2017 Taiwan – Asean drug Regulatory Forum

A Health System perspective of pharmaceutical care

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Outline

- UHC as the Ultimate goal
- The Dual role of regulatory authority
- Who’s to develop medical products for our region
- Conclusion
My Track Records in Public Health Administration:

— Head of Taiwan’s CDC (1999-2000)
— Head of Taiwan’s NHI (2001-2004)
— Deputy Minister(2004)
The WHO Health System Framework

SYSTEM BUILDING BLOCKS

SERVICE DELIVERY

HEALTH WORKFORCE

INFORMATION

MEDICAL PRODUCTS, VACCINES & TECHNOLOGIES

FINANCING

LEADERSHIP / GOVERNANCE

OVERALL GOALS / OUTCOMES

ACCESS

IMPROVED HEALTH (LEVEL AND EQUITY)

COVERAGE

RESPONSIVENESS

QUALITY

SOCIAL AND FINANCIAL RISK PROTECTION

SAFETY

IMPROVED EFFICIENCY


How to satisfy the medical needs of our people?

• UHC to provide basic health care: Inpatient/outpatient, Essential drug list, long term care/home care for the chronically ill
• A supplementary risk-pooling system for the better-off for more expensive treatment modalities
• Unmet medical needs
Humbled in Taiwan

Taiwan's highly efficient system of national health insurance should humble and inspire the US.

Tagging along with Tsung-Mei Cheng, an expert on Taiwan's health system, on her recent visit to Taiwan's Bureau of National Health Insurance, turned out to be a bit humbling because as someone who focuses mainly on the US health system.

The bureau is the government agency that administers Taiwan's single payer national health insurance system. Its staff members fret when hospitals and walk-in clinics fail to submit completed claims within the required 24 hours after delivery of service. Private health insurance companies in the United States count themselves lucky if high priced actuaries cancel then in the middle of the year what the carrier ultimately will have to pay the providers of health care for services rendered in the previous year. Taiwan's Bureau can track almost in real time what goes on in the nation's healthcare system. In the US, even a vague idea of what has been going on a year or two ago can be

in Taiwan jumped from roughly 57% of the population before 1 March 1995 to virtually the entire population. For US policy makers and presidential contenders — who, for half a century now, have engaged in a perpetual "national conversation" on universal health insurance, only to see the number of uninsured people grow at a pace over the years — the speed of Taiwan's move to a national health insurance system seems overnight.

Taiwan's system is financed in roughly equal share by the government, employers, and households in a complex scheme that includes subsidies, payroll taxes, and premiums paid by self-employed people. Health care is delivered by a mixed system that includes private clinics, private nonprofit hospitals, and public hospitals, among which patients have freedom of choice. The main tool for cost containment has been sectoral global budgets, while effective in the short run,
The U.S. learned from Taiwan
Benefits

- Inpatient care
- Outpatient care
- Prescription drugs
- Dental services (orthodontics, prosthodontics excluded)
- Traditional Chinese medicine
- Day care for the mentally ill
- Home nursing care
High Public Satisfaction
(1995~2016)

Premium & Copayment Adjusted
Second Generation NHI

Years: 1995-2016

Satisfied
Dissatisfied
How we developed a world class Universal Health Care (UHC)-National Health Insurance (NHI)

• “NHI is like A car, with parts imported from a dozen different countries, but domestically made in Taiwan.”

Hongjen Chang
President & CEO, BNHI
2003
Possible factors contributing to the success of Taiwan’s NHI

- Single-payer system
- Free market on delivery side
- **IT intensive:**
  - 100% electronic claim processing
  - smart card
- **Strong generic pharmaceutical industry**
- Physicians willing to work very hard at relatively low physician fee
- Tradition of family support
NHI Card

- Simplification of management process
- Daily update of medical visit data
- Infectious disease tracing & monitoring
- Heavy-user detection & management

1. Last Six Medical Visits
2. Drug Prescriptions, Drug Allergies
3. Catastrophic Diseases
4. Organ Donation Consent
5. Palliative Care
NHI Medi-Cloud System

Specific Medication (Controlled drugs)

History of Drug Allergy

Rehabilitation Care

Chinese Medicine

PharmaCloud

No. of Surgeries

Records of Test/Examinations

Dental Services

Results of Tests/Examinations

Discharge Summary
My Health Bank system was established in 2014 and added newly functions in 2016:

- 3 Years of medical data
- Health information is displayed in the form of diagrams to enhance readability
- Provide educational guidelines
- Simpler access
- Certain disease prognosis and evaluation

APP of My Health Bank
Does Universal Health Insurance Make Health Care Unaffordable? Lessons From Taiwan

Evidence from the first half-decade of universal coverage in Taiwan suggests that overall costs do not rise because of increased use of services.

