

Historical shifts in other vaccination programs – hepatitis B

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Disclaimer

My university receives support from industry to run our HPV, HBV and AIB prevention and control board meetings

content

- Definition
- History
- Facts
- Way forward

Thanks to Marc Kane



Immunization programmes: definition - semantics

- Universal routine
- Target risk group

Universal immunization program

- = reaching a whole age cohort
 - E.g. newborns, infants, school children, 65+
- Usually free of charge
- Often through tender to obtain best price for vaccine
 - No free choice for parents
- Successful when offered by well baby clinics, GP,
 pediatricians, school doctors, structured healthcare, ...
- Follow a certain schedule for infant immunization programs = more a standard
 - 2 plus 1 or 3 plus 1
- Better guarantee for higher coverage



Immunization programs

- Universal immunization program
 - Targeting one age cohort
 - National/regional implementation
 - High coverage
 - Standard
 - Target easy to reach
- Risk group immunization program
 - Targeting risk groups groups with common risk behaviour:
 - Occupational risk health care providers and hepB vaccine
 - Elderly and influenza vaccine
 - Pregnant women andd pertussis vaccine/influenza vaccine
 - •
 - More difficult to reach the target



What kind of HBV immunization programme is recommended?

Starting in Western world – 80ies

- Knowledge about safe blood supply and exposure prevention
- Since 1981 safe and effective vaccine was licensed and available; sustained vaccine supply in place; vaccine is affordable; delivery system in place
- Recommendation for vaccination of people at risk



What happened

- This strategy failed. No impact on morbidity and mortality of hepatitis in spite of all available vaccines
- VHPB became a driving force to change the strategy towards infant universal vaccination
- Monitoring of compliance
- Addressing constraints and hazards



Advocacy through Viral Hepatitis

HIGH-RISK STRATEGY IS FAILING

Dr Mark Kane outlines the inadequacies of selective hepatitis B vaccination programmes

The epidemiology of hepatitis B in Europe, North America, and Australia is similar. Most infections occur in adult groups definable by lifestyle or occupation.

This was the historical basis for the 'high-risk strategy' in areas of low and intermediate hepatitis endemicity, aimed at groups such as those who might become infected sexually (including homosexual men and prostitutes), injecting/intravenous drug users (IVDUs), healthcare and other occupationally at-risk workers, and travellers

This strategy has failed for several reasons. At-risk workers represent a minority of total infections, yet most



Programme for Control of depatitis. ivision of Communicable Diseases, WHO, Geneva, Switzerland

effort and most vaccine was directed at

In many low endemicity countries sexual activity is the dominant means of hepatitis B transmission. It has proved difficult to target the homosex-

ual community successfully, and similarly efforts to deliver vaccine comprehensively to heterosexuals attending STD clinics have failed.

Attempts to reach IVDUs have been the least effective for many of the reasons discussed on page 7. IVDUs are often infected before they become aware of the hepatitis B risk.

The last reason for the failure of the high-risk strategy is that a substantial minority of those infected fall outside the known risk factors. These 'unknowns' are a very difficult group to target and unless a high-risk strategy can reach them hepatitis B infection will continue to be a serious public health problem.

WIRAL HEPATITIS

PUBLISHED BY THE VIRAL HEPATITIS PREVENTION BOARD

facts Short - 1 - January 1996

THE CLOCK IS RUNNING,

1997: DEADLINE FOR INTEGRATING HEPATITIS B VACCINATIONS INTO ALL NATIONAL IMMUNISATION PROGRAMMES

Recommendations for universal vaccination policies for infants and young adolescents, the use of maternal screening and combined vaccines, and the need for education

Viral Hepatitis Vol 2 N° 1, 1994

1. Universal vaccination: the need for early cover

Universal childhood and early adolescent vaccination protects individuals from infection later in life, whether because of occupational risk, sexual activity or other behaviour such as intravenous drug use which poses a hepatitis B risk.

The sooner individuals are vaccinated against hepatitis B the better. Early vaccination protects individuals from childhood infection which results in high carrier rates and chronic disease. Chronic disease is associated with serious and fatal liver diseases such as cirrhosis and liver cancer.

