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AUTHOR	Fitzgibbon, Joy Darlene
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THE RECKONING:

IMPROVING THE WORLD HEALTH ORGANIZATION'S TUBERCULOSIS CONTROL POLICY THROUGH PRACTICAL KNOWLEDGE

by

Joy Darlene Fitzgibbon

A thesis submitted in conformity with the requirements

for the degree of Doctor of Philosophy

Graduate Department of Political Science

University of Toronto

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Abstract

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Is it possible on a global scale to improve the lives of our most vulnerable and impoverished citizens? One fundamental challenge is to create dynamic political institutions that learn incrementally from policy failures. This dissertation shows how international institutions can learn. It explores how the World Health Organization learned to create a more effective tuberculosis control policy.

WHO's experience in defining TB management strategies demonstrates that international organizations can learn when they create networks of public and private organizations that improve their access to practical knowledge. Practical knowledge reflects the lessons and perspectives of those who receive and implement policy. International organizations may access this practical knowledge through knowledge entrepreneurs.

WHO strengthened its ability to learn by more deeply and widely engaging with knowledge entrepreneurs through the Stop TB Partnership. WHO accessed practical knowledge through the presence and persistence of Partners in Health (PIH)—a highly critical and pragmatic private organization within their policy network.

First, PIH gained practical knowledge because its commitment to human rights empowered it to see public health problems that WHO did not see and to partner with community activists to implement public health projects. Second, as multi-disciplinary scholars, PIH was able to analyze, act upon and communicate this practical knowledge persuasively and credibly to WHO. Third, PIH engaged strategically to develop and further accelerate policy changes in the UN system writ large and collaborated with NGOs and foundations sympathetic to their perspectives thus enabling and empowering their research and credibility at WHO.

An enabling environment outside these policy relationships empowered critical voices at the table. Specifically, two external conditions were important: an ideational

environment that complemented the agenda of critical partners and external critiques of the organization's responsiveness and effectiveness.

International organizations, like the World Health Organization, can learn to improve their policies through trial and error policy development by learning incrementally through policy failures. NGOs with these dispositions and skills can contribute to developing and implementing effective global policy at international organizations. Such contributions strengthen transnational state-based institutions by improving their practical legitimacy amongst policy implementers and thus their capacity to govern.

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CHRONOLOGY

1940s Sanatoria and BCG Vaccination campaigns

1946 International Health Conference New York at which WHO is created and its Constitution written. TB is one of the priority diseases of the new organization and its Interim Commission. The IUATLD participates in discussions around tuberculosis, urging the new organization to focus on its management.

1947 First expert committee on tuberculosis meets in Paris. Focus on BCG vaccinations

1948 First World Health Assembly

1949 Dr. J.B. MacDougall, WHO's Chief of Tuberculosis control, publishes *Tuberculosis: A Global Study in Social Pathology* calling for improved scientific knowledge to enhance disease control efforts in developing countries

1949 Antibiotic era for managing TB begins. The first successful randomized controlled trial is carried out by the Tuberculosis Trials Committee of British Medical Council verifying efficacy of streptomycin and supported by WHO's Expert Committee Third World Health Assembly. Relations with NGOs revised

1950s Development of isonizid

1950s Tuberculosis strategy is failing in the Third World due to lack of access to drugs

1957 The Panel on Tuberculin Testing and BCG Vaccination as well as study groups on Chemotherapy and Chemoprophylaxis in Tuberculosis Control created

1959 Madras Experiment discovers that ambulatory care is sufficient, as an alternative to hospital-based treatment, confirming the efficacy of intermittent regimens of isonizaid and streptomycin administered twice weekly on a supervised outpatient basis. The WHO Expert Committee on Tuberculosis outlined these new policies in their 1964 report, and refined and reaffirmed them in 1973. These were the core strategies of the current strategy of DOTS

1962-1969 Dr. H. Mahler heads TB division

1964-1976 Tuberculosis experts led by WHO created an integrated strategy for TB care.

1962 The British Medical Research Council discovered the efficacy of the three-drug regimen—streptomycin, PAS and isonizid, administered on an outpatient basis over a two-year period

1970s TB division staff grows to 20 people

1970s Development of pyrazinamide and rifampicin. Rifampicin, also developed through the work of the British Medical Council, shortened the therapy to nine months.

