Journal of Optimization in Industrial Engineering,
Vol.17, Issue 1, Winter & Spring 2024, 183-188
DOI: 10.22094/QJIE.2024.951267

Research Article

Assessing the Influence Factors of Audit Fatigue and its Impact on Audit Quality

Siti Zaharah Yacob [a], Sallaudin Hassan [b]*

[a,b] *Universiti Kuala Lumpur - Malaysian Institute of Industrial Technology (UniKL MITEC), Pasir Gudang, Johor*

Received: 03 February 2024; Revised: 07 March 2024; Accepted:16 April 2024

Abstract

The thesis is intended for investigating the relationship between audit fatigue and audit quality in the pharmaceutical company. The pharmaceutical industry, being as one of the highly regulated industry face stringent requirements by the regulatory body where the company must comply with minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations will provide assurance mechanism that a product is safe for use, and that it has the ingredients and strength it claims to have. However, limited literature is observed in studying the audit fatigue especially with regards to its contribution factor. Several studies and literatures are reviewed, and it was found that most of the literatures are indicating framework of the integration, benefits and type of integration that can be conceptualized and implemented. This research aims to explore the relationship between audit frequency, internal audit management, system workload/ employees’ experiences and audit fatigue. In addition, impact of the audit fatigue on audit quality/ audit outcome shall be investigated and subsequently a conceptual framework will be proposed as per identified hypotheses. Five out of seven hypotheses were supported in the study. The structural model result shows that there are significant and direct effects in the relationship between audit fatigue, audit frequency, workload, and audit quality. The framework developed in this study was able to contribute to the limited body of knowledge in audit fatigue.

Keywords:

1. Introduction

The pharmaceutical sector is one of the industries with the stringent regulations and faces rigid requirements that are set by the regulatory bodies (Adamec et al., 2009; Campos e Reis et al., 2013; Poblete García et al., 2013). Events in the past decade have demonstrated that poorly controlled pharmaceutical manufacturing can have adverse effects on users, and, in some cases, have led to the death of a significant number of people when they were provided. Conducting an audit of a pharmaceutical company ensures that CGMP (current Good Manufacturing Practice) requirements are being met, provides the company an advantage over its competitors, supports necessary product-security programs, and facilitates entry into a new market place. This is resonated by Agarwal and Mishra (2019), who state that a quality audit is an instrument for evaluating compliance with the defined objectives

defined in the quality management system and must be able to establish its ability to produce consistent products where the validated processes are dependable and optimal. In other meanings, the company is able to control the quality of its product and processes in the context of its quality control and quality assurance enforcement.

Audit fatigue is defined as the result of duplicating efforts because of numerous audits that result in high costs and effort (Khalid M. et al., 2020). Audit fatigue not only audited people, potentially compromising the quality of the information gathered by the auditor and making the company's information less beneficial. If the auditors are unable to acquire compelling information as requested, the audit would likely result in a negative outcome, and all attempts to perform it will be pointless.

The auditor's judgment influences both the quality and the efficiency of the audit (Janvrin & Bierstaker, 2015). Auditee's side, the audit quality will be severely affected. There have been instances in which businesses have declared bankruptcy only a few short months after getting audit findings (Mareque et al. 2015).

Although research on audit fatigue remains less explored by other researchers, Khalid et. al. (2020) proposed a conceptual framework for audit fatigue, in which it portrays correlation between audit frequency and audit outcomes. As the possibility of having multiple audits is unavoidable by the organization, the main questions are how the organization can prepare themselves by managing the factors of the audit fatigue and what is the impact of audit fatigue on the audit outcome. By placing appropriate mitigations, the organization can avoid cost of compliance and ensure survival of the organization in a long run.

The focus of this study is of pharmaceutical organization in Malaysia. The pharmaceutical industry is one of the new growth areas that the government plans to encourage and cultivate in the future. The pharmaceutical industry in

Corresponding Author Email Address: sallaudin@unikl.edu.my

Malaysia produces over the counter (OTC) goods, traditional treatments, nutritional supplements, and drugs that require a doctor's prescription. Generic pharmaceuticals, traditional cures, and herbal supplements are all produced by the pharmaceutical companies, in addition to contract production for international multinational corporations (MNCs).

