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Research article

A structured model for continuous improvement methodology deployment and sustainment: A case study

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ABSTRACT

This research focuses on designing a clear methodology for problem-solving. It investigates the application of a defined 'Lean' methodology for the proactive application of process improvement activities using a phased digitized measurement and monitoring system. This case study in a Medtech organisation utilized the Plan, Do, Check, Act (PDCA) model to develop a Lean system and structure to support managing the process improvement or project management element of a Continuous Improvement (CI) framework. The results from the pilot of this study delivered financial gains and demonstrated how a robust structure and methodology to measure improvement activity and success provided a strong, sustainable foundation for customer satisfaction, efficiency, cost reduction and employee engagement improvement. It also highlighted the importance of focusing on proactive process improvement as part of a CI framework. The study provides valuable insights into the effective implementation of Lean principles and process improvement via a sustainable model, thereby contributing to the body of knowledge in this field. This study demonstrated how the developed model supported process improvement activity underpinning the development of a wider continuous improvement culture to support Lean deployment and sustainment and that systems can drive behaviour. Additionally, this application in the healthcare manufacturing sector adds to the sparse application in the literature from this sector.

1. Introduction

The global medical device industry is expected to experience steady growth, reaching almost US$800 billion by 2030 due to rising demand for innovative devices and services, amounting to approximately 5 % growth year on year [1]. Congruently, the industry faces challenges from continuous downward pressure on pricing, with hospitals and healthcare settings looking for ways to pay less for medical devices while ensuring better patient outcomes [2]. To remain competitive globally, medical device companies are increasingly focusing on continuous improvement (CI) and Operational Excellence (OpEx) to gain operational efficiency to meet the evolving needs of the healthcare industry [3].

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OpEx is a framework for businesses to focus on growth and execute their strategy to give a competitive advantage. The first step toward OpEx in an organisation is to build efficient processes that make it clear to all employees whether or not an organization's systems are running smoothly and make it possible for team members to step in with improvements when necessary[3.4,5].

Many manufacturers are adopting OpEx methodologies such as Lean Six Sigma (LSS) to eliminate waste, improve quality, and reduce costs [4]. Studies have demonstrated that the majority of CI projects fail [5]. The adoption of CI or Operational Excellence (OpEx) initiatives uses a systematic and structured methodological approach usually led by CI experts and relevant team members [6–8]. However, applying these methodologies can be restricted to one Project. It can need a systematic step-wise guide for running and managing process improvement (PI) projects as part of a wider CI framework and Lean journey towards sustainability [4].

Additionally, there is limited research on how a hybrid workforce can participate and engage in this process [9,10]. While Quality improvement and PDCA as a methodology to drive continuous improvements is already widely recognized and has been discussed and developed many times in organisations and literature and merged with other CI methods and tools; there is a gap in the literature in relation to the need for a structured and procedural guide for PI projects that aligns with other systems within a company. Such a guide could potentially increase participation levels, embed a desired culture, improve collaboration, effectiveness, and efficiency of PI projects and manage PI projects within the context of a broader CI framework and Lean. This research focuses on a case study within a medical device company that manufactures various cardiology, radiology, oncology, critical care, and endoscopy devices. The company faced a challenge after 5 years of Lean implementation due to the lack of a standardized methodology and system for structured, measurable, and well-managed process improvement projects aligned with their current systems and CI framework. PI projects and structured PI methodology were simply not embedded into the wider organisations and systems despite the training, knowledge and receptive culture to PI. Thus, PI opportunities were getting lost or not realised, and opportunities for quality improvement and cost reduction were being missed. In an organisation that manufactures and designs medical devices, enhancing product quality is essential to protecting patient health and ensuring adequate device supply as well as being mandated by the regulators. The consequences of poor CI frameworks could also in effect lead to regulatory recalls which is very damaging for corporate image as well as confidence in the device being manufactured.

Consequently, the research objective is to provide a practical guide for running and monitoring PI projects, which may be leveraged to improve the sustainment of CI participation within the site.

Section 2 outlines the literature review, section 3 describes the methodology deployed, and Section 4 discusses the results. Finally, sections 5 and 6 discuss and conclude the results.

2. Literature review

2.1. PDCA in lean deployment

Bhamu and Singh Sangwan [4] suggest the significance of culture in successful Lean deployment. Similarly, this is supported by Ref. [4] who proposed that culture is not just a driver but a result when the correct framework is put in place. A study on Lean sustainability factors [11] suggests three PDCA as facilitators for the sustainment of Lean programs. Firstly, the utilization of the PDCA cycle as a foundation for CI and PI activities. Plan-Do-Check-Act is a structured approach to drive and manage change introduced by Deming [12]. PDCA involves systematic testing and refining processes to achieve better results, and it is deployed as a structured approach to CI that can deliver measurable results [4]. Several studies have demonstrated the application of PDCA, emphasizing the versatility and adaptability of the methodology (Table 1) (see Table 2).

Furthermore Buckley et al. [22] utilize the PDCA approach as a tool to support policy deployment, describing it as an iterative CI approach which forms the cornerstone of Lean. Chiarini [23] postulates that the PDCA cycle is the foundation of many PI and problem-solving methodologies.

