

EMBARGO: 00:01H (UK time) Friday July 13, 2007. In North America the embargo lifts at 18:30 (EST) Thursday July 12, 2007

## Protective efficacy of a monovalent oral type 1 poliovirus vaccine

We are shocked and dismayed that *The Lancet* should have published the paper on the protective efficacy of monovalent oral type 1 poliovirus vaccine by Nicholas Grassly and colleagues (April 21, p 1356),<sup>1</sup> having overlooked the serious ethical issues involved.

The article describes how the international oversight body on polio eradication recommended the rapid development, licensing, and introduction of a new monovalent type 1 oral vaccine for India. WHO (and its organ, the National Polio Surveillance Project [NPSP], from where some of the authorship of this article was drawn) was party to this accelerated introduction of the new vaccine in the country. What was introduced, according to this article, was a new vaccine that was five times more potent than previous vaccines, presumably also with increased likelihood of adverse effects. No informed consent was taken, nor was the public told that the vaccine was experimental. Efforts were made to give the impression that the monovalent vaccine was not new but was just the monovalent vaccine used in the 1960s, before the introduction of the trivalent vaccine.<sup>2</sup>

The oversight body that introduced this experimental vaccine should also have monitored adverse effects. Now that same body has published a paper without ethics approval on the grounds that it was not a prospective intervention study.

In the absence of proper postvaccination surveillance of adverse effects we have to rely on indirect evidence of possible adverse effects available from the NPSP.<sup>3</sup> Data from Uttar Pradesh (where Grassly and colleagues show improved vaccine efficacy) show an increase in the incidence of non-polio acute flaccid paralysis since

the introduction of the monovalent vaccine.<sup>3</sup>

We declare that we have no conflict of interest.

\*Jacob Puliyel, C Sathyamala, D Banerji  
puliyel@vsnl.com

St Stephens Hospital, Delhi 110054, India (JP); Public Report on Health, Council for Social Development, 53 Lodhi Estate, New Delhi, India (CS); and Centre for Social Medicine and Community Health, Jawaharlal Nehru University, New Delhi, India (DB)

- 1 Grassly NC, Wenger J, Durrani S, et al. Protective efficacy of a monovalent oral type 1 poliovirus vaccine: a case-control study. *Lancet* 2007; **369**: 1356–62.
- 2 Chatterjee A, Chawla A. Monovalent polio immunisation—a strategy for India. *J Ind Med Assoc* 2005; **103**: 682–85.
- 3 Government of India/National Polio Surveillance Project. AFP surveillance bulletin—India. <http://www.npsindia.org/bulletin.pdf> (accessed June 18, 2007).

Nicholas Grassly and colleagues<sup>1</sup> conclude that monovalent oral polio vaccine is about three times more efficacious than trivalent oral polio vaccine in the northern Indian state of Uttar Pradesh.

Their hypothesis was that a “high prevalence of diarrhoea and other infections in areas of high population density and poor sanitation has led to very low efficacy of trivalent oral polio vaccine”. That is probably the reason polio could not be eradicated from these areas and hence the need to look for alternatives.

Grassly and colleagues conclude that “the increased efficacy [of the monovalent vaccine] is probably caused by the absence of interference between the three Sabin vaccine strains.” However, if the interference is between the three strains of poliovirus, then this hypothesis is probably not relevant and the conclusion applicable wherever trivalent vaccine is used. Can Grassly and colleagues kindly explain the apparent contradiction between the hypothesis—the *raison d’être* for the study—and the conclusion?

If the hypothesis is true, would it not be better to use inactivated vaccine at this stage of polio eradi-

cation in this limited area, which would do away with the problem of interference with other infections and diarrhoea altogether? Wouldn't that be a more cost-effective option than experimenting with oral vaccines?

I declare that I have no conflict of interest.

Paul T Francis  
paultfrancis@aims.amrita.edu

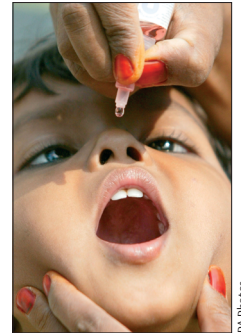
Amrita School of Medicine, Cochin, Kerala 682026, India

- 1 Grassly NC, Wenger J, Durrani S, et al. Protective efficacy of a monovalent oral type 1 poliovirus vaccine: a case-control study. *Lancet* 2007; **369**: 1356–62.

