Determinants of infant feeding practices and immunization status: a case study of the Philippines

Howard Sobel

Doctoral Thesis submitted to the Faculty of Medicine and Health Sciences, Ghent University

PhD Supervisor: Prof. Dr. Marleen Temmerman
Department of Obstetrics and Gynaecology, Ghent University
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Table of Contents

List of Figures. i
List of Tables i
List of Abbreviations and Terms ii
Acknowledgments v
EXECUTIVE SUMMARY vi

Chapter 1: INTRODUCTION 1

1.1. Causes of neonatal, post-neonatal and 1-4 year old child mortality 1

1.2. Lifesaving interventions for infants and young children, worldwide 4

1.3. Epidemiology of infant feeding 7
   1.3.1. The relation of infant feeding to mortality and morbidity 7
   1.3.2. Prevalence of early initiation of breastfeeding and reasons for not initiating early 10
   1.3.3. Prevalence of exclusive breastfeeding (0-<6 months of age) and reasons for not breastfeeding 11
   1.3.4. Barriers to initiation and exclusive breastfeeding 12

1.4. Epidemiology of immunization and its benefits toward reduced mortality and morbidity 14
   1.4.1. Hepatitis B 17
   1.4.2. Measles 17
   1.4.3. Diphtheria, Pertussis and Tetanus 17
   1.4.4. Poliovirus 19
   1.4.5. Barriers to higher immunization coverage 20

1.5. Review of policies related to breastfeeding, immunization and reducing barriers to facility-based deliveries. 22
   1.5.1 Breastfeeding-related policies to which Philippines ratified or issued 22
   1.5.2 Immunization-related policies which the Philippines issued 26
   1.5.3 Policies on reducing barriers to access to facilities for childbirth which the Philippines issued 20
1.5.4 Review of International Evidence and Philippine Policy Translation 30

1.6 Management issues resulting in sub-optimal coverage of basic interventions 32
1.6.1 Effective methodologies to build human resource capacity 34
1.6.2 The effectiveness of marketing controls on breastfeeding 35
1.6.3 The effectiveness of community interventions 36

Chapter 2: STUDY HYPOTHESES AND OBJECTIVES 41

Chapter 3: METHODS 43
3.1 Overview of characteristics of studies. 43
3.2 Study sites 47
3.3 Study design and procedures 50
3.4 Data management and analysis 52
3.5 Ethical Approval, Funding and Statement of Conflict of Interest 54

Chapter 4: RESULTS 55
4.1 Manuscripts 55


4.2 Summary of the Main findings and implications of the included studies

Chapter 5: DISCUSSION AND RECOMMENDATIONS

5.1 Overview

5.1.1 Initiation, exclusivity and continuation of breastfeeding

5.1.2 Immunization coverage

5.1.3 Financial barriers interfering with immunization

5.1.4 Limitations

5.2 Analysis within the context of implementation research

5.2.1 Management level influences

5.2.2 Human health resource capacity building

5.3 External economic and social issues

5.3.1 Out-of-Pocket costs for facility-based childbirth and immunizations

5.3.2 Marketing of breast-milk substitutes including through the health system

5.3.3 Community linkages and empowerment

5.4 Recommendations

5.4.1 Recommendations for policies

5.4.2 Recommendations for research

REFERENCES
List of Figures.

Figure 1. GLOBAL Under-5 deaths by cause, 2012 .........................5
Figure 2. Pie chart of lives saved in the Philippines using LiST, baseline 2008, full implementation in 2030 .........................8
Figure 3. early initiation of breastfeeding by country in WPR ..............11
Figure 4: Exclusive Breastfeeding Rates (0-<6 months) by Country in WPR .................................................................13
Figure 5. Increase in milk infant formula retail value in China and India .................................................................................36
Figure 6. Subnational study sites. Note that study 4 was conducted in approximately the same locations as Study 1 but with more sites selected. In study 5, each flag represents two nearby cities. ........50
Figure 7. WHO-UNICEF monitoring scale up readiness (August- November 2014) .................................................................84

List of Tables.

Table 1. Cause specific neonatal, post-neonatal and infant mortality per thousand live births, United States, 1930 .........................4
Table 2. Underlying preventable causes of under-5 deaths ...............6
Table 3. Inherent risks of suboptimal feeding ..................................9
Table 4. US average cases in early 20th century compared with 1998. .........................................................................................16
Table 5. Comparison of global vaccination coverage, vaccine preventable disease cases and deaths between 1980 and 2013 ....17
Table 6. Summary of literature on a) user-related barriers, b) Socio- economic-related barriers and c) provider-related barriers to improved immunization status .........................................................22
Table 7. Conceptual framework of area of influence and underlying influence on infant breastfeeding and completeness and timeliness of immunizations .................................................................41
Table 8. Characteristics of the studies used .....................................45
Table 9. Main findings of the seven original research studies used in the thesis ........................................................................68
## List of Abbreviations and Terms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC</td>
<td>Antenatal Care</td>
</tr>
<tr>
<td>Barangay</td>
<td>The lowest administrative government unit in the Philippines</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacillus Calmette-Guerin vaccine for preventing extra-pulmonary and miliary tuberculosis</td>
</tr>
<tr>
<td>BEmOC</td>
<td>Basic Emergency Obstetric Care</td>
</tr>
<tr>
<td>BFHI</td>
<td>Baby-Friendly Hospital Initiative</td>
</tr>
<tr>
<td>BHW</td>
<td>Barangay Health Worker</td>
</tr>
<tr>
<td>CEmOC</td>
<td>Comprehensive Emergency Obstetric Care</td>
</tr>
<tr>
<td>CRC</td>
<td>Conventions of the Rights of the Child</td>
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<tr>
<td>CHN</td>
<td>China</td>
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<tr>
<td>DALYs</td>
<td>Disability Adjusted Lives Saved</td>
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<tr>
<td>(National)DHS</td>
<td>(National) Demographic and Health Survey</td>
</tr>
<tr>
<td>DOH</td>
<td>Department of Health</td>
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<tr>
<td>DTP</td>
<td>Diphtheria, tetanus and pertussis vaccine</td>
</tr>
<tr>
<td>EENC</td>
<td>Early Essential Newborn Care</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Program on Immunizations</td>
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<tr>
<td>FGD</td>
<td>Focus Group Discussion</td>
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<tr>
<td>GFF</td>
<td>Global Financing Facility</td>
</tr>
<tr>
<td>GPS</td>
<td>Global Positioning System</td>
</tr>
<tr>
<td>GRADE</td>
<td>Grading of Recommendation, Assessment, Development and Evaluation</td>
</tr>
<tr>
<td>HiB</td>
<td>Hemophilus influenza type B</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Human Immunodeficiency Virus/Acquired immunodeficiency syndrome</td>
</tr>
<tr>
<td>HBV/HepB</td>
<td>Hepatitis B vaccine</td>
</tr>
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<td>HPE</td>
<td>Health professional education</td>
</tr>
<tr>
<td>HPSS</td>
<td>High performing sentinel sites</td>
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<td>HRH</td>
<td>Human Resources for Health</td>
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<tr>
<td>IYCF</td>
<td>Infant and young child feeding</td>
</tr>
<tr>
<td>IgM</td>
<td>Immunoglobulin M (antibody indicating initial or acute infection).</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>IBCLC</td>
<td>International Board Certified Lactation Consultant</td>
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<tr>
<td>IMR</td>
<td>Infant mortality rate</td>
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<tr>
<td>KHM</td>
<td>Cambodia, Khmer</td>
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<tr>
<td>Lao PDR</td>
<td>Lao People’s Democratic Republic</td>
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<tr>
<td>LAO</td>
<td></td>
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<tr>
<td>LHW</td>
<td>Lay health worker</td>
</tr>
<tr>
<td>LiST</td>
<td>Lives Saved Tool (Johns Hopkins School of Public Health)</td>
</tr>
<tr>
<td>LMIC</td>
<td>Low and middle income countries</td>
</tr>
<tr>
<td>LSIS</td>
<td>Laos Socio-economic Indicator Survey</td>
</tr>
<tr>
<td>MDG</td>
<td>Millennium Development Goal</td>
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<tr>
<td>MNCHN</td>
<td>Maternal Newborn Child Health and Nutrition</td>
</tr>
<tr>
<td>MNG</td>
<td>Mongolia</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>NCD</td>
<td>Non-communicable diseases</td>
</tr>
<tr>
<td>NESSS</td>
<td>National Epidemic Sentinel Surveillance System</td>
</tr>
<tr>
<td>NHP</td>
<td>Not healthcare professional</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
</tr>
<tr>
<td>NMR</td>
<td>Neonatal mortality rate</td>
</tr>
<tr>
<td>NSO</td>
<td>National Statistics Office</td>
</tr>
<tr>
<td>OPV</td>
<td>Oral poliovirus vaccine</td>
</tr>
<tr>
<td>OR (95% CI)</td>
<td>Odds Ratio (95% Confidence Interval)</td>
</tr>
<tr>
<td>PEPI</td>
<td>Philippine Expanded Programme on Immunization</td>
</tr>
<tr>
<td>PHAP</td>
<td>Pharmaceutical Health Care Association of the Philippines</td>
</tr>
<tr>
<td>PhilHealth</td>
<td>Philippine national health insurance agency</td>
</tr>
<tr>
<td>PHL</td>
<td>Philippines</td>
</tr>
<tr>
<td>PNG</td>
<td>Papua New Guinea</td>
</tr>
<tr>
<td>POS</td>
<td>Point of Sale</td>
</tr>
<tr>
<td>PPS</td>
<td>Philippine Pediatric Society</td>
</tr>
<tr>
<td>RCA</td>
<td>Rapid Coverage Assessment</td>
</tr>
<tr>
<td>PFMEC</td>
<td>Philippines Follow up Measles Elimination Campaign</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized Clinical Trial</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>RIRR</td>
<td>Revised Implementing Rules and Regulations</td>
</tr>
<tr>
<td>RITM</td>
<td>Research Institute of Tropical Medicine</td>
</tr>
<tr>
<td>SBA/SHP</td>
<td>Skilled birth attendant/skilled health professional</td>
</tr>
<tr>
<td>SDG</td>
<td>Sustainable Development Goal</td>
</tr>
<tr>
<td>SES</td>
<td>Socio-economic status</td>
</tr>
<tr>
<td>SLB</td>
<td>Solomon Islands</td>
</tr>
<tr>
<td>TBA</td>
<td>Traditional Birth Attendants</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TRO</td>
<td>Temporary restraining order</td>
</tr>
<tr>
<td>TV</td>
<td>Television</td>
</tr>
<tr>
<td>TWG</td>
<td>Technical Working Group</td>
</tr>
<tr>
<td>UHC</td>
<td>Universal health care</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>VNM</td>
<td>Viet Nam</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>WPR</td>
<td>Western Pacific Region</td>
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</table>
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EXECUTIVE SUMMARY

The Philippines is one of 42 countries accounting for 90% of global deaths of children under five years of age. Annually an estimated 82,000 Philippine children die before reaching five years of age, most in infancy. Simple interventions such as breastfeeding and immunization can prevent a large portion of these deaths. These have strong policy frameworks in support but no budget lines for enforcement.

This thesis was undertaken to better define why Philippine infants are sub-optimally fed and are not fully immunized and identify effective strategies to redress them. Seven primary research studies were conducted. In addition, one commentary was written.

The first study consisted of 481 consecutive births observed for care given in the first hours after childbirth in randomly selected large government hospitals nationwide. 100% of babies received inappropriate practices. Less than 10% received skin-to-skin contact, associated with early initiation of breastfeeding. Babies were put to the breast at a median 10 minutes, separated after a median of two minutes for routine weighing, bathing, examinations and injections with hepatitis B vaccine and vitamin K and returned to the mother after 2½ hours. The mean time for the initiation of breastfeeding is 55 minutes and a baby needs at least 15 minutes to ingest colostrum. Furthermore, almost all will be asleep when returned from the separation. Thus, for all intents and purposes, the median baby in our study did not initiate breastfeeding until much later (Two studies found delaying initiation was associated with a doubling the risk of death).

The second study took place in three disadvantaged rural and urban municipalities in Quezon and Negros Occidental Provinces, Philippines. All households with children younger than 24 months old (N=345) were surveyed in randomly selected communities (barangays the lowest administrative government unit in the Philippines) to determine factors associated with formula usage. Health providers were found to recommend and write prescriptions for infant formula in even relatively poor parts of the Philippines. This was associated with a quadrupling of infants being formula fed. This was compounded with a doubling of risk of using formula if the mother
could recall an advertising message. Consequently, 41% were found using formula. Once infants were started on formula, they were six times more likely to stop breastfeeding.

The third study took place in Barangay Pembo, Makati, Metro-Manila. Peer counselors identified mothers with infants under 2 months of age. Of those with sub-optimal feeding, health staff advised peer counsellors what to counsel mothers on a second visit to improve feeding practices. They then made a third visit and documented the practice after counseling. 51% were found initially using formula. Post peer-counselling, exclusive formula feeding decreased nearly 8-fold.

The fourth study, part 1, consisted of 55,719 births taking place in 91 randomly selected government hospitals nationwide where birth records were reviewed for documentation of administration of hepatitis B given within 24 hours of birth. Only 16% of the selected hospitals had more than half of children born receive a documented birth dose of hepatitis B within 24 hours of birth. This corresponded to only 22% of total infants with a documented birth dose. Hospitals with a copy of the hepatitis B policy readily available, that included the birth dose in standing orders and who trained staff on the policy were many times more likely to have vaccinated infants in the first 24 hours after childbirth. However, hospitals designated as training sites, national health insurance or Philippine Pediatric Society accredited hospitals performed statistically no better than those not.

The fourth study, part 2, consisted of 1231 babies pre and 394 post intervention in all health centers in Pateros Municipality of Metro-Manila. Records review was conducted pre and post intervention to determine coverage with a timely birth dose of hepatitis B vaccine. The intervention consisted of assessment of health facility, training workshop on gaps and coordination with community health volunteers to vaccinate all infants. Compared to pre-intervention, post-intervention infants were 12 times as likely to have received hepatitis B vaccine within 24 hours of birth.
The fifth study took place in birthing and primary health facilities in selected health facilities based on the proportion of births that take place in a facility and the Hepatitis B vaccination at birth coverage. All children 5-7 months old born between 1 October and 31 December 2008 were included. 1431 births with complete records were reviewed at birthing facilities and health facility where immunizations received HBV and DTP. Timeliness and completion were measured. Staff were found to mostly not simultaneously administer all vaccines for which the child was eligible and seemingly followed random vaccine schedules. Not giving vaccinations simultaneously and not following the national EPI programme or that of the Philippine Pediatric Society vaccine schedules was associated with lower coverage.

The sixth study consisted of analysis of surveillance data of 10,061 measles cases from 228 sentinel hospitals across the nation pre and post a measles vaccination campaign. Compared with previous campaigns only the 2004 measles vaccination campaign penetrated primarily urban poor populations enabling interruption of measles transmission. Measles cases decreased by 96.4%, deaths by 99.2% and fever and rash cases that were IgM positive for measles by 100% after the 2004 campaign. This was the first time hospital reported measles indicators decreased significantly following a measles vaccination campaign. Immediate feedback in the form of the Rapid Coverage Assessments (RCA) emphasizing urban poor areas was the only policy shift from previous campaigns.

The seventh study consisted of secondary analysis of the 2003 Demographic and Health Survey, including mapping of GPS coordinates of home unattended deliveries. 7098 women who delivered were reviewed for health outcomes, location of residence in reference to major hospitals and factors associated with home unattended deliveries. More than 90% of Philippine women who delivered at home unattended lived near (i.e., <15 km) a hospital. Major barriers were primarily economic and social.
The last paper is a commentary on the need for future global financing mechanisms to focus on quality of care and of human health resources. Analysis of findings, implications and review of evidence-based actions to address the gaps was conducted.

Recommendations:

*Ensure rapid information feedback:* The RCA experience shows that timely feedback on implementation at multiple levels of the health system is critical for successful implementation.

*Ensure budgets are available for monitoring:* the legal and policy framework is strong for protection, promotion and support of breastfeeding and immunization. However, they are poorly implemented partially because they have no budgets for monitoring.

*Ensure hospital managers make the policies widely known and easy to follow:* hospital staff tend to respond to posting, orientation and inclusion of relevant policies in standing orders.

*Focus beyond training on building health worker capacity:* many trainings have been done with few changes in practices. Training is more likely to work if it is action oriented, relevant to their immediate needs, focused, competency-based, and monitored. Supervisors need to have capacity, time and authority to assess staff skill retention, observe practices directly and through exit interviews, provide feedback and engage with staff to find a few key actions around high priority needs.

*Eliminate financial barriers to access to facilities for childbirth:* financial barriers for transportation to accessing health facilities, childbirth and basic services were found to inhibit childbirth in a facility for women and children in the bottom two quintiles.
Community engagement can be effective: but requires significant funding and effort for activities, supervision, monitoring and back up support.

Recommendations for research

It would be helpful to develop a framework for a desk review and primary data collection to delineate the major bottlenecks for policy implementation, management and human health resource capacity. Additionally, it would be helpful to carry out studies with health workers to better understand how marketing of breast-milk substitutes through the health system can be curtailed.
SAMENVATTING

De Filipijnen zijn één van de 42 landen waarin samen 90% van de kindersterfte optreedt. Naar schatting 82.000 Filipijnse kinderen sterven jaarlijks voor de leeftijd van vijf jaar. Eenvoudige interventies zoals borstvoeding en vaccinatie kunnen een groot deel van deze overlijdens voorkomen. Deze interventies kunnen rekenen op sterke steun in beleidsdocumenten, maar er zijn geen budgetten om de implementatie ervan af te dwingen.

Deze thesis heeft tot doel meer inzicht te krijgen in waarom Filipijnse kinderen suboptimaal gevoed en niet afdoende gevaccineerd worden, en effectieve strategieën te identificeren om de situatie te verbeteren. Er werden zeven originele studies uitgevoerd. Daarnaast werd één commentaar geschreven.

De eerste studie bestond uit de observatie van de zorg tijdens de eerste uren na de geboorte bij 481 opeenvolgende geboortes. Dit gebeurde in willekeurig geselecteerde grote overheidsziekenhuizen over het hele land. 100% van de baby’s kreeg ongeschikte zorg. Meer dan 10% had huid-huidcontact, wat te maken had met vroege initiatie van borstvoeding. Baby’s werden aan de borst gelegd na 10 minuten (mediaan), er weer afgenomen na twee minuten (mediaan) voor weging, wassen, onderzoek en inenting met hepatitis B vaccin en vitamine K, en teruggegeven aan de moeder na 2,5 uur. Daarbij komt dat bijna alle baby’s slapen als ze terug bij de moeder komen. De gemiddelde tijd waarna baby’s borstvoeding starten is 55 minuten, en baby’s hebben minstens 15 minuten nodig om het colostrum op te nemen. De mediaan baby in onze studie startte dus pas veel later met borstvoeding, waardoor het overlijdensrisico minstens verdubbeld.

De tweede studie vond plaats in drie kansarme rurale en urbane gemeenten in de Filipijnse provincies Quezon en Negros Occidental.
Alle gezinnen met kinderen jonger dan 24 maanden (N=345) in willekeurig geselecteerde gemeenschappen (barangays: de laagste administratieve overheidsinstelling in de Filippijnen)) werden bevraagd om de factoren vast te stellen die samenhangen met het gebruik van flesvoeding. Gezondheidswerkers bleken zelfs in relatief arme delen van de Filippijnen flesvoeding aan te raden en voor te schrijven. Dit werd in verband gebracht met een verviervoudiging van het aantal kinderen dat flesvoeding krijgt. Bij moeders die zich een reclameboodschap konden herinneren bleek er een verdubbeling van de kans op flesvoedinggebruik te zijn. 41% gebruikte flesvoeding. Eenmaal kinderen gestart waren met flesvoeding hadden ze zes keer meer kans om te stoppen met borstvoeding.

De derde studie vond plaats in Barangay Pembo, Makati, Metro-Manila. Peer counselors identificeerden moeders met kinderen jonger dan 2 maanden. Bij diegenen met suboptimale voeding adviseerden gezondheidswerkers de peer counselors over wat ze bij een tweede bezoek de moeders moesten aanraden om de voeding te verbeteren. Bij een derde bezoek werd nagegaan wat de voedingspraktijken waren na het advies. 51% gebruikte initieel flesvoeding. Na de peer-counseling daalde het exclusieve gebruikt van flesvoeding met een factor acht.

De vierde studie, deel 1, bestond uit het nazicht van de geboortedossiers van 55.719 geboorten in 91 willekeurig geselecteerde overheidsziekenhuizen over het hele land. In slechts 16 van de geselecteerde ziekenhuizen kregen meer dan de helft van de pasgeboren kinderen een gedocumenteerde geboortedosis van het hepatitis B vaccin binnen de 24 uur na geboorte. Slechts 22% van het totaal aantal kinderen kreeg een gedocumenteerde dosis. Ziekenhuizen die een exemplaar van het hepatitis B beleid bij de hand hadden waarin de geboortedosis verplicht gesteld werd, en die hun personeel trainden m.b.t. dit beleid, hadden vele malen meer kans om kinderen te vaccineren binnen de 24 uur na geboorte. Ziekenhuizen die
aangeduid waren als opleidingssites en ziekenhuizen die
geaccrediteerd waren door de nationale gezondheidsverzekering of de
Philippine Pediatric Society presteerden echter statistisch niet beter
dan de andere ziekenhuizen.

De vierde studie, deel 2, bestond uit 1.231 baby’s pre-interventie en
394 post-interventie in alle gezondheidscentra van de gemeente
Pateros in de regio Metro-Manila. De dossiers werden zowel voor als
na de interventie bestudeerd om na te gaan in hoeveel gevallen er een
geboortedosis van het hepatitis B vaccin was toegediend. De
interventie bestond uit een evaluatie van de gezondheidsinstelling, een
vorming over de gebreken en afstemming met
gemeenschapsgeneeskundewerkers voor het vaccineren van alle
boorlingen. Na de interventie was de kans voor een boorling om
binnen de 24 uur na geboorte een hepatitis B vaccin gekregen te
hebben 12 keer groter dan voor de interventie.

De vijfde studie vond plaats in gezondheidsinstellingen die
geselecteerd werden op basis van het aantal geboorten en het
percentage boorlingen dat het hepatitis B vaccin ontvangt. Alle
kinderen van 5 tot 7 maanden oud, geboren tussen 1 oktober en 31
december 2008 werden geïncludeerd. Voor 1.431 geboorten met een
volledig dossier in instellingen waar DTP en hepatitis B vaccinatie
werd toegediend, werd het tijdstip van vaccinatie nagegaan. Het
personeel bleek de verschillende vaccins die een kind moest
ontvangen meestal niet tegelijkertijd toe te dienen en volgde een
schijnbaar willekeurig vaccinatieschema. Het niet gelijkvrij
toedienen van vaccins en het niet volgen van het nationaal EPI
programma of het vaccinatieschema van de Philippine Pediatric
Society was gecorreleerd met een lager percentage gevaccineerde
kinderen.

De zesde studie bestond uit de analyse van de opvolgingsgegevens
van 10.061 mazelgevallen uit 228 ziekenhuizen over het hele land,
voor en na een mazelcampagne. Vergeleken met voorgaande
De zevende studie bestond uit secundaire analyse van de 2003 Demographic and Health Survey data, met mapping van GPS coördinaten van ongeassisteerde thuisbevallingen. De gezondheidsuitkomsten van 7.098 bevallen vrouwen, de ligging van hun verblijfplaats ten opzichte van grote ziekenhuizen, en factoren geassocieerd met ongeassisteerde thuisbevallingen werden geanalyseerd. Meer dan 90% van de Filipijnse vrouwen die ongeassisteerd thuis bevielen leefden nabij (<15 km) een ziekenhuis. Belangrijke barrières waren vooral economisch en sociaal.

Het laatste artikel is een commentaar over de nood aan globale financieringsmechanismen om te kunnen focussen op kwaliteit van de zorg en van gezondheidspersoneel. De bevindingen en de implicaties werden geanalyseerd en er vond een review plaats van evidence-based acties om tekortkomingen te verhelpen.

**Aanbevelingen:**

**Zorg voor snelle feedback:** De RCA ervaring toont aan dat tijdige feedback over de implementatie op verschillende niveaus van het gezondheidssysteem kritiek is voor een succesvolle implementatie.

**Zorg voor budgetten voor monitoring:** er is een sterk wettelijk en beleidskader voor bescherming, promotie en ondersteuning van borstvoeding en immunisatie, maar ze worden slecht toegepast, onder meer omdat er geen budgetten zijn voor monitoring.
Zorg ervoor dat ziekenhuismanagers de beleidslijnen ruim bekend en gemakkelijk op te volgen maken: ziekenhuispersoneel heeft de neiging goed te reageren op bekendmaking, voorlichting en opname van beleidslijnen in reglementen.

Ga verder dan enkel vorming bij het uitbouwen van de capaciteit van gezondheidswerkers: veel vormingen hebben weinig impact op de praktijk. Vorming heeft meer kans op succes als het actie-georiënteerd is, beantwoordt aan onmiddellijke behoeften, gefocust, gebaseerd op competenties, en gemonitord. Leidinggevenden moeten beschikken over de capaciteiten, de tijd en het gezag om hun personeel te beoordelen, hun gedrag te observeren (direct en door exit interviews), feedback te geven en samen met hun personeel te zoeken naar enkele sleutelacties gericht op prioritair noden.

Elimineer financiële barrières voor de toegang tot gezondheidsinstellingen: financiële barrières voor transport naar gezondheidsinstellingen en voor basisdienstverlening bleken ziektenhuisbevallingen af te remmen voor vrouwen in de twee laagste kwintielen.

Werken met gemeenschappen kan effectief zijn: maar vereist aanzienlijke financiering en inspanningen voor activiteiten, supervisie, monitoring en ondersteuning.

Aanbevelingen voor onderzoek

Het zou nuttig zijn om een kader te ontwikkelen voor een desk review en primaire datacollectie gericht op het afbakenen van de voornaamste bottlenecks voor beleidsimplementatie, management en capaciteitsuitbouw. Ook zou het nuttig zijn om studies uit te voeren met gezondheidswerkers om beter te begrijpen hoe de marketing van borstvoedingsvervangers via het gezondheidssysteem kan worden ingeperkt.
Chapter 1: INTRODUCTION

Breastfeeding and immunizations are among the most effective interventions that can reduce infant morbidity, disability and mortality. This thesis is comprised of eight studies examining different perspectives on factors that interfere with or facilitate optimal breastfeeding and receipt of infant immunizations. Specifically, it aims to examine the influence of healthcare worker practices, external influences and community empowerment. Healthcare worker practices are further classified into influence of management, individual training backgrounds, physical environment and policies.

1.1. Causes of neonatal, post-neonatal and 1-4 year old child mortality

Analysis of historical vital statistics among high income countries may provide insights for what is to come and ways to accelerate progress in currently low and middle income countries such as the Philippines. Under five deaths today are a rare event in high income countries. However, in 1900, 18 European countries\(^1\) with data ranged in under-five mortality between 133 (Norway) and 409 (Russia) deaths before the fifth birthday per thousand live births. Spain, Hungary, Germany, Austria and Russia tragically had more than one in three children die before their fifth birthday. Estimates for the United States and Canada fell in this same range. Today, only Bulgaria, Romania and Russia barely exceed 10 deaths per 1000 live births.\(^1\)

Next, cause of death in a couple of selected currently high income countries is reviewed. Infants in England (1900) reportedly died most

\(^1\) Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Netherlands, Norway, Romania, Russia, Serbia, Spain, Sweden and Switzerland.
commonly from prematurity, wasting (both of which were considered non-preventable), diarrhea, acute pulmonary diseases, convulsions and acute infectious fevers.\(^2\)

Interestingly, as early as 1857 in England, “The direct and baneful agency of want of good breast-milk may be inferred from the table from which it appears that the longer the supply of breast-milk and the more exclusively it is given the better the child is developed and vice versa”.\(^2\) This story seems to be the same in Sweden, where substitutes to breastfeeding around 1900 were found in high mortality areas.\(^3\)

Vital statistics became routinely collected in the United States (US) in 1930, eighty years before being collected in most low and middle income countries (including the Philippines). This was delayed compared to many of its European neighbors noted above. The US birth cohort in 1930 amounted to 2.3 million births. This is approximately the same as that of Philippines currently. Of the 2.3 million US births, 150,000 died in infancy in 1930 (Infant mortality rate, IMR of 64.6 deaths per thousand live births). The leading cause of death was due to premature birth. Deaths of pre-term babies have long been known to result from their organs not being sufficiently developed.\(^4\) We now more specific issues such as lungs not having surfactant can lead to respiratory distress syndrome; blood vessels in the brain, specifically the germinal matrix, being fragile are susceptible to disturbances in cerebral blood flow\(^5\); and necrotizing enterocolitis may be multifactorial including from blood flow disturbances and infection.\(^6\) Infections directly accounted for 22.4 deaths per thousand live births (34.6% of total infant deaths). However a large portion of deaths among premature births and congenital malformations were also due to infection. Pierre Budin, the father of perinatology, showed in 1907 the importance of breastfeeding, hygiene and warmth to saving pre-term baby lives.\(^4\)

Unfortunately, similar data for 1-4 year old children was not available (Table 1).\(^7\)
TABLE 1. CAUSE SPECIFIC NEONATAL, POST-NEONATAL AND INFANT MORTALITY PER THOUSAND LIVE BIRTHS, UNITED STATES, 1930.

<table>
<thead>
<tr>
<th>Cause of death</th>
<th>Under 1 month, rate</th>
<th>1-11 months, rate</th>
<th>Infant mortality, rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature birth</td>
<td>16</td>
<td>0.7</td>
<td>16.7</td>
</tr>
<tr>
<td>Pneumonia and influenza</td>
<td>1.7</td>
<td>8.5</td>
<td>10.2</td>
</tr>
<tr>
<td>Diarrhea, enteritis, ulceration of the intestines and dysentery</td>
<td>0.9</td>
<td>7.3</td>
<td>8.2</td>
</tr>
<tr>
<td>Congenital malformation or debility(^{ii})</td>
<td>5.4</td>
<td>2.4</td>
<td>7.8</td>
</tr>
<tr>
<td>Injury at birth</td>
<td>4.8</td>
<td>0</td>
<td>4.8</td>
</tr>
<tr>
<td>Whooping cough</td>
<td>0.1</td>
<td>1.4</td>
<td>1.5</td>
</tr>
<tr>
<td>Syphilis</td>
<td>0.1</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>Measles</td>
<td>0</td>
<td>0.4</td>
<td>0.4</td>
</tr>
<tr>
<td>Convulsions</td>
<td>0.2</td>
<td>0.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Other infections</td>
<td>0.2</td>
<td>0.7</td>
<td>0.9</td>
</tr>
<tr>
<td>Other total</td>
<td>6.3</td>
<td>6.6</td>
<td>12.9</td>
</tr>
<tr>
<td><strong>Total All-cause</strong></td>
<td><strong>35.7</strong></td>
<td><strong>22.3</strong></td>
<td><strong>64.6</strong></td>
</tr>
</tbody>
</table>

The recent global rates and major causes of death reflect those of the US in 1930.

In 2012, globally, almost 5 million (73% of all under-five deaths) occurred within the first year of life. Deaths from pneumonia, diarrhea, sepsis, diarrhea, measles, tetanus and meningitis directly

\(^{ii}\) International List of Causes of Death, 1938, cause number 158. Pierre Budin, The Nursling, 1907 provides a more descriptive treatment of the term, essentially, a premature newborn with small, poorly formed and vulnerable organs.
accounted for 36.8% of all deaths of under five children. Indirectly, infectious diseases similarly contribute to deaths of premature babies and babies with congenital anomalies (Figure 1: note that neonatal deaths are in hues of yellow and deaths from 1 month to five years of age in darker colours). 8

**FIGURE 1. GLOBAL UNDER-5 DEATHS BY CAUSE, 2012.**

![Diagram of global under-5 deaths by cause, 2012.]

Source: WHO. Global Health Observatory

1.2. **Lifesaving interventions for infants and young children, worldwide**

In 1998, a landmark publication estimated actual underlying cause of death for all ages in the United States. 9 In 2003, the Child Survival Series used a similar methodology to present the proportion of under-five child deaths that could be prevented by public health interventions (Table 2). 10 The group has updated these estimates periodically, but the overall proportions changed little.
The Lives Saved Tool (LiST, Johns Hopkins School of Public Health) uses the most recent updates to estimate the proportion of infants that could be saved from basic interventions such as immediate delivery care, breastfeeding and immunizations. Many of these are self-evident however two interventions, vitamin A and zinc supplementation need further description. Vitamin A supplementation is associated with reduced diarrhoeal and all-cause mortality and incidence of diarrhoea and measles morbidity (but not incidence of respiratory disease or
hospitalisations due to diarrhoea or pneumonia or measles mortality). Zinc supplementation is associated with a tendency toward reduced all-cause mortality and cause-specific mortality due to diarrhoea, lower respiratory tract infection and malaria, and diarrhoea morbidity.

