Audit and risk management in community child health

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A focus on preventive care programmes

The widespread acceptance of clinical governance as a tool for improving the quality of health care delivery means that consultant community paediatricians share responsibility for setting and maintaining standards of practice in the community. One aspect of developing a high quality of care is risk management (RM), which has been defined as “the process of reducing or eliminating losses due to accident or misadventure”.¹ An essential feature of RM within clinical governance is that individual practitioners assume responsibility for their part in reducing and eliminating risk. The overall aim is to improve the quality of care, by identifying and reducing risks that might result in damage to a patient or healthcare professional, or result in complaints and litigation. There are three aspects of RM:

- Setting up systems that monitor practice, identify weaknesses and adverse incidents, and allow analysis of mistakes and omissions before harm, complaints, and litigation occur. It is important that “near misses” are included in this category.
- Analysis of complaints received to derive lessons that may be learnt to improve quality of care.
- Managing litigation.

The aims of this paper are to suggest what systems might be needed to minimise risk and raise quality, and to suggest areas where trusts should focus their RM activities. The focus is on preventive care programmes and we will not discuss “vaccine damage”, child protection, or aspects of professional practice, which involve the same principles and hazards in a community setting as in any other area of clinical work.

The concept of RM has been applied most commonly to “high risk” areas such as obstetrics, orthopaedics and accident & emergency medicine. By comparison, community child health is a low risk activity. The NHS Litigation Authority (NHS LA) operates a Clinical Negligence Scheme for Trusts (CNST), but the quality checklists produced by CNST have yet to address quality guidelines or standards for preventive care, such as immunisation or screening programmes.

Risk management principles are nevertheless important in community child health, for several reasons. The first is to improve the quality of care and encourage better use of the evidence base. Secondly, preventive health care often involves multiple professional groups, in different trusts and in other agencies. There is a risk of fragmentation of responsibility and of difficulties in setting and maintaining quality standards. Thirdly, application of sound RM principles affords protection against complaints and litigation by an increasingly litigious population combined with an easier facility for making claims. RM policies must address misunderstandings or grievances as well as negligence claims.

A government publication² discusses the importance of learning from near misses, adverse events, complaints and litigation to improve quality of care across the whole of the NHS. It is a general feature of the NHS that adverse event reporting is least developed in sectors where the most patients are seen. In 1998–99, there were 277 million medical and dental primary care consultations and 16 million new episodes in community health care, contrasting with 8.6 million hospital admissions and 24.6 million outpatient and accident & emergency attendances.³

Although primary and community care are barely mentioned compared to acute care in *An organisation with a memory*,² there are many lessons for the practice of community paediatrics. Community paediatrics does not feature in the document itself except as an example of excellence furnished by the rapidity of the introduction of the “back to sleep” campaign in reducing sudden infant death nationwide.

Along with other NHS bodies, Community Paediatrics will need to develop an organisational culture to ensure that identified adverse incidents are appropriately reported so that necessary changes in practice are introduced. This must be done in association with the development of a “safety culture” with open reporting of problems coupled with the avoidance of a “blame culture” which can encourage the cover up of errors. Unlike other areas of medical practice

where drug treatments and surgical operations predominate, Community Paediatrics will have to concentrate on diagnostic and screening errors and failures. Unified reporting systems will be vital and are likely to be more difficult to develop in community paediatrics than in other areas of the NHS because of its special problems of many sites, single handed practitioners, and independent practice.

Organisational and systems failures both contribute to serious adverse incidents in patient care. System failures include failures in equipment and defects in procedures, protocols, and administrative controls. Human error caused by, for example, forgetfulness, inattention, carelessness, and negligence are usually only part of the cause of poor quality care. It is emphasised that errors fall into recurrent patterns and that sometimes the best practitioners can make the worst mistakes. It is likely that organisational and systems failures will be far more important than errors by individuals in causing community paediatric adverse incidents.

