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# The Role of Social and Technical Lean Implementation in Improving Operational Performance: Insights from the Pharmaceutical Industry

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***Abstract*—**The objective of this paper is to examine the relationships between technical and social lean bundles as well as operational performance in the context of the pharmaceutical industry. We investigate the direct and mediating effects of the lean bundles Total Productive Maintenance (TPM), Total Quality Management (TQM), Just-In-Time (JIT), and Human Resource Management (HRM) on operational performance. Our analysis relies on 113 manufacturing facilities from the St.Gallen OPEX benchmarking database. The results show that HRM has a positive indirect effect on operational performance mediated by the technical lean bundles.

***Keywords*—**Human resource management, operational performance, pharmaceutical industry, technical lean practices.

## I. Introduction

LEAN production combines multi-dimensional practices aiming at systematically eliminating waste along the value chain and within the company [1]-[3]. Waste reduction is reached by focusing on performing the simple things well, and continuously searching for standardization and improvement. However, no standard lean implementation model does exist, and each industry and adopter have developed its own understanding of lean manufacturing tailor-suited to the company's needs [4].

Numerous articles concentrate on the relationship between lean and operational performance. During the 90s, scholars tested the positive impact of one or two lean elements on performance [5], [6]. Successively, academics concentrated on broader approaches, thus confirm the relationship between lean and performance (e.g. [7]-[9]).

This paper examines the causal relationship between the multi-dimensional lean practices and operational performance. We aim at investigating the effect of social and technical lean practices on operational performance in the context of the pharmaceutical manufacturing. Our analysis relies on 113 plants from several countries. We use the mediation analysis to test our hypotheses and investigate the direct and indirect effects.

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## II. Theoretical Background

### A. Technical, Social Lean Practices, and Performance

Lean manufacturing is a broad and well researched topic, which can be perceived as world class manufacturing [10], management system [11], management practices [12], culture [13], [14], just to cite some of the possible interpretations. To reduce the complexity and improving the interpretability of the results, this study focuses on the concept of lean bundles argued by Shah and Ward [7].

Shah and Ward [7] defined lean production as a system composed of four bundles of practices: JIT, TQM, TPM, and HRM. Every bundle consists of a set of practices. Some bundles are more technically oriented (JIT, TQM, TPM), while HRM is more socially oriented.

JIT aims at reducing and ultimately eliminating all forms of waste [15]. Cua et al. [8] mention common JIT practices, such as set-up time reduction or pull production. The TQM bundle focuses on continuous improvement of process and product quality [7]. Representative TQM practices are, for example, process management and supplier quality management [6]. The TPM bundle emphasizes the maximization of equipment effectiveness during its entire life to reduce breakdowns [8]. Common examples of TPM practices are autonomous maintenance and safety measures [7], [8]. The HRM bundle defines all the human-centered practices; examples are cross-functional workforce and committed leadership [7].

Distinguishing between HRM and technical lean practices proved to be helpful for researching lean and its impact on operational performance. Prior research investigated the relation of HRM and technical lean practices on operational performance separately (e.g., see [7]-[9]).

Other scholars take a complementarity perspective and agree that HRM as well as technical lean practices are interrelated [16], [17]. These often tested the interrelation via moderation analyses in which HRM has a moderating effect on the relation between technical lean practices and operational performance. However, scholars also coincide on the importance of social practices for the success of lean implementation [11], [18], [19]. The latter would mean that social practices can impact operational performance in two ways. Thus, we want to shed

light on how the HRM bundle impacts operational performance – directly or indirectly by driving the implementation of technical bundles which eventually impacts operational performance.

Additionally, this research setting is based on the pharmaceutical industry, which differs from other industries in several ways and has not been sufficiently analyzed [20]. Pharmaceutical manufacturing is a process industry, and compared to discrete manufacturing, process industry has for example larger equipment, higher volumes, lower variety, complex product changeovers, and limitation of throughput driven by equipment and not workforce [21]. The pharmaceutical industry is characterized by strict market access regulations, which impact the speed of process change. Additionally, the industry still suffers from large market volatility and drug shortages caused by manufacturing and quality failures [22]. These particularities of the pharmaceutical industry may affect the way technical lean practices can be implemented and their impact on operational performance [23]. However, pharmaceutical organizations are implementing lean like other industries [20], the empirical evidence on the effectiveness of their efforts is limited for social and technical lean practices.

### *B. Hypotheses Development*

This paper examines the role of technical lean practices and mediator of the relationship between HRM and performance. Firstly, the research team hypothesizes the existence of a direct positive relationship between HRM and performance. Secondly, the team supposes a direct positive relationship between HRM and technical lean practices. Finally, the team investigates the presence of a direct linear relationship between technical lean practices and performance. Fig. 1 displays the research model for this paper.