The LiST uses only interventions that have evidence from random-clinical trials as a basis of impact. Therefore these estimates likely underestimate the additional impact of interventions without such trials. It would be unethical to carry out random clinical control trials to determine the impact of drying (beneficial), bathing (harmful), breastfeeding (beneficial) and traditional vaccines (beneficial). Thus, the LiST may underestimate the benefit of applying a core package of interventions. Many of the impact magnitudes used are based on “promotion of …” rather than the direct impact of drying, delayed bathing, breastfeeding or traditional vaccines. One might expect direct impact of these beneficial and harmful practices to be greater on survival than the impact of promotion as promotion may or may not result in the desired practice. Thus, the magnitude of the impact presented in LiST will likely underestimate the positive impact of drying, breastfeeding and traditional vaccines and the negative impact of early bathing. Furthermore, this model does not take into consideration the impact of birth spacing and limiting on child mortality which is substantial. Nevertheless, this is the only tool we are aware of to make such estimates and the only such tool WHO promotes. Applying this model to the Philippines using estimates of coverage from 2008 onward to full implementation, we can see the impact of these interventions (Figure 2).
Of the 57,800 deaths of Filipinos before their fifth birthday,\textsuperscript{13} 14,950 (27\%) could have been prevented by promotion of breastfeeding.

1.3. Epidemiology of infant feeding

1.3.1. The relation of infant feeding to mortality and morbidity

WHO/UNICEF Global Strategy for Infant and Young Child Feeding (2002),\textsuperscript{14} recommends optimal infant and young child feeding as:

1. Initiation of breastfeeding within one hour of birth
2. Exclusive breastfeeding for the first six months of life
3. Continued breastfeeding for two years and beyond
4. Introduction of adequate and appropriate complementary foods from 6 months onwards.

Exclusive breastfeeding for the first six months and continued breastfeeding would prevent 13\% of global under-five deaths, primarily from infections resulting in diarrhoea, pneumonia and neonatal sepsis (Table 3).\textsuperscript{15} These amount to more than one million lives whom optimal breastfeeding could save annually worldwide.
Beyond early childhood period, breastfeeding may be associated with lower asthma, ear infections, allergies, and diabetes.\textsuperscript{16} Two meta-analysis of 18 and 15 studies, respectively indicated that any breastfeeding for 6 months or longer was associated with a 19% lower risk for childhood leukemia (odds ratio, 0.81; 95% CI, 0.73-0.89) and ever breastfed compared with never breastfed with an 11% lower risk for childhood leukemia (odds ratio, 0.89; 95% CI, 0.84-0.94).\textsuperscript{17} The United States, where we have cost estimates, breastfeeding overall could save about $13 billion annually through improved exclusive breastfeeding alone. Breastfeeding promotion could avert 21.9 million disability adjusted life years (DALYs).\textsuperscript{16}

Breastfeeding seems to additionally have a positive impact on intelligence quotient. In a systematic review, breastfed subjects had 3.44 additional intelligence quotient points (95% confidence interval: 2.30; 4.58)] compared to those who did not.\textsuperscript{18}

\textbf{TABLE 3. INHERENT RISKS OF SUBOPTIMAL FEEDING.}

<table>
<thead>
<tr>
<th>Comparison Groups</th>
<th>Outcome</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>After vs. during first hour for breastfeeding initiation (neonates, pooled OR)\textsuperscript{19}</td>
<td>Neonatal mortality Neonatal infection</td>
<td>2.0 (1.4 to 2.9)</td>
</tr>
<tr>
<td>Partial vs exclusive breastfeeding\textsuperscript{20}</td>
<td>All-cause mortality Neonatal infection</td>
<td>3.7 (2.0-6.6) 3.5 (2.4-5.0)</td>
</tr>
<tr>
<td>Formula feeding/not breastfeeding vs. Exclusive breastfeeding (0-5 Months)</td>
<td>All-cause mortality Diarrhea hospitalization</td>
<td>14.4 (6.1-34.0) 19.5 (6.0-63.0)</td>
</tr>
<tr>
<td>Not breastfeeding vs. continuing to breastfeed (6-24 months)\textsuperscript{20}</td>
<td>All-cause mortality Diarrhea hospitalization</td>
<td>3.7 (1.5-9.2) 6.1 (2.4-15.0)</td>
</tr>
<tr>
<td>Low Birth Weight (LBW) infants not fed breast-milk vs. exclusively fed mother’s own milk (pooled OR)\textsuperscript{21}</td>
<td>Mortality Severe Infection</td>
<td>1.2 (1.1-1.4) 2.5 (1.9-3.2)</td>
</tr>
<tr>
<td>Proportion of powder infant</td>
<td>C. Sakasakii</td>
<td>14%</td>
</tr>
<tr>
<td>Comparison Groups</td>
<td>Outcome</td>
<td>Risk</td>
</tr>
<tr>
<td>-------------------------------------------------------</td>
<td>--------------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>formula with intrinsic contamination (presence of</td>
<td>B. cereus</td>
<td>50%</td>
</tr>
<tr>
<td>bacteria during manufacturing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extrinsic contamination</td>
<td>Multiple causative agents</td>
<td>No systematic data</td>
</tr>
<tr>
<td>Other industrial errors</td>
<td>Multiple causative agents</td>
<td>No systematic data</td>
</tr>
</tbody>
</table>

Cohort studies with an overall estimated quality of evidence "moderate" following the GRADE methodology suggested delaying initiation more than doubled and non-exclusivity of breastfeeding nearly quadrupled the risk of death, and increased the risk of morbidity and hospitalization many fold.\(^{20,22,23,24}\). In a cohort of 22,838 Nepalese breast-fed neonates surviving to 48 h, partially versus exclusively breast-fed infants and infants whose initiation delayed beyond 1 day versus those within 1 day had higher mortality risk [(RR = 1.77; 95% CI = 1.32-2.39) and (RR = 1.41; 95% CI = 1.08-1.86)] after adjusting for covariates. They authors conclude approximately 7.7% of all neonatal deaths may be avoided with universal initiation of breast-feeding within the first day. This increases to 19.1% deaths prevented if initiated within the first hour of life. Similarly, 10 942 Ghanian breastfed singleton neonates who survived to day 2 had a 2.6-fold risk [adjusted odds ratio (adj OR): 2.61; 95% CI: 1.68, 4.04] increased risk of death if initiation was delayed after the first hour. Partial breastfeeding was associated with a 5.7-fold adjusted risk of death as a result of infectious disease (adj OR 5.73; 95% CI: 2.75, 11.91). Both studies showed a dose-response curve with increased risk of death associated with longer delay in initiation of breastfeeding. Formula fed, low birth weight infants also had increased risk of death and illness.\(^{25}\)
1.3.2. Prevalence of early initiation of breastfeeding and reasons for not initiating early

Of the 135 million babies born globally every year, 42% (57 million) of newborn infants initiate breastfeeding within the first hour of life. In the 13 of 27 countries in the Western Pacific Region (WPR) with data, early initiation of breastfeeding ranges 15 – 88%. Philippines ranks in the lower third (Figure 3).

Figure 3. Early initiation of breastfeeding by country in WPR

Source: UNICEF State of the World’s Children 2013

Of the six countries with available data, reasons for low early initiation of breastfeeding could be subdivided into those who never breastfed (7%) and those who delayed breastfeeding initiation until after 1 hour (32%). Pre-lacteal feeds and (unnecessary) separation of the newborn from the mother may be contributing factors to both those who delay and those who never breastfed. Finally, the common incorrect belief of not having enough milk results in many mothers introducing infant formula or not breastfeeding at all.
Keeping babies in sustained skin-to-skin contact is associated with successful breastfeeding.\textsuperscript{26}

1.3.3. Prevalence of exclusive breastfeeding (0-<6 months of age) and reasons for not breastfeeding

Of the 135 million babies born globally every year, 38\% were exclusively breastfed during the first six months.\textsuperscript{27}

The 18 countries in WPR with data show exclusive breastfeeding under six months range 17 – 74\%.\textsuperscript{28,30,31,33} Half the countries (9), including Philippines have rates well below 50\%. As this target averages of infants 0 – 5 months, exclusively breastfeeding rate for the full six months is much lower (Figure 4).
FIGURE 4: EXCLUSIVE BREASTFEEDING RATES (0–6 MONTHS) BY COUNTRY IN WPR

Of the six countries with available data, reasons for low exclusivity include not breastfeeding (7%), breastfeeding while introducing water (14%), infant formula (17%) and other foods (17%). While 36% of Filipino children under 6 months were given breast-milk substitutes, only 34% exclusively breastfed during the first six months of life in 2008. Myths and misperceptions include not having enough breast milk, or the breast milk is not sufficient to satisfy the nutritional needs of the baby.

1.3.4. Barriers to initiation and exclusive breastfeeding

Virtually all mothers can breastfeed and when mothers are given correct information and support, they breastfeed. WHO (1994) notes, “Lactation failure is one of the reasons frequently given
by mothers for not breastfeeding their infants; it is claimed to occur almost exclusively in industrialized countries and in the higher socioeconomic groups in urban areas of developing countries. Yet the women in question are, in the main, healthy and well-nourished, with healthy and strong infants and there is no apparent physiological reason for their not being able to secrete milk. In contrast, in traditional societies, even women who live in unsanitary conditions, who are poorly nourished and often ill, who engage in strenuous physical labour, and who bear the greatest number of low-birth-weight infants do not generally fail to secrete milk. For example, in the WHO collaborative study on breastfeeding, it was found that out of a total of 3898 mothers studied in Nigeria and Zaire, not one was unable to secrete milk. This sample included both women from the urban elite and those from poor urban and rural populations. In a prospective study undertaken in a small, poor India village in the mountains of Guatemala, children born during an 8-year period were followed longitudinally. All 448 infants born alive during the period, and who survived for 48 hours, were successfully breastfed. In societies where breastfeeding is regarded as a natural physiological function and the only way to nourish an infant, and where it is highly valued and therefore strongly encouraged and supported by society in general and families in particular, lactational failure is virtually unknown. Women in these societies are also less exposed to health systems likely to undermine lactation.” In contrast, mothers who receive confusing messages and do not have societal support, tend not to breastfeed or stop breastfeeding early.

Marketing of breast milk substitutes, in violation of the WHO International Code of Marketing of Breast-Milk Substitutes, occurs globally. Television advertisements are the main above board marketing channel with the greatest reach. For example, 16% of Laos rural, 51% of urban and 75% of Vientiane mothers with children recalled TV advertisements. Radio, billboards and direct representation to mothers (where gifts and free formula samples are
often provided) reached far fewer. Emerging channels include mobile phones, internet and social technologies.\textsuperscript{44,45}

Globally, 500 violations of the Code of Marketing of Breast-milk Substitutes have been reported in 46 countries.

Laotian and Malaysian mothers reported the TV advertisements were attractive and many were influenced to buy a particular brand.\textsuperscript{43,45}

\textit{Availability of breast-milk substitutes}

Breast-milk substitutes are ubiquitously available. Family owned traditional shops, modern chains of local convenience stores and groceries exist in most localities in countries in the WPR. Shopping malls, supermarkets and hyper-markets are expanding to countries without historical presence and widely present in most middle and upper income countries. Philippine and even Laos families living in remote areas have access to and purchase formula.\textsuperscript{46}

Independent drugstores and pharmacies carrying infant formula products are located in a close proximity to every hospital in the Philippines and Viet Nam (even if products are technically not allowed to be displayed in the healthcare system).\textsuperscript{44}

\textbf{1.4. Epidemiology of immunization and its benefits toward reduced mortality and morbidity}

Based on the US census, given the birth cohort in 1930 was 2.3 million, annually about half a population equivalent to the birth cohort was infected with at least one vaccine preventable disease. By 1998, nearly all cases of all vaccine preventable diseases had decreased to a small fraction in the US (Table 4).\textsuperscript{7,47}

<table>
<thead>
<tr>
<th>Disease</th>
<th>Early 20th century average annual cases</th>
<th>1998 Cases</th>
<th>Decrease (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smallpox</td>
<td>48,164</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>175,885</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>Pertussis</td>
<td>147,271</td>
<td>6,279</td>
<td>95.7</td>
</tr>
<tr>
<td>Tetanus</td>
<td>1,314</td>
<td>34</td>
<td>97.4</td>
</tr>
<tr>
<td>Poliomyelitis (paralytic)</td>
<td>16,316</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>Measles</td>
<td>503,282</td>
<td>89</td>
<td>100</td>
</tr>
<tr>
<td>Mumps</td>
<td>152,209</td>
<td>606</td>
<td>99.6</td>
</tr>
<tr>
<td>Rubella</td>
<td>47,745</td>
<td>345</td>
<td>99.3</td>
</tr>
<tr>
<td>Congenital Rubella Syndrome</td>
<td>823</td>
<td>5</td>
<td>99.4</td>
</tr>
<tr>
<td>Haemophilus influenza type b</td>
<td>20,000</td>
<td>54</td>
<td>99.7</td>
</tr>
<tr>
<td>Total Cases traditional vaccine preventable diseases</td>
<td>1,113,009</td>
<td>7,413</td>
<td>99.3</td>
</tr>
</tbody>
</table>

In 1980, near the beginning of the Expanded Programme on Immunizations (EPI), when vaccination coverage for the then routine vaccines was at or below 20%, vaccine preventable diseases cases and deaths were globally commonplace. By 2013, both have dramatically decreased. WHO estimates that “Immunization averts an estimated 2 to 3 million deaths every year from diphtheria, tetanus, pertussis (whooping cough), and measles” (Table 5) .
TABLE 5. COMPARISON OF GLOBAL VACCINATION COVERAGE, VACCINE PREVENTABLE DISEASE CASES AND DEATHS BETWEEN 1980 AND 2013

<table>
<thead>
<tr>
<th>Disease</th>
<th>Vaccination coverage, (^i) (%)</th>
<th>Cases, n in 1000s</th>
<th>Deaths, n in 1000s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis &lt;24hr</td>
<td>-</td>
<td>38</td>
<td>-</td>
</tr>
<tr>
<td>Diphtheria</td>
<td>20</td>
<td>84</td>
<td>97.5</td>
</tr>
<tr>
<td>Pertussis</td>
<td>20</td>
<td>84</td>
<td>1982.4</td>
</tr>
<tr>
<td>Tetanus PAB(^iv)</td>
<td>20</td>
<td>84</td>
<td>114.31</td>
</tr>
<tr>
<td>Polio</td>
<td>86</td>
<td>21</td>
<td>52.8</td>
</tr>
<tr>
<td>Measles</td>
<td>16</td>
<td>85</td>
<td>4211.4</td>
</tr>
</tbody>
</table>

In 2003, in the Philippines around 73% of infants were vaccinated with three doses of DTP and polio vaccine, 70% with measles vaccine and 59% with all of these.\(^35\) By 2013, these rose to 83%, 81%, 77% and 70%, respectively. Thus, in ten years, all of these indicators improved by more than 10% points. In terms of fully immunized children, the Philippines ranked in 13\(^{th}\) (highest) of 58 countries who conducted a demographic and health survey within 5 years of 2003. In 2013, they ranked 8\(^{th}\) of 40 countries who conducted a survey after 2008.\(^51\) Thus, Philippines ranks in the top 20-22% of countries who conducted a DHS in the specified time periods. Yet, one in three infants remains not fully vaccinated by 1 year of age.

\(^i\) Diphtheria, pertussis, tetanus vaccine are 3 doses, measles-1 dose, hepatitis B birth dose within 24 hours of birth, and 3 doses ever.

\(^iv\) "Protected at birth" is at least 2 doses tetanus during current pregnancy or 3 doses ever.
1.4.1. Hepatitis B

Globally, hepatitis B virus (HBV) has infected around two billion people, of whom 360 million were chronic causing around 600,000-780,000 deaths from liver cirrhosis and hepatocellular carcinoma annually.\textsuperscript{52,53} Infection during the first 28 days of life has up to 90% risk while adults have less than 10% risk of chronic infection.\textsuperscript{54} Up to 40% of chronic HBV infections are acquired during birth in Asia.\textsuperscript{55} Of all Filipinos, 10-12%, and of pregnant woman, 5-8%, have chronic HBV infection.\textsuperscript{56}

1.4.2. Measles

Before licensure of a vaccine (1963), measles was the most lethal infectious agent. Up to 135 million measles cases and 6 million deaths occurred annually.\textsuperscript{57} Measles causes immunosuppression, increasing risk of pneumonia, diarrhoea, and acute encephalitis.\textsuperscript{58} Following greatly strengthened global measles vaccination, WHO estimated deaths from measles had reduced to 2.6 million in 1990 and to 145,000 in 2013.\textsuperscript{59,60}

1.4.3. Diphtheria, Pertussis and Tetanus

\textit{Diphtheria:} epidemics have been known since the 6th century AD. Diphtheria most commonly infects the pharynx and the tonsils whereupon substantial absorption of toxin occurs. The toxin can cause severe prostration, pallor, rapid pulse, stupor, coma, and death (up to 20% in children under 5 years old who represent 40% of the total cases in US, and Europe). Myocarditis and neuritis are common sequelae of diphtheria infection. A vaccine was developed in the 1920s. There were 100,000–200,000 cases of diphtheria and 13,000–15,000 deaths annually in the 1900’s in the US; recent high vaccination coverage has reduced the numbers of cases to a few.\textsuperscript{61}
The 15 Newly Independent States of the former Soviet Union had more than 157,000 cases and 5,000 deaths in 1990-1996. Unusually, up to 80% of the epidemic diphtheria cases were among adults. Decreasing infant immunization coverage, a large adult immunity gap, and large population movements, fuelled the outbreak.62

Pertussis: Otherwise known as whooping cough, pertussis causes extensive repeated cough which in small children can lead to pneumonia, apnea, cyanosis, encephalopathy and death.63 It can attack up to 90% non-immune household contacts during the catarrhal stage. Prior to vaccines, pertussis was extremely common. Following large-scale vaccination efforts during the 1950s and 1960s, incidence and mortality decreased by greater than 90% in the industrialized countries.64 Despite reasonably high vaccination coverage in 2008, 16 million pertussis cases and 195,000 child deaths were reported.65 The vaccine efficacy is around 85% in preventing typical whooping cough.66

Neonatal tetanus: Neonatal tetanus is a usually lethal infection of the newborn. Starting between day 3 and 28 days of life, after being apparently well, the baby starts to manifest characteristic signs such as stiffening of the neck in hyper-extension and limbs, "sardonic smile" and seizures.

Every neonatal tetanus case represents a triple failure of the public health system. First, mothers who received protective doses of tetanus either during or before antenatal care (including through DTP vaccination in childhood) can effectively prevent most cases. Tetanus vaccine is the one universal vaccine for mothers (in the Philippines and globally). Second, clean delivery using sterile blades to cut the umbilical cord would prevent most of the rest. Finally, safe handling of the cord primarily by caregivers until it falls off would prevent the rest.
In 1988, neonatal tetanus claimed the lives of over 787,000 infants. In 1989, the World Health Assembly called for elimination of neonatal tetanus. Due to vast efforts to eliminate neonatal tetanus, deaths have decreased to an estimated 49,000 in 2013.\textsuperscript{67} Note that neonatal tetanus is one of the most under-reported vaccine preventable disease. Table 5 tetanus cases represents under-reporting, while the deaths are global estimates based on community surveys.

1.4.4. Poliovirus

Children infected with poliovirus are usually asymptomatic, but around 10% become affected by post-polio syndrome. There is no proven therapy for this. Only prevention exists.

First reported in 1789, this illness targeted children with residual debility of the lower extremities. Outbreaks were documented in the United States and Europe throughout the 19\textsuperscript{th} century. Early in the 20\textsuperscript{th} century, paralytic poliomyelitis reached epidemic proportions, exceeding 21,000 cases in the US alone. In 1955, the Salk polio vaccine was announced followed by the Sabin polio vaccine in 1963 which heralded the rapid decline of poliomyelitis cases. The last case of poliomyelitis due to infection with wild type virus was reported in 1979 in the US.

In 1988, WHO launched a global campaign to eradicate poliovirus.\textsuperscript{68} At that time, more than 350,000 cases were reported from 125 countries. By 2000, that had decreased by 99%. By 2002, three WHO Regions (the Americas, Western Pacific and European Regions) had been certified polio-free. By 2005, transmission had been interrupted in all but 4 'endemic' countries: India, Nigeria, Pakistan and Afghanistan. Wild poliovirus exported from northern Nigeria and northern India subsequently caused more than 50 outbreaks. New strategies led to new polio cases in 2010 falling by 95% in both northern Nigeria and northern India with no new cases appearing by
mid-2011; in Nigeria, endemic transmission appeared only in the north-east and north-west. Uncontrolled wild poliovirus transmission appeared restricted to Chad and Pakistan.69

1.4.5. Barriers to higher immunization coverage

Misperceptions of safety, importance of the vaccine or simple unawareness, rural residence, poverty, low educational attainment, single marital status, unemployment and from being certain ethnic groups are common user-related barriers cited in the literature (Table 6a).

Costs, accessibility, knowledge of timing of immunization, where to go, and how to arrange transportation are common socio-economic constraints cited in the literature. Often mothers depend on social networks for getting services. Negative experiences often occur among these groups making them less apt to get immunizations. They may feel shame due to poverty such as their children being dirty or poorly clothed. Neonates of women delivering outside a facility have more logistical challenges to receive a dose of hepatitis B vaccine within 24 hours of birth (Table 6b).

However, the problem contributed by the health providers include inflexible schedules, waiting times, poor communication to mothers, vaccine stock outs, poor follow up or historically an ineffective programme. Other barriers include health workers' poor knowledge about the vaccine schedule, immunization status or contraindications to vaccinate. Fear of wastage stops health workers from opening a multi-dose vial, creating missed opportunities. Finally, injection abscesses or other indications of safety lapses reduce likelihood children will be brought to be immunized (Table 6c).
### TABLE 6. SUMMARY OF LITERATURE ON A) USER-RELATED BARRIERS, B) SOCIO-ECONOMIC-RELATED BARRIERS AND C) PROVIDER-RELATED BARRIERS TO IMPROVED IMMUNIZATION STATUS

<table>
<thead>
<tr>
<th>a) User-related barriers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Awareness of the diseases</td>
<td>70</td>
</tr>
<tr>
<td>Misperceptions of safety or importance/unawareness, perceived efficacy</td>
<td>70, 71, 72, 73, 74, 75, 76, 77</td>
</tr>
<tr>
<td>Knowledge on timing of immunizations</td>
<td>70, 71, 75, 76, 77</td>
</tr>
<tr>
<td>Knowledge about place to get immunized</td>
<td>77</td>
</tr>
<tr>
<td>Reliable transportation/distance</td>
<td>71, 74, 78</td>
</tr>
<tr>
<td>Dependence on social networks for getting services</td>
<td>79</td>
</tr>
<tr>
<td>b) Socio-economic related barriers</td>
<td></td>
</tr>
<tr>
<td>Economic constraints, low income, unemployment</td>
<td>70, 80, 80</td>
</tr>
<tr>
<td>Low family educational level, marital status of parents, religion, ethnicity, place of residence, and sex of child</td>
<td>74, 75, 81, 82, 80, 83</td>
</tr>
<tr>
<td>Late start for immunizations</td>
<td>80</td>
</tr>
<tr>
<td>c) Provider Related</td>
<td></td>
</tr>
<tr>
<td>Inflexibility of scheduling</td>
<td>71, 81</td>
</tr>
<tr>
<td>Waiting time</td>
<td>71, 82</td>
</tr>
<tr>
<td>Poor communication to mothers</td>
<td>79, 84</td>
</tr>
<tr>
<td>Vaccine availability at health centers for monthly visits all SES factors disappeared</td>
<td>72, 84, 85, 86</td>
</tr>
<tr>
<td>Client accessibility to the services</td>
<td>79</td>
</tr>
<tr>
<td>Recording and reporting</td>
<td>86</td>
</tr>
<tr>
<td>Fear of wastage of 10 dose vials</td>
<td>80</td>
</tr>
<tr>
<td>Primary source of health information</td>
<td>72</td>
</tr>
<tr>
<td>Poor follow up</td>
<td>87</td>
</tr>
<tr>
<td>Health worker knowledge about vaccine schedule</td>
<td>86</td>
</tr>
<tr>
<td>Health worker knowledge about immunization status, practice or policy failure to vaccinate</td>
<td>84</td>
</tr>
<tr>
<td>Health worker knowledge about contraindications</td>
<td>83, 84, 85</td>
</tr>
<tr>
<td>Injection abscesses</td>
<td>83</td>
</tr>
<tr>
<td>Ineffective programme historically</td>
<td>79</td>
</tr>
<tr>
<td>Clients having negative experiences at HCs (e.g., unfriendly staff, turned away)</td>
<td>78, 83</td>
</tr>
<tr>
<td>Clients feeling of shame associated with poverty to attending clinic with dirty or poorly clothed child</td>
<td>78</td>
</tr>
</tbody>
</table>
In the Philippines, attendance at birth in facilities increased modestly from 38% to 44.5% between 2003 and 2008. This low attendance will impede gaining high HBV coverage within 24 hours of birth. A systematic review by Bohren et al. (2014) found health facility characteristics that deterred clients to attend included lack of privacy, lack of supportive attendance, fear of cutting and not making logistical plans for childbirth. Policies limiting the involvement of traditional birth attendants (TBA) and family members during birth provoked anxiety. Many women noted poor patient-provider interactions deterred seeking delivery care, describing providers as verbally or physically abusive, rude, bossy, unhelpful, disrespectful, critical, easily angered, having a poor attitude, and lacking compassion.

1.5. Review of policies related to breastfeeding, immunization and reducing barriers to facilitate based deliveries

1.5.1 Breastfeeding-related policies to which Philippines ratified or issued

The Philippines has signed, ratified or issued many treaties, laws and policies pertinent to breastfeeding.

- Conventions of the Rights of the Child (CRC) article 24
  “Recognizes the right of all children to the highest attainable standard of health, and specifically the right to good nutrition: 1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. 2. State Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: (a) To diminish infant and child mortality; (b) To ensure the provision of
necessary medical assistance and health care to all children with emphasis on the development of primary health care; (c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution; (d) To ensure appropriate pre-natal and post-natal health care for mothers; (e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding…”

- **CRC General Comment 16 on State obligations regarding the impact of the business sector on children’s rights (2013)** further clarifies: “States have an obligation to protect against infringements of rights guaranteed under the Convention and the Optional Protocols thereto by third parties. It means that States must take all necessary, appropriate and reasonable measures to prevent business enterprises from causing or contributing to abuses of children’s rights. Such measures can encompass the passing of law and regulation, their monitoring and enforcement, and policy adoption that frame how business enterprises can impact on children’s rights” (section 53). “Legislation and regulation are essential instruments for ensuring that the activities and operations of business enterprises do not adversely impact on or violate the rights of the child...States are also required to implement and enforce internationally agreed standards concerning children’s rights, health and business, including …the International Code of Marketing of Breast-milk Substitutes and relevant subsequent World Health Assembly resolutions” (section 57).
• **Covenant on Social, Economic and Cultural Rights** article 10, states “Special protection should be accorded to mothers during a reasonable period before and after childbirth. During such period working mothers should be accorded paid leave or leave with adequate social security benefits.”

• **Philippine Code of Marketing of Breast-Milk Substitutes (1981):** “No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code” (Article 6.2). “Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specific in Article 4.3” (Article 6.3). “Health workers should encourage and protect breast-feeding” (Article 7.1). “Financial and material inducements to promote products within the scope of the Code should not be offered by manufacturers or distributor to health workers or members of their families, nor should they be accepted by health workers or members of their families” (Article 7.3). 

• **Republic Act 7600 (1992)** called for the implementation of the *Ten Steps for Successful Breastfeeding* and the global BFHI standards in the Philippines. The 10-steps state “every facility providing maternity services and care for newborn infants should: 1) Have a written breastfeeding policy that is routinely communicated to all health care staff. 2) Train all health care staff in skills necessary to implement this policy. 3) Inform all pregnant women about the benefits and management of breastfeeding. 4) Help mothers initiate breastfeeding within half an hour of birth. 5) Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants. 6) Give newborn infants no food or drink other than breast milk, unless
medically indicated. 7) Practise rooming-in - that is, allow mothers and infants to remain together - 24 hours a day. 8) Encourage breastfeeding on demand. 9) Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants. 10) Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic. In 2003-2004, 79% (1427/1798) of all the health facilities with maternity services were certified as Mother-Baby Friendly.\(^9^4\) Taken in context of relatively poor initiation of breastfeeding in the first hour, being certified may not mean that practice continues after the certification process was completed.

- In 2005, the Philippines Health Insurance Corporation (PhilHealth), issued Circular No. 26, s-2005, requiring all accredited hospitals to be certified as Mother-Baby Friendly.\(^9^5\) The Government and development partners revised the policy and issued Administrative Order (2007-0026) to revitalize MBFHI in health facilities for both maternity and newborn care services. The 2007 policy required all health facilities to pass the external assessment receive a Certificate of Commitment; and after two years, a re-assessment. If the health facility maintained the standards, the health facility will be accredited. Health facilities would be re-assessed every three years. In practice, only one-quarter have received the Certificate of Commitment and 26 have been accredited. The major activities occurred before 2008 without recent assessments.

- **Republic Act 10028 (Expanded Breastfeeding Promotion Act), 2010.** Along with its Implementing Rules and Regulations, this was the most comprehensive act to protect, promote and support breastfeeding including maternity protection.\(^9^6\)
• **Infant and Young Child Feeding National Policy** (AO 2005-0014), 2005, a local adaptation of the Global Strategy on Infant and Young Child Feeding (2002), translated the various laws and policies on breastfeeding into the first comprehensive policy on initiation, exclusivity and continued breastfeeding with appropriate complementary feeds. It also included workplace protections and other items. As it predated Republic Act 10028, the latter superseded the policy.

Taken together, the international treaties, laws, regulations and policies provide a strong legal and policy framework for breastfeeding.

1.5.2 Immunization-related policies which the Philippines issued

Similarly, the Philippines has a strong legal and policy framework for supporting immunizations.

• **Presidential Decree no. 996, Providing for compulsory basic immunization for infants and children below eight years of age, 1976** had made BCG, DPT, OPV and Measles available toward universal vaccination.

• **Administrative Order 2006-0015, Implementing Guidelines on Hepatitis B Immunization for Infants**, issued by the Secretary of Health was the first policy to require Department of Health to procure 75% of the national hepatitis B vaccine needs for 2007 and 100% in 2008 onwards. It also mandated all newborn infants to be given hepatitis B within 24 hours of birth which constituted the first immunization schedule change in 20 years.
• The Secretary of Health also issued a memo, **List of highest priority areas for EPI (2006)** targeting local governments accounting for half the unimmunized in the country. It was the first policy to make publically visible these local governments and gave the chief executives roles to improve immunization coverage since decentralization occurred. This memo also mandated supportive supervision by regions.

• Prior to every supplementary immunization activity (i.e. “vaccination campaign”) an executive order has been issued by the President of the Philippines. **Executive Order 663** represented the first to address roles of functions of various government agencies to improve routine immunizations. It also instructed local governments to provide routine vaccinations completely free of charge.

• **Republic Act no. 7846** - An act requiring compulsory immunization against hepatitis-b for infants and children below eight (8) years old, amending for the purpose presidential decree no. 996, and appropriating funds, 2007 established a legal inclusion of hepatitis b vaccine as part of routine funds to be routinely procured.

• **Republic Act no. 10152** An act providing for mandatory basic immunization services for infants and children, repealing for the purpose presidential decree no. 996, as amended, 2010 further expanded procurement to include H Influenza type B and rubella vaccine. The act further made clear that midwives were allowed to provide immunizations which previous laws were ambiguous on.
1.5.3 Policies on reducing barriers to access to facilities for childbirth which the Philippines issued

Finally, the ratified treaties, laws and policies are strongly protective of women’s rights to access facilities for childbirth.

- **Convention on Elimination of All Forms of Discrimination Against Women** article 12 states “ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.”

