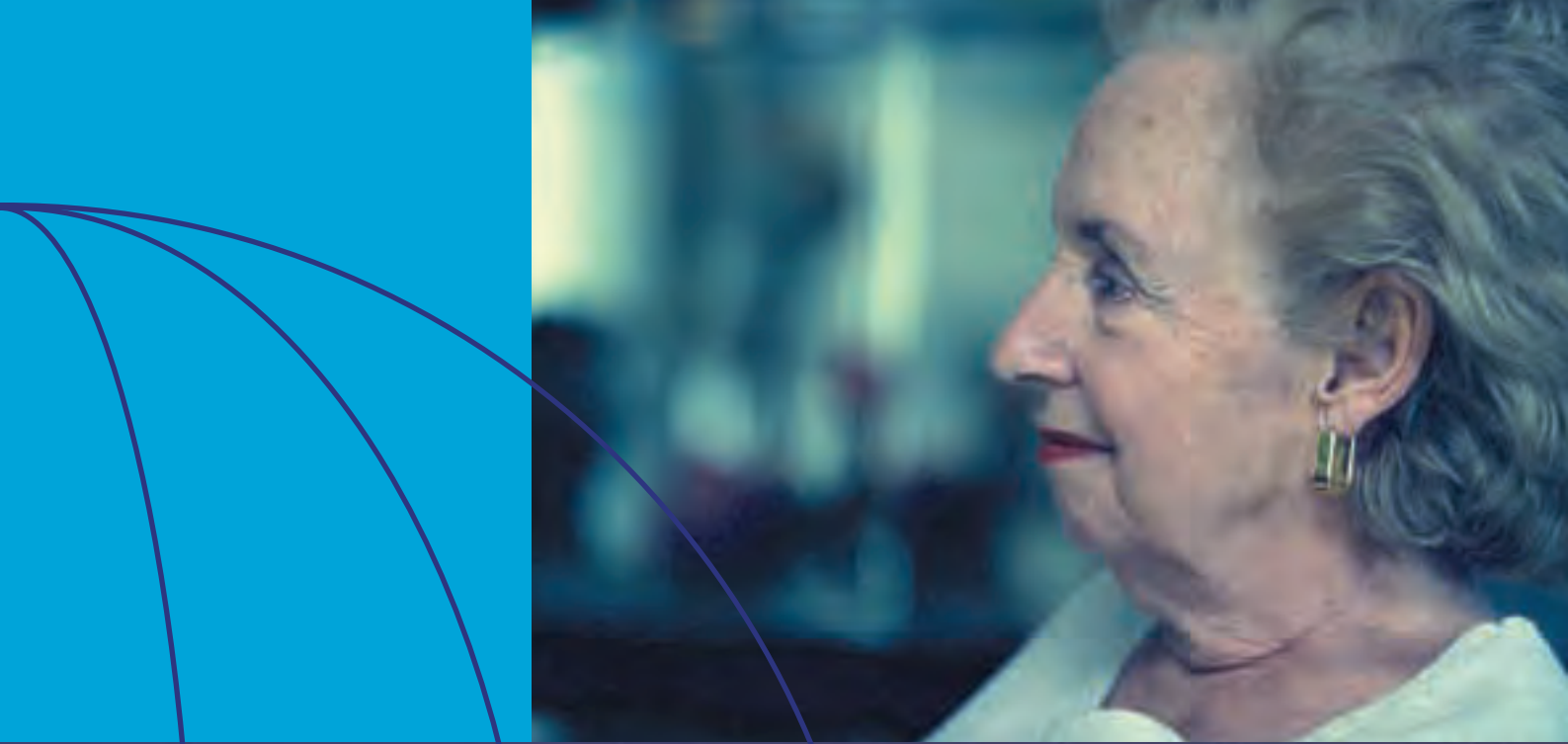




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PATIENT EXPERIENCES AND
THE VALUES OF MEDICINES

IV

INTRODUCTION

In our first paper (The Need to Assess the Value of Medicines), we pointed out that pharmaceutical agents are the fastest rising expenditure component of the health care system, certainly in the most affluent countries. We argued that evidence-based data on the benefits and risks of medicines must inform political and budgetary decisions, in order to shift the focus of debate from cost to value.

In our second paper (Achieving the Value of Medicines), we concluded among other things: There is no need for further investment in investigating and

documenting the issue of drug-related morbidity and mortality, in order for actions to be taken in this regard by the various stakeholders, and particularly by health care professionals. The key to addressing this problem is the collaboration between the various stakeholders, and particularly between **health care professionals** and **patients**. Leadership is essential to implement positive strategies. In the current vacuum of initiatives, pharmacists have a unique opportunity to provide this leadership and gain new professional opportunities.

