Understanding Steps and Challenges to Take-home Naloxone and Buprenorphine/naloxone Implementation in Québec Emergency Rooms: Suboxed Project

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Study protocol

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Abstract

Background

Deaths attributable to drug abuse are on the rise across Canada. It is estimated that there were more than 13,900 opioid-related deaths from January 2016 to June 2019 in the country. Emergency departments (EDs) are often on the frontline of care provided to people at risk of opioid overdose within Québec's healthcare system. A variety of programs to implement take-home naloxone distribution and/or the provision of opioid agonist treatment for ED patients who are at risk for overdose have been created in the United States and in Europe. However, few EDs in Canada have developed protocols for the provision of take-home naloxone and/or opioid agonist treatment by ED doctors.

Methods

A clinical algorithm for take home naloxone (THN) and prescription of buprenorphine/naloxone (B/N) was implemented in three EDs of Québec, Canada. This first phase of the SuboxED project required selecting clinical experts, describing the patient population, and creating partnerships with pharmacists and opioid agonist treatment clinics.

Results:

The clinical experts developed tools based on literature reviews and national and international guidelines. They also created educational tools and trained over 328 ED clinical staff. In addition, SuboxED ensured that a supply of take-home naloxone and B/n was available in the three ED sites for the study.

Conclusion

Implementing the proposed clinical algorithm for THN and prescription of B/N was challenging: drug supply and ED staff's buy-in were among the most notable difficulties of SuboxED. Planning training sessions at three different institutions, each with its own governance structure and clinical culture, local realities and harm reduction priorities was complicated. Engaging already overworked ED teams consistently working in a gridlocked environments, revealed in itself to be a difficult endeavour.

In the next phase of SuboxED, we will focus on data collection and analysis to evaluate both the implementation of the protocol through a retrospective review of electronic health records and satisfaction surveys of patients and healthcare professionals.

Trial registration: none

Contribution to the literature

In the midst of the opioid overdose crisis, initiating a clinical algorithm for take-home naloxone and prescription of B/n in three operationally different Canadian emergency departments was feasible.

Implementing a clinical algorithm for take-home naloxone and prescription of B/n is challenging; significant barriers involve drug supply, ED staff buy-in, training, engaging already overworked ED team.

Background

Deaths attributable to drug abuse are on the rise across Canada (1). It is estimated that there were more than 13,900 opioid-related death from January 2016 to June 2019 in Canada, of which 202 occurred in the province of Québec (2). Emergency departments (ED) are often the first point of care for people at risk of opioid overdoses, who are among the most disenfranchised patients. Wiener et al. (2019) conducted a one-year retrospective observational study on a total of 17,241 patients discharged from ED after a nonfatal opioid overdose between 2011 and 2015. Their data indicate that the mortality rate is more than 5% for patients treated for nonfatal opioid overdose in ED (3). Leece et al. (2020) measured predictor of mortality in the same population post-ED visit in a Canadian context for a total of 6,140 patients. The authors reported that 1.9% died of opioid overdose within one year (4). Hence, an ED visit for a nonfatal overdose could become an opportunity to prevent an eventual lethal overdose by offering adequate treatment.

According to the Canadian Research Initiative in Substance Misuse (CRISM) guidelines, opioid agonist therapy with Buprenorphine/naloxone (B/n) should be considered the standard of care for patients with opioid use disorders (5). In a 2017 randomized clinical trial, patients who were initiated on B/n during their ED visit were more engaged in the treatment: up to 78% of patients were still in addiction treatment at 30 days and indicated decreased opioid use (6, 7). D'Onofrio et al. (2015) found that the ED initiation of B/n was cost-effective for patients with opioid use disorders (6). Following this landmark study, emergency physicians across the United States (Oakland, California; Camden, New Jersey; Syracuse, New York) and in Canada (Alberta and Ontario) have initiated programs that use the ED proactively to address the opioid epidemic by initiating treatment with B/n as part of opioid agonist therapy for opioid use disorders (8–11). Other provinces in Canada, like Nova Scotia and British Columbia, have started a take-home naloxone programs from their EDs (12).

