Polio eradication scheme suffers summer setback

It was a dispiriting summer for Rotary club volunteers in the southern Indian states of Karnataka and Andhra Pradesh, where a recent polio outbreak has saddled the organization with the challenge of intensifying an already considerable grassroots immunization campaign.

India is one of only seven countries in the world where polio is still endemic—and perhaps the most troublesome. Last year, the nation recorded nearly 1,600 cases—a sixfold increase over the previous two years, representing 85% of cases worldwide. Concentrated immunization efforts in the northern states of Uttar Pradesh and Bihar have reduced India's total cases this year to 115, with record-setting lows for the season of high transmission.

But Karnataka and neighboring Andhra Pradesh, which had been polio-free since 2000, recorded 16 cases between July and early September.

In Bangalore, where 2,000 members from 37 Rotary clubs participate in polio eradication efforts, news of the virus's resurgence has prompted a reassessment of the tactics that had taken more than a decade to refine.

"I'm worried; I'm very worried, because even one case means we have a desperate situation," says Prasad Sundaram, assistant district director of the Bangalore Rotary. One recent planning session was marked by finger-pointing, Sundaram adds, with Rotarians asking, "How could this happen? Who let whom down?"

Rotary Bangalore

A drop in the bucket: Rotary volunteer Prassad Sundaram immunizes a young child in India.

The Global Polio Eradication Initiative, a partnership between the World Health Organization (WHO), Rotary International and the US Centers for Disease Control and Prevention, this year refocused its strategy, with the goal of worldwide eradication by 2005. The initiative is moving US$35 million and 297 million additional doses of oral polio vaccine (OPV) to all polio-endemic countries and to another seven countries at risk from the virus.

But whether that money will trickle down to the local level—where volunteers drop OPV into the mouths of the 170 million Indian children under the age of five—remains unclear.

Rotary clubs in India still receive Rs 4,000 (approximately US$87) from their national council to coordinate the two national immunization days (NIDs) scheduled for early next year. Sundaram says his club raises and spends more than Rs 50,000 per NID. They are now scrambling for additional funds to rent billboards across Bangalore—at a cost of Rs 1.5 million—to urge parents to immunize their children.

During the NIDs, volunteers mark immunized children on the cuticles, then comb the city and outlying villages for untagged children. They chalk the doors of the thousands of houses they have visited. Full immunization requires five OPV doses during a child's first 1.5 years, supplemented during NIDs with at least 10 doses through age five.

Given India's birth cohort of nearly 28 million children per year, any lapses in routine immunization can cause significant setbacks, says Louise Baker of the WHO's Southeast Asia office in New Delhi. With some two million children born between immunization days, disenfranchised or geographically isolated areas can quickly become hotbeds of transmission.

According to P. Narayana, vice chairman for Rotary India's national PolioPlus committee, a study commissioned after the virus's resurgence found that less than 70% of the children—considerably less than the 98% the organizers believed they had reached—in some southern districts had been immunized during the past year

"People have become apathetic," says Narayana. "Some here got the impression that [the NIDs are] good enough, but the newborn children are not adequately protected."

Bruce Diamond, Bangalore

Cancer patients sue for access to experimental drugs

A cancer advocacy group has filed a lawsuit against the US Food and Drug Administration (FDA) in a bid to get experimental cancer drugs into the hands of patients who have exhausted approved treatments.

The Virginia-based Abigail Alliance for Better Access to Developmental Drugs—with mixed support from other advocacy groups—filed the suit on the grounds that current regulatory policies violate patient rights to privacy and liberty. The group charges that end-stage cancer patients should, in consultation with their doctors, be able to try unapproved drugs, particularly in light of the FDA's lengthy drug approval process. The agency declined to comment on the lawsuit but has 60 days to respond.

"Despite good communications with the FDA for a long time, nothing was changing," says Frank Burroughs, the Alliance's founder. "Every day delayed is thousands of lives lost." Burroughs named the group after his 21-year-old daughter, who died of cancer two years ago. Before her death, Abigail Burroughs tried, and failed, to get the experimental drugs Erbitux and Iressa, now touted as wonder drugs for cancer.

Alliance members say that investigational drugs are often the last hope for the terminally ill. But under FDA rules, only a fraction of patients can access them, either by participating in clinical trials or through expanded access and 'compassionate use' programs, in which pharmaceutical companies provide a small number of patients with free experimental drugs. Only 3% of all cancer patients participate in clinical trials, however.

Cancer patients in the UK face similar problems because the UK Medical Research Council's drug approval process is at least as slow as the FDA's, says Renee Watson, policy and program coordinator at the UK's government-backed National Translational Cancer Research Network. What's worse, Watson says, is that the country has no tradition of patient advocacy, so patient needs often go unheard.

The Alliance is calling for various policy changes, including allowing companies to market—on a limited basis—drugs that demonstrate safety in phase 1 and 2 trials, while also pursuing accelerated drug approvals. Only terminally ill patients who are denied a place in clinical trials and are beyond other treatments would be eligible to buy the drugs.

But critics of the plan say that in pushing for accelerated drug approvals, advocacy groups may inadvertently lower standards for drug safety and efficacy. The National Breast Cancer Coalition has also argued that early access to experimental medicines raises false hopes among patients because, on average, the FDA approves only one out of five investigational drugs.

Paroma Basu, New York