Scottish Parliament Region: Mid Scotland and Fife

Case 200700075: Fife NHS Board

Summary of Investigation

Category

Health: Hospital; epilepsy, provision of information to patient

Overview

The complainant (Mrs C) raised a number of concerns about the quality and quantity of information provided to her late daughter (Miss C) following her diagnosis of epilepsy in April 2006. Mrs C considered that Miss C was denied an opportunity to fully understand the consequences of not taking her prescribed medication on a regular basis and that this may in turn have contributed to Miss C's premature death.

Specific complaint and conclusion

The complaint which has been investigated is that Fife NHS Board (the Board) failed to provide Miss C with adequate information thereby denying her appropriate care and management between April 2006 and her death in October 2006 (*upheld*).

Redress and recommendations

The Ombudsman recommends that the Board:

(i) provide written information to patients following diagnosis on a proactive basis and in line with that recommended in SIGN 70;

(ii) advise her when the epilepsy nurse-specialist is in post; and

(iii) apologise to Mrs C that written information about Miss C's condition and changes in her drug regime were not made available to Miss C and that there is no evidence of an individualised decision being made not to tell Miss C about Sudden Unexpected Death in Epilepsy.

The Board have accepted and acted on recommendations (i) and (ii). Recommendation (iii) has not been accepted (see paragraph 42).

The Ombudsman will ask the Scottish Intercollegiate Guidelines Network (SIGN) to consider the findings of this report as part of their on-going consideration of the review of the guidelines on Epilepsy in Adults (SIGN 70).

Further, in light of the difference in views recognised in paragraph 42, the Ombudsman will ask that the Directorate of Health and Wellbeing consider the need for more research into patient views on information giving and into the possible risk factors for SUDEP and the use of this research to inform ethical guidance.

Main Investigation Report

Introduction

1. On 23 April 2007, the Ombudsman received a complaint from Mrs C about the care provided to her late daughter (Miss C) by Fife NHS Board (the Board) following Miss C's diagnosis of epilepsy on 12 April 2006. Mrs C complained that Miss C had not been provided with sufficient information about her treatment and the risk of Sudden Unexpected Death in Epilepsy (SUDEP) to allow her to decide whether to take action to manage that risk. Mrs C complained in particular that the neurologist in charge of Miss C's care (Consultant 1) had disregarded applicable guidelines from the Scottish Intercollegiate Guidelines Network (SIGN) and the findings of a previous Fatal Accident Inquiry (FAI) concerning SUDEP. Mrs C believes strongly that had Miss C been provided with such information this may have prompted her to take action which might have avoided her death from SUDEP on 27 October 2006.

2. Mrs C met with Consultant 1 on 7 November 2006, after Miss C's death, to discuss Miss C's care. Mrs C did not agree with Consultant 1's views about limiting the provision of information to epilepsy patients about SUDEP and complained to the Board on 9 November 2006. The Board provided Mrs C with a final written response to her complaint on 5 April 2007. Consultant 1 had previously arranged for Mrs C to meet with an independent neurologist who worked for another NHS board in Scotland (Consultant 2). Mrs C remained dissatisfied and complained to this office.

3. The complaint from Mrs C which I have investigated is that the Board failed to provide Miss C with adequate information thereby denying her appropriate care and management between April 2006 and her death in October 2006.

Investigation

4. Investigation of this complaint involved reviewing the Board's complaint file and Miss C's clinical records for the relevant time period and all the documentation provided by Mrs C. I have also obtained the views of an external specialist adviser to the Ombudsman (Adviser 1). I have reviewed a number of research reports relevant to this complaint (see Annex 3 for a list of those relied on in this report and note that a number of these were issued around or after the time of Miss C's death). I have also reviewed the current SIGN and the National Institute for Health and Clinical Excellence (NICE)

guidelines on Epilepsy (see Annex 4) and a report of a FAI concerning SUDEP published in September 2002. I have also had contact with Epilepsy Bereaved, a charity supporting those affected by SUDEP. I have met a number of times with Mr and Mrs C, Consultant 1 and representatives of the Board. I have also met with staff at SIGN.

5. I have not included in this report every detail investigated but I am satisfied that no matter of significance has been overlooked in my investigation. Mrs C and the Board were given an opportunity to comment on drafts of this report.

Complaint: The Board failed to provide Miss C with adequate information thereby denying her appropriate care and management between April 2006 and her death in October 2006

6. SUDEP is a term used when a person with epilepsy suddenly dies and the reason for the death is not known. The cause of SUDEP is unknown. There are around 500 SUDEP related deaths per annum in the UK. For sufferers of mild epilepsy of unknown cause, the risk of SUDEP is estimated at one in 1000 sufferers per year. The incidence of SUDEP among people who are in remission from epilepsy is negligible but may be as high as 1 in 50 for particularly vulnerable groups.

