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Efficacy of albumin in critically ill patients

Large trial in Australia and New Zealand may provide an answer

In 1998, the BMJ published a meta-analysis that compared the effects of fluids containing albumin and crystalloids on death rates in critically ill patients. The analysis included 24 studies involving 1419 patients. The report concluded that there was no evidence that albumin reduced mortality and a strong implication that it might increase the risk of death. The authors recommended that use of albumin in critically ill patients be reviewed urgently and that albumin should not be used outside the context of rigorously conducted randomised controlled trials. Despite the fact that the reviewers themselves advised that their results must be interpreted with caution, an accompanying editorial called for a total halt to the use of albumin preparations, such as plasma protein fraction, that are no longer in clinical use in developed countries, placed no restriction on the clinical indication for the use of albumin, and did not limit its analysis to studies in critically ill patients with albumin. Additionally, the results of subsequently published meta-analyses have done little to reduce this uncertainty.

A recent meta-analysis published in the Annals of Internal Medicine used different selection criteria to those used by the Cochrane Group. This meta-analysis included only studies using purified albumin (the Cochrane review included older studies using less pure preparations, such as plasma protein fraction, that are no longer in clinical use in developed countries), placed no restriction on the clinical indication for the use of albumin, and did not limit its analysis to studies in critically ill patients. In addition, the authors planned a priori to investigate the relation between the methodological quality of the trials and the reported outcomes.

The resulting meta-analysis included 55 trials involving 3504 patients—more than twice the numbers included in the original Cochrane review. Overall, this analysis detected no difference in mortality between patients treated with albumin and patients treated with other fluids. However, in the subgroups of trials that were judged to be of higher quality or of larger sample size (n > 100), the estimates of treatment effect and the lower confidence limits were consistent with the use of albumin being beneficial, although the upper confidence limits remained consistent with a moderate adverse effect. The Annals of Internal Medicine published an accompanying summary for patients, which concluded that it is not known whether albumin improves or worsens survival of critically ill patients.

The Cochrane Injuries Group Albumin Reviewers have recently published an update of the original meta-analysis. As the update reported only one additional study and 100 additional patients it is not surprising that it reached the same conclusion as the first analysis. Thus, subsequent meta-analyses of completed trials have not resolved the clinical uncertainty. The only issue on which everyone seems agreed is that one or more large, high quality, randomised controlled trials of albumin in critically ill patients are needed.

In Australia, human albumin is produced by the fractionation of blood from volunteer blood donors. It is supplied free of charge to hospitals through the Australian Red Cross Blood Service. This contrasts with other countries, where hospitals pay for the albumin they use and where albumin is generally viewed as an expensive product. Possibly because of these local circumstances, albumin is widely used as a resuscitation fluid in Australia’s intensive care units, and the issue of albumin’s safety and efficacy is of particular public health importance.

The Australian and New Zealand Intensive Care Society, the Institute for International Health of the University of Sydney, and the Australian Red Cross Blood Service, have initiated a large double blind randomised controlled trial of albumin versus saline for fluid resuscitation of critically ill patients in intensive care. The saline versus albumin fluid evaluation (SAFE) study plans to recruit 7000 adult patients from 16 intensive care units in Australia and New Zealand over an 18 month period. A detailed description of this ongoing study is published on bmj.com. By the sixth anniversary of the original Cochrane meta-analysis, we hope the uncertainty about the use of human albumin in critically ill patients will be resolved.

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Competing interests: All four authors are members of the management committee of the SAFE study, which is part funded by CSL Limited. CSL Limited fractionates blood and distributes human albumin and other blood products in Australia, New Zealand, and other countries.
Achieving health for children in public care

New Department of Health guidance emphasises a rounded approach

Every year in England and Wales over 80,000 children experience public care because their parents are unable to look after them, enough to fill the new stadium at Wembley on cup final day. Unlike football crowds their voices remain largely silent. A primary care trust serving a population of 200,000 will be responsible for the health of about 300 looked after children, equivalent to a medium sized primary school. The recent guidance from the Department of Health, Promoting the health of looked after children, for the first time explicitly charges chief executives of primary care trusts with improving the health of these most disadvantaged children.1

Efforts to address the poor health of looked after children are not new. Since 1948 children entering care have been subject to regular medical surveillance. Despite 50 years of medical checks the House of Commons Select Committee published a damning report in 1998, highlighting the appalling health outcomes for these children and the failings of a system that should have been protective.2 The government responded by injecting £885m ($1426m; €1359m) into the budgets of local authorities through the “Quality Protects” (England) and “Children First” (Wales) programmes. However, performance monitoring of local authorities has highlighted continued neglect of health in looked after children. In September 2001 only 71% were up to date with the national immunisation schedule, only 67% had had a recent dental check, and only 71% were up to date with the national immunisation schedule. Analysis is superficial and conclusions exaggerated. BMJ 1998;317:884-5.

The new guidance is welcome and emphasises a rounded approach to health, set firmly in the context of interagency working. Each primary care trust should appoint a designated doctor and nurse to ensure that robust mechanisms are in place to promote the health of children in public care. Statutory health checks are recommended that assess not only physical health but also a child’s mental, emotional, developmental health, and lifestyle—a far cry from the veterinary “freedom from infection medicals” of the past.

Children must be offered a health assessment with a suitably qualified doctor within four weeks of entering public care. Responsible commissioners will need to review carefully the qualifications and training of doctors undertaking this role. The specialist medical skills required must include knowledge of the lifelong sequelae of abuse, neglect, and loss; and an ability to work in an integrated way with local authorities. All children should have a healthcare plan that is reviewed annually (biannually for children under 5 years). The guidance signposts the potential for nurse led health review, now integrated into new 2002 statutory regulations of the Children Act 1989. The employment of over 90 specialist nurses in England and Wales has already shown the value of multiprofessional input to health promotion in children living in public care.3

Primary care trusts are now charged with explicit responsibilities for all looked after children resident in their boundaries. Children looked after by local social services will be relatively easy to identify. Those in the care of geographically distant local authorities, who may be placed with private agencies, may not be known to any local health professional. Robust notification and tracking systems are needed to ensure that these children are not lost to the system.

Assessment and healthcare planning for children cannot redress historical health neglect and high levels of mental health needs.4-7 Provision of services is crucial, and mental health needs in particular must be addressed. Healthcare plans must move with the child, and as the general practitioner’s record will be the lead health record for each child fast tracking mechanisms will become essential for this highly mobile population.

The views of young people themselves are well known but worth repeating: they want to be listened to and have their health concerns taken seriously. Trusts are exhorted to consult with children and young people to develop services appropriate to their needs. Confidentiality, information sharing, and consent are key issues, and local protocols will need to be devised to address these in line with statutory requirements and the common law.

All who advocate for children in public care will embrace the vision of the new guidance. The introduction of national health targets for looked after children in the NHS local delivery plans should encourage shared responsibility between primary care trusts and local authorities for children in public care. However, as social services are the lead agency for these targets, none of which is a health outcome, it is questionable whether immature primary care trusts overwhelmed by new responsibilities will prioritise children in public care. Hopefully the profile of children in “special circumstances” in the children’s national service framework will give further impetus to local work to support families, protect children, and, where children are unable to require public care, promote their health. The guidance provides a welcome direction to achieve

5 McClelland R. Albumin: don’t confuse us with the facts. Rather than