

# Risk assessment of the hospital discharge process of high-risk patients with diabetes

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## ABSTRACT

**Objectives** Describe the application of a risk assessment to identify failures in the hospital discharge process of a high-risk patient group, liver transplant (LT) recipients with diabetes mellitus (DM) and/or hyperglycaemia who require high-risk medications.

**Design** A Failure Modes, Effects and Criticality Analysis (FMECA) of the hospital discharge process of LT recipients with DM and/or hyperglycaemia who required DM education and training before discharge was conducted using information from clinicians, patients and data extraction from the electronic health records (EHR). Failures and their causes were identified and the frequency and characteristics (harm, detectability) of each failure were assigned using a score of low/best (1) to high/worst (10); a Criticality Index (CI=Harm×Frequency) and a Risk Priority Number (RPN=Harm×Frequency×Detection) were also calculated.

**Setting** An academic, tertiary care centre in Chicago, Illinois.

**Participants** Healthcare providers (N=31) including physicians (n=6), advanced practice providers (n=12), nurses (n=6), pharmacists (n=4), staff (n=3) and patients (n=6) and caregivers (n=3) participated in the FMECA; EHR data for LT recipients with DM or hyperglycaemia (N=100) were collected.

**Results** Of 78 identified failures, the most critical failures (n=15; RPNs=700, 630, 560; CI=70) were related to variability in delivery of diabetes education and training, care coordination and medication prescribing patterns of providers. Underlying causes included timing of patient education, lack of assessment of patients' knowledge and industry-level design failures of healthcare products (eg, EHR, insulin pen).

**Conclusion** Most identified critical failures are preventable and suggest the need for the design of interventions, informed by the failures identified by this FMECA, to mitigate safety risks and improve outcomes of high-risk patient populations.

## BACKGROUND

Current gaps in transitions of care from the inpatient to outpatient setting have prompted both local and national initiatives to improve care processes more proactively.<sup>1</sup> Acute care transitions, in particular, continue to result in communication breakdowns that have consistently been at the root of over 80% of

reported events resulting in death or serious injury.<sup>2</sup> After discharge from the hospital, 49% of patients experience a medical error and 19%–23% suffer an adverse event within 3 weeks of discharge, most commonly an adverse drug event.<sup>3,4</sup>

Insulin and oral antihyperglycaemic agents are identified as the second and fourth most common medications leading to hospitalisation due to adverse events.<sup>5</sup> This study focuses on a particularly high-risk group of patients, post-liver transplant (LT) recipients with diabetes mellitus and or hyperglycaemia (heretofore referred to as 'DM'), who are discharged with a new DM medication(s). Indeed, up to 50% of LT recipients have new hyperglycaemia and 30% develop long-term DM.<sup>6</sup> Most LT recipients have multiple healthcare providers and often times encounter transportation barriers to the urban care setting (downtown Chicago), making postdischarge chronic care planning especially complex. However, assuring safe postdischarge care of LT recipients with DM is critical because of the significant impact of unstable glucose levels on organ rejection and infection.<sup>7–9</sup>

While robust risk assessment approaches, such as a Failure Mode Effects and Criticality Analysis, have been used in surgery and emergency medicine, none have been applied to the complex discharge process for patients with new DM care needs.<sup>10,11</sup> Although interventions, focused on the discharge process, have been evaluated,<sup>12–15</sup> results are mixed and none have focused exclusively on risks in the hospital discharge process of patients with DM. A recent, systematic review of hospital-initiated transition programmes found that many of the tested interventions had little impact on rehospitalisation<sup>16</sup> and, those that did, such as the Care Transitions Program and Project Red,<sup>15,17,18</sup> were complex and resource intensive.



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The objective of this study was to conduct a comprehensive, proactive risk assessment of the discharge process for LT recipients with DM at an academic, tertiary care hospital that cares for >350 transplant patients (~100LT) per year to identify opportunities to mitigate potential failures and prevent harm.<sup>19</sup> Similar to many other high-risk industries (eg, nuclear energy, automotive), a Failure Modes Effects and Criticality Analysis (FMECA) was used,<sup>20</sup> with all relevant stakeholders (clinicians, staff, patients, caregivers) qualitatively describing the process with additional relevant electronic health record (EHR) data and direct observations to identify, characterise and rank identified failures. Underlying causes were classified and initial containment or permanent solutions were proposed for the most critical failures of the process.

