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# Operationalising the Lean principles in maternity service design using 3P methodology

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## ABSTRACT

The last half century has seen significant changes to Maternity services in England. Though rates of maternal and infant mortality have fallen to very low levels, this has been achieved largely through hospital admission. It has been argued that maternity services may have become over-medicalised and service users have expressed a preference for more personalised care. NHS England's national strategy sets out a vision for a modern maternity service that continues to deliver safe care whilst also adopting the principles of personalisation. Therefore, there is a need to develop maternity services that balance safety with personal choice.

To address this challenge, a maternity unit in North East England considered improving their service through refurbishment or building new facilities. Using a design process known as the production preparation process (or 3P), the Lean principles of understanding user value, mapping value-streams, creating flow, developing pull processes and continuous improvement were applied to the design of a new maternity department. Multiple stakeholders were engaged in the design through participation in a time-out (3P) workshop in which an innovative pathway and facility for maternity services were co-designed. The team created a hybrid model that they described as "wrap around care" in which the Lean concept of pull was applied to create a service and facility design in which expectant mothers were put at the centre of care with clinicians, skills, equipment and supplies drawn towards them in line with acuity changes as needed.

Applying the Lean principles using the 3P method helped stakeholders to create an innovative design in line with the aspirations and objectives of the National Maternity Review. The case provides a practical example of stakeholders applying the Lean principles to maternity services and demonstrates the potential applicability of the Lean 3P approach to design healthcare services in line with policy requirements.

## PROBLEM

Each year, there are around 665,000 births in England and this is forecast to rise to over 690,000 by 2020.<sup>1</sup> The last half century has seen significant changes to Maternity services in the UK.<sup>2</sup> Since the establishment of the

NHS, rates of maternal and infant mortality have fallen to very low levels. However, this has been achieved largely through hospital admission for delivery activity.<sup>3</sup> Some reports suggest that maternity services may have become over-medicalised<sup>4 5</sup> and surveys of new mothers have suggested a preference for more personalised maternity services.<sup>6</sup> Based on the principles of "women being able to make choices about their care, and the safety of the mother and baby", NHS England's national strategy sets out a "vision for a modern maternity service that delivers safer, more personalised care".<sup>1</sup> Therefore, there is an ongoing need to develop maternity services that balance choice, safety and cost effectiveness.

To address this challenge, a maternity unit in North East England considered improving their service through refurbishment or building new facilities. Capital developments such as this present an opportunity for improvement that "supports safe, effective and efficient patient care"<sup>7</sup> whilst also impacting positively on staff wellbeing, efficiency and patient experience.<sup>8 9</sup>

The project took place at a small acute Foundation Trust with an annual turnover of around £184 million and employing over 3,300 staff. The Trust offers a range of general and acute services including maternity services which have been rated amongst the safest in the country. There are currently around 2,500 births per annum in the Trust's local area and the majority of expectant mothers in the area access the Trust's maternity services.

The Trust operates a joint obstetric and midwifery-led maternity unit from its main hospital campus. Improvements have been made to the unit previously, including the development of a delivery suite and the addition of a pregnancy assessment unit. However, due to the age of the building it is relatively expensive to manage and maintain.



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The Trust also considered that improving the maternity facilities made sense from a business perspective. Historically, the Trust has delivered around 2,000 babies per year, about 80% of the births in its local area. Since the opening of a new birth centre at a neighbouring Trust, this has reduced by around 100 to 200 births per year. Given that labour and childbirth are natural phenomena, the promotion of patient choice in the NHS<sup>1</sup> is arguably particularly compatible with maternity services. Also, the arrival of a new baby is a major event in a woman's life and it is unsurprising that expectant mothers want the best possible environment in which to deliver their baby. Perceptions of quality by service users have been related to the environment in which the services take place.<sup>10 11</sup> These perceptions can be influenced by a range of factors including ambient conditions, subjectivity and emotion in addition to physical layout, signage and equipment.<sup>8 12</sup> Based on user feedback (survey data from 400 women) the trust determined the important factors to women choosing maternity facilities which included: private, single rooms; amenities for their partners to stay with them; easy access to parking and family friendly environments for siblings. Midwives and doctors were more or less taken as a given though women expected that those who were looking after them would be caring and compassionate. Therefore, in today's NHS where patient choice is increasingly promoted, and in a service where choice is a real option, the Trust could see the strategic business case for improved facilities that met with the expectations of women in the community they served.

