The HyDAPI framework: a versatile tool integrating Lean Six Sigma and digitalisation for improved quality management in Industry 4.0

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Abstract

Purpose – Quality management practitioners have yet to cease the potential of digitalisation. Furthermore, there is a lack of tools such as frameworks guiding practitioners in the digital transformation of their organisations. The purpose of this study is to provide a framework to guide quality practitioners with the implementation of digitalisation in their existing practices.

Design/methodology/approach – A review of literature assessed how quality management and digitalisation have been integrated. Findings from the literature review highlighted the success of the integration of Lean manufacturing with digitalisation. A comprehensive list of Lean Six Sigma tools were then reviewed in terms of their effectiveness and relevance for the hybrid digitisation approach to process improvement (HyDAPI) framework.

Findings – The implementation of the proposed HyDAPI framework in an industrial case study led to increased efficiency, reduction of waste, standardised work, mistake proofing and the ability to root cause non-conformance products.

Research limitations/implications – The activities and tools in the HyDAPI framework are not inclusive of all techniques from Lean Six Sigma.

Practical implications – The HyDAPI framework is a flexible guide for quality practitioners to digitalise key information from manufacturing processes. The framework allows organisations to select the appropriate tools as needed. This is required because of the varying and complex nature of organisation processes and the challenge of adapting to the continually evolving Industry 4.0.

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This publication has emanated from research that was part-funded by Science Foundation Ireland (SFI) through MaREI, the SFI Research Centre for Energy, Climate, and Marine [Grant No: 12/RC/2302_P2], with supporting funding obtained from DePuy Synthes.
Originality/value – This research proposes the HyDAPI framework as a flexible and adaptable approach for quality management practitioners to implement digitalisation. This was developed because of the gap in research regarding the lack of procedures guiding organisations in their digital transition to Industry 4.0.

Keywords Quality management, Lean Six Sigma, Digitalisation, Industry 4.0

Paper type Research paper

1. Introduction

1.1 Digitalisation in the context of Industry 4.0

Industry 4.0 has become pervasive in literature; however, it does not have an exact definition, and many researchers agree that there is no clear method to undergo the transformation to Industry 4.0 (Karacay, 2018; Schneider, 2018; Piccarozzi et al., 2018; Buer et al., 2021; Lasi et al., 2014; Moeuf et al., 2018; Schuldt, 2014). Industry 4.0 has previously been characterised by its technologies (Klingenberg et al., 2019), these technologies to date can be summarised as: big data and analytics (BDA), autonomous robots, artificial intelligence, simulation, horizontal and vertical system integration (HVSI), Internet of Things (IoT), Cloud Computing, Additive Manufacturing, Augmented Reality and Cyber Security (Erboz, 2017). Buer et al. (2021) state that the term “Industry 4.0” is unclear and undefined in literature. The focus of their research is the part of Industry 4.0 that they refer to as “factory digitalisation” – to digitise, integrate and automate data flows in production (Buer et al., 2021). This study similarly focuses on the digitalisation of manufacturing rather than the overall concept of Industry 4.0. Industry 4.0 is one of the biggest drivers for manufacturing companies to undergo a digital transformation (Erboz, 2017; Verhoef et al., 2021), and the digitalisation of supply chains has now become a business imperative, according to the 2021 State of Manufacturing Report (Fictiv, 2021). This report demonstrates that 95% of companies agree that the digital transformation of manufacturing is essential to their company’s future success (Fictiv, 2021). However, undertaking this digital transformation in practice is proving challenging for many companies. For instance, Antony et al. (2021) interviewed a number of senior managers in leading organisations which revealed that they do not know where or how to start in merging with the digital world (Antony et al., 2021). In an effort to address this uncertainty, this study proposes that digitalisation is first implemented to act as a foundation for Industry 4.0 via the hybrid digitisation approach to process improvement (HyDAPI) framework. The following examples demonstrate how the digitalisation of manufacturing processes can ease the implementation of advanced data-related Industry 4.0 technologies. BDA uses large data sets to improve organisational decision-making (Erboz, 2017); therefore, a significant amount of high quality, real time, digitalised process information is required to carry out effective BDA. HVSI is the integration of the inside of the factory and supply chains, in which the industrial network collects big data that is sent to the cloud to optimise system performance (Erboz, 2017), which also relies heavily on digitalisation. Finally, IoT is also related to digitalisation, as it involves the collection of data from physical objects, and provides solutions for computations and analytics by relying on cloud-based systems (Erboz, 2017). These examples demonstrate how “factory digitalisation” directly feeds into and lays the groundwork for Industry 4.0 technologies.

1.2 Quality management in Industry 4.0

These digital technologies of Industry 4.0 allow the integration of information throughout the supply chain with real-time processing, enabling data-driven decision-making and the optimisation of manufacturing process (Núñez-Merino et al., 2020; Cottyn et al., 2011). If the
flow of process information through an organisation is accelerated, the organisation becomes inherently more efficient (Arey et al., 2020). Supply chain quality issues are exacerbated by poor data visibility (Fictiv, 2021). Digitalisation enhances quality management by providing real-time data regarding the current quality status, enabling the quick detection, diagnosis and resolution of quality issues (Dragulanescu and Popescu, 2015). Problem detection and problem-solving are core practices of quality management, and with increasing automation and digitalisation, production issues can be detected in real time using a measurement system (Elg et al., 2020). In this era of Industry 4.0, companies need to become more efficient by using tools and processes that increase their productivity, and also remove non-value added activities (CIMdata, 2021). Achieving these increases in productivity and efficiency requires a digital transformation to leverage the value of digital technologies and applications (CIMdata, 2021). Similar to Lean manufacturing, digital transformation can also reduce waste by entering information only once at the first point when it is known, and leveraging this information throughout the product’s lifecycle (Autodesk, 2019).

Sutrisno et al. (2018) describe various types of digital waste, including obsolete data, poor access to information and dispersed information. Inaccessibility to required data can lead to superfluous tasks being performed, which is an inefficiency that can be improved through digitalisation (Mathiasen, 2020). Digitalising key manufacturing process information can reduce the amount of time spent entering, gathering, amalgamating and analysing data. Data integration and processing is a key element of Industry 4.0 that allows for a dataflow-based performance analysis of networked machines and processes (Blanchet et al., 2014). A literature review of Industry 4.0 pilot projects revealed that the most common performance benefits achieved were increased flexibility, improved quality and improved productivity (Moeuf et al., 2018). This study similarly focuses on how digitalisation can lead to productivity and quality improvements. The identification, prediction and optimisation of quality relies heavily on data mining (Köksal et al., 2011). Data mining and BDA techniques have the ability to continuously analyse and predict business problems and monitor process improvements (Köksal et al., 2011). The term Quality 4.0 looks at closely aligning quality management with Industry 4.0 to help organisations improve efficiency and performance (Sony et al., 2020; Zonnenshain and Kenett, 2020). Digitalisation in the era of Industry 4.0 enables organisations to reach new optimums in operational excellence and performance (Sony et al., 2020). Quality professionals need to develop their knowledge of Industry 4.0 technologies and combine this with best quality management practices so that decisions are based on big data (Santos et al., 2021). The question of how Industry 4.0 will influence established management practices such as Lean manufacturing needs to be further studied (Azadegan et al., 2013). Companies need to integrate Industry 4.0 technologies into their existing Lean manufacturing systems (Wagner et al., 2017). However, the knowledge of how this should be done is immature (Kolberg and Zühlke, 2015; Wagner et al., 2017), and there is a lack of studies providing an integration strategy of quality management and Industry 4.0 (Zonnenshain and Kenett, 2020).