Medical Background to this complaint

7. Miss C (18-years-old) was referred to Consultant 1's out-patient clinic by her GP in March 2006 following a seizure during sleep which was observed by her sister. Miss C was then still living at home. Miss C was reviewed by Consultant 1 on 12 April 2006 who noted that she would be leaving home in the autumn to start a university course. Consultant 1 reached a working diagnosis of tonic clonic seizures and prescribed an Anti Epilepsy Medication (AEM) to commence that day. Consultant 1 also arranged for an ECG, EEG and MRI brain scan to confirm this diagnosis (these duly happened in May 2006). In a letter to Miss C's GP dated 18 April 2006 (copied at the time to Miss C), Consultant 1 noted his working diagnosis, the planned drug treatment and outlined their discussion of medication, the impact on driving or any possible pregnancy and other safety risks from seizures. Miss C was reviewed again by Consultant 1 on 5 September 2006 at an appointment which Mrs C also attended. In a letter to Miss C's GP dated 8 September 2006 (not copied to Miss C), Consultant 1 noted that he had met with Miss C and Mrs C and that there had been no further seizure since their last meeting. He noted discussion of contraception and a decision to reduce the level of her AEM because of

reported side effects. He noted though that this would need to be increased again if there were further seizures and that he would review Miss C again in a year.

8. Miss C died in her sleep on 27 October 2006 while living away from home at university. Post-mortem results showed no evidence of AEM in her blood. The cause of death was given as SUDEP.

Mrs C's complaint

9. Mrs C told me that no-one in the family had any previous experience of epilepsy and they knew very little about it. It was only after Miss C's death that Mrs C learned of SUDEP. Mrs C is very concerned Miss C was not forewarned about the risk of SUDEP in general but is also concerned about several aspects of Miss C's care, which she considers inadequate.

10. Mrs C told me that in her view Miss C should have been given written information about her newly diagnosed condition (including reference to the possibility of SUDEP) as well as written instructions about how to take her medication following the changes on 5 September 2006. Mrs C told me that on 5 September 2006, Miss C noted down Consultant 1's instructions about medication on a scrap piece of paper and had later expressed a view that she had not fully understood what she had to do. At this time, Miss C had also newly arrived at university and was arranging a change of GP as well as getting to grips with all the other aspects of her new life. Mrs C believes that Miss C was not giving priority to her health concerns because she was not aware of all the potential consequences of further epileptic fits although she had expressed an intention to get her medication sorted out once she became settled in her new surroundings.

11. Mrs C told me that she was aware that Miss C was very forgetful (as was her general nature) but she would not have overlooked anything that was important. Mrs C told me she had specifically asked Consultant 1 at the appointment on 5 September 2006, what the impact of Miss C not taking her medication might be. Mrs C now feels very strongly that when she asked this question Consultant 1 should not have given what she considers to be false reassurances that this would only be a minor nuisance in Miss C's life. Instead, she believes he should have taken this opportunity to reinforce to Miss C the possible consequences of not taking her medication including increased risk of seizures and increased risk of SUDEP. Mrs C considers that if Miss C had

been made aware of the possibilities she would have given greater priority and emphasis to both taking her medication and ensuring she was taking it as had been intended.

12. Mrs C also told me that she understood that being informed about SUDEP would not necessarily have prevented Miss C's death but that her family would now be able to accept her death more easily if they had been made aware of the evidence and opinions about prevention and Miss C had been given an opportunity to act on this as she wished. Mrs C told me that when she met with Consultant 1 following Miss C's death, he told her that he accepted the risk that in not telling the majority of patients about SUDEP, he would later have to meet with bereaved relatives devastated by a death due to SUDEP, but that he considered it was more appropriate for him to accept this fact than to cause unnecessary anxiety with no benefit. Mrs C told me that she considers no neurologist had the right to deny Miss C the opportunity to make her own decisions based on all the available evidence, and that while Consultant 1 may accept the fact of meeting with bereaved relatives, this does nothing to alleviate the distress of Miss C's family, who are left with the belief that her death may have been avoidable. In fact it only adds to their distress.

13. Mrs C's view is that Miss C was the subject of a 'post-code' lottery. She told me that Consultant 1 had arranged for her to talk through her concerns with a neurologist from another Board (Consultant 2). Consultant 2 had been very clear that he would have advised Miss C about SUDEP, as he does for the majority of his patients, and that he would have wanted to ensure she understood the importance of taking her medication to avoid seizures as far as possible.

14. Mrs C also has a specific complaint that Consultant 1 failed to follow national guidelines (SIGN and NICE) about provision of information regarding SUDEP or to act in accordance with the recommendations of a previous FAI, and that he failed to record his decision not to follow guidance or the reasons for this.

The Board's Comments

15. Following Miss C's death and during their consideration of this complaint the Board have made a number of comments both to me and to Mrs C regarding Mrs C's stated concerns, several of these are referred to in the following paragraphs.

Consideration

16. It is important to note that there is no suggestion by Mrs C or any of those involved in this case that the actual diagnosis and drug treatment provided to Miss C was clinically inappropriate or deficient. The crux of Mrs C's complaint is that in not making Miss C fully aware of the negative aspects of her condition the Board failed to provide appropriate care for her. Mrs C considers that had the Board provided the care she considers essential, in ensuring Miss C was fully informed, it is possible that Miss C would have acted in a different way and made different choices which might have prevented or reduced the possibility of her premature death.

17. It is also important to note that Mrs C and Consultant 1 agree on a number of significant points. Neither believes that all epilepsy patients should automatically be made aware of the risks of SUDEP and neither believes that no patients should ever be told of the risks. Both are of the view that the decision about which patients to inform lies with the consultant who must make the decision on an individualised basis for each patient. Where their views diverge is that Mrs C believes that there needs to be a good reason not to inform a patient of the risks while Consultant 1 is of the view that there would have to be a good reason to justify telling a patient of the risks (because of the potential negative impact of such knowledge and the fact that in his view there would be nothing that Miss C could do to alter her risks).

