Vaccination program: governance and policy decision process in Malaysia

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Objective
Immunisation Program Malaysia

To protect people against diseases by ensuring accessibility of immunization services to every eligible person. These objective is driven by attributes of MOH's mission which are:

1. quality (quality and safe vaccine, services delivered based on best practice),
2. equity (no discrimination of race, religion, political belief, socioeconomic condition;
3. affordability (all childhood vaccination under the MOH services are given free),
4. efficiency,
5. technologically appropriate
6. and consumer-friendly.

Aims

a. To sustain high immunisation coverage. This include ensuring coverage for the unreached population.

b. To introduce new vaccines and new technologies related to immunisation.

c. To reduce the morbidity and mortality due to these vaccine preventable diseases and SDG 2030

Through:

- Capacity and capability building i.e. resources, training
- Strong monitoring and surveillance capacity

Government's commitment:

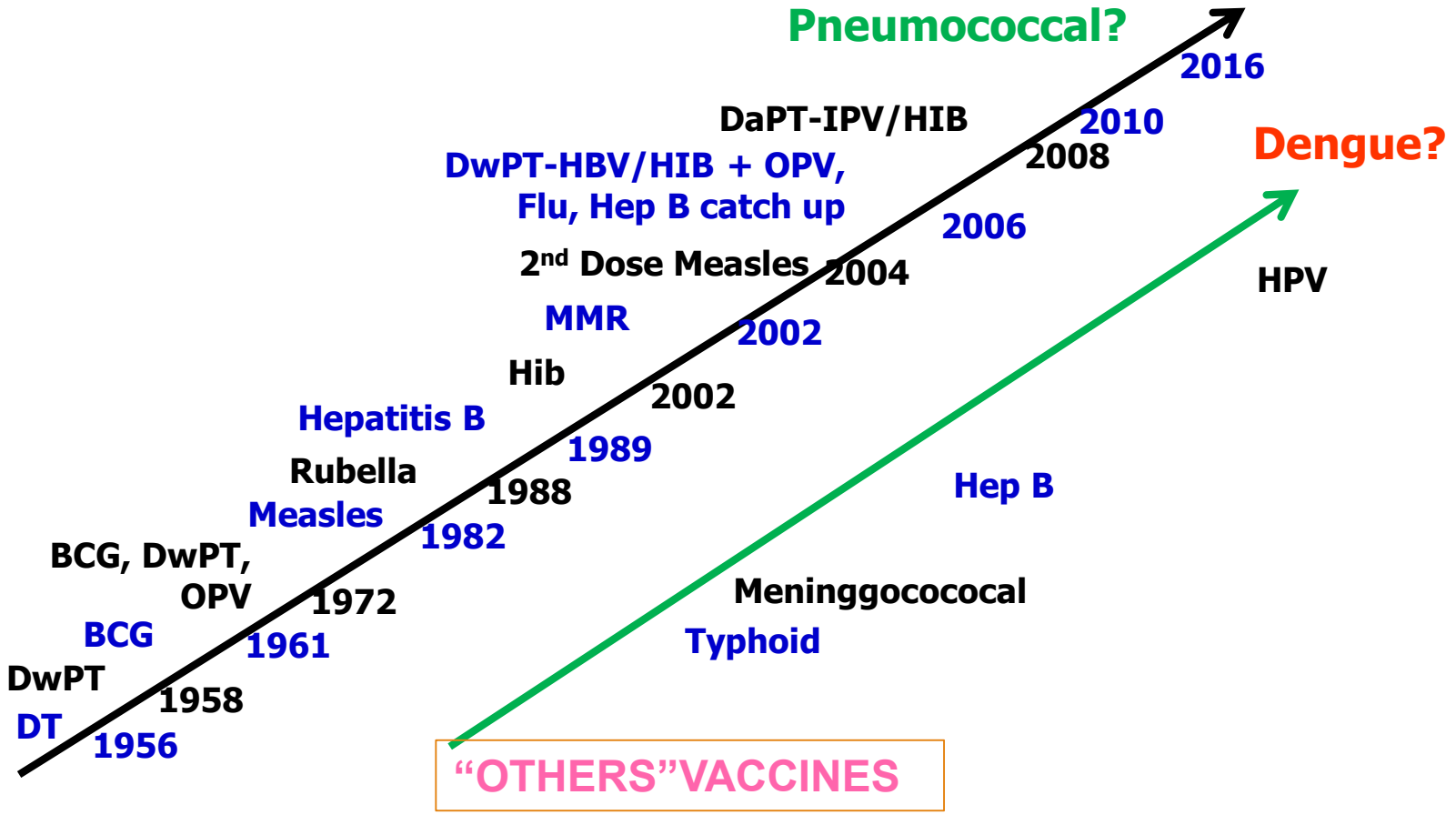
- Targets high immunisation coverage. Achieve Polio free status. Next is measles. All vaccination targets to achieve 95% and more.
- Childhood vaccination remains Government's priority.
  - The impact of immunisation program contributes to the reduction of under five mortality, even though more than 50% of the deaths were due to conditions originating in perinatal period, congenital malformations and chromosomal abnormalities.
- MOH has to ensure that the capacity is adequate and the capability is continuously developed, including laboratory capability to diagnose cases accurately and VPD outbreak response capacity.
- Strong surveillance capacity and monitoring system

