Buprenorphine in the Treatment of Opioid Addiction: Balancing Medication Access with Quality Care

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Opening Remarks

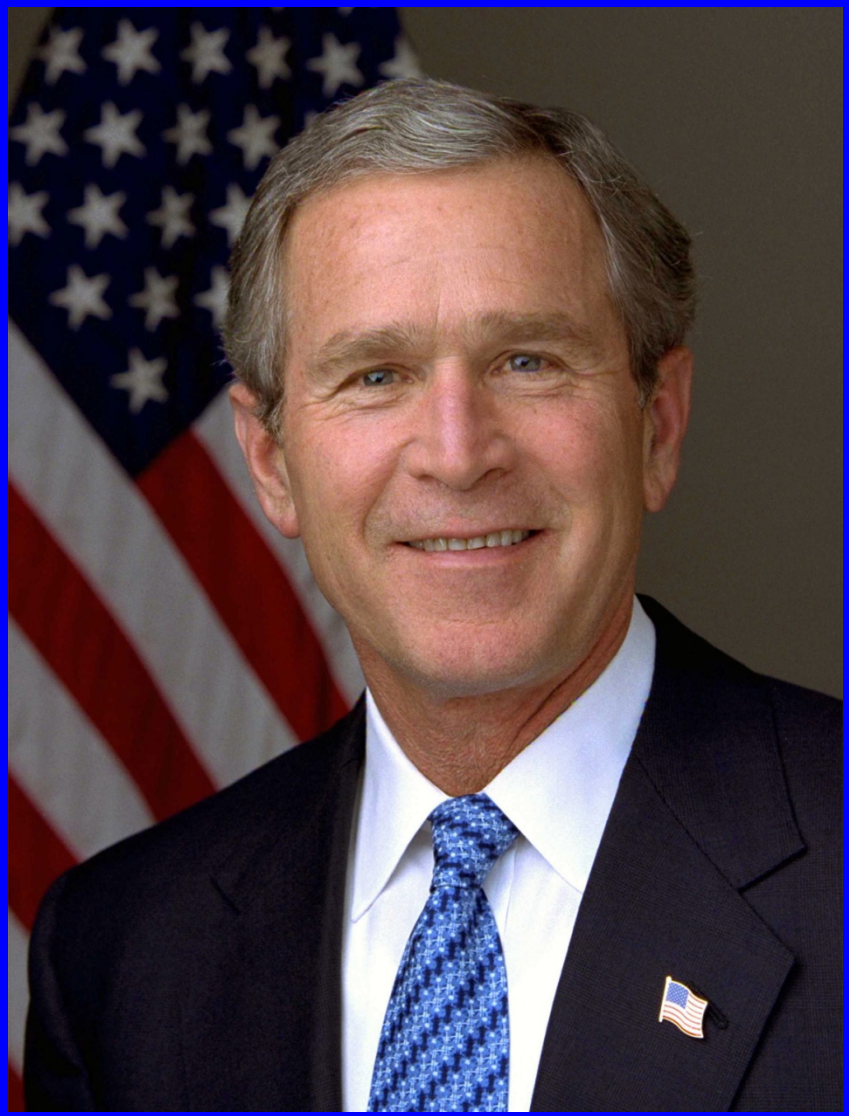
February 21, 2008

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM

Director

Center for Substance Abuse Treatment

Substance Abuse and Mental Health Services Administration



President George W. Bush

"Alcohol addiction and drug addiction are diseases that touch all Americans -- young and old, rich and poor, male and female. As a Nation, we must continue our efforts to offer the best possible opportunities, settings, and approaches to prevent and treat alcohol and drug addiction."

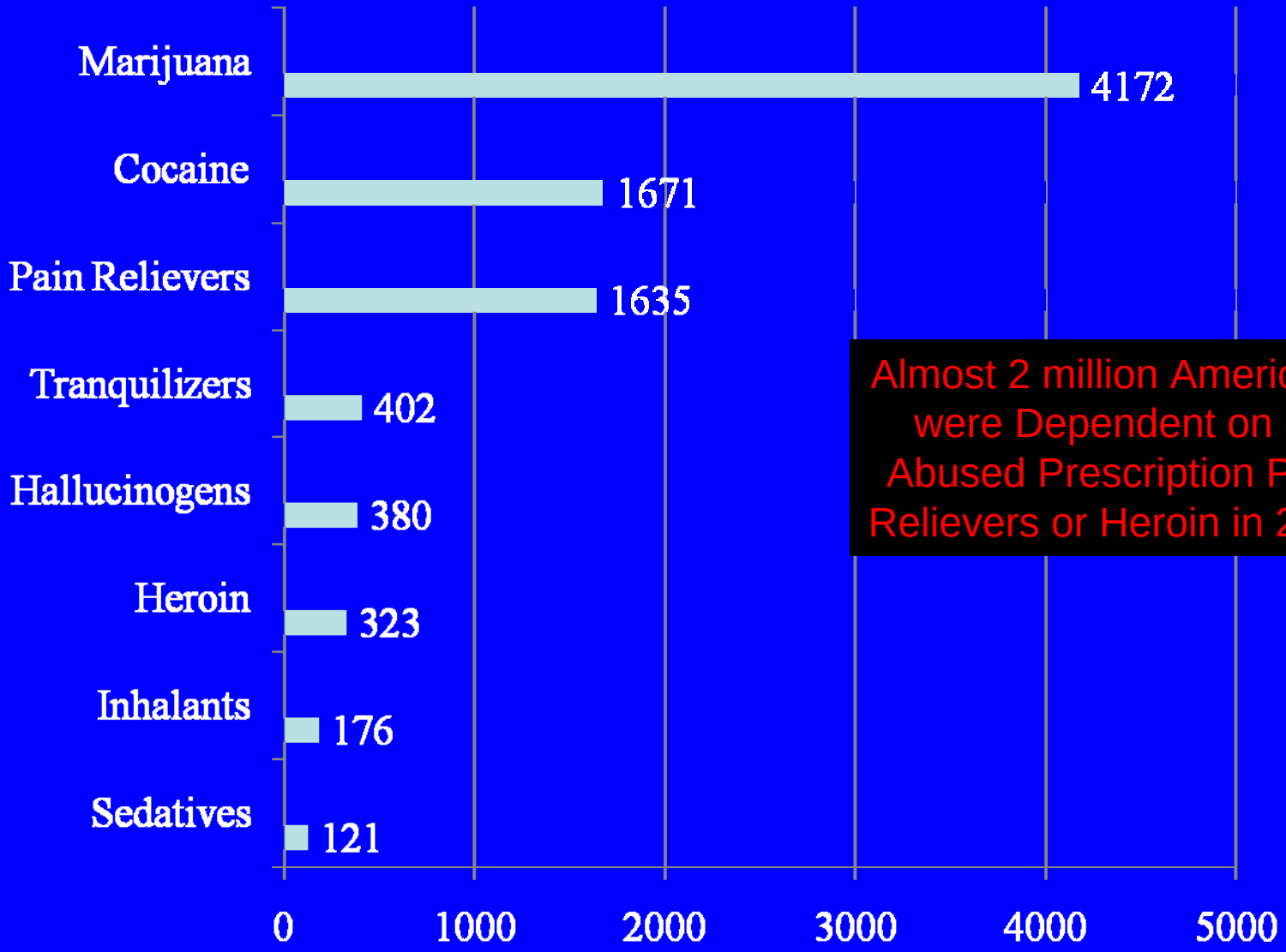
September 2003

President George W. Bush

"The drug trade has enriched our society's enemies. It has funded acts of terror. It feeds an addiction that causes some Americans to turn to crime ."

December 11, 2007

Dependence on or Abuse of Specific Drugs in the Past Year among Persons Aged 12 or Older: 2006



Almost 2 million Americans were Dependent on or Abused Prescription Pain Relievers or Heroin in 2006

NSDUH 2006

The Case for Buprenorphine

- The spread of HIV in the U.S. is fueled in part by the use of illicit drugs.
- Injection drug use is directly related to HIV transmission through the sharing of drug equipment
- The use of both injected and noninjected drugs impairs decision-making and increases sexual risk-taking behavior, which increases the risk for acquiring HIV.
- "Even though substance abuse treatment is crucial for staying in HIV care and adhering to a treatment regimen, it is in short supply. The introduction of buprenorphine…offers hope for improved access to treatment for addiction."

Source: Health Resources and Services Administration, *Substance Abuse and HIV/AIDS In the United States*, June 2006, retrieved 2/15/08

HIV/AIDS

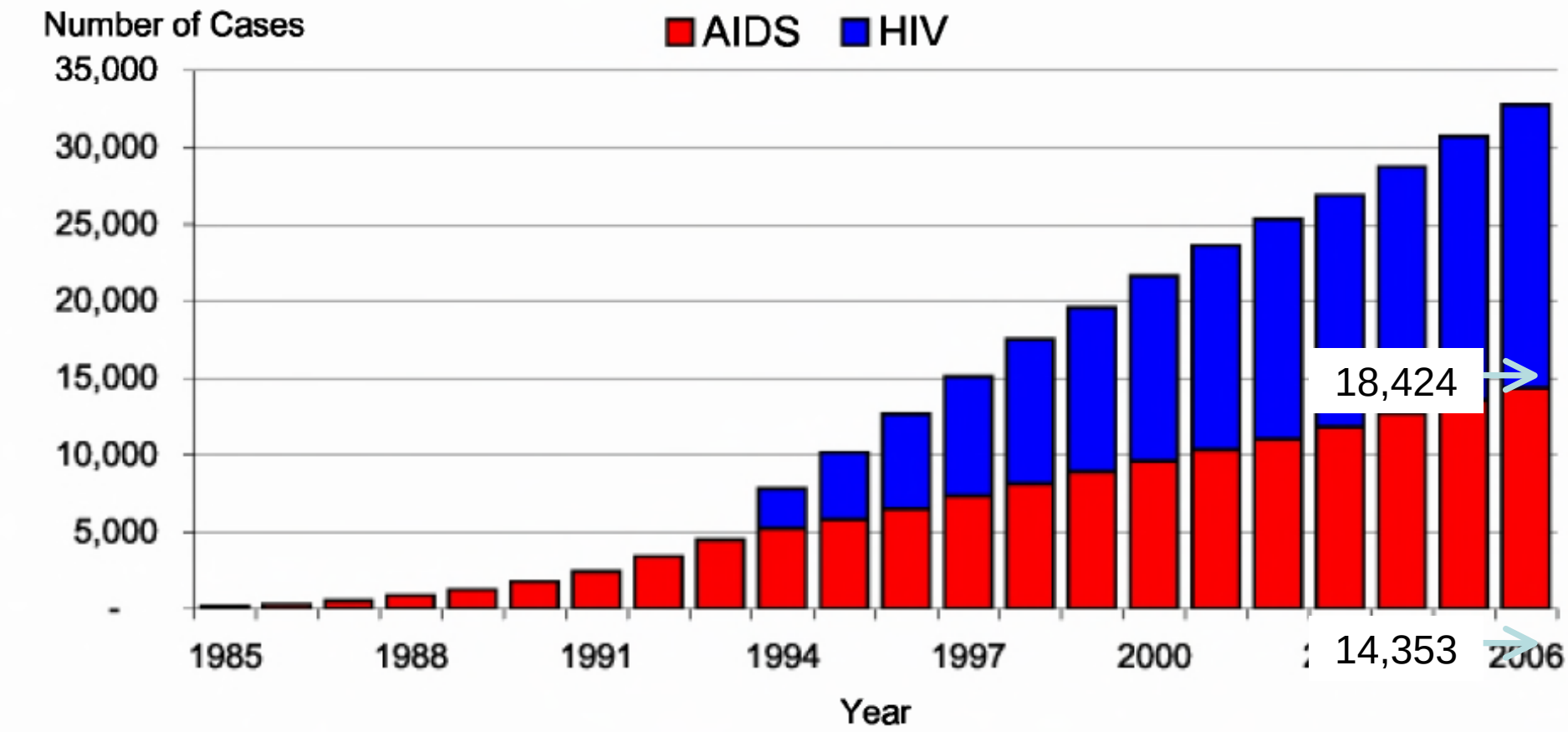
According to CDC data on U.S. adolescents and adults – in 2005:

- Approximately 20% of the reported new AIDS cases were related to injection drug use.
- 20% of males and 33% of females living with AIDS were exposed through injection drug use.
- Almost one-third (28.2%) of AIDS deaths were adolescents and adults infected through injection drugs.