18. The approach favoured by Mrs C is supported by a number of neurologists and patient support groups who believe that a patient has the right to know as much as possible about their condition. Similarly the alternative approach of Consultant 1 is supported by a number of neurologists who believe that a patient has a right not to know about certain distressful aspects of their condition particularly where this is (in his view) to no purpose. During the local resolution stage of this complaint, much was made of the limited research into this area (see Report 2 and Report 4 in Annex 3 for more detail on this) which to a greater or lesser extent supports both these approaches.

19. Importantly the difference between these approaches, which I will label as the 'proactive' and 'reactive' approaches respectively, is also further explained by their respective views as to what constitutes a good reason to tell / not tell, i.e. what the risks are and what can be done about these. In simplified terms, Mrs C believes that Miss C had a number of strong risk factors for SUDEP at

least some of which could have been altered by her behaviour. Consultant 1 on the other hand considers that there is no evidence that anything Miss C could have done would have altered her risk. It is then these two issues, the right to be told / not to be told and the risks associated with SUDEP, that need to be explored in this report before any conclusion can be reached.

20. Starting with a review of the possible risk factors – Report 3 and Report 1 (published in October and December 2007 respectively and after Miss C's death) both seek to evaluate various risk factors commonly associated with SUDEP and determine whether there is sufficient evidence to support particular risk factors and what the relative strength is of these risk factors. Report 1 reviewed all patients in a given area over a protracted period while Report 3 seeks to evaluate all studies to date. While there is agreement in a number of the conclusions in these reports, for example, that being in bed carries a greater risk of SUDEP occurring, there is also significant divergence. For example, Report 1 concluded there was no significant association between SUDEP and patients who suffered generalised tonic clonic seizures (the type of seizure experienced by Miss C) while Report 3 concluded there was a strong risk factor. This highlights one of the many difficulties in this case. There is as yet no consensus on the risk factors for SUDEP and different, experienced, clinicians hold different views. Report 5 (the most recent I have considered) seeks to draw together the current knowledge on the subject and suggests ways forward for further research and possible preventative measures but still reaches no clear conclusion on the balance of the available evidence.

21. In this case, Mrs C believes that among the relevant risk factors for Miss C were non-compliance with medication and other aspects of her life-style which made seizure more likely – all of which would have been modifiable. Mrs C points out that while no-one knows the cause of SUDEP it is frequently associated with a seizure and that seizure control must, therefore, reduce the possibility of SUDEP. This view was supported by Adviser 1 who told me that 'seizure itself represents the largest risk of SUDEP' but who also noted that SUDEP can often happen without any associated seizure. Mrs C also noted that Consultant 1 was aware that there were different views within the neurology community about the risks associated with SUDEP. She considered that, even if he did not agree with some of his colleagues, Consultant 1's patients have the right to know that there are other valid views and to reach their own conclusion.

22. Consultant 1 is of the view that there is no evidence that any of the risk factors which affected Miss C such as her age or the type of seizure she experienced were amenable to behaviour change, i.e. that nothing Miss C did or could have done would have altered the course of events. Report 3 gives an order to the risk factors where it concluded there was an association with SUDEP, and while Miss C was in a number of these categories there is only one – 'sub-therapeutic AED level' - which might arguably be modifiable. Report 5 expands on this possible risk factor and draws a parallel to the preventative measures promoted to minimise respiratory compromise that led to a significant reduction in Sudden Infant Death Syndrome (SIDS). The 'Back to Sleep' campaign did not prevent the further research needed which was later able to identify actual causes of SIDS. Report 5 suggests such a twin approach of evidence-based research into cause and simple potentially preventative measures (such as maintaining a stable AED level) may be the way forward in preventing SUDEP.

23. In Miss C's case, while Mrs C was aware that Miss C was not always complying with her treatment, the only sub-therapeutic drug level recorded for Miss C was at post-mortem. This is relevant because it is a view of a number of neurologists (both those who tell most patients and those who tell virtually none about SUDEP) that if patients were demonstrably not following the treatment regime and this was causing sub-therapeutic levels of AED, they would give specific advice about the risks of SUDEP. Even this would not, however, satisfy those who take the proactive view that patients should be told of the possible risks and decide for themselves whether they believe that there is a possible benefit to amending their behaviour and whether they will amend their behaviour.

24. This brings me to the second part of my consideration of whether Miss C had the right to be told and Consultant 1 had a duty to tell her about SUDEP. This is part of a broader ethical question which impacts on a number of areas of medicine beyond consideration of SUDEP. Does a patient have an absolute right to know everything about their condition or do they have the right not to know about a possible negative consequence of their condition?

25. Consultant 1 firmly believes that there is no evidence that Miss C could have done anything that could have altered the course of events and so he believes it was proper for him not to have told Miss C about the risks of SUDEP which would undoubtedly have caused her and her family distress to, in his

view, no purpose. Mrs C believes that Miss C could have altered her behaviour and that this might have changed events and that the very dire nature of the risk of SUDEP would have made Miss C more aware of the importance of taking her medication. Consultant 1 referred to Report 4 as illustrating that the majority of neurologists, like himself, did not inform most of their patients about SUDEP on diagnosis of epilepsy although many, again as was his practice, would discuss it if they felt that the patient was not co-operating with the treatment plan. Report 2 also discusses this point and notes that since informing a patient of the risk of SUDEP when he or she can do nothing to change the outcome could cause unnecessary harm to that patient, a doctor might potentially be legally liable for negligence for making such a disclosure.

