Transdisciplinarity in strategic decisions for oncological treatments

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ABSTRACT

The current models for equity and access to new oncological treatments are under strain due to the economic and demographic crisis in Europe as well as the rising costs of innovative drugs.

Cancer treatment needs a model of patient-centered care in which an interdisciplinary care plan, based on evidence-based practice is essential for patient wellbeing. The drug review process should distinguish what is real innovation from what is just new. The breakthrough of innovation lead to a huge rising of costs all over Europe.

Accordingly with the Article 64 of the Constitution of the Portuguese Republic (CRP), the state has the primary duty of ensuring health protection regardless of their economic circumstances. The state has to ensure a rational and efficient nationwide coverage in health human resources and facilities and to direct its action towards the socialization of the costs of medical care and medicines.

Physicians should be focused in the doctor-patient relationship and informed consent is important especially when new medicines are prescribed (amount of information, what information and end of life information)

Related with informed consent there is therapeutic privilege which can be resumed to the retain of information considering the beneficence principle (Portuguese penal code 157)

Also utilitarianism and social justice (Beauchamp, 2009) has to be considered without compromising human dignity. The principle of economy cannot be ignored in the

provision of public services and it implies excellence, clinical governance and optimization of social rights through good governance of public and private resources allocated to the health system.

An interdisciplinary approach is essential for the new oncological drugs approval, considering several interrelated areas such as human rights, economic opportunities, good governance and development. A close relation of all healthcare stakeholders can improve policies and operating practices that enhance the competitiveness to catalyze social change and/or address economic and social needs.

The healthcare stakeholders will require a deeper understanding of global oncology trends, multidisciplinary decisions will be mandatory and governments will have to decide what they will be able to pay in the next years. Transdisciplinary decision between civil society, pharmaceuticals, healthcare professionals and policymakers is essential in order to assure quality, access to innovation and equity in oncological care.

Keywords:

Cancer, innovation, costs, transdisciplinarity, utilitarism, social justice

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The current models for equity and access to new oncological treatments are under strain due to the economic and demographic crisis in Europe as well as the rising costs of innovative drugs.

Cancer treatment needs a model of patient-centered care in which an interdisciplinary care plan, based on evidence-based practice is essential for patient wellbeing.

Physicians should be focused in the doctor-patient relationship and informed consent is important especially when new medicines are prescribed.

Related with informed consent there is therapeutic privilege. Moreover, utilitarianism and social justice has to be considered without compromising human dignity and the principle of economy cannot be ignored in the provision of public services.

An interdisciplinary approach is essential for the new oncological drugs approval. Therefore, transdisciplinary decision between civil society, pharmaceuticals, healthcare professionals and policymakers is essential in order to assure quality, access to innovation and equity in oncological care.

Keywords:

Cancer, innovation, costs, transdisciplinary, utilitarism, social justice

INTRODUCTION

The multidisciplinary in the treatment of oncological patients is essential for patient wellbeing given the nature of their illness and its multimodal treatment. The unmet healthcare needs of cancer patients, with potentially harmful repercussions on patients' health and well-being[1, 2] presents a challenge for the different professionals involved in the treatment.

The provision of health care is considered a public good and in some countries a right in which the government has an important role in funding both basic and clinical research; regulating safety and efficacy; determining availability, equity and access; and often pricing and/or reimbursement of health products and services.[3]

Patients with cancer usually receive care from multiple professionals, working in a variety of settings, whose services may be provided either concurrently or at different points in time.[4, 5] Cancer treatment needs a model of patient-centered care in which an interdisciplinary care

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[1] Morrison V et al. Common, important, and unmet needs of cancer outpatients. Eur J Oncol Nurs, (2012), 16: 115–123.

[2] Tremblay D et al. Conditions for production of interdisciplinary teamwork outcomes in oncology teams: protocol for a realist evaluation. Implementation Science, (2014), 9.1: 76.

[3] OCDE - Biomedicine and health innovation: synthesis report - 2010 http://www.oecd.org/health/biotech/46925602.pdf (Accessed: 14 Jan 2015).

