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STS AS A THIRD SPACE BETWEEN EVIDENCE-BASED MEDICINE AND THE HUMAN SCIENCES

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We should seek our instruction neither from science alone, nor the sacred, nor any singular form of understanding, but should rather seek to occupy the spaces of transformation which lie between—neither one nor the other but the “third space.” Hence Serres (1991) gives the name “third-instructed” (*tiers-instruit*) to him or her who is able to give up the comforts of disciplinary specialism and risk putting themselves into perpetual translation. (Brown 2002, 12)

If you are inspired by this quote, which I of course hope you are, let me alert you that a “third space” between disciplines isn’t so much something one can simply occupy at will. *Seeking* to occupy it comes with its histories; histories of individual scholars but also of relationships between fields. Equally, “giv[ing] up the comforts of disciplinary specialism” is not something one can simply decide to do. As far as this quote provides inspiration, it does so for the long haul. As Michel Serres (1983) proposes, seeking to occupy the third space is best imagined as traveling the Northwest Passage, which he, drawing on the messy coastlines in northern Canada that connect the Atlantic and Pacific Oceans, uses as a metaphor for the division between so-called natural and human sciences. As Serres suggests, “The passage resembles a jagged shore, sprinkled with ice, and variable. . . . It’s more fractal than truly simple. Less a juncture under control than an adventure to be had” (1995, 70).¹ This demo account is about how to navigate the Northwest Passage² and how to make sure critique from the shore does not render its straits impassable. I argue that STS scholarship may be particularly well positioned for such travel, provided it is ready to be transformed by the journey. “Spaces of transformation” are not about impact; they are about being translated. About becoming something that is neither the same nor different from what you currently are. Sounds esoteric. It can happen by email.

1. INTRODUCTION: A GUIDELINE DEVELOPER'S INVITATION

Find enclosed the info for the abstracts for G-I-N 2011 [conference].³ We'd like to submit an abstract with you on the safety study.⁴ They don't mention safety norms in the call, so we have to find a nice heading to slot it under, or we broaden up the abstract based on the final report on Diversity in Guidelines.⁵ Teun, let's talk about this when we see each other next week.

Not an irregular email for an academic to receive. But it was the first time I had gotten such a message from the secretary of a funding agency, and I was excited to receive it. It came from the secretary of the Dutch Council for Quality of Healthcare, a temporary policy agency that was formed in 2009 to commission research as input for setting up the National Health Care Institute (in Dutch, Zorginstituut Nederland, or its predecessor, het Kwaliteitsinstituut), which was to play a major role in the regulation of Dutch health care. The council had been including the Erasmus School of Health Policy and Management, my employer at the time, in top-down tenders because the school is one of the leading players in the Netherlands on health policy research. But developing the studies of the tenders we won was helped much by the fact that this secretary was a former graduate student from the school; the kind of theoretically informed empirical work we delivered was familiar to her. Fortunately, it also resonated well with the remaining leadership of the council, who wanted a broad knowledge base for setting up the institute. Submitting an abstract together was a way to extend and deepen the relationship and, I hoped, strengthen the connection between our claim in a report and the ongoing policy development for the new regulatory agency. That claim—that considering guidelines as regulatory documents for setting *minimum* quality and safety norms or as quality improvement instruments for *complex issues* draws upon two different modes of safety (Jerak-Zuiderent 2012), which require profoundly different knowledges, roles of professionals and regulators, and regulatory ecologies—was a message we wanted to learn to convey. Working on a conference presentation together could thus be an interesting experience for all of us. Moreover, the secretary was a well-known member of the Guidelines International Network (GIN), understanding its conference and abstract conventions as well as being able to provide a clearer sense of how we could best present the study for an international guideline development audience.

All in all, this seemed an interesting way to extend and deepen the connection to guideline development practices that I had been pursuing since completing my dissertation on experimental interventions with standardization of hospital care (Zuiderent-Jerak 2007). In that work I tried, inspired by the work of my PhD supervisor and colleagues (Timmermans and Berg 2003), to bypass sociological work that criticizes the reductionism of standardization by reifying complexity. Through collaboration in projects, Marc Berg, Roland Bal, and I developed an approach⁶ that I would later call situated standardization, which consists of organizational experiments that

empirically elucidate specific issues in health care delivery to help situate standardization attempts in those issues (Zuiderent-Jerak 2015, 72). This approach seemed to speak to guideline development too; a field that in the 1990s developed from a dominance of consensus statements, in which experts agreed, on the basis of their experience, on the weight of different forms of knowledge, to a dominance of epidemiological evidence-appraisal methods, with topic expertise and deliberation coming into the picture only after the epidemiological evidence searches and summaries were done.⁷ This development was often referred to as a move from eminence-based to evidence-based medicine (EBM), a move that was heavily criticized from within and outside medicine for being reductionist. But STS colleagues like Tiago Moreira (2005) had painted a more nuanced picture by studying how guideline developers mobilize different repertoires of evaluation when formulating guidance. Moreira showed that guideline developers, rather than being reductionist, include a much wider and more sensible range of considerations in addition to their appraisal of the robustness of scientific evidence from systematic reviews of randomized controlled trials (RCTs) when formulating recommendations.

