



Northern Ireland

**Public Services**

Ombudsman

# **Investigation of a complaint against the Belfast Health & Social Care Trust**

**Report Reference: 202000068**

The Northern Ireland Public Services Ombudsman

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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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**Case Reference: 202000068**

**Listed Authority: Belfast Health & Social Care Trust (the Trust)**

## **SUMMARY**

I received a complaint about the Belfast Health and Social Care Trust's (the Trust) '*persistent*' use of the drug *Itraconazole* for the treatment of cystic fibrosis (CF) even though the patient (the complainant) reported a serious worsening of her condition with its continued use. Over a period of 14 weeks, the complainant was told to '*persevere*' with the drug while she suffered loss of appetite, weight loss, decline in lung function and a cough.

The complainant asked for the CF drug *Orkambi* on compassionate grounds. At that time, *Orkambi* was not licensed for use in the UK. Although the patient believed her declining health had met the criteria needed to qualify for the drug, she felt the Trust did not make an application to the drug manufacturer quickly enough, thereby prolonging her suffering.

The effects of cystic fibrosis are significant on those who are coping with the condition, and I appreciate the path to better health is often difficult, even with the support available. I want to acknowledge the complainant's determination in persisting with her complaint, particularly if she has had to do so during periods where her health has been of greater concern.

My investigation found the Trust appropriately prescribed and managed *Itraconazole* during the 14-week period the drug was administered. I did not find evidence which suggested the Trust wrongly persisted with the drug even though the complainant's condition worsened during that time. Neither did I find evidence that the Trust could have applied for the use of the drug *Orkambi*, at an earlier point.

Although I found the patient's health concerns to be compelling, I concluded there was no evidence of any failure in the care and treatment provided to the patient in relation to the drugs *Itraconazole* and *Orkambi*.

However, through enquiries initiated by concerns the complainant raised in response to a draft of this investigation report, I found the Trust failed to provide adequate community dietetic review of the complainant for a period of 12 months. I was satisfied this failure caused the patient an injustice through the lost opportunity of community dietetic support and left the patient '*at potential risk of harm*'. I therefore upheld this additional issue of complaint. Related to this, I found the Dietetic Department's record-keeping was also inadequate.

I recommended the Trust apologise in writing and address the failures with relevant staff in a supportive manner that encouraged learning, for the benefit of all those who use the Trust's cystic fibrosis care services.

## THE COMPLAINT

1. I received a complaint about the actions of the Belfast Health & Social Care Trust (the Trust). The complainant said she had concerns over the *'lack of care and compassion'* she experienced at the Cystic Fibrosis Unit in Belfast City Hospital. She said her main concern was the length of time she *'was made persevere'* on the drug *Itraconazole* whilst experiencing *'severe side effects'* and her *'symptoms were not being alleviated.'*
2. Also, *'given how fast and severely [her] health was declining'*, the complainant believed she met the qualifying criteria for compassionate use of the drug *Orkambi*, which was not licensed for use in the UK at that time. The Trust did eventually apply to the manufacturer for its use; however, the complainant felt strongly that the qualifying criteria had been met sooner than the eventual date the drug was obtained by the Trust and put to use.

## Background

3. The patient turned 18 years of age in August 2018 and moved to the care of the adult Cystic Fibrosis Unit in the Trust.
4. She began taking Itraconazole on 4 December 2018 having been told by Trust staff that levels of the fungus *Aspergillus fumigatus* in her sputum had increased. She obtained an information leaflet about the drug, which contained details of side effects, including *'loss of appetite'*. Unfortunately, within a few days of starting the drug the complainant's appetite *'completely disappeared'* and she was *'unable to eat'*.
5. The Trust's *'team'* said it would take time to get used to the drug and she should *'persevere'*, which she did. However, by 4 January 2019, the complainant had lost weight and her lung function had deteriorated. The Trust maintained its previous advice that she should *'persevere'*.
6. Trust staff remained consistent in this advice and the complainant continued to lose weight through loss of appetite and developed an increased cough with decreasing lung function.

