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Moving Beyond Program to Population Impact: Toward a Universal Early Childhood System of Care

Families have clearly benefited from increased availability of evidence-based intervention, including home-visiting models and increased federal funding for programs benefiting parents and children. The goal of population-level impact on the health and well-being of infants and young children across entire communities, however, remains elusive. New approaches are needed to move beyond scaling of individual programs toward an integrated system of care in early childhood. To advance this goal, the current article provides a framework for developing an early childhood system of care that pairs a top-down goal for the alignment of services with a bottom-up goal of identifying and addressing needs of all families throughout early childhood. Further, we describe how universal newborn home visiting can be utilized to both support alignment of, and family entry into, an early childhood system of care with broad reach, high quality, and evidence of population impact for families and children.

Over the past 50 years, advances in developmental and prevention science have moved discussions surrounding early child interventions from whether they are even effective (e.g., Bronfenbrenner, 1974) to a recognition of the long-term societal benefits of such efforts

(e.g., Heckman, 2006; Nores & Barnett, 2010). This work is grounded in decades of theory and empirical research demonstrating the centrality of family interactions and the home environment in shaping child development and well-being (e.g., Bronfenbrenner & Morris, 1998; Cox & Paley, 1997). A multitude of findings from evidence-based early childhood interventions has demonstrated positive benefits to children and families in rigorous, randomized controlled trial (RCT) evaluations (for a review, see Olds, Sadler, & Kitzman, 2007; Shonkoff & Meisels, 2000) and the centrality of the family in effective service delivery (Dunst, Trivette, & Hambry, 2007). Federal policies and expenditures during this time period have also evolved—adjusted for inflation, annual federal expenditures on children grew from \$58 billion to \$445 billion between 1960 and 2010, a sevenfold increase in total dollars devoted to programs supporting children (Isaacs, Toran, Hahn, Fortuny, & Steuerle, 2012). More recently, the Patient Protection and Affordable Care Act of 2010 established the Maternal, Infant, and Early Childhood Home Visiting program (MIECHV; Adirim & Supplee, 2013) that, to date, has allocated more than \$2 billion to support the dissemination of evidence-based home visiting programs. These programs, serving predominantly low-income mothers with infants and young children, are designed to promote outcomes such as child health, child development and school readiness, family economic self-sufficiency, maternal health, positive parenting, and child maltreatment prevention.

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Despite both increased availability of evidence-based programs serving families of infants and young children and increased federal funding allocated to programs benefiting children, these efforts have yet to produce population-level impact on the health and well-being of children across entire communities. Indeed, there is evidence to suggest that national indicators of multiple domains of child well-being have remained stagnant or declined over the past 15 years, including infant low-birth-weight and preterm births, family economic well-being, social relationships, emotional well-being, education attainment, and health (Child Trends Data Bank, 2016; Land, Lamb, & Fu, 2015; Martin, Hamilton & Osterman, 2017). Further, despite evidence of positive impact for individual families, population-level progress in reducing socioeconomic and race-based disparities in child health and developmental outcomes remains elusive (Shonkoff, 2016).

THE IMPORTANCE AND ABSENCE OF AN EARLY CHILDHOOD SYSTEM OF CARE

Beyond the limitations identified in attempting to achieve population impact through scaling individual models, a significant barrier to achieving “breakthrough” change for children and families is the lack of a continuous, integrated system of care in early childhood. Federally funded universal systems exist at multiple stages of the life course, most notably the K–12 public education system for children and adolescents and Medicare and Social Security for the elderly. No such system, however, exists in infancy and early childhood, despite rapidly growing awareness of the critical importance of child developmental outcomes from birth to 5 years in shaping long-term adjustment and well-being. As a result, during this critical time parents are often left on their own (a) to identify community services and supports that are both available and needed and (b) to navigate the network of community services in the absence of a system to scaffold that process (Tolan & Dodge, 2005). This lack of coordinated, community-level support results in agencies and programs serving families with young children operating in a similarly isolated fashion, with limited cross-agency communication and limited capacity to share information about the services families need and utilize during this period.

Historical trends in public policies and public investments throughout childhood and adolescence further highlight the lack of prioritization for a system of care to drive population-level outcomes in infancy and early childhood. Although significant interest remains in ensuring key developmental milestones among all school-aged children (e.g., kindergarten readiness, third-grade reading, high school graduation), no such population-level policies and strategies currently exist for children before school entry. Similarly, Edelstein, Isaacs, Hahn, and Toran (2012) found that annual per-child government expenditures for children ages 6–11 (\$14,641 per child) and ages 12–18 (\$13,663) far exceed expenditures for children ages 0–2 (\$5,415 per child) and ages 3–5 (\$8,602 per child).

