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Health Policy Analysis

Portuguese Global Medicines Access Index 2021: An Indicator to Measure Access to Hospital Medicines

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ABSTRACT

Objectives: Access to innovative and effective medication is a citizen's right. The main objectives of this study were to build an indicator to measure access to medicines within hospitals, the Global Medicines Access Index, and to identify the main existing barriers.

Methods: Cross-sectional study carried out in Portuguese National Health Service hospitals. A consensus methodology (expert panel of 7 members) was used to define which dimensions should be included in the index and the weighting that each should take. The panel identified 6 dimensions: access to innovative medicines, proximity distribution, shortages, access to medicines before financing decision, value-based healthcare, and access to medication depending on cost/funding. Data were collected through an electronic questionnaire (September 2021).

Results: The response rate was 61.2%. Most hospitals used medicines with and without marketing authorization before the funding decision. Monitoring and generating evidence of new therapies results is still insufficient. The identified barriers were the administrative burden as the major barrier in purchasing medicines, with a relevant impact on shortages of medicines. Most respondents (87%) had a proximity distribution program, mainly implemented in the pandemic context, and the price/funding model was only identified by 10% as a barrier to access. The 2021 Global Medicines Access Index was 66%. Shortages and value-based use of medicines were the dimensions that had more influence in lowering the index value.

Conclusions: The new formula used to obtain a unique and multidimensional index for access to hospital medicines seems to be more sensitive and objective and will be used to monitor access.

Keywords: access to medicines, healthcare quality indicators, health services accessibility, real-world evidence.

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Introduction

Medicines are largely responsible for increasing life expectancy and improving quality of life. In the United States, 35% of improved life expectancy was attributable to pharmaceuticals (1990-2015). These numbers emphasize the crucial need for patients to have access to pharmaceutical innovation or simply access to medicines, to improve life expectancy.[1]

Various definitions of access to medicines exist. The World Health Organization (WHO) defines access to medicines using 2 main metrics: (1) availability, referring to the extent to which new medicines are available in the market for which they are intended, and (2) affordability, referring to the extent to which prices of medicines are in line with the purchasing ability of healthcare systems and patients.[2] Key aspects of access include, among others, affordability and availability but also timely access.[3]

Because of the referred evidence, the United Nations Committee on Economic, Social, and Cultural Rights, authoritatively recognized access to medicines as a means of fulfilling the right to health.[4]

Although access to healthcare is a fundamental human right and includes essential medicines access, the WHO estimates that nearly 2 billion people (one-third of the world population) do not regularly receive all medicines they need.[5]

But access to medicines is not a concern only in developing countries. In the WHO European Region, the pursuit of an agenda to improve access to medicines is not new and many obstacles to progress persist.[6]

Access to innovative medicines varies greatly across European countries and remains a concern, especially for specific therapeutic areas. Significant variations in access exist because of diverse regulatory settings, differing inclusion criteria for funding decisions, countries' purchasing power based on gross domestic product per capita, healthcare expenditure, and pharmaceutical prices and utilization rates, among other factors.[7-9]

According to the Lancet Commission on Essential Medicines Policies, the availability of medicines is a difficult problem to solve because it presents several issues, namely the fact that the pharmaceutical industry is demanding higher prices for most

new products that are being developed so that innovative medicines can be unaffordable even in high-income and middle-income countries, but at the same time, some key essential medicines are disappearing from the market globally due, in part, to prices becoming so low that it seems no longer commercially viable for manufacturers to supply them.[7] There is a supply risk that might endanger patients' health in case of medicines shortages.[10]

The Lancet Commission proposes a combination of clearly important policies for addressing this problem. These include creating information systems for routine monitoring of affordability, price, and availability, implementation of a comprehensive set of existing pricing policies for achieving affordable prices, use of health technology assessments to define benefits packages and determine value, and increasing transparency.[7]

However, as significant variations in access exist between European countries, it is important to analyze what are the specific problems in each country, and which may be the solutions at a national level.