- **Philippine Constitution** states: “a. Art. XIII, §11—The State shall adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all people at affordable cost. There shall be priority for the needs of the underprivileged, sick…women, and children. c. Art. II, §9—The State shall promote a just and dynamic social order that will ensure the prosperity and independence of the nation and free the people from poverty through policies that provide adequate social services, promote full employment, a rising standard of living, and an improved quality of life for all. d. Art. II, §10—The State shall promote social justice in all phases of national development. e. Art. II, §11—The State values the dignity of every human person and guarantees full respect for human rights. f. Art. II, §14—The State recognizes the role of women in nation building, and shall ensure the fundamental equality before the law of women and men. g. Art II, §15—The State shall protect and promote the right to health of the people and instil health consciousness among them.”
• **Administrative Order 2008-0029: Implementing Health Reforms for Rapid Reduction of Maternal and Neonatal Mortality** ordered “the shift from home-based deliveries to facility-based births attended by skilled birth attendants” through development of a three tiered system with “aggressive promotion… deliberate planning and special provisions for hard-to-reach segments.” It further called to “Facilitate process in transferring financial resources to the regions and Local Government Units as part of overall grants approach to local health system development and enhancing procurement and supply chain management of essential MNCHN logistics….Philippine Health Insurance Corporation …assist facilities in improving the management of claims, payments and reimbursements; and Strengthen existing benefit packages in support of the MNCHN Strategy.”

• **Department Memorandum 2009-0110: Adoption of the Manual of Operations on Maternal, Newborn and Child Health and Nutrition (MNCHN) in the Implementation of Programs, Projects and other Initiatives for Women and Children** in support of the above administrative order states, “…those at the lowest income levels may avail of the services for free.”

• **Republic Act no. 10354, 2012: An act providing for a national policy on responsible parenthood and reproductive health.** It allowed midwives and nurses to administer oxytocin, magnesium sulfate and other lifesaving emergency obstetric drugs; and required Philippine Health Insurance Corporation to treat serious obstetric complications, and provide funding for the upgrading of faculties necessary to meet Basic and Comprehensive Emergency Obstetric Care.
1.5.4 Review of International Evidence and Philippine Policy
Translation

Pulzi and Treib (2006) reviewed 20 years of policy implementation
and in summary found the following. Traditionally, the policy
implementation starts with a decision made by central government and
assumes a direct causal link between policies and observed outcomes.
Therefore adequate procedures need to ensure that policies are
executed as accurately as possible. These include sufficient resources
and systems of clear responsibilities and hierarchical control to
monitor and supervise the actions of implementers.

Twenty years of implementation research has changed this traditional
viewpoint. Four major issues are highlighted in the research.

First, implementation is a continuum located between central guidance
and local autonomy. The end-user preferences, incentives and
negotiations within implementation networks have to be taken into
account to the same extent as centrally defined policy objectives and
efforts at hierarchical control. Problems in policy execution were
noted as insufficient administrative resources, inter-organizational co-
ordination problems or cumbersome legislative or administrative
procedures at the domestic level.

The second major finding of implementation research is that
implementation is a process where policies maybe locally re-shaped,
re-defined or overturned. Deeply entrenched policy traditions and
administrative routines and the extent to which implementers must
depart from their traditional “ways of doing things” poses great
obstacles to reforms.

The third major finding of implementation research is that
implementation and policy formulation are highly interdependent
processes. Prior debates and policy meanings influence implementers’
understanding of the policy problem thereby affecting implementation.
Fourth, influences from other policy fields or external economic developments need to be taken into account. Implementing agents face multiple policy meanings as policy formation frequently involves the accommodation of contradicting interests.

Rowe et al,\textsuperscript{105} in a systematic review noted the likelihood of health workers implementing a policy related to complexity and clarity of guidelines, health topic addressed by guidelines, and changes in guidelines over time.

The central Philippines government has a comprehensive set of policies, laws and ratification of treaties for protection of breastfeeding and universal access to immunization and facility-based childbirth care. These policies were reviewed by many levels including responsible legal offices internally for policies and to the Office of the Secretary General for treaties to ensure wording is legally accurate. In all the regulations (accompanying laws) and policies mentioned, roles and responsibilities to implement the policy are noted.

Unfortunately, no law, regulation or policy had a budget line for monitoring of implementers. Reviewing Philippine policies and laws revealed they all undergo a consultative process which includes end-users and other stakeholders. Regulations additionally undergo public hearings. Prior to every measles vaccination campaign, an administrative order is issued on the campaign guidelines. Regions, provinces and cities all hold meetings to review the policy. A similar process took place for the new hepatitis B at birth and other immunization policies. This is supposed to take place with all other nationally issued policies but assessments of the degree to which this is done or the number of competing policy disseminations was not found. No formal assessments were found on end-user perspectives of any of the policies noted above. Furthermore, like monitoring, no law,
regulation or policy had budget lines or legally supported dedicated administrative resources at national or local level.

The Philippines set up an ad hoc passive reporting mechanism to monitor breastfeeding code violations and enforce escalating actions. In 2012, the reporting website [http://www.milkcodephilippines.org/cases.php](http://www.milkcodephilippines.org/cases.php) was introduced. Attempts between 15 December 2014 and 1 May 2015 to get the number of cases from the website, the message perpetually appeared, “Sorry, we're currently updating this section. Thank you!” Since 1986 when the Philippine Milk Code was passed, no violating companies, industry representatives or health workers have been prosecuted.

In summary, the Philippines is an example of where existence of a reasonably comprehensive and clear framework of policies may not translate into implementation. Health worker expectations are spelled out in the various Philippine policy documents. Although policy formation is consultative in the Philippines, no studies were found on implementers’ understanding of the policy problems. The major gap in the framework is that no law, regulation or policy specified resources for national and local administration, monitoring and enforcement.

1.6 Management issues resulting in sub- optimal coverage of basic interventions

In a systematic review of global data on why women die after reaching facilities, Knight et al. (2013) reported the most commonly cited barriers were inadequate training/skills mix (86%); drug procurement/logistics problems (65%); staff shortages (60%); lack of equipment (51%) and low staff motivation (44%) due to low wages and poor conditions. Inability or late referral was another contributor.
Rowe et al (2005) studied factors influencing health worker practices. First, health worker practices were related to their own knowledge of guidelines, skills, motivation, job satisfaction, remuneration, confidence to implement the guidelines, belief that the guidelines are effective, professional values toward corruption, personal profit motives, fear that unsatisfied patients will go to another health worker and comprehension of work responsibilities. Additional factors related to patient and socio-demographic factors. Health workers were influenced by clinical practices and attitudes of co-workers, peer pressure, leadership of the director, supervision, patient caseload, availability of supplies and equipment, communication and health-worker participation in planning and organizing work. Finally, health workers were influenced by professional associations, certifying bodies, educational opportunities, rules governing health-worker behaviors and working conditions, amount of salary and regularity of payment, non-financial incentives, job security, presence of quality improvement processes, availability of information, decentralization and promotion of products by industry.

A literature search only turned up analysis of a few of these items in the Philippines. Specifically highlighted here is availability of essential drugs and staff.

*Availability of drugs in the Philippines:* A WHO study in 2006 revealed only 11% of the core essential medicines (30 drugs that WHO defines as needing to be available at all levels and at all times) were available in public health facilities. Reviewing budgets of local government (e.g., municipalities and cities) revealed that only a few local governments included a budget line for more than a few essential drugs. Local Governments who procured drugs included non-essential medicines (e.g., multi-vitamins, cough syrup and analgesics). Another study found key medicines are available in 53.3% of the public health facilities, 100% of private pharmacies and 33.3% of central-district warehouses. The average stock out duration for public
health pharmacies was 24.9 days while it was 43.8 days for central-district warehouses.\textsuperscript{108} Stock out of HBV will directly impact providing HBV at birth, trust in the health system and one would expect with these health worker moral.

\textit{Availability of staff in the Philippines:} A total of 24,941 health workers (2838 doctors, 4576 nurses and 17,525 midwives) in the country corresponds to 28 health workers per 100,000 population. This meets the WHO standard of 23/100,000. However, one region, the Autonomous Region of Muslim Mindanao has only 19/100,000.\textsuperscript{109} The maternal health programmes identified 1514 Basic Emergency Obstetric Care (BEmOC, which meet standards as measured by six signal functions) and 760 Comprehensive Emergency Obstetric Care (CEmOC as measured by meeting 8 signal functions) throughout the country. This surpasses the global standard of at least one BEmOC per 125,000 population and one CEmOC per 500,000 population.\textsuperscript{110,111} Training is addressed below (1.7)

1.6.1 Effective methodologies to build human resource capacity

Knight et al. (2013)\textsuperscript{106} reported the most commonly cited barrier was inadequate training/skills mix (86%). Rowe et al\textsuperscript{105} found dissemination of printed information or guidelines were ineffective in changing health worker practices as a single intervention. Large, didactic trainings and workshops focusing on multiple problems were far less effective than ones with smaller groups, focused topic, with role playing and practical skills development. A systematic review by Patterson et al. (2010)\textsuperscript{112} revealed that quality improvement teams improved patient outcomes.

In-service training for staff in the Philippines includes Reaching Every Barangay and cold chain management (Immunization), the WHO 5-day course on breastfeeding counseling and the 5-day course on
Emergency Obstetric Care. The immunization related courses are limited in didactic training (less than 1 hour per day) and focus most of the time on data analysis, site visits assessments and planning to address gaps. The counseling course has 33 sessions with didactic, role play and observation. The course spends more than 50% of the time didactic with some practicums and skills labs.

1.6.2 The effectiveness of marketing controls on breastfeeding

Studies suggest that only comprehensive bans on advertising, promotion and sponsorships have been effective in controlling marketing of breast-milk substitutes. Partial bans were exploited for ongoing marketing. Examples include India which prohibits advertising and China which allows TV advertising and celebrity endorsers. India sales has remained flat while China sales has vastly increased (Figure 7).

![Figure 5. Increase in milk infant formula retail value in China and India.](image)

Article 7.3 of the International Code of Marketing of Breast-milk Substitutes states, “Financial and material inducements to promote
products within the scope of the Code should not be offered by manufacturers or distributor to health workers or members of their families, nor should they be accepted by health workers or members of their families.” It also states "to ensure that nutrition and health claims are not permitted for unhealthy foods for infants and young children, except where specifically provided for in national legislation.”  

The Royal College of Paediatrics, Child Health (RCPCH) in the UK and the Pakistan Paediatric Association, stopped accepting direct sponsorship from Infant Formula Manufacturers, and with no adverse financial effects. These show it is possible for professional bodies to divest from milk formula manufacturers.

1.6.3 The effectiveness of community interventions

Linking with communities can be direct community participation or through a trained cadre of lay health workers (LHW). WHO has identified which functions LHW or community members can safely administer. In both cases, linkages with local health facilities, packaging interventions, retention strategies, supports with incentives, ongoing LHW re-skilling, supervision, mentoring, and integration with the formal health system help improve the effectiveness and sustainability of the interventions.

Community mobilisation to increase facility-based childbirths also has a heterogeneous range of interventions including women’s groups with community action cycle, community education meetings, village health committees and community campaigns. Community-based mobilisation interventions were associated with a 71% increase in facility-based childbirth coverage (RR=1.71, 95% CI 1.11–2.64). These community mobilisation strategies were associated with reduction of perinatal and newborn mortality by 25% (RR=0.75, 95% CI 0.59–0.96) and 36% (RR=0.64, 95% CI 0.48–0.85),
respectively. Community group education sessions alone have not been associated with impact. Intensity and inclusion of action-learning cycles are necessary for improving care practices, facility utilisation and birth preparation. Behaviour change communication requires stakeholder engagement and particularly community workshops to ensure tailoring of messages to local customs. In a heterogeneous group of studies, community-based health worker or LHW facilitated participatory action of women’s groups was found associated with reduced NMR by 23% (RR=0.77, 95% CI 0.61-0.96). The effect size is greatest where baseline NMR and program coverage is high.

A Cochrane review which included 7 relevant studies revealed that community-based interventions increased tetanus immunisation by 5 (average RR 1.05; 95% CI 1.02 to 1.09) and 11 studies showed that rates of early breastfeeding increased by 93% (average RR 1.93; 95% CI 1.55 to 2.39). In Bolivia, community action cycle has increased ANC attendance, tetanus immunisation and contraceptive prevalence, with a concomitant decrease of 63% in perinatal mortality rate ($P<0.001$). In Indonesia, 30.7% of complicated deliveries took place in health facilities in intervention areas where TBAs had a radio to facilitate risk-based referral for facility-based obstetric care compared to 11% in control areas. In Uganda, equipping TBAs with radios to communicate with medical staff to triage and refer women with obstetric complications, coupled with ambulance transport and drivers, contributed to a 13% increase in supervised births and a 50% reduction in hospital-based maternal case fatality rate. In Pakistan, training TBAs to recognise obstetric complications and providing wireless telecom systems enabled TBAs to arrange emergency transport. Perinatal mortality in intervention areas was 49.4 per 1000 compared to 85.2 per 1000 in the comparison areas. Mobile phones and a text service increased likelihood of skilled birth attendance, ANC and increased satisfaction and confidence in health workers during delivery in Tanzania, Zambia and the Thai-Myanmar border. A 24-hour obstetric telephone helpline in India reduced delays in deciding to seek care and obtaining care during
Two large RCTs supported community groups to establish emergency funds for transport during birth and showed that the likelihood of skilled birth attendant (SBA) use in a facility tripled, in Pakistan (OR=3.0, 95% CI 2.1–4.4) and Nepal (OR=3.6, 95% CI 2.7–4.7). Other challenges with emergency communications and transport schemes include establishing appropriate communication systems for remote areas and ensuring adequate coverage of drivers.

Role definition, training, supportive supervision and communication systems for TBA increases maternal and child health service utilisation. Training health workers to collaborate effectively with TBAs increased skilled birth attendance 58% in Peru and 44% in Myanmar; while training hospital staff in the cultural practices of women and TBAs and standards of care led to an almost three-fold increase in TBA referrals to a SBA. In Malaysia role definition for SBA and TBA increased SBA coverage by 28% while in Cambodia role definition coupled with free delivery vouchers for women and financial incentives for TBAs to refer women led to a 29% increase in SBA utilisation. Encouraging TBAs to refer women for childbirth in a facility, without additional support, incentives or integration does not increase coverage of skilled birth attendance.

Logically, these community-based strategies for increasing demand for facility-based childbirth are more likely to succeed when quality services, referral to higher level facilities for obstetric emergencies and reduced user fees exist.

Community involvement to improve immunization utilization is common but no specific studies were found in the literature beyond that noted above. In the Philippines, community health volunteers frequently provide health information to residents, maintain lists of individuals needing immunizations, motivate families to get immunized, track defaulters and other such functions.
Peer counseling has been found to be effective in increasing breastfeeding rates in controlled environments. However, no studies showed how to do this at scale.

1.7 Summary

The following can be highlighted from the review.

1. Optimal feeding and receipt of immunizations are among the most effective interventions to save lives and prevent disability.
2. Rates of immunization and initiation, exclusivity and continuing breastfeeding can be vastly improved in Philippines.
3. While a strong policy framework exists, no mechanisms for monitoring and enforcement exist.
4. Provider-related barriers affect breastfeeding and immunization coverage.
5. Environmental barriers, especially out-of-pocket expenditure, (i.e., expenditures for health care paid by families), can impede access to basic care.
6. Linkages with communities can improve basic services.

Given these barriers, we developed a conceptual framework to explore how specifically policies, management, provider capacity and communities linkages influence feeding and immunization in the Philippines (Table 7).
### TABLE 7. CONCEPTUAL FRAMEWORK OF AREA OF INFLUENCE AND UNDERLYING INFLUENCE ON INFANT BREASTFEEDING AND COMPLETENESS AND TIMELINESS OF IMMUNIZATIONS

<table>
<thead>
<tr>
<th>Area of influence</th>
<th>Underlying influence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Health care worker practices:</td>
<td>a. Policy translation into local action</td>
</tr>
<tr>
<td></td>
<td>b. Management level influences</td>
</tr>
<tr>
<td></td>
<td>c. Human health resource capacity</td>
</tr>
<tr>
<td>2. External and social influences</td>
<td>a. Out of pocket expenditures</td>
</tr>
<tr>
<td></td>
<td>b. Marketing of breast-milk substitutes including through the health system</td>
</tr>
<tr>
<td>3. Community empowerment</td>
<td>Linkages of health system with communities</td>
</tr>
</tbody>
</table>
Chapter 2: STUDY HYPOTHESES AND OBJECTIVES

Hypothesis: Health worker practices and health system barriers are determinants of the effectiveness of life-saving interventions such as measures toward eliminating vaccine preventable diseases and optimizing breastfeeding. Developing means to change practices and circumvent health system barriers will improve immunization and optimal feeding rates.

Overall Objective: To study policy-level, provider and user-related facilitators and barriers on feeding and immunizations to help drive policy change, strategic planning and hospital reform in the Philippines.

Specific Objectives:

To determine the influence of the following on coverage of immunization and breastfeeding:

4. Health care worker practices:
   a. Policy translation into local action
   b. Management level influences
   c. Human health resource capacity

5. External and social influences
   a. Out of pocket expenditures
   b. Marketing of breast-milk substitutes including through the health system

6. Community linkages and empowerment
Chapter 3: METHODS

3.1 Overview of characteristics of studies.

Table 7 provides an overview of the study sites, design, sample size and main outcomes of the studies.
Table 8. Characteristics of the studies used.

<table>
<thead>
<tr>
<th>Study number, title, journal and year.</th>
<th>Study site</th>
<th>Study design</th>
<th>Sample size</th>
<th>Main Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate newborn care practices delay thermoregulation and breastfeeding initiation. Social Science and Medicine (2011)</td>
<td>Simple random selection of 51 of the largest 150 government hospitals nationwide.</td>
<td>Observation of consecutive births within a 24 hour period (with follow up on the second day of life) using a detailed practice assessment form.</td>
<td>N=481 births</td>
<td>Average, % (drying, skin-to-skin contact, breastfeeding initiation, various routine interventions) Median, time (second or minute, cord clamped, drying, bathing, put to breast, separated, various routine interventions).</td>
</tr>
<tr>
<td>Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines? Acta Paediatrica (2011)</td>
<td>Three disadvantaged rural and urban municipalities in Quezon and Negros Occidental Provinces.</td>
<td>All households with children younger than 24 months old surveyed in randomly selected communities (barangays).</td>
<td>N=345</td>
<td>Factors associated with infant formula use, OR (p-values).</td>
</tr>
<tr>
<td>A people's initiative to counteract misinformation and marketing practices: The Pembo, Philippines Breastfeeding Experience. J Hum Lact (2009)</td>
<td>Barangay Pembo, Makati, Metro- Manila.</td>
<td>In consultation with health staff, peer counselors identified mothers with infants under 2 months of age with sub-optimal feeding, counselled on improved feeding practices; and</td>
<td>N=161</td>
<td>Exclusive breastfeeding, mixed feeding and exclusive formula feeding pre and post three visits of peer-counselors, OR (p-value).</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
</tbody>
</table>

<p>| Timing of Hepatitis B vaccination and impact of non-simultaneous vaccination with DTP vaccine following introduction of a Hepatitis B birth dose in the Birthing and primary health facilities | Combination of random and purposive selection based on proportion of health facility births and HBV at birth coverage. All 5-7 month old infants born | N=1431 births with complete data. | Timely doses of infant vaccines, %. HBV and DTP timeliness and completion, OR (p-value). | ⁵ 4 hospitals were excluded due to not having data available; OR-Odds Ratio; HBV-Hepatitis B vaccine; DTP-Diphtheria, tetanus and pertussis vaccine. ⁶ High performance was considered above 50% documented birth dose coverage. However, in reality, all 91 hospitals either achieved above 92% or below 7% documented birth dose coverage. |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Study Details</th>
<th>Study Methodology</th>
<th>Findings</th>
<th>Implications</th>
</tr>
</thead>
</table>
| Philippines. J Public Health Pol (2012) | between 1 October and 31 December 2008 were included. Records were reviewed at birthing facilities and health facility where immunizations received. | Nationwide 228 sentinel hospitals. Analysis of surveillance data following a measles vaccination campaign. | N=10,061 | Reduction in measles cases, deaths and IgM positive specimens pre and post campaign, %.
| The need for quality of services and human resources to be central for universal health care. Health Policy Plan (2015) | Commentary on the need for future investments into universal health care to focus on quality of care and of human health resources | Analysis of findings, implications and review of evidence-based actions to address the gaps | | |
3.2 Study sites

All studies took place in the Philippines. The Philippines is an atoll with 7107 islands covering about 300,000 square kilometres situated in the South China Sea. The country is divided into 3 major island groups (Luzon, Visayas and Mindanao) with 17 regions, 80 provinces and more than 1500 cities and municipalities. The study sites of sub-national studies are shown below (Figure 6).

FIGURE 6. SUBNATIONAL STUDY SITES. NOTE THAT STUDY 4 WAS CONDUCTED IN APPROXIMATELY THE SAME LOCATIONS AS STUDY 1 BUT WITH MORE SITES SELECTED. IN STUDY 5, EACH FLAG REPRESENTS TWO NEARBY CITIES.
Cost of travel and staff time limited site selection in the subnational studies (Studies 1-5). Study 1 (*Immediate newborn care practices delay thermoregulation and breastfeeding initiation*) was carried out in 51 randomly selected sites of the 91 sites selected for Study 4 part 1 (*Implementing a national policy for hepatitis B birth dose vaccination in Philippines: Lessons for improved delivery*). These in turn were randomly selected from the 150 largest hospitals in the country which represented more than 20% of the total births in the country. The major limiting factor for Study 1 was that it required at least 48 hours on site while Study 4 could be carried out in several hours.

Study 2 (*Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines?*) took place in three of seven poor municipalities riding on an educational survey. The three sites selected were the most rural, an urbanizing and a mixed municipality. These three municipalities had 75 barangays which were categorized into proximity strata (within, near or far from the town center). Of these, 16 were randomly selected within proximity strata. All households with children <24 months in the selected barangays were surveyed with the marketing questionnaire.

Study 3 (*A people’s initiative to counteract misinformation and marketing practices: The Pembo, Philippines Breastfeeding Experience*) included one purposively selected, very large barangay (lowest administrative unit in the Philippines) whose Barangay Captain made a strong request in a national meeting of barangay captains to receive technical assistance to improve breastfeeding rates. Similarly Study 4 part 2 (*Implementing a national policy for hepatitis B birth dose vaccination in Philippines: Lessons for improved delivery*) included one purposely selected municipality whose municipal health officer made a strong request at a national meeting for technical assistance to reach the large number of mothers who deliver at home with a birth dose of hepatitis B vaccine.
Due to its complex study design, Study 5 (*Timing of Hepatitis B vaccination and impact of non-simultaneous vaccination with DTP vaccine following introduction of a Hepatitis B birth dose in the Philippines*) required minimizing and clustering sample sites. Two regions were excluded due to inadequate security (Autonomous Region of Muslim Mindanao) and concerns about generalizability of results to rural areas (National Capital Region). The fifteen remaining regions were categorized into four groups defined by the percentage of infants born at health facilities and DTP1 vaccination coverage as follows: <50% of infants born in health facilities and <90% DTP1 vaccination coverage; <50% of infants born in health facilities and ≥90% DTP1 vaccination coverage; ≥50% of infants born in health facilities and <90% DTP1 vaccination coverage; and ≥50% of infants born in health facilities and ≥90% DTP1 vaccination coverage. To further minimize the sample, three of the four groups were randomly selected and from each group one region was randomly selected. In each selected region, two districts were purposively selected based on high and low proportion of facility-based deliveries. Within each selected district, birthing facilities were stratified by size and then randomly selected: one large, one medium and one small (defined in the manuscript). A total of 18 Birth Providers, six from each region, were selected.

Study 6 (*Philippines 2004 Measles Campaign: A success story towards elimination*) used 228 sentinel surveillance sites which represented every region and province.

Study 7 (*Secondary analysis of a national health survey on factors influencing women in the Philippines to deliver at home and unattended by a healthcare professional*) used the Philippine National Demographic and Health Survey, a nationwide representative proportional sampling based on sample size.
3.3 Study design and procedures

Study 1 (Immediate newborn care practices delay thermoregulation and breastfeeding initiation) was an observational study by trained physicians of 481 consecutive births in 51 hospitals. A priori, the observers were found to be capable to observe at least 10 deliveries a day (in a busy hospital). This corresponded to 3650 births a year, which is typical of hospitals included in the study. As noted above, financial limitations constrained the sample size. Fifty-one hospitals from nine regions was within the budget. As the study was exploratory on obtaining median [and interquartile] times of events around newborn care and the percentage of babies who received key interventions as well as harmful practices, the sample size and selection constraints should not affect the validity of the study.

Study 2 (Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines?) was a cross-sectional survey of all households with children under 24 months of age in the randomly selected barangays to look at factors associated with infant formula usage. Based on a priori estimates of population size, the expected number of children under 24 months was approximately 400. Using national statistics where formula usage rates are around 35%, with a z of 1.96, and 1-β of 0.842, a statistically significant odds ratio of 1.5 could be detected.

Study 3 (A people's initiative to counteract misinformation and marketing practices: The Pembo, Philippines Breastfeeding Experience) was a pre-post intervention study of all mothers with infants under two months of age with sub-optimal feeding in Barangay Pembo, Makati, Metro-Manila to look at improvements in breastfeeding. Specifically, the baseline practices obtained on visit 1 were compared to those on visit 3 which followed peer-counseling conducted on visit 2. As this work was exploratory, a priori sample size calculations were not considered. Retrospectively, a population of 30,000 would have a birth cohort of 3% or 900 infants. As the peer-
counseling was initially expected to take 4 months, an estimated 450 infants would be 0-2 months. With formula use prevalence exceeding 50%, the target population would be around 225. This should be sufficient to see a reduction by half of the prevalence of formula use.

Study 4 part 1 (Implementing a national policy for hepatitis B birth dose vaccination in Philippines: Lessons for improved delivery) consisted of records review of births to determine timing of hepatitis B administration and a birthing facility assessment of policies, standard operating procedures and availability of various supplies and equipment. Study 4 part 2 consisted of health facility assessments of all nine health centers in a Municipality in Metro-Manila, including pre-post training on gaps and communication with community health workers to identify and vaccinate all infants in a timely manner. As this work was exploratory, a priori sample size calculations were not considered. Retrospectively, with a population of 60,000, the annual birth cohort should be around 1,800 in the pre-intervention and for one-quarter, 450 in the post-intervention. These sample sizes should be sufficiently large enough to detect relatively small changes if they are present.

Study 5 (Timing of Hepatitis B vaccination and impact of non-simultaneous vaccination with DTP vaccine following introduction of a Hepatitis B birth dose in the Philippines) included a cohort of 5–7 month old infants born at Birth Providers between 1 October and 31 December 2008, where trained data collectors abstracted data at birthing centers from infants’ birth and vaccination records, birth date and time and HBV birth dose date; and from primary health facilities vaccination records and dates. The target number of records was set at 1650, including 150 each from six large Birth Providers, 75 each from six medium Birth Providers, and 50 each from six small Birth Providers.
Study 6 (*Philippines 2004 Measles Campaign. A success story towards elimination*) was based on measles cases over a 10 year period in 228 sentinel hospitals before and after a measles vaccination campaign.

Study 7 (*Secondary analysis of a national health survey on factors influencing women in the Philippines to deliver at home and unattended by a healthcare professional*) was secondary analysis of Demographic and Health Survey, 2003 including review of baseline characteristics and barriers to accessing health facilities and a mapping of GPS coordinates of home unattended deliveries.

### 3.4 Data management and analysis

Study 1: Data were presented as percentages for the categorical variables and median ± interquartile range for times. All variables were analysed by subgroup, including training of the delivery attendant, mode of delivery and hospital size. Sensitivity analysis was carried out by replacing missing data with the largest and smallest value in the data set.

Study 2: Chi-square and t-tests were used to measure differences in categorical and continuous variables. Logistic regression was used to calculate adjusted odds ratios for formula use relative to breastfeeding.

Study 3: Test of proportions was used to determine the statistical significance between feeding practices and different baseline characteristics and to compare feeding practice before and after the intervention.
Study 4: For part 1, the nationwide hospital assessment, percentages, prevalence odds ratios, and 95% confidence intervals were calculated for hospitals with hepatitis B birth dose coverage >50% and compared to those with ≤50% coverage. The 50% cut point was established based on a bimodal distribution of birth dose coverage across hospitals. Test of proportions was used to determine the statistical significance of pre versus post intervention hepatitis B at birth administration (stratified for less than and greater than 24 hours after birth).

Study 5: Univariate analyses was conducted to determine vaccination coverage and the proportion of infants vaccinated by demographic characteristics. Chi-square tests to compare the proportion of infants vaccinated by various characteristics. Missed opportunities occurred when providers gave only DTP1 or HBV2, or only DTP3 or HBV3 at the same visit.

Study 6: The average number of reported measles cases, deaths, the proportion of specimens positive for IgM serology and the proportion of suspect measles cases that had received measles vaccination were compared for the five years before the start of the campaign (January 1999-December 2003) with those two years after the campaign (April 2004-March 2006).

Study 7: All Demographic and Health Survey data consisted of discrete responses to a series of questions. Data were weighted using the sample weight variable. Statistical significance was determined using test of proportions or chi-square test for categorical variables. ORC Macro-International randomly offset GPS coordinates to ensure confidentiality: rural points contained 0–5 km of positional error; urban points contained 0–2 km of error; and a further 1% of the sample points were offset by 0–10 km.
STATA 9.1 (STATA Corporation, Texas, USA) was used for data analysis in Studies 1-4, 6 and 7. SAS 9.2 was used for Study 5. Statistical difference was considered significant at the p<0.05 for all studies.

3.5 Ethical Approval, Funding and Statement of Conflict of Interest

Ethical approval was received for Studies 1, 4 and 5 from the Institutional Review Board of the National Institutes of Health, and for 2 and 3, from the Department of Health Research Ethics Committee, both in Manila, Philippines. Studies 4 and 5 were supported by the US Centers for Disease Control as well as by World Health Organization. The others were supported exclusively by World Health Organization financial and in-kind support. There were no conflicts of interests in any of the studies presented.
Chapter 4: RESULTS

4.1 Manuscripts

Immediate newborn care practices delay thermoregulation and breastfeeding initiation

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4. Department of Health, National Centers for Disease Prevention and Control, Manila, Philippines

Keywords
Breastfeeding initiation, Essential newborn care, Hypothermia, Immediate newborn care practices, Neonatal sepsis

ABSTRACT

Aim: A deadly nosocomial outbreak in a Philippine hospital drew nationwide attention to neonatal sepsis. Together with specific infection control measures, interventions that protect newborns against infection-related mortality include drying, skin-to-skin contact, delayed cord clamping, breastfeeding initiation and delayed bathing. This evaluation characterized hospital care in the first hour of life with the intent to drive policy change, strategic planning and hospital reform.

Methods: Trained physicians observed 481 consecutive deliveries in 51 hospitals using a standardized tool to record practices and timing of immediate newborn care procedures.

Results: Drying, weighing, eye care and vitamin K injections were performed in more than 90% of newborns. Only 9.6% were allowed skin-to-skin contact. Interventions were inappropriately sequenced, e.g. immediate cord clamping (median 12 sec), delayed drying (96.5%) and early bathing (90.0%). While 68.2% were put to the breast, they were separated two minutes later. Unnecessary suctioning was performed in 94.9%. Doctors trained in neonatal resuscitation were 2.5 (1.1–5.7) times more likely to unnecessarily suction vigorous newborns. Two per cent died and 5.7% developed sepsis/pneumonia.

Conclusions: This minute-by-minute observational assessment revealed that performance and timing of immediate newborn care interventions are below WHO standards and deprive newborns of basic protections against infection and death.

INTRODUCTION

A deadly neonatal sepsis outbreak in one city hospital in the Philippines garnered national attention (1). The authors, who investigated the outbreak, wanted to understand how immediate newborn care practices may impact on neonatal sepsis rates in hospitals nationwide.

Annually, 82,000 of the 2.4 million live births die before reaching their fifth birthday, making the Philippines one of 42 countries accounting for 90% of all global under-five deaths. About half of these deaths occur in the first 28 days (neonatal mortality rate of 16 per thousand live births) and one-quarter in the first 2 days of life. Birth asphyxia, complications of prematurity and severe infections account for the majority of newborn deaths (2–4). The decline in childhood deaths witnessed in 1993–2003 was minimal because of negligible changes in neonatal death rates. If newborn mortality is not reduced more rapidly, the goal of reducing childhood mortality by two-thirds (Millennium Development Goal no. 4) by 2015 will not be met (5).

WHO has identified simple interventions that, if applied routinely, mitigate some of the threats newborns face. These early interventions are integral to hospital infection control practices because they reduce the risk of neonatal sepsis (6,7).