KEY CONCEPTS

Expert patients, external validity, feedback, leadership, lived illness, Patient Provided Information (PPI).

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This brings us to the focus of the current paper: the patient **perspective** and the patients' experienced **values versus costs** for medication. These values (in plural) and also the costs (in all its meanings) may differ considerably from those that could be gained from ordinary **Randomized Controlled Trials (RCTs)** and **Patient-Reported Outcomes** by patients or their proxies (PROs), as proposed by the American Food and Drug Administration. PRO studies in drug development and evaluation include information about functional status, symptoms, psychological well-being, treatment satisfaction and treatment adherence; they are related to RCTs and should follow the same rules ^[1].



However, outside clinical settings there are no reliable and validated tools and methods that in a systematic way measure the patient's daily experiences of drugs-in-use. We now propose **Patient Provided Information (PPI)** as a novel approach to evaluate medications and get answers to the question "Does the medicine help?" ^[2], including the effects of long-term medication, interaction with other medications, forgetfulness, meaning, eating habits, biological variations, etc. The purpose of PPI is to assess the effectiveness of medicines related to the health or illness experienced by the patients in their contexts, preferably on a longitudinal basis ^[3].

PPI

Patient Provided Information

PRO

Patient-Reported Outcome

RCT

Randomized Controlled Trial

The question "Does the medicine help?" is one of the most usual in consultations, yielding answers valuable for diagnoses and medical treatments. PPI is intended to be a **systematic way** of collecting this kind of information and making it available, not only to individual doctors but to all groups, patients included. In this way, new and important connections and patterns might be recognized by patients as well as professionals.

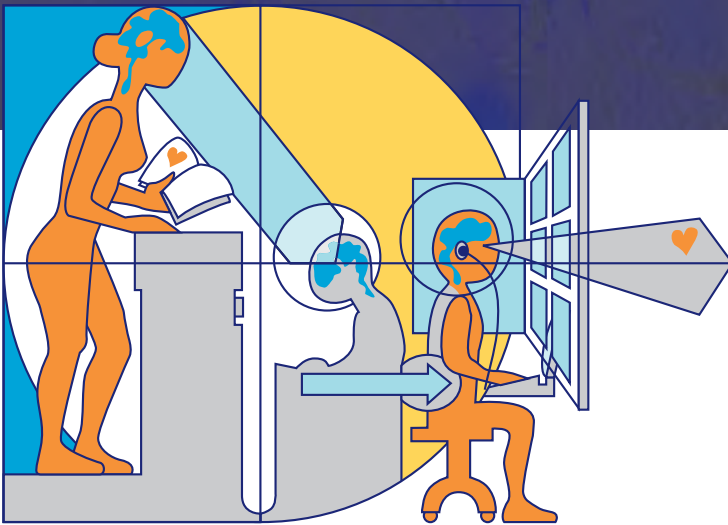
THERE IS A NEED FOR SITUATED RESEARCH, PERFORMED WHERE THE ACTION IS

The patients' own aims will be incorporated in PPI. Individuals are not blank slates, not even after the biological variations have been taken into account. Individuals have a context, a history, needs, wishes, dreams and fears, all influencing the effectiveness of medicines. For some the most important goal might be to get rid of symptoms, for others to be able to fulfill important tasks, and for still others to be able to take part in appreciated activities, if so only for short moments. To cover all this, the relevant research must be **situated** and performed **where the action is** ^[4], from the perspectives of the individual. In the context of disability, this has long been well established ^[5].

THE PATIENT IS THE EXPERT ON THE LIVED ILLNESS

PPI is closely related to the "**people first**" concept and the worldwide movement among people with disabilities for the right, in the first place, to be considered persons –human beings– with human, legal, social and consumer rights, cf. ^[6], and only after that as having a disability ("**people** who are blind"). Accordingly, patients should first of all be regarded as "**people** who are patients": experts on their own **lived illnesses**, including personal intentions and perceived meanings of health as well as medical treatment. Many scientific studies have shown that "subjective" health perceptions can be the best predictors of future longevity or mortality, better than the "objective" measures by the physician ^[7]. Facts only known by physicians need to be supplemented by values known only by patients ^[8].

