

# Investigation Report

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## Investigation of a complaint against the South Eastern Health & Social Care Trust

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**NIPSO Reference: 20732**

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## **The Role of the Ombudsman**

The Northern Ireland Public Services Ombudsman (NIPSO) provides a free, independent and impartial service for investigating complaints about public service providers in Northern Ireland.

The role of the Ombudsman is set out in the Public Services Ombudsman Act (Northern Ireland) 2016 (the 2016 Act). The Ombudsman can normally only accept a complaint after the complaints process of the public service provider has been exhausted.

The Ombudsman may investigate complaints about maladministration on the part of listed authorities, and on the merits of a decision taken by health and social care bodies, general health care providers and independent providers of health and social care. The purpose of an investigation is to ascertain if the matters alleged in the complaint properly warrant investigation and are in substance true.

Maladministration is not defined in the legislation, but is generally taken to include decisions made following improper consideration, action or inaction; delay; failure to follow procedures or the law; misleading or inaccurate statements; bias; or inadequate record keeping.

The Ombudsman must also consider whether maladministration has resulted in an injustice. Injustice is also not defined in legislation but can include upset, inconvenience, or frustration. A remedy may be recommended where injustice is found as a consequence of the failings identified in a report.

## **Reporting in the Public Interest**

This report is published pursuant to section 44 of the 2016 Act which allows the Ombudsman to publish an investigation report when it is in the public interest to do so.

The Ombudsman has taken into account the interests of the person aggrieved and other persons prior to publishing this report.

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## SUMMARY

I received a complaint regarding the actions of the South Eastern Health and Social Care Trust. The complaint concerned the Trust's actions in relation to the care and treatment provided to a patient (the complainant) who had attended at the Ulster Hospital, Dundonald with spontaneous rupture of membranes at 38+2 weeks gestation and a history of a positive Group B Streptococcus test in the pregnancy. The complainant was concerned that her induction of labour was not managed appropriately and that there was a delay in antibiotic treatment which caused both her and her baby to contract a severe infection.

The investigation of the complaint focused on the steps taken when the complainant required an induction of labour, and on the risks associated with the complainant's Group B Streptococcus infection and whether these were appropriately managed. .

The investigation of the complaint did not identify failings in the care and treatment provided to the complainant by the Trust in respect of the induction process or in the management of her Group B Streptococcus, or the infection which she subsequently contracted.

## THE COMPLAINT

1. The complainant tested positive for Group B Streptococcus infection (GBS)<sup>1</sup> during this (her first) pregnancy. On 3 September 2017, at 38 +2 weeks gestation, she experienced spontaneous rupture of membranes (SRM) (breaking waters) and contacted the Emergency Obstetrics Unit (EOU) of Ulster Hospital, Dundonald (UHD). She was advised to attend in person. She was examined and steps were taken to induce her labour. The complainant developed sepsis during the induction process. Her baby girl was delivered on 4 September 2017 following a complicated delivery. Both the complainant and her daughter were treated with IV antibiotics in hospital for five days following delivery. She complained to the South Eastern Health and Social Care Trust (the Trust) about the care and treatment she received on 3 and 4 September 2017. She complained that her labour ought to have been induced more expeditiously and that she ought to have been administered anti-biotics immediately at the EOU.

### Issues of complaint

2. The issue of complaint which I accepted for investigation was:

**Issue 1: Whether the care and treatment provided in relation to Group B Streptococcus infection and induction was in accordance with good medical practice.**

## INVESTIGATION METHODOLOGY

3. In order to investigate the complaint, the Investigating Officer obtained from the Trust all relevant documentation together with the Trust's comments on the issues raised by the Complainant. This documentation included information relating to the Trust's handling of the complaint.

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<sup>1</sup>GBS is a common bacterium which is carried in the vagina and rectum. If GBS is passed from mother to baby around the time of the birth, there is a small chance the baby will develop an infection and become seriously ill. 7 out of 10 babies diagnosed recover fully, 2 in 10 babies with GBS infection will recover with some level of disability, and 1 in 10 infected babies will die. (Source: RCOG: 2013)

## **Independent Professional Advice Sought**

4. After further consideration of the issues, I obtained independent professional advice from the following independent professional advisor (IPA):

- Midwife, Registered Midwife (MIPA), who has worked for 25 years as a midwife, including working as a labour ward coordinator Band 7 midwife. Currently working as a maternity clinical advisor reviewing maternity records providing an expert witness opinion on care where a clinical incident has occurred.

