



Evaluating Pharmaceutical Compounding Practices and Quality Management Gaps in Nigeria

John Alfa¹, Abraham Amlogu², Qazeem Abdulganiyu², & Ibrahim Lawal³

1. Faculty of Pharmaceutical Sciences Bingham University, Nigeria

2. State House Medical Center, Abuja, Nigeria

3. National Institute for Pharmaceutical Research and Development, Abuja, Nigeria

Abstract: In Nigeria, compounding practices have historically been confined mainly to hospital and institutional pharmacies and remain relatively under-documented despite their clinical significance. This study assessed the current practices, challenges, and future directions of pharmaceutical compounding in Nigeria, with the aim of identifying gaps in training, regulation, infrastructure and quality assurance that influence the safety and effectiveness of compounded medications. A descriptive cross-sectional mixed-methods design was employed. The quantitative component involved a structured questionnaire administered to registered pharmacists engaged in compounding activities, while the qualitative component consisted of Key Informant Interviews (KIIs) with experienced pharmacists from hospital, institutional, and regulatory settings. Quantitative data were analyzed using descriptive and inferential statistics in SPSS, while qualitative data were examined through thematic analysis to identify recurring professional and institutional themes. Integration of both datasets enabled triangulation and a comprehensive interpretation of findings. A total of 69 valid survey responses were analyzed. Results indicated that most pharmacists possessed at least a Bachelor of Pharmacy or Pharm. D qualification and reported moderate to high familiarity with compounding practices. However, only about one-third had received formal or specialized compounding training beyond undergraduate education. Non-sterile compounding—such as oral suspensions, creams, and capsules—was the predominant practice, with sterile compounding performed by fewer than 10% of respondents due to inadequate facilities. Key challenges identified included limited access to quality raw materials, insufficient infrastructure, regulatory ambiguity, and the absence of standardized operating procedures and validated stability data. Qualitative findings further highlighted reliance on informal learning, gaps in regulatory enforcement, and concerns regarding quality assurance and patient safety. Overall, the study demonstrates that while pharmaceutical compounding remains an essential component of healthcare delivery in Nigeria, systemic limitations hinder its optimal practice. Strengthening regulatory frameworks, expanding professional training, improving infrastructure, and developing national compounding guidelines are essential to enhance quality, safety, and sustainability in pharmaceutical compounding practice

INTRODUCTION

Background to the Study

Pharmaceutical compounding is the process of customized drug preparation by combining, blending, or reformulating ingredients to fit unique patient requirements like dosage strength, form, or the exclusion of certain chemicals (53). Compounding is the basic professional responsibility of the pharmacist, (6). The global renaissance in the movement toward personalized medicines and the growing scarcity in medicines placed renewed

emphasis on the role of compounding in contemporary pharmaceutical therapy (53). In Nigeria, compounding is a historically developed but poorly chronicled activity that is limited essentially to institutional and hospital pharmacies (5, 36). Though it has pharmaceutical relevance, compounding in Nigeria is fraught with some perennial setbacks. Literature presents limited infrastructure, which lacks quality assurance measures, established stability data and limited continuing professional development among the major challenges towards effective and safe compounding (5, 53). Other situational constraints entail unavailability of the national compounding formulary and inadequate regulatory oversight.

Statement of the Problem

Pharmaceutical compounding is an essential in pharmacy practice however, in Nigeria it faces challenges such as lack of standard operating procedures (SOPs) in most facilities, centralized documentations, validated stability data for compounded products (5), scarce availability of the right infrastructure in the form of cleanrooms, laminar-flow cabinets, and accurate equipment impacts quality assurance (11), shortage in human resources, inadequate training, lack of continuing education, and minimal exposure to advanced compounding techniques (53), technical vulnerabilities like Poor weighing, wrong calculations, incompatibility of excipients, microbiological contamination (8). Ambiguity in regulation makes the situation worse: existing pharmaceuticals law and inspection regimes center on industrial manufacture with extemporaneous compounding in effect given scanty oversight by the Pharmacy Council of Nigeria (PCN) or the National Agency for Food and Drug Administration and Control (NAFDAC). These variables generate doubt on the quality, reliability, and safety of compounded drugs available in all the Nigerian centers of healthcare.

Aim and Objectives

1. To assess the current practices, challenges, and future directions of pharmaceutical compounding in Nigeria.
2. To characterize the prevailing patterns of pharmaceutical compounding in Nigerian pharmacy practice.
3. To examine the training background and competence of pharmacists involved in compounding.
4. To identify key operational, institutional, technical, regulatory challenges affecting compounding and explore opportunities for innovation, standardization, and capacity-building within compounding practice.
5. To propose evidence-based recommendations for policymakers, regulatory agencies, and training institutions.

Research Questions

1. What are the common types and patterns of pharmaceutical compounding currently practiced in Nigeria?

2. What level of training and professional competence do pharmacists possess regarding compounding procedures?
3. What operational, institutional, and regulatory barriers limit effective and standardized compounding?
4. What innovations and best practices can enhance the safety and sustainability of compounding in Nigeria?
5. How can identified gaps inform national guidelines, educational curricula, and policy reforms?