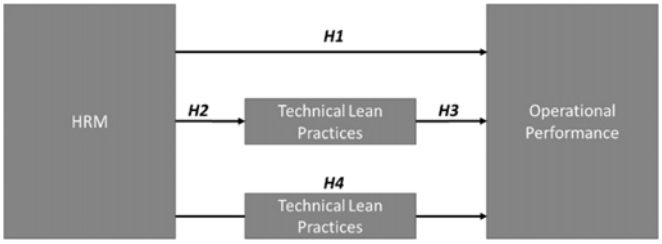


Fig. 1 Conceptual framework

HRM aims at managing the social system of the firm and enlarges the lean thinking and acting to all members belonging to the organization. However, empirical studies have provided contradicting results. Some studies revealed a positive direct relationship between HRM and a firm's overall performance [24]-[27]. Other studies provided inconclusive evidence for the relationship between the two variables [28], [29]. Adding to that, scholars [30]-[32] provided findings supporting the existence of an indirect relationship between HRM and performance. We therefore hypothesize:

H1. The application of HRM is associated with higher operational performance in pharmaceutical manufacturing companies.

Lean production literature supports that HRM provides the backbone for the successful implementation of lean technical practices. HRM enhances shop-floor employees to be innovative and therefore creates teams aimed at problem solving and improving JIT [33]. Moreover, educated and trained workers understand and are oriented towards high-quality standards [34]. Prior research already suggested that technical lean bundles (framed as JIT and TQM) may be a good mediator of the relationship between HRM and operational performance [9]. MacDuffie [35] proved that HRM practices cause synergies between all the bundles improving productivity and quality. However, the effect of HRM on operational performance is still not solid. The uncertain linear relationship between HRM and operational performance and the existence of indirect effects provide a solid background to perform a mediation analysis aiming at understanding if HRM may influence other mediating variables, which may influence operational performance [36]. Based on the literature, we formulate the following hypothesis:

H2. The application of HRM is associated with higher lean technical practices implementation in pharmaceutical manufacturing companies.

As mentioned before, lean scholars [7], [8], [37], [38] extensively support that the implementation of technical lean practices may increase the firm operational performance. A greater operational performance will result in better manufacturing competitive capability for the firm [39]. The analysis of the relationship between technical lean practices and operational performance within pharmaceutical manufacturing firms concludes the mediation analysis. This may provide evidence for the relationship between HRM and operational performance mediated by technical lean practices. Therefore, the third hypothesis is:

H3. The application of technical lean practices is associated with higher operational performance in pharmaceutical manufacturing companies.

The implementation of HRM or technical lean practices only is not capable of depicting the complexity of deploying lean within operations. Technical lean practices provide the methodological backbone supporting the daily activities; however, the human element is the component responsible for defining if the organization is embracing lean or not [40].

The link between HRM practices and technical lean practices is necessary to sustain successful operations [41]. In fact, in a fully deployed lean production situation, high inventories are not available to mitigate production and quality failures, the employee must be capable of taking quick decisions [42]. To investigate the system perspective, we hypothesize:

H4. The application of technical lean practices mediates the link between HRM and operational performance.

## III. Methodology

### *A. Data Collection*

This paper focuses on pharmaceutical manufacturing firms to study the impact of HRM on technical lean practices and

operational performance. The analyses rely on data from the University of St.Gallen Operational Excellence (OPEX) benchmarking study. The benchmarking tracks the maturity of lean practices in pharmaceutical manufacturing firms globally. The questionnaire is structured in three sections. The first section collects contextual data, such as information on the product portfolio, cost structure, or headcount structure. The second section focuses on assessing the implementation level of lean practices. The third section measures the operational performance. Manufacturing facilities filled in the questionnaire on their own with the assistance of researchers at the Institute of Technology Management. Filling in the questionnaire took between four to six weeks and different functions within a manufacturing facility were considered to increase data reliability.

The number of datasets used for the analytics is composed of 113 manufacturing facilities.

### *B. Measures*

The constructs in the OPEX benchmarking study are drawn from the measures developed and tested by Cua et al. [8]. Our study measures technical lean bundles using the Cua et al.'s [8] TPM, TQM, and JIT. The HRM is structured similar to the construct of cross-cutting supportive practice [8]. Table I displays the operationalization of technical lean bundles and HRM. Items were measured on a 5-point Likert scale. To increase data accuracy, each answer choice for respective items is precisely described (e.g., ranging from *no training program in place* to *we have a structured program rolled out in the entire facility*). Bundles are measured with several items to increase construct reliability. To provide respondents with guidance in filling in the questionnaire, items were structured in categories.

