



**Salient Issues on the Global Health Agenda:
How Science/Policy Boundary-Work Builds
Confidence in Global Governance. An indepth
study of UNESCO's International Bioethics
Committee and the WHO's Strategic Advisory
Group of Experts on Immunization**

Sameea Ahmed Hassim

A thesis submitted in partial fulfillment of the requirements for
the degree of

Doctor of Philosophy

Political and Social Sciences, Université Libre de Bruxelles
Political Theory, LUISS Guido Carli

Erasmus Mundus Joint Doctorate: Globalisation, Europe &
Multilateralism (GEM PhD School)
Academic Year 2016-2017

Under the supervision of:

Raffaele Marchetti, LUISS Guido Carli
Jean Frédéric Morin, ULB

Abstract

This study examines the science/policy interactions in global health science and technology governance. It focuses on the institutional design of organizations that sit at the interface of science and policy, conceptualizing them as Boundary Organizations (BOs). The analysis considers how the institutional design of BOs affect boundary-work. The study examines two case studies, UNESCO's International Bioethics Committee and the WHO's Strategic Advisory Group of Experts on Immunization. The study examines the ways in which boundary-work is carried out and finds that the concept of a BO demonstrates an institutionalization of science/policy interactions and the analysis of these two cases show that there are different ways that boundary-work is practiced as a function of the design of BOs.

Acknowledgements

This thesis is dedicated in loving memory to Muriel Casals, my mentor and friend. Her kindness and encouragement will always be an inspiration. She will always be remembered.

Whilst undertaking this research I had the incredible privilege of meeting some exceptional people from all across the globe. I will forever be grateful for the kindness, warmth, generosity and helpfulness that I was shown by my many friends and new acquaintances over the years.

A special thanks go to Raffaele Marchetti and to Jean- Frédéric Morin for their guidance and support through this process. I want to especially thank Jean-Frédéric Morin for his unwavering belief in me and for always showing me that there are many opportunities to be taken. I thank him immensely for supporting me through it all.

I am grateful to the European Commission for awarding me the Fellowship that enabled me to complete this work. I am also grateful for the funding received from Berkeley, ULB and Université de Montréal.

I owe a debt of thanks to Massimo Mazzotti and the department of History and Philosophy of Science and Technology at UC Berkeley for graciously hosting me as a Visiting Student Researcher. The Center for Science, Technology, Medicine and Society was an incredibly rich source of inspiration for this work. Thanks go to my colleagues for the stimulating discussions in the weekly CSTMS meetings, and to the members of the Social Science Writing Group who gave me the opportunity to improve my writing. I would also like to thank colleagues from the various UC campuses who I had the opportunity of sharing and learning from at the 2015 STS Retreat. To my colleagues and friends who made Berkeley all the more special, particularly Matthieu Mondou, Geremias, Jazleyn Sandhu, Kate, Matthew, Eric, Becky and the lovely Lana Husser.

I would also like to thank my hosts at the Université de Montréal, who welcomed me so warmly as a visiting researcher. I owe a huge thank you to Frederic Merand and Éric Montpetit for their support and for facilitating my many interactions and exchanges with the researchers there.

I would like to thank the GEM Community, the REPI community, and the LUISS community for the support and the exchanges. Each and every one made a difference in one way or another and I am truly grateful.

A huge debt of thanks goes to Frederik Ponjeart who I would like to thank for his friendship, incredible guidance in both administrative and academic matters as well as in broadening my knowledge and understanding of countless issues. Your unwavering support and belief in me were a beacon of hope for me right till the very end.

I owe my deepest thanks to Ragnar for his support. Because of his constant encouragement, his tolerance during my stressful moments and his support at the most crucial moments, I never felt alone.

And finally a special thanks to my family who I was away from for so long. I missed you every step of the way.

List of Abbreviations

IR – International Relations
STS – Science Technology & Society
BO – Boundary Organization
IBC – International Bioethics Committee
IGBC – Inter-Governmental Bioethics Committee
WHO – World Health Organization
UNESCO – United Nations Educational Scientific and Cultural Organization
PA – Principal-Agent
IO – International Organization
IPCC – Intergovernmental Panel on Climate Change
FCCC – Framework Convention for Climate Change
WMA – World Medical Association
CIOMS – The Council for International Organizations of Medical Sciences
UDHGHR- The Universal Declaration on the Human Genome and Human Rights
COMEST – The World Commission on the Ethics of Scientific Knowledge and Technology
UNIACB – United Nations Inter-Agency Committee on Bioethics
EPI – Expanded Program on Immunization
UNICEF – United Nations Children’s Education fund
UNDP – United Nations Development Program
GAVI – Global Alliance for Vaccines and Immunization (now known as The Vaccine Alliance)
PPP – Public-Private Partnership
GIVS – Global Immunization Vision and Strategy
WHA – World Health Assembly
GVAP – Global Vaccine Action Plan
NGO – Non-Governmental Organization
DoV – Decade of Vaccines
IVB – Immunization, Vaccines and Biologicals
ACIP – Advisory Committee on Immunization Practices

Table of Contents

Acknowledgements	2
List of Abbreviations.....	5
Figures.....	8
1. Chapter 1: Setting the Scene – Studying International Organizations and Knowledge in Global Governance.....	9
1.1. Introduction	9
1.1.1. Medical and Health Practices	11
1.1.2. Governing Beyond Borders.....	14
1.2. Aims of the Study	17
1.3. Theoretical Perspectives in (Global) Governance:	25
1.4. From Rationalist to Constructivist Readings... ..	26
1.4.1. ...Of International Relations.....	26
1.4.2. ...Of Science	37
1.5. Conclusion	43
2. Chapter 2: Selecting the Tools – Crafting a Way of Studying Boundary Phenomena	43
2.1. Introduction	44
2.2. Why Boundary Phenomena? Perspectives on the Science-Policy Interface	45
2.2.1. Problems with the Linear Model of Policy-Making	47
2.2.2. The Case for a Separation of Science and Power	50
2.2.3. Salience, Credibility and Legitimacy: When Knowledge is Used ..	55
2.2.4. The Case for Blurring the Boundary Between Science and Policy	58
2.2.5. Returning to the Boundary Question	64
2.2.6. The Role of Boundary-Work	65
2.2.7. Stabilizing the Science-Policy Interface with Boundary Organizations	68
2.3. Studying Boundary Organizations: The Tools and Methods.....	71
2.3.1. Incorporating a Structural Analysis: A Principal-Agent Approach	73
2.3.2. Analyzing the Knowledge Production Process: A Boundary-Work Analysis	76
2.4. Conclusion	79
3. Chapter 3 – Institutional Design of UNESCO’s Bioethics Governance Apparatus: A State-Centric Model?	82

3.1. Introduction	82
3.1.1. Science-Policy Instability and the IBC.....	87
PART I: Contextualizing the Committee	91
3.2. Global Bioethics: The Background	91
3.3. UNESCO’s Bioethics Program	93
3.3.1. Appointing the Members of the IBC.....	97
3.3.2. IBC Members: A Historical View	98
PART II – Producing Knowledge	110
3.4. Introduction	110
3.5. From Concept Note to Final Report: A Research Method	112
3.6. Outputs of the IBC	114
3.6.1. Organizing Deliberation.....	118
3.6.2. Pre-Meeting Preparations	124
3.6.3. Deliberation in Meeting Sessions	131
3.7. Conclusion	Errore. Il segnalibro non è definito.
4. Chapter 4 – Institutional Design of WHO’s Immunization Governance Apparatus: An Expert-Driven Model?	148
4.1. Introduction	149
4.1.1. Science-Policy Instability and SAGE.....	156
PART I – Contextualizing the Committee	162
4.2. WHO’s Vaccine and Immunization Activities: The Background	162
4.3. SAGE: Role and Function	166
4.4. Appointing the SAGE Members	176
PART II – Producing Knowledge	179
4.5. Introduction	179
4.6. From Report to Recommendations: Examining Boundary-Work ...	180
4.6.1. Organizing Deliberation.....	181
4.6.2. Discussion	190
4.6.3. Findings.....	191
5. Chapter 5 Conclusion	194
Annex	200
Bibliography	208

Figures

19	Table 1 Macro-level, meso-level and micro-level organizational structures
101	Figure 2 - IBC Members by Geographical Sub-Region
104	Figure 3 - IBC Members by Country
105	Figure 4 - IBC Members' Professional Backgrounds
110	Figure 5 - IBC Members' Affiliations to Bioethics Committees or Associations
116	Figure 6 - Reports Produced by the IBC
126	Figure 7 - Excerpt from a Concept Note cover page
128	Figure 8 - Sample of an Invitation for Written Consultation on the work of the IBC
128	Figure 9 - Excerpt from a Compilation of Written Submissions on the Concept Note
133	Figure 10 - IBC & IGBC Members Who Returned Written Submissions
135	Figure 11 - Composition of the IGBC (2014-2015)
136	Figure 12 -Program of the 21st Session of the IBC & IGBC
137	Figure 13 - Time each speaker took to make their statement in the discussion session (displayed in the order in which they made their statements)
140	Figure 14 - Table of Contents of the Final Draft on the Principle of the Sharing of Benefits.
168	Figure 15 - Technical Advisory Groups and their Functions
170	Table 16 - Current and Previous SAGE Working Groups
179	Figure 17 - SAGE Member Composition
190	Figure 18 - SAGE Decade of Vaccines Working Group Members

1. Chapter 1: Setting the Scene – Studying International Organizations and Knowledge in Global Governance

1.1. Introduction

“It would be possible to describe everything scientifically, but it would make no sense; it would be without meaning, as if you described a Beethoven symphony as a variation of wave pressure.”¹

— *Albert Einstein*

Praised as an archetypical scientist and exemplary expert in his field, Albert Einstein made significant contributions to physics in the first half of the 20th Century that still influence our understanding of the world today. However, his monumental scientific discoveries - also attributed to his sheer genius - have overshadowed a lesser-known side of his thinking: his recognition of the limits of the scientific endeavor and thus his contributions to the philosophy of science (Howard, 2015). His words in the epigraph imply that not everything that has a social value would necessarily have that value if it were interpreted scientifically. In today’s world where scientific discoveries, a scientific way of thinking and the use of scientific methods increasingly contribute to an understanding of

¹ Albert Einstein, *The Ultimate Quotable Einstein*, ed. Alice Calaprice (Princeton, NJ: Princeton University Press, 2010), p. 409.

natural phenomena, Einstein's perspective points to the role of interpretation as a (dis)connector between science and society. Understood in this way, it becomes possible to find social explanations for why science - in the form of ideas, knowledge and artifacts - at times develops slowly or other times rapidly, is accepted or rejected and often becomes controversial. Science has a lot to gain and lose when it is acclaimed for its positive effects, or criticized for actually/potentially disrupting a way of life. In this context in which science and society interact, it becomes important to understand how knowledge derived from particular interpretations in an otherwise pluralist world shapes the development of science and technology, defining when they are appropriate; and how it shapes scientists by defining the limits of their work (Wynne, 1992).

The study of politics in and of science and technology questions the assumption that science and technology interact with the world in an apolitical way. How science and technology depend on, and are influenced by structures of political and social order, human agency and competing interpretations of the world are thus central in understanding not only the connections between science and society, but also the power of knowledge in our world today. There is little doubt that scientific knowledge is playing a more significant role in policy-making and world affairs. The problem is that there is limited understanding of the dynamics at play when science interacts with society and disagreement about what kind of engagement improves the productive capacity of science while also contributing to better policy decisions for the benefit of society.

This dissertation focuses on the organizational aspects of public policy-making processes to better understand the power of knowledge. It seeks to add empirically to an understanding of how knowledge about societal problems comes to be, through an analysis of the practices of organizations at the interface of science and politics. The organizations examined here represent two advisory models from what is referred to herein as the global health science and technology regime. The first is the Strategic Advisory Group of Experts on Immunization (SAGE) and the second is the International Bioethics Committee (IBC). Both organizations produce knowledge aimed at informing and advising governments around the world and at influencing global medical and health practices.

1.1.1. Medical and Health Practices

Disease and illness continue to affect the global population in various ways and forms. In modern medicine, professionals draw on sophisticated scientific understandings of disease-causing viruses and bacteria and the human body's response to them. More recently, geneticists uncovered a world of causative genetic predispositions, the dynamics of gene expressions and the effects of genetic manipulation, made possible by the success at decoding the human genome. Public health activities and their emphasis on the social context have helped to develop an understanding of the effects of the social determinants of health such as culture, social inequalities, economic well-being and

political systems.² This perspective draws attention to the limited role of traditional medical care in the overall health of the population and the need for social determinants to be taken into account in health interventions. Most importantly the recognition of the social context as a cause of illness in itself has emphasized a need to reduce the social inequalities in health (Marmot 2005, 2008). A vast array of poor to well-functioning national health systems that include hospitals, clinics, laboratories, and public health services test, treat, and distribute technologies to their citizens. National health systems across the globe however consist of varying combinations of public and private entities and are governed by differing regulatory standards. Public and private organizations conduct research while straddling the contentious line between providing social goods and protecting their own economic interests. Moreover, healthcare practices are influenced by different understandings of health and illness, understandings of what constitutes health³ and by extension the ways diseases and illnesses are managed.

In many respects, expert medical professionals hold a privileged place in society commanding authority in matters related to the field of medicine and are well positioned to broaden the influence of biomedical

² See Evans, Robert G., Morris L. Barer, and Theodore R. Marmor, eds. 1994. *Why Are Some People Health and Others Not? The Determinants of Health of Populations*. Aldine de Gruyter. Their book examines the limits of health care interventions by probing the links between social hierarchy, the macroeconomic factors causing illness and other social factors determining population health.

³ For an analysis of the multiple meanings of health see: Blaxter, Mildred. 2010. *Health*. 2nd ed. Polity Press.

interpretations of health and illness. Their authority has not however remained unchallenged, furthermore, the governance of biomedical practices is a persisting concern, in light of what the practices mean for the integrity and essence of human life and the relative importance of these values to different communities around the world. For these reasons, as values become contested, the conditions create an uneasy relation between science and society. Expert authority also plays out in a broad global context in which the value of democracy, and by extension the ideals of human rights have gained a foothold in global discourses.⁴ Expert discourses interact with and are influenced by these ideas and both the experts and democratic governance continue to be contested forms of authority (Forsythe 2012).

The governance of the medical and health domain therefore covers a range of activities. These include the technical issues such as managing and developing medical procedures and techniques. the political, social and economic issues such as resource allocation and distribution, and legal and philosophical issues such as the moral and ethical aspects as well as the appropriateness of techniques and health interventions. Moreover, medical knowledge and biomedical interpretations of health compete with other forms of knowledge in a diverse global medical and health landscape that values the contested ideas of democracy and human rights.

⁴ In his book, *Human Rights in International Relations*, Forsythe discusses the predominance of a human rights perspective in international law and offers insights into how a human rights discourse often fails to improve conditions or creates different sets of issues when attempting to govern with these ideas.

1.1.2. Governing Beyond Borders

The spread and threat of diseases, the social and economic capital to provide solutions to many health issues as well as the transnational nature of the social determinants of health blur the physical borders of the state, thereby often requiring cooperation between states. Where state concern is lacking, the gap is often filled by collective state action through International Organizations (IOs), and by non-state actors such as Non-Governmental Organizations (NGOs) and philanthropic organizations. Regional and international institutions⁵ are developing around the Westphalian system in which individual nation states and their sovereignty are upheld. Institutions; public or private organizations; international non-governmental and philanthropic organizations; IOs; professional associations; large corporations; transnational civil society groups; treaties; networks as well as inter-governmental activities are developing on a global scale, consolidating international and multilateral⁶ arrangements in various shapes and forms. The constellations of activities do not only provide a means that make circumventing trans-

⁵ International institutions are understood in terms of the definition given in Rittberger, Volker, Bernhard Zangl, and Andreas Kruck. 2012. *International Organization*. 2nd ed. Palgrave Macmillan. They refer to the formal and informal sets of rules and processes that structure the relationships, interactions and expectations of people working on a particular policy issue' (Keohane 1989:3).

⁶ Multilateralism is discussed by John Gerard Ruggie in "Multilateralism: The Anatomy of an Institution," *International Organization* 46 (1992): 561–598.

border issues possible but also contribute towards the formation of networks of interdependence that help to create the conditions for globalization (Keohane and Nye 2001). Globalization is said to be ‘associated with the transformation or an ‘unbundling’ of the relationship between sovereignty, territoriality and political power’ (Held 2004), thus creating new sources of authority. It has been argued that these interdependencies and network arrangements contribute towards the creation of IOs. The impetus to cooperate is explained from a variety of theoretical perspectives. The central drivers, that have formed the basis of much of the work thus far in International Relations (IR) theorizing are interests and power. The pursuit of interests and power are seen as an explanation for why states opt to be a part of IOs in the first place. However, this view falls short of explaining how state interests form, how and through what mechanisms state interests change and the reasons why states choose to cooperate when there are no clear gains that can be identified especially under conditions of uncertainty (Adler and Haas 1992). There are thus different explanations offered by IR scholars for why IOs are created, and for state cooperation. The main theoretical propositions, namely driven through realist, institutionalist and constructivist conceptions of IR will be elaborated on further in this chapter.

Depending on the theoretic perspective, power lies between or within nation states, with agents and/or through the propagation of norms and ideas/knowledge. The traditional realist understandings of commands stemming from structures driven by the geopolitical formation of an either anarchical global order determined by competing state interests, or a hierarchical global order dependent on the power of a hegemon, is

challenged by cooperation through multilateralism. As a way of explaining cooperation beyond rationalist conceptions, a social constructivist perspective considers ideational structures as the internalized norms and rules that constitute actors' interests and identities (Rittberger, Zangl, and Kruck 2012:25), expanding the sources of change beyond behavior. Understanding the ways in which multilateralism affects issues over which states cooperate, such as science and technology, or health and disease management contributes to an understanding of these dynamic interactions between structures, agents and knowledge and between behavior, interests and identities in global governance. *Global governance* here refers to 'rule-making and power-exercise at a global scale, but not necessarily by entities authorized by general agreement to act' (Keohane 2006:3). Global governance includes the activities in which states participate through international institutions and multilateral arrangements and through which they participate in knowledge, norm and standard creation at the international level. It is also made up of a large variety of organizations that 'exercise authority and engage in political action across state boundaries' (Keohane 2006).

Global governance is here understood to be forming through multiple formal and informal arrangements with a multitude of sources of authority. The analysis draws on constructivist understandings of IR, in general and of science in particular, placing knowledge/ideas at the center of the analysis and emphasizing its relevance in global governance. Since the two advisory models studied here are closely associated with IOs, SAGE with the WHO and the IBC with UNESCO, the analysis draws on IR theories of global governance to explain their influence.

1.2. Aims of the Study

This research aims to examine the relationships between science, technology and society with an emphasis on the politics of knowledge production in global governance. The central theme of the research deals more generally with the power of knowledge in IR and the role of IOs in global governance. More specifically, the study casts the practices of the actors involved in knowledge production processes under the critical light of Science, Technology and Society (STS) scholarship, explaining the influence of expert knowledge at the global level as well as the politics in and of technologies for health and life science research & development (R&D) and their application. As such, the study rests on the assumptions that states and their relations as well as science and technology are socially constructed and knowledge and social order co-produced. The *co-production* idiom asserts that meanings and norms in society are characterized by the mutually reinforcing interactions between natural and social orders (Jasanoff 2004; Jasanoff and Wynne 1998). This social construction and co-production is understood to occur as power to shape the world emanates from multiple dynamic material, social and cognitive sources.

To elucidate these phenomena, this study examines two advisory models. These advisory models share macro-institutional contexts as they are part

of the same global-level structure i.e. the UN body. The most prominent difference is that they provide advice to two different entities within the UN's global macro-structure, namely to the WHO and UNESCO. It should be noted that vaccine program advice informs some of the work of other agencies within the UN system, including UNICEF and UNDP. Likewise, bioethical norms are taken into account in some of the work of other UN agencies such as the WHO and UNICEF. The differences in the organizational structure at this global meso-level will be taken into account in the analysis and examined to account for the differences in approach to the issue of science and technology governance at the global micro-level at which the advisory models sit. This is illustrated in Figure 1.

The advisory models are organizations situated within a global health science and technology regime. *Regimes* have been defined as 'implicit or explicit principles, norms, rules, and decision-making procedures around which actors' expectations converge in a given area of international relations' (Krasner 1983:2). 'They thus comprise a normative element, state practice, and organizational roles' (Kratochwil and Ruggie 1986). Examples of these are the trade regime, environment regime, oceans regime or the money regime (Ibid.). This perspective considers that the global health science and technology regime is a regime that is first and foremost interested in governing global health practices. They share the goal of reducing diseases and minimizing risks brought about through the application of technologies, while their aims are in essence to govern the development and application of science, technology and research. Governing here includes providing guidance on the use, limits and usefulness of science and technologies, monitoring

technological developments, research and its application, decision-making regarding resource allocations, the social aspects of technology application and incentives for compliance. The global health science and technology regime is defined here as consisting of experts, organizations, governments and other social groups who define what technology can/cannot or should/should not do to influence health and diseases in the global population.

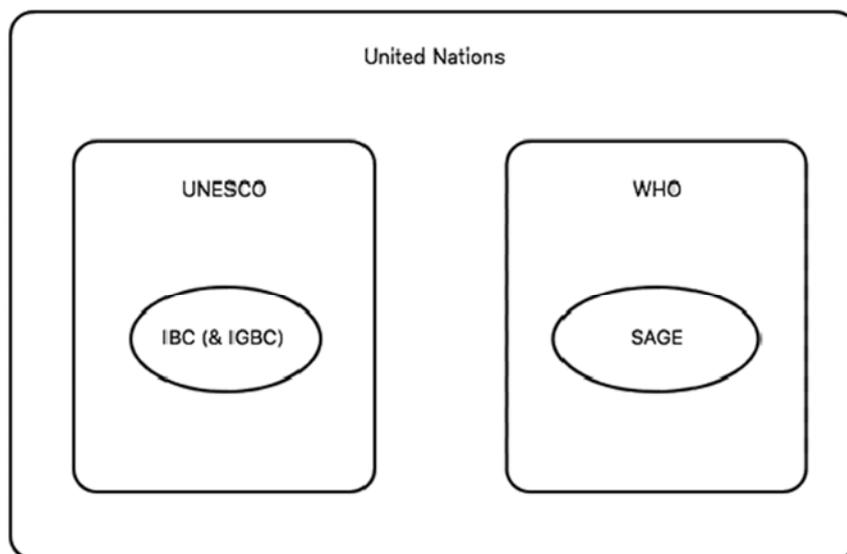


Figure 1. Macro-level, meso-level and micro-level organizational structures

Although they are conceptualized as part of the same governance regime, the two models use and produce different kinds of knowledge and produce knowledge in different ways. SAGE's work plays a role in

building knowledge on a specific biotechnological intervention with a view to applying science and technology as a solution to a particular problem i.e. combatting disease with vaccines. Their advice on vaccines and immunization science and policy relies on the use, the construction and synthesis of scientific data drawn from surveillance and monitoring that form the basis of problem definitions, the measurement of risks and adverse events and that form the basis upon which to determine the scope of issues. Their work also provides guidance on programmatic strategies and country context-specific issues regarding immunization interventions in which vaccine technologies are practically applied as solutions to combatting specific disease risks. This includes considering costs of vaccines; a consideration of the means of delivery of a vaccine i.e. injection or oral; the costs of implementing immunization programs or campaigns; identifying problems in the supply chains i.e. manufacturing, refrigeration etc; as well as building networks between donors, the pharmaceutical industry and governments. The application of vaccines and the conduct of immunization activities are then evaluated for their effectiveness in reducing disease burdens.

The IBC on the other hand plays a role in building an understanding of the risks and benefits of research and interventions on the human genome in the pursuit of health and combatting diseases. This organization governs the normative basis of science, research and interventions by setting norms and standards that are collectively agreed upon. In essence, they set standards on what research is permissible using the human genome. The experts (making up the IBC) and the government representatives (making up the Intergovernmental Bioethics Committee (IGBC)) consider bioethical issues – including moral and ethical concerns

- surrounding scientific techniques and technologies, focusing on the human genome in particular. The work that the IBC does sets norms that countries around the world are expected to uphold. The declarations developed by the group form the basis of UNESCO's education campaigns and the basis for the evaluation of the application of norms at the national level.

The analysis considers aspects of institutional design, including the people and organizational culture that make up the organizations. This includes analyzing decision-making processes and practices through which the actors validate knowledge as they develop recommendations for governments to act upon. Employing a discourse analytical framework informed by theoretical understandings derived from Foucault's ideas of power and knowledge, the analysis examines the power dynamics that lie in seemingly neutral language and particular understandings of problems and their solutions.

The advisory models are conceptualized using Boundary Organization (BO) theory, proposed by David Guston. Guston (2001) proposed that BOs 'straddle the shifting divide between science and politics'. The analysis of institutional design draws on the Principal-Agent (PA) framework borrowed from Rational Choice theorizing. As with the work of David Guston, the PA framework helps to structure the analysis and serves to frame the thick boundary description (Guston 1999). Guston's work and the concept of a BO puts into focus the notion of a separation between science and politics, challenging the assumption that scientific knowledge is pre-determined and in a sense 'pure' in policymaking. His ideas lie within a stream of STS, science studies and policy studies

scholarship that recognize the ‘impurity’ of scientific knowledge, and proposes that knowledge and thus public policies are instead socially constructed and co-produced.

BOs are said to facilitate interactions between the various stakeholders through boundary-work. Boundary-work is characterized as ‘the attempts to define practices in contrast to each other through demarcation, as well as attempts to find productive coordination through a division of labour’ (Hoppe, Wesselink, and Cairns 2013). In making these demarcations, boundary-work has been identified as operating in two ways, it tries to narrow the scientific domain, and at other times tries to expand it, depending on the agenda of who is doing the drawing (Jasanoff 1987). Boundary-work is thus defined by, and defines relations between actors and domains of knowledge through discursive and rhetorical means.

At the level of global governance, while the fields of medicine, public health, epigenetics, research in molecular genetics and genomics have made significant contributions to building knowledge about health and illness, there are a number of scholarly disagreements about how science and politics engage that this dissertation hopes to make a modest contribution towards.

The first debate questions how knowledge is established when science and politics interact. The idea of a boundary organization seeks to explain knowledge production through a co-productionist lens, viewing the social construction of knowledge as central to this question. Furthermore, insights from the discourse analysis are intended to draw attention to the power dynamics that bring about certain understandings in

science, technology and policymaking and that consequently silence others.

The second debate questions whether and to what extent experts are powerful. The analysis brings into focus power struggles by looking at who is involved in the knowledge production process. The analysis looks at the members of the group/committee, analyzing their expertise and influence to understand the underlying dynamics. Taking a historical view of the membership in conjunction with the kinds of knowledge and strategies the group/committee employ and the discourses they produce, the analysis seeks to understand the organizational culture and in what ways membership plays an active role in shaping that culture. The study also asks what the relationship is between experts and politics drawing on two different models, one with expert advice based on evidence-based and traditional-modern rationality in pursuit of efficiency and productivity and the other concerned with the institutionalization of, and expert advice on morality. It looks at whether it is possible to speak of epistemic authority as a function of institutional design.

The third debate questions how translating knowledge into practical use across the globe should be done and by whom. The analysis draws on boundary organization theory, critiquing the premises that BOs serve to facilitate the transfer of usable knowledge between science and policy. The analysis also serves to bring further insights on the premise that blurring the boundary between science and politics is necessarily productive.

The fourth debate questions whether and in what ways IOs matter. The

analysis looks at two advisory committees that are modelled to inform and advise governments through IOs. The analysis contributes to an understanding of knowledge as an important element in shaping global governance. Ascribing to the constructivist perspective of both IR and science, the analysis seeks to explain the relevance of BOs in constructing knowledge and social order and assessing to what extent this reflects on IOs' independent power.

By examining the means through which BOs facilitate public policy processes and the kinds of knowledge and discourses that are produced through their work, this research seeks to highlight and resolve a puzzle at the science-policy interface. The puzzle is that BOs are created to take the politics out of the policy process, yet it is unclear in what ways they best serve this role, by which means they produce neutral claims or, to the contrary, in what ways they contribute to the politicization of issues instead. This puzzle is set in the contemporary context in which experts as well as scientific knowledge play a central role in politics yet they no longer hold the unquestioned authority and public trust they once did (Maasen and Weingart 2005).

This study thus examines the dynamic interplay between science and society, with a focus on the organizational formations at the global micro-level science-policy interface, involving global experts in the politics of knowledge production. The insights contribute to understanding the ways in which knowledge is produced, how co-production unfolds and intends to contribute to resolving the puzzle stated above. Therefore, the overarching research question that guides the enquiry is stated in the following way:

How does institutional design influence boundary work?

This research question therefore focuses attention on the relations between experts, policy actors and other stakeholders, and examines the boundary-work – with its discursive and rhetorical devices – in the practices of BOs. The theory builds an understanding of the knowledge production process at the interface of science and politics. The following sections discuss the theoretical literature and the choice of theoretical perspective underlying this study, discussing the constructivist views of both IR, and of science and discusses how an STS approach compliments an IR approach.

1.3. Theoretical Perspectives in (Global) Governance:

This section reviews the academic literature which lends theoretical approaches and perspectives to the object of this study – BOs, and their role in global governance. The review justifies the conceptual approach to the study of IOs and boundary phenomena at the science-policy interface in international affairs. The review presents a framework which begins by outlining the main perspectives in IR theorizing. For this purpose, the following section lays out perspectives derived from the rationalist schools of thought, namely realism and liberalism, and discusses the theoretical basis of the constructivist perspective. The choice of approach taken in this study is explained, namely the perspective of social constructivism as an approach to understanding the role of knowledge in international affairs in general and the formation, role and influence of IOs in particular.

The study looks at practices, deconstructing and unpacking them in order to understand the underlying power dynamics in social interactions, thereby ascribing to the constructivist approach which seeks to explain relations between states as a social construct with a multiplicity of power dynamics including cognitive power, rather than as a system of competing states aiming to achieve their own material interests. The review will delve into global governance theory emphasizing constructivism which takes cognizance of this multiplicity by taking into account the construction and diffusion of norms, values and practices, seeing the heterogeneity of actors, processes and social interactions across contexts as sources and locations of power and influence.

1.4. From Rationalist to Constructivist Readings...

1.4.1. ...Of International Relations

WHO and UNESCO are specialized agencies of the United Nations system. Reeling from the devastation brought about by the Second World War, nations across the world were united in their desire for a more cooperative world order. In 1945, the United Nations was formed with the aim of dealing with the pressing issues that affect the international community: 'peace and security, climate change, sustainable development, human rights, disarmament, terrorism, humanitarian and health emergencies, gender equality, governance, food production, and

more' (United Nations 2016b). Currently, it has 193 states as members and functions through the main organs including the General Assembly, the Security Council, the Economic and Social Council, the Trusteeship Council, the International Court of Justice, and the UN Secretariat which were set up in 1945 (United Nations 2016a).

As IOs⁷ contributing to multilateral cooperation in the global political context, the role of WHO and UNESCO in international politics has long been debated. In attempts to understand IOs better, a variety of theoretical underpinnings offer explanations as to when, why and how states engage with each other at the international level and how IOs play a role in their interactions.

IR theory has two main schools of thought, amongst several, that follow rationalist epistemologies, namely realism, and liberalism. Rationalists see states as central actors in international affairs whose behavior is explained as self-interested and self-protecting as states face each other in an anarchic system (Barnett and Finnemore 1999; Caporaso 1992). For realists, self-sufficiency and the avoidance of exploitation are deemed important self-interests. They see conflict as inevitable and a need to defend state interests as central. States are seen as competing with each other for the maintenance of power which is largely driven by their material power, i.e. their militaries (Kegley, Jr. 1995). For realists power is exerted in a rational way, '[a] political policy seeks either to keep power, to increase power, or to demonstrate power' (Morganthau

⁷ International Organizations are understood to be 'international social institutions that are collective or corporate actors and can cover several issue areas of international relations' (Rittberger, Zangl, and Kruck 2012)

1960:39). For realists, '[s]ince the struggle for power and security follows objective laws, there is only one way of avoiding war, and that is to pursue a security policy based on the balance of power' (Morgenthau 1948 in Rittberger, Zangl, and Kruck 2012:16). The neo-realist approach (Waltz 1979, Keohane 1986) explains state relations in terms of states acting in their own interests in an anarchic global system, although from this perspective, state behaviors are explained as being driven by the structure of the system itself rather than human nature that classical realists view objectively and emphasize. In this understanding, 'states have to ensure their survival themselves, and states that do not orient their policy according to this self-help imperative will inevitably perish' (Waltz 1979:79-101 in Rittberger, Zangl, and Kruck 2012:16).

Realists argue that without any centralized government, international politics is operating in a state of anarchy in which states are then the central actors, and the source and location of legitimate public authority (Hall and Biersteker 2002). Thus IOs, international laws and global governance are deemed to be of limited use in their conceptions of state-centric interests and power in IR (Kegley, Jr. 1995). State behavior can be influenced but their interests and preferences cannot. IOs would be mere conduits of state power and their establishment and success largely dependent on the power resources of a hegemon (Rittberger, Zangl, and Kruck 2012). IOs would reflect existing interests of powerful states and maintain a balance of power. IOs are thus seen as tools in the power struggle between states rather than as having independent power to act or to effect change (Barkin 2006:8).

For neo-realists, IOs add little to the gains of cooperation since

cooperation is about pursuing relative rather than absolute gains (Rittberger, Zangl, and Kruck 2012). The only way IOs can be sustained is if the hegemon takes on the burden of costs, punishments and incentives. The hegemonic position would however be subject to realists' deeply held law of international politics that sees the hegemon rise and fall as a result of a loss of power over time. For this reason, realists expect IOs to reflect the interests of the powerful states, and expect them to be designed as intergovernmental rather than supranational organizations (ibid.).

