

Review of the Health Service Ombudsman's approach to complaints that NHS service failure led to avoidable death

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Introduction by Dame Julie Mellor, DBE, Health Service Ombudsman

This review by Baroness Fritchie, DBE looks at how we respond to some of the most serious complaints we receive: that someone's death could have been avoided if NHS care or treatment had been better.

We were established by Parliament to make the final decision on complaints about the NHS in England. If, following a complaint to the NHS, the complainant is dissatisfied with the response, they can bring their complaint to us. Our work is with individuals – patients and families – listening to their experiences and concerns and making independent judgements on their complaints.

When a loved one dies suddenly, or unexpectedly, family members seek information, explanation and reassurance that such events will never happen again. No-one can change the situation but, when we listen and respond, our work can make a difference. Our investigations can ensure that grieving families are listened to and receive explanations about what happened, and, if mistakes have been made, make recommendations for change which can help drive improvements within the NHS.

In my first months as Ombudsman, I listened to feedback from complainants and from Parliament's Health Committee which suggested that, at times, our work had not made the difference that it should. I wanted us to learn from this feedback, and in July 2012 we commissioned Baroness Fritchie to give us an external view on our response to these complaints to see if there was more we could do to help both the people who complain to us and the NHS bodies, regulators and other organisations with responsibility for ensuring patient safety.

I am grateful to Baroness Fritchie for her consideration of 100 cases, and her recommendations which cover the service we provide as well as our approach and processes. We have accepted her recommendations and will begin action quickly to conduct more investigations and improve when and how we share information and insight with the organisations responsible for the quality of NHS care and ensuring patient safety. Our management response to each recommendation is included at the back of the review.

From 1 February we will begin our consideration of any complaint about a potentially avoidable death with the presumption that it will be investigated. The outcome of these investigations will be based on our independent assessment of the facts, but even when complaints are not upheld, investigations can be of value by providing families with explanation about what happened or reassurance that the care and treatment was of the right standard.

Baroness Fritchie's review contributes to our own broader consideration of how, as an Ombudsman service, we can have more impact for more people. In November, we published our new strategy, setting out how we will help more people by investigating more complaints and by using what we learn to help

others improve the quality of care and patient safety across the NHS. Our strategic plan and business plans set out how we will make this happen.

Our independence from the NHS, and from government, is enshrined in law and the decision about whether or not to investigate a complaint is ours alone. But this does not mean we work in isolation. What we learn during our investigations can provide useful insight for those organisations responsible for the quality of NHS care and ensuring patient safety. Our new strategy commits us to sharing this insight more widely, and in a timely way, and we have new powers in law which enable us to do this.

Our new strategy also sets out how we want to contribute to improving the broader complaints system, to make it easier for people to complain. We cannot do this alone. We are leading and contributing to wider discussions with regulators and professional bodies so we can work together better to make the complaints system clearer, simpler and easier to access.

When people complain about the events leading to the death of someone they love, they often tell us that they want to achieve two things. They want to know what happened, and to make sure that changes are made to stop the same situation happening to someone else. Where mistakes have occurred, we share that motivation. The actions we will take following Baroness Fritchie's review will help us to help the NHS to learn from what has gone wrong and help us deliver a service that can make a difference for everyone who comes to us.

Dame Julie Mellor, DBE
Health Service Ombudsman

Baroness Fritchie's review of the
approach taken by the Office of the
Parliamentary and Health Service
Ombudsman (PHSO) to complaints
that NHS service failure led to
avoidable death



Foreword

For all of us the loss of someone we love is both sad and difficult. However, if that loss is compounded by a strong belief that the death was avoidable, and that the place they were being cared for had contributed to service failure which led to this loss, then most of us can only imagine the additional feelings and thoughts experienced.

In undertaking this review I have kept this at the forefront of my mind, ensuring that the people who complain to the Ombudsman have been central to my consideration.

I recognise that, not only have they had to deal with loss and grief, but in most cases have had what they have experienced as unclear and unsympathetic complaints processes to battle with, within the very organisations which they are challenging, before they reach the Ombudsman's Office.

It is understandable that they would expect that clarity, understanding and fair dealing would be a mark of the service they received from the Office of the Parliamentary and Health Service Ombudsman.

I was asked by PHSO:

'To undertake a casework review of a sample of complaints to PHSO, about avoidable death to ensure that our [PHSO's] work in this area can be of most benefit to the people who complain to us and to the wider public. The review will include looking at how we can best share patient safety concerns and lessons learned from complaints about avoidable deaths with service providers, and healthcare and professional regulators. The recommendations will contribute to a wider review of our corporate strategy, which is looking at how we can have more impact for more people in all aspects of our work.'

My review did not consider the actions and decisions taken in individual cases and this report does not, therefore, comment or make judgments on any specific cases. The intention was to review the general approach taken by PHSO and its impact in these cases, and consider how that impact might be improved or increased.

Together with a researcher I have:

- Reviewed 100 cases: 30 were selected for further investigation, 60 were not, and 10 were under active consideration during the review.
- Examined the electronic records of all cases selected, including:
 - the assessment forms (including the analysis of the information provided by the organisations complained about);
 - notes of management and assessment panel discussions;

- the clinical advice sought to inform the assessment/investigation;
- any exchanges with the organisations and complainants;
- the consideration given to the risks to other service users; and
- the decision letters and reports.

I have drawn on my own background, in the Health Service and as a former Regulator and Ombudsman, in my analysis and in making my recommendations. I have become familiar with the current work of the Office of the Parliamentary and Health Service Ombudsman on vision, mission, and strategy. I believe that my recommendations will add value to this work.

It is clear to me that although every person seeking understanding and justice may not get the outcomes they initially desire, PHSO can make the experience a positive one, giving support and assurance, and a voice and influence to make services better.

I would like to recognise the work of Christine Corrigan, the researcher who worked with me, and PHSO staff who made all files requested available and engaged fully to make sure my work was progressed.

Rennie Fritchie

The remit

1. The aim of the review was:

'To undertake a casework review of a sample of complaints to PHSO, about avoidable death to ensure that our [PHSO's] work in this area can be of most benefit to the people who complain to us and to the wider public. The review will include looking at how we can best share patient safety concerns and lessons learned from complaints about avoidable deaths with service providers, and healthcare and professional regulators. The recommendations will contribute to a wider review of our corporate strategy, which is looking at how we can have more impact for more people in all aspects of our work.'

