ment of the risks and benefits of the study as a whole. This approach often requires analysts to make judgments when comparing one sort of risk to another. The communication of information on these various forms of risks and benefits to potential study participants requires a balancing act. Detailed explanation of each separate risk may be overwhelming and confusing. Summaries of the risks may oversimplify or underemphasize particular risks.[5] Evaluation of the acceptability of studies and of the adequacy of consent forms must reflect consideration and communication about these potential risks and benefits both separately and as a whole.

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Community Health Workers — A Local Solution to a Global Problem

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In the face of persistently lackluster job creation, the U.S. health sector is paradoxically seen as both a contributor to torpid macroeconomic growth and a source of local employment opportunities. Labor costs account for more than half of U.S. health care spending, but as payment structures shift from volume-based reimbursement to the rewarding of value in improving health, the locus of health care delivery will expand from facilities to communities. Ideally, patient care will take place not just in episodic encounters but also through continuous, community-based partnerships that include new entities and workers. Elsewhere in the world, such care has involved the use of community health workers (CHWs) — lay community members with focused health care training. We believe that scaling up the community health workforce in the United States could improve health outcomes, reduce health care costs, and create jobs.

In many countries, CHWs are becoming paid, full-time members of community health systems. In sub-Saharan Africa, the One Million Community Health Workers Campaign is training, deploying, and integrating CHWs into the health system.[1] In India, 600,000 CHWs are paid through a fee-for-service system to perform a specific set of primary care functions, such as immunization. In Brazil, community health agents are part of family health teams that now care for 110 million people. And growing evidence reveals the effectiveness of interventions by CHWs in multiple health arenas, such as maternal and child health and chronic-disease management.[2]

CHWs have been part of the U.S. health care landscape for decades, serving as community advocates, social activists, health promoters, and patient navigators, among other roles. In California and other border states, *promotoras* and *promotores de salud* address reproductive health, diabetes, and cardiovascular health. In Arkansas, CHWs have been shown to reduce Medicaid spending by reaching out to people with long-term care needs; in Alaska, they're part of an effective primary care extension system. Multiple states have created formal accreditation programs for CHWs, and in 2009, the Department of Labor recognized CHWs' jobs as a distinct category of employment. Yet despite these gains — and in part because of the organic way in which CHWs have emerged — there is little standardization across health systems in terms of gaining access to CHWs, integrating them into health care processes, and compensating them.

There are three models for or-

Models for Organizing Community Health Workers (CHWs) in the United States.

Model	Example
Extensions of hospital or clinic systems, with health care system as base of operations; CHWs are integrated with disease-management or care teams and are focused on clinical services.	New York–Presbyterian Hospital Washington Heights/Inwood Network (WIN) for Asthma Program, New York: CHWs serve as the single point of contact for families; in clinics, the hospital, and the community, they provide asthma education, support, and referrals for social services.
Community-based nonprofit organizations, rooted in community mobilization, activism, or faith; organizations often provide a host of other services for the community, both health-related and non–health-related.	Latino Health Access, Orange County, CA: CHWs educate their neighbors about a broad range of social and health issues, including nutrition, diabetes, mental health, domestic violence, parenting, and access to health care.
Management entities, organizations dedicated to CHWs that are integrated with clinical and community organizations; oriented around financial sustainability, population and environmental health goals, and local workforce development.	City Health Works, New York: A close-to-client network of CHWs who perform protocol-driven early risk detection, self-management support in community settings, and primary care coordination for chronic conditions.

ganizing U.S. CHWs: employment of CHWs as extensions of hospital systems, management of CHWs through community-based nonprofit organizations, and management of CHWs by entities that operate at the interface between health systems and the community (see table). The first two approaches reflect CHWs' historical roles — as a means for broadening the health care system's reach and as community activists and health educators. The third approach aims to synthesize these roles while borrowing principles from global experiences with scalability and opportunities for financial sustainability. For example, the Prevention and Access to Care and Treatment (PACT) project drew from the nonprofit organization Partners in Health in integrating CHWs into a care-management program for patients in Boston who have HIV–AIDS. The PACT model was subsequently expanded to cover patients with diabetes or other chronic conditions. More generally, organizations dedicated to CHWs could support health systems by recruiting, training, and supervising CHWs. Longitudinally developed expertise in CHW management allows such organizations to provide interventions that are costly when delivered by more extensively trained health care workers and that are difficult to coordinate in community settings.