Critics of the realist school found that 'the school's treatment of international organizations has been its emphasis on 'high politics', the question of peace and war, to the neglect of 'low politics' such as economic, technical and cultural relations' (Archer 2001:122). These neglected elements are important drivers that shape global politics. The realist point-of-view is further criticized for neglecting the legitimacy and authority of international norms and rules operating in the wider context (Hurd 1999). Furthermore, realists are criticized for emphasizing conflict instead of recognizing cooperation (Grieco 1995). Liberalism sits in juxtaposition to the realist claims, placing emphasis on the influences of globalization. The premises of liberalism suggest that cooperation is central to shared issues that transcend physical national borders, such as economic transactions, intercultural exchange and social interaction. Neo-liberalism offers a synthesis of the oppositions between realism and liberalism. Neo-liberalism emphasizes the cooperative nature of international politics, wherein it 'connotes global economic liberalization, privatization, market competition, and the pursuit of efficiency' (Ng and Ruger 2011). In a neo-liberal institutionalist perspective, states are also

assumed to act rationally whilst the international system is assumed to be anarchic. However, in this view international organizations transcend the state-centric anarchical system and the emphasis is on the importance of power differentials between states. Cooperation is understood to be driven by states' rational desire to avoid losses and reap joint gains by forming cooperative links and creating constellations of interests. To neo-liberal institutionalists, states cooperate in order to overcome market failures and cross-border issues. However, theory in both realist and liberal schools have been shown to fall short of recognizing the expressions of IO power. In viewing the influence of social life as a form of agency, a constructivist approach shows how IO power is exerted on and through the social world as IOs and their social agency influence the creation of actors, define their roles and responsibilities, create categories of activities and in doing so construct the social world.

A Weberian sociological approach to organizations has influenced the ways IOs are studied by some scholars. In this stream of research an emphasis is placed on IO bureaucracies as sources of power and independence.⁸ In this view a 'bureaucracy is a peculiarly modern cultural form that embodies certain values and can have its own distinct

⁸ Kratochwil and Ruggie (1986) reviewed this work on bureaucracies and found the most relevant to be: 'Kay and Skolnikoff, eds., special issue, 10 26 (Spring 1972); Robert Russell, "Transgovernmental Interaction in the International Monetary System, 1960-1972," 10 27 (Autumn 1973); Thomas Weiss and Robert Jordan, "Bureaucratic Politics and the World Food Conference," World Politics 28 (April 1976); Raymond F. Hopkins, "The International Role of 'Domestic' Bureaucracy," 10 30 (Summer 1976); and John Gerard Ruggie, "On the Problem of 'The Global Problematique': What Roles for International Organizations?" Alternatives 5 (January 1980)'

agenda and behavioral dispositions' (Barnett and Finnemore 1999). Studies of bureaucratic culture have brought to light the ways that IOs can exert independent power. Bureaucracies are seen to have authority which gives them autonomy. 'Weber's insights about the normative power of the rational-legal authority that bureaucracies embody and its implications for the ways bureaucracies produce and control social knowledge provide a basis for challenging [a realist] view and treating IOs as agents, not just as structure' (ibid.). Barnett and Finnemore (2004) define 'authority' as 'the ability of one actor to use institutional and discursive resources to induce deference from others.' Indeed, much IR theory presumes that states are the only authority as they possess sovereignty which is the basis of authority (Barnett and Finnemore 2004:5). Constructivists argue that sovereignty itself is a social construct. Thus recognizing bureaucratic power in cultural practices challenges a narrow understanding of authority, thus broadening the idea of authority. *Culture* is defined as:

'(a) a pattern of basic assumptions, (b) invented, discovered, or developed by a given group, (c) as it learns to cope with its problems of external adaptation and internal integration, (d) that has worked well enough to be considered valid and, therefore (e) is to be taught to new members as the (f) correct way to perceive, think, and feel in relation to those problems.' (Schein 1996).

The idea of an organization culture supports the view that IOs are social and contributes to an understanding of their autonomy and authority:

'Rather than treating organizations as mere arenas or mechanisms through which other actors pursue interests, many sociological approaches explore the social content of the organization-its culture, its legitimacy

concerns, dominant norms that govern behavior and shape interests, and the relationship of these to a larger normative and cultural environment. Rather than assuming behavior that corresponds to efficiency criteria alone, these approaches recognize that organizations also are bound up with power and social control in ways that can eclipse efficiency concerns' (Barnett and Finnemore 1999)

A sociological approach looks at the social structure of IR. Constructivist theory, indebted to Durkheim's concept of social facts, seeks to bring in and explain IR, organizations and knowledge as social constructs. *Social facts* come to be "whenever certain elements combine and thereby produce, by the fact of their combination, new phenomena, it is plain that these new phenomena reside not in the original elements but in the totality formed by their union" (Durkheim [1895] 1938, xlvii in Ruggie 1998). Social facts contribute towards defining reality. The basis of the constructivist perspective explains agency in IR and how '*the manner in which the material world shapes and is shaped by human action and interaction depends on dynamic normative and epistemic interpretations of the material world.*' (Adler 1997:322 italics in the original). Constructivism emphasizes processes of social interaction and interpretation and in doing so emphasizes the social construction of reality. The influence of ideas and knowledge are central to their view of international politics, which emphasizes a pattern of networked interactions across states and other actors that by virtue of being jointly-held understandings create cooperative behavior. 'Constructivists focus on the role of ideas, norms, knowledge, culture and argument in politics, stressing in particular the role of collectively held or "intersubjective" ideas and understandings on social life' (Finnemore and Sikkink

2001:391-3). Tracing the debates in IR, we see that in recent years, bold academic discussions have emerged around the theory of social constructivism in a context that was traditionally dominated by realist and liberal theorizing (Wendt, 1992)⁹. In IR, constructivism offers a “critical reflection on the limits of neo-utilitarianism” (Ruggie 1998). Neo-utilitarianism is a way of understanding preferences in self-interested and in efficiency terms. Constructivism sees interests and preferences as socially constructed, emphasizing the intersubjective nature of human action as people jointly interpret the world. A view of the social also offers explanations for why institutions persist despite failures at reaching specific efficiency objectives and unfulfilled interest objectives set out from the beginning. Constructivists argue ‘that international institutions play a vital, independent role in spreading global norms’ (Koremenos, Lipson, and Snidal 2001). Constructivism thus argues that states themselves are social constructs rather than naturally occurring entities and that ideas play a major role in the ways international relations are shaped and practiced. In essence constructivists see the international system as a collection of mutually agreed rules and practices that are both created and maintained. As such they are also concerned with how international norms, practices and rules affect domestic politics. Actors and organizations at both the domestic and international levels are viewed as being influenced by the social due to their ability to learn, adapt and through socialization as collective ideas spread. These mechanisms of learning, adaptation and socialization are key in the transformation and

⁹ Other constructivist theorists include: Emanuel Adler, David Dessler, Martha Finnemore, Ernst Haas, Peter Katzenstein, Elizabeth Kier, Audie Klotz, Friedrich Kratochwil, Thomas Risse, John Ruggie, Alexander Wendt. (Sil and Doherty 2000)

reproduction of international structures (Barnett and Duvall 2005).¹⁰

The traditional rationalist conceptions of authority and anarchy have thus been challenged from a variety of perspectives, that recognize non-material resources in the international system (Hall & Biersteker, 2002:4). These non-material resources include norms, cognitively shared values, ideational convergence and knowledge produced by international regimes; governance through conventions, treaties and contracts, and have facilitated an understanding of what has come to be termed as global governance (Hall & Biersteker, 2002:4).

In a context where a world government is lacking, the term *global governance* has come to be understood as the converging authoritative controls over transnational activities and transactions between different actors across the world. The traditional frameworks and idea of IR as an interstate system is appreciated more in terms of what James Rosenau calls “the crazy-quilt nature of modern interdependence” (Rosenau 1995). Global governance is understood to mean ‘governing, without sovereign authority, relationships that transcend national frontiers. Global governance is doing internationally what governments do at home’ (Finkelstein 1995).¹¹ The task of global governance is to:

‘discern powerful tensions, profound contradictions, and perplexing paradoxes. It is to search for order in disorder, for coherence in

¹⁰ For further discussion on this point, see also Katzenstein 1996; Risse 2001; Checkel 2001; and Finnemore 2003

¹¹ For a similar view see James N. Rosenau, Ernst-Otto Czempiel, 1992 *Governance Without Government: Order and Change in World Politics*. Cambridge University Press

contradiction, and for continuity in change. It is to confront processes that mask both growth and decay. It is to look for authorities that are obscure, boundaries that are in flux, and systems of rule that are emergent' (Rosenau 1995).

The challenge of conducting trans-governmental activities without a supranational government has facilitated at least the partial development of institutions to take on the task of creating stability, reliability, responsibility and continuity. In the current arrangement, the problem lies with the intergovernmental arrangement that characterizes global governance. 'The evolution of intergovernmental institutions to facilitate robust international responses lags well behind the emergence of collective problems with transborder, especially global, dimensions' (T. G. Weiss and Thakur 2010). At the same time, there is a proliferation of different kinds of transnational actors, the means through which transactions take place and the shape of global activities is influenced by multiple normative and practical interpretations of problems and ways of resolving them. Consequently, there are a variety of global issues that are amenable to change through agreements between states whilst there is a lack of effective enforcement mechanisms to ensure that they are implemented and maintained. This has meant that some issues that are unfolding in menacing directions are in need of more rigorous control, such as human cloning, terrorism, human trafficking or epidemics that require far more transparency from governments, more effective coordination and stricter regulation but the lack of jurisdictional enforcement mechanisms limit the effectiveness of global governing institutions, since the authority lies in the hands of state governments.

IOs have been viewed as a means through which states can overcome market failures, collective action problems and solve dilemmas requiring collective action (Barnett & Finnemore, 1999:700). There is however evidence to suggest that IOs sometimes stray from their intended and expected efficiency function and conduct themselves more independently (Ibid.). The question of authority and legitimacy in global governance is thus central to the question of how transnational issues are handled and who has the power and authority to influence global activities. While IO autonomy may seem to be a necessary and positive development, the latest financial crisis and criticisms towards the autonomy and power of the World Trade Organization, the International Monetary Fund and the World Bank illustrate how this can be of concern (Miller 2007:326). Legitimacy is central in understanding the reasons why state actors accept and comply with rules made collectively that do not necessarily serve particular interests, in a context where other actors will always have to respect the rule of non-intervention if some do not accept and comply with the rules (Hurd 1999). IOs, it is argued, have the power and authority to structure processes of reasoning and deliberation. How these processes of reasoning and deliberation are conducted so that both authority and legitimacy can be gained are viewed by constructivists as central to the analysis of power.

The BOs that will be analyzed in this study sit at the interface of science and politics capturing the processes of reasoning and deliberation. They are set in this heterogeneous context in which the authority, legitimacy and credibility of IOs are constrained by competing actors and institutions. The BOs bring together international experts, hosting discussions between a variety of communities, produce knowledge that

IOs use to develop their own agendas, and knowledge that IOs refer to when asking governments to consider particular actions on issues on the global agenda. Their role is to not only bring clarity to the issues needing attention by political actors but to help in constructing a global agenda for action in that specific issue area that the IOs are governing. They are thus analyzed through a constructivist lens that emphasizes the social construction of reality. The focus here is however on the centrality of knowledge and role of experts and expertise in international politics.

The following section will discuss the theoretical perspectives that have developed around scientific knowledge. It will elucidate the positivist perspective of science, that has characterized and dominated the theoretical landscape. The constructivist perspective will then be introduced as a contrasting view of science, one that challenges the nature of science as a self-containing, self-regulating practice that reaches absolute truths, by focusing on the social nature of scientific work.

1.4.2. ...Of Science

The dominant view of science regards it is a self-validating practice that stands alongside, but quite distinctively from ‘the babbling and agitating of the ideologues and of the politicians’ (Merton 1973)¹². In his seminal paper on the sociology of science, Robert K. Merton (1973) [1942]

¹² This essay was originally published as “Science and Technology in a Democratic Order” (1942).

described four virtues of science that affords the practice a special status in society. Describing the normative structure of science, Merton describes these virtues as:

1. *Universalism* which is the idea that science is independent of the people and place that produce it, it is instead impersonal and a general expression of a truth-claim.
2. *Communism* which is the idea that science is a product of social collaboration and thus a commonly owned good.
3. *Disinterestedness* that refers to the moral integrity of the scientist, and driven by the public and testable character of science and the accountability of scientists to their peers.
4. *Organized Skepticism* that refers to the collective peer group and any other authority that should always question the scientific claims made by any scientist.

Science was for the Enlightenment a useful technology that produced reliable knowledge. The technological manifestation of science served to validate the premise that science produced knowledge that no-one could question. Furthermore, the universality of the truth-claims more deeply entrenches the idea that science produces true knowledge since we tend to naturally accept the public view of things (Ziman 1974).

This normative landscape that grounded science for most of the 20th century progressively turned tumultuous as critiques of science by science studies scholars turned science itself into an object of study. Science as a disinterested, progressive, self-governing practice has come to be

challenged by observations of social influences in scientific work.

Bruno Latour (1999) explains that '[science studies academics] tell the scientists that the more connected a science is to the rest of the collective, the better it is, the more accurate, the more verifiable, the more solid... and this runs against all of the conditioned reflexes of epistemologists.' Rather than seeing science studies as an enrichment of science, offering a deeper understanding of science as a social activity, driven by a fascination with the making of facts and the historicity of facts and human experience, scientists have felt threatened by their claims, that seem to come in direct conflict with their own deeply-held beliefs about what science is. Unsurprisingly, many disciplines come to be canonized into silos in which discussions beyond disciplines and with other disciplines hardly take place (Jasanoff 1996b). When left unabridged, disciplines that are 'othered' often become shrouded by skepticism and distrust. Such was the experience with science studies and the entrenched scientific practices on the other side. The pinnacle of the battle of beliefs in what became known as the "science wars" culminated in the 90's (Moore and Hess 1999; Newton 1998). Scientists saw their 'reality' incompatible with the idea of subjectivity and contingency, to them, their facts are objective and real. At the same time, science studies posed a similar threat to the believers on the other end of the scale, the humanists. '[Science studies academics] tell the humanists that the more non-humans share existence with humans, the more humane a collective is, and this too runs against what they have been trained for years to bite at...they scream that the iron hand of objectivity is turning frail and pliable souls into reified machines' (Latour 1999).

For positivists¹³, the most persuasive methodology that science offers is inductivism. Inductivism sets out to find the truth, accepting scientific propositions that can be proven true from facts or, deductively or inductively, based on already proven propositions (Lakatos in Hacking, 1981). However, constructivists argue that '[t]echnical facts and artifacts do not become socially established merely because they are true or effective' (Brown, 2009). Tables, graphs, measurements, survey results and statistical charts *become* facts and objective pieces of information. It is argued that 'a fact is taken to refer to some objectively independent entity which, by reason of its "out there-ness" cannot be modified at will and is not susceptible to change under any circumstances' (Latour, 1986). Constructivists argue that facts are authoritative 'because they are validated through processes of informal negotiation and can be ranged into frameworks of shared assumptions and inferences. Social processes colour the extent to which pieces of scientific knowledge are perceived as certain, leading to differences in the interpretation of the same facts by scientists of different disciplinary training' (Jasanoff, 1987). Importantly, they recognize how facts and values intermingle in disputes arising at the frontiers of science (Jasanoff 1990).

¹³ Positivism involves: (a) 'a commitment to a unified view of science, and the adoption of methodologies of the natural sciences to explain the social world'; (b) 'the view that there is a distinction between facts and values, and, moreover, that "facts" are theory neutral'; (c) 'a powerful belief in the existence of regularities in the social as well as the natural world. This, of course, licenses both "deductive-nomological" and the "inductive statistical" forms of covering law explanation'; and (d) 'a tremendous reliance on the belief that it is empirical validation or falsification that is the hallmark of "real" enquiry' (Smith, 1996:11, 16, as cited in E. Adler 1997)

This gradual recognition of the social influences on scientific work form the basis of the growing constructivist literature. While I do build on a constructivist approach in this study, it is because I agree with the constructivists that science should not be taken-for-granted as a self-validating enterprise, that sits as a virtuous interest-free alternative to other forms of social activity. Like others in STS, I do not reject science completely, but rather advocate for more attention towards the implicit assumptions that science is free from all social bias and a need for a more nuanced view to uncover the hidden or implicit forms of power that science has over society when science and those who use it understand science in terms that the rationalist perspective holds as sacred.

Perspectives in the philosophy of science such as Thomas Kuhn's influential thesis on scientific revolutions¹⁴, and constructivist sociology of science (Law 2008) challenge the prevailing Mertonian logic of scientific rationality and its truth-claims. Scholars in STS are skeptical of the idea that there is one public view. For them, democracy lies in more situated and socially involved science (Brown 2009; Guston 2004; Hilgartner, Miller, and Hagendijk 2015; Hisschemoller 2005). Since social and cultural biases as well as interests can become so intertwined in the production, transmission and maintenance of particular ways of

¹⁴ Kuhn, Thomas S. 1962. *The Structure of Scientific Revolutions*. University of Chicago Press.

viewing and understanding reality, it is imperative to pay attention to the kinds of power, ideologies and reproduction of repressive systems that can develop. Their view recognizes how difficult it can be to produce alternatives when one way comes to dominate through the combination of ideologies in material forms (Bijker 2009; Klein and Kleinman 2002; Latour 1999).

STS scholarship is also concerned with how the pursuit of truth through science can on the one hand serve to drive its support blindly, giving undue power to those using it, and on the other hand could lead to undesirable consequences for human life, for example when race or individual abilities become the object of scientific reification. In such delicate situations, the question has become less about what science can explain and more about the implications of looking for scientific explanations. Given how difficult it is to undo technological systems once they are in place, scholars look at the ways in which more democratic involvement in decision-making processes can and should take place before the fact, including the representativeness of experts, expertise, knowledge and institutions (Brown 2009; Carolan 2006; Collins and Evans 2002; Emmerich and Halsall 2016; Hilgartner, Miller, and Hagendijk 2015; Howa 2013; Jasanoff 2003, 2008; Kelly 2003; Liberatore and Funtowicz 2003; Limoges 1993; Maasen and Weingart 2005; Martin and Richards 1995; Pestre 2008; Turner 2016). Given the economic, political and privatized contexts in which science is produced and scientists work, it becomes imperative to question the honesty of science and the level of trust that can be given to them (Gibbons et al. 1994; Jasanoff 1995a).

1.5. Conclusion

This chapter has outlined the aims of the study and discussed the different perspectives from which scholars from the rationalist and constructivist schools build theoretical understanding of IOs in IR. The constructivist perspective sets the theoretical framework for the study of knowledge, science and technology. The chapter also discussed the rationalist and constructivist views of science. The study looks at how science is used, discussed and understood in global policy-making contexts. With insights on the role of science in society, constructivist scholars are developing innovative ways of viewing the interface between science and policy. The next chapter discusses the state-of-the-art, reviewing the literature and presenting a way of studying these phenomena as boundary phenomena.

2. Chapter 2: Selecting the Tools – Crafting a Way of Studying Boundary Phenomena

2.1. Introduction

In the previous chapter, I situated the objects of study (SAGE and IBC/IGBC) as organizational forms at a micro-level within a meso-level organizational context (WHO and UNESCO) that is a part of a larger macro-level global governing structure (UN). Both BOs, I argue, contribute towards the global health science and technology regime that consists of experts, organizations, governments and other social groups who define what technology can/cannot or should/should not do to influence health and diseases in the global population. The chapter discussed the role of IOs in IR and discussed the differing points-of-view across theoretical perspectives, mainly between rationalists and constructivists. The chapter then discussed the differing perspectives of science. Rationalists see science as a self-governing activity that produces truth-claims because of its ability to claim objectivity and universality. In this view science is validated and becomes stable before it becomes generally accepted by the public. Constructivists, on the other hand, see science as a social activity, that is not completely devoid of subjectivity and that gains validity through social means. Science is seen to exert power in ways that are sometimes implicit or hidden because scientists, and often the public, take its objectivity for granted. Constructivists challenge the implicit asocial assumptions in understandings of the nature of science, and are interested in the details of how science is practiced and how it interacts with society. Without discounting its usefulness, constructivists attempt to lay bare the social processes which are hidden behind seemingly neutral science. Indeed, this is not to say that science is not useful, constructivists rather point to

the reasons why some claims hold while others do not, reasons why some questions can be answered by science while others cannot. They try to understand why differences abound in people's regard for science as a positive progressive force or as a fateful endeavor working against nature, asking how science works and how others become convinced of its 'workingness', and are curious about how conflicts are resolved and standards are made (Jasanoff, 1996:266).

The study looks at how science is used, discussed and understood in global policy-making contexts and the role of experts and expertise in policy discussions. With insights on the role of science in society, constructivist scholars are developing innovative ways of viewing the interface between science and policy. In this chapter, I present the state-of-the-art, reviewing the literature and presenting a way of studying these phenomena as boundary phenomena.

2.2. Why Boundary Phenomena? Perspectives on the Science-Policy Interface

Global, regional and national entities, including public and private actors, are already well into laying plans, policies and commitments towards improving health and combatting diseases worldwide, guided along by the solutions that science offers, its theories and models, or its explanations regarding causes and effects derived from the results of clinical trials and studies demonstrating the utility of biotechnological interventions. Scientists and policy-makers envision scientific futures in

which science plays a more pivotal role in healthcare, but they are also held back by a hesitance to change or alter the natural order of things. Scientific rationality, offers neatness, logical reasoning and clarity with which to execute health policies and programs, however public policies are often challenged by incongruent beliefs about what kind of action should be taken, that there are social, economic or political issues that weigh in, concerns that the science may be misleading by telling only part of the story, or that the technological fixes proposed may have disruptive tendencies to a way of life at an individual, or at societal level.

The study looks at two contexts in which science and technology are discussed and interact with policy. As mentioned previously, one model deals with the application of science and technology while the other with the ethical and moral aspects of research and development and each deal with particular kinds of science – vaccines research and its application and research on the human genome respectively. This section will look at insights into how experts, expertise and science and technology have been understood to interact at the science-policy interface. In many issue areas, the interface at which science and policy meets is poorly understood and under-theorized. One field in which theoretical perspectives abound is in the environmental field. Researchers are drawing on a broader STS analytical perspective to explain the interactions, and some of the insights that look to be the most promising will be discussed in this section.

Reasonable doubt has been cast on the idea that solutions lie in more and better scientific knowledge (Jasanoff 2004; 1995). Policy-makers have attempted a one-size-fits-all approach to policymaking, they have

implemented linear approaches whereby science serves to inform policy, and have believed that evidence-based policy approaches provide superior models. Researchers have however learnt some important lessons about the limited utility of these approaches to the science-policy interface.

One of the problems is brought about by the assumption that science can provide ready solutions to policy problems. Rittel and Webber (1973) described most public policy problems as ‘wicked’, i.e. the problem is contested and has no definable solution, and therefore, ‘[i]n order to *describe* a wicked-problem in sufficient detail, one has to develop an exhaustive inventory of all conceivable *solutions* ahead of time.’ [italics in original] (Rittel and Webber 1973). Therefore, a linear understanding of a known solution leading to the resolution of a particular problem is challenged by the understanding of complexity, uncertainty and value divergences in policy-making.

2.2.1. Problems with the Linear Model of Policy-Making

The science-policy interface has often been seen as a place at which there is a transfer of science to politics (Davies, Nutley, and Smith 2000; C. H. Weiss 1979). This view sees research moving from basic to applied research, to the development phase, then to application. When science and policy meet, science should be ‘on tap’ whenever policy-makers, who are ‘on top’, call on science to provide answers to policy problems. This model values science in the Mertonian sense, seeing it as objective and neutral. The linear model however assumes that science and policy-

makers are to some degree aligned and that science produces policy-relevant solutions. However, research has highlighted some of the shortcomings of this model.

Silk Beck (2010) analyzed the Intergovernmental Panel on Climate Change (IPCC) and argues that by using a linear model of expertise, or a model that “speaks truth to power”, the process led to a depoliticizing of politics and a politicizing of science instead. This he contends happened because the linear model of expertise constrained the scientific and political debate about a particularly political concept of ‘adaptation’. He argues that ‘[i]ts real importance for society is obscured and the political debate fails to address the core societal, political, and cultural problems involved’ (Beck 2010). Instead the discussion led to proxy debates about the scientific evidence which narrowed the discussion to the question of whether there was enough evidence to warrant a particular political action, thereby stifling discussion of alternative policy approaches. Beck based his assumption of linearity in the model on three propositions. That the IPCC believed that:

- More research will necessarily lead to more certainty (the linearity of knowledge production).
- More and better science will help to solve political disagreements (science as a harmonizing force).
- By keeping problems away from the political ‘whirl’ (Haas 1992), science makes policies evidence based and thus more rational. (Beck 2010)

Climate change was seen as a technical issue, that could be solved with technical solutions. However, as has come to be understood, climate

change is a ‘wicked’ problem, it is unstructured, rife with uncertainty and the societal side of the debate is not well articulated (Hoppe, Wesselink, and Cairns 2013).

The IPCC has been criticized for giving economists a major voice in the assessment process. However, they are also criticized for avoiding controversy through consensus which was enhanced through the centrality of apolitical scientific models. In doing so, the IPCC has been criticized to a point where some may charge that it is becoming irrelevant as an environmental policy actor:

‘The big problem with the IPCC’s output is not the widely levelled charge that it has become too policy prescriptive or is captivated by special interests. Its main affliction is pabulum – a surfeit of bland statements that have no practical value for policy. Abstract, global numbers from stylized, replicable models get approved because they do not implicate any country or action.’ (Victor 2015)

In much the same way, the criticism of the Framework Convention for Climate Change (FCCC) has been linked to its ‘highly technocratic, linear view of environmental policy making’ (Boehmer-christiansen 1994:152). It is seen as a success for a small group of computer modelers and the scientific bureaucracy. The effect has been that ‘[w]ith the FCCC ratified, more basic research can be directed by governments and justified with reference to global change and a need for more knowledge before any action is taken’ (Boehmer-Christiansen 1994:152).

The linear model has proven to be inadequate since the expectation in

policy-making is that science is capable of solving policy problems in most cases. It also assumes that policy emerges when, and because, there is a scientific understanding of a particular phenomenon (Jasanoff 1987; Pielke 2004; Sarewitz 2004). Research shows however, that the science-policy interface is far more complex than that.

2.2.2. The Case for a Separation of Science and Power

Another problem at the science-policy interface stems from the tendency to take science and policy as separate domains of activity. Science is seen as an activity conducted by expert scientific practitioners; they produce scientific and objective knowledge while policy communities tend to act in interest-driven ways, calling on science to provide clarity to the problems that they face. The tendency has been to believe that too much science will result in highly technocratic dominance over policy issues that policy-makers would not find useful, while scientists would fear that an encroachment of politics into the scientific domain would result in the politicization of science. A separation between the two domains is thus believed to serve as a safeguard against such encroachments. When science fails to influence policy, building bridges between science and policy, improving communication between scientists and policy-makers and better translation of science for policy-makers are often seen as a solution to this problem (Andresen and Skjærseth 2007; Lidskog 2014).

Scholars have looked deeper into this question of why only some attempts to change policy succeed and have looked into it from a variety of perspectives. One problem points to the importance of how the scientific community is defined. Is it some kind of interest group, a culture or an organization? And how should we envision the role of scientific facts? Are scientific facts used strategically by different actors? Or do they play an independent role in solving societal issues?

When the scientific community is envisioned as an interest group, it is taken to act in much the same way as an NGO, or an actor that tries to influence policy by confronting other normative arguments. NGO strategies, social movements, issue coalitions, and expert communities are some of the main actors that are seen to compete for policy influence through their appeals to norms, values and knowledge. Regime theorists see state interests as central to negotiations and thus argue that only science that is interest-specific and aligned to state's interests would have the potential to influence policy. Science is used as a resource in such negotiations (Lidskog and Sundqvist 2015). It is instead the idea that there is a process of learning that helps the convergence of state interests that lead to the formation of international agreements, rather than the power of the science itself. Knowledge communities can become powerful agents in this context, however, state interests are still regarded central and so scientific communities would have limited influence overall. The question of authority is central to this issue. Two questions stem from this line of thinking: should science be authoritative? And to what extent is science authoritative?

IR scholars have argued that by science being more autonomous and

independent from the policy context, science has a greater potential to influence policy (Haas and Stevens 2011:131). The epistemic community approach (Haas 1992b) suggests that science plays an independent role in policy-making and that the scientific community should be insulated from politics.

Epistemic communities are defined as ‘a network of professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area.’ (Haas 1992a). Haas contends that along with state power, epistemic networks have the ability to shape interests and thus play a crucial role in international governance. They help states define their goals, bring clarity to the issues at hand and define the solutions. Haas and Stevens (2011) argue that scientific communities should define their own agendas and select the most accomplished experts to serve on their committees, and that those experts should not be chosen by states, but rather on the basis of their merit. In doing so, the committees will appear more legitimate. The epistemic community approach sees consensus as lying in the domain of the scientific community; if the scientific community sets its agenda independently based on the consensus within the community, it is more likely that they will produce credible science that has less potential of becoming politicized on the grounds that the scientific evidence falls short of answering the policy question. As states solicit advice from these epistemic communities, who are deemed capable of producing information that states need, ‘[t]he members of the prevailing community become strong actors at the national and transnational level’ (Haas 1992a:4).

In subsequent work, Haas argued that political actors at times are skeptical of the truth-claims that scientists produce and that at times they do not listen to them at all. Haas argues that ‘power rarely listens to truth’ and he suggests conditions that could be linked to the few times that it actually does. Haas calls the route from truth to power ‘circuitous’, citing the reasons as follows:

1. Science isn’t wisdom (or true). Science studies scholars dismiss the prospects of objective knowledge about the world, and stress the political dimensions to science and science policy.
2. Science is politically tainted and suspect. Organized modern science embodies implicit values of control, so that decisions made with scientific warrants may unconsciously reflect such hidden values. In addition the distributional consequences of science-based advice are themselves political (Jasanoff et al. 1995; Miller and Edwards 2001). Science is political in its consequences, because some benefit and others suffer as a consequence of policy options that are supported by the application of scientific understanding. To the extent that those affected by the use of science in formulating policy are not consulted in its development and application, the use of science is potentially regarded by those affected as an illegitimate and exploitative set of discursive practices (Lidskog and Sundqvist 2002).
3. Power doesn’t care about truth anyhow. Politicians don’t want science; they want a justification for pre-existing political programs which are driven principally by political anticipations of gain (Miles 1998; Nelkin 1979). (Haas 2004:571)

In light of the problems that stem from the complex nature of science,

Haas identified what he calls ‘usable knowledge’. Usable knowledge:

‘encompasses a substantive core that makes it usable for policy-makers, and a procedural dimension that provides a mechanism for transmitting knowledge from the scientific community to the policy world and provides for agency when theorizing about broader patterns of social learning, policy-making, and international relations.’ (Haas 2004:573).

Haas contends that epistemic communities that produce usable knowledge are able to influence the policy process. He argues that the epistemic community would however need to use *existing* knowledge for this purpose. This is knowledge that has been developed and settled by consensus by epistemic communities. Haas argues for existing knowledge as usable knowledge because he sees that with most new knowledge saliency and credibility conflict, due to the long time it takes to produce credible knowledge in comparison to the short-term needs of policy-makers.

In recognizing the failure of sustainability governance to take in the multiple social, economic and environmental concerns, the international sustainability development agenda expanded to take into account the need to address these issues simultaneously. The policy context shifted towards a more transparent and participatory approach to promote inclusiveness and to encourage the diverse stakeholders to take up the policy recommendations. They also incorporated more integrated modeling that took into account a variety of different academic disciplines as well as a more systematic approach towards impact assessments that promoted a wider view of the planning and policy formulation issues (P. Haas 2004:570). However, Haas concludes that

‘the IPCC is designed to keep science on a tight leash by controlling the selection and autonomy of individual scientists engaged in the assessment process. Consequently, the degree of usable knowledge generated by the IPCC has been limited. And not surprisingly IPCC scientists have been unable to exercise sufficient discretion to develop more politically tractable advice.’

There is a core of basic consensual knowledge about the problem and though this does highlight the distinctive role that knowledge can play, it is limited by the weak institutional structure. Strong institutions, Haas argues, are important for producing patterns of social learning.

2.2.3. Saliency, Credibility and Legitimacy: When Knowledge is Used

There is a growing body of work in environmental governance that takes the criteria of accurate and politically tractable knowledge to be the measure of the saliency, credibility and legitimacy of knowledge (Cash et al. 2002, 2003; Guston 1999; Keller 2010; Sarewitz 2004; Schneider 2008; Tuinstra 2008; William et al. 2010).

‘An assessment process or its products are salient, when the participants in a certain area of policy making perceive them as relevant to them and their decision-making situations’ (Siebenhüner, 2003:12).

‘An assessment is regarded credible by a participant when he or she is convinced that the facts, causal beliefs, and options outlined in the

assessment deserve to be believed. He or she decides that the information is either "true" or, at least, worth using instead of other information. For information to be credible, the recipient must be convinced that the facts and causal beliefs promoted in the assessment correspond to those that the user her- or himself would have arrived at had she conducted the assessment' (Siebenhüner, 2003:12).

'The legitimacy of an assessment will be understood as its ability to convince a participant that the goals pursued in the assessment correspond to those that the recipient would have used had he or she been responsible for the assessment' (Siebenhüner, 2003:12).

It is argued that organizations are more effective at policy change when they simultaneously enhance the salience, credibility and legitimacy of the knowledge they produce (Cash et al. 2003). These criteria have been studied in various issue areas and has mainly assessed the perceptions of end-users of knowledge to gauge how they view knowledge (Cash et al. 2002; White et al. 2010). Researchers also studied the design of assessment processes (Farrell, VanDeveer, & Jäger, 2001; D. Guston, 2001; Hilgartner, 2004; Tuinstra, 2008) to see how they produce salient, legitimate and credible knowledge and others have looked at the acceptability and use of the outputs (reports/recommendations) using different case-studies and different kinds of data (D. H. Guston, 1999; Mitchell, Clark, & Cash, 2006).

Some of the findings of the research identified *thresholds* at which the criteria can be balanced. This refers to the perceived deficiencies in any of the criteria, for example, of only achieving salience at the expense of achieving credibility and legitimacy. Organizations can also find *tensions*

between these criteria meaning that in increasing one aspect, another will be adversely affected. For example, increasing plurality may increase legitimacy but adversely affect salience if the topics become too broad as a consequence. *Complementarities* can be achieved whereby increasing one attribute can increase others. For example, increasing stakeholder participation can help to legitimate the policy process, create transparency which positively affects credibility and by increasing the sources of knowledge, it can increase saliency. Organizations may also create instances when *trade-offs* are necessary in order to meet these criteria. This entails ensuring that none fall below their thresholds and cause adverse effects that might result in a controversy or cause resistance against the policy (Cash et al. 2002).