I had also been following the work of STS scholar Loes Knaapen (2013), who was doing pioneering research on how guideline developers search, appraise, and compose knowledge when formulating recommendations. She had also helped highlight possibilities for including patient knowledge in guidelines through her membership in the GIN Working Group on Patient and Public Involvement. I knew she would be at that GIN 2011 conference too and could (and would!) prove an enormous help in introducing me to participants and active GIN members whom she, through her interviews and committee work, had gotten to know so well.

Moreira's articles and Knaapen's scholarship and professional relations, plus the conversations I had had with them and related scholars over the years, supported my impression that the invitation by the Dutch Council for Quality of Healthcare reflected an openness among guideline developers to empiricize and experiment with their standardization practices. Some colleagues, most notably a professor of political science at my university, thought I was being naïve for accepting the invitation; a senior STS colleague told me I was being courageous for going. Neither view really resonated with me because both seemed to assume a more hostile environment than I had encountered so far. "I guess the biggest risk is that I will learn something" was my reply to both. And soon I learned one more reason to be skeptical about overly gloomy pictures painted of the chances of relating to evidence-based guideline developers.

2. FINDING FRICTIONS WITHIN ASCRIBED FOUNDATIONS

Evidence-based medical practice purports to achieve these goals by enlisting numerous techniques for the management, evaluation, and application of clinical data into medical practice. Its hallmark is the hierarchy of evidence that consistently places the evidence derived

from randomised controlled clinical trials on top (Sackett et al. 1996, 72). (Goldenberg 2006, 2622–2623)

So Maya Goldenberg writes in her contribution to a 2006 special issue in *Social Science & Medicine* titled “Gift Horse or Trojan Horse? Social Science Perspectives on Evidence-Based Health Care.” This is also how sociological scholarship on EBM is commonly presented. As the chapter on EBM in the *Handbook of Medical Sociology* summarizes these sociological readings,

EBM represents a break with the past, when the most reliable evidence in medicine was pathophysiological, to augur a time where epidemiological evidence prevails (EBM Working Group 1992). Since the late 1980s, the goal of EBM has been to inform clinical decision making with an evaluation of a clearly defined hierarchy of available evidence. EBM elevated population-based, epidemiological studies with randomized controlled double-blind clinical trials to the apex of the “hierarchy of evidence” (Sackett et al. 1996). (Timmermans 2010, 309)

I was rereading these texts when working on a conference paper on guideline development and realized that much of the current trouble with EBM must have occurred in 1996. That is when epidemiology defined the hierarchy of evidence as its foundation, making study design more important than the match between knowledge produced and the issue at hand. At some point I got curious about precisely how the EBM founders, in their 1996 *British Medical Journal* paper “Evidence Based Medicine: What It Is and What It Isn’t,” phrased the privileged position of the RCT within the hierarchy of evidence. Following Goldenberg’s page number in her citation (page 72), I could navigate straight to the heart of EBM epistemological politics. This is what I found:

Evidence based medicine is not restricted to randomised trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions. (Sackett et al. 1996, 72)

Okay, not quite what I expected. But surely there will now follow a definition of what counts as “best” evidence, and that will, in the end, always be an RCT, with other forms of knowledge being of value only when “best” is not available, right?

To find out about the accuracy of a diagnostic test, we need to find proper cross sectional studies of patients clinically suspected of harbouring the relevant disorder, not a randomised trial. For a question about prognosis, we need proper follow up studies of patients assembled at a uniform, early point in the clinical course of their disease. And sometimes the evidence we need will come from the basic sciences such as genetics or immunology. (Sackett et al. 1996, 72)

That is a bit of a list as it is, since diagnostics, prognosis, and “sometimes” adds up to quite a range of questions for which study designs other than the RCT are “best.” Perhaps there will be a rhetorical turn soon that indicates RCTs would ideally be available for such questions but too often aren’t?

It is when asking questions about therapy that we should try to avoid the non-experimental approaches, since these routinely lead to false positive conclusions about efficacy. Because the randomised trial, and especially the systematic review of several randomised trials, is so much more likely to inform us and so much less likely to mislead us, it has become the “gold standard” for judging whether a treatment does more good than harm. (Sackett et al. 1996, 72)

Avoiding false positives about efficacy of treatment is a lot more specific than arguing for a hierarchy *per se*. But then again, many questions *are* about treatment. And if they state the RCT is best for all treatment questions, that is still a big claim.

However, some questions about therapy do not require randomised trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomised trial has been carried out for our patient’s predicament, we must follow the trail to the next best external evidence and work from there. (Sackett et al. 1996, 72 [really!])

Dave Sackett and colleagues, the very ones who were ascribed the politically non-innocent epistemic naïveté of placing the RCT on top of the hierarchy of evidence irrespective of the question at hand, seem to argue quite the opposite. Restricting the superiority of RCTs to the *effectiveness of treatment* questions and listing those questions for which other study designs are superior, they challenge the very foundations of EBM as ascribed to them. Although sociologists like Goldenberg could be seen as challenging what Gary Downey would call the “dominant image” of evidence that prevails in EBM, and helped call attention to what forms of knowledge it made in/visible (Downey 1998, 18), were they not also active producers of that image—only to then disagree with it?