This is further supported by Lindermann et al. [24], who imply that the Six Sigma structured methodology of Define, Measure, Analyse, Improve and Control or DMAIC is patterned after PDCA. PDCA has significant applications, whether in process improvement or design of a new process and for change management processes [25], and Bateman [11] suggests it provides a structured environment for PI to take place.

Table 1
PDCA application; Case study examples across a variety of industries.

Article	Summary of PDCA application.
[13]	Improvement in a Dairy Laboratory. The authors chose to implement the PDCA cycle in their study due to its adaptability and suitability for their specific laboratory context.
[14]	Propose a conceptual approach (PDCA 4.0) to support sustainable Industry 4.0 supporting the CI shift towards Industry 4.0.
[15]	Use PCDA in the manufacturing industry to decrease defective components.
[16]	Utilized PDCA to facilitate quality improvement in sustainable packaging.
[17]	Influence and success of PCDA Cycle management mode on teamwork, efficiency and quality of hospital nursing work.
[18]	Used PDCA as a tool to optimize internal logistics in the automotive sector.
[19]	Practical application of PDCA to introduce cleaner production to a beverage company.
[20]	Plan-Do-Check-Act Cycle (PDCA) and Auxiliary Tools for Troubleshooting Manufacturing Processes
[21]	A Plan-Do-Check-Act-Based Process Improvement Intervention for Quality Improvement

Table 2
Templates provided per phase for CI projects (Source: Authors own).

Template Name	File Form	Description/Purpose and Stage	
Decision Tree Problem Solving and Projects.	.doc	This tool should help the proposer decide where the opportunity for improvement or idea fits within the Continuous Improvement Framework. Is it a Just Do It (JDI), 4C (Concern, Cause, Countermeasure, Confirmation), 4 Step, or a project? It can also be used by the Value Stream (VS) team or Manager and appropriate team when assessing Project Proposals to prioritize.	Pre-Proposal & Proposal
Proposal (E-Projects)	Power App	When a new CI opportunity or idea is identified, the proposer populates the Proposal form on E-Projects.	Proposal
Scoping Document	Power App	The Scoping document gives an overview of the Project and outlines what is in scope and out of scope for the Project. It will be used in conjunction with the Projects Selection Scoring Matrix to decide on the process.	Proposal
Projects Selection Scoring Matrix (E– Projects)	Power App	This Project Selection Matrix is used by the Value Stream Team or Manager and team members for support areas to review all CI project proposals and prioritize against other projects in the hopper. The output will be a priority number.	Proposal
Project Charter (E– projects)	Power App	The Project Details: The Project Charter describes the Project and expected outcomes. The purpose and justification for completing the Project. It identifies what is in and out of scope. It identifies team members and stakeholders. It is agreed upon and signed off by the project sponsor, project lead, and business process owner.	Initiate
Milestone Timeline (E-Project)	Power App	The Milestone Timeline is beneficial for presenting a visual schedule for the project. It is used as a "visual" representation of the schedule for key project milestones.	Initiate
Gantt	Share Point subsite	The Gantt Chart is used to schedule, assign, and track project tasks from kick-off to completion of the Project.	Plan Monitor & Control
Stakeholders Analysis/Communication	.xlsx	The stakeholder analysis template can be used to identify stakeholders. Who are your customers? It will help you decide both the type and frequency of communication to engage both the stakeholders and customers of the Project.	Initiate, Execute, Control
Analysis tools (Cause & Effect, 5 Whys and Brainstorm templates)	.xlsx	These tools are both useful for root cause analysis, Brainstorming or the sorting of ideas.	Execute
Opportunities and Goals	.xlsx	This template can be used to list the opportunities and goals of the Project.	Execute
Cost Analysis	.xlsx	The cost analysis tool is used to assess the cost of savings and cost incurred for the potential Solutions to aid in the evaluation of options.	Execute
Solution Selection	.xlsx	The solution selection template can be used to score Impact vs Do-Ability and its effect on People, Quality, Delivery and cost to assess which are the best solutions.	Execute
Project Close Out Checklist	.xlsx	This Checklist is used to direct the Project lead and sponsor to what should be completed in the execution phase to ensure the Project's success.	Close
Template for Lessons Learned.	.xlsx	This template helps the project team share knowledge gained from the experience. A successful Learned Program will help project teams repeat desirable Outcomes and avoid undesirable outcomes in the future.	Close

2.2. Sustaining PI

Another key element of sustaining PI programs is the provision of a supporting strategy and structure by management to make sustainment more probable. There is a plethora of evidence outlining successful PI programs and the potential effectiveness of PI initiatives in driving productivity [26,27]. Friedli [28] recognizes that a non-committal attitude to PI can lead to issues. McDermott et al. [28] discuss the importance of a long-term strategy in CI to prevent the PI program from regressing and a lack of organisational readiness for CI. Upton [29] describes several possible remedies to prevent backsliding, recommending clear structure, clear targets, and consistent focus on improvement strategy, measurement, training, and project selection, with a supporting leadership and culture. This is further supported by Ref. [30], who also highlight the importance of measurement and feedback systems, focusing on critical processes, stakeholder focus, and engagement.

