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ABSTRACT

This project aimed at investigating online damages of packaging materials generated during production because of imperfectness of production processes. These online damages may lead to upsurge in production cost and/or market returns, causing the company to experience losses and even damage its reputation. Data on online damages were collected for 20ml, 40ml and 100ml labels of an acaricide product for the period between July 2018 and June 2019 and statistically analyzed. Investigation was done on the causes of online damages, then corrective and preventive actions carried out. Analysis of online damages of labels of the three pack sizes revealed a loss of 1.01% on labels alone during the year under analysis. After implementing corrective and preventive actions, there was a reduction of online damages of labels.

Keywords: zero defects policy, defective items, imperfect production, root cause robustness, analysis of defects, IN state, OUT state, in-control, out-of-control, just-in-time

1. INTRODUCTION

This paper extends previous models of production process in relation to packaging materials that were issued for packaging processes. One product line with several stock keeping units (SKUs) was selected for the study where labels of three SKUs of 20ml, 40ml and 100ml were considered. An assumption was made in the production process design that production processes are imperfect and all material issued to production are used, without rejection. Shih and Wang stated that products are produced by an imperfect process that may shift randomly from the IN state control to the OUT state control (Shih & Wang, 2013). Further, they stated that when the process is in the OUT state, it had a higher probability of producing a nonconforming product compared to when it is in the IN state (Shih & Wang, 2013). Some companies have, therefore, adopted a "zero defects" policy, to reduce the many online production defects that may otherwise increase production cost. Accordingly, several authors have alluded to the fact that a "zero defects" policy can be easily achieved by a model by setting both cost parameter values for wrongly accepting a nonconforming product and rejecting a conforming product as infinity (Capdevilla et al., 2020; Kancherla et al., 2017; Shih et al., 2018; Li, et al., 2015) while investigating by jointly considering product deterioration and a deteriorating production system, state that, not only does the machine produce defective product, but also the machine is subjected to quality deterioration (Li et al., 2015). It was noted that while producing, defective products occurred because of labeling nonconformance at different time intervals during the labeling process which are isolated then kept aside till end of normal production process. The defective products because of labeling nonconformance are then assessed and a decision is made whether to rework or reject. The production system is assumed to produce some time-varying proportion of defective parts which can be repaired at some unit cost. (*European Journal of General Practice*, 2020). When reworked, extra cost is incurred so as to restore their quality to compliance to specifications and customer expectation. Datta, in his journal *An Inventory Model with Price and Quality Dependent Demand Where Some Items*

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Produced Are Defective, analyzed an inventory system for joint determination of product quality and selling price where he stated that a fraction of items produced were defective and that only a fraction of the defective items can be repaired or reworked (Datta, 2013). As for the 20ml, 40ml and 100ml labels of acaricide product that were under review, it was noted that most online damages could not be reworked or repaired at all, leading to outright rejection. The cost of rejection was therefore incurred because these labels ended up being disposed. To complete production, additional labels had to be obtained, hence, causing inflated cost of production. He et al.(2015), in the journal, *Optimal Production Planning for Manufacturing Systems with Instantaneous Stock-Dependent Demand and Imperfect Yields,* state that during production process, the system can evolve from in-control state into out-of-control state at any random time. They further go on to state afterwards, the defective items will be generated and likely cause quantity loss (He et al., 2015). This is mostly the case when large numbers of packaging, like labels, are issued to production. As such, it was noted that production labeling machines required accurate setup at the initial stage, along with continuous monitoring to maintain the system in an in-control state constant.

Process yield target and production costs are based on the assumption of process imperfectness. The imperfectness in production process result in the projected production yield assuming that some product's inputs are lost or damaged. This result results into a relatively low target yield which eventually may lead to high cost of production. From the this study, data analysis of defects of 20ml, 40ml and 100ml Labels of the acaricide product revealed this through labels being damaged due to misalignments in the labeling machine and improper machine setting by the operators. During the period between July 2018 and June 2019, out of 1,229,966 pieces of labels for the three pack sizes issued to production, 1.01% was damaged online, prompting additions for completion of production batches. 1.82% of the damages were for 20ml labels, 1.12% for 40ml and 0.58% for 100ml.

