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ORIGINAL RESEARCH ARTICLE

Pharmacovigilance Systems in Developing Countries: An Evaluative Case Study in Burkina Faso

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Abstract
Background Burkina Faso, like other Sub-Saharan African countries, has recently experienced a large-scale deployment of new medicines for the prevention and treatment of notable diseases of public health interest, including malaria, HIV/AIDS and meningitis. This new context rendered the implementation of pharmacovigilance necessary in order to monitor and establish the safety and effectiveness of these medicines. In 2008, the Ministry of Health of Burkina Faso, West Africa, launched a formal pharmacovigilance system to respond to this need.
Objective The aim of this study was to evaluate the early-stage pharmacovigilance system of Burkina Faso through a comprehensive and system-based approach with the prospect of identifying areas for improvements.
Methods We conducted a descriptive cross-sectional study in Burkina Faso. Sixteen key informants from the National Drug Authority (NDA), public health programmes (PHPs) and hospitals were interviewed. Study participants were selected based on a convenience sampling in the NDA, three teaching hospitals, two regional hospitals and six PHPs. Data were collected using the Indicator-based Pharmacovigilance Assessment Tool (IPAT), a metric instrument recently designed and validated by 'Management Sciences for Health', a US non-profit organization. The evaluation also involved the collection and review of relevant pharmacovigilance-related documentation in the institutions assessed. A scoring system was used for the quantification of assessment results.
Results The NDA of Burkina Faso, the institution statutorily in charge of pharmacovigilance, achieved a performance score of 70 %. The basic structures for pharmacovigilance activities were in place; however, the lack of specific laws dedicated to pharmacovigilance, the lack of national guidelines and standard operating procedures on pharmacovigilance, and the insufficient coordination of pharmacovigilance stakeholders in the country were identified as the main weaknesses. Safety data collected thus far have not led to the identification of local drug-related risks; yet, relevant external safety alerts are monitored and acted upon. In 2010, 31 marketing authorizations were modified to include new safety information; seven others were suspended and the corresponding medicines were withdrawn from the national market.
In PHPs, pharmacovigilance activities were not formalized, and in hospitals, pharmacovigilance structures were still under development.
Conclusion Relevant interventions aimed at strengthening the legal framework and structures for pharmacovigilance activities, and improving the coordination of

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stakeholders countrywide, should be undertaken as soon as possible. Such an investment is necessary before the national pharmacovigilance system is able to collect its own data, generate signals, evaluate and manage local medicine-related risks and then become a genuine tool for public health.

1 Background

Patients' safety is a central component of the quality of healthcare. Besides the therapeutic benefits that justify their use, medicines can also induce unwanted effects. To minimize the adverse outcomes associated with the use of medicines in healthcare, pharmacovigilance appears to be an essential tool in clinical medicine and public health. The WHO has defined pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems" [1].

The rationale for pharmacovigilance is primarily based on the necessity to mitigate the shortcomings of premarketing clinical trials, mainly designed to demonstrate efficacy. Considering the intrinsic limitations of current clinical trials, such as lack of statistical power, selection of study participants, and too-short follow-up time [2–4], pharmacovigilance offers the possibility of gathering further information on the safety and effectiveness of medicines during their postmarketing life, thereby permitting drug-related morbidity and mortality to be minimized; it could also help detect and prevent medication errors, another common drug-related problem [5, 6]. Furthermore, preventing adverse drug reactions (ADRs) can be cost efficient as a result of the financial costs associated with their medical management [7–9].

Pharmacovigilance was initiated in developed nations in the 1960 s following the landmark disaster of thalidomide [10, 11]. Conversely, postmarketing surveillance of pharmaceuticals is still in its early stages in many developing countries where it has often been perceived as a luxury [1]. In the developing world and Sub-Saharan Africa in particular, pharmacovigilance has recently gained enhanced attention. This interest is due to the current public health context in many African countries, characterized by: (i) the large-scale deployment of relatively new medicines such as the new meningococcal A conjugate vaccine [12], artemisinin-based combined therapies and antiretroviral drugs (ARV) [13–16]; (ii) the growing phenomenon of fake and substandard drugs [17–19]; and (iii) the need for cost effectiveness in public health interventions.

