Northern Ireland
Public Services
Ombudsman

Investigation Report

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

NIPSO Reference: 202000308

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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: 202000308

Listed Authority: South Eastern Health and Social Care Trust

SUMMARY

This complaint is about care and treatment the South Eastern Health and Social Care Trust (the Trust) provided to the complainant's late wife (the patient) between June 2019 and May 2020. The Trust's dermatology team diagnosed the patient with bullous pemphigoid with mucous membrane involvement, (BP)[1] in June 2019. The Trust revised its diagnosis to '*likely mucous membrane pemphigoid*[2]*'* in January 2020. The complainant queried why the Trust changed its diagnosis. He also raised a concern about the Trust's long-term use of steroids to treat the patient. This is especially as it prevented the patient from receiving treatment for lung adenocarcinoma, diagnosed in March 2020[3]. The complainant raised further concerns that the Trust did not refer the patient for tests to confirm her cancer diagnosis, or appropriately manage an ENT referral for the patient.

The investigation did not identify any failures in the Trust's care and treatment of the patient. In relation to the concern about the revision of the patient's diagnosis, the investigation found the Trust's actions reasonable and in accordance with relevant guidance. It also established that the Trust prescribed the patient appropriate steroid medication in line with relevant guidance. In relation to the concern about the absence of a referral to confirm a cancer diagnosis, the investigation found the Trust acted appropriately and did not identify a link between pemphigoid and cancer. The investigation also established that the Trust referred the patient to ENT at the earliest opportunity. It identified that the Trust cancelled the patient's first ENT referral at her request made during a telephone call to its booking team.

It is hoped the findings outlined in this report reassure the complainant that the Trust

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[1] Bullous Pemphigoid with mucous membrane involvement is a rare autoimmune blistering disease of the skin and mucous membranes.

[2] Mucous membrane pemphigoid (MMP) is a group of rare chronic autoimmune disorders characterized by blistering lesions that primarily affect the various mucous membranes of the body. The mucous membranes of the mouth and eyes are most often affected.

[3] Adenocarcinoma is the most common type of non-small cell lung cancer (NSCLC). It develops from cells that make mucus. It is more often found in the outer area of the lung.

provided appropriate care and treatment to the patient.

THE COMPLAINT

1. This complaint is about care and treatment the South Eastern Health and Social Care Trust (the Trust) provided to the complainant's late wife (the patient) between June 2019 and May 2020.

Background

2. The patient attended the Emergency Department in the Royal Victoria Hospital, (RVH) (within the Belfast Health and Social Care Trust) on 2 June 2019 with a skin complaint. A dermatologist examined the patient and arranged for her to attend the Ulster Hospital to have a biopsy of the affected area. The Trust's dermatology team subsequently diagnosed the patient with bullous pemphigoid with mucous membrane involvement[4]. The Trust later revised this diagnosis to mucous membrane pemphigoid[5] (MMP) in January 2020. The Trust treated the patient with steroids from her initial diagnosis in June 2019 until her death in May 2020.

3. The Belfast Health and Social Care Trust diagnosed the patient with lung adenocarcinoma[6] in March 2020. A consultant oncologist from the Belfast Trust explained in a letter to the patient's GP on 26 March 2020 that surgery or radiotherapy[7] were '*not useful treatments'*. She also ruled out immunotherapy[8] to treat the lung adenocarcinoma. The oncologist documented that she discussed pemetrexed and carboplatin[9] with the patient and explained the risks. The oncologist did not start treatment and planned to review the patient in 2 months. The complainant said the patient '*was informed that chemotherapy was deemed too dangerous due to her immune deficiency, which had been brought on by use of steroids and other medication for the pemphigoid'*.'

Issues of complaint

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4 Bullous Pemphigoid with mucous membrane involvement is a rare autoimmune blistering disease of the skin and mucous membranes.

5 Mucous membrane pemphigoid (MMP) is a group of rare chronic autoimmune disorders characterized by blistering lesions that primarily affect the various mucous membranes of the body. The mucous membranes of the mouth and eyes are most often affected.

6 Lung adenocarcinoma is a type of non-small cell lung cancer that accounts for about 40% of all lung cancers.

7 Radiotherapy is a treatment where radiation is used to kill cancer cells.

8 Immunotherapy is a type of cancer treatment that helps your immune system fight cancer

9 Pemetrexed and carboplatin is a combination treatment used to treat mesothelioma and non-small cell lung cancer (NSCLC).