7. On 25 February 2019, the CF unit reduced the dosage of Itraconazole from 200mg to 100mg following a telephone discussion with the complainant.
8. On 14 March 2019, the complainant obtained a second medical opinion, on a private basis. The doctor, a consultant respiratory physician, told her that *'if the negatives outweigh the positives you stop'*. At the next clinic (the following day) the complainant told her team she wanted to stop taking the drug.
9. On 21 March 2019, the complainant stopped taking Itraconazole.
10. On 2 July 2019 the Trust informed the complainant that the manufacturer of the unlicensed drug Orkambi had approved its use for the patient because the deterioration in her health had met the strict qualifying criteria set out in the company's Managed Access Programme (MAP).
11. The complainant subsequently moved house to the Republic of Ireland, transferring to the care of the Cystic Fibrosis centre in Dublin.

### **Issues of complaint**

12. The issues of complaint accepted for investigation were:

*Issue 1: Whether the care and treatment provided to the patient between 5<sup>th</sup> December 2018 and 21<sup>st</sup> March 2019 was of an appropriate standard in relation to the use of Itraconazole.*

*Issue 2: Whether the Trust followed appropriate procedures and guidance in relation to alternative medication, namely Orkambi.*

### **INVESTIGATION METHODOLOGY**

13. In order to investigate this complaint, the Investigating Officer obtained from the Trust all relevant documentation together with its comments on the issues raised by the complainant.

## **Independent Professional Advice Sought**

14. After further consideration of the issues, I obtained independent professional advice from the following independent professional advisors (IPAs):

- a Consultant Physician in Respiratory Medicine with a special interest in Cystic Fibrosis (the Respiratory IPA); and
- an Advanced Clinical Specialist Dietician with 10 years of experience (the Dietician IPA).

The clinical advice received is enclosed at Appendix three to this report.

15. The information and advice which informed the findings and conclusions are included within the body of this report. The IPAs provided 'advice'; however how this advice was weighed, within the context of this particular complaint, is a matter for my discretion.

## **Relevant Standards and Guidance**

16. 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. I also make reference to relevant regulatory, professional and statutory guidance.

The general standards are the Ombudsman's Principles<sup>1</sup>:

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

17. The specific standards and guidance referred to are those which applied at the time the events occurred. These governed the exercise of the administrative functions and professional judgement of those individuals whose actions are the subject of this complaint.

The specific standards and guidance relevant to this complaint are:

- *The diagnosis and management of respiratory tract fungal infection*

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<sup>1</sup> These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.



*in cystic fibrosis: A UK survey of current practice*. February 2019 (Boyle et al);

- *Practice Guidelines for the Diagnosis and Management of Aspergillosis: 2016 Update by the Infectious Diseases Society of America* (Patterson et al);
- *Respiratory Fungal Diseases in Adult Patients With Cystic Fibrosis*, May 2019 (Delfino et al); and
- Orkambi Managed Access Programme criteria (MAP criteria)
- The Cystic Fibrosis Trust's *Nutritional Management of Cystic Fibrosis*, September 2016 (CF Trust guidance); and
- The British Dietetic Association's *Guidance for Dietitians for Records and Record Keeping*, August 2008 (BDA record-keeping guidance).

Reference is made to the guidance in the Trust's response to the complaint.

Reference is made to the MAP criteria in the Respiratory IPA advice enclosed at Appendix three to this report.

18. I did not include 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 was taken into account in reaching my findings.
19. My office shared a draft copy of this report with the complainant and the Trust for comment on factual accuracy and the reasonableness of the findings and recommendations. The complainant submitted comments in response and I have addressed these below, where I considered it appropriate. The Trust made no comment on the draft report but did respond to subsequent enquiries from the Investigating Officer in relation to the support its Dietetic Department gave to the complainant. I considered all the comments I received before finalising this report.

