based on professional judgment and individual circumstances. Grade D indicates that the service is not recommended and its use discouraged. Grade I indicates that there was insufficient evidence to assess the harms and benefits adequately. The evidence was insufficient because it was lacking, of poor quality, or conflicting. The National Institutes of Health Office of Disease Prevention receives supplemental funding to support additional research to build an evidence base for topics graded I. If new evidence for a topic that was previously graded I emerges, then the USPSTF will prioritize its re-review. Under the ACA, recommendations that are graded A or B must be covered by all public and private insurers and will thus be available to nearly all individuals in the United States.

Pediatric topics under review often receive a grade of I, which means that potentially life-altering interventions are not offered to children and adolescents who may benefit from them.

TABLE 2: ADOLESCENT AND PEDIATRIC TOPICS REVIEWED BY THE USPSTF BETWEEN 2017 AND 2020

TOPIC	AGE GROUP	YEAR	GRADE
High Blood Pressure in Children and Adolescents: Screening	Adolescent, Pediatric	2020	I
Illicit Drug Use in Children, Adolescents, and Young Adults: Primary Care-Based Interventions	Adolescent, Pediatric	2020	I
Prevention and Cessation of Tobacco Use in Children and Adolescents: Primary Care Interventions	Adolescent, Pediatric	2020	B, I
Elevated Blood Lead Levels in Children and Pregnant Women: Screening	Adolescent, Adult, Pediatric	2019	I
Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: Preventive Medication	Pediatric	2019	A
Child Maltreatment: Interventions	Adolescent, Pediatric	2018	I
Adolescent Idiopathic Scoliosis: Screening	Adolescent, Pediatric	2018	I
Vision in Children Ages 6 Months to 5 Years: Screening	Pediatric	2017	B, I
Obesity in Children and Adolescents: Screening	Adolescent, Pediatric	2017	B
Celiac Disease: Screening	Adolescent, Pediatric	2017	I

Source: USPSTF (2017-20)

In 2016, the USPSTF convened an expert panel to address the challenges that make it difficult for pediatric research to build the evidence base needed for policy evaluation. The panel identified five areas for consideration by researchers, funders, and guideline-issuing groups (Kemper et al. 2018):

1. focusing on quality-of-life data to measure pediatric health outcomes, rather than morbidity and mortality data;
2. identifying meaningful intermediate child and adolescent outcomes, which can help assess the impact of a service on long-term health outcomes;
3. evaluating the time frame for potential benefits and harms of a preventive measure, especially when benefits might be delayed and/or when the risk of harms accrue over time;
4. understanding when a preventive service should be offered to yield the most impact; and
5. considering how family members and the broader community might be impacted by a child or adolescent receiving the intervention.

Understanding these challenges will help researchers and other stakeholders to design studies that will address them. In turn, these studies will build an evidence base for pediatric topics that can withstand the rigor of a USPSTF evaluation.

AAP POLICY REVIEW

The AAP publishes a variety of policy documents that guide medical care in the United States, with the goal of optimizing the physical, mental, and social health and well-being of all infants, children, adolescents, and young adults. The AAP policy review process can last for two to five years. First, experts in AAP committees and sections suggest new pediatric preventive care policies. Second, academics in subspecialty groups review and grade the evidence for the policy using a national rubric. Third, the AAP Board of Directors reviews the evidence and makes the decision whether to approve or reject. Approved policies are published in *Pediatrics* and, if applicable, added to the Bright Futures Periodicity Schedule.

The Periodicity Schedule recommendations are supported by the highest level of evidence. The *Bright Futures Guidelines*, *4th Edition* provides practitioners with guidance for implementing the recommendations and describes other beneficial preventive care services that lack the same degree of evidence. It also acknowledges that lack of evidence does not mean lack of effectiveness and emphasizes that, sometimes, provision of interventions must continue in the best interests of children's health while the evidence base is improved. The Periodicity Schedule is reviewed annually.

AAP policy and clinical practice guidelines are reviewed by, but not required to be adopted by, private or public insurance (Children's Health Insurance Program) at the state level. States may choose to meet ACA guidelines by developing their own version of the Periodicity Schedule. However, most choose to use the Bright Futures Periodicity Schedule. Therefore, AAP-recommended preventive services become available to the majority of pediatric patients.

SPECIALIST PROFESSIONAL SOCIETIES/VOLUNTARY HEALTH ORGANIZATIONS

Professional societies and voluntary health organizations also play a unique role in policy adoption and change. Because it can take a long time to generate and collect enough data to meet the high evidentiary standards of the USPSTF and AAP, professional societies have an opportunity to shape the field. They are typically more aware of current research in specialty topics and are better able to include data from large cohort studies in their assessment of evidence for specialty clinical practice guidelines. Further, they can often make and update clinical practice guidelines ahead of large landscape changes from the USPSTF and AAP that depend on necessary general population studies.

