

# Preventing Harm from High Risk Drugs: Anticoagulants

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Utah Patient Safety Steering Committee  
Adverse Drug Effects User Group

June 2005

# Objectives

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- Describe the Failure Mode Effects Analysis process
  - Outline the process of how anticoagulants are used in organizations
  - Identify 5 potential vulnerabilities
  - Identify 5 opportunities to prevent harm
  - Describe how to use these tools
  - Create a plan for preventing harm in your organization
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# Adverse Drug Event Users Group

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- ❑ Subcommittee of Utah Patient Safety Steering Committee
  - ❑ Established to help address the adverse drug event (ADE) issues in Utah Patient Safety Regulation
  - ❑ Ultimately, prevent harm from using medications
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# High Risk Drugs

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- ❑ Drugs that pose the most risk to the organization in terms of harm
  - ❑ Represent the drugs with “low therapeutic index”—small changes in dose can have severe consequences
  - ❑ JCAHO expects organizations to develop plans to prevent harm from high risk drugs
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# Focus on anticoagulants

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- Unfractionated heparin
  - Warfarin (Coumadin®)
  - Low Molecular Weight Heparins
    - Enoxaparin (Lovenox®)
    - Dalteparin (Fragmin®)
  - Argatroban (Acova®)
  - Fondaparinux (Arixtra®)
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# Why anticoagulants?

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- ❑ Nationally, anticoagulants, opioids and insulin are the top 3 high harm drugs
  - ❑ Second most common cause of inpatient adverse events in Utah
    - 55% resulted in harm
    - Top high harm category
  - ❑ 33-55% of inpatients are on anticoagulants on any given day
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# Failure Mode Effects Analysis

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- Proactively prevent harm
  - Analyze system for vulnerabilities
  - Identify ways to help prevent harm (system failures)
  - Used IHI methodology
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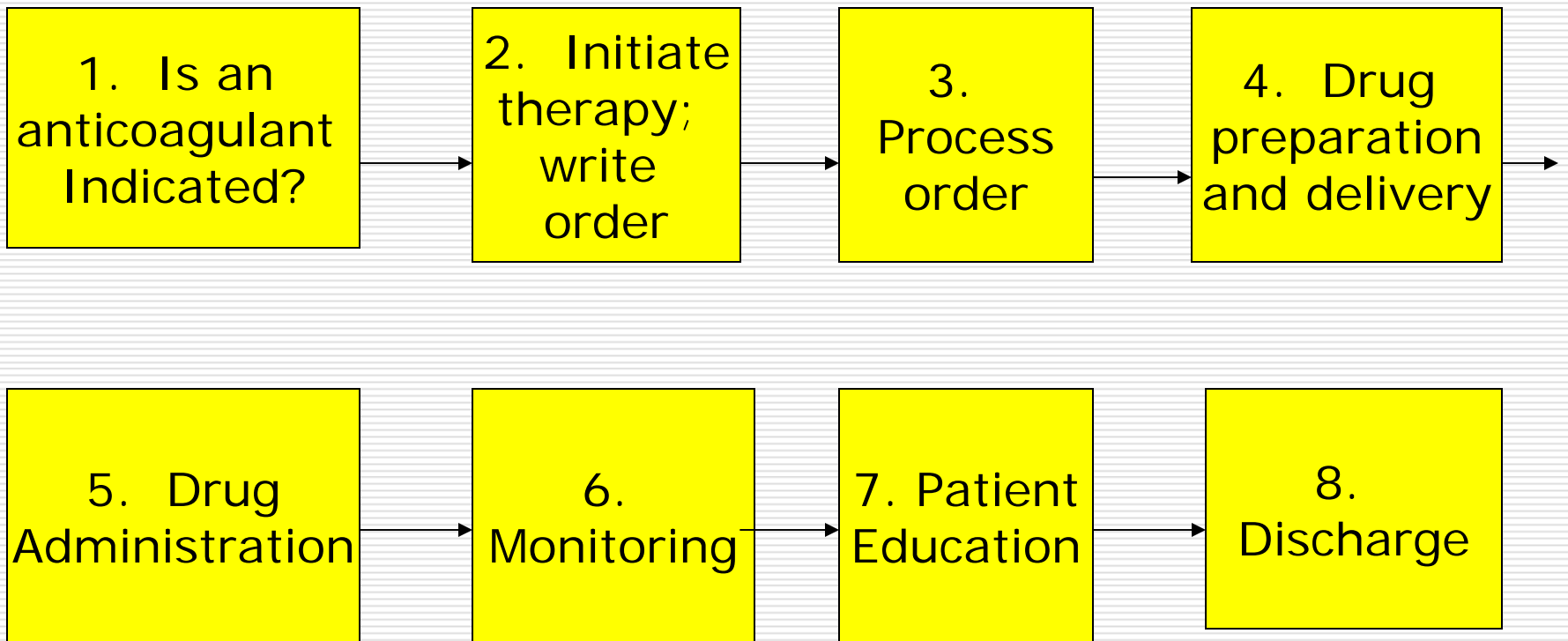
# Using FMEA

