NHS

Musgrove Park Hospital

Report of Musgrove Park Hospital's Review of Care and Treatment provided by Vanguard Healthcare Solutions Ltd.
October 2014
Strictly Confidential: Not to be Disclosed to Any Other Party

Contents

1. Introduction

- In autumn 2013 Musgrove Park Hospital ("MPH") of Taunton and Somerset NHS Foundation Trust ("the Trust") decided it needed a solution to help address a waiting list backlog of patients needing surgery to remove their cataracts.
- A range of options were explored, including working with external providers, but although this slowed the rate that the waiting list was growing, it did not provide a solution.
- In spring 2014 the Trust realised it needed a decisive solution to address this waiting list backlog of ophthalmology patients. As no internal solution could be found, the Trust decided to enter into a contract with Vanguard Healthcare Solutions Ltd. ("Vanguard") under which Vanguard agreed to provide the Trust with a complete solution to treat 400 patients during May 2014 in a mobile theatre on site at MPH. Vanguard sub-contracted the provision of surgeons and equipment to The Practice plc ("The Practice"), who in turn sub-contracted the provision of some of the equipment to Kestrel Ophthalmics Ltd ("Kestrel").
- Vanguard started operating in its mobile theatre on 2nd May 2014. On the 9th May 2014, following concerns raised by the Trust about complications from surgery, it was agreed to cancel all operating lists. By this date, 62 patients had been treated out of the 400 planned.
- This report looks at:
    - the care and treatment the 62 patients operated on received and potential causes of the problems experienced

- the circumstances surrounding the cancelling of the contract on 9th May 2014.

- This report is not intended to apportion blame upon any organisation or person connected with this episode, but to act as a learning exercise to ensure that a similar situation does not occur again.

2. Background to commissioning with Vanguard and internal processes since issues were identified:

- In the past, waiting list initiatives have involved both internal (our team of consultants operating both at Musgrove Park Hospital and the Nuffield) and external providers.
- Over the winter of 2012/13 Musgrove Park Hospital saw an increase in demand for all of its services across the hospital. This pressure, coupled with a loss of capacity in ophthalmology and increases in demand for some ophthalmic procedures, led to a growing waiting list backlog of patients needing treatment.
- There have been a number of pressures on the ophthalmology service since June 2013. The growing demand was compounded by additional pressures on the service, including:
  - Changes in the theatre plan which reduced the absolute number of ophthalmology surgical lists each week, with a plan to replace capacity through increased flexibility of the remaining lists which has proved hard to achieve
  - Increase in treatment using Lucentis for age-related macular degeneration where treatment has to be given within one week of decision to treat; this treatment is frequently carried out in theatre due to lack of capacity in the Outpatient Department.
  - Increased workload for providing temporal artery biopsies
  - Long term sickness of a team member.
- The Department of Health requires hospitals to treat 90% of patients within an 18 week time period, the 'referral to treatment' target, in order for them to meet their regulatory responsibilities.
- Given the size of the backlog, the Trust Board took the view that it was not appropriate to only treat a limited number of long wait patients each month, as those that had passed 18 weeks could end up waiting even longer, while other patients referred after them for the same treatment were being treated sooner. A decision was taken to see and treat patients in order of clinical priority and then waiting time.
- A meeting between senior operational management team members and the ophthalmology team at MPH in September 2013 failed to identify any internal solutions to the waiting list backlog. Therefore it was felt by the hospital's senior management team that an external solution was required.
- The company previously used by the Trust for this type of work had ceased to undertake this sort of work three to four years ago and a search by the operational management team at MPH in 2013/14 failed to find any companies offering a similar service.

