

The New Patient and Responsible Self-Medication Practices: A Critical Review

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Abstract: Due to a wide range of factors, such as increasing access to health information and government policies to promote self-care during the past 20-30 years, the “new patient” or ‘expert patient’ has become information strong, information seeking, increasingly demanding (or even aggressive) and skeptical of expert knowledge. This evolution in the patients’ profile has deeply changed the relationship between the patient and the health-care professional and the patients’ self-medication practices. As a result, the classical paternalistic model of health-care professional/patient relationship has shown its limitations, and new models have been proposed and adopted in the health-care community. In this paper, we have carefully analyzed the causes behind the changes in the patients’ behavior and their consequences on the self-medication phenomena, and discuss which of the known models of patient/health-care professional relationship (from the paternalistic to the deliberative model) should be adopted in order to move forward to responsible self-medication conducts.

Keywords: Responsible self-medication, informed patient, OTC shift, direct to consumer advertising, physician-patient encounter.

INTRODUCTION

The use and advertising of drugs has experienced what seems to be a pendular movement between being low regulated (or even non-regulated) activities at the early XXth Century to strong drug regulation that reached its maximum around 1960s, after the thalidomide tragedy. A progressive and clear movement in the opposite direction (‘deregulation’) can be traced since 1970s, due to several and complex socioeconomic factors which include social movements to secure patients’ rights, pressure from the pharmaceutical industry to lessen restrictions, and governments’ Public Health policies [1-3]. Greater access to medications and health information and greater participation in medical decision making have dramatically changed the public’s attitude regarding control over health and life quality. As a consequence, traditional paternalistic, physician-centered model of patient/health care provider relationship and health care professionals’ authority have been undermined, and new participative models of health professional/patient relationship have emerged and been adopted in the health care community.

The recognition of both the limitations of the traditional professional health system and the patient’s rights to an active involvement in the management of its own health has resulted in the reinvigoration of self-care conducts, among them, responsible self-medication. Responsible self-medication is defined as the use of over-the-counter (OTC) medicines for the treatment of self-recognizable conditions, or chronic conditions whose symptoms the patient easily recognizes based on previous experience and previous diagnosis by a physician [4]. World Health Organization (WHO) considers the safety of the drugs used in self-medication and the accessibility of the patient to the necessary information for safe, correct use (for example, through the packaging or information inserts and health-professionals’ advice) as fundamental conditions for self-medication to be considered a safe practice. Self-prescription (the use of prescription medicines without a physician prescription, whether the availability of medications is due to left-over medications from previous prescriptions or to illegally acquired medicines) constitutes a clear non-responsible self-care

behavior, since ‘prescription only’ status indicates that a particular medication can not be safely used without a physician’s diagnosis and surveillance.

This article discusses the profile of the new, empowered patient, the socioeconomic factors that have contributed to its emergence and its relationship with self-medication. We also review the features of the new, participative models of patient/health care professional relationship that have been proposed in the frame of those changes and discuss the advantages of these models in this new context.

Before proceeding with the next sections of the article, we would like to make a few considerations.

We have preferred the use of the term ‘new patient’ instead of ‘new consumer’ or ‘new consumer of Medicine’ to describe an information strong and information seeking patient, committed to actively participate in the promotion and restoration of its own health and no longer showing blind faith in the health professional advice [5, 6]; in some extreme cases, the new patient can show himself skeptical on expert knowledge and be perceived as challenging, demanding or even aggressive by the health care provider. Our preference of the expression ‘new patient’ is related to philosophical considerations. The word ‘consumer’ refers to a buyer of goods and services; the term ‘patient’ refers to a person that is recipient of a health care service, and its meaning has been developed outside the context of commercial markets and without regard to the existence or source of payment for health care. Although many patients pay for a health service, the buying role is not essential to (nor always present in) the patient/health care provider relationship. The patients’ rights to an active participation in their own health management are founded on humanitarian and ethical reasons, and not in economic causes [2, 7]. Furthermore, Lupton has pointed toward the unique nature of the medical encounter in relation to embodiment and emotional features, which prevents from completely taking up the consumer approach [8]. Even when some features of the new consumer might be present in the new patient (for example, the greater access to information sources) we believe the new patient concept suits better to the aims and nature of this article¹. Further discussion on this subject may be

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¹ It is worth mentioning that sometimes “consumer” has been preferred over “patient” because the etymology of “patient” suggest a passive role, in disagreement with the modern model of participative health care services.

found in the *Consumption culture, medicalization and self-medication* section of this review.

Secondly, while most of the literature regarding models of patient/health professional relationship specifically refers to the patient/physician relationship, we believe they can also be applied to much extent to the interaction between the patient and other health professionals, such as the pharmacist. This is consistent with the new model of pharmacist promoted by WHO, and also by many academic institutions and government agencies, which, in the light of the growing interest on self-care, describes the pharmacist not only as a quality drug supplier but as a communicator, trainer, supervisor and health promoter [4].

We have divided the body of the review in seven sections. In the first four sections we have considered the socioeconomic factors that we believe have shaped the new patient relationship with medications and the health care services: Internet, increased drug availability through shifts from prescription only medicine to OTC status, consumption (or market) culture and drug advertising in massive media. For practical reasons we have tried to analyze concisely these four aspects of the new patient's background in a rather reductionist approach, although we admit that all of them overlap to some extent (as explicitly indicated in the different sections) and they should be looked at holistically. The fifth section describes different models for the patient/health care professional encounter. The last sections are meant to integrate, through a critical discussion, the different subjects approached throughout the article presenting some brief final conclusions.

INTERNET AND THE INFORMED PATIENT

As we have already mentioned, consumer involvement in health has been radically transformed during the past decades. Since the 1970s, patients' rights movement has advanced towards a more active participation of patients in decision making about their own health. This process, through which individuals achieved information disclosure and participation in treatment decisions, has been referred as patients' empowerment and has reshaped the boundaries of medical responsibility.

