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REVIEW ARTICLE

Expanded Program of Immunization in India: Time to Rethink and Revamp

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Abstract:
The decades old Expanded Program of Immunization (EPI) needs a relook in the context of availability of newer vaccines and changing epidemiology of diseases targeted by this program. There is marked geographic variation in the performance of this program all over the developing world. Many countries have adopted and tailored it to address the diseases prevalent in their communities. Of late, there are voices of concern over the utility of its current format and need to urgently revamp this program with inclusion of certain new vaccines. On immunological basis the EPI schedule currently adopted by many countries is not impeccable. The current viewpoint article examines virtues and shortcomings of current Universal Immunization Program (UIP) - an adopted avatar of EPI in India and offers suggestions to improve it further. The article takes a look at both the old as well as new vaccines and issues recommendations on the need of inclusion of them. It also scrutinizes the performance of UIP in India and offers solutions to further strengthen it.

Keywords: *Expanded Program of Immunization, Universal Immunization Program, vaccination schedules.*
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Introduction

Expanded Program of Immunization (EPI) was introduced in India in the year 1978 under the aegis of the WHO programme launched in 1974. When introduced in India, it included BCG, DPT (3 doses) and typhoid vaccine. OPV was added a year later. Apart from 3 primary doses of DPT and OPV, two additional doses of the same were given at 1.5 and 5 years of age. Children under 5 years were being covered in the program. In 1985, the program was converted into Universal Immunization Program, with the lofty goal of covering *all* the eligible children in the country. Although the first booster of DPT was retained, the second booster at 5 years was reduced to DT (with omission of pertussis component). Emphasis was shifted to universal coverage of children till one year of age reducing the denominator of potential beneficiaries to approximately 25 million from earlier 115 million under 5 children. In 1985 a dose of measles vaccine was added at 9 months of age, but at almost the same time typhoid vaccine was dropped from the

vaccination program. Thus since 1985, the Universal Immunization Program (UIP) has remained focused on 4 vaccines (BCG, DPT, OPV & measles) against 6 diseases and predominantly for infants up to 1 year of age. Another 9 vaccines have been introduced in the Indian market since then and some more are in the pipeline, but no rational thought process has gone to determine whether (or not) to incorporate one or more of these in the national UIP.

Numerous CMEs/Updates held in the last two decades (organized, hosted and paid for by vaccine manufacturers) have focused attention only on these 'newer' vaccines (1,2), relegating the UIP vaccines to the background. The Indian Academy of Pediatrics Committee on Immunization (IAPCOI) has also been making recommendations "for its members" (and not for the children of India) on how to incorporate these new vaccines in their personal practice schedule for the privileged few. Various euphemisms like 'desirable', 'optional',' those who can afford', 'one to one basis' etc have been used (3,4) that subtly promote the sale of these newer vaccines under the garb of scientific recommendations. IAP members have responded enthusiastically and incorporated these vaccines in their practice.

These twin events- Government apathy and private sector hyperactivity- have resulted in further neglect of the UIP (principles, practice and products) vaccines. In addition, the need for incorporating one or more of these vaccines for the benefit of India's children, (as opposed to manufacturers, practitioners and the individual well-to-do child) has also not been considered.

Nevertheless, the undue commercial thrust creates an excellent opportunity to have a relook at the UIP; to determine how the existing programme can be strengthened (with the available and newer vaccines) to maximize the benefit for Indian children.

UIP: Current status

UIP performed quite well in the first decade of its introduction. Between 1985 to 1995, the coverage levels for various vaccines reached 70-85% and the incidence of various VPDs rapidly declined in the country (5). However since then, there has been a decline by 15 to 20% in coverage of different vaccines (5). In fact surveys carried out during National Family Health Survey (NFHS) I, II and III and by independent agencies such as UNICEF, have revealed that the coverage levels may be lower by as much as 15-40% (6-8), compared to reported levels of coverage in the UIP. In Bihar in the year 2002, only 13 % of 13-24 months children had received all the vaccines (6). Thus the UIP has been struggling to achieve fair levels of coverage even with just 4 vaccines.