Significance of the Study

1. **Policy and Regulation:** The study could also facilitate the Pharmacy Council of Nigeria (PCN) and the NAFDAC in coming up with specific regulatory mechanisms, levels of inspection, and quality requirements for compounded drugs.
2. **Education and Training:** The study can permit curriculum alterations in pharmacy schools and the development of tailored continuing education programs for professional pharmacists through the identification of competency gaps.
3. **Professional Practice:** Exemplary practices and operational hindrances within the operational domain can facilitate internal quality-assurance frameworks enhancement for both practitioners and healthcare organizations.
4. **Patient Safety:** Increased compounding requirements reduce the risk of pharmaceutical mistakes, ensure therapy consistency, and achieve better treatment results in vulnerable patients.
5. **Academic Contribution:** The study fills the large research gap in the pharmaceutical practice papers in Nigeria and other low- and middle-income countries by generating a conceptual model for future empirical and interventional research.

Scope of the Study

The study focuses on registered pharmacists in Nigeria who engage in pharmaceutical compounding within hospital, institutional, or community settings. Emphasis is placed on non-sterile and extemporaneous compounding activities. Sterile compounding will be acknowledged but not examined in depth. The geographical scope spans selected regions representing Nigeria's major geopolitical zones, while the temporal focus covers current practices between 2023 and 2025. The study is observational and descriptive; it does not include laboratory stability testing of compounded preparations.

RESEARCH METHODOLOGY

Research Design

A descriptive cross-sectional mixed-methods design was adopted. This design enabled both numerical analysis of current compounding practices and contextual exploration of practitioners' experiences, attitudes, and institutional challenges. The quantitative phase

involved a structured questionnaire distributed to pharmacists, while the qualitative phase employed semi-structured interviews with key informants (KIs) such as hospital and institutional pharmacists. Mixed-method designs are particularly suited to studies exploring professional practices because they merge the generalisability of quantitative data with the depth of qualitative narratives (28, 46). This methodological complementarity ensured that findings from one method could confirm, expand, or contrast with those of the other, thereby increasing the robustness and trustworthiness of the conclusions.

Table 1: Research Design Framework

Phase	Approach	Data Collection method	Purpose	Output/Analysis
Phase 1	Quantitative	Structured Questionnaire	To assess pharmacists' knowledge, practices and challenges in compounding	Descriptive and inferential Analysis (SPSS, Excel)
Phase 2	Qualitative	Key Informants Interviews (KIs)	To gather deeper insights and triangulate quantitative findings	Thematic analysis (manual coding)
Integration	Mixed Analysis	Comparative Interpretation	To identify convergence, divergence and complementarity between datasets	Integrated discussion and policy recommendations

Study Area

The study was conducted in selected healthcare facilities and pharmacy institutions across Nigeria, with emphasis on regions demonstrating active or potential pharmaceutical compounding practice. Both hospital and institutional pharmacies were included to capture variation in infrastructure, regulatory exposure, and professional culture.

The State House Medical Centre, Aso Rock, Abuja, Nigeria; a tertiary-level facility providing specialized services, served as a key qualitative site, reflecting a model institutional environment. Other participating sites represented a mix of public and private healthcare facilities across major urban centers, aligning with the study's goal of obtaining a realistic picture of compounding practice nationwide (36).

Population of the Study

The population comprised registered pharmacists in Nigeria who engage in or supervise compounding activities. These included: Hospital pharmacists in tertiary and secondary institutions, Community pharmacists with extemporaneous formulation roles; and Institutional or regulatory pharmacists involved in quality assurance, formulation, or policy oversight. This population was appropriate because pharmacists are the principal custodians of pharmaceutical compounding knowledge, professional ethics, and quality assurance practices (8).

Sampling Technique and Sample Size Determination

A standardized sampling procedure was employed for the quantitative phase. Pharmacists were approached across institutional and community settings using a stratified approach that ensured representation across regions and practice categories.

However, due to a low response rate, the quantitative sample was smaller than initially projected. To mitigate this limitation, the study employed Key Informant Interviews (KIIs) a qualitative complement designed to triangulate, enrich, and validate the survey data. This adaptive design ensured methodological completeness despite logistical constraints (13).

Sample Size Determination

The target sample size for the quantitative survey was calculated using Cochran's formula (1977) for large populations:

$$n_0 = \frac{Z^2 p(1-p)}{e^2}$$

Where: n_0 = sample size, Z = z-value (1.96 at 95% confidence level), p = estimated proportion of attribute present in the population (assumed 0.5 for maximum variability), e = desired precision (0.05). Substituting values

$$n_0 = \frac{(1.96)^2(0.5)(0.5)}{(0.05)^2} = 384.16 \approx 384$$

Thus, 384 respondents represented the target sample. The number of usable responses obtained was below this threshold, warranting the inclusion of KIIs to strengthen interpretive validity.

Qualitative Sampling

A purposive sampling technique was adopted for KIIs, selecting pharmacists with at least five years post registration experience and demonstrable engagement in compounding. Five participants were interviewed representing hospital, institutional, and regulatory perspectives -aligning with Braun and Clarke's (2021) guidance on qualitative depth through purposeful information richness.

Research Instruments

Questionnaire (Quantitative Tool)

The questionnaire was designed based on a comprehensive literature review and validated instruments from previous studies on pharmaceutical compounding (5, 53). It consisted of five main sections:

- Section A: Demographics and professional background.
- Section B: Knowledge and awareness of compounding standards (USP, BP, PCN, NAFDAC).