The WHO developed a set of indicators to evaluate drug policies.[11-13] Together, WHO and the Management Science for Health established indicators and methods to evaluate pharmaceutical assistance on 3 levels. Level I evaluates structure and process, level II evaluates results, and level III evaluates each country's specific aspects.[14,15]

Other authors have been using indicators related to the health results and use of health services as its outcomes to evaluate access to medicines. However, this relationship is not direct, and there are a lot of characteristics of each specific health system, which can affect access.[16,17] For example, in Portugal, where a National Health System is the main healthcare deliverer (public, universal, and trending free), primary care is not always the main door to the health system in the context of access to medicines, depending on the pathologies of the patient—several medicines are only hospital dispensed, namely, most of the innovative ones (cancer, HIV, immunosuppression, etc), and without costs for the patients.

Nonetheless, up to now, there is no consensual model to monitor medicine access in a country or to make comparisons across countries.[18] This confirms the subject as an area under the major conceptual and methodological building. It is, therefore, important to identify barriers to access and to build an indicator to measure and monitor access to medicines.

The main objectives of this research were to build an indicator to measure access to medicines in Portugal and to study the level of access to hospital medicines—Global Medicines Access Index (second edition, the first was in 2019[19]), to identify the existing barriers and problems associated with medicines within National Health Service (NHS) hospitals.

Methods

A cross-sectional, observational study was carried out, whose period under analysis was the year 2020. For data collection, a questionnaire was constructed by the researchers, based on the objectives of the study. The construction of the questionnaire includes a phase of consultation and validation for calculating the Global Medicines Access Index using a panel of 7 national experts using the consensus group methodology.

The expert panel included academics from the fields of pharmacy, medicine, economics, and public health, policymakers, and members of professional and patient associations. The panel of experts was asked to define which dimensions should be included in the access index, what weight should be attributed to each dimension, and how to operationalize each dimension to obtain a more objective and robust indicator.

Six dimensions were identified as relevant to integrate the final formula of the index (Fig. 1):

1. Access to innovative medicines – subjective evaluation by the respondent (updated from the 2019 edition).[19]
2. Proximity medicines dispensing—it was asked if the hospital has implemented the distribution of hospital medicines directly at the home of the patient, facilitating access to medicines.[20]
3. Shortages—frequency and clinical severity of the occurrence of medicines shortages along the year.
4. Possibility to access to medicines before the final decision of funding (pre- and post-marketing authorization [MA])—it was asked if the hospital, when needed, asks for an exceptional authorization for use of medicines that are still not approved for use in the hospital.
5. Medicines value-based healthcare—it was asked if the hospital performs a value-based analysis of the use of innovative medicines in real-world use context.
6. Access to medication depends on cost/funding, as a possible barrier to access—it was asked to the hospital if dimensions as cost and/or funding have been a barrier to access to medicines in 2021.

To build an indicator to measure Global Medicines Access Index in Portugal, the above expert panel was asked to define which dimensions should be included, what weight should be attributed to each dimension, and how to operationalize each one. In the obtained global formula, the ponderations were applied to the result of each dimension and a total index was calculated through the sum of dimensions subtotals.

Two rounds were organized, to obtain consensus on the above points. Documentation was always previously sent to every expert, to facilitate the conduct of the meetings. Answers were obtained in the meetings through anonymous online polls. Figure 1 presents the 6 dimensions identified by the panel and the weight attributed to each one (from 1 to 10 points).

