Research Quality Management Policy

Yousef Ahmed Alomi*, BSc. Pharm, MSc. Clin Pharm, BCPS, BCNSP, DiBA, CDE
Critical Care Clinical Pharmacists, TPN Clinical Pharmacist, Freelancer Business Planner, Content Editor, and Data Analyst, Riyadh, SAUDI ARABIA.
Amal Hassan Al-Najjar, BSc, MSc, Drug and Poison Information Center, Security Forces Hospitals, Riyadh, SAUDI ARABIA.
Maha Hussein Almadany, Bsc. Pharm.
Health Care Quality Management Professional Diploma (HCQM), Pharmacy Quality Department, King Salman bin Abdulaziz Medical City, Al Madina Al Monwarah, SAUDI ARABIA.
Abeer Hussin Almasoudi, Bsc. Pharm
Director, Administration of Research and Studies, Ministry of Health, Tabuk, SAUDI ARABIA.

Correspondence:
Dr. Yousef Ahmed Alomi, Bsc. Pharm, msc. Clin pharm, bcps, bCNSP, DiBA, CDE
Critical Care Clinical Pharmacists, TPN Clinical Pharmacist, Freelancer Business Planner, Content Editor and Data Analyst, P.O.BOX 100, Riyadh 11392, Riyadh, SAUDI ARABIA.

Phone no: +966 504417712
E-mail: yalomi@gmail.com

Received: 05-11-2021;
Accepted: 25-01-2022.

Access this article online
www.ijpcs.net
DOI: 10.5530/ijpcs.2022.11.11

ABSTRACT

Objectives: This study illustrates the Research policy of quality management in pharmacy research practice as a new initiative project in Saudi Arabia. **Methods:** It is a narrative review of pharmacy research's quality management policy and procedures. Litterateur researched specific quality management research policies and procedures in pharmacy practice using various databases, including PubMed, Medline, and Google Scholar. The time covered for the search is from the 1960s to October 2021. The keyword used is in the English language and encompasses systemic reviews, meta-analyses, narrative reviews, and guidelines or regulations. The search term includes all hospital and community pharmacy-related services. Besides, the national and international guidelines for conducting general research in hospital and pharmacy practice. The committee of quality management policy of pharmacy research formulated and consisted of numerous expert members, including clinical pharmacists, drug information pharmacists, and clinical research specialists. A member drafted the policy and procedures, which were then reviewed and corrected by another member. The research specialist made the third revision. The topic emphasizes the quality management of Pharmacy Research policy as the narrative review model. **Results:** Pharmacy research policy quality management is a new topic in pharmaceutical care services. It covered various topics, the steps involved in conducting quality management, and indicator policies and procedures. Besides, quality management pharmacy research can be implemented into various sections. That included patient care, research skills, communication, Professionalism, cautious development. Each part had a key performance indicator and related optimal level. **Conclusion:** The quality management policy for pharmacy research is a new initiative within pharmacy research. The quality management pharmacy policy assists the pharmacy research performance and keeps up-to-date development with key performance indicators. Therefore, all quality management models in pharmacy research policy are highly suggested for the pharmacy research practice in Saudi Arabia
Keywords: Research, Policy, Pharmacy, Quality management, Key performance indicator, Saudi Arabia.

INTRODUCTION

Over the years, the Saudi center of healthcare organization's accreditation has established a quality management system for pharmacy practice.[1] The standards were straightforward to implement; they lacked in-depth detail and specific limitations. However, the updated pharmacy standards were released in their entirety in 2016.[1] The new guidelines are comparable to those established by international pharmacy organizations such as the American Society of Health-System Pharmacists (ASHP). Additionally, the new standards included some requirements, such as if specific pharmacy standards were not fully met, healthcare organizations would fail. Pharmacy leaders founded numerous quality management services on pharmacy practice programs.[2-3] The pharmacy strategic plan and updated plan with the new vision 2030 included quality management indicators.[4-5] The new initiative program for research and development services necessitates a comprehensive quality management system with a premium on indicators.[4-5] However, few studies in pharmacy research[6-9] have discussed the policies and procedures for research quality management.[10] The authors are unaware of any published research on total quality management or quality indicators for pharmacy practice research.[11] This study aims to establish comprehensive quality management and indicator policies and procedures for pharmacy research.

