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**Lean Six Sigma implementation and sustainability roadmap
for reducing medication errors in hospitals**

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Lean Six Sigma implementation and sustainability roadmap for reducing medication errors in hospitals

Purpose: The purpose of this study is to propose a Lean Six Sigma (LSS) roadmap to guide healthcare practitioners in the implementation of LSS along with a customized LSS tool kit for reducing medication errors.

Methodology: The authors critically reviewed several frameworks/roadmaps of Lean, Six Sigma and LSS that have been proposed in the healthcare sector from the existing literature. This review has led to an understanding of key characteristics, limitations, and reasons behind the development of such frameworks/roadmaps. A conceptual roadmap was developed and then validated by LSS experts and a healthcare practitioner. Based on the previous studies and taking LSS experts' opinions into account, a revised roadmap for reducing medication is presented.

Findings: The roadmap for LSS in reducing medication errors is developed. This roadmap includes three phases: Phase 1 cultural readiness for LSS employment in reducing medication errors; Phase 2 preparation, initialization and implementation, and Phase 3 sustainability.

Research limitations The roadmap has been tested with only a small number of LSS practitioners. Moreover, only two case studies have been carried out in a Thai hospital setting. In order to improve the validity of research, more case studies need to be executed and more people should be used for testing the roadmap with varied cultures.

Originality/value: This is the first attempt in the development of a LSS roadmap that healthcare practitioners can follow to reduce medication errors using LSS methodology and sustaining LSS in their organizations.

Key word: Lean Six Sigma, Six Sigma, Roadmap, Framework, Medication Errors

1. Introduction

Patient safety is an important goal of healthcare quality (WHO, 2017). It is a necessary dimension for both healthcare providers and patients (Limpanyalert, 2018). During the treatment process, patients need to receive the correct medication at the right dose, in the right concentration and at the appropriate time. However, medication errors can occur at every stage of the medication process, from prescribing, transcribing, dispensing, administration by the nurse and monitoring (Baril *et al.*, 2014). In the prescribing stage, physicians play an important

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3 role in prescribing the right medication to the patients. Prescriptions of medication can be
4 ordered by a handwritten prescription, computerised physician order entry (CPOE), electrical
5 or verbal order from physicians to pharmacists in order to give instructions on how to dispense
6 medication to patients (Velo and Minuz, 2009). Then the details of the prescribed medication
7 are manually copied by nurses onto the medication administration (MAR) chart (NHS, 2015)
8 or entered into the medication administration record. Medications are delivered or dispensed
9 by pharmacists in the dispensing stage (Yoelao *et al.*, 2014). Administration of medications by
10 nurses is the final step of the medication process (Berdot *et al.*, 2016). Finally, the monitoring
11 stage involves the activities, which aim to monitor the impact of medication on the patients
12 (Management Science for Health, 2012). Medication errors could lead to patient injury and
13 death and contribute to an increase in hospital costs. Several studies over the past decade have
14 identified medication errors as a global issue with prescription errors in the UK, reportedly
15 affecting 12% of all primary care patients and 38% of those aged 75 years and above (WHO,
16 2016). In the USA, medication errors cause at least one death every day and injure
17 approximately 1.3 million people every year (U.S. Food and Drug Administration, 2016).
18 Globally, the cost associated with medication errors is US\$ 42 billion each year, which
19 represents almost 1 per cent of the global expenditure on health (WHO, 2017).
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33 Reducing medication errors and the harm caused by such errors is a critical issue internationally
34 that offers clear socio-economic benefits (Crane and Crane, 2006). Hence, there is an urgent
35 need to address healthcare problems caused by medication errors at a global level. Many
36 interventions aimed at improving patient safety using continuous improvement methodologies
37 such as Lean and Six Sigma have been found to have a positive effect on reducing medication
38 errors and on improving patient care. Several studies have been published on the
39 implementation of Lean Six Sigma (LSS) in reducing medication errors (Esimai, 2005; Luton
40 *et al.*, 2015; Al Kuwaiti, 2016). However, these studies have only focused on the applications
41 of LSS. The existing literature does not address the need of a LSS roadmap in reducing
42 medication errors and this paper presents the development of such roadmap explicitly showing
43 a systematic and organized step-by-step methodology.
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53 A roadmap helps the healthcare practitioners to understand and follow the steps for
54 implementing LSS projects in a hospital setting (Antony *et al.*, 2016). It can guide healthcare
55 organizations in the successful implementation of LSS. Al-Qatawneh *et al.* (2019) proposed a
56 framework for applying Six Sigma in the areas of healthcare logistics. This study aims to
57 answer the following research question:
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3 *How can an LSS implementation and sustainability roadmap be developed to guide*
4 *healthcare practitioners in the reduction of medication errors?*
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7 The next section critically reviewed several frameworks/roadmaps of Lean, Six Sigma and
8 LSS which have been proposed in the healthcare sector from the existing literature.
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11 **2. LSS roadmap in healthcare sector – a review of literature**

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14 Very limited existing literature proposes a roadmap for the deployment of LSS in the healthcare
15 context. Similarly, Nonthaleerak and Hendry (2007) mentioned that few published papers have
16 proposed a practical implementation of LSS roadmap in a service context. Antony and Kumar
17 (2012) pointed out that hospitals do not have a roadmap to sustain LSS. Therefore, a critical
18 review was carried out to determine what was available in terms of frameworks or roadmaps
19 of Lean, Six Sigma and LSS which have been suggested for healthcare sectors. This review
20 has led to an understanding of the key characteristics, limitations, and reasons behind the
21 development of such frameworks and roadmaps.
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30 Yeh *et al.* (2011) and Cheng and Chang (2012) proposed a framework of DMAIC methodology
31 to improve the medication process and to increase the efficiency of resource management in
32 physical disabilities services. These frameworks provided the details in each phase of the
33 DMAIC methodology, along with a limited description of strategic issues such as top
34 management support and leadership to facilitate the implementation of LSS. Similarly, Furterer
35 (2014) provided a roadmap for applying LSS and its tools and techniques in the healthcare
36 processes. This LSS roadmap outlines each phase of DMAIC methodology but is without an
37 explanation of the critical factors for successful deployment of LSS. Subsequently, Honda *et*
38 *al.* (2018) systematically reviewed the existing frameworks of LSS implementation in the
39 healthcare sectors. The results show that most of the included studies used DMAIC
40 methodology as a framework for implementation. Then, Al-Qatawneh *et al.* (2019) proposed a
41 framework for applying Six Sigma in the areas of healthcare logistics. Al-Qatawneh's study
42 also used DMAIC methodology as a framework and explained the phases of the methodology.
43 The proposed framework was further applied by a private hospital in Jordan which resulted in
44 an improvement in the warehousing process. Almutairi *et al.* (2019) suggested a framework
45 for implementing the Lean principle in the supply chain management in Saudi healthcare
46 organizations. This framework could assist healthcare practitioners to implement Lean
47 successfully in the hospital supply chain management practices. However, this framework is
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3 limited to Saudi Arabian settings. Most of the frameworks are based on DMAIC methodology
4 which is useful for reducing medication errors, however, these frameworks will never change
5 the culture of the hospitals. Several aspects of such frameworks are omitted such as, *inter alia*,
6 communicate the need for LSS in hospitals, training of LSS tools, curriculum of training,
7 project selection and its links to strategic objectives to the hospitals, teamwork, and formulation
8 for the execution of projects.
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11 Table 1 summarises the key features of frameworks/roadmaps, the methodology used, aim,
12 limitations of the LSS frameworks/roadmaps as promoted by several researchers. The key
13 findings regarding the proposed frameworks/roadmaps are summarised as follows.
14

