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RESEARCH ARTICLE

Stakeholder perspectives on the need for professional education and competence in pharmacovigilance in Zambia: A cross-sectional survey

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Abstract

Background: Knowledge and skills in pharmacovigilance (PV) are required to mitigate adverse events associated with medicine use which are among the leading causes of morbidity, mortality, and healthcare costs. This study explored the local perspectives and needs for PV education in Zambia. **Methods:** A mixed-methods study utilising a descriptive cross-sectional survey with an embedded desk review was conducted from November 2021 to December 2022 in Zambia. The quantitative survey used a self-administered questionnaire distributed to 150 participants drawn from key stakeholder groups identified. Qualitative information was extracted from the respective university websites for the desk review. **Results:** Out of 150 targeted participants, 144 (96%) responded to the survey. The majority (92.4%) affirmed the need for formal PV education programmes locally. Most (95.8%) perceived that training professionals in PV would add value to strengthening the health system. Furthermore, 45.1% preferred a postgraduate diploma and a master's degree in PV. About half (48.6%) preferred an interprofessional training approach. Only 6/1207 (0.5%) of the universities in Sub-Saharan Africa offered PV education programmes. **Conclusion:** This study underscored the pertinent need for formal PV education programmes and identified the type of education, expected competencies, and suggested educational strategies to guide curriculum development. These findings serve as a starting point for developing programmes to consolidate PV practice in Zambia and beyond.

Introduction

Pharmacovigilance (PV) is the science of detecting, assessing, understanding, and preventing adverse effects or other possible drug-related problems. Its scope extends beyond conventional medicines, encompassing herbal, traditional, and complementary remedies, blood products, biologicals, medical devices, and vaccines (WHO, 2021). Low- and middle-income countries (LMICs), especially in Sub-Saharan Africa (SSA), continue to grapple with challenges such as substandard and falsified medicines, medication errors, loss of efficacy (including antimicrobial resistance), and the abuse or misuse of prescription-only medicines due to self-medication, leading to drug-related morbidity and mortality (Chabelenge *et al.,* 2022; Saleem *et al.,* 2022; Mengesha *et al.,* 2024). Despite these challenges, PV activities in Africa are hindered by the scarcity of well-trained personnel and the lack of adequate budgetary support from national governments (Kiguba *et al.,* 2023).

The rising burden of diseases, including emerging pandemics like COVID-19, has led to increased demand, use, and cost of medicines (Ogunleye *et al.,* 2020; Godman *et al.,* 2021), giving impetus and relevance to create, implement, and capacity-build robust PV systems locally and across countries. Inadequate PV systems and practices can have severe consequences for populations. Firstly, Africa bears the highest burden of communicable diseases, including HIV/AIDS, malaria, tuberculosis, and acute respiratory diseases (Dwyer-Lindgren *et al.,* 2019; Nkengasong & Tessema, 2020; Bell & Schultz Hansen, 2021), leading to a considerable increase in medicine consumption, with high rates of self-medication (Belachew *et al.,* 2021; Yeika *et al.,* 2021; Guma *et al.,* 2022; Saleem *et al.,* 2022), and heightened the risks of adverse events. Secondly, the high rates of inappropriate use of medicines have resulted in SSA having the greatest burden of adverse drug reactions (ADRs), including treatment failure and considerable cost implications (Hofer, 2019; Murray *et al.,* 2022; Sulis *et al.,* 2022).

A lack of training has long been recognised as a barrier to effective PV practice across SSA (Terblanche *et al.,* 2017; Prashar & Musoke, 2019; Masuka & Khoza, 2020). This gap needs to be addressed going forward, given the current number of unreported and undetected ADRs that risk further harming patients (Olsson *et al.,* 2015; Al Meslamani, 2023). The low reporting of ADRs across most of SSA is unsurprising and a cause for concern (Ampadu *et al.,* 2016; Terblanche *et al.,* 2017; Haines *et al.,* 2020; Sefah *et al.,* 2021; Mahmoud *et al.,* 2023). However, in South Africa, pharmacist-led interventions coupled with enhanced regulatory enforcement are starting to address this issue proactively (Terblanche *et al.,* 2018).

While Zambia has an established national PV system with regulatory structures and tools to monitor medicine safety (ZAMRA, 2023), it lacks adequately trained human resources capacity at health service delivery points (Prashar & Musoke, 2019; Banda *et al.,* 2022). Existing evidence suggests gaps in PV knowledge and competence, hindering the ability to ensure medicine safety and sustain continuous monitoring through multidisciplinary and multi-stakeholder communities of practice within the healthcare system. Well-trained, collaborative communities of PV practice are required to jointly participate, anticipate, understand, and respond to the ever-increasing demands and expectations of maintaining public health and safety arising from medicine use (Al-Worafi, 2020; WHO, 2021). Well-trained, collaborative communities of PV are currently lacking in Zambia.

These gaps require, among other pivotal interventions, the development of an adequate human resources capacity across the medicine use value chain to detect medicine safety and quality concerns in the country (Isah *et al.,* 2012). Such interventions are especially crucial across SSA, which is faced with an increase in substandard and falsified medicines targeting this market. There are currently reports of substandard medicines and medical devices that necessitate regulatory action and recalls, especially in the public healthcare sector in Zambia (Chabalenge *et al.,* 2022). Following the growing concerns about inadequate PV practice culture due to professionals lacking training in this field, the main objective of this study was to explore local stakeholder perspectives on whether formal education in PV is needed to address the current knowledge and skills gaps in Zambia.

Specifically, this study aimed to (i) determine the local situation and need for PV education and training programmes; (ii) determine the type and level of education and competency requirements needed for effective PV practice; (iii) identify the educational strategies critical to the success of PV education; and (iv) compare and benchmark formal PV education programmes offered in other SSA countries.

