

Safety of Propoxyphene Containing Products as Reported to the National Poison Data System (NPDS)

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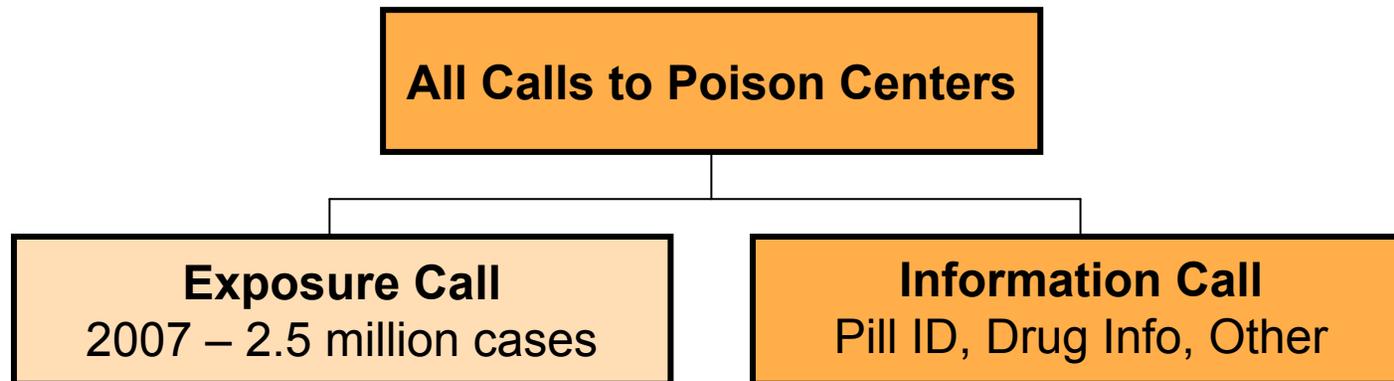
Valuable Tool to Understand Drug Safety



- Nationwide network of 61 regional call centers
 - Provide advice on care
 - Collect data
- Trained, certified professionals take calls
- Nationally standardized data collection system
- Spontaneous reporting

NPDS

Exposure Does Not Equal Overdose



- **Exposure** – Any case in which a patient reportedly took the substance involved
 - May involve therapeutic dose or overdose
 - Reason – adverse drug reaction, intentional, unintentional
 - Outcome – no effect, minimal, moderate, major, death

Objectives of National Poison Data System (NPDS) Analysis

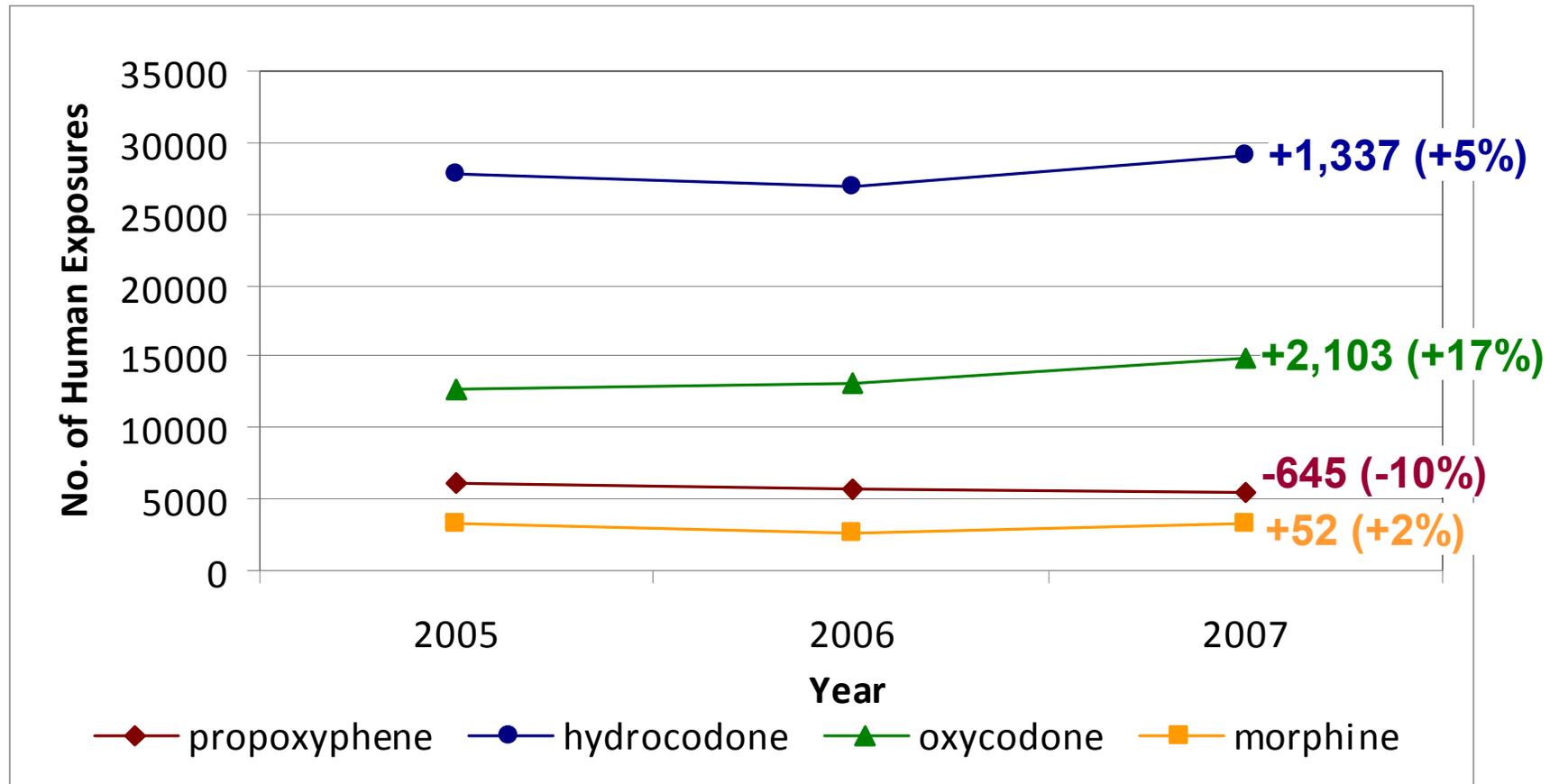
- Objectives

- Characterize propoxyphene exposures reported to NPDS
- Describe the rate of exposure in terms of drug availability.
- Compare propoxyphene results to other commonly prescribed opioids

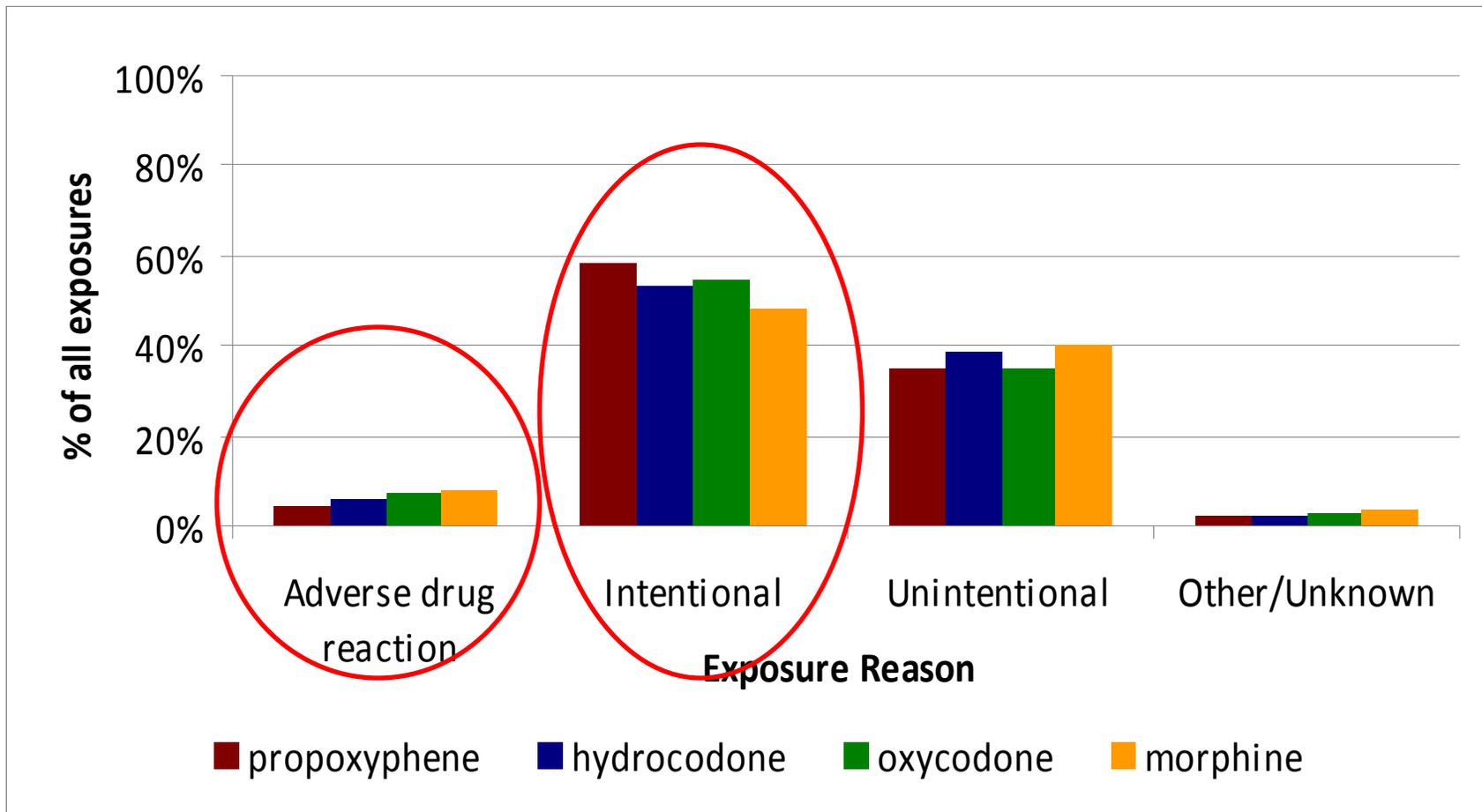
Methods for National Poison Data System (NPDS) Analysis

- Methods
 - NPDS search
 - human exposures
 - reporting period January 1, 2005 through December 31, 2007
 - propoxyphene containing products (~200 products)
 - Search repeated for hydrocodone, oxycodone and morphine as comparator drugs

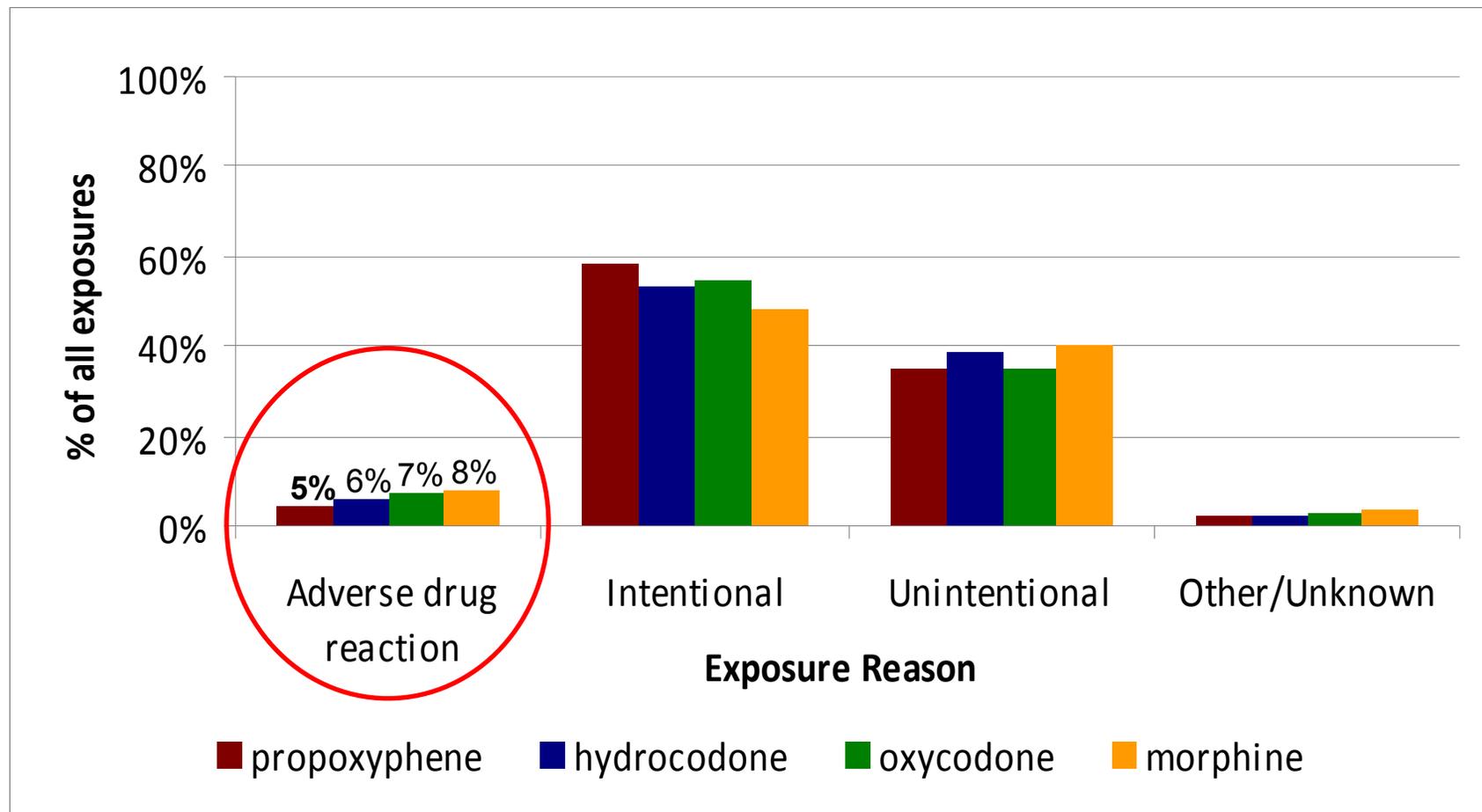
Propoxyphene Exposures Reported to NPDS have Decreased from 2005 to 2007



