**Covering letter**

**Title:** **Optional Vaccines in India: Time to develop a surveillance system for future**

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**Optional Vaccines in India: Time to develop a surveillance system for future**

**Abstract**

New vaccines inclusion in UIP has occurred many times in India and latest inclusion is IPV, Rubella, Japanese encephalitis & rota virus vaccine. In essence, as new-generation vaccines emerge, India's vaccine market will transition from being a publicly-funded initiative to a private business where vaccines are prescribed by private practitioners across the country. Unfortunately in India there is a lack of surveillance for optional vaccines. Indian Academy of Pediatrics has recommended 13 vaccines as optional vaccines outside the UIP. There are more than 200 different brand vaccines available in India’s private market targeting 27 different diseases and the list is increasing gradually. In the absence of any surveillance system for optional vaccine government don’t have any evidence about their efficacy, AEFI, Safety etc. In case of disease outbreaks situation will be nearly miserable. Evidence suggest that optional vaccine scenario is changing and to match step with this changing scenario Government of India should think for introducing a well-planned surveillance system for optional vaccines.

**Introduction**

Vaccination is one the most cost effective way for child survival intervention and has been proven in many medical literatures (1). History of vaccine in India and China are more than 500 years old and those days they were using it in “some form of inoculation” (2). However, modern immunization developed in India in 19th century, parallel to the Western world. Post independent era India, launched its first vaccine 68 years back: BCG in 1962 as a part of National Tuberculosis Program (3).Vaccination got the status of a programme in India after introduction of the Expanded Programme of Immunization in 1978.After that new vaccines addition have occurred many times and latest inclusion is the government of India’s policy level decision of inclusion IPV, Rubella, Japanese encephalitis & rota virus vaccine in national Universal Immunization Program (UIP) (4,5).According to WHO there are at least 27 causative agents against which vaccines are available and many more agents are targeted for development of vaccines (6).Expenditure on health in India during the last 10 years is mainly dominated by out of pocket (80-90%) (7). Similarly scenario is also changing in the market of vaccine. It is estimated the current Indian vaccine market is around $900 million, with a potential to touch $4.6 billion by 2017 (8).In essence, as new-generation vaccines emerge, India's vaccine market will transition from being a publicly-funded initiative to a private business where vaccines are prescribed by private practitioners across the country. Unfortunately in the present scenario of health care delivery system in India there is no surveillance mechanism for those vaccines available in the open market of India. Authors have tried to highlight the importance of surveillance of the optional vaccines available in Indian market.

**Vaccines outside the UIP in India**:

Present UIP cover 6 vaccine preventable diseases across India. Hepatitis B also expanded for whole country from 2013.Pentavacvaccine is available only 8states, MMR in 4 states and Japanese encephalitis only in 113 districts of India under UIP (8, 9, 10). There is different surveillance system in India for generating information regarding the coverage of the vaccines under UIP. National Family Health Survey (NFHS), District level Household Survey (DLHS), Coverage and evaluation survey(C&ES), Annual health Survey (AHS) are few of them who generate data on the coverage of primary immunization in India. Beside this Health Management Information System (HMIS), report of Ministry of health & family Welfare also generate data on immunization coverage. Integrated Disease Surveillance Project (IDSP), acute flaccid paralysis (AFP surveillance), adverse event following immunization (AEFI surveillance) also generates information regarding the burden of different vaccine preventable diseases.

**Comparison of Coverage of vaccines outside UIP between India& global scenario**

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| --- | --- | --- |
| **Name of the vaccine** | Global coverage (%) | India coverage (%) |
| Hib vaccine | 52% (11) | 4% (study conducted in 16 states of India) (12) |
| Rubella | 44% (11) | NA |
| Rota viral vaccine | 14% (11) | NA |
| Pneumococcal vaccine | 25% (11) | NA |
| Yellow fever vaccine | 41%(11) | NA |
| Influenza vaccine | 16% (Europe) (13)  41.1% (US) (2011-2012) (14) | NA |
| Hepatitis A vaccine | ≥ 1 dose 83.1%  ≥ 2 dose 54.7% (US -2013) (15) | NA |
| MMR | 91.9% (US-2013)(15) | NA |
| Chicken pox vaccine | 91.2(%)(US-2013) (15) | NA |
| Japanese encephalitis vaccine | NA | 66.5% (30 endemic districts in India 2009) |
| HPV vaccine | Girls-57.3%  Boys-34.6% (US- 2013) (15) | NA |