FACTS ONLY KNOWN BY PHYSICIANS NEED TO BE SUPPLEMENTED BY VALUES KNOWN ONLY BY PATIENTS



In the authoritarian era, professionals (to the left in the figure) acted as **senders** and students, patients, etc. as **receivers** (the crouched boy in the middle). Today, well educated students or patients have raised their backs, turned around and act also as **searchers** (the boy to the right) and **senders**, in need of listeners and providers of feedback. (Key picture by Peter Broberg, Sweden)

We distinguish among four different patient perspectives

1. Patients as receivers and obedient subjects. One extreme is the authoritarian worldview with the professionals (to the left in the illustration) as the ones who know, prescribe and (sometimes) inform, and the patients as the ones who receive the medication and information. From this perspective, compliance is the main task of the patients.

2. Patients as RCT outcome searchers. Now many patients have come to regard themselves as empowered and enabled persons, qualified to search for information and medication themselves among available data from RCTs and, to a limited extent, PROs. The new technology, especially the Internet, is extremely favourable, especially when patients regard physicians as too busy and too distracted to care for them fully. Besides, online pharmacies now specialize in medicines which are highly valued by users. Just as an example: right now one of them markets Viagra, Cialis, Meridia, Propecia, Lipitor, Xanax, Valium, Celebrex and Paracodin (the same as Vicodin).

3. Patients as information providers. We anticipate patients demanding their right to provide the health care systems with their own experiences of drugs-in-use, i.e. PPI (Patient Provided Information).

4. Patients as PPI searchers. For the patients as well as for the professionals, structured feedback from PPI will play an important role (together with those from RCTs and PROs) and contribute to fastest possible decisions on the best medication for the concerned individual. For the patients themselves, the possible identification with others with similar experiences could enhance the meaning of the medicine as well as patient adherence.

Some remarks on the different roles:

1. Patients as receivers and obedient subjects

Professionals with profound knowledge are as valuable as ever for patients. Empowerment and enabling of the patients has not changed the need for professional expertise in diagnosis, caring and prescribing medication. Besides, **trust is a must**, and the effects of the meaning of a treatment to a patient^[9], often wrongly labeled “placebo effects”, is strongly dependent on the perceived trustworthiness of the professionals, and even more often, their enthusiasm for the medicines they prescribe.



THE PATIENT AS A RECEIVER

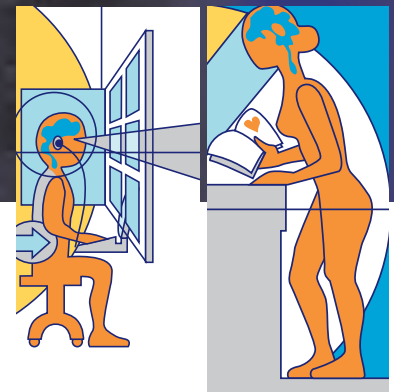
2. Patients as RCT and PRO searchers



FROM RECEIVER TO SEARCHER



AN AUTHORITY FACING THE BACK OF A NONLISTENER



WITH A NEED FOR PROFESSIONAL FEEDBACK AND STRUCTURING

Empowered patients, accustomed to seeking information, expect to be able to make their own choices. They are no longer only receivers, but also independent searchers, i.e. they have a twofold role pulling them in what could be opposite directions.

It is futile to expect obedient compliance from such patients.

Leadership is now needed for new education, new resource allocation and new strategies for the development of new roles for the professionals and relevant necessary listening- and feedback- functions to the patients.

3. Patients as information providers

Patients as senders of their experience of the effects of drugs-in-use are almost nonexistent outside of individual consultations. There are only vague preliminary steps to **systematize** Patient Provided Information Banks. Two of the most renowned large sample studies are the Nurses' Health Study ^[10] and the Framingham Heart Study ^[11]. The Nurses' Health Study started in 1976 with approximately 120,000 participants. The primary motive was to investigate long term consequences of oral contraceptive use. With time the range of questions has broadened and every two or four years cohort members receive questionnaires concerning diseases and health-related topics such as diet, smoking, hormone use, menopausal status and quality of life issues.

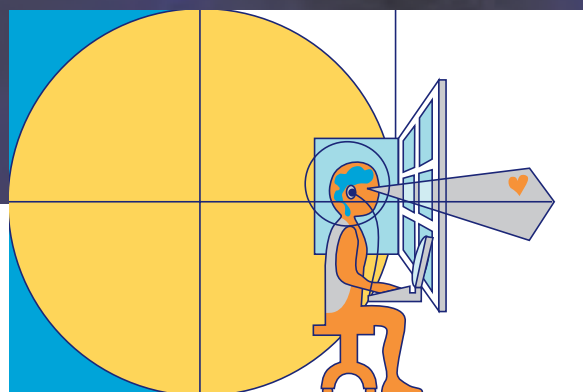
When the Framingham Heart Study started 50 years ago, more than 5,000 healthy residents of the town of Framingham were enrolled as the first cohort of participants. The aim was to investigate why heart disease had become the primary cause of death in the US by the late '40s. Not only was it the first major cardiovascular study to include females, by 1971 a second generation of Framingham citizens was enrolled. Data are collected every two to four years when participants are given extensive medical examinations.