- 15 • Most of the existing frameworks used DMAIC methodology as the LSS framework.
- 16 • Most of the frameworks are developed based on the existing literature. There were
17 limited frameworks/roadmaps that have been developed, based on empirical studies
18 such as surveys and case studies.
- 19 • There was limited discussion on the cultural readiness of healthcare organizations and
20 strategic issues such as management commitment and resource planning.
- 21 • Lack of empirical evidence in the validation of existing roadmaps for LSS in the
22 healthcare context.
- 23 • No framework/roadmap identified in the current literature focuses on how to sustain
24 LSS across the healthcare organization.
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39 *Table 1 insert here*
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42 Each framework/roadmap was further evaluated based on the different key characteristics
43 adopted from Nonthaleerak and Hendry (2007) (see Table 2). Most of them have used DMAIC
44 as a framework, explaining the steps in each phase and suggesting tools to be used in the
45 DMAIC methodology. None of the frameworks have been validated by LSS experts or
46 healthcare practitioners. The roadmap proposed in this paper addresses such limitation
47 explained above.
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52 *Table 2 insert here*
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55 **3. Methodology**

56 Due to the limitations of the LSS framework/roadmap and its characteristics in healthcare
57 sectors, an LSS roadmap was developed based on the LSS roadmap for SMEs proposed by
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3 Kumar *et al.* (2011), Antony *et al.* (2016), and Timans *et al.* (2016), the key articles on Lean
4 readiness in the healthcare context such as Al-Balushi *et al.* (2014) and Alnajem *et al.* (2019)
5 and the experiences that the authors gained from undertaking the action research in two
6 hospitals in Thailand. Figure 1 presents the conceptual LSS roadmap which includes three
7 phases: **Phase 1** Cultural Readiness, **Phase 2** Preparation, Initialisation and Implementation,
8 and **Phase 3** Sustainability. Following the presentation, the conceptual LSS roadmap was
9 validated by a number of LSS experts (e.g. Master Black Belts and Black Belts), and a
10 healthcare practitioner to ensure that it could be applied successfully in the hospital. The criteria
11 for choosing the LSS experts included that they: 1) had to complete at least five Black Belt or
12 Green Belt projects; 2) had experience in coaching Black Belts with successful project
13 completion; and 3) had leadership and change management skills (Watson, 2003). Most of
14 them were contacted by the authors via LinkedIn and the details of the LSS roadmap were
15 explained to them. The experts and the healthcare practitioner were asked to provide the
16 comments or suggestions on the conceptual LSS roadmap (Alnajem *et al.* 2019). Table 3
17 summarises the background and comments of LSS experts and the healthcare practitioner.
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32 *Figure 1 insert here*

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42 Then, the comments from LSS experts and the healthcare practitioner lead to the revised LSS
43 roadmap, as shown in Figure 2. Phases 1 and 2 of the revised version mostly contain the same
44 elements as the initial LSS roadmap. The greatest modification has been made in phase 3. Three
45 factors: future trend of LSS, succession planning, and organization review and strategy review
46 have been added into this phase. The factor 'management declares commitment to pursue
47 continuous improvement' has been replaced by an investor in people (IIP). In phase 2, training
48 has been replaced by 'project champion training and LSS training'. Moreover, the timeframe
49 of each phase has been added to the initial LSS roadmap. This timeframe has been
50 benchmarked with the timeframe provided by the Master Black Belt.
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Figure 2 insert here

4. LSS implementation and sustainability roadmap to reduce medication errors

The following section explains the three phases of LSS implementation and sustainability roadmap for reducing medication errors. These three phases were developed based on the existing literature including Kumar *et al.* (2011), Al-Balushi *et al.* (2014), Antony *et al.* (2016), Timans *et al.* (2016), and Alnajem *et al.* (2019).

Phase 1: Readiness factors for the implementation of LSS in the reduction of medication errors;

Phase 2: Preparation, Initialisation, and Implementation;

Phase 3: Sustainability

Phase 1: Readiness factors for the implementation of LSS in the reduction of Medication Errors

This phase aims to assess the readiness of the hospitals before commencing on the execution of LSS projects (Kumar *et al.*, 2011). Readiness factors are an important element that facilitates the successful implementation of LSS before the hospital invests some resources such as finances, time, and manpower (Antony, 2014). These readiness factors are important to assess the ability of the department or a business function for its readiness to implement LSS in improving the medication process. If the department is not ready for LSS deployment, it could lead to the failure of next phase (i.e., implementation) frustration among staff and resistance from the staff (Antony, 2014; Antony *et al.*, 2016). The following readiness factors have been identified in order to commence the LSS initiative.

A. Recognize the need for change at a project level

The implementation of LSS can lead to alterations in the current medication process, systems or staff's roles in a department (e.g. inpatient/outpatient pharmacy or wards) so that resistance to change may occur. For example, pharmacy technicians do not want to change from their current roles or follow a new process. Prior to embarking on an LSS project, it may be difficult to make changes in the existing medication process due to internal resistance from staff. Therefore, all staff in the pharmacy service or other departments involved in the medication

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3 process should be notified in advance that LSS will be implemented to reduce medication
4 errors, and this implementation may affect their routine working practices. It is important to
5 explicitly explain in detail the reason for a change to establish a sense of urgency (Kotter,
6 2007). For example, the Head of the Pharmacy Service may arrange a meeting to explain the
7 existing problems in the dispensing process that contribute to patient injury and death and
8 increase in hospital costs.
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11 A successful transformation of change at a project level requires clear communication, vision,
12 and motivation from the leader to overcome resistance to change (Mustapha *et al.*, 2019). The
13 following variables should be considered in this factor.
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- 15 • Staff who are involved in the medication process should understand the need for change
16 through a clear communication, vision and motivation from the leader.
- 17 • The leaders should recognize the need for a major change in the medication process.
- 18 • A clear vision should exist and this vision should be communicated to clarify the
19 direction in which the department needs to move (Kotter, 2007). For example,
- 20 • Clear communication channels are required within the department about the need for
21 change (Schweikhart and Dembe, 2009).
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33 *B. Strong leadership and vision*

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35 Leadership can change the attitude of the healthcare staff, their readiness for within the
36 medication process through exchanging of information and ideas (Tsironis and Psychogios,
37 2016). Leadership is required to sustain improvement (Snee, 2010) and should cut across every
38 phase of the LSS roadmap. It is important to put the effective leadership in place to ensure the
39 success of LSS deployment, coupled with the top talent in the organization involved in LSS,
40 providing them with the right project management tools and methodology, and making them
41 financially accountable for the success of the initiative (Trakulsunti and Antony, 2018). The
42 following variables are important in relation to this factor, as adapted from Antony *et al.* (2007),
43 Antony (2014), and Trakulsunti and Antony (2018).
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- 51 • Identify a clear direction for and guidance on the implementation of LSS
- 52 • Top leaders should be able to describe why LSS is needed.
- 53 • Communicate the vision to staff at different levels to gain organizational commitment
54 and create a LSS culture by getting staff buy-in.
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- Leaders should provide support, direction, and encouragement to staff for a successful implementation of LSS.
- Leaders are able to address all types of resistance to change (technical, political, etc.)
- Leaders should communicate the improvements resulting from the LSS project through a range of media such as newsletters, social media, and forums throughout the hospital.
- Recognizing and rewarding staff who are involved in the improvements in the medication process is important (Kotter, 2007). The recognition and rewards that staff can receive from the organization can be financial (e.g. bonus) and non-financial (e.g. LSS certification ceremony, promotions) (Hoerl, 2001).

