

REFLECTIONS ON THE SCIENTIFIC METHOD IN MEDICINE

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Summary

Since the 1940s, medical research has suffered a crisis of efficiency in its effort to achieve the humane goals of medicine. It has been disfavored the clinical ortho-investigation of high quality induced directly from lacunae inside the clinical sciences, originated-in-the-patient and investigator-driven. Clinical progress is being practically achieved through clinical meta-investigation, mostly induced from outside the clinics by the basic-sciences and technological-sophistication processes, and by the measuring of death-disease-risk indexes decline of the health-sciences. The aim of this chapter is to reflect on the concept of a comprehensive scientific method to make clinical medicine research more creative, fruitful, and rigorous strengthening its internal logic of progress. Using scientific system analysis and intuition are made suggestions on the application of the scientific reasoning and method in clinical research, for the strengthening and completion of its scientific foundation, and the benefit of an advanced and integral clinical teaching and care of the patient. The chapter reflects on a better adjustment of

the scientific method hypothesis-driven in clinical medicine, science of particularities and generalities too, now a huge empirical research domain but a too little theoretical research realm yet, between the more mature pre- and post-clinical dominions. It meditates on the complementarity of an integrative inductive-deductive theoretical-research strategy for discovery of new medical hypotheses; of two computerized knowledge- and data-driven systems: one, for discovery of “recombinant” hypotheses from knowledge-bases, and other, for optimization of research design through human modeling-simulation-prediction from databases; and on the medical probabilistic and determinist systems of inference, as well as on the need to accelerate an empirical-theoretical solution for the medical body-mind dualism problem. It concludes that a unified scientific methodology with a solid foundation could be created for medicine, through a trans-methodological model of clinical, basic and health sciences, re-unifying the clinical scientific method for practice and research.

1. Background

Working since 1946 with its very broad definition of health, World Health Organization policy has been unable to resolve the problem of finding a balance between the biological and disease paradigms of medicine, on the one hand, and public health, on the other. The explosion of medically-applicable knowledge and high technology has rendered a balance even more difficult to achieve. This situation has encouraged the biomedical model of world health policy that continues to demand increasing research to cure acute and chronic diseases, rather than focusing also on promoting – in the individual and the population – an optimum state of health in the most developed countries, and a good, or at least minimum state of health in the less developed countries. It is now argued that there is a need for a different kind of methodology in medicine that will lead to a different global health policy, yet also impact on clinical care.

The aim of this chapter is to reflect on the concept of a comprehensive scientific method to make clinical medicine research more innovative, fecund, and valid strengthening its internal logic of progress. Using scientific system analysis and intuition are made suggestions on the application of the scientific reasoning and method in clinical research, for the strengthening and completion of its scientific foundation, and the benefit of an advanced and integral clinical teaching of the physicians and care of the patient.

1.1. The Approach to a Scientific Method in Clinical Medicine

To achieve a realist view of the beginnings, advances, trends, limitations, and challenges of the scientific method in medicine in the 21st century, it is desirable to review the historical context of the practice of medicine, of science in general, and of the particular science of medicine with its three dimensions of medical sciences, of their allied sciences, and of scientific attitude, thought, objective and method.

The American economist Jeff Sachs writes, “human ignorance, poor health, brutish and short lifetimes have changed dramatically with economic development from prehistory up to ten millennia ago, when agriculture arose and practically all people had to survive

unending epidemics, famines, miseries, local wars and political despotism with very primitive knowledge, technologies, sanitation, and natural medicine that did not help enough. From those times up to around the mid-1700s, there was a very slow change for the better but most people still lived in ignorance with ill health and poor quality of life, advancing from extreme poverty through moderate and mild poverty”.

“However, from the world’s 0.9 billion people around 1750 to the 2000s, merely 250 years, an extraordinary and sustainable global market-based international economic and social development has spread industrialization, wealth, democracy, technological-scientific progress, with an increasing middle class - coming from and reducing the poorest class. While these changes have also brought about global environmental degradation, wars, and terrorism during the 20th and beginnings of the 21st century, ignorance, ill health, hunger and poverty have been more than halved, life span and living standards have been more than doubled”, although the need still remains for more social justice and attention to what people feel.

