National Addiction Centre

Institute of Psychiatry at The Maudsley

King's College London

Take-home emergency naloxone:
Origins and history of concept and delivery

Professor John Strang

National Addiction Centre, King's College London, UK

Declaration (personal & institutional)

- DH, NTA, Home Office, NACD, EMCDDA, WHO, UNODC, FDA, NIDA.
- NHS provider (community & in-patient); also Phoenix House, Lifeline, Clouds House, KCA (Kent Council on Addictions).
- 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-Benkiser/Indivior, UCB, MundiPharma, Lundbeck, Alkermes, Teva, Rusan/iGen and also discussions with Lightlake, Lanacher, Fidelity International and 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 registering intellectual property on a novel naloxone product, and JS has been named in a patent registration by a Pharma company as inventor of another naloxone product.

Thanks and Acknowledgements

- Patients and advocates and their families
- Immediate and international colleagues
- PhD student Rebecca McDonald

Why does the take-home naloxone issue matter?

- Overdose is the major cause of death among drug users – mainly opiates
- Most heroin overdoses are witnessed
- Most witnesses intervene actively (even if wrongly)
- Many family members witness overdose (rarely taught)
- We now know when and where it is more likely to occur and we know how to prevent fatality

Two separate levels of naloxone advocacy

- **The activist movement, civilian action, and assertion of legitimacy of take-home naloxone**

- **The adoption and incorporation by policymakers and health professionals of take-home naloxone as permitted and required action**

Key steps in the naloxone story

- **Original articulation – the application of harm reduction**
- Peers as work-force – acceptability and feasibility
- Times and places of particular concern
- Early action – pioneers and campaigners
- Legal obstacles – some real, some self-inflicted
- Family as work-force (and ‘first responders’)
- The normalisation of emergency care and naloxone
- Naloxone without needles – good if reliable (and approved)
- The absence of good science – sort it out

(1992-96)

Papers

Frequency of non-fatal heroin overdose: survey of heroin users recruited in non-clinical settings

BMJ 1996; 313 doi: http://dx.doi.org/10.1136/bmj.313.7054.402 (Published 17 August 1996) Cite this as: BMJ 1996;313:402

Michael Gossop, head of research[a], Paul Griffiths, senior researcher[a], Beverly Powis, research psychologist[a], Sara Williamson, research psychologist[a], John Strang, professor of the addictions[a]

[a] *Drug Transitions Study, National Addiction Centre, London SE5 8AF*

‘Harm Reduction: from Faith to Science’
(3rd International Harm Reduction Conference)
John Strang, Melbourne, March 1992

“From the point of view of harm reduction, the case for such interventions seems incontestable. They stand as examples of virtually all benefit and virtually no cost. These surely stand as excellent vanguard projects for a harm reduction movement. **And if your heart is just not in to such obvious but uncontroversial harm reduction measures, then why not give some thought to the idea of distribution of supplies of naloxone, the opiate antagonist, to opiate users who may at some later date be able to give a life-saving injection of the drug to a fellow drug user who has inadvertently overdosed.”**

Harm minimisation for drug misusers

When second best may be best first

orthodox medicine must also take up the challenge and explore these new territories. Why don't we already offer injecting drug users testing and vaccination for hepatitis B infection?[19 20] Perhaps a case can be made for distributing ampoules of the opiate antagonist naloxone. Its potential for abuse is nil, the risks are probably minimal, and considerable benefit may accrue if drug users could give emergency doses of antagonist to fellow injectors who inadvertently overdose.

BMJ
British Medical Journal

Strang & Farrell, BMJ, 304: 1127-1128.

Strang J. (1993). Chapter in 'Psychoactive Drugs and Harm Reduction: From Faith to Science'. Whurr Publishers, London, UK. (eds: Heather N Wodak A., Nadelmann E an O' Hare P.).

Chapter 1
Drug Use and Harm Reduction: Responding to the Challenge

JOHN STRANG

Some thought should also be given to more controversial options – for example, the possible distribution of supplies of naloxone (the opiate antagonist) to opiate users who may at some later date be able to give a life-saving injection of the drug to a fellow drug user who inadvertently overdoses, as has recently been put forward (Strang and Farrell, 1992).

(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.

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Addiction

(1999)

Addiction (1999) 94(2), 199–204

RESEARCH REPORT

Preventing opiate overdose fatalities with take-home naloxone: pre-launch study of possible impact and acceptability

JOHN STRANG, BEVERLY POWIS, DAVID BEST, LOUISA VINGOE, PAUL GRIFFITHS, COLIN TAYLOR, SARAH WELCH & MICHAEL GOSSOP

National Addiction Centre (The Maudsley/Institute of Psychiatry), London, UK

Abstract

Aims. *Before proceeding with the introduction of an overdose fatality prevention programme including teaching in cardio-pulmonary resuscitation and distribution of naloxone, a pre-launch study of treatment and community samples of injecting drug misusers has been undertaken to establish (i) the extent of witnessing overdoses, (ii) the acceptability of naloxone distribution and training; and (iii) the likely impact of such measures.* **Design and setting.** *Structured interview of two samples: (a) a community sample of injecting drug misusers recruited by selected privileged access interviewers (PAI) and interviewed by them in*

Naloxone? - personal O/D

	Treatment sample (n=142)	Community sample (n=312)
Ever overdosed?	78/142 (55%)	118/312 (38%)
last personal overdose..		
-involved opiates	72/78 (92%)	102/118 (86%)
-at own or friends home	61/78 (78%)	84/118 (80%)
own home	43	52
friends home	18	42
-in company of others	66/78 (85%)	95/118 (81%)
sexual partner	33	32
close friends	27	57

(Strang, Powis, Best, Vingoe, Griffiths, Taylor, Welch and Gossop, Addiction, 1999)

Naloxone? -witnessed O/D

	Treatment sample (n=142)	Community sample (n=312)
Witnessing overdoses		
Ever witnessed overdose?	**44/48* (92%)**	**167/ 312 (52%)**
Witnessed O/D in last year?	**13/48 (27%)**	**81/312 (26%)**
last overdose witnessed…		
-involved opiates	**44/44 (100%)**	**153/159*(96%)**
-O/D by sexual partner	**6**	**18**
close friend	**32**	**84**
casual acq.	**1**	**53**
stranger	**5**	**10**

* data collected from only 48 * data missing on 8 cases

(Strang, Powis, Best, Vingoe, Griffiths, Taylor, Welch and Gossop, Addiction 1999)

Naloxone? - witnessed fatal O/D

	Treatment sample (n=142)	Community sample (n=312)
Witnessing fatal overdoses		
Ever witnessed overdose fatality?	14/48* (29%)	55/312 (18%)
last fatal O/D witnessed…		
-involved opiates	14/14(100%)	34/38* (89%)
-death of sexual partner		2
close friend		33
casual acquaintance		15
stranger		3

* data collected from only 48 ** data missing on 8 cases * data available from only 38 subjects

(Strang, Powis, Best, Vingoe, Griffiths, Taylor, Welch and Gossop, Addiction, 199

INTERVENTION OPPORTUNITY?

- Extensive witnessing of overdoses (including fatal outcomes) …

INTERVENTION OPPORTUNITY?

- O.K., so extensive witnessing of overdoses (including fatal outcomes);

- but what about resuscitation efforts (even if incorrect)?

ELSEVIER

International Journal of Drug Policy 11 (2000) 437–445

THE INTERNATIONAL JOURNAL OF DRUG POLICY

www.elsevier.com/locate/drugpo

Peer-initiated overdose resuscitation: fellow drug users could be mobilised to implement resuscitation

John Strang *, David Best, Lan-Ho Man, Alison Noble, Michael Gossop

National Addiction Centre, Institute of Psychiatry The Maudsley, Denmark Hill, London SE5 8AF, UK

Accepted 7 August 2000

Abstract

Research interviews about overdose experiences were conducted with 115 patients attending a methadone maintenance clinic in south London, UK. While almost half (49.6%) reported having experienced overdose personally (on an average of four occasions each), almost all (97.4%) reported that they had witnessed overdoses (on an average of six occasions each). This represents a total of 706 overdoses witnessed, of which 106 had resulted in fatalities. The vast majority of patients (86/97) reported that they had taken actions when they had witnessed overdoses with those acting taking an average of nearly threee different actions on the last occasion on which they had seen someone overdosing. Most respondents reported that they would be willing to act, even if they did not know the overdose victim personally and that they had not been deterred from acting by the previous response from the emergency services. Fear of punishment was not a strong deterrent from acting certainly not for this sample, with many

Table 1
Willingness to take specific overdose actions as a function of degree of familiarity[a]

	Partner	Friend	Parent	Sibling	Acquaintance	Stranger	All	No-one
Place in recovery position	73	72	72	72	67	67	67	1
Mouth-to-mouth resuscitation	73	73	73	73	58	52	52	1
Walk around the room	73	73	73	73	70	69	69	1
Call ambulance	74	74	74	74	74	71	71	1
Wait for ambulance	73	73	73	73	70	70	70	1
Use smelling salts	62	62	62	62	60	59	59	11
Inflict pain	70	70	70	70	67	66	66	4
Cover with blanket	68	68	68	68	65	64	64	5
Cardiopulmonary resuscitation	71	71	71	71	68	67	67	3

[a] Data available for 75 subjects.

