

Research paper

Women's experience of a look-back exercise following inadequate decontamination of vaginal specula

Lisa K Wilkins BM MRCP (UK) MPH MFPH

Locum Consultant in Public Health, Oldham Primary Care Trust, UK

Gifford Kerr MD MRCGP FFPH

Consultant in Public Health, East Lancashire Public Health Network, UK

Paul Milne MB BS FRCGP

Senior Lecturer in General Practice, School of Health and Postgraduate Medicine, University of Central Lancashire and Teaching PCT for East Lancashire, UK

ABSTRACT

Background Following the identification of inadequate decontamination of vaginal specula at a general practitioner (GP) surgery, over 400 women were offered screening for chlamydia, hepatitis B and hepatitis C.

Aim To explore the women's experience of being notified of the error and participating in the look-back exercise.

Design of study Qualitative interviews.

Setting Primary care.

Method Semi-structured interviews were held with 17 women, two to four months after completion of the look-back exercise.

Results All interviewees had negative screening results. Although complimentary about the way the recall had been conducted, many women had experienced significant distress, and reported feeling shocked, anxious, frightened and angry. These emotions were mixed with a sense of disbelief that failures in basic decontamination could occur, and be unrecognised for so long in the NHS. Overall

confidence in the cervical screening programme, however, had not been damaged. The women felt the media coverage increased anxiety and breached patient confidentiality. All interviewees strongly agreed with the primary care trust's decision to inform women of the error and felt they had the right to be informed if they had been put at risk, no matter how small that risk.

Conclusions Despite the significant anxiety caused, the interviewees strongly endorsed the decision to inform women of the poor clinical practice and conduct a look-back exercise. Issues are raised regarding the potential conflict between patients' rights and desires and the opportunity costs of undertaking look-back exercises when the estimated risks to health are low.

Keywords: decontamination, disclosure, mass screening, medical errors, patient satisfaction, vaginal smear

Introduction

In April 2003 an English primary care trust (PCT) became aware that vaginal specula had been inadequately decontaminated at a singled-handed general practitioner (GP) practice over a period of 12 years. Contrary to Department of Health guidance, specula had been chemically disinfected, not sterilised.

When examined by the infection control nurse, debris was visible on 'decontaminated' specula. Although difficult to make an accurate assessment of the risk of transmission of sexually transmitted infections (STI) and blood-borne viruses (BBV), the Health Protection Agency (HPA) estimated the risk to be

low but not negligible. The infection with the highest estimated risk was human papilloma virus (HPV) at 1 in 3400 speculum examinations and the lowest was HIV at 1 in 68 million examinations. The total number of infections that the HPA estimated could have resulted from the failure of decontamination was between zero and two (95% confidence interval).

The PCT's legal advice stated 'women have the right to know and should be informed'. All women, registered with the practice between 1991 and 2003, were informed by post of the error. A helpline was established and women who had had a speculum examination were invited to nurse-led recall clinics (Figure 1). Screening was offered for infections with an estimated transmission risk of greater than 1:100 000 per examination (hepatitis B and C, urinary polymerase chain reaction (PCR) for *Chlamydia*) excluding HPV which we were unable to test for due to a lack of appropriate screening tests and treatment options. Ninety per cent of the 440 local women invited to the recall clinics attended. All accepted the offer of screening.

The decision whether or not to undertake a look-back exercise is often complex. Weller has described the objectives of look-back (or patient notification) exercises as being to inform exposed patients of their level of risk, detect infections or other consequent harm, provide care, prevent transmission of infection to others and ideally to collect data to help refine estimates of risk.¹ The potential health benefits from tracing and offering treatment to patients should be balanced with the distress experienced by patients and the opportunity costs to the NHS of undertaking such a time-consuming exercise.

Although look-back exercises have been conducted for a range of reasons (infected healthcare workers, blood product contamination, clinical or pathology errors) little is known about the experience and views of patients involved in such procedures. In order to inform future decision making and implementation of look-back exercises, we invited women who had attended the recall clinics to tell us about (a) the personal impact of the incident on them; (b) whether they felt the PCT was right to inform them of the error; and (c) their views on how the look-back was conducted.

