Care Standards

The Tribunal Procedure Rules (First-tier Tribunal) (Health, Education and Social Care) Rules 2008

Pocock Street, Southwark, London
On 4 - 6 December 2013

Before:

Tribunal Judge – Mr John Burrow
Specialist member – Ms Susan Last
Specialist member – Mr Mike Flynn

The Pemberdeen Laser Cosmetic Surgery Clinic Ltd

-v-

CQC

[2012] 2016.EA and [2013] 2056.EA

DECISION

1. The Pemberdeen Laser Cosmetic Surgery Clinic (Pemberdeen) appealed under the Health and Social Care Act 2008 against the decision of the Care Quality Commission (CQC) made on the 8 January 2013 to impose a condition on Pemberdeen in respect of the registration of the Belvedere Private Hospital (BPH) and the decision of the CQC made on 29 May 2013 to cancel the registration of the BPH. The two matters were joined by directions issued on 5 August and were heard together.

2. The appeals were heard at Pocock Street on 4, 5 and 6 December 2013. Pemberdeen were represented by Rebecca Hayes of counsel, instructed by Karslakes Solicitors. Also in attendance for part of the hearing was Derek Cockle solicitor. Ellen Shields, trainee solicitor attended throughout. Their witnesses were James McQuillan, of Green Maze Support Ltd, Richard Slimm of RCS Consultancy, Emma Bird, manager of the BPH. Naveen Cavale, Consultant Surgeon, who was listed as a witness, did not appear. Her statement was not agreed and was withdrawn.

3. The CQC were represented by Paul Spencer of counsel, who was instructed by Weightmans solicitors. Also present was Simon Turner, solicitor, and Richard Bird, who was the CQC representative. Their witnesses were Fiona Wray, compliance manager with the CQC, Sarah Moynihan, inspector with CQC, Tim Weller, enforcement advisor with

the CQC, and Jean Carter, pharmacist inspector. Susan Howard, Head of Regional Compliance Central West Region of the CQC, who was listed as a witness, was stood down, and we had regard to her witness statement. There were two observers.

4. The bundle ran to 1576 pages. Further documentation submitted before and during the hearing were an extract from contemporaneous notes by Tim Weller relating to an inspection of BPH on 29 November 2013, a supplementary witness statement of Tim Weller dated 2 December 2013 with photos No's 1 – 47, and an Inspection Report of an inspection of 29 November 2013. Also submitted were the Controlled Drugs (Supervision of Management and Use) Regulations 2013, and a guide to these Regulations, a photographic record of items found at BPH on 7 November 2012, and a supplementary witness statement of Jean Carter dated 2 December 2013.

5. There were skeleton arguments from Ms Haynes dated 2 December 2013, and from Mr Spencer dated 2.12.13. There were closing submissions from Mr Spencer dated 13 December 2013 and from Mr Hayes dated 16 December 2013, along with attached documentation. An email of 6 September 2013 from Ms Ndagire to the CQC about the CQC inspection of 4 September 2013 was admitted. A summary of issues and matters agreed dated 29 November 2013, was admitted. There was a supplementary witness statement of Emma Bird dated 5 December 2013, along with documentation and photographs. This additional evidence was not opposed, appeared relevant and we allowed it in.

Background

6. The Pemberdeen Private Hospital is an independent hospital registered under the 2008 Act to provide cosmetic surgery procedures. It reopened in March 2012 after a two year refurbishment programme. It has an operating theatre, reception and consulting rooms and administrative offices. Most patients are day patients, but the hospital also has facilities for overnight patients with 5 single or shared rooms.

7. During the relevant period the hospital often only carried out operations on 1 or 2 days a week. It has no salaried surgeons or nurses, but employs clinical staff on an agency or bank basis. It has a small number of administrative staff, also not employed but retained on an agency basis, with some cleaning staff. There is a full time salaried manager.

Legal Framework

8. The Health and Social Care Act 2008 requires any person carrying on a regulated activity (the service provider) to be registered under the 2008 Act. The services provided by the BPH are a regulated activity and fall to be registered under the 2008 Act. Under Section 4 of the

Act the CQC must have regard in performing its functions inter alia to views expressed by or on behalf of members of the public about health and social care, the experiences of service users and their family and friends, the need to protect and promote the rights of people who use the health and social care services and the need to ensure that action taken by the CQC is proportionate and targeted only where it is needed.

9. The CQC may under Section 12 of the Act impose at any time such conditions on a service provider as it thinks fit. Under Section 17 of the Act, the CQC may cancel the registration of the service provider on the ground the regulated activity is or has been carried on otherwise that in accordance with the relevant regulations. Under Section 18, the CQC may suspend registration.

10. Under Section 26 of the 2008 Act, the CQC must give notice to the service provider of a proposal to cancel registration or impose a condition on registration. The service provider then has 28 days to make representations. Under Section 29 the CQC may issue warning notices specifying conduct which they believe may constitute a failure to comply with the relevant requirement. Under Section 30 the CQC has the power to apply to a justice of the peace for an order cancelling the registration if there will be a serious risk to a person's life, health or well-being unless the order is made. Under Section 31 the CQC may, if it has reasonable cause to believe that a person may be exposed to a risk of harm, vary, remove or add a condition to a service provider's registration.

11. Under Section 32 of the 2008 Act, the service provider may appeal the CQC's decisions on registration to the First Tier Tribunal within 28 days of the decision. The FTT may confirm the decision or direct it is not to have effect, or vary a condition, or impose any condition itself it thinks fit.

12. The BPH provides services which fall to be regulated under The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Where the service provider is other than a partnership, an individual (the "nominated individual" or NI) who is a director, manager or secretary of the service provider, must be registered with the CQC and must be of good character, and have the necessary qualifications, skills and experience to carry out the regulated activity. The manager of the regulated activity must be registered and must be of good character, physically and mentally fit and have the necessary qualifications, skills and experience.

13. Under the 2008 Regulations the service provider must comply with 16 aspects of the regulated activity, (regulations 9 to 24 of the 2010 Regulations) including ensuring the care and welfare of patients, cleanliness and infection control, management of medicines, safety of premises and equipment, complaints handling, patient records and

training, and recruitment of staff. Where regulated activities are carried on in such a way as not to comply with the required standards, the CQC can issue a waning notice, specifying the necessary action to be taken, and by when. If the warning notice is not complied with, an offence may be committed, and if found guilty the hospital can be fined.

14. The Controlled Drugs (Supervision of Management and Use) Regulations 2013 contain provisions relating to Accountable Officers (AO).

Evidence

15. On 16 May 2012, the registered manager of BPH applied to cancel her registration as manager under Regulation 6 on the grounds she felt she could not manage the hospital well with the way the company manages its finances. Her registration was cancelled on 19 June 2012, leaving the BPH without a registered manager.

16. On 28 May 2012, BPH was inspected by the CQC, as part of its routine schedule of planned reviews. The inspectors found the hospital was not meeting standards in obtaining consent of patients, in risk assessment following repositioning of the theatre suite, in controlled drugs (CD) procedures which were not followed and there was no CD Accountable Officer (AO). These matters were assessed to have a minor impact on users.