Methods

Design and setting

This study adopted a mixed-methods design involving a descriptive cross-sectional survey and an embedded desk review. It was conducted in Zambia between November 2021 and December 2022.

Participants

Participants were purposively drawn from local stakeholder groups identified as being involved in or interfacing with PV practices across the medicine use value chain in Zambia. Only representatives of stakeholder groups relevant to PV were included in the study.

Participants were formally invited to participate in the survey without preferences based on gender, ethnicity, or race. Age was not a criterion for selection, as the aim was to adequately cover as many relevant stakeholder groups as possible, and the age range could vary significantly across groups. Participants were only recruited after providing written informed consent.

Variables

The outcome variables of interest included the stakeholders' perspectives on the need for PV education programmes, the preferred type of programmes, educational strategies for programme delivery, and expected competencies in PV.

Participants' demographic characteristics were collected as independent variables. For the desk review, variables of interest included the number of universities in SSA offering PV education programmes, the types of PV programmes, and their content coverage.

Data sources and measurements

For the survey, a self-administered questionnaire (Appendix A) was the primary data collection tool. The questionnaire was adapted with permission and minor modifications from similar unpublished works, following best practices for adapting data collection tools (Gehlbach et al., 2010). The questionnaire incorporated constructs for assessing training needs. Specifically, it consisted of sections with closed-ended questions that evaluated perspectives on the local situation and need for PV education, including the type and level of education required. Another section included open-ended questions about the required competencies and educational strategies for delivering PV education.

A desk review of internet resources was conducted to compare and benchmark PV education programmes currently offered by universities in SSA. The World Higher Education database (https://www.whed.net/home.php) was searched for universities in SSA countries as of July 2021. A total of 1207 public and private universities were isolated from the database, and those with an active website were searched online to check if they offered specific education programmes in PV. For universities offering programmes of interest, the data recorded included the name of the programme, the university offering it, the mode of delivery, duration, and content coverage.

Bias

Where possible and pertinent, bias was minimised in the recruitment of potential participants in the survey. Since the population of relevant stakeholder groups was pre-defined (WHO, 2002) for the purpose and context relevant to the study, purposive non-probability sampling was utilised to select the participants who met the inclusion criteria. In general, comprehensive coverage of stakeholder groups and subgroups from both the public and private sectors was ensured. This condition was deemed essential to guarantee the inclusion of a comprehensive range of stakeholders in the survey.

Study size

Eight different stakeholder groups meeting the inclusion criteria were initially identified (Table I). A multistage objective sampling approach aimed at maximising response rates and participant adherence to the survey was then employed to allocate the target number of respondents per stakeholder group. The specific number of respondents targeted per stakeholder group was based on attainable population density rather than a probabilistic sample size. This approach was chosen because the objective was to obtain diverse perspectives from different subgroups within each stakeholder category.

Overall, the target sample size for the survey was 150 participants, with an expected overall response rate of at least 90%.

Table I: Identified local stakeholder groups and target number of participants, n=150

Sn	Stakeholder group	Inclusion criteria	Subgroups	Target number of participants
1	Healthcare Professionals (HCPs)	HCPs practicing in the public and private health service sectors in Zambia	Pharmacists (n = 10); Medical Doctors (n = 10); Nurses (n = 10); Biomedical Scientists (n = 10); Paramedical staff (n = 10)	50
2	Health Professions' Students	Students enrolled and undertaking bachelor degree level training in health professions programmes at universities in Zambia	First Year (n = 10); Second Year (n = 10); Third Year (n = 10); Fourth Year (n = 10)	40
3	Educators in Higher Learning Institutions (HLI)	Educators involved in health training programmes offered both by the public and private HLI in Zambia	Educators in Public HLI (n = 15); Educators in Private HLI (n = 15)	30
4	Healthcare Managers	Managers of hospitals and community pharmacy establishments in Zambia	Hospital Managers (n = 5); Community Pharmacy Managers (n = 5)	10
5	Pharmaceutical Manufacturing Industry	Pharmaceutical personnel in local pharmaceutical manufacturing companies with medicine products in Zambia	Company 1 (n = 2) Company 2 (n = 2) Company 3 (n = 2)	6

Sn	Stakeholder group	Inclusion criteria	Subgroups	Target number of participants
6	Medicine Regulatory Agency	Officials from medicines regulatory agency conducting PV activities in Zambia	PV Officers (n = 5)	5
7	Professional Associations	Representatives of professional bodies or associations with vested interest in pharmacovigilance and medicine utilisation in Zambia	Association Executive Members (n = 5)	5
8	National level governance institutions responsible for health services	Officials representing health system governance institutions including the Ministry of Health (MOH) Headquarters and the Zambia National Public Health Institute (ZNPHI), respectively	MOH-HQ Officials/Technocrats (n = 2); Specialists at ZNPHI (n = 2)	4

With the aid of two research assistants, a total of 150 questionnaires were then distributed to potential participants across the subgroups identified (Table I). The principles of maximising survey response rates were applied (Hohwü *et al.,* 2013). Subsequently, participants were allowed to select their preferred mode of responding to the survey, that is, either via electronic or hardcopy versions. Recruited participants could choose either response mode but not both. A total of 83 participants opted to respond via hardcopy, while the rest responded using the electronic version administered online via Google Forms®.

All the data, whether collected electronically or via hardcopy, were collated, checked for completeness, and entered into a master sheet in Microsoft Excel® for statistical analysis.

Quantitative variables

A five-point Likert scale was used for unipolar responses and multiple-choice items assessing discrete variables of interest, consistent with similar studies (Kandasamy *et al.,* 2020; Altwaijry *et al.,* 2021; Mbonane *et al.,* 2023).