- To enable the Trust to treat patients as soon as possible, without also making other patients wait longer than they should have to, MPH contacted Vanguard, a provider of interim surgical facilities and services across the UK, to develop a proposal to carry out 400 cataract operations. MPH has used Vanguard before on other projects and Vanguard has worked extensively with a number of other NHS trusts and private healthcare organisations. MPH entered into a contract with Vanguard on 1 May 2014.
- The operations were to be carried out in a mobile theatre provided by Vanguard based at Musgrove Park Hospital in May 2014. A meeting was held on 10th April 2014, with representatives from Vanguard, The Practice, Kestrel and Trust representatives from a number of departments, to prepare for installation of the mobile theatre.
- Vanguard began operations on Friday, 2nd May 2014, and continued on Saturday, 3rd May 2014 and Sunday 4th May 2014.
- The Trust established a process for patients to report any concerns and information was given to patients with contact details for Vanguard and the ward at Musgrove Park Hospital in case of any problems.
- Formal follow up arrangements for these patients had yet to be confirmed, although they had formed part of the contract negotiations with Vanguard. Dates for patient follow-up appointments were to be arranged for approximately three weeks after surgery.
- On 6th and 7th May, concerns were raised by the hospital's consultants regarding 3 patients who had attended eye casualty at MPH with problems following surgery within the Vanguard facility. The numbers presenting with problems were considered unusual for the numbers of operations carried out. No issues or concerns had been raised by Vanguard.
- As a result of the concerns raised by the Trust, it was decided by the Trust that all patients who had been on the operating list for Sunday, 4th May should be contacted and asked about their experience and postoperative symptoms.
- As a result of the calls, an outpatient clinic was set up for Friday, 9th May to review patients from Sunday 4th May.
- Following discussions between senior clinical and managerial staff, Vanguard and The Practice, it was decided that operations could continue subject to a change in the products used during the operations, as it was felt that this was likely to be the cause of the problems identified so far. The lists were set to resume as planned on Friday 9th May.
- On Friday 9th May, further concerns were raised from the clinic set up to review patients from the previous weekend, which was running at the same time as the operating list, and it was decided to stop the operations. By this time a further seven patients had been operated on as part of the morning operating list.
- All 62 patients operated on in the Vanguard mobile theatre have been contacted via telephone to discuss their aftercare, the majority have also had face to face reviews and a significant proportion have now been discharged needing no further care.
- Of the 62 patients who underwent surgery, 25 had a normal recovery and experienced no clinical or patient experience problems. At the time of writing this

report, of the remaining 37 patients, 32 have been discharged as their vision is now satisfactory and 5 are still under active follow up. More detailed information is available in Appendix A.

3. Scope of review:

This review was established to investigate the concerns identified in the care and treatment of patients by Vanguard at Musgrove Park Hospital in May 2014.

The review looked to answer the following questions:

- What is the likely cause of the high rate of complications in this cohort of patients?
- What were the governance processes around:
  1. *Health and safety issues*
  2. *Infection control*
  3. *Training for their staff using new equipment*
  4. *Whether the (Vanguard and other) staff usually work together as a team*
  5. *Checking the competencies of the surgeons and what were these competencies*
  6. *Setting of the case numbers at 20 each day*
  7. *Determining the number of cases on the first list for each surgeon (including confirming why induction time was not built in (i.e. fewer cases on the first list to allow for additional training time for new equipment e.g. the phacoemulsification machine)*
- For the surgeons undertaking these procedures, how many procedures have they performed and what are their complication rates? Is there any information available from their responsible officers and if so, what is this information?
- What were the circumstances surrounding the decision to cancel the contract on Friday 9th May 2014?
- What clinical follow up had been arranged for these patients post-operatively, before these concerns were evident? Were the patients aware of the follow up processes available?
- What are the final patient outcomes following surgery?