First, hypothermia can threaten newborns with delayed fetal-to-newborn circulatory adjustment, acidosis, hyaline membrane disease, coagulation defects, infection and brain haemorrhage (8). Every second of exposure to the outside environment results in heat loss via evaporation, conduction, convection and radiation. Thorough drying, direct skin-to-skin contact immediately upon delivery and covering with a blanket and bonnet (prior to cord clamping) mitigates this threat (9,10). Drying also stimulates breathing. Sustained skin-to-skin contact also initiates colonization of the newborn with maternal flora (as opposed to hospital flora) and facilitates olfactory learning, successful intake of...
Immediate newborn care

Physician assessors (paediatricians and internists) were trained to use the tool. Secured informed consent, administer the questionnaire and conduct interviews. Pre-testing of the assessment tool was performed in two hospitals in Manila.

Facility selection

The largest 150 government hospitals were identified and nine (of 17) regions were selected per previous protocol (23). Fifty hospitals were then selected from these regions by random sampling using the Excel RAND function. The single largest delivery centre in the country was added purposively. This was the greatest number of hospitals and regions that could be feasibly studied.

Subject selection

After informed consent, consecutive births were observed within a 24-h period with the intent to observe 10 mother–baby dyads per hospital. Physician assessors started observations with the first delivery of their shift. For hospitals with fewer than 10 births at the end of the 24-h recruitment period, additional births were included from a neighbouring, higher volume hospital already on the selection list to make up for the shortfall. For practical reasons, at the end of 24 additional hours, recruitment was stopped. For multiple births, only the first newborn was included. Infants with obvious lethal deformities were excluded.

Data collection

Trained physicians completed the assessment tool to document the minute-by-minute sequence of events and interventions occurring just prior to delivery to the first hours after birth and rooming-in. They were instructed to observe only, without commenting or intervening. Health staff were unaware of the practices being observed. The direct observations recorded the performance and timing of immediate newborn care interventions. Time of skin-to-skin contact, breastfeeding, weighing, examining, vitamin K injection and hepatitis B vaccinations, while essential, typically are not ready to initiate breastfeeding between 20 and 60 min (14).

Infants, however, cry newborn care practices are absent. About half (54%) of newborns initiated breastfeeding in the first hour of life (3). Data on cord clamping, drying and immediate skin-to-skin contact are anecdotal. Furthermore, hospital reports of neonatal deaths and sepsis are incomplete at the national level.

The goal of this evaluation was to characterize minute-by-minute newborn care done in the first hour of life in 51 large hospitals in the Philippines. These data will be used to drive policy change, strategic planning and hospital reform.

METHODS

Evaluation design

A detailed observational assessment of immediate newborn care practices was performed on consecutive deliveries in each selected hospital during the fourth quarter of 2008. Data on total hospital deliveries, live births, deaths and sepsis/pneumonia were abstracted from annual reports.

Assessment tool and protocol development

Intrapartum assessment tools were developed through collaboration between the University of the Philippines – Phil- ippine General Hospital, WHO, and the Department of Health (DOH) (Please see http://www.wpro.who.int/NE/PDF/ rdllykeny/940EHDBA-1047-4541-BE98-3E87173857/0/ Delivery_Assessment_Tool_EINC_Philippines.pdf).

Physician assessors (paediatricians and internists) were trained to use the tool, secure informed consent, administer the questionnaire and conduct interviews. Pre-testing of the assessment tool was performed in two hospitals in Manila.

Facility selection

The largest 150 government hospitals were identified and nine (of 17) regions were selected per previous protocol (23). Fifty hospitals were then selected from these regions by random sampling using the Excel RAND function. The single largest delivery centre in the country was added purposively. This was the greatest number of hospitals and regions that could be feasibly studied.

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Data collection

Trained physicians completed the assessment tool to docu- ment the minute-by-minute sequence of events and interven- tions occurring just prior to delivery to the first hours after birth and rooming-in. They were instructed to observe only, without commenting or intervening. Health staff were un- aware of the practices being observed. The direct observations recorded the performance and timing of immediate newborn care interventions. Time of skin-to-skin contact, breastfeeding, weighing, examining, vitamin K injection and hepatitis B vaccinations, eye prophylaxis and rooming-in were recorded to the minute. Time of drying and cord clamping were recorded to the second. Details of rooming-in and breastfeeding initiation that occurred after the 2-h direct observation period were obtained from records or health staff interviews. A brief questionnaire was administered to the attending health provider to determine his or her training background.

Data management and analysis

Data were presented as percentages for the categorical vari- ables and median ± interquartile range for times. All vari- ables were analyzed by subgroup, including training of the delivery attendant, mode of delivery and hospital size. Sensi- tivity analysis was carried out by replacing missing data with the largest and smallest value in the data set. Analysis was performed using Stata version 9.1 (Stata Corp, College Station, TX, USA).

Ethical considerations

Informed consent was secured from each mother prior to the second stage of labour to assure confidentiality and
anonymity for the data collected. Women presenting to the hospital during the second stage of labour were excluded. Ethical review was secured from the Institutional Review Board, National Institutes of Health, Manila.

RESULTS

Hospital records review (2007)

Of the 201,760 deliveries, 197,328 (97.8%) were live births and 43,373 (21.5%) were delivered by caesarean section. Of the live births, 11,003 (5.7%) infants developed neonatal sepsis/pneumonia and 3,980 (2.0%) died. A large variation among each of the indicators existed across the 51 hospitals (Table 1). The smallest hospital, a tertiary perinatology centre, had 479 deliveries and the largest, an exclusive maternity hospital, 2,524. Three hospitals reported noneonatal deaths, and six reported no sepsis or pneumonia cases.

Observational assessment

A total of 481 mother–baby pairs were observed between 19 October and 28 December 2008. A minimum of five and a maximum of 16 consecutive deliveries were observed per hospital. Of the 481 newborns, 67 (14.1%) were low birth weight (<2.5 kg), 6 (1.3%) very low birth weight (<1.5 kg) and 43 (9.0%) macrosomic (>3.8 kg).

Table 1. Variation in deliveries across 51 hospitals

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Median</th>
<th>Inter-quartile range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total annual deliveries, n</td>
<td>3330</td>
<td>2277–5199</td>
</tr>
<tr>
<td>Caesarean section, n (%)</td>
<td>794 (22.3%)</td>
<td>292–1364 (15.9–31.4%)</td>
</tr>
<tr>
<td>Total live births, n</td>
<td>3385</td>
<td>2217–5003</td>
</tr>
<tr>
<td>Neonatal mortality, n (%)</td>
<td>55 (1.8%)</td>
<td>18–99 (0.8–2.9%)</td>
</tr>
</tbody>
</table>

Obstetricians attended 374 (77.8%) deliveries, midwives attended 62 (13.0%) and non-obstetric physicians 43 (8.9%). Although monitored during the first stage of labour, one subject delivered in an elevator, unattended. Paediatricians attended 209 (43.5%) of newborns, nurses 169 (35.1%), midwives 65 (13.1%), obstetricians 19 (4.0%) and other doctors 13 (2.6%). Delivery was by caesarean section in 107 (22.2%), forceps in 7 (1.5%) and spontaneous vaginal in 567 (76.3%).

Performance of appropriate interventions

More than 90% of infants were dried, weighed, given eye prophylaxis and injected with vitamin K. Approximately 50% were put to the breast, examined and vaccinated against hepatitis B virus. Less than 10% were allowed skin-to-skin contact (Fig. 1).

Performance of inappropriate interventions

Early bathing, non-immediate drying, placement on a cold surface and transfer to a nursery were commonplace (Fig. 2). Of the 455 newborns who were breathing spontaneously at delivery, 432 (94.9%) were suctioned, with 363 (84.0%) suctioned more than once. Of the 26 newborns (5.4%) that had no breaths or occasional gasping, only 1 (3.9%) was dried during the sequence (Fig. 2).

Sequence of interventions (median time to start of intervention)

Cords were clamped immediately (12 sec), newborns were then dried (1 min), bathed (8 min), put to the breast (10 min), separated (12 min) for weighing (15 min), physical examination (17 min), eye prophylaxis (20 min), transfer to a ‘nursery’ (20 min), injections (22 min) and then returned to their mothers (2 h and 35 min). A median
duration of only 2 min was allowed for their first colostrum feed. Wide interquartile ranges were observed (Fig. 3).

Attendant training

Nearly half of the attendant paediatric staff was trained in neonatal (236, 49.1%) and paediatric resuscitation (208, 43.2%) while only 75 (15.6%) in infection control and 11 (2.3%) in infant and young child feeding.

Subgroup analyses

All variables were assessed by previous training, modes of delivery and hospital size. Those trained in neonatal resuscitation were 2.5 (1.1–5.7) times and in paediatric resuscitation 2.2 (0.96–5.2) times more likely to unnecessarily suction babies who were already breathing. Having no attendant training correlated with breastfeeding initiation within one hour or a duration longer than 20 min. Timing
Sobel et al. Immediate newborn care

of the physical examination was affected by a maximum of 23 min when comparing groups trained or not trained in resuscitation. The timing of other interventions varied by a maximum of 4 min. Comparisons between abdominal and vaginal delivery and between hospitals with more than vs. fewer than 3000 deliveries a year showed a maximum difference of 2 min for all variables except for cord clamping (which did not differ).

Missing data and sensitivity analysis
One hospital annual report was missing data for number of deliveries and live births, eight were missing data for caesarean sections, five for neonatal deaths and 14 for sepsis. After replacing all missing data with the minimum and maximum values, the median number of deliveries and live births changed a maximum of 147; the caesarean section rate a maximum of 2.5% and the neonatal mortality rate 0.4%. Sepsis pneumonia ranged 1.3–11.4% after similar sensitivity analysis.

For the observational assessments, no data were missing for performance of each intervention. One (0.2%) had missing data on delivery attendant and 6 (1.3%) for attendant of the neonate. Missing data on timing of interventions produced a maximum of 10.1%. Median and interquartile ranges were calculated assuming all missing data were either the smallest or the largest value of the variable. In no case did this cause the median to change.

DISCUSSION
Available 2007 hospital records revealed neonatal sepsis/pneumonia and mortality rates of 5.7% and 2.0%, respectively. Many interventions, such as drying, weighing, examining, providing eye prophylaxis and supplying vitamin K, were omitted. Timelines for administration of hepatitis B vaccine tripled from baseline levels (25). Unfortunately, these interventions were not part of the sequence that did not allow the newborns to benefit from all of their mothers’ natural protection in the first hour of life, i.e. provision of warmth, blood transfusion from the placenta, protection from infection via skin-to-skin contact and completion of colostrum feeding (8,12,18,19,21,27). Colostrum newborns in ‘nursery’ for mandatory observation periods and clearance exposed them to hospital-acquired flora.

Hospital practices permitted the overwhelming majority of newborns to be exposed to cold, similar to practices in other countries (27). Only one of 26 newborns with apnoea was dried. Most newborns with primary apnoea will start breathing from stimulation during drying.

This evaluation found that 58.2% were put to the breast, similar to national survey results (3). However, this process was not optimal because the infants’ mouths were pried open, positioned onto the areola and their cheeks were stroked to trigger rooting only 10 min after birth, a time when newborns younger than 24 h are usually asleep. When newborns eventually initiate breastfeeding, the risk for infection-related death is doubled or tripled (21).

The need for basic life-saving interventions and for beneficial parent-newborn interactions indicates that procedures carried out immediately after delivery should be standardized in time and order. Unnecessary procedures, such as routine suctioning, early bulb- and separation of newborns from their mothers, should be discontinued. Aside from potential for harm, these procedures burden already overworked hospital staff.

These findings should not be surprising. Pre- and in-service training in medical and allied schools do not address key WHO guidelines in newborn care (28). WHO guidelines have not emphasized the importance of the timing of early interventions for newborns. Even with formal training, optimal outcomes may not be realized (29). This is particularly true when the physical and policy environments do not enable appropriate newborn care practices or disable outdated and inappropriate practices.

This evaluation was limited to the largest hospitals in only nine of the 17 regions. However, the deliveries in the 51 hospitals accounted for more than 60% of the deliveries nationwide. It did not include either home deliveries or those in smaller centres. We focused on the large hospitals because changing practices here will affect training of obstetric/paediatric residents and midwifery training medical students.

Extraction of data from hospital records was limited by problems inherent in hospital recording. Many hospitals had missing data for key doses of hepatitis B vaccine. The sensitivity analysis revealed that, regardless of missing data, a high burden of disease exists in these large hospitals. We could not validate reports of zero deaths or sepsis. Accurate reporting of sepsis cases was limited by variation in interpretation of clinical presentations and laboratory results. While gestational ageing techniques were not uniformly performed in the hospitals, birth weight categories were available.

Despite the Hawthorne effect implicit to the observational methodology, serious hospital practice issues were evident. The problems are likely to be more severe than our evaluation uncovered. Recording bias is another potential limitation for data on rooming-in and breastfeeding after the 2-h observation window.

A secondary analysis of a nationwide survey revealed death rates of neonates born to women delivering in a healthcare facility to be statistically different. Newborns born at home attended by a non-health professional (OR 1.0; 95% CI 0.85–1.37) (20). This comparative data together with the findings of the present evaluation set off a series of responses to address inappropriate practice and standardization of immediate newborn care practices. The Department of Health convened a technical working group to review current evidence and draft evidence-based...
recommendations. The resulting Essential Newborn Care protocol is a downstream effect and stakeholder panel review in a guideline development process. It specifically defined the time for each intervention and made explicit statements to stop unnecessary interventions. It has now become an official publication (10). The DOH is spearheading strategies to (i) jumpstart the hospital reform agenda as the next phase of health sector reforms; (ii) develop model hospitals and networks of excellence in each of 17 regions; (iii) update the pre-service and in-service medical, nursing and midwifery curricula and (iv) conduct a nationwide social marketing campaign. Preliminary results show that the one hospital that implemented the protocol has seen historically low neonatal deaths.

Globally, 450 newborns die every hour (9). Their limited reserves and defenses make newborns vulnerable to attendant practices. The scope and seriousness of threats, even with skilled attendants, were not clear until embarking on this direct observational assessment. We believe this is the first evaluation of its kind that enables quantification of the timing and performance of various interventions. Although standards for immediate newborn care exist in high- and low-income countries alike, direct observational studies may uncover substantial practices. Even in developed countries, the sequence and timing of critical interventions may still require changes or standardization.

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Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines? An exploratory survey and focus group analysis

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Abstract

Infant mortality and morbidity risk is linked to formula usage. The proportion of Filipino infant formula users rose from 0% between 2001 and 2008. It is hypothesized that this resulted from aggressive formula industry marketing.

We conducted a household survey between April and December 2006 and focus groups in April—May 2007 in The Philippines to examine the association between mothers’ exposure to advertising and other information sources and formula feeding decisions. Sixteen barangay communities were randomly selected from four districts of one city and three rural municipalities. Also, 345 households had children under 24-months age: 114, 142 and 89 households from the rural, urban and mixed municipalities, respectively. In addition, 84 respondents participated in 3 focus groups of 10–15 participants each, from those selected barangays.

After adjusting for education and economic indicators logistic regression analysis showed that, children were more likely to be given formula if their mother recalled advertising messages, or a doctor, or mother or relative recommended it. Those using formula were 6.4 (1.8–23.1) times more likely to stop breastfeeding before 12 months. The focus groups described how informal advertisements, doctors and medical representatives enticed them to use formula. We conclude that two factors were strongly associated with the decision to formula feed: self-reported advertising exposure, and physicians’ recommendations.

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Introduction

Globally, 10 million children died before the age of 5 years in 2005. Breastfeeding is the most effective intervention which could prevent 1.3 million deaths (Jones, Sokolove, Back, Bisasa, & Morris, 2001). A WHO pooled analysis reported not breastfeeding was associated with a 5.8 times increased risk of all-cause mortality in the first two months of life and remained elevated into the second year. Non-breastfed under-six-month old Brazilian infants had 14 times greater risk of dying from sepsis and 3.6 times from respiratory disease compared to those exclusively breastfed (Chen & Rogan, 2004). Studies also show an increased risk of illness associated with formula feeding (PAWHO, 2002). Intravenous salmonella, a bacterial illness known to be harmful to pre-term infants, sometimes contaminates infant formula during manufacturing (UNICEF, 2004).

The Philippines, with 82,000 annual deaths, is one of 42 countries accounting for 98% of under-five years old deaths globally (Black, Morris, & Bryce, 2003). Study 305 of 4–5-month-old Filipino infants were breastfed exclusively while 305 formulas fed, up 65% in 5 years (NSO, 2003, 2008).

Research shows that factors influencing the decision to breastfeed include: infant weight (Sercén, 1997); breast milk as the first feed (Sachdev & Mehrotra, 1995); frequency of crying (Kocacar, 2001); mother’s educational level (Kocherlakota, Desai, & managing, 2007); income level (Alvares, 1984) and employment (Kocherlakota et al., 2009).

Mothers tend to breastfeed when given accurate information (Boku, Segvet, & Bondre, 2005; Horton et al., 1995; Saunes et al., 1993), through media campaigns (McDermott, Zimbik, Howke, &
Abulaban, 1993; and social (Byrant, 1982) and medical professional recommendations, respectively. Formula use includes any bamboo, nipa and salvaged/makeshift materials, are found among Abulaban, 1993. Breastfeeding “educational materials” produced by infant formula manufacturers (Stahly, Li, Bottlen- Doss, & Gutierrez-Strossen, 2003) and formula sample distribution were found to negatively impact breastfeeding (Stewart et al., 2000). Television advertisements, doctors and relatives also influ- ence the decision to use formula (Feller & Castello, 1995; Suleiman, 2001). However, a Philippine study reported a minor impact of formula sample distribution and advertising on feeding decisions (Stewart et al., 1991).

The Philippines provides an ideal setting to study the effect of marketing on infant feeding practice with its aggressive industry practices (Raya, 2008) and rising formula usage. According to Ecosanstats (2008), “Filipino Milk Formula Market Grows Unim- peded”. More than US$ 100 million was spent on advertising breast milk substitutes in half of 2006 (Ecosanstats, 2007).

The present study examines factors influencing decisions to formula feed infants, including mothers’ recall of advertising messages, health professionals’ recommendations, personal sales representation and other information sources in purposely selected disadvantaged communities in the Philippines.

Methods

We conducted a household survey in a sample of disadvantaged rural and urban barangays (communities) and then conducted focus groups to examine factors influencing decisions to formula feed infants.

Survey tool and implementation

Questions related to feeding and marketing were added to an E- Net (a network of educational NGOs; educational questionnaire conducted in Iligan). E-Net developed and pre-tested the 10- min educational survey to determine the basic household profile, housing and amenities, employment status, education profile, reasons for formula use, and school expenses in seven municipalities and one city where they work. The marketing questions were developed in June 2005, pre-tested and finalized in April 2006. Community workers were trained using a standard enumerators’ manual including field-testing. E-Net supervised the interview. The survey was conducted April in December 2006.

Of the seven E-net municipalities, three were selected to represent varying population dynamics: Toboso (rural), Marica (urbanizing wealthier), and Sariaya (rural and urban mix). Barangay selection was the same used for the overall E-net survey. These three municipalities had 75 barangays which were categorized into proximity strata (within, near or far from the town center). Of these, 16 were randomly selected within proximity strata. All households with children under 24 months were interviewed. Chi-square and t-tests were used to measure differences in cate- gorical and continuous variables. Logistic regression was used to calculate adjusted odds ratios for formula use relative to breastfeeding. SAS 9.0 (SAS Corporation, TX, USA) was used for data analysis.

Most variables were defined using a standardized tool (MAMAP, 2000). Households with light house roofing materials, including bamboo, nipa and salvaged/makeshift materials, are found among poor families (NSO 2008). Light roofing materials were used as a proxy of low socio-economic status (MAMAP). Formula use included any formula regardless of addition of other foods, liquids or breastfeeding.

The predictor variables and corresponding questions used to define them are as follows: 1) Educational background. In the past six months, how much did you or any member of your household read any advertisement for Formula M&I? (2) Advertising messages. Can you recall the messages or information given by the advertisement? 3) Primary source of advertising message promotion was the first answer given to the question. “Where did you or your husband see the advertisement for Formula M&I?” They were then asked, “Where else did you see...?” until the respondent had no more answers. 4) Source recommending use of infant formula: “Who recommended formula to you?” For each question respondents gave unaided responses which were classi- fied according to predetermined categories.

Focus group discussion

The research team of AER, an E-Net member, developed Focus Group Discussion (FGD) guides based on the survey results to probe for factors that may influence infant feeding choices. Themes explored included: What led you to feed your child as he/she is currently fed? What sources of information have you come across on infant feeding? Can you remember any specific messages? What is special about the messages? In what ways do they appeal to you? What are the reasons you use a given brand of formula milk? How do milk companies promote their products? How do the milk companies influence you? Facilitators were trained to encourage free-flowing dialogue by following up on participants’ answers.

The FGDS were organized in Toboso (rural) and Sariaya (rural and urban mix) where the survey took place, and Makan City (urban), April-May 2007. Health workers in these localities selected a mixture of 10–15 mothers with children aged under 6 months, 6–12 months and 1–2 years.

Each FGD had handwritten, tape recorded and transcribed notes. Participants were informed the sessions would be tape recorded. The team leader reviewed the transcriptions multiple times and tape recordings at least once. Specific attention was paid to determine that the facilitator did not interrupt the flow of the discussion, nor ask leading questions. Transcripts were coded as follows: all answers were grouped, categorized and labeled according to the aforementioned themes. These were then reviewed to identify common patterns within each thematic area and across participants. Only those themes reflected in comments made by more than one participant were included in the results.

Informed consent

All participants were informed about the study, that confiden- tiality would be maintained and that they could withdraw at any time without explanation. They were given an opportunity to clarify questions. All participants provided informed consent. Department of Health Human Research Ethics Committee granted ethical clearance on October 28, 2005.

Results

Of the total 5210 households, 6.7% (345) had at least one child under 24 months old. Of these, 3205 (94%) were from Toboso, 42.2% (142) from Marica, and 25.8% (89) from Sariaya. All house- holds with children under 24 months age agreed to participate in the survey. Questions in the survey had no missing data except for coding materials which had 9.1% (34) missing observations.

Of the 345 children under 24 months of age, 41.1% (142) were using formula (Table 1). Formula use was associated with municipality of residence (p < 0.05). Around two-thirds (67.2%) of mothers of formula users had graduated high school versus one- third (32.5%) of those not using formula (p < 0.05). About one- fifth (21.8%) of formula users lived in a house made with light
of the 345 respondents, 59.1% (204) recalled an advertisement message. Of these 204, 47.1% (96) recalled it contained more than 3% (11) in a health center, hospital, magazine, newspaper, billboard, poster, grocery supermarket or shop.

Of the 345 respondents, 50.1% (204) recalled an advertisement message content. Of these 204, 47.1% (96) recalled it contained more than 3% (11) in a health center, hospital, magazine, newspaper, billboard, poster, grocery supermarket or shop.

The participants had high recall of the advertising messages, primarily on television. When asked “How do these milk companies promote their products?”, representative answers included “Television”, “We are children who admire us” and “There are others who give out some books and brochures.”

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Table 1

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<td>Age of Child (months)</td>
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<tr>
<td>Gender of Child (male)</td>
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<td>37.4%</td>
<td>184</td>
<td>0.015</td>
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<td>Occupation of mother</td>
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<tr>
<td>Mother’s education</td>
<td>48.3%</td>
<td>37.4%</td>
<td>184</td>
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</tbody>
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Discussion

This study found 50.1% of mothers of young children recalled an infant formula advertisement message and one-sixth reported a doctor recommended using formula. Those who recalled a message were twice as likely to use formula as those who did not recall a doctor recommended using formula from about 4 times as likely to feed their infants and young children formula. Formula use increased with increasing educational level and decreasing poverty. When women are provided with accurate information and professional and social support, they tend to breastfeed (Dulot et al., 2003). In contrast, early formula use and premature breastfeeding termination is likely when mothers are
exposed to pervasive and persuasive messages (Shiley et al., 2001; UNICEF, 2007). Other studies, similar to ours, reported teller's advertisements, doctors, and relatives influence the decision to use formula (Elfer & Corlett, 1995; Sulaiman, 2002). We cannot explain the known Philippine study that found sample distribution and formula advertising had a minor impact on feeding decisions (Sulaiman et al., 2001).

This study found that the role of breastfeeding termination within one year of age was increased by 6-8 times by infant formula use. UNICEF/WHO recommends breastfeeding for at least 2 years. Addition of formula leads to decreased stimulation from suckling and its reflex for breast milk production (WHO, 2001). Virtually all women are physiologically able to breastfeed (WHO, 1989).

Alternatives to maternal breastfeeding include feeding with expressed breast milk, surrogate breastfeeding, expressed breast milk from a healthy donor or a human milk bank and lastly infant formula feeding by cup (WHO, 2001). Situations where these alternatives are warranted include active biliary or stromal stenosis type 1 lesions on the mother's breasts, maternal medications such as sedating psychotherapeutic drugs, anti-epileptic drugs, opioids, radioactive iodine, and cytotoxic chemotherapy; and a few rare inborn errors of metabolism of the newborn. Even with mothers with HIV, exclusive breastfeeding was found to have the same disease free survival as exclusive formula feeding. Mixed feeding increased the risk of HIV infection (WHO, 2001). Advertisements and physician messages reported by the respondents never mentioned these medical indications as the basis to decide to formula feed.

Limitations

The populations from the 3 purposively selected municipalities are not representative of the whole nation. Participants were less educated, more rural and presumably of lower SES than the nation as a whole. The authors believe these limitations do not diminish the results, but suggest the marketing messages are reaching the most vulnerable sector of the Philippine population, which also has the highest infant mortality rates.

Possible recall as a concern. Participants were asked to recall messages up to 6 months before. Even so, 59.1% could state the highest infant mortality rates.

The transcripts and recordings confirmed the spontaneity of the respondents' question. The resolution of how doctors continued participants to use formula, the industry representatives' pronouncements, and the participants' singing the advertisement were striking.

In 1978, the late Senator Edward Kennedy held a U.S Senate hearing to prepare a protocol to the Infant formula Eleanor Roosevelt World Health Assembly resolutions including the International Code of Marketing of Breast Milk Substitutes (WHO, 1980) were adopted to curb unethical marketing practices (IBFAN, 2005). However, few countries have fully implemented Art.5 of the Code: ‘There should be no advertising or other forms of promotion to the general public of products within the scope of this Code.’ This study strongly supports the need for enforced, total ban of marketing advertisements and other promotions of breast milk substitutes worldwide. Finally, in the context of the Hippocratic Oath, this study strongly recommends all health professionals to identify and weed out promotions of medically unnecessary and unsafe feeding practices within its membership.

References


People’s Initiative to Counteract Misinformation and Marketing Practices: The Penmo, Philippines, Breastfeeding Experience, 2005


Abstract

The Philippines is among 42 countries accounting for 90% of under 5-year-old deaths. Only 16% of 4 to 5 month old Filipinos exclusively breastfed. In 2006, almost $100 million was spent advertising formula in the Philippines. To counter widespread misinformation and improve breastfeeding a peer counseling intervention was developed to target mothers with infants less than 2 months of age who were not exclusively breastfeeding or had difficulty breastfeeding. Participants received 3 peer counseling visits. At baseline and 3 weeks later, 24-hour food recalls for infants were collected. The number of exclusively formula-fed infants decreased seven-fold (P < .001). Mixed-fed infants decreased 37% (P < .001). Overall, 95% of the 148 non-exclusively breastfeeding infants, 69.5% had changed feeding methods after 3 home visits, 78% of whom to exclusive breastfeeding. Community-based peer counseling was associated with a drastic improvement of exclusive breastfeeding practices. This intervention evolved and became sustainable by engaging political figures, cities, and communities throughout the process. In 2 years, the Department of Health, World Health Organization (WHO) program has scaled up to improve health service delivery for 161,812 persons in depressed urban communities in the Philippines. J Hum Lact. 25(3):341-349.

Keywords: exclusive breastfeeding, peer counseling, misinformation, sustainability

Science shows that breastfeeding is the single most effective preventive, lifesaving measure among 23 interventions that could prevent two thirds of all child deaths. Science further shows that suboptimal feeding practices burden society with illness and economic loss. Improving breastfeeding rates is critical, particularly in the Philippines, where 1 of 42 countries accounting for 90% of all global deaths of children before their fifth birthday. However, translating scientific evidence into improved large-scale breastfeeding rates proves exceedingly difficult.

Compared with any of 56 countries that have conducted a Demographic and Health Survey (DHS) in the past 10 years, a smaller percentage of Filipino children were ever breastfed. Nationwide, the median exclusive breastfeeding duration is only 3 weeks. Only 16.1% of Filipino children were exclusively breastfed in their fourth and fifth months of life; 41.5% were still breastfeeding but received other solid foods and liquids other than infant formula during the same period. At the same time, nationwide, 36.1% of Filipino children between 4 and 5 months of age receive infant formula (14.5% receive both infant formula and breast milk and 21.6% receive infant formula without breast milk). More than 6% of infants between 4 and 5 months of age are not breastfeeding or using any formula.

Per year, of the 2 million annual births, 720,000 children begin consuming formula between 4 and 5 months. Formula costs about $40 to $80 per month for a Filipino family with an infant. Many Filipinos whose infants either exclusively or partially use formula annually spend an aggregated $376 million a year to purchase formula. This is in a country where 30% of the population lives on less than a dollar per day.

Aggressive marketing practices for breast milk substitutes have been blamed for the dangerously low breastfeeding rates in the Philippines. In the Philippines, nearly $100 million is invested annually in advertising infant formula. Beyond using advertisements, key infant industry representatives have admitted giving innumerable giveaways
to health workers and mothers, sponsoring their attendance at medical association conventions; and paying for overseas trips, educational courses, and similar activities. DOH led an effort to develop a National Policy for Infant and Young Child Feeding (IVCF) in 2004 to address these and other issues. The overall goals were to increase initiation of breastfeeding in the first hour, exclusive breastfeeding for the first 6 months, and continued breastfeeding for 2 years with introduction of safe and appropriate complementary foods from 6 months onward. The policy focused on developing environments conducive to meeting the goals in 6 target settings: health system, workplace, community, schools (i.e., education system), public places, and industry. The national policy was signed by the Secretary of Health in May 2005.

One priority action highlighted in the policy was to update and improve the National Milk Code (1986) to bring the Philippines in line with the WHO/UNICEF Global Infant and Young Child Feeding Strategy 2002, the International Code of Marketing of Breastmilk Substitutes 1981, and the other 14 World Health Assembly Resolutions. However, these efforts met resistance from industry opposition and threats. On May 15, 2006, the Secretary of Health signed the revised Implementing Rules and Regulations (IRR) of the 1986 Milk Code. The Pharmaceutical Health Care Association of the Philippines (PHAP) petitioned the Supreme Court for a temporary restraining order (TRO) to declare the new rules unconstitutional. A month later, the US Chamber of Commerce delivered a letter inviting the President of the Republic to reconsider the RIR to avoid complications in US-Philippines economic ties. A TRO was issued 1 week later. On October 5, 2007, the Supreme Court lifted the TRO on the IRR of the Milk Code. The ruling represented a great victory for public health and upheld the prerogative of the Department of Health to regulate.

In parallel to the RIR, a national/international team embarked on the current work in 2005 to translate the national policy into a large-scale local intervention. The team identified several studies that aimed to prove that peer counseling is effective. The interventions used peer counselors who were trained to contact and advise peers from the same community. The results have shown that breastfeeding counseling increases breastfeeding rates in controlled environments.

The team found it hard to fathom how to translate these impressive findings into a wide-scale impact in the Philippines, given the situation described above. This article describes the process by which this community-driven intervention was developed and evaluates the intervention by comparing breastfeeding rates before and after the intervention.

**Methods**

**Site Selection**

Mobilization for this intervention began in January 2005 at a National Assembly of the National Secretariat Ligan ng mga Barangay (an association of all 41,995 barangays, the smallest administrative unit in the Philippines) where 150 presidents representing all regional chapters attended and another where 2,500 municipal delegates attended. Several chapter presidents indicated interest in locally implementing an exclusive breastfeeding promotion intervention.

The Ligan president of Makati City volunteered Barangay Pesoho to be an intervention site for the community-based breastfeeding program. This barangay has the largest population in Makati City, with a total
of 25,499 residents in 15 zones. It is residential, with 1 locally owned hospital and an elementary school.

Local leaders and Barangay Pembo officials held numerous discussions over the months following the national January meeting. In line with the celebration of World Breastfeeding Week, they organized, financed, and eventually launched the exclusive breastfeeding promotion intervention in August 2005. The event was attended by the City Health Office, DOH, and World Health Organization (WHO). However, the main strategy for implementation was not yet clear.