For open-ended responses, the questionnaire collected participants' input on the expected competencies and their suggestions for educational strategies to develop PV education programmes.

Statistical methods

Descriptive statistics, including frequencies and percentages, were used for analysis. Continuous variables such as age were presented as medians with interquartile ranges. Responses captured using the five-point Likert scale were summed and grouped in ordinally limited ranges, as such data defied parametric assumptions. Consequently, nonparametric measurements such as medians and interquartile ranges were applied to analyse the Likert scale data. Open-ended responses were grouped and thematically reported. Since the sample was not adequately powered, subgroup analysis and hypothesis testing for interactions were not conducted. Variables with some missing data were also reported. All statistical analyses were performed using Stata version 16.0 (Stata Corp., Texas, USA).

Results

Descriptive characteristics of the survey participants

Out of 150 targeted participants, 144 responded to the survey, yielding a response rate of 96%, with 80 (55.6%) male and 64 (44.4%) female participants. The median age was 33 years (IQR: 26, 39). A large proportion, 56 (38.9%), were pharmacists, and 52 (36.1%) were associated with the healthcare sector for more than ten years in Zambia. The majority, 126 (87.5%), had qualifications in a health-related field, and 75 (52.1%) had a bachelor's degree as their highest academic qualification. Half of the participants, 72 (50.0%), reported that they were currently serving in a healthcare-related industry (Table II).

Table II: Sociodemographic characteristics of the respondents, n=144

Variable	Level	Frequency, n (%)/ median (IQR)
Age (years)		33 (26, 39)
Sex	Female	64 (44.4)
	Male	80 (55.6)
Qualification in a health-related field	No	18 (12.5)
	Yes	126 (87.5)
Duration of association with	<1 year	11 (7.6)
	2-5 years	51 (35.4)
	6-10 years	30 (20.8)

Variable	Level	Frequency, n (%)/ median (IQR)
the healthcare sector in Zambia	>10 years	52 (36.1)
Professional background	Biomedical sciences	20 (13.9)
	Medicine	25 (17.4)
	Nursing	21 (14.6)
	Pharmacy	56 (38.9)
	Other[a]	17 (11.8)
	(Missing data)	5 (3.5)
Highest academic qualification	Bachelor degree	75 (52.1)
	Diploma	27 (18.8)
	High School certificate	11 (7.6)
	Other[b]	31 (21.5)
Capacity currently serving as primary duty in the healthcare industry	Educator	27 (18.8)
	Health sector administrator/official	21 (14.6)
	Health worker	72 (50.0)
	Student	24 (16.7)

IQR = interquartile range, [a] Other = engineering, natural sciences, physiotherapy, public health, veterinary medicine, [b]Other = Masters, PhD, postgraduate diploma)

Situation analysis and need for Pharmacovigilance education programmes

Table III presents the results of the situational analysis. The majority of participants, 96 (59.0%), reported an average and good level of understanding of PV. Nearly all participants, 133 (92.4%) and 137 (95.8%), confirmed the pressing need for PV education programmes and the relevance and added value of PV in the health sector in Zambia, respectively. Additionally, 68 (47.2%) participants strongly agreed that offering formal PV education programmes would help address the skill gaps in the sector. Almost all participants (96.5%) supported introducing a new specialised PV training programme at local universities.

Table III: Contextual situation and need for pharmacovigilance education programmes

Statement	Level	Frequency, n (%)
Understanding of Pharmacovigilance	Very poor	4 (2.8)
	Poor	7 (4.9)
	Average	48 (33.3)
	Good	48 (33.3)
	Very good	37 (25.7)
Pharmacovigilance is a relevant field and adds value to the health sector	Yes	137 (95.8)
	No	2 (0.7)
	Not sure	5 (3.5)
There is a major need for formal Pharmacovigilance education programmes in Zambia	Yes	133 (92.4)
	No	4 (2.8)
	Not sure	7 (4.9)
Offering Pharmacovigilance education programmes would help address the knowledge and skills gaps in the sector	Strongly disagree	3 (2.1)
	Disagree	2 (1.4)
	Undecided	10 (6.9)
	Agree	61 (42.4)
	Strongly agree	68 (47.2)
Would you support introducing a new training programme in Pharmacovigilance at a local university?	No	5 (3.5)
	Yes	139 (96.5)

Type of education programmes and strategies for PV education in Zambia

A high proportion of participants, 65 (45.1%), indicated that both a postgraduate diploma (PGDip) and Master's degree is the type and level of educational qualification best suited for the needs of Zambia's PV sector (Table IV). Furthermore, 98 (68.1%) indicated that a programme consisting of a combination of coursework and experiential learning was the most preferred educational pathway. On the one hand, 61 (42.4%) participants suggested a one-year duration for a PGDip training programme, whereas 61 (44.9%) favoured a two-year master's degree programme, with 87 (60.4%) suggesting that it should consist of coursework and fieldwork educational exposures. Regarding learning methods, 62 (43.1%) participants indicated that full-time blended learning would be optimal, and 74 (51.4%) preferred a term exam to be run twice a year for assessment. Slightly below half, 67 (46.5%) participants preferred a curriculum oriented to specific core subjects in PV.

