Parliamentary and Health Service Ombudsman

Clinical advice review
Consultation paper

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Foreword

Advice from healthcare professionals plays a crucial role in helping inform PHSO's decisions on the complaints it handles. Around 88% of casework relates to complaints about NHS bodies, and of the almost 2,500 investigations it conducted last year, advice from clinicians was requested in nearly three-quarters of the cases. It is therefore essential that caseworkers ask the right questions about the clinical issues that arise in a case, that the responses they receive are of the right quality and that it is clear to complainants and NHS bodies how this has informed the final decision that has been made.

Given the importance of this function, PHSO committed in its new 3-year strategy to conduct a full review to ensure that the best clinical advice is obtained and used in a way that is easily understood by all. I was asked by the Ombudsman to Chair the Review on behalf of the Board to ensure that there was independent scrutiny of the proposals developed and to provide assurance to the Board and the Chief Executive on the final recommendations that are made.

I have been supported by a number of senior staff from across the organisation, as well as by Julia Tabreham, a Board colleague who also sits on its Quality Committee. The Ombudsman has also appointed Sir Liam Donaldson as an Independent Adviser to the Review Team. Sir Liam's input to date has been invaluable in shaping our approach and he is now in the process of looking closely at the principles that underpin our clinical advice processes. We are inviting feedback on this area as part of the consultation to inform Sir Liam's work.

To date, Sir Liam and I have found it particularly helpful to meet clinical advisers and caseworkers from across PHSO to understand how the system currently operates and where improvements could be made. In addition to being struck by the dedication and professionalism of staff at all levels across the organisation, this input has also been crucial in helping us develop our thinking.

We now want to get views from outside the organisation. We would welcome feedback both on this consultation and the background and policy paper published alongside it, which includes some of the more detailed recommendations that the Review is considering putting forward. We look forward to hearing your thoughts as we move towards developing our final proposals.

Sir Alex Allan, KCB
Chair of Clinical Advice Review
and Non-Executive Director

Introduction

The Parliamentary and Health Service Ombudsman (PHSO) is the last resort for people who are dissatisfied with the treatment or service they have received – be it from government departments, their agencies or an NHS organisation. Each year it is contacted by tens of thousands of people to look into complaints where they believe there has been injustice or hardship because an organisation has not acted properly or fairly, or has provided a poor service and not put things right.

Usually people must complain to the organisation first so it has a chance to put things right. If, after an organisation has responded, an individual believes the dispute or situation remains unresolved, they can ask PHSO to look into the complaint. If it finds maladministration or injustice, it can make recommendations to put things right. Organisations failing to act on recommendations can be called before Parliament to be held to account.

This consultation focusses on PHSO's role in making decisions on complaints that have not been resolved by the NHS in England, specifically those cases where the PHSO caseworker has concluded it is necessary to obtain advice from an independent clinician to inform a decision. This advice can be an important part of the evidence used by caseworkers to help them decide on some of the most complex and sensitive complaints. Equally, it is vital that complainants and organisations investigated understand how clinical advice has been used to inform caseworkers' decisions. Getting this process right is therefore crucial.

To inform the Review's work, this consultation asks for feedback on three specific areas.

The first relates to the principles that underpin PHSO's use of clinical advice.

The second is around the level of information about clinical advice that is provided to complainants, to organisations investigated, and that will be available once PHSO begins publishing the majority of our investigation reports.

Finally, views are also sought on the new clinical standard used by the Ombudsman to support decisions on whether there has been service failure in the exercise of clinical judgement or practice in the NHS.

Alongside this consultation, a more detailed background paper has also been published, which provides more context about how PHSO currently uses clinical advice and some additional proposals from the Review for improvement.

For ease of reference, the proposals in the background paper are included in Appendix 2. The Review would welcome your feedback on either paper.

You can respond easily by completing the online survey **by 5pm on Monday 15 October 2018.** Alternatively you can email responses to ClinicalAdviceReview@ombudsman.org.uk

If you would like this document in a different format, such as Daisy or large print, please contact ClinicalAdviceReview@ombudsman.org.uk

Setting the scene

In its recently published strategy 2018-21, PHSO set out its ambition to become an exemplary ombudsman service. The starting point for delivering this has been to refocus on the Ombudsman's core role in making final decisions on complaints, including on those cases in the NHS where complainants have raised issues regarding what they perceive as clinical failings.

