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RADARS System Update!

StreetRx
www.streetrx.com

Recently launched in France, Germany, Italy and Spain

Did You Know?

There were 4 new FDA New Drug Application filings this quarter for prescription opioid pain products: Bunavail®, MoxDuo® CR, Targiniq® ER and Zalviso®

SAVE THE DATE!!

RADARS System Annual Scientific Meeting 2014

The 8th Annual RADARS System Scientific Meeting is to be held April 9, 2014 at The Westin Georgetown in Washington DC.

New Frontiers in Prescription Drug Abuse Surveillance

More information will be posted to our website as it becomes available. Please sign up at www.RADARS.org to receive updates on this event and other RADARS System news.

Highlights on 2 New RADARS System Manuscripts:

Non-medical use of tapentadol immediate release by college students

Dart RC, Bucher Bartelson B, Adams EH
Clinical Journal of Pain

E-publication Date 9/18/2013 ([click here](#))

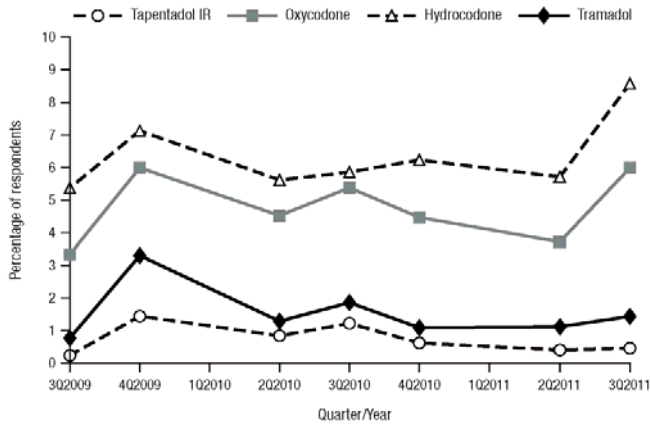
Recent studies have shown that prescription opioids may be easily accessible to young adults, such as college students, who may perceive prescription drugs to be safer than illicit drugs. Estimates from the 2010 National Survey on Drug Use and Health indicate that non-medical use of pain relievers is second only to marijuana abuse in the 18- to 25-year-old age group. This is concerning as this behavior may escalate to substance abuse and addiction.

Opioid analgesics are leading causes of preventable injury and death. This study reports rates and methods of non-medical use of the analgesic tapentadol immediate release (IR) and other commonly prescribed opioid analgesics among US college students following the launch of tapentadol IR in June 2009.

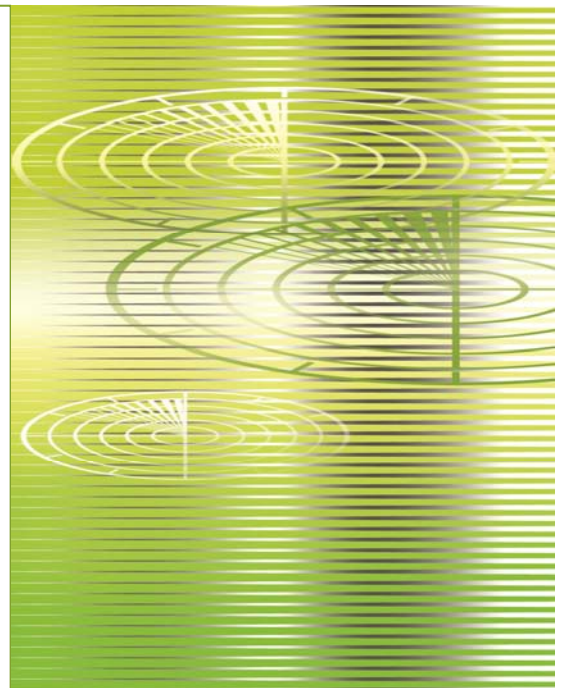
The RADARS System College Survey Program collects data from approximately 2,000 self-identified college students throughout the US during fall, spring, and summer terms using a web-based questionnaire. Responses from July 2009 through September 2011 were analyzed for the rate of non-medical use of tapentadol IR.

Since its launch, rates of non-medical tapentadol IR use by college students have been low and have decreased over time (Figure 2—next page). The initial levels of reported non-medical use may represent a brief period of experimentation after introduction.