* NA = Not available

The above table shows Hib (189 countries), Rubella (137), Rota (52 countries), Pneumococcal (103) and Yellow fever (35 countries) vaccine coverage in the world. (11) Influenza, hepatitis A, MMR, Varicella, HPV vaccine coverage of USA is also presented in the above table. Other than these vaccines there is few more vaccine like: Pentavac vaccine, Japanese encephalitis vaccine, Cholera, typhoid, meningococcal meningitis and rabies vaccine are also available in Indian vaccine market similar to global scenario. Unfortunately since these vaccines are not included in the UIP there is no surveillance system in India for their coverage.

**Negative effect of unavailability of surveillance system for optional vaccines in India**

Indian Academy of Pediatrics has recommended 13 vaccines as optional vaccines outside the UIP (16) .Optional from mother or doctors prospective are not clearly mentioned. Regrettably socio- economic status of the parents becomes the major determinant factor over the scientific wisdom while selecting the vaccine for client (17).Indiscriminate use of these optional vaccines can change the disease scenario in future.

There are more than 200 different brand vaccines available in India’s private market targeting 27 different diseases and the list is increasing gradually (18). Number of private hospitals/ polyclinic/ nursing homes etc registered in India is almost 20,000 (19) and along with these there are 218 private medical colleges (20) and most of these hospitals & private medical colleges are running immunization clinic by pediatric doctors. IAP recommends those optional vaccines for vaccination of children. India is having a 330 million middle class population and most of them are from urban area (8). These middle class populations are fewer prices sensitive so they prefer these private clinics. A report of government of India shows that from 1970-2000 in India there is upward trend of production of optional vaccine by the vaccine manufacturers compare to the vaccines covered under UIP (21). As a result this produces an indirect pressure on these private clinic/ hospitals to promote more optional vaccines.

In the absence of any surveillance system for optional vaccine if any disease outbreak occurs government will be in a state of ambiguity that whether disease was occurring among the vaccinated population or among the unvaccinated. There is evidence also that mumps occurred among those who were vaccinated by MMR [Belgium, (22) & Switzerland (23)]. So, in case of crisis/ outbreak government will have to face a great hardship.

Moreover, in India we don’t have any documented evidence on the efficacy, effectiveness and coverage of many optional vaccines. Before including a vaccine in national UIP, National immunization technical advisory group (NATGI) considers the efficacy, safety, effectiveness etc of a particular vaccine. Science optional vaccines are also present in India’s private market for a sustainable period if government starts surveillance system for these optional vaccines among the private sector, it will answer many questions regarding the efficacy, cost- effectiveness, safety among Indian population in future. Policy level decision of introducing any optional vaccine in UIP will become easier for administrators in coming future.

In the absence of any surveillance system health authorities in India will not be able to know if any adverse events following immunization (AEFI) happens when these optional vaccines are administrated. Responsibility of unwanted AEFI following optional vaccine will remain unclear which will increase the misery of the beneficiaries.

**Way forward**

1. India has a system of disease surveillance under IDSP where private hospitals are also involved. But for routine vaccination reporting system private hospitals are not involved. GOI can take policy level decision for monthly reporting of immunization (Vaccine under UIP and Optional vaccine) mandatory for all the vaccination centers running by private hospitals/ polyclinics etc. throughout India.
2. There should be a system of registration for each vaccination center run by private authorities in India similar to yellow fever vaccination center, Sonography center etc. It will increase the accountability of private players on immunization.
3. Indian has UIP for vaccination but on the other hand IAP also recommends vaccines for Indian children. Most of the vaccine in private sector are prescribed by Pediatricians and they are following IAP vaccination schedule. There should be a policy level decision on the uniformity of recommendation. Only mentioning optional vaccine depends on the choice of the parents doesn’t solve the purpose.
4. AEFI for optional vaccine should exist to prevent any unwanted event in future.

**Conclusion**

Presently only little more than 10% of vaccinations under UIP are covered by the private sector but for the optional vaccine the scenario is different. Private sector contribution to vaccination is increasing gradually and science India is moving towards from rural to urbanized world, a large middle class population are preferring this private clinics for vaccination. Evidence suggest that optional vaccine scenario is changing and to match step with this changing scenario Government of India should think for introducing a well-planned surveillance system for optional vaccines.

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