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Evidence for health policy in India: do we have enough data?

Recently, two reports were published in leading journals. The first report in *Lancet* (Vol.379: May12, 2012) by Rajesh Dikshit *et al.*, infers that the most common fatal cancer in women aged 30–69 years is cervical with burden of 17.1%.¹ The latest paper in the *Journal of the Royal Society of Medicine* states the highest age-adjusted mortality rate of 7.7 per 100,000 as being for cervical cancer.² Earlier evidence suggests it is around 65.5 in a rural area.³ Thus the range of estimates for the disease burden varies from a low of 7.7 to a high of 65.5. For policy makers, this poses as a significant problem, as to which estimate to trust?

All the population-based registries from India and other data sources, as in the recent article, refer to data mostly from cancers reported from registries. Those depend mainly data from urban conurbations of the country.² The data from registries in India cover less than five percent of the total population of the country. Conclusions drawn from these registries cannot be viewed as representative of the total population, given that rural areas are mostly missed out, and cervical cancer rates might be higher in rural areas. The new cases of cancer detected by registries underrepresent the total number of cases, and may overrepresent the less severe cases or cases from upper socioeconomic strata who are able to afford healthcare.⁴

At best, none of these studies can provide causal interpretations. Methodologically, none of these papers have sufficient information to tackle one putative question: whether cancer of the cervix is highly prevalent or not in India. Hence, authors of the paper did not have reliable data to either support or reject the idea that HPV vaccine should be put to trial.⁵

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Competing interests

None declared

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Do cervical cancer data justify human papillomavirus vaccination in India? Epidemiological data sources and comprehensiveness

In their paper, Mattheij *et al.*¹ propose that current epidemiological data do not justify human papillomavirus (HPV) vaccination in India. They state 'current data on HPV type and cervical cancer incidence do not support [the] claim that India has a large burden of cervical cancer'. As the source of many of these data, we strongly contest this viewpoint.

Our GLOBOCAN 2008 estimates of the burden of cervical cancer in India indicate that the incidence rates are substantially in excess of those observed in, for example, the UK, where the authors are based and where there is a school-based vaccination programme (age standardized rates of 27 and 7 per 100,000, respectively).² The national estimates for India have a complex derivation due to the need to adequately balance rural/urban populations in different geographical regions, but the methods are clear and reproducible.²

Cervical cancer is the most common or the second most common female cancer in data from the seven highest-quality Indian cancer registries.³ Our recent nationally representative mortality study based on verbal autopsies showed that, in 2010, cervical cancer was the leading fatal cancer among women aged 30–69 years in both rural and urban areas.⁴ Overall we estimate that over a quarter of the world's cervical cancer cases and over a third of the cervical cancer deaths occur in India.²

While we agree with Mattheij *et al.* that incidence rates are declining over time in some urban regions,³ this is mainly due to the impact of multiple social factors (family planning, education and socio-economic improvement)^{5,6} combined with the developing programmes for screening and early detection.⁷

What is known about HPV and high-risk HPV prevalence in India would indicate that, rates are at the higher end of a global scale (exactly as for cervical cancer incidence) and, unlike in many other populations, tend to stay high in middle-age women.⁸ More than elsewhere, high-risk HPV types 16 and 18 predominate in invasive cancer⁹ indicating current vaccines would be very effective.

Cancer surveillance in India is incomplete and faces uncertainties in estimation. However, there are a large number of cancer registries and more data are available than for many other countries at a similar developmental level. The surveillance data that we have, indicate quite clearly that HPV infection and associated cervical cancer risk in India is a substantive burden and clear health priority which can be addressed now by a combination of screening and vaccination.

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Should the ideal be the enemy of the good?

In Mattheij *et al.*¹, the authors claim that HPV vaccine is not warranted in India due to supposedly low rates of cervical cancer and poor data. While we agree that the quality of registry data on cancer is far from ideal, that is true for many global health problems (including diabetes, which has no disease registry at all). Fortunately, lack of registries has not prevented governments from tackling pressing health problems.

We believe the authors have misinterpreted the Indian registry data. For

example, they do not acknowledge that the decline in rates was an urban phenomenon, and that it was not reflected in the one rural registry (Barshi)². To understand disease burden PATH relied upon the WHO's GLOBOCAN database³, which estimates that India has the highest absolute number of cervical cancer cases in the world.

The study sites in Andhra Pradesh and Gujarat were selected in consultation with a national project advisory committee and were based on multiple criteria, not only regional disease incidence; these included immunization coverage, experience with new vaccine introduction, and commitment to adolescent health and cervical cancer prevention⁴.

The authors cite the WHO document on new vaccine introduction⁵ as requiring that disease burden data and national surveillance be in place before any new vaccine can be used. While these guidelines set out a worthy ideal to strive for, they did not hold up the introduction of polio or measles vaccines, neither of which has the kind of comprehensive surveillance system the authors call for.

Finally, the study was not an effort to introduce or rollout HPV vaccine either nationally or in the two Indian states. Its purpose was to generate evidence on feasible, acceptable, and affordable strategies for delivering the vaccines, should the Indian government decide one day that such a service belongs in their cervical cancer control program. Should that day come, the data generated by the HPV vaccine study will prove useful to immunization planners.

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Author's Response: HPV vaccination in India

Babu makes the important point that cervical cancer estimates are not representative of the country as a whole as they draw on data derived from registries which cover around 5% of the population who are mainly living in urban areas.¹ This is a major problem for their use in policy making. It is important to point out that contrary to Babu's claims our study was not designed to look at causality, rather it took a critical look at the comprehensiveness, quality and coverage of cervical cancer data collected by Indian registries supplementing it with a lit search of epidemiological studies of cancer incidence and human papillomavirus (HPV) type prevalence. Our aim was to establish whether there was high-quality public health evidence to support the claims made by PATH in justifying the conduct of the HPV trials in India and whether in line with World Health Organization criteria there is effective surveillance to support the role out of HPV vaccination.

GLOBOCAN draws on data from eight randomly selected cancer registries which do not represent all regions of India equally, but mainly central and southern areas.¹ The large differences in incidence and mortality rates between and within states reported by registries indicate difficulties in extrapolating such data to the whole of the population.² The Lancet paper cited by Forman *et al.* reporting on mortality rates is highly problematic