

Violation of Linguistic and Patient's Rights in Kenya

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ABSTRACT

Health communication, particularly patients' rights, has become an issue of concern in the recent past. This paper exposes the patients' rights violation on two main planes: the linguistic plane and the right to information plane. The paper also assesses the world trend on the aforementioned violations and finally contextualises the patient-physicians relationship models. The paper makes the following observations: there is need to reinforce the law on package inserts, especially, the inserts for the patients in both content and language. The PPIs should be translated into Kiswahili for ease readability and access to information. There is also need to enlighten the public and patients in particular on the patients' rights and enact and implement the Freedom of Information for the public to hold the state responsible for accountability and quality service including health services. Lastly, the paper recommends the adoption of interpretive model which harmonises physician's medical facts and the patient's personal values in arriving at a balanced decision on health issues.

Key words: Linguistic Human Rights, Patients' Right, Health Communication, Patient Package Inserts.

Introduction

Patient's right to health information is an important component of human rights. This paper exposes the patients' rights violation on two main planes: the linguistic plane and the right to information plane. The paper will support its claim by discussing the world trend in the two aforementioned violations. The paper will finally contextualise the patient-physicians relationship models give recommendation on what ought to be done.

Health communication has developed over the last twenty five years as an important field of study concerned with the powerful roles of human and mediated communication in health promotion. The focus on the importance of health communication especially health communication with the general public has been tremendous. The enforcement of human rights acts in the world has seen many patients demand for them to be able to make informed choices about their health and the use of drugs etc. The demand for patient information and involvement is partly due to a societal push to involve patients in their own health, and consequently, the concept of patient empowerment has become increasingly popular (see Hall, 2006; Holmstrom & Roing 2010; Ojwang, Ogutu & Mati 2010).

Patient information also aim at opting the use of medicines (Raynor, 2007), and ensure safe, effective and appropriate use when decision has been made to take it (Raynor & Dickinson, 2009). Important as it is, the issue of language and patient information has been taken for granted here in Kenya.

Linguistic Human Right

Language is the avenue through which members of a society interact. Through language, members of a society are able to participate in the national development. It is, therefore, a crucial tool in the dispensation and achievement of national aims, objectives and development (Amuseghan, 2008; Mugambi, 2001) members of the community inform and get informed through language. The word informed here is used to mean: first, people getting to know about happenings around them. Secondly, people receiving information that influences or modifies their attitudes, opinions or behaviour (Chaffe, 1982).

The work of Toke skutnabb-kangas and Robert Phillipson (see Phillipson, 1992, Skutnabb-kangas & Phillipson, 1995) has been crucial in crusading for Linguistic Human Rights in sociolinguistic. Ibid, (1995) contents:

Linguistic rights should be considered basic human rights. Linguistic majorities, speakers of a dominant language, usually enjoy all those linguistic human rights which can be seen as fundamental, regardless of how they are defined. Most linguistic minorities in the world do not enjoy these rights. ... it is only speakers of official languages who enjoy all linguistic human rights p1-2.

In the case of health and other crucial sectors the opposite is true. It is the minority group enjoying the linguistic right to medical information whereas the majority are denied their right. As a critique to LHR, Blommaert, (2001) suggests a different approach to the issue of language. Ibid, (2001) coins the expression: Linguistic Citizenship instead. In Linguistic citizenship, speakers of a language exercise control over their language, deciding what languages are, what they may mean and where language issues, policy issues and questions of equity. The main argument of linguistic citizenship is that it does not assume that the rights of citizens will be necessarily protected by the state or the country's constitution. This is the situation in Kenya. Kenya presents a triglossic language situation where the majority use their first languages for in-group communication, Kiswahili for intergroup communication and English for official matters. Only a few Kenyans use English in their day-to-day activities. Waitiki, (2010) refers to it as a language of an educated few. One would therefore expect most communication channels (and for the purpose of this paper medical channels) to be a language that is fairly understood and used by the majority of the people. This seems to be a neglected role of the State to its people.

Guidelines for parallel importation of medicines section 8 on procedures for obtaining registration of a medicine to be imported says

An application for the registration of parallel imported medicine must be accompanied by the following: 1) copies of package insert and patient information leaflets, which must be translated into either English or Kiswahili. p.11.