4. Timeline

TIMELINE FOR DECISION MAKING ON LISTS FOR 9TH – 11TH MAY 2014		
Date	**Time**	**Events**
06/05/14	12:47	E-mail from Ophthalmic Consultant highlighting concerns regarding a patient who had attended Eye Casualty after being operated on in temporary theatre 2 days earlier (04/05/14) and focussing on lack of follow up arrangements
06/05/14	13:05	E-mail from Ophthalmology Clinical Service Lead reiterating concerns about lack of follow up arrangements

06/05/14	15:01	E-mail from ST6, Ophthalmology, highlighting concerns regarding 3 patients (including the patient referred to in the e-mail from Ophthalmology Consultant at 12:47) attending Eye Casualty after being operated on in temporary theatre on 04/05/14
06/05/14	15:16	E-mail from Ophthalmology Consultant highlighting that there had been 3 complications identified from one list when 1 a year would have been an issue and raising concerns about forthcoming surgery.
07/05/14	n/a	Agreement that there was a need to discuss the issues identified in advance of up-coming lists. Clinical Director for Head and Neck / Specialist Surgery asked to identify appropriate time to ensure availability of Clinical Service Lead. Teleconference call arranged to follow Clinical Service Lead's outpatient clinic.
07/05/14	n/a	Deputy Medical Director contacted by Director of Operations (in Medical Director's absence) and briefed about complications and plans to discuss further.
07/05/14	17:15	Teleconference to discuss concerns following identification of 3 patients with complications; call included representatives from the Trust and Vanguard and the surgeon from The Practice who carried out the surgery on 4th May. Clinical Service Lead identified the probable cause as product / chemical (potentially the visco-elastic) and plans were made to review all products involved before a further teleconference on 08/05/14 with a smaller group (although all were welcome) to discuss the issues and agree a way forward.
07/05/14	22:16	E-mail from Director of Operations summarising 17:15 teleconference.
08/05/14	11:30	Teleconference to discuss issues; call included representatives from the Trust, Vanguard, Kestrel and The Practice Although no clear cause had been identified, there was agreement that the products (drugs and chemicals) were the most likely cause. 2 options were put forward for consideration; to replace the drugs with a new batch of the same product or to replace with alternative products. Director of Operations wished to discuss with the Exec Team, so a further call was arranged for later.
08/05/14	12:45	Teleconference to discuss issues. It was agreed to continue with operating on 09/05/14 with the proviso that an alternative visco-elastic was used and all other drugs were replaced with a new batch. This would need to be confirmed with The Practice.
08/05/14	Various	Telephone calls between Director of Operations and Vanguard confirmed arrangements for replacement visco-elastic and agreed arrangements for next day follow-up of patients being operated on on 09/05/14. A "Stop Operating" process would be put in place if any concerns were identified.

08/05/14	n/a	Decision taken at meeting of Chief Executive, Deputy Chief Executive, Director of Operations and Head of Operational Delivery to continue surgery as planned on 09/05/14.
08/05/14	c.17:00	Deputy Medical Director off site, but called Deputy Chief Executive for update. Advised that it had been decided that it was not a surgical issue (agreed by the Ophthalmology Team) and was likely to be due to visco-elastic, with plans in place to replace this and restart surgery on 09/05/14
08/05/14	c. 17:30	Clinical Service Lead learned that the decision had been made to continue surgery at an unrelated meeting with the Directorate Manager; Clinical Service Lead (who was due to be away on 09/05/14) then phoned Clinical Director that evening and left a message on his answerphone.
08/05/14	19:34	E-mail from Director of Operations summarising 11:30 and 12:45 teleconferences.
09/05/14	08:41	E-mail from Clinical Service Lead highlighting concerns that surgery was to continue despite his concerns raised at the teleconference on 07/05/14 and the fact that a cause had not been identified and there was no clarity on the scale of the issue. The e-mail asked for a formal response.
09/05/14	n/a	Clinical Director texted Clinical Service Lead to confirm that he would sort the situation out.
09/05/14	09:46	E-mail from Clinical Director (including forward of e-mail from Clinical Service Lead at 8:14) confirming that the actual cause had not been identified, but identifying the products as the most likely cause, and suggesting a more cautious approach of proceeding with just 1 day of operating rather than 3.
09/05/14	c.09:46	Following receipt of e-mail from Clinical Director, Deputy Medical Director tried to contact Clinical Service Lead, but he was away on professional leave and another Ophthalmology Consultant, but he was in theatre.
09/05/14	am	Clinic to review the cases from 04/05/14
09/05/14	09:48	Surgery commences.
09/05/14	c.11:00	Meeting between Deputy Medical Director, Deputy Chief Executive and Director of Operations to discuss options and consequences of halting surgery. Discussions between Deputy Medical Director, Deputy Chief Executive and Director of Operations continued and it was agreed that final decision was with Deputy Medical Director in Medical Director's absence. Deputy Medical Director discussed with Clinical Service Lead and returned to office to make one further call, but was called by Deputy Chief Executive to say that operating had been stopped after 7 cases following identification of further concerns at clinic.

