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Memorandum by Action for Victims of Medical Accidents (MS 53)

INTRODUCTION

1.1 Action for Victims of Medical Accidents (AVMA) was established in 1982 to work on behalf of the victims of medical accidents. AVMA's work covers three main areas: to provide advice and support to medical accidents victims and their advisors; to campaign to ensure that the needs of injured patients are addressed including where appropriate, access to a fair system of compensation; and to work with healthcare professionals and other agencies to reduce the number of avoidable medical accidents.

1.2 Enquiries relating to maternity services represents the highest proportion of enquiries that AVMA deals with. This is both through AVMA's direct services to patients and through our Lawyers Resource Service, an advice and information service for clinical negligence lawyers.

1.3 AVMA's role in advising patients has given us a particular insight into the problems associated with failures in our maternity services from the patient's perspective.

1.4 The rise in legal claims relating to obstetric care is often blamed on unrealistic parental expectation ie the right to a perfect baby. However, the reality is that only a relatively small proportion of avoidable adverse outcomes in obstetric care result in a claim for compensation. The picture is somewhat distorted because cerebral palsy claims take up a disproportionate amount of the clinical negligence budget because of the high costs associated with these claims. Obstetric claims currently represent one in five of cases dealt with by the NHS Litigation Authority and 80% of the costs of all claims. However, it is important not to concentrate on the issue of litigation because this distorts what is the real issue, that of the frequency of avoidable adverse outcomes and the harm being done to mothers and their babies. Historically we have had a situation where the issue of medical accidents was perceived not so much from the perspective that too many mistakes were taking place but that too many patients were litigating. This meant that rather than focusing on reducing the number of accidents, the emphasis was on reducing the amount of litigation. When the concept of risk management was first introduced, this was often interpreted as litigation management and less that of reducing the risks of harm to patients. This is something that we need to move away from to enable everyone to concentrate on reducing accidents by introducing a more systematic approach to identifying and responding to adverse events. This is something the NHS has been very poor at doing up until the present time.

1.5 AVMA is particularly concerned that the same causative factors which have resulted in a poor outcome or injury to mother or baby continue to be seen. This is

despite the fact that this is one area of medicine that has been subject to two separate confidential inquiry processes, the Confidential Inquiry into Stillbirths and Deaths in Infancy (CESDI, established 1992) and the Confidential Inquiry into Maternal Deaths (CEMD, established 1952), and well before the introduction of bodies such as the Commission for Health Improvement and other systems of scrutiny. These reports have continued to highlight the causes of adverse outcomes in maternity care but progress has been very slow in translating these lessons into practice. It is unclear whether this is primarily a resources issue or a more general failure to overcome the complacency that has been associated with medical accidents.

1.6 Similarly, the fact that the same maternity units have been known to crop up in a disproportionate number of cases also raises concerns about how and why that situation is being allowed to continue and why there are not more effective systems in place to react more immediately to unsafe practices and procedures.

1.7 No one should underestimate the human cost of adverse outcomes in obstetric care. The death of a healthy baby or a lifetime of caring for a disabled child who should have been healthy is a devastating outcome from what should have been a happy event. The families concerned have every right to question how this could be allowed to happen and why. Both the CESDI reports and the EuroNatal Study—European comparisons of perinatal care—identify that suboptimal care is responsible or contributes to substantial numbers of avoidable stillbirths and neonatal deaths. At a conservative estimate, we are looking at over 800 potentially avoidable stillbirths a year. What is of particular concern is that many stillbirths classified as "unexplained" by healthcare providers, would have been explained if a proper analysis and investigation had been undertaken at the time to look at the potential causative factors. This is a critical issue because we cannot begin to address failures in service provision if we are not identifying and responding to adverse incidents and thereby learning from what has happened.

1.8 It should also not be forgotten that healthcare professionals involved in medical accidents are often left in an invidious position. The failure to openly acknowledge and investigate adverse events, means that healthcare professionals may not have access to effective debriefing and support systems and the means to put their actions into context. This is perhaps particularly true in the case of maternity services, where usually a good outcome is to be anticipated. Until we can meet the needs of healthcare professionals, it is unrealistic to expect them to meet the needs of their patients.

1.9 By the nature of AVMA's work, this response will concentrate on AVMA's experience of maternity services from the perspective of the parents who believe they have been let down by the service leading to an injury to either the mother or the baby.

