National Addiction Centre

Institute of Psychiatry at The Maudsley

KING'S College LONDON

Take-home emergency naloxone: Achievements and challenges

Professor John Strang

National Addiction Centre, King's College London, UK

KING'S HEALTH PARTNERS

Pioneering better health for all

Declaration (personal & institutional)

- DH, NTA, Home Office, NACD, EMCDDA, WHO, UNODC, NIDA.

- NHS provider (community & in-patient); also Phoenix House, Lifeline, Clouds House, KCA (Kent Council on Addictions).

- Dialogue and work with pharmaceutical companies re actual or potential development of new medicines for use in the addiction treatment field (incl re naloxone products), including (past 3 years) Martindale, Reckitt-Benckiser/Indivior, MundiPharma, Braeburn and trial product supply from iGen; & discussions with Lightlake, Rusan, Fidelity International, Titan.

- UKDPC (UK Drug Policy Commission), SSA (Society for the Study of Addiction); and two Masters degrees (taught MSc and IPAS) and an Addictions MOOC.

- Work also with several charities (and received support) including Action on Addiction, and also with J Paul Getty Charitable Trust (JPGT) and Pilgrim Trust.

- The university (King's College London) has registered intellectual property on a buccal naloxone formulation, and JS has been named in a patent registration by a Pharma company as inventor of a novel concentrated naloxone nasal spray.