Now, in 2004, The Swedish "Apoteket" – the government run pharmacy system of Sweden – is starting preliminary investigations on how to include **PPI** from the consumers in its **regular work**, cf. ^[2].

On the whole, few efforts have been made to collect Patient Provided Information, to structure it and make it available in different forms to other patients, relatives and experts, that is, to utilize it to its full extent.

Patient Provided Information will involve situated experiences and be related to patients in their contexts. Situated experiences differ from abstracted ones in many ways. By definition, they will not appear in clinical double-blind tests. There the setting is purely "clinical", and the mutual expectations of patients and doctors most often suppress important everyday experiences as well as wishes, fears and preferences. Instead you must search for the relevant information "Where the action is"^{[4], [12]} – a perspective well known and developed in many design areas^{[13], [14]}, such as contextual design, participatory design, and rehabilitation design^[15]. In the disability context, "useworthiness is the individual user's assessment of the extent to which the technology meets the user's high-priority needs"^[16].

Situated experiences of medication include not only the effects on the illness but get their flavour also from personal traits, preferences and backgrounds. This has major influence on the design of PPI studies. One of the effects is that the traditional independent control group will not be used: individuals will have to serve as their own controls in longitudinal studies.



THE PATIENT AS AN
INFORMATION PROVIDER

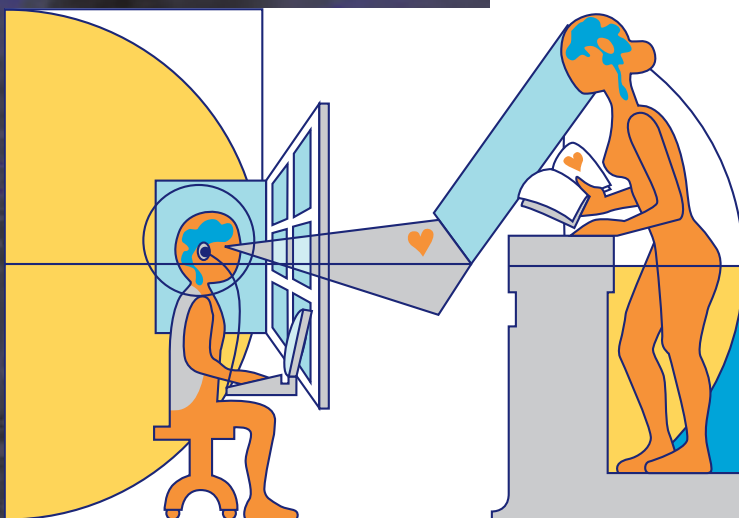
Although health care professionals have always committed themselves to the good of the patient, they can never share the patients' perspectives and lived illnesses in its contexts. It might help (at least in an early stage) to cut the umbilical cord between the patient perspectives and the professional ones rather than pretending they can be combined. To illustrate this, let us give some examples of individual Values Versus Costs for the patients:

- EXAMPLE:** For some people with rheumatism, there might be high values versus costs in specialized physical therapy or medication that enables them to get down on the floor (and up again) so as to be able to play with their grandchildren. For others, the necessary effort and the side effects of this treatment might be unacceptable.
- EXAMPLE:** For some people with SLE, the values versus costs of predictability in medical treatment are extremely high when indescribable pain occurs due to sudden inner bleedings. The values of knowing in advance that the next time this happens, I will receive adequate pain relief even if the doctor is inexperienced and hesitates due to the risk of heart failure, are great compared to the costs that I myself will take for the risk of the heart failure.
- EXAMPLE:** For some people with special neuropsychiatric disabilities, the values versus costs of amphetamines are great. The values in being not only awake but also concentrated for many hours of the day compensates by far for the costs that one's daily rhythm is controlled by the amphetamine and that many persons around might be sceptical to the medication.

4. Patients as PPI feedback receivers

Patients have a legitimate right to receive feedback from the PPI system. They will quickly find their own subgroups and expert patients, i.e. the contexts that are meaningful to them. Although this is an empirical question, it seems reasonable to expect that their adherence will increase when a prescribed medication can be related to identified role models.