### Authors' reply

Jacob Puliyel and colleagues highlight the importance of ensuring appropriate ethical standards are adhered to in the course of scientific studies. In our study of the field efficacy of monovalent oral type 1 poliovirus vaccine (mOPV1), we analysed existing surveillance data from acute flaccid paralysis (AFP) cases collected since 1997. The vaccines assessed were licensed for administration in India by the national regulatory authority, the Drugs Controller General of India. The mOPV1 formulation assessed in our study has been used since mid-2005 by the Government of India, and now in over 20 countries around the world. The absence of interference from types 2 and 3, particularly type 2, seems to be the reason for the three-fold greater efficacy per dose of mOPV1 against paralysis from type 1 wild poliovirus compared with trivalent vaccine in northern India.

To clarify the background to the increase in cases of AFP in recent years noted by Puliyel and colleagues, this is the result of a deliberate effort that began in 2004 to intensify surveillance and reporting as India pushes to eradicate polio. The increase in AFP cases began before mOPV1 was introduced, and occurred across India, including states where mOPV1 has not been used. The introduction of mOPV1 is not, therefore,



PA Photos

Submissions should be made via our electronic submission system at <http://ees.elsevier.com/thelancet/>

the cause of the increase in cases of AFP. The National Polio Surveillance Project continues to monitor cases of vaccine-associated paralytic poliomyelitis (VAPP), which typically occur at a rate of two to four cases per million birth cohort immunised with trivalent oral poliovirus vaccine.<sup>1</sup> The postmarketing surveillance of mOPV1 that was implemented as part of its licensing has not detected any increase in the proportion of AFP cases with VAPP in areas where this vaccine has been used.

That the efficacy of mOPV1 is still lower in northern India than in high-income countries seems to be mainly due to the fact that the efficacy of oral poliovirus vaccines is reduced in children with diarrhoea or other infections.<sup>2,3</sup> Contrary to the suggestion of Paul Francis, removing the problem of interference between vaccine virus strains does not address this problem of diarrhoea or other infections. Francis also suggests the use of inactivated poliovirus vaccine (IPV) in limited areas of India. Although successful immunisation with IPV would protect children against paralytic poliomyelitis, children immunised solely with IPV are much more likely to transmit poliovirus than those immunised with oral poliovirus vaccine (OPV)—as evidenced by challenge studies, which show a significantly lower effect of IPV on faecal excretion than OPV.<sup>4,5</sup> Therefore the effect of IPV on transmission of wild poliovirus can be expected to be substantially less than that of OPV, particularly in settings where faecal-oral transmission is important, such as northern India.

That said, if a decision were made to add IPV as a supplement to immunisation with OPV, and if high coverage could be achieved, IPV could potentially boost immunity and might reduce the number of paralysed children while eradication campaigns are intensified in the limited remaining poliovirus reservoir areas of northern India. Recognising this, the Government of India is planning a seroprevalence survey to assess the immunity of young children in western Uttar Pradesh. If deemed appropriate, this will be followed by a pilot study to determine whether sufficiently high coverage could be achieved with a supplemental dose of IPV in western Uttar Pradesh to effectively improve population immunity.

We declare that we have no conflict of interest.

\*Nicholas C Grassly, Jay Wenger, Sunil Bahl, Roland W Sutter, R Bruce Aylward  
n.grassly@imperial.ac.uk

Department of Infectious Disease Epidemiology, Imperial College London, Norfolk Place, London W2 1PG, UK (NCG); National Polio Surveillance Project, WHO, Nas Delhi, India (JW, SB); and Global Polio Eradication Initiative, WHO, Geneva, Switzerland (RWS, RBA)