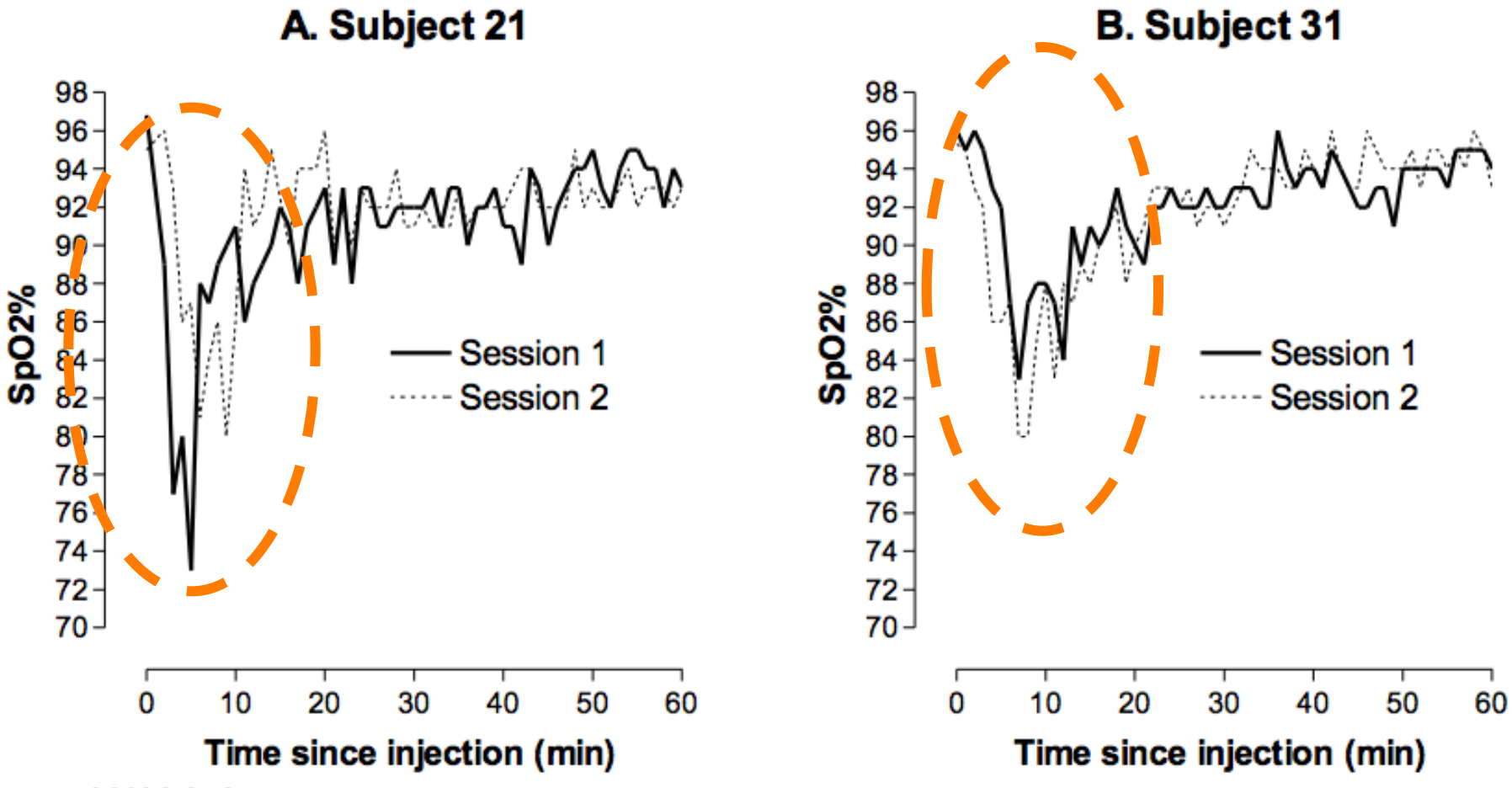
EMCDDA INSIGHTS

Preventing overdose deaths from heroin and other opioids: pre-provision of emergency naloxone (take-home naloxone)

Authorship
Professor John Strang*, Rebecca McDonald*, Dr Anna Williams, Basak Tas, Dr Kylie Reed, and Dr Ed Day
National Addiction Centre, Institute of Psychiatry, Psychology, & Neuroscience, King's College London, UK

* *joint first authors*

Oxygen saturation: case study



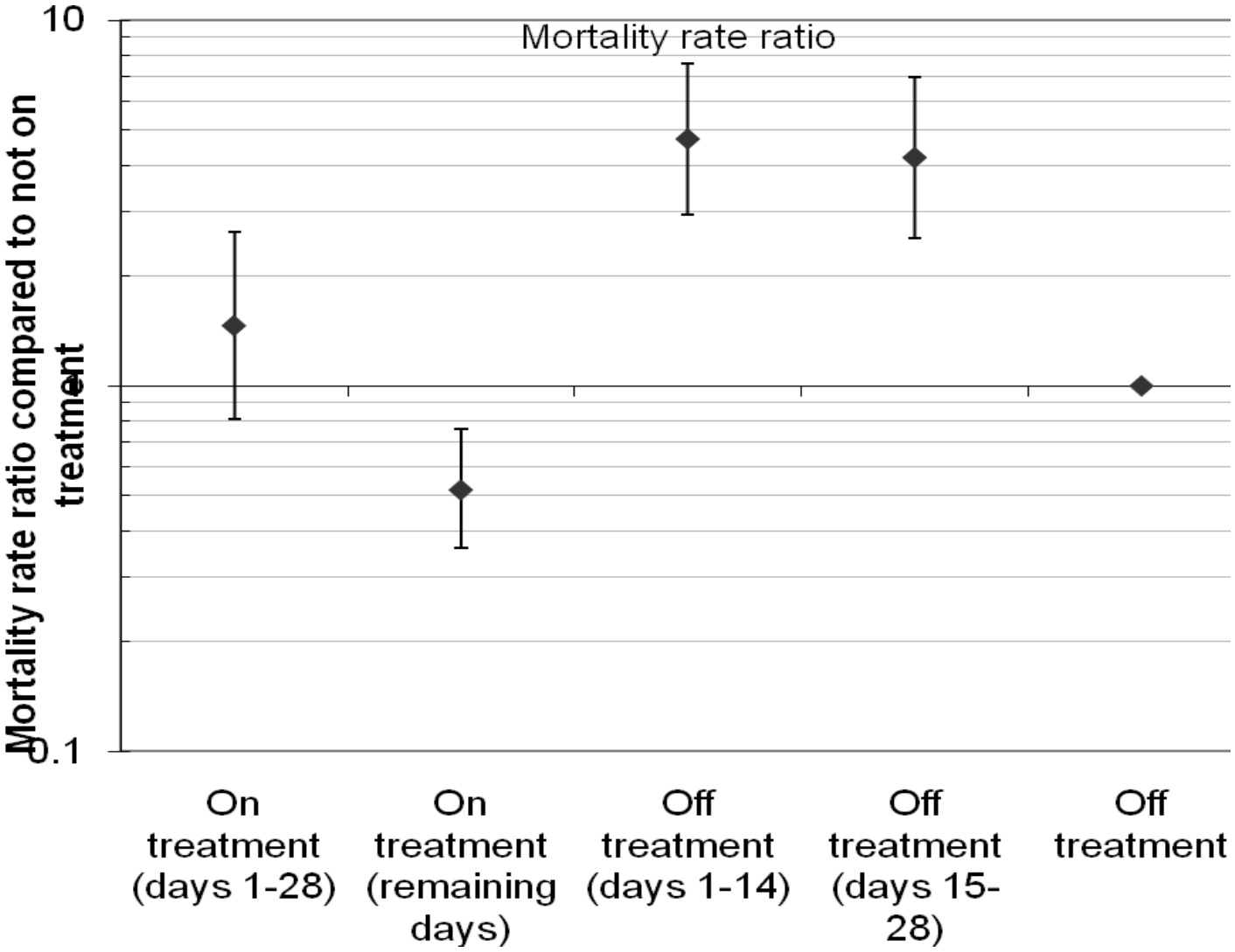
Subject 21 (41 year old male) injected 180mg heroin intravenously on both occasions.

