The timeline: Civil society participation and the bureaucracy

ABI Health Cluster-Social Watch Philippines
9 March 2018
1-5PM
UP CIDS
- Social Watch embarked on a mission to push for increased social spending in the national budget; a mission that continues to this day.

- The work of ABI-Social Watch and WomanHealth is to push for healthcare based on equity and social justice.

- People’s real priorities, needs, and demands should meaningfully inform policy, plans, and budget. This is done through people’s alternative budget proposals.

- Proposals are outcomes and outputs of collective work of the 9 ABI Health Subclusters:

  Health promotion and integrative health; Health human resource; Reproductive health; Indigenous peoples; Access to medicines; Children and youth; Persons with disability; Older person; HIV and AIDS
Why is this about people’s right to health?

- Participatory governance plays a major role in achieving Universal Health Care
- There is a need to put public back into governance
Declaration of Alma-Ata

International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978

The International Conference on Primary Health Care, meeting in Alma-Ata this twelfth day of September in the year Nineteen hundred and seventy-eight, expressing the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world, hereby makes the following

Declaration:

I
The Conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.
Public health services also enforce the dynamic forms of public participation and accountability.

People’s right to participation is considered as the “the right of rights,” the basic right of people to have a say in how decisions that affect their lives are made.

The United Nations Committee on Economic, Social and Cultural Rights (UNCESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12) adopted in 2000: participation in all health-related decision-making at the community, national, and international levels is an important aspect of the right to health. It particularly directs states to use participatory methods to adopt and implement a national public health strategy and implement a plan of action to achieve it.
On cutting corners: Ethical short cuts and health risks should not be made in the name of “public health.”

Participation in policy, planning, and budgeting has been technicalized.

The public finance process is, despite efforts, still an “open yet closed” space for people’s participation.
Basic social services, equity, and the market

• It is our priority that social services have substantive investment – not leaving them to the private sector and the market.

• Support for basic social services, such as education and health, has very powerful redistributive impact

• There is a dominant market forces in the health sector, hence the dire need to scrutinize and engage public investments in social services, including health care.

• Health policies should be oriented towards the people and not the market. This means rethinking the development and regulation of vaccines and drugs, to ensure not just accessibility and affordability but safety and security. For the longest time, our push has been, for regulatory bodies such as the Food and Drug Administration (FDA) and the National Center for Pharmaceutical Access and Management (NCPAM) to be independent from drug-procuring agencies to ensure check and balance.
The timeline: Civil society participation and the bureaucracy
Public Health Finance and People’s Right to Health and Participation

• The Dengvaxia issue shows us how the health sector policy, planning, budgeting, and monitoring principles and processes are closely interlinked.

• Government-civil society advocacy on generating funds for health, of which is the Sin Tax revenues, has helped increase the DOH budget to up to three fold from 2013–2018.

• Apart from pushing for and our advocacy on generating resources, our main responsibility is the tracking and efficient monitoring of the funds. We push for substantive investment in health and remain questioning, are we spending on the right things?
The timeline:

- May 2015: Civil Society consultation on the FY 2016 DOH budget
- Sept to Dec 2015: CSOs attended House of Representatives and Senate Budget briefings, hearings, and plenary discussions on the FY 2016 DOH budget

The PhP 3.5 Billion-worth Dengvaxia program was never discussed in any of these discussions in 2015, during budget preparation and legislation phases for FY 2016 budget.

Nor in these documents that CSOs use: budget briefer, technical budget notes, people’s proposed budget, National Expenditures Program.

### Table 8: Major Programs and Activities for FY 2016

<table>
<thead>
<tr>
<th>Program</th>
<th>Major Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Health Insurance Program</td>
<td>- Subsidize enrolment of 15.44 million DSWD identified NHTS-PR families</td>
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<tr>
<td></td>
<td>- Subsidize enrolment of 2.8 million Senior Citizens</td>
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<tr>
<td>National Immunization Program</td>
<td>- Infants:</td>
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<tr>
<td></td>
<td>- Fully immunize 2.2 out of 2.3 million infants (95%)</td>
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<td>- Provide 400,000 infants with Pneumococcal vaccine</td>
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<td>- Adolescents:</td>
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<td></td>
<td>- Provide 4.7 million Grade 1 and Grade 7 students with Tetanus-Diphtheria and Measles-Rubella vaccine</td>
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<tr>
<td></td>
<td>- Senior Citizens:</td>
</tr>
<tr>
<td></td>
<td>- Provide 1.2 million senior citizens with influenza vaccine</td>
</tr>
<tr>
<td></td>
<td>- Provide 500,000 senior citizens with Pneumococcal vaccine</td>
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### Department of Health