C. Effective communication at all levels

Effective communication means that the information is successfully delivered, received and understood between two or more people without any distractions (Sibiya, 2018). The implementation of LSS requires effective communication channels within the hospital or department to minimize the resistance to change (Schweikhart and Dembe, 2009; Antony and Kumar, 2012). Effective communication channels at all levels for the people who are directly involved in the project or affected by the LSS implementation is crucial to help the project run smoothly and successfully (Antony and Banuelas, 2002; Antony *et al.*, 2007; Salah *et al.*, 2010). Staff who are involved in the medication process should understand the importance of LSS and how LSS could be applied to improve the current medication process. The following variables should be considered under this readiness factor, as adapted from Antony and Banuelas (2002) and Shitu *et al.*, (2018):

- Effective communication between healthcare practitioners and departments is crucial (Alnajem *et al.*, 2019).
- Effective communication entails top-down and bottom-up communication (Antony and Banuelas, 2002).
- Effective sharing of information between doctors, nurses, pharmacists, and patients is needed.
- Attention should be paid to ensure a correct exchange of information (Shitu *et al.*, 2018).
- Be clear and specific when explaining important information

D. Patient focus

A primary goal of the healthcare service is to protect patients from harm, improve patient safety and provide a high-quality service. An LSS project should begin with the understanding of patients' needs and identification of the factors that are critical to the patient (Antony and Banuelas, 2002; Burgess and Radnor, 2013 Alnajem *et al.*, 2019). It would be difficult to initiate an LSS project without a thorough understanding of patient requirements (Alnajem *et al.*, 2019). In healthcare, the voice of the patient (VOP) can be used to capture the patients' needs and expectations of today and tomorrow. The needs of patients can be identified by two types of data: reactive data (e.g. patient complaints, compliments, and feedback for improvement) and proactive data (e.g. interviews, surveys, and focus groups) (Breslin *et al.*, 2014; Antony *et al.*, 2016). The set of variables under this readiness factor, adapted from Antony (2014) and Antony *et al.*, (2016), are listed as follows:

- Linking patient focus to the hospital's strategy and projects (Antony *et al.*, 2016);
- Understanding patient's requirements and performing only those activities that serve their requirements;
- Staff accepting and understanding that patients are not the only customers of the hospital; internal customers such as doctors, nurses, and pharmacists are also equally important as they serve the external customers (i.e., patients) (Antony, 2014).

E. Linking LSS to hospital's strategy

Linking LSS to the organization's strategy has been widely emphasized as a key success factor for LSS deployment (Manville *et al.*, 2012; Alhuraish *et al.*, 2017). Linking the LSS project objectives to hospital strategic goals can create a long term change in the hospitals (Dick *et al.*, 2006; Psychogios *et al.*, 2012; Al-Balushi *et al.*, 2014). The staff can understand the nature, the purpose, and benefits of their routine work (Al-Balushi *et al.*, 2014). Without a clear vision and purpose of the initiative, the staff may not realize the importance of LSS. The staff are more willing to accept change in their roles when LSS deployment is clearly communicated as a long term policy within the hospital's strategy (Bateman and Rich, 2003). The following variables, adapted from Antony (2014), are important under this readiness factor.

- Ensure that the LSS project is aligned with the hospital's strategy;

- Determine the success of the project by identifying measurement factors such as hospitalization costs, number of medication errors and staff and patient satisfaction.
- Top management communicates the strategy and the purpose of the initiative across the hospital. Moreover, senior management should be involved in making sure that projects have an alignment with the strategic objectives of the hospital.

To ensure that the department is ready to embark on LSS and cultural transformation, the degree of cultural readiness should be assessed. Research has shown that each readiness factor may be attributed to a set of variables and it is important to understand how ready a hospital is with regards to such variables. A five-point Likert scale was adopted for each variable ranging from (1) percept not implemented at all; (2) percept slightly implemented; (3) percept moderately implemented; (4) good implementation of percept; and (5) percept fully implemented (Kumar *et al*, 2011). The hospital can continue to the next phase, if each variable gets a score of 3 (Kumar *et al*, 2011).

Phase 2: Preparation, initialisation, and implementation

Preparation

This phase helps the hospital to evaluate the commitment from top management to make changes in the medication process and allocates resources to the LSS project team. Top management support and involvement, as well as resource planning are important elements in this phase, each of which is explained below.

A. Top management support and involvement

The application of LSS in the hospital is difficult because most of the healthcare staff are unfamiliar with LSS principles. Hospital managers should understand the concepts, benefits of LSS and how to implement LSS (Raghunath and Jayathirtha, 2013). LSS deployment should start with a two-day overview of the methodology in order to gain top management buy-in (Antony, 2014; Trakulsunti *et al.*, 2018). Once top management is convinced of the need for LSS implementation, they can communicate with staff as to how their involvement contributes to the success of LSS and achieves the hospital's strategy. All levels of managers should provide assistance, the necessary resources (e.g. time, budget and human) for executing the LSS projects, training and ownership to solve problems (Antony and Banuelas, 2002; Habidin and Yusof, 2013; Antony, 2014).

B. Resources planning

The allocation of resources such as time and budget for the employment of LSS is an important factor before the execution of a LSS project (Antony, 2014). The major challenge of LSS implementation to reduce medication errors in hospitals is the allocation of time. The success of the LSS project depends primarily on the allocation of time to team members. During the LSS project, team members are very busy with other jobs or responsibilities. It is important to ensure that the team members provide sufficient time to engage in LSS projects (Antony, 2014). Prior to the project, the project team should develop an implementation plan to ensure that the team can complete it on time and project champion should monitor the progress of the project. In the hospital setting, it might take more time to complete the LSS project depending on how well the team members have been trained on the methodology and the associated tools of LSS. In addition, a necessary software programme, such as Minitab, should be made available to support the project team during the implementation of LSS to help with data analysis.

Initialisation

This phase helps the hospitals to select the right LSS project and the right people to work in the team. Once the LSS project has been identified, the formation of the project team is an important aspect to be considered by the hospitals. Afterwards, the selected team members should receive LSS training to drive the project successfully.

A. LSS project selection and prioritisation

In healthcare, project selection and prioritisation is critical to the success of the project (Antony *et al.*, 2007; Desai *et al.*, 2012; Manville *et al.*, 2012). Selection of the right project can help the management and staff to realise the true benefits of LSS (Bhat *et al.*, 2016). The project selection in the hospital should focus on the voice of the patient and identify the Critical-to-Quality characteristics (CTQs) which are linked to the voice of patient. Before implementing LSS in the pharmacy service or other departments in the hospital, it is important to choose a project that is patient-oriented and financially beneficial. The authors adopted project selection guidelines identified by Antony *et al.* (2007). These are:

- The project should be linked to the hospital's strategy or policies, and patient care problems.
- The project should have an impact on both internal customers and patients' needs and expectations.
- The project should be looking into a chronic problem where previous attempts to tackle it have not been successful.
- Project goals should be clear, specific and measurable such as the number of dispensing errors, waiting time and patient satisfaction.
- During the project selection process, the project team should identify the criteria to select the projects (Sharma and Chetiya, 2010). The following criteria should be considered, including: patient satisfaction, financial benefits, top management support, duration of the project, data availability, risks involved, and resources required for the project.