1.3 Previous research
In previous research, the author developed the HyDAPI methodology, as shown in Figure 1. The HyDAPI methodology was developed as a stepping stone to Industry 4.0, to aid managers with the digitisation of their supply chains, enabling data-driven quality management and the reduction of waste from manufacturing processes (Clancy et al., 2021). In the development of this methodology, existing quality management and data mining methodologies were assessed using a decision matrix. Six Sigma and Cross Industry
Standard Process for Data Mining (CRISP-DM) were found to be the most suitable methodologies, and key elements of these were combined to develop the HyDAPI methodology. The CRISP-DM data-mining process was used because data science, statistical analysis and predictive analytics are critical in this new era of quality management, referred to as Quality 4.0 (Antony et al., 2021). In our previous research, Six Sigma was determined to be the most suitable quality improvement methodology, as it focuses on the reduction of defects, and the manufacturing process being digitised had a level of scrap periodically exceeding expectations (Clancy et al., 2021). However, one shortfall of Six Sigma is the exclusion of time as an important metric (George, 2002a, 2002b, 2002c, 2002d, 2002e). The reduction of lead times and variation in process time has equal potential as the reduction in quality variation for improving supply chain performance.
The goal of the previous research was to document a formal approach to digitising a manufacturing process and achieve data-driven quality improvement of supply chain performance (Clancy et al., 2021). The Define, Measure and Analyse phases were outlined in detail in the previous study; however, the Improve and Control phases required further development. Nonthaleerak and Hendry (2008) suggest that the Define and Control phases are the weaknesses of the DMAIC methodology. Although the Define phase in the HyDAPI methodology was well developed through the additions of Business Understanding and Project Plan from CRISP-DM, along with Collaboration, Process Overview, User Requirement Specification and Data Catalogue proposed by the author, the Improve and Control phases need advancement. The Control phase is one of the main reasons for the failure of Six Sigma (Hines and Rich, 2019), i.e. organisations struggle to maintain the improvements gained from Six Sigma projects. However, we propose that digitalisation, which provides access to real time and historical data from the production process, enables employees to monitor key performance process parameters and ensure that project improvements are sustained in the Control phase.

According to Khillar (2021), Six Sigma is the ultimate strategy for an organisation to become more effective and efficient. Six Sigma is based on the use of statistical tools, whereas, the Lean toolbox involves mainly visual tools (Chiarini and Kumar, 2020). Therefore, it may be beneficial to incorporate visual tools from Lean in the HyDAPI methodology. One of these Lean tools is known as Visual Management, and it enables the real-time seizing and signalling of abnormal conditions that could create non-conformities (Dragulanescu and Popescu, 2015). It provides a visual means to monitor shop floor performance in real time, and enables workers to manage their processes more efficiently and effectively (Chiarini and Kumar, 2020). This naturally aligns with digitalisation and the overall objective of Industry 4.0, which is to improve the efficiency and responsiveness of the manufacturing system (Fatorachian and Kazemi, 2018; Ahuett-Garza and Kurfess, 2018). Therefore, other quality management concepts, outside of Six Sigma shall be investigated in this study, for their potential combination with Six Sigma and CRISP-DM, to develop further the HyDAPI methodology.

As stated by Carnerud et al. (2020), digitalisation has not been addressed in the scholarly quality management literature, and the quality management field is not addressing the full potential of digitalisation. Quality management practitioners have not yet seized the potential of digitalisation and are having difficulty with the implementation of digitalisation because they do not know where to start (Legner et al., 2017). Therefore, the research gap that this study aims to address is the lack of literature providing a guidance for practitioners to integrate digitalisation with their existing quality management practices. This research gap led to the development of the following overall research questions:

**RQ1.** How has quality management been integrated with digitalisation in literature (focusing on Industry 4.0 requirements)?

**RQ2.** What aspects of the integration of these two domains can be used to strengthen and improve the HyDAPI methodology?

Hence, this study aims to extend the limited research on the understanding of the integration and implementation of quality management and digitalisation in practice. The research objective of this study is to provide practicable guidance for the implementation of digitalisation in practice. The development and expansion of the previous HyDAPI methodology was borne out of the research gap and motivation to give organisations a flexible, adaptable and versatile approach to aid the digitalisation of their varying, complex
and unique manufacturing processes. Furthermore, previous work focused solely on
digitisation; however, companies face a significant challenge in moving to the field of
Industry 4.0 and identifying and implementing the appropriate information and
communication technologies (Leyh et al., 2017). Therefore, this study focuses on the
digitalisation of production, as opposed to just digitisation, as digitalisation includes
digitisation, integration and automation of data flows, which can enable a real-time view of
the production process (Kagermann et al., 2013).

The remainder of the paper is structured as follows. To address the defined research
questions, studies on the integration of quality management concepts with digitalisation are
reviewed in Section 2. The purpose of this review was to inform the development and
expansion of the HyDAPi methodology regarding applicable quality management
techniques. Section 3 outlines the method taken to develop the HyDAPi framework. A
comprehensive summary of quality management tools are assessed for their suitability and
inclusion in the newly developed HyDAPi framework. Section 4 proposes the newly
developed HyDAPi framework as a more adaptable and versatile approach for
organisations to implement digitalisation. Section 5 presents the results from the
implementation of this framework in an industrial case study. Finally, Section 6 concludes
the theoretical and practical contributions in relation to the research objectives, the
limitations from this study and proposals for future work.

2. Literature review

2.1 Lean manufacturing and digitalisation in the context of Industry 4.0
Lean manufacturing is widely recognised as a leading methodology in the improvement of
production processes (Seleem et al., 2017). The objective of Lean is to increase production
efficiency through consistently and thoroughly eliminating waste (Salah et al., 2011).
Research has shown that a synergistic relationship exists between Lean manufacturing and
factory digitalisation, i.e. greater effects are achieved when Lean and digitalisation are
implemented together than individually (Buer et al., 2021). Sanders et al. (2017) suggest that
Lean manufacturing will not disappear but that it will become an even more important and
integral part of Industry 4.0 implementation. The crucial question is not, whether Lean and
digital technologies should be integrated, but how they can be (Haartman et al., 2021).
Furthermore, although Industry 4.0 and Lean manufacturing are different in approach, they
share the same general objectives of increased flexibility, productivity, efficiency and supply
chain integration (Schuldt, 2014; Chiarini and Kumar, 2020). Many studies have been
published recently suggesting that the concurrent implementation of Industry 4.0
technologies and Lean manufacturing leads to performance improvement (Tortorella and
Fettermann, 2018; Rossini et al., 2019). An example of how Industry 4.0 can enhance Lean
manufacturing tools is “value stream mapping 4.0”, proposed by Meudt et al. (2017). The
traditional value stream map is an analogue activity using pen and paper and collecting
data to develop this map can be problematic (Meudt et al., 2017). Creating a digital depiction
of the shop floor increases visibility and supports decision makers by providing real-time
information (Chen and Chen, 2014). Other tools from Lean manufacturing shown to have
been enhanced through digitalisation are just-in-time (JIT) and autonomation (jidoka) (Zelbst
et al., 2014). A digitalised supply chain aids the successful implementation of JIT by
providing accurate and timely information about inventory levels (Zelbst et al., 2014).
Autonomation, also known as Jidoka, refers to intelligent machines that have the ability to
distinguish between normal and abnormal operations (Buer et al., 2018b).