MATERIALS AND METHODS

It's a narrative review of pharmacy research's quality management policy and procedures. Litterateur searched for specific topics related to quality management research in pharmacy practice. Various databases are used for literature search. For an instant, PubMed, Medline, Academic Microsoft, and Google Scholar. The time frame for the search is from the 1960s until October 2021. The terms used were in English and included systemic review, Meta-analysis, narrative review, and guidelines or regulations. In a search term, all hospitals or community pharmacies had. Various pharmaceutical care services included inpatient pharmacy, outpatient or ambulatory care pharmacy, extemporaneous preparation, repackaging units, satellite pharmacy, pharmacy store, drug information center, and clinical pharmacy services.

Furthermore, the National and international guidelines for general research in hospital and pharmacy practice are used as a guide in writing the current topic.[12-25] The research guidelines included of various organizations; the Saudi Food and Drug Authority (SFDA),[13-14] the European Medicine Agency,[24] the American Society of Health-System Pharmacist (ASHP),[25] and the World Health Organization (WHO),[22] and other literature.[11,26-27] Besides Equator Network, a library of guidelines for health research in observational studies. that's included (Standards for QUality Improvement Reporting Excellence (SQUIRE), Guidelines for Publication Revisions A Detailed Consensus Process guided by writing policy the and procedures.[8-10] The pharmacy research committee was formed and consisted of numerous expert members. That includes clinical pharmacists, drug information pharmacists, and clinical research specialists. One member drafted the policy and procedures guidelines, another member reviewed and corrected them, and a research specialist revised them for the third time. The topic covered various areas, including investigational drug research, the research and ethical committee, data collection and organization, the quality of pharmacy research services, pharmacy research competency, and pharmacy research education and training. The current reviews emphasized quality management and indicator policies and procedures for pharmacy research. It was reported according to the internationally adopted Appraisal of Guidelines, Research, and Evaluation (AGREE) standard.[28]

Search: **pharmacy research policy[Title/Abstract]** Filters: **Full text, Humans, English**

((“pharmacie”[All Fields] OR “pharmacies”[MeSH Terms] OR “pharmacies”[All Fields] OR “pharmacy”[MeSH Terms] OR “pharmacy”[All Fields] OR “pharmacy s”[All Fields]) AND “research policy”[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

pharmacy: «pharmacie»[All Fields] OR «pharmacies»[MeSH Terms] OR «pharmacies»[All Fields] OR «pharmacy»[MeSH Terms] OR «pharmacy»[All Fields] OR «pharmacy›s»[All Fields]

Search: **pharmaceutical research policy[Title/Abstract]** Filters: **Full text, Humans, English**

((“biopharmaceutics”[MeSH Terms] OR “biopharmaceutics”[All Fields] OR “pharmaceutic”[All Fields] OR “pharmaceutics”[All Fields] OR “pharmaceutical preparations”[MeSH Terms] OR (“pharmaceutical”[All Fields] AND “preparations”[All Fields]) OR “pharmaceutical preparations”[All Fields] OR “pharmaceutical”[All Fields] OR “pharmaceuticals”[All Fields] OR “pharmaceutical s”[All Fields] OR “pharmaceutically”[All Fields]) AND “research policy”[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

pharmaceutical: «biopharmaceutics»[MeSH Terms] OR «biopharmaceutics»[All Fields] OR «pharmaceutic»[All Fields] OR «pharmaceutics»[All Fields] OR «pharmaceutical preparations»[MeSH Terms] OR («pharmaceutical»[All Fields] AND «preparations»[All Fields]) OR «pharmaceutical preparations»[All Fields] OR «pharmaceutical»[All Fields] OR «pharmaceuticals»[All Fields] OR «pharmaceutical›s»[All Fields] OR «pharmaceutically»[All Fields]