Access to quality information is considered central to the empowerment of patients, bringing some balance to the asymmetric nature of the patient/health care professional relationships and pushing the development of participative models [9]. Although a considerable degree of information disclosure had been reached since late 1970s (for example, through development of new models of patient/medical encounter and the request from regulatory agencies to include package inserts) [2], the advent and expansion of the Internet have revolutionized patients' access to information. According to surveys conducted in both developed and emerging countries by the World Internet Project (WPI, a major international collaborative project looking at the social, political and economical impact of Internet and other modern technologies) a very large, growing percentage of Internet users go online occasionally for information about health topics (see Fig. 1 for a comparison of percentages through some of the countries involved in WPI) [10a-10f]. Online assistance on health topics may be provided through a wide range of alternatives, such as health related sites in the World Wide Web, mailing and discussion groups, e-mails, news groups and other forms of computer mediated communication [11]. Eysenbach has emphasized that the increasing availability of interactive information through modern communication technologies coincides with the desires of most consumers to assume responsibility in their health [12]; according to him, information technology and consumerism are synergistic forces that promote emergence of an 'information age healthcare system'².

Although we accept that consumers' rights movement and patients' rights movement claims overlap to some degree (specially regarding the importance of information disclosure to bring balance to an asymmetric power relation), we will refer once more to the fundamental distinction between patients and consumers that we have discussed in the introductory section of this article. From our point of view, information technologies interrelates in a synergistic manner with both consumers and patients' rights movements, which are phenomena clearly previous to the Internet era.

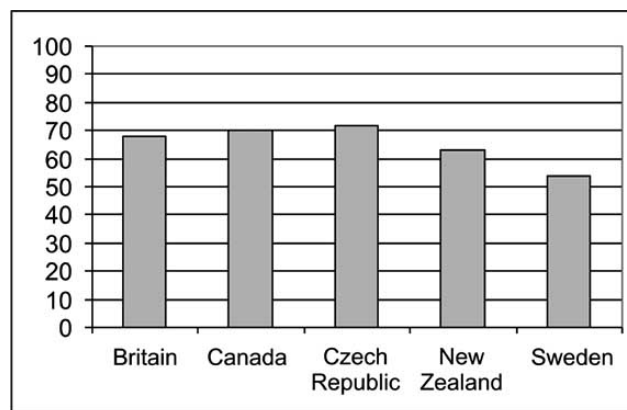


Fig. (1). Percentage of Internet users that look up health/medical information in the web in various countries according to recent findings of the World Internet Project.

How does increased access to medical and health related information through modern communication technologies influences self-care behaviors? Although Internet provides information to assist the patient in self-management and decision making for the treatment of general diseases and ailments, it is a particularly important source of information for those patients interested in complementary and alternative medicines (CAM) [6, 13-18]. A culture of 'professional disinterest' and silence in relation to CAM has been described by patients; consequently, patients often show themselves reluctant to raise the subject of CAM at the medical encounter, because they fear that the practitioner may disagree, and the level of disclosure of CAM to medical practitioners and other health care professionals remains low [19-22]. Practitioners, nurses and pharmacist are rarely cited as sources of information on CAM [6, 23]; instead, patients often rely on other information sources such as the Internet and lay referral networks that include friends, family, work colleagues and other acquaintances. Consequently, a very high proportion of CAM corresponds to self-treatment and self-medication practices. The use of the Internet to look for CAM could be especially significant in the case of diseases which are not adequately managed through orthodox medicine [15-17]. There are also some distinctive characteristics of the Internet (such as privacy and 24 hour availability) that make it an interesting source of information for self-diagnosis and self-treatment of stigmatized health conditions, such as sexually transmitted infections, urinary incontinence, depression and drug-abuse; the associated social stigma of these and other embarrassing diseases may prevent patients from seeking professional medical care or even help in the lay referral network [24-26].

Since we have already mentioned that quality information is essential to allow patient empowerment and make judicious, shared medical decisions (or judicious self-management of health decisions in the case of self-treatment), can we actually think of the new patient as a true empowered patient? A huge issue regarding

² Even though the term consumerism is used by Eysenbach with the sense of 'promotion of consumer rights and protection' we will prefer, throughout the article, the concept of consumers' rights movement, reserving

'consumerism' or 'consumption culture' to describe conspicuous consumption and pursue of personal happiness or satisfaction through purchase of trade item or services.

the use of the Internet as health care information source is the quality of the information provided by the unregulated electronic space of the World Wide Web. Both expert and lay agree that the Internet provides access to a lot of useless and potentially misleading and dangerous health-related information. A very large number of systematic studies prove that the quality of the online medical information is extremely variable [27-37] and reports can be found on cases of death associated to Internet misleading information [38-40].

Many public and private initiatives have been directed to provide patients and practitioners with reliable search engines of medical information online, supply quality certifications to health websites which accomplish standardized quality criteria, provide guidelines to identify high quality websites and develop ethical codes for self-certification of websites [41-43]. Developing credibility markers and reliable search engines is important, but it is an incomplete solution to the problem of quality of health-related resources in the web if the patients that use Internet as information source on a disease or treatment do not develop the habit of looking for quality markers.

Several studies illustrate patients' difficulties when searching and appraising medical information in the web. In a qualitative study based in focus groups, naturalistic observation and post-observation interviews which took place in Germany, Eysenbach and Köhler found that there seems to be a gap between the self-perceived searching and appraisal competence of patients and the actual competences of the patients when surfing the web [44]. Even though participants of the focus groups stated that they looked for the source of information (among other quality indicators) to appraise the content of a website, the observational study showed that no participants checked the "about us" section of websites, disclaimers or disclosure statements. Moreover post-search interviews indicated that few patients (20.9%) remembered which websites or company or organization they retrieved information from. The authors of the study recognized the small number of participants (N=21), the artificial environment in which the search was conducted and their uncertainty regarding the representativity of the sample as limitations that prevent them from arise general conclusions. Another observational study on adolescents (N=12) showed that adolescents with strong Internet searching skills rarely look for the source of the information that they gathered from the web when looking for health information [45]. Lack of representativity of the sample was also pointed out by the authors as and impediment to generalize the results to all adolescents. A qualitative study using focus groups on a sample of Internet users from Sidney, Australia (N=46) revealed that many patients appraise medicines-related information on the web by just looking at the URL of the results; most participants do not pay conscious attention to how they select Internet-based medicine related information or experience difficulties when trying to articulate their selection process, mentioning vague quality indicators (frequencies are not shown in the original article) [46]. Many participants of this study admitted experiencing difficulties in their evaluation of information and most of them used Google as search engine, instead of a more specific one. This study also revealed a very interesting inconsistency in the users experience when looking for information on medicines on the web: even though most of the users were skeptical on the reliability of Internet-based information on medicines, all saw Internet as an important source of information, mainly due to its accessibility. A study based in information review groups on 32 members of patients support groups from Scotland showed that patients fail to find indicators of evidence-based information and that they manifest lack of confidence about their abilities to select quality health information [47]. An observational study with post-observational interviews on 48 participants from Toronto and Vancouver showed that summaries and URLs are key elements for the user to select a particular website from results list, while participants tend to rely on websites sponsored by