Source: Centers for Disease control and Prevention, *HIV/AIDS Surveillance Report*, Vol. 17, Revised Edition, June 2007, retrieved 2/15/08.

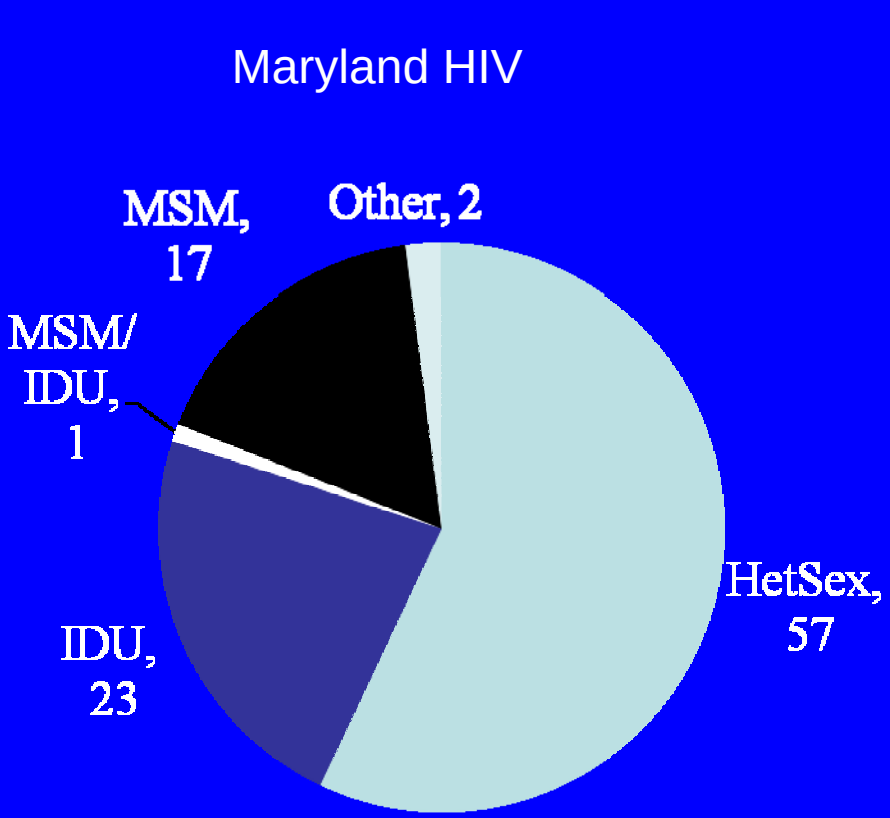
Maryland HIV/AIDS Epidemiological Profile as of September 30, 2007

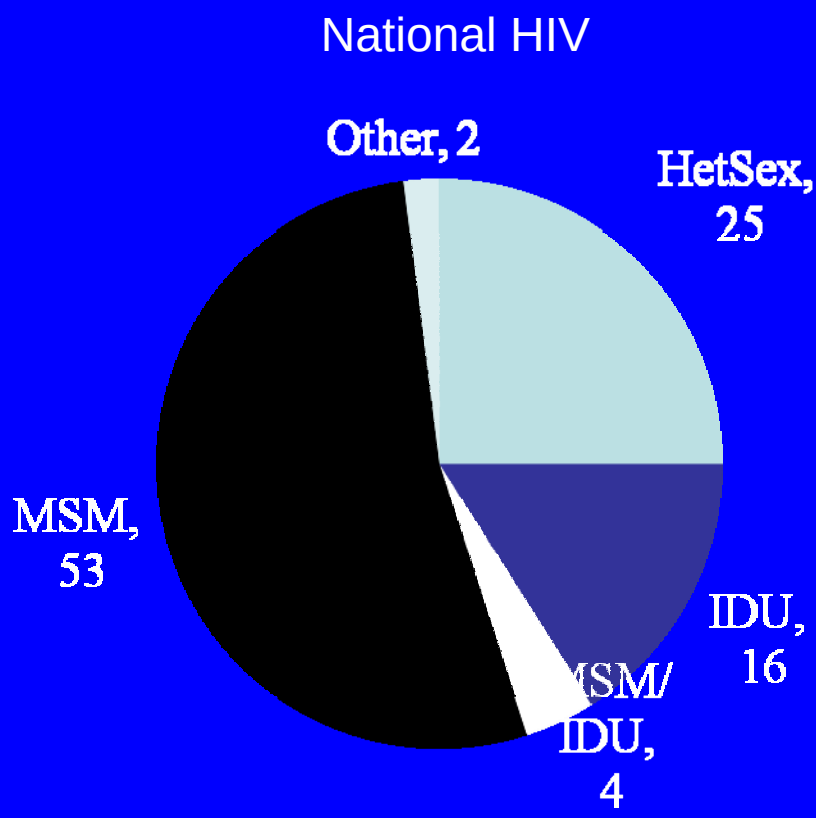
Prevalent (Living) HIV and AIDS Cases on December 31st of Each Year as Reported through 9/30/07



Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

HIV Cases Reported During 1/1/05-12/31/05

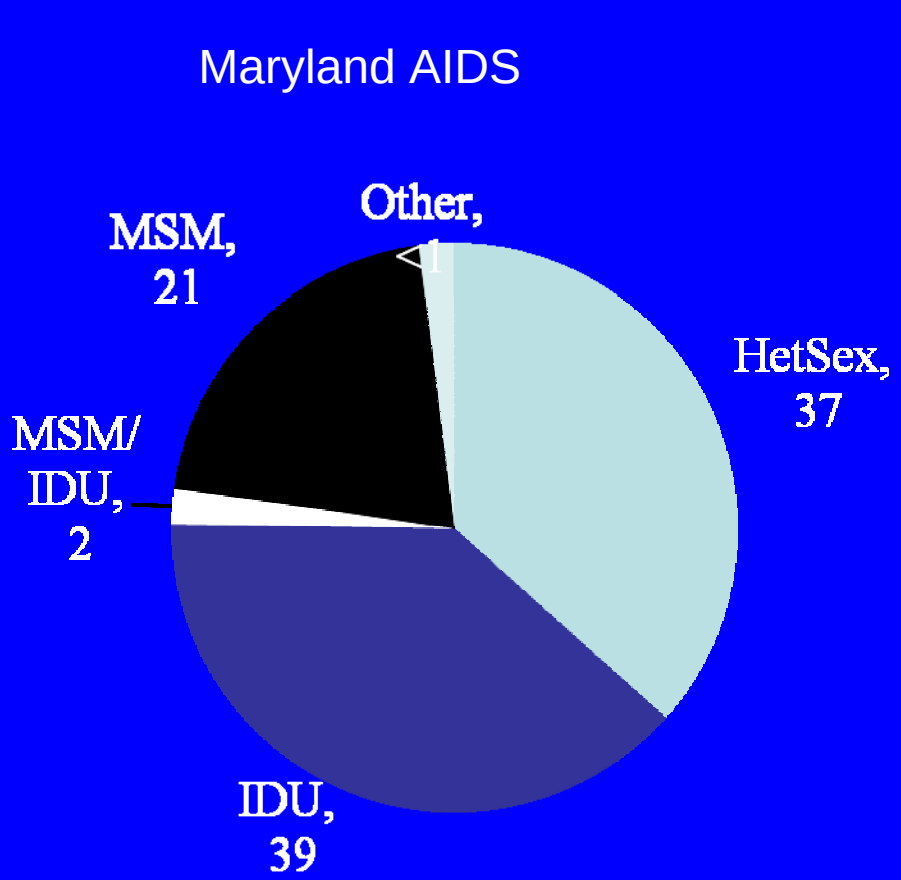


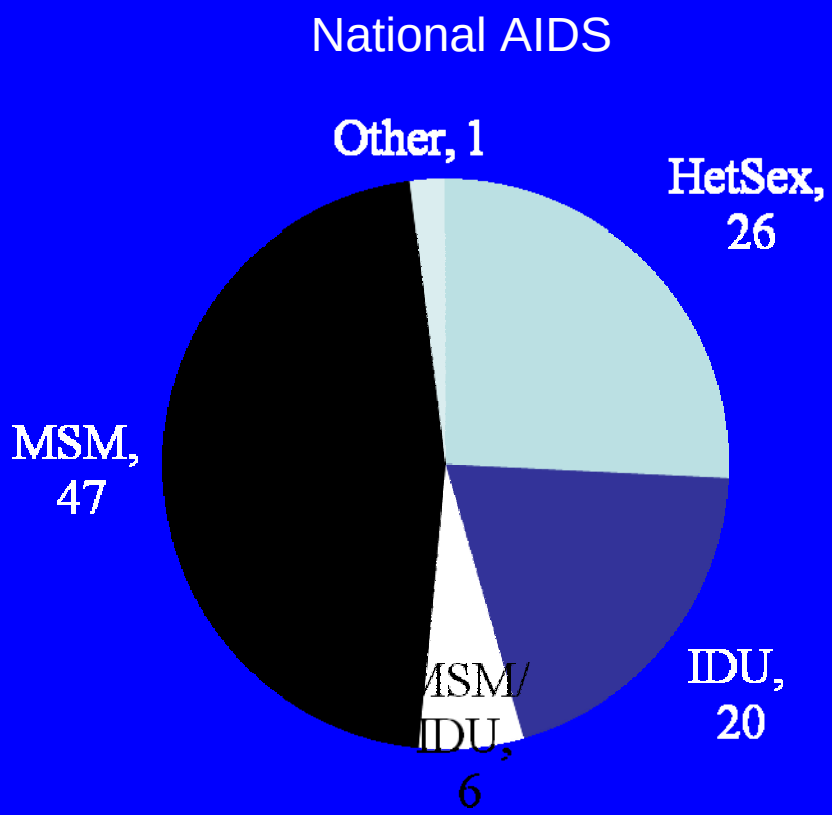


Percent

Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

AIDS Cases Reported During 1/1/05-12/31/05





Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

AIDS Cases Reported During 1/1/05-12/31/05

- Maryland had the third highest annual AIDS case report rate of any state in 2005
  - 28.5 cases per 100,000 population
- Baltimore-Towson had the second highest rate of any metropolitan area in 2005
  - 40.5 cases per 100,000 population
- The National rate in 2005 was 14.0 cases per 100,000 population

