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Keynote Address: Eleventh Qualitative Health Research Conference

Proving or Improving: On Health Care Research as a Form of Self-Reflection

Annemarie Mol

As it is, clinical trials are the gold standard of health care research, employed to prove that the care practices they study are good. Here, the author suggests that we would do better to develop research methods that work toward another goal: to improve care practices. This requires that we no longer foreground the effectiveness but, instead, investigate the various effects of interventions. If undesirable, they might then be tinkered with. As a part of this, the effects on bodily parameters and on the intricacies of daily lives should not be separated out but studied in connection. With examples drawn from studies into care practices for patients with diabetes or atherosclerosis, the author argues that instead of trying to turn the clinic into a laboratory, we should strive to support and strengthen clinical ways of working.

Keywords: quality of care; research methods; disease/illness diabetes; atherosclerosis

ll those who work in or study health care are likely to subscribe to the ideal of "good care." But what is good care? What does it bring, what does it require, and how should we go about achieving it? These questions have no obvious answers, and that is why I will address them here.

In the past—or, at least, in some simplified past that we may use as a backdrop for the complex present—there was a clear point of orientation for health care, a solid norm to adhere to: that of health. Health was the good to be persistently strived for; and it was good enough. Since then, two kinds of complications have arisen. The first is that social scientists have spent a great deal of time and energy showing that good care is not only, or should not only be, oriented toward the body and its physical diseases. Illness, the experience of living with a disease, is more than the disease itself and is not determined by it. Good care includes attending to the lived experience of patients. It encompasses more, and is more difficult, than sustaining health. The second complication is that in many situations, and for many of the patients of present-day health care services, health is too far-fetched a goal.

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Nowadays, we deal and live mostly with chronic diseases. Good interventions might well bring substantial improvements, and they might be for the better, but they do not bring health. This begs the question of what to appreciate as an improvement, what "for the better" means. Which good should we strive after, if health is beyond the horizon? That has become a question that has to be dealt with, time and again.

But how to do so? How to face the question of the good that care might hope to bring?

EFFECTIVE TREATMENTS AND TREATMENT EFFECTS

These days, the most prominent way of handling the question of whether care is good enough is to seek evidence for its quality.² It is not by chance that this term appears in the title of our conference. Seeking evidence is one of the things that researchers do. They try to contribute by finding evidence that some therapy, some intervention or other, some procedure, is, indeed, for the better, that it is effective, that it has the desired effects.

This research style has a specific provenance: It arose in the '50s and '60s of the 20th century in the context of the extensive growth of the possibilities of pharmaceutical intervention. Many new drugs were being developed. Which ones should, indeed, be used? Earlier, these kinds of questions had been superfluous. If even a few people with diabetes who were bound to die suddenly survived when they were injected with insulin produced outside the body, then who needed more "evidence"? Who would not give it a try? But when the number of drugs started to grow quickly, and some led to side effects far worse than the problem they were meant to solve, some outside rules and regulations seemed to be called for. Modern states wanted to protect their populations from being poisoned by bad drugs; and where health care costs were shared, the collective needed to know that the money was spent wisely. Thus, the clinical trial was gradually established. Pharmaceutical companies had first to seek evidence for the effectiveness of their pharmaceuticals by means of solid research before they were allowed to put them on the market.

This is an example of one of the more clever strategies invented in modern societies to combine capitalism with state regulation. The requirement to prove drugs to be effective and safe before they can be put on the market protects the collective against bad products, while there is still enough incentive for companies to invent new, potentially beneficial drugs. So far, so good. The strange thing is that this very specific research style subsequently took over in so many other sites and situations or that it became generalized. In the subsequent decades, all kinds of elements (far too many to unravel here) jointly made the clinical trial into the dominant style of public accountability in health care—not just for drugs but for just about any kind of intervention. What is more, the trial became the model of "science" par excellence—the gold standard for just about any kind of research. This is truly intriguing. And it is sad. For however well clinical trials might be able to prove or disprove therapeutic claims, and however strong their credentials when it comes to seeking evidence, they have their limits when it comes to assuring good care.