- Section C: Current compounding practices and frequency.
- Section D: Challenges and constraints.
- Section E: Suggestions for improvement and innovations.

Questions combined Likert-scale items, multiple-choice, and open-ended responses to balance quantifiable metrics with qualitative nuance.

Key Informant Interview (KII) Guide

The KII guide was semi-structured, allowing flexibility while ensuring thematic coverage. It focused on professional experience, perceived regulatory gaps, safety and quality issues and recommendations for strengthening compounding practice.

Questions were open-ended to encourage detailed responses, and probing was used where clarification or elaboration was required. The design ensured alignment with the research objectives and facilitated thematic comparison with the quantitative data (37).

Validity and Reliability of Instruments Content and Face Validity

Both the questionnaire and interview guide underwent expert review by academics and practicing pharmacists from Bingham University, Nigeria, State House Medical Centre, Abuja, Nigeria and National Institute for Pharmaceutical Research Development, Nigeria. Their feedback on clarity, relevance, and language led to revisions that enhanced internal consistency. Face validity was confirmed through a pilot test with 10 pharmacists who were later excluded from the final study. Responses helped identify ambiguities and test completion time, ensuring usability and comprehension.

Reliability Testing

Instrument reliability was assessed using Cronbach's alpha, which measures internal consistency. Reliability coefficients exceeding 0.70 were deemed acceptable (45). Pilot data yielded $\alpha=0.81$, indicating good reliability. For qualitative data, dependability was maintained through audio recording, transcription accuracy checks, and peer debriefing of coded themes (30).

Method of Data Collection

Data collection occurred in two sequential phases:

1. Quantitative Phase (Survey): The structured questionnaire was distributed electronically (Google Forms) and physically where possible. Respondents were given a two-week completion period, with follow-up reminders. Completed responses were downloaded into Excel, cleaned, and imported into SPSS (Version 25) for analysis.
2. Qualitative Phase (Key Informant Interviews): Five KIIs were conducted in English, each lasting approximately 30-40 minutes. Interviews were recorded with consent and later transcribed verbatim. Field notes were taken to capture non-verbal cues

and contextual details. This phased collection ensured convergence of datasets, enabling rich triangulation (19).

Method of Data Analysis Quantitative Analysis

Quantitative data were analysed using SPSS (Version 25) and Microsoft Excel (2021). Descriptive statistics (frequency, mean, percentage, standard deviation) summarised responses, while cross-tabulation explored relationships between demographic and practice variables. Where applicable, Pearson's correlation and chi-square tests were used to assess associations ($p < 0.05$). Tables and graphs were employed for clarity and visual presentation.

Qualitative Analysis

Qualitative data were analysed using thematic content analysis following Braun and Clarke's (2021) six-step framework:

1. Familiarisation with data, 2. Generation of initial codes, 3. Identification of themes, 4. Review and refinement of themes, 5. Definition and naming of themes, 6. Interpretation and presentation of results.

Manual coding facilitated close engagement with the data. Findings were later compared with survey results for triangulation.

Integration of Findings

The final stage integrated both data strands using convergence analysis, identifying points of agreement, complementarity, or divergence. This integration ensured that quantitative patterns were validated or explained by qualitative insights (13).

Data Management and Security

Data management followed ethical and institutional best practices to ensure confidentiality, integrity, and traceability. All electronic data (survey responses and transcripts) were stored on an encrypted password-protected drive accessible only to the principal researcher. Hard copies were stored in locked cabinets at Bingham University. Backup copies were maintained on institutional cloud storage, compliant with General Data Protection Regulation (GDPR) principles. All identifying information (names, emails, affiliations) was anonymised during transcription and coding. Audio recordings were destroyed after transcription verification. These measures safeguarded participant data and maintained compliance with research governance frameworks (41).

Ethical Considerations

Ethical approval for this research was obtained from both:

1. Bingham University Research Ethics Committee (Ref: BU/REC/2025/PHARM/004), and

2. State House Medical Centre Ethics Committee, Aso Rock, Abuja, Nigeria (Ref: SHMC/ETH/2024/021).

RESULTS

This section presents the quantitative results from the survey (N=72), organised as charts followed immediately by their corresponding SPSS-style tables, followed by inferential analyses.

Descriptive Statistics

A total of 69 valid responses were obtained from the survey on Current Practices, Challenges and Future Directions in Pharmaceutical Compounding. The analysis provides an overview of respondents' demographic characteristics, training exposure, familiarity with compounding processes, regulatory awareness, and perceptions of quality and innovation in pharmaceutical compounding practice.

Descriptive statistics were computed using SPSS-style frequency and percentage summaries, while figures and tables have been used to visualize the data and enhance interpretability.