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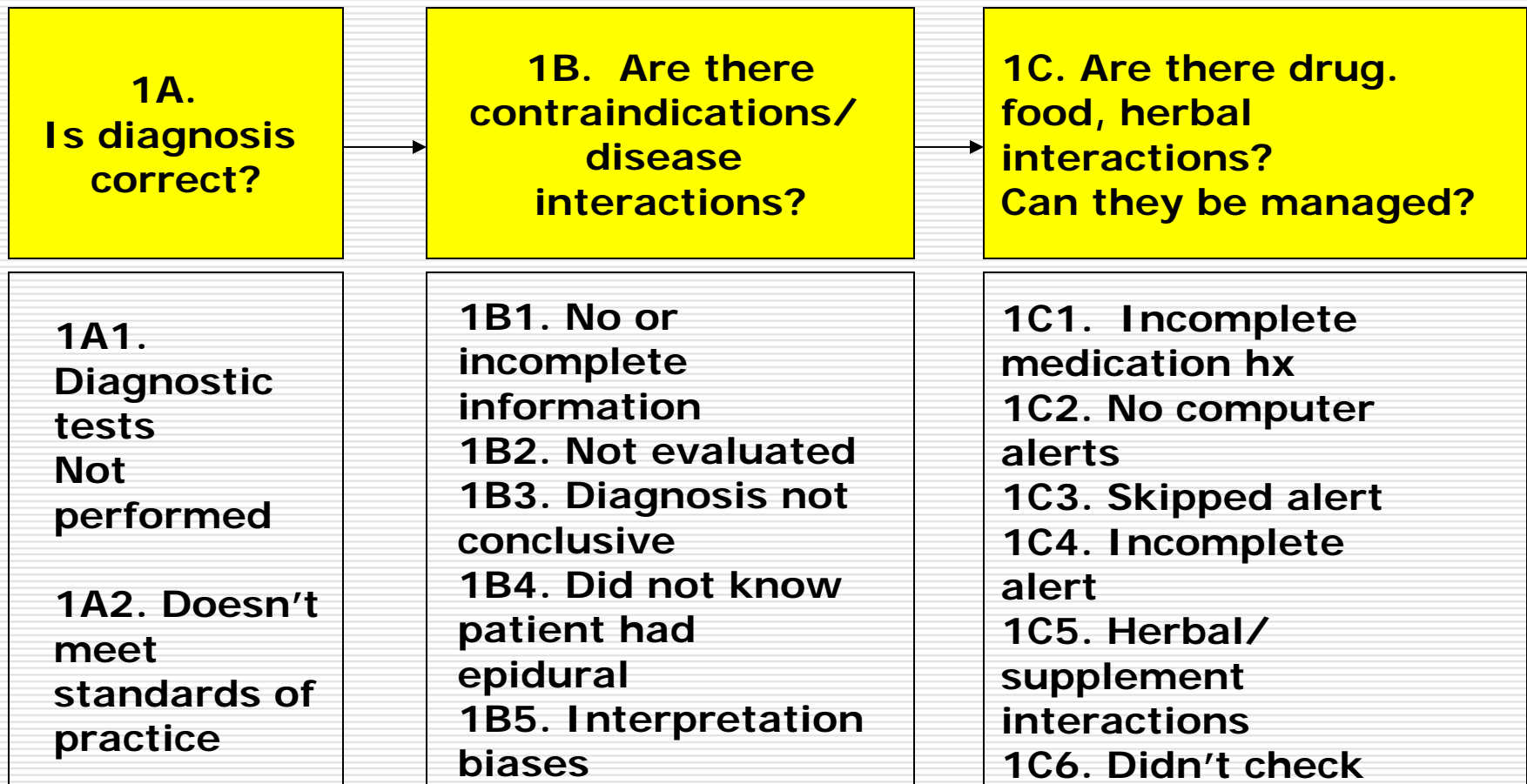
- ❑ Flowchart process
  - ❑ Assess failure modes, causes, and effects
  - ❑ Score likelihood, severity, and if event would be detected before harm occurred
  - ❑ Analyze process
    - Key vulnerabilities and opportunities
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# High Level Flowchart

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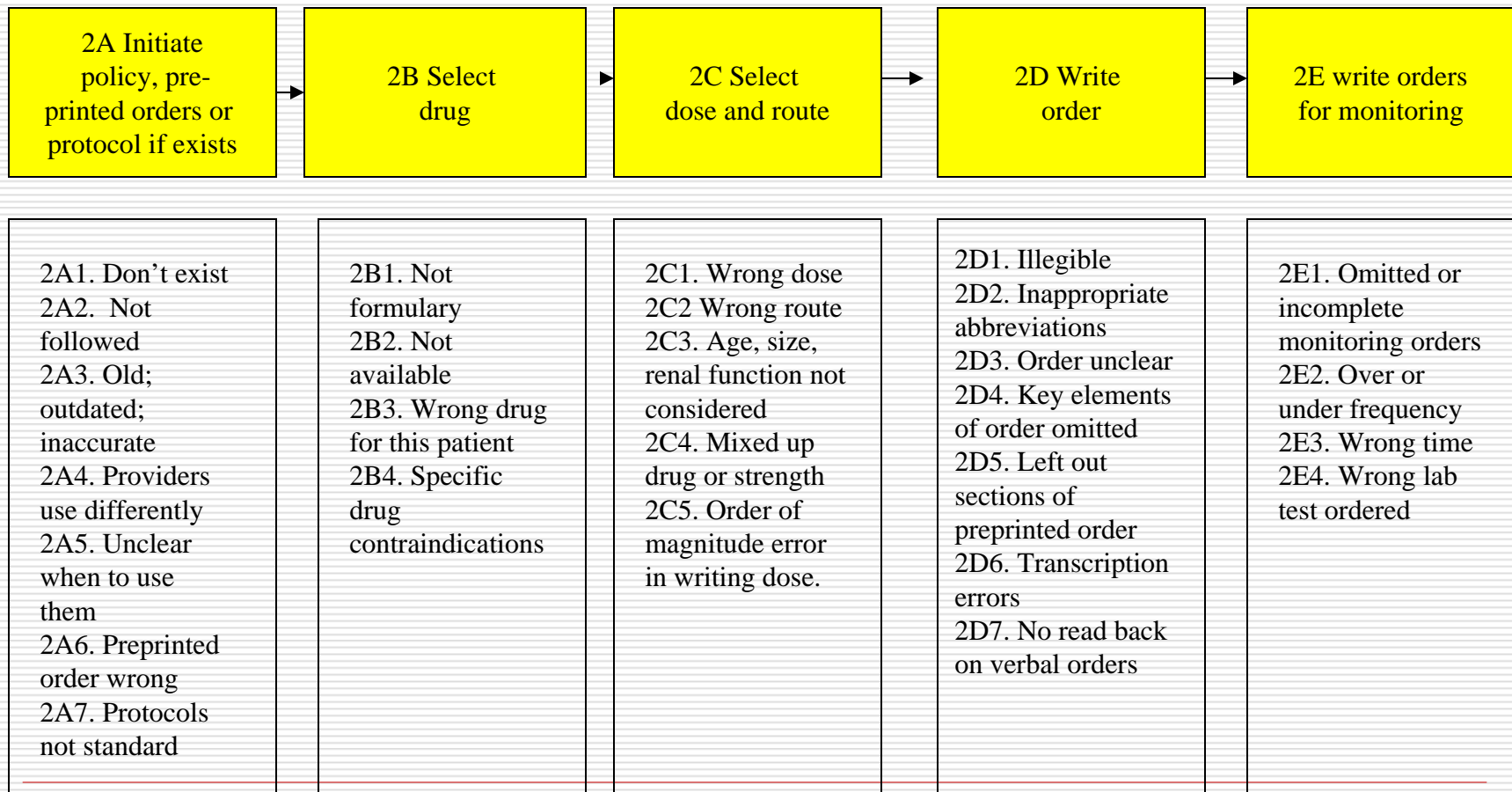