Chronology of vaccine introduction in Malaysia

MORE THAN 20 MILLION CHILDREN HAVE BEEN IMMUNISED

VS

30 MILLION POPULATION



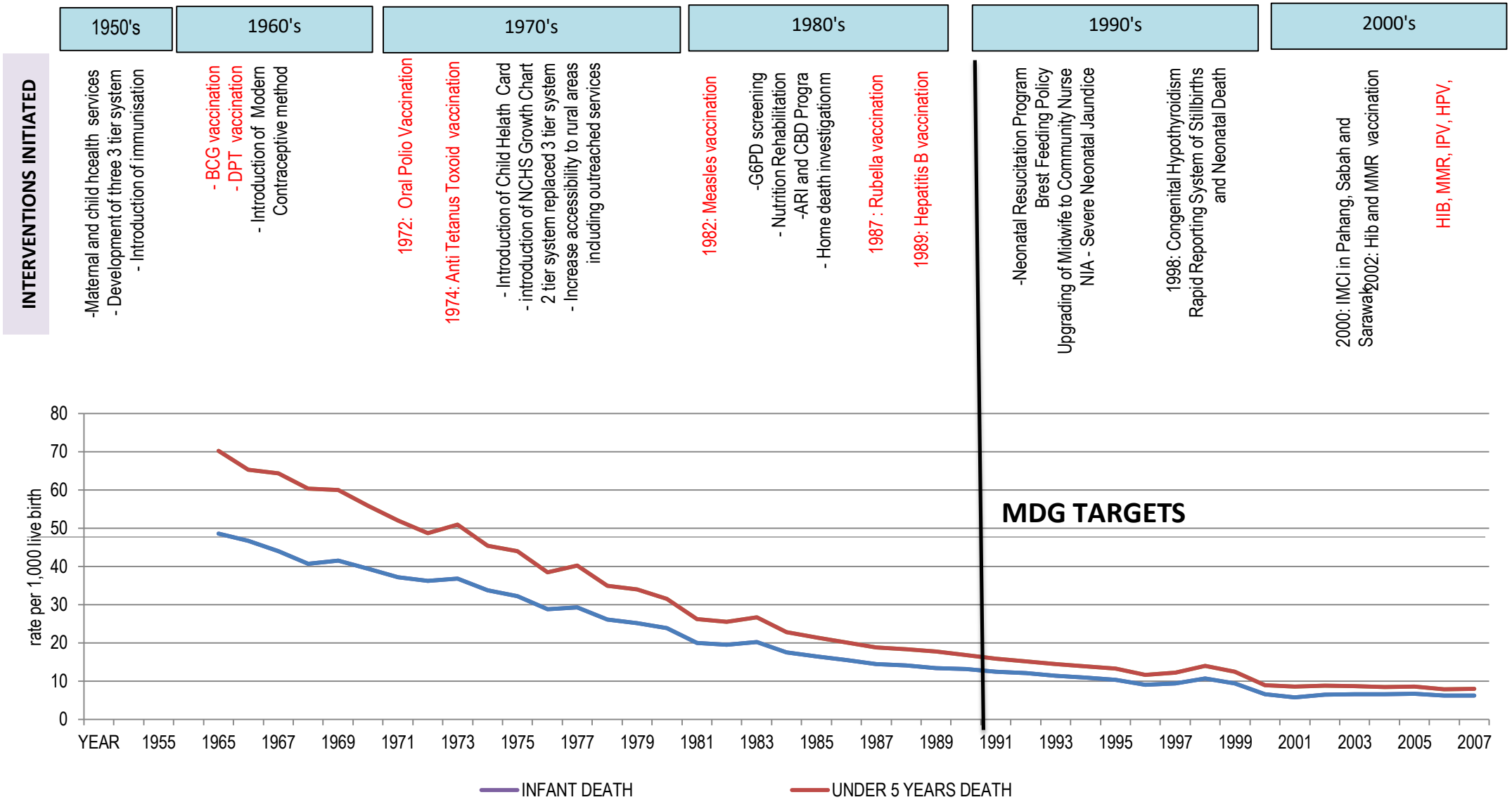
National Immunisation Schedule

VACC.	AGE (Month)											AGE (year)		
	0	1	2	3	4	5	6	9	12	18	21	7	13	15
BCG														
Hepatitis B														
DTaP														
Hib														
Polio (IPV)														
Measles														
MMR / MR								MMR	MMR			MR		
JE														
DT														
HPV													2 doses	
ATT														

MR at 7 years old will be discontineued in year 2022.

Primer dose Booster dose 2nd dose Sabah only

