REGULATORY COMPLIANCE OF MEDICAL PRESCRIPTIONS IN BOBO - DIOULASSO, BURKINA FASO

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Abstract
To ensure the safety and effectiveness of drugs delivered to patient, certain references of medical prescription are made compulsory by law. This study aimed to check the regulatory compliance of medical prescriptions in the city of Bobo - Dioulasso (Burkina Faso).

A descriptive cross-sectional study was undertaken between June and September 2015 to analyze digitized prescriptions in private pharmacies chosen randomly. The regulatory compliance was checked according to the standards of the country. Prescriptions originated from private health structures (34.11%) and first level public ones (17.54%). The qualification of the prescriber was missing on 68.4% of prescriptions and if mentioned it was the fact of physicians (18.92%), nurses (12.15%) and midwives (0.55%). Omissions were related to the identity of the prescriber and patient characteristics. About 64.2% of prescriptions were unreadable. The study has revealed a low compliance of medical prescriptions in Bobo-Dioulasso that can be improved through the sensitization and retraining of prescribers in this city.

Introduction
Medical prescription is a written medico legal document, dated and signed by a qualified prescriber indicating suitable drugs and medical devices necessary to care a patient as well as hygienic and dietetic advices. 
In Burkina Faso, the prescriptions of physicians and dentists are free within their respective competences. Midwives and nurses are allowed to prescribe through a limited list of medicines according to national public health code.1 Last year medical students are also authorized to prescribe under the guide of a senior physician in university teaching or public hospitals
In 2012, studies conducted in Switzerland estimated that at least 7.5% of hospital patients were concerned with prescription errors.2 In Burkina Faso, studies on the quality of medical prescriptions have showed deficiencies. In urban environment, Sondo et al. (2002)3 found in Ouagadougou that 14.8% of prescriptions were inadequate. More recently in 2013, Zoungrana et al. (2013)4 revealed that at Yalgado Ouédraogo University Teaching Hospital (CHU) of the same city, no prescription was compliant with all the regulatory prescription standards.
These studies proved that regardless of the level of care, with or without qualified prescribers, there were shortcomings in the writing of prescriptions. In the city of Bobo-Dioulasso, studies on the quality of medical prescriptions are rare or patchy although many studies have shown that the majority of drug iatrogenic events are consequences of inadequate writing of medical prescriptions. This study was undertaken to access the nature and the extent of lack about medical prescription requirements in city of Bobo-Dioulasso. Correcting identified weaknesses will enhance the safe and effective use of medicines.

Materials and methods
The study was designed as a cross sectional survey conducted from June to September 2015 in private pharmacies of the city of Bobo-Dioulasso (Burkina Faso) to evaluate regulatory compliance of medical prescriptions. For determination of the number of pharmacies to visit, the 43 functional private pharmacies of Bobo-Dioulasso mentioned on the official list (2013) of Health Ministry were grouped in five zones East, West, North South and Centre. Then 13 pharmacies were randomly determined according to a quota of 1 pharmacy per 3 by zone. Selected pharmacy in the absence of consent was systematically replaced. In retained pharmacies, any document with mention "medical prescription" and containing at least one prescribed drug, presented by a customer was considered. Prescriptions with only medical devices or which had poor or bad digitization (dark, unreadable or a part incompletely visible) were not selected.

By setting a risk of error of 0.05 (Z = 1.96) and accuracy (α) of 10%, and a proportion of 50% of prescriptions meeting regulatory aspects, a minimum of 384 prescriptions was required according to the following formula for the study. We have increased this number to 724 in order to prevent loss due to invalid samples.

Medical prescriptions were digitized using a scanner brand Deskjet 1510 All-in-One Printer 032.000.1180.44630 version. The Public Health Code and regulatory texts of Burkina Faso were used to access the respect of compulsory information of medical prescriptions. A prescription was considered of good regulatory compliance quality if it was respectful of all the regulatory standards (authorized prescriber, presence of all compulsory information) and writing requirements (legibility, correct spelling and understandable instructions). Was considered as illegible, any prescription with at least one compulsory information not easily readable by two persons.

Collected data were analyzed using Epi-Info software. Figures were made using Microsoft Office Excel 2013 and Tables with Microsoft Office Word 2013.

