Time for an additional paradigm? The community-based catalyst approach to public health

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Introduction

Governments, major foundations, and international organizations sometimes shift the focus on development initiatives in a fad-like manner, even changing in mid-course. They may also rely on single approaches for tackling complex problems rather than employing multiple strategies.

An additional paradigm for public health could bridge the divide between building systems and focusing on a specific disease. A community-based catalyst approach appears to be useful in some situations; the approach presented here is based on ten essential elements and five criteria for using local volunteers in community-based initiatives.

Fads and single-mindedness

Governments, major foundations and other organizations tend to change focus roughly in unison, suggesting that they are vulnerable to fads, perhaps more so because of the often destructive tension that has existed since the 1800s between "horizontal" and "vertical" approaches (*1*). Also, they frequently select one principal approach to complex problems, although complexity generally demands multiple strategies. In the middle of the twentieth century, large projects were in favour among those seeking to facilitate development, but in the 1970s, bad press about "white elephant" projects (e.g. big hospitals in poor countries) helped to drive a dramatic switch to low-technology infrastructure in peripheral localities. In 1970 "traditional birth attendants" (who assist with normal births after limited training) became a focus of the United Nations Population Fund (UNFPA) and of the United Nations Children's Fund (UNICEF), with little back-up for obstetric complications. The Declaration of Alma-Ata in 1978 reinforced the heavy focus on local (under-supported) health workers. Subsequently, education and the goal of developing "civil society" (enhancing social structures outside government) gained favour, as bilateral donors, and especially the major foundations, largely abandoned support for health. Now, with the exception of Japan and the USA, the favoured avenue for bilateral assistance is budget support via ministries of finance for health and other "soft" development areas, though not for airports, harbours and similar "hard" development areas.

Massive shifts from one primary strategy to another have numerous disadvantages. For instance, successful activities being carried out under an approach no longer favoured may be terminated. At The World Bank, most loans for distinct health projects have been cancelled following a shift to budgetary support through "poverty reduction support credits" (PRSCs), a "sector-wide approach". AbouZahr showed how "cautious champions", including well-intentioned international agencies, had even changed their approach several times during a single initiative as they tried to reduce the persistent and scandalously high rates of maternal mortality (*2*) — equivalent to the number of people who would be killed if one jumbo jet crashed every 4 hours.

Contrasting realities

Considerable funding for health infrastructures since the Declaration of Alma-Ata has arguably brought relatively little improvement in the provision of adequate health care to poor populations in some contexts. "For a decade, the figure of 500 000 maternal deaths a year has been part of the statistical liturgy" (*3*).

Meanwhile, several disease eradication efforts have been singularly successful in the face of severe corruption, poverty, weak health infrastructures, political chaos and war, using limited resources. The eradication of dracunculiasis (guinea-worm disease) has received less funding since its inception than the poliomyelitis campaign uses each year. Yet the incidence of dracunculiasis has been reduced by more than 99.5%, from an estimated 3.5 million cases in 1989 to 15 522 cases, of which only 1479 were outside Ghana and Sudan, provisionally reported in 2004. The Onchocerciasis Control Programme (which was not an eradication programme) enjoyed similar success for 28 years (1974–2002). For less than US$ 1 per person protected per year, 25 million hectares of land, abandoned due to river blindness, was re-cultivated and able to feed 17 million people. And more than 9 million children were born to a future free of this scourge. Similarly, efforts to eliminate lymphatic filariasis are making real progress using annual mass administration of donated drugs to interrupt transmission among the billion people at risk, in combination with treatment (mostly self-treatment) of lymphoedema and elephantiasis, and surgery for men with urogenital manifestations.