Subject 31 (42 year old female) injected 150mg intramuscular heroin in session 1 and 160mg heroin in session 2. (unpublished)

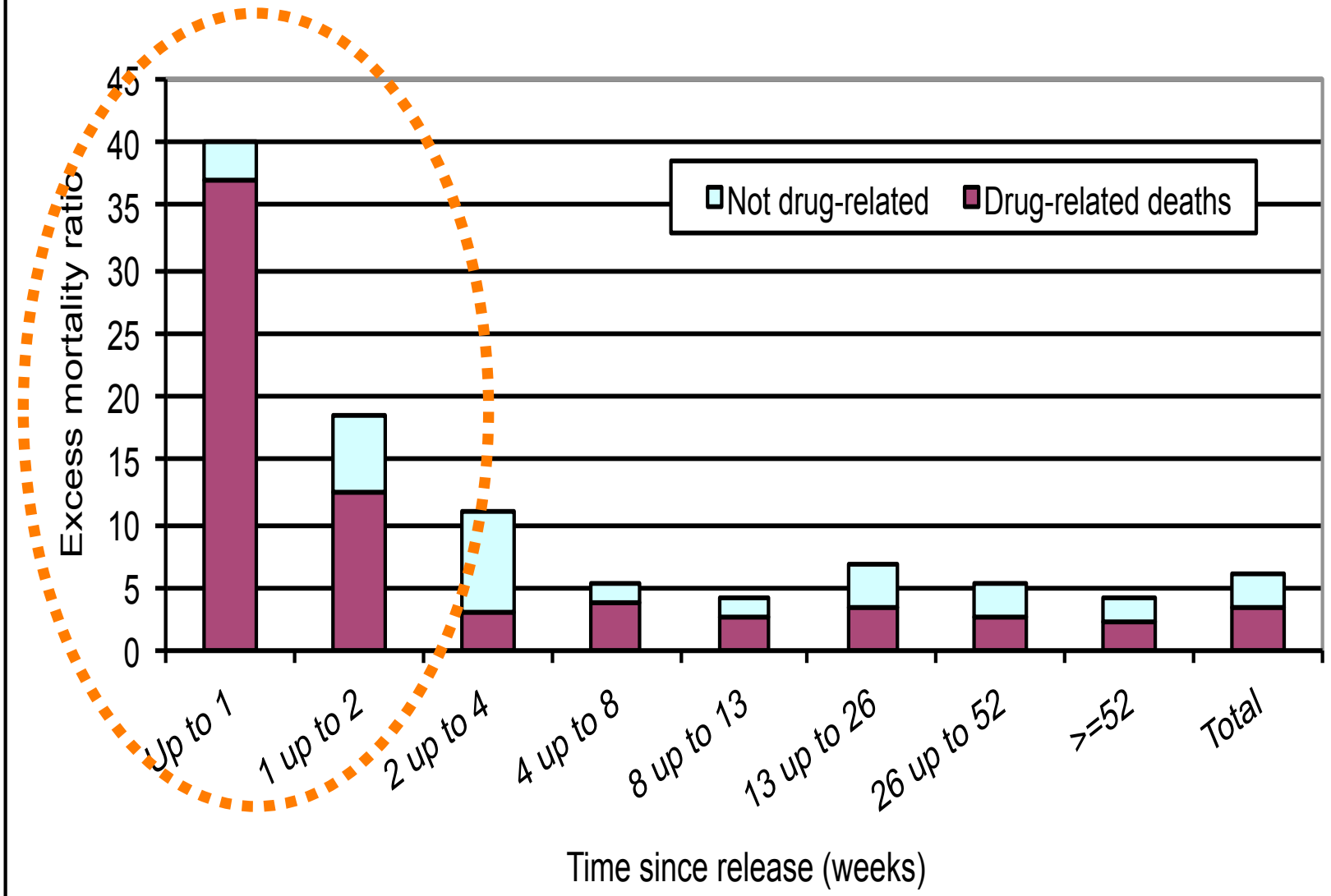
When in particular excess?