The focus of this study is of pharmaceutical organization in Malaysia. The pharmaceutical industry is one of the new growth areas that the government plans to encourage and cultivate in the future. The pharmaceutical industry in Malaysia produces over the counter (OTC) goods, traditional treatments, nutritional supplements, and drugs that require a doctor's prescription. Generic pharmaceuticals, traditional cures, and herbal supplements are all produced by the pharmaceutical companies, in addition to contract production for international multinational corporations (MNCs).

In order for researchers to analyze the problem of audit fatigue, three pharmaceutical companies in Malaysia were selected for the study. The essential criterion that is taken into consideration during the process of developing the scope of the research is the company that has been subjected to several audits by a variety of regulatory agencies. However, due to confidentiality concerns, the name of the companies will not be disclosed in this study.

This research aims to contribute to the current body of knowledge by investigating the relationship between audit frequency, internal audit management system, audit workload, and audit fatigue in the pharmaceutical industry. By establishing the relationship between the aforementioned variables, the study's findings will help to experimentally address the problem statements that have surrounded the subject. Since the audit fatigue issue is rarely acknowledged by industry participants and academics, the findings of this study may be useful to other pharmaceutical businesses.

2. Literature Review

2.1 Audit fatigue.

While searching for literature on audit fatigue, the first reflection is that there is limited scholarly literature about audit fatigue specifically. The available literature outlines the problem facing the supply chain industry, but none offer any in depth study on critical factor that impart significant effect on the audit fatigue. Although conceptual framework on audit fatigue is present, in-depth understanding on its factor and impact remains vague and poorly understood.

Many literatures available are focusing on necessary measures in preventing and minimizing the audit fatigue, but there is no further study on effect of the audit fatigue. For example, study conducted by J. Fraser et. al., (2020) was suggesting various approaches such as sustainability framework and integrated audit system as methods for reducing the audit fatigue. These are further espoused by Khalid M. et. al. (2020) where the authors highlighted the existing scholar literatures are not further analyzing and elaborating impact and antecedent of the audit fatigue.

Khalid M. et. al. (2020) stated that audit fatigue can be summarized as an outcome from duplication of efforts because of numerous audits which resulting in high costs and effort. The authors also highlighted that audit fatigue situation is not only adversely influence auditors' morale, but it is also impacting the morale of audited personnel where it might affect quality of information that the auditor gathers and renders limitation in the usefulness of the information organization can use. The inability of providing compelling information as requested by the auditors will be resulted in negative outcome on the audits and caused all efforts for the audit to be wasted. Therefore, it seems imperative to find a sustainable method in mitigating audit fatigue.

Although research on audit fatigue remains less explored by other researchers, Khalid et. al. (2020) proposed a conceptual framework for audit fatigue, in which it portrays the relationship between audit frequency, audit fatigue and audit outcomes. The authors also described the relationship of the audits on culture of audits where a new term called as "sustainability fraud" was emerged as a result from audit fraud. The conceptual framework proposed by these authors are depicted as per Figure 1.

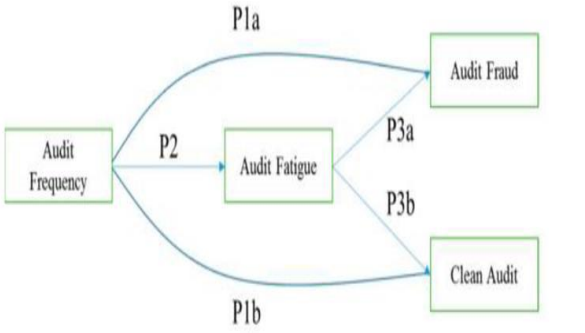

Fig. 1. Conceptual Framework of Audit Fatigue (Khalid et al., 2020)

Based on the conceptual framework, the authors discussed thoroughly on concept of the audit fatigue, factor and impacts on outcome of the audit. Khalid et. al. (2020) discussed how most of the organization faced audit fatigue but somehow it is remained less explored by the research scholars. The authors also stated the audit fatigue is able to steer the auditee from the true purpose of the audit. This will further influence them to view the audit process as routine tasks that do not require to be completed promptly. Based on this, the authors come up with the hypothesis on audit fraud where once the audit fatigue sets in, the auditee might present wrongful claim, data, and documentation to the auditor.