Throughout these transformations, there will obviously be significant need for leadership, for new education, new resource allocation and new strategies for the development of feedback functions and roles for several sorts of professionals.



SENDING PATIENTS TAKE FOR GRANTED THAT LISTENING PROFESSIONALS ARE AVAILABLE, YIELDING STRUCTURED FEEDBACK.

Patient Provide Information (PPI) banks, freely available for patients, relatives, doctors, nurses and pharmacists, are meant to be an expansion and a structuring of the ordinary processes where the professionals gather information asking their patients about treatments, and listening to them; this is the foundation of “clinical experience”.

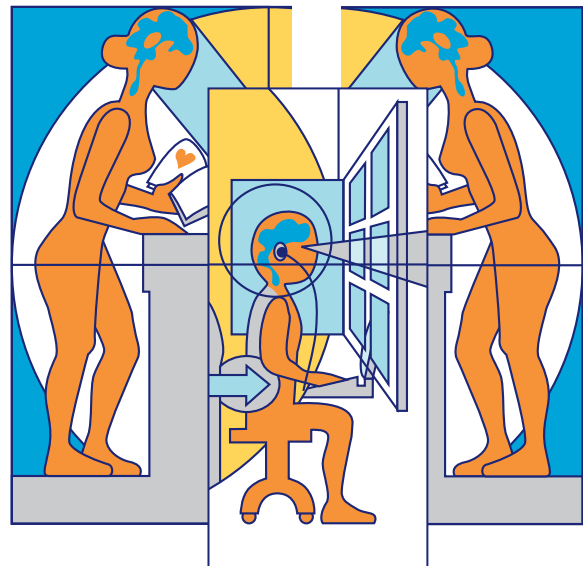
The legitimacy of the shift in the system from having professionals mainly as senders to also having professionals as listeners and structured feedback-yielders depends on the skillfulness in inventing, prioritizing and putting the reversal into ordinary practice. The very best professionals of today ought to act as inventors and role models. In the long run, it could be that entirely new professionals groups (medication coaches, for instance) should enter the arena.

Diagnosis, medication and now the concentration on biological variations are kindred spirits. They are scientific in a mechanistic sense: first comes the reason, then the effect. But when medication is related to functioning, symptom relief and personal preferences, the context is of a more teleological nature. It is the future and the aims that are in focus, not the reasons. We do not question the importance of RCTs and PROs, nor do we advocate pure myths. But peoples' wishes for the future influence the effectiveness of the existing medication, and this is not accounted for in the mechanistic paradigm.

According to Gadamer ^[17], health is **not** the same as the absence of illness. Health is something else: a rhythm of life, a harmony, a permanent stabilization of a balance, a wholeness. Arne Naess, the Norwegian philosopher, even has come up with a “formula” for this ^[18]:

$$\text{WELL-BEING} = \frac{(\text{PASSION})^2}{\text{PHYSICAL STRAIN} + \text{PSYCHICAL STRAIN}}$$

The “formula” draws attention to the fact that the aims, the passions, the future oriented aspects are as relevant for the “now” as are the effects of the stress caused by the efforts. A severe side effect of a medicine might be bearable for one person but not for another, due to different degrees of passion. A person preparing an important occasion might be willing to stand her pain rather than getting tired and unconcentrated through tough medication. Another person might have painlessness immediately as the one and only wish. Some people with severe pain willingly refrain from morphine if they only can keep their thoughts clear, others make the opposite choice. **PPI** might help distinguish specific communities inside a given diagnose group with different outspoken preferences for their drug use, effects and tolerable side effects.



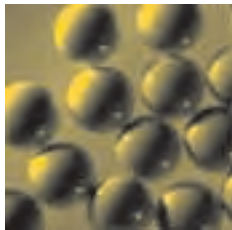
DIFFERENT PROFESSIONAL ROLES

MEANING, MEDICINE AND THE “PLACEBO EFFECT”

Classical efficacy trials do not typically include contextual matters that affect the meaning of pills and the consequences of that meaning for treatment. In RCT, “meaning” is considered an irrelevant response, a “placebo effect” that should be eliminated for the study of the “true” scientific effect on the human body of a certain molecular combination. “Eliminating” the placebo effect is one of many ways to abstract human factors to a level where all the permanent human searching for meaning is neglected.

