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21 Entangled Knowledges: Three Modes of Articulating Differences in Clinical Trials

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I. Introduction

Disease comes in many different forms, not only—as old textbooks of medical anthropology may suggest—in the diverse lives of diverse people, but also in biomedical science. Or, more precisely, *in between* the two, as Ilana Löwy has emphasized in connection with AIDS trials: "If…medical innovations have to make room in a 'full world,' the world is full not only with other devices and practices, but also with cultural, institutional, economic and political constraints.…The implementation of life-sustaining technologies [for example] interacts with cultural and religious values, as well as with instruments and tools, with the division of labor in modern hospitals, or with socialization of doctors and nurses" (Löwy 2000: 71). The fact that, in medicine, human and scientific differences emerge side by side and in a constant interplay presents scientists and physicians with unique challenges.

Diabetes is far from an exception. It runs in the family as a genetic trait, as documented in the public database of the newly established *Biobank Japan*, or threatens the nation as a lifestyle-related disease, as addressed by the health care campaign of *Kenkō Nippon 21*.[1] Diabetes is an autoimmune destruction of insulin-producing cells in the pancreas when classified as type 1, or an inadequate secretion of insulin over the whole body in the case of

type 2. In yet another turn, high levels of glucose in the blood may be a daily *regimen* of injections for some or a *choice* between various pills for others.

The assessment of such incommensurable levels of disease is a constant matter of concern in the work of physicians, clinical researchers, and epidemiologists. Which variations should be accounted for? How much heterogeneity can be allowed without compromising the integrity of research? What is similar and different between numbers and suffering? These are highly charged questions requiring new technologies that enable the assessment of human difference and biological variation in their everyday interactions. Clinical trials are one way to do so. Here, in the process of trying to understand what different sets of numbers tell about different groups of people, relationships between them are established. Such links, in turn, articulate new differences through *collaboration*, *participation*, and *inclusion*.

The tendency toward more patient involvement in research—and a growing concern with lay experience and personal choice—gave birth to a new politics of participation and accountability that came to define what may be called a new mode of differentialist medicine in contemporary Japan (Rabeharisoa 2008). This notion is based on sociologist Steven Epsteins's influential formulation, the *inclusion-and-difference paradigm*, which marks a shift of scientific interest toward social categories of identity. He addresses the simultaneous emergence of issues concerning sex and race differences in recent clinical research in the United States. But he treats them as analogous and distinct cases, and, apart from locating "a contingent set of historical circumstances" (Epstein 2007: 232, 282), he provides little discussion of the situations and events in which such differences come to be entangled.

In contrast, my interrogation here doesn't take "difference" as its point of departure. Rather than considering clinical trials as a ubiquitous work on the knowledge of things and persons in an epistemological sense, what I seek to explore is how such differences come to count in relation to situations and events. To do so, I attempt to follow the practicalities of this differentialist mode of medicine in a Japanese setting through two kinds of diabetes trials: epidemiological and pharmaceutical studies.

[1.] For more details see the *Japan Biobank* website at http://www.src.riken.jp/english/database/index.html and the *Kenkō Nippon 21 Forum* at http://www.kenko-nippon21forum.gr.jp/ (both accessed 11 November 2011).

II. Framing Clinical Research

Technically speaking, clinical trials are the final stage in the development of new drugs and medical devices. Yet such measures of safety and effectiveness also provide the indispensable means for improving the treatment (and prevention) of diseases through the active involvement of its human subjects. Historians and sociologists have thoroughly described the disciplinary alliances and conflicts between statistical and medical expertise in the quest for proper scientific evidence throughout the 20th century and the way they facilitated a growing interest in human variations.[2] In line with this, others have drawn attention to the biopolitical work of including such social differences and "ethical variability" into clinical research during the past decade or so[3]. Clinical trials, as many commentators of evidence-based medicine note, have become crucial in giving sense to the links between social inequalities and medical categories by making such links powerful tools of including patients in the production of medical facts. In Japan, this innovative logic of participation has, at least in part, emerged from the complex relationship between patient organizations and the pharmaceutical industry in the aftermath of a series of public scandals of tainted blood involving AIDS patients and hemophiliacs.