## **THE INVESTIGATION**

**Issue 1:** *Whether the care and treatment provided to the patient between*

*5<sup>th</sup> December 2018 and 21<sup>st</sup> March 2019 was of an appropriate standard in*

*relation to the use of Itraconazole.*

### **Detail of Complaint**

20. The complainant said the Trust insisted that she continued to take Itraconazole despite experiencing immediate loss of appetite when she commenced the course. She said the Trust's team told her to persevere and they continued to tell her to persevere even when she lost weight due to her loss of appetite and developed a cough.
21. The patient said she was worse off as a result of taking the drug but the Trust insisted she keep taking it. The patient was concerned that this was wrong advice given that her condition seriously deteriorated for the duration of the course of treatment.

### **Evidence Considered**

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

22. I considered the following guidance:
  - Boyle et al;
  - Patterson et al; and
  - Delfino et al.

#### **Trust response to investigation enquiries**

23. The Trust said that from 21 June 2018 the patient's health deteriorated with symptoms of increased cough and thick sputum. This continued despite interventions with *'multiple courses of antibiotics, inhaler increases, and oral courses of prednisolone<sup>2</sup>.*' However, the patient's *'symptoms persisted and her lung function and weight decreased.'*
24. Those treating the patient found greater concentrations of the fungus *Aspergillus fumigatus* in blood and sputum samples, which prompted discussions within the MDT<sup>3</sup> that the fungus was contributing to the decline in the patient's health. The Trust said *'research supports that Aspergillus*

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<sup>2</sup> A strong anti-inflammatory steroid.

<sup>3</sup> Multi-Disciplinary Team

*fumigatus can cause a decline in the health of people with CF (Boyle).’ The Trust said ‘it is also recognised that weight loss and fatigue are the most common general symptoms of aspergillus bronchitis and may be profound (Patterson).’*

25. The Trust decided to actively treat the patient for *Aspergillus* bronchitis and obtain an opinion from the National Aspergillus Centre (NAC) in Manchester. The Trust said the NAC *‘advised treatment with Itraconazole for 4 months. This anti-fungal therapy is the current standard of care for aspergillus bronchitis (Delfino).’*
26. The Trust said:  
*‘Prolonged treatment is required as it can take many months before any clinical improvement is observed. It was hoped that this therapy would help with [the patient’s] symptoms and stabilize the decline in her health.’*  
*‘[The patient] completed 14 weeks of treatment; there was serological and microbiological improvement, but unfortunately, no patient reported benefit.’*
27. The Trust said that traces of the fungus were found to be at normal levels during the period of treatment with Itraconazole.

### **Relevant Trust records**

28. The investigation considered the patient’s medical records obtained from the Trust, including inpatient notes, outpatient reviews, blood and x-ray reports.

### **Relevant Independent Professional Advice**

29. Having reviewed the patient’s medical records, the Respiratory IPA advised that *‘the introduction of Itraconazole in December 2018 for a diagnosis of Aspergillus bronchitis was an appropriate intervention.’* The adviser referred to evidence in the medical records that led the medical team to this diagnosis and advised that the decision to *‘prescribe Itraconazole for a period of 4 months’* was *‘a typical course of treatment for this condition.’*
30. The Respiratory IPA noted the Trust sought an opinion from the *‘National Aspergillus Centre (NAC) in Manchester, which is a centre of excellence with a*

*National and International reputation.*’ They advised that the NAC agreed the patient *‘met their criteria for a diagnosis of Aspergillus Bronchitis.’*