In these terms, concern over the independence of scientific experts is translated into the question of whether saliency – a perceived political activity - can be attained without compromising credibility – a perceived (scientific) expert activity. Or in other words, would the attempt at achieving saliency, by connecting science to policy more closely, result in the lowering of the threshold for credible science? Keller (2009) has offered a compelling case for refuting the suggestion that credibility is compromised by attempts at achieving saliency, meaning that sometimes it is possible to achieve policy relevance without compromising the quality and scientific potency of the ideas and knowledge behind the policy. Studying these criteria is a useful step towards understanding the accuracy and tractability of knowledge. However, as with other studies, there are context-specific issues which do not permit the generalization of findings so far to other contexts and issue areas.

The case for a strict separation between science and policy has been strongly argued by IR scholars. Discernably, there is a case to be made on an ontological level – science and politics are in essence different things. Advocating for a separation may well help to create consensus and develop scientific expertise, leaving choices up to the most qualified to do so, and perhaps this is the better option in a context where such diverging values and interests abound. Attempts are being made to identify criteria by which to judge the accuracy and political tractability of knowledge. Perhaps as evidence mounts these will lead to a better understanding of the conditions that enhance these criteria and avoid the rejection or resistance towards policies that is often experienced. Perspectives are forming, however conclusions are difficult to draw given that there are significant differences in scientific and political practices across different issue areas and between organizational forms.

The following section turns to the STS literature in more detail to understand their approaches towards studying phenomena at the science-policy interface.

2.2.4. The Case for Blurring the Boundary Between Science and Policy

Contrary to the rationalist idea that the scientific enterprise is a self-contained activity and scientific experts by virtue of their expertise wield independent power - thus producing impartial scientific knowledge, some

constructivists argue that experts from the scientific domain along with experts outside it, policy-makers and the general public become jointly engaged in knowledge construction, what Jasanoff (2004) terms a ‘co-production of knowledge and social order.’ This constructivist view recognizes that knowledge depends on the social context for its meaning. Knowledge is therefore characterized by its interpretive flexibility.

STS scholars argue that science and politics are coproduced. Coproduction is an idiom which asserts that natural and social orders reinforce each other, thereby stabilizing understandings in a mutually reinforcing way (Jasanoff 2004; Jasanoff and Wynne 1998). At the science-policy interface, this has come to mean that science and policy mutually reinforce each other - ‘policy influences the production and stabilization of knowledge while knowledge simultaneously supports and justifies policy’ (Lidskog and Sundqvist 2015:6). This idea puts into question the assumption that science and politics are naturally in tension and, for observers to view the productive potential instead across the perceived strict divide (Keller 2010:358).

In understanding the coproduction of science and policy, a useful STS conceptualization is that of Stage Management (Hilgartner 2004). Hilgartner identified forms of strategic behavior that often hides coproduction. In a bid to improve credibility, forums may present a ‘front stage’ to the public that is well represented and maintains science and policy as seemingly separate realms. In the meanwhile, there are ‘back stage’ activities that are messy and mix the realms of science and policy. Stage management can elucidate the kinds of interactions that are presented and determine the kinds of connections and coproduction that

lie behind the ‘front stage’ that is presented publicly.

Another useful STS concept is that of Civic Epistemologies (Jasanoff 2005). These encompass the variety of ways in which the world is understood by different people and the ways in which nations are ‘acculturated into relatively settled forms of public knowledge-making and argumentation.’ (Lidskog and Sundqvist 2015:7)

Seen as a false dichotomy, STS asserts that science and politics are more integrated than traditionally conceived. As was explained in the previous sections, IR perspectives take as central the formal structures that reify these distinctions, calling for a separation between the two worlds and being concerned with the formal procedures such as membership and setting the agenda, whereas STS is concerned with the informal cognitive processes. STS looks beyond the formal structures to reveal the networks, connections and collaborations among actors, activities and spheres of influence that contribute towards hybridization or coproduction (Lidskog and Sundqvist 2015).

In their analysis of the differences between the IR approach and an STS approach, Lidskog and Sundqvist (2015) illustrate the case of the IPCC as one that is seen as more of a failure by the IR scholars and as a partial success by STS scholars. In order to bring some clarity to the ways in which an STS perspective could help in understanding the science-policy interface, I will briefly summarize their analysis here.

As previously discussed, Haas and Stevens (2011) contend that the IPCC

is designed inadequately to enable scientific autonomy. Not only does ‘government keep science on a short leash’ by appointing scientists, thereby limiting social learning that scientists could enable if they were given more authority, but governments also formulate the research agenda. Furthermore, the membership of the IPCC is biased towards the global North (Lidskog and Sundqvist 2015:11). In this view, science has failed to influence policy because it is too connected to the policy process, it is more about reaching compromises than being based on scientific consensus and it is therefore not producing adequate usable knowledge (ibid.).

From an STS perspective, the picture is different. Lidskog and Sundqvist (2015) contend that ‘STS sees the work of the IPCC as a partial success in terms of creating a shared scientific understanding of the climate issue’. They base this conclusion on several findings:

The first finding is that the IPCC has become a central and pivotal institution in the climate governance context - a finding made by several authors, including Hulme and Mahony (2010); Mahony (2013); Miller (2004); van der Sluijs (2010); Wynne (2010).

The second finding is that the IPCC has authoritatively and clearly defined the meaning of climate change. ‘[C]limate change is framed and defined as a political issue in pressing need of multilateral agreements and concerted political action with carbon emissions as the primary focus. This understanding of the issue has been successfully disseminated to political institutions, and few governments disagree with the assertion’

(Lidskog and Sundqvist 2015:12).

Thirdly, the design of the IPCC is being replicated for the Intergovernmental Panel for Biodiversity and Ecosystem Service (IPBES). This has been seen as an endorsement of its strength and role in world politics.

Fourthly, the IPCC's scientific authority has not lost credibility despite the many uncertainties in climate science. '[S]cientific uncertainty has even been used to give science a more central position in public discussions of climate change, not least because science is generally regarded as the institution best suited to competently interpret and address scientific uncertainty' (Lidskog and Sundqvist 2015:12-13).

The IPCC defined the problem and capacity of actors to address it, also defining the kind of knowledge that can be used to solve the problem and by making explicit the roles of science and policy in solving it. Science and policy are thus seen to be coproduced: 'science involves not only a diagnosis of climate change but also an understanding of society' (Lidskog and Sundqvist 2015). In essence, the science gives a perspective on how society operates.

The main problems with the IPCC that the STS perspective brings to the fore are the lack of public input and therefore a shared normative and cultural understanding of the world (Jasanoff 2010; Welsh and Wynne 2013). Also problematic are the ways it gains consensus through the expert assessment. The IPCC also produces a specific epistemology of

what it means by relevant knowledge. The way it frames knowledge and defines the problem of climate change basically limits alternative approaches.

The lack of attachment to civic epistemologies in the STS view is problematic, '[t]he existence of different civic epistemologies further complicates the argument that the IPCC's problems are caused by its lack of detachment from society; it is primarily connected to a rather small segment of society, and the meaning it assigns to climate change resonates poorly with broader social and cultural understandings of what matters' (Lidskog and Sundqvist 2015:14).

Lidskog and Sundqvist demonstrate how a more connected approach towards the science-policy interface brought about a more successful coproduction of knowledge and social order. The IPCC gained centrality in environmental policy without compromising its credibility. While I do agree with the added value of using the STS lens, it is however important to understand the hidden or even express forms of power in discursive practices. Therefore, I do agree with the premise that science should be closer to society and should be enhanced by taking into account the variety of civic epistemologies. However, given the power that is inherent in any form of dialogue, it will be helpful to understand from a Foucauldian perspective, how power is exerted through discursive means. Furthermore, I agree that the IR and STS approaches are complementary. An analysis of the formal structure, including the membership and their specific expertise are necessary to determine if there are any epistemological biases. A useful tool that has not yet been discussed in

much detail but that adds to the STS analysis by giving form to the definition, framing and the reproduction of structures of cognitive elements is through an analysis of boundaries. The following section deals with this in more detail.

2.2.5. Returning to the Boundary Question

Returning to the question of why study boundary phenomena? The case of coproduction has been presented and presents interesting avenues for studying the connections between domains of activity, groups of people, and spaces across multiple levels and contexts. How boundaries are drawn, negotiated and in some instances fixed, become interesting aspects when trying to understand the influence of knowledge in the global context.

Recognizing that science and politics are mutually reinforcing, STS scholars seek to understand the ways in which distinctions are made; how communities develop an identity; how experts derive their disciplinary character and how knowledge works in a way that makes classification possible. The notion of *boundaries* is used across the social sciences and offers a way of capturing the relational processes that work in the building of institutions as well as the multitude of social phenomena that come to be enacted. The idea of relationality is useful in understanding the rhetorical and discursive means through which distinctions are made

and the ways in which understandings of one phenomena come to be bounded up and fixed (Lamont and Molnar 2002).

Scholars have also found the use of the notion of *boundaries* to be a useful tool in understanding the interactions between science and policy. ‘The notion of boundaries is also an essential tool to map how models of knowledge are diffused across countries and impact local institutions and identities’ (Ibid.). Boundaries are also seen as a means of communication. Instead of enforcing division, they enable the circulation of knowledge and information; and boundaries facilitate the production of knowledge. In knowledge production, divisions enable classifications, that create inter-related categories as well as distinctions (S. L. Star and Griesemer 1989).

2.2.6. The Role of Boundary-Work

“Boundary-work”, a term coined by Gieryn (1983) is used to describe the ‘rhetorical boundary between science and some less authoritative, residual non-science’ (Gieryn 1983, 1995, 1998). This denotes the discursive means by which scientists attempt to demarcate themselves from others, how they define what scientific methods are, and how they reach claims that are deemed scientific.

Through boundary-work, science is able to establish authority. Gieryn

argues that ‘the boundaries of science are ambiguous, flexible, historically changing, contextually variable, internally inconsistent, and sometimes disputed’ (Gieryn, 1983:792), making room for them to be negotiated. Boundary-work captures this demarcation effort. Its flexibility is based on contingent circumstances and boundary-work is carried out through strategic behavior (Gieryn 1995, 1999).

Boundary-work is thus found in ‘the attempts to define practices in contrast to each other through demarcation, as well as attempts to find productive coordination through a division of labour’ (Hoppe et al., 2013). In making these demarcations, boundary-work has been identified as operating in two ways, it tries to narrow the scientific domain, and at other times tries to expand it, depending on the agenda of who is doing the drawing (Jasanoff, 1987). Boundary-work is thus defined by, and defines, relations between actors and domains of knowledge through discursive and rhetorical means.

‘The drawing and redrawing of the boundaries of science amount to credibility contests that employ three genres of boundary-work: expulsion, expansion, and protection of autonomy. Expulsion characterizes contests between rival authorities when each claims to be scientific. In this context “boundary-work becomes a means of social control” (p. 16), sanctioning the transgression of the (symbolic) boundaries of legitimacy. Expansion is used when rival epistemic authorities try to monopolize jurisdictional control over a disputed ontological domain. Finally, boundary-work is mobilized in the service of protecting professional autonomy against outside powers (legislators, corporate managers) that endeavor to encroach upon or exploit

scientists' epistemic authority for their own purposes (pp. 5–17)' (Lamont and Molnar 2002).

Boundaries are also stabilized through the use of “boundary objects” and “standardized packages”. Boundary objects (Star & Griesemer, 1989:387) are ‘physical objects that engage participants in joint deliberation’ (Schneider 2008), and since they are able to connect science and policy, ‘they are flexible enough to have meaning in both social worlds, and stable enough to travel back and forth between them’ (Turnhout, 2009:405). The boundary object concept ‘is particularly important because it underlines that boundaries are conditions not only for separation and exclusion, but also for communication, exchange, bridging, and inclusion’ (Lamont and Molnar 2002).

In the policy context, researchers have found the concept of boundary objects to be a useful means of understanding the kinds of communication tools and spaces that enable the production of knowledge and enable the coproduction of policies and activities. Boundary objects are seen to ‘deliberately blur boundaries between two or more distinct social worlds to allow all sides of the boundary to present their discussions in a way most favorable to their own perspectives and constituencies whilst leading to more productive policy making’ (Guston, 1999 in Franks, 2010:286).

Another useful conceptual tool to understand the forms of communication i.e. short meeting notes, summaries and reports is the notion of “standardized packages”. These are considered to be a set of ‘scientific

theory and a standardized set of technologies which is adopted by many members of multiple social worlds to construct a new and at least temporally stable definition' (Fujimura, 1992:169). Fujimura finds standardized packages to be better suited to stabilizing facts in comparison to boundary objects which are taken to be less robust than standardized packages. Standardized packages gain their robustness by the way that actors coproduce knowledge (Fujimura, 1992:168) and 'emphasize the collaboration between actors "to get work done"' (Guston, 1999:90).

2.2.7. Stabilizing the Science-Policy Interface with Boundary Organizations

Gieryn makes the claim that any agreements made at the science-policy boundary are always temporary (Gieryn 1995:406). Scholars have responded by offering boundary organizations as a mechanism that enables the temporary stabilization of the boundary between science and policy (Affolderbach, Clapp, and Hayter 2012; Guston 1999, 2001b; Guston et al. 2000). Boundary Organizations (BOs) are seen as organizational forms that sit at the interface of science and policy and perform the task of coordinating the needs of both sides. The relationships that are built are those of mutual trust as the boundary organization acts as an agent to two principals – the scientific principals and the policy principals - doing the bidding for both sides while

maintaining accountability to both sides at the same time (Guston 2001a). BOs coordinate and delegate tasks and activities to the two sides, while ensuring the communication and mutual understanding of scientific and policy objectives using boundary objects and standardized packages and through performing the coordinative tasks through boundary-work.

The idea of a boundary organization rests on the assumption that science and policy are coproduced and in need of coordination. They provide the context through which salient, credible and legitimate knowledge are established by acting as a forum for the negotiation of scientific and policy needs. It is argued, that by straddling the shifting divide between science and policy, the boundary organization manages, coordinates and institutionalizes activities, creating stability at the interface (Agrawala, Broad, and Guston 2001).

BOs have been found to have a positive impact by impacting on the efficiency of the decision-making process. In cases with especially heterogeneous experts and a diversity of opinions, BOs help to reduce the diversity of opinions and help build consensus or agreement (Boissin 2011). BOs can act as legitimate entities that enable the discussion of uncertainty. By virtue of their own legitimacy, the knowledge they produce can be seen to be acceptable. Design of these BOs thus play an important role in providing this legitimacy for the production of knowledge that both science and policy find mutually acceptable. In dealing with uncertainty and ambivalence, BOs can act as coordinators and do the boundary-drawing when they are seen to be legitimate in the eyes of the principals, thereby reducing the likelihood of either side being

seen to taint the knowledge production process for their own interests.

BOs are seen as institutional arrangements that transcend the idea of science speaking ‘truth to policy’ and they are an institutional response to the existing plurality of scientific and normative perspectives of the world with a deeper appreciation of uncertainty in many issue areas.

The notion of a BO was first developed in a national context (Guston 1999), however, it has been applied to numerous contexts and has been seen as a useful means of conceptualizing interactions at the science-policy interface. In the literature so far, BOs exhibit different configurations of actors and differing means of incorporating interested and affected stakeholders and the public in decision-making processes. This multiplicity is not easy to manage and has posed a significant challenge, particularly to global entities (Cash et al. 2002, 2006; Cash and Moser 2000).

This research situates BOs in the context of global governance but posits that they are connected to multiple levels and jurisdictions through their embeddedness in IOs. Therefore, the BOs are straddling the boundary between science and politics and they are embedded in a context that coproduces knowledge in a complex network of interactions of actors with different interests, values and norms. An expert body that is more deeply connected through various interlinkages through one of the UN agencies, warrants further study since UN agencies are connected to national constituencies, with far-reaching programs at the regional and local levels, thus making way for the study of complex multi-level

interactions.

2.3. Studying Boundary Organizations: The Tools and Methods

The study employed a mixed-method approach, collecting data via interviews, direct observations, and document analyses. The first phase of the research involved direct observations of key meetings of the committees. The SAGE meeting took place at the WHO headquarters in Geneva¹⁵ and the joint IBC/IGBC meeting took place at the UNESCO headquarters in Paris.¹⁶ Permission to attend was sought in advance from both Secretariats. In the case of the IBC, permission was gained to attend the Joint IBC and IGBC sessions which were open to the public with

¹⁵ see SAGE meeting report October 2014 at:
<http://www.who.int/immunization/sage/meetings/2014/october/en/>

see SAGE meeting report October 2015 at:
<http://www.who.int/immunization/sage/meetings/2015/october/en/>

¹⁶ see the Joint IBC&IGBC 2014 meeting report at:
<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/ibc-sessions/twenty-first-and-joint-session-paris-2014/>

see the Joint IBC&COMEST 2015 meeting report at:
<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/ibc-sessions/twenty-second-session-and-ninth-session-of-comest/>

permission to attend, however access was not permitted to the closed IBC sessions.

The two case studies selected for this study vary in institutional design. In terms of membership of the expert groups, SAGE is considered more closed because it incorporates a limited set of experts who share basic epistemological understandings of nature. These include medical doctors, and health practitioners. The IBC is considered more open in expert membership, consisting of philosophers, lawyers, medical doctors, university professors, geneticists and micro-biologists.

They also vary significantly in terms of their epistemological perspective, SAGE is interested in the practical application of a particular biotechnological intervention. The discussions of their appropriateness are limited by the scope of their epistemological gaze, which sees vaccines as an appropriate technology for lowering the risks of disease contagion. The IBC on the other hand is concerned with the normative and moral and ethical aspects of emerging technologies and techniques that act on the human genome. Their epistemological gaze is broad, requiring an in-depth and pluralist approach to arrive at legitimate conclusions about the appropriateness of techniques and technologies that will impact on diseases in individuals.

The ways in which these organizations incorporate experts and the representation of Member States differ. The IBC holds meetings annually for the expert groups. Every second year, their meetings incorporate the IGBC which is a group of representatives of national ministries from 36 countries. Although SAGE does not formally incorporate Member States

that in their deliberation process, they do rely on the World Health Assembly, that is made up of government representatives to ratify their recommendations and suggestions made towards the work program of the WHO in the area of vaccines and immunization.

The study aims to draw out the role and purpose of the BOs in global governance and in doing so, build on the perspective that sees IOs as both relevant actors, and as producers of knowledge that can be a source of independence. One observation concerning the BOs that are studied here, is that they are designed in different ways, and so too are the IOs within which they are based. The study considers aspects of their design: who is included, or more precisely their expert membership and how the interactions between the expert and policy communities are laid out. The analysis also looks into the kinds of knowledge that are included in deliberations, that make their way into the knowledge production processes, and those that come out of it.

2.3.1. Incorporating a Structural Analysis: A Principal-Agent Approach

For rationalists, institutional design is important, since they hold that IOs ‘are the result of rational, purposive interactions among states and other international actors to solve specific problems’ (Koremenos, Lipson, and Snidal 2001). Such rational arguments place states squarely at the center of the decision of how IOs should be designed, seeing design as a relevant

feature that impacts on the way IOs perform their functions. Rational design choices provide a tool with which to study the boundaries that are created between expert and policy tasks.

The study will look at the ways in which the BOs relate to their stakeholders and in doing so discuss the implications of their role and influence on IO autonomy. The BOs will be subjected to the same line of reasoning as the IOs for the purposes of this analysis. The research will assess the institutional design of the BOs and discuss its implications on autonomy. Rational choice theorizing employing the Principal-Agent (PA) framework has been found to be useful in understanding autonomy as well as in theorizing the relationships between stakeholders that are engaged in a hierarchical structure wherein one party performs a task on behalf of another, particularly between organizations and states (Barnett and Finnemore 1999). The analysis intends to draw out these relationships by applying a PA framework. In this case, the framework will be discussed in order to describe the BOs and their agency. Thereafter, the discussion will turn to the implications of the analysis on IO autonomy.

PA theory assesses relationships between actors as if they were parties that entered into a contract with specified rights and obligations (Guston 1999). Parties undertaking a task (agents) are performing tasks on behalf of the actors to whom they are accountable i.e. states (principals). The political-economic theory of PA, suggests that there are two problems that are encountered in such a relationship that are brought about by the problem of delegation: 'adverse selection' (or hidden information) and 'moral hazard' (or hidden behavior). The problem points to the lack of

oversight of the agent that is not possible because the principal needs the agent to undertake activities that the principal itself is unable to carry out. In a doctor-patient relationship for example, the principal would be the patient and the agent the doctor. The doctor possesses specialized skills that the principal needs but is lacking the expert capacities that the doctor has gained and is unable to gain without undertaking the necessary training. The principal must then trust that the agent is qualified and will give the best advice. To avoid the problems of delegation, the agent could be subject to monitoring and offered incentives in their delegatory role.

BO theorizing suggests that the PA relationship exists between the BO who is the agent to two principals – the scientific community and the policy community. In the case of SAGE, the IO (WHO) and states have delegated a role to the BO (SAGE). For the IBC, the IO (UNESCO) and states have also delegated the task to the BO (IBC). This role - to provide advice on behalf of IOs in the science and technology regime is particular. The principals are not only states, but they include a variety of policy actors including the IO itself. For SAGE, INGOs, NGOs, philanthropic organizations and international funding agencies additionally make up the policy community. For SAGE, the scientific side consists of the principals including scientific communities, research institutions and biotechnology firms.

This is not a new approach to the study of BOs. Guston (1999) analyzed the Office for Technology Transfer, a US-based technology transfer agency, conceptualizing it as a BO and examined it through a PA framework. The assessment combined PA theory and boundary-work

which was found to be complementary when examining phenomena at the science-policy interface, ‘providing structure to the thick boundary description’ (Guston 1999). Guston argues that BOs stabilize the boundary between science and politics by bringing stability to a science-policy relationship that was in the process of being negotiated.

2.3.2. Analyzing the Knowledge Production Process: A Boundary-Work Analysis

The analysis will thus incorporate boundary-work into the analysis, examining the ways in which the scientific and policy domains are defined and meaning is attributed. The boundary-work will take into account the discursive and rhetorical demarcations in knowledge production. Boundary-work, proposed by Gieryn (1962) is understood here to refer to those strategies that characterize boundary-drawing struggles in socially engaged interactions between actors, institutions, science and different ways of knowing. Rather than seeing knowledge as having independent power, constructivists consider values, norms and culture to play a role in the production of knowledge, including scientific knowledge (Keller, 2009). Boundaries in this sense act as exclusionary devices (Eden, Donaldson, & Walker, 2006), creating a dualistic form of knowledge, for example ‘when scientists define their own domain as scientific, the work of those outside of this domain is defined as unscientific and/or irrelevant’ (Lidskog & Sundqvist, 2002).

Boundary-work has found useful application in policy contexts, more specifically in the strategic demarcation between political and scientific tasks (Jasanoff, 1990). The popular view of the relationship between science and politics is that scientists aspire to ‘speak truth to power’, while policymakers want ‘politics on top and science on tap’. STS scholars theorize that the role of boundary-work is ‘to coordinate these apparently incompatible aspirations’ (Hoppe, Wesselink, & Cairns, 2013). Critics of the dualistic, exclusionary view of science and politics (as well as science and other forms of knowledge), argue for a more open, democratic knowledge production process.

The study analyses process and power relations in a second way, which adds to the rational-choice approach as an explanatory mode, by providing a constructivist critique of the *modus operandi* of boundary organizations, giving way to potential change such a task creates. A Foucauldian reading offers a means to develop a shift in focus which ultimately has the potential to change the way power is configured in a social setting. A Foucauldian reading looks at the power of rationality and the power wielded by those in powerful positions. To Foucault, ‘[p]ower is only a certain type of relation between individuals. Such relations are specific, that is, they have nothing to do with exchange, production and communication, even though individuals combine them. The characteristic feature of power is that some men can more or less entirely determine other men’s conduct – but never exhaustively or coercively’ (Noam, Chomsky & Michel, 2006:208). Such a perspective draws on the idea that the Western state system and its institutions operate as a form of ‘pastoral [power], whose role is to constantly ensure, sustain,

and improve the lives of each and every one' (Foucault:185) which is an idea he developed considering forms of governing from even before the Enlightenment. He explains this as, 'the development of power techniques oriented toward individuals and intended to rule them in a continuous and permanent way. If the state is the political form of a centralized and centralizing power, [he says,] let us call pastorship the individualizing power' (Noam, Chomsky & Michel, 2006:175).

In this study, the state and international institutions working for the state are such forms of centralized power governing individuals. Culture is a form of power as is the form of 'governmentality' exhibited by morals and ethics. Through a post-structuralist lens, interpretations and assumptions are interrogated, with rationality brought into particular focus. It builds on the idea that culture is more than the everyday classifications of social objects and scientific facts, but has changed and these changes have come about by the questioning of power such classifications and facts have over individuals. Therefore, what becomes important are the oppositions, the different viewpoints, which viewpoints come to dominate and how that takes place. This allows for the analysis of legitimacy in competing knowledge claims and the meaningful production of knowledge. How consensus comes about, both political and scientific, as either a scientization of politics or a politicization of science become central to the analysis and the means to balance them would be the aim. In this way, pluralistic accounts of reality, or civic epistemologies can be analyzed as competing cultures in which knowledge, meaning, values and norms are embedded in power relationships which can be deconstructed to understand how forms of

knowledge gain dominance over others and how knowledge is instrumentalized by states and institutions.

This Foucauldian account of power would complement the PA analysis and the boundary-work analysis by adding a more critical view of the implicit power of the various forms and functions of boundary-work. The critical stance of boundary-work is in agreement with Foucault in that ‘the creation of classification schemes by setting the boundaries of categories “valorizes some point of view and silences another” (Bowker & Star 1999, p. 5), reflecting ethical and political choices and institutionalizing differences’ (Lamont and Molnar 2002).

2.4. Conclusion

This chapter outlined the different approaches to the study of the science-policy interface, discussing the central question that considers the separation or blurring of the boundary between science and policy. The chapter demonstrates the value of an STS perspective and discussed the ways in which the boundaries will be studied. The study will look at the configurations that structure the organizations, employing insights from Stage Management to identify hidden coproduction. It looks to analyze the two case studies, SAGE and IBC as Boundary Organizations, analyzing boundary work as well as the use of boundary objects and

standardized packages. The analysis will look at the power relations that are implicit in boundaries. A further insight will be gained on how far the BOs incorporate civic epistemologies and contribute towards a more democratic form of governance.

The approach offered by STS, takes the critique of social constructivism a step further than the IR insights do. Unlike constructivist arguments that see science as needing to be separated to gain authority, and that still relies on the value of consensual knowledge developed by the scientific community for that authority, the STS perspective challenges the absolute reliability on the vetting process by the scientific community and they acknowledge the coproduction of science and social order. Because STS assumes that science is socially constructed, scholars thus place the source of failed attempts at policy influence on the failed attempts at implementing specific understandings of the nature of science and therefore see these failures as unsurprising. To them, what matters most is that science is representative, situated and inclusive, so as to incorporate a just societal virtue, taking into account civic epistemologies and the value of broad consensus models. STS focuses on the democratic, participatory legitimacy of policy processes asking questions such as: ‘Can the scientific advisory process be organized in ways that further public participation but do not lead to the capture of science by political interests?’ (Jasanoff 1990) and asking how scientific communities can remain neutral: ‘Can scientists be more deeply involved in the regulatory process without risking their political neutrality, or, worse yet, actually make policy, and thereby eroding democratic controls on decision making?’ (Ibid.).

3. Chapter 3 – Institutional Design of UNESCO’s Bioethics Governance Apparatus: A State- Centric Model?

3.1. Introduction

There is as much modern uneasiness about putting scientists in a position to make ethical decisions as there is about releasing them totally from such responsibilities. On the one hand, many contemporary areas of ethical choice implicate such technical knowledgeability that few but the possessors of relevant expertise can hope competently to address the issues involved, while, on the other, it is not now supposed that those who have expert knowledge are ethically privileged or more likely to make virtuous decisions than anybody else in our society... That, indeed, is a way of stating the problem... Authority to speak on what is true is disengaged from authority to speak on what is good.

- S. Shapin (1995:388)¹⁷

¹⁷ Shapin, Steven. 1995. “Trust, Honesty and the Authority of Science.” In *Society’s Choices: Social and Ethical Decision Making in Bioethics*, eds. R. E. Bulger, E. M. Bobby, and H. V. Fineberg. Washington, DC: National Academy Press, 388–408.

This chapter presents the institutional design of the IBC and defines the advisory role that it plays. Furthermore, this chapter analyses the practices at the science-policy interface in terms of boundary-work. I argue that the IBC can be analyzed as a BO that manages the science-policy interface through rhetorical and discursive strategies. The analysis draws out these strategies in order to understand the mechanisms that enable internal deliberation, enable boundary management and enable mediation. The IBC considers science through a rights-based approach which broadens the interpretation of science as a universal social good and in so doing broadens the audience to whom science is made to matter. The IBC therefore creates space for a broad societal discussion and contributes to a broad agenda. By analyzing the organization using a PA framework, I argue that not only is the IBC an agent to two principals i.e. the scientific and policy communities, but it is also an agent to an IO (UNESCO). An analysis of these relationships seeks to establish how the configuration of the BO characterizes its function and its navigation of science and policy boundaries.

The chapter will bring empirical evidence to bear on the question of how institutional design affects boundary-work. To respond to this question, the chapter will discuss the science-policy relationship that the BO is bringing stability to. Thereafter, the chapter discusses the ways in which the BO stabilizes the boundary through boundary-work. At the same time, the analysis will take into account the power relations and means through which power manifests in the activities and practices being undertaken by the IBC.

In the epigraph, Shapin (1995) draws our attention to the problem of scientific authority, essentially pointing to the insufficiency of relying on expert scientists to make decisions that necessarily demand ethical judgements. This problem is particularly stark in bioethics. Given the need to address the moral and ethical concerns that biotechnology bring up, bioethics could potentially play an important role in defining the limits within which human engagements with scientific research and biotechnologies are admissible and more importantly in limiting the power of science in shaping human experience. Bioethics is regarded as a multi-disciplinary endeavor. The hybridity of expertise involved in defining these limits of biotechnology necessitate boundary-work that contribute to what Jasanoff (1987, 1990) calls the discursive “repurification” of knowledge into discrete categories of science and politics – a strategy that in turn contributes towards the credibility of experts (Kelly 2003).

Where possible, scientific experts provide an understanding of the mechanisms and outcomes of the scientific and technical issues involved in scientific and biotechnological research, and are a necessary source of awareness and understanding, while in contemporary global affairs, democratic representation stands as a conveyor of the needs and values of the public – the source of permission. However, to what extent should research be allowed when a full understanding is not guaranteed and who is to judge that a full understanding of all possible outcomes of research is reached? How should governments regulate science so that it is productive yet does not over-step the boundaries of social acceptability

that different communities and wider society might disagree over? How should permission be sought when the implications might affect an entire community, future generations and/or society at large and not only those with the willingness and ability to consent? These are some of the dilemmas faced in governing scientific research and biotechnologies. There are no clear answers, however there is a growing recognition that their resolution cannot be left to medical and scientific experts alone. In Michel Foucault's terms, the techniques of science-based ordering of human life, along with the governance of life and human bodies through science, is the exercise of 'biopower'.¹⁸ The non-trivial nature of categories, have the power to influence the articulation of scientific categories into standardized forms that enable the enactment of discourses and agendas, such as disease reduction (Jasanoff 2005:248). For this reason, science and biotechnology have the potential to shape human experience in profound and powerful ways. Bioethics works to limit this biopower since '[t]he authority of bioethics...nonetheless rests in its discursive repurification as distinct from, and a corrective both to the unbridled authority and privilege of, science' (Kelly 2003:345).

The need for expert scientific input as well as the need for the permission of the global community present a troublesome dilemma for bioethics and the governance of science and research. The task of undertaking certain kinds of research/interventions is complicated by the need to understand 'admissibility' in moral and ethical terms. Furthermore, research entails the need to inform, and to obtain the 'permission' from subjects who may

¹⁸ Michel Foucault, *Madness and Civilization: A History of Insanity in the Age of Reason* (New York: Vintage Books, 1973); *The History of Sexuality* (1976); *Discipline and Punish: The Birth of the Prison* (New York: Random House, 1979).

directly/indirectly be affected by a course of action(s). These challenges are particularly difficult in the global context. Permission implies that the subject is fully aware of the technical aspects as well as the consequences of particular research/interventions. Permission is thus complicated when there is a lack of awareness or understanding of the ways in which research and interventions do have an effect on the integrity of human life. Moreover, with limited enforcement mechanisms, international institutions have weak power over states and their differing legal cultures. Here the idea of *civic epistemologies* helps in articulating the complexity of governing biotechnologies at the global level. Jasanoff (2005:248) argues that ‘it is the three-cornered relationship among science, state, and society that gives the politics of biotechnology its cultural specificity.’ She argues that cross-national variation in politics and policymaking can be explained by the idea of civic epistemologies. The concept moves away from the assumption of what the public should know about science, instead to how they know what they know about it. Communities, in other words, have:

‘shared understandings about what credible claims should look like and how they ought to be articulated, represented, and defended—and these understandings vary across well-defined cultural domains such as nation-states...Public reasoning, then, achieves its standing by meeting entrenched cultural expectations about how knowledge should be made authoritative’ (Jasanoff 2005).

So while some kinds of knowledge may appeal to some communities in terms of robustness, accuracy or any other quality or measure of credibility, the differences that exist between countries in the ways that

they interpret and act on the same knowledge contribute to the difficulties faced in drawing up standardized, universal policies and knowledge claims.

3.1.1. Science-Policy Instability and the IBC

To understand the science-policy interface at which the IBC operates, this section presents the science-policy relationship that the IBC has sought to manage. The science-policy relationship can be seen to contribute to the way that the IBC is designed and the way that it practices boundary-work. The instability at the science-policy boundary that the IBC initially set out to manage can be traced to its recognition of the tensions arising from the biomedical, scientific, social, legal, political and economic influences on, and extending from, research on the human genome. On the one hand, scientists argue that progress in genetic research has the potential to enhance the understanding of diseases and their remedies. On the other hand, tinkering with the genome could have profound and even damaging effects. The scientific community stands to gain if research brings about a better understanding of diseases and cures, however, they could instead produce changes to the genome through their research or reconfigure social norms that run contrary to wider societal values, for example by creating exclusionary rights through patenting. A common problem faced by the policy community is that they are largely unsure of the extent to

which research should be permitted, given that they often lack an understanding of the technical aspects of genetic research. They find themselves in a predicament since they should not however stifle progress if the results prove to be positive for the public. The scientific and policy communities therefore rely on each other but at the same time belong to two different social worlds; the scientific community trying not to tread on political turf which could bring about a politicization of science. The government, lacking complete information cannot fully trust scientists to be unbiased or to perform their research tasks on its behalf. Some governments contribute substantial funding towards genome research, and need to monitor and correctly incentivize research to ensure that scientists produce research that is in the interests of the public good. With the growing need to limit the negative effects of the globalization of biotechnology, even governments that do not fund biotechnology find themselves with a stake in genomic developments. These tensions that arise at the interface of research on the human genome and politics, define the role and function of the IBC. The instability at the science-policy interface, I argue, is stabilized by a BO that provides institutionalized social interactions between scientists and non-scientists. These institutionalized practices support interaction and interdependence and provide a space for engagement in boundary-work.