by Jui-Fen Rachel Lu and William C. Hsiao

ABSTRACT: This paper examines the performance of Taiwan’s National Health Insurance (NHI), a universal health insurance program, implemented in 1995, that covers comprehensive services. The authors address two key questions: Did the NHI cause Taiwanese health spending to escalate to an “unaffordable” level? What are the benefits of the NHI? They find that Taiwan’s single-payer NHI system enabled Taiwan to manage health spending inflation and that the resulting savings largely offset the incremental cost of covering the previously uninsured. Under the NHI, the Taiwanese have more equal access to health care, greater financial risk protection, and equity in health care financing. The NHI consistently receives a 70 percent public satisfaction rate.
Taiwan’s New National Health Insurance Program: Genesis And Experience So Far

Taiwan’s health policymakers continue to tinker with the country’s NHL, which covers almost all citizens with modest cost sharing.

by Tsung-Mei Cheng

ABSTRACT: In 1995, after a planning effort of about half a decade, the Republic of China (Taiwan) replaced a previous patchwork of separate social health insurance funds with one single-payer, national health insurance scheme that is administered by an agency of the central government’s Department of Health. Within a year this bold legislative act brought the health care utilization rates of the 41 percent of Taiwan’s hitherto uninsured population up to par with those of the previously insured population. This paper describes the achievements of this policy initiative so far, along with the growing pains it has encountered, and seeks to extract lessons from the experience for health policymakers in other countries.
Statement of US FDA Mission

FDA is responsible for **protecting the public health by assuring the safety, efficacy and security** of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.

FDA is also responsible for **advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable** and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health...

Regulatory Agency plays critical roles in:

- Essential Drug list
- Promoting the use of Generics.
- Promoting Self medication (OTC)
- Emphasis on prevention (vaccines)
- Rare diseases (orphan drugs)
- System to prevent /compensate drug injuries.
- Information System to promote rational use of medicine.
# Top 10 “suspects” of drug injuries

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug</th>
<th>number</th>
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<tbody>
<tr>
<td>1</td>
<td>Allopurinol</td>
<td>242</td>
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<tr>
<td>2</td>
<td>Phenytoin</td>
<td>149</td>
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<td>3</td>
<td>Carbamazepine</td>
<td>123</td>
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<td>4</td>
<td>Rifampin / Isoniazid / Pyrazinamide</td>
<td>108</td>
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<td>5</td>
<td>Diclofenac</td>
<td>70</td>
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<td>6</td>
<td>Co-trimoxazole</td>
<td>56</td>
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<td>7</td>
<td>Lamotrigine</td>
<td>43</td>
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<tr>
<td>8</td>
<td>Ibuprofen</td>
<td>42</td>
</tr>
<tr>
<td>9</td>
<td>Mefenamic acid</td>
<td>40</td>
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<tr>
<td>10</td>
<td>Cefazolin</td>
<td>37</td>
</tr>
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A unique drug-injury relief system in Taiwan: comparing drug-injury compensation in different countries

Angela W.F. On, Lan Hui Chih, Cindy Liu, Kuo Hwa Lin, Yu Wen Huang Hsueh Yung Tai and Mei Ling Hsiao
Taiwan Drug Relief Foundation, Division of Drugs and New Biotechnology Products, Food and Drug Administration (TFDA) and Department of Health, Executive Yuan, Taiwan

Abstract
Taiwan operates a unique no-fault compensation-based scheme for injuries caused by medication use. This article describes the operation of the Taiwan Drug Relief Foundation and some results since the Taiwan Drug Hazard Relief Act was enacted in 2000. We also briefly review similar no-fault compensation systems in Germany, Japan, New Zealand and Nordic countries. The existence of these schemes provides timely relief and compensation to victims by avoiding the otherwise lengthy court process; however, medication safety education and applied pharmacogenomic and pharmacoepidemiological research are future aspirations to proactively address and prevent drug-induced injuries.

Keywords adverse drug reaction; drug injury; no-fault compensation scheme; pharmacogenomics; Stevens–Johnson syndrome; Taiwan Drug Relief Foundation
Unmet needs of an advanced economy (US. Europe Japan)

• Cancer treatments
  Immune Oncology, Precision medicine
  Liquid Biopsy...etc.
• Minimally invasive surgeries and interventions, interceptions, medical devices
• Unique diseases of the region
• Rare diseases and orphan indications
Definition

◆ Rare disease
  – the prevalence of <1/10,000 with genetic disorder in the population
  – difficult to diagnose and treat
◆ Orphan medical product*
  – Indications for rare diseases
  – Hard to access
◆ Special food supplement

* Medical product: medicinal products & medical devices
Spotlight on...

How specific legislation for rare diseases and orphan drugs is changing life for some patients in Taiwan...
"We can’t take care of our children forever, but a well-established system can."

-The Taiwan Foundation for Rare Disorders
Unmet medical needs of our region

- **UHC**: Provision of “Basic” health services at affordable cost (The 30 Baht scheme of Thailand was a brilliant idea)
- A supplementary system for risk sharing for more expensive treatment modalities
- Diseases unique to the Region
Who is to develop products and vaccines for our region?