Only partly. Following the history of EBM—for example, through current guideline development methods (which I do below)—shows how much the hierarchy of evidence *has* become infrastructured in an almost paradigmatic sense. But what if what happened after the 1996 paper is bracketed—even if strategically so? What if the paper is read more literally as pointing to the need for non-RCT knowledge and is mobilized to try to reopen a reflexive space for thinking about different knowledges for different questions? Could such a reading resonate with some of the frictions within (Kember 2003) EBM and help destabilize the idea that EBM has the hierarchy of evidence as its clear foundation? Isn’t that a way to let the founders of EBM point to something quite close to the need for knowledges in the plural, rather than leaving that task up to the STS scholar? Could this result in inventive communication melting some of the passages between the shores? Steve Brown helps me take inspiration from Serres:

In order for there to be any kind of relationship between sender and receiver, some form of noise or interference, that is, an injection of difference, is required. This comes about by the very opening up of a passage, which inevitably exposes the signal to noise, and thus also to potential transformation. Serres then arrives at the interesting paradox that successful communication necessarily involves the risk of failure. Communication may be thwarted

or ‘betrayed’ by the medium through which it passes. But if we take the position “down-stream,” at the point of destination rather than departure of the message, we may see this failure, this betrayal, as also the process of invention. (Brown 2002, 8)

Could my betrayal of sociological readings of EBM help inject a dose of difference in both EBM and sociology and lead to a passage, to invention? When challenging the foundations that sociology ascribes to EBM the shorelines do change. Fractal contours emerge. Straits of nuance appear that may become a way to navigate past the frozen passage that resulted from the—what Helen Verran (2001, 38) calls—“foundationist critique” by sociology of EBM; a critique of how both shores “assume a foundation to be out there that one can know about—either one world, the same for everyone everywhere and at all times . . . or multiple worlds in different places” (Jerak-Zuiderent 2015, 902). Could opening up such foundationist critique help produce travel as an adventure to be had? Or would the GIN conference make me end up in icier waters?

3. NAVIGATING THE FROZEN PASSAGES OF SOCIOLOGY-EPIDEMIOLOGY INTERACTIONS

“So, what is a sociologist doing at a guideline conference?” While I mistake the question for a conversation starter, the questioner turns away to greet another, more legitimate, conference participant.

This was right after an intriguing talk in a plenary session that focused on when RCTs, often considered the gold standard of clinical evidence, are *not* needed for developing guidance. The speaker had started out with a legendary example from a *British Medical Journal* Christmas issue on “Parachute Use to Prevent Death and Major Trauma Related to Gravitational Challenge: Systematic Review of Randomised Controlled Trials,” a mock paper that argues that, because the authors were “unable to identify any randomised controlled trials of parachute intervention” and “advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data, . . . everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute” (Smith and Pell 2003, 1459). The message: “Individuals who insist that all interventions need to be validated by a randomised controlled trial need to come down to earth with a bump” (1460). That is hardly the Christmas spirit, but it is for the *British Medical Journal*, which traditionally dedicates the Christmas issue to “light-hearted fare and satire.”⁸

The speaker had taken the satire seriously—at the risk of killing a pretty good joke—and asked what made the parachute example “obvious.” Listing similar examples, like sewing arms back on after “alligator rip off” (the speaker was from Australia) and the “mother’s kiss technique” for taking out a bee that is stuck in a child’s nose (keeping the other nostril closed and blowing into the child’s mouth), he argued

that they shared important similarities. The effect of the intervention is “mechanically obvious,” there is a “rapid effect with large magnitude,” and the “relative risk” (an epidemiological term for the probability of an event occurring irrespective of whether one is exposed to the intervention or not) is calculated as being “beyond the realm of bias.” In such cases, the speaker argued, there is no need for evidence from RCTs.⁹

I found it interesting how the talk highlighted that quality of evidence is contextual and not solely dependent on study design, but because the question was raised only about when *RCTs* are not needed, I wondered if, again listening to this speaker literally, he thought it could be extended to other designs too. When would *other* types of knowledge *not* be necessary for developing guidance? For example, when would an ethnographic study of patient experiences with an intervention not be needed? During the break, I waited till others had asked their questions and then approached the speaker. Before replying to my question, he asked, “What is your background?”

“I am a social scientist interested in questions of knowledge standardization,” I replied, adopting a label I sometimes use when I think “STS” will require so much explanation that it may not travel well. I wanted to focus on the content of the conversation, not lose my interlocutor in a wordy description of a field. But instead of an easier disciplinary presentation surely helping the conversation, as I thought, that’s exactly as far as the conversation went.

Should this even have come as a surprise? Shouldn’t I have known that social scientists don’t have the best reputation within the EBM community? For example, the “Parachute” paper mocks the social sciences under the subheading “The Medicalisation of Free Fall”: “It is often said that doctors are interfering monsters obsessed with disease and power, who will not be satisfied until they control every aspect of our lives (*Journal of Social Science*, pick a volume)” (Smith and Pell 2003, 1460). Whereas I imagine a generic *Journal of Social Science* to be full of frictions within, that is not what epidemiological interlocutors imagine it to be. I had surely managed to make myself more legible to the speaker but in exactly the wrong terms; I had become part of a side that was party to so many previous tensions between proponents and critics of the RCT. Tensions between medical researchers claiming privileged epistemic access to a foundation of biological facts and sociologists claiming privileged epistemic access to a foundation of social complexity. Becoming legible in those terms made my question appear a poorly disguised attack the speaker would not spend another moment on. Enough other, legitimate conference participants for him to not want to waste time repeating the Science Wars.