The practice of community paediatrics has received little scrutiny from regulatory bodies to date. In the future, this is likely to change dramatically with attention and inspections from the CNST arm of NHS LA, the Commission for Health Improvement (CHI), and the National Patient Safety Agency (NPSA). The ability to learn from adverse events and near misses is a key component of clinical governance: although these events are likely to prove relatively few in community paediatrics, a robust system for identifying and preventing them will be necessary to avoid criticism of our practices.

EVIDENCE BASED MEDICINE IN COMMUNITY PAEDIATRICS

NHS bodies have a statutory duty of quality in the health care they provide. Section 18(1) of the Health Act 1999 states: “It shall be the duty of each Health Authority, Primary Care Trust, and NHS Trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare which it provides to individuals”

Part of this duty has particular relevance to community paediatrics,

Abbreviations: CHI, Commission for Health Improvement; CHT, congenital hypothyroidism; CNST, Clinical Negligence Scheme for Trusts; DDH, developmental dysplasia of the hip; GP, general practitioner; HACCP, Hazard Analysis Critical Control Point; NHS LA, National Health Service Litigation Authority; NPSA, National Patient Safety Agency; PCHR, Personal Child Health Record; PKU, phenylketonuria; RM, risk management; TB, tuberculosis; TBM, tuberculous meningitis

namely the use of an evidence base to develop and modify clinical guidelines for use by practitioners. Equally important is continuing professional development through education, training, and updating so that guidelines are appropriately applied and modified to deliver the best possible service.

Guidelines based on evidence are the main basis of the work of the National Institute for Clinical Excellence, but it is likely that it will be some considerable time before this body considers issues of relevance to Community Paediatrics. Nevertheless, authoritative guidelines based on sound evidence not only lead to better standards of care, but their application provides a robust defence to litigation when a mishap inevitably occurs. The more senior the health care body providing the guidelines, the greater their impact in the medicolegal arena of complaints and litigation. Senior and experienced community paediatricians should give a high priority to developing wide ranging nationally agreed policies. A major contribution to RM in Community Paediatrics will then be provided.

EXAMPLES OF ACTUAL AND POSSIBLE EVENTS RELEVANT TO RM

National recommendations were reviewed, supported by personal knowledge and discussions with medical and legal colleagues.

Five possible areas were identified where a community child health service may be vulnerable: failure to take appropriate action to prevent infectious diseases; failure to initiate other appropriate primary prevention measures; failure to identify disorders by not offering a screening programme or by providing an ineffective screening programme; failure to give information; and misuse of information.

Infectious diseases

Although vaccine damage has received much publicity, litigation may also result from withholding a vaccine where there was no good contraindication. In the USA, since 1977 no lawsuit has been successful against doctors who followed the standard programme of immunisation,⁴ but parents have sued successfully for failure to immunise children against measles, hepatitis B, and *Haemophilus influenzae* type B. In a recent UK case measles vaccine was withheld for a contraindication which was said to be invalid; the child subsequently developed measles encephalitis which resulted in permanent brain injury.

Most routine vaccines are now given by general practitioners (GPs). The immunisation coordinator should provide a well publicised and easily accessible

immunisation advice service, which might reduce the risk of erroneous decisions in vaccine administration by primary care staff; the advice given in such a clinic must be clear, accurate, up to date, and well documented. Consent procedures must be in place and their effectiveness checked.

Problems for trusts could arise in the prevention of other infectious diseases.⁵ BCG vaccine, when given to the neonate, does not prevent tuberculosis (TB) but probably does reduce the risk of tuberculous meningitis (TBM) in early childhood. The current recommendation is that BCG should be given to any child in a high risk ethnic group, defined as coming from a country of origin with a TB rate in excess of 40 per 100 000.⁶ This policy is not always followed; for instance, one local survey showed that babies born to families from the Indian subcontinent had a high rate of BCG immunisation, but only a minority of babies born to parents from other high risk countries had been immunised. The uptake of neonatal BCG was poor in southeast London in spite of an intensive effort to improve the situation.⁷ Vaccine shortages have compounded the problem.

