

CLINICAL ADVICE REVIEW COMMISSIONED BY THE PARLIAMENTARY AND HEALTH SERVICE OMBUDSMAN



December
2018

Report of the Independent Adviser to the
Review

INTRODUCTION

The Parliamentary and Health Service Ombudsman (PHSO) asked Sir Alex Allan, a non-executive director of the PHSO's board, to oversee a comprehensive review of the use of clinical advice in his NHS complaints casework to ensure that the system used is consistent with the new organisational values of independence, fairness, excellence and transparency. The Review has been overseen by a Steering Group chaired by Sir Alex and is making recommendations to the PHSO and to the Chief Executive of the PHSO's service.

I was appointed as the Independent Adviser to the Review and, in this role, have advised Sir Alex and the Steering Group. This, then, is the final report of my independent review submitted to the Steering Group. At the conclusion of the Review, I have been asked to provide written assurance directly to the PHSO and his Chief Executive that the final approach outlined by the Steering Group is compliant with the principles I have recommended.

The Review has examined the commissioning and use of clinical advice by the PHSO's service during the assessment and investigation of complaints made by (or on behalf of) recipients of NHS care. In establishing my findings, conclusions, and recommendations, I have asked a series of important questions, including: Does the current process for engaging clinical advice work effectively? What, if any, are the main problems, risks, and areas of dysfunction? Does the process need to be improved and if so why and how?

In presenting the report, I have tried to keep a clear line of sight to these questions and, for that reason, I have not reproduced detailed contextual and background material, nor the precise terms of reference for the Review and for my work. All this is available in other public documentation created for the Clinical Advice Review (1, 2).

METHODS OF WORKING

I have used multiple inputs to inform my findings, conclusions, and recommendations. I attended a series of internal meetings led by the Chair of the Review Steering Group. These involved meetings with: the independent professional advisers, sometimes called "clinical advisers" (who provide much of the clinical advice); the caseworkers (who manage the complaints process from beginning to end); the lead clinicians (a group of clinicians who advise on, and coordinate, the procurement of clinical advice internally); a complex caseworker; the *Review and Feedback Team*. I have also attended external meetings, again convened by the Chair of the *Review Steering Group*, with representatives of NHS bodies and with a gathering of patients and family members who had made complaints to the

PHSO. I had one-to-one conversations with individual caseworkers and clinical advisers. I read all policy and procedural documents used in the running of the PHSO's service. I read the judgement of the *Court of Appeal (Civil Division)* in the case of two doctors, Miller and Howarth, who had appealed against the PHSO's decision to uphold a complaint against them. This contained a detailed and informative account of the PHSO's complaints handling procedures and made criticisms. I have read all the responses to public consultation, including a dossier presented to me by a complainants' network, *PHSOtheFACTS*. I have read case-specific documents, and discussed the handling of particular cases of complaint mentioned by clinical advisers in their discussions with me. Although the granular clinical details of the complaints cases that I have read and discussed provide powerful insights into the current procedures, I have not described them in this report to protect confidentiality.

FAILURES IN THE SAFETY AND QUALITY OF HEALTHCARE: THE WIDER CONTEXT

In the last decade of the 20th Century, and the first decade of the 21st Century, much greater attention than hitherto was focused on the safety and quality of care delivered in health systems around the world. Most are striving to make quality of care and patient safety the central focus of their systems. The challenges of establishing this, but also demonstrating tangible improvement in the quality of care and sustained reduction in the risk to patients, are enormous. Few countries have come close to this ideal.

The challenges of delivering high quality healthcare

The constraints on delivering safe, high quality care are formidable: the difficulty in transforming cultures of health organisations; the weakness of care coordination; the resistance to standardising professional behaviours around evidence-based best practice; the high prevalence of medical error; education and training that is uni-professional rather than multi-professional and team-based; and the absence of a strong patient voice.

There are six main sources of failure that produce a threat to the quality and safety of patient care:

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| Type 1: | Infrastructure or critical mass of care settings, or access to them, is inadequate; |
| Type 2: | Incompetent or dysfunctional practitioners; |
| Type 3: | Sudden or unexpected events (usually triggered by errors); |
| Type 4: | Exposure to health organisations with poor culture and leadership; |
| Type 5: | Service performance that is clinically sub-optimal; |
| Type 6: | Services that fail to match international best practice. |

The relevance of this analysis of the causation of poor care, to the current *Clinical Advice Review*, is that almost all substantiated complaints to the PHSO will reveal one or more of these failings.

There have been well-publicised examples of harm or poor experiences of care occurring from each of these within the NHS in England over recent years: Numerous incidents of prolonged trolley waits and adverse clinical events in accident and emergency departments in both winter and summer periods (Type 1); An estimated 120 years of doctor/dentist work were lost because of suspension or exclusion from work (type 2); Around 1.9 million patient safety incidents reported in a year (Type 3); Poor and neglectful care of elderly patients at *Mid-Staffordshire Hospital NHS Foundation Trust* (Type 4); The rate of two important, life-threatening and preventable complications of diabetes in NHS hospitals has remained unchanged for seven years (Type 5); Cancer survival rates are a third lower than Sweden (Type 6).

A *National Quality Board* for the NHS has produced various statements, strategies, frameworks, and guidance aimed at improving the quality of NHS care (3). *NHS England's Five Year Forward View*, published in 2014 (4), sets as one of its three key challenges: closing the care and quality gap. It is not clear whether this statement of intent and the work of agencies such as the regulator, the *Care Quality Commission*, are sufficient to bring about large scale and sustained improvements in the quality and safety of NHS care.

Complaints and quality improvement: undervalued and underpowered

In theory, against this background of multiple policies, actions, and organisations seeking to improve the quality and safety of healthcare, complaints should have a part to play even in such a crowded landscape. It is always said that complaints provide an opportunity to learn from something that has gone wrong. A shortfall in the quality and safety of care that led to a complaint should therefore act as a vehicle for remedial action, including procedural or process review and changes in the area of service concerned. This beneficial change, flowing from complaints, should take place both at the local level, where the care took place, but also throughout the NHS where the service failure is of a kind that could or does occur in similar settings.

The nearest parallel to using complaints as a tool for learning and improvement of services is the way that patient safety incident reports have functioned (5). Here, the methods have not been effective. The sustained reductions in risk to patients revealed by incident reports have been few and far between, not only in this country but most others as well.