5. The information and advice which have informed my findings and conclusions are included within the body of my report. The IPA has provided me with 'advice'; however how I have weighed this advice, within the context of this particular complaint, is a matter for my discretion.

## **Relevant Standards**

6. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those which are specific to the circumstances of the case.

The general standards are the Ombudsman's Principles<sup>2</sup>:

- The Principles of Good Administration
- The Principles of Good Complaints Handling
- The Principles for Remedy

7. The specific standards are those which applied at the time the events occurred and which governed the exercise of the administrative functions of the Trust and the professional judgement of the clinicians whose actions are the subject of the complaint.

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<sup>2</sup> These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

The specific standards relevant to this complaint are:

- South Eastern Health and Social Care Trust '*Management of Group B Streptococcal (GBS) Infection and Early Onset of Neonatal Infection*' dated November 2015 (the Trust's GBS Management Policy)<sup>3</sup>;
- National Institute for Health and Care Excellence (NICE) clinical guideline entitled '*Intrapartum care for healthy women and babies*' published on 3 December 2014 (NICE guideline 190);
- National Institute for Health and Care Excellence guideline entitled '*Prevention of Early Onset Neonatal Group B Streptococcal Disease*' published in July 2012 (the NICE GBS guideline);
- National Institute for Health and Care Excellence clinical guideline entitled '*Inducing labour*' published in July 2008(the NICE induction guideline);
- Nursing and Midwifery Council, '*The Code*' published in March 2015 (the NMC Code);
- Royal College of Gynaecologists (RCOG) publication '*Information for you: Group B streptococcus (GBS) infection in newborn babies*' (the RCOG information leaflet),and
- Department of Health, Social Services and Public Safety (DHSSPS) Circular HSS(MD) 18/2013 issued on 10 June 2013 (the DHSSPS circular)

8. I have not included all of the information obtained in the course of the investigation in this report but I am satisfied that everything that I consider to be relevant and important has been taken into account in reaching my findings.

9. A draft copy of this report was shared with the complainant and the Trust for comment on factual accuracy and reasonableness of the findings and recommendations.

## INVESTIGATION

### Issue 1: Whether the care and treatment provided in relation to the

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<sup>3</sup> The Trust's GBS Management Policy incorporates the Royal College of Gynaecologists (RCOG)'s 'Green-top Guideline number 36' entitled 'Prevention of Early-onset Neonatal Group B Streptococcal Disease

## **Complainant's Group B Streptococcus infection and induction was in accordance with good medical practice.**

### a. Induction of labour

#### **Detail of Complaint**

10. When the complainant attended at the UHD EOU, she was examined and her labour was induced by way of a Prostaglandin pessary (Propess)<sup>4</sup>. Later in the induction process, Syntocinon<sup>5</sup> was administered. The complainant said that because she had tested positive for GBS in her pregnancy, her labour ought to have been induced more expeditiously by use of a more fast acting method, namely Syntocinon IV<sup>6</sup> medication at the outset.

#### **Evidence Considered**

#### **Legislation/Policies/Guidance**

11. I considered the Trust's GBS Management Policy. Section 4.22 of the Trust's GBS Management Policy refers to 'pre-labour rupture of membranes at term' and state *'4.20 Women known to be colonised with GBS who experience spontaneous rupture of membranes at 37 weeks gestation or more should be offered the induction process immediately and commence IAP<sup>7</sup>*
- 4.21 However these infants must be observed at ward level and have clinical observations taken and recorded...'*
12. I also considered the NICE guideline 190. Section 1.3 refers to the 'latent first stage of labour' and states
- '1.3.1 For the purposes of this guideline, use the following definitions of labour:*
- *Latent first stage of labour – a period of time, not necessarily continuous, when:  
-there are painful contractions and*

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<sup>4</sup> Prostaglandin is a hormone administered in the induction of labour

<sup>5</sup> A hormone based administration, used to induce labour

<sup>6</sup> Intravenous (through a vein)

<sup>7</sup> Intrapartum antibiotic prophylaxis – antibiotic therapy used to treat GBS from the onset of labour