- During methadone early treatment
- Prison release
- Post-detox/rehab

Risk of death during and after treatment



Cornish et al, *BMJ* 2010; 341: c5475



Singleton et al, 2002

Achievements

- **Acceptability and feasibility of mobilising (a) peer group, (b) family members, (c) other personnel such as hostel staff and police**
- **Successful training of peers, family, staff**
- Local and national schemes for pre-supply of naloxone – being done, and appear successful
- UN and WHO recognition and guidance

"Pilot sites trained the carers and relations of opiate misusers to respond to overdoses and use the antidote naloxone. This appears to have helped save lives..."

THE NTA OVERDOSE AND NALOXONE TRAINING PROGRAMME FOR FAMILIES AND CARERS

NHS
National Treatment Agency for Substance Misuse

Achievements

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Naloxone kits issued across Scotland

31/07/2012

The Scottish Government today welcomed figures that show naloxone is being distributed the length and breadth of Scotland and is being made available to those at risk of opiate overdose.

Scotland was the first country in the world to announce a national naloxone programme, in November 2010. The programme is centrally coordinated and funded by the Scottish Government, empowering individuals, families, friends and communities to reverse an opiate overdose. Naloxone provides more time for an ambulance to arrive and further treatment to be given to those in opiate overdose situations.

Figures published today show that 3,445 naloxone kits were issued in Scotland in 2011/12 through this national programme. Scottish Government investment in the programme funds a national coordinator based at the Scottish Drugs Forum and support to Alcohol and Drugs Partnerships and Health Boards to enable them to deliver naloxone training and supply naloxone kits to people at risk.

Social Research

Evaluation of the Take Home Naloxone Demonstration Project

Ymchwil Gymdeithasol y Llywodraeth
GSR
Social Science in Government

CURRENT RELEASE

Release date: 27 June 2011

19 November 2013

Medicines & Healthcare products Regulatory Agency

GOV.UK

PROPOSALS FOR AMENDMENTS TO THE HUMAN MEDICINES REGULATIONS 2012 TO ALLOW WIDER ACCESS TO NALOXONE FOR USE IN EMERGENCIES

training programmes could build on past and existing initiatives, including:

- the National Treatment Agency's 2011 overdose and naloxone training programme for families and carers pilot: http://www.nta.nhs.uk/uploads/naloxonereport2011.pdf
- The Scottish Drugs Forum's Take Home Naloxone Overdose Intervention Training: http://www.sdf.org.uk/drug-related-deaths/take-home-naloxone-thn-overdose-intervention-training/
- The Welsh Government's take-home naloxone programme: http://wales.gov.uk/topics/housingandcommunity/safety/substancemisuse/publications/naloxone/?lang=en