Just one example illustrates the ineffectiveness in system level learning and improvement. Recently, the government's Health and Social Care Secretary commissioned a major academic study of the prevalence of medication error in the health service in England (6). This showed that an estimated 237 million errors occur at some point in the medication

process each year. This is a shocking number, yet error rates in Britain are similar to those in other comparable health settings such as the United States of America and other countries in the European Union. The global cost of medication error is around \$42 billion annually (7). A single litigation claim in a country's health service can be huge. Damages in a single case of medication error in Britain amounted to £24 million (8). Yet, most categories of medication-related harm that happen today were delineated in a study in 1961 (9). No other major high-risk industry has such a poor record of safety improvement.

There were around 208,000 written complaints made to the NHS in England in 2017/18 (10). This equated to about 572 per day. There is no information available to show how these complaints align with each of the six sources of poor quality or unsafe care. There is little information to show how complaints are used to systematically improve in these areas of quality and safety.

Having been involved in hundreds of policy and academic discussions about the quality and safety of health services over the years, I have found that the importance and value of complaints is seldom brought into the conversation. Yet, when I have looked at the clinical content of actual complaints, whilst conducting the work of this *Clinical Advice Review*, I have found them very similar to situations that I have seen described in patient safety incident reports and topics being scrutinised by service and professional regulators. The types of healthcare problems in complaints to the PHSO are “of a feather” with those that have come to light through other channels.

The most recent official national review of the NHS hospital complaints procedure (11) sought pledges from different bodies to help in a process of transformation. Each was asked to say what their part would be. Amongst other pledges, the PHSO committed to: a) participate actively in discussions on whether an NHS vision for excellence in complaint handling can be developed; b) develop ways of measuring individual hospital level performance against that vision; c) regularly share insights from the complaints that they see with Parliament, the Department of Health and Social Care, regulators and the NHS itself; d) collate and provide this information in the way most useful in showing key learning (both of good practice, and failures) and so support improvement in the complaints system; e) contribute to work by the NHS to define the competencies for complaint handlers and develop a suitable accreditation framework.

Through this pledge, the PHSO has therefore committed publicly to play a major role in using his team's experience of NHS complaints to improve the quality and safety of clinical services.

Decades of criticism of the NHS complaints system and multiple reviews

The NHS complaints system has been examined or evaluated by special reviews, by parliamentary select committees, inter alia during public enquiries into care failures, and by

academic institutions at least six times since the beginning of the 1990s in: 1994, 1999, 2001, 2004, 2011 and 2013 (11,12-15). The same broad themes have been talked about, including: processes for resolution, speed of response, transparency, independence of investigation, single route of access for complainants, apologies, clarity of explanations and communication. Much less attention has been given to the clinical quality of investigative and assessment processes and to the methods through which future patients will benefit from what has been learnt from complaints.

The ability to make formal complaints is a vitally important way in which patients and families draw attention to failings in the quality and safety of care. They have been a component of the governance of the NHS since it was founded. They predate other sources of currently available information on service failure by several decades.

Most studies of complaints in healthcare show that those bringing them have three main expectations of the process. Firstly, that they will be given a clear explanation of what happened in the care; secondly, that they will receive an apology; and thirdly, that they will be told about action being taken to ensure that no one else suffers a similar service failure.

THE PARLIAMENTARY AND HEALTH SERVICE OMBUDSMAN'S ROLE

The PHSO is the second and final tier of the procedure that governs the handling of complaints about NHS care. Complainants come to the PHSO when they remain dissatisfied with the standard of care provided to them (or their family member) even after the investigation and response by the local service provider. Most NHS complaints are resolved at this local level. There is no right of appeal once the PHSO has made his adjudication on the complaint, except in the exceptional circumstances of a judicial review of the procedure and a higher court's scrutiny of the application of the Ombudsman's powers under Acts of Parliament.

The NHS complaints procedure used to comprise three levels. The first has always been at the local service level. The second was at the level of the NHS regulator (at the time, the *Healthcare Commission*). The third level was the Ombudsman. The current two-tier system was established on the 1st April 2009 when the *Healthcare Commission* was abolished and replaced by the *Care Quality Commission*. The government decided not to transfer the complaints function to the new NHS regulator but to merge the second and third levels under the jurisdiction of the PHSO. In its last full year of operation on complaints (16), the *Healthcare Commission* received 7827 requests for review, employed 150 staff to deal with complaints and spent £9.6 million on this aspect of its service. Of the complaints received by the *Healthcare Commission* in this last full year: 30% were upheld, 18% were not upheld, 17% were sent to dispute resolution, and 27% were outside the jurisdiction of the procedure.

At that time around 500 unresolved complaints came to the Ombudsman sitting in the third level.

The *Healthcare Commission* itself had only operated this second level of the complaints system for four and a half years before its organisational demise. During complaints investigations, it placed as much emphasis on judging the quality of the complaints handling as it did on the problems that caused the allegedly poor standard of care. Over its lifetime, it made a total of 16,500 recommendations to NHS organisations designed to strengthen the handling and resolution of complaints at local level and to improve services (17).

It is not clear how much joint work took place between the *Healthcare Commission* and the PHSO at the time to ensure maximum transfer of knowledge and experience in complaints handling.

The PHSO's role in relation to NHS complaints is set out in the *Health Service Commissioners Act 1993* (18). The initial and primary purpose of the legislation was to enable the investigation of the maladministration of complaints. In 1996, the legislation was amended (19) to widen the remit to investigate the merits of action taken by a medical practitioner in the exercise of his or her clinical judgement. The terminology here is very important. No modern authority on health service quality would accept this clinical judgement paradigm as the basis for investigating a complaint about poor quality or unsafe care. It is beyond anachronistic and renders flawed the consideration of adherence to guidelines and good practice in adjudicating complaints. This is because modern healthcare and medical guidance frequently goes beyond individual decision-making to service organisation and delivery. Clinical judgement cannot influence such factors. The legislation does not preclude taking into account wider systemic factors but it does so under the umbrella of "maladministration." This is a legalistic term that leaves the Ombudsman's investigative teams clinging to another narrow and incomplete understanding of what truly generates poor and unsafe care.

The PHSO received 24,664 complaints relating to NHS care during the financial and reporting year 2017/18. Many of these needed to be redirected to the appropriate body, including the provider of NHS service. In all, 5,545 were judged eligible and appropriate to undergo assessment. A total of 2,232 passed through to the investigation stage. Further statistics on performance and the costs of the staff and services are available in the *Annual Report* (20) and the *Consultation* and *Background* papers for the Clinical Advice Review (1,2).