Although such an early childhood system has not been prioritized historically, advances in scientific understanding of, and public awareness about, the importance of infancy and early childhood in shaping long-term development has begun to change these trends. Findings from developmental, clinical, and neuroscience research highlight both critical importance of healthy cognitive and brain development during this period, as well as the role of stress and adverse experiences in disrupting this process (e.g., Shonkoff, 2016). Findings from developmental and prevention science also demonstrate that investments in early childhood services, including preventive interventions when appropriate, produce far greater lifetime returns on investment than do remediation services in later childhood, adolescence, and adulthood (e.g., Heckman, 2006). Consistent with this growing awareness, a number of public policies have begun to prioritize investments in early childhood, such as expansion of state-funded prekindergarten programs (e.g., Muschkin, Ladd, & Dodge, 2015) and greater federal funding for evidence-based home-visiting programs (Avellar & Supplee, 2013).

Toward the goal of promoting positive outcomes for all infants and young children, several approaches have emerged with an explicit goal of improving outcomes at the population level. Perhaps the best known and most widely implemented is the Positive Parenting Program (Triple-P; Sanders, Turner, & Markie-Dadds, 2002), which attempts to reduce rates of child behavioral problems by improving parenting skills and efficacy. The program targets all

parents in a community, offering resources and supports ranging from light-touch community messaging and self-help resources to intensive family intervention programs, depending on family need. Although focused more on parenting than on developing a community system of care, program effectiveness is supported by more than 150 randomized controlled trials conducted worldwide (Prinz, in press). A more recent example of a program designed to support family engagement in a system of care is First 5 Los Angeles (<https://www.first5la.org>). Although formal evaluation of impact is not yet complete, the program goal is to strengthen families with children 0–5 years in Los Angeles, California, by assessing needs and connecting families to high-quality services, including health care, child care, and home-visiting programs.

Building on these examples, we begin by identifying the inherent challenges of scaling up evidence-based programs to achieve societal impact, then turn to the key components of developing a universal system of care for early childhood. To illustrate one approach to engaging families in early childhood system of care, the article is organized to describe the design, implementation, and evaluation of an innovative, communitywide postpartum home-visiting program. The article concludes with implications for theory, research, and practice.

CHALLENGES TO ACHIEVING POPULATION IMPACT BY SCALING EVIDENCE-BASED PROGRAMS

Challenges to achieving positive outcomes for all children can be partly attributed to current best practices for developing, evaluating, and disseminating early childhood interventions. A foundation of this practice, promoted and endorsed both by the Institute of Medicine (IOM; Mrazek & Haggerty, 1994) and the National Institutes of Health (NIH; Zerhouni, 2003) is a belief that program development should follow a four-stage progression. Theory and basic science first inform processes underlying child development. This foundation then leads to an efficacy trial involving the development and testing of an intervention through small-scale, RCTs administered under carefully monitored conditions. If sufficient evidence supporting model efficacy accumulates, larger trials are undertaken in conditions that more closely replicate “typical” community

conditions, ideally in the context of an RCT. Finally, programs that demonstrate positive impact in community-based settings are translated to public policy and scaled. Although this development model is both theoretically and practically sound, to date, the approach has resulted in few programs that have successfully progressed through all four stages to produce positive impact on an entire population (Dodge, Goodman, Murphy, O’Donnell, & Sato, 2013a; Shonkoff & Bales, 2011). Rarely has such a goal even been attempted (for exceptions, see Muschkin, Ladd, & Dodge, 2015; Prinz, in press). More common, effectiveness of early childhood interventions decreases as programs move from small-scale trials to serve larger and more diverse populations. Welsh, Sullivan, and Olds (2011) noted that effectiveness can decrease by as much as 50%.

Specific examples of these challenges can be observed through efforts to implement and scale home-visiting programs, one of the most popular and successful means of engaging families in infancy and early childhood (Avellar & Supplee, 2013). First, although numerous home-visiting programs have demonstrated success in improving outcomes for the families they serve, they typically serve a small percentage of all families in a community and of families who meet their eligibility criteria. As a result, population impact by that program alone is not possible (Kilburn, 2014). Challenges in achieving positive impact on larger proportions of children and families result both from targeted eligibility criteria (e.g., mothers with low income and one or more additional risk factors), as well as high per-family costs that make such community-level implementation cost prohibitive (e.g., Department of Health and Human Services, DHHS, 2015; DHHS, 2011).

Second, enrollment and retention rates for families participating in long-term home-visiting programs is typically low, even in the context of rigorous randomized trials consisting of motivated, volunteer families participating in carefully controlled conditions (e.g., Harding, Reid, Oshana, & Holton, 2004; Olds, Henderson, Chamberlin, & Tatelbaum, 1986). Even among those families who remain engaged, participation and intervention dosage is considerably lower, on average, than is intended by the model developers. In a comprehensive review of evaluation results from six different national home-visiting models,

Gomby, Culross, and Behrman (1999) found that, once enrolled, families received approximately half the total number of home visits originally prescribed, regardless of intended frequency.