Exposure Reason 2005-2007

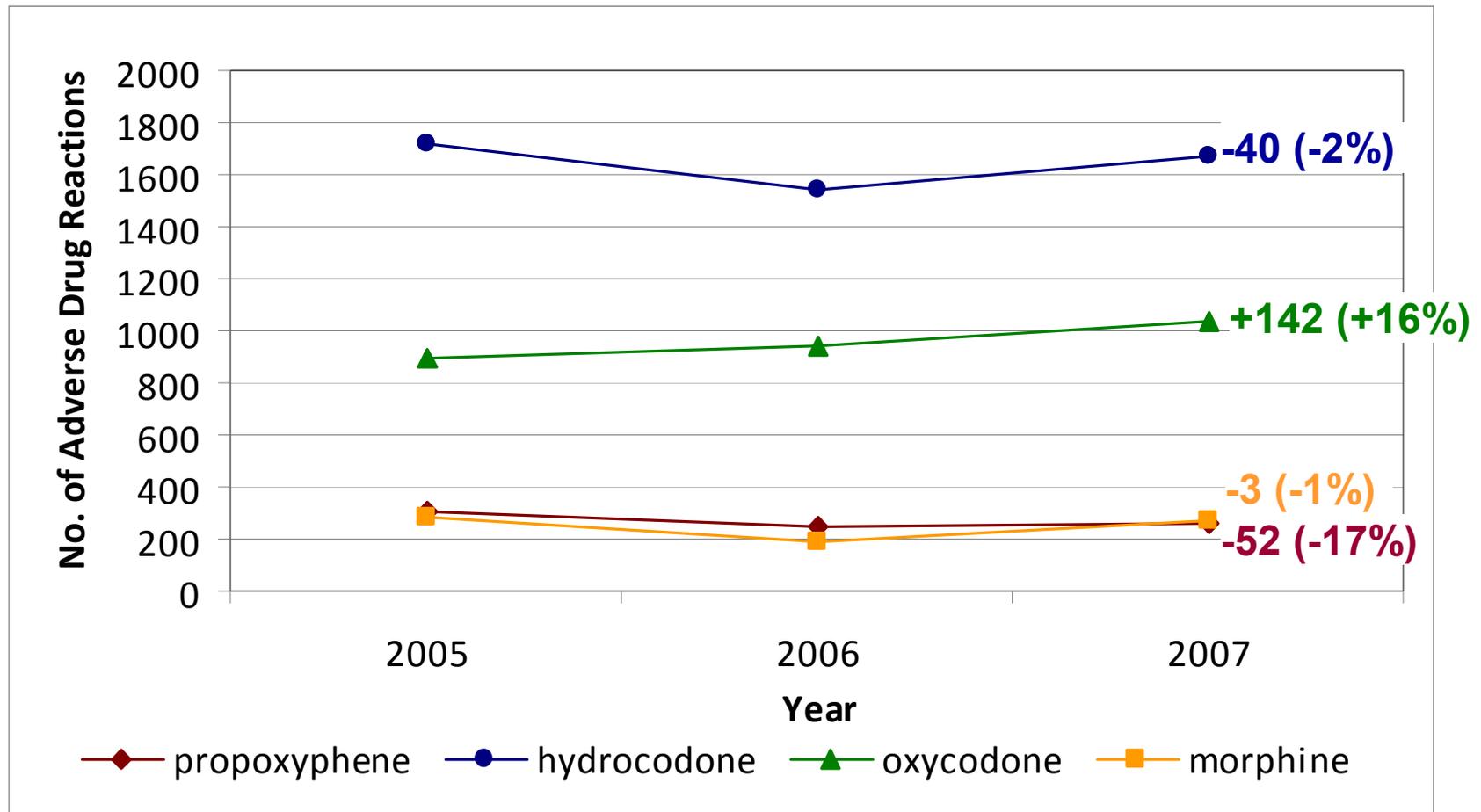


Adverse Drug Reactions Associated with Propoxyphene: Lowest of All Drugs Studied

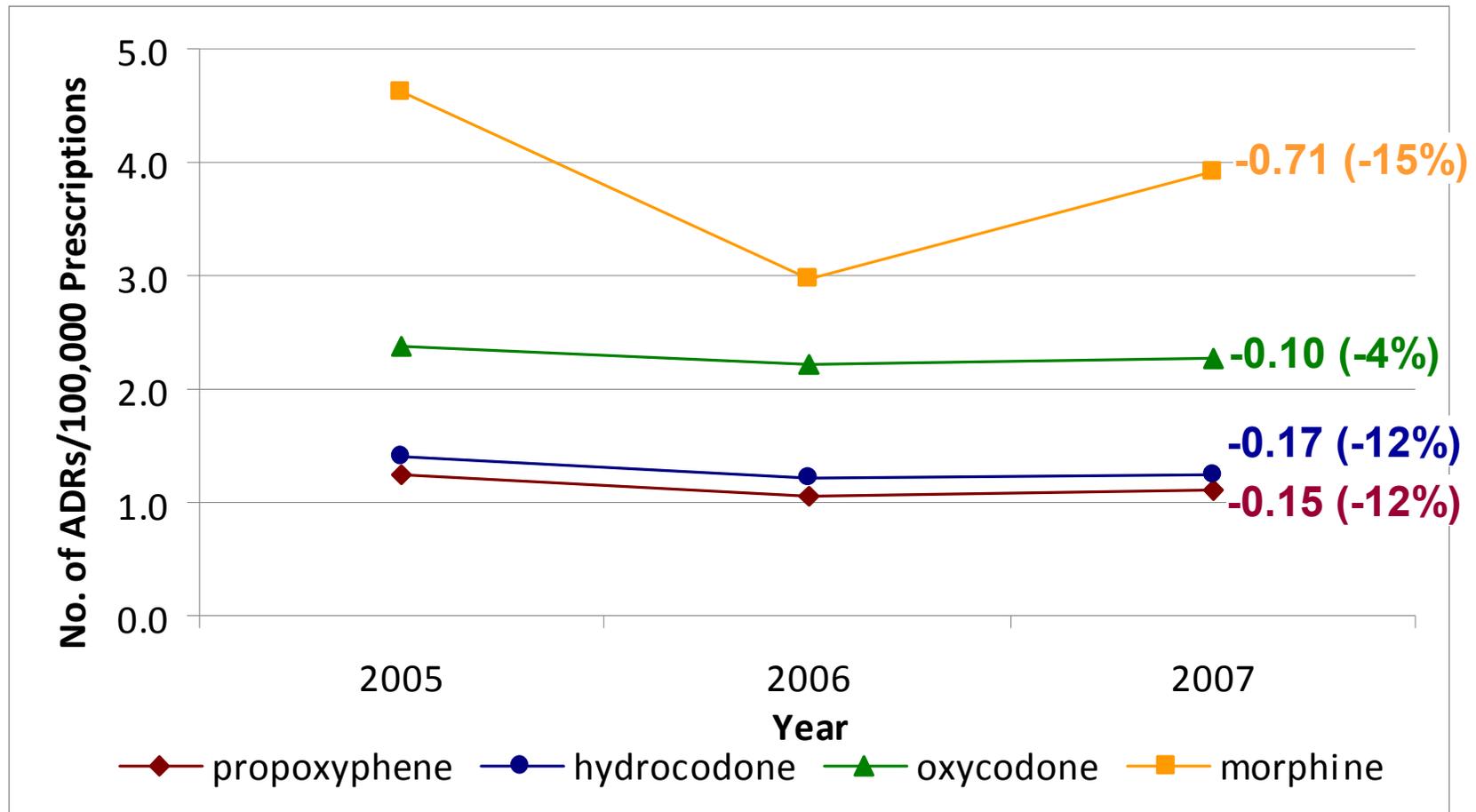


Adverse Drug Reaction: normal, prescribed, labeled or recommended use

Adverse Drug Reactions to Propoxyphene Decreased from 2005 to 2007



Rate of Adverse Drug Reactions Lowest Among Opioids Studied



Propoxyphene Adverse Drug Reaction Rates Lowest Among Commonly Prescribed Opioids