**DOH Budget briefer for the FY 2016 budget**

<table>
<thead>
<tr>
<th>Program</th>
<th>Major Activities</th>
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<tbody>
<tr>
<td>Family Health</td>
<td>- Provide 4.4 million children &lt; 5 years old with vitamin A supplementation</td>
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<td>- Provide 2.7 million poor women with FP commodities and services</td>
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<td>- Routine and School-based immunization</td>
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<td></td>
<td>- High Impact Strategies for 5 Critical Health Programs (Hi5) for Regions and Hospitals (Infant, Under-5 and Maternal Health, HIV/AIDS, and Service Delivery Network)</td>
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<tr>
<td>Control and Elimination of Infectious Diseases (TB, HIV/AIDS, Rabies, etc.)</td>
<td>- Diagnosis and treatment of:</td>
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<td></td>
<td>- 280,607 TB cases;</td>
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<tr>
<td></td>
<td>- 3,885 Malaria cases;</td>
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<tr>
<td></td>
<td>- 35,000 HIV/AIDS cases</td>
</tr>
<tr>
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<td>- Increase from:</td>
</tr>
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<td></td>
<td>- 29 to 36 Malaria-free provinces</td>
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The timeline

Nov-Dec 2015
Negotiation of price of Dengvaxia with Sanofi (Pres. Aquino and Sec Garin)

Dec 10, 2015
Sec Garin submits proposal to DBM

Dec 29, 2015
DBM issues P3.5B SARO to Sec Garin’s office to purchase Dengvaxia

Jan 2016
PCMC makes a purchase request in the absence of FEC approval

Jan-Feb 2016
FEC meetings and debates on safety and efficacy of dengue vaccine

Feb 2016
FEC certified provisional exemption of dengue vaccine from EO No. 49 (directing the mandatory use of Philippine National Drug Formulary as the basis of procurement of drugs by government)

Feb 2016
Sec Garin launched the national program

Mar 8-9
Sec Garin issued disbursement voucher to PCMC. PCMC issued purchase order to Zuellig Pharma (distributor)

The timeline does not cite other major events. Source: CNN, presentor’s own notes, HOR DOH budget hearing minutes
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Sept 27, 2016
DOH Budget Hearing, a legislator threatened to defer the passage of the DOH budget in plenary
“if I cannot get a clear answer from you that you will include Region VII and continue with the program that is properly budgeted for...I am sorry I will have to move for the deferment of your budget.”

Oct 3, 2016
Sec. Ubial convened Dengue Vaccine Advisory Group to consult on the expansion of the dengue vaccination program. Advisory Group recommended expansion of the immunization program to Region 7 and other areas based on epidemiologic data (signed by 7 specialists)

Oct 3, 2016
CSOs held press conference in response to legislators holding the DOH budget hostage:
“Health advocates raised alarm on House members’ attempt to hold 2017 DOH budget due to dengue vaccine with unproven safety”

Oct 4, 2016
DOH Budget Plenary - As per new expert panel recommendation,

Oct 2016
Dengue vaccination program continues

Oct 27, 2016
DOH “Dengue Meeting” with FEC, Dengue Vaccine Advisory Group, NITAG, Dengue Expert Panel, FDA

Oct 2016
CSOs sent letter to Philippine Health Research Ethics Committee to look into the trial

The timeline does not cite other major events. Source: CNN, presenter’s own notes, HOR DOH budget hearing minutes
The timeline:

- **Nov 2016**: CSOs had dialogues with a few legislators from HoR and Senate re Dengvaxia.
- **Dec 2016**: Senate Blue Ribbon hearings on Dengvaxia was held, main point: P3.5 billion program with no congressional approval, cost effectiveness, ADE, safety and efficacy, testimonies of parents, among others.
- **Nov 29, 2017**: Sanofi announced that Dengvaxia is more risky for people not previously infected by the dengue virus.
- **Dec 1, 2017**: Sec Duque ordered Temporary Restraining Order of the dengue vaccination program.
- **Dec 4, 2017**: The Justice Department orders the National Bureau of Investigation to look into the dengue vaccination program.
- **Dec 5, 2017**: The FDA suspends the sale and distribution of Dengvaxia.

*The timeline does not cite other major events. Source: CNN, presenter's own notes, HOR DOH budget hearing minutes*
The timeline does not cite other major events. Source: CNN, presenter's own notes, HOR DOH budget hearing minutes.
"Why the rush to roll out the dengue vaccine?"

Health advocates urged DOH to delay vaccination until it is proven safe for children.

Public health advocates, healthcare workers, academics and civic organizations decried the Department of Health’s haste in the roll out of the vaccine to fight dengue infection among children aged nine to ten years of age.

Dr. Antonio Dans, Professor of the University of the Philippines College of Medicine, pointed out that from the start, Sanofi Pasteur was concerned about a potential problem with dengue vaccines – while the vaccine could lower the number of cases of dengue initially, it could later increase the severity of disease for those who get it. Dans said this phenomenon, called “antibody dependent enhancement (ADE)” is being monitored closely by the pharmaceutical company.

Dans explained that it takes time to study ADE. Citing the company’s own studies, Dans explained that this may be happening by the 3rd year after vaccination. While the Sanofi and the DOH claimed ADE was only seen in children younger than 9 years old, the data showed that it could be happening in both younger and older children, and in adults as well.