ADVERSE OUTCOMES IN MATERNITY CARE

2.1 There is perhaps a fine line between avoiding over-medicalisation of normal childbirth whilst retaining the skills and knowledge to detect and respond to the abnormal. There is considerable concern expressed over what are perceived as

unnecessary interventions including the increasing number of deliveries by caesarean section and yet many of the cases that AVMA sees relate to a failure to intervene when intervention is required. Some would argue that less intervention would be required if maternity services were more patient-centred and better equipped to respond to the needs of pregnant women. For example, through providing continuity of care, avoiding interventions such as induction of labour when not necessary, improving the quality of training for maternity staff etc.

2.2 AVMA receives a wide range of maternity related cases, but many follow a familiar pattern. These include cases involving:

— Antenatal care eg antenatal screening, the identification of risk factors, intrauterine growth retardation, treatment of pre-eclampsia, care of the diabetic mother, diagnosis of rare conditions of pregnancy.
— Intrapartum care eg the interpretation of electronic fetal monitoring, diagnosis and management of shoulder dystocia, haemorrhage, management of multiple births, breech deliveries, erbs palsy, maternal injuries, use of forceps.
— Induction and augmentation of labour and its complications.
— Complications of caesarean sections including injury to mother and/or fetus and vaginal delivery after caesarean section.
— "Trial of labour".
— Management of premature labour.
— Neonatal care eg hypoglycaemia, infection.
— Specific problems associated with home births and independent/private healthcare.
— Issues of consent.

2.1 This list is not exhaustive and it is not appropriate to cover all of these issues within the remit of this paper but we would like to highlight certain of these to illustrate why it its so important that a more systematic approach is developed for identifying and learning from mistakes.

INDUCTION AND AUGMENTATION OF LABOUR

2.4 The use of oxytocics (eg prostaglandins and syntocinon) in the induction and augmentation of labour has long been a source of concern with respect to the adverse outcome of labour. There is an apparent lack of adequate research into the risks associated with these drugs with the result that healthcare professionals often appear unaware of the significant potential for harm in their use of these drugs. In turn, mothers themselves are not warned of the potential risks which includes hyperstimulation of the uterus, uterine rupture and fetal hypoxia as well as the "cascade of intervention" that is often associated with induction. These risks were exacerbated following the change towards increasing the number of vaginal deliveries in mothers who had had a previous caesarean section. The particular risks in this situation were often underestimated (see below, Trial of Labour).

2.5 AVMA has seen too many examples where repeated attempts at induction of labour have been made involving repeated doses of prostaglandins. A typical scenario would be where no apparent progress is made after the first, second or third application of prostaglandin and then the uterus suddenly becomes hypertonic, leading to fetal compromise, hypoxia and in some cases uterine rupture and fetal death.

2.6 More recently, the problems of underestimating the risks associated with induction were highlighted in relation to a trial of a relatively new prostraglandin agent, Misoprostol. Misoprostol is known to reduce delivery time but perhaps inevitably, also increases the risks of uterine rupture and hyperstimulation. Some might argue that the use of such an agent is a symptom of the "medicalisation" of labour. There is anecdotal evidence of some disturbing issues arising out of trials of this drug in women in the United Kingdom leading to disastrous outcomes for mother and baby.

TRIAL OF LABOUR

2.7 AVMA has seen many examples where a "trial of labour" has been planned in the light of pre-existing risk factors including diabetes, previous caesarean section, potential cephalo-pelvic disproportion etc, but due a breakdown in communication or a failure in management at the time of delivery, a "trial" does not appear to have taken place, labour being allowed to continue without cognisance of the trial or the risk factors that are present. In some cases it appears that this is due to a failure of the clinician to provide adequate instructions in terms of how long the labour should be allowed to continue, the risk factors that those attending the mother need to be aware of and the indications for intervention.

2.8 It is important that where a trial of labour is being embarked upon, the resources and staff are available should intervention be required. AVMA has seen a number of examples where a trial of labour following induction has failed and urgent intervention is required but no theatre staff were available when needed.