Practically nonexistent before World War II, controlled clinical trials became the gold standard for evaluating the risks and benefits of medications and treatments in the current Japanese medical system. The ways of controlling how drugs are put on the market have been drastically changed since the implementation of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) by Japan's Ministry of Health and Welfare in 1997.[4] This new frame-

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2. On the history of clinical experimentation in the United States, see Marks 1997; for sociological case studies from Europe, see Will and Moreira 2010.
3. See for example Abraham 2008; Petryna 2009.
4. The introduction of new safety standards for clinical research was part of the revision of Japan's Pharmaceutical Law that went into effect in April 1997. This included the harmonizing regulations for the pharmaceutical industry along with the implementation of ICH Good Clinical Practice (GCP) guidelines. Further modifications have been added for the regulation of clinical trial standard operating procedures (July 1997) and clinical trial auditing and compliance inspection (April 1998).

work promised to overcome discrepancies on three levels: first, by encouraging communication between overseas and Japanese clinical data (scientific incompatibility); second, by improving the ethical monitoring of patient involvement in medical research (human diversity); and third, by enhancing Japan's competitiveness in an increasingly transnational pharmaceutical industry (market niches).[5] Evidence based medicine (EBM) thus has been facilitating the collaboration between global business and local science under the guidelines of Good Clinical Practice (GCP)—a public framework of ethical dispositions toward the inclusion of patients in medical research. As a result, the assessment of clinical efficiency has come to occupy an instrumental position in the standardization of medical practice.

Diabetes research itself has been instrumental in this transformation, especially through *epidemiological studies* that have been striving to put an end to the long-standing controversy between advocates of "symptomatic" and "tight" control of glucose levels. These so-called large-scale prospective clinical trials (*chōki ni wataru maemuki rinshō shiken*) investigate disease mechanism by asking how a certain factor (a medication, a gene, self-management, or lifestyle) is related to the progression of complications. Multicenter prevention studies that evaluate the management of glucose levels have been conducted with the primary objective of comparing foreign findings with Japanese data, raising important questions of difference and similarity across populations, ethnicities, and lifestyles.

On the other hand, another type of trial has exposed the problems of generalizing results across ethnic and racial variation. This second form of clinical trials mostly includes studies of new pharmaceutical innovations, also called *therapeutic studies* (*chiken*). Antidiabetic drug development in Japan typically involves basic research and animal experiments followed by three human trial phases: on healthy volunteers (Phase I), on a small group of patients (Phase II), and on more differentiated groups of sick people (Phase III). Patients are divided into two or more cohorts (mostly, but not necessarily, at random) of different therapeutic interventions and followed up for months or years comparing their blood-glucose levels and complica-

5. See Applbaum (2006) on the impact of these administrative changes in the context of the introduction of SSRIs in Japan.

tions. Given the long time span of developing complications, the difficulty of keeping patients motivated, and the rapidly changing pharmaceutical solutions that may promise better—or easier—treatment than the one being investigated, the implementation of diabetes trials requires the long-term collaboration of doctors, nurses, and patients in several hospitals, as well as further planning and management by clinical epidemiologists, statisticians, endocrinologists, and social workers.

III. Articulating Differences

1. Collaboration: Pharmaceutical Trials

The Suzuran Diabetes Center—the ethnographic focus of this paper—is an outgrowth of medical reforms toward specialization. Health-care institutions designated to the treatment of lifestyle diseases and chronic conditions have begun to proliferate in regional hubs all over Japan since the 1980s, providing expert treatment of complex diseases such as cardiac disorders and cancer, as well as their complications, all under the same roof. The founders of Suzuran Center had similar ideas and hopes about the future of diabetes care in Hokkaido, the northernmost island of Japan.

Dr. Komata, one of the founding physicians, with years of experience in American research institutes, mentioned this in passing during a conversation we were having on the prospects of specialized diabetes treatment in regional Japan: "You probably won't believe this, but I saw old people occupying beds for years just because there wasn't a relative or a friend who could inject insulin for her three times a day….Every day I was dreaming of a place where I could treat *disease*, not do elderly care."

The new hospital soon began to build a reputation as a highly innovative and patient-focused institution providing total care (*tōtaru keā*) for the treatment and follow-up of diabetes and its major complications. While representing public health concerns and reacting to regional incentives, the management also carefully aligned scientific and business convictions in order to carry on as a medium-sized private health care institution. The device that made such links possible was found in the apparatus of clinical trials.