Method

Ethical approval was obtained. Women who had attended the recall clinics were invited to semi-structured, face-to-face, audiotaped interviews. The interviewers (three health visitors) were unaware of the patients' results and had not participated in the look-back exercise. The interview schedule (Box 1) was not prescriptive but served as a prompt to ensure

coverage of the three areas of interest. All interviews were held in private at a health facility and lasted 20 to 45 minutes (mean 30 minutes).

We aimed to interview 12 subjects, comprising a mixture of women including those with negative results and those positive for *Chlamydia* and/or past hepatitis B infection. The three women with hepatitis C or hepatitis B carrier status were excluded as their diagnosis predated the look-back exercise. The PCT had previously sent local women at risk who had not attended the recall clinics a 'reminder' letter including a promise of no further correspondence about the look-back. This prevented us inviting these women for interview. For logistical reasons women who no longer lived locally were also excluded.

Due to difficulties in predicting the likely response rate, the research protocol included two sampling rounds, with the second sample size adjusted according to initial response. Eligible women within each result group were selected randomly. In total, 114 women with negative results and all those with positive results for *Chlamydia* (6) and past infection with hepatitis B (13) were invited. Eighteen women, all with negative screening results, agreed to participate; 17 interviews were conducted in December 2003 and February 2004.

Transcripts were analysed using a thematic framework, devised from the first six transcripts by the lead analyst (LW) (see Box 2). A second analyst (PM) reviewed these six transcripts, confirmed agreement with the framework and identified no additional themes. In light of the high degree of concordance between the two analysts, subsequent transcripts were analysed by the lead analyst only. Two tapes were damaged, resulting in the inability to transcribe one and a half interviews. Sample saturation was obtained, with no new views being expressed in the last interviews. The analysis was fed back to the interviewers who agreed it was a true reflection of the opinions expressed.

Results

Impact on the women and their families

Most women recalled being upset, shocked, scared, anxious and/or angry when they heard about the incident. Women talked about how it was always on their minds, impairing concentration, and of a feeling of disbelief that such an error had occurred. Some women had felt personally invaded or soiled.

'I cried when I got the letter ... From when I got the letter, to getting the results it was on my mind all the time ... I felt really angry and scared ... I was more conscious of myself and just felt dirty, unclean.' (I15)