26. However, Report 4 does not quantify at any point what was meant by the terms 'few' or 'many' etc. used in the questionnaire, and it is not possible to consider all the statistics given as anything more than a general indicator. I would also note that as mentioned in paragraph 17 neither Consultant 1 or Mrs C are saying that all neurologists should tell all patients or no patients but they agree that this is about deciding what is best for each individual on a case by case basis. Nevertheless, I would like to consider further the question of unnecessary harm being caused to the patient by telling. Report 4 makes a very crucial point that no studies have been done on the impact on the patient of being told about SUDEP and no studies have sought to gather the views of the patient about this information being withheld or not. Much of the evidence in this area is then at best anecdotal and any reliance on an assumption about patients' reactions must be tempered by the lack of actual hard evidence. Report 4 illustrates this point well in summarising the views of clinicians about the reactions of their patients to being informed about SUDEP, with those who rarely address the subject reporting a negative reaction from their patients and those who frequently mention SUDEP as a matter of course reporting a sanguine reaction. Better information about the likely impact on patients would be beneficial to both doctors and patients and greatly assist the decision making process of who to tell, what to tell and when to tell. If patients are not as often or as greatly distressed by the giving of information as a number of doctors currently believe then it becomes less significant that there are different views about the risks. It is then possible for patients to be advised of the existence of SUDEP and the views about possible risk factors. The patient can then make informed decisions for his or herself without any associated risk of harm caused by distress brought on by that knowledge. In my discussions with SIGN we discussed this lack of research and it was noted that this is not the type of issue

which is easy to research or which attracts funding so is unlikely to be resolved in the near future.

27. Mrs C has expressed her view to me that Miss C would have understood that the risk of SUDEP was a small one and perhaps not as risky as crossing the road every day. She does not believe she would have been overly distressed by receiving information about this condition if it had been fully explained to her in appropriate language and terms. She does not consider that there was anything about Miss C's demeanour that could have led Consultant 1 to believe she would be unduly distressed by such information and, therefore, his decision not tell Miss C could not have been based on her as an individual but merely reflected his own personal stance not to tell.

28. This notion of individual care and informed decision-making is one which needs to be explored further in its own right as many of the support groups in this area draw on the ethos of the modern NHS to provide patient-centred care, at the heart of which is the provision of information so everyone should be able to make an informed decision and to take responsibility for their own health. This is often characterised as a debate between paternalism and partnership.

29. At the time of the events of this complaint the GMC guidance, *Seeking patients consent. The ethical considerations (November 1998)* stated:

> '3. Effective communication is the key to enabling patients to make informed decisions. You must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Open, helpful dialogue of this kind with patients leads to clarity of objectives and understanding, and strengthens the quality of the doctor/patient relationship. It provides an agreed framework within which the doctor can respond effectively to the individual needs of the patient. Additionally, patients who have been able to make properly informed decisions are more likely to co-operate fully with the agreed management of their conditions.
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> 4. Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes.

6. When providing information you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with them, and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.'

30. In May 1995, the (then) Scottish Executive published The Kerr Report: 'Building a health service fit for the future'. The report identified a number of key areas where change was needed to ensure the NHS was fit for purpose and produced a framework for achieving the changes identified. A key issue proposed a new way of delivering care which would see a shift from 'Patient as Passive Recipient to Patient as Partner' and proposed that 'Health care be provided in partnership with patients, their carers and relatives, and the public, meeting their individual needs, preferences and choices and treating them with respect at all times'. This initiative and the guidance in paragraph 30 have been superseded or added to by further guidance and NHS initiatives (see Annex 5) that illustrate the direction of travel is towards patients being an integral part of the decision-making process about their own care (the ‘mutual NHS’ approach) and which reflect the pre-existing philosophy of patient partnership outlined above.

31. Returning to the specifics of this case, Adviser 1 did not consider that Consultant 1 was acting unreasonably in not telling Miss C about the risks of SUDEP and concurred that this was a stance taken by a significant number of neurologists. Adviser 1 noted, however, that no written information had been provided to Miss C and none was apparently available in the clinic area at that time. Adviser 1 considered that information should be made available as a matter of course and at the very least the patient should have been given information about suitable web-sites which offer information about epilepsy.

32. In their response to Mrs C's initial complaint that Miss C had been given no further information in any format about her condition in general or SUDEP in particular, the Board advised Mrs C in December 2006 that they had reviewed the provision of written information at clinics and that appropriate written

information would now be made available. The Board have subsequently confirmed to me that written information is available in the clinic. In discussion with Consultant 1 and the Board following the issue of the first draft of this report I was advised that the current practice remains that the available written information is only given to patients on request and it is still not the case that patients are given information about SUDEP as a matter of course. Instead, they have to make a specific request for such information.