ANTENATAL CARE

2.9 AVMA sees a range of problems arising as a result of failures in antenatal care from failure to detect and/or respond to intrauterine growth retardation, failures in antenatal screening for fetal abnormality, rhesus incompatibility, management of threatened miscarriage or premature labour. Communication is often a critical factor and again, particularly in relation to listening to the individual mother and her concerns.

MATERNAL INJURIES

2.10 It is only in relatively recent years that the complacency surrounding maternal injuries during delivery has begun to be challenged. In the past, AVMA regularly received enquiries from mothers who had been left incontinent of urine and faeces following a difficult delivery where the problem was either not acknowledged or little in the way of active intervention was offered, the response being that this was an avoidable

part of bearing children. We would like to say that this is no longer the case but AVMA is still seeing cases where there has been a failure to acknowledge the impact of such an injury on the mother's ability to cope physically, practically and emotionally. This might also explain why cases involving retained vaginal swabs are still being seen and not detected for considerable periods of time despite the mother expressing concern that something is wrong.

2.11 The psychological trauma associated with childbirth has also only relatively recently been recognised. There has been a tendency, where both mother and baby have physically recovered, to dismiss such trauma on the basis that the mother should be pleased that they are both healthy albeit that they might have had a "near miss". However, where a mother (and partner) have experienced a traumatic delivery, perhaps involving an instrumental delivery or emergency caesarean section, this can have a significant impact on the parents to the extent that the mother may be unable to face a future pregnancy. Many mothers report that as a consequence of the trauma they have been unable to bond with their baby. It is essential that staff are alert to the trauma that can sometimes be associated with a difficult delivery and be able to offer the appropriate support and counselling that may be required to help the mother (and partner) come to terms with the experience.

2.12 Perhaps the most significant trauma associated with childbirth is that of anaesthetic awareness, where either an epidural or a general anaesthetic has failed during the course of a caesarean section. This is fortunately far less frequent than was the case some 10 to 15 years ago although cases are still being seen, particularly in relation to failed epidurals during caesarean section. This is again an issue of not listening to the mother.

Independent Sector

2.13 The independent sector is not immune to avoidable adverse outcomes in maternity care. There was considerable disappointment that following the introduction of the Care Standards Act 2000, the regulations governing independent healthcare, and in particular clinical care, still failed to address in any substantial form, the systemic failures in service provision. It is essential that along with other areas of independent healthcare, that gaps in the regulatory system are addressed to ensure minimum safe standards of care.

CAUSATIVE FACTORS FOR ADVERSE OUTCOMES IN MATERNITY SERVICES

3.1 In reviewing the range of maternity cases that AVMA receives, it is possible to identify a number of common causative factors that arise in these cases.

- Poor communication.
- Staffing and resources.
- Use and interpretation of electronic fetal monitoring.
- Training.

— Misapplication of protocols.

Communication

3.2 Communication is often quoted as a significant factor in relation to healthcare complaints. This potentially sounds like a relatively minor issue and there can be a tendency to interpret it as meaning that patients have failed to understand or listen to information that is given to them ie an issue of "misunderstanding" rather than there actually being a significant failure in healthcare provision. Communication is a critical factor in adverse events generally but is also a significant factor in obstetric accidents, particularly where there is a lack of continuity of care.

3.3 Communication skills training has in the past tended to concentrate far too much on how to convey information and far too little on how to actively listen to patients. Failing to listen to what mothers are telling healthcare professionals is a critical factor in a significant number of cases that come to AVMA. In theory, if healthcare is to become more patient centred, then greater emphasis should be given to listening to the individual patient and their needs rather than trying to make the patient fit the needs of the service.

3.4 With the increasing use of overseas recruitment, it is also important to ensure that effective communication between professionals and with parents is not further undermined by language difficulties.

3.5 A number of examples have been set out below to illustrate the importance of communication.

Example A

> This was Mrs B second pregnancy. In her third trimester she began to develop a number of apparently non-specific symptoms including extreme tiredness which led to her having to spend long periods in bed where ultimately, she was effectively bedridden. Over a period of three weeks she was seen by a number of GPs and midwives attached to her GP practice. Her condition was put down to pregnancy and having an active toddler. She rarely saw the same practitioner on more than one occasion so that no one individual developed a clear picture of her evolving symptoms. On the final occasion that she was seen by a GP, it was only on the mother's insistence that something was wrong, that it was reluctantly suggested that if she was that concerned, she should attend the local hospital for fetal well being to be checked. Her family took her to the local hospital where acute fatty liver of pregnancy was immediately diagnosed and "blue-light" referral to a specialist liver unit arranged. Unfortunately, the baby had already died within the previous twenty-four hours. Although acute fatty liver of pregnancy is a rare condition, if the mother and her family had been listened to and their concerns taken on board, an earlier referral to hospital could well have resulted in a different outcome.