In response to the opioid crisis, and in the absence of a harmonized process for ED harm reduction, a clinical algorithm for dispensing take-home naloxone and prescribing B/n in EDs for at-risk patients was developed and implemented in three emergency departments in Québec, Canada. This effort was titled the SuboxED project; it required engaging with key Opioid agonist treatment (OAT) and medication-assisted treatment (MAT) harm reduction clinical experts, developing tools, training and internal information campaigning plans in collaboration with ED care stakeholders.

This manuscript describes the processes of SuboxED phase 1, challenges encountered in the clinical implementation of the algorithm, including the development of criteria to determine the eligibility of patients for naloxone kits and/or B/n and associated medical prescriptions, as well as the selection of participating EDs, retail pharmacies, and opioid agonist therapy clinics.

Method

This multi-site implementation science study is funded by Health Canada and the *Ministère de la santé et de services sociaux du Québec* (MSSS), Substance Use and Addiction Program (SUAP), grant (Projet 20 PUDS). SuboxED took place between December 3, 2017 to March 31, 2020 in the French-speaking province of Québec in three different Health center EDs. The sites were selected by invitation from the clinical experts based on manifested interest and capacity by clinical leaders from the three respective EDs. The three EDs are 1.The Centre hospitalier de l'Université de Montréal (CHUM), a university hospital in Montreal offering highly specialized services; 2. The Notre-Dame Hospital: a downtown community hospital in Montreal with clinical activities oriented towards inner-city medicine; and 3. The Hôtel-Dieu Hospital Centre intégré universitaire de santé et des services sociaux (CIUSSS) de l'Estrie-CHUS, located in downtown Sherbrooke, a mid-sized town in southern Québec.

SuboxED experts

A group of clinical experts including hospital pharmacists, emergency room physicians, drug addiction physicians and fellows, emergency room and drug addiction nurses, and administrators from the three EDs, were invited to contribute their expertise in emergency care and drug addiction medicine. Between March 2018 and April 2019, they met monthly to review the literature, develop the ED algorithms and educational plans, and establish relationships with three addiction clinics and eight retail pharmacies to facilitate naloxone distribution and B/n prescription and initiation. This group worked collaboratively with the three health centers to make sure the take-home naloxone was available in each ED.

Implementation process

Target population

The target population consisted of opioid users who met the naloxone prescription criteria developed by the SuboxED experts, which were in turn based on guidelines from the *Institut National d'Excellence en Santé et Services Sociaux (INESSS)*, the Centers for Disease Control and Prevention (CDC), and World Health Organization (WHO). The target population included individuals who have an opioid use disorder diagnosis according to the criteria set out in the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) (Fig. 2) (13–16).

Collaborations

Follow-up treatment for patients discharged from the ED with B/n prescription was to be provided either at the CHUM's addiction medicine outpatient clinic, the Notre-Dame Hospital addiction and urban medicine outpatient clinic, or the Hôtel-Dieu Hospital opioid agonist therapy outpatient clinic. B/n was to be supplied by participating retail pharmacies. Eight retail pharmacy were approach to collaborate in the

post ED phase of SuboxED by fast track B/n in pharmacy initiation, provide naloxone kits and B/n following reception of prescriptions.

Clinical Process readiness

Each site described their ED organization, population, and treatment program for opioid agonist treatment in each area.

In May 2017, the province of Québec established a take-home naloxone program as part of a national strategy to prevent opioid overdoses. Since then, naloxone has been available in retail pharmacies and community-based harm-reduction groups to persons who meet the *Institut national de santé publique de Québec* (INSPQ) criteria (17). Until October 25, 2019, the date when hospitals were added to the provincial government's free dispensing program, hospital administrations were absorbing the costs of providing take-home naloxone given at the ED. B/n medication provided at ED was covered by hospital budgets. Once in the community, the medication was covered by the patient's private or public insurance plan.

Results

Triage Tools

SuboxED clinical experts were able to suggest a triage tool for nurses and pharmacists, by setting clinical criteria for ED patients at risk of opioid overdose (Figure 1). The group added an item to the existing ED triage questionnaire to identify patients exposed to opioids. The ED triage is a process through which patients are registered upon arrival and ranked in order of treatment priority following a nurse's assessment. If a patient is flagged as at-risk, either by a computer-based triage system at CHUM or by manual triage at Hôtel-Dieu and Notre-Dame Hospital, the triage nurse stamped an "OPIOD" label on the patient's chart. This stamp alerted the ED physician to assess the patient for take-home naloxone or B/n eligibility using a clinical decision algorithm.