- 1 Kohler KA, Banerjee K, Hlady WG, Andrus JK, Sutter RW. Vaccine-associated paralytic poliomyelitis in India during 1999: decreased risk despite massive use of oral polio vaccine. *Bull WHO* 2002; **80**: 210–16.
- 2 World Health Organization Collaborative Study Group on Oral Poliovirus Vaccine. Factors affecting the immunogenicity of oral poliovirus vaccine—a prospective evaluation in Brazil and the Gambia. *J Infect Dis* 1995; **171**: 1097–106.
- 3 Posey DL, Linkins RW, Oliveria MJC, Monteiro D, Patriarca PA. The effect of diarrhea on oral poliovirus vaccine failure in Brazil. *J Infect Dis* 1997; **175**: S258–63.
- 4 Ghendon Y, Robertson SE. Interrupting the transmission of wild polioviruses with vaccines: immunological considerations. *Bull World Health Organ* 1994; **72**: 973–83.
- 5 Galindo M, Lago PM, Caceres V, et al. Randomized, placebo-controlled trial of inactivated poliovirus vaccine in Cuba. *N Engl J Med* 2007; **356**: 1536–44.

## Surveillance of acute flaccid paralysis in India

The Comment by Paul Francis (April 21, p 1322)<sup>1</sup> is based on a misunderstanding of poliomyelitis surveillance methods, and particularly the definition of “poliomyelitis-compatible” cases. Francis assumes that compatible cases are true cases and uses them to inflate the number of polio cases in India. He further suggests that standard surveillance methods and interpretation of

compatible cases have contributed to persistence of poliovirus transmission in India.

In fact, poliomyelitis-compatible cases are those from whom adequate specimens were not collected for laboratory assessment. In India, if the expert committee cannot rule out poliomyelitis, the case is considered compatible. The purpose of this classification is “to indicate the failure of a surveillance system to collect adequate specimens... and to ensure that an area... remains under close observation”.<sup>2</sup> Poliomyelitis compatibles are thus not to be equated with poliomyelitis cases, but serve a programmatic function identifying areas that need to improve surveillance.

Poliovirus persists in India not because virus transmission was missed through slipshod surveillance, but because of challenges eliminating the virus in areas in which it is known to exist.<sup>3</sup> Francis erroneously concludes that continued polio transmission in India is linked to surveillance failure and that introduction of a new surveillance “quality indicator” based on compatible cases will help address the issue. The risk of these assertions lies in the diversion of attention from the real challenges of polio eradication—protection of children through immunisation—to surveillance, which, in India, is operating at a higher level of sensitivity than in any other country in Asia.

We declare that we have no conflict of interest.

Sunil Bahl, Madhav Ram, Sunita Durrani, \*Jay Wenger  
wengerj@npsuindia.org

National Polio Surveillance Project/World Health Organization, New Delhi 110029, India

- 1 Francis PT. Surveillance of acute flaccid paralysis in India. *Lancet* 2007; **369**: 1322–23.
- 2 WHO. Acute flaccid paralysis (AFP) surveillance: the surveillance strategy for poliomyelitis eradication. *Wkly Epidemiol Rec* 1998; **73**: 113–14.
- 3 Grassly NC, Fraser C, Wenger J, et al. New strategies for the elimination of polio from India. *Science* 2006; **314**: 1150–53.

### Author's reply

Contrary to Sunil Bahl and colleagues' contention, I did not suggest that confirmed cases of polio and polio-compatible cases were the same thing.

Poliomyelitis cases are confirmed only when poliovirus is identified in the stools of a patient with acute flaccid paralysis (AFP). However, it is impossible to collect stool samples from all such patients, which satisfy the stringent conditions to be labelled as adequate. When an AFP patient without an adequate stool sample has residual paralysis beyond 60 days from the date of onset, detailed clinical, laboratory, and epidemiological investigations are done, and the evidence is submitted to the National Expert Review Committee. The committee sifts through the available evidence and diagnoses any poliomyelitis cases; these are classified as "polio-compatible" cases (figure).

One of the essential criteria for certification of polio-free status is that the rate of collection of adequate stools should be 80%, since at least 80% of polio cases have to be "confirmed". However, we must not ignore the potential polio cases we

cannot confirm, hence this second-best method of identifying them. Nevertheless, polio-compatible cases are kept as a separate category from confirmed polio cases. When we are into the business of polio eradication we are interested in polio and nothing else.