5. Overview of investigation, details of Incident and Consequence

- The contract agreed with Vanguard was for the provision of a complete service, including a mobile theatre suite and nurses. Vanguard subcontracted with The Practice for the provision of the surgeons, products and equipment and The Practice subcontracted to Kestrel for the provision of a phacoemulsification machine, the hand pieces needed for surgery and the operating fluids and eye drops.
- The two surgeons had both previously worked in operating facilities provided by Vanguard, and one of the surgeons had worked with Kestrel in the past. However, this particular combination of staff, equipment and facilities had not been brought together before which meant that there was no outcome data available from previous projects.
- In advance of progressing further with the contract, the CVs of the surgeons were reviewed by the hospital's Medical Director, who also checked their GMC status. The CVs of the nursing staff were reviewed by the interim Associate Director of Nursing. Both surgeons had significant relevant experience in an acute hospital setting, one working at consultant-level, one as an Associate Specialist carrying out consultant-level work. Both were working in NHS Consultant posts; one substantively and one as a locum.
- The decision to go ahead using Vanguard was communicated on 8 April 2014, with plans put in place to deliver the mobile theatre unit on 13th April 2014. The infection control team passed the facility as suitable.
- The Trust's procurement department supported the hospital's operational team in contract negotiations. The final contract was agreed on 1st May 2014, shortly before services started.
- Lists were booked at 20 cases per day. This decision was made jointly by Vanguard and The Practice and was a caseload that both surgeons felt comfortable with. Consultants at MPH usually undertake 12-14 cases a day, although these are often more complex cases requiring procedures additional to cataract surgery. Guidance from the Royal College of Ophthalmologists suggests that two cases per hour is reasonable, however, units specialising in high volume cataract surgery can increase this significantly to 2.5 cases per hour, allowing for 20 cases in 8 hours of operating.

Details from 2-6 May 2014

- Lists were booked and patients allocated, with the aim of providing the bulk of the surgery by the end of May 2014. Lists were carried out by two different surgeons on 2nd, 3rd and 4th May 2014.
- On 6th May 2014 a patient from the list on 4th May 2014 presented at eye casualty with severe corneal decompensation. They had been trying to seek help and, in line with the agreed process for reporting concerns, as the mobile unit was not open, they contacted the emergency Eye Clinic at MPH and received an appointment the same day.
- This patient was followed by two other patients from the list on 4th May 2014. All of these had severe corneal decompensation.

- The three cases were discussed within the ophthalmology department and it was felt that the cause was most likely to represent product / toxic reactions.