This meant that online quality control checks were paramount at regular intervals. The machine operators ensured regular adjustment of labeling machine in cases of misalignment or variations.

In a scenario in which a company adopts a "just-in-time" (JIT) Policy, Salari and Makis in the journal *Joint maintenance and just-in-time spare parts provisioning policy for a multi-unit production system*, explain that quality improvement investment is a function of defects rate (Salari & Makis, 2020). The strategy for quality improvement should commence at the point of receiving materials and continue all through to production. This is to ensure proper inventory management of materials and ensure that delays in delivering products to customers that may be attributed to reworks do not occur.

First, in this study, all defects were considered of 20ml, 40ml and 100ml labels that were attributed to online inspection were analyzed. Then the Pareto Analysis tool was used to establish the top three probable causes (Giraldo-Londono et al., 2020; Hajabdollahi et al., 2020; Liu et al., 2020; Vo-Duy et al., 2020). Second, corrective and preventive actions were carried out. Essentially, key strategies and improvements implemented in the Henry Ford Production System during a period of 1 year that were responsible for the success in markedly reducing waste and rework in the labelling process of the three SKUs were shared (Hodgson et al., n.d.). To measure progress in this effort, comparisons were made of the baseline pre-improvement with post-improvement rates and types of process defects encountered in the process. The continuous quality and process improvements were accomplished by empowered workers in a blame-free environment using innovative tools for real-time data collection (Hodgson et al., n.d.).

An additional aspect of the study considered process inspection during normal production for a period of six months. During this time the process was documented to be IN state control and/or OUT state control, as per Shih, et al. (2018) model. The study was extended by adopting quality improvement investment as per Salari and Makis (2020) model.

2. METHODS

Data on 20ml, 40ml and 100ml online labels damages were collected from packing batch records for all the batches manufactured in the period between July 2018 and June 2019. Tabulation of data was done per month for all the labels issued against all that were damaged online. Sum and mean values of online damages and total labels issued per month were calculated and tabulated in Table 1.

Graphical presentation was done to show the general distribution per pack size (or SKU) per month as shown in Figure 1. Investigation on root cause with the help of Ishikawa Fish- Borne diagram was carried out to help establish the causes of damages to inform actions to be taken to mitigate problem of damages. Pareto analysis was carried on three causes of online damages. These three causes were selected for mitigation because of their potential to significantly impact the reduction of damages.

Corrective actions and preventive actions (CAPA) were proposed and documented for the three selected causes. Proposed actions were implemented immediately after CAPA implementation. Fresh data was collected for 20ml, 40ml and 100ml labels in July 2019 and tabulated per month against all that were damaged online.

Sum and mean values of online damages and total labels issued per month were calculated and tabulated in Table 2. Graphical presentation was done to show the general distribution per pack size (or SKU) per month as shown in Figure 2.

Table 1: Quantities of Labels' Damages by Month (July 2018 to June 2019)

MONTH	20ML			40ML			100ML		
	Total Damages	Qty Issued	% Damages	Total Damages	Qty Issued	% Damages	Total Damages	Qty Issued	% Damages
Jul 2018	0	0	**0**	532	49128	**1.08**	121	14049	**0.86**
Aug 2018	260	2520	**10.32**	98	16800	**0.58**	282	21000	**1.34**
Sep 2018	208	24000	**0.87**	404	31200	**1.29**	35	15540	**0.23**
Oct 2018	283	9600	**2.95**	770	32400	**2.38**	55	5334	**1.03**
Nov 2018	105	21600	**0.49**	1853	110640	**1.67**	93	28539	**0.33**
Dec 2018	134	12005	**1.12**	423	71976	**0.59**	82	8400	**0.98**
Jan 2019	207	51197	**0.4**	1037	124368	**0.83**	30	51662	**0.06**
Feb 2019	47	8400	**0.56**	895	45600	**1.96**	41	10500	**0.39**
Mar 2019	30	13200	**0.23**	327	36880	**0.89**	43	18900	**0.23**
Apr 2019	518	79896	**0.65**	403	55584	**0.73**	177	38094	**0.46**
May 2019	1529	36000	**4.25**	1166	114456	**1.02**	130	27930	**0.47**
Jun 2019	6	9784	**0.06**	101	28584	**0.35**	23	4200	**0.55**
Total	**3327**	**268202**	**0.06**	**8009**	**717616**	**1.12**	**1112**	**244148**	**0.58**