1970s WHO embraces policy of sub-optimal chemotherapy for tuberculosis, which emphasizes active case finding rather than the treatment of ill patients.

1973 Dr. H. Mahler is elected Director General and cuts support for the TB program. It is believed that he did so because, as the former Director of the TB program, he sought to avoid perceptions of favoritism. Others suggest that he lost confidence in WHO's tuberculosis program. Still others suggest that the rise in TB eradication success in the West through cocktails of antibiotics may have led he and his advisors to overstate the prospects for disease eradication globally.

1974 Expert committee on tuberculosis meetings cease

1975 The Special Programme for Research and Training in Tropical Diseases created

1976 Mahler acknowledges the continued "crucial" contributions of IUATLD

1978 Declaration of Alma Ata

1980s Dr. Karl Styblo creates the strategy later known as "DOTS"

1980 Report released on *BCG Vaccination Policies*

1981 Health for All by the Year 2000

1982 Report released on *Tuberculosis Control*

1985 Erosion of the TB Program. The department declines to two staff and tiny operating budget. No persons from headquarters are operating at country levels. Dr. Karl Styblo goes to IUATLD. Dr. Fabio Luelmo to WHO's Acute Respiratory Infections division.

1985 TB falls off the global radar. British Medical Council disbands TB unit

1986 Dr. Jonathan Mann takes leadership of HIV AIDS program

1987 Relations with NGOs revised in *Principles Governing Relations Between the WHO and NGOs*

1987 IUATLD sends special commission to the Director General to encourage WHO to prioritize tuberculosis, warning of a global crisis. IUATLD begins working with KNCV

1988 Dr. H. Nakajima is elected Director General

1988 Working Group on HIV Infection and Tuberculosis created

1989 Dr. Arata Kochi appointed Chief of Tuberculosis control

1989 Peru begins tuberculosis program centred on Styblo's strategy under WHO and IUATLD assistance

1990 Dr. Jonathan Mann resigns from HIV AIDS program

1991 CARG created

1993 World Health Resolution declaring Tuberculosis a global emergency

1993 Six staff members in tuberculosis control department including Dr. Karl Styblo, Dr. Fabio Luelmo, Mr. Kraig Klaudt, Dr. Jacob Kumarson, Dr. Sergio Spinachi. Ongoing collaboration with IUATLD and KNCV. Headquarters staff visits field projects. WHO advocates standardized strategy of directly observed, short-course chemotherapy as created by Styblo. MDRTB is not to be directly addressed rather standardized strategy for standard TB is thought to prevent its emergence.

1994 Global Programme on Vaccine and Immunization created

1994 WHO and IUATLD's Global Project on Anti-Tuberculosis Drug Resistance Surveillance finds MDRTB is shaping up to be a significant global problem

1995 Klaudt creates term "DOTS" to describe WHO's strategy

1996 Partners In Health begins to detect problems with MDRTB in Peru, in contrast with the WHO 1994 report. They begin treating MDRTB patients, with innovative community-based care modeled on programs successfully implemented in Haiti and relying on referrals from MOH program of failed cases. Cure rates 85 per cent.

1997 Medicines for Malaria Venture created

1997 Peru agrees to treat MDRTB with a standardized regimen. PIH continues with individualized regimens.

1997 PIH begins to collaborate with WHO and demonstrate the problem of amplified resistance, calling into question WHO's re-treatment strategy. PIH works with a network of community patient activists and the Catholic Church to begin individualized regimens for MDRTB

1998 Dr. Gro Harlem Brundtland is elected Director General

1998 Roll Back Malaria Partnership created

1998 *Integrated Management for Childhood Illness Initiative* created.

1998 *Choosing Interventions: Cost Effectiveness, Quality and Ethics* programme created

1998 TB division grows to 65 people

1998 Stop TB created. IUATLD, KNCV and CDC core members. Critical partners PIH and MSF aggressively engage.

1998 A meeting of the *Ad Hoc Committee on Tuberculosis* at WHO reported, "progress in the highest burden countries was stalled

1998 April 4-5, Harvard's *Medical Program in Infectious Disease and Social Change* convened a group of 50 experts in TB and public health to re-examine WHO's policies in light of new empirical research generated by PIH identifying amplified resistance. DOTS-Plus proposed by Dr. Kochi as name for task force on MDRTB.