Contact tracing following diagnosis of an adult case is a more important aspect of preventing TB. In one local audit, following identification of a sputum positive adult case of tuberculosis, the average delay before the contacts were examined was four weeks but some cases were taking many months. Failure to give BCG when indicated, or delay in contact tracing, might lead to avoidable damage because of development of TBM; such a claim would be hard to resist.⁸

A similar problem arises with the administration of three doses of hepatitis B vaccine to at risk infants. An audit in Sheffield showed that while all 21 eligible infants received the first dose, only nine were known to have received the third. An audit in Leicestershire showed similar deficiencies.⁹ If a child developed liver disease which could have been prevented by vaccine, the case would be difficult to defend. The advent of universal hepatitis B screening in pregnancy should be the stimulus to review the delivery of this programme.

These examples have in common the need to identify and monitor a numerically small but high risk group of babies, who for many reasons are likely to be particularly difficult to contact and track. This type of situation presents a significant risk and the trust must devise systems to ensure that all eligible babies are immunised.

Primary prevention

The administration of vitamin K to breast fed babies, to avoid bleeding in the early weeks of life, is a good example of

primary prevention. Unresolved concern over the safety of vitamin K has created confusion over the optimal policy and it is unclear which professional group is responsible for giving the vitamin K after the mother has left hospital, or for monitoring coverage. There have been several tragic and expensive cases of severe intracranial bleeding as a result of a baby not receiving vitamin K.

Screening

The National Screening Committee, which now has a Children's Subgroup, was set up to oversee screening programmes and determine whether they meet agreed criteria for screening.¹⁰ The provision of screening tests that do not perform well is legally hazardous, unethical, and a waste of resources. Conversely, those tests that are worth performing must be done to a high standard, offered to all susceptible subjects, properly documented, and clearly explained to the parents.

Screening is a high risk activity for complaints and litigation. From the consumer's perspective, the test was available but either was not done or was done incompetently, thus leading to avoidable damage or death. Informing the parent that screening tests are fallible and that they should return if they have any concerns may confer some protection, but only if it can be shown that the test was done and recorded correctly.

Congenital dislocation of the hip (now referred to as developmental dysplasia of the hip (DDH)) is the most expensive area of litigation in child health screening. Clinical screening is still the best option and the use of ultrasound should be confined to secondary screening. Even in the best hands, some cases will be missed.¹¹ This is more likely to be defensible if there is a written policy in line with national guidance, a well documented staff training programme, good record keeping, and information for parents about DDH in the Personal Child Health Record (PCHR). As with many screening programmes in child health, missed cases are too rare for any one trust to use as a marker of quality, so annual audit of this whole programme is an essential and sound investment.

The national screening programme for phenylketonuria (PKU) and congenital hypothyroidism (CHT) performs well, but there is no room for complacency and constant monitoring is vital.¹² Litigation arising from failure to do the screening test or act appropriately and promptly on the results is probably indefensible. Screening for haemoglobinopathies is another area where many trusts will increasingly be vulnerable.¹³

Although GPs usually provide child health surveillance services under the 1990 Contract for General Practice, primary care trusts will be vulnerable in

several ways.¹⁴ They will have to organise screening for vision and hearing defects; they will usually specify the details of the programme, including the development of responsive referral mechanisms; they will organise the training for GPs and health visitors; and the trust is likely to be responsible for the actions of most health visitors and midwives.

Provision of information

Parents have a right to clear information. If a parent believes that they have not been told about a problem in their child or an aspect of health care that could have helped avoid an illness or tragedy, they may make a complaint or bring an action against the trust; for example, one parent of a baby who died unexpectedly was aggrieved that she had not been told about "reducing the risk" of sudden infant death and said that had she known that her baby was at high risk she would have acted differently.

