

Issue Notification

Patient Safety Escalation

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Summary

We have identified an issue relating to the use of our software that may potentially affect patient safety at your organization. Please read this document closely and work with your Epic Technical Services representative to determine if your organization is affected by this issue and to identify an appropriate resolution plan.

Title	One-Step Medication Orders Can Use an Incorrect Medication for Drug-Allergy Checks Under Certain Conditions
Reference #	5874316
Products	Anesthesia, ASAP, Bones, Cupid, EpicCare Inpatient Orders, Kaleidoscope Ophthalmology, OpTime, Radiant, Willow Inpatient
Versions	February 2020, May 2020, August 2020, November 2020, February 2021

Table of Contents

Description	2
Resolution	6
Patient Safety Evaluation Matrix	7

Description

CE Marked Medical Device – Urgent Field Safety Notice

This issue affects Epic's Regulated Decision Support Framework (RDSF), which is CE Marked as a Class I medical device under the Council Directive 93/42/EEC on Medical Devices (MDD). In accordance with its obligations, Epic is informing the relevant regulatory authority of this issue.

Background Information

One-Step Medication Activities

One-step medication activities allow clinicians to document a medication administration in one step. One-step medications are beneficial in fast-paced workflows, such as during a procedure. In one-step medication activities, users can document medication administrations in real time, as the medications are given to patients. The following activities in the associated applications are one-step medication activities:

- ASAP and EpicCare Inpatient: Code, Trauma, and Sedation narrators
- Cupid and Radiant: Procedure Log
- OpTime: Intra-op Navigator
- Anesthesia: Intraprocedure activity

Drug-Allergy Warnings

Drug-allergy warnings notify clinicians when a drug, drug ingredient, or drug class interacts with a known and documented patient allergy. You can also choose to show clinicians cross-sensitivity class matches. In general, drug-allergy warnings are triggered when a medication is ordered. However, in one-step medication activities, a list of commonly used medications to order and document is presented to the clinician, and the system checks for drug-allergy warnings for each medication in the list when the clinician opens the activity. If a clinician searches for additional medications to document in the one-step medication activity, the system checks for drug-allergy warnings for the additional medication when the clinician selects that medication.

In Denmark, Trifork provides a platform called ATAH to provide medication decision support. When checking for drug-allergy interactions in Denmark, the Epic system sends patient and medication order information to the ATAH platform, which then returns the drug-allergy warning information to the Epic system. One-step medication activities query Trifork for drug-allergy interactions using the following method:

1. The one-step medication activity gathers the list of medications presented to the clinician to order and document.
2. The activity assigns a temporary identifier (ID) to each medication in the list.
3. The list of medications and the patient's allergies are sent to Trifork.
4. Trifork returns any drug-allergy warnings for the list of medications.
5. The system matches the drug-allergy warnings to the list of medications in the one-step medication activity by matching the drug-allergy warning to the temporary IDs.

When a clinician documents a medication in a one-step medication activity, a permanent order ID is assigned.

Interaction Setting Records (FIS)

Interaction setting (FIS) records allow administrators to adjust how the system shows medication warnings to different groups of clinicians.

Storyboard

Storyboard appears on the left side of the workspace when a patient's chart is opened and concisely curates information for clinicians. From Storyboard, clinicians can quickly review patient information, take common actions such as acknowledging orders or reviewing the problem list, and navigate to common activities.

Issue Overview

In a system configured as described in the Configuration section, one-step medication activities can send an incorrect medication to Trifork to check for drug-allergy interactions in the following scenario:

1. A clinician opens the one-step medication activity and views a list of medications to order and document. The clinician can also search for additional medications to document.
2. The one-step medication activity assigns a temporary ID to a medication that is the same ID as the ID for a medication order (ORD) record that already exists in the system. The medication to which the temporary ID is assigned is not the same medication as the medication in the existing order with the same ID.