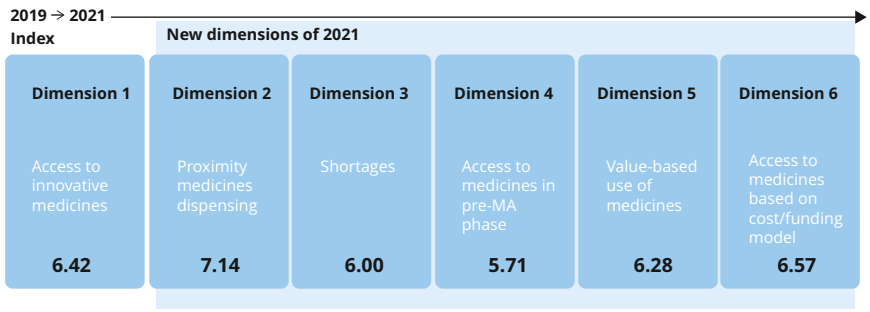
A structured questionnaire was used, which thus began to address 7 main topics:

1. Characterization of the health institution.
2. Access to medicines (pre-MA, post-MA without funding, and post-funding).
3. Monitoring and generating evidence of use.
4. Access to value-based medicines.
5. Proximity medicines dispensing /pharmaceutical consultation.
6. Barriers to access to medicines.
7. Global Medicines Access Index—based on the results obtained in the 6 dimensions identified by an expert panel.

The sampling method was nonprobabilistic, namely, a convenience sample of 49 NHS Portuguese hospitals. Data collection was performed through an electronic questionnaire sent to all NHS hospitals in mainland Portugal (N = 49), between 15 September and 15 October 2021, with voluntary participation. The questionnaire was previously validated by the College of Hospital Pharmacists from the Portuguese Pharmaceutical Society, the Portuguese Association of Hospital Pharmacists, and the Portuguese Association of Hospital Managers. A pretest was developed by 3 different NHS Portuguese hospitals.

The data were collectively analyzed. The distribution by groups was based on the national classification of hospital institutions in Legal Ordinance number 82/2014.[21] The overall index was

Figure 1. Dimensions and weight of the dimensions that integrated the Global Medicines Access Index.



MA indicates marketing authorization.

calculated based on the dimension's ponderations obtained through the previous outcomes from the focus group contribution.

The study was presented to the participants, to experts from the panel and to the NHS hospitals. The informed consent was obtained in all cases. The data confidentiality was granted, and the study was performed according to the Declaration of Helsinki principles. The descriptive analysis comprised frequencies, measures of central tendency, dispersion, and position were performed using IBM SPSS Statistics software (version 27, Armonk, NY).

Results

Characterization of the Health Institution

The global response rate was 61.2% (30 of 49). In regional terms, a higher percentage of institutions answered in the North Region (37%), followed by the Lisbon and Tagus Valley Region (33%), Central Region (20%), Alentejo Region (7%), and Algarve Region (3%).

According to the national classification of hospital institutions referred in the methods,[19] most institutions belonged to group I, local hospitals (53%); 17% to group II, regional hospitals; 13% to group III, central hospitals; and 17% to group IV, specialized hospitals.

Access to Medicines (Pre-MA, Post-MA Without Funding, and Post-Funding)

Almost all the hospitals (86.6%) used medicines in 2020 before the funding decision (pre-MA/MA phases without funding).

Access to Medication in the Pre-MA Phase

It was found that 54% of the NHS hospitals used innovative medicines that did not yet have MA, via an exceptional use authorization request to the Portuguese Authority for Medicines and Health Products (INFARMED, I.P.).

However, in 58% of institutions, the process involves at least 6 departments/decision-maker authorization in this type of the request before being submitted to INFARMED, I.P., leading to the average time between the moment of the request by the physician and the communication to INFARMED, I.P. being 15 days, and the average time between the approval of INFARMED, I.P. and the purchase of the drug of 13 days, leading to an average delay in the use of the medicine of 28 days. The majority of the submitted requests (83%) were approved by INFARMED, I.P.

Access to the Medicine in the Post-MA Phase, Without Funding Decision

Most NHS hospitals (85%) reported the use of innovative/recently approved medicines, which are, however, still awaiting a funding decision from the Ministry of Health. In the Portuguese hospitals belonging to the NHS, innovative medicine can only be freely used after a positive funding decision, issued by the Ministry of Health.