The ED pharmacist could in parallel recommend take-home naloxone and OAT initiation assessment with an ED physician for all patients at risk of overdose, including patients who were unconscious due to overdose or those that had received intravenous naloxone in the ED.

Training of ED staff

The SuboxED ED staff training plan consisted of the 3 training formats: 1. online modules, 2. in person clinical course; and 3. Clinical question and answer sessions.

Two 20-minute online training modules explaining the use of the Clinical Opioid Withdrawal Scale (COWS) and the provision of take-home naloxone were created by a group of key training leads including nurses and physician specialized in addiction medicine from the CHUM. These COWS modules were

developed specifically for ED staff and provided general information about naloxone, overdose risk factors, signs and symptoms of an opioid withdrawal or overdose. The training modules are available the online provincial learning management platform (https://fcp.rtss.qc.ca/ena-login/index.html). Pre and post training competency verification tests are integrated into the training plan with systematic personalized feedback to those who failed the post-test. In addition to these online modules, a 60-minute in-person course was offered at ED team meetings. At Notre-Dame Hospital, training leads offered a 30-minute in-person session on a regular basis during the SuboxED training window to answer questions and explain the new project to all ED staff.

ED head nurses prioritized completion of the two online modules in their annual curriculum training, within the SuboxED training window of November 2018 to March 2019. Human resources departments' facilitated training uptake by making training time paid time for ED staff. The results of the ED staff training are included in Table 1. When we excluded the attendees who did not complete the training, competency verification failures were mostly anecdotal post review.

Table 1
Emergency department staff training

CHUM (n min = 150)			
	Registered attendee (n)	Post-Test success (%)	Incomplete test n (%)
COWS training	269	78%	57 (21,18)
Naloxone training	189	67%,	60 (31,74)
HND (n min = 90)			
COWS training	48	79%	9 (18.75)
Naloxone training	45	82%	8 (17, 77)
CHUS (n min = 85)			
COWS training	17	71%	5 (29, 41)
Naloxone training	13	85%	2 (15, 38)
CHUM = Centre hospitalier de l'Université de Montréal			
COWS = Clinical Opioid Withdrawal Scale			
HND = Notre-Dame Hospital			
CHUS = Hôtel-Dieu Hospital CHUS			
N min: minimum number to be trained in each site			

Topics covered during the training included: epidemiology of opioid use disorders; DSM-V criteria for diagnosing opioid use disorders; indications for opioid agonist therapy, take-home naloxone, and ED-

initiated B/n; overdose recognition and prevention education; protocol for B/n initiation; and the adverse effects of B/n, including induced withdrawal (Fig. 2). The treatment algorithm and the clinical tools were presented to ED staff at team meetings, to increase the ED- staff awareness, implement new evidence-based practices and to promote skill retention and increase rapid incorporation of this algorithm into their practice.

Availability and complete engagement of head nurses, ED physicians, and pharmacists to support their teams, identify and solve operational problems, and to ensure practice adoption and sustainability, were imperative to the implementation phase.

Implementation

Take-home naloxone

Naloxone and B/n ED prescription templates, were reviewed and approved by each participating health centers' medical board. For take-home naloxone, after the patient was flagged for opioid exposure by the triage nurse or pharmacist, the emergency physician checked for eligibility of the screened patient (Fig. 2). Patients who received take-home naloxone in the ED were provided information to ensure that they understood why they were at risk and knew how to use the naloxone if they witnessed an overdose. Family members and significant others were invited to the information session if available.

The information given included how to recognize the signs of an opioid overdose, how to contact local emergency services, and how to stay and assist the person until help arrives, as highlighted in the information card from Health Canada (https://www.canada.ca/content/dam/hc-sc/documents/services/publications/healthy-living/opioid-overdose-wallet-cards-public-events/full-wallet-card-eng.pdf).