Demographic Characteristics of Respondents

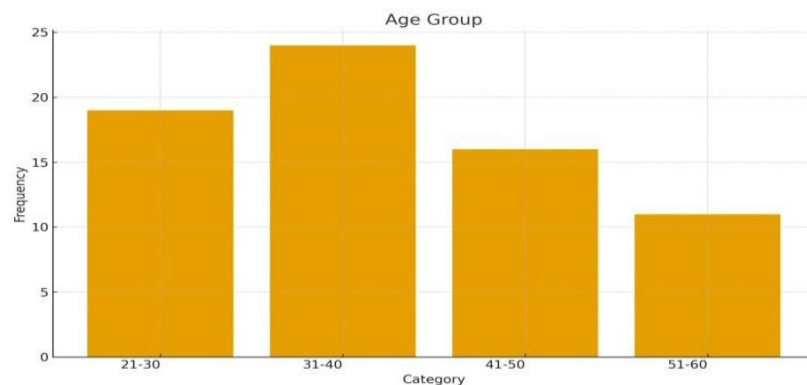


Figure 1: Age Group



Figure 2: Highest Qualification

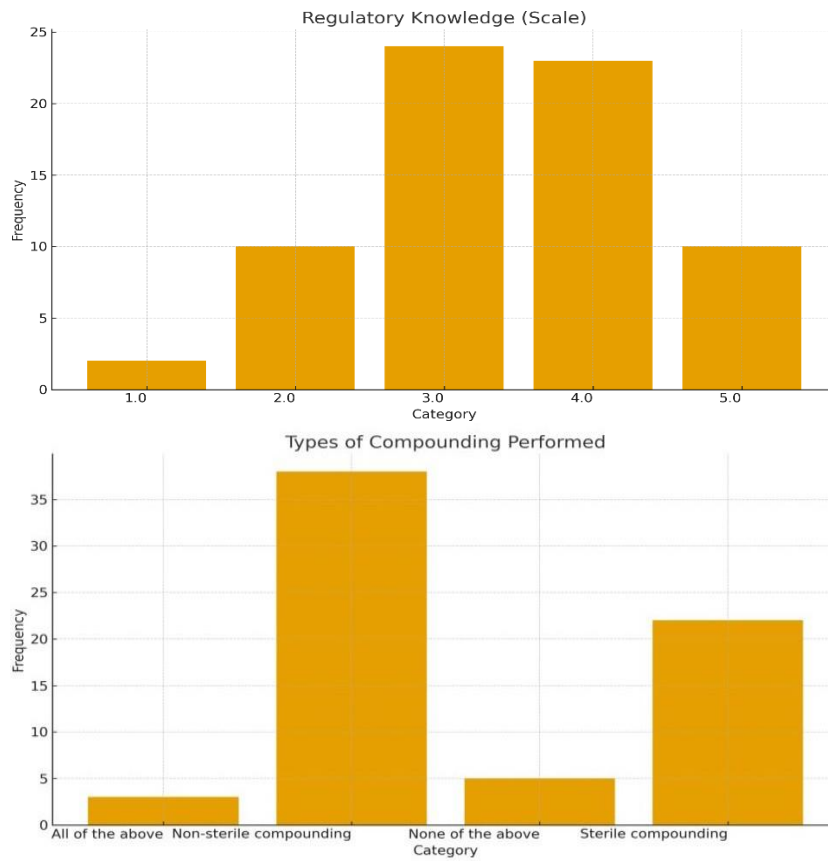


Figure 3: Types of Compounding Performed

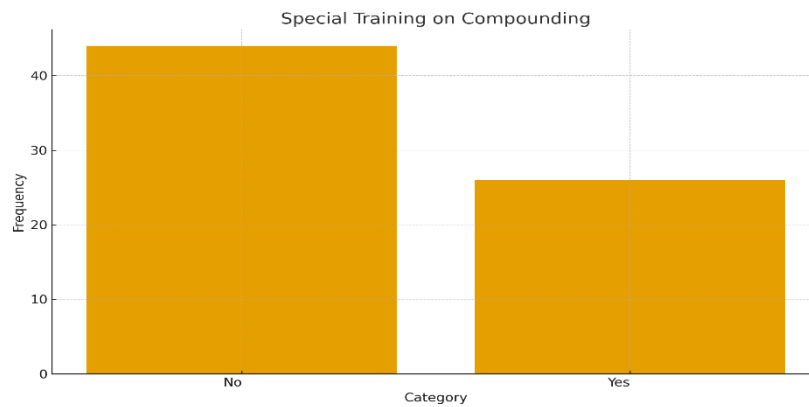


Figure 4: Special Training on Compounding

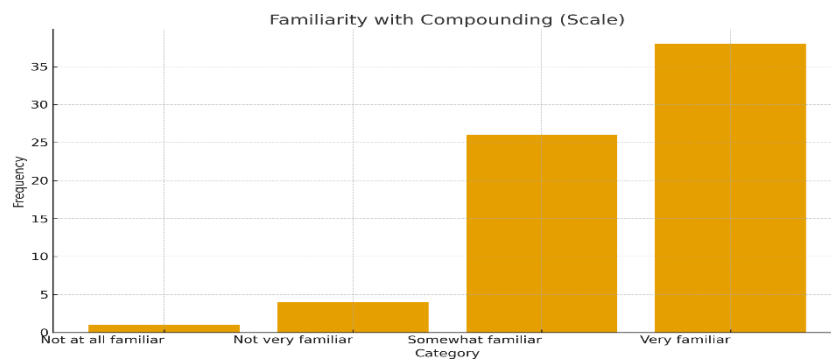


Figure 5: Familiarity with Compounding (Scale)

Table 6: Regulatory Knowledge (Scale)

