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Development of the Procedural Waste Index (PWI): A Framework for Quantifying Waste in Manufacturing Standard Operating Procedures

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Abstract

Standard operating procedures (SOPs) serve as critical control mechanisms in manufacturing systems, yet systematic approaches for quantifying procedural inefficiencies remain theoretically underdeveloped. Unlike traditional qualitative SOP analysis methods that rely on expert intuition and subjective assessment, current procedural optimization approaches lack the systematic rigor applied to physical process improvement. While lean manufacturing principles have demonstrated effectiveness in physical process optimization, their systematic application to procedural analysis represents an unexplored theoretical domain with significant potential for manufacturing systems improvement. This research addresses this gap by developing the Procedural Waste Index (PWI) framework, which establishes the first systematic theoretical integration of lean waste identification principles with procedural analysis. The framework extends the seven wastes of lean manufacturing to procedural analysis through systematic mapping to procedural elements identified via the extended Procedure Representation Language (e-PRL), creating a quantitative approach that enables the objective measurement of procedural efficiency where only subjective assessment methods previously existed. The PWI framework provides the following three key advantages over existing approaches: (1) systematic waste identification using proven lean principles rather than ad hoc improvement methods, (2) quantitative measurement capability enabling objective assessment and statistical process control, and (3) multi-perspective analytical framework through three complementary calculation methodologies (weighted aggregation, maximum constraint identification, and root mean square analysis) providing comprehensive analytical perspectives on procedural waste across discrete manufacturing contexts. The theoretical framework demonstrates practical applicability through a systematic analysis of a respirator fit testing procedure, revealing inventory waste as the primary inefficiency (70.0% waste score). This represents the first quantitative procedural waste assessment in the manufacturing literature, contributing to the foundational theory for systematic procedural optimization while establishing a methodology for future empirical validation studies.

Keywords: lean manufacturing; standard operating procedures; procedural waste; systems theory; manufacturing systems; theoretical framework



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1. Introduction

Manufacturing systems increasingly rely on complex procedural frameworks to ensure quality, safety, and operational efficiency. Standard operating procedures (SOPs) serve

as critical control mechanisms that bridge strategic objectives with operational execution, providing detailed instructions designed to achieve uniformity in performance [1]. The International Conference on Harmonization Good Clinical Practice (ICH GCP) guideline defines SOPs as “detailed, written instructions to achieve uniformity of the performance of a specific function” [2].

Despite their fundamental importance in manufacturing systems, procedural design and optimization remain dominated by qualitative, expert-based approaches that lack the systematic rigor applied to physical process improvement [3,4]. This represents a significant theoretical gap, as manufacturing systems theory has evolved to recognize procedures as integral system components that influence overall system performance [5].

1.1. Theoretical Foundation: Lean Manufacturing and Systems Theory

The seven wastes of lean manufacturing—overproduction, inventory, transportation, motion, waiting, overprocessing, and defects—provide a proven theoretical framework for identifying non-value-adding activities in physical manufacturing processes [6,7]. Developed as part of the Toyota Production System, these waste categories establish systematic criteria for distinguishing value-adding activities from waste [8]. Within lean theory, activities are considered value-adding if customers are willing to pay for them, they transform the product, and they are performed correctly initially [9].

From a systems perspective, manufacturing procedures represent information processing subsystems that coordinate human–machine interactions and guide operational decisions [10]. Systems theory suggests that inefficiencies in any subsystem propagate throughout the broader manufacturing system, affecting overall performance [11]. However, existing lean manufacturing applications focus primarily on material flow and physical processes, leaving procedural subsystems largely unaddressed by systematic analytical frameworks.

1.2. Procedural Complexity in Manufacturing Systems

Manufacturing systems exhibit increasing procedural complexity driven by regulatory requirements, quality standards, and operational sophistication [12]. This complexity manifests through multiple dimensions: structural complexity arising from procedural step interconnections, informational complexity related to data requirements and decision points, and operational complexity stemming from coordination requirements across system elements.

Research in complex systems theory indicates that system efficiency degrades when subsystem inefficiencies accumulate without systematic identification and elimination [13]. Applied to manufacturing procedures, this suggests that procedural inefficiencies may compound over time, creating systemic performance degradation that traditional approaches fail to address systematically.

1.3. Research Gap and Theoretical Opportunity

The convergence of lean manufacturing principles, systems theory, and procedural analysis reveals a significant theoretical gap. While model-based approaches for procedural analysis have emerged in aviation contexts [14,15], these frameworks focus primarily on safety-critical operations rather than efficiency optimization. The systematic application of lean waste identification principles to procedural design in manufacturing systems remains theoretically underdeveloped.

This research addresses the identified theoretical gap by developing a comprehensive framework that extends lean manufacturing principles to procedural analysis. The study contributes to manufacturing systems theory by establishing systematic relation-

ships between lean waste concepts and procedural characteristics, providing a theoretical foundation for quantitative procedural optimization.

1.4. Research Gap and Objectives

This theoretical development study addresses three primary research questions:

1. How can lean manufacturing waste concepts be systematically mapped to procedural characteristics in manufacturing systems?
2. What theoretical framework can integrate lean principles with procedural analysis to enable systematic waste identification?
3. What are the theoretical properties and limitations of such a framework for manufacturing systems applications?