Table 2
Extent to which participants had been put off acting in previous overdose witnessing situations[a]

	Not at all	A little	Quite a lot	A lot
Ignorance	93	3	2	–
Fear of arrest	91	3	2	2
Fear of police surveillance afterwards	92	2	2	2
Did not think it was your responsibility	90	2	5	1
Did not realise the person was overdosing	94	4	-	–
Because you did not know the person well enough	91	-	3	4
It was not your house it happened in	95	-	2	1

[a] Data available for 98 subjects.

FROM SALT INJECTION TO NALOXONE: ACCURACY AND MYTHS IN PEER RESUSCITATION METHODS FOR OPIATE OVERDOSE

TRACY BESWICK, DAVID BEST, JENNY BEARN, SIAN REES, MICHAEL GOSSOP, ROSS COOMBER, JOHN STRANG

One hundred and eight opiate addicts attending an in-patient opiate treatment unit were interviewed, using a mixed quantitative–qualitative approach, to investigate their experiences of witnessing overdoses, the associated interpretations and perceived cause of the overdose. Poly drug use and frequency of witnessed overdose was high among the sample. Use of 14 different combinations of drugs were reported, 8 of which involved the use of alcohol, and 7 benzodiazepines. Perceived cause of overdose involved attributions relating to the use of alcohol, in particular strong lager, small quantities of heroin and low levels of current opiate tolerance. Peer initiated resuscitation techniques revealed a range of responses from the probably valuable (recovery position, summon ambulance, administer naloxone) to the ineffective or frankly harmful (injecting with salt solution, immersing in a cold bath). The findings highlight the need for an overdose prevention program during in-patient detoxification and rehabilitation.

TABLE 2

NUMBER AND PERCENTAGE OF PARTICIPANTS REPORTING TAKING SPECIFIC ACTIONS (N=84)

Action	Number who had done it (%)
Waited with them	64 (80)
Slapped them	62 (77.5)
Walked them around the room	55 (69)
Recovery position	47 (59)
Called an ambulance	45 (56)
Shocked them with water	36 (45)
Mouth to mouth resuscitation	20 (25)
Cardio-pulmonary resuscitation (CPR)	17 (21.3)
No action taken	4 (5)
Alternative methods	13 (16)*

*Techniques included putting ice on the victim (n=1), injecting the person with salt solution (n=3), giving them a cold bath (n=2), praying (n=1), administering cocaine (n=1), administering amphetamines (n=1), clearing the air pathways and putting an upside spoon in the mouth (n=1), pulling their sideburns to wake them up (n=1), and giving them a naloxone injection (n=1).

Key steps in the naloxone story

- Original articulation – the application of harm reduction
- Peers as work-force – acceptability and feasibility
- **Times and places of particular concern**
- Early action – pioneers and campaigners
- Legal obstacles – some real, some self-inflicted
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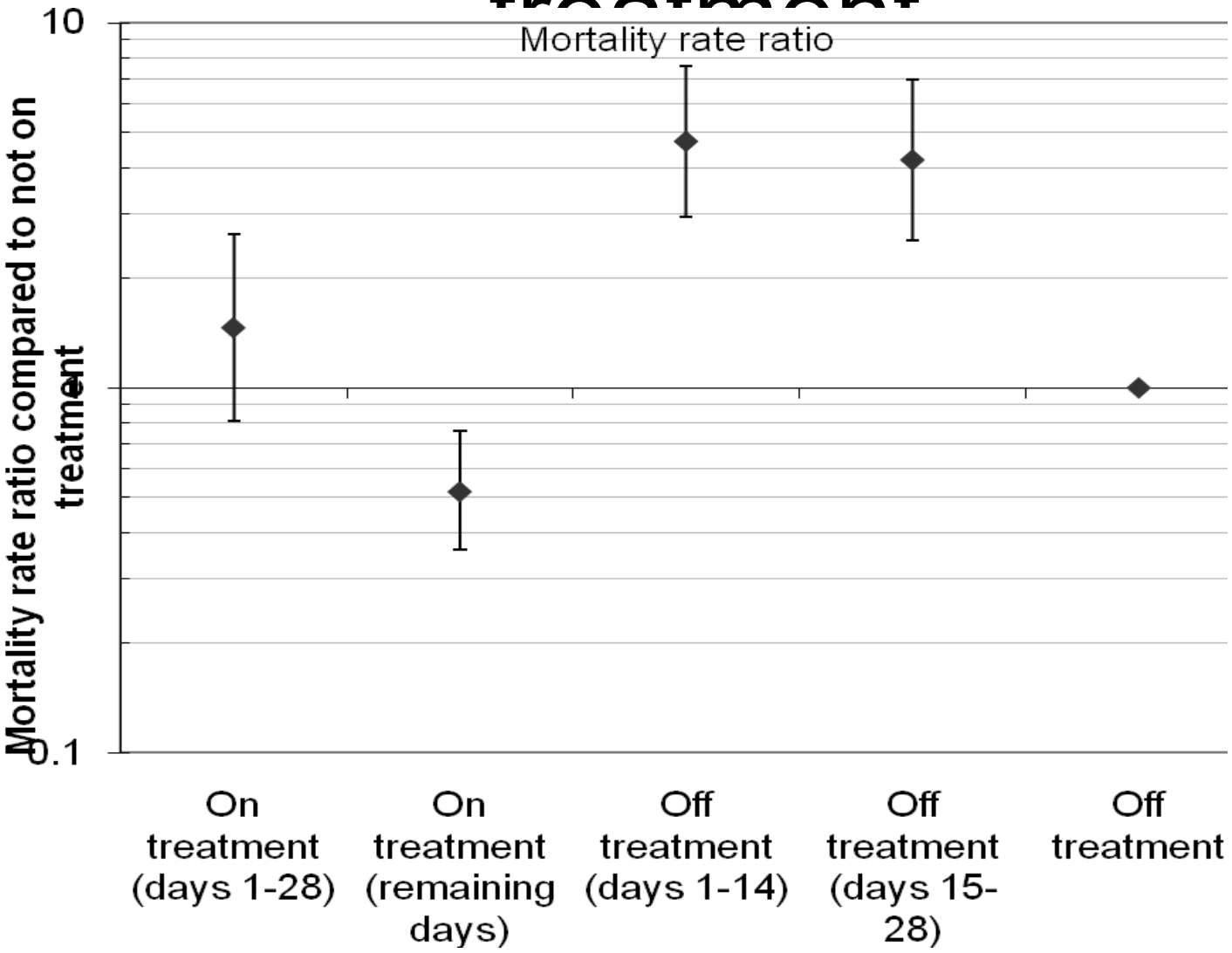
- The absence of good science – sort it out

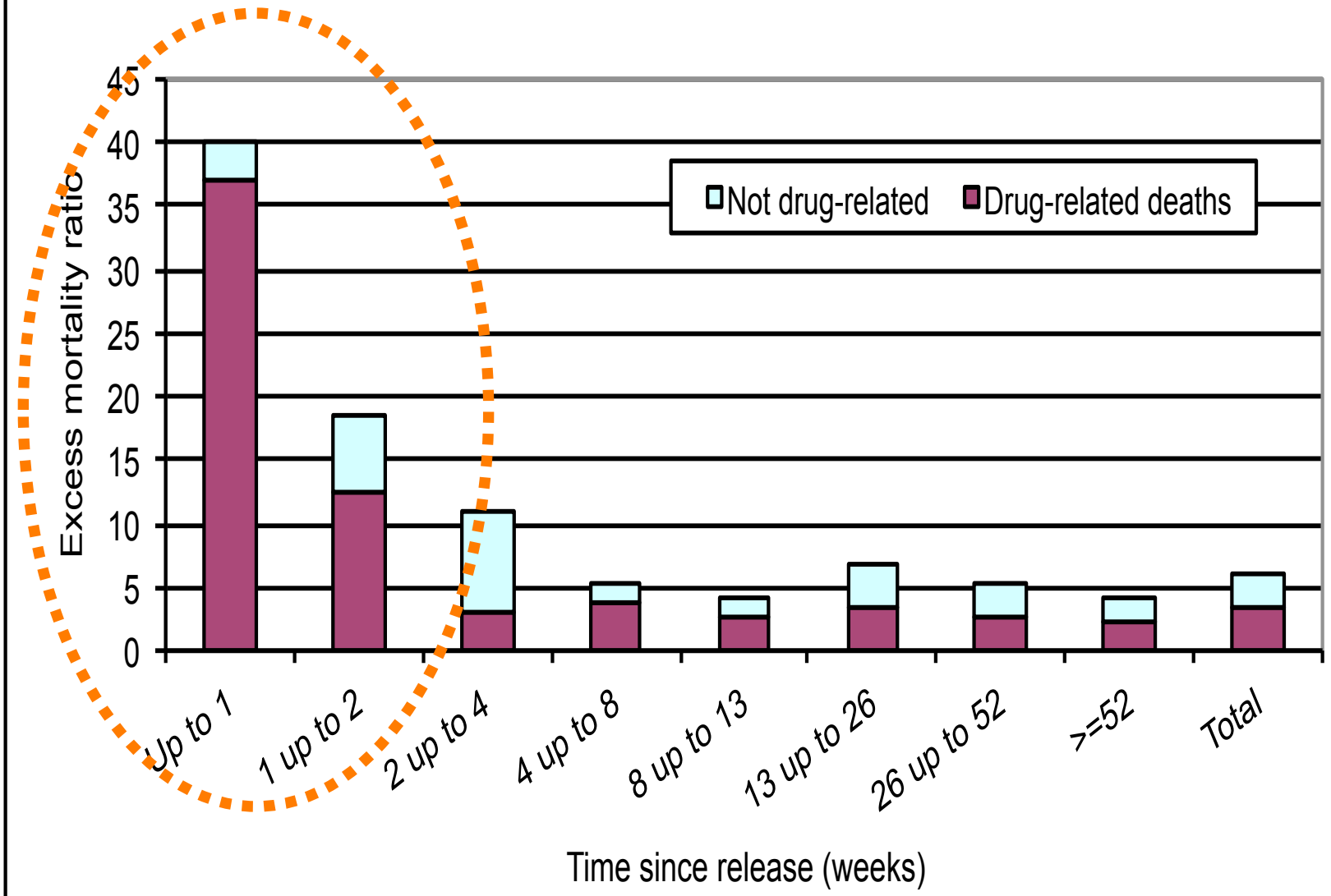
When in particular excess?

