FROM OTHER JOURNALS

Cheaper HPV vaccines

The Global Alliance for Vaccine and Immunisation (GAVI) has succeeded in its negotiations with the manufacturers of human papillomavirus (HPV) vaccine to lower the price of the vaccine. Once considered as the most expensive childhood immunisation vaccine in the world, the HPV vaccine has now been made available at a relatively cheaper cost of \$4.50 and \$4.60 by the manufacturers Merck and GlaxoSmithKline (GSK), respectively. Pilot vaccination programmes are due in many African countries with Rwanda leading the block by making it part of the national vaccination programme in 2014. However, Médecins Sans Frontières (MSF) points towards the huge profits earned by the drug companies from the HPV vaccine and the fact that HPV vaccine, when added to the basic immunisation package, increases its cost by 35%. The editorial in the Lancet also indicates the need for further reduction in the price, as well as the need for stronger health systems capable of handling the additional immunisation. In the wake of this new development, it would be interesting to follow the developments regarding the HPV vaccine in India and the case regarding the controversial study of the HPV vaccine conducted in 2010.

Horton R, editor. GAVI introduces new life into the HPV vaccine rollout. *Lancet*. 2013 May 18; 381:1688.

Informed consent and the SUPPORT trial

A low level of oxygen in the blood is a major cause of mortality in premature babies. The Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT) was initiated in multiple centres in the USA in 2005, and was completed in 2009. Similar trials were conceived in 2006 in Australia, the United Kingdom and New Zealand. At the time of the start of the trial, the guidelines of the American Academy of Pediatrics recommended the partial pressure of oxygen in the blood to be between 50 and 80 mmHg, corresponding to oxygen saturation levels of 85% and 95%, respectively. Prolonged exposure to supplemental oxygen carried the risk of retinopathy of prematurity (ROP), resulting in impaired vision. The comparative research enrolled premature babies in two groups, one receiving a lower range of oxygen of 85%-89%, while the other group received oxygen in the higher range of 90%–95%. Both sets of babies were receiving oxygen within the levels prescribed by the guideline and hence were receiving the standard care as specified at that time. The 5-year study results showed that "even within the recommended oxygen saturation range, babies with a higher saturation level had a

higher risk of ROP and those with a lower saturation level had a higher risk of death." Similar findings from the UK and Australia studies resulted in a change of practice regarding oxygen supply at many medical institutions in 2010.

Subsequently, the researchers and investigators were criticised by the Office for Human Research Protections (OHRP) for not including a proper description of risks and discomforts in the informed consent form. The authors contest this allegation and point out that the risks were revealed as a result of the trial and were not known before the study. They point out that the parents were given sufficient information to make an informed choice about enrolling their babies in the study. They also point out that since the babies in both groups received care that fell within the spectrum of standard care, no baby was subjected to a higher risk during the course of the study. They argue that equating the risks associated with different modalities of treatment accepted under the standard care with the risks associated with randomisation creates confusion and undermines the value of comparative effectiveness research.

Drazen JM, Solomon CG, Greene MF. Informed consent and SUPPORT. *N Engl J Med*. 2013 May 16;368(20):1929-31. Magnus D, Kaplan AL. Risk, consent and SUPPORT. *N Engl J Med*. 2013 May 16;368(20):1864-5.

Setting the standard for rural practitioners

That India has a shortage of qualified medical practitioners working in rural areas is well known to the policy-makers. There is also a huge disparity in health indicators between the states and within the states. The authors point out that the presence of a strong private healthcare system is often not the remedy for a weak public healthcare system, as the services of the private sector are either not affordable to the poor or are of uneven quality. The majority of allopathic doctors practise in the urban areas, especially in the private sector. The authors express the view that insufficient posts in rural areas as well as the insecurity of contractual employment under the National Rural Health Mission (NRHM) are dissuading allopathic doctors from serving in the rural sector. The authors also highlight infrastructural deficiencies and other structural issues related to the lack of basic amenities in rural healthcare settings. They maintain that creating an unbalanced and biased structure, with rural practitioners with insufficient training for the rural areas and super specialists with advanced degrees to cater to the urban rich is an unjust one. The Licentiate Medical Practitioner (LMP) was one such system that has been done away with. They express the doubt that the rural practitioner

training of three years would be inadequate to equip the young practitioner with enough knowledge and skill to deal with cases in rural areas, where there is less support from technology and referral services. They argue that instead of creating a system with lower standards, the effort should be to sufficiently incentivise rural practice and also address structural issues associated with the rural centres.

Thayyil J, Jeeja MC. Issues of creating a new cadre of doctors for rural India. *Int J Med Pub Health*. 2013 Jan–Mar;3(1):8–11.

