Examining Availability of a Packaging Unit: A Pharmaceutical Case

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Abstract

In this paper, an oral solid dosage (OSD) packaging unit in a reputed pharmaceuticals company of Bangladesh is thoroughly investigated for its present availability level and a practical approach to improve the same is pursued. Such work is a new practice from the context of the pharmaceutical industry in Bangladesh. Availability is one of the three factors upon which overall equipment efficiency (OEE) depends. It is found that lower availability of machines acts as the main culprit behind the overall lower availability value in OEE for the considered OSD packaging unit. However, machine availability – defined as the ratio of machine uptime and the summation of machine uptime and machine downtime – depends on many external factors that are liable for unfavorable machine downtime and uptime. Maintenance personnel index (MP), task severity index (TS), and daily maintenance index (DM) are identified as the external factors crucial to the availability of the Blister packaging machine in the considered OSD unit. The interpretations of these three indices are in detail demonstrated for the considered packaging section. For determining the complex relationship between the mentioned three indices and machine availability, a model trained by an artificial neural network (ANN) using field data is used. Using the trained model, the values of these three indices that result in the various availability values in the desirable range are determined. Finally, which values of these three indices can be practically attained with respect to their present values are discussed briefly.

Keywords
Machine availability, Overall equipment efficiency (OEE), Artificial neural network (ANN).

1. Introduction

In this competitive business environment, companies are always trying for performance improvement. One of the factors on which the companies always hunt for is the availability and performance of their production machine equipment. In developing countries like Bangladesh lack of skilled machine operators and maintenance personnel hamper the quality of maintenance activity which results in low performance and availability of machine equipment. Overall equipment efficiency (OEE) gives information about the performance and productivity of a production process. The improvement in the effectiveness of the equipment can also be monitored through OEE. Literature considering OEEE is not so vast. Lesshammar et al. (1999) studied the OEE measure, but evaluated it from the overall systems level and developed a framework for evaluating overall manufacturing performance measurement systems. Dal et al. (2012) performed a practical analysis of OEE as an operational improvement in Airbags International Limited. Besides, Eti et al. (2004) implemented total productive maintenance (TPM) in a Nigerian company to improve OEE. These are some of the very few literature focusing on OEE evaluation. OEE is calculated by multiplying the three OEE factors: availability, performance, and quality. Availability takes into account all events that stop planned production; machine failure is one of them. Thus, machine availability is one of the factors of availability while calculating OEE. Machine Availability or production uptime is the part of active time during which a machine equipment or system is either fully operational or actual production is going on. A case study on the reduction of the machine downtime on engine cylinder block production line by analyzing and improving the available PM schedule and thus improving operational availability of machines was performed by Tejas S. Kolte et al. (2017). Reineke et al. (1999) showed a way to deal with the problem of determining the appropriate age preventive maintenance policy for a complex system that has high availability requirements. However, the techniques to improve machine availability also include storing more spare parts, better training of workers and engineers, usage of high-reliability instruments, computerized on-line techniques, expert systems/artificial intelligence techniques, etc. Marty et al. (1993) showed some techniques on selecting optimum availability and no loss availability as expending too much on maintenance activities can result in net losses. The effect of several external factors on reliability, availability and maintainability (RAM) was first studied by Rajpal et al. 2006. An artificial neural network (ANN) model for assessing the effect of input parameters on a composite measure of reliability, availability and maintainability (RAM) of a repairable system was developed by them where eight external factors were considered that contribute to RAM. However, their work was for the airline industry. In this paper, we have utilized their technique in line with the pharmaceutical industry.

This study in detail investigates the lower availability of a packaging section in a pharmaceutical company from scratch, studies the corresponding principal contributors, and comes up with a practical solution approach to the existing lower availability problem. Pareto analysis is conducted first to trace the factors mainly affecting the availability level in OEE. Then, through an extensive study of the packaging system, the most frequently failed machine parts are discovered as the main culprits for lower availability. Thus, studying a system and discovering the root causes is one of the main contributions of this study. Another main contribution of this study is exploring a way to correlate the outputs from man and machine with the corresponding values of machine availability, which is a very new practice in the pharmaceutical industry in Bangladesh. We have first identified three principal external factors (task severity index (TS), maintenance personnel index (MP), daily maintenance index (DM)) accountable for the lower machine availability in the packaging section and then defined them from the considered section perspective. Next, we have utilized the relevant data regarding the performance of man and machine available in the company to determine the values of those three external factors as well as the corresponding machine availability for the last twenty-four months. Using ANN, we finally search for the range of the values of the external factors that can engender the machine availability values, which are desirable as well as feasible from the present context of the considered company.