Let me illustrate this by telling you about my favorite clinical trial, which I came across when studying the diagnosis and treatment of atherosclerosis of the leg vessels in a Dutch university hospital, hospital Z.³ The trial compared two treatments

for patients with atherosclerosis of the leg vessels: percutaneous transluminal angioplasty (PTA) and walking therapy. It is my favorite trial because it did not add up the various parameters for success that were attended to but kept them separate. Thus, it became visible that one treatment, PTA, improved one of the relevant parameters—blood pressure in the patients' ankles—even if it did not improve the other parameter, the so-called pain-free walking distance. By contrast, the other treatment, walking therapy, did have a positive effect on the patients' ability to walk without hurting: It increased the pain-free walking distance. However, it did not improve blood pressure in the ankle of the affected leg. Thus, the result of the trial was not that one treatment was more effective than the other. Instead, both therapies had a positive effect, but these effects were different.

What, then, is good care or, in this case, the better treatment: PTA or walking therapy? The trial does not give, and cannot give, evidence that allows one to answer that question, because the answer depends on the character of the desired effect, on what is more important. If, for instant, a patient has undernourished skin, or even a nasty wound in his foot, increasing the blood pressure in his ankle (thus improving the local food and oxygen situation) might be a good idea. But if he is getting miserable from staying indoors, scared to walk because walking hurts so much, a serious walking therapy, in which he learns to not be scared and is encouraged to walk twice a day for at least half an hour, may make him go out again and become more outgoing. There may be further issues to take into consideration. But what is required in order to establish what might be the better treatment is, indeed, precisely that: consideration. An additional trial would not answer the question. ⁴

The good, in this case, is not unequivocal. There are different goods at play, and somehow this complication has to be lived and dealt with. Note that this is not a merely social matter. It is not the case that the body, and its disease, is singular and easy to survey, while as soon as we attend to illness, to social life, as well as to a disease, things become messy and complex. Obviously, the way one lives with atherosclerosis as a patient differs greatly depending on whether one has a PTA or engages in walking therapy. But in both cases, the body itself is as implicated in what is happening as one's social life. In one case, this body is opened up and probed (even if this is only done with a large needle rather than a scalpel). A small balloon is inserted that pushes aside the stenosis in one's leg arteries, while one is lying there, slightly dazed. In the other case the body has to drag itself out of its chair twice a day and get out, go, walk—even though this hurts. And what to do when you stop for a bit to let the pain subside, and people stare at you, not understanding what makes you stand there, without moving?

The practices of living with one treatment differ from those of living with the other. These practices deserve our attention if we are interested in good care. But beware: They are as material as they are social.

I'll give you another example that, again, shows that the question of what good care is cannot be answered with the use of trials alone, however impressive their evidence. The example has to do with the treatment of diabetes type 1. With large-scale clinical trials, it has been established that tight regulation improves the long-term health of people with diabetes. In the long run, diabetes tends to lead to nasty complications, such as blindness, atherosclerosis, and neuropathy. These complications occur later in life, or to a lesser extent, if one manages to keep one's blood sugar levels relatively low over the years. This, then, is an effective treatment. This time, I will not compare it with another treatment that has other "good effects": Let us

agree that preventing or postponing complications is a desirable long-term goal. However, there is, again, something else to take into consideration. It has to do with the actual practice of the tight regulation. Low target levels for blood sugar are fine—but if one has diabetes they come with a higher risk of blood sugar levels that are *too low*. In diabetes there is not only a lack of insulin, which incites the cells to take up sugar and thus lowers high blood sugar levels. The bodily process of counterregulation, the increase of blood sugar levels that get too low, doesn't function properly either. This is a problem, for if your blood sugar level is too low, you get aggressive and nasty. And if it gets lower still, you slide into a coma. Now, if you drive a car, or take care of children, teach, are in a meeting, or are active in almost any other way, you definitely do not want that. And it not only disturbs your social life. It is also bad for your brain: Each time you slide into a hypoglycemic coma, brain cells die.