In the scenario above, the system sends the medication information from the existing medication order to Trifork instead of sending the medication information from the medication in the one-step medication activity. This issue can have the following outcomes:

- Trifork does not return a drug-allergy warning when one exists for the medication that appears in the one-step medication activity. If a drug-allergy warning is not shown for a medication for which the patient has a documented allergy, a clinician might administer the medication without knowing that the patient is allergic to the medication.
- Trifork returns a drug-allergy warning for a medication for which the patient has a documented allergy, but that medication is not the one that appears with the warning in the one-step medication activity. For example, say that the patient is allergic to aspirin and not allergic to lidocaine. If this issue occurs with the temporary ID for lidocaine in the one-step medication activity matching the order ID for an existing aspirin medication order, Trifork returns a drug-allergy warning for aspirin, and that warning is shown with the lidocaine medication in the one-step medication activity even though the patient is not allergic to lidocaine. If a drug-allergy warning is shown for a medication for which the patient has no documented allergy, a clinician might delay administration to take time to investigate the unnecessary warning, or the clinician might choose an alternative medication or unnecessarily pre-medicate to lessen a potential reaction.

This issue is mitigated by the following circumstances:

- Storyboard is configured to show a patient's documented allergies by default. A clinician can review a patient's allergies by checking Storyboard, which appears in Hyperspace alongside the one-step medication activity.
- A clinician can review a patient's allergies elsewhere in the system, such as in the Allergies activity or in various patient reports.
- In procedural workflows, it is common for clinicians to review the patient's allergies with the patient prior to a procedure. This step allows a clinician to be made aware of medication allergies prior to the procedure.

Configuration

This issue affects systems configured as follows:

- You use Trifork to provide medication decision support in the form of drug-allergy warnings.
- You show drug-allergy warnings to at least one group of clinicians who use a one-step medication activity. This is the case if the Suppress the following interaction types (IFIS 100) field on the Suppress/Sort form of the Interaction Settings Editor does not include the following values:
 - 2-Drug-Allergy (Active and Inactive Ingredients)
 - 13-Drug-Allergy (Inactive Ingredient)

Example Workflow

This issue occurs in a variety of one-step medication workflows, including the following example where a drug-allergy warning does not appear:

1. In a system configured as described in the Configuration section, a clinician has previously documented that a patient is allergic to lidocaine. This allergy appears in Storyboard:

Search: Søg

Infektionsstatus: Ej udfyldt
Isolation: Ej udfyldt

MiBa

CAVE: **Lidocain**

FMK synkr.: Ikke forespurgt

Medicinoversigt

2. The same or a different clinician opens the Procedure Log to document a one-step medication. A lidocaine injection is available for documentation, but a drug-allergy warning does not appear:

CP

Preadmissionstestthree, Cupid
Mand, 66 år
080954-3442
Aktuelt oph.afs.: SJ ROSKAI71-Ekstra
Beh.niveau: Ej udfyldt
Patient-FYI: Ingen

Search: Søg

Infektionsstatus: Ej udfyldt
Isolation: Ej udfyldt

MiBa

CAVE: **Lidocain**

FMK synkr.: Ikke forespurgt

Medicinoversigt

PAL: Ingen
Akt. læge: IKG

Procedurelog

✓ Fuldfer | Logtilføjelse | Filstyring | Opdater | Lægemiddelsammendrag | Procedurelog

Værktøjskasse

Medication	Action
Glycerylnitrat og verapamil (LS) (onestep) injektion	X
Heparin ukonservet injektion 5.000 IE/ml	X
Human albumin infusion 20 %	X
Humant albumin infusion 5%	X
lomeprol injektion 300 mg iod/ml	X
lomeprol injektion 350 mg iod/ml	X
Ipratropium inhalation, opl. opl. 0,25 mg/ml	X
Isoprenalin 2,5 mg i glucose isoton infusion 500 ml. Slutkonc. 5 mikrog/ml	X
Isosorbiddinitrat (LS) Inf.væske, opløsning 0,1 %	X
Lidocain injektion 10 mg/ml (+ED)	X
Magnesiumsulfat konc.t.inf.væsk.opl. 500 mg/ml~2 mmol/ml	X
Mepivacain injektion 10 mg/ml	X