In addition to the IBC's role and function to manage the tensions between the scientific and policy communities, UNESCO itself plays a role in promoting collaboration in science through education, advocacy work and intergovernmental collaboration. This IO element has meant that as its agent, the way in which the IBC is designed and undertakes its specific

boundary-work relates to the institutional culture of UNESCO itself which encourages open, intercultural exchange and education, and centralizes the participation of Member States. These institutional design aspects and the science-policy relationship will be analyzed further in the next section.

The central work of UNESCO's Bioethics Program has sought to grapple with the tensions borne from the questioning of the kinds of moral authority needed to answer ethically contentious scientific and policy questions, a questioning of the role of expertise, and the means through which representative democratic mechanisms should be incorporated in the decision-making process at the global level. Moreover, the IBC has contended with the tensions between a scientific approach to bioethics and a political interpretation of bioethics. Bioethics, as will become clear in the discussion that follows, is not only about bringing clarity to ethical and moral questions around scientific issues, but it is also a political activity itself. An analysis of these tensions and the means through which the IBC manages them will form the core of the analysis of the interactions at the science-policy interface in the IBC.

UNESCO's activities in governing global science and bioethics are guided by its constitution which sets out its ambition to seek 'the intellectual and moral solidarity of humanity that is the only guarantee that progress in science will contribute to human flourishing, peace and security' (Ten Have in Bagheri, Moreno, and Semplici 2015:1). UNESCO's role in the post-war context is to emphasize the need for solidarity and collaboration across education, science and culture. These

broad aims of the organization and its particularly broad global and disciplinary approach to the governance of scientific practices makes it a useful case for understanding the dynamics of expert authority, as well as the interactions between science, politics and society.

This chapter is divided into two parts. The first section will develop a view of the institutional design and the organizational culture of the IBC. After introducing the context within which UNESCO's bioethics program came into being, an analysis of the ways in which UNESCO's bioethics program developed and how the composition of experts in the IBC changed over time will be presented. The analysis takes a historical view of its membership and the members' profiles, and details the ways in which meetings have been conducted as a means of drawing out the kinds of knowledge and perspectives that the members have brought into discussions. The analysis will highlight the ways in which the interactions with political actors and the public are structured, and outlines the output of these interactions. The second part of the chapter presents an analysis of the IBC as a BO, elaborating on the Principle-Agent relationship between the IBC, and the scientific and political communities. The analysis takes a micro-level analysis of the issue of 'Sharing of Benefits' as a means of illustrating the ways in which the IBC manages the science-policy boundaries through boundary-work.

PART I: Contextualizing the Committee

3.2. Global Bioethics: The Background

Until recently, medical ethics guided medical practice (Ten Have 2013). Medical practitioners, at first, were expected to be responsible as well as competent, guided by a set of ethical rules set out in the Hippocratic Oath. Debates and controversies surrounding the authority and ability of the medical profession to self-govern its practices have however become a focus of attention in the post-war era. The infamous 1946-1947 Nuremberg trials that saw 23 Nazi doctors implicated in the unethical treatment and use of concentration camp inmates as research subjects set the stage for the development of a set of global ethical standards for research practices that involve human subjects. The defendants' actions were evaluated against a set of standards called the Nuremberg Code that were developed, it is argued, largely by American judges (Shuster 1997). The main emphasis was on the principle of informed consent and an absence of coercion. Although the Code is still largely recognized as a cornerstone of ethics in scientific research, debate over its applicability in the modern context and its biased authorship have drawn much questioning over its authority (Katz 1992).

As a way of dissociating ethics from the Nazi experience, the World Medical Association (WMA) developed the 1964 Declaration of Helsinki which took into consideration and expanded upon the Nuremberg Code, producing guidelines for the medical community (World Medical Organization 1996). Whereas the Nuremberg Code focused on the human rights of research subjects, the Declaration of Helsinki emphasizes the responsibilities and obligations of physician-investigators towards their research subjects (Shuster 1997). It has been argued that these guidelines developed by the WMA are ‘the most widely recognized source of ethical guidance for biomedical research’ (Macklin 2003).

In the meantime, the WHO and UNESCO had set up The Council for International Organizations of Medical Sciences (CIOMS) in 1949. As an international non-governmental organization that represents the global biomedical scientific community, the CIOMS developed guidelines based on both the Nuremberg Code and the Declaration of Helsinki, but dealt with the omitted issue of cross-cultural considerations in research (Kim 2012). The main concern of their guidelines sought to protect research subjects in developing countries, which meant that through their guidelines fair standards should extend to all countries.

There were therefore a number of attempts at developing global principles to govern the practices of biomedical research that was taking place both within national and international contexts.

3.3. UNESCO's Bioethics Program

Since the 1970s, UNESCO convened symposia and hosted conferences on bioethics including on issues related to genetics, life sciences and reproductive technologies (Ten Have 2016:98). Its main impetus to establish a bioethics program came from its concern with genetic research, issues surrounding genetic data and concerns arising from the Human Genome Project (Solínis 2015:5). Of major concern in 1991, was the United States' National Institutes of Health attempt at privatizing and patenting the genome (ibid.). Under the then Director-General of UNESCO Federico Mayor, a Spanish Scientist by training, the IBC was established and inaugurated on the 15th and 16th September 1993 – the symbolic 40th anniversary of Crick and Watson's discovery of the double helix DNA structure. That same year, the United Nations Commission on Human Rights adopted a resolution that called on 'governments, the specialized agencies, and other United Nations bodies, and specifically UNESCO, to inform the Secretary-General of activities being carried out, in order to ensure that the life sciences develop in a manner respectful of human rights' (Lenoir in *International Bioethics Committee: Proceedings* 1994:5).

The IBC is managed by the Secretariat in UNESCO's Social and Human Services Sector that oversaw the Division of Ethics of Science and Technology. The Division was directed from 2003 to 2010 by Henk ten Have, a Physician and Professor of Philosophy and Medical Ethics. Dafna Feinholz, with training in Bioethics and experience working on

Bioethics in the Ministry of Health in Mexico, took over directorship of the Division in 2010 and in 2014 the Division was renamed the Bioethics and Ethics of Science.

The IBC has played a key function in steering UNESCO's Bioethics Program. Through the IBC, UNESCO has set a vision of bioethics that is broad and extends beyond the responsibility of scientists:

Bioethics is more than a discipline involving the sole responsibility of scientists. It is a democratic challenge, which must be shared by all members of a society, from the expert to the layman, because the resolution of ethical issues raised by scientific advances determines the way we live together. Societies' choices affect our future and the future of coming generations (Social and Human Services 2013).

The initial aim of the Committee was to conduct a global debate about the moral, ethical, social and human consequences of developments in the life sciences (Division of the Ethics of Science and Technology of UNESCO 1999). In the proceedings of the first session of the IBC, Noelle Lenoir, a Lawyer, member of the Constitutional Council of the French Republic and the Chairperson of the IBC at the time, stated that '[t]o control changes that are evolving faster than people's ideas about them, an international ethic for the life sciences and society needs to be developed' (Lenoir in *International Bioethics Committee: Proceedings* 1994:3). To meet this end, the first task of the IBC was to look into the social, political, cultural, ethical and legal aspects of research on the human genome:

Under its terms of reference, the International Bioethics Committee of UNESCO is required particularly to study the social, political, cultural, ethical and legal implications of research on the human genome and its applications. Operationally, its purpose is to promote practical activities in the field with a view to raising the awareness of all those involved. Last of all, it also has to give consideration to the preparation of an international instrument on the human genome (*International Bioethics Committee: Proceedings 1994*).

The establishment of the IBC was preceded by studies undertaken by a Scientific and Technical Orientation Group.

‘The Group conducted extensive consultations, focusing on five themes: genome research, embryology, neurosciences, gene therapy, and genetic testing. For each theme various dimensions were studied: the current state of progress in research at the world level, the application of the results of this research, and the principal ethical concerns for the present and for the future. On the basis of these studies, the Group identified the reference points likely to secure the broadest agreement, proposing principles that were most likely to respond to the ethical concerns.’ (Ten Have and Jean 2009:24).

The Group met eight times between January and July 1993 and its report set out ‘the major ethical and juridical problems raised by research on the human genome and its application’ (*International Bioethics Committee: Proceedings 1994:55*).

UNESCO's Bioethics Program works towards ensuring that all Member States are aware of the three normative instruments produced by the IBC (see section on Outputs of the IBC below), and helps States apply the provisions of the Declarations. This is done by encouraging the establishment of National Bioethics Committees and the expansion of ethics teaching programs. Dissemination of information through conferences and publications are another aspect of their work. The Division is tasked to raise public awareness and stimulate public debate around emerging ethical challenges in science and technology (Daar et al, 2006). Their goal is to have an influence at the global level and on national policies at the same time. Therefore, they attempt to bring about a broad consensus between states without becoming too tied down by the detailed attention to the myriad issues that different national contexts present. The Program is becoming more involved at national and regional levels in an attempt to improve its effectiveness at influencing national policies and practices (see discussion later on about Figure 5). Recognizing that Member States lack expertise, educational programs, bioethics committees, legal frameworks and public debate (Ten Have), UNESCO's Bioethics Program have launched a number of initiatives to support them in their development. One initiative was the establishment of a Global Ethics Observatory (GEO) which aims to gather information on bioethical and other ethical issues to enable Member States and other interested parties to identify experts, establish ethics committees, learn from each other's experiences and develop informed policies in the area of ethics, and design ethics teaching curricula.

The IBC also contributes to the work of other UN agencies through the UN Inter-Agency Committee on Bioethics (UNIACB) which was established in 2002. The IBC also advises on The Assisting Bioethics Committees (ABC) Project and the Ethics Education Program (EEP) trainings that aim to provide National Bioethics Committees (NBCs) with knowledge and skills to better manage their local bioethics programs (Joint session report 2014). As a part of the Ethics Education Program, IBC members along with representatives of the UNESCO Chairs in Bioethics, the Third World Academy of Sciences (TWAS) and the WMA sit on the Advisory Expert Committee on the Teaching of Ethics.

3.3.1. Appointing the Members of the IBC

The Director-General makes the appointment of the members of the IBC. The members can however be nominated by Member States, Associate Members, and non-Member States with a permanent observer mission to UNESCO, and the Director-General is required to take the nominees into account in the appointment decision. The Director-General should also take into consideration the cultural diversity in the selection and ensure a balanced geographical representation. The members should also come from a variety of specialties including the social and human sciences including law, human rights, philosophy, education, communication and the life sciences. IBC's 36 members are to serve as independent experts for a four-year period, renewable for only one additional term.

The Committee has a Bureau, which is composed of the Secretary-General of the Committee, the Chairperson, four Vice-Chairpersons, and a Rapporteur. The Bureau co-ordinates the work of the Committee and makes the logistical decisions such as the date, time and agenda of the meetings.

3.3.2. IBC Members: A Historical View

Between 1993 and 1997, the IBC consisted of around fifty members. Of the fifty-one members listed in 1996-1997, three were Nobel Laureates and four were Ministers in government. Nine of the IBC members were a part of a Legal Commission chaired by Héctor Gros Espiell a Law Professor, previous Minister of Foreign Affairs and former President of the Inter-American Court of Human Rights. Two additional experts were called upon as Advisors. This group of experts developed the first legal instrument on the human genome – The Universal Declaration on the Human Genome and Human Rights UDHGHR. It should be noted that during this period there were no restrictions on the number of representatives coming from one country, while the emphasis was on prominence of the individual in their field.

In 1998, heeding to the call from Member States for more institutionalized debate in which governments played a more inclusive

role, a parallel committee – the Intergovernmental Bioethics Committee (IGBC) was formed consisting of 36 government representatives. The rules of practice differ to those of the IBC and warrant mentioning here. The IGBC elects a Bureau consisting of a Chairperson, the Vice-Chairpersons, a Rapporteur as well as the Secretary-General of the IBC. Each member participates with voting rights.

The number of members of the IBC was also reduced to 36 experts and the selection rules changed to restrict the selection to one national representative per State. The data in Figure 2 Illustrates the balance of representation in the IBC by sub-region. The time periods were chosen to illustrate a more general trend of the IBC membership over time.

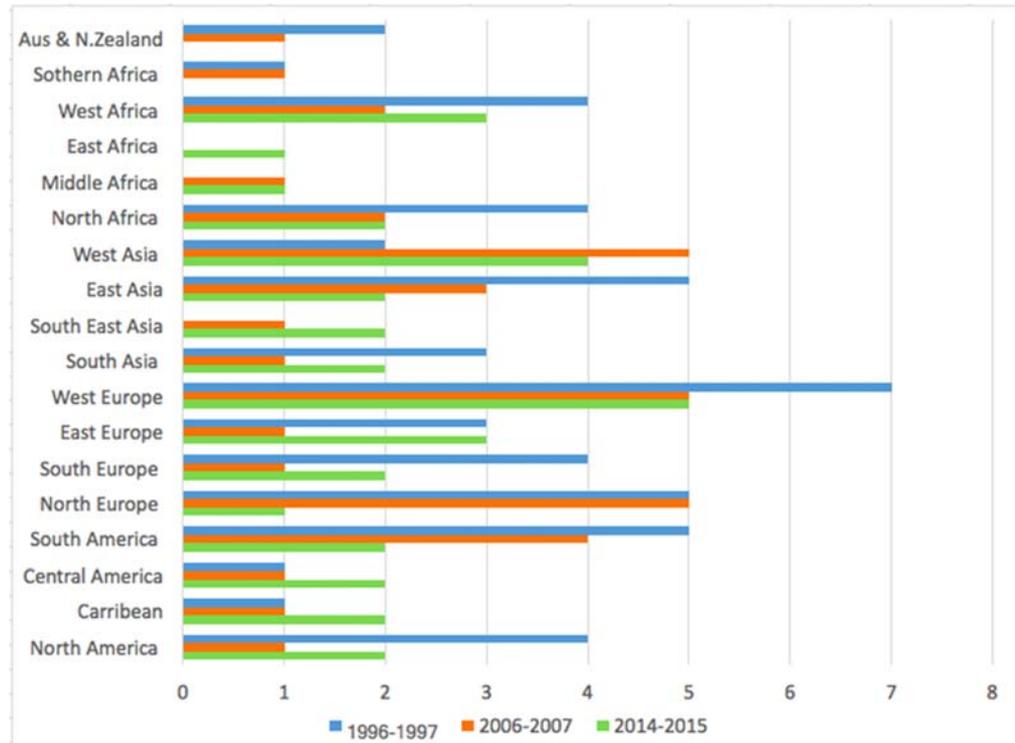


Figure 2 - IBC Members by Geographical Sub-Region

The data by sub-region indicates a persistent under-representation of the Southern, Eastern and Middle African sub-regions and a persistently high representation of the Western European sub-region. Together the European sub-regions had more representatives overall in all three periods. In 1996-1997, there were four members representing the Western Africa sub-region and four representing the Northern Africa sub-region. While the representation of the Western Asia sub-region has increased over the years, dropping slightly from five to four members between the 2006-2007 and the 2014-2015 time periods, the representation of the Eastern Asia sub-region has fallen over the years.

The Southeast Asia sub-region was not represented in 1996-1997 and had one representative in 2006-2007 and two in 2014-2015. In 2006-2007 there was lower representation of both Eastern and Southern Europe, and a higher representation of North European. For the Americas, representation of South America declined while Central America and the Caribbean had one representative each in the first two periods and two each in 2014-2015. In 1996-1997 North America had three representatives from the United States of America and one from Canada, however Canada was not represented in 2006-2007 and both were represented in 2014-2015. Figure 3 illustrates the national cultures represented by the members of the IBC.

Professional Backgrounds of the IBC Members

There is value in understanding the diversity of experiences and social connections that the individual members possess and the ways in which they connect with different ways of knowing in the global context. This can indicate which ways of knowing come to dominate and how individuals' experiences come to be significant in the eyes of the Bureau. For this reason, this section presents and analyzes the profiles of individual members which contributes to an understanding of changes in the organizational culture over time. The professional backgrounds of the IBC members and thus how particular disciplines are represented by the group is illustrated in Figure 4. The data compiled on the members incorporates a view of the professional profile of individual members.

The data is understood to represent the members' professional competencies and is based on their professional experiences. This data was retrieved from published IBC documents and additional data was retrieved from the Global Ethics Observatory Database that contains partial data on most of the experts.

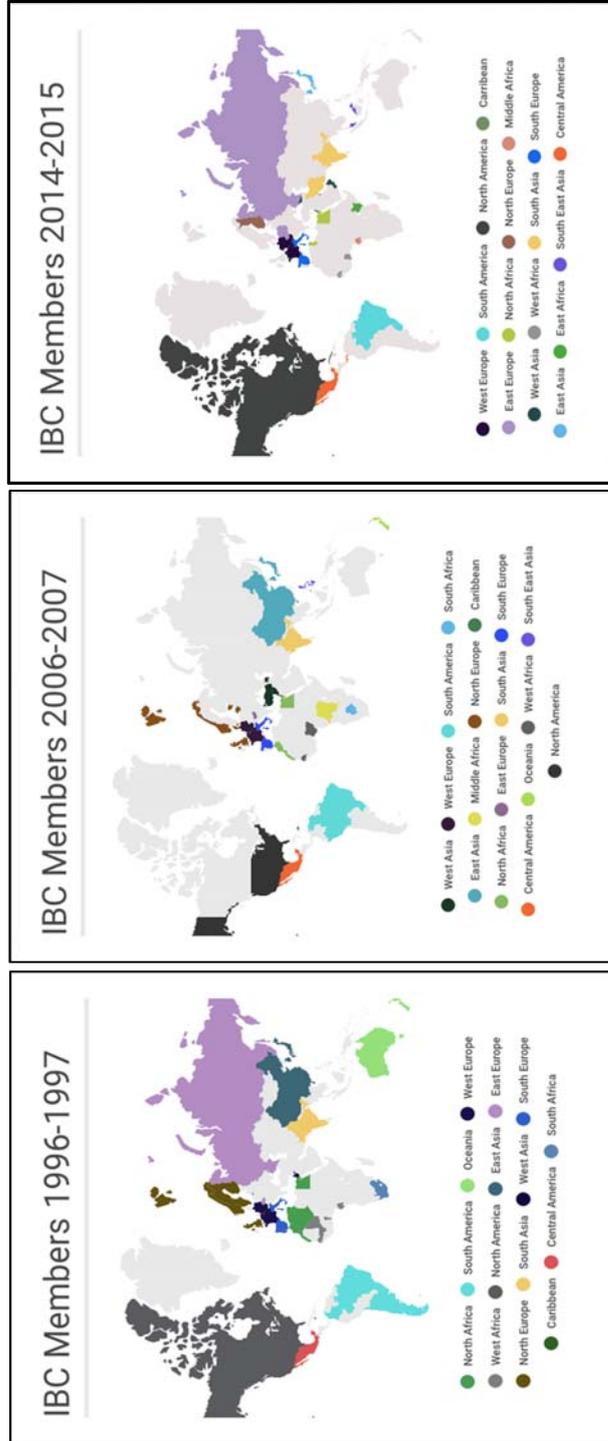
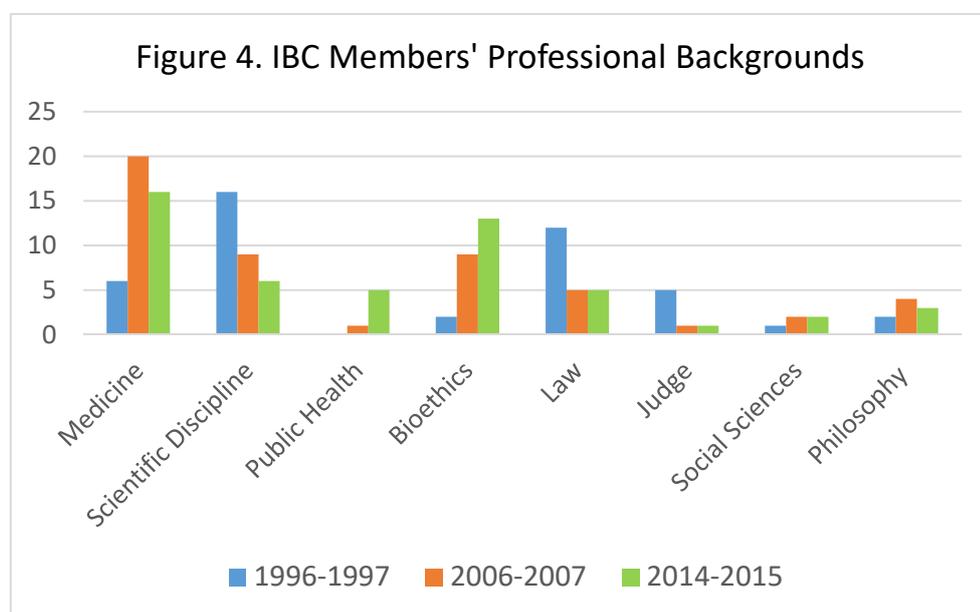


Figure 3. IBC Members by Country

It should be especially noted that some members listed multiple expertise and positions held in their past experiences therefore the data displays these multiple affiliations rather than assigning one discipline per individual.



From Figure 4, it can be seen that in 1996-1997 there were more specialists from scientific disciplines and with legal backgrounds than any other discipline. In 2006-2007, there were twenty members whose experiences associated them with the medical discipline, nine who were associated with a scientific discipline and nine who were associated with bioethics. The number of people who were identified in bioethics therefore increased over the three periods, while those identified with the medical discipline remained high at sixteen. Five members were identified as having experience in public health in the last period, up from

one in the previous period and none in the first. However, the number who were identified with experience in law decreased to six over the last two periods, with even fewer judges amongst the group as compared with the first period. The number of members identified as having backgrounds in social sciences was low and members who had backgrounds in philosophy remained low with two in the first period, four in the second period and three in 2014-2015.

As a group, most of the members felt that they are a pluralistic group, not lacking in expertise, although the idea of what it meant to be an expert in bioethics is not altogether clear:

‘[F]rankly I don't know that everyone who is thrown onto the IBC is an expert but its considered to be an expert committee. So if you were going to go to peers and ask them have you ever heard of these 36 people frankly I don't think they have ever published in bioethics, now some of them are from under-resourced countries where publishing is going to be difficult although frankly not as hard these days than 10 years ago given the internet. So we are experts by fiat.’ (Interviewee: IBC Member)

This statement brings up two issues. The first is that the members take their role in the Bioethics Committee to mean that they represent the discipline of Bioethics rather than different disciplinary specialties. The second issue is that there are different expectations of what it means to be an expert in their field. The statement was made by a member of the 2014-2015 cohort and the group does compare drastically with the very

high-powered and renowned members that made up the IBC in the 1996-1997 cohort. For example, the 1996-1997 cohort included two members with Nobel Prizes in Medicine, and one with a Nobel Prize in Chemistry, three Government Ministers and the President of the International Criminal Court. In an interview with the then Director of the Secretariat, Henk ten Have, he mentioned that part of the problem with having a group of highly accomplished experts was that Member States felt that they were unable to contribute much to the discussions since they were up against such powerful experts. This insight offers a further explanation for the choice of members on the committee.

The diversity of opinions and expertise is deemed a strength of the group, it encourages debate, brings about rich discussions and helps draw out the nuances from the different disciplinary perspectives. There is however, an organizational culture that develops over time.

‘[It is] important to have different views, with the same, it would be very dull, instead its rich and their engagement is important. Change of membership helps. People in the beginning think they have to produce an academic paper they are too into the philosophical reflection but then slowly they grasp from the dynamics of the group that this is something that needs and requires academic expertise because it would be a weak document, at the same time the requirements are very practical, they need to be clear to decision makers who are not experts and to other stakeholders who are not necessarily experts or academics’ (Interview: IBC Secretariat).

What became clear in the discussions at the meetings was that clearly articulated and simplified ideas travelled further than long convoluted and complicated academic-style proposals. The on-going debate, the short discussion time, the need to keep a debate going and not just reiterate one point after another contributed to the ‘dynamics of the group’ mentioned in the excerpt above. Another important consideration for the experts was for them to take into account the audience and the need to be clear in order to enable the non-experts to understand their reflections. The credibility of experts lies in their ability to demonstrate their academic sophistication and in their ability to articulate complex academic reflections while at the same time communicating them in uncomplicated terms across to non-experts.

On the question of multi-disciplinarity, the choice of experts was as much a means of gaining a diversity of opinions and engagement in rich discussion as a means of increasing the credibility of experts who found themselves working on a broadening agenda.

‘not everyone is a bioethicist, bioethics is multidisciplinary and we don't want to gather only bioethicists because it won't serve the purpose the discussions are on very different topics, now they are discussing refugees and have discussed benefit sharing, social responsibility, or consent’ (Interview: IBC Secretariat).

There was however a need for technical expertise on genomics to be able to include more nuanced knowledge on the human genome.

'but genomics they have been working on updating the reflection on the human genome and human rights and for that you need real expertise and you need the perspective of the geneticists, public health, legal perspective so not all of them are bioethicists by training but at the same time we have philosophers, anthropologists and what we aim is that they have some experience in reflection in bioethics because you can be a very important scientist that has never had any reflections on bioethics and that makes it very difficult. so even if they are trained the they are experts in their own field but that they have had some reflection or some activity in bioethics even if they are not trained in bioethics. We also have those who are trained in bioethics specifically coming from philosophy, teachers in philosophy or publish. [But their specific] training doesn't mean they haven't had reflection on bioethics' (Interview: IBC Secretariat).

This excerpt supports the finding illustrated in figure 5. More IBC Members with experience working in national and/or regional and/or international bioethics committees or associations are being selected to the expert group. The Bureau considers it important for the IBC members who are not bioethicists by training to have specialized training as well as experience in bioethics.

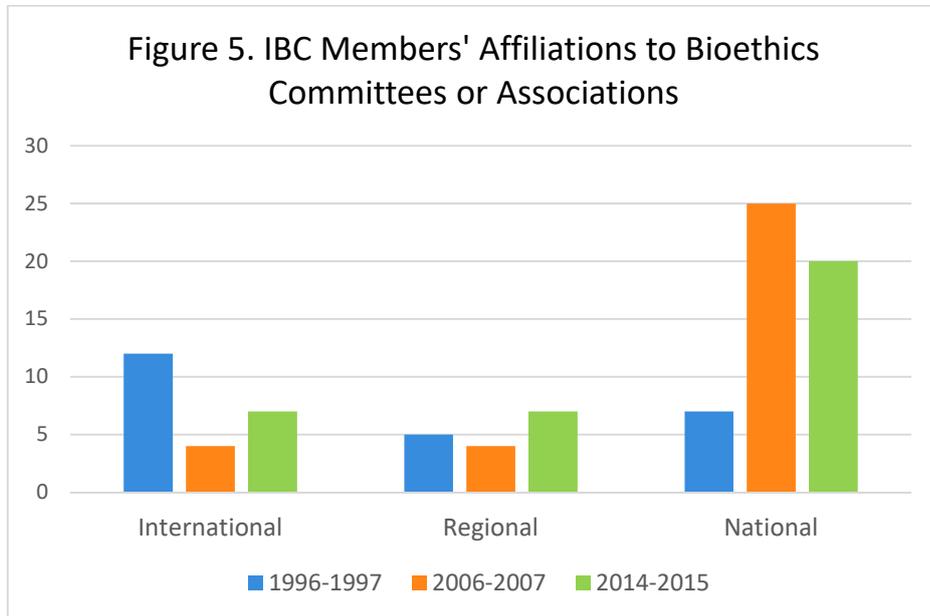


Figure 5 depicts the IBC members' international, regional and national affiliations to bioethics committees or associations. The data indicate that most of the members were affiliated with international, regional and/or national committees and associations over the years. Members of the IBC who were also members of national bioethics committees or associations increased from six in the first period to twenty-five in the second period and down to twenty in the last period which seems to indicate that this is an important criterion for membership. The number of members who were a part of regional bioethics committees or associations decreased from five to four and rose to seven in 2014-2015. The first cohort (1996-1997) had more members who were affiliated with international committees and associations as compared to subsequent periods. The data seem to indicate that national and regional affiliations to bioethics committees and associations have become more important criteria for

members to have. This finding would indicate that the IBC is interested in members' national and regional influence, that either shapes their understandings of the needs of their regions and national contexts, or allows the IBC to influence these regional and national contexts through their members' affiliations.

Part I of this chapter has provided the context in which the IBC operates. It has highlighted the issues and tensions at the science-policy interface that the IBC as a BO manages. The empirical data presented in this section has drawn out the institutional design by analyzing its membership over time and the organizational culture. With this in mind, the following Part II discusses what the IBC does and how it manages the science-policy boundary through boundary-work.

PART II – Producing Knowledge

3.4. Introduction

This section discusses what the IBC does, what it produces and how it manages the science-policy interface through boundary-work. It highlights the three main instruments that were developed over the years and that form a central point of reference in their on-going discussions. The section also looks in detail at the development of a specific report,

the report on *The Principle of the Sharing of Benefits (Article 15 of the Universal Declaration on Bioethics and Human Rights)*.

The report illustrates the ways in which the IBC brings clarity to complex philosophical, ethical and social issues that are valued differently and have different meanings to different countries around the world. The Universal Declaration on Bioethics and Human Rights articulates the need for global standards in the face of new bioethical dilemmas brought about by developments in medicine and the life sciences, stating that:

‘As transnational cooperation in scientific activities intensifies, there is a growing need to develop universally applicable ethical guidelines within a context of cultural pluralism inherent in bioethics. This involves the identification and promotion of universally shared values and the stimulation of lively international debates between scientists, medical professionals, lawmakers and citizens’ (UNESCO 2005a)

The idea of ‘sharing benefits’ of research recognizes the problem of global inequality and primarily recognizes that countries with the resources to undertake research, should take into consideration the needs and concerns of the countries that are indirectly involved in the research, as either participants or hosts. The issues that are discussed illustrate the use and development of rhetorical tools and discourses that challenge the status quo which sees the global North accruing the decision-making power and securing economic interests over wider concerns that are particularly important to the global South. The rhetoric also builds on the idea of a universally applicable practice of research and of developing a

consciousness of inequalities and power dynamics. Since the exercise entailed a revision of a Principle already set out in the Universal Declaration on Bioethics and Human Rights, the ensuing discussion allows for a view of the ways in which the IBC has re-conceptualized and added to previous work.

3.5. From Concept Note to Final Report: A Research Method

Researchers have studied BOs using a variety of methods and perspectives. Some have gained insights through interviews that captured participant perceptions of the science-policy interface (Boezeman, Vink, and Leroy 2013; White, Corley, and White 2008) and perceptions of outcomes and processes in terms of saliency, credibility and legitimacy (Cash et al. 2002; Guston 1999; White et al. 2010). Others have sought to use diverse sources of materials to derive indicators to compare salience and credibility (Keller 2009). Researchers also analyzed institutional design across cases (Farrell, VanDeveer, and Jäger 2001) and interactions between science and policy actors and between different stakeholders (Affolderbach, Clapp, and Hayter 2012; Parker and Crona 2012).

This analysis focuses on the internal dynamics of BOs and follows a method similar to the one used by Jones, Wall & Horlick-Jones (2006). The analysis incorporates first-hand observations of meetings and

combines them with data obtained from interviews and by examining the reports produced by the IBC and its Secretariat. Although this does not present a full picture of the organization and its workings, it does however capture elements of how the organization functions, how the actors interact and how knowledge is produced.

The observations made in the public meetings provide an opportune instance to capture the ways in which debates develop and the kinds of interactions that take place between the various actors. Recordings of the sessions were captured on a digital recorder and hand-written notes were taken to capture the various visual observations. The drawback of this method was that discussions continued outside the public meetings and it was not possible to gain a first-hand experience of the various interactions. For this reason, reports and documents written by the Secretariat and the expert group were used to fill the gaps. However, the reports did not capture the nuances in discussions in as much detail as the recordings allowed and missing information resulted from the second-hand interpretations. Interviews were conducted in an attempt to gain more insights on the dynamics of the group and their interactions beyond the public meetings and the processes involved in the drafting of the report.

The following section looks at the general output of the work of the IBC before delving into the specific example of Benefit Sharing.

3.6. Outputs of the IBC

The IBC proposed its first major international instrument on the human genome in 1997, the Universal Declaration on the Human Genome and Human Rights (UDHGHR). The UDHGHR was adopted unanimously and by acclamation at UNESCO's 29th General Conference on 11 November 1997, becoming the first important legal instrument produced by the IBC, and it was subsequently endorsed by the UN General Assembly the following year.

The IBC was instrumental in producing two more important legal instruments in global bioethics governance: The International Declaration on Human Genetic Data, finalized in 2003, and the Universal Declaration on Bioethics and Human Rights, approved in 2005. Additionally, since its creation, the IBC has had discussions on technical issues such as direct-to-consumer testing, mitochondrial genetics, embryonic stem cell research, pre-implantation genetic diagnosis. They have also discussed access to experimental treatment, genetic counseling, ethics and neurosciences, confidentiality and genetic data, and the ethics of intellectual property and genomics. Figure 6 lists the Reports produced by the IBC.