There are four key stages of the casework process: a) the *Assessment Stage* during which the caseworker decides whether the complaint should go to investigation; b) the *Investigation Stage*, which is again led by the caseworker but relies heavily on clinical advice; c) the *Provisional View stage* when the outcome of the investigation is shared with the complainant

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and the organisation that provided the care to obtain views and feedback; d) the *Post-Final report stage* involves the *Review and Feedback Team* where a complainant requests a review of the findings. Further work may be commissioned at this stage.

The *Background Paper* published for the public consultation sets out the steps, decisions and other activities in a series of process maps (2). There are over a hundred process elements across the four stages.

The Government published a *Draft Public Service Ombudsman Bill* in 2016 (21). This proposes merger of different Ombudsman roles and introduction of certain new powers. However, in relation to NHS complaints, it retains concepts that I regard as anachronistic and inappropriate to a complaints investigative approach that seeks to establish the truth of what happened and to prevent harm to future patients.

THE USE OF CLINICAL ADVICE IN OTHER RELEVANT FIELDS

There are other situations in which clinical opinions are sought and used to reach a determination of the validity of a concern or complaint about the care or treatment of a NHS patient.

There are a few points of relevance to the PHSO's *Clinical Advice Review* in these other procedures. All involve, to some degree, a multi-step process that includes: selecting the source of clinical opinions, commissioning a clinician or clinicians to do the work, applying a fee scale, recording the resulting clinical information, balancing the clinician's view with non-clinical factors, and reaching a decision on whether the quality or safety of the service provided fell below an acceptable level.

Medical litigation cases involve clinical assessment of a complaint and an eventual decision on whether there was damage or loss to the individual and whether fault for this can be placed on the provider of care. This is essentially an adversarial process. The legal teams on both sides (complainant and provider of care) will commission clinical opinions and assessments of the circumstances of the care and treatment. The eventual decision-maker on the winner of this legal dispute, if it kept running, would be a court. However, most such cases today are settled out-of-court with a financial payment or alternatively resolved. This is because, some 20 years ago, the NHS set up an agency called the *NHS Litigation Authority* (22) to handle negligence claims on behalf of NHS organisations and independent sector providers of NHS care in England. Prior to this, all NHS organisations fought their legal cases individually. The organisations now pay into an indemnity scheme that largely funds this process.

The case management function was taken over a few years ago by a new agency called *NHS Resolution* (23). In 2017/18, *NHS Resolution* received 10,683 clinical negligence

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claims. The great majority of claims were resolved without the need for formal court proceedings; less than 1% goes to a full trial. *NHS Resolution* works by negotiation (in correspondence and in meetings) between the parties. This results in damages payments or alternative dispute resolution, including formal mediation.

During the decade 2008 to 2018, 46% of cases were resolved with a damages payment, and 31% without such a payment. The percentages do not add to 100% because there are cases still in train. On average, claims made to *NHS Resolution* take 1.65 years to reach a conclusion.

Some complainants are seriously disadvantaged by current legislation as it applies to clinical negligence claims. From 2013, patients have not been able to receive *Legal Aid* to bring a claim, except for cases involving severely brain-damaged children. Also claimants can no longer receive their full legal costs if they are successful. In practice, most cases are funded by conditional fee agreements (no win, no fee) between complainants and firms of solicitors. This means that solicitors will only take on cases that they judge will have a high chance of success. This reduced access to justice will certainly have influenced the number, and nature of, complaints made to the PHSO.

In this medical negligence arena, as far as the process of obtaining clinical advice is concerned, on the complainant's side, solicitors and their legal assistants undertake the casework. Certainly in the more specialist firms, such individuals will be very skilled in evaluating cases with a predominant clinical component, even if they are not themselves medically qualified. They will be extremely thorough in obtaining all medical records and clinical data. They will make an exhaustive assessment of this material.

Clinical opinions will be commissioned to review all the evidence and provide an authoritative view. A key part of the process is an assessment of the damage and loss to the patient. There would also be similar levels of skill amongst lay caseworkers working for *NHS Resolution* on the NHS provider's side. A comparison between the role of the PHSO's clinical advisers and medical experts in litigation cases is not straightforward. In the latter, it is common to get seriously conflicting expert opinions, plaintiffs against defence; in the longer term many doctors who regularly do this work are perceived as polarised on different issues. Their positioning on different subjects can determine when they are commissioned.

Complainants often say that they went into litigation for two reasons, firstly because they believed it was the best way to find out all of the facts of what happened, and secondly, because they wanted to see those responsible confronted in court. Many found that the process of settlement gave them neither, and the financial restitution was no compensation for the dissatisfaction they were left feeling.

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The *General Medical Council* received 8,300 complaints about doctors in 2017 (**24**); 75% were closed at the triage stage. The processes and procedures of the *General Medical Council* are more relevant to the PHSO context.

The similarities are that the *General Medical Council*: has the equivalent of assessment and investigation stages; it has lay caseworkers who manage the progression of the complaints; it uses both written advice and documented discussions; it seeks and evaluates both non-clinical (service and organisational) and clinical information; it uses clinical advice at both the triage stage and the investigation stage; it does not publish the names of its clinical advisers or experts; it publishes information on its procedures; the weight to be attached to a piece of evidence is left to the individual decision-maker (i.e. caseworker).

The differences are that the *General Medical Council*: employs clinically qualified (in addition to lay) case examiners; operates so that all its clinical advisers are asked to ensure that their advice is recorded clearly and accurately following a documented discussion and that a signed version is made for on-going use in the case; permits the disclosure of the clinical adviser's identity but only if requested by any of the involved parties and that the adviser agrees; requires that the decision at the end of the investigation stage is taken unanimously by a medical and a lay case examiner; makes sure that case examiners are appointed following a rigorous, competency-based, recruitment process designed to assess their decision-making competencies and skills; entrusts its case examiners, when making decisions, to place strong emphasis on the duty to protect the public. The care and attention that the *General Medical Council* has given to its complaints procedure has not kept it free of major public and professional criticism.

The comparisons between the use of clinical advice in the PHSO's service and its use in litigation and with professional regulation are important and helpful; however, they are not a gold standard to which the PHSO should aspire.

FINDINGS

The handling of complaints by the PHSO service is very procedurally driven. In part, this is because of legislation governing the PHSO role in NHS complaints, in part because of internal procedures, both written and unwritten. Both are underpinned and reinforced by the induction, training and supervision of the organisation's staff. Generally, close adherence to these procedures is important and a good thing but not when they do not serve a necessary wider purpose (e.g. of safeguarding future patients from harm) or when they discourage thinking and common sense reasoning (e.g. not taking up a serious concern about care because it is not one of the strands of the complaint) or when they confuse and upset too many complainants. Some staff are very protective of the current procedures and seem to hold the belief that, because of the statutory role of the PHSO, little can be changed.