I. Revamping UIP

The urgent need of the hour is to look at the reasons for this abysmal performance and to urgently take steps to revamp the UIP. Lack of infrastructure and manpower (vacant posts in the health-care sector), especially in some of the chronically underperforming states such as UP, Bihar etc are traditionally blamed. However in recent times, undue emphasis on polio eradication with pulse polio rounds being carried out almost every month has taken further toll on the crumbling health infrastructure in these states. Pernicious practice of house to house visits for delivering "polio drops" to each child, during each round has made the public dependent on the health workers "to deliver whatever vaccine is desirable, to the children at their homes". Parental and societal motivation for the vaccination program has thus largely been killed. Health workers are being paid for (and assessed) for their performance in pulse polio rounds limiting their time, motivation and accountability for delivering UIP vaccines. Thus revamping of the health infrastructure and making the health workers accountable for delivering UIP vaccines is extremely important. Toning down of activities under pulse polio program will greatly help in achieving this, particularly because polio control itself demands scaling down of pulse-polio activities. The following are some suggestions to revamp the UIP.

A) Accountability

It is critical that each health worker involved in routine immunization be allocated a designated area and be held accountable for the vaccination status of a defined group of 150-200 children in his/her area. Besides fixing responsibility, it also strengthens the bond between the health-worker and the community (almost like one to one contact); making the program

more humane, rather than impersonal and mechanical. The health workers should be trained to maintain records of each vaccine dose administered to each child and offer explanation to the parents regarding potential benefits, and possible side effects of each vaccine.

B) Documentation

There is a need to make immunization records comprehensive, objective and complete. The current practice involves passively recording the date of administration of a given dose in the National Immunization Schedule card. Quite often a corresponding record is not maintained at the health-centre. Therefore, in the event of doubtful vaccination, non-response, disease after vaccination (suspected vaccine failure), alleged/suspected adverse event, loss of card etc; it is sometimes impossible to verify the actual status.

This problem can be overcome if each dose of vaccine administered is recorded with a code containing a unique sequence of letters and numbers reflecting state, district, health-care centre, name of vaccine, dose number, date and a unique serial number for the particular child. This will have several benefits viz (i) objective record of vaccination, (ii) identification of the date and source of vaccination, (iii) person responsible, and (ii) identification of clustering of cases /adverse events, (iii) correlation with vaccine batch number in the event of outbreak of cases / adverse events. Such an Immunization record (card) could be included as an essential component of the "Unique Identity Card scheme".

Proper documentation of vaccination has the twin added advantage of enabling vaccinated children to file claims for compensation in the event of vaccine adverse events; and also linking it to other (health and non-health) Governmental schemes.

C) Failure of target-based approach

Practical experience has confirmed that 'target-based' approaches often end up with excellent reports certifying targets being achieved and even exceeded; irrespective of the ground reality. This is the problem with using 'coverage' as an indicator for the success of the vaccination programme. For example, if health-care workers are under pressure to achieve targets for childhood vaccination in excess of 90% coverage, it is possible that they would produce reports to reflect this. This is perhaps the reason why official coverage figures for all vaccines are about 20 to 40% higher than coverage data acquired independently by national and international agencies. Therefore, the emphasis has to shift from "coverage to cases", whereby health-care workers are not held accountable merely for coverage, but for the 'cases' that occur in their area. In this revised scenario, the HCW's actions are likely to become proactive (get children vaccinated) rather than reactive (vaccinate if demanded). Comparison of the incidence/prevalence of cases, correlated with vaccination records will immediately identify individual levels of performance, and iron out glitches at the ground level.

Reverse hierarchy of accountability wherein each rung of the health-care machinery is answerable to the immediate superior rung, will ensure that there is a top-down approach to accepting responsibility (and ensuring action) for the performance in a given area/district/state.

D) Surveillance

Strangely, the need for surveillance hand-in-hand with a disease prevention program seems to have escaped the planners and implementers of the UIP, again highlighting the inappropriate emphasis on coverage rather than cases. The polio eradication initiative has shown that it is possible to have robust active surveillance machinery, to detect and confirm cases of vaccine-preventable diseases (provided there is a will to do it well and a monitoring mechanism in place). Since the existing polio surveillance is likely to continue indefinitely, it makes sense to introduce National Vaccine-preventable disease surveillance on the same framework by suitably training health care workers (HCWs), developing case definitions and lab tests, and instituting a monitoring mechanism with the same reverse hierarchical accountability described above.