Suzuran joined the newly launched program Good Clinical Practice in

1998 by hiring two clinical research coordinators (*chiken kōdinētā*). Bringing together the pharmaceutical industry, the medical corporation (*iryō hōjin*), and the ethical discourse of patient-centered treatment, such a synergy worked toward the justification of entrepreneurialism to health—a notion that resonates profoundly in the Japanese context of socialized medical care. As related by one of the new coordinators, their presence at the clinic may have raised the eyebrows of some who considered it an overcommitment to pharmaceutical companies. The more than twenty Phase II and III trials conducted during the following years, however, made Suzuran one of the leading institutions for the clinical study of diabetes in Japan.[6]

The poster on the wall recruiting volunteers for pharmaceutical studies indicated that this hospital was at the forefront of medical research. As Dr. Mihara, the director of the center, expressed it in an interview: "I take both the interest of pharmaceutical companies and the readiness of patients to participate in these trials as a sign of recognition of the expertise in diabetes that we pursue in this hospital…This implies," the article concludes, "that the engagement in clinical trials is an imperative for institutions at the frontier of medical practice" (*Iryō Renkei no Jissen* 2002).

Thus, the apparatus of clinical trials (under the legislative framework of the ICH-GCP regulation) turned out to be a strong public proof of scientifically credible healthcare at the clinic, which could proudly claim now to have provided both up-to-date medication to its clients and a medically literate pool of patients to drug manufacturers.

2. Inclusion: *Sarariman*, as Lifestyle

The first and one of the most critical tasks researchers of diabetes in Japan have to confront is the chronic shortage of patients willing to participate in clinical trials. This problem is particularly overwhelming in prevention studies, which lack even that slight prospect of a new and better medication offered by pharmaceutical trials.

Overcoming such obstacles was an essential part of the work of clinical coordinators at Suzuran Hospital. In the coordinator's room, I observed

6. As of the first five years of operation (1998–2003), nineteen protocols have been completed.

several long conversations in which she tried to persuade patients about the benefits of being closely controlled by a clinical staff and "leading experts" in the field. Normally, she would stake claims to science seeking to invoke a sense of trust in the sick person while earnestly specifying a long list of possible risks involved, ending each such session by ritually handing over the form of informed consent: "Would you please carefully read this before you put your seal on it?"

Questions of access and recruitment are decisive not only in terms of who will be enrolled in a trial but also of what will be studied. Scientific articles have much to say about alternative methods for finding appropriate individuals to participate, about who is being included and excluded (and how) in the process of making facts—facts, for example, that prove the efficiency of lifestyle modification in the primary prevention of diabetes:

> Male subjects with IGT [impaired glucose tolerance] recruited from health-screening examinees were randomly assigned in a 4:1 ratio to a standard intervention group (control group) and intensive intervention group (intervention group)….Only men were selected for the present study, because in our previous long-term follow-up experience there were more dropouts among the women than among the men in a similar setting. (Kosaka, Noda, & Kuzuya. 2005: 152–153)

The confluence of the subjects and objects of diabetes research thus emerges, for example, from the everyday operations of the medical checkup (*kenkō shindan*) at the clinic.[7] Men may be too busy to start eating proper breakfasts and go down to the gym in the evening, but they are ideal research subjects. Given that they are corporate workers, or *sarariman*, they are less likely to quit trials once their health-check results prove them to be at risk, because the following year their employers will send them to repeat the checkup either way, as mandated by the law.

Thus, being a working man (rather than a working woman, or an entre-

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7. That epidemiological studies make use of health screening as an entry point to trials makes some sense, given that the most likely way for people with, or at risk of, diabetes to encounter the medical system is through the annual physical checkup.

preneur for that matter) may come as a scientific parameter, an *inclusion criteria* in some cases. But the fact that masculinity is a salient aspect of treating and diagnosing diabetes from the very admission of patients is a detail left unaccounted for in most studies.

