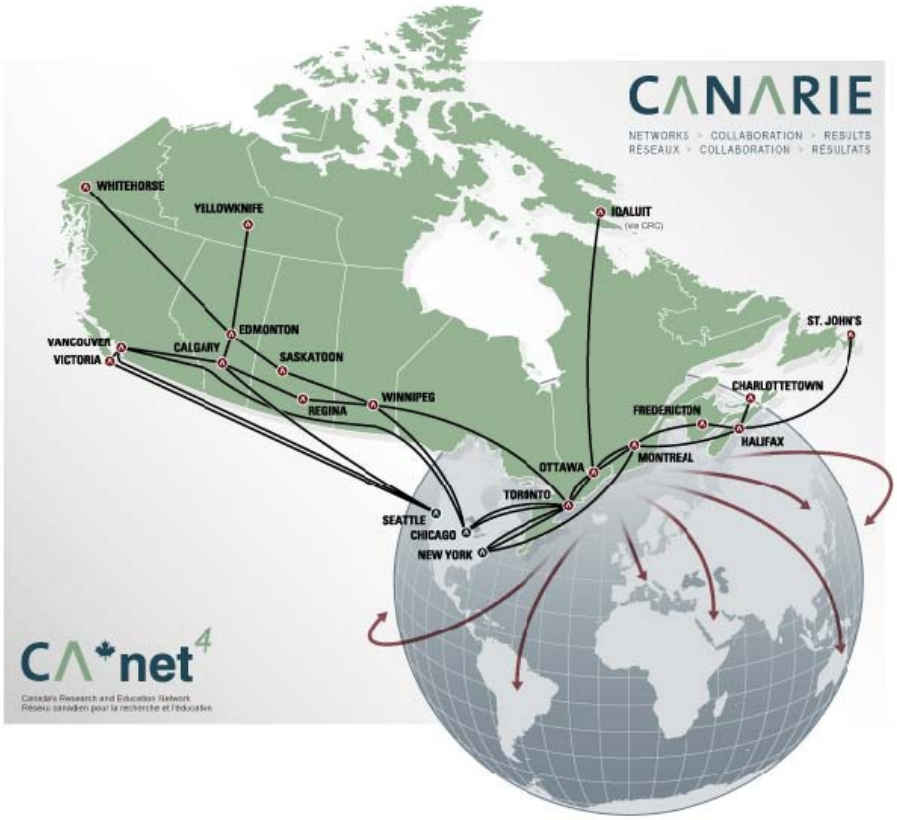
scripted

Volume 7, Issue 1, April 2010

REPORT ON THE TECHNOSCIENCE AND REGULATION RESEARCH UNIT (TRRU) AND THE QUALITATIVE RESEARCH COMMONS AND STUDIO (QURCS)

Emily Uhrig[*]



DOI: 10.2966/scrip. 070110.210

[*] Research Administrator for Dr Janice E Graham, Technoscience and Regulation Research Unit (TRRU) Department of Bioethics, Dalhousie University, Canada.

1. Introduction

The Technoscience and Regulation Research Unit (TRRU) is an interdisciplinary team of researchers led by medical anthropologist, Professor and Canada Research Chair in Bioethics, Janice Graham. Graham's team within the Faculty of Medicine at Dalhousie University (Halifax, Nova Scotia, Canada) draw upon anthropology, science studies, technology assessment and bioethics to approach cultural, technical, regulatory and moral issues in health. TRRU is a CIHR-funded team that is uniquely positioned for interdisciplinary analysis of health-care system capabilities and capacities. TRRU has significant combined expertise in policy research, medical anthropology, and science and technology studies. Our researchers hail from backgrounds in anthropology, biology, economics, political science, sociology, and collaborate with a wide range of researchers from epidemiology, history, immunology, law, medicine, pharmacology, and philosophy.

Dr Farah Huzair is investigating the regulation and production of influenza vaccines in Canada. Her work uses a science and technology studies (STS) perspective to understand how networks, institutions and systems are involved in bringing a novel vaccine to market. Her work has highlighted not only the regulatory and technical difficulties emerging from the H1N1 vaccine production process but also challenges for future vaccine production.

Dr Amrita Mishra is engaged in a Halifax-based study of views and practices around vaccination against oncogenic Human Papillomavirus (HPV). Certain HPV strains are linked to cervical cancer, which, although preventable, takes a high toll of women worldwide. Although Nova Scotia has good infrastructure for cancer surveillance, rates of cervical cancer remain relatively high compared to other Canadian provinces.

Dr Alexander Borda-Rodriguez is currently working on knowledge translation and institutional dynamics in healthcare. His work explores the politics behind knowledge production, translation and dissemination across private and public organisations in both developed and developing countries. He is currently looking at healthcare interventions in the global south (e.g. vaccines) and knowledge translation between vaccine scientists, government agencies and the public in Canada.

Dr Emma Varley is analysing sectarian identity and affiliation as social determinants of health in northern Pakistan. Her ethnographic research explicates how sect-specific medical ethics and bioethics shape patient and physician decision-making, as well as clinical service provision, access and uptake.

