

Characterizing safety triggers for high-risk medical device recalls, 2022

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BACKGROUND

- Increasing use of medical devices and growing safety concerns
- Devices are less stringently regulated than drugs due to the 510k pathway which doesn't require safety/efficacy data
- Medical device recalls are critical for patient safety, with many recent high profile recalls affecting millions of patients
- High risk (class 1) recalls are indicated when a product will cause serious health problems or death if left in use
- There is a need to better understand what kinds of safety events lead to a high-risk recall
- Goals of study are to 1) characterize high-risk medical device recalls and 2) understand if there is a consistent safety threshold for triggering a high-risk device recall

METHODS

Searched FDA recalls database for 2022

Characterized class 1 recalls and reviewed safety data reporting

Recall Characteristics

- Devices and approval pathways
- FDA reason for recall

Safety Data

- Was safety data reported?
- If yes, how many injuries, complaints, or deaths?

RESULTS

- There were 66 class 1 recalls in 2022
- Majority of recalled devices are considered intermediate risk and cleared through the 510k pathway (Figure 1)
- Many recalls are remaining without determined cause by the FDA more than a year after the recall (Figure 1)
- 47 (71%) of recalls provided safety data; of these, 35 recalls reported complaints, serious injuries, or deaths (Figure 2)

DISCUSSION

- Majority of recalled devices were cleared through 510k pathway which underscores the urgency to reform this pathway (used for 99% of medical devices, intended for intermediate risk only)
- High proportion of recalls remaining under investigation demonstrates need for faster FDA review to determine a cause
- It was difficult to determine a safety threshold given spotty availability of safety information, which highlights the need for more complete inclusion for safety data

ACKNOWLEDGEMENTS

Thank you Dr. Redberg for your mentorship.



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It was difficult to determine a safety threshold for high-risk recalls given **spotty availability of safety information** in recall reports.

Figure 1. Recall Characterization

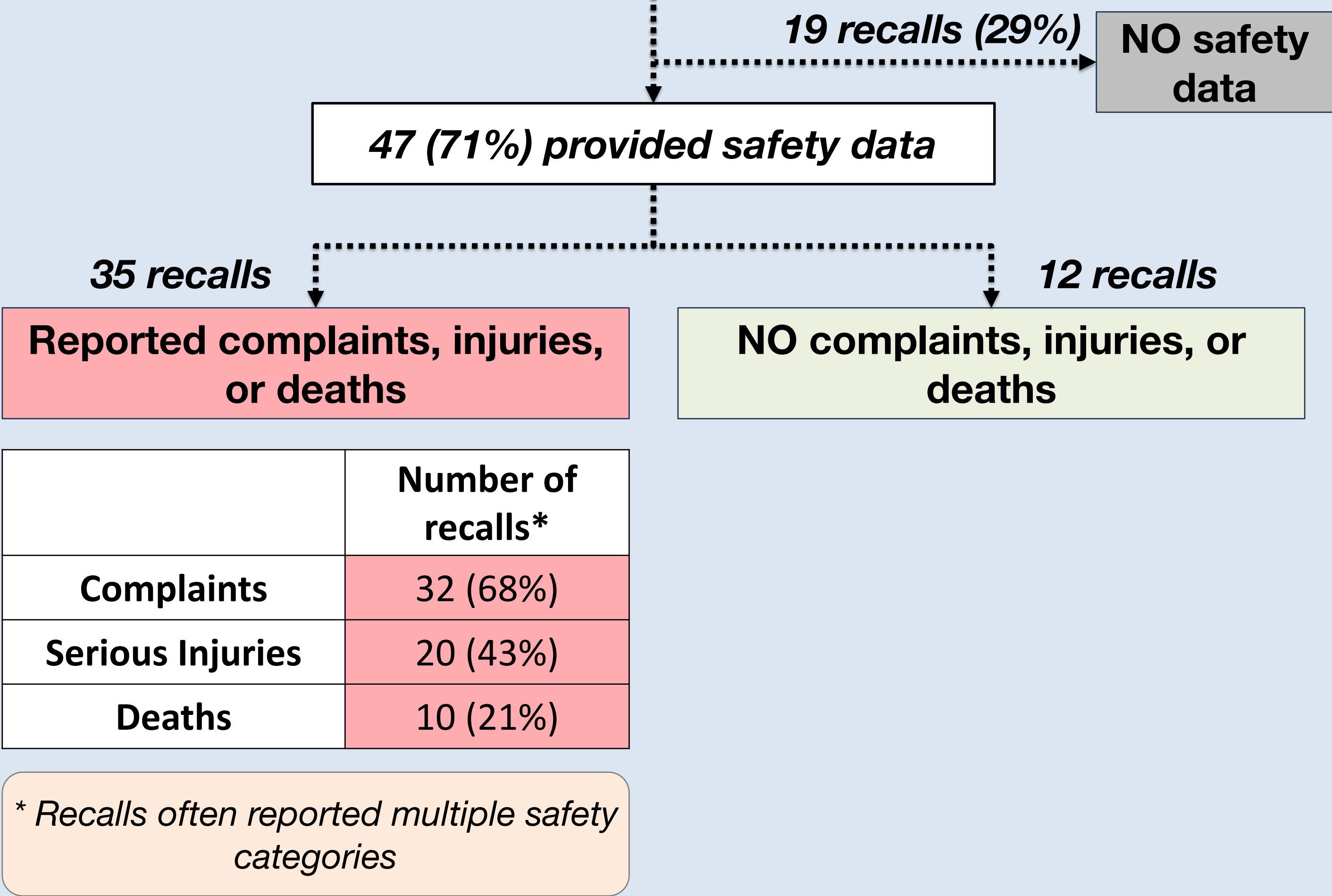
66 class 1 recalls in 2022

Recalled Devices		FDA Reason for Recall	
FDA Risk Classification		“under investigation” or “pending”	17 (25%)
Class 3 (highest risk)	7 (11%)	“device design”	14 (21%)
Class 2 (intermediate risk)	43 (65%)	“process”	10 (15%)
Class 1 (lowest risk)	4 (6%)	“no marketing application”	10 (15%)
Unclassified*	12 (18%)	“labeling error”	5 (8%)
Device Approval Pathway		“software”	5 (8%)
Premarket approval (PMA)	7 (11%)		
510k clearance	40 (61%)		
510k exempt	5 (8%)		
Not FDA approved*	14 (21%)		

* Unclassified COVID-19 diagnostics not yet cleared by FDA for marketing

Figure 2. Safety Data

66 class 1 recalls in 2022



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