Public Health England

Protecting and improving the nation's health

Take-home naloxone from October 2015

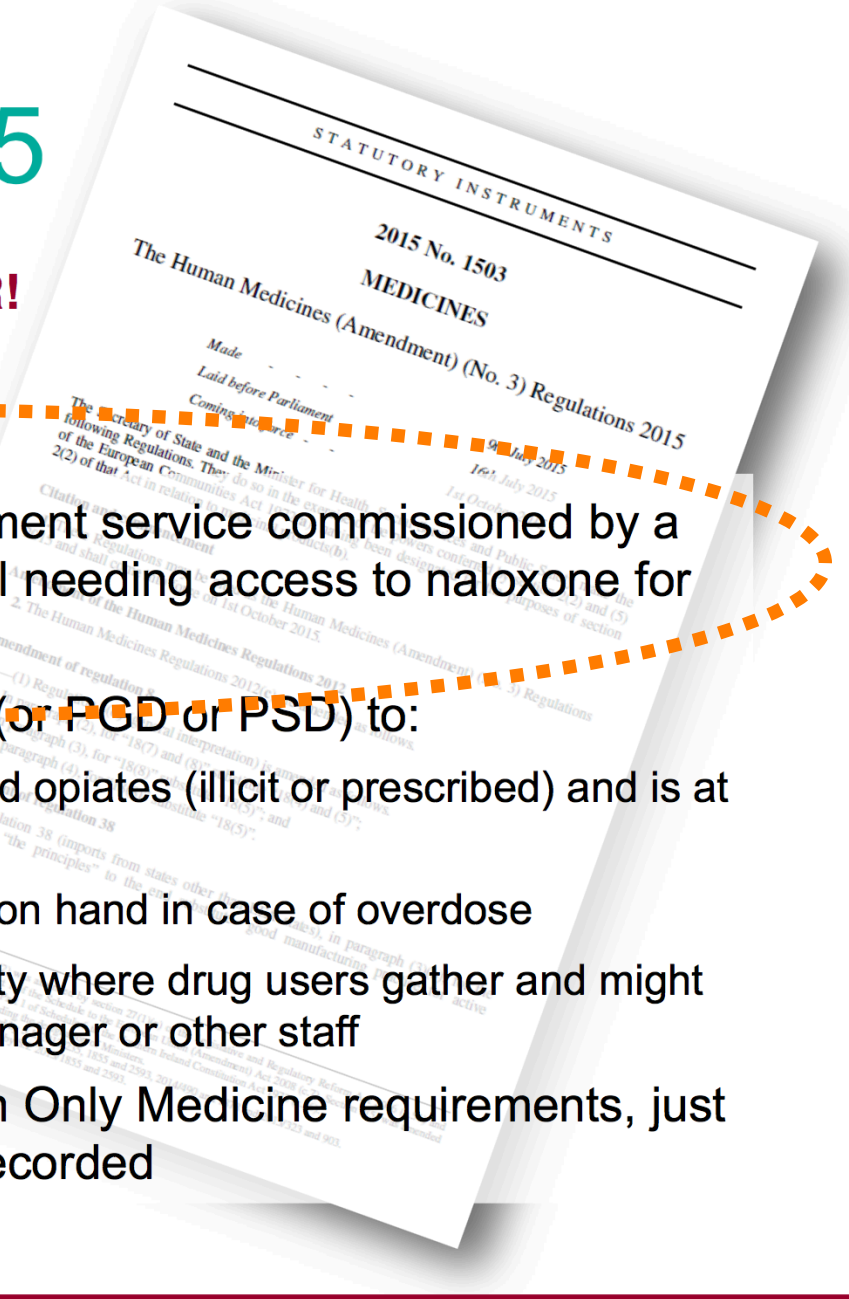
Alcohol, Drugs & Tobacco Division, PHE
September 2015 v1

So, from October 2015

- **ALL THE SAME AS BEFORE OCTOBER!**

But in addition:

- Naloxone can be supplied by a drug treatment service commissioned by a local authority or the NHS to any individual needing access to naloxone for saving a life in an emergency
- So it can be supplied without prescription (or PGD or PSD) to:
  - someone who is using or has previously used opiates (illicit or prescribed) and is at potential risk of overdose
  - a carer, family member or friend liable to be on hand in case of overdose
  - a named individual in a hostel (or other facility where drug users gather and might be at risk of overdose), which could be a manager or other staff
- There is no need for the usual Prescription Only Medicine requirements, just a requirement that the supply is suitably recorded