Example B

> A mother and her husband attended her local maternity unit believing herself to be in labour and concerned that something was not right. This was her first baby. The unit was very busy. Without performing an examination or making a record of the visit, a midwife advised the mother that she had come in too early and should return home until labour was more established. This the mother did but she and her husband became increasingly concerned about her condition and telephoned the unit for advice. They were told to wait at home. The couple became more anxious and returned to the hospital and saw a different midwife. Again they were advised to return home which they did. A short while later they telephoned the hospital but were still advised to remain at home. After a further telephone call, the couple decided to return to hospital of their own accord. On this occasion the mother was examined and it was diagnosed that the baby had died.

Staffing

3.6 A significant proportion of midwives would probably support the view that resources and in particular, staffing levels, prevents them from providing the sort of care that they believe is both safe and meets the needs of mother and baby. Midwives are often in the firing line when it comes to adverse outcomes in maternity care and yet the midwife may have been working in an environment that meant that a disaster was waiting to happen.

3.7 It is essential that we move towards a twenty-four hour service as opposed to a nine to five, Monday to Friday service. It is of no surprise when dealing with enquiries to find that a serious adverse outcome has taken place either "out of hours", on a bank holiday or coinciding with the intake of new junior doctors.

3.8 Minimum safe staffing levels across all maternity services need to be set and to be enforceable. There needs to be an effective on-call system to cope with busy periods—a department being over-stretched being an explanation often given to parents when something has gone wrong.

3.9 Minimum standards for consultant and senior midwife cover need to be established to ensure that in emergency situations, or where intervention is required, there are experienced members of the team available. Senior cover at night is particularly important. The CESDI reports have frequently identified the lack of consultant cover as a significant factor in avoidable stillbirths. It is notable that the difficulty is not so much that of identifying there is a problem requiring intervention as that of there being someone available of sufficient seniority and experience to make the decision about what needs to be done and to act upon that decision.

Use and Interpetation of Electronic Fetal Monitoring

3.10 If used correctly, electronic fetal monitoring (EFM) or cardiotachographic (CTG) monitoring can be a useful adjunct to the management of labour. However, there are a number of risks associated with the use of electronic fetal monitoring. Firstly, there is a temptation to use CTG monitoring as a "proxy midwife", CTG monitoring replacing continuous care by a midwife, particularly when the maternity unit is under pressure. The fact that the well-being of the fetus is being "monitored" by a CTG machine can give a false sense of security in that there is some reassurance that labour is being supervised, albeit electronically.

3.11 Secondly, the failure to correctly interpret CTG tracings continues to be a feature in a substantial proportion of cases involving fetal hypoxia, cerebral palsy and stillbirths. CTG monitoring is only as good as the healthcare professional interpreting the traces. Interpretation of CTG traces is somewhat more complex than simply identifying particular patterns on the trace; these have to be interpreted within the overall context of such issues as previous obstetric history, risk factors, maternal well-being, stage of labour, results of other procedures such as fetal blood sampling etc. Whilst there has been some considerable improvement in training in the interpretation of CTG traces, the failure to correctly use and interpret electronic fetal monitoring is still a major cause for concern. This has continued to be highlighted in the reports of the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI). There are still examples where healthcare professionals have interpreted poor CTG traces as a machine fault rather than a hypoxic infant and it is only after the machine has been changed several times that this is recognised. One might question why there is not greater availability of more advanced machines which are capable of identifying when clinical input is required to check the status of mother and baby.

3.12 An additional risk associated with electronic fetal monitoring is that of unnecessary intervention but this largely relates to the failure to correctly interpret the CTG trace in the context of that particular mother and baby.

Training

3.13 Evidence of inadequate training and supervision being a causative factor in adverse outcomes is often apparent in cases that are seen by AVMA. Some aspects of training are dealt with under separate sections, most notable, that of electronic fetal monitoring, the use and risks of protocols and communications training.

