EXAMPLE PROTOCOL FOR ADMINISTRATION OF THE 'NARCAN CHALLENGE'

CLINICAL CONDITION TO WHICH THE PROTOCOL APPLIES

(i) Naltrexone as described in this protocol is for use as adjunctive prophylactic therapy in the prevention of relapse to opioid drug misuse following planned community opiate detoxification with lofexidine.

(ii) The inclusion criteria are as for the community lofexidine detoxification protocol. In addition the patient will be required to give informed consent for the prescription of naltrexone, following a pre-detoxification clinical assessment of suitability. This assessment will be accompanied by agreed documentation.

(iii) Exclusion criteria for treatment under the protocol are:

A: Naltrexone Specific Exclusion Criteria.

- A history of sensitivity to naltrexone.
- Concurrent acute hepatitis or liver failure.
- Concurrent elevation of AST or other transaminases by greater than two-fold above the upper limit of the normal range.
- Concurrent pregnancy or breast feeding.
- Concomitant use of illicit opiates during detoxification.
- Detoxification with methadone or other opioid medication.
- The commencement of naltrexone in the community must always be preceeded by administration of a naloxone challenge.

B: General Exclusion Criteria for Community Detoxification.

- As for community lofexidine protocol.

(iv) The CDAT consultant should be contacted to advise on an appropriate relapse prevention measures if any of these exclusion criteria are present.

(v) Patients will be assessed by the Community Drug and Alcohol Team before admission. Patients not wishing to receive naltrexone will not be excluded from planned detoxification.

CHARACTERISTICS OF STAFF AUTHORISED TO TAKE REPONSIBILITY FOR THE SUPPLY OR ADMINISTRATION OF MEDICINES UNDER THE PROTOCOL

(i) A qualified medical doctor will be required to prescribe naltrexone as described in this protocol.

(ii) A qualified nurse will be required to administer naloxone and naltrexone as described in this protocol. The nurse must be qualified to administer medication and basic measures in the case of an anaphylactic reaction.

(iii) The patient's general practitioner will be responsible for continuing naltrexone prescription following completion of detoxification.

DESCRIPTION OF TREATMENT AVAILABLE UNDER THE PROTOCOL

Names of all medicines to be administered under the protocol: Naltrexone hydrochloride & Naloxone hydrochloride, both PoM.

PRESCRIBING REGIMES

STAGE A: NALOXONE CHALLENGE

All patients for whom commencement of naltrexone is planned in the community should receive a naloxone challenge immediately before commencement of naltrexone.

a. Day of naloxone challenge.

For patients detoxifying from heroin only, naloxone challenge may be administered on day 4 (Thursday) if the following conditions are met:

- **The patient was not using any other opiate drug in combination with heroin, in the period leading up to commencement of detoxification.**
- **On-site urine screens have been negative for opiates and methadone on all of days 1 to 4 (Monday to Thursday week 1) of the detoxification period.**

For all other patients naloxone challenge should be administered on day 8 (Monday of week 2) if the following condition is met:

- **On-site urine screens have been consistently negative since and including day 3 (Wednesday of week 1) of the detoxification.**

If the above conditions are not met for administration of naloxone challenge, the case should be discussed with the CDAT consultant.

b. Site.

- **The naloxone challenge should occur at the patient's GP Surgery, by previous arrangement with the GP, or at the CDAT base. The patient's care coordinator should arrange this in advance of the detoxification occurring.**
- **Easy access to emergency resuscitation equipment must be ensured before giving the naloxone challenge.**

c. Administration.

- **The challenge will be administered by the detoxification nurse.**

d. Procedure.

- **Complete Short Opiate Withdrawal Scale.**
- **Give 0.4mg naloxone hydrochloride IM.**
- **Complete Short Opiate Withdrawal Scale at 15 minutes.**
- **Observe for a further 15 minutes.**

IF ANY INCREASE IN WITHDRAWAL HAS BEEN OBSERVED OVER THIS PERIOD, DO NOT PROCEED FURTHER.
Discuss the case with the CDAT consultant.

