Original Article

Patient lawsuits and treatment provision on the Brazilian National Health Service

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ABSTRACT

Objective. To analyze the qualitative coverage of treatment policies at the federal level in the Brazilian National Health Service (SUS) for diseases that have been the subject of patient lawsuits.

Methods. An exploratory research study was undertaken based on a sample comprising diseases referred to in lawsuits against the city of São Paulo Municipal Health Department in 2005. The Brazilian Ministry of Health's electronic pages were searched for the standards that set out treatment policies and the Diseasedex database was searched for the recommended treatment resources (surgical procedures and drugs). A table was drawn up summarizing the coverage for each disease provided by the federal treatment policy in force, on the basis of the medications or procedures recommended as first line treatment.

Results. Public treatment policies cover the greater part (n = 26) of the diseases analyzed, either through public policies for primary care or public policies for rare diseases and/or high treatment cost diseases. This represents 96% of the sample analyzed (n = 27). It was observed that 3 of the 27 diseases, which corresponds to 11% of the sample, are covered by deficient treatment policies. This means that public policies do not offer full first-line therapy. There was only one disease that was not covered by a public treatment policy: attention deficit hyperactivity disorder.

Conclusion. The qualitative treatment coverage for some diseases in the sample analyzed was deficient, which could compromise the integral nature of treatment and healthcare in some cases.

Key words: Public health policy. Legal decisions. State healthcare coverage. Right to health.

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Introduction

Brazil's healthcare legislation (Lei Orgânica da Saúde, Law number 8,080 of 1990)[1] states that the care provided by the Brazilian National Health Service (SUS - Sistema Único de Saúde) must be integral and must include pharmaceutical treatment. The term "integral healthcare provision" (*assistência terapêutica integral*) has no legal definition. It is associated with the idea that care is provided through the medium of providing treatments for patients. At this point, it is worth making some observations about the meaning of the word "integral" that is used to qualify this care. Within the SUS, "integral" relates to a coordinated conjunction of interventions to promote, prevent and recover health, and these interventions and services are considered at three different levels of complexity. This implies analyzing and meeting all of people's healthcare requirements, from the most basic to the most complex.[2,3]

Given that the market in medications and healthcare products is extremely large, it can be imagined what the consequences for the Brazilian National Health Service would be if the concept of integral healthcare were to be interpreted in a manner different to that described above. To do so, it is enough to consider the size of these markets, which, according to data from a retail prices magazine, consist of 14,286 medications and 48,720 hospital supply items (already broken down into their different presentations).[4]

If the word "integral", as used to qualify healthcare treatment, were to acquire the meaning of "everything that is available on the market", it is obvious what the effect of this interpretation would be for the SUS. The consequences of this can already be observed in the increase in lawsuits filed against Health Departments by citizens demanding medications and other products.[5-7]

In principle, these suits can be divided into two groups: a) justified; and b) unjustified. Recent studies have demonstrated that a proportion of these lawsuits request the provision of medications that are on the list of publicly-provided products.[5-7] It would seem reasonable and, as such justified, that these requests are made through legal channels in the event that the failure to supply these medications is the result of poor management of pharmaceutical provision on the part of the Department of Health, since treatment using the pharmaceutical product requested is provided for in a healthcare policy. It would also seem reasonable to think that an absence of a treatment policy for a given disease would constitute a reason for considering such a request as being justified, as long as an effective and/or efficacious treatment option exists that is safe and is available nationally and which the health system can finance.

On the other hand, it would not appear reasonable for people to request medications and healthcare products when there is already an established and high-quality treatment policy. Nor

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would it appear reasonable to request products of doubtful efficacy and of a cost that is prohibitive to the health system, thereby compromising thousands of other people's access to medications by exhausting the budget.

At this point it is necessary to consult the Brazilian Constitution of 1988,[8] which states that the right to health will be guaranteed through social and economic policies. It is clear that the Constitution defines public policy as the mechanism through which this right will be upheld.

Saravia defines public policy as the flow of decisions aimed to maintain the social equilibrium or to introduce disequilibria intended to change that situation.[9] Therefore, considering that public policies are the means through which the right to health is to be realized, it is necessary to analyze these policies from the perspective of their coverage of diseases and conditions and their adherence to recommendations found in published scientific data on the use of treatment resources for these diseases and conditions.