Table 2: Summary of Damages

SKU	Total Qty of Damages	Total Qty Issued
20ML	3327	268202
40ML	8009	717616
100ML	1112	244148
Total Damages	**12448**	**1229966**
% Damages(Average)	**1.01%**	

Figure 1: Monthly distribution of online damages of 20ml, 40ml and 100ml labels of the acaricide product between July 2018 and June 2019

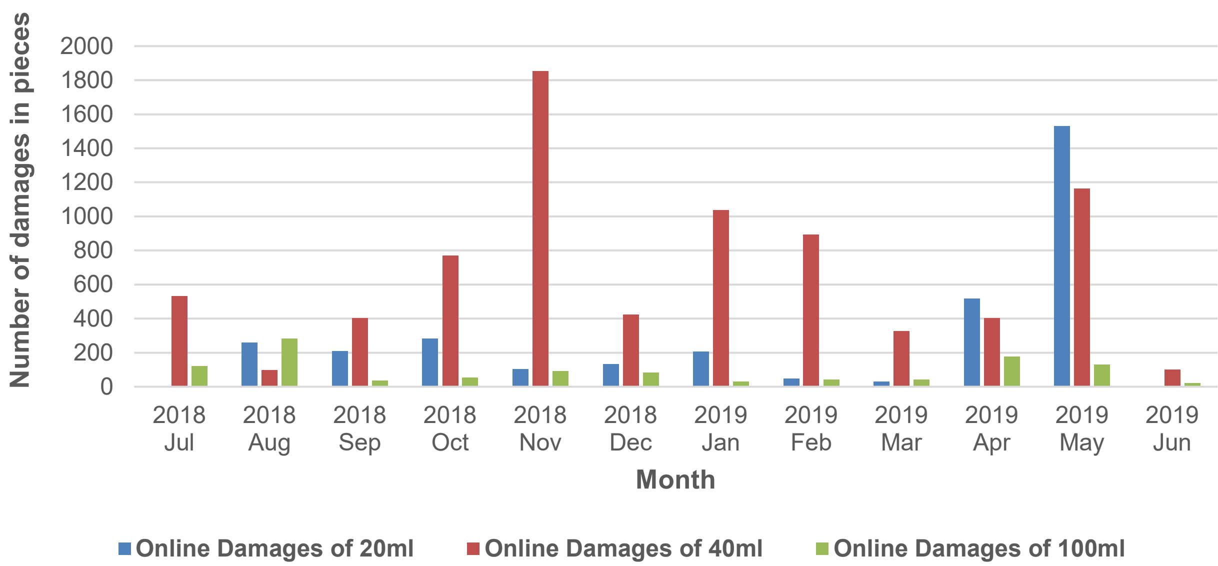


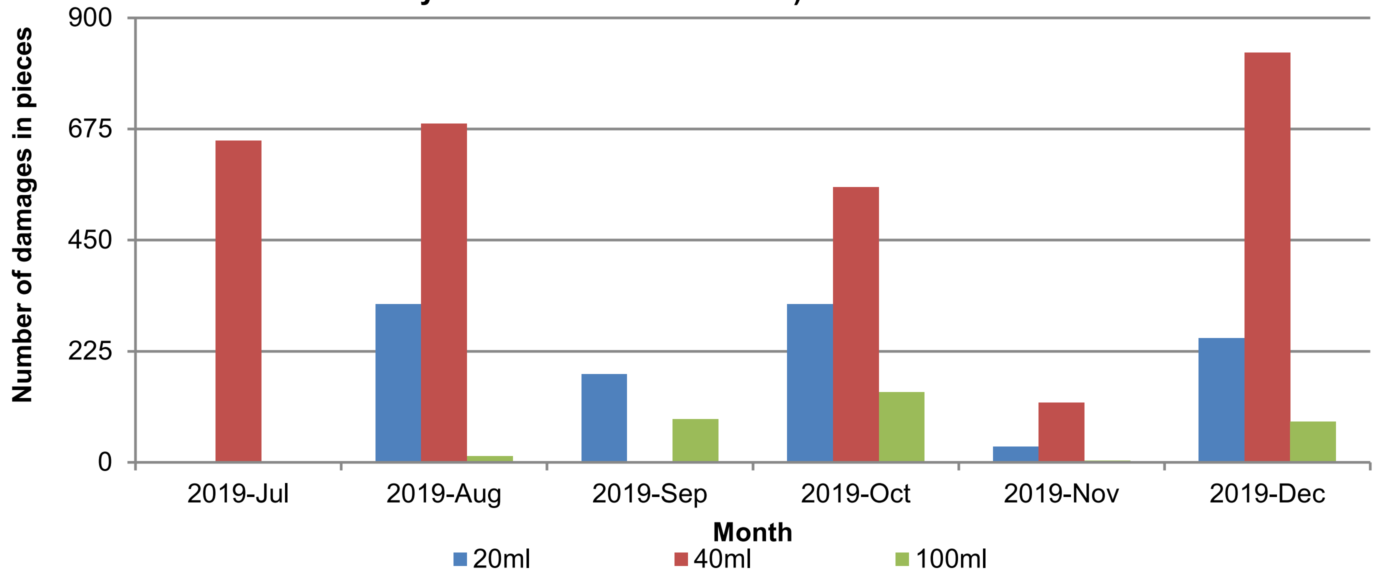
Table 3: Quantities of Labels' Damages by Month (July 2019 to December 2019)

MONTH		20ML			40ML			100ML	
	Total Damages	Qty Issued	% Damages	Total Damages	Qty Issued	% Damages	Total Damages	Qty Issued	% Damages
Jul 2019	0	0	**0**	651	48984	**1.33**	0	0	**0**
Aug 2019	320	69674	**0.46**	686	60386	**1.14**	12	6301	**0.19**
Sep 2019	179	36152	**0.50**	0	0	**0.00**	88	21211	**0.41**
Oct 2019	320	56401	**0.57**	557	38760	**1.44**	142	20581	**0.69**
Nov 2019	32	24048	**0.13**	121	36985	**0.33**	4	4830	**0.08**
Dec 2019	252	49992	**0.50**	830	57985	**1.43**	82	13923	**0.59**
Total	**1103**	**236267**	**0.47**	**2845**	**243100**	**1.17**	**328**	**66846**	**0.49**

Table 4: Summary of damages

SKU	Total Qty of Damages	Total Qty Issued
20ML	1103	236267
40ML	2845	243100
100ML	328	66846
Total Damages	**4276**	**546213**
% Damages (Average) 0.78%		

Figure 2: Monthly distribution of damages of labels of the acaricide product between July 2019 and December 2019)



3. RESULTS AND DISCUSSION

Table 1 above is quantity of all the labels for 20ml, 40ml and 100ml of the acaricide product that were issued monthly to production during the period between July 2018 and June 2019. The table also has quantities of labels that got damaged during packaging process in production (i.e., online damages). Table 2 is a summary of total quantities issued and online damages per SKU. A total of 1,229,966 pieces of labels were issued to production for 20ml, 40ml and 100ml SKUs at different months during the period. Out of that was issued, 12,448 pieces were recorded as online damages during labeling. Percentage online damages was 1.012% of the total labels issued during the period for the three SKUs. Out of the total recorded online damages, 3,327 pieces were for 20ml, 8,009 pieces for 40ml and 1,112 pieces for 100ml. The total online damages of labels amounted to an equivalent cost of USD 52 for the period between July 2018 and June 2019, based on the unit price of the labels alone. That is, USD 22 for 20ml, USD 14.5 for 40ml and USD 15.5 for 100ml. Unit price of labels for each SKU was multiplied by the total online damages for that SKU. The totals for each SKU were then summed up to obtain the total of USD 52. This cost, however, did not include the man and machine hours during reworking of the affected units.