"The real dengue we are afraid of is severe dengue, not the mild ones", said Dans. "If a vaccine prevents mild disease but causes severe dengue, we shouldn't be using it at all." Dans pointed out that Sanofi and DOH are aware of the possibility they there may be a rise in cases of severe dengue two years after this program is implemented.

The DOH is planning intensified surveillance, and is securing parental consent for vaccination. Dans said these procedures are not usually done for vaccines proven safe. He claimed the greatest proof that DOH and Sanofi are aware of the possibility of ADE is the fact that their clinical trial is going on. "If they are sure that ADE is no longer possible, they should stop the trial," Dans added.

Dr. Anthony Leachon, President of the Philippine College of Physicians Foundation, raised the apparent haste in the vaccination.
Health advocates raised alarm on House members’ attempt to hold 2017 DOH budget due to dengue vaccine with unproven safety

By Press Release
Published: October 3, 2016 | No Comments

Doctors and other public health advocates urged the House of Representatives members to stop the threat of some legislators to defer the passage of the 2017 budget of the Department of Health because of exclusion of vaccine with unproven safety.

The groups also appealed to the legislators to continue investigating the safety and efficacy of the dengue vaccine that is being administered to children starting this year.

“There is significant doubt in the scientific community about the safety of the dengue vaccine in question,” said Dr. Antonio Dans, an epidemiologist from the UP College of Medicine who has been analyzing the studies on the dengue vaccine. “A trial that included Filipinos showed that the incidence of severe dengue increased up to five times more, three years after children were vaccinated.”

Mercy Fabros, Coordinator of Alternative Budget Initiative (ABI) Health Cluster, a consortium of civil society organizations engaging the annual health budget, feared that the legislators’ insistence to continue the dengue vaccination program was grounded on incomplete information.
WE APPEAL TO THE LEGISLATORS
NOT TO DEFER
THE 2017 BUDGET OF THE DOH
BECAUSE OF [THE CANCELLATION
OF THE DENGUE VACCINE
PROGRAM].

THEY SHOULD ALSO
INVESTIGATE FURTHER
HOW THE PROGRAM WAS
APPROVED IN HASTE.
CSO letter to the Philippine Health Research Ethics Board, request for a review of the Dengvaxia trial

October 2016

Dr. Leonardo D. de Castro
Chairman
Philippine Health Research Ethics Board (PHREB)

Dear Dr. de Castro,

It has come to our attention that a placebo-controlled trial on the vaccine Dengvaxia, developed by Sanofi-Pasteur, which started 4 years ago, is currently continuing in selected areas of the country despite the manufacturer’s public pronouncement that the vaccine has been proven “safe and effective.” In fact, as you may very well know, the Department of Health launched it as a public health program earlier this year, targeting a million 9 year-old children from three (3) regions in the country: NCR, IV-A, and III.

We are alarmed that the children who started the trial are still receiving the placebo. Guided by the Declaration of Helsinki, as summarized in the International Conference on Harmonization, it is unethical to continue giving them placebo if it is indeed true that the vaccine has been proven safe and effective. To quote from Section 2.1.3 (Ethical Issues under Choice of Control Group and related Issues in Clinical Trials):

“When a new treatment is tested for a condition for which no effective treatment is known, there is usually no ethical problem with a study comparing the new treatment to placebo. Use of a placebo control may raise problems of ethics, acceptability, and feasibility, however, when an effective treatment is available for the condition under study in a proposed trial. In cases where an available treatment is known to prevent serious harm, such as death or irreversible morbidity in the study population, it is generally inappropriate to use a placebo control.”

In addition, if the claims of the manufacturer about the safety and effectiveness of the vaccine is true, and that there are no longer doubts about the drug, we believe that the health of children in the placebo group is under threat, and that that the trial should be stopped immediately. In the interest of public safety, ethics in research, and as mandated by ICH, we, from civil society, therefore request for a review of this trial by PHREB.

We hope for your prompt action on this urgent matter.

Sincerely,
CSO position paper on the dengue vaccination program
November 2016
Who decides for people’s health?

- Who decides what for public health?
- When and where are decisions regarding public health are made?
- How are these decisions made?

How does the government decide on how much to spend for what? Is this process democratic, transparent, and participatory? Are decisions made by legitimate actors reflected in the real spending of the resources? The answer to these questions will lead us to conclude that what we have is not actually a scarcity of resources, but of democracy and people’s participation in the budget.
There is scarcity of democracy, not of resources – scarcity is a matter of perspective – it is determined by the ideology and preferences of the state.

Health is too important to merely subject to medical experts.

Corporations and pharmaceutical companies are strong but the solidarity of people will make us not surrender.

Hard-learned lessons should inform reforms such as the Budget Reform Bill (on procurement lapses issues) and the Universal Health Care Bill (HTAC/HTAG representation and independence)