Infant vaccination programmes: The Viral Hepatitis Prevention Board (VHPB) endorses the 1991 statement of the World Health Organisation's (WHO) Working Group on the Control of Viral Hepatitis in Europe which stated: 'The routine immunisation of infants and adolescents should receive the highest priority. Hepatitis B High-risk strategies plus universal vaccination should be integrated into vaccination: the routine infant immunisation programme in all countries."

The Board also supports recommendations made by the WHO Global Advisory Group of the Expanded Programme on Immunisation endorsed by the World Health Assembly in 1992: 'Hepatitis B vaccine should be integrated into the national immunisation programmes ... in all countries by 1997. Countries with a [low] prevaence may consider immunisation of all dolescents as an addition or alternative to infant immunisation.

Adolescent programmes should be directed at young adolescents before 2. Recommendations for he age of 13, and are appropriate in countries where there are structures and resources for delivery of vaccines to for hepatitis B markers exists, it should

The routine immunisation of infants and adolescents should receive the highest priority

young adolescents such as school health services.

Infant plus adolescent vaccination programmes: Combined universal early adolescent and infant vaccination programmes have been shown to have the fastest impact on reducing levels of hepatitis B infection. Vaccination of young adolescents can of course stop once the first group of individuals vaccinated as infants reach early adolescence.

High-risk group approaches have failed to control hepatitis B infection in the general popula-Adolescent vaccination programmes: tion. But it is good medical practice to protect individuals in these groups. Strategies aimed at vaccinating and changing behaviour in high-risk groups should therefore continue.

However, universal vaccination programmes are also needed to eliminate hepatitis B infection, even in areas of low endemicity, because high-risk strategies alone are clearly failing. Public health officials, healthcare providers and the public need to be aware of this and take action.

maternal screening

Where screening of pregnant women

continue, but any screening programme should cover all women rather than selected groups. Selective screening has been shown to miss many cases of hepatitis B.

The VHPB recommends that, within 12 hours of birth, babies born to carrier mothers should receive specific hepatitis B immunoglobin (HBIG) and the first dose of vaccine at another injection site.

Where effective maternal screening programmes do not exist, the VHPB feels that resources may be better directed towards a universal vaccination programme aimed at adolescents or infants, or both.

Combined vaccines

The VHPB supports efforts to add hepatitis B vaccine to existing childhood vaccines in combinations. However, it believes that universal hepatitis B vaccination of infants should not be delayed until such combined vaccines are available. The introduction of these combined vaccines may take

4. Raising awareness about the dangers of hepatitis B

The VHPB recognises the importance of raising the awareness of healthcare providers, health policy makers and the general public (especially parents) about the dangers of hepatitis B as a community health risk and the need for preventive measures - the most important of which is universal vaccination. It aims to produce and support educational initiatives targeted at these groups.

1. World Health Organisation. Control of Viral Reparitie in Europe. Report on a WHO Working Group, Munich. Germany, 22-25 April, 1991.

2. Expanded Programme on June Spinisation, Report on the 14th Clobal Advisory Group. Antalia, Turkey, 14-18 October, 1991.





Introduction of Hep B vaccine

- Initial strategy to immunize "high risk" groups failed (except for HCW's)
 - Depended on knowledge and action of 10's of thousands of individuals
 - No guaranteed funding
 - Stigma of some risk groups
- In general "high risk" strategies are not very effective (flu, adult pneumo)
- Realization that only "routine" funded immunization would have impact on HB disease even in industrial countries
- Cost (~ \$50/ 3 doses) prohibited consideration of public health use in developing world

Key Implementation Steps

- Demonstration projects establishing efficacy in developing countries: Taiwan, Senegal, Gambia, Thailand, Indonesia
- International Task Force on Hepatitis B Immunization: demonstration projects and transfer of vaccine technology to Korea
- Reduction in price making it affordable for the developing world.
- Global strategy change from "high risk" mostly adult groups to universal immunization of young children
- WHO recommendation in 1991 that all children receive Hep B vaccine
- GAVI founded in 2000 and includes Hepatitis B vaccine for all eligible countries
- VHPB instrumental in European policy and introduction