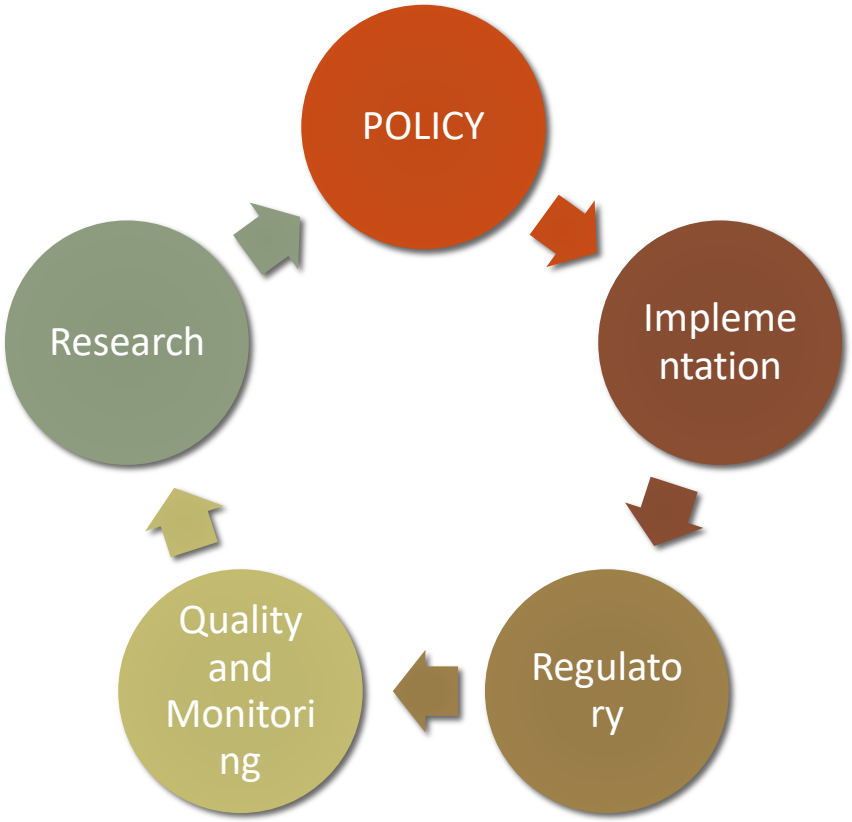
INTERVENTIONS AND TRENDS OF INFANTS AND UNDER 5 YEAR MORTALITY 1950 - 2016



Source: Family Health development Division

Approaches to introduction of new vaccines

1. **Disease burden assessment**; control and prevention plan/goals, efficacy,
2. Develop **strategy for service delivery**: advocacy, effectiveness and sustainability of program, procurement / supply, logistic / cold chain, training and supervision
3. **Monitoring and surveillance**: coverage, disease, AEFI
4. **Regulatory**: registration, vaccine safety, quality control.



