

## Reviews of books and studies

*A.P.Hardon: Confronting ill health: medicines, self-care and the poor in Manila. Academic thesis, Department of Anthropology, University of Amsterdam; accepted March 9th 1990. To be published by Health Action Information Network, Quezon-city, Philippines, 1990.*

This dissertation – running to 227 pages in the form in which it is at present available – is the fruit of a study to determine how the poor treat ill-health in two communities in Manila, the Philippines. The focus is on the self-care of everyday problems, in particular coughs and colds, diarrhoea and fever. The investigation set out to describe the pattern of self-medication, to assess the impact of mobilizing consumer opinions and initiative, and to develop methodologies for assessing drug misuse in primary health care. Anita Hardon has chosen a very broad approach to these objectives. Her thesis indeed opens with a total overview of the national pharmaceutical context, i.e. the market and government policies in the Philippines, followed by a description of the socio-economic and health care background in the geographical areas in which the research was conducted.

The heart of the study lies in its documentation and examination of popular views on health and illness and of drug use in connection with everyday health problems. The investigation was deliberately designed to centre on the user's perspective, because insight in this aspect is usually lacking. The need for greater insight is clear if one considers experience to date with certain efforts to improve the situation. WHO's Action Programme on Essential Drugs recommends the use of a limited number of essential drugs selected on the criteria of need, efficacy, quality, price and availability. When designing their national essential drugs lists, governments are advised by WHO to take local health and health care conditions into consideration. This process at the national level is usually carried out by medical professionals. In view however of the dominance in third-world countries of informal distribution channels and self-medication this approach is likely to fail unless it is complemented by others. What in the author's view is lacking is community involvement and an understanding of how people use prescribed and non-prescribed drugs.

The study provides ample evidence of the difficulties that lie ahead for many Third World countries which seek to rationalise drug use merely by implementing the Essential Drug Program and banning hazardous drugs from the market. Without positive community involvement, vested interests and conservatism are likely to win the day. Even such simple measures as the obligation to use the generic name on drug labels alongside the brand name meets with virulent opposition, not only from the pharmaceutical industry, but also from the medical profession. Indeed, Dr Hardon advances evidence that politicians from the U.S. have exerted pressure on the Philippine government to impede the rationalisation of drug policy.

Dr Hardon's thorough examination of the living conditions of the urban poor and of the health care facilities available to them in the research areas makes it clear how the use of

health care resources and of drugs should be understood in the context of survival strategies. Health services are physically accessible, but in many instances not financially so. In actual fact therefore, the cost of drugs or of medical visits determine people's choices. Popular views on the causes of illness are mainly naturalistic, i.e. illness is perceived as being caused by natural processes. In the regions studied, "hot-cold notions", i.e. a belief that an imbalance between heat and cold is the cause of manifest illness, proves to be dominant in the public mind. However, no relation exists between the perceived cause of illness and the therapy chosen. Lay criteria for the choice of drugs include their expected effect on symptoms, the dosage form (tablets or syrups), the age of the patient and the severity of the symptoms. It is a pity that in the section of the study dealing with these matters so little attention is devoted to the pharmacological aspects of the drugs considered, since this has led the author to draw unwarranted conclusions. The fact, for example, that age matters in the choice for or against a particular brand name may well be related quite validly to the dose, i.e. specific drugs may be chosen for children because they contain a lower dose. Moreover the author tends to classify some preparations as similar in view of the fact that they have one component in common. Later in the study however, the frequent use of combination preparations in the Philippines is stressed and it is evident that drugs which are presented as similar may well be highly dissimilar if the effects and doses of all the components are known. One of the examples discussed is the use of Baralgin® for stomach ache rather than other preparations similarly containing pyrazolidon derivatives. Baralgin® however, as sold in many countries, contains not only pyrazolidon but also antispasmodics. Thus the use of Baralgin® for stomach ache is from a pharmacological point of view reasonable, even if it is not a preparation of first choice because of the unwanted characteristics of the pyrazolidon component. The components of the other drugs grouped here alongside Baralgin® are not given at all, rendering comparison impossible unless the reader has a Philippines Drug Directory to hand. This example at all events reminds one that lay criteria for drug choice may be much more related to their pharmacological effects than suggested by Dr Hardon.

On the other hand, in this population in which lay evaluation of the effects of drugs is in the first place related to their effect on the symptoms, the criteria used may be misleading. Thus drugs for diarrhoea are only thought to be effective if they harden the stools. Since oral rehydration salts do not have this effect sufficiently early, they are not considered to be an effective remedy against diarrhoea and are thus not used. Other criteria are less easy to evaluate; in the view of the Philippine lay person, for example, drug efficacy depends not only on the characteristics of the illness or of the drugs concerned, but also on whether the drugs are "hiyang", i.e. whether they agree with the individual concerned. This concept is used to explain individual differences in reaction to a specific drug. Whether valid or not, the belief is typical of those which exist and must be taken into account if drug policies are to be attuned to reality and thus attain acceptance and support.