E) Adverse event detection and redressal system

An important spin-off benefit of robust documentation and surveillance systems is that it can also be linked to a National database of vaccine

adverse events. This will not only help in generating national data, but also be useful to allow (and settle) compensation claims for vaccination-related injury and serious adverse events. It will also provide a sound basis for decisions to modify/abandon certain vaccine preparations based on reactogenicity profile, should the need arise.

II. Rethinking UIP

A) UIP Schedule

In the UIP, after birth dose of BCG, 3 primary doses of DPT and OPV are given at 6,10 and 14 weeks. In most developed countries a schedule of 2,4 and 6 months is followed which allows a gap of 2 months between three primary doses. India adopted 6, 10 and 14 week schedule primarily to complete the primary schedule rapidly and minimize the drop-out rates. The WHO had used this rationale for proposing the accelerated schedule for all developing countries, without considering epidemiological difference across continents/countries.

While for Diphtheria and Tetanus Toxoids, a 4 week interval produces equally effective seroconversion, for most other vaccines (pertussis, OPV etc) seroconversion rates are lower by as much as 10-15% than with a 2 month interval schedule (9). Many new vaccines like Hib, Rotavirus , Pneumococcal, (even hepatitis B in some developed countries) etc have primarily been evaluated for seroefficacy with 2/3 primary doses given at 8 weeks interval but are being perforce being incorporated in the vaccination schedule of 6,10 and 14 weeks with unpredictable compromise in efficacy.

Can India think of deviating from the WHO-inspired 6, 10, 14 week schedule and consider a 2,4 and 6 months schedule? Besides ensuring superior immunogenicity, it has the advantage of facilitating visits at the crucial ages of 4 and 6 months when infants are being weaned (from breast feeding) and hence vulnerable to development of malnutrition in the absence of proper nutritional advice. It will also help to reduce the large gap and hence drop-out rate (between the third DPT at 14 weeks and measles vaccine at 9 months) and thereby ensure implementation of more comprehensive child health practices like growth monitoring, nutritional advice etc.

B) Individual UIP Vaccines

BCG

We know that BCG is not a very effective vaccine. In various studies it has been shown to have an efficacy varying from 0-80% (10). It certainly does not protect against secondary forms (adult type) of tuberculosis. However it offers some protection against disseminated forms of primary tuberculosis such as TBM, miliary tuberculosis etc (10). Thus it does help in reducing the mortality from tuberculosis although it is unlikely to affect the morbidity or to help in tuberculosis control as such. We need to continue BCG in the schedule till a better vaccine is developed. Also in view of high endemicity of the disease we will need to continue doing it at birth or at the earliest contact. There is certainly no need of any boosters.

DPT

DPT with whole cell pertussis (DPwT), should also continue in the vaccination schedule. The cost-benefit analysis does not favor its replacement by acellular pertussis in the UIP. The main advantage with the acellular preparation is the reduced incidence in adverse reactions. Three points must be remembered viz that reduced reactogenicity does not imply absence of side effects; it is impossible to predict which child will develop these unpleasant effects; and the risk of severe adverse effects with DPwT itself is very small (11). Further, the lower reactogenicity with acellular preparations has to be contrasted against the 10-15% lower rates of seroconversion (9). As the pertussis components are different in different types of acellular vaccines, they cannot be used interchangeably (unlike Hib).

While the IAPCOI (3) is now advising acellular pertussis vaccine to even adolescents (quite unnecessarily) it is surprising that in the UIP, Pertussis vaccine is being given only till 18 months of age. The second booster of DPT at 5 years of age was converted to DT in the UIP in 1981 without any explanation and continues to be the same. It is absolutely essential that this second booster of DPT

is immediately restored in the UIP. There is no epidemiological evidence in our country which warrants use of pertussis vaccine beyond 6 years of age. Even in countries such as the USA, the overall incidence among adolescents increased gradually in populations with high rates of childhood immunization. Similarly, outbreaks with higher number of adolescent/adult cases also occurred in highly vaccinated (immunized) populations (12), whereas the disease continued to affect young infants where immunization coverage was lower (13). In an area where majority of children had received three doses of vaccine, an outbreak affected predominantly infants below 2 years (14). These data are in stark contrast to the Indian scenario where childhood immunization rates are low so that an epidemiological shift is highly unlikely.