*-there is some cervical change, including cervical effacement and dilation up to 4 cm.*

- *Established first stage of labour – when:*
  - there are regular painful contractions and*
  - there is progressive cervical dilation from 4 cm’*

13. I also considered the NICE GBS guideline. I note the following relevant extract:

*‘5.4 How should women known to be colonised with GBS who experience spontaneous rupture of membranes at term be managed?’*

*Immediate induction of labour and IAP should be offered to all women with prelabour rupture of membranes at 37+0 weeks of gestation or more.*

*The NICE guideline on induction of labour recommends that all women with prelabour rupture of membranes at term (37 weeks +0 days of gestation or greater) should be offered immediate induction of labour, or induction after 24 hours. If GBS colonisation was identified earlier in the pregnancy...immediate induction of labour and IAP should be offered’*

14. I considered the NICE induction guideline I note the following relevant extract:

*‘1.2.3 Prelabour rupture of membranes at term*

*1.2.3.1 Women with prelabour rupture of membranes at term (at or over 37 weeks) should be offered a choice of induction of labour with vaginal PGE [Prostaglandin] or expectant management.*

*1.2.3.2 Induction of labour is appropriate approximately 24 hours after prelabour rupture of the membranes at term’*

15. Finally, I considered the NMC Code, in particular point 4 which states:

***‘4 Act in the best interests of people at all times***

*To achieve this, you must:*

*4.1 balance the need to act in the best interests of people at all times with the requirement to respect a person’s right to accept or refuse treatment Nursing and Midwifery Council*

4.2 make sure that you get properly informed consent and document it before carrying out any action...'

### **Trust's response to investigation enquiries**

16. In response to investigation enquiries , the Trust stated '*a syntocinon drip was not commenced upon [the complainant's] admission, as findings from the initial examination confirmed that, despite the membranes having ruptured, The Complainant was not in labour. Furthermore, examination confirmed the cervix was not favourable for labour. The rationale for inserting a pessary and commencing the Induction of Labour (IOL) was to prepare the cervix to dilate...the prostaglandin in the pessary softens the cervix in preparation for the next stage of the induction process: the commencement of a Syntocinon infusion...*'

### **Clinical Records**

17. I carefully reviewed the complainant's maternity records. The clinical records document as follows :

3 September 2017

**11.05** [first attendance at EOU] '*...clear liquid draining since 09.15 hours nil tighenings*

*Relevant medical history*

*H/O [history of] GBS...plan to admit to IOL [induction of labour] bay'*

**12.05** '*admitted via EOU for IOL...IOL checklist completed'*

**12.30** '*vaginal examination to insert propess. Dilation – fingertip'*

4 September 2017

**02.30** '*[The complainant] remains sore with cramps and tighenings. Offered to do VE [vaginal examination] to assess progress and give diamorphine for pain relief. Consent given.'*

*Vaginal examination to assess progress in view of pain relief. Dilation – 1 cm*

**07.30** '*vaginal examination to assess progress, reinsert propess*

**09.30** '*propess removed*

**12.30** '*propess reinserted*

**12.40** *Syntocinon regime commenced as per [Consultant Obstetrician]*

**12.50** *vaginal examination prior to Syntocinon assessment*

**15.35** *Syntocinon increased to 12 mls/hr as per protocol*

**16.35** *Syntocinon increased to 15 mls/hr*

**17.00** *vaginal examination 4 hours since Syntocinon. Dilation – 6 cm*

**17.30** *Syntocinon increased to 18 mls/hr'*

### **Relevant Independent Professional Advice**

18. The MIPA was asked about the complainant's presentation when she first attended the EOU. The MIPA advised '*...the clinical history and observations of vital signs confirmed that [the complainant] was not in established labour and was in the early phase of labour known as the latent phase*'. The MIPA further advised that following the initial clinical assessment '*immediate Induction of labour commenced at 12.30 hours with Propress 10mgs being administered*'. The MIPA advised that these steps were appropriate and in accordance with the NICE clinical guidelines.
19. The MIPA was asked about the administration of syntocinon drip. The MIPA advised '*... at 11.30 hours on 4 September 2017 the Obstetrician reviewed [the complainant] and a care and treatment plan was put in place to continue with the current management for augmentation of the labour with a syntocinon infusion...*' The MIPA was asked to explain the reason for this. The MIPA advised there were two reasons, namely that the labour had not progressed and that the complainant was developing symptoms of sepsis, meaning that the labour had to be accelerated.
20. Further, the MIPA was asked to address the complaint that the Syntocinon drip ought to have been administered upon the first attendance at the EOU. The MIPA advised that the propress is released continuously over a period of 24 hours and '*on balance of the single risk factor, it was appropriate to commence an induction of labour rather than administer the Syntocinon infusion*'.