Figure 2. Non-medical use of tapentadol IR, oxycodone, hydrocodone, and/or tramadol in the past 90 days, RADARS System College Survey Program, 3Q2009 to 3Q2011.



RADARS, Researched Abuse, Diversion and Addiction-Related Surveillance; IR, immediate release.



Using poison center exposure calls to predict prescription opioid abuse and misuse-related emergency department visits

Davis JM, Severtson SG, Bucher-Bartelson B, Dart RC
Pharmacoepidemiology and Drug Safety

E-publication Date 10/17/2013 ([click here](#))

Emergency department (ED) visits resulting from prescription drug overdose have more than doubled from 2004 to 2010. The Drug Abuse Warning Network (DAWN), a federally-funded program which reported ED data, was downsized dramatically in 2011, leaving a gap in prescription drug surveillance.

Poison centers (PCs) have the potential to act as sentinel reporting entities for prescription drug abuse and misuse due to near-real-time data reporting and abundant coverage in the US.

Data from the RADARS System PC Program were compared with data from DAWN from 2004 through 2010 to determine if PCs could fill the gap in surveillance of prescription drug abuse and misuse.

Data on prescription opioid drug abuse from the RADARS System PC program correlate well with ER data from DAWN (Figure 4). Due to timeliness of data, geographic coverage and strong associations with other warning systems, PC data can be used for sentinel reporting on prescription drug abuse and misuse in the US.

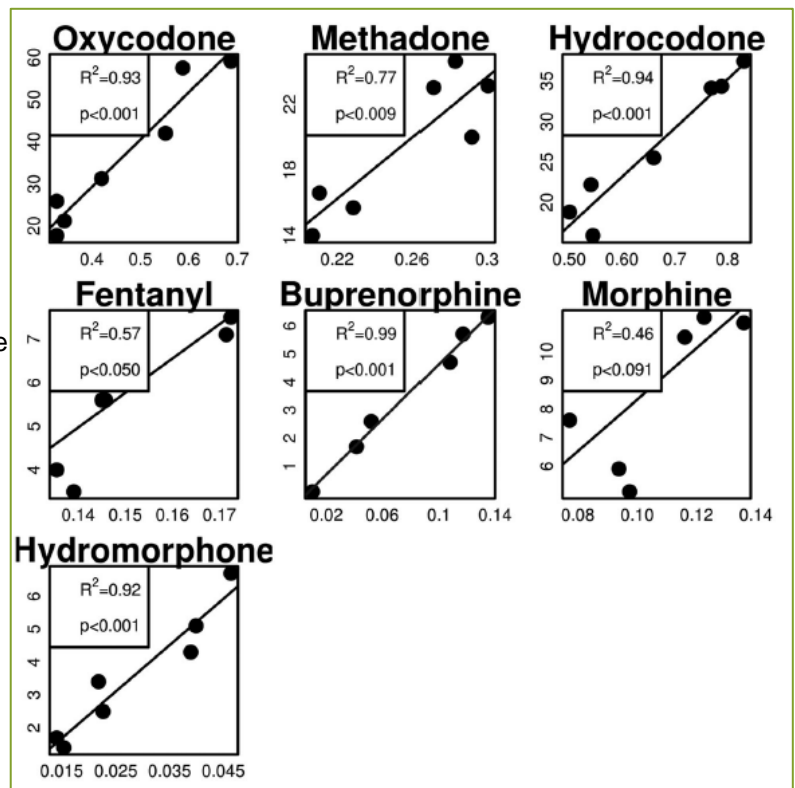


Figure 4. Class-specific linear associations between programs including all Researched Abuse, Diversion and Addiction-Related Surveillance System poison center program exposure calls with recorded medical outcomes. Rates per 100 000 population from Drug Abuse Warning Network are presented on the y-axis, and rates per 100 000 population from Researched Abuse, Diversion and Addiction-Related Surveillance are presented on the x-axis.

Recent Conference Attendance

2013 American Association for the Treatment of Opioid Dependence (AATOD) Conference
November 9-13, 2013 in Philadelphia, PA

Dr. Green presented “**New Substances of Abuse in Europe: Results from a EUROPAD Pilot Study in Four Countries**” at the World Federation for the Treatment of Opioid Dependence (WFTOD), which is a part of the 2013 AATOD Conference (<http://www.wftod.org>).