A way forward: the community-based catalyst approach to public health

Rather than abandoning the lessons that led to "basket funding", "poverty reduction" and "budget support" for public health, and suggesting a new fad, this and other evidence (*4*, *5*) argues for using perhaps 5–10% of funds on an additional approach, termed the community-based catalyst approach to public health. This option focuses on observable results and

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Box 1. **Ten elements are arguably essential in a community-based catalyst approach to public health**[a]

1. **A few people who really care:** 5–10 deeply committed people in a handful of organizations.
2. **A data manager and programme manager in each country:** data managers usually work full-time for the programme. Programme managers are usually ministry of health professionals, either full-time or part-time.
3. **An organization:** one or two people with considerable expertise in epidemiology must, through friendly insistence, collect data from countries, analyse them promptly, and provide monthly feedback to all partners. A fast, non-bureaucratic organization is best.
4. **Resident technical advisers in each country:** usually expatriates, resident advisers must work collaboratively, but be funded from outside the infrastructure within which they work. They must have some funds for meetings, travel and stimulation of activities, yet have no formal power. The combination of independence, commitment and lack of formal power, makes them effective.
5. **International meetings:** staff from countries and supporting agencies present data, plans, budgets, achievements and problems, and seek solutions, ideally twice a year. Broad annual meetings and smaller reviews 6 months later (e.g. organized by language) may work best.
6. **Annual programme review meetings in each country:** representatives from all levels of the national programme discuss successes, problems and ways forward.
7. **Annual training and re-training for village volunteers:** volunteers receive 2–3-day updates on progress in their localities, countries and elsewhere. They brush up their knowledge and are given new technical information.
8. **A network of supervisors:** supervisors visit each village volunteer at least monthly, gather collected data, and relay messages between villages and the national level. They encourage volunteers, visit homes with them and help them become more proficient. Regular, announced and unannounced visits by national staff are part of the supervisory system.
9. **Transportation:** from bicycles to 4-wheel-drive vehicles and the occasional camel or boat for supervisors, transportation needs include annual funding for fuel and maintenance, and replacement of vehicles every 4–6 years.
10. **Course-correction mechanisms:** continuous research is needed to improve technical tools and approaches specific to the health initiative.

[a] A national task force is sometimes established, traditionally one per disease. However, in Togo, a Task Force for Parasitic Diseases and Family Health maintains the focus of individual programmes while maximizing the effect of scarce resources and strengthening collaboration. Although potentially useful, national task forces are apparently non-essential.

applies the tools of disease eradication to selected non-eradicable diseases, with the aims of dramatically improving health outcomes and strengthening health systems.

Observations over 15 years have helped the author to identify 10 elements of recently successful disease-eradication programmes (Box 1). These elements must arguably all be in place for the community-based catalyst approach to function, as an engine, brakes and a steering mechanism must be present for a car to function successfully. When specific criteria are met (Box 2), a community-based catalyst approach is ideal.

Community-based catalyst elements can cost approximately US$ 2 million per annum for a 12-country effort in Africa, a paltry amount when compared to the economic and other benefits obtainable, including averted suffering and enhanced dignity. For consortia of donor countries and foundations, such amounts are well within reach.

Several conditions appear ready for a conscientious effort. Obstetric fistula, as a signal indicator for the obstructed labour, maternal and infant deaths and suffering that lie behind it, seems particularly well suited. Although this condition was eliminated in many places years ago, it still afflicts millions elsewhere (*6*). Also, routine health services seem unlikely to adequately address African trypanosomiasis (sleeping sickness) in the immediate future. Yet, a community-based catalyst approach might bring that deadly impediment to the public's health under even better control than was achieved in the 1960s.

At the health systems level, using the human resources organized for eradicating dracunculiasis, Burkina Faso and Togo are considering addressing issues as diverse as cleft lip and palate, club foot, noma, Buruli ulcer and malaria. For noma (a childhood infection with 90% mortality causing major facial damage in survivors), and artemisinin combination therapy for uncomplicated malaria, correct treatment within 24 hours is key, as it is for detecting and containing dracunculiasis.