Bessant et al. [31] argue that a maturity model for CI involves embedded routines. He further states that a lack of systematic application can impede CI, identifying key elements for sustainment, namely a workforce that understands the principles behind CI, recognizes habit, and uses appropriate tools and techniques to measure and participate in the process. It is important to prioritize, measure, align to strategy and share knowledge [5].

Adding to the challenge of Lean sustainment and engagement, COVID-19 has resulted in a new hybrid model for workforces in many manufacturing sites, which has accelerated the move towards digitization and enhanced the appetite already present for Industry 4.0. With this in mind, the sustainability of PI and CI implementation programs can become even more challenging [32]. However, there may also be significant benefits through the integration of Lean and Industry 4.0, which includes participation and learning [33, 34]. Studies within the Medtech industry have reported that CI and PI programs are more difficult to sustain and implement due to a culture of "compliance" over "quality." [3,35,36]. The requirement to revalidate processes or seek regulatory bodies approval for changes that could affect marketing authorizations has led to the FDA recognising the caution within Medtech companies in relation to PI and CI in the industry [37].

Despite the potential benefits of successful Lean deployment that is sustained, the development of a culture of CI can be challenging [5,38]. Hines and Butterworth [4] suggest that the focus for companies sits in the initial investment with a lack of consideration of the long-term commitment required for CI, resulting in sustainment rates for Lean implementation, with meaningful results remaining variable. In some studies, failure rates of 60–90 % have been noted [39].

2.3. A stepwise approach to PI

Antony et al. and Laureani and Antony [40–42] suggest that the lack of step-wise guides or processes to implement Lean may be a contributory factor to a lack of success. Mohanty et al. [43] highlight that after the initial burst of implementation energy, improvement often remained localized; however, to avoid this, opportunities for CI need to be created through a thorough review of processes.

Given these challenges, the value of a structured step-wise approach to Lean is clear. In terms of problem-solving, this is evident from methodologies such as Toyota's A3 [44–46], the 8D process [47] and DMAIC from the perspective of LSS [48]. There is also an attestation to proclaim the benefits of process activity mapping, value stream mapping and line balancing (LB) in a number of different industries in improving capacity, reducing bottleneck impact and identifying opportunities for improvement by eliminating waste [49,50]. Nevertheless, current research on methodologies for LSS and the use of line balancing and Yamazumi charts is limited in scope and primarily focused on mathematical models and Kaizen events [51,52]. Rebaiaia [53,54] argue that the Project Management Institutes Project Management Body of Knowledge or PMBOK® and Lean can be effectively integrated to improve project management activities and achieve better outcomes. Lean tools complement the PMBOK® focus on planning, monitoring, and controlling project activities with integration, overcoming some of the limitations of each approach [55].

Many organisations have leveraged Industry 4.0 technology and digitilisation in helping run their quality management systems and continuous improvement project tracking as well as in manufacturing floor systems [56]. Digitilisation has enabled improved data analytics and use of apps as well as reduced documentation by eliminating papers, improved traceability and tracking as well as merging of systems which reduces the administration time involved in CI and quality management [57].

2.4. Gaps in the literature

While process improvement methodologies are widely discussed within the literature and implemented in many forms in different organisations, there is a gap in the literature in relation to PI measurement and sustainment. Studies discussing a structured and procedural guide for PI projects that enables their maintaining and tracking is a gap both in the literature and in practice. In particular studies reflecting PI in regulated industries such as the Medtech sector are sparse. This study will add to the current literature by demonstrating the implementation of a structured PI methodology within a manufacturer.

3. Methodology

The methodology chosen to facilitate the creation of the new integrated model for process activity mapping projects was the Plan, Do, Check, Act (PDCA) cycle whilst also employing a qualitative approach, as shown in Fig. 1, where each phase is further broken down.

3.1. Phase 1 and 2: plan and Do

The planning stage prioritized understanding the needs of potential stakeholders and customers and the creation of change

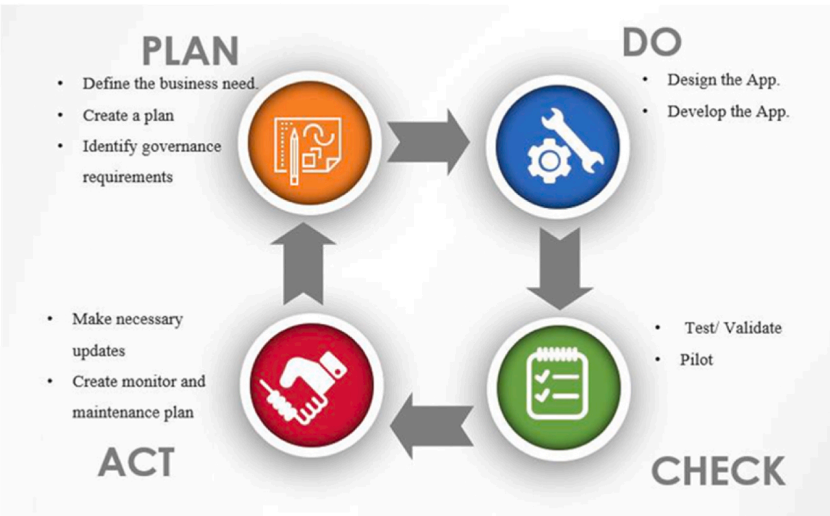

Fig. 1. Outline of Study Methodology using PDCA Cycle (Authors Own work).