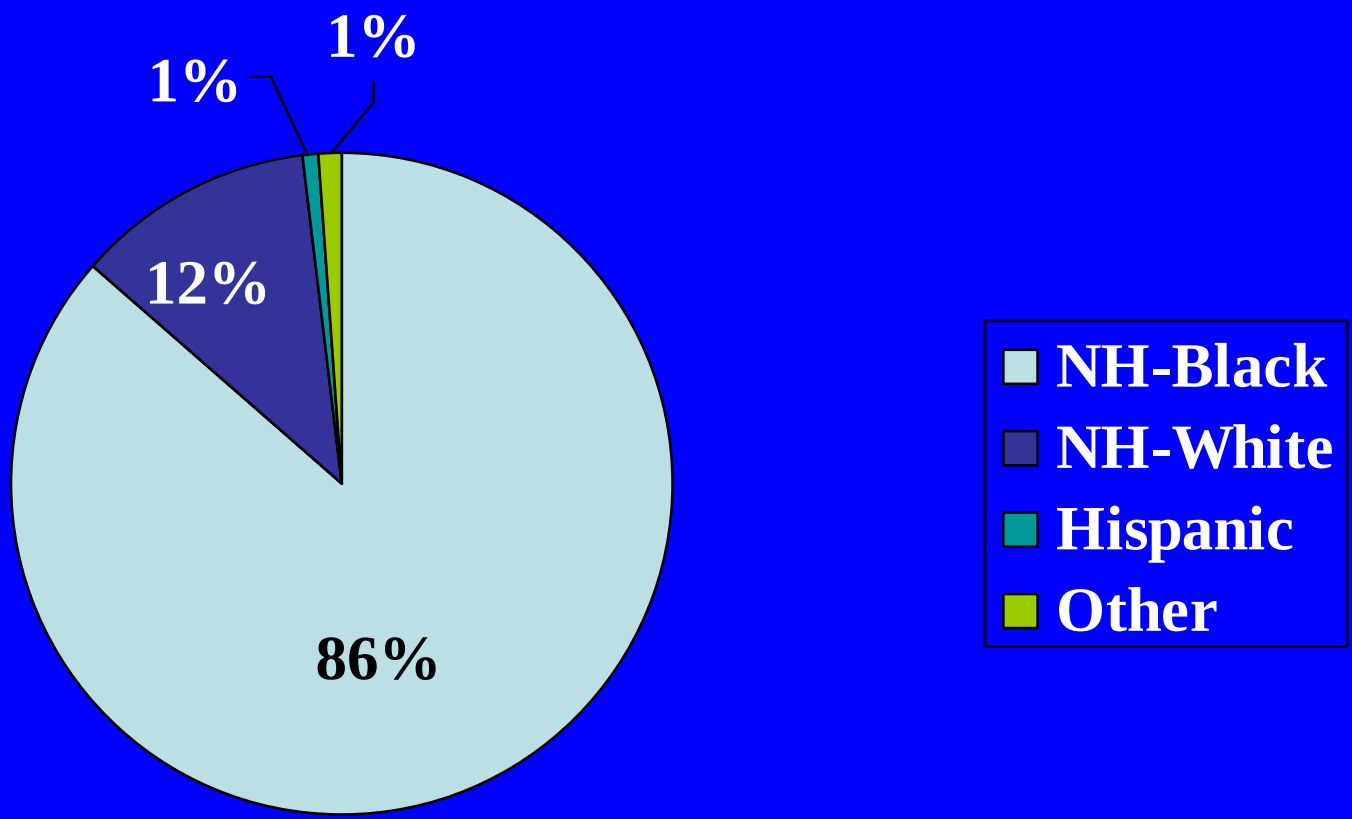
Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

Baltimore City HIV/AIDS Statistics October 4, 2007

	Cases	**Cases per 100,000 Population**
HIV Incidence during 2006	1,021 Cases	156.8 cases per 100,000 population
AIDS Incidence during 2005	690 Cases	106 cases per 100,000 population
HIV/AIDS Prevalence on 12/31/2006	15,685 Cases	2,451.8 cases per 100,000 population
AIDS Deaths during 2005	326 deaths	

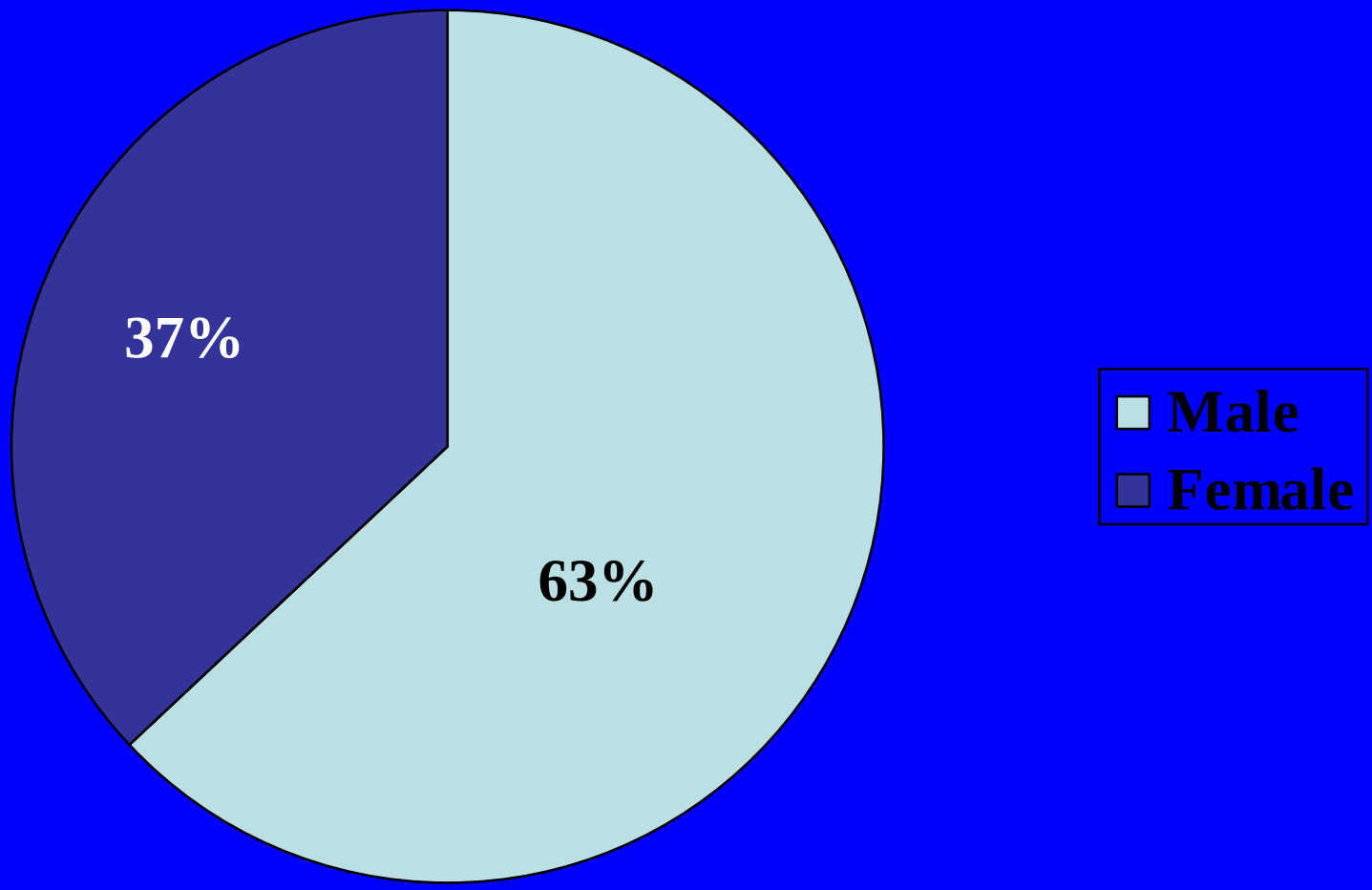
Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

Race/Ethnicity for 2006 HIV Incidence Baltimore City



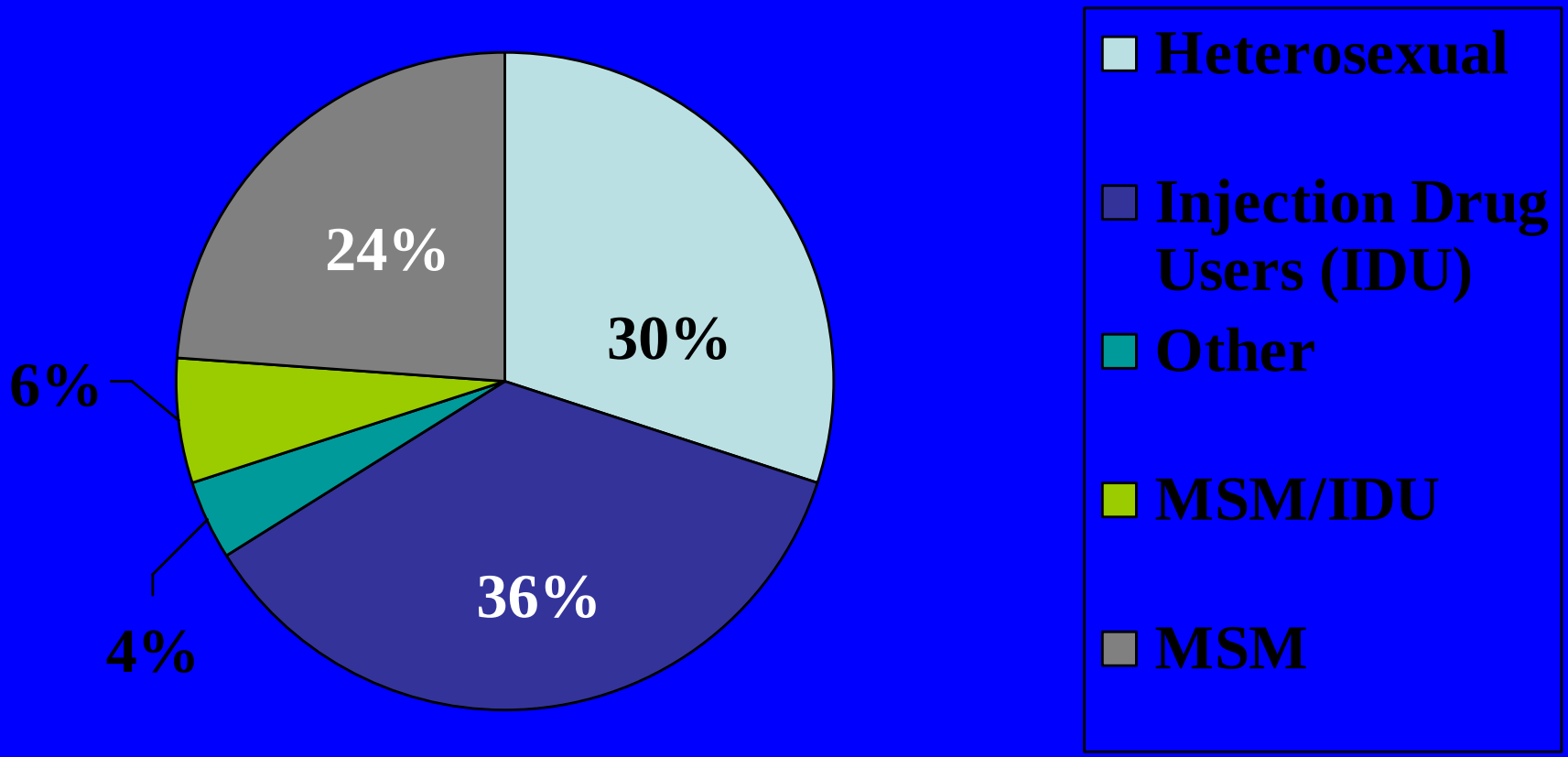
Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