government agencies and disregard sites that aim to sell products [48]. Ease of finding and understand information also impacted on the use of the site. Although most of these studies agree in the need of further studies with more participants, a more representative sample or other methodological approaches, and even though quantitative studies on this subject would be valuable, the reports of qualitative studies clearly indicate that quality markers are not enough to segregate reliable from non reliable health information sources in the Internet, but that also campaigns or interventions to provide the user with the basic tools to recognize quality markers and correctly appraise online medical information are needed.

Another issue of concern regarding online medical info is information overload [49-51]. Usually, an individual's efficiency in using information is hampered by the amount of relevant and potentially useful information available, leading to what have been called "information pathologies" such as information anxiety (a condition of stress caused by the inability to make use of or understand available information) [52]. We may refer to the "paradox of choice" [53]: in many social and economic settings it has been observed that, while some degree of choice is good, too much choice leads to indecision or bad decisions. Information avoidance and information filtering (ignoring potentially relevant information because there is too much information to deal with) are extremely common strategies for coping with information overload [54]. When the cost of information is high (e.g. if it takes a lot of time to get complete information or if the patient feel distressed when looking for medical information) limited information tends to be retrieved; the use of partial, incomplete information is of course particularly dangerous in the case of medical data gathered to assist self-medication practices. Some of the strategies that have been developed to help the patient to cope with information overload include adaptive websites (sites that automatically improve their organization and presentation by learning from visitor access patterns, e.g. facilitating additional meta-information or guidance) and medical virtual reference desks (directories of selected, indexed web pages generally compiled by medical institutions), among others [49, 51, 55].

Healthwise, a non-profit organization aimed to develop health contents to help patients to make well-informed health decisions, summarizes the features of quality information for the patients as follows: a) the information must be organized in a way that helps patients make good decisions; b) it must be evidence-based; c) it must be unbiased; d) it must be referenced and reviewed by experts and; e) it must be up-to-date [56]. Note that some of these requirements coincide with those expressed by the participants of the Canadian study from Toms and Latter. Fig. (2) presents a summary of the advantages, disadvantages and possible solutions of the use of Internet to retrieve medical data to assist self-medication decisions and practices.

SWITCHES FROM PRESCRIPTION TO OTC STATUS

As a part of a worldwide ongoing deregulation process, the number of medications available OTC is increasing and the OTC status is no longer linked to medicines aimed to treat minor ailments but is currently expanding (not without controversy) to medicines for the treatment of chronic and sometimes silent conditions (e.g. simvastatin).

Many economic and public health interests lie behind a medication switch from prescription only to OTC status; moreover, there is no doubt the availability of a medication OTC favors the opportunities of self-management of a disease by the patient, encouraging self-medication and patients' active involvement in health management, thus redefining the balance of power among a) the different healthcare professionals (pharmacists seem to benefit from the ever-increasing number of OTC drugs) and, b) the healthcare professionals and the patients [57-61].

ADVANTAGES	DISADVANTAGES	POSSIBLE SOLUTIONS
<ul style="list-style-type: none"> ✍ Accessibility to general medical information to assist the patient in self-medication practices ✍ Accessibility to info on CAM (traditionally underestimated by health care providers) ✍ Privacy (valuable in the case of socially stigmatized conditions) ✍ 24-hour availability 	<ul style="list-style-type: none"> ✍ Plenty studies confirm that the quality of medical information in the web is highly variable ✍ Many patients manifest difficulties appraising health-related info ✍ Information overload ✍ Online pharmacies allow acquisition of prescription drugs on the mere basis of answering an online questionnaire 	<ul style="list-style-type: none"> ✍ Development of quality certifications ✍ Development of public websites on health matters ✍ Development of specialized search engines that retrieve reliable data ✍ Interventions and guidelines to educate the patient about medical info search and appraisal ✍ Adaptive websites ✍ Virtual Reference Desks

Fig. (2). Advantages and disadvantages of the use of Internet to obtain medical information to assist the patient in self-medication decisions, and possible solutions to the identified difficulties.

Economic reasons behind a status switch include patent owners' desire to extend viability of brand names and expand the market around the time a patent expires, and attempts from healthcare founders (e.g. health insurers) to contain costs (there is a strong tendency from health insurers to remove switched drugs from their formularies and raise co-payments in the same therapeutic class; for patients with limited means, OTC status may then paradoxically reduce the accessibility to medication) [59, 60]. The fact that OTC medications can be advertised directly to consumer constitutes an additional incentive for pharmaceutical companies to push status switches in those countries where direct-to-consumer (DTC) advertising of prescriptions drugs is illegal [62].

Public health interests behind a status switch include increased and faster accessibility to pharmacologic treatment for the patient, a major advantage in countries with congested health systems and large urban centers where getting an appointment with a physician is problematical, and also when the delay implicit in visiting a doctor might jeopardize the treatment efficacy, e.g. contraception pills [52-61]. In a deregulated scenario, hard-pressed practitioners are freed from prescribing medications for minor ailments and pharmacist professional skills are better exploited [62]. OTC status also increases drug accessibility for people that lack health insurance, for who the need to see a physician to get a prescription may be a financial barrier for the management of their medical condition. Somewhere between economic and public health interests is the reduction of prescribed drug costs associated with publicly founded health programs, which might help to divert governments expenditure on minor ailments to the funding of treatment of more serious health conditions.

