



Patient Safety Alert

Stage One: Warning

Risk of distress and death from inappropriate doses of naloxone in patients on long-term opioid/opiate treatment

Alert issue date: 20 November 2014

Alert reference number: NHS/PSA/W/2014/016

Alert stage: One - Warning

Further supporting information - issued February 2015

- Following distribution of the recent NHS England Patient Safety Alert, *Risk of distress and death from inappropriate doses of naloxone in patients on long-term opioid/opiate treatment NHS/PSA/W/2014/016*, there has been a period of helpful dialogue, which has stimulated the publication of this supporting information for the original alert. This document is intended to provide further assistance to those considering their local policies for naloxone use in the light of the risk of acute cardiac problems in chronic opioid users, including further clarification on the use of naloxone for suspected acute opiate/opioid overdose.
- The alert noted that incidents involving life-threatening or fatal acute withdrawal syndrome from unnecessary or excessive doses of naloxone in patients on long-term opioid/opiate treatment were probably under-recognised and under-reported; information received since the alert was issued suggests the number of fatal cases that have occurred in the past maybe higher.
- A number of naloxone practice resources of interest have been collated, and can now be viewed on the Patient Safety First website: <http://www.patientsafetyfirst.nhs.uk/Content.aspx?path=/interventions/medicationsafety/>
- Further clarification has been requested by a number of correspondents on the recommended dosing regimens to be used for a patient following a suspected acute opiate/opioid overdose (as distinct from the advice for management of reduced consciousness and/or respiratory depression in chronic opiate/opioid users including some palliative care patients). We consider this a fair request and accept that the answer is not straightforward for clinicians. For example, there is no clearly definitive naloxone starting dose recommended for each possible route of use; and there are some differences in dosing advice from different sources (such as that provided in the BNF, in the manufacturers' individual Summary of Product Characteristics (SPC) documents, from ToxBase and in the Palliative Care Formulary) It is important to emphasise, however, that low starting doses are recommended in all of these clinical scenarios.
- UK Medicines Information (UKMI) has agreed to undertake the production of a Q&A document titled "*What naloxone doses should be used in adults?*" This will consider the relevant literature base and will consult with, amongst others, the College of Emergency Medicine, the National Poisons Information Service, the Department of Health Drugs and Alcohol Team, the College of Mental Health Pharmacy, the Association of Palliative Medicine, UK Ambulance Services and the expert group currently developing the update to *Drug misuse and dependence – UK guidelines on clinical management*. The UKMI document is expected to be published before April 2015.

- NHS England, in discussion with the Department of Health's Dugs Policy Team, has taken expert advice in providing the following clarification:
 - In considering the appropriate dosing schedule for emergency use of naloxone in suspected life threatening opioid/opiate overdose in adults, practitioners are expected to take account of authoritative sources of guidance such as the 'poisoning' section of the BNF.
 - The BNF currently recommends starting with a small dose of naloxone, such as 400mcg; and adding further doses, either if there is inadequate response to the previous one or if a further such increment is needed to maintain the beneficial effect achieved.
 - This advice for suspected life threatening overdose applies whether the case is known previously to be in receipt of long-term opiates/opioids or not.
- The approach of NHS England, and its use of Patient Safety Alerts, is intended to support clinical practitioners in exerting their own expert clinical judgement, and not to replace this. Given the very serious nature of the risks involved, practitioners will want to reflect on the recent naloxone Patient Safety Alert and this supporting information, and any relevant evidence or authoritative guidance; in case there are any changes they consider are needed in their local policies or in related local training content concerning these risks.