What is good care: tight regulation, which is good in the long run—for your eyesight, your arteries and your sensitivity? It may be. But then again, if tight regulation undermines your possibilities of living actively in the present, it may not be all that desirable after all. The contrast is not between social life now and bodily health in the future. Both the body and social life are implicated all along.⁵ Low blood sugar is as bad for brain cells as it is for one's relations with colleagues and children. But if a high blood sugar were to bring forward the moment of getting blind, it is obvious that along with one's eyesight, one's social life also runs into trouble. The so-called social and the so-called biological norms and ideals are completely intertwined. Thus, we cannot tell what good care is: not easily, not in general, not in a grand gesture. It has to be established closer to home: in day to day health care practice—in day-to-day life.

CHOOSING OR CARING?

If the question of which care is and which care isn't good cannot be answered by measuring effectiveness, because it is a matter of unraveling and comparing effects, the question of how to handle such comparisons becomes all the more urgent.° If ranking treatments is not so easy because it is not the case that one treatment is simply better than the other, because they come with different goods (qualitatively different goods)—as well as bads—then how to handle that?⁷ The trope available at this point is that of the well-informed choice. A decision has to be made. If there are different goods and bads at stake, a value judgment is called for. This seems to require an evaluation. Pros and cons deserve listing and balancing—just like the credit and the debit sides of an accountant's books. The task of researchers might still be to provide the evidence that forms the backdrop against which choices may take shape. Caregivers would then have to explain this evidence—in the form of "information"—to patients and support them in making the right choice. What is good in your case: PTA or walking therapy? What might suit your situation? What do you want to achieve? Or take the case of diabetes: If there is a trade-off between the short term and the long term, what, then, does this imply for you? What is more important in your life?

This is a common trope, indeed, and it gets more common every day. However, it is, again, not necessarily the best way of dealing with questions of good care. In the first instance, it might seem just great: evidence insofar as facts are concerned

and personal choice when values come into play. However, in practice things don't work this way—and it is doubtful whether we should try to make them do so. Let us look again at each of the examples presented earlier.

The case of walking therapy suggests a first intriguing lesson. There *is* hardly any walking therapy for people with atherosclerosis of their leg vessels. If I had restricted my research to doing fieldwork in the one hospital, hospital Z, where I spent most of my time, I would not even have known about it. I came across this treatment only because I read around in the medical literature and it struck my eye. Hospitals that published about this treatment were sometimes able to avoid or seriously postpone 70% of their invasive treatments (including both PTA and surgery). That seriously impressed me. In the Dutch claudication protocols for general practitioners, walking appeared to be mentioned, but this took the form of the friendly doctor telling a patient, "You'd better get into walking, Mr. Jones." A short conversation about the topic was all Mr. Jones was to expect. However, the literature is clear about the issue: Walking treatment is impressively effective if it is supported, if there is a therapist of one kind or another with whom patients can regularly discuss the kinds of problems they face when they actually try to walk. Some therapists have successfully experimented with groups of peers facing similar problems.

In the middle of the '90s, when I studied the issue, Jeannette Pols, then my research assistant, went out of her way to find out about all structured walking therapy in the Netherlands. She may have missed a physical therapist here or there, but after quite a lot of sustained effort she found five small centers countrywide, with one or two professionals each. Yet there were five vascular surgeons in hospital Z alone! Later, financial conditions for walking therapy improved, but even this does not seem to have had a very large effect. The lesson is that clinical trials may be useful when it comes to evaluating existing interventions, but that this is not enough to improve practice. In one way or another, improving health care mainly through evaluation supposes that there is a "natural" (or, rather, a market) push behind treatments; that, as with the drugs manufactured by pharmaceutical companies, someone will want to provide treatments if only they smell that there is a market for them. However, this isn't necessarily the case. As things are at present, hardly anybody feels moved to provide walking therapy. Not under market conditions, and neither in countries like the Netherlands, where health care costs are paid collectively and where the concern about keeping them low is pressing. Proving effectiveness, then, is not enough to improve health care. Other kinds of activities are called