1994	Genetic Screening and Testing	2001	Use of Embryonic Stem Cells in Therapeutic Research	2010	Social Responsibility and Health
1994	Human Gene Therapy	2001	Solidarity and International Cooperation between Developed and Developing Countries (concerning the Human Genome)	2013	Report of the IBC on Traditional Medicine Systems and their Ethical Implications
1995	Ethics and Neurosciences	2002	Ethics, Intellectual Property and Genomics	2013	Human Vulnerability and Personal Integrity
1995	Bioethics and Human Population Genetics Research	2002	Human Genetic Data: Preliminary Study on its Collection, Processing, Storage and Use	2014	Non-Discrimination and Non-Stigmatization
1995	Genetic Counselling	2003	Pre-implantation Genetic Diagnosis and Germ-line Intervention	2015	Updating its Reflection on the Human Genome and Human Rights
1995	Food, Plant Biotechnology and Ethics	2003	Possibility of Elaborating a Universal Instrument on Bioethics	2015	Principle of the Sharing of Benefits
1996	Ethical Considerations Regarding Access to Experimental Treatment and Experimentation on Human Subjects	2008	Consent		
2000	Confidentiality and Genetic Data	2009	Human Cloning and International Governance		

Figure 6 – Reports Produced by the IBC

Each year, the IBC decides to work on, between two and four topics, placing them on their agenda for discussion at their annual meeting. The agenda covers diverse topics that the group tries to balance by looking at what they refer to as recurrent issues, salient issues and emerging challenges (Interview: IBC Secretariat). Every second year their meetings are held in joint session with the IGBC. The members of the

IGBC are selected by UNESCO's General Conference, in accordance with the criteria of cultural diversity and geographical representation. The IGBC is managed by the same Secretariat as the IBC but has its own Bureau with a Chairperson and four Vice-Chairpersons. The IGBC mechanism is intended to open the topics that are discussed by the IBC to government representatives, to give them an opportunity to discuss the IBC reports and to make adjustments to the statements and recommendations. In terms of setting the agenda the IBC is given the task of deciding on the topics to be considered in the meetings. However, this does not necessarily result in an imbalance between the needs of States and the selection of the issues by the IBC:

‘since there are so many things that can be addressed, so many topics, there is always some matches between what the IBC and IGBC consider relevant. So it makes it easier because it's not an imposition, it's really coincidence, not always, but sometimes there are coincidences. It should not be seen that the agenda was imposed but that both independent groups and governments consider that there is something useful so it makes it easier to choose that topic' (Interview: IBC Secretariat).

The IBC has re-visited specific Principles that were set out in the three main Declarations, providing an opportunity for wider consultation as well as more nuanced critiques of the Principles, especially in terms of ‘updating’ them to reflect the more recent developments in the field.

The original Principles were drafted with a purpose in mind, to minimize the precision of the wording. Andorno (2007) explains this as ‘a common practice in law, in conformity with the old maxim “Omnis definitio in

jure periculosa est’’. (Every definition in law is perilous.) Except for very technical terms, lawmakers normally prefer not to define precisely most of the words they use. Rather, they tend to leave that task to common understanding and, ultimately, to courts’ interpretation, in order not to be constricted in advance by rigid definitions.’ However, over the years, the IBC has revised a number of Principles since it had developed a forum that facilitated wider discussions, with a mechanism for Member State discussion in conjunction with a diverse expert group. In 2014, it was decided that the Principle of Sharing of Benefits should be revised to reflect the changed context.

On the whole, the IBC has managed to agree with Member States on most of their reports. There was only one topic in which the IBC were unable to gain consensus from all parties and that was on the topic of Human Cloning.¹⁹ The IBC considered drafting a legally-binding convention to ban cloning, however wide disagreements ensued and the issue was not pursued (Langlois 2013).

¹⁹ For a detailed account of the drafting and discussions on the issue of cloning see Langlois, Adele. 2013. *Negotiating Bioethics - The Governance of UNESCO’s Bioethics Programme*. Routledge.

3.6.1. Organizing Deliberation

The Director-General of UNESCO convenes the IBC at least once a year. It holds closed sessions between the members, the Secretariat and the Bureau over two days and holds public sessions over an additional two-day period. The IBC meets once a year for regular sessions and extraordinary sessions are convened at the request of at least two thirds of its members or by decision of the Director-General. The IBC held its Twenty-Second Session in October 2015. Two extraordinary sessions were called, one in 2004 entitled “Towards a Declaration on Universal Norms on Bioethics” and another in 2005 in order for the IBC to officially adopt the preliminary draft of the Universal Declaration on Bioethics and Human Rights. The extraordinary meetings followed a timetable for the ‘Elaboration of a Declaration on Universal Norms on Bioethics’, approved by the Executive Board at its 169th Session, on 28 April 2004.

The public sessions are attended by the IBC, Member States and Associate Members of UNESCO. Non-Member States which have set up permanent observer missions to UNESCO take part as observers in the meetings. Other UN agencies with which UNESCO has a reciprocal relationship as well as international governmental and non-governmental organizations can be invited to participate as Observers. Every second year, the IGBC participates in the joint public sessions. Dividing the work between small working groups, the IBC produces ‘Concept Notes’ to guide discussions and then develops advice and reports on specific

issues in collaboration with the IGBC. Once an agreement by consensus is reached, the reports are submitted to the Director-General for transmission to the Member States, the Executive Board and the General Conference. The Concept Notes can be conceptualized as boundary objects, serving the purpose of producing a common understanding between the expert and policy communities. They serve to guide the discussions and as a pretext for further analysis.

The Secretariat sets up the various stages of the meetings and the development of the reports so that the process allows for the independence of the IBC to stand out:

‘IBC are independent in 2 senses, independent in that they can decide their own agenda except if the DG requires them to address something specific. They are independent basically in the sense that they are not there representing any political vision on any topic. That’s the independence. So if they are there they are not representing any country or government they are there representing their own person not even their university. They are nominated and appointed because they have the requirements that we need in terms of being able to draft because the thing is they are not only very good at speaking and thinking, it’s about drafting, they draft the reports, it’s not the secretariat who writes them, they are the ones who draft. So in that sense they are independent’ (Interview: IBC Secretariat).

The display of the independence of the experts in the IBC is an important strategy to enhance the legitimacy of the claims made by the committee.

One can observe however that at times, experts draw on their own experiences from their countries when discussing their position on a topic. In the open debates, for example, a number of IBC members made reference to their experiences in their own countries and brought in their perspectives gained from living and working in their home countries (own observation). Therefore, the diversity of the membership also contributes to the diversity of the perspectives from a cultural point of view. The opinions of the experts are however clearly demarcated from the opinions of the ‘governments’ through their rhetorical claims to ‘expert’ opinion, rather than a political position. The fact that there is a discursive separation between the expert group and the government group seems to add further legitimacy to the claims of the experts in the IBC.

Over the years the IGBC has played a marginal role in the development of reports, contributing comments close to the end of the drafting phase of reports which meant that they were often not considered very closely by the drafting process which was handled by the IBC. This practice has however been rectified in recent years. ‘Concept Notes’ are now shared with the IGBC to elicit comments before meetings take place. The IGBC is also consulted more often along the process of producing drafts. However, the Secretariat reiterates that the IBC maintains the discretion to consider, include and exclude comments that the experts deem necessary.

‘If they think that Member States are really feeling the need to have guidance on topics they hear that but it’s in order to

respond to these needs not because they have to do it'
(Interview: IBC Secretariat).

By responding to the needs of Member States the IBC can be seen to be increasing the saliency of its reports. However, their claim to saliency lies in their broad agenda instead, which covers topics that they consider already politically-relevant. It should also be noted that when topics are being decided upon by the IBC, the members bring in their own experiences from their home countries and regions and these have an element of salience to them. For example, one member was concerned by the large number of trained doctors that leave his country to work in developed countries. In order to bring the issue onto the agenda, it was included in the discussion on 'Benefit Sharing' under 'brain drain' (Interview: IBC Member). The IBC decided that the agenda should include further reflections on the principles laid out in the Declarations:

'Since the 2005 declaration they decided to prepare reports focusing on specific articles on the declaration to try to flesh them out. Of course a principle is so general that it gives no information for anybody so they decided to concentrate and produced a series of reports based on the principles. As the principles are interlinked you can't write reports on each principle because you absolutely touch on another if you chose one of them' (Interview: IBC Secretariat)

The IBC therefore reference the already agreed upon Declarations and build on them. In this way, they again claim legitimacy by building on

topics that have already gained acceptance through their endorsements by UNESCO and Member States.

The number of meetings that the group of experts held in the past have been reduced over the years due to major constraints on UNESCO's budget since the USA withdrew its funding in protest of the inclusion of Palestine as a UNESCO member. Reports are put together jointly by members of working groups but their interaction is limited mainly to email communication. Each member of the group adding comments, additions and edits to pre-meeting documents and to draft reports before the reports are submitted to the Secretariat. Some members mentioned that there are language issues amongst working group members and since they are working on the reports on a voluntary basis, the additional editing work can be burdensome for the people with the language proficiency (Interview: IBC Member). For others, the language barrier meant that they were at a disadvantage in the closed meetings at which there were no translation services available.

'we are some francophone, we have to work in the language of the text but the translation after that is lost, and translation, and meaning of the words is not the same this is the first problem, the second problem is that we don't have enough time to discuss because we have to work in our countries on the topics but in fact only few of us read the whole text, they came here and they discover the problems, so these problems make me feel that we are losing time. We have to think of the function of the IBC, I don't think that it functions as it should be because of language and we don't meet enough. If you only meet for 4 days once a

year its supposed we have to talk, we don't have conference. Communication via email but we started 15 minutes ago, I received 10 emails. All of us are like that so when you receive an email with 30 pages to read you say I will do it tomorrow, and like everybody, I suppose, you never do it or when you do it in the plane when coming here, it's not enough to study, and every word is important some times' (Interview: IBC Member)

Time at the main annual meetings is limited and while simultaneous translations are a valuable resource in the room, it can also add pressure to the already restricted discussion time when the translators are unable to work beyond a specified period of time (own observation). In a bid to improve transparency and access to meeting materials and content, the Secretariat makes all documents and meeting reports freely accessible on the organization's webpage.

These various repeated interactions, social norms and rules help to create stability and organizational continuity, that serve to give authority to the work being done by the organization. "Public displays" and transparency strategies help to demonstrate that a variety of actors already subscribe to the principles and strategies that the organization represent (Moore 1996).

In order to illustrate the ways in which the deliberation process is organized, the following sections present the pre-meeting preparations and the deliberation process with insights gained from the September 2014 Meeting. The meeting was a joint meeting between the IBC and the IGBC.

3.6.2. Pre-Meeting Preparations

The 21st Session of the IBC and IGBC was held on the 9-10 September 2014. Leading up to the meeting a number of preparations were made in order to both streamline the discussions as well as to stimulate thoughts and ideas before the meeting.

Four issues were to be discussed in the up-coming meeting. The first issue was to discuss ‘The Principle of the Sharing of Benefits (Article 15 of the Universal Declaration on Bioethics and Human Rights)’. The second issue was a discussion on ‘Updating the IBCs Reflections on the Human Genome and Human Rights’. The third issue was a ‘Revision of the Recommendation on the Status of Scientific Researchers’, and fourth on the agenda was a ‘Global Reflection: Addressing the Ethical Aspects of Converging Technologies’.

To meet this end, working groups made up of members of the IBC prepared what they called ‘Concept Notes’. The Concept Notes provided a preliminary outline of potential areas of reflection. Figure 7 is an excerpt of the cover page from all Concept Notes. It is emphasized that concept notes are ‘*only potential areas of reflection* and that there should be *no expectation that they will be covered by a report*’ and that the

concept notes ‘[do] not necessarily represent the final opinion of the IBC’ [emphasis in original].

This concept note was prepared by a small working group of the Committee in order to provide a preliminary outline of potential areas of reflection for this topic. It is important to emphasize that the issues identified in this concept note are *only potential areas of reflection*, and there should be *no expectation that they will be covered by a report* to be eventually prepared and adopted by the IBC at a later stage.

As it stands, this concept note does not necessarily represent the final opinion of the IBC and it is subject to further discussions within the Committee. This concept note also does not pretend to be exhaustive nor prescriptive and does not necessarily represent the views of the Member States of UNESCO.

Figure 7. - Excerpt from a Concept Note cover page

These Concept Notes were prepared by 30th May 2014 and sent out to the Member States of the IGBC, the Members of the IBC, the Members of COMEST, the Members and Associate Members of the UNIACB. The Secretariat invited these groups to comment and propose suggestions for additional issues that the IBC should consider. See Figure 8 below.

Interestingly, the document that is eventually created - a ‘Compilation of Written Submissions on the Concept Note’ reiterates the ‘independence of the IBC in taking its own decisions concerning the eventual direction of the reflection’. See Figure 9 below.

The independence of the IBC in taking its own decisions concerning the eventual direction of its reflection on this topic must be emphasized. There should be no expectation that these comments will be fully or even partially covered by any report to be eventually prepared and adopted by the IBC.

Figure 9. – Excerpt from a Compilation of Written Submissions on the Concept Note



Bioethics and Ethics of Science Section
Division of Ethics, Youth and Sport
Social and Human Sciences Sector

To Members of the UN Interagency
Committee on Bioethics (UNIACB)

30 May 2014

Ref. : SHS/YES/14/075

Subject: **Written Consultation on the work of the International Bioethics Committee (IBC) for 2014-2015**

Dear UNIACB Members,

Based on discussions during the 20th Session of the IBC in June 2013, the conclusions of the 8th Session of the Intergovernmental Bioethics Committee (IGBC) in September 2013, as well as inputs from the Secretariat, the Work Programme of the IBC was finalized by its Bureau in March 2014, focusing on the following two topics: the **elaboration of the principle of sharing of benefits** as set out in Article 15 of the *Universal Declaration on Bioethics and Human Rights* (2005); and the **update of the IBC's reflection on the human genome and human rights**.

In an effort to encourage wider consultation and collaboration, the Chairperson of the IBC has agreed with the suggestion of the Secretariat to invite UNIACB Members to submit written comments or suggestions on the Committee's ongoing work at a much earlier stage in its reflections.

Figure 8. – Sample of an Invitation for Written Consultation on the work of the IBC

(See Annex for a full version of the document)

To elucidate some of the ways in which the Concept Notes help to frame the issues to be discussed as well as to reflect upon the ways in which discussions unfold, I will go in-depth into the Concept Note and the meeting sessions on the topic of *The Principle of the Sharing of Benefits (Article 15 of the Universal Declaration on Bioethics and Human Rights)*.

The IBCs Concept Note on The Principle of the Sharing of Benefits (Article 15 of the Universal Declaration on Bioethics and Human Rights) builds on much of the previous work of the IBC, including the three Declarations and is noted as being linked to Article 27 (the right to share in scientific advancement and its benefits) of the Universal Declaration of Human Rights and Article 15 (the right to enjoy the benefits of scientific progress and its applications) of the International Covenant on Economic, Social and Cultural Rights. These links to other global instruments provide additional validation and context to the ideas presented in the Concept Note.

Through the Concept Note, the discussion is anticipated to be steered to enable the groups to provide comments in a more structured way. The Concept Note states that comments should reflect ‘policy-relevant needs, gaps and interests concerning the topic, which might be useful for the

IBC to strengthen the policy focus of its report' (International Bioethics Committee 2014b). In this way, by stating the ways in which the invitees should present their comments, the IBC makes a distinction between the IBC's bioethical expertise function and the policy function of the groups providing comments.

The aim of the Declaration on Bioethics and Human Rights has been to 'address ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions' (UNESCO 2005b).

The principle of Sharing of Benefits in Article 15 states that:

- "1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
 - (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
 - (b) access to quality health care;
 - (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
 - (d) support for health services;
 - (e) access to scientific and technological knowledge;
 - (f) capacity-building facilities for research purposes;
 - (g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research."

(International Bioethics Committee 2014a)

With reference to this principle of Sharing of Benefits, the Concept Note lists potential areas of reflection. These points pose questions and reflections on each part of Article 15 on Sharing of Benefits listed above. In summary, the working group puts forward the following thoughts:

A. Explaining the Principle

In particular, how to meet the aspirations of the statement “benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries”.

B. Production of knowledge in the life sciences

In particular, it proposed looking at whether ‘benefits’ could extend beyond ethical issues in research on human subjects and the idea of science as property of all mankind, recognizing scientific knowledge as a universal public good. The concept note proposes a reflection on the meaning of knowledge and sources of knowledge and state all sources should be accessible to all. Then they reflected on how to put the principle into effect i.e. if it includes access to existing knowledge and the production of new knowledge and that this would have profound implications for education. They ask how to do this in a fragmented context and question the role of intellectual property.

C. Sharing of Benefits in Research

In particular, it proposed a reflection on issues of knowledge production and access - discussing the human rights-based approach, the ‘reasonable availability’ approach or the ‘fair-benefit’ approach. Also to consider the implications on production of knowledge and research outcomes.

D. Extending the reflection beyond the context of production of knowledge

It was proposed that the IBC reflect on other applications of Article 15 beyond production of knowledge. Particularly the scope of beneficiaries and beyond participants in research as stated in the Article. They emphasized a need to deal with gaps, e.g. should research participants be given comprehensive healthcare access or just care for the pathology being researched? They posed questions such as: who is responsible for providing quality health care, how fairly should research sponsors be treated? and how should health systems be supported? They highlighted long-term sustainability issues, also a need to clarify what is consistent and what is inconsistent with the principles when leaving room for creativity and future developments. Finally, they ask what would be considered improper inducement of research subjects?

These questions, comments and reflections of the IBC build on Article 15 closely. The topics are however broad, ranging from very philosophical notions such as scientific knowledge as a public good, to ethical questions such as how the global community should treat research participants. There are questions of fairness and access as well as questions of healthcare quality that focus not only on biomedical issues, but extend the debate to include issues of a social, economic, moral, and philosophical nature.

Figure 10 lists the names of those people who sent in written submissions from amongst the IBC Members and IGBC Members, after the concept note was disseminated. Eight of the submissions were sent in by IBC members and two submissions from IGBC members. Two submissions were sent in by Ministries of Health and four were sent in from UNESCO

delegations, one submission was sent in by a member of COMEST and one from a National Bioethics Commission. The comments were extensive and detailed. The submissions were compiled into a booklet which was then referenced in the meeting session at the joint IBC & IGBC meeting in September 2014. The process whereby the written submissions were referenced and discussed in the meeting will be elaborated on in the next section.

IBC Members	Other Stakeholders	
Mr Amnon Carmi (Israel)	Cote d'Ivoire	Mr Lazare Poamé (Vice-President IGBC)
Ms Ekram Mohamed El-Shabrawy (Egypt)	Lithuania	Ms Eugenijus Gefenas (IGBC)
Ms Therese Leroux (Canada)	Canada	Mr Peter Monette (Ministry of Health)
Mr Francois-Xavier Putallaz (Switzerland)	Singapore	Ms Charmaine Chan (Min. of Health)
Ms Lizbeth Sagols-Sales (Mexico)	Jordan	Jordan Delegation
Mr Johannes (Hans) Van Delden (Netherlands)	Dominican Rep.	Ms Josefina Alvarez (Perm. D. UNESCO)
Mr Volnei Garrafa (Brazil)	Germany	Mr Jens Streckert (Perm. D. UNESCO)
Ms Claude Verges de Lopez (Panama)	Turkey	Turkish Nat. Commission for UNESCO
	Argentina	Ms Susana Sommer (COMEST)
	Mexico	Nat. Bioethics Commission of Mexico

Figure 10 – IBC & IGBC Members Who Returned Written Submissions

3.6.3. Deliberation in Meeting Sessions

Towards the First Draft

The annual meetings are opened with a speech given by the Director-General of UNESCO. The formal speeches given by the Director-General as well as by the Chairperson of the IBC - and at joint meetings, the Chairperson of the IGBC - serve to set the formal, ritualized tone of the meetings. The Chairperson is obliged to declare the opening of the meetings and ensure that the rules are adhered to throughout the sessions. Following the opening speeches, the Chief of the Bioethics and Ethics Section gave a report on the work of the Bioethics Program. This detailed the activities carried out by the group in terms of its mandate to improve education in bioethics, strengthen national bioethics committees and disseminate the output of the work of the IBC.

Each attendee was given a file containing meeting documents. These consisted of the Program (see Figure 12 on the next page), the Agendas for both the IBC and the IGBC meetings, the Statutes of the IBC, the Rules of Procedure of the IBC and of the IGBC, the Concept Notes for three items on the agenda and the compilation of written submissions on the Concept Notes. It should be noted that the concept notes and the written comment submissions were in English, and the rest of the documents were in English and French.

In the opening presentation of the issue of the Sharing of Benefits (Article 15 of The Universal Declaration on Bioethics and Human Rights), the Coordinator of the IBC Working Group, Dalia Sanchez-Varela was given time to present the Concept Note and highlight the written submissions. In her address, she stated that there were a number of submissions on the

Concept Note, however it was not important who made the comments but rather the substance of the comments that was.

‘They are organized by paragraph and they are independent of who said them because I think that we should be discussing ideas and not where they came from.’ (Dalia Sanchez-Varela IBC Meeting September 2014)

Here, the deliberate blurring of the boundaries between the two groups enables a flowing discussion by not separating out the political statements. As the meeting proceeded, speakers were given an opportunity to comment on the Concept Note and the submitted comments. The Chairperson gave the floor to speakers in the order in which they indicated their desire to speak. The speakers raised the placards containing either their name (in the case of the IBC experts) or the country they represent (in the case of the IGBC members and Observers). Observers could only take the floor if they had asked for permission to do so from the Chairperson ahead of the meetings. This strategy, limited the input of the Observers and focused attention and importance on the comments made by the members of the two committees. It also limited the ability of Observers to object or criticize the comments made by others who spoke before them since they had to ask for permission to speak before-hand and likely had prepared comments. During the discussion, comments were made by IBC members, IGBC members (see figure 11 for a list of countries represented on the IGBC) and some Observers.

Argentina	India	Niger
Brazil	Indonesia	Pakistan
Cameroon	Israel	Republic of Korea
Canada	Jordan	Russian Federation
Cote d'Ivoire	Kenya	Singapore
Denmark	Kuwait	Slovakia
Dominican Republic	Lebanon	Thailand
France	Lithuania	Togo
Georgia	Madagascar	Tunisia
Germany	Mexico	Turkey
Greece	New Zealand	United Republic of Tanzania
Guatemala	Nicaragua	Zambia

Figure 11. - Composition of the IGBC (2014-2015)

21st Session of the International Bioethics Committee of UNESCO (IBC) and Joint Session of the IBC and the Intergovernmental Bioethics Committee (IGBC) 9-10 September UNESCO Headquarters Paris, France		
Co-chaired by Mr Stefano Semplici, Chairperson of the IBC and Mr Peter Monette, Vice-Chairperson of the IGBC		
Programme		
Tuesday 9 September 2014		Wednesday 10 September 2014
10.00 – 10.30	Opening Ceremony with Mrs Irina Bokova , Director-General of UNESCO (video message) Mr Stefano Semplici , Chairperson of the IBC Mr Peter Monette , Vice-Chairperson of the IGBC	10.00 – 10.30 Presentation by Prof. Ewa Bartnik Professor of Molecular Biology and Human Genetics, University of Warsaw, Rapporteur of the IBC
10.30 – 11.15	Progress Report on the UNESCO Bioethics Programme Presentation by Mrs Dafna Feinholz , Chief of Bioethics and Ethics of Science Section, UNESCO	10.30 – 11.30 Discussion 11.30 – 11.45 Break 11.45 – 13.00 Discussion 13.00 – 14.30 Lunch
11.15 – 11.30	Break	14.30 – 17.00 Global Reflection: Addressing the Ethical Aspects of Converging Technology Presentation by Dr Anne Forus , Chairperson, Committee on Bioethics (DH-BIO), Council of Europe and Mrs Laurence Lwoff , Secretary, Committee on Bioethics (DH-BIO), Council of Europe
11.30 – 13.00	Revision of the Recommendation on the Status of Scientific Researchers (1974)	14.30 – 15.10
11.30 – 11.40	Introduction Presentation by Mrs Dafna Feinholz , Chief of Bioethics and Ethics of Science Section, UNESCO	15.10 – 16.00 Discussion 16.00 – 16.15 Break
11.40 – 13.00	Discussion and Conclusion	16.15 – 17.00 Discussion
13.00 – 14.30	Lunch Break	17.00 – 17.30 Closing Ceremony with Mr Stefano Semplici , Chairperson of the IBC Mr Peter Monette , Vice-Chairperson of the IGBC and Mrs Lalla Aicha Ben Barka , Assistant Director-General a.i. Social and Human Sciences Sector, UNESCO
14.30 – 15.00	Presentation by Prof. Delia Sanchez Varela , Academic Coordinator, MERCOSUR Health Systems Observatory, Vice-Chairperson of the IBC	
15.00 – 16.00	Discussion	
16.00 – 16.15	Break	
16.15 – 17.30	Discussion and conclusion	

Figure 12 Program of the 21st Session of the IBC & IGBC

The first comments made were well-prepared opinions and then the discussion opened up to people referring to previous points made, thus creating a continuous discussion. Intermittently, speakers would again give well-prepared opinions and someone would pick up a point from previous speakers and create more continuity.

Figure 13 shows the time each speaker took to make their statement during the discussion session. Eight of the comments were made by IBC members, fourteen IGBC member countries made statements and two Observers commented. The most time taken to make a statement was the IGBC member representing New Zealand, speaking for six minutes and twenty-one seconds, while the IGBC member representing the Republic of Korea spoke for fifty-seven seconds. On average, the speakers spoke for three minutes and fourteen seconds. This analysis shows that the discourse in the public meeting was dominated by the IGBC members who spoke for a total of forty-one minutes and eighteen seconds whereas the IBC members had the floor for a total of twenty-eight minutes and forty-five seconds. Observers spoke for a total of seven minutes and fifty-four seconds.

Name/Country	Min/Sec	Name/Country	Min/Sec
1. New Zealand	6:21	13. Lithuania	3:21
2. Brown (IBC)	2:39	14. Argentina	2:27
3. Daar (IBC)	4:51	15. France	3:03
4. Kubar (IBC)	3:23	16. Rep. of Korea	0:57
5. Garrafa (IBC)	6:12	17. Verges (IBC)	1:24
6. Putallas (IBC)	3:05	18. Brazil	3:11
7. Jordan	4:14	19. Piedra (IBC)	2:18
8. Singapore	2:59	20. Kenya	2:29
9. Germany	2:24	21. Canada	1:25
10. Denmark	2:49	22. Ian (Observer)	5:35
11. Montalvo (IBC)	4:53	23. Japan (Observer)	2:19
12. India	4:06	24. Mexico	1:32

Figure 13 - Time each speaker took to make their statement in the discussion session (displayed in the order in which they made their statements)

In summary, the following key points were raised:

- That Article 15 is to be understood in relation to all articles of the Declaration
- There should be one ethical standard for all populations
- Article 15 focuses on scientific knowledge in the life and biomedical sciences and this should therefore be the focus in the final report.
- There should be a consideration of wider society and the sharing of benefits with individual research participants
- The role of Intellectual Property Rights needs to be considered
- The importance of engaging and cooperating with the community needs to be mentioned

- The role of pharmaceutical companies, universities and other research funding bodies in privatizing knowledge needs to be tackled
- The importance of dissemination and use of documents produced by the IBC needs to be carried forward.

(Social and Human Sciences Sector 2014:9-10)

Towards the Second Draft

Thereafter, the report was re-written to take into account the points brought up in the 21st Session. The report was then presented to the IGBC for further revision at the IGBC's 9th Session, held in 2015.

A summary of their comments are as follows:

- The IGBC appreciates the innovative concept of sharing as participation and not only top-down beneficence;
- *Invites* the IBC to ensure a balanced approach to the topics covered by the draft report, and to further address, among others, the following issues: definition of what is a benefit; sharing of benefits with society as a whole; the question of financing of health and research; and vulnerable groups, migrant workers and refugees;
- *Suggests* that the draft report should include an executive summary; a clear outline of the conclusions and recommendations; an indication of whom these recommendations

are addressed and the appropriate manner for their implementation; and better clarification and references on normative statements;

- *Invites* the IBC to revise the language of the text in both English and French for better clarity, and *requests* the Secretariat to improve the grammar and spelling of the text accordingly;

(IGBC 9th Session Meeting Report, 2015).

The Final Draft

Following the 21st Session of the IBC and IGBC, a larger working group was put together to write up the report which took into consideration the discussions at the 21st Session. The draft report was then presented at the 9th Session of the IGBC in July 2015. This draft report was then revised to take into consideration the comments made at the 9th Session of the IGBC. The final draft of the report was then presented and finally adopted at the 22nd Session of the IBC in October 2015.

REPORT OF THE IBC ON THE PRINCIPLE OF THE SHARING OF BENEFITS	
EXECUTIVE SUMMARY	
I.	INTRODUCTION
II.	PEOPLE AND GROUPS PARTICIPATING IN RESEARCH
	II.1. Benefits as improper inducement
	II.2. Burdens and benefits of participating in research. Criteria of justice
	II.3. Double standards
	II.4. Post-trial obligations
III.	ACCESS TO HEALTH CARE
	III.1. With society as a whole
	III.2. Possible trade-off with the protection of intellectual property
	III.3. Adapting appropriate technologies
	III.4. Transnational practices
IV.	SHARING AS PARTICIPATION AND NOT ONLY TOP-DOWN BENEFICENCE
	IV.1. Capacity building and science education
	IV.2. Brain drain, brain circulation
	IV.3. Open Access
	IV.4. Empowerment
V.	RECOMMENDATIONS
BIBLIOGRAPHY	

Figure 14. Table of Contents of the Final Draft on the Principle of the Sharing of Benefits.

The final report was twenty-six pages in length. The table of contents of the document is captured in figure 14. The main message that the document transmits is a broad approach to fairness, participation and beneficence that governments, research organizations and individual researchers should consider when undertaking scientific research. The report stresses that researchers, organizations and governments should consider the impact of their work. The document also includes a consideration of access to health care as a universal right. The document then suggests the need to take into consideration equal participation in

transnational research endeavors as a form of solidarity and not only in terms of compensation.

The process that led to the finalization of the initial Declaration on Bioethics and Human Rights in 2005 was said to be a highly political one:

‘it was an absolutely political construction because the vision of bioethics in the US for example has a different vision than the vision of bioethics in UNESCO. In the US and some European countries, it’s related very much to the interests of international laboratories of medicines. So it’s a bioethics that’s very reduced, very *biomedical*, *biotechnological*. And the declaration of UNESCO moreover, interprets the *bio* in bioethics not only in terms of medicine but rather as life, *bio* as life, life, rights, clean water, pure air, literacy, social exclusion, access to health, the US never wanted access to health as a universal right, rather than as a market, a good that can be bought. If you have a health issue, pay the hospital and they see to you, it’s not a public good. So the declaration reflected the agenda of the international community. This is the problem.’ (Interview: IBC Member)

This insight contributes towards an understanding of the changed nature of the final report that internalizes the political debate and gives a clear stance and position on the issue of access to health care i.e. that health is a human right and that everyone should be able to access health care, regardless of their ability to pay. The report conveys other political stances, such as, that countries recognize the shared responsibility to ensure that research protocols generate new knowledge and respect the

rights of individuals and groups. The report also mentions that progress should not bring about further inequalities between people and countries. Referring to inequalities, the report points out that it is unacceptable for research priorities to be driven by interests of industry with a profit motive. Especially in socially and economically vulnerable contexts, incentives are seen to be a form of exploitation and an improper inducement. Pointing out the intellectual property issue, the report makes it a priority for fundamental rights of access to quality health care to take precedence and for it not to be treated as a trade problem, rather as an ethical issue that requires a focus on human rights.

The report states the problem as a need to clarify what is meant by the Principle when it makes specific mention of individuals and groups that take part in research, access to health care and scientific and technological knowledge. Also to clarify capacity building, and benefits as a possible cause of improper inducement. The IBC contributes to the report by elaborating on the Principle of benefit sharing and by elaborating on International Bioethics. Of concern are the double standards in the ways that research is conducted in developed countries as compared to the way the same research is managed in developing countries. They are also concerned by the inappropriateness of monetary inducements, the burdens of participating in research and post-trial obligations. The report clarifies sharing as beneficence rather than as a political responsibility. The report also touches on issues of science education, brain circulation, open access to health-related information, and empowerment and participation in the production of knowledge.

The report sets out some broad normative claims including that benefits resulting from scientific research should be shared with society as a whole. It also sets out that economic actors should make personal interests compatible with respect for human rights and knowledge and health as a common good of humankind, and companies should never take advantage of weak legislation nor prevent people from benefiting from their research results. The report also emphasizes that solidarity should be obtained through participation.

The report also suggests ways in which governments and other actors can resolve the problems identified in carrying out a benefit sharing agenda. They call on the scientific and research community to comply with the highest ethical standards of research and sharing them at the global level. The media and educators should be called upon to promote the values of sharing and help change mindsets. In this regard illiteracy should be tackled and adequate standards for scientific education should be set. It stresses the need for international agreements and the activities of Research Ethics Committees, backed by strong legislation. It suggests that possible conflicts of interest should always be disclosed. They also suggest that there should be an assessment of progress in this regard, and finally, the evaluation and dissemination of these advances.

In summary the meaning of benefit sharing has been elaborated to include ‘the awareness of belonging to one and the same community of human beings. We use our intelligence and capacities to fight against the consequences of our limited means and our fragility and to improve the conditions of our life on earth.’

The final report on benefit sharing was considered comprehensive on the whole and included both expert-driven elements as well as government-driven elements.

‘I think there were very good inputs about the very realistic problems that governments can face about limitations and also about possibilities of how to comply with benefit sharing. All the perspective on public health were very interestingly brought by the Member States particularly taking into account the views of some of the countries. And then I think everybody was very happy with the idea that benefit sharing should be something which is called the umm co-authorship, it’s not only about benefit from the research or but really being part of producing also the knowledge you see, coproduction, the coproduction and it shouldn’t be something top down, nor bottom-up either, something joint’ (Interview: IBC Secretariat).

The main ideas that were brought across through the development of the report contributed to the understanding of sharing of benefits as something that is coproduced while the interpretation of health was reconceptualized as a human right. It also contributed to the practical ways in which the principle of benefit sharing can be applied. This can be seen as a productive ‘coproduction’ of knowledge and social order. However, it is yet to be seen if and how the principles will be implemented. The report went through a number of revisions that proved satisfactory to the Member States. The process was however said to be a negotiation:

'It's difficult, we have to find consensus it's difficult because they are often conflictive, its important the argument, the rationality, that the reasoning is strong and good in a discussion, the reasoning to convince another person about the one position. There are constructions, difficult constructions, consensus, but this is the form of construction of all the documents. Sometimes we have to lose a finger rather than loose a hand. So we have to negotiate. I would like a very social document, but like this its ok. It's a political construction' (Interview: IBC Member).

The coproduction, with the elements of expert knowledge and the ways of implementing them (knowledge from the political side) reflect the perspectives of both the IBC and IGBC. The ability of the report to obtain its relevance was enhanced by the inputs from the government mechanism. Since there were no strong objections to the report, the signaling of the approval of the claims by the IGBC contribute towards their credibility and legitimacy. Since the IBC members are closely associated with national bioethics committees, the next step will be the dissemination of the report and subsequent uptake. This study does not look at uptake but does recognize the role of the IBC members as advocates of the UNESCO Bioethics Program.