Table IV: Aspects of pharmacovigilance education strategies and programming attributes

Statement	Level	Frequency, n (%)
Type and level of Pharmacovigilance education needed in Zambia	PG Diploma level only	32 (22.2)
	Masters degree level only	29 (20.1)
	Both PG Diploma & Masters degree	65 (45.1)
	Other[a]	10 (6.9)
	(Missing data)	8 (5.6)
Type of educational programming best for Pharmacovigilance training	Taught by coursework with experiential learning component	98 (68.1)
	Taught by coursework with a dissertation component	34 (23.6)
	Taught by coursework only	5 (3.5)
	(Missing data)	7 (4.9)
Appropriate duration of specialist training programme in Pharmacovigilance	6 months	23 (16.0)
	12 months	62 (43.1)
	18 months	48 (33.3%)
	24 months	3 (2.0)
	(Missing data)	8 (5.6)
Mode of learning best suited for Pharmacovigilance education programme	Full-time, blended learning	62 (43.1)
	Full-time, in-person learning	30 (20.8)
	Full-time, virtual learning	5 (3.5)
	Open distance learning	20 (13.9)
	Part-time learning	10 (6.9)
	Block release (batch) learning	8 (5.6)
	(Missing data)	9 (6.3)
Assessment modality appropriate for Pharmacovigilance training programme	Annual examination (once a year)	21 (14.6)
	Competency exam (at end of each module)	41 (28.5)
	Semester exam (twice a year)	74 (51.4)
	(Missing data)	8 (5.6)
Curriculum orientation best suited for Pharmacovigilance training programme	Experiential (Practice-based)	50 (34.7)
	Specific core subjects (Discipline-based)	67 (46.5)
	Themes (Systems-based)	16 (11.1)
	Combination of all 3 above	1 (0.7)
	(Missing data)	10 (6.9)
Student enrolment strategy for Pharmacovigilance education programme	Inter-professional (multidisciplinary) programme	94 (65.3)
	Special programme (for specific cohorts)	6 (4.2)
	Specialist programme (for single profession)	27 (18.9)
	(Missing data)	17 (11.6)
Suitable class size for effective learning per intake of formal training in Pharmacovigilance	Less than 15 students	29 (20.1)
	16-30 students	69 (47.9)
	More than 30 students	28 (19.4)
	(Missing data)	18 (12.5)
Essential (must have) facilities to support formal learning of Pharmacovigilance	Electronic library with online resources	48 (33.3)
	Physical classroom & library with hard copy books	59 (41.0)
	Practicum/experiential learning sites	20 (13.9)
	(Missing data)	17 (11.8)

A high proportion, 70 (48.6%), preferred an interprofessional programme, and 69 (47.9%) viewed a class size of between 16 and 30 students as the most suitable enrolment strategy per intake. Regarding the necessary facilities required at a training institution offering PV education, 59 (41.0%) participants considered it essential to have physical classrooms and libraries with hardcopy reference materials.

Emerging themes of the expected competencies in PV

From the open-ended responses, most participants suggested cognitive and skill competencies for PV graduates. These included the ability to "*demonstrate advanced knowledge and understanding of PV concepts*" (suggested by 18 participants); "*skills to identify, assess, prevent, manage and report medicine-related problems*" (9 participants); "*analytical skills and strategies to monitor and assess medicine safety*" (9 participants); "*ability to communicate and transfer PV information*" (9 participants); and "*research skills*" (8 participants).

Factors mainly highlighted as possible challenges to PV education programmes in Zambia were "*inadequate infrastructure and tools for teaching and learning*" (22 participants), "*inadequate qualified and experienced lecturers*" (17 participants), and a "*general lack of funding/sponsorship to support students to study at university*" (12 participants). Some participants, 21 (15.3%), suggested "*practical experiential learning*," including industrial placements, as beneficial for students to reach their potential (Table V).

Table V: Emerging themes from the participants' open-ended responses

Construct	Aligned theme from grouped responses	No. of Responses aligned to theme
Competencies a graduate who has undertaken Pharmacovigilance specialised training at the postgraduate level must have to meet the job requirements in the sector	*Advanced knowledge and understanding of PV concepts*	18
	Skills to identify, assess, prevent, manage and report medicine-related problems	9
	Analytical skills and strategies in monitoring and assessing medicine safety	9
	Communication and transfer PV information	9
	Develop systems and tailored PV programmes for industry	3
	Research and investigative skills	8
	Clinical PV skills	6
	Organise and manage PV systems and activities	4
	Apply good PV practice and attitude	4
	Teamwork	3
Potential challenges and opportunities for PV education in Zambia	*Inadequate infrastructure, tools for teaching & learning*	22
	General lack of appreciation of PV importance in health system	8
	Inadequate industrial/experiential learning sites	11
	Inadequate suitably qualified & experienced teachers	17
	Lack of funding/sponsorship	12
	Educational strategies & programming	13
	Few professionals & institutions offering training in PV	5
	Career progression	3
Best ways that PV training can enable the students and faculty reach their peak potential	*Practical training to include real industry experience*	21
	Interactive training	4
	Blend local and global best practices in medicines safety	2
	Collaboration with other institutions offering similar programs	10
	Research mentorship should be core part of training	6
	Good learning environment & lecturers	10
	Furthering professional development	3
	Sponsorship (scholarships)	4

Desk review of PV education programmes offered at universities in Sub-Saharan Africa

Out of the 1207 universities (both public and private) in SSA accessed from the World Higher Education database and whose websites were desk-reviewed, only 6 (0.5%) universities in 4 countries were found offering full-fledged PV education programmes, distributed as follows: 3 in South Africa, 1 in Kenya, 1 in Ghana, and 1 in Nigeria. Among these, only four universities offered specialised training programmes leading to postgraduate-level qualifications, while one offered a fellowship programme (Table VI). None of the reviewed universities offered a pre-graduate PV programme, with some only teaching topics on PV aspects within other programmes such as medicine and pharmacy. The programme duration ranged from 1 to 6 years, with delivery modes varying from full-time on-site, blended, online (e-learning), open-distance, and part-time learning modes. Table VI presents the outline of the curricula content of the various PV education programmes.