[4] Howell D et al. A Pan-Canadian Clinical Practice Guideline: Assessment of Psychosocial Health Care Needs of the Adult Cancer Patient. Toronto: Canadian Partnership Against Cancer (Cancer Journey Action Group) and the Canadian Association of Psychosocial Oncology, (2009). http://www.capo.ca/Fatigue_Guideline.pdf. (Accessed: 10 Jan 2015).

[5] Comité des représentants de la population atteinte de cancer et des proches (REPOP): Besoins des personnes atteintes de cancer et de leurs proches au Québec, Recommandations, Avis, (2005). [http://www.merici.ca/ Bibliotheque_pdf/msss_quebec/besoins_pers_cancer.pdf] (Accessed: 2 Feb 2015)

plan, based on evidence-based practice, can be developed with objectives shared by the different practitioners on the team.[6]

It is increasingly important that the drug review processes reflect not only increased survival and quality of life of patients but essentially, to distinguish what is real innovation that is just new. This is even more important at each year since the breakthrough of innovation is changing the paradigm, especially in oncology where the discovery of new oncological drugs lead to a huge rising of costs.[7] In Europe, this problem has increased due to the economic crisis because funding has decreased and there was also a general trend towards cuts in new drugs, with consequent loss for the patients.[2]

The OECD has done important work in the development of a comprehensive policy strategy to harness innovation for stronger and more sustainable growth and development, and to address the key societal challenges of the 21st century such as the growing constraints on public health expenditures and funding gaps.[3]

The type of government funding is different between the different European countries. In the Netherlands, the coverage of health care is universal and guaranteed by the government although there is regulation by the private law and there are private insurers to offer a health care package. These insurers must accept all individuals and they can choose the insurer.[8, 9]

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[6] Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. Soc Sci Med, (2000), 51:1087–1110.

[7] Price P and Karol S. Treatment of Cancer Sixth Edition. CRC Press, (2014).

[8] Schäfer W. et al. The Netherlands: health system review. Health systems in transition, (2010), 12.1: xxvii-1.

[9] Thompson JR. Counterparty risk in financial contracts: Should the insured worry about the insurer? Available at SSRN 1278084, (2009).

In Spain the model is universal and free but each of the 17 autonomous regions have a Ministry of Health responsible for the financing and delivery of health care. National and regional taxes account for about 68% of total health expenditure.[9, 10]

Also in Italy the health model is based on cost-free and universal access and is funded by the state.[9,] On the other hand, the French model is based on the contributions of users and employers for the National Health Insurance Required. This covers almost the entire population but the government focused on the protection of vulnerable groups.[9, 11, 12] France also uses models of risk sharing in drugs, based on the framework agreement between the LEEM (Les Entreprises du Medicament - group of pharmaceutical companies) and the CEPS (Committee Economique des Produits De Santé).[11]

In the Belgian health model there is a system of compulsory health funds, individuals pay taxes according to their income and may freely choose their health fund.[13]

In Germany, there is a social insurance that covers about 88% of the population that is financed by compulsory contributions. This requirement applies to all employed persons with incomes up to € 48,000 / year. Above this value, individuals can choose to continue or not to benefit from the health fund.[14]

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[10] Vogler S et al. Pharmaceutical pricing and reimbursement information (PPRI)–new PPRI analysis including Spain. Pharmaceuticals Policy and Law, (2009), 11.3: 213-234.

[11] Vogler S et al. Pharmaceutical policies in European countries in response to the global financial crisis. Southern med review, (2011), 4.2: 69.

[12] Latitude iniciativa. Avaliação clínica e económica do medicamento com vista ao seu financiamento - Síntese da sessão plenária e recomendações, (2013). www.iniciativalatitude.org/ (Accessed 3 Jan 2015).

[13] Gerkens S and Merkur S. Belgium: Health system review. Health Systems in Transition, (2010), 12.5: 1–266.

[14] Busse, Reinhard, and Miriam Blümel. Germany. Health system review, (2014).