Finally, when expanding from smaller randomized trials to serve larger and more heterogeneous populations in community settings, many evidence-based programs, including home-visiting models, experience challenges in maintaining high standards for implementation that were established and monitored during randomized trial evaluations. These challenges, in turn, may contribute to both smaller and inconsistent effects over time. A multitude of factors may contribute to observed declines, such as insufficient capacity of model developers to support dissemination (e.g., inadequate capacity to support training of staff, monitor fidelity across sites, or provide strategies to address implementation barriers in a timely fashion), greater heterogeneity in the population of families served, variations in quality of community agencies implementing the model, or reductions in per-family funding for implementation (Daro, McCurdy, Falconnier, & Stojanovic, 2003; Olds, Hill, O'Brien, Racine, & Moritz, 2003). Collectively, these results underscore the significant and persistent limitations in attempting to "move the needle" on important outcomes in infancy and early childhood by developing programs in small-scale settings and then scaling those with positive impact to serve both more communities and more families in each community.

DEVELOPING A NEW SYSTEM OF CARE FOR EARLY CHILDHOOD

To achieve population impact on the well-being of infants and young children, a new systemic approach is required. This system should move beyond an emphasis on developing and scaling individual models and measuring improvement at the individual child and family level to pursuing population change through an emphasis on coordination across programs and accountability for outcomes at the population level. Such an approach would seek to combine top-down alignment of high-quality, preferably evidence-based, services with a bottom-up goal of reaching each family in a community. The goal of these efforts is to organize and align resources into a more efficient, coordinated

network capable of identifying and meeting the diverse needs of families throughout early childhood. Further, while such a system would be guided by a set of key principles held consistent across communities, flexibility must be retained so that individual communities can fully capitalize on their own unique configuration of resources and relationships.

Key Components of an Early Childhood System of Care

Universal reach with services concentrated for highest-risk families. To achieve population impact, a new approach to an integrated system of care begins by engaging all children and families, to assess their needs and then allocate resources on the basis of those identified needs. Such an approach holds the potential for widespread public support and family participation by addressing several challenges endemic among programs and policies for families with young children. First, the community inclusive approach transcends political divisions because services are offered to all families. Second, when all families are included, participation does not stigmatize families as "at risk" on the basis of demographics alone.

Grounding an early childhood system of care in universal eligibility does not mean, however, that all families have similar risk for poor child outcomes or that all families have equal needs for services. An extensive body of research findings has demonstrated significant inequality in social determinants of health and well-being, with experiences of persistent poverty being particularly detrimental to optimal child development (e.g., Aber, Bennett, Conley, & Li, 1997; McLoyd, 1998). As a result, a primary goal of a universal system of care should be to identify family-specific risk and needs and then rapidly triage and concentrate resources to those families with greatest needs to maximize both efficiency and impact. Universal efforts should not replace more intensive, targeted programs, including long-term, intensive home-visiting services; rather, they should complement such efforts by ensuring that the programs serve families best suited for, and most likely to benefit from, the services.

Prescriptive assessment and prevention focus. Maximizing the impact and efficiency of an early childhood system of care depends both

on systematic efforts to identify family-specific risk and needs and on investments in preventive programs that promote the health and well-being of children. Similar to a pediatrician or other primary-care provider who diagnoses illness or disease before providing treatment, the foundation of an early childhood system of care is the effective use of screeners, observations, parent information, and other assessment tools that (a) include items based on theory and developmental science and assess the most salient risks to promoting optimal development at all levels of the child's ecology; (b) identify both strengths and protective factors that may promote optimal development, as well as risks and needs requiring support or intervention; and (c) customize assessment to adapt to changing child and family risk and needs across early childhood and to family choices.

Unlike traditional medical care that is often utilized to treat illness or disease after it has emerged, screening efforts in an early childhood system of care will support the triaging families with identified risk into prevention programs rather than waiting to provide services once problems have emerged. This approach is consistent with trends in pediatrics and family medicine to become more proactive in addressing and minimizing risks. Palliative-care approaches must also be included to provide treatment and support for issues that cannot be addressed through prevention alone. However, emphasizing early identification of risk and supporting connections to preventive services matched to family need holds the best promise for promoting child health and well-being, increasing efficiency among programs serving families, and reducing financial burdens on government by preventing poor child outcomes such as development of chronic health problems, educational delays, and developmental disorders.

Collaboration among key service providers. For a system of universal assessment and support to function cohesively, community services and resources must be aligned and coordinated, such that disparate services spanning a wide variety of community agencies are perceived by the family as one collective entity. Efforts supporting such alignment should include (a) ongoing collaboration and coordination across agencies regarding both the availability

of services and agency capacity to serve families; (b) identification of, and strategies for, addressing domains in which family demand exceeds community capacity and resources; (c) strategies and processes for monitoring changing community resources and needs over time; and (d) common mechanisms or forums for discussing and troubleshooting challenges and barriers to effective system implementation, as they arise. These efforts can be enhanced by supporting community capacity for bidirectional data and information sharing. Such data resources could serve multiple functions, including increasing awareness of services families have already received; decreasing both family and provider burden by reducing or avoiding duplicative collection of demographic, risk, and service data; and promoting warm hand-offs between agencies to prevent families from "slipping through the cracks" as they transition between various services providers within the system of care.