POLICY: Disease Control Plan

1. Disease assessment & burden.
2. Disease control, prevention and eradication (disease control plan/goals, respond to emergency situation)
3. Immunisation performance, coverage, monitoring disease (evaluation)

Implementation

1. **Strategy of service delivery.**
   - Procurement / supply
   - Logistic / cold chain.
   - Advocacy
   - Vaccine quality / safety.
   - Training and supervision
2. **Management.**
   - Accessibility, Routine Immunisation.
   - New Vaccine/technologies.
   - Budget.
3. **Monitor Implementation.**

Regulatory Control

The National Pharmaceutical Control Bureau oversees the registration of new drugs including vaccines in Malaysia. Before a new drug can be marketed in the country, submission for approval experts committee review.

1. **Good Manufacturing Practice.**
2. **Safety of vaccine products.**
3. **Registration.**
4. **Vaccine Adverse Event Reporting System**.

http://www.pharmacy.gov.my/

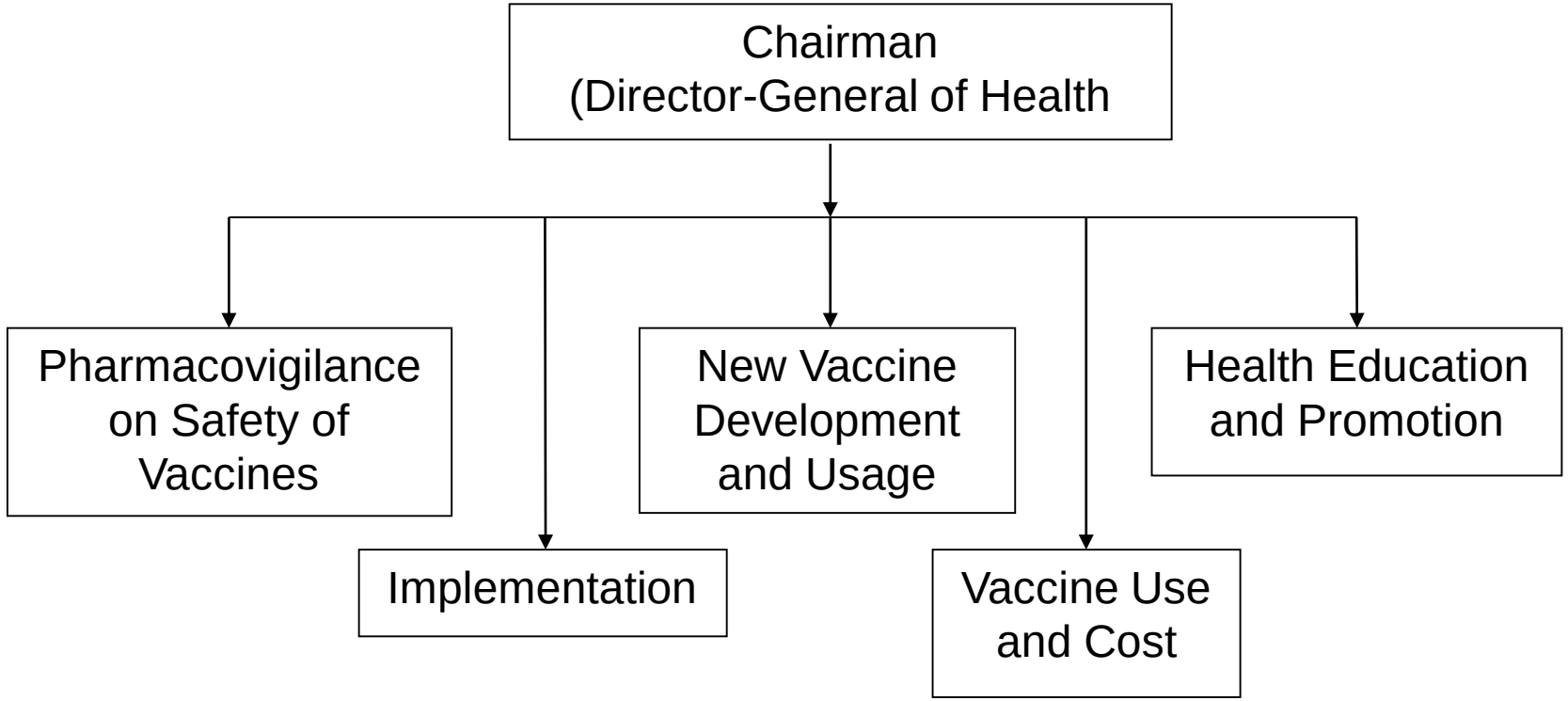
Quality Control & Research

1. **Quality Control Testing of Vaccine.**

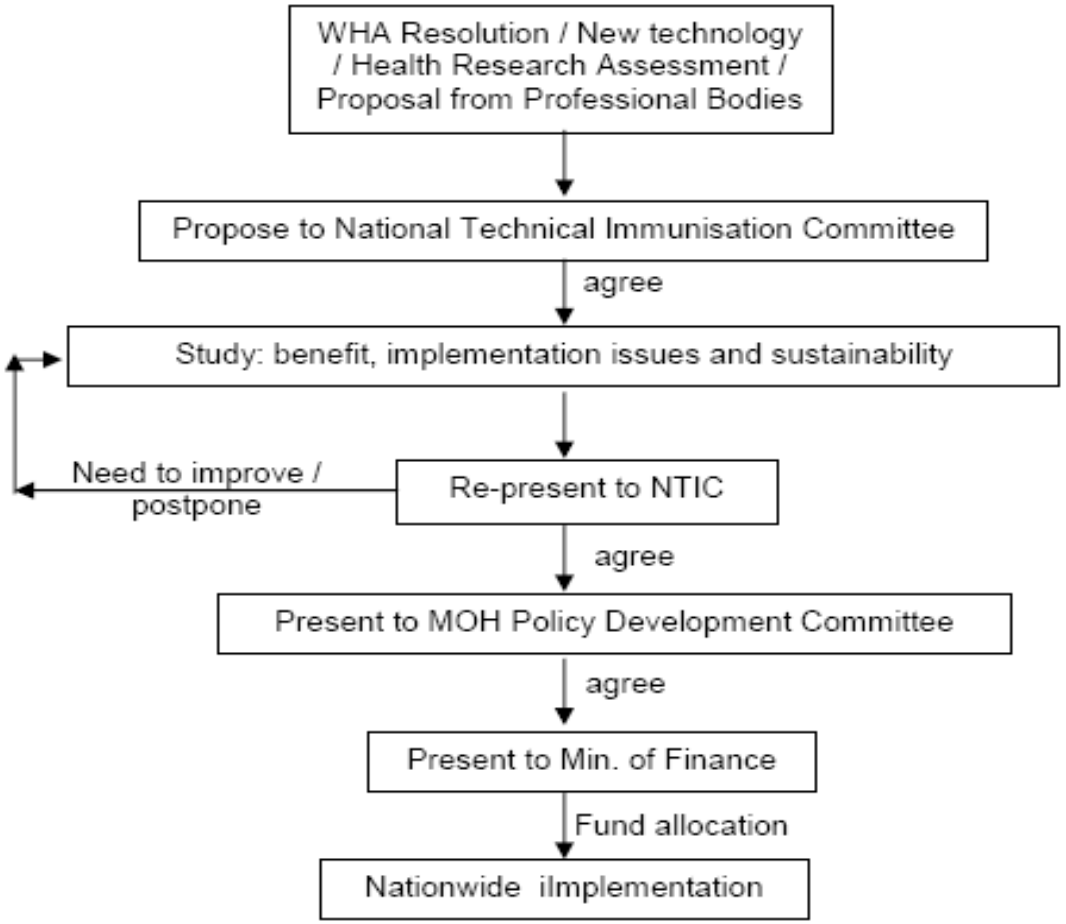
   (Live attenuated, Toxoid..etc)