# Detailed flowchart and failure mode for each step

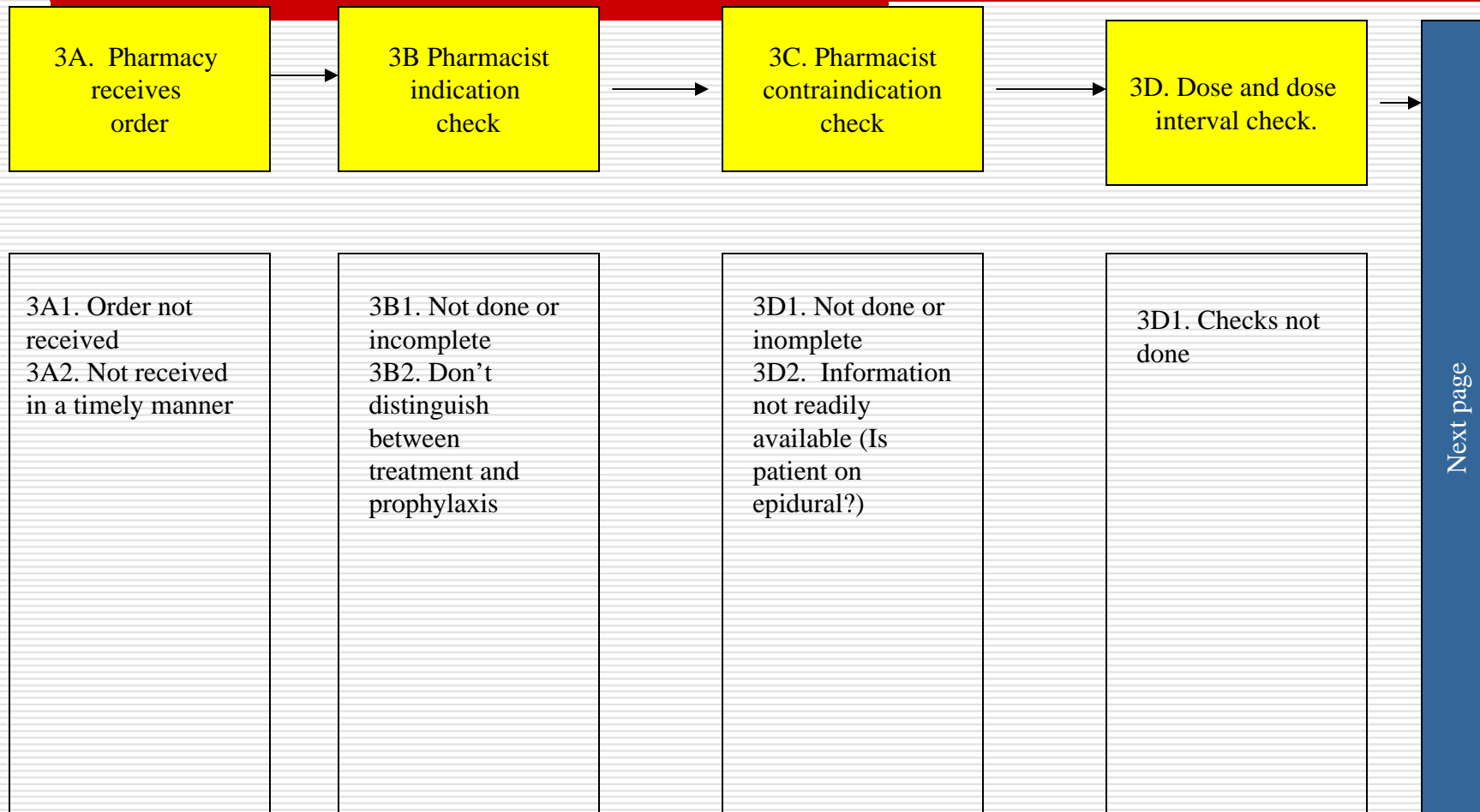


## 2. Initiate therapy, write order

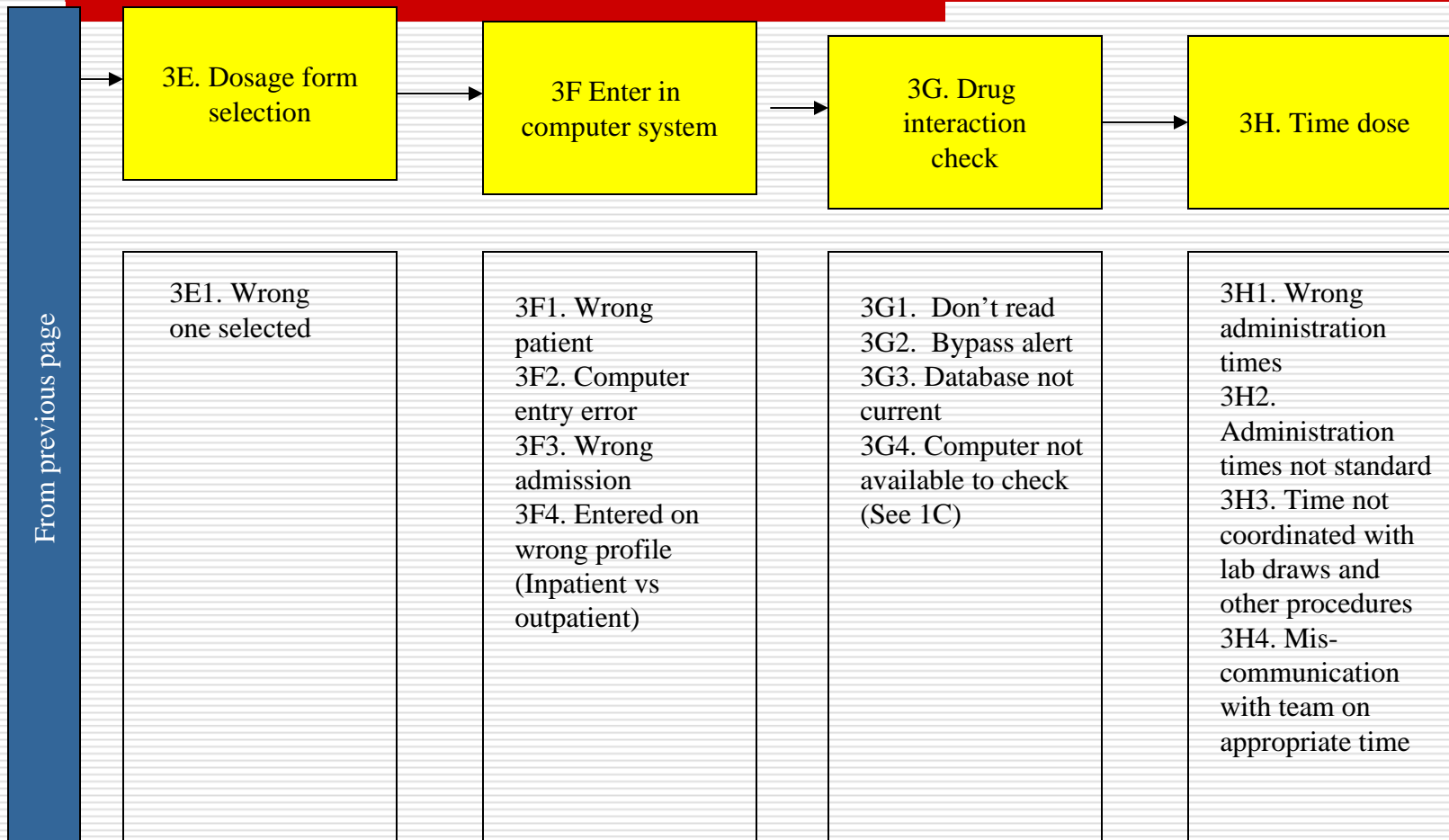
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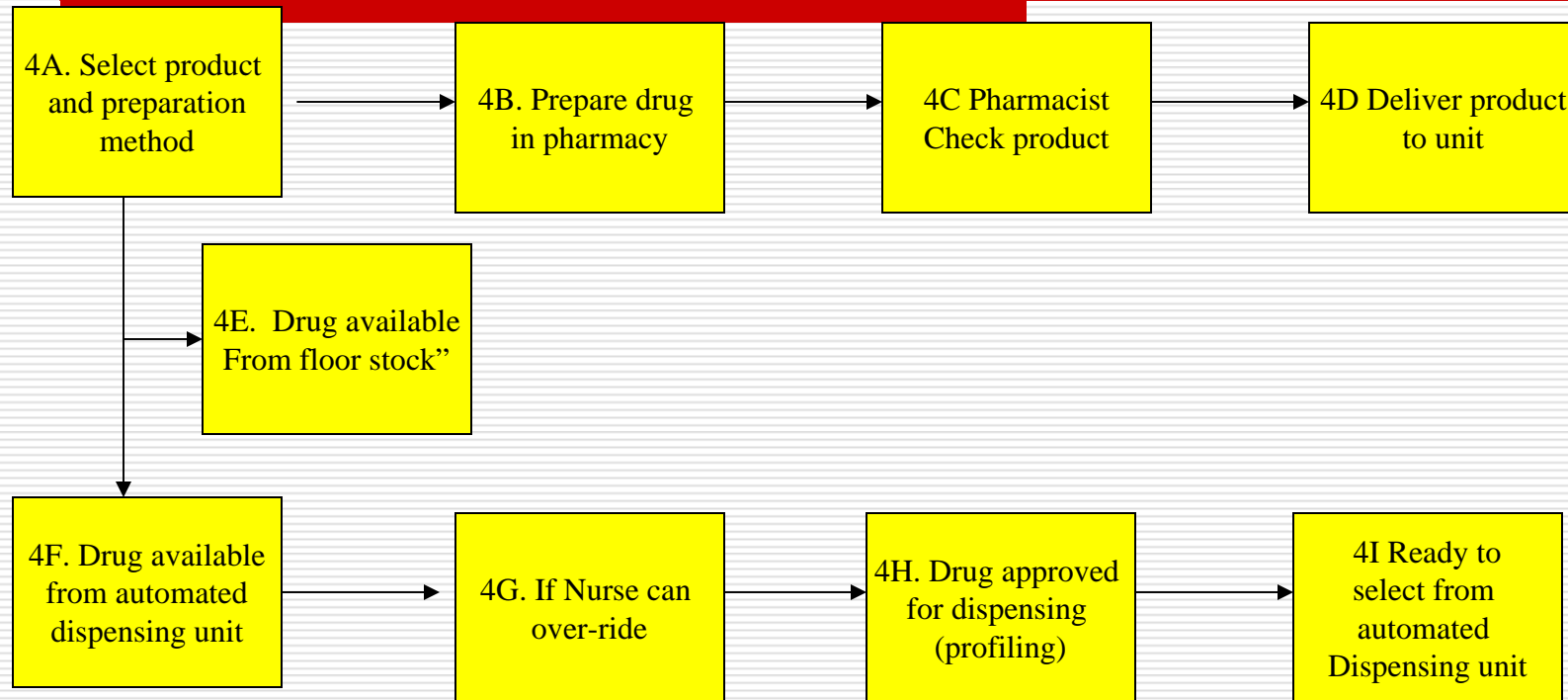
# 3. Process Order (part 1 of 2 parts)