The research contributes both theoretical extensions to lean manufacturing principles and practical frameworks for systematic procedural analysis in manufacturing systems contexts.

2. Materials and Methods

2.1. Theoretical Development Methodology

This study employs design science research methodology to develop theoretical frameworks that address identified practical problems while contributing to scientific knowledge [13]. Design science research is appropriate for this investigation as it focuses on creating innovative theoretical artifacts (the PWI framework) that extend existing theory (lean manufacturing) to new domains (procedural analysis) while establishing foundation for future empirical validation.

The theoretical development follows a systematic three-phase approach: (1) theoretical synthesis of lean manufacturing principles with procedural analysis concepts, (2) framework architecture development through systematic mapping methodologies, and (3) theoretical characterization of framework properties and limitations.

2.2. Theoretical Foundation Integration

2.2.1. Extended Procedure Representation Language (e-PRL)

The theoretical foundation for procedural decomposition utilizes the extended Procedure Representation Language (e-PRL) framework developed by Bashatah and Sherry [15]. The e-PRL provides systematic methodology for decomposing procedural steps into constituent elements, enabling quantitative analysis of procedural characteristics.

The e-PRL framework identifies sixteen distinct procedural elements organized around five core components: (1) Actor: the operator responsible for step execution, (2) Trigger: conditions and data required for step initiation, (3) Decision: cognitive evaluation requirements, (4) Action: physical tasks to be performed, and (5) Waiting/Verification: timing and confirmation requirements for step completion.

Each core component is further decomposed through three specification dimensions: “What” (specific requirements), “How” (methods or data needed), and “Where” (location or source). This systematic decomposition enables identification of specific procedural elements that can be systematically analyzed for efficiency characteristics.

2.2.2. Lean Manufacturing Theoretical Integration

The theoretical integration of lean manufacturing principles with procedural analysis requires systematic examination of how waste concepts manifest in information processing and coordination activities rather than physical material flow. Each lean waste type is analyzed for its conceptual applicability to procedural contexts:

Theoretical Waste Manifestations in Procedural Contexts

- Transportation Waste: Information transfer inefficiencies between sources or systems
- Inventory Waste: Excessive documentation or informational redundancy
- Motion Waste: Redundant procedural steps or unnecessary repetition
- Waiting Waste: Delays caused by approval requirements or verification processes
- Overproduction Waste: Excessive procedural detail beyond operational requirements
- Overprocessing Waste: Redundant verification or checking activities
- Defects Waste: Missing critical information leading to execution errors

2.2.3. Theoretical Basis for PWI Parameters and Framework Architecture Development

The PWI framework employs specific parameters and thresholds for waste identification that require theoretical justification to ensure systematic rigor and consistent application across different manufacturing contexts. This section establishes the cognitive, mathematical, and manufacturing systems theory foundations underlying the framework's measurement approaches and threshold values, followed by the systematic mapping methodology used to develop the framework architecture.

Cognitive Load Theory Foundation for Overproduction Waste Thresholds

The 30-word threshold for identifying overproduction waste in procedural instructions derives from the established cognitive load theory and working memory research. Miller's (1956) seminal research on working memory capacity demonstrated fundamental limitations in human information processing, establishing that individuals can effectively process approximately seven (plus or minus two) discrete information units simultaneously [16]. This foundational work has been extensively validated and refined through subsequent cognitive psychology research.

Mayer's (2002) multimedia learning theory extends these principles to instructional design, demonstrating that procedural instructions exceeding cognitive processing capacity create extraneous cognitive load that impedes rather than supports task execution [17]. Specifically, research in instructional design indicates that procedural instructions containing more than 25-30 words consistently exceed working memory capacity, leading to cognitive overload and reduced comprehension effectiveness [18].

Sweller's (1994) cognitive load theory provides additional theoretical support, distinguishing between intrinsic cognitive load (essential task requirements), extraneous cognitive load (inefficient presentation), and germane cognitive load (schema construction) [19]. The 30-word threshold represents the empirically validated point where additional procedural detail transitions from germane (helpful) to extraneous (wasteful) cognitive load [20].

Information Processing Theory for Inventory Waste Parameters

The elements-per-action ratio parameters for inventory waste identification derive from information processing theory and procedural complexity research. Paivio's (1986) dual-coding theory establishes that human cognition processes visual and verbal information through separate but interconnected channels, each with limited capacity [21]. Procedural instructions containing excessive informational elements relative to essential actions overwhelm these processing channels, creating informational inventory waste analogous to physical inventory accumulation in manufacturing systems.

The baseline threshold of 3.0 elements per action reflects the minimum information requirements for effective procedural execution, which involves actor identification, trigger recognition, and action specification. Research on human factor engineering demonstrates that procedural steps requiring fewer than three informational elements typically lack sufficient detail for consistent execution [22]. The maximum threshold of 15.0 elements per

action represents the upper boundary where additional information consistently reduces rather than enhances execution effectiveness.

Clark and Mayer's (2003) research on multimedia instruction provides empirical support for these thresholds, demonstrating that optimal procedural information density balances completeness with cognitive accessibility [18]. Procedures exceeding the 15-element threshold show decreased execution accuracy and increased completion time, indicating that excessive information creates procedural inventory waste.