In analyzing the actual pattern of drug use the author uses a symptom-related approach, which is well suited to the purpose of studying self-medication from the user's perspective. The symptoms taken for study comprise those of coughs and colds as well as diarrhoea and fever. For each, Hardon examines the percentage of illness episodes treated using self-care with western medicines, the percentage treated with herbal medicines and the average number and type of drugs used for an episode of illness, and compares her findings from the two geographical areas studied. It might be expected that in one of these areas, where a community primary health care program is active, there will be a greater use of herbal remedies since this is promoted in the program. This effect on the public's practice is confirmed, though it is only a slight one. On the other hand no differences between the two areas are found as regards the use of western medicines, suggesting that the program has not

been successful in substituting herbal remedies for western medicines where this is possible and desirable. In both the areas studied the intensity of treatment is found to be high, most symptoms being treated with a drug. The author notes that the widespread use of antibiotics in suboptimal doses, the frequent use of analgesics and the high proportion of combination preparations are the most problematic situations. These findings reflect a pattern familiar from other countries in the Third World. Striking too is the finding that self-medication patterns follow professional prescribing patterns, partly because people re-use old prescriptions.

From a public health point of view major problems include the availability of antibiotics for self-medication in neighbourhood stores, the fact that the patient retains prescriptions and can take them back repeatedly for dispensing, the overuse of many drugs (especially antibiotics) without proper diagnosis and the prescription of doubtful combination products, although this latter point is only touched upon in the study.

The findings of this study have been reported back to the community, but no systematic evaluation of its impact has been included in the report. What at all events can and must be learnt from the investigation is that any attempt to change medical consumption behaviour need to take the beliefs and attitudes of the target population and the existing health care situation into account. As such the study underlines findings from work in industrialized countries relating to patient education programs. The study provides a wealth of detail on how people actually think and act with regard to treatment of everyday problems. However a more thorough integration of the many different aspects which are touched upon would help to clarify the issue, for example drug use and popular views on drugs. As pointed out above, the investigation would have benefited from a greater consideration of the known pharmacological properties of the western drugs which are being consumed; the same however also applies to the herbal remedies promoted by the community primary health care program; with the exception of the oral rehydration therapy included in this category nothing is said about the value of these therapies for the people more than as a placebo. Subject to these reservations Dr Hardon's work is a milestone on the road to acquiring the insights needed to implement effective drug policies in a country such as the Philippines; it is, however, only a milestone, and there are many miles to go.

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*Osinga M. (1989): The patient's responsibilities in medical care and treatment. World Health Organization, Regional Office for Europe. Available from the W.H.O. Collaborating Centre for Clinical Pharmacology, University of Groningen, The Netherlands. US\$ 20.00.*

Marijke Osinga's study of patients' duties and responsibilities is inspiring reading. It investigates the ethical, moral and legal responsibilities which the individual may have towards the health professions, towards the community to which she belongs, and towards

herself. This is done with thoroughness (plenty of case histories, references to literature and to national laws) and with an enthusiasm which provokes, inspires – and sometimes puzzles the reader: whose moral standards are being discussed? At the end, the reader is left with the understanding that we all have the responsibility, as members of society, to participate in the discussion.

The study makes sense. To begin with, there are a number of simple duties which any patient has to recognize, and it is good to see them lined up, discussed and defined. An infected person has a duty to avoid disseminating the virus. Nobody should drive a car under the influence of drugs, be they alcohol, tranquillizers or beta-blockers. We should all do our best to collaborate with health personnel, we should keep our appointments, pay our bills and so on. Marijke Osinga's study seems to provide a complete list.

Marijke Osinga is careful in her discussion on patients' responsibilities towards themselves, and rightly so, as this is a very different matter from our duties towards the health care system and society as a whole. Although it is agreed that we all have an obligation to preserve and promote our own health, this view is delicately balanced against the right to self-determination. The study concludes, however, that patients' responsibilities will play an increasing role as patients become fully-fledged partners in health care, and this may very well be true. As patients we always had to take the consequences, no matter where the legal or moral responsibility was placed. Now, if we interfere with our own treatments, we shall have to take not only the pity and the pain as usual, but also the blame, if things go wrong.