B. Project reviews

A project review is an important activity to ensure a successful implementation of LSS and completion on time. Antony *et al.* (2016) suggested that the review could be performed by a LSS champion and along with other LSS experts (e.g.: Green Belts or Black Belts). The champion reviews the overall progress of the project to ensure that the project meets the schedule, project objectives, goal, budget and aligns with the hospital's strategy. The reviews should be carried at the end of each phase of the DMAIC methodology to understand if there any bottlenecks with regards to progress of the project. The followings questions could be included during the review by the LSS project champion:

- Is the project executed as planned and scheduled?
- Is the overall progress made in each phase of DMAIC methodology acceptable?
- Is there a problem regarding budget and resources which could potentially hinder the progress of the project?

However, the review performed by the champion mainly focuses on the DMAIC methodology. The key points to be reviewed include the appropriateness of data collection, analysis and interpretation and the appropriateness of tools and techniques applied in each phase of the LSS methodology.

C. Team formation and team dynamics

The formation of the LSS project team is an essential component in LSS implementation (Antony *et al.*, 2016). An LSS project requires a multidisciplinary team to facilitate its deployment. The team should include all staff who are involved in the medication process which consists of doctors, pharmacists, pharmacy technicians, nurses, IT staff and other stakeholders. The head of the pharmacy service or consultants should lead the project. Moreover, it is important to choose a team leader and members who have experienced in the medication process and be confident to express their ideas or opinions with other members. They should also have some good understanding of the DMAIC problem-solving methodology and the associated tools.

Team dynamics can be defined as ‘the motivating and driving forces that propel a team towards its goal or mission’ (Eckes, 2002, p.3). Poor team dynamics such as lack of motivation of the team members could lead to the failure of LSS implementation (Antony *et al.*, 2019). Several approaches should be considered to improve team dynamics such as identifying a leader, defining roles and responsibilities of project team members and dealing with resistance to change at a project level. The hospitals should have internal or external project champions to monitor and review the progress of the LSS project and deal with resistance to change at the project level.

D. Selecting the right team members

Identifying the appropriate composition of team members is an important factor leading to the success of LSS implementation (Trakulsunti *et al.*, 2018). The LSS project should include staff who are motivated intrinsically to implement LSS to minimize medication errors. Team members should be selected based on criteria: who has the complementary skills needed, familiar with the process, can generate the solutions, and will be involved in LSS implementation (Hoerl and Snee, 2002). The team should include a diversity of team member skills and expertise such as change management, problem-solving, project management and analytical skills (Raghunath and Jayathirtha, 2013; Antony, 2014). The team members not only should have experience regarding the medication process, but should also understand LSS methodology and be able to apply appropriate tools and techniques in each phase of the methodology.

E. Lean Six Sigma organizational infrastructure in healthcare

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3 The LSS infrastructure plays an important role in the implementation of LSS in any
4 organizations (Antony *et al.*, 2016). Generally, the roles within the LSS project include: the
5 project Champion, Master Black Belts, Black Belts, Green Belts, and Yellow Belts. The
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7 Champion is responsible for supporting the team when they need resources, periodically
8 reviewing the project progression and removing all obstacles during the project execution
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10 (Mahanti and Antony, 2005; Gijo *et al.*, 2013). Master Black Belt has the highest level of LSS
11 expert which involves in mentoring and coaching, followed by Black Belts and Green Belts
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13 (Stankalla *et al.*, 2019). The team leader is trained as the Black Belt or Green Belt who works
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15 as a full-time Six Sigma expert and has responsibility for leading the team to complete the
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17 project on time and communicate with the champion regarding the status of the project
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19 (Coronado and Antony, 2002; Gijo *et al.*, 2013). Team members are trained as Green Belts or
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21 Yellow Belts to execute the LSS project and work under the guidance of Black Belts and collect
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23 the data (Van den Heuvel *et al.*, 2006; Taner *et al.*, 2007).
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29 Figure 3 shows the LSS infrastructure in the hospital which was developed based on the
30 experiences of the authors gained from undertaking the action research in two hospitals in
31 Thailand. The Champion could be a director of the hospital. The project leader could be the
32 Head of Pharmacy Service who is trained as Black Belt or Green Belt or a hiring Black Belt.
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34 However, when the Green Belt becomes the leader, the time constraint is a significant factor
35 that affects the project timelines (Eckes, 2002; Laux *et al.*, 2015). This is because they have
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37 their own regular work to perform and may lack motivation to lead the LSS project. It is
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39 suggested that the project leader should be the hiring Black Belt who leads the LSS project in
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41 the hospitals to reduce medication errors. If the LSS experts do not exist in the healthcare
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43 organizations, the hospitals may send staff to be trained or employ an experienced external
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45 Black Belt or Master Black Belt (Ganti and Ganti, 2004; Heuvel *et al.*, 2005). For example,
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47 Six Sigma was implemented in the Red Cross Hospital in 2002, with the first group of Green
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49 Belt training (de Koning *et al.*, 2006). As the number of the project increased, the Green Belts
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51 faced difficulties in closing their project and, therefore, a Master Black Belt was appointed to
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53 support the Green Belts (Van den Heuvel *et al.*, 2006). The Master Black Belt also provided
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55 the necessary training to the Green Belts and ensure that they completed a project before
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57 initiating another project (Van den Heuvel *et al.*, 2006).
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3 Finally, the team members should receive at least Yellow Belt training and have experience
4 with regard to the medication process. The team members should ideally include pharmacist(s),
5 nurse(s), doctor(s), pharmacy technician(s) and staff from the information technology
6 department.
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13 *Figure 3 insert here*
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18 *F. Project champion training and LSS training*

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21 Training is a significant factor leading to the success of LSS projects. Leaders may receive
22 project champion training to understand the LSS approach and questions to ask at each stage
23 when reviewing the LSS projects. The training covers the information that helps the LSS
24 project to run smoothly such as data-based decision making emphasizing the importance of
25 data collection and analysis for process improvement (Antony *et al.*, 2016).
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31 LSS project team members should receive LSS training provided by external or internal LSS
32 facilitators who have the skills and experience in LSS implementation. The duration of LSS
33 training is 6-10 days (Pande *et al.*, 2000). The training covers the information that helps the
34 LSS project to run smoothly such as data-based decision making emphasizing the importance
35 of data collection and analysis for process improvement (Antony *et al.*, 2016). However, in
36 order to minimize the budget and resources, the hospital may select one or two staff to receive
37 Six Sigma Black Belt training (Kumar *et al.*, 2011). Then, the hospital may employ a train-the-
38 trainer approach which means that the Black Belts can train the Green Belts and the Yellow
39 Belts. The LSS project is likely to be more successful if all staff in the hospitals who relate to
40 the improvement of the medication process understand the fundamentals of LSS via a one-day
41 White Belt course.
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50 **Implementation**

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53 The project team can follow the DMAIC methodology and use a number of LSS tools and
54 techniques in each phase of the methodology. The following section explains each phase of
55 DMAIC methodology, and the tools and techniques that could be used in each phase of the
56 methodology.
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1) Define Phase

The first phase of LSS methodology aims to identify the scope and goals of the project and problems associated with the medication process. The project team should develop a project charter including all details of the project: scope; team member and problem statement. For example, the goal statement of the project is “to reduce medication errors in an outpatient pharmacy by 20%” (Al Kuwaiti, 2016). The project team needs to identify problems that have the largest impact on the hospital and patients who receive the medication such as those that could harm or cause death to the patient and which are a financial burden to the hospital. In order to ensure that the problem is a high priority, the project team should develop a problem statement, supported by facts and data. The problem statement may include:

- Impact: Does the problem affect patients?
- Severity: How big is the problem from a safety perspective?
- Area: Where does the problem appear? When does the problem appear? How often this problem occurs?