Nevertheless, these advances have come accompanied with global confusion bringing setbacks in economic and social matters as well as in science and medicine. As written in the American biologist Paul Gross’s book, “in the 20th century, the whole spectrum of pre-scientific medicine: remedies and techniques coming from prehistory up to the 19th century: was once again re-established in the most developed countries. In USA alone, in the 1990s, the estimated number of visits to unconventional medical providers was 425 million/annum with an out-of-pocket cost of \$10.3 billion/annum, whereas there were 388 million visits to US primary care physicians, whilst the cost of all US hospitalization was \$12.8 billion”.

Sachs resumes, “in 2005 one half of the world’s 6.3 billion people still live in closely regulated centrally-controlled systems and 40% in poverty — including one billion in extreme poverty”. Like their ancestors in the 1750’s, they still suffer ignorance, ill health, poor quality of life; they lack necessary education and essential health care, in spite of the existence of oceans of wide and deep knowledge, the highest technologies, advanced sanitation, and total or at least partially effective scientific medicine for most known illnesses.

The persistence of long-established infectious epidemics in the developing countries together with those lately emergent and re-emergent, is conspiring at the global level not only against the health of the world’s poor population, but also against the best health of the affluent and middle classes in developing and transitional countries, and even of the most developed countries, in addition to their own specific burden of chronic non transmissible illnesses of affluence.

The clever option in facing this situation is not to go back to a previous socio-economic and techno-scientific period. It is not to retreat to all the primitive and pre-scientific medicine remedies and techniques of health care. Instead, the developed and developing countries, with the guidance and help of the most advanced countries, should seek the way to achieve auto-sustainable economic, educational, scientific, and health care growth, with reduced suffering of the whole population (and environment), using the vast potential of modern economic, educational, scientific and medical systems and of

the material, energy, information and communication technologies. How is this to be achieved? A digression on the training of medical practitioners and researchers is instructive.

1.2. How the Current Situation Developed

Usually in most world universities, when medical school undergraduates and residents learn the scientific method as a preparation for research in medicine, they first receive a short introduction to a universal, abstract scientific method. It starts with schemes for devising and writing a research design, a report, a presentation, and an article on empirical results. This is followed by a long, abstract, and detailed examination of mathematical statistics: from estimation and hypothesis testing, to the meaning and use of means, standard deviations, correlation and regression coefficients; non parametric statistics, tables, graphics, and statistical software to simplify procedures. Gaussian and Bayesian probability theories, analysis of variance, multivariate analysis, all have a part in the quest for medical certainty in the results of medical surveys and trials, but are often presented without a specific orientation towards medical science and research.

The scientific method as received by these students has self-contained form that seems to have existed indefinitely, as the scientific method in medicine. However, the origins, application and development of the scientific method in medicine and the scientific foundation of medicine are much more complex and by no means free of methodological complexities and flaws as yet incompletely understood. Scientific research in medicine is much more than the simple use of a universal and abstract scientific method assisted by statistical procedures and software because, unlike for example, agronomy and veterinary care, it involves the human being.

As the American historian of science Rosser Matthews writes, “the emphasis on abstract statistical inference began in the late 18th century. Then in 1946, after more than a century of debate, medical statistics was first accepted when the British epidemiologist-statistician Austin Bradford Hill made the first randomized, controlled clinical trial of streptomycin in tuberculosis” —beginning to move the pendulum to the other extreme. Since then, “the scientific credentials given by experimental physiology and bacteriology laboratory techniques to medical research from the 1840s to the 1940s, depended upon experimental statistical techniques applied to clinical and epidemiological research, all the rest being considered merely clinical art and technology”. It seems that the just balance in clinical research will be achieved only when the pursuit of clinical results by a clinician, surgeon or psychiatrist investigator, using a more explicit creative and powerful method, retakes scientific leadership in clinical research, assisted where appropriate in statistical issues by a statistician who understands clinical medicine. This will be possible when the new generations of physicians includes full time theoretical clinical investigators to work, like clinical investigators up to the 1940s, with the logic of facts again.