management strategies to mitigate resistance to change. The Kotter [58] strategies for managing resistance were considered, with the first three - education and communication, participation and involvement, and facilitation and support - being incorporated throughout the implementation. Stakeholders were engaged through brainstorming sessions to understand the current state of the system. Initial sessions involved all stakeholders, and employees were encouraged to suggest openly and voice opinions. These ideas were then gathered and grouped using the affinity diagram technique. The sessions were centred on understanding the structure and tools currently in use and identifying gaps in process improvement project management in terms of the company's CI framework. Leadership buy-in, engagement and commitment were deemed essential for the success and sustainability of the initiative [6]. This resulted in a communication and engagement plan being developed early on and a sponsor being elected from the senior leadership team. Pilot areas for a step-wise PI model were identified through Value stream mapping (VSM). The driver behind these pilot area projects was a need to align projects to strategic needs [3]. Improving the capacity for the top of the organisation's device assembly 'guide wire' lines and reducing costs was integral to the overall company strategy for growth. From there, a clear scope and project charter were identified, a key aspect of the success of the Project.

An existing site, Power App™, E-projects, was refined to host the new aligned structure and enabled the creation of stage gates with automatic alerts to ensure necessary steps were completed. SharePoint sites were created for approved projects, allowing auto-population of templates.

A decision matrix was put in place to ensure the correct tools were selected for each Project, such as the 4 steps or 4C for problem-solving, or the Propose, Initiate, Execute and control (PIPEC) structure for larger PI projects outside the remit of the PMO. An overview of the process flow for PI projects as they move through the stage gates on the E-project app can be seen in Fig. 2. This process was developed via various conversations and brainstorming sessions with stakeholders as well as via different stages of process mapping.

This was further disseminated into step-wise models for the two types of projects (CI and LB), as shown in Figs. 3 and 4. Having finalised the process flow, the stepwise process to "propose", "initiate", "plan", "execute", and "close" a project were developed. As mentioned previously within each phase, step or stage, a suite of appropriate tools were put forward or suggested that could be used to progress the project and CI effort. A specific stepwise model was put forward for line balancing manufacturing line projects as well as a stepwise model for generic PI/CI projects.

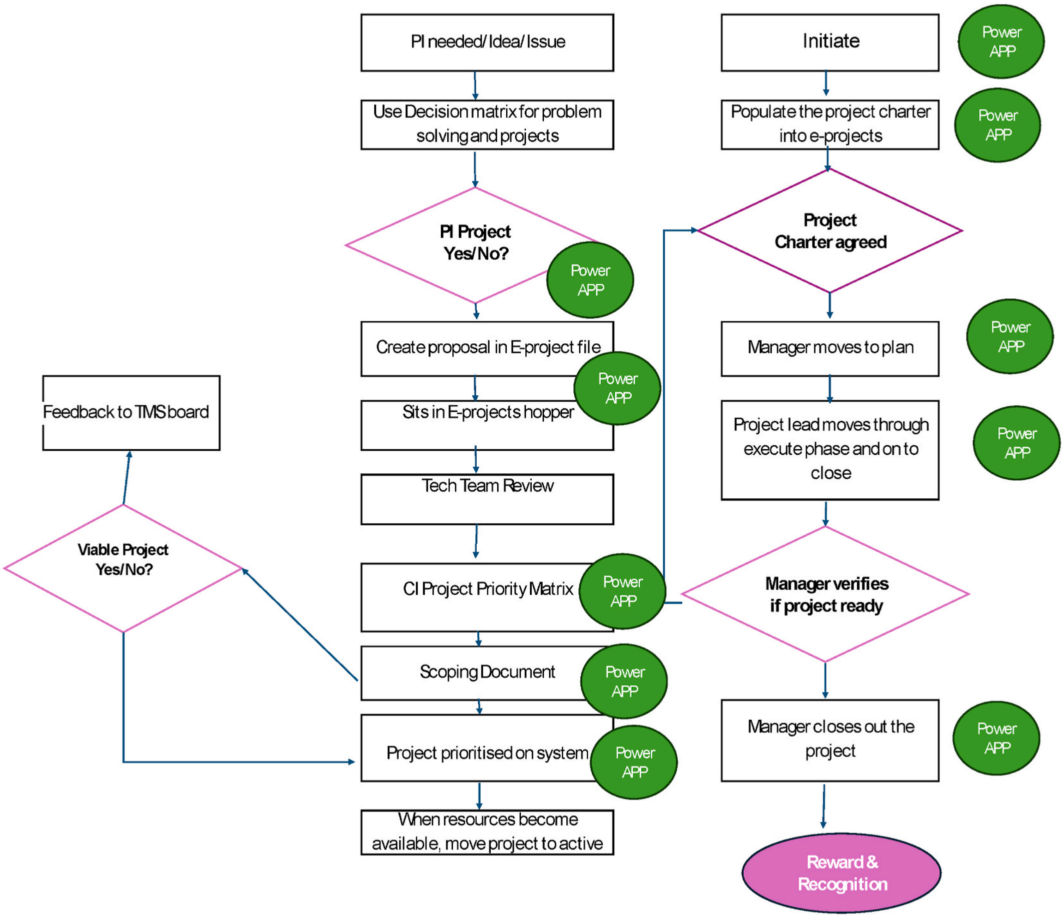

Fig. 2. Process Flow for Process Improvement Projects (Source: Authors own).