Search: **investigational drug policy[Title/Abstract]** Filters: **Full text, Humans, English**

(“investigational”[All Fields] AND “drug policy”[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: **clinical trial policy[Title/Abstract]** Filters: **Full text, Humans, English**

(“clinical trial policy”[Title/Abstract]) AND ((fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Search: **research quality managament[Title/Abstract] - Spellcheck off** Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, Humans, English**

((“research personnel”[MeSH Terms] OR (“research”[All Fields] AND “personnel”[All Fields]) OR “research personnel”[All Fields] OR “researcher”[All Fields] OR “researchers”[All Fields] OR “research”[MeSH Terms] OR “research”[All Fields] OR “research s”[All Fields] OR “researchable”[All Fields] OR “researche”[All Fields] OR “researched”[All Fields] OR “researcher s”[All Fields] OR “researches”[All Fields] OR “researching”[All Fields] OR “researchs”[All Fields]) AND “quality managament”[Title/Abstract]) AND ((guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research: «research personnel»[MeSH Terms] OR («research»[All Fields] AND «personnel»[All Fields]) OR «research personnel»[All Fields] OR «researcher»[All Fields] OR «researchers»[All Fields] OR «research»[MeSH Terms] OR «research»[All Fields] OR «research›s»[All Fields] OR «researchable»[All Fields] OR «researche»[All Fields] OR «researched»[All Fields] OR «researcher›s»[All Fields] OR «researches»[All Fields] OR «researching»[All Fields] OR «researchs»[All Fields]

Search:**research quality indicator[Title/Abstract]** Filters: **Full text, Guideline, Meta-Analysis, Practice Guideline, Review, Systematic Review, in the last 10 years, Humans, English**

((“research personnel”[MeSH Terms] OR (“research”[All Fields] AND “personnel”[All Fields]) OR “research personnel”[All Fields] OR “researcher”[All Fields] OR “researchers”[All Fields] OR “research”[MeSH Terms] OR “research”[All Fields] OR “research s”[All Fields] OR “researchable”[All Fields] OR “researche”[All Fields] OR “researched”[All Fields] OR “researcher s”[All Fields] OR “researches”[All Fields] OR “researching”[All Fields] OR “researchs”[All Fields]) AND “quality indicator”[Title/Abstract]) AND ((y_10[Filter]) AND (guideline[Filter] OR meta-analysis[Filter] OR practiceguideline[Filter] OR review[Filter] OR systematicreview[Filter]) AND (fft[Filter]) AND (humans[Filter]) AND (english[Filter]))

Translations

research: «research personnel»[MeSH Terms] OR («research»[All Fields] AND «personnel»[All Fields]) OR «research personnel»[All Fields] OR «researcher»[All Fields] OR «researchers»[All Fields] OR «research»[MeSH Terms] OR «research»[All Fields] OR «research›s»[All Fields] OR «researchable»[All Fields] OR «researche»[All Fields] OR «researched»[All Fields] OR «researcher›s»[All Fields] OR «researches»[All Fields] OR «researching»[All Fields] OR «researchs»[All Fields]

RESULTS AND DISCUSSION

The pharmacist must follow the policy and procedures of quality management in pharmacy research:[8,9,11]

1. The pharmacy should establish quality control procedures for its research or investigational drug pharmacy.
2. The pharmacy should follow the quality standards for its research performance and activities.
3. Pharmacy departments appoint or designate researchers or investigational drug pharmacists.
4. The researcher or investigational drug pharmacist establishes the research or investigational drug pharmacy's strategic plan for quality improvement.
5. The researcher or investigational drug pharmacist established key performance indicators for each aspect of care or component of their research or investigational drug pharmacy competency as explored in Table 1.