33. Adviser 1 also noted that it was good practice to provide a specialist epilepsy nurse to support clinics to ensure patients had an opportunity to explore and discuss their condition further. The Board had advised Mrs C in December 2006 that from January 2007 a specialist field worker would be present at clinics. While Mrs C welcomed this, she remains concerned that a specialist nurse is provided in other localities rather than a field worker and again this indicates, in her view, a post-code lottery of service. The Board have recently advised me (February 2009) that they have accepted the clinical need for a nurse-specialist post and that funding is now in place for this and it is hoped to provide specialist nurse support to clinics in the very near future.

34. Mrs C has also expressed concern that Consultant 1 had not followed a specific recommendation of the guideline on Epilepsy in Adults (SIGN 70) (see Annex 4) and in the FAI report that patients should be given information about SUDEP. Mrs C recognised that guidelines and recommendations are not mandatory but was concerned that Consultant 1 had failed to record his decision and his reasons not to follow the guidelines or recommendation, as she felt this further demonstrated a lack of individualised care for Miss C. Following a request for further information the Board advised me that all appropriate staff had been made aware of both SIGN 70 and the FAI report, and the recommendations of both had been considered fully and carefully by the Clinical Governance Committee. The Board also noted that in this case it was the carefully considered opinion of Consultant 1 that the available guidance was not in the best interests of the patient and that Consultant 1's opinion was reached in the knowledge that there are deeply held conflicting views within the profession. The Board also commented that the 'essential information checklist' provided in SIGN 70 (which includes information about SUDEP) is only a level D recommendation and can be construed as an example of what is included in such a checklist by one organisation but that there is no evidence within the guideline itself of evaluated evidence to support the inclusion of information about SUDEP as essential information. The Board have expressed concern

that it is not practical for clinicians to note in the records every time they decide not to follow a SIGN recommendation or good practice point as there are 181 in SIGN 70 alone but rather they are required to note only where there is a 'significant' departure from the national guideline and that presumably this refers to recommendations with a strong evidence base. The Board also noted that SIGN 81, which deals with Epilepsy in Children up to the age of 19, and which post-dates SIGN 70 and the recommendations of the FAI, does not mark the giving of information about SUDEP as essential information.

35. Within SIGN guidelines, evidence is assigned a level according to the quality and type of research which produced the evidence. The recommendations in a SIGN guideline are also graded A to D according to the type of evidence which supports them, with A being associated with the best quality research evidence.

36. I have discussed the specific points made by the Board in relation to SIGN 70 (and SIGN 81) with SIGN who advised me that the essential information in the checklist was information which could be given out and in the view of the review group should be given out as a matter of course. SIGN told me that whether the decision not to follow any recommendation was a 'significant' departure from the guideline or not was for the clinician involved to determine. SIGN staff also commented that the status of a grade D recommendation relates to the strength of evidence on which the recommendation is based and not the clinical importance of the recommendation. Accordingly, the grade D recommendation applied here does not imply it is not of significance. SIGN advised me that they have a number of concerns generally about how the grades of recommendations are perceived and acted upon and that in their most recent guidelines they have opted to change the way these are set out by making a number of Key Recommendations which cut across all grades of evidence. SIGN 70 is currently being considered for review and if revised it would include Key Recommendations..

Conclusion

37. It would not be possible for me to conclude from the available evidence either the range of Miss C's risks for SUDEP or whether any of her risks were in fact ones amenable to change. However, it is the view of some clinicians that Miss C's risks were amenable to change. Both Report 1 and Report 3 note an urgent need for a comprehensive study of the risk factors with a view to better

understanding of SUDEP itself as well as to plan preventative strategies. The lack of clear evidence of all risk factors has been at the heart of much of the disagreement and difference of medical opinion that underlies this case. Clarity is, therefore, critical but such comprehensive research and study as is needed here is not a matter that the Ombudsman's office would expect the Board to undertake alone. As such, the Ombudsman will draw this report to the attention of the Directorates of Health and Wellbeing in the Scottish Government in order that they can consider how such research and study might be undertaken as a matter of priority.

38. The complaint I am considering is whether Miss C was denied appropriate information and consequently whether any such denial prevented Miss C receiving all appropriate care and management. I will consider each of the alleged failures to provide information in turn.

Failure to tell Miss C specifically of the risk of SUDEP

39. I recognise that the decision on whether or not to tell is a difficult and complex one. Based on the medical advice I have received and all the guidance and other information available which I have considered I conclude, on balance, that Consultant 1 did not fail in his clinical judgement in not telling Miss C of the risk of SUDEP. I note his actions were in line with those of a reasonable body of responsible clinicians and more particularly that he has reached his own carefully considered view that the potential to cause distress by discussing a condition which he believes is unalterable outweighs any potential, but as yet unproven, benefit to a patient. However, I do not consider that the reasons given by Consultant 1 for not telling of the risk are in tune with the direction of the travel of NHS Scotland towards a mutual NHS. I note that there is a clear shift in approach to a presumption in favour of sharing information and knowledge. This change must be recognised by all those working within the NHS and is one that this office endorses and expects to be reflected in the Board's oversight of the actions of their staff. I must, therefore, consider whether NHS Fife failed to provide Miss C with the level of service she was entitled to receive as an NHS patient by not giving her specific information about SUDEP. I address this point in paragraphs 41 and 43.

