

The Portuguese Guidelines and Patients Values



As Normas de Orientação Clínica em Portugal e os Valores dos Doentes

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ABSTRACT

Introduction: Clinical guidelines are support tools, aiming to improve quality of the clinical practice. Patient centered care allows best satisfaction rates, with greater health self-management, and potential gains in quality with fewer costs.

Objective: To evaluate the integration of patients' values in Portuguese guidelines.

Material and Methods: We reviewed the 18 guidelines about cardiovascular diseases published in Portugal from 2011 to 2013, searching for the integration of patients' ideas, fears, expectations and preferences.

Results: Eight guidelines were related to diagnosis approach and 10 with treatment. We found references to patients' values in 5 (28%) guidelines, all about treatment aspects. The incorporation of patients' expectations was the most present feature. Reference to financial costs was present in 78% of the guidelines.

Discussion: Clinical guidelines are health technology instruments available to practitioners in order to improve the quality of care provided to patients, who are the real users of these tools. As in other countries, there is a tendency to disregard the users' value systems in the conception of the guidelines, giving the privilege to a population logic, not always applicable to the individual, and to financial arithmetic with low support in cost-effectiveness assessments. In the Portuguese case, the way guidelines were proposed conditioned also some suspicion both in the professionals and in the users.

Conclusion: Portuguese guidelines have low incorporation of references to patients' values. This is more evident when questions about diagnosis are addressed, placing patients in a secondary role in the clinical decision-making process with potential losses in quality of care and eventual increase in costs.

Keywords: Guideline; Patient Preference; Physician-Patient Relations; Portugal; Quality of Health Care.

RESUMO

Introdução: As normas de orientação clínica são instrumentos de apoio à decisão que visam a melhoria da qualidade, promovendo as boas práticas clínicas. Os cuidados orientados para o utente permitem uma melhor satisfação e autogestão da saúde, com ganhos de qualidade e potencialmente menores custos.

Objetivo: Avaliar o grau de integração dos valores dos doentes nas normas de orientação clínica publicadas em Portugal.

Material e Métodos: Reviram-se as 18 normas de orientação clínica da área cardiovascular publicadas em Portugal entre 2011 e 2013, procurando avaliar a introdução das ideias, medos, expectativas e preferências dos doentes.

Resultados: Oito normas de orientação clínica estavam relacionadas com processos de diagnóstico e 10 com aspetos de terapêutica. Em cinco normas de orientação clínica (28%) foram encontradas referências a valores dos doentes, todas na área da terapêutica, não existindo nenhuma nas normas de orientação clínica relacionadas com o diagnóstico. A incorporação das expectativas dos doentes foi o aspeto mais presente. Em 78% existiam referências à valorização dos custos financeiros.

Discussão: As normas de orientação clínica constituem-se como uma tecnologia de saúde ao dispor dos profissionais com o objetivo de melhorar a prestação dos cuidados assistenciais aos cidadãos, utilizadores últimos destes instrumentos. Como noutros países, há uma tendência a não considerar os utentes e os seus sistemas de valores na estrutura das orientações, privilegiando-se uma lógica populacional nem sempre aplicável ao caso concreto, e uma aritmética financeira pouco suportada em avaliações de custo-efetividade. No caso português, a forma como foram propostas foi também condicionadora de desconfiança tanto nos profissionais como nos utentes.

Conclusão: As normas de orientação clínica em Portugal apresentam uma baixa taxa de incorporação dos valores dos utentes, de uma forma mais visível na definição do diagnóstico, o que os coloca numa posição secundária no processo de decisão clínica com potenciais perdas na qualidade.

Palavras-chave: Normas de Orientação Clínica; Portugal; Preferências dos Doentes; Qualidade de Cuidados de Saúde; Relação Médico-Doente.