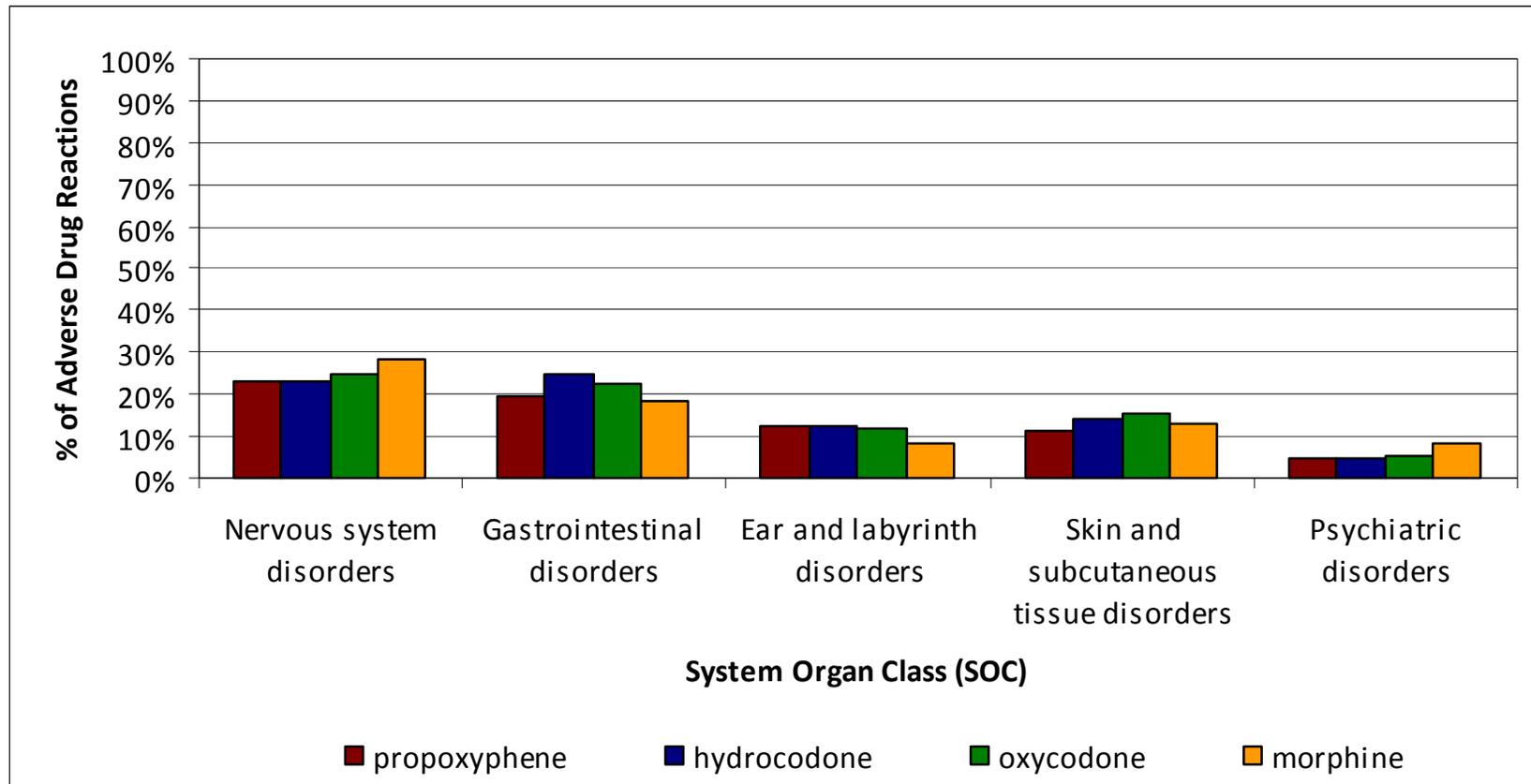
Number of Adverse Drug Reactions

- 1)hydrocodone
- 2)oxycodone
- 3)propoxyphene**
- 4)morphine

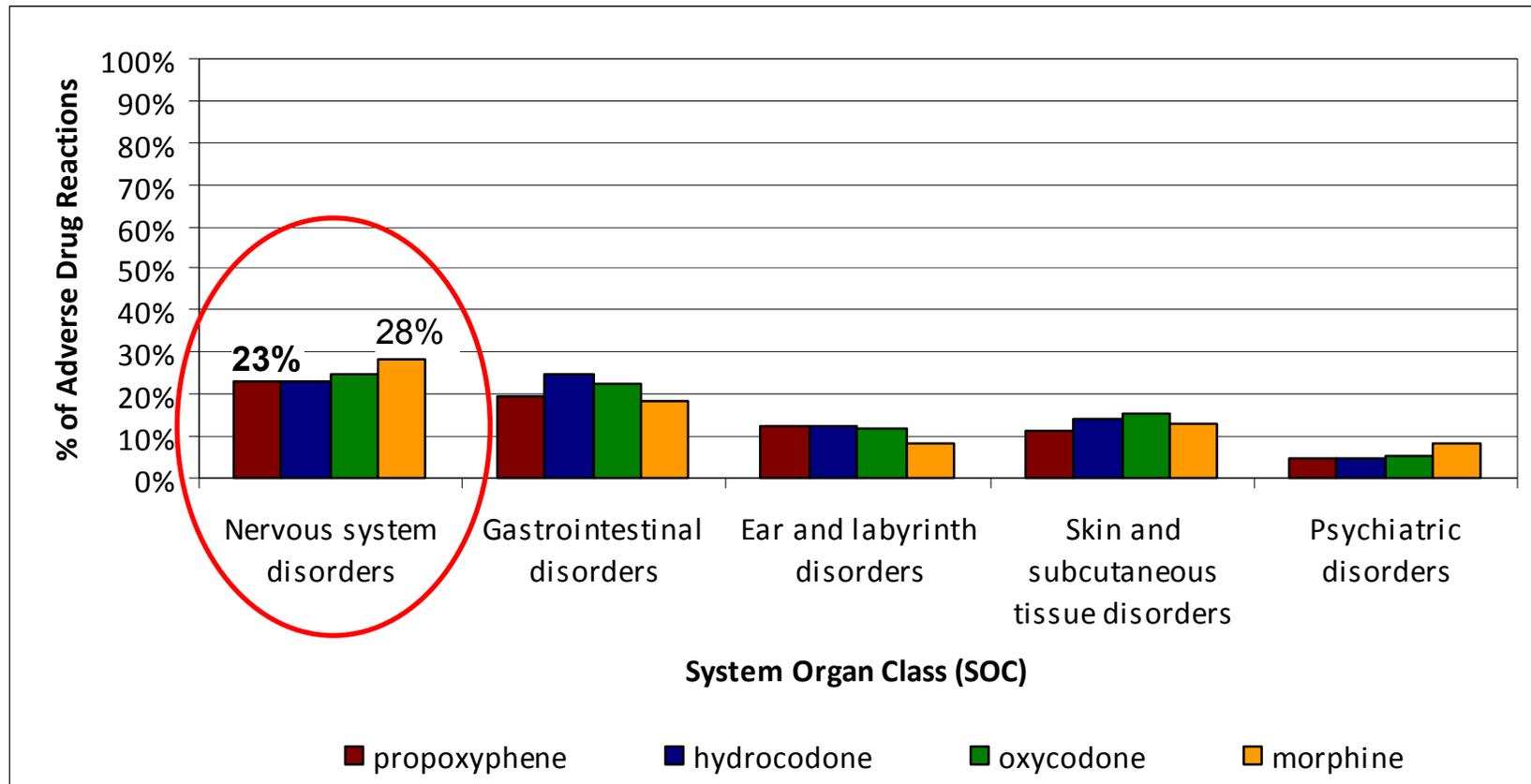
Adverse Drug Reactions per 100,000 Prescriptions Dispensed

- 1)morphine
- 2)oxycodone
- 3)hydrocodone
- 4)propoxyphene**

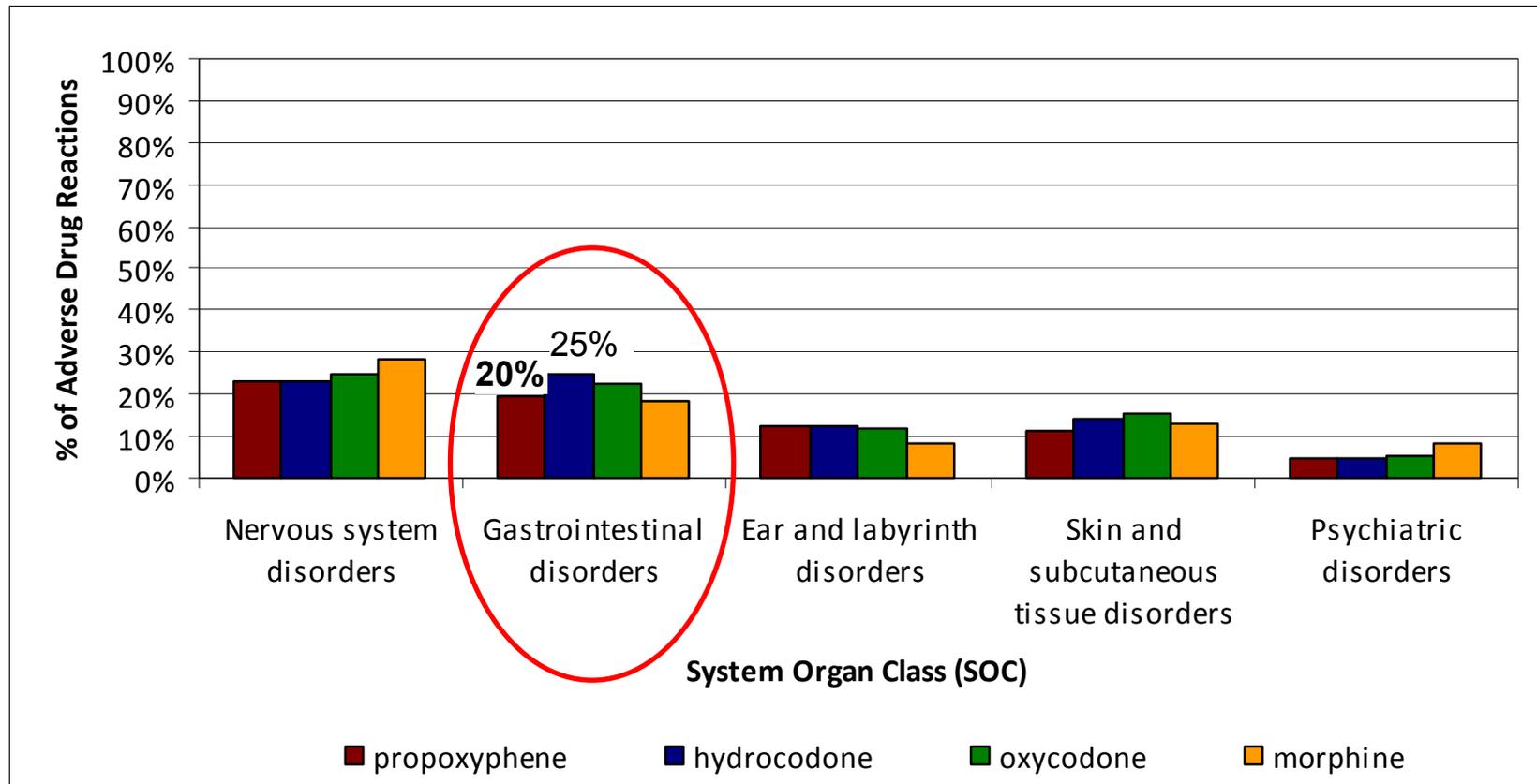
Five Most Common System Organ Class (SOC) Associated with Opioids Studied



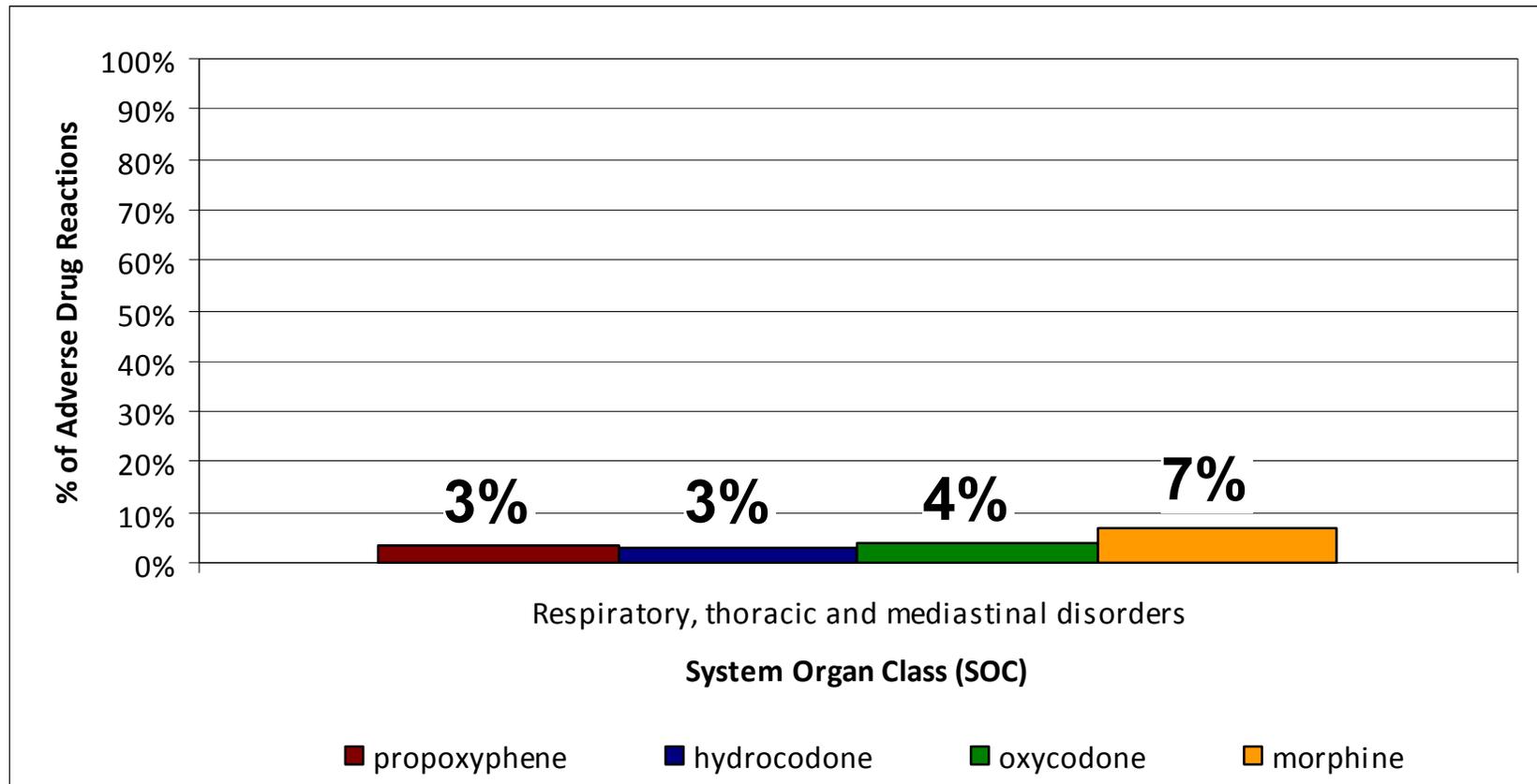
Nervous System Disorders Most Common Type of Effect Associated with Propoxyphene