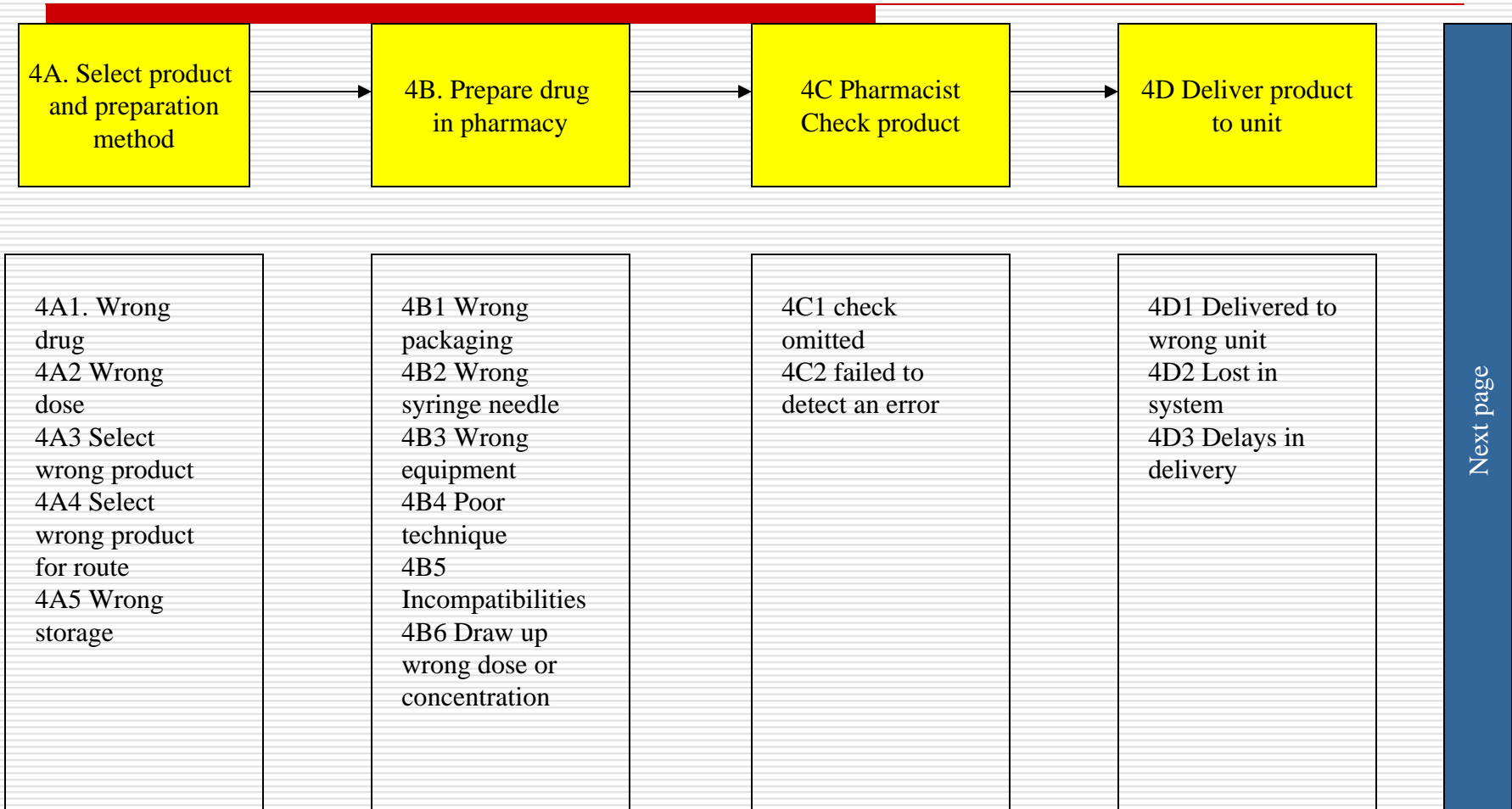
# 3. Process Order (part 2 of 2 parts)