4. I accepted the following issue of complaint for investigation:

Whether the care and treatment the Trust provided to the patient between June 2019 and May 2020 was appropriate and in accordance with relevant policies and standards. In particular this will consider:

- **Revision of the patient's pemphigoid diagnosis;**
- **Management of the patient's steroid medication;**
- **The lack of diagnostic tests for cancer; and**
- **Referral to ENT.**

INVESTIGATION METHODOLOGY

5. In order to investigate this complaint, the Investigating Officer obtained from the Trust all relevant documentation together with its comments on the issues the complainant raised. This documentation included information relating to the Trust's complaints process.

Independent Professional Advice Sought

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

- A consultant dermatologist, MB BS BAO BMedSci MRCP, with 12 years' experience of working in the NHS (D IPA); and
- A consultant clinical oncologist, MB, ChB, MRCP, FRCR, MD, with 28 years' experience in clinical oncology (O IPA).

I enclose the clinical advice received at Appendix two to this report.

7. I include the information and advice which informed my findings and conclusions within the body of this report and its appendices. The IPA provided 'advice'. However, how I weighed this advice, within the context of this particular complaint, is a matter for my discretion.

Relevant Standards and Guidance

8. In order to investigate complaints, I must establish a clear understanding of the standards, both of general application and those specific to the circumstances of the case. I also refer to relevant regulatory, professional and statutory guidance.

The general standards are the Ombudsman's Principles[10]:

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

9. 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:

- British Association of Dermatologists' (BAD) guidelines for the management of bullous pemphigoid, September, 2012, (BAD Guidance);
- The British Journal of General Practice's Long-term oral prednisolone exposure in primary care for bullous pemphigoid: population-based study, December 2021 (BJGP);
- Journal American Medical Association's (JAMA) Association of Bullous Pemphigoid and Malignant Neoplasms, September 2018 (JAMA);
- British Journal of Dermatology's Incidence, prevalence and mortality of bullous pemphigoid in England 1998–2017: a population-based cohort study*, 2021, (BJD); and
- National Institute for Health & Care Excellence's Lung cancer: diagnosis and management, March 2019, (NICE NG122).

I enclose relevant sections of the guidance considered at Appendix three to this report.

[10] These principles were established through the collective experience of the public services ombudsmen affiliated to the Ombudsman Association.

10. I did not include all information obtained in the course of the investigation in this report. However, I am satisfied I took into account everything I considered relevant and important in reaching my findings.

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

THE INVESTIGATION

Whether the care and treatment the Trust provided to the Patient between June 2019 and May 2020 was appropriate and in accordance with relevant policies and standards. In particular this will consider:

- **Revision of the patient's pemphigoid diagnosis;**
- **Management of the patient's steroid medication;**
- **The lack of diagnostic tests for cancer; and**
- **Referral to ENT.**

Detail of Complaint

12. The complainant said the Trust revised the patient's diagnosis of bullous pemphigoid with mucous membrane involvement to mucous membrane pemphigoid[11] in January 2020. He questioned why the Trust changed its diagnosis.

13. The complainant also said, '*the Dermatologist maintained a regime of steroids for a (sic) excessively long period, weakening [the patient's] immune system and rendering her unfit for cancer treatment when lung cancer (adenocarcinoma) was diagnosed in March 2020'*. The complainant felt the dermatology team could have referred the patient for a '*biopsy which may have revealed the presence of adenocarcinoma at a crucially early stage'*. Finally, the complainant said the Trust referred the patient to ENT, but subsequently cancelled this referral.

Evidence Considered

[11] Both bullous pemphigoid and MMP may affect skin and mucosa, the classical clinical findings in bullous pemphigoid are tense, fluid-filled bullae on skin, whereas the prevailing clinical feature in MMP is mucosal involvement.

Legislation/Policies/Guidance

14. I considered the following guidance:
    - BAD Guidance;
    - BJGP;
    - JAMA;
    - BJD; and
    - NICE NG122.

The Trust's response to investigation enquiries

Revision of the patient's pemphigoid diagnosis

15. The Trust explained it conducted a biopsy on the patient on 3 June 2019 and initially diagnosed her with '*bullous pemphigoid with mucous membrane involvement or a viral infection such as hand foot and mouth*[12]*'*. The dermatology team accepted the diagnosis of bullous pemphigoid. However, the Trust said that '*Due to the mucosaI involvement, the possibility that [the patient] had one of the rarer variants of Pemphigoid such [as] MMP [mucous membrane pemphigoid] or EBA [epidermolysis bullosa acquisita*[13]*] was considered early in her care and treatment'.*

16. The Trust explained that after examining the patient on 22 November 2019, the consultant dermatologist felt '*the degree of blistering in [the patient's] mouth with limited response to treatment was unusual for typical BP'*. As a result, the consultant dermatologist considered the possibility that the patient '*might have one of the rarer variants of Pemphigoid'*. The Trust said, '*The extent of mucosal involvement seen in [the patient] was more suggestive of MMP clinically and [the consultant dermatologist] felt that this might explain why [the patient's] disease was so difficult to get under control'*.