17. The hospital had no registered manager and there was no evidence of sufficient staff or staff training, which was judged to have a moderate impact. Regulations 6, 9, 13, and 22 were not being met. The Review of Compliance report relating to the findings of this inspection was published in July 2012 and BPH was requested to send a report within 7 days setting out the action they will take to remedy the noncompliance. On 5 July Ms Moynihan emailed the BPH seeking an update on compliance.

18. On 11 July 2012 Ms Moynihan contacted Mr Terrence Bartlett, the Nominated Individual (NI) for BPH requesting an update on compliance. Mr Bartlett said a Registered General Nurse would provide interim cover as the AO, although she had not yet taken up permanent employment.

19. On 11 and 12 July the CQC received complaints about the service at BPH. On 13 July 2012 Ms Moynihan again emailed the BPH about an update on compliance. On the 13 July 2012 the CQC received an application from Susan Adebanjo to be registered as AO. On 17 July 2012 David Mills (of the BPH) notified the CQC that a registered manager was now in place, although no application had been received by the CQC. On 17 August Terrence Bartlett called the CQC and said the managers were in place but the Operating Department Assistant (ODA) at BPH was not under permanent contract. He confirmed there

was a complaints procedure. Mr Bartlett said as NI he was complying with regulations. He said the BPH was carrying out operations on 1 or 2 days a week.

20. On 17 and 23 August David Mills emailed the CQC to provide updates on compliance, and to say the BPH was carrying out operations on one day a week. On 4th September Susan Adebanjo called the CQC and appeared uncertain if she was the AO. On 7 September David Mills contacted the CQC seeking information about registering an AO. On 13 September 2012 there was a further complaint about the hospital.

21. On 13 September 2012 there was an unannounced inspection of BPH to check compliance with previously identified areas of non-compliance on 28 May 2012. The inspectors found that BPH was not providing sufficient emergency medication and equipment, and other essential equipment was out of stock. Further the hospital did not have appropriate arrangements to manage medicines. These were judged to have a major impact on service users.

22. The inspectors also found the BPH had not taken reasonable steps to identify the possibility of abuse of patients, was not always caring or supporting patients with suitable staff, was not providing appropriate training to staff in safe care and treatment and was not always keeping records in a way to keep them confidential. These were judged to have a moderate impact on service users.

23. During the course of the inspection, CQC inspectors spoke to Susan Adebanjo who said she was not supported appropriately. She was not aware she had been identified as the AO prior to her appointment, and expressed concerns about CD operational procedures. Mr Bartlett was informed the inspectors were concerned about the welfare of people at the hospital. He said the hospital would stop operating until they could sort out the issues. The BPH was asked under Regulation 10(3) of the 2010 Regulations to submit a report within 14 days setting out their remedial action.

24. On 13 September 2012 the BPH submitted formal notification to stop surgical procedures until they achieved compliance. On 19 September 2012 the CQC issued two Warning Notices on regulations 9 (Care and Welfare of Service Users) and 13 (Management of Medicines). The Notices required compliance by 1 October 2012. Subsequently Dr Vassilera, who was an anesthetist working at BPH on 13 September 2012 was referred to the GMC in respect of working as an anesthetist while there was a lack of emergency drugs and equipment available.

25. On 25 September 2012 there was a further complaint against BPH. On 28 September 2012 the CQC received an action plan from BPH relating to the inspection of 13 September 2012. The plan was sent by Augustine Fashola, the new manager at BPH since 25 September

2012, and stated the hospital would be compliant by 28 September 2012.

26. The action plan contained proposals to remediate non-compliance identified in previous inspections. It set out the individuals bearing responsibility for implementation and it set out the completion dates for the remedial actions. The plan referred inter alia to the AO, the SOPs, out of date medicines, care, welfare and safeguarding of services users, management of medicines, staff, records and the registered manager. Most of the implementation was to be by the hospital manager and the completion date was stated to be by the 26 or 27 September 2012.

27. On 1 October 2012 Susan Adebanjo telephoned the CQC to say she had never undertaken the AO role and she was never registered as the Registered Manager – so there had been no registered AO or manager for some 5 months.

28. On 7 November 2012 the hospital was inspected again, to check whether the BPH had taken remedial action in respect of previous non-compliance. It was apparent surgical operations were still being carried out at the hospital. The inspectors found that there were insufficient arrangements in place to deal with foreseeable emergencies in that the resuscitation trolleys contained no defibrillator on the first floor trolley, and no anaphylactic shock pack. Otherwise the trolleys were compliant. The inspectors found the BPH did not have effective measures for handling medicines. There were out of date medicines and there was no registered AO. CDs were kept appropriately although there was no record of an AO monitoring the CDs.

29. Appropriate CRB checks had not been carried out on staff before they started work and there was no risk assessment of staff. There was no Responsible Medical Officer (RMO) on duty overnight, and a nurse may have worked shifts which were too long and management of staff was inadequate. Patient records were not kept securely, and staff records were not all accurate. All these matters were judged to have a major impact on users of the service.

30. The fire doors were not in fact proper fire doors, and no action had been taken to implement a fire inspection report in September 2012. This was judged to have a moderate impact. There were no adequate systems to protect from risk of infection. This was judged to have a minor impact.

31. There was a new hospital manager at BPH, Augustina Fashola, who said she was in the process of registering with the CQC. Jonathon Beacon, a surgeon, was at PBH premises during the inspection and appeared to the inspectors to be representing the BPH. There was non-compliance with Regulation 9,12,13,15, 20, 21 and 22.

32. Mr Bartlett again said he would stop operating if the hospital was non-compliant, and on 7 November called the CQC to confirm this. BPH was issued with warning notices in respect of Regulations 20 and 21 on 20 November 2012, requiring compliance by 30 November 2012.

33. On 22 November 2012 the CQC issued a Notice of Proposal to impose a condition requiring BPH not to undertake any further surgical procedures without the prior written agreement of the CQC. The Notice referred to the CQC reports of inspections in May, September and November, and the fact BPH had failed to comply with two of the Warning Notices.

34. On 30 November 2012, CQC received an action plan from the BPH which was stated to be a response to the inspection of 7 November 2012 and the warning notices of 20 November 2012. The action plan stated there would be full compliance by March 2013, failures in respect of Regulation 21 would be remediated by January 2013, that in relation to Regulation 21 compliance would be by February 2013 and all other matters had been or were in the process of being rectified. In fact these matters were the subject of subsequent inspections where continuing concerns were found.

35. The Action Plan also stated the BPH would have a comprehensive complement of full time / part time and permanent staff, which was also not supported by subsequent inspections. The plan accepted past compliance failures and said the organisation had been restructured, including the appointment of Staff Nurse Marva Golden (who later resigned in May or June 2013). Jonathon Beacon was said to be the new manager but it later transpired he was suspended by the GMC and was subsequently erased. He resigned from BPH in May 2013, to be replaced by Pia Davies.

36. On 8 January 2013 the CQC again carried out an unannounced inspection at BPH to check on compliance arising from previous inspections. Surgical procedures were still being carried out by the hospital. The inspectors found continuing examples of out of date medicines and surgical sutures. There was still no registered AO, with the person nominated not meeting the statutory requirements for the role.