Polio

Apart from routine doses of OPV at birth, 6, 10, 14 weeks and at 18 months of age tremendous efforts have been made in the last 15 years to achieve zero polio status in the country, through several rounds of pulse polio vaccination and other activities associated with polio eradication. It is estimated that more than 4000 crore Rupees ($850 million) have been spent on polio eradication program itself. The program has achieved considerable success and except for the epidemic years of 2002 and 2006, only 200-600 cases of paralytic polio are being reported each year. In fact, in the year 2005 only 65 cases occurred when an unfortunate (and ill advised) policy decision of introducing monovalent OPV1(hastily assembled) in pulse polio rounds was taken, resulting in resurgence of P3.Now only P1 is being considered the major villain and P3 is almost projected as a 'benign' virus.

In search of the ever elusive target of zero polio, children all over the country are being repeatedly exposed to the possible hazard of Vaccine associated paralytic polio (VAPP) and vaccine-derived polio virus (VDPV) (15). While several countries across the world- many of them smaller than some of our states- have started implementing post eradication strategies, we are still continuing with a uniform nation-wide policy attempting polio eradication. If we consider our country as separate epidemiological zones based on states (or even regions) with zero-polio, many states qualify for the initiation of post-eradication strategies owing to sustained polio-free status for several years. Neither the rationale nor the efficacy of using international boundaries for epidemiological decisions has ever been demonstrated. For precisely these reasons, we have been advocating phased introduction of post eradication strategies in our country beginning from States/regions which qualify for 'certification of eradication' based on polio-free status for more than 3 years (16-20). Well defined geographical regions like Southern India, North East India and even J&K qualify for immediate introduction of post-eradication phase activities.

WHO has suggested two post eradication strategies. One for (developed) countries to completely replace OPV by IPV in routine immunization and the other for (developing) countries to stop all polio vaccination, continue polio surveillance and depend on WHO stocks of monovalent vaccine to contain outbreaks if (when) they occur. We have strong reservations about the latter policy for several reasons. The policy of containment (after detection of a paralytic polio case) has not been successful as demonstrated by the experience in Indonesia where it took almost 6 months to ultimately control an outbreak (21). The policy will continue to incur high costs of AFP surveillance and will make a large country like India ever dependent on a single external agency (WHO) for supply of monovalent vaccine for outbreak control. The priority that will be accorded to India in the event of a number of countries competing for a limited stock of oral vaccine is left to anybody's imagination. We strongly feel that IPV is the only option for our country in the post eradication phase and the strong point of this strategy is that it can be introduced even without actually achieving zero polio status.

The rational approach would be to start IPV in polio-free states, while continuing OPV in the endemic states, curtail pulse polio to only two annual, country-wide rounds, at 8 weeks interval. Obviously a large country like India cannot depend on import of large quantities of IPV which will be required in the UIP and therefore we must take immediate steps to establish facilities for indigenous manufacture of IPV.

Measles

Measles continues to be a public health problem in the country. It is reported that about 54,000 cases of

measles are still occurring every year in our country. This is a considerable improvement over pre measles vaccination scenario in the country (UNICEF and NFHS data). Prior to 1985, measles was almost universal with most cases occurring before 5 years of age and almost one-fourth cases occurring before 1 year of age. Because of this early age incidence ,we were compelled to choose 9 months of age for

measles vaccine in the UIP, despite the fact that efficacy of measles vaccine at this age is at least 15% lower than given at 15 months of age. This policy has served well as seen by the overall decrease in incidence of measles. But what about the age incidence? Despite measles surveillance in the country (together with AFP surveillance) for the last 3 years it is difficult to get the exact incidence of measles, as the data has not been looked at or properly analyzed. We had to look at alternate sources for this information. In a report published in 2007, age incidence of measles has been analyzed in more than 6400 cases occurring during 132 outbreaks of measles of which 101 were virologically proven. The investigators found that only 7.7% cases occurred below 1 year of age and more than 55% cases occurred after 5 years of age. This would suggest a definite shift in incidence towards higher age-group. At the same time, there are also reports indicating measles in infants as young as 6 months. These apparently contradictory reports argue strongly for careful analysis of surveillance data, to confirm a possible epidemiological shift and consider a vaccination strategy based on scientific principles.