Box 2. **Criteria for effective use of local volunteers**

1. **Diagnosis** by the trained volunteer must generally be as accurate as that by a physician.
2. **Correct action** by the trained volunteer must positively and clearly affect the clinical outcome.
3. **The event** must initially not be so rare that individual volunteers are unlikely to experience it or so frequent as to require almost full-time activity.
4. **A functioning system** must provide annual re-training, regular supervision, monthly collection and analysis of data, timely re-supply of materials and feedback on progress achieved compared with that in other districts, regions and countries (see Box 1).
5. **The issue must be important** to people of the community, e.g. carry a high risk of death, disability or suffering that "all" would wish to avoid.

All five criteria must arguably be met before it is ethically acceptable to ask individuals in impoverished communities to volunteer time that could otherwise be spent striving to sustain themselves and their families.

Recent disease eradication efforts under the most difficult of circumstances have demonstrated how successful a catalytic approach to public health can be. It seems to be time to use tools from disease eradication programmes in some focused community-based efforts, to address carefully selected non-eradicable diseases.

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Availability of miltefosine for the treatment of kala-azar in India

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Miltefosine, an alkylphospholipid, was registered in India for the treatment of visceral leishmaniasis (kala-azar) in 2002. The identification of miltefosine was an important therapeutic advance because it is the first effective oral agent for treating kala-azar, including infection that is resistant to conventional therapy with pentavalent antimony (*1*, *2*), and it has opened the door to outpatient management. However, these clinical advances are being undermined and action is required.

India carries approximately 50% of the world's burden of kala-azar. Ninety per cent of cases of kala-azar in India occur in people living in poverty in rural Bihar State where daily family income is approximately US$ 1; infection there remains epidemic and transmission (anthroponotic) is high (*1–4*). Bihar is also the only endemic region where large-scale resistance, probably the result of years of suboptimal treatment (*4*), has ended the usefulness of antimony treatment (*4*). Thus, approximately 45% of the world's kala-azar patients are in a precarious position.

In Bihar, most patients with kala-azar are expected to purchase the treatment drug themselves. The cost of miltefosine, initially US$ 200 per 28-day course of treatment and now US$ 145, has predictably either prevented access for many impoverished patients, or encouraged purchase of small supplies of the drug — often just enough treatment to allow the patient to begin to feel better and return to work or school. That individuals can buy as much of the drug as they can afford reflects the Indian system of drug dispensing — miltefosine is now widely available over the counter without prescription or restriction on the quantity dispensed.

Regulatory authorities must act now to end the above-mentioned practices and firmly regulate this critically important antileishmanial drug. Miltefosine should be prescribed only by qualified physicians, experienced in kala-azar management, after a proper diagnosis has been established, and it should be provided in a controlled manner at government-designated outlets. A form of directly observed therapy, similar to that already well-established in India for tuberculosis, could be instituted rapidly, ideally with government-purchased miltefosine. The need for this type of logical mechanism is underscored by the experience at one centre in Bihar which enrolled 367 of 1167 participants in India's first outpatient miltefosine trial. Despite monitoring adherence and distributing 1 week's supply of medication at a time for 4 weeks, 10 patients discontinued their treatment early or were lost to follow-up and 23 (6%) apparent responders subsequently relapsed — yielding a 92% cure rate at this centre

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(S. Sundar, unpublished data). If this 8% overall failure rate is confirmed in the final study analysis, it would represent a disturbing doubling of the 3% failure rate observed in the strictly-monitored, phase 3 study in inpatients (*1*). This situation also underscores the need to develop strategies for using miltefosine in combination with other drugs to reduce the likelihood of developing resistance.

Consideration of the already voiced concerns about the potential development of resistance to miltefosine (*5*) and the experience with, and loss of usefulness of, pentavalent antimony in Bihar (*4*), shows that unrestricted use of miltefosine needs to end. Although not a simple undertaking, we believe that now is the time to pull back and provide miltefosine through a strictly supervised public distribution system, free of charge in accordance with the prevailing national policy on the treatment of visceral leishmaniasis, lest the only oral (and therefore precious) antileishmanial drug becomes another therapeutic relic in India. ■

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