37. CRB checks were still not being carried out before staff commenced work, and there was no staff risk assessment procedure. References and work history records were inadequate. Medical records were all accurate, complete and fit for purpose. Temperature checks on the medication fridge were incomplete, staff rota records were incomplete, records were not kept securely, and staff signing in and out records were inaccurate. All these matters were judged to have a major impact on service users. Jonathan Beacon told inspectors he had been fulfilling the role of manager since 1 December 2012. He said Gavin

Abbots had applied to the CQC on 4 December 2012 to be the AO, but he appeared not to meet the statutory requirements.

38. The draft CQC report relating to the inspection on 8 January 2013 was issued and BPH sent factual accuracy comments which were later considered and rejected by the CQC, and the final, unchanged report was issued on 5 February 2013. The report found non-compliance with Regulations 9, 12, and 21. On 1 March 2013 an anonymous complaint raised concerns about staff shortage through lack of money.

39. On 8 January 2013 the notice of decision to impose a condition was sent to Pemberdeen. It stated Pemberdeen must not undertake any further surgical procedures at the BPH without the prior written agreement of the CQC.

40. On 1 February 2013 the Appellant appealed against the decision of the CQC to impose the condition. The grounds were that the CQC had failed to have regard or sufficient regard to the Appellant's report of 29 November 2012, and had failed to give the Appellants a reasonable opportunity to remediate non-compliance.

41. In a response dated 27 February 2013, the CQC said the decision was properly based on persistent, repeated and serious non-compliance by the Appellant, despite warning notices. The response refers to the various breaches of regulations ascertained in the inspections of BPH. The response stated that the Appellant's report of 29 November 2012 was flawed in many respects, including the proposed date of implementation which was 4 months away. The effect of the appeal was to suspend the decision to impose a condition until the appeal could be determined by the First Tier Tribunal.

42. On 11 and 12 March 2013 there was a further unannounced inspection of BPH. The inspections were carried out because of concerns of non-compliance. Surgical operations were being carried out. The inspection found emergency equipment checklists were not completed accurately. Some items in the resuscitation trolley were out of date. An emergency alarm rang 5 times without explanation. There was now a registered AO in place but there was no record of the AO monitoring the CDs and CD records of use were inaccurate.

43. Anesthetic medication was not available as needed. The medications fridge was run for a period at too low a temperature. Staff CRBs were still not being completed before staff commenced work and one nurse's professional registration had expired. One staff member had no employment history. There was not always enough qualified, skilled and experienced staff on duty in that the RMO arrived late at BPH, and the anesthetic nurse was also the circulating nurse. These matters were considered to have a major impact on service users.

44. The inspection also found appropriate information was not always given to patients about the cancellation of their operation. This was considered to have a moderate impact on service users. Jonathan Beacon arrived at the hospital, and provided information about the RMO, and about the supply of medication, which proved inaccurate, although he later claimed there had been a misunderstanding. Mr Beacon was acting as AO. There was non-compliance with Regulations 9, 13, 17, 21 and 22. On 19 March 2013 the draft Inspection Report for 11/12 March was sent to the BPH and on 5 April 2013 the BPH sent factual accuracy comments, of which two minor matters were accepted.

45. Following the inspection on 11/12 March 2013, on 3 April 2013 a Notice of Proposal to Cancel BPH's registration was approved and sent to BPH because of continuing failures to comply, despite repeated demands for action, warning notices, and despite repeated assurances by BPH it would comply.

46. The BPH sent an 'Action Plan' of 29 April 2013 to the CQC in which they accepted the findings of the notice of proposed cancellation. The plan said BPH would be compliant with Regulation 17 by 17 May 2013. The Plan also said a wholesale re-organisation had been commenced, and there would be voluntary suspensions of all surgical procedures after 1 May 2013. The plan said Mr Bartlett would cease as Nominated Individual, who would now be Pia Davies, who would also be the registered manager. Ms Davies's CV was attached. The Action Plan set out how each of a number of regulations would be met, and who would be responsible for implementing the changes, along with resource implications.

47. On 30 April 2013 Mr Bartlett contacted CQC, asking if 7 surgical procedures could be performed, as it would cause problems to cancel. He said the BPH still intended to halt operations thereafter. On 21 May 2013, Pia Davis informed the CQC that BPH intended to continue with operations after 21 May 2013. On 21 May 2013 a complaint about late cancellation of an operation and other matters was received by the CQC. On 29 May 2013 the Head of Compliance for CQC Central West Region reviewed and approved the Notice of Proposal to Cancel Registration.

48. On 5 June 2013 the CQC carried out an inspection of BPH solely to check on compliance with Regulation 17. The inspection found that patients were not provided with appropriate information about the hospital's complaints procedure in that a patient information guide contained contradictory information. Patient feedback forms were not distributed or used. Also cancelled operations were not being recorded as significant events as stated in the Action Plan. It was judged that these matters would have a moderate impact on service users.

49. It was noted Ms Davies' CV indicated she did not have clinical qualifications. She told inspectors she would rely on the theatre manager and the ward manager for clinical expertise. However, the theatre manager had left the week before and there was an agency RMO currently in the post. Ms Davies said during the inspection and in an email of 6 June 2013 that she was in the process of addressing the difficulties found by the inspectors, including inaccurate staff working records, and complaints from service users. On 11 June 2013 Ms Davies emailed an updated patient guide which still contained errors and on 18 June 2013 Mr Bartlett emailed that she was preparing an Action Plan.

50. On 25 June 2013 the Appellant appealed against the decision of the CQC to cancel registration. The grounds of appeal set out the steps BPH intended to take to become compliant, and expressed an intention to work closely with CQC, and set out steps which had already been taken, including the process of registering Pia Davies as the manager, NI and AO, staff training measures, revised complaint procedures, new IT, revised patient records, new clinical audit, risk assessment, and a new management and clinical governance structure. The grounds also stated the decision to cancel registration was flawed and erroneous because the CQC had failed to give proper consideration of the proposed remediation by the appellant. On 9 July 2013 Pia Davies was registered as the manager and NI of BPH.

51. The CQC issued a response on 16 July 2013 stating the decision to cancel was properly based on persistent, repeated and serious non-compliance by the Appellant, despite warning notices and the imposition of a condition to cease surgical procedures. It referred to the various instances of non-compliance revealed by the inspections. It referred to the several assurances of remedial action and a subsequent failure to comply with those assurances and a continuing failure to attain improvement. The effect of the appeal is to suspend the CQC's decision to cancel registration until the appeal is determined by the First Tier Tribunal.

52. On 4 September 2013, the CQC carried out an unannounced inspection to check whether BPH was compliant. Pia Davies was not present and the inspectors were informed by a staff member that James McQuillan was covering the manager's position, although other staff were unaware of the situation. Mr McQuillan was on the premises and introduced himself as consulting for BPH. He said he had been involved since mid-July 2013.

53. Shaun Murphy, a bank ODP at BPH since 3 September 2013 said 'as far as he knew' he was the hospital manager, although he had not been registered. He said he intended to register and he said he had been offered the post by "the owner" over the telephone. The inspectors were told Pia Davies had resigned on 30 August 2013. The inspectors subsequently asked Mr Murphy about his responsibilities as

manager under the Regulations but he said he was not too familiar with them and he would read up on them.