Another element from Lean manufacturing that can be enhanced through digitalisation
is standardised work. Standardised work is a method of establishing precise, safe and
effective procedures through the use of current technologies (Dragulanescu and Popescu, 2015). By standardising and automating the collection of data, time is significantly reduced and the probability of errors are eliminated (Meudt et al., 2017). The implementation of cyber-physical systems (CPS) based smart Jidoka was also found to be cost-efficient and effective in improving production system flexibility (Ma et al., 2017). CPS comprises a smart system integrating advanced IoT, embedded control and cloud computing technologies (Ma et al., 2017). Digitalisation supports the creation of the appropriate digital infrastructure needed for advanced Industry 4.0 technologies such as CPS. However, this research integrating Lean manufacturing and digitalisation is in its infancy, and there is a lack of studies providing implementation frameworks (Chiarini and Kumar, 2020). Future research should focus on determining how these two domains can be applied together in practice (Buer et al., 2018a).

Many organisations find it difficult to sustain the momentum following their Lean projects (Buer et al., 2018b). Buer et al. (2018b) suggest that information and communication technology (ICT) could provide a solution to this. Although Lean manufacturing was originally independent from any type of ICT, the emergence of more advanced ICT solutions has led to a surge of research investigating how Lean and ICT can be used simultaneously to achieve better performance (Azadegan et al., 2013). ICT has been shown in research to be a crucial factor in Industry 4.0 requirements (Buer et al., 2018b; Leyh et al., 2017). Carnerud et al., 2020 describe digitalisation as an ongoing continuation of previous concepts labelled as information technology (IT) or information systems (IS). The rapid advancements in ICT is what enabled this revolution in manufacturing, known as Industry 4.0 (Kang et al., 2016).

As previously described, Industry 4.0 is a broad term that is not yet fully understood and encompasses many technologies. A literature review of Lean and Industry 4.0 models by (Leyh et al., 2017) indicates that future research is necessary to combine existing approaches with key aspects of Industry 4.0. Furthermore, there is a lack of studies investigating how Lean supply chain management principles can aid the adoption of digital technologies for Industry 4.0 (Wang et al., 2016). Núñez-Merino et al. (2020) recommended future research to investigate what factors facilitate and drive the use of the Industry 4.0 information and digital technologies in Lean supply chain management contexts. They further highlight that frameworks or roadmaps should be developed to support managers in the transition to Lean supply chain management 4.0 (Núñez-Merino et al., 2020).

2.2 Lean Six Sigma and digitalisation

It should be noted that of all performance improvement techniques, Lean and Six Sigma are the most practised in the industry (Antony, 2011). Six Sigma relies on data to enable process improvement; hence, the digitalisation of manufacturing can empower Six Sigma by increasing the breadth and availability of digital data relating to the process (Antony, 2011). The integration of Lean and Six Sigma overcomes the shortcomings of both (Salah et al., 2011), and has resulted in dramatic improvements across corporations (George, 2002c). Lean Six Sigma combines the tools used to reduce variability in Six Sigma with the techniques used to reduce waste and non-value added activities from Lean manufacturing (Kumar et al., 2006). Continuous improvement (CI) of processes is a crucial part of operations management, and it focuses on the reduction of waste and the improvement of quality (Gupta et al., 2020), which is the essence of Lean Six Sigma. In quality improvement, Six Sigma guides process engineers to identify critical to quality parameters and monitor these through statistical process control (Chang et al., 2012).

When implementing Six Sigma projects, teams are often surprised at how little of their process is mapped or studied (George, 2002c), as manufacturing processes often
significantly lack valuable, informative data relating to the process. The original integration of engineering tools from Lean and statistical tools from Six Sigma represented a new wave of quality management evolution (Salah et al., 2011); however, there is now another new evolution of quality management driven by the introduction of Industry 4.0. Digital solutions provide enhanced support for improving internal processes as part of quality management (Alić, 2018). Automation and digitalisation have brought significant improvements to Lean Six Sigma in the sense of performing process control, eliminating waste and reducing defects (Dragulanescu and Popescu, 2015). By digitalising manufacturing processes, information of cycle times, stoppages, set-up times, non-conformances and rework times can be collected through a manufacturing execution system (MES) and integrated with an enterprise wide software (Fatorachian and Kazemi, 2018). Research shows that digitalisation has an impact on organisational performance (Guo et al., 2017). However, the digitalisation of assets alone will not bring value, process improvement initiatives such as Lean-based quality management systems are crucial for manufacturing organisations to gain efficiency benefits (Peter and Honggeng, 2006). In other words, using technology does not guarantee that improvements will be made; process excellence is the driver. Essentially, “technology is not the goal, but the instrument” (Martinez, 2018). Tortorella et al. (2019) similarly agree, that merely implementing digital technology will not lead to long-term improvement, but that Lean is a required precursor to Industry 4.0. This reiterates the importance of using existing well-proven quality management concepts in combination with digitalisation in organisations’ transition to Industry 4.0.

2.3 Digitalisation implementation

Industry 4.0 has been considered a model for significantly improving productivity through automation and digitalisation (Chiarini and Kumar, 2020). Pfohl et al. (2017) propose that the digitalisation of processes is a key enabler of Industry 4.0. Other researchers suggest that digitalisation is a core element of Industry 4.0, enabling intelligent planning and control of processes (Erol et al., 2016). However, studies proposing a practical digitalisation path for organisations to follow is currently rare in literature (Martinez, 2018; Buer et al., 2021). One example of this type of research is the study by Martinez (2018), who presents four industrial case studies illustrating the digitalisation path that each organisation followed. Although this multi-case study investigation lacks a single general procedure, it usefully highlights the differences and similarities in the four organisations’ approaches to implement digital solutions. Findings from this study indicate that although different methodologies, tools and techniques were used for CI projects, Lean manufacturing was the most commonly adopted approach (Martinez, 2018). This study combined the similarities in the four company’s approaches to form a singular digitalisation path, as shown in Table 1. Insights are drawn from this digitalisation path in the following section to develop further the HyDAP methodology. Buer et al. (2018a) proposed a data-driven process improvement cycle seen in Figure 2. While their study did not outline how the digitalisation transition should occur, they did highlight the potential digitalisation areas. The process starts with a

<table>
<thead>
<tr>
<th>Step</th>
<th>Common path</th>
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<tbody>
<tr>
<td>1</td>
<td>Customer orientation and operational efficiency</td>
</tr>
<tr>
<td>2</td>
<td>Understanding the operation</td>
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<tr>
<td>3</td>
<td>Develop solutions with technology if necessary</td>
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<tr>
<td>4</td>
<td>Solutions implementation and integration</td>
</tr>
<tr>
<td>5</td>
<td>Review and maintain new improvements and solutions that fit the operation</td>
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</tbody>
</table>

Table 1. Common digitalisation path (Martinez, 2018)
defined optimisation goal such as increased productivity. They then design an analysis process specifying which data should be collected to facilitate improvements. Finally, they plan how data will be supplied and collected. It is thus a “pull” way of thinking, i.e. specifying the required data for improvement rather than “push”, where improvements are sought based on whatever data is available. This highlights the need to focus digitalisation efforts on specific, defined requirements such as key process performance metrics.