Table 1: Research and development Quality management indicators.

No	Topic	Activity	Key performance indication	Target
1	Patients care	Monitor investigational medication-related problems	Number of adverse drug reaction	Zero
			Number of medications errors	Zero
			Number drug quality reporting	Zero
		Monitor and document the outcome of research in pharmacy practice	Number of patient reduction or morbidity	Unlimited, define the number based on the annual plan
			Number of patient reduction or mortality	Unlimited, define the number based on the annual plan
			Number of patients improving clinical outcomes	Unlimited, define the number based on the annual plan
			Number of new pharmacy practice program	Unlimited, define the number based on the annual plan
			Total cost avoidance	
2	Research skills	Monitor the authors	The number of pharmacists that had complete clinical practice certificates / total number of pharmacy staff samples	100%
		Monitor the research	Number of scientific research done annually	Unlimited, define the number based on the annual plan
			Number of research per author through Google Scholar and academic Microsoft	Unlimited, define the number based on the annual plan
		Monitor the research publications	Number of scientific publications done annually	Unlimited, define the number based on the annual plan
			Number of scientific research presented as a poster at international conferences	Unlimited, define the number based on the annual plan
			Number of scientific research publications citations through Google Scholar and academic Microsoft	Unlimited, define the number based on the annual plan
		Monitor the research in compliance with international guidelines	Number of research adherence/total number of research	100%
		Monitor the research publication's compliance with international guidelines (10)education and training to facilitate good research reporting and assists in the development, dissemination and implementation of robust reporting guidelines. This paper presents a collection of tools and guidelines available on the EQUATOR website (http://www.equator-network.org	Number of scientific publications adherence/ total number of publications	100%
		Monitor plagiarism in the research	Check plagiarism for publication	Not exceed 15-20%
3	Communication	Monitor the number of educational lectures and number of attendees	Number of educational lectures for pharmacy staff and healthcare professionals quarterly	Unlimited, define the number based on the annual plan
			Number of attendees of pharmacy staff and healthcare professionals per each lecture quarterly	Unlimited, define the number based on the annual plan

continued...

Table 1: Research and development Quality management indicators.

No	Topic	Activity	Key performance indication	Target
4	Professionalism	Monitor the research based on ethical guidelines	Number of research appropriately exempted / total number of research exempted	Documentation
			Number of research appropriate expedited/total number of expedited research	Documentation
			Number of research appropriate reviewed by ethical committee/ total number of reviewed research	Documentation
		Write the comments on the original research throat letter to the editor or comment only and	The number of pharmacists that had Written the comments on the original research / total number of pharmacy staff samples	Documentation
		Not to Write the comments on the original research by social media	The number of pharmacists that had Written the comments on the original research social media/ total number of pharmacy staff samples	Zero
5	Continuous development	Update the research policy in pharmacy practice annually	The updating of the research policy every two years	Documentation
		Present the annual plan of research in pharmacy practice	Annual plan of research in pharmacy practice	Documentation
		Availability of electronic survey for pharmacy staff	The number of electronic survey access to the pharmacy staff / total number of pharmacy staff samples	100%
		Availability of biostatistics software for pharmacy staff	The Number of biostatistics software for pharmacy staff / total number of pharmacy staff samples	100%
		Availability of references managers for pharmacy staff	The number of references managers for pharmacy staff / total number of pharmacy staff samples	100%
		Availability of evidence medicine database for pharmacy staff	The number of evidence medicine database / total number of pharmacy staff samples	100%
		Take a sample of existing references pharmacy units and hospitals.	Number of available references/ total references available units	100%