Composite Indicator Methodology for PWI Calculations

The three PWI calculation methodologies are derived from the established composite indicator development theory and multi-criteria decision analysis. The theoretical foundations for each calculation method ensure systematic rigor while providing complementary analytical perspectives.

(1) PWI-Weighted Theoretical Foundation

The PWI-Weighted calculation employs linear aggregation methodology proven effective in manufacturing performance measurement systems, following the methodology established by Nardo et al. (2005) for composite indicator construction [23]. This approach assumes compensatory relationships between waste types, where improvements in one area can offset deficiencies in another. The OECD (2008) handbook on composite indicators validates this methodology for complex performance assessment, requiring balanced evaluation across multiple dimensions [24].

Equal weighting (0.143 for each waste type) provides a theoretically neutral starting point that treats all waste types as equally important until industry-specific evidence suggests a differential impact. This approach aligns with established composite indicator practices where equal weighting represents the default assumption in the absence of empirical weight determination [25].

(2) PWI-Maximum Theoretical Foundation

The PWI-Maximum calculation applies Goldratt and Cox's (2004) theory of constraints (TOC) principles to procedural efficiency assessment [26]. The TOC establishes that system performance is limited by the weakest component, making constraint identification critical for improvement prioritization. Applied to procedural analysis, the highest waste score represents the primary constraint limiting overall procedural efficiency.

This non-compensatory approach recognizes that severe inefficiency in one waste category cannot be offset by efficiency in other categories, reflecting the manufacturing systems reality, where bottlenecks determine overall system performance regardless of excellence elsewhere.

(3) PWI-RMS Mathematical Properties

The PWI-RMS calculation utilizes the mathematical properties of root mean square calculations to emphasize extreme values while maintaining sensitivity to overall waste distribution. Freudenberg's (2003) analysis of composite indicator methodology demonstrates that RMS calculations provide superior outlier detection compared to simple averaging approaches [25].

The RMS approach proves particularly valuable for identifying procedures with concentrated waste problems that might be masked in weighted averaging. The mathematical emphasis on squared terms ensures that procedures with extreme waste concentrations receive appropriate attention for comprehensive redesign consideration.

Manufacturing Systems Theory Integration

The PWI framework parameters integrate manufacturing systems theory principles with procedural analysis requirements. The threshold values reflect the recognition that procedures function as information processing subsystems within broader manufacturing systems, requiring optimization approaches consistent with overall system performance objectives.

Manufacturing systems theory establishes that subsystem inefficiencies propagate throughout broader systems, affecting overall performance [5]. PWI parameters are calibrated to identify procedural inefficiencies at levels that significantly impact system performance while avoiding the false positive identification of acceptable procedural complexity.

The framework's multi-threshold approach recognizes that different manufacturing contexts require different efficiency standards while maintaining systematic identification principles. Baseline thresholds ensure universal applicability while maximum thresholds prevent framework insensitivity to extreme inefficiencies.

Parameter Validation Framework

The theoretical foundations established in this section provide a conceptual basis for PWI parameters while recognizing that practical implementation requires empirical validation across different manufacturing contexts. The parameters represent theoretically grounded starting points that may require calibration based on industry-specific characteristics and operational requirements.

The validation framework establishes criteria for future empirical research examining the correlation between PWI-identified inefficiencies and actual operational performance metrics. This approach ensures a systematic basis for parameter refinement while maintaining consistent application across different research contexts.

Future empirical validation should focus on (1) correlation analysis between PWI scores and execution time metrics, (2) sensitivity analysis of threshold values across different manufacturing environments, and (3) comparative analysis of PWI effectiveness relative to traditional procedural assessment methods. The theoretical foundation provides a systematic basis for such empirical validation while ensuring consistent application across different research contexts.

2.3. Comparison with Existing Procedural Analysis

The PWI framework addresses the limitations in existing procedural analysis methodologies by providing systematic waste identification principles specifically designed for manufacturing procedural optimization. This section examines how PWI differs from and complements established approaches in procedural analysis, process improvement, and manufacturing optimization.

2.3.1. Business Process Management (BPM) and Workflow Analysis

Business process management methodologies, including the business process model and notation (BPMN), focus primarily on organizational workflow optimization and process mapping [27]. BPMN approaches excel at visualizing process flow and identifying bottlenecks in organizational workflows but lack systematic frameworks for identifying specific waste types within procedural content. BPMN provides comprehensive process visualization capabilities and supports process automation, yet it does not incorporate lean manufacturing principles or provide quantitative waste measurement methodologies.

The PWI framework extends beyond traditional BPMN workflow mapping by incorporating lean waste identification principles specifically adapted for procedural contexts. While BPMN focuses on process flow efficiency, PWI addresses procedural content effi-

ciency through a systematic analysis of information redundancy, verification processes, and cognitive load optimization. This complementary relationship enables organizations to optimize both workflow structure (through BPMN) and procedural content (through PWI) for comprehensive process improvement.

2.3.2. Six Sigma and Traditional Process Improvement Methods

Six Sigma methodologies, employing the Define, Measure, Analyze, Improve, Control (DMAIC) framework, provide systematic approaches to process improvement through statistical process control and variation reduction [28]. Six Sigma demonstrates effectiveness in manufacturing process optimization by focusing on defect reduction and process capability improvement. However, traditional Six Sigma applications concentrate primarily on physical manufacturing processes and measurable quality metrics, with limited systematic approaches for knowledge work and procedural optimization.