While organisations have prioritised digitalisation, its implementation is proving difficult and is seldom a straightforward process (Legner et al., 2017). An important finding from literature in this area is that interoperability issues frequently occur when trying to integrate existing systems across the value chain (Chiarini and Kumar, 2020). These difficulties in implementation, along with not knowing where to start, may explain why quality management practitioners have not yet seized the opportunity offered by digitalisation (Legner et al., 2017). Clausen et al. (2018) agree that practitioners involved in shop floor management decision-making have not yet profited from the benefits of digitalising manufacturing. In summary, the potential benefits from digitalisation for quality management remain an explorative research area (Legner et al., 2017), and there is a lack of procedures for managers to follow in the implementation of digitalisation in their organisations (Moef et al., 2018). Based on these findings, we propose to continue using the DMAIC process but to include the addition of appropriate tools and techniques from Lean Six Sigma. However, it is unclear which tools and practices should be combined with digital solutions, which complement and which contradict each other (Buer et al., 2018b), and the developed solution is unique and independent for each organisation (Martinez, 2018).

Many companies try and fail by implementing inappropriate Lean practices and tools in unsuitable environments (Azadegan et al., 2013). A study by Chiarini and Kumar (2020), found that an organisation had tried to implement sort, set in order, shine, standardise, and sustain (5S), but the results proved inadequate; however, they were successful in their implementation of smart sensors and radio-frequency identification. Mahamani and Rao (2008) found that over 30% of Six Sigma projects failed because the wrong tools or techniques had been selected. Hence, it is critically important for organisations to correctly select appropriate tools for successful digitalisation implementation and ultimately process improvement. A significant finding from this literature review was the proposal by researchers for the development of frameworks integrating Lean manufacturing and digitalisation (Núñez-Merino et al., 2020). Buer et al. (2018b) outline that a maturity model is problematic to use in an emerging field where the end goal is not clearly defined (Buer et al.,

**Figure 2.** Data-driven process improvement cycle

Source: Adapted from Buer et al. (2018a)
Similarly, we agree that a methodology is too rigid and does not give practitioners the flexibility to adapt to the evolving and ambiguous concept of Industry 4.0. Although the previous study proposed a methodology, we now propose to redevelop the HyDAPI methodology as a flexible and adaptable framework that can be applied by practitioners. A methodology is a systematic and somewhat limiting approach as it is based on pre-defined rules. In contrast, a framework is a skeletal structure around which something can be built; it provides room for creativity, allowing users to select according to their needs (Khillar, 2021). Therefore, we propose that a framework is a more suitable approach than a methodology, for the digitalisation of manufacturing, due to the varying and complex nature of manufacturing processes. Hence, organisations can use the framework developed as a guide to develop their own bespoke approach that fits with their environment and requirements.

3. Method

Kumar et al. (2006) provide a clear presentation of the tools associated with Lean and Six Sigma. Table 2 depicts the relevance of each of these tools for the HyDAPI framework. This

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<td>Robust design</td>
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<td>Failure mode and effects analysis</td>
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<td>Production flow balancing</td>
<td>✗</td>
<td>Robust design</td>
<td>❌</td>
</tr>
<tr>
<td>Kaizen</td>
<td>✓</td>
<td>Quality function deployment</td>
<td>✓</td>
</tr>
<tr>
<td>Cellular manufacturing</td>
<td>✗</td>
<td>Failure mode and effects analysis</td>
<td>❌</td>
</tr>
<tr>
<td>5 why’s</td>
<td>✗</td>
<td>Project management</td>
<td>✓</td>
</tr>
<tr>
<td>Cause and effect</td>
<td>✗</td>
<td>Regression analysis</td>
<td>✓</td>
</tr>
<tr>
<td>Pareto analysis</td>
<td>✓</td>
<td>Analysis of means and variance</td>
<td>✓</td>
</tr>
<tr>
<td>Change management tools</td>
<td>✓</td>
<td>Hypothesis testing</td>
<td>✓</td>
</tr>
</tbody>
</table>

Table 2. Relevance of Lean Six Sigma tools for HyDAPI framework
section discusses the reasoning behind the judgement of the relevance of each of these tools for inclusion in the HyDAPI framework.

Digitalisation of the Kanban system (replacement of physical cards) has been known for several years (Kolberg and Zühlke, 2015), and is not relevant for digitalisation projects; therefore, it is not necessary to be included in the HyDAPI digitalisation framework. Workplace management or cross-functional management (CFM) is a process designed to support and encourage interdepartmental communication and co-operation in a company (Bicheno, 2000c). This CFM tool from Lean will be included in the HyDAPI framework as the collaboration between different departments and experts in the organisation, as it is vital for the evolution of quality management due to Industry 4.0 and its associated digital technologies. Set-up reduction time is not related to digitalisation; therefore, it is deemed not relevant for the HyDAPI framework. Total productive maintenance (TPM) aims at zero breakdowns and zero defects (Bicheno, 2000b). TPM relates to quality and process control, and the area of research regarding predictive maintenance is data-driven in nature and can be practised through the integration with digital technologies such as IoT; therefore, TPM is relevant for the Plan Monitoring and Maintenance activity as part of the HyDAPI framework. Mistake proofing or poka-Yoke in Japanese, is relevant to the HyDAPI framework, as human errors in data gathering or analysis can be prevented through automation and digitalisation. 5S refers to the cleaning and setting up of the physical workplace; it is not relevant for the HyDAPI digitalisation framework, as processes instead monitor the locations of items relating to the process or machine through the implementation of advanced sensors (Chiarini and Kumar, 2020).

Value stream mapping is a widely used and proven tool that allows the analysis of processes, and digitalisation has the potential to increase its ability to derive areas for improvement (Meudt et al., 2017); therefore, it is relevant for the HyDAPI framework. According to Bicheno (2000a), takt time analysis is the rate at which products should be manufactured. It has not been included as a tool in the HyDAPI framework, as it refers to a specific calculation, and the goal of the HyDAPI framework is to provide versatile and adaptable guidance for digitalisation projects. However, the HyDAPI framework could be implemented from start to finish with the objective of being able to continuously monitor the takt time of a process. JIT or Lean manufacturing can be thought of as a procurement strategy that focuses on levelling demand and aligning production to meet the actual demand (George, 2002d). As JIT is more of an overall approach to manufacturing (Peter and Honggeng, 2006), it has not been included as a tool in the HyDAPI framework. Production flow balancing, also known as line balancing, is a technique used to maximise production, and one of its common objectives is to reduce the number of workstations (Adnan et al., 2016). This specific line balancing technique is not relevant to the goal of the HyDAPI framework, which is to guide the implementation of digitalisation initiatives to bring data-driven process improvement.