Gender for 2006 HIV Incidence Baltimore City



Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

Risk for 2006 HIV Incidence Baltimore City

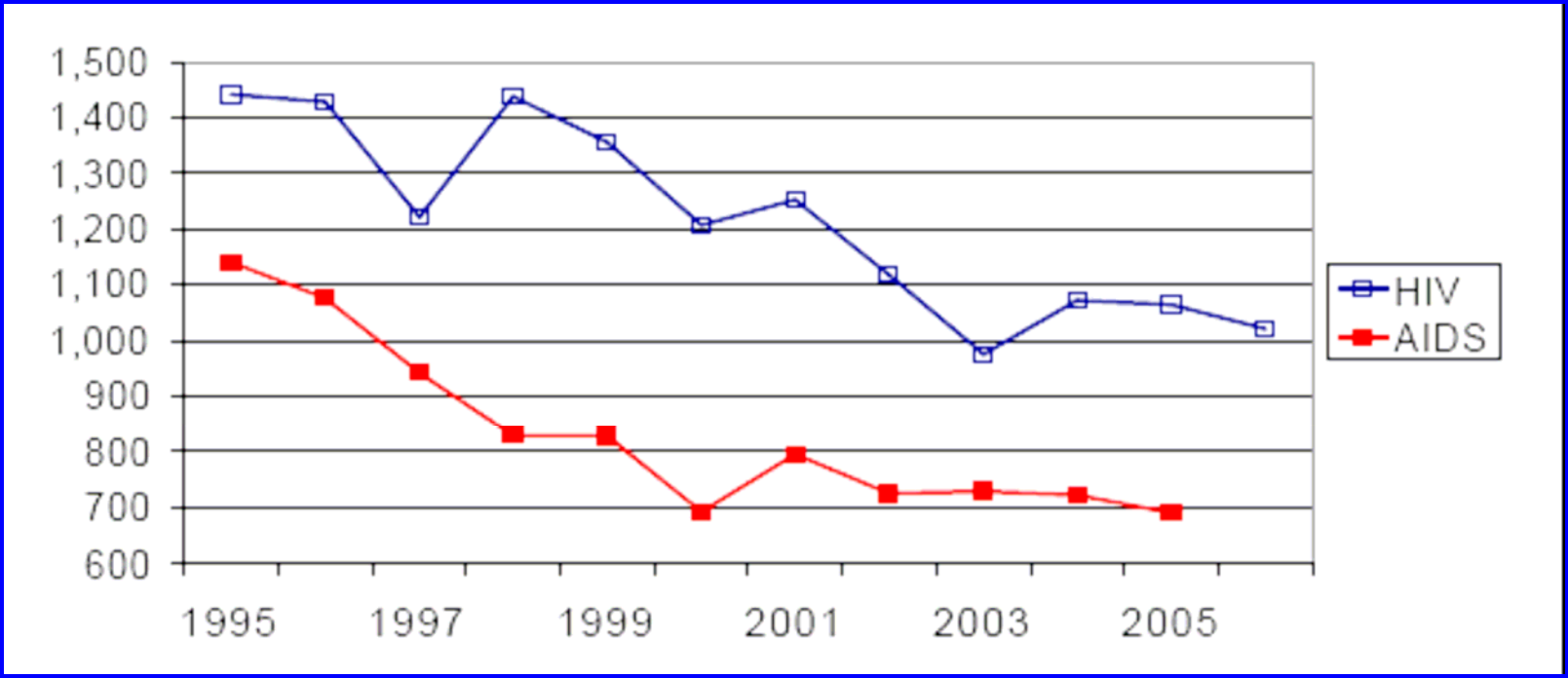


MSM= Men who had sex with men

MSM/IDU = Men who had sex with men & were injection drug users

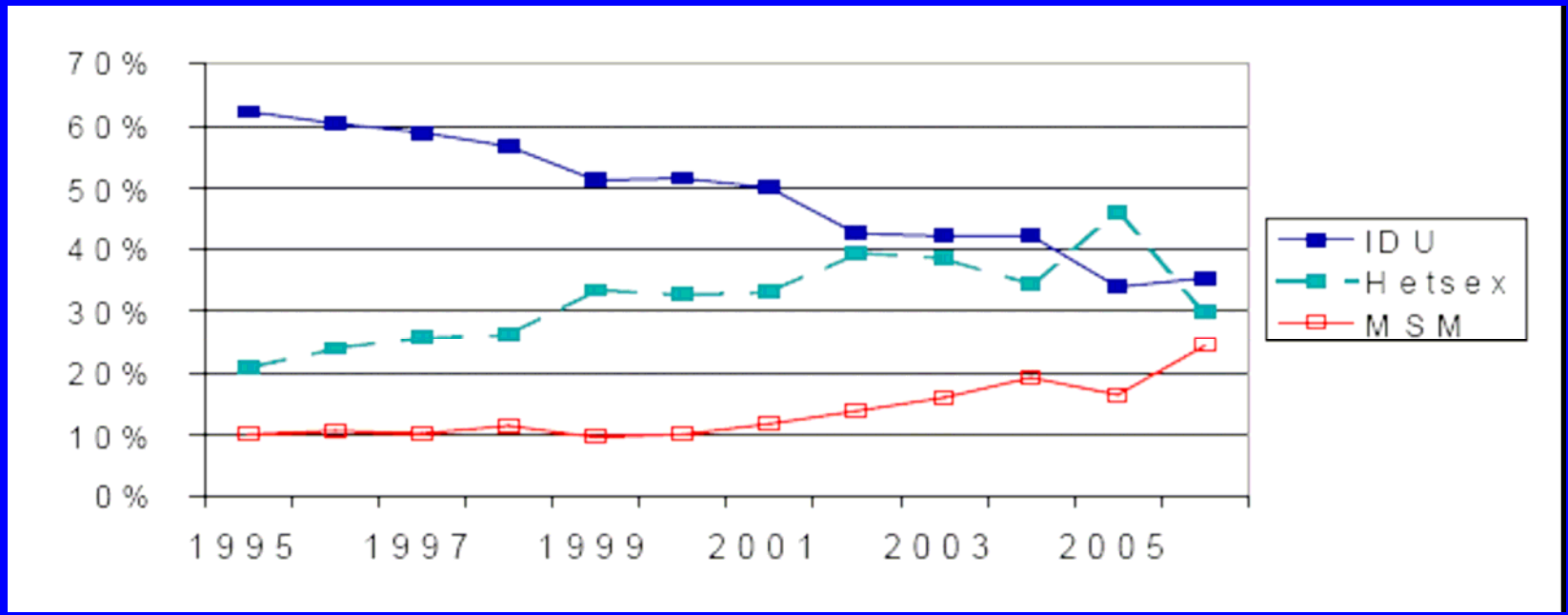
Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

Baltimore City HIV and AIDS Incidence



Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

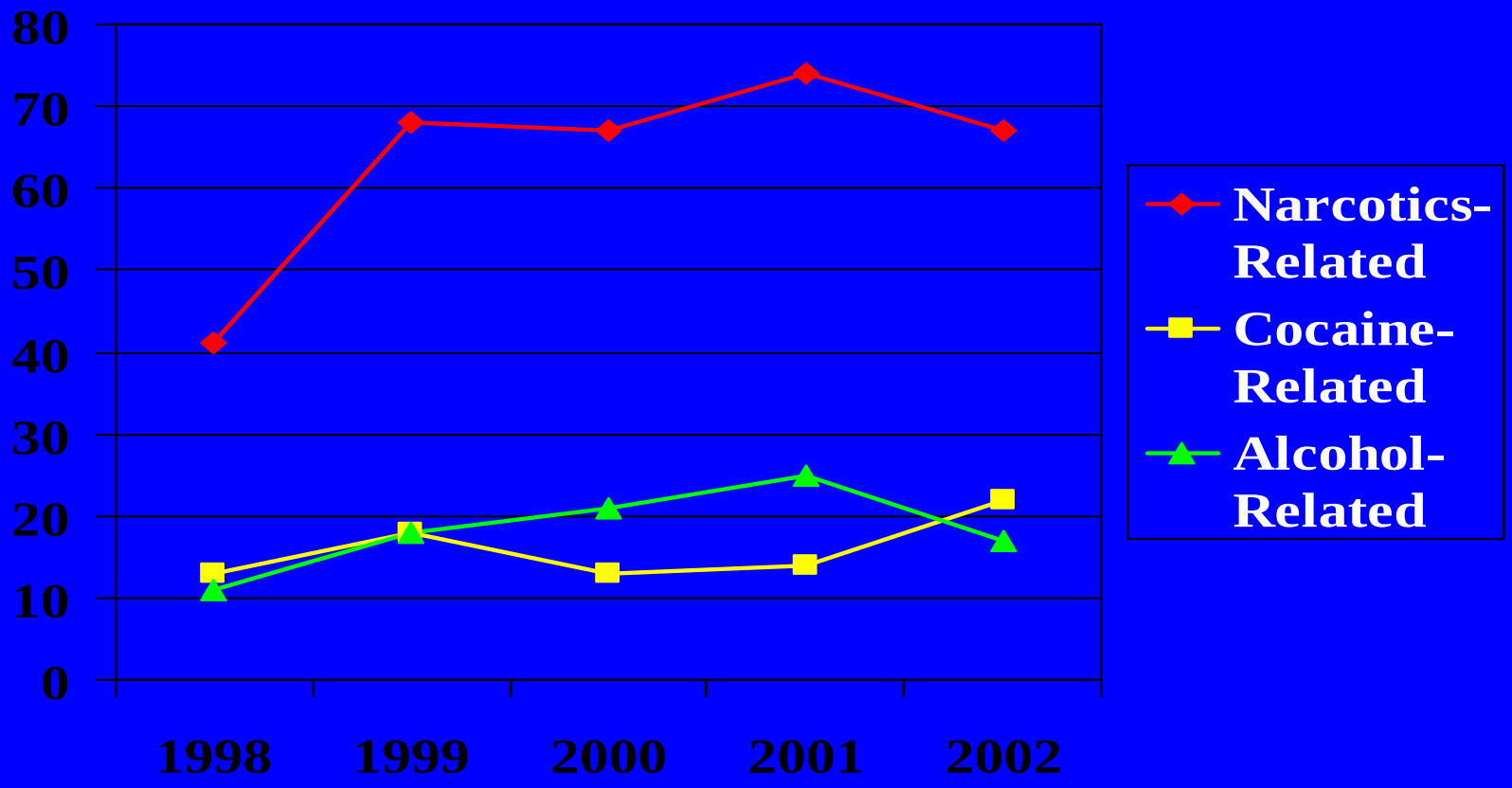
Risk by Year of HIV Diagnosis Baltimore City



MSM= Men who had sex with men
IDU = injection drug users

Source: Maryland Dept. of Health & Mental Hygiene, AIDS Administration, October 4, 2007, retrieved 2/20/08

Overdose Deaths in Baltimore County 1998-2002



Source: Adapted by CESAR from data from the Office of the Chief Medical Examiner (OCME), October 2001, February 2002, and February 2003. retrieved 2/20/08

2008 Summit Goals

To bring together experts in epidemiology, pharmacology, toxicology, and addiction treatment to build upon the findings of the previous summits in 2003 and 2005 by:

- Assessing the successes, progress and continued barriers to access to opioid treatment with buprenorphine,
- Identifying best practices and useful clinical supports to enhance the quality of treatment, and
- Identifying and developing strategies to address emerging issues and concerns.

Building upon the 2005 Summit Findings

April 2005 Summit Findings

- There is a critical need to expand the number of primary care physicians who are trained and certified to prescribe buprenorphine.
  - Emerging challenge: many physicians who have not previously treated addiction require more than one-time buprenorphine training.
  - Widespread support and mentoring strategies are needed.

April 2005 Summit Findings

- There is a need for the government to overcome barriers to access to buprenorphine treatment, specifically:
  - Limitations caused by the 30 patient restriction
  - Inadequate funding by buprenorphine medication
  - Insufficient physician interest in buprenorphine training
  - A need for physician linkages to ancillary services, including psychiatric services.

Increases in Patient Limits

- In July 2005, Congress removed the 30-patient restriction on medical groups that prescribe buprenorphine for opioid dependence & addiction.
  - The 30-patient limit was then applied to each physician's caseload, rather than to that of the entire clinic.
- Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) increased the number of buprenorphine patients a physician can treat to 100, if specific conditions are met.

