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Correspondence

Pentavalent & other new combination vaccines: Solutions in search of problems

Sir,

The pentavalent vaccine and many other combination vaccines waiting to enter Universal Immunization Programme (UIP) have brought into sharp focus the gaping gap between lofty slogans of 'evidence based medicine' and the actual dynamics that drive policy on the ground[1-4]. Notwithstanding the theatrics of the 'experts' of the World Health Organization (WHO) and the Global Alliance for Vaccines and Immunization (GAVI) globally and National Technical Advisory Group on Immunization (NTAGI) in India, it is becoming increasingly obvious that the pentavalent vaccine, like many other recent combination vaccines, is a solution searching for problems.

There is no scientifically valid evidence of a high enough disease burden due to *Haemophilus influenzae type b* (Hib) or Hepatitis-B (HepB) that justifies universal vaccination in India[5-7]. Indeed, every attempt to find such evidence for HiB in India and elsewhere in Asia has failed[4]. In the absence of evidence for individual vaccines, it defies logic how one can justify combining them into a pentavalent vaccine. It seems that there was a need only for 'expert' recommendations behind closed doors which were unquestioningly accepted. Unfortunately, increasing awareness and rising dissent against medicines-sans-evidence is forcing the policy makers to find *post-facto* evidence that is becoming increasingly difficult to manufacture. By now it is obvious that except to the determined 'experts' who drive our immunization policies, that there has never really been a real public health demand for many of these new vaccines, let alone their combinations.

Indeed, combination vaccines were invented precisely to overcome the poor penetration of the individual vaccines in the global market, as well as to overcome the expiry of their patents and establish eternal market monopolies. Scientific evidences indicate that combination vaccines bring no new health benefit to the immunized people[8-11], except the convenience of not having to take each vaccine separately, provided all those vaccines are actually needed. The issue of safety and efficacy of combination vaccines was often a cause for concern[12]. For instance, MMR in combination with Varicella vaccine reported to have enhanced fibrile seizures in children[13-14], and Hepatitis A vaccine is not protective enough when combined with typhoid vaccine[15]. It is a mere marketing trick. Every dubious new vaccine needs a piggyback ride on a diphtheria tetanus pertussis (DTP), measles or some other essential vaccine to get a back door entry into the UIP[16]. Pushing Hib, Hep-B, mumps measles rubella (MMR), rotaviral, human papilloma virus (HPV), *etc*., through combination vaccines among people who do not need them in this manner also amounts to siphoning public money to benefit industry.

Why is it that 'equity' argument is often given only when it comes to government spending on vaccines? Why not for all other health care services or other basic amenities such as food, shelter, water and clean environment, which are ruled by market forces? Why are health concerns so muted when it comes to OPV induced paralytic cases? Is the government or NTAGI willing to take responsibility and compensate for vaccine induced paralytic cases? Why do we not have proper vaccine injury compensation in this country? Why should our immunization experts enjoy so much immunity from the unhealthy consequences of their advice for health? In any case, the hollowness of the 'equity' argument becomes obvious when we consider that the total coverage of 'universal' immunization is below 50 per cent of the children in India, even for the most essential and affordable vaccines.

Another side of the equity argument is that manufacturing these combination vaccines in public sector units (PSUs) would bring down their prices and make these more affordable to all. This would have been a welcome move (lest we too be branded as anti-vaccine), provided the public health need for these new vaccines is firmly established. Unfortunately, even well meaning minds in the government committed to reviving the crucial role of PSUs in Indian vaccine security seem to be lost in supply side arguments without firmly establishing the demand for these vaccines based on disease burden. This is inspite of having all the human, financial and technological resources to document disease burden scientifically. This is the fundamental tragedy of medicine-sans-evidence policy that rules in Indian vaccines.

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