TABLE I
OPERATIONALIZATION OF THE TECHNICAL LEAN PRACTICES & HRM

| System (alpha) | Bundle (alpha) | Sub-Category (nr. of items) |
|---|---|---|
| Technical Lean Practices (.914) | TPM (.796) | Preventive Maintenance (8) |
| | | Technology Assessment & Usage (6) |
| | | Housekeeping (3) |
| | TQM (.746) | Process Management (9) |
| | | Cross Functional Product Development (5) |
| | | Customer Involvement (6) |
| | | Supplier Quality Management (8) |
| | JIT (.828) | Set-up Time Reduction (6) |
| | | Pull Production (7) |
| | | Layout Optimization (9) |
| | | Planning Adherence (6) |
| HRM (.927) | HRM (.927) | Direction Setting (7) |
| | | Management Commitment & Company Culture (11) |
| | | Employee Involvement & Continuous Involvement (11) |
| | | Functional Integration & Qualification (7) |

Construct reliability for the survey items was tested leveraging the Cronbach's alpha. HRM has a Cronbach's alpha of 0.927. The construct "technical lean practices" (aggregation of three technical bundles) has a Cronbach's alpha of 0.914. Both values exceed the threshold of 0.7 to consider a construct reliable [7]. Additionally, the three technical bundles show a Cronbach's alpha above the level of 0.7.

Table II summarizes the key performance indicators (KPIs) building up the operational performance score. We utilized 23 KPIs to holistically assess the current performance of a facility. All performance metrics are structured with the system in which a higher value indicate a higher performance.

TABLE II
OPERATIONALIZATION OF OPERATIONAL PERFORMANCE

| Category | KPIs |
|---|---|
| TPM | Overall Equipment Effectiveness |
| | Setup & Cleaning |
| | Unplanned Maintenance |
| | Maintenance Costs/ Conversion Costs |
| TQM | Customer Complaint Rate |
| | Yield |
| | Right First Time |
| | Rejected Batches |
| | Scrap Rate |
| | Supplier Complaint Rate |
| | Quality Costs/ Conversion Cost |
| | Deviation per Batch |
| | Deviation Closure Time |
| JIT | Production Lead Time |
| | Changeover Time |
| | Service Level-Delivery |
| | Forecast Accuracy |
| | Production Schedule Accuracy |
| | Replacement Time to Customer |
| | Material Turns |
| | Order Lead Time |
| | Days-On-Hand |

### *C. Data Analysis*

The paper aims at investigating the existence of a causal mechanism between the described measures, in this case a mediation. The mediation mechanism is divided in direct, indirect, and total effect [43]. Literature recognizes a four phases approach to test mediation [44]-[46]: First, test if a relationship between the independent variable and the dependent variable exists or not; second, investigate the relationship between the independent variable and the mediator; third, show the existence of a relationship between the mediator and the dependent variable; finally, define what kind of mediation the mediator performs on the relationship between the independent and the dependent variable. Not all the four steps must be taken to prove the mediation. Kenny et al. [47] questioned the equal importance of the four steps. Scholars [48], [49] tend to highlight step 2 and 3 as the crucial steps in the mediation analysis. In fact, the non-existence of a linear relationship between the independent variable and the dependent variable does not prove that the mediation effect is not given [48], [49].

The indirect effect is tested with the bootstrapping. Bollen & Stine [50] and Shrout & Bolger [51] argue the reliability of bootstrapping to test the indirect effect. Analyses are performed with the statistical software "R", specifically relying on the package for causal mediation analysis "mediation" developed

by Tingley et al. [52].

## IV. Results

Table III illustrates the descriptive statistics and correlations of the variables used to test the three hypotheses: HRM, technical lean practice, and operational performance.

TABLE III
DESCRIPTIVE STATISTICS OF THE VARIABLES

| | Mean | SD | 1 | 2 | 3 |
|---|---|---|---|---|---|
| 1. HRM | 0.6392 | 0.1126 | 1 | | |
| 2. Technical Lean Practices | 0.5936 | 0.1199 | .177 | 1 | |
| 3. Operational Performance | 0.4909 | 0.1164 | .322 | .701 | 1 |

Note: All correlations are significant at the 0.01 level.

The results of the three linear models to test phase one to three are displayed in Table IV. The first step of the mediation analysis tests the relationship between the independent variable HRM and the dependent variable operational performance. Model 1 is not statistically significant at the $P < 0.05$. Therefore, we can reject our first hypothesis. There is no direct effect HRM on operational performance.