3.7. Discussion

The role of the IBC is to provide a venue for the exchange of ideas and the negotiation over technical and policy issues related to scientific research, particularly concerning genomics. Its aim has been to create an understanding of scientific research from different perspectives and to develop normative positions that serve to encourage regulatory cultures across the globe to move in a particular direction that all countries are in agreement with. The empirical insights presented in this chapter have demonstrated when and in which ways the IBC asserts its authority and the manner in which it seeks to preserve its autonomy during the drafting process and in the public meeting sessions. At times, the IBC and IGBC jointly blur the lines between expert, scientific and other disciplinary boundaries and political boundaries. The ‘repurification’ of the expert and political discourses into discrete categories serves to contribute towards the credibility and authority of expert knowledge. The IGBC works as a legitimizing mechanism, contributing insights to the final reports as well as legitimacy through the approval process.

The Concept Notes function as boundary objects, that stabilize and routinize the ways in which social groups create linkages with each other thus organizing social interactions. The use of the Concept Notes contributes toward defining the role of expert opinions and delineate the political input, by making a discursive difference between the IBC’s input in the Concept Note and that called upon from the IGBC and others. At times, the differences between scientific, expert and political opinions in debates are not apparent, as experts also appeal to perspectives drawn from their own countries or reflecting the political culture of the nation-states they come from. Experts negotiate amongst themselves and with

each other, needing to articulate their ideas into easily understandable forms of rational arguments. The appeals to universal, international and global bioethics principles signal consensus and serve to further legitimate the claims. Boundary-work in the IBC internalizes contingencies and enables negotiation.

In terms of power, the IBC's work has brought about an understanding of the dynamics that cause inequality and that reinforce them. The insights gained through the discussions on benefit sharing in particular take scientific research as a powerful source of social and economic capital that needs to be balanced with a rights-based approach to health care access and access to the benefits of research. In terms of biopower, the IBC touches on the need for a bioethical approach to health and scientific knowledge that opposes the strict and narrow asocial view of biomedicine and biotechnology. On the whole the IBC deals with genetic research in a similar light, valuing a broad rights-based approach to science and technology, as evidenced by the micro-processes highlighted in this empirical work.

The IBC sets out to develop guidelines that anticipate new developments in science and biotechnology. Their aim is to deal with recurrent issues, salient issues and emerging challenges by creating norms that would precede and anticipate bioethical dilemmas. The particular issue of benefit sharing resulted in a negotiated position. The negotiation led to the reconceptualization of benefit sharing as both a global responsibility and one that requires that individual researchers, organizations and nation-states recognize the idea of a joint non-hierarchical approach to

research and the results of research. The final report sets out the ideas and how to implement them, thus reflecting a co-production of knowledge and social order. The power of science as conceptualized through a bioethical framing of research and scientific knowledge as a universal human right, reflects a broadening of the audience to whom science and research should matter. The IBC members serve as advocates in the dissemination and use of the IBC's reports and recommendations as they participate in national, regional and/or international bioethics committees.

3.8. Findings

The IBC illustrates how science is shaped and brings insights to the idea that science is neutral and serves the purpose of only providing objective and policy-relevant solutions. This case study illustrates how different uses of science can have implications for different communities in very different ways. The IBC provides a space for policy-makers to become involved in shaping the expectations of what science can prove, and when and how it should/should not and can/cannot be used. This can be seen as a coproduction of knowledge and social order.

The IBC tends to the issue of representation by enrolling rules that enhance the geographical representation of both the expert group and the government group. The experts maintain authority by having control over the writing process and by prioritizing consensus within the group.

This case study shows how a BO transcends the notion of ‘speaking truth to power’ by virtue of its position in the policy-cycle. The BO is an institutional response to the plurality and uncertainty of problems and their solutions and devises a means for the conversation to be had. In this case, expert advice is given authority through boundary-work. There are various ways that expert knowledge and policy are separated through rhetorical and discursive means.

4. Chapter 4 – Institutional Design of WHO’s Immunization Governance Apparatus: An Expert-Driven Model?

‘Expertise is less a form of knowledge deployed by specialized actors than a form of knowledge work undertaken by all kinds of people in their relationship with others. Expert work positions the people who do it between what is known and what must happen. The work is interpretive, translating the known into action and knitting the exercise of power back into the fabric of fact. One characteristic of this work is disagreement. Experts struggle with one another using tools of interpretation, articulation, and persuasion that are, when effective, at once words and authority’

- David Kennedy (2016:109)

4.1. Introduction

This chapter presents the institutional design of SAGE and defines the advisory role that it plays. Furthermore, this chapter analyses the practices at the science-policy interface in terms of boundary-work. As in the previous chapter, I argue that SAGE can be analyzed as a BO that manages the boundaries between science and policy through rhetorical and discursive strategies that aim to enhance the saliency, credibility and legitimacy of the knowledge they produce. The analysis draws out these strategies in order to understand the mechanisms that enable internal deliberation, enable boundary management and enable mediation between a variety of actors in BOs.

The introduction of routine, universal infant immunization into health systems took place mostly in the late 1970s (Burton et al. 2009). Thereafter, immunization practices have become widely accepted across the globe and are an integral part of health systems, a cornerstone of general medical practice and a priority issue on global development agendas. Immunization is widely considered an effective preventive strategy. A recent study - conducted by a multidisciplinary group with expertise in mathematical modelling - for example, of '[t]he estimated mortality impact of vaccinations forecast to be administered during 2011–

2020 in 73 countries supported by the GAVI Alliance’ found that ‘vaccination can be expected to have substantial public health impact, particularly in Africa and Southeast Asia, two regions with high mortality’ (Lee et al. 2013). A growing number of studies consider the cost-effectiveness of immunization strategies. The International Vaccines Access Center at Johns Hopkins Bloomberg School of Public Health, for example, project the potential cost of illnesses averted (in billions of USD, resulting from vaccinations 2011-2020) to be \$63 Billion. However, these kinds of rational arguments tend to contribute towards the powerful immunization rhetoric of immunization practices which can easily be taken-for-granted. The weaving of facts, data, justifications and interpretations across institutions, and into various national and international political forums reveals a complex interplay of institutions, governance tools, expertise, politics and scientific authority. Furthermore, the power of such discourses has the potential to limit opportunities for contestation. With the persistent call to maintain high levels of vaccination coverage as a global health priority, the appeal of immunization in terms of cost-effectiveness, along with the little contestation over the introduction of new vaccines, such rational policies have raised concern that the pursuit of these goals can impinge on the rights and concerns of those affected by immunization policies (Fisher 2012:218). I argue that while immunization practices are an important resource in global health, the practices are however inherently political and should therefore be held to the same kinds of societal scrutiny and accountability measures as any other scientific or technological intervention and that it is these demands for accountability measures that have forced experts to engage with other stakeholders in spaces that

enable negotiation and engagement between scientific communities, policy communities and with society. This analysis aims at identifying the means through which BOs are designed to enable such negotiations and engagement, highlights the ways in which decisions are taken and the ways that knowledge is made, focusing attention on the interplay between science, politics and society.

This chapter highlights some of the ways in which immunization rhetoric gains its power in the knowledge-production process and demonstrates the ways in which knowledge is built upon this rhetorical power and is propagated by experts and through technical expertise. I argue that the boundary between science and policy is managed through strategic boundary-work that harnesses the power of data, indicators and technical materials as tools that embed particular ways of defining a problem and solutions into discourses and the language of technical expertise. Discourse and language become central elements in the struggle over the definition and means of achieving a common objective. Experts thus create saliency, legitimacy and credibility through strategic demarcation, by maintaining expert authority over decision-making and through the transformation of policy language into the language of science and expertise through a variety of strategic boundary activities.

In the epigraph, Kennedy calls the activities of expert actors, *knowledge work* and *expert work*. 'Expertise is...a form of knowledge work undertaken by all kinds of people in their relationship with others. [And] [e]xpert work positions the people who do it between what is known and what must happen' (Kennedy 2016). This perspective points out that

expertise and knowledge are made through a process of social interaction. ‘The work is interpretive, translating the known into action and knitting the exercise of power back into the fabric of fact’ (ibid.). Biomedical discourses that appeal to evidence and facts, prescribe to a view of the world that is set apart from others, differentiating between science and pseudoscience being one key demarcation. Boundary-drawing sets the kinds of interpretations that are deemed relevant and those that are not; interpretation, argument and persuasion are tools that are employed to demarcate the position of the group in a pluralistic context. ‘One characteristic of this work is disagreement. Experts struggle with one another using tools of interpretation, articulation, and persuasion that are, when effective, at once words and authority’ (ibid.).

SAGE considers the effectiveness of vaccines, safety issues, financing and access issues related to the WHO’s global vaccine and immunization activities and gives advice on these aspects. Evidence-based practice has become a hallmark feature of the way the WHO justifies its activities, and characterizes the way that the WHO and SAGE see evidence, as informing policy. A large proportion of evidence and rational inputs are developed by mathematicians, epidemiologists, economic modelling experts, biostatisticians and biologists. A deeper analysis of the making of policy documents, plans and the evaluation of programs reveals the competitive nature of knowledge orders. While evidence-based practice is called on as means of practice, other competing narratives call for different kinds of knowledge, and the involvement of different actors.

Vaccine effectiveness is measured as an extrapolation of vaccine efficacy data. Efficacy rests on the premise that when an individual is vaccinated

with an antigen (dead, or live but weakened, form of a disease), the effects can result in a number of outcomes:

- Vaccination may reduce the probability, severity and/or speed of progression of clinical disease (including towards mortality) in vaccinated persons.
- Vaccination may reduce susceptibility to infection of vaccinated persons upon exposure.
- Vaccination may modify infectivity of vaccinated persons to others. That is, when vaccinated persons acquire natural infection they may be less infectious than non-vaccinated persons who acquire an infection.
- Vaccinated persons may immunize non-vaccinated persons indirectly by shedding vaccine-induced viral load (irrespective of whether these vaccinated persons have been exposed to natural infection).
- Furthermore, the immune system shows different responsiveness based on the age of the vaccinee as well as to the number of doses they receive (World Health Organization (WHO) 2008).

Vaccine effectiveness is then defined by the impact on measurable observations on the occurrence of infections in vaccinated and unvaccinated groups (*ibid.*). Vaccine delivery and uptake or vaccine coverage are considered because these too affect vaccine effectiveness. Issues such as potency of vaccines due to temperature exposure, administrative errors and improper dosing are estimated. Two main sources of data are used to estimate vaccine coverage. Health system delivery records and household-based surveys. Biases can occur in the

absence of standardization in data sources and methods of collection. WHO and UNICEF conduct annual reviews of official data and reporting, consult published and grey literature and consult with local experts to derive the most accurate estimates (ibid.). The spread and management of diseases, therefore, are understood in technical and biomedical terms, which informs the approaches to health and disease management that SAGE ascribes to.

Vaccine and immunization science and policy have developed and are shaped within a field of knowledge and practice with its own ways of producing knowledge, and its own way of managing the relationship between science, politics and society. SAGE creates a space for the negotiation of these particular interactions between science, politics and society, producing knowledge for the purposes of governing global vaccine and immunization activities. As with the previous discussion around the IBC, SAGE will be analyzed using a PA framework that sees SAGE as an agent to three principals, i.e. the scientific community, the policy community and the WHO. The framing that a PA analysis allows gives perspective to what Guston (2005) highlights is a ‘deceptively simple question that politicians or the public may ask, “How do we trust scientists when they say and do things we have little substantive knowledge about?”’ (Guston in Maasen and Weingart 2005:63). The analysis of the relationships between science and politics in the case of SAGE seeks to establish how the configuration of SAGE as a BO characterizes its function and its navigation of science and policy boundaries in order to overcome the problems associated with delegation. To elucidate how SAGE navigates the science-policy interface as an

agent to the scientific community, policy community and the WHO, the analysis looks in detail at some of the micro-processes to show how boundary-work is carried out. As a BO, SAGE is a site of what Sheila Jasanoff (1996:397), following Bruno Latour, has referred to as *co-production* - the simultaneous production of knowledge and social order. Boundary organizations are involved in coproduction by facilitating collaboration between scientists and nonscientists and by creating this combined "scientific and social order" (Guston 2000:149).

Focusing on micro-processes brings to the fore the adaptability of expertise, allowing for an understanding of how disagreements are made, shaped and reshaped into consensual agreements. It also allows for an understanding of the boundary-work that allows for a decision to be based on one way of knowing rather than another and to pinpoint the arrival at a decision.

As with the previous chapter, this chapter will bring empirical evidence to bear on the question of how institutional design affects boundary-work. The chapter will firstly discuss the science-policy relationship that the BO is bringing stability to. Thereafter, the chapter discusses the ways in which the BO stabilizes the boundary through boundary-work. At the same time, the analysis will consider the power relations and means through which power manifests in the activities and practices being undertaken by SAGE.

4.1.1. Science-Policy Instability and SAGE

To understand the science-policy interface at which SAGE operates, this section presents the science-policy relationship that SAGE has sought to manage. The science-policy relationship can be seen to contribute to the way that SAGE is designed and the way that it practices boundary-work. The instability at the science-policy boundary that SAGE set out to manage is characterized by tensions arising from the promotion of vaccines across the globe as a safe and effective public health intervention, and uncertainties over the safety, effectiveness and costs associated with immunization programs. Furthermore, in a context in which countries have differing national agendas and health priorities and where a majority of countries lack the resources to develop sustainable immunization programs or produce their own vaccines, the WHO has played a pivotal role in standardizing health interventions across the globe and in bringing a variety of actors and resources together to solve the global inequalities in vaccine production and access.

As a convener, WHO has had to deal with different stakeholders and had to manage a variety of interests. Governing in the global context has meant needing to manage interests and concerns across a range of national contexts as well as levels of government. For this reason, global policy activities have had to consider the differing contexts and the ways of managing vaccine programs. Bringing about a global agenda has been a central task, albeit one fraught with differing perceptions of policy goals and how to approach vaccine coverage. The WHO has had to prove that

the benefits of vaccination compared favorably to other kinds of community interventions and research agendas have thus focused on developing such proof.

The WHO has had to deal with mistrust and controversies as a consequence of its convening role. Mistrust has appeared as a problem in the WHO's handling of the interests of the pharmaceutical industry. The WHO had to contend with another controversy that arose from a study on the effects of vaccines that purported to show a link between vaccines and autism. In managing the boundaries between science and policy, SAGE, as an agent to the scientific community, needs to maintain a boundary between science and pseudoscience. For the policy community, as an agent, SAGE is tasked with providing clear policy options and for the WHO, as an agent to the organization, SAGE seeks to shield the organization from the possible tainting of its legitimacy by separating out the task of convening the multiple stakeholders and providing the WHO with advice that has taken into consideration the multiple interests necessary for policy options to be relevant to the global community.

In the global governance landscape, the WHO is tasked with steering global health policies and activities as the 'directing and coordinating authority on international health within the United Nations' system. It does this by:

- **Providing leadership** on matters critical to health and engaging in partnerships where joint action is needed;
- Shaping the **research agenda** and stimulating the generation, translation and dissemination of valuable knowledge;
- Setting **norms and standards** and promoting and monitoring their implementation;
- Articulating **ethical and evidence-based** policy options;
- Providing **technical support**, catalyzing change, and building sustainable institutional capacity; and
- **Monitoring** the health situation and assessing health trends (World Health Organization 2016a).

In its efforts to promote vaccines and immunization practices and to standardize immunization interventions as well as to enable it to provide monitoring and build awareness of the benefits of vaccine and immunization activities, and to develop a global agenda that means the same thing to different actors, the WHO has developed a ‘technology of global governance’: indicators. ‘Indicators are typically aimed at policymakers and are intended to be convenient, easy to understand, and easy to use’ (Davis, Kingsbury, and Merry 2012:6). Indicators in vaccine and immunization governance frame and highlight the problems associated with under-immunization, justify the need to increase coverage and help governing bodies to monitor trends in immunization activities. These indicators serve to simplify phenomena into numerical form so that States as well as funding agencies and development agencies are able to

develop their own policies around them. However, the use of indicators, as social constructs, are laden with social, political and epistemic particularities that make them inherently political despite their appearance as objective and scientific. In an analysis of the use of indicators in global governance Davis, Kingsbury and Merry (2012) bring attention to the problems associated with an uncritical view of indicators:

‘Indicators are typically aimed at policymakers and are intended to be convenient, easy to understand, and easy to use. Yet, the transformation of particularistic knowledge into numerical representations that are readily comparable strips meaning and context from the phenomenon. In this numerical form, such knowledge carries a distinctive authority that shifts configurations and uses of power and of counter-power. This transformation reflects, but also contributes to, changes in decision-making structures and processes.’ Davis, Kingsbury, Merry (2012:6)

The use of indicators, data, research and science by SAGE and the WHO is a characteristic feature of their organizational culture. In her genealogy of vaccine coverage indicators in the WHO, Fisher (2012) demonstrates the integral part that indicators play in shaping the identity of the WHO itself, and that there has been a demand for indicators which has been fueled by international development agencies involved in health reform. These highly technical scientific processes are an integral part of the work of SAGE, who uses indicators as a basis for the development of their recommendations. The use of indicators is a governing tool, in that it embodies the exercise of power in its influence:

‘Indicators can be used to evaluate the conduct of states against the standards embodied in the indicator. Those evaluations can in turn form a basis for various actors’ decisions on how to create or distribute resources, and how to try to alter the behavior of others or their own behavior. Where a single actor (or set of actors) outside the state have governing power in relation to the state, the governing actors may use indicators in the exercise of this power, for example in taking decisions on whether the state merits particular resources and on whether measures aimed at inducing or achieving compliance with the relevant standard are warranted’ (K. E. Davis, Kingsbury, and Merry 2012)

The WHO’s role in promoting vaccines and immunization practices and concerns over the influence of the pharmaceutical industry in WHO decision-making processes, the need to balance the demands for science with the consideration of policy, the need to consider research without allowing undue influence from industry and the standardization of immunization practices across countries with different priorities are the core issues that WHO has had to contend with. SAGE was set up in order to bring stability to these tensions that arose in the governance of vaccines and immunization. I argue that SAGE is a BO that brings stability by acting as an ‘honest broker’ (Guston 2001b) between the various parties involved and by developing ways of managing these tensions without politicizing science. SAGE manages to translate science into policy-relevant recommendations that serve the WHO and policymakers, and protect the science from criticism through effective demarcation.

Furthermore, these tensions that arise, define the role and function of SAGE. The instability at the science-policy interface, I argue, is stabilized by a BO that provides institutionalized social interactions between scientists and non-scientists. These institutionalized practices support interaction and interdependence and provide a space for engagement through boundary-work.

This chapter is divided into two parts. The first section will develop a view of the institutional design and the organizational culture of SAGE. After introducing the context within which the WHO's vaccine and immunization activities came into being, an analysis of the ways in which the WHO's vaccine and immunization activities developed and how the composition of experts in SAGE changed over time will be presented. The analysis takes a historical view of its membership and the members' profiles, and details the ways in which meetings have been conducted as a means of drawing out the kinds of knowledge and perspectives that the members have brought into discussions. The analysis will highlight the ways in which the interactions with political actors and the public are structured, and outlines the output of these interactions. The second part of the chapter presents an analysis of SAGE as a BO, elaborating on the Principle-Agent relationship between SAGE, and the scientific and political communities. The analysis takes a micro-level analysis of the issue of 'Measles' and of 'Vaccine Hesitancy' as a means of illustrating the ways in which SAGE manages the science-policy boundaries through boundary-work.

PART I – Contextualizing the Committee

4.2. WHO's Vaccine and Immunization Activities: The Background

Vaccination efforts have resulted in the eradication of small pox, and the elimination of poliomyelitis²⁰ and of measles²¹ from some regions across the globe. Vaccination is widely recognized as making a valuable contribution to global health and towards reducing the burden of diseases worldwide. The small pox eradication campaign efforts carried out by the WHO in collaboration with key partners between 1967 and 1977, brought heightened attention to immunization and to the idea that eradication was possible as a global health goal. Although eradication is seen to be beneficial, critics argue against eradication as a priority and necessity. Competing priorities, a lack of global commitment to eradication efforts,

²⁰ Global Polio Eradication Initiative 'Certification': WHO Region of the Americas year certified polio-free: 1994; WHO South-East Asia Region year certified polio-free: 2014; WHO European Region year certified polio-free: 2002; WHO Western Pacific Region year certified polio-free: 2000. Information can be found at: <http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/certification/>

²¹ 'Region of the Americas is declared free of measles' September 2016 (PAHO/WHO). Information can be found at: http://www.paho.org/hq/index.php?option=com_content&view=article&id=12528%3ARegion-americas-declared-free-measles

and ethical disputes about the extent of coercion inflicted by eradication campaigns have been major impediments to subsequent eradication goals. Instead, disease control has been put forward as an acceptable alternative. Accounts of discussions within the WHO have brought this issue to the fore, for instance Birn (2011) has argued that ‘smallpox eradication and WHO's concurrent social justice-oriented primary health care approach (following from the Declaration of Alma-Ata) became competing paradigms.’

In 1973, WHO established an Expanded Program on Immunization (EPI) which targeted six more diseases: diphtheria, whooping cough, tetanus, measles, poliomyelitis and tuberculosis. The WHO set a goal to achieve universal immunization for all children by 1990 which was to contribute to its broader goal of achieving ‘health for all by 2000’. This goal was set out in the 1974 WHA Resolution 27.57. The Joint UNICEF/WHO Committee on Health Policy was tasked with ensuring that universal immunization was on the agenda of every country. Countries thereafter began reporting national immunization data to the WHO and to UNICEF.

The 1980s were a difficult decade for the WHO, which saw the organization lose its influence to multilateral organizations (the World Bank, UNDP, etc.) and bilateral donor governments (the USA, Europe, and Scandinavian countries) which it became reliant on due to budgetary issues (Godlee 1994). The US with-held its contribution to the WHO in 1985, partly in protest to WHO's ‘Essential Drug Program’ which major US-based pharmaceutical companies opposed (ibid.) The World Bank

had also in that decade begun offering loans for health financing, which further curtailed WHO's global influence and redirected global priorities.

In the 1990s, under the direction of Director General Gro Harlem Brundtland, the Commission on Macroeconomics and Health was established, chaired by Jeffrey Sachs. The 2001 report produced by the Commission re-emphasized the control of communicable diseases and maternal and child health as top priorities (Sachs 2001).

In the year 2000, the Global Alliance for Vaccine and Immunization (GAVI) was established 'to improve access to new and underused vaccines for children living in the world's poorest countries' (GAVI 2016b). Established as a Public-Private-Partnership (PPP), GAVI initially received a US\$750 million five-year pledge from the Bill & Melinda Gates Foundation, and was set up to leverage funds from private sources. In support of the EPI, GAVI brought together 'UN agencies, governments, the vaccine industry, private sector and civil society to work together to improve childhood immunization coverage in poor countries and accelerate access to new vaccines' (ibid.). With the prevention of more than 7 million deaths since its creation, GAVI envisions 'reaching an additional 300 million children between 2016 and 2020, preventing a further 5-6 million more deaths' (ibid.).

In 2005, the 58th World Health Assembly recognized the role that vaccines and immunization can play in reducing under-five mortality. The Global Immunization Vision and Strategy (GIVS) 2006–2015 developed by WHO and UNICEF was set out as a framework for

strengthening national immunization programs and set out a path for the attainment of sustained and high levels of vaccine coverage (Bilous et al. 2006; Unicef 2005).

The integration of vaccination as a part of the global development goals has further emphasized its importance as a global health strategy, both in terms of mortality reduction as well as in economic terms. ‘Mortality reduction is already reason enough to have every child on this planet fully immunised, as shown by the Millennium Development Goals and the post-2015 development agenda. Now this fight is not simply about saving lives, but about maximising the full lifetime potential of these children and the economic health of the families and countries in which they live.’ (Bärnighausen et al. 2014)

In 2010, the global health community declared the next ten years to be the Decade of Vaccines (GAVI 2016a). The Decade of Vaccines (DoV) Collaboration created a global consultation with stakeholders which culminated in the development of the Global Vaccines Action Plan (GVAP). In 2012, the Sixty-Fifth World Health Assembly (WHA 65.17) discussed and endorsed the GVAP,²² which lays out a plan for the 2011-2020 period. The WHO is one of the players involved in implementing GVAP and the framework serves to inform vaccine activities:

²² The DoV Collaboration initiative ended in 2012, for more information see: <http://www.dovcollaboration.org>

‘GVAP was the product of the DoV Collaboration, an unprecedented effort that brought together development, health and immunization experts and stakeholders. The leadership of the Bill & Melinda Gates Foundation, GAVI Alliance, UNICEF, United States National Institute of Allergies and Infectious Diseases and WHO, along with all partners – governments and elected officials, health professionals, academia, manufacturers, global agencies, development partners, civil society, media and the private sector – are committed to achieving the ambitious goals of the GVAP. Many more are expected to add their support in the future as the plan is translated and implemented at the country and regional levels’ (World Health Organization 2016b).

There are various key players in the global vaccine and immunization policy context, including PPPs, donors, civil society organizations, NGOs, development agencies, national governments, the private sector, health professionals, academia, pharmaceutical manufacturers, and international organizations. The WHO works amongst them to provide countries with support and guidance. SAGE provides the WHO with advice on its goals and how to accomplish them. The following section discusses the key roles and functions that SAGE provides in the global governance of vaccines and immunization.

4.3. SAGE: Role and Function

The Strategic Advisory Group of Experts (SAGE) on Immunization was established by the Director-General of the World Health Organization in 1999 to provide guidance on the work of the WHO. SAGE advises the WHO on its global immunization plans and activities. SAGE currently states its role as follows:

SAGE advises the WHO Director-General specifically on the:

1. adequacy of progress towards the achievement of the goals of control of vaccine-preventable diseases worldwide such as those laid out in the Decade of Vaccines Global Vaccine Action Plan 2011-2020.
2. major issues and challenges to be addressed with respect to achieving the disease control goals, including issues and challenges to achieving and sustaining high and equitable vaccination coverage;
3. immunization programme response to current public health priorities;
4. major general policies, goals and targets including those related to vaccine research and development;
5. adequacy of WHO's strategic plan and priority activities consistent with its mandate and considering the comparative advantages and the respective roles of partner organizations;
6. engagement of WHO in partnerships that will enhance achievement of global immunization goals. (World Health Organization 2016c)

The reason that SAGE calls itself the 'Principal' advisory group is because WHO has a network of technical advisory committees that all report to SAGE. The Committees that report to SAGE are shown in Figure 15.

Technical Advisory Groups	Functions
The Global Advisory Committee on Vaccine Safety (GACVS)	To provide scientific advice on issues of vaccine safety that are of potential global or regional concern and may have an impact on national immunization programs.
The Expert Committee on Biological Standardization (ECBS)	To set norms and standards for manufacturing, licensing and control to ensure the quality of vaccines and other biological products.
The Immunization and Vaccines Related Implementation Research Advisory Committee (IVIR-AC)	To provide advice and recommendations on immunization and vaccine-related implementation research, including reviews of the relevance and applicability of quantitative methods, agenda setting and prioritization of research, and reviews of implementation progress and best practices.
The Immunization Practices Advisory Committee (IPAC)	To advise WHO on the formulation of immunization strategies and operational standards, the tools and technologies necessary to reach and sustain high levels of immunization coverage and to promote immunization services of high quality.
Regional Technical Advisory Groups (RTAGs) on Immunization - <i>Established in each of the six WHO regions (Africa, the Americas, the Eastern Mediterranean, Europe, South-East Asia and the Western Pacific).</i>	To provide WHO Regional Directors and countries in the respective regions with recommendations on regional immunization priorities and strategies considering the regional epidemiological and social context.
National Technical Advisory Groups (NITAGs) - Most industrialized and some developing countries have formally established NITAGs to guide immunization policies.	To provide guidance to national policy-makers and program managers to enable them to make evidence-based immunization-related policy and program decisions.

Figure 15 – Technical Advisory Groups and their Functions

SAGE also relies on ad hoc Working Groups which are set up when the need arises. The Working Groups consist of no more than ten to twelve members. Two or more members are members of SAGE, one of whom serves as the Chair of the Working Group. In addition, WHO staff take the function of technical lead and serve as the Secretariat of the Working Group. Other UN agencies can be co-opted if necessary. Members serve for three year terms, renewable for one additional term and are selected based on the need for expertise and considering geographical and gender representation.

A public call for nomination is made and SAGE members, regional offices, diplomatic missions, WHO staff and key partner organizations are approached for nominations. From the pool of nominees, the Working Group Chair, SAGE Executive Secretary and Lead WHO staff propose a composition of the Working Group for endorsement by the SAGE Chair and the Department of Immunization, Vaccines and Biologicals (IVB). The positions are non-remunerated. (World Health Organization 2016c). Table 16 lists the current and previous Working Groups set up by SAGE. The second part of this chapter will go into detail on how the Working Groups operate, illustrated by the work of the Decade of Vaccines Working Group.

CURRENT WORKING GROUPS	PREVIOUS WORKING GROUPS	PREVIOUS WORKING GROUPS
BCG	Conjugate pneumococcal vaccine	Meningococcal vaccines
Cholera	Dengue	Non-specific effects of vaccines
Decade of Vaccines	H5N1 influenza vaccine	Optimizing the use of conjugate vaccines
Ebola	Hepatitis A vaccines	Pertussis vaccines (March 2013 - August 2015)
Maternal and neonatal tetanus elimination and broader tetanus control	Hepatitis B	Pertussis vaccines (July 2009 - October 2010)
Measles and rubella	Hepatitis E	Pneumococcal polysaccharide vaccines
Polio vaccine	Influenza A(H1N1) vaccine	Rubella vaccines
Rabies	Influenza vaccines and immunization	Vaccination in Humanitarian Emergencies
Typhoid fever	Japanese Encephalitis	Vaccine Hesitancy
	Joint Technical Expert Group (JTEG) on Malaria Vaccines	Varicella and herpes zoster vaccines
	Measles	Yellow fever vaccines

Table 16 – Current and Previous SAGE Working Groups

SAGE meetings are held twice a year and the agenda is decided in advance. The agenda setting process is developed in consultation with SAGE members, WHO departments, regional offices, stakeholders and countries through the WHO Secretariat. SAGE practices center around transparency, wherein public meetings are conducted, meeting reports are published and detailed information on the decision-making process are made available on their SAGE website. A further feature of its practices are the publication of Conflicts of Interest that any member of SAGE or a Working Group member may have. Much work goes on behind the scenes, with conference calls before meetings, the production of preliminary documents, and work carried out with the secretariat prior to meetings. As is customary, all major global reports and plans that the WHO produces and that affect global vaccine and immunization policy pass through the World Health Assembly for approval.

During the SAGE meetings, the decisions are taken by consensus of SAGE members, after considering the recommendations suggested by the technical advisory groups and working groups and any other issues that might arise in the discussions with the stakeholders at the meetings. Stakeholders often communicate their concerns either to the SAGE Chair or to the Secretariat and their comments are discussed by the SAGE members collectively (Interview: SAGE Member). SAGE maintains strong links with the RTAGs and the RTAG Chairs usually contribute a substantial amount to the discussions and are given priority to take the floor to speak along with SAGE members during the deliberation process

in public meetings. SAGE deliberations take place in the open sessions that are attended by UNICEF, the Secretariat of the GAVI Alliance, the WHO Headquarters and Regional Offices, Chairs of WHO regional technical advisory groups and other relevant WHO technical advisory groups who participate as observers. WHO also invites ‘representatives from international professional organizations (such as the International Pediatric Society, the World Medical Association and the International Council of Nurses), other nongovernmental organizations (such as Médecins Sans Frontières and OXFAM International), technical agencies (such as the US CDC, the UK Health Protection Agency and the European CDC), donor organizations, country representatives, vaccine manufacturers’ associations, immunization technologies and other industry experts’ (Duclos, Okwo-Bele, and Salisbury 2011).

Prior to the establishment of SAGE, very little consideration was given to the representation, and the activities were far removed from the context on vaccine implementation. The WHO’s decision to create SAGE followed the example of the US Advisory Committee on Immunization Practices (ACIP) as a basis for its design (Smith 2010). The groups do however differ, for instance in their handling of competing discourses:

‘the SAGE may choose to listen or not to that individual/individuals unlike the ACIP meetings which are also public open meetings at sage not only is the press not there, there are also no patients or patient groups or parents of deceased patients or those types of individuals who come to ACIP meetings and often make statements on the

vaccines whether pro or anti-vaccination. (Interview: Previous SAGE Member).

Some clarifications were given in defense of the choices in the design of SAGE. For instance, the SAGE invites Diplomatic Missions to the meetings however, are not in favor of having Ministers of Health in attendance *‘as long as it’s not a minister pushing a political agenda but basically respecting the scientific debate’* (Interview: SAGE). Working Group meetings are conducted as closed meetings,

for the Working Groups, we have those closed unlike the full SAGE and the reason for the close initially we tolerated observers but when we do that then invariably you only have the wealthy US or UK organizations attending and again these people don’t attend really as observers. (Interview: SAGE)

A related point on the design choices was made concerning the inclusion of industry in vaccine and immunization science and policy:

industry obviously, depending on the nature of the issue, if the recommendation has to be discussed with the vaccine, they have to be in the loop and we have to get a mutual exchange now clearly they have to be in the loop of the providing information but absolutely not in the decision making so we are putting very clear boundaries on their involvement (Interview: SAGE).

The issue of influence is a key factor in the consideration of how SAGE is designed. The group is designed to resist the influence of special interests

from States, industry and wealthy countries and demonstrate the separation of these groups through the design.

Presentations are usually given by the technical advisory groups, usually the WHO department of Vaccines, Immunization and Biologicals gives a report on their activities, the GAVI Alliance gives reports on their work since they are a key partner in vaccine financing and operations and the Working Groups give reports on the work they have done. The presentations usually conclude with a list of recommendations for SAGE to approve. Participants are given a written version of the presentations and any other relevant documents, in the form of a 'Yellow Book'. The meetings are Chaired by the Chair of SAGE and priority is given to the SAGE members and TAG Chairs to take the floor. The floor is then opened for further comments from the other attendees. Usually, due to time constraints, only a few comments can be made by other attendees and emphasis is placed on dealing with any objections to recommendations presented and in finding consensus amongst the SAGE members.