INTRODUCTION

In its original 1990 definition, *guideline* referred to systematically developed statements that assist physicians and patients to make decisions about appropriate healthcare for specific clinical circumstances¹ aimed to continuous quality, adequacy and effectiveness improvement in healthcare, as well as to the promotion of good clinical practice.²

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Therefore, the use of scientifically sound recommendations as tools for guiding clinical practice may be considered as an equity strategy both for health professionals and users aimed at fostering transparency based on the best available evidence, moving away paternalist medicine in which paradigmatic medical decision had an absolute power.

The application of evidence-based medicine calls for justice to reassert its primacy as fundamental ethical principle, suggesting efficient solutions for each specific case and healthcare system, without compromising physician's care of patients, insofar as clinical experience and patient's values are involved in research data³ and in decision-making.

It is a patient-oriented medicine rather than disease-oriented and it will provide more and better health gains⁴ which is everyone's aim.

All over the world, different specialized agencies

regularly release clinical practice guidelines. In Portugal, this role has been legally assigned to the *Direção Geral da Saúde* (DGS).⁵ In 2011, within the need for an international financial assistance agreement, the Portuguese State has committed to an economic and social reorganisation at different levels.⁶ As regards healthcare, one of the aims involved the publication of clinical practice guidelines (*normas de orientação clínica* (NOC's)) and an audit system applied to its implementation.

In total, 70 NOCs were published in 2011, 39 in 2012 and 32 in 2013, involving Primary, Hospital and Rehabilitation healthcare, aimed at promoting Portuguese healthcare improvements, even though only 16 of these were validated by the agreement established with the Portuguese College of Physicians (*Ordem dos Médicos*).

Our study aimed to analyse the level of incorporation of patient values into the NOCs published in Portugal between 2011 and 2013.

Table 1 – Clinical practice guidelines (*Normas de orientação clínica*) included in the study

ID	Title	Reference	Date
1	<i>Abordagem terapêutica da hipertensão arterial</i> (Therapeutic approach to high blood pressure)	026/2011	19 Mar 2013
2	<i>Abordagem terapêutica das dislipidemias</i> (Therapeutic approach to dyslipidaemia)	019/2011	11 Jul 2013
3	<i>Abordagem terapêutica farmacológica da angina estável</i> (Pharmacologic approach to stable angina)	046/2011	27 Nov 2013
4	<i>Abordagem terapêutica farmacológica na diabetes mellitus tipo 2</i> (Pharmacologic approach to type-2 diabetes mellitus)	052/2011	30 Jul 2013
5	<i>Avaliação do risco cardiovascular SCORE</i> (SCORE cardiovascular disease risk assessment)	005/2013	26 Nov 2013
6	<i>Diagnóstico e classificação da diabetes mellitus</i> (Diagnosis and classification of diabetes mellitus)	002/2011	14 Jan 2011
7	<i>Ecodoppler cerebrovascular</i> (Cerebrovascular evaluation by Doppler scanning)	031/2011	30 Sep 2011
8	<i>Ecodoppler venoso dos membros inferiores</i> (Lower limb venous Doppler technique)	030/2011	30 Sep 2011
9	<i>Hipertensão arterial: definição e classificação</i> (High blood pressure: definition and classification)	020/2011	19 Mar 2013
10	<i>Insulinoterapia na diabetes mellitus tipo 2</i> (Insulin therapy in type-2 diabetes mellitus)	025/2011	30 Jul 2013
11	<i>Prescrição de exames laboratoriais para avaliação de dislipidemias</i> (Laboratory tests for dyslipidaemia assessment)	066/2011	30 May 2013
12	<i>Acidente vascular cerebral: prescrição de Medicina Física e de Reabilitação</i> (Stroke rehabilitation care)	054/2011	27 Dec 2011
13	<i>Prescrição e determinação da hemoglobina glicada A1c</i> (Measurement of glycated haemoglobin levels)	033/2011	06 Dec 2012
14	<i>Revascularização miocárdica: acompanhamento hospitalar e em cuidados de saúde primários</i> (Myocardial revascularization: inpatient and primary care follow-up)	037/2012	30 Dec 2012
15	<i>Terapêutica da diabetes mellitus tipo 2: metformina</i> (Type-2 diabetes mellitus therapy: metformin)	001/2011	07 Jan 2011
16	<i>Tratamento conservador médico da insuficiência renal crónica estágio 5</i> (Conservative medical treatment of stage 5 chronic kidney disease)	017/2011	14 Jun 2012
17	<i>Utilização de ecodoppler arterial dos membros inferiores</i> (Use of lower limb arterial Doppler technique)	034/2011	30 Sep 2011
18	<i>Utilização e seleção de antiagregantes plaquetários em doenças cardiovasculares</i> (Use and selection of platelet antiaggregants in cardiovascular diseases)	014/2011	08 Jul 2013