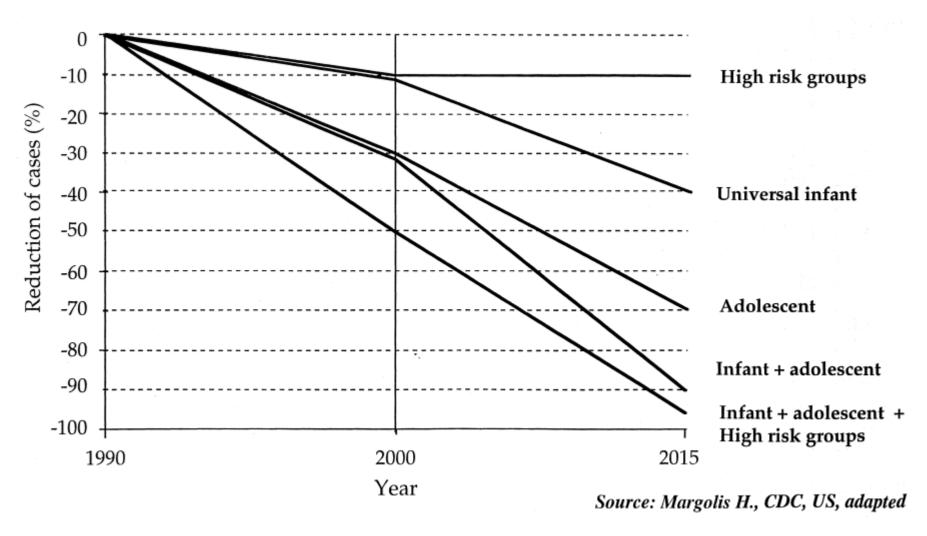


Fig. 3. Estimated proportion of cases of hepatitis B prevented, based on different vaccination strategies.

Hepatitis B Vaccine Timeline

- 1982: Hepatitis B vaccine licensed for use
- 1992: WHA resolution 45.17 called for member states, "...to integrate hepatitis B vaccine, into national immunization programs ..."
- 1992: WHO recommended that all countries integrate hepatitis B (HepB) vaccine into national immunization programs by 1997

Integration of hepatitis B vaccination into national immunisation programmes

Pierre Van Damme, Mark Kane, André Meheus on behalf of the Viral Hepatitis Prevention Board

Summary

Hepatitis B is a major public health problem even though safe and effective vaccines have been available for over 10 years. Because hepatitis B infection is largely asymptomatic with long term complications occurring after many years it has not received the

attention it deserves. Strategies to immunise those at high risk have failed to control the disease. Delegates to the World Health Assembly of the World Health Organisation recommended in May 1992 that all countries should integrate hepatitis B vaccination into their national immunisation programmes by 1997.

Some western European countries remain unconvinced that the burden of disease warrants the expense of universal vaccination. However, epidemiological data and economic evaluation show that universal hepatitis B vaccination is cost effective in countries with low endemicity and that it will control hepatitis B, reinforcing the necessity for action.

Size of the problem

More than one third of the world's population are estimated to have been infected with hepatitis B virus. Most have recovered, but there are around 350 million chronic carriers of the hepatitis B virus, about 5% of the world's population. About a quarter of these carriers will develop serious liver disease, including chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma. The World Health Organisation estimates that hepatitis B infection results in more than one million deaths every year worldwide. 1-3

Based on the prevalence of carriers of hepatitis B surface antigen in the general population, countries

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BMJ VOLUME 314 5 APRIL 1997

High risk strategies

Although safe and effective hepatitis B vaccines have been available for over 10 years, universal vaccination is still being postponed in many countries. One reason is the weakness of our social commitment to preventive medicine and vaccines.⁵ Important also is the lack of medical and public awareness: the public does not perceive hepatitis B as a threat to the population at large, and governments, expected to respond to public demand, have not considered hepatitis B prevention as a priority and have opted for selective prevention strategies. Although the incidence of hepatitis B infection has decreased in many countries as a consequence of behavioural changes secondary to the AIDS epidemic, experience has shown that targeting hepatitis B vaccine at high risk groups and screening pregnant women do not work. Such strategies, which have been used in countries with low endemicity since 1982, have failed to control hepatitis B for various reasons¹ 6: most high risk groups are difficult to access, there is a lack of perceived risk among those at risk, and over 30% of those with acute hepatitis B infection do not have identifiable risk factors. In some countries with low endemicity universal antenatal screening for hepatitis B is not well implemented, and even when used selective antenatal screening failed to identify about half of the pregnant women whose neonates were at risk.78

