Legal and Regulatory Frameworks for NPHIs

Andre Verani, JD, MPH
Public Health Policy Analyst
U.S. Centers for Disease Control and Prevention

IANPHI Annual Meeting
October 14-15, 2015
Overview

- Background
  - Role of law in establishing or reforming NPHIs

- Methods
  - Analyzed NPHI laws across geographic regions and income groups

- Results
  - Similarities and differences among NPHI legal mandates

- Discussion
  - Considerations for countries establishing or reforming NPHIs
Background

• Legal institutional mandates may evolve over time.

  ▪ History of the U.S. Centers for Disease Control and Prevention
    • Public Health Service established by law in 1912 (e.g., research)
    • PHS Office of Malaria Control in War Areas (1942; Atlanta)
    • Public Health Service (PHS) Act of 1944 (e.g., state grants, quarantine)
    • Communicable Disease Center (1946; tropical & “other diseases”)
    • Centers for Disease Control (1980; communicable and non-communicable)
    • Centers for Disease Control and Prevention (1992)

  ▪ Today’s CDC legislatively mandated functions
    • Epidemiology, Laboratory, Surveillance, Statistics, Workforce, Support to State and Local Health Departments, and Global Health (e.g., NPHIs)

http://www.cdc.gov/about/history/ourstory.htm
http://uscode.house.gov/
PHS/CDC mandate changed as needs evolved
Role of law in establishing or reforming NPHIs

- **Scope**
  - Jurisdiction over public health may be shared by levels of government

- **Staff**
  - PHAC Act delineates process for selection of Chief Public Health Officer

- **Functions**
  - Delineating core public health functions as part of the NPHI mandate

- **Financing**
  - Chile’s Public Health Institute submits annual budget request per norms

- **Autonomy and Accountability**
  - PHAC autonomous yet under direction of Minister of Health. “The Minister presides over the Agency and has the management and direction of it.” However, as a Legislated Service Agency, the PHAC has “greater financial and administrative authorities than traditional departments.”
Methods

- Convenience sample from Americas, Africa, Asia & Europe representing varied national income groups and cultures
  - Bangladesh, Canada, Chile, Czech Republic, and Tanzania

- Searched online sources

- Reviewed and analyzed legal and regulatory frameworks by:
  1. Type of policies used to create NPHIs (e.g., legislation, ordinance)
  2. NPHI core functions as reflected in NPHI mandates
“Policy” as used in this presentation

- CDC definition: “Policy is a **law, regulation, procedure**, administrative action, incentive, or voluntary practice of governments and other institutions.” (emphasis added)

The Laws

CONSOLIDATION

Public Health Agency of Canada Act

CODIFICATION

Loi sur l’Agence de la santé publique du Canada
An Act to establish the National Institute for Medical Research and to provide for the functions and powers of the Institute in relation to the promotion of medical research
<table>
<thead>
<tr>
<th>Country</th>
<th>Policy Types</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td><strong>Ordinance</strong> (creating the International Centre for Diarrhoeal Disease Research in 1978 as an autonomous, non-profit, corporate body)</td>
</tr>
<tr>
<td>Canada</td>
<td><strong>Legislation</strong> (Public Health Agency of Canada Act creating PHAC as a Legislated Service Agency), <strong>Order</strong> transferring control of Population and Public Health Branch from Department of Health to PHAC, <strong>Regulations</strong> (Special Appointments Regulations, appointing Chief Public Health Officer)</td>
</tr>
<tr>
<td>Chile</td>
<td><strong>Decree Law</strong> (creating Institute of Public Health), <strong>Ministry of Health Supreme Decree</strong> (establishing internal bylaws), <strong>Resolution</strong> (new structures including Departments and Director’s units)</td>
</tr>
<tr>
<td>Czech Republic</td>
<td><strong>Legislation</strong> (Act 258 creating National Institute of Public Health as a contributory organization and stating its Mission and Tasks), <strong>Rules</strong> (org structure)</td>
</tr>
<tr>
<td>Tanzania</td>
<td><strong>Legislation</strong> (Act 23 of 1979 establishing National Institute for Medical Research as corporate body run by Council albeit under direction of Minister)</td>
</tr>
</tbody>
</table>
### Results: core public health functions in NPHI mandate

<table>
<thead>
<tr>
<th>Critical NPHI Core Function</th>
<th>Bangladesh</th>
<th>Canada</th>
<th>Chile</th>
<th>Czech Republic</th>
<th>Tanzania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evaluation and Analysis of Health Status</td>
<td>✓</td>
<td>✓</td>
<td>MoH</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Public Health Surveillance, Investigation, and Control</td>
<td>✓</td>
<td>✓</td>
<td>✓ (lab)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Public Health Research</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>
Core public health function in Bangladesh NPHI

- **Evaluation and Analysis of Health Status**
  - “To publish books, periodicals, reports and research and working papers on the studies.”

- **Public Health surveillance, investigation, and control**
  - “To conduct clinical research, laboratory and animal experiments, epidemiological and survey research, field investigations, demonstration projects”

- **Public Health research**
  - “to undertake and promote study, research and dissemination of knowledge in diarrhoeal diseases and directly related subjects of nutrition and fertility with a view to developing improved methods of health care and for the prevention and control of diarrhoeal diseases and improvement of public health programmes with special relevance to developing countries”

- “To take such other actions as may further the aims and objectives ...”
Core public health functions in Canada NPHI

- **Evaluation and Analysis of Health Status**
  - “The Chief Public Health Officer shall, within six months after the end of each fiscal year, submit a report to the Minister on the state of public health in Canada.”