17. The Trust explained that in November 2019, the consultant dermatologist sought specialist advice from a Professor of Oral and Dermatological Medicine. She

[12] Hand, foot, and mouth disease (HFMD or HFM) is a common mild and short-lasting viral infection most often affecting young children.
[13] Epidermolysis bullosa acquisita (EBA) is a rare autoimmune disorder that causes the skin to blister in response to minor injury. Common areas of blistering include the hands, feet, knees, elbows, and buttocks. It can also affect the mouth, nose, and eyes.

subsequently arranged for an ELISA[14] test at a specialist laboratory in London in December 2019. The Trust sent the sample to London on 7 January 2020. The consultant dermatologist discussed the results of the ELISA test with the patient at a clinic on 17 January 2020. The consultant dermatologist explained to the patient '*that the results of her Immunofluorescence[15] and Elisa testing would be more consistent with MMP than EBA'*. The consultant dermatologist explained '*mucous membrane pemphigoid (MMP) is a rare group of autoimmune blistering disorders, the symptoms of which can be very similar to that of BP, Epidermolysis bullosa acquista (EBA), Pemphigus vulgaris (PV[16]) and Lichen planus (LP)[17] for example'.*

18. The Trust explained that '*Establishing the variant of Pemphigoid, where possible, is helpful for prognosis, in that, the latter variant of MMP can be more resistant to usual treatments and can require more aggressive treatment*.' It further explained, '*the diagnosis and management of this condition can be challenging'*. The Trust explained '*there is no single test that will define a condition as either BP or MMP. The diagnosis of one condition over another is based upon thorough clinical evaluation, a detailed patient history and identification of characteristic findings along with biopsy and immunofluorescence, enzyme-linked immunosorbent assay (ELISA) test and response to therapies. With Pemphigoid disease, a period of time is needed to assess the disease progression, obtain the results of the investigations and monitor response to any treatment initiated and so early diagnosis is difficult for any specialist*'.

Management of the patient's steroid medication

19. The Trust explained that '*Steroids have been widely used in dermatology since the 1950s and are commonly prescribed for Immunobullous diseases'*. It said the consultant dermatologist was very '*familiar with the use of oral steroids, the risks of steroid use and potential side effects, both in the short and long term*'.

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[14] ELISA stands for enzyme-linked immunoassay. It is a commonly used laboratory test to detect antibodies in the blood. An antibody is a protein produced by the body's immune system when it detects harmful substances, called antigens

[15] Immunofluorescence staining is the most frequently applied technique to detect and visualize various molecules in biological samples.

[16] Pemphigus vulgaris is a rare long-term condition caused by a problem with the immune system. It causes blisters in the mouth and on the skin.

[17] Lichen planus (LP) is a rare, chronic, inflammatory autoimmune skin and mucous membrane disease

20. The Trust explained that '*For severe or symptomatic Pemphigoid disease, oral steroids are usually a first line of treatment to try and gain rapid disease control and control of symptoms, which can be very disabling, especially when blisters affect the mouth and throat, as in [the patients] case'*. The Trust said it is normal for clinicians to prescribe patients high doses at the outset and then reduce the dosage. It said, '*At every stage of [the patient's] treatment [the consultant dermatologist] endeavoured to keep her dose of steroids to a minimum by considering and commencing alternative treatments and tapering down [the patient's] steroid dose when her symptoms were better controlled'.*

The lack of diagnostic tests for cancer

21. The Trust cited BAD guidelines which state '*there is no conclusive evidence for an association with malignancy or other autoimmune diseases*'. The Trust explained that '*It would not therefore be our usual practice to routinely screen patients with BP for malignancy'.*

22. The Trust said the patient's medication could explain her respiratory symptoms. Additionally, the patient's pemphigoid could have caused '*sensations of a cough if there is airway or laryngeal involvement'*.