54. The inspection found there were insufficient arrangements to deal with foreseeable emergencies, including that checks of the resuscitation trolley in the operating theatre had not been completed before an operation commenced. An item of emergency equipment on the trolley was out of date despite several checks having been recorded as taking place. The CD book was completed incorrectly in that partly used dosages were not appropriately recorded. Expired medicines were found in the recovery and anesthetic rooms, and in the ward area.

55. A cool cupboard was kept at too high a temperature for a week. Staff files were inspected and it was found references were not always appropriate and there was an unexplained employment gap for a staff member. Patient discharges were not always appropriately handled, and staff working records were not always accurate, and on occasion there was an overlong shift. Records of staff training, including mandatory training, were inadequate. These matters were judged to have had a moderate impact on service users.

56. There was no hot water to the recovery or the anesthetic room sinks, the theater clogs were unclean, there had been no deep cleaning of the wards, and the sharps bin had no record of when it was first placed in position. There was no record of a recent Legionella risk assessment. Some staff did not have an up to date record of infection control training. Patient's complaints were not always fully investigated and resolved, and there were no staff instructions on handling complaints. These matters were judged to have a minor impact on service users. There was continuing non-compliance with Regulations 9,12,13,19,20,21,22 and 23.

57. Mr McQuillan subsequently produced a response to the CQC draft report of 4 September 2013 inspection, commenting on staff training, cleanliness of operating foot wear, inaccuracy of staff logging on and off, and management structure. The issues raised by Mr McQuillan were considered by the CQC, but no changes were made to the report. The CQC said most of the comments concerned proposed future action by BPH, when CQC was concerned with current compliance.

58. Mr McQuillan, in his witness statement and his oral evidence, explained his involvement with BPH. He is a director of Green Maze Support Ltd (GMS), a company which provides services to businesses which are registered or are seeking to be registered with the CQC. Prior to this he had been a training manager with the CQC and the Commission for Social Care Inspection. From January to November 2010 he had been a contractor with the CQC as a project manager for the re-registration of service providers.

59. He said in August 2013, Pia Davies, then the hospital manager, invited him to review the compliance of BPH, and conduct an audit, and recommend improvements. He visited BPH on 13 August 2013. He found BPH had invested heavily in equipment and premises, and some improvements in systems and procedures had been made, although there were areas for improvement. He produced a report dated 19 August detailing those areas where action had been taken and compliance achieved and where further action was necessary. He found the BPH was compliant with Regulations 23, 22, 21, 20,17, 6, 11, 12, 13, 15, and 10.

60. He identified some action points and suggested the use of observation audits to monitor compliance, and the insertion in staff files of a training matrix, and a monthly audit of all areas to ensure procedures are embedded, a compliance record signed by a staff member, and further work to bring policies and procedures up to date. He said the complaints procedure should be updated, that BPH should provide a feedback link in the website, amend patient interview assessment forms so they are more personal, and suggested a number of other documentary and procedural amendments. He submitted a 'Belvedere Compliance Improvement Plan' with his report, setting out responsibilities for implementing his recommendations, a Belvedere Staff Structure Chart, and an Employee Handbook.

61. After completing the report he had no further dealings with Pemberdeen until 31 August 2013 when he was asked by Mr Bartlett to advise on a new management structure following the resignation of Ms Davies. He said in his evidence that Ms Davies had made poor decisions including the purchase of an IT system which was unsuitable for BPH. Mr McQuillan visited BPH on 4 September 2013 with the intention of organizing the new structure.

62. He found the CQC inspectors on the premises and told them Ms Davies had resigned and he was overseeing a new management structure, and the Registered Manager, NI and AO would be separate individuals. This would help avoid difficulties if one resigned. He appointed Sean Murphy as interim manager for the day, although it transpired he did not have the necessary knowledge and further action would need to be taken. He believed Juanita Ngdagine, a director of Pemderdeen was in the process of registering as the NI. He thought BPH did not now need a AO due to having less than 10 employees.

63. He said he had attended the CQC inspection debrief on the 4 September 2013 inspection, and again mentioned a management restructure and mandatory training. On 6 September the CQC was sent an email dealing with some of the non-compliance issues found by the inspectors, and setting out proposed remediation. Mr McQuillan received the draft report of the 4 September 2013 inspection which he had been told incorporated the issues of the 6 September email.

64. Mr McQuillan said the CQC were inspecting the BPH, which performed operations on only 1 or 2 days a week, as if it were a much larger operation. He referred to the report as unduly harsh and disproportionate. He stated in his opinion BPH was compliant with the regulations He said in his view the problems experienced by the BPH stemmed from a poor choice of management structure and personnel, and the lack of a clinician manager.

65. In his evidence he said he accepted many of the concerns raised by the inspectors on 29 November 2013, including the need for a full check of the resuscitation trolley, although clinicians carrying out the operations would carry out a check themselves. Similarly clinicians would check for out of date medications themselves. He had found OOD medicines during his audit of 4 August 2013 but the fact out of date medicines were found does not necessarily mean out of date medicines were being used. Accordingly risks to patients were reduced.

66. The use of monthly medicine audits would deal with the problem and they were getting their house in order. The temperatures to the sinks should be right but staff wash in the scrubs room and the boilers were switched off if there were no operations. The fridge temperatures should be right but it was not clear if there were any medicines in the fridge at the time. He accepted leaving dirty clogs was poor practice but there were no further operations that day and cleaners would go in the following day. In respect of the Legionella assessment he had since found a risk assessment report. Risk was low in any event where water was turned on and off frequently.

67. He said deep cleans of wards was carried out every 6 months, and he has since found documentary evidence that this was being carried out. He accepted the sharps bin should have been signed and dated, but this was sloppy practice and could be easily remedied. He said the bin was not full merely that the syringe plunger was sticking out of the top, which did not present any risk, particularly as no patients would be present and the bin would be cleared away.

68. On the 4 September 2012 inspection he had asked Shaun Murphy to be temporary manager for the day only. He accepted that it was best practice to obtain two references but there was no statutory duty. He accepted that any gaps in employment should be investigated but the staff member was professionally registered. In his report of the 13 August 2013 he had listed what he regarded as mandatory training although it was for the service provider to decide what they regarded as mandatory.

69. The email of the 6 September 2013 from Ms Ndagire indicates the categories of mandatory training including safeguarding which are being reviewed by the BPH. For agency staff, training would be provided by the agency. He accepted safeguarding was very important.

Chaperones were available in reception area and checks were carried out on staff. Some of the clinical staff were NHS employees, some were from bank or agencies. They were provided with an induction process. Mr McQuillan said he was still involved in providing advice to Pemberdeen and the intent was to raise standards as far as possible.

70. Richard Slimm is a social worker who has extensive experience in the regulation of care services, including safeguarding service management and promotion of best practice. He is the author of several books in these areas. He was a compliance inspector with the CQC for health and social care regulation in 2009 and a regulatory inspector with the National Care Standards Commission, and the Commission of Social Care Inspection from 2002-2009. He has never, however, undertaken clinical inspections of either private or NHS hospitals, and he has no specific clinical experience.

71. He was instructed by Mr McQuillan to review inspections of BPH by the CQC, including methodology of inspections and on 4 November 2013 he carried out an audit. In his audit he spoke to service users, inspected BPH website, spoke to staff, inspected BPH procedures, records and documents and hospital equipment and premises. He found the BPH compliant with all the relevant regulations.