From the clause above, one expects three conditions to be met; the enclosure of package inserts the patient information leaflet which should be translated into either in English or Kiswahili. The truth of the matter is, even though one would argue that the inserts are not meant for the patient, whenever you buy or receive medicine either the over-the-counter (OTC) or the prescription only medicines (POM) you will get some inserts in the packets. I stand to be corrected if there any of them translated in Kiswahili, the language of the majority. Isn't this a violation of linguistic right and patients' right to information?

Research has shown that language barrier completely hinder progress in health communication. Waitiki's, (2010) research on the *linguistic challenges in the fight against HIV and AIDS* observe that language barrier can completely hinder progress especially in Doctor-Patient communication whereby a patient cannot communicate directly to the doctor in the language she/he is not competent. She adds that this problem is most prevalent in multilingual nations like Kenya, where knowledge of either the national or official language is a preserve of an educated few. In such a situation the communication process is mitigated by a third party which in itself denies the patient confidentiality he/she requires. Sometimes, it leads to gross miscommunication or misrepresentation of the ideal picture to the doctor or

the patient. A culture of silence is then the end result. This is the same situation in written communication model. When a patient gets written information in a language unfamiliar, what happens? Most of them don't attempt to even read them at all.

Language should therefore, be given the attention it deserves if the fight against infections in Kenya is to be fruitful. Now that the Kenyan constitution gives a level ground to English and Kiswahili, there is need to revitalise the modes of communication to suit the literacy levels of the citizens.

Patient Package Inserts

In developed nations, due to the demand for patient involvement a great amount of legislation has been passed during the past fifteen years. The pharmaceutical companies are by law required to provide patients with information about the medicine. This has paved way for the genre of patient information leaflet (PIL). PIL is referred to by other terms in other parts of the world. Outside Britain, it is also referred to as patient package inserts, written medicine information, patient package inserts, written drug information etc. This study chooses to use patient package insert (henceforth referred to PPI) as referred to in the Guidelines for parallel importation and the pharmacy and poisons board, regulatory bodies under the Ministry of Health.

PPI accompanies medication both OTC and the POM. They are included to inform the patient what the drug is, how it should be used, how it works, safety concerns to be aware of and precautions to be taken (Bjerrum & Foged, 2003). PPIs have become an important source of information about medication for the patient (ibid 2003 p 58). They seem to an option to a situation where little or no information is provided during the general practice consultation (Kenny et al 1998). In the study by Ojwang, Ogutu & Mati (2010) on nurses' impoliteness, it was noted that distorted or incomplete information from the nurses featured commonly as an undesirable strategy. They also noted some nurses asked patients questions that they were unable to answer. By doing this, the nurses imposed communication roadblocks, which Matthew McKay and colleagues have described as communication behaviours that stop or temporarily halt a meaningful dialogue; these authors argue that roadblocks can deprive the client of autonomy and dignity (McKay, 1995).

Regulations on PPI in other countries

Regulations on package inserts was introduced and reinforced in the late 1970s in Europe (Koo, 2005). In the UK, for instance, many medicines were distributed without printed information until mid-1970s (Dickinson, Raynor & Duman, 2001). In the Netherlands, a PPI was mandatory as from 1975 (Dijkstra, 2007). From the late 1990s it was required by law that all medicines in Europe come with an understandable leaflet by means of the council directive 92/27/EEC (Koo, 2005, Dickinson, Raynor & Duman, 2001). The EEC stated that the purpose of the PPI is to provide guidance on how to ensure that the information on the labelling and package leaflet is accessible to and can be understood by those receive it. At the same time, also consumers' demand for information about the medicine's condition and

general health matter (Ley & Morris, 1984; Kay & Punchak, 1988). PPIs have also been found instrumental supplement for verbal information since such information is soon forgotten or not even given at all.

The European commission, for instance, applied two interventions to guarantee an accessible leaflet. Firstly, the Guidelines on the Readability of the labelling and package leaflet of medical products for human use introduced in 1998 and updated 2009. These guidelines give advice about the leaflets content and layout, as well as preparation suggestions, references to other applicable documents and information on how the Braille requirements can be met (EC, 2009). Additionally, a reference to the Quality Review Document (QRD) is made. The second intervention is user testing. User testing has been a mandatory step since November 2005 for every PPI that enter the European market and the criteria are also adopted in the guidelines on the readability of the labelling and package leaflet of medicinal products for human use. The goal of user testing is to discover the PPI's flaws by evaluating the participant's comprehension and ability to use the information in the PPI. This is done by asking the participant questions about the PPI. User testing has been credited as a powerful tool to localise potential problems people may encounter when reading the PPI in real life. It also improves the consumer's ability to handle the PPI. Once a PPI passes the user test, it is translated into other languages unconditionally.

