THE COST AND QUALITY OF LABORATORY AUTOMATION: A SYSTEMATIC REVIEW

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ABSTRACT

Background: An increased number of visit to health facilities increases the number of laboratory examination. Laboratories are required to achieve better efficiency, accuracy, standardization, quality, and patient safety. A strategy to meet this demand is laboratory automation. However, some laboratories are hesitant to implement laboratory automation because of high cost and quality. This study aimed to systematically review the cost and quality of laboratory automation.
Subjects and Method: A systematic review was conducted by searching articles from 2009 to 2019 using PubMed, Science Direct, and Scopus databases. The keywords were "laboratory automation", "clinical", "cost", and "quality". The inclusion criteria were: (1) Articles published in English language; (2) Research or review articles; (3) Published from January 2009 to July 2019. The articles were reviewed based on PRISMA flow diagram.
Results: Seven articles reported a decrease in cost due to laboratory automation. The decrease in cost was mainly due to a decrease in the number of employees needed for certain jobs. The quality aspect was mainly assessed using Turnaround Time (TAT). In routine test laboratory, quality through TAT showed an increase, whereas in cito-examination the results can still be validated according to the specified time. The first six months after the implementation of laboratory automation was a vulnerable time due to several factors, including untrained staff. Continuous improvement and close monitoring were needed at this time.
Conclusion: When implemented properly, laboratory automation can reduce cost and increase the quality.

Keywords: laboratory automation, clinical laboratory, cost, quality, turnaround time

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BACKGROUND

With the National Health Insurance (JKN) in Indonesia since 2014, a new era of health has begun. There has been an increase in the number of visits to health facilities.

The average annual increase in JKN participants reaches 12-14 million with the number of visits to the Primary Health Care (PHC) reaching 400,000 visits per day, while hospital visits are around 26,000-

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27,000 visits per day (BPJS, 2019). The increase number of visits to the health facilities has caused an increase in the number of laboratory examinations.

In addition, the demand for laboratory examinations is increasing progressively for several reasons, including; an aging population, chronic disease growth, the discovery of new more effective biomarkers and an increase in general health demand (Dolci et al., 2017).

Laboratories are required to achieve better efficiency, accuracy, standardization, quality, and patient safety. One strategy to meet this demand is laboratory automation. Laboratory automation is a process or workflow in a laboratory that integrates pre-analytics (check-in, sorting, centrifugation, and aliquoting) and postanalytic (storage and disposition) with analytic processes. Each operation is managed by a software system that also mediates human operator intervention (Ialongo et al., 2016).

Laboratory automation began in 1956 when the first automation tool, the auto-analyzer, was introduced with the colorimetric method. Then in the late 1970s the era of information technology began and robotics technology was introduced as a new generation of laboratory automation. Since 1990, laboratory automation has been implemented with a conveyor system for sending specimens for inspection (Zaninotto and Plebani, 2010).

The purpose of automation is to save time and improve performance through the elimination of human error. Benefits of replacing manual procedures with automation include; eliminating potentially hazardous error-prone manual procedures with automated processes that require minimal technician involvement, increasing productivity, reducing turn around time (TAT), increasing safety, minimizing errors, improving sample handling, and enabling laboratory staff settings.

The process of selecting tools for laboratory automation is a complicated and time-consuming process. This change to laboratory automation technology requires major efforts in terms of economic resources, changes in infrastructure and changes in employee culture (Ialongo et al., 2016). The challenge of laboratory automation is to balance among costs, quality, patient safety, and service needs (Armbruster et al., 2014).

For this reason, it is very important to evaluate the impact of laboratory automation on various aspects of the laboratory, including its cost implication and quality. It follows that a systematic review is needed that focuses on the cost and quality aspects of laboratory automation.

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SUBJECTS AND METHOD

1. Study Design

This systematic review was carried out by searching electronic databases in PubMed, Science Direct, and Scopus.

2. Inclusion and Exclusion Criteria

The inclusion criteria were: a) English-language articles, b) articles in the forms of research and review, c) articles published from January 2009 to July 2019.

The exclusion criteria were articles obtained with the above keywords but only discuss laboratory automation from one aspect, either quality aspect or cost aspect. Articles that cannot be accessed in full text were also excluded.

3. Article Extraction

The process of searching for articles was carried out using the Preferred Reporting Items for Systematic Reviews and Meta-Analyzes (PRISMA) instruments (Liberati et al., 2009). Since the beginning of the search, the search year had been restricted, i.e. from 2009, while other inclusion criteria in the form of language and type of articles were applied after all articles were found in accordance with the keywords. 6,614 articles were found with the keyword "laboratory automation" which were then refined again by adding keyword "clinical" so that the number of articles dropped to 1,530. Then the search was narrowed by entering keyword "cost", and the number of articles was reduced to 266. When adding keywords "quality", article was reduced to 123. In the end, the articles that met the inclusion and exclusion criteria and could be included in this systematic review were 7 articles.