2. The review did not consider the actions and decisions taken in individual cases and this report does not, therefore, comment or make judgments on any specific cases. The intention was to review the general approach taken by PHSO and its impact in these cases, and consider how that impact might be improved or increased.
3. To place the subsequent observations in context, the annex gives a brief explanation of the approach that PHSO adopts when considering all complaints. The annex does not provide a comprehensive guide to

PHSO's process, but covers the key areas relevant to the review.

The process the review followed

4. PHSO caseworking staff who deal with complaints relating to the NHS were asked to identify the cases they had dealt with that had involved an allegation that service failure had led to an avoidable death.¹
5. One hundred cases were selected from those put forward. The selection was spread across all the caseworking teams handling health complaints, and included:
 - 60 cases in which PHSO had decided not to conduct a formal investigation² (33 of which had been concluded in 2012);
 - 30 cases where a formal investigation had been carried out (13 of which concluded in 2012); and
 - 10 cases which were under active consideration, and which were discussed during the review by PHSO's internal assessment panel. Those discussions were observed. (See annex: the panel is made up of senior operational managers and determines which cases are accepted for investigation.)

¹ It was not possible to identify these from PHSO's electronic caseworking system, so those staff who handle health complaints were asked to put cases forward.

² It was decided that it was appropriate to include in the 100 cases reviewed a higher proportion of cases in which PHSO had declined to conduct a formal investigation. This was because it was, in part, the concerns raised by complainants whose cases had not been subject to formal investigations that led to this review.

6. The electronic records of all of these cases were examined, including:
- the assessment forms (including the analysis of the information provided by the organisations complained about);
 - notes of management and assessment panel discussions;
 - the clinical advice sought to inform the assessment/investigation;
 - any exchanges with the organisations and complainants;
 - the consideration given to the risks to other service users; and
 - the decision letters and reports.

Key findings

Overall

7. The evidence suggested that, generally, all of the cases reviewed were treated seriously and given ample consideration. It was evident from the case file notes that staff were very aware of the importance and significance of these cases to the complainants; and of the potential wider risks to patients, should there be a possibility that service failure had contributed to the deceased's death. As a result, the case files frequently showed evidence of considerable deliberation, including discussions and exchanges with clinicians and senior management about how a case might best be handled both at the initial assessment stage and during the formal investigation. There were

also often several exchanges with the organisations complained about, as well as with the complainants. However, the review also found that PHSO's internal processes may sometimes have unintended consequences that may not always provide maximum benefit to the complainant, or to the wider public.

Specific findings

8. The review found the following:
- a) As already indicated, PHSO's current electronic caseworking system (called Visualfiles) does not enable the identification of complaints about the NHS which involve allegations of avoidable deaths.
 - b) During PHSO's initial assessment of each case, efforts were made to identify themes and trends (this involved researching whether previous complaints had been made to PHSO about the organisations in question, the substance of those complaints, and the outcomes). In none of the cases was the information identified in this way judged by PHSO to be of particular significance to the handling of the case.
 - c) In 59 of the 100 cases the Ombudsman's discretion was exercised to allow them to be considered, even though they were outside the statutory 12-month time limit. (The other 41 cases were put to PHSO within the statutory time limit.)

- d) Although PHSO has a target of closing 90% of enquiries³ within 40 working days, those involving allegations of avoidable death were frequently given longer consideration. Of the 70 cases reviewed that PHSO decided not to investigate or which were put to the assessment panel, 45 were over the 40-day target when they were closed or put to the assessment panel (indicating the significant level of investigative activity and consideration these cases were subject to).
- e) Full NHS papers were obtained in all but one of the cases, to support consideration of the complaints at the assessment stage. (The case where papers were not obtained was still under local resolution.)
- f) The legislation governing health complaints prevents the Ombudsman from conducting an investigation unless she is satisfied that the complaints procedure of the health organisation/service provider has been invoked and exhausted. (The Ombudsman does, however, have specific discretion in the legislation not to require this if she thinks it unreasonable in the circumstances of the specific case.) PHSO's guidance to caseworkers is therefore that, as a general principle, a complainant should have given the organisation complained about the opportunity to respond formally to the complaint that they are seeking to bring to PHSO.
- g) The case files showed that in a number of cases, there was significant discussion about whether specific aspects of the complaint had been put to the organisation or not, and whether that should be done before PHSO considered the matter further.
- h) In 13 of the 60 enquiry cases in the review, and in 1 of the 10 cases considered at the assessment panel, the outcome was that they were referred back to the organisation complained about for further or continuing local resolution.
- i) In 34 of the total sample of 100 cases, the complainant had previously been referred back to the organisation for local resolution to continue, or for further action by the organisation. In 9 of those cases, the complainant had been referred back to the organisation twice.
- j) The process that caseworkers then follow, as set out in PHSO's detailed guidance, is that they consider:
 - whether there are indications of service failure. This includes referencing the general standard (the Ombudsman's Principles) and the specific standards applicable to the case (such as legislation, guidance and professional standards);

³ See annex – complaints to PHSO which have not been accepted for investigation are called enquiries.

- whether it appears that the injustice claimed by the complainant, or other forms of injustice, may have arisen in consequence of that service failure;
- whether that injustice appears to have already been remedied by the organisation complained about;
- what outcome the complainant is seeking and whether it is likely to be achievable;
- what more PHSO might reasonably achieve through a formal investigation; and
- would a formal investigation be a good and appropriate use of the resources available to PHSO, or might there be a quicker, more proportionate way of resolving the complaint – such as an intervention

by PHSO with the organisation in question to get them to offer an appropriate outcome to resolve the complaint.