Category	Frequency	Percent (%)
1.0	2	2.9
2.0	10	14.5
3.0	24	34.8
4.0	23	33.3
5.0	10	14.5

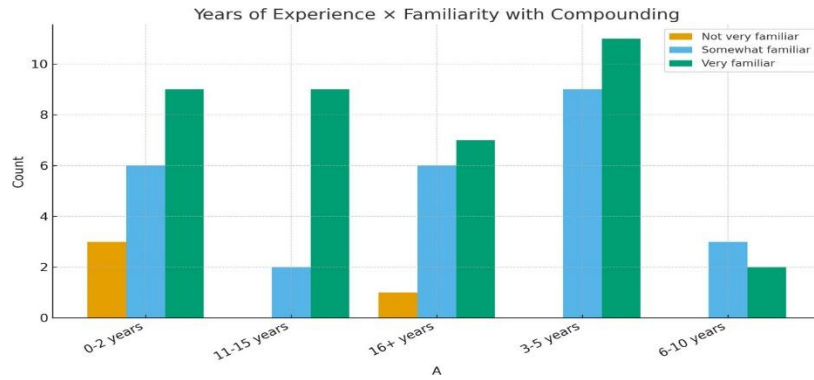


Figure 6: Years of Experience x Familiarity with Compounding

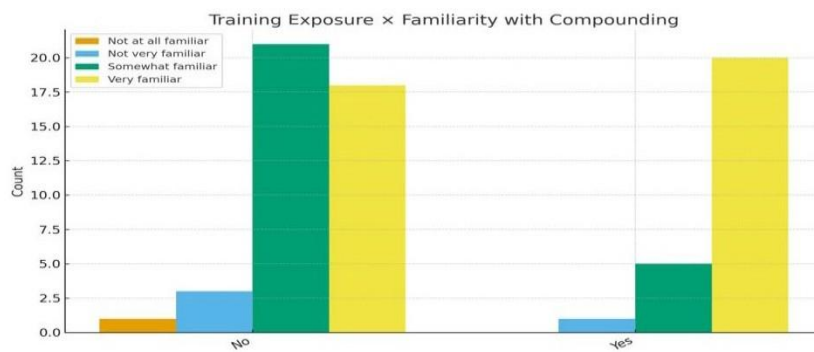


Figure 7: Training Exposure x Familiarity with Compounding

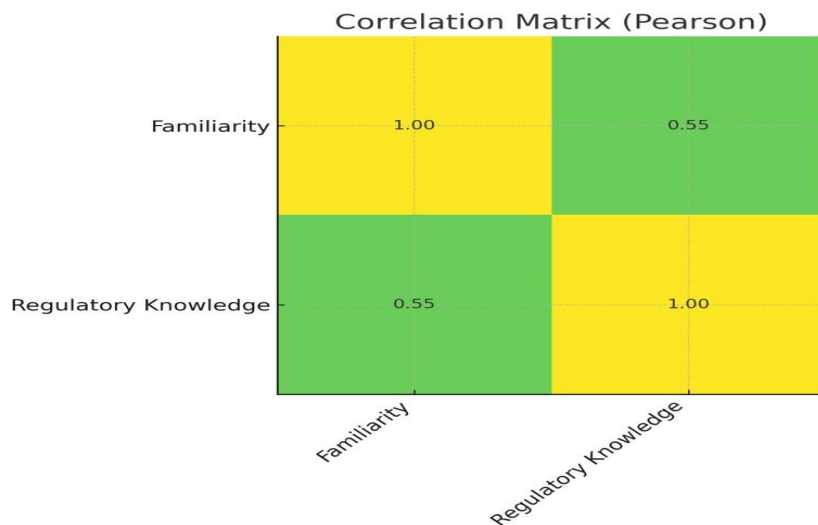


Figure 4.9: Pearson Correlation Matrix

DISCUSSION

Respondents were drawn from diverse sectors, hospital and community pharmacies accounted for the majority of participants, followed by a smaller proportion from academic or regulatory institutions. This reinforces the view that compounding remains largely a patient-care-driven activity rather than an industrial function, emphasizing pharmacists' clinical role in personalized medicine (15).

Analysis revealed that most respondents possessed at least a Bachelor of Pharmacy (B. Pharm or Pharm. D) degree, while a growing fraction (around 20%) held postgraduate qualifications such as MSc or MPH. This distribution suggests a relatively well-educated sample with potential for continuous professional development. (47).

Respondents with longer professional tenure tended to compound medications more frequently. However, even among early-career practitioners, engagement in simple non-sterile compounding was common. This suggests that foundational compounding competencies are embedded early in practice, consistent with the Quality Management Theory (QMT) principle that continuous process learning strengthens quality culture (14, 27).

Only about one-third of respondents reported having received formal or specialized training in compounding beyond their undergraduate curriculum. The limited training exposure underscores a systemic gap in structured professional development. Respondents without additional training often relied on experiential learning or peer mentorship, confirming observations by Okeke and Bamidele (33) that informal knowledge transfer remains a major feature of Nigerian pharmacy practice.

Most respondents rated their familiarity as "familiar" or "very familiar", while less than 15% identified as "not familiar." The high self-reported familiarity may reflect frequent exposure to routine non-sterile preparations such as suspensions, creams, and paediatric formulations. This finding aligns with Rogers' (42) innovation diffusion model, where sustained engagement fosters skill internalization and behavioural adoption.