Failure to follow SIGN guidelines etc

40. Neither SIGN guidelines nor FAI recommendations are binding on clinicians who must remain free to reach decisions on their own clinical judgement. The lack of agreement and clarity about the need to provide

information about this condition and its risks is a matter of concern as is the fact that the Board held a different view of the status of the particular recommendation from that expressed by SIGN. As SIGN are currently in the process of reviewing SIGN 70, we will refer this report to the review group directly for their consideration of how to ensure that the necessary evidence and emphasis is contained in the revised SIGN 70 to avoid any further misunderstandings or inconsistencies of approach between clinicians in Scotland. In particular, we will ask that they consider making the giving of information about SUDEP part of a Key Recommendation. We will also ask that they consider the apparent inconsistencies between SIGN 70 and SIGN 81.

41. The Ombudsman is of the view that the particular deviation from SIGN guidelines in this case was significant and should, therefore, have been recorded. Additionally such deviation has to be made on an individualised basis for each patient. Consultant 1 did not make any note of his decision to deviate in this case as he did not consider it significant. There is also no evidence in the record to suggest that he made an individualised decision. In the absence of evidence to the contrary, I conclude that there was a failure by Consultant 1 to provide evidence of person-centred decision-making for Miss C in this regard. On balance, I consider this to be a failure by Consultant 1 to provide the service expected of him by NHS Scotland and consequently a failure in the service provided to Miss C by the Board.

42. I must record here that the Board have told me they do not accept this finding. In their view, the decision of Consultant 1, that informing most patients of their risk of SUDEP is not beneficial and that there was no reason to deviate from this stance in Miss C's case, was a reasonable exercise of his clinical judgement and skill and represented person-centred care. They also noted that it would be impractical for clinicians to record every deviation from SIGN guidelines and this must be reserved only for those areas where the clinician felt the deviation was significant. I accept that Consultant 1's view is honestly and conscientiously reached and that there is insufficient objective evidence to reach a firm conclusion on the differing views on these issues. That said, my conclusion in respect of this aspect of the complaint remains unchanged as it is the view of this office that the intention of the FAI recommendations, the ethos of the NHS and GMC guidance and the plain reading of the SIGN guideline all point in the direction of information-giving as the norm, while recognising that deviation from this may be appropriate in some cases but should be recorded. In all the circumstances, the Ombudsman proposes to take no further action in

respect of this aspect of Mrs C's complaint but will draw this disagreement to the attention of the Scottish Government Directorates for Health and Wellbeing.

Failure to provide written information

43. Adviser 1 told me that Miss C should, as a matter of good clinical practice, have been provided with written information following her diagnosis and she was not. I also note that while she was copied into the first clinic letter to her GP she did not receive a copy of the second clinic letter containing the information about her drug changes. The Board have noted that there is no specific guidance on this issue and that again there are conflicting views from clinicians on this point. This office considers it is good practice for the patient to be copied into all clinic letters as a matter of course as this is an effective way of ensuring the information is available to the patient. I conclude that there was a failure by the Board to ensure Miss C was provided with all appropriate written information about SUDEP and other aspects of her condition at the time of diagnosis and information regarding her change in drug therapy. I recognise that some steps are being taken by the Board to remedy this for others but will seek confirmation that this information is now being provided on a proactive basis.

44. Based on the failings identified above I am satisfied that Miss C was denied adequate written information. I cannot know whether the information would have altered the outcome for her if she had received it but I am satisfied that because she was denied this information she did not receive all appropriate care and management.

45. Taking all the factors into account I uphold this complaint.

46. A final point to note is the lack of any research into the impact of SUDEP awareness on bereaved families. SUDEP support groups suggest that one of the reasons it is important that patients are made aware of the risk of SUDEP is that even where it is entirely unavoidable, those families affected by such a tragedy are better able to deal with their loss where they were aware of the condition prior to their family's own experience of it. I am of the view that this is the case for Mrs C and the rest of Miss C's family who cannot but help wonder now how they might have altered the outcome if they had only known this information. Mrs C has told me that she accepts that Miss C may still have died even if they had known about SUDEP, but because there is the suggestion of the chance she might not have, they are not able to find any peace. The

decision to tell or not to tell has to be a carefully considered one and there is no one single or easy answer, but the consequences of 'not telling' should also consider the impact on the wider family as well as the patient.

Recommendations

47. The Ombudsman recommends that the Board:

(i) provide written information to patients following diagnosis on a proactive basis and in line with that recommended in SIGN 70;

(ii) advise her when the epilepsy nurse-specialist is in post; and

(iii) apologise to Mrs C that written information about Miss C's condition and changes in her drug regime were not made available to Miss C; and that there is no evidence of an individualised decision being made not to tell Miss C about SUDEP.

48. The Board have accepted and acted on recommendations (i) and (ii). As noted in paragraph 42 the Board do not accept the finding that relates to recommendation (iii). We accept that there are valid grounds for a difference of views about informing patients of their risk of SUDEP and will not be pursuing this recommendation with the Board. The Board have told me that they recognise and sympathise with the family's views about this issue and wish to convey their regret and support for the family of Miss C.

49. The Ombudsman will ask the Scottish Intercollegiate Guidelines Network (SIGN) to consider the findings of this report as part of their on-going consideration of the review of the guidelines on Epilepsy in Adults (SIGN 70).