2.2 Audit frequency.

Frequency can be defined as the rate of occurrence of an item or event. Therefore, in this context, audit frequency can be referred to as the rate of occurrence of audit in an

organization or system. In context of supply chain management, high number of audit frequency is a common thing where the supplier is subjected to multiple audits as a part of the client's requirement. Several researchers, including Khalid et al. (2020), I. J. Fraser et al. (2020), and LeBaron et al. (2017), have demonstrated that audit frequency has a positive correlation to audit fatigue. This demonstrates that audit frequency is directly related to audit fatigue.

Similar context in terms of audit frequency can be observed in the pharmaceutical industry. The pharmaceutical company will be subjected to multiple audits by the regulatory bodies and also government agencies such as FDA, EMA and also NPRA (in Malaysia). This is also supported by studies made by Ubohov et. al., (2019) and Jørgensen et. al. (2006) where the authors discussed the audits faces by a pharmaceutical company by the multiple regulatory bodies.

2.3 Internal audit management

Internal audits are meant to help pharmaceutical companies figure out how well they follow the Pharmaceutical Quality System's principles and criteria for good practices. (Lebedynets et al., 2019a). Internal audits should be done regularly and according to detailed procedures that have been set up. (Agarwal & Mishra, 2019).

Internal auditing is comparable to external auditing in terms of its fundamental procedures. In turn, the steps pharmaceutical companies take to plan, organize, and carry out an external audit of their suppliers and customers are similar to the main requirements for planning, organizing, and carrying out official inspections in the guidelines from the PIC/S, the EMA, and the FDA (Agarwal & Mishra, 2019).

21 CFR 211 contains no specific requirement for internal audits, but this system is present in every well- managed pharmaceutical company. A company without a robust internal audit system is at the mercy of regulators and subsequently, customers can discover GMP deviations which should have been known about and addressed (Valeriy Nikityuk et al., 2019). If a company chooses to ignore a well-supported internal audit conclusion, it will hurt its audit readiness and GxP system (Tsvetanova, 2014).

When the benefits of internal audits outweigh the expenses or efforts required to implement them, value is created. Directly or indirectly, an internal audit can add value in the following areas: efficiency, quality, timeliness, cost reductions, regulatory compliance, and better monitoring. This is echoed by studies conducted by Mahzan and Yan (2014) and Hyland and Beckett (2002) where the authors highlighted the importance of the internal audit in the context with a proper internal audit management.

In the pharmaceutical context, the internal audits allow the organization to gain a greater understanding of any operational problems and non- compliance areas, such as repeated deviations, inadequate CAPAs, and other problems related to drug safety, quality, and efficacy.

2.4 Workload

Different pharmaceutical companies have different level of complexity of the system which is depending on the process complexity. The maturity of GxP adoption differs between organizations. Hence, the amount of work needed to get ready for an inspection range from a full examination of the whole system, like getting a manufacturing site ready for its first GMP inspection, to an evaluation of a specific system with a negative trend.

The latter condition is definitely caused by a particular problem, and the approach that it will follow is going to be quite similar to the CAPA technique and the analysis of the deviation (Linna et al., 2008). The first scenario calls for a strategy that is more all- encompassing and methodical, and in many instances, it will result in the evaluation of a specific region and system based on the evaluation of the entire system. In a similar way, while looking into a single problem, a systemic flaw may be found. This means that the whole thing needs to be looked at.Work processes or services provided to customers will be hindered if employees are overburdened. The term "work morale" refers to an individual's or group's attitude toward the job they do in order to achieve their objectives. Since an attitude is defined as a willingness to act, it is more distinct. When people or groups make an effort to take part in all activities, it shows how they feel about work and the workplace (Wakhyuni & Sari, 2018).

The performance of a task demands some expenditure of effort, often including both mental and physical resources, leading to a progressive increase in fatigue and a commensurate decline in performance capability (MacDonald, 2003). As fatigue is viewed as a result of exertion, it was anticipated that it would be connected with workload (MacDonald, 2003). When predicted, fatigue ratings increased as workload and necessary work rate increased (which is closely linked, conceptually, to high workload). The connection between weariness and job satisfaction was unfavorable. Stress was also positively increased with work that was repetitive because the cycle time was short, which made people less excited and made it harder to keep up the required level of performance, and because of the boredom (MacDonald, 2003).