At this stage, 91% of the institutions involve 5 to 6 departments/decision-makers' authorization in this type of request, with an average time of 16 days between the time of the request by the physician and the communication of INFARMED, I.P., and 14 days the average time between the approval by INFARMED, I.P. and the purchase of the medicine, accounting for a total of 30 days. The majority of the submitted requests (74.4%) were approved by INFARMED, I.P.

Access to Medicines After the Positive Funding Decision

The overwhelming majority of NHS hospitals (96%) use internal procedures before the introduction of new medicine, even after a positive decision of funding, namely, a positive opinion from the Pharmacy and Therapeutics Commission of the hospital. Furthermore, for 80% of the institutions, inclusion in the National Medicines Formulary is a fundamental condition for triggering the process. The therapeutic and financial impact of a new medicine is evaluated in 91% and 100% of the NHS hospitals, respectively, and the therapeutic decision algorithm for the condition to be treated is reviewed in 78% of the institutions, including the new medicine, before the innovative medicine is freely used in the hospital.

Monitoring and Generating Real-World Evidence of Utilization and Access to Value-Based Medicines

Regarding the mechanisms for monitoring and generating real-world evidence, nearly half of the institutions (47%) do not have mechanisms for monitoring the results of new pharmacological therapies. When carried out, monitoring focuses mainly on consumption data (83%) and the number of patients treated (63%). Even in the case of medicines for which the funding decision is based on risk-sharing mechanisms and the monitoring of results associated with this sharing, 27% of institutions do not monitor these results, a worrying fact that can jeopardize this funding model. Only 30% of institutions manage data related to the use of medicines in a real-life context.

Table 1. Medicines therapeutic groups distributed through the proximity programs in 2020.

Therapeutic area	Frequency, %
Rheumatoid arthritis	80
Multiple sclerosis	76
Hormone anticancer drugs	68
Plaque psoriasis	60
HIV	56
Crohn disease and ulcerative colitis	52
Chronic renal insufficiency (epoetin)	48
Oral cytotoxic	44
Immunosuppression (transplantation)	32
Hepatitis C	28
Growth hormone	28

Proximity Medicines Dispensing /Pharmaceutical Consultation

In Portugal, certain groups of patients have free access to medicines in NHS hospitals, such as those taking HIV or anticancer medicines. Over the past few years, several NHS hospitals have implemented pharmaceutical ambulatory care mainly proximity initiatives, to respond to the needs of patients and difficulties related to mobility, geographic distance, or socio-economic conditions. Because of the COVID-19 pandemic, there was a need for quick development and implementation of proximity solutions, to ensure the continuity of the supply of medicines dispensed in NHS hospitals.[20]

The provision of hospital medication in proximity has been allowed, using several channels to deliver the medication to patients or relatives, namely, community pharmacies, Primary Care facilities, or home delivery. However, the safety or effectiveness of such medication should be assessed through a pharmaceutical consultation. The proximity distribution of hospital medication should be meant to ease access to innovative medicines.

In the studied sample, most institutions have a proximity drug dispensing program (87%), and in 54% of cases, these programs were implemented in the context of the pandemic. Medications reach the patient predominantly via a community pharmacy (29%) or a nearby NHS hospital (27%). The most frequently pharmacological therapies covered by these programs were intended for the treatment of rheumatoid arthritis (80%), multiple sclerosis (76%), and hormonal anticancer drugs.

Table 1 presents the therapeutic groups of medicines distributed using the proximity distribution model in the respondent NHS hospital institutions.

Within the scope of proximity programs, 46% of institutions have implemented pharmaceutical consultations, in 58% of cases for all patients who wish to do so, in a face-to-face format, and in 42% in the form of teleconsultation and/or video consultation.