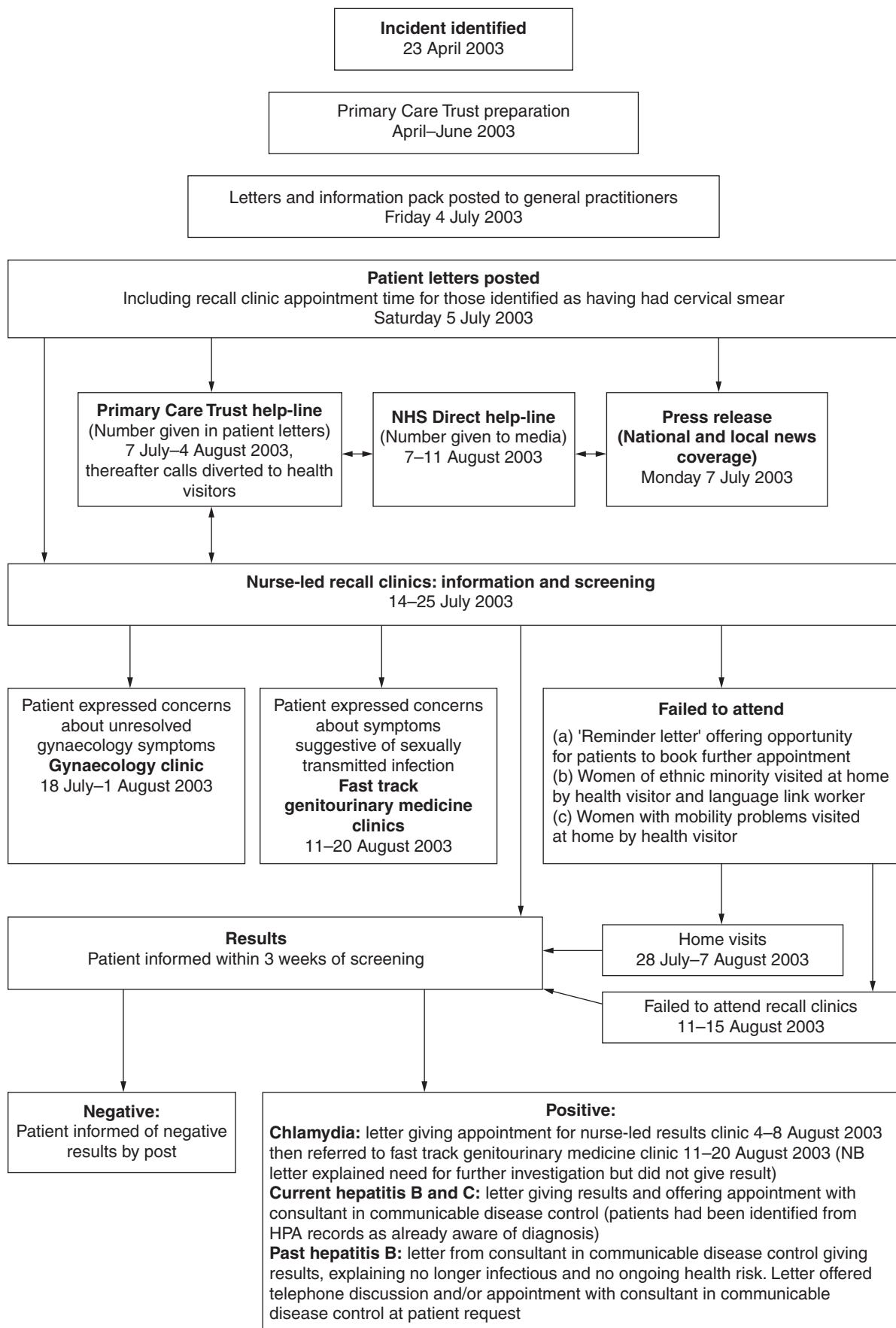


Figure 1 Look-back programme algorithm

Box 1 Interview schedule and patient prompt card

Section A: The way the recall was done

- 1 When and how did you first learn about the problem with cleaning of specula at the surgery?
- 2 Was there anything about the way the recall procedure was carried out that you think was particularly good and anything that you think was particularly bad?
- 3 Could the PCT have done anything differently to make this process easier for the women involved?

Section B: How being involved with the recall affected you

- 4 How did you feel when you first heard about this?
- 5 What impact has it had on you or your family?
 - what emotions, feelings and thoughts have you had during the recall procedure?
 - what effect has this had on your family?
- 6 Has this incident affected your views about the health service?
- 7 What did you think about the press coverage of the incident? How has this affected you?

Section C

The PCT thought long and hard about contacting women who could have been affected, because the risk was very small. They decided to go ahead.

- 8 How do you feel about this decision?

Section D

- 9 Is there anything else you would like to share that would help us learn from your experience?

While many women felt reassured after speaking to the help-line and clinic nurses, others remained anxious until getting their results.

‘[Waiting for the results] That was three weeks of sheer hell.’ (I2)

However, some women took a more philosophical view about the incidence or had a belief they weren’t affected.

‘I just thought it was one of those things and they’ve put in place whatever needs to be done and the risks are actually incredibly low.’ (I6)

Two women had thought about the potential long-term implications for their families, while another two were concerned they may have put their children at risk.

