We are the Drug Policy Alliance.

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Injectable diacetylmorphine (i.e., pharmaceutical-grade heroin) under supervision for severe opioid use disorder

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Background

- Opioid dependence is a **chronic** relapsing disease.
- **First-line treatments** (e.g., oral methadone or buprenorphine) work, however not for everyone, or all the time.
- Evidence from Canada and Europe: medically prescribed **injectable diacetylmorphine** (and hydromorphone), is an effective, feasible and safe treatment approach.
- No single treatment is effective for all individuals, diverse treatment options are needed.

Background

- Six RCT have tested injectable diacetylmorphine (the active ingredient in heroin) as a second-line treatment for severe opioid use disorder.
- Injectable diacetylmorphine improved treatment outcomes: greater reduction in the use of street heroin, involvement in illegal activities, overall health and retention, compared with control groups (mostly oral methadone).
- The positive findings have not in general persuaded policy makers to roll-out the treatment more widely to bring into care those not doing well with first-line treatments (e.g., methadone, buprenorphine).

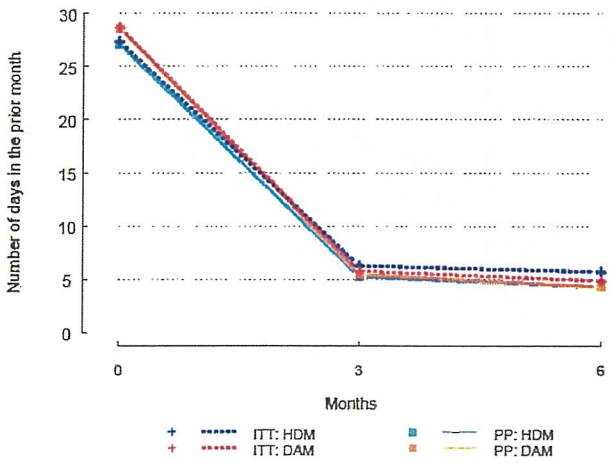
Supervised model of care

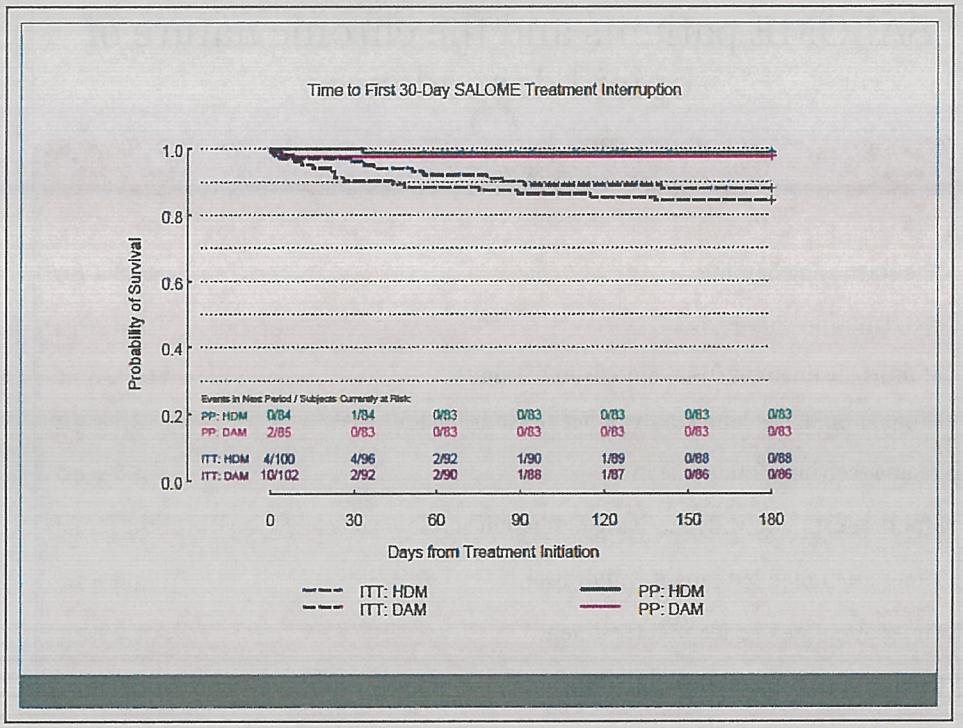
- Medication is dispensed and self-administered by injection under supervision.
- The supervision ensures safety of the patients (e.g., overdoses) and the community (e.g., secure the medication)
- For some, injectable diacetylmorphine seems to provide enough motivation to attend and comply with much needed structured treatment
- The supervised model of cares provides a tremendous opportunity to offer comprehensive care.