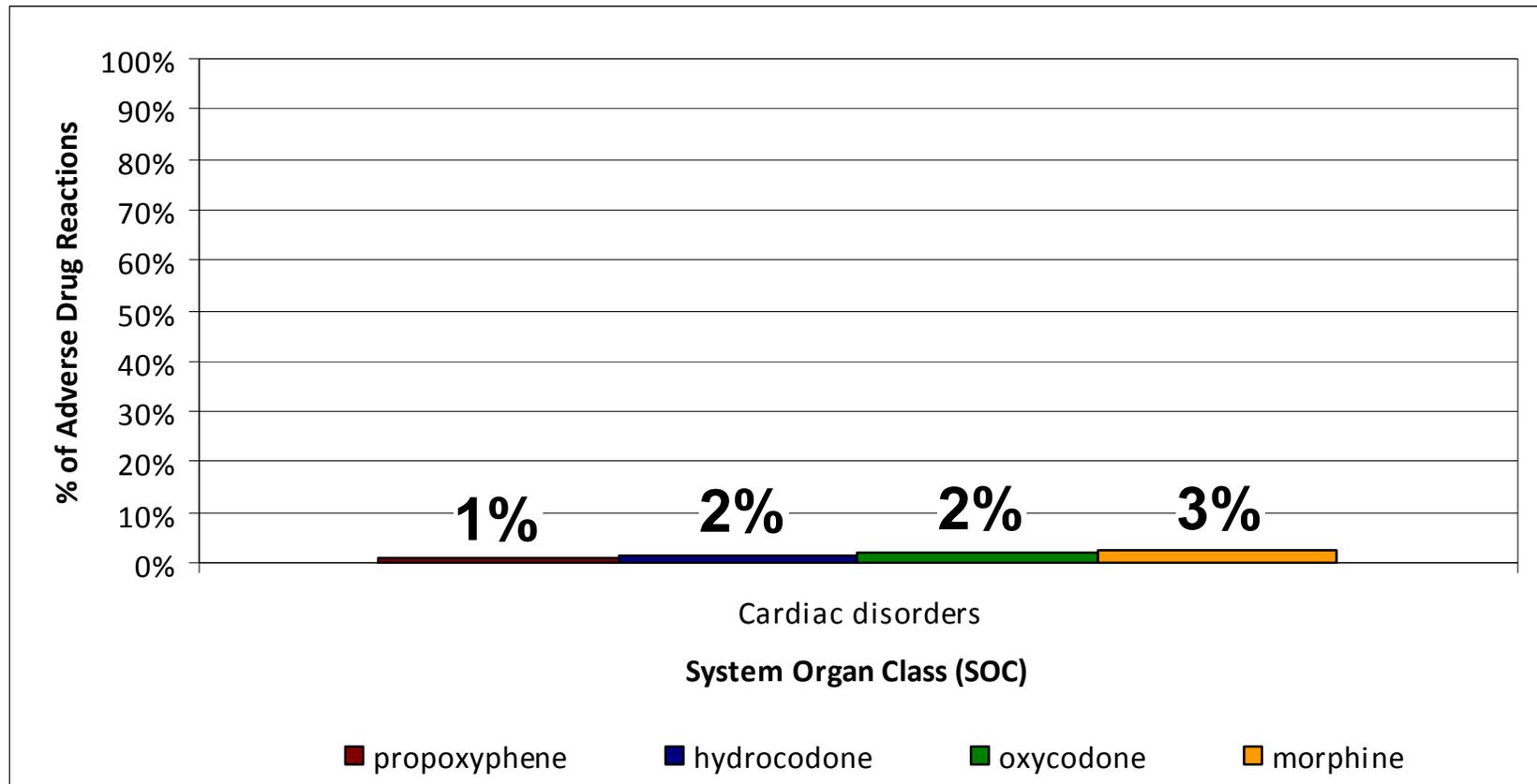
Gastrointestinal Disorders Second Most Common Effect Associated with Propoxyphene



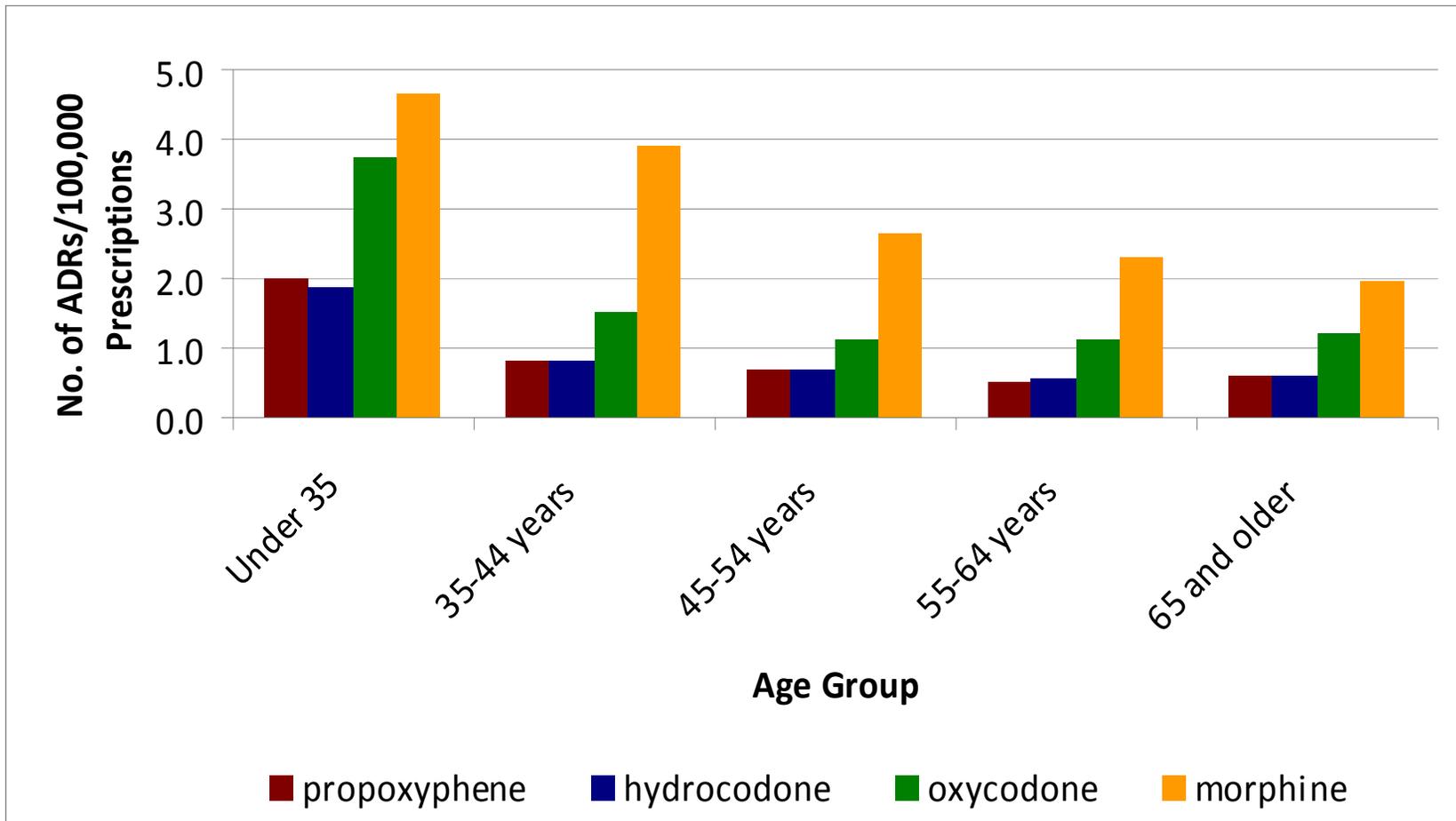
Respiratory Events Associated with Propoxyphene Uncommon



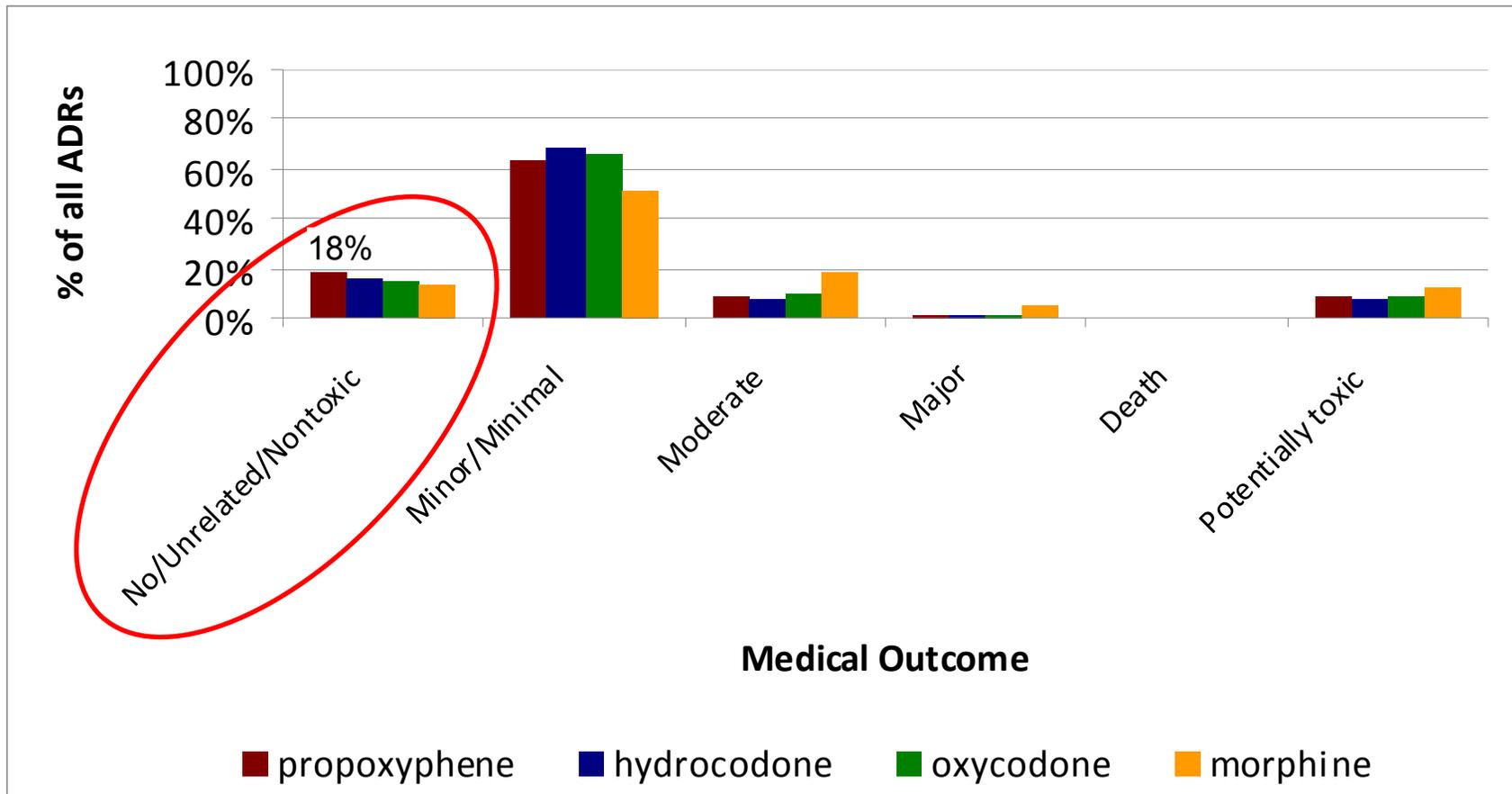
Cardiac Events Associated with Propoxyphene Rarely Reported to NPDS



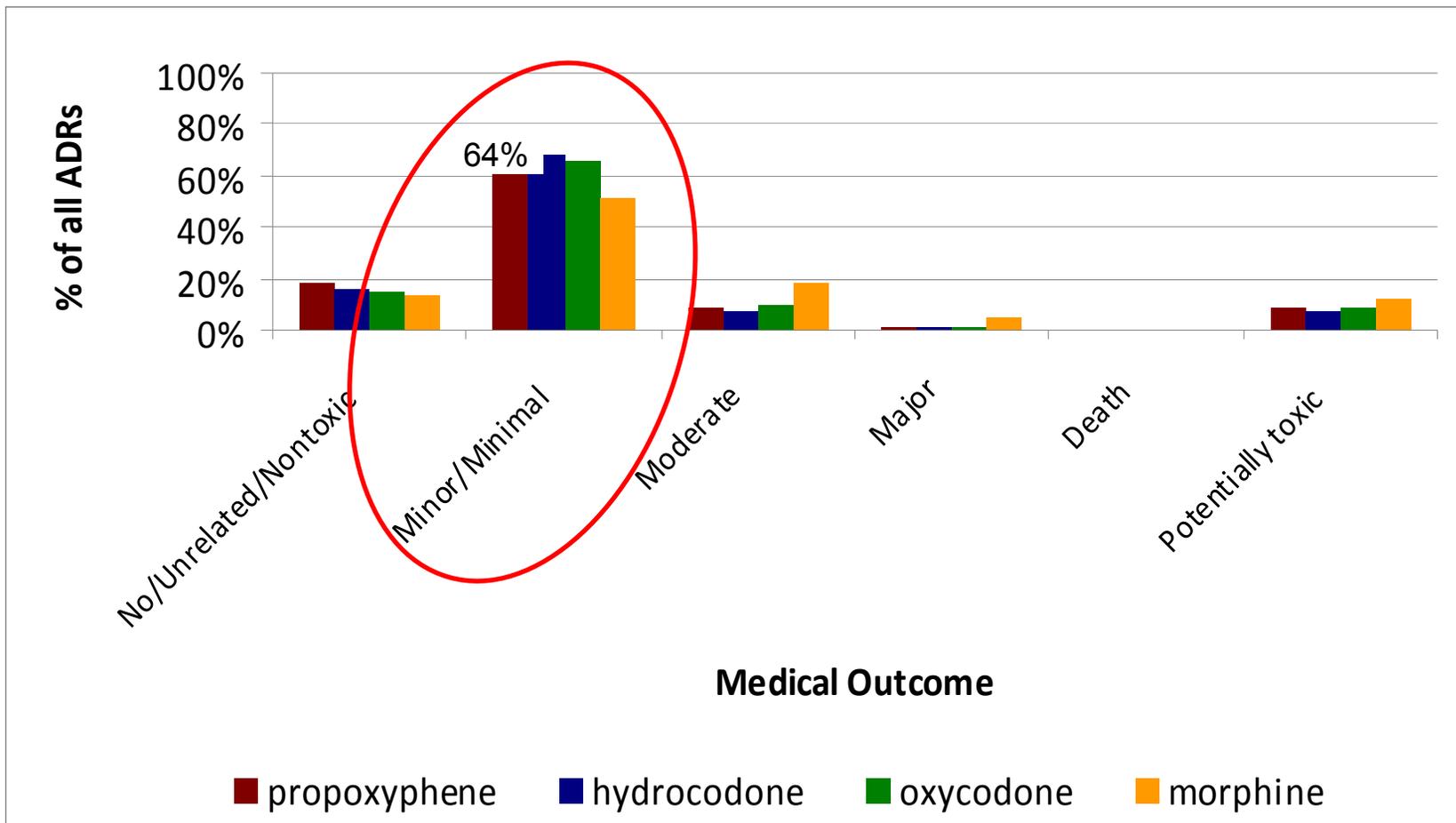
Rates of Propoxyphene Adverse Drug Reactions Among Lowest Across Age Groups