The rest of the paper is outlined as follows: section 2 of this paper includes the basic concepts review, section 3 includes the detail case study, and the implication of the findings and section 4 concludes the study with future scope.

2. Basic Concept Review

2.1 Overall Equipment Efficiency (OEE)

OEE is used for measuring manufacturing productivity. It identifies the percentage of manufacturing time that is truly productive. It is the product of availability, performance, and quality. An OEE score of 100% means the company is manufacturing only Good Parts, as fast as possible, with no stop time. In other words, 100% OEE means 100% quality (only Good Parts), 100% performance (as fast as possible), and 100% availability (no stop Time). OEE is the single best metric for identifying losses, benchmarking progress, and improving the productivity of manufacturing equipment (i.e., eliminating waste). The equation used to calculate OEE is:
OEE = Availability × Performance × Quality

2.2 Availability and Machine Availability

Availability takes into account all events that stop planned production long enough, where it makes sense to track a reason for being down (typically several minutes). Availability is calculated as the ratio of run time to planned production time. Run time is planned production time minus unplanned downtime. Planned production time is the time actually needed to finish the batch minus planned downtime. Unplanned downtime can happen for many reasons, one of which is the failure of the machine components. Such failure of the machine components leads to the machine unavailability for production. The time between the failure of the machine components and the restoration of the machine to its working state is known as downtime of the machine while the time between the new operating conditions of the machine and its next failure is known as the uptime. The more the downtime is, the more the machine is unavailable for production. Thus, machine availability can be defined as the ratio of machine uptime to the sum of machine uptime and machine downtime. Defining machine uptime and downtime as the mean time between failure (MTBF) and mean time to restore (MTR), respectively, we get the following widely used definition of machine availability. MTR can be defined as the summation of supply delay time, maintenance delay time, and repair time.

Machine availability = $\frac{MTBF}{MTBF + MTR}$

2.3 Artificial Neural Network (ANN)

Artificial neural networks (ANN) systems "learn" to perform tasks by considering examples, generally without being programmed with any task-specific rules. Neural networks consist of input and output layers, as well as (in most cases) a hidden layer consisting of units that transform the input into something that the output layer can use. They are excellent tools for finding patterns that are far too complex or numerous for a human programmer to extract and teach the machine to recognize. They are designed for spotting patterns in data. Specific tasks could include classifying data sets into predefined classes), clustering, and prediction using past events to guess future ones (Zurada, 1992).

3. Case Study

3.1 Problem Description

The study has been performed on the Oral Solid Dosage department of a reputed Pharmaceuticals Limited. This department produces medicines which are orally consumable. The produced medicines are in the form of tablets or capsules. The tablets are produced in the compression unit. The tablets are then carried to the Blister Packaging machine of the packaging unit followed by their production. The Blister Packaging machine used by this company has six consecutive sections: forming, feeding, sealing, code embossing, perforation, and punching. The forming section forms small pockets in the hot-rolled PVC or aluminum sheet using high-speed air jets. The feeding section simultaneously feeds the tablets and the pocket formed sheets. The sealing section seals the tablets into the pockets. The code embossing section embosses the company logo and other required information of the medicine on the sealing sheet. The perforation section creates small cuts on the sheet to facilitate the separation of the blisters. Finally, the punching section separates the blisters by punching. The machine cuts two blisters per stroke. Each blister contains ten tablets. So, in each stroke, a total of 20 tablets are packaged.