Except in a few countries the high risk strategy has resulted mainly in the immunisation of healthcare workers and some categories of patients—for example, those receiving haemodialysis, transplants, and multiple blood transfusions of widt hepatids & infection. About 85% of vaccine has gone to the healthcare workers, who account for only 5 to 10% of reported cases of hepatitis B infection in most European countries and North America. While healthcare workers should certainly be immunised, this high risk strategy will not control hepatitis B on a population basis.

Need for universal immunisation

The failure of the high risk immunisation strategy and a better knowledge of the burden of disease have emphasised the necessity for action to control the risk of acquiring hepatitis B in the community. In 1991 the global advisory group of the Expanded Programme on Immunisation recommended integration of hepatitis B vaccine into all national immunisation programmes.

The deadline for countries with a prevalence of carriers of 8% or more was 1995 and for other countries was 1997.^{2 3} This recommendation was endorsed in May 1992 by the World Health Assembly, the governing body of the WHO. In 1994, the World Health Assembly added a disease reduction target, calling for a 80% decrease in the incidence of new hepatitis B virus carriers in children by 2001.

- -difficult to access
- -lack of perceived risk
- -more than 30% of acute hepatitis B no identifiable risk
- -stigmatisation
- -no major public health impact

Conclusion

Emerging data on the long term effectiveness of hepatitis B vaccines, knowledge that infants and adolescents can be reached through already established vaccination delivery systems, and studies showing that these interventions are cost effective, indicate that hepatitis B virus can be controlled and eliminated by universal immunisation. The choice of whether to immunise infants or adolescents depends on each country's epidemiology and organisation of the vaccine delivery systems.

In future, combination vaccines containing hepatitis B will be used. Such vaccines will mean fewer injections; save on syringes, storage, transportation, record keeping, and training; and improve acceptance, integration into existing vaccination programmes, and harmonisation of vaccination schedules. However, countries should not wait for the arrival of combined vaccines before implementing universal immunisation.

In Europe much work remains to be done to implement interventions that will bring us closer to the WHO goal and to control hepatitis B in the community. Only a united effort by all those involved in preventive health care can ensure effective implementation of these important preventive measures.

Commentary: Antenatal screening and targeting should be sufficient in some countries

Philip P Mortimer, Elizabeth Miller

Central Public Health Laboratory, London NW9 5HT Philip P Mortimer Director, Hepatitis and Retrovirus Laboratory Communicable Disease Surveillance Centre, Public Health Laboratory Service, London Elizabeth Miller, Head, Immunisation Division Correspondence to: Dr Miller.

Van Damme and colleagues criticise some European countries for failing to integrate hepatitis B vaccine into national immunisation policies as recommended by WHO. But does their analysis really apply to countries which, like Britain, have hepatitis B virus carrier rates as low as $0.3\%^1$ and report yearly incidences of acute infection of about $1/100~000?^2$ And is the inclusion of three doses of vaccine in infant schedules, or an attempt to deliver three doses to all adolescents, the most cost effective preventive approach for these countries? We doubt it and suggest that at present it would be preferable to concentrate on reinforcing existing strategies.

The most important step is to stop maternal transmissions of hepatitis B virus, with their high risk of long term carriage developing in the newborn. Thus, in Britain the Departments of Health advise that "antenatal clinics should ... consider offering [HBsAg] screening to all antenatal patients" and that neonates born to positive mothers should be fully immunised. Even if, as Van Damme et al suggest, there was a universal immunisation programme for infants, those born to women infected with hepatitis B would still have to be identified and immediately given hepatitis B immunoglobulin or vaccine, or both, at birth, with at least two further doses of vaccine. This intervention has been shown to prevent 90% of maternal transmissions and universal infant immunisation would merely be a supplement, not an alternative, to it.