Among the necessary criteria that a drug should accomplish in order to acquire OTC status are safety, efficacy and ease of diagnosis of the condition that the drug is aimed to treat [61]. Since very rare idiosyncratic adverse reactions to medications are possible for any drug, very uncommon severe reactions are generally not considered impediments for a drug to attain OTC status if the

potential benefit is considered to outweigh the potential harm. Efficacy should be mandatory: it has been argued that patients might choose low effective but readily available medications instead of more effective but less readily available ones. Reviews on clinical trials of cold and cough medications indicate that there is no conclusive evidence on them being effective in children either as cure or symptom relief, and that some medications have neither shown definitive proof of efficacy in adults [63-65]; if that were the case, safety should not be considered as enough criteria to reach OTC status, and neither should placebo effect. Finally, the medical condition treated through OTC medicines should be easily diagnosed by the patient or, alternatively, a previous diagnosis should exist from a physician in the cases of chronic conditions. This last point is tricky, since at present there is no practical way to know whether this initial diagnosis by a practitioner does or does not exist, while some studies suggest that in many cases diagnosis and treatment selection take place almost exclusively within a lay network, and some of the symptoms targeted by OTC medications are highly unspecific and common to several conditions [1, 58]). These criteria are not uniform or uniformly applied across the different national regulatory agencies, and therefore notable differences exist among the medications that have acquired OTC status in different countries worldwide [66].

There are several concerns regarding OTC medications related to safety and public health. A major safety issue is polypharmacy [61]. OTC medicines can be acquired in many countries through commercial circuits that completely exclude health care providers, such as Internet or drugstores. Even in those countries where there exist behind the counter medications (BTC, an in-between category consisting on medications that can only be assessed through pharmacies, with pharmacist surveillance) pharmacists do not have access to patients' medical records and this increases the risk of potential interactions. Due to a higher prevalence of chronic conditions, risk of interactions is particularly high in the elder population [67, 68]. Several studies confirm association between adverse reaction to medicines in patients attending the emergency

service of hospitals or being admitted in hospitals and OTC drug consumption (particularly, NSAIDs) [69-71], while Rieger *et al.* have proved high prevalence (61%) of unknown co-medications in urine samples of hospitalized patients (N=44) [72]. Another potential risk of OTC drugs is the delayed of suboptimal treatment of serious diseases (e.g., the use of H₂ receptor antagonists, which reached OTC status for short-term treatment of dyspepsia, may delay optimal care for more severe gastrointestinal diseases). Furthermore, a tendency to erroneously suppose that OTC medicines are absolutely innocuous has been recognized. In a multiple approach that included non-participant observations in 10 community pharmacies in the North West of England, interviews to consumers of deregulated medicines (N=94), focus groups with patients and interviews to pharmacies' staff, Hibbert *et al.* identified associations between the relative availability of OTC medicines and risk perception by the patient; in fact, many participants reconsidered their perception of risk of OTC medicines when the authors signaled that many OTC medicines had prescription only status in the near past [1]. Other public health concerns of moral nature regarding OTC medications have been raised: does the availability of OTC medications prevent positive changes in lifestyle (e.g. in the case of ant-obesity and hypolipemiant drugs)? OTC status of contraception pills favors unsafe sexual behavior? The answers to these latter questions are nonetheless difficult to assess and may involve large quantitative epidemiological studies on populations in which those drugs present different availability status; the analysis may be complicated by the probable proliferation of confounding factors such as cultural differences between the groups compared. At last, self-medication also increases the probability of misuse or even abuse.

The increasing availability of medicines without professional surveillance, together with the surrounding consumption culture and the progressive deregulation of medications advertising (issues that will be analyzed in the next two sections of this article) may have contributed to the banalization of medication, what Lopes have described as the transformation of the status of medicines from goods of rare, exceptional use to readily available goods of common use [73], promoting a culture of "a pill for every ill". In this scenario, medium-regulated BTC status appears as a healthy alternative to low-regulated OTC status. The possible acquisition of OTC medications without surveillance of any health professional at all in many countries makes the availability of clear information (from the point of view of a non-expert consumer) through package labels and package inserts mandatory (note that the FDA requires studies on patients' understanding of labels for a drug to reach OTC status). A clear distinction between cure and symptomatic relief should also be indicated to the patient through the label and the inserts. Since in many countries the pharmacist remains as the only health professional in contact with the patient during the process of acquisition of deregulated medicines, a resignification of the pharmacist professional role, with strong emphasis on its educational and pharmacovigilance responsibilities sounds appealing. Access of the pharmacist to medical records of the patients would also reduce the chances of dangerous interactions, simultaneously allowing him to verify the existence of previous physician diagnosis when an OTC medicine is used for the management of a chronic conditions. In the context provided by modern communication technologies, the development of central, remotely accessible medical records seems quite feasible. The new role of the pharmacist may be better developed through modern, participatory models of healthcare provider/patient encounter, that will be described later. This may call for a sharpening of pharmacist communication skills, which is in good agreement with the recent changes in the curriculum of professional pharmacy degrees, from a focus on products to an emphasis on clinical care, which have been promoted in the last decade by many universities worldwide [74]. Fig. (3) presents a summary of Public Health and economic

interests behind status shift of medications, risks associated to self-medication with OTC medications and possible solutions.

CONSUMPTION CULTURE, THE MEDICALIZED SOCIETY AND SELF-MEDICATION

Although the shopping analogy does not fit comfortably within the health care sector, many studies indicate that at least some patients consider the acquisition of a medicinal product, essentially, as a commercial transaction that should be completed promptly and efficiently; these patients view little difference between medicines (particularly, non prescription ones) and other items of commerce and may well wish to avoid what consider intrusive, unnecessary questions from pharmacy staff [75-78]. However, it is precisely the expert intervention of a health care professional (e.g. a physician or a pharmacist) assisting in the selection of a medicine that fits the patient's specific, individual needs, what produces the symbolic transformation of the drug from a simple article of trade into a medicine, even in the case of medicines that can be regarded as familiar [79, 80]. The service of the expert, then, imbues what may be viewed for some as a mere commercial item with an additional, intangible³ value, changing its status. When talking of medicines we should always keep in mind that, from a humanitarian point of view, its social dimensions greatly exceed its economic aspects.