B/n Initiation

Triage was carried out in the same way as for naloxone but with differing criteria. Inclusion criteria for the prescription of B/n by an emergency physician were: meeting the criteria for opioid use disorder using the DSM-V (13), having a COWS score ≥ 12 (i.e. moderate to severe withdrawal) or no opioid use for ≥ 5 days, and having no contraindication. Multiple substance use disorders, pregnancy, and acute pain were the main exclusion criteria for B/n initiation; these exclusion criteria did not apply to take-home naloxone. Patients who had exclusion criteria were referred to the drug addiction expert of each hospital for evaluation and follow-up.

When a patient was confirmed eligible (no exclusion criteria, all inclusion criteria) and consented, the ED physician initiated 4 mg of sublingual B/n under nurse supervision. Patients were re-assessed 1–2 hours after the first dose for B/n-induced opioid withdrawal. In the event of withdrawal, the ED physician prescribed an additional opioid or contacted a physician with expertise in addiction medicine.

Additional doses of 4 mg B/n could be administered every 2 hours until the patient was free from withdrawal symptoms or until a dose of 12 mg was reached. If considered appropriate, these additional doses could be prescribed and retrieved at a retail pharmacy, thus reducing the patient's ED stay. If the patient had an opioid use disorder and a COWS score of < 12, and no contraindication to be released from the ED, a prescription for B/n would be faxed to the patient's preferred pharmacy among eight participating locations for an in-pharmacy outpatient induction.

Patients discharged from the ED received: an instruction card detailing the use of B/n; information on take-home naloxone, overdose, and opioid withdrawal management; the address of the selected pharmacy; and a follow-up appointment at an opioid agonist therapy clinic within 5–7 days.

The physician also indicated to the retail pharmacy the initial ED-administered dose and the final dose to be administered along with B/n dosage adjustments for withdrawal symptoms (to be further verified at the retail pharmacy). The maximum dose given during the first 24 hours was 12 mg. The clinical tools and ready-to-use printed prescriptions facilitated this task for ED physicians to ensure dosage safety.

An addiction medicine expert was always available to answer clinical questions from ED physicians and pharmacists and was ready to take charge of more complicated cases directly on site. Participating retail pharmacists sent a memo to the opioid agonist therapy clinic regarding follow-up for patients, in accordance with their professional code of ethics.

Discussion

SuboxED developed a mechanism for Hospital EDs to take part in opioid crisis management in the context of a universal and free healthcare system in Québec, Canada. Patients at risk for fatal overdose often seek ED services, whether or not they have an opioid use disorder. SuboxED provides a process to assist these patients.

Convincing ED teams of the importance of treating patient with opioid use disorder or at risk of overdose, was a challenge, requiring persuasion and perseverance, as well as mutually respectful relationships and ongoing dialogue among all parties involved.

High rates of staff turnover presented another significant challenge to screening procedures in a busy ED; so on-going training must be available. Prioritizing Naloxone and buprenorphine naloxone training could have resulted in displacing other training topics that might have a potential impact on other required trainings for the ED staff. We are not aware of any such impacts but this remains a potential contextual issue in implementing new projects.

ED physicians required screening tools that were clear, straightforward, and quick to use: pre-printed prescriptions also saved time. ED physicians preferred clinical protocols that allowed them to quickly stabilize the patient and reduce the patient's time in the ED. None the less, implementing a common protocol with common clinical research forms and SOPs across different institutions, each with its own

structure resulted in delays in the implementation of the study by roughly 3 months. Beyond the delay we do not feel that the overall outcomes were impacted.

Triage nurses found the screening questions for patients with overdose risk lengthy and overlapping with other important screening questions. To resolve this issue, the SuboxED clinical experts proposed a single question easily integrated into nurses' triage screening questionnaire.

Linkage to care after ED visits for opioid agonist therapy required close collaboration between opioid agonist therapy outpatient clinics and retail pharmacists. A protocol like SuboxED requires that opioid agonist therapy is readily available in the community and that the patient can receive treatment within one week at any given time, which is not the always possible throughout Québec. For SuboxED, addiction specialists were available 24/7 to answer any questions related to opioid agonist therapy, opioid use disorder, or overdose, but unfortunately these specialists are not necessarily available in every region of Québec. Additionally, the question remains as to whether participating EDs will be able to sustain the intervention without the support of the research team once the project is over.