6. The pharmacist responsible for research or investigational drugs establishes that KPIs are quantified using percentages and appropriate documentation is completed, as illustrated in Table 1.
7. The schedule for the research or investigational drug pharmacist and the frequency with which KPIs are measured is monthly or quarterly.
8. The pharmacist who designs the research or investigational drugs, the KPI datasheet, compared to previous reports.
9. The pharmacist responsible for research or investigational drugs shall discuss the report with the pharmacy administration.
10. The research or investigational drug pharmacy unit analyzed and discussed quarterly quality management reports with pharmacy staff.
11. The research or investigational drug pharmacist develops a road map plan for the research or investigational drug pharmacy's quality improvement.
12. The research or investigational drug pharmacist is responsible for monitoring the roadmap for all pharmacy services and making necessary changes and improvements to the research or investigational drug pharmacy.
13. The pharmacist who works on research or investigational drugs examines the pharmacy's previous and current status and any changes. Adapt your practice accordingly.
14. The research or investigational drug pharmacist writes the final quality improvement report based on international standards or guidelines. The last information may include a summary or detailed description of the problem, problem outlines, key performance indicators, data collection method, analysis, and interpretation. Additionally, changes in strategies, effects, and future steps.[8-9,29]

CONCLUSION

Quality management policies and procedures for research and investigational medications are required for research and development units in pharmaceutical care services. In addition, it serves as the basis for evaluating and quantifying the quality of pharmacy practice research and clinical trials. To ensure patient safety, improve research outcomes, and avoid undue economic burden on the healthcare system, the quality of available research or investigational medications must be high. As a result, it is strongly recommended that Saudi

Arabia implement pharmacy research quality standards emphasizing policy and procedures.

ORCID ID

Yousef Ahmed Alomi https://orcid.org/0000-0003-1381-628X

ACKNOWLEDGEMENT

None.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

KSA: Kingdom of Saudi; **SFDA:** Saudi Food and Drug Authority; **WHO:** World Health; **WHO:** World Health Organization; **ASHP:** American Society of Health-System Pharmacists; **SQUIRE:** Standards for QUality Improvement Reporting Excellence; **AGREE:** Appraisal of Guidelines, Research, and Evaluation.