23. The Trust explained that the patient presented with a cough at her dermatology appointment of 30 August 2019. It said the patient's reported symptoms may have '*suggested a chest infection, including a cough and green sputum'.* The consultant dermatologist felt it was not unreasonable to assume that the patient may have had a chest infection, *'given her treatment with oral steroids and history of smoking'*. The consultant dermatologist advised the patient to '*attend her GP for assessment and antibiotics, if needed*'.

24. The patient's GP referred her for a chest x-ray in October 2019. A consultant radiologist reported the x-ray showed '*Normal cardiac contour and pulmonary vascularity. Mild chronic inflammatory changes present in both lungs'.* The Trust said the chest x-ray findings of 30 October 2019 reassured the consultant dermatologist.

25. The patient reported a '*cough and sputum'* at her dermatology appointment on 19 January 2020. The patient told the consultant dermatologist that her GP prescribed a five day course of antibiotics. However, at a clinic on 14 February 2020, the patient said she stopped her antibiotics and her chest symptoms had settled.

26. Finally, the Trust said the consultant dermatologist is aware that '*lung adenocarcinoma cannot be detected on blood tests. [She] is aware that a routine chest X-ray is a useful first line screening tool test to look for any abnormal areas in the lungs'.* The Trust noted the patient's GP managed her chest symptoms.

Referral to ENT

27. The Trust explained that the consultant dermatologist referred the patient to ENT after her first appointment on 18 July 2019. It said the patient was '*noted to have some erosions / ulcers in her larynx and also in the buccal mucosa and so she was referred as an urgent new patient to ENT, South Eastern Trust (SET) for help with further management of the oral and pharyngeal symptoms'*. The Trust said the partial booking team sent the patient a letter on 24 July 2019 asking her to book an appointment with ENT. It explained its partial booking team discharged the patient following a telephone call on 30 July 2019, when the patient told them the ENT at the RVH already examined her.

28. The Trust explained the consultant dermatologist referred the patient for a second urgent appointment with the Trust's ENT after her consultation on 17 January 2020. The Trust explained that '*An initial appointment scheduled for her ENT appointment on 6 March 2020 was cancelled due to the [patient's] admission to the RVH. A further appointment for 3 April 2020 was cancelled due to the Covid-19 Pandemic. An ENT virtual appointment was held on 19 May 2020'.*

Relevant Trust records

29. I enclose a summary of the records considered during this investigation at Appendix three to this report.

Relevant Independent Professional Advice

30. A Consultant dermatologist (D IPA) provided advice on the care and treatment the Trust provided to the patient. I enclose the advice the D IPA provided at Appendix two to this report.

Revision of the patient's pemphigoid diagnosis

31. The D IPA advised that the patient '*was initially diagnosed with Bullous Pemphigoid with mucous membrane involvement. This was based on clinical impression and supported by the histological analysis of the skin biopsy'*. The D IPA advised that this was '*an entirely reasonable initial diagnosis to reach, and upon which to base initial treatment decisions'*. The D IPA referred to BAD guidelines on bullous pemphigoid which state the '*diagnosis is confirmed with immunofluorescence studies (IF*)'.

32. The D IPA advised that '*The diagnosis is revisited in clinic appointment of 22/11/2019, based on atypical clinical features, and an incomplete response to treatment'*. The D IPA advised that the Trust considered alternative diagnoses including '*Epidermolysis Bullosa Acquisita (EBA)*[18] *and Linear IgA Disease*[19]*'* (LAD). The D IPA advised '*this is an entirely reasonable and comprehensive differential diagnosis*[20]*'*.

33. The D IPA advised that the Trust requested additional tests including ELISA studies and salt split skin studies. She further advised the ELISA test allowed confirmation of the diagnosis of MMP on 17 January 2020. The D IPA advised that '*neither the revision of the diagnosis, nor the slight delay in the serum being sent to the laboratory in London, had any impact on the clinical course of the patient; the treatments and outcome would not have differed in either case'*.

[18] Epidermolysis bullosa acquisita (EBA) is a rare autoimmune disorder that causes the skin to blister in response to minor injury. Common areas of blistering include the hands, feet, knees, elbows, and buttocks. It can also affect the mouth, nose, and eyes
[19] Linear IgA bullous disease is a mucocutaneous autoimmune disease characterized by linear deposition of IgA and disruption of the dermoepidermal junction, resulting in blisters with a tense clinical appearance
[20] Differential diagnosis refers to the process of differentiating between two or more conditions which share similar signs or symptoms.

Management of the patient's steroid medication

34. The D IPA advised that '*Prednisolone[21] is the most common prescribed treatment for the management of bullous pemphigoid'*. She further advised the Trust co-prescribed *'appropriate protective medications alongside the oral corticosteroid[22] treatment'*. The D IPA advised this indicates '*a good standard of practice and takes in to account the side effects of steroids on bone health and the gastric mucosa'*.