While it is understood and accepted that this is an area of discussion that still needs to mature, this study ventures to initiate the debate, taking as its objective an analysis of the qualitative coverage of therapeutic policies within the SUS, on the federal level, based on the constellation of diseases mentioned in lawsuits filed against a Municipal Health Department. The concept of qualitative coverage comprises two dimensions. The first is related to the extent to which treatment policies exist for the diseases in the sample, as embodied in regulatory acts (for example, ministerial directives). The second is related to the adherence of the treatments recommended in national health policies to those listed in a database of published scientific data as the first line treatment for the diseases and considering specific population groups.

Methods

This is exploratory research starting from the identification of diseases referred to in lawsuits against the Municipal Health Department of São Paulo during 2005,[7] which will make up the sample of diseases studied here.

Working from this list of diseases, searches were run on the Ministry of Health (http://www.saude.gov.br) web site for the regulations that set out the pharmaceutical treatment programs and the SUS Unified Table of Procedures, Medications and Ortheses, Prostheses and Special Materials (OPM)[10] was used to identify treatments described in clinical or hospital procedures that list the medications and procedures that are financed by SUS and offered to its patients. Furthermore, the National List of Essential Medicines (2006)[11] was used to consult recommendations on the treatment of the diseases considered most prevalent, due to the fact that this list is used to guide the acquisition, prescription and dispensation of medications on the SUS.

The Diseasedex[a] database, which is part of the Micromedex system (and is available via the CAPES web site),[12] was consulted to determine the treatment procedures used for each of the diseases chosen and a summary table was drawn up to facilitate visualization of the recommendations and to allow comparison of these procedures with the medications or procedures defined by the federal SUS treatment policies, making it possible to verify the level of agreement between the treatment offered by the public health system and current scientific evidence.

Finally, the coverage and qualitative agreement between the prevailing federal treatment policies and the treatment recommendations found in the Diseasedex database was analyzed for each disease, i.e., the compatibility between the medications or procedures recommended in the database as first line treatment[b] and federal treatment policies.

Results

The results of these investigations, both into the existence of treatment policies and about the treatment recommendations, are provided in Table 1.

In this study it was found that, whether in the form of primary care policies or in the form of policies for diseases that are rare and/or generate high costs, treatment is described for the majority of the diseases studied (n = 26), which equates to 96% of the sample (n = 27), as can be observed in Table 1. However, it was also observed that three (11%) of these 27 diseases are covered by deficient treatment policies, i.e., the policies do not offer the entirety of the first-choice treatment options. The only disease that is not covered by a treatment policy is attention deficit hyperactivity disorder (ADHD).

Discussion

One initial point that should be made clear is that this paper is discussing the extent to which treatment policies are adequately covering the range of diseases studied and the extent to which they are in consonance with the prevailing model, which looks to scientific evidence for the basis on which to define the best treatment options. One is not dealing here with a holistic therapeutic approach, centered on the patient rather than the disease. The objective is to provide a snapshot of the manner in which the majority of healthcare is currently organized, according to the biomedical model, and use it to analyze the treatment policies in force on the basis of the aspects described above.

This analysis is needed for two reasons. First, there may be cases in which the manager responsible for defining the policy does not keep up-to-date with scientific development and knowledge or may not achieve the necessary and alacrity in introducing new technologies. This would result in the SUS continuing to provide the population with technology that is no longer the best treatment choice, since there would be evidence, i.e. proof, of alternatives offering greater safety, efficacy and/or efficiency and with better cost-effectiveness ratios.

The second reason is that there may also be cases in which no treatment policy has been defined for less prevalent diseases and so patients are left with no access to these resources, even when such exist on the domestic market and have been proven to be safe, efficacious, effective and cost-effective.

At this point, it is also necessary to point out that the treatment of these diseases is also affected by the treatment setting, whether in clinics and/or hospitals, or exclusively in hospital. Where cases are treated in hospital, the majority of treatment policies are defined by the institution providing care, since they will define what medications will be administered to patients. Where treatment is surgical, the policy followed is that laid out in the SUS Unified Table of Procedures, Medications and OPM, as defined by the Ministry of Health .[10] It is also the Ministry

Table 1. Comparison between prevailing federal treatment policy and treatment recommendation in the Diseasedex database for the diseases studied