Standing there, staring at the back of the speaker, I became an embodied reminder that being “third-instructed” not only means living without the comforts of disciplinary specialism but also requires avoiding the problematic historical encounters between disciplines. The pitfalls of the journey, the thick ice encountered, the dangers of frozen passages, all were shaped by how similar travels played out in the past. In fields like epidemiology, previous travels by social scientists seem to have left thick

layers of ice that obstruct what could be crucial straits in navigation. I will never know if this speaker would have entered the conversation if I had given a wordy description of my interests, but at least I was right about running the risk of learning something—namely, that disciplinary presentation matters and that disciplinary clarity can work to one's disadvantage. That could have been somewhat of a liberating lesson for an STS scholar if not for my concern about how conversations at this conference would unfold. Let's see what happens after the break.

4. TIME-PRESSURE, KNOWLEDGE-PRESSURE: THE WISDOM OF PUBLIC HEALTH

What should a government do when there are, say, reports of malaria infections in Greece that appear endemic? Should there be export restrictions—for example, on car tires, because water tends to accumulate in them, possibly allowing larvae to survive transport and spread the disease? Should there be other restrictions? For which products or persons? And how can a government know what actions to take?

After the coffee break, this question is asked in a workshop called “Development of Public Health Guidance in Settings with Lack of Evidence and Lack of Time.” One of the session organizers, who gives the introduction, makes clear that the answer is not “Give us ten years and lots of funding, and we'll do a range of RCTs to test different interventions, after which we'll do metareviews of those, and then we'll have high-quality evidence for you, dear government officials.”¹⁰ Endemic malaria in Greece is presented as an example to point to the strong mismatch between the knowledge needs for developing guidance for complex public health questions and current guideline development methods, particularly the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methodology.

GRADE firmly abandons the ideas that I had been so happy to find in that 1996 EBM paper about the importance of matching the preferred type of study to the clinical question at hand. GRADE works with tables that classify reported findings on the basis of study design: RCTs start out as high quality, whereas observational studies or any other designs start out as low or very low quality (Guyatt et al. 2011, 386).¹¹ GRADE is generally seen as an important development in making evidence assessment more transparent and is close to becoming an obligatory passage point if not a paradigmatic feature of current guideline development. Lead developers of this approach are based at McMaster University, where Dave Sackett established Canada's first Department of Clinical Epidemiology & Biostatistics. Yet in GRADE the dreaded hierarchy of evidence that defines what counts as high-quality evidence on the basis of study design from the outset is foundational to the approach. Hamilton, Ontario, by now clearly goes far south of the Northwest Passage. The frozen passage that emerges clearly isn't just a problem for STS scholars; it is even more so for those in public health who have to respond to the types of questions the public health guideline developers at this session are asked.

In a clever strategic move, the *British Medical Journal* paper that helped establish the dominance of the approach is titled “GRADE: An Emerging *Consensus* on Rating Quality of Evidence and Strength of Recommendations” (Guyatt et al. 2008; emphasis added). This title draws on the history of guideline development, in which systematic consensus statements played a major part, while giving the meaning of “consensus” quite a twist. Consensus statements became institutionalized with the launch of the Consensus Development Program by the US Department of Health in 1977, which “served as a model for consensus conference programs developed in many other countries” throughout the 1980s (US Department of Health and Human Services, n.d.). This approach had the same aim as current guideline initiatives, that is, to produce “unbiased, evidence-based assessments of controversial medical issues important to researchers, healthcare providers, policymakers, patients, and the general public” (US Department of Health and Human Services, n.d.), but knowledge appraisal was primarily considered a professional rather than a statistical exercise for which the program drew on the RAND Delphi method for consensus conferences. Delphi uses statistics, but mainly in the supportive role of presenting expert judgment. This approach is largely abandoned in current guideline development, and the Consensus Development Program was “formally retired” in 2013 (US Department of Health and Human Services, n.d.).

Methods that have replaced it, like GRADE, use the hierarchy of evidence to classify the knowledge that experts bring to the table as low or very-low quality from the outset. Compared with how consensus statements considered expert knowledge, such methods somewhat resemble a landslide. So for GRADE to draw on the language of *consensus* for its legitimacy, not merely through the title of this paper but also by listing the large number of organizations that adopted it on its website, is a little more than ironic. Rather than considering GRADE a new *consensus*, those concerned that current methods have a narrow understanding of what counts as knowledge think the focus on having a majority vote gives them, as I would later learn, “a rather evangelical feel” about how the approach is being positioned (GIN board member, personal communication, September 3, 2012). The public health guideline developers at this well-attended workshop, for example, clearly do not feel included in this emerging consensus.

But neither do they have a clearly articulated alternative guideline development method to challenge this dominance. When the lead organizer of this session from the European Centre for Disease Prevention and Control asks who of the fifty-something people in the audience recently had good experiences with developing or using other methods for including different knowledge in public health guidance, one person raised a hand. *One* in a room full of guideline developers for public health—who have to integrate wide-ranging knowledges while under constant time pressure. The lead presenter seemed puzzled by this but went on to stress that time pressure is merely an entry point into a broader discussion on how to develop guidance given the inherent uncertainty in evidence. In the case of developing guidance

on endemic malaria, time pressure is an important reason for challenging the solution of RCTs as providing more certain knowledge. But more profoundly, he stressed, uncertainty is inherent in RCT evidence too, which means guideline developers have to stop “measuring with one stick.” A more variable set of evidence-appraisal practices could be considered a dire need for the transdisciplinary collaboration that guideline developers gathered here have to engage in.