Barriers to Access to Medicines and Shortages

When asked about the medicine acquisition process by the hospital, 57% consider that the process is never triggered in time to have medicines available.

The 3 main barriers identified in the medicine procurement process were administrative burden (70%), the inefficiency of the Portuguese Central Acquisition Agency (50%), and the lack of available NHS hospital budget (37%).

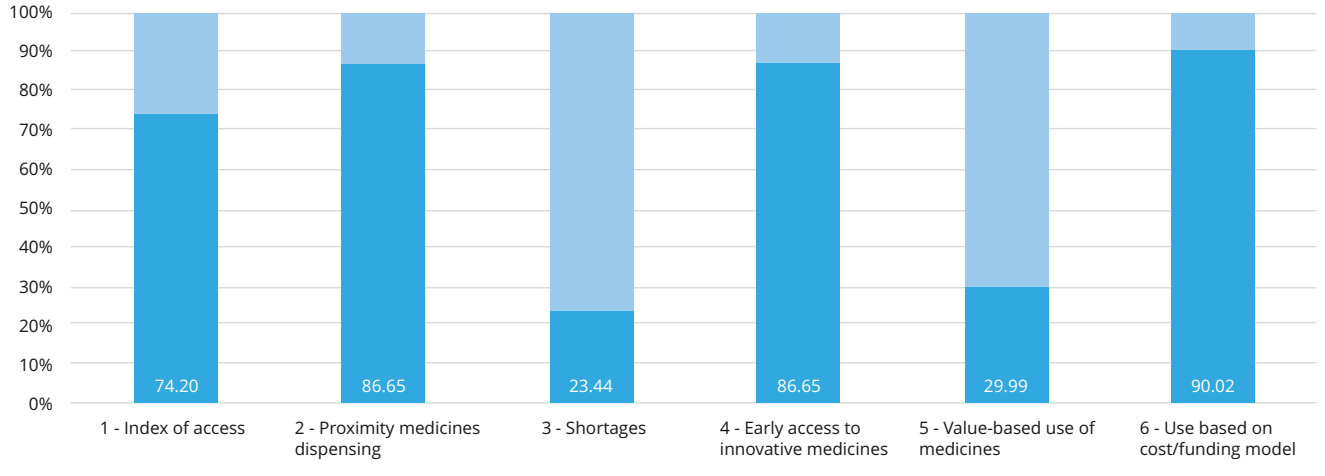
The results also show that shortages are a real problem, with concrete consequences in terms of access to medicines, given that, in 77% of cases, they are identified as a serious problem, 15% of hospitals have disruptions in the supply of medicines every day, 30% weekly, and 50% monthly.

Regarding the acquisition of medicines through European negotiation, used for COVID-19 medicines, 83% believe that it would make sense, 87% that it could accelerate access to innovation, and 83% that it could lead to lower prices.

Global Medicines Access Index

As already mentioned in the methodology, in 2021 the Global Medicines Access Index, according to the opinion of the expert panel, included 6 dimensions, with only dimension 1 remaining from the 2019 version.[19] In the first dimension (updated from the 2019 version), respondents were asked to rate on a scale from 0 to 100 according to the respondent's experience in the last 12 months and their perception of the access to new medicines in their institution (from 0 no access to new medicines to 100 access to all new medicines). The average value of the Global Medicines Access Index (Fig. 2), integrating the 6 dimensions, was 66% in 2021, with the average values by type of institution—64% for group

Figure 2. Average values obtained for each dimension of the Global Medicines Access Index.



I and II, 69% for group III, 92% for group IVa (oncology hospitals), and 58% for both group IVb (rehabilitation hospitals) and IVc (psychiatric and mental health hospitals), seeming to indicate different levels of access depending on the type of hospital institution. The main differences between hospital groups were identified in dimension 3—shortages impact, where regional hospitals seem to report a higher impact than local and specialized hospitals. Globally, oncology hospitals present a higher value of the index, but it may result from the small number of responding hospitals included in this group (n = 3).