Study Objective:

- ◆ Assess overall rates and trends of prescription drug misuse in European countries.

Study Methods:

- ◆ Survey newly-enrolled patients (at intake) about their recent use of prescription drugs to get “high”.
- ◆ Data collected from January 2012 through August 2013.

Key Findings:

- ◆ Drug endorsements vary depending on country – fentanyl concentrated in Germany; heroin was by far the highest reported endorsed drug across participating countries.
- ◆ Drug rankings much different than United States.
- ◆ This pilot proof of concept study was successful; therefore, expansion will begin with new sites and into new countries.

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EUROPAD Drug Rankings by Country					
Rank	France	Germany	Italy	Spain	Total
1	Heroin	Heroin	Heroin	Heroin	Heroin
2	Buprenorphine	Methadone	Buprenorphine	Methadone	Methadone
3	Codeine	Fentanyl	Methadone	Codeine	Buprenorphine
4	Methadone	Buprenorphine	Codeine	Tramadol	Fentanyl
5	Morphine	Tramadol	Tramadol	Buprenorphine	Codeine
6	Fentanyl	Morphine	Fentanyl	Morphine	Tramadol
7	Tramadol	Codeine	Hydrocodone	Fentanyl	Morphine
8	Methylphenidate	Oxycodone	Oxycodone	Hydrocodone	Oxycodone
9	Oxycodone	Methylphenidate	Hydromorphone	Hydromorphone	Hydrocodone
10	Hydrocodone	Hydrocodone	Methylphenidate	Methylphenidate	Methylphenidate
11	Hydromorphone	Hydromorphone	Oxymorphone	Oxycodone	Hydromorphone
12	Oxymorphone	Oxymorphone	Morphine	Oxymorphone	Oxymorphone

Colloque Européen et International Toxicomanies Hépatites SIDA European Conference and International Symposium (THS-11: Addiction-Hepatitis-AIDS).

October 8-11, 2013 in Biarritz, France.

Dr. Dart led 2 sessions: “**Are Abuse Deterrent Formulations Effective?**” and “**Prescription Opioid Analgesic Dependence and Addiction: Experience in the United States**”.

Asia Pacific Association of Medical Toxicology (APAMT) International Scientific Congress

November 21-23, 2013 in Dubai, United Arab Emirates

Dr. Green presented **“Strategies that have been effective in tackling prescription medicine misuse in the USA”** (<http://www.asiattox.org/>).

International Society of Addiction Medicine (ISAM) Annual Meeting

November 21-23, 2013 in Kuala Lumpur, Malaysia

Presented as posters:

- ◆ Primary Drug of Health Care Workers in Italy and Spain using EUROPAD Pilot Study Data (Lavery et al.)
- ◆ Opioid treatment patient drugs of use trends in Europe: A comparison with U.S. trends from the past decade (Martinez et al.)

Upcoming Conference Attendance

American College of Medical Toxicology (ACMT) Annual Scientific Meeting

March 27-30, 2014 in Phoenix, AZ

To be presented as platforms:

- ◆ Buprenorphine/Naloxone Addiction and Diversion: Film Rates are Less Than Tablet Rate (Green et al.)
- ◆ Buprenorphine/Naloxone Pediatric Ingestion: Exposure Rates Differ Between Film and Tablet Formulations (Green et al.)

American Society of Addiction Medicine (ASAM) Annual Medical-Scientific Conference

April 10-13, 2014 in Orlando, FL

To be presented as a poster:

- ◆ Buprenorphine/Naloxone Pediatric Ingestion: Exposure Rates Differ Between Film and Tablet Formulations (Lavonas et al.)

American Pain Society (APS) Annual Scientific Meeting

April 30 – May 3, 2014 in Tampa, FL

To be presented as posters:

- ◆ The role of tapentadol ER in the illicit market for opioid analgesics in the United States (Le Lait et al.)
- ◆ Reformulation of extended release oxycodone: changes in intentional abuse exposures before and after introduction of tamper resistant formulation (Severtson et al.)

Canadian Pain Society Annual Scientific Meeting

May 20-23, 2014 in Quebec City, Canada

Dr. Dart to present the following Symposia: **“The Changing Landscape of Prescription Opioid Abuse and Misuse: A North American Epidemic”**.