In terms of the performance of the surveillance system in India, Kohler and colleagues<sup>1</sup> found that "as a result [of measures taken to improve surveillance] the proportion of compatible cases was lower in 2001 than in 2000". This shows a realisation early on that there is a need to reduce the number of compatible cases. Since AFP surveillance is an important strategy to eradicate polio, surveillance quality will affect the eradication process. India has made great progress towards polio eradication and the National Polio Surveillance Project has been doing excellent AFP surveillance. However, delay in achieving the goal of eradication compels us to look beyond what is known, and this anomaly of more than 20% of polio cases being "compatible" should be addressed.

I declare that I have no conflict of interest.

Paul T Francis

paultfrancis@aims.amrita.edu

Amrita School of Medicine, Cochin, Kerala 682026, India

- 1 Kohler KA, Hlady GW, Banerjee K, et al. Compatible poliomyelitis cases in India during 2000. *Bull World Health Organ* 2003; **81**: 2–9.

### Eradication versus control for poliomyelitis

Two articles (April 21, pp 1321 and 1356)<sup>1,2</sup> have highlighted the need to sustain high levels of immunisation for the eradication of wild poliovirus. However, data on health systems indicators for the Indian states of Uttar Pradesh and Bihar<sup>3,4</sup> raise questions about whether the singular focus on efficacious vaccines will be able to overcome the weaknesses in the health services in these two states.

Both Uttar Pradesh and Bihar were unable to report (as of September, 2005, the year before a polio outbreak), the number of primary-health centres (PHCs) without a doctor. In Uttar Pradesh, 25% of auxiliary nurse-midwife positions and 72% of health-worker positions were vacant.<sup>3</sup> Although only 5% of PHCs in Uttar Pradesh were reportedly without an electricity supply, 75% of subcentres were without electricity, 59% were without a regular water supply, and 56% did not have motorable roads. In a state that is notoriously power-deficient, pulse polio immunisation rounds were done in the month of April, when average temperatures are around 40°C.

In Uttar Pradesh and Bihar, 23.8% and 18.6% of deliveries are institutional, and only 20% and 31% of infants are fully immunised.<sup>4</sup> Although 80% of children report having had three doses of oral polio vaccine, the timeliness of the doses being given becomes questionable, since only 27.8% and 45.2% of rural children in these two states complete routine immunisation with three doses of triple antigen.

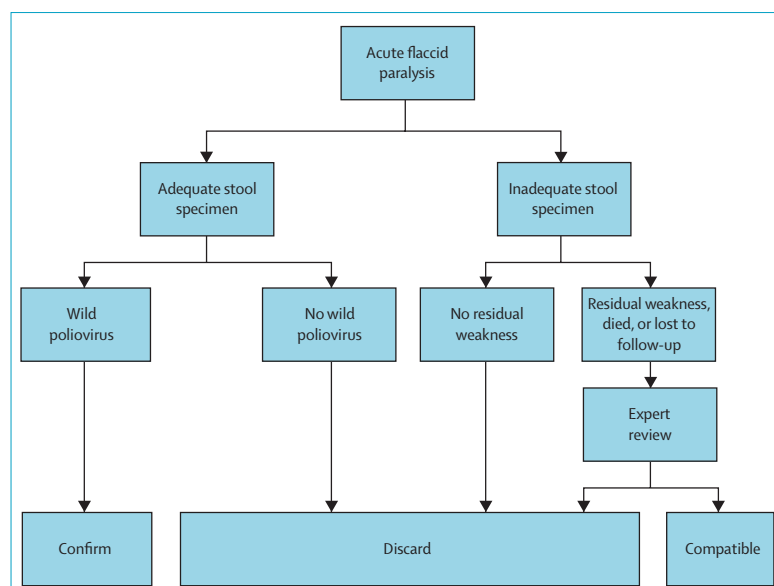


Figure: Virological classification scheme

Source: National Polio Surveillance Project website (<http://www.npsindia.org>).



PA Photos

Cost-benefit studies<sup>2</sup> that favour eradication through a concentrated vaccination effort should examine the larger picture. This should include an assessment of the consequent effects of targeted polio eradication activities on health and health systems in poor countries.

I declare that I have no conflict of interest.