- k) Clinical advice was sought in 50 (of the 60) cases declined at assessment stage, and in all of the 10 cases under consideration during the review, to support PHSO's consideration at the assessment stage. (The only cases where such advice was not sought were the 9 cases assessed to be premature; and in 1 other case where a comprehensive, independent clinical review had already been carried out and was available to the caseworker.) The following table sets out the number of different clinical advisers consulted:

Number of advisers consulted	Number of cases
1	37
2	17
3	4
5	2

- l) The guidance also requires caseworkers to consider whether a complaint raises a wider public interest that might justify an investigation. This would clearly include whether any indications of service failure identified might suggest that other patients could potentially be at risk. Caseworkers are not, however, required to demonstrate on the assessment forms the consideration that has been given to the potential risks to other service users. Some caseworkers did refer to such concerns on the assessment forms, but others did not (including on 2 occasions where clinical advisers had specifically raised such concerns).
- m) PHSO's publicly stated objective is that it will try to resolve as many complaints as quickly as possible through direct contact with the organisation complained about; and only conduct formal investigations in a small number of cases where it is decided that this is the only way to get to the bottom of things.⁴ The review cases demonstrated that the caseworkers adhere to this approach.
- n) However, it was also evident that a number of cases were also quickly taken forward for formal investigation. These were cases where the clinical advice obtained clearly indicated that there appeared to have been significant service failure that might have impacted on the deceased's chances of survival; and the NHS organisation concerned did not appear to recognise that, or be prepared to take steps to prevent a recurrence.
- o) Often complaints are broken down by PHSO not only into the different organisations involved, but also into the different aspects of care and treatment involved in the relevant events. Some aspects of care and treatment may be investigated and others not. The complainant will be told at the start of the investigation which matters will not be looked into and why that is, and then receive a report on the other aspects of their complaint at the end of the formal investigation. Most formal investigations take around a year to complete. In 6 of the investigated cases the complainant was told that only certain aspects of the complaint would be formally investigated.
- p) The vast majority of cases that were subject to a formal investigation were upheld wholly or in part. Of the 30 investigated cases included in the review:
- 21 were fully upheld;
 - 8 were upheld in part;
 - 1 was not upheld;
 - in 13 cases the deceased's death was found to have been avoidable;

⁴ *Your complaint and us: how we can help*, PHSO leaflet published in August 2012.

- in 8 cases it was found that the deceased's chances of survival had been compromised;
- in 4 cases it was found that it was no longer possible to say whether the death was in consequence of the service failure identified; and
- in 4 cases significant service failure was identified, but this failure was not linked to the deceased's death.

q) The clinical advice obtained in the course of the 30 formal investigations was also critical to the findings in those cases. Additional external specialist advice was frequently obtained. The following table shows the number of different advisers consulted in each case:

Number of advisers consulted	Number of cases
6	1
5	3
4	6
3	8
2	9
1	3

- r) PHSO's clinical advisers frequently challenged the clinical explanations given by the organisations complained about, both at the assessment and formal investigation stages, and criticised the clinical handling in many cases; they also frequently challenged the robustness of action plans put forward by organisations to bring about service improvement.
- s) It was also noted that the advice the clinical advisers gave was always referenced to current professional clinical guidance and good practice, and that where advisers believed that further specialist information was required, they would recommend consultation with other colleagues or with external specialists.
- t) In 2 of the investigated cases, the organisations complained about initially disputed PHSO's clinical advisers' advice. The Royal College of Physicians was contacted and asked to nominate independent clinicians to review the advice. In both cases the College nominee agreed with the advice and consequently with PHSO's clinical findings in the reports concerned.
- u) PHSO's clinical advice directorate audits its advice on a regular and ongoing basis to ensure that it is of the required quality. Specifically, the clinical advisers routinely peer review each others' advice provided in an investigation, and the lead clinicians audit a sample of the advice given on an ongoing basis. In addition to these internal quality assurance procedures, PHSO is undertaking a pilot whereby a sample of clinical advice is audited externally. To this end, the Royal Colleges of Physicians, Obstetrics, and Gynaecology have reviewed samples of PHSO's clinical advice. If the pilot proves successful, it is intended to be rolled out to cover all specialties.
- v) Interviews with relevant NHS staff were carried out in 4 of the 30 investigations reviewed.
- w) Investigation reports follow a set template that sets out what should have happened (in terms of the applicable standards and guidance relating to the care and treatment provided); what did happen in that specific case; and then addresses whether the gap between the two was sufficient to amount to service failure. The reports then go on to consider issues of injustice and, where appropriate, of remedy.
- x) The case files showed that advice that was not consistent was given to staff on the following issues:
 - whether, when initially assessing cases, caseworkers should be looking solely at the organisations' complaint handling in the first instance, rather than looking at the substance of the complaint too;
 - whether clinical advisers should be asked to comment solely on the specific complaint made and the adequacy of the organisation's response to the complaint in the first instance, or whether they should be asked to comment

on the core care and treatment provided to the deceased;

- the potential value of interviews (the investigation planning meetings showed that some caseworkers were encouraged to consider these, while others were told they were effectively a last resort for obtaining information); and
- whether investigators should build on the investigative activity that had taken place at the initial assessment stage, or start the investigation again from scratch.

During the course of the review it was suggested by PHSO staff that these inconsistencies may stem from the fact that, although PHSO's approach has changed in some respects, the detailed guidance has not been updated accordingly, and no longer, therefore, reflects intended current practice.

- y) Specific concerns about the potential risks to other patients arising from health organisations' actions were raised at the assessment stage with the Care Quality Commission (CQC – the organisation responsible for the regulation and inspection of NHS services) in 2 cases, and in 1 of those, also with Monitor (the foundation trust regulator). In one other case included in the sample, PHSO considered referring an individual to the General Medical Council, but subsequently decided not to do so.

