

Methodological Limitations in the Analysis of Medical Activities*

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The image of the physician and his effectiveness depend upon the extent to which his professional activities — which I would like to call «medical actions» — can be properly understood. Any considerations about developing medicine, about its humanization, but also about medical systems research are based upon the empirical definition and detailed description of professional action.

The basis for medical action is laid down in medical school. Subsequently, these skills and responsibilities are practiced and deepened in the years of professional activity. The specific characteristics of this pattern are, in turn, affected by postgraduate courses and continuing medical education as well as by the specialty chosen. In addition, the school of thought to which the physician subscribes, the availability of specialized techniques and equipment, the mode of payment for services rendered, the extent of government intervention, the availability of trained secondary health care personnel, last not least the patients' opinions and wishes, all these factors influence the physician's professional actions.

Surprisingly, little empirical research has so far been done on the activities of medical doctors. While the patients' medical histories, diagnostic techniques as well as therapeutic strategies and their results are frequently studied, studies on medical practice tend to remain on the surface and mainly deal with organisational problems. Epidemiological research is generally not concerned with the care of medical action. So far, medical research has focussed on the patient rather than on the physician. This was correct as long as the patient represented the largest and most important source of variability. Hence, the basic rules and the development of medical activities were defined by parameters related to the patient rather than by those related to the physician himself. In fact, however, medicine has long since passed beyond this developmental stage with the consequence that strict patient orientation is, for some problems, no longer optimal. To what extent will a research strategy centered fundamentally on the physician and his actions rather than on the patient lead to relevant insights? Certainly, more will be gained than would appear possible at first sight.

Medicine is currently undergoing a process of development leading to a standardized mass production of medical services of a given quality. It is, furthermore, in the process of transferring its emphasis from the individual to the population, from individual medicine to population medicine. Not the treatment of the individual patient alone is important but services must be made available to the entire population, whereby treatment of special risk groups is to be optimized whenever possible.

When considering these developments, it is appropriate to discuss and specify the limits of our ability to acquire empirical knowledge about medical activities. The hope that we will some day know everything and that through this knowledge it will be possible to make unrestricted improvements might prove as fallacious in medicine as it did in other disciplines. It is becoming increasingly clear that real limits to growth as well as to

what is feasible exist, in turn preceded by limits to the process of understanding and discerning.

If we wish to shape medicine by applying statistical and computer science techniques, we will have to investigate the limitations of the extent to which medical action is recognizable, be it with the intention of going beyond these limits.

In what follows I have tried to avoid getting submerged by literature, choosing rather to involve you in a process of reflective thought, using our accumulated experience as a basis.

I will first discuss the conceptual definition of a physician's actions, of his professional services, and the manner how these may be empirically and formally described.

Subsequently, I will indicate the limitations imposed on the analysis of medical action. Finally, I will briefly discuss the role played by statistics and computer science.

What is «medical action» and how can it be empirically analysed?

A doctor uses his medical skills with the goal of helping a particular patient. His activities, seen globally, represent an open process which is guided by this primary objective. The process itself is many-sided and involves a great variety of support activities, equipment and personnel. In its entirety, it is certainly more than the sum of its component parts. It is a dynamic «gestalt». Professional medical action may be regarded as a system which is not static but has the characteristics of a process and can be subdivided into its individual elements. By doing so, one arrives at a schema which is shown in Fig. 1.

THE PROCESS OF PROFESSIONAL MEDICAL ACTION AND ITS ELEMENTS

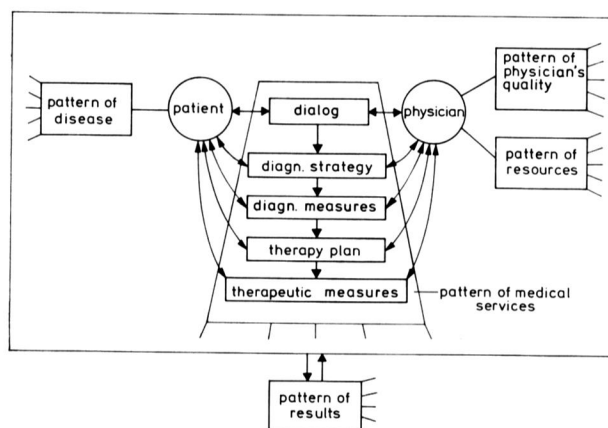


Fig. 1: The process of medical action and its elements

The patient is characterized by his or her disease pattern. This pattern includes in theory all possibilities of disease, a certain combination of which may materialize in the individual case. This combination may be simple or complex, acute or chronic, life-threatening or merely a hindrance. Its focus may be in the psycho-social or rather in the somatic sphere of medicine. It includes the patient's

*) Paper presented on the occasion of the award of the Paul Martini Prize at Medical Informatics, Berlin 79.

expectations with regard to the result of the therapy and course of disease as well as what he expects of the physician. The fact that this disease pattern contains more complexities than could be captured by even the most thorough attempt at description is indicated by a series of lines on the margin of the box »disease pattern« in the figure.