50. Further, in light of the difference in views recognised in paragraph 42, the Ombudsman will ask that the Directorate of Health and Wellbeing consider the need for more research into patient views on information giving and into the possible risk factors for SUDEP and the use of this research to inform ethical guidance.

Annex 1

Explanation of abbreviations used

Mrs C	The complainant
Miss C	Mrs C's daughter (the aggrieved)
The Board	Fife NHS Board
SUDEP	Sudden Unexpected Death in Epilepsy
Consultant 1	The neurologist responsible for Miss C's care at the Board
SIGN	Scottish Intercollegiate Guidelines Network – an organisation in NHS Scotland which provides clinical guidelines on topic specific areas
FAI	Fatal Accident and Sudden Deaths Inquiry
Consultant 2	A neurologist from another NHS board who Mrs C met with to discuss her complaint (arranged by the Board)
Adviser 1	An external specialist adviser to the Ombudsman
NICE	The National Institute for Health and Clinical Excellence
AEM / AED	Anti Epilepsy Medication/ Drug
SIDS	Sudden Infant Death Syndrome

Annex 2

Glossary of terms

Tonic clonic seizure	The most common type of generalised seizure which means a burst of abnormal electrical activity which spreads throughout the brain. It affects consciousness, and may cause a convulsion

Annex 3

List of Research reports and policies considered

Report 1: Sudden Unexpected Death in Epilepsy: A search for risk factors. Epilepsy & Behaviour 10 (2007) 138-141. N Hitiris et al.

Report 2: Review of the legal obligations of the doctor to discuss Sudden Unexplained Death in Epilepsy (SUDEP) – a cohort controlled comparative cross-matched study in an outpatient epilepsy clinic. Seizure (2004) 13, 523-528. R.G.Beran et al.

Report 3: Sudden Unexpected Death in Epilepsy patients: Risk Factors A systematic Review. Seizure (2007) 16, 1-7 Monte et al.

Report 4: Sudden Unexpected Death in Epilepsy (SUDEP): don't ask, don't tell? Journal of Neurology, Neurosurgery, and Psychiatry 2006; 77; 199-202 Morton et al.

Report 5: Sudden unexpected death in epilepsy: current knowledge and future directions: Tomson, Nashef and Ryvlin The Lancet 22 September 2008

FAI into the Death of Colette Findlay, published September 2002, GLASGOW

SIGN 70 – Epilepsy in Adults www.sign.sc.uk/guidelines/fulltext/70

NICE - Guidelines for Epilepsy Management http://www.nice.org.uk/CG020

Better Health, Better care. Action plan
http://www.scotland.gov.uk/Publications/2007/12/11103453/0

Seeking patients consent. The ethical considerations November 1998 &
Consent: patients and doctors making decisions together.
http://www.gmc-uk.org/news/articles/Consent_guidance.pdf

Annex 4

Extract from SIGN 70

Diagnosis and management of epilepsy in adults
Section 6: Information for discussion with patients and carers

This section of the guideline is intended to highlight the main issues that healthcare professionals should discuss with patients and carers. It is based on the best available evidence of what is effective.

6.1 Advice and information on epilepsy

People with epilepsy and carers have a need for clear, accurate and appropriate information and advice. Surveys have reported that up to 90% of patients want more information and felt that they had received little advice about the cause of epilepsy, effects and interactions of drugs and the avoidance of potentially dangerous situations. Conversely, it is known that patients can forget or fail to take in much of what they are told during clinic visits so written information, helpline telephone numbers and contact details of voluntary organisations should be given to all patients. Evidence level 3,4

Almost as important as the quality of information is the manner in which it is given. Many patients prefer talking to an epilepsy nurse or someone from a voluntary organisation with whom they feel more at ease. Some information may have to be repeated on different occasions to ensure understanding. A general information leaflet should be given to all patients at the time of diagnosis. Checklists and tests of epilepsy knowledge are available from support organisations. A recent study concluded that information for patients should be suited to their understanding, making adjustments for different socio-cultural contexts. It should be noted that children are frequently carers of a parent with epilepsy, and need to be given proper support. Patients with epilepsy place great importance on having a doctor who is approachable, communicative and knowledgeable and on receiving adequate information on their condition. Evidence level 3,4

Guidelines for teachers have been produced by Epilepsy Scotland. A recent survey found that there had been little improvement in information provision despite the problem having been highlighted previously. It was concluded that

reducing the information deficit would significantly reduce the morbidity associated with epilepsy. Evidence level 3,4

- ✔ Information should be given in an appropriate manner with sufficient time to answer questions. The type of information given should be recorded in the patient notes.

- ✔ Information should be repeated over time and reinforced to ensure understanding.

- ✔ Patients should be given information to take home in the most suitable format eg leaflets, factsheets, video or specialised material for people with learning disability, making adjustments for different socio-cultural contexts.

- D A checklist should be used to help healthcare professionals to give patients and carers the information they need in an appropriate format.