Conflict of interest in clinical practice guidelines

Treatment practices are guided by clinical practice guidelines, which in turn are based on expert opinions. The authors point out that the conflict of interest of these experts plays a significant role as the guidelines recommended by them will have an impact on the profits generated by the pharmaceutical companies. The study looks at the prevalence of conflict of interest and its under-reporting by the authors of the clinical practice guidelines in Denmark between July 2010 and March 2012. The authors looked at five guidelines each of those issued by the 27 Danish clinical specialty societies between July 2010 and March 2012; limiting their study to guidelines dealing with drugs and not procedures. 45 clinical practice guidelines satisfying the inclusion criteria were finally selected which had a total of 247 individual authors. The study revealed that 53% of the authors involved had conflicts of interest and that 96% of the guidelines had one or the other author who had conflict of interest. However, only one guideline had declared the conflict of interest of its authors publicly. The authors also found that only six societies provided manuals for the preparation of guidelines, with no society providing any instruction for the declaration of conflict of interest. The authors recommend a disclosure list with full financial information of the authors to help in maintaining transparency. They also maintain that disclosure will not eliminate bias and a more concrete step would be to include only those experts without any conflict of interest in the process of preparing a clinical treatment guideline.

Bindslev JBB, Schroll J, Gotzscge PC, Lundh A. Underreporting of conflict of interest in clinical practice guidelines: cross sectional study. *BMC Med Ethics*. 2013 May 3;14(1):19. doi: 10.1186/1472-6939-14-19.

Relevance of baby hatches

This article talks about the arguments raised for and against baby hatches in the Japanese context. A baby hatch is a place where mothers can leave their babies anonymously and the babies thus left are taken care of. First introduced in Germany, baby hatches are currently in place in 20 countries including India. In this paper, the authors discuss the major criticisms of the concept of baby hatches. These include denial of the baby's right to know the identity of his/her biological parents. The authors argue that forcing parents to reveal their identity might push them towards more extreme steps such as infanticide

or abortion thereby jeopardising the right to life; and that in such instances, the right to anonymity of the parent should be upheld in the best interests of the parent and the child. Another criticism is that it induces abandonment of babies for selfish reasons, which is countered by supporters of the facility stating that leaving the baby in the hatch is not exactly abandonment; and that its purpose is to protect the baby rather than leaving him/her unattended and uncared for. They also point out that often there are compelling reasons behind the decision to leave a baby in the hatch, including lack of family and societal support, single parenthood, poverty, mental disorders of the parent, etc. While the authors do not refute the fact that some may actually abuse the system of baby hatches, they believe that there are people who genuinely need such a support system. The authors also discuss the criticism that baby hatches compromise the right of one parent if the other parent decides to drop the baby without the partner's consent and that it puts the child's life in peril. However, they argue that there is a need to distinguish between hardships arising exclusively due to the presence of baby hatches, and those which are more general in nature. They also point out that legal ambiguity alone cannot be a justification for terminating the service of baby hatches; and that societal realities should be taken into consideration while deciding on the future of such services.

Asai A, Ishimoto H. Should we maintain baby hatches in our society? *BMC Medical Ethics* [Internet]. 2013 Feb 22[cited 2013 May 30];14:9. Available from: http://www.biomedcentral.com/1472-6939/14/9

Hiring policies related to smoking

The practice of not hiring smokers as employees is becoming increasingly prevalent, especially in organisations in the health sector. The authors agree with 65% of Americans who through a poll expressed their dissatisfaction with such hiring policies and state legislations that considerably reduce employment opportunities for smokers in such environments. Organisations such as the World Health Organisation (WHO) have taken the stand that their hiring policy is in alignment with their commitment towards tobacco control and that their employees are expected to act as role models for patients. Another argument in favour of not hiring smokers is that they should be taking responsibility for the extra burden placed by them on other employees and employers. The authors argue that such practices are counterproductive, since they place an extra burden on the already disadvantaged population, and jeopardise other more effective methods of quitting smoking. They point out that these very same health organisations strive hard to care for patients whose ill health can also be attributed to their behaviour. They point out that a smoking habit often starts early and becomes addictive and soon the individual loses control over the habit. They refute the financial argument by pointing out the high cost of care, absenteeism and burden associated with many other conditions which could also be the result of simple lifestyle choices. They argue that since the prevalence of smoking is higher among the unemployed and less educated groups, the discrimination in hiring based on

tobacco use adds to their already existing burden and stigma. The authors opine that more positive measures should be employed to assist employees who smoke to quit smoking rather than discriminating and not hiring them in the first place.

A counterargument is that such restrictive policies are for the common good and that in the long run they have a positive effect on the same population that would have felt disadvantaged in the first place. Another article cites the example of the Cleveland clinic which stopped hiring nonsmokers in 2007, and the county where the clinic is situated showed a higher percentage of reduction in smoking rates when compared to the whole state. They maintain that harsher steps become inevitable when gentle interventions fail to produce the desired result.

Schmidt H, Voigt K, Emanuel EJ. The ethics of not hiring smokers. *N Engl J Med.* 2013 Apr 11;368(15):1369–71. Asch DA, Muller RW, Volpp KG. Conflicts and compromises in not hiring smokers. *N Engl J Med.* 2013 Apr 11;368(15):1371–3.

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