Improved Physician & Treatment Program Locator

- **The Physician & Treatment Program Locator** is an on-line resource designed to assist States, medical and addiction treatment communities, potential patients, and/or their families in finding information on locating physicians and treatment programs authorized to treat opioid addiction with buprenorphine.
- In response to physician requests, the locator was expanded to list multiple locations for physicians who have more than one practice location.
- Web site: http://buprenorphine.samhsa.gov/bwns_locator/dr_facilitylocatordoc.htm

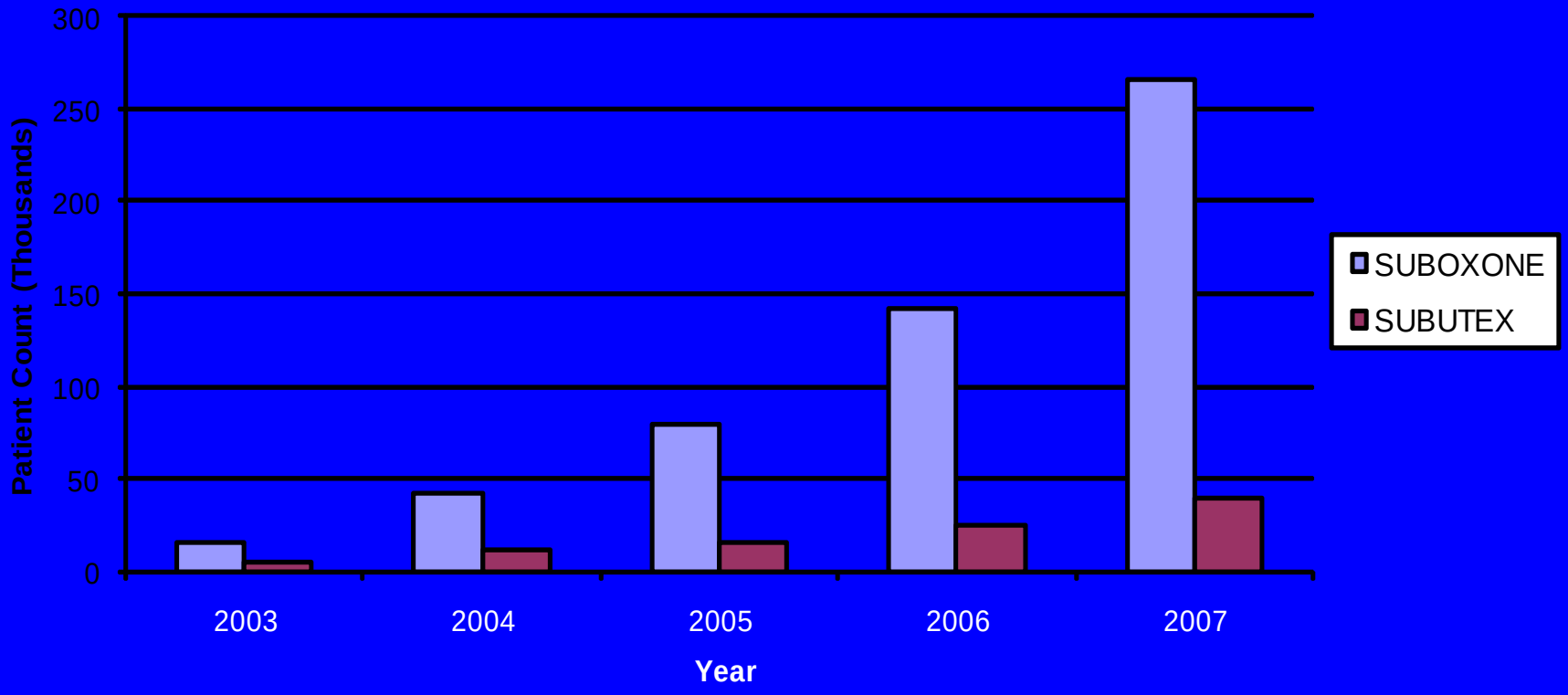
Additional and Expanded Training Materials

- **Additional and expanded training materials** have been developed – many through the NIDA-SAMHSA "Blending Initiative."
- The initiative is a unique partnership that uses the expertise of both agencies to quickly apply research results to practical use in improving the treatment of substance use disorders.
- Web site: www.nida.nih.gov/blending

The Physician Clinical Support System

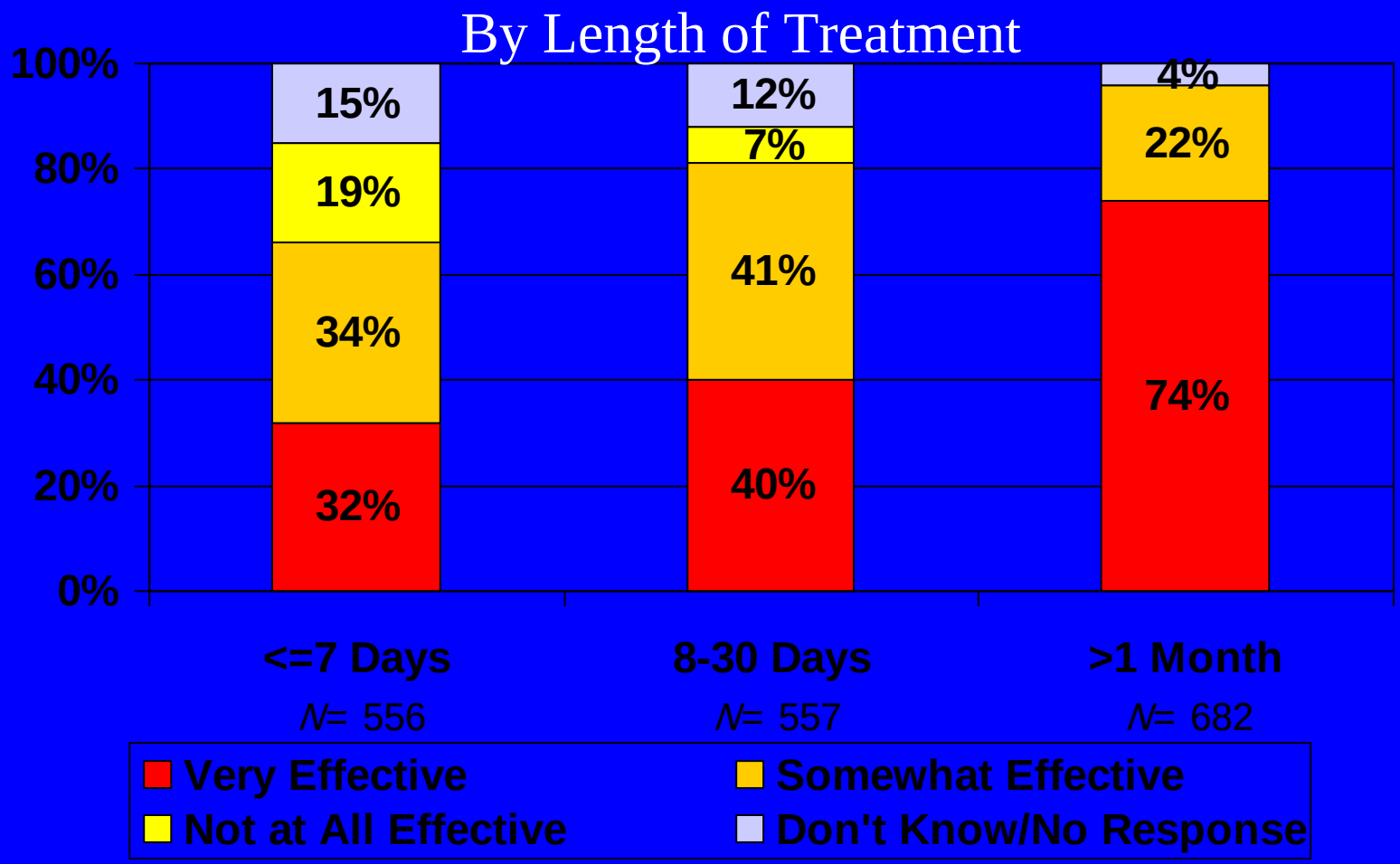
- **The Physician Clinical Support System (PCSS)** for Buprenorphine has been created in collaboration with the American Society of Addiction Medicine (ASAM).
- Physicians who prescribe or dispense buprenorphine can contact the PCSS.
- The PCSS is a free, national service staffed by 45 trained physician mentors, a PCSS medical director and 5 physicians, who are national experts in the use of buprenorphine.
- Support is via telephone, email, and/or at the place of clinical practice.
- Web site: www.PCSSmentor.org

Total Number of Patients that Filled a Prescription for Suboxone and Subutex in U.S. Retail Pharmacies, 2003-2007



Source: Verispan Total Patient Tracker, Extracted Feb. 2008

Prescribing Physicians'* Perceptions of BUP Effectiveness, 2005



*Views of physicians who reported some experience treating for that length of time

Source Waivered Physician Survey, 10/31/05

Challenges

Buprenorphine Treatment Issues

- Training within medical school and residence
- Use in pain management and addiction
  - Managing patients with pain conditions and who are addicted to opioids
- Adverse events reported to emergency rooms and poison control centers
- Diversion
- New patient limits
- Prescription Drug Monitoring Programs
  - National All Schedules Prescription Electronic Reporting (NASPER)

Accidental Ingestion by Children

- The increased use of buprenorphine magnifies the risk to children in homes in which it is used.[1]
- Clinicians should remain vigilant for pediatric exposures.[1]
- Clinicians should not assume that because Suboxone is a combination of buprenorphine and naloxone that pediatric patients are not at risk for opioid toxicity.[2]
- Patients receiving buprenorphine on an outpatient basis should be educated regarding steps they can take to ensure the drug is not accessible to any young children in their homes.[1]

[1]Geib, A; Babu, K; Ewald, M; Boyer, E; Adverse Effects in Children After Unintentional Buprenorphine Exposure, *Pediatrics*, October 2006, published online October 2, 2006, retrieved 2/15/08

[2]Schwarz, K, Cantrell, F, Vohra, R, Clark, R, Suboxone (Buprenorphine/Naloxone) Toxicity in Pediatric Patients: A Case Report, *Pediatric Emergency Care*, September 2007, retrieved 2/15/08

ED Visits Involving Accidental Ingestion by Children

Drugs	5 yrs & younger	6-11 years
Buprenorphine	**26**	**0**
Oxycodone/combination	167	9
Methadone	55	3
Hydrocodone/combination	252	12
Fentanyl/combinations	13	2
Hydromorphone/combinations	10	0

Source: SAMHSA DAWN Live!, 2004-2/15/08, accessed 2/15/08
NOTE: Data is unweighted and is from hospitals participating in DAWN, so is not representative of total hospitals in the U.S.

National Drug Intelligence Center Intelligence Bulletin- Buprenorphine: Potential for Abuse

- September 2004
- Suboxone can be diverted and abused
  - More likely to be abused by individuals who are addicted to low doses of opiates since it can precipitate withdrawal symptoms in high doses.
    - The naloxone in Suboxone guards against abuse by causing withdrawal symptoms in abusers who crush and either inject or snort the drug;
    - however, law enforcement and pharmacist reporting indicates that Suboxone is being abused successfully when snorted.

Subutex Abuse & Diversion

- Subutex, the form that does not contain naloxone, is more vulnerable to abuse because it can be crushed and injected or snorted without causing withdrawal symptoms in the abuser.
- Subutex has been prescribed legally for years in some foreign countries, where its diversion for illicit use is common.
- There are lucrative black markets for diverted Subutex in Germany, New Zealand, and the United Kingdom. In France, India, and Scotland, where buprenorphine is far more common in opiate addiction therapy than methadone, many individuals are addicted to Subutex. Suboxone is not available in these countries.