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

Risk of death during and after treatment

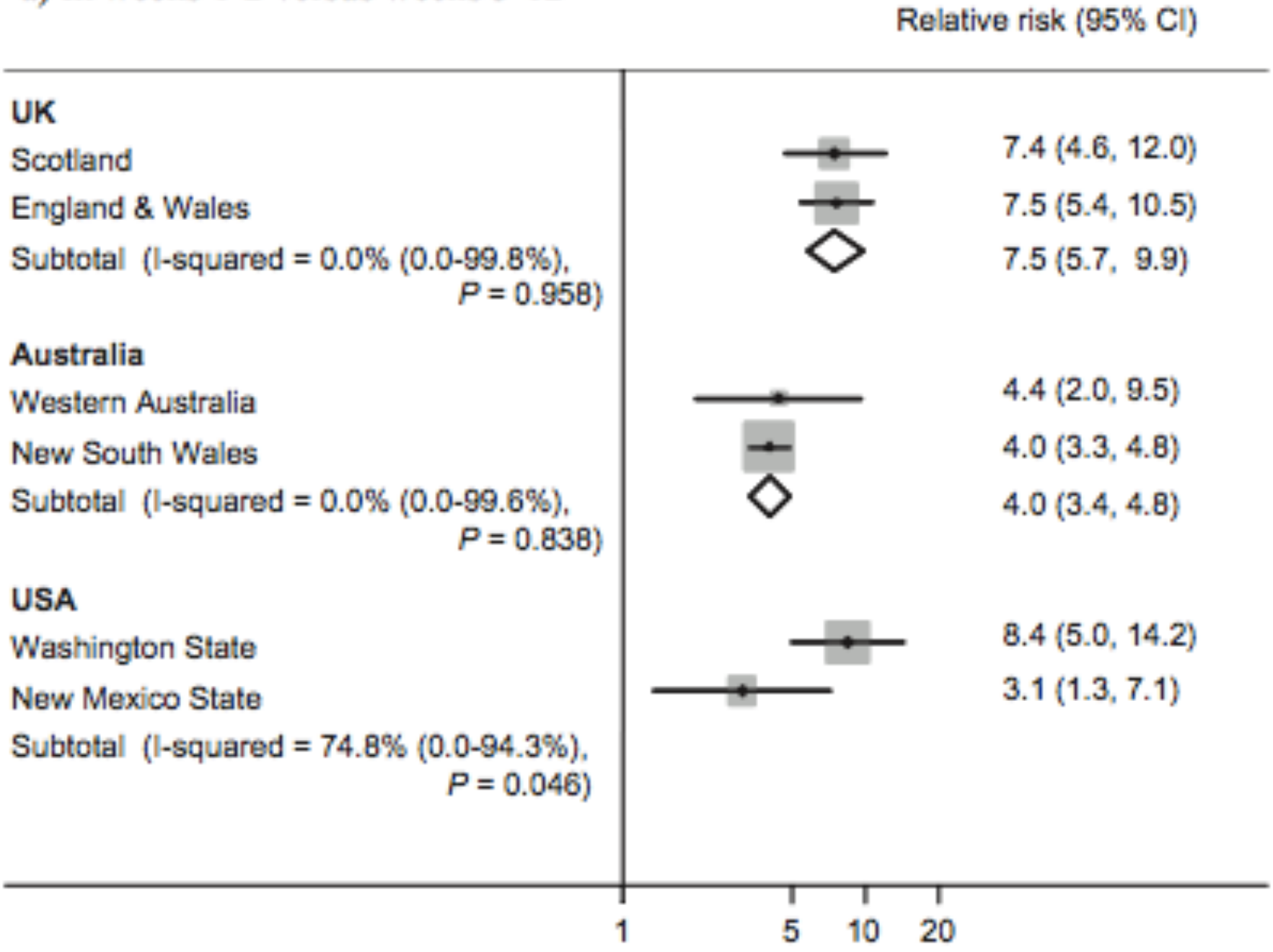


Cornish et al, *BMJ* 2010; 341: c5475



Singleton et al, 2002

a) In weeks 1-2 versus weeks 3-12



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The earliest naloxone providers, late 1990s and by 2001

- Chicago, USA – 1996 approx
- Padua, Italy – 1996
- Jersey, UK – 1998
- Berlin, Germany – 1999
- Barcelona, Spain – 2001
- New Mexico, USA – 2001
- London, UK - 2001

The Chicago Recovery Alliance

ANY POSITIVE CHANGE • ANY POSITIVE CHANGE • ANY POSITIVE CHANGE •

positive change

Chicago Recovery Alliance

Prescribing Naloxone to Actively Injecting Heroin Users: A Program to Reduce Heroin Overdose Deaths

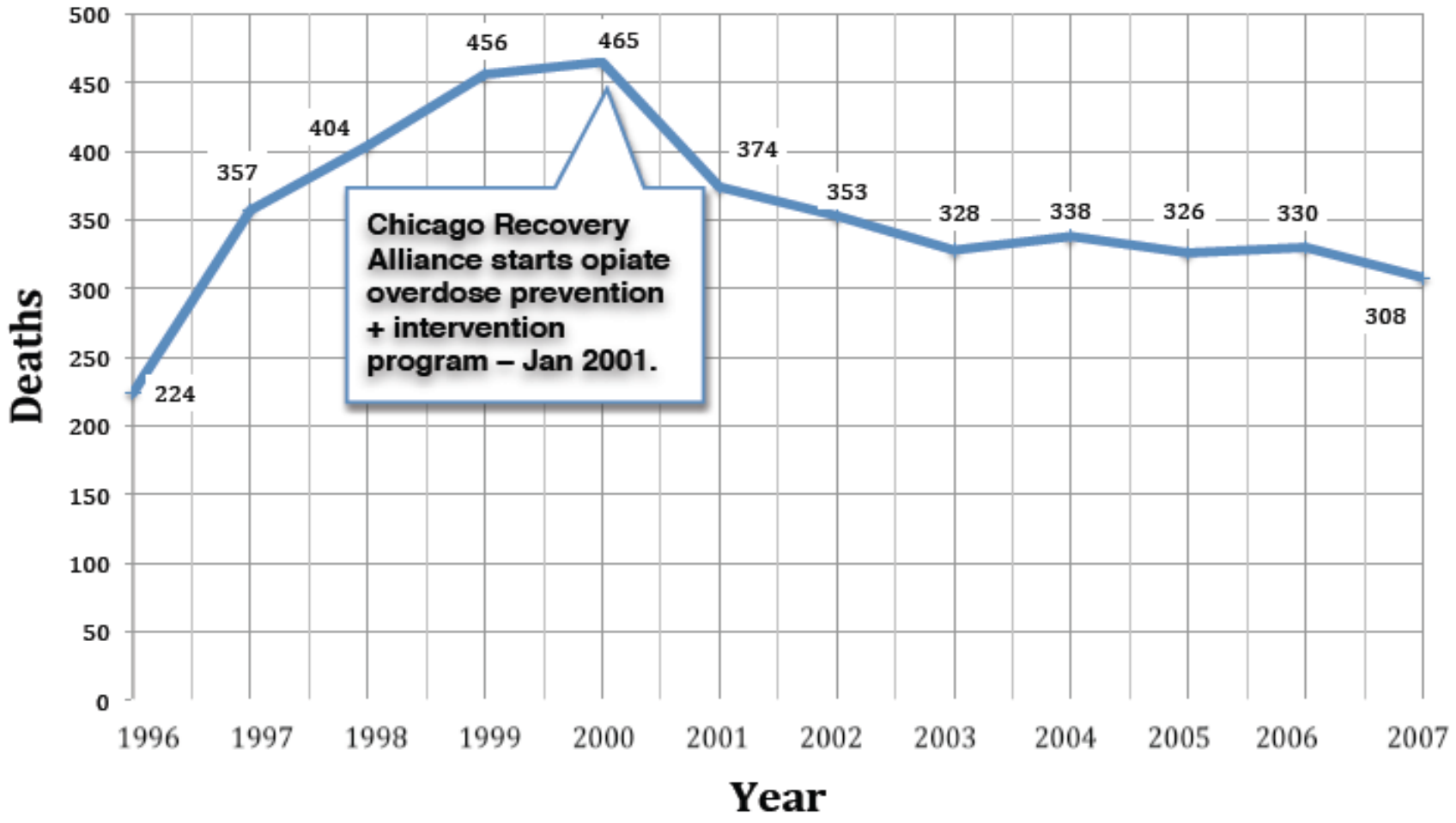
Sarz Maxwell, MD, FASAM
Dan Bigg, CRADC
Karen Stanczykiewicz, CADC
Suzanne Carlberg-Racich, MSPH