The Kenyan situation

The expression Patient package insert as it is seem to be attracting several interpretations. Firstly, as used in developed nations, these are documents intended for the patient to furnish oneself with more medical information about the medicine given or bought. In the Kenyan context, there seems to be misconceptions about PPIs. To some people, it means a document packed along with the medicine to furnish the physician with more information about the medicine and the intended patient. It seems also a mere document that is needed to meet the requirements to market a new drug. There is no difference between package inserts which may include information inserts for medical professionals, information inserts for patients and information inserts for approval of the drug.

According to Löning, (1981)'s model of classification of medical discourse, there are four main levels according to degree of specialisation among the communication partners as illustrated below;

level	Text type	Communication partners	Aim	Example
1	scientific texts	professionals to professionals	transfer of current specialised knowledge	Product summary
2	instruction	professionals to half professionals or health persons	transfer of basic knowledge	Information inserts for physicians
3	education	professionals to lay-person	education and	Patient package

			practical instruction	insert
4	popular science texts	non-professionals to lay-person	arouse interest and turn problems public	Academic papers

Adapted from Löning, (1981) *Models of medical discourse*.

The patient package inserts which is the focus of this study fall in level 3 in which the medical professional writes the insert for a patient who has not familiar to medical language. The essence of such inserts is to enlighten educate the patient on the medicines and its usage.

From the ad hoc interview conducted among physicians in medical centres and chemists in Bungoma town and Kimilili town, it was observed that out of 164 of those interviewed only 25 (15%) were aware of the difference between information package inserts for medical professional and the information package inserts for patients. Those aware of the difference, however, admitted that they rarely inform the patients about it for lack of time. Shockingly, the 75% argue that the inserts are meant for both the physicians and the patients. When they were asked about the readability of the inserts, they wondered why a patient should struggle to read sections of the inserts not meant for him/her. When they were asked to single out the sections they think are meant for the patient, they said it is the Dosage section.

When a sample of Patient Information Leaflet for *ivyroxan eye/ear drop* was shown to them and asked if they had seen such inserts, one said “ Hii ya kaa geni kwangu. Ni ya dawa gani na kutoka wapi?” scrutinizing the insert. (This looks new to me. It is for which medicine and where is it manufactured from?). This expression of shock in the chemist is not surprising at all since the statistics of a few inserts that were collected supports it. The physicians and mostly the chemists could not give you an insert to drug that has not been bought but were willing to unpack them for viewing. We managed to access about 301 information inserts for various medicines. Out this only 57 (18%) were meant for the patient. They had the headline bearing the name of the drug on the left hand side and the label: patient information leaflet on the left. Of note again is that these were drugs manufactured by only particular pharmaceutical companies, for instance, IVEE AQUA EPZ LTD, Athi River: Kenya.

Most of those interviewed claim that their work is enormous and with many patients to be attended to, it was impossible to explain all important information to the patients. One of the chemists says “Boss yako akirudi, atakuuliza ni hela ngapi umeuza hiyo siku ama wagonjwa wangapi umeelimisha juu ya dawa na magonjwa yao? Cha msingi ni umuandikie dosage na side effect moja au mbili basi.” (At the end of the day, your boss (owner of the chemist) will ask you how much money you have made from the sales or how many people you have enlightened about the drugs and their diseases. What is important is to write for them the dosage and tell them one or two side effects. That is enough.)

In one of the chemists the lady attendant was moody and as I waited just to be served as a customer, she rudely answered a customer who had asked for more information about the drug to go and read the insert that was in the packet. The customer paid for the drug and after confirming that the insert was packed with the drug, he left quietly. When I sought audience to know a few issues concerning the package inserts, she excused herself claiming to be having a few reports to write about the day's business.

The interview and the package insert collection was simply a pilot study to the author's intended PhD research on "Genre Analysis of Patient Package Inserts: the Kenyan Medical Situation". The little information collected, however, confirms what has been discovered elsewhere in health communication.

