Updates on take-home naloxone in France

Anne-Claire BRISACIER
OFDT

French Monitoring Center for Drugs and Drug addiction

EMCDDA DRD national expert Meeting
Lisbon 18-20 September 2017
Background

• 1977
  MA Narcan® in France
  Naloxone ampoule 0.4 mg/1 ml, injectable solution
  Only available in hospital pharmacies
  Used in emergency medicine

• 2014
  WHO Recommendations on community management of opioid overdose
  Meeting EMCDDA: take-home naloxone to reduce fatalities
French legal framework (1)

• February 2015

The consultative commission on narcotics and psychotropic substances (French national Agency for medicines and health products safety, ANSM) voted in favour of the nasal route of administration for naloxone by drug users.

• October 2015

Naloxone for nasal use has been exempted from list I of poisonous substance (decree)

➤ Naloxone dispensing does not require a medical prescription
➤ however, naloxone will still be a medication only available in pharmacies
French legal framework (2)

- **November 2015**
  
  Nalscue® (Indivior company) = naloxone for nasal use
  
  Cohort Temporary authorization for use (cTAU)

- **July 2016**
  
  Nalscue® available through cTAU

- **May 2017**
  
  Decree setting out the list of medicinal products which may be dispensed in harm reduction facilities (CAARUD)
  
  ✔ Naloxone is in the list
Cohort temporary authorisation for use
naloxone for nasal use

Temporary Authorisation for Use

- exceptional measure making available medicinal products that have not yet been granted a Marketing Authorisation (MA)
- to provide early access to new promising treatments when a genuine public health need exists
## Cohort TAU: Roles of the various parties

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physician</strong></td>
<td>Must comply with the protocol for therapeutic use: inclusion criteria, conditions for monitoring and informing patients; data collection; pharmacovigilance procedures.</td>
</tr>
<tr>
<td><strong>Company</strong></td>
<td>Labelling. Package leaflet. Distribution only to an internal pharmacy or authorised structure. Compliance with protocol for therapeutic use. Monitoring of users’ compliance with the protocol. Collection of information passed on by prescribing physicians, particularly adverse reactions. Periodic reports to the ANSM on all the data collected in the cTAU. Summary of reports to be sent to users, following validation by the ANSM. Submission to the ANSM, for its opinion, of any information relative to the medicinal product, before its circulation.</td>
</tr>
<tr>
<td><strong>Hospital pharmacist</strong></td>
<td>Studies and complies with the protocol for therapeutic use. He/she ensures that he/she holds information relative to the implementation of treatment of patients included in his/her hospital. He/she orders, takes receipt of and dispenses the medicinal product and manages stocks in accordance with good practices.</td>
</tr>
</tbody>
</table>
Target population
cTAU-naloxone for nasal use Nalscue®

Any individual at risk of opiate overdose

✓ identified during
  • a presentation in treatment center for addiction
  • an hospital emergency presentation following an opiate OD
  • an hospitalisation

✓ Hospitalised patients for an opiate withdrawal
✓ Identified among newly released inmates
Inclusion settings
cTAU - naloxone for nasal use Nalscue®

✓ Only physicians practicing:
  • in specialised treatment and prevention centres for addiction (CSAPA)
  • in hospital addiction medicine departments
  • in emergency departments
  • in any other departments in which an addiction liaison and treatment team operates (ELSA)
  • in prison treatment units
may include patients in the cohort TAU

✓ These physicians must be trained by the company
✓ Theses doctors have to train the patient and his relatives to recognize the signs of an opiate overdose and to use Nalscue®
✓ The doctor fills a tracking sheet every 6 months for each of his patients and transmits it to the pharmaceutical company
Supply

cTAU - naloxone for nasal use Nalscue®

Supply is exclusively restricted to pharmacists in charge of dispensing

• within hospital pharmacies
• within treatment centers for addiction (CSAPAs)
Presentation, dosage and route of administration

1 sprayer = 1/2 dose = 1 nostril = 0.9 mg

Nalscue is a kit of 4 sprayers for single use with 0.9 mg of naloxone each
First dose = 2 sprays (one per nostril) = 1.8 mg naloxone
Number of patients included
Number of kits distributed

Regular synthesis reports from the Indivior company to the ANSM
Results after 11 months of inclusion in cTAU

Regular synthesis reports from the Indivior company to the ANSM

As of 25 June 2017

• 287 physicians are registered with the cohort TAU scheme
• 141 of whom had included at least 1 patient
• 260 dispensing pharmacists or physicians are registered
• 949 patients have been included
• 644 Nalscue® kits have been distributed (free until 9 000 kits)

✓ 4 patients + 7 third parties treated with Nalscue®
  ➢ favourable outcome for 10 patients
  ➢ 1 patient self-administered Nalscue® without showing signs of overdose and developed effects related to opioid withdrawal
New developments: MA naloxone for nasal use

- 28/07/2017

Market authorization

Nalscure® 0.9mg / 0.1ml (Indivior company)
Next steps

➢ Following Nalscue® MA:

- conformity of the package leaflet and labelling
- wider dispensation including harm reduction facilities (CAARUD) by the end of the year
- modality of marketing (availability in retail pharmacies), price, reimbursement rate by national health insurance ???

➢ Marketing of other forthcoming devices

- Prenoxad® (Ethypharm company)
- Naloxone by intramuscular route
- other kits of naloxone for nasal use more dosed
Conclusion

- Opportunity for France to be involved in the dynamics in favor of take-home naloxone carried out EMCDDA and WHO
- Benefits of foreign experiences
- Support from the Ministry of Health needed to improve the legislative framework for allow a wide access of take-home naloxone at the national level
- Support from the French national Agency for medicines and health products safety (ANSM)
Sources

AFFSAPS (2001) Temporary Authorisations for Use (ATU), Agence française de sécurité sanitaire des produits de santé, Saint-Denis.

http://bit.ly/1OJJwoO

ANSM (2017) NALSCUE 0,9 mg/0,1ml solution pour pulvérisation nasale en récipient unidose.
http://bit.ly/2yv0ftw


Arrêté du 5 mai 2017 fixant la liste des médicaments pouvant être dispensés dans les centres d'accueil et d'accompagnement à la réduction des risques et des dommages pour usagers de drogues. NOR: AFSP1713296A.

Remus A., et al. (2017) Naloxone, pour qui, comment et quelle forme utiliser ?
Thank you for your attention