In 2008, the drug regulatory authority of the Ministry of Health (MoH) of Burkina Faso, West Africa, launched a formal pharmacovigilance system with the purpose of monitoring the safety of medicines in the country. The aim of the present study was to evaluate this early-stage drug safety monitoring system through a comprehensive system-based approach. The study was interested in how the public health system is organized at different levels to respond to the challenges posed not only by ADRs, but also by other relevant drug-related issues, such as medication errors, treatment failure and pharmaceutical product quality.

2 Methods

2.1 Study Setting

The study was conducted in Burkina Faso, a landlocked West-African country with an estimated population of 16 million in 2011. The national public health system is composed of 1443 peripheral health facilities, 44 district hospitals, 9 regional hospitals, 1 national hospital and 3 university teaching hospitals. The ratios of physician, pharmacist and nurse to population were 1:22,017, 1:72,863 and 1:2,679, respectively, in 2011 [20].

2.2 Study Design and Sampling

We interviewed a convenience sample of pharmacovigilance stakeholders of the public healthcare system in a cross-sectional study. Study participants were recruited across four cities (Ouagadougou, Bobo-Dioulasso, Ouahigouya and Tenkodogo) and from the following institutions:

- The National Drug Authority (NDA)
- Six Public Health Programmes (PHPs):
  - the National Malaria Control Programme
  - the National Tuberculosis Control Programme
  - the National HIV/AIDS Control Programme
  - the National Schistosomiasis Control Programme
  - the National Lymphatic Filariasis Elimination Programme
  - the National Expanded Programme on Immunization (EPI);
- Three teaching hospitals (two in the capital city of Ouagadougou and one in Bobo-Dioulasso, the second largest city)
- Two regional hospitals (one in the city of Ouahigouya in the Northern region, and one in the city of Tenkodogo in the Central-Eastern region).

2.3 Data Collection

2.3.1 Data Collection Tool

We used the Indicator-based Pharmacovigilance Assessment Tool (IPAT) [21] for data collection. The IPAT was designed and validated by the US-based non-profit organization 'Management Sciences for Health' through its Strengthening Pharmaceutical Systems (SPS) programme, for the specific purpose of pharmacovigilance systems assessment in developing countries. The tool is meant to conduct customized evaluations through a series of assessment questions reflecting on structures, processes and outcomes of medicines safety systems. It encompasses five areas of interest in drug safety monitoring:

1. Policy, law, and regulation (four indicators, 1.1–1.4)
2. Systems, structures, and stakeholder coordination (15 indicators, 2.1–2.15)
3. Signal generation and data management (six indicators, 3.1–3.6)
4. Risk assessment and evaluation (eight indicators, 4.1–4.8)
5. Risk management and communication (ten indicators, 5.1–5.10).

The IPAT is thus made up of 43 indicators, including 26 core indicators and 17 supplementary indicators. 'Core' refers to the most essential indicators for an operational pharmacovigilance system and 'Supplementary' to the others.

The first area (Policy, law, and regulation) is designed to evaluate the NDA or a similar institution at national level. Thus, only the four other areas are relevant for health facilities and PHPs.

For our evaluation, the most relevant indicators for each type of institution were selected, leading to:

- 37 indicators for the NDA (1.1–1.4, 2.1–2.11, 2.13–2.15, 3.1, 3.3–3.6, 4.1–4.5, 5.1–5.7 and 5.9–5.10);
- 21 indicators for hospitals (2.1–2.5, 2.8–2.11, 2.13, 3.3–3.6, 4.1, 4.3–4.5, 5.1 and 5.3–5.4);
- 22 indicators for PHPs (2.4, 2.5, 2.8–2.9, 2.13, 3.3–3.6, 4.1, 4.3–4.8, 5.1–5.3, 5.6–5.7 and 5.9).