Diseases mentioned in lawsuits	Federally financed (partially or completely) treatment policy in force			National List of Essential Medicines 200611	DISEASEDEX General Medicine Summary12
	Treatment Program	Regulation	Medication and/or procedure	Essential medicines (Directive)	
Rheumatoid arthritis	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SCTIE/MS nº 66, 6 November, 200613 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Chloroquine, 150 mg tablets; hydroxychloroquine, 400 mg tablets; methotrexate, 25 mg/mL injectable; cyclosporine, 100 mg/mL oral solution and 10, 25, 50 and 100 mg capsules; leflunomide, 20 mg tablets; infliximab, 10 mg/mL injectable; adalimumab, 40 mg injectable; etanercept, 25 mg injectable	Rheumatic disorder disease modification and adjuvant medications: azathioprine 50 mg tablets; folinic acid 15 mg tablets and powder to make up injectable solution 50 mg; sodium methotrexate 2.5 mg tablets and 25 mg/mL injectable solution; sulfasalazine 500 mg tablets; hydroxychloroquine 400 mg tablets. Steroidal anti-inflammatories: dexamethasone 4 mg tablets and 0.1 mg/mL elixir; dexamethasone disodium phosphate 4 mg/mL injectable solution; prednisolone sodium phosphate 1.34 mg/mL oral solution; prednisolone sodium succinate 500 mg powder to make up injectable solution; prednisone 5 mg and 20 mg tablets; hydrocortisone sodium succinate de 100 and 500 mg powder to make up injectable solution; Non- steroidal anti-inflammatories: ibuprofen 200 mg and 600 mg tablets, oral suspension 20 mg/mL	Omeprazole, hydroxychloroquine sulphate, sulfasalazine , prednisone, methotrexate, misoprostol, minocycline, acetylsalicylic acid (coated tablets), ibuprofen, celecoxib, naproxen
Cancer	National Oncological Care Program (Política Nacional de Atenção Oncológica): promotion, prevention, diagnosis, treatment, rehabilitation and palliative care (Specialized care provided at High Complexity Oncology Centers [Cacon] and High Complexity Oncology Treatment Units [Unacon])	Ministerial Directive GM/MS nº 2,439, 27 December, 200515, Ministerial Directive GM/MS nº 3536, 2 September, 199816 and Ministerial Directive SAS/MS nº 741, 19 December, 200517	Integral patient care: consultations, admissions, tests and medications all provided at the Cacon and Unacon	Chemotherapy: cyclophosphamide 1 g powder to make up injectable solution and 50 mg tablets; chlorambucil 2 mg tablets; dacarbazine 200 mg powder to make up injectable solution; iphosfamide 1 g powder to make up injectable solution; melphalan 2 mg tablets; cytarabine 100 mg, 500 mg and 1 g powder to make up injectable solution; cladribine 1mg/mL injectable solution; fluorouracil 50 mg/g cream and 25 mg/mL injectable solution; mercaptopurine 50 mg tablets; sodium methotrexate 2.5 mg tablets and 25 mg/mL injectable solution; thioguanine 40 mg tablets; docetaxel 20 and 80 mg injectable solution; etoposide 50 mg capsules and 20 mg/mL injectable solution; paclitaxel 6 mg/mL injectable solution; vinblastine sulphate 10 mg powder to make up injectable solution; vincristine sulphate 1 mg powder to make up injectable solution; teniposide 10 mg/mL injectable solution; daunorubicin hydrochloride 20 mg powder to make up injectable solution; doxorubicin hydrochloride 10 and 50 mg powder to make up injectable solution; idarubicin hydrochloride 10 mg powder to make up injectable solution, 5 mg and 25 mg capsules; dactinomycin 100 mcg/mL injectable solution; bleomycin sulphate15 UI powder to make up injectable solution; carboplatin 150 and 450 mg powder to make up injectable solution; cisplatin 1 mg/mL injectable solution; asparaginase 10,000 UI injectable solution; hydroxyurea 500 mg capsules	Treatment is discussed for each type of cancer

Depression	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Amitriptyline, 25 mg tablets; clomipramine, 10 and 25 mg tablets; nortriptyline, 10, 25 and 50 mg capsules	**Antidepressants:** amitriptyline hydrochloride 25 mg tablets; clomipramine hydrochloride 10 and 25 mg tablets; nortriptyline hydrochloride 10, 25 and 50 mg capsules; fluoxetine 20 mg capsules	**Children, adolescents and pregnancy: fluoxetine; First line treatment:** fluoxetine, sertraline, paroxetine, citalopram, escitalopran, venlafaxine, bupropion, nefazodone, mirtazapine, desipramine, nortriptyline
Atopic dermatitis	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Dexamethasone, cream 0.1%	**Antipruritics and anti-inflammatories:** hydrocortisone acetate 1% cream; dexamethasone 0.1% cream	Clobetasol, fluocinonide, betamethasone diproprionate, betamethasone valerate, fluocinolone, triamcinolone, amcinonide, diflorasone diacetate, desoximetasone, halobetasol propionate, halcinonide, fluticasone propionate, desonide, hydrocortisone
Diabetes (types I and II)	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Glibenclamide 5 mg tablets; gliclazide, 80 mg tablets; metformin, 500 and 850 mg tablets; NPH human insulin, injectable suspension and regular injectable solution	**Insulins and oral antidiabetics:** metformin hydrochloride 500 and 850 mg tablets; glibenclamide 5 mg tablets; gliclazide 80 mg tablets; NPH human insulin 100 UI/mL injectable suspension and regular human insulin 100 UI/mL injectable solution	**Initial treatment for diabetes type 2 with simultaneous lifestyle changes: metformin; Second line treatment for type 2 with persistent symptomatic hyperglycemia after lifestyle changes and metformin tolerance:** insulin, glimepiride, glipizide, glyburide, pioglitazone, rosiglitazone; Type 1: insulin
Diabetes insipidus	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SCTIE/MS nº 68, 6 November, 2006 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Desmopressin nasal spray 0.1 mg/mL	There are no recommendations on which medications can be used to treat this disease	Monograph not available