## METHODS

The study consisted of four phases (table 1).

The scope of the study began with the decision to discharge the patient by the primary team (transplant team) and ended when the patient was deemed ready to be discharged from the hospital.

*Phase I* consisted of the conduct of an FMECA, direct observations of the discharge process and patient tracers,<sup>21 22</sup> led by an industrial engineer (RK). First, potential failures, their underlying causes and the potential impact or harm of each identified failure were elicited during six FMECA sessions; one session with patients/caregivers (n=9) and five sessions with clinicians/staff, including Certified DM Educators (CDE), physicians, advanced practice providers, nurses, pharmacists and clinic staff (n=32). Next, direct observation (n=10) of the discharge process from the perspective of all involved (eg, clinicians, staff) was conducted. Patient tracers (n=6), a

method developed by the Joint Commission, in which a patient's medical record is used to 'trace' the processes of care, were conducted.<sup>21 22</sup> For this study, the processes were traced from the perspective of an LT recipient with DM (and their caregiver) during the discharge process. The research team used the medical record to follow all the steps in the discharge process by interviewing patients and caregivers about what he/she experienced at each step. These data were used to create a process map.

For *phase II*, data were retrieved from the Enterprise Database Warehouse for LT recipients with DM (n=100) to estimate hypoglycaemia and hyperglycaemia ( $\leq 70$  mg/dL,  $\geq 200$  mg/dL) occurrences within 30 days post-transplantation, DM medication discrepancies in discharge instructions and 30-day outpatient telephone encounters to the specialty team (endocrinology team).

*Phase III* involved scoring the frequency (F), potential harm (H) and current detection methods (D) of each failure using a high/best (1) to low/worst (10) scale, based on a scoring sheet, customised for DM (table 2).

A Criticality Index (CI=Harm×Frequency) and a Risk Priority Number (RPN=Harm×Frequency×Detection) were then calculated for each failure.<sup>11 23</sup>

In *phase IV*, failures were ranked by their highest *index rank*, a combination of both CI and RPN. Failures that involved processes for which the underlying cause was beyond the authority of the patient, clinician or health-care institution were then identified as the responsibility of the healthcare industry. The highest ranked failures were reviewed with primary and specialty teams to ascertain clinical relevance and to gather initial containment or permanent solutions. Causes of the failures were classified using the Joint Commission Root Causes by Event Type (2004–2013).<sup>24</sup>

**Table 1** Study phases

Phase I	Phase II	Phase III	Phase IV
<b>Qualitative data</b>	<b>Quantitative data</b>	<b>Scoring</b>	<b>Ranking</b>
Identify and list potential failures (effects and causes)	Medical record review (n=100)	Harm (H) Frequency (F) Detection (D)	<i>Top ranked CIs</i> Example: max (H=7)×(F=10)=70
Six participant sessions	<ul style="list-style-type: none"> <li>▶ DM history and medication</li> <li>▶ Incidence of hypo/hyperglycaemia postdischarge (30 days)</li> </ul>	See table 2. Diabetes mellitus scoring sheet	<i>Top ranked RPNs</i> Example: max (H=7)×(F=10)×(D=10)=700
Create process map	<ul style="list-style-type: none"> <li>▶ Endocrinology or Certified Diabetes Educator consultation prior to discharge</li> </ul>	<i>Scoring Scale</i> High/best: 1 Low/worst: 10	<i>Assign root causes</i> Joint Commission Classifications
Direct observations	<ul style="list-style-type: none"> <li>▶ Discharge regimen</li> <li>▶ Outpatient follow-up with endocrinology clinic (phone calls and complete visits, 30 days)</li> </ul>	<i>Criticality Index (CI)</i> (H)×(F) scores	
Patient tracers	<ul style="list-style-type: none"> <li>▶ Readmissions (30 days, 1 year, n=50 patients)</li> <li>▶ Rejection and infection (1 year, n=50 patients)</li> </ul>	<i>Risk Priority Number (RPN)</i> (H)×(F)×(D) scores	

DM, diabetes mellitus.