Analysis of findings

Assessment of complaints

Referring complaints back to the organisations complained about

9. It is clearly important that organisations are given the opportunity to respond to a complaint, and to put things right, before PHSO takes further action on a complaint. However, the considerable discussions that took place in some instances about whether the different, specific aspects of the complaint (as put to PHSO) had been put to the organisations complained about, suggested that a lot of emphasis was being placed on complainants having been able to identify correctly what went wrong, and therefore knowing precisely what they should be complaining about. This approach appears to remove the focus from the key issue: namely, whether there are indications that there has been service failure which may have contributed to an injustice.
10. It is acknowledged that referring cases back to the organisations to take further action in this way is generally in the best interests of the complainant, in that it can lead to speedier resolution of an extremely distressing situation. However, referring the case back to the organisation several times may have other consequences, in that:
 - complainants are less likely to have confidence that service improvements proposed by NHS organisations as remedies will be taken forward, when the organisations concerned have already demonstrated a reluctance to act;

- should further attempts at local resolution or an intervention by PHSO fail, the events are even further in the past and may therefore be more difficult to investigate;
 - NHS organisations' offers of remedy may be driven more by a wish to avoid a formal investigation, than by the desire to provide an appropriate response and take the necessary steps to avoid a repeat of service failure.
11. Further, the figures in paragraph 8 (i) relating to the numbers of complainants whose cases had been referred back to organisations, sometimes more than once, together with those in 8 (c) (the number of cases accepted for consideration outside the 12-month statutory time limit) would suggest that the whole complaints process is an extremely lengthy one for many complainants. This could serve to add to complainants' distress.
- Assessment process
12. It is evident that significant investigative activity generally takes place at the assessment stage, which may in some cases be similar to that undertaken in a formal investigation. However, the value of the work that PHSO has carried out is unlikely to be readily apparent to, or accepted by, those complainants who are subsequently told that it is not proposed to conduct an investigation into their complaint, when clearly significant investigative activity has already taken place.
13. The discussions recorded in the case files and on the assessment forms indicated that the assessment process that PHSO follows (paragraph 8 (j)), although generally appropriate and reasonable in itself, may (in some instances) lead to a great deal of emphasis being placed on one particular aspect of the assessment of the complaint – rather than the matter as a whole – and a decision not to conduct a formal investigation being made on that basis. The particular aspects in question were:
- whether the complainant had been able to identify what had gone wrong and make the correct complaint (as referred to in paragraph 9 above);
 - whether an investigation was likely to uphold the injustice the complainant had identified as flowing from the service failure (in the review cases, this was the death of the deceased); and
 - whether an investigation might provide a complainant with the outcome they said they would like to achieve.
14. These are clearly all important considerations that need to be addressed. However, the consequent emphasis on caseworkers trying to pre-judge the likely outcome of an investigation meant that in some cases other important issues (such as whether a formal investigation might bring the complainant some form of resolution or closure, or identify lessons which might be of wider benefit to others) may not have been given as much weight as they may have warranted.

Potential patient safety concerns

15. Patient safety concerns are clearly more likely to become apparent during a formal investigation. However, although caseworkers at the assessment stage are expected to consider broadly the question of whether any indications of service failure identified might suggest that other patients could potentially be at risk (paragraph 8 (l)), it is not entirely clear how they are to do this. Further, they are not required to demonstrate on the assessment forms the consideration given to the potential risks to other service users. As a result, it was not possible to determine why in 2 cases potential patient safety concerns raised by clinical advisers at the assessment stage were not judged to be sufficiently compelling to warrant the cases being taken forward for formal investigation.

Formal investigations

16. The fact that in 6 cases (paragraph 8 (o)) the complainant was told that only certain aspects of the complaint would be formally investigated meant that those complainants received the necessary information about their whole complaint in a fragmented way: namely, at two different times (at the beginning and end of the formal investigation), separated by a lengthy period. This would undoubtedly have made it more difficult for them to see the whole picture.
17. The overwhelming number of investigations upheld wholly or in part (paragraph 8 (p) above) could be seen as signifying that PHSO is focusing its resources appropriately on those cases which merit investigation.

However, it might also be an indication that the threshold for conducting a formal investigation is set very high, and that cases are generally only taken to formal investigation where it is judged at the outset that the complaint is likely to be upheld.

18. This in turn would seem to indicate that, during the assessment process, very little weight is given to the possibility that an investigation which does not result in the complaint being upheld may still have value. Similarly, it does not appear to recognise that an investigation that concludes that no more information about the events in question is likely to be found, may in itself be a positive outcome. Such outcomes might be able to provide a complainant with some resolution and, at the very least, demonstrate to the complainant that their voice has been heard and acted upon.

Clinical advice

19. The clinical advice provided to PHSO's caseworking staff during their consideration of the complaints and the formal investigations (mainly by PHSO's own clinical advisers, but also by specialist external advisers) was clearly a key factor in determining what happened to the cases included in the review. Such advice was seen to be essential to the consideration of whether:
- there were indications of service failure at assessment stage and evidence of service failure during investigations;
 - the organisations' clinical explanations about what had happened were reasonable;

- the steps the organisations were taking to remedy matters were sufficiently robust to prevent recurrences of service failure; and
- whether the organisations'/ individual's actions could pose a risk to other service users.

20. It was also evident from the challenges raised by PHSO's clinical advisers to the explanations provided by health organisations, and to those organisations' proposed action plans for preventing the recurrence of service failure (see paragraph 8 (r) above) that there was no indication that the advice provided by PHSO's clinical advisers in any way favoured the views of their professional colleagues.

21. Further, there was clear evidence that PHSO's clinical advisers conducted themselves in a highly professional manner (paragraphs 8 (s) and 8 (t) above), and that significant steps were taken to ensure that the advice provided was of the appropriate professional standard (paragraph 8 (u) above).

22. However, although clinical advice was clearly vital in determining that service failure had occurred and its likely consequences, what the clinical advisers could not generally do was advise on how or why those failures might have happened.

Maximising learning

23. It is possibly as a result of this, combined with the process-driven approach adopted by the Office to try and ensure consistency in the outcomes delivered (including advising

caseworkers to use a set report template – paragraph 8 (w) above), that investigation reports could appear somewhat formulaic. For although the reports set out what should have happened (in terms of the applicable standards and guidance in respect of the care and treatment provided), and explained why those requirements had or had not been met, the question of why any failings identified had occurred (the 'human element' of the failure) was frequently left unexplored.

24. This omission may be linked to the fact that very few interviews were carried out with individuals in the organisations complained about, even where an individual was named in the complaint. As detailed in paragraph 8 (v) above, interviews with relevant NHS staff were carried out in only 4 of the 30 investigations reviewed.

25. This appears to be a missed opportunity, because such information (that is, an understanding of how or why the failure might have occurred) could be extremely valuable, both in terms of the individual/organisation learning from the service failure, and by helping to ensure that action plans to prevent recurrences are as relevant and appropriate as possible.