Dyslipidemia	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Public Consultation SAS/MS nº 13, 12 November, 200220 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Lovastatin, 10, 20 and 40 mg tablets; simvastatin, 5, 10, 20, 40 and 80 mg tablets; atorvastatin, 10 and 20 mg tablets; pravastatin, 10, 20 and 40 mg tablets; fluvastatin, 20 and 40 mg; bezafibrate, 200 and 400 mg capsules; etofibrate, 500 mg capsules; fenofibrate, 200 and 250 mg capsules; ciprofibrate, 100 mg tablets; gemfibrozil, 600 mg capsules or tablets and 900 mg tablets	**Hypolipemiant:** simvastatin 10 and 40 mg tablets	**Primary secondary or familial hypercholesterolemia,:** atorvastatin, fluvastatin, lovastatin, pravastatin, simvastatin; **Hypercholesterolemia without hypertriglyceridemia:** colesevelam, colestipol, cholestyramine; **Hypertriglyceridemia or low HDL levels:** gemfibrozil, fenofibrate; **Adjuvant therapy for hypercholesterolemia:** ezetimibe
Chronic obstructive pulmonary disease - COPD	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Beclomethasone, 200 mcg and 50 mcg powder, inhaled solution or aerosol; salbutamol, 100 mcg aerosol; prednisone, 5 and 20 mg	**Anti-asthmatics:** ipratropium bromide 0.25 mg/mL inhaled solution and 0.02 mg/dose aerosol; beclomethasone dipropionate 200 mcg and 50 mcg powder, solution or aerosol; prednisolone sodium phosphate 1.34 mg/mL oral solution; prednisone 5 mg and 20 mg tablets; hydrocortisone sodium succinate 100 and 500 mg powder to make up injectable solution; salbutamol sulphate 5 mg/mL inhaled solution, 5 mg/mL injectable solution and 100 mcg/dose aerosol	**Short action beta-2 agonists:** albuterol, terbutaline, levalbuterol; **Long action Beta-2 agonists:** formoterol, salmeterol; **Short action anticholinergic:** ipratropium; **Long action anticholinergic:** tiotropium; **Methylxanthine: theophylline; Inhaled glucocorticoids:** beclomethasone, budesonide; **Systemic glucocorticoids:** prednisone
Meningoencephalitis	Hospital care (for inpatients)	SUS Unified Table of Procedures, Medications and OPM. Ministerial Directive SAS nº 7, 4 January, 2008.10 Republished on 19 March, 2008.	Medications necessary for the integral treatment of patients admitted to hospital	Miscellaneous medications for hospital use	**Cytomegalovirus encephalitis:** ganciclovir/foscarnet; **Enteroviral encephalitis:** pleconaril; **Herpes simplex encephalitis in immunodepressed patients:** foscarnet, aciclovir, ganciclovir; **Varicella zoster encephalitis:** aciclovir, ganciclovir; **Encephalitis with convulsions:** lorazepam, diazepam, fosphenytoin, phenytoin, phenobarbital