ABSTRACT. Heroin overdose deaths have increased alarmingly in Chicago over the past decade. Naloxone, an opioid antagonist with no abuse potential, has been used to reverse opiate overdose in emergency medical settings for decades. We describe here a program to educate opiate users in the prevention of opiate overdose and its reversal with intramuscular naloxone. Participant education and naloxone prescription are accomplished within a large comprehensive harm reduction program network. Since institution of the program in January 2001, more than 3,500 10 ml (0.4 mg/ml) vials of naloxone have been prescribed and 319 reports of peer reversals received. The Medical Examiner of Cook County reported a steady increase in heroin overdose deaths since 1991, with a four-fold increase between 1996 and 2000. This trend reversed in 2001, with a 20% decrease in 2001 and 10% decreases in 2002 and 2003. *[Article copies available for a fee from The Haworth Document Delivery Service: 1-800-HAWORTH. E-mail address: <docdelivery@haworthpress.com> Website: <http://www.HaworthPress.com>*

Heroin-related Overdose Deaths in Cook County

1996 - 2007

Source: Cook County Medical Examiner's Office



BMJ
British Medical Journal

Take home naloxone and the prevention of deaths from opiate overdose: two pilot schemes

Kerstin Dettmer, Bill Saunders, John Strang

(2001)

Doctors routinely give naloxone during emergency resuscitation after opiate overdose. The distribution of naloxone to opiate addicts has recently been addressed,[1–4] and a survey of drug users shows extensive support for the provision of supplies to take away.[4] We present the preliminary results of two pilot schemes to provide take home naloxone to opiate users.

Methods and results

The Berlin project

In January 1999 drug users in Berlin were given naloxone to take home. Opiate misusers attending a healthcare project (operating from a mobile van or ambulance) were offered training in emergency resuscitation after overdose, provided with naloxone (two 400 µg ampoules), needles, syringes, an emergency handbook, and information on naloxone. They were asked to report on any use of the drug. After 16 months, 124 opiate misusers had received training in resuscitation and were provided with supplies of naloxone to take away; 40 reported back, with 22 having given emergency naloxone (two on two occasions, one on three, and one on four).

The methods of administration were diverse.

Case 1 (Berlin)

"Three days ago, I was walking along the canal with a friend of mine. We saw a guy lying on the ground, with two people trying to help him—they were trying to help him breathe by mouth to mouth. When we ran over to them, we could tell it wasn't really working. The guy was blue in the face and hardly breathing any more. I could barely feel his pulse. Right away I gave him one ampoule of naloxone—I didn't think I could find a vein so I just shot it real slow into his upper arm. We tried to give him CPR and we called 911. Then the guy started to wake up and he started to breathe and shake a little bit. He was so thankful, he wanted to give me 50 Marks, but I wouldn't take it. When the medics came I told them I had given him the naloxone. The medics said 'Wow! So you guys have even got naloxone now?' But he thought it was great. He said we had probably just saved the guy's life." The ambulance staff then took the overdose victim to hospital for further observation.

The Jersey project

From October 1998 over the next 16 months naloxone (one minijet ready filled with 800 µg naloxone) was provided to 101 drug misusers in contact with local

Two separate levels of naloxone advocacy

- **The activist movement, civilian action, and assertion of legitimacy of take-home naloxone**

- **The adoption and incorporation by policymakers and health professionals of take-home naloxone as permitted and required action**

- *Different decisions on way forward ??*

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- The absence of good science – sort it out

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?)*

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Drugs: education, prevention and policy,
April 2008; 15(2): 211–218

Family carers and the prevention of heroin overdose deaths: Unmet training need and overlooked intervention opportunity of resuscitation training and supply of naloxone

JOHN STRANG, VICTORIA MANNING, SORAYA MAYET, EMILY TITHERINGTON, LIZ OFFOR, CLAUDIA SEMMLER, & ANNA WILLIAMS

National Addiction Centre (Institute of Psychiatry/The Maudsley), Denmark Hill, London, UK

Drugs: education, prevention and policy,
April 2008; 15(2): 211–218

Abstract

Aim: To assess (a) carers' experiences of witnessing overdose; (b) their training needs; and (c) their interest in receiving training in overdose management.

Design: Postal questionnaire distributed through consenting participating local carer group co-ordinators in England.

Sample: 147 carers attending local support groups for friends and families of drug users.

Findings: Carers were usually parents (80%); 89% were currently caring for a heroin user of whom 49% had already had an overdose (93% involving opiates). One third had witnessed heroin being used, and 31 had witnessed an overdose. For eight carers, there had already been a death from drug overdose. There was poor knowledge of how to manage an overdose. Only a quarter had received advice on overdose management (26%) and only one third knew of the opiate antagonist naloxone (33%). The majority (88%) wanted training in overdose management, especially in emergency naloxone administration (88%). Interest in training did not differ according to carer type nor previous overdose experience.

Conclusion: We found evidence of an extensively overlooked carer population, many of whom have already been faced with an overdose situation and yet have received minimal training. We also found high levels of interest in receiving overdose training, in particular, in emergency naloxone administration.

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BMJ
British Medical Journal

(2006)

Emergency naloxone for heroin overdose

Should it be available over the counter?

Naloxone saves lives. Timely injection of the opiate antagonist naloxone rapidly reverses the respiratory suppression of heroin overdose,[1 2] a major cause of death in young people.[3 4] Recent regulatory amendments increase significantly the extent to which naloxone can now be used to prevent opiate overdose deaths. In June 2005, in the Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order,[5] the United Kingdom added naloxone to the limited list of medicines that may be given by injection "by anyone for the purpose of saving life in an emergency" (alongside emergency adrenaline, glucagons, and snake antivenin). An emergency dose of naloxone may now be given to prevent death from heroin overdose without specific medical instruction. In August 2005, New York state passed legislation (bills A.7162-A (Dinowitz) and S.4869-A (Hannon)) establishing that physicians may lawfully prescribe naloxone explicitly for potential future opiate overdose, including the situation where it may be administered to someone else.

Many people who take overdoses of heroin die even though friends or family are present.[6] Peers often attempt to resuscitate,[7] sometimes incorrectly,[w1] and death may occur from respiratory arrest before

P+ *Summary of good practice with take-home naloxone and extra references w1-w7 are on bmj.com*

(2008)

Addiction

RESEARCH REPORT

doi:10.1111/j.1360-0443.2008.02314.x

Overdose training and take-home naloxone for opiate users: prospective cohort study of impact on knowledge and attitudes and subsequent management of overdoses

John Strang, Victoria Manning, Soraya Mayet, David Best, Emily Titherington, Laura Santana, Elizabeth Offor & Claudia Semmler

National Addiction Centre (Institute of Psychiatry/The Maudsley), Addiction Sciences Building, Denmark Hill, London, UK

ABSTRACT

Aim To examine the impact of training in overdose management and naloxone provision on the knowledge and confidence of current opiate users; and to record subsequent management of overdoses that occur during a 3-month follow-up period. **Design** Repeated-measures design to examine changes in knowledge and confidence immediately after overdose management training; retention of knowledge and confidence at 3 months; and prospective cohort study design to document actual interventions applied at post-training overdose situations. **Method** A total of 239 opiate users in treatment completed a pre-training questionnaire on overdose management and naloxone administration and were re-assessed immediately post-training, at which point they were provided with the take-home emergency supply of naloxone. Three months later they were re-interviewed. **Results** Significant improvements were seen in knowledge

(2011)

International Journal of Drug Policy 22 (2011) 9–15

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/drugpo

Research paper

Impact of training for healthcare professionals on how to manage an opioid overdose with naloxone: Effective, but dissemination is challenging

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[b] National Addiction Centre, Institute of Psychiatry, Kings College London, at King's Heath Partners, UK