35. The D IPA advised the dosage *'of the prednisolone was appropriate both initially at diagnosis, and then in response to disease control*'. She also advised *'the clinicians caring for the patients were always careful to ensure that a reducing regimen was suggested between appointments, so that the patient was on the lowest possible level of prednisolone at any time. This constitutes good prescribing'.*

36. The D IPA further advised the Trust tried '*3 different steroid-sparing agents[23] over the course of the 12 month period: doxycycline[24], dapsone [25] and azathioprine[26]'*. She said that '*these choices are instituted in a logical order and in keeping with the advice of the BAD Guidelines'*. The D IPA advised that trying three different steroid-sparing agents was indicative of *'very good practice'.* She also advised '*I do not consider that any other actions could have been taken by the clinicians to reduce the patient's steroid usage'*.

37. The D IPA advised '*the patient was closely followed up in secondary care dermatology, with clear letters addressed to the GP created at each appointment. There is no ambiguity whatsoever in the clinical letters regarding treatment...*'

38. I also sought advised from an Oncologist IPA (O IPA). I enclose the advice the O IPA provided at Appendix two to this report.

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[21] Prednisolone is a man-made form of a natural substance (corticosteroid hormone) made by the adrenal gland. It is used to treat conditions such as arthritis, blood problems, immune system disorders, skin and eye conditions, breathing problems, cancer, and severe allergies. It decreases your immune system's response to various diseases to reduce symptoms such as pain, swelling and allergic-type reactions.

[22] Oral corticosteroids, are anti-inflammatory medicines used to treat a range of conditions.

[23] Steroid sparing agents allow clinicians to keep the steroid dose as low as possible some people may be considered for additional therapy in order to reduce the need for steroids. Steroid sparing medicines can all decrease long term steroid requirements but have significant side effects.

[24] Doxycycline is in a class of medications called tetracycline antibiotics. It works to treat infections by preventing the growth and spread of bacteria.

[25] Dapsone belongs to a class of drugs known as sulfones. It works by decreasing swelling (inflammation) and stopping the growth of bacteria.

[26] Azathioprine is a type of medicine called an immunosuppressant. Immunosuppressants help "calm" (or control) your body's immune system. This medicine helps treat inflammatory conditions

39. I asked the O IPA about the letter the oncologist sent to the patient explaining her options and how the steroid medication affected her treatment options. The O IPA advised '*The letter from the oncologist…indicates correctly that because of the extent of the disease, neither radiotherapy surgery was not an option'.* The O IPA further advised the patient was performance status two[27]. As a result, the O IPA advised that *'immunotherapy was likely not an appropriate treatment for [the patient].* He further advised that immunotherapy may have worsened the patient's pemphigoid.

40. The O IPA advised that '*In summary the letter carefully details why the patient was not suitable for radiotherapy surgery or immunotherapy in accordance with best practice and contemporaneous medical literature'.*

41. I asked the O IPA if the patient's long term steroid usage would have impacted her access to cancer treatment. The O IPA advised '*high doses of steroids reduce the effectiveness of immunotherapy in patients with advanced lung cancer by about half'.* The O IPA advised the patient's steroid usage meant the immunotherapy would have been ineffective.

The lack of diagnostic tests for cancer

42. The D IPA advised '*There [is] no clear association between pemphigoid and malignancy; however both malignancy and pemphigoid are more common in older individuals. There is no causative association between pemphigoid and malignancy'*.

43. The D IPA advised '*I would not expect a reasonable dermatologist to perform any other investigations in the absence of compelling symptoms. As a long-term smoker, that the patient contracted a chest infection was a reasonable explanation for her symptoms, and I would not consider it the role of the dermatologist to pursue this further'*. The D IPA added that '*a dermatologist would not be expected to know*

[27] Performance status 2 means the patient is able to walk and manage self-care, but unable to work. The patient is out of bed more than 50% of waking hours.

that a chest x-ray might not demonstrate a lung adenocarcinoma. This would be the remit of a general practitioner or a specialist respiratory physician.

Referral to ENT

44. The IPA advised that '*it would not typically be the role of the dermatology team [to] chase a referral to another specialty'*. The IPA concluded '*I do not find any shortcomings on the part of the dermatology department with regard to this. The delay in seeing ENT did not have any impact on the outcome of the patient'*.