The PHSO's role is uniquely positioned compared to other bodies involved in safeguarding the quality and safety of care in the NHS. Funding is approved directly by Parliament. A government grant plus fees from those that it regulates fund the *Care Quality Commission*. Largely, fees from doctors fund the *General Medical Council*. Thus, by comparison, the PHSO has no perceived conflicts of financial interest. His or her reputation for fairness, impartiality, and judgemental competence, therefore, is very dependent on how their work is undertaken and on the content and communication of their reports.

Any criticism especially by an external entity that is itself perceived as impartial is potentially very damaging to the PHSO's reputation and public image. This is especially so if a court is making the criticism. A recent example is a judgement of the *Court of Appeal (Civil Division)* on the case of two doctors, Miller and Howarth, and The Health Service Commissioner for England (one of the Ombudsman's titles in legislation and used to refer to him by the Court) (25). The doctors lodged an appeal against The Health Service Commissioner's decision to uphold a complaint against them. The Court of Appeal found for the doctors and criticised various aspects of the handling of the complaint by The Health Service Commissioner's staff, particularly the commissioning, use, communication and standard employed in the clinical advice to assess, investigate and adjudicate the complaint. The case dated from 2012, where the PHSO position had originally been upheld in the High Court and many of the criticisms related to ways of working that were out-dated by the point of the judgement. This is why the PHSO did not appeal and decided instead to address the fundamental outstanding issue in relation to the Clinical Standard.

On reading the judgement, it is a perfect example where the internal world and the external world see things differently. Those handling the complaint believed themselves to be following the normal rules, customs and practices. Yet, the account of the Appeal Court Justices on the handling of the complaint brings an entirely reasonable expectation from the external world that decisions and actions should be appropriate and fair. The PHSO's team in this case believed that their work was procedurally sound. Impartial scrutiny found that they were not.

Experience of complainants

The period prior to the current PHSO taking up office was marked by severe and strident criticism of the PHSO service's handling of complaints.

Criticisms of the PHSO's work in NHS complaints came from the *Patients Association* in reports (26-27) between 2014 and 2016, based on the experience of complainants. The reports stated that the PHSO:

- Is biased in favour of the organisation they are supposed to be investigating;
- Does not investigate complaints fairly with some evidence ignored;
- Makes the process unnecessarily complicated;

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- Often takes weeks or months to respond to queries from complainants;
- Produces reports that are inadequately investigated, inaccurate and incomplete;
- Fails to use the complaints process to ensure that lessons are learned at local level.

It is striking, that in the *Clinical Advice Review Team's* meeting with complainants, there was a widespread view that the PHSO would take sides with, or protect, the NHS organisation complained against, or fail to challenge the provider of care robustly enough.

The *Patients Association* also surveyed the opinions of 200 PHSO complainants and found that:

- 66 per cent found their original report incorrect, inconsistent or substandard. They found levels of investigations below standard or that analysis was inconsistent or weak;
- 22 per cent felt “completely let down.” For example, patients having to deal with key decisions being made on their case based on NICE guidance not even in place at the time;
- 62 per cent felt that the PHSO appeared “to overlook or ignore” evidence that contradicted the Trust’s account. This had a detrimental impact on the patient who felt the entire process was weak which made them feel ignored;
- 52 per cent said the PHSO was too slow, while 10 per cent said their comments were not reflected in the final report after they provided comments on a draft;
- 40 per cent reported the PHSO was unwilling to challenge a Trust’s decision;
- 18 per cent said their complaint was narrowed and did not consider key parts of the original complaint and 12 per cent said recommendations were ineffective and weak.

In the period that the *Patients Association* was receiving representations from PHSO complainants, and making its reports on the PHSO’s work, other high profile criticisms were being made. The Health Secretary wrote to the then PHSO, Dame Julie Mellor, about the handling of a complaint by the parents of a three year-old boy, Sam Morrish, who died from septicaemia: “I consider you have failed to meet the high standards the public have a right to expect and, most importantly, you have let down Sam’s parents in the most serious way.” (28).

Furthermore, the Enquiry into avoidable neonatal deaths at *Morecambe Bay Hospital* (29) expressed disquiet that the then PHSO, Dame Ann Abraham, declined to investigate a complaint from one of the parents that might have uncovered the scandal. However, the Enquiry found that she did so on the clear understanding that it would be taken on as a

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Care Quality Commission investigation in light of the evidence that there were deeper systemic problems.

This is an unprecedented and sustained level of criticism of an independent public body dealing with the higher levels of the NHS complaints process. It certainly was not a feature of the period when the *Healthcare Commission* occupied the supra-local level. Accusations of bias, secrecy, insensitivity, error and failure to listen, occurring as they did, in the period before this *Clinical Advice Review* was commissioned are extremely important in considering what changes now need to be made. One way or another, the process of clinical evaluation of complaints is interwoven with such criticisms and concerns.

The information provided by complainants to the *Clinical Advice Review* has been particularly valuable. It was received in written communications from those who had complained to the PHSO about their (or their family member's) NHS care and had then been very critical of the assessment and/or investigation procedures used in their complaint, or the final decision on it. Information was also provided in formal submissions to the public consultation on the *Clinical Advice Review* both from individual former complainants and from organisations representing them (including the *Patients Association* and *PHSOtheFACTS*). Information on complainants' experience of the PHSO service was also gathered during a meeting convened by the *Clinical Advice Review Team* to hear the views of a sample of complainants who were critical of the way that their complaints had been dealt with. All this information contained two main elements: firstly, detailed accounts of the cases that were the subject of the original NHS care and of the PHSO service's handling of the complaint; secondly, general and thematic criticisms by some of the complainants as well as the two patient organisations. The *Patients Association* conducted a further survey of 36 people who have had experience of bringing a complaint to the PHSO.

I have read, listened and reflected on this material. It was not within my terms of reference to explore complainants' cases further and produce my own assessment and judgement of them. Nevertheless, hearing and reading accounts of cases was immensely helpful.

It is only fair to point out that the views of those who felt positive about their experience, and those who voiced no concerns about the handling of their case must also be taken account of. Since 2016, the PHSO has begun a *Service Charter* process, which has collected the views of over 4000 complainants using its service to better understand their experience. This information is collected through an independent research company and shows, for example, that:

- Of the complaints investigated and fully upheld, 85% of people were satisfied with the PHSO service in 2017-18 compared to 81% in 2016-17.
- Of the complaints investigated and partly upheld, 67% of people were satisfied with the PHSO service in 2017-18, compared to 73% in 2016-17.