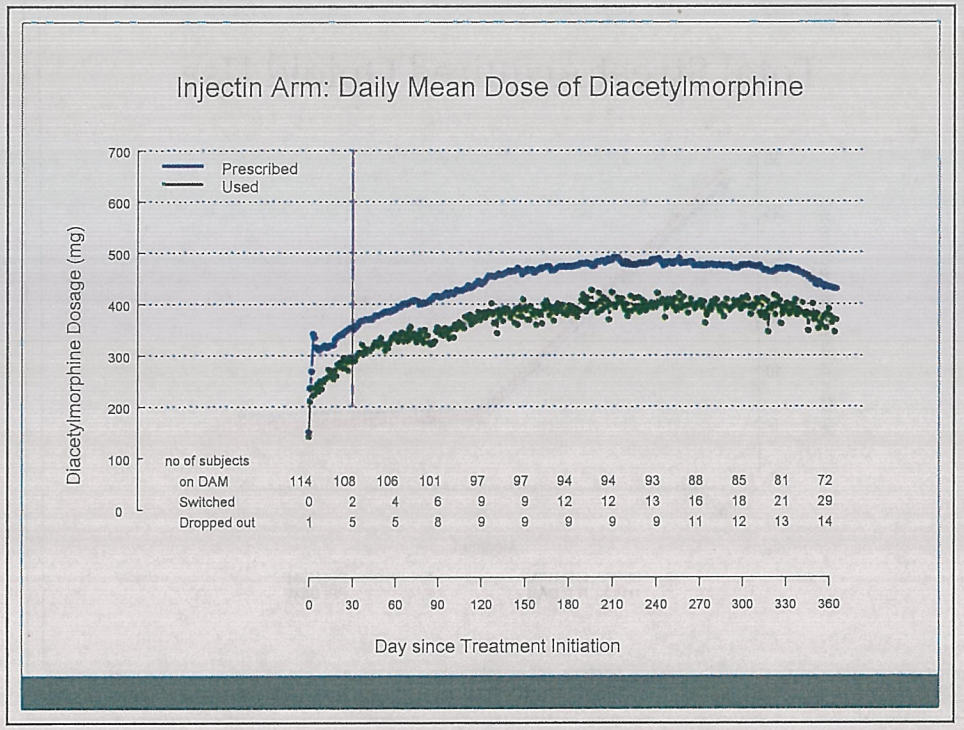
SALOME patients and the chronic nature of opioid dependence

Baseline Characteristics	Total n= 202 Mean ± SD/n (%)
Age	44.3 ± 9.6
Age start using heroin	24.8 ± 8.7
Years injecting heroin in life	15.4 ± 9.4
Months abstinent of street opioids in lifetime	21.9 ± 40.2
Number of Methadone Maintenance Episodes in life	5.1 ± 3.4
Years receiving Methadone in life	4.8 ± 4.7
Months abstinent while receiving Methadone or Suboxone	7.1 ± 19.4
Times attempted outpatient withdrawal	5.6 ± 7.6
Times attempted residential treatment	2.2 ± 3.5
Ever accessed outpatient counselling	127 (62.9)

Total Street Acquired Opioid Use




Time to First 30-Day SALOME Treatment Interruption
Probability of Survival
1.0
0.8
0.6
0.4
0.2
0.0
Events in Next Period / Subjects Currently at Risk:
PP: HDM 0/84 1/84 0/83 0/83 0/83 0/83 0/83
PP: DAM 2/85 0/83 0/83 0/83 0/83 0/83 0/83
ITT: HDM 4/100 4/96 2/92 1/90 1/89 0/88 0/88
ITT: DAM 10/102 2/92 2/90 1/88 1/87 0/86 0/86
0 30 60 90 120 150 180
Days from Treatment Initiation
ITT: HDM
ITT: DAM
PP: HDM
PP: DAM


Injectin Arm: Daily Mean Dose of Diacetylmorphine
Diacetylmorphine Dosage (mg)
700
600
500
400
300
200
100
0
Prescribed
Used
no of subjects
on DAM 114 108 106 101 97 97 94 94 93 88 85 81 72
Switched 0 2 4 6 9 9 12 12 13 16 18 21 29
Dropped out 1 5 5 8 9 9 9 9 9 11 12 13 14
0 30 60 90 120 150 180 210 240 270 300 330 360
Day since Treatment Initiation

Diacetylmorphine and methadone dose in RCTs (daily average)

RCT	Participants	DAM	Oral MMT	HDM
Geneva 1998	51	509 mg		
Netherlands 2003	174	549 mg	71 mg	
Spain 2006	62	274 mg	105 mg	
Germany 2007	1032	442 mg	99 mg	
NAOMI 2009	226	392 mg	96 mg	212 mg
UK 2010	127	399 mg	107 mg	
Belgium 2015	74	573 mg	77 mg	
SALOME 2016	202	506 mg	-	261 mg

NAOMI/SALOME adverse events

- 197,662 treatment injections
- Common expected side effects:
  - drowsiness
  - local histamine reaction (itchiness, pins and needles)
- SAEs:
  - 18 episodes of seizures (none with hydromorphone)
    - Occurred mostly on patients with previous history of seizures
  - 27 episodes of overdoses (SAEs)
    - Reversed with naloxone
    - no hospitalization

Conclusion

- A large body of evidence supports the implementation of injectable diacetylmorphine as a second-line treatment for the most vulnerable individuals with severe opioid use disorder.
- This treatment modality is meant to reach a important minority (no more than 10% of all those in treatment), in order to keep them safe and provide comprehensive care.