A French version of the IPAT was used.

2.3.2 Data Collection Process

Prior to data collection, key informants were requested to participate in the study through emails or phone contacts. One to three respondents per institution provided information during face-to-face interviews in May 2011.

Besides the indicator-related items, the questionnaires included open-ended questions to probe the respondents' opinions regarding the current pharmacovigilance system.

Relevant documents were also collected and reviewed; they served as written evidence in support of interviews and included the National Pharmaceutical Policy, annual reports, regulatory texts and medicines information bulletins.

2.4 Data Analysis

Data analysis was both qualitative and quantitative. We used Microsoft Excel (Microsoft Corporation, Redmond, WA, USA) to compute scores. For scoring purposes, 2 points were allocated to any core indicator fulfilled, 1 point to any supplementary indicator fulfilled, and 0 points to any indicator not fulfilled. For quantitative indicators (2.13, 4.4, 5.3, 5.4, 5.5, 5.6, 5.7 and 5.10), critical thresholds have been set, as described in the IPAT [21].

2.5 Ethical Considerations

An authorization to conduct the study was requested and obtained from the MoH of Burkina Faso. All study participants consented to be interviewed. Data were processed anonymously to preserve confidentiality.

3 Results

A total of 16 key informants from 13 institutions were interviewed, including 8 respondents from PHPs, 5 from hospitals and 3 from the NDA. The sample comprised 2 physicians, 12 pharmacists and 2 specialized nurses.

3.1 The National Drug Authority (NDA)

Thirty-seven indicators (22 core and 15 supplementary) were applied to evaluate the NDA, for a maximum score of 59.

The NDA achieved an overall score of 68 % (40/59) (Table 1). This performance by pharmacovigilance area was as follows:

- Policy, law, and regulation: 50 % (3/6);
- Systems, structures, and stakeholder coordination: 68 % (17/25);
- Signal generation and data management: 60 % (6/10);
- Risk assessment and evaluation: 71 % (5/7);
- Risk management and communication: 82 % (9/11).

The NDA hosts a pharmacovigilance unit with a clear mandate and designated staff, but the lack of national guidelines and standardized operating procedures (SOPs) on

Table 1 Results for the National Drug Authority

Pharmacovigilance area		Type of indicator	Score
I. Policy, Law, and Regulation			
1.1	Existence of a national policy document taking pharmacovigilance into account	C	2
1.2	Specific references to pharmacovigilance in the national medicine legislation	C	0
1.3	Legal requirement for marketing authorization holders to mandatorily report serious ADRs to the NDA	S	1
1.4	Legal requirement for marketing authorization holders to conduct postmarketing surveillance of their products	S	0
	Subtotal score (%)		*3/6 (50)*
II. Structures, systems, and stakeholders coordination			
2.1	Existence of a pharmacovigilance unit	C	2
2.2	Clear mandate, role and responsibilities for the pharmacovigilance unit	C	2
2.3	Availability of a Question-Answer service on the safety of medicines	C	0
2.4	Designated staff for pharmacovigilance	C	2
2.5	Existence of a budget for pharmacovigilance	C	2
2.6	Existence of a national medicine safety advisory committee	C	2
2.7	Existence of national pharmacovigilance guidelines	C	0
2.8	Existence of patients' safety standard operating procedures	C	0
2.9	Existence of basic communication material for reporting/providing information	C	2
2.10	Existence of a bulletin on the safety of medicines	C	2
2.11	Existence of basic material in the pharmacovigilance unit	S	1
2.13	Healthcare professionals trained on pharmacovigilance last year	S	1
2.14	Existence of a platform of coordination across all pharmacovigilance stakeholders	C	0
2.15	Membership with the WHO Uppsala Monitoring Centre	S	1
	Subtotal score (%)		*17/25 (68)*
III. Signal generation and data management			
3.1	Existence of a system for coordination and collation of pharmacovigilance data from all sources	C	2
3.3	Existence of a form for reporting suspected ADRs	C	2
3.4	Existence of form for reporting suspected defective product quality	C	0
3.5	Existence of form for reporting suspected medication errors	C	2
3.6	Existence of a form for reporting suspected treatment failure	C	0
	Subtotal score (%)		*6/10 (60)*
IV. Risk assessment and evaluation			
4.1	Medicine utilization review carried out last year	S	0
4.2	Pharmaceutical product quality survey conducted within the last 5 years	S	1
4.3	Study quantifying incidence of medication errors	S	0
4.4	Number of ADR reports received last year	C	2
4.5	Current or recent (5 years) active surveillance of ADRs	C	2
	Subtotal score		*5/7 (71)*
V. Risk management and communication			
5.1	Risk mitigation plan targeting high-risk medicines	S	1
5.2	Prequalification scheme of drugs' manufacturers	S	1
5.3	Number of medicines safety information requests received and addressed last year	S	0
5.4	Percentage of publication (of issues) of any medicine information bulletins	S	1
5.5	Number of medicine safety issues of local relevance identified from outside sources	S	1
5.6	Number of letters sent to healthcare professionals on the issue of medicines safety	S	1
5.7	Average time lag between serious ADR identification and communication to healthcare professionals	C	2
5.9	Community education activities on the safe use of medicines	S	0
5.10	Percentage of medicines sampled in the last year that passed product quality tests	C	2