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- Of the complaints not upheld, 49% of people were satisfied with the PHSO service, compared to 51% in 2016-17.

It would be wrong to simply note the critical comments and conclude that they were an unrepresentative minority. The sources of information on complainants' experience provide rich and important insights into the functioning of the PHSO service. It was particularly striking that the group of complainants, with whom I, and the *Clinical Advice Review Team*, met, was not made up of vexatious or unreasonable people. They expressed frustration and, anger, but the problems that they described with the handling of their complaints should be a vital source of learning. Many of their criticisms of the PHSO's processes, and those in the documented accounts and submissions, were consistent with what I had already observed, having read a sample of records provided to me.

In the *Clinical Advice Review Team's* meeting with the complainants, and in the documents I have seen, those who have had experience of the PHSO's procedures are raising questions such as:

- What questions were put to the clinical adviser?
- What evidence and information were made available to the clinical adviser?
- Why is the complainant not involved at different points in the process?
- Why is the identity of the clinical adviser kept secret?
- How can we be sure that someone with the right clinical expertise and professional standing has been chosen?
- Why isn't more weight put on the complainant's analysis of what happened in the care?

These are perfectly reasonable questions based on complainants' experience of the system and on common sense.

The involvement of complainants in the process is again procedurally determined and causes a variety of problems. The formality of communications of the outcome of investigations, including the terminology used to describe decisions, could lead to feelings of humiliation for some complainants.

Review of a sample of cases

I was given documentation relating to eight cases at various points in the process of casework involving the seeking, provision and subsequent use of clinical advice. Generally, these included: a summary of the case; the caseworker's perspective on the experience of obtaining clinical advice; the status of the case (i.e. investigation stage, sharing of provisional view, closed); a note on at what stage clinical advice was obtained; the clinical advice questions (asked by the caseworker); the clinical advice answers (given by the clinical adviser); and either a decision form, a draft report, a provisional view report or a final

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report (depending on the stage of the case). I have read and discussed other cases during the process of the Review.

Clinical advice is captured in different ways so I was able to see the various formats as displayed in these documents. I found that the balance of weight given to the clinical adviser's opinion versus the caseworker's understanding of the quality of care provided varied across the series of cases.

In some, the caseworker set out their view clearly, in detail and then, in effect, asked the clinical adviser whether they concurred and if not why not, as well as asking if there were clinical points that had been overlooked.

I thought of this as the "straw man" approach. At first sight, it seems entirely reasonable and is a way to provide a clear focus to assist the clinical adviser in forming their view of the adequacy of the care provided. However, it creates a dynamic that left me uneasy as I read through the documentation. The approach tends to push the clinical adviser to express an overall view (agree or disagree) and then qualify it. There is a risk that the qualification or reservation in the clinical opinion then becomes subordinate and less influential to the final judgement. For example, in one case that I reviewed, the caseworker put their analysis and conclusions to the clinical adviser in quite assertive terms, using the sort of definitive language that would be unusual in a clinical statement.

In contrast, the clinical adviser, whilst generally agreeing with the caseworker's overall conclusion, drew attention to possible missing clinical information and expressed his conclusion more cautiously. Essentially, this reflected the clinical adviser's caveat to his overall agreement. In other words, the clinical reassurance that supported the caseworker's analysis only went as far as what was in the notes. These subtleties of emphasis were not reflected in the report. In other words, the clinical advice was not firm enough to set the straw man alight. The patient's family were the complainants and their view on the state of their relative did not greatly influence the judgement either.

This illustrates the complexity of most clinical situations. It also throws light on the skill required by the caseworker, not just to decide which clinical information to include in the explanatory account but to judge how much *weight* to give to various pieces of information, both clinical and non-clinical.

This unequivocal way of using the clinical advice by caseworkers was reflected in other cases. For example, a caseworker stating that particular circumstances did not "cause death" is not in keeping with a non-forensic review of paperwork. Also there was a tendency to focus on a factor that is close to the point of death at the expense of the identifying earlier opportunities to change the course of events.

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Many of the caseworkers engaged with a clinical adviser by asking a series of specific questions, which, to varying degrees, were open-ended enough to enable the clinical adviser to add relevant comments that did not precisely relate to the question.

Amongst the cases, I saw two examples where the clinical adviser identified key clinical points that were not part of the complaint but, in my view, were directly relevant to the adverse outcome. In one of the cases, this seemed to cause irritation to the caseworker who remarked that the clinical adviser had: “Strayed outside the scope of the investigation.” It struck me that the “straying” was a very important thing to do since it certainly could have influenced the outcome for the patient. Surely, no family member complaining would want a pivotal piece of clinical information ignored because they did not complain about it. Yet, the subsequent documented discussion between the caseworker and the clinical adviser did not return to the concern. The caseworker continued to clarify and seek further advice on the precise components of the complaint and the clinical adviser responded diligently to the points put to him. The conclusion did not reflect the clinical concern that fell outside the scope of the original complaint.

The main points that emerge from my review of the sample of cases are consistent with many of the themes that surfaced in my discussions with individual staff members and clinical advisers. I consider the implications in the next section.

The clinical advice process

The processes operated by the PHSO service in assessing and investigating complaints is set out in an explanatory documents that were produced as part of the public consultation for the *Clinical Advice Review (1,2)*. The flow diagrams communicate the detailed steps involved in these processes very well.

The crucial relationship and interaction in the clinical advice process is that between the caseworker and the clinical adviser. The effectiveness of the relationship is the vital component of the clinical advice process in the PHSO’s service. It is largely what determines whether the outcome of the process is good or bad.

Clinical advisers can be those doctors and nurses that are in-house, part-timers (“independent professional advisers”), or those who are commissioned from outside or both.

The key judgements and decisions by the caseworker include:

- The selection of an appropriate clinical adviser;
- The questions put to the clinical adviser;
- The information sought from the NHS organisation providing care;
- The way that the organisational factors have interacted with the human factors to produce the allegedly poor standard of care;

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- The handling of matters falling outside the heads of complaint;
- The way that a documented discussion with the clinical adviser is written up;
- The gathering and assessment of information on the complainant's observations on the care provided;
- The selection and use of clinical advice in the final report;
- The nature of the explanation to complainants about the source, content and meaning of the clinical advice being used.

These are a difficult and challenging set of responsibilities. The first three of them have been repeatedly highlighted in concerns expressed by complainants who are dissatisfied with the PHSO response to their complaint.