‘I was frightened for the children more than anything ... [my youngest child] was only 18-months and it was “How long have I had it? Would I have passed it on to her whilst I was carrying?”’ (I16)

Although the majority of partners were felt to have been supportive, several women were apprehensive about how their partners would react. One felt she could not confide in her partner. Another terminated a new relationship to avoid discussing it. Two women reflected differing views about how the incident had affected their sexual relationships.

‘We knew it was both of us ... It didn’t affect our personal life ... You’d have already got what you’ve got anyway.’ (I5)

‘It stops your sex life because you think “What if I have got something?”’ (I2)

The recall was also felt to have caused wider family and friends concern and anxiety. In some cases family and friends were seen as supportive, but for others their concern increased the women’s anxiety.

‘They were making it worse ... Even though I was worried, I wasn’t getting too upset but they were like “Are you all right?”, the more they did that [the more I thought] “Should I be?”’ (I5)

Decision to conduct the look-back exercise

All the interviewees strongly supported the decision to inform them of the error. Interviewees wanted, and felt they had a right, to be told if something was wrong with their care, no matter how small the risk to health.

‘It doesn’t matter how small it is. It is still a percentage.’ (I1)

‘It has been extremely stressful ... but I wanted to know and when you know what you’re dealing with, you can deal with it ... They have a duty to tell me if something has gone wrong.’ (I18)

The PCT was praised for its openness. Several women commented that the repercussions would have been worse if a ‘cover-up’ was later exposed.

‘It is a difficult one, and you do end up causing unnecessary anxiety, but the other side of it is when something

comes out and people haven't been informed. The backlash could be worse. So, I think probably it was the right decision ...' (I6)

Organisation of the recall and media coverage

The women were complimentary about the operational aspects of the recall programme, and particularly praised the nursing staff who had manned the help-line and clinics. However, they were upset and angered by the media coverage. Unfortunately, despite the letters being sent out in advance of the media statement, many of the women interviewed heard about the incident from the media before receiving their notification letter. This understandably caused much distress.

'I was really angry. Angry because we didn't get to find out first.' (I4)

'I felt so let down because it had been on national news ... and I hadn't even had the information ... I think that was a huge mistake.' (I18)

Many felt the recall was a personal matter and should not have been in the public domain. Concerned friends and families informed by the press often contacted the women. In some cases this was felt to be supportive, but for others this increased their anxiety.

'It shouldn't have gone public; nobody should have known about it ... my mum and dad knew which doctor I had. So they were ringing me up and it's private. You don't want to tell everyone what kinds of diseases or what's wrong with you.' (I2)

The women felt the media interest made the incident seem more serious. They were also uncertain of the accuracy of the press reports, and were concerned the media did not report how low the risk was.

'... because it's on the news it's more [serious] ... because you watch the news and the news is always about everybody else. And then all of a sudden it's you. That's what upset me. That was more [upsetting] than the letter ... that is what really hit me ... They don't mention the little things. It was bang on HIV, hepatitis B ... You never saw it's only going to be one-tenth of a percent.' (I5)

Box 2 Thematic framework

The lead analyst read the first six transcripts. The content of each of the transcripts was 'cut and pasted', grouping together quotes on similar topics. The recurring themes that emerged were used as the framework (see below). For each category, quotes were grouped into positive, negative and neutral comments. The second analyst then reviewed these transcripts and the framework. This analyst identified no additional themes. Subsequent transcripts were analysed by the lead analyst only. Awareness was maintained for additional themes while analysing the subsequent transcripts but no additional categories were identified. Each transcript was colour coded so quotes could be traced back to each interviewee.