- **Public Health surveillance, investigation, and control**
  - “The Chief Public Health Officer may, in any report submitted or published under this section, refer to public health problems and their causes, as well as any measures that may, in his or her opinion, be effective in preventing or resolving those problems.”

- **Public Health research**
  - “The Public Health Agency of Canada is established for the purpose of assisting the Minister in exercising or performing the Minister’s powers, duties and functions in relation to public health.” Department of Health Act: “investigation and research into public health” is Minister’s function.
Core public health functions in Chile NPHI

- **Evaluation and Analysis of Health Status**
  - Ministry of Health, not INSP, function: “evaluate pop. health situation”

- **Public Health surveillance, investigation, and control**
  - “The Institute will serve as the national reference laboratory”
  - “supervisor of public health laboratories”
  - Ministry of Health, not INSP, function: “carry out public health surveillance”

- **Public Health research**
  - “promote and carry out applied research efforts related to its functions”
Core public health functions in Czech Republic NPHI

• **Evaluation and Analysis of Health Status**
  - “To prepare background information for national public health policy making and health protection and promotion”

• **Public Health surveillance, investigation, and control**
  - “To process data on population health relevant to prevention of the emergence and spread of infectious diseases, occupational health risks and other occupational health damage, human exposure to occupational and environmental pollutants and the epidemiology of drug addiction, with the aim of obtaining background information for national policy making and the monitoring of long-term trends in the incidence of infectious and other diseases of high prevalence”

• **Public Health research**
  - “To promote preventive medicine disciplines and research”
  - “To assess risks in the field of food safety”
Core public health functions in Tanzania NPHI

• **Evaluation and Analysis of Health Status**
  - “may require in writing any hospital, health centre, dispensary or other medical establishment or a category of them to furnish to it such information relating to such … diseases as the Institute may specify.”

• **Public Health surveillance, investigation, and control**
  - “carry out and promote the carrying out of research and investigation into the uses and the ways of controlling and preventing the occurrence in Tanzania of particular diseases or a category of them, including- …”
  - “carry out and promote the carrying out of basic applied and operational research designated to provide effective measures for the control of diseases endemic in Tanzania”

• **Public Health research**
  - “to carry out and promote the carrying out of, medical research designed to alleviate disease among the people of Tanzania”
  - “to monitor, control and co-ordinate medical research”
### Results: NPHI autonomy and accountability

<table>
<thead>
<tr>
<th>Country</th>
<th>Autonomy</th>
<th>Accountability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh (ICDDR)</td>
<td>“body corporate … with power … to acquire, hold and dispose of property, both movable and immovable, and … sue and be sued.”“autonomous, international, philanthropic, and non-profit”</td>
<td>“To conduct clinical research, laboratory and animal experiments, epidemiological and survey research … within the applicable laws and regulations, or concurrence where necessary, of the Government”</td>
</tr>
<tr>
<td>Canada (PHAC)</td>
<td>“established for the purpose of assisting the Minister in exercising or performing the Minister’s powers, duties and functions in relation to public health.” “The Minister may … delegate to an officer or employee of the Agency any of the powers, duties and functions”</td>
<td>“The Minister presides over the Agency and has the management and direction of it.”“The Chief Public Health Officer shall, within six months after the end of each fiscal year, submit a report to the Minister on the state of public health in Canada.”</td>
</tr>
<tr>
<td>Chile (ISP)</td>
<td>“created as a functionally decentralized public service with legal personality and property ownership”</td>
<td>“depends on the Ministry of Health to supervise its operations and is subject to policies, norms and general plans”</td>
</tr>
<tr>
<td>Czech Republic (NIPH)</td>
<td>“contributory organization” “functional and organizational economic unit that acts in all legal relations on its own”</td>
<td>“directly controlled by the Ministry of Health”</td>
</tr>
<tr>
<td>Tanzania (NIMR)</td>
<td>“body corporate … capable of suing and being sued; holding, purchasing, or acquiring … property and disposing of any of its property.”</td>
<td>“Minister may give to the Council directions … regarding the performance … of any of its functions … and the Council shall give effect to every direction given to it.”</td>
</tr>
</tbody>
</table>
Discussion: learning from varied national experiences

• Countries establishing or reforming NPHIs may consider:
  
  ▪ IANPHI NPHI Toolkit [www.ianphi.org/resources/toolkit/index.html](http://www.ianphi.org/resources/toolkit/index.html)
  
  ▪ Varied legal and policy approaches of other nations
    • Ex.: normative instruments, core functions, autonomy/accountability
  
  ▪ Reviewing internal legislative/regulatory/policy options
  
  ▪ Practical experiences of other NPHIs (e.g., budgets, staff, autonomy)
References

- International Centre for Diarrhoeal Disease Research, Bangladesh, Ordinance, 1978
- Legislative Summary, LS-523E, Bill C-5: Public Health Agency of Canada Act
- Department of Health Act, Canada, S.C. 1996, c. 8., current to September 10, 2015
- Order Transferring from the Department of Health to the Public Health Agency of Canada the Control and Supervision of the Population and Public Health Branch and Ordering the Minister of Health to Preside Over the Agency, SI/2004-123, current to September 10, 2015
- Decree Law establishing the coordinated and systematized text of Decree Law 2.763 of 1979 and Laws 18.933 and 18.469, Version of 10/10/2014, Chile
- Statutes of the National Institute of Public Health, Nov. 12, 2003, Czech Republic
- National Institute for Medical Research Act, 1979, United Republic of Tanzania
Thank you from our NPHI to yours!

Andre Verani averani@cdc.gov
Acknowledgements:
IANPHI, CDC’s Division of Global Health Protection, InVS

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.