The national Swedish health service is free, universal access and state funding but based on taxes paid by users.[15]

The model most frequently reported health in the literature is the UK, which is a national health service based on the principle of a free service to all residents, with the state guaranteeing universal access of users to care for via taxes paid by users.[15] The National Institute for Health and Clinical Excellence (NICE), a special health authority of the national health service English (NHS) established in 1999, is a model for the development of clinical guidelines and also plays an important role in pioneering technology assessment in health systems.[16] This institute makes decisions at national level, which may conflict with what is (or is believed to be) the best interests of a particular patient. However, process transparency and decisions, the logic of those decisions, the opportunity to appeal any decisions and the presence of mechanisms to ensure that the other conditions are met make this institute a reference in Europe for decisions on approval medicines in oncology. These features are also defended by Browman the presentation of the "6-STEPPS tool"[17], which is a Canadian oncology decision tool with a perspective similar to that of NICE. Another feature of NICE is the ability to negotiate the price of new medicines and to set rules for co-payment for new pharmaceutical products.[15, 18] However, in 2006 the NICE refused cetuximab and

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[15] Kanavos P et al. Differences in costs of and access to pharmaceutical products in the European Union. Directorate general for internal policies policy department a: Economic and scientific policy, PE 451.481 (2012), 20-25.

[16] Schlander M et al. Budget impact analysis of drugs for ultra-orphan non-oncological diseases in Europe. Expert review of pharmacoeconomics & outcomes research, (2015), 1-9.

[17] Browman GP et al. 6-STEPPPs: A modular tool to facilitate clinician participation in fair decisions for funding new cancer drugs."Journal of Oncology Practice, 4.1(2008): 2-7.

[18] Espín J et al. Experiences and impact of European risk-sharing schemes focusing on oncology medicines. Brussels: Commissioned by the European Commission, Directorate-General Enterprise, (2011).

bevacizumab for administration to patients with colon-rectal carcinoma metastatic considering that this medicine was too expensive compared to the survival provided to patients, which led to severe public criticism. This demonstrates how ethical issues about rationing of medicines is a controversial and sensitive issue and demonstrated the need for an involvement of civil society in oncological decisions.[19] In fact, the criteria for decisions in the process should consider internal and external factors. Internal factors to consider are the clinical benefit (effectiveness and adverse effects), drug costs, alternative treatments available, decisions in other hospitals /systems, the size of the affected population, severity of illness and past decisions. External factors that influence the decision-making are the doctors, patients, the pharmaceutical industry and independent researchers.[20]

All of the above health models are focused on funding issues and cost-effectiveness. A change of mentality ("new mindset") to realize that health is necessary, human rights, economic opportunities, good governance and development are interrelated areas in a complex and interdependent world.[21]

In Portugal, accordingly with the Constitution of the Portuguese Republic (article 64), everybody has the right to health protection and the primary duty of the State is to ensure the right to health protection such as the access for all citizens to medical care, regardless of their economic circumstances.[22] However, the economic recession associated with population

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[19] Fleck LM. Just Caring: Defining a Basic Benefit Package. J Med Philos, (2011), 36.6: 589-611.

[20] Vuorenkoski L et al. Decision-making in priority setting for medicines—A review of empirical studies. Health Policy, (2008), 86.1: 1-9.

[21] Benatar SR et al. Global health ethics: the rationale for mutual caring. International Affairs, 79.1 (2003): 107-138.

[22] Rueff, MC. Rationalization in Health: A Legal-Constitutional Perspective. Medicine and Law - World Association for Medical Law, (2015), 34.2: 321-334.

ageing, lead to a decrease in the resources of the state[22, 23] which affects several medical areas such as the approval of new oncological drugs. The state, in order to ensure that it is still able to satisfy the health care requested by citizens, must have enough resources.

The crisis has caused civil society and the governments that serve them to place renewed focus on the social welfare benefits of investment in innovation.[3]

The authors intend to analyze the different fundamental bioethical tensions that can arise when the cancer patient's health care may be compromised by financial restrictions in the National Health Service.

METHODOLOGY

The researchers used a qualitative methodology (transdisciplinary method) for the analysis of the medical-legal content[24, 25] where, from a right of autonomous medicine, develop the branches representing the segments correspondingly relevant major classical disciplines which are civil law, public law and criminal law. The researchers considered the dimensions of medical care; economic restrains and clinical governance; human rights; healthcare management; corporate social responsibility and corporate social value. This inductive methodology, own the right of medicine, is relevant to address the various problems inherent to the issues of medical law for the strategic management of hospital cancer therapy because it allows a global view and from the inside out of the problem under study.