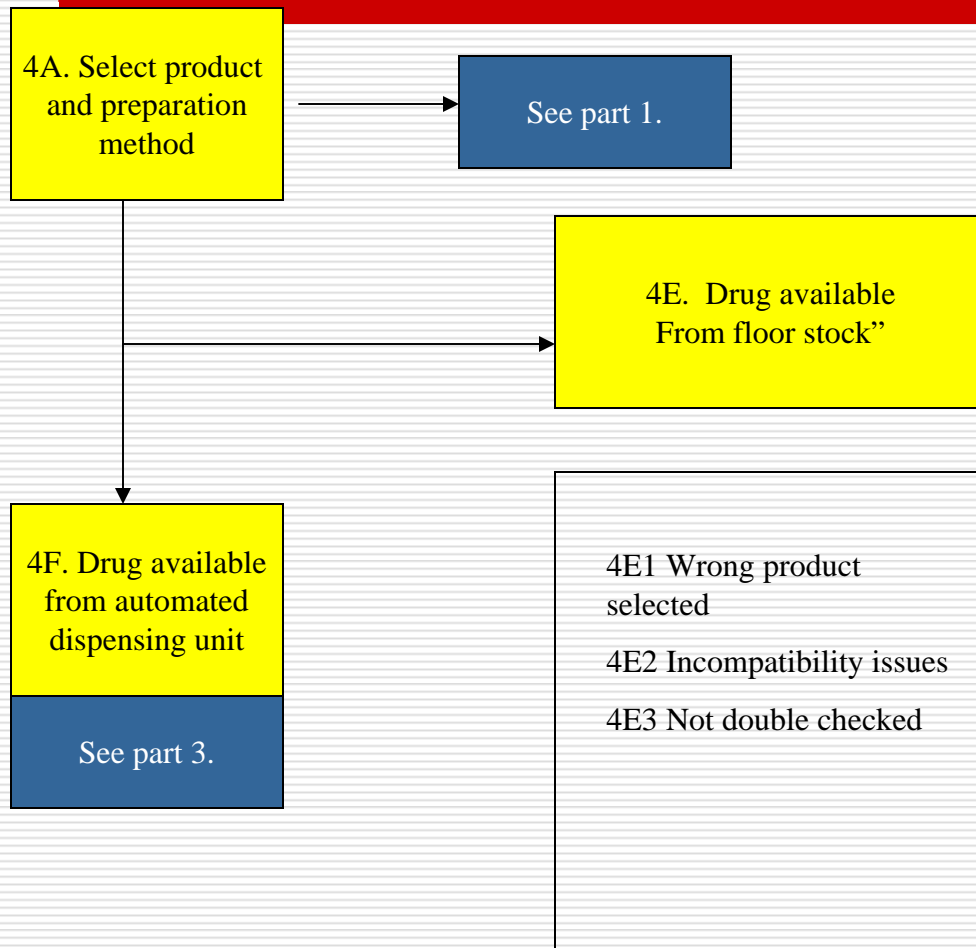
# 4. Drug preparation and delivery (High level diagram for this step)



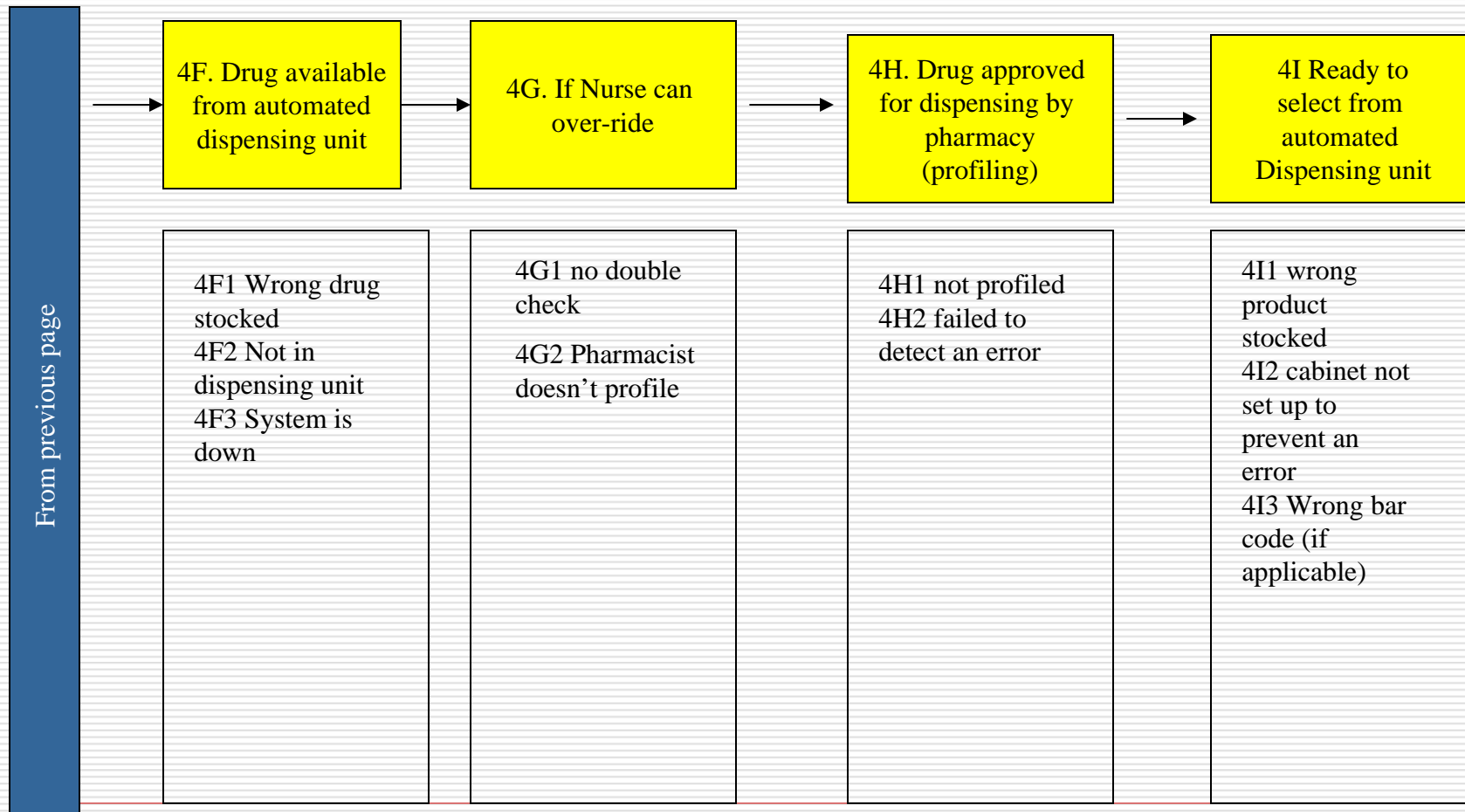
# 4. Drug preparation and delivery (part 1 of 3 parts, drug prepared in pharmacy)