### **Analysis and Findings**

21. The complainant said that her labour ought to have been induced by a different method namely by administration of IV syntocinon. She also believes that this would have expedited her labour.

22. I considered the relevant NICE guidelines in relation to the induction of labour in general and the specific guidelines in relation to the prevention of GBS related complications in cases where there is prelabour SROM. I note that the recommendation in a non-GBS pregnancy is for induction after 24 hours of SROM, however in a GBS pregnancy, immediate induction of labour is recommended. I also considered the MIPA's advice in relation to the induction of labour process. In particular, I accept the MIPA's advice that the Trust actions were correct in that staff identified a requirement to induce labour quickly. I also accept the advice of the MIPA that the means of inducing labour, that is the insertion of a Propess, was appropriate for the stage of labour indicated by the complainants examination. She also advised that the steps taken were in compliance with the NICE guidelines in relation to induction of labour.

23. I note that the following day (4 September 2017), the complainant was commenced on a syntoncinon infusion. I accept the advice of the MIPA that this was due to the labour not progressing and a requirement to expedite labour due to the complainant's examination. I therefore find that there was no failing in the Trust's actions to commence induction of labour on 3 September 2017 by means of a pessary [propess] rather than IV syntocinon or by any other means.

b. Antibiotic therapy

**Detail of Complaint**

24. The complainant stated that as she had tested positive for GBS in her pregnancy, she ought to have been immediately administered with antibiotics when she presented on 3 September 2017 with SROM. She considers this would have prevented the GBS infection from developing and passing to her unborn baby.

**Evidence Considered**

**Legislation/Policies/Guidance**

25. I considered again the Trust's GBS Management Policy (paragraph 11 refers) and I also note the following relevant extract:

'4.7 INTRAPARTUM:

#### 4.8 Indications for offering GBS Specific IAP are:

*...GBS Bacteriuria in the current pregnancy'*

26. I also considered the RCOG information leaflet. In particular I note the following extract:

***'Why would I not be given antibiotics for GBS during my pregnancy?***

*-if you are a carrier; treating GBS with antibiotics before labour begins will not reduce the chance of passing it to your baby. This is because, in the majority of cases GBS returns after the antibiotic course has finished and therefore it is usual to wait and offer you antibiotics when you go into labour. This has been shown to be effective in reducing infection in babies...'*

27. I considered the DHSSPS circular. This circular contains a clinical matrix as '*an aide memoire for staff and is based on the revised RCOG guideline...*'. In relation to a patient where GBS has been identified in the current pregnancy, the matrix indicates '*> 37+0 wks and not in labour and ROM, **immediate IOL***'.

#### **Trust's Response to investigation enquiries**

28. In response to investigation enquiries, the Trust stated '*when the Complainant was admitted to the IOL<sup>8</sup> Ward, she was not in the intrapartum stage and therefore, not at the stage for commencement of antibiotics...*' The Trust referred to the NICE guideline 190 referred to in paragraph 12. The Trust also referred to the DHSSPS Circular which it stated '*informs professionals that when a mother is diagnosed as GBS [positive] in the current pregnancy and presents at terms with pre-labour rupture of membranes, the management plan is for immediate IOL and intravenous intrapartum antibiotics (IAP) to be commenced as soon as possible after the onset of labour*'.