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[23] Garel P and Lombardi G. Hospitals in Europe – data and trends. Hospital Healthcare. Hope Bulletin, 020, (2012).

[24] Rueff MC. O segredo médico como garantia da não-discriminação – estudo de caso: VIH-SIDA. Coimbra editora, (2009), 173-180.

[25] Eser, A. Perspectivas do Direito (Penal) da Medicina. Revista Portuguesa de Ciência Criminal, (2004b), 14 (1 e 2): 11-63.

RESULTS AND DISCUSSION

a) Medical consent and evidence based medicine

Innovation in cancer account for an increasing proportion of developed-country health budgets.[26] The increased cancer risk awareness and better access to more effective preventive and curative treatments allowed a prolonged survival for cancer patients. However, it is essential that patients can be informed about the new medicines and, based on that, to decide if they want to do the treatments especially since cancer treatments have a lot of secondary effects and can even be life-threatening. Patient autonomy is facilitated by informed consent and a physician–patient dialogue educates the patient about the available treatment options, their risks and benefits and allows for the creation of a negotiated treatment plan guided by the patient's values and goals. Moreover, informed consent include roles and responsibilities of patients and providers and will lead providers to prioritize the more self-directed (and self-protective) goals of describing patient obligations and the consequences of their noncompliance and to seek procurement of the patient's signature on the agreement over the discussion which lies at the core of the informed consent process.[27]

A physician–patient relationship remains dependent upon trust, not contract enforcement.[27] Therefore, informed consent is important when new medicines are prescribed but there are questions about: the amount of information; what information; end of life information. Related with informed consent there is therapeutic privilege (retaining of information

[26] Chamberlain C. et al. Does the cancer drugs fund lead to faster uptake of cost-effective drugs? A time-trend analysis comparing England and Wales. British journal of cancer, (2014), 111.9: 1693-1702.

[27] McGee S. and. Silverman D. Treatment Agreements, Informed Consent, and the Role of State Medical Boards in Opioid Prescribing. Pain Medicine, (2015), 16.1: 25-29.

considering the beneficence principle).[28] The term "Therapeutic privilege" refers to the withholding of information by the clinician during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient.[29]

A legitimate question that arises is whether it is permissible to inform all cancer patients about the risks of treatment and prognosis. For example, if the patient is depressed, can this information have negative effects that become detrimental to the patient? This question arises incidentally contemplated in paragraph 1 " in fine " Article 157 of the Portuguese Criminal Code that allows the non-disclosure of information to the patient " if it involves the communication of circumstances , to be known by the patient , would endanger his life or would be likely to cause serious harm to health, physical or mental" .

b) Economistic criteria and clinical governance

The multidisciplinarity in oncology is important to promote the improvement of cancer care quality but patients and clinicians may have different ideas about what constitutes a cancer care decision[27] and the economic European restrictions is forcing a change in healthcare.

There are controversies considering the restricted access to cancer drugs as an important cause to relatively poor survival from cancer in UK.[26] However, in spite of the European economic crisis,[30] health care reforms across all countries in Europe aimed to maintain health care quality with lower costs.

We can analyze the Portuguese paradigm of European recession. Accordingly with the Article 64 of the Constitution of the Portuguese Republic (CRP), the state has the primary duty of

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[28] Richard C et al. Therapeutic privilege: between the ethics of lying and the practice of truth.. Journal of medical ethics, (2010), 36.6: 353-357.

[29] Etchells, Edward, et al. "Bioethics for clinicians: 2. Disclosure." Canadian Medical Association Journal, (1996), 155.4: 387-391.