As previously noted, availability and coverage of take-home naloxone for EDs was not established until October 25, 2019, which may have impacted conformity with the protocol.

Finally, should SuboxED be made available in all Québec EDs or only in those with a significant prevalence of opioid use in their region? Some clinicians might ask whether this algorithm is applicable in regions where the prevalence of opioid use is less than in major cities (18). According to the Canadian Institute for Health Information, the rate of opioid intoxication in smaller communities is more than double compared to the largest cities (18). We have to bear in mind that overdoses can also happen in patients who are prescribed opioids for pain management (19). The scale of implementation is to be considered.

Conclusion

For a clinical algorithm for dispensing take-home naloxone and prescribing B/n in EDs to be implemented successfully, it must provide simple protocols, uncomplicated screening questions at ED triage for people at risk for opioid overdose, targeted training for ED physicians and nurses, support from addiction specialists, and partnerships with retail pharmacists and opioid agonist therapy organizations in the community. These conditions may not exist in most areas of Québec, and expanding the SuboxED program across all EDs in Québec will require involvement from hospitals, retail pharmacies, and opioid agonist therapy outpatient clinics.

The next phase of SuboxED will be to measure the performance of the three EDs and their conformity with the protocol for take-home naloxone and B/n prescription. ED clinical professionals, managers, and patient satisfaction will be assessed through self-reporting surveys. A retrospective review of the ED electronic health records will be conducted. A future study could concentrate on following up with patients over a longer period of time.

Abbreviations

(CIUSSS): Centre intégré universitaire de santé et des services sociaux ;

(CRCHUM) : Centre de recherche du centre hospitalier de l'Université de Montréal ;

(ED) : Emergency department ;

(THN) : take home naloxone;

(B/N) : buprenorphine/naloxone ;

(CRISM) : Canadian Research Initiative in Substance Misuse;

(OAT) : Opioid agonist treatment;

(MAT): medication-assisted treatment ;

(MSSS) : Ministère de la santé et de services sociaux du Québec ;

(SUAP) : Substance Use and Addiction Program ;

(CHUM) : Centre hospitalier de Montréal;

(CDC) : Centers for Disease Control and Prevention ;

(WHO) : World Health Organization;

(DSM-V) : Diagnostic and Statistical Manual of Mental Disorders:

(INSPQ): Institut national de santé publique de Québec;

(COWS): Clinical Opioid Withdrawal Scale.

Declarations

Ethics approval and consent to participate

The study's implementation assessment protocol was approved by the CHUM Research ethics committee (MP-02-2019-7709-18.289) as the lead IRB. Authorization to conduct research at Notre Dame and Hotel were conferred by their respective IRBs. Naloxone and B/n ED prescription templates, educational material (information about B/n initiation) were reviewed and approved by each participating health centers' medical board.

Consent for publication

Not applicable

Availability of data and materiel

The data that support the findings of this study are available from the corresponding author but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of the corresponding author.

Completing interest

AT has a family member who works for a pharmaceutical firm (unrelated to the SuboxED project).

The authors declare that there are no conflicts of interest.

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The views expressed in this paper do not necessarily represent those of Health Canada and Québec Health Minister, the MSSS.

Authors' contribution

AT is the corresponding author of this manuscript. AT is the principal investigator and takes responsibility for the study as a whole. AS and RK are part of the research team coordinating the study conception in support of AT. All authors are collaborators contributed to the components of the study's design and protocol. AT drafted the initial manuscript. All authors provided feedback on the manuscript, edited and approved the final version of the manuscript submitted for publication.

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Authors' information

Not applicable

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Figures

Triage Question: Identification of at Risk of Overdose Patient

This questionnaire will be used by the ED nurse on a computer-based triage system at the CHUM, or on a paper sheet at the CHUS and HND. It will be used as a reference document to help the nurse with the triage process:

Is the patient at risk of opioid overdose?

Yes ☐

No ☐

In order to confirm the previous eligibility criteria, the triage nurse will have the following questions for reference:

1. *To the patient:* Do you use prescribed opioids (hydromorphone or Dilaudid, morphine or Statex, oxycodone or Supeudol, OxyNeo, codeine or Empracet, fentanyl, methadone, suboxone)?