#### **Clinical Records**

29. The clinical records referred to in relation to the induction of labour are also relevant to the issue of the administration of antibiotics (paragraph 17 refers). However the following entries in the complainant's maternity records are particularly relevant to

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<sup>8</sup> Induction of labour

this issue:

3 September 2017

**12.05** Intrapartum Risk Factors table completed. '*GBS in Urine and/or Vaginal / Rectal swabs (current pregnancy)*' noted

4 September 2017

**10.00** ...*antibiotic therapy d/w [discussed with] MO [medical officer] as requires sepsis 6 antib's and GBS antib's. Decision to give sepsis 6 antib's only as it adequate cover*

**10.30** *Amoxicillin 2 gms commenced in 100mls*

**11.20** *Metronidazole<sup>9</sup> 500mg IV commenced*

**18.55** *Amoxicillin 2 gms in 100ml NaCl<sup>10</sup> IV*

### **Relevant Independent Professional Advice**

30. The MIPA was asked to review the Trust's assertion that the complainant was not immediately administered antibiotics as she was in the 'latent' stage of labour. The MIPA stated that following a review of the relevant policies, they '*clearly state that antibiotics should only be administered when a woman is in the intrapartum episode of care*'. The MIPA referred to NICE guideline 190 and advised '*When [the complainant] presented she was not contracting and cervical dilation admitted a fingertip/1cm - subsequently [the complainant] was induced with prostaglandin and whilst she experienced mild crampy tightening's ( not painful ) the cervical dilation remained unchanged at 1cms throughout the night. Therefore based upon the definition of NICE guidance [the complainant's] clinical picture informs that she was not in the intrapartum pathway of care*'.
31. The MIPA also advised that the reason why it is not recommended to administer antibiotics prior the intrapartum stage is that '*the point of greatest risk for transmission of the bacteria to babies is during labour or during the birth. Additionally the RCOG stated that women who are known to be a carrier (as in the case of [the complainant]) treating Group B Streptococcus with antibiotics before labour begins*

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<sup>9</sup> Antibiotic

<sup>10</sup> Sodium Chloride

*will not reduce the chance of passing it on to the baby.’* The MIPA advised that in this case *‘the antibiotics administered [to the complainant for sepsis] would be effective with treating GBS...’*

32. The MIPA concluded that the actions taken by Trust staff were appropriate and in accordance with the guidance and policies relevant at the time of the complainant’s treatment. The MIPA advised *‘there is no evidence to suggest that the infection lead to the traumatic or fast birth of [the complainant’s] daughter’.*

Complainant’s response to draft investigation report

33. In response to the draft investigation report, the complainant stated her daughter *‘had sepsis/GBS infection and was in distress and born very quickly as a result’* and that she required hospital treatment for five days following delivery. The complainant also stated that no risks of infections or complications were explained to her. Further, the complainant said that she considered she should have been observed more closely by Trust staff.

### **Analysis and Findings**

34. I note the complainants concerns about the timing of the administration of antibiotics in her care. She also believes that earlier administration may have avoided her becoming acutely unwell or her daughter acquiring an infection.
35. However, I note and accept the advice of the MIPA that all the sources of policy and guidance in relation to this clinical area indicate that antibiotic treatment should commence when the patient is in the intrapartum stage of care, which is established labour, through the administration of IAP (as the name suggests). I note the MIPA’s advice that the reason for this is that antibiotic treatment is most effective when labour is at that particular stage and closer in time to the birth. I note also that in the complainant’s case, antibiotic therapy commenced prior to the intrapartum stage however this was due to the complainants deteriorating condition and there was a concern that the complainant was developing sepsis<sup>11</sup>, not to treat GBS. I accept the advice of the MIPA that the antibiotics administered were suitable for treating both, and that the action was appropriate and reasonable. I accept this as further evidence

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<sup>11</sup> Sepsis is a potentially life threatening reaction to an infection (Source:nhs.uk)

that despite the earlier administration of antibiotics, and taking action in accordance with the guidance, Trust staff were unable to prevent the complainant's baby from contracting the infection. I note the complainant's comments in relation to communication and I trust that the complainant is reassured somewhat by my findings that Trust staff took the reasonable steps to avoid complications by following the guidance in place at the time of her care.

36. I therefore find there was no failing in the Trust's actions in relation to when the complainant was first administered with antibiotics.