Recently various state governments have initiated a catch-up campaign with a dose of measles vaccine to be given to all children 1-5 year of age, irrespective of previous immunization status. This is essentially an attempt to provide another opportunity to children, who may have missed their dose at 9 months to get a dose of vaccine. Thus it is an attempt to increase measles vaccine coverage with *one* dose of vaccine and not an attempt to give a second dose as erroneously believed (and propagated) by some

C) Non EPI Vaccines

Typhoid

One of the reasons given for the withdrawal of typhoid vaccine from the EPI was that the reported incidence of 1% was not sufficient to warrant universal immunization against typhoid. Subsequent studies have shown that India's incidence is probably the highest in the world (22). Further, increasing emergence of antibiotic resistance and the threat of multi-drug resistant strains have tremendously increased the cost of care although this has not significantly affected the mortality from typhoid. Epidemiological studies, however, have revealed that maximum incidence of typhoid is below 5 years of age with many cases occurring before 2 years of age (23) and that paratyphoid A may be responsible for well over 20% of all enteric fever cases in the country (24,25)

Therefore, there is need for a vaccine against typhoid, but which is effective against both typhi and paratyphi strains and can be given before 2 years of age. None of the currently available vaccines meet these requirements. The conventional TAB vaccine was immunogenic below 1 year of age but had to be withdrawn because of unacceptable reactogenicity. One option could be to refine this to reduce its reactogenicity while retaining its efficacy.

The currently available Vi vaccine has reasonable efficacy above 5 years of age and a possible efficacy above 2 years of age but does not qualify to be included in the UIP. Efforts are on to develop a conjugate Vi vaccine which could be given below 2 years of age. This vaccine although likely to be more useful, would not be helpful in preventing cases of paratyphoid fever and we would need more epidemiological studies to define its potential benefit in the UIP.

Hepatitis B

Since 1995, hepatitis B (HB) vaccine has been touted (by the vaccine industry and supported by WHO) as the seventh EPI vaccine capable of eliminating Hepatitis B if introduced in the UIP. The WHO has been persuading member countries to introduce HB vaccine in their UIP schedule. Two lines of reasoning have been employed (i) that HB is a huge public health problem, and (ii) it can be prevented by widespread vaccination. Vaccine manufacturers used both these to great advantage over the past two decades. Their efforts seem to be succeeding since as many as 118 countries in the world have introduced Hepatitis B vaccine in the UIP.

To accommodate the HB vaccine in the UIP of developing countries, the standard 0,1,6 month vaccination schedule (26,27) itself was modified to 6,10 and 14weeks. It is another matter that no study in the world has shown the efficacy of this schedule in reducing perinatal transmission or in reducing overall prevalence of HB carrier rate in the community (28). Even the data on sero-efficacy demonstrates that the levels of antibodies achieved with this schedule may be as much as several-fold lower than those achieved with classical 0,1 and 6 months of age (29). Thus 6, 10 and 14 weeks schedule primarily serves to achieve consumption of vaccine rather than achieving goals of vaccination. We must remember that for optimal vaccine efficacy of Hepatitis B vaccine, the first dose must be given within 48 hours of birth, while a minimum gap of 4 months must separate the second and third doses.

There is controversy regarding overall carrier rates of Hepatitis B in our country and the incidence of diseases such as hepatocellular carcinoma, which occur as a consequence of the carrier stage. An average carrier rate of 3.5 to 5%, quoted for nearly three decades has recently been shown to be as low as 1.4-1.8% (30). This moves India into the low endemicity zone; forcing a rethink on the value of universal immunization vis-à-vis other strategies. Further the oft-repeated 184000 *estimated* hepatocellular carcinoma cases (31, 32) are in stark contrast to the 5000 odd *detected* cases as per the ICMR National Cancer Registry (33). Epidemiological studies in India have also shown that perinatal transmission may be contributing up to 30 to 50% (34) towards overall carrier rates of Hepatitis B in the community.

Considering the overall epidemiological situation, HB vaccine does not merit high priority for incorporation into the UIP. Unless this vaccine is introduced at birth and a rational schedule (of 0,1 &6 months) is used, no benefits would accrue to the consumers as no other schedule will prevent perinatal transmission or give sustainable levels of antibodies to make any significant dent on the overall carrier rates of Hepatitis B and its sequelae.