31. The Respiratory IPA advised that it was appropriate to encourage the patient to continue with the course of Itraconazole treatment because:
- *‘the diagnosis of Aspergillus Bronchitis was a reasonable working diagnosis,*
  - *the intended duration of therapy was appropriate,*
  - *the drug was being monitored,*
  - *the drug has a generally safe profile and*
  - *the drug is regularly used in CF medicine.’*
32. The Respiratory IPA advised:
- ‘Severe loss of appetite’ is mentioned in the Itraconazole product literature (supplied to me by youelves), in a section related to patients with a history of liver disease, as one of a group of symptoms that could indicate liver failure.’*
- ‘The prescription of Itraconazole by the Belfast team was appropriately monitored using blood tests including Itraconazole levels and there was no evidence of serious systemic toxicity such as liver failure or congestive cardiac failure.’*
33. The Respiratory IPA advised:
- ‘the use of Itraconazole in this case falls within what I would regard as standard and reasonable practice within CF medicine’.*
34. The Respiratory IPA advised that the *‘allergy’* section, as it appeared on identified Trust documentation, represented a *‘loose application of the term allergy to include drug “intolerance” or “side effect encountered”.*’ They advised: *‘This “loose interpretation” or alternatively “misuse” of the Allergy section in medical documents is widespread throughout primary and secondary care and is intended to avoid side effects.’*

#### **Other information considered**

35. The complainant commented on the draft investigation report after obtaining

her medical records from the Trust. Referring to examples from those records, the complainant reiterated her view that medical staff could see how her health was deteriorating yet they continued to ask her to persevere with Itraconazole. She said she was never listened to or given honest answers. She referred to examples from Trust correspondence which she claimed demonstrated the Trust failed to meet GMC standards that require doctors to be sensitive and responsive to the patient and those close to the patient.

36. The complainant said that, according to the Trust, there had been a serological<sup>4</sup> improvement after she had taken Itraconazole for 14 weeks. Referring to medical records dated 21 September and 22 November 2018, the complainant claimed that Aspergillus levels in her lungs had reduced to a greater degree before Itraconazole was considered by the Trust. Referring to her medical records, the complainant refuted the Trust's claim (see paragraph 27) that traces of the Aspergillus fungus were normal during the treatment period.
37. The complainant said this investigation report focuses more on the appropriateness of starting Itraconazole rather than the issue of the Trust not stopping the drug when her weight '*plummeted dangerously*' and her health was '*deteriorating as a result*'.
38. The complainant highlighted comments in correspondence between practitioners with which she disagreed. She also noted how one medic had expressed apprehension to another about whether something had been '*missed*' in their efforts to care for the patient.
39. The complainant expressed surprise that the Trust had described her as having '*significant anorexia*' in a record dated 27 February 2019. She said she had no deliberate intention to stop eating, rather her lost appetite was due to Itraconazole.
40. The complainant said she experienced '*irreparable damage*' to her health whilst

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<sup>4</sup> The examination of antibodies and other substances in the serum (the clear liquid part of the blood).

under the care of the CF team in Belfast City Hospital.

### **Analysis and Findings**

41. I note the complainant experienced a sustained downward spiral in her health during 2018. Notably, the patient's lung function fell well below a level of 80% which she had enjoyed previously and which I understand compared well to what could be considered to be normal lung function.
42. Understandably, the complainant and her family were very concerned at the deterioration in her health and, naturally, they relied heavily upon the professional expertise of the Adult CF team in Belfast to whose care she transferred when she turned 18 years of age in August 2018.
43. I note the Trust's CF team identified the fungus *Aspergillus fumigatus* and through MDT discussion and specialist input from the NAC, diagnosed *Aspergillus Bronchitis*. I note this is why the drug Itraconazole was introduced into the patient's care. Having carefully considered the Trust's responses and the Respiratory IPA advice, I am satisfied this was a proper course of action taken by the CF team. In her response to a draft of this report, the complainant highlighted apparent concern among CF team members that they had '*missed*' something. I consider this was a part of the machinations of patient care where the medical team sought to provide the correct care and treatment. I accept the IPA advice that the diagnosis and the chosen drug were appropriate. I acknowledge it was important that the Trust treated the fungus.
44. I note the Trust was clear that the outcome was good in that the incidence of *Aspergillus fumigatus* in the patient's lungs decreased as had been hoped. **If true**, I am satisfied this can be attributed to the treatment albeit the intended four months duration was not quite achieved.
45. It is disappointing that the complainant did not experience an improvement as the course of treatment progressed even though the drug was successfully attacking the fungus. Indeed, it is very unfortunate that the complainant actually deteriorated further through loss of appetite and worsening lung function. I appreciate how distressing this must have been for the complainant

and her mum. Understandably, I acknowledge the complainant therefore was anxious about the wisdom of the treatment, and no doubt felt conflicted when each time she raised her concerns, the medical team, upon whom she relied, encouraged her to persevere.