For its NHS casework, caseworkers seek clinical advice where they need the expertise of a clinician to help them make a fully informed decision. Clinical advice is used in the majority, although not all, of the cases the Ombudsman investigates. For example, a complaint about removal from a GP's list may not require such advice. There are two stages in PHSO's process where clinical advice is requested.

The first is the assessment stage. This is where caseworkers look in detail at a complaint to decide whether it is something that should be investigated. Data shows that clinical advice is used in a minority of these cases, although this is likely to increase as the Ombudsman seeks to use early dispute resolution to help resolve complaints more quickly. In 2017/18, 3313 cases were closed at the assessment stage and clinical advice was requested in 230 (7%) of these, though that has risen to 15% in the first quarter of this year.

For the cases that proceed to a full investigation, caseworkers more often find they need to ask for clinical advice. In 2017/18, 2355 health investigations were concluded, with clinical advice requested in 1736 (74%) of these. Advice is sometimes needed more than once on a case, whether from the same or multiple clinicians. This happens because, for example, there may be different specialist issues raised by the complaint or new issues that emerge during the investigation. In these 1736 cases, 3320 pieces of advice were received.

Feedback that PHSO has received to date indicates that the use of clinical advice can sometimes be confusing for those using the service, whether they are complainants or the organisations investigated. As a result, the PHSO committed in its new strategy to establishing a Clinical Advice Review to look at the full process we follow when commissioning, using and communicating the clinical advice we receive.

To help the Review develop its proposals for improvement, we have sought expert external support from an independent adviser. Sir Liam Donaldson, the former Chief Medical Officer for England and current World Health Organisation Patient Safety Envoy agreed to take on this role.

The Review's Terms of Reference can be viewed at Appendix 1. In developing the proposals and questions included in this paper, the Review and the Independent

Adviser have examined existing processes, looked at how other organisations – including ombudsmen and professional regulators – source clinical advice. They have also spoken to a range of individuals with detailed knowledge of how the system currently works, including clinicians who currently provide advice to caseworkers.

The Review would now like to invite input from outside the organisation to help inform and develop its eventual recommendations and to make sure they are as robust as possible. We would particularly welcome feedback from those with recent experience of using PHSO's service in this area, whether they are complainants or the organisations investigated.

The process

PHSO has had well established processes for how it commissions and utilises clinical advice as part of casework for several years and already publishes this information online as part of its Service Model. Further detail, including new process maps, are included in the background paper (pp. 5-9) published alongside this consultation.

Caseworkers will usually seek clinical advice when they need the knowledge or expertise of a clinician in order to help make a decision on a case. This will usually be when caseworkers cannot be expected to have the relevant knowledge themselves, or are unable to obtain or understand the information required. The caseworker will look for relevant standards and guidance to inform their questions to the clinical adviser before seeking advice. The majority of advice is provided by 'in house' clinicians employed on a permanent part-time basis. The remainder is commissioned on an ad hoc basis from external advisers, with specialisms in areas where fewer complaints are usually received.

Under the current process, advice will often be requested as part of what is called a 'documented discussion'. This can be done face to face or over the telephone, but following either approach, the caseworker will go on to make a record of the discussion on the complainant's casefile so it can be referred to as needed. This record will be reviewed and approved by the adviser. Advice can also be provided in writing by the adviser themselves. In general, requests that cover a long period of care or require an explanation of more complex clinical treatment are likely to be more suited to written advice as the adviser will often have to go through a more significant volume of clinical records than they would for oral advice. It is usually the caseworker that decides which approach they wish to take, often in discussion with a manager in more complex cases.

It is important to stress that the clinical advice that caseworkers receive is exactly that, advice, not a decision. The caseworker uses the advice as one part of the evidence they have collected. They will then make a decision based on the full

individual facts of the case and communicate this. To do this, they will incorporate key elements of the clinical advice and other evidence that has informed their decision making process in the provisional views as well as the final report they go on to share with the complainant and organisations we are investigating.