Encephalopathy	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Chlorpromazine, 25 and 100 mg tablets and 40 mg/mL oral solution; diazepam, 5 mg tablets; phenytoin, 100 mg tablets and 25mg/mL oral suspension; phenobarbital, 100 mg tablets and 40 mg/mL oral solution; haloperidol, 1 and 5 mg tablets and 2 mg/mL oral solution	**Anticonvulsants:** Diazepam 5 mg tablets; phenytoin 100 mg tablets and 25mg/mL oral suspension; phenobarbital 100 mg tablets and 40 mg/mL oral solution; **Antipsychotics:** chlorpromazine 25 and 100 mg tablets and 40 mg/mL oral solution; haloperidol 1 and 5 mg tablets and 2 mg/mL oral solution; **Vitamins and mineral salts:** thiamin hydrochloride 300 mg tablets; thiamin palmitate 100,000 UI/mL injectable solution	Haloperidol, lorazepam, midazolam, risperidone, olanzapine, quetiapine, ziprasidone, trazodone, physostigmine, chlorpromazine, multi vitamins
Epilepsy	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Carbamazepine, 200 mg tablets and 20 mg/mL syrup; phenytoin, 100 mg tablets and 20 mg/mL oral suspension; phenobarbital, 100 mg tablets and 25 mg/mL oral solution	**Anticonvulsants:** Carbamazepine 200 mg tablets and 20 mg/mL syrup; clonazepam 0.5 and 2 mg tablets and 2.5 mg/mL oral solution; diazepam 5 mg/mL injectable solution; phenytoin sodium 100 mg tablets, 20 mg/mL oral suspension and 50 mg/mL injectable solution; phenobarbital 100 mg tablets, 40 mg/mL oral solution and 100 mg/mL injectable solution; sodium valproate 288 mg capsules (equivalent to 250 mg of valproic acid), 576 mg tablets (equivalent to 500 mg of valproic acid) and 57.624 mg/mL syrup or oral solution (equivalent to 50 mg/mL of valproic acid)	**Acute epileptic state:** lorazepam, diazepam, phenytoin, fosphenytoin, midazolam, phenobarbital; **Refractory acute epileptic state:** phenytoin, propofol, midazolam, phenobarbital, thiopental, valproic acid, lidocaine, ketamine; **Acute epilepsy:** carbamazepine, ethosuximide, oxcarbazepine, phenytoin, valproic acid, lamotrigine, topiramate, phenobarbital, felbamate, gabapentin, levetiracetam, primidone, tiagabine, zonisamide
	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SAS/MS nº 864, 5 November, 200221 and Ministerial Directive GM/MS nº 2,577, 27 October, 2006[14]	Lamotrigine, 25 and 100 mg tablets; vigabatrin, 500 mg tablets; gabapentin, 300 and 400 mg capsules; topiramate 25, 50 and 100 mg		
Ankylosing spondylitis	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 2007[18]	Ibuprofen, 600 mg tablets	Ibuprofen, 600 mg tablets	Persistent ankylosing spondylitis: Etanercept, infliximab, adalimumab; Pain control: indomethacin, naproxen, diclofenac, celecoxib; Ankylosing spondylitis with recalcification and synovitis of peripheral joints: intraarticular triamcinolone and methylprednisolone; Ankylosing spondylitis with peripheral arthritis: sulfasalazine

Glaucoma	Glaucoma Sufferers Support Program (ophthalmological treatment for patients with glaucoma, at Centers of Ophthalmological Excellence, is allowed for in the SUS Clinical Information System Table of Procedures - SIA/SUS)	Ministerial Directive GM/MS nº 867, 9 May, 200222 and Ministerial Directive SAS/MS nº 338, 9 May, 200223	Timolol 0.25 and 0.5% aqueous solution; timolol 0.1%gel; dorzolamide 2% solution; brinzolamide 1% solution; brimonidine 0.2% solution; latanoprost 50 mcg/mL solution; travoprost 0.004% solution; bimatoprost 0.3% solution; acetazolamide 250 mg tablets; pilocarpine 1, 2 and 4%	**Antiglaucomatous drugs:** acetazolamide 250 mg tablets; pilocarpine hydrochloride 2% eye drops; timolol maleate 0.25 and 0.5%	**Closed angle glaucoma:** Pilocarpine, carbachol, timolol, betaxolol, levobunolol, metipranolol, meperidine, physostigmine, acetazolamide, dorzolamide, brinzolamide, mannitol; Open **angle glaucoma:** pilocarpine, carbachol, timolol, betaxolol, latanoprost, unoprostone, physostigmine, acetazolamide, levobunolol, dorzolamide, metipranolol, epinephrine, dipivefrin, brinzolamide, brimonidine, echothiophate iodide, apraclonidine
Hepatitis B	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SAS/MS nº 860, 4 November, 200224, Ministerial Directive SAS/MS nº 469, 23 July, 200225 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Interferon-alpha 2b 3,000,000 UI, 5,000,000 UI and 10,000,000 UI injectable; lamivudine 10 mg/mL oral solution and 150 mg tablets	There are no recommendations on which medications can be used to treat this disease	**Chronic hepatitis B:** lamivudine, adefovir, interferon alpha 2b; **Hepatitis B with evidence of viral replication:** telbivudine
Hepatitis C	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SAS/MS nº 863, 4 November, 200226 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Interferon-alpha 2b 3,000,000 UI, 5,000,000 UI and 10,000,000 injectable; peginterferon alpha 2a or 2b injectable; ribavirin 250 mg capsules	There are no recommendations on which medications can be used to treat this disease	Peginterferon alpha 2a, peginterferon alpha 2b, ribavirin
Chronic autoimmune hepatitis	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Prednisone 5 and 20 mg	Prednisone 5 and 20 mg and azathioprine 50 mg	Monograph not available
	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SCTIE/MS nº 70, 6 November, 200627 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Azathioprine 50 mg		