From Table 2 it can be seen that 40ml labels contributed to the highest number of the total online damages. This was because 40ml labels were the highest used, as a total of 717,616 pieces were issued to production. The 20ml SKU had just been introduced as a new pack size towards the end of the year in 2018, so production volumes were still not as much as 40ml which was the fastest moving SKU. However, damages were still being experienced with 20ml SKU because the labels quality specifications such as dimensions and grammages were still not fully aligned with the dimensions of the labeling machine.

Figure 1 shows distribution of online damages of 20ml, 40ml and 100ml labels by month between July 2018 and June 2019. This was before implementation of proposed corrective and preventive actions in Table 5. Online damages were highest in October to December 2018 due to high personnel turnover that was experienced, leading to inadequately trained operators handling the machine. More experienced machine operators left the company, leaving the organization with inexperienced operators to handle the machines. This led to regular machine interruptions due to setup issues. Many cases of label misalignments were being reported and would lead to stoppages. By the time mitigation measures were taken, several labels were already damaged.

Root Cause Analysis:

a. The outcome of data analysis of Tables 1 and 2 prompted investigation which led root cause analysis by use of Ishikawa diagram (Chokkalingam et al., 2017; Liliana Luca et al., 2017; Petr Kedaj & Josef Pavlíček, 2015; Stefanovic, Kiss, Stanojevic, & Janjic, 2014). Investigation report identified the following as probable causes of online damages of labels of the acaricide product: Material: 20ml and 40ml labels' specifications of grammage and dimensions were not compatible with the labeling machine's drumhead, making labels picking not symmetrically automatic, as was expected.

b. Man:

i. Personnel operating the labeling machine were relatively new and so were not experienced in identifying and correcting the problem during operation.

ii. Operators were not trained on the autonomous maintenance of the machine, making it difficult for them to adjust in case of misalignment or variation after initial setup.

c. Method:

i. Procedure for receiving packaging materials (including labels) was inadequate in that it did not have a sampling plan that ensured that labels sampled were representative. The scope of quality control checks was inadequate with respect to parameters that were being checked at receipt.

ii. Online quality control checks were inadequate.

d. Machine: Though preventive maintenance schedule was in place; it was not being followed as per frequency defined. In addition, the scope of parameters that were being maintained was not adequate.

e. Management:

The machine was old and therefore deteriorated due to wear and tear. The spares were not available, even with the manufacturer, because of the model being obsolete, forcing the maintenance team to regularly fabricate the parts. This introduced a lot of variations, including not being able to set and/or determine the speed. **Pareto Analysis of Root Causes and Corrective and preventive action (CAPA).**

Pareto analysis (Bajaj et al., 2018; Davis, 1981; Galloway, 2014; X. He & Khouja, 2011) tool was used to isolate main causes with significant effect. These were reduced to the following three causes:

i. Man

ii. Method

iii. Material

Corrective and Preventive Actions done are shown in Table 5 below.

Table 5: Corrective and Preventive Actions

Root Cause	Observation	CAPA
Man	i. Personnel operating the labeling machine were relatively new and so were not experienced in identifying and correcting the problem during operation. This was due to high personnel turnover because of short term contract.	Management increased the terms of contract of machine operators from short to long term with increased remuneration.
	ii. Operators were not trained on the autonomous maintenance of the machine, making it difficult for them to adjust in case of misalignment or variation after initial setup	Operators were trained on autonomous maintenance by a qualified external party.
Method	i. Procedure for receiving packaging materials (including labels) was inadequate in that it did not have a sampling plan that ensured that labels sampled were representative. Besides, the scope of quality control checks was inadequate with respect to parameters that were being checked at receipt.	Procedure for receiving packaging materials was reviewed to include a robust sampling plan and scope of quality checks at receipt increased.
	ii. Online quality control checks were inadequate	Batch packing records were reviewed to increase frequency of in-process checks in production.
Material	20ml and 40ml labels' specifications of grammage and dimensions were not compatible with the labeling machine's drumhead, making labels picking not symmetrically automatic as was expected	Specifications of 20ml and 40ml labels were reviewed to align with labeling machine and with bottles.
Machine	Though preventive maintenance schedule was in place, it was not being followed as per frequency defined. In addition, the scope of parameters that were being maintained was not adequate	Scope of parameters for preventive maintenance defined and frequency of maintenance enforced as per standard operating procedure.