As a result of physical and mental exhaustion, continuous job pressure can lead to a decline in employee productivity. Low levels of productivity have an effect on not meeting production goals (Lastya Sari et al., 2021). Khalid et. al. (2020) describes that due to duplication in efforts for audit activity, the auditee has been pushed to the point where the audit activity is perceived as a mundane activity.

In addition to that, the authors also described that the once audit fatigue is set, the auditee will not be able to maintain their focus on the main goal of the audit and subsequently may impact the quality and transparency of data presented to the auditors. Hence, based on the previous studies above, the relationship of workload and audit fatigue is deemed interesting to be further explored.

2.5 Audit quality

The complexity of audit quality, according to Istianingsih (2020), precludes a single definition. As auditing is a service, and the amount of service supplied is unobservable, it is difficult to quantify audit quality objectively. The author claims that audit quality can be characterized as a theoretical perspective in which audit quality, which is measured by audit failures, ranges from low audit quality to high audit quality.

In pharmaceutical companies, failure in regulatory audit can impart many consequences such as product recall, damaged reputation, and worst, revoked in regulatory certification and cGMP licensing (Moy, 2009). In order to ensure positive audit quality, the organization must ensure the quality management system is at an optimal state. According to Khalil et. al. (2020), audit fatigue provides a significant impact on the audit quality where it is either promoting a clean audit or a fraud audit.

3. Methodology

A good research design is important in determining types of data, data collection method and sampling method. This is essential in ensuring accomplishment of the research objectives. This quantitative study employed a descriptive survey to identify the relationship between audit fatigue, audit frequency, internal audit management, workload, and audit quality.

A 7-Likert Scale questionnaire was utilized where it is consisted of six sections which Part A (Demographic), Part B (Audit Fatigue), Part C (Audit Frequency), Part D (Internal Audit Management), Part E(Workload) and Part F (Audit Quality). The scale is arranged by 1 to 7 which represents the level of agreement with the statement in the survey questionnaire. Scale 1 represents strongly disagree and 7 represent strongly agree. The Likert scale is reliable and has been widely used in the past research. The sections in the questionnaire are representing the five construct of the conceptual framework. Measuring items for all of the constructs are adapted and adopted from previous research. Pilot test was conducted as to ensure the measuring items are met the reliability test. The pilot test was conducted in a small scale where 24 respondents were participated. Cronbach's Alpha value obtained for each of construct. The value of Cronbach's Alpha obtained are more than 0.700, hence the measuring items are reliable and can be proceeded for real data collection.

4. Data Analysis and Discussion

Structural model involves the analysis on the relationship between laten constructs. In this stage, developed hypotheses shall be assessed accordingly. Hair et al. (2017) explained that the structural model examines predictive ability of the model and also relationship between the latent constructs. This stage involves collinearity assessment, significance and relevance tests, level of determination (R2), effect size (f2) and predictive relevance. Details of criterion for structural model is as explained by Hair et al. (2017). Significance and relevance test will determine whether the developed hypotheses are supported or not as outlined in Table 4. Out of 7 hypotheses, 2 hypotheses, H2 and H5 were not supported.

Table 1
Hypotheses testing result.

Hypotheses		β	T-Value (>1.96)	P Values (<0.05)	Supported?
H_1	Audit Frequency → Audit Fatigue	0.378	3.052	0.002	Yes
H_2	Internal Audit Management → Audit Fatigue	0.236	1.596	0.110	No
H_3	Workload → Audit Fatigue	0.248	2.262	0.024	Yes
H_4	Audit Fatigue → Audit Quality	0.546	5.752	0.000	Yes
H_5	Audit Frequency → Audit Fatigue → Audit Quality	0.189	2.467	0.014	Yes
H_6	Internal Audit Management → Audit Fatigue → Audit Quality	0.128	1.463	0.144	No
H_7	Workload → Audit Fatigue → Audit Quality	0.146	2.067	0.039	Yes

Findings in this research contribute to the body of knowledge of audit system in pharmaceutical industry. This study contributed to the literature by investigating the relationship between audit fatigue, audit frequency, internal audit management and audit quality by hypothesizing the existence of relationship between these

constructs. Since there are scarce literature on the relationship between these constructs, this research provides a new insightful platform to be explored by the scholars.