(By the way, when the Dutch patient organization for people with atherosclerosis found out about walking therapy, it did not claim that walking therapy should be organized and made available for all those concerned. Instead of calling for support for patients, it made a video to provide them with information—as if for active patients, "information" is enough and care superfluous. But that is another story.)

Thus, if improvement in health care depends on the choice between forms of treatment that are already there, solidly institutionalized, then it falters. This is because possibilities for treatment do not just materialize by themselves. Somehow, someone needs to get them organized. If nobody does, they cannot be opted for either. In addition to this, there is yet another, entirely different reason that "choice" does not deserve to be celebrated as a mode of handling the coexistence of different goods. The argument is quite elaborate, and I can give you only a snippet here, but to say it quickly: Choice implies a quite specific model of care: a model, to begin

Take the care trajectory of Mr. Homer. He has been living with diabetes for a while now and starts to get used to his disease. His doctor thinks she may introduce a new idea, that of tight regulation. So far, she has not told him about this. Things need to be taken one step at a time. But during this particular routine visit, there seem to be no pressing problems that need to be sorted out, so she explains to Mr. Homer that tight regulation will improve his long-term health. However, it does require that he start to measure his blood sugar levels frequently. She needs these numbers to better calibrate his insulin doses, and he needs the routine of measuring so that he can detect possible hypoglycemias quickly and easily when there is a risk they might occur. Thus, she presents him with the facts, and he nods: "Yes, doctor, I want that, tight regulation. Of course I would like to postpone complications if I can." So Mr. Homer is sent to talk to the diabetes nurse to get further instructions.

If someone were to do a vignette study of patient choice, this might seem the end of it. A patient making a well-informed choice: What more might one wish? In real life, however, there is more—whether wished or not. For in real life, Mr. Homer comes back 3 weeks later. The physician expects him to hand over the special booklet that comes with miniature blood sugar measurement machines, in which the numbers are filled out. She expects him to have filled in a few pages, at least one working day of measurements a week, for that is what they agreed. Alas, Mr. Homer shrugs, as if he were feeling guilty and says, "Sorry," because he did not stick to the agreement. He has no numbers to show—or maybe two or three. What next? A rationalist might think Mr. Homer has changed his mind and made another choice, but a health care professional is unlikely to let things rest at that. The task at hand is to find out why Mr. Homer agreed to measure his blood sugar levels and yet did not get around to doing it. The doctor may take some time to find this out, and if she doesn't quite get there, she sends the patient to see the diabetes nurse. There are a lot of details to attend to.

Maybe Mr. Homer did not quite understand the explanation the diabetes nurse gave about measuring 3 weeks ago. She tries again. Maybe she finds the measurement machine she provided him with was too small for his large fingers, or too big to carry to work. The numbers on the display are hard to read. Perhaps he doesn't like pricking his finger or squeezing out blood. He is afraid of blood. Or maybe he works as a builder: The only private place is the toilet, which isn't anywhere close to clean. And going there five times during a working day may not be what one's colleagues consider acceptable. The devil may be in all these details—and in many more. It is part of the professional skill of a good clinician to find out which of the various details is relevant and then to do something about it. All kinds of things may be done. Almost every single variable in the complex cluster of Mr. Homer's lifewith-diabetes—and with treatment—is open to change. Even the technological bits that seem so fixed where "decisions" are to be taken are fluidly adaptable. Why not measure once every day, Mr. Homer, instead of five times on a single day?