72. He found service users had been consulted and assessed and provided with appropriate information. He found emergency equipment in place. There was appropriate safeguarding. Cleanliness and infection control was maintained to a very good standard, including staff clothing. Medicines were stored safely and securely including CDs. Each patient has an individual care pathway.

73. He said there was a clear recruitment and selection process with clear policies and procedures. There were appropriate DBS checks prior to employment, and staff were competent, qualified and experienced, although clearer systems were necessary to monitor staff performance and care training. There was a clear complaints procedure made available to all service users, although previous managers had not always followed he procedures. There were appropriate patient and staff records which were safe and secure.

74. In his evidence to the Tribunal Mr Slimm said he considered Mr Weller's report to be high on information but low on assessment of risk. He said he was not sure the report was fit for purpose as there was not always supporting evidence for their findings on the degree of risk. Risk guidelines should have been consulted. Service users should have been spoken to. He said judgments should have been made to reflect a more proportionate regulatory approach. There was not a clear distinction between a requirement and what is best practice. Mr Slimm said the CQC should consider fining hospitals or using other alternative methodologies as a preliminary step.

75. He considered the BPH to be entitled to treat all patients as a VTE risk. He said he considered overfilled bins to be a health and safety risk rather than a care and welfare issue. Laryngoscopes don't need to be sterile just clean. BPH were now compliant with resuscitation trolleys and the CQC should have said so. He said he did not consider the BPH handling of medicines to be a moderate risk, but a minor one. The out of date medicines problem has been resolved and there was no evidence that out of date medicines had ever been used. The gas cylinders were not really a management of medicines issue and presented a very minimal risk.

76. Mr Slimm said in respect of a second reference for staff this was not a requirement but merely helpful. Photo identification for agency staff was not necessary because the agency itself would hold photos. A full employment history was not necessary and was not required by the regulations. The training matrix was an indication BPH was moving in the right direction but changes could not be completed overnight. Mr Slimm did not accept that the risk relating to records was "moderate". Records are often incomplete through human error and it takes time to change the culture. The CQC had not set targets and there was no evidence of harm.

77. On 29 November 2103 the CQC again inspected the BPH to check if the hospital had taken action to meet previously identified areas of non-compliance. The inspection found the hospital was not assessing all patients for Venous Thromboembolism (DVT) risk (including a patient over 60), and overall risk had not been scored on the day of the inspection. There was an overfilled sharps bin in the consultation room that had no assembly date. A used syringe was protruding from the top. Used and clean clogs were lying unseparated in the changing rooms. Some clogs had stains which the inspectors believed were human fluids stains.

78. A sharps bin the in theatre suite did not have an assembly date. A tracheal tube was partially protruding from its sterile package, 2 laryngoscopes were protruding from an opened sterile package. An out of date nasal dressing was in the stock room. The monitoring checklists for the resuscitation trolleys had been appropriately completed. Some equipment in the hospital was out of date. The medicines refrigerator showed it was being kept at the correct temperature. Some medicines in the medicine cupboard were out of date, expiring in June, October and November 2013.

79. Ms Bird was on the premises and informed the inspectors she had been appointed manager. She informed the inspectors of changes to the procedures for ordering medicines, but she accepted there was no written procedure. The AO (Ms Davies) had left the hospital in September. Ms Bird informed the inspectors she had identified a member of staff who could perform the AO role, although she said it

was uncertain if the Regulations about AOs applied to BPH due to the small number of staff.

80. The inspectors found a new CD record book had been introduced on 4 November 2013 and since then had been correctly filled in, although there was no AO monitoring the system. Some gas cylinders in an outside locked storage space appeared not to be secured appropriately. The theatre ledger records were not all accurate or complete. Some patient files were incomplete. These matters were considered to have a moderate impact on service users.

81. The inspection found personnel references in staff files were not all appropriate, one did not have photographic proof of identity, and one did not have a full employment history. A clinical staff check matrix appeared to indicate a surgeon's professional indemnity insurance was invalid and a staff training matrix appeared to show only 2 of 13 staff had completed all mandatory training. These were judged to have a minor effect on service users.

82. In his statement, CQC Inspector Timothy Weller said he had asked Ms Bird about mandatory training and Ms Bird said she would not offer staff shifts to staff who could not show they had undertaken training, although one nurse who had not completed training appeared to have been on duty prior to Ms Bird's appointment. Ms Bird said remaining mandatory training was to be delivered in the week commencing 2 December 2013. The training matrix was in the process of being drawn up. Ms Bird said she could talk the inspectors through the drugs ordering process, but there was nothing written down. Ms Bird accepted there were unacceptable gaps in the theatre ledger since the last CQC inspection on 4th September 2013, but prior to her appointment.

83. In his evidence to the tribunal Mr Weller said he had no clinical background, although the lead inspector on the visit Mr Duggal did have clinical experience and Jean Carter was a pharmacist inspector. In 2000 he had been appointed an inspector for the London Borough Croydon, and later deputy head of Inspection for the LB Hackney, neither in a clinical environment. He held operational management posts with the NCSC and the CSC.

84. He currently provides advice to the inspection service of the CQC, including on evidence brought back from inspections. He said his advice on inspections was a robust and proportionate application of regulatory principles. He is also warranted with the full powers of CQC Inspectors and attended the inspection on 29 November 2013. The purpose of the 29 November inspection was to assess whether the BPH was compliant with regulations and to assess risk and was carried out following advice from solicitors. It focused on compliance at the

date of the inspection and found noncompliance in respect of regulations 9, 13, 20 and 21.

85. Mr Weller said he considered Ms Bird should have made it clearer in her statement of 7th November 2013 that she was in the process of applying to be registered as the manager of BPH. He accepted she may have begun the process by 7 November 2013. In respect of staff without full mandatory training being offered shifts at BPH, he accepted there was no evidence of this happening after Ms Bird had been appointed manager. Ms Bird had explained this to him, and that she said new procedures were being put in place which would turn the matter around.

86. He accepted it was not necessary to obtain a retrospective reference. He accepted he had not ascertained if information about professional insurance was available from any source other than the BPH staff matrix. He accepted that the medical gas may have been chained immediately before inspection. He had been told by the staff that the bottles connected to the theatre were empty although there were conflicting accounts. Medical gas is a medicine and a matter that falls within the regulations.

87. He said Ms Bird had not explained the details of the auditing process merely that one was to take place on Monday of the following week. He accepted he had not asked Ms Bird about the new procedures she was implementing, although improvements were looked for and were mentioned in his report. He said Ms Bird had agreed the feedback on the inspection and agreed the theater ledger was not complete for periods before her appointment. He accepted that the tracheal tube did not have to be sterile, and that Ms Bird had given an explanation why they were there, but he said it was best practice that they were opened at the time they were used.

88. Mr Weller accepted that the operating theatre was clean and ready to go. He did not see any out of date equipment actually being used, but its presence in a hospital constituted a risk. Surgeons do not always check drugs or equipment. There was no written procedure for ordering medicines but Ms Bird had explained them and there was no reason to believe that her verbal explanation was not being followed. He accepted Ms Bird had contacted the CQC about whether an AO was necessary. He stood by the inspection report's assessment of risk.