In studying the packaging of several batches of tablets, data regarding planned and unplanned downtime as well as the number of rejected tablets are recorded. These data include rpm of the machine, cutting per stroke, number of blisters per cut etc. We have used these data to calculate the overall equipment efficiency of the machine. The average values of the OEEE factors and the corresponding OEE are determined next. Among the factors, availability, performance, and quality have values of 0.718, 0.738, 0.9897, respectively, and resultant OEE is 52.51%. We have focused on the lowest of them, i.e., the average value of availability. Availability is low mainly due to recurring failure of different spare parts of the machine that consequently results in high unplanned downtime as explored in the next section (Section 3.2) through Pareto analysis in detail. Thus, it is observed that machine-related availability mainly affects the availability factor of OEE for this particular case. To deal with this problem, in this study, we have pursued a practical approach to come up with pertinent solutions.

3.2 Sorting out the Main Culprits through Pareto Analysis

Data are gathered from the maintenance logbook to find out the frequency of the failure of the spare parts and other interrupting causes of production downtime. Pareto analysis is then conducted to find out the main contributing factors. Figure 1 represents the findings of the Pareto analysis. From Pareto analysis, we can find that the motor belt problem, lack of readiness of tablets, web clamp problem, improper forming, and erroneously spotting the tablet during packaging mainly contribute to the production downtime. Among them, only lack of readiness is not a machine-related problem as it depends on the performances outside of the packaging section. Hence, the lack of readiness for tablet consideration is out of the scope of this study. Moreover, it is invented that for the issues considered, only a few specific spare parts are liable as they occur the majority of the machine downtime. Using the 80-20 principle, a conclusion is made that the failure of three specific parts of the machine accounted for almost 80 percent of the production downtime. The parts in question are motor belt, webcam, and air hose liable for forming problems. Next, the present availability of the machine through these three frequently failed parts is calculated with the corresponding confidence level. The value of this present machine availability is only 30.84% with the corresponding confidence level ranging from 21% to 70% only as calculated by generalized *p*-value approach. In calculating machine availability, exponential distribution and lognormal distribution are used for mean time to failure (MTBF) and mean time to repair (MTTR), respectively, which is supported by the statistical testing of the field data.

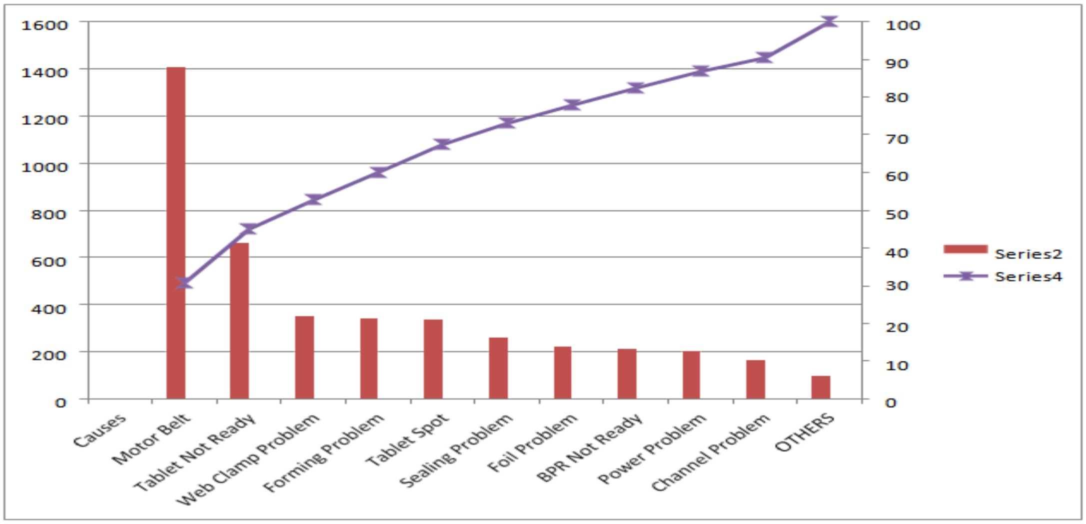

Figure 1. Pareto analysis

3.3 Introducing External Factors

As we can see that the present machine availability is very low. The low machine availability can be traced back to two broad factors: internal factors and external factors of the considered blister packaging machine. Internal factors include machine design, machine specifications and intrinsic properties of the blister packaging machine. Dealing with internal factors is no way a practical approach from the company perspective. This is because the company uses specific machines throughout the whole packaging section, which are of reputed brands. Thus, we do have control over the mentioned external factors only to investigate lower machine availability. As external factors, we consider mainly three factors: maintenance personnel index (MP), task severity index (TS), daily maintenance index (DM). We can also consider other external factors as introduced by Rajpal et al. (2006) and Rajpal (2014). However, for the considered case, the effects of those factors are assumed to be negligible. These external factors are quantifiable and directly affect the availability of the machine. In this paper, we specifically focus on improving low machine availability through these external factors. Maintenance personnel index, daily maintenance index and task severity index – the three external factors we have concentrated – are explored in detail next from the perspective of our considered pharmaceutical company.