Summary

There are multiple pathways to policy change/adoption, and each requires varying amounts of resources and time. Most experts in the field identified the USPSTF's evidence requirements as the most stringent. Although the review typically takes one year, amassing the required amount and level of evidence can take decades.

Each year, the AAP evaluates new and existing evidence on pediatric preventive care services and makes necessary updates to the Periodicity Schedule, adding AAP policy and USPSTF topics with A and B grades. Experts in the field have reported that the rigorous AAP policy review process balances the well-being of the whole child with the need for a high evidentiary bar. Therefore, policy generated by the AAP review process can result in services being added to the Periodicity Schedule even though they do not have an A or B grade from the USPSTF because they have been deemed to be in the best interest of the pediatric population.

Specialist professional societies and insurers employ an alternative and arguably more nimble process for policy change. These groups can use new and accumulating evidence to inform changes to their society's clinical practice guidelines. These changes will only affect those patients under the purview of the organization or insurer, whereas a USPSTF recommendation with an A or B grade must appear on the ACA list of covered services. A recommendation included on the Bright Futures Periodicity Schedule will also be included on the ACA list. In both cases, the service will be offered to the general pediatric population.

SCIENTIFIC RESEARCH IN PEDIATRICS

Pediatric research is necessary to ensure that children and adolescents benefit from important scientific studies and discoveries. Adult research cannot be extrapolated to children, and an ever-increasing understanding of child physiology means it is possible to study interventions in children accurately. As previously mentioned, groups that review and issue health policy have a rigorous review process that requires a large evidence base. This requirement is especially true for pediatrics, and extra care is taken to ensure that the long-term benefits of a service or treatment outweigh any harms.

Challenges in Pediatric Scientific Research

The federal government and research community have identified the need to expand pediatric health research. As a result, the numbers of studies involving children and therapeutics labels for pediatrics have increased. However, a large gap remains between the number of studies that involve children compared to adults, resulting in fewer treatment options for children and adolescents. Experts have identified several reasons for the for the disparity between adult and pediatric research.

STUDY SIZE AND DURATION

The number of participants that are available and qualify for pediatric studies may be low because the cohort of afflicted children tends to be relatively small. In addition, the wide range of developmental differences in infants, children, and adolescents may require sub-analyses of each age group and higher numbers of participants to power the study. Therefore, the study timeline may lengthen to allow for sufficient participant recruitment. Even then, studies may not be large enough to generate statistically reliable data (Field, Behrman, and Children 2004).

The potential long-term harms and benefits of any intervention must be evaluated for years and sometimes decades. This need is especially true for prevention interventions. Study participants must be followed for at least as long as the time expected for the condition to develop naturally. Longitudinal studies are costly and require a clinical trial infrastructure that can track and evaluate participants even as participants and study investigators relocate. Further, it is difficult to retain study participants for such a prolonged time because of relocation and an unwillingness to devote the necessary time and energy. This challenge can be especially true as children and adolescents age into adulthood and must consent themselves (Field, Behrman, and Children 2004).

AVAILABILITY OF THERAPEUTICS

During the past decade, stronger laws for the safety and efficacy of drug products in children and legislative calls for additional studies involving children have increased the availability of preventive therapeutics for children. However, researchers still face many challenges because many drugs enter the market without pediatric indications and labeling. On average, the time between drug

approval for adults and the addition of pediatric data on labeling is nine years (Bogue et al. 2016). The lack of available therapeutics results in few opportunities to use a control treatment in trials or to conduct trials to compare the efficacy of two standard treatments. This lack poses a particular challenge for trials that study interventions such as screening; without a therapy or cure for the condition, such studies are likely to be considered unethical.

ETHICAL CONSIDERATIONS

As with all clinical research, participants must give consent. In pediatric research, this consent is provided by one or both parents and, in some cases, the child. Parents can be hesitant to involve children in research and to expose them to unnecessary hardship or pain. Because most studies are long term, periodic re-consent is often required. Prevention research and placebo-controlled trials face additional scrutiny if the child receiving the prevention intervention or placebo will not benefit or faces even a minimal amount of risk. Finally, studies of a screening service can also be considered unethical if there is no therapy or cure for the condition being screened for.

CLINICAL INVESTIGATOR AND INFRASTRUCTURE NEEDS

Following participants for an extended period of time requires robust research infrastructure. A key element of this infrastructure is pediatric clinical researchers. Yet, fewer pediatricians choose to enter this specialized field partly because post-residency fellowships focus on laboratory rather than clinical research.