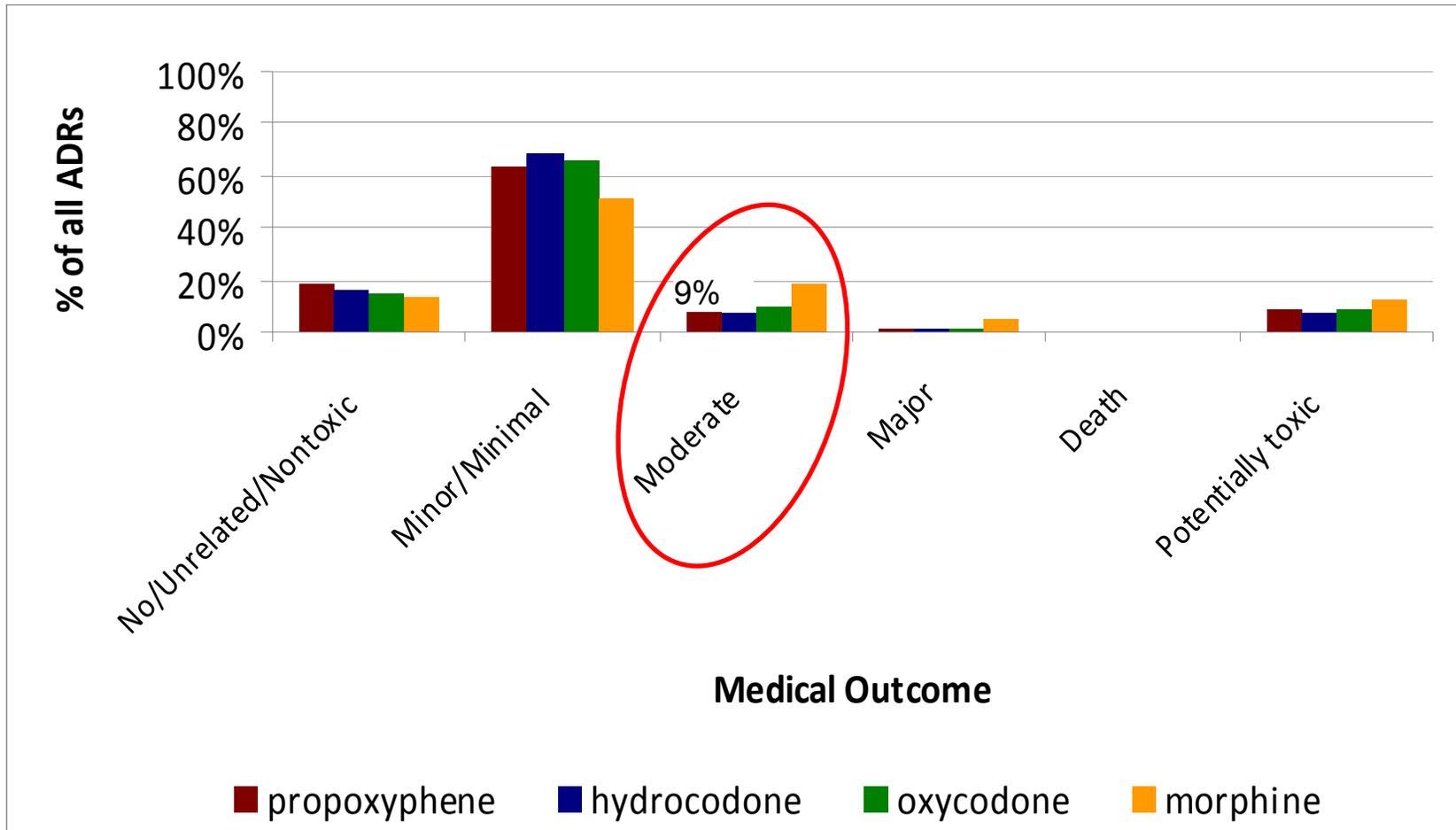
Severe Outcomes Rarely Associated with Propoxyphene Adverse Drug Reactions



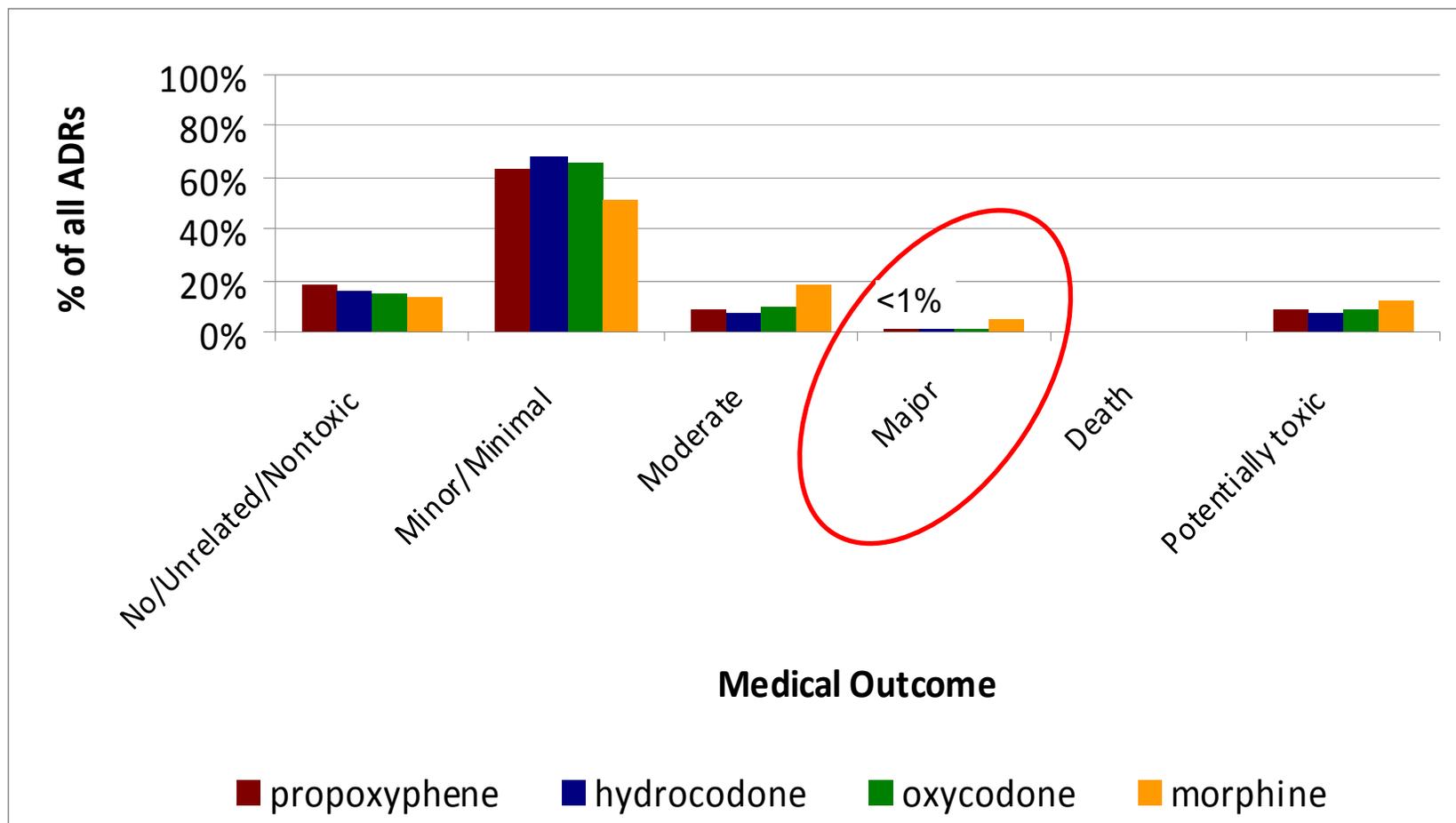
Severe Outcomes Rarely Associated with Propoxyphene Adverse Drug Reactions



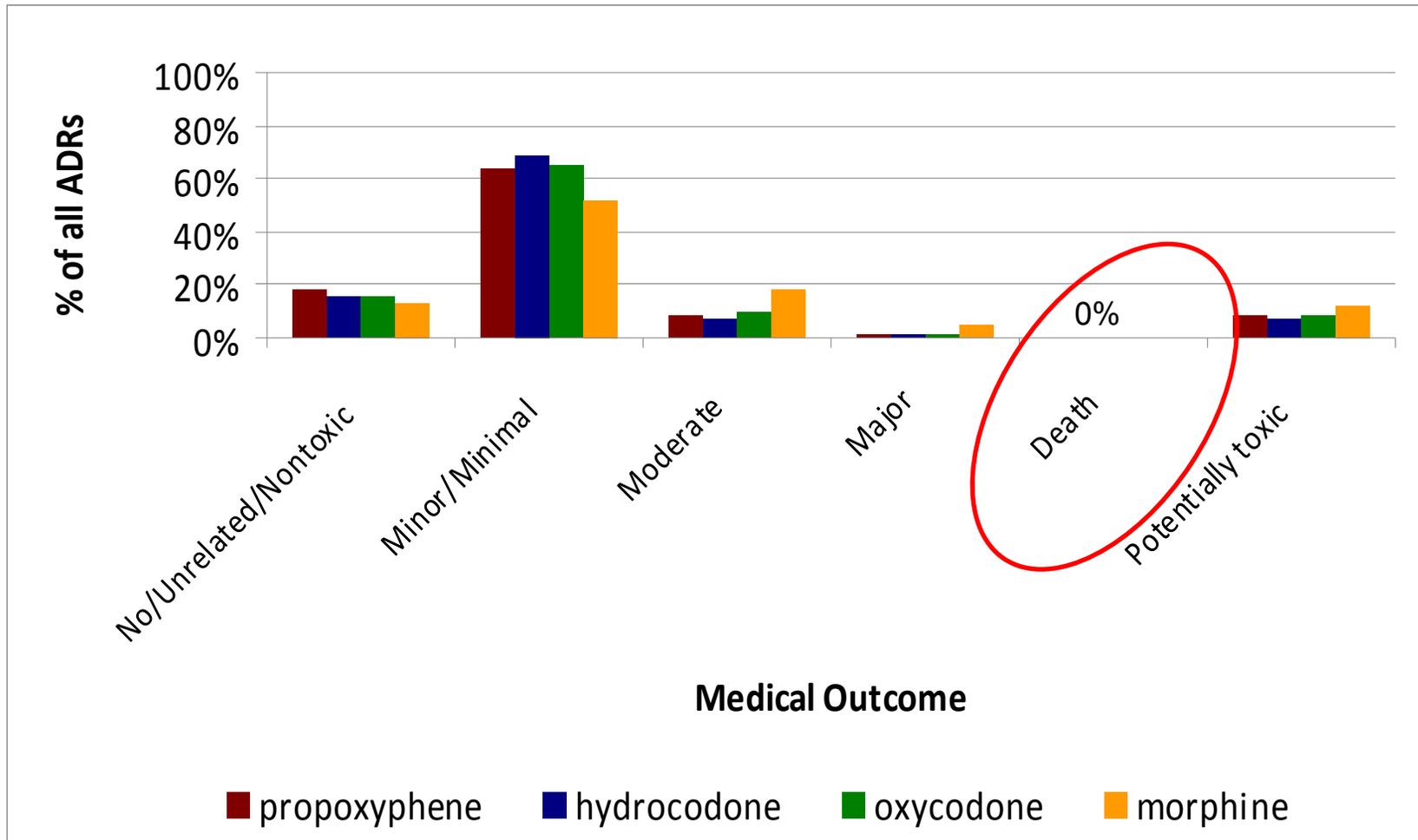
Severe Outcomes Rarely Associated with Propoxyphene Adverse Drug Reactions



