

Medical device report analyses: device failures, adverse events, and sex-based differential outcomes



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Introduction/Hypothesis



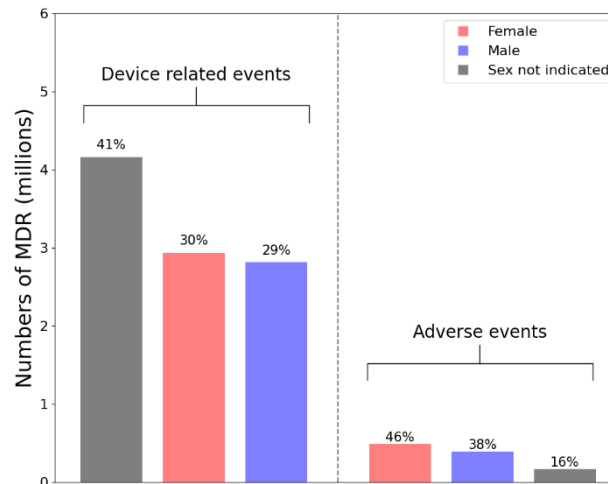
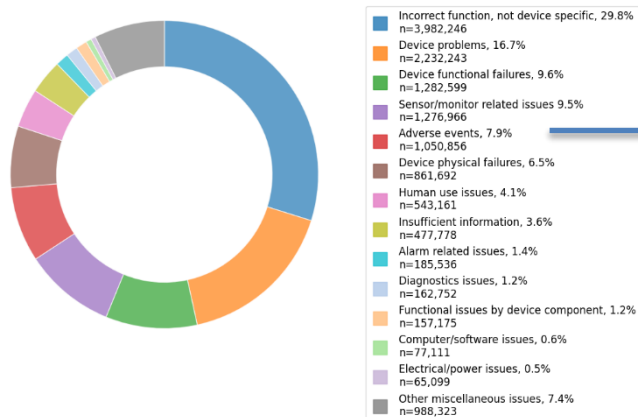
- Medical device-associated failure and adverse events are reported to FDA through medical device reports (MDRs). Since 1990, FDA has received more than 10 million MDRs to this day, with numbers increasing annually.
- Sex differential adverse events involving medical devices are of interest and relevant to promoting the health of women and diverse populations.
- In this study, we will present an overview of reported device failures and sex-based differences of adverse events by analyzing MDRs from 2011 to 2021.

Findings/Results



- More than 90% of reports involved device physical or functional failures and 8% are adverse events
- Significant sex-based differences were observed in the adverse events: 46% female, 38% male, and 16% sex not indicated.

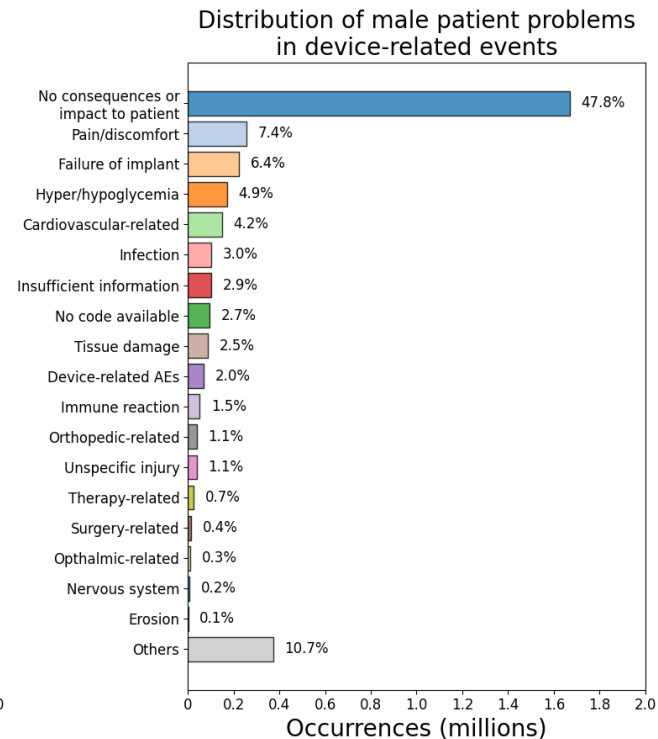
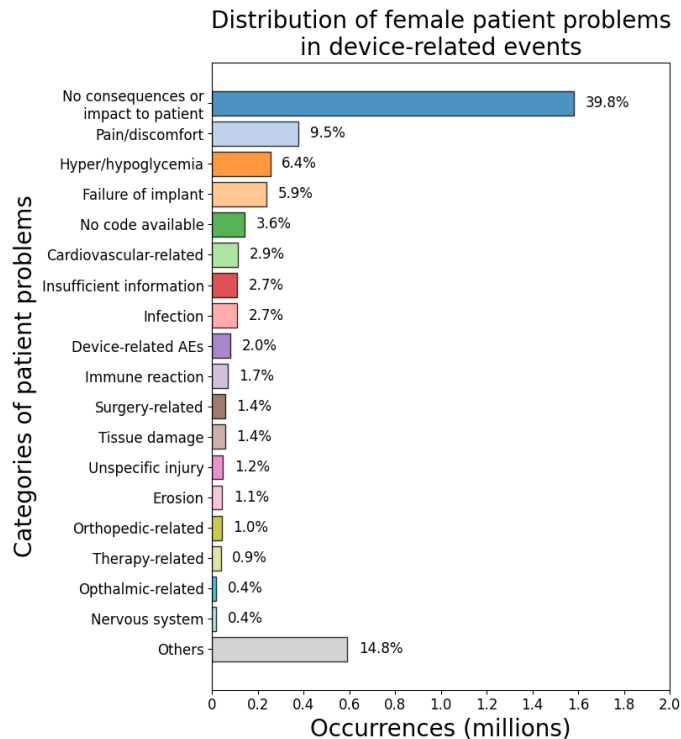
Distribution of medical device events from 2011 to 2021