To again take inspiration from Serres, in the reading of Brown, the concern of the guideline developers in this conference session seems to require guideline practices that are based on “understanding communication between forms of knowledge”:

Such communication is noisy, it is a mixture of messages subject to transformation. What Serres then describes are the connections, the translations that occur as part of the distribution of knowledges. Serres then advances a particular view of wisdom as that which is garnered by occupying the middle position, right in the midst of the confluences and mediations. (Brown 2002, 12)

If wisdom is what these public health guideline developers have cultivated rather than methodological rigor, would that make for a better chance of connecting their puzzles to STS concerns about standardizing situated knowledges?

5. INFRASTRUCTURING DIFFERENT KNOWLEDGE

The talk the main session convener and I have this time during the break doesn't end with a rhetorical question but with a plan. He has a medical background but also studied sociology during his freshman year, which surely troubles the understanding of the human sciences and EBM as shores connected by a frozen passage. It is not quite clear which coast he belongs to. Too many fractals for that. Too many frictions within.

Our conversation revolves around the dominance of the hierarchy of evidence that public health guideline developers were struggling with in the session. He states that this is especially problematic for public health, whereas I indicate that I came to this session without a particular interest in public health: I saw the main value of the session in pointing to a general problem in *all* of guideline development, with public health as a setting where confronting that problem head on is unavoidable. I refer to the 1996 *British Medical Journal* paper and suggest that the current state of guideline development is largely inconsistent with its founding principles. I also refer to the study I will be presenting at the conference and the related larger project that showed a direct relationship between the amount of RCT evidence on an issue and how well that issue was addressed in Dutch guidelines (Zuiderent-Jerak et al. 2011). This triggers his interest, and he immediately thinks about other guideline developers—for example, in the field of oncology care—who have expressed similar concerns about where guideline development is heading. When I suggest that he seems to argue that in public health, and in other areas, current guideline development methods lead to

the crowding out of other knowledges that are crucial for meaningful guidance, he recognizes that this is a different language for addressing a shared concern (that all knowledge gets “measured with one stick”). By a stroke of luck, he turns out to be a GIN board member and we agree that the question on how to weigh and include different knowledges should probably be a core issue for many guideline developers and that GIN as an association can play an important role here. The emerging plan is threefold: (1) conduct a survey and follow-up interviews of GIN members about the methods and approaches they use for knowledge appraisal and integration, (2) organize a workshop on this topic at the next GIN conference, and (3) write a position paper to kick off the discussion.¹²

The closing plenary of the conference strikingly points to the relevance of this plan, as well as to the opposition it may face. A Yale professor and coauthor of the new Standards for Guideline Development presents the approach developed under the aegis of the US Institute of Medicine and published as *Clinical Practice Guidelines We Can Trust* (Committee on Standards for Developing Trustworthy Clinical Practice Guidelines, Institute of Medicine 2011). This document mobilizes a highly restrictive definition of “guideline,” and the speaker argues that, for guidance documents to even carry the label of guideline, recommendations need to be based solely on high-quality evidence, by which he means that it should come from RCTs. He provides compelling examples, but they are all regarding the effectiveness of clinical therapies, which few in the audience would disagree with. But the restrictive policy would pose huge problems for the knowledge needs for other types of questions. Unsurprisingly, the discussion becomes a rather fierce controversy. If guidelines can be developed only for issues that have fully conclusive RCT evidence, a member of the audience concludes, we have a “perfect example on when we do not need clinical guidelines!”—a comment that gets a round of applause. The questioner goes on to explain that the Institute of Medicine definition makes the difference between evidence summaries and clinical practice guidelines negligible, which reduces the latter to implementation tools for what is already known rather than guidance documents for complex clinical questions. A second questioner, a former GIN president who has published on the need for moving beyond the evidence in EBM (see Burgers and van Everdingen 2004), brings home that point, saying, “The scope of this definition is much narrower: it excludes all documents that are not evidence based but still do guide doctors and patients in doing their work.” But the way the question is phrased (“not evidence based”), which equates evidence with RCTs, makes the rhetorical reply easy: “The question is: ‘*should* such documents assist doctors and patients in taking decisions?’ We have many such documents and they really should diminish. There is a place for carefully constructed documents that are partly evidence based and partly carefully consensus based. However, we do not call them guidelines.”

At the end of the closing plenary, the chair of the GIN board presents the history and future of the network and describes how, from systematic consensus statements

in the 1970s, via large national guideline programs in the 1980s (e.g., US Agency for Healthcare Research and Quality) and 1990s (many other countries), twenty-first-century guideline development now mainly consists of international collaboration. He describes how GIN at that moment has six working groups and proposes that the future of GIN should be geared toward harmonization of guideline development. But he also states that this can be achieved by two main routes: as networked collaboration or as a center of authority. He makes it clear that he is not willing to take the latter route,¹³ which seems an elegant way to further trouble the debated, authoritarian approach proposed by the Institute of Medicine.¹⁴

Importantly, if the harmonization he envisioned required a *network* approach—and this professional organization uses working groups as its infrastructural format—the public health session chair and I realize that we need to add an item to our emerging plan, making it fourfold: (4) establish a working group on appraising and including different knowledge. Traveling the Northwest Passage just became the adventure of setting up a new working group within GIN. Not much of a hostile crowd after all.