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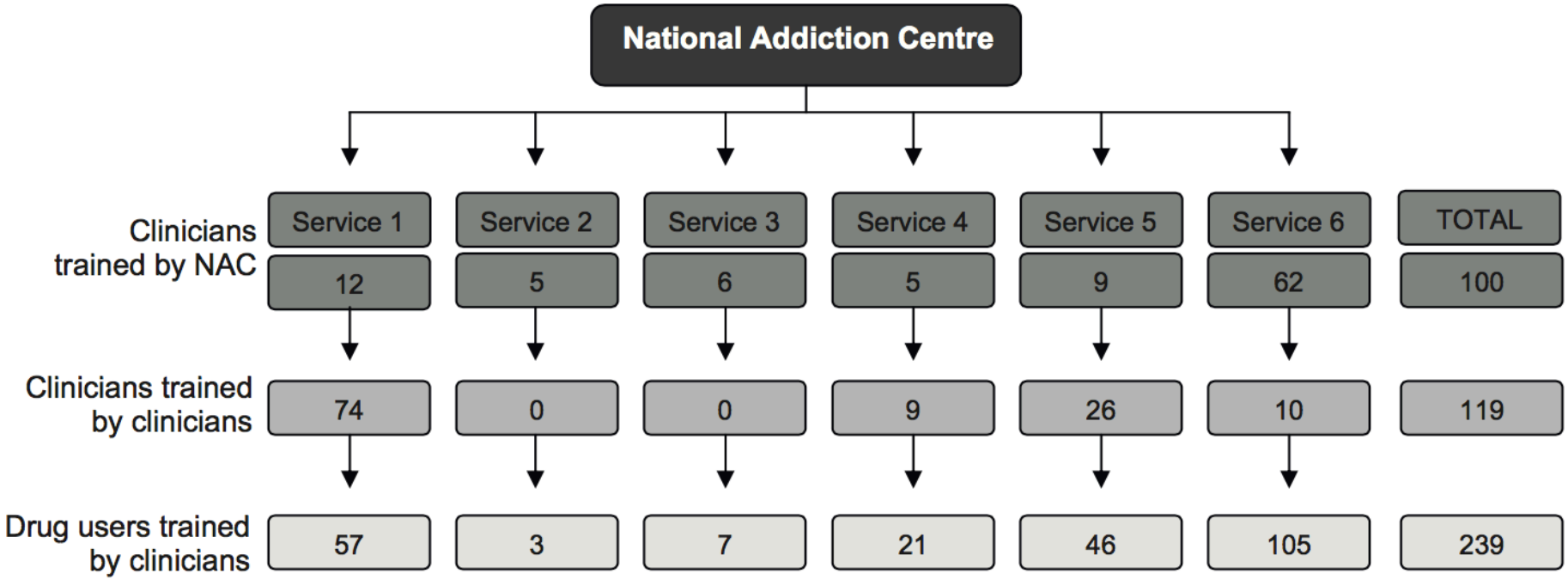
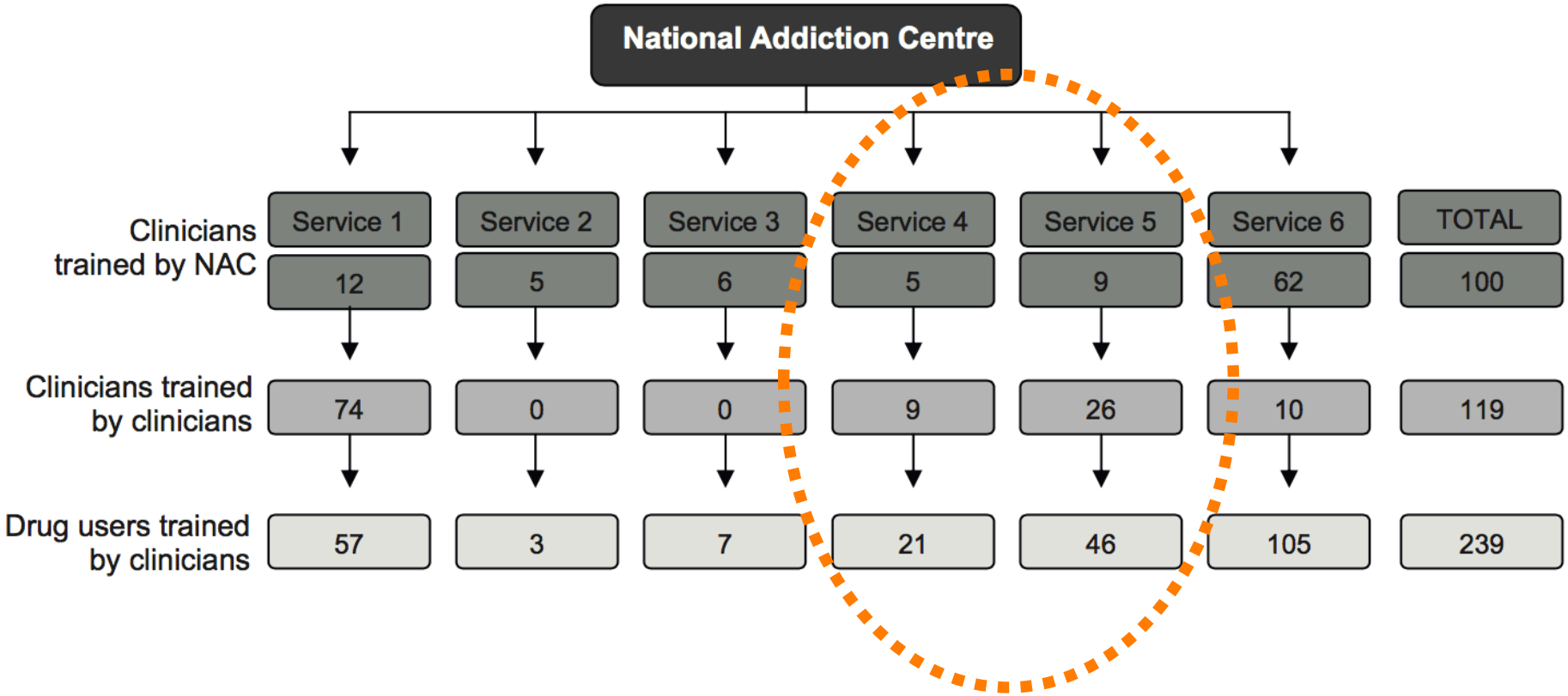
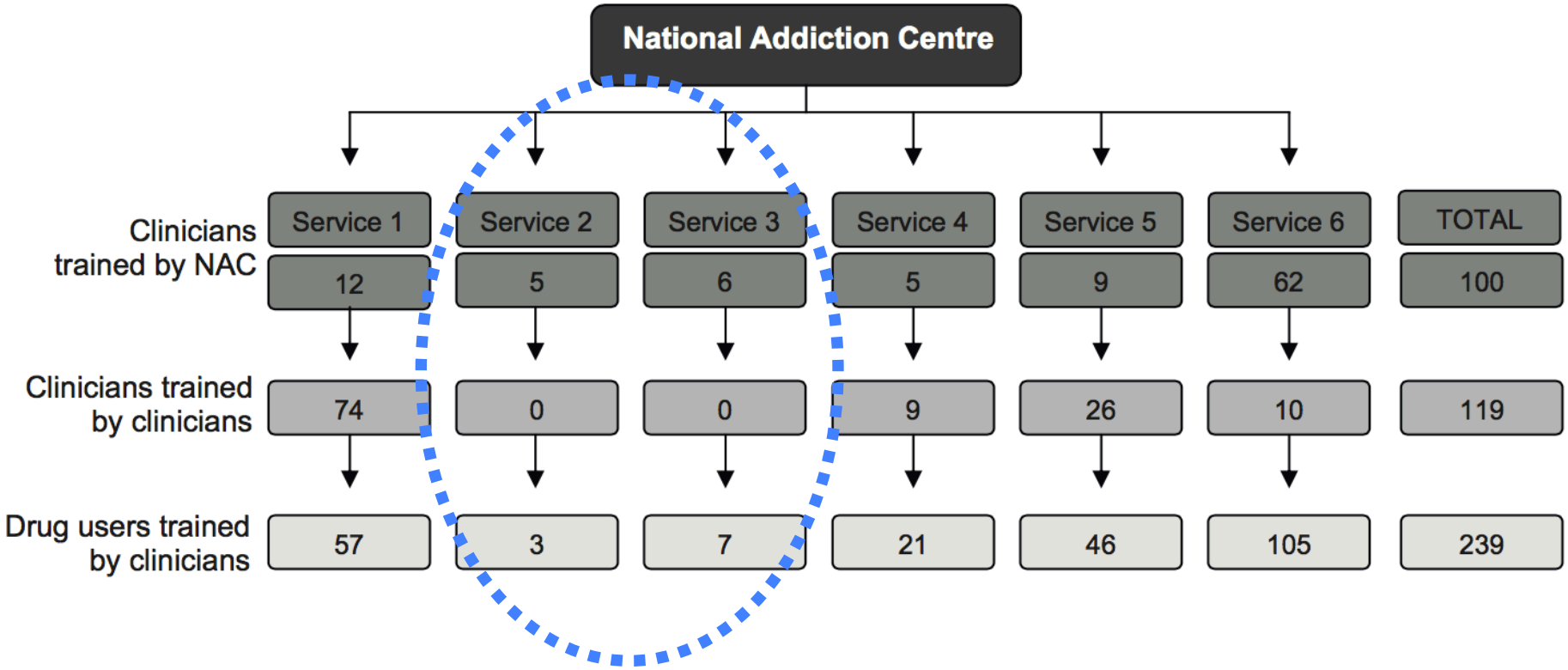
ABSTRACT

Background: Opioid overdose has a high mortality, but is often reversible with appropriate overdose management and naloxone (opioid antagonist). Training in these skills has been successfully trialled internationally with opioid users themselves. Healthcare professionals working in substance misuse are in a prime position to deliver overdose prevention training to drug users and may themselves witness opioid overdoses. The best method of training dissemination has not been identified. The study assessed post-training change in clinician knowledge for managing an opioid overdose and administering naloxone, evaluated the 'cascade method' for disseminating training, and identified barriers to implementation.
Methods: A repeated-measures design evaluated knowledge pre-and-post training. A sub-set of clinicians were interviewed to identify barriers to implementation. Clinicians from addiction services across England received training. Participants self-completed a structured questionnaire recording overdose knowledge, confidence and barriers to implementation.
Results: One hundred clinicians were trained initially, who trained a further 119 clinicians ($n = 219$) and thereafter trained 239 drug users. The mean composite score for opioid overdose risk signs and actions to


National Addiction Centre
Service 1
Service 2
Service 3
Service 4
Service 5
Service 6
TOTAL
Clinicians trained by NAC
12
5
6
5
9
62
100
Clinicians trained by clinicians
74
0
0
9
26
10
119
Drug users trained by clinicians
57
3
7
21
46
105
239