89. Jean Carter in her statements and in her evidence to the tribunal said that once medicines or medical equipment had become out of date, their potency or effectiveness or suitability cannot be guaranteed. Medications should not be used past their sell by date. Ms Carter said she would expect a sharps bin to be signed and dated, and not to have syringes sticking out of the top. She expected any excess in single use items to be discarded.

90. Emma Bird in her witness statement and in her evidence said she was appointed as hospital and theatre manager of BPH on 21 October 2013, and had commenced the procedure to be registered as manager by the CQC. She is registered with the HPC and has extensive clinical experience as both a theatre manager and as a registered manager with the Health Care Commission between 2006 and 2009. She has had nearly 20 years experience of theatre and hospital management in the NHS and private sector which was similar to BPH. She has worked since April 2012 as an agency ODP.

91. When appointed she familiarized herself with the difficulties at BPH and has worked with James McQuillan to implement an action plan. She noted the considerable investment there has been in the operating theatre and concluded the difficulties BPH has experienced stemmed from the lack of good clinical management and committed theatre staff. She planned to recruit new theatre staff, to be in the theatre for each operation and to review services with surgeons at the end of each operating day. She will be responsible for management of medicines and will implement monthly management meetings.

92. She has analysed the non-compliance aspects found in the CQC inspections, and she says these have been addressed or are being addressed. She has carried out a patient feedback analysis and found the overwhelming majority of patients have responded good or excellent. She appended a job description for hospital manager, a CV, detailed analyses of the CQC Notice of Proposal to Impose Conditions of 22 November 2012, and the Notice of Proposal to Cancel Registration of 3 April 2013, and set out how the shortcomings are being addressed.

93. Ms Bird was present at the inspection of 29 November 2013 by the CQC. She said there had been surgical operations the previous day (28 November 2013), but none were scheduled for 29 November 23013 and none until Wednesday 4 December 2013. She said that she had applied to be the registered manager but it was a lengthy process, taking over 2 weeks. She had not misled inspectors or the CQC when she said she was in the process of becoming registered.

94. She did not accept the finding of non-compliance relating to risk assessments for DVT, as BPH automatically deem all surgical patients as high risk and take appropriate measures including anti-embolism stockings and intermit pneumatic compression garments are applied during surgery. Patients are routinely asked about medications relevant to VTE risk and a clinical assessment is carried out by the surgeon. This is in accordance with NICE guidelines. Appropriate examples of checklists for VTE were appended to her witness statement.
95. Ms Bird did not accept the sharps bin in the consultation room was overfilled, merely that a syringe which had been disposed of in the bin

had not fallen completely into the bin, but lodged on the rim. She shook the bin and the syringe fell into the bin, which was not overfilled. There was no risk to patients. Photographs were appended which showed space in the bin below the "fill line". Ms Bird explained that because surgical operations had been performed on 28 November 2013, but no more were to be carried out for several days, the consultation and other rooms were due to be cleaned during the 29 November 2013 (the day of the inspection).

96. Ms Bird did not accept the clogs were stained with bodily fluids, but with iodine splashes. Blood would have turned black and the spots were not black. These would have been dealt with during the cleaning process on 29 November 2013. The tracheal tubes had been opened, as was normal, in readiness for any anesthetic emergency during surgery, but none had occurred, and the opened tube would have been disposed of and a new one prepared when operations were next performed.

97. In respect of out of date drugs and equipment, Ms Bird explained to the inspectors that she was in the process of implementing monthly audits. She had commenced in post towards the end of October, and planned to carry out the first audit on 29 November 2013, which was disrupted by childcare difficulties, so it was put back to Monday, 2 December 2013. That audit had now been completed – a copy of the audit record was produced – and medicines have been reorganized and rationalized and some 21 further out of date medicines disposed of. This was over and above the medicines found by the CQC inspectors and was shown in the audit record. The out of date medicines found on 29 November 2013 by the CQC inspection were assessed by Ms Bird as being highly unlikely to have been used. She had emailed staff with instructions about to do with out of date medicines, and reminded staff of their responsibilities. Emails were appended. She accepted she had responsibility for implementing safe procedures for the handling of medicines.

98. Ms Bird explained the new system of ordering CDs to the pharmacist inspector. She said she had not been in post long enough for a full written procedure. Ms Bird explained that following the implementation of the Controlled Drugs (Supervision of Management and User) Regulations 2013 in April 2013, it was uncertain, because of the small number of staff at BPH, whether it was necessary for BPH to have an AO. The Regulations apply if there are over 10 employees. There were 9 clinical staff on operations days including herself. There are 3 admin staff but they are not present on operation days, and in any event they are in a separate building.

99. A cleaner comes in when the operation lists finishes and would be present when clinical staff are present and this might make a total of 10 staff being present. The consulting rooms are not used on operating days. She had been told by the CQC on enquiring that they did not

need one. She has attempted to submit an application for exemption but has not had time to complete the process. There are no permanently employed staff other than herself.

100. Ms Bird said the one instance of the use of 1 ampoule of a CD for multiple patients was on 26 September 2013, before her appointment. Ms Bird said the practice was wrong, she would not tolerate it and it no longer happens at BPH. With respect to the gas cylinders, the two cylinders attached to the pipeline to the operating theatre were full, and gas was available. With respect to staff files, the staff members who had supplied references for each other had been working at BPH for over 10 years, and were very well known. Alternative or additional references were unnecessary. Those files without photo ID related to agency staff and there was no requirement for BPH to hold photo ID for these staff. The professional indemnity insurance for the surgeon had been received after the matrix was constructed and was available had she been asked about it. The matrix has now been updated.

101. The training matrix was in the process of being constructed. Many of the staff are agency staff, and it is the agency's responsibility to keep training up to date. This training is very rigorous. Agency staff who cannot demonstrate up to date training are not hired. Other staff are administrative staff and a training company has been contacted to provide their training. Emails confirming contact had been appended to the witness statement. An email confirming this has been sent to the CQC.

102. The staff member without exposure prone cover does not need it because he is only health cleared for non-exposure prone procedures. With respect to patient files, Ms Bird explained this forms part of her monthly audit which includes a spot check of 10 patient files, and any errors will be taken up with staff who will be further trained to ensure accuracy.

103. In her witness statement Ms Bird lists further improvements and changes she has made. These include revised checking procedures for resuscitation trolleys to meet the Resuscitation Council guidelines. There is a revised complaints procedure where all complaints come to Ms Bird, with a 2 day initial response and 20 day full response. The BPH is now registered with the Medicines and Healthcare Products Regulatory Agency, who provide daily updates on equipment and drugs.

104. All HR files have been reviewed and an undated checklist developed to ensure compliance. All clinical staff now have a full complement of mandatory training. Copies of training certificates were appended. If personnel did not have training they would not be employed. Ms Bird's own registration as hospital manager has been progressed with the CQC. Medical records are audited each month to

ensure compliance, and a full clinical audit, including drug prescriptions, fridge temperatures, resuscitation trolley checks, CD checks, full drug checks in 4 locations, audit of theatre register, anesthetic machine checkbook, is carried out monthly.