Unfortunately only a minority of pregnant women in Britain are currently screened for hepatitis B surface antigen despite government advice. Moreover, the proportion of infants thereby identified who complete the three dose vaccine schedule is disappointingly low. Infants to whom the Public Health Laboratory Service Communicable Disease Surveillance Centre issues hepatitis B virus immunoglobulin are all followed up, and reminders are sent to the paediatrician or general practitioner to ensure that the second and third doses of vaccine are given. Nevertheless, of 2514 infants followed up between 1987 and 1995, only 1633 (65%) received all three doses. Failure by the hospital to inform the general

practitioner that second and third doses are required, poor understanding of the need for immunisation by parents (many of whom are immigrants with English language difficulties), and lack of an identified individual with local responsibility for the programme seem to be contributing factors. In Connecticut, United States, by contrast, completion of the three dose course has increased from 48% to 91% since dedicated nurses were appointed to implement the neonatal programme, and a computerised tracking system has been used to identify impending births to carrier mothers and the need for follow up doses of vaccine.⁴

Full implementation of the rest of the existing British immunisation strategy would, by protecting more of those at identifiable risk, prevent many of the remaining virus transmissions. It should be actively promoted in clinics and in the primary care of groups at risk and by counselling known carriers and immunising their contacts. Those known to have antibody to hepatitis C virus who lack markers for hepatitis B virus should also be immunised. Admittedly, it is not easy to deliver full courses of vaccine, but there has been partial success. The falling incidence of reported acute hepatitis B infections in England, Wales, and Scotland over the past 10 years are a be attributed to the vaccination policy as well as to changes in sexual behaviour and intravenous drug abuse.

Global strategy is inappropriate

Countries with a low incidence or prevalence of hepatitis B should therefore not be bound by a global strategy that, for them, is inappropriate. Two recent studies in Britain have examined the likely cost effectiveness of universal immunisation, though both suffer from a lack of accurate information about the age specific incidence of infection and the proportion of overt to cryptic infection. These uncertainties have led to substantially different cost benefit calculations. Mangtani *et al* suggested that supplementing the existing selective strategy by universal infant or adolescent immunisation would improve cost effectiveness, but Fenn and colleagues remain sceptical. The assump-

