



Review

Twenty years of take-home naloxone for the prevention of overdose deaths from heroin and other opioids—Conception and maturation



Rebecca McDonald^a, Nancy D. Campbell^b, John Strang^{a,*}

^a National Addiction Centre, Institute of Psychiatry, Psychology and Neuroscience (IoPPN), King's College London, Addictions Sciences Building, 4 Windsor Walk, Denmark Hill, London, SE5 8BB, United Kingdom

^b Department of Science and Technology Studies, Sage Labs 5202, Rensselaer Polytechnic Institute, 110 Eighth Street Troy, NY, 12180, United States

ARTICLE INFO

Keywords:

Opiate
Naloxone
Overdose
Prevention
Drug-related deaths
Harm reduction

ABSTRACT

Background: Opioid overdose is a major cause of mortality, but injury and fatal outcomes can be prevented by timely administration of the opioid antagonist naloxone. Pre-provision of naloxone to opioid users and family members (take-home naloxone, THN) was first proposed in 1996, and WHO Guidelines were issued in 2014. While widespread in some countries, THN is minimally available or absent elsewhere. This review traces the development of THN over twenty years, from speculative harm reduction proposal to public health strategy.

Method: Medline and PsycINFO were searched for peer-reviewed literature (1990–2016) using Boolean queries: 1) “naloxone OR Narcan”; 2) “(opioid OR opiate) AND overdose AND prevention”. Grey literature and specialist websites were also searched. Data were extracted and synthesized as narrative review, with key events presented as chronological timeline.

Results: Results are presented in 5-year intervals, starting with the original proposal and THN pilots from 1996 to 2001. Lack of familiarity with THN challenged early distribution schemes (2001–2006), leading to further testing, evaluation, and assessment of challenges and perceived medicolegal barriers. From 2006–2011, response to social and legal concerns led to the expansion of THN programs; followed by high-impact research and efforts to widen THN availability from 2011 to 2016.

Conclusions: Framed as a public health tool for harm reduction, THN has overcome social, clinical, and legal barriers in many jurisdictions. Nonetheless, the rising death toll of opioid overdose illustrates that current THN coverage is insufficient, and greater public investment in overdose prevention will be required if THN is to achieve its full potential impact.

1. Introduction

Over the past two decades, take-home naloxone (THN) has moved from its initial conceptualization as harm reduction measure for preventing opioid overdose deaths to becoming an evidence-based public health strategy with organized implementation (UNODC/WHO, 2013). Strong advocacy by local early adopters has enabled emergence of THN initiatives around the world. In Italy, a harm reduction service on the outskirts of Turin reportedly provided naloxone access to clients as early as 1991 (ForumDroghe, 2016). Today, formal THN programs exist in Australia, Canada, at least nine European countries (EMCDDA, 2016), and the US; as well as pilots in low- and middle-income countries, including Afghanistan, China, India, Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Thailand, Ukraine, and Vietnam (UNODC/WHO, 2013). The World Health Organization issued new guidelines for community-based overdose management, suggesting that “[p]eople

likely to witness an opioid overdose should have access to naloxone and be instructed in its administration” (WHO, 2014).

Despite these recent advances, dissemination of THN remains remarkably slow. THN was first proposed in 1996, and it was not until the late 2000s that serious consideration of THN implementation at state or national level began.

Opioid overdose continues to account for approximately 68,000–104,000 annual deaths worldwide (UNODC, 2016b), with sharp increases reported for the UK (ISD, 2016; ONS, 2016) and US (CDC, 2016). Many of these deaths could be prevented if THN was available: A recent analysis of the time course of opiate metabolites post-mortem found that survival times post-injecting exceeded 20–30 min in the majority of heroin overdose deaths (Darke and Dufloy, 2016), suggesting that there is indeed sufficient time to intervene (Darke and Dufloy, 2016; Tas and McDonald, 2016). However, adequate intervention is only possible where witnesses recognize the

* Corresponding author.

E-mail address: john.strang@kcl.ac.uk (J. Strang).

<http://dx.doi.org/10.1016/j.drugalcdep.2017.05.001>

Received 13 March 2017; Received in revised form 2 May 2017; Accepted 2 May 2017

Available online 25 May 2017

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opioid overdose. In addition to naloxone supply, it is thus essential for THN programs to teach awareness of overdose risk factors (e.g., using alone, street injection), crisis detection (e.g., snoring following opioid use may signal overdose), interim emergency care aid, and need for continued care (McAuley et al., 2010; Seal et al., 2005; Strang et al., 2008a).

This brief history chronicles major milestones and events in the emergence and evolution of THN.

2. Method

2.1. Literature search

The first author (RM) searched Medline and PsycINFO for THN-related peer-reviewed literature published between January 1990 and December 2016 using the Boolean queries: 1) “naloxone OR Narcan”; 2) “(opioid OR opiate) AND overdose AND prevention”. Specialist websites and databases of Public Health England, the European Monitoring Centre for Drugs and Drug Addiction, US National Institute on Drug Abuse, and United Nations agencies were also searched for THN-related entries. Additional materials from the non-peer-reviewed literature were consulted to reconstruct the historical timeline.

2.2. Data extraction and evidence synthesis

THN-related evidence was extracted and synthesized as narrative review by all three authors (RM, NC, JS). Relevant events were considered according to occurrence in one of four developmental phases of constructed quinquennia (with some overlap naturally occurring), which cover the 20-year period from 1996 to 2016.