105. There is a new process for ordering CDs and supplies with a new specified order book, with a serial registration number allocated on delivery, signed by a doctor. There will be a formal written policy. The theatre and ward staff skills sets have been reviewed and a system implemented which ensures 4 qualified staff for theatre or 2 qualified staff for the ward. Quotes have been obtained for essential work to address water temperatures and heating issues, and copies of emails and quotes were appended. It was expected matters would be resolved on 9 December 2013, when works would be carried out.

106. It was suggested the risk of Legionella risk had been brought to the hospitals attention some time ago. Ms Bird said this was unacceptable but Legionella risk was now being addressed. The unfulfilled assurances in the Pemberdeen response of 29 November 2012 were put to Ms Bird. She accepted this was unacceptable and shouldn't have happened but these matters were now being addressed by her. She said Mr Bartlett had been poorly advised in the past, but she knew what she was doing and she is implementing the necessary changes.

107. All the staff they employ are registered with their professional bodies, and all have CRB checks, but it was not yet possible to employ full time staff as there are only operations once or twice a week. When operations increase she will be able to offer 20 hour contracts. The director she works to is Joanita Ndagire, not Mr Bartlett. She said she had confidence that appropriate financing would be available and the director had confirmed this. She had never felt constrained in implementing the new procedures, and she felt well supported by Joanita Ndagire. She had not stopped the operations pending implementation of the changes – it was not necessary. The CQC had powers to close BPH if there was a serious risk.

108. All patient satisfaction questionnaires are now reviewed individually; results are followed up and entered on a spreadsheet for reference for the Monthly Management Report. A Patient Questionnaire Review was appended. Monthly hospital reports are completed, highlighting areas to note with updates on staffing, audits and complaints. An example for November 2013 was appended. There are monthly management meetings, with the next meeting which had been scheduled for 5 December 2013 to take place on 10 December 2013.

Decision with reasons

109. Under section 32(3) of the 2008 Act, on an appeal from decisions of the CQC, the FTT may confirm the decisions or direct that they are not to have effect. Under Sec 32(6) of the 2008 Act the FTT may direct that any discretionary condition the FTT think fit shall have effect. In deciding the appeals the FTT steps into the shoes of the CQC and will have regard inter alia to views expressed by or on behalf of members of the public about health and social care, to the experiences of service users and their family and friends, to the need to protect and promote the rights of service users, and the need to ensure any decision is proportionate to the risks and targeted only where it is needed. The burden of proof is on the CQC to show on the balance of probabilities that they were justified in imposing the condition and cancelling the registration.

110. We had regard to all the documentary and oral evidence in the case, including evidence of events both before and after the date of the appeals. We also had regard to the summary of agreed issues dated 29 November 2013, which states inter alia that the findings of the CQC inspectors prior to 29 April 2013 (the date of the Appellant's action plan) are not challenged. There was in fact little challenge to the evidence of the CQC inspectors arising from the inspections of BPH save for the more recent inspection in November 2013, although some of the evidence of the appellant's experts seemed to suggest more general challenges to CQC methodology. We also had regard to the parties' skeleton arguments and written closing submissions.

111. The case for the respondents is that they say BPH has a long and significant history of non-compliance in a significant number of areas which have affected the safety of service users sometimes in a major way. They say non-compliance has persisted despite a significant number of adverse inspection reports, follow ups, warning notices, the imposition of a condition and the cancelling of the hospital's registration. They submit that assurances of change given by BPH in several action plans and by more informal contacts have not been met.

112. More specifically they submit BPH's non-compliant handling of medicines including out of date medicines and the absence of an AO has persisted. They say staff checks including CRB and references have been a further persistent area of non-compliance. They say the appointment of senior members of BPH responsible for compliance including the NI, the manager and the AO has often been unsatisfactory and short lived. There has been no evidence from Mr Bartlett, and evidence from BPH experts has been given by witnesses who do not have relevant experience.

113. Other persistent areas of concern have been the hot water system and legionella risk assessment, and also the areas of patient

safety identified in the November 29 2013 inspection. Further they say the BPH has shown lack of insight in downplaying risks to patient safety including risks of cross infection, out of date medications and incomplete records. The respondents have opted not to make submissions (or suggest conditions) specifically in respect of imposing conditions.

114. The case for the appellants is that they submit the CQC has failed to have regard to the matters set out in section 4 of the 2008 Act, and has not been reasonable, rational or fair in its decisions. The appellants note that the CQC does not rely on any instances of actual harm, but on perceived risk. The respondents note the CQC has not resorted to its emergency powers under sections 30 and 31 of the 2008 Act. They say they accept the historic compliance issues but say there has been progress which has not been recognised by the CQC. They submit the CQC has not distinguished between regulatory requirements, guidance and best practice. They submit even on the basis of the CQC's inspections there has been a clear pattern of improvement.

115. More specifically they say it was not necessary to call Mr Bartlett who no longer has any direction over the day to day operation of BPH and is no part of its corporate structure. His replacement as NI, Ms Ndagire, has been supportive financially and managerially. They note Mr Duggall the author of the inspection report for the 29 November 2013 did not provided a witness statement, was not called as a witness and could not therefore be cross examined.

116. The appellants state that both Mr McQuillan and Ms Bird have given evidence about the improvements that have recently been made or are in the process of implementation and suggest that much of this evidence is unchallenged. They say the inspection of the 29 November 2013 found noncompliance in respect of only 4 regulations. The appellants say their DVT procedure followed the NICE guidelines, the sharps bin posed no identified risk, the respondents had not shown the laryngoscopes were not being checked appropriately or shown that the clogs were stained with human fluids. Cleaning was to take place later on the day of the inspection.

117. It is submitted by the appellants that the respondent failed to appraise itself of the many improvements which had or were in the process of being implemented, including out of date medicines, existence of an AO and gas cylinder management (which they say is a non-statutory matter in any event). They also say the respondents gave a disproportionate assessment of risk in respect of out of date medicines, failing to take account of its location, likelihood of use and the nature of the medication.

118. It is submitted by the appellants that alleged noncompliance in respect of staff records, the training matrix and the audit matrix by the

CQC are pedantic and don't recognise the real level of risk, are erroneous in parts and/or the CQC has failed to mention the explanations given by Ms Bird, and have not consulted service users. They say there is no statutory requirement as to the minimum number of employed personnel.

119. The appellants say the difficulties in compliance at the hospital stem from poor choices of management staff, but that more recently the BPH has begun to remedy this problem with appropriate managerial appointments, and appropriate systems are now in place. They submit cancellation of registration or the imposition of the non-practicing condition would be disproportionate. They suggest that any condition should be limited to reporting the monthly audits to the CQC. The appellants submitted that for various reasons that an AO is not necessary for BPH under the terms of the Controlled Drugs (Supervision of Management and Use) Regulations 2006.

120. We considered the matter. We did not feel it necessary to resolve every disagreement between the parties. For example we did not feel it necessary or appropriate to seek to resolve the issue of whether the 2006 Regulations apply to BPH. We concluded that whether or not BPH required a AO could not be decisive of the appeals whether considered as either a separate discrete concern or taken incrementally with other concerns.

121. We accepted that during May to December 2012 and during 2013, the CQC implemented an appropriate compliance assessment process in respect of BPH. We considered 2012 first. In 2012 there were 4 inspections and 4 warning notices. We accepted that inspections and warnings were properly implemented as a result of legitimate compliance concerns. We noted that some 6 of the areas of non compliance during this period were judged to be of major impact.