The PWI framework addresses this gap by extending systematic improvement principles to procedural analysis through lean waste identification concepts specifically mapped to informational and coordination activities. While Six Sigma provides statistical tools for process control, PWI offers systematic waste identification methodologies for procedural content optimization. The frameworks maintain compatibility through a shared emphasis on quantitative measurement and systematic improvement approaches, enabling integrated implementation where Six Sigma addresses process performance while PWI addresses procedural efficiency.

2.3.3. Industry 4.0 and Digital Work Instructions

Industry 4.0 initiatives emphasize digital transformation through smart manufacturing systems, IoT integration, and digital work instructions. Digital work instruction systems focus on information delivery optimization, real-time guidance provision, and integration with manufacturing execution systems. These approaches excel at improving information accessibility and reducing execution errors through enhanced user interfaces and automated guidance systems.

PWI complements Industry 4.0 approaches by providing systematic methodology for optimizing the content and structure of digitized procedures before implementation in smart manufacturing environments. While digital work instructions optimize information presentation and delivery, PWI optimizes information content through systematic waste elimination. This integration enables comprehensive procedural optimization, where digital systems provide enhanced delivery mechanisms while PWI ensures optimal procedural content design.

2.3.4. Procedural Analysis in Safety-Critical Domains

Existing procedural analysis frameworks, particularly those developed for aviation and nuclear power contexts, focus primarily on safety assurance and regulatory compliance [29,30]. These approaches emphasize safety-critical operation analysis, human factor considerations, and regulatory requirement satisfaction. The e-PRL framework, upon which PWI builds, provides systematic procedural decomposition methodologies proven effective in safety-critical contexts.

PWI extends established procedural analysis capabilities by incorporating efficiency optimization alongside safety considerations through lean waste identification principles. While safety-critical procedural analysis emphasizes error prevention and compliance verification, PWI addresses efficiency optimization through systematic waste elimination. This extension enables comprehensive procedural assessment that maintains safety standards while achieving operational efficiency improvements.

2.3.5. Lean Manufacturing in Physical Processes

Traditional lean manufacturing applications focus on physical material flow optimization, inventory reduction, and waste elimination in production processes [6,7]. Lean principles demonstrate proven effectiveness in identifying and eliminating waste in manufacturing operations through a systematic application of the seven waste categories. However, existing lean implementations largely exclude procedural and knowledge work optimization from systematic analytical frameworks.

The PWI framework represents the first systematic extension of lean waste identification principles to procedural analysis, creating a theoretical bridge between proven lean methodologies and knowledge work optimization. This extension maintains the systematic rigor and proven theoretical foundation of lean principles while addressing the previously unaddressed domain of procedural inefficiency in manufacturing systems.

2.3.6. Comparative Framework Analysis

Table 1 provides a systematic comparison of PWI with existing procedural optimization approaches across key analytical dimensions.

Table 1. Comparison between PWI and other approaches.

Approach	Systematic Waste Identification	Quantitative Metrics	Multi-Method Analysis	Manufacturing Focus	Procedural Content Optimization
Traditional SOP Review	No	No	No	Limited	Subjective
BPM/BPMN	Limited (workflow)	Partial	No	No	Process Flow Only
Six Sigma (DMAIC)	Yes (physical processes)	Yes	Limited	Yes	Limited
Industry 4.0/Digital Instructions	No	Partial	No	Yes	Delivery Optimization
Safety-Critical Procedural Analysis	No	Limited	No	Limited	Safety Focus Only
PWI Framework	Yes (procedural-specific)	Yes	Yes	Yes	

2.3.7. Integration Opportunities and Complementary Applications

The PWI framework is designed for theoretical compatibility and practical integration with existing manufacturing optimization approaches. Organizations implementing comprehensive improvement initiatives can utilize PWI alongside established methodologies to achieve systematic optimization across multiple dimensions.

BPM Integration: PWI procedural content optimization combined with BPM workflow optimization enables comprehensive process improvement, addressing both structural and content efficiency.

Six Sigma Integration: PWI waste identification provides input for Six Sigma improvement projects focusing on procedural efficiency, while Six Sigma statistical methods enable PWI validation and continuous monitoring.

Industry 4.0 Integration: PWI-optimized procedural content enhances the effectiveness of digital work instruction systems and smart manufacturing implementations.

This multi-method integration approach recognizes that comprehensive manufacturing systems optimization requires multiple theoretical perspectives working in coordination

rather than single-method approaches that may miss critical system elements. The PWI framework fills a specific theoretical gap in systematic procedural optimization while maintaining compatibility with established improvement methodologies.

3. Results

3.1. Procedural Waste Index (PWI) Framework

The primary result of this theoretical development is the Procedural Waste Index (PWI) framework, which provides systematic methodology for extending lean manufacturing principles to procedural analysis in manufacturing systems. The framework integrates lean waste identification with procedural decomposition to create a comprehensive approach for systematic procedural efficiency assessment.

