# Adverse Drug Event (ADE) Data Collection Fact Sheet

## Excessive Anticoagulation Due to Warfarin (HIIN-ADE-1a)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>• Inpatients experiencing excessive anticoagulation with warfarin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>• Inpatients receiving warfarin anticoagulation therapy</td>
</tr>
</tbody>
</table>

### Data Sources

**Numerator:**
- Small numbers and volumes can be hand-collected
- Daily concurrent review of patients on warfarin by pharmacy
- Weekly or monthly retrospective review of labs for patients on warfarin
- Medication dispensing cabinet reports
- Trigger tools
- Pharmacists’ intervention systems
- Medical record review

**Denominator:**
- Pharmacy systems
- Billing systems

### Partners to Team Up With

- Pharmacy
- Lab
- Information technology

### Tips and Tricks

- Very few clinical situations other than warfarin can cause an International Normalized Ratio (INR) >5 or 6. Assuming all excessive INRs are from patients on warfarin will eliminate the need to cross-check to see if they are all on warfarin. Numerators can be obtained from the lab, denominators can be obtained from the pharmacy and the resulting rate can be calculated manually.
- Note: A single patient with multiple INRs above threshold during a single admission is only counted once. Duplicate events for one patient during the same admission should be removed.
- Any INR above threshold after admission should count in the numerator. However, some hospitals report only high INRs that occur at least 48 hours after admission.

### Tools

- Please share useful tools, tips and tricks on the ADE Listserv: [http://www.hret-hiin.org/engage/listserv.shtml](http://www.hret-hiin.org/engage/listserv.shtml)

### Frequently Asked Questions

Q: What threshold should be used to define an excessive INR?  
A: No national standard defines a threshold for excessive INRs. While many hospitals use an INR of >5, each hospital may define its own threshold provided it consistently maintains this definition throughout the entirety of the HIIN project.
Hypoglycemia in Inpatients Receiving Insulin (HIIN-ADE-1b)

<table>
<thead>
<tr>
<th>Numerator</th>
<th>• Hypoglycemia (for example, plasma glucose concentration of below 50mg/dl) in inpatients receiving insulin or other hypoglycemic agents.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Denominator</td>
<td>• Inpatients receiving insulin or other hypoglycemic agents. Hospitals may choose to include only patients on insulin, those on insulin plus those on selected oral hypoglycemics or those on insulin plus those on any oral hypoglycemic. This decision should be made based on data of harm for each hospital and should remain consistent during the remainder of HIIN.</td>
</tr>
</tbody>
</table>

Data Sources

**Numerator:**
• Hand-collected “tally sheets” each time IV Dextrose 50% or Glucagon is administered
• Medication dispensing cabinet reports
• Lab or POC testing reports on blood sugar <50
• Trigger tools
• Pharmacists’ intervention systems
• Medical record review

**Denominator:**
• Billing systems
• Pharmacy systems

Partners to Team Up With

• Pharmacy
• Lab
• Information technology

Tips and Tricks

• Attach reporting sheet or sticker to D50 or Glucagon for easy reporting of utilization.
• Small numbers and volumes can be hand-collected – review each discharge chart.
• Perform daily concurrent review of patients on insulin with pharmacy staff.
• Perform weekly or monthly retrospective review of lab reports for patients on insulin.
• Severe hypoglycemia is rare in patients not on insulin or an oral hypoglycemic, so assume that all glucose levels representing severe hypoglycemia are from patients on hypoglycemics. Numerators can be obtained from the lab, denominators can be obtained from the pharmacy and the resulting rate can be calculated manually.
• Note: A single patient with multiple glucose levels below threshold during a single admission is only counted once. Duplicate events for one patient during the same admission should be removed.
• More information may be found in the ADE Change Package at: [http://www.hret-hiin.org/Resources/ade/17/ADE_ChangePackage-508.pdf](http://www.hret-hiin.org/Resources/ade/17/ADE_ChangePackage-508.pdf)

Tools

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Frequently Asked Questions

Q: How is hypoglycemia defined?
A: The American Diabetes Association (ADA) defines severe hypoglycemia as a plasma glucose <50 mg/dl. While many hospitals use the ADA threshold, each hospital may define its own. Please refer to individual hospital definitions and maintain consistent use of this definition throughout the HIIN project.
### Adverse Drug Events Due to Opioids (HIIN-ADE-1c)

| Numerator | • Number of patients treated with opioids who received naloxone.  
|           | • Hospitals may choose to include only injectable opioids, injectable opioids plus selected oral opioids or injectable opioid plus any oral opioids. This decision should be made based on data of harm for each hospital and should remain consistent during the remainder of HIIN. |
| Denominator | • Number of patients who received an opioid agent. |
| Inclusions | • Inpatients  
|           | • Patients in hospital outpatient departments where opioids are used (e.g., gastroenterology, cardiology, radiology, ambulatory surgery) |
| Exclusions | • Emergency department patients  
|           | • Patients on naloxone for pruritus or nausea |
| Data Sources Numerator: | • Hand-collected “tally sheets” each time naloxone is administered  
|           | • Paper or stickers attached to naloxone vials placed for pharmacy retrieval on regular basis as defined by hospital policy, practice or standards  
|           | • Medication dispensing cabinet reports  
|           | • Trigger tools  
|           | • Pharmacists’ intervention systems  
|           | • Medical record review |
| Denominator: | • Pharmacy systems  
|           | • Billing systems |
| Partners to Team Up With | • Pharmacy  
|           | • Procedural areas (e.g., respective procedural area charge nurses)  
|           | • Information technology |
| Tips and Tricks | • Small numbers and volumes can be hand-collected.  
|           | • Perform daily concurrent review of patients on opioids with pharmacy personnel.  
|           | • Perform weekly or monthly retrospective review of labs for patients on opioids.  
|           | • Attach reporting sheet or sticker to naloxone for easy reporting of utilization.  
|           | • Recurrent doses of naloxone to a single patient during a singular hospital stay count as one event.  
|           | • More information may be found in the ADE Change Package at: [http://www.hret-hiin.org/Resources/ade/17/ADE_ChangePackage-508.pdf](http://www.hret-hiin.org/Resources/ade/17/ADE_ChangePackage-508.pdf) |
| Tools | • Please share useful tools, tricks and tips on the ADE Listserv: [http://www.hret-hiin.org/engage/listserv.shtml](http://www.hret-hiin.org/engage/listserv.shtml) |
| Frequently Asked Questions | Q: Can you clarify what should be counted?  
|           | A: Any use of naloxone to treat oversedation including those events when naloxone is used to awaken post-procedure patients |