3.14 All maternity staff should have regular updating of skills which should include feedback from specific adverse incidents ie learning from mistakes.

3.15 Learning about medical accidents, the causes and consequences, should be a core part of all clinical training. This is important because it will aid the process of creating a more open culture where mistakes can be acknowledged and dealt with in a more systematic way. This in turn will help ensure lessons can be learnt and services

improved. It is to be hoped that through a combination of the work of CESDI, CEMD, the National Patient Safety Agency, the Commission for Health Improvement and the Royal Colleges, there will be far greater dissemination of information between healthcare providers in relation to adverse outcomes in maternity services. In the meantime, healthcare providers need to much better systems for identifying and investigating adverse outcomes within their service. At the present time, there is still a considerable amount of work to do and the investigation of adverse incidents is very much in its infancy with only a limited number of professionals with the relevant skills to undertake an effective forensic investigation which is capable of identifying the often complex chain of events that lead up to an adverse outcome.

3.16 AVMA has for a long time advocated involving the parents in the investigation of an adverse event. Parents are often very accurate historians and can provide a perspective on events which is often not found within the medical records or from the testimony of staff.

3.17 A small proportion of cases seen by AVMA involve home deliveries. This does raise some questions as to the nature of training and supervision required for midwives to undertake home deliveries as compared to midwives working in a hospital environment. The level of responsibility and type of decision making required is quite different in the two settings and training and accreditation must take this into account.

Protocols

3.18 Clinical protocols and guidelines can represent a useful tool but if followed blindly can provide a false sense of security whereby there is a failure to actively intervene when the protocol is no longer appropriate in light of changes in either fetal or maternal condition. Such situations are frequently well-documented in cases seen by AVMA but what is perhaps obvious by its absence is an intelligent application of the protocol. It is important that the design of protocols does not undermine the clinical skills of maternity staff such that the protocols supersede their own clinical judgement.

4. Responding to the Needs of Parents Following an Adverse Event

4.1 As little as five years ago, it was still more often the case that parents faced an uphill struggle to obtain any form of explanation following a major adverse event during maternity care. Even after pursuing a lengthy complaint through the NHS complaints procedure, parents were not guaranteed to receive a full or accurate explanation.

4.2 There have been some improvements in terms of providing explanations but this is by no means universal. Parents are still being given inaccurate or misleading information. In the aftermath of an adverse outcome occurring during pregnancy or childbirth, in addition to providing support to help the parents cope with the trauma, one of the most important issue from the parents' perspective is information: information about what happened and why. If the outcome was caused by a failure in the delivery of care, they need this to be openly investigated and acknowledged. They also need

evidence of the steps that are going to be taken to prevent a recurrence of the same mistake. This is not just for the benefit of the individual patient. It is an important part of clinical risk management generally in that there needs to be a willingness to openly explore where mistakes have been made and what action is needed to prevent it happening again.

4.3 AVMA has always advocated a pro-active approach to responding to adverse events. This means that instead of waiting to see whether the patient complains, as soon as an adverse event is identified, an immediate investigation is instituted which involves the patient and/or relatives.

4.4 Intrapartum stillbirths are a particular instance where healthcare professionals need to be pro-active in their approach to responding to the needs of the parents. The Stillbirth and Neonatal Death Society (SANDS) have produced very helpful guidelines for health professionals in supporting parents after a baby has died. However, an essential part of that support should also include responding to the particular needs of parents where an adverse event may have played a part in the loss of their baby. In this situation, a pro-active approach to responding to the parents concerns is an essential part not only of the support process, but of patient care.

4.5 AVMA has seen many examples where the failure to provide an explanation has greatly compounded the parents' grief, sometimes leading to long-standing psychiatric illness. In one particular case, a woman had to wait twenty years for an explanation following an avoidable stillbirth. In the intervening period she suffered severe depression and was effectively housebound. It was only following the intervention of a doctor who obtained her old obstetric records and explained what had happened that she began the process of recovery. It is not uncommon in the case of stillbirths to find that mothers will not visit their baby's grave until their complaint or legal claim is concluded, even if this is many years after the event.

