The necessity of booster vaccination after neonatal hepatitis B vaccination

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Soon after introducing recombinant hepatitis B virus (HBV) vaccine, universal neonatal vaccination became the cornerstone of the preventive measures for this potentially life threatening infection (1-3). By 2006 more than 177 out of 193 member states of world health organization (WHO) introduced HBV vaccination in their national infant immunization programs (1). Following a complete series of vaccination during neonatal period, protective antibody level raises in more than 95% of infant’s blood test up to 18 months after vaccination (3-5). The effectiveness of this strategy has been shown by several investigators in reducing the incidence of HBV carrier rate and probably cirrhosis and hepatocellular carcinoma (1, 2, 5-7).

A level of 10 IU/L of anti hepatitis B surface antibody (Anti HBsAb) is usually considered as a protective level against future infections. Although this level was initially determined in studies about passive prophylaxis of HBV infection, the same level was arbitrary applied to active immunization though this was debated by some researchers (8-10). Universally there is a consistent decline in antibody titer over time. The reported rate of persistent protective level of Anti HBsAb titers varied from 33% up to 79%, at least 5 year after vaccination (10-14).

Currently about 21% of worldwide HBV related mortalities are linked to the vertical transmission, and the other depends on unsafe injection and high risk behavior that causes more concern of long lasting immunity extending to adolescent and even adulthood (1, 2, 5).

Tosun et al. (15) in a published article in Hepatitis Monthly reported that the protective level of antibodies 9 years after neonatal vaccination was roughly near 50% in children from Turkey (15). Although the authors of the mentioned study have checked the health records and enrolled only those received complete vaccination, there were still many infants who did not receive vaccination appropriately. So, there was a wide variation of utilization of HBV vaccination both within and between countries.

The coverage of complete vaccination of infants against HBV was estimated 69% in 2008 worldwide (1, 5) while this rate for neonatal received vaccination within 24 hours after birth was about 27% globally with a wide variation among countries (3-71%) (1, 5). Later immunization may leave the neonates vulnerable to possible transmissions both horizontally (e.g. within the health services or through household contacts with infected family mem-

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Implication for health policy/practice/research/medical education:
Since HBV prevention and need assessment for its vaccination has high priority in each population, we decide to draw reader’s attention towards this issue.

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bers) and vertically (2, 8, 9) that leads to WHO recommenda-
tion regarding implementation of neonatal vaccina-
tion against HBV within the first 24 hours of life (5, 9).

Some problems such as maintaining cold chain in
transportation and handling of vaccine, improper in-
jection and other technical problems in this context are
still real challenges in many countries making effective-
ness of vaccination, like HBV which need a stable cold
chain, lower than expected in real practice (2, 5, 8, 9). For
instance a recent study from Mongolia mentioned that
the HBV incidence rate after 7-12 years of vaccination was
more than two times in rural infants who received HBV
vaccination in winter compared to other seasons (16)
which probably is related to vulnerable cold chain. Some
studies showed that those who were born of infected
mothers specially mothers with higher HBV DNA level
have lower rate of vaccination response (17, 18). Accord-
ing to available studies on HBV screening during pregnancy
in Turkey, 2.1-12.3% of Turkish women infected with HBV in
different geographic locations (19-21). The status would
be probably much higher if Anti HBC Ab was measured.
In Tosun’s study only two children were HBsAg positive
(0.15%). There would be a concern whether a proportion
of non-responders have been born to HBV infected moth-
ers and were infected vertically. There is also possibility
of being infected horizontally in early childhood.

The HBV infection rate in children received vaccina-
tion after determining by Anti HBC Ab positivity might be
as high as 0.5% (11). The impacts of childhood infection
probably would not be high in the population studied
by Tosun although in her study Anti HBC Ab status of chil-
dren were not evaluated.

Tosun et al. also reported lower protection rate in lower
socioeconomic groups compared to middle and high
classes and in those who were delivered in health insti-
tution versus those who were delivered elsewhere. There
are many reports on high prevalence of HBV carriers (1,
2, 5, 9) and few HBV vaccination (9, 22, 23) among lower
socioeconomic groups. But we are not informed of any
previous reports showing the lower response rate to HBV
vaccine in lower socioeconomic classes. There could be
many confounding factors including malnutrition, con-
comitant diseases or even receiving vaccine in bad tech-
niques such as inappropriate handling of vaccine includ-
ing stable and sustained the cold chain (8, 9, 16, 24, 25).
This issue needs to be confirmed in larger studies and
needs to be analyzed in more details to find the possible
etiology of such difference.

After all we still confront with this major question: How
long the protective effect of neonatal HBV vaccination
persists? Is there a need for booster after complete series
of vaccination? If so when this booster should be admin-
istered and to whom? Should it be universal like the neo-
natal vaccination itself or only be given after monitoring
or given only to selected groups?

Answer to these questions is not easy and there are
contradictory evidences in the literature. The debate is
whether the reduction in antibody levels is indicating
lower immunity or not. An anamnestic response may
occur when people who were previously immunized
against an antigen are re-exposed to the same antigen (9,
10, 26). How can we be sure that the same would not be
happened to the children when they re-exposed to the
virus? The persistence of specific B cell population com-
mitted to antibody production against HBSAg has been
shown years after vaccination (26). In a recent report
from Taiwan, researchers have shown that after 20 years
post vaccination the immune system memory is lost in
up to 80% of vaccines (27). As with all experimental stud-
ies it would be debatable to apply this laboratory based
study to real practice specially considering other contra-
dictory studies (9-12, 28, 29). A recent Cochrane review
was not able to identify any randomized study to assess
the benefit of booster vaccination in prevention of HBV
(30).

The same group reported the rate of breakthrough
infection among vaccines was less than 0.1% (31). Even
chronic infection may not develop in those patients if
they have completed their HBV vaccine series. They also
concluded the protection provided by complete series of
monovalent HB vaccine persists for at least two decades
in the vast majority of general population and they
found that there was no evidence of need for booster vac-
cination, although they recommended further studies to
assess the need for booster in different subgroups (31).
In conclusion we still do not have enough evidence
to recommend universal booster vaccination. None of the
international guidelines for HBV vaccination currently
recommend booster dose (1-3, 5, 8, 9). Probably in some
high risk groups this might be of real concern though evi-
dence for this recommendation does not exist. We need
more detailed long term studies to change our current
recommendation of no need for booster vaccination.

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