The following example demonstrates how a drug-allergy warning can appear unnecessarily due to the issue:

1. In a system configured as described in the Configuration section, a clinician has not documented that a patient is allergic to lidocaine. Lidocaine is not listed as an allergy in Storyboard:

Search: Søg

Infektionsstatus: Ej udfyldt
Isolation: Ej udfyldt

MiBa

CAVE: **Ace-hæmmere, Usammensatte**

FMK synkr.: Ikke forespurgt

Medicinoversigt

PAL: Ingen

Heparin ukonservet injektion 5.000 IE/ml X

Human albumin infusion 20 % X


Humant albumin infusion 5% X

CAVE

Fuldt gennemgået af Læge Generel, Læge den 30-03-2021

Sværhedsgrad	Reaktioner	Kommentar
Ace-hæmmere, Usammensatte	Angioødem	

2. The same or a different clinician opens the Procedure Log to document a one-step medication. A lidocaine injection is available for documentation and a drug-allergy warning appears for a patient allergy other than lidocaine:


Preadmissionstesttwo, Cupid
 Mand, 80 år
 121240-2331
 Aktuelt oph.afs.: SJ ROSKA175- Ekstra
 Beh.niveau: Ej udfyldt
 Patient-FYI: Ingen

Infektionsstatus: Ej udfyldt
 Isolation: Ej udfyldt
 MiBa
 CAVE:
Ace-hæmmere, Usammensatte
 FMK synkr. Ikke forespurgt
 Medicinoversigt
 PAL: Ingen
 Akt. læge: IKG
 PROCEDURER
 KORONAR ARTERIOGRAFI (KAG) -
 -
 Invasiv Kardiolog Generel
 På Kard Lab, KAT 1
 Patienttype: 0 Indlagt

Snapshot | Vis journal | MDA | Vurderingsskema | Ordinationer

Procedurelog

✓ Fuldfør | Logfilfejelse | Filstyring | Opdater | Lægemeddelsammendrag | Procedure afbrudt | Præproceduresa

Værktøjskasse

Vis alle

Dato	Tidspunkt
31. mar	09:44
30. mar	15:17

- Glucose infusion 500 mg/ml
- Glycerylnitrat (onestep) 100 ml infusion
- Glycerylnitrat 20 mg i NaCl isoton 96 ml (0,2 mg/ml) infusion (onestep)
- Glycerylnitrat og verapamil (LS) (onestep) injektion
- Heparin ukonserveret injektion 5.000 IE/ml
- Human albumin infusion 20 %
- Humant albumin infusion 5%

CAVE Fuldt gennemgået af Læge Generel, Læge den 30-03-2021

	Sværhedsgrad	Reaktioner	Kommentar
Ace-hæmmere, Usammensatte	Ikke alvorlige	Angioødem	

- Lidocain injektion 10 mg/ml (+ED) **Reaktioner: Angioødem**
- Lidocain kulanspray 10 mg/dosis
- Magnesiumsulfat konc.t.inf.væsk.opl. 500 mg/ml-2 mmol/ml
- Mepivacain injektion 10 mg/ml
- Methylprednisolon injektion 40 mg

Resolution

The following special updates resolve this issue:

- February 2021: E9604654
- November 2020: E9507760

Until you validate and install the special updates resolving this issue, you can reduce the potential impact of this issue by reminding clinicians that Storyboard shows a patient's documented allergies by default. A clinician can use Storyboard to compare a patient's documented allergies to any drug-allergy warnings that appear in a one-step medication activity.

Patient Safety Evaluation Matrix

Patient Safety Evaluation Matrix		Potential Patient Care Impact			
		Negligible	Low	Moderate	High
Likelihood	High				
	Moderate				
	Low				
	Negligible				

Key	
	Red PSE
	Yellow PSE
	Care Concern
	Not PSE or CC

Important Notice

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