Source: NDIC Intelligence Bulletin: September 2004

Abuse & Diversion of Buprenorphine: U.S.

Despite controls designed to make buprenorphine diversion-proof, there have been reports of buprenorphine diversion throughout the United States, primarily in the Northeast region.

- **Chittenden County, Vermont**. A pharmacist in this area reports that Suboxone is being diverted and sold for $25 per 8-milligram tablet. Abusers are grinding the tablets and snorting them.

Source: NDIC Intelligence Bulletin: September 2004

Abuse & Diversion of Buprenorphine: U.S.

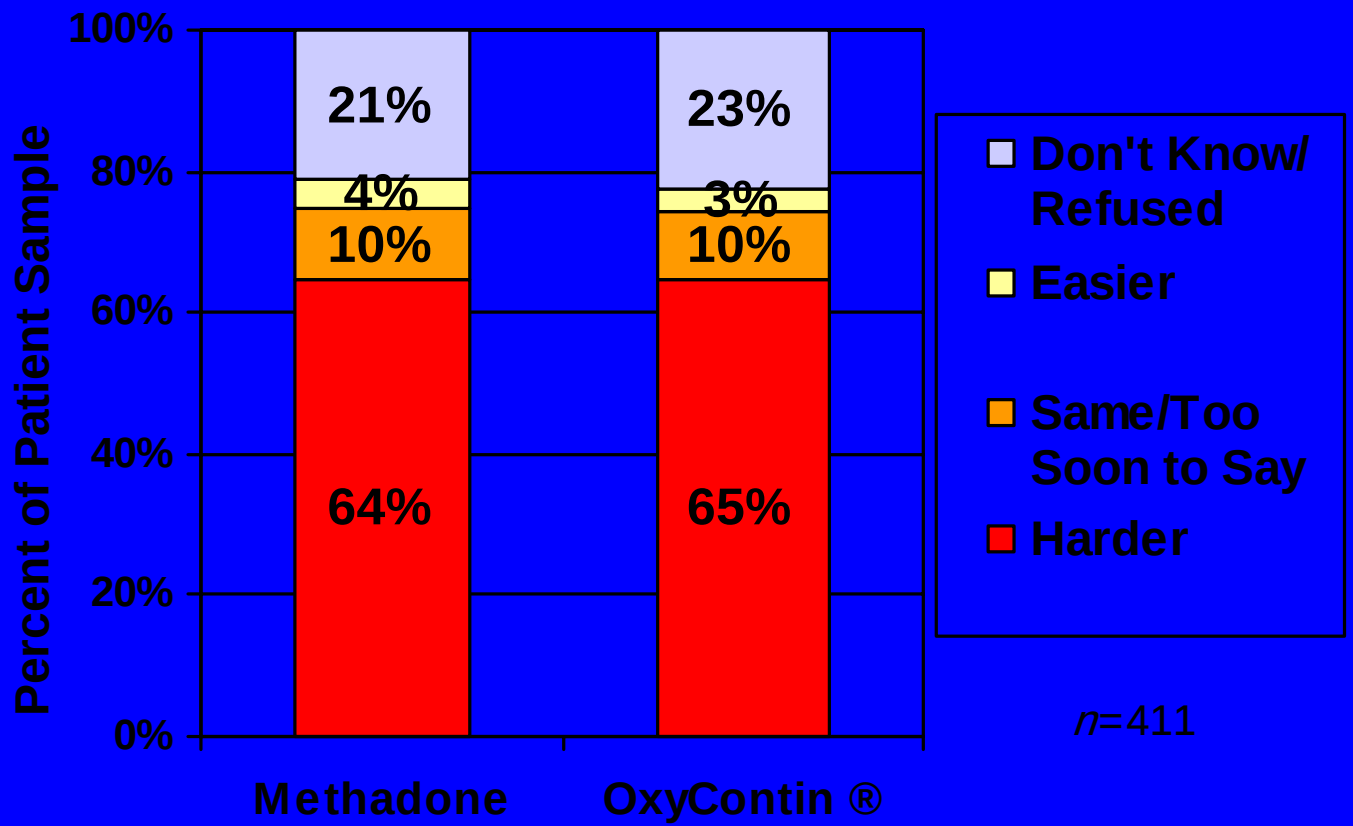
- **Washington County, Maine**. The Washington County Sheriff's Office reports that buprenorphine is being diverted in that area and sold for $50 per tablet. The size of the tablet is unknown, and it is unclear whether Subutex or Suboxone tablets are being diverted in this case.
- **Pennsylvania**. The Pennsylvania Department of Health reports that diverted Subutex and Suboxone are being illegally distributed on the street. Specific locations have not been identified.

Source: NDIC Intelligence Bulletin: September 2004

Buprenorphine Patient Reports of Diversion, 2005

"Compared to **OxyContin®** or **methadone**, how easy or hard do you think it is to buy or sell BUP on the street?"

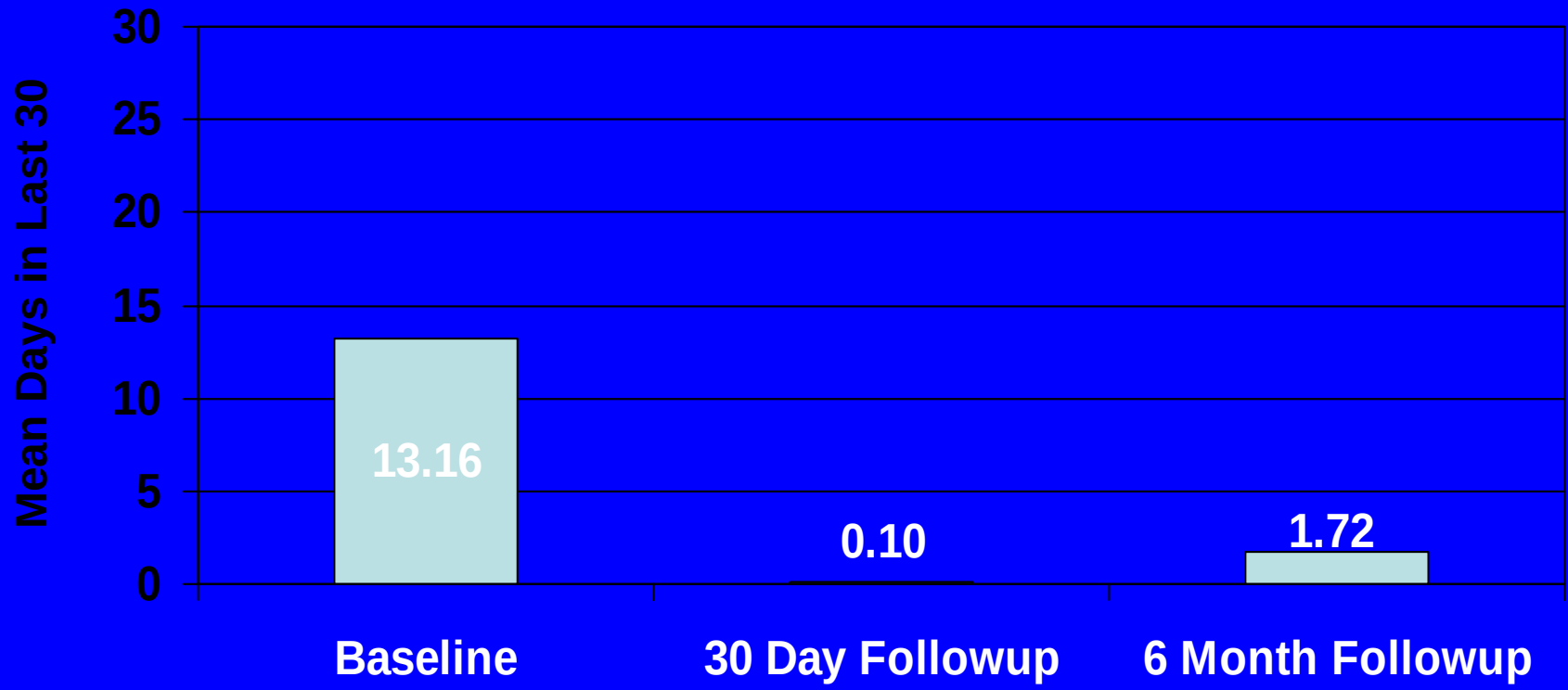
Responses were similar at baseline and 6 month followup.



Source: SAMHSA Patient Longitudinal Study, November 2005

Buprenorphine Patient Outcomes: Acquisition of Drugs on the Street

"In the past 30 days, how many days did you get drugs 'on the street'?"



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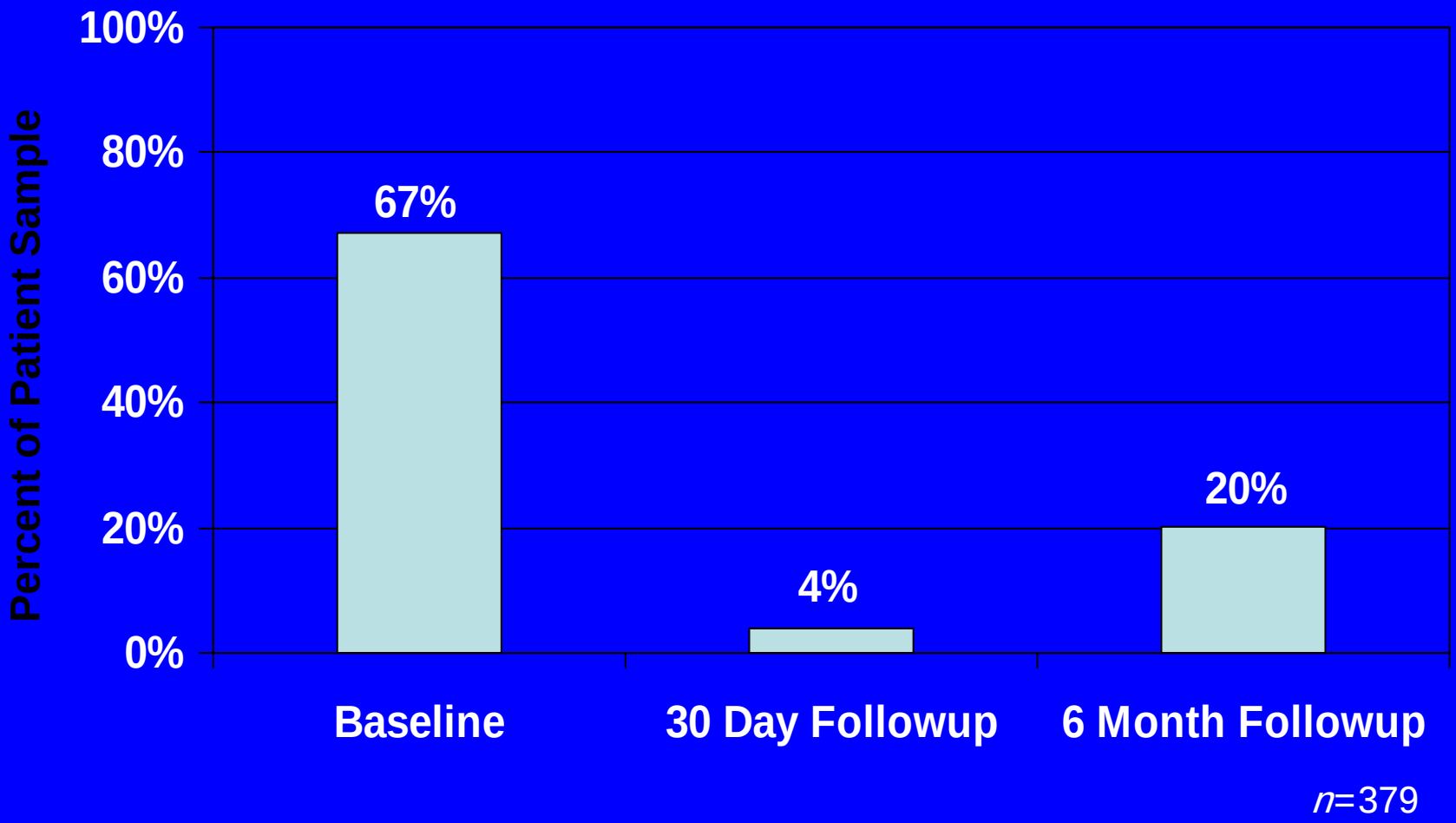
Source: SAMHSA Patient Longitudinal Study, November 2005