SAGE then reports directly to WHO's Director-General. The SAGE Chair usually meets with him/her immediately after the SAGE meeting to deliver the meeting conclusions. Working documents, reports and other relevant materials are posted on the WHO/SAGE website for further consultation and to maintain transparency. In addition, the conclusions of the SAGE meetings and the recommendations that SAGE produces are published shortly after the meetings in the 'Weekly Epidemiological Record' (ibid.).

SAGE undertook a major restructuring operation in 2005. This exercise sought to improve the acceptance of the WHO policy recommendations on vaccines and immunization and strengthen its normative and policy-setting function, with an emphasis on evidence-based decision-making and transparency. This has come in response to the fragile science-society relationship particularly between vaccine governance organizations and the public. The WHO has been subject to conspiracy theories, and been accused of conflicts of interest with regards to its dealings with the pharmaceutical industry.²³ The organization has sought to deal with its legitimacy issues by systematizing vaccine decision-making. It does this by uses the GRADE²⁴ (Alonso-Coello et al. 2016a, 2016b; Guyatt et al. 2008) method, an evidence to decision framework to develop their recommendations as well as for decision-making processes in the Working Groups. While the systematization of decision-making procedures provides some form of accountability and credibility, there are disagreements over whether this approach is the right one for the kind of work that is done by SAGE:

the grade approach which really comes out of the clinical world how do you read the clinical evidence that the

²³ For a detailed critique of the WHO and the transparency problem see Cohen, Deborah. 2010. "WHO and the Pandemic Flu 'conspiracies.'" *BMJ* 340(c2912).

²⁴ GRADE is an acronym for the Grading of Recommendations Assessment, Development and Evaluation, which is used as a systematic and transparent framework approach to decision-making.

treatment works for this disease, you have randomized trials, it works better in that setting than it does for public health programs and often for epidemiologic data so i think some of us think it is not a perfect fit and that therefore not optimal but A the organization has decided that that is the process that they are going to use and there's no alternative and secondly its not clear that there's some better approach that ends up giving you different answers so people have basically said that if that's what the organization has decided there's no point arguing about it (Interview: Former SAGE Member).

In terms of information, the design allows for there to be a variety of experts to work on an issue.

for the topics that are fairly complex, involve a review of evidence and for which we figure we need this multi-faceted type of approach of expertise and we need expertise beyond that of SAGE members ok because SAGE members are very knowledgeable on immunization and other fields, they are prominent people when you go on the very narrow field they know less than some other people. (Interview: SAGE)

SAGE however finds that it lacks information on the poorer countries, because research is expensive and usually undertaken in rich countries, and on topics of interest to the rich countries (Interviews: Multiple Interviewees). The kind of information that is demanded by the field of practice is resource intensive, including systematic reviews; data

intensive and time consuming to manage. These have led to inconsistencies in information and the need for SAGE to develop its own means of understanding and influencing the global context.

4.4. Appointing the SAGE Members

SAGE consists of 15 Members who serve in their individual capacity for a three-year term, renewable for one additional term. The members are selected based on their prominence, as exceptional experts in their field. The experts also possess a variety of skills and expertise, not only in their specialty, but also in practice and across disciplines.

SAGE members are recruited and selected as acknowledged experts from around the world in the fields of epidemiology, public health, vaccinology, pediatrics, internal medicine, infectious diseases, immunology, drug regulation, program management, immunization delivery, health-care administration, health economics, and vaccine safety (World Health Organization 2016c).

The membership of SAGE shall seek to reflect a representation of:

1. professional affiliation (e.g., academia, medical profession, clinical practice, research institutes, and governmental bodies including national immunization programs, public health departments and regulatory authorities);

2. major areas of expertise (e.g., vaccine research, vaccine and immunization safety, optimization of immunization schedules, vaccine delivery, disease control strategies, impact monitoring); and
3. the strategic focus areas of the WHO's vaccine and immunization work including vaccines norms and standards, vaccine regulation, vaccine program management, delivery and surveillance and monitoring, and vaccine research & development. (ibid.).

In addition, the Secretariat tries to achieve a balance of professional affiliation, area of interest and geographic representation. An important criterion is that the members divulge any conflicts of interest and it is important for the members to not have any conflicting interests. Though important, this is a difficult balance to achieve since most of the top experts are somehow involved in research themselves (Interview: SAGE Member). A public call is sent out and the members are appointed by the WHO Director-General based upon a recommendation of an external selection panel. Since the members are rotated every three to six years, the group maintains some continuity whilst also encouraging change over time. See Table 17 for an example of the composition of SAGE.

Name	Position	First SAGE meeting participated in	Expected last SAGE meeting to be participated in
Professor Jon S. Abramson (Chair)	Chair, Wake Forest University School of Medicine, Department of Pediatrics, United States of America	Apr-2009 (reappointed Nov-2012, Chair since Nov. 2013)	Oct-2016
Dodot Yagob Yousef Al-Mazrou	Secretary General, Health Services Council, Kingdom of Saudi Arabia	Nov-2012	Oct-2015*
Professor Narendra Arora (Vice-Chair)	Executive Director, International Clinical Epidemiology Network, India	Apr-2010 (reappointed Nov-2013)	Apr-2016
Professor Zulfikar Ahmed Bhutta	Professor, Pediatrics and Child Health, The Aga Khan University, Pakistan	Apr-2009 (reappointed Nov-2012)	Apr-2015
Professor Juhani Eskola	Director General, National Institute for Health and Welfare, Finland	Oct-2009 (reappointed Apr-2013)	Oct-2015
Professor J. Pieter Figueroa	Department of Community Health & Psychiatry, Faculty of Medical Sciences, University of the West Indies, Jamaica	Apr-2009 (reappointed Nov-2012)	Apr-2015
Dr Jaleela Jawad	Ministry of Health, Manama, Bahrain	Apr-2015	Apr-2018*
Dr Karl Johansen	Expert Vaccine Preventable Diseases, European Centre for Disease Prevention and Control (ECDC), Sweden	Apr-2014	Apr-2016*
Professor Terence Nolan	Melbourne School of Population Health, University of Melbourne, Australia	Nov-2012	Oct-2015*
Professor Katherine O'Brien	Johns Hopkins Bloomberg School of Public Health, Washington, United States of America	Nov-2012	Oct-2015*
Professor Claire-Anne Siegrist	Director of the Department of Pediatrics, University of Geneva, Switzerland	Nov-2010 (reappointed Apr-2014)	Oct-2016
Dodot Piyarit Thammaphompilas	Manager, National Immunization Program, Ministry of Public Health, Thailand	Nov-2010 (reappointed Apr-2014)	Oct-2016
Professor Oyewale Tomori	Redeemer's University, Nigeria	Apr-2009 (reappointed Nov-2012)	Apr-2015
Dr Nikki Turner	Associate Professor, Director, Immunisation Advisory Centre, University of Auckland, New Zealand	Oct-2014	Oct-2017*
Professor Fredrick Were	Professor of Pediatrics, University of Nairobi, Kenya	Nov-2013	Oct-2016*

Source: WHO - http://www.who.int/immunization/sage/members/former_members/en/

Figure 17 – SAGE Member Composition

PART II – Producing Knowledge

4.5. Introduction

Part I of this chapter has described the institutional design of SAGE and its functions. It discussed the ways in which SAGE functions and how its interactions are structured. Part II of this chapter will elaborate on the ways in which SAGE produces knowledge. This will be done by examining in detail the 2014 Assessment Report of the Global Vaccine Action Plan developed by the Decade of Vaccines Working Group and the subsequent development of a set of recommendations issued by SAGE. The analysis will bring to the fore the ways in which SAGE manages the boundaries between science and policy and practices boundary-work. This case-study offers a view of the use of scientific facts, the discussions on the development of evidence and indicators and the scientific and political virtues of target-driven planning mechanisms. The analysis also examines the science and policy implications of governance by indicators, targets and milestones. It demonstrates how the rational and pragmatic activities involved in scientific assessments and policy making are inherently political and discusses the ways in which the scientific community manages the political discourse. Moreover, the analysis considers how power is being exerted in the ways and means of governing science and technology for health in the field of vaccines and immunization. The analysis will examine the role of SAGE

as a BO in this governance context and offers a perspective of the ways and means through which boundaries are maintained and the ways in which saliency, credibility and legitimacy are produced.

4.6. From Report to Recommendations: Examining Boundary-Work

As in Chapter 3 and as outlined in Section 3.6., the following analysis details the micro-processes that lead from, in this case, the 2014 Assessment Report of the Global Vaccine Action Plan to the development of a set of SAGE recommendations. The analysis incorporates first-hand observations of meetings and combines them with data obtained from interviews and by examining the reports produced by the SAGE and its Secretariat. Although this does not present a full picture of the organization and its workings, it does however capture elements of how the organization functions, how the actors interact, how knowledge is produced and allowing for a gaze into the boundary-work practices.

The observations made in the public meetings provide an opportune instance to capture the ways in which debates develop and the kinds of interactions that take place between the various actors. Recordings of the sessions were captured on a digital recorder and hand-written notes were taken to capture the various visual observations. The drawback of this method was that discussions continued outside the public meetings and it

was not possible to gain first-hand experience of the various interactions. For instance, the researcher did not attend the WHA meeting which will be referenced in this section. For this reason, reports and documents written by the Secretariat and the Decade of Vaccines Working Group were used to fill the gaps. However, the reports did not capture the nuances in discussions in as much detail as the recordings would allow and missing information resulted from the second-hand interpretations. Interviews were conducted to facilitate more insights on the dynamics of the group and their interactions beyond the public meetings and to substitute for the gaps in the processes involved.

4.6.1. Organizing Deliberation

The Decade of Vaccines (DoV) Working Group (see figure 18 for the composition), which was established in 2013, produced the 2014 Assessment Report of the Global Vaccine Action Plan (Department of Immunization Vaccines and Biological (IVB) 2014:158). The report sought to provide an assessment of the progress towards reaching a set of targets that were laid out in the GVAP. Of the six targets with a 2014-2015 Mid-Point target deadline (the complete targets are to be met by 2020), only one was on track and the assessment emphasized that overall progress was far off-track. The targets relate to different vaccines and diseases and the assessment points to the ‘failure to extend vaccination services to people who cannot access them and failure to strengthen the

healthcare system so that all doses of vaccine are reliably provided' (Ibid.) as the most common obstacles towards their achievement. The six Mid-Point targets set out in the GVAP were:

1. **DTP3 (Diphtheria, Tetanus, Pertussis):** National vaccination coverage of 90% in all countries by 2015, with no district's coverage less than 80%
2. **Introduction of under-utilized vaccines:** At least 90 low or middle income countries to have introduced one or more such vaccines by 2015
3. **Polio:** No new cases after 2014 ('interruption of transmission')
4. **Maternal and neonatal tetanus:** Global elimination by end-2015
5. **Measles:** Elimination from three WHO regions by end-2015
6. **Rubella:** Elimination from one WHO region by end-2015 (Ibid.)

The report also listed five priority problems that have led to the stagnation of vaccination coverage and to the eradication and elimination goals being repeatedly missed:

- Three years after its start date, implementation of the Global Vaccine Action Plan is patchy and slow. All countries and organizations that have committed to this endeavor should re-examine the level and nature of their contributions, and urgently make the improvements necessary to achieve results.
- Poor quality and use of data is substantially impeding program management and improvement.
- The affordability and supply of vaccines need to be urgently examined. Each may be causing a significant problem for a

large number of countries, and the current lack of proper information hinders understanding and corrective action.

- Basic failures of integration mean that healthcare workers are repeatedly missing easy opportunities to offer vaccinations when people attend clinic with other problems.
- Vaccine delivery is impeded by disruptive situations, including war and major disease outbreaks (such as Ebola, currently). Such situations will always exist. Vaccines must be delivered despite them. (ibid.).

The report was compiled by the Working Group after close collaborative meetings and discussion sessions amongst the members. Two meetings were held face-to-face and one over a conference call. The assessment used seven indicators to draw its conclusions on how far the goals were to their targets. To add to the credibility of the indicators used in the report, the indicators are explained in a 60 page report and were further reviewed by the Global Vaccine and Immunization Research Forum²⁵ and an independent consultant was engaged throughout the process of producing the assessment report (Cherian 2014). Another two-hundred and eighty paged document detailed the analytical work that went into analyzing the data and measuring the global assessment. The group discussed how to improve data quality and examined case studies from Uganda, Sudan and Chad as well as the Electronic Immunization Registries from the Americas to gather an understanding of the problems countries faced and

²⁵ 'The GVIRF is co-hosted by WHO, the National Institute of Allergy and Infectious Diseases, and the Bill & Melinda Gates Foundation. Gathering leading experts from public health, academia, government, civil society and private sector, the forum is held every second year.'

For further details see:
http://www.who.int/immunization/research/forums_and_initiatives/gvirf/en/ (accessed 2016).

possible solutions. The use of case studies is a common practice, and this method was used to gather information about measles elimination, vaccine hesitancy and changing epidemiology (Ibid.).

The Assessment Report was presented to the 67th World Health Assembly in May 2014 and was the most highly discussed agenda item with fifty-four speakers including Member States taking the floor during the discussion.²⁶ The WHA session highlighted several issues to address including: Sustainable access to vaccines, technology transfer, guidance to improve data quality, assistance on risk communication and management, and requested support to review evidence and conduct economic analyses that will lead to evidence-informed decisions based on local priorities and needs. (Department of Immunization Vaccines and Biological (IVB) 2014:199).

In September 2014, the Report was presented at the SAGE public meeting. The report was well-received and it was widely agreed that the report presented a sobering, frank and accessible view of the global progress towards reaching the GVAP targets and the statistical analysis presented innovation in measurement.

²⁶ Fifty-four speakers including 50 representatives from Member States, one observer, civil society organizations and the GAVI Alliance took the floor during the discussion on the Global Vaccine Action Plan (GVAP).

Member States included: Brazil; Cote d'Ivoire; Jamaica; Malaysia; Bahrain; Colombia; Thailand; Lebanon; Republic of Korea; China; Ecuador; Burundi; Indonesia; Japan; Vietnam; Russia; Iraq; Kenya; Surinam; Congo; Oman; Spain; Togo; Mexico; Namibia; Maldives; Morocco; South Africa; Germany; Mongolia; Algeria; Iran; India; Egypt; Barbados; Burkina-Faso; Jordan; Costa Rica; UAE; Uruguay; Tunisia; USA; Ethiopia; Trinidad-Tobago; Grenada; Azerbaijan; Malawi; Libya; Argentina; Tanzania.

The Observer: Taipei

The Civil Society Organizations: International Pharmacists Federation and MSF

The main issues that were raised in the public discussion can be split into four categories: implementation problems, implementation actions and suggestions, critiques of the scientific report and critiques of the policy dimension. The main points raised are presented in the document in Annex 2. SAGE members discussed the problems that the report pointed out in the report, that were listed previously and were concerned that the report was not able to translate the findings into concrete actions to be taken on the ground. The issues of country ownership, stewardship, price transparency and reporting inaccuracies, for example, were mentioned as problems of implementation. Therefore, they highlighted the implementation problems that exist and this drew attention to the possible implementation actions that could be taken, such as, strengthening the health system and making vaccination a key building block, or analyzing the effects of transparency or taking a strategic, systemic approach to countries with the lowest vaccination coverage rates. The discussion also turned to the report itself, concerning the scientific basis of the assessment. Interestingly, the report was seen by some to frame the problem in technical terms and the solution as a technical one. Others mentioned that there was a need for social factors, logistical considerations and a need to build product confidence. The Working Group mentioned that they were working with a huge amount of data, which needed to be cleaned up, and needed to answer the question of how much progress was made. This was done in a two month period and the report was limited by the available data. On this point, a question was raised about the extent to which the reporting measures reflect reality and the problem of validity of data especially considering the missing data.

The audience was assured that there was a two-hundred and eighty paged document detailing the analytical work.

SAGE considers the GVAP from a global perspective, however it is important to note that each region has its own Regional Vaccine Action Plan with their own priority areas and measures to understand the progress in achieving them. The European EVAP has a set of five targets, each with a measurable outcome. The European Region is however heterogeneous, with large differences between the ways in which the western side of Europe and eastern side of Europe operate. Differences in vaccine uptake, the prioritization of vaccines, ways of collecting, storing data and monitoring and evaluation practices, for example, contribute to the differences in understanding the problems associated with vaccination coverage and in its governance (Interview: SAGE). The use of targets can therefore mask the particularities of more specific contexts. Science, scientific assessments and the development of scientific or evidence-based interventions are tools for creating a political or social need to act. The danger is when assessments mask the nuances, creating a vision that is good for most but not good for individual cases. Vaccination programs ascribe to a utilitarian vision of health whereas, medical practice ascribes to an individualistic vision of health. These can often create tensions and misunderstandings. Furthermore, measurements, evidence-based practice and technical problem framing is resource intensive and may provide only partial information. The evidence may not necessarily show the right effects or the evidence that is being used may not be the right kind of evidence.

In the SAGE discussions, the tensions between meeting the global needs versus more specific needs are apparent. Governance at the global level is normative, creating standards, expectations, systems and knowledge that gets everyone to work towards a common purpose. However, given the many particularities, SAGE avoids giving highly prescriptive and specific recommendations. The recommendations (See Annex 3) are oriented towards a particular vision and require the political will to improve coverage through prioritization, monitoring of health systems and the management of data, vaccine supply and the provision of integrated service delivery. Indicators travel across space and time and act in a generalizing manner. Governance through indicators, rankings and targets have powerful effects on the ways in which problems are framed, solutions are driven and global governance is done. They shape expectations and create trajectories. As a means of galvanizing support from different actors, these tools can mean the same thing to many actors and embody political ambitions.

The GVAP provides a set of targets that are not very strictly defined but applicable in each region. Each region is then working towards achieving their own targets that again are not very strictly defined. The main issues as defined by SAGE are that vaccination should be prioritized, vaccine pricing and supply should be improved, integration of vaccination with other services and disruptive events such as wars and disease outbreaks. These are issues that require social interventions, and they are inherently political. Therefore, in developing a vision of immunization coverage, SAGE is encouraging the political implementation of that vision, and co-producing knowledge and social order.

Although Member States are not directly involved in the SAGE meetings, other policy makers, such as the donors, WHO, GAVI, USAID, (Center for Disease Control) CDC and the Gates Foundation for example are a part of the policy community and how they respond to the development of vaccination goals makes a difference to the global availability of resources for the achievement of those goals. In the SAGE meetings, for instance, the funding agencies will state whether they intend to contribute towards the financing of vaccine campaigns that will take place over a certain number of days, or if they will fund larger immunization programs. These logistical considerations can impact the ways in which SAGE considers its recommendations, therefore also contributing to co-production.

WORKING GROUP MEMBERS

Narendra Arora (Chair, SAGE member), Republic of India

Executive Director, International Clinical Epidemiology

Yagob Al Mazrou (SAGE member), Kingdom of Saudi Arabia

Secretary General Health Services Council

Alejandro Cravioto, Republic of Korea

Senior Epidemiologist, Global Evaluative Sciences, Seattle, USA

Fuqiang Cui, People's Republic of China

Professor, Deputy Director National Immunization Program, China CDC

Elizabeth Ferdinand, Barbados

Associate Lecturer, University of West Indies (Affiliation as of September 2014 and previously Senior Medical Officer of Health and EPI Manager)

Alan Hinman, United States of America

Senior Public Health Scientist – Taskforce for Global Health

Stephen Inglis, United Kingdom of Great Britain and Northern Ireland

Director, National Institute of Biological Standards & Control, Health Protection Agency

Marie-Yvette Madrid, Switzerland

Independent Consultant, Geneva, Switzerland

Amani Mahmoud Mustafa, Republic of the Sudan

Project Manager, Sudan Public Health Training Initiative, The Carter Center (affiliation as of May 2014 and previously EPI Manager Min of Health)

Rebecca Martin, United States of America

Director, Global Immunization Division US CDC

Rozina Mistry, Islamic Republic of Pakistan

Lecturer and Course Director, Aga Khan University

Helen Rees, Republic of South Africa

Executive Director, Reproductive Health Research Unit, University of Witswatersrand (former Chair of SAGE 2010-2013)

David Salisbury, United Kingdom of Great Britain and Northern Ireland

Associate Fellow, Centre on Global Health Security, Chatham House (affiliation as of January 2014 and previously Director of Immunization, Dpt of Health, and former SAGE Chair 2005-2010)

Independent consultant: **Paul Rutter**

WORKING GROUP SECRETARIAT

Bill & Melinda Gates Foundation

Gavi, the Vaccine Alliance

United States National Institute of Allergy and Infectious Diseases

United Nations Children's Fund

World Health Organization

Figure 18 - SAGE Decade of Vaccines Working Group Members

4.6.2. Discussion

SAGE endeavors to develop transparency by systematizing its decision-making procedures, publishing data that it works with, the sources of data and the processes that lead to the development of targets, indicators and measurement tools. The organization publishes its reports, makes the materials produced for meetings available to the public and holds deliberations in public forums. A large part of their work is technical however, discussions around technical issues feature much less in the SAGE discussions than more social and programmatic issues. Discussions around indicators for instance revolve around what the indicators mean or how they are used in the field. There were comments made in the meetings concerning the use of the indicators, showing that there is concern about the wide use of indicators and their implications, however, there is little contestation over the indicators themselves. Transparency adds credibility to the data that is produced and to the people who produce it. Furthermore, transparency brings about legitimacy, since the actors involved and the public are given information on how decisions are made.

The GVAP Report was well received at both the WHA meeting as well as the SAGE meeting. There was a sense that something new was presented, it was clear what the intention of the document was, the purpose it served and with the prognosis that it presented. The points that were made in the report acted as key talking points. Therefore, it is useful to consider how the use of language, style and presentation as a form of

argument and the presentation of a position gains its power and significance.

The BO enables the discussion of technical issues, however, the scientific assessments, programmatic judgements and political aspects are justified in a rational way through the use of technical plans, targets and monitoring of the achievement of milestones. Though it is not the states who are involved directly in the discussion, the science/policy debate is negotiated, policy needs are translated, interpreted and justified and science and policy are co-produced. In the interactions that SAGE enables, it is the form of argumentation that is important. SAGE is careful to not be prescriptive, however, the discussions consider the nuances in the problems that affect vaccination coverage. The GVAP report is an example of a particular kind of work that SAGE undertakes. They also consider more specific diseases and issues such as vaccine hesitancy which require different expertise, different kinds of considerations and different ways of knowing.

4.7. Findings

In the context of SAGE, the idea that more knowledge will lead to better policy has proven to be a difficult endeavor. The experts are aware of the limited data that is available to make judgements, the problems inherent in science, such as the limited view that it projects and the limits of technical solutions and problem frames. SAGE however uses science in particular ways. It uses science to develop a global assessment of targets

and goals and it evaluates different aspects of vaccine efficiency and effectiveness.

The separation out of the discussion of the technical advisory groups and Working Groups, helps to create what Hilgartner calls 'Stage Management'. The messiness of the scientific process is hidden from public view, and science and its authority is kept intact. SAGE undertakes the messy business of negotiating the science and policy and in translating the science into usable knowledge. While the technical advisory groups and Working Groups do have the opportunity to present their findings in the public forums, the clean and clear presentation of the scientific work into coherent ideas legitimizes and gives credibility to the science that is presented. SAGE has made increased efforts to be transparent in the various decision-making processes by claiming to use clear approaches such as GRADE. There are however disagreements amongst practitioners that this approach is suitable for the work done by SAGE. SAGE takes into consideration a variety of perspectives, allows for the airing of concerns regarding science, measures, policy problems, implementation issues and other concerns and maintains neutrality by not allowing any particular country or regional entity to influence the final recommendations. The recommendations are neutral from a global political point of view and this is achieved through its broad approach and by not being overly prescriptive. The recommendations are however political in nature. They prescribe a way of doing things, the means of getting them done and that they should be done. The recommendations therefore exert power as they require certain things to be done in a certain way and by a certain time.

The process of making scientific knowledge in the form of indicators and fact-making out of global assessments, have their own sets of problems. The experts face the problem of delegation when relying on governments to be honest about their data and methods of assessment. They also need to deal with problems of limited knowledge and the unequal distribution of knowledge amongst the rich and poor countries.

The issues that SAGE manages are what can be called ‘wicked problems’ their resolution lie outside the domain of science. Vaccination is not only a technical problem, it is unstructured, uncertain and the societal side is not well articulated. Although eradication and elimination seem like possible goals, they have proven to be difficult to achieve.

As SAGE develops an understanding of the global context, the demand for evidence-based economic assessments that countries would like to achieve, can be seen as a need for policy communities to justify their activities through technocratic means and have policies seen less political. Given that SAGE develops recommendations that are standardized and applicable to many countries at once, the idea of civic epistemologies becomes a central contention. There seems to be little space for local epistemologies to be included in a formal way. However the use of regional and national advisory mechanisms and avenues, develop connections to civic epistemologies and Regional Technical Advisory Groups have the possibility to influence SAGE recommendations in some ways.

The analysis of SAGE as a BO is helpful in understanding the ways that knowledge is managed, science is kept intact and different interests and points of view are aired. This case highlights the coproduction of science and policy at the global level and illustrates one way this can be done.

5. Chapter 5 Conclusion

This empirical work has demonstrated that there are two different kinds of influence of institutional design on boundary-work. On the one hand the IBC formally includes the government representatives in deliberations through the mechanism of the IGBC. The idea is to limit the influence of any particular ways of knowing and in democratizing the means of gaining consensus and a full understanding of the issues and means of effectively developing norms on research and scientific practices. On the other hand, SAGE is designed to provide a space for the airing of concerns over the scientific and policy basis of the plans and activities in vaccine and immunization at the WHO. The advisory model separates the scientific and policy activities through boundary-work, effectively keeping science intact and limiting the influence of any one country. Both organizations are agents to the scientific community, the policy community and to the IOs they advise. For this reason, they develop strategies that are able to speak to each of these three constituencies and balances and manages the expectations through expert mediation.

The role of the IBC is to provide a venue for the exchange of ideas and the negotiation over technical and policy issues related to scientific research, particularly concerning genomics. Its aim has been to create an understanding of scientific research from different perspectives and to develop normative positions that serve to encourage regulatory cultures across the globe to move in a particular direction that all countries are in agreement with. The IBC is designed to include policy-makers through the IGBC in deliberations, however the expert group maintains its authority over reports and advice by having control over the writing process. Civic epistemologies however have the potential to become integrated into the knowledge that is produced because of the experts' affiliations to national advisory committees and the diversity of country representation that is achieved by valuing diversity of the expert committee membership. At times, the IBC and IGBC jointly blur the lines between expert, scientific and other disciplinary boundaries and political boundaries. The 'repurification' of the expert and political discourses into discrete categories serves to contribute towards the credibility and authority of expert knowledge. The IGBC works as a legitimizing mechanism, contributing insights to the final reports as well as legitimacy through the approval process.

The Concept Notes function as boundary objects, that stabilize and routinize the ways in which social groups create linkages with each other thus organizing social interactions. Experts negotiate amongst themselves and with each other, needing to articulate their ideas into easily understandable forms of rational arguments. The appeals to universal, international and global bioethics principles signal consensus

and serve to further legitimate the claims. Boundary-work in the IBC internalizes contingencies and enables negotiation.

In terms of power, the IBC's work has brought about an understanding of the dynamics that cause inequality and that reinforce them. The insights gained through the discussions on benefit sharing in particular take scientific research as a powerful source of social and economic capital that needs to be balanced with a rights-based approach to health care access and access to the benefits of research. In terms of biopower, the IBC touches on the need for a bioethical approach to health and scientific knowledge that opposes the strict and narrow asocial view of biomedicine and biotechnology. The particular issue of benefit sharing resulted in a negotiated position. The negotiation led to the reconceptualization of benefit sharing as both a global responsibility and one that requires that individual researchers, organizations and nation-states recognize the idea of a joint non-hierarchical approach to research and the results of research. The power of science as conceptualized through a bioethical framing of research and scientific knowledge as a universal human right, reflects a broadening of the audience to whom science and research should matter. The IBC members serve as advocates in the dissemination and use of the IBC's reports and recommendations as they participate in national, regional and/or international bioethics committees.

The IBC illustrates how science is shaped and brings insights to the idea that science is neutral and serves the purpose of only providing objective and policy-relevant solutions. This case study illustrates how different uses of science can have implications for different communities in very

different ways. The IBC provides a space for policy-makers to become involved in shaping the expectations of what science can prove, and when and how it should/should not and can/cannot be used. This can be seen as a coproduction of knowledge and social order.

The IBC tends to the issue of representation by enrolling rules that enhance the geographical representation of both the expert group and the government group. The experts maintain authority by having control over the writing process and by prioritizing consensus within the group.

In the context of SAGE, the idea that more knowledge will lead to better policy has proven to be a difficult endeavor. The experts are aware of the limited data that is available to make judgements, the problems inherent in science, such as the limited view that it projects and the limits of technical solutions and problem frames. SAGE however uses science in particular ways. It uses science to develop a global assessment of targets and goals and it evaluates different aspects of vaccine efficiency and effectiveness. Furthermore, the separation out of the discussion of the technical advisory groups and Working Groups, helps to create what Hilgartner calls 'Stage Management'. The messiness of the scientific process is hidden from public view, and science and its authority is kept intact. SAGE undertakes the messy business of negotiating the science and policy and in translating the science into usable knowledge.

The analysis of SAGE as a BO is helpful in understanding the ways that knowledge is managed, science is kept intact and different interests and points of view are aired.

Both case studies show how a BOs transcends the notion of ‘speaking truth to power’. The IBC demonstrates this by virtue of its position in the policy-cycle and SAGE demonstrates this by not producing prescriptive policies.

In terms of the scholarly debates in global governance, these case studies contribute to the debates in the following way: The first debate questions how knowledge is established when science and politics interact. Both cases illustrate the ways in which knowledge is coproduced. Both cases illustrate how science is socially constructed, the IBC case highlighting the shaping of science itself and the SAGE case demonstrating the ways in which knowledge changes when it comes to the global forum for translation into recommendations. In terms of power, the IBC is able to create a space for the management of very diverse ways of knowing and understanding, however, the power of individual experts with specific expertise such as law and medicine are replaced with experts with a more interdisciplinary bioethics profession. This has enabled the power to be more distributed between disciplines and with the experts being less renowned, the power of what they say is on a more equal-footing, allowing for a more equal participation by government representatives. In this way the knowledge is also accessible, through the simplification of arguments and wider consensus.

The second debate questions whether and to what extent experts are powerful. The study illustrates how BOs are an institutional response to the plurality and uncertainty of problems and their solutions and devises a means for the conversation to be had. In these cases, expert advice is

given authority through boundary-work. There are various ways that expert knowledge and policy are separated through rhetorical and discursive means and in the design of the BOs. The experts in the IBC are able to exert their influence by taking charge of the writing process of the final reports and by having more control over the drafting process. SAGE members are regarded as the top experts in their fields and are seen to be disinterested and neutral in their representation of both science and decision-making. The results of the study show that it is possible to speak of epistemic authority as a function of institutional design.

The third debate questions how translating knowledge into practical use across the globe should be done and by whom. This study alludes to the virtues of democratic governance and the benefits of the institutionalization of science-policy interactions. BOs serve to facilitate the transfer to knowledge from science to policy however, the kind of knowledge that they produce is particular and global knowledge.

The fourth debate questions whether and in what ways IOs matter. The analysis highlights the institutionalization and existence of BOs as an institutionalization of the relation between science and politics. In this way, BOs associated with IOs can have the function of developing more acceptable normative practices and facilitate a wider discussion on the limits of science and the power that particular visions of the world can have. BOs serve to develop knowledge that is different to other kinds of knowledge and at the same time develops knowledge that is more acceptable to more people. Through facilitating open and inclusive BOs, the IO is able to achieve this task.

Annex

1. Sample of an Invitation for Written Consultation on the work of the IBC



United Nations
Educational, Scientific and
Cultural Organization

Bioethics and Ethics of Science Section
Division of Ethics, Youth and Sport
Social and Human Sciences Sector

To Members of the UN Interagency
Committee on Bioethics (UNIACB)

30 May 2014

Ref.: SHS/YES/14/075

Subject: **Written Consultation on the work of the International Bioethics Committee (IBC) for 2014-2015**

Dear UNIACB Members,

Based on discussions during the 20th Session of the IBC in June 2013, the conclusions of the 8th Session of the Intergovernmental Bioethics Committee (IGBC) in September 2013, as well as inputs from the Secretariat, the Work Programme of the IBC was finalized by its Bureau in March 2014, focusing on the following two topics: the **elaboration of the principle of sharing of benefits** as set out in Article 15 of the *Universal Declaration on Bioethics and Human Rights* (2005); and the **update of the IBC's reflection on the human genome and human rights**.

In an effort to encourage wider consultation and collaboration, the Chairperson of the IBC has agreed with the suggestion of the Secretariat to invite UNIACB Members to submit written comments or suggestions on the Committee's ongoing work at a much earlier stage in its reflections.

In order to facilitate this process, two small IBC working groups have prepared concept notes on the topics mentioned above (attached with this letter), providing preliminary outlines of potential areas of reflections. It must be underlined that the issues identified in these concept notes are only potential areas of reflections, and there should be no expectation that they will be covered by any eventual reports of the IBC. As it stands, these concept notes do not necessarily represent the final opinion of the IBC and they are subject to further discussions within the Committee.

The purpose of the concept notes is to invite feedback on the potential areas of reflections identified so far, as well as suggestions on additional issues that could be considered by the Committee. The comments received will be contained in an information document for the 21st Session of the IBC and the Joint Session of the IBC and the IGBC (UNESCO Headquarters, Paris, September 2014), during which these topics will be discussed in more detail.

At this point, the independence of the IBC in taking its own decisions concerning the eventual direction of its reflections on these topics must be emphasized. Feedback and suggestions provided at this preliminary stage of the IBC's reflections will definitely enrich the upcoming discussions on the topics, but there should be no expectation that these comments are required to be fully or even partially incorporated by the IBC in its work.

7, place de Fontenay
75352 Paris 07 SP, France
Tel.: +33 (0)1 45 68 36 57
Fax: +33 (0)1 45 68 55 15
www.unesco.org

- 2 -

As such, UNIACB Members are invited to submit their written comments either in English or French to the Secretariat via email (preferred method) or regular mail **before 31 July 2014**. All submissions should clearly indicate which of the two topics the comments are related to. Contact information for the Secretariat is as follows:

International Bioethics Committee (IBC)
Social and Human Sciences Sector, UNESCO
1, rue Miollis
75732 Paris Cedex 15
France

Email: ibc@unesco.org (submission by email is preferred)

We would like to thank UNIACB Members in advance for their contributions to this process, and we hope that this enhanced consultation will lead to fruitful and intellectually stimulating discussions during the upcoming sessions.