## BACKGROUND

To develop the new facility design, Lean methodology was applied. Derived from the practices of Japan's automotive industry, Lean is an improvement philosophy that seeks to optimise end-user value and reduce waste.<sup>13</sup> Recent reviews have demonstrated the increasing application of Lean thinking to improve healthcare processes.<sup>14–18</sup> Lean has also been reported as a practical means of improving the design of healthcare facilities by early adopters in the USA.<sup>19–21</sup> Beyond our own research however,<sup>22–26</sup> there are few examples in the literature of application of Lean to healthcare facilities design in the UK NHS where the context differs significantly from the US' privately provided, insurance based system.

The principles of Lean were first described by Womack and Jones<sup>13</sup> to help practitioners realise an ideal Lean system.<sup>27 28</sup> They provide a five step roadmap and guide to putting Lean thinking<sup>13</sup> concepts into action and are:

**VALUE** – Specifying value from the end customer's perspective is considered the critical starting point for Lean.<sup>13 29</sup> In healthcare, the customer is usually taken to be the patient.<sup>30</sup> It has been observed however, that determining the customer is more complex in state

funded systems as there is a separation of who specifies, pays for and uses healthcare services.<sup>31 32</sup> It has been asserted that applications of Lean in public services such as the NHS have failed to take account of the context in which it is being implemented and have been characterised by manufacturing logic<sup>33</sup> in which patients have been seen as products.<sup>34</sup> Furthermore, it has also been observed that many applications of Lean to healthcare have adopted an internal operational view of value in which cost reduction has been the primary goal.<sup>31 32</sup> It has been reported that the principles of Lean have therefore been misunderstood and a more service oriented logic is required<sup>33</sup> alongside a more holistic view of value that incorporates the perspectives of service users balancing the experiential, clinical as well as operational dimensions of value.<sup>32 33</sup>

**VALUE-STREAM** - Value-streams are all of the steps in a process (both helpful & unhelpful) involved in delivering a product or service to a customer.<sup>13 35</sup> Value-streams in healthcare are typically considered to be the pathways of care that patients experience as they move through the system.<sup>36 37</sup> Mapping these value-streams has been recommended to “understand the steps in the patient journey and patient experience”<sup>38</sup> so as to help staff to identify problems in their pathways and processes<sup>39</sup> and redesign them to enable value to flow.<sup>30</sup>

**FLOW** - Flow is derived from Toyota's Just-in-Time (JIT) concept<sup>13</sup> and has been defined as “doing work for the right item at the right time in the most appropriate quantity, and moving this along to the next step of the process”.<sup>40</sup> This involves lining up value creating actions in the best sequence and conducting them without interruption whenever they are requested.<sup>13</sup>

In healthcare, improving flow has been reported to improve quality and utilise resources more effectively.<sup>41</sup> Improving flow in healthcare typically involves working along care pathways to reduce waiting times and remove barriers to moving patients to the right part of the system to meet their needs.<sup>41 42</sup> However, there are multiple operational flows in healthcare which must be considered<sup>43</sup> and these have been identified as: patients; families and carers; staff (both clinical and non-clinical); medication; equipment; consumable supplies; and information.<sup>43 44</sup> It has been observed that if all relevant healthcare flows have not been considered, this can lead to inappropriate designs and inefficient use of space.<sup>45</sup>

**PULL** - In manufacturing, pull refers to linking production activity to real demand.<sup>30 46</sup> This involves operating the system through pull signals that link internal processes.<sup>47</sup> The advantages of pull systems are that resources are not wasted on over production and response times to customer demands are reduced.<sup>47</sup> The ideal is to have everything happen in the system only in response to a specific customer demand.<sup>46</sup>

In healthcare pull has been described as “delivering care in line with demand”<sup>30</sup> to help regulate patient flow.<sup>30 37</sup> However, pull also seeks to create processes that direct value towards the patient recognising that

value is created through their interactions with clinical services and staff.<sup>42 48</sup> In part this involves creating processes that “pull patients from the one before”.<sup>38</sup> However, healthcare services have also been advised that “every step in the patient journey needs to pull people, skills, materials and information towards it, one at a time, when needed”.<sup>39</sup> Pull therefore requires that process are connected<sup>49</sup> and designed around patient needs so that care and services can be delivered for them in line with demands. Such processes allow staff, equipment, supplies and information to be pulled towards the patient as needed.<sup>39</sup> In the Lean healthcare literature, the pull concept has been identified as being “poorly discussed”<sup>50</sup> and there is a need for case studies that illustrate its application in this sector.