This marked category of the *sarariman* at the clinic (but not in the literature) elicits a number of important issues regarding the distribution of biomedical knowledge across cultural differences in diabetes research. One is the concept of lifestyle. Indeed, diabetes has been understood both in Japan and elsewhere as a lifestyle-related disease *(seikatsu shūkan byō)*, which means one's everyday routines have to be taken into consideration from the beginning of the treatment. It requires complex cultural assessments from eating habits to daily walking distances, from smoking to sleeping. But how can such diverse aspects be included in clinical studies? How can they be compared? The figure of the *sarariman* helps to turn such multiplicity into a fact of lifestyle.[8]

Epidemiological data that indicate a growing rate of diabetic complications with age, for example, may serve as a rationale for measuring waistlines and blood sugar levels in people above forty. But they indicate different problems for men and women, as Dr Nazono, the senior physician at Suzuran explained to me in an interview:

> We thought before that glucose levels didn't show significant differences between the sexes, but we were quite wrong. It is clear from survey results now that men are most vulnerable in their 50s and 60s, while the number of female patients keep rising linearly with age. But, believe me, this is not simply an epidemiological problem. I'm talking about individual cases. I see all these relatively young working men day after day and, yes, I know that they have absolutely no time and energy for eating healthy food or jogging in the park. They're just too busy, which makes it very difficult for me to help them. So the complications strike down

[8] The figure of the *sarariman*—a Japanese version of the corporate worker—is deeply ingrained into the epidemiological imaginary as a model of the collapsing middle-class lifestyle. His daily routine of smoking, drinking, and no exercise makes him a relatively straightforward subject of compartmentalized health advice on lifestyle changes and clinical trials in Suzuran Hospital.

on them much faster than on women who pay more attention to their health and will develop the disease later in their lives. [Fieldnotes, July 20, 2005]

3. Interference: Epidemiological Trials

The notion that (harmful) lifestyle is the cause of and the key to controlling type 2 diabetes is the guiding assumption behind epidemiological research that calls for better public health strategies and multibillion-yen drug development programs that promise chemical solutions to "bad" habits. It is, consequently, the condition of possibility for any scientific knowledge about diabetes. But so too is much of the concern with lifestyle a contested domain of national identities that may be raised from the hotbeds of science.

It was certainly so for the researchers in Suzuran Center who participated in setting up the Japan Diabetes Clinical Data Management Study (JDDM), a multicenter research that was expected to produce evidence on the effects of active intervention in the prevention of complications. The largest study of its kind, it brought together close to seventy clinics around the country—including Suzuran Hospital—that collaborated in the observational study of more than sixty thousand patients. Funded by the Japanese Diabetes Society, the JDDM has been collecting laboratory data of diabetes indicators, such as HbA1c, and analyzing them in the light of complications developed by patients. Doing so, they were slowly but surely piecing together all epidemiologists' dream of a comprehensive national registry of diabetes therapy. Meanwhile, the original research, which started in 2000 as a study group of specialists, evolved into as many as eleven independent projects by 2007 thanks to a computerized system (CoDic) provided by the leading insulin manufacturer, Novo Nordisk, and the collaborative work of statisticians, clinicians, and public-health experts.

While these independent studies were still going on, the first preliminary results were published during 2005 in the middle of the so-called metabolic syndrome controversy that revolved around the differences between Japanese and Chinese data in the assessment of the cardiovascular risk of diabetes.[9] The authors of the JDDM study were stressing the "superiority of Japanese HbA1c levels" when compared to other, especially Asian, countries. They also suggested that complications could be prevented by patients' education on lifestyle and additional diabetes treatment, and that the inten-

sive intervention based on monthly visits in Japan could serve as a lesson to other countries.

The reason I cite this research is to demonstrate how lifestyle becomes an impetus for mobilizing collective attributions, such as "Western" or "Asian" attitudes in managing diabetes—not by rendering them to the realm of the social, to be sure, but rather by measuring them accurately in changing hemoglobin levels.

> In UKPDS [UK Prospective Diabetes Study], the average HbA1c was 8.0% in conventional treatment group and in Asian countries, the average HbA1c was 8.5% in type 2 diabetes. Our results are unlikely to be due to selection bias since the medical institutes in this study are evenly distributed throughout Japan on both a geographic and socioeconomic basis. The accuracy of most of the institutes and laboratories conducting HbA1c measurements was confirmed with standardized samples supplied by the JDS [Japanese Diabetes Society]. Therefore, the results are unlikely to be due to selection biases or measurement errors. (Kobayashi et al. 2006: 202)

When "lifestyle" is expressed as HbA1c levels, it becomes a transportable fact. It can move across oceans either as a medical parameter or as a cultural stereotype, although these are not always neatly tied together. A patient participating in the above study echoed this mobility when she recounted her visit to the United States. To her great surprise, one of her relatives was encouraged by his physician to cut back on bread or pasta in his daily menu, since quitting ice cream had been clearly improbable. "They just simply