The patient with this disease pattern is confronted with the doctor. The doctor, in turn, is characterized by a pattern of specific medical quality attributes as well as by a pattern of resources which he has at his disposal.

Facets of this pattern are the physician's special knowledge and experience, his manual skills, his powers of observation, his ability to think intuitively, his reliability and his ability to critically analyse his own actions. The pattern of available resources includes medication, equipment, trained personnel etc. In Fig. 1, the multiplicity of these aspects which cannot be enumerated in detail is shown by a series of lines emanating from the boxes.

The interactive relationship that results from the contact between physician and patient develops continuously such that the secondary goals and background considerations are constantly changing. The result of these interactions is a pattern of services (see Fig. 1). It contains all the diagnostic and therapeutic activities that are undertaken in a particular case. These include the dialog between physician and patient, setting up a diagnostic strategy, carrying through diagnostic tests as well as setting up and implementing a therapy plan. The various arrows indicate that these 5 essential elements of medical activity are constantly being re-entered as new information or as a feedback from other parts of the process. In particular, these components must not be considered to follow a general order or rule. At times, the process may actually bypass one or more of these elements of action. All parts of the service pattern are influenced by the patient. Making up this service pattern represents the nucleus of the medical activity process; hence, in the diagram the service pattern is specified up to one step further than is the case with the other patterns.

In fact, the whole process of professional action takes place in the triangle between patient, doctor and pattern of services. It begins with an agreement to accept or provide services, oscillates for some time and then proceeds by virtue of interactions, feedback loops and, in some cases, stable circuits. Finally, the medical action is terminated, be it as a result of a successful therapeutic regimen, by a standstill of the disease, by death, or by the unwillingness of the patient or physician to further pursue the process.

At the end of medical action there always is a pattern of outcome. This refers primarily to patient-specific success indicators. However, it may also refer to the quality of the professional services rendered. The pattern of outcome can be related to the pattern of disease, to the objectives of the treatment and to the patient's expectations.

This yields generally discernable elements of medical action. What has not been shown in the figure is the time sequence of the process, the more or less regular connections that exist between disease pattern, patient, physician, pattern of professional services and pattern of outcome. These are to be concretized in the individual case.

It is certainly true that the process of medical action can also be analysed by using other concepts and categories. One can, for example, use the motives of the patient and the doctor, the categories of ethics, or the terminology of law. The system of categorization used here has several advantages: it captures the process as a

whole, incorporates the other categories as special cases and, most important, it is a system which is consistent with both empirical study and specification. Professional medical action defined as a goal-oriented process will become an empirically analysable process and with the aid of statistics and computer science techniques, such models can be tested by comparing them with reality.

In order to analyse professional medical action it is, therefore, decisive

- to consider medical services as a goal-oriented, interactive, open process;
- to observe empirically and quantify the fundamental elements of this process — including the pattern of disease, of resources, of specific medical attributes, of services and of outcome;
- to reduce by the introduction of standards for disease and service patterns, the variability of the process with the result that certain outcome patterns will become predictable;
- to analyse the process of professional medical activity by manipulating the system, thus rendering it more easily recognizable as such.

We thus consider professional medical action as a phenomenon which we wish to study empirically. It is of interest to us to see how it proceeds without any preconceived notions on our part with regard to the way in which it should function. We wish to empirically consider the question: to what extent can we improve medicine by looking into the process of professional medical action as a whole rather than looking at the patient component alone? Great physicians have often conceived their activities in this sense.

This, too, is a methodologist's answer to the current questions as to the limitations set to professional services and physician's activities. The methodologist is concerned with facts rather than with ideology. No one knows exactly how medical professional activity and services really happen, nor is it possible to know the level of variability, success or failure of medical action. Let us then study empirically the process as it occurs before discussing the quality of medical care or of the nemesis of medicine. I am convinced — and our experiences confirm this in some fields — that medicine need not shy away from empirical investigations. A careful analysis of professional medical activity is a challenge to medicine for the next decades.