Family- and provider-friendly administration with standardized protocols and ongoing monitoring of performance. Ensuring high rates of interest and participation among both families and service providers requires a system that minimizes perceived barriers and burdens while maximizing perceived benefits. For families, this includes implementation that adheres to principles of a preventive system of care. As articulated by Tolan and Dodge (2005), a preventive system of care approach provides services and supports that are child and family centered and received in accordance to family needs and wishes, with families actively participating in planning for ongoing services and support. This approach also directs communities to provide services in a manner that is both sensitive and responsive to demographic and cultural differences, in order to increase family acceptance and participation in needed services (Dunst et al., 2007). For services providers, this means designing a system in which participation enhances efficiency—that is, participation results in agencies spending less time recruiting families, learning about specific family needs, or engaging with families who either are not eligible or are a poor match for the services offered. Instead, the system should increase time serving families that who motivated to receive services as well as families for whom need and eligibility has

been predetermined through a universal needs assessment. Additionally, as described earlier, appropriate data and information sharing across community agencies in the system is critical to reduce provider burden as a result of duplicative data collection.

Although principles of a preventive system of care are designed to maximize family and provider participation, research has demonstrated that positive impact for children and families is unlikely when implementation quality is poor (e.g., Durlak & DuPre, 2008). Developing standardized protocols for program operations and conducting ongoing monitoring of implementation quality are essential for ensuring consistency in adherence to the program model across service providers, increasing the likelihood of positive program impact. While detailed metrics of interest are likely to vary across communities and implementation designs, core assessment metrics that could be measured across all communities include (a) number of eligible families engaged or assessed for risk, (b) demographic characteristics of eligible and participating families, (c) fidelity in adhering to manualized implementation protocols, (d) reliability in assessing family risk, (e) rates of risk identification, (f) rates of referrals and successful connections to community resources, and (g) family engagement and satisfaction. Collectively, this relatively small set of core metrics can provide valuable information on critical aspects of system functioning, including community reach, implementation quality, population-level profiles of strengths and needs, and connections to community resources and services.

Financing through public-private partnerships. Considering both the limited public investments currently allocated to services and resources for infants and young children, and the multiple domains of the child and family ecology that may present risk, financial resources from any single entity are unlikely to be sufficient to address fully the broad array of services and supports that may be needed to promote optimal child health and well-being for an entire population. Rather, a comprehensive early childhood system of care is likely to require collaborative, coordinated resources and funding from both public and private sectors. From the public sector, an early childhood system of care can leverage dollars and resources

from available from public health sources, including health care (e.g., Child Health Insurance Program, CHIP) and care coordination for low income and at-risk children and families; formal government supports such as the Supplemental Nutrition Assistance Program (SNAP), Medicaid, and child-care subsidies; government funding for programs such as Early Head Start and state-funded prekindergarten; and prevention programs, such as MIECHV. From the private sector, an early childhood system of care is most likely to leverage dollars and resources from social organizations, including community nonprofits and philanthropic organizations. These entities can provide both services and funding either to expand services beyond the capacity of the public sector or to address gaps for needed services that are not adequately resourced by the public sector. Other private-sector entities, including health-care systems and private child-care education services, can also provide resources and support to an early childhood system of care through mechanisms such as sliding-scale fee-for-service models that adjust service costs on the basis of family income.

An additional approach gaining popularity for encouraging private-sector investments in social programs supporting families of infants and young children is social impact bonds (Liebman, 2011). Social impact bonds, or “pay for success” models, are a form of performance-based contracting between private-sector investors and public- and nonprofit-sector service providers. Private investors provide initial funding for interventions or other services that have promising evidence of reducing outcomes that are costly to the public sector, such as premature births or childhood special education placements. If the funded programs are successful in reducing these costly outcomes, the private investors receive a return on their investment based on the magnitude of government cost savings. If the funded program is not successful, however, the investors may lose some or all of the initial investment. This model is designed to increase public investments in early childhood prevention services by shifting financial risk from taxpayers to the private sector, with public dollars committed to programs only on the basis of demonstrated evidence of public cost savings (Dubno, Dugger, & Smith, 2013). Although this approach holds promise for expanding

investments in early childhood systems, to date such investments have been primarily limited to investments in individual programs rather than more comprehensive systems (e.g., Utah High Quality Preschool Program in Salt Lake City). Additionally, as noted by Warner (2013), development of contracts for social impact bonds are time and resource intensive, often requiring a series of complex and costly sets of legal agreements among investors, service providers, contract brokers, and independent evaluators before an initiative can begin serving families. While potentially promising for expanding successful services for families with infants and young children, the extent to which this approach is widely replicable remains unclear.