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[9] The Japanese Society of Internal Medicine, with eight other organizations, compiled the diagnostic criteria for metabolic syndrome in April 2005. The pillar of this definition became the waistline: more than 85cm and 90cm for men and women respectively were judged to be the threshold values for the syndrome. So, when visceral fat was counted, women tended to be less vulnerable to metabolic syndrome than men—given that they were Japanese, because in any other countries the numbers for men would be higher. After initially accepting these results, the International Diabetes Federation, a transnational association of diabetes experts, later decided to revise the Japanese values to conform them "with the rest of Asia" (Nango & Saio 2006: 711).

calculated daily calories, I guess," she commented and told me how she had tried to explain him that, rather than daily measures, he should find out about his HbA1c levels at the hospital, because they show his condition more fully. "I told him to check his hemoglobin results to see the effect of such advice, but he didn't listen. He said he was feeling fine, so why worry so much. No wonder so many Americans end up with their legs cut off," she concluded. [Fieldnotes, July 25, 2005]

Note that here it is glucose levels along lifestyles that frame differentiation: Western lifestyles that make Japanese people more susceptible to diabetes than others, and numbers that seem to indicate more compliance in Japanese patients. And although hemoglobin levels are normally assessed in automated blood analyzers, while social and environmental data on lifestyle are recorded in interviews or on questionnaires, in clinical research they *interfere*: rather than one determining the other, new and original differences emerge.

IV. Events

The three accounts of collaboration, inclusion, and interference I assembled here do not reveal anything new to those who have ever had a chance to take a closer look at clinical research; neither do I use them as case studies of this-is-the-Japanese-way-of-doing-medicine. The question is, rather, how can we deploy the events of clinical experimentation in the anthropological reconceptualization of difference?

As I have tried to demonstrate, rather than simply "straightening out" inconsistencies in medical practice, the changing landscape of clinical trials has sparked new entanglements between scientific and cultural claims of differentiation in Japan. From thrifty genes to pot bellies, the body of the diabetic patient is among the most important sites of medical innovation that facilitate confluence between human and scientific variation on different levels. It is here that different types of diabetes are linked with one another, where the *sarariman*, in his search for a better treatment, meets other men and women of different lifestyles. The argument, in short, is that the events in which notions of gender difference are mapped onto a Japanese-versus-Western polarity in the treatment of diabetes reflects the complex differen-

tiating implementations of collaboration and inclusion in clinical research.

The recognition that difference is *not* exclusively an anthropological problem should be put to the test of ethnography to challenge anthropology in two related fields of research: cultural analyses of postcolonial medicine and studies of patient movements. To the extent that social scientists have been concerned themselves with the problem of differentiation in biomedicine, they have tended to describe clinical trials as an apparatus that either reduces existing social identities or constitutes new ones. In the former case, it is the neoliberal state, the pharmaceutical corporation, or simply biomedicine that produces new identities and interests through the marginalization of certain groups (Adams 2002; Montoya 2011). Other researchers stress the important ways in which new groups and identities are mobilized and established in and around clinical research (Rabeharisoa 2006; Whitmarsh 2008).

My aim here was to step back from these fundamental questions of cause and effect and point to some events around clinical trials that are part and parcel of the differences being evaluated. As Isabelle Stengers reminds us, "What comes first…is the activity of mediation, which not only creates the possibility of translation but also 'that which' is translated, insofar as it is capable of being translated. Mediation refers to the event, insofar as its possible justification by the terms between which it becomes situated comes after the event, but even more so insofar as these terms themselves are then expressed, situated, and make history in a new sense" (2000: 98–99).

Put this way, clinical trials of diabetes seem to suggest that collaboration and inclusion are very practical matters indeed. They are events in the ethnographic sense of the term—in other words, events in which differences come to count in new and unpredictable ways. Thus, rather than questioning *who* are the collaborators or *what* is included, such events tell us about *how* differences come to matter in practice. While keeping in mind that it is only one possible approach to clinical trials among many, I can't help stressing, again, the importance of ethnography in recognizing that political questions are, in the end, questions of method.

A Note on Names

The name of the hospital and all personal names appearing in the article have been changed to protect the privacy of those who were willing to tell me their stories. Japanese personal names are given in the customary Japanese order, putting the family name first, then the given name.

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