Mumps and Rubella

While vaccines against Mumps and Rubella have been used in the private sector for more than 15 years, there has been a general reluctance to incorporate them in the UIP, probably because of non-fatal nature of these illnesses. However both are capable of considerable morbidity. Mumps is a highly infectious disease with almost 100% transmission to susceptible contacts with 7-10 days of school (or work) absence in each episode.. It has the potential to cause serious complications like encephalitis, pancreatitis, orchitis etc.

Rubella in childhood is essentially benign but rubella in pregnant mothers can cause congenital rubella syndrome. Studies from our country suggest that up to 15-40% women in the child bearing age group may be susceptible to Rubella (35).

The vaccine against both these diseases available in combination with measles as MMR is a highly efficacious and safe vaccine. A single dose of MMR given at 15 months of age is capable of providing 95% protection against the three diseases. As pointed above, if the upward shift in age incidence of measles is confirmed, then a single dose of MMR at 15 months can easily replace that of measles at 9 months of age. Contrary to popular misconception based on US epidemiology, we do not need a second dose of MMR in our country as rampant subclinical exposure keeps boosting the vaccine-induced immunity. We must concentrate on achieving maximum coverage with one dose of MMR at 15 months rather than waste our energies and resources for giving second dose to a few privileged children

Hemophillus influenza B (Hib)

Effective vaccines against *Haemophillus influenza b* (Hib) have been available for quite some time and their introduction in immunization programs of many developing countries like USA and Finland have dramatically brought down the incidence of Hib infections in these countries

The vaccine is highly efficacious and can be easily incorporated in the existing UIP. It is even available as combination vaccine with DPT and can be given at the same time as other UIP vaccines. It is also a very safe vaccine. The vaccine has been used in the private sector for several years in our country. Recently indigenous brands of this vaccine have also become available. Thus the vaccine has all the attributes of being introduced in the UIP.

However doubts remain about the exact epidemiology of Hib in our country. Most studies show low rates of Hib isolation from invasive diseases such as pneumonia, meningitis etc., although high rates of pharyngeal carriage have been demonstrated (36). This has led to the belief that we may be having more non-invasive infections with Hib and this may even be providing some sort of 'natural immunity' against invasive disease (37). From the limited data generated from tertiary care centres in India, two important points emerge. First Hib appears to be responsible for approximately one-third of culture-proven meningitis cases (range 0 to 65%) and a smaller proportion of pneumonia (38, 39). Second, it is often not isolated on culture being a fastidious organism; however indirect tests such as antigen detection and PCR in CSF increased the yield by two and three fold respectively (40). Although epidemiological data on exact prevalence of Hib in our country are lacking, but considering the safety, efficacy indigenous availability and ease of incorporation in the UIP, it can be recommended that Hib (in combination with DPT) be introduced in the UIP.

Pneumococcus

Unlike Hib, there is no doubt about the wide prevalence of invasive pneumococcal infections in our country. Although there is no evidence that prevalence of penicillin resistant Pneumococci is high (it is probably less than 3%), there is sufficient epidemiological evidence to warrant a vaccine against Pneumococcal infections in our country. Considering that most fatal infections due to this organism occur early in life, it is essential to have a vaccine efficacious in that age group- hence only a conjugate vaccine is worth introducing in the UIP. However the currently available 7-valent conjugate pneumococcal vaccine does not provide coverage against most disease causing serotypes in our country (41) and may be capable of preventing only 20% of all pneumococcal infections in India. Hence it is not suitable for use in either UIP or in personal practice. We need to wait for vaccines with greater serotype coverage and examine efficacy before reconsidering inclusion in the UIP. It should be noted that although the 7-valent vaccine covered nearly 85% serotypes in the USA; search for even better serotype coverage has let to the recent introduction of 13-valent vaccine. This suggest that even 85% serotype coverage may be unsatisfactory. In other words, India may require a novel pneumococcal conjugate vaccine.

Rotavirus

A monovalent (G1P8) live oral Rota virus vaccine has been recently introduced in the Indian market. In a large scale field trial it has been shown to have over 80% efficacy against type specific Rota virus infections. However it has only 45% efficacy against non vaccine Rota virus strains. While this vaccine is capable of preventing almost 40-45 % of all severe diarrheas in the developed countries (where Rota virus is responsible for almost 80% of diarrheal episodes) (42,43), its efficacy has not been demonstrated in Indian settings.