Anita Kar

akar@unipune.ernet.in

Interdisciplinary School of Health Sciences,  
University of Pune, Pune 411007, India

- 1 Thompson KM, Duintjer Tebbens RJ. Eradication versus control for poliomyelitis: an economic analysis. *Lancet* 2007; **369**: 1363–71.
- 2 Grassly NC, Wenger J, Durrani S, et al. Protective efficacy of a monovalent oral type 1 poliovirus vaccine: a case-control study. *Lancet* 2007; **369**: 1356–62.
- 3 Ministry of Health and Family Welfare. Bulletin on rural health statistics in India 2006. [http://mohfw.nic.in/dofw%20website/Bulletin%20on%20RHS%20-%2006%20-%20PDF%20Files/bulletin\\_on\\_rural\\_health\\_statistics.htm](http://mohfw.nic.in/dofw%20website/Bulletin%20on%20RHS%20-%2006%20-%20PDF%20Files/bulletin_on_rural_health_statistics.htm) (accessed April 29, 2007).
- 4 International Institute for Population Sciences. National family health survey, India. <http://www.nfhsindia.org/factsheet.html> (accessed April 29, 2007).

The extensive economic analysis by Kimberly Thompson and Radboud Duintjer Tebbens<sup>1</sup> plausibly favours polio eradication; however, the expenditure assumptions seem provincial, ignoring grass-roots logic.

Unlike smallpox eradication, a “magic bullet” approach (vaccination alone) is unlikely to yield a solution for polio, which is more of a sanitation problem. Poliovirus is known to resurface after two decades of environmental dormancy and the oral vaccine can eventually give rise to vaccine-derived viral infection.<sup>2</sup> Again, in the real world, foreign investment soon slips into the “donor fatigue” phase and the recipient (developing nation) eventually gets pulled into a debt trap.<sup>3</sup> Furthermore, the lack of political commitment and waning motivation of community health workers make a unique set of financial impediments in a country such as India.<sup>3</sup>

The proposed eradication strategy would imply even greater costs than

already assumed in the analysis because of its collateral effect on the existing routine vaccination infrastructure,<sup>4</sup> and thus its adverse consequences on other preventable diseases which cause more deaths than polio.

In a country with high rates of malnutrition and diarrhoeal diseases, and low rates of routine immunisation (90% of infants in Bihar and 81% in Uttar Pradesh are not fully immunised),<sup>5</sup> an integrated approach taking into account strategies such as strengthening ongoing routine immunisation, and improving nutrition, safe water, and sanitation could justify the economically escalated strategy proposed by Thompson and Tebbens.

We declare that we have no conflict of interest.

Nishith K Singh, \*Vineet Gupta,  
Vikas K Singh

Vineet\_gsvm@yahoo.com

Division of Internal Medicine, Southern Illinois University School of Medicine, 701 N First Street, Springfield, IL, USA (NKS); Division of Emergency Medicine, All India Institute of Medical Sciences, New Delhi 110029, India (VG); and Department of Emergency Medicine, Vardhman Mahaveer Medical College and Safdarjung Hospital, New Delhi, India (VKS)

- 1 Thompson KM, Duintjer Tebbens RJ. Eradication versus control for poliomyelitis: an economic analysis. *Lancet* 2007; **369**: 1363–71.
- 2 Puliye JM, Gupta MA, Mathew JL. Polio eradication and the future for other programmes: situation analysis for strategic planning in India. *Indian J Med Res* 2007; **125**: 1–4.
- 3 Mittal SK, Mathew JL. Polio eradication in India: The way forward. *Indian J Pediatr* 2007; **74**: 153–60.
- 4 India universal immunization programme review. [http://www.whoindia.org/LinkFiles/Routine\\_Immunization\\_Acknowledgements\\_contents.pdf](http://www.whoindia.org/LinkFiles/Routine_Immunization_Acknowledgements_contents.pdf) (accessed April 30, 2007).
- 5 WHO. WHO strategic plan for strengthening routine immunization in India. April 2004–March 2007. [http://www.whoindia.org/LinkFiles/Routine\\_Immunization\\_Strategic-Plan-RIM-2004.pdf](http://www.whoindia.org/LinkFiles/Routine_Immunization_Strategic-Plan-RIM-2004.pdf) (accessed April 30, 2007).