Table 1 continued

Pharmacovigilance area	Type of indicator	Score
Subtotal score(%)		*9/11 (82)*
Total score (%) achieved		*40/59 (68)*

A grade of 2 points was allocated to each core indicator fulfilled, 1 point for each supplementary indicator, and 0 points for any indicator not fulfilled

Thresholds set for quantitative indicators: 2.13 = 5 % of healthcare workers trained; 4.4 = 100 reports per million people; 5.3 = 100 per million people; 5.4 = at least 70 % of planned issues published; 5.5 = at least 70 % of relevant alerts have been acted on; 5.6 = at least 70 % of alerts communicated to healthcare professionals; 5.7 = at least 70 % of alerts communicated to healthcare professionals within 3 weeks; 5.10 = 80 % of sampled medicines pass the quality test-

ADR adverse drug reaction, *C* core indicator, *NDA* National Drug Authority, *S* supplemental indicator

pharmacovigilance, as well as the insufficient coordination of pharmacovigilance stakeholders throughout the country, were observed. There was no specific legislation on pharmacovigilance. The reporting form designed by the NDA takes ADRs and medication errors into account, but neither treatment failure nor pharmaceutical product quality is included.

Positive findings from the NDA included a membership obtained from the WHO Uppsala Monitoring Centre and the existence of a national drug information bulletin published regularly.

In 2010, a survey was carried out in order to evaluate the quality of pharmaceuticals in the country; it found that 90.6 % of the 25 products assessed conformed to quality standards [22].

By the time of the study, the pharmacovigilance unit had received 1986 suspected ADR reports, most of which were due to active surveillance implemented during the first ever introduction of the new meningococcal A conjugate vaccine in Africa [12].

The assessment revealed that the NDA had addressed medicine-safety issues identified from external sources. These issues were mostly related to the contraindications of carbocisteine, acetylcysteine and meglumine benzoate, in infants, and led to risk management actions which consisted of:

- communication to healthcare professionals;
- suspension of seven marketing authorizations and recall of corresponding products;
- modification of 31 marketing authorizations (restriction of indication).

3.2 Hospitals

Twenty-one indicators (14 core and 7 supplementary) were used to assess the five hospitals for a maximum possible score of 35 (Table 2).

The teaching hospital Yalgado Ouedraogo, first national referral hospital, achieved a score of 63 % (22/35). The teaching hospital Sanou Sourou of Bobo Dioulasso, second national referral hospital, achieved a score of 49 % (17/35). The paediatric teaching hospital Charles de Gaulle obtained a score of 43 % (15/35). The regional hospitals of Ouahigouya and Tenkodogo both achieved the score of 34 % (12/35). Two hospitals out of five (40 %) had a Drug and Therapeutics Committee (DTC). The same proportion of the hospitals (40 %) had a drug information bulletin. None of the hospitals were implementing patients' safety SOPs.