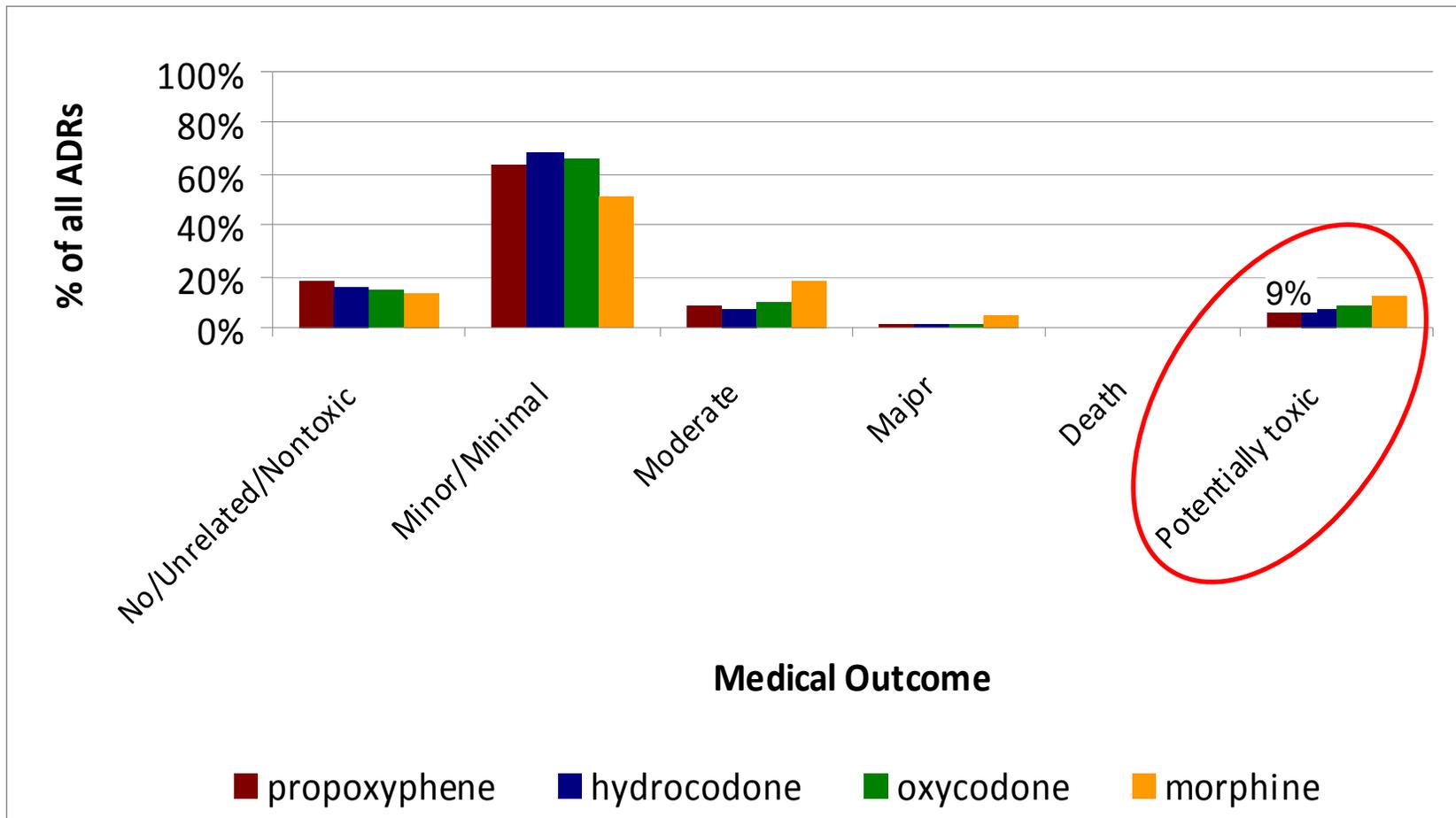
Severe Outcomes Rarely Associated with Propoxyphene Adverse Drug Reactions



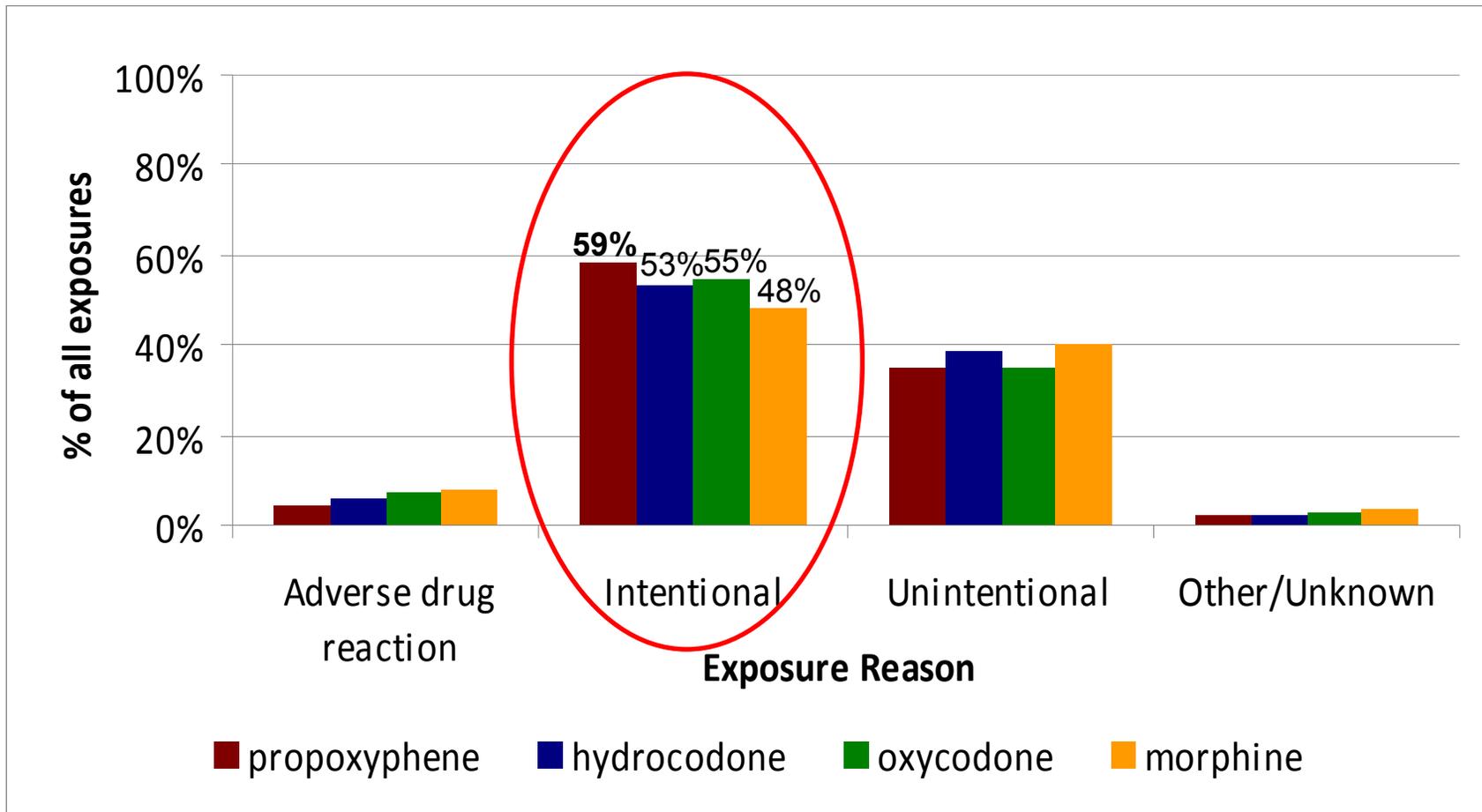
Severe Outcomes Rarely Associated with Propoxyphene Adverse Drug Reactions