**PERFECTION** - Perfection refers to the ideal state that is to be pursued through the practice of continuous improvement.<sup>13</sup> In Lean, continuous improvement is driven by the scientific method<sup>27</sup> and the Plan, Do, Study, Act (PDSA) cycle.<sup>51 52</sup> PDSA is a powerful improvement and learning cycle which can be applied to detailed process problem solving as well as drive whole organisation learning<sup>51 53 54</sup>. Lean uses PDSA to test and implement small scale changes<sup>28 55</sup> to produce “steady results along the path to perfection”.<sup>13</sup>

## BASELINE MEASUREMENT

The design process for the project adopted ideas from Japan’s automotive industry and the principles of Lean thinking. In particular the design process followed a novel Lean product development approach known as the production preparation process (or 3P)<sup>22</sup> which comprises a set of methods and tools to facilitate innovation when new space, products or services are needed.<sup>21 43 56</sup> Lean 3P is typically comprised of three phases which are: scoping and planning; a time-out participative design workshop; and follow-up and implementation.<sup>25</sup>

In the scoping and planning phase, a meeting was held with key stakeholders in the maternity unit to facilitate a diagnostic exercise. The meeting focussed on sharing information about the upcoming time-out 3P design workshop and comprised midwives, healthcare assistants, consultants of various disciplines (e.g. obstetrics, gynaecology, paediatrics, surgery and anaesthetics), theatre staff and managers. The clinical leads for maternity set out the broad vision for the new unit and introduced the facilitators who would lead the design workshop.

The facilitators undertook a scoping exercise with the stakeholders which used a flip-chart and post-it note approach to engage them in a discussion about the maternity facility. The discussion was themed around five headings: symptoms (of problems experienced in the current facility); causes (of the problems identified); outcomes (that they hoped to achieve); effects (that might be observed if outcomes were achieved); and

resources (to help achieve the desired outcomes). Stakeholders identified various operational and experiential problems that they felt were caused by the facility not being arranged in line with the pathway and processes that were constrained by the physical environment. The outcomes they wanted to achieve included: improving user experience; a seamless pathway with better flow; fully en-suite; and better hotel facilities. The anticipated effect of delivering these outcomes was expressed as a “unique, state of the art, maternity unit to be proud of that would deliver great quality midwifery and obstetric led care as required by the users of the service”. Money was identified as both a potential constraint and necessary resource for facilities improvement. That aside, the department’s staff were identified as the key resource to help achieve the outcomes. The maternity team felt that they had the enthusiasm, motivation and a track record of multi-disciplinary working to create a vision of a far superior facility.

Engaging stakeholders in this qualitative diagnostic baselining exercise allowed the aims described below to be articulated. The aims of the project were to produce a design for a modern maternity unit which would:

- ▶ provide a flexible environment with the patient at the centre of care;
- ▶ facilitate flow of different patient categories/risk profiles;
- ▶ provide high-spec facilities such as ensuite etc.;
- ▶ provide good access to the unit for patients, visitors, staff and other services/departments;
- ▶ provide access to theatre facilities;
- ▶ provide a suitably located bereavement room;
- ▶ provide efficient back of house functions such as stores, waste, admin, domestic and office facilities

These aims were used as evaluation criteria to quantitatively assess design proposals for the new maternity unit in the Lean 3P design workshop.

## DESIGN

To develop a case study, action research was adopted to collect data in real time whilst delivering the Lean 3P design workshop.<sup>57</sup> Defined by its characteristics, action research tends to include: group participation to affect positive change; collaboration between the researched and researcher; and a dual focus on solving practical problems as well as contributing to scientific knowledge.<sup>58 59</sup> Action research “actively involves participants”<sup>60</sup> and is an approach “which has an explicit focus on promoting and facilitating change”.<sup>60</sup> Whilst action research has been criticised for its emergent nature, it is considered appropriate for the evaluation of novel interventions and the development of new services.<sup>58</sup> Given that the project applied a novel Lean design intervention with the objective of bringing about a positive change, this was considered appropriate for an action research approach.

Data collection was comprised of: participant observation; design artefacts (such as drawings, layouts and

models); photographs of the 3P workshop; and participant feedback from the workshop including knowledge capture flip charts. Following the 3P workshop, a focus group was conducted with event facilitators and project architects and interviews with the department's clinical leads (senior midwife and consultant obstetrician) and one of the service user representatives.