Importantly, the project team should spend enough time to gather sufficient information about the problem. If the project team does not identify the problem carefully, it could lead to the failure of the project (Antony *et al.*, 2016).

2) Measure Phase

The measure phase aims to collect the data from the current process to measure the baseline performance of the medication process before any improvements. Data collection and analysis is used to ascertain the baseline performance, showing the current state of the problem. Based on the LSS principle, the project team should identify the errors in the process steps and at the end of the medication process. The project team first prepares a data collection plan consisting of types of data to be collected, the person who is responsible for collecting the data, and length of data collection. For example, at an outpatient clinic, pharmacists and nurses are trained to use data collection sheets to record the errors when they find medication errors in a process to collect baseline data regarding medication errors (Chan, 2004).

3) Analyse Phase

This phase aims to identify the root causes of the problems that contribute to the occurrence of medication errors. Firstly, the project team identifies all the potential causes of the problem

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3 through a brainstorming session. All the potential causes are further classified, based on
4 different categories: personnel, environment, methods, communication, and machine and,
5 presented in a cause and effect diagram. The project team may narrow down the list of potential
6 causes by using a multi-voting tool. Finally, the identified potential causes are further analysed
7 to identify the root causes.
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11 12 4) Improve Phase 13 14

15 The improve phase aims to identify, explore, and implement the solutions. The key output of
16 this phase is the potential solutions that can minimize or eliminate the impact of the selected
17 root causes of the problems. Ideas about the potential solutions ideas can be generated from
18 brainstorming, best practices, published articles or other projects that have encountered similar
19 problems. Once the solutions are identified, the project team need to check if the potential
20 solutions work effectively to reduce the impact of the problem. After the solutions are
21 identified, the project team may pilot the solution, then implement and observe the results to
22 see if the situation has been improved or not.
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30 5) Control Phase 31 32

33 The final phase of DMAIC methodology is to sustain the improvement obtained from the
34 previous phase. The sustainability of the achieved results is challenging and difficult in the
35 healthcare sector. However, the project team can gain the results through three important
36 actions: standardisation; monitoring and training (Antony *et al.*, 2016). The procedure of the
37 new methods/process is standardized and placed near to the workstation of the staff (Bhat *et*
38 *al.*, 2016). The staff are trained to follow standard operating procedures so that everyone can
39 perform the same process steps and achieve consistency. The control chart can be used to
40 monitor the number of medication errors over a period of time and to identify when additional
41 process interventions might be required.
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49 **Phase 3: Sustainability** 50

51 There is evidence that hospitals have failed to sustain LSS for a long-term (Matteo *et al.*, 2011).
52 Most of the previous studies have applied the control phase in the DMAIC methodology to
53 achieve continued the improvement; however, this is not possible throughout all organizations
54 (Matteo *et al.*, 2011). This phase aims to ensure that the LSS as an initiative of continuous
55 improvement will be sustained and embedded in a hospital's culture for a period of time.
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A. Create Lean Six Sigma culture

Creating the LSS culture is an important element to maintaining LSS in the hospitals for a period of time. LSS culture involves encouraging and empowering staff across the hospital and continuously focusing on identifying problems in the medication process and waste, then identifying root causes and developing solutions to minimize them on a continuing basis (Matteo *et al.*, 2011). Ensuring staff use LSS methodology every day to solve problems and improve the medication process requires behavioural change, long-term investment, and commitment. To achieve this, staff buy-in is very essential. The key approaches in getting staff buy-in are: showing and sharing the success stories of LSS throughout the hospital (e.g. reduced medication errors, improved employee morale, and patient safety) of LSS throughout the hospital; using a common language and education and training (Michael, 2002). Rewards and recognition system are an important motivation factor to encourage staff to continue implementing LSS in the organizations. Several approaches of reward and recognition can be employed by the organizations such as sharing a financial benefit to the team member, LSS certification awards, bonus and promotions (Jeyaraman and Teo, 2010; Antony *et al.*, 2018).

When the staff have 'bought into' the initiative, they will understand the potential benefits of LSS and how the implementation of LSS can make their life easier, so that they can change their working behaviour or the way of working. For example, when staff face problems in the medication process, LSS can be established in the daily routine improvement by asking and answering five questions (Geier, 2001) (see Table 4).

Table 4 insert here

B. Staff knowledge and understanding of LSS methodology

Staff knowledge and understanding of LSS methodology are important factors to drive LSS sustainability. To retain and update staff's LSS knowledge, a LSS refresher workshop is needed periodically. Staff can obtain LSS knowledge through several ways such as in-house training, independent learning, internet, conference, and workshops. Moreover, the hospital should continue investment in LSS belts training and certification. The number of LSS experts,

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3 particularly Green Belts in the hospital, should be increased in order to enhance the knowledge
4 of LSS across the hospitals (Kowang *et al.*, 2016). For example, all middle managers in the
5 hospital should be trained and certified as Green Belt and other staff should be trained for Green
6 Belt to get promoted (Hoerl, 2001). Harry and Schroeder (2005) also suggested that at least
7 50 per cent of staff should receive Six Sigma training. The transition of Green Belts or their
8 promotion to be Black Belts, could also increase the number of LSS experts in the hospital.
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14 *C. Investor in people (IIP) standard*

17 Leaders are committed towards LSS is a key factor for the sustainability of LSS. The IIP
18 standard can be used to ensure that the leaders are always looking for improvement. The IIP
19 standard is “a UK government-backed scheme aimed at enabling organizations to develop their
20 training and development culture and, thereby, their competitiveness” (Smith *et al.*, 2014). IIP
21 is a UK-based standard; however, it has been introduced to 66 countries worldwide through
22 Investors in People International (Wilson, 2005; Investors in People, 2020). To become
23 accredited, an organization is assessed against nine indicators that cover three principles: 1)
24 leading; supporting; and improving (Wilson, 2005). Achieving IIP accreditation can improve
25 organizational performance, improve management and enhance quality.
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34 *D. Institutionalising Lean Six Sigma*

37 External LSS experts or key members who have experienced with LSS may leave the hospitals
38 to work elsewhere. It is important, therefore, for the hospital to ensure that the benefits from
39 LSS can be sustained in the long term (Hu *et al.*, 2016). Institutionalising LSS is a key factor
40 that can sustain the approach in the organizational culture. It means that the hospital should
41 embed LSS as a part of the hospital. Leaders play an important role in institutionalising LSS in
42 daily organizational routines. For example, the CEO of the hospital should ensure that LSS is
43 integrated into existing strategic plans, operating plans and budgets (Michael, 2002) so that the
44 LSS projects are aligned with the hospital’s strategy. Even though consultants and key
45 members leave the organization, the established strategy and principles can still guide its daily
46 operations.
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54 *E. Future and trends of LSS*

57 LSS is an ongoing improvement process, therefore the future and trends of LSS are vital in
58 helping healthcare organizations to sustain LSS. Healthcare organizations should continuously
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3 adapt to the latest trends of LSS because it is very helpful to generate new ideas to improve the
4 process. The LSS emerging trends include: use of robotic process automation (the use of
5 software robots to perform high-volume and repetitive tasks that humans do), using Big Data
6 in decision making in each phase of DMAIC methodology more correctly and quickly,
7 applying Internet of Things (IoT), integration of LSS into educational systems (Antony *et al.*,
8 2017; Gupta *et al.*, 2019). For example, the use of the radio frequency identification sensor
9 (RFID), an IoT sensor, to identify patients and their corresponding medications in real-time
10 (Paaske *et al.*, 2017). Another example is the use of a wearable sensor for Parkinson's disease
11 which improves medication management and patient outcomes (Dimitrov, 2016). However,
12 data security and privacy are the key issues that should be concerned by healthcare
13 organizations. Most technologies are widely used to ensure security and privacy are access
14 control, data encryption, monitoring and auditing (Abouelmehdi *et al.*, 2018).