122. We also accepted that feedback to BPH, including inspection reports, informal communications, warning notices and the notice of proposal to impose a condition, properly ensured BPH were fully aware of the areas of noncompliance and what was expected by way of remediation and the date when remediation should be completed. The response of the BPH during this period was undoubted poor. It failed to secure a registered manager for a significant period, and it failed throughout the period to implement procedures to ensure medicines were always appropriately managed, or that there was appropriate care and welfare of service users.

123. Further it was slow to seek to implement remedial measures, including the appointment of appropriate staff, and assurances made were often not kept. There was evidence that management staff, when appointed, were not always appropriately supported. The position at the end of 2012 appeared to have deteriorated, not improved, from May of that year, with important emergency medicines and equipment

not always available. Matters had deteriorated to the point where the CQC sought to impose a condition to prevent operations without the agreement of the CQC.

124. However it is not the case that the noncompliance identified by the CQC was simply ignored by BPH. We accepted that some effort was made by the hospital to implement remediation measures through action plans and other contact with the CQC, and some improvements were made, although these remediation efforts were not sufficiently effective. The reason for the failure to bring about effective change is not entirely clear but the appellants have suggested that it stemmed from the fact that appropriate managerial staff were not appointed, and we concluded in view of the turnover of management staff this may well have been a significant contributing factor. There also is some evidence to suggest poor support for managerial staff and poor financial management may have been factors.

125. Compliance was still very poor at the beginning of 2013. Up to the inspections of 11 and 12 March matters seemed to worsen as action plans were not fully implemented and there was noncompliance with a major impact in 5 areas of the regulations. For example management of medicines was still an area of major concern, as was staff management. The CQC sought to impose deregistration as a result of these escalating failures.

126. However after March 2013 there appeared to be signs of the start of some improvement albeit there were still areas of concern. In the 3 inspections that took place after March 2013, none of the areas of concern were judged to be of a major impact on service users, although there were a significant number of moderate and minor matters and there was still some turnover of managerial staff.

127. Pia Davies, appointed in May 2013, appeared to make some improvements but she did not have clinical experience and knowledge and appeared to make decisions for BPH which were not always appropriate. However she sought assistance from outside consultant Mr McQuillan who found the hospital generally compliant but made some recommendations for improvements to the system in his report of 19 August 2013, and it appears from the reduction in major impact noncompliance that improvements were beginning to be implemented by Ms Davies. These are documented in Mr McQuillans report.

128. This improving trend was temporarily halted when Ms Davies left PBH at the end of August 2013, and an inspection just a few days later on 4 September 2013 found matters in some disarray at the hospital. We accepted Mr McQuillan made efforts to stabilize the situation but a number of concerns were found by the inspectors. We did not accept Mr McQuillan's criticisms of the inspection of the 4 September 2013. In our view the findings of the CQC inspectors must be assessed against

the lengthy background of non-compliance by BPH, and we concluded their judgments were appropriate.

129. Improvements were further indicated by the engagement of Mr Slimm. He produced a report following a site visit on 4 November 2013. We noted his interviews with some users of the hospital had been included in the report and we accepted that this was a useful methodology and reflected the criteria set out in section 4 of the 2008 Act. Mr Slimm found the hospital generally compliant and we accepted that this audit reflected a general improvement of standards at BPH, albeit there were still areas of concern. We did not accept his criticisms of the CQC risk assessment, both because he had no clinical experience and because the risks at BPH had in our view to be assessed against the long background of non-compliance at the hospital.

130. We noted that by the time of Mr Slimm's site visit on 4 November 2013 Ms Ndagire had been appointed to the role of NI. This was an important step because it removed Mr Bartlett who had been the NI during BPH's periods of greatest non-compliance. Ms Ndagire proved to be an effective NI and supportive of improvements at the hospital, according to Ms Bird.

131. We noted also that by 4 November 2013 Ms Bird had been appointed hospital manager. It was apparent to us that she was very well qualified for the position having held similar posts and crucially having relevant clinical experience. Moreover it was apparent as we listened to her evidence that she was not just well qualified and experienced but she had the right qualities of determination, persistence and attention to detail that were in our view required for the post.

132. She was in our opinion a very good witness – knowledgeable and experienced in clinical and managerial matters – and a very good manager. It was the case that inspectors found 3 areas of moderate concern and 1 area of minor concern during the inspection on 29 November 2013 but in the short time available to her before the inspection, Ms Bird had already established a number of important procedures that would significantly assist in achieving compliance. Furthermore she was in the process of implementing others. She produced documentary evidence of these procedures.

133. These improvements were that she had commenced the procedure to be registered with the CQC. She was working with the consultant Mr McQuillan to implement his action plan. She was in the process of implementing a monthly medicines audit and has now completed the first such audit which resulted in a number of out of date medicines being removed. She produced documentary evidence of this. She has developed patient feedback procedures. She has established monthly management meetings.

134. She has also established written checklists for DVT assessment which set out actions taken in this respect. She has established cleaning rosters and a new system of ordering CDs. We were satisfied a written version of the medicine ordering policy would quickly follow. She has established new systems of collating staff and training records and was in the process of implementing them, and has established a system of checking patient records.

135. There is a revised complaints procedure, and a clinical audit system which includes regular monitoring of the resuscitation trolleys. New requirements for skill sets in respect of clinical staff and legionella risk assessments would, we were satisfied, be implemented. Ms Bird was moving towards offering staff 20 hour contracts, which would assist in securing regular staff.

136. In any event we did not consider the current arrangement of hiring regular agency and bank staff was inherently unsatisfactory, so long as systems were in place to manage them appropriately, and we accepted that Ms Bird would implement such systems. We noted that Ms Bird worked well with Ms Ndagire, feeling appropriately supported, and had not experienced any financial restrictions on her ability to bring about change.

137. We did not accept Ms Bird's views about the risks of some aspects of noncompliance being less than that assessed by the CQC. But neither did we accept that this demonstrated a lack of insight. We were satisfied that Ms Bird took risks to patients from noncompliance extremely seriously and would do all she could to ensure compliance.

138. We could understand the CQC's reluctance to accept Ms Bird's assurances during the inspection of 29 November 2013. They are required to assess the position as they find it on the day of the inspection. Furthermore they had been given a number of assurances by BPH staff in the past which had not been kept. However for all the reasons set out above we accepted that Ms Bird was coming to grips with the problems at BPH in a realistic and effective manner, and would raise standards at the hospital and ensure a proper level of compliance. Once all the systems described by Ms Bird were embedded then we accepted compliance could be maintained by any other appropriately qualified and experienced manager.

139. Both parties criticized the other for not calling certain witnesses. We do not draw any adverse inferences from the non-appearance of a witness or speculate as to what might have been said.

140. We considered conditions but the CQC did not seek or suggest any and we concluded that we had received sufficient assurance that standards will be improved and maintained without additional

conditions. We concluded that the CQC's existing powers were sufficient without further conditions.

141. For the reasons set out above we concluded the proportionate decision taking into account all relevant matters was to uphold both appeals.

Decision

Both appeals are successful. No condition is to be imposed and registration is not cancelled.

Judge John Burrow
Tribunal Judge Care Standards

Date Issued: 7 January 2014