Simulation-based Training for Safety Incidents: Lessons from Analysis of Adverse Events in Robotic Surgical Systems
Homa Alemzadeh1, Zbigniew Kalbarczyk1, Ravishankar K. Iyer1, Thenkurussi Kesavadas1, Stephan Small2, Jai Raman3
University of Illinois at Urbana-Champaign1, University of Chicago Medical Center 2, Rush University Medical Center3

ADVERSE EVENTS IN ROBOTIC SURGERY
- During 2000–2013, more than 1.75 million robotic procedures were performed in the U.S. across different surgical specialties.
- We analyzed reports to U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.
- 10,624 adverse events related to robotic surgery [1]
- 1,535 (14.4%) with significant negative patient impact:
  - injuries (1,391 cases) and deaths (144 cases)
- procedure interruptions (970 cases) to:
  - Manually reset of the system
  - Convert the procedure to non-robotic surgery
  - Reschedule the procedure to a later date
- 9,382 (88.3%) involving device and instrument malfunctions

SYSTEM-RELATED SAFETY HAZARDS

Example device and instrument malfunctions
- Master tool manipulator (mtm) malfunctions
- Patient side manipulator (psm) failures
- Unintended operation of instruments (e.g. uncontrolled movements, power on/off)
- Video/imaging problems at the surgeon’s console
- Recoverable and non-recoverable system errors
- Burns and holes in tip cover accessories, leading to electrical arcing, sparking, or charring of instruments
- Broken parts of instruments falling into patients

Example inadequate operational practices
- Inadequate handling of emergency situations
- Lack of training with specific system features
- Inadequate troubleshooting of technical problems
- Inadequate system/instrument checks before procedure
- Incorrect port placements
- Incorrect electro-cautery settings or cable connections
- Inadequate manipulation of robot master controls
- Inadequate hand and foot coordination by main surgeon
- Incorrect manipulation or exchange of instruments

PRELIMINARY RESULTS

<table>
<thead>
<tr>
<th>Safety Hazard Scenario</th>
<th>Injected Fault</th>
<th>Target Software Module</th>
<th>No. Manifested/ Injected Faults</th>
</tr>
</thead>
<tbody>
<tr>
<td>H4. Recoverable System Errors</td>
<td>Intermittent master tool manipulator malfunction</td>
<td>Faulty input stream</td>
<td>22/30</td>
</tr>
<tr>
<td>H4. Non-recoverable System Errors</td>
<td>Sensor (encoder) reading malfunctions</td>
<td>Faulty output stream</td>
<td>64/64</td>
</tr>
<tr>
<td>H2. Unintended Instrument Movements (Sudden jumps)</td>
<td>Patient-side manipulator malfunctions</td>
<td>Faulty Output Stream</td>
<td>10/12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3/4</td>
</tr>
</tbody>
</table>

SUMMARY
- A simulation framework for creating realistic safety hazard scenarios during robotic surgery training
- Prepare surgical trainees for handling safety-critical events
- Future work:
  - Conduct human subject testing on a group of surgical trainees exposed to hazard scenarios in a simulated environment
  - Evaluate surgical trainee’s behavior and performance to obtain feedback on the simulated environment

REFERENCES