25 *F. Succession training*

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27 A succession plan is a way of identifying the new leaders who are needed in the future to
28 replace key leaders who leave the organizations. The loss of key leaders who used to
29 support and motivate the LSS project team may result in failure in LSS projects or project
30 delay. Ensuring continued leadership buy-in for LSS and long-term leadership
31 commitment is a key factor for sustaining LSS when the leaders who understand about
32 LSS projects have left the hospitals. The hospital should ensure that the people inside
33 or outside the organization who experience and understand LSS are recruited (KPMG
34 international's Healthcare Practice, 2019). Therefore, LSS should include in the criteria
35 for selecting new leaders in a succession plan.

52 *G. Organizational review and strategy review*

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54 The LSS project should align with the hospital's strategy in order to sustain LSS across the
55 entire hospital (Cheng, 2013; Goh, 2014; Antony *et al.*, 2016). However, when the hospital's
56 strategy is reviewed, the leaders should ensure that the LSS project is incorporated into the
57 organization's strategic imperatives, operating plans, and budgets. To achieve the alignment
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3 between LSS project and the hospital's strategy, the following elements should be considered
4 (Pexton, 2020).

- 5 • **Staffing:** Have sufficient resources (e.g. time, budget and people) been dedicated?
- 6 • **Measurement and accountability:** Are LSS projects supported by the right metrics
7 and aligned with strategic objectives?
- 8 • **Communication:** Is there a detailed plan in place (who, what, when) to provide clear
9 and consistent communication at all levels of the organization?
- 10 • **Information Technology:** Are there sufficient software programmes or IT solutions?
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19 **5. Discussion**

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21 In this study, the LSS implementation and sustainability roadmap was developed to reduce
22 medication errors by adapting the existing frameworks in other sectors such as SMEs. This
23 roadmap was developed based on the work pursued by other research scholars including Kumar
24 *et al.* (2011), Al-Balushi *et al.* (2014), Antony *et al.* (2016), Timans *et al.* (2016), and Alnajem
25 *et al.* (2019).
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32 In contrast to the previous studies, most of the LSS frameworks/roadmaps proposed for
33 healthcare sectors have been developed from the existing literature rather than through an
34 empirical study. Previous frameworks in healthcare organizations have used DMAIC
35 methodology as an LSS framework (Yeh *et al.*, 2011; Chenge and Chang, 2012; Furterer, 2014;
36 Honda *et al.*, 2018; Al-Qatawneh *et al.*, 2019).
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43 The LSS roadmap developed in this study is different to previous studies in several respects.
44 First, it focuses on how to implement LSS successfully by considering the readiness factors
45 and the application of LSS methodology along with its tools and techniques. Second, it
46 concentrates on how to sustain LSS in healthcare organizations for a period of time. Lastly, it
47 was validated by LSS experts and a healthcare practitioner. Moreover, the decision point and
48 timeframe have been added into the roadmap to ensure that the healthcare organizations
49 involved in the project can successfully implement LSS to reduce medication errors.
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56 **6. Practical Implications and Limitations**

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Hospitals can improve the medication process by following the LSS implementation and sustainability roadmap, which can be used as a guideline for healthcare leaders and healthcare practitioners to reduce medication errors. The proposed roadmap enables the healthcare practitioners or hospital managers to understand how to initiate, implement and sustain LSS in their organizations. This roadmap could can facilitate healthcare practitioners to apply LSS in a more disciplined, organised and systematic way. The application of this roadmap may not only improve the medication process, but also increase awareness of healthcare staff about LSS benefits and enhance LSS culture in the respective organizations. One of the major limitations of this research is that roadmap has been tested with only a handful number of practitioners of LSS. In order to improve the validity of research, more case studies need to be executed and more people should be used for testing the roadmap in different hospital settings (private and public) with varied cultures.

7. Conclusion

This study proposes a LSS roadmap for reducing medication errors and embedding LSS across the organization. This roadmap can facilitate healthcare practitioners and professionals to apply LSS in a disciplined, organised and systematic way to reduce medication errors. The first phase of the roadmap assesses the cultural readiness to determine whether the organization is ready to employ LSS. The next phase highlights the key factors for preparing the organization to implement LSS such as top management commitment, LSS project selection, team formation, training and towards the implementation of LSS methodology. The final phases focus on the sustainability of LSS in healthcare organizations. The roadmap can be used as a reference for the implementation of LSS to reduce medication errors.

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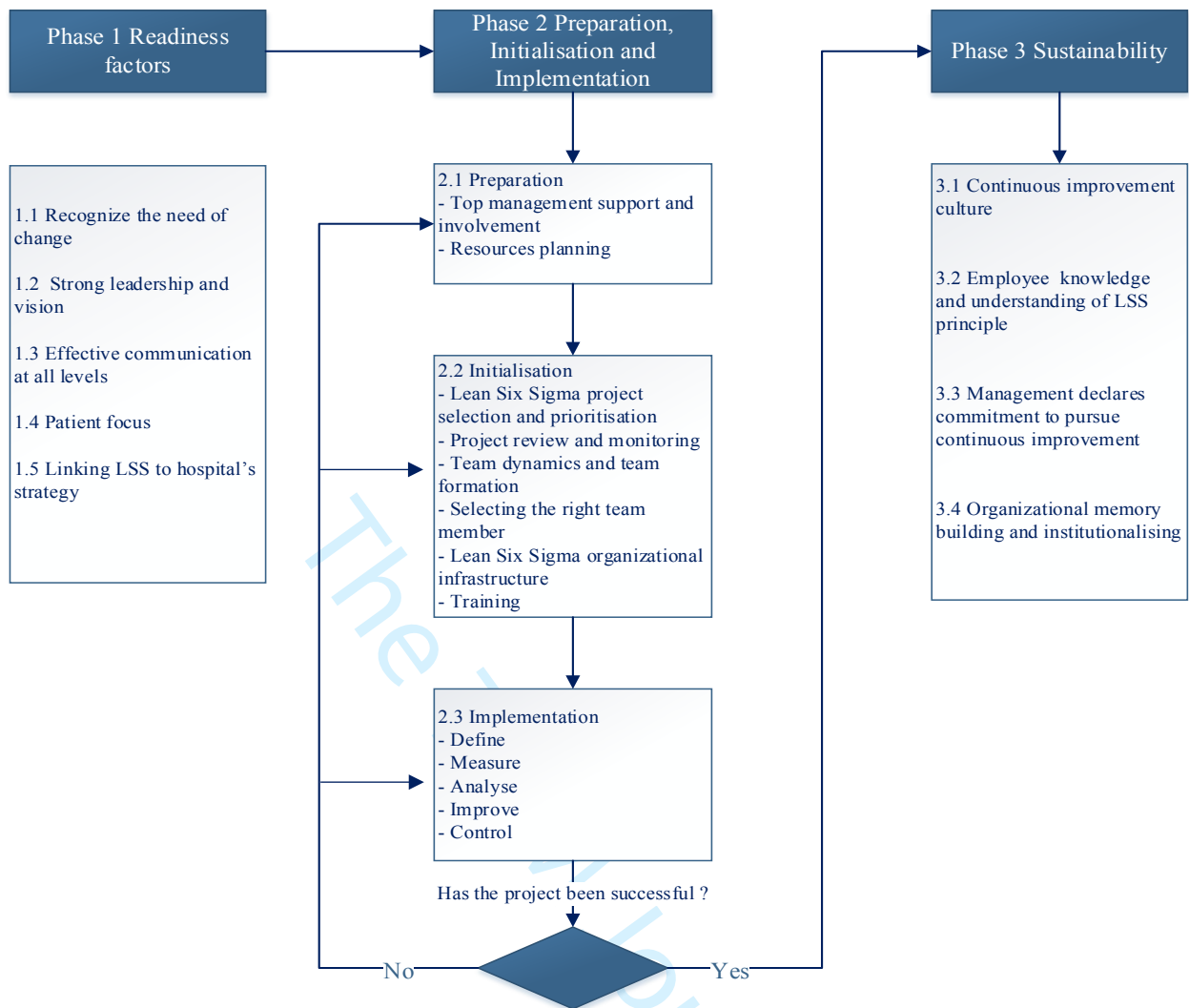