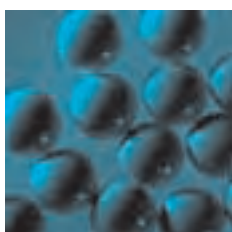
From the patients’ point of view, the concept of meaning should be not only positively considered but also used in a more conscious way and turned to a research object of its own. As long as it was considered only a product of the imagination it was regarded as almost unethical to try to enhance the “placebo effect”^[9]. But meaning is not about imagination, and meaning might be strongly specific. Compliance in using a certain medication might grow if the patients in **their** subgroup-of-intent in a PPI-bank can grasp something relevant to them– whether they can find it on their own or need professional guidance. It might influence life style factors such as physical activity, perceived stress, eating and sleeping habits, if people easily can get in contact with their likes and some expert patients.

The paradigmatic change of focus from “placebo” and “placebo effect” to “meaning” and “meaning response” is suggested by Moerman in his enlightening book with the same title as this chapter^[9]. The kind of rethinking that he suggests could lead to another insight into how treatment works. In its extension, it could even yield new evidence based methods for better healthcare, realizing that “meaning” gets its meaning only on the individual level and that, consequently, the evidence basis for measurements on “meaning” must be on the personal level.



EXAMPLE:

Sometimes substitutions upset people. They want to trust their own senses, and if a pill looks different and tastes different, it is no wonder that many people resist the professional information on the similarity of the effective substances. The “nocebo effect” takes over. Gone is an earlier high degree of compliance.



We would like to go even further and add that **meaning** and **different meanings for different patients** could and should be given a high priority in everyday health care, drug prescription and evaluation. **PPI on meaning** could be given a scientific priority. Efforts to find **specific** meanings for different patients could increase the influence of “meaning” far above the “placebo effect”. In the **lived illness**, meaning has a strong impact. It is neither decent, appropriate nor effective to go on neglecting it scientifically. The needs for new patterns of thought and new concepts are obvious.

This is just one of many indications that “meaning” makes a difference. To the doctor and the pharmacist, it is the molecular content that counts, but to the person it is the pills **per se**. If you have become accustomed to pills of a certain size, a certain color and in a certain box, you might have become conditioned to that appearance; their **meaning** is, in part, conveyed by their appearance. For substitutions to be not only cost-effective but also **values-versus-costs-effective**, the aspect of meaningfulness for the person can no longer be neglected and rejected. At the top of the agenda for substitutions should be the issue of **perceived** sameness for the person.

Efficacy –that a medicine is efficacious in clinical trials– is a necessary but not sufficient condition for a medicine to be effective. Efficacy is measured in clinical trials with a patient population based on certain inclusion and exclusion criteria. Children, pregnant women, the very elderly, and those taking other medicines are often excluded since the aim is to minimize possible confounding factors that would shadow the “pure” effects of the tested drug. The consequences are that even though a clinical trial may be internally valid, interpretation of results are by necessity restricted to the population where the treatment has been evaluated. It may, therefore, be of limited value – a fact that is too often both neglected and ignored. **External** validity is today hardly on the agenda, but it is the external validity that is closely related to the **effectiveness** of medicines and relates to **values versus costs**. Without **Patient Provided Information** and with efficacy as the only measure, the picture is oversimplified.

EFFICACY IS A NECESSARY BUT NOT SUFFICIENT CONDITION

Methods are needed to measure **effectiveness/usefulness**: that the medicine works well in everyday usage. As early as 1995, Johnson and Bootman ^[19] estimated the “efficacy versus effectiveness” gap in both clinical and economic terms. Drug-related problems were found to account for as much of the health care costs as were the pharmaceutical expenditures themselves. Revisiting this gap from the patient’s perspectives we notice that not only should the pitfalls of drugs-in-use be taken into account, but also the possible benefits of systematically focusing on a patient’s “community of **meaning**” should be attended to.

How questions are to be formulated, studies to be carried out, and answers to be analyzed and followed up is in part virgin territory. Medical science has been so trapped by randomized controlled trials that other lines of action have been literally inconceivable. Now, there is a need for numerous contributions from experimental work, developmental work and research. Different set-ups should be tried in different countries. Interviews in the privacy of the patients’ homes or mail or web questionnaires might be feasible everywhere. In Sweden with its integrated health system, PPI could also be collected at the national pharmacies or in the waiting rooms at the medical care centres, using computers placed in quiet corners.