Fig. 3. Step-wise model for Continuous Improvement projects derived from PMBOK®.

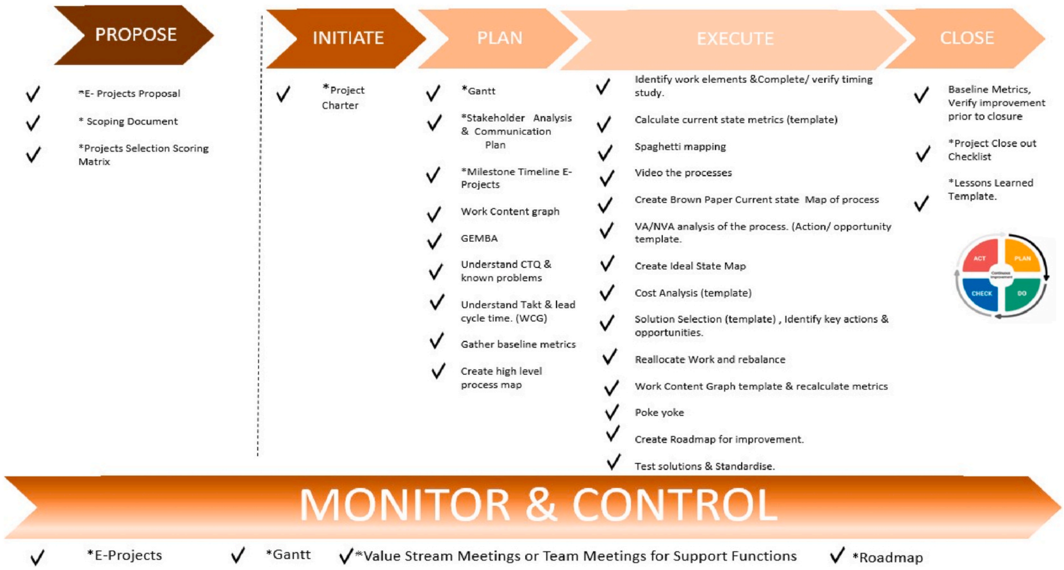

Fig. 4. Step-wise model/Framework for Line balancing process improvement projects, derived from PMBOK®.

3.2. Training and E-project development

Within the Plan and Do phases it was important to look at training requirements. After the step-wise models were agreed upon, a skills gap analysis was conducted, and a training plan was created for the pilot areas. The site Leadership team allocated both time, resources and finance to support classroom and team training, including Lean awareness, waste walks, timing study, work content graphs, line balancing theory, and standard work creation. Additional funding was allocated for a self-learn video training was created to support the use of templates supplied in the "Power App ™," E-Projects. The pilots were conducted in two assembly lines, with a Lean black belt providing support, coaching, and mentoring. The pilots aimed to increase capacity in these areas, as identified through earlier value stream mapping. The Lean black belt guided the teams through all project phases, resulting in the creation and fulfilment of a roadmap.

The engineering team, in the absence of a standard, had developed an application called 'E−projects' which was a "Microsoft PowerApp ™" and had been in use on an ad hoc basis as a platform to manage smaller projects. PowerApps is a low-code application development platform created by Microsoft that allows users to create custom business applications easily without the need for extensive coding expertise. This approach was chosen with a view to accommodating hybrid workers, providing a dashboard, and providing easy access to recommended tools and templates for the defined project type. The E-project application was adopted and adapted to incorporate the new standard methodologies for PI projects.

3.3. Phase 3 and 4 -check and act

Evaluation of the effectiveness of pilot projects using the new system was based on feedback from stakeholders and improvements in capacity and productivity measured in terms of a dollar value. Feedback from the stakeholders included some qualitative data on the effectiveness of the tools. This was completed through feedback sessions and workshops. This feedback was measured against the original customer requests, such as being suitable for managers who were working in a hybrid model to track progress easily. Overall, these sessions provided valuable insights into the effectiveness of the methodology in helping to identify further areas for improvement. Furthermore, a solution selection matrix was introduced in response to feedback concerns on prioritization. Any outcome from this phase was incorporated into the PI model.

In the phase, the changes that needed to be made to the templates were standardized, and a wider rollout was captured. A skills gap analysis exercise was completed across the plant. Training was then provided based on the model developed by the pilots across the site. Handbooks and further self-learning resources were created and uploaded to the training management platform. This standard methodology for PI projects was then rolled out site-wide. The initiative was supported by the leadership team and buoyed by the successful pilot areas. Training on the new systems was delivered to all teams. A lessons-learned session was also conducted with the entire project team to understand what could have been completed differently.