The large turnout of 400 mothers compelled the Makati City Health Department, DOH, and WHO to rapidly develop practical tools in line of theoretical strategies for communities to improve breastfeeding.

**Intervention Development**

An International Board Certified Lactation Consultant (IBCLC) working for WHO helped conceptualize and design the intervention. DOH and WHO reviewed scientific, research-based studies for infant nutrition and guidelines that used peer counseling to develop an effective intervention. Many studies incorporated methods such as a 24-hour food recall, technical inputs by a nutritionist, a follow-up visit with negotiation, recorded statements by counselors, and home visits to record outcomes. The guidelines addressed counseling mothers with common breastfeeding problems. Both DOH and WHO recognized that these scientific studies had great potential but were cumbersome as public health interventions. With limited information on interventions conducted outside a controlled environment, DOH and WHO held meetings to transform these scientific studies into sustainable community-driven interventions. The Makati City Technical Working Group (TWG), consisting of 10 members from the Makati Health Department, was formed in August 2005 to support these efforts. The TWG, DOH, and WHO discussed how to modify these methods to work in the community. TWG began by agreeing to use a peer counseling approach. TWG then reviewed questionnaires used in other interventions and agreed on a minimum data set needed for the intervention. These included general data about the mother and the infant, who is feeding the infant, and a 24-hour food recall. The question “What has the infant been given in the past 24 hours?” was supplemented with other questions, such as how many bottles were consumed (if the infant was formula or mixed-fed). Breastfeeding was further probed if bottle or formula was given. The TWG simplified the wording of questions; for example, complementary feeding was replaced with family foods. Members of the working group translated the questionnaire and guidelines into the local vernacular (Filipino) and presented this survey with mothers to refine the questions.

In September 2005, the TWG organized a series of meetings with the 15 zone leaders in Pembo. During the first meeting, TWG urged zone leaders to openly discuss day-to-day community experiences with breastfeeding, including sharing personal anecdotes about why women decided not to breastfeed. It was agreed that more information was needed to counter these problems and establish a supportive breastfeeding environment. TWG then presented the questionnaire line by line and requested feedback. A week later, the TWG facilitated role-play of the survey with the zone leaders. Initially, the TWG asked each zone leader to interview 1 mother with an infant and 1 pregnant woman within the zone. Eight of the original 15 zone leaders returned with data from their interview. The TWG facilitated a discussion based on the interviews to identify feeding practices, problems, and technically sound suggestions for improving feeding. The 8 zone leaders made a second visit to the interviewed mothers and proposed recommendations for changing feeding practices. Two weeks later, zone leaders met with the mothers again to evaluate changes in feeding practices.

**Peer-Support Counselor Selection and Training**

The TWG encouraged the Pembo-Council for Health and zone leaders to recruit peer-support counselors for Pembo. Zone leaders helped identify counselors from the 400 mothers present at the Pembo launch on August 1, 2005. Key criteria for the recruitment of peer counselors included successful breastfeeding experience, established favorable and credible reputation in the community, active involvement in community affairs, local residence in the community, and eagerness to support the community breastfeeding initiative. A total of 23 counselors were recruited, and the barangay agreed to financially support the next meetings and trainings for the counselors. Newly recruited counselors entered into a similar training process as the zone leaders for implementing the survey. As counselors began their fieldwork, specific issues arose, such as relocation and invested supplies, that they were not able to address immediately.

After problems were identified, training sessions were provided by the health center staff and city health
office staff on how to provide specialized counseling. The curriculum of the training was patterned after the UNICEF/WPRO counseling training tools, basically composed of 3 main modules: breastfeeding, complementary feeding, and infant feeding for HIV-positive mothers. Considering that peer counselors are community residents with limited time availability, the health center staff agreed that one 3-hour training session per week would be conducted at the health center. The peer counselors completed a total of 23 sessions.

The final modification of the intervention occurred when peer counselors realized that they were missing only a portion of the population based on community statistics. The TWG consulted the peer counselors on how to scale up the intervention to the whole community. They agreed that collaborating with the local health center staff would create another avenue to identify pregnant women and mothers in need of assistance during early immunization visits. After identifying women, the health staff provided a list of names and addresses for peer counselors to visit.

**Intervention Design**

Peer counselors or health center staff interviewed all households with children less than 1 year of age and pregnant mothers to categorize the feeding practice and problems encountered. The peer counselors and health center staff agreed to focus on assisting mothers of infants early in life less than 2 months of age, to maximize the benefit of the intervention. The peer counselors made 3 visits to those with breastfeeding problems or suboptimal feeding practices, that is, infants given infant formula (exclusive or mixed with breast milk); water, tea, or juice; or other solids and semisolids before the age of 6 months. The first visit included a 24-hour food recall, questions, and reasons why mothers did or did not breastfeed. The counseling then went from the city TWG and health staff at the local health center (along with DOH and WHO) to discuss their experiences, identify feeding practices that needed improvement, and discuss ways to encourage behavior change. Each feeding practice needing improvement was discussed. The second visit was within the week and involved counseling mothers about improving feeding practices. For issues that counselors could not address like medications, illness, and other complications, they recommended that the mother seek health center staff support (and offered to accompany the mother during the visit). Two weeks later, counselors interviewed mothers a third time to observe changes in feeding practices and receive feedback from the families based on the agreed changes. Counselors then reconvened with the health center staff, TWG, DOH, and WHO to discuss their experiences and modify the intervention accordingly. These modifications included better organization of the mother’s baseline information at the health center and standardization of interview documents. Counselors met weekly with health center staff to discuss feeding problems revealed by the mothers during home visits. Ethical clearance was received from the DOH Human Research Ethics Committee.

**Subject Recruitment**

Peer counselors identified mothers from Barangay Pembo by attending women’s group meetings, churches, and schools; conducting door-to-door visits; and encouraging community members to recommend mothers with infants for counseling. The health center physician also referred mothers with infants as of August 2006. A total of 725 women residents of Barangay Pembo had been identified, 312 infants less than 2 months old were the focus of this article. As noted above, any mothers who practiced nonexclusive breastfeeding (mixed feeding or formula feeding) or experienced problems breastfeeding were selected for 3 home visits.

**Data Management**

Health center staff recorded baseline data from mothers who brought their infants for routine immunization. In addition, each peer counselor was provided with a logbook to record all relevant information exchanged during house-to-house visits. Data recorded in the logbook included the name, age, address, and working status of the mother; the name, birth date, age, and sex of the child; feeding practices at the first interview and after 3 weeks; reasons mothers stated for choosing feeding practices; and infant feeding problems, suggested changes, and whether recommended feeding practices were adopted. Primary outcome variables were prevalence of exclusive breastfeeding after 3 peer counselor visits. Exclusive breastfeeding was defined as having received only breast milk in the past 24 hours. Exclusive breast milk feeding was defined as having received only milk formula in the past 24 hours. Mixed feeding was defined as having received breast milk and formula in the past 24 hours. There were no infants less than 2 months old in this cohort who did not fit into one of these categories. Specifically, none reportedly received solid food, tea, or water alone.
The health center staff regularly reviewed the peer counselor logbook to look for consistency between the log and the health center intake list. In the process, the staff also updated the health center intake lists. Percentage consistency was not recorded; however, the few inconsistencies were dealt with at the time. Health staff tabulated the intake lists to compare overall results at baseline with those after the intervention to measure its impact. EXCEL was used to produce bar charts that showed feeding habits before and after the intervention.

Statistical analyses were conducted using STATA version 9.1 (Statacorp, College Station, Tex). Test of proportions was used to determine the statistical significance of differences between feeding practices and different baseline characteristics and to compare feeding practice before and after the intervention.

Chi-square analysis was used to determine the statistical significance of the overall difference in improvement of feeding practices before and after the intervention.

Results

A total of 312 infants less than 2 months of age were identified in the community. At baseline, 153 (49%) of the 312 infants younger than 2 months were exclusively breastfed, 107 (34%) were mixed fed, and 52 (17%) were formula fed.

Exclusively breastfed children were about 3 days younger than mixed-fed infants ($P < .009$) and 6 days younger than exclusively formula-fed infants ($P < .005$) at the first visit. The mean age of mothers was 27 years regardless of type of feeding. At baseline, firstborn children tended to be less likely to exclusively breastfeed than second-born or higher order children ($P < .054$). The other differences between the type of feeding versus age of mother and birth order did not approach statistical significance.

Of the 312 infants whose mothers disclosed working status, 55 (18%) had working mothers. Of these 55 infants, 11 (20%) were exclusively breastfed, 27 (49%) were mixed fed, and 17 (31%) were exclusively formula fed. Of 255 nonworking mothers, 144 infants (57%) were exclusively breastfed, 79 (31%) were mixed fed, and 35 (14%) were exclusively formula fed. Working mothers were less than half as likely to exclusively breastfeed ($P < .001$). 1.6 times more likely to mix feed ($P < .01$), and twice as likely to exclusively formula feed ($P < .005$) their infants as nonworking mothers.

Of the 159 mothers who did not exclusively breastfeed, 99 (62%) mothers cited reasons for alternative feeding practices. Fifty-one (51%) mothers cited they had insufficient milk, 24 (24%) mothers had no work or were unavailable to breastfeed, and 11 did not breastfeed because of illness (11%).

Of the 133 infants who were exclusively breastfed, 151 did not experience any difficulties breastfeeding. The 2 infants who experienced problems while breastfeeding were selected for further peer support counseling (Figure 1).
One hundred and fifty of the 167 infants included for the intervention successfully completed all 3 visits. Of the 148 infants who were not exclusively breast-feeding, 133 had changed feeding method after 3 home visits, 73 to exclusive breastfeeding ($P < .001$). After 3 home visits, the number of exclusively formula-fed infants decreased sevenfold from 53 to 7 ($P < .001$). Of the 46 initially exclusively formula-fed infants who changed, 21 switched to exclusive breastfeeding and 25 to mixed feeding. Similarly, the number of infants who were mixed fed decreased 27-fold from 95 to 30 infants ($P < .001$). However, the 53 infants who were mixed fed after the intervention included 25 who were originally formula fed. The 2 infants who experienced difficulties with exclusive breastfeeding continued to breastfeed (Figure 2).

All 103 mothers who changed their habits noted that this was the first time that they knew the relation between suckling and breast milk production. Of the 56 who were working, 29 (50%) noted they now knew how to and actually expressed and store breast milk. All of them received the advice from the peer counselors. All 46 who were formerly exclusively formula feeding and then started breastfeeding received their counseling from the peer counselors with initial support from the health workers.

Discussion

Misinformation and misconceptions strongly influenced mothers in Baragay Pembo to use unwise feeding practices. Feeding practices drastically improved in this peer counseling intervention because community members and health workers removed barriers to breastfeeding created by contradicting and misleading propaganda. This resulted from a process of engaging political figures, city health staff, health center staff, community members, neighbors, and families.

The knowledge that "breast milk is best" may be common. However, our baseline findings reflect findings of the National Demographic Health Survey (NDHS), which show that only 52.5% of infants younger than 2 months of age exclusively breastfed. Nationally, similar to Pembo, mothers cited they never breastfed because they did not produce enough milk (31%), they returned to work (17%), they had nipple or breast problems (17%), the child was ill (11%), the child refused (11%), or the mother was ill (9%). None of these are contraindications to breastfeeding. The most common reasons that peer counselors encountered during interviews with the mothers included having insufficient milk, working, and being out of the house.
Preliminary and ephemeris reports that mentioned the great influence of media advertising for en fants that mutually themselves were not attractive to them, and that mothers could not recall these advertisements' products and messages. Most mothers expressed direct-to-consumer marketing via milk-formula representatives. Several mothers recalled being approached during their prenatal appointments and being asked to fill out forms. Several mothers received phone calls from milk company representatives. The mothers described having attended meetings at local fast food restaurants and having received gifts. Several admitted that they eventually tried the formulas, but the mothers often found it to be too expensive. Others said that their doctors or midwives prescribed infant formulas. Some mothers noted that their doctors or midwives said that the mothers did not have enough milk for their child according to the child's age. All discussions who used the formula acknowledged that it was costly.

In environments where contradicting messages are pervasive and constant, women are prone to stop breastfeeding. The intervention was developed to counteract those conflicting messages by ensuring the presence of skilled and knowledgeable community members. Establishing a supportive environment enabled mothers to obtain correct and unbiased information. Peer counseling directly facilitated this. However, in the absence of a larger support system, sustainability of peer counseling is unlikely. This intervention was designed to engage and gain commitment from local health professionals, city and local health workers, and local leaders and community members to set up supportive environments for pregnant and breastfeeding women. It began with informal and formal discussions at the national and local levels among health professionals, policy makers, organizers, and community members. The intervention evolved as these stakeholders saw the situation, the negative impact of unethical practices, and the success of the intervention. With continued support, this intervention has become part of routine activities at local and national levels. It became formalized locally by Pembi's resolution (January 13, 2005) that directed the barangay governments to ensure full compliance with the Philippine Milk Code and supported establishing a community support group to correct misconceptions and clarify issues regarding breastfeeding. The barangay also funded the training of peer counselors, provided them with uniforms for a total amount of $400, and funded meetings between the peer counselors and health center staff. The City Health Department, the Regional Office of the DOH, and WHO provided funds to train the health workers and conduct the initial series of meetings, for a total amount of $5000.

Because health workers trained the peer counselors, the health workers were directly consulted when problems arose. Thus, when peer counselors encountered mothers who wanted to escalate, express, and store breast milk, or breastfeeding despite having inverted nipples or who had children with chilling and palate, the health workers had to respond. However, the health workers in this case only had book knowledge. Challenged, they sought training from local professionals on how to support these interventions. Ultimately, these requests led to focused practical training sessions based on the needs expressed by the community. The entire health system benefited.

Although the IBCLC helped conceptualize and design the intervention, the study emphasized building local capacity. When problems arose, attempts were made to solve them with local resources. The challenge was to identify skilled health workers certified as IBCLCs. For reluctant of the numerous women so destitute, the city managed to find a local resource person with much experience in the area. The local resource person, a public health registered nurse, had extensive training and direct experience with infant and young child feeding counseling and lactation management. Consequently, local capacity was built without engaging expensive personnel. At the same time, this experience highlighted the great need that the country has to train and certify more health care professionals who specialize in the clinical management of breastfeeding as IBCLCs. This would ensure that community-based peer counselors are provided with prompt and timely support in addressing their clients' needs.

The peer counselors, through their home visits, helped mothers identify the key barriers that were affecting their breastfeeding practices and provided practical suggestions to overcome the barriers. For many mothers, leaving the home was a major reason for not breastfeeding or for mixed feeding. The peer counselors told the women that they could express their own breast milk and store it for the caregiver to feed the baby. Provision of accurate practical information helped to encourage and support the peer counselors and the health center staff contributed to a major increase in breastfeeding.
As noted above, the first woman requesting relaxation challenged the health system. All involved recognized the paramount importance of succeeding to gain confidence of the community and health center alike. The health center staff located a local health worker with successful experience in relaxation. This person worked closely with the mother, peer counselors, and health center staff. The peer counselors closely supported the mother to carry out the advice given and provided regular massage therapy to the mother to stimulate the secretion of breast milk. The woman succeeded, which led all involved to gain confidence.

Others requiring relaxation received support.

Unlike clinically based studies, this intervention was conducted outside a controlled environment. Although, this may limit our ability to objectively measure direct relationships and identify confounding variables, our primary intention was not to prove scientific causality but practical feasibility. Our results and the results of previous research-based studies indicate that peer counseling is an effective and feasible methodology for improving breastfeeding rates.23-24

This was not a randomized, double-blind trial and was not designed to determine generalizability. Data were collected and managed locally; however, all data were validated through external records review. Data were collected by the peer counselors and this may have introduced bias, although much effort was made to train the peer counselors to objectively collect information. Although bias may be a concern, having the same people implement, collect, and analyze the data is also a strength of the study. It provides for ownership of the work and responsiveness to identified needs. The authors recognize that triangulation of data and external validation such as data on the institutional anencephaly method, which were not collected by the peer counselors, would be important for future work to support the self-reported rates of exclusive breastfeeding. Although there is no external validation of these results, as infant formula representative complained that infant formula sales decreased by 9% in Barangay Pembo in the initial months of the work.

At the time of the intervention, there were no external campaigns that would account for the results. The major breastfeeding media campaign linked to the national Supreme Court case of the TRC on the RR1 occurred in 2007. These results presented here are complete through 2006 only.

This intervention is distinguished from other research studies because it was designed to be sustainable from its inception. As noted above, it sought to develop a support system by engaging local government, barangay officials, and local leaders in addition to the local constituents and health workers. The local legislator that was passed, the local funding of activities, and the avoidance of external funding further increase the likelihood that this work will be sustained.

Pembo continues to conduct peer counseling. Pembo elected to focus on pregnant women and later on complementary feeding. The method continues to be replicated in the rest of the city and in other urban areas. Peer counseling has been applied to other programs such as family planning and immunization.

The use of peer counselors in Barangay Pembo has been associated with dramatic increases in exclusive breastfeeding rates. These aims have undergone similar transformations as Barangay Pembo. Nine others are in the early process. This shows how the strategy implemented is very feasible for other barangays to replicate. In just over 2 years, the joint DOH-WHO program that is aimed to improve health service delivery in depressed urban communities in the Philippines has scaled up from only 2000 persons participating to 16,612. Funding to support this increase is provided by the participating local governments, local nongovernmental organizations, the DOH, and WHO. Additionally, the workplace implements the intervention. DOH aims to scale up these programs to reach 1 million persons living in depressed urban areas.

Contributors

All authors participated in the study design. M. A. L. Salud, J. Dictoros, J. Gallardo, A. Gammad, B. Sorja, and J. Basilio managed and implemented the intervention in the intervention site. B. Sorja and J. Basilio implemented at the national level. A. Ibelasco, L. Wromb, J. M. Olivad and H. Sobel drafted the manuscript and analyzed the data and participated at all other levels. All authors reviewed and commented on the draft manuscript and approved the final version.

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Implementing a national policy for hepatitis B birth dose vaccination in Philippines: Lessons for improved delivery

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ABSTRACT

Background: An estimated seven million Filipinos (10–12% of the population) are chronically infected with hepatitis B virus (HBV). Achieving high birth dose coverage with hepatitis B vaccine is critical for achieving the World Health Organization’s Western Pacific Regional goal of reducing the prevalence of chronic HBV among children 5 years of age to <2% by 2012.

Methods: Seven months after the Philippines adopted a hepatitis B vaccine birth dose policy, hospitals with the highest number of deliveries were invited to participate in an assessment of implementation of the birth dose policy. Additionally, in metro Manila birth dose coverage was estimated before and after conducting a training workshop and supervisory follow-up for practitioners conducting home deliveries or deliveries at lying-in clinics.

Results: Of the country’s largest 150 hospitals in terms of authorized bed capacity, 85 (56%) were included in this assessment. These hospitals had 55,719 deliveries during July–September 2007. Of these, 54% infants had a documented birth dose; however, only 22% were vaccinated within 24 h of delivery. Having a copy of the hepatitis B vaccine vaccination policy (prevalence odds ratio [pOR] = 4.7, 95% confidence interval [CI] = 1.2–18.0), having standing orders pOR = 4.8, 95% CI = 1.3–18.1 and providing training pOR = 18.9, 95% CI = 5.3–67.0 were associated with >50% birth dose coverage in a hospital. In metro-Manila, regardless of place of birth, the training workshop and supervisory follow-up significantly improved hepatitis B vaccine administration within 24 h after birth, increasing from 19% before to 74% after the training workshop and follow-up.

Conclusions: Experience in the Philippines showed that actions by national, regional and health facility policy makers such as establishing national policies, distributing detailed and specific guidelines, conducting effective training and supervision, and having hospital standing orders substantially increased hepatitis B vaccine birth dose coverage.

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1. Introduction

Globally, an estimated two billion people have been infected with hepatitis B virus (HBV). 350 million have chronic infection and approximately 600,000 die each year from HBV-related liver disease including cirrhosis and hepatocellular carcinoma [1]. The majority of HBV-related morbidity and mortality occur among persons with chronic infection and after years of destruction of HBV-infected liver cells. The risk of chronic HBV infection is highly age dependent with newborns having up to 90% risk compared to adults with <10% risk [2]. Therefore, a substantial burden of chronic infection and disease among adults is a result of infection that occurred during birth or childhood.

In Asia, up to 40% of chronic HBV infections are acquired perinatally and another 30% in early childhood [3]. With this predominance mode of transmission and hyperendemic chronic HBV infection in most of its Member States, the World Health Organization’s Western Pacific Region adopted a regional goal of reducing the prevalence of chronic HBV infections among children aged 5 years or <25 by 2012 [4]. High birth dose coverage with hepatitis B vaccine is critical for achieving this goal since providing a birth dose within 24 h of birth can prevent 70–95% of mother-to-child transmission when given as part of a complete hepatitis B vaccine series [5].
In the Philippines, an estimated seven million people (10–12% of the total population) are chronically infected with HBV. The prevalence of chronic HBV infection among pregnant women is 5–8%, of whom 2% are estimated to be hepatitis B–antigen positive meaning they have a 90% chance of passing the virus to their infants [1,5]. In the Philippines, hepatitis B vaccine was first introduced in the national immunization program in 1992 [7]. Initially, for ease in service delivery, the hepatitis B vaccine doses were given concurrently with the three doses of diphtheria–tetanus–pertussis vaccine (DTP) scheduled at 6, 10 and 14 weeks of age. The Philippines Expanded Programme on Immunization (EPI) had a target of reaching 100% of children with three hepatitis B vaccine doses by 1999. However, insufficient funds prevented full implementation and coverage with three hepatitis B vaccine doses among infants was only 10% in 2002, compared to 70% for DTP. Hepatitis B vaccine has been fully funded since fourth quarter of 2005. In June 2006, the Philippines Department of Health (DOH) issued a policy changing the hepatitis B vaccine schedule to provide a timely birth dose (defined as ≥24 h after birth); in January 2007, a three-dose schedule to administer hepatitis B vaccine at birth, 6 weeks, and 14 weeks was implemented nationwide [8].

A 2006 survey reported that 25% of the nation’s births occur in government hospitals and 15% in private hospitals or clinics [9]. A key strategy for achieving high hepatitis B birth dose coverage is to have high coverage in all hospitals and health care facilities. Efforts are also being made to increase birth dose coverage among home births; however, these are viewed as an interim measure with the ultimate goal of increasing facility birth to ≥90%.

In 2007 in support of the roll-out of the hepatitis B vaccine birth dose policy, we conducted two studies with the following objectives: (1) to assess the implementation, coverage, documentation, logistics systems, policies, and awareness of hepatitis B vaccine vaccination at birth in large hospitals nationwide, and (2) to evaluate the impact of a training workshop and supervisory follow-up held in metro-Manila for providers to ensure that all infants, regardless of place of delivery received a timely hepatitis B vaccine birth dose. This article presents results of both studies.

2. Methods

2.1 Nationwide hospital assessment

To estimate the extent of hepatitis B vaccine birth dose implementation in hospitals, 150 of the nation’s hospitals with the largest authorized bed capacity were identified and invited to participate in this assessment [10]. At each participating hospital, an interviewer conducted an in-person interview with a senior pharmacist (i.e., person in charge of the cold chain), a neonatal practitioner (i.e., physician, pediatrician or neonatologist responsible for care of newborns), and a nurse or midwife in charge of administering vaccine at birth. The interview team consisted of 17 regional medical doctors and staff who attended a two-day training on conducting in-person, face-to-face observations and reviewing records using standardized forms. Information gathered during the interview included knowledge of hepatitis B vaccine vaccination at birth, whether standing orders for administering hepatitis B vaccine at birth existed, whether the neonatal practitioners in the hospital received training on the hepatitis B vaccine vaccination policy, whether the hospital was accredited by the Philippine Pediatric Society or the national health insurance agency (PhilHealth), whether the hospital had a designated training site, whether the hospital had immunization guidelines and how administered vaccination were recorded. The interview team also conducted a review of records for all deliveries occurring during July–September 2007 to determine the number of deliveries, the number of infants receiving a timely birth dose (defined as vaccine administered within 24 h of delivery), the number of infants receiving vaccine after 24 h of delivery, and the number of infants receiving vaccine prior to discharge (defined as vaccine administered anytime prior to discharge).

2.2 Metro-Manila health center assessment

Nine health centers in metro Manila were selected to participate in this assessment. Metro-Manila is made up of 17 local governments and has a population of 11.5 million, making up 13% of the national population. This assessment included: (1) a baseline assessment conducted from July 16–18 measuring indicators of hepatitis B vaccine implementation including timely hepatitis B birth dose vaccination for births from January 1–July 15, 2007; (2) a 3-day training workshop conducted from September 17–19 for the 45 health center staff, 120 community health workers and 23 private practitioners followed by intensive monitoring and supervision, and (3) a post-training reassessment of implementation and performance including birth dose coverage of births from July 16–September 16, 2007. The assessments, training and supervisory follow-up were conducted by a team of four public health professionals led by a municipal health officer with 20 years experience in immunization program management, assessments and records review. The assessments included review of supervisory reports, vaccination records, interviews with service providers and mothers of infants, and observation of vaccine and cold chain management. The training was designed to address areas for improvement identified during the baseline assessment and consisted of detailed discussion on characteristics of the disease, vaccine and cold chain management, supportive supervision and recording and reporting, the importance of early immunization, and myths and misconceptions regarding birth dose administration. The new schedule for hepatitis B vaccine as provided by the birth dose policy was also clarified.

For both assessments, data was entered and analyzed in STATA 9.0. For the nationwide hospital assessment, percentages, prevalence estimates, and 95% confidence intervals were calculated for hospitals with hepatitis B birth dose coverage ≥50% and compared to those with ≤50% coverage. The 50% cut point was established based on the bimodal distribution of birth dose coverage across hospitals.

3. Results

3.1 Nationwide hospital assessment

Of the 150 largest hospitals, 91 (61%) agreed to participate and 85 (56%) had patient records available to enumerate the total number of births for the assessment period. These 85 hospitals were located in all three island groups (Luzon, Visayas and Mindanao) in the Philippines. In the 85 hospitals, 85,719 deliveries took place between July and September 2007 amounting to >10% of the country’s births in 2007 (Table 1). Of 23,994 (28%) infants documented to have received hepatitis B vaccine prior to discharge and 12,728 (22%) infants received a timely birth dose. A timely birth dose administered for 5420 (65%) infants delivered at 11 hospitals in Visayas, 4908 (28%) infants delivered at 60 hospitals in Luzon, and 0 (0%) infants delivered at 14 hospitals in Mindanao (Table 1). A documented timely birth dose was provided to >50% of infants delivered at 14 (16%) hospitals. Hepatitis B vaccine was given to >50% of infants prior to discharge in 28 (34%) hospitals, but the timing was not specified (Table 1).
Table 1

<table>
<thead>
<tr>
<th>Geographic location/timing of hepatitis B vaccine vaccination</th>
<th>Infants with hepatitis B vaccine vaccination before discharge (n=53,519 deliveries)</th>
<th>Hospitals with hepatitis B vaccine administered to &gt;50% of infants (n=65 hospitals)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>National</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;24h</td>
<td>12,778 22%</td>
<td>14 16%</td>
</tr>
<tr>
<td>≥ 24h</td>
<td>642 1%</td>
<td>3 5%</td>
</tr>
<tr>
<td>Timing not documented</td>
<td>19,049 30%</td>
<td>29 40%</td>
</tr>
<tr>
<td>Island Groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Luzon</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;24h</td>
<td>8,858 20%</td>
<td>7 12%</td>
</tr>
<tr>
<td>≥ 24h</td>
<td>642 2%</td>
<td>3 5%</td>
</tr>
<tr>
<td>Timing not documented</td>
<td>11,839 27%</td>
<td>14 20%</td>
</tr>
<tr>
<td>Visayas</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;24h</td>
<td>3,404 65%</td>
<td>7 64%</td>
</tr>
<tr>
<td>≥ 24h</td>
<td>0 0%</td>
<td>0 0%</td>
</tr>
<tr>
<td>Timing not documented</td>
<td>1,641 31%</td>
<td>4 36%</td>
</tr>
<tr>
<td>Mindanao</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;24h</td>
<td>0 0%</td>
<td>0 0%</td>
</tr>
<tr>
<td>≥ 24h</td>
<td>0 0%</td>
<td>0 0%</td>
</tr>
<tr>
<td>Timing not documented</td>
<td>3,594 50%</td>
<td>8 57%</td>
</tr>
</tbody>
</table>

*a Number of hospitals per island group were 60, 11, 14 for Luzon, Visayas and Mindanao.

Having a copy of the hepatitis B vaccine vaccination policy (prevalence odds ratio [pOR]=4.7, 95% confidence interval [CI]=1.2–18.0), having standing orders (pOR=4.8, 95% CI=1.3–18.1) and providing training on the birth dose policy (pOR=18.9, 95% CI=5.3–67.0) were associated with >50% birth dose coverage in a hospital (Table 2). Birth dose coverage was not associated with accreditation by the national health insurance agency or the Philippine Pediatric Society, or with designation as a training hospital.

3.2 Metro-Manila health center assessment

Overall timely hepatitis B birth dose coverage increased from 19% among 1231 infants delivered during the six-month period before implementing the training workshop and supervision to 74% among 294 infants delivered after the intervention (Table 3). Timely birth dose coverage increased from 17% to 86% among infants born at home and from 26% to 75% among infants born in a lying-in clinic.

Prior to the intervention, no health center maintained copies of all EPI policies and guidelines, and there were no documented supervisory visits. After the intervention all nine health centers had copies of all relevant EPI policies and guidelines, and had documentation of supervisory visits.

4. Discussion

As the 2012 goal for reducing chronic HBV infection among children in the Western Pacific Region approaches, sharing the experience gained in the Philippines is timely and valuable to other countries in the region. The present assessments showed that hepatitis B birth dose vaccination is being implemented in large hospitals in the Philippines and that targeted training and supervision can significantly increase timely birth dose coverage in and out of hospital settings.

Timely birth dose administration and monitoring coverage is essential in the Philippines because pregnant women are not screened for hepatitis B infection and therefore, all newborns should receive a birth dose as a prophylactic measure against potential perinatal exposure to HBV. Establishing the practice of timely birth dose administration is most feasible in hospital settings with trained healthcare professionals and facilities for cold storage of the vaccine. However, even under the best conditions barriers to implementation have been reported [11–13]. The Philippines’ hos...

Table 2
Factors associated with being a hospital achieving >50% timely hepatitis B birth dose coverage, metro-Manila health center assessment, Manila, Philippines, July–September, 2007.

<table>
<thead>
<tr>
<th>Potential predictor</th>
<th>Number (%) of hospitals with potential predictor</th>
<th>Prevalence odds ratio* (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospitals with &gt;50% birth dose coverage (n=14)</td>
<td>Hospitals with ≤50% birth dose coverage (n=71)</td>
</tr>
<tr>
<td>Presence of copy of immunization policyb</td>
<td>44 (31%)</td>
<td>60 (84%)</td>
</tr>
<tr>
<td>Presence of copy of hepatitis B vaccine vaccination policy</td>
<td>44 (31%)</td>
<td>60 (84%)</td>
</tr>
<tr>
<td>Staff trained on hepatitis B vaccine administration</td>
<td>11 (79%)</td>
<td>13 (20%)</td>
</tr>
<tr>
<td>Accredited by national health insurance agencyc</td>
<td>7 (50%)</td>
<td>19 (26%)</td>
</tr>
</tbody>
</table>

*a Oddsofhospitals with >50% birthdosecoveragerelativetothosewith ≤50%.
*b Administrative Order 39s 2003.
*c Administrative Order 2006-0015.

Table 3
Factors associated with being a hospital achieving >50% timely hepatitis B birth dose coverage, metro-Manila health center assessment, Manila, Philippines, July–September, 2007.

<table>
<thead>
<tr>
<th>Potential predictor</th>
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</table>

*a Oddsofhospitals with >50% birthdosecoveragerelativetothosewith ≤50%.
*b Administrative Order 39s 2003.
*c Administrative Order 2006-0015.
Implementing a training workshop and supervision by place of delivery, health center assessment, metro-Manila, Philippines, 2007.