Kimberly Thompson and Radboud Duintjer Tebbens<sup>1</sup> model the economic and health effects of strategies for poliomyelitis eradication and control. They conclude that eradication (defined as the interruption of wild poliovirus

transmission globally) is less costly and more effective than control.

Thompson and Radboud previously estimated a 50–100% chance of a poliomyelitis outbreak within 20 years of eradication and oral polio vaccine cessation.<sup>2</sup> Sustained eradication is not achievable without continued vaccination. As Paul Fine and Ulla Griffiths correctly note in their accompanying Comment,<sup>3</sup> use of live vaccine to control future outbreaks is fighting fire with fire. To leave future birth cohorts unprotected would be irresponsible given the acknowledged chance for future infections, possibly at older ages when there is an increased rate of paralytic poliomyelitis per infection.

Any discussion of the economic cost of polio eradication should include a transparent and pragmatic assessment of the posteradication options from the outset.<sup>4</sup> A realistic estimate of the cost of sustainable poliomyelitis eradication must include the cost of continued vaccination—about US\$3–6 billion every 20 years for low-income countries only,<sup>1</sup> in line with other estimates of \$20–24 billion for the entire world.<sup>5</sup> Claimed funding shortfalls for the Global Polio Eradication Initiative (GPEI) of \$575 million are therefore illusory.

Semantic redefinitions of polio eradication might serve political goals and promises but should not come at the jeopardy of poor countries that look for public-health guidance. GPEI can celebrate the striking reductions in poliomyelitis. Failure to ensure long-term protection by not accounting for the continued need for vaccination would risk greater incidence and be negligent.

We declare that we have no conflict of interest.

Katherine Sturm-Ramirez,  
\*Mark A Miller  
millermark@nih.gov

National Institutes of Health, Bethesda, MD 20892, USA

- 1 Thompson KM, Duintjer Tebbens RJ. Eradication versus control for poliomyelitis: an economic analysis. *Lancet* 2007; **369**: 1363–71.
- 2 Tebbens RJ, Pallansch MA, Kew OM, et al. Risks of paralytic disease due to wild or vaccine-derived poliovirus after eradication. *Risk Anal* 2006; **26**: 1471–505.
- 3 Fine PE, Griffiths UK. Global poliomyelitis eradication: status and implications. *Lancet* 2007; **369**: 1321–22.
- 4 Miller M, Barrett S, Henderson DA. Control and eradication. In: Jamison DT, Breman JG, Measham AR, et al, eds. *Disease control priorities in developing countries*, 2nd edn. New York/Washington: Oxford University Press/World Bank, 2006: 1163–76.
- 5 Sangrujee N, Caceres VM, Cochi SL. Cost analysis of post-polio certification immunization policies. *Bull World Health Organ* 2004; **82**: 9–15.

### Authors' reply

We agree with Anita Kar that cost-benefit studies related to eradication versus control should examine the larger picture, and we believe that our study represents the most extensive effort to date to do so. We focused part of our study on Uttar Pradesh and Bihar because they present large challenges. Our results suggest that, in the absence of targeted eradication activities (ie, under a policy of control relying only on routine vaccination through the weak health services in these two states), cases of paralytic poliomyelitis could rapidly resurge to large numbers in those areas and beyond. We suggest that the solution to the weak health system in areas of poverty is not acceptance, but greater investment to achieve significant and cost-effective improvements.

Nishith Singh and colleagues raise important issues related to rethinking strategies for poliomyelitis. Although they suggest that polio represents a "sanitation problem" (by pointing to an Albanian outbreak that resulted from importation<sup>1,2</sup>), environmental dormancy and non-human reservoirs are not issues.<sup>3</sup> Our study emphasises that eradication requires simultaneous elimination of wild polioviruses everywhere, which would prevent future wild poliovirus importation outbreaks that might otherwise be (mis)perceived as environmental.

We appreciate the opportunities to strengthen routine immunisation and provide additional beneficial interventions, and we emphasise that eradication of wild polioviruses seems to offer the best deal from both a humanitarian and economic perspective. Focusing on short-term opportunity costs associated with completing eradication should be weighed against the opportunity costs of forever paying the financial costs of control and human costs of cases that could have been prevented, which will continue to burden the system.