3.3 Public Health Programmes (PHPs)

In the absence of a formal pharmacovigilance organization within PHPs, only a few indicators of the assessment tool could be verified, making the quantification of results less meaningful; therefore, we provided a qualitative description of the state of pharmacovigilance within each PHP.

3.3.1 Malaria Control Programme

This programme had neither a pharmacovigilance unit nor any staff specifically responsible for pharmacovigilance. The current treatment guidelines and the training modules on malaria did not take pharmacovigilance into account. No information on ADRs was collected by the programme.

3.3.2 Tuberculosis Control Programme

The respondent admitted to having pharmacovigilance responsibilities included in his job description, but no specific activities had been implemented yet. Only treatment failure information was collected through treatment reports to monitor the effectiveness of the programme.

3.3.3 HIV/AIDS Control Programme

The programme had no designated pharmacovigilance staff. The national treatment protocol had references to ADRs of ARV drugs, but the quarterly treatment reporting

Table 2 Results for the five hospitals

Pharmacovigilance area		Scores for each hospital					
		Type of indicator	CHUYO	CHUSS	CDG	OHG	TNK
II. Structures, systems and stakeholders coordination							
2.1	Existence of a pharmacovigilance unit or a DTC	C	2	2	0	0	0
2.2	Clear mandate, role and responsibilities for the pharmacovigilance unit	C	2	2	0	0	0
2.3	Availability of a Question-Answer service on the safety of medicines	C	0	0	0	0	0
2.4	Designated staff for pharmacovigilance	C	2	2	2	2	2
2.5	Existence of a budget for pharmacovigilance	C	2	2	2	2	2
2.8	Existence of patients' safety standard operating procedures	C	0	0	0	0	0
2.9	Existence of basic communication material for reporting/providing information	C	2	2	2	2	2
2.10	Existence of a bulletin on the safety of medicines	C	2	0	2	0	0
2.11	Existence of basic material in the pharmacovigilance unit or DTC	S	1	0	1	0	0
2.13	Healthcare professionals trained on pharmacovigilance last year	S	1	1	0	1	1
	Subtotal score (%)		*14/18 (78)*	*11/18 (61)*	*9/18 (50)*	*7/18 (39)*	*7/18 (39)*
III. Signal generation and data management							
3.3	Existence of a form for reporting suspected ADRs	C	2	2	2	2	2
3.4	Existence of a form for reporting suspected defective product quality	C	0	0	0	0	0
3.5	Existence of a form for reporting suspected medication errors	C	2	2	2	2	2
3.6	Existence of a form for reporting suspected treatment failure	C	0	0	0	0	0
	Subtotal score (%)		*4/8 (50)*	*4/8 (50)*	*4/8 (50)*	*4/8 (50)*	*4/8 (50)*
IV. Risk assessment and evaluation							
4.1	Medicine utilization review carried out last year	S	0	1	0	0	0
4.3	Study quantifying incidence of medication errors	S	0	0	0	0	0
4.4	Number of ADR reports received last year	C	2	0	0	0	0
4.5	Current or recent (5 years) active surveillance of ADRs	C	0	0	0	0	0
	Subtotal score (%)		*2/6 (33)*	*1/6 (17)*	*0/6 (0)*	*0/6 (0)*	*0/6 (0)*
V. Risk management and communication							
5.1	Risk mitigation plan targeting high-risk medicines	S	1	1	1	1	1
5.3	Number of medicines safety information requests received and addressed last year	S	0	0	0	0	0
5.4	Percentage of publication (of issues) of any medicine information bulletin	S	1	0	1	0	0
	Subtotal score (%)		*2/3 (67)*	*1/3 (33)*	*2/3 (67)*	*1/3 (33)*	*1/3 (33)*
Total score (%) achieved			*22/35 (63)*	*17/35 (49)*	*15/35 (43)*	*12/35 (34)*	*12/35 (34)*