The quality of advice is regularly checked by sampling the advice provided over the course of the year. This involves checking three key areas:

- Is the advice clinically correct and supported by the use of relevant standards and guidance where they exist?

- Is it fit for purpose, by which is meant does it meet the needs of the case worker that commissioned it?

- Was it provided effectively and efficiently in line with the accepted format and to the expected standard?

Areas for consultation

The Review and its Independent Adviser are seeking views in particular on the areas outlined in this section of the consultation.

There are some more detailed process related proposals that have been developed by the Review (see Appendix 2), the detailed rationale for which is included in the background paper published alongside this consultation. Comments on these are also welcome and can be provided through our online survey.

The approach to clinical advice

To date, a set of core values and behaviours has underpinned PHSO's approach to commissioning and using clinical advice. These are that:

- Caseworkers and clinical advisers work in partnership
- Caseworkers and clinical advisers understand and have respect for each other's distinct role
- Caseworkers and clinical advisers will communicate effectively along the pathway of a case, which includes the request for, and provision of clinical advice
- Problems are anticipated and addressed proactively in order to learn from casework and avoid delays

There are also two core principles that caseworkers and clinical advisers are expected to incorporate into their approach. More detail on these principles is included in the background paper, but in short they are that:

- The caseworker should make clear, informed and proportionate requests for Clinical Advice
- The clinical adviser should provide high quality, timely clinical advice

The Independent Adviser to the Review has been considering whether this approach is robust and clear enough. As part of his work to date he has been having extensive discussions with caseworkers and clinical advisers to get their views on what works well in our current system and how our approach could be improved.

This engagement has led to the Review exploring some potential options for change, such as greater involvement of clinical advisers in ensuring their advice is translated as clearly as possible into the provisional views and final reports on complaints. These are set out in the background paper.

The Independent Adviser is now considering the wider issues around the clinical content of PHSO reports and responses to complainants. He and the Review would therefore welcome external feedback on the questions raised on page 15, including impressions and views on the clinical assessment of complaints and whether they seem generally comprehensive, well-founded, and authoritative, and on how clinical advice received by PHSO should be balanced with other evidence received from complainants and from the organisations that PHSO investigates.

Transparency

Being more transparent was one of three core objectives that PHSO committed to delivering in its new 3-year strategy. The Review has noted from the feedback heard to date, that more needs to be done to improve understanding of the purpose of clinical advice in casework and how it is used by caseworkers.

This includes greater transparency about why clinical advice is used and how it informs their decision making process. At present caseworkers usually summarise key elements of the clinical advice they have received in the provisional views that are shared with complainants and organisations investigated. This includes reference to the qualifications and experience of the adviser, as well as confirmation that there are no conflicts of interest that would have prohibited them from providing it. The full advice received or the name of the adviser is not usually shared, however.

As part of its research, the Review has looked at a range of individual cases, submissions made by complainants to the Public Administration and Constitutional Affairs Committee as part of their annual inquiries into PHSO and considered views expressed in fora such as the Ombudsman's recent open meetings. There is clear evidence that, despite the level of detail that is currently provided, in some cases complainants do not understand why clinical advice has (or indeed has not) been sought. They can have questions about why a particular type of adviser has been chosen and who that is, as well as if there are any conflicts of interest, or whether advice has been used correctly by caseworkers.

Unfortunately, in a small minority of cases where a decision has been made not to uphold a complaint, there are rare examples where the complainant has gone further than is acceptable in expressing their discontent. The Review has heard directly from some clinical advisers their concerns about naming them. They expressed concerns that this could lead to harassment by dissatisfied

complainants, whether on social media or in their place of work in the NHS, where they are often more accessible than they would be when working in PHSO's offices. This puts them in a different position to caseworkers, who engage directly with complainants but are permanently based in the office. Clinical advisers have also highlighted the risks of their contact details being discovered and approaches to them being made directly rather than through official channels to the PHSO's office.

There have also been concerns raised about potentially vexatious referrals to professional regulators. There are therefore potential challenges around recruitment and retention of clinical advisers depending on the extent to which these risks are realised.

The Review Team is sensitive to these concerns, although it has also received conflicting views, with some advisers indicating that they would not have any problem with being named and that they would see this as consistent with their provision of advice in their day-to-day roles in the NHS.