The CAPA implementation, as per Table 5 above, was done gradually between December 2018 and March 2019.
From Table 1, labels damages were unusually low in the months of March and April 2019 for 20ml labels. This was since a review of labels specifications of grammage and dimensions had just been done, leading to improved quality of labels being received from the supplier. Besides, the volumes of 20ml SKU were relatively low during these two months. This was not so in the month of May 2019 for 20ml and 40ml labels due to the breakdown of the labeling machine, which was caused by the old state of the machine. One of the machine parts had to be fabricated because the manufacturer did not have the part since the machine model had been rendered obsolete. The matter was reported to management for a consideration to procure modern equipment which would be considered a current technology.

Reviewing of batch packing records to include additional online quality checks, training of personnel on autonomous maintenance and machine setup were conducted in June and July 2019. Additional personnel were included in the training schedule to increase the number of operators that were able to operate the machine. Training requirements were not only a need for the personnel on the labeling line for these three SKUs, but for all the lines in production.

From Table 3, data collected for a period of six (6) months from July to December 2019 after (and as) changes were (being) made revealed that a total of 546,213 pieces had been issued so far for 20ml, 40ml and 100ml production. Out of this, 1,103 pieces of 20ml labels were damaged online against 236,267 pieces that were issued, 2,845 pieces of 40ml labels were damaged online against 243,100 pieces that were issued while 328 pieces of 100ml labels were damaged online against 66,846 pieces that were issued. This represented percentage online damages of 0.36%, 0.94% and 0.33% for 20ml, 40ml and 100ml labels, respectively. In terms of cost, these online damages amounted to an equivalent of USD 16.8 for the period (i.e., USD 7.21 for 20ml, USD 5.04 for 40ml and USD 4.55 for 100ml).). This cost did not include the man and machine hours, and production downtime. The cost was only based on the cost price of each label. This was too early to conclude, though, as it was only a half-year period. However, between July to December 2019, online damages of 20ml labels reduced from 1.8% in Table 1 to 0.36% in Table 3. For 40ml labels, reduction of online damages was from 1.12% in Table 1 to 0.94% in Table 3 while that of 100ml labels was from 0.58% in Table 1 to 0.33% in Table 3. Reduction in damages was overall reduced from 1.01% to 0.5%, though this was for a half-year period.

From Figure 2, online label damages generally reduced during July to December 2019. This was at a time when the proposed CAPA had generally been implemented, meaning that the actions taken yielded results.

The projected cost for the whole year for the period starting July 2019 would be USD 33.6, implying that cost would reduce by 35.4% i.e., USD 18.4. This though was too early to conclude.

During the period between July and December 2019, the management also reviewed contract of short-term employees to three (3) years, and this motivated staff to not only be more focused but also to remain with the company.

4. CONCLUSION

Machine setup, packaging mmaterials specification and personnel competence is key to reduction of online damages. This is more so with respect to compatibility of label' specification with labeling machine which, with use of competent machine operators, significantly improve efficiency. Most misalignment of labels during labeling occur because of improper initial setup. Review of labels Quality Control specifications also impacted positively on the reduction of online damages for 20ml SKU of the acaricide product.

Online damages also contribute to total cost of production. This is because they lead to actual losses by reducing the profit margins. Any reworks of unit packs amount to additional cost due to use of extra materials, man and machine hours to complete the production lot.

There was significant reduction of online damages of 20ml, 40ml and 100ml labels of the acaricide product after implementation of proposed actions. This means that the mitigation measures that were put in place were effective.

5. RECOMMENDATIONS FOR NEXT STEPS

a) Monitoring of online damages to continue for the next six months to conclusively have a trend on the impact of the CAPA.

b) Online damages of other packaging materials such as bottles, unit cartons, etc. of the acaricide product to be monitored to give overall cost of production defects of the Product.

c) Online damages of other packaging materials of other products to be monitored so as to give overall cost of production

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