Findings/Results



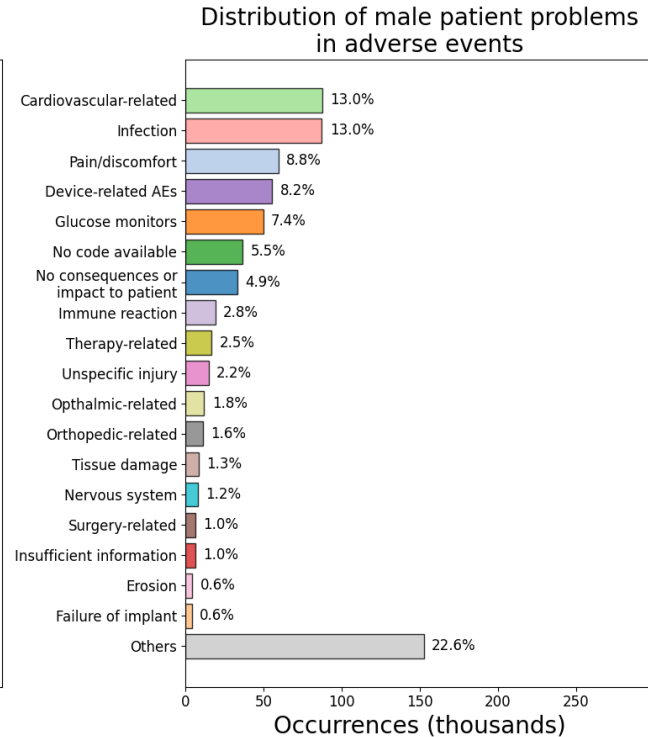
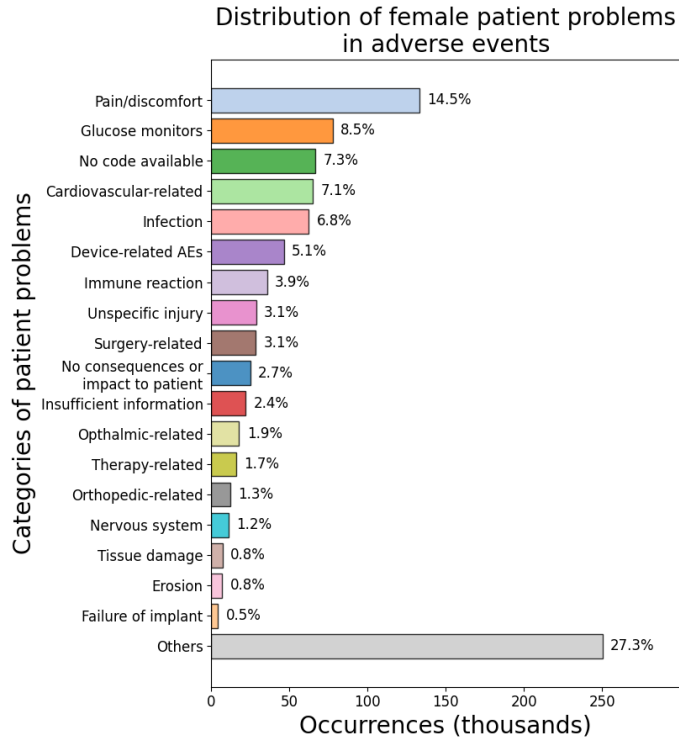
- Most device events have no impact on patients.
- Both sexes have similar distribution of device related events.