2. **Vaccine research/development.**

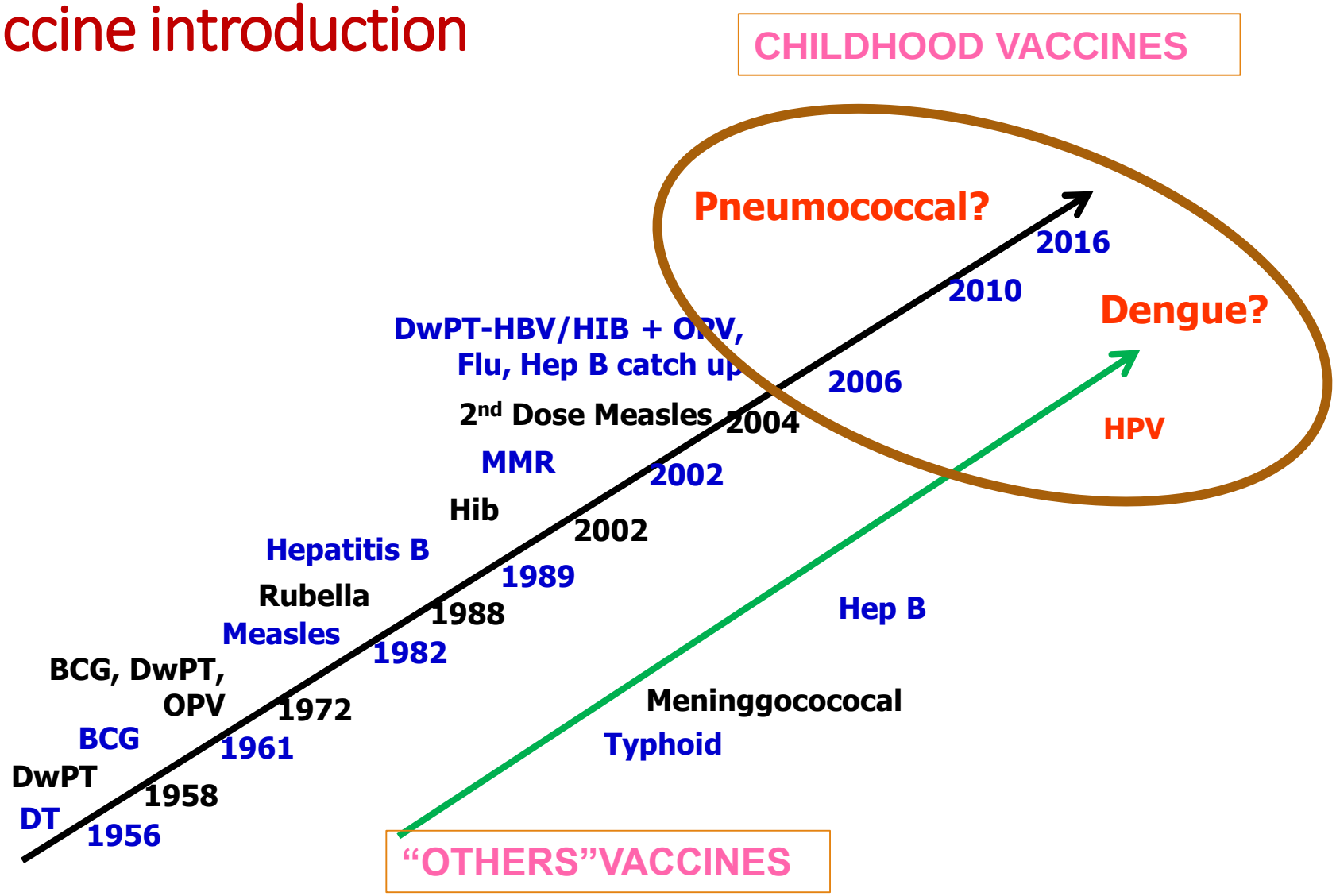
Committees involved with introduction of new vaccines