Finally, we agree with Katherine Sturm-Ramirez and Mark Miller that the economic costs of polio eradication should include transparent and pragmatic assessment of post-eradication options. We explicitly included the costs and risks of four post-eradication options in our study, but we do not presume as they suggest that global and national health leaders will uniformly choose to continue vaccination in perpetuity after eradication, particularly given the reality of vaccine-derived polioviruses causing outbreaks in areas with low oral polio vaccine (OPV) coverage,<sup>4</sup> the relatively high costs of inactivated vaccine (IPV), which posed a challenge from an economic perspective even in high-income countries,<sup>5</sup> and the low risk of emergence of new circulating vaccine-derived polioviruses 3 or more years after OPV cessation.

However, even with IPV vaccination after eradication, our analysis suggests net benefits of polio eradication versus control forever. We believe the goal of the Global Polio Eradication Initiative has always been to eradicate wild polioviruses and that this remains a goal that dominates the alternatives. We previously characterised the probability of at least one post-eradication outbreak (defined as at least one paralytic case),<sup>4</sup> considering the real risks that exist as a function of the policy options for managing

polioviruses into the future (including continued OPV use). This exercise led us to emphasise the need for global health authorities to have adequate response strategies in place.

We declare that we have no conflict of interest.

\**Kimberly M Thompson,  
Radboud J Duintjer Tebbens  
kimt@hsph.harvard.edu*

Harvard School of Public Health, Boston, MA 02115, USA

- 1 Prevots DR, Ciofi degli Atti ML, Sallabanda A, et al. Outbreak of paralytic poliomyelitis in Albania, 1996: high attack rate among adults and apparent interruption of transmission following nationwide mass vaccination. *Clin Infect Dis* 1998; **26**: 419–25.
- 2 Fiore L, Genovese D, Diamanti E, et al. Antigenic and molecular characterization of wild type 1 poliovirus causing outbreaks of poliomyelitis in Albania and neighboring countries in 1996. *J Clin Microbiol* 1998; **36**: 1912–18.
- 3 Dowdle WR, Birmingham ME. The biologic principles of poliovirus eradication. *J Infect Dis* 1997; **175** (suppl 1): S286–92.
- 4 Duintjer Tebbens RJ, Pallansch MA, Kew OM, et al. Risks of paralytic disease due to wild or vaccine-derived poliovirus after eradication. *Risk Analysis* 2006; **26**: 1471–505.
- 5 Miller MA, Sutter RW, Strebel PM, Hadler SC. Cost-effectiveness of incorporating inactivated poliovirus vaccine into the routine childhood immunization schedule. *J Am Med Assoc* 1996; **276**: 967–71.

### Bans on smoking in public places: policy enforcement needed

Passing laws to ban smoking in public places is a vital step towards a smoke-free Europe. As noted by Laura Spinney (May 5, p 1507),<sup>1</sup> the decision by the members of European parliament to scrap laws to make their workplace smoke-free creates great concern about the implementation of these much needed measures in Europe, and especially in Greece, which is the country stigmatised as Europe's reigning champion in adult-smoking prevalence.<sup>2</sup>

Smoke-free environments in Greece are scarce. Despite existent legislation that forbids smoking in all educational institutes, environmental tobacco smoke is evident in establishments

See [Comment](#) page 110



Getty Images

from primary schools to university campuses, mainly because of the non-compliance of teachers, staff, and students. Even health-care services are not always smoke-free, despite being declared to be so since 2002.<sup>3</sup> Medical doctors and nursing staff can be noticed smoking in rest rooms and corridors, posing an obvious threat to their patients' fragile health; some pharmacists provide medication over the counter while puffing on cigarettes. One need not ponder over compliance in designated smoke-free areas in hospitality venues, since, as stated previously,<sup>4</sup> compliance with such legislation in Greece is completely non-existent.