The study got approbation of Direction of Regional Health of Hauts-Bassins and the West Regional Council of Pharmacists Order. We obtained consent of the holder of prescription prior to its digitizing. The digitized prescriptions were saved by one operator in a protected access file. For bad quality prescriptions, pharmaceutical intervention was immediately made in each case in accordance to good pharmacy practices of drugs dispensing.

Results
A total of 727 medical prescriptions was collected, 724 were analyzed and three (03) were not included because of absence of the mention “medical prescription”.

Origin of medical prescriptions
The structure of the prescriber was not mentioned on 180 prescriptions (24.86%). Where this information was indicated, health and social promotion centers (CSPS) followed by private medical clinics were the most represented, respectively with 17.54% and 15.88% (figure 1). Prescriptions from private structures (medical clinic, nursing or medical office and private dispensaries) accounted for 34.11%.
Legibility of medical prescriptions
Illegible prescriptions represented 64.2% of the total. Unreadable items concerned the stamp (34.7%) and the identity of prescriber (12.4%), the name of patient (4.1%), lines of prescription (14.5%) and abbreviation of name of drugs (2.6%).

Qualification of prescribers
The qualification of the prescriber was unknown for 495 (68.4%) prescriptions. Physicians were authenticated authors of 126 (17.4%) prescriptions which accounted for 63.1% of certified prescriptions (Figure 2).

In the study, 139 prescriptions (19.20%) had neither the qualification nor the working structure of the prescriber mentioned. Among medical prescriptions, 410 (56.60%) were dated and signed, of which 123 (16.9%) by a physician. These prescriptions were from private structures (69.30%), universitary teaching hospital CHUSS (25.40%) and lower level medical structures (CSPS, CMA), 7.56%.

Compulsory information
No prescription was compliant with all regulatory requirements. The most compulsory information frequently found on prescriptions were the date of prescription (87.0%), patient’s identity (79.0%), designation (86.2%), form (88.8%) and dosage (90.7%) of prescribed drugs (Table 1). Omissions concerned the identity and qualifications of the prescriber, address, age, patient’s sex and weight of children.
Table 1: Distribution of medical prescriptions according to the compliance with compulsory information

<table>
<thead>
<tr>
<th>Compulsory information of medical prescription</th>
<th>Number of compliant prescriptions n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relative to prescriber</strong></td>
<td></td>
</tr>
<tr>
<td>- Identity (name and first name)</td>
<td>175 (24,2)</td>
</tr>
<tr>
<td>- Address (job location, phone number)</td>
<td>476 (65,7)</td>
</tr>
<tr>
<td>- Qualification</td>
<td>229 (31,6)</td>
</tr>
<tr>
<td>- Date and place of prescription</td>
<td>630 (87)</td>
</tr>
<tr>
<td>- Readable seal and signature</td>
<td>475 (65,6)</td>
</tr>
<tr>
<td><strong>Relative to patient</strong></td>
<td></td>
</tr>
<tr>
<td>- Identity (name and first name)</td>
<td>572 (79,0)</td>
</tr>
<tr>
<td>- Address (phone number, residence)</td>
<td>00 (0,0)</td>
</tr>
<tr>
<td>- Age</td>
<td>149 (20,6)</td>
</tr>
<tr>
<td>- Sex</td>
<td>32 (4,4)</td>
</tr>
<tr>
<td>- Child weight (n =27)</td>
<td>1 in 27</td>
</tr>
<tr>
<td><strong>Relative to content of the prescription</strong></td>
<td></td>
</tr>
<tr>
<td>- Correct writing of drugs names</td>
<td>624 (86,2)</td>
</tr>
<tr>
<td>- Prescription in INN</td>
<td>197 (27,2)</td>
</tr>
<tr>
<td>- Pharmaceutical form</td>
<td>643 (88,8)</td>
</tr>
<tr>
<td>- Dose</td>
<td>314 (43,4)</td>
</tr>
<tr>
<td>- Route / mode of administration</td>
<td>33 (4,6)</td>
</tr>
<tr>
<td>- Dosage</td>
<td>657 (90,7)</td>
</tr>
<tr>
<td>- Duration of the treatment</td>
<td>104 (14,4)</td>
</tr>
<tr>
<td>- Delimitation of the prescription</td>
<td>551 (76,1)</td>
</tr>
</tbody>
</table>