Kaizen refers to CI, which is a key component of data-driven quality management; therefore, it is relevant for the HyDAPI framework. The Lean concept of cellular manufacturing refers to a system in which machines are grouped into several cells, where each cell is dedicated to a particular family and the objective is to maximise cell independence (Pattanaik and Sharma, 2009). Cellular manufacturing is not relevant for the digitalisation of processes to achieve data-driven process improvement; therefore, it is not included in the HyDAPI framework. The 5 whys technique involves asking the question “Why?” five times and is used to find the root cause for a problem (Sweeney, 2017). However, this technique has been critiqued for oversimplifying the process of problem exploration (Card, 2017). It is particularly risky, to define a single cause of a problem for a complex
manufacturing process from a series of high-level qualitative questions that are not backed up by data. The 5 whys technique may limit the exploration and analysis of other possible relationships in the process; therefore, it has been determined as not relevant for the HyDAPI framework. The HyDAPI framework aims to guide digitalisation projects for manufacturing processes using carefully curated tools including the Project Charter, User Requirement Specification and Data Catalogue that ensure that the required key process indicators (KPI) are specifically defined, along with all of the variables needed to enable monitoring of these KPI’s. The cause and effect or fishbone diagram is a structured brainstorming tool, not data (George, 2002b); therefore, it is not relevant tool for the HyDAPI framework. Pareto analysis charts analyse the causes that account for 80% of a problem (George, 2002b). This is a very effective method and is included as part of Exploratory Analysis in the HyDAPI framework. One important aspect of the change management tool is the collaboration between everyone involved in the project (Noori and Latifi, 2018), which is a relevant for the HyDAPI framework. Histograms are a useful and relevant technique for data exploration and understanding in data mining; therefore, this tool is relevant for the HyDAPI framework. Control charts are used to study how a process changes over time (George, 2002b); they can be used for the Continuous Monitoring of KPI’s; therefore, they are relevant for the HyDAPI framework. Scatter diagrams, similar to histograms, are a useful technique in data mining; therefore, they are relevant for the HyDAPI framework. The DMAIC methodology is the solid basis for Lean Six Sigma implementation (Chakravorty and Shah, 2012) and makes up the foundation of the HyDAPI framework, therefore, it is relevant.

Variability reduction is relevant for quality management of manufacturing processes and can be represented in the overall goal or objective of the digitalisation project. Statistical process control can be applied to the key process indicator variables to achieve process control (George, 2002b) as part of the Continuous Monitoring activity. Process capability analysis can be a useful tool to demonstrate the improvement made to a process; however, it requires that no special causes of variation are present. Furthermore, there are a multitude of ways to measure the improvement made to a process and the HyDAPI framework aims to be versatile and adaptable to various digitalisation projects. Therefore, the tool Measure Improvement is instead included as an umbrella term encompassing process capability analysis along with other methods of Improvement Measurement that practitioners find suitable. There is a belt system for six sigma that includes Green Belts, Black Belts and Master Black Belts in which individuals are trained on the use of six sigma tools and techniques. However, this is a separate matter for each individual organisation and is not relevant for the HyDAPI framework.

Measurement system analysis is a method of determining the amount of variation that exists within a measurement process (Galli, 2019). As part of the HyDAPI framework, the required digital information is carefully planned and deployed to achieve the defined user requirements. This ensures that the information is automatically provided without errors; hence, the measurement system analysis tool is not relevant for the HyDAPI framework. Design of Experiment (DOE) is a tool used to find the most effective combination of actual operating conditions; however, this is a very detailed, in-depth analysis of the relationships between process factors and requires a process that is stable and controlled (George, 2002e). Therefore, as it is not widely adaptable to many digitalisation projects, it is not relevant for the HyDAPI framework. Robust design is an application of DOE in which a product or process’ performance is minimally sensitive to factors causing variability (George, 2002a); therefore, it is not relevant for digitalisation projects or the HyDAPI framework. Quality function deployment is an approach to defining customer needs or requirements and then
creating specific plans to meet these needs, it is very relevant to the HyDAPI framework and it is included as the user requirement specification (URS).

Failure mode and effect analysis (FMEA) is another tool similar to the cause and effect diagram that is typically used in the measure phase to brainstorm potential causes for failure modes and the associated recommended actions (George, 2002b). However, the goal of the HyDAPI framework is to digitalise a non-digital or analogue process, to enable monitoring and data-driven decision-making; therefore, FMEA is not relevant for the HyDAPI framework. The Six Sigma project management method focuses on understanding customer requirements, improving systems throughout the organisation and enhancing performance (Anbari, 2002). Therefore, Six Sigma project management is relevant to the HyDAPI framework, as it has the ultimate goal of implementing digitalisation to enable data-driven decision-making, leading to improved quality management. Regression analysis is a statistical tool used to help identify the factors or input variables that affect the output variable (George, 2002b). This is a relevant tool for the HyDAPI framework, and it is incorporated in the Data Analysis activity and Model tool. It is not specifically called out as regression analysis in the HyDAPI framework because regression analysis is dependent on the data meeting a number of required assumptions. Therefore, depending on the type of data available, practitioners can choose the appropriate statistical or modelling technique. The same principle applies to the analysis of variance and hypothesis testing tools, which are also specific statistical techniques. In summary, although some of the Lean Six Sigma tools seen in Table 2 are not relevant for the HyDAPI framework, it is not to say that practitioners cannot use and benefit from their use in concurrence with the HyDAPI framework.

4. HyDAPI framework
The aim of the literature review was to identify published research that combines existing quality management concepts with digitalisation in the transition to Industry 4.0. The findings from the literature review led to the integration of tools and techniques from Lean manufacturing with digitalisation (in the context of Industry 4.0) to redevelop the HyDAPI methodology as the HyDAPI framework illustrated in Figure 3. Note that “D” in HyDAPI that stood for digitisation in the HyDAPI methodology has been changed and updated to represent digitalisation in the HyDAPI framework. This framework targets digitalisation as successful digital transformation is more than digitisation; it eliminates information silos by creating a digital thread connecting information sources (Autodesk, 2019). Referring to Figure 3, the innermost layer contains the project phases Define, Measure, Analyse, Improve and Control. The middle layer in the HyDAPI framework contains recommended activities to be carried out in each phase, and the outer layer contains suggested tools and techniques that can be used. Some of the suggested tools are recommended on the basis of previous successful implementation of the HyDAPI methodology in an industrial case study (Clancy et al., 2021). New activities and tools have been included based on findings from the literature review in this study. These tools are suggestions, with the aim of giving organisations the flexibility to select those most applicable to their environments. This toolset is not exhaustive in terms of using all relevant tools and techniques from Lean Six Sigma. Organisations may follow the HyDAPI framework in combination with the implementation of other tools and techniques that they find applicable.