A number of review articles on health communication show that many patients want to know more about their medicines (see Kenny et al, 1998; Mayeaux et al, 1996). These works also highlight a definite need and expectation for information regarding the safe, effective use of medicines. Communication between health care professional (HCPs) and patients often fail to inform patients effectively due to a number of factors. The most common ones include: failure to recall the information (Kenny et al 1998), language barrier (Waitiki, 2010; Singleton & Krause, 2009), HCPs impoliteness (Ojwang, Ogutu & Mati, 2010), lack of information (Kitching, 1990) among other. This paper agrees fully with Kitching (1990) that lack of information is one of the major factors among the 250 factors why patients do not take their medicines as prescriber intends. There pertinent sections in the PPI genre such as the side effects, precautions, in case of overdose etc. which the patient may review later in case of any problem and then take appropriate measures. When such information is not given at all, it becomes a matter of chancing or guessing what could be the problem. Many patients not only stop using the drugs but also form a negative opinion about the drug and the hospital. Chances of going back to the same doctor for who had treated with disrespect are very minimal.

PPIs provide additional information about their medicines and /or disease state that does not appear on the medicines label. The failure by HCPs to provide adequate information coupled with the desire of patients for more information and a frequent lack of understanding and recall of information presented orally, all point to the need to provide written information.

Ministry of Health, "Service Charter for Health Service Delivery," 2006, ¹states the patients' Rights as follows: right to care by qualified health provider, right to accurate information, right to timely service, right of choice of health provider/service, right to protection from harm or injury, right to privacy and confidentiality, right to courteous treatment, right to dignified treatment, right to continuity of care, right to personal/own opinion, right to emergency treatment anywhere, and right to dignified death.

The Bill of Rights **Article 46: Consumer rights** in Kenya guarantees the rights of consumers to goods and services of reasonable quality, information about them, compensation for loss or

¹ www.medical.go.ke

injury arising from defects in goods or services and protection of health, safety and economic interests. Under the **Fourth Schedule, Part 1 (14)**, consumer protection is the duty of the National Government. This Article can be linked to **Article 33 (Freedom of expression)** which guarantees the right to seek and receive information and **Article 35 (Right to access information)** which guarantees the right to access to information required for the exercise or protection of a right or fundamental freedom. Its spirit is reflected in provisions on right to information guaranteed under international human rights instruments

Over the years, concern among stakeholders' in the pharmaceutical industry over the proliferation of legal and illegal pharmaceutical players, and the increasing number of generic and counterfeit drugs has been on the increase. The Ministry of Health (MOH) and other concerned bodies have been trying to find a long-lasting solution to this problem. Pharmacy and Poisons Board, a section of the MOH has clear guidelines on the parallel importation of medicines. These guidelines regulates the importation of medicines thus ensures quality, safe and efficacious medicines to the public at affordable prices. On the same as noted earlier in this paper, for any application for parallel importation of medicines to be approved copies of package inserts and patient package inserts (patient information leaflet) must be submitted and they are to be translated into either English or Kiswahili. But where do the patient package inserts go to? Whom do they target? A close look at the various Acts on the issue of importation of drugs (pharmacy and poisons act, cap 244, public health act, cap 242,etc, seem not to have full control over illegal trade in pharmaceuticals. The possibility that our Kenyan market is flooded with counterfeit drugs cannot be ruled out. The concern for affordability of drugs has had more attention than the quality of the products. Of note here is that this paper does not undervalue the efforts made by various regulatory bodies including the Pharmacovigilance section of the MOH. However, the concern here is why the patient has not been given his/her right to information yet the regulations seem to recognise the importance of PPIs? Why should one insist on item x claiming it belongs to Mr. Y yet the item is not given to Mr. Y or worse still Mr. Y is not aware that such an item belongs to him?

Freedom of Information

Freedom of information is the citizen's right to know and access the official information held by the government, public bodies and some private bodies. The right to freedom of information is enshrined in Article 19 of the 1948 Universal Declaration of Human Rights (UHDR), the International Convention of Civil and Political Rights (ICCPR), to which Kenya is a party and the African Charter on Human and People's Rights. UHDR states that "everyone has the right to freedom of opinion and expression; this right includes freedom to hold opinions without interference and to seek, receive, and impart information and ideas through any media regardless of frontiers". The right to information is protected in Section 79 of the current Constitution of Kenya.