Table 3

<table>
<thead>
<tr>
<th>Hospital assessment</th>
<th>Written policy (≥24h)</th>
<th>After intervention (≥24h)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Na (0.001)</td>
<td>Na (0.001)</td>
</tr>
<tr>
<td>Hospital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GHQ</td>
<td>51 (17.0)</td>
<td>180 (60.9)</td>
</tr>
<tr>
<td>Not investigated</td>
<td>40 (13.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Overall</td>
<td>91 (19.0)</td>
<td>180 (60.9)</td>
</tr>
<tr>
<td>GHQ</td>
<td>56 (20.5)</td>
<td>46 (75.9)</td>
</tr>
<tr>
<td>Not investigated</td>
<td>7 (5.5)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Overall</td>
<td>63 (21.7)</td>
<td>46 (75.9)</td>
</tr>
<tr>
<td>Hospital</td>
<td>130 (40.5)</td>
<td>31 (48.6)</td>
</tr>
<tr>
<td>Not investigated</td>
<td>18 (5.2)</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Overall</td>
<td>148 (45.8)</td>
<td>32 (49.7)</td>
</tr>
<tr>
<td>Unrecorded place</td>
<td>82 (22.7)</td>
<td>27 (36.2)</td>
</tr>
<tr>
<td>Not investigated</td>
<td>86 (15.5)</td>
<td>1 (0.0)</td>
</tr>
<tr>
<td>Overall</td>
<td>90 (24.2)</td>
<td>28 (37.2)</td>
</tr>
<tr>
<td>Hospital</td>
<td>232 (101.5)</td>
<td>239 (86.5)</td>
</tr>
<tr>
<td>Not investigated</td>
<td>104 (45.6)</td>
<td>8 (12.0)</td>
</tr>
<tr>
<td>Overall</td>
<td>336 (146.5)</td>
<td>247 (98.5)</td>
</tr>
</tbody>
</table>

NA, not applicable.

*p < 0.001 for difference in proportions between coverage before and after training and supervision.

The metro-Manila health center assessment showed increases in timely birth dose coverage in and out of hospital settings. Programmatic evaluations and interventions aimed at building knowledge and capacity to ensure high timely birth dose coverage among two of hospital deliveries are currently being implemented since 505 of deliveries are take place at home [9]. Because of the success of the training workshop and supervision conducted in metro-Manila, these activities are currently scaling up to cover an additional 77 strategic health centers.

These assessments had some limitations. The hospital survey included only large hospitals; it is not known if smaller hospitals are more or less likely to implement hepatitis B birth dose vaccination. We also do not know if there is selection bias resulting from the 5% participation rate. It is possible that the six hospitals that were excluded because they did not have patient records at the time of the assessment may not have had them because a birth dose program was not yet been implemented. If this is the case, the birth dose coverage would be underestimated. The metro-Manila training assessment did not include rural areas where coverage may be lower and impact harder to achieve due to greater challenge in having a birth attendant and vaccine present during or soon after a birth. The increase in birth dose coverage found after the training workshop in the metro-Manila assessment could have been partly due to the start-up time required to implement the change in national policy.

Administration of a hepatitis B vaccine birth dose within 24 h of birth is a critical strategy for preventing mother-to-child transmission and morbidity and mortality caused by HBV infection. The Philippines experience showed that actions such as establishing national policies, distributing detailed and specific guidelines, conducting effective training and supervision, and having hospital standing orders can substantially impact hepatitis B vaccine birth dose coverage and prevention of perinatal HBV transmission.

Conflict of interest statement

All authors stated having no conflict of interest related to the authorship of the submitted paper.

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References


Timing of hepatitis B vaccination and impact of non-simultaneous vaccination with DTP vaccine following introduction of a hepatitis B birth dose in the Philippines

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Abstract Timely administration of hepatitis B vaccine beginning at birth prevents up to 95 per cent of perinatally acquired hepatitis B virus infections in infants of infected mothers. The Philippines changed its national HepB schedule in 2007 to include a dose at birth. We evaluated vaccination schedule change by reviewing infant records at selected health facilities to measure completeness and timeliness of HepB administration and frequency of recommended, simultaneous vaccination with diphtheria-tetanus-pertussis (DTP) vaccine. Of 1431 sampled infants, 1106 (77 per cent) completed the HepB series and 12 per cent followed the national schedule. The proportion with timely vaccination declined with successive doses: HepB1 (71 per cent), HepB2 (47 per cent), and HepB3 (26 per cent). Twenty-six per cent received HepB2 simultaneously with DTP1 and 34 per cent received HepB3 simultaneously with DTP3. If HepB and DTP vaccination were given simultaneously, 10 per cent more infants could have received all HepB doses. Program implementers should monitor vaccination timeliness and increase simultaneous administration to improve vaccination coverage and decrease disease incidence.

Keywords: hepatitis B birth dose; vaccination timeliness; immunization schedule adherence; expanded program on immunization

Introduction

The complexity of vaccination schedules in low- and middle-income countries (LMIC) has increased because these countries have introduced new vaccines and additional doses. These changes may increase the number of infants who do not receive vaccines according to a recommended schedule. And the changes may negatively impact vaccination coverage and timeliness. Research and data on timeliness of vaccination come largely from the United States. In LMICs, researchers frequently focus on assessing strategies for reaching unvaccinated infants rather than adherence to timeliness. Because of narrow age requirements for certain new vaccines, such as rotavirus vaccine, researchers have increased attention to the timely administration of infant immunizations. Delay beyond the date recommended in the schedule may leave infants unprotected for longer periods against vaccine preventable diseases.

Chronic hepatitis B virus (HBV) can cause liver cancer and cirrhosis. Infection is often transmitted from mother to child. The World Health Organization (WHO) recommended an HBV control strategy that reduces mother-to-child transmission: administration of a first hepatitis B vaccine (HepB) within 24 hours of birth, to be followed with a high level of population coverage with the remaining two doses. In Southeast Asia, an estimated 5 per cent of infants are infected perinatally with HBV. Ninety per cent of them will develop chronic HBV infection if not immunized within 24 hours of birth.

The Department of Health (DoH) manages the Philippines Expanded Programme on Immunization (PEPI) with technical and programmatic support from WHO, other UN agencies, and medical organizations. In 1994, the DoH introduced HepB into PEPI as a three-dose schedule given at 6, 10, and 14 weeks of age to coincide with the diphtheria-tetanus-pertussis (DTP) vaccine schedule. In January 2007, the DoH changed its policy so that a first HepB dose (HepB1) was to be given within 24 hours of birth, second dose (HepB2) at 6 weeks, and third dose (HepB3) at 14 weeks of age. For infants weighing less than 2000g at birth, the PEPI vaccination schedule recommends a fourth dose (HepB4) at 10 weeks of age. The Philippines Pediatric Society (PPS) recommends a different vaccination schedule: HepB1 within 24 hours of birth, HepB2 between 4 and 16 weeks of age, and HepB3 between 14 weeks and 12 months of age.
PEPI recommends that health workers give the HepB birth dose at the delivery location, usually a hospital or other health facility with capacity for delivery care, or at home. Infants usually receive subsequent HepB doses elsewhere. Filipino mothers commonly travel to their family’s home to give birth, returning to their own domicile shortly after birth. In 2008, 41 per cent of pregnant Filipino women gave birth in facilities; of these, 63 per cent were in public facilities and 36 per cent in private facilities.12

Our assessment team collaboratively reviewed immunization records of children born at selected health facilities in late 2008, approximately 17 months after initial implementation of the HepB birth dose policy in the Philippines. The assessment team measured the effect on receipt of subsequent doses of introducing the new schedule with a birth dose. To assess the effect, we used as an indicator estimates of completeness and timeliness of second and third doses of HepB and DPT vaccination for infants born in a health facility. We also evaluated the frequency of simultaneous administration of HepB and DPT doses in the series and the impact on overall coverage.

Methods
Site selection
The Filipino government organizes the 81 provinces in the Philippines into 17 administration regions. To select sites for the immunization record review, our assessment team used purposive, multi-stage sampling, starting at the regional level. We excluded two regions due to inadequate security to protect our team (Autonomous Region of Muslim Mindanao) and concerns about generalizability of results to rural areas (National Capital Region). We then stratified the sample into four groups defined by the percentage of infants born at health facilities and DTP1 vaccination coverage; factors potentially correlated with success of HepB birth dose introduction.12 The four groups were as follows:

- < 50 per cent of infants born in health facilities and < 90 per cent DTP1 vaccination coverage;
- < 50 per cent of infants born in health facilities and ≥ 90 per cent DTP1 vaccination coverage;
- ≥ 50 per cent of infants born in health facilities and < 90 per cent DTP1 vaccination coverage; and
• ≥50 per cent of infants born in health facilities and ≥90 per cent DTP1 vaccination coverage.12

We then randomly selected three of the four groups and from each, the team randomly selected one region. In each selected region, we purposively selected two districts based on high and low proportion of facility-based deliveries: Legaspi and Naga (Bicol), Tagum and Davao (Davao), and Cebu and Mandaue (Central Visayas) Cities. Within each city, we stratified three birthing facilities (referred to as Birth Providers) by size and then randomly selected: one large (≥3000 births per year), one medium (500–3000 births per year), and one small (<500 births per year). We had a total of 18 Birth Providers, six from each region. Among the 18 Birth Providers selected, 16 were public hospitals and two private hospitals.

Data collection
From May 2009 to June 2009, for a cohort of 5–7 month old infants born at Birth Providers between 1 October and 31 December 2008, our team of trained data collectors abstracted data from infants’ birth and vaccination records, including gender, birth weight, birth date and time, and HepB birth dose date. We set the target number of records at 1650, including 150 each from six large Birth Providers, 75 each from six medium Birth Providers, and 50 each from six small Birth Providers. If the number of records available at a Birth Provider for the selected cohort was greater than the required target number, then data collectors systematically sampled records to obtain the requisite number.

Data collectors used infants’ address information from the records to determine the health facility (known as the EPI Site) where the infant was likely to have received subsequent HepB and DTP doses. Collectors matched EPI site records to Birth Provider records based on infant’s name and birth date, and mother’s name and address. Collectors contacted parents to determine which EPI site they visited, only if the Birth Provider records could not be matched at the expected EPI site. Collectors abstracted HepB and DTP dose information from EPI site records or from the infant’s vaccination card at a home visit.

Definitions
We considered infants as completely vaccinated if they received at least the three scheduled doses of HepB (and included those who may have
received more than three doses). We defined *timely* vaccination based on the PEPI schedule:

- **HepB1** was considered *timely* if received within 24 hours of birth.
- **HepB2** and **HepB3** vaccinations were considered *timely* if received 4–8 weeks and 12–16 weeks, respectively.
- Complete and timely vaccination meant receiving all three doses of HepB as above, no less than 4 weeks apart.
- **HepB** and DTP *simultaneously administered* meant the dates of both vaccinations were the same.

**Data analysis**

We conducted univariate analyses to determine vaccination coverage and the proportion of infants vaccinated by demographic characteristics. We used Chi-square tests to compare the proportion of infants vaccinated by various characteristics. We used a *P*-value < 0.05 to test significance. *Missed opportunities* occurred when providers gave only DTP1 or HepB2, or only DTP3 or HepB3 at the same visit. We used SAS 9.2 (Research Triangle Institute, NC, USA) to conduct our analyses. The Philippines Department of Health’s Institutional Review Board and the review boards of participating health facilities approved our protocol.

**Results**

**HepB vaccination**

We collected 1470 records from Birth Providers and matched and completed 1431 of these records at the corresponding EPI site or with vaccination cards retrieved from parents (Figure 1).

We did not reach our target number of records, because there were fewer births than expected in some small facilities. Of these 1431 infants, 1056 (74 per cent) had completed the three-dose DTP series by the time of the survey, a time at which they would have been 5–7 months of age and 1106 (77 per cent) completed the three-dose HepB series (Table 1). In addition, 1369 (95 per cent) received at least two HepB doses and 1419 (98 per cent) received at least one HepB dose. One thousand and ten or 71 per cent of infants received the HepB1 dose within 24 hours of...
Thirteen of the 1106 infants who completed the HepB series, all weighing \( \geq 2000 \) grams at birth, received a fourth HepB dose, which PEPi does not consider necessary based on their weight.

Vaccination timelines in the Philippines

![Diagram](image)

Figure 1: Selection of infant records from birth providers.

Table 1: Hepatitis B (HepB) vaccination rates among 1431 5–7 month-old Filipino infants in six selected districts of the Philippines, by provider and infant characteristics—May 2009

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of infants</th>
<th>HepB1 (birth)(%(^a), %(^b))</th>
<th>HepB1 (birth)(%(^c), %(^d))</th>
<th>Complete HepB vaccination (%(^e))</th>
<th>Complete and timely HepB vaccination (%(^f))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>766</td>
<td>71</td>
<td>99</td>
<td>77</td>
<td>10</td>
</tr>
<tr>
<td>Female</td>
<td>665</td>
<td>70</td>
<td>99</td>
<td>75</td>
<td>10</td>
</tr>
<tr>
<td>Provider size</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small (10–500 births/year)</td>
<td>230</td>
<td>69</td>
<td>100</td>
<td>90</td>
<td>9</td>
</tr>
<tr>
<td>Medium (500–3000 births/year)</td>
<td>391</td>
<td>78</td>
<td>99</td>
<td>78</td>
<td>9</td>
</tr>
<tr>
<td>Large (43000 births/year)</td>
<td>810</td>
<td>67</td>
<td>99</td>
<td>71</td>
<td>8</td>
</tr>
<tr>
<td>Provider type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>211</td>
<td>81</td>
<td>100</td>
<td>75</td>
<td>15</td>
</tr>
<tr>
<td>Public</td>
<td>1220</td>
<td>69</td>
<td>99</td>
<td>79</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>1431</td>
<td>71</td>
<td>99</td>
<td>76</td>
<td>10</td>
</tr>
</tbody>
</table>

\(^a\)Received HepB1 within 24 hours of birth.

\(^b\)Complete vaccination defined as infant receiving at least three HepB doses.

\(^c\)Received HepB1 at any age.

\(^d\)Timeliness defined as infant receiving each HepB dose according to the Philippines National Expanded Program on Immunization Vaccination Schedule recommendations and using a buffer period of \( \pm 2 \) weeks for HepB2 and HepB3 doses and within 24 hours for HepB1 dose.

birth. Thirteen of the 1106 infants who completed the HepB series, all weighing \( \geq 2000 \) grams at birth, received a fourth HepB dose, which PEPi does not consider necessary based on their weight.
Complete and timely HepB vaccination

Of the 1431 infants surveyed, 140 (10 per cent) received three timely HepB doses per the PEPI schedule. An additional 307 (21 per cent) infants received three timely HepB doses per the PPS schedule (Table 1). The remaining 659 (46 per cent) infants who also completed the HepB series did not receive all the three HepB doses according to either the PEPI or the PPS schedules. Of the 1431, 1010 (71 per cent) infants received HepB1 within 24 hours of birth, 672 (47 per cent) received HepB2 at age 4–8 weeks and 366 (26 per cent) received HepB3 at age 12–16 weeks. Of the 1010 (71 per cent) infants who received HepB1 within 24 hours of birth, all received it at the Birth Provider; of the 419 HepB1 doses given more than 24 hours after birth, 192 (47 per cent) received it at Birth Provider and 217 (53 per cent) received it at an EPI site.

Infants received timely DTP doses in a similar fashion to HepB vaccination timeliness: 762 (53 per cent) infants received DTP1 and 254 (18 per cent) received DTP3 on time. Those infants who received a timely HepB1 dose had the same likelihood to complete the HepB or DTP series as those infants who received a late HepB1 dose (OR = 1.12, $P = 0.41$; OR = 0.86, $P = 0.24$, respectively) (Table 2).

Those infants who received a timely HepB2 dose were significantly more likely to complete the HepB series than those who received a late HepB2 dose (OR = 1.85, $P < 0.01$). HepB1–3 and DTP1–3 coverage rose rapidly after the due dates, although a small proportion of infants did receive HepB2 (2 per cent) and HepB3 (14 per cent) before the recommended ages (Figure 2).

By 8 weeks of age, 49 per cent of the infants received HepB2 and by 16 weeks of age, 40 per cent of infants received HepB3. The median interval between the first and second doses of HepB was 56 days and between the second and third doses of HepB was 55 days.

Simultaneous HepB and DTP vaccination

Of all 1385 infants who received DTP1, 461 (33 per cent) simultaneously received HepB2 as recommended in the PEPI schedule. An additional 108 (8 per cent) of these 1385 infants simultaneously received HepB1 or HepB3. Of all 1093 infants who received HepB3 vaccine, 288 (26 per cent) simultaneously received DTP3, as recommended.
An additional 346 (32 per cent) of the 1093 infants received HepB3 vaccine with either DTP1 or DTP2 vaccine.

Among 1056 (74 per cent) infants who received DTP3, 137 had not received HepB3. If these 137 infants had received HepB3 simultaneously with DTP3, the proportion that received HepB3 would have increased 10 per cent, from 1106 (77 per cent) to 1243 (87 per cent) infants. Among the 1106 (77 per cent) infants who received three or four doses of HepB, 201 had not received DTP1. If these 201 infants had received DTP3 simultaneously with HepB3, the proportion that received DTP3 would have increased 14 per cent, from 1056 (74 per cent) to 1257 (88 per cent). Completion of the HepB vaccination series was significantly higher for infants who received HepB3 simultaneously with DTP3, those who received HepB3 simultaneously with DTP2, and those who received either DTP1 or DTP3 simultaneously with any HepB dose than for those

Table 2: Completeness of HepB and DTP vaccination series among 1431 5–7 month-old Filipino infants in six selected districts of the Philippines, by provider and infant characteristics – May 2009

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>HepB series completeness</th>
<th>Odds ratio (P-value)</th>
<th>DTP series completeness (%)</th>
<th>Odds ratio (P-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HepB2 and DTP1 given:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>simultaneously</td>
<td>91.1%</td>
<td>3.30 (&lt;0.01)</td>
<td>81.1</td>
<td>1.46 (&lt;0.01)</td>
</tr>
<tr>
<td>non-simultaneously</td>
<td>75.6%</td>
<td></td>
<td>73.3</td>
<td></td>
</tr>
<tr>
<td>HepB2 and DTP2 given:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>simultaneously</td>
<td>89.7%</td>
<td>2.14 (&lt;0.01)</td>
<td>91.7</td>
<td>3.90 (&lt;0.01)</td>
</tr>
<tr>
<td>non-simultaneously</td>
<td>79.7%</td>
<td></td>
<td>73.9</td>
<td></td>
</tr>
<tr>
<td>HepB3 and DTP2 given:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>simultaneously</td>
<td>NA*</td>
<td>NA*</td>
<td>74.4</td>
<td>0.89 (0.41)</td>
</tr>
<tr>
<td>non-simultaneously</td>
<td>NA*</td>
<td>NA*</td>
<td>76.4</td>
<td></td>
</tr>
<tr>
<td>DTP1 or DTP2 and any HepB dose given:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>simultaneously</td>
<td>91.6%</td>
<td>4.61 (&lt;0.01)</td>
<td>82.1</td>
<td>1.98 (&lt;0.01)</td>
</tr>
<tr>
<td>non-simultaneously</td>
<td>70.5%</td>
<td></td>
<td>69.9</td>
<td></td>
</tr>
<tr>
<td>HepB1 received as a:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>timely dose</td>
<td>78.5%</td>
<td>1.12 (0.41)</td>
<td>71.1</td>
<td>0.86 (0.44)</td>
</tr>
<tr>
<td>Late dose</td>
<td>76.5%</td>
<td></td>
<td>76.0</td>
<td></td>
</tr>
<tr>
<td>HepB2 received as a:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>timely dose</td>
<td>81.6%</td>
<td>1.85 (&lt;0.01)</td>
<td>74.2</td>
<td>0.91 (0.51)</td>
</tr>
<tr>
<td>Late dose</td>
<td>76.5%</td>
<td></td>
<td>76.7</td>
<td></td>
</tr>
</tbody>
</table>

*NA: HepB series completeness cannot be calculated in this instance as all infants in this analysis of whether HepB3 and DTP2 were given simultaneously or not would have received HepB3.
Discussion

Our evaluation suggests that health workers adapted well to the changes to the national schedule, as measured by infants’ vaccination levels.

who did not receive them simultaneously (OR = 3.3; \( P < 0.01 \)) (Table 2). Completion of the DTP vaccination series was not significantly higher for infants who received HepB3 simultaneously with DTP2 than for those who did not receive it simultaneously (OR = 0.89; \( P = 0.42 \)).
Only 18 months after implementation of the national policy began, 71 per cent of infants received the HepB1 dose within 24 hours of birth, and 77 per cent of infants completed the three-dose HepB series. This closely aligns with the 2008 National Demographic and Health Survey where 82.8 per cent received DPT3 and 75.7 per cent received HepB3 by first birthday.12 HepB1 vaccination within 24 hours of birth prevented approximately 46 chronic HepB infections among our study cohort of 1,431 infants. Extrapolating this HepB1 coverage to the Philippines’ annual birth cohort of 2.5 million, the birth dose prevents approximately 80,000 chronic HepB infections. An additional 32,000 infections could have been prevented with 100 per cent coverage. Only 44 per cent of infants received complete and timely HepB vaccination as defined in either the national or PPS schedules. Most infants received one or more doses of HepB or DTP vaccine later than the recommended age. Finally, the majority of infants did not receive HepB and DTP vaccines simultaneously, despite the national policy supporting such administration.

Timely vaccination ensures protection of children from infection at the earliest possible age. A first HepB vaccine dose within 24 hours of birth remains critical in preventing perinatal HBV transmission.13–15 Timeliness of the second and third HepB doses can also improve early protection against horizontal transmission. Infants who received a timely HepB2 dose were significantly more likely to have completed the HepB series than those who received a delayed HepB2 dose. On-time vaccination will become more important as new vaccines are introduced. The rotavirus vaccine schedule, for example, comes with age restrictions because of potential safety concerns.16

Program managers can reduce missed opportunities by improving simultaneous vaccination. In our study, approximately 10 and 14 per cent more children might have received third doses of HepB and DTP, respectively, if health workers had always administered them simultaneously. Infants who received simultaneous vaccinations were significantly more likely to complete the HepB and DTP vaccine series. Non-simultaneous vaccination increases program operating costs, wasting scarce resources. Parents face increased transportation costs and lost work time.1,2

Our study did not determine whether non-simultaneous administration of HepB and DTP was caused because of caretaker or health-care provider decisions or a combination of both. Follow-up surveys could examine this. As HepB and DTP are injectable vaccines, concerns about
pain may have reduced simultaneous use. We did not examine simultaneous administration with the oral polio vaccine used in the Philippines; additional research could usefully pursue the frequency of simultaneous administration between the polio vaccine and HepB vaccine versus DTP vaccine and HepB vaccine.\textsuperscript{17} The Philippines recently introduced an injectable pentavalent (Hib, HepB, DTP), a single combination vaccine. It may redress non-simultaneous administration. In the near future PEPI plans to introduce additional vaccines, including pneumococcal vaccine. The schedule calls for this vaccine coincides with that for DTP-HepB. Thus, simultaneous administration of multiple vaccines remains an important element for vaccine programs – to achieve higher rates of coverage with multiple antigens, and to understand any issues that may arise from the new combinations and schedules.

Our evaluation also raised the issue conflicting infant vaccination schedules: PEPI and PPS. We found twice as many surveyed infants received vaccinations at times that fit the PPS schedule as the national schedule; perhaps the lower rates of timely completion of the national schedule has to do with the larger age windows in the PPS schedule. Or perhaps the wider acceptance of the PPS schedule. Surely, having two recommended schedules may confuse health-care providers, thus it would be useful to harmonize the two schedules, as other countries have done.\textsuperscript{18}

Our findings are subject to several limitations. The results of this evaluation cannot be nationally generalized, as we selected only three of the 17 regions of the Philippines, and within each selected district we sampled only three Birth Providers. Our sample only included those infants born in a facility and later traced to either an EPI site or their home. These infants do not represent the current Filipino birth cohort, because 59 per cent of Filipino mothers give birth at home.\textsuperscript{19} If infants switched EPI sites after receiving their initial vaccines, our method would not have captured their complete record. Thus our measured vaccination rates may underestimate the true coverage.

Understanding the reasons for delayed vaccination remains vital to addressing timeliness. In previous studies, researchers identified certain demographic factors associated with delayed receipt of vaccines, including rural locations and birth order.\textsuperscript{5,13,19} Countries should identify local issues contributing to delayed vaccination. Learning reasons parents and health workers give for delayed vaccinations can inform policy and standards intended to reduce barriers to timely vaccination.
In places where timeliness is poor, defaulter tracking systems and a focus on strengthening record-keeping may improve schedule adherence.\textsuperscript{1,5,19} Most important, we believe, health workers require training and supportive supervision to ensure they understand the national vaccination schedule and the value of adhering to it.

Acknowledgements

We thank the data collection team from the University of the Philippines. We also thank Eric Mast, Jacqueline Gindler, Karen Hennessey, and Elizabeth Luman for their valuable comments on the draft manuscript and the protocol and Earl Bradbury on his contributions towards the protocol. Lastly, we thank the health workers from the Philippines Department of Health for their participation in the evaluation. The findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention. The work was supported by the World Health Organization and the US Centers for Disease Control and Prevention.

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more cases in males which agrees with other reports from Ethiopia.1–3 Although there might be predisposing factors that we do not know about, it could also just be because some families are more likely to take males to hospital. The mean duration of the illness was shorter in most of the reported series in adults and in children.4–7 In contrast to previous studies,8 we have not found a shorter duration of symptoms before admission to hospital in children than in adults.

The clinical features of LBRF in childhood are similar to those in adults.1–3 However, we find clinical differences between pediatric and adult patients with less common symptoms like headache, dizziness or other pains, which could be attributed to the fact that children are less capable of communicating their problems.9 But there were also significant differences in objective features such as headache, which was less frequent in children and which suggests that there really are important clinical differences in the presentation of the disease among these two age groups. The treatment was also different for children and adults; tetracycline being used more frequently for adults and penicillin or erythromycin for children who agree with previous reports. The overall case fatality in our series was low, as in previous reports (< 5%).5,9,10 When we compared the fatality rates among children and adults, like other authors, we had fewer mortalities among children.1–4 The hospitalization was shorter for children (average 3.7 days) which is a similar result reported in other studies.10

In conclusion, many symptoms of LBRF occur less frequently in children than in adults and the prognosis is better in most of the reports from Ethiopia.

Acknowledgements
We thank the nursing and laboratory staff at the Gambo Rural General Hospital for their help in this study.

References

The Philippines 2004 measles campaign: a success story towards elimination
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Summary
Prior to the 2004 Philippines Measles Follow-up Elimination Campaign, measles caused an estimated 5000 deaths among Filipino children. After the campaign, cases and deaths decreased by 95.4% and 99.2%, respectively.1 The Nationwide Rapid Coverage Assessments, with an extensive system of feedback, was the prime factor in reaching the under-immunized areas.

Introduction
In 2003, an estimated 6000 Filipino children died from measles.2 Poor children are at the highest risk and have the least access to basic public health services.2 Philippine million Filipinos live on less than USD1 per day.3 The Philippines is one of the 42 countries that account for 90% of global deaths in under-5 year-old children.4

Reaching under-immunized populations requires focused efforts.50% of children aged 9 months – 15 years were reportedly vaccinated during a 1998 nationwide measles campaign.5 Measles cases only marginally decreased which suggests that pockets of unimmunized children remained.6 Other countries have had similar experiences.7 Countries in the American use Rapid Coverage Assessments (RCA) where supervisors review the immunization status of 20 children in each community. When two or more unimmunized...
children were found, supervisors re-initiated vaccination activities.

The 2004 Philippines Follow up Measles Elimination Campaign (PFMEC) aimed to vaccinate 18 million children aged 9 months to 8 years against measles. Pre-campaign key informant interviews, data analysis and planning workshops revealed that 50% (9860) more vaccinators were needed than were available at the time; the door-to-door strategy would not be widely used; the population estimate was unreliable; and local health workers felt that as they had undertaken similar activities before they did not need extra training.

The Philippines instituted RCA, along with an extensive feedback system, during the 2004 PFMEC to focus attention on reaching the under-immunized population.

Methods

The campaign outcome was assessed by measuring the number of measles cases and deaths identified in the National Epidemic Sentinel Surveillance System (NESSS) during the five years before and two years after the campaign. A suspect measles case is defined as an illness with three days of fever, maculo-papular rash, accompanied by cough, coryza or conjunctivitis.

Initiated in 1993, NESSS is an active surveillance system for 14 notifiable diseases, including measles, from 228 hospitals covering all 17 regions. Attending staff and hospital infection control teams investigate all suspect cases, including specimen collections. They submit investigation forms to the Regional Epidemic Surveillance Unit who report to the National Epidemic Center monthly. Data is entered into the NESSS database.

Twenty-eight hospitals in 14 regions had at least a 100-bed capacity, weekly active measles surveillance and reported cases every year between 2003 and 2005 (referred hereafter as High-Performing Sentinel Sites [HPSS]). Six of these have more than 50% of their clientele residing in rural areas.

Measles serology testing began in 1999. Blood specimens were sent to the Research Institute of Tropical Medicine (RITM) in Manila for IgM testing by ELISA. They are part of the World Health Organization (WHO) Western Pacific Regional laboratory network and have consistently passed WHO proficiency testing.

We compared the average number of reported measles cases, deaths, the proportion of specimens positive for IgM serology and the proportion of suspect measles cases that had received measles vaccination for the five years before the start of the campaign (January 1999-December 2003) with those two years after the campaign (April 2004-March 2006). We also used the same analysis for the 28 HPSS and the six rural HPSS, comparing the same periods.

Percentage decrease is defined as:

\[
\frac{\text{5-year average annual cases pre-campaign}}{\text{1–2-year average cases post-campaign}} \times 100\%.
\]

Results

Measles cases reported to the NESSS during 1995–2003 ranged from 100 to 1000 per month (Figure 1). Reported cases and deaths decreased by 96.4% and 99.2%, respectively, after the campaign compared to the five years prior to the campaign (Table 1). These results are consistent whether comparing all NESSS cases or those from any or just rural HPSS.

Between 1995 and 2003, 19.3% of suspect measles cases reported to NESSS were vaccinated. This increased to 44%
Measles cases remain after a campaign has been conducted. It was populations and prioritized them. The Secretary of Health, regional directors and health scientists and health staff. Within three weeks, discussions found our repeated reports of low coverage alarmed politicians and health professionals aware that attaining international elimination targets and United Nations Millennium Development Goals meant that they had to reach these districts which had not been covered in previous surveys.11

Table 1 Comparison of measles surveillance parameters two years after and four years before the campaign

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Measles cases in 234 sentinel hospitals</td>
<td>7688.2</td>
<td>2775.0</td>
<td>64.6</td>
</tr>
<tr>
<td>Measles deaths in 234 sentinel hospitals</td>
<td>269.4</td>
<td>2</td>
<td>99.2</td>
</tr>
<tr>
<td>Measles cases in 28 sentinel hospitals</td>
<td>4720.2</td>
<td>526.5</td>
<td>87.8</td>
</tr>
<tr>
<td>Measles cases in six rural hospitals</td>
<td>150</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>

RCA should be considered in any country where measles cases remain after a campaign has been conducted. It was particularly helpful in our set up where the authority to deliver health services is decentralized to local governments. National programmes cannot force local health teams to reach the unreached. Rather, they must persuade and support regions, provinces, cities and municipalities to employ effective strategies. Extensive national pre-campaign advocacy and planning did not accomplish this. The nationally conducted validation of 45% districts identified that under-immunized populations existed. It made policymakers, politicians and health professionals aware that attaining international elimination targets and United Nations Millennium Development Goals meant that they had to reach these districts which had not been covered in previous surveys.11

Discussion

After 10 years of reported measles cases, deaths, vaccination status of cases and five years of IgM positive serology the situation was stabilized and dramatically improved after the campaign. HPSS followed this trend. Likewise, IgM positivity declined from above 80% to zero after June 2004. As none of these changed during previous campaigns, those campaigns probably did not penetrate the pockets of the under-immunized populations.

We acknowledge that NESSS only detects hospitalized cases located in 228 of the 954 total hospitals (23.9%); 7

Effect of RCA

In the Americas, RCA has proven to be an important adjunct to focused campaigns on reaching at-risk populations. We found our repeated reports of low coverage alarmed policymakers and health staff. Within three weeks, discussions about the RCA results caused five large regions and 13 cities to admit to falling short of their target. We then negotiated for an enforced door-to-door strategy and an area-wide validation. The Secretary of Health who validated the findings himself, issued a policy requiring nationwide validation and provided the support costs. Eventually, regional staff validated 17,333 districts and identified an estimated 26 times more with lower coverage than their international partners. The Secretary of Health, regional directors and health workers reported that validation exposed large unreached populations and prompted them.