Respondents' understanding of compounding regulations was moderate overall, with many acknowledging partial familiarity with NAFDAC and Pharmacists Council of Nigeria (PCN) guidelines. This gap suggests the need for clearer regulatory communication and accessible quality standards (34). Strengthening regulatory awareness aligns with the QMT view that compliance and documentation form the backbone of continuous quality improvement.

An overwhelming majority considered pharmaceutical compounding "very important" to healthcare delivery, citing its role in dose personalization, patient adherence, and the management of supply-chain shortages. Such positive perception indicates a readiness among practitioners to support structured compounding programs if institutional support and resources improve (17).

Non-sterile compounding, including oral suspensions, topical creams, and capsules, dominated respondents' activities. Only a minority (<10%) engaged in sterile preparations such as eye drops or injectables, largely due to the absence of aseptic facilities. The pattern corresponds with international observations that resource constraints limit sterile operations in developing contexts (3).

Respondents highlighted recurring difficulties, including: Limited access to quality raw materials, inadequate equipment and infrastructure, Regulatory uncertainty and Lack of formal training frameworks. These challenges mirror the quality-management concerns raised by (4), who identified supply-chain and infrastructure gaps as barriers to sustained quality in small-scale pharmaceutical production.

Qualitative Results: Narrative Thematic Analysis

This section presents the qualitative findings from the five Key Informant Interviews (KIIs), anonymized as KII 1, KII 2, KII 3, KII 4, and KII 5 to maintain confidentiality. These interviews provided rich insights into the training gaps, regulatory challenges, infrastructure limitations and opportunities for innovation in the pharmaceutical compounding sector.

Theme 1: Training and Competence Gaps

KII 1 shared: “Most of the training I received was informal. I didn't get much during school, but I learned from colleagues and supervisors. We need more training to stay updated.” This observation underscores the absence of formalized compounding training in undergraduate pharmacy curricula, forcing practitioners to rely on peer-based learning.

KII 2 reflected on the absence of structured learning: “There is no structured curriculum for compounding in our schools. It would be good if we had workshops or seminars regularly to update our skills.”

KII 3 further emphasized the desire for more professional development: “I feel like we could be better at compounding if there were formal workshops and mentorship programs, even outside of work. Right now, everything is trial and error.”

This theme aligns with the Diffusion of Innovation Theory (DOI), where early adopters in compounding practice face significant barriers to the adoption of new techniques due to the lack of formalized training systems (42). The innovation adoption curve suggests that formal training and structured systems could help fast-track the transition from early adopters to the early majority (42).

Theme 2: Regulatory and Institutional Challenges

KII 4 explained the complexity of navigating these regulations: “We are sometimes unsure whether we are following the correct guidelines. There are regulations, but they are not always clear, and there is no clear support system for ensuring compliance.”

This sentiment reflects a systemic gap in the regulatory framework for pharmaceutical compounding, making it difficult for pharmacists to stay compliant.

KII 5 added: “I think the regulatory framework is good, but it is very difficult to implement it effectively without clear enforcement and continuous monitoring. We often improvise due to resource constraints.” KII 3 further explained the challenges related to lack of enforcement: “Sometimes the policies are there, but they are not enforced. If we had consistent checks, we would do much better with compounding.”

These responses suggest that regulatory challenges are a significant barrier to effective compounding. From a Quality Management Theory (QMT) perspective, clear and enforceable quality standards are essential for institutional continuous improvement (43). Consistent regulatory oversight and infrastructure support are key to ensuring that quality systems in compounding pharmacies are robust and sustainable.

Theme 3: Quality Assurance and Infrastructure Deficits

KII 1 commented: "We don't have proper sterile rooms or laminar flow units. The preparation of sterile products is compromised because we simply don't have the right environment."

KII 3 echoed this concern: "There's no clean room for sterile compounding in my hospital. We do the best we can with what we have, but it's not ideal."

The lack of dedicated quality assurance (QA) infrastructure is a barrier to maintaining compounding quality. QMT emphasizes that systemic process controls and continuous monitoring are essential for ensuring that compounded products meet required standards (14). However, without the necessary infrastructure, these systems cannot function effectively, resulting in inconsistencies in compounded products (27).

Theme 4: Innovation and Modernization in Pharmaceutical Compounding

Respondents also expressed a strong desire for innovation and modernization in compounding practices. There was a clear push for the adoption of new technologies and automation to improve both accuracy and efficiency in the compounding process.

KII 2 suggested: "Innovation is the future of pharmaceutical compounding. We should invest in better equipment and automated systems to make our work easier and more accurate."

KII 5 also shared: "With the right technology, compounding can be more precise, faster, and more effective. We need to start thinking about automation in compounding."

This reflects a latent demand for modernization, particularly in environments where resource constraints limit access to cutting-edge technologies. According to DOI, the adoption of new technologies is a key driver for increasing efficiency and improving outcomes in compounding practice (42). The innovation curve also suggests that early adopters of technology will pave the way for broader adoption across the profession.

Theme 5: Ethical and Safety Considerations

KII 5 stated: "There are no formal checks in place to assess whether compounded medications are truly safe. We don't have a proper system to monitor stability or side effects."