46. I consider the seriousness of the complainant's decline can be seen in the Trust's use of the phrase '*significant anorexia*' to describe the patient. The complainant referred to this in her response to a draft of the investigation report saying, '*not once was I ever told that I had anorexia*'. The Oxford Concise Medical Dictionary defines *anorexia* as weight loss. I understand the eating disorder *anorexia nervosa* is often shortened to *anorexia*. I hope this helps explain any confusion that may have arisen.
47. I note the complainant had good cause to be concerned because '*loss of appetite*' was listed in the drug information leaflet available for patients. The leaflet gave instructions to contact the doctor '*straightaway*' if this side effect was experienced.
48. I note the Respiratory IPA advised that the leaflet '*describes the very rare circumstance of loss of appetite due to liver failure*'. They also advised that appropriate tests were conducted which ruled out liver failure in this case. I consider this was reassuring news that would have been of benefit to the patient. However, it is not clear whether the CF team gave this information to the complainant.
49. I appreciate it was extremely difficult for the patient to persevere given the serious decline in health she was experiencing. I consider the patient required much encouragement, support and understanding from the CF team in order to face the monumental challenge of continuing to take the drug and, to trust the professionals and to persevere. I am disappointed to learn that the patient did not enjoy the level of support she needed. I acknowledge the Trust has previously noted the patient's experience in this case and offered an apology.
50. My investigation focussed on the appropriateness of the use of the drug and the decision to continue asking the complainant to persevere with the course

even though her health was in sharp decline. In that regard, I accept the advice provided by the Respiratory IPA. I am satisfied the drug was appropriate and the advice to persevere was correct albeit understandably very challenging for the complainant. I therefore do not uphold this issue of the complaint.

51. I acknowledge the complainant's comments (in response to a draft of this report) where she claimed that levels of the fungus in her lungs had decreased to a greater degree before the Trust considered Itraconazole. This information does not affect my view, based on the independent advice I have received, that the Trust acted appropriately in its approach to the use of Itraconazole in this case.

**Issue 2:** *Whether the Trust followed appropriate procedures and guidance in relation to alternative medication, namely Orkambi.*

### **Detail of Complaint**

52. The complainant believed the Trust should have applied for '*compassionate*<sup>5</sup> *use*' of the drug Orkambi sooner than they did. The patient said she '*requested on many occasions to discuss this.*'
53. The patient believed she did meet the criteria given how '*fast and severely*' her health was declining.

### **Evidence Considered**

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

54. I considered the following guidance:
- MAP criteria

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

55. The Trust said:
- 'At the time of [the patient's] treatment Orkambi<sup>6</sup> was not a licensed medication for treatment of Cystic Fibrosis in the UK.*

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<sup>5</sup> Compassionate use provides access to medicines that are not otherwise available on the NHS to people in critical need, where attempts to treat them with licensed medicines have been exhausted or there is no appropriate licensed treatment available. (Source – Cystic Fibrosis Trust)

<sup>6</sup> Trade Mark



*'Orkambi™ received a license for use in patients with Cystic Fibrosis and two copies of the F508 del mutation in 2019. Prior to this it could be sought directly from the pharmaceutical company, Vertex, under a Managed Access Programme (MAP). There were a strict set of Vertex criteria, an individual had to meet before it could be accessed, and this included lung function. If all criteria were not successfully met, the application was immediately refused. Once the criteria were met an application was made. Standard practice at the time was to admit patients to consider a treatment course of IV antibiotics prior to commencing Orkambi™, in an effort to reduce the accepted side effects of breathlessness.'*

56. The Trust said:

*'In general terms the managed access programme could be accessed for patients who were to have been referred for lung transplant assessment or deemed unsuitable for lung transplant assessment, or to have had a drop in lung function, which was sustained (i.e. lung function which did not improve following an admission and treatment with the use of bronchodilators, physiotherapy or IV antibiotics) below 40 % of predicted for at least 2 months prior to the application being submitted.'*

*'The Cystic Fibrosis team feel strongly that in this situation once the criteria were met, an application was made and was successful.'*

### **Relevant Trust records**

57. The investigation considered the complainant's medical records obtained from the Trust, including inpatient notes, outpatient reviews, blood and x-ray reports.