1998 October Meeting at White House with Hilary Clinton to address drug resistance and implementation of DOTS Plus

1999 First Informal Consultation on Health and Human Rights held at WHO, jointly organized by the Department of Health in Sustainable Development and the Globalization and Cross-Sectoral Policies and Human Rights Initiative.

1999 Harvard Medical School/Open Society Institute publishes, *The Global Impact of Drug-Resistant Tuberculosis* identifying MDRTB as a greater problem than was previously acknowledged.

1999 July-Task Force on MDRTB becomes a Working group. WHO and PIH held meeting at the American Academy of Arts and Sciences to establish a foundation for appropriate MDR case management, evaluating treatment programs and procuring affordable second-line antibiotic medications of high-quality. The

International Dispensary Association commits to make available all second-line anti-tuberculosis control drugs within the next six months to a year. Discussion quickly moved to creating a mechanism for pooled procurement whereby a central organization would acquire drugs at dramatically reduced prices and would then delve them out to countries following DOTS Plus guidelines and administered through "The Green Light Committee

1999 Commission on Macroeconomics and Health

2000 PARTNERS Network in Peru created, formalizing prior relationships, focusing on expanding DOTS Plus MDRTB treatment.

2000 *WHO Report: Health Systems: Improving Performance*, introduces concepts of health responsiveness and stewardship. Reflects divergent tendencies towards cost-effectiveness and human rights

2000 Millennium Development Goals

2001 PIH receives $44.7 million from Gates foundation to scale up MDRTB projects in Peru, through the PARTNERS sub network. Largest known grant in TB history

2002 UN Commission on Human Rights appoints Special Rapporteur, Paul Hunt, to WHO

2002 WHO reverses its policy on MDRTB, officially placing it on their policy agenda as a key priority for global TB management.

2002 Global Fund for HIV AIDS, TB and Malaria created

2002 Peruvian response to MDRTB expanded throughout Lima. Lessons learned funneled into Russian projects

2002 Global Plan to Eradicate Tuberculosis

2003 Dr. Lee Jong-Wook is elected Director General. Dr. Jim Yong Kim (PIH) and Dr. Ian Smith (Stop TB) appointed Special Advisors

2003 3x5 Initiative created which seeks to provide three million people living with HIV/AIDS in developing and middle income countries with antiretroviral treatment (ART) by the end of 2005.

2004 Jim Yong Kim appointed director of HIV AIDS Department and leads the 3X5 Initiative

Chapter 1

REFLECTIONS ON LEARNING AT INTERNATIONAL ORGANIZATIONS

The microbe is nothing; the terrain, everything.[1]
Louis Pasteur

History is littered with grand schemes to improve human welfare that tragically and unexpectedly failed.[2] Is it possible to improve the lives of the most vulnerable and impoverished citizens on a global scale? One way is to create dynamic political institutions that learn incrementally from small policy failures. These organizations detect when their policies are failing to solve the problems under their jurisdiction and discover ways to remedy these policy deficiencies. This dissertation shows how such learning can occur by exploring how and why the World Health Organization (WHO) learned to improve its global tuberculosis control policy.

Students of international organizations have spent significant time exploring why international organizations are created. We know little of the functioning and impact of these organizations.[3] Few scholars explore when and why international organizations

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[1] As quoted in Paul Farmer, *Infections and Inequalities. Global Inequality and the Health of the Poor,* (Berkeley: University of California Press, 1999) 37.

[2] For a persuasive analysis of such failures see James C. Scott, *Seeing Like a State. How Certain Schemes to Improve the Human Condition Have Failed.* (New Haven: Yale University Press, 1998).

[3] Michael N. Barnett and Martha Finnemore, "The Politics, Power, and Pathologies of International Organizations" *International Organization*, 53, 4, (1991): 699-732. For a fuller presentation of these ideas see Michael N. Barnett and Martha Finnemore, *Rules for the World. International Organization in Global Politics.* (Ithaca: Cornell UP, 2004).

learn. Those who most vigorously explore this question suggest that bureaucratic pathologies and hegemonic interest-based coalitions of powerful states may limit learning.[4]

When might those barriers be overcome? When and why do international organizations improve the quality of their policies in the midst of bureaucratic constraints and diverse, uncertain and shifting social environments? The literature on international organizations suggests that expanding policy relationships may provide opportunities for learning by redefining the causes of the policy problem.[5] This study complements and contributes to these research findings.