3.1.1. Lean Waste to Procedure Element Theoretical Mapping

The framework establishes systematic theoretical relationships between each lean waste type and specific procedural characteristics identified through e-PRL decomposition (Table 2).

Table 2. Mapping of Lean Wastes to Procedure Elements.

Lean Waste	Procedure Manifestation	e-PRL Elements Analyzed	Theoretical Measurement Approach
Transportation Waste (TW)	Information transfer between sources	Trigger (Where, Decision (Where), Verification (Where))	Ratio of unique information sources to total procedural steps
Inventory Waste (IW)	Excessive documentation	All e-PRL elements vs. Action (What)	Ratio of total procedural elements to essential action elements
Motion Waste (MW)	Redundant steps	Action (What) across all steps	Frequency of duplicate actions within procedures
Waiting Waste (WW)	Approval delays	Waiting (What), Verification (What)	Count of delay-inducing procedural elements
Overproduction Waste (OW)	Excessive detail	Action (How), Decision (How), Trigger (How) with >30 words	Proportion of overly detailed instructional elements
Overprocessing Waste (OPW)	Redundant verifications	Verification (What), Verification (How), Verification (Where)	Frequency of redundant verification elements
Defects Waste (DW)	Error-prone instructions	Missing Actor, Action (What), Trigger (What)	Proportion of procedural steps lacking critical elements

3.1.2. PWI Calculation Methods

The framework provides three complementary calculation methodologies, each capturing different theoretical perspectives on procedural efficiency:

PWI-Weighted (PWI_w) is a weighted aggregation approach enabling industry-specific customization and can be calculated using Equation (1).

$$PWI_w = \sum (W_i \times S_i), \quad (1)$$

where W_i represents the weight for waste type i and S_i represents the score for waste type i .

PWI-Maximum's (PWI_m) approach follows the theory of constraints principle for identifying limiting is calculated using Equation (2), where S_i represents the score for waste type i .

$$PWI_m = \text{Max}(S_i), \quad (2)$$

Finally, the root mean square approach emphasizes outlier sensitivity, making it sensitive to extreme waste values and procedural imbalances. PWI-Root Mean Square (PWI_{RMS}) is calculated using Equation (3).

$$PWI_{RMS} = \sqrt{\frac{\sum S_i^2}{7}} \quad (3)$$

3.2. Framework Validation Through Case Study Application

To demonstrate practical applicability and validate theoretical predictions, the PWI framework was applied to a standard operating procedure for respirator fit testing in accordance with OSHA regulations. This procedure represents a typical safety-critical manufacturing support process requiring precise execution, comprehensive documentation, and regulatory compliance.

The respirator fit testing SOP, a hypothetical SOP, contained 48 distinct procedural steps organized across the six following main phases: pre-test preparation (eight steps), initial respirator familiarization (13 steps), conducting the fit test (18 steps with multiple protocol options), fit test exercises (eight steps), evaluating results (three steps), and post-test procedures (five steps). The procedure encompassed both qualitative and quantitative testing methodologies, multiple equipment configurations, and comprehensive documentation requirements, providing sufficient complexity to demonstrate all seven waste types within the PWI framework.

3.2.1. e-PRL Decomposition Analysis

The complete 48-step procedure was decomposed using e-PRL methodology, identifying 546 total procedural elements. This comprehensive decomposition provides the quantitative foundation for subsequent waste analysis.

Key decomposition findings include complete actor specification in 95.8% of steps (46 of 48), universal action (What) element presence across all steps, and verification requirements in 75% of steps (36 of 48). The systematic analysis revealed eight steps containing decision requirements and 11 steps requiring explicit waiting periods, with an average of 11.4 e-PRL elements per procedural step.

This decomposition enables precise waste calculation by providing an explicit identification of all procedural elements required for the application of lean waste identification principles.

3.2.2. Waste Analysis

The respective waste analysis for the decomposed SOP is provided in Table 3.

3.2.3. PWI Calculation Results

The waste analysis presented in Table 3 yields individual waste scores that demonstrate significant variation across waste categories, with inventory waste achieving the highest score of 70.0, followed by overproduction waste at 30.8, overprocessing waste at 25.0, transportation and motion waste both at 12.5, defect waste at 6.3, and waiting waste at 0.0. These individual scores provide the foundation for calculating overall PWI scores using the three complementary methodologies developed in the framework.

Table 3. Waste analysis for hypothetical SOP.

Waste Type	Elements Analyzed	Findings	Calculation	Score
Transportation (TW)	Information sources across all steps (Trigger Where)	6 unique sources identified	$(6 \text{ sources}/48 \text{ steps}) \times 100$	12.5
Inventory Waste (IW)	Total e-PRL elements vs. action (What) elements	546 total elements across 48 steps Elements per action ratio: 11.4 Baseline threshold: 3.0, Maximum threshold: 15	$((11.4 - 3)/(15.0 - 3)) \times 100$	70.0
Motion Waste (MW)	Duplicate actions across procedures	6 duplicate actions identified	$(6 \text{ duplicates}/48 \text{ actions}) \times 100$	12.5
Waiting Waste (WW)	Explicit waiting requirements	11 waiting steps Normal baseline: 14.4 steps (30% of 48)	$\max(0, (11 - 14.4)/48 \times 100)$	0
Overproduction Waste (OW)	“How” elements >30 words	8 verbose elements out of 26 total	$(8 \text{ verbose}/26 \text{ total}) \times 100$	30.8
Overprocessing Waste (OPW)	Redundant verification elements	9 redundant verifications out of 36 total	$(9 \text{ redundant}/36 \text{ total}) \times 100$	25.0
Defects Waste (DW)	Steps missing critical elements	3 defective steps identified	$(3 \text{ defective}/48 \text{ total}) - 100$	6.3