To inform its approach in this area the Review has also looked at what other organisations do in respect of naming advisers and has found that there is no consistent approach. For example, the General Medical Council and the Nursing and Midwifery Council do not routinely do so, while organisations including the General Dental Council and the Public Service Ombudsman for Wales do.

The Review is also conscious that as part of PHSO's wider transparency agenda, it is committed to publishing the vast majority of final investigation reports by 2021-22. In order to ensure that this is compliant with data protection and other legal constraints will involve fundamentally redesigning how final investigation reports and the letters that accompany them to complainants are produced.

In light of all the issues outlined, the Review is considering:

- how the new final investigation reports can support better understanding about how and why clinical advice is used;

- whether clinician's names should be routinely published;

- If so, how this should be achieved, for example whether they should only be shared in the cover letters sent to complainants and the organisations investigated or included in the full investigation reports that PHSO is eventually planning to publish; and

- What supporting material, policies and processes would be necessary to achieve any change in this area?

The new clinical standard

Earlier this year, the Court of Appeal made a number of findings in response to a Judicial Review of one of our decisions. The need to respond to this led PHSO to consider the clinical standard that it applies in relation to complaints about judgments and decisions made by clinicians. This had to be done before this Review was established.

Following detailed consideration of the issues raised by the Court, PHSO therefore published a new clinical standard designed to bring greater clarity and predictability to how it makes judgements about care and treatment as part of its decision making process.

This work progressed separately to that conducted by the Review, although members of the team, including the Independent Adviser, were consulted for their views as it developed. The Review would like to take the opportunity presented by this consultation, however, to seek views on the new standard that has been established.

In the contextual introduction to the new standard, the Ombudsman set out the following background.

Setting the Clinical Standard
As the Ombudsman, I have been given the power by Parliament to set my own standard to support decisions on whether there has been service failure in the exercise of clinical judgement or practice in the NHS. By publishing this Clinical Standard, my aim is to give clarity and predictability to all parties about how we consider the appropriateness of the clinical care and treatment in the complaints we investigate.

There are many factors in combination that can contribute to service failure, putting patients at risk of harm or poor care outcomes. Some of these factors may relate to the decisions and actions of individual health professionals, and others to how the local service is designed and delivered.

When we look at a case, we begin our scrutiny of the health service that has been complained about with the expectation that good clinical care and treatment can be demonstrated by reference to standards or guidance. Good care and treatment will incorporate professional and health service standards and guidance and may incorporate the most up-to-date scientific evidence, for example, regarding the effectiveness of treatments. Where there are no established standards or

guidance, we will expect to see a rationale or justification for the care or treatment provided.

A unique place in the constitutional landscape

The Ombudsman service has a unique place in the constitutional landscape and we play an important role in administrative justice. We do not provide a substitute for the legal remedies available in the courts – we bring something different.

People come to us seeking outcomes that go beyond the financial remedies available through the courts. They want to find out what happened, why it happened and to be reassured that a similar adverse event could not happen to anyone else. Parliament recognises this and has given us wide powers to decide how we investigate each case. This context means that we use inquisitorial processes rather than the adversarial approach the courts take.

The Ombudsman's Clinical Standard that I have adopted is different from the legal standard used by the courts in clinical negligence. I considered adopting the standard used by the courts and decided against this because the constitutional place held by the Ombudsman in investigating complaints about the NHS is different to that of the courts. In some cases, applying my Clinical Standard to the circumstances of the complaint will produce a similar outcome to the courts' clinical negligence standard. In some cases, it will be more rigorous.

Driving improvements in public services

I am keen that our approach to considering good clinical care and treatment can be readily understood by those who engage with PHSO. It is for this reason that we built our new Standard around the standards and guidance used by NHS staff and clinicians themselves.

In turn, I believe that the Clinical Standard will support my aspiration to help improve how the public sector responds when things go wrong, and therefore lead to a reduction in the numbers of complaints that come to PHSO.

The standard we have developed in light of the Court's judgement is then set out underneath this context as below.