Many factors reinforce the perception of medicines as articles of trade by the patient. Firstly, we should consider factors related to the political and social perceptions of medicines and their socially and legally legitimated uses. Secondly, we could list factors associated to the singularities of the traditional environment where drugs are purchased: the pharmacy.

Several countries allow legal availability of OTC medicines from non-pharmacy outlets (such as drugstores) with the logical associated inference in the mind of the patient that no expert supervision and advice is necessary [80]. Even in the same country one may find differences regarding drugs availability among states or provinces, with some of them allowing selling of OTC medicines outside the pharmacies and some not. The lack of an international unique position regarding this matter, and, even worse, the absence of a consistent, harmonizing national health policy in some federal countries may act as a contradictory message in the mind of the patient, clashing with official discourses about the importance of expert advice and surveillance. The concurrent emergence of internet-based pharmacies and other web-based outlets that sell pharmaceutical products also contributes to health consumption [81]. Even though some of them require prescriptions before dispensing a drug, other supply prescription drugs on the sole basis of an online consultation questionnaire; thus, pharmaceuticals can be purchased online and dispatched worldwide (see, for example: <http://rxpill.com/>, <http://international.drugstore.com/>, <http://www.cvs.com/> and <http://www.masterpills.com/>). Another factor that induces assimilation of medicines to general commercial items is the use of advertising and the same promotional strategies already used in the case of ordinary commercial items. In the US, where DTC advertising of prescription only drugs is legal, about 30% of the patients that visit a physician make a request for a specific medication that they have seen in the media and, more worrying, around 44% of those patients get their DTC-activated request granted by the physician, according to a study on national random sample of 2511 individuals [82, 83]. The competitive environment in Medicine and Pharmacy might mean that many requests are complied with; there is an underlying awareness on both the patient and the health care professional that if a patient is not prescribed or sold (in the case of OTC drugs) the medicine they request, they will probably get the prescription or the drug from another doctor or pharmacist [80, 82]. Finally, the use and abuse of what have been

³ But, nevertheless, sometimes significant in terms of the results of the treatment.

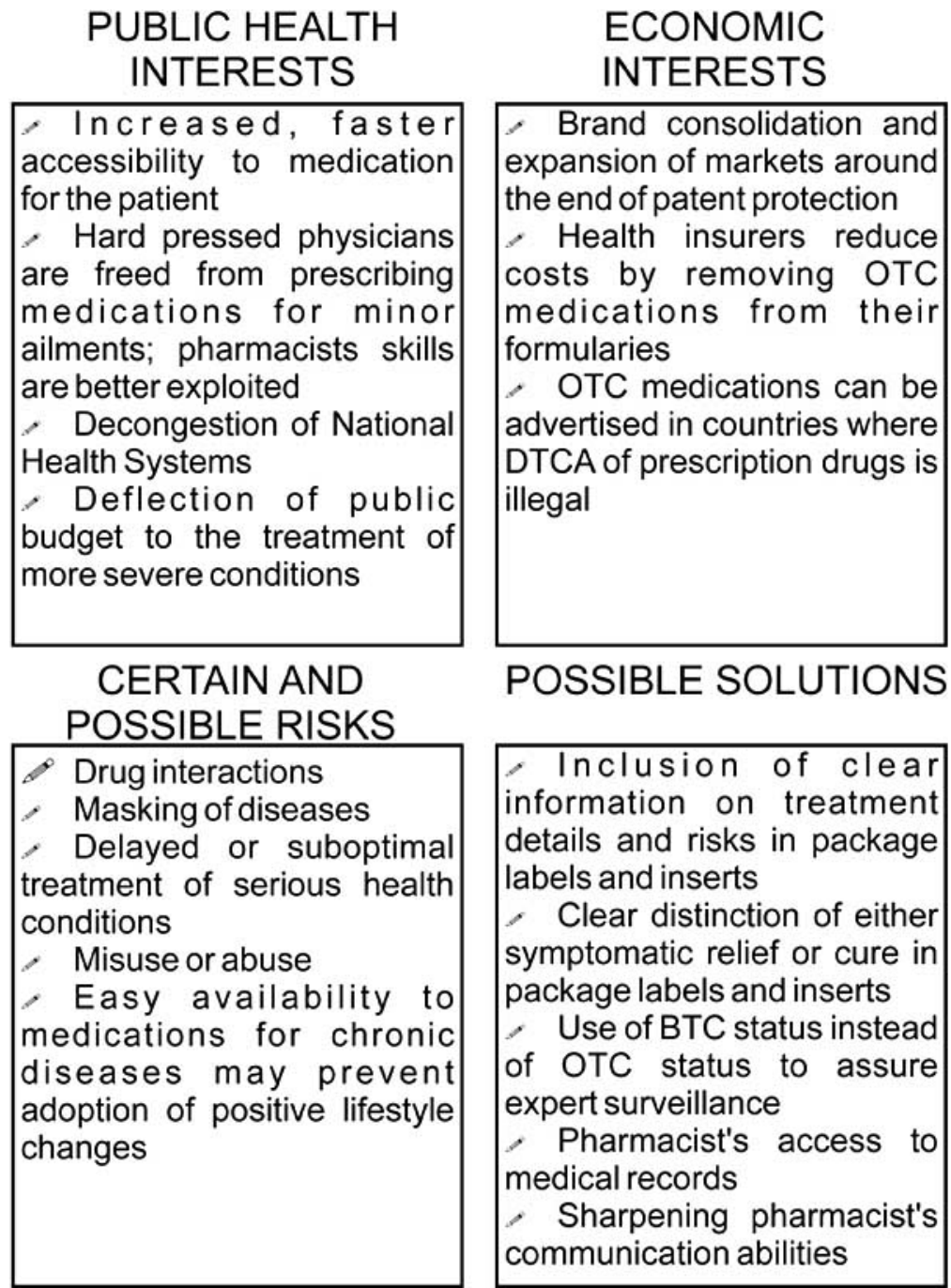


Fig. (3). Summary of interests behind changes of status of medications, potential risks and possible solutions.

called “lifestyle medicines” could be assumed as an additional indicator of the medicalized society [84]. Lifestyle medicines have been defined as medicines that are used to satisfy a non-health-related goal or are used for treating problems that lie at the margins of health and well being [85]. Three good, paradigmatic examples are the use of minoxidil and finasteride for the treatment of baldness, the consumption of sildenafil by young people to enhance sexual performance or the use of bupropion to treat the addiction to nicotine, and many more can be found in literature. Lifestyle drugs’ market has been estimated in 29 billion by 2007 [84]. Since broad definitions of health that refer to a general and complete well being (that includes physical, psychical and social aspects) are internationally accepted, it is really difficult to define when a non fulfilled need or desire becomes an illness, but it looks like if at least some of these medicines are being used to treat natural

conditions or expressions of the human being or of individuals’ personalities, or for mere aesthetic (and thus, cultural) reasons. Extremely wide definitions of health tend to portrait health as a rather utopical, unreachable condition. Anyway, the use of medicines as a chemical patch to emend society vices and social pressures seems in accord with a consumption culture that pursues happiness through purchasable, fast and usually transient and superficial solutions.