Details from 7-9 May 2014

- A conference call took place on 7th May 2014 with representation from both clinical and operational backgrounds and representatives from Vanguard and The Practice. During this call it was felt that the reaction that had been seen was more likely to be due to products than surgical issues.
- This information was fed into a further teleconference involving members of the executive team at MPH and a decision was made to change the viscoelastic from the one supplied by Kestrel to Healon (a brand used in the Trust's own ophthalmological operating theatres) as it was felt to be the most likely cause of corneal decompensation.
- A plan was made to review cases from 4th May list on 9th May in an outpatient clinic.
- The Ophthalmology Clinical Service Lead did raise concerns on the evening of the 8th May 2014 about whether surgical problems had been sufficiently ruled out, leaving a telephone message with the Clinical Director, followed by an e-mail on the morning of the 9th May 2014.
- Following receipt of the e-mail, the Clinical Director then e-mailed senior clinical and managerial members of staff to share their concerns and suggest a more cautious approach whereby on-going surgery should only go ahead on the 9th May, but should be cancelled for 10th and 11th and reviewed before any further days are planned.
- Surgery commenced as planned on 9th May. In tandem with this, the review of patients who had surgery on Sunday 4th May was ongoing.
- Discussions were taking place between senior operational managers, clinical managers and an ophthalmology consultant following the concerns raised by the Ophthalmology Team. However, as the clinical review of cases progressed that morning it became apparent that there were other patients with complications from previous days and the decision was taken to stop surgery entirely while a full review was carried out. By this time, seven people had received operations on 9th May.
- The contract with Vanguard was suspended on 9th May and then cancelled following a meeting on Monday, 12th May. The remaining patients awaiting surgery were cancelled pending an alternative solution.

6. Causes of High Complication Rate

A study of complications relating to cataract surgery across UK hospitals in 55567 patients has shown retained lens fragments in 0.18%, corneal oedema in 0.14%, and phaco burns or wound problem in 0.25%. Overall there are one or more other post-operative complications in 4.64%, with this figure including data from trainee surgeons. This figure differs ten-fold from the complication rate for the patients involved in this investigation.

Toxic Anterior Segment syndrome is a rare acute post-operative sterile inflammatory reaction, which occurs 12-48 hours after cataract surgery with characteristic clinical findings

of corneal oedema secondary to toxic damage to the corneal endothelial cells, fibrin deposition in the anterior chamber, secondary glaucoma from damage to the trabecular meshwork and iris damage with irregularity or a dilated pupil. Most cases recover well with treatment such as intensive steroid therapy, but severe cases may suffer residual problems including corneal oedema or glaucoma. Potential causes include introduction of toxins into the anterior chamber of the eye including talc, inappropriate dilution of fluids used in surgery or irritants on the surface of intraocular surgical instruments. More frequently, as in this case, it is impossible to find a specific cause.

Specific clinical issues considered as part of this investigation:

- Possible poor surgical technique: retention of lens matter requiring further surgery in three patients, phacoemulsification burns in two patients, iris pigment loss which implies damage to the iris during surgery in at least six patients and at least four patients with microscopic metallic fragments. However, it would appear that possible poor surgical technique cannot be the whole explanation, or these problems would have been picked up in the surgeons' own hospitals or while doing other work for The Practice. Patients were affected following operations by both surgeons, which also makes possible surgical error less likely as a sole problem as this would be unlikely to affect both operators. The fact that complications worsened in severity and number through the days would suggest that possible surgeon error does not provide the whole explanation, as this would be less likely with increased familiarity with their surroundings, personnel, and the kit used.
- The pressures of operating on 20 patients each day may have contributed to the possible deterioration of surgical quality and reduction in patient experience. Although the majority of patients reported having a good overall experience, one patient reported that the procedure felt 'rushed' in comparison with previous experience of cataract surgery at MPH and other patients reported similar concerns. Several patients reported experiencing pain at the time of the procedure and also being shouted at for moving. At the planning stage, The Practice and Vanguard were happy with listing 20 cases for each day as the cases selected were uncomplicated and this fits with the business model for The Practice which is based on high throughput local anaesthetic cases such as these.
- Very painful surgery was reported by several patients, irrespective of whether they suffered complications. This may have resulted from inadequate local anaesthetic drops and indeed as the first few cases experienced pain on 2nd May, the surgeon changed from using proximetacaine to tetracaine drops. Drops were given outside the theatre, so it is possible that they were less effective as they had partially worn off or alternatively they were not given every 5 minutes as required. 1% lidocaine was used for direct intraocular injection for deeper anaesthesia rather than the 2% normally used at Musgrove Park which may have been less effective for providing anaesthesia. Another potential cause for the pain experienced was damage to the iris, evident in several patients from this cohort on subsequent review.
- Cefuroxime was used by mixing the powder contents of a vial with diluent then injecting into the eye, with a fresh vial used for each patient. Along with the risk of

dilution errors, it appears that different amounts (between 0.1 and 0.2 ml) were given which may increase the risk of toxic reaction.