This dissertation explores the process of policy learning that occurred around multi-drug-resistant tuberculosis (MDRTB) emerging as a consequence of existing policy that effectively allowed for poor or partial pharmacologic treatment of tuberculosis (TB). WHO's experience in managing tuberculosis demonstrates that international organizations can learn when they expand their understandings of legitimacy by creating diverse networks of public and private organizations that improve their access to practical knowledge made evident through an iterative and dialectic process of policy debate. International organizations may access this practical knowledge through knowledge

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[4] See Barnett and Finnemore, "The Politics, Power and Pathologies of International Organizations," 699-732 and Ernst B. Haas. *When Knowledge is Power, Three Models of Change in International Organizations* Berkeley: University of California Press, 1990.

[5] See Haas., Ibid..

entrepreneurs. These knowledge entrepreneurs demonstrate a commitment to the groups that the policy is failing. They have the scholarly skills to generate new knowledge by analyzing their experiences and to translate this new knowledge into policy formulations valued by the state or its associated institutions. Finally, they are strategically nimble organizations—that is, they adapt their social and organizational strategies to engage strategically with the international organization while building a broader network of support. In this analysis of global tuberculosis control, the knowledge entrepreneur referred to a non-governmental organization (NGO) that combined a commitment to human rights, interdisciplinary scholarly expertise and the capacity to engage strategically and deeply with policy agencies within and outside the UN system. These changes created an enabling environment for learning within the international organization's policy relationships on tuberculosis control.

An enabling environment outside these policy relationships further empowered critical voices at the table. Specifically, two external conditions were important: an ideational environment that complemented the agenda of critical partners and external critiques of the international organization's responsiveness and effectiveness. In particular, the WHO's Commission on Macroeconomics and Health and the UN Millennium Development Goals reinforced messages of social justice presented by the critical partners. Further, criticisms of the UN's relationship with the for-profit sector as part UN's Blue Compact placed the WHO on the defensive to prove both its responsiveness

and effectiveness. These criticisms encouraged greater openness in policy relationships and helped to drive policy reform.

The process of learning was a messy one of trial and error policy development where an international organization learns incrementally and iteratively through policy failures. These policy failures were identified through evidence based critical analysis on the impact of policy at that time. In this case, WHO learned that it is necessary and feasible to address multi-drug resistant tuberculosis (MDRTB) as an essential part of its global tuberculosis control policy because failing to do so promptly would accelerate drug resistance and increase the long-term impact and costs of managing an expanded double crisis of both epidemic TB and MDRTB. WHO discovered new ways to expand tuberculosis policy and thus treatment for high-risk patients. These changes strengthen global surveillance and management efforts by enabling health workers to reach and more effectively treat a larger number of patients with tuberculosis while successfully containing and eradicating the more virulent forms of the condition. This form of learning is referred to as "double loop learning" and involves a re-orientation of policy goals as a consequence of new understandings of the policy problem.

How did this learning take place? WHO learned sometimes painfully through unanticipated failure in what was considered its tremendously successful Peruvian tuberculosis control project. Further, WHO learned by accident: it learned even though the organization didn't think its policies needed to be revised. WHO significantly

strengthened its opportunity to learn by more deeply engaging with NGOs through a formal policy network called The Stop TB Partnership.

WHO remains a highly bureaucratic transnational agency. The Stop TB Partnership changed WHO's bureaucratic practices in one important area, however: it partially weakened the highly restrictive, centralized policy pathway that governed decision-making prior to Stop TB. These changes took place as a result of prior policy failure at WHO.