Using equal weights of 0.143 for all waste types, the PWI-Weighted calculation yields a score of 22.4, computed as the sum of each weighted waste component: $(0.143 \times 12.5) + (0.143 \times 70.0) + (0.143 \times 12.5) + (0.143 \times 0.0) + (0.143 \times 30.8) + (0.143 \times 25.0) + (0.143 \times 6.3)$. The PWI-Maximum approach identifies the highest individual waste score of 70.0, representing the inventory waste constraint that limits overall procedural efficiency. The PWI-Root Mean Square calculation produces a score of 30.4, computed as the square root of the sum of squared individual scores divided by seven: $\sqrt{((12.5^2 + 70.0^2 + 12.5^2 + 0.0^2 + 30.8^2 + 25.0^2 + 6.3^2)/7)}$.

The three PWI calculation methods demonstrate distinct analytical characteristics that validate the framework’s multi-perspective design, with the substantial 47.6-point difference between PWI-Weighted (22.4) and PWI-Maximum (70.0) revealing concentrated waste in a specific category rather than distributed inefficiency across multiple waste types. The PWI-RMS score (30.4) provides intermediate sensitivity, emphasizing the extreme inventory waste value while maintaining mathematical balance across all waste components, producing a result 35.8% higher than PWI-Weighted due to the squared emphasis on outlier values. This method differentiation confirms theoretical predictions about complementary analytical perspectives, with PWI-Maximum successfully identifying the primary constraint requiring immediate attention, while PWI-Weighted provides a balanced assessment acknowledging that six of the seven waste categories show moderate or low inefficiency levels.

3.2.4. Result Interpretation and Framework Validation

The systematic PWI analysis reveals inventory waste as the dominant procedural inefficiency with a score of 70.0, indicating that the respirator fit testing procedure contains excessive documentation elements relative to essential actions. With 546 total e-PRL elements distributed across 48 steps, the procedure exhibits an elements-per-action ratio of 11.4, substantially exceeding the framework’s baseline threshold of 3.0 elements per action. This

finding validates the theoretical mapping of excessive procedural documentation to lean inventory concepts, demonstrating the framework's sensitivity to information-based waste manifestations that parallel physical inventory accumulation in manufacturing systems.

The PWI-Maximum score of 70.0 correctly identifies inventory waste as the critical constraint requiring immediate attention, confirming the framework's bottleneck identification capability. This concentration of waste in a single category, while other waste types remain below 31%, indicates that procedural optimization efforts should prioritize documentation streamlining over other efficiency improvements, providing clear guidance for resource allocation decisions.

Overproduction waste emerges as the secondary inefficiency (30.8%), reflecting overly detailed procedural instructions that exceed cognitive processing requirements. The identification of eight verbose elements exceeding 30 words among 26 total "How" elements validates the framework's ability to detect information overload that impedes rather than supports procedural execution effectiveness.

Framework Performance Validation

The case study validates several critical theoretical framework properties. Discrimination capability is confirmed through the 70-point spread between the lowest (0.0) and highest (70.0) waste scores, demonstrating adequate sensitivity for meaningful procedure comparison and improvement prioritization. Method complementarity is validated through logical relationships between calculation approaches, with PWI-Maximum highlighting critical bottlenecks, PWI-Weighted providing balanced assessment, and PWI-RMS emphasizing extreme values appropriately.

The framework's identification of zero waiting waste despite explicit time requirements (5-min comfort assessment, 2-min stabilization periods, exercise durations) validates the theoretical distinction between value-adding operational timing and wasteful delays. This finding confirms adherence to fundamental lean principles that recognize necessary operational requirements as distinct from non-value-adding waste.

Validated Improvement Recommendations

Priority 1: Reduce documentation complexity by eliminating non-essential e-PRL elements, targeting 70.0% inventory waste through a systematic review of the 546 total procedural elements to identify consolidation opportunities.

Priority 2: Streamline verbose instructional content by reducing "How" element word counts to essential information only, addressing the 30.8% overproduction waste through cognitive load optimization and clearer communication.

Priority 3: Standardize remaining inefficiencies, including information source coordination (12.5% transportation waste) and verification process optimization (25.0% overprocessing waste), to achieve comprehensive procedural improvement.

Framework Limitations Identified

The case study reveals important implementation considerations for safety-critical procedures. The high inventory waste score (70.0%) reflects regulatory compliance requirements inherent in OSHA-mandated procedures, indicating that PWI thresholds may require industry-specific calibration for safety-critical contexts where comprehensive documentation serves legal and safety functions beyond operational efficiency.

The framework's performance across different waste types demonstrates varying sensitivity levels, with inventory and overproduction waste showing high discrimination capability while transportation and motion waste exhibit moderate sensitivity in this procedural context. This variation suggests that framework effectiveness may depend on procedural characteristics and industry context.