Among the factors related to the pharmacy itself that induce to assimilate medicines to trade items, we may mention parallel sale of non-medical products or services, such as cosmetics and beauty products, photography services and others, at pharmacies [80], the briefness of the average patient-pharmacist encounter [86], the distribution of medical products inside the pharmacy (that

sometimes reminds the one of an outlet) and the ethically controversial use of traditional commercial resources such as special offers. Furthermore, the commercial aspect of the pharmacy is more easily recognized by the patient than in other private health-care settings and pharmacists are likely to be sensitive to losing trade on a single occasion and in future ones [80]. Some simple strategies to divert attention from the commercial aspect of medicines and emphasize their social dimension and the added value conferred through pharmacist assistance are implemented in some practice models of pharmacy, such as restricting stock to health related items or providing spaces away from the counter for consultations [80]. However, we feel that more general interventions from governments, professional associations and international institutions are required to change the social perception of medicines (see Discussion section).

ADVERTISING

Although most of the recent studies on medications advertising focus on direct-to-consumer-advertising (DTCA) of prescription drugs, there are some common features between advertising of prescription and OTC medications: they both appeal to emotional features, they usually highlight the beneficial aspects of medications rather than the associated risks and they describe the uses and benefits of medications in vague and qualitative terms [87-89]. The main argument in favor of DTCA of prescription drugs is that it may enhance participative patient-physician relationships, encouraging patients to voice previously unspoken concerns and providing confidence in visits; it is also assumed that DTCA on prescription drugs results in increased diagnoses and treatment of under-diagnosed and under-treated conditions [90]. In the case of DTCA of OTC medicines, promotion of OTC medicines may enhance the incidence of the advantages described in the *Switching from Prescription to OTC Status* section of this article; moreover, the positives effects on patient-physician relationship mentioned for DTCA of prescription medicines may be applied to some extent to the patient-pharmacist relationship in the case of DTCA of OTC products. However, the biased, unbalanced information provided by DTCA may be counterproductive. Many patients erroneously believe that advertised medications are completely safe, that advertising of drugs with serious side effects are banned and that only extremely effective drugs are marketed [91]. At the same time, a survey on 1050 American doctors revealed that, according to physicians, the effect on the doctor-patient relationship is strongly associated with doing what the patient wants, and, although around half of the patients' requests are deemed to be clinically inappropriate by physicians, 69% of these clinically inappropriate requests are filled by doctors [90]. In other words, patients' misconceptions and lack of fair balance between presentation of benefits and risks in ads tend to raise high expectations in the patient and may cause severe distress when its effects are disappointing. The patient-health care provider relationship tends to be damaged if the health professional refuses or resists requests generated by DTCA or if the health professional feels challenged by the patient discussing (partial) information obtained from DTCA [90, 92, 93]. Optimal use of DTCA may then require stricter guidelines or more aggressive enforcement of current guidelines to assure delivering balanced, unbiased information [92]; these measures might be complemented by availability of reliable health information and health promotion focused on public health priorities, founded by governments or private non-profit organizations [92, 94]. Once again, sharpening of health professionals' communicational skills is essential to guarantee fluent patient-health care provider encounters. A summary of DTCA pros and cons and possible solutions to the emergent problematic may be found in Fig. (4).

MODELS OF PATIENT-HEALTH CARE PROFESSIONAL RELATIONSHIPS

In the previous sections we have described the factors and social processes that have contributed to an evolution towards more participative, inclusive models of health. Those factors can be synthesized as follows: greater availability of health information, greater availability of medicines and a strong consumer frame of reference (with a tendency to carry expectations and customs from other markets to health care, which in fact may not necessarily be considered a market or a pure market). In this section we will briefly discuss the features of the different models of patient-health care professional relationship. We will use as main reference for this section the review work from Emanuel and Emanuel [95], considering four patient-health care professional models: paternalistic, informative, interpretative and deliberative (or shared-decision making) models. We consider three dimensions of patient-health professional relationships: manners, information transfer and decision making [96]. The professional's interpersonal manners and attitudes (friendliness, sensitivity, concern, respect and listening skills) are rather intrinsic attributes of the expert and they might not be distinctive of any of the models. Nothing prevents from thinking of a concerned, friendly doctor acting on the basis of a paternalistic model, although intuitively one would expect a communicative doctor to lean forward more participative models of encounter. Furthermore, positive manners and attitudes that favor the communication between the patient and the expert are essential if interpretative or deliberative models are applied, while they may or may not be present when paternalistic or informative approaches are chosen without jeopardizing the efficacy of the medical intervention⁴. This said, we will focus in the differences related to information disclosure and decision making across the four models explored here. In the context of a wide, increasing availability of OTC medications, the same models might be applied to conduct the assistance of the pharmacist in treatment selection for minor ailments and safe medications for chronic conditions easily diagnosed or previously diagnosed by a physician, approved for OTC commercialization.