The Freedom of Information Network was formed on the 7th of March 2005: its functions are to raise awareness of the FOI campaign: facilitate wider participation: capacity-building: and promoting the acceptance of the campaign. Network members are able to exchange information and documentation on substantive issues, advise each other and engage in joint research, under the leadership of the ICJ Kenya Chapter. The ICJ Kenya Chapter in

collaboration with the Freedom of Information Network implemented a Freedom of information project aimed at having a freedom of information legislation in Kenya. The Kenya Human Rights Commission has also been involved in the campaign for the right to information in Kenya. Improvement to law on freedom of expression was mooted in 2007 through a FOI Bill that was presented to Parliament but lapsed when parliament was dissolved for elections. The bill has yet to be introduced, and Kenya remains without a substantive and express FOI legislative provision despite the efforts of civil society and the NGO groups.

Access to information remains a struggle. Four years since the Freedom of Information Bill (2005), was first proposed by government in 2005, its fate hangs in the balance, as the draft bill gathers dust on government shelves. The civil society, upon realizing that the government was dragging its feet in presenting the bill before Parliament, drafted its own version, the Freedom of Information Bill 2006, which, unfortunately, has not been treated with the urgency it deserves. As noted earlier in this paper, the New Constitution under the Bill of rights Article 51 guarantees the right to Access to information and states that every citizen has a right to information held by the state and to any information that is held by another person and that is required for the exercise or protection of any right or freedom. It also states that, "Every person has the right to demand the correction or deletion of untrue or misleading information that affects that person."

Having freedom of information legislation and policies is very important for any democratic state as it is fundamentally related to good governance and sustainable development. The benefits of having the FOI legislation which makes it a right of the people to know what and how the power holders are making decisions that impact on their lives are numerous. What has remained is enactment and implementation.

Agnes Callamard, ARTICLE 19 Executive Director says, "Once implemented, the Right to Information will have a huge impact on Kenya, enabling and empowering people to see what their government is doing, and therefore making the government more responsive and accountable."

Lack of legislative force leaves many loop holes in health sector of the country consequently, making its citizens lack pertinent services. This also greatly affects the doctor/ patient relationship. The government has a responsibility to make information about patients' rights readily available and accessible (in the form that they can understand and use).

PATIENTS' RIGHTS

For patients' rights to be realised, it requires educating citizens about what they should expect from their governments and their health care providers about the kind of treatment and respect they are owed. It is by enlightening the citizens that they can have an important part to play in elevating the standards of care. Patients' rights was formalised in 1984, when the Universal Declaration of Human Rights recognised "the inherent dignity" and the "equal and unalienable rights of all members of the human family" (Ojwang, Ogutu & Mati, 2010).

Patients' rights vary in different nations and in different jurisdictions, often depending on prevailing cultural and social norms. Different models of patient-physicians relationship which can also represent the citizen-state relationship have been developed and these have informed the particular rights to which patients are entitled. In North America and Europe, for instance, there are at least four models which depict this relationship: the paternalistic

model, the informative model, the interpretative model and the deliberative model. Each of these models is discussed, showing its applicability in the Kenyan situation. Understanding each model informs on the professional obligation of the physician toward the patient, and also exposes the fact-value dichotomy which has been a bone of contention between physicians and patients.

The paternalistic model

It is also referred to as the priestly model according to Veatch, (1972). In this model, the best interests of the patient as judged by the physician are valued above the provision of comprehensive medical information and decision-making power to the patient. The physicians are authoritative parents and patients are passive and submissive recipients of medical benefits. There is coercion in this relationship since the physician authoritatively orders patients to assent. The physicians control the fact-value dichotomy and as long as the physicians can always act faithfully in the patients' best interests, and patients don't object to being treated from a parental perspective, the fact-value tension in this model is minimal. Taken as citizen-state relationship, then the state controls the fact-value and decides for its citizen Emanuel, (1992). This has been the relationship for long; however, the WHO, (2005) predicts change in the trend. Many people want to have involvement in the decision making about their state and medication. Paternalistic model has been common in Kenya due to partly the cultural divide and partly due to lack of exposure to patients' and physicians' value systems. There has been an underlying assumption that medical knowledge and technology could be too complex to understand for patients in general.