**Table 2** Diabetes mellitus risk scoring sheet

Score	Effect/consequence (harm)		Frequency of failure (frequency)/patients		Safeguard detectability (detection)	
1	None	No reason to expect failure to have any effect on safety, health, environment or mission.	None	1/10 000	Almost certain	Current control(s) almost certain to detect failure mode. Reliable controls are known with similar processes.
2	Very low	Minor disruption to discharge process. Repair of failure is accomplished through verbal communication with team member. Process example: Patient's DM status is unknown.	Very low	1/5000	Very high	Very high likelihood current control(s) will detect failure mode. Example: Automatic mean of detection that prevents the process from continuing.
3	Low	Minor disruption to discharge process. Repair of failure may take 30–60 min to correct. Outcome example: Blood glucose is 150–200 mg/dL. Process example: The provider cannot find supplies immediately because supplies are in different locations.	Low	1/2000	High	High likelihood current control(s) will detect failure mode. Example: Semiautomatic mean of detection with warning that does not prevent the process from continuing (eg, a pop-up window reminder).
4	Low to moderate	Moderate disruption to discharge process. Repair of failure takes 2 hours to correct. Outcome example: Asymptomatic hyperglycaemia (blood glucose value is 200–249 mg/dL). Process example: The caregiver is not present for diabetes education session, discharge is delayed.	Low to moderate	1/1000	Moderately high	Moderately high likelihood current control(s) will detect failure mode. Example: Semiautomatic mean of detection (eg, an alarm that does not prevent the process from continuing).
5	Moderate	Moderate disruption to discharge process. Discharge is delayed for 2–4 hours because steps are not completed in a timely fashion. Outcome example: Symptomatic hyperglycaemia (blood glucose is 200–250 mg/dL). Process example: Primary team does not contact diabetes team for discharge recommendations on time. Diabetes education is delayed and happens later in day.	Moderate	1/500	Moderate	Moderate likelihood current control(s) will detect failure mode. Example: Double human inspection with a checklist or standard aid, or triple human inspection without checklist or standard aid.
6	Moderate to high	Moderate disruption to discharge process. Discharge is delayed 4–8 hours. Outcome example: Asymptomatic hypoglycaemia (blood glucose is <70 mg/dL) or asymptomatic hyperglycaemia (blood glucose value is 250–349 mg/dL). Process example: New diabetes or hyperglycaemia onset, patient needs more time with diabetes team to feel comfortable prior to discharge. Discharge is delayed.	Moderate to high	1/200	Low	Low likelihood current control(s) will detect failure mode. Example: Double human inspection with a checklist or standard aid, or triple human inspection without checklist or standard aid.

Continued

Table 2 Continued

Score	Effect/consequence (harm)	Frequency of failure (frequency)/patients	Safeguard detectability (detection)
7	High High disruption to discharge process (1 day). Outcome example: Symptomatic hypoglycaemia (blood glucose is <70 mg/dL) or symptomatic hyperglycaemia (blood glucose value is 250–349 mg/dL). Process example: Patient deemed ready for discharge and diabetes team consulted. Patient needs more time with diabetes team before leaving the hospital. Discharge is delayed to the next day.	High 1/100	Very low Very low likelihood current control(s) will detect failure mode. Example: Informal single human inspection (inspection is not routinely part of the process).
8	Very high Patient suffers non-permanent damage or needs acute intervention. Outcome example: Asymptomatic hypoglycaemia (blood glucose is <40 mg/dL) or asymptomatic hyperglycaemia (blood glucose is >350 mg/dL). Rejection and infection risk increased.	Very high 1/50	Remote Remote likelihood current control(s) will detect failure mode. Example: Informal single human inspection (inspection is not routinely part of the process).
9	Hazard Potential safety, health or environmental issue. Outcome example: Symptomatic hypoglycaemia (blood glucose is <40 mg/dL) or symptomatic hyperglycaemia (blood glucose is >350 mg/dL). Heart attack or seizure or retransplant is associated with hypoglycaemia or hyperglycaemia.	Hazard 1/20	Very remote Very remote likelihood current control(s) will detect failure mode.
10	Hazard Potential safety, health or environmental issue. Outcome example: Blood glucose is <40 mg/dL. Patient dies.	Hazard 1/10+	Almost impossible No known control(s) available to detect failure mode.

DM, diabetes mellitus.