The scientific method in medicine must be studied more actively taking account of the great spectrum of empirical research methods, which use supplementary statistical techniques to handle factual data, and the no less important creative, rational research methods of the scientific medical hypothesis, theory, and law. (The concept of ‘medical

laws' has been very little handled by most medical researchers, with the exception of the French physician-physiologist Claude Bernard.) Thus the conceptual and operational framework needed in order to use the power of a comprehensive scientific method in clinical medicine, presupposes the existence of a minimal, very critical and, above all creative, attitude of thought, reasoning, goals, strategy, and procedure. So the first step in examination of a research problem, leading to a first hypothesis, should be the study and design of a complex matrix of facts and ideas, in such framework, without excluding either empirical or rational elements. The opportunity will arise subsequently for the guided selection and design of the clinical research, with its essential statistical procedures to handle the sets of variables and group(s) of patients.

But medical scientific research since the 1940s continues to be subject to heated debates in the ethical, ontological, and epistemological fields throughout the world, in the task of trying to balance ambitious goals with limited means. One main discussion is about which research is the more human-oriented: high-technology research to cure disease and delay death, or low or non-technological research directed to care and palliative action for patients, to promote healthy persons and prevent them from becoming sick or disabled. Another major controversy is about which is more effective on a medium and long-term for human beings: conceptual, complex, and expensive research to explain disease mechanisms and to cure at least to some extent, or simpler and cheaper research to improve an individual's lifestyle and increase the preservation of health.

So today, methodological discussions in medical research continue, about measuring the partial research facts about the patient and establishing their reliability, on the one hand, and about the clinical understanding and judgment resulting from research on the patient as a whole. Regrettably, the growing fusion — and/or confusion — of technology with science that has arisen, has originated acceptance of the randomized, controlled, double-blind clinical trials of industrial bio-pharmaceuticals, bio-devices, procedures and equipment, and more from the 1960s of natural and traditional remedies and techniques, as the only true and objective clinical research.

2. Essential Methodological Principles

This contribution is based on five main methodological principles:

1) Some scientific general problems still require scientific solutions that go beyond the limits of the present set of medical sciences and the simple articulation of their growing knowledge. This could be achieved through a broad integrative scientific research strategy. It would aim to complement the necessary, successful but insufficient research methodology of reducing complexity to its elements; it would need to employ a process of iterative induction. In this way, unifying principles within a general body of theory of a unified medical science might be obtained, and original hypotheses revealed.

2) Medical research and intervention (R&I) as well as medical research and development (R&D), have many areas of operation: the person and the family at home or in the community, the clinical office, the ward, surgical theatre, involving activities of a basic or an industrial laboratory, or a health service. R&I and R&D may utilize a

medical knowledge base, a database or an internet virtual net-clinic or net-lab. These are all related fields or facilities and, taken together, offer opportunities for a unique creative process for solving scientific problems. If their scientific methodologies could be integrated, greater scientific efficacy would result than when they are used separately.

3) There could be a rapprochement and a linkage between existing medical research methodologies, including both empirical and quantitative methods, and the rational inductive and qualitative ones recommended here. This broader methodology could include more data-driven discovery support systems for extending and developing hypotheses. It could include pre-physical experimentation and prediction by modeling and computer simulation, and new ways of formulating scientific hypotheses, law-like generalization, and theory formation; this development would make medical scientific research enterprise more complete and coherent, and would allow the establishment of some scientific general methodological principles of clinical medicine first — and later — of the totality of medicine.

4) Tacit epistemological principles about the nature of knowledge in medical science could be identified explicitly in the conceptual framework composed of sub-disciplinary, inter-disciplinary and super-disciplinary paradigms governing current medical scientific research. These could be also taught in order to enhance scientific critical and creative thought, and the aims and methods of the clinical medical scientist. Learning concepts, hypotheses, laws, and theories in a practical way, but with an abstract approach as well, would help practical and empirical clinical investigators to guide and enrich their own research, and that of more theoretically directed investigators.