STATUTORY INSTRUMENTS

2015 No. 1503

MEDICINES

The Human Medicines (Amendment) (No. 3) Regulations 2015

So, from October 2015

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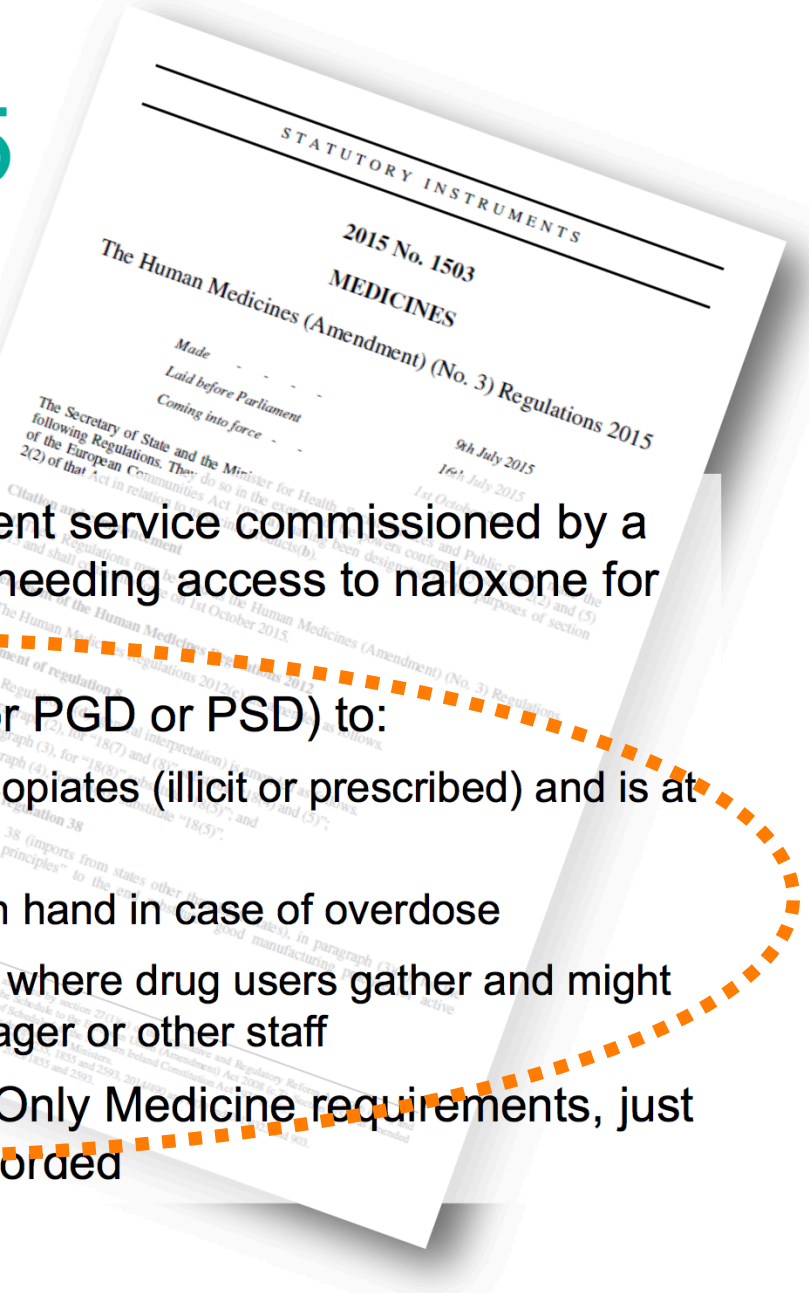
STATUTORY INSTRUMENTS

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Made - - - - 9th July 2015

Laid before Parliament 16th July 2015

Coming into force - - 1st October 2015

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What is a drug treatment service?

- Commissioned by a local authority or the NHS

  (or by Public Health Wales or Public Health England, which doesn't commission services but is there in case of any future changes)

- Services are not defined in legislation but generally understood to include:
  - Specialist drug treatment services
  - Primary care drug services
  - Needle and syringe programmes, including those provided from pharmacies
  - A pharmacy providing supervised consumption of opioid substitute medication

- These services will be able to order naloxone from a wholesaler

Dosing

- The principle is to use the minimum needed to reverse an overdose without throwing someone into unpleasant (and occasionally dangerous) withdrawal
- So:
  - Give 400 micrograms naloxone (0.4ml of 1mg/1ml naloxone hydrochloride solution or, less commonly, 1ml of 0.4mg/1ml naloxone hydrochloride solution)
  - Wait
  - Repeat according to effect every minute or so
- Depending on the product supplied, up to five 400-microgram doses may be available
- If five doses have been given and the patient is still not responding, the diagnosis of opiate overdose should be reviewed

Overdose and naloxone training

- Local areas will want to consider what training is appropriate to different groups of people according to their circumstances and how naloxone is supplied to them
- Training should be about responding to an overdose, not just naloxone. It will usually cover:
  - overdose risks: polydrug (especially benzodiazepines) and alcohol use, getting older, post-detox/rehab/prison
  - what naloxone can and can't do: it just reverses opiate overdose. If someone has also taken too many other drugs or too much alcohol, it won't reverse their effects
  - how to identify an opiate overdose – lack of consciousness, shallow or no breathing, 'snoring', and blueing of the lips and fingertips
  - steps to take in responding to an overdose (see next slide)
  - how to use naloxone, including addressing any fears about needles and injecting
  - how to get naloxone replaced when it has either been used or is approaching its expiry date

UNODC
United Nations Office on Drugs and Crime

World Health Organization

DISCUSSION PAPER
UNODC/WHO 2013

Opioid overdose: preventing and reducing opioid overdose mortality

Community management of opioid overdose

World Health Organization

Challenges

- **Challenge to inertia and the status quo**
- Challenge to current clinical practice
- Challenge to scientific study
- Challenge to ethics

(1996)

First serious consideration:

Strang, J., Darke, S., Hall, W., Farrell, M. & Ali, R. (1996) **Heroin overdose: the case for take-home naloxone.** *British Medical Journal*, 312: 1435.