The HyDAPI framework is unique in comparison to existing digitalisation strategies, as it provides a detailed and structured toolset for practitioners. There are a number of digital transformation strategies in literature; however, these models are too high level and lack significant detail to be practical for practitioners to implement, and there is a need for a
detailed, actionable framework for practitioners to implement in the digitalisation of their processes. An example is the four steps proposed by Parviainen et al. (2017). The simplicity of this model is admirable; however, the model is currently quite generic by the authors own admission that further studies are needed to add detail and bring it closer to practice. Another example is the “BUILD” model (Bridge, Uncover, Iterate, Leverage, Disseminate) proposed by Herbert (2017), which poses the same issue, as it has been criticised by for being too generic and unsuitable for unique and complex processes (Bhattacharya and Momaya, 2021). Matt et al. (2015) propose a high-level digital transformation framework consisting of four dimensions, namely, financial aspects, changes in value creation, structural changes and use of technologies. Zaoui and Souissi (2020) performed a review of literature and found the three indispensable phases for the process of digital transformation. Tonder et al. (2020) similarly propose a conceptual framework for the digital transformation of business models consisting of five steps. Hence, there is a plethora of literature covering proposing high-level frameworks for digital transformation, however, the HyDAPI framework is widely contrasting to these approaches, as it provides a detailed set of activities and tools that can be selected and implemented by practitioners to achieve digitalisation in a structured, yet flexible manner.
4.1 Define phase

The activities in the Define phase of the HyDAPI framework remain the same as in the original HyDAPI methodology, and they are Process Overview, Collaboration and Business Understanding. The purpose of the Process Overview activity is to ensure that the implementation team thoroughly understand the manufacturing process. The Collaboration activity is included as successful digitalisation initiatives require a substantial interaction between quality management and an IT function due to the competencies needed from both (Elg et al., 2020). IT functions should be closely aligned and connected with digitalisation initiatives from an early stage in the project (Elg et al., 2020). This highlights the importance of the collaboration between any third-party software vendors and the different departments within an organisation. The third activity in the Define phase is Business Understanding. A common trap that companies fall into is to install a number of smart sensors that measure anything apart from what is actually necessary (Chiarini and Kumar, 2020). As stated by one of the respondents in a survey by Chiarini and Kumar (2020), “you soon realise that before implementing whatever new technology, you must deeply analyse processes for figuring out what you really need”. Therefore, digitalisation efforts need to reflect the business requirements and not be carried out simply for the sake of it (Buer et al., 2018a). It is essential that the digitalisation procedure will guide managers to clearly define the business requirements that will direct a precise focus on the key elements in the process that require digitalisation. The defined business requirements will inform the remaining steps of the digitalisation project including the identification of key process variables and how these process variables will be automatically collected and visualised in the organisation. This explains the inclusion of the URS and Project Charter tools as part of the Business Understanding activity.

As mentioned in the literature review, Martinez (2018) highlighted a five-step common digitalisation path as seen in Table 1. The first step in this digitalisation path refers to the reason that the digitalisation path was initiated, this is often prompted by customer or business requirements or a weakness in the process. This further emphasises the importance of the URS and Project Charter tools. The required KPI's that the user would like to digitalise for the purpose of monitoring and analysis are defined in the URS. The variables required to generate these defined KPI's are then documented in the Data Catalogue. The Data Catalogue is a novel tool proposed by the authors to document details of the key process parameters, including the variable’s name as displayed in the database, the collection frequency and the unit of measure. In summary, the tools in the Define phase are Project Charter, URS and Data Catalogue. Although the framework is described as flexible in allowing users to select tools as needed, we recommend that practitioners complete the three tools in the Define phase. As the purpose of this study is to describe the development of the HyDAPI framework, and due to limited space in this article, we direct readers to our previous research for specific guidelines detailing how to create the Project Charter, URS and Data Catalogue (Clancy et al., 2021). We propose that the three tools Project Charter, URS and Data Catalogue in the Define phase are not optional, as it is crucial to clearly define the project objective, the user requirements and the current data collected for the process to create a distinct and clear pathway to successful digitalisation.

4.2 Measure phase

The activities in the Measure phase of the HyDAPI framework are Process Understanding, Data Collection and Exploratory Analysis. According to Martinez (2018), the aim of the second step in the common digitalisation path (Table 1) is to ensure that there is a deep understanding of the process. Weaknesses in the process can be identified through the
A Process Map can help to identify the key process variables that require digitalisation. Therefore, the Process Understanding activity and Process Map tool in the HyDAPI methodology remain important elements in the HyDAPI framework. The second activity in the Measure phase is Data Collection. By collecting sample data, where possible, for the key process variables outlined in the URS, the data source, structure and format will be revealed. The collection, coding, storage and accessibility of data for decision-making requires the development of a dependable data architecture (Dai et al., 2019; Tao et al., 2018). Therefore, a Data Architecture diagram can be generated by assigning the automation level to each variable listed in the Data Catalogue, using the automation pyramid seen in Figure 4. The field level includes physical hardware on the production floor, and the control level includes programmable logic controllers that take information from the sensors or switches to make decisions (Cope, 2018). The supervisory level is comprising a supervisory control and data acquisition system, which combines the previous levels to access data and control systems from one location (Cope, 2018). The planning level uses a computer management system such as a manufacturing execution system (MES) to monitor the entire manufacturing process (Cope, 2018). Finally, the management level uses a company’s integrated management system, such as enterprise resource planning. The final activity recommended in the Measure phase is Exploratory Analysis. This activity should include producing visualisations to describe, summarise and evaluate the key process variables. With regard to the operational efficiency, a pre- and post-project analysis should be complete. Therefore, inspired by baseline performance in Lean, Baseline Measurement has been added as a tool to the Measure phase (Salah et al., 2011). This measurement is taken to enable any performance improvement resulting from the project to be quantified in the Control phase. In summary, the tools in the Measure phase are Process map, Data Architecture and Baseline Measurement. The Process Map is a helpful but optional tool as the organisation may already have their own method of displaying information relating to the process. The Data Architecture tool is entirely optional to the organisation, as it is simply a helpful method to illustrate the data sources and hierarchy of each variable. Finally, the Baseline Measurement tool is strongly recommended; however, the type of
approach taken to measure the baseline measurement can be decided by the practitioner, as this may vary depending on the type of organisation and the process being digitalised.