Complainant's response to the draft report

45. The complainant said he had '*reservations about the reference to cancellation of the ENT appointment in July 2019'*. He explained that, however, he did not have any *'evidence to support my firm belief that [the patient] did not cancel the appointment by telephone'.* The complainant said he based this '*solely on my recollection that [the patient] continued to wait for a date with ENT after her consultation with the Dermatologist in July 2019'*.

46. The complainant referred to the regime of steroid use *'which appears to have been well managed until January 2020'.* He requested my office to seek advice from an oncologist IPA to advise on the increased level of steroid use from January 2020 to March 2020 and if it rendered immunotherapy or chemotherapy *'too dangerous'.*

Analysis and Findings

Revision of the patient's pemphigoid diagnosis

47. The complainant queried why the Trust revised the patient's diagnosis. He explained that in its response to his complaint, the Trust said, '*the more likely diagnosis for [the patient's] skin condition was Mucous Membrane Pemphigoid and not Bullous Pemphigoid'*. I examined the Trust's records to consider how it reached its diagnosis and whether it was appropriate.

48. The Trust's records show it initially took '*bacterial and viral swabs'* from the patient. In addition, the Trust said an '*incisional biopsy for histology and immunofluorescence [was] also … performed under local anaesthetic'* in June 2019.

I note the BAD guidelines on bullous pemphigoid state that this is the appropriate test to use to confirm this diagnosis. The Trust wrote to the patient on 10 June 2019 and confirmed her diagnosis as '*Bullous Pemphigoid (mucous membrane variant)*'. Clinical notes from the patient's next appointments 30 August 2019 and 11 October 2019 also confirm the diagnosis of bullous pemphigoid.

49. I note the D IPA's advice that '*Bullous pemphigoid is the most common blistering skin eruption in this age group. This was an entirely reasonable initial diagnosis to reach, and upon which to base initial treatment decisions*'. I accept her advice.

50. The records evidence that the Trust kept the patient's diagnosis under review. They also evidence that the patient's symptoms did not respond to treatment as expected. Therefore, it pursued specialist testing.

51. The D IPA advised that the ELISA test allowed confirmation of the diagnosis of MMP on 17 January 2020. She also advised that the revision of the diagnosis did not impact on the patient's clinical pathway. I accept her advice.

52. I appreciate the complainant's concern surrounding the revision of the patient's diagnosis. However, based on the records and D IPA advice I received, I am satisfied the Trust acted appropriately and in accordance with relevant guidance. I am also satisfied that revising the patient's diagnosis did not impact her clinical pathway. I do not uphold this element of the complaint.

Management of the patient's steroid medication

53. The complainant was concerned that the patient's long term steroid use weakened her immune system. The complainant believed that the treatment rendered her unfit for cancer treatment.

54. The BAD guidelines state that '*Systemic corticosteroid therapy*[28] *was demonstrated to be effective in BP in uncontrolled clinical studies during the 1950s and has*

[28] Systemic steroids are synthetic derivatives of the natural steroid, cortisol, produced by the adrenal glands, and have profound anti-inflammatory effects.

become established as the mainstay of treatment'. They further state that the mostly commonly used drugs are '*prednisone and prednisolone which are assumed to be bioequivalent*[29]*'*. The D IPA advised that prednisolone was the mostly commonly used medication for the treatment of pemphigoid. I accept her advice and am satisfied the Trust prescribed appropriate medication to treat the patient's condition.

55. The complainant also raised concerns with the Trust's long-term use of the steroids. I examined the Trust's records outlining the patient's steroid treatment. They document the Trust prescribed the patient Prednisolone 30mg once daily in June 2019. The Trust increased the dosage in July 2019 to 40mg. However, it reduced it again in August 2019 by 5mg per fortnight to 15mg. There was a further reduction in October (to reduce to 10mg once daily for 2 weeks, 7.5mg once daily for 2 weeks, and then 5mg once daily for 2 weeks). In November 2019 the prescription changed to 10mg once daily for 2 weeks, then 7.5mg once daily for 2 weeks, then 5mg once daily for 2 weeks. However, the Trust increased the dosage to 20mg in January 2020 due to a flare up of blistering. It reduced the prescription again over a period of two weeks (17.5mg once daily to reduce to 15mg once daily).

56. The D IPA advised that the timetable outlined above '*indicates a good standard of practice and takes into account the side effects of steroids on bone health and the gastric mucosa'*. She also advised it demonstrates that the patient was on the '*lowest possible level of prednisolone at any time. This constitutes good prescribing'*.