Figure 1 A conceptual LSS roadmap

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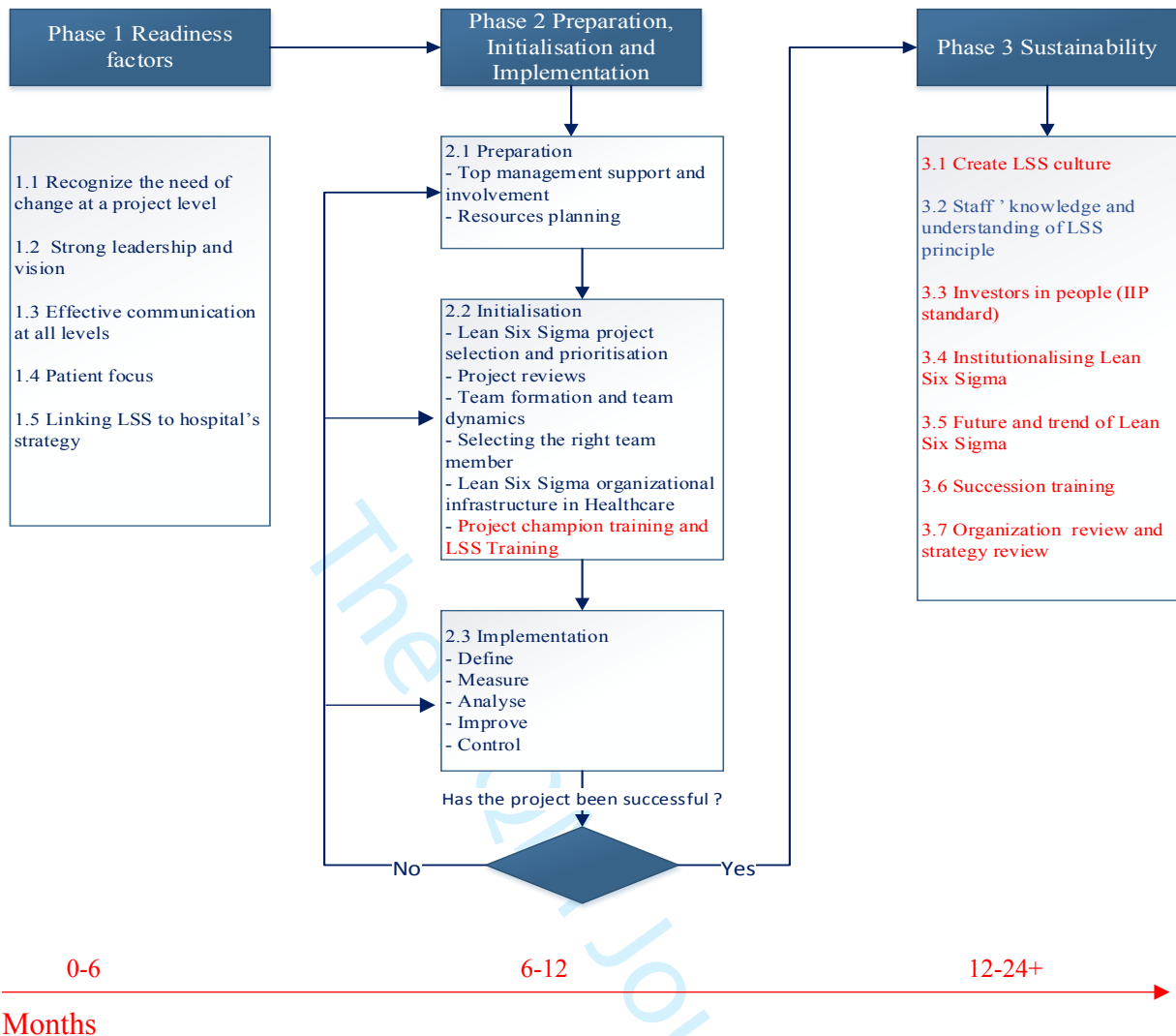