Hypertension	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/ MS nº 3,237, 24 December, 200718	Captopril 25 mg tablets; enalapril 5 and 20 mg tablets; sprinolactone 25 and 100 mg tablets; furosemide 40 mg tablets; hydrochlorothiazide 12.5 and 25 mg tablets; methyldopa 250 mg tablets; propranolole 10 and 40 mg tablets; verapamil 40, 80 and 120 mg tablets	**Antihypertensive drugs:** sprinolactone 25 mg tablets; hydrochlorothiazide 25 mg tablets; atenolol 50 and 100 mg tablets; propranolole hydrochloride 10 and 40 mg tablets; methyldopa 250 mg tablets; metoprolol succinate 50 and 100 mg tablets; amlodipine besylate 5 and 10 mg; verapamil hydrochloride 80 and 120 mg; hydralazine hydrochloride 25 mg tablets and 20 mg/mL injectable solution; sodium nitroprusside 50 mg powder to make up injectable solution; captopril 25 mg tablets; enalapril maleate 5 and 20 mg tablets	Hydrochlorothiazide, chlorthalidone, indapamide, triamterene, captopril, enalapril, fosinopril, lisinopril, ramipril, carvedilol, labetalol, amlodipine, felodipine, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan, atenolol, clonidine, methyldopa, eplerenone, sprinolactone, doxazosin, prazosin, terazosin, hydralazine, minoxidil, diltiazem, verapamil
Cirrhosis induced portal hypertension	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/ MS nº 3,237, 24 December, 200718	Prevention of hemorrhage caused by esophageal varices: propranolole 40 mg tablets; isosorbide mononitrate 40 mg tablets	Propranolole 40 mg tablets and isosorbide mononitrate 40 mg tablets	**Acute hemorrhage of esophageal varices:** somatostatin, octreotide, vasopressin; **Primary hemorrhage prevention:** propranolole, nadolol, isosorbide mononitrate
	Hospital care (for inpatients)	SUS Unified Table of Procedures, Medications and OPM.	Esophagoscope and tamponade of esophageal varices; surgical treatment for esophageal varices		
Pulmonary hypoplasia	Hospital care (for inpatients)	SUS Unified Table of Procedures, Medications and OPM. Ministerial Directive SAS nº 7, 4 January, 2008.10 Republished on 19 March, 2008.	No procedure specified	There are no recommendations on which medications can be used to treat this disease	Monograph not available
Hyperphosphatemia (chronic renal failure)	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SAS/MS nº 845, October 31, 200228 and Ministerial Directive GM/ MS nº 2,577, 27 October, 200614	Sevelamer 400 and 800 mg tablets	There are no recommendations on which medications can be used to treat this disease	Hemodialysis
Osteoporosis	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SAS/ MS nº 470, 23 July, 200229 and Ministerial Directive GM/ MS nº 2,577, 27 October, 200614	Alendronate 10 and 70 mg tablets; pamidronate 30, 60 and 90 mg injectable; risedronate 5 and 35 mg tablets; raloxifeno 60 mg tablets; calcitonin 100 UI injectable and 200 UI nasal spray; alphacalcidiol 0.25 and 1 mcg capsules; calcitriol 0.25 mcg capsules and 1 mcg injectable	There are no recommendations on which medications can be used to treat this disease	Alendronate, risedronate, calcitonin, cholecalciferol, ibandronate, calcium