What are the methodological limitations in the analysis of professional medical actions?

I would like to list nine barriers which an empirical study of this topic will eventually have to face, none of them sufficiently grave to prevent such studies being undertaken, but sufficiently relevant to seriously impede recognizability.

To me understanding and discerning means to intuitively grasp an entity in its complexity to project objects and their relationships into the brain, the projection being perceived, making sense and leading to consistent action.

1. As a first barrier to understanding and analysing medical professional action we have to mention the difficulties inherent in the formulation of feasible tasks.

Substantial segments of professional medical action have never been approached in a way that is amenable to an empirical investigation. The process itself is inadequately formulated. A serious barrier lies in working out what we would like to ask and will be able to ask. The formulation of workable research projects is a challenge to the creative individual among us. We cannot investi-

gate what has not been formulated. Most things in this field have not yet been adequately formulated.

2. The second limitation lies in the complexity of the process, its elements and its temporal succession. The mere listing of the individual elements presents problems. There are surely ten thousands of patterns of disease and as many available resource elements such as drugs, operations, artificial replacements, cures and aids etc. Additionally, we have the entire broad palette of available diagnostic techniques and interventions. The complexity of medical technology is immense. Because of this complexity it will nearly always be possible for the doctor to choose a pattern of response which lies outside the experimental research plan: this complexity thus represents a serious limitation.

3. A third source of limitation lies in the high level of inconstancy and variability. Disease is partly a spontaneous phenomenon which changes whenever the organism is trying to regulate itself. As a result, new states of equilibrium find their level. Variability from one patient to the next is still larger. The number and nature of diseases in the population is changing. But variability as between physicians is also considerable. Not only is there a great variability between specialists, but also between different schools of thought, between different countries and decades. The doctors we are training today will not be comparable to the generation now in practice. The variability in the pattern of resources is also impressive.

New diagnostic and therapeutic procedures are continuously replacing existing ones. This variability is especially attractive to the experienced methodologist; it not only represents a serious barrier but also offers distinct chances for acquiring knowledge.

4. A fourth limitation lies in the rarity of events. This rarity of specific phenomena is directly coupled with the huge variability inherent in medicine. Rare events can only be grasped by looking at and observing a large number of non-randomized cases, which represents yet another barrier to the feasibility of such a study.

5. A further limitation is the totality of the phenomena which is coupled with the fundamentally unobservable character of certain processes. The totality of such a thing as «professional medical action» approaches the boundaries of the knowable when the phenomenon is destroyed by dissection. An exact analysis of what occurs during the process of dying, in conjunction with continuous observation of a number of variables in an intensive care unit, can considerably modify the phenomenon of individual death, and it may even become impossible to record it correctly. The intimacy of the dialog between a gynaecologist and a female patient will be modified or even be destroyed by real-time observation.

There are situations in medical action where something is destroyed by being recognized. Recognition at least changes the object. One can in fact speak of a principle of uncertainty of medical action, namely: the clearer one recognizes a situation, the more thoroughly one has changed it, the less one knows about it; the better one gets hold of a phenomenon, the less one is able to grasp of its content.

6. Yet another difficulty lies in the fact that causal relationships are very difficult to prove in complex systems, of which man is certainly one. A somewhat definite proof of a causal relationship requires an experimental setting with control over side conditions, defined allocation, prospective observation and clearly defined goal criteria. Due to ethical considerations, the process by which doctors render professional services does not lend itself very well to being compressed into such a setting.

This is, to some extent, possible in controlled clinical

trials but more difficult in other settings. We have only limited possibilities to interfere with the process of medical professional action, to actively disturb its equilibrium, thus the better to study its functions and to know which are the boundaries of its effectiveness. Ethics set limitations to what can be recognized. However, as a consequence of the inherent variability, situations naturally arise which make it possible to investigate the system in borderline situations. Competent physicians from various parts of the world act differently in the same situation. In certain situations, resources are lacking for reasons not to be charged to anyone. Some patients refuse certain procedures on ethical grounds, although professional medical opinion wants to force them upon them. Such situations may partly replace a planned interference with the system of professional medical action with regard to the capacities of knowledge.

7. The inadequacy of theoretical models represents yet a further limitation. Our models are sometimes very complicated theoretical models that have been developed from a mathematical edifice of thought. They are not based upon the structure of observed professional medical activity. The available models are at best applicable to partial processes. Developing a complete and uniform mathematical model of «professional medical action» appears to be a hopeless task. We can, therefore, only attempt to construct submodels with simplifying formulae and, subsequently, to join these submodels by describing them.