KII 2 echoed similar concerns: "We do the best we can, but we don't have the equipment or monitoring tools to ensure the safety of compounded medications. It's just not ideal."

These safety concerns underscore the importance of process validation and continuous quality monitoring, key principles of QMT. Implementing formal checks and risk management strategies is essential for improving the ethical standards and patient safety in compounding practices (Sollecito & Johnson, 2021).

CONCLUSION

Pharmaceutical compounding is a very important healthcare delivery service and it remains largely a patient-care-driven activity carried out primarily in hospitals and community pharmacies by relatively well-educated pharmacists with a minimum of a B. Pharm or Pharm D qualification. Most respondents were “familiar” or “very familiar” with compounding and respondents with longer professional tenure had a higher tendency to compound medications more frequently relative to early-career practitioners. However, only about one-third of respondents reported having received formal or specialized training in compounding beyond their undergraduate curriculum - indicating a systemic gap in structured professional development. Many respondents reported moderate understanding of compounding regulations being familiar with NAFDAC and PCN guidelines. Over 90% of respondents’ activities involved non-sterile compounding, while only a minority (<10%) engaged in sterile preparations such as eye drops or injectables, largely due to the absence of aseptic facilities.

The qualitative findings underscore significant gaps in training, regulatory compliance, infrastructure, and quality assurance in pharmaceutical compounding. However, there is also evidence of a willingness to innovate and modernize compounding practices. Pharmacists expressed the need for formalized training programs, structured regulatory oversight, and upgraded infrastructure to meet the demands of personalized healthcare. The findings suggest a systemic need for reform, especially in education, training, and quality assurance systems. These results provide a valuable foundation for addressing the key challenges facing the profession and enhancing its role in healthcare.

LIMITATIONS OF THE STUDY

While the mixed-method approach enhanced data richness, the study faced certain limitations: The low survey response rate limited statistical generalisation. However, triangulation with KIs strengthened validity. The geographical scope was limited to selected regions due to logistics, though purposive inclusion captured diverse perspectives. Self-reported data may contain bias, though methodological rigor (validity checks and triangulation) mitigated this risk. Despite these limitations, the study provides a credible and holistic understanding of pharmaceutical compounding practices in Nigeria.

REFERENCES

1. Adeniran S, Ogunleye O, Bello I. Adoption of pharmaceutical innovations in sub-Saharan Africa: applying diffusion of innovation theory. *Afr J Health Prof Educ.* 2022;14(2):101-110.
2. Adeoye O. Extemporaneous compounding in Nigerian hospital pharmacies: patterns, error rates, and implications for training. *West Afr J Pharm.* 2024;35(1):45-54.

3. Adeyemi B, Giwa A. Capacity and constraints in hospital compounding practice in sub-Saharan Africa. *Int J Pharm Pract.* 2020;28(5):401-408.
4. Ameh PO, Nwokorie VC, Ezenwa AC. Assessing barriers to quality assurance in small-scale drug production in Nigeria. *Afr J Health Prof Educ.* 2023;15(1):22-31.
5. Alfred-Ugbenbo B, Orubu S, Adekoya A. Contemporary challenges of pharmaceutical compounding in Southern Nigeria. *J Pharm Pract Policy.* 2016;9(2):115-124.
6. Assefa T, Bekele D, Gebre-Mariam T. Compounding practice and personalized therapeutics: a systematic review of developing countries. *Pharm Pract.* 2023;21(1):1-9.
7. Awad A, Khalil A, Mohamed R. Automation and robotics in compounding pharmacy. *Int J Pharm Technol.* 2021;12(4):47-58.
8. Ayenew A, Gashaw S, Tesfaye T. Quality and safety risks in extemporaneous compounding: a global review. *Int J Pharm Sci.* 2024;14(2):27-38.
9. Bello M, Ogunbanjo A, Okonkwo J. Resource constraints and quality gaps in Nigerian hospital compounding. *Niger J Pharm Pract.* 2023;22(1):33-42.
10. Braun V, Clarke V. Thematic analysis: a practical guide. *Qual Res Psychol.* 2021;18(3):328-350.
11. Contemporary challenges of pharmaceutical compounding in Southern Nigeria. *Sci Rise Pharm Sci.* 2016;(3):11-20.
12. Creswell JW, Creswell JD. *Research design: qualitative, quantitative and mixed methods approaches.* 6th ed. Thousand Oaks (CA): Sage; 2023.
13. Creswell JW, Plano Clark VL. *Designing and conducting mixed methods research.* 4th ed. Thousand Oaks (CA): Sage; 2022.
14. Deming WE. *Out of the crisis.* Cambridge (MA): MIT Press; 1986.
15. Eze CI, Okorie N, Akintunde L. Hospital pharmacists and the evolution of patient-specific compounding in Nigeria. *J Pharm Pract Res.* 2023;53(2):145-155.
16. European Medicines Agency. *Guidelines on good compounding practice.* Amsterdam: EMA; 2022.
17. Fadare JO, et al. Perceptions of clinical compounding among pharmacists in West Africa. *BMC Health Serv Res.* 2022;22(1):1-9.
18. U.S. Food and Drug Administration. *Compounding quality act guidance for pharmacies.* Silver Spring (MD): FDA; 2023.
19. Fetters MD, Freshwater D. The 1+1=3 integration challenge of mixed methods research. *J Mix Methods Res.* 2021;15(3):283-296.
20. Field A. *Discovering statistics using IBM SPSS statistics.* 5th ed. London: Sage; 2018.
21. International Pharmaceutical Federation. *Good practice guidelines for pharmaceutical compounding.* The Hague: FIP; 2021.
22. Fosu E, Mensah P, Owusu R. Assessment of compounding competence among hospital pharmacists in Ghana. *Afr J Pharm Sci.* 2022;3(2):55-66.
23. GMI Insights. *Compounding pharmacies market report 2023-2032* [Internet]. 2023 [cited 2026 Mar 12]. Available from: <https://www.gminsights.com/industry-analysis/compounding-pharmacies-market>
24. Grand View Research. *Compounding pharmacies market size report 2023* [Internet]. 2023 [cited 2026 Mar 12]. Available from: <https://www.grandviewresearch.com/industry-analysis/compounding-pharmacies-market>