To gauge the impact of the wider rollout, an online questionnaire was completed to understand what worked and did not work for the customers (i.e., system users). The target audience for this was users across the entire site. This included the Value Stream team, which consists of operations managers and process and quality engineers. The survey was conducted to ascertain the effectiveness of the development of a facility to track, measure and control PI projects. In addition to questioning if it had a positive impact on CI culture and engagement levels, The online questionnaire assessed both pre- and post-incorporation of Improvement Projects and Process Activity Mapping within E-projects supported by the PIPEC structure and stage gates. The questions are related to user experience and views on the potential advantages or disadvantages of using the E-Projects platform to manage, track, and evaluate the success of improvement projects and process activity mapping. Also, consideration was given to assessing the model's contribution to the site's overall CI framework and CI culture and its ease of use for Hybrid workers [9].

4. Results

The 'Plan' and 'Do' phases resulted in the development of a comprehensive step-wise guide for the two types of PI projects. This was the development of a system that would support the management and measurement of these types of projects, providing easy access to the necessary tools to run these improvement initiatives. This new system integrated and aligned with existing tools and CI framework within the company and supported using project decision matrices. Using PowerApps as a host for this activity enabled hybrid teams to engage with PI projects with ease [59]. During the 'Do' phase, the pilot areas were executed, which resulted in a roadmap for improvement in these areas, which was prioritized and actioned.

The 'Check' phase demonstrated significant financial results from the two test areas, with Area 1 of the medical device organisation achieving a 10 % productivity gain, resulting in a potential saving per annum of $166,883, while Area 2 achieving a 7 % productivity improvement, with a potential saving per annum of $90,519. The prioritization matrix supported teams in the assessment and prioritization of the outputs of the mapping exercises (Fig. 5). The Impact Vs Do -ability score for the Project above was weighted at 35 %

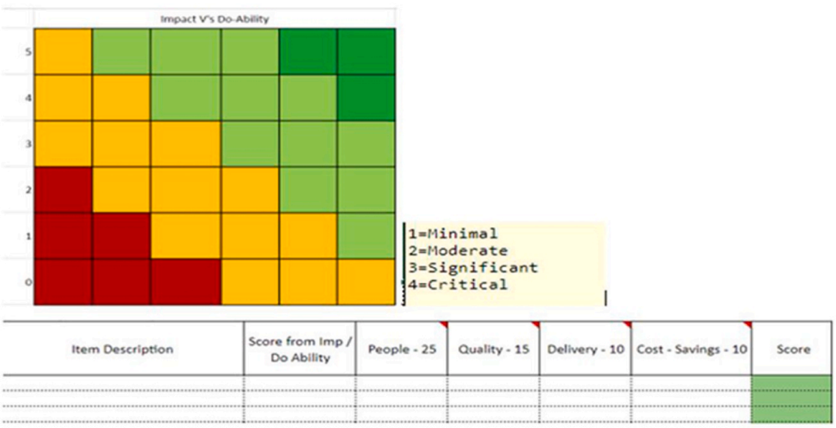

Fig. 5. Task Prioritization Matrix (Source: Authors work).

by using the Matrix with the impact scoring on the vertical line and the ease of implementation on the horizontal line. The success of the pilot led to the site-wide implementation of the prioritization matrix.

4.1. Online questionnaire results

An online questionnaire was conducted post-project rollout. Its purpose was to ascertain whether this new model provided a robust structure and facility to measure project activity and success. It also strove to assess whether it provided a strong and sustainable foundation to improve results and employee engagement levels. The participants of this study were from the organisation's Value Stream, who were the end users of the new model. The questions derived from brainstorming sessions as well as literature review and the survey. The survey was validated by piloting with 5 employees and getting feedback. The anonymous survey was distributed to 30 participants, with 11 questions and achieved a response rate of 24 participants (80 %) which was deemed to be appropriate as there was a sizeable response [60]. The online questionnaire responses can be seen in Table 3, and all questions indicated positively towards the new PI step-wise model. Results compiled from the organisation's internal project tracker indicated a 20 % improvement in employee participation in CI activities on-site since the implementation of the model.

Table 3
Results of post site wide implementation survey (n = 24).