A grade of 2 points was allocated to each core indicator fulfilled, 1 point for each supplementary indicator and 0 points for any indicator not fulfilled

Thresholds set for quantitative indicators: 2.13 = 5 % of healthcare workers trained; 4.4 = 100 reports per million people; 5.3 = 100 per million people; 5.4 = at least 70 % of planned issues published

ADR adverse drug reaction, *C* core indicator, *CDG* Teaching Hospital Charles de Gaulle, *CHUSS* Teaching Hospital Sourou Sanou, *CHUYO* Teaching Hospital Yalgado Ouedraogo, *DTC* Drug and Therapeutics Committee, *OHG* Regional Hospital of Ouahigouya, *S* supplemental indicator, *TNK* Regional Hospital of Tenkodogo

form did not mention items related to adverse effects. Treatment failure information is regularly collected as it is required for ARV protocol shift.

3.3.4 Lymphatic Filariasis Elimination Programme

Although no staff were specifically responsible for pharmacovigilance, this programme implements some pharmacovigilance activities during mass treatment campaigns. It has a specific form for reporting serious adverse events that occur during campaigns. After each campaign, a survey is conducted to evaluate the incidence of ADRs and the quality of treatment administration.

3.3.5 Schistosomiasis Control Programme

There were no staff responsible for drug safety monitoring. Nevertheless, adverse effects were monitored during supervision of treatment campaigns and aggregated in final reports.

3.3.6 Expanded Programme on Immunization

This programme had some staff responsible for the safety of immunization. Guidelines on vaccines' safety and forms for reporting serious adverse events following immunizations are also utilized routinely during campaigns.

For all six PHPs, the procurement of medicines and vaccines was based on the WHO prequalification of manufacturers, an international scheme that ensures the implementation of Good Manufacturing Practices.

3.4 Stakeholders' Points of View

The stakeholders' suggestions for improving the current pharmacovigilance system were classified as either strategic or operational.

Strategic suggestions included 'hospitals developing partnerships with pharmacovigilance centres in developed countries', 'advocating for funding for pharmacovigilance activities', 'independence of the pharmacovigilance centre from the NDA to avoid conflict of interest' and 'adopting a pharmacovigilance system that starts from the field, before being centralized; the current system happens to be bureaucratic and thus too heavy to be rolled out successfully'.

Operational suggestions comprised 'more training', 'supervision, follow-up and feedback towards stakeholders in the field', 'strengthening the capacity of DTCs within hospitals' and 'further motivation and involvement of clinicians to report ADRs'.

4 Discussion

4.1 The NDA

We showed that the NDA as a national pharmacovigilance institution performed nearly at the level of 70 %. Although a threshold of performance defining a functional pharmacovigilance system in a given country has not been established, the authors of the IPAT consider that an NDA should achieve all the core indicators in order to be considered as minimally functional [21]. Only 15 of the 22 core indicators (68 %) were achieved by the NDA, which would indicate that it is non-functional. The most probable explanation of this result is the recent inception of formal pharmacovigilance activities within the NDA (2008). Indeed, time is needed to build an effective drug safety monitoring system as it requires a legislative framework, resources and political commitment.

Although the theme of human health products vigilances (including pharmacovigilance) is clearly mentioned in the National Pharmaceutical Policy of Burkina Faso, specific pharmacovigilance regulatory texts were lacking. Legislation and regulations for drug safety monitoring are highly important as they provide the legal basis for action and official directives for the compliance of relevant parties with the national system.

The pharmacovigilance unit of the NDA had the minimal resources (material, people and budget) to function. However, as the national pharmacovigilance system is expected to expand in the coming years, we anticipate a shortage of qualified human resources; therefore, acquiring additional staff and developing training plans should be considered carefully.