A vital first step in the entire process *should* be to gain an understanding, “in the round,” of what happened in the care that is the subject of the complaint. That means being clear what happened clinically, non-clinically and organisationally and how these elements contributed to what allegedly went wrong. In some cases, a complex range of interactions between different health organisations will have been involved. It is essential that the full pathway of care and the critical events at each stage is fully mapped out. The understanding does not have to be perfect early on in the investigation. It can be shaped as more information comes in. However, an “in the round” understanding cannot be achieved without clinical expertise and without a systems perspective. This holistic approach is not really part of current procedures.

From the cases that I have looked at, and the staff whom I spoke to, I feel that the primary driver of the process from the outset is the heads of complaint (put together in communication between the caseworker and the complainant). There is no urge to get a good grasp of the “story of care” for that patient. The only early rule is to clarify and state the complaint in formal terms so that it can be addressed to the letter. This means that the gathering of information and the framing of questions for the clinical adviser coalesce around the heads of complaint agreed between the caseworker and the complainant. As a consequence, as the process progresses, there is a constant risk of a fragmented, and even incomplete, understanding of the story of care.

The clinical advisers do not always have access to all the information they need to fully understand the clinical circumstances of the case. Some feel that the process is not an investigation but simply a case note review. They are asked to comment on some very specific points put to them by the caseworker, and these strictly follow the lines in the complaint.

The tone of the internal guidance reinforces the idea that the role of the clinical adviser is circumscribed and merely providing technical support to the overall complaint management being led by the caseworker. For example: “Please only address the specific questions that

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you have been asked.” There is a separate section of the guidance entitled *Raising issues outside the scope of the investigation* but this contains warnings: “It is crucial that you focus on the issues of the complaint and the questions put to you by the caseworker. This is because the Ombudsman does not have a legal basis upon which to review matters that have not been complained about;” and “Do not document it [the issue] but raise it separately.” On more than one occasion, I heard staff say: “We are not allowing fishing expeditions here.”

The clinical advisers give their views either in written form or after a discussion that the caseworker writes up (a so-called documented discussion). These days, the majority of these assessments are documented discussions. The clinical adviser sees the write-up of the documented discussion.

The clinical advisers do not generally see how the caseworkers or their supervisors have used, or expressed, their advice in the documentation and decisions that follow their interactions with the caseworker. As lay people, the caseworkers make the judgement about where the clinical factors fit in and how they are operating to produce the perhaps substandard outcome of care. Since a recent reorganisation, there has been a loss of very experienced caseworkers; they have been replaced by less experienced ones.

In some other fields where an independent clinical view is required, the clinician would usually have access to much more information. They would also be empowered to ask for, and receive, all additional information that they might request. They would make a full exploration and assessment of the clinical circumstances. The integrity of the original opinion would be protected and retained, rather than filleted up and used selectively.

It was clear from my discussions with clinical advisers that they believe they are giving their clinical advice within the boundaries set by the PHSO’s complaints handling procedures. Generally, they are responding to the questions that they are asked. So it is a qualified and caveated clinical opinion. However, they take pride in doing it well.

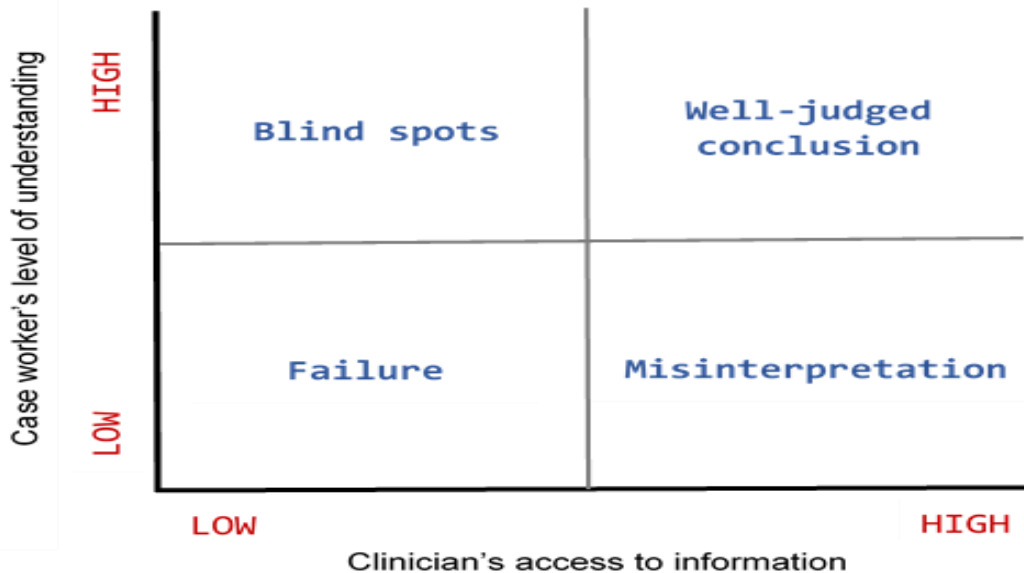
The clinical advisers will usually get a reasonable understanding of the clinical circumstances of the care, but they are not producing a full clinical report based on all information. They often request additional information but still, in effect, see a subset of the whole clinical picture. Often, they “don’t know what they don’t know.” It is not clear whether complainants understand that this is what they are getting.

There may be things in the records or other information held by the provider that if the clinical adviser knew about it would change their opinion entirely. Imagine, for example, a patient deteriorated in hospital and died. The handwritten record did not show that the patient was very unwell. However, there is separate information in the records to show that the early warning score had been high for 36 hours and that had been no medical review. That additional clinical information completely changes the situation. A high warning score

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and failure to act on it is bad care. The clinical record without the warning score suggests a more naturally occurring death.

Overall, based on my review of cases, together with my discussions with staff and complainants, I judge that the current process of commissioning and use of clinical advice is prone to three types of error: errors of fact, errors of interpretation, and errors of omission.



During the course of my meetings, there was extensive discussion as to whether the clinical advisers should be named to the complainants and in the reports. Keeping the names of the clinical advisers secret sits badly with the PHSO's commitment to transparency. Publishing their names has medico-legal implications that are not simply resolved by providing indemnity. Moreover, the clinical advisers were concerned that they may be threatened by vexatious complainants or pursued by Internet trolls. They gave examples of such cases. As a result, publishing names could make it difficult to recruit good quality clinicians to this role.

OVERALL CONCLUSIONS

The positioning of the PHSO as the highest authority in the eyes of complainants and the NHS, as well as the general public perceptions of impartiality and wise judgment inherent in the Ombudsman concept, means that any poor handling causes heavy reputational damage.