Extensive epidemiological studies on Rotavirus in our country have revealed that i) Rotavirus is responsible for 7-15% of all diarrheal episodes in the community and up to 15-25% of all dehydrating diarrheas admitted to hospitals,(44, 45) ii) a wide variety of serotypes are prevalent in the country and they differ from regions to regions and from year to year even in the same regions (46, 47) and iii) newer serotypes are emerging in different parts of our country from time to time (44, 46, 48,49).

Therefore the currently available Rotavirus vaccine can be expected to prevent only 8-12% of all diarrheas and about 40-45% of all severe diarrheas due to Rotavirus. As such it is unlikely to be cost effective in our setting to introduce in the UIP. It requires extensive multi-centric studies spread over 2-3 years to asses its actual efficacy in our country. Till then it cannot be even recommended for use in personal practice.

Varicella

Chicken pox is widespread in our country. There are no sub-clinical infections and the disease is highly infectious .While in the northern parts of the country it follows a temperate pattern with most infections occurring during childhood, in the southern states it follows the tropical pattern with most infections occurring in adolescents and adults. The disease tends to be severe in older individuals. Even in its milder forms it causes a debilitating disease lasting for 7-10 days. Unfortunately it tends to happen mostly in months of March and April coinciding with the examination periods for school going children,

causing much mental agony, apart from physical disablement.

Varicella vaccine is highly efficacious, largely safe and just one dose of the vaccine at 15-18 months can provide life long protection. Hence, this may be a vaccine which could be considered for inclusion in the UIP. On the other hand, there is the counter argument that chicken pox is usually a mild(er) disease in children, and an episode usually results in life-long immunity. It must also be remembered that vaccination is not designed to prevent chicken pox, but to prevent severe forms of the disease (50-52). It has also not been shown to be efficacious against development of varicella zoster in later life.

Hepatitis A

Hepatitis A is also wide spread in our country. However unlike Varicella, most infections due to Hepatitis A are subclinical or cause very mild symptoms. Epidemiological studies from most parts of our country show that up to 80%, 90% and 95% children get infected by this virus before 5,10 and 15 years of age respectively (53-56). Till now there is no definite evidence of epidemiological shift in age incidence, despite improvements in economic status and standards of environmental hygiene. Natural infections besides being benign, lead to strong immunity providing life long protection. Although a few cases of fulminant hepatic failure (FHF) in older children have been reported from tertiary care centers, by and large, a rare phenomenon. Studies from AIIMS show that over last several years, FHF due to hepatitis A continues to be a very small proportion of all cases of FHF most of which are due to Hepatitis E (57, 58). Thus at present there are no valid reasons to incorporate Hepatitis A vaccine either in the UIP or in personal practice.

We should continue to monitor epidemiological status in different parts of the country if there is an epidemiological shift, it may be worth considering it in future.

Summary

- EPI needs revamping and rethinking
- Pediatricians, (especially their National organization The Indian Academy of Pediatrics) as custodians of child health in this country must think of all the children rather than only the privileged few.
- DPT must continue till 5-6 years of age (second booster)
- As per evidence available today MMR, Hib and Varicella vaccines could be incorporated in the EPI.
- We should consider shifting the dose of measles to 15 months (instead of 9 months) and combine it with mumps and rubella vaccine, if analysis of epidemiological data suggests an upward shift in age-incidence.
- IPV should replace OPV in the EPI in a phased manner. Birth dose of OPV should be dropped.
- Only two rounds of pulse polio should be carried out in the country.
- We should review the necessity of Hepatitis A on an yearly basis with representative epidemiological data
- Currently available Pneumococcal vaccine cannot be recommended either for personal use or for EPI
- Typhoid Vi vaccine does not provide desirable protection in the vulnerable age group hence can not be recommended for routine use
- The only rational way to use Hepatitis B vaccine is starting at birth and a scientifically proven schedule such as 0,1 and 6 months. It can not be considered a priority vaccine for UIP
- Multicentric RCT spread over 2-3 years are required to asses the efficacy of currently available Rota Virus vaccine
- It would be desirable to alter primary schedule to 2,4 and 6 months from the current 6,10 and 14 weeks.
- UIP needs to be strengthened by incorporating an active Disease surveillance system, Adverse event reporting system, robust documentation and stringent monitoring system to ensure accountability at all levels of health-care. This will also help us to take our own decisions regarding any changes which need to be incorporated in the UIP and to asses the efficacy of our efforts.

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