- Balanced saline solution with adrenaline for irrigation – problems with dilution have been found to cause TASS in the past.
- The Phacoemulsification machine was provided to Vanguard by Kestrel; it had just come back from servicing prior to use at Musgrove Park and has subsequently been independently assessed as fine. A representative from Kestrel was present for each of the surgeon's first days with the phaco machine as it is an unusual one in UK practice which neither surgeon was very familiar with. The scrub nurses reported problems with the reservoir within the phaco machine emptying then cutting out while it refilled; the phaco machine cuts out to prevent eye damage with a resulting delay of a few seconds each time this happened. The phaco times by these surgeons were considerably longer than those usually seen within Musgrove Park, but there is no correlation between time of phaco use and severity of corneal decompensation. At review, it was noted that there were multiple microscopic metallic fragments present in the anterior iris surface of at least four patients, probably arising from either the phaco machine or inadvertent touch between the phaco tip and the manipulator.
- Viscoelastic was used for the first three days of operating and was thought to be possible cause of this TASS outbreak, so this solution was changed to Healon for the fourth day. This fourth day had the highest complication rates, thus ruling out Viscoelastic as the sole possible cause.
- Decontamination of the handpieces was carried out by the Sterile Services Department at Musgrove Park Hospital and no concerns were identified around this process. As reusable equipment, each handpiece had a removable sticker to put into the patient's notes as a tracker. Following review, it was identified that a number of stickers are missing from each day of operating.

7. Conclusions

As with the majority of similar clusters of ophthalmic complications, no clear single cause was identified by the investigations. A number of potential clinical causes have been identified, as listed above, but the Trust has not been able to identify any clear cause that explains all of the complications.

The following additional underlying issues were identified during the investigation:

- *Pre-procedure training*. From the first session on the first day of operating, the number of cases was fixed at 20 per day. This did not allow for significant on-site training time on new equipment for medical staff who were unfamiliar with the phacoemulsification machine to be used and/or had not worked within this facility. Thus, patients were arriving at the Vanguard facility while training was going on, creating pressure to start the lists promptly and shorten training. The Qube phacoemulsification machine is one which is not in common use in the UK and for this reason, the representative was present for the first few days of operating to

assist the surgeons and scrub nurses with its function and one surgeon received training a week earlier. Training for scrub nurses was carried out on 1st May 2014.

- *Planned follow up of cases*. Although arrangements were in place for patients to report any problems or concerns, the arrangements for the planned follow up of patients had not been finalised when operating started. Although, plans were in place to resolve this and inform patients of follow up appointments, patients were not given a date for planned follow up at the time of surgery.
- *Decision to undertake surgery on 9th May 2014*. The decision to go ahead with surgery was taken on 8th May, taking into account information from the teleconference on 7th May that it was considered unlikely to be surgeon error and the decision to change the visco-elastic and other fluids. In retrospect the viscoelastic and other fluids are unlikely to have been the sole cause of earlier complications. Further concerns were raised by the ophthalmology consultant who is the Clinical Service Lead and detailed in an e-mail on the morning of the 9th May. This led to further discussions; simultaneous to these discussions, review of the patients who received cataract surgery on 4th May showed that complications were more widespread than the initial three cases and so the decision to stop operations scheduled for that day and onwards was made. It is possible that clearer escalation processes may have resulted in an earlier decision being made on the morning of the 9th May 2014 stop the operating list.

8. Recommendations

This investigation has covered a number of key aspects of the events leading up to the commencement of the contract along with the specific clinical issues. This section covers the recommendations for the Trust from the findings of the investigation. Details of the investigation will be shared with the other organisations involved.