Inconsistencies in approach

26. Although the inconsistencies in approach identified at paragraph 8 (x) were small in number, they were not unimportant. They could clearly have a significant impact on the handling of the assessment of complaints, the time taken to consider them, and even on the outcome for the complainants. Furthermore, telling a complainant – who is convinced that a loved one

has died as a result of service failure – that PHSO’s initial focus will be on the health organisation’s complaint handling, is likely to diminish a complainant’s experience of, and their confidence in, PHSO’s work.

27. It is, therefore, important that these matters are clarified by the leadership of PHSO, that the relevant changes in approach are clearly communicated to caseworking staff, and that PHSO’s detailed casework guidance is appropriately updated.

Language

28. The language that PHSO has historically used (internally to describe its work and in its communications with complainants) appears to have been based largely both on the legislation which governs its remit, and the processes it has adopted to carry out that remit. Consequently, in some cases PHSO described the reason for deciding not to investigate cases as ‘no unremedied injustice’ (which is derived from the legislation, and meant that PHSO considered the remedy already provided to the complainant to be appropriate to the injustice suffered); and in others ‘no worthwhile outcome’ (meaning that it was considered that an investigation would be unlikely to add any value/ resolve issues further for the complainant). The review noted that such language could be experienced as unsympathetic, particularly in sensitive cases involving complaints involving potential/actual avoidable death.

29. It was, however, also noted by the review that PHSO had already identified this as an issue and that work had already been done to halt the use of such terms in communications with complainants. Some changes have also already been made to internal documents to reflect that work. This was evident from the most recent cases reviewed. It is important that the strategic development work going forwards includes continuing efforts to develop a more empathetic language which is both clear and meaningful to complainants, and which can be used in all circumstances – both internally and externally.

Knowledge management

30. The fact that PHSO’s current electronic case management system does not enable it to identify and capture information specifically relating to complaints about alleged avoidable deaths (paragraph 8 (a) above) suggests that PHSO is missing significant opportunities to maximise knowledge of its own caseload, and learning from the complaints put to it.
31. Such cases are self-evidently amongst the most serious complaints considered by PHSO. Capturing such vital information would not only tell the Ombudsman more about the complexion of the casework being undertaken, but might also help identify trends, themes and clusters, which could be fed back to the relevant regulators and commissioning organisations.

32. Further, although it is clear that efforts are already made during the initial assessment of complaints to identify themes and trends (paragraph 8 (b) above), the fact that these attempts resulted in no significant information being identified in respect of any of the 100 cases included in the review may also be an indication that PHSO's current information systems are not able to make best use of the information held.
33. It is noted that, as part of its project to refresh its corporate strategy, PHSO is committed to a fundamental review and overhaul of its knowledge management systems, in order to be able to extract more meaningful data and learning to try to ensure that its work has more impact for more people. That is clearly an extremely important and significant piece of work, which will take some time to complete. In the interim, it is important that some way should be found of identifying these highly significant cases on the system.

Other observations

Maximising the benefit of PHSO's work to the wider public

34. The review was also asked to consider how PHSO could best share patient safety concerns and lessons learned from complaints about avoidable deaths with service providers, and healthcare and professional regulators.
35. The review noted that, where service failure requiring an action plan has been found following a formal investigation, it is already PHSO's practice to send a summary of the

investigation to relevant regulatory organisations (such as the CQC and Monitor) and to ask the NHS organisation concerned to send them a copy of the action plan for them to take into account in their subsequent oversight of those organisations.

36. It is also already PHSO's current practice to send the reports of the outcome of formal investigations to the organisations complained about (annex). However, the reports are sent to the Chief Executive/head of those organisations, and there was no evidence of how often those reports were shared internally with those at the most senior levels with ultimate accountability (for example, trust boards). It is particularly important that investigation reports which uphold complaints about avoidable deaths reach those who are best placed to ensure that appropriate action and learning is taken forward.

Relationship with the regulators and commissioners of health services

37. PHSO clearly does not work in a vacuum, and it is not a regulator. Nor is it there to monitor the performance of healthcare providers going forwards. It is there to be a last resort for those who consider that the NHS has failed them, in that they feel that their complaints have gone unheeded and their voice has not been heard.
38. In addition, given the small number of complaints that PHSO deals with after local NHS resolution has failed (compared to the large amount of health service activity underway on a daily basis, together with the time

lapse between the actual events complained about and the approach to PHSO), the Office can only act as an early warning system to a very limited extent.

39. However, PHSO still has an important role to play in ensuring that it does actively and promptly consider, at all stages of its work, whether there are any patient safety concerns being raised which should be shared with healthcare and professional regulators (and possibly healthcare commissioners). It should therefore ensure that the process it follows requires that any potential patient safety issues identified – particularly by clinical advisers – are discussed as quickly as possible and at an appropriate level, and that if it is decided not to communicate these concerns to the relevant regulators, the reasons for that decision are properly documented.
40. Further, in order to ensure that any such concerns that PHSO considers should be shared are dealt with promptly and appropriately, there should be a clear and agreed process and communication channels between PHSO and the regulatory organisations in question for this purpose. This would both help to ensure that any concerns PHSO might have could be passed on speedily, and that confirmation could be provided to PHSO that those concerns had been received and acted upon.
41. In order to do that, PHSO needs to have strong working relationships with both the commissioners and regulators of NHS healthcare services. It is also extremely important that PHSO and regulatory organisations have a

mutual and transparent expectation of each other's roles and responsibilities, so that it is fully understood, when concerns are identified, what action each organisation will be expected to take.

Maximising learning from complaints

42. The information that PHSO gathers from individual complaints and their outcomes can help to give the organisations providing healthcare services greater insight into both the quality of service being provided and the patient experience. However, that information is only a small part of the much bigger picture that the information drawn from the NHS complaints process, and the work of the regulatory organisations, provide.
43. It is clearly desirable that all that information, including PHSO's contribution to it, should have the greatest impact possible and help to drive service improvements for the wider public benefit. In order to do that, it is important that all the organisations involved have a shared understanding of, and agreement on, which indicators and measures (in relation both to complaints and to lessons learned) are the most relevant.
44. It is possible, however, that the new and changing NHS landscape might mean that the vital intelligence that all complaints can provide – but most particularly about avoidable deaths – may be lost, as different definitions and data capturing systems develop. There is a clear need, therefore, for PHSO, healthcare providers, commissioners and regulators to work together not only to develop

clearer and speedier information-sharing channels, but also to develop meaningful, comparable complaints information going forward.