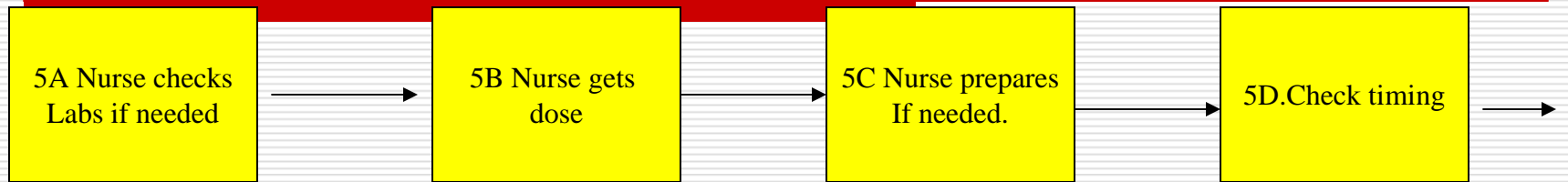
# 4. Drug preparation and delivery (Part 2 of 3 parts: Drug Available from floor stock)



# 4. Drug preparation and delivery (part 3 of 3 parts: drug available from automated dispensing unit)



# 5. Drug Administration



5A1 Labs not Available on time  
 5A2 Labs not checked  
 5A3 wrong lab checked (time mixed up)

5B1 Dose not available  
 5B2 Gets wrong dose  
 5B3 Gets wrong drug

5C1. Error in preparation

5D1 Incorrect time  
 5D2 Failure to communicate dose due



5E1 Programmed wrong  
 5E2 Incorrect use  
 5E3 Wrong tubing (heparin)  
 ? If free flow pumps used

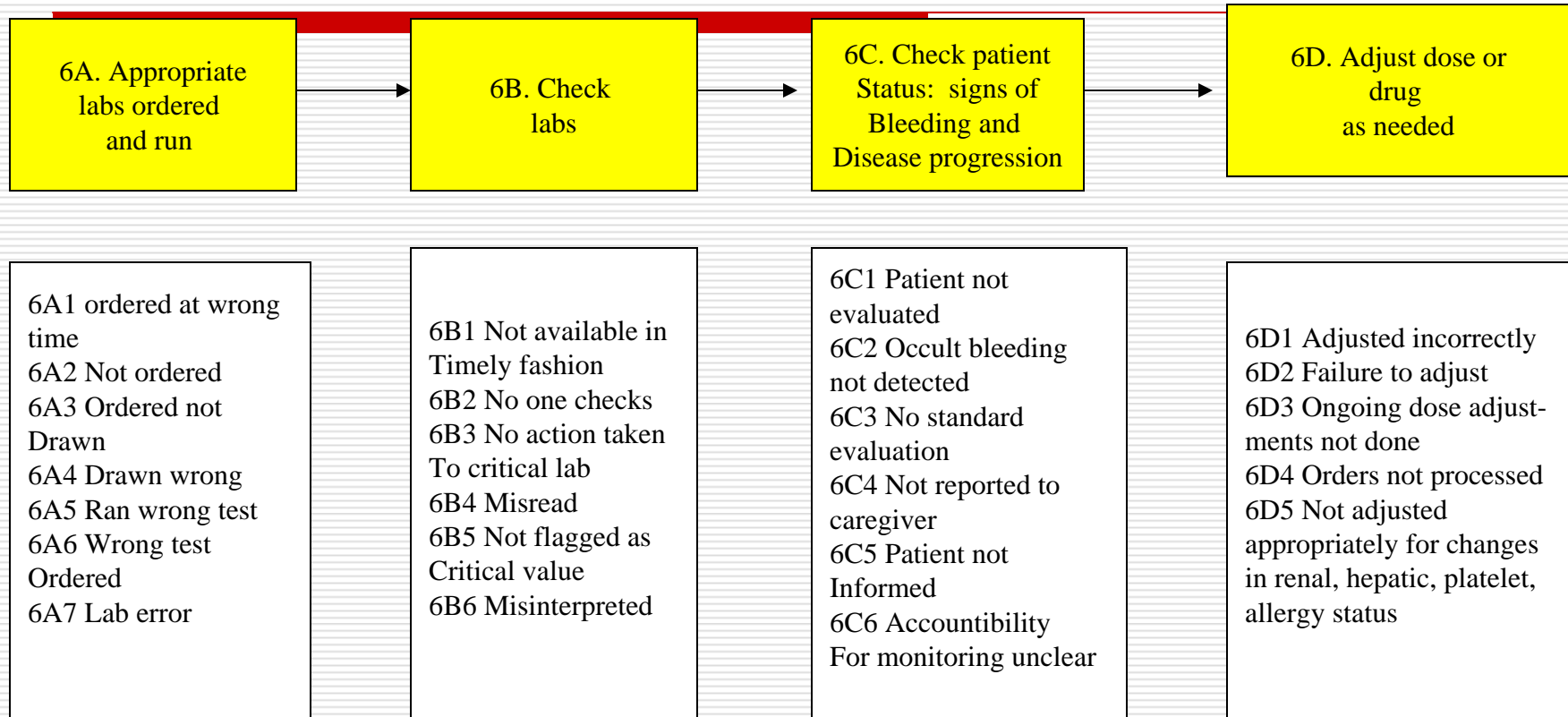
5F1 Didn't check  
 5F2 References not available or poor info