Buprenorphine Patient Outcomes: Percent of Patients Acquiring Drugs on the Street

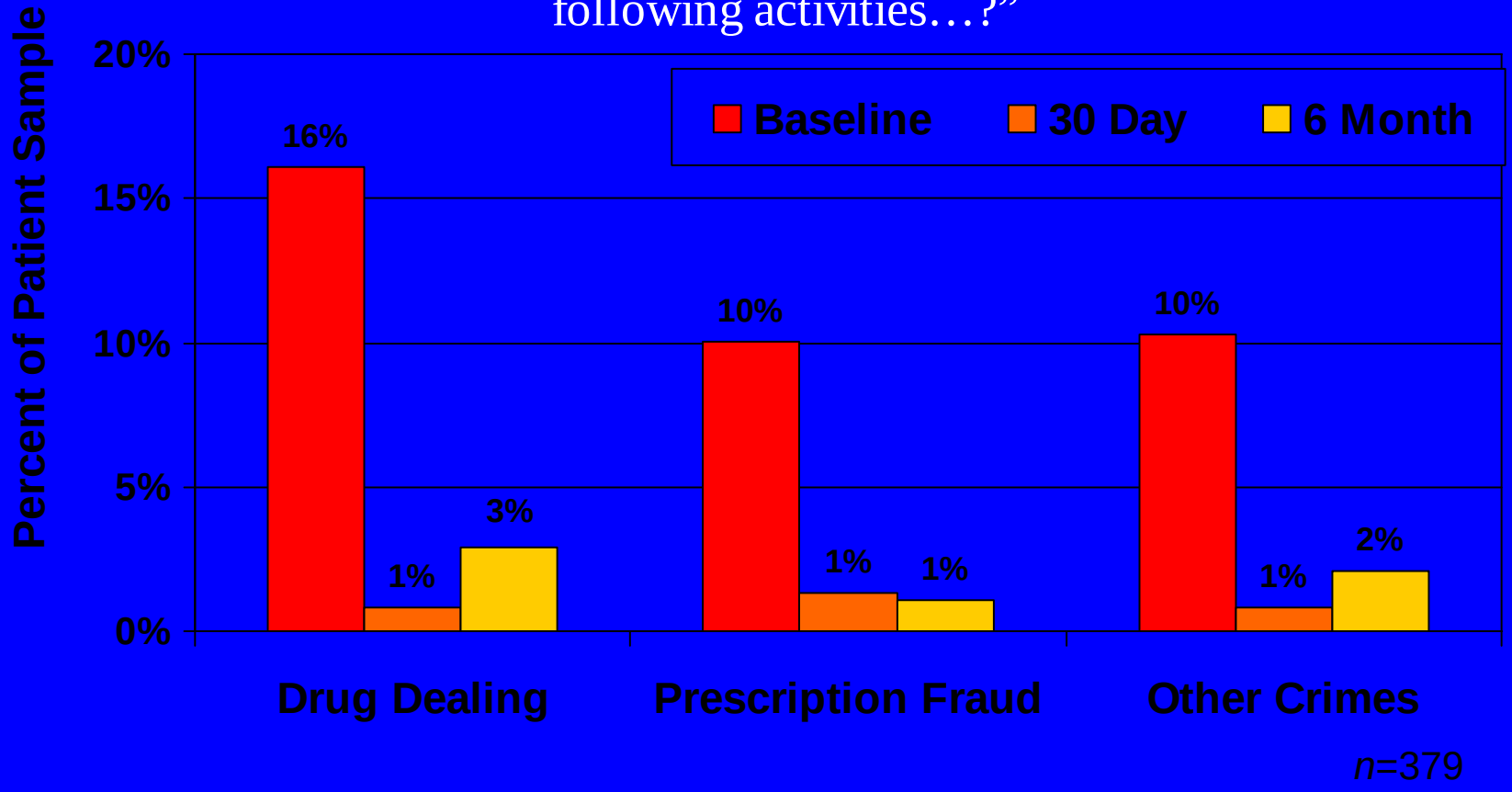


n=379

Source: SAMHSA Patient Longitudinal Study. November 2005

Buprenorphine Patient Outcomes: Specific Criminal Activities

"In the past 30 days were you involved in any of the following activities…?"



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Source: SAMHSA Patient Longitudinal Study, November 2005

Surveillance Report Conducted by CRS Associates LLC

- Monitoring of discussions within Internet newsgroups and interviews found that the buprenorphine products are viewed primarily as medications to avoid or ease withdrawal symptoms rather than means of getting high.
- There is evidence that there is experimental use and illegal diversion of buprenorphine…However, the extent of abuse and diversion does not come close to approaching that of methadone or OxyContin.
- Intravenous drug use of either Suboxone or Subutex appears to be rare, but it is evident from street interviews.

Source: *Surveillance Report*, July 1 thru September 30, 2007, CRS Associates LLC.

Potential for Buprenorphine Abuse

- Most common pattern of abuse involves crushing the sublingual tablets & injecting the resulting extract.
- When injected intravenously, addicts claim buprenorphine effects are similar to equipotent doses of morphine or heroin.
- Indications are that buprenorphine obtained for non-medical purposes in the U.S. is diverted from prescriptions written for treatment of addiction or obtained through “doctor shopping.”

Source: *Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators*, Final Report conducted by JBS International for SAMHSA, November 2006

Potential for Buprenorphine Abuse

- More than one-third of buprenorphine abusers reported that they took the drug in an effort to self-medicate and ease heroin withdrawal.[1]
- A majority of buprenorphine abusers are young white males with extensive histories of substance abuse.[1]
- When asked in a NASADAD study, **33%** of physicians considered Subutex to be a significant abuse and/or diversion threat in their states.[2]
- In the same study, only **6%** of physicians considered Suboxone to pose a significant abuse threat, and only **8%** considered it to be a significant diversion threat in their states.[2]

[1] Cicero, T & Inciardi, J, Potential for Abuse of Buprenorphine in Office-Based Treatment of Opioid Dependence, *The New England Journal of Medicine*, October 2005

[2] States' Perspectives on Buprenorphine and office Based Medication Assisted Opioid Dependency Treatment, NASADAD study prepared for CSAT, June 2004.

Buprenorphine, Health Disparities and Diversion

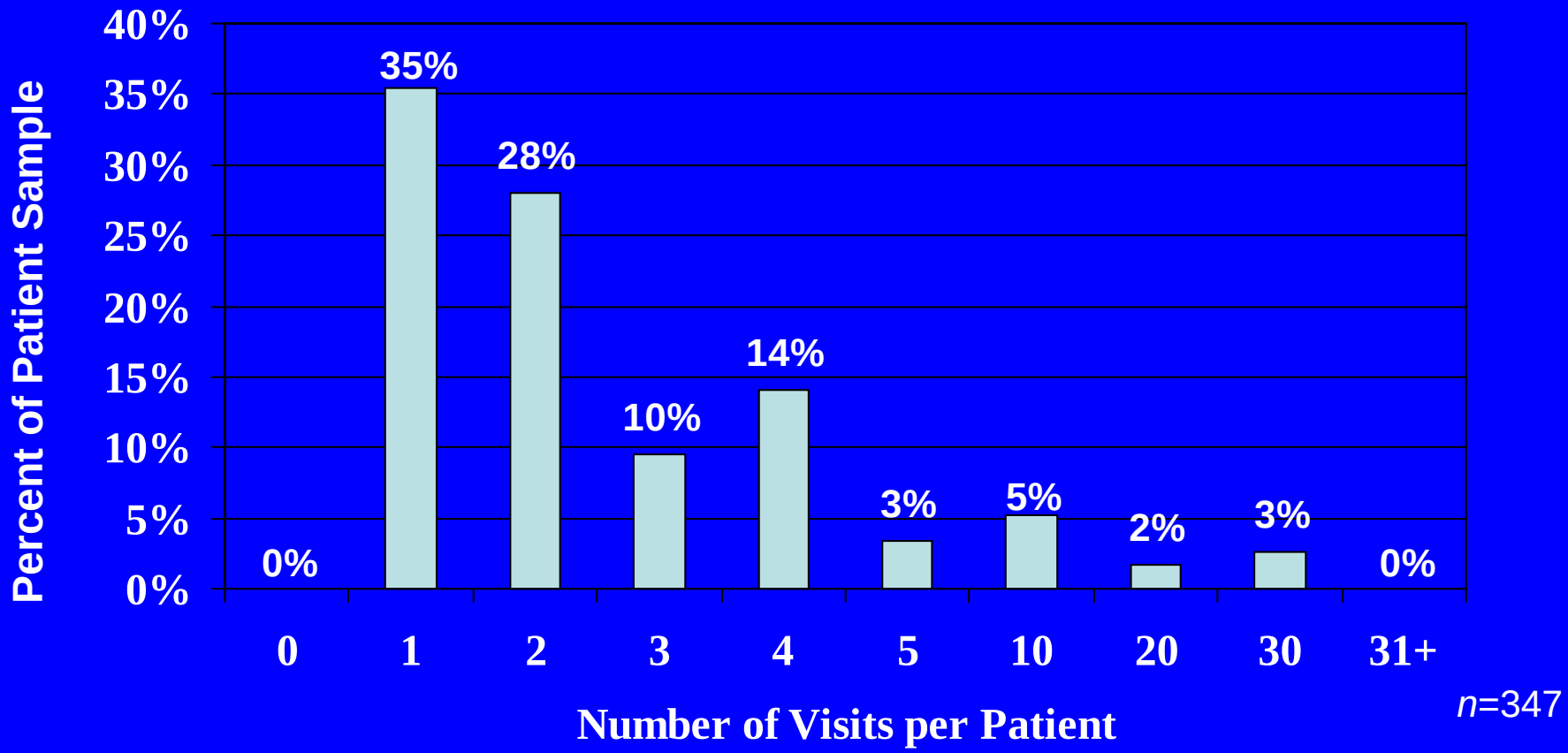
- Lack of access to physician services may be contributing to the diversion and abuse of buprenorphine
  - Financial barriers keep some patients from being able to get their own prescription from a physician
  - Limited number of prescribers may also be a factor.
- Patients selling their buprenorphine to others dependent on opioids may not hesitate to sell their drugs to non-opioid dependent users.

Monitoring Diversion

- Because of its ceiling effect and ability to precipitate withdrawal symptoms if taken in high doses, buprenorphine is more susceptible to abuse by individuals who are addicted to low doses of opiates or individuals in the early stages of opiate addiction.
- The drug also can be abused in combination with methadone, making buprenorphine diversion more problematic in areas where heroin abuse and methadone therapy are common, such as the Northeast region.
- As buprenorphine therapy becomes more widespread, the potential for increased diversion of Subutex and Suboxone should be closely monitored.