Source: Website of the *Direção Geral da Saúde*. www.dgs.pt. Consulted 2014 fev 01.

MATERIAL AND METHODS

A review of the NOCs published by the DGS between 2011 and 2013 was carried out, based on the texts at www.dgs.pt, visited in 1 February 2014. (Table 1).

Cardiovascular diseases are the major cause of death in Portugal and consume a significant part of the available resources, corresponding to a health priority.⁷ Therefore, the NOCs on adult cardiovascular pathology were selected (18 of the 141 available; 10 original NOCs were updated). Only the latest available version was considered for the review, as it was published at the DGS website.

Data collection

Two different authors separately reviewed the text (with attachments) of the selected NOCs and the level of incorporation of patient values was assessed, represented by patients' ideas, concerns, expectations, satisfaction and participation in medical decision-making process. The final conclusion was obtained by consensus based on the results from each individual reading.

Study variables

Study variables were previously defined for systematic research. Ideas were defined as patients' opinions regarding a possible diagnosis, treatment or outcome.⁸ Concerns were defined as the expression of fear from a diagnosis or a treatment.⁸ Expectations referred to the anticipation of about what is to be encountered in medical diagnosis, treatment or procedure.⁸ Satisfaction was the level at which patients perceive utility, effectiveness or benefit from a specific healthcare or technology. The participation in clinical decision-making was defined by the expression of patients' own choice on any diagnostic or therapeutic decision.⁹

The presence of any reference to the assessment of patient's compliance to diagnostic or therapeutic measures,

the expression of financial costs for patients as for the healthcare system, the expression of iatrogenic costs regarding potential adverse effects of proposed procedures and the presence of indicators of evaluation were also studied. The latter were ranked as clinical indicators when aimed to assess clinical objectives, such as for instance NOC 1, the evaluation of the percentage of users diagnosed with high blood pressure, with a history of stroke or acute myocardial infarct over the last 12 months, or as non-clinical indicators as for instance in this same NOC the evaluation of the cost of prescription of antihypertensive drugs per patient. NOCs were ranked according to their content into the group of NOCs related to diagnostic procedures for the specific clinical condition and into the group of NOCs related to therapy.

The variable of the expression of financial costs was dichotomised, including any reference to aspects related to costs regardless of being included in an economic analysis or just related to market prices or prescription volume.

RESULTS

In total, 18 NOCs with 88,731 words in 240 pages were reviewed. Ten NOCs addressed aspects regarding therapy and eight regarded diagnosis. (Fig. 1)

The incorporation of patients' values was found in five NOCs. The result distribution according to the classification in terms of whether the guideline was diagnosis or therapy-oriented is shown in Fig. 1.

The reference to patients' ideas and opinions was found in three NOCs in expressions such as '*A opção por qualquer dos fármacos depende...da preferência do doente*' (The option between either of the drugs depends... on patient's preference) (NOC 3 in Table 1), '*A eficácia terapêutica ... depende ... da aceitação da terapêutica*' (The therapeutic efficacy... depends... on accepting the therapy) (NOC 10) and '*adequado esclarecimento do doente e dos seus*

