

# Isotretinoin and Pregnancy Risk: A Multicenter Saudi Observational Study

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## Background

- Isotretinoin is a potent acne treatment but with **severe teratogenic effects**.
- Regulatory agencies worldwide, including SFDA, had implemented various programs to prevent fetal exposure to isotretinoin
- However, the rate of fetal exposure to isotretinoin in Saudi Arabia is **unknown**

## Aim

- **Primary aim** is to quantify fetal exposure rate among female isotretinoin users in Saudi Arabia.
- **Secondary aim** is to evaluate risk minimization measure compliance, including contraceptive use and pregnancy test orders.

## Methods: Study Population

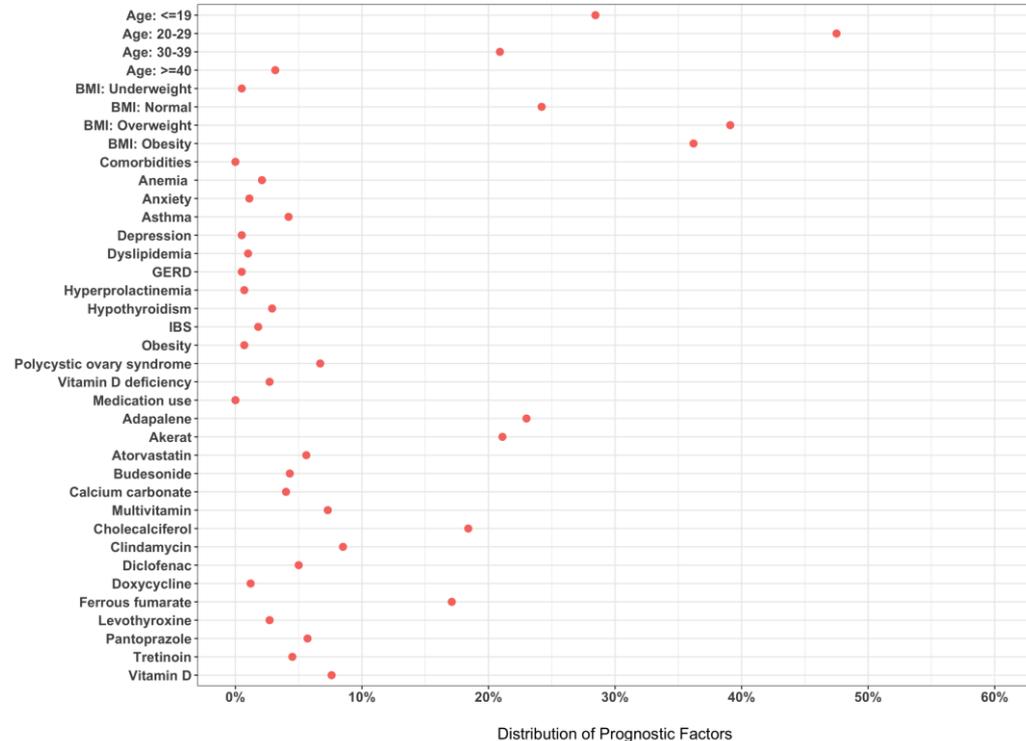
- We included 1367 women of childbearing age (WCBAs) who initiated isotretinoin using two hospitals' electronic health records.
- Isotretinoin users were followed from 1st day of dispensing to 30 days post discontinuation, during which WCBAs must avoid pregnancy.
- Pregnancy was defined as any positive pregnancy test (urine or serum), any diagnosis or procedure related to pregnancy, or from medical notes.

## Methods: Study Population

- The pregnancy risk was estimated as the total number of pregnancies divided by isotretinoin users.
- We estimated the contraceptive use and pregnancy test among isotretinoin users to quantify adherence to risk minimization measures (RMM).