This comprehensive case study demonstrates the PWI framework's capability to systematically identify specific procedural inefficiencies, quantify their relative impact through multiple analytical perspectives, and provide evidence-based guidance for improvement prioritization in complex manufacturing support procedures while maintaining recognition of necessary regulatory and safety requirements.

4. Discussion

4.1. Theoretical Contributions to Manufacturing Systems

4.1.1. Extension of Lean Manufacturing Theory

This research makes a significant theoretical contribution by systematically extending lean manufacturing principles beyond their traditional application in physical material flow to the domain of information processing and procedural design. The successful conceptual mapping of lean waste concepts to procedural characteristics demonstrates that fundamental lean principles maintain theoretical validity when applied to knowledge work optimization within manufacturing systems.

The integration of lean principles with procedural analysis creates a novel theoretical bridge between operations management and human factors engineering. This extension contributes to the evolution of lean manufacturing theory by recognizing procedures as critical system components that require systematic optimization approaches comparable to those applied to physical processes.

4.1.2. Systems-Theoretic Framework Development

The PWI framework contributes to manufacturing systems theory by providing systematic methodology for analyzing procedural subsystems using established efficiency principles. This represents an advancement in systems-theoretic approaches to manufacturing optimization by explicitly addressing information processing and coordination mechanisms that influence overall system performance.

The framework's recognition of procedures as analyzable system components with quantifiable efficiency characteristics extends systems theory applications in manufacturing contexts. This theoretical advancement enables more comprehensive system optimization approaches that address both physical and informational system elements.

4.2. Framework Design Rationale

4.2.1. Multi-Method Calculation Approach

The development of three complementary PWI calculation methods reflects theoretical recognition that procedural efficiency encompasses multiple analytical dimensions. The weighted aggregation approach provides comprehensive assessment capability, while the maximum constraint approach emphasizes critical limitation identification. The root mean square approach offers sensitivity to extreme conditions that may indicate systemic problems.

This multi-method design acknowledges that manufacturing organizations require different analytical perspectives depending on their improvement objectives and operational contexts. The theoretical framework provides flexibility while maintaining systematic rigor across all calculation approaches.

4.2.2. e-PRL Integration Justification

The integration of the e-PRL framework for procedural decomposition provides the necessary theoretical foundation for systematic procedural analysis. The e-PRL's systematic element identification enables consistent application of lean waste concepts across different procedural contexts, ensuring theoretical rigor in waste identification processes.

This integration represents theoretical synthesis of established procedural analysis methodology with lean manufacturing principles, creating coherent framework that leverages strengths of both theoretical domains while addressing limitations of purely qualitative procedural assessment approaches.

4.3. Theoretical Positioning and Comparative Analysis

4.3.1. Advancement Beyond Existing Approaches

The PWI framework advances beyond existing procedural optimization approaches by providing a systematic theoretical foundation for waste identification rather than relying on expert intuition or ad hoc improvement methods. This represents a significant theoretical advancement in knowledge work optimization within manufacturing contexts.

Compared to traditional procedural assessment methods, the framework provides theoretical rigor, systematic methodology, and quantitative measurement capability that enables consistent application across different organizational contexts. This theoretical advancement addresses long-standing limitations in procedural optimization approaches.

4.3.2. Integration with Existing Theoretical Frameworks

The PWI framework is designed for theoretical compatibility with existing manufacturing systems optimization approaches. The framework complements rather than replaces existing quality management and continuous improvement methodologies by providing systematic procedural analysis capability.

This integration approach recognizes that comprehensive manufacturing systems optimization requires multiple theoretical perspectives working in coordination rather than single-method approaches that may miss critical system elements.

4.4. Implementation Theoretical Requirements

4.4.1. Organizational Prerequisites

Successful framework implementation requires organizational commitment to systematic procedural analysis and willingness to invest in procedural optimization initiatives. The framework assumes organizational maturity in quality management and continuous improvement practices.

Theoretical implementation requirements include the availability of detailed procedural documentation, personnel trained in systematic analysis methodologies, and management support for data-driven procedural improvement initiatives.

4.4.2. Technical Infrastructure Requirements

The framework requires technical capabilities for systematic procedural decomposition and quantitative analysis. Organizations must possess or develop competencies in procedural documentation analysis and systematic efficiency assessment methodologies.

Integration with existing manufacturing information systems may require technical development to enable automated procedural analysis and continuous monitoring of procedural efficiency metrics.

4.5. Future Research Requirements

4.5.1. Empirical Validation Priorities

The theoretical framework requires comprehensive empirical validation to establish practical utility and measurement accuracy. Priority validation studies should examine the correlation between PWI scores and actual operational performance metrics, including execution time, error rates, and compliance measures.

Empirical research should validate the theoretical mapping relationships between lean wastes and procedural elements through controlled studies using actual manufacturing

procedures. This validation must demonstrate that PWI-identified inefficiencies correspond to real operational problems.

4.5.2. Framework Refinement Opportunities

Future research should explore industry-specific adaptations of the framework, particularly weight determination for different manufacturing contexts and threshold calibration for waste measurement algorithms. Advanced algorithmic development may enhance waste detection accuracy and reduce subjective elements in waste identification processes.

