Risk management methods applied to healthcare transportation solutions

Christelle Laot, PhD, MBA - Technical Fellow

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FedEx Express

The largest express transportation company in the world (revenues of $27B)

Links 99% of the world’s GDP

Custodial control

Speed

Reliability

Industry experts community
What goes in cargo planes?

Variety of shipment types

**Letters**
538,000 overnight envelopes per day on average within the US

**Freight**

**Small parcels**

**Exceptional shipments**
Shipment type: letters

Letters are handled in a separate automated sort system

Dedicated sort system: conveyor belts and bags, which are placed in containers

Buildings are typically temperature controlled
Shipment type: small parcels

From conveyor belts to containers
Container type, position and mix

Letters and small parcels travel in containers

Unit Load device (ULD)
Standard IATA codes: AYY, AKE, AMJ
Different materials: aluminum, polycarbonate

Shipment position within container
Other shipments within the container

Temperature (°C)

ULO made of:
- clear plastic
- clear plastic
- aluminum
- aluminum
- aluminum

Reported weather of 37°C

Local date and time

Sunday afternoon

MEM
Shipment type: freight

Palletized freight is placed on aircraft pallets often referred to as cookie sheets (PMC, PAG)

Comment: bypass containers are handled as freight shipments and do not go through sort at all transit locations
Risk of temperature excursion by air?

The highest risk is sometimes near shipment origin rather than near final destination.

Example of temperatures experienced by small packages without special thermal protection in FedEx Express® air transportation network.

Temperature devices programmed for 1 data point every 4 minutes and placed inside FedEx® boxes.

FedEx Priority Overnight® US shipments: Delivery next business day by 10:30am local time to most areas.
Environmental conditions in flight

SenseAware® powered by FedEx offers near-real time monitoring of:
- Temperature
- Pressure
- Relative humidity
- Position
- Light

Multi-sensor devices can be programmed to send alerts if a shipment travels off-route or is exposed to unexpected conditions.

Learn more at senseaware.com
Air transportation parameters

- **Shipment type:** letters / parcels / freight

- **Tarmac exposure**
  - Environmental conditions
  - Service level
  - Day versus night operations
  - Day of the week for shipping
  - Seasonality

- **Plane-related**
  - Plane type
  - Cargo compartment
  - Temperature gradient within cargo compartment
  - Cold spot near the cargo door
FedEx® thermal blanket solution

- Passive cold chain turnkey solution for express freight shipments
- Ideal for controlled room temperature (CRT) shipments at 15-25°C, with allowable short variances of ± 5°C
- Relatively inexpensive and green solution
- Protection from rain and dirt
- Proactive monitoring
- Priority boarding and clearance handling priority
- Temperature-controlled FedEx aircraft
- Contingency storage
- First and last mile delivery on refrigerated trucks, if requested
- Reverse logistics managed by FedEx
Blanket protection

When you need to protect your pallets of pharmaceuticals, medical devices, computer sensors or other high-value items from temperature excursion during the entire transportation cycle, FedEx has you covered with the end-to-end FedEx® thermal blanket solution. Here’s how it works:

1. **Your shipment is picked up by a FedEx temperature-controlled vehicle and transported to the nearest FedEx Express origin ramp.**
   - Your shipment is unwrapped, loaded onto a FedEx temperature-controlled vehicle and delivered to the recipient.

2. **Our crew wraps your shipment in reusable thermal blankets that maintain a consistent temperature range for your pallets of freight and provide insulation protection against direct sunlight, rain and humidity.**
   - Your shipment receives priority boarding and travels aboard a FedEx Express aircraft to the destination ramp.