Flow Process on introducing new vaccines in National Immunisation Program



Chronology of vaccine introduction in Malaysia



Introduction of HPV vaccines – governance and decision process

HPV : Opportunities and Threats

OPPORTUNITIES / STRENGTH

Availability of vaccine

Energised medical and social experts

Strong lobbyist

Receptive members of Cabinet

Stable financial phase

Pervasive infrastructure

Easily integrated Health system

Thrust in the MOH

Tender price was “affordable”

Partnership between various ministries, NGOs, commercial sectors

THREATS/ WEAKNESSES

Anti-vaccine
- Religious matters
- “promiscuity”
- Other products

New delivery procedures
- Short window period in school
- Reaching out to schools in remote areas

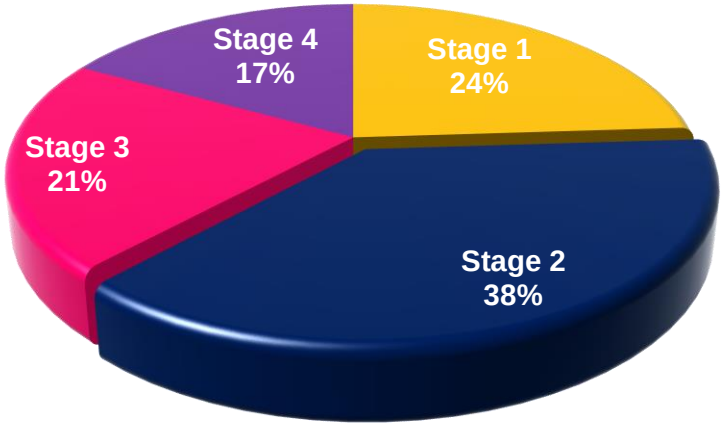
Aggressive social media

Availability of cytotechnicians and Gynae oncologist

HPV immunisation information system

Why HPV vaccination ?

Cervix, Uteri stage at diagnosis among Malaysian citizen 2008



Why HPV vaccination become part of Cervical Cancer strategy?

- Low Cervical smear uptake among high risk women
- Delay in seeking treatment
- WHO endorsed on safe HPV vaccine to prevent Ca Cx

	Ca Cervix	HPV Vaccination
Budget/ Target	**1,627 cases** (2003)	**266,000 girls (** 2009)
Cost	**RM 381.8 millions** RM 2.8 millions for pre invasive • RM 285 millions for treating new cases (invasive) • RM 94 millions for treating old cases	**RM 322.2 millions** Vaccine RM319.2 million • Additional Cost RM 3 millions (Health Education, Training and logistic
Cost/ person	**RM 234,665.02**	**RM 1,211.28**
Incidence	**19.7 /100,000 women-** unchanged	**8/1,000,000** (estimate vaccine efficacy at 98%)

Aljunid, 2007. HUKM

HPV : Decision Making and Planning

2006

- Family Health Development Division (Women Health)
- Disease Control Division (Cancer Unit)

- **Proposal for introduction of HPV vaccination as Cervical Cancer Preventive Measures**

MOH DRIVEN INITIATIVE

2007 - 2009

- Disease Control Division
- (Vaccine preventable disease unit)

- **Approval of vaccine use in Malaysia by National Vaccine Policy and Implementation Committee**
- **Cabinet Approval to finance HPV vaccination**
- **Vaccine procurement**

- Pharmaceutical Division

- **Licencing HPV vaccine into Malaysian market**
- **Monitor AEFI**

2010 onwards

- Family Health Development Division (School Health)

- **Execution of HPV vaccination policy**

- Health Education Division

- **Risk communication strategy**

HPV : Key strategies

GOAL: To reduce the incidence of Cervical Cancer related to HPV type 16 and 18 infection among immunized 13 years old girls over next 20 years.