6. KEEPING OPEN ICY PASSAGES IN IMRAD STRUCTURE

EXECUTIVE SUMMARY¹⁵

Introduction: Despite the nuanced ideas within EBM about the importance of appraising and including different types of knowledge for different guideline questions, the methodology for developing clinical practice guidelines has generally focused on assessing (systematic reviews of) RCTs. There is a real need for methods that focus on appraising and including other kinds of knowledge in a robust way. The questions in this study therefore are: what methods are available for appraising and including these different types of knowledge? And what experience do guideline developers have with these methods?

Methods: An internet survey was carried out among all G-I-N members and those attending the G-I-N annual conference in 2012. All 130 responses were analyzed and used for selecting respondents for follow-up interviews. Interviews were held with guideline developers from Australia, Canada, Colombia, Germany, the Netherlands, Norway, Spain, the United Kingdom, and the United States. Results were presented at the G-I-N '12 conference, and further development steps were taken during a well-attended post-conference workshop following that same G-I-N meeting.

Results: Despite the good response rate of the survey (32.5%) and the high number of active participants in the post-conference workshop (around 55 guideline developers), there is limited experience of methods for appraising and including different kinds of knowledge. Only just over 50% of the respondents involved in guideline development within the last three years reported having any experience with using appraisal methods for including non-RCT knowledge. 85% of the methods are used to address clinical questions, rather than e.g. patient experiences (5%), quality of care considerations (4%), user/professional considerations (3%), organizational considerations (3%), cost considerations (1%), or safety, ethical, or legal considerations (all 0%). The reasons for including other types of knowledge was reported to be the lack of (systematic reviews of) RCTs for such questions, or a high

availability of RCT evidence that addresses the wrong issues or that is irrelevant to the setting. Developers who reported using methods to appraise and include different knowledge, scored usefulness a 5.6 on a 7-point Likert scale. They positively evaluate such methods, despite difficulties they report with appraising and including different knowledge within the framework of evidence-based guideline development.

Analysis: While the project aimed at identifying a wide range of methods for the appraisal and inclusion of a broad array of types of knowledge, methods are mainly used for addressing clinical questions about treatment interventions. When RCTs and systematic reviews are lacking, guideline developers mainly focus on appraising and including observational studies for clinical questions. Some promising initiatives for evaluating other types of knowledge have been identified, such as methods for assessing the quality of quality improvement (QI) knowledge, for performing secondary analysis of qualitative narrative interviews on patient experience, and for assessing economic and ethics questions through checklists.

Discussion: Given the limitations of the availability and suitability of RCTs, the importance of methods for appraising and including different knowledge is well recognized by guideline developers. This should come as no surprise, given the nuanced ideas among the founders of EBM about the dangers of equating EBM with RCTs. Up to now most resources and attention have been used on methods for appraising and including (systematic reviews of) RCTs. The guideline community has still a way to go to develop robust methods for appraising and including non-RCT knowledge. This leaves guideline developers with many problems of substantiating recommendations based on the best external knowledge available. This either leads to ad-hoc ways of appraising and including such knowledge, or to its exclusion from guidelines that thereby are at risk of becoming RCT-biased.

Recommendations: The issues identified in the project deserve the attention from the guideline development community. There is certainly enthusiasm for further collaboration among guideline developers. Given the role of the Guidelines International Network in facilitating such collaboration, a G-I-N Working Group on Appraising and Including Different Knowledge (AID Knowledge) seems an important and appropriate next step.

Not without discussion, this working group was approved by the GIN board in 2013. In the next section I discuss one way the group transformed the focus on infra-structural (methods) development that I thought was the crucial STS content of this initiative. I should have been warned, though, that what I thought was STS content was likely to get transformed by the journey as well.

7. A LESSON FROM STAYING BETWEEN THE SHORES: IT'S THE EPISTEMOLOGY, STUPID!

I've been going on about this for some time now, a line of thought that runs as follows: The mistake of much of the sociological criticism of EBM was that it portrayed guideline developers as stuck in poor epistemology, one that privileges RCT evidence over other knowledges through the hierarchy of evidence. But if we read the founders of EBM differently, more closely, and while attending to the diverse understandings of what counts as good knowledge among guideline developers, such as those in public health, it becomes clear that their epistemology is far from naïve. Some of the most sophisticated critiques of RCT evidence come from *within* this community.

So the sociological critique of EBM *epistemology* has obfuscated a much more consequential development of the EBM *knowledge infrastructures* for appraising a highly limited set of study types in tremendous detail. The dominance of GRADE, more than a dominance of a limited epistemology, is a dominance of limited knowledge infrastructures. This relocates the need for action into the heart of developing novel knowledge infrastructures—like appraisal methods—for a wider range of knowledges.

I've made this argument in different settings, including during presentations at the annual Society for Social Studies of Science (4S) meeting and during a workshop at the annual GIN conference. The focus of the AID Knowledge Working Group on highlighting such ongoing methodological developments is, I judge, a way to turn STS knowledge on knowledge infrastructures, as a site for doing politics, into an STS sensibility within the guideline development community. We may be, for lack of a better word, making progress. And that's when I get called back.