3. **A dedicated team of analysts provides round-the-clock support, proactive monitoring and coordination and customized recovery procedures.**

Call 1.800.GoFedEx 1.800.463.3339 or go to fedex.com/healthcare to learn more.
Timeline of solution design

R&D within transportation provider: collaboration towards innovative solution

Pre 2010

- No dedicated healthcare division within FedEx Express until January 2010

2010

- Customer request for passive CRT freight solution from India to the US
- Successful planning and implementation of unique solution by project engineers
- Standardization of solution
- Beta program opened to limited number of shippers by word of mouth

2011

- Marketing gets engaged
- Scalability efforts
- Additional transportation lanes
- Proofs of concept for qualification by potential shippers
- Thermal blanket design
- Risk management document
- Metrics
- Proactive monitoring

2012

2013

2014

- Automate the solution with specific handling code for increased reliability and scalability
- SenseAware® add-in for near real-time location and environment

Beyond 2014

Christelle Laot, PhD, MBA
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October 24th, 2014
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Creating risk management document

Internal document

Literature review; a few references

ICH Q9 “Quality Risk Management”
PQG “A Guide to Supply Chain Risk Management for Suppliers to the Pharmaceutical Industry”
AFF/SFSTP “Practical Guidelines - Cold Chain for Medicines”

Scope of work

FedEx® thermal blanket solution

Teamwork

Regular meetings with internal key stakeholders
Review of existing operating procedures
Risk assessment and control
Identifying and evaluating risk

To look at 2 phases:

- **Phase 1**: Pickup and delivery, along with blanket wrapping and unwrapping
- **Phase 2**: Shipment within FedEx Express® transportation network

Risk management methods applied to healthcare transportation solutions

- Identification of operational parameters
- Failure mode and effects analysis (FMEA)
- Risk prioritization

Risk assessment → Risk quantification
Ishikawa “fishbone” diagram
6 categories of causes of failure, and associated operational parameters

Phase 1

- **Materials**
  - Thermal blanket
  - Aircraft pallet
  - Netting
  - External temperature and relative humidity
  - Infrastructure
  - Traffic conditions
  - Internal and customer pest control, cleanliness
  - Premises

- **Methods**
  - Training materials around blanket wrapping/unwrapping
  - Internal standard global SOP
  - Customer SOP
  - Shipment conditioning
  - Regulatory clearance
  - Compliance with delivery time and place
  - Training

- **Measurements**
  - Asset numbers
  - Temperature devices
  - Number of skids
  - Height of shipment
  - Type and number of vehicle
  - Dedicated account number
  - Blanket inspection

Issues related to pickup and delivery, along with blanket wrapping and unwrapping
### Failure Mode and Effects Analysis (FMEA)

**Phase 1: Pickup and delivery, along with blanket wrapping and unwrapping**  
**Category: Materials**

<table>
<thead>
<tr>
<th>Operational parameter</th>
<th>Potential failure mode</th>
<th>Possible causes</th>
<th>Potential effects / consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thermal blanket</strong></td>
<td>Supplier issue; no new blanket available anymore (temporarily or permanently)</td>
<td>Unique supplier</td>
<td>Interruption of service</td>
</tr>
</tbody>
</table>
|                       | Not enough inventory at shipment pickup | Lack of robust inventory management system  
Poor communication around blanket movements  
No records of blankets thrown away  
Poor customer forecasts  
Mismatch of tops and bottoms | Pickup to be postponed |
|                       | Vendor qualification not established | Lack of defined criteria to accept new vendor | Concerns from customers |
|                       | Damaged blanket (wrapping / unwrapping) | No visual inspection  
No checklist | Temperature excursion |
|                       | Wet blanket at wrapping | Stored while still wet | Reduced thermal performance |
| **Aircraft pallet**   | PMC instead of PAG cookie sheet, and vice-versa | Unexpected change in system form  
Poor communication | Delays |
| **Netting**           | Not tight enough | Poor training | Shipment could move around and break |
Risk Prioritization Number (RPN)

RPN is a product of the 3 following parameters:
Severity (SEV)
Probability of occurrence (OCC)
Probability of detection (DET)

<table>
<thead>
<tr>
<th>Value</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low risk</td>
<td>Unlikely</td>
<td>Certainly detected before delivery</td>
</tr>
<tr>
<td>2</td>
<td>Medium risk</td>
<td>Yearly</td>
<td>Likely to be detected before delivery</td>
</tr>
<tr>
<td>3</td>
<td>Product endangered</td>
<td>Quarterly</td>
<td>Detected after delivery</td>
</tr>
<tr>
<td>4</td>
<td>Product lost</td>
<td>Weekly</td>
<td>Current controls will not detect</td>
</tr>
</tbody>
</table>

We have: \[ RPN = SEV \times OCC \times DET \], with \( 1 \leq RPN \leq 64 \)