This study developed a scale for measuring the level audit fatigue, audit frequency, internal audit management, workload, and audit fatigue in the context of pharmaceutical organization. The survey instrument was tested and could be applied for another research in this field. Overall, the instrument that has been made can be utilized by other researchers in the future due to the fact that it has been validated, reliable, and verified by experts in the subject that it pertains to. In addition, the results of this research demonstrated that the quantitative survey instrument that was used is capable of producing significant results and can function as an efficient instrument for assessing the constructs.

This study provided valuable feedback from professional employees as a major stakeholder in audit management. The outcomes from this research could act as a reference and possible as a north star in guiding the top management during strategies development in improving the audit fatigue. The top management is also able to make decisions in improving the audit system. This will help in curbing the audit fatigue faced by the employees. This study has successfully proved the direct relationship between audit fatigue and audit quality. The audit quality is important in ensuring competitiveness and relevancy of an organization in the global market.

In addition, audits are widely acknowledged as an essential instrument for management in the pursuit of continuous improvement. It is an essential part of any successful organization and offers suggestions for enhancement. Audits are absolutely necessary in order to evaluate how effectively processes have been put into place. It was successful in reaching any and all predetermined effectiveness targets. Employees and managers will begin to view auditors as productive members of the business rather than as police officers when they begin to view audits as opportunities to enhance processes rather than as checks and balances. Any improvement made to an organization will reflect positively on its staff, its program, and its profession. Hence, handling of audit fatigue in an organization will benefit the organization.

Second, this study has developed a quantitative survey instrument which has been tested its reliability and validity. Thus, this instrument is fit to be used to obtain feedback of the employees with regards to audit fatigue. The indicator of the constructs is able to provide a very useful information for corporate planning and quality department of the organization. Having these important constructs as a tool of gaining the response from the employees will ease the management in data collection. The instrument is arranged in a systematic and structured way which will ease management for data analysis and presentation.

5. Conclusion

Based on the employees' perceptions of audit fatigue, this study provides significant information to the management of pharmaceutical organizations from a practical standpoint. As a contribution to the management team, audit fatigue is highlighted as a significant variable capable of influencing audit quality. There is also empirical evidence that workload and audit frequency have a direct and significant association with audit fatigue. In this competitive business, these inputs are useful for managers of pharmaceutical organizations to build appropriate strategies for continuous improvement.

Acknowledgement

Thank you to Post Graduate (PG) section and master project teams for all supports in completing this study.

Reference

Hair Jr, J. F., Hult, G. T. M., Ringle, C., and Sarstedt, M. (2013). A primer on partial least squares structural equation modeling (PLS-SEM). USA: Sage Publications.

Hair, J. F., Anderson, R. E., Tatham, R. L. and Black,W. C. (2006). Multivariate analysis. Prentice-Hall, London.

Hair, J. F., Black, W. C., Babin, B. J. and Anderson, Rolph E. (2010). Multivariate Data Analysis: A Global Perspective (7th ed.). New Jersey: Pearson.

Hair, J. F., Ringle, C. M., and Sarstedt, M. (2011). PLS-SEM: Indeed a silver bullet. The Journal of Marketing Theory and Practice, 19(2), 139-152.

Hair, J., Anderson, R., Tatham, R., & Black, W. (1995). Multivariate data analysis with readings (4th ed.). Englewood Cliffs: Prentice-Hall International.

Hair, J.F., Hult, G.M., Ringle, C.M., and Sarstedlt, M. (2017). A primer on partial least squares structural modelling (PLS SEM). USA: Sage Publication, Inc.

Henseler, J., Ringle, C. M., & Sarstedt, M. (2015). A new criterion for assessing discriminant validity in variance-based structural equation modeling. Journal of the Academy of Marketing Science, 43(1). https://doi.org/10.1007/s11747-014-0403-8

Hosseinzadeh A, Yektadoost A, Hozouri H, Dinarvand R, Kebriaeezadeh A. Quality Assurance Status in Iranian Pharmaceutical Industry: A Survey. JPPM. 2015;1(1/2):14-21.