INN: International Nonproprietary Name

Discussion

The majority of prescriptions originated from top level public health structures and from private medical clinics. Physicians, nurses and midwives were identified prescribers. Compulsory elements the most frequently found on prescriptions were the date of prescription, patient’s identity, designation, pharmaceutical form, and dosage of prescribed drugs. Omissions related to the identity and qualifications of the prescriber, address, age, patient’s sex and weight of children. The entitlement to prescribe was difficult to assess because of the frequent omission of the prescriber’s qualifications.

Origin of medical prescriptions

The majority of prescriptions originated from public health facilities first level (17.54%) and from private medical clinics (15.88%). The same result was found in Mali and in South Africa. In Burkina Faso, health system is pyramidal with at its base CSPSs, more numerous, close to communities and where first contacts with health services occur. The predominance of private clinics in terms of origin of prescriptions could be justified by their high attendance by urban populations who attribute them a relatively better quality of care, hospitality and accommodation conditions. But, Sudar Codi et al. (2015) revealed that prescriptions from private health practitioners were less rational than those from public hospital prescribers.

The existence of internal pharmacies to public hospitals and CMA could explain the low frequency of medical prescriptions from these structures.

Legibility of prescriptions

The study has revealed that 64.2% of medical prescriptions were illegible. Illegible medical prescriptions are the cause of many medical errors. The high workload of prescribers is often cited as the main cause. In Switzerland and in France, the proportions of illegible prescriptions are low, respectively 5.8% and 8% because of the computerization of most drug prescriptions. But in our context, this proportion is 34.7%. In Bobo-Dioulasso,
prescriptions being handwritten, prescribers should write correctly and legibly if they want to ensure the proper execution of the prescription and the safety of the patient.

Absence of compulsory information concerning the prescriber
Several medical prescriptions did not mention prescribers’ identities (75.8%). In many studies, this information, though compulsory is not always found. Some hospital authors have reported lower proportions. Prescribers, mainly physicians, easily give their identity by simply affixing a legible seal or by using prescriptions with preprinted letterhead, contributing to better inform on the identity of the prescriber. The prescriber’s identity is required in Burkina Faso. It protects the responsibility in the implementation of the therapy and facilitates exchanges with other stakeholders.

The study has shown that qualification was not always mentioned (68.37%) as in other studies on prescriptions in Burkina Faso. In France, more than two thirds of the orders carry the qualification of the prescriber. In Switzerland, 96.1% of prescriptions mention the qualification of the prescriber. This higher rate in developed countries may be due to the computerization of prescription system, which has the advantage of systematically printing on prescriptions certain information related to prescribers such as qualification, address and identity. In the context of Burkina Faso, where derogation is granted to nurses and midwives, the mention of the prescriber’s qualification will permit to check the competence or entitlement to prescribe certain drugs in accordance with regulations.

The date of the prescription (87.0%) and the signature of the prescriber (70.6%) were well mentioned as in other studies conducted in Burkina Faso. But in Switzerland and Saudi Arabia more than half of prescriptions did not indicate this information. The date of the prescription permits to monitor the disease progression and the treatment used. It also determines the validity period of the prescription. As for the signature of the prescriber, it is compulsory and is a component to authenticate the prescription.

Absence of compulsory information concerning the patient
In the study, information on the patient was missing such as patient’s age in 79.4% of prescriptions, weight in 26 out of 27 cases of pediatric prescriptions and identity in 21.0% of prescriptions. Zoungrana et al. (2013) and Zongo et al. (2013) in their studies found frequencies of age omissions on prescriptions respectively of 66.73% and 71.1%.

Yet the identity of the patient on a prescription is compulsory in Burkina Faso. Patient’s name allows personalization of the prescription and avoids delivery or treatment mistakes. The presence of the name alone is not sufficient for safely drugs dispensing. The age, weight and sex are also distinctive features between two patients. Our study also found that these characteristics were often omitted. This non-compliance seems not to have changed in Burkina Faso since 1999. Indeed, several previous studies before ours have reported these deficiencies.