Diabetic polyneuropathy	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Amitriptyline 25 mg tablets; nortriptyline 10, 25 and 50 mg capsules; carbamazepine 200 mg tablets and 20 mg/mL syrup	Amitriptyline 25 mg tablets; nortriptyline 10, 25 and 50 mg capsules; carbamazepine 200 mg tablets and 20 mg/mL syrup	Amitriptyline, nortriptyline, carbamazepine, gabapentin, pregabalin, duloxetine
Diabetic retinopathy	Hospital care (for inpatients)	SUS Unified Table of Procedures, Medications and OPM. Ministerial Directive SAS nº 7, 4 January, 200810 Republished on 19 March, 2008.	Laser endophotocoagulation	There are no recommendations on which medications can be used to treat this disease	Laser photocoagulation of the retina
Cerebral palsy (spasticity)	Hospital care (for inpatients)	SUS Unified Table of Procedures, Medications and OPM. Ministerial Directive SAS nº 7, 4 January, 200810 Republished on 19 March, 2008	Medications necessary for the integral treatment of patients admitted to hospital	Miscellaneous medications for hospital use	**Generalized spasticity and athetosis in cerebral palsy:** diazepam, baclofen
	Pharmaceutical Support Within Primary Care (Assistência Farmacêutica na Atenção Básica)	Ministerial Directive GM/MS nº 3,237, 24 December, 200718	Diazepam 5 mg tablets	Diazepam 5 mg tablets and 5 mg/mL injectable solution	
Stevens Johnson Syndrome	Hospital care (for inpatients)	SUS Unified Table of Procedures, Medications and OPM. Ministerial Directive SAS nº 7, 4 January, 200810 Republished on 19 March, 2008	Medications necessary for the integral treatment of patients admitted to hospital	Miscellaneous medications for hospital use	Methylprednisolone sodium succinate
Lennox-Gastaut Syndrome	Exceptional Dispensation Medications (Medicamentos de Dispensação em Caráter Excepcional)	Ministerial Directive SAS/MS nº 864, 5 November, 200221 and Ministerial Directive GM/MS nº 2,577, 27 October, 200614	Lamotrigine 25 and 100 mg tablets; vigabatrin 500 mg tablets; gabapentin 300 and 400 mg capsules; topiramate 25, 50 and 100 mg	There are no recommendations on which medications can be used to treat this disease	Monograph not available
Attention deficit hyperactivity disorder	No treatment policy has been defined	No treatment policy has been defined	No treatment policy has been defined	There are no recommendations on which medications can be used to treat this disease	**First line treatment:** methylphenidate, dextroamphetamine, amphetamine, atomoxetine; **Second line:** imipramine, bupropion, desipramine; **Patients with ADHD or Tourette's syndrome or with associated anxiety or preschool children with severe hyperactivity and impulsivity:** clonidine, guanfacine

of health that establishes treatment policies for care in clinics, within specific programs.[30]

Clearly, the fact that the parameter of comparison chosen for these treatment policies was a single database (Diseasedex) restricts the analysis, since it rules out confirming information from several different sources. It is also a limitation to define a treatment policy as adequate merely because the first line treatment laid out in that policy agrees with the database, since, due to idiosyncrasies, certain people may not respond to the medications chosen. Nevertheless, despite the existence of these restrictions, it is important to, in an initial approach to the subject, analyze the extent to which, and the manner in which, the policies that have been established achieve or fall short of the goal of guaranteeing integral therapeutic care. Dissonance between the criteria defined for this analysis, in this study, would indicate that the policy is very likely in need of reformulation or, in the case it does not exits, of formulation.

For example, we can observe the case of ADHD, which is defined in the Diseasedex database[c] as a persistent pattern of inattention and/or hyperactivity/impulsivity which is more frequent and severe than that typically observed among individuals at a comparable level of development. The worldwide prevalence of this disease among school age children has been estimated at 5.3%[31] and, in Brazil, a number of different studies have reported varying prevalence rates ranging from 5.8 to 17.1%.[32-35]

The fact that this disease is not covered by a treatment policy indicates that, where state and municipal health departments have not introduced technology to care for the disease, many children may be without access to treatment. To provide an idea of what this means; the population of children aged five to 14 years in Brazil was 37.8 million, in 2007, according to the Brazilian Institute of Geography and Statistics (IGBE - Instituto Brasileiro de Geografia e Estatística).[d] If we assume an ADHD prevalence of 6%, it can therefore be estimated that the country has approximately 1.9 million children with the disease.