Consent, privacy, and use of information

Parents may also be concerned about the use of information about themselves, for instance data held on the community child health computer. It may be helpful to include a note in the PCHR explaining about the community child health system, its possible uses, and the parents' right to see their entry. Collection of data beyond that needed for monitoring of the screening and immunisation programmes enters a grey area between public health monitoring and research, and it may be necessary to ask for consent to record and analyse such information and specify its possible uses. Legal experts currently differ on the precise interpretation of the Data Protection Act (1998) and recent legal cases, and on the impact of the Human Rights Act which became law in England on 2 October 2000.

Questions of consent and privacy also arise¹⁵; for example, whether or not a teenager has a right to decide for herself whether she wishes to receive a vaccine, or at what age a child can give or withhold consent for physical examination. Staff may be particularly vulnerable to complaints with regard to child protection proceedings where the evidence of clinicians can have far reaching consequences. There is a body of advice and legal precedent which can be applied, but staff must use their judgement in many situations; again, staff training is the key to minimising complaints and dissatisfaction.

WHAT TO DO ABOUT IT

A trust can improve its service and protect itself against complaints and litigation at the same time. The first task is to define its programmes of care clearly:

who does what, to whom, with what aims, and, most important, how the coverage and performance are monitored. While most trusts have computer systems, the ability to extract and analyse data is variable and often limited—the investment in entering the data is much greater than in extracting and analysing reports, so weaknesses in service delivery are not identified until a tragedy occurs.

The person in charge of each programme must be identified—the responsibility for many community programmes is spread between several professional groups. For example, the management of hepatitis B vaccination or of the PKU programme involves midwives, health visitors, GPs, the laboratory, and paediatricians, in addition to the community information systems. Appointing a district child health promotion coordinator is the first step¹⁶—this person in turn must ascertain who will take the lead responsibility for each aspect of preventive care and for each area of staff training.

The second challenge is to examine systems like the delivery of hepatitis B vaccine, which look easy but are actually complex because so many individuals and departments are involved. In the food industry, Hazard Analysis Critical Control Point (HACCP) involves identifying points in the production process where there is a particular vulnerability to contamination, which would not subsequently be eliminated.¹⁷ This concept could be used more widely in health care, to identify the points in the process where the system might break down or an error pass undetected. For example, if there is no positive recording of the PKU and CHT tests results in the PCHR, an opportunity is lost for checking that a normal result has in fact been received. In some systems there may be errors at several points, though in many the majority of problems occur at just one. In one audit of hepatitis B vaccine the main weakness was not in case finding or laboratory testing, but in the lack of a protocol for administration of the second and third doses and monitoring completion of the course.

The third area of risk management is to make sure that the various programmes provided by the trust are in line with national policy. The trust should be able vigorously to defend its decision not to provide a programme discarded as unreliable or ineffective by an expert committee or working party. It might elect to depart from national recommendations, but the arguments should be well researched and carefully documented, so that it can justify its actions in the event of litigation. Where there is no national policy, trusts have to devise their own, with correspondingly greater hazards to themselves and perhaps to the children—it is a challenge for the

relevant professional groups to remedy such deficiencies, for example in the vitamin K issue.

In parallel with this it is important to make sure that parents know what the trust does and does not offer as part of routine well child care. The PCHR offers an excellent way of ensuring that this information goes to every parent, but it is still incumbent on the professionals (usually the health visitors) to make sure that the parents can read it, or else explain it to them. Failure to make sure that an illiterate or non-English speaking mother is fully briefed about vital health care issues would probably be regarded as a breach of the duty of care. If, for example, parents have been told that the screening test for deafness is not infallible, they are more likely to remain on the alert themselves for problems in the future.

Lastly, the issues of consent and confidentiality should be addressed, by staff training and by reminding all health professionals, and in particular the health visitors, to explain to parents what information is collected in the PCHR and elsewhere, and how it is used. The management of confidential personal information is a difficult issue and needs resolution at national level, but in the meantime these precautions can be adopted locally.