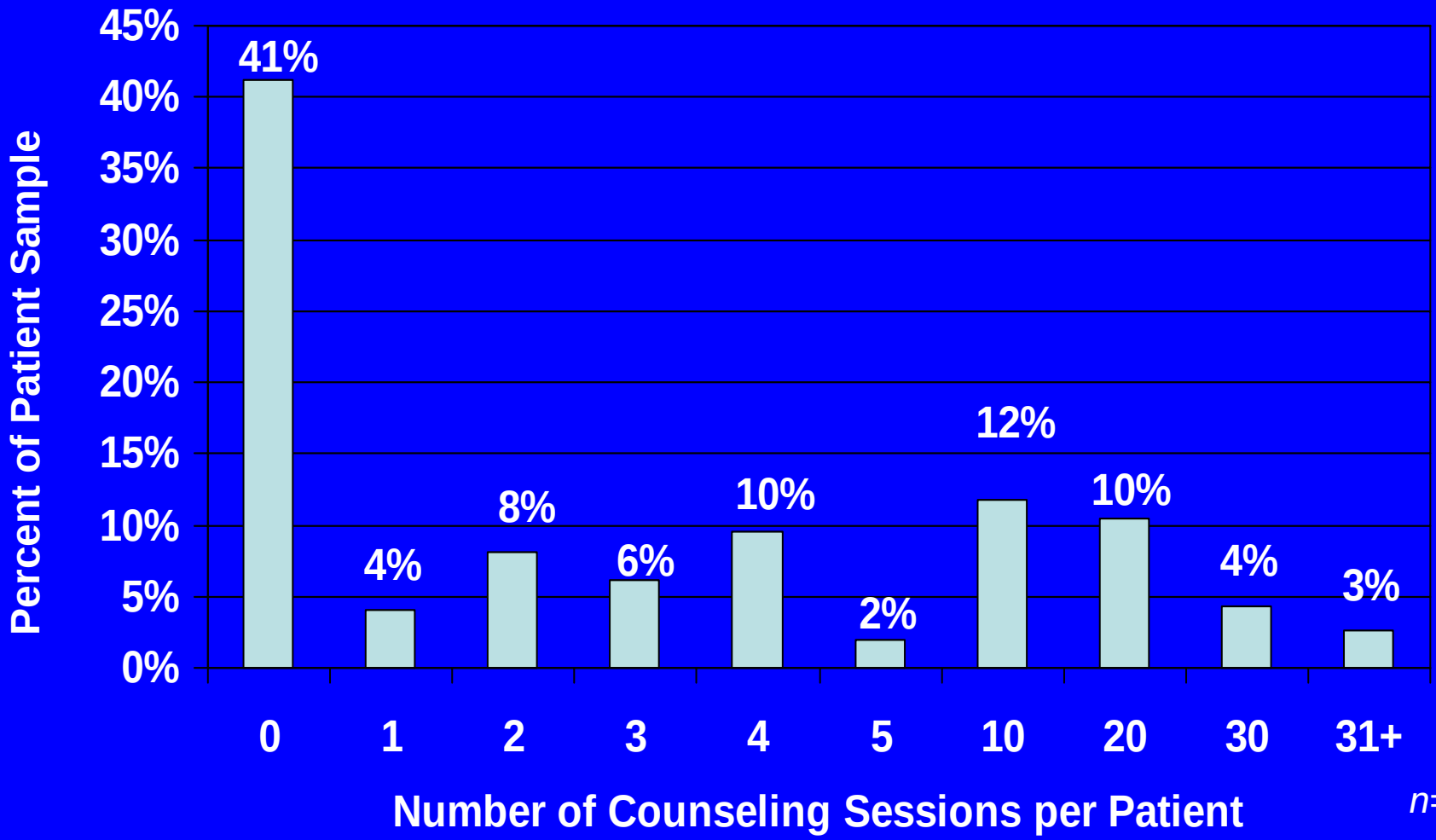
Source: NDIC Intelligence Bulletin: September 2004

Patient Physician Visit Reports: First 30 Days of Buprenorphine Treatment



Source: *Evaluation of the Buprenorphine Waiver Program, conducted by SAMHSA/CSAT from 2002-2005*

Patient Report of Counseling Sessions: First 30 Days of Buprenorphine Treatment



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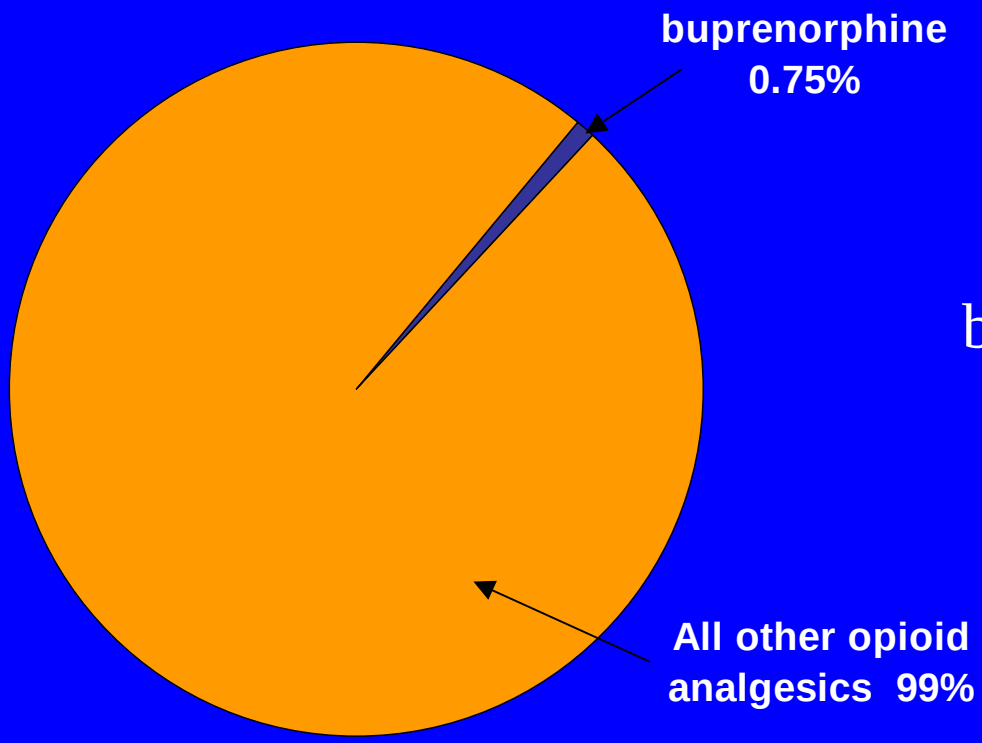
Source: *Evaluation of the Buprenorphine Waiver Program, conducted by SAMHSA/CSAT from 2002-2005*

Emergency Department Visits - 2006

- In 2006, of 346,946 reported Emergency Department visits, 47,538 involved opioid analgesics – only 356 of which involved buprenorphine or a combination of buprenorphine and other medications.
- Of those involving buprenorphine:
  - 52 were due to adverse reactions
  - 63 were seeking detox
  - 225 were due to nonmedical use
  - 11 were due to accidental ingestion

Source: DAWN *Live!*, Unweighted reports from 292 to 304 EDs. Accessed 10/2/2007.

Opioid Analgesics in Drug-related ED Visits 2006

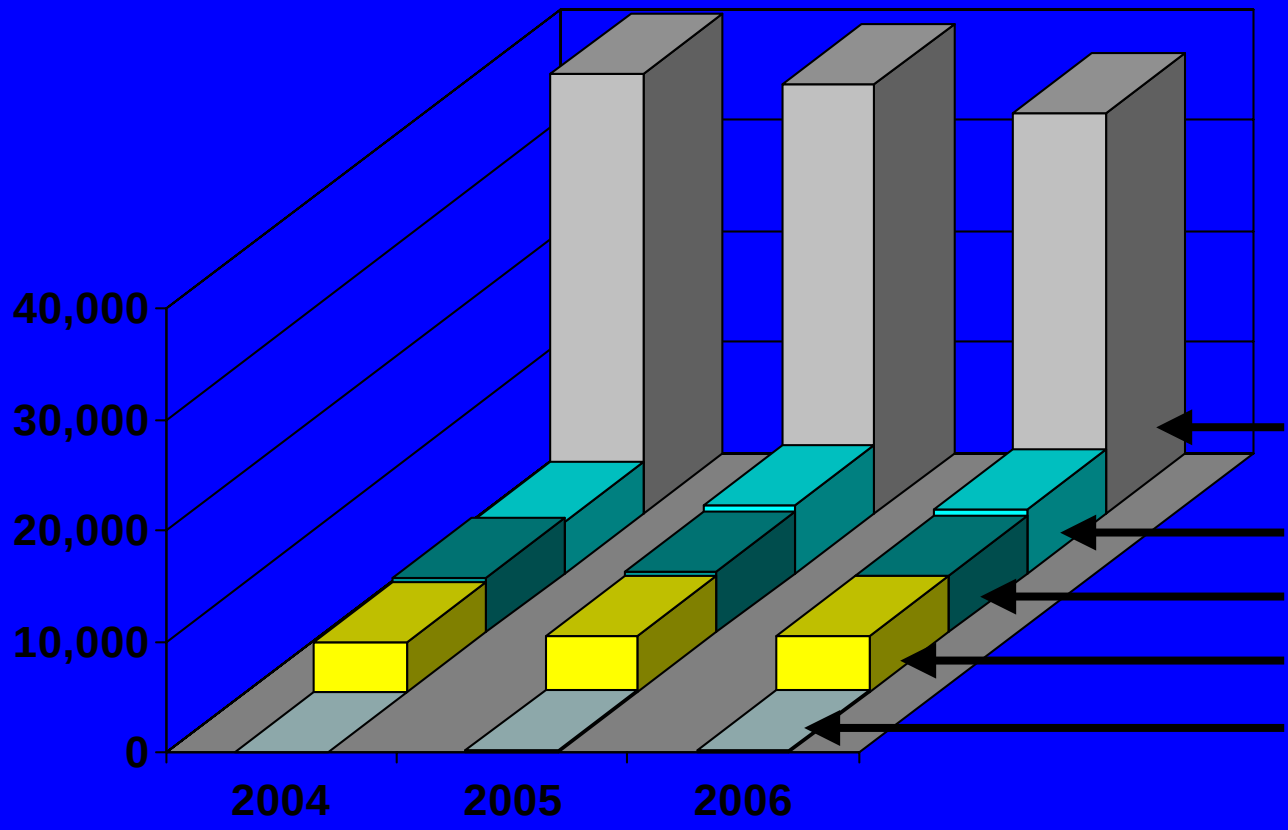


Of the 47,538 opioid analgesics reported in drug-related ED visits, 358 were buprenorphine (all case types)

*Includes single and multi-ingredient product

Source: DAWN *Live!*, Unweighted reports from 292 to 304 EDs. Accessed 10/2/2007.

Opiate Reports in Emergency Department Visits Related to Drug Misuse/Abuse



36,007 Heroin

5,694 Methadone

5,085 Hydrocodone*

5,066 Oxycodone*

225 Buprenorphine*

Unweighted reports from 243-445 U.S. hospitals

*** Includes single- and multi-ingredient products**

Source: U.S. SAMHSA; DAWN *Live!* Oct 2, 2007

Workgroup Goals

Workgroups

- Work Group 1: Improving Data collection and Dissemination
- Work Group 2: Emerging Clinical Issues
- Work Group 3: Special Population Needs
- Work Group 4: Evolving Educational Strategies
- Work Group 5: Developing System Supports
- Work Group 6: Identifying Research Needs

SAMHSA/CSAT Information

- www.samhsa.gov
- Information web site: www.buprenorphine.samhsa.gov
- SHIN 1-800-729-6686 for publication ordering or information on funding opportunities
  - 1-800-487-4889 – TDD line
- 1-800-662-HELP – SAMHSA's National Helpline (average # of tx calls per mo.- 24,000)