The *Clinical Advice Review* must recognise and take account of events that preceded the appointment of the current PHSO. The PHSO service's handling of complaints has been the subject severe public criticism from about 2013 onwards. It is unprecedented for the PHSO to be openly criticised by the Government's Health Secretary, as she was. It is disturbing to

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have a major enquiry express concern that division of responsibility, or confused communication, between the PHSO and the *Care Quality Commission* meant that there was no early investigation in a service later found to be responsible for avoidable deaths of babies. It is extremely worrying to have one of the country's main patient representative bodies make three separate reports on the poor quality of aspects of the PHSO's complaints assessment and investigation function, using the experience of 200 patients. It is disturbing to read, in the media, stories of victims of harm let down by the PHSO investigative process.

These may be thought of as past events of no direct relevance to the current *Clinical Advice Review*. This would be a mistake. Addressing their underlying causes and dysfunctions is essential to the new PHSO continuing to implement his reforms whilst retaining the confidence of patients and the public. These past criticisms echo many of the risks that are quite clear in the present handling procedures for complaints. Also, the negativity from these events is swirling around the present service, even though it has made a fresh start under the new PHSO. Moreover, the complainants, with whom the *Clinical Advice Review Team* met, brought serious concerns about their cases to the meeting. Their experience was consistent with the previous criticisms. Although information is available on people who were satisfied with the PHSO's work, the complainants who responded to the consultation should not be regarded as an unrepresentative minority. Changes to the current way of working should be such as to restore confidence in the PHSO's ability to get right the assessment and investigation of complaints. Errors should be rare. There should be no hint of bias towards NHS bodies. Complainants should feel fully engaged in the process.

The handover of responsibility for the second stage of the NHS complaints procedure to the PHSO in 2009 was a major undertaking. It is not clear if there was sufficient advance thought and expertise involved in designing the new service.

The nature and volume of complaints is very different to those received when the Ombudsman was at the third level of the procedure. At the third level, the Ombudsman investigated matters that had been investigated locally but *also* by a second and independent investigation at the supra-local level. An Ombudsman function does not align so easily with complaints that are at an earlier stage in the cycle and, arguably, at a more emotionally charged point. Moreover, it is not clear why the Government decided to abolish the second level rather than transfer it to the new regulator, the *Care Quality Commission*. It would seem to fit perfectly with the NHS regulator's role. There is an opportunity to use complaints as an early warning of service failure and to apply systemic learning from analysis of complaints (as the *Healthcare Commission* used to do). In contrast, the handover placed an implicit onus on the PHSO to absorb these quasi-regulatory functions as well as look at complaints that have been incompletely scrutinised. In my view, this proximity to the NHS is inappropriate for an Ombudsman. He should be dealing with a smaller number of cases at a more advanced stage of investigation. This would also free him up to play a stronger leadership role in helping the NHS to identify opportunities for systemic learning

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and improvement. It would also allow the PHSO more time and scope to investigate concerns from others, such as whistleblowers, and thereby contribute to public protection. The Government's decision now looks to have been a bad one and will remain problematic for the PHSO. Strictly speaking, these matters are beyond my terms of reference but I find it difficult to ignore poor organisational design when I see it.

The PHSO's referrals will also have been affected by the removal of Legal Aid for litigants, meaning that cases that would have gone to medical litigation come to him.

The current procedure for commissioning, using and reporting clinical advice is vulnerable to errors of fact, errors of interpretation, and errors of omission. In my review of cases dealt with by the PHSO, plus examples cited by staff during interviews, I saw all three types of error. It is difficult to judge their level of occurrence in a typical year but I believe that they could be higher than appropriate for a service expected to make the right judgments and get a high quality outcome almost every time. Simply retraining staff will not eliminate them.

Caseworkers can have an unwittingly incomplete understanding of a complainant's care and the clinical adviser is left not knowing what she/he doesn't know. The rigid pursuit of the elements of the complaint can lead to a fragmented appraisal of the quality of care, and possibly missing something serious. The clinical advice can be interpreted in the wrong way because the clinical adviser does not know how it is being used. The clinical adviser may be told only to answer the questions asked, and not stray beyond them. There may be a failure to take into account anything but the last avoidable factor as relevant to the outcome.

The current procedures have clear problems with a real risk of drawing the wrong conclusions. My recommendations are aimed at addressing this.

RECOMMENDATIONS

Despite past criticisms of the handling of complaints by the PHSO's service, there should be no sense of crisis. The new PHSO has taken positive steps to address areas of concern, including commissioning the Clinical Advice Review. An independent review by the Ombudsman for the Republic of Ireland (30) concluded that there have been: "organisation-wide improvements." The PHSO acknowledges that the process of reform and improvement must continue, notwithstanding the need to consider resource availability.

A strongly developmental approach is now needed, consulting with complainants and all other stakeholders en route. A "fire-fighting" reaction to problems in the current procedures will lead to a series of short-term fixes that will not resolve deeper factors that require change.

Many independent reviews of organisations do not make the impact that their insights warrant because of failures of implementation. This is because recommendations are implemented in a

technocratic way. Achieving the changes necessary effectively to address the findings in this review will be a developmental process: changing behaviour; listening to staff, stakeholders, and complainants; shifting cultural norms; generating enthusiasm for improving the quality of the service; restoring trust with those who have lost confidence in the PHSO. These are just some of the activities that will be needed. This is a “people” not a technocratic task. Moreover, whilst the recommendations will set the right direction of travel, they may need to be shaped or modified during the process of implementation. Again, this is a developmental approach.

1. Clinical advisers should be much better integrated into casework

In-house clinical advisers should be more extensively involved at all key stages of the complaints handling process. This should include:

- a) At the outset, clinical advisers should jointly, with the caseworker, create an understanding of the care “in the round,” identify the clinical information to be requested and assembled, and relate this to the heads of complaint. This early work can comfortably be done by clinicians, acting as generalists, even if the field of care is outside their specialty.
- b) When the first round of information comes back, clinical advisers should help to choose the specialist adviser(s) required whether internal or external.
- c) When the specialist adviser reports are received, the clinical adviser should be represented at a multidisciplinary meeting convened by the caseworker, at which the preliminary view will be debated and formed.
- d) The clinical adviser should see and comment on the provisional view report (when findings are shared with the organisation investigated and the complainant for comments), as well as the final report stage.