The occurrence of shortages and the value-based real-life use of medicines are the 2 dimensions with lower values. On the contrary, proximity medicines dispensing services, early access to innovative medicines authorization, and cost/funding model are not barriers to the acquisition of innovative medicines, supporting that these dimensions assure access to medicines in NHS hospitals.[22]

Discussion

According to the Oslo Initiative, equitable and sustainable access to safe, effective, affordable, and quality-assured medicines and health products is critical to achieving universal health coverage. Despite this goal being shared by the public and private sectors, achieving it has proved difficult.[23]

Usually, medicines across countries are made available through a combination of public and private supply routes and are subject to regulations regarding their quality, safety, and supply. Several determinants and barriers relating to access to medicines have been identified according to the health system perspective of each country.[24-26]

One challenge and potential contribution to public policy would be the development of unique access to innovative medicines indicators, but once the determinants and barriers depend on the health system organization and operation, it is important that, in each country, an indicator exists to measure and monitor access to medicines. This was the main goal of this project.

Dimensions that should integrate the indicator were identified by an expert panel, comprising key decision makers of the country. All health system stakeholders were represented in this expert group to avoid bias.

This study was, to the best of our knowledge, the first survey aiming to build a national indicator to access hospital medicines, and the identified dimensions that were integrated into this indicator can be further evaluated in other countries to make them fit their national realities.

The average value of the Global Medicines Access Index, obtained for 2021 was 66 (on a scale from 0 to 100), with shortages and value-based real-life use of medicines being the 2 dimensions that pushed the value down.

Medicine shortages are a major concern worldwide and have been widely reported in recent years.[27,28] Several studies indicate that medicine shortages affect patient care and healthcare professionals' everyday tasks.[29,30] Sarnola et al[31] found that reimbursable medicines and medicines exposed to changes in the life cycle are more likely to face a shortage. Because of its heavy impact, medicine shortages should be studied in more detail.[31]

Value-based real-life use of medicines was identified as the second dimension that affects the value of the Global Medicines Access Index in NHS hospitals. Information on the added therapeutic value of medicines should represent the basis for therapeutic decisions.[32] Payers expressed interest in using outcomes-based contracting in oncology, for example, even if few have direct experience, and operationalizing through value measurement is challenging.[33,34]

Various factors influence access to medicines; key impacting challenges include budgetary constraints, increasing costs, and aging populations.[35] Innovation needs to be coupled with access to medicines and technologies, and access must be considered a fundamental human right.[36] For that, access must be measured in each country to identify major barriers to it.

A major limitation, the fact that some part of the results was based on the perception of the respondent was identified. Thus, a degree of reporting error cannot be excluded. However, institutions were asked to identify qualified field reporters to reduce this limitation. Likewise, answers may not be fully representative of the situation in respondents' institutions. A selection and information bias can also be present in the study.

Conclusion

The new formula used to obtain the Portuguese Global Medicines Access Index in 2021 seems to be more sensitive and objective.

The Global Medicines Access Index 2021 (data from 2020) was 66%, with the existence of serious shortages and value-based real-life use of medicines as the dimensions that showed space for improvement.

It will be important to monitor Global Medicines Access Index, using the newly created indicator, at least every 2 years, to validate the obtained results and identify negative and positive tendencies regarding access to hospital medicines.

Recommendations

The following recommendations are made for policy makers:

- Create mechanisms for evaluating results (effectiveness and safety) based on real-life use of medicines.
- Standardize/converge internal procedures in NHS hospitals to reduce access times and bureaucratic burden.
- Define a legal framework for pharmaceutical ambulatory care programs.
- Explore the possibility of the European Commission negotiating innovative medicines to ensure equitable access across European countries.

Author Disclosures

Author disclosure forms can be accessed in the Supplemental Material section.

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