5G1 wrong patient

5H1 Site not rotated  
 5H2 Site not Documented  
 5H3 IV not patent

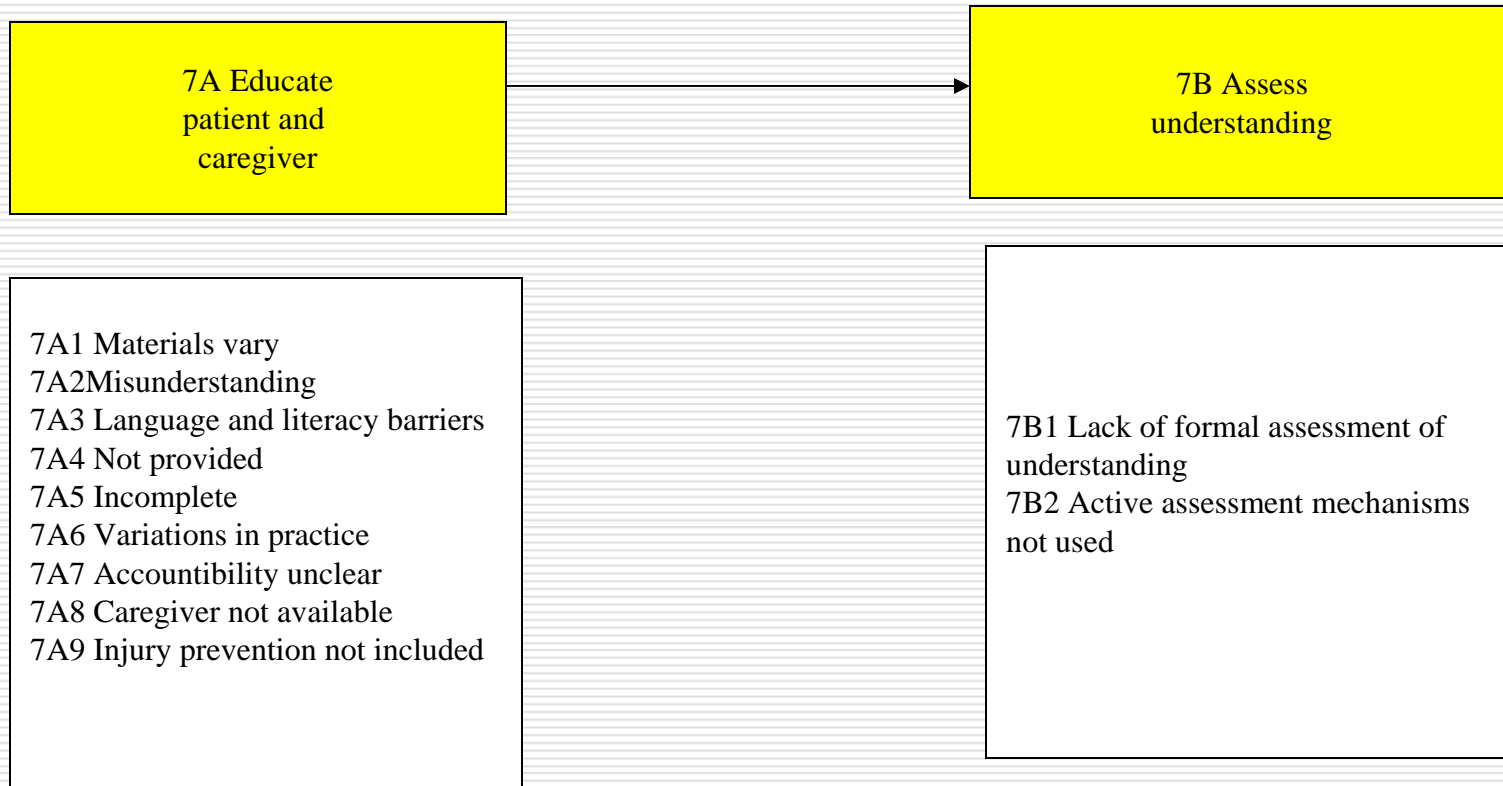
5I1 Poor technique  
 5I2 Lack of doc.  
 5I3. Administered Incorrectly  
 5I4 Wrong route

# 6. Monitoring



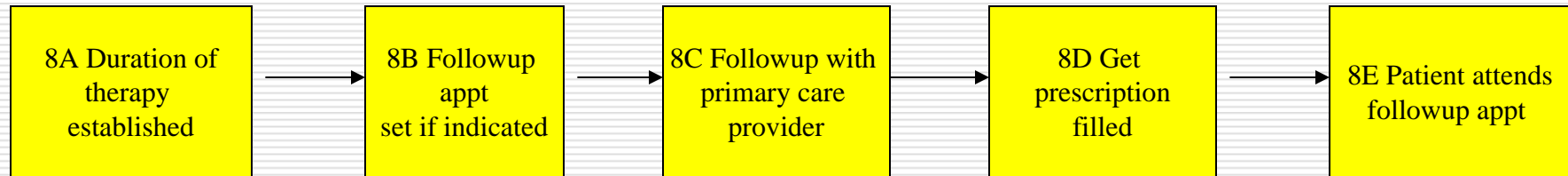
# 7. Patient Education

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# 8. Discharge Process

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8A1 Not established  
 8A2 Variation in Standards and guidelines  
 8A3 Physician variation  
 8A4 Not communicated to patient

8B1 No appt. set  
 8B2 Appt or place not communicated to patient  
 8B3 Pt or family does not understand.

8C1 Communication doesn't happen  
 8C2 Communication not received.

8D1 Payment or reimbursement issues not addressed.  
 8D2 Pharmacy doesn't carry  
 8D3 Don't get script Filled  
 8D4 Variations in counseling; conflicts with other information received

8E1 Transportation problems  
 8E2 Patient reschedules  
 8E3 No followup on missed appts.

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# Assess failure causes and effects

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- 1. Is anticoagulant indicated?
  - 1A. Is diagnosis correct?
  - Failure causes
    - Diagnostic tests not performed
    - Doesn't meet standard of practice
  - Failure effects
    - Anticoagulant administered when not indicated
    - No treatment when indicated
    - Failure of diagnostic test
    - Inappropriate prescribing
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# Score failure causes and effects

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- Likelihood of occurrence
    - 1-10, 10=very likely to occur
  - Likelihood of detection
    - 1-10, 10=Very unlikely to detect
  - Severity
    - 1-10, 10=most severe effect, death
  - Risk Priority Number (RPN)
    - Multiply the 3 other scores (1-1,000)
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# High vulnerabilities

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- Evaluated items with high individual scores (9 or 10)
  - RPN > 300
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# Scoring

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- ❑ 3C Contraindication check
    - Information not readily available (other diseases; epidurals)
    - Death, Bleeding, Thrombois
    - Frequent=5
    - Detect =8
    - Severity =8
    - RPN=320
    - Actions to prevent harm:
      - ❑ Consistent process for checking all orders
      - ❑ Pharmacist needs easy access to medical record
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# Excel spreadsheet

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|    |                        |  |                                 |   |   |   |     |   |
|----|------------------------|--|---------------------------------|---|---|---|-----|---|
| 3C | Contraindication check | Not done<br>Information not readily available (eg is patient on epidural?) | Bleeding<br>Death<br>Thrombosis | 5 | 8 | 8 | 320 | Use consistent process for checking for all orders.<br><br>Pharmacist needs access patient information. |
|----|------------------------|--|---------------------------------|---|---|---|-----|---|