Professional care is not a matter of separating out elements, fixing them, and putting them to use in a linear manner. It is a matter of tinkering, of doctoring, if I

dare to reclaim that word from the negative connotations it has acquired and give a positive appreciation to the creative calibrating of elements that make up a situation, until they somehow fit—and work. Doctoring requires a sensitivity to sensible compromising. And professional care includes nursing, too: consolation when some things simply do not work. Mr. Homer need not feel guilty about not having measured: Someone needs to reassure him. "Don't look too sad, Mr. Homer, it isn't easy, is it? This happens to a lot of people. We'll get there, it may take some time. But you'll find your way to deal with this."

And then, a few weeks later, there is the next appointment. And some things are going better, but a new problem has cropped up that has to be dealt with. How to cross time zones when traveling and still keep one's blood sugars tamed? What to do about a sporting event that lasts all day? And is a current loss of eyesight simply a consequence of getting older or the diabetes complication one has learned to fear? It is obvious that good care is never finished—and this becomes clear when one does not do vignette studies but follows care practices over longer periods of time. Good professionals are never satisfied with their own work. On each visit they will ask a patient, "How are you doing?" And if the patient is not doing well, they will try to improve his situation—and their care.

HOW TO CONTRIBUTE?

This, then, leads on to my last point. How to contribute to *good care* with research? The tradition of the clinical trial was shaped so as to allow inventors of new treatments to relate to others. The task was to prove to others that this or that intervention should be allowed on the market, should be paid for. The trial, as a design, includes the relation between the pharmaceutical industry and food and drug control organizations of governments. This is fine. There are people providing treatment, and there are outsiders who have (in one way or another) an interest in what goes on under the heading "care." This means that the relations between these two parties need to be managed. As a part of this, it may be necessary to engage in some form of accountability. It may be necessary to prove that an intervention is good, or that it is not good. In this context, then, evidence may serve a function.

But not always and everywhere. This is what I would like to suggest: that not all health care research should be structured as if it were meant to convince outsiders of the quality of existing care. Research might just as well, or at least also, be structured as a form of self-reflection. However, as soon as one engages in self-reflection, being pleased with oneself is not all that interesting. More may be learned if we try to differentiate, subtly and in detail, between what is going well and what could be made to go better. I am not promoting self-castigation in Maoist mode, nor criticism for the sake of criticism. But I suggest that the way professionals in day-to-day care practices engage in doctoring and nursing, in tinkering with and in calibrating care, deserves some back-up. It deserves to be strengthened. Thus, I suggest that there should be a genre of research that seeks to contribute to clinical work. The point of such research would not be *proving* practices right—or wrong. The more interesting and appropriate thing to do is to try to contribute to *improving* them.

This might be done in various ways. These include attempts to unravel health care practices in the way I did above in talking about PTA and walking therapy, and of the contrast between tight and less tight regulation for people with diabetes. Such

unraveling lays bare tensions that people, both professionals and patients, live with. We researchers can only learn about it from interviewing and observing them. Participants sometimes articulate these tensions in as many words. However, a lot goes on without being sharply articulated, or without being articulated in a manner that travels from the speaker to people and practices, elsewhere. This, then, might be our contribution as researchers: that we unravel tensions, articulate them, and cast them in the words that allow them to travel—so that they may be more widely reflected on.¹⁰

For instance, unraveling the problems linked up with comparing PTA and walking therapy makes it possible to point out that part of the difficulty is that "talking" has such a different status in the two treatments. It is a mere precondition for making the right treatment decision in the case of PTA or it may be some added kindness, but kindness is not crucial to the treatment of PTA as such. When it comes to engaging in walking therapy, however, the conversation between professionals and patients is a crucial element of the treatment itself. A therapist must find a way to encourage the patient to keep walking time and again, and such encouragement is largely a matter of words. While talking is additional in one case, it is essential in the other. A detailed comparison between these two treatments also brings out that each "treatment" is done by a different set of actors. When one undergoes a PTA, a large team is involved. Sure, as a patient one has to collaborate, and lying down patiently isn't always easy. However, it is very different from the exigencies of walking therapy, where some therapist needs to give support but patients have to do most of the work themselves. What does this imply for the comparison of treatments?