- **At 30 minutes give a further 0.4mg naloxone hydrochloride IM only if there has been no significant increase in withdrawal symptoms.**
- **Complete the Short Opiate Withdrawal Scale at 45 minutes.**
- **Observe for a further 15 minutes.**

IF ANY INCREASE IN WITHDRAWAL HAS BEEN OBSERVED OVER THIS PERIOD, DO NOT PROCEED FURTHER. Discuss the case with the CDAT consultant.

If there was no significant reaction to the administration of naltrexone over the first one hour, then progress to B.

STAGE B: NALTREXONE ADMINISTRATION

- **Administer naltrexone 25mg (half a tablet) orally once immediately following successful completion of the naloxone challenge.**

- **Naltrexone 50mg orally once daily from day 2 onwards.**

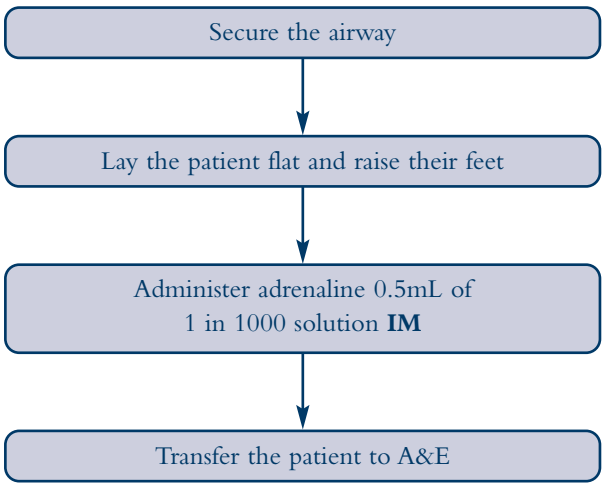
Withdrawal symptoms should be monitored by use of the 'Short Opiate Withdrawal Scale'. Lofexidine may be administered on an 'as required' basis as stated within the lofexidine protocol, for opiate withdrawal symptoms associated with naltrexone administration.

MANAGING ADVERSE OUTCOMES

Anaphylaxis occurring in response to IM naloxone administration.

This should be treated as for any other anaphylactic reaction. Resuscitation equipment and emergency medication must be available at the GP surgery in which naloxone induction will take place. Immediate medical advice should be sought from a GP on-site at the surgery.

Anaphylaxis is characterised by the rapid onset of hypotension, tachycardia, and collapse. There may also be bronchospasm and laryngeal oedema.



- **Chlorpheniramine 10-20mg IV, given slowly over 1 minute, can be a useful adjunct, but should only be given after adrenaline has already been given.**

INCREASING LOFEXIDINE DOSAGE DUE TO PRECIPITATION OF OPIATE WITHDRAWAL SYMPTOMS

1. 'As required' lofexidine should be administered by titrating against the short opiate withdrawal scale as described in the lofexidine protocol.

2. The CDAT consultant should be informed in all cases of markedly increased opiate withdrawal following naltrexone administration. In rare cases where delirium or vomiting supervene, the patient should be transferred to A&E.

MANAGING ABNORMAL LIVER FUNCTION

1. Naltrexone should not be commenced if the AST is greater than approximately two times normal (reference range 0-35units/l).

2. All patients receiving naltrexone should have baseline liver function studies and then repeat tests once a month for the first 4 to 6 months. Patients with baseline liver abnormalities should be tested every 2 weeks for up to 6 weeks before going on to a once a month frequency.

3. Naltrexone should be discontinued if the AST rises to greater than 3 times normal unless some other cause is found (eg alcohol misuse).

Depression.

4. Naltrexone may possibly induce a depressive disorder in some patients after days or weeks of use – the continued prescription of naltrexone should be reviewed in such cases.