Findings/Results



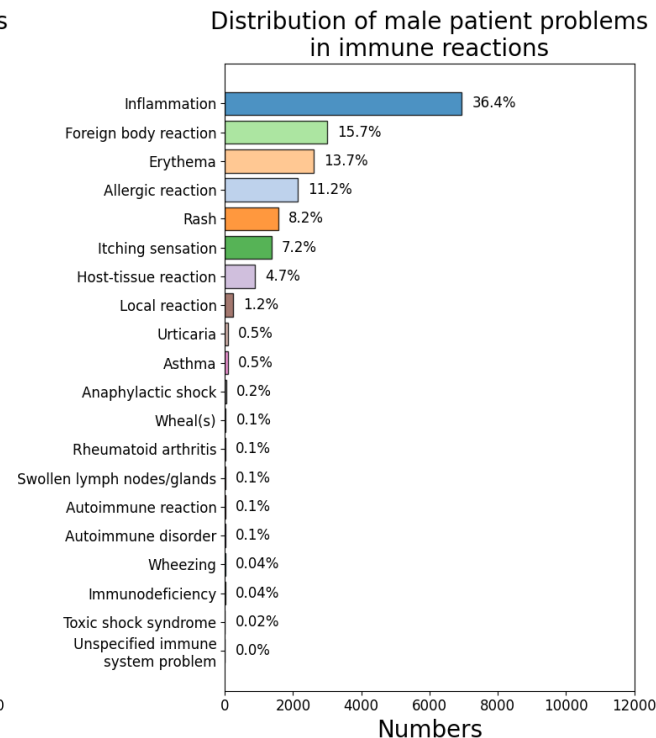
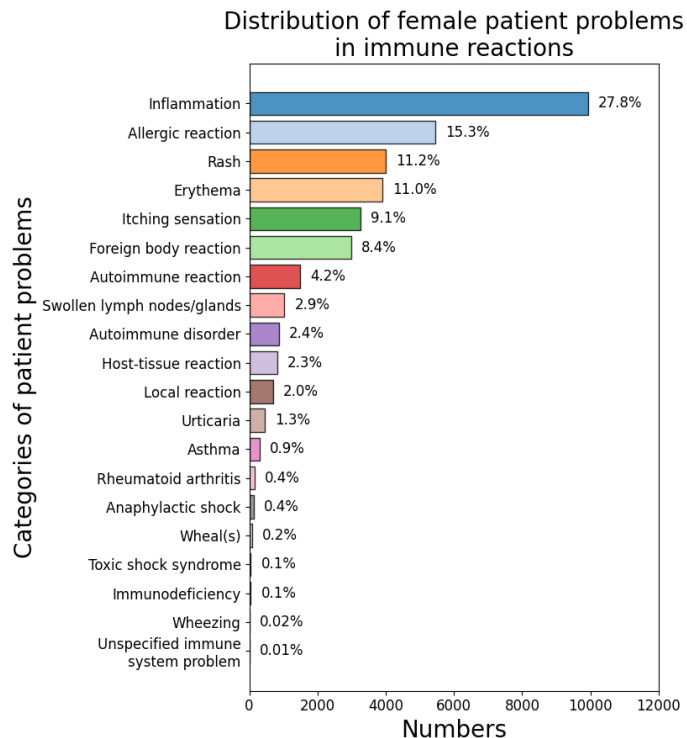
- Female patient reports contain higher numbers of pain as well as glucose monitor issues, while male patient reports have more cardiovascular-related problems and infections.
- Immune reactions show higher occurrence in females (3.9%) than males (2.8%)



Findings/Results



- Inflammation is the most common immune reaction in both sexes.
- Females have a greater number of immune reactions and a greater diversity of immune-related effects than males.



Conclusions

- Medical device physical and functional failures accounted for >90% of MDR reports
- Adverse events were about 8% of all reported events in MDRs. Females showed a higher number of adverse events than males.
- In adverse events, the most commonly-reported events were different for males and females.
- Females have greater numbers and more diverse immune reactions than males. Inflammation is the most common immune reaction in both sexes.
- More research is necessary to confirm these results and to formulate hypotheses to explain the differences observed

Thank you!

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