CONCLUSION

The practice of Community Paediatrics will be enhanced for both patients and practitioners by the application of the principles of RM. This in turn will be facilitated by the introduction of the main requirements of Clinical Governance including clear lines of responsibility and accountability, audit, evidence based practice, education, training, and the identification and remedy of poor performance. Building a knowledge base of problems encountered in screening and developmental assessments, particularly through complaints and litigation, will help make the practice of Community Paediatrics effective and safe.

ACKNOWLEDGEMENTS

We thank Janice Smith of Capsticks Solicitors, and Dr Lewis Rosenbloom for helpful comments; Dr Trish Field who conducted an unpublished audit on BCG and TB contact tracing; and Dr J-M Michel who carried out an unpublished audit of hepatitis B immunisation.

Arch Dis Child 2002;**87**:87–90

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IMAGES IN PAEDIATRICS.....

Achieving a coat of arms

Shortly after receipt of the charter for the Royal College of Paediatrics and Child Health, its executive committee appointed the late Professor David Baum (then president-elect) and myself (honorary archivist) to arrange the production of a coat of arms. I phoned the College of Arms for advice and was put through to the Richmond Herald, who was duty herald for the day. After asking a few questions he said that, provided that we were prepared to pay £7000, there should be no difficulty. I made an appointment to meet him with David Baum at the College of Arms near St Paul's Cathedral. The ground floor contains a courtroom where cases of dispute on heraldic matters can be heard. We went up a creaking wooden staircase lined with framed sheets of parchment containing coats of arms belonging to dynasties long dead.

The Richmond Herald, who with his half moon spectacles resembled a friendly family solicitor (attorney), suggested that we should decide on the concepts that should be incorporated, bearing in mind that the coat of arms should be distinctive and easily recognised. We included the aims of the College, the history of British paediatrics and child health, and some double meanings. Through the college newsletter we asked members for suggestions, most of which were incorporated in the final design, which was approved by the executive committee without change.

The coat of arms was painted on parchment in time for the design to be used on the programme for the first annual general meeting of the new College in April 1997. The members were delighted with the design, apart from some Lancastrians who objected to the rose, which was white. We had chosen a white rose because it represented the City of York, where many annual general meetings had been held, as well as the rose of England. After consultation with the Richmond Herald one of the white roses was repainted red. There were three symbols with double meanings.

The position of the child represents the concept that paediatricians wish to be as altruistic as parents by aspiring that the child should reach a level of attainment higher than their own. The tree of life (oak) represents child development and health and also refers to the first president of the College (David Baum). The tree is placed on a green field, referring to Professor Roy Meadow, the midwife of the College.

Coats of arms began in England in the middle ages, to distinguish individuals during tournaments. The knight carried his shield,

distinctively painted, and wore his helmet with a crest. The idea was not original. In ancient times Jewish, Greek, and Roman families adopted special symbols. Armorial bearings are commonly called a coat of arms but heraldically speaking this term refers only to the devices borne on a shield. The full display of all the devices is called a an achievement. The central element is the shield, which is surmounted by a helmet on which is borne the crest. Mantling, representing protective drapery, flows from the helmet. The figures at the sides of the shield are called supporters.

A more detailed description is found in Valman B. A coat of arms for paediatrics and child health. *J R Soc Med* 2000;**93**:389.

Bernard Valman

Editor's note

I hope non-UK readers are not too bemused by the arcane nature of the process described above. Rather they should be reassured that, despite the pressures of the electronic age, tradition has not totally flown off into cyberspace.

Those of you who dare to admit that they have not read Shakespeare may be puzzled at the reference to Lancaster and York. Please be reassured that the medieval rivalry between these two counties are alive and well, at least on the cricket square.

Finally, to preserve what little secrecy is left to us, the author, as archivist of the RCPCH is unrelated to ADC's Archivist, whose pseudonymous contributions have graced our pages for decades.