## RESULTS

Seventy-eight (78) total failures in the discharge process of high-risk patients with DM were identified. Of the 78 failures, 50 (74%) had an estimated frequency of 1 in 100 patients (frequency score  $\geq 7$ ) and 27 (35%) had evidence of patient harm (harm score  $\geq 7$ ) (eg, symptomatic hypoglycaemia or hyperglycaemia). Failures with harm scores  $< 7$  were not further characterised. No failures with a harm score of 9 or 10 (permanent harm or death) were identified. The underlying causes of failures were variability and suboptimal performance in three specific areas: (1) delivery of diabetes education and training (comprehension/self-care assessment); (2) care coordination; and (3) lack of standardised prescribing by providers. Table 3 shows the top ranked failures in each area, and potential containment and permanent solutions.

### Failures in delivery of DM education and training

Lack of availability of training supplies, specifically the insurance covered DM supplies for self-care at home, was identified as the highest ranked failure given the inconsistent availability of DM supplies. Other failures were lack of systematic and readily available pre-discharge evaluation of patients' self-care competencies and variability in length and intensity of pre-discharge education, due to clinician time constraints and also occurred whether a CDE was available or not (eg, weekdays or weekends, evenings).

### Failures in care coordination

Overall, failures in coordination of postdischarge care needs by the transplant team were highly ranked and included inconvenient and/or uncoordinated follow-up

**Table 3** High-risk failures and potential solutions

Failure	Effect	H	Causes	F	D	CI	RPN
Variability in the delivery of DM education and training							
<ul style="list-style-type: none"> <li>▶ DM medication dosage education not fully understood by patient or caregiver</li> </ul>	<ul style="list-style-type: none"> <li>▶ Patient delays contacting provider with questions</li> <li>▶ Patient experiences symptomatic hypoglycaemia (<math>\leq 70</math> mg/dL) or symptomatic hyperglycaemia (250–349 mg/dL)</li> </ul>	7	<ul style="list-style-type: none"> <li>▶ Patient education</li> <li>▶ Duration of DM medication education inadequate</li> <li>▶ Poor timing of education as patient/caregiver is often overwhelmed and dealing with multiple discharge issues</li> </ul>	10	8	70	560
Assessment							
▶ Lack of DM self-care competency assessment							
<b>Containment solution:</b> ▶ Hire additional DM educators; ensure staffing on nights and weekends <b>Permanent solutions:</b> ▶ Develop a standardised diabetes education and training toolkit with an electronic interface that allows for 24-hour delivery ▶ Integrate individualised DM medication instructions within the EHR for immediate delivery to patients with low health literacy ▶ Develop a DM self-care competency assessment to assure optimal postdischarge DM self-care							
Variability in care coordination							
<ul style="list-style-type: none"> <li>▶ Discharge instructions do not include follow-up with DM provider or primary care appointment</li> </ul>	<ul style="list-style-type: none"> <li>▶ Follow-up appointment for DM does not take place</li> <li>▶ Patient experiences symptomatic hypoglycaemia (<math>\leq 70</math> mg/dL) or symptomatic hyperglycaemia (&gt;250–349 mg/dL)</li> </ul>	7	<ul style="list-style-type: none"> <li>▶ Care planning</li> <li>▶ Discharge can occur on weekends/off hours when clinic staff are not available</li> </ul>	10	9	70	630
Human factors							
▶ Unanticipated discharge, unable to schedule appointment before discharge							
<b>Containment solution:</b> ▶ Manual verification of subspecialty appointments prior to discharge that align with patients' availability/choice <b>Permanent solutions:</b> ▶ Automatic verification of subspecialty appointments prior to discharge that align with patients' availability/choice ▶ Advocate for multidisciplinary team care model and reimbursement model for care of multiple coexisting conditions at single visit							
Variability in provider prescribing patterns							
<ul style="list-style-type: none"> <li>▶ DM provider makes clinical judgement to send patient home without DM medication or on oral medication when insulin is needed</li> </ul>	<ul style="list-style-type: none"> <li>▶ Patient experiences symptomatic hypoglycaemia (<math>\leq 70</math> mg/dL) or symptomatic hyperglycaemia (250–349 mg/dL)</li> </ul>	7	<ul style="list-style-type: none"> <li>▶ Human factors</li> <li>▶ Clinician cognitive biases about risks and benefits of medications</li> </ul>	10	10	70	700
Leadership/communication							
▶ Lack of physician consensus and standardisation of discharge DM medication protocol							
<b>Containment solutions:</b> ▶ Need to reach consensus and standardise discharge protocol for DM medications ▶ Develop clinical decision support for standardised protocol for DM medications <b>Permanent solution:</b> ▶ Use historical, EHR patient-level data to develop personalised DM discharge medication plans							