57. The D IPA also advised that the Trust attempted the use of steroid-sparing agents over the course of the 12 month period. She advised that doing so was '*entirely appropriate'*, '*good practice'* and in accordance with BAD guidelines. I accept her advice.

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[29] Bioequivalence is the property wherein two drugs with identical active ingredients or two different dosage forms of the same drug possess similar bioavailability and produce the same effect at the site of physiological activity.

58. In his response to the draft report, the complainant asked my office to seek advice from an oncologist IPA to advise on the increased level of steroid use from January 2020 to March 2020, and if it rendered immunotherapy or chemotherapy *'too dangerous'.* I note the O IPA advised it would have been inappropriate to treat the patient with immunotherapy or chemotherapy. He advised that doing so may have worsened the patient's pemphigoid. He also advised that given the patient's steroid treatment, immunotherapy would have been ineffective. I accept his advice.

59. I note how the use of steroids over this period of time later impacted the availability of medication to treat the patient's lung cancer. I appreciate the concern this would have caused both the complainant and the patient at that time. However, based on the evidence available to me, I have not identified that the Trust's prescription of steroid medication represents a failure in the patient's care and treatment. I do not uphold this element of the complaint.

The lack of diagnostic tests for cancer

60. The complainant was concerned that the consultant dermatologist was unaware that blood tests and x-rays could not detect adenocarcinoma. He said the patient presented to the dermatologist with '*a persistent cough and shortness of breath'*. The complainant added that the dermatology team told him there was a link between pemphigoid and cancer, and as such, he believed the Trust should have pursued further testing and referred the patient for biopsy.

61. I examined the Trust records and noted two incidents when the patient brought her respiratory symptoms to the attention of the dermatology consultant. After the consultation on 17 January 2020, the consultant dermatologist wrote to the patient's GP. She documented in her letter that the patient described '*a new onset productive cough and I understand she was commenced on Augmentin yesterday for a presumed chest infection'*. On 30 August 2019, another consultant dermatologist wrote to the patient's GP after a consultation. The letter documented, '*She complained of a cough and green sputum today and is going to contact her GP in relation to this as she feels she may have a chest infection*'. On 14 February

2020, the consultant dermatologist documented in a letter to the patient's GP that *'she has now stopped her Antibiotic and her chest symptoms have settled'*.

62. The D IPA advised that the Trust's actions as outlined in the paragraph above were appropriate. She also advised that she '*would not expect a reasonable dermatologist to perform any other investigations in the absence of compelling symptoms'.* I accept her advice.

63. The complainant also raised a concern about a link between pemphigoid and cancer. In considering this element of the complaint, I refer to the JAMA study. It found '*no significant increase in the incidence of cancer among patients with BP compared with those in the age- and sex-matched general population'.* I also note the D IPA advised there is no clear association between pemphigoid and malignancy. Based on this evidence, I cannot be satisfied that a link between pemphigoid and cancer exists. Therefore, I would not expect the Trust to undertake any routine tests for those patients diagnosed with pemphigoid.

64. I appreciate the complainant's concerns regarding the patient's cancer diagnosis. However, I find no evidence to suggest that the Trust ought to have taken any action in addition to that outlined. I do not uphold this element of the complaint.

Referral to ENT

65. The complainant said the Trust delayed referring the patient to an ENT consultant. He said the Trust explained the delay by saying that the ENT team in the RVH had already seen the patient. However, the complainant said this was not the case. I note the consultant dermatologist initially referred the patient to ENT on 18 July 2019. However, ENT did not review the patient (as an outpatient) until May 2020.

66. The Trust explained it cancelled the referral as the patient informed it that the ENT team in the RVH already treated her. I examined the Belfast Health and Social Care Trust's records relating to the patient's attendance at the RVH. They document the patient attended the ED on 18 July 2019 reporting difficulty with her swallow. The Trust's letter to the patient's GP about the attendance documented '*attended with*

throat pain and ulceration. Seen by ENT. Throat pain secondary to Bullous Pemphigoid'.

67. I also considered the Trust's records relating to this referral. They document that its booking team wrote to the patient on 24 July 2019 and asked her to contact them to book an appointment with ENT. They further document that the patient telephoned the booking team on 30 July 2019. The Trust then cancelled the appointment at the patient's request following her call.