Hyland, P., & Beckett, R. (2002). Learning to compete: The value of internal benchmarking. Benchmarking, 9(3). https://doi.org/10.1108/14635770210429036

Ikart, E. M. (2019). Survey Questionnaire Survey Pretesting Method: An Evaluation of Survey Questionnaire via Expert Reviews Technique. Asian Journal of Social Science Studies, 4(2). https://doi.org/10.20849/ajsss.v4i2.565

Istianingsih. (2020). The Effect of Corporate Social Responsibility and Good Corporate Governance on Pharmaceutical Company Tax Avoidation in Indonesia. Systematic Reviews in Pharmacy, 11(12). https://doi.org/10.31838/srp.2020.5.140

Janib, J., Rasdi, R. M., Omar, Z., Alias, S. N., Zaremohzzabieh, Z., & Ahrari, S. (2021). The Relationship between Workload and Performance of

Research University Academics in Malaysia: The Mediating Effects of Career Commitment and Job Satisfaction. Asian Journal of University Education, 17(2). https://doi.org/10.24191/AJUE.V17I2.13394

Krejcie, R.V., D.W. Morgan, 1970. Determining Sample Size for research activities. Educational and Psychological Measurement, 30, 607-610.

Lastya Sari, D., Storyna, H., Intan Putri Sinaga, R., Gunawan, F. E., Asrol, M., & Perwira Redi, A. (2021). the Relationship Between Job Stress and Employee Performance in Manufacturing Industry in Indonesia. Journal of Academic Research and Sciences), 6(2).

Lebedynets, V., Kotvitska, A., & Karmavrova, T. (2019). The PDCA cycle implementation at the internal audit process of quality management systems of pharmaceutical companies. The Pharma Innovation Journal, 8(2).

Macdonald, W. (2003). The impact of job demands and workload on stress and fatigue. In Australian Psychologist (Vol. 38, Issue 2). https://doi.org/10.1080/00050060310001707107

Meyers, L. S., Gamst, & A.J. Guarino, A. J. (2016). Applied Multivariate Research: Design and Interpretation (Third Edition). Sage Publication.

Moy, A. (2009). EMEA and FDA approaches on the ICH Q10 on pharmaceutical quality system. In Pharma Times (Vol. 41, Issue 8).

Patel, D. S., Patel, A. R., & Patel, N. A. (2012). The FDA cGMP Inspection is Coming: Make the Best of It. Journal of GXP Compliance, 16(4).

Pratama, W. (2019). Perception of Auditors and Auditee on Public Sector Performance Audits. Policy & Governance Review, 3(1), 60-72. doi:10.30589/pgr. v3i1.12

S Kannan, S R Morais, S Prema, K. Chitra (2020), "Auditing as A Management Tool in Pharmaceutical Companies", International Journal of Pharmacy and

Sallehuddin, M., Huzaidy, H., & Rosli, N. M. (2019). The Relationship between Stress, Workload and Time Management towards Academic Performance among Working Postgraduate in Universiti Utara Malaysia (UUM). In American International Journal of Business Management (AIJBM (Vol. 2, Issue 11).

Tsvetanova, Y. (2014). Features of internal audit in pharmaceutical industry. In Pharmacia (Vol. 61, Issue 2).

Ubohov, S. H., Trokhymchuk, V. V., Todorova, V. I., & Zahoriy, V. A. (2019). Process model of the pharmaceutical integrated management system. Wiadomosci Lekarskie (Warsaw, Poland: 1960), 72(2). https://doi.org/10.36740/wlek201902112

Valeriy Nikityuk, Tetiana Karamavrova, & v. Lebedynets. (2019). The Self-inspections (Internal Audits) Process as a Part of the Pharmaceutical Quality System: Formation of a Risk-Based Approach to Internal Audits Planning. Journal of Pharmacy and Pharmacology, 7(7). https://doi.org/10.17265/2328-2150/2019.07.004

Wakhyuni, E., & Sari, D. S. (2018). An Empirical Investigation of the Effect of Workload and SOPs on Employees Work Morale. International Conference of ASEAN Perspective and Policy, 1(1).

Wong, K. K. K. (2013). Partial Least Squares Structural Equation Modeling (PLS-SEM) Techniques Using SmartPLS. Marketing Bulletin, 24.

Xiao, T., Geng, C., & Yuan, C. (2020). How audit effort affects audit quality: An audit process and audit output perspective. China Journal of Accounting Research, 13(1), 109-127.