National Addiction Centre
Service 1
Service 2
Service 3
Service 4
Service 5
Service 6
TOTAL
Clinicians trained by NAC
12
5
6
5
9
62
100
Clinicians trained by clinicians
74
0
0
9
26
10
119
Drug users trained by clinicians
57
3
7
21
46
105
239


National Addiction Centre
Service 1
Service 2
Service 3
Service 4
Service 5
Service 6
TOTAL
Clinicians trained by NAC
12
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62
100
Clinicians trained by clinicians
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119
Drug users trained by clinicians
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105
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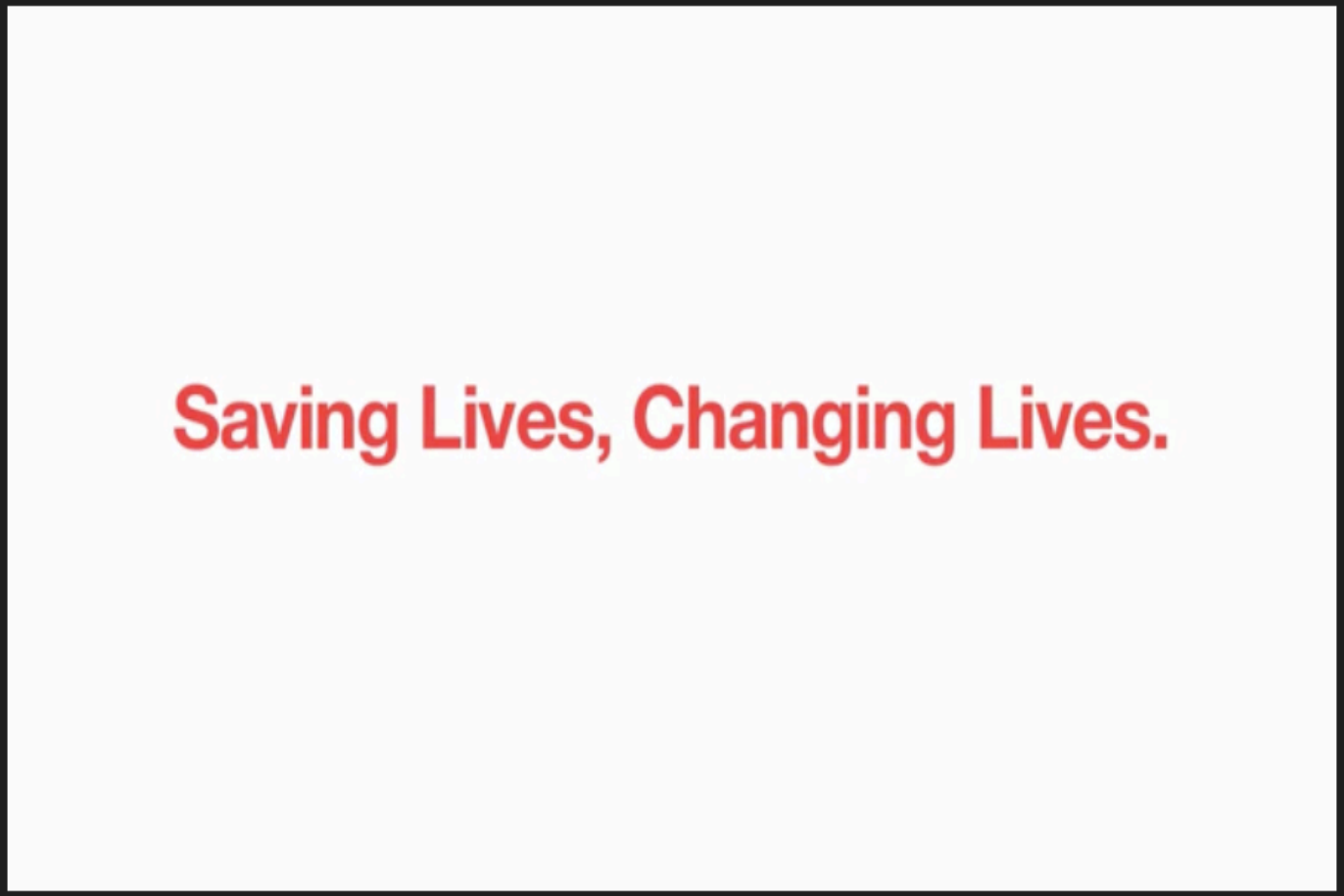
British Red Cross
Community Based First Aid Film

Interview Based Inspiration



Use the Recovery Position

Lay the victim on their side to stop them from choking on their own vomit

1

Put their right hand by their head (as if they were waving)

2

Put their left arm across the chest, so that the back of the hand rests against the cheek

3

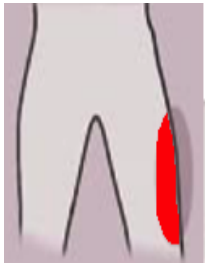
Hold the hand in place and lift up the left knee

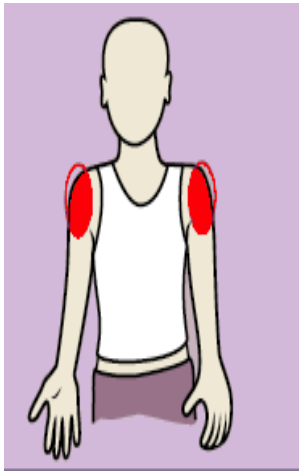
4

Turn the victim on their side by pushing down on the knee

How to inject Naloxone – intramuscular (into muscle)

- Remove syringe from box and packet
- Attach needle to syringe
- Inject into the outer thigh, upper arm or outer part of buttock
- Hold needle 90 degree above skin
- Insert needle into muscle (needs pressure)
- Slowly and Steadily push plunger all the way down
- Put syringe back in box. Don’t cover needle





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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.

Publication Report

National Naloxone Programme Scotland – naloxone kits issued in 2013/14 and trends in opioid-related deaths

Publication date – 28 October 2014

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

Drugs: education, prevention and policy, August 2012; 19(4): 320–328

ISSN: 0968-7637 print/1465-3370 online
DOI: 10.3109/09687637.2012.658104

informa
healthcare

The impact of take-home naloxone distribution and training on opiate overdose knowledge and response: An evaluation of the THN Project in Wales

Trevor Bennett & Katy Holloway

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

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

Regulations 2012 to allow people providing drug treatment services to supply naloxone to anyone requiring access to it for use in an emergency. The amendment is aimed at making stocks of naloxone available in settings which drug users are likely to access, for example, hostels. It will also allow family members or carers to receive direct supplies of naloxone which they can administer in an emergency if needed. The proposal will apply to publicly

Regulatory Impact Assessment

9. The proposal is intended to improve public health by widening access to naloxone.

19 November 2013

Medicines & Healthcare products Regulatory Agency

GOV.UK

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Regulatory Impact Assessment

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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*

United Nations E/CN.7/2012/

Economic and Social Council

Distr.: Limited
14 March 2012

Original: English

Commission on Narcotic Drugs

Fifty-fifth session
Vienna, 12-16 March 2012
Agenda item 6 (a)
Implementation of the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem: demand reduction and related measures

Croatia, Denmark* and Israel: revised draft resolution

Promoting measures to prevent drug overdose, in particular opioid overdose

Understanding that opioid overdose treatment, including the provision of opioid receptor antagonists such as naloxone, is part of a comprehensive approach to services for drug users and can reverse the effects of opioids and prevent mortality,

Recognizing that a range of factors contribute to drug overdose, including mental health problems and polysubstance use, indicating the need for a comprehensive response that includes supply reduction, information-sharing, education, emergency responses and treatment,

Affirming that close cooperation at all levels among experts from the criminal justice, health, social and drug control sectors is critical in devising an effective and scientific evidence-based response to drug overdose prevention, in particular opioid overdose prevention, for drug users,

Recognizing that fatalities due to drug overdose, in particular opioid overdose, can be substantially reduced through effective drug abuse prevention strategies, the provision of information, counselling, education, drug treatment, and related support measures, monitoring and programming,

1. *Encourages* all Member States to include effective elements for the prevention and treatment of drug overdose, in particular opioid overdose, in national drug policies, where appropriate, and to share best practices and information on the prevention and treatment of drug overdose, in particular opioid overdose, including the use of opioid receptor antagonists such as naloxone;

2. *Requests* the United Nations Office on Drugs and Crime, in collaboration with the World Health Organization, subject to the availability of extrabudgetary resources and upon the request of and in collaboration with Member States, to collect and circulate available best practices on the prevention and treatment of and

[3] United Nations publication, Sales No. E.11.XI.10.

UNODC
United Nations Office on Drugs and Crime

World Health Organization

DISCUSSION PAPER
UNODC/WHO 2013

Opioid overdose: preventing and reducing opioid overdose mortality

C. Potential new areas for overdose prevention and treatment

While naloxone has been traditionally used by medical staff to treat opioid overdose, a number of countries have recently adopted policies and procedures that allow medical staff to distribute naloxone to first responders (e.g., police and firemen) and to people dependent on opioids, their peers and family members who are likely to be present when an overdose occurs. Additionally, some countries are considering making naloxone a medicine that is available in pharmacies without a prescription due to the low risk/high benefit ratio associated with naloxone. For example, in Italy, naloxone is available in pharmacies without a prescription and is also distributed through outreach programmes, with anecdotal reports of success in reversing opioid overdose and no adverse events.[62]

In programmes that distribute naloxone, peers and family members are provided overdose prevention education and equipped with naloxone to be used in case of opioid overdose. In some cases, naloxone is prescribed to the person using opioids, who then entrusts it to someone else to administer when needed. This is similar to the practice of prescribing adrenaline to people with severe allergic reactions and placing it in the care of family members or others to administer to the person suffering the allergic reaction, if needed. In other cases, naloxone is provided directly to a friend or family member who is likely to be present during an overdose.