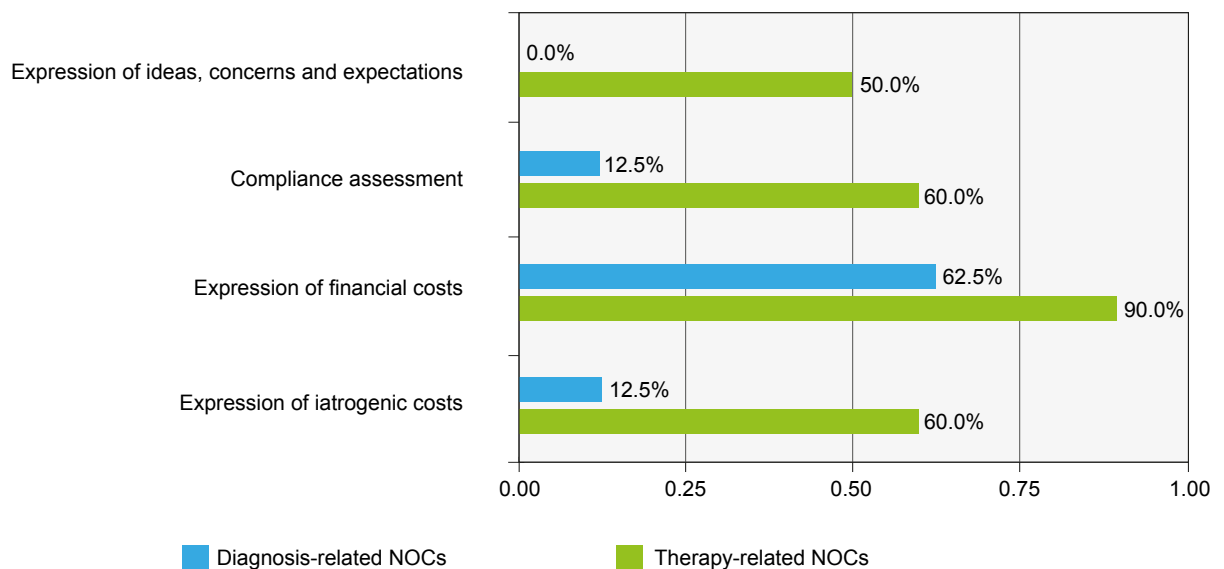


Figure 1 - Assessment of cardiovascular-related clinical practice guidelines (NOCs) according to the study variables.

NOCs: Normas de orientação clínica

próximos acerca dos resultados esperados e contribuir, desta forma, para uma opção informada por uma modalidade de tratamento, mais ou menos agressiva, de acordo com a sua perspetiva pessoal (patient and their relatives being adequately clarified regarding the expected outcomes and therefore contributing to an informed option for any treatment modality, more or less aggressive, according to his/her own personal perspective) (NOC 16).

A reference to the expression of patient's concerns or fears was found in two NOCs, expressed by '*a eficácia terapêutica ... depende ... da desmontagem dos falsos mitos e receios*' (therapy efficacy... depends... on dispelling false myths and worries) (NOC 10) and '*em alguns momentos da sua vida futura, podem surgir ansiedade, receio do futuro, depressão*' (anxiety, fear for the future and depression may arise somewhere in the future) (NOC 16).

Patients' expectations were expressed in two NOCs: '*A eficácia terapêutica ... depende ... da aceitação da terapêutica*' (therapy efficacy... depends... on accepting the therapy) (NOC 10) and '*considerar, para cada doente, o direito à escolha do melhor tratamento para a sua pessoa, no seu contexto individual e familiar, de acordo com as suas expectativas e opções de vida*' (considering the right for each patient to choose his/her own best treatment, within his/her own and family context, according to his/her life expectations and options) (NOC 16).

The process of decision-making process for healthcare management was found in four NOCs, focusing on patient's capacity (NOC 10), his/her involvement and family on the decision (NOC 12) and the possibility to freely obtain an informed option (NOCs 1 and 16) using formal or informal evaluation of patient's satisfaction (three NOCs).