Challenges

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Obstacles

- **Some easy areas** *('doctors treat patients') (patients live with their families)*

- **Some challenging areas** *(controlled drugs; unknown recipients; lack of specific evidence-base)*

- **Some 'self-inflicted' areas** *(why different from insulin and glucagon, EpiPen, defibrillators, etc?)*

Challenges

- Challenge to inertia and the status quo
- Challenge to current clinical practice
- **Challenge to scientific study**
- Challenge to ethics

Several different types of naloxone – all probably work

(but need improvement)

Addiction

FOR DEBATE

doi:10.1111/add.13209

Clinical provision of nasal naloxone without experimental testing and without regulatory approval—imaginative shortcut or dangerous bypass of essential safety procedures?

Q1 J. Strang*, R. McDonald*, B. Tas & E. Day

National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK

ABSTRACT

NHS Medicines Q&As UKMi UK Medicines Information

Q&A 227.1

What naloxone doses should be used in adults to reverse urgently the effects of opioids or opiates?

Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals

Date prepared: April 2015

Summary

Naloxone is a highly effective antidote for opioids and opiates and its use is potentially life-saving in many circumstances. It is used across a range of care settings where opioid and opiate use is common, and for a number of scenarios that range from management of drug misuse and dependence to the provision of palliative care.

However, as with any drug, its use may also pose risks against which the benefits of treatment need to be weighed. Giving too much naloxone can cause acute withdrawal syndrome (AWS) which is undesirable and unpleasant; other effects, which in some circumstances can be potentially life-threatening in themselves, are also possible. Hence thought needs to be given to the use and dosing of naloxone.

Regardless of the reason for the exposure to opioids or opiates, urgent or emergency use of naloxone should only ever be considered where there is an immediate threat to life or a diagnosis of respiratory depression. The primary aim of treatment is to reverse the toxic effects of opiates such that

Addiction

SSA SOCIETY FOR THE STUDY OF ADDICTION

RESEARCH REPORT

doi:10.1111/add.13027

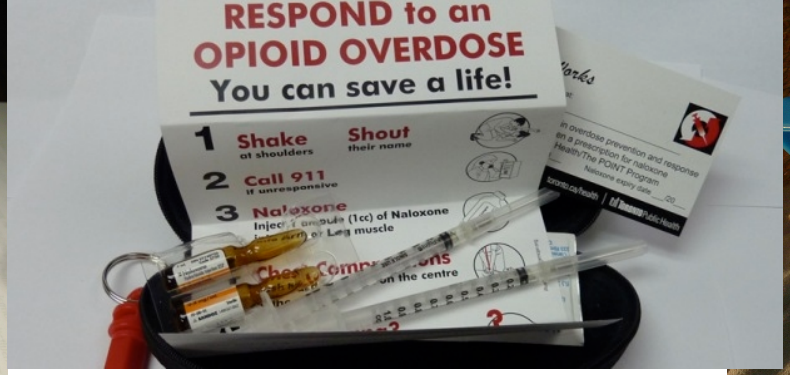
Naloxone—does over-antagonism matter? Evidence of iatrogenic harm after emergency treatment of heroin/opioid overdose

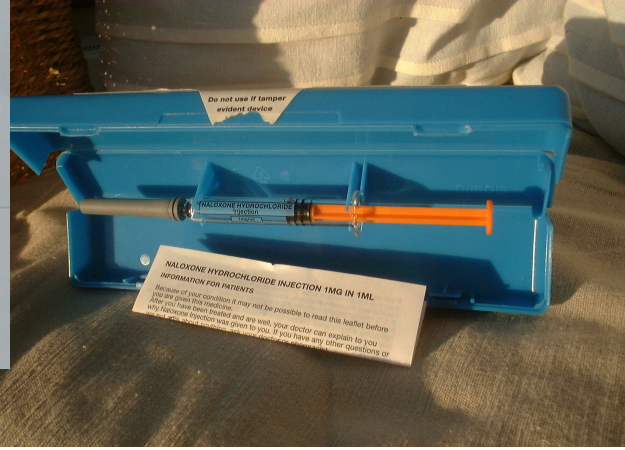
Joanne Neale[1] & John Strang[2]