Marijke Osinga points to the dilemma of new and costly means of cure, set against limited resources. Who will take the responsibility for their apportionment? Patients? Politicians? Physicians? If scarcity of resources demands that we choose, according to which rules shall we decide who should live and who should die? Should we use irresponsible behaviour as one of the criteria for the refusal of treatment? With our very limited understanding of the true course of sickness and health, we are morally on very thin ice if we do. Insurance companies are however already on the track. "If you are lucky you will pay less." But wasn't the whole idea of insurance to beat the devil, wherever he might choose to strike?

Society will always applaud certain patterns of behaviour, irrespective of whether they are healthy or not. Sports contests (pain and effort) are "good", candy-eating is "bad". Drinking (to your health) is "social" and unhealthy, while sex is healthy but very often sinful. We cannot make health a new religion which regulates all our behaviour, and this is one of the reasons why it is unfair to blame the patient for being sick.

Marijke Osinga does not blame anyone. She opens the international discussion on patients' responsibilities in a sober, sensible and responsible way while she, at the same time, calls for more studies on the subject. It is tempting, therefore, to end with a word of warning: sometimes the answer to a question is so complex that it is wrong to try and set rules. To which degree do we actually wish to define patients' responsibilities? And do we, at the end of the day, dare to hold the patient responsible?

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*perspective on signal generation and analysis*", 22–23 September 1989. Uppsala, Sweden, 1990, Price n.i.

When Kjell Strandberg, as Director of WHO's Collaborating Centre for Adverse Drug Reaction Monitoring, opened the Centre's anniversary symposium last September, he raised great expectations. The "global perspective" which was promised was designed to analyze the prerequisites needed before a series of adverse reaction reports are interpreted as a signal; the symposium was also intended to examine the advantages and disadvantages of the methods which are available to follow up the signals which such monitoring systems generate.

The total picture as presented during the Symposium does give a good view of the current state of the art in the post-marketing surveillance of suspected adverse reactions to medicines. What I should in fact do here is to play the role of Devil's advocate and discuss the prerequisites which were *not* presented or discussed. Why in particular, in view of all the excellent programmes described in the Symposium, do some of us still feel that we have not done as well as we might in identifying adverse drug reactions over the past ten – or twenty or forty – years? Perhaps confounding the issue is that the very basics of our so-called facts and primary prerequisites are not what they seem to be. I believe, on examining what was not said, that a number of factors turn up which may explain why a difficult problem is rendered much more complex than it should be. That question, the factors in question, and the solutions which could emerge, were not addressed in this Symposium.

Here are some of the basic and fundamental factors that must not only be accepted and understood but also taken into account in legislation, academic research, the literature and practice – however immense the undertaking. To begin with, current terminology and definitions are at odds with each other and therefore make for difficulties in using pooled data, especially if the pooled data are to be approached using conventional statistical and epidemiological methods. For example, are drug experience reports, drug adverse reactions reports (ADR), drug events reports, suspected drug adverse reaction reports and medicine adverse reaction reports the same? The answer, obviously, is that they are not the same; I believe they should not be mixed or pooled. These terms represent extremes; at one extreme there is no attempt to impute the drug product in the adverse reaction, whereas at the other extreme the physician has attempted to impute a relationship in the manner one uses in the practice of medicine – as one of many possibilities in the differential diagnosis of the disease in question. Pooling blindly the data from these two extremes leads only to increased difficulties. Another prerequisite that has to be addressed relates to the distinction between the terms "drug", "drug product" and "active ingredient" which are too often used interchangeably, again confounding the literature, the regulators and the practice of adverse reaction monitoring. A related problem concerns the extent of ignorance as to the potential effects of so-called non-active ingredients; their toxicology and pharmacology have yet to be properly addressed, and the dissemination of the role of these ingredients to be investigated. Without taking due account of the above before drawing conclusions as to "drug adverse reactions" one will certainly end up with misleading information and most probably the wrong chemical(s) will be incriminated. How does one expunge information that is in the literature and which blames an adverse reaction attributable to an "unknown excipient" on the active ingredient, since the active ingredient is the only chemical known to the investigator? And once the apparently "safe level" of an excipient has been determined, why are academia so unconcerned about the possibility that a patient on multiple drugs may be receiving many times this level? I call this the chemical load or "Z-factor" – specific or otherwise.

No less important is recognition of the fact that there are country differences in drug adverse reaction profiles and even differences within countries, from hospital to hospital and region to region. The WHO data base as well as national data bases should be programmed so that appropriate searches can be made by country, district, hospital and suchlike.