[30] Garel P and Lombardi G. Hospitals in Europe – data and trends. Hospital Healthcare. Hope Bulletin, 020. (2012).

ensuring health protection regardless of their economic circumstances. The state has to ensure a rational and efficient nationwide coverage in health human resources and facilities and to direct its action towards the socialization of the costs of medical care and medicines.[22] The right to health is a social right, implies legislative measures and is dependent on existing economic resources.[22, 31] Since Portugal is a country with a high level of legal health protection, it requires excellence and hospital governance as a vehicle for clinical quality and an instrument of health care excellence.[22] As also defended by Canotilho, the doctors (including medical oncologists and hematologists, needed to take into account the economic conditions mentioned in the code of ethics and the basic law (principle of economy) for public health in their freedom for prescription.[22, 31]

The innovation is increasing and the availability of new drugs all over Europe is also growing.[32, 33] Moreover, as the effectiveness of treatments increase (as we could recently observed with hepatitis C treatment), that restrictions can became a real problem for patients and governments.[34]

At the moment the restrictions placed by NICE in England National Health Service, did not increase cancer death rates probably because there is the Cancer Drugs Fund which provides £200 million annually in England for oncological drugs.[26] However, the controversy

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[31] Canotilho JG and Moreira V. Constituição da República Portuguesa Anotada, vol. I, 4th edition, (2007), Coimbra Editora, Coimbra.

[32] Berndt ER et al. Decline In Economic Returns From New Drugs Raises Questions About Sustaining Innovations. Health Affairs, 34.2 (2015): 245-252.

[33] Schlander M et al. Budget impact analysis of drugs for ultra-orphan non-oncological diseases in Europe. Expert review of pharmacoeconomics & outcomes research 0, (2015), 1-9.

[34] Obach D et al. How to optimize HCV treatment impact on life years saved in resource-constrained countries. Hepatology, (2015).

surrounding the future of the Cancer Drugs Fund in England is already debated because there is a lack of funds.[35]

In 2010, was created a Cancer Drugs Fund (CDF) in order to minimize the disparity in oncological patients' access to new drugs in England compared with other countries'.[26] The CDF was to provide access to drugs not yet appraised by NICE, not licensed or that was not considered cost-effective.[26] However, the huge raise of innovation imply that from the £200 million annual CDF, a further £400 million investment will be needed to continue the CDF beyond 2014.[36] The CDF in England, are assumed to reflect societal preferences for NHS resource allocation but a recent study conducted by Linley[37] explored, with a survey to 4118 UK adults, the societal preferences for these and other criteria, including those proposed for rewarding new medicines under the future value-based pricing (VBP) system. Respondents supported the criteria of innovation with substantial health benefits but did not support several issues such as the CDF and the end-of-life premium which rise the question of policies introduced on the basis of perceived—and not actual—societal values in the different countries may lead to inappropriate resources allocation.

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[35] Smith E and Raftery J. Value Assessments in UK Cancer Care: Measuring Benefit, Assessing Cost and Determining Funding. ASCO daily news, (2014). http://am.asco.org/value-assessments-uk-cancer-care-measuring-benefit-assessing-cost-determining-funding (Accessed: 20 Feb 2015).

[36] Cancer Research UK. Government announces extension of Cancer Drugs Fund, Cancer News, (2013). http://www.cancerresearchuk.org/cancer-info/ news/archive/cancernews/2013-09-28-Government-announces-extensionof-cancer-Drugs-Fund (Accessed: 18 Dec 2014).

[37] Linley WG., and Dyfrig A. Hughes. Societal Views on Nice, Cancer Drugs Fund And Value-Based Pricing Criteria For Prioritizing Medicines: A Cross-Sectional Survey Of 4118 Adults In Great Britain. Health economics, (2013), 22.8: 948-964.

Although cancer will always be a devastating condition with serious physical and emotional components for patients and their caregivers, change is clearly necessary to preserve equity of access to care to all patients, regardless of their disease. NICE operates within a country and political environment where, for some, the notion of a QALY has proved unpalatable, leading to a parallel system of drug funding through the Cancer Drugs Fund, which operates counterpoint to NICE's principles. This may benefit patients and the pharmaceutical industry in the short term, but is economically unsustainable.[35]

In Portugal the health system is funded mostly through transfers from the Government budget, meaning general taxation is the main funding source of the National Health Service (NHS). The public transfers to the NHS account for 16.1% of the planned Government expenditure for 2012.[38]

The life quality of the Portuguese population and availability of the health care services has improved in the last 50 years with the consequent longer life expectation.[39] However, the health inequalities, made the current system inefficient. In oncology the main problems are the centralization of physicians in the main cities, the lack of alignment in decision making for new drugs, the insufficient culture of management performance and accountability in the hospitals and the limited information to monitor and drive performance improvements.