3. Results

We present results in four sections which discuss the following themes. Firstly, we examine formal articulation of the need for THN, along with preliminary testing and implementation (1996–2001; Section 3.1). We then document early THN schemes and challenges (2001–06; Section 3.2). We then explore new national or state-level naloxone programs made possible through the identification and response to legal concerns (2006–11; Section 3.3). Finally, we review the emergence of research studies meeting higher evidentiary standards and examine efforts to widen THN availability (2011–16; Section 3.4). Key events are also summarized as a chronological timeline (see Table 1).

3.1. 1996–2001 circa: conception, testing the notion, and early implementation

3.1.1. Original articulation

Naloxone was first synthesized and patented in the early 1960s (Blumberg et al., 1961; Lewenstein and Fishman, 1966) and FDA-approved in 1971 for intravenous, intramuscular, and subcutaneous administration for partial or complete reversal of opioid overdose (Garfield, 1983) (see Table 1). Although not the first opiate antagonist, naloxone was the first largely free of agonist effects. Naloxone became standard rescue medication in emergency management of heroin overdose in hospital and ambulance settings and has been included in the WHO List of Essential Medicines since 1983 (WHO, 2011, 2014).

The idea to enable opioid users and/or family and friends to take naloxone home did not arise until more than two decades after initial FDA-approval. It was first mooted at the 3rd International Harm Reduction Conference in March 1992 (Strang, 1992, 1993; Strang and Farrell, 1992) as a mere throwaway example of harm reduction alternatives that were being overlooked. However, the first serious consideration of THN was in the 1996 BMJ editorial (Strang et al., 1996) which identified key elements of the intervention, including provision

to: (1) individuals at high risk of overdose, e.g., those leaving emergency care following overdose and those who lost tolerance due to detoxification, incarceration, or abstinence-based treatment; (2) patients enrolled in treatment programs (despite treatments’ protective benefits, they remain at risk); and (3) active users.

The editorial also described the poor suitability of existing naloxone products (ampoules, vials) compared to pre-filled syringes and identified medico-legal challenges raised by the prospect of third parties, such as family members, requesting or administering naloxone. Finally, the editorial urged reconsideration of naloxone’s prescription-only medication status. These central points of the editorial shaped implementation and research in the subsequent years.

3.1.2. Early implementation

The introduction of THN was made possible through user advocates working with physicians willing to prescribe naloxone despite medico-legal barriers. First THN provision occurred in the late 1990s, in the United States (Chicago, San Francisco), Germany (Berlin), the UK (Jersey), and Italy (Turin, Bologna, Padua).

3.1.2.1. United States. The Chicago Recovery Alliance (CRA) began obtaining and distributing naloxone in 1996. Due to high user demand during a fourfold increase in drug-related deaths from 1996 to 2000, distribution by mobile van was introduced in 1998 and converted into a formal training curriculum in 2001 (Bigg, 2002).

During the late 1990s, CRA began discussions with harm reduction advocates in other places around starting THN-programs and served as central clearinghouse for THN across the US.

San Francisco Needle Exchange introduced a small-scale THN pilot for youth in the Haight-Ashbury district in 1999 (Bigg, 2000; Giuliano, 2000; Seal et al., 2001). The pilot was later scaled up in conjunction with the DOPE (Drug Overdose Prevention and Education) project (Giuliano, 2000; Seal et al., 2001) and moved to the San Francisco Public Health Department in 2003.

In 2000, the Drug Policy Alliance (formerly Lindesmith Center) partnered with the University of Washington Alcohol and Drug Abuse Institute to explore pragmatic approaches to “Preventing Heroin Overdose,” which included sessions on naloxone distribution.

3.1.2.2. Continental Europe. Multiple sources point to largely undocumented early community-based naloxone availability in parts of Italy, notably Turin (1991) and the Emilia Romagna region (incl. Bologna) in 1998 (ForumDroghe, 2016; Simini, 1998).

There were reports of THN distribution in Padua in 1996, where a methadone clinic distributed 150 naloxone vials within 18 months. While overdose deaths decreased citywide, there was no formal evaluation of THN usage (Schifano, 2001).

Two pilot schemes in Berlin and the British island of Jersey (Dettmer et al., 2001) constitute the first published outcomes report on THN provision. Between 1998 and 2000, 101 clients of a community-based drug clinic in Jersey were trained in overdose management and received THN kits, with five reported overdose reversals (Dettmer et al., 2001). In Berlin, THN was introduced at a mobile needle and syringe exchange scheme (“Fixpunkt”) in 1999. Within 16 months, 124 THN kits had been issued; 22 users reported administering naloxone for a total of 29 overdose reversals (Dettmer et al., 2001). The article attracted support but also sharp criticism (Ashworth, 2001; Blackwood, 2001; Mountain, 2001), noting low response rate and the lack of systematic follow-up, objective mortality data, and risk assessment – concerns echoed in the THN debate throughout the 2000s. The Berlin pilot was discontinued after 2002 due to lack of funding (AIDS-Hilfe, 2013; Dettmer, 2014).

3.1.3. Testing the notion: is the intervention necessary?

Several studies in the late 1990s and early 2000s identified situations in which naloxone should be made available:

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