Single type of vaccine utilization during one procurement cycle

- 2010/11 : Cervarix
- 2012 – 2016 : Gardasil
- Schedule : 0, 1, 6 month
- Shifted to 2 doses in 2015 (0, 6 month)

STRATEGY: delivered as part of the Cervical Cancer Prevention and Control Program and the Expended Program of Immunization (EPI)

OPERATIONAL POLICY: Free Voluntary School Based HPV Vaccination to Form 1 Malaysian girls

- High school attendants in Malaysia
- HPV vaccine as an additional vaccination to existing EPI program
- Availability of structured comprehensive school health program
- Strong commitment and support from Ministry of Education

HPV : Communication Strategies

Theme: HPV Vaccine as Cervical Cancer Vaccine

Media Campaign Based on Health Belief Model

1. Cervical cancer is preventable
2. Parental awareness on voluntary vaccination
3. Persuade girls to complete 2 doses of vaccination as scheduled

Public Access to Interactive Information

1. Social Media
   - HPV Facebook
   - HPV twitter
2. Phone Hot line
3. Email
4. Print and electronic advertisement

Rumours Surveillance and Program Monitoring

1. Response to media and public queries
2. Provide guideline to implementers
3. Monitor potential program threat and proposed counter measures

Addressing the religious and cultural aspect of the HPV vaccination

Leading to establishment of Fatwa or religious ruling on HPV vaccination for the Muslim.

Key Factors when introducing the HPV vaccine into the public health system

Finance	• Invest energy in negotiating the price… what's the final bid?
Coverage	• Who can be covered with these budget ? • How much of significant protection at the person level or population level?
Dissent	• Identify tricky areas and plan to overcome : what mechanism of intervention or engagement?
Marketing	• Plan for massive health education and buying in.
Implementation	• Data collection and analysis • Reap the results!

PNEUMOCOCOAL ?
&
DENGUE ?

RESEARCH PAPER

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Cost-effectiveness analysis of infant universal routine pneumococcal vaccination in Malaysia and Hong Kong

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Keywords: herd effect, incremental cost-effectiveness ratio (ICER), Markov transition-state model, pneumococcal disease, 13-valent pneumococcal conjugate vaccine (PCV13), 10-valent pneumococcal conjugate vaccine (PCV10)

Pneumococcal disease causes large morbidity, mortality and health care utilization and medical and non-medical costs, which can all be reduced by effective infant universal routine immunization programs with pneumococcal conjugate vaccines (PCV). We evaluated the clinical and economic benefits of such programs with either 10- or 13-valent PCVs in Malaysia and Hong Kong by using an age-stratified Markov cohort model with many country-specific inputs. The incremental cost per quality-adjusted life year (QALY) was calculated to compare PCV10 or PCV13 against no vaccination and PCV13 against PCV10 over a 10-year birth cohort's vaccination. Both payer and societal perspectives were used. PCV13 had better public health and economic outcomes than a PCV10 program across all scenarios considered. For example, in the base case scenario in Malaysia, PCV13 would reduce more cases of IPD (+2,296), pneumonia (+705,281), and acute otitis media (+376,967) and save more lives (+6,122) than PCV10. Similarly, in Hong Kong, PCV13 would reduce more cases of IPD cases (+529), pneumonia (+172,185), and acute otitis media (+37,727) and save more lives (+2,688) than PCV10. During the same time horizon, PCV13 would gain over 74,000 and 21,600 additional QALYs than PCV10 in Malaysia and Hong Kong, respectively. PCV13 would be cost saving when compared against similar program with PCV10, under both payer and societal perspective in both countries. PCV13 remained a better choice over PCV10 in multiple sensitivity, scenario, and probabilistic analyses. PCV13s broader serotype coverage in its formulation and herd effect compared against PCV10 were important drivers of differences in outcomes.

SUMMARY: Full Public Health Value of Vaccines?

1. Vaccination is the most effective means of controlling infectious diseases.
2. Making vaccination programme equitable, sustainable, efficient and safe : benefitted the poor to better health improvements
3. Successful implementation with strong advocacy, collaboration and commitment of all parties including public increase vaccination acceptance
4. Malaysia is receptive to introduce new vaccines :
   - *narrow health benefits*
   - *broad Non-Health Benefits*