INTERNATIONAL CLASSIFICATION OF

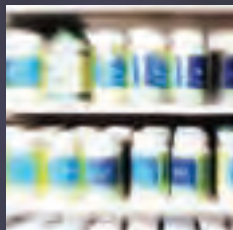
FUNCTIONING, DISABILITY AND HEALTH

The **International Classification of Functioning, Disability and Health (ICF)**, so far scarcely used in medical contexts, could be helpful, at least initially, while exercising the imagination on how **Patient Provided Information** can influence health care on the whole. The ICF was endorsed by the World Health Assembly in 2001 after five years of systematic field trials and international consultation ^[20]. The overall aim of the ICF classification is to provide a unified and standard language and framework for the **description of health and health-related states**. It could be that Patient Provided Information (PPI) could be analyzed in terms of the categories and structures of ICF, thus structuring experience into meaningful data.

It was a big step forward when WHO relinquished its previous disability classification system, the **International Classification of Impairment, Disability and Handicap (ICIDH)**, and came up with the **ICF**. To base the classification system on **function** rather than disability, starting with the **function** rather than the **dysfunction**, constituted a 180 degree turn around. Its influence on the disability context has been comprehensive. It could be that the **ICF** and its followers can influence the pharmaceutical area as well. ICF is not only about people with disabilities; in fact, it is about **all people** and has **universal application**.

In the pharmaceutical and medical world, the **ICD-10**, the **International Classification of Diseases** ^[21], is a well known classification system. From the doctor's point of view, it is the ICD diagnoses of illnesses that are considered relevant for the prescriptions and the follow-ups of the medications. But for patients and their experience of drugs-in-use, the ICF might be at least as relevant as is the ICD-10. Being able to handle a **desired function** –for example eating, sleeping, walking, cooking, driving, climbing stairs, playing tennis, going hunting, and being free of pain– is what makes the difference to the patient.

Information about diagnosis plus functioning provides a broader and more meaningful picture of the health of persons or populations and can be used for decision-making purposes. WHO encourages users to utilize the ICF and the ICD-10 together. Drug reimbursement decisions, for instance, could be influenced if the ICF and the ICD-10 were used in a complementary fashion. ICF is as complementary to ICD-10 as is PPI to RCT.



ICF IS AS COMPLEMENTARY
TO ICD-10 AS IS PPI TO RCT

Medicine has traditionally been subjected to the scientific ideal of **objective** assessments of disease and health. Consequently, the evaluation of efficacy of medicines often includes outcomes such as laboratory values, recording of performance and physiological measures. However, during recent decades the patients have come more in focus and research has documented results quite contradictory to what sometimes could be expected from the objective approach. The “paradox of health” has illuminated that mental health cannot be explained by physical and/or medical factors only ^[22]. For example, better health status, as measured by traditional indicators, is not automatically accompanied by improvements in well-being or perceived health gain. To people with COPD (chronic obstructive pulmonary disease) improved mental health does not necessarily follow an increased walking capacity from 100 to 200 meters. Nor does deterioration in physical health always result in impaired mental health: several population studies have documented a powerful capacity in people to adjust to the burden of chronic disease or disability ^[e.g.23]. A large part of the variance in mental health seems to follow from the individual’s perception of himself, the situation, and his possibilities.

PARADOX OF HEALTH - MENTAL HEALTH IS NOT EXPLAINED BY PHYSICAL AND/OR MEDICAL FACTORS ONLY

Consequently, patients’ assessments of the effectiveness or usefulness of medicines are vital. The consumer is the natural and primary source of information. The collection of data in a new area like this is decidedly complex: methodological combinations of ethnography, open interviewing, and survey technique (either by structured interview, self-report, or computer assisted survey) must be used in each case. The goals are concision, precision, and aptness; no two situations will be quite the same. For a thorough consideration of the issues, we recommend the work by Patrick and Chiang ^[24].



WE SUGGEST THAT EXPERIMENTAL WORK AND RESEARCH ON PPI SHOULD

- be hypothesis driven
- be longitudinal in design
- include an internationally verified instrument, like SF-36 ^[25]

With all studies come limitations. With PPI, some of these concern practical issues: the risk of self-selection of participants, possible channelling biases, and privacy issues, just to mention a few of them. All these questions have to be addressed and evaluated.