Under the Coordination and Advisory Review Group (CARG), decision-making was tightly controlled by a narrow group of technical agencies working with WHO. It soon became clear to TB staff that the policy structures under the CARG were failing to generate the funds and political support necessary to manage the problem of MDRTB emerging from poor or partially treated TB. Further, WHO was experimenting with a variety of different internal administrative structures as the organization faced stiff criticism from critical non-governmental organizations on the grounds of both effectiveness and responsiveness. These broader organizational experiments created disorientation amongst TB staff and weakened departmental strongholds. The need for resources and external criticism created an enabling environment for WHO to alter its policy relationships. These internal and external developments coalesced to open a door at the organization for the creation and further development of Stop TB—a broader partnership with less centralized policy pathways.

The Stop TB Partnership opened up avenues for communication at WHO that did not exist under the CARG partnership by broadening the number, and more importantly, the types of organizations that could be part of the discussion on TB priorities. The most important new contributors to this discussion were a hybrid non-governmental organization that combined scholarly training with advocacy and development projects and a second advocacy, relief and development non-governmental organization. This broadening emerged over time, as a result of the intentional strategic actions of these critical partners to negotiate positions at the table. The broadening created new avenues for policy construction that were less rigid and centralized. WHO staff cautiously opened up to new ideas proposed by critical partners who have been given a place at the table. In the midst of debate at WHO over its changing relationships with non-governmental organizations, the practice of the Stop TB Partnership weakened the highly inflexible and centralized process of policy making that previously characterized the tuberculosis control department. Even though WHO's staff officers retain final authority on the content of WHO's tuberculosis control policy, there has been a dispersion of authority in who generates policy-relevant knowledge that informs decision-making.

The Stop TB Partnership organized the policy relationships through which learning took place. This network was not a sufficient instrument for learning, however. WHO accessed practical knowledge through Stop TB. Practical knowledge reflects the lessons and perspectives of those who implement a defined policy (i.e.: in this case health care

workers) and the experiences of those whom the services need to reach (i.e.: in this case, tuberculosis patients). Policy makers require iterated access to practical knowledge when the policy problem requires a complex intervention and knowledge is thus evolving. WHO was able to access this practical knowledge through the presence and persistence of a highly critical private organization within their policy network. This organization—Partners in Health (PIH)—had three qualities that provided them with access to practical knowledge.

First, PIH's commitment to human rights enabled it to see public health problems that WHO did not see and to partner with community activists to implement public health projects. PIH measured the negative impact of WHO's generic macro-level approaches to tuberculosis control against the experiences of specific high-risk patients and groups of patients. These findings called into question the macro-level statistical data on which WHO was measuring program effectiveness, the scientific claims of causality that followed, and in sequence, the generic strategy that it endorsed in its policy. PIH collaborated with national networks of patient activists to implement pilot projects rooted in and responsive to the experiences and needs of high-risk patients. PIH used these projects to test and verify alternative strategies. WHO subsequently contextualized their approach to TB by including MDRTB in their policy agenda and thus constructed a global tuberculosis control policy with richer and wider reach.

Second, PIH held multi-disciplinary scholarly expertise that combined clinical research expertise (i.e.: the practice of medicine and clinical epidemiology) with social

science analysis in anthropology and political economy. These diverse scholarly foundations enabled the organization to formulate hypotheses, analyze, interpret, act upon and communicate practical knowledge persuasively and credibly to WHO. PIH linked the distribution of tuberculosis to underlying socio-economic and political factors and decisions. This critique enabled PIH to target these socio-economic and political foundations when launching its policy intervention. Staff also accessed the academic and political resources provided to them as members of Harvard University to propel their ideas forward.

Third, PIH was strategic in the tactics it used to relate to WHO and other partners. The organization both exploited and further accelerated policy changes in the UN system writ large around the Millennium Development Goals while establishing collaborative alliances with NGOs and foundations sympathetic to their perspectives. Of particular importance was their relationship with Médecins Sans Frontières (MSF). These broader elite networks funded and supported PIH's proposals and thus enabled PIH's research and bolstered its arguments at WHO.

The result of all these developments is that WHO began to see MDRTB as a soluble issue. WHO altered its global policy to include MDRTB. It created a working group on MDRTB to assemble and disseminate knowledge and mobilize support for DOTS Plus—the new strategy to manage MDRTB derived from PIH's experiences in Peru. Drawing upon the experience of WHO's Green Light Committee for Malaria, WHO and its partners created a Green Light Committee to ensure poor countries have