

## Health technology assessment and incorporation in Brazil: critical reflections on an emerging public-private field

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Evidence concerning public health efforts and interventions is gaining in importance as governments are struggling with how to best guarantee sustained access to healthcare for their populations. Health technology assessment (HTA) was developed as a way to assess the effectiveness, safety and cost of health technologies in order to inform policy decisions. In 2006, the Brazilian Ministry of Health overhauled the institutions responsible for the incorporation of new health technologies into the country's public healthcare system. "The unsystematic incorporation and use of inadequate technologies create risks for users and compromise the health system's overall effectiveness," stated a Ministry paper outlining the reform (Decit, 2006). Two years later, I spoke with Dr. Anderson Pereira,\* an official involved in making recommendations to the Minister on health technology incorporation decisions. Dr. Pereira had no elusions about the health technology incorporation system's failings and limitations. In contrast to the Ministry's neatly stated goals of systemization, he said, "Brazilian society builds things and then thinks about how to fix them – it changes the wheel of the car while the car is driving."

My conversation with Dr. Pereira was part of an anthropological inquiry into health technology assessment and incorporation in Brazil. Despite the purported "systematic" nature of the new incorporation scheme, there was much improvisation, revision and, above all else, uncertainty in this emerging field, as Dr. Pereira's comment indicates. From June to August of 2008, I observed the activities of a Brazilian HTA start-up company called Health Net,\*\* which specialized in performing analyses that inform the Ministry's health technology incorporation decisions. Health Net's employees were a mixture of health professionals, experienced at interpreting medical evidence and sensitive to on-the-ground realities, and engineers, knowledgeable in the area of mathematical modeling. During my time at Health Net, I interviewed

public and private-sphere professionals involved in health technology assessment and incorporation. Most of these professionals never expected they would be working in this field. In this article, I will put the experiences of pioneering private-sphere professionals and experienced public sphere officials in dialogue with a social scientific literature on the public uses and commercial interests of scientific evidence, in order to arrive at possibilities, limits, insights and dilemmas concerning the Brazilian health technology assessment and incorporation field as it is emerging.

### An evidence shortage

While I was at Health Net, I spoke extensively with José Bento, a nurse who had worked in a variety of clinical care environments. At the time, he was helping to construct a cost-benefit analysis of a medical device that was being proposed for incorporation into the public healthcare system. He was relying on foreign data for his assessment. "I have to assume the data is similar [for Brazil], but it's obvious that it isn't," he said. The dearth of health data specific to Brazilian populations, both basic health statistics and studies, was a frequent challenge in his work. Sometimes the needed data existed in health posts, José said, but it was "written by hand, mixed with others paper, in some notebook, inside an old cupboard and no one knows where it is." José said employees in the public healthcare system have little incentive to organize and report information, since the results rarely, if ever, are returned to local care environments in order to improve services. When aggregated data was available, it was through difficult-to-navigate online databases.

When it came to studies, José and his colleagues blamed the dearth of needed evidence on the absence of a "research culture" among Brazilian health professionals. Such claims are difficult to substantiate, especially in places where resources and training may also be impediments to research. While more evidence would certainly have eased and improved this company's work, other countries' experiences prove

\* Names have been altered to protect informants' identities.

\*\* The name of the company has been altered to protect informants' identities.

that more research does not always translate into better informed public health efforts. Anthropologist Adriana Petryna (2009) discusses how many developing countries, including Brazil, have become prime destinations for randomized clinical trials (RCTs) wherein local doctors carry out protocols and report back raw data to contract research organizations, working for drug companies. Such trials are primarily used to gain access to profitable markets (see also Lakoff 2002; Lakoff 2006). Local physicians profit, as do drug companies, but healthcare infrastructures and public health decision-makers are left no better-off, and patients are in no way guaranteed future access to treatment.

### Health priorities and market offerings

Randomized clinical trials frequently seek to recruit "ideal" patients in order to produce measures of efficacy, severed from context-specific considerations (Dobrow *et al*, 2004). As anthropologist Andrew Lakoff discusses in the case of trials for anti-depressants, favorable results depend on the selection of the "right" patients for the drug (2002). Clinical trials using ideal patients are both highly context specific, because they occur in highly controlled conditions, and wholly non-specific, because they supposedly produce a measure of a drug's theoretical ability to work.

Drug companies make the contextual non-specificity of such studies into an advantage. Because results are not region-specific, they can be extended to virtually any locality (Petryna, 2009). As economist Michael Kremer discusses, drug development is overwhelming directed towards developed world diseases, rather than developing world health priorities (2002). Dr. Pereira, the official involved in making health technology incorporation decisions, noted that at some point commercial interests meet public needs. "After all, [drug companies] are not producing astronomical artifacts, they are producing health products." The meeting of public health priorities and available health technologies becomes, in practice, a chance occurrence. While virtually anyone can propose a new technology for the public health system, in practice, Dr. Pereira said, drug companies file almost all the applications. The Ministry is ostensibly left to select among the industry's offerings, which are neither geared to the country's health priorities nor tested in the country's epidemiological or infrastructural context. The drug industry, here, is not some calculating villain, but an increasingly outdated machine, producing both products and evidence that are not appropriate for current problems and priorities.