The Affordable Care Act (ACA) includes levers to shift our health care system's focus toward comprehensive, high-quality care for populations. Through structures such as accountable care organizations and incentives such as readmissions penalties, hospitals are increasingly responsible for the care of patients both in and outside the hospital. For example, hospital systems have invested in care coordinators, aiming to reduce readmission rates by stratifying patients according to risk level and tailoring their discharge interventions. As these systems look further beyond their own walls, they may see opportunities for lower-cost, CHW-based programs to demonstrate superior value.[3]

Beyond reducing readmissions, CHW programs may help to address the root causes of preventable chronic disease. Social exclusion, poverty, marginalization, and the built environment contribute to the high burden of chronic disease, particularly in low-income communities. But social services addressing these social determinants of health are too often fragmented. CHWs who can integrate knowledge of the local social service milieu with knowledge of patients' individual circumstances can create a vital link for vulnerable populations. In concert with social workers, CHWs can mobilize social support, create avenues for family members to engage in the care process, and strengthen long-term community relationships that help patients sustain healthful behaviors.

There's also an economic rationale for considering CHW programs. Employment of CHWs creates meaningful job growth for people with lower educational attainment (passage of the General Educational Development [GED] or higher tests) — often in low-income communities that have been hardest hit by the economic downturn — and particularly for women. From the perspective of a health system, CHWs may be a bargain, with mean annual pay of about $37,000 in 2012. Further research is needed to assess the cost-effectiveness of interventions by CHWs, but pilot programs have shown both reductions in spending for Medicare and Medicaid populations and clinical improvements in areas such as medication adherence and glycemic control.

To further develop the promise of CHWs, policymakers and health system leaders could take five initial steps. First, the evidence base for CHW programs should be shored up, through both additional, pragmatic clinical studies and consensus assessment of completed research. The Community Preventive Services Task Force could perform the evidence assessment, building on the 2007 Community Health Worker National Workforce Study. Additional studies should move beyond examining disease-specific, single-site pilots to larger-scale analyses of CHW integration into primary care, drawing from global research paradigms.[4]

Second, policymakers could address continued stagnation in job growth by promoting CHWs as a linchpin for health system restructuring. Indeed, Section 5313 of the ACA was dedicated to grants for underserved communities to employ CHWs — but was left unfunded. Revisiting this possibility could be productive, since the federal government is investing $67 million in the hiring and training of ACA "navigators" to help consumers with the new health insurance exchanges. Existing CHWs might be a natural fit for this role — and newly trained ACA navigators might consider becoming CHWs.

Third, the Department of Labor could support a harmonized approach to CHW certification across states. Certification helps to professionalize the community health workforce, driving quality standards for training and performance. The experience that Massachusetts had with policy development toward its 2010 CHW-certification law may hold lessons for a national effort.[5]

Fourth, the $1 billion second round of Health Care Innovation Awards from the Innovation Center of the Centers for Medicare and Medicaid Services (CMS) could include a focus on CHW-based interventions. If such innovations had beneficial effects on population health and cost, CMS could consider payment schemes to more broadly support CHW programs — for example, as part of Medicaid case management.

Fifth, dedicated community health workforce organizations could collaborate with insurance companies and hospitals to measure return on investment and to refine clinical protocols that support CHWs, as well as information technology linking patients, CHWs, and providers.

The most crucial lesson from global CHW programs is that the community rootedness of CHWs should be retained through careful, representative selection and by ensuring that CHWs spend most of their time in the community. In the United States, certain structural advantages, such as the strong network of community health centers, could facilitate CHW integration into the health system. The timing for investment in CHWs is also propitious, given the post-ACA landscape and the potential for meaningful job creation. Although the operational challenges of CHW integration are manifold, the global experience offers hope for U.S. communities.

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Big Pharma and Social Responsibility — The Access to Medicine Index

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Despite much progress in the past decade, about one third of the world's population still has no regular access to essential medicines.[1] Many of the most neglected people live in sub-Saharan Africa, but another billion live in emerging economies that have widening gaps between rapidly growing middle classes and poor people who live on less than a dollar a day.[2] Such people face