4.3 Analyse phase

In the Analyse phase, the inputs are investigated to determine the critical few inputs negatively affecting the outputs (Salah et al., 2011). Data analysis can be used as a tool to portray the opportunity provided by acquiring an asset (Dragulanscu and Popescu, 2015). Data Analysis is the first activity recommended in the Analyse phase of the HyDAPI framework. Descriptive Statistics are part of the Data Analysis activity. If the data is of sufficient quality and relationships are found to exist, a statistical Model can be developed, for example, to identify optimal settings of process parameters to reduce the number of defects. Machine learning algorithms can also be developed if applicable; however, they will not exceed practitioners creative intelligence, intuition and judgement regarding decision-making; therefore, decision-making will require both digital technologies and practitioners knowledge (Mathiasen and Clausen, 2019). After conducting Data Analysis of the key process variables, the next activity in the Analyse phase is to Communicate Results to the wider team and management in the organisation. A Report of the findings and insights from the Data Analysis is recommended to avoid repetition of already completed work and to build documentation regarding statistical findings relating to the process. The tools in the Analyse phase are Descriptive Statistics, Model and Report. We recommend that the Descriptive Statistics tool is used by practitioners if the data allows. The Model tool, on the other hand, is an optional tool, especially since sufficient data quality and the apparent existence of relationships between variables are prerequisites for the development of a Model. Finally, we recommend that a Report of findings from the Analyse phase is documented regardless of whether a Model is developed.

4.4 Improve phase

In the Improve phase, the identified critical inputs are studied to determine solutions (Salah et al., 2011). There is an uncertainty from managers regarding the management and storage of big data, and the solution to this is the use of new business intelligence software which offers storage solutions and data analysis opportunities to drive decision-making (Chiarini and Kumar, 2020). Previous literature on IS found that there is a focus on traditional systems such as MES, and there is a lack of studies on the introduction of Web-based business platforms (Carnerud et al., 2020). A few interviewees in Chiarini and Kumar’s (2020) study stated that they were analysing the KPI’s that they really needed, and then implementing new analytics software for managing the collected big data, but that it was proving to be far from easy. The purpose of the proposed HyDAPI framework in this study is to provide a practical and adaptable guide that aids organisations to pinpoint specific areas of the supply chain that need to be digitalised based on business requirements. By following the HyDAPI framework, digitalisation initiatives are based on defined requirements or KPI metrics that, when digitalised, can be continuously monitored and analysed for decision-making. When implementing Industry 4.0 technologies, practitioners cannot forget to implement a business analytics platform capable of mapping the KPI’s needed (Chiarini and Kumar, 2020). Therefore, it is essential that organisations Plan the Monitoring and Maintenance of these critical process parameters through the use of a business analytics platform.

Graphical User Interface (GUI) has been proposed as a tool in the Improve phase to display data for key process metrics. GUI is widely used in software development as the foundation for graphics-based systems, and it is composed of a visual part (front end) and application code (back end) (Mondava, 1998). The development of the GUI will require
collaboration between the developers and the quality professionals to ensure that the system developed will meet the user requirements. The second suggested tool in the Improve phase is Digital Andon. Digital Andon originates from Lean manufacturing and refers to a system that notifies management and operations of quality issues (Buer et al., 2018b). This suggested Lean tool integrates quality management and digitalisation, and it is an optional tool for organisations to implement, if it is applicable to their processes.

The fourth step in the common digitalisation path emphasises the need for employee involvement to ensure that the identified solutions are implemented (Martinez, 2018). This aligns with the second activity in the Improve phase, Deployment. Deployment refers to the launch of the developed user interface for monitoring of the KPI’s. The tools linked to the Deployment activity are Poka–Yoke and Standardised Work. Standardised Work is one of the principles of Lean manufacturing, and it refers to the generation and use of established procedures to effectively produce products, in the safest way, based on current technologies. Implementing the developed solution using a business analytics platform ensures that data is collected, formatted, coded and stored in a standardised way; therefore, Standardised Work is included as a tool in the Improve phase of the HyDAPI framework. Poka–Yoke is a Lean tool that refers to the implementation of devices or systems to prevent mistakes or defects from occurring (Thomas, 2018). The Deployment of a Web-based business analytics platform can prevent human errors (mistakes) that may occur during the collection, formatting and analysis of process data. Digitalised process information provided through the business analytics platform can be continuously monitored and analysed, to avoid the occurrence of defects, therefore, Poka–Yoke is a suggested tool in the Improve phase of the HyDAPI framework. In summary, the tools in the Improve phase are Standardised Work, GUI, Digital Andon and Poka–Yoke. All of these tools are optional as they will depend on the KPI’s required and the previous non-digital information collection. However, it is likely that they will be relevant for many digitalisation projects.

4.5 Control phase
According to the digitalisation path proposed by Martinez (2018), the aim of the final step is to review and quantify the success of the project. Therefore, the first suggested activity in the Control phase of the HyDAPI framework is Review Project. The objective of the Control phase in the DMAIC process is to ensure that financial and non-financial improvements are maintained effectively in the long-term (Khillar, 2021; Singh and Khanduja, 2014). Therefore, Measure Improvement is included as part of the Review Project activity. The improvement can be measured in the Control phase and compared to the Baseline Measurement recorded in the Measure phase to summarise the success of the project in terms of the organisations appropriate performance measure(s). The focus of the Control phase is to monitor and maintain the inputs and outputs on a day-to-day basis (Salah et al., 2011); therefore, the second activity in the Control phase is Continuous Monitoring. Martinez (2018) also recommends that the process be continually observed for further potential improvements and that employees must be aware of new technologies that could be implemented. We agree that further digitalisation projects could be identified after implementing the designed solution. Therefore, “Kaizen”, which is a key component of Lean Six Sigma (George, 2002c), meaning “continuous improvement”, is included as an optional tool in the Control phase. This is in line with the idea that digitalisation is not just a one and done, but that it is a continuing evolution (Autodesk, 2019). CI is viewed as an evolution that operates on the principle of making minor changes to obtain results in the long-term (Iwao, 2018). In the context of digitalisation and quality management, CI refers to the gradual adoption of technologies based on specific small needs (Martinez, 2018).
Digitalising key process variables using a business analytics Web-based application not only provides a means for daily management of process parameters, but it also provides a platform for long-term improvements (Singh and Khanduja, 2014). Therefore, Kaizen is included as a tool for organisations to identify potential further improvements in the Control phase. Jidoka, Visual Management and Control Charts are Lean Six Sigma tools that have also been included as part of the Continuous Monitoring activity in the Control phase of the HyDAPI framework. Jidoka, meaning autonation (automation with human intelligence), is an appropriate Lean tool, as the developed solution for the business analytics platform will automatically collect and display appropriate real-time information from the organisations processes. Visual Management is a recommended tool from Lean as its purpose is to establish a visual means to monitor day-to-day manufacturing floor performance (Khadem et al., 2008). Finally, control charts monitor process parameters in relation to their specification limits over time. This applies to the goal of Continuous Monitoring of the digitalised KPI's as a result of implementing the HyDAPI framework. To summarise, the tools in the Control phase are Jidoka, Control Charts, Visual Management, Measure Improvement and Kaizen/CI. We recommend that practitioners definitely use the Measure Improvement tool to quantify the success and performance improvement resulting from the digitalisation project to encourage further digitalisation initiatives in the organisation. We also strongly recommend the Kaizen tool as part of the Review Project activity, as this promotes the continuing improvement of processes within the organisation through digitalisation projects. The Visual Management, Control Charts and Jidoka are optional tools that are dependent on the specific KPI's and method of monitoring.