CI, Criticality Index; D, detection; DM, diabetes mellitus; EHR, electronic health record; F, frequency; H, harm; RPN, Risk Priority Number.



appointments; failure to address specific DM discharge needs and failure to consider level of glycaemic control at discharge (eg, initiating a post-transplant discharge process while patient still has elevated glucose level); and conflicting EHR-generated discharge instructions, particularly medications (eg, different DM medication doses in different sections of discharge instructions). Underlying causes of these failures included variation in staffing level; particularly outside of regular work week hours, and lack of integration and consideration of specialty care team discharge recommendations by the transplant team.

### Failures in provider prescribing patterns

Variation in discharge medication prescribing by clinicians had the highest RPN and CI. Both observational and EHR data revealed clinician preferences for prescribing oral antihyperglycaemics rather than insulin. This may be due, in part, to clinicians' awareness of the failures in DM education and skills training and belief that more comprehensive DM education and training prior to discharge is essential for patients being discharged on insulin, or perhaps provider perception that patient/family may be unable to safely deliver a high-risk medication such as insulin.

### Product design and patient/caregiver-reported failures

Surprisingly, several major failures were identified with underlying causes beyond the control of patients, clinicians or the healthcare institution, but related to fundamental aspects of product design, as summarised in [table 4](#). These high-risk failures are specifically the responsibility of the Food and Drug Administration (FDA), pharmaceutical industry and/or the EHR companies.

Patients and caregivers noted that external similarities (eg, colours, shape) of DM insulin pens could lead to self-administration of the wrong type of insulin (eg, long acting instead of short acting). Patients and caregivers noted other significant failures including incomplete, inaccurate or conflicting medications and medication dosing in discharge instructions (both EHR generated and handwritten), and lack/variability of verification of insurance coverage of prescribed medications and supplies. The lack of EHR capability to automatically reconcile inpatient medications with discharge medications in a user-friendly and timely manner is a design failure and the underlying cause of incomplete, inaccurate or conflicting medication discharge instructions.

Patients/caregivers noted the high frequency of change in insurance coverage of supplies (eg, glucose meter, strips) and medications (eg, type of insulin, oral antihyperglycaemics). Providers confirmed that this failure leads to suboptimal outcomes, including delays in obtaining medications/supplies or needing to request changes in non-covered supplies, which can be difficult outside of regular workweek hours because of difficulties in availability of pharmacists and/or educators.

### Proposed solutions

All failures were further categorised as either institutional or industry related. For failures identified by patients and caregivers during the qualitative sessions, they were asked, at the end of the session, to offer potential 'patient-centered' solutions to address each of their identified failures ([table 5](#)).

Potential solutions for institutional-related failures were developed by having the principal investigator (AW) present the findings at several institutional Quality Committee Meetings and at several stakeholder (CDE, physicians, advanced practice providers, nurses, pharmacists and clinic staff) meetings, facilitated by the principal investigator (AW) and the industrial engineer (RK). Both groups were asked to propose solutions and to then reach consensus. Potential containment solutions were additionally generated by the research team in conjunction with the clinical teams. Solutions for industry-related failures (eg, similarity of insulin injector pen colours) were generated by the patient safety expert (JLH) and the industrial engineer (RK) after reviewing FDA device approval processes.

With regard to DM education and training, recommended potential proposed solutions include standardisation of education for DM medications and creation of a training toolkit with web-based videos, development of an evidence-based DM medication prescribing protocol, customised for transplant patients, as well as discharge medication reconciliation, with EHR clinical decision support. Routine data audits (eg, glucose discharge data) could be used to provide continuous feedback about medication prescribing decisions and patient outcomes postdischarge. Additional recommended solutions include integration of a primary team representative (eg, transplant pharmacists or nurses) into the specialty (endocrinology) service discharge and DM education processes.