We're in an AID Knowledge Working Group meeting at the 2015 Amsterdam GIN conference. I've outlined the agenda, which includes efforts to harvest some of the methodological developments going on among guideline developing agencies. In line with the vision of networked collaboration, we want AID Knowledge to foster a community of practice that connects different initiatives regarding methods development. I've invited four members of AID Knowledge to give five-minute presentations on cutting-edge developments in promising sites, such as on public health and social care at NICE, the UK National Institute for Health and Care Excellence that has kept the same acronym over the years but was founded in 1999 as the National Institute for Clinical Excellence. Adding such an increase in scope (from clinical to health and social care) also comes with new methods needs, the kind AID Knowledge would like to learn from—especially because NICE leaders have been involved in developing AID Knowledge right from the start.

Another talk focuses on occupational health, in which uncertainty in evidence is often approached not through increasing the number of studies but through applying the precautionary principle. Two other talks focus on recent developments in public health based on a project some AID Knowledge members, including me, were involved in (Harder et al. 2015) and on current developments relating to guidance for rare diseases. My hope is that during the next agenda item, "Plan of further action of AID Knowledge," we can collectively find ways to highlight such developments, perhaps by building a database of good practices regarding guideline methods for different questions. But the discussion takes quite a different turn.

The group starts to discuss how all methods try to justify themselves in relation to what one of the members, drawing on Ian Hacking's *An Introduction to Probability and Inductive Logic* and *The Taming of Chance* (Hacking 1990, 2001), calls "frequentist reasoning." At least I was right about guideline developers and researchers not being epistemologically naïve! His concern is that, without attending to what he calls different styles of reasoning, guideline development methods for different

knowledge will be set up for an impossible task: justifying such knowledge within a frequentist epistemological frame. All efforts to highlight methods for appraising different knowledges will, he fears, either be ignored or will be slotted into a hierarchy of evidence that still starts with RCT-derived evidence and adds other appraisal methods later—but in RCT terms. The hierarchy of evidence is easy to uphold, he argues, according to the frequentist epistemological assumption that the more we observe a (controlled) phenomenon, the better our knowledge of it. RCTs are inherently better at this, in spite of drawbacks that come from prioritizing internal validity (the methodological rigor of the study design) over external validity (the extent to which the frequently found result can be extrapolated to the single-case scenario in the world). Without pointing to the limits of frequentist reasoning, and without highlighting alternatives, appraisal infrastructures for all other knowledges will, he argues, continue to look inherently less reliable and knowledge inclusion will be on unequal terms because other knowledges will have the wrong frequentist measures applied to them.

Many group members respond enthusiastically, and I start to realize quite soon that, although I am probably not the only one struggling with some of the epistemological notions discussed, I *am* probably one of the last people left in the room who is ambivalent about writing a more philosophically oriented paper on styles of reasoning in relation to appraising and including different knowledge in guidelines. I guess this is part of the adventure to be had: a philosophical excursion that makes me read up on philosophy of science. The working group members seem convinced that my proposal of entering the open passage of knowledge infrastructures rather than the icy one of epistemology would be a dead end, because we would still be stranded at the shore of current EBM and its frequentist reasoning. What they propose instead is to use styles of reasoning as an icebreaker to open up a strait that would get us to knowledge infrastructures, no doubt, but not without having first challenged the politics of knowledge hierarchies. Shifting from ontological to epistemological politics; not something I often see at STS conferences or in STS journals these days, but something that AID Knowledge—and a leading EBM journal—turned out to be interested in (Wieringa et al. 2018).¹⁶

I must admit it felt quite odd to be reminded of the importance of epistemology by the guideline developers in AID Knowledge. Being trained in a version of STS that considers the action to be located in ontology rather than epistemology, the latter leaving you blind only to the “missing masses” in your analysis (Latour 1992), I had turned that disciplinary suggestion into a disciplinary stereotype that made me feel infrastructures were an inherently more interesting site for analysis and intervention than styles of reasoning. I could have been reminded of the entwined nature of ontology and epistemology through feminist STS scholarship but had to be called back by members of the AID Knowledge Working Group, providing a fine example of the importance of attending to STS sensibilities out there (i.e., how such sensibilities

“are by no means the exclusive domain of STS scholars”; Downey and Zuiderent-Jerak 2017, 228). These guideline developers weren’t going to fall for my disciplinary overestimation of the material agency of knowledge infrastructures without attending to the epistemologies that they believe will easily swallow them. They wouldn’t want to have their commitment to different knowledges end up in the dead end of making knowledge infrastructures live up to frequentist demands. What did I learn from this shift of focus for AID Knowledge about staying between the shores of EBM and the human sciences?

8. CONCLUSION: COMMITMENT TO THE THIRD SPACE AS NEITHER THE SAME NOR DIFFERENT

Moments like the one I encountered here may be helpful for thinking through what it could mean to follow Serres’s suggestion that we “seek to occupy the spaces of transformation which lie between—neither one nor the other but the ‘third space.’”