A form has been designed as the national standard tool to report ADRs and medication errors. An ADR reporting form is the result of a compromise between the need for information and the necessity of simplicity. We think that the current reporting form is too extensive as it lies beyond a single page and features too many details. As simplicity is acknowledged as a key aspect to consider when designing a reporting form [13, 23], revising the current form towards a shorter and simpler version is warranted. An overloaded form might overburden healthcare professionals and impede proper data collection.

Risk assessment is essential in pharmacovigilance given that it can provide the critical information needed for timely decision making. Studies evaluating the quality of marketed pharmaceuticals, such as the quality control conducted in 2010 [22] by the NDA, are very relevant and should be implemented on a yearly basis to ensure continuous surveillance. The pharmacovigilance unit was also involved in the implementation of the mass immunization campaign against bacterial meningitis with the new

meningococcal A conjugate vaccine [12]. This opportunity has provided valuable insights into the safety of this vaccine during its inaugural large-scale administration in the field. Moreover, the surveillance has enhanced the reporting of ADRs and accounted for the majority of reports sent to the NDA in 2010. In general, active surveillance of medication use should be undertaken whenever possible to supplement spontaneous reporting of ADRs.

Prevention and minimization of the unintended effects of medicines should be the main focus of pharmacovigilance [14]. In 2010, the NDA had addressed medicines safety issues coming from external sources, especially the French drug regulatory authority, the Agence Nationale de Sécurite du Médicament et des produits de santé (ANSM). This resulted in the suspension of marketing authorization for several products; others have been withdrawn, including Mediator™ (benfluorex), which was responsible for a public outcry in France [24]. These actions suggest that the NDA has been reactive in protecting the health of the public based on information gathered from stronger pharmacovigilance systems. Before the national pharmacovigilance system is properly equipped to generate its own safety alerts to inform risk management, tracking external safety alerts relevant to the medicines registered in the country should remain a priority.

4.2 Hospitals

Hospitals and other health facilities are very suited for drug safety monitoring activities as various medicines are used to treat patients in different circumstances. Owing to their multidisciplinary composition, DTCs within hospitals are anticipated to play leading roles in drug safety monitoring. Yet, we noticed that pharmacovigilance is not always on top of the agenda. As one key informant in a teaching hospital mentioned, "before you monitor adverse events in patients, you need first to make medicines available for their treatment". Because hospitals are essential stakeholders in pharmacovigilance, strategies emphasizing DTCs are warranted to set up a dynamic system.

Underreporting was also mentioned by informants as an obstacle to pharmacovigilance, even after trainings. Underreporting of ADRs is a well-documented problem in pharmacovigilance, irrespective of the level of development [27–29]. Nevertheless, inculcating the reflex of routinely reporting ADRs in healthcare professionals with effective measures can help secure a critical threshold of reports for appropriate action.

4.3 PHPs

In spite of the existence of funding opportunities, pharmacovigilance was not formalized in most PHPs. In general, no staff member is responsible for pharmacovigilance activities. At best, activities related to medicines safety are entrusted to some staff members having other activities deemed to be more important. The role of pharmacovigilance in PHPs might be undervalued by programme managers. The WHO considers pharmacovigilance to be an integral component of PHPs as it will help ensure the acceptance and effectiveness of these programmes through the collection, analysis and interpretation of relevant safety data [25]. The lack of pharmacovigilance within PHPs may negatively impact treatment adherence, thus putting their success in jeopardy. A striking example comes from neighbouring Ghana where, in 2007, an independent pharmacovigilance centre was requested to investigate rapidly-spread rumours over a mass distribution of mebendazole tablets; that intervention had helped to manage what almost became an emergency and had contributed to restoring confidence from the population thanks to the evidence provided [26]. Interestingly, the programmes that operate with seasonal treatment campaigns (lymphatic filariasis, schistosomiasis) and the EPI document serious adverse reactions, as opposed to those that provide continuous treatments for patients (malaria, tuberculosis and HIV/AIDS).