1. *When we are considering complaints about clinical care and treatment we consider whether there has been "good clinical care and treatment". We aim to establish what would have been good clinical care and treatment in the situation complained about and to decide whether the care and treatment complained about fell short of that.*

2. *We will seek to establish what constituted good clinical care and treatment on the facts of the case by reference to a range of material, including relevant standards or guidance, the accounts of the complainant and the clinician or organisation complained about and any other relevant records and information.*

3. *Relevant standards or guidance we may consider include National Institute for Health and Care Excellence guidance, clinical pathways, professional regulators' Codes of Practice and guidance, guidance from Royal Colleges, local protocols or policies, and published research including clinical text books or research reported in peer review journal articles.*

4. *In deciding whether a standard or guidance was relevant in the situation complained about we will consider factors such as whether it was in place at the time of the events complained about and whether it was applicable to the care and treatment the person received and to the setting in which the care and treatment took place.*

5. *We will ask the clinician or organisation complained about to tell us what if any standards or guidance they based their practice on, whether they followed them or departed from them in the situation complained about and why. If there is a relevant standard or guidance and the clinical decisions, actions and judgements do not appear to have been in line with it, we will consider what evidence there may be to explain this. We will reach a decision about whether there has been good clinical care and treatment. In doing so we will consider the explanations of those complained about and balance them against the relevant standards or guidance.*

6. *We will also consider the 'Principles of Good Administration' insofar as they apply to the clinical context.*

The Review would welcome views on the questions set out below about this new clinical standard.

Questions from the Review Team

The Review would welcome feedback on all of the areas outlined either in this consultation or in the accompanying background paper. Outlined below are some specific questions to help inform feedback and that can be found in our online survey.

The clinical content of PHSO reports and responses to complainants

Q1 What are your impressions and views on the clinical assessment of complaints, particularly whether they seem generally comprehensive, well-founded, and authoritative? Examples from complainants or from organisations that PHSO investigates of their experience of clinically-based reports or communications would be particularly valuable.

Q2 How should clinical advice received by PHSO be balanced with other evidence received from complainants and from the organisations that PHSO investigates? In the reports that you have read do you feel that the assessment of, or judgements on, complaints adequately and fairly balance clinical and non-clinical factors?

Q3: Based on your experience, in what other ways could the way clinical content that underlies the Ombudsman's decision-making be improved? Why do you think this is necessary?

Transparency

Q4: What are your views on the issues outlined in the section on transparency, in particular about how the new final investigation reports can support better understanding about how and why clinical advice is used; and whether clinician's names should be routinely published? Do you have any evidence or examples you can share with the Review to inform your view?

The Clinical Standard

Q5: Do you agree that the new clinical standard is clear?

Q6: Do you have any views on how either the standard itself, or the contextual information preceding it, could be improved to increase this clarity?

The Background Paper

Q7: Do you have any comments or views you wish to feed in on the recommendations and proposals in the Background Paper, summarised in Appendix 2?

Next steps

The Review will carefully consider all responses to the consultation and take them into account when finalising its recommendations.

The Review expects to receive the Independent Adviser's final proposals and to submit a full set of proposals for consideration by the Ombudsman and Chief Executive before the end of 2018.

Once they have considered the Review's final proposals, the Ombudsman and Chief Executive will update PHSO's full Board on the full package of final changes they have agreed.

PHSO plans to inform its stakeholders and all those that responded to the consultation in early 2019 about any changes it is making in the light of the Review's recommendations. This will include any contextual information that is considered necessary to explain what has changed and why, in light of the responses received as part of this consultation.

Appendix 1

Terms of Reference for Clinical Advice Review

The Parliamentary and Health Service Ombudsman has asked Sir Alex Allan, a non-executive director of PHSO, to oversee a comprehensive review of the use of clinical advice in the Ombudsman's case work to ensure that the system used is consistent with the new organisational values of independence, fairness, excellence and transparency.

The review overseen by a steering group chaired by Sir Alex will examine the options for, and make recommendations to, the Ombudsman and Chief Executive about:

- what process the Ombudsman should use for incorporating clinical advice into casework decisions, including how advice is commissioned and utilised in decision making through to how the function itself is staffed and supported;

- the level of detail that reports communicating any Ombudsman decisions informed by clinical advice should provide about that advice;

- the short and long term options for obtaining clinical advice and the support, staffing and financial implications of each option;

- what, if any, additional training is needed for clinical advisers and/or the caseworkers commissioning advice to help ensure it is correctly formulated to inform lay decisions under the process recommended; and

- any other improvements that could be made to PHSO's overall clinical advice process in line with its values.