5) Strengthening the internal logic of the methodology of clinical medicine research, mainly depends on the revitalizing the scientific method of clinical judgment. In practice this demands a more explicit algorithm of procedures for care, and a renewed creative and heuristic method for research. This should provide a powerful tool that would attract many more young students, generalists and specialists - giving them a better training in clinical research methods to face and solve the greatest scientific challenges still facing clinical medicine science, for the benefit of the individual patient and family.

The scientific method has evolved over millenniums. Mario Bunge, the Argentinean physicist- mathematician defined it well. The decisive breakthrough came with the British Isaac Newton's "Principles of Mathematics" in 1687. His hypothetical-deductive method has now come to be specified in terms of a heuristic series of steps. First, information is gathered by observation of the fact being studied. Second, based on that information a preliminary description or explanation conjecture or hypothesis is created by inductive reasoning. Third, this in turn leads by deductive logic to some consequences that must be tested logically and theoretically with the known knowledge. Fourth, ultimately these deductions are tested by further empirical observation and experiment. If the conclusions drawn from the original hypothesis successfully meet all these tests, the hypothesis become non rejected and accepted as a scientific theory or if sufficiently strong, as a law. If additional facts observed or experiments are in

discrepancy with the hypothesis, it may be modified or discarded in favor of a new hypothesis, which is then subjected to further scientific tests. The capacity to predict or not new facts and data, is a key test of a scientific theory.

Thus we have the framework of a new coherent and comprehensive scientific methodology. It is intended to re-conceive, educate, and make clinical medicine research more inventive, fertile and reliable for the benefit of patients and healthy individuals, at the same time strengthening the internal logic of research progress with integrative strategies. The hope is, while recognizing the success of the reductionist approach (assuming that a system can be understood in terms of the operation of its constituent parts), to take greater account of the totality of the patient, his environment, family and social milieu.

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Biographical Sketch

Dr. Rodolfo-Javier Stusser is a physician trained since 44 years ago as researcher-professor on top basic science labs, on internal-general medicine practice in urban/rural centers, and on public health, biostatistics/informatics in Havana University (HU), who founded the HU Basic Sciences Institute (1962) and Scientific Research Center (1968), Health Development Institute -MOPH- (1976), Clinical Research Center (1992) of West-Havana Scientific Pole, and assisted the Plaza- (1990-) and Vedado Community-Polyclinics to become Science-Technology Units. He has 38-year studies on the logic, forecast, policy/program of clinical/population research/trials, health services research, on infant and maternal, cancer, myocardial infarction and stroke preventable mortality, global health research, among other matters, in Cuba, Nicaragua, and East Europe Comecon 1969-1989, PAHO/WHO 1988-2006, and 43-year teaching students/residents, researchers/professors in neuro-physiology, semiology, research method/statistics, epidemiology/informatics. He designed and founded the laboratories of medical research methodology for 15 Cuban institutes of health in 1977, and was teaching pioneer in Cuba at the Cancer Institute of the logic of clinical and epidemiological research/trial at HU 1977-2006, as well as at Managua University and PAHO/WHO Office 1988-1990. His Ph.D. degree-thesis results: "Five unified-scenarios for cancer research and prevention for Cuba 1985-2000" (first in Iberian America), were applied in the planning of three-MOPH-programs: "Anti-Cancer Struggle" and "Oncology-Specialty" 1987-2000,

and "National Health System's Objectives, Goals and Directives 1992-2000".

Dr. Stusser is the first Cuban International Member of the American Academy of Family Physicians, member of the International Societies of Clinical Biostatistics and Internet in Medicine, and founding Partner of the WHO-Alliance for Health Policy/System Research. Since 2000, he is Adviser/Lecturer at Havana to US People-to-People Ambassadors-Professional Program, Sam Nunn School of Foreign Affairs-Georgia Tech Institute, doing lobby work to restore the US-Cuban scientific research collaboration initiated 250 years ago. In 2006, he retired from his state physician job to make personal travels and studies.

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