Reflecting on the methodological challenges to the sustainability of the social state maybe we can consider Canotilho who believes that the Law continues to be an essential command and a reliable tool in our society.[40]

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[38] Barros PP. Health policy reform in tough times: the case of Portugal. Health Policy, (2012), 106.1: 17-22.

[39] Appleby J. Spending on health and social care over the next 50 years. The King's Fund, London. Available via http://www. kingsfund. org. uk/time-to-think-differently/publications/spending-health-and-social-care-over-next-50-years, (2013).

[40] Canotilho, José Joaquim Gomes. Estudos sobre Direitos Fundamenais. 2nd ed., Coimbra Editora, (2008), Coimbra.

c) Human rights

The right to health is a fundamental right and governments must generate availability of health services besides healthy and safe working conditions, adequate food, clothing, housing, food and clothing. (Universal declaration of human rights, article 25).

Changes in society, with the notion of social responsibility, brought the perception that ethical behavior is essential in organization's practices especially in the way they deal with aspects such as human rights.[41] The concept that health and human rights are both powerful and important for human well-being and health workers should consider their responsibilities to respect human rights in developing policies, programs and practices, and to contribute actively to improve societal realization of rights.[42] However, the European economic crisis can compromise the right to health since governments do not have money enough in order to continue financing national health services.[43] The huge technological growth and the amount of innovation in oncological and infectious diseases (especially, HIV and HCV) turn this situation even more problematic.[44]

Considering the example of Portugal, the Constitution of the Portuguese Republic prohibits discrimination based on disability and on aggravated health risk (Law 46/2006, of 28 August

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[41] Brandão C et al. Social responsibility: a new paradigm of hospital governance? Health Care Analysis, (2013), 21.4: 390-402.

[42] Mann JM. et al. Health and human rights. Health and human rights, (1994), 6-23.

[43] Cervero-Liceras F et al. The effects of the financial crisis and austerity measures on the Spanish health care system: A qualitative analysis of health professionals' perceptions in the region of Valencia." Health Policy, (2015), 119.1: 100-106.

[44] Tabish, SA and Syed N. Future of Healthcare Delivery: Strategies that will reshape the Healthcare Industry Landscape. International Journal of Science and Research (IJSR), (2015), 4.2: 727-758. ISSN (Online): 2319-7064 (Accessed: 3 Mac 2015)

– direct and indirect discrimination) so, with differentiation in drug assessment between hospitals, we are infringing a fundamental right. Moreover, the enforcement of Law 46/2006 implies that every citizen should prevent and mend actions that can result in breach of any fundamental right or in denial or infringement of exercise of any economic, social, cultural or other, by any person, based on disability.[45]

d) Classical utilitarism and social justice or common good an corporate social responsibility

It is essential to consider the classical utilitarism and social justice, in which the physician must act so that the consequences are beneficial to the patient and to society.[46] The underlying ethical utilitarianism is to consider the individual and should be sacrificed for the common good of the function.[46] Whereas social justice advocated by Beauchamp and Childress, for cancer patients, access to new drugs in similar cases, should be comparable and distributed to all eligible patients.[46]

Considering the problem in Portugal, we find that there is a basic principle which is not fulfilled that is the principle of equity.[45] In fact, in two different hospitals, even separated by a few kilometers, two different patients may not have access to the same drugs. Although equity of access to health care is a central objective of many health care systems, this is not always possible because socio-economic constraints.[47] We could discuss the issue of doctors

[45] Initial Report of Portugal on the implementation of the Convention on the Rights of Persons with Disabilities, (2012). (http://cdhps.fpasurdos.pt/ficheiros/files/Relatorio%20inicial%20de%20Portugal%20sobre%20a%20implementacao%20da%20CDPD_%2007_08_2012.pdf (Accessed: 29 Nov 2014).

[46] Beauchamp TL and Childress JF. Principals of biomedical ethics. 6th ed. New York: Oxford University Press, (2009).