The structure of the design workshop was developed using Lean expertise gained from North East England's learning from Virginia Mason Medical Centre (VMMC). VMMC has earned a world leading reputation for pursuing perfection in healthcare through applying the Lean principles for continuous improvement.<sup>44 61–63</sup> To achieve this, VMMC has used a combination of incremental and step change Lean improvement workshops.<sup>43</sup> Lean 3P is a step change workshop derived from Lean product development practices.<sup>22</sup> The application of Lean 3P to design healthcare facilities has been pioneered by VMMC<sup>44 61–63</sup> and they have reported significant financial benefits as a consequence.<sup>21 43</sup> Beyond our own research,<sup>22–26</sup> there are, to our knowledge, no cases reported in the literature of Lean 3P being applied to design healthcare facilities in the NHS in the UK. This case used the Lean 3P format to operationalise the Lean principles<sup>13</sup> in the design of a new maternity facility.

The Lean 3P design workshop applied an iterative approach through a number of PDSA design cycles<sup>25 64</sup> to develop a design for the new maternity facility in line with the Lean principles to meet the vision and aims of the stakeholders.

## STRATEGY

The time out 3P workshop used an iterative approach to apply the Lean principles to: consider value to end users; develop a value-stream, or pathway, for end users; consider and model the inter-related flows of people and equipment in the value-stream or pathway; use pull as a concept to draw care towards end users in line with acuity changes; and pursue perfection through repeated cycles of design that built and improved upon the best features and ideas from earlier cycles.

The 3P workshop took place over three consecutive days and involved 37 participants – 24 clinicians, 3 service users and 10 corporate support staff. Clinical delegates were comprised of midwives, healthcare assistants, obstetricians, paediatricians and anaesthetists. Service users were women who had recently delivered their babies at the existing unit. Corporate staff included architects and estates staff, management and administrative staff and the improvement staff who facilitated the event.

Delegates were split into four teams. Each team was cross-functional and broadly comprised similar skills and role representatives such as obstetrics, midwifery, healthcare assistants, service users and estates and architectural professionals. Teams worked together on their own

designs, presenting them to, and gaining feedback from, each other at the end of each design cycle.

Design cycle 1 – Initially, design ideas were created using 2D templates of the available design footprint. The aim of this cycle was to generate a high volume of design options and concepts. Presentation and discussion of ideas/designs was used to understand the intended benefits of each design. This was followed by dot voting within each team to narrow design options. This helped each of the four teams to select its top three most promising outline designs to develop further (giving a total of twelve outline designs in the workshop at this stage).

Design cycle 2 – The next iteration remained in 2D but moved to a larger outline template at 1:100 scale. Each team developed their three designs and incorporated features and ideas from their earlier discussions. These designs also started to incorporate early ideas on how the pathway would work and how the mothers, family members and staff would move, or flow, through the department. A further round of dot voting was conducted within teams to determine each team's preferred design to take forward and further develop.

Design cycle 3 – To size key design features, full scale mock ups of delivery suites (one standard and one pool suite) were constructed. These full scale design features not only provided assurance to delegates on size appropriateness but also opportunities to discuss and test location of key equipment and try out concepts about how suites could be reconfigured quickly to respond to acuity changes in expectant mothers. This helped the team develop a concept of 'wrapping care' around users. That is, the suites were designed to give a good aesthetic experience to expectant mothers rather than a clinical feel but, if circumstances changed, the relevant equipment and clinicians could be drawn quickly to the mother as needed.

Design cycle 4 – This cycle incorporated what was learned from the previous cycles to refine each team's preferred design option. An additional level of detail was added in this cycle as the 2D 1:100 layouts of each team's most promising design were developed in to 3D models. At this point, teams reported out to each other on their various design concepts to describe the features, pathway and anticipated benefits. Following these information sharing exchanges, the teams used nominal group voting against the previously agreed criteria to score and rank each design. Design concepts were then taken forward for final development in the next cycle.

Design cycle 5 – Designs were further developed in to larger 1:50 scale 3D models. Designing in 3D at this scale helped bring the teams' designs to life and facilitate a better understanding of each design's proposed pathway. Again the main user, staff and equipment flows were incorporated into the models. A final round of reporting out and nominal group voting was used to determine the overall preferred design.

See supplementary data for examples of design outputs at the end of each cycle (See supplementary–“Supplementary Data”).