European Association of Poison Centres and Clinical Toxicologists (EAPCCT) International Congress

May 27-30, 2014 in Brussels, Belgium

Dr. Dart to present: **“International Overview of Prescription Drug Misuse”** (provisional title).

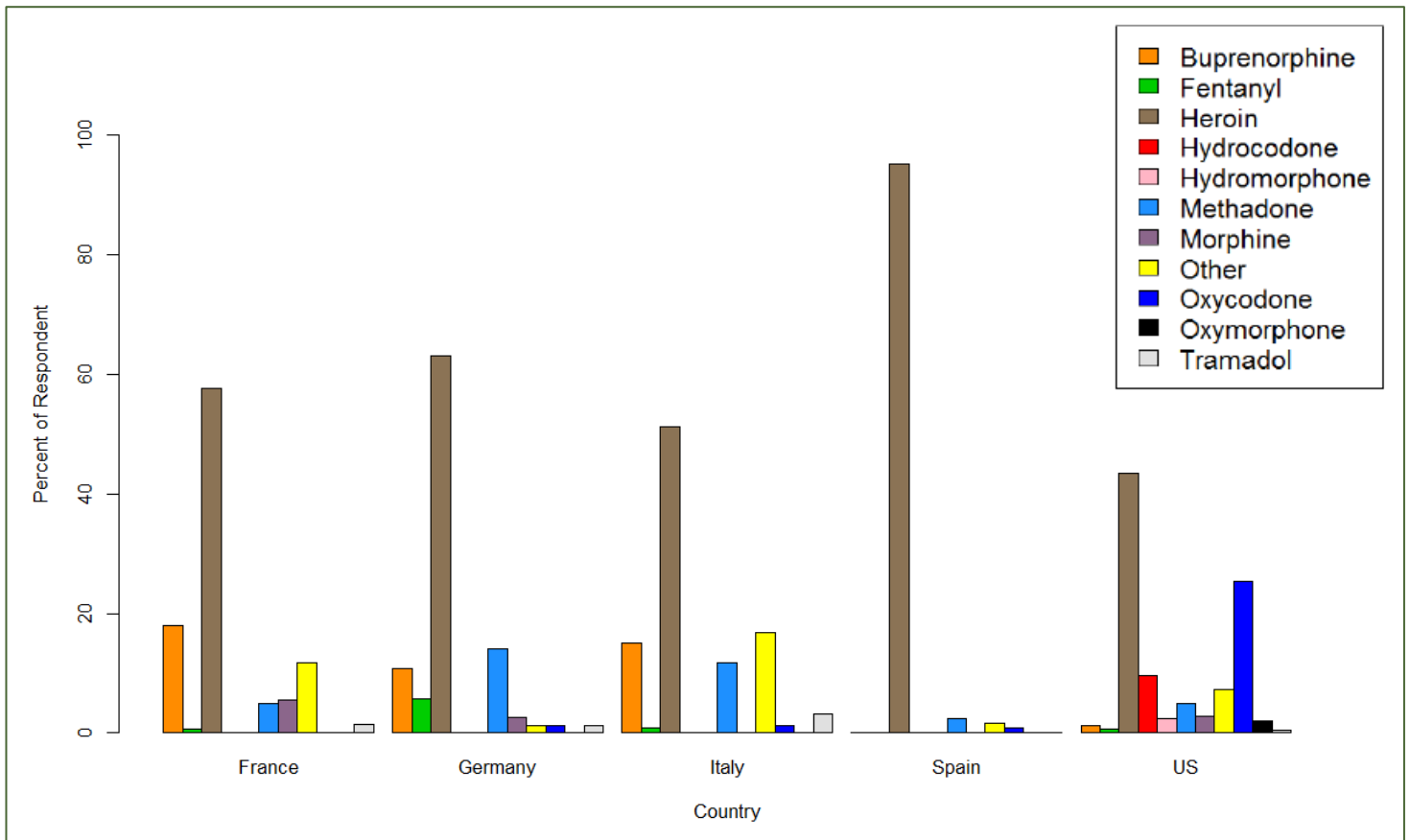
Primary Drug of Patients Entering Treatment for Opioid Dependence: Europe and the US

Prescription opioid abuse is a well-documented issue in the US; the RADARS System is expanding to include surveillance of prescription opioid abuse in Europe.