The paternalistic model is based on the assumptions that a single best treatment exists for every medical case and that, due to knowledge asymmetry between the expert and the patient, health professionals are in the best position to objectively determine which treatment option is the best for a particular patient [95, 97]. This approach may have worked reasonable well in the past, in a context of patients' illiteracy on health matters, but has been strongly questioned from 1970s to the present, due to a wide range of reasons: proliferation of treatment options for an increasing number of illnesses result in a more complex decisional context where different treatments had different tradeoffs between benefits and risks; evidence was found that physicians' treatment choices for the same disease often varied considerably in small geographic areas; the principles of *caveat emptor* (let the buyer beware) and patient/consumer sovereignty became popular and; as a consequence of patients' movement, legislation precluding treatment implementation without informed consent and safeguarding patients' rights to be informed about all available treatment options was sanctioned [97]. In the paternalistic model, the information exchange is largely one way (from the health professional to the physician). The professional provides selected information that encourages the patient to consent the intervention that the physician considers best; at an illegal and unethical extreme, the physician authoritatively informs the patient when the treatment will be initiated. Although the patient has the legal and moral right to assent the suggested treatment, the decision making is clearly bended towards the expert when a single treatment option

⁴ The efficacy of medical intervention is defined by the model of relationship practiced by the physician.

ADVANTAGES	DISADVANTAGES	POSSIBLE SOLUTIONS
<ul style="list-style-type: none"> ✍ Patients gain knowledge on new medications ✍ DTCA advertising on prescription drugs favors the patient approach to the physician ✍ Higher chances of diagnoses and treatment of under-diagnosed and under-treated conditions ✍ DTCA gives patients confidence to express concerns and opinions to health professionals 	<ul style="list-style-type: none"> ✍ DTCA tends to present biased, unbalanced information ✍ Patients tend to believe that advertised drugs are extremely effective and absolutely safe ✍ The patient/health professional relationship may be damaged if the expert feels challenged or manifests resistance to patients' clinically inappropriate requests ✍ Patients may rise high, unrealistic expectancies on drugs ✍ The use of promotional strategies applied to common trade items may undermine medications status 	<ul style="list-style-type: none"> ✍ Provision of unbiased, balanced information on medications by the government or non-profit organizations ✍ Sanction and enforcement of stricter guidelines for DTCA advertising ✍ Sharpening health experts communication skills

Fig. (4). Summary of benefits and risks of DTCA and possible solutions.

is presented to the patient or the information on treatment alternatives is biased by the expert's opinion.

In the informative model the flow of information exchange is also largely one-way, from the expert to the patient [97]. According to this model, a physician must objectively and extensively inform to the patient the state of his disease and all treatment options, together with the benefits and risks and uncertainties of each treatment alternative. A pharmacist acting on the basis of the informative model might provide the patient all available information on all the OTC medications for a particular condition. In the informative model, then, the professional provides unbiased facts about therapeutic options and the choice of the alternative that best suits the patient's values is completely left to the patient. Therefore, this model assumes that the patient's values are well defined and known by the patient and that the only thing that the patient lacks is facts [95].

In the interpretive model, the health care provider provides the patient with medical facts about treatment options, but he also assists the patient in elucidating and articulating his values and determining which intervention best realizes them [95]. This model assumes that the patient's values are not necessarily known to (or fully understood by) the patient. The exchange of information in this model is two-way, and both medical and personal information is discussed. The deliberation and decision process are left exclusively to the patient.

Finally, in the deliberative or shared decision model the health care provider tries to persuade the patient about what treatment option represents the best health-related values [89]. The expert not only listens to the patient's personal information to elucidate the

patient's values, but his own values are incorporated into the discussion as well. The defining characteristic of the deliberative model is its deep interactional nature [98]; each person needs to be willing to engage in the decision-making process expressing treatment preferences. The process is likely to be consensual if both parties start close in their positions about the preferred treatment and a negotiation process is likely to occur if they are wider apart in their perspectives [97]. This model is the one that demands the most from the expert's communication skills; the fact that the professional bears the officially legitimized 'expert' title and other factors like education, culture, income and gender differences may inhibit the patient from freely expressing his points of view. The highest challenge for professionals that want to practice a shared approach is to create a safe environment where the patient feels comfortable with exploring information and expressing opinions [99]. This model is also time-demanding. The information exchange is two-way and both medical and personal information are considered. Although the final decision regarding which treatment will be implemented remains with the patient, both parties are committed in the decision making process, (since the deliberative instance is an undoubtedly important part of decision-making) and ideally an agreement should be reached on the treatment to be implemented.

We have briefly described the feature of the different models of patient/health care professional relationships, and at this point it is worth mentioning that plenty studies establish that, although shared decision model is increasingly advocated as an ideal model of relationship, and patients' rights to get involved in decision making about their own health are morally undeniable, a range of patients exists with respect to decision making in both the hospital and the

pharmacy (see a large list of examples in the review from Guadagnoli and Ward) [9, 79, 80, 99]. Many patients prefer not to assume full-decision-making control and others prefer not to participate in the decision making process at all. Some patients prefer to be informed; others prefer to receive no information. To complicate the scenario, the same patient may pursue both 'active patient' and 'passive patient' (or 'challenging patient' and 'permissive patient') positions simultaneously or variously, depending on the circumstances [1, 8, 80]. In this context, experts' observational and communicational skills are heavily challenged in order to adapt the communication and decision-making approaches to the different type of patients and the different positions that a single patient may assume depending on the background.

DISCUSSION

During the last four decades we have witnessed intense changes in the way lay people face health management and their relationships with health care providers. Those changes include: a wider accessibility from lay people to medical knowledge through modern communication technologies (fundamentally, Internet); emergence of strong lay referral networks highly considered by the patient; a persistent deregulation of the use and advertising of medications (growing number of OTC drugs, acquisition of OTC status by medications indicated for chronic conditions, authorization of DTCA of prescription drugs in some countries, legal permission to offer OTC medicines in spaces that lack expert surveillance in some countries). All these processes are closely interrelated with the emergence and spread of a global patients' right movement claiming for information disclosure and active participation in medical decisions, which undermined traditional models of patient/health care provider encounter and resulted in a remarkable increase of self-care practices, among them self-medication.

Throughout this article we have described what from our viewpoint are currently the main factors influencing and promoting self-medication practices: accessibility to medical knowledge through Internet, increase of readily available OTC medicines, a strong consumer frame of reference and proliferation of biased, unbalanced drug advertising. Even though responsible self-care and self-medication are possible and mean several positive contributions to Public Health interests, the evident and vast purely economic motivations behind the above mentioned factors usually mislead patients, engaging them in dangerous self-medication practices and jeopardizing the patient/health care provider relationships (expert knowledge is usually challenged on the basis of inaccurate, incomplete information and low levels of satisfaction with the patient/health care provider encounter are reported when the expert refuses a request).