Passing laws banning smoking in public places is one matter, but as painfully seen in Greece, enforcing it is another. Declaring the environment smoke-free without proper control mechanisms that will actually deal with violators will lead to implementation of the law merely on paper and not in practice. A total ban on smoking in public places in Greece will also be openly disregarded unless feasible means of regulation are adopted and strictly complied with. Considering Greece's current situation, it is becoming apparent that the missing link in Europe's evolution from a smoky past to a smoke-free future is effective policy enforcement.

We declare that we have no conflict of interest.

*C I Vardavas, \*A G Kafatos*  
**kafatos@med.uoc.gr**

Preventive Medicine and Nutrition Unit, Faculty of Medicine, University of Crete, PO Box 2208, 71003, Crete, Greece

- 1 Spinney L. Public smoking bans show signs of success in Europe. *Lancet* 2007; **369**: 1507–508.
- 2 WHO. European country profiles on tobacco control, 2003. [http://www.euro.who.int/InformationSources/Publications/Catalogue/20050114\\_3](http://www.euro.who.int/InformationSources/Publications/Catalogue/20050114_3) (accessed June 21, 2007).
- 3 Health Law 76017. Legislation Newspaper of the Government of the Hellenic Democracy. 2002; **2**: 1001
- 4 Vardavas CI, Kafatos AG. Smoking policy in Greece: another myth? *Lancet* 2006; **367**: 1485–86.

## Tobacco control efforts: where is India now?

70% of the billion or so tobacco-related deaths expected by 2025 will occur in developing countries.<sup>1</sup> Such staggering figures could have a profound effect on the global economy.

India is the second largest producer and consumer of tobacco products worldwide,<sup>2</sup> but it has taken great strides to be recognised as a global player in the fight against the tobacco epidemic. The recent legislation to ban smoking while driving vehicles in the national capital, New Delhi, is a landmark verdict.<sup>3</sup> No doubt compliance and enforcement will be a challenge, but the motivation and the seriousness of perceiving the dangers of second-hand smoke exposure are crucial.

India's role in pushing forward WHO's Framework Convention on Tobacco Control (FCTC) is well known. Such an effort honoured the Indian Health Ministry with the prestigious Luther Terry Award in Washington, DC, USA, in 2006. What is even more heartening is India's successful bid to host the 14th World Tobacco Conference in the commercial capital, Mumbai, in February, 2009.<sup>4</sup> The organisers of this event cannot wait to see their dreams coming true as Mumbai is declared "smoke-free".

India's tobacco use is complex. Most consume smokeless tobacco products, which are socially acceptable and therefore difficult to "denormalise". 40% smoke bidis,<sup>5</sup> the small, often flavoured cigarettes, that are still non-taxable, and whose production is considered to be the "lifeline" of thousands of hungry stomachs. 40% of physicians continue to smoke. Urban youngsters are lured into smoking because of tobacco companies' dubious product innovations and glamorous media campaigns. The Bollywood film industry is also a powerful influence.

70% of India's population lives in rural areas where illiteracy is high.

Full implementation of the FCTC principles will make smoking history in India, but are rich and powerful nations doing enough to support such a movement?

We declare that we have no conflict of interest.

*\*Zubair Kabir, Luke Clancy,*  
*Gregory N Connolly*  
**zkabir@hsph.harvard.edu**

Harvard School of Public Health, 401 Park Drive, Landmark Center, 3rd Floor (East), Boston, MA 02215, USA (ZK, GNC); and Research Institute for a Tobacco Free Society, Dublin, Ireland (ZK, LC).

- 1 Stewart BW, Kleihues P. World cancer report. Lyon: IARC, 2003.
- 2 Reddy KS, Gupta PC. Tobacco control in India. New Delhi: Ministry of Health and Family Welfare, Government of India, 2004.
- 3 Rees VW, Connolly GN. Measuring air quality to protect children from secondhand smoke in cars. *Am J Prev Med* 2006; **31**: 363–68.
- 4 14th World Conference on Tobacco OR Health, India; Feb 8–12, 2009. <http://www.14wctoh.org> (accessed April 20, 2007).
- 5 Subramanian SV, Nandy S, Kelly M, Gordon D, Davey Smith G. Patterns and distribution of tobacco consumption in India: cross sectional multilevel evidence from the 1998–9 national family health survey. *BMJ* 2004; **328**: 801–06.