

Exposure to monoclonal antibodies during pregnancy and lactation – a growing concern

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Introduction

- ❖ Use of monoclonal antibodies (mAbs) during pregnancy and lactation has increased in recent years
- ❖ The Summary of Product Characteristics (SmPC) typically includes precautionary restrictions
- ❖ Expert clinical guidelines provide helpful recommendations for pregnancy-related use, but they may not cover all drugs quickly enough

Objective

To compare product labeling recommendations, expert guidelines