The case of diabetes suggests further lessons. It helps to draw "treatment" out of the linear time line into which it is inserted in the clinical trial: the line between intervention now and long-term health outcomes later. When we no longer foreground effectiveness but shift to the varied effects of treatment, hypoglycemia loses its status as an unfortunate "side effect" of tight regulation and comes to be recognized as something on an equal plane and thus as something equally important. When we begin to unravel the clinical reality of living with diseases this is a way of taking that reality more seriously. This clinical reality to be foregrounded, is a cluster of elements that far too often are kept separate in research: bodily parameters, such as blood sugar level; social tasks (or desires, or obligations), such as driving a car or taking care of children; technological tools, such as blood sugar measurement machines and the intricacies of using and adapting them; and hopes and fears with which the people concerned, patients and professionals, live.

As it is, these concerns tend to get separated out in research, and all too often social science researchers study the meaning of illness by interviewing patients about their hopes and fears, without going into the technicalities and the specificities of their bodily impairments and their treatment regimens. My proposition is that if we want to do research that may improve care practices, we would do better to study practices without too much differentiation between the elements relevant to them. Disease, illness, technology, treatment, life: They come as a package, so it would be better to study them in this way. Difference would be better made between forms of practice than between the elements within practice. Thus we may come to find out how one form of practice differs from another. This may not help with managing care until it has become good, and can be proven to be good.

However, it may help with doctoring: with tinkering with care in the persistent hope of improving it.

NOTES

- 1. Many thanks to the colleagues with whom I have been working on the issue of "good care" over the past few years, more specifically to Jeannette Pols, Tsjalling Swierstra, Rita Struhkamp, Dick Willems, and John Law. Thanks as well to the professionals and patients who allowed me to interview them and/or to observe them in the clinic. The names I use for them here are my invention. Thanks finally to NWO and ZON/Mw for various research grants. A remark about the references: As this was originally a talk, I have tried to insert only very few. They do not begin to give an overview of the work that has informed the present thinking but merely lead the reader on to a few other articles by me and a few friends that develop the arguments presented here more extensively.
- 2. Or, to be more specific, the professional answer is sought in "evidence," but there is an ethical investment in care's goodness as well, and it goes in another direction. See for this, and for the suggestion of a way out, Harbers, Mol, and Stollmeijer (2002).
- 3. See about this study, which shows how each technique that engages with atherosclerosis (angiography, duplex measurement, operations, drug treatments, consulting room conversations, walking therapy, and so on) engages with a slightly different object—so that the body dealt with in the hospital, not fragmented but hanging together despite all these differences, is a multiple object (Mol, 2002a).
- 4. For a more extensive analysis of the intricacies of comparing treatments, with the example of operation versus walking treatment, see Mol (2002b).
- 5. For a theoretical discussion of the implications of this for our understanding of "the body" that uses the risk of getting a hypoglycemia when one has diabetes as its example, see Mol and Law (2004).
- 6. I owe this differentiation of effectiveness and effects to Ant Lettinga, who first mobilized this contrast in her study of various treatments for patients with hemiplegia. See, for example, Lettinga and Mol (1999).
- 7. The attempts to rank treatments and to come to good guidelines are themselves worthy of study—if only because their conclusions are not unequivocal. See for this Moreira (2005).
- 8. See for a slightly different take on this, highlighting various dilemmas involved, Timmermans and Berg (2003).
- 9. See for a good analysis of the way goals may change and shift over time, researched in a rehabilitation clinic, Struhkamp (2004).
- 10. And not only tensions between clinical approaches can thus be investigated. Others as well, such as the tension between a legal understanding of patient rights and one that has to do with caring about their well-being (see Pols, 2003).

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414 QUALITATIVE HEALTH RESEARCH / March 2006

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