D. Specific proposals to prevent the recent rise in prescription opioid overdoses

The recent increase in prescription overdose in the United States has prompted some, such as the United States Office of National Drug Control Policy, to call for a multipronged approach to preventing prescription opioid overdose, including distribution of naloxone to first responders.[82]

Community management of opioid overdose

World Health Organization

RECOMMENDATION 1 (KEY QUESTION 1)

People likely to witness an opioid overdose should have access to naloxone and be instructed in its administration to enable them to use it for the emergency management of suspected opioid overdose.

Strength of recommendation: **Strong** Quality of evidence: **Very low**

RECOMMENDATION 2 (KEY QUESTIONS 2 AND 3)

Naloxone is effective when delivered by intravenous, intramuscular, subcutaneous and intranasal routes of administration. Persons using naloxone should select a route of administration based on the formulation available, their skills in administration, the setting and local context.

Strength of recommendation: **Conditional** Quality of evidence: **Very low**

RECOMMENDATION 3 (KEY QUESTION 4)

In suspected opioid overdose, first responders should focus on airway management, assisting ventilation and administering naloxone.

Strength of recommendation: **Strong** Quality of evidence[1]: **Very low**

RECOMMENDATION 4 (KEY QUESTION 5)

After successful resuscitation following the administration of naloxone, the affected person should have their level of consciousness and breathing closely observed until they have fully recovered.

Strength of recommendation: **Strong** Quality of evidence: **Very low**

Key steps in the naloxone story

- Original articulation – the application of harm reduction
- Peers as work-force – acceptability and feasibility
- Times and places of particular concern
- Early action – pioneers and campaigners
- Legal obstacles – some real, some self-inflicted
- Family as work-force (and ‘first responders’)
- The normalisation of emergency care and naloxone
- **Naloxone without needles – good if reliable (and approved)**
- The absence of good science – sort it out

Several different types of naloxone – all probably work

(but need improvement)

Academic
Emergency Medicine

Acad. Emerg. Med. 1998; 5:293–299.

Intravenous vs Subcutaneous Naloxone for Out-of-hospital Management of Presumed Opioid Overdose

Karen Wanger, MDCM, Laura Brough, BSc, EMA II, Ian Macmillan, EMA II, Jim Goulding, MD, Iain MacPhail, MD, MHSc, James M. Christenson, MD

ABSTRACT

Objective: To determine whether naloxone administered IV to out-of-hospital patients with suspected opioid overdose would have a more rapid therapeutic onset than naloxone given subcutaneously (SQ).
Methods: A prospective, sequential, observational cohort study of 196 consecutive patients with suspected opioid overdose was conducted in an urban out-of-hospital setting, comparing time intervals from arrival at the patient's side to development of a respiratory rate ≥10 breaths/min, and durations of bag–valve–mask ventilation. Subjects received either naloxone 0.4 mg IV (n = 74) or naloxone 0.8 mg SQ (n = 122), for respiratory depression of <10 breaths/min.
Results: Mean interval from crew arrival to respiratory rate ≥10 breaths/min was 9.3 ± 4.2 min for the IV group vs 9.6 ± 4.58 min for the SQ group (95% CI of the difference −1.55, 1.00). Mean duration of bag–valve–mask ventilation was 8.1 ± 6.0 min for the IV group vs 9.1 ± 4.8 min for the SQ group. Cost of materials for administering naloxone 0.4 mg IV was $12.30/patient, compared with $10.70/patient for naloxone 0.8 mg SQ.

Addiction (1999) 94(2), 205–207

Take-home naloxone: the next steps

John Strang

overdose prevention. However, there are obstacles to practical implementation which will need to be resolved in the next stages of development. Four of these areas will now be considered.

now exploring the feasibility of administering naloxone by routes other than the recommended intravenous route, and we are testing whether the speed of onset may be sufficient with subcutaneous, intramuscular or possibly even intranasal naloxone. And there may be other drugs which, in

(2000)

Company A:

- Concentrated nasal spray
- Disposable nasal spray in single unit or multiple unit format
- 0.1ml concentrated fluid unit dose
- For nasal or buccal administration

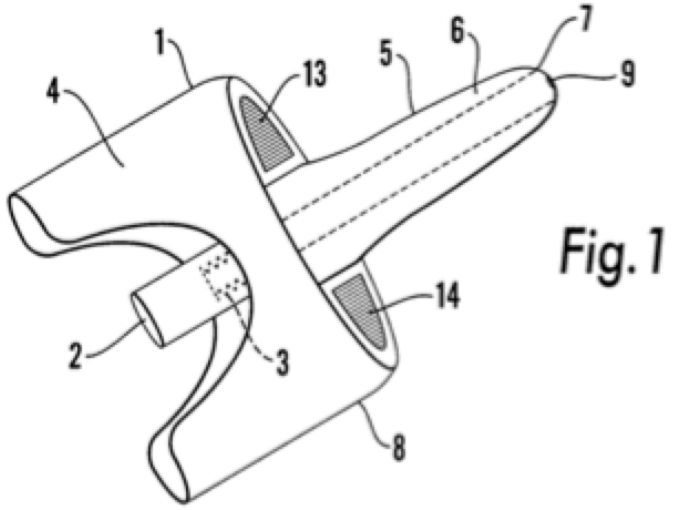


Fig. 1

(2007)

Company B:

- Discovery of archived bioavailability data on nasal naloxone
- Concentrated naloxone spray
- Failure to obtain full pharmacokinetic data

Outline application for a research project grant 2009/2010

Title of application

Effectiveness of Intranasal Naloxone for the Prevention of Opioid Overdose

Total grant requested	Over how many months?
£255,000	36 months

Contact details of lead applicant

Title Professor	**First name** John	**Surname** Strang
Job Title	Head of the Addictions Department Kings College London	
Department	Addictions	
Research Division (if applicable)		
Organisation	Kings College Lonodn	
Contact telephone no.	020 7848 0438	
Email	john.strang@kcl.ac.uk	

Other applicants (***copy and paste the table below for the required number of additional applicants***)

Title Ms	**First name** Anna	**Surname** Williams
Job Title	Project Coordinator	
Department	Addictions	
Research Division (if applicable)		
Address	Addiction Sciences Building 4 Windsor Walk Denmark Hill London SE5 8AF	

(2010)

Company C:

Lightlake Therapeutics

Agreement to develop joint project
to test and trial concentrated nasal naloxone

(2011)

Press Release | Tue Jan 3, 2012 3:30pm EST

Lightlake Therapeutics Inc. to Discuss with King`s College London`s Institute of Psychiatryon the Development of a New Opiate Overdose Treatment

Lightlake Therapeutics Inc. to Discuss with King's College London's Institute of Psychiatry on the Development of a New Opiate Overdose Treatment

Lightlake Therapeutics Inc. (OTCBB: LLTP - News) (the "Company" or "Lightlake"), an early stage biopharmaceutical company developing modern addiction treatments based on its expertise using opioid antagonists, announced today that it is seeking to collaborate with Europe's largest centre for research and post-graduate education in psychiatry, King's College London Institute of Psychiatry, to develop a new treatment for opiate overdose.

Lightlake has agreed to liaise with Professor John Strang, Head of Addictions at King's' Institute of Psychiatry (IoP) and Director of the National Addiction Centre who has pioneered the approach of Take-Home Emergency Naloxone to prevent heroin overdose deaths. It is now established that there are times of particular risk, such as on release from

MJA The Medical Journal of Australia

(2005)

Randomised trial of intranasal versus intramuscular naloxone in prehospital treatment for suspected opioid overdose

Anne-Maree Kelly, Debra Kerr, Paul Dietze, Ian Patrick, Tony Walker and Zeff Koutsogiannis

ABSTRACT

Objective: To determine the effectiveness of intranasal (IN) naloxone compared with intramuscular (IM) naloxone for treatment of respiratory depression due to suspected opiate overdose in the prehospital setting.

Design: Prospective, randomised, unblinded trial of either 2 mg naloxone injected intramuscularly or 2 mg naloxone delivered intranasally with a mucosal atomiser.

Participants and setting: 155 patients (71 IM and 84 IN) requiring treatment for suspected opiate overdose and attended by paramedics of the Metropolitan Ambulance Service (MAS) and Rural Ambulance Victoria (RAV) in Victoria.

Main outcome measures: Response time to regain a respiratory rate greater than 10 per minute. Secondary outcome measures were proportion of patients with respiratory rate greater than 10 per minute at 8 minutes and/or a GCS score over 11 at 8 minutes; proportion requiring rescue naloxone; rate of adverse events; proportion of the IN group for whom IN naloxone alone was sufficient treatment.

Results: The IM group had more rapid response than the IN group, and were more likely to have more than 10 spontaneous respirations per minute within 8 minutes (82% v 63%; $P = 0.0173$). There was no statistically significant difference between the IM and IN groups for needing rescue naloxone (13% [IM group] v 26% [IN group]; $P = 0.0558$). There were no major adverse events. For patients treated with IN naloxone, this was sufficient to reverse opiate toxicity in 74%.