4.6 If health providers do adopt a pro-active approach to identifying and investigating adverse events, the investigation should move away from simply targeting individual health professionals. Whilst individuals may ultimately be culpable, there is sufficient data to suggest that attention needs to be focused on the systems within which those health professionals work and the sort of failures in those systems which lead to human error. Such failures may include, for example, systems that allows people to make decisions beyond their competency or experience, unsafe staffing levels, poor resourcing resulting in faulty or substandard equipment, poor communication between health professionals, inadequate protocols, people working when they are overtired or stressed etc. An investigation sufficiently rigorous to identify such failures is not an easy task and requires people trained to carry out such investigations but is essential if you are going to address the underlying causes. The present reality is that the true causes of an adverse event often remain undisclosed. Individual healthcare professional may well be disciplined but this will not in itself prevent one of their colleagues making the same mistake.

5. DISCUSSION

5.1 AVMA acknowledges that improvements have been made in maternity care but as highlighted in the CESDI reports and the EuroNatal International Audit, believes there is no room for complacency, particularly at a time where resources are being increasingly stretched.

5.2 Giving mothers choice in childbirth is important but we first need to be able to ensure that as a minimum, all units are able to provide mothers and babies care that is safe and that minimises the risks of error and avoidable adverse outcomes.

5.3 Whilst most of the focus in relation to obstetric accidents has been on the cost of meeting clinical negligence claims, this hides the fact that the number of adverse outcomes, particularly in relation to avoidable stillbirths, is perhaps no less of a scandal than the tragic events at the Bristol Royal Infirmary.

5.4 This is a time of considerable change with respect to the patient safety agenda. Until recently, whilst the confidential enquiries were able to identify what was going wrong and why, there were no effective mechanisms for ensuring that this was translated into the necessary changes in the provision of maternity services to prevent the same mistakes being repeated. Following on from the Bristol Royal Infirmary inquiry and the Chief Medical Officer's report, An Organisation with a Memory (June 2000), medical accidents or adverse events are now beginning to be recognised as a key issue in healthcare provision. AVMA has long argued that patient safety and reducing the frequency of adverse events should be an underlying principle of all healthcare policy and provision.

5.5 There have been some significant developments over the recent past including the introduction of the Commission for Health Improvement, its role to be reinforced when it becomes the Commission for Health Audit and Inspection in April 2004; the establishment of the National Patient Safety Agency to collate and disseminate data on the frequency and causes of adverse events; the introduction of clinical governance; and the establishment of the National Clinical Assessment Authority to address issues of performance and competency. It is still relatively early days in terms of assessing whether these developments are sufficiently robust to prevent another Bristol. There is ongoing concern that there are still gaps in the regulatory system and that with so many different bodies dealing with different parts of the regulation of healthcare, the system is fragmented and there is a real risk that even cases such as Bristol could still fall between the cracks.

5.6 The first step is to ensure that patient safety is firmly embedded in the healthcare culture and that medical accidents are not simply dismissed as "one of those things" or remain "unexplained".

6. RECOMMENDATIONS

(i) Provide a full 24 hour service with appropriate consultant and senior midwifery cover.
(ii) Develop more effective systems for identifying and investigating adverse incidents and for auditing outcomes so that failures in care can be quickly addressed.
(iii) Set clear targets for reducing the number of adverse outcomes in maternity care and ensure that the findings of the CESDI reports and other inquiry systems such as the NPSA, are translated into practice.
(iv) Incorporate training on adverse incidents in all clinical training programmes for all members of the team.
(v) Employ a pro-active approach to adverse outcomes and recognise the needs of parents to have an accurate and timely explanation. Recognise the contribution that parents can make to our understanding of the causes of adverse outcomes.
(vi) Recognise the support needs of staff whilst ensuring poor practice or issues of competency are dealt with effectively.
(vii) Greater emphasis on communication training, and in particular, listening skills.
(viii) Further research into the use of oxytocic drugs in labour and for better training of healthcare professionals so that they fully understand both the benefits but more importantly, the risks associated with induction and augmentation of labour.
(ix) Better information for pregnant women so that they can make an informed choice about interventions.
(x) Minimum enforceable standards for resourcing of maternity units so that the explanation for an adverse outcome is not that the unit was "particularly busy" on that occasion.
(xi) Revise the regulations governing the private/independent sector to ensure that minimum standards of clinical care are established.
(xii) Make compliance with CESDI (and other reporting systems), mandatory for both the NHS and private providers.

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