   Yes ☐

   No ☐

2. *To the patient:* Do you use illicit opioids? (Purchase other than from a pharmacy, share a prescription from another person, from the street)

   Yes ☐

   No ☐

3. Did the patient come to the ED for an opioid overdose?

   Yes ☐

   No ☐

4. Does the patient have opioid withdrawal symptoms?

   Yes ☐

   No ☐

Figure 1

Triage question: patient identification

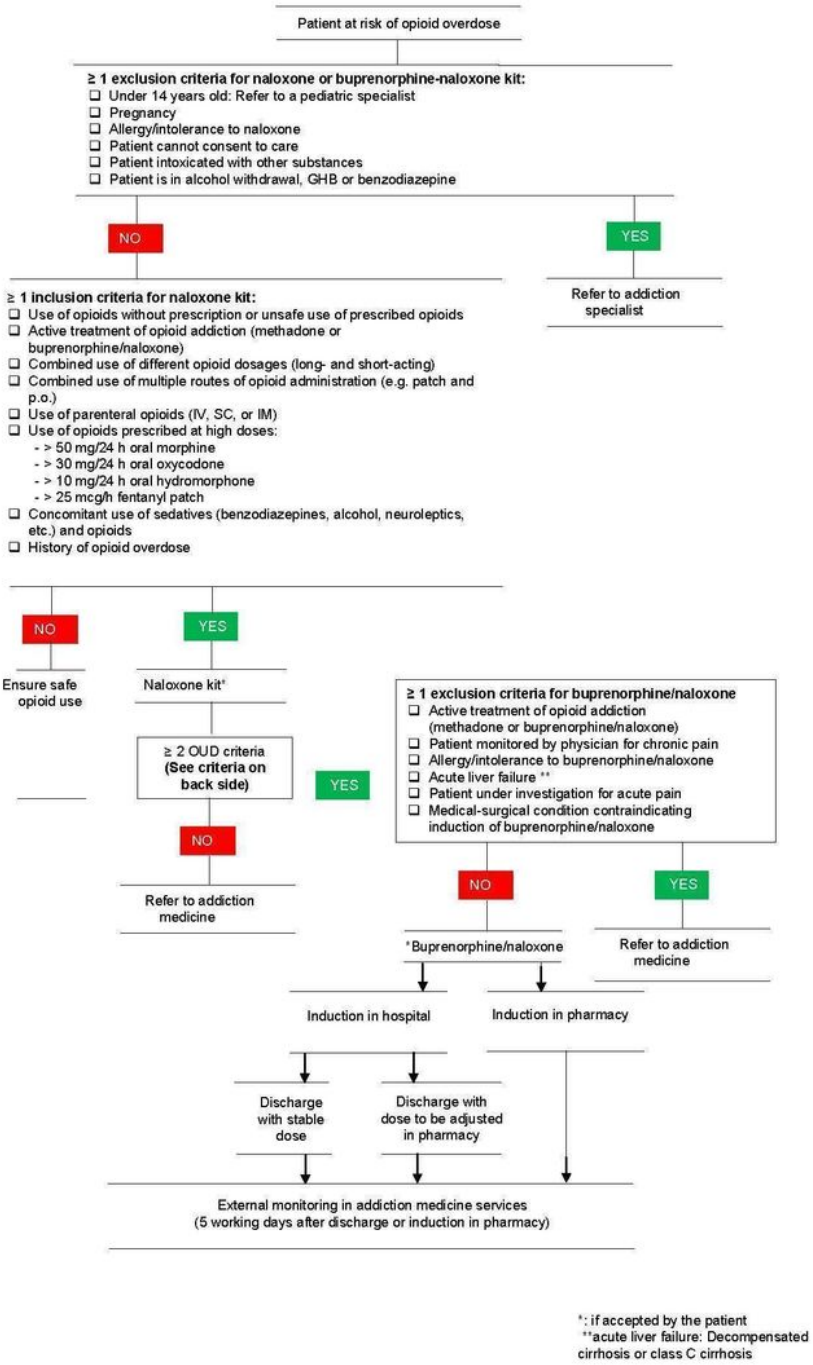

Figure 2

Prescription algorithm for emergency physician: naloxone and buprenorphine/naloxone initiation

Supplementary Files

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- supplement4.pdf
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