DISCUSSION

Patients' values are scarcely represented in cardiovascular-related NOCs published in Portugal from 2011 to 2013, in which three out of four NOCs did not show any sort of proposal related to the incorporation of patients' ideas, concerns, expectations and shared decision-making regarding therapy or diagnosis. Even when included, the expressions are just small sentences included in medical decision-making on which is the best option for the patient rather than truly shared responsibility in the choice between different possible solutions.

The same concern was found in other realities. In Canada, McCormack¹⁰ analysed five therapeutic guidelines in 2007 and found similar results and Chong¹¹ found a scarce integration of patients' preferences. In the United States, MacLean *et al.*¹² called the attention to the need for patients' opinions to be included in the clinical decision as a strategy to improve the results of medical intervention, in a consensus study on antithrombotic therapy.

In Portugal, the scarce integration of patient's values in clinical practice guidelines is a specific cause for concern, considering that NOCs are presented within a legislative framework, which does not occur in other countries.

In classic biomedical vision, the patient presents with

different signs and symptoms leading to a list of differential diagnoses from where the defining disease comes from and for which a therapeutic plan and an outcome is established. The introduction of the concept of patient-oriented healthcare¹³ has changed this paradigm into a holistic approach to clinical practice, giving emphasis on the role of the patient in his/her own health management and involving his/her own biological, psychological, social and spiritual multi-dimensionality in diagnosis, therapeutic and outcome strategies. Health professionals act mainly as active allies in this process rather than single guides, involving patient's knowledge and experience in decision-making¹⁴ which is therefore shared by both¹⁵ without reducing physician's relevance¹⁶ as well as the responsibility in handling the available technologies.

Multiple factors could somehow interfere with this balance according to the model proposed in 2000 by Mead and Bower¹³, depending from the physician, the patient, the context, from socio-cultural variables and the very own clinical practice, suggesting the need for a continuous and stable relationship of mutual knowledge to overcome those factors.

Our study involved one variable related to clinical practice and to a legal framework that could condition the usual professional activity. NOCs came up at a very high pace throughout the study, making the perception of contents more difficult for the professionals, producing mistrust as regards scientific rationale and doubts regarding its applicability to each specific case.¹⁷ In fact, the simple publication of rules is not enough for a quick change of behaviours,¹⁸ predisposing to a change of attitudes in professionals that may and should be used to start a quality improvement process that periodically and continuously will improve the current reality.

The need for the best available evidence-based guidelines rather than based only in expert consensus is obvious¹, adapted to local reality and to a personalized decision and including the enhancement of clinical experience as well as patients' expectations, for whom these are intended.

The expression of the financial costs assumes a particular relevance in the evaluated NOCs and was found in most texts. Nevertheless, this may not reflect a real economic crisis for which a specific methodology is used and such studies, even when available for the national reality, were not included in NOCs' legal framework. In fact, in Portugal, health financing was spread across public and private providers, with a 68.5% average weight of the public sector from 2001 to 2010, according to OECD data and with a reduction trend to 62.6% in the 2012 estimate and representing a national investment of 10.2% of the gross domestic product in 2009 and in 2010. However, when considering an assessment per capita in monetary terms, we find that health expenditure in Portugal is systematically below the OECD average, with a growing difference over the last few years (Fig. 2) and of -750 US\$ in 2011 for overall health levels assessed by average life expectancy