RESULTS

Data extraction is done by analyzing articles based on the author's name, title, purpose, research method and results. This is called grouping important data in the article. The results of data extraction can be seen in Table 1.

The seven articles in this systematic review calculate the cost reduction after the implementation of laboratory automation. All articles get a decrease in costs caused by a decrease in employee costs and increased productivity where the calculation of employee workload by 5 articles is done using Full-time Equivalent (FTE).

Ellison et al. (2018) stated that get a reduction in costs due to a reduction in the number of employees (less than 6 full-time employees required), changes in staff skills (fewer senior staff are needed) with the ultimate goal of more efficient use of clinical staff time. Staffing costs result in a reduction in the cost of 1.14 million SAR per year.

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Table 1. Summary of articles in a systematic review

No	Author (Year)	Title	Purpose	Method	Results
1	Zaninotto and Plebani, (2010)	The 'hospital central laboratory': automation, integration and clinical usefulness	To complete review of laboratory automation	Review	Technical staff decreased from 10 to 7, increased productivity; FTE> 34% and increased test complexity. The cost of test and staff are cheap. The total error in hormone testing and clinical chemistry is better than standard clinical guidelines.
2	Armbruster, et al (2014)	Clinical Chemistry Laboratory Automation in the 21st Century - Amat Victoria curam (Victory loves careful preparation)	To illustrate laboratory automation related to clinical chemistry	Review	The total cost per test decreased from $ 0.79 to $ 0.15. The number of staff decreased by 24% and productivity increased by 58.2% (number of tests / number of employees) and 82% (number of samples / employees). TAT decreases.
3	Rin et al (2015)	Integration of Diagnostic Microbiology in a Model of Total Laboratory Automation	Share experiences in integrating automated diagnostic microbiology instruments into laboratory automation	Comparison of pre and post automation	TAT is reduced by 1 day. Reduced costs from FTE, incubator devices, consumables and avoidable injuries. Investment in laboratory automation returns after 7.3 years
4	Archetti et al (2017)	Clinical laboratory automation: a case study	To demonstrate the impact of laboratory automation on patient care through TAT evaluations and costs.	Case Study	Total cost decreased by 12.55%. Emergency examination TAT increased (<1 hour), Urgent TAT examination (standard 2 hours) and routine TAT examination (standard 1 day) decreased.

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5	Lou et al (2017)	Multiple pre- and post-analytical lean approaches to the improvement of the laboratory turnaround time in a large core laboratory	For evaluating the impact of laboratory automation, electric track vehicles (ETV) and auto-verification trough TAT	Comparison of pre and post automation	Median TAT for the urgent samples decreased by 16%. Percentage of urgent Tests> 60 minutes increased. Routine TAT examination decreased. Decreasing operational costs by 2 million dollars per year. Investment in laboratory automation returns after 3.5 years
6	Ellison et al (2018)	Implementation of total laboratory automation at a tertiary care hospital in Saudi Arabia: effect on turnaround time and cost efficiency	To ensure that total laboratory automation is efficient in terms of cost and a small number of staff can increase productivity and reduce TAT	Comparison of pre and post automation	TAT for random Glucose test decreased by 21%. TAT for all tests decreased 32%. Decreased employment costs 1.14 million SAR per year, reduced costs from contract consolidation of 28.8 million SAR.
7	Yu et al (2018)	Improving Laboratory Processes with Total Laboratory Automation	To improve workflow efficiency after implementing laboratory automation	Time motion study	86% reduction in workflow steps. Time for repeat examination was reduced by 82%. Reduction of room requirements decreased 45% maintenance costs. Reduction in labor costs of $ 232,650 per year. Before Automation it takes 2 chemical analyzers to reach TAT 45 minutes, after automation only 1 analyzer is needed

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Armbruster et al. (2014) reported a decrease in staff numbers of 24% and productivity increased by 58.2% (number of tests/ number of employees) and 82% (number of samples/ employees).In addition to the cost reduction due to employee factors, Ellison et al. (2018) received a cost reduction due to contract consolidation (5 contracts reduced to 1) and resulted in a direct cost reduction of 28.8 million SAR. Yu et al. (2018) found a 45% reduction in space requirement reduces maintenance cost.

Rin et al. (2016) noted cost saving from employees, incubator, consumables, and avoidable injury. Two articles noted the return of investment costs in 3-5 years (Lou et al., 2017) and 7 years with amortization of the automation tool was 10 years (Rin et al., 2016).

Quality indicators according to the stages of the laboratory process were: (1) Test ordering; (2) patient identification and specimen collection; (3) specimen identification, preparation, and transportation; (4) analysis; (5) reporting results; and (6) Result interpretation and ensuing action. At the results reporting stage, an indicator that is often used is the TAT. The definition of TAT is the percentage of specific laboratory tests that do not meet a reporting deadline and what is calculated is the time the sample arrived at the laboratory until the results of the examination were reported (Shahangian and Snyder, 2009).