Maintenance Personnel Index: A Likert scale is used to quantify the maintenance personnel index specifically applicable for the considered case. The index depends on three factors which are: competence, performance and availability of the maintenance personnel. The individual points from three factors are added to determine the value of this index. The highest value that can be achieved in this index is 12. These indices are presented next in brief.

The Likert scale to measure competence for maintenance personnel working in the considered company has been formulated as follows:
Scale 0 - None: The maintenance employee has just joined the company. He has studied the information, ideas and situations related to the emergency maintenance activities; however, he has not yet had an opportunity to practice it. He has been in the newly joined department for a minimum time of 1 year.
Scale 1 - Limited: The maintenance employee just started to find opportunities to work inside the packaging unit on machinery like the Blister machine. He is making initial assessments of what is expected from his role. However, his understanding of the impact of his actions is limited. He has the knowledge of the basics but he needs to improve in his work.
Scale 2 - Basic: The maintenance employee now can perform some emergency activities on his own but he needs someone senior to accompany him. He can assess correctly what needs to be done and knows the consequences of

his actions if something goes wrong. He engages in conversations with others about how he can perform the intricate maintenance activities efficiently.
Scale 3 – Proficient: The maintenance employee now performs regular maintenance activities on his own without needing the supervision from anyone senior. He has the ability now to train the young maintenance employees of the company. He has already performed some complex emergency maintenance successfully, but he knows he can do it more efficiently.
Scale 4 - Expert: The maintenance employee has an overall mastery of maintenance competency. He understands and demonstrates it all through the company. He is considered to be a role model by others and regularly exceed expectations. He can perform regular maintenance activities with high efficiency with very high or exceptional quality and has a significant impact on the production of the company. He can successfully deal with intricate unplanned emergency maintenance activities and can deliver in any situation.

The Likert scale to measure availability for maintenance personnel working in the considered company has been formulated in the below fashion:
Scale 0 - Absent: The maintenance employee tends to be absent frequently without any justified reasons. If an employee is found to be absent at the workplace for more than 7 working days, and cannot be found in emergencies he falls in this category.
Scale 1 –Very Poor: The maintenance employee tends to be absent due to sickness or other unexplained reasons and he is never on time. However, he can be found to execute the maintenance tasks on the days he is present. He is genuinely committed to the workplace and understands his importance as an employee.
Scale 2 – Moderate: The maintenance employee is found to be present on every shift of his working day. He tries to be on time but frequently gets late. He can be found to execute emergency maintenance tasks when needed. He is motivated and sometimes works on the shifts he is not assigned to, however, just for the need of the company.
Scale 3 - High: The maintenance employee is never absent or late at the workplace. He is even ready to work on the shifts he is not assigned to if his expertise is needed. He is almost always available. He has the confidence of his superiors and accepts to work both in preferred time and on-call times.
Scale 4 - Excellent: The maintenance employee is highly regarded by his co-workers, respected by the juniors and is referred to as a role model for workplace availability. He is almost always available and the company needs his expertise in emergency situations. He comes forward willingly in times of need and leads the emergency maintenance tasks. He never misses his shifts and is never late. He understands the importance of his role in running the company.