ENGAGING FAMILIES IN AN EARLY CHILDHOOD SYSTEM OF CARE THROUGH UNIVERSAL HOME VISITING

The Family Connects (FC) model is an innovative, community-based, universal, newborn nurse home-visiting program designed to achieve population impact on well-being in infancy and early childhood by reaching the families of every birth in a community, assessing family-specific needs, and connecting families to services in the broader community for longer-term support as needed and wanted. Developed and piloted by a team of researchers and community leaders in Durham, North Carolina, over several years before formal evaluation, the program is designed for population impact through complementary foci of increasing alignment and efficiency of community resources for children and families while delivering individual home-visiting services to all families in the community. The Durham community provided a number of advantages for the initial development of such a model, including a relatively large number of community resources (both formal and informal), a strong university–community partnership, and a birth population concentrated in a small number of hospitals. Consistent funding from a private philanthropic organization committed to innovation was also critical for initial program development. The following sections describe the theoretical approach, core components, and implementation and evaluation results to date for the FC model.

An Ecological Approach to Promoting Child Well-Being

Consistent with a bioecological model of child development (e.g., Bronfenbrenner & Morris, 1998), risk for poor child health and well-being accrue from factors at all levels of the child's ecology. These factors include infant and child characteristics, such as temperament and genetic characteristics, which make some infants harder to care for or more susceptible to illness; parent and family (microsystem) characteristics, such as parent mental health, household poverty, and intimate partner violence; and community (exosystem and macrosystem) characteristics, such as work–family conflict, community violence, and lack of accessible resources and supports. The most compelling lessons for prevention models offered by this perspective are that risks for poor child health and well-being vary across families and across communities. Preventive interventions will be most successful when the system can identify family-specific risk factors for poor child well-being and identify and align community resources at the appropriate level of ecology to address these risks. The FC program draws on these aims by reaching all families, assessing family-specific risk and protective factors across multiple levels, and connecting families with collaborative community services and resources, as needed and desired, to support their needs.

Addressing Challenges to Developing and Scaling Prevention Programs

The FC program was designed to address the many known limitations to scaling prevention programs resulting from first developing a model through testing in small-scale randomized trials before scaling the program to serve larger and more diverse populations. The model was designed to be brief, with typically 5–7 total contacts between 2 and 12 weeks after birth. As a result, family dropout rates are low, and the program is relatively inexpensive (\$500–\$700 per birth) so that communities can afford its costs. The program is delivered to families of every birth in a community. As a result, families do not perceive participation as stigmatizing them as “poor or high risk,” thereby maximizing community acceptance. Further, because the program was designed to be implemented universally from the start, the program

avoids potential decreases in fidelity and impact that might result from scaling up from smaller randomized trials. Although the goal is to reach families of every birth, intervention is tailored to specific family needs. Families are triaged according to assessed risk and needs and connected to collaborating community resources within the early childhood system of care for additional resources and continued support.

Ongoing Identification and Alignment of Community Services and Resources

The most effective home-visiting nurse cannot have an enduring impact on child and family well-being if needed community resources such as health care, child care, and financial and parenting supports are not available or not accessible to families as they are needed. A key component of the FC model is an extensive process of community alignment that includes the following:

1. Engaging and obtaining the support of virtually all relevant community agencies, providers, and volunteer groups in the community toward the goal of participating in a preventive system of care (Tolan & Dodge, 2005). This system focuses on the needs of the child, includes all relevant members of the child's ecology, and "wraps" preventive and curative services around the child in a family-centric manner.
2. Maintaining a community advisory board of community stakeholders who serve as resources or key supporters of the program, including parents. Quarterly board meetings support maintaining ongoing collaboration across agencies, identifying changing community resources and needs, and troubleshooting challenges as they arise.
3. Assessing capacity and infrastructure of organizations providing services to children and families. This assessment helps identify community strengths and gaps in services and resources, as well as ensure that families are referred to high-quality, preferably evidence-based, services whenever possible.
4. Developing an electronic directory of all relevant community services available to the nurses to support the community referral process during home visits.
5. Establishing and maintaining "feedback loops" with key stakeholders, such as

community coalitions, pediatricians, and OB/GYNs, child-care agencies, and health and human services agencies. This allows for ongoing, bidirectional information sharing between FC staff and community partners toward the goal of continuous quality improvement in program implementation.

Because communities often contain hundreds of agencies that provide services or resources to children and families, Family Connects incorporates a community resource specialist into each implementation site to lead this alignment work and support system-level change.