58. In particular, the patient's sequential lung function data was considered which was specifically relevant to the question of when the patient may have qualified for the unlicensed drug Orkambi under the criteria set by the pharmaceutical company's MAP.

### **Relevant Independent Professional Advice**

59. The Respiratory IPA gave detailed advice about how the MAP for Orkambi operated. He advised that the complainant's lung function readings '*did not meet the criterial until June 2019.*'
60. In particular, the Respiratory IPA advised of the two ways in which the complainant could have met the MAP criteria given her individual circumstances. They advised that, whilst the complainant's sequential lung function data indicated '*progressive decline in lung function*', he did not find evidence that the criteria was met earlier than June 2019.
61. The Respiratory IPA gave further advice on the timing of the complainant's Orkambi qualification related to the transition between children and adult services, and a reported change to the MAP criteria in 2019.

### **Other information considered**

62. Having considered a draft of this investigation report, the complainant accepted the findings in relation to this issue.
63. Having considered a draft of this investigation report, the Trust offered no comments in relation to the findings in relation to this issue.

### **Analysis and Findings**

64. The explanation provided by the Respiratory IPA on how a decision was reached in relation to prescribing Orkambi for a patient on compassionate grounds has been very useful in highlighting the detailed information required in order that a patient may qualify for the drug.
65. It is clear that the complainant deteriorated in the months that led to eventual approval of Orkambi. I note the Trust notified the patient by telephone on 2 July 2019 that Orkambi had been approved. I note the patient gave consent on 30 July and the Orkambi trial commenced on 2 August 2019.
66. I carefully considered the Respiratory IPA advice, which is unequivocal about the timing of the Trust's application for Orkambi. Taking account of the IPA's

specialist knowledge and experience, I am satisfied about the timing of the Trust's application for the drug. I accept the IPA advice. I therefore do not uphold this issue of the complaint.

67. I hope the Respiratory IPA reports give the complainant some assurance that the drug was secured as soon as was possible despite the traumatic experience she endured. I am pleased to note there was some improvement in the complainant's condition when she subsequently began taking the drug.

#### **Additional Issue – dietetic support**

68. In her response to the draft investigation report, the complainant said the Dietetics Department did not engage with her during the four-month period in which she was encouraged to persevere with Itraconazole. Although the complainant did not include the issue of dietetic support in her original complaint, I decided it was appropriate to investigate her comments rather than expect her to return to the Trust's complaints procedure again.

#### *The issue*

69. The complainant said the Trust's Dietetic Department did not support her during the four-month period the Trust asked that she persevere with the drug Itraconazole.

#### *Trust's response*

70. In response, the Trust said that, at an outpatient appointment on 3 August 2018, *'the specialist Cystic Fibrosis (CF) dietician'* gave the complainant a landline number and their direct mobile number and asked her to contact the Dietetic Department *'if she had any concerns'*. Staff reminded her of their availability to help on two further occasions, December 2018 and March 2019.
71. The Trust listed the support which dieticians provided to the complainant during several hospital admissions between August 2018 and August 2019, including advice and support in relation to supplement drinks and the offer of enteral tube feeding.

72. Referring to four outpatient clinics in January and February 2019<sup>7</sup> (when the complainant was taking Itraconazole) the Trust said *'CF dietitians were present at each of these clinics however [the complainant] declined input.'*
73. Referring to an outpatient clinic on 23 August 2019, the Trust said the complainant *'again declined to see the dietitian'*.