Reader in Qualitative and Mixed Methods Research, National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK[1] and Professor of the Addictions, National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK[2]

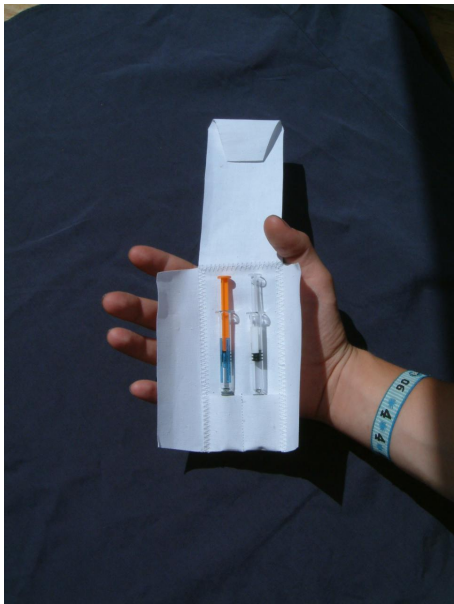
ABSTRACT

Aim To analyse drug users' views and experiences of naloxone during emergency resuscitation after illicit opiate overdose to identify (i) any evidence of harm caused by excessive naloxone dosing ('over-antagonism'); and (ii) implications for the medical administration of naloxone within contemporary emergency settings. **Design** Re-analysis of a large qualitative data set comprising 70 face-to-face interviews conducted within a few hours of heroin/opioid overdose occurring, observations from hospital settings and a further 130 interviews with illicit opiate users. Data were generated between 1997 and 1999. **Setting** Emergency departments, drug services and pharmacies in two Scottish cities.





- All work
- None perfect



Challenges

- Challenge to inertia and the status quo
- Challenge to current clinical practice
- Challenge to scientific study
- **Challenge to ethics**

Challenge to ethics

- Population perspective, not indivdual treatment perspective
- We have naloxone, a heroin/opioid antidote – who has the right to decide?
- Empower and confer skills; pre-supply naloxone
- Improve the various products (inj; nasal; ?)

Conclusion

First-responder overdose management and emergency naloxone; the challenge

- New category of preventing deaths (EpiPen; de-fibrillator; etc)
- Incremental technology transfer (wider workforce)
- Better understanding of the product and application
- Institutional inertia (‘*whilst we dither, overdose victims die*’)

Ongoing issues that create hesitation

- Route
- Dose
- Legal (third party; family; outreach; OTC)
- Opt-in or maybe opt-out

BMJ
British Medical Journal

BMJ 2014;349:g6580 doi: 10.1136/bmj.g6580

EDITORIALS

Take-home emergency naloxone to prevent deaths from heroin overdose

Now enough experience to justify it

John Strang *professor*[1], Sheila M Bird *professor*[2], Paul Dietze *professor*[3], Gilberto Gerra *chief*[4], A Thomas McLellan *chief executive officer*[5]

[1]National Addiction Centre (Institute of Psychiatry and The Maudsley), King's College London, London SE5 8AF, UK; [2]Biostatistics Unit, Cambridge CB2 0SR, UK ; [3]Burnet Institute, Melbourne, Australia; [4]UNODC Drug Prevention and Health Branch Division, United Nations Office on Drugs and Crime, Vienna, Austria; [5]Treatment Research Institute, Philadelphia, PA 19106, USA

A paradigm shift is occurring in the treatment of heroin overdose. On 5 November the World Health Organization launched guidelines on the community management of heroin

In 2012, a United Nations resolution identified the need for more effective prevention of drug overdose, including the use of naloxone.[6] The same year, the first large scale randomised

Thank you

Finally Twelve Scenarios

- (A1) patient commencing OST;
- (A2) patient concluding OST;
- (A3) client finishing rehab or hospital care;
- (B1) named client at syringe exchange scheme;
- (B2) named resident at hostel for homeless;
- (B3) unnamed contact of outreach worker;
- (C1) individual leaving prison;
- (C2) family member (e.g. parent) for their at-risk son/daughter/etc;
- (D1) stock supply for hostel staff or day centre;
- (D2) open availability at a syringe exchange scheme;
- (E1) to be carried by a taxi driver or non-clinical 'first responder';
- (F1) over-the-counter from a community pharmacy.