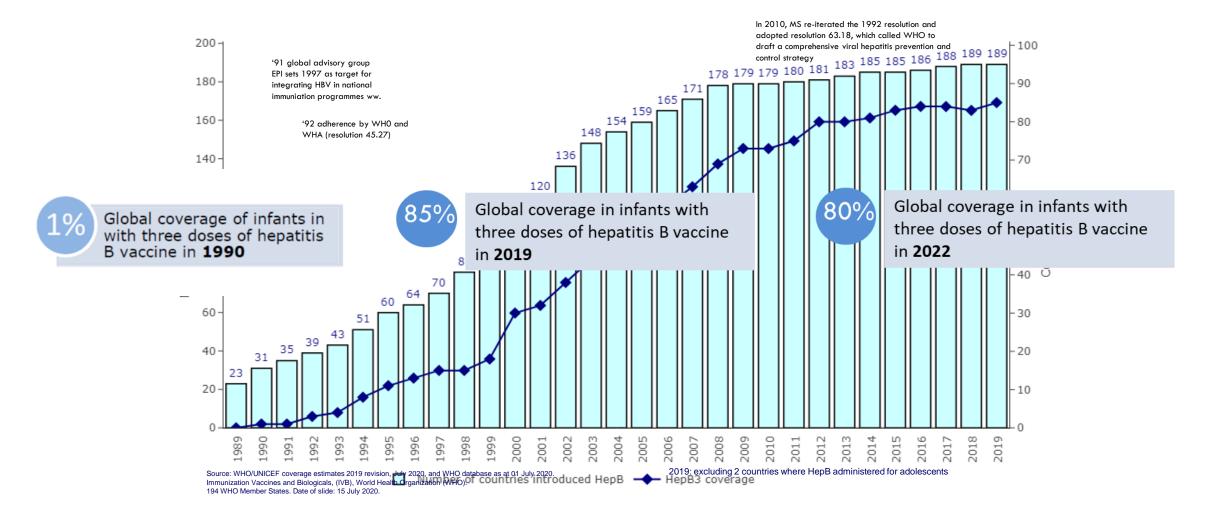
Hepatitis B Vaccine Timeline

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- 1992: WHO recommended that all countries integrate hepatitis B (HepB) vaccine into national immunization programs by 1997
- Early 2000's: GAVI milestone, that by 2007, all countries with adequately performing immunization systems should have integrated hepatitis B vaccine into their national programmes.

The GAVI Alliance and Fund

- Major source of funding for 72 poorest countries
- Now has ~\$ 7 billion committed over next 10 years
- Most countries introduced Hepatitis B vaccine and safe injections, some Hib and YF
- Coverage up significantly in most countries –Many African countries up from 40% to ~ 70%
- Developing country manufacturers now making DTP-HB and DTP-HB Hib and AD syringes
- Now introducing Rotavirus and Pneumo Conjugate
- Deciding this week on HPV and others
- Needs to balance investment in new vaccines with infrastructure development and "health system strengthening"

Number of countries having introduced Hepatitis B vaccine and global infant coverage for Hepatitis B 3rd dose (HepB3), 1989-2019





Hepatitis B Vaccine Timeline

- In 2010, Member States re-iterated the 1992 resolution and adopted Resolution WHA63.18
 - which called WHO to draft a comprehensive viral hepatitis prevention and control strategy,
 - including universal hepatitis B immunization programmes and development of time-specific immunization goals.
- In recognition of the public health issue the World Health Assembly has designated July 28 as World Hepatitis Day.

Repeated messages in scientific papers





Ped1

Review

A cohesive European policy for hepatitis B vaccination, are we there yet?



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Damme^{1,2}

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in countries with medium and low prevalence, is a priority. There is no reason why hepatitis B should not follow the success of smallpox, polio, diphtheria and measles vaccination.



Lessons learned from Hepatitis B

Vaccine 27 (2009) 1254-1260



Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine



Model based analysis of hepatitis B vaccination strategies in the Netherlands

Mirjam Kretzschmar^{a,b,*}, Marie-Josee Mangen^b, Marita van de Laar^c, Ardine de Wit^{b,d}

- Risk groups were targeted for vaccination
 - Children of whom at least one parent was born in endemic country
 - Men who have sex with men
 - Heterosexuals with high rates of partner change,
 - Commercial sex workers
 - People who inject drugs

But these risk groups are very hard to identify



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Vaccine





Model based analysis of hepatitis B vaccination strategies in the Netherlands

Mirjam Kretzschmar^{a,b,*}, Marie-Josee Mangen^b, Marita van de Laar^c, Ardine de Wit^{b,d}

Conclusion of this study

 Universal vaccination has by far the largest impact on incidence at the cost of having to vaccinate large number of children, of whom the majority run little risk of ever being exposed to the hepatitis B virus.



BMJ 2013;346:f4057 doi: 10.1136/bmj.f4057 (Published 10 July 2013)

HEAD TO HEAD

Should Europe have a universal hepatitis B vaccination programme?

WHO recommends that hepatitis B virus should be included in childhood vaccination programmes. **Pierre Van Damme and colleagues** argue that universal immunisation is essential to stop people becoming carriers but **Tuija Leino and colleagues** think that a targeted approach is a better use of resources in countries with low endemicity

Problems of targeted vaccination

Reliance on vaccination of groups at high risk of infection is seldom as effective as universal vaccination and is more difficult to implement. Considerable effort is needed to identify and reach people in the high risk groups— men who have sex with men, commercial sex workers, heterosexuals with multiple partners, and injecting drug users. ¹⁰ Many are not identified until after they are infected, with median age at first vaccination around 30 years. 10 Uptake is also a problem, with figures of less than 60% for the first dose in sex workers, 11 12 less than 50% in men who have sex with men,¹³ and less than 30% in injecting drug users. 10 14 In addition, over half of acute HBV infections in industrialised countries occur among people outside the risk groups, so targeted programmes will not prevent many infections.¹ It is therefore not surprising that a focus on men

who have sex with men and other risk groups has been shown not to control countries' transmission rates. 10 15