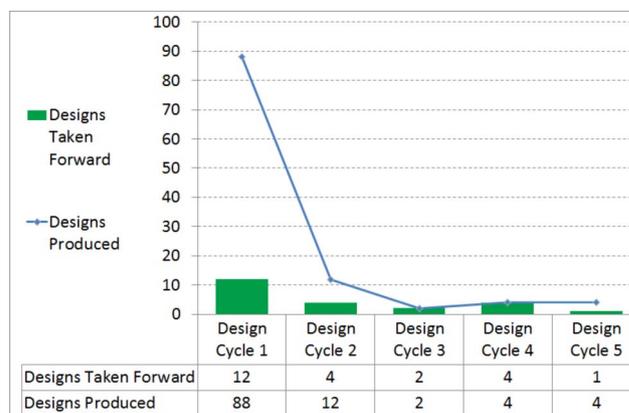
## RESULTS

Group decision making techniques were used to identify the leading designs at the end of each cycle. In the earlier design cycles, where a high volume of conceptual designs were generated, simple dot voting<sup>38</sup> was used to measure the leading ideas. In the later, more detailed design cycles, measurement was carried out using nominal group voting against agreed design criteria in conjunction with a weighted average scoring system. Figures 1 and 2 below summarise the approach.

Nominal group is an effective technique to facilitate group decision making and reach consensus.<sup>65–66</sup> The approach involves idea generation, group feedback, individual voting and ranking, group discussion on consensus and agreement of next steps.<sup>65–67–68</sup> It has been reported that nominal group techniques: facilitate participative group discussion of ideas;<sup>67–69</sup> help with “qualitatively analysing and evaluating the ideas”;<sup>69</sup> and are superior to ordinary group decision making.<sup>67</sup> Nominal group was considered by the facilitators to fit well with the Lean 3P approach in which teams presented their designs to each other and engaged in discussion before voting and ranking designs. Participants did not rate their own team’s designs. Each participant voted individually and scored designs against the pre-agreed criteria on a pro-forma template (an example of a participant’s individual scoring template for one round of voting is shown in the supplementary data). Rankings were determined by taking the mode of participant scores for each element and applying the weighted average. Whilst this measurement approach provided a quantitative, democratic decision making process, it also provided further valuable qualitative feedback to each team on both the strengths and areas for improvement of their design concepts.

	Design Cycle 1	Design Cycle 2	Design Cycle 3	Design Cycle 4	Design Cycle 5
No. Teams	4	4	4	4	4
Design Scale	2D Not to scale	2D 1:100	3D Full Scale	3D 1:100	3D 1:50
No. Designs Produced	88	3 per team (12 total)	1 Std Suite 1 Pool Suite	1 per team (4 total)	1 per team (4 total)
Decision Method	Dot Voting	Dot Voting	Group Discussion	Nominal Group	Nominal Group
No. Designs Taken Forward	3 per team (12 total)	1 per team (4 total)	Suite dimensions	1 per team (4 total)	1 preferred design

**Figure 1** Overview of design cycles and group decision/voting results



**Figure 2** Number of designs produced and taken forward

At the end of the 3P event, the architectural experts from the Trust’s estates team who had been present throughout the event took the models away. Combined with what they had learned from participating in the 3P, architects were then able to translate the conceptual designs into working architectural drawings for a capital scheme that reflected the participants’ requirements.

## LESSONS AND LIMITATIONS

The Lean 3P method was applied to operationalise the Lean principles of value, value-streams, flow, pull and perfection to design a maternity unit and pathway.

Value - Specifying value from the customer’s perspective is the starting point for Lean.<sup>13–29</sup> US advocates of applying Lean to design healthcare facilities have defined value as “the efficient delivery of healthcare to the patient”<sup>43</sup> and something “for which the patient and/or customer would be willing to pay”.<sup>70</sup> Such definitions are likely derived from Lean’s commercial manufacturing logic. Whilst this may be appropriate for the US’ system of privately provided healthcare, the application of commercial manufacturing logic has been criticised as inappropriate for public services such as the NHS.<sup>31–33</sup> It has been argued that a more service oriented view is required that takes account of the service users’ experience as well as clinical and operational perspectives when defining value.<sup>32–33</sup> In this case, the various stakeholders that participated in the 3P were able to articulate and share their value perspectives. Most importantly this included end users who shared their experiences and views on how these could be improved. The stories from service users present at the event were also supplemented with survey information from previous and prospective users. Over 400 women responded to report on factors they considered important for choosing maternity facilities. These factors included: private rooms; facilities for their partners to stay; parking facilities; family friendly environments for siblings; sound privacy; and caring staff. The 3P format appeared helpful for stakeholders to explore together their perspectives of value and individual requirements

which they could then act on through multiple cycles of design.