The informative model

It is equivalent to engineering model by Veatch, (1972). In this model the physicians provide medical information, and patients make medical decisions independently based on their personal values. Patients in this model are autonomous. And so they control the fact-value dichotomy (Hui, 2005) and the physicians are reduced to moral-neutral providers of medical services. Physicians provide patients with presumably value-neutral medical information and leaving patients to make decisions independently based on personal values. According to Ojwang, Ogutu & Mati, (2010), such a relationship causes tension since the nurses, for instance, would want to have their dignity preserved. When a patient undermines them they retaliate. This model is best suited in society with low illiteracy levels. As noted earlier in this work, the state has a role to play to boost the literacy levels of its citizens. Patients can only make informed decisions if they are able to relate their medical conditions to personal values.

The deliberative model

In this model according to Hui, (2005) physician's act as mentors guiding patients to identify and focus on values that affect or are affected by the patients' disease or treatment (Emanuel, 1992). The physician is assumed to be aware of the patients' medical and personal values before they can persuade or dissuade them on some health-related matters. Here the fact-value remains with the physician something that creates tension. It is not possible for the physicians to know the patients' personal values in the first place. Due to inadequacy of medical professional, it is not practicable to have them posted in their cultural settings since culture influences personal values to a greater extent.

The interpretive model

This model is also referred to the collegial model. Here, the physicians' medical facts and patients' personal values contribute to balanced medical decision making. This model

acknowledges that physicians have full access to medical facts and limited access to patients' values. Physicians provide medical expertise and are capable of counselling patients as friends to make decisions that best realise the patients' own personal values. This approach upholds patients' autonomy without undermining the physicians' duty and dignity. There is a balanced control over the fact-value dichotomy and hence a balanced decision-making. This would be the best model to adopt if a few of following challenges can be checked. These challenges include patient-physician ratio, the language barrier, the patients' literacy level in the medical matters and their rights as patients, cultural inclinations.

CONCLUSION

If Kenya is to realise its millennium goals especially in health communication, then it has to accord its people their linguistic right by availing health information in Kiswahili and even vernacular, languages that can be understood and be used easily by the majority. This will reduce complications arising from the challenge of language barrier. There is also need to reinforce the law on package inserts, especially, the need to enclose both information inserts for the medical professional and those for the patients. The inserts for the patients should be translated into Kiswahili for ease readability and access to information. This is one of the patients' rights to health information. Having Freedom of Information legislation and policies is very important for any democratic state as it is fundamentally related to good governance and sustainable development. The benefits of having the FOI legislation which makes it a right of the people to know what and how the power holders are making decisions that impact on their lives are numerous. There is need to speed up the enactment and implementation of FOI. As the rest of the world embrace the issue of informed consent in medical field, Kenya needs to enlighten the public about patients' rights in general and the right to health information in particular. It is from the information supplied and the patient's competence, that the patient or proxy can make voluntary decision without coercion to accept or reject treatment. To promote active participation of patients, this study urges physicians to be flexible in their adoption of the models of patient-physician relationship. The interpretive model by Emanuel, (1992), however, is recommended because it balances the fact-value dichotomy hence reduces tension between patients and the physicians.

REFERENCE

Amuseghan SA (2008b). 'Language Policy Provisions and Curriculum Issues and Challenges in Nigeria'. A paper presented at the 53rd Annual Conference of International Linguistic Association held at Sunny College at Old Westbury, New York, USA.

Blommaert, J. (2001) The Asmara Declaration as a sociolinguistic problem: reflections on scholarship and language rights. *Journal of Sociolinguistics* Vol. 5 No.1, p. 131-155.

Bjerrum, L. & A. Foged, (2003). "Patient Information Leaflets – helpful guidance or a source of confusion?" *Pharmacoepidemiology and Drug Safety* Vol.12 p. 55-59.

Chaffee S.H (1982). Mass Media and Interpersonal Channels: Competitive, Convergent, or complementary. In Gumpert G, Cathcart R (eds.), *Inter/Media: Interpersonal Communication in a Media World*. New York: Oxford University Press.

Constitution of Kenya, Article 19. Available at <http://www.kenyalaw.org>.

Dickinson K., Raynor D.K. & Duman R. (2001). Patient information leaflets for medicines: using consumer testing to determine the most effective design. *Patient Education and Counselling*, Vol.43 No.2, p.147 – 159.

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001.

Emanuel E.J & Emanuel L.L. (1992) “Four models of the physician-patient relationship.” *JAMA* Vol. 267 p.2221-6.