Severe Outcomes Rarely Associated with Propoxyphene Adverse Drug Reactions

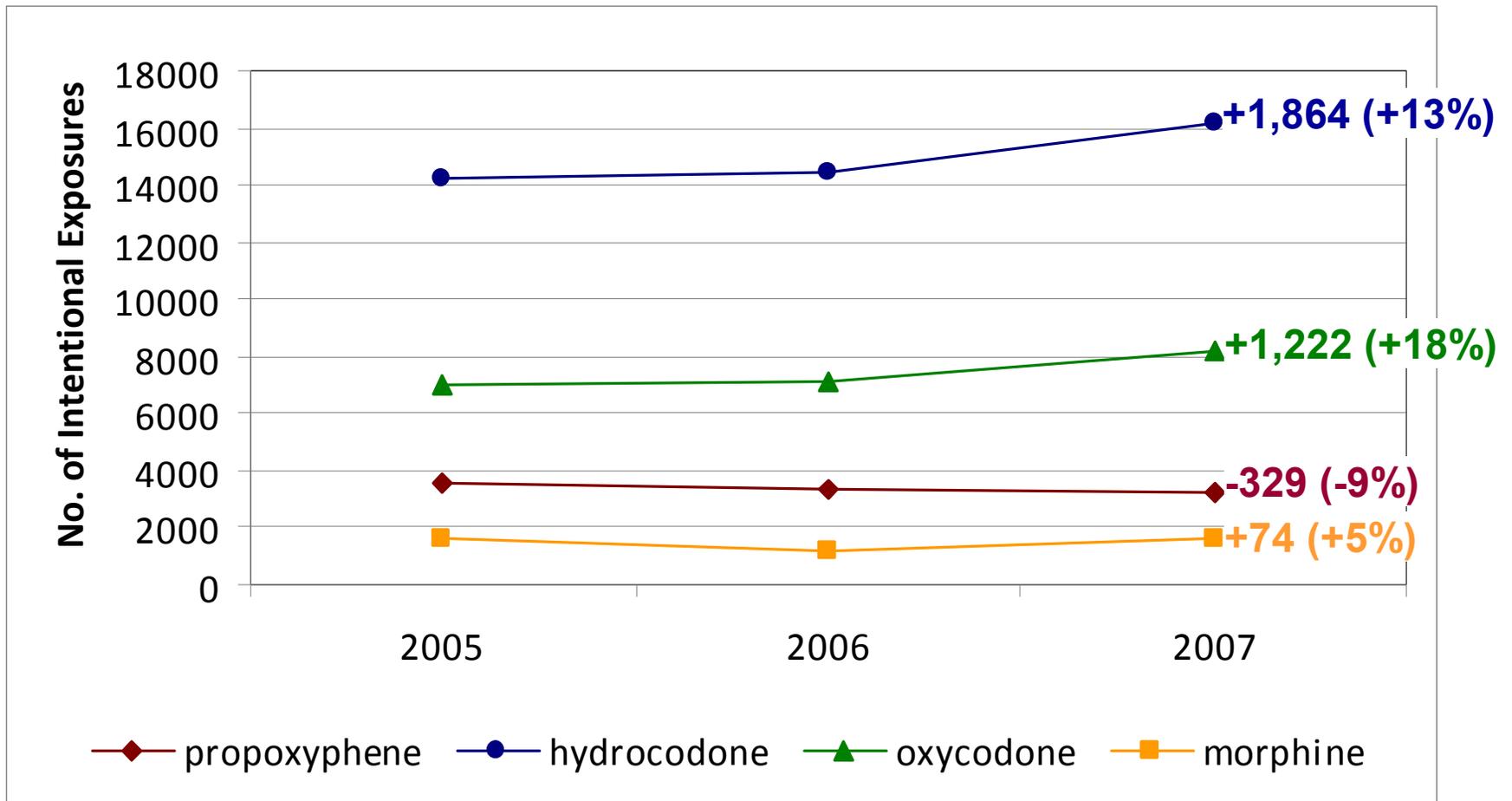


Intentional Exposures

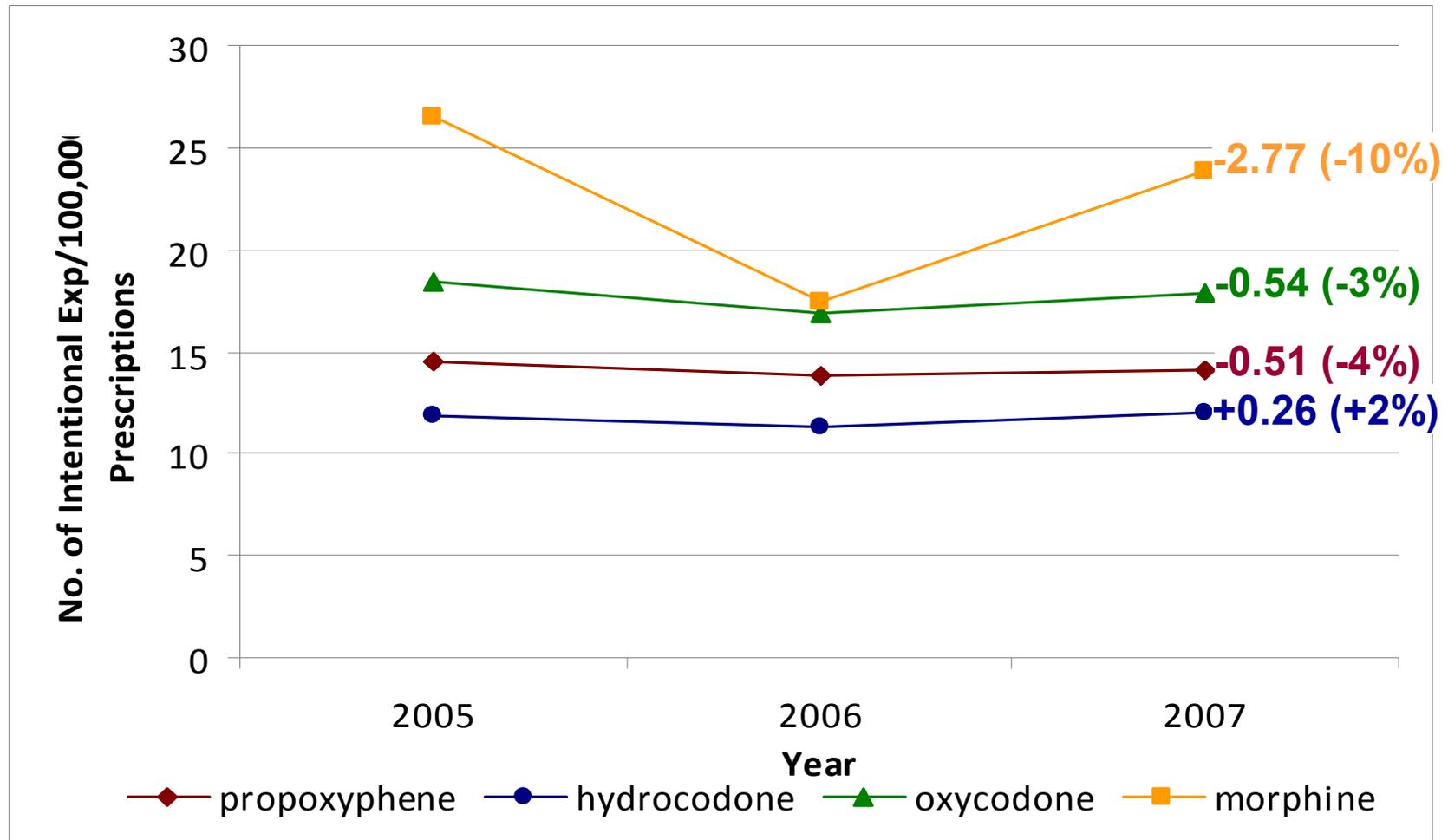


Intentional Exposures: purposeful, including abuse, misuse and suicidal intent

Intentional Propoxyphene Exposures have Decreased from 2005 to 2007



Rate of Intentional Propoxyphene Exposures Decreased from 2005 to 2007



Intentional Propoxyphene Exposure Rates Consistent with Commonly Prescribed Opioids

Number of Intentional Exposures

1)hydrocodone

2)oxycodone

3)propoxyphene

4)morphine

Intentional Exposures per 100,000 Prescriptions Dispensed

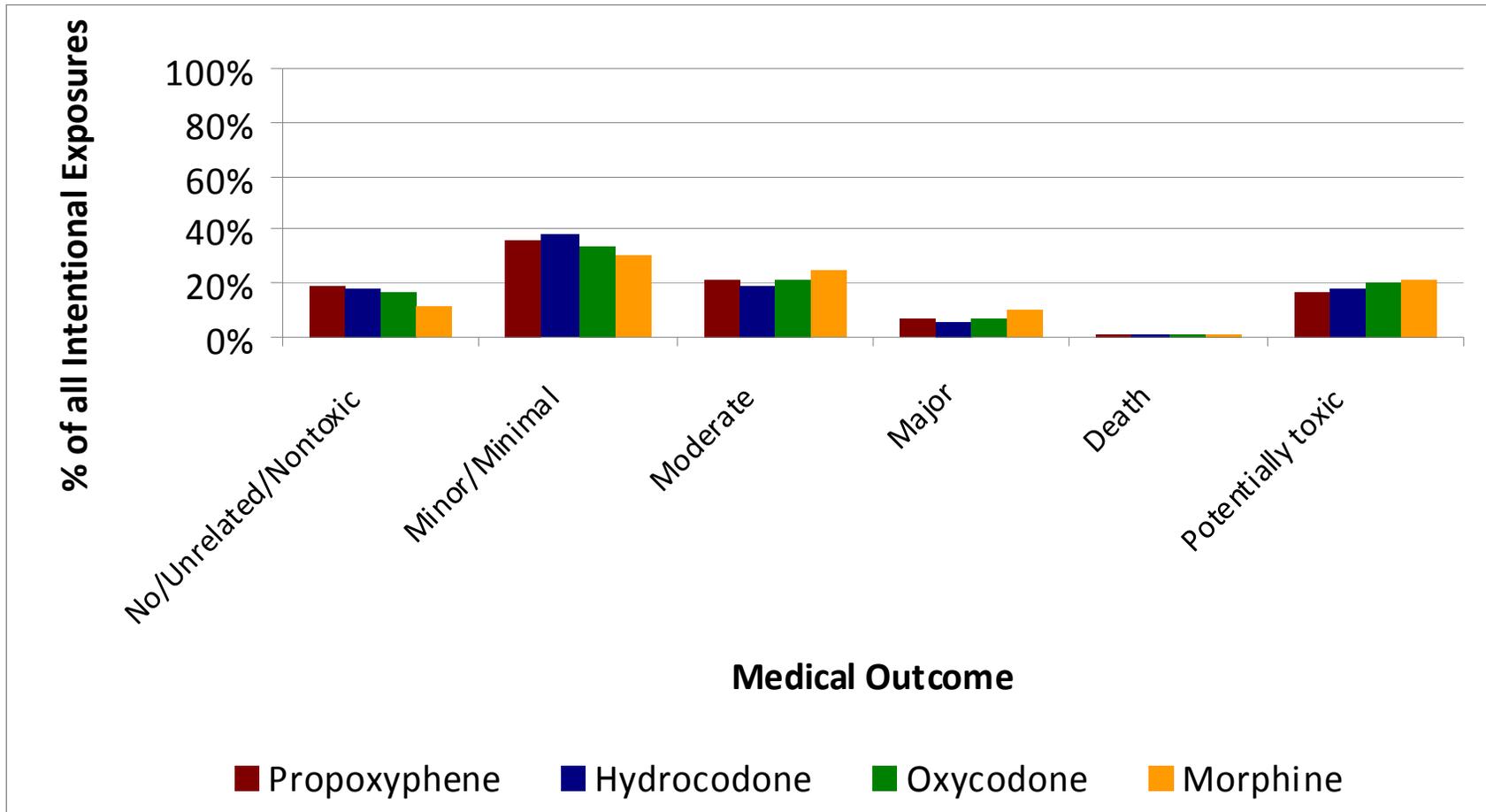
1)morphine

2)oxycodone

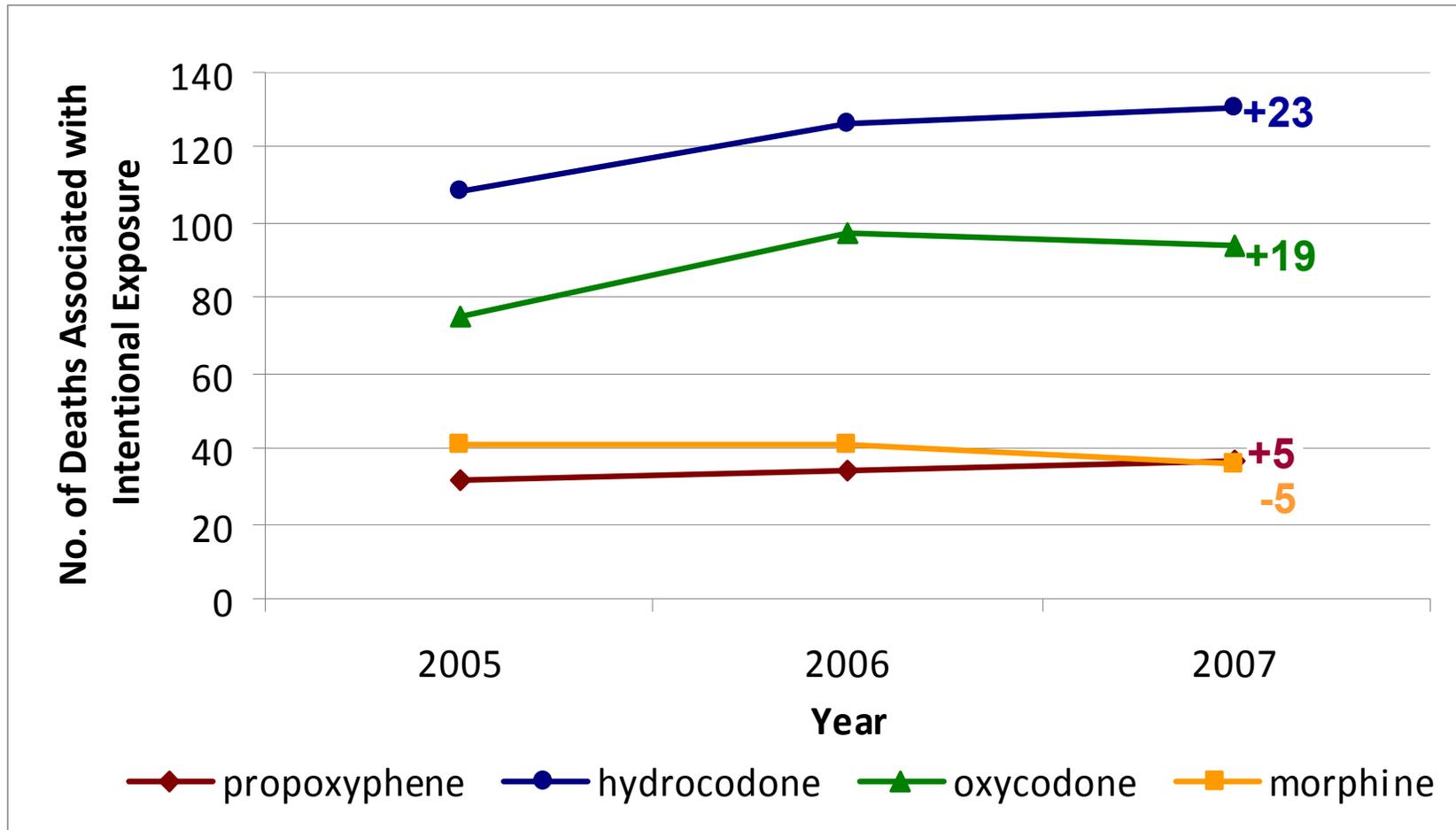
3)propoxyphene

4)hydrocodone

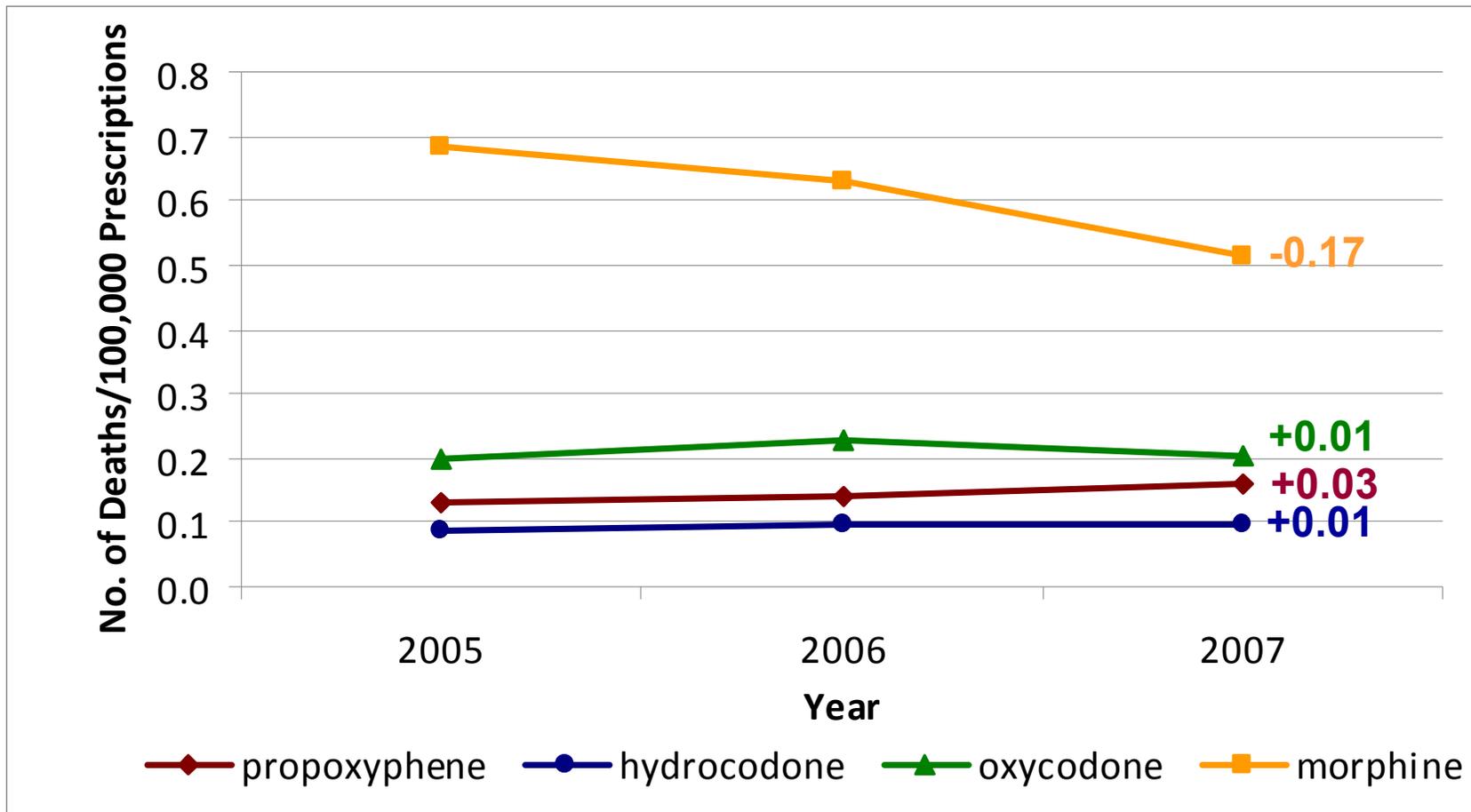
Outcome Associated with Intentional Propoxyphene Exposures Similar to Other Opioids