25. Greenhalgh T, Wherton J, Papoutsi C. Diffusion of innovations in healthcare organisations. *Milbank Q.* 2020;98(3):635-687.
26. Institute for Safe Medication Practices. Best practices for safe pharmaceutical compounding. Horsham (PA): ISMP; 2022.
27. Jallow M, et al. Embedding continuous learning in pharmaceutical quality systems. *Int J Qual Reliab Manag.* 2024;41(3):612-629.
28. Johnson RB, Onwuegbuzie AJ, Turner LA. Toward a definition of mixed methods research. *Educ Res.* 2020;49(6):451-458.
29. Kassa H, Tadesse S, Tarekegn M. Hospital compounding practices and barriers in Ethiopia. *Ethiop J Health Sci.* 2021;31(4):719-730.
30. Nowell LS, Norris JM, White DE. Thematic analysis: striving to meet trustworthiness criteria. *Int J Qual Methods.* 2021;20(1):1-13.
31. Oakland JS. Total quality management and operational excellence: text with cases. 4th ed. London: Routledge; 2014.
32. Ogunleye O, Adebisi YA, Bello S. Workforce dynamics and gender distribution in Nigerian pharmacy practice. *Pharm Educ.* 2022;22(4):75-84.
33. Okeke E, Bamidele D. Experiential learning in Nigerian community pharmacy practice. *Res Social Adm Pharm.* 2021;17(3):589-597.
34. Olatunde FE, Odeyemi T, Akingbade O. Regulatory enforcement and pharmacist awareness in compounding practice. *J Pharm Policy Pract.* 2024;17(2):101-113.
35. Orubu S, Adejare A, Adeosun O. Extemporaneous formulation practices in sub-Saharan Africa. *Int J Pharm Pharm Sci.* 2017;9(8):65-72.
36. Orubu S, Adekoya A, Etuk E. Hospital compounding in Nigeria: gaps, challenges and prospects. *Niger J Pharm Res.* 2021;19(2):98-108.
37. Palinkas LA, Horwitz SM, Green CA. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. *Adm Policy Ment Health.* 2020;47(6):1012-1021.
38. Parisi O, Tinto C, Rossi F. 3D-printing of personalised medicines: implications for compounding pharmacists. *Pharmaceutics.* 2024;16(2):224.
39. Pharmacy Council of Nigeria. Annual report on pharmaceutical regulation and inspection. Abuja: PCN; 2023.
40. Rahman S, Ahmed H, Hossain M. Pharmaceutical compounding in South Asia: practices, perception and barriers. *Asian J Pharm Pract.* 2021;11(3):143-151.
41. Resnik DB. Ethics of research with human subjects: protecting people, advancing science, promoting trust. Cham: Springer; 2020.
42. Rogers EM. Diffusion of innovations. 5th ed. New York: Free Press; 2003.
43. Sollecito W, Johnson J. McLaughlin and Kaluzny's continuous quality improvement in health care. 5th ed. Burlington (MA): Jones & Bartlett; 2021.
44. Tabachnick BG, Fidell LS. Using multivariate statistics. 7th ed. Boston: Pearson; 2019.
45. Taber KS. The use of Cronbach's alpha when developing and reporting research instruments in science education. *Res Sci Educ.* 2018;48(6):1273-1296.

46. Tashakkori A, Teddlie C. *Mixed methodology: combining qualitative and quantitative approaches*. 3rd ed. Thousand Oaks (CA): Sage; 2021.
47. Umeh C, Adeoye S. Linking postgraduate training to pharmaceutical service quality in Nigeria. *Health Policy Syst Res*. 2023;21(4):55-67.
48. United States Pharmacopeial Convention. *United States Pharmacopeia chapters <795> and <797> on pharmaceutical compounding*. Rockville (MD): USP; 2023.
49. World Health Organization. *Good pharmacy practice: standards for quality of pharmacy services*. Geneva: WHO; 2021.
50. Wairimu K, Mburu P, Ndirangu G. Competence and regulation of pharmaceutical compounding in Kenya. *East Afr Pharm J*. 2023;25(1):19-30.
51. Yuliani S, Yanti D, Rachmawati N. An overview of pharmaceutical compounding techniques and challenges. *Pharmaceutics*. 2023;15(3):840.