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PRESS RELEASE

NICE publishes guidance on the use of drotrecogin alfa (activated) for severe sepsis

The National Institute for Clinical Excellence (NICE or the 'Institute') has issued guidance to the NHS in England and Wales recommending the use of drotrecogin alfa (activated) to treat severe sepsis in adults that has resulted in multiple organ failure. The guidance also recommends that the drug should only be initiated and supervised by a specialist consultant with intensive care skills and experience in the care of patients with sepsis.

Sepsis results from an exaggerated response of the body to infection, most commonly arising through bacterial infection acquired in general medical and surgical wards. Sepsis is termed severe when it is associated with hypotension (abnormally low blood pressure) or hypoperfusion (inability of blood to pass through tissue – usually because of an abnormal clotting response). This in turn can interfere with normal blood circulation and damage organs such as the kidneys, heart and lungs. In many cases, more than one organ is affected ('multiple organ failure').

Severe sepsis imposes a significant burden on hospital resource use in England and Wales, with some 21,000 cases per annum accounting for an estimated 27 per cent of ICU admissions and 46 per cent of all ICU bed days. Despite advances in critical care, the mortality rate from severe sepsis is estimated to vary between 30 per cent and 50 per cent. Severe sepsis can also cause permanent damage to organs or

tissues, which may result in long-term poor health or disabilities. Current management of severe sepsis involves treatment of the underlying infection, primarily with antibiotics, and supportive treatment which may include fluids, vasopressors (drugs to stimulate the contraction of the blood vessels, so increasing blood pressure), ventilatory and renal support.

Drotrecogin alfa (activated) is a new treatment licensed for patients with severe sepsis with multiple organ failure. It is a genetically engineered form of human activated protein C, a protein molecule that is normally found in the body and has a role in helping to reduce blood clotting and inflammation, which can be caused by severe sepsis. Patients with sepsis have low levels of protein C and a reduced ability to produce activated protein C.

Andrea Sutcliffe, Planning and Resources Director and executive lead for this appraisal said: “Currently, as many as half of the patients who develop severe sepsis die. Today’s guidance represents a major step forward for the treatment of patients with severe sepsis that has resulted in multiple organ failure.”

Ends

Notes to Editors

About NICE guidance on drotrecogin alfa (activated) for severe sepsis

1. A quick reference version of the guidance is available on the NICE website at www.nice.org.uk/TA084quickrefguide. The full guidance is also available on the NICE website at www.nice.org.uk/TA084guidance

About NICE

2. NICE is part of the NHS. It is the independent organisation responsible for providing national guidance on treatments and care for those using the NHS in England and Wales. Its guidance is for healthcare professionals and patients and their carers to help them make decisions about treatment and healthcare. For further information about NICE you can visit www.nice.org.uk.
3. NICE produces guidance in three areas of health:
 - the use of new and existing medicines and treatments within the NHS in England and Wales technology appraisals.
 - the appropriate treatment and care of patients with specific diseases and conditions within the NHS in England and Wales – clinical guidelines.
 - whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use – interventional procedures.
4. NICE also funds three enquiries that undertake research into the way patients are treated to identify ways of improving the quality of care (the investigations are known as confidential enquiries).

5. NICE guidance and recommendations are prepared by independent groups that include professionals working in the NHS and people who are familiar with the issues affecting patients and carers.