Yours sincerely,



Dafna Feinholz
Chief of Section

Encl. 2

Annex 2

GVAP Progress Report – Issues raised at the open meeting September 2014

Implementation problems

1. The problem of missed opportunities
2. The need for verification commissions
3. What should be integrated
4. Finance and budgeting priorities
5. Country ownership
6. Are Institutions and their tactics and strategies the solution?
7. Uncertainty about reporting accuracy
8. Prioritizing vaccinations at the frontline
9. Problem of implementation
10. Incentives and disincentives to follow plan
11. A need to understand causes
12. Lack of stewardship
13. Country ownership problem. GVAP needs to mean something
14. GAVI support cut-off based on finance
15. Issue of price transparency

Implementation actions and suggestions

1. Health System Strengthening with vaccination as a key building block
2. Strategic systematic approach to countries with the lowest vaccination rates
3. The goal should be disease control
4. Affordability of vaccines and transparency
5. Analysis of the effects of transparency
6. Need to consider human usage of data and the meaning of data to people

7. Integration and missed opportunities linked to confidence of health professionals
8. Confidence in vaccines is more important than knowledge about vaccines
9. Need to understand why prioritization is an issue
10. The problem of dependency therefore must invest in routine immunization
11. Civil Society Organizations (CSOs) involvement in regional and country plans
12. How to implement, and additional resources for CSOs
13. Accountability, responsibility and evaluation of CSOs
14. Closer collaboration with GAVI
15. NITAGs to be multi-disciplinary, include one communications expert, be independent and maintain good data quality
16. Should formalize relations with International Organization for Migration (IOM) and UNHCR
17. Countries that can should develop their own plans, SAGE gives the tools and partners support them
18. Need to do a qualitative evaluation of vulnerability of GAVI graduating countries
19. Push hard on tetanus elimination as it targets the issues of integration and equity

Critiques of the Scientific Report

1. Annual targets should be set as well as the target to be achievement in 10 years
2. Need to know why countries didn't reach targets
3. Problem with the definition of 'middle income' countries
4. The report tells us the signs and symptoms but we don't know the diagnosis and treatment
5. To what extent do the reporting measures reflect reality
6. Problem of validity of data
7. Should use intermediate targets to show change that will give a psychological effect of improvements
8. Psychology of positive indicators e.g. resilience factors, psychology of champions

9. Tailored recommendations and scores countries to countries so they have faith in change
10. What do countries have to do?
11. Report is innovative in measurement
12. Lack of secondary measures and local approaches
13. Ambitiousness of targets
14. Framing of the problem as technical and of the solution. Emphasis is on the plan more than implementation
15. We are too technical and vaccines are a product to sell. Need social factors, logistics, product confidence
16. Countries have incentives to falsify data
17. Amount of data was large, needed to clean it up and answer question between June and August and were limited by available data
18. Only able to generalize can't say what to do

Critiques of the Policy Dimension

1. How to get around asking countries to be honest about pricing
2. Priorities of Central and Western Europe need attention
3. Implications of GAVI graduating countries on GVAP
4. Need to know how immunization partners are working
5. Even WHA are not talking about the how to implement, they mentioned vaccines as tool, price, technology transfer, risk communication and economic analysis
6. Missed deadlines are a problem, can't keep missing targets
7. The goals are achievable and 194 countries signed up to them
8. Essential for implementation is accountability

Annex 3

GVAP Progress Report - Final SAGE Recommendations

SAGE concurred with the main conclusions from the Working Group and recommended that:

The Director-General of WHO, during the 68th World Health Assembly in 2015, convene side meetings in collaboration with the GVAP secretariat agencies. For countries with routine vaccination (DTP3) coverage of <80%, to which each Minister of Health will be asked to report on their challenges, plans and timelines to improve coverage to meet the GVAP goals.

1. The SAGE's GVAP assessment reports remain as standing items at the WHA until 2020.
2. Failure to achieve the 2013 milestone for Maternal and Neonatal Tetanus elimination is largely related to the funding gap. Partners should lead a concerted effort to fill this gap, by refreshing the communication approach and seeking novel partners for this vital, and repeatedly missed, goal.
3. Regions and countries rapidly finalize their own vaccine action plans based on the GVAP, using this assessment report as a further guide and establishing bodies to guide and monitor implementation.

4. Countries give CSOs substantially more formal involvement in the delivery and improvement of vaccination services, establishing clear responsibilities for which they are accountable.
5. After consulting with their respective Regional Technical Advisory Group, every Region establish a regional verification commission, and after consulting with their respective National Immunization Technical Advisory Group, every country explore options for establishing a national verification commission, to scrutinize and monitor progress towards the measles elimination targets.
6. The heads of the GVAP secretariat agencies (the Bill and Melinda Gates Foundation, Gavi, the US National Institute of Allergy and Infectious Diseases, WHO and UNICEF) meet to consider this report and agree on specific corrective actions.
7. The heads of GVAP secretariat agencies report to the 2015 World Economic Forum on the plan's establishment, its lack of progress so far and what forum participants – who supported the Decade of Vaccines concept in 2010 – can do to help its implementation.
8. Countries invest in improving data quality at the local level, and use data to strengthen accountability and to improve understanding of the programmatic issues.
9. Technical agencies further develop and deploy tools to help countries with limited personnel with the practical task of improving the quality and use of data.
10. Technical agencies conduct urgent assessments of (i) the extent to which the reported national-level stock-outs are affecting local

vaccine supply and delivery, and (ii) the root causes of these stockouts.

11. Countries change their approach to vaccine affordability, creating transparency by making pricing information publicly available, and by collaborating with WHO and all technical agencies to develop solutions. Technical partners support countries to improve the transparency of vaccine pricing. Technical agencies themselves should do everything possible to share pricing data.
12. Countries conduct studies to understand how opportunities to vaccinate people are being missed by health-care workers and their systems, and act to reduce their incidence.
13. WHO discuss and develop guidelines on how to fully integrate vaccination into the operation of all aspects of the health-care system and to reduce missed opportunities to vaccinate.
14. Countries ensure that health-care workers understand and follow WHO or national guidelines on what does, and does not, contraindicate vaccination, particularly in relation to childhood febrile illness, so that vaccination is not avoided unnecessarily.
15. Following adoption of the GVAP and subsequently revision and adoption of regional and national plans, countries have the responsibility to ensure that immunization goals are shared, discussed and fully adopted by health-care workers.
16. WHO expand its existing guidance on immunization in humanitarian emergencies to detail how routine and other immunization services are best maintained despite disruptive situations such as war and disease outbreaks.

(World Health Organization 2014)

Bibliography

- Adler, Emanuel. 1997. "Seizing the Middle Ground:: Constructivism in World Politics." *European Journal of International Relations* 3(3): 319–63.
- Adler, Emanuel, and Peter M. Haas. 1992. "Conclusion: Epistemic Communities, World Order, and the Creation of a Reflective Research Program." *International Organization* 46(1): 367.
- Affolderbach, Julia, Roger Alex Clapp, and Roger Hayter. 2012. "Environmental Bargaining and Boundary Organizations: Remapping British Columbia's Great Bear Rainforest." *Annals of the Association of American Geographers* 102: 1391–1408.
- Agrawala, Shardul, Kenneth Broad, and David H. Guston. 2001. "Integrating Climate Forecasts and Societal Decision Making: Challenges to an Emergent Boundary Organization." *Science, Technology & Human Values* 26: 454–77.
- Alonso-Coello, Pablo et al. 2016a. "GRADE Evidence to Decision (EtD) Frameworks: A Systematic and Transparent Approach to Making Well Informed Healthcare Choices. 1: Introduction." *BMJ (Clinical*

- research ed.*) 353(11): 1–10.
- . 2016b. “GRADE Evidence to Decision (EtD) Frameworks: A Systematic and Transparent Approach to Making Well Informed Healthcare Choices. 2: Clinical Practice Guidelines.” *BMJ (Clinical research ed.)* 353(11): 1–9.
- Andresen, S., and J.B. Skjærseth. 2007. “Science and Technology: From Agenda Setting to Implementation.” In *The Oxford Handbook of International Environmental Law*, Oxford.
- Archer, Clive. 2001. *International Organizations*. Third.
- Bagheri, Alireza, Jonathan Moreno, and Stefano Semplici. 2015. *Global Bioethics: The Impact of UNESCO International Bioethics Committee*.
- Barkin, J. Samuel. 2006. *International Organization : Theories and Institutions*. Palgrave Macmillan.
- Barnett, Michael, and Raymond Duvall. 2005. “Power in International Politics.” *International Organization* 59(1): 39–75.
- Barnett, Michael, and Martha Finnemore. 1999. “The Politics, Power, and Pathologies of International Organizations.” *International organization* 53(4): 699–732.
- . 2004. *Rules for the World*. Cornell University Press.
- Bärnighausen, Till et al. 2014. “Reassessing the Value of Vaccines.” *The Lancet Global Health* 2(5).
- Beck, Silke. 2010. “Moving beyond the Linear Model of Expertise? IPCC and the Test of Adaptation.” *Regional Environmental Change* 11(2): 297–306.
- Bijker, Wiebe E. 2009. “How Is Technology Made?-That Is the Question!” *Cambridge Journal of Economics* 34(1): 63–76.

- Bilous, J. et al. 2006. "A New Global Immunisation Vision and Strategy." *The Lancet* 367: 1464–65.
- Birn, A E. 2011. "Small(pox) Success?" *Ciencia & saude coletiva* 16(2): 591–97.
- Boehmer-Christiansen, Sonja. 1994. "Global Climate Protection Policy : The Limits of Scientific Advice." *Social Research* 4(2): 140–59.
- Boezeman, Daan, Martinus Vink, and Pieter Leroy. 2013. "The Dutch Delta Committee as a Boundary Organisation." *Environmental Science and Policy* 27: 162–71.
- Boissin, Denis. 2011. "Boundary Organizations: An Evaluation of Their Impact Through a Multi-Agent System." In *Agent-Based Approaches in Economic and Social Complex Systems*, eds. Chu-Heng Chen, Takao Terano, and Ryuichi Yamamoto. Springer Japan, 177–88.
- Brown, Mark B. 2009. *Science in Democracy - Expertise, Institutions and Representation*.
- Burton, A. et al. 2009. Bulletin of the World Health Organization *WHO and UNICEF Estimates of National Infant Immunization Coverage: Methods and Processes. Bull World Health Organ*.
- Caporaso, James A. 1992. 46 International Organization *International Relations Theory and Multilateralism: The Search for Foundations*.
- Carolan, Michael S. 2006. "Science, Expertise, and the Democratization of the Decision-Making Process." *Society & Natural Resources* 19(7): 661–68.
- Cash, David W. et al. 2002. John F. Kennedy School of Government Harvard University Faculty Research Working Paper Series *Salience, Credibility, Legitimacy and Boundaries: Linking Research,*

Assessment and Decision Making.

- . 2003. “Knowledge Systems for Sustainable Development.” *Proceedings of the National Academy of Sciences of the United States of America* 100(14): 8086–91.
- . 2006. “Scale and Cross-Scale Dynamics: Governance and Information in a Multilevel World.” *Ecology and Society* 11(2): 8.
- Cash, David W., and Susanne C. Moser. 2000. “Linking Global and Local Scales: Designing Dynamic Assessment and Management Processes.” *Global Environmental Change* 10(2): 109–20.
- Cherian, Thomas. 2014. *Decade of Vaccines Global Vaccine Action Plan SAGE Progress Report 2014 - Presentation.*
- Collins, H. M., and R. Evans. 2002. “The Third Wave of Science Studies: Studies of Expertise and Experience.” *Social Studies of Science* 32(2): 235–96.
- Davies, Huw T O., S M. Nutley, and P C. Smith, eds. 2000. *Health and Social Care in the Community Using Evidence: How Research Can Inform Public Services.* Bristol: Policy Press.
- Davis, Kevin E., Benedict Kingsbury, and Sally Engle Merry, eds. 2012. *Global Governance by Indicators: Global Power through Classification and Rankings.*
- Department of Immunization Vaccines and Biological (IVB). 2014. “Strategic Advisory Group of Experts on Immunization 21-23 October 2014 Yellow Book.”
- Division of the Ethics of Science and Technology of UNESCO. 1999. *Birth of the Universal Declaration on the Human Genome and Human Rights.*
- Duclos, Philippe, Jean-Marie Okwo-Bele, and David Salisbury. 2011.

- “Establishing Global Policy Recommendations: The Role of the Strategic Advisory Group of Experts on Immunization.” *Expert Review of Vaccines* 10(2): 163–73.
- Emmerich, Nathan, and Jamie Halsall. 2016. “A Sociological Analysis of Ethical Expertise: The Case of Bioethics.” *Cogent Social Sciences* 2(1): 1143599.
- Farrell, Alex, Stacy D. VanDeveer, and Jill Jäger. 2001. “Environmental Assessments: Four under-Appreciated Elements of Design.” *Global Environmental Change* 11(4): 311–33.
- Finkelstein, Lawrence S. 1995. “What Is Global Governance?” *Global Governance* 1(3): 367–72.
- Finnemore, Martha, and Kathryn Sikkink. 2001. “Taking Stock: The Constructivist Research Program in International Relations and Comparative Politics.” *Annual Review of Political Science* 4(1): 391–416.
- Fisher, Angelina. 2012. “From Diagnosing Under-Immunization to Evaluating Health Care Systems: Immunization Coverage Indicators as a Technology of Global Governance.” In *Governance by Indicators: Global Power through Quantification and Rankings*, eds. Kevin Davis, Benedict Kingbury, and Sally Engle Merry. Oxford University Press, 217–48.
- Forsythe, David P. 2012. *Human Rights in International Relations*. Third.
- Franks, Jeremy. 2010. “Boundary Organizations for Sustainable Land Management: The Example of Dutch Environmental Co-Operatives.” *Ecological Economics* 70(2): 283–95.
- Fujimura, Joan H. 1992. “Crafting Science: Standardized Packages, Boundary Objects and ‘Translation.’” In *Science as Practice and*

- Culture*, , 168–211.
- GAVI. 2016a. “Decade of Vaccines Collaboration.”
- . 2016b. “GAVI’s Mission.” <http://www.gavi.org/about/mission/>.
- Gibbons, Michael et al. 1994. *The New Production of Knowledge: The Dynamics of Science and Research in Contemporary Societies*. SAGE Publications, Inc.
- Gieryn, Thomas F. 1983. “Boundary-Work and the Demarcation of Science from Non-Science : Strains and Interests in Professional Ideologies of Scientists.” *American Sociological Review* 48(6): 781–95.
- . 1995. “Boundaries of Science.” In *Handbook of Science and Technology Studies*, ed. and T. Pinch Jasanoff, Sheila, G. E. Markle, J. C. Peterson.
- . 1998. “Chapter 1 of Cultural Boundaries of Science.” In *Contesting Credibility Cartographically*, , 1–35.
- Godlee, F. 1994. “WHO in Retreat: Is It Losing Its Influence?” *BMJ (Clinical research ed.)* 309(6967): 1491–95.
- Grieco, J.M. 1995. “Anarchy and the Limits of Cooperation: A Realist Critique of the Newest Liberal Institutionalism.” In *Controversies in International Relations Theory: Realism and the Neoliberal Challenge*, ed. C.W Kegley, Jr. cap: New York: St Martin’s Press.
- Guston, David H. 1999. “Stabilizing the Boundary between US Politics and Science:: The Role of the Office of Technology Transfer as a Boundary Organization.” *Social Studies of Science* 29(1): 87–111.
- . 2000. *Between Politics and Science - Assuring the Productivity and Integrity of Research*. Cambridge University Press.
- . 2000. 9–10 December 1999, Bloustein School of Planning and

- Public Policy, Rutgers University, New Brunswick, NJ. Belfer Center for Science and International Affairs (BCSIA) Discussion Paper 2000–32 *Report of the Workshop on Boundary Organizations in Environmental Policy and Science*.
- . 2001a. “Boundary Organizations in Environmental Policy and Science: An Introduction.” *Science, Technology & Human Values* 26: 399–408.
- . 2001b. “Boundary Organizations in Environmental Policy and Science: An Introduction.” *Science, technology, and human values* 26(4): 399–408.
- . 2004. “Forget Politicizing Science. Let’s Democratize Science!”
- Guyatt, Gordon H et al. 2008. “GRADE : An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations.” *BMJ* 336(April).
- Haas, Peter M. 1992a. 46 *Epistemic Communities and International Policy Coordination*. University of Warwick.
- . 1992b. 46 *International Organization Introduction: Epistemic Communities and International Policy Coordination*.
- . 2004. “When Does Power Listen to Truth? A Constructivist Approach to the Policy Process.” *Journal of European Public Policy* 11(4): 569–92.
- Haas, Peter M., and Casey Stevens. 2011. “Organized Science, Usable Knowledge, and Multilateral Environmental Governance.” In *Governing the Air: The Dynamics of Science, Policy, and Citizen Interaction*, eds. Rolf Lidskog and Göran Sundqvist. MIT Press, 125–62.
- Hall, RB, and TJ Biersteker. 2002. *The Emergence of Private Authority in*

Global Governance.

- Ten Have, Henk. 2013. "Islam and Biomedical Ethics." *Zygon* 48(3): 600–617.
- . 2016. *Global Bioethics: An Introduction*. Routledge.
- Ten Have, Henk, and S. Michèle Jean. 2009. "Introduction." In *The Unesco Universal Declaration on Bioethics and Human Rights: Background Principles and Application*, UNESCO Publishing.
- Held, David. 2004. "Democratic Accountability and Political Effectiveness from a Cosmopolitan Perspective." *Government and Opposition* 39(2).
- Hilgartner, Stephen. 2004. "The Credibility of Science on Stage." *Social Studies of Science* 34(3): 443–52.
- Hilgartner, Stephen, Clark Miller, and Rob Hagendijk. 2015. 1 *Nat Nano Science and Democracy: Making Knowledge and Making Power in the Biosciences and Beyond*.
<http://www.nature.com/nnano/journal/v1/n1/full/nnano.2006.71.html>
- .
- Hisschemoller, Matthijs. 2005. "Participation as Knowledge Production and the Limits of Democracy." In *Democratization of Expertise? Exploring Novel Forms of Scientific Advice in Political Decision-Making*, eds. Sabine Maasen and Peter Weingart. Netherlands: Springer, 189–208.
- Hoppe, Rob, Anna Wesselink, and Rose Cairns. 2013. "Lost in the Problem: The Role of Boundary Organisations in the Governance of Climate Change." *Wiley Interdisciplinary Reviews: Climate Change* 4: 283–300.
- Howa, Michelle K. 2013. 53 unpublished paper *Democratizing Expertise:*

Implications for Policy Advice.

- Hurd, Ian. 1999. "Legitimacy and Authority in International Politics." *International Organization* 53: 379–408.
- International Bioethics Committee. 2014a. *Concept Note on The Principle of Sharing of Benefits (Article 15 of the Universal Declaration on Bioethics and Human Rights (2005))*.
- . 2014b. *Concept Note on Updating the IBC's Reflection on the Human Genome and Human Rights*. Paris.
- International Bioethics Committee: Proceedings*. 1994.
- Jasanoff, Sheila. 1990. "The Fifth Branch of Science Studies."
- . 1995. 36 Science Technology And Human Values *Handbook of Science and Technology Studies*.
<http://sth.sagepub.com/cgi/doi/10.1177/0162243910366154>.
- . 1996a. "Is Science Socially constructed—And Can It Still Inform Public Policy?" *Science and Engineering Ethics* 2: 263–76.
<http://link.springer.com/article/10.1007/BF02583913> (March 4, 2014).
- . 1996b. "Is Science Socially Constructed —And Can It Still Inform Public Policy?" *Science and Engineering Ethics* 2(3): 263–76.
- . 2003. "(No?) Accounting for Expertise." *Science and Public Policy* 30(3): 157–62.
<http://spp.oxfordjournals.org/content/30/3/157.short> (March 4, 2014).
- , ed. 2004. *States of Knowledge: The Co-Production of Science and Social Order*. Routledge.
- . 2005. *Designs of Nature: Science and Democracy in Europe and*

- the United States*. Princeton, NJ: Princeton University Press.
- . 2008. “Speaking Honestly to Power.” *American Scientist*: 1–2.
<http://www.americanscientist.org/bookshelf/pub/speaking-honestly-to-power>.
- Jasanoff, Sheila. 1987. “Contested Boundaries in Policy-Relevant Science.” *Social studies of science* 17(2): 195–230.
- Jasanoff, Sheila, and Brian Wynne. 1998. “Science and Decisionmaking.” In *Human Choice and Climate Change: Volume I: The Societal Framework*, eds. Steve Rayner and Elizabeth L. Malone. Columbus, OH: Batelle Press, 1–87.
- Jones, Mavis, John Walls, and Tom Horlick-Jones. 2006. “Seperated at Birth? Consensus and Contention in the UK Agricultural and Human Biotechnology Commissions.” *Science and Public Policy* 33(10): 729–44.
- Katz, J. 1992. “The Consent Principle of the Nuremberg Code: Its Significance Then and Now.” In *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation.*, ed. Grodin MA Annas GJ. New York: Oxford University Press, 227–39.
- Kegley, Jr., C.W. 1995. “The Neoliberal Challenge to Realist Theories of World Politics: An Introduction.” In *Controversies in International Relations Theory: Realism and the Neoliberal Challenge*, ed. C.W. Kegley, Jr. New York: St Martin’s Press.
- Keller, Ann C. 2009. “Credibility and Relevance in Environmental Policy: Measuring Strategies and Performance among Science Assessment Organizations.” *Journal of Public Administration Research and Theory* 20: 357–86.
<http://jpart.oxfordjournals.org/cgi/doi/10.1093/jopart/mup001>.

- . 2010. “Credibility and Relevance in Environmental Policy: Measuring Strategies and Performance among Science Assessment Organizations.” *Journal of Public Administration Research and Theory* 20(2): 357–86.
- Kelly, SE. 2003. “Public Bioethics and Publics: Consensus, Boundaries, and Participation in Biomedical Science Policy.” *Science, Technology & Human Values*.
<http://sth.sagepub.com/content/28/3/339.short> (July 7, 2014).
- Kennedy, David. 2016. “A World of Struggle: How Power, Law, and Expertise Shape Global Political Economy.” : 312.
<https://books.google.com/books?id=Ai3FCgAAQBAJ&pgis=1>.
- Keohane, R. O. 2006. “Global Governance and Democratic Accountability.” *ary political philosophy: An anthology* (April): 697–709.
- Kim, Won Oak. 2012. “Institutional Review Board (IRB) and Ethical Issues in Clinical Research.” *Korean Journal of Anesthesiology* 62(1): 3–12.
- Klein, Hans, and Daniel Kleinman. 2002. “The Social Construction of Technology: Structural Considerations.” *Science, Technology & Human Values* 27(1): 28–52.
<http://sth.sagepub.com/cgi/doi/10.1177/016224390202700102>.
- Koremenos, Barbara, Charles Lipson, and Duncan Snidal. 2001. “The Rational Design of International Institutions.” 55(4): 761–99.
- Kratochwil, Friedrich, and John Gerard Ruggie. 1986. “International Organization: A State of the Art on an Art of the State.” *International Organization* 40(4): 753.
http://www.journals.cambridge.org/abstract_S0020818300027363.

- Lamont, Michèle, and Virga Molnar. 2002. "The Study of Boundaries in the Social Sciences." *Annual Review of Sociology* 28(1965): 167–95.
- Langlois, Adele. 2013. *Negotiating Bioethics - The Governance of UNESCO's Bioethics Programme*. Routledge.
- Latour, Bruno. 1999. 16 Essays on the Reality of Science Studies
Pandora's Hope.
<http://search.ebscohost.com/login.aspx?direct=true&db=bsh&AN=3533124&site=ehost-live>.
- Law, John. 2008. "On Sociology and STS." *Sociological Review* 56(4): 623–49.
- Lee, Lisa A. et al. 2013. "The Estimated Mortality Impact of Vaccinations Forecast to Be Administered during 2011-2020 in 73 Countries Supported by the Gavi Alliance." *Vaccine* 31(SUPPL2): B61–72. <http://dx.doi.org/10.1016/j.vaccine.2012.11.035>.
- Liberatore, Angela, and Silvio Funtowicz. 2003. "Democratising Expertise, Expertising Democracy: What Does This Mean, and Why Bother?" *Science and Public Policy* 30(3): 146–50.
<http://www.ingentaconnect.com/content/beechn/spp/2003/00000030/0000003/art00001>
<http://dx.doi.org/10.3152/147154303781780551>.
- Lidskog, Rolf. 2014. "Representing and Regulating Nature: Boundary Organisations, Portable Representations, and the Science–policy Interface." *Environmental Politics* 23(4): 670–87.
- Lidskog, Rolf, and Göran Sundqvist. 2015. "When Does Science Matter?: International Relations Meets Science and Technology Studies." *Global Environmental Politics* 15(1): 1–20.
- Limoges, Camille. 1993. "Expert Knowledge and Decision-Making in Controversy Contexts." *Public understanding of science* 2: 417–26.

- Maasen, Sabine, and Peter Weingart. 2005. Springer *Democratization of Expertise? - Exploring Novel Forms of Scientific Advice in Political Decision-Making*.
- http://books.google.com/books?hl=en&lr=&id=pkfzBCrDzflC&oi=fnd&pg=PR7&dq=Democratization+of+Expertise+Exploring+novel+forms+of+scientific+advice+in+political+decision-making&ots=dyM_NBbbi5&sig=2DvolQ7UyXe_XgVEe9ta2FXQ8ss\nhttp://books.google.com/books?hl=
- Macklin, R. 2003. "Future Challenges for the Declaration of Helsinki: Maintaining Credibility in the Face of Ethical Controversies."
- Marmot, Michael. 2005. "Public Health Social Determinants of Health Inequalities." *Lancet* 365: 1099–1104.
- . 2008. Health Equity Through Action on the Social Determinants of Health *Closing the Gap in a Generation*.
- <http://www.bvsde.paho.org/bvsacd/cd68/Marmot.pdf>npapers2://publication/uuid/E1779459-4655-4721-8531-CF82E8D47409.
- Martin, Brian, and Evelleen Richards. 1995. "Scientific Knowledge, Controversy, and Public Decision-Making." *Handbook of science and technology studies*: 1–14.
- <http://www.bmartin.cc/pubs/95handbook.html> (March 4, 2014).
- Merton, Robert K. 1973. "The Normative Structure of Science." In *The Sociology of Science: Theoretical and Empirical Investigations*, Chicago: University of Chicago Press, 267–78.
- Moore, Kelly. 1996. "Organizing Integrity : American Science and the Creation of Public Interest." *American Journal of Sociology* 101(6): 1592–1627.
- Moore, Kelly, and David J. Hess. 1999. "Science Studies: An Advanced

- Introduction.” *Contemporary Sociology* 28: 315.
- Morgenthau, Hans. 1960. *Politics Among Nations: The Struggle for Power and Peace*. New York: Knopf.
- Newton, Roger G. 1998. “The Science Wars.” *American Journal of Physics* 66(4): 282.
- Ng, Nora Y, and Jennifer Prah Ruger. 2011. “Global Health Governance at a Crossroads.” *Global Health Governance* 3(2): 1–37.
- Noam, Chomsky & Michel, Foucault. 2006. *The Chomsky-Foucault Debate on Human Nature*. The New Press, New York.
- Parker, John N, and Beatrice I Crona. 2012. “All Things to All People: Boundary Organizations and the Contemporary Research University.” *Social Studies of Science* 42(2): 262–89.
- Pestre, Dominique. 2008. “Challenges for the Democratic Management of Technoscience: Governance, Participation and the Political Today.” *Science as Culture* 17(December): 101–19.
- Pielke, Roger a. 2004. “When Scientists Politicize Science: Making Sense of Controversy over The Skeptical Environmentalist.” *Environmental Science & Policy* 7(5): 405–17.
- Rittberger, Volker, Bernhard Zangl, and Andreas Kruck. 2012. *International Organization*. 2nd ed. Palgrave Macmillan.
- Rittel, Horst W J, and Melvin M Webber. 1973. “Dilemmas in a General Theory of Planning Dilemmas in a General Theory of Planning.” *Policy Sciences* 4(2): 155–69.
- Rosenau, James N. 1995. “Governance in the Twenty-First Century.” *Global Governance* 1(1): 13–43.
- Ruggie, John Gerard. 1998. “What Makes the World Hang Together ? Neo-Utilitarianism and the Social Constructivist Challenge.”

International Organization 52(4): 855–85.

Sachs, Jeffrey D. 2001. “Macroeconomics and Health: Investing in Health for Economic Development: Report of the Commission on Macroeconomics and Health.” *WHO Commission on Macroeconomics and Health*: 1–210.

Sarewitz, Daniel. 2004. “How Science Makes Environmental Controversies Worse.” *Environmental Science & Policy* 7(5): 385–403.

Schein, Edgar H. 1996. “Culture: The Missing Concept in Organization Studies.” *Administrative Science Quarterly* 41(2): 229.
<http://search.proquest.com/docview/203985866?accountid=13042>
http://oxfordsfx.hosted.exlibrisgroup.com/oxford?url_ver=Z39.88-2004&rft_val_fmt=info:ofi/fmt:kev:mtx:journal&genre=article&sid=ProQ:ProQ:abiglobal&atitle=Culture:+The+missing+concept+in+organi.

Schneider, A. L. 2008. “Why Do Some Boundary Organizations Result in New Ideas and Practices and Others Only Meet Resistance?: Examples From Juvenile Justice.” *The American Review of Public Administration* 39: 60–79.

Shuster, Evelyne. 1997. “Special Article.” *The New England Journal of Medicine* 337(20): 1436–40.

Siebenhüner, Bernd. 2003. “The Changing Role of Nation States in International Environmental Assessments—the Case of the IPCC.” *Global Environmental Change* 13(2): 113–23.

Sil, Rudra, and Eileen M. Doherty, eds. 2000. *Beyond Boundaries?: Disciplines, Paradigms and Theoretical Integration in International Studies*. State University of New York.

- Smith, Jean Clare. 2010. "The Structure, Role, and Procedures of the U.S. Advisory Committee on Immunization Practices (ACIP)." *Vaccine* 28 Suppl 1: A68-75.
<http://www.ncbi.nlm.nih.gov/pubmed/20413002> (February 25, 2014).
- Social and Human Sciences Sector. 2014. "Twenty-First Session of the International Bioethics Committee of UNESCO (IBC): Joint Session of the IBC and the Intergovernmental Bioethics Committee (IGBC)." (September).
- Social and Human Services. 2013. *1993-2013: 20 Years of Bioethics at UNESCO (SHS-2013/WS/2)*.
- Solinís, Germán, ed. 2015. *Global Bioethics: What for? 20th Anniversary of UNESCO's Bioethics Programme*.
- Star, S. L., and J. R. Griesemer. 1989. "Institutional Ecology, 'Translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-39." *Social Studies of Science* 19: 387-420.
- Star, SL, and JR Griesemer. 1989. "Institutional Ecology, translations' and Boundary Objects: Amateurs and Professionals in Berkeley's Museum of Vertebrate Zoology, 1907-39." *Social studies of science*.
- Tuinstra, Willemijn. 2008. "European Air Pollution Assessments: Co-Production of Science and Policy." *International Environmental Agreements: Politics, Law and Economics* 8(1): 35-49.
- Turner, Stephen. 2016. "What Is the Problem with Experts?" *Social studies of science* 6(2): 185-206.
- Turnhout, Esther. 2009. "The Effectiveness of Boundary Objects: The Case of Ecological Indicators." *Science and Public Policy* 36(5):

403–12.

- UNESCO. 2005a. *First Intergovernmental Meeting of Experts Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics: Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics*.
- . 2005b. “Universal Declaration on Bioethics and Human Rights.” http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html.
- Unicef. 2005. “GIVS: Global Immunization Vision and Strategy, 2006–2015.” *Givs*: 12–13.
http://www.who.int/immunization/givs/GIVS_strategies.pdf?ua=1
<http://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:Global+Immunization+Vision+and+Strategy+2006+?+2015#2>.
- United Nations. 2016a. “About the UN.” *Www.Un.Org*: 3–4.
<http://www.un.org/en/about-un/index.html>.
- . 2016b. “United Nations-Overview.” *Website of United Nations*.
<http://www.un.org/en/sections/about-un/overview/index.html>.
- Victor, David. 2015. “Climate Change: Embed the Social Sciences in Climate Policy.” *Nature* 520(7545): 27–29.
- Weiss, Carol H. 1979. “The Many Meanings of Research Utilization Author.” *Public Administration Review* 39(5): 426–31.
- Weiss, Thomas G., and Ramesh Thakur. 2010. *Global Governance and the UN: An Unfinished Journey*. Indiana University Press.
- White, Dave D. et al. 2010. “Credibility, Salience, and Legitimacy of Boundary Objects: Water Managers’ Assessment of a Simulation Model in an Immersive Decision Theater.” *Science and Public*

- Policy* 37(April): 219–32.
- White, Dave D., Elizabeth A. Corley, and Margaret S. White. 2008. “Water Managers’ Perceptions of the Science-Policy Interface in Phoenix, Arizona: Implications for an Emerging Boundary Organization.” *Society & Natural Resources* 21(3): 230–43. <http://www.informaworld.com/10.1080/08941920701329678>.
- William, C et al. 2010. *Toward a General Theory of Boundary Work : Insights from the CGIAR’s Natural Resource Management Programs*. 199.
- World Health Organization. 2014. “Meeting of the Strategic Advisory Group of Experts on Immunization, October 2014 – Conclusions and Recommendations.” *Weekly Epidemiological Record* 89(50): 561–76.
- . 2016a. “About WHO: What We Do.” <http://www.who.int/about/what-we-do/en/>.
- . 2016b. “Global Vaccine Action Plan.” http://www.who.int/immunization/global_vaccine_action_plan/GVA_P_doc_2011_2020/en/.
- . 2016c. *Strategic Advisory Group of Experts (SAGE) Terms of Reference*.
- World Health Organization (WHO). 2008. “WHO Guide for Standardization of Economic Evaluations of Immunization Programmes.” *World Health Organization (WHO/IVB/08.14)*: 71.
- World Medical Organization. 1996. “Declaration of Helsinki (1964).” *BMJ* 313(7070): 1448–49.
- Ziman, John. 1974. *Public Knowledge: The Social Dimension of Science*. Cambridge University Press.