On the basis of the information analyzed in this paper, four general strategies may be proposed to assure an optimum balance between positive and negative consequences of self-medication practices: promotion of stricter laws and enforcement of current laws related to DTCA and drug availability; interventions from public agencies and non-profit organizations aimed to provide unbiased, quality health information and guidelines to appraise medical data; development of health care providers' observational and communicational skills and; resignification of pharmacist role in the health care providers' team.

Vague and unbalanced DTCA tends to raise unreal expectations regarding drugs efficacy and safety; patients are likely to think advertised drugs and OTC medicines are absolutely safe and that only extremely effective drugs enter the pharmaceutical market. Moreover, availability of OTC medications (and, sometimes, even prescription medications) without any expert surveillance (e.g. in outlets and virtual outlets) clearly alters the social risk perception on medicines, favoring the assimilation of drugs to ordinary trade items. More strict guidelines and adequate enforcement of current

guidelines for DTCA are needed to assure balanced information about benefits and risks of advertised drugs, restriction on emotional appeal of DTCA and inclusion of clear, specific therapeutic indications in the advertisement. Government agencies should provide pre-broadcasting or pre-publication approval for an advertisement to reach public. Purchasing of drugs outside pharmacies and health centers should be restricted or banned, as already occurs in many countries, and BTC status should be considered as a mid-regulated alternative to OTC.

Since regulation of the contents that can be found in Internet is highly unlikely, governments should consider the delivery of unbiased medical information to the patients through public campaigns and development of public-founded websites and search engines for reliable health data retrieval. Although there are many examples of development of quality markers to help the appraisal of health information in the web, and specific search engines to retrieve evidence-based, clear, reviewed and up-to-date health information, these efforts should be complemented with interventions aimed to educate the patient in the search and evaluation of health information sources, since several qualitative studies reveal patients' difficulties to find reliable information on health matters, and a gap between the perceived self-competence and the actual competences searching and evaluating medical data. Other interventions directed to understand the risks of self-medication would also be valuable.

Sharpening health care providers' observational and communicational skills and developing clinical care practices may well be the fundamental strategy to promote safe self-medication practices. Efforts should not only be merely invested in increasing drug availability but in increasing access to quality encounters with health care experts as well. What is a quality encounter between a patient and a health care professional? In a quality medical encounter neither the patient nor the health professional ends up frustrated: the patient is able to disclose his concerns and to choose the treatment option that embodies his personal values best, while the health professional feels he has transmitted the medical facts and his own values and perspective accurately but without any coercion on the patient. It has been proved that different patients feel comfortable with different models of patient/health care provider relationships. A traditional patient may feel more comfortable with the paternalistic approach instead of being engaged in a set of questions to disclose his values and preferences, or being forced to choose a treatment alternative. A consumer-like patient may prefer an informative model and may present some resistance to engage in deliberations with the health care expert. The development of observational skills in health care professionals may help the medical expert to identify which model suits best each patient's expectancies and to sympathetically redirect the patient to a deliberative approach if he feels it is necessary. The fact that many patients visit the doctors with a preformed expectation regarding treatment and that many doctors assent prescription of drugs that they feel are not clinically appropriate clearly denotes that several doctors find difficulties to overcome patients' resistances to appraise other treatment options. Expanding communicational skills may also help avoiding self-medication dangers due to the reluctance of some patients to share important pieces of information with the health care professional (e.g., patients often rely on Internet to get information on use of CAM, because they anticipate a negative response from the physician to these type of therapies).

Finally, a redefinition of the pharmacist's role and a revision of the background where medicines are dispensed may be valuable to relocate medicines as much more than simple commercial commodities. Restricting pharmacies' stock exclusively to health-related products, generating away-from-the-counter spaces for consultations and restructuring pharmacies to remind less of an outlet and more of a health facility are simple strategies for the pharmacies to regain professional status emphasizing the especial,

social dimension of medications. Guarantying access to national available medical records of patients to the pharmacist would give him the media to prevent potentially dangerous drug interactions (although some confidentiality concerns on this matter may be anticipated).

CONCLUSION

A pendular movement between regulation and deregulation of medications (and in general, of medical activity) may be inferred worldwide if we look at recent medical history (XXth and XXIst Centuries). Although at present it appears that we are still moving towards deregulation, it feels like the equilibrium point has not been found yet and that some issues call for a more strict regulation (e.g. advertising on medications and purchase of prescription medicines without medical surveillance in online virtual stores). Since strong Public Health and economic reasons lie behind current deregulation, and considering that participation of the patient in informed health decisions is a legitimate right, is extremely unlikely to return to highly regulated medication policies. Self-medication and self-care are here to stay, and they may surely continue to increase in the near future. A reasonable attitude of health care professionals might be not to resist this new scenario but to accept it and accompany the patient's adjustment to its modern active role in self-management of his own health and decision making. Providing the patients with quality, unbiased medical information and with the resources to appraise medical information and select evidence-based, quality info is also the challenge and the responsibility of health care providers operating in this new background. If lay knowledge on health matters continues to rise, it is possible that more and more patients will eventually become comfortable with either the informative or the deliberative models of patient/health care provider relationships. The role of the health professional will move away from its traditional, authoritative position (paternalistic models) to a partnership-like, shared-decision model. This more humanitarian, patient-centered model of Medicine demands development of health professionals' observational and communicational skills; this should be considered in present and future revisions of the curriculum of Medical, Nursery, Dentistry and Pharmacy degrees (as has been made in the last decade at many universities throughout the world). Due to the continued increase in the number of medications shifted to OTC status, emphasizing the pharmacist role as educator and counselor and providing him with the education to play this role fluently is critical to assure safe, responsible self-medication practices.

Further studies are needed in order to deepen the theoretical reflection on self-medication, as well as on the practices and rationalities of its social actors. This review has not problematized the issue of self-medication from the standpoint of lay rationalities (i.e. patients), but from the professional perspective. Further work reviewing the subject of self-medication from a lay perspective would be very valuable.

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