Data from surveys provided to adult patients entering opioid treatment programs from 2012Q1 through 2013Q3 were summarized to describe the primary drug used “to get high”.

In the US, data were collected by the RADARS System Opioid Treatment Program (OTP) and Survey of Key Informants' Patients (SKIP) Program. In France, Italy, Germany and Spain, data were collected by the EUROPAD Program.

- ◆ Heroin was the most frequently reported primary drug in all countries surveyed.
- ◆ In EU countries surveyed, methadone and buprenorphine were the most frequently reported primary drug.
- ◆ In the US, oxycodone and hydrocodone were the most frequently reported primary drug.
- ◆ The reported primary drug for prescription opioids abused varies across countries surveyed.



The RADARS® System Opioid Treatment Program and Survey of Key Informants' Patients and EUROPAD Program percent of respondents primary drug from 2012Q1 through 2013Q3



Hydrocodone in the News

In late October 2013, the FDA announced a formal recommendation to the Department of Health and Human Services that hydrocodone combination products, such as Vicodin®, be reclassified from a schedule III to a schedule II drug. This move comes despite past concerns that this reclassification may result in added hardship for pain patients.

A New York Times article (10/24/2013) reported the reclassification, set to take effect in early 2014, will reduce the patient prescription supply by half (90 days from 180 days) and require the patients to take the prescription to the pharmacy, eliminating the option for doctors to call it in. As hydrocodone is the most widely abused prescription drug in the US, the FDA has been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse.

Recently, the FDA approved Zohydro® ER (hydrocodone bitartrate extended-release capsules) as a schedule II opioid analgesic. Zohydro ER will be the first ER hydrocodone product approved for chronic use. The manufacturer, Zogenix, has announced a partnership with Altus Formulation Inc. to develop an abuse deterrent formulation to reduce abuse potential; currently, Zohydro has no such deterrent mechanisms in place.

The FDA approved Zohydro ER only for patients whose chronic pain cannot be managed by non-opioid analgesics or immediate-release opioids and is not indicated for as-needed use. The new hydrocodone product is set to hit US market in early 2014.



RADARS System Programs

The RADARS System has been growing - we now have 7 programs in our United States surveillance mosaic:

- ◆ **Drug Diversion:** Over 300 drug diversion investigators and regulatory agencies across the US are surveyed quarterly and asked to report the number of new diversion cases investigated in that quarter.
- ◆ **Poison Center:** Spontaneous reports of intentional exposure mentions of acute medical events are collected from 51 of 60 US poison centers. Reports are sent weekly for internal validation.
- ◆ **Treatment Programs:** Consists of both the Opioid Treatment Program and the Survey of Key Informants' Patients Program combined, providing prescription drug abuse data from the perspective of the patient seeking treatment for opioid abuse. The participating substance abuse treatment programs (public and private) from across the United States recruit patients at enrollment to complete an anonymous questionnaire on the patient's drugs of choice, drug use in the past month, lifetime drug abuse, age at first use and primary source of abused drugs.
- ◆ **College Survey:** Online questionnaire collecting data from self-identified students attending a 2- or 4-year college, university or technical school at least part-time during the specified sampling period. Data are collected at the completion of fall and spring academic semester/quarters and at the end of summer.
- ◆ **StreetRx:** Street price of prescription and illicit drugs is captured through a publically accessible website (www.StreetRx.com) allowing for anonymous submissions of prices paid for specific drugs. Geographical area is also captured. Site visitors can view others' submissions of price paid for illicit and prescription drugs.
- ◆ **Web Monitoring:** Qualitative measure of prescription drug abuse, misuse and associated consequences reported via the internet. The qualitative data captured in this program are intended to complement other RADARS System Programs, lending context and depth to the counts and rates generated.

And we are expanding our international efforts by partnering with professionals around the globe to institute similar surveillance programs in Canada and Europe.