In contrast to studies that utilize ideal patient populations, a growing literature is highlighting the importance of practical or pragmatic studies (Zwarenstein and Treweek, 2009; Tunis *et al*, 2003). Such studies hold the potential to elucidate the effects of technologies on the patients who will actually use them as well as reveal challenges to implementation if the

technologies are tested within public health infrastructures. Dr. Paulo Picon\*\*\* is an academic scientist in southern Brazil and pioneer in the area of independent evidence analysis and production (Amaral *et al*, 2006; Picon *et al*, 2007; Krug *et al*, 2009). Much of Dr. Picon's research occurs in public reference centers for complex and high-cost treatments he has championed, an approach to HTA that is not dissimilar to the one being proposed by American President Barack Obama. Most recently, his group conducted a pharmacovigilance study of patients with hepatitis C genotype 1 infection treated with pegylated interferon and ribavirin. "The selection criteria in these studies are the habitual selection of real life," Dr. Picon told me. Sustained virological response occurred in 35% of these real-life patients in this study (de Almeida *et al*, 2009), a marked difference from the 46% achieved in a 2002 clinical study (Fried *et al*, 2002). While the studies cannot be directly compared, such wide divergences are crucial for integrative studies and public health decisions. Even pragmatic studies are of limited value, however, without policy mechanisms that seek technologies specific to Brazilian health priorities.

### Deliberation and Innovation

From this initial engagement with HTA professionals' views and experiences, it seems to me that health technology assessment and incorporation in Brazil is seriously hampered by the absence of easily-accessible and up-to-date public health statistics, the dearth of pragmatic studies to appropriately inform integrative analyses and public health decisions, and the limitations of an international system of knowledge-production geared towards gaining access to profitable markets. These inequities are informed by theoretical limitations in knowledge use and production that elide context-specific considerations, study formats that are focused on technologies rather than people, and a health technology incorporation policy that narrowly strives for "rationalization" while ignoring systemic considerations that subvert its efforts to serve public health priorities.

"No one studies this in college, not production engineers, not economists, not statisticians, not doctors, not nurses, no one," José Bento said concerning health technology assessment. At the time, there were few if any training opportunities in Brazil. Harmonization of HTA practices may promise wider education and greater ease in judging the quality of analyses (Hutton *et al*, 2008). However, harmonization may also threaten to solidify existing biases concerning contextual considerations. As Dr. Picon's work indicates, innovation is needed over harmonization.

Health technology assessment and incorporation are a small but important part of constructing a health system that is both efficient and humane. In Brazil, where public health

\*\*\* Dr. Picon gave his permission to print his real name.

efforts are dominated by concerns with drugs (Biehl, 2006, 2007a, 2007b), successful health policy will depend on actors' abilities to transcend technology-centered paradigms and cost-effectiveness orthodoxies to fulfill demands for basic services and social rights (Farmer, 2008; Biehl *et al*, 2009). Evidence aimed at accomplishing this goal must be sensitive to social categories and needs (Biehl, 2006) as well as areas of inefficiency and poor value (Porter and Teisberg, 2006).

I spoke with a Health Net engineer who plainly told me the drug she was working to propose for incorporation "was bad." She thought Ministry officials would certainly see this. At the time I was conducting research, Ministry of Health officials had asserted health technology incorporation decisions would be made public. Almost one year later, the decisions, the analyses that supposedly inform them, the standards by which they are judged, and the means of judging them are still not made public. As a result, neither is it possible to independently assess the quality of such analyses nor to determine to what extent the Minister of Health relies on such analyses to inform incorporation decisions.

The Ministry's failing is not that it did not construct a rational or systematic incorporation scheme, but that it has not allowed for a public discussion of the merits and limitations of its approach. There is much at stake in health technology assessments and incorporation decisions. "You're not selling a bed-sheet where the worst that can happen is that it is a lousy bed-sheet and no one dies as a result," José Bento said. "Your distance to the patient is very great but so is your responsibility to him," a psychiatrist at Health Net told me. José and his colleagues, several of them doctors who had worked in the public healthcare system, knew of the limitations of their evidence, but found no way within the methods and system they used to mitigate these limitations. A critical assessment of the assessment and incorporation field itself is in order. For starters, the Brazilian system has been too preoccupied with constructing avenues of incorporations and has not given thought to corners where ideas can be exchanged, uncertainties cultivated and sensibilities, such as those of the dedicated professionals already working within the system, can be brought to bear on methods and institutions.

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