Therapeutic Drug Monitoring (2008)

Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers

Jonathonm Dowling, Geoffrey K. Isbister,†‡¶ Carl M. J. Kirkpatrick,‡ Daya Naidoo,§ and Andis Graudins*‖*

Therapeutic Drug Monitoring (2008)

Population Pharmacokinetics of Intravenous, Intramuscular, and Intranasal Naloxone in Human Volunteers

Jonathonm Dowling, Geoffrey K. Isbister,†‡¶ Carl M. J. Kirkpatrick,‡ Daya Naidoo,§ and Andis Graudins*‖*

Abstract: To investigate the pharmacokinetics of naloxone in healthy volunteers, we undertook an open-label crossover study in which six male volunteers received naloxone on five occasions: intravenous (0.8 mg), intramuscular (0.8 mg), intranasal (0.8 mg), intravenous (2 mg), and intranasal (2 mg). Samples were collected for 4 hours after administration for 128 samples in total. A population pharmacokinetic analysis was undertaken using NONMEM. The data were best described by a three-compartment model with first-order absorption for intramuscular and intranasal administration, between-subject variability on clearance and central volume, lean body weight on clearance, and weight on central volume. Relative bioavailability of intramuscular and intranasal naloxone was 36% and 4%, respectively. The final parameter estimates were clearance, 91 L/hr; central volume, 2.87 L; first peripheral compartment volume, 1.49 L, second peripheral compartment volume, 33.6 L; first intercompartmental clearance, 5.66 L/hr; second intercompartmental clearance, 29.8 L/hr; Ka (intramuscular), 0.65; and Ka (intranasal), 1.52. Median time to peak concentration for intramuscular naloxone was 12 minutes and for intranasal, 6 to 9 minutes. A combination of intravenous and intramuscular naloxone provided immediate high and then detectable concentrations for 4 hours. Intranasal naloxone had poor bioavailability compared with intramuscular. Combined intravenous and intramuscular administration may be a useful alternative to naloxone infusions.

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

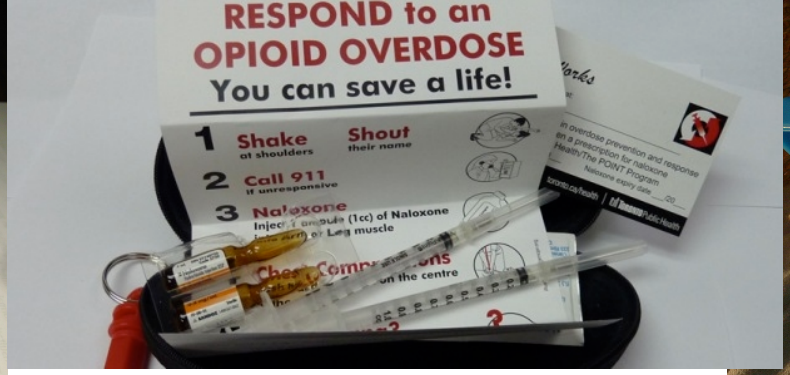
Naloxone—does over-antagonism matter? Evidence of iatrogenic harm after emergency treatment of heroin/opioid overdose

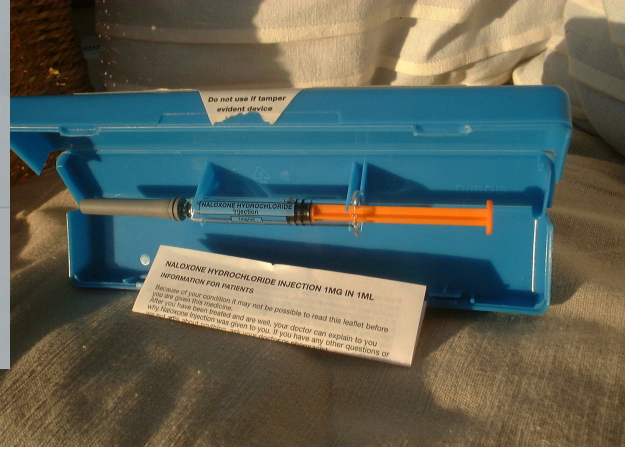
Joanne Neale[1] & John Strang[2]

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]

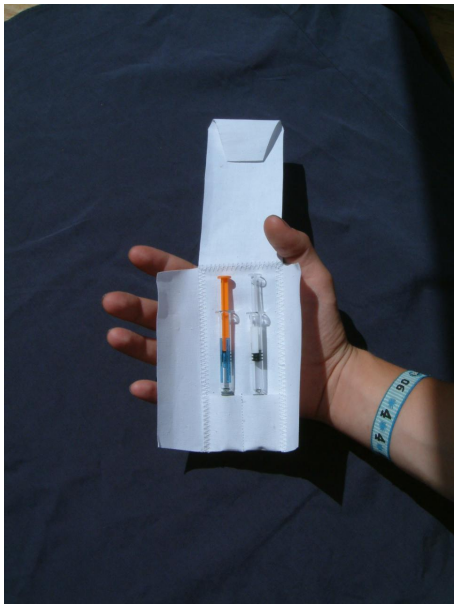
ABSTRACT

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



Key steps in the naloxone story

- Original articulation – the application of harm reduction
- Peers as work-force – acceptability and feasibility
- Times and places of particular concern
- Early action – pioneers and campaigners
- Legal obstacles – some real, some self-inflicted
- Family as work-force (and ‘first responders’)
- The normalisation of emergency care and naloxone
- Naloxone without needles – good if reliable (and approved)
- **The absence of good science – sort it out**

BMJ
British Medical Journal

(2013)

Opioid overdose rates and implementation of overdose education and nasal naloxone distribution in Massachusetts: interrupted time series analysis

Alexander Y Walley *assistant professor of medicine, medical director of Massachusetts opioid overdose prevention pilot*[1 3], Ziming Xuan *research assistant professor*[2], H Holly Hackman *epidemiologist*[3], Emily Quinn *statistical manager*[4], Maya Doe-Simkins *public health researcher*[1], Amy Sorensen-Alawad *program manager*[1], Sarah Ruiz *assistant director of planning and development*[3], Al Ozonoff *director, design and analysis core*[5 6]

[1]Clinical Addiction Research Education Unit, Section of General Internal Medicine, Boston University School of Medicine, Boston, MA, USA; [2]Department of Community Health Sciences, Boston University School of Public Health, USA; [3]Massachusetts Department of Public Health, USA; [4]Data Coordinating Center, Boston University School of Public Health, USA ; [5]Design and Analysis Core, Clinical Research Center, Children's Hospital Boston, USA ; [6]Department of Biostatistics, Boston University School of Public Health, USA

Abstract

Objective To evaluate the impact of state supported overdose education and nasal naloxone distribution (OEND) programs on rates of opioid related death from overdose and acute care utilization in Massachusetts.

strata with 1-100 enrollments per 100 000 population (adjusted rate ratio 0.73, 95% confidence interval 0.57 to 0.91) and community-year strata with greater than 100 enrollments per 100 000 population (0.54, 0.39 to 0.76) had significantly reduced adjusted rate ratios compared with

Addiction

(2013)

RESEARCH REPORT

doi:10.1111/add.12360

Training family members to manage heroin overdose and administer naloxone: randomized trial of effects on knowledge and attitudes

Anna V. Williams, John Marsden & John Strang

Addictions Department, Institute of Psychiatry, King's College London, London, UK

ABSTRACT

Aims To evaluate a heroin overdose management training programme for family members based on emergency recovery procedures and take-home naloxone (THN) administration. **Design** A two-group, parallel-arm, non-blinded, randomized controlled trial of group-based training versus an information-only control. **Setting** Training events delivered in community addiction treatment services in three locations in England. **Participants** A total of 187 family members and carers allocated to receive either THN training or basic information on opioid overdose management ($n = 95$ and $n = 92$, respectively), with 123 participants completing the study. **Measurements** The primary outcome measure was a self-completion Opioid Overdose Knowledge Scale (OOKS; range 0–45) and an

Journal of Urban Health: Bulletin of the New York Academy of Medicine
doi:10.1007/s11524-013-9803-1

Journal of Urban Health

Take-Home Emergency Naloxone to Prevent Heroin Overdose Deaths after Prison Release: Rationale and Practicalities for the N-ALIVE Randomized Trial

John Strang, Sheila M. Bird, and Mahesh K. B. Parmar

ABSTRACT *The naloxone investigation (N-ALIVE) randomized trial commenced in the UK in May 2012, with the preliminary phase involving 5,600 prisoners on release. The trial is investigating whether heroin overdose deaths post-prison release can be prevented by prior provision of a take-home emergency supply of naloxone. Heroin contributes disproportionately to drug deaths through opiate-induced respiratory depression. Take-home emergency naloxone is a novel preventive measure for which there have been encouraging preliminary reports from community schemes. Overdoses are usually witnessed, and drug users themselves and also family members are a vast intervention workforce who are willing to intervene, but whose responses are currently*

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

BMJ British Medical Journal

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

EDITORIALS

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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]

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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

Ongoing issues that create hesitation

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

First-responder overdose management and emergency naloxone; necessary next steps

- The emergency context (pre-preparation; ABC-naloxone; rescue breathing; ambulance)
- The regulatory context (pre-supply; OTC?; Samaritan; message)
- Improving the product (dose/effect; IM good but needs to be easier; right dose, pre-filled, stake needle; non-injecting potential?; longer-acting?)
- Target especially … (individuals at known high risk; settings of known high risk; wider intervention workforce)
- Tracking the impact (case studies OK; crucial to track population impact)

Thank you