The Likert scale to measure performance for maintenance personnel working in the considered company has been formulated.
Scale 0 – Below Average: The maintenance employee just started to find opportunities to work inside the packaging unit on machinery like the Blister machine. He is making initial assessments of what is expected of his role. But his understanding of the impact of his actions is limited. He has knowledge of the basics but he needs to improve in his work. He has successfully completed at least two years of active maintenance in this company.
Scale 1 - Average: The maintenance employee now can perform some emergency activities on his own but he needs someone senior to accompany him. He can assess correctly what needs to be done and knows the consequences of his actions if something goes wrong. He engages in conversations with others about how he can perform the intricate maintenance activities efficiently.
Scale 2 - Above Average: The maintenance employee now performs regular maintenance activities on his own without needing supervision from anyone senior. He has the ability now to train the young maintenance employees of the company. He has already performed some complex emergency maintenance successfully, but he knows he can do it more efficiently. He usually meets the expectations of his seniors regarding maintenance and he looks for ways to implement his knowledge on new machines.
Scale 3 - Excellent: The maintenance employee has successfully completed at least five years of active maintenance in this company. He demonstrates responsibility, efficiency, and teamwork in his daily maintenance activities. He has previously successfully dealt with several unplanned emergency maintenance situations and is regarded highly by both superiors and juniors.
Scale 4 - Exceptional: The maintenance employee has achieved mastery in both regular and unplanned maintenance tasks. He does the tasks with the utmost efficiency. In dealing with unplanned and intricate maintenance tasks he is always consulted due to his expertise. He can lead a maintenance team with effective teamwork and oral communication. He provides quality in his performance. He has successfully performed maintenance tasks in this company for at least ten years.

Task Severity Index (TSI): TSI for Blister packaging machine is used which depends on three factors: no stop packaging duration, number of starts, and stops during a batch packaging and packaging speed of the machine. The index is computed using the following relationship:

$$TSI = \frac{\bar{a}}{\hat{a}} + \frac{\bar{b}}{\hat{b}} + \frac{\bar{c}}{\hat{c}}$$

where $\bar{a}$, $\bar{b}$ and $\bar{c}$ are average values of no stop packaging duration, number of starts and stops during a batch packaging and packaging speed, respectively and $\hat{a}$, $\hat{b}$ and $\hat{c}$ are their corresponding threshold values. For example, if the thresholds values are 4 hours, 3 start-stops and 25 blisters per minute, respectively and the average values are 6 hours, 10 start-stops and 30 blisters per minute, respectively, TSI has a value of 6.03.

Daily Maintenance Index (DM): Besides the above mentioned two external factors, the daily maintenance index is another factor affecting the availability, which is defined as the ratio of total daily maintenance time to the total operation time. Generally, this index should have a value between 0.14 and 0.162.

3.4 Training through ANN and Prediction:

Our next challenge was to form a relationship between machine availability and the considered external factors as the corresponding relationship is quite complex. For building this relationship, we consider maintenance personnel index, daily maintenance index. and task severity index as the input variables and the machine availability as the output variable. ANN is then used to have a trained model that depicts the desired complex relation. However, note that we have not obtained the necessary data of any of the input variables readily as the company had no prior conception about the external factors we have just defined. However, fortunately, for monitoring purposes, the company keeps the detail records of when, where, and how the machines fail as well as all data regarding the performance of the operational and maintenance personnel. We have utilized those records to translate them for determining the values of three indices (MP, TS, and DM) and the corresponding availability of the machine. Such utilization is one of the main contributions of this study as we mentioned earlier. The credit also goes to the company for having the practice of keeping track of the performance of man and machine as part of its disciplinary rules. The ANN tool in MATLAB is used to train the obtained data set. A network is developed which can predict the desired machine availability with the values of the considered three indices. Desired availability is targeted at least to be 60%. Therefore, which value of the three indices can give us our desired target availability is evaluated through several trials made on the trained artificial neural network model. Also, to obtain the availability greater than 60%, how the values of these three indices change is observed up to the 95% machine availability. All these findings are shown in Table 1.