A targeted approach also requires effective programmes to prevent perinatal HBV transmission, and these do not seem to be implemented effectively even in industrialised countries.¹⁶

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Hepatitis B vaccination

Risk group approach versus universal vaccination

policy	
Risk group vaccination	Universal vaccination
 Individual risk perspective Difficulty of accessing high risk groups No identifiable risk among 50% of acute HBV patients in industrialized countries Infections often acquired before risk is recognized Often low completed schedule coverage Negative social stigma So far, programmes targeting risk groups failed to eliminate HBV circulation 	 Global approach More easy to implement through existing structures and use of combination vaccines Protection of future risk groups Optimal coverage Cost-effective in low to high endemic setting Impact on HBV control and endemicity
	Source: Van Damme et al. BMJ 2013;346:f4057



Lessons learnt from adult immunization programmes

Influenza, pneumococcal coverage, ...

- Different recommendations per country
- Cost
- Healthcare strcuture to reach adults access issue
-

Point of view of the vaccinator:

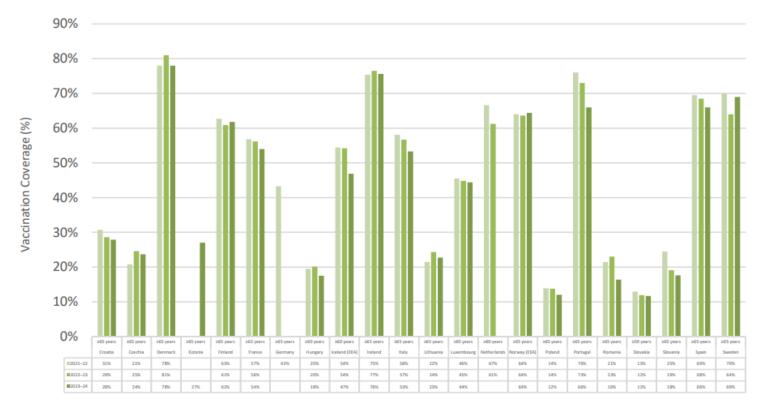
- Targeting an age cohort is feasible
- Checking age, risk factors, medication, ...: = threshold to discuss/offer vaccination
 - Average of 17% coverage pneumococcal vaccine in adults in Belgium (last 10 years)



challenge 2 = Are older adults getting vaccinated?

Seasonal influenza

Figure 2. Seasonal influenza vaccination coverage rates in older adults, EU/EEA countries, influenza seasons 2021–22, 2022–23 and 2023–24



Source: 2024 ECDC Influenza Survey in EU/EEA countries.

EEA: European Economic Area.

VCR data was collected via an administrative method for Croatia, Czechia, France, Hungary, Ireland, Italy, Lithuania, Luxembourg, Slovakia, Slovenia and Spain. Denmark, Iceland, Norway, Poland, Portugal and Romania used electronic immunisation registries. The Netherlands used a combination of administrative and survey methods. Germany's data came from health insurance claims. Bulgaria provided absolute numbers, not presented in the chart, and used an administrative method.

For Portugal, note that 2023–24 coverage data is for those aged 60 years and above, following changes in the recommendation.

Hepatitis B: Lessons learnt

- Strategy to reach "high risk groups" protected individuals but no impact on transmission nor on public health.
- Move to universal immunization programmes targeting age groups in the community for hepB vaccination = newborns/infants/school children
- Define targets and objectives
- Incorporate the vaccine in existing programs (combination vaccines, mother and child care)
- Integrate vaccination in a control and elimination plan with screening/therapy
- Enhancing collaboration between stakeholders: within and with MOH, partners and civil society to strengthen advocacy, policy, programme implementation and monitoring for elimination and its validation
- Go for elimination of the pathogen if possible
 - Set up Regional and national elimination committees