2. There should be greater contact and better communication with complainants

As the new process is developed, there should be much more communication and consultation with complainants, especially before key decisions are taken. The complainant should be asked to comment on the request for clinical advice and the questions posed. The complainant should have the opportunity to comment on the subsequent clinical advice before it is formally adopted. Other opportunities should be created to involve and consult with the complainant without compromising the independence of the investigation. Should clinical advisers meet complainants? As a general rule, face-to-face is best. It is highly desirable and potentially very valuable that there should be an option for clinical advisers to meet complainants in very complex cases, those with a serious adverse outcome, or in circumstances when there are multiple care providers involved. However, there may be resource constraints but every effort should be made to address the benefit of bringing people together.

The qualifications and specialty of the clinical adviser whom it is proposed to use should be shared with the complainant. Introducing a policy to name clinical advisers publicly could have unintended negative consequences even though it would fit with the PHSO's commitment with transparency. A decision on this is a matter for the *Clinical Advice Review Steering Group*. One option would be to pilot an approach in which the name was given to the complainant with the agreement of the clinician, followed by an evaluation.

3. The opinions of patients and family members on clinical events should be given proper weight and emphasis

Many clinical complaints involve care that the patient or family member will have observed at very close quarters and will have an opinion on. For example, where a child has died of sepsis, this might involve a mother feeling that her assessment of the severity of her child's illness was much better than staff seeing the child for the first time. Guidance should be developed for caseworkers to describe the types of clinical situations where the patient's or family member's observations should be given particular weight. Furthermore, it is accepted that the NHS provider will send the PHSO a great deal of information on the care episode at the outset. Often, more will be supplied following requests from the PHSO's caseworker. There will be a smaller number of situations where the NHS provider, and/or its clinicians, makes specific representations and request opportunities to defend a position on the standard of care. It would be unfair if a dynamic interaction involving arguments and extra information of this kind was happening whilst the complainant was static and effectively in the dark. This would be especially so where the complainant's observations are disputed, or doctors' defence societies bring in a team of lawyers to construct a rebuttal. This is a complex and subtle area where impartiality and fairness to both sides is essential. However, it must not be forgotten how easily a complainant can be disempowered in such situations. The area covered by this recommendation is at the heart of an effective and trusted PHSO service. It depends on organisational culture and values being strongly aligned with the operation of procedures on a daily basis. Implementation of my tenth recommendation will do much to ensure that there is a compass on the desk of every caseworker and clinical adviser.

4. Those providing the clinical advice should agree how their advice is used in the final report

Currently, the clinical advisers (whether internal or external) do not see how their advice has been incorporated in the final report. They should now formally agree the version that is to be used. This recommendation should be looked at in conjunction with the first recommendation.

5. The organisation should take a system-based approach to investigating the causes of poor care

The caseworkers currently dealing with complaints have had little exposure to the systems approach to analysing failures in the quality and safety of care, nor in the role of human factors in the causation of harm. Instead, the current approach has placed too much emphasis on the culpability of individual clinicians. In part, this is because the Ombudsman legislation anachronistically frames his remit as examining “clinical judgement.” It is not enough to point to his other legislative power of identifying “maladministration.” Caseworkers should receive training in the modern way of investigating failures in the standard of care (the *General Medical Council* is currently embarking on such an approach). The whole clinical course should be examined to look for missed opportunities, not just the last phase when the “error of clinical judgement” might be seen as leading directly to the poor outcome. Indeed, in serious failures of care simpler actions, correctly executed in the first place, often have the power to prevent major and higher-risk actions being necessary.

6. Clinical advisers should be encouraged to identify any serious problems in the care even if it is not an area covered by the complaint

Currently, clinical advisers are discouraged from pursuing any findings suggesting the presence of failures in care not mentioned by the complainant. Internal guidance and practice reinforces the need to avoid wider scrutiny of this kind. However, PHSO legislation does allow caseworkers to discuss with the complainant whether the scope of the complaint is right. What is against the legislation is looking into issues that the complainant explicitly says they do not want investigated. Such matters can materially affect the outcome of care or on occasions the survival of a patient. It does not seem right that findings that could save the life of a future patient should be blocked for legal or bureaucratic reasons, or because of complainants’ preferences. It is important that this avenue for clinical advice should not be shut down. Changes to guidance need to be made. An “own initiative” legal power for the PHSO to investigate would also be helpful in this regard. The current PHSO has suggested changes to the *Draft Public Service Ombudsman Bill* to include this. This recommendation should also be considered along with the first recommendation.

7. The tone and content of final reports and letters conveying decisions to complainants should be improved

The way in which the PHSO’s service conveys the outcome of its assessments and investigations to complainants is problematic. The dichotomy of “Upheld” or “Not upheld” is inflexible and does not convey the nuanced nature of many judgements. This and other

formal language can seem to a complainant, perhaps grieving over the loss of a loved one, as a “put down.” It risks building a false impression of the PHSO as a heartless bureaucrat. Also, the use of the phrase “in accordance with good practice” to describe something that was not found to be service failure is also problematic. It is clearly possible for practice not to amount to a service failure without being “good practice”, and such a description, in these circumstances, is potentially inflammatory to complainants.

8. A new system of data and information should be created

There is a wealth of knowledge about the causation of failures in the quality and safety of care in the complaints seen by the PHSO service each year. A new way to capture and analyse data from the complaints should be designed and information used to point, on a more timely and regular basis, to areas of learning for NHS services. Also, the development of a “severity of potential harm” classification for all incoming complaints would enable the tailoring of investigative approaches, and reduce unnecessary delays in some cases.

9. A Medical Director should be appointed to lead and oversee the development of the new system of working

A Medical Director should be appointed for an initial two-year period to oversee, and develop further, the redesign of the clinical advice procedures so that they are fit for purpose and carry much lower risks.

10. A Director for Patients and Families should be appointed to develop a more complainant-centred service

The years running up to the appointment of the current PHSO have been scarred by serious failures of the PHSO complaints handling services. There has been a breakdown of trust with some complainants and their representative organisations. It is vital that the PHSO rebuilds trust with complainants and their representatives. Equally importantly, there is a need to listen to new complainants’ experience on an on-going basis and work to improve the system for them. The culture of the organisation needs to be more attuned to patients’ and families’ experience of the NHS and how their voices are heard and respected. The PHSO has already made a wider strategic commitment to: “Develop options for involving complainants in improving our service, to improve confidence and trust in our decision making”. The creation of a new post to lead transformation in this vital area would represent a bold, modern and innovative action. The post would operate in such a way as to not distort

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the PHSO role as an impartial decision-maker between complainants and the organisations investigated.

Liam Donaldson
18th December 2018

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