8. Transformation into empirical investigation sets further practical limits. Data collection methods required for an analysis of professional medical action have not yet been developed. This is true to virtually the same extent for the description of the patterns of disease, the doctor-specific attributes, the pattern of resources and services. We have no validated instruments for the collection of data relevant to medical dialogs and interviews, to outlining a diagnostic strategy, the implementation of diagnostic or therapeutic procedures, or of the therapy plan, nor are we able to evaluate the pattern of outcome. The practical limitations to what is empirically verifiable can certainly be substantially extended. However, for the foreseeable future, these limitations represent a serious barrier to the analysis of professional medical action and services.

9. A last limitation which I would like to mention here concerns the acceptance of examinations and results. Some approaches are not acceptable to the patient, others not to the physician. Some examinations are opposed by the health insurance companies or by the hospital authorities. The refusal of those affected and the refusal of scientists, constitute a legitimate limitation. Just as some physicists refused to participate in the development of the atomic bomb, medical scientists are justified in withholding their services for the development of certain instruments in health care. The collision of interests in health care systems is a serious problem and attempts to solve it will have to be made again and again. Today it is possible to ask questions which 10 years ago could not even have been successfully formulated. Other questions can no longer be formulated, while yet others may perhaps be studied in 10 years time. After all, the wisdom of previous generations is discarded though it contains valid and enduring truths.

If one considers the nine limitations outlined above (for reasons of simplification and in order to adhere to the time allotted I have not mentioned any others), it is clear that the process of professional medical action can be empirically studied and the limitations of its understandability can be further extended. This can be done

in a relatively short time with the aid of appropriate techniques. Part of the process of professional medical action will always remain undiscernible; however, this part is not very large. The most important part of the process of professional medical action is empirically discernible, a very small part is already known.

At present, we are incorporating statistical and computer science techniques into the field of medicine, a bundle of scientific instruments apt to conceive and extend the boundaries of our understanding. In fact, the role of biostatistics and computer science lies precisely in this area: they specify and modify the limits of our understanding. We use biostatistics and computer science not as an end in themselves, but rather as a means to better recognize and improve the fundamentals of medicine. Here statistical methodology, which has always occupied a position midway between theory and observation, is the essential element. Computer science has, by contrast, always had rather a functional character; it contributes not directly to gaining knowledge.

What the methodologist in medicine would like to do today is not completely covered by any of the currently available names of specialties. Neither biostatistics, medical informatics, medical statistics, epidemiology, nor systems research characterize what would be optimal and desirable under our conditions. What we need is a constructive clinical methodology which, to a large extent, is built upon statistical foundations, one which includes and uses techniques of epidemiology, social science and informatics. Such a clinical methodology, when applied to analysing professional medical action, could improve the level of understanding step by step and give it an empirical foundation.

A good methodology is like a door through which as many meaningful questions as possible may pass from the regions of uncertainty to the region of relative certainty of knowledge. However, statistics must not become a trap door through which every hypothesis falls without ever reaching the region of relative certainty. The hatchet of

the statistical test, by which many a meaningful hypothesis has been erroneously executed, is not our only methodological instrument. We have today well-equipped methodological torture chambers where any desired truth can be wrung from the delinquent nature. Finding the truth in medicine is not made easier by the multiplicity of methods and the sheer number of scientific tortures. The yardstick by which we measure knowledge is not the number nor the type of instrument used but rather the increasing plausibility of our knowledge. Neither statistical tests nor the computer produce a medical methodologist but rather the sharp thoughts of an active mind. These considerations lead us to the following two conclusions:

1. A science of professional medical action should be developed, centering around empirical research into precisely that action. Medical action, seen as a goal-oriented, systemic process including as elements the patterns of disease, resources, doctor-specific attributes, services and outcomes, should be more thoroughly studied than has been the case so far.
2. To make this possible, a constructive and aggressive clinical methodology is required, one for which essential building stones will come from statistics, informatics, social science, from epidemiology as well as from the clinicians' experience and knowledge.

The fact that, rationally speaking, there are limits to our knowledge about the world — at least about some parts of it — inevitably means that part of professional medical action will also remain unintelligible. Intelligence does not always suffice to light our lamp. The totality of knowledge implies that one first knows and then proves. The range of our mind which we cause to wander through the world winged by hope, will continue to represent the limit of recognizability.

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