#### Record keeping

37. In providing advice, the MIPA raised an issue about the detail of record keeping within the complainant's maternity records. The MIPA advised *'the midwifery record keeping is acceptable, however, discussion from the midwife with [the complainant] about ongoing care, management and treatment have not been recorded within the record keeping...'*

38. The MIPA referred to the NMC code and advised *'...due to the use of checklist proforma the records (sic.) keeping records are limited and do not demonstrate fully that [the complainant] had given informed consent to go ahead with the induction of labour.'*

*Furthermore there are not any written records that evidence the detailed discussion with [the complainant] re induction of labour process and with particular reference to augmentation took place. Alongside there are not any written records around the discussion whereby [the complainant] was informed of the risk and benefits of the process, the proposed methods to be used and plan should the Induction of labour fail, infection rates for fetal and maternal . All of these points should have been recorded within the records...'*

39. The MIPA raised a further issue regarding the use of checklist proformas within the records and advised that *'...it is difficult to know the level of detail for any discussions that took place between [the complainant] and the midwife with particular reference to the following point*

- *when [the complainant] presented with ruptured membranes and following confirmation of the rupture of membranes, she should have been counselled of the risks of maternal and neonatal infection. This would have provided an opportunity for [the complainant] to discuss the administration of antibiotics within the induction of labour process and an opportunity to raise any questions or concerns that she had...'*

40. Although not an issue which is the subject matter of this complaint, the issue of record keeping is pertinent and important to all aspects of care and treatment. I note within the complainant's clinical records, an information leaflet regarding the induction of labour and an information leaflet regarding the GBS test that the complainant undertook privately. I therefore conclude that the complainant had information available to her regarding these issues. However, I note the advice of the MIPA and make an observation that the records identified by the MIPA lack the detail required by the NMC code. The Trust may wish to reiterate to the staff involved in the complainants care and treatment the importance of keeping an appropriate record of discussions with patients as well as clinical observations and decisions made regarding care and treatment to ensure that they comply with professional standards and trust policies.

## CONCLUSION

41. The complainant submitted a complaint to me about the actions of the Trust regarding her care and treatment from the time she presented with SR0M at the EOU.
42. I have not found failings in respect of the care and treatment provided to the complainant. However, I did make an observation to the Trust about the importance of good records and that they may wish to reiterate to staff the importance of keeping an appropriate record of discussions with patients.

43. In response to the draft investigation report, the Trust stated it agreed with the findings and conclusion within the draft report including an action in regards to record keeping.

A handwritten signature in black ink, appearing to read 'Paul MCFADDEN', written over a faint horizontal line.

**PAUL MCFADDEN**  
Acting Ombudsman

**July 2020**

## PRINCIPLES OF GOOD ADMINISTRATION

Good administration by public service providers means:

**1. Getting it right**

- Acting in accordance with the law and with regard for the rights of those concerned.
- Acting in accordance with the public body's policy and guidance (published or internal).
- Taking proper account of established good practice.
- Providing effective services, using appropriately trained and competent staff.
- Taking reasonable decisions, based on all relevant considerations.

**2. Being customer focused**

- Ensuring people can access services easily.
- Informing customers what they can expect and what the public body expects of them.
- Keeping to its commitments, including any published service standards.
- Dealing with people helpfully, promptly and sensitively, bearing in mind their individual circumstances
- Responding to customers' needs flexibly, including, where appropriate, co-ordinating a response with other service providers.

**3. Being open and accountable**

- Being open and clear about policies and procedures and ensuring that information, and any advice provided, is clear, accurate and complete.
- Stating its criteria for decision making and giving reasons for decisions
- Handling information properly and appropriately.
- Keeping proper and appropriate records.
- Taking responsibility for its actions.

**4. Acting fairly and proportionately**

- Treating people impartially, with respect and courtesy.
- Treating people without unlawful discrimination or prejudice, and ensuring no conflict of interests.

- Dealing with people and issues objectively and consistently.
- Ensuring that decisions and actions are proportionate, appropriate and fair.

**5. Putting things right**

- Acknowledging mistakes and apologising where appropriate.
- Putting mistakes right quickly and effectively.
- Providing clear and timely information on how and when to appeal or complain.
- Operating an effective complaints procedure, which includes offering a fair and appropriate remedy when a complaint is upheld.

**6. Seeking continuous improvement**

- Reviewing policies and procedures regularly to ensure they are effective.
- Asking for feedback and using it to improve services and performance.
- Ensuring that the public body learns lessons from complaints and uses these to improve services and performance.