#### *Dietician IPA*

74. The Dietician IPA advised that the Trust supported the complainant in accordance with good practice during her several hospital admissions between August 2018 and August 2019.
75. The Dietician IPA noted the complainant was *'pancreatic insufficient'*<sup>8</sup> and advised a dietician should aim to see such a patient *'at each outpatient CF clinic visit.'*
76. The Dietician IPA advised she could find no evidence of dietetic staff providing support to the complainant during outpatient appointments at any time between August 2018 and August 2019, *'despite her weight dropping from 60kg to 46.3kg'*, a drop of 22.8% in body weight.
77. The Dietician IPA advised *'one would expect a continuation of care from the inpatient to outpatient setting in any patient group, but particularly within a highly nutritionally vulnerable patient with ongoing nutritional deterioration and significant weight loss.'*
78. The Dietician IPA advised it was important for the complainant to be offered such support because she was pancreatic insufficient and clearly losing weight.
79. The Dietician IPA advised that *'within the community setting, there appears to have been no interventions or reviews provided by the dietitians.'* They advised this was *'against national guidelines . . . and standards'*, (CF Trust guidance, page 8) and *'this left the patient at potential risk of harm'*.

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<sup>7</sup> 4 and 25 January, 8 and 15 February 2019

<sup>8</sup> A condition which occurs when the pancreas does not make enough of a specific enzyme the body uses to digest food.

80. The Dietician IPA advised that, where the complainant declined input at outpatient appointments, the Trust should have recorded this information. They referred to the standards for dietetic record keeping outlined in the BDA record-keeping guidance.

#### Other information considered

81. Having considered a draft of the investigation report, the complainant accepted the findings in relation to this issue.
82. The Trust said patients remain under the care of the specialist CF centre in Belfast when they leave hospital or clinic and follow-up is offered on an ongoing basis. The specialist team of CF dieticians in the Belfast centre are the only adult CF dieticians in Northern Ireland. That being so, it is the same team that are responsible for inpatient and outpatient contact with CF patients, and so the issue of '*handover*'<sup>9</sup> between teams does not arise.
83. The Trust said five of the patient's outpatient appointments resulted in her subsequent admission to hospital.
84. The Trust said its dieticians reviewed the patient by telephone on 30 May 2019.
85. The Trust said it noted the patient was pancreatic insufficient and the CF specialist dietician conducted a bowel assessment regularly between August 2018 and August 2019.
86. The Trust said in keeping with standard practice, '*a senior CF specialist dietitian was present at every outpatient clinic the complainant attended*' and gave input at multidisciplinary meetings before and after each clinic.
87. The Trust said that, in line with its records management policy, it had destroyed records that noted the complainant's choice not to see the dietician at the identified outpatient visits.

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<sup>9</sup> This comment appears to relate to a suggestion in the Dietician IPA's report that: '*Thorough handovers between inpatient and outpatient settings should be provided and documented within the patient notes or file to ensure adequate continuation of care into the community setting.*'

88. The Trust said its practice had been to leave the clinic sheet blank in the medical notes where an outpatient had declined dietetic input or left the clinic instead of waiting to see the dietician.
89. The Trust accepted the findings in relation to record keeping.

### *Analysis and Findings*

90. The Trust's record shows that the complainant lost weight over a sustained period after she began taking Itraconazole. This weight loss continued in the months following her decision to stop taking the drug.
91. The Trust's records contain evidence of the support which dietetic staff gave to the complainant during her several hospital admissions between August 2018 and August 2019. I note the Trust's assertion that a CF specialist dietician was present, and gave input, at multidisciplinary meetings that occurred before and after each outpatient clinic. However, the Trust's records do not contain evidence that dietetic staff reviewed the complainant at the outpatient clinics she attended while she was taking Itraconazole. The Dietician IPA advice is clear that the Dietetic Department should have reviewed the complainant due to her *'ongoing nutritional deterioration and significant weight loss.'*
92. The Trust's records indicate that, on 30 May 2019, the Trust called the complainant and helped her obtain a particular flavour of supplement drink which a CF nurse indicated she was *'requesting'*.
93. The CF Trust guidance highlights the importance of dietetic support being given to patients with Cystic Fibrosis who are pancreatic insufficient. The guidance includes the following:  
*'Untreated pancreatic insufficiency will result in maldigestion and malabsorption of intestinal fat and to a lesser extent protein, consequently contributing to sub-optimal nutritional status and deficiency of fat soluble vitamins.'*  
I consider this highlights the importance of adequate engagement with such patient's and it corroborates the Dietician IPA advice that the support provided by staff in the community setting was inadequate. I accept this advice. I note the Trust referred to regular bowel assessment of the patient between August