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| Steps | Failure Mode  | Failure Causes   | Failure Effects                               | O | D | S  | RPN | Actions to Reduce Occurrence of Failure  |
|-------|---|--|---|---|---|----|-----|--|
| 1     | Is Anticoagulant Indicated?                               |  |   |   |   |    |     |  |
| 1A    | Is diagnosis correct?                                     | Diagnostic tests not performed   | Anticoagulant administered when not indicated | 1 | 5 | 4  | 20  | All caregivers double check diagnosis  |
|       |   |  | No treatment given when indicated             | 1 | 1 | 8  | 8   |  |
|       |   |  | Failure of test to diagnosis.                 | 2 | 9 | 8  | 144 | Use 2 tests to diagnosis when possible. Repeat inconclusive tests.   |
|       |   | Doesn't meet standards of practice<br>Clinicians unaware of standards  | Inappropriate prescribing of anticoagulants   | 2 | 1 | 7  | 14  | Pharmacists check indication<br>Educate prescribers<br>Establish treatment guidelines.   |
| 1B    | Are there contraindications or disease interactions?      | No or incomplete patient information<br>Not evaluated<br>Diagnosis inconclusive<br>Didn't know patient had a given contraindication (ie epidural)<br>Interpretation biases | Bleeding<br>Death<br>Thrombosis               | 2 | 2 | 10 | 40  | Pharmacists double check<br>Establish treatment guidelines that include information on contraindications.                                      |
| 1C    | Are there drug or food interactions? Can they be managed? | Incomplete medication history<br>No computer alerts<br>Skipped alert<br>Incomplete alert<br>Herbal/supplement interactions not considered<br>Didn't check                  | Bleeding<br>Death<br>Thrombosis               | 7 | 2 | 1  | 14  | Use pharmacy computer system that screens for drug interactions<br>Take a complete medication history including herbal/supplement information. |
|       |   |  | (Severity can range from 1-10)                | 7 | 2 | 10 | 140 |  |

| 7  | Patient Education             |   |   |   |    |    |     |   |
|----|-------------------------------|---|---|---|----|----|-----|---|
| 7A | Educate patient and caregiver | Materials vary<br>Misunderstanding<br>Language and literacy barriers<br>not provided<br>incomplete<br>variations in practice<br>Accountability unclear<br>Caregiver not available<br>Injury prevention not included | Bleeding<br>Death<br>Thrombosis                       |   |    |    | 0   | Systematic process for educating patients on anticoagulants.                |
|    |                               |   | Failure to educate patient on disease and efficacy    | 5 | 9  | 8  | 360 |   |
|    |                               |   | Failure to educate patient on ADRs including HIT      | 9 | 10 | 10 | 900 |   |
|    |                               |   | No education received by patient                      | 2 | 9  | 10 | 180 |   |
| 7B | Assess understanding          | Lack of formal assessment of understanding<br>Active assessment mechanisms not used   | Use drug inappropriately<br>Increase risk of bleeding | 4 | 3  | 10 | 120 | Formalize options when patient and or caregiver do not understand education |

| 8  | Discharge                              | Causes   | Effects  | O | D  | S  | RPN | Prevention  |
|--|--|--|--|---|----|----|-----|---|
| 8A   | Duration of therapy established        | Not established<br>Variation in standards and guidelines<br>Physician variation<br>Not communicated to patient   | Exposed to drug longer than needed<br>Progression of disease   | 5 | 9  | 7  | 315 | Use protocols<br>Document clearly disease being treated and duration of therapy<br>Communicate information to outside caregivers                      |
| 8B   | Follow-up appointment set if indicated | No follow-up appt set<br>Appt or place not communicated to patient<br>Pt or family does not understand   | Patient has complications and unclear where to go<br>Develops drug or disease interactions   | 4 | 9  | 10 | 360 | Use protocols<br>Discharge documentation process established<br>Communicate with outside caregivers<br>Follow-up that patient went to follow-up appt. |
| 8C   | Follow-up with primary care provider   | Communication doesn't happen<br>Communication not received   | Patient has complications and unclear where to go<br>Develops drug or disease interactions   | 7 | 9  | 10 | 630 | Establish process to communicate with outside caregivers  |
| 8D   | Get prescription filled                | Payment or reimbursement issues not addressed<br>Pharmacy doesn't carry<br>Don't get script filled<br>Variations in counseling.<br>Conflicts with other information received | Patient has complications and unclear where to go<br>Develops drug or disease interactions (depending on system, can vary in frequency from 3-7) | 3 | 10 | 10 | 300 | Establish process to work with patient/caregiver to address these issues prior to leaving the hospital and as part of the follow-up.                  |
|  |  |  |  | 7 | 10 | 10 | 700 |   |
| 8E   | Patient attends follow-up appointment  | Transportation problems<br>Patient reschedules<br>No follow-up on missed appointments  | Bleeding<br>Death<br>Thrombosis  | 6 | 10 | 10 | 600 | Use follow-up protocol.   |
| (O)=Likelihood of occurrence1-10, 10=very likely to occur, (D)=Likelihood of detection1-10, 10=Very unlikely to detect, (S)=Severity1-10, 10=most severe effect, death, RPN=Risk Priority Number |  |  |  |   |    |    |     |   |

# Specific Vulnerabilities

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- Checking for contraindications, food and drug interactions
  - Double checking process in pharmacy
  - Drug available from floor stock
  - Nursing able to “over-ride” and administer before pharmacist double checks order
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# Specific Vulnerabilities (cont)

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- Failure to monitor patient
  - Failure to educate patient and caregiver
  - Duration of therapy not established
  - Follow-up not established
  - Patient does not receive follow-up or does not get prescriptions filled
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# Actions to reduce harm

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- Establish and follow guidelines and protocols
  - Consider drugs other than heparin where appropriate
  - Assign clear accountabilities
  - Develop alerting systems
  - Use standard concentrations of parenteral solutions
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# More actions to reduce harm

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- ❑ Consider use of “smart” pumps or other safety check for administration
  - ❑ Standard process for educating patients and providing for follow-up care
    - Assign clear accountability for these tasks
  - ❑ Double check therapy at transfer of care situations
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# Resources

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- Literature guidelines and references
  - Websites specific to anticoagulation therapy
  - Comparing heparin and low-molecular weight heparins
  - Samples of system checklist, preprinted orders, and protocols
  - User group participants
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# Resources available

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- Available at [www.uha-utah.org](http://www.uha-utah.org)
  - Select publications
  - Resources available
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# Apply to your organization

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- Apply key learning from this project
    - Are the vulnerabilities issues in your system?
    - Are the actions to prevent harm possible in your organization?
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# Applying to your organization: FMEA for anticoagulants

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- ❑ Conduct similar process using framework used in project
    - Evaluate if flow charts apply
    - Conduct own scoring
    - Identify own opportunities to prevent harm
    - Evaluate changes in scores as implement measures
  - ❑ Use blank spreadsheet from [www.uha-utah.org](http://www.uha-utah.org)
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# Applying to your organization: Using FMEA for other processes

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- Examples: [www.ihl.org](http://www.ihl.org)
  - <http://uuhsc.utah.edu/pharmacy/rxweblinks/>
    - Links to other patient safety websites
    - [www.patientsafety.gov](http://www.patientsafety.gov) other method for healthcare FMEA
  - Other high risk drugs
  - Major changes to your system
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# Utah Patient Safety Regulations

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- Requires organization to have a program to reduce adverse drug events
  - Audit every 3 years
    - JCAHO: Will want to see a FMEA for high risk drugs
    - Can be part of any program to reduce ADEs
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# Summary

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- ❑ Anticoagulation therapy is highly complex
  - ❑ Many opportunities for harm
  - ❑ Recommendations for reducing harm
  - ❑ FMEA is a useful tool both for this statewide initiative and for individual facilities as applied to high-risk drugs
  - ❑ Apply to your organization!!
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