A risk prioritization matrix is an effective tool to quantify risks and to prioritize activities when various parameters have the potential to impact performance.
### Risk prioritization matrix

**Phase 1: Pickup and delivery, along with blanket wrapping and unwrapping**

**Category: Materials**

<table>
<thead>
<tr>
<th>Category</th>
<th>Operational parameter</th>
<th>Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Materials</td>
<td>Thermal blanket</td>
<td>Supplier issue; no new blanket available anymore (temporarily or permanently)</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Not enough inventory at shipment pickup</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vendor qualification not established</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Damaged blanket: wrapping</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Damaged blanket: unwrapping</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wet blanket at wrapping</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Aircraft pallet</td>
<td>PMC instead of PAG cookie sheet , and vice-versa</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Netting</td>
<td>Not tight enough</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Respective values for SEV, OCC, and DET decided in team meetings

RPN values calculated and marked with following colors in tables:
White from 1 to 17, gray from 18 to 40 and black from 41 to 64
RPN graphs

Phase 1: Pickup and delivery, along with blanket wrapping and unwrapping

RPN of 18 under Category “Materials”

Maximum RPN of 48 for Phase 1
Controlling risk

4 potential risk control approaches:
Risk avoidance (eliminates the conditions causing the risk)
Risk mitigation (minimizes the risk)
Risk acceptance (acknowledges the existence of the risk; no action)
Risk transfer (other parties responsible, insurances)

High RPN scoring values obtained in the risk prioritization matrix were identified as critical and should be tightly controlled

<table>
<thead>
<tr>
<th>Phase</th>
<th>Operational parameters</th>
<th>Identified risks</th>
<th>RPN</th>
<th>Risk control approach</th>
<th>Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Training materials around blanket wrapping/unwrapping</td>
<td>Employees not following guidelines</td>
<td>48</td>
<td>mitigation</td>
<td>Reinforce training Document issues</td>
</tr>
<tr>
<td>2</td>
<td>Communication to pilots</td>
<td>No temperature adjustment communicated to pilots</td>
<td>48</td>
<td>mitigation</td>
<td>Develop process</td>
</tr>
<tr>
<td>2</td>
<td>Cargo compartment</td>
<td>Temperatures in aircraft bellies not adjusted to account for FedEx thermal blankets</td>
<td>48</td>
<td>mitigation</td>
<td>Develop process</td>
</tr>
<tr>
<td>2</td>
<td>Location and time of FedEx thermal blankets on tarmacs</td>
<td>Unknown</td>
<td>48</td>
<td>acceptance</td>
<td></td>
</tr>
</tbody>
</table>

Outcome of risk management initiative ➔ Prioritization of activities and resources associated with FedEx® thermal blanket solution project
Flight temperatures

Default temperature settings implemented for B777F FedEx fleet on all routes

Temperature profile around positions after 9 hours in the air:

- **main deck**
  - 8°C (bottom) to 20°C (top of container)

- **forward belly**
  - 7°C to 15°C

- **aft belly**
  - 2°C to 8°C

- Time and temperature-sensitive shipments are typically placed on the main deck
- If needed, temperature settings in the B777F bellies can be adjusted to accommodate healthcare shipments
Aircraft temperature compliance
B777F temperature data accessible in near-real time and archived

• Proprietary FedEx B777F temperature software designed by FedEx aircraft engineers
• Information in near-real time during B777 flights
  ACARS messages
• Temperature data archived on internal server

• Reports
  Temperature compliance across the FedEx B777F fleet
  Risk-based approach focusing on main transportation lanes for healthcare shippers
• Corrective actions, if necessary
Sampling, continuous improvement, Corrective and Preventive Actions (CAPA)

Risk reduction tools

**Sampling**
Temperature measurements by FedEx team for research purposes

**Continuous improvement**
Internal inspections
Customer feedback

**CAPA forms**
for reported issues
Key takeaways

• Air transportation is complex and inside knowledge is often needed to interpret temperature results.

• Special products and services are available to minimize risk of temperature excursions in transit and maintain product integrity.

• FedEx technical experts use risk management methods in the design of healthcare transportation solutions.
Questions?

Direct contact (christelle.laot@fedex.com) or fedex.com/healthcare