Dr Mavis Jones is focusing on risk governance, particularly how policies and regulations to mitigate health and environmental risks are shaped in different nations. Within this, she examines a) the shifting nature of the expertise used to support decision-making, and b) how transparency and openness operates within government bodies.

Dr Christina Holmes' research interests in the anthropology of science focus on three main areas: 1) globalization and science (including international connections and networks between scientists); 2) science related to food security, policy, and regulatory issues; and 3) scientific change and innovation..

Dr Marylene Dugas studies the relationships between global health, disease and society. Her research explores the transfer and acquisition of medical knowledge relating to the management of infectious diseases by communities in a West African context. She also has an interest in bioethical issues of transfer of knowledge necessary to obtain informed consent in clinical research on the African community.

Sharon Batt is investigating two longstanding obsessions – social justice and the politics of health and medicine – which led her to science and technology studies. Her PhD dissertation is an ethnographic study examining how practices and discourses about funding from the pharmaceutical industry evolved over two decades within breast cancer patients' organisations in Canada.

2. Our Current Projects

Research at TRRU began with a wider focus on heath care and biotechnologies and the regulatory issues related to their safety, efficacy, quality, governance and innovation. In recent years Canadian regulators have initiated a process of modernisation and are updating current regulations of pharmaceuticals and biologics. Biologics are more complex molecules, manufactured in a different way from synthetic pharmaceutical products. Within the general category of biologics, are radiopharmaceuticals, genetic therapies and vaccines. Given our interdisciplinary expertise on regulation, STS, anthropology, knowledge translation, our knowledge of the regulatory history of pharmaceuticals in Canada, and our links to the national vaccine community, we are positioned now to move into a more concerted focus on the social and science studies of vaccines.

Vaccines are particularly interesting from the STS perspective. While vaccines are a significant means for ensuring public health, through induced and herd immunity, they face the challenge of introduction into an immunologically naïve population. Vaccines are often associated with unknown risks of side effects in the short and long term. This comes from a very long and contentious, and often political history. The public response to vaccines brings up questions of privacy, autonomy, choice, access, equity, and responsibility, at individual and also wider societal levels. Along with the persistence of diseases such as malaria, meningitis, and HIV which take a heavy toll in the developing world, we are also confronted with diseases that either return in more virulent form (drug resistant tuberculosis) or are entirely new to public health experience and pose lethal risks at the global population-level (SARS, Avian influenza). The recent experience with H1N1 has highlighted the multiple roadblocks and bottlenecks that impede efforts to get vaccines to as many people as possible. In the process of confronting a pandemic, people in the developing world and also the poor and isolated in the developed world are the most underserved.

At TRRU, we aim to bring our diverse academic skills and backgrounds into an interdisciplinary synergy to understand how better regulation and coverage may be understood and achieved when appropriate with vaccines against Human Papillomavirus, pandemic influenza, and meningitis. We plan to animate macro-level data and theory with the richness of micro-level observation from ethnography by examining the roles and interconnections of local, national and international actors. We also examine the socio-cultural, historical, economic, and political factors that underpin and activate health concerns and responses. An ecosystems health approach figures prominently in our research models. Our studies pay attention to lessons

learned from experience to suggest improvements for vaccine decision-making models located within and specific to the populations themselves.

2.1. Regulatory Challenges to the Development of New Vaccines: Mapping Emergent Relations amongst Science, Evidence and Policy

This project studies the regulatory challenges to the development of new vaccines. We are investigating the important evolving relationships between science, evidence and policy for three new types of vaccine. In doing so, we hope to fill a crucial gap in the literature on the social dimensions of vaccines by generating novel insights on how governmental regulation and social practice converge in the administration of new vaccines. Our studies will generate data to facilitate national and international comparisons of vaccine administration across diverse geopolitical platforms. To this end, we use a multi-sited ethnographic approach to investigate and compare three case studies. Case 1 examines new questions and issues for the field of cervical cancer prevention with the availability of vaccination against high-risk HPV. Case 2 examines the innovation and production of the pandemic influenza vaccine in Canada. Case 3 studies the introduction of the new conjugate Meningitis A vaccine in Burkina Faso. The data from this case study will provide a basis for comparing between the issues around vaccines in developed and developing countries.

2.2. Assessing Knowledge Translation Tools Used During H1N1 to Improve Transferability of Health Research Systems

This research project will help us produce an analytical framework for assessing which knowledge translation (KT) tools work best, under which conditions and with what limitations. Our framework extends the work of Lavis et al. (2003) with a qualitative analysis of what is transferred, to whom, by whom, how and with what effect. We ask: i) what KT activities were important during the H1N1 pandemic between federal, provincial (Nova Scotia) and local levels; ii) what were the tools associated with different activities and iii) how effective were they with regard to real world conditions and the target population? Our work will support research on public health and health care system responses to the H1N1 outbreak to inform future planning and decision-making.