REFERENCES

1. Saudi Central Board for Accreditation of Healthcare Institutions. National Hospital standards. Third edit. Saudi Central Board for Accreditation of Healthcare Institutions; 2016.
2. Alomi YA. National antimicrobial stewardship Program in Saudi Arabia; initiative and the future. OAJS. 2017;4(5):1-7. doi: 10.19080/OAJS.2017.04.555646.
3. Alomi YA. National pharmacy anticoagulation program at Ministry of Health in Saudi Arabia. BAOJ PharmSci. 2017;3(3):3-7.
4. Alomi YA, Alghamdi SJ, Alattyh RA. Strategic plan of general administration of pharmaceutical care at Ministry of Health in Saudi Arabia 2012-2022. J Pharm Pharm Sci. 2015;1(13):1-8.
5. Alomi YA, Alghamdi SJ, Alattyh RA, Elshenawy RA. The evaluation of pharmacy strategic plan in past. Commun Med. 2013-2016 and Forecasting of New Vision 2030 at Ministry of Health in Saudi Arabia. J Pharm Pract;2018(Jun 10);4(2):93-101.
6. Rev Educ. P, Sahai P, Sahni R. Strategies for defining key performance indicators in research. Clin Res.. 2016 (Aug):16-9.
7. Baethge C, Goldbeck-Wood S, SANRA MS. A scale for the quality assessment of narrative review articles. Res Integr Peer Rev. 2019 Dec;4(1):1-7.
8. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2016;25(12):986-92. doi: 10.1136/bmjqs-2015-004411, PMID 26369893.
9. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (standards for QUality improvement reporting excellence): Revised publication guidelines from a detailed consensus process. Am J Med Qual. 2015;30(6):543-9. doi: 10.1177/1062860615605176, PMID 26497490.
10. Simera I, Moher D, Hoey J, Schulz KF, Altman DG. A catalogue of reporting guidelines for health research. Eur J Clin Investig. 2010;40(1):35-53. doi: 10.1111/j.1365-2362.2009.02234.x, PMID 20055895.
11. Aparasu RR. Research methods for pharmaceutical practice and policy; 2011. 333 p.
12. Bawazir S, Hashan H, Al Hatareshah A, Al Ghamdi A, Al Shahwan K. Regulating clinical trials in Saudi Arabia. ACCTRA. 2014;1(1):2-9. doi: 10.2174/2213476X01666140321182641.
13. Saudi Food and Drug Authority. Guideline for good clinical practice (GCP) E6. Vol. 6. (p. R1) [internet]; 2013. Available from: http://www.sfda.gov.sa/En/Drug [cited 21/4/2022].
14. Saudi Food and Drug Authority Drug Sector. Guideline for good clinical practice (GCP). 3rd version. Saudi Food and Drug Authority; 2020.
15. Wermeling DP. Clinical research: Regulatory issues. Am J Health Syst Pharm. 1999;56(3):252-6. doi: 10.1093/ajhp/56.3.252, PMID 10030513.
16. Mahan VL. Clinical trial phases. Int J Clin Med. 2014;05(21):1374-83. doi: 10.4236/ijcm.2014.521175.
17. Berger VW, Antsygina O. A review of randomization methods in clinical trials. Clinical Investigation. 2015 Dec;5(12):847-53. doi: 10.4155/cli.15.53.
18. Baghbaninaghadehi F. Fundamentals of randomization in clinical trial. IJANHS. 2016;4(1):174-87. doi: 10.23953/cloud.ijanhs.143.
19. Davidson RA. Source of funding and outcome of clinical trials. J Gen Intern Med. 1986;1(3):155-8. doi: 10.1007/BF02602327, PMID 3772583.
20. Noorzurani MHR, Aziz NA, Abdul Aziz AF, Abd Hamid MZ, Mohamed M, Othman S, *et al*. The need for "good clinical practice" in health care research. S Afr Fam Pract. 2009;51(3):202-5. doi: 10.1080/20786204.2009.10873848.
21. Vijayananthan A, Nawawi O. The importance of Good Clinical Practice guidelines and its role in clinical trials. Biomed Imaging Interv J. 2008;4(1):e5. doi: 10.2349/biij.4.1.e5, PMID 21614316.
22. Handbook for good clinical research practice (GCP): guidance for implementation. World Health Organization; 2002.
23. Earls F, Cook S. Integrated addendum to ICH. ICH harmonised guidelines. 2016;E6:(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE.
24. European Medicines Agency (EMA). Guideline good. Clin Pract. 2017;(December 2016);E6(R2):1-68.
25. Kay SC, Luke DG, Tamer HR. ASHP guidelines for the management of investigational drug products. Am J Health Syst Pharm. 2018;75(8):561-73. doi: 10.2146/ajhp170812, PMID 29626006.
26. Zenda S, Uchitomi Y, Morita T, Yamaguchi T, Inoue A. Establishment of a research policy for supportive and palliative care in Japan. Jpn J Clin Oncol. 2021;51(4):538-43. doi: 10.1093/jjco/hyab008, PMID 33561254.
27. Almarsdóttir AB, Kaae S, Traulsen JM. Opportunities and challenges in social pharmacy and pharmacy practice research. Res Soc Admin Pharm. 2014;10(1):252-5. doi: 10.1016/j.sapharm.2013.04.002.
28. Brouwers MC, Kerkvliet K, Spithoff K, AGREE Next Steps Consortium. The AGREE reporting checklist: A tool to improve reporting of clinical practice guidelines. BMJ. 2016;352:i1152. doi: 10.1136/bmj.i1152, PMID 26957104.
29. Moss F, Thompson R. A new structure for quality improvement reports. Qual Health Care. 1999;8(2):76. doi: 10.1136/qshc.8.2.76, PMID 10557680.