- Dengue vaccine, therapeutics, and diagnostic tests
- Snake venom Anti-serum
- Test for the early diagnosis of Oral Cancer
- Malaria AI screening system
Taiwan’s self sufficient in Vaccination

Vaccinia
Typhoid/paratyphoid
Cholera
Snake venom antiserum

DPT
JBE
Plaque

1959 Taiwan Serum and Vaccine institute
Taiwan was the first country to implement Universal HBV Vaccination

Priorities and Timetable of Hepatitis B Vaccine Program

<table>
<thead>
<tr>
<th>Priority</th>
<th>84</th>
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<th>95</th>
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<th>2010</th>
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<tbody>
<tr>
<td>Newborns of HBsAg carrier mothers</td>
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<td>All newborns</td>
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<td>Preschool children</td>
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<td>Elementary school**</td>
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  After Oct. 1990: Catch-up vaccination without charge for children up to 1st graders.
** After July 1991, all first graders were checked for their vaccination record.
   Non- or incompletely vaccinated pupils needed to be vaccinated.
Bungarus multicinctus

Naja atra
Deinagkistrodon acutus
Protobothrops mucrosquamatus

Viridovipera stejnegeri
Daboia russellii siamensis
Dengue Fever (Break-bone Fever)

Characteristics

• As painful as it sounds....

• Skin-rash (as demonstrated in the photo inserts)

• Caused by 1 of 4 virus serotypes (DENV 1-4)

• Prevails in tropical and sub-tropical areas

• Global warming expands mosquitos habitat

• Transmitted by infected Aedes aegypti mosquitos

Wild type dengue fever

Courtesy by Dr. Whitehead, NIAID
Dengue is both an established disease and an emerging/re-emerging disease.

- 2.5 billion people at risk
- 390 million annual infections
- 96 million infections are clinically apparent
- Endemic in over 100 countries, especially in SE Asia and Brazil

Source: WHO and Bhatt et al., Nature 2013
Dengue Development

Medigen Vaccine Biologics Corp.
Dengvaxia®: First Marketed Dengue Vaccine Yet Fails to Fulfill Medical Need?

- Sanofi’s Dengvaxia® is the world’s first marketed dengue vaccine (2015/12). However, its clinical trial data showed lower efficacy in preventing DENV2 (only 47%).

- Dengvaxia® requires 3 doses to complete the series, with unit price ranges from 20 EUR/ dose (Philippines)~38 EUR/ dose (Brazil), the complete vaccination costs 60 EUR~114 EUR/ person.

- From 2016 Q1~Q3, Dengvaxia generated 50 million EUR, 75% lower compared to what Sanofi’s CEO, Dr. Bradicourt had predicted in early 2016 that the annual sale would have reached 200 million EUR in first year.

- Sanofi’s product cannot fulfill market needs, providing entry opportunities for new products.
Competitive Edge of the NIAID Dengue Vaccine*

- Tetravalent (DENV-1, DENV-2, DENV-3 and DENV-4)
- Single dose
- Tested in 1600+ subjects (Phase 1 & 2) in 3 countries
- Phase III efficacy study has begun in Brazil (~17,000 subjects, Feb., 2016)
- 100% Protection in human challenge study
- Economical to produce: Administer 3 logs, produce bulk at > 7 logs
- Cell-based vaccine (Vero)

*Courtesy by Dr. Whitehead, NIAID
MVC’s 2nd Generation of Dengue Vaccine: VLP*

- Tetravalent VLP vaccine against dengue fever
- Transferred from the US CDC
- Progress: early stage development

*VLP: Virus-Like-Particle
PixoTest Dengue / Zika/ Chikunguya Control System

Dashboards that visualize the spread of disease in real time

- Test Results (Positive/Negative)
- Location (GPS)
- Temperature
- Humidity
- Fever
- Sickness
- Pregnant or not
- Travel history
- Other
DNA Methylation Assay Platform

Innovation  Sciences  Technology  Affordability  Trusted Partner

[Image of laboratory setting with lab technicians]
The role of DNA methylation in cancer

DNA methylation is an important regulator of gene transcription. However, promoter hypermethylation also plays a major role in tumorigenesis through transcriptional silencing of critical tumor suppressor genes such as PAX1 and ZNF582. These discoveries in the field of DNA methylation in carcinogenesis create new opportunities to identify biomarkers for early detection and personalized treatment of cancer.

Clinical applications

Methylation level of PAX1 and ZNF582 in DNA extract from swab sample.

- Screening: Am I at risk?
- Diagnosis: What condition do I have?
- Monitoring: Is the treatment working well for me?
Oral-M®

A novel technology for DNA methylation determination for right treatments of Oral Cancers.
— the sooner the better —

Assist in screening, diagnosing, and monitoring treatment of oral premalignant lesion or cancer, for which reliable and affordable screening methods are currently not available.

Sensitivity 88% : Specificity 86%

In a cross sectional clinical study involving 267 subjects (normal, lesion, moderate dysplasia, and worse), sensitivity and specificity of Oral-M® gene methylation kit were 0.88 and 0.86, respectively.

References:
AI: Image Diagnosis System for Malaria

https://www.cdc.gov/dpdx/malaria/dx.html
How do regulatory bodies play an active roles?

- Unmet medical needs
- Promoter(facilitator) vs. traditional “regulator”
- Regional Collaboration

regulatory collaboration to facilitate people’s access to urgently needed medical products.