To inform development of the clinical advice process, the Review will initially prepare proposals for consultation with PHSO staff and stakeholders, so that their views can be incorporated into the final recommendations of the Review.

Sir Liam Donaldson has been appointed as the Independent Adviser to the Review. In his role advising Sir Alex and the Steering Group, Sir Liam will:

- develop and recommend a set of core principles for the types of cases where PHSO should seek clinical advice to incorporate into its process, including reference to the balance between where more general and specialist advice is

needed and how decisions involving clinical advice can be devised to have the best impact;
- review the current quality of clinical advice used in Ombudsman decisions and make recommendations on any ways to improve this;

- set out how clinical advice received by PHSO should be balanced with other evidence received from complainants and relevant organisations we investigate;

- give advice to the Steering Group on the different models of delivery that may be available; and

- make recommendations in respect of the training needs of advisers and caseworkers to optimise the benefits of clinical advice.

In each area, Sir Liam will present proposals for discussion at the Steering Group, before then confirming his final recommendations. At the conclusion of the Review, Sir Liam will then also provide written assurance directly to the Ombudsman and Chief Executive that the final approach outlined by the Steering Group is compliant with the principles he has recommended.

The Review will aim to share its final recommendations with the Ombudsman and Chief Executive by the end of 2018. It will also ensure that the final recommended process is prepared in such a way so that, once signed off by the Ombudsman and Chief Executive it, as well as the principles and standards prepared by the Independent Adviser, can be published online.

Appendix 2

Proposals contained in the Background Paper

Quality

Please note further detail on the rationale for these proposals can be found in pages 12-14 of the background paper.

- *Asking the right questions in the right format as early as possible in a case can have a real impact on how quickly it progresses. Ensuring that caseworkers are drafting clear and appropriate requests for clinical advice is therefore crucial.* **The Review Team has therefore recommended that a formal system be established as part of our processes to enable clinical advisers to provide structured feedback on the quality of requests for advice they receive.**

  In the course of its work the Review Team has seen work already developed by the clinical advice management team that identified this gap. Unfortunately, however, the useful online survey solution they had identified to fill it has consistently been delayed due to the wider change pressures faced by the organisation. **The Review Team recommends that this online survey should now be implemented as quickly as possible.**

- *Under our current process, Clinical advisers can be referred by caseworkers for specific quality assurance in relation to the advice they provide.* **The Review Team recommends that the reverse should also apply. This would mean that where clinical advisers have concerns about how their advice has been recorded, whether through a documented discussion, in a provisional views report, or a final investigation report they should have a formal mechanism for reporting this**

- *Although clinical advice is only one part of the evidence considered by the caseworker when reaching their views on a case, it can often be the most complex element. It is clearly essential that there is full confidence that the clinical advice provided has been fully understood and applied by the caseworker in relation to the case.* **The Review Team has therefore proposed that it should become an established part of the process that clinical advisers are always given the opportunity to comment on the application of the advice they have provided in the provisional views and final investigation reports that are issued to ensure their advice has been accurately summarised.**

- *The Review Team has noted that there is a wider ambition to develop a formal accreditation process for caseworkers as part of the new 3-year strategy.* **The Review Team has recommended that once the new feedback process it proposes has been developed and implemented, consideration is given to how the information generated can be built into the new accreditation process.**

Service Charter

Please note further detail on the rationale for these proposals can be found in pages 14-15 of the background paper.

- **The Review Team has proposed that once the new investigation report templates that are being developed are implemented, the views of complainants and organisations investigated should be sought, as part of our regular Service Charter survey, on whether the use of clinical advice in relevant decisions has been sufficiently clear. This could be done either through existing surveys or other means.**

- *The Review Team's view is that this would increase understanding about whether some of the underlying issues that led to the review being established in the first place have been addressed or if more work may be needed. The* **Review Team has also recommended that if it is possible to collect any such data before the changes to the investigation report templates are implemented, this should be done.**

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