Figure 1 the revised LSS roadmap

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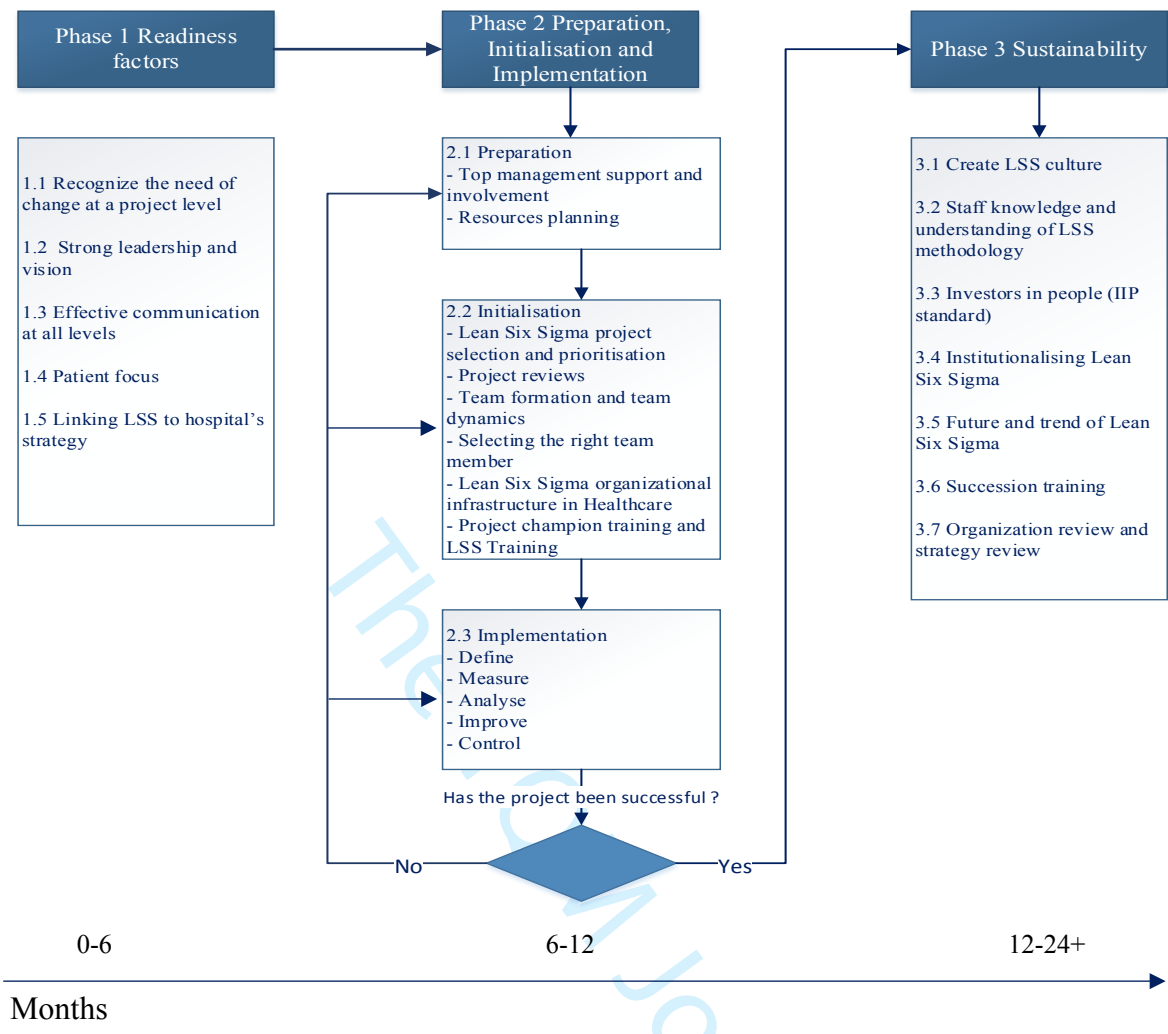


Figure 1 The final version of LSS roadmap

Table 1 The key features of each LSS framework/roadmap proposed in healthcare

Framework no.	Authors, year	Methodology used	Aim of LSS frameworks/roadmap	Limitations of the frameworks/roadmap
1	Yeh <i>et al.</i> (2011)	Not mentioned	To implement the framework for improving the medical process of acute myocardial infarction.	Use of DMAIC as a framework Lack of management focus discussion No validation of the framework by healthcare practitioners
2	Cheng and Chang (2012)	Not mentioned	To implement LSS framework in non-profit organizations	Use DMAIC as a framework and lack of strategic focus No validation of the framework by healthcare practitioners
3	Furterer (2014)	Not mentioned	To apply the roadmap and the key tools in healthcare processes.	Roadmap focuses on DMAIC methodology without consideration of strategic issue No validation of framework by healthcare practitioners
4	Honda <i>et al.</i> (2018)	Systematic review of existing frameworks implementing in hospitals	To improve the hospital performance	No explanation of any details related to the framework Use of DMAIC as a framework No validation of the framework by healthcare practitioners
5	Al-Qatawneh <i>et al.</i> (2019)	Literature review	To implement a proposed framework in the area of healthcare logistics. To present a case study that implemented the proposed framework in the Jordanian Hospital.	Use of DMAIC as a framework No discussion on strategic issue such as leadership, top management support and resources planning No validation of the framework by healthcare practitioners
6	Almutairi <i>et al.</i> (2019)	Literature review and case study	To propose a new framework and for implementing lean in hospital supply chain management in Saudi settings	There is a limited explanation of Lean tools The framework is limited to healthcare organizations in Saudi Arabia.

Table 2 the key characteristics of each framework/roadmap

Roadmap characteristics	Yeh <i>et al.</i> (2011)	Cheng and Chang (2012)	Furterer (2014)	Honda <i>et al.</i> (2018)	Al-Qatawneh <i>et al.</i> (2019)	Almutairi <i>et al.</i> , 2019	The researcher's roadmap
Identify objective of each phase		✓	✓		✓	✓	✓
Present in diagram or flow chart	✓	✓				✓	✓
Explain step of work in each phase	✓	✓	✓			✓	✓
Validated by healthcare practitioners					✓	✓	✓
Validated by LSS experts							✓
Identify tools and explanation in the road map	✓	✓	✓			✓	✓
Management focus							✓
Using DMAIC as a framework	✓	✓	✓	✓			

Table 1 Background and comments of LSS experts and the healthcare practitioner

Sr. no.	Six Sigma Belt	Positions	LSS experience (years)	Comments
1	Master Black Belt	The CEO of The Institute of Six Sigma professionals, UK	16	Add four factors under phase 3 (sustainability) which includes: investors in people (IIP standard), future trend and development, succession training and organization review and strategy review Instead of saying management declares commitment to pursue continuous improvement. IIP standard would be used to measure the management commitment.
2	Master Black Belt	General Manager of Green Sport (Thailand) Co Ltd. Coaching healthcare practitioners to implement LSS in public hospitals (Volunteer)	16	The overall roadmap is good. The timeframe should be added to the roadmap. Normally, it takes 2-3 years for LSS transformation.
3	Master Black Belt	Plant Director of Ansell (Thailand) Ltd.	8	The sequences of the roadmap are good. It is important to ensure that the top leader trusts that LSS is the right tool for improvement and transformation.
4	Master Black Belt	Lean Six Sigma Master Black at Michelin, Thailand	15	Phase 2 focuses more on a top-down approach. There is no bottom-up approach because lean focuses on bottom-up, change mind-set and change a culture.
5	Master Black Belt	Head of Operational Excellence, Asset World Corporation, Thailand	20	Project champion training could be added into phase 2
6	Master Black Belt	Lean Six Sigma Consultant / Minitab trainer	15	The sequence of the road map is good; however, it is a lack of tangible specific activities. The timeframe should be included in the roadmap.
7	Black Belt	The Director of Bespoke Clinical Care Ltd, UK	6	LSS is an ongoing improvement process so that future, trend, and development is important in term of where will see the LSS in the future. The key step to sustain LSS is showing people what is the advantage of doing LSS and then braking the culture.
8	Black Belt in Healthcare	Head of Strategic Supply Chain Management	6	The overall roadmap is good. Staff buy-in is very important for LSS sustainability. To sustain LSS in hospitals, the hospitals may create an event about process improvement by using LSS every year.
9	Black Belt	LSS Black Belt at 3M Thailand Ltd.	6	The overall roadmap is good. Project scope is important and should be clearly identified.
10	Black Belt	Head of Service Delivery, Krungthai-AXA Life Insurance PCL.	13	The sequences of the three phases are reasonable. However, create a LSS culture should be moved to phase 1.

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11	-	Clinician in hospital	6	The sequence of the roadmap is good. To sustain LSS in hospitals for a period of time, LSS should become a part of staff's daily life. Start with a small thing and simple that people can understand. Show successful stories and how LSS can make their life easier and then staff will get attention. They can see how LSS benefits them.
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Table 4 Problem Solving questions Source: Geier (2011)

Step	Activity	Ask and Answer
1	Define the issue	What do we need to resolve?
2	Measure what matters	What is the current situation, and the impact on the organization?
3	Analyse the causes	What causes this, and how do we know?
4	Improve the situation	How can it be fixed?
5	Control the future	How do we keep the solution in place?