Assessing Individual Family Needs Through Nurse Home Visiting

The birth of a child represents a period of significant transition, stress, and needs for all families (e.g., Verbeist, Tully, & Steube, 2017). It is also a period of time during which families may be particularly receptive to, or actively seek out, support (e.g., Glade, Bean, & Vira, 2005). Home visiting may be particularly appealing during this transition because services are brought to the family rather than the family going out to seek assistance. Further, nursing is the most trusted profession in the United States (Olshansky, 2011), which may increase the acceptance of nurse home visiting specifically. Family Connects works to bring families, community agencies, and health-care providers together during this transition through nurse home visits to ensure that all families have the support and resources they need to promote child well-being.

The model begins with an initial family contact with all new parents, ideally in the hospital after delivery. The program is described, and the mother (and father or partner, when possible) is invited to participate in a home visit with a Family Connects nurse. One to three home visits, typically at between 2 and 12 weeks of infant age, provide brief intervention and supportive guidance, assess infant and maternal health, identify longer-term family needs, and connect families with community resources, as needed and desired, to provide ongoing support. The program concludes with a follow-up contact 1 month after the nurse closes the case. Letters from the program also connect families to maternal and infant health-care providers for ongoing support.

During the first home visit (the integrated home visit), the nurse's tasks are to (a) engage the mother and father or partner (when available), (b) provide brief educational interventions organized as supportive guidance for all families (e.g., safe sleep), (c) offer extended education in areas specific to parent-centered concerns and needs (e.g., feeding, crying, postpartum depression or anxiety), and (d) facilitate mutually agreed-on connections to community resources, as needed, on the basis of assessed family needs. To evaluate a family's risk and needs, the nurse assesses and scores health and psychosocial needs in each of 12 empirically derived areas in four domains known to predict child and family health and well-being: health care (parent health, infant health, health-care plans), parenting and child-care (child-care plans, parent–infant relationship, management of infant crying), family violence and safety (household safety and material supports, family and community violence, parent history of parenting difficulties), and parent mental health and well-being (parent well-being, substance abuse, parent social–emotional support).

The nurse listens to parents' questions and concerns, directs discussion toward the 12 factors, and rates family risk and needs separately in each area on a 4-point scale. A score of 1 (*low risk*) receives no subsequent intervention. A score of 2 (*mild to moderate risk*) receives short-term nurse-delivered intervention on that particular topic over one to two sessions. A score of 3 (*significant risk*) receives a nurse-facilitated referral to community resources tailored to address the particular risk (e.g., treatment for depression, substance abuse). The nurse not only makes a referral but also follows up to help ensure that each connection "sticks," possibly requiring one to two additional contacts with the family or service provider. A score of 4 (*imminent risk*) receives emergency intervention (very rare). A final telephone contact made 4 weeks after case completion ascertains whether services have already been received from any community referrals, and whether further problem solving is needed to address new or existing needs. Data collected from both the 12-factor assessment of family risk and community service receipt rates are reported back to the community through routine feedback loops (e.g., quarterly community advisory board meetings) to support ongoing alignment of resources and services.

Randomized Controlled Trial of FC Implementation

To evaluate the effectiveness of universal newborn home visiting by nurses as a mechanism for introducing all families to an early childhood system of care, Family Connects was evaluated through a communitywide RCT. All births between July 1, 2009, and December 31, 2010, to a resident of Durham at a Durham hospital were included in the trial. Families were randomly assigned a priori to a condition according to infant birth date: every infant born on an even birth date ($n = 2,327$) was assigned to receive the intervention, and every infant born on an odd birth date ($n = 2,450$) was assigned to receive "all other community services as usual" and act as controls. An advantage of this design is that all 4,777 births could be included in the implementation trial without informed consent but with ethical care for confidentiality. This study was approved by the Duke University School of Medicine Institutional Review Board and registered through ClinicalTrials.gov (Identifier NCT01406184). Additional information on the RCT design and implementation results reported below can be found in Dodge et al. (2014).

The effectiveness of a universal system depends on how many families participate, who participates, and the risks or needs identified. Of the 2,327 even-date birth families, 80% were successfully contacted and agreed to receive a FC nurse home visit. Of those families, 1,596 (86%) successfully completed the entire program (net participation = 69%). Participating families were 40% European American, 37% African American, and 23% other or multiracial, with 26% reporting Hispanic ethnicity, 62% receiving Medicaid or having no health insurance, and 44% reporting being married.

Examining patterns of family risk, of the 1,596 families receiving a nurse home visit, 50 assessments (1%) could not be completed fully because of family choice or family emergency that precluded their participation in the integrated home visit (scored 4 on the 4-point risk factor matrix). Of the 1,546 fully assessed families, 681 (44%) were determined to have at least one significant risk that could best be served by a community agency provider (scored 3). In these cases, nurse and family together discussed which need should be addressed first (if more than one need was identified), which service or resource

could help the family, and who could most effectively secure the connection (nurse or parent). An additional 757 families (49%) were assessed as having at least one moderate risk that could be addressed by brief nurse intervention (scored 2). For some of these families, the nurse also engaged the family with a community service provider for additional information or resources; for others, the need was modest enough that no additional community support was needed beyond the nurse intervention. Finally, 91 (6%) families received lowest-need scores (1) across all 12 factors. In addition, for all families, nurses administered brief educational “teachings” on specific topics using protocols from the program manual. Nurses reported implementing an average of 13.8 teaching interventions per family (Dodge et al., 2014).