Pediatric research infrastructure also requires additional funding, time, and staff to ensure that participants and families are comfortable with any procedures and instructions. Children may require extra attention and benefit from working with providers specially trained for working with children. Families may need additional counseling and communication prior to providing consent for child participation in a study (Field, Behrman, and Children 2004).

Summary

Pediatric preventive health care plays an important role in ensuring that children have safe and healthy childhoods.

Preventive screening and treatment services are evaluated by groups that review and create policy with rigor. To change or add to their recommendations, these groups require a substantial evidence base about the service, including data on long-term harms and benefits. To meet this requirement, children must be involved in clinical research studies, which can be difficult to launch but are important and necessary to ensure that children fully benefit from advances in medicine and technology and have every opportunity to grow into healthy adults.

OPPORTUNITIES TO SUPPORT THE PEDIATRIC PREVENTIVE CARE LANDSCAPE

For children to grow into healthy adults, preventing disease in the pediatric years is crucial. There are many preventive care measures in place, and infants, children, and adolescents have increased opportunities today to receive these services. Still, adding new preventive care interventions remains a challenge. Philanthropy can directly support the pediatric preventive care landscape through the following opportunities:

FUND LONG-TERM SCIENTIFIC RESEARCH STUDIES

Pediatric research studies are costly in part because their design involves features and services not needed in adult research studies. In addition, the number of pediatric patients to benefit from any one intervention is typically small. As a result, traditional study sponsors are rarely willing to fund the long-term follow-up required for pediatric research. Philanthropic collaboratives can operate for longer periods of time, which makes them especially poised to shoulder the cost of extended follow-up. The data generated from extended follow-up can build the evidence base required by groups that evaluate pediatric research.

FUND COST/BENEFIT ANALYSES

Insurance payers require cost/benefit analyses to determine the value of adding a particular service to their offerings—particularly in the case of prevention services. The case must be made that the cost of the prevention intervention for healthy children will be less than the cost of the diagnosis and treatment of the condition in those that develop it. Philanthropy can fund these analyses so that other funds granted can be applied to the research itself.

SUPPORT VOLUNTARY HEALTH ORGANIZATIONS

In addition to the USPSTF, voluntary health organizations and specialist societies issue guidelines and make recommendations for preventive services. These groups operate very close to the research and trends in a specific field and can change their guidelines and recommendations more quickly than larger, national groups that issue policy. These recommendations can lead to implementing a service in the group under the specialist society's purview and fostering growth of the evidence base prior to evaluation by groups such as the USPSTF and AAP. Philanthropists can support these organizations as they develop guidelines and recommendations for specific disease areas.

SUPPORT PATIENT ADVOCACY GROUPS

Patient advocacy groups have been very successful at lobbying for policy change at the local and national levels. For example, many conditions included on newborn screening panels, such as cystic fibrosis and phenylketonuria, were added as a result of patient advocacy groups lobbying their state legislatures. Once a single state adopted the condition, additional states followed. In many cases, the conditions are now included on the Recommended Uniform Screening Panel for newborn

screening issued by the US Department of Health and Human Services. These advocacy groups, often largely composed of parents, are highly motivated and action-oriented but, as grassroots organizations, they often lack funding. Supporting them can affect change at the local level, ultimately resulting in change at the national level.

Summary

Philanthropists can engage in a number of different ways to help overcome challenges in the pediatric preventive health landscape and play a crucial role in advancing pediatric health policy. By funding long-term studies and cost/benefit analyses, donors can help ensure that groups that evaluate and issue policy recommendations have adequate data to review and insurers have the justification they need for adding a service. Supporting voluntary health organizations and patient advocacy groups can bolster support for a service at a local level, paving the way for larger landscape changes.

CONCLUSION

Often, donors who engage in philanthropy for pediatric diseases enter the space because of a distressing personal experience, only to find a disease landscape that can be overwhelming and confusing. For some diseases, donors report that better preventive measures in the pediatric years or earlier intervention may have made a positive difference.

Implementing pediatric prevention services is a complex process. While there are some strong pediatric preventive measures in place, for example, childhood vaccines and newborn screening for many genetic and metabolic conditions, there are many more interventions that could be applied if there was sufficient research to support their implementation. There are several unique challenges that make pediatric research difficult, resulting in a lack of evidence for new preventive care recommendations.

By taking the time to understand the pediatric preventive health landscape and the bodies that issue policy recommendations, strategic philanthropists can accelerate preventative medicine for children. And then, with the right investments, philanthropy can create a legacy of good health for millions of children and adults for decades to come.

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