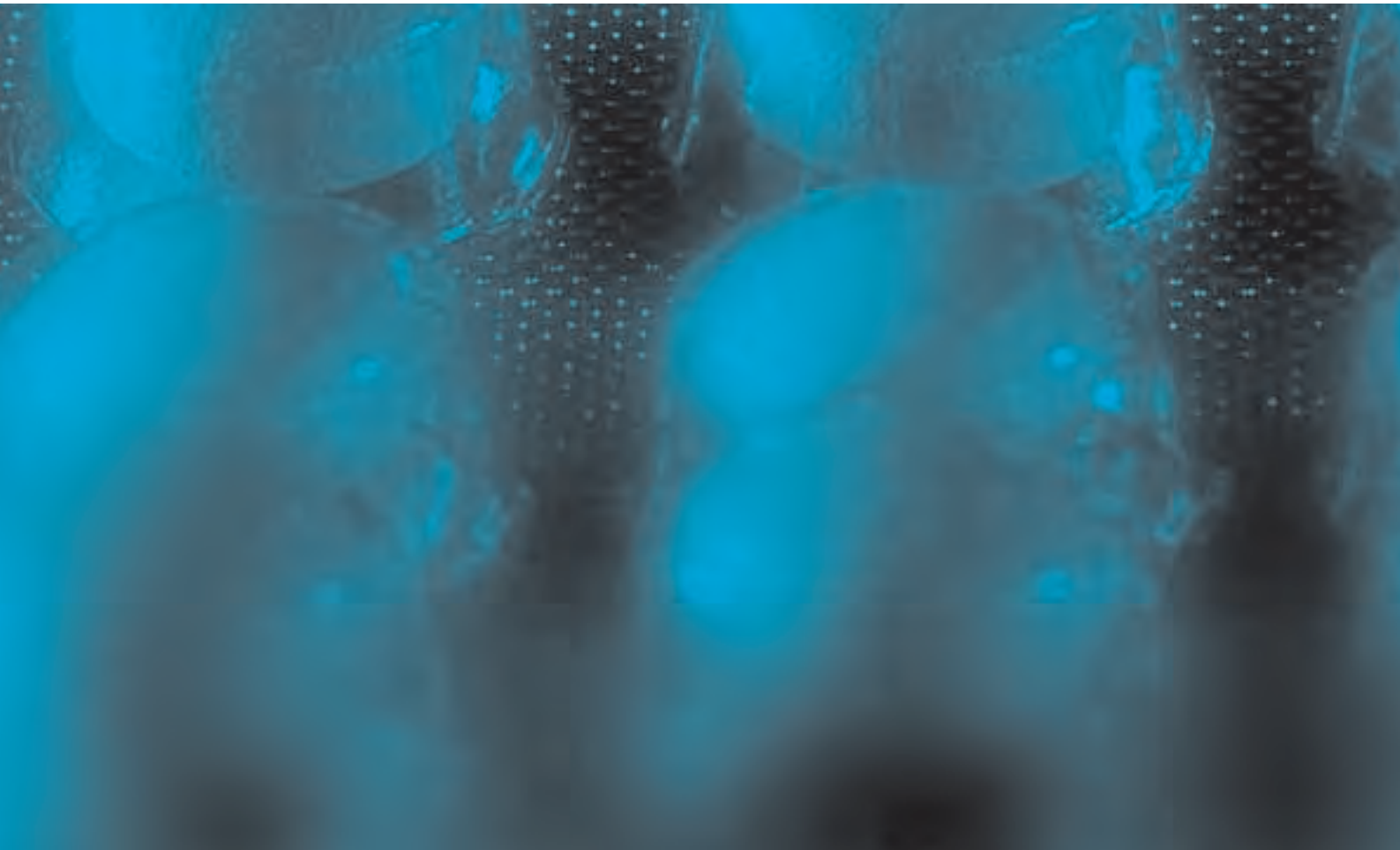
CONCLUSIONS

For some years now, **efficacy, safety** and **cost-effectiveness** have been focussed on by health professionals. However, far too little attention has been paid to patients' **lived illnesses** and their **perspectives on medication**. We propose the concept of **Patient Provided Information (PPI)** as a novel approach to evaluate medications.

We reemphasize that results from **double-blind clinical trials** are indispensable but they do not give the whole truth. One leg is missing, PPI: the systematically compiled perspectives originating from the patients outside a clinical scenario. It will be a challenging and inspiring mission to introduce evaluations through PPI. Interesting controversies will arise when conventional results and PPI yield contradictory results.

WE URGE HEALTH PROFESSIONALS AND POLICY MAKERS, IN PARTICULAR WHO, TO PUT PPI ON THE AGENDA AND FUND EXPERIMENTAL WORK IN ORDER TO DEVELOP AND VALIDATE METHODS AND TOOLS.

It is an open question who will take leadership for this. It might be WHO, national health departments, professional health organizations, patients' organizations, political parties or NGOs. Whoever does so will contribute significantly to the outcome of future healthcare.



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