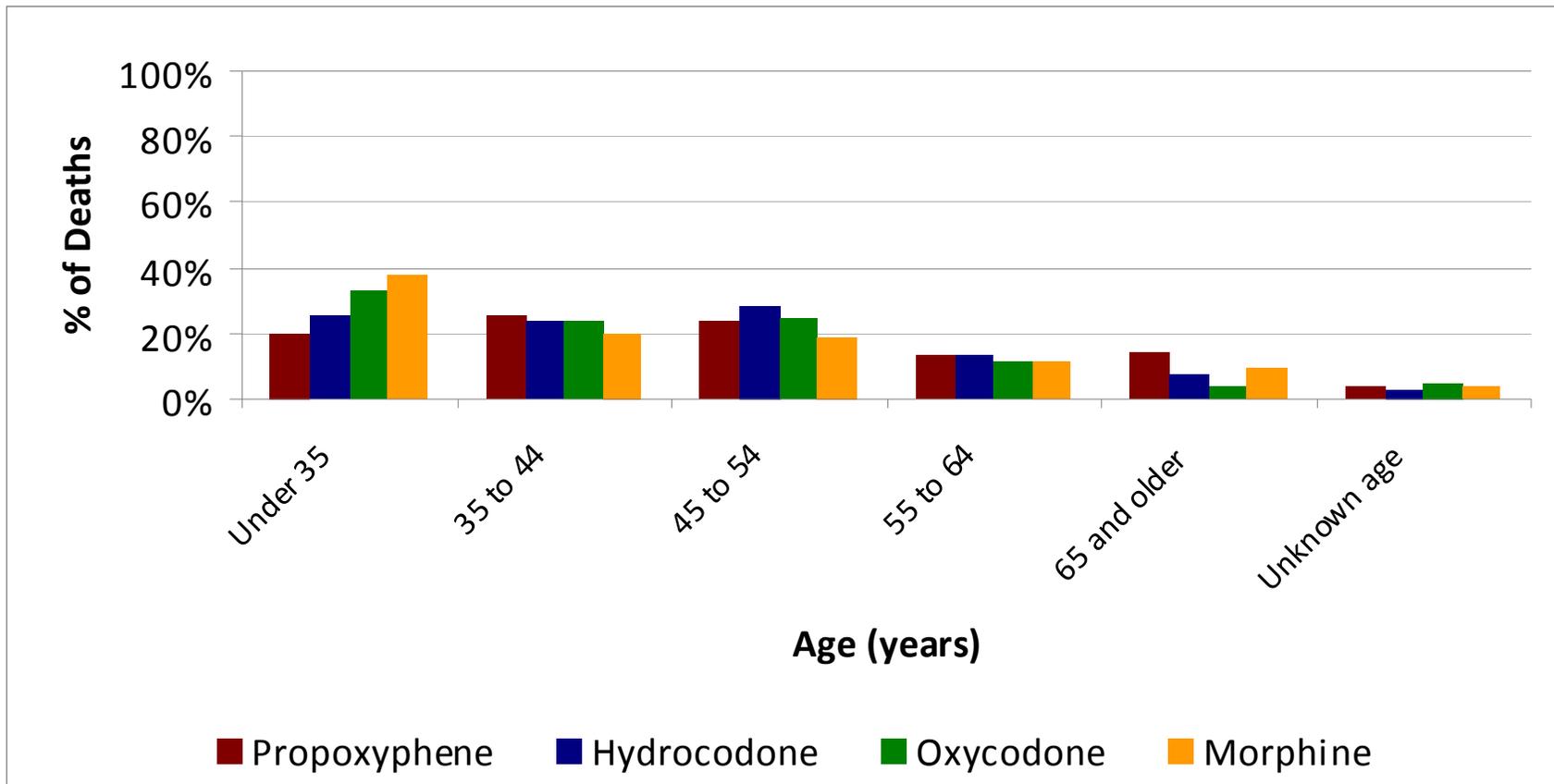
Number of Deaths 2005-2007



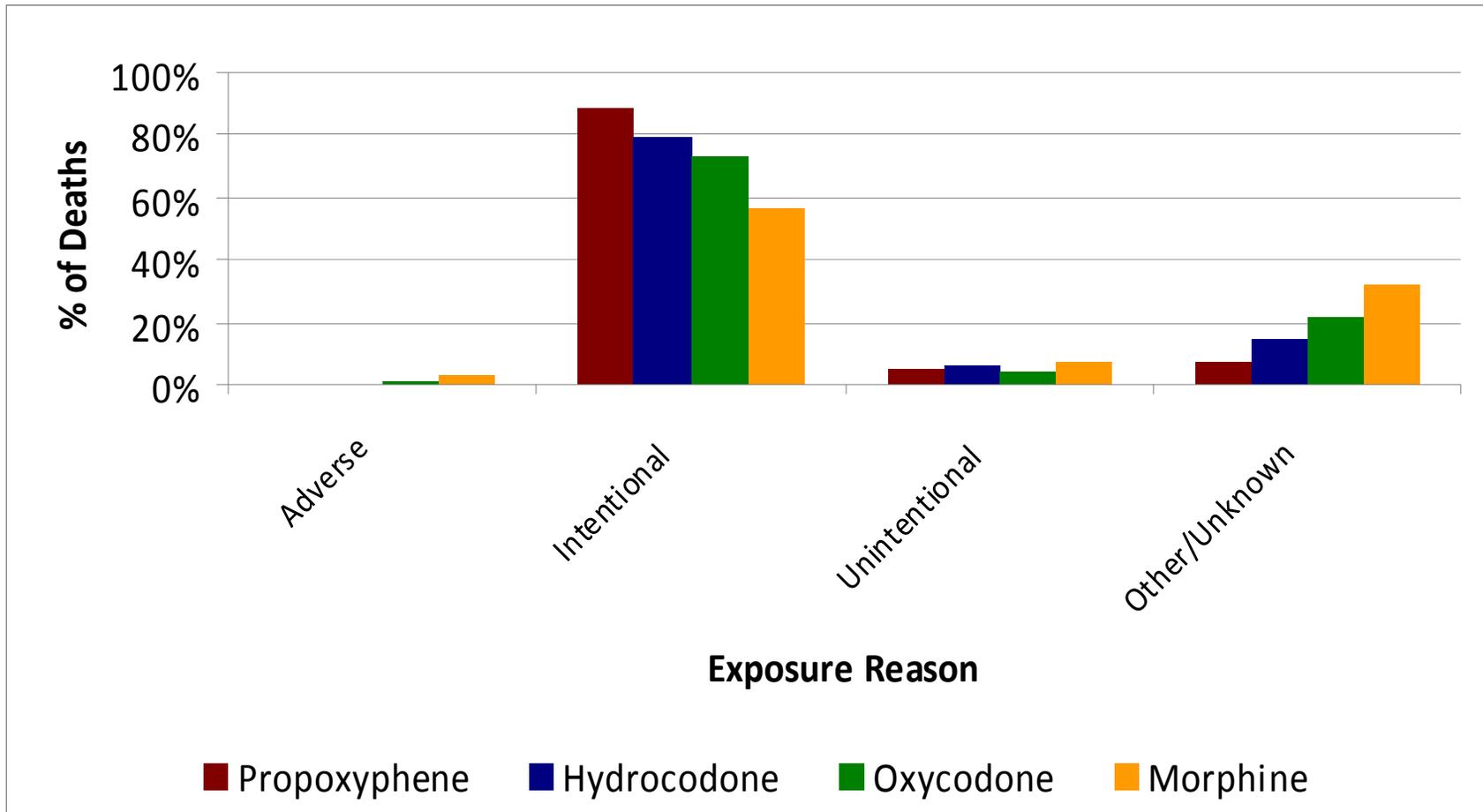
Rate of Death Associated with Propoxyphene Similar to Other Opioids



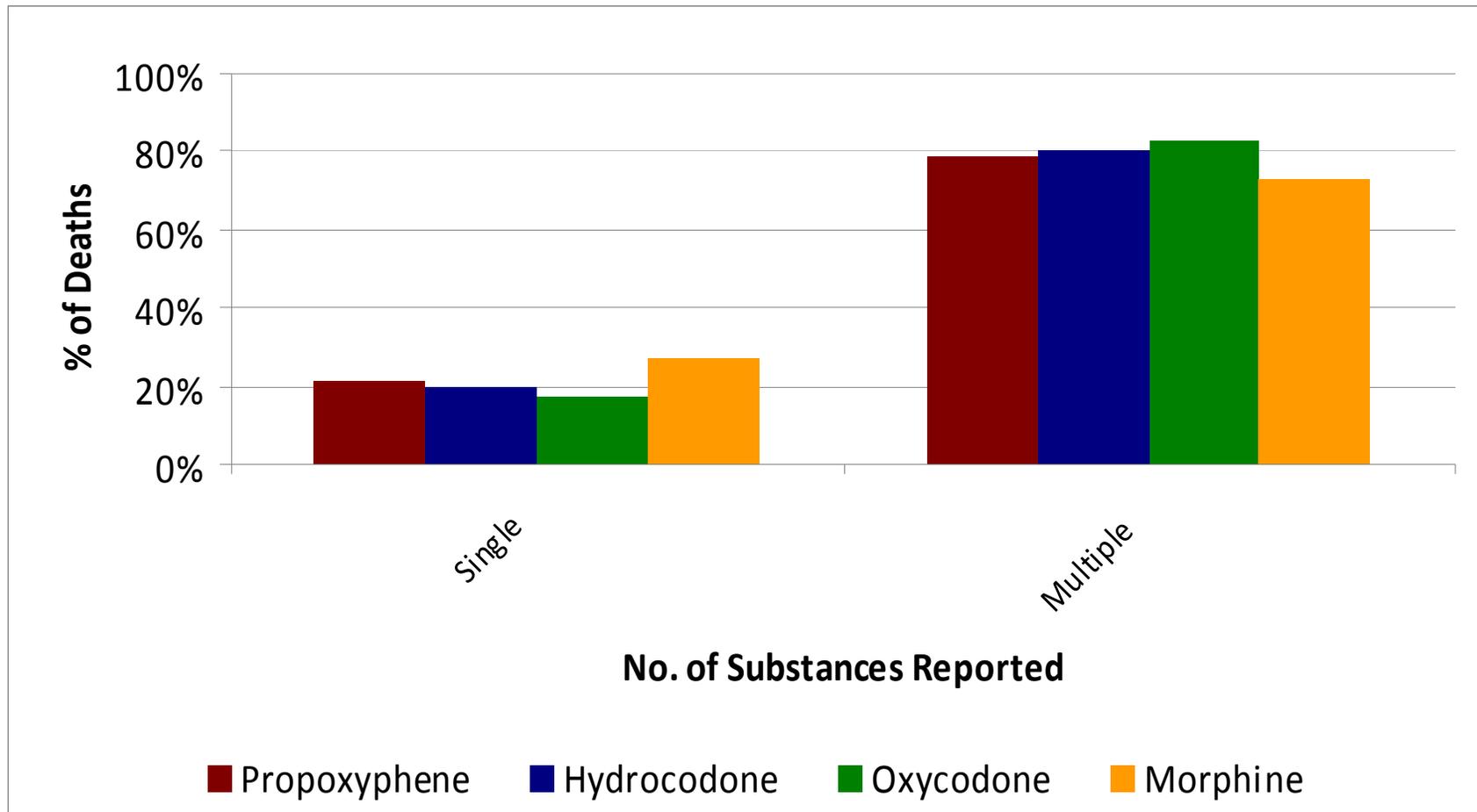
Age Distribution of Deaths Reported to NPDS



Majority of Deaths Associated with Intentional Exposure



Multiple Substances Reported in the Majority of Deaths



Conclusions

As reported to NPDS:

- Adverse drug reactions and intentional exposures to propoxyphene are decreasing.
- Propoxyphene exposure rates similar to most commonly prescribed opioids.
- Severe outcomes rarely associated with propoxyphene adverse drug reactions.