Given the importance of consistent, high-quality implementation for program effectiveness, we assessed nurse fidelity to the home-visiting protocol and nurse reliability in assessing family risk and needs by having an independent expert accompany the nurse on, or listen to an audiotape of, an integrated home visit for 116 families. The expert checked nurse adherence to 62 individual protocol items (fidelity) and independently rated the 12 family risk factors to compare to nurse ratings (reliability). Nurse fidelity to the protocol averaged 84% (range = 66%–99%). Nurse reliability in assessing family risk was $\kappa = 0.69$ (range = 0.55–0.82) across all nurses, judged to be high (Cohen, 1988). When adherence was low, feedback was provided, supervision was intensified, and future improvement was monitored.

One month after the nurse closed the case, the mother was contacted by phone to learn whether the community services were received for nurse-directed referrals, whether further problem solving was needed, and whether the family was satisfied with their experience in the program. Of families receiving one or more referrals, 79% reported a successful community connection. Almost every mother indicated that she would recommend the visit to another new mother (99%).

Independent Evaluation of Impact in the Family Connects RCT

Independent of program implementation and staffing, impact on child and family well-being was evaluated in a random,

representative sample of RCT births beginning at infant age 6–8 months. Utilizing a random subsample of the broader population is a common procedure for intensive evaluation of population-level interventions because of the high costs associated with blinded in-home interviewing (e.g., Moving to Opportunity for Fair Housing intervention; Ludwig et al., 2011). Using publicly available birth records, a computer program selected one family per birth date between July 1, 2009, and December 31, 2010. Each family was then contacted at 6–8 months of age and asked to participate in a longitudinal research study of infant development. Selection was independent of FC participation. Interviewers had no knowledge of whether families received FC, and families had no knowledge of any study relation to FC. Once enrolled, families were followed even if they moved out of county ($N = 549$, with 269 even-date and 280 odd-date births). We tested the similarity of our sample with the full population and the similarity between our intervention sample and control sample on 13 demographic and birth characteristics, as well as study participation rate, and found no pattern of difference between groups. We concluded that the evaluation sample was demographically representative of the broader population and that evaluation study participation was not biased between intervention and control groups.

Impact at infant age 6–8 months was examined using two-tailed intent-to-treat analyses estimating the impact of random assignment to Family Connects (or not) on multiple child and family outcomes, regardless of intervention participation or adherence (Dodge et al., 2014). An important indicator in universal systems is whether families have increased access to high-quality community resources and supports. Examining this proximal target of intervention, intervention-eligible families utilized 16% more community resource agencies than control families (effect size = 0.28). Further, among families using out-of-home child care, intervention families reported attending child-care centers that were licensed as significantly higher quality, as measured by the number of “stars” in the five-star North Carolina system, than those attended by control families (effect size = 0.86).

Another important indicator is whether participation in a universal system promotes improved child and family well-being for all families. Examining impact on child and family

well-being, intervention mothers reported more positive parenting behaviors than control mothers (effect size = 0.25) and were also less likely to report possible clinical anxiety (28.3% decrease). Interviewers blinded to FC participation status rated intervention families as having significantly higher home safety and quality scores (effect size = 0.25).

To better understand the impact of Family Connects on infant emergency medical care utilization, hospital administrative records were obtained to examine emergency medical care use through infant age 12 months (Dodge, Goodman, Murphy, O'Donnell, & Sato, 2013b). Multivariate Poisson regression models revealed that intervention families had 50% less total infant emergency medical care than control families through infant age 12 months (effect size = 0.28), including 59% less care through infant age 6 months (effect size = 0.26), and an additional 31% less care from 6 to 12 months (effect size = 0.14). Importantly for a universal intervention, follow-up analyses revealed that intervention effects held across a diverse range of family characteristics, including infant medical risk at birth (risk vs. no risk), insurance status (Medicaid or no insurance vs. private insurance), race/ethnicity (minority vs. White), single-parent status (single parent vs. two parent), and infant gender (male vs. female).

CONCLUSIONS AND FUTURE DIRECTIONS

Results from this randomized trial evaluation of Family Connects suggest that universal home visiting by newborn nurses can be successful both in serving as an initial portal of entry into a broader early childhood system of care and in addressing numerous barriers to effectively scaling intervention services for children and families for population impact. Family Connects reached a high percentage of all births in the community, conducted comprehensive assessment of family strengths and needs with high implementation quality, and connected families with a broad array of matched community resources on the basis of nurse-identified needs. Independent evaluation identified positive impact on increasing family connections to community resources, improving mother positive parenting and home environment quality, and reducing maternal anxiety and use of infant emergency medical care. Further, by designing the model to be implemented at scale from

the start, Family Connects achieved population implementation and impact without experiencing common "scale-up penalties" (Welsh et al., 2010) observed in programs adhering to IOM recommendations to first test a model with small subpopulations prior to scaling (Mrazek & Haggerty, 1994).