Although the direct effect is non-significant, the indirect effect can still be significant [49]. Similarly, to the fact that correlation does not prove causation, the non-existence of a linear relationship does not disprove a possible indirect causation [48], [49]. Moreover, not all the four steps must be met to prove a mediation effect [47]. For these reasons, we continue with the step 2, testing the relationship between independent variable and mediator. Model 2 shows a positive linear relationship between HRM and lean technical practices, which is statistically significant at $P < 0.001$. Based on the findings of the second model, we can accept our hypothesis number two, a higher implementation of HRM will result in better technical lean practices level.

The third step is to investigate the effect of the mediator on the dependent variable. Model 3 reveals the existence of a positive linear relationship between technical lean practices and operational performance. The relationship is statistically significant at $P < 0.001$.

TABLE IV
RESULTS FOR HYPOTHESES 1-3

| | Standardized β coefficients | | |
|---|---|---|---|
| | Model 1 | Model 2 | Model 3 |
| HRM | 0.1834 | 0.6791*** | |
| Technical Lean Practices | | | 0.3432*** |
| $R^2$ | 0.0315 | 0.4914 | 0.1036 |
| Adjusted $R^2$ | 0.0227 | 0.4868 | 0.0955 |
| *F* Statistic | 3.61 | 107.2 | 12.83 |
| P-value of Overall Model | | *** | *** |

Note: *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$

In order to conclude the mediation analysis, the fourth step investigates the type of mediation performed by the mediation on the relationship between the independent and the dependent variables. The significance of the indirect effect has been tested with the bootstrapping method (see Table V). Unstandardized indirect effects were computed for each 500 bootstrapped samples, and the 95% confidence interval was computed by determining the indirect effects at the 2.5th and 97.5th percentiles. The bootstrapped unstandardized indirect effect was 0.24 and the 95% confidence interval ranged from 0.09 to 0.48. The indirect effect was statistically significant ($P < 0.05$). Therefore, we can accept our fourth hypothesis, technical lean practices fully mediated the relationship between HRM an operational performance.

TABLE V
MEDIATION RESULTS

| | Estimate | 95% CI Lower | 95% CI Upper | p-value |
|---|---|---|---|---|
| Average Causal Mediation Effect | 0.2498 | 0.0910 | 0.48 | *** |
| Average Direct Effect | -0.0983 | -0.3332 | 0.15 | |
| Total Effect | 0.1865 | 0.0059 | 0.37 | * |
| Prop. Mediated | 1.4231 | 0.1920 | 11.89 | * |

Note: *** $P < 0.001$, ** $P < 0.01$, * $P < 0.05$

## V. Discussion

The objectives of this study were to investigate how HRM practices are related to pharmaceutical companies' operational performance and to understand the role of technical lean practices. The importance of HRM on operational performance should not be underestimated. In this study, HRM has no direct linear relationship with operational performance, respectively, in a sample of pharmaceutical companies. This finding is in line with previous studies performed in other industries [28], [29]. However, HRM is positively related to technical lean practices and explains, this is in line with the literature on the topic [40]. Moreover, the technical lean practices are positively associated to operational excellence. This study shows that HRM has a positive effect on operational excellence, but this effect is mediated by the technical lean bundles. The complete mediation is in line with other studies [9], [30]-[32] arguing for an indirect effect of HRM on operational performance. The findings support the idea that despite the later adoption, the pharmaceutical industry shows similar lean patterns as other industries with longer lean history.

The research within the pharmaceutical industry confirms the central role of HRM as a key component of lean implementation. Although, HRM only has no direct impact on performance, it has an impact on the technical lean bundles. HRM provides the fundamental capabilities and behaviors necessary to build upon lean production. However, the relationship between HRM and technical lean practices does not speak for a chronologically order [9]. The implementation should be understood as a complementary system with both HRM and technical lean practices. Lean initiatives should be well planned and deployed to avoid failures. In fact, the complexity of socio-technical lean systems is often one of the criteria of failure or lower performance of the entire system [53].

## VI. Conclusion

This study argues, along with other scholars [9], [30]-[32], that HRM has a positive indirect effect on performance, and that

these effects are primarily mediated by the implementation of technical lean practices. However, this study suffers from some limitations. The data focus primarily on facilities situated mainly between Europe and North America, which does not consider patterns related to other cultures. The process of data collection of the OPEX benchmarking relies on a self-reporting system, that might be affected by respondent bias.

Future studies should concentrate on the impact of single HRM practices (e.g., functional integration, management commitment, …) on operational performance based on different technical lean practices maturity levels.

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