More general patient and caregiver recommended solutions include use of comprehensive discharge 'packets', with a medication reconciliation form including pictures of each medication, a description, in lay terms, of each medication's purpose, and clear dosing and administration instructions of each medication; use of a method (eg, colour coding) that links each medication to its disease process or care team (eg, all instructions for DM care on pink-coloured paper); a document with photographs of key clinicians involved in the patient's care, their name, role and routine and off hours contact information.

### DISCUSSION

The FMECA is a robust method, adapted from industrial and quality engineering, for identifying multiple failures in the discharge process of high-risk, hospitalised patients, such as LT recipients with DM. Indeed, many of the identified failures are highly applicable to this patient population who will need complicated self-care, immediately after discharge. The three key areas of patient safety risks

**Table 4** High-risk industry failures and potential solutions

Failure	Effect	H	Causes	F	D	CI	RPN
High-risk industry level							
<ul style="list-style-type: none"> <li>▶ Diabetes education does not highlight similarity in insulin pens (eg, colour of rapid-acting vs long-acting pen); patient does not remember or realise the difference</li> </ul>	<ul style="list-style-type: none"> <li>▶ Wrong insulin pen used; incorrect dose; incorrect type of insulin</li> <li>▶ Patient experiences symptomatic hypoglycaemia (<math>\leq 70</math> mg/dL) or symptomatic hyperglycaemia (250–349 mg/dL)</li> </ul>	7	Medication use <ul style="list-style-type: none"> <li>▶ Similarity of insulin pens</li> </ul> Patient education <ul style="list-style-type: none"> <li>▶ Variation in training by endocrinology/diabetes providers/educators in addressing the similarities of pens</li> <li>▶ Not all pens are available for inpatient teaching; potential failure not detected</li> </ul>	10	9	70	630
Containment solution: <ul style="list-style-type: none"> <li>▶ Instructions highlighting the design similarities of insulin pens during education</li> </ul> Permanent solution: <ul style="list-style-type: none"> <li>▶ Add provision to FDA approval mechanism (release to market approval) for improved differentiation of pens (type/design)</li> </ul>							
<ul style="list-style-type: none"> <li>▶ Contradicting DM medication instructions in different sections of discharge instructions</li> </ul>	<ul style="list-style-type: none"> <li>▶ DM postdischarge medication error leading to symptomatic hypoglycaemia (<math>\leq 70</math> mg/dL) or symptomatic hyperglycaemia (250–349 mg/dL)</li> </ul>	7	Healthcare information technology, Leadership <ul style="list-style-type: none"> <li>▶ Lack of integration of discharge instructions from multiple care teams, specifically for high-risk medications</li> <li>▶ Automated discharge medication list does not provide accurate discharge instructions</li> </ul> Human factors and communication <ul style="list-style-type: none"> <li>▶ Transcription error when discharge instructions are manually integrated</li> <li>▶ Complexity of instructions</li> </ul>	10	8	70	560
Containment solutions: <ul style="list-style-type: none"> <li>▶ Primary inpatient service/team or pharmacist integrates medication discharge instructions and removes duplicate, conflicting entries</li> <li>▶ Create an EHR ‘work around’ to permit flexibility of high-risk medication (eg, insulin) discharge instructions</li> </ul> Permanent solution: <ul style="list-style-type: none"> <li>▶ Use of user (provider/patient) centred design methods in creation of electronic health record software for discharge instructions for high-risk medications such as insulin</li> </ul>							
<ul style="list-style-type: none"> <li>▶ Lack of/incorrect verification of whether DM medication(s) and supplies are covered by patient’s insurance</li> </ul>	<ul style="list-style-type: none"> <li>▶ Prescriptions/supplies not covered by insurance; patient experiences symptomatic hyperglycaemia (250–349 mg/dL)</li> <li>▶ Delay in patient being able to fill prescription and taking DM medication</li> </ul>	7	Information management <ul style="list-style-type: none"> <li>▶ Lack of a system where providers can easily verify patient coverage and patient-specific out-of-pocket payments to enable shared decision-making</li> </ul>	10	2	70	140
Containment solution: <ul style="list-style-type: none"> <li>▶ Provide patient with samples of covered pharmaceutical supplies or medications prior to discharge</li> </ul> Permanent solution: <ul style="list-style-type: none"> <li>▶ Automated EHR function that verifies insurance coverage of prescribed medications and/or supplies</li> </ul>							