Yet, sex and age are easy information to get when the questioning is well conducted. Information on weight is required on children’s prescription, especially when the dosage is given in mg/ kg of the patient body weight. The mention of the age and sex is required on any prescription regardless of the type.

Designation of drugs on prescriptions
The designation of drugs by their International Nonproprietary Name (INN) was less frequent, (27.2%). This was also the case in India, in Mali, and in Benin. Ignorance and pressure of medical representatives are the main causes. Prescribing in INN has many advantages which, avoid pharmacological redundancy, facilitate the monitoring of adverse events and ensure that the patient will receive the cheapest medication for his treatment.

The study has revealed that pharmaceutical form and dosage were frequently omitted (56.6%). El Bara et al. (2013) and Shaibani et al. (2012) also found a high proportion of prescriptions without any mention of form or dosage (88% and 35%). This insufficiency is probably due to an ignorance of prescribed drugs dosages or to a mere negligence. The prescriber preferred to indicate the pharmaceutical form or the age of patient instead of the dosage. The failing to mention the dosage of medicines can lead to medication errors such as dispensing error type.

Medication instructions
On many prescriptions medication schemas were not described. The route of administration (95.42%), drugs intake time (99.25%) or intake moment (95.97%) and the duration of the treatment (85.57%) were missing. In 2013, Zongo et al. and Zoungrana et al. made similar observations in urban hospitals. The low rate of reference to the route of
administration could be explained by the fact that some prescribers let to deduct the route of administration from the pharmaceutical form. However, some drugs exist in the same form but are differently administered. It is the case of Nystatin (oral and vaginal tablet). The failure to indicate the route of administration is a source of medicinal error.\(^{28, 29}\) The route of administration influences the bioavailability and effectiveness of the drug.

The mention of the intake time or moment is not respected in prescribers’ practice. The high workload and lack of knowledge of pharmacokinetics properties of drugs could also explain this non-compliance. In the study, intake time was usually indicated by inappropriate words such as «morning, noon and night ». Drug intake intervals are fixed either by taking into account the half-life of the drug, or by taking into account the duration or the action period of drug. Intake time and / or moment determine the effectiveness of a treatment. The intake moment is important especially for the oral route because of the influence of food on the bioavailability of certain drugs.

Our study noted a lack of treatment duration on 85.5% of studied prescriptions. The treatment period is the time required for a successful treatment. Our results are similar to those found by Sondo et al. (2002) and Kaboré et al. (2007), who found respectively 88.1% and 87.6% of prescriptions without treatment duration.\(^{3, 18}\) In the study of Zoungrana et al. (2013) 96.31% of prescriptions received in the hospital pharmacy of CHU YO did not have any treatment duration.\(^4\)

The duration of treatment is determined by taking into account the time necessary to achieve and maintain an effective steady state. The lack of treatment duration can lead to the administration of doses therapeutically below or above. At last, treatment duration helps to deliver precise quantities of drug to the patient, avoiding the keeping of treatment remains which is responsible for self-medication. All the prescriptions of the series were not delimited. It is a very serious non-compliance than to leave a prescription without a delimitation line. Indeed, a medical prescription is necessary to obtain some drugs often listed. When the prescription is not delimited, it might be violated. Some drugs may be added for other purposes.

Entitlement to prescribe

The entitlement to prescribe is assessed according to the qualification of the prescriber to secure the use of prescribed drug. In Burkina Faso, physicians and dentists’ prescriptions are free within their respective competences. The law gives permission to Midwives and nurses to prescribe only under the conditions set by a Decree of the Minister of Health.\(^1\) During the study, the entitlement could not be verified in private pharmacies of Bobo-Dioulasso because of frequent omission of prescribers’ qualification and location on prescriptions (68.4%). Also there is a need to have well trained collaborators of pharmacist to check the ability of prescriber to use prescribed drugs in accordance with the list adopted by the Ministry of Health and defining the levels of utilization of different medicines.

Conclusion

The study revealed frequent cases of non-compliance with regulatory standards of prescription writing. Sensitization and training of prescribers in Bobo-Dioulasso would be needed to improve the quality of medical prescriptions and to secure the use of medicines.

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References