Good practice

45. The sharing of any patient safety concerns and of lessons learned is, of course, of paramount importance to reduce the risks to other patients. However, PHSO also deals with many cases where not only is no service failure found, but the care and treatment provided was found to be of a high standard; and others where the complaint handling demonstrated good practice.
46. This may not be readily apparent to those providing NHS services. Indeed, the fact that PHSO upholds such a high proportion of the complaints involving allegations of avoidable deaths which are subject to formal investigation (paragraph 8 (n) above) may give NHS service providers the impression that PHSO is not balanced in its work.
47. Since July 2012, following a change in the legislation governing its work, PHSO has been able to share information about cases which have not been formally investigated (including where PHSO found that there had been no service failure) with the organisations that were the subject of the complaint, and with others (such as the regulators). This should provide some reassurance to the NHS that the Ombudsman's approach is fair and balanced. However, in addition to this, PHSO should also seek to find easily accessible ways of feeding examples of good practice back to the NHS more widely, perhaps through electronic

means. This would provide NHS staff with examples of what good practice looks like in their everyday working context, and therefore also help to drive service improvements.

Summary of conclusions

48. This review has found that, overall, PHSO treats complaints involving allegations of avoidable deaths extremely seriously, and gives them ample and appropriate consideration. It has also found that significant efforts are made to ensure the quality of the most critical element in determining such complaints to PHSO: namely, the clinical advice obtained from its own internal advisers and from external specialist advisers.
49. However, it has also identified that PHSO's approach of formal investigations being a last resort, and the internal processes it follows, can have unintended consequences that may not always provide the maximum benefit to the complainant, or to the wider public. These consequences could affect public understanding of, and therefore confidence in, PHSO's work.
50. The review further concluded that there were some additional steps that PHSO might consider to ensure that any potential patient safety concerns were fully considered and addressed.
51. The review also suggested that PHSO needs to focus on developing a knowledge management system, which will enable it to share meaningful and helpful information with regulators, commissioners, and providers of health services. Further, that PHSO, healthcare providers, commissioners

and regulators should work together to develop clear and speedy information-sharing channels and meaningful, comparable complaints information.

52. Finally, the review concluded that PHSO should consider how it might best feed back examples of good practice to the NHS.

Recommendations

53. PHSO should consider the following ten recommendations.

To improve the benefit to the individual

- 1) Consider at what earlier point in its process it might best describe the investigative activity it undertakes as a formal investigation.**

This should:

- Increase access to formal investigations.
- Enable more complainants to recognise that their voice has been heard and that appropriate investigative activity has been undertaken.
- Help to increase public confidence in PHSO's work, and possibly encourage people to use and trust this service.

- 2) Undertake to investigate all cases where there are indications of serious service failure which could have impacted on an individual's chances of survival, including where that has already been acknowledged by the organisation concerned.**

(Depending on whether PHSO accept recommendation 1, and if so at what point they decide that investigative activity amounts to a formal investigation, many of these cases will already become the subject of a formal investigation. However, it is by no means certain that all of them would, which is why this recommendation is considered essential.)

This should:

- Enable some resolution for those complainants who believe that there is still more to learn about what happened to their loved ones.
 - Enable PHSO to ensure that the relevant healthcare and professional regulators have been alerted to patient safety concerns about organisations and individual practitioners where necessary.
 - Enable PHSO to seek to ensure maximum learning from the events complained about, to promote patient safety and improve patients' experience more generally.
 - Enable some speeding-up the overall process, as less time should be spent on the assessment stage of such complaints.
- 3) Consider whether there are ways in which they can develop a more holistic approach to complaint handling, to help complainants see the whole picture (in relation to the events involved in their complaint) and better understand the overall findings.**

(This is particularly relevant to those cases where decisions are made to investigate some, but not all, aspects of a complaint – see paragraph 8 (o).)

This should:

- Enable complainants to understand better the events as a whole, and recognise that the whole of their complaint has been comprehensively addressed (because they will receive all the information and explanations together).
- Make it easier and quicker for caseworking staff at the assessment stage to deal with cases that are to be taken through to formal investigation.

Benefit to the wider public – patient safety

4 Ensure that PHSO's process requires caseworkers to consider, and document consideration of, any potential risk to other patients which has been identified during the assessment process.

This should:

- Ensure that caseworkers consider the relevance of any indications of service failure not just to the complainant, but to other patients.
- Demonstrate that PHSO has fully addressed wider patient safety concerns and explained why further action is, or is not, considered necessary in this regard.

5) Give greater emphasis in more investigations to identifying not only what did go wrong, but also how or why any service failures identified in investigations might have occurred (particularly through the use of interviews) to help identify patient safety risks and thereby reduce risks to other patients.

This should:

- Enable PHSO to provide complainants with a better understanding of what went wrong and why.
- Enable better identification of the steps required by the individual/organisation complained about to prevent a recurrence of the service failure.
- Ensure that risks to patient safety can be better understood and effectively dealt with, including through alerts to the relevant regulatory organisations where required.

6) Consider whether investigation reports that uphold complaints relating to avoidable deaths (and any other serious service failure) should be shared more widely and at more senior levels (for example, with trust boards) to ensure appropriate accountability, action, and learning.

This should:

- Enable local NHS leaders to have a better understanding of the patient experience of the healthcare they provide.

- Enable NHS leaders to ensure that appropriate and robust steps are taken to prevent a recurrence of the service failure identified.

7) Develop a knowledge management system which can better identify trends, themes and the most serious complaints (such as those involving alleged avoidable deaths); and while that is in development, find an interim way of identifying complaints involving allegations of avoidable death on the current caseworking system.

This should:

- Give PHSO a much better understanding of the complexion of its casework.
- Enable PHSO to extract more meaningful data and learning to be fed back to all the relevant organisations.
- Further identify emerging healthcare issues or problem areas.

8) Work with regulatory organisations to develop a mutual and transparent expectation of each other's roles and responsibilities.