CI, Criticality Index; D, detection; DM, diabetes mellitus; EHR, electronic health record; F, frequency; FDA, Food and Drug Administration; H, harm; RPN, Risk Priority Number.

identified in this study are consistent with factors identified by a previous study of a re-engineered discharge process that lead to rehospitalisation and complications.<sup>25</sup>

This study suggests that standardisation and consistent delivery of DM education and training, followed by assessment of patients’ comprehension and demonstration of self-care instructions, tasks and skills prior to discharge, are potential high-value, impactful and permanent solutions. This is currently reflected in the

care delivery by a CDE; however, it remains time intensive and with the high patient demand the resources are limited. In addition, 24-hour access and standardisation of education, regardless of provider function, and outside the healthcare setting, were solutions requested by patients and their caregivers. Specific patient comprehension assessment tools or tests to assess deficiencies in comprehension, beyond current, ad hoc, single assessments typically conducted by a nurse or

**Table 5** Patient and caregiver recommended solutions

Failures	Recommended solutions
<b>Pretransplant</b>	
<ul style="list-style-type: none"> <li>▶ Diagnosis of DM not expected 'I was not told this was a possibility before my transplant'</li> </ul>	<ul style="list-style-type: none"> <li>▶ During the pretransplant education sessions, explain to patients that developing high blood sugar and needing medications can happen after transplantation.</li> </ul>
<b>Post-transplant discharge</b>	
<ul style="list-style-type: none"> <li>▶ Many different providers giving different sets of instructions at discharge 'We can't tell who is who' 'Too much information that does not register at that time' 'Dietician did not talk to me about diabetic diet'</li> </ul>	<ul style="list-style-type: none"> <li>▶ Have the clinical teams work together to give one set of instructions (transplant, endocrine, nutrition)</li> <li>▶ Colour code the discharge instructions by clinical service</li> <li>▶ Provide a single list of emergency contact for each clinical service (transplant, endocrine) and telephone number</li> <li>▶ Create a brochure that includes a picture, name, clinical service and role of all providers:               <ul style="list-style-type: none"> <li>– Physician name</li> <li>– Attending physician</li> <li>– Endocrinology (diabetes)</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>▶ Medication identification and training 'We overshot ourselves' 'No one took this pen and told us how to uncap it' 'I created my own list [meds] since they were all not on it...' 'I was on syringes and had to switch to pens but was not trained on pens'</li> </ul>	<ul style="list-style-type: none"> <li>▶ Provide patients with a chart with a picture of each medication that they will be taking, as part of the discharge instructions.</li> <li>▶ Provide accurate training materials for each type of medication type and each delivery system</li> </ul>
<ul style="list-style-type: none"> <li>▶ Insufficient or missing supplies 'I ran out of the supplies right away'</li> </ul>	<ul style="list-style-type: none"> <li>▶ Use patient-specific supplies for education and training prior to discharge</li> <li>▶ Identify high-risk individuals who may require medication/supplies immediately</li> </ul>
<ul style="list-style-type: none"> <li>▶ Insufficient explanation about importance of each medication, how it works and how long it works 'I missed a dose and was so worried about it'</li> </ul>	<ul style="list-style-type: none"> <li>▶ Provide a uniform discharge 'packet' with complete diabetes and medication information, including pictures of each medication</li> </ul>
<b>After discharge</b>	
<ul style="list-style-type: none"> <li>▶ Problems with making appointments after discharge 'If they can schedule the first appointment for us... we haven't even met the doctor...'</li> </ul>	<ul style="list-style-type: none"> <li>▶ Make follow-up appointments before patient is discharged from the hospital</li> </ul>
<ul style="list-style-type: none"> <li>▶ Communication after discharge 'It was helpful to have one point contact throughout our care'</li> </ul>	<ul style="list-style-type: none"> <li>▶ Patient portal (MyChart) is a very effective tool for communicating with physicians and providers</li> <li>▶ Set patients up as early as possible with a MyChart account</li> <li>▶ Help establish and refer patients to a 'Patient Group' that can provide peer support for new-onset DM</li> <li>▶ Provide more support (eg, training, education materials) to help caregivers</li> </ul>

DM, diabetes mellitus.

educator are lacking in the hospital discharge process. This study strongly supports the need to develop technology-enabled and more systematic assessment tools, incorporating proven methods, such as the 'teach back' method, where the patient explains in his/her own words and/or demonstrates a taught technique, skill or task.<sup>26</sup> The ability to offer standardised, comprehensive education and training outside of regular workweek hours is strongly supported by the findings.