**Value-stream–Service user experience** was combined with staff experience to inform design concepts and pathways (value-streams). Working in cross-functional teams with the service user representatives, care pathways were developed to deliver the desired user experience. Staff brought their clinical experience and professional knowledge to ensure that this could be done safely and effectively. Clinical adjacencies were considered to inform the designs so that the steps in the pathway lined up with the physical layout to facilitate good flow.

**Flow** - The various flows of service users and their families as well as different clinical staff groups were mapped and simulated at each cycle of design. This helped the participants to exchange information on how pathways would work within each design concept and to improve their designs based on feedback.

**Pull** - There are relatively few examples in the literature of the pull concept being applied in healthcare.<sup>50</sup> Those identified<sup>49 71 72</sup> are typically in line with Lean's original manufacturing logic in which patients are pulled through the system in a product like way. Aiming to develop a design for a better overall experience of care, the example presented here applied a more service oriented view of pull. Guided by Westwood's definition that "every step in the patient journey needs to pull people, skills, materials and information towards it, one at a time, when needed"<sup>39</sup> [p.15], the pull concept was applied to develop an innovative vision and model for maternity care. Through iterative cycles, teams developed a flexible maternity design to respond optimally to changes in circumstances or risk profile of women. Drawing on elements of traditional midwife-led, obstetrics led and the labour, deliver, recover, postnatal discharge (LDRP) models of maternity,<sup>73 74</sup> the teams conceived of a hybrid concept which they described as "wrap around care" in which services could be pulled towards patients as required.

**Perfection** - Through multiple cycles of design and PDSA, the Lean 3P workshop participants iterated toward an agreed outcome and preferred model and design for maternity services.

A further lesson learned related to the Lean 3P format. Lean 3P workshops typically run over five days.<sup>64</sup> However, due to the number of stakeholders to be released from frontline clinical work, availability for this workshop was limited to three days. To accommodate this reduction in time, the workshop was run at a very fast pace which delegates found challenging. Furthermore, maternity services are complex and comprise several sub-systems (such as theatres and special care baby units, for example). Arguably, these sub-systems could have been considered for additional 3P workshops to consider their design and layout in more detail - this however was beyond the scope of the project. A key lesson was that the Lean 3P format can be

flexed in terms of length and content but this should be matched to the scope and complexity of the service being designed.

The study has a number of limitations. First of all, whilst nominal group technique has been demonstrated to be effective in facilitating group consensus and is a recognised research tool<sup>66 67</sup>, it is considered to work best with smaller groups (typically 10 or fewer participants).<sup>68</sup> The 3P workshop was comprised of 37 participants and, although these were split into smaller teams (which is recommended),<sup>68</sup> this may impact on the approach. Second, though nominal group is recognised for its utility in ranking participant's views quantitatively against pre-agreed criteria,<sup>65 68 69 75</sup> it is not possible to remove all subjectivity and test-retest reliability cannot be guaranteed.<sup>68</sup> It has been reported that voting should be used only to rank options and not for the assignment of specific values.<sup>75</sup> Therefore, whilst the approach worked well to help the 3P participants converge on a preferred design, it is not possible to compare rating scores across design cycles. Finally, in healthcare capital development schemes, there can be significant time lags between conceptual design, business case development and approval and commencement and completion of construction. The scope of this research has been limited to reporting on the application of Lean in the conceptual design phase. Therefore outcomes are limited to the output of the design stage only.

## CONCLUSION

This paper shares preliminary results from postgraduate research and presents the second of three planned cases describing the application of Lean 3P to design healthcare services and facilities. The first case presented the application of Lean 3P to design endoscopy services.<sup>23 25</sup> This case describes how the Lean 3P method helped participants to create a maternity design that sought to deliver care that would "wrap around" the lady and is in line with current policy which calls for just such approaches to be developed.<sup>1</sup> Taken together, the cases demonstrate the potential applicability to a wider range of contexts of the Lean 3P approach to designing healthcare services.

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**Declaration of interests** Nothing to declare.

**Ethical approval** The study was approved by the research ethics committee of the author's academic institution. The research proposal was also reviewed by the Chair of an NHS research ethics committee, who confirmed in writing that NHS research ethics was not required for the study as it was considered to be service improvement.

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