RCA should be consulted in any country where measles cases remain after a campaign has been conducted. It was particularly helpful in our set up where the authority to deliver health services is decentralized to local governments. National programmes cannot force local health teams to reach the unreached. Rather, they must persuade and support regions, provinces, cities and municipalities to employ effective strategies. Extensive national pre-campaign advocacy and planning did not accomplish this. The nationally conducted validation of 45% districts identified that under-immunized populations existed. It made policymakers, politicians and health professionals aware that attaining international elimination targets and United Nations Millennium Development Goals meant that they had to reach these districts which had not been covered in previous surveys.11

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10 United Nations General Assembly. A/Res/57/1. Agenda Item 104

Tropical Doctor January 2009, 39
Secondary analysis of a national health survey on factors influencing women in the Philippines to deliver at home and unattended by a healthcare professional

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A R T I C L E  I N F O

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Philippines
Unattended deliveries

A B S T R A C T

Maternal Technology factors that influence Philippine women to deliver at home and not be attended by a healthcare professional. Methods: Analysis of hospital data that were collected through Global Positioning System technology uploaded into the WHO HealthMapper and data on 7,880 women from the Philippines Demographic and Health Survey, 2003. Results: Most of the home deliveries that were not attended by healthcare professionals occurred within 15 km of a hospital. Women who had home deliveries and were not attended by a healthcare professional were more likely to be of lower educational and economic status and to reside in rural areas. Conclusions: Maternal technology that were not attended by a healthcare professional occurred near a hospital. Financial barriers will need to be addressed to increase the number of deliveries in a healthcare facility. The apparent failure of hospitals to reduce neonatal mortality may be related to suboptimal neonatal care practices.

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1. Introduction

The Philippines is among 55 countries that account for 94% of all maternal deaths in the world [1,2]. Annually, more than 4000 Philippine women and 30,000 newborns die during or shortly after childbirth [2]. The maternal death rate has not reduced sufficiently to meet the target of Millennium Development Goal (MDG) number 5, to reduce maternal mortality, between 1990 and 2015, by three-quarters [3]. The vast majority of maternal deaths are due to hemorrhage, hypertensive disease, sepsis, obstructed labor, and problems related to abortion. These disorders can be treated when deliveries occur where there are persons skilled to identify and treat them and when pregnancies are spaced by at least 2 years [4-7].

In the Philippines, in the 5 years prior to the 2003 National Demographic and Health Survey (NDHS), 50% of deliveries occurred at home. Of these, 65% were not attended by a healthcare professional [2]. Overall, the percentage of deliveries attended by a skilled healthcare professional has increased from 22.8% (1993) to 62.3% (2003), and institutional deliveries have increased from 20% (1993) to 43.1% (2003) [1,3]. The Department of Health (DOH) has made major efforts to increase the number of deliveries in healthcare facilities [7].

Data are few and not widely disseminated on where and why home deliveries that are not attended by healthcare professionals are so prevalent in the Philippines. Anecdotally, healthcare workers often attribute this common practice to residence in remote areas and to cultural beliefs.

The aim of the present study was to use a large nationwide sample to identify factors that influence the decision of women in the Philippines to deliver at home and unattended by a healthcare professional.

2. Materials and methods

A secondary analysis of the 2003 NDHS was conducted. The electronic database of the NDHS including the global positioning system (GPS) coordinates was provided by ORC Macro-International (Calverton, MD, USA) upon request of the government of the Philippines. The Philippine health facility layer of WHO HealthMapper, containing the GPS coordinates of hospitals, was supplied by the Philippine DOH and was uploaded into WHO HealthMapper in the third quarter of 2004 (smaller hospitals were not included).

Women who delivered at home and had been attended by persons who were not healthcare professionals (NHPs) were identified. These data including GPS coordinates were loaded into WHO HealthMapper. A map was then developed to chart home births attended by NHPs in relation to hospital locations. Indicators of demographics, use of healthcare services, and perceived barriers among women who delivered at home attended by NHPs, those attended by skilled health...
professionals (NHPs), and those who delivered in healthcare facilities were determined using data from the Demographic and Health Survey (DHS) and other sources. Data were weighted using the sampling weight variable. Statistically significant differences were determined using t-tests for proportions or χ² tests for categorical variables. P < 0.05 was considered statistically significant.

ORB: Macro-International randomly offset GPS coordinates to ensure confidentiality: rural points contained 0–5 km of positional error; urban points contained 0–2 km of error; and a further 1% of the samples points were offset by 0–10 km. The database did not include the names or addresses of the women.

This study consisted of a secondary review of existing data at the request of the ORB. As there were no direct interviews or identifying information of the women included, informed consent was not needed and ethical review for the study was not required.

2. Results

Compared with women who delivered in a healthcare facility, women who delivered at home attended by NHPs were at least twice as likely to live in rural areas, to have lower levels of education, to live in a lower economic quintile, and to reside in households without radios, piped water, or solid flooring (Table 1). These women or their children were 12.5–21.3% less likely to have received 3 doses of diphtheria–pertussis–tetanus (DPT3) vaccine by 1 year of age or a vitamin A capsule in the past 6 months, or to have received oral rehydration therapy during the last episode of diarrhea, or to use modern methods of contraception; they were 7% less likely to receive antenatal care visits. Compared with women who delivered in a healthcare facility, women who delivered at home with NHPs had 1.5 more living children and twice as many deaths of children younger than 5 years old. However, about 1.6% of mothers felt that whether delivery was in a healthcare facility or at home with NHPs (OR 1.0; 95% CI, 0.95–1.05; P = 0.85).

The overwhelming majority of home deliveries occurred within 15 km of a hospital. The majority of women reported “wanting to go transport” or “distance to the health facility” compared with 10.35 and 17.25, respectively, for those who delivered in healthcare facilities. Women who delivered at home attended by NHPs were also 2–3 times more likely to not know where to go for treatment, to need to get permission from partners for treatment, to not want to go alone, or to be concerned that there might not be a female provider.

Women who delivered at home attended by an NHP had intermediate values for each item in the analysis except for newborn and child mortality. Even after adjusting for maternal education, economic, or health status, the housing indicators in Table 1, and birth weight, delivering at home attended by an NHP had less than half the risk of the newborn dying compared with delivery in a healthcare facility (OR 0.59; 95% CI, 0.48–0.85; P = 0.012).

4. Discussion

The study revealed that most home deliveries in the Philippines that were not attended by healthcare professionals were close to hospitals. Despite the proximity, however, half of the women listed distance to the healthcare facility and having to take transport as major problems. Many did not know where to go, needed to get permission for treatment, did not want to go alone, or were concerned
Concerns over cost were voiced by women regardless of their economic status. Normal spontaneous vaginal deliveries in healthcare facilities cost a minimum of 5310 Philippine pesos (approximately US $120), but the cost is double for tertiary care centers, excluding cesarean deliveries [8]. The poorest 30% of Philippine families earn annually an average of 49000 Philippine peso (approximately US $1030) [9]. Clearly, the cost of delivering in a healthcare facility would represent a significant portion of the annual income of the family. The average Philippine family pays for about half of their health care. Globally, for every 1% increase in the proportion of total healthcare expenditure paid for by the family, there is a 2.25 increase in the proportion of households facing catastrophic payments [10].

Community organizing initiatives have been shown markedly to improve the use of healthcare services and the health of the poor in the Philippines [11,12]. However, failure to address barriers, such as facility and transportation costs, lack of a companion of choice, and the manner in which health professionals interact with poor pregnant women, has undermined attempts to improve use of healthcare facilities for deliveries [13].

For ethical reasons, the GPS coordinates of respondents were randomly offset, which may slightly limit the accuracy of the results. The location of smaller hospitals were not uploaded into the WHO HealthMapper. Despite these limitations, most of the home deliveries that were not attended by healthcare professionals occurred within 15 km of a hospital. The NDHS questions covered the barriers in accessing general health care and were not specific to delivery in a hospital. It is possible that the barriers to accessing relatively distant and expensive hospital care are greater than those for routine services in health clinics. Thus, the present study probably underestimates the barriers to poor women delivering in a hospital.

Another limiting factor is that maternal deaths could affect the accuracy of data collection on questions about maternal and child health. Although the NDHS did not have questions about maternal mortality, the most recent maternal mortality data suggest that this would occur in 0.162% of all deliveries [13].

As expected, the barriers and use of healthcare facilities by women whose deliveries at home were attended by an SHP fall between those of SHP-attended deliveries at a healthcare facility and NHP-attended deliveries at a hospital. The lower neonatal mortality among SHP-attended deliveries at home compared with SHP-attended and healthcare facility-attended deliveries is intriguing, but preliminary. Caution must be taken when interpreting these data for several reasons. The NDHS does not have data on healthcare worker practices, maternal morbidity, or causes of neonatal death. Furthermore, we are unsure about the extent to which referral biases the results. For example, women who intended to deliver at home but were identified with danger signs during pregnancy, or risk factors for newborns, may have been referred to the hospital for care. Delayed referral further increases the risk.

Community hospitals need to be safe havens for vulnerable people. Newborns are completely dependent on the environment and care they might not be a female provider. The same population generally used other healthcare services. These results are in contrast to the commonly held notions among healthcare workers that women deliver at home without the attendance of healthcare professionals primarily because of cultural beliefs or residence in remote areas.

Table 2

<table>
<thead>
<tr>
<th>Barriers to accessing health care</th>
<th>Women who delivered at home without a healthcare professional</th>
<th>Women who delivered a home without a healthcare professional</th>
<th>Women who delivered at a healthcare facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivering is too expensive*</td>
<td>1137 (35.0)</td>
<td>351 (22.3)</td>
<td>489 (18.4)</td>
</tr>
<tr>
<td>Delivering is too expensive*</td>
<td>1547 (48.1)</td>
<td>412 (26.6)</td>
<td>424 (16.3)</td>
</tr>
<tr>
<td>Delivering is too expensive*</td>
<td>1614 (49.9)</td>
<td>426 (27.1)</td>
<td>461 (17.2)</td>
</tr>
<tr>
<td>Delivering is too expensive*</td>
<td>2615 (83.0)</td>
<td>1129 (74.4)</td>
<td>1515 (59.0)</td>
</tr>
<tr>
<td>Delivering is too expensive*</td>
<td>2808 (89.3)</td>
<td>1231 (81.2)</td>
<td>1767 (68.8)</td>
</tr>
<tr>
<td>Distance to health facility</td>
<td>789 (24.5)</td>
<td>230 (14.4)</td>
<td>262 (9.7)</td>
</tr>
<tr>
<td>Distance to health facility</td>
<td>571 (18.3)</td>
<td>155 (9.0)</td>
<td>149 (5.3)</td>
</tr>
<tr>
<td>Distance to health facility</td>
<td>752 (23.6)</td>
<td>232 (15.4)</td>
<td>275 (10.8)</td>
</tr>
<tr>
<td>Distance to health facility</td>
<td>2698 (86.2)</td>
<td>1201 (80.2)</td>
<td>1797 (68.8)</td>
</tr>
</tbody>
</table>

*Values are given as number (weighted percentage).

Conversely, hospitals need to be safe havens for vulnerable people. Newborns are completely dependent on the environment and care...
provided. Hospitals can provide access to lifesaving intensive and invasive emergency care not immediately available for home deliveries whether attended by an NHP or an SHP. However, substandard practices may increase the risk of iatrogenic neonatal sepsis. A recently completed evaluation of maternal and newborn care practices in hospitals in the Philippines revealed that hospital practices are below WHO standards. Furthermore, large hospitals are invariably crowded, and this is a known risk factor for neonatal sepsis [15]. This might also explain the relatively high newborn mortality rates that occur among deliveries in healthcare facilities.

There are no recent studies on the practices of NHP attendants in the Philippines. Neonatal mortality due to unsafe delivery and care is well known to be much higher among deliveries with these attendants [16]. SHP attendants of home deliveries in the Philippines are almost exclusively midwives. Midwives have had a minimum of 2 years training following a standard curriculum, including 1377 hours of clinical, exclusive midwifery. Midwives have had a minimum of 2 year's training in delivery care and recognition of danger signs in mothers and newborns, but an unspecified small number have received training and are in a network with physicians who allow them to provide emergency care including newborn resuscitation [7]. The combination of formal training in maternal and newborn care and the lower risk of neonatal infections may help to explain the lower neonatal mortality rates among home deliveries attended by SHPs.

The extent that each of the above factors contributes to the different neonatal mortality rates in home deliveries attended by NHPs or SHPs and healthcare facility deliveries is unknown and further studies are warranted.

The DOH has a vision of all women and newborns having access to emergency care. This vision must be balanced with steps to improve maternal and newborn hospital care and related hospital infection control practices. Unburdening healthcare workers of unsafe and unnecessary practices, including eliminating routine episiotomies, suctioning, and early bathing, will provide more opportunity to improve other practices. In addition, reducing congestion in the large hospitals by redirecting uncomplicated cases to smaller birthing centers will partially improve the burden placed on the large hospitals. Finally, improving use of facilities for elective deliveries will require addressing the financial barriers, organizing transportation, and having a companion of choice to accompany the women during delivery. The recent United Nations Joint Programme on Maternal and Newborn Health has made these the focus of a pilot project [14]. The DOH convened a multi-agency task force, including groups represented in this study, to focus on reducing the barriers identified in this and other studies.

Conflict of interest

The authors have no conflicts of interest to disclose.

References

Commentary

Quality at the centre of universal health coverage

Howard L. Sobel, 1,* Dale Huntington, 2 and Marleen Temmerman 3

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ABSTRACT

Abstract: The last decade of the MDG era witnessed substantial focus on reaching the bottom economic quintiles in low and middle income countries. However, the inordinate focus on reducing financial risk burden and increasing coverage without sufficient focus on expanding quality of services may account for slow progress of the MDGs in many countries. Human Resources for Health underlie quality and service delivery improvements, yet remains under-addressed in many national strategies to achieve Universal Health Coverage. Without adequate investments in improving and expanding health professional education, making and sustaining gains will be unlikely. The transition from the Millennium Development Goals (MDG) to the Sustainable Development Goals (SDG), with exciting new financing initiatives such as the Global Financing Facility brings the potential to enact substantial gains in the quality of services delivered and upgrading human health resources. This focus should ensure effective methodologies to improve health worker competencies and change practice are employed and ineffective and harmful ones eliminated (including undue influence of commercial interests).

Key words: Health systems, maternal and child health, Millennium Development Goals, policy, priority setting, quality of care, Sustainable Development Goals

Key Messages

• The last decade of the MDG era witnessed substantial focus on reaching the bottom economic quintiles in low and middle income countries (LMIC).
• There is a compelling need to shift what has been an inordinate emphasis on reducing financial risk burden towards policy and increased coverage to expand quality of services.
• As the SDG era emerges onto the global scene, countries will be increasingly called upon to address long-standing challenges.
The transition from the Millennium Development Goals (MDG) to the Sustainable Development Goals (SDG) brings new opportunities to countries to achieve national health coverage (NHC) in low- and middle-income countries. The Global Financing Facility in support of the renewed Global Strategy for Women’s, Children’s and Adolescents’ Health (UNICEF 2015) in the post-MDG world (Das and Hammer 2014). The Global Financing Facility in support of the renewed Global Strategy for Women’s, Children’s and Adolescents’ Health (UNICEF 2015) and others acknowledge the quality of care as an integral part of national health care (WHO, The World Bank 2013). However, in our opinion, reducing financial risk barriers and increasing coverage has been inordinately emphasized without sufficient focus on expanding quality of services.

In common to many perceptions, quality usually means basic services and interventions, our high-tech high-cost care. Poor hand hygiene is rampant among health workers in lower- and middle-income countries and is a grossly underemphasized source of death of babies and mothers alike. For simplicity, quality means providing an appropriate health-care service in the right quantity and at the right time.

Improving quality is not limited to low-income countries. In middle-income countries, economic development has fueled growth in the middle class who have heightened aspirations for health care and low tolerance for poor quality. Witness the violence against doctors in China and Vietnam as consumers react to malpractice and misconduct. Jing et al. (2014) in technology, service attitudes of primary care services in rural areas of many countries remain underdeveloped. However, studies looking at health services utilization from China and Vietnam in rural areas of many countries, countries will be increasingly called upon to address longstanding challenges—just as they confront new ones—such as high-prevalence infectious diseases, aging societies and a proliferation of costly, high-technology medical devices and drugs. The issue of wide coverage with quality services remains paramount in our opinion.

The Know-Do gap, i.e. what health workers know vs what they do, is large. Clinicians in Delhi, India were found in public clinics to practice just over one-tenth what they described as their standard practice. The same clinicians practiced worse than what they described in private clinics (Das and Hammer 2014). Basic hand hygiene is something most health providers were taught as children. Hand hygiene is something most health providers were taught as children. Poor infection control including hand hygiene leads to nosocomial having 20 times the risk of acquiring a health-care-associated infection in lower- and middle-income to high-income countries. In many countries, health care-related infection account for more than half of maternal deaths (WHO Global Alert and Response 2013). This half of health facilities do not have running water further exacerbates the problems. Meanwhile, absence of technology often increases the risk of death. For example, keeping a stable pre-term baby in an incubator doubles the risk of death compared with a child with lactation and breast milk feeding (Kangaroo Mother Care) (Das and Hammer 2014). Harmful and non-urgent practices often interfere with最佳care. ladder skin-to-skin contact between newborns and mothers at birth boosts babies’ warmth, calm and breathing well and makes that lifesaving first breastfeeding almost universal. Yet this does not happen or is interrupted by routine care in most low- and middle-income countries (Das et al. 2014, Sobel et al. 2014a, WHO 2013, Khan et al. 2013). The first breastfed is too often held hostage to health-workers providing infant formulas (Sobel et al. 2015). Even high coverage of essential interventions is not sufficient to lower maternal mortality if quality is not achieved such as trainings and back-up with comprehensive emergency obstetric services (Sobie et al. 2016). However, coverage of each such service is low and shortages also increase adverse outcomes (Khanbhai et al. 2010). Quality means performing the right evidence-based action at the right time and eliminating interventions and practices that cause at increased risk of death and illness.

With the Global Alliance on Vaccines and Immunizations supporting broad scale delivery of new vaccines in low- and middle-income countries, children are protected against more diseases than ever before (GAVI, The Vaccine Alliance). The increased protection comes at a cost that has increased 50–60 times per fully immunized child compared with earlier set of vaccines provided by many countries. Meanwhile, 21.8 million children remain unvaccinated against diphtheria, tetanus or pertussis, as well as other vaccines preventable diseases (WHO 2014). Ensuring national immunization programmes reach underimmunized populations needs to remain a priority for the GAVI, just as it will be addressing difficult issues in the transition from Global Alliance Vaccine Initiative to domestic funding sources for the fully immunized child in HICs. Persistent issues that need to date have largely unaddressed, such as reaching the urban poor and remote, sparsely populated settings will require innovative delivery strategies. The WHO Committee on the Social Determinants of Health report (2008) provides good insights into the scale of challenges that are required to reduce normative barriers and final broad-based constraints on achieving equity in income (SSDIN 2012). Improving health care services requires among other things, expanding the number of health workers and investments in other inputs, increasing capacity of human resources for health and accountability of health providers. The growth of the private sector needs to be specifically looked at.

Human Resources for Health underlie quality and service delivery improvements, yet remains under-addressed in many national strategies to achieve UHC. Without, adequate investments in improving and expanding health professional education, retaining and maintaining gains will be unlikely. Broad options strategies are ultimately challenging, requiring locally adaptive responses to ensure high-quality health providers are available. Financing is needed to scale up and expand health professional education, particularly pre-service educational expansion to ensure access to comprehensive-based and client-centered pedagogies curricula on methods to improve quality in ambulatory and tertiary care settings. Governments need to专栏investments in non-infectious infection-based pedagogies which abound and are often weighted by clinical training (Richter 2015). Updating medical and nursing school curricula and professional recertification processes are important priorities that are overlooked in many countries. However, better training does not address the Know-Do gap. Addressing this gap requires focus on improving health worker effort (e.g. increasing...
time spent with patients and tailoring protocols to make correct diagnoses, improved hand hygiene. Provide perinatal care methods that aim to influence clinical practice are required and feature in the Global Financing Facility development. Cambodia provided incentives to health providers for every birth resulting in a live newborn and a live baby. This approach led to skilled attendance at birth rising from below 20 to nearly 90% in a decade while increasing im-
proving attention to care for patients (National Institute of Statistics, Directorate General for Health, and ICF Macro 2011). Other trends in purchasing mechanisms such as the use of care-based payment systems can also be valuable to improve quality of care. In all cases we hope that further directions of global financing will make invest-
ments in developing national capacities for monitoring performance and quality of care.

The expansion of the private sector during the past two decades has challenged governments to develop effective and appropriate regulatory mechanisms to ensure quality, control costs, and manage the labour-market dynamics of the health professional workforce. In recent countries in the Asia Pacific region, the health sector has become pluralistic, with multiple service delivery systems operating simultaneously. Some studies suggest care provided by the same doc-
tors in the private sector may differ from that of the public sector largely due to different incentives in each setting. In general both sectors provide good and poor quality services. This again points to the need to increase accountability (Tuoitrenews.vn). Furthermore, unregulated practitioners in private clinics, especially by lay health workers, have led to visible increase accountability (Tuoitrenews.vn). Furthermore, unregulated practitioners in private clinics, especially by lay health workers, have led to visible

tors in the private sector provide care for a substantial part of the population and quality of care. The Global Financing Facility and other financing initiatives in the post-MDG era have the potential to enact substantial gains in the quality of services delivered and upgrading human resources through country-level strategies and operational plans. This focus should involve effective methodologies to improve health worker competency and change practices are enforced and ineffective and harmful ones eliminated (including social influence of commercial systems).

Conflict of interest statement: None declared.

References

CABR 2008. Using the gap in a prevention health equity (slightly) acceptable social determinant of health (Rep of the Committee on the Status of Women) 


Jiang N. 2014. Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines? An exploratory survey and focus group analysis. Social Science 


Sobel HL, Iellamo A, Raya R. 2011a. Impacts of breastfeeding interventions for reduction of maternal mortality (the WHO Multicountry Evaluation of Immediate newborn care practices delay thermoregulation and breastfeed-


4.2 Summary of the Main findings and implications of the included studies

Seven original studies are included in this thesis, the major findings of which are summarized below (Table 8). These studies collectively show:

1. Health worker practices contribute to sub-optimal and dangerous interventions and missed opportunities (Studies 1-3 and 5). However they can be overcome by:
   a. Policy translation into local action. Scaling up nationwide facilities implementing a timely birth dose was associated with policy assessments (Studies 4, 5). Strategic collection and timely use of data through Rapid Coverage Assessment (RCA) had influenced health workers to conduct the measles vaccination campaign better resulting in stopping transmission of measles (Study 6).
   b. Management level influences. Improved delivery of timely birth dose of hepatitis B vaccine by health workers was associated with facilities having a HBV policy available, standing orders and trained staff on the policy (Study 4).
   c. Human health resource capacity. Breastfeeding and immunization coverage was associated with health workers training (Studies 1 – 4).
2. External and social influences have a direct effect on breastfeeding and immunization:
   a. Out of pocket expenditures impedes utilization of health facilities (Study 7) thereby reducing access to HBV at birth.
   b. Sub-optimal feeding is specifically associated with recommendations of doctors, mothers and relatives, recall of advertising messages and inappropriate practices at childbirth (Studies 1-3).
3. Community linkages and empowerment can directly improve breastfeeding and immunization, especially utilizing peer-counseling approaches (Studies 3, 4).
### TABLE 9. MAIN FINDINGS OF THE SEVEN ORIGINAL RESEARCH STUDIES USED IN THE THESIS.

<table>
<thead>
<tr>
<th>Study number, title, journal and year.</th>
<th>Outcome of interest</th>
<th>Comparison groups</th>
<th>OR (95% confidence intervals)\textsuperscript{vii}</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Immediate newborn care practices delay thermoregulation and breastfeeding initiation. Social Science and Medicine (2011)</td>
<td>Inappropriate practices (%) Placed in skin-to-skin contact (%) Timing after birth (min) Babies forced onto breast: Separated from mother</td>
<td>Recall advertising message: Doctor recommendation: Mother/relative recommendation:</td>
<td>100% &lt;10% 10 min 12 min</td>
</tr>
<tr>
<td>2. Is unimpeded marketing for breast milk substitutes responsible for the decline in breastfeeding in the Philippines? Acta Paediatrica (2011)</td>
<td>Use vs non-use of infant formula</td>
<td></td>
<td>2.0 (1.2-3.4)\textsuperscript{vii} 3.7 (1.7-8.2)\textsuperscript{vii} 2.7 (1.2-4.8)\textsuperscript{vii}</td>
</tr>
<tr>
<td>3. A people’s initiative to counteract misinformation and marketing practices: The Pembo, Philippines Breastfeeding Experience. J Hum Lact (2009)</td>
<td>Exclusively breastfed vs Mixed or formula fed: Mixed fed:</td>
<td>Working vs non-working mothers: Pre vs Post-intervention:</td>
<td>4.9 (2.4–11.1)\textsuperscript{vii} 2.8 (1.3–5.8)\textsuperscript{vii} 2.4 (1.5–3.9)\textsuperscript{vii}</td>
</tr>
<tr>
<td>4. Implementing a national policy for hepatitis B birth dose vaccination in Philippines: Lessons for improved delivery. Vaccine</td>
<td>Hospital timely HBV birth dose HBV given within 24 hours</td>
<td>Copy of HBV policy: Standing orders including HBV: Training staff on policy: Post vs pre intervention:</td>
<td>4.7 (1.2-18.0)\textsuperscript{viii} 4.8 (1.3-18.1)\textsuperscript{vii} 18.9 (3.1-87.9)\textsuperscript{viii} 12.3 (9.4–</td>
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\textsuperscript{vii} Unless otherwise stated. For comparability, where odds ratios were not presented in the original manuscripts, they have been calculated and included in the table.

\textsuperscript{viii} P<0.0001
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<tr>
<th>(2011)</th>
<th>Timely birth dose</th>
<th>16.3&lt;sup&gt;iii&lt;/sup&gt;</th>
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<tr>
<td>HBV&lt;sub&gt;1&lt;/sub&gt;: HBV&lt;sub&gt;1&lt;/sub&gt;; DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>Timely vs not timely HBV&lt;sub&gt;2&lt;/sub&gt;</td>
<td>71%</td>
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<tr>
<td>HBV&lt;sub&gt;3&lt;/sub&gt;: DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>Simultaneous vs not simultaneous HBV&lt;sub&gt;2&lt;/sub&gt; and DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>1.9 (1.5–2.3)&lt;sup&gt;ii&lt;/sup&gt;</td>
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<tr>
<td>HBV&lt;sub&gt;3&lt;/sub&gt;: DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>0.9 (0.8–1.1)&lt;sup&gt;iii&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>HBV&lt;sub&gt;3&lt;/sub&gt;: DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>3.3 (2.7–4.2)&lt;sup&gt;iv&lt;/sup&gt;</td>
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<tr>
<td>HBV&lt;sub&gt;3&lt;/sub&gt;: DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>1.6 (1.3–1.9)&lt;sup&gt;iv&lt;/sup&gt;</td>
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<tr>
<td>HBV&lt;sub&gt;3&lt;/sub&gt;: DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>4.6 (3.7–5.8)&lt;sup&gt;iv&lt;/sup&gt;</td>
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<tr>
<td>HBV&lt;sub&gt;3&lt;/sub&gt;: DTP&lt;sub&gt;3&lt;/sub&gt;</td>
<td>2.0 (1.7–2.4)&lt;sup&gt;iv&lt;/sup&gt;</td>
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<tr>
<td>Measles Cases</td>
<td>pre vs post campaign</td>
<td>99.2%</td>
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<tr>
<td>Measles Deaths</td>
<td></td>
<td>100%&lt;sup&gt;a&lt;/sup&gt;</td>
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<tr>
<td>IgM positivity of cases</td>
<td></td>
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<th>7. Secondary analysis of a national health survey on factors influencing women in the Philippines to deliver at home and unattended by a healthcare professional. Int J Gynecol and Obstet (2010)</th>
<th>Richest/poorest quintile</th>
<th>75 (56.4–100)&lt;sup&gt;iii&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total living children</td>
<td>1.6 (1.1–2.3)&lt;sup&gt;iii&lt;/sup&gt;</td>
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<tr>
<td>Under 5 mortality</td>
<td>1.8 (1.3–2.5)&lt;sup&gt;iii&lt;/sup&gt;</td>
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<tr>
<td>Neonatal mortality</td>
<td>1.0 (0.6–1.5)&lt;sup&gt;iii&lt;/sup&gt;</td>
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<tr>
<td>Having Barriers:</td>
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<tr>
<td>Getting money</td>
<td>3.7 (3.3–4.2)&lt;sup&gt;iii&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Having to take transport</td>
<td>5.0 (4.4–5.7)&lt;sup&gt;iii&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Knowing where to go</td>
<td>3.0 (2.5–3.5)&lt;sup&gt;iii&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Getting permission</td>
<td>3.6 (3.0–4.4)&lt;sup&gt;iii&lt;/sup&gt;</td>
<td></td>
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<tr>
<td>Distance &lt;15 km to hospital</td>
<td>&gt;90%</td>
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<sup>ii</sup> P<0.01
<sup>a</sup> No positive cases were found after the campaign
Chapter 5: DISCUSSION AND RECOMMENDATIONS

Overview

The following sections are structured so that the studies are put in the larger context of Philippines and neighbouring countries (5.1), analysed in the context of implementation research including management level influence (5.2) and external economic and social issues (5.3). What can be done is then proffered in the recommendations (5.4).

5.1 Implications of the findings

5.1.1. Initiation, exclusivity and continuation of breastfeeding.

As noted above, 14,950 deaths of children before their fifth birthday could be prevented through optimal breastfeeding. Studies 1-3 documented the challenges and potential solutions toward improving breastfeeding in the Philippines.

Initiation of Breastfeeding

Babies were put to the breast at a median 10 minutes, separated after a median of two minutes for routine weighing, bathing, examinations and injections with hepatitis B vaccine and vitamin K and returned to the mother after 2½ hours (Study 1). The mean time for the initiation of breastfeeding is 55 minutes and a baby needs at least 15 minutes to ingest colostrum. Furthermore, within two hours, the average baby will fall into a long sleep. Thus, babies in our sample, having not ingested colostrum and will be asleep when returned from the separation, for all intents and purposes, did not initiate breastfeeding until much later, often the second day of life.
Not only does this contradict global and local policies,\textsuperscript{91,92,93} it doubles the risk of neonatal death and infection. To the author’s knowledge, this was the first study to document and quantify the problems around initiation of breastfeeding. However, the writer has since observed forced breastfeeding before feeding cues arise in Cambodia\textsuperscript{135} and since in many countries.

In the intervening period since the initial study (2008), any skin-to-skin contact had risen from under 10% observed (Study 1) to 64% of national facility births reported by mothers according to the 2013 National Demographic and Health Survey (DHS).\textsuperscript{151} However, breastfeeding initiation rates in the first hour remain at around 50%. In a study consisting of exit interviews of mothers in 17 randomly selected hospitals, 47.0% (85/179) of Philippine mothers reported immediate skin-to-skin contact (<1 minute after birth), 86% (154/179) reported rooming-in over the entire period, and 75/176 (43%) reported early initiation of exclusive breastfeeding (between 15-90 minutes) during the hospital stay.\textsuperscript{136} Because this evaluation has more strict definitions than the DHS, the percentages here appear lower than the 2013 DHS.\textsuperscript{151} In fact, if any skin-to-skin contact was included, the coverage increases to 72% (129/179).

Study 1 led to a cascade of events ultimately spurring Member States to develop the Action Plan for Healthy Newborn Infants in the Western Pacific Region (2014-2020).\textsuperscript{13} For the first biennial review (September 2015) following adaptation of the Plan, observations and interviews with 446 mothers in seven implementing countries were conducted. Prelacteal feeds were not commonly reported by mothers in Solomon Islands, Cambodia and Lao People's Democratic Republic (6%, 19% and 23% respectively) but commonly reported in Viet Nam (62%) and Philippines (36%).\textsuperscript{137} Furthermore, 63% of mothers reported immediate skin-to-skin contact, but only 25% reported completing the first breastfeed before separation. Most (83%) babies were exclusively breastfed in the postnatal period.