1 Impact on the women of being recalled

- Emotions experienced on being informed
- Emotions experienced later on during the recall process
- Impact of results
- Impact on sexual relationships
- Impact/response of friends and family
- Impact on health/future of children
- Potential long-term effects

2 Thoughts on the PCT's decision to undertake the look-back exercise

- Openness
- Trust
- Taking action

3 Organisation of the recall

- Notification
- Content of letter
- Helpline
- Recall clinics
- Results
- Follow-up

4 Media coverage

- Timing of notification by letter and time of media coverage
- Media coverage of risk
- Accuracy of media reports
- Impact on perceived confidentiality
- Response of friends/families to media coverage

5 Views about the NHS

- NHS in general
- Thoughts re practitioners directly involved with incident
- Nurse
- Doctor
- Systems to detect poor practice

6 Confidence in the cervical screening programme

- Future participation in screening
- Risks of recurrence of poor practice
- Risk of not having screening

7 Other comments

Views about the NHS

Many of the respondents reflected on the apparent lack of systems within the NHS for identifying poor practice, and wanted answers as to how it had happened. Much blame was directed at the nurse but many interviewees expressed support for the GP practice in general.

‘There are supposed to be checks. Why was it not picked up and why did it go unnoticed? ... Hopefully, she’ll never practice again, but you can reverse back to [the fact that] it was the doctor’s fault ... she wasn’t trained properly.’ (I2)

‘I thought I could end up losing a good doctor just for the sake of something and nothing really ... The practice has always been so helpful. It’s just human error as far as I’m concerned.’ (I12)

Confidence in the cervical screening programme

Although all interviewees intended to continue having regular cervical smears, several said they would be more questioning of standards in future.

‘When you stand back and put it into perspective, you’ve got to think to yourself, all right it’s a worry something like that, but getting cancer is an even bigger worry and there is no way I would stop having smears.’ (I15)

Discussion

Healthcare errors are inevitable despite the best efforts of practitioners.^{2,3} However, there is little published information regarding how patients respond to disclosure of actual clinical errors.^{3–5} When presented with hypothetical scenarios, or asked their views on disclosure of error, the majority of patients want open acknowledgement of errors, even if minor.^{2,4–7}

Having identified the inadequate decontamination of vaginal specula, the PCT faced a complex dilemma in deciding whether potentially affected women should be informed of the error (see Box 3). The PCT was sensitive to the distress this event would cause but was also aware of the increasing expectation of openness following medical errors.

There was a paucity of literature on the views and values of patients recalled in previous look-back exercises to help guide the PCT’s decision. In order to help future decision making in similar circumstances, our study sought to further the understanding of the impact of look-back exercises on patients and to determine their views on whether the PCT had been right to disclose the error.

We found that while some women were fairly philosophical about the poor clinical practice and subsequent look-back exercise, for many of those interviewed, it had been a very distressing experience.

Box 3 Factors taken into account in the risk–benefit analysis of informing women of the risk of infection and conducting a look-back exercise

- 1 *Many of the potential infections are asymptomatic yet have long-term sequelae.* Affected women may therefore not have presented clinically. Treatment of previously unidentified infections could lead to health gain for the women and the wider population.
- 2 *The actual risk to health:* although the risk to health was thought to be low, an accurate risk assessment was not possible. Hence, there was uncertainty about the actual risk to health and likely numbers (if any) infected.
- 3 *No way of ascertaining whether specula were the transmission vector in positive cases:* if women were informed of the error, then the PCT felt it would be obliged to offer microbiological testing where possible. Due to the background prevalence of STIs and BBVs, some women would undoubtedly test positive, with no way of ascertaining whether the specula were the transmission vector. However, because of the context in which the infection was identified, there would almost inevitably be some presumption towards transmission by specula, potentially magnifying the seriousness of the incident in the public’s mind.
- 4 *Distress to patients and families.*
- 5 *Need for openness in response to clinical errors.*
- 6 *Impact on public confidence uncertain:* adverse publicity could undermine confidence in the national cervical screening programme, PCT and NHS. Alternatively, the PCT’s openness in dealing with the clinical error could enhance the public standing of the organisation.
- 7 *Uncertain impact on service quality in the practice concerned:* the publicity may alienate the practice from the PCT, making them less receptive to future clinical governance support. Alternatively, it could be an additional driver for quality improvement.
- 8 *Obligation to patients:* the legal opinion given to the PCT was that women should be informed.
- 9 *Resource implications.*

This is despite the women complimenting the organisation of the recall. Patients reported being worried, scared, frightened, unable to concentrate or sleep and always having it on their mind. For some, the ramifications of the incident went much further, affecting physical and emotional relationships with partners, generating concern about potential long-term effects and the health of their children. Wider family and friends also experienced significant anxiety.