[47] Goddard M and Smith P. Equity of access to health care services: Theory and evidence from the UK. Social science & medicine, (2001), 53.9: 1149-1162.

are not all the same and not have the same training and / or update however, the available means must be the same and not dependent on hazard. In Portugal, measures are being implemented to reduce or even end these arbitrary as the formation of the National Commission of Pharmacy and the implementation of SINATS.[48] The fear of many clinicians and society is that the measures that seem beneficial "*ad initium*" may be too restrictive and prevent the prescription of drugs already approved and marketed in Europe for its clinical benefit, which goes against the principle of state social, already debated in countries like Germany. German doctrine, recognized by the German Constitutional Court (BVerfG of 12.06.2005), refers to the right of a "minimum of existence", as "derived from the rights to life, physical integrity, and freedom in general, all in connection with the principle of the social state".[22]

e) From corporate social responsibility to corporate social value

The regulatory agencies (such as the EMEA and FDA), governments, non- governmental organizations and patient associations have identified the most efficient route to market for health products. Formal network of health professionals help in providing feedback and data about health innovation[3] such as new drugs in oncology. Cancer is a priority for health systems around the world because of three main factors: a) the higher incidence, growing and aging populations; b) the impact of patients and caregivers productivity loss; c) and due to rising treatment costs.[49] It is necessary to find technical and legal solutions to improve research and patient's access to new drugs with a reduced bureaucracy. Moreover,

[48] Cortegaça P et al. Economic Evaluation in Portugal–Establishment of The National Health Technology Assessment System (Sinats). Value in Health, (2014), 17.7: A452.

[49] IMS Institute for Healthcare Informatics. Innovation in Cancer Care and Implications for Health Systems: Global Oncology Trend Report, (2014). Available at: http://www.obroncology.com/imshealth/content/IMSH_Oncology_Trend_Report_020514F4_screen.pdf. (Accessed: 26 Feb 2015)

governments should tolerate and encourage experimentation and search for emerging best practices even knowing that there is no single model of firm or inter firm organization which has emerged as a clear success.[3]

Health organizations, especially the ones in public service, have more extensive duties to key stakeholder groups such as the employees, communities, customers (patients) and suppliers (health care professionals).[50] Friedman defended that ‘‘social responsibility of business is to maximize profits’’[51] which is not the case in public organizations, especially in healthcare.[50] In general, the legitimacy of an organization’s behavior is one of the cornerstones upon which its survival and development within society is founded.[52] In public healthcare service the survival mainly depends on government funds and if it responds to the satisfaction of stakeholder demands (specially the main clients). The clients are the patients which represent the society. This kind of stakeholders wants to have accessibility,[53] quality and equity.[54] The

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[50] Heath J and Wayne N. Stakeholder theory, corporate governance and public management: what can the history of state-run enterprises teach us in the post-Enron era? Journal of Business Ethics, (2004), 53.3: 247-265.

[51] Friedman M. The social responsibility of business is to increase its profits. springer berlin heidelberg, (2007).

[52] Álvarez-Gil, MJ, and Husillos J. A stakeholder-theory approach to environmental disclosures by small and medium enterprises (SMES). Revista de contabilidad: Spanish accounting review, (2008), 11.1: 125-156.

[53] Easton G and Baker R. Seven Days a Week, 8 am to 8 pm: Improving Access to National Health Service Primary Care. The Journal of ambulatory care management, (2015), 38.1: 16-24.

[54] Fischer S. Patient Choice and Consumerism in Healthcare: Only a Mirage of Wishful Thinking? Challenges and Opportunities in Health Care Management. Springer International Publishing, (2015), 173-184.

problem is that it is difficult to have all these three characteristics with limited funds since health innovation is growing and the costs are rising, especially in oncology.[55] "The average cost per month of branded oncology drug treatment in the U.S. is now about $10,000, up from an average of $5,000 a decade ago" which implies an incremental value considering the variability of patient response, the frequent changes to protocol needed for patient care, and underlying issues of equity and patient care.[49] The American Society of Clinical Oncology (ASCO) is committed to improving cancer prevention, diagnosis, and treatment and eliminating disparities in cancer. Moreover ASCO considered that pharmaceutical industry investment and those paying patient treatments should be guided by evidence-based and cost-effective practices.[56]