The continued use of the term “placebo effect” to mean a psychological effect only is misleading. Again one is reminded of all those so-called inert substances – tartrazine, lactose, metabisulphites and suchlike – which may make up a placebo preparation. In many clinical studies, nevertheless, the so-called placebo is merely the trial product minus the “active” ingredient. In such a case the adverse reactions resulting from the administration of this placebo are nevertheless subtracted from the “product adverse reaction profile” and what remains is attributed to the “drug”, whatever that may mean. A safer and more accurate adverse reaction profile for a new product would surely be that attributable to the entire product, since this is what the patient will actually receive. The final drug product should also undergo the usual toxicity safety studies.

The Uppsala Symposium leaves the reader with other questions. No reference is made to the fact that, at one time, causality in this field was graded on a 5–6 level scale; today there are only two grades or none. Was the change well considered?

And what about revising our definitions of a “drug”, a “drug product” and a known or suspected “adverse reaction”? That could solve only our confusion regarding excipients, but also the situations in which lack of the desired action is the first indication of an adverse reaction or interaction.

The literature on which so many algorithms and other apparently logical trains of thought in this field are based is misleading; it is misleading since as a rule the adverse reactions of the whole product are attributed to the “active ingredient” since that is the only aspect of the product of which the investigator is aware, all others being dismissed as irrelevant or unknown.

The most critical factor, as one looks both backwards and forwards a decade in drug adverse reaction monitoring, is the attitude of mind of the professionals involved. The Uppsala Symposium was excellent as regards the issues which it did address, but some of the basic research thinking in this field is still based on quicksand without addressing some of the basic requisites set out above. Unless they are addressed as we move ahead, we shall be back at Uppsala in 1999 to celebrate systems and structures once more but without having made the headway on D.A.R. surveillance which we must – and can – make.

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*In vitro diagnostische tests voor thuisgebruik (In vitro diagnostic tests for home use). Recommendation no. 05 of the Presidium Commission of the Netherlands Health Council, February 1990*

*Annual Report of the Netherlands Health Council (1990): no. 3.7, Doe-het-zelf tests (pp. 85–89). (“Do-it-yourself tests”)*

*Symposium “Thuis doktoren met doe-het-zelf tests: zin of onzin?” (Home doctoring with do-it-yourself tests: sense or nonsense?) February 8th, 1990*

Any international journal struggles (or should struggle) with the problem that some of the most important papers in its field are likely to have appeared in a language which is not accessible to most of its readers. Sometimes there can be a reason to draw attention to such work, simply because it may be an early sign of a new development. The emerging debate in The Netherlands on do-it-yourself diagnostic tests for the lay public is a case in point.

There is no reasonable doubt that, alongside professional care, self-care can contribute considerably to the wellbeing of mankind. Improved hygiene has been effective in eradicating infectious disease while changes of lifestyle (such as a sensible diet and abstention from “social drugs”) can substantially decrease the occurrence of, for example, cardiovascular and hepatic disease or lung cancer. The appropriate use of self-medication can alleviate a number of conditions safely and cheaply.

Although diagnosing a disease is largely the responsibility of medical practitioners, an increasing number of *in vitro* tests for self-diagnosis are being developed, covering a wide range of conditions, including pregnancy, urinary tract infections and diabetes mellitus; the assessment of genetic disorders, AIDS and various kinds of malignant disease is also coming within reach. Since the arrival of simple and reliable pregnancy tests in the sixties, however, self-diagnosis has been the subject of controversy and discussion. A change of attitude has followed, and many of us will now agree that self-detection of pregnancy has promoted feminine privacy and independence, although erroneous results and false conclusions have no doubt caused a certain amount of harm.

The Health Council of The Netherlands has recently reviewed the issue of self-diagnosis and its related problems, and the same subject was addressed during a recent symposium. A particular problem of self-diagnosis is that the reliability, i.e. sensitivity and specificity, of such tests is often limited; many of them can on occasion give false positive or false negative results. This may pose great problems with regard to interpretation and consequences to inexperienced users. A diagnosis is more than a step towards treatment; many a diagnosis may permanently change one’s life and prospects. The possible psychological effects of a test result should not be underestimated.

In the Health Council’s view, appropriate decision-making with regard to the quality and acceptability of self-diagnosis kits would require a special regulatory system in order to ensure that only reliable and practicable kits will become available to the public. Such a system is not provided for under current legislation, and the advice is given to use existing regulation with regard to medical devices for the pre-marketing approval of diagnostic kits.

Many people, on the other hand feel – for psychological or financial reasons – hesitation about consulting a medical practitioner, and early signs of disease may for that reason all too often be overlooked. One should ensure, therefore, that irrational and paternalistic considerations do not interfere unduly with the introduction of new approaches to the cheap and effective early diagnosis of potentially important diseases.

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