In two readings of the third space, something important would be lost. First, if we read “neither” as equaling “not,” the third space would risk becoming a shoreless ocean rather than a passage that is shaped by its shores. Although to occupy the third space it is crucial not to get stuck on either shore, it is equally important to cultivate a pertinent awareness of how the shores relate and to be surprised by them. They indeed are “jagged . . . , sprinkled with ice, and variable”; they are “more fractal than truly simple” too. Plus, quite a few are trying to change the shorelines, possibly opening up passages that seemed impassable at first. Surveying the shores and the thickness of the ice in the passage can manifest in the form of a research funder proposing a shared conference talk, a philosophically trained guideline developer referencing Ian Hacking, or an STS scholar closely rereading a founding EBM paper. In all of these, the awareness of the shores helped in testing the ice, finding an opening. The one time I chose disciplinary legibility over sensitivity to the shores, the passage froze up in less than a moment. If the third space is explored in the oscillation between the shores, the nomadic nature and elasticity of STS may become its crucial strength. Inhabiting an overwhelming range of academic departments, disciplinary positionings, and publication venues, which is sometimes regarded as one of the main risks STS as a discipline faces, could well be a main source of vitality that comes from trying to navigate between the shores while being involved in changing them.

In the second limited reading of the third space, “neither” would be thought of as “hybrid.” It is true that the lead organizer of the public health session had studied sociology as a freshman, and that the lead author of the paper on styles of reasoning was working on a philosophically inspired dissertation on EBM, but that surely does not apply to all AID Knowledge Working Group members, while I would consider all of them as *tiers-instruit*. Where a hybrid is something made of two materials, two strands of thought, two somethings; AID Knowledge thrives on the commitment to

perpetual translation that comes from being “neither”—at least not in any singular form. This commitment is made out of necessity by public health guideline developers, for whom the “comforts of disciplinary specialism” that dominate epidemiology would render their guidance useless. A commitment to perpetual translation can also be infrastructured, as in the case of the Dutch College of General Practitioners, who have as one of their operating principles that professionals involved in guideline development also need to be practicing GPs. Furthermore, AID Knowledge is intended to be a third space in itself: a semiorganizational, quasi-epistemic space that helps exchange the comforts of disciplinary specialism for the risk of perpetual translation. It is not a hybrid of the human sciences and epidemiology. It is neither, but it does take a keen interest in both shores and how they may limit or enable appraising and including different knowledge in guideline development. Importantly, the space is also occupied *together*, which is why spaces like AID Knowledge can become crucial for strengthening each other’s sense of being third instructed.

To pursue a commitment to the third space, perhaps a conundrum like “neither the same nor different” would then be more generative. Sounds esoteric. Indeed, I am most familiar with this phrase used by spiritual guides explaining the continued flow of mind and matter to a new existence, trying to avoid referring to an essential “I” that transmigrates between matter, as invoked by the term “reincarnation.” That may be an unexpected way to end a chapter on third spaces between the human sciences and EBM, but didn’t Serres and Brown warn us to seek our instruction neither from science alone nor the sacred?

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NOTES

1. Cited in Brown (2002).
2. For an exploration of this passage in relation to medical informatics and integrated care, see Bal and Mastboom (2007).
3. The annual conference of the Guidelines International Network (GIN), the professional association of guideline developers for health-related topics.
4. Zuiderent-Jerak, Jerak-Zuiderent, and Bal (2010).
5. Zuiderent-Jerak et al. (2011).
6. For an early rendering of it, see Zuiderent-Jerak, Bal, and Berg (2012).
7. Details regarding the history of evidence-based medicine are documented elsewhere and are beyond the scope of this demo account.
8. See <https://www.bmj.com/about-bmj/resources-authors/article-types/christmas-issue>.
9. For related arguments from within the EBM community about when RCTs are not necessary or preferred, see Aronson and Hauben (2006), Glasziou et al. (2007), and Golder, Loke, and Bland (2011).
10. For a study on how US public health and regulatory agencies entwine judgment and systematization to make sure such action in relation to food outbreaks is fast but right, see Boyce (2014).
11. Several versions of this classification exist, some of them including “any other evidence” as the very-low category, with observational studies classified as low. Also the nomenclature has shifted from quality of evidence to confidence in evidence, which, while clarifying that a high classification is a statistical notion rather than a qualitative judgment, further narrows the focus on what counts, because the whole classification becomes statistically frequentist, without making that assumption explicit. These more nuanced developments of GRADE leave untouched the basic epistemic assumptions and—while interesting—are beyond the scope of this demo account.
12. Published as Zuiderent-Jerak, Forland, and Macbeth (2012).
13. This position resonates strongly with the detailed analysis of the development and institutionalization of guideline development in GIN performed by Loes Knaapen (2013), and because Knaapen has interviewed many in the GIN community, including this chair of the GIN board, there is every chance this position was further clarified for all involved during those conversations.
14. This is an approach that needs to be understood in the context of the US marketized health care setting, in which care providers at times use guidelines as part of their marketing strategy and many guidelines are not developed by independent guideline development agencies. This contrasts with guideline development practices in many welfare states, which explains part of the difference in approaches proposed to regulate guideline development.
15. IMRAD stands for the “introduction, methods, results, and /analysis discussion,” which is a standard structure for articles in the biomedical sciences. See, for example, Day (1989). Paragraphs taken from Zuiderent-Jerak, Forland, and Macbeth (2013), 3–4.
16. This is not to say the writing or publishing of the paper was necessarily smooth, and it did involve a rejection by a leading US-based medical journal on the basis of reviews that were nothing less than silly. Not all EBM is equally epistemologically nuanced.

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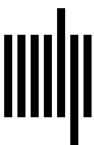
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