68. The records document that the patient attended the consultant dermatologist on 30 August 2019. In her letter to the patient's GP, the consultant dermatologist documented '*She had an episode of hoarseness 5 weeks ago and explained to me today that she was seen by ENT in Emergency Department who visualised blisters in her throat. Unfortunately there was no letter on ECR relating to this'.*

69. I note and appreciate the complainant's understanding that the patient still awaited an ENT appointment, and I have no reason to doubt his view. However, based on the evidence available, and on the balance of probability, I am satisfied the Trust cancelled the appointment further to the patient's telephone call and at her request. Therefore, I have not identified any maladministration on the part of the Trust regarding cancellation of this referral.

70. I note the patient reported to the consultant dermatologist that she experienced ongoing pain and a *'sticking sensation'* in her throat in January 2019. Subsequent to this, on 17 January 2019, the consultant dermatologist sent an urgent referral to the Trust's ENT for specialist advice, as she considered the patient '*at risk of laryngeal involvement and possible scarring* or *stenosis'*. The D IPA advised this was appropriate and did not identify '*any shortcomings'* relating to the referrals to ENT. I accept her advice.

71. I note the Trust scheduled the ENT appointment for 6 March 2020. However, when the patient was admitted to a different hospital, it cancelled the appointment. I also note the Trust cancelled a later appointment (on 3 April 2020) due to the Covid-19

Pandemic. The patient later attended an appointment with ENT on 19 May 2020, which it held virtually.

72. I consider it unfortunate that the patient did not attend an ENT outpatient appointment until May 2020. I appreciate that circumstances (as outlined) led to the cancellation of appointments. However, I am satisfied these occurred following the referrals and were outside of the consultant dermatologist's control. I have not identified any evidence to suggest that the Trust delayed *referring* the patient. Conversely, I consider the Trust referred the patient on both occasions at the earliest opportunity. Therefore, I do not uphold this element of the complaint.

CONCLUSION

73. This complaint is about care and treatment provided to the patient between June 2019 and May 2020. I examined the management of the patient's revised diagnosis from BP to MMP, her steroid medication, the patient's cancer diagnosis and referral to ENT. I do not uphold the complaint for the reasons outlined in this report.

74. It is evident from my reading of the records how involved the complainant was in the patient's care. I note the IPA's advice that the Trust's care and treatment of the patient was of a high standard. I hope this provides an element of reassurance for the complainant.

MARGARET KELLY
Ombudsman **November 2022**

Appendix 1

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.

Appendix Two

PRINCIPLES OF GOOD COMPLAINT HANDLING

Good complaint handling by public bodies means:

Getting it right

- Acting in accordance with the law and relevant guidance, and with regard for the rights of those concerned.
- Ensuring that those at the top of the public body provide leadership to support good complaint management and develop an organisational culture that values complaints.
- Having clear governance arrangements, which set out roles and responsibilities, and ensure lessons are learnt from complaints.
- Including complaint management as an integral part of service design.
- Ensuring that staff are equipped and empowered to act decisively to resolve complaints.
- Focusing on the outcomes for the complainant and the public body.
- Signposting to the next stage of the complaints procedure, in the right way and at the right time.

Being customer focused

- Having clear and simple procedures.
- Ensuring that complainants can easily access the service dealing with complaints, and informing them about advice and advocacy services where appropriate.
- Dealing with complainants promptly and sensitively, bearing in mind their individual circumstances.
- Listening to complainants to understand the complaint and the outcome they are seeking.
- Responding flexibly, including co-ordinating responses with any other bodies involved in the same complaint, where appropriate.

Being open and accountable

- Publishing clear, accurate and complete information about how to complain, and how and when to take complaints further.
- Publishing service standards for handling complaints.
- Providing honest, evidence-based explanations and giving reasons for decisions.
- Keeping full and accurate records.

Acting fairly and proportionately

- Treating the complainant impartially, and without unlawful discrimination or prejudice.
- Ensuring that complaints are investigated thoroughly and fairly to establish the facts of the case.
- Ensuring that decisions are proportionate, appropriate and fair.
- Ensuring that complaints are reviewed by someone not involved in the events leading to the complaint.
- Acting fairly towards staff complained about as well as towards complainants.

Putting things right

- Acknowledging mistakes and apologising where appropriate.
- Providing prompt, appropriate and proportionate remedies.
- Considering all the relevant factors of the case when offering remedies.
- Taking account of any injustice or hardship that results from pursuing the complaint as well as from the original dispute.

Seeking continuous improvement

- Using all feedback and the lessons learnt from complaints to improve service design and delivery.
- Having systems in place to record, analyse and report on the learning from complaints.
- Regularly reviewing the lessons to be learnt from complaints.
- Where appropriate, telling the complainant about the lessons learnt and changes made to services, guidance or policy.