Integration research should examine framework compatibility with emerging manufacturing technologies, including digital work instructions and smart manufacturing systems that may provide new data sources for procedural analysis.

4.6. Theoretical Limitations and Assumptions

4.6.1. Foundational Assumptions

The framework assumes that lean manufacturing principles are universally applicable to knowledge work optimization, which may not hold across all cultural or organizational contexts. The framework also assumes that procedural efficiency can be meaningfully quantified using systematic measurement approaches.

The theoretical development assumes that manufacturing procedures exhibit sufficient standardization to enable systematic analysis, which may not apply to highly customized or adaptive operational contexts.

4.6.2. Boundary Conditions

The framework's theoretical applicability is bounded by several conditions: discrete manufacturing contexts, moderate procedural complexity, documented procedural standards, and organizational commitment to systematic improvement. Applications outside these boundary conditions may require significant framework modification.

4.6.3. Empirical Validation Requirements and Rationale

The PWI framework requires empirical validation to establish a correlation between theoretical waste measurements and actual operational performance outcomes, following established practices in manufacturing systems research for theoretical framework development. This validation approach aligns with similar frameworks in the lean manufacturing literature, where theoretical constructs must demonstrate predictive validity through controlled studies measuring execution time, error rates, and compliance metrics.

The framework's theoretical development provides the necessary foundation for rigorous empirical testing by establishing systematic measurement criteria, consistent calculation methodologies, and clear validation protocols. Without this theoretical groundwork, empirical validation would lack the systematic rigor required for reliable results and consistent application across different manufacturing contexts.

This sequential approach, theoretical development followed by empirical validation, represents standard practice in manufacturing systems research, as demonstrated by the historical development of lean manufacturing tools, quality management systems, and process optimization frameworks. The current study establishes the prerequisite theoretical foundation that enables future empirical research to proceed with methodological rigor and consistency.

The framework's readiness for empirical validation is demonstrated through the systematic case study analysis, which shows practical applicability and generates specific, measurable recommendations. Future empirical studies can utilize this theoretical foundation to establish statistical relationships between PWI scores and operational performance metrics across diverse manufacturing contexts.

5. Conclusions

5.1. Theoretical Contributions Summary

This research addresses a significant gap in manufacturing systems theory by developing a systematic framework for extending lean manufacturing principles to procedural analysis. The Procedural Waste Index (PWI) framework provides a theoretical foundation for systematic identification and quantification of procedural inefficiencies in manufacturing contexts.

The study makes several important theoretical contributions: systematic extension of lean waste concepts to knowledge work optimization, integration of established procedural analysis methodology with lean principles, and development of a multi-perspective quantitative framework for procedural efficiency assessment. These contributions advance both lean manufacturing theory and manufacturing systems optimization approaches.

5.2. Framework Theoretical Properties

The PWI framework exhibits several important theoretical properties that establish a foundation for practical application. The systematic mapping of lean wastes to procedural elements provides a consistent methodology for waste identification across different manufacturing contexts. The multi-method calculation approach offers flexibility while maintaining analytical rigor.

The framework's integration with existing quality management and continuous improvement approaches enables comprehensive manufacturing systems optimization that addresses both physical and informational system elements. This integration capability represents a significant advancement in systematic manufacturing optimization methodology.

5.3. Research Limitations and Future Directions

This theoretical development study establishes a conceptual foundation for systematic procedural analysis but requires empirical validation before practical implementation. The framework's reliance on threshold values and weighting schemes necessitates industry-specific calibration through empirical research.

Future research priorities include empirical validation studies using actual manufacturing procedures, industry-specific framework adaptation, and integration research with emerging manufacturing technologies. Advanced algorithmic development may enhance framework accuracy and reduce implementation complexity.

5.4. Implications for Manufacturing Systems Practice

The PWI framework provides manufacturing organizations with a theoretical foundation for systematic procedural optimization initiatives. The framework's quantitative approach enables integration with existing performance measurement systems and continuous improvement methodologies.

Organizations seeking to implement comprehensive lean manufacturing approaches can utilize the framework to extend optimization efforts beyond physical processes to include procedural analysis. This comprehensive approach may yield significant operational improvements through systematic elimination of procedural inefficiencies.

5.5. Contribution to Systems Theory

This research contributes to manufacturing systems theory by demonstrating systematic approach to analyzing procedural subsystems using established efficiency principles. The framework's recognition of procedures as critical system components requiring systematic optimization represents a theoretical advancement in comprehensive systems optimization approaches.

The successful integration of lean principles with procedural analysis establishes precedent for applying established optimization methodologies to knowledge work components within manufacturing systems. This theoretical advancement opens new research directions in systematic knowledge work optimization within industrial contexts.

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Abbreviations

Abbreviation	Full Term
SOP	Standard Operating Procedure
PWI	Procedural Waste Index
e-PRL	extended Procedure Representation Language
ICH GCP	International Conference on Harmonization Good Clinical Practice
TW	Transportation Waste
IW	Inventory Waste
MW	Motion Waste
WW	Waiting Waste
OW	Overproduction Waste
OPW	Overprocessing Waste
DW	Defects Waste
PWI_w	PWI-Weighted
PWI_m	PWI-Maximum
PWI_RMS	PWI-Root Mean Square

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