2018 and August 2019. I have understood this to be a reference to bowel assessments conducted when the complainant was an inpatient. However, I have found no evidence the Trust reviewed the complainant at outpatient clinics during the period she was taking Itraconazole. Moreover, I see no evidence of review at subsequent outpatient clinics, despite the complainant's weight continuing to drop.

94. The Trust said the complainant '*declined input*' from dieticians at each of the outpatient clinics she attended while taking Itraconazole. The Dietician IPA advised there was no evidence the complainant declined dietetic intervention during that period. In fact her report shows that, except for the 23 August 2019 clinic, she found no evidence the complainant declined input in the outpatient clinics that took place between August 2018 and August 2019. She referred to the BDA record-keeping guidance which requires bodies to keep accurate and complete records. I accept this advice. I appreciate that, from the Trust's perspective, it is particularly important to make a written record where a patient declines support. If a patient makes a complaint, the Trust should be able to demonstrate in any subsequent related investigation that it had offered support. I consider this failure in record keeping prevents the Trust from doing so.
95. Therefore, in this instance, I consider the Trust failed to review the complainant in the community setting during that period. I am satisfied this failure caused the patient an injustice through the lost opportunity of community dietetic support and left the patient '*at potential risk of harm*'.
96. I am pleased to note the Trust accepted my findings in relation to record keeping.

## **CONCLUSION**

97. I received a complaint about the Trust's continued use of the drug Itraconazole despite the complainant's repeated concerns that it was causing a serious deterioration in her health. The complainant also claimed the Trust did not apply for compassionate use of the drug Orkambi as soon as it could, again despite the complainant's continued appeals that she met the criteria for its unlicensed use given the extent of her ill health in the first half of 2019.

98. My investigation found the Trust did appropriately use the drug Itraconazole and was not wrong to encourage the complainant to persevere with the course of treatment. I also found the Trust applied for Orkambi as soon as it could have done so given the strict criteria laid down by the manufacturer for the unlicensed use of the drug.
99. However, I did find the Trust failed to provide adequate dietetic support in the community to the complainant. I consider this failure extended beyond the period the complainant was taking Itraconazole and covered the period August 2018 to August 2019. I am satisfied this failure caused the patient an injustice through the lost opportunity of community dietetic support and left the patient '*at potential risk of harm*'. The Trust also failed to keep an adequate record of the complainant's outpatient appointments. I therefore uphold this additional issue of complaint.
100. I recommend that the Chief Executive of the Trust provides the complainant with a written apology in accordance with NIPSO 'Guidance on issuing an apology' (June 2016), for the injustice caused as a result of the failures identified (within **one month** of the date of this report).
101. I further recommend the Trust provides evidence that the findings of this report have been fed back to relevant staff in a supportive manner that encourages learning, including reference to what that learning is (for example a record of a meeting with staff or feedback given at one-to-one sessions). The following areas should be covered:
- The importance of providing community dietetic support to those with Cystic Fibrosis who are pancreatic insufficient, in accordance with the CF guidance.
  - The importance of work being recorded clearly, accurately and legibly and in accordance with the BDA record-keeping guidance.
102. I understand there are other drugs now available, which offer further improvement in the treatment of CF. I trust the patient has been able to benefit



from the latest advancements in this field and I hope she will experience a sustained level of good health in the future.

**MARGARET KELLY**  
**Public Services Ombudsman**

**28 March 2024**

## 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.