Table 1. Predicted values of the desired availability with the corresponding target values of the indices

Target values			Predicted availability
MPI	TSI	DMI	
10.4	6	0.149	0.6
10.55	5.9	0.147	0.7
10.6	5.85	0.148	0.75
10.85	5.7	0.147	0.8
11	5.65	0.146	0.85
11.2	5.5	0.147	0.9
11.7	5.4	0.146	0.95

Based on the present values of the three indices, it will not be tough to achieve moderate availability values ranging between 0.6 and 0.75 for the specific company considered in this paper. However, naturally more intervention is required for more machine availability. Complexity may arise when the company strives for a higher availability than 0.75. For example, to achieve a high availability of 90%, the MP needs to be above 11. That corresponds to the fact that the personnel needs to be highly competent, excellent in availability, and exceptional in performance all at the same time. This is in some cases hard to achieve and can involve vigorous training and evaluation system. This, in turn, increases the expenditure of the company. In most cases, it can take a considerable amount of time to reach that level of expertise. And a similar conclusion can be drawn from other index values also. A low TSI value of 5.5 can be achieved through substantial financial investment. Further decisions lie solely on the upper management and the company stakeholders.

Here, one mention-worthy issue that although MP intrinsically entails the effect of maintenance delay time and MTTR for maintenance, the supply delay time is not directly included in the ANN training to eventually obtain the desired targeted availability; because it is yet to be defined how to incorporate the same. However, the unavailability of the spare parts resulting from the supply delay may directly hamper machine availability. How the required spare parts can be calculated for the determined target availability, though not explored in this paper, is expected to disclose in our future work in the same context.

4. Conclusion

The study demonstrates that how the improvement of some external factors of machine availability affects the desired machine availability level. This study is pursued for a packaging section of a reputed pharmaceutical company in Bangladesh. For such exploration, initially, the current availability of the system is determined. To find out the principal causes behind the present low availability, Pareto analysis is performed. This analysis finally shows that specific machine components are mainly responsible for the overall lower availability of the studied packaging section. Having defined the three external factors, namely personnel index, daily maintenance index, and task severity index, from the pharmaceutical company perspective, we have gathered their values for the last twenty-four months. However, these values were not directly available. Their values are shaped by utilizing the corresponding historical data available regarding the performance and operations of machines as well as the manpower required to maintain them. To establish the complex relationship between these external factors and corresponding machine availability, we have taken the help of artificial neural network that yields a trained model. This model is then used to obtain the target value of those external factors for the desired machine availability level. Moreover, how much machine availability can be attained from the current perspective of the company is discussed. In the future, extending this study, the researchers can determine the complex relation of machine availability influenced by the availability of the spare parts too.

References

Dal, B., Tugwell, P. and Greatbanks, R., Overall equipment effectiveness as a measure of operational improvement-a practical analysis. *International Journal of Operations & Production Management*, vol. 20 no. 12, pp. 1488-1502, 2000.

Eti, M.C., Ogaji, S.O.T. and Probert, S.D., Implementing total productive maintenance in Nigerian manufacturing industries. *Applied Energy*, vol. 79, no. 4, pp. 385-401, 2004.

Jonsson, P. and Lesshammar, M., Evaluation and improvement of manufacturing performance measurement systems-the role of OEE. *International Journal of Operations & Production Management*, vol. 19, no. 1, pp. 55-78, 1999.

Kolte, T.S. and Dabade, U.A., Machine Operational Availability Improvement by Implementing Effective Preventive Maintenance Strategies-A Review and Case Study. *Int. J. Eng. Technol.*, vol. 10, no. 1, pp. 700-708, 2017.

Reineke, D.M., Murdock, W.P., Pohl, E.A. and Rehmert, I., Improving availability and cost performance for complex systems with preventive maintenance, *IEEE Annual Reliability and Maintainability Symposium*, pp. 122-128, Washington, DC, January 1999.

Murty, A.S.R. and Naikan, V.N.A., Availability and maintenance cost optimization of a production plant, *International Journal of Quality & Reliability Management*, vol. 12, no. 2, pp. 28-35, 1995.

Rajpal, P.S., Shishodia, K.S. and Sekhon, G.S., An artificial neural network for modeling reliability, availability and maintainability of a repairable system, *Reliability Engineering & System Safety*, vol. 91, no. 7, pp. 809-819, 2006.

Zurada, J.M., *Introduction to artificial neural systems* (Vol. 8), St. Paul: West publishing company, 1992.

Rajpal, P.S., Reliability modeling of a complex repairable system, *2014 International Conference* on *Optimization*, *Reliability*, and *Information Technology* (*ICROIT 2014*), pp. 17-20, Faridabad, NCR, India, 6-8 February 2014.

Biographies

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