Current limits of the FC model reflect broader challenges in creating, implementing, and evaluating an early childhood system of care. First, although Family Connects utilizes an electronic data system to document available community resources and family connections to services following postnatal nurse home visits, this data system is not integrated with data systems of other key community agencies and service providers. As a result, it is not currently possible to share referral information electronically, to assess families' ongoing engagement in the system of care over time, or to assess how community resource utilization may predict improvements in health and well-being over time without costly independent impact evaluation. A possible solution to this limitation is the development of integrated data systems (Fantuzzo, Henderson, Coe, & Culhane, 2017). An integrated data system seeks to integrate individual-level administrative data from a wide variety of government and community sources into a central data repository for the purposes of social problem solving. Although significant time and resources are required at start-up to address challenges related to governance, legal matters, and data security, integrated data systems hold great promise for advancing early childhood systems of care by creating the data architecture to support sharing of referral information directly with community service providers, as well as ongoing monitoring engagement and impact for individual families over time.

The current FC model is also limited to engagement and assessment of family needs in the early postpartum period and direct assessment of the mother and infant. The early postpartum period represents a time in which almost all families have some level of unmet needs (e.g., Verbeist et al., 2017). Family needs, however, change over time, with new needs emerging as infants transition into toddlerhood and early childhood. A comprehensive system of care should include coordinated strategies for ongoing, systematic assessment of family strengths and needs, as well as for connections

to community resources, from birth through the transition to kindergarten. A possible mechanism for coordinating assessment of family needs over time is pediatric practices. Routine pediatric care in one of the few services utilized almost universally by children before kindergarten entry, and there is strong alignment between the timing of routine well-child care and standardized time points for assessing child developmental outcomes. Another alternative mechanism would be downward expansion of early education services. State-funded preschool programs have grown considerably over the past several decades, with multiple states now offering preschool for all 4-year-olds (Barnett, Lamy, & Chung, 2005). Further expansion of these programs could provide a means of assessing child needs and connecting families to community supports systematically while also maintaining efficiency by building this system within an existing infrastructure supported by local, state, and federal resources.

Finally, it should be noted that although considerable research underscores the importance of fathers (e.g., Lamb, 2004; Parke, 2004) in promoting optimal child development outcomes, the Family Connects model is currently limited to direct assessment of mother and infant. The FC protocol includes systematic assessment of mother-partner relationship quality and support, and fathers are encouraged to attend home visits when possible (fathers were present for approximately one-third of integrated home visits in the randomized trial described earlier). During program development and piloting, however, community focus groups revealed that some mothers were unwilling to participate if the program included direct involvement or assessment of the father. This trade-off was made toward the goal of maximizing community reach after considerable discussion among model developers. Family Connects has recently increased the effort to include fathers and other significant caregiving partners in the home visit(s) by opening scheduling to late afternoon and Saturday mornings. Future opportunities for model innovation also exist, such as aligning Family Connects with a coparenting intervention supporting at-risk couples.

The FC model has been certified as an evidence-based program by the federal Home Visiting Evidence of Effectiveness review (<https://homevee.acf.hhs.gov>) and is currently implemented in more than two dozen

communities throughout the United States. Although the model emphasis on local ownership and alignment of existing community resources allows for implementation in any community, implementation success is likely greatest when the program is housed in an administrative organization that is well respected in the community and when local agencies serving families have a history of collaboration and cooperation rather than isolation and competition. The program is funded by a variety of sources across implementation sites, including federal funding through MIECHV, Temporary Assistance for Needy Families (TANF), and Medicaid; state funding through Education and Health and Human Services; local funding through county government; and private philanthropy. Importantly, all sites are currently supported through blended funding across multiple sources, which suggests that collaborative funding approaches may be more promising than single-payer models. Family Connects is also exploring social impact bonds. As currently designed, however, that process is time and resource intensive. Thus, it is unlikely to serve as a major resource for broad program expansion.

Overall, existing evidence highlights both the clear need for, and the potential benefits of, moving beyond an emphasis on developing, testing, and scaling individual interventions toward the development of broader integrated systems of care that provide a comprehensive network of supports for families throughout infancy and early childhood. Further, programs such as universal nurse home visiting represent a promising method for both assessing families' risk and systematically connecting families into the early childhood system of care, with evidence of positive impact of child and family well-being and cost savings to the community. Collectively, early childhood systems of care, committed to goals of reaching all families, systematic assessment of identified risk, and connections of families to matched and well-aligned community resources hold tremendous potential for achieving transformational change in child and family well-being across entire communities desired by researchers, practitioners, and policy makers alike.

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