Table VI: Sub-Saharan African countries and universities offering PV education programmes, including content

Place/ Country	South Africa	South Africa	Kenya	South Africa	Ghana
Institution (Funding)	Stellenbosch University (Public)	North West University (Public)	University of Nairobi (Public)	University of Kwazulu-Natal (Public)	University of Ghana (Public)
Programme Title	Postgraduate Diploma in Pharmaceutical Medicine	Master of Pharmacy in Pharmacy Practice with Pharmacovigilance and Pharmacoepidemiology	Master of Pharmacy in Pharmacoepidemiology and Pharmacovigilance	Master of Health Sciences (with specialization in Pharmacovigilance and Bioethics)	Pharmacovigilance Fellowship Programme (by WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance, WHO-CC)
Programme Duration (Mode)	2 years (part-time)	1-2 years	2-4 years (full-time); 3-6 years (part-time)	2 years	Variable
Mode of study delivery	Onsite (in-person learning)	Onsite (in-person learning)	Open distance-learning (ODL) or face-to-face and blended learning	Online (e-learning)	Blended (partly in-person, online and practical experience, including project work)
Curriculum content	Module I: Introduction to Pharmaceutical Medicine - Drug Discovery - Principles of Clinical Pharmacology Module II: Non-clinical Development of Medicines - Pharmaceutical Development - Non-clinical Safety Pharmacology and Toxicology - Ethical and Regulatory Issues Module III: Clinical Development of Medicines - Clinical Development of Medicines - Biometrics, Epidemiology and Data Management Module IV: Pharmacovigilance, Marketing, Economics of Health Care - Safety of Medicines; Pharmaceutical Marketing; Economics of Health Care	-Research methodology, biostatistics and evidence-based practice for healthcare professionals -Adverse drug reactions and drug related problems -Advanced drug utilization review and Pharmacoepidemiology -Pharmacovigilance -Dissertation	-Health and pharmaceutical policy -Clinical chemistry -Medication safety -Advanced biostatistics -Advanced Pharmacoepidemiology -Research methodology and biostatistics -Regulatory pharmacovigilance -Evidence based healthcare and implementation science research -Therapeutic risk management -Health supply chain and marketing management -Pharmacoeconomics -Principles of pharmacoepidemiology -Clinical toxicology -Principles of pharmacovigilance and risk communication -Research project	-Basic epidemiology -Introduction to biostatistical concepts -Research methods and design -Evidence based practice -Pharmacovigilance -Bioethics -Research project	- Training: Fellows typically receive training on various aspects of pharmacovigilance, including reporting ADR, signal detection, data analysis, regulatory requirements, and risk management. - Practical experience: Fellows may have the opportunity to participate in real-world PV activities, such as monitoring and assessment of ADRs. - Research: Fellows conduct research on topics related to PV. - Workshops and Seminars: Fellows may participate in workshops, seminars, and conferences related to pharmacovigilance to improve their knowledge and network with experts in the field.

Discussion

This study explored the need for professional education in PV and the competency requirements expected of PV graduates from the perspective of local stakeholders in Zambia. It specifically determined the preferred level of formal training and included suggested strategies for the successful development and implementation of PV education programmes locally. Lastly, the study also explored other formal PV education programmes offered by universities in SSA countries.

Need for PV education programmes

The questionnaire-based survey revealed that nearly all stakeholder groups (96%) perceived formal education programmes in PV to be of high importance for adding value to Zambia's health sector. A similar proportion supported introducing specialist training programmes in PV at local universities, as this would positively address current skills gaps in the sector and enhance the field's importance to public health. Existing evidence in Zambia (Prashar & Musoke, 2014; Prashar *et al.,* 2019; Banda *et al.,* 2022) and the SSA region (Terblanche *et al.,* 2017) indicates that PV practice in both the public and private healthcare sectors is relatively low and inadequate for such a crucial field. This is compounded by the lack of PV education and capacity-building programmes in SSA, among other factors. This study builds on previous findings showing that the levels of PV knowledge and practice among healthcare professionals in Zambia were relatively inadequate, negatively impacting ADR reporting rates (Prashar *et al.,* 2019). Additionally, the study's findings corroborate prior evidence about lessons learnt from introducing PV activities in SSA (Stegmann *et al.,* 2022). Given the increasing need to strengthen healthcare systems and improve patient management, Zambia's healthcare system would benefit from investing in human capital development in the scientific field of PV through formal education programmes.

None of the universities in SSA reviewed in this study offered a fully-fledged pre-graduate programme leading to a professional qualification in PV. The few universities offering PV education provide training at the postgraduate level. The authors were aware that some aspects of PV are taught in some undergraduate education programmes, often as components or topics within medical and pharmacy curricula (Smith & Webley, 2013; Arici *et al.,* 2015; Pires, 2021), and in the form of in-service training workshops for healthcare professionals in some countries (Shrestha *et al.,* 2020), including Zambia. Evidence shows that the content and focus of most of these educational interventions are often not standardised and vary in depth and duration, leading to fragmented and insufficient competence development for contemporary PV practice and industry needs. Undergraduate PV teaching interventions have ranged from short 15-minute PowerPoint lectures and training workshops offered to medical or pharmacy students to more innovative clinical experiences in ADR reporting or assessment (Reumerman *et al.,* 2018). Although these interventions improve short-term knowledge (Arici *et al.,* 2015) and attitudes towards PV (Shrestha *et al.,* 2020), the knowledge gained is often insufficient (Smith & Webley, 2013; Abubakar & Haque, 2016; Reumerman *et al.,* 2018). In this study, the majority of respondents indicated that a PV education programme with a minimum duration of 12 months could be adequate to instil long-term knowledge, skills, and attitudes for PV practice.