Question/Response	Extremely difficult	Difficult
Q1. **Prior** to Incorporating Improvement projects and process activity mapping within E-Projects, please rate how easy/difficult it was to track improvement projects.	42 %	58 %
Question/Response	***Extremely easy***	***Some what easy***
Q2. **Post/since** the Incorporation of Improvement projects and process activity mapping within E-Projects, please rate how easy/difficult it was to track improvement projects.	25 %	75 %
Question/Response	***Extremely True***	***Some what true***
Q3. How would you rate the following statement: "*Prior to the introduction of PIPEC-Propose, Initiate, Plan, Execute, Close, and the stage gates/phases being incorporated within E-Projects requiring approval, projects could often end up going in the wrong direction using inappropriate tools.*'	50 %	43 %
Question/Response	***Extremely True***	***Some what true***
Q4. How would you rate the following statement: "*Since the introduction of PIPEC-Propose, Initiate, Plan, Execute, Close, and with the stage gates/Phases incorporated within E-Projects requiring approval, projects are usually followed through to completion, using the correct tools*?"	67 %	33 %
Question/Response	***Difficult***	***Extremely Difficult***
Q5. Prior to incorporating improvement projects/Process Activity Mapping into E-Projects, please rate how easy or difficult it was to prioritize improvement projects.	67 %	33 %
Question/Response	***Extremely Easy***	***Somewhat Easy***
Q6. Post/Since the incorporation of improvement projects/Process Activity Mapping into E-Projects, please rate how easy or difficult it was to prioritize improvement projects.	58 %	25 %
Question/Response	***Extremely Difficult***	***Somewhat difficult***
Q7. Prior to incorporating Improvement/process activity mapping within E-Projects, how easy/Difficult was it to measure success?	50 %	33 %
Question/Response	***Extremely Easy***	***Somewhat Easy.***
Q8. Since the incorporation of Improvement/Process Activity mapping within E-projects, how easy/Difficult has it been to measure success?	50 %	50 %
Question/Response	***Strongly Agree***	***Agree***
Q9. The Structured Approach for Improvement projects within E-projects helps support accountability and process focus as part of our Behaviours and Ways of Working.	67 %	25 %
Question/Response	***Strongly Agree***	***Agree***
Q10. The Continuous Improvement Framework and structures all contribute to developing a Continuous Improvement Culture in the company.	75 %	25 %
Question/Response	***Yes***	***No***
Q11. Since the introduction of the mixed model work type of On-Site, Hybrid and Working from home during/post-COVID, has the E-project App in place made the management of continuous improvement projects more successful?	100 %	0 %

5. Discussion

The study research objective was to provide a comprehensive and practical guide and inclusive system for running and monitoring PI projects, with a focus on alignment, to improve the sustainment of CI participation and culture within a Medtech manufacturer. In terms of Lean deployment, sustaining and measuring the program is one of the biggest challenges for organisations, with ineffective implementation highlighted as a potential reason for failure [61]. This study demonstrates how providing structure for PI and Process Activity Modelling (PAM) contributes to the sustainability of a Lean programme by closing one of the gaps in the organisations' Lean implementation. Klein and Sorra [62] describe partially implemented programs as contributors to the lack of success, with a lack of effective project management and training also being called out by McLean et al. [63] as potential contributors to failure.

5.1. Implemented model for PI

The implemented model (Fig. 6) enhanced the sustainability of the PI program via the incorporation of integrated learnings from Refs. [4,64,65] to propose a framework for achieving operational excellence and sustainment through the establishment of purpose, process, people and results. These are further disseminated into alignment, engagement and improvement with the identification of key systems supporting this framework.

There are many other frameworks suggested in the literature for LSS implementation. McLean and Antony [66] provide a comprehensive evaluation of these frameworks and suggest their own. However, this study proved the Hines and Butterworth [4] "*Essence of Excellence*" framework to provide the foundation for its Lean journey. The research took place at a site mid-way through a five-year Lean transformation plan. Portions of the continuous improvement (CI) system outlined by Hines and Butterworth [4] had already been developed on the site prior to the study. Desired behaviours, such as trust, positive intent, respect, accountability, process focus, and improvement, had been established as part of the effort to create a culture conducive to lean transformation and sustainment. These behaviours are also embedded in Lean principles of "Respect" and the 8th Lean waste of "under-utilization of employee skill set" as key components of any Lean PI program [7,67].

5.2. Standardising the PI methodology

The final piece of the sustainment program in terms of the CI system was PI. The company needed a standard defined method or system to give structure and enable measurement and management of PI projects within the site CI framework that aligned with existing systems such as the Problem-solving (PS) methodology and Project Management Office (PMO), accommodating a changing workforce. This research presented a methodology for the running and management of these types of projects. The model developed presents a facility for accountability, alignment, and the inclusion of the company's hybrid workers. It incorporated the existing PMBOK® model in use by the project team at the company, combining it with Lean tools with PDCA as a methodology at its core. The model provided a step-wise guide for both CI and line-balancing projects with staged phases.

Guidance on what tools should be applied during each of the phases with a strong monitor and control phase supporting the PDCA ethos. The stage gates within the model also provided a facility for accountability and ensuring that the correct tools were used at the correct phase as a standard. Studies have demonstrated that many CI projects can fail due to the use of incorrect tools [68,69], so

Fig. 6. The implemented Step-wise PI model incorporating PDCA (Source: authors own derivation).

ensuring employees were aided in the tool section was critical.

5.3. Overcoming the challenges to PI sustainment

The E-projects app was effective in terms of managing the PM and CI system. Digitized applications enabled real-time tracking, reduce non-value add waste associated with accessing documents and filling out project templates as well as enabling real-time visual management [70]. The models were hosted on an 'E-projects' application developed on-site; this provided a facility for hybrid workers to monitor and control projects with ease and hold teams accountable to commitments as well as enhance collaboration. Hybrid working has presented many challenges for sites in terms of Lean initiatives, managing CI projects, and conducting brainstorming [9]. According to Cheung et al. [71], trust is a key factor in effective collaboration, working towards a common result, being a contributor, and having the right culture to build trust amongst hybrid teams. Having a standard digital tool to manage and support these projects has helped to mitigate this risk for the site. This is evidenced by the results of the survey indicating that 92 % felt that the system contributed to the site behaviours, with participants finding it overwhelmingly easier to measure success and track projects since its introduction.