Variation in discharge recommendations, particularly DM medications, prescribed by the endocrinology team,

was also a highly ranked failure, suggesting the need for clinicians and healthcare institutions to better examine and understand the underlying causes of variability in clinical care decisions among providers. Consensus-derived DM discharge prescribing guidelines and subsequent institution-level auditing and feedback are critically needed to optimise medication prescribing, reduce medication errors, and reduction of harm from hyperglycaemia or hypoglycaemia. Validated institution-specific guidelines could then be embedded within an EHR decision support tool.



Perhaps the most interesting findings, given the numerous recommended solutions from patients, caregivers and clinicians, reveal the need for user-centred design of the discharge process at several levels. This study highlighted failures beyond the reach of the institution, such as automated discharge instructions generated by the EHR, thought to be convenient and time saving, yet, in the case of multiple, complex medications, leading to inaccurate/incomplete instructions causing patient confusion and medication errors at home. However, application of user-centred design principles to EHR software to support coordination of medication prescribing, education and training, reconciliation, and discharge instructions of high-risk medications, while a potential permanent solution, is beyond the capability or control of any single healthcare institution or clinicians, requiring substantial investment and fundamental informatics system redesign by EHR vendors. Indeed, EHR vendor adherence to usability certification requirements and testing standards are generally low<sup>27</sup> and 'gag' orders make it difficult for investigators or safety experts to directly investigate EHR-related failures.

Several critical product design failures were also uncovered. Pharmaceutical companies do not currently have any initiatives to clearly differentiate the external appearance of medications, such as insulin pens, to decrease medication errors. Currently, adverse, postdischarge events are estimated to cost \$12–\$44 billion annually in the USA<sup>28</sup> and hospitals are now penalised for readmissions with reductions in reimbursement but also with payments available for high-quality discharge practices.<sup>1 29</sup>

This study has several limitations. First, generalisability may be limited because the study was conducted at a single institution within an academic hospital, in a highly subspecialised patient population, with a specialised diabetes service. However, the results appear to reveal many common failures, applicable to many patients on many hospital services, and recommended solutions are likely to be applicable to any inpatient with a chronic disease(s). Second, the FMECA methodology itself has some known limitations. Among other high-risk industries, the method is considered to be a moderate-level safety assessment method.<sup>30 31</sup> While it is recognised as a good way to map a process, the subjective nature of asking participants to estimate numerical scores for frequency, potential harm and detection of each failure denotes an unwarranted impression of objectivity and precision.<sup>32</sup> However, for this study, we leveraged patient-level EHR data to improve the precision, accuracy and comprehensiveness of scoring identified failures.

A strength of this study is the inclusion of patients and caregivers in the FMECA. We are unaware of any prior published study that includes results provided by patients and caregivers, although the WHO endorses patient/caregiver involvement<sup>33</sup> 'as full partners in reform initiatives, and learning can be used to inform systemic quality and safety improvements.' Patient satisfaction is a key metric in healthcare and is related to better health

outcomes<sup>34</sup> and is now used for reimbursement by Medicare/Medicaid,<sup>35</sup> and many institutions give patients the opportunity to provide feedback in the form of surveys or ability to share experience,<sup>36</sup> but none have actually integrated their feedback into this type of risk assessment method.

A proactive, comprehensive risk assessment is, first, critical steps for healthcare institutions to better understand patient risks in complex care processes, such as patient discharge. However, accountability for improvement in the discharge process may need to extend well beyond the patient, clinician or institution. Other institutions can use the methods outlined here to evaluate risks of their current discharge process. Eventually potential cross-institutional comparisons could identify more generalisable failures and potential solutions to better address the complexities of the transition of care for high-risk patients. Further root cause evaluation with subsequent development and testing of containment and permanent solutions needs to occur at the patient, clinician, institutional and product design levels.

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