When it comes to treatment of cancer, it should be pointed out that the services are organized in a different manner. Patients are treated at what are known as High Complexity Oncology Centers (Cacon - Centros de Alta Complexidade em Oncologia) and High Complexity Oncology Treatment Units (Unacon - Unidades de Assistência em Alta Complexidade em Oncologia).[15] These healthcare units are service providers to the SUS and are remunerated by means of procedures laid out in the Unified Table of Procedures, Medications and OPM,[10] in order to provide the patient with integral care. This means providing consultations, tests, hospital admission and medications for cancer treatment, plus their adjuvants, even when the patient uses these pharmaceutical products in outpatients or a clinic, as laid out in the prices for chemotherapy procedures defined within the Unified Table.[36] Only opioid analgesics (codeine, morphine, and methadone) are excluded from this coverage, since they are part of the Exceptional Dispensation Medicines Program (Programa de Medicamentos de Dispensação em Caráter Excepcional).[37]

The three diseases that are partially covered, i.e., the qualitative coverage as measured by the Diseasedex database does not provide for supply of those medications considered the first choice treatments, even taking specific population groups into account, are: chronic obstructive pulmonary disease (COPD), depression and ankylosing spondylitis.

According to the Diseasedex database, the following alternatives are employed to treat chronic obstructive pulmonary disease: short-acting beta-2 agonists; b) long-acting beta-2 agonists; c) short-acting anticholinergics; d) long-acting anticholinergics; e) methylxanthine; f) inhaled glucocorticoids; g) systemic glucocorticoids. The medications provided on the Pharmaceutical Support Within Primary Care Program (federal) are beclomethasone (inhaled glucocorticoid), salbutamol (short-acting beta-2 agonist and prednisone (systemic glucocorticoid). The Diseasedex database does not define a hierarchy between these pharmaceuticals, which was also observed for the treatment protocol for COPD produced by the State of São Paulo Health Department,[38] differentiating usage according to the severity of symptoms, such as dyspnea and limitation to physical capacity, rather than in relation to the disease. Therefore, it cannot be stated that certain of the pharmaceuticals listed on the Diseasedex database are considered the first line treatment, which evidently leads to the consideration that all of the pharmacological groups are relevant to treatment of this disease. Therefore, the treatment provided for by the federal program (three medications) is inadequate for treating these patients.

With relation to treating depression, the federal program is limited in that it does not provide the first choice medication for treating children, adolescents and expectant mothers, i.e., fluoxetine. This often means that treatment will be chosen that is less appropriate for these groups and, therefore, is a failure of the treatment policy itself.

In the case of ankylosing spondylitis, the restriction in therapeutic provision is even greater. Of the drugs listed in Diseasedex, only one is included in the Pharmaceutical Support Within Primary Care Program – ibuprofen – a non-steroidal anti-inflammatory, which can be used for pain control. Although many of the medications listed on the rheumatoid arthritis clinical protocol can be used to treat spondylitis, that treatment policy does not cover using them for spondylitis patients. This situation means that there is a significant limitation in terms of integral healthcare provision to these patients.

It was further observed that for the majority of diseases, including those for which the treatment policy is limited, the list of medications included on the National List of Essential Medicines[11] is longer, i.e., it includes a larger number of medicines. Nevertheless, there are two important points that should be highlighted.

The first is that the National List of Essential Medicines embodies the World Health Organization's concept of essential medicines,[11] which is a list of medicines that meet the priority health needs of the population and which should be available at all times, in appropriate doses, to all levels of society.[39] Therefore, the National List of Essential Medicines is not intended to provide complete coverage of the constellation of diseases that affect the Brazilian population, since it only selects medicines to treat priority diseases.

Secondly, the National List of Essential Medicines is not a list of drugs that must be provided by SUS health services. It is a list that is intended to guide the provision, prescription and dispensation of essential medicines within the system, providing guidance for the choice of medicines to be included in federal,

state and municipal treatment policies (pharmaceutical support programs).[40] For this reason, only medications listed in the different treatment policies; whether of a wide scope, such as primary care policies, or with a more specific focus, such as the Protocols for each disease covered by the Exceptional Dispensation Medicines Program.

Conclusions

What this study has shown is that there are deficiencies in terms of the qualitative treatment coverage for some of the diseases in the sample studied, on the federal level, which compromise the integral nature of treatment and healthcare in some cases and which, as a consequence, compromise the guarantee of the right to health. If there is no treatment policy or the policy is flawed, the universal and integral nature of healthcare is compromised.

Since the right to health must be guaranteed through policies,[8] it is necessary to select those treatment resources which offer complete qualitative coverage for the treatment of these diseases, based on the best and strongest available evidence on their efficacy, safety, efficiency, and cost-effectiveness and to the extent that society is able to bear the costs. This is the basic condition for the state to be in a position to defend the argument that the right to health can indeed only be guaranteed through public policies and to be able to respond to the large number of lawsuits that do not distinguish between guaranteeing rights (suits requesting treatment resources that are included in policies or for diseases that are not covered by policies) and requests/consumption of specific technologies, despite treatment for the disease in question being covered by a treatment policy specifying the use of other technologies.

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