In summary, while the findings of Study 1 ultimately influenced the entire region, further progress is needed.
Exclusive and Continued Breastfeeding

Health providers were found to recommend and write prescriptions for infant formula in even relatively poor parts of the Philippines. This was associated with a quadrupling of infants being formula fed. This was compounded with a doubling of risk of using formula if the mother could recall an advertising message (Study 2). In all, between 41% (Study 2) and 51% (Study 3) were found using formula. Once infants were started on formula, they were six times more likely to stop breastfeeding (Study 2). However, community linkages through peer-counselling supervised by health centers was associated with a near 8-fold reduction in infants being exclusively formula fed (Study 3). During and after the period of this pre-post peer-counselling study, metro-Manila and nationally, exclusive breastfeeding rates remained unchanged. Thus, secular trends do not likely account for the vast improvement seen in the community.\textsuperscript{35,89}

Doctor recommendations and marketing was in violation of Articles 6.2, 7.1 and 7.3 of the Philippine Code of Marketing of Breast-milk Substitutes. These health provider actions not only violate global and international policies and Philippine law, they cause harm to infants. Study 2 further revealed working mothers had drastically lower breastfeeding rates yet should have been protected by provisions in the Covenant on Economic, Social and Cultural Rights, a human rights doctrine which the Philippines ratified.

Infants who are formula feeding and not breastfeeding have an associated 14-fold increased risk of mortality and 20-fold increased risk of hospitalization compared to if they optimally (exclusively) breastfed during their first six months of life. Six to 24 month olds who do not breastfeed have an associated four-fold increased risk of death compared to those that continue to breastfeed.

Although studies in many countries\textsuperscript{43,43,45} have characterized various mechanisms of marketing and violations of international policy, to the writer’s knowledge, Study 2 was the first to quantify the association with sub-optimal feeding. Peer-counselling has been associated with improved breastfeeding in many parts of the world.\textsuperscript{138,139,140} However, previous studies used a research approach that was not amenable to wide scale use. The peer counselling approach employed here supported programme managers to simplify the research approach.
Specifically, the tools enabled health providers supervise peer counsellors to identify eligible mothers, conduct a simple survey, analyse data, and counsel mothers. Furthermore, the methodology has expanded to all barangays in Makati City reaching a population of over 500,000.

5.1.2 Immunization coverage

Between 2003 and 2013, improving hepatitis B and measles vaccination coverage alone probably prevented or will prevent more than 18,000 deaths annually of Filipino children and later when they become adults (see below). Studies 4-6 documented some of the successes and challenges faced in raising immunization coverage.

*HBV birth dose*

Only 16% of the selected hospitals had more than half of children born receive a documented birth dose within 24 hours of birth (Study 4). This corresponded to only 22% of total infants with a documented birth dose. Hospitals with a copy of the hepatitis B policy readily available, with the birth dose in standing orders and who trained staff on the policy were many times more likely to have vaccinated infants in the first 24 hours after childbirth. However, hospitals designated as training sites, accepting national health insurance or Philippine Pediatric Society accredited hospitals performed statistically the same as those not. In an unpublished study, the hospitals that had not been previously included in Study 4 had a birth dose coverage of 16% but those that had been included rose (from 22%) to 69%.

Study 5 showed the total birth dose coverage had risen to 71% a year after this with little variation according to level of facility. Albeit Study 5 took place in only three provinces, these performed at or below the average for three doses of HBV compared with the rest of the country.

Finally, Study 4 also showed linking health centers with community resulted in a vast improvement hepatitis B given within 24 hours of birth. The study has the limitation of not being randomized and not having a control group. Recent studies in the Philippines show birth dose coverage continues to rise: however, at the time of the pre-post study, no such secular trends were noted.
Administrative Order 2006-0015, Implementing Guidelines on Hepatitis B Immunization for Infants mandated all clinically stable neonates regardless of gestational age or birthweight to be given hepatitis B within 24 hours of birth. Around one in five hospitals translated this policy into vaccinating infants with hepatitis B at birth. Unfortunately, the problem of low hepatitis B at birth coverage has been reported in other countries. However, success stories are emerging especially in China.

Based on the Studies 4 and 5, and other sources, hepatitis B vaccination coverage at birth increased from 22% (2007) to around 70 (2009) of facility births. Given that the birth dose policy was only issued early in 2007, it probably started from a baseline near zero. Conservatively 5% of pregnant women have chronic infection, 25% of whom with presence of hepatitis B e-antigen indicating a risk of 90% of passing the virus to the infant. Given Philippines has approximately 2.6 million births, an estimated 32,500 cases of mother-to-child transmission occur annually in the absence of vaccine. 29,250 (90%) will develop chronic infection and 7300 (25%) will die from complications of cirrhosis of the liver or liver cancer later in life. Given that 70% of the now 61.1% of infants born in a facility (2013) received a birth dose, and the vaccine has an efficacy of 70-90%, the program may have prevented 2200-2800 deaths of these infants in later years from the birth dose alone.

Conservatively, 10% of the more than 100 million Filipinos are chronically infected with hepatitis B virus, 40% of whom acquired it in the perinatal period and 60% thereafter. As three doses of hepatitis B vaccine rose from 38% (2002) to 77.6% (2013), the vaccine efficacy is 95%, 57,000 cases and 14,250 additional deaths were prevented from horizontal transmission.

Routine coverage of traditional vaccines

Study 5 (further) showed staff did not simultaneously administer all vaccines for which the child was eligible and that seemingly random vaccine schedules were followed. Not giving vaccinations simultaneously and not following the national EPI programme or that of the Philippine Pediatric Society vaccine schedules was associated with lower coverage.
The literature shows health provider practices of not simultaneously administering all vaccines for which the child is due result in parents facing increased transportation costs and lost work time.\textsuperscript{153,154}

In 21 sites in the United States, children were found to have many opportunities for simultaneous administration vaccines. This could have potentially raised coverage levels by 12\% to 22\% (median, 17\%).\textsuperscript{155} Similarly in Italy, the overall coverage for mandatory vaccines (OPV, DT and HBV) exceeded 94\%, but only 79 had been vaccinated according to the recommended schedule (i.e. during the first year of life). Measles coverage (56\%) and HiB (20\%) coverage remained inadequate.\textsuperscript{156}

No studies in LMIC were found aside from Study 5. However, with global vaccination coverage of 86\% for DTP3 and 82\% for HBV3, at least 4\% more children could receive HBV3 if given simultaneously with DTP3.\textsuperscript{49} This global estimate masks national, subnational and local differences. If such were taken into consideration as we had done in Study 5 in the Philippines, simultaneous administration of vaccines would likely account for much larger gains in overall coverage.

\textit{Measles Supplementary Immunization Activity}

Compared with previous campaigns only the 2004 measles vaccination campaign penetrated primarily urban poor populations enabling interruption of measles transmission (Study 6). Stated more specifically, measles vaccination campaigns prior to the 2004 campaign systematically failed to reach urban poor populations. This ran counter to clearly stated policies that every household should be searched for target aged children. Immediate feedback in the form of the Rapid Coverage Assessments (RCA) was the only policy shift from previous campaigns.

Reaching unreached populations, especially urban poor, is a common problem.\textsuperscript{157,158} In the Americas, RCA has proven to be an important adjunct to focusing campaigns on reaching at-risk populations.\textsuperscript{159} Unique to the approach taken in Philippines is the a priori random selection in proportion to population size of barangays, site selection with prioritization of urban poor and household selection with a wide variety of accessibility to the central site selected.
Unpublished special tabulations of RCA data accompanying Study 6 compared health worker beliefs vis-à-vis community member reports on reasons for missed children. Vaccination teams commonly report family transience (i.e., families who live only a short time in a place and move around frequently, often as a result of work availability), parental refusal due to religious beliefs or due to seeking care from private pediatricians as the primary reasons children were not vaccinated. Of 1231 children not vaccinated during the campaign, absence at the time of vaccination (29%), sickness (26%) and failure of the vaccination team to visit the house (15%) were the reasons listed. Transience, maternal refusals, and private pediatricians accounted for 5%, 5%, 2%, respectively. Thus, the RCA helped to counter prevailing health provider misconceptions. Sixty-eight percent of unvaccinated children came from sites not employing the national issued policy specifying the door-to-door strategy to be used in the measles vaccination campaign. Absence and sickness accounted for fewer missed children in sites that used door-to-door. Mothers also reported the health teams did not communicate about the schedules. The RCA, by uncovering these problems helped health providers, management and politicians understand what needed to happen to interrupt measles transmission. The Secretary of Health himself went to the field and issued the RCA policy that the Department of Health would follow the example of WHO. This ultimately led to more health worker vigilance to continue vaccinating until all children were vaccinated.141

Most recently, 78% of children received at least one dose of measles vaccine in the first year of life. This is 8% higher than in 2003.151

From the measles vaccination campaign alone, an estimated 6000 lives were saved annually by interrupting measles transmission between 2004 and 2006. The 8% rise in coverage with measles vaccine corresponds to approximately 2000 lives saved every year.11

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xi The birth cohort is approximately 2.6 million (http://www.indexmundi.com/philippines/demographics_profile.html ) and the case fatality rate is assumed around 1%.
5.1.3 Financial barriers interfering with immunization

It is much easier to administer a timely birth dose of hepatitis B in children born in health facilities than those born elsewhere. Even with laws and policies financially supporting health facility deliveries, the reality did not reach the bottom quintiles where the cost of using facilities was the single most identified barrier among women delivering at home unattended (Study 7). Nationwide, despite the policy, only 3.2% of mothers delivered in a facility free of cost. This problem was not limited to accessing a health facility during delivery. For example, rapid coverage assessments done to assess reasons children were not routinely immunized among poor communities revealed that cost in the form of a donation (in some cases “mandatory donation”) was the most commonly cited reason for not accessing immunization services. This contradicted Executive Order 663 mandating elimination of charges for vaccinations, syringes and needles and extensive national monitoring of the EPI programme.

Many countries have taken actions that addressed the financial barriers found in Study 7. Removal of user fees was associated with increased maternal and newborn health service utilisation in South Africa, Uganda and Ghana. In South Africa and Uganda, removal of user fees increased total number of ANC visits by 37% and 45% respectively 12 months after intervention. One review found an increase of 14-17% in skilled birth attendance in Ghana with removal of user fees. A voucher scheme that waived user costs in Bangladesh increased ANC between 30-60% and skilled birth attendance by 10-40%, while a scheme in India increased facility-based childbirth for the poor from 27% to 48%. Vouchers for free childbirth care, coupled with financial incentives for TBAs to refer women and role definition led to a 29% increase in skilled care at birth in Cambodia.

Decreasing user fees by 25%, 50% and 75% in Sudan increased utilisation by pregnant women treated for malaria by 52%, 28% and 131%, respectively (P<0.001). Introducing user fees appears to decrease utilisation of preventative maternal health care. In Papua New Guinea, introducing a user fee of K 1.00 (US$ 0.35) reduced ANC visits by 18% while ANC visits increased in control areas by 20.7% over an 18-month period.
5.1.4 Limitations

Each study has limitations noted in the discussion section. This serves to highlight the most important limitations.

Study 1: Extraction of data from hospital records was limited by problems inherent in hospital recording including missing and inaccurate data. It is unlikely for a hospitals to have no deaths or sepsis cases and probably represents underreporting. Accuracy of reported sepsis cases was limited by variation in interpretation of clinical presentations and laboratory results. Results based on observation are subject to the Hawthorne effect. However, serious hospital practice issues were evident. The problems are likely to be more severe than our evaluation uncovered.

Study 2: Recall bias is a potential concern. Participants were asked to recall messages up to 6 months before. Even so, 59.1% could state advertising message content without prompting.

Study 3: The definition of exclusive breastfeeding follows the questions used in the DHS which focuses on the 24 hours before the interview. It is augmented with specific questions to probe if bottle or formula was given. Framing the question over the last 24 hours could miss adding of other foods or infant formula in the days or weeks before the interview.

Study 4: The data presented in Table 2 in the study is presented based on hospitals having coverage birth dose within 24 hours being > or ≤ 50% using logistic regression. Linear regression might have been a more appropriate test; however, given that hospitals performed in the extremes (<7% or >88%), the choice of statistical test probably would not have changed the outcomes.

Study 5: Albeit by random sampling, one of the four groups into which the regions were stratified was excluded. This was done for feasibility reasons but might have affected the results. Given that two of the regions selected perform well-below average for immunization coverage, the results in other regions may be better.

Study 6: Only hospitalized cases located at 228 of the 954 total hospitals (23.9%) were included. However, given all indicators
dramatically improved, and every region was included, the impact of the campaign was probably strong.

Study 7: For ethical reasons, the GPS coordinates of respondents were randomly offset. This may limit the accuracy of the results by spreading out clusters of cases. However, most home deliveries that were not attended by healthcare professionals occurred within 15 km of a large hospital. The NDHS questions covered the barriers in accessing general health care and were not specific to delivery in a hospital. Barriers to accessing relatively distant and expensive hospital care may be greater than those for routine services in health clinics. Thus, the present study probably underestimates the barriers to poor women delivering in a hospital.

5.2 Analysis within the context of implementation research

This section looks at the seven studies in the context of Philippine policies according to the framework for policy translation by Pulzi and Treib.104

1. Clarity, complexity and dissemination of guidelines, and procurement of supplies104

Breastfeeding initiation and exclusivity remain chronically suboptimal despite laws and policies giving health workers a clear mandate. While breastfeeding initiation written in the policy is simple, the act is a complex learned behaviour for mothers and newborns. Study 1 shows breastfeeding initiation is easily disrupted. Health workers nominally carried out breastfeeding support, but in reality, inhibited it. Policies also mandated all newborn infants regardless of gestational age or birthweight except those deemed clinically unstable to be given hepatitis B within 24 hours of birth.98 The policy was disseminated via the usual route through Regional Directors to local governments to health workers. Study 4 revealed despite the simplicity of the order and presence of vaccines, only 16% of 85 facilities actually carried out steps toward policy translation. Clarity of the guidelines is a
starting point, but other factors are critical to see a guideline implemented beyond a minority. Study 6 similarly showed that clarity of the guidelines and provision of supplies do not result in high uptake without other factors present.

2. Policy monitoring

*Breastfeeding and immediate newborn care practices:* As noted above while no nationwide follow up assessments of immediate newborn care practices (Study 1) were done, skin-to-skin contact had risen from under 10% observed (Study 1) to 64% of national facility births reported by mothers according to the 2013 National Demographic and Health Survey (DHS). Perhaps related, of all deaths of various age groups under five years of age, only the newborn mortality rate decreased (from 17/1000 in 2008 to 14/1000 in 2013). The only other known change during the period was a 9% rise in skilled birth attended deliveries. Further analysis is needed to understand the accuracy of maternal recall of skin-to-skin contact, the timing and duration of skin-to-skin contact, hospital sites with high and low coverage, and the relation between various causes of newborn death.

As noted in section 5.1.1, breastfeeding initiation and exclusivity remain chronically suboptimal. A comparison between Study 1 (2008) and Philippine Demographic and Health Survey (DHS) 2008 revealed similarity of rates of nominal initiation. However, Study 1 calls into question the reported DHS breastfeeding rates. If mothers report putting baby to breast for two minutes as initiation of breastfeeding, then DHS responses may not be valid or useful for monitoring. Recently, WHO-WPRO developed tools to support improved childbirth and early essential newborn care practice in facilities and national monitoring and planning. These have been applied in Cambodia, Mongolia, Philippines, Solomon Islands and Viet Nam. They rely on interviewing mothers within 24 hours of birth to assess timing and duration of skin-to-skin contact and breastfeeding including separations and introduction of infant formula and other feeds. Selected results are presented in section 5.1.1.

*Immunizations:* Follow up assessments revealed a vast rise in hepatitis B at birth coverage and elimination of measles, respectively (Studies 5 6). Though impossible to prove causality with scientific rigor,
circumstantial evidence suggests it is related to the assessments themselves.

In 2008, the year following the initial HBV assessment (Study 4), birth dose coverage in the same hospitals had risen from 22% to 69%. However, hospitals that had not been previously studied had birth dose coverage of 16%.165 In 2009, Study 5 revealed the total hepatitis B at birth dose coverage was 71% (Study 5). Consistent with the findings of Rowe et al,105 assessments with immediate feedback were associated with the improvement from 22% to 71% in three poor to average performing regions.

The impact of Study 5 which assessed timing of DPT and HBV on health workers following the national schedule and administering doses simultaneously was not evaluated. However, DHS showed fully immunized child status rose nationally by 10% from 2003 to 2008.35,89 Further analysis is in section 5.1.2.

In line with the findings of Rowe et al105, health professionals conducting the RCA (Study 6) and the HBV birth assessment (Study 4) were trained to use an assessment tool and were fully budgeted to carry out the monitoring including transportation.

3. Re-shaping, re-defining or overturning policies104

Study 5 revealed local translation of policies sometimes ran counter to the original intent. For example, local reshaping of policies was exemplified where health workers did not give hepatitis B vaccine and DPT simultaneously at 6, 10 and 14 weeks of age which resulted in lower coverage.111 Study 6 found similar reshaping of policies occurred in the 2004 measles vaccination campaign where health care workers did not follow the door-to-door strategy; however, the RCA uncovered the connection between health workers not following the policy and missed children. Overturning of policies 104 is evident in Studies 1-3 where health workers are promoting breast-milk substitutes and where health worker hospital practices resulted in none of 481 babies to receive completely correct newborn care.

111 At the time of the study, hepatitis B vaccine and DPT were separate injections.
5.2.1 Management level influences

Study 4 showed that having a copy of the hepatitis B at birth policy, incorporating administration of HBV birth dose into standing orders and training staff on the policy were predictive of hospitals to reach most babies with a documented birth dose of HBV within 24 hours. Stockouts, highlighted by Knight et al (2013)\textsuperscript{106}, and false contraindications which the policy provided advice to avoid were associated with lower HBV coverage.

Studies 4, 5 and 7 were part of a larger effort to improve external monitoring with immediate feedback. The DHS revealed routine vaccination coverage had remained unchanged from 1987-2003. As noted in section 1.5.2, multiple policies were issued during and after that period. Systematic monitoring and supervisory mechanisms were instituted beginning the second half of 2004. These included Reaching Every Barangay workshops, routine review and feedback to regions of sub-national inconsistencies of data, and systematic supervisory visits using the Child Survival Monitoring Checklist to the local governments accounting for half the unimmunized nationwide.\textsuperscript{166,167} Only after 2003 had fully immunized child risen from 69% to 79% in 2008.\textsuperscript{35,89}

However, immunization coverage improved unequally during this period in the Philippines. WHO and national counterparts conducted extensive monitoring in all the Philippine regions. They found evidence in the form of documented health facility assessments in Regions IV-A, VI, VII, IX, X, CAR and Caraga. These same regions had 10 – 20% rise in fully immunized child coverage between 2003 and 2008 while the remaining regions that did not conduct monitoring had marginal increases or even decreases in coverage.\textsuperscript{168}

In these three cases, monitoring and supervision was done locally but reaching national scale is critical again confirming the findings of Rowe et al.\textsuperscript{105}

*Optimal feeding and care of neonates*: Studies 1 – 3 showed despite international treaties, national laws and protocols, health providers did not adhere to optimal feeding and care of neonates guidelines. As
noted above (section 1.6.3) and consistent with the findings Rowe et al., though clearly stated in the various policies, monitoring and enforcement was neither budgeted nor enforced. No supervisory mechanisms were found for the breastfeeding or safe motherhood programs. None of the programs had a formal monitoring mechanism of supervisors.

**Deterrents to delivering in a health facility**: Unpublished data accompanying Study 1 found 0.8% of women had a birth companion. The author has commonly observed low rates of companion of choice in LMICs. Reasons health providers proffered for not allowing companion of choice in the delivery room included lack of space, maintaining privacy in rooms with more than one women delivering at a time and fear of contamination or theft by allowing too many people in the delivery room. Another common practice which are known deterrents to delivering in a facilities is that half of woman in unpublished data from Study 1 had an episiotomy. These deterrents to delivery are mentioned by Bohren et al.

**A regionwide perspective on improving health care practices for neonates**: As noted above, Study 1 and the consequent work in Philippines spurred Member States to develop the *Action Plan for Healthy Newborn Infants in the Western Pacific Region (2014-2020)*. The Plan focuses on changing health worker practices with a large focus on management. The Action Plan has agreed steps for countries with the aim to achieve improved facility management nationwide. These include national action and implementation plans, updating clinical protocols, engagement with professional societies and updated pre-service education to meet practice standards. Health facility strengthening is the penultimate intervention taken for improving health worker practices. Specifically, health facilities need to systematically monitor practices, and establish policies and physical environments to ensure core practices are institutionalized and harmful ones eliminated as revealed in Study 1. The region has made great progress, but health facility strengthening outside the Philippines has only begun in 2013 (Figure 7).

<table>
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<tr>
<th>Benchmark</th>
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<th>Laos</th>
<th>Mongolia</th>
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<tr>
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<td>Mechanisms established to ensure professional association membership implement EENC</td>
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* Planned, ++ ongoing, +++ completed; EENC-Early Essential Newborn Care; MOH-Ministry of Health;
As noted above, for the first biennial review (September 2015) following adaptation of the Plan, observations and interviews with mothers in seven implementing countries were conducted. Prelacteal feeds were commonly reported in Viet Nam and Philippines, and while two-thirds reported immediate skin-to-skin, only one in four reported completing the first breastfeed before separation. Thus, while the findings of Study 1 influenced the entire region, further progress is needed.

5.2.2 Human health resource capacity building

Study 1 showed health care worker practices have a huge effect on the rates of breast feeding starting in the delivery room. None of 481 neonates were observed to receive completely appropriate newborn care. Aside from establishing prolonged mother-newborn skin-to-skin contact, eliminating separation in the immediate postpartum period will greatly improve initiation of sustained exclusive breastfeeding. This poor situation is despite all doctors, nurses and midwives in Philippines receive basic training in newborn care. Even worse, staff who have been trained in newborn resuscitation were twice as likely to perform harmful routine suctioning as those not trained.

Trying to further understand how in-service training has affected overall newborn care practices is difficult. Early newborn care is historically part of Basic Emergency Obstetric Care (BEmOC). BEmOC training is 5 days long and largely didactic. One Philippine region (V) had a high coverage of staff having taken the BEmOC training. Of the facilities in this region assessed, 52% were BEmOC facilities accredited; of those accredited, it was not clear how well the standard functions were practiced. A USAID review of numerous trainings for maternal care found: 1) Only about half of the rural health units were accredited by MCH; this resulted in large hospitals to often be the only option for delivering, leading to overcrowding and reduced quality of care; 2) although the training modules for BEmOC are standard, the quality and consistency of actual training may not be monitored; 3) large numbers of health care providers were not yet trained; 4) active management of third stage of labor was not available; 5) even if midwives were trained on active management, they were prohibited by law to administer it.
Newborn care was not mentioned. Thus, the findings in Study 1 are not surprising.

Despite inclusion of breastfeeding in pre-service and in-service education, Study 2 revealed health workers promote infant formula. The resulting misinformation and misconceptions influenced mothers to use unsafe feeding practices even among the poor. Once mothers start using infant formula, their babies have a 6-fold likelihood of stopping breastfeeding. 26

Staff in Study 3 were trained in the WHO Breastfeeding Counseling. 113 However, when confronted to address community concerns (e.g. relactation, inverted nipples), the staff were unable to perform the practical counselling. Once the 7-pages of relevant sections were taught as a refresher at the client’s side, staff were able to perform counselling thereafter.

Studies 3 and 4 revealed that health center-led capacity building and community peer support led to improved breastfeeding (counteracting misleading information) and immunization status. The process was frequent short visits discussing findings from client interviews and agreeing on next steps.

Study 4 revealed if hospitals trained staff on the HBV policy, the hospital was nearly 19 times more likely to administer to most babies a timely birth dose. However, in contrast to findings of Rowe et al105, neither being pediatric society or national health insurance accredited was associated with hospitals performing well in terms of providing hepatitis B at birth.

Studies 1 – 4 have consistent findings with those of Rowe et al105: large multi-topic trainings were ineffective, but small focused ones were effective. In addition, our studies found the staff needed to perceive they needed the training and that the training was relevant and practical to their current needs. Large trainings may not answer burning questions of staff, but trainings focused around problems staff already identified will probably be received with close attention. Studies 1 and 4 also show a disconnection between training, hospital and professional society accreditation and performance and call into question the quality of the accreditation process.
5.3 External economic and social issues

5.3.1 Out-of-pocket costs for facility-based childbirth and immunizations

Whatever the mechanism Philippines pursues, those living below the poverty line need to be given access to low or no cost basic health services in ways beyond the current status which fully reaches only 3.2%.\textsuperscript{161}

5.3.2 Marketing of breast-milk substitutes including through the health system

This section explores various ways in which breast-milk substitutes are marketed both in Philippines and globally. It looks for factors associated with restrictions of marketing. Finally, it draws from other areas such as marketing of tobacco for further international evidence.

Study 2 revealed recall of television advertisements were associated with a doubling of risk of use of infant formula and recommendations by doctors nearly a quadrupling of risk. Study 3 also revealed infant formula promotion including from the neighbouring hospital. Though observer bias may have caused an underestimate of the pre-lacteal infant formula given while in Study 1, according to the Philippine Demographic and Health Survey, 2013, four out of 10 mothers reported their children received pre-lacteal feeds.\textsuperscript{151}

Study 2 did not find marketing displays to be effective; however, they are common and industry would presumably not invest if they thought it did not increase profit. Furthermore, the applicability of results of tobacco point of sale advertisement should be of concern. Studies our group have done since Study 2 have reaffirmed that paediatricians and other health workers commonly advise mothers to use infant formula and that they are the most influential source in the decision mothers make for choice of feeding. Sponsorship of health professionals is common-place.\textsuperscript{171}
In summary, marketing of breast-milk substitutes through advertisements and health workers remains a problem. The legal and policy framework for stopping marketing of breast-milk substitutes is strong, but the enforcement is virtually nil (section 5.2.1).

5.3.3 Community linkages and empowerment

At the root of the problems that arose during the measles vaccination campaign (Study 6) was poor linkages between the health system and communities. This was exemplified in the post-campaign survey where families on organized streets were randomly selected, but the more than 80% of the population who lived in disorganized depressed areas were excluded.

Study 3 revealed community engagement can result in reduced breast-milk substitute use, through dispelling incorrect and providing correct information. Study 4 showed it can result in improved hepatitis B administered at birth. Two facilitating factors for both studies included working through community officials, but ensuring representation came from the poorer populations. Many challenges identified in Study 7 such as poor transportation, insurance and empowerment could be ameliorated through better linkage with communities.

Home births present a particular challenge for timely birth doses of HBV. HBV can be used out of cold chain for up to 28 days provided the Vaccine Vial Monitor does not reach the discard point, and proper storage and safe use has been maintained. However, without a strong system of tracking pregnancies until childbirth, timely administration of HBV cannot happen. Study 4 showed linking with communities made this possible. Similarly, linkage between health facilities and community in Study 3 showed all mothers in a large barangay could be effectively counselled on breastfeeding. Eventually, this covered the whole city of Makati.

The methods to link health workers with communities published in Studies 3 and 4 led to improvements in:

1. *Reaching the Urban Poor* facilitated by WHO where family planning and skilled birth attendance improved in several urban slums in the Philippines.
2. Poorly performing city (Cabanatuan) and Municipality (Posorubio) where the City and Municipal Health Officers, respectively, held Barangay Captains responsible for unvaccinated children. Barangay Captains took seriously mobilizing community members to ensure every child was fully vaccinated (2009-2010). During the measles outbreaks in the Philippines in 2011, these localities were spared.

*Applicability of Studies 3 and 4 for scale up in the Philippine context:* The Philippines has several cadres of LHW, including Barangay Health Workers (BHW) and Barangay Nutrition Scholars. In 1995, the BHW became a legal entity with benefits and accreditation requirements. They are supposed to be involved in first aid and equipment sterilization; assisting in health center activities' collecting vital statistics and maintaining records and making reports; participating in community meetings; assisting in nutrition education, monitoring and feeding; assisting in immunization education, monitoring, and dispensing; assisting in family planning services and assisting in sanitation and hygiene promotion and education.

Reviews completed by Department of Health (funded by WHO) revealed that BHW most often stated they swept floors, fetched food for health workers and campaigned for barangay officials. Many depressed urban areas had no representation of BHWs and some municipalities have 1 BHW covering poor populations exceeding 100,000. As the average poor family in Philippines has 6 children, this BHW would need to cover a birth cohort exceeding 6000. As the average DPT3 coverage is 64% in poor communities, 36% (2160) annually will need defaulter tracing for DPT3 alone. Measles coverage is similar and DPT 2 is about half. At a minimum, 6000 cases of defaulter tracing needed a year. This amounts to 512 per week, excluding campaigns where at least 30,000 will need to be gathered. Follow-up means time spent finding the infants and escorting them to be immunized at the health center or satellite outreach site. This is only one of many health-related tasks for a person receiving an “honorarium” of under $100 per month.

Aside from not having representation from poor communities, these community-based interventions need to be designed with sustainability in mind. At least one champion has to have time, interest and persuasiveness to keep momentum on linking community
and health facilities. This is an enormous burden if it is to be scaled up nationwide considering 200,000 BHWs are distributed among more than 40,000 barangays in 1500 local governments, each with several local health facilities. Finally, BHWs often get approached to promote breast-milk substitutes. Therefore, close monitoring with strict enforcement of the code would be needed which is not happening. Studies 3 and 4 provide an ideal, but for this to happen at national scale will require a change in the approach given to BHWs.

5.4 Recommendations

5.4.1 Recommendations for policies

The results show that the interplay of policies, health care workers, and communities have large influences on immunization coverage and breast feeding practices in the Philippines.

**Rapid information feedback**: The RCA experience shows that timely feedback on implementation at multiple levels of the health system is critical for successful implementation. Based on this study, the recommendation is that future activities, like the 2004 measles vaccination campaign, should have an inbuilt real-time monitoring and feedback mechanisms. It is also important to ensure that health workers and senior policymakers alike receive the feedback.

**Policies**: the legal and policy frameworks are strong for all three issues but need to be implemented. The cross-cutting problem with all the laws, regulations and policies was national and local administration and monitoring did not have specified budgets. This directly impedes monitoring and enforcement of the National Code on Marketing of Breast-milk Substitutes and wide dissemination of infractions of the code. It also impedes ensuring managers and staff to follow the national immunization schedule. The government needs to reassess how to institutionalize budget lines attached for administration and monitoring of the laws, regulations and policies.

**Managers**: Managers should take the lessons learned from the HBV at birth study (Study 4) to post relevant policies for general viewing and orient staff on them and inclusion of actions needed in the standing
orders. As noted in the literature review, supervision needs to be
protected in terms of timing, logistics and funding.

*Health worker capacity:* Training of health care workers needs to
focus on skills building toward competency and concrete actions that
they actually need to take back to their facilities. Supervisors through
periodic onsite visits need to assess staff skill retention, observe
practices directly and through exit interviews, provide feedback and
engage with staff to find a few key actions around high priority needs.
Additional monitoring can take place remotely (e.g., by cell phone,
but needs budget lines).

*Financial barriers to access to facilities for childbirth:* the Philippines
needs to ensure that whichever mechanism they choose, all persons in
the bottom two quintiles have no financial barriers including
transportation to accessing health facilities for childbirth and basic
services for women and children.

*Community linkages:* Our studies show community engagement can
be effective. However, it is not sustainable unless mechanisms are in
place to ensure adequate funding for activities, supervision,
monitoring and procurement. Taking such mechanisms to national
scale is very expensive, difficult to monitor and will rarely reach the
people in most need of them. Thus, unless this is planned and
budgeted, it may not be worthwhile to invest in formal community
linkage mechanisms.

*Generalizability:* As many of the issues highlighted above have been
observed in Cambodia, China, Laos PDR, Mongolia, Papua New
Guinea, Philippines, Solomon Islands and Viet Nam, the
recommendations may be pertinent to these countries also. The
results may not apply to LMICs outside the region or high income
countries in general. Countries should conduct similar analyses to
identify steps for country specific improvements around the above
areas.

5.4.2 Recommendations for research

The studies and follow-up review suggest that it would be helpful to
develop a framework for a desk review and primary data collection
survey based on the studies of Pulzi and Treib, Rowe et al and Knight
et al. to delineate the major bottlenecks for policy implementation, management and human health resource capacity. Additionally, it would be helpful to carry out studies with health workers to better understand how marketing of breast-milk substitutes through the health system can be curtailed. Also, repeat studies of hospital practices will be beneficial to understand nationwide changes that accompanied the increase of skin-to-skin contact to 60%. Secondary analysis of the 2013 Demographic and Health Survey could add information to the impact of this change to neonatal mortality and breastfeeding. Research can be considered on a minimal set of health activities for barangay health workers that could be done at national scale.

Ongoing studies need to be completed on validating the effectiveness of exit interview of mothers on the accuracy of timing and duration of skin-to-skin and breastfeeding initiation.
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