2.3. The Rollout of the New Meningococcal A Vaccine in sub-Saharan Africa

A new meningococcal serogroup A conjugate vaccine, MenAfriVac, is the first vaccine developed, manufactured and licensed in the global south for use in developing countries. It is scheduled for introduction in the West African country of Burkina Faso in the last quarter of 2010.

This study will examine the actors and activities involved in the planning and implementation of MenAfriVac in Burkina Faso. The manner in which decision-makers and citizens develop, plan for, respond, accommodate or resist a new vaccine intervention requires baseline evaluation and subsequent attentive monitoring and analysis. The rollout of MenAfriVac across Burkina Faso, which will vaccinate the entire population aged one to twenty-nine years of age, offers a unique opportunity to gather and analyse essential historical, socio-cultural, economic, political,

environmental and epidemiological events related to the vaccine development and country-wide intervention.

We will gather and collate ethnographic and quantitative data from the district of Nouna, Burkina Faso. We anticipate that our analyses will inform a decision-making model applicable for vaccines and other health technologies in developing countries. To this end, we have brought together a team of partnered collaborators that include WHO, the Program for Appropriate Technologies in Health/Meningitis Vaccine Project (PATH/MVP), the MultiDisease Surveillance Centre in Ouagadougou, Ministry of Health of Burkina Faso, and the Centre de Recherche en Santé de Nouna (CRSN).

3. Recent Projects

TRRU's recent ethnographic research activities have investigated regulatory issues associated with emerging biotherapeutics and vaccines at Health Canada and internationally.

3.1 Risk and Regulation of Novel Therapeutic Products: A Case Study of Biologics and Emerging Genetic Technologies

The Health Products and Food Branch, the regulatory arm of Health Canada, is responsible for the protection and management of risks for the entire range of drugs and therapeutic devices. The determination of regulatory policy, the reach of regulatory activity, and the scientific and ethical competencies of regulators are central to the debate about the nature of a just society and the relative importance of public health issues. But, for many Canadians, regulatory processes are obscure, unclear, and unfathomable. In this project, our researchers described a set of regulatory actors and their activities. They have been mapping the regulatory territory of scientific evidence and policy decisions, and illustrating how a regulatory system adapts in response to external factors, rapidly emerging scientific and policy changes, and contingency. Graham's primary field site was the Biologics & Genetic Therapies Directorate of the Health Products and Food Branch, where she sought to dispel the prevalent image of "the black box" of regulation. Jones worked closely with the Office of Consumer and Public Involvement (OCAPI) and Holmes worked at various sites of regulatory activity in Canada and Colombia.

Graham's study followed the step-by step process of product submission and regulatory review as teams of research scientists, biologists, medical officers, and technicians, equipped with state-of-the-art technologies and instrumentation, tweak basic science in response to regulatory needs. Scientists, clinical evaluators and policy advisors review submissions, sample consistency, conduct extensive chemistry and manufacture confirmatory tests, reanalyse data and check back with the sponsors for missing data or for any queries they might have about the submitted evidence. Decision-making frameworks have been established by the various parties, but decisions to submit, re-submit or finally withdraw the application are almost completely in the hands of the sponsor. Inevitably the actors on both sides must balance legislated deadlines with partial data, and weigh individual and public health safety against public and industry desires. The oft-heard expressions that "biologicals are illogical" and "biologics are different" underlie the special status these categories of therapies and diagnostics hold. Biologics are heterogeneous products involving

inherently process-related events unlike the purity/impurity profile of a chemical drug product. Unlike synthetic pharmaceuticals, complex biologics require stringent containment conditions to prevent adventitious agents and impurities during cell culture based production. Antibody response to a protein presents immunogenicity issues. Protein products from molecular pharming present emerging issues, as do combination products which represent hybrid chemistry/biologic/medical device crossovers challenging existing classifications. Unlike a pill that can be stored on a shelf for five years, many biologicals last only days, perhaps only hours in the case of radiopharmaceuticals.

4. Our Infrastructure for Qualitative Research

We are located within the Qualitative Research Commons and Studio (QuRCS), a state-of-the-art multimedia research facility equipped for live, real-time high-speed audio and video connectivity among multi-sited national and international research groups. Our facility was funded by the Canada Foundation for Innovation (CFI) infrastructure project and the Nova Scotia Research and Innovation Trust (NSRIT). QuRCS consists of two suites, comprised of a Research Commons and a Studio located within the Clinical Research Centre on the Carleton Campus of Dalhousie University.

QuRCS provides the physical platform for TRRU's innovative, interdisciplinary, and participatory qualitative research program. Inspired by the traditions of medical and visual anthropology and ethnographic film, this facility enables interactive access among participants and communities in multi-sited research projects. The Research Commons has seven computer workstations including video editing and qualitative analysis software for Dr Graham's research team who are exploring pharmaceutical grammars and the regulation of pharmaceutical, biologics, new genetic therapies and vaccines. The Studio is a dedicated site for research interviews including patient and clinician encounters, focus groups, and community meetings, with full video receiving, recording and transmission capabilities.

Research today involves the widening of networks and the strengthening of nodes. Our unique Research Commons seeks to realise that principle.