In agreement with previous concerns about PV activities in developing countries, the lack of mainstream PV education at both the undergraduate (pre-service) and postgraduate (in-service) levels has been a primary barrier to introducing and improving robust PV systems across Africa (Elshafie *et al.,* 2018). This issue must be addressed, especially given the growing trend of increased use of unconventional (traditional) and herbal medicines in most parts of Africa, including Zambia. Most of these medications are not quality-assured and medically prescribed, posing a risk to the safety of consumers, including those with COVID-19 (Silveira *et al.,* 2020; Khanna *et al.,* 2021). Suitably qualified PV specialists and responsible officers are thus necessary to generate medicine safety information for decision-making, including the operation of robust PV systems at the institutional level, ensuring that medicine safety measures are mainstreamed across all healthcare sectors. The lessons learnt from a healthcare professional (HCP) training and mentoring programme in health facilities in Malawi, Côte d'Ivoire, and the Democratic Republic of Congo suggested that country-owned training programmes and capacity-building initiatives can sustain PV systems and build a stronger safety and use culture in the SSA region (Stegmann *et al.,* 2022), aligning with the findings from the present study and providing guidance for key stakeholder groups in Zambia and beyond. The present study has identified from stakeholders the type of qualification level and the potential content areas that can be streamlined into a standard curriculum for training PV specialists at the postgraduate level in Zambia.

Competence requirements for PV practice

Regarding the expected key competencies of trained PV specialists, this study found that graduates would be expected to demonstrate advanced knowledge and understanding of PV concepts and be able to conduct scientific research using investigative skills, including drug utilisation techniques and principles. Additionally, they should demonstrate the skills to identify, assess, prevent, manage, and report medication-related problems, using analytical skills and strategies to monitor and assess medication safety concerns in communities. PV graduates should also be able to communicate and transfer PV information effectively. Instilling these competencies would require effective educational strategies that maximise practical and problem-based learning, including clinical and experiential learning. Given these points, the authors agree with previous findings that the competence to handle ADRs in clinical practice is essential for the safety of patients in clinical care and for monitoring medication safety at the population level (van Eekeren *et al.,* 2018). Based on the findings from this study, it is advocated that specialist training in PV should advance the primary content and learning outcomes contained in the World Health Organisation PV core curriculum (Beckmann *et al.,* 2014; van Eekeren *et al.,* 2018). Core activities include a greater understanding of the importance of PV in the context of pharmacotherapy, preventing ADRs when possible, recognising ADRs when they occur, and managing and reporting them to relevant authorities (van Eekeren *et al.,* 2018).

The findings from this study suggest the emergence of another notable competence area where PV education programmes must adequately address Good Clinical Practice-compliant clinical trials. With the emergence of infectious diseases of pandemic proportion and the introduction of more Investigational New Drugs (INDs) and vaccines, clinical trials in Africa are anticipated to continue increasing. Regulatory authorities and ethics committees are struggling with inadequate local expertise to critically evaluate clinical trial protocols for safety concerns, further strengthening the need for appropriately trained PV personnel and sufficient resources to monitor drug safety issues and prompt regulatory actions to safeguard public health. Additionally, regulators and PV scientists must partner with industry groups to pool their respective skillsets and collaborate to further develop appropriate expectations and systems for medication safety, including herbal medicines, whose use is on the rise in Africa amidst limited safety data (Rasmussen, 2022).

Educational strategies and types of PV training programmes required

With a high proportion of the stakeholders surveyed preferring a postgraduate diploma or a master's degree qualification in PV as being the best-suited types and education levels needed in Zambia, these standard qualifications are at levels 8 and 9 of the Zambia Qualifications Framework (ZAQA, 2016), similar to other countries in the region (SAQA, 2017). Moreover, the majority of the respondents preferred a core subject-based education programme taught through coursework with an experiential learning component. In terms of delivery mode, this study found that blended full-time learning with term assessment points was the most preferred. These findings align with existing evidence that blended learning, which combines in-person learning and e-learning, has expanded rapidly to be commonly used in education (Vallée *et al.,* 2020), whether in Africa or elsewhere, as a result of the COVID-19 pandemic and its implications (Etando *et al.,* 2021).

Evidence from systematic reviews and meta-analyses indicates that, compared with traditional learning, blended approaches consistently improve knowledge outcomes in health science education (Li *et al.,* 2019; Rasheed *et al.,* 2020; Vallée *et al.,* 2020). The finding that the majority (55%) of stakeholders preferred an interprofessional learning programme is encouraging, corroborating the evidence that interprofessional education is effective in providing better quality healthcare outcomes compared to those delivered by single health disciplines while creating an atmosphere of mutual respect and value for other professions (Musenge et al., 2022). Hence, implementing an interprofessional learning model for PV training has the potential to produce beneficial results and build a community of practice that will improve and advance this vital field in the future (Walker *et al.,* 2019).

Studies have shown that developing capacity and performing effective PV can be particularly challenging in low-resource settings, especially in SSA, due to the lack of infrastructure, weak regulatory systems, and limited access to education opportunities (Walker *et al.,* 2019). Similarly, this study also found that Zambian stakeholders underscored the need for investments in adequate infrastructure for teaching and learning and suitable experiential learning sites for clinical and scientific skills-based learning for successful PV education in Zambia. These needs include having a pool of suitably qualified and experienced lecturers, as well as funding (sponsorship) for students to successfully undertake PV education programmes offered at local universities. When these core elements are in place, any university in the SSA region can successfully provide quality PV education programmes.