Assessment of the quality of laboratory automation in the articles in this review is generally carried out using TAT, only Zaninotto and Plebani (2010) use total errors and obtain lower total error results than expected total errors. In the TAT assessment is calculated separately between CIT and routine TAT examination.

Archetti et al. (2017) and Lou et al. (2017) obtained an increase in Emergency examination TAT even though it did not exceed the standard set. Armbruster et al. (2014) obtained a Emergency examination that does not need to be prioritized or examined separately with TAT results <1 hour.

DISCUSSION

In this systematic review, the articles chosen vary from review to case study research because no limitation of the research method is carried out. This is because the topic of this systematic review discussion is laboratory automation where for the implementation of laboratory automation it takes a long time and high costs so the chances of finding study on this subject are few.

Besides, discussed is the cost and quality together which narrows the amount of study so that the search is broadened to include all types of discussion and research on

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the cost and quality of laboratory automation.

Hawker (2007) identified 10 reasons why laboratory automation was not as expected, including, a lack of understanding of current conditions in the form of processes, costs and what customers expect, unrealistic expectations in terms of costs, throughput, return on investment, non-cost such as employees, consumables and maintenance.

The major cost reduction from the employee factor is proven by all articles in this systematic review. Cost reduction in the study of Archetti et al. (2017) is not only caused by a decrease in employee costs but also due to the strategy of implementing their laboratory automation that is to reuse as much equipment as previously used in pre-automation laboratories so that even though there is an increase in equipment costs but it can be offset by a decrease in employee costs so in the end the total cost decreased by 12.55%. This strategy can be applied by other laboratories in starting the implementation of laboratory automation.

Worker safety is one of the most important benefits of automation. The automated system not only removes staff from job sites, but also protects them from the risk of doing biologically hazardous work that is handling biohazard materials (Lippi and Da Rin, 2019). This condition was also analyzed by Rin et al. (2016) where with automation reduced injuries that could be experienced by workers due to repetitive work thereby reducing indirect costs by $14,304.

The application of laboratory automation in the presence of new equipment causes additional costs to run the system (electricity and water) and for supplies (aliquots and caps for sealers). In addition, maintenance costs will also increase (Lippi and Da Rin, 2019). However, Rin et al. (2016) found decreased cost of consumables and maintenance cost due to space reduction.

All articles in this review showed cost reduction. Zaninotto and Plebani (2010) reported a reduction in direct cost and an increase in internal workflow. However, there were no studies reported on the cost effectiveness and quality of laboratory automation. Therefore, further studies are recommended to examine the cost effectiveness and quality of laboratory automation.

The health care system has changed in the last decade, where hospitals are expected to serve critical patients and patients with emergency conditions where laboratory test results are very important and must always be reported in a short time. Laboratories in the hospital environment can meet this challenge by changing their organizations from compartmentalized laboratory departments to integrated laboratories. This requires the imple-

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mentation of laboratory automation using technological innovations for analytic needs. In this laboratory department model, a short TAT for all first-line tests is the main thing, where all samples are handled in real-time and validated results are sent immediately in a time that meets clinical needs. STAT comes from the Latin "Statim" which means immediately which is sometimes also interpreted as Short TAT (Dolci et al., 2017).

The impact of laboratory automation on TAT reported by the articles in this study varies in magnitude. Although all showed a decrease in TAT, Archetti et al. (2017) reported an increase in TAT on emergency examination even though it did not exceed one hour, especially during the initial laboratory automation. Lou et al. (2017) also noted an increase in the percentage of the number of emergency examinations that were completed in 1 hour. This is because the initial period of automation is still an adjustment of employees to the new system so that the response of employees to the emergency checks that must be done manually such as repetition and moving the sample to the front lane for early inspection is still slow. Therefore, training before and during the application of automation is important for the success of laboratory automation.

Errors in the laboratory are a source of ongoing problems and are mainly caused by human factors. It is estimated that the number of errors in clinical laboratories is around 1-2%, although many errors are unknown. Some of these errors have clinical consequences. There is no data about the cost of this laboratory error. Some estimate about 10% of all errors in hospital treatment, equivalent to more than $ 1.5 billion per year in the US.

Most of these errors are at the pre-analytic stage, which is when processing samples. Implementation of laboratory automation is an opportunity to reduce human errors that occur during labeling specimens, aliquots, request entries, and so on (Swaminathan and Wheeler, 2000). Zaninotto and Plebani (2010) also find the total errors for clinical chemical and hormone testing better than the standard set in his laboratory.

Automation can reduce costs primarily from employee costs, and improve laboratory quality as measured using TAT and total error. Therefore, when applied properly, laboratory automation can effectively optimize laboratory processes and its efficiency. The first six months after the implementation of laboratory automation is a vulnerable time due to several factors, including due to the untrained staff. Therefore continuous improvement and close monitoring are needed at that time.

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