- ◆ **Global Toxicosurveillance Network (GTNet):** European Poison Centre Program
- ◆ **European Opioid Treatment Patient Survey (Europad):** European Opioid Treatment Program
- ◆ **StreetRx:** Street price of prescription and illicit drugs captured through a publically accessible website (www.StreetRx.com: currently in Canada, France, Germany, Italy, Spain and the United Kingdom)
- ◆ **European Web Monitoring (eWM):** Qualitative measure of prescription drug abuse reported via the internet
- ◆ **European Internet Survey (eIS):** Self-reported online survey

RADARS System in Social Media – Get Connected!



The RADARS System is tweeting [@RADARS_System](#). You can find news relating to prescription drug surveillance and abuse, in the US and abroad. RADARS System tweets include publication announcements, conference attendance and program updates. We have doubled our followers since September, **come follow us!**



In addition, publication and conference attendance news can be found on our LinkedIn site (www.linkedin.com).



Exciting news for www.RADARS.org: active links to available presentations, conference abstracts and manuscript abstracts ([Publications](#)).

RADARS System Quarterly Technical Report

RADARS System Technical Report #2013Q4

Impact of Tamper Resistant Formulations on Rates of Abuse of Schedule II Opioids

[Click Here for Access](#)

Recent RADARS System Publications

Manuscripts in Press (E-publication not yet available):

- ◆ Surratt HL, O'Grady C, Kurtz SP, Stivers Y, Cicero TJ, Dart RC, Chen M. Reductions in prescription opioid diversion following recent legislative interventions in Florida. *Pharmacoepidemiology and Drug Safety*.
- ◆ Davis JM, Searles VB, Severtson G, Dart RC, Bucher-Bartelson B. Seasonal variation in suicidal behavior with prescription opioid medicine. *Journal of Affective Disorders*.

Just Published:

- ◆ Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. Factors influencing the selection of hydrocodone and oxycodone as primary opioids in substance abusers seeking treatment in the United States. *Pain*. 2013;154(12):2693-2648. No Epub date available.
- ◆ Giraudon I, Lowitz K, Dargan PI, Wood DM, Dart RC. Prescription Opioid Abuse in the United Kingdom. 2013. *British Journal of Clinical Pharmacology*. 2013;76(5):823-824. Epub Date 04/19/2013.
- ◆ Lavonas EJ, Banner W, Bradt P, Bucher-Bartelson B, Brown KR, Rajan P, Murrelle L, Dart RC, Green JL. Root causes, clinical effects, and outcomes of unintentional exposures to buprenorphine by young children. *Journal of Pediatrics*. 2013;163(5):1377-1383. Epub Date 09/03/2013.
- ◆ Severtson SG, Bucher Bartelson B, Davis JM, Muñoz A, Schneider MF, Chilcoat H, Coplan PM, Surratt H, Dart RC. Reduced abuse, diversion, and therapeutic errors following reformulation of OxyContin® in 2010. *Journal of Pain*. 2013;14(10):1122-1130. Epub Date 07/03/2013.
- ◆ Smith SM, Dart RC, Katz NP, Paillard F, Adams EH, et al. Classification and definition of misuse, abuse, and related events in clinical trials: ACTION systematic review and recommendations. *Pain*. 2013;154:2287-2296. No Epub date available.

Did You Know?

The DEA is proposing to place tramadol into Schedule IV
Docket No. DEA-351

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RADARS System Mission Statement

The RADARS System provides timely, product specific and geographically-precise data to the pharmaceutical industry, regulatory agencies, policymakers and medical/public health officials to aid in understanding trends in the abuse, misuse, and diversion of prescription drugs.

Rocky Mountain Poison and Drug Center and Denver Health and Hospital Authority

The RADARS System is a governmental nonprofit operation of the Rocky Mountain Poison and Drug Center (RMPDC), an agency of Denver Health (DH). The RMPDC has been in operation for more than 50 years, making it one of the oldest poison control centers in the nation. DH is the safety net hospital for the City and County of Denver and is the Rocky Mountain region's academic Level I trauma center and includes Denver Public Health, Denver's 911 emergency medical response system, nine family health centers, 12 school-based clinics, NurseLine, correctional care, Denver CARES, the Denver Health Medical Plan, and the Rocky Mountain Center for Medical Response to Terrorism, Mass Casualties and Epidemics.

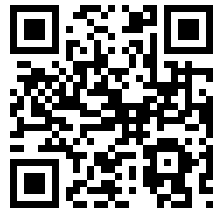


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