5. Case study
An industrial case study was identified to digitalise and automate an inefficient, time-consuming process of gathering, amalgamating and analysing manufacturing process information for on-hold batches that require quality review. A review report is generated if any one of several test results in the process are out of specification. The previous process conducted by quality technicians for review reports was to individually access four different production workstations along the value stream, that are physically located in different locations, and manually download large static data files. Each of the four files were manually merged and formatted before a detailed review could be carried out. This process was conducted at least once a day. The quality technician would review each specification according to documented procedures to determine if the batches on hold would be passed or failed. The HyDAPI framework was used as a guide to digitalise this process information to automatically be fed to a business analytics platform. The performance improvement resulting from the project was quantified through the Baseline Measurement in the Measure phase. This Baseline Measurement was recorded by conducting a time study for the collection and formatting of the raw data from the value stream, as seen in Figure 5.

The user interface for this business analytics platform was developed as part of the GUI tool in the Improve phase. This user interface was designed to depict to the user or quality technician in this case, whether each batch is pass or fail. The process specifications and requirements have been codified into the backend model of the user interface in the business intelligence platform. A unified modelling language (UML) class diagram is a software development technique that can be used to illustrate the information of interest for an application; it depicts the relationships between objects in
a system, along with their respective attributes and operations (Berardi et al., 2005). The UML diagram shown in Figure 6 was generated to represent the objects contained in the business analytics platform. The quality technician can now see the history of batches processed and whether or not each batch has met all specifications.

In summary, the previous inefficient data acquisition process was digitalised, with batch data reports automatically sent to the business analytics platform, accessible to the wider organisation. The time study conducted as part of the Baseline Measurement tool to measure the time taken to collect the raw data revealed that this task required

Figure 5.
Time study for collection of raw data

Figure 6.
UML class diagram
1.9h to 3.7h per week. This time has been completely eliminated through the development of the digitalised solution. As stated by Dragulanescu and Popescu (2015), it is important to recover even minimum times, as they could be repetitive operations. Digitalising this information not only reduces time wasted, but it also enables the root cause analysis of frequent issues, and it frees up valuable employee time which can be better spent on higher skilled work. This digitalised solution also standardises the decision-making process, which could be valuable for entry-level employees without the necessary experience to make optimal decision choices. Many organisations say that 70% of their time is spent on non-value added tasks (Autodesk, 2019), by creating a digitalised, automated solution, employees time and skills can be better used. By implementing digital environments to enable organisation-wide access to data, faster and informed decision-making can be achieved (CIMdata, 2021), resulting in efficiency gains for the organisation. Therefore, by digitalising this information, the time taken to identify a defective product, which is critically important to a manufacturing organisation (Arey et al., 2020), can be significantly reduced. The project required regular communication between the quality department, the automation department and the third-party vendor developing the backend model for the user interface on the business analytics platform. The collaboration of the three parties was essential to the success of this digitalisation project. Furthermore, the URS outlined the specific user needs to be required in the user interface, for the quality technicians to be able to conduct the review process, and decide if the on hold batches pass or fail. These are some examples of how the activities and tools in the HyDAPI framework were beneficial in guiding this digitalisation project.

6. Conclusion
This study is targeted towards quality practitioners attempting to adapt their practices in the emerging field, Industry 4.0. Digitalisation is a key enabler for organisations to transition to Industry 4.0, as it involves the automatic collection of data sources across the value stream, which provides the groundwork for many Industry 4.0 technologies. The synergistic relationship of quality management and digitalisation, along with the lack of understanding of how these domains can be applied by practitioners, drove the development of the research questions. The research questions were set to investigate how quality management has been integrated with digitalisation in literature and which aspects of this integration can be used to strengthen and improve the HyDAPI methodology. The HyDAPI methodology was proposed in previous research; however, the Improve and Control phases required further development. A literature review was conducted to provide an overview of research that has combined digitalisation and quality management. The review of literature led to the conclusion that key elements of Lean manufacturing were lacking from the HyDAPI methodology, including the creation of a visual workplace, the standardisation of work, mistake proofing and the reduction of waste. Lean Six Sigma tools were reviewed regarding their relevance for the HyDAPI framework. These tools were used to supplement the existing HyDAPI methodology.

Another finding from the literature review was that a one size fits all approach is not suitable due to the vast array of complex manufacturing processes. Organisations will need to develop a unique solution based on their environments and requirements; therefore, we propose that a framework is a more suitable approach due to its flexibility in allowing users to select appropriate tools as they need. Thus, the HyDAPI methodology from existing research was enhanced and further developed through the
additions from Lean Six Sigma, driven from the review of literature integrating quality management with digitalisation. The enhanced HyDAPI framework, proposed in this study, was implemented in an industrial case study to digitalise the time-consuming, inefficient process undertaken by quality technicians in manually collecting data from isolated information silos to review products that required quality review. By implementing a digitalised solution, human errors were reduced, decision-making was standardised, leadership and planning were informed and the time to gather and compile data was eliminated. This digitalised solution resulted in improved efficiency of the production quality control responsiveness and enabled root cause analysis of product non-conformances.

6.1 Theoretical contributions
This study demonstrated how Lean Six Sigma practices can effectively be incorporated to aid the successful implementation of digitalisation and adoption of digital technologies as organisations migrate towards Industry 4.0. This study proposes that digitalisation initiatives are conducted to pave the way for organisations in their transition to Industry 4.0. Existing approaches for digitalisation are too high level and do not provide the necessary detail for practitioners to actually adapt the suggested processes to the context of their organisations (Zaoui and Souissi, 2020). Furthermore, literature is lacking tools such as frameworks or guidelines to help managers embark of their digital transformation journey (Morakanyane et al., 2020). Therefore, we propose the HyDAPI framework address these gaps in literature by providing a versatile, practical approach for practitioners to follow in implementation of digitalisation.

6.2 Practical contributions
Organisations can follow the HyDAPI framework to ensure that digitalisation initiatives are based on defined requirements or KPI metrics that when digitalised, can be continuously monitored and analysed for decision-making. Digitalisation has the potential to improve quality management practices through the provision of real-time data from the manufacturing process. The HyDAPI framework presents a versatile, flexible and adaptable framework that can be implemented in a variety of organisations and processes. Standardising a common, repeatable digitalisation approach can aid quality practitioners to use the full potential of digitalisation and improve quality management of their supply chains. The HyDAPI framework is a detailed, actionable digitalisation strategy that practitioners can implement, in comparison to the existing high-level digital transformation frameworks that exist in literature.

6.3 Limitations and future work
The toolset in the HyDAPI framework is not inclusive of all relevant tools and techniques from Lean Six Sigma. It would certainly be interesting and beneficial for future research to conduct case studies implementing the HyDAPI framework either alone or in combination with other quality management tools and techniques. Research should test the effectiveness of the HyDAPI framework alone and in combination with other techniques as part of various organisation digitalisation initiatives.

References


CIMdata (2021), “Digital transformation: driving competitive advantage”.


Fictiv (2021), “2021 state of manufacturing”.


Mondava, S.V. (1998), Process in User Interface Development, University of Montana, Missoula, MT.


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