This should:

- Ensure that agreed information-sharing processes and clear communication channels are established so that patient safety concerns can be passed speedily to those responsible for further action.

- Ensure that PHSO, and healthcare and professional regulators can all be reassured that patient safety concerns will be appropriately shared and acted upon.

9) Work together with healthcare providers, commissioners and regulators to develop meaningful, comparable complaints information.

This should:

- Enable the best possible intelligence to be extracted from the complaints data collected, through the development of shared definitions and agreed data priorities.
- Enable potential patient safety concerns and emerging problems to be identified more easily and addressed more speedily.
- Enable the NHS complaint handling system to become a unified source of learning for the NHS nationally.

10) Find easily accessible ways of feeding back good practice to the NHS, both in terms of care and treatment and in complaint handling.

This should:

- Provide NHS staff with a better understanding of PHSO's work and approach.
- Provide NHS staff with clear and realistic examples of what good practice looks like in their everyday working environments.

Annex

The process followed by PHSO in the handling of complaints put to it

(This is not intended to be a comprehensive guide to PHSO's process; it covers the key areas relevant to the review which are referred to in the main body of this report.)

Remit

The Ombudsman's remit, as set out in legislation, is to consider complaints that maladministration or service failure by organisations within its remit has led to an injustice to the complainant.

If it is found that there has been maladministration/service failure leading to an injustice, then the Ombudsman will determine what needs to be done to remedy the injustice, or whether the organisation has already done enough to put things right.

Staff

Caseworking staff dealing with the assessment and investigation of complaints work in teams, which specialise in handling either complaints about the NHS in England, or complaints about government departments and organisations.

PHSO employs a number of clinicians who advise caseworking staff on clinical matters.

Process

Complaints being dealt with by PHSO are referred to either as enquiries (that is, cases which have not been accepted for investigation) or investigations.

Initial scrutiny

PHSO staff check that:

- the complaint is about an organisation and subject that by law it can look into;
- the complaint is made in writing; and
- the complaint has been put to the organisation complained about and it has had an opportunity to put things right.

Assessment

PHSO staff:

- consider whether it would be more appropriate for the complainant to pursue a legal remedy;
- consider whether the complaint has been referred to PHSO within the statutory time limit (which, for health complaints, is 1 year from the day when the complainant first became aware of the matters complained about). If it has not, staff consider whether the Ombudsman should use her specific discretion to waive the time bar;
- obtain copies of the relevant NHS papers;
- speak to the complainant to ensure that the caseworker understands the complaint (including what specific matters they wish to complain about

and what specific injustice they claim to have suffered as a result), and how the complainant would like the complaint to be resolved (in terms of the outcome they are seeking);

- review the papers;
- get clinical advice as necessary (usually from the specialist clinical advisers who are employed by PHSO, but occasionally from an external clinical expert);
- speak to the organisation complained about to check that local resolution of the complaint has been completed. (At the assessment stage PHSO's guidance to staff is that the organisation concerned must have been given the opportunity to respond fully to the complaint, and to put things right.) If it has not been completed, or if it is considered that the organisation can take further steps which might resolve matters, staff refer the complaint (with the complainant's agreement) for further local resolution, and the case is closed as being 'premature';
- complete an assessment form which sets out the facts of the case, the advice obtained, and gives the assessor's view on the way forward;
- consider whether, if there are indications of service failure/ maladministration leading to an injustice, PHSO may be able to resolve the complaint through an 'intervention' (when they agree a proposed remedy with the organisation and the complainant);
- refer the case to the team manager if the proposal is that the complaint

should not go forward for formal investigation, (all decisions not to conduct a formal investigation have to be approved at team manager level or above); put the case before an assessment panel (in the form of the assessment form) if it is proposed to conduct an investigation, or if the decision as to whether or not an investigation could achieve anything more is finely balanced. (The panel is made up of senior operational managers, and determines which cases will be taken to formal investigation.) And;

- write to the complainant to tell them either that it is proposed to conduct a formal investigation into the complaint (or into aspects of the complaint), or that it is proposed to take no further action; setting out in full the reasons for that decision. (Until July 2012 such 'decision letters' could only be sent to the complainant and/or their representative.)

Formal investigation

PHSO staff:

- gather all the necessary information, including seeking specialist clinical advice (from the clinical advisers employed by PHSO and from external experts where appropriate) to ensure that a sound, evidence-based judgment can be reached;
- prepare a formal report (usually sent to the Chief Executive/head of the organisation) which follows a set format, identifying any service failures and making recommendations for how those failures should be remedied;

- share the formal report in draft form with the complainant and the organisations involved in the complaint for them to comment on;
- get the organisation's agreement to any proposed remedy and, where appropriate, for them to prepare an action plan showing the steps they will take to avoid a recurrence of the failure;
- refer specific individuals to the relevant professional regulatory organisations where considered appropriate; and
- check that the action plan has been prepared within the agreed time frame and sent to the complainant and other relevant organisations (which will include such organisations as the Care Quality Commission and Monitor), so that the organisation can keep them updated on progress against the action plan.

PHSO's response to Baroness Fritchie's recommendations



We welcome and accept all the recommendations in Baroness Fritchie's report.

In the table below, we outline the actions we will be taking to address each of the recommendations. We also set out some of the things that are already underway.

The actions will be built in to our business plans for 2013-14 and onwards. We will report on the implementation of the recommendations in our annual report for 2013-14.