The key recommendations are:

- Musgrove Park Hospital to share findings of its investigation with Vanguard to enable them to review the clinical causes and develop their own recommendations to prevent recurrence. This should include a review of the number of cases per list, particularly at the start of the contract, the equipment and products used and surgical technique.
- There should be work to maximise the utilisation of in-house Ophthalmology resources, especially theatre sessions, with the introduction of more flexible working arrangements.
- Clear protocols need to be put in place around escalation and decision making processes before any contract commences so that there is appropriate assurance re the involvement of key clinical and managerial personnel. The Trust needs to review and reconsider its reporting mechanisms around raising concerns, particularly those involving patient safety and governance issues.
- Formal follow-up arrangements with patients need to be fully in place before any contract commences.

9. Learning

Actions will be taken to address each of the recommendations in this report and the learning from this investigation will be shared across the Trust to ensure it is applied to any work carried out in partnership with other organisations in the future.

The findings will be shared with the other organisations involved to enable them to develop their own action plans.

Key learning points will be shared with other NHS organisations via the learning processes that are currently in place.

Appendix A – Details of Complications

REDACTED
Potentially identifiable patient information

Executive Summary Report of Musgrove Park Hospital's Review of Care and Treatment provided by Vanguard Healthcare Solutions Ltd October 2014
Strictly Confidential: Not to be Disclosed to Any Other Party

Contents

10. Introduction and background

By the autumn of 2013 Musgrove Park Hospital had a backlog of patients waiting for cataract surgery and senior management decided that a solution to deal with this was needed as some patients were waiting a long time for their surgery. The Department of Health requires hospitals to treat 90% of patients within an 18 week time period, the 'referral to treatment' target, in order for them to meet their regulatory responsibilities.

Given the size of the backlog, the Trust Board took the view that it was not appropriate to only treat a limited number of long wait patients each month, as those that had passed 18 weeks could end up waiting even longer, while other patients referred after them for the same treatment were being treated sooner. A decision was taken to see and treat patients in order of clinical priority and then waiting time.

There were a number of reasons for the waiting list backlog, which was ultimately down to a mismatch between the number of patients being treated and the number being added to the waiting list. The Trust experienced a reduction in the numbers of ophthalmology doctors and was unable to fill the vacant posts. Theatre scheduling was changed to try and improve efficiency across the whole range of the surgery that the Trust provides, which required greater flexibility in the deployment of ophthalmology doctors. This proved difficult because of additional factors including an increasing need for them to treat patients with age-related macular degeneration and diabetic eye disease [amongst other conditions]. Given these challenges, it was decided that a bespoke solution was needed to ensure that the cataract patients were treated as soon as was possible.

The Trust explored a number of possible internal solutions to provide the additional capacity but was unable to identify sufficient capacity to treat 400 patients. Having used them successfully in the past, the Trust approached Vanguard Healthcare Solutions Ltd (Vanguard) to see if they could provide the solution. The Trust entered into a contract with Vanguard under which Vanguard agreed to provide the Trust with a complete solution to treat 400 patients in a mobile theatre on site at the hospital. Vanguard sub-contracted the provision of some staff (including surgeons) to other organisations. Following a meeting of

all parties on 10th April 2014, the mobile theatre was installed on the Musgrove Park Hospital site later that month. Vanguard began the first operations on Friday, 2nd May continuing throughout the weekend of Saturday 3rd and Sunday 4th May.

The Trust established a process for how patients were to report concerns or queries and all patients were given information on how to contact Vanguard and the eye ward at Musgrove Park Hospital in case of problems. Formal follow up arrangements for these patients had yet to be confirmed, although they had formed part of the contract negotiations with Vanguard. A couple of days after the surgery started, on the 6th and 7th May, three patients who had been treated at the unit on the Sunday (4th May) attended the hospital's emergency eye clinic with problems. This number of patients experiencing problems was considered by the Trust's ophthalmology team to be unusual given the number of operations that had been carried out. Following identification of these concerns the Trust decided to contact and review all patients who had undergone surgery on Sunday 4th May in order to enquire about their experience and determine whether they had experienced any postoperative problems. As a result of these calls the Trust decided to hold a formal follow-up clinic on Friday, 9th May to review the patients from the previous Sunday's operating list.