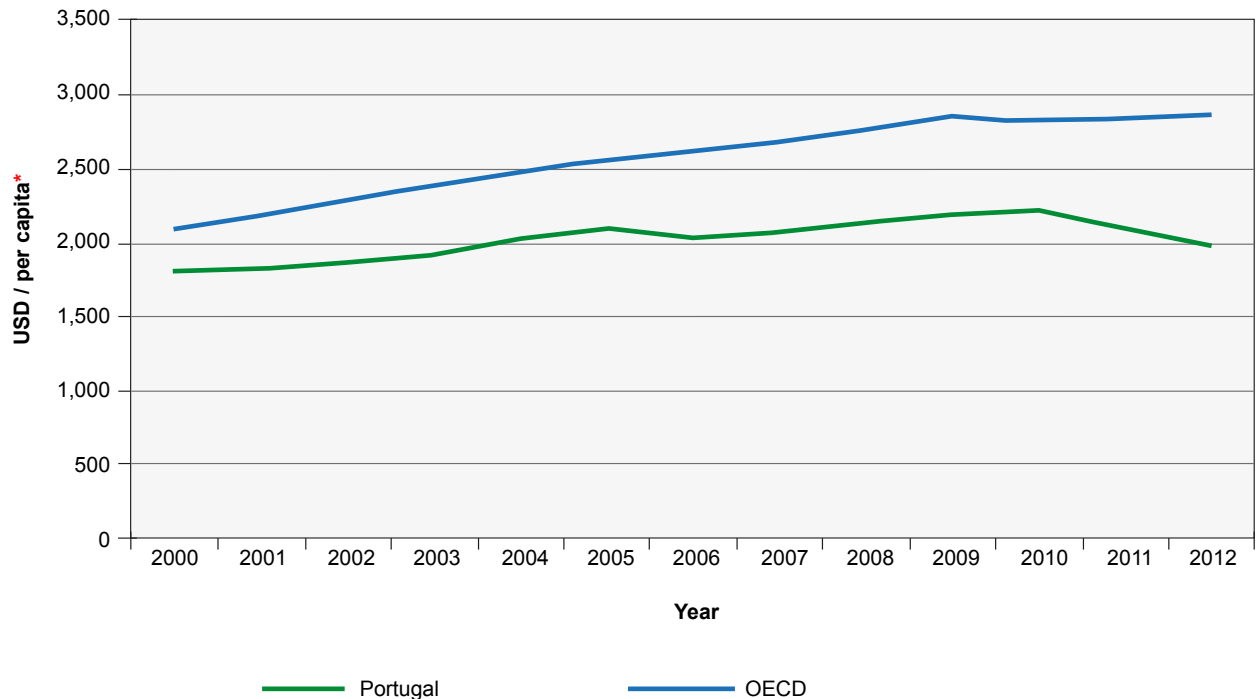


Figure 2 - Evolution of healthcare expenditure in Portugal compared to OECD average.

* Currency unit – USD, on a 2005 purchasing power parity basis (Source: OECD Health Data, 2014)

and by children mortality rate above the comparator.

Every country is ethically required to provide citizens with the best available healthcare. The justice principle within a situation in which resources are limited leads to the need for a careful weighting of allocated available resources, combining basic beneficence of clinical practice with the constraints that arise from an adverse situation. NOCs may play a positive role in this apparently ethical dilemma, supporting clinical decision, reviewing the best available evidence as regards key issues for healthcare services and their consequences and providing the NOCs under a simple understanding format allowing for its applicability to each specific case,¹⁹ assuming a patient-centred rationale²⁰ rather than population or healthcare-centred. This may be improved if the evidence regarding patient's preferences would be incorporated into decision-making fluxograms.^{21,22}

The absence of standardised and validated scales for the evaluation of patients' values is a limitation to our study, involving a risk of subjectivity.²³ Variable definitions were selected from literature and accepted by consensus in order to minimize this concern, ensuring that the results would show the reality of the NOCs published between 2011 and 2013.

CONCLUSION

Much has been said and written about the *Normas de Orientação Clínica* that came to public discussion. The cardiovascular-related NOCs published in Portugal were assessed in our study as regards the incorporation of patients' values shown by the expression of patients' ideas, concerns and expectations regarding their health and the

way this is oriented with the physician and a low level of integration in the texts was found.

The introduction of clinical guidelines is positive in the sense that it makes the review of the huge evidence easier and should be considered from a continuous quality improvement point of view. The efficacy of this tool depends on professionals, patients and environmental characteristics²⁴ requiring a more careful look to patient's characteristics in its design²⁵ who are ultimately the real users of this technology.

HUMAN AND ANIMAL PROTECTION

The authors declare that the followed procedures were according to regulations established by the Ethics Committee and to the Helsinki Declaration of the World Medical Association.

DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

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