A positive culture was developed and fostered via change management and communication as vital components of the success of the case study; having an effective communication plan mitigated perceived potential negative aspects of the change. Another key culture driver in terms of success was ownership. A key aspect of this was involving the team in the creation of the models; this contributed to creating this sense of ownership. Respect for people and empowerment of the team are vital to CI deployment and are important pillars of operational excellence methodology [72]. Team and people involvement is a key. It was also hugely important that team members fully understood their roles and responsibilities within the projects. Hence, time was also spent at the early stages of the model concept working with the teams to produce Responsibility, Accountability, Consulted and Informed or RACI charts for process improvement projects that made roles clear and incorporated these into the model. The pilots for the programme were successful in terms of both engagement levels and return on investment with significant dollar savings with Area 1, achieving a 10 % productivity gain resulting in a potential saving per annum of $166,883 and Area 2, achieving a 7 % productivity improvement with a potential saving per annum of $90,519. These savings resulted from labour manhour savings; reduced scrap levels and more product being shipped.

One of the key enablers for the success and sustainment of lean deployment was leadership buy-in Refs. [23,61]. The success of these pilots provided the foundation for a keen leadership interest in the success of both the PI system and the overall CI framework. Another important element around the rollout of the model was training and coaching, ensuring that our teams understood both how to use the tools effectively and their purpose. It was doubtful that the endeavour would have been as successful without this investment.

The feedback sessions completed with the teams on completion of the pilot were an important contribution to the final model whilst also supporting engagement. One area of resistance identified was that initially, the system and tools were seen as needing to be more labor-intensive and unnecessary. The value of the tools, however, has proved itself in better outputs and projects as a result of both models. Alignment and the use of the PowerApp ™ helped mitigate this. Kotter's [58] theories were key as a guide in anticipating and navigating resistance. Results from the user survey support this, with 100 % of respondents seeing an improvement in the success of projects through the use of the provided tools and stage gates when compared to before the introduction of the model.

5.4. Implications, limitations, and contribution of the study

The findings from the questionnaire suggest that the establishment of a standard method for running PI projects as part of a CI framework supports alignment facilitates accountability and contributes to the development of a culture of CI, which in turn contributes to sustainment in terms of Lean deployment. Further supporting this, participation levels derived from company data also indicate an increase of 20 % in PI project participation. Hence, the results may support the hypothesis that the provision of the correct systems facilitates and drives the desired behaviours.

A limitation of the study was that it is a single case study within one manufacturing site. However, the results are generalizable for other organisations. A further limitation was the self-reporting of data from the survey. However, the financial results and completed PI projects reinforce and correlate with the survey results. A further longitudinal study in the future would aid the examination of the implemented model and obtain more qualitative and quantitative results of the model.

The creation of step-wise models for PAM provides valuable insights into the effective implementation of lean principles and process improvement, thereby contributing to the body of knowledge in this field. Although the research takes place in a medical device manufacturing facility, the CI framework methodology and step-wise models could have implications and use across many disparate industries. The study also further demonstrates the adaptability of the PDCA model, from managing the overall study to providing the foundation for the models developed to its use in the creation of the PowerApp.

6. Conclusion

This work provided a new combined approach for managing PI projects, which accommodated changing workforce practices and demonstrated how important PI is within a larger Lean deployment initiative. The results indicated that providing a comprehensive CI framework supports the creation of a CI culture.

The success of the step-wise models developed in this study could have implications for companies undertaking similar transformational change. The study also provided evidence to suggest that introducing digital tools and models can provide a facility for accountability and measurement of success and have a positive effect on collaboration and participation in terms of hybrid teams. The developed model provided a practical guide and lessons learned for manufacturing companies to unlock capacity and achieve cost savings, enabling sites to remain competitive in an ever-challenging market.

From a theoretical viewpoint, this study adds to the literature by demonstrating the importance of having developed a model for sustainable PI.

From a regulated industry viewpoint, the model clearly demonstrates a deployable PI and CI framework that doesn't compromise quality or compliance, and that can only enhance patient safety.

The limitations of the research are that it was conducted on one site only and limited to those actively using the new system and tools. Future research will involve a wider survey of all employees in the company and will deploy the model across other sites in the organisation.

CRediT authorship contribution statement

Eileen Naughton: Writing – original draft, Formal analysis, Data curation, Conceptualization. **Rachel Moran:** Investigation, Formal analysis, Data curation. **Manjeet Kharub:** Resources, Investigation, Formal analysis. **Jose Carlos Sa:** Investigation, Formal analysis. **Olivia McDermott:** Writing – review & editing, Writing – original draft, Supervision, Investigation, Conceptualization.

Data and code availability

Data will be made available on request.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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