However, despite the distress they experienced, all of the women interviewed endorsed the PCT's decision to inform them about the error and to conduct the look-back exercise even though the estimated risks to health were low. Many women appeared to have undertaken sophisticated assessments of the risks, as illustrated by their intentions to continue to have cervical smears in the future.

Contrary to the PCT's fear that confidence in the organisation may be adversely affected, the women commended the PCT for being open and taking the necessary action. However, they were shocked by failure of systems within the NHS to detect prolonged poor practice.

The women were highly critical of the media coverage. Particular concern was expressed that some notification letters were not received until after the initial media coverage. In view of the size of the recall it was inevitable that the media would learn about the look-back exercise. The PCT, therefore, wanted a proactive media strategy to minimise the probability of inaccurate information in the press. In line with the Department of Health's guidance on notifying patients exposed to HIV infected patients,⁸ the letters were sent (first class) to patients so that they should arrive on the day of the planned press release (which was embargoed until midday). However, postal delivery is unpredictable. This regrettably meant some patients heard about the incident from the media before receiving their notification letters. In future, practitioners may wish to consider more reliable alternatives to Royal Mail for delivery of notification letters, and evening embargoes on media releases. We recommend that the patient letters include a warning that a press release will be made and that their letters contain all of the information to be given in the media statement. However, one would still need to be aware of the high likelihood of patients informing the media on receipt of their letters.

The views expressed in this study are those of a small number of the women recalled. All of the interviewees had attended the local recall clinics and had negative screening results. Their feelings may differ from those with negative results who did not participate; those found to have *Chlamydia* or past hepatitis B infection; and women who no longer lived locally. The interviews were conducted about six months after the initial notification letters were posted. The women's

views may have changed over time. A prospective study, run in parallel with the recall exercise, may have more accurately captured their experiences. However, this was logistically not possible as the look-back itself stretched the PCT's resources to the limit.

Although the study has limitations, it has provided a useful insight into the experience of a group of women recalled following the identification of prolonged suboptimal clinical practice. It demonstrated that despite the distress incurred, the women placed a very high value on the right to information following errors, even if the risk to health was minimal.

While a culture of transparency over clinical errors is important for improving patient safety and maintaining public confidence, look-back exercises are not without risks, and result in significant costs.⁹ Over 50 clinicians and NHS managers were involved over a six-month period in this recall programme. Business continuity within the PCT headquarters and community nursing team was severely stretched. The negative public health consequences, due to the patient and family distress caused and the diversion of resources to the recall programme, may have outweighed the benefits of treating the few infections found. However, there was significant uncertainty before undertaking the recall programme of the degree of risk, and the patients believed it was their right to be informed.

The National Patient Safety Agency requires all English healthcare organisations to have a 'being open' policy by June 2006.¹⁰ This policy currently applies only to incidents where individual patients are known to have suffered moderate to severe harm. In this incident we were uncertain at the outset as to whether any patient had actually suffered harm. In similar circumstances to this, a potential conflict may exist between the public health consequences of the opportunity costs of undertaking a look-back exercise and the patient's rights and desires to be informed of clinical errors, no matter how small the risk to health. Further public debate in this area is required in order to guide healthcare professionals in the response to be taken in similar situations in the future where there is uncertainty as to whether patients have actually suffered harm.

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CONFLICTS OF INTEREST

None.

ADDRESS FOR CORRESPONDENCE

Paul Milne, East Lancashire Teaching PCT, Unit 4, Sentinel Court, Wilkinson Way, Haslingden Road, Blackburn, Lancashire BB1 2EH, UK. Tel: +44 (0)1254 226452; fax: +44 (0)1254 226440; email: pmilne@doctors.org.uk

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