Recommendations	Our response
<p><i>To improve the benefit to the individual</i></p> <p>1) Consider at what earlier point in its process it might best describe the investigative activity it undertakes as a formal investigation.</p>	<p>We accept this recommendation. We are redesigning the way we deal with complaints about NHS services. We will be helping more people by investigating more complaints. From 1 April 2013, this will include earlier decisions on allocating cases for investigation and using a wider range of investigative tools.</p>
<p><i>To improve the benefit to the individual</i></p> <p>2) Undertake to investigate all cases where there are indications of serious service failure which could have impacted on an individual's chances of survival, including where that has already been acknowledged by the body concerned.</p>	<p>We accept this recommendation in principle. From 1 February 2013, we will always start from the presumption that we will investigate these complaints. The legislation that governs the Ombudsman's work says that we must exercise discretion and consider each case on its merits. As a result, there will be exceptional circumstances in which we do not investigate such cases. This change will apply to future complaints. We will not re-open cases that we have already considered.</p>
<p><i>To improve the benefit to the individual</i></p> <p>3) Consider whether there are ways in which they can develop a more holistic approach to complaint handling, to help complainants see the whole picture (in relation to the events involved in their complaint) and better understand the overall findings.</p>	<p>We accept this recommendation. We agree that it is important to view complaints in context. In some cases, it can be helpful to identify elements of the complaint that can be answered quickly before embarking on a more complex investigation. However, we agree that we should accept complaints for investigation sooner and avoid unhelpful fragmentation. We will start this with immediate effect.</p> <p>We will take this into account as we redesign our processes more generally to improve the customer experience.</p>

Recommendations	Our response
<p><i>Benefit to the wider public –patient safety</i></p> <p>4) Ensure that PHSO’s process requires caseworkers to consider, and document consideration of, any potential risk to other patients which has been identified during the assessment process.</p>	<p>We accept this recommendation. We already make use of our power to inform regulators and others, where we consider there may be risks to patient health and safety. For example in 2011/12 we shared information with the Care Quality Commission on 199 occasions and referred 11 individual clinicians to their professional regulators. However, we agree that patient safety is an important risk factor that should be better reflected in our processes. We are designing our new complaints handling process with a clearer risk-based approach to decision making, which builds on our current approach. We will ensure that potential risk to others is considered more explicitly at every stage of the process and that potential risks are clearly recorded, and where appropriate, concerns are communicated to Regulators. See also our response to recommendations 6,7 and 8.</p>
<p><i>Benefit to the wider public –patient safety</i></p> <p>5) Give greater emphasis in more investigations to identifying not only what did go wrong, but also how or why any service failures identified in investigations might have occurred (particularly through the use of interviews) to help identify patient safety risks and thereby reduce risks to other patients.</p>	<p>We accept this recommendation. We will more systematically generate insight into service failures from our complaints investigation work, using a wider range of investigation tools including interviews, root cause analysis, and more face-to-face dialogue with people who complain and the organisations we investigate. We will also be looking at whether NHS bodies have followed national guidance on patient safety. In addition, we will establish who, in the new NHS landscape, will set minimum standards for serious untoward incident investigations and how compliance is audited.</p> <p>We will also seek extensions in our powers, for example, to extend the scope of investigations where we think that is appropriate.</p> <p>We will ensure that we can help to understand why something happened, not just what happened. In appropriate cases we will ask the organisation to undertake a root cause analysis or we may initiate one ourselves.</p>

Recommendations	Our response
<p><i>Benefit to the wider public –patient safety</i></p> <p>6) Consider whether investigation reports that uphold complaints relating to avoidable deaths (and any other serious service failure), should be shared more widely and at more senior levels (e.g. with trust boards) to ensure appropriate accountability, action and learning.</p>	<p>We accept this recommendation. We agree that it is important that boards and senior managers within the organisation complained about take an active role in holding their organisations to account to ensure that learning is embedded, deficiencies are addressed, and service failures are prevented from happening again. We already send our investigation reports to the chief executive of the body complained about.</p> <p>We sought, and have been given a new legal power to enable us to share our health investigation reports more widely. We are looking at how we can use our new power to best effect. We are also looking at how regulators can use our findings and providers' action plans for accountability and learning.</p> <p>We will also explore with Parliament's Health Select Committee what information they would like to receive about such cases to fulfil their scrutiny responsibilities. We are also looking at publishing summaries of all our cases.</p>
<p><i>Benefit to the wider public –patient safety</i></p> <p>7) Develop a knowledge management system which can better identify trends, themes and the most serious complaints (such as those involving alleged avoidable deaths); and whilst that is in development, find an interim way of identifying complaints involving allegations of avoidable death on the current caseworking system.</p>	<p>We accept this recommendation. During 2013-15, we will be investing in appropriate technology to capture the right information across our new complaints process from initial contact to investigation. An enhanced case management system will enable us to generate up to date insight to enable us to share more timely and relevant information with commissioners and providers of health services to inform their efforts to improve services and patient safety.</p> <p>We will share up-to-date insights with regulators to inform their regulatory decision making. We will also share information with Parliament. See also our response to recommendation 6.</p>

Recommendations	Our response
<p><i>Benefit to the wider public –patient safety</i></p> <p>8) Work with regulatory bodies to develop a mutual and transparent expectation of each others' roles and responsibilities.</p>	<p>We accept this recommendation. We have proposed a strengthening of our Memorandum Of Understanding with the Care Quality Commission and are strengthening our operating protocol. This sets out the framework for our working relationship. We aim to update our Memorandum of Understanding with Monitor. We will also look to strengthen the way we work with regulators such as the General Medical Council and the Nursing and Midwifery Council.</p>
<p><i>Benefit to the wider public –patient safety</i></p> <p>9) Work together with healthcare providers, commissioners and regulators to develop meaningful, comparable complaints information.</p>	<p>We accept this recommendation. We will work with others to make it easier to complain about public services, to help public services resolve complaints better, and to help public services improve as a result of complaints. We will do this more effectively by encouraging the development and sharing of best practice in complaints resolution. We will also work with others to develop systems for generating insight from the data relating to complaints that we each hold.</p> <p>We are initiating discussions with regulators and others about the development, longer term, of a 'complaints hub' to create a unified system for complainants so that it is easier for them to complain to the right place. It could also provide a source of information to feed into early warning systems being developed by others. See also our response to recommendation 7.</p>
<p><i>Benefit to the wider public –patient safety</i></p> <p>10) Find easily accessible ways of feeding back good practice, both in terms of care and treatment and complaint handling, to the NHS.</p>	<p>We accept this recommendation. We will share our insight and data with Parliament, policy makers and service providers. Our new power in our health legislation enables us to share information about good practice as well as where we have found service failure.</p>

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**Parliamentary and Health Service
Ombudsman**

Millbank Tower
Millbank
London SW1P 4QP

Tel: 0345 015 4033

Fax: 0300 061 4000

Email: phso.enquiries@ombudsman.org.uk

www.ombudsman.org.uk

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