CSR has four dimensions which can be visualised has a piramid.: a) In the botton there are the economic responsabilities where we can include the production of goods and services to earn profit; b) then we have the legal responsabilities because it is essential to obey the law and to attain the profits within the confines of the law; c) the third step is the ethical responsabilities since it is necessary to be ethical special in medicine; in the top of the pyramid there are the discretionary responsibility which is strong related with philantrophy.[57]

Therefore, considering the model of Piaggio, it is necessary to define strategic objectives for sustainability at the economic, environmental and social levels. To acomplish that sustainability plan considering the corporate social responsability it is essential a code of

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[55] Masters GA et al. Clinical Cancer Advances 2015: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology. Journal of Clinical Oncology, (2015).

[56] Meropol NJ et al. American Society of Clinical Oncology guidance statement: the cost of cancer care. Journal of Clinical Oncology, (2009), 27.23: 3868-3874.

[57] Corporate social responsability. http://www.slideshare.net/RobbySahoo/corporate-social-responsibility-13975540 (Accessed: 12 feb 2015)

ethics and the colaboration of all stakeholders (customers, employees, trade unions, civil society, research institutes, media, public administration sector, pharmaceuticals, politics, shareholders and financers).[58]

The concept of shared value has emerged from a series of Harvard Business Review (HBR) articles written by Porter and Kramer with work focusing explicitly on the nonprofit sector, specifically an examination of how foundations can create social value.[59] Later, there where the idea to create social *and* economic value, using social programs to enhance the firm's competitive context.[60] By 2006, this had developed into a broader analysis of how to integrate corporate social responsibility (CSR) into core business strategy, where the term 'shared value' was coined for the first time.[61] "The concept of shared value can be defined as policies and operating practices that enhance the competitiveness of a company while simultaneously advancing the economic and social conditions in the communities in which it operates".[62] "Shared value creation focuses on identifying and expanding the connections between societal and economic progress".[62]

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[58] Piaggio 2011. Piaggio´s corporate social responsibility model. www.piaggiogroup.com/.../piaggiogroup/.../CSR_2012_eng_26Marzo.p (Accessed: 20 May 2015).

[59] Porter ME and Kramer MR. Philanthropy's new agenda: creating value. Harvard Business Review, (1999), 77: 121-131.

[60] Porter ME and Kramer MR. The competitive advantage of corporate philanthropy. Harvard Business Review, (2002), 80: 56-68.

[61] Porter ME and Kramer MR. Strategy and society: the link between competitive advantage and corporate social responsibility. Harvard Business Review, (2006), 78-92.

[62] Porter ME and Kramer MR. Creating shared value. Harvard business review, (2011), 89.1/2: 62-77.

The concept of shared value rests on the premise that both economic and social progress must be addressed using value principles in which "value is defined as benefits relative to costs…" and recognizes that "social harms or weaknesses frequently create internal costs for firms".[62]

It is important in healthcare, namely in oncology to increase efficiency, quality and sustainability. Shared value is defining a whole new set of competitive advantages that arise from creating shared value and will often be more sustainable than conventional cost because quality improvements prevail.[62]

The notions of CSR and CSV are strongly related but there are differences between them.[63] In CSR the value is "doing good"; it is related with citizenship, philanthropy, sustainability; it is discretionary or happens in response to external pressure; it is separated from profit maximization; the agenda is determined by external reporting and personal preferences; the impact is limited by corporate footprint and CSR budget. For another site, in CSV the value is economic and consider the societal benefits relative to cost; joint company and community value creation; it is integral to competing and to profit maximization; the agenda is company specific and internally generated; and realigns the entire company budget. However, in both cases, compliance with laws and ethical standards and reducing harm from corporate activities are assumed.[63]

CONCLUSION

The healthcare stakeholders will require a deeper understanding of global oncology trends (IMS institute for healthcare informatics, 2014), multidisciplinary decisions will be mandatory and governments will have to decide what they will be able to pay in the next years. This kind of transdisciplinarity between civil society, pharmaceuticals, healthcare professionals and policymakers is essential in order to assure quality, access to innovation and equity in oncological care.

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[63] Tkaczyk J and Krzyżanowska M. Shared Value Creation and Marketing. *Management and Business Administration. Central Europe,* (2014), 4.127: 153-167.