Even if implementation of pharmacovigilance in health facilities could help monitor the effects of the medicines used in PHPs, coordination and stewardship still remain with the managers.

4.4 Stakeholders' Suggestions

Stakeholders' suggestions underscored the need for training, supervision, feedback and decentralization. This is consistent with the findings of previous studies in resource-poor settings where regular training, monitoring and feedback were found to be key factors of success in pharmacovigilance [15, 30, 31].

4.5 The Methodological Approach

The method used to assess the pharmacovigilance system of Burkina Faso is subject to limitations inherent to the IPAT itself and to the way it has been applied.

4.5.1 Limitations Inherent to the Indicator-based Pharmacovigilance Assessment Tool

The assessment tool has the following possible limitations. First, the sensitivity and specificity of the IPAT as a measurement tool have yet to be established. Second, the quantification of responses in the scoring process is prone to imprecision. Third, the assessment has to rely on respondents' declarations unless written evidence is

available as a source of verification. Fourth, a local adaptation of the tool may be necessary prior to an evaluation because of the limited settings where the IPAT was tested and validated. This adaptation could include:

- A preliminary discussion with stakeholders to reach a consensus about which indicators should be used, and which ones should be classified as Core or Supplementary.
- The use of locally relevant references to assess certain indicators, such as the number of medicine safety issues of local relevance identified from outside sources (indicator 5.5). For example, sources of external safety alerts in Burkina Faso mainly included alerts from the French drug regulatory authority (ANSM) instead of the US FDA mentioned in the IPAT.
- In francophone settings, the list of key documents for medicines information (for indicator 2.11 'Existence of basic material in the pharmacovigilance unit') needs to include references (books, databases and journals) in French in addition to the English ones.

4.5.2 Limitations Related to the Evaluation Process

The assessment was based on a convenience sample and did not include other stakeholders of the pharmacovigilance arena, such as health professions' boards (medicine, pharmacy, dentistry and nursing), the private sector and research institutes where safety evaluations of some medicines are probably done. This could affect the generalizability of the results.

The study sample features an overrepresentation of pharmacists (75 %; $n = 12$). This finding corresponds to the reality in the field. Indeed, pharmacists have been at the forefront of pharmacovigilance activities at the MoH, probably in part because they receive training on pharmacovigilance at the University of Ouagadougou, as opposed to physicians. However, this situation should not lead to the wrongful view of pharmacovigilance as an activity for just pharmacists, as any ADR reporting system relies primarily on prescribers such as physicians and nurses. Our limited sample in number and diversity could weaken the reproducibility of the results; however, the sample could be explained by the limited number of institutions and people actively involved in pharmacovigilance by the time of the study. Furthermore, the use of documents as sources of verification of respondents' declarations contributes to the reproducibility of the results.

4.5.3 Strengths of the Study

The main strength of this study is its comprehensive and system-based approach which explores the capabilities of the health system to respond to the challenges related to a host of relevant medicines-related problems, including ADRs, medication errors, product quality and treatment failure. To our knowledge, this is the first study of its kind in francophone Africa.

5 Conclusion

The study assessed the organizational patterns of Burkina Faso's public health system regarding several medicine-related challenges. The NDA, the leading pharmacovigilance institution in the country, had the basic pharmacovigilance resources in place and displayed encouraging endeavours in risk management and communication. Nonetheless, the study uncovered some gaps, mainly related to the lack of pharmacovigilance-specific regulations and guidelines and to the insufficient coordination of stakeholders. PHPs and hospitals need to formalize pharmacovigilance and consider it as essential for the quality of healthcare. We hope that the feedback sent to stakeholders (particularly the NDA) at the conclusion of the study will inform the design and implementation of pertinent activities to advance pharmacovigilance in the country. These could include developing pharmacovigilance legislation, improving the coordination of stakeholders countrywide and addressing the problem of underreporting of medicine-related problems by healthcare professionals. This evaluative approach of utilizing a standard metric tool can be replicated in similar resource-limited settings.

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