During the week commencing Monday 5th May 2014, a number of face to face meetings and teleconference calls were held between senior medical, operational and management team members from the Trust, Vanguard and others to discuss potential causes of the problem [corneal decompensation] that the patients had experienced.

Products and chemicals used in cataract surgery had been known to cause similar problems for patients in the past. Although there was no clear evidence that there were any problems with the chemicals used, it was concluded that switching the products to those used routinely at the Trust would most likely eliminate the issue and surgery could go ahead as planned on Friday 9th May.

Surgery continued on 9th May 2014 as planned. In tandem with this, the review of patients who had surgery on Sunday 4th May was ongoing. When the deputy chief executive and deputy medical director became aware of the concerns of the Trust's clinical service lead and it became clear from the review of patients that there were further complications, the surgery was stopped. By this time a further seven people had had surgery. The contract with Vanguard was suspended on 9th May and subsequently cancelled following a meeting on Monday 12th May. The operations for the remaining 300 plus patients were cancelled pending an alternative solution.

2. Causes of high complication rate

The complication rate experienced by the patients treated by Vanguard was ten times the complication rate of 4.6% reported in a very large (55,567 patients) study of cataract surgery. There were a number of areas explored as possible causes of the complications the patients experienced, however the Trust's investigations failed to provide any significant conclusions to show a direct link. The areas considered are as follows:

- Toxic Anterior Segment Syndrome (TASS). A rare sterile inflammatory reaction to the operation and/or the chemicals used, usually occurring 12-48 hours after surgery. Most cases recover completely.
- There is evidence of lens [cataract] fragments remaining after surgery in three patients which needed further surgery to remove them. Two patients experienced phacoemulsification burns (burns to the eye from the phacoemulsification machine

used to break up the cataract during the operation). There was iris pigment loss in at least six patients and at least four patients had microscopic metallic fragments in the eye when examined later.

- The pressure of operating on 20 patients each day. However, neither surgeon reported feeling under pressure and were both comfortable with the operating timetable, equipment and surroundings.
- A number of factors around the products and solutions used during surgery were considered.
- The phacoemulsification machine (the machine used to destroy and remove the cataract) was provided to Vanguard (via its subcontracting arrangements). It had just returned from servicing prior to its use at Musgrove Park Hospital and was subsequently independently assessed as being satisfactory with no technical issues. This machine was not one routinely used in the UK.
- One of the solutions (viscoelastic) used during the first three days of operation was thought to be a possible cause of the [TASS] problem so this was changed to Healon for the fourth day. However, the patients on the fourth day had the highest complication rates which would appear to suggest that viscoelastic was not the cause of the problems.
- Decontamination of the hand pieces used on the phacoemulsification machine was carried out by the Sterile Services Department at Musgrove Park Hospital and no concerns were identified around this process. As reusable equipment, each hand piece had a removable sticker which should be placed in the patient's notes as a tracker. A number of these stickers are missing from the notes of patients on each day of operating.

3. Conclusions

As with the majority of similar clusters of cataract surgery problems no clear single cause was identified by the investigation. A number of factors were explored as listed above.

4. Recommendations

This investigation has covered a number of key aspects of the events leading up to the start of the contract along with a number of areas explored as part of this investigation. This section covers the recommendations from the findings relevant to Musgrove Park Hospital. Details of the investigation will be shared with Vanguard to enable them to develop their own recommendations and to learn from this.

The key recommendations for Musgrove Park Hospital are:

- There should be a renewed focus on improving the utilisation of ophthalmology resources including addressing the underlying capacity issues and putting in place more efficient working arrangements.
- Protocols within the Trust need to be reviewed around timely reporting of concerns and the Trust's decision making processes at times of emergency/urgent action so that there is appropriate assurance re the involvement of key clinical and managerial personnel.