Introduction
Polygeline (Haemaccel, Aventis) is a plasma substitute listed in the WHO Model Formulary for the correction of low blood volume. The Model Formulary also lists Dextran 70 for a similar indication ie for short-term blood volume expansion. Both products are colloidal solutions that exert their activity by virtue of their physico-chemical properties; neither product possesses any intrinsic pharmacological activity.

Product and Dosage
Polygeline 3.5% is available as a 500ml solution for infusion, containing electrolytes. Dosage is initially 500-1000ml.

Evidence of Value
According to a Cochrane systematic review, last amended in September 2002, there is no evidence that one colloid solution is more effective or safer than any other. However, the confidence intervals are wide and do not exclude the possibility that there may be clinically significant differences between colloids. The relative risk was not estimable for the gelatin versus dextran groups (2 trials, n=42) as no deaths were reported. For albumin or plasma protein fraction versus gelatin, 4 trials (n=542) reported mortality; the relative risk (RR) was 0.99 (0.69, 1.42). For gelatin vs hydroxyethyl starches, 11 trials (n=945) reported mortality; the RR was 1.00 (0.78, 1.28). Since this review was undertaken there do not appear to be any further published evidence which contradicts this position (see database searches undertaken). Polygeline, with its smaller molecular weight, exerts a greater initial osmotic pressure as well as being more quickly cleared than dextran. Its resultant shorter half life allows blood or plasma to be given sooner, with reduced risk of fluid overload. Polygeline does not interfere with haemostatic mechanisms in vivo, nor with blood typing or cross-matching, even when given in large or repeated volumes. This gives it an advantage over dextran 70 which, when given in large volumes, can effect coagulation and make cross-matching inaccurate.

Price Comparisons
International data on supplier prices of polygeline suggest that polygeline solutions are usually slightly more expensive than dextran 70 solutions. In the UK the opposite appears to be the case. Either way, the price differences between polygeline and dextran 70 do not appear to be substantial.

A Quality Issue
Polygeline is a derivate of gelatin, which is obtained from bovine-derived bone products. According to manufacturer’s product information, Haemaccel is manufactured from gelatin derived from BSE-free bovine material sourced only from the USA. Furthermore, it has been concluded "that the polygeline manufacturing process is capable of inactivating BSE agents to a very high extent". However, a recent French trial of the use of polygeline, "had to be prematurely interrupted due to theoretical concern regarding safety of bovine-derived products."
Recommendation
There is no reliable clinical evidence that would support the de-listing of polygeline, rather than dextran 70, from the WHO Model List of Essential Medicines. Indeed polygeline has some advantages over dextran 70. Accordingly, and subject to WHO eliciting a guarantee of worldwide quality assurance for Haemaccel from its manufacturer (Aventis), it is recommended that polygeline should continue to be available in the Model List for its current indication.

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(October 2004)

References
2. Product information, Haemaccel (Polygeline), Aventis Pharma, Auckland, New Zealand (latest amendment 30.4.2002).

Search Strategy
Searches were carried out using Medline and PubMed databases. In view of the public interest surrounding the potential for BSE-contamination, a search was carried out using "non-medical" search engines (Yahoo, Google).

Search words: The main words/terms used were:
Polygeline
Polygeline AND dextran
Polygeline AND safety
Colloid plasma substitutes
Plasma substitutes

Publication types: In addition to all types, search limits were also set as follows:
Randomised controlled trials
Reviews
Meta-analysis
Practice guidelines

A search was also carried out of Journal Watch Emergency Medicine from 1997-June 2004. Search words were: fluid resuscitation, resuscitation, shock.
Additional papers consulted included:

- Colloid volume expanders: frequently used, but should they be? Drugs & Therapy Perspectives 13(4):13-16, 1999.