## Results: Sample Characteristics

- We included 1367 isotretinoin new users from two hospitals between 2015 and 2020

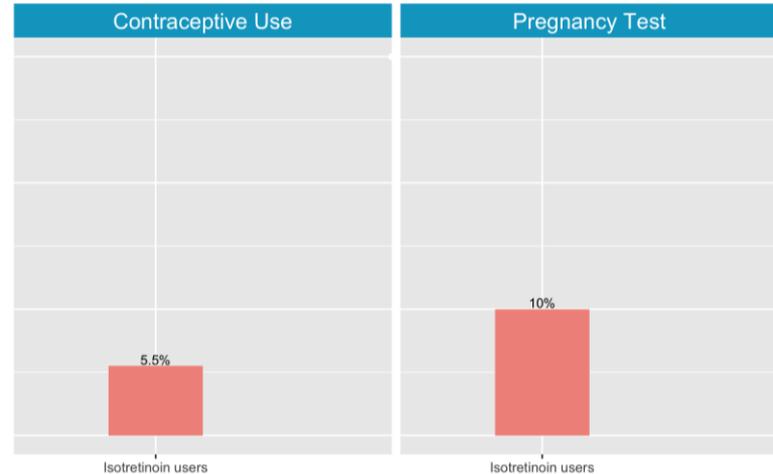


## Results: Estimates

- Pregnancy risk:

|              | Sample | Event | Cumulative Incidence Per 1000 |
|--------------|--------|-------|-------------------------------|
| Isotretinoin | 1367   | 17    | 12.5                          |

- Risk minimization measures:



## Discussion: Comparison with Literature

Significant fetal exposure to isotretinoin in Saudi Arabia compared to several countries.

|                          | Study time  | Cumulative Incidence / 1000 |
|--------------------------|-------------|-----------------------------|
| Saudi Arabia (our study) | 2015 - 2020 | 12.5                        |
| USA                      | 2005 - 2015 | 2                           |
| France                   | 2003 - 2006 | 0.5 - 1                     |
| Canada                   | 1996 - 2011 | 3                           |
| New Zealand              | 2000 - 2005 | 1                           |

## Discussion: Limitations

- Our study is not representative to all isotretinoin users in Saudi Arabia.
- Our estimate may be underestimated because we included all users regardless of marital status.
- Measurement error may occur if pregnant visited other hospitals that we did not have access to, which also may underestimate the actual fetal exposure to isotretinoin.

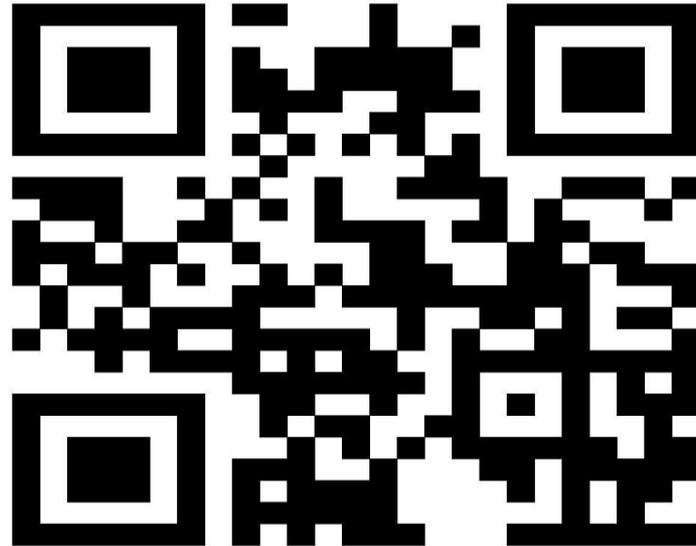
## Conclusion

- Although risk minimization measures exist in Saudi Arabia, **considerable fetal exposure to isotretinoin occurred**.
- Continuous evaluation of risk minimization measures is required to identify **potential improvement** to the system to prevent fetal exposure.
- Our study **sets a baseline** to examine the effectiveness of future updates of precautionary measures concerning isotretinoin use

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## Reference



Thank you!