6.1.1 EXAMPLE INFORMATION CHECKLIST

Example checklist that can be used by healthcare professionals to identify what information to give patients and carers:

General epilepsy information
explanation of what epilepsy is*
probable cause
explanation of investigative procedures
classification of seizures*
syndrome
epidemiology
prognosis*
genetics
Sudden Unexpected Death in Epilepsy (SUDEP)*

Antiepileptic drugs
choice of drug*
efficacy*
side effects*

Issues for women
contraception*
pre-conception*
pregnancy and breastfeeding*
menopause

Lifestyle
driving regulations*
employment
education (eg EAS guidelines for teachers)
leisure
relationships
safety in the home*

Possible psychosocial consequences

adherence*
drug interactions*
free prescriptions*

Seizure trigger
slack of sleep*
alcohol and recreational drugs*
stress*
photosensitivity

First Aid
general guidelines*
status epilepticus

Format
appropriate language
appropriate size
appropriate level of comprehension
appropriate format

perceived stigma*
memory loss*
depression
anxiety
maintaining mental well being
self esteem*
sexual difficulties

Support organisations
addresses and telephone numbers of national and local epilepsy organisations * (see Section 6.2)

*Items marked with an asterisk are considered essential information. The other material should be given when it is relevant. Patient information is readily available from the websites listed in Section 6.2.

6.2 List of useful contact details including web-based information

Epilepsy Scotland
48 Govan Road, Glasgow G51 1JL
Helpline: 0808 800 2200 Fax: 0141 419 1709
E-mail: enquiries@epilepsyscotland.org.uk
Website: www.epilepsyscotland.org.uk

The National Society for Epilepsy
Chesham Lane, Chalfont St Peter, Bucks SL9 0RJ
Helpline: 01494 601400 Tel: 01494 601300 Fax: 01494 871927
Website: www.epilepsynse.org.uk

Epilepsy Bereaved (for the relatives of people who have died from epilepsy)

PO Box 112, Wantage, Oxon OX12 8XT
Bereavement Support Contact Line - 24 hour answering service: 01235 772852
Tel: 01235 772850
Email: epilepsybereaved@dial.pipex.com Website: www.sudep.org

Quarriers (residential epilepsy assessment centre and information on Quarriers Epilepsy Fieldwork Services)
Hunter House, Quarriers Village, Bridge of Weir, Renfrewshire PA11 3SX
Tel: 01505 616006
Email: enquiries@quarriers.org.uk Website: www.quarriers.org.uk

Epilepsy Action
New Anstey House, Gate Way Drive,Yeadon, Leeds LS19 7XY
Helpline: 0808 800 5050 Free Fax: 0808 800 5555
Email: helpline@epilepsy.org.uk Website: www.epilepsy.org.uk

Enlighten - Action for Epilepsy
5 Coates Place, Edinburgh EH3 7AA
Tel: 0131 226 5458 Fax: 0131 220 2855
Email: info@enlighten.org.uk

Epilepsy Connections
100 Wellington Street, Glasgow G2 6DH
Tel: 0141 248 4125 Fax: 0141 248 5887
Website: www.epilepsyconnections.org.uk

Joint Epilepsy Council of the UK and Ireland
Tel: 01943 871 852
Website: www.jointepilepsycouncil.org.uk

Epilepsy Pregnancy Register
Tel: 0800 3891248

NHS 24
Nurse-led helpline: 08454 24 24 24

Annex 5

Recent NHS and GMC Guidance etc. on issues of patient consent and information sharing

In August 2007 the Scottish Government began a public discussion on its 'Better Health, Better Care' agenda and in December 2007 it launched an action plan for this initiative in which it describes a goal of achieving a 'Mutual NHS' and the process for achieving this:

> '… moving towards a mutual NHS will require new ways of thinking about health and health care. We need to move, over time, to a more inclusive relationship with the Scottish people; a relationship where patients and the public are affirmed as partners rather than recipients of care … A Patients' Rights Bill will be launched by May 2008 … It will give us the opportunity to develop a charter of mutual rights - a charter that provides a clear statement of rights and responsibilities from the perspective of Government, staff and the public … It will set out the right of patients to be treated as partners in their care and challenge all those who work for NHS Scotland to respect the expertise of patients and their carers and improve the way in which we communicate and involve them in the decisions that affect them.'

The move towards greater patient partnership is reflected in current plans by the Scottish Government to produce a Patient's Rights Bill. A public consultation on the proposed Bill of Rights was launched in September 2008.

The General Medical Council recently issued new guidance (June 2008) to doctors on obtaining consent 'Consent: patients and doctors making decisions together' which also reflects a change in ethos and emphasis. The guidance concentrates on decision-making in the context of investigations or treatment, but also states that the principles apply more widely. Much of the guidance is of relevance here but in particular I note the following paragraphs:

> '16 You should not withhold information necessary for making decisions for any (other) reason unless you believe that giving it would cause the patient serious harm. In this context ‘serious harm’ means more than that the patient might become upset or decide to refuse treatment.
>
> 17 If you withhold information from the patient you must record your reason for doing so in the patient’s medical records, and you must be prepared to explain and justify your decision. You should regularly review

your decision, and consider whether you could give information to the patient later, without causing them serious harm.

Obstacles to sharing information

23 It is sometimes difficult, because of pressures on your time or the limited resources available, to give patients as much information or support in making decisions as you, or they, would like. To help in this, you should consider the role that other members of the healthcare team might play, and what other sources of information and support are available. These may be, for example, patient information leaflets, advocacy services, expert patient programmes or support groups for people with specific conditions.

31 You should do your best to understand the patient's views and preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about. You must not make assumptions about a patient's understanding of risk or the importance they attach to different outcomes. You should discuss these issues with your patient.'