EMA, Compilation of QRD decisions on stylistic matters in product information. Version 9, December 2005. <http://www.emea.europa.eu/htms/vet/qrd/qrdreference.htm>

European Commission (1992) ‘Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets’, Official Journal of the European Communities, No. L, April 30, 113/8-12

Hall, D.R. (2006). “Medical leaflets, empowerment and disempowerment”. In *Advances in Medical Discourse Analysis: Oral and Written Contexts, Studies in Language and Communication* 45, M. Gotti and Salager-Meyer, F. (eds). Bern: Peter Lang. 271-288.

Holmström, Inger and Röing, Marta. (2010). “The relation between patient-centeredness and patient empowerment: A discussion on concepts”. *Patient Education and Counselling* Vol.79 No.2; p.167-172.

Hui EC. (2005). “The physician as a professional and the moral implications of medical professionalism”. *Hong Kong Med J* Vol.11 p.67-9.

Kay E.A. & S.S. Punchak .(1988). Patient understanding of the causes and medical treatment of rheumatoid arthritis, *Br J Rheumatol*; Vol.27 p.396-398

Kenya Ministry of Health, Patients’ service charter (Nairobi: Government Press, 2006).

Kitching J.B (1990) “Patient information leaflets—the state of the art”. *J Soc Med*;Vol.83 p.298-300.

Kenny T, et al (1998) “A PIL for every ill? Patient information leaflets (PILs): a review of past, present and future use”. *Fam Pract*;Vol. 15 p.471-9.

Koo M.M, Krass I., Aslani P. (2003) *Factors influencing consumer use of written drug information*. *Ann Pharmacother*;Vol.37 p.259-67.

Koo, M. M. (2005). *The use of written medicine information by consumers*. (PhD, University of Sydney, Australia

Ley, P. & L.A Morris. Psychological aspects of written information for patients. In: Rachman S, ed. (1984) *Contributions to medical psychology*. Oxford: Pergamon Press.

Löning, P. (1981): Zur medizinischen Fachsprache. Stilistische Gliederung und Textanalysen", in: *Muttersprache* 91, 79-92.

Mayeaux E.J et al (1996) "Improving patient education for patients with low literacy skills" *Am Fam Physician*;Vol.53 p.205-11.

McKay M., M. Davis, & P. Fanning (1995), *Messages: The communication skills book*. Oakland: New Harbinger Publishers.

Ministry of Medical Services and Ministry of Public Health and Sanitation Kenya: Pharmacy and Poisons Board: Guidelines for the National Pharmacovigilance Systems in Kenya, 2009.

Mugambi, P. J., (2001). An analysis of the politics of language in Kenya: Harnessing linguistic diversity for national and regional development.

Ojwang O.B., Ogutu E.A & Mati P.M. (2010) "Nurses' impoliteness as an impediment to patients' rights in selected Kenyan Hospitals" in *The Journal of Health and Human Rights* Vol.12, NO. 2.

Raynor D.K (1992) 'Writing Patient Information – A Pharmacist's Guide', *Pharmaceutical Journal*, August 8, 180-2

Raynor, D. K. (2007). "The importance of medicines information for patients". *Prescriber* vol.18. No. 2 p. 60-62.

Raynor, D. K. & Dickinson, D. (2009). "Key Principles to Guide Development of Consumer Medicine Information – Content Analysis of Information Design Texts". *The Annals of Pharmacotherapy* 43: 700-706.

Singleton, K., Krause, E. (2009) "Understanding Cultural and Linguistic Barriers to Health Literacy" *OJIN: The Online Journal of Issues in Nursing*. Vol. 14, No. 3, Manuscript 4.

Skutnabb-Kangas, T. & Phillipson, R. (Eds.) (1995) *Linguistic Human Rights*. Berlin: Mouton de Gruyter.

Veatch R.M. (1972) "Models for ethical medicine in a revolutionary age. What physician-patient roles foster the most ethical relationship?" *Hastings Cent Rep*; vol.2 p5-7.

Waitiki, S.W. (2010) "Linguistic challenges in the fight against HIV and AIDS: An analysis of Doctor-Patient Discourse in Kenyan Health Centres" in *The Journal of Language, Technology and Entrepreneurship in Africa*, Vol. 2, No.2 p.60-74

World Health Organization, "Patients' rights" (2005). Available at <http://www.who.int/genomics/public/patientrights/en/>.