The desk review findings show that very few countries and universities in SSA currently offer specific PV education and specialist training programmes. These findings underscore the urgent need for scaling up PV education across Africa and provide insights for guiding future curriculum development in this critical field.

Notably, the educational strategies identified by the survey findings could serve as a starting point to further develop and consolidate the PV culture in Zambia and beyond. The authors plan to follow this line of inquiry in future studies.

Limitations

This study has some limitations. First, the participants in the survey were purposively selected from the identified relevant local stakeholder groups based on the WHO guidance list of PV stakeholders (WHO, 2002). In addition, the inclusion of local stakeholder groups was further based on their experience and familiarity with PV aspects at either policy, regulatory, professional, academic, or other related support system levels in Zambia. As such, this study strived to maximise coverage and minimise bias in the selection process. Consequently, a probabilistic method of sample size determination was not used because the majority of identified stakeholder groups did not have robust population sizes to draw a random sample. Notwithstanding this, the goal of sampling a specific number of participants per stakeholder group in this study was to obtain a range of perspectives from the different subgroups of respondents to provide future direction.

Second, the survey questionnaire relied on a self-reported rating of the participants' understanding of PV. The data collection tool did not measure knowledge but instead used modified questions, asking participants to rate their understanding of PV on a rating scale in an effort to neutralise and control social desirability bias. Additionally, possible associations between exposure and outcome variables were not measured in this study, preventing the derivation of causal inferences.

Lastly, this study did not use a detailed desk review protocol because, in this case, desk review aimed to benchmark PV education programmes offered in SSA and thus only considered reviewing the qualitative information that universities published on their websites.

Overall interpretation and potential contribution to pharmaceutical workforce development

With the increasing role of new medicines, vaccines, and biosimilars in contemporary healthcare, particularly for managing chronic diseases in genetically diverse populations, African countries need to strengthen their regulatory systems by developing the workforce capacity in specialised areas such as PV to better monitor the safety and quality of pharmaceutical products used in public health programmes (Godman *et al.,* 2021). A suitably trained PV workforce is crucial for supporting regulatory authorities, ministries of health, and the public in making informed decisions about medicines. It can also develop pharmacoepidemiology systems to improve medication safety reporting and communication (Sabaté & Montané, 2023).

In public health emergencies and situations requiring immediate, rapid, and effective interventions, PV is crucial for facilitating adequate access, risk communication, and supervision of medicines, including vaccines (Saint-Raymond *et al.,* 2022). This role encompasses responding promptly to potential and future public health emergencies, not merely epidemics and pandemics. The recent spread of misinformation regarding COVID-19 treatments and vaccines highlights the importance of trained pharmacists and other healthcare professionals in counteracting false information (Erku *et al.,* 2021; Calac *et al.,* 2022; Ogunleye *et al.,* 2022; Schellack *et al.,* 2022). Consequently, there are considerable opportunities currently for more universities across SSA to develop and offer competency-based and needs-based PV education programmes. The authors will continue to monitor the situation closely.

Generalisability

Notwithstanding the limitations, the findings from this study are generalisable and provide current and future directions to all key stakeholder groups in Zambia and beyond to address this increasingly important area of pharmaceutical workforce development.

Conclusion

The findings from this study underscore the need for introducing formal PV education programmes locally to address current skill gaps in the sector and subsequently improve medication safety in future. With no formal PV education programmes currently offered locally and too few universities in SSA providing such training, there is an opportunity to develop an interprofessional PV education programme at the postgraduate level to train PV specialists locally. The educational strategies highlighted in this study call for the development of PV education to further consolidate the PV practice and culture and improve medicine safety in Zambia and beyond.

Conflict of interest

The authors declare no conflict of interest.

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Ethics approval and informed consent

This study protocol was approved by the University of Zambia Health Science Research Ethics Committee (IRB no. 00011000, IORG no. 0009227) with approval ID number 202212030189. Written informed consent was obtained from all participants prior to their participation in the study. We ensured confidentiality of all data collected.

Authors' contributions

ACK and MB: conceptualisation, design, methodology; MB: data collection; MM: Data curation and analysis; MC, SM, SSB, JS, AH, and BBG: Manuscript writing and internal review – original and final draft. All authors reviewed and approved the final draft for publication.

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Appendix A: Pharmacovigilance education needs assessment in Zambia key informant questionnaire

PHARMACOVIGILANCE EDUCATION NEEDS ASSESSMENT IN ZAMBIA

KEY INFORMANT QUESTIONNAIRE

General Questionnaire Particulars

1.1: Province:

1.2 Institution:

1.3 Stakeholder Type:

1.4 Date: DD MM YYYY

No.	Question	Response	Code
SECTION 1: Demographic Data			
Q.1.1	Gender	Male ………. Female ……..	1 2
Q.1.2	How old are you?	………. years old	
Q1.3	How long have you been associated with the health sector in Zambia?	Less than 1 yr …….. 2 – 5 yrs …… 6 – 10 yrs …… More than 10 yrs …..	1 2 3 4
Q.1.4	Which sector of the health industry are you currently engaged or based as your primary duty?	Health worker …….. Health service administrator/manager … Educator/Trainer … Training Institution/programme administrator/manager …. Statutory/Non-statutory institution/system manager …… Professional association …….. Student ….. Other ………	1 2 3 4 5 6 7 8
Q.1.5	Do you have an academic qualification in a health-related field?	Yes …… No ……. → *SKIP TO Q.1.7*	1 2
Q.1.6	What is your professional background?	Pharmacy Medicine Nursing Biomedical Sciences Physiotherapy Public Health Veterinary Medicine Social Sciences Engineering Natural Sciences Law Education Other: (Specify) ………….	1 2 3 4 5 6 7 8 9 10 11 12 13
Q.1.7	What highest level of academic qualification have you attained?	PhD Degree ……… Masters Degree …….. Postgraduate Diploma ……. Bachelor Degree ……. Diploma Certificate ……..	1 2 3 4 5

		Professional Qualifications (memberships/fellowship) ……… Grade 12 certificate …… Other: (Specify) ……	6 7 8 9

SECTION 2: Situational Analysis This section addresses whether there is a need for the programme of interest and the contextual situation			
Q.2.1	How would you rate your level of understanding of Pharmacovigilance?	Very Poor Poor Average Good Very Good	1 2 3 4 5
Q.2.2	Do you think education and training in Pharmacovigilance is relevant and adds value to the health sector in Zambia?	Yes No Not sure	1 2 3
Q.2.3	How would you respond to the following statement: "There is a Major need for Pharmacovigilance education and training programmes in Zambia"	Yes No Not Sure	1 2 3
Q.2.4	How would you respond to the following statement: "Offering specialized training programmes in Pharmacovigilance at local universities would help address the skills gaps in the sector."	Strongly Disagree Disagree Undecided Agree Strongly Agree	1 2 3 4 5
Q.2.5	Would you support the introduction of a new specialized education programme in Pharmacovigilance at a local university in Zambia?	Yes No	1 2
SECTION 3: Educational Strategies of the Training Programme This section requests your responses to aspects of the education strategies and programming attributes.			
Q.3.1	List the competencies (behavioural attributes) a graduate in Pharmacovigilance must demonstrate which would make them meet the job requirements in the sector? (Categorise as Knowledge, Skills, and Attitudes)	1. ……… 2. ……… 3. ……… 4. ………	
Q.3.2	Given a choice to choose, which type of qualification level is best for the training needs in Pharmacovigilance education in Zambia?	Undergraduate diploma (Dip.) … Bachelor degree (BSc.) … Postgraduate Diploma (PGDip.) … Masters (MSc.) … Both PGDip & MSc … PhD … Other: (Specify) ………….	1 2 3 4 5 6 7
Q.3.3	Which type of educational programming do you think is best for a specialised training programme in Pharmacovigilance?	Taught coursework only … Taught coursework with practical/field placement component … Taught coursework with an extended essay/research project component … Research only … Other (specify): ……………………	1 2 3 4 5
Q.3.4	What duration of educational programming do you think would be appropriate for a specialised training programme in Pharmacovigilance?	6 months (0.5 year) 12 months (1 year) 18 months (1.6 years) 24 months (2 years) 36 months (3 years) Other: (Specify) ………..	1 2 3 4 5 6
Q.3.5	Which type of educational delivery method do you consider best for a specialised training programme in Pharmacovigilance?	Full-time in-person (classroom-based), residential learning … Full-time virtual real-time e-learning … Full-time blended (in-person & e-learning) real-time learning …	1 2 3 4 5

		Open distance learning, self-paced, non-residential … Back-to-back batch scheduled learning for working professionals … Part-time learning, taking subject sets at a time … Other: (specify) …………	6 7
Q.3.6	Which type of assessment modality do you think is appropriate for a specialised training programme in Pharmacovigilance?	Semester examinations (Twice a year exams at the end of each semester) … Annual examinations (once a year exams at the end of the academic year) … Competency examinations (At the end of each phase/theme of the curriculum) … Other: (Specify) ………	1 2 3 4
Q.3.7	What kind of curriculum orientation would be best suited for a specialised training programme in Pharmacovigilance?	Specific core subjects (Discipline-based) curriculum … Thematic (systems-based) curriculum … Experiential (practice-based) curriculum … Other: (specify) …………………	1 2 3 4
Q.3.9	What potential challenges would a local training programme in Pharmacovigilance face with regards to educational strategies? 1…………………………………………………………………………………………… 2…………………………………………………………………………………………… 3……………………………………………………………………………………………		
Q.3.10	Suggest ways for improving the general educational programming of a specialised training programme in Pharmacovigilance in Zambia? 1…………………………………………………………………………………………… 2…………………………………………………………………………………………… 3……………………………………………………………………………………………		
SECTION 4: Student Affairs This section addresses aspects of students' affairs on the proposed programme			
Q.4.1	Which enrolment strategy would be best for a specialised training programme in Pharmacovigilance?	A specialised programme enrolling students from one health profession (e.g. pharmacists only) … An interprofessional programme enrolling students from multiple health professions/fields … A multidisciplinary programme enrolling students from across the value chain … A special programme enrolling students from particular/specific sector … Other: (Specify) ……………………………	1 2 3 4 5 6
Q.4.2	What would you consider a suitable for effective learning class size per intake for a specialised training programme in Pharmacovigilance?	Not more than 15 students per intake … 16 to 30 students per intake … More than 30 students per intake … Other: (Specify) ……………………………	1 2 3
Q.4.3	Select the items that you would consider essential (must have) facilities/infrastructure for a specialised training programme in Pharmacovigilance?	1. Physical library with hard copy books. 2. Electronic library available to all students. 3. Practicum or experiential learning sites for field-based learning and placements. 4. Computer laboratory. 5. Interactive web-based learning management system 6. Physical classroom/lecture rooms 7. Other (specify): ………………….	
Q.4.4	How best do you think a a specialised training programme in Pharmacovigilance can enable the students and faculty reach their peak potential? 1…………………………………………………………………………………………… 2……………………………………………………………………………………………		
Q.4.5	Suggest ways of improving student affairs on a specialised training programme in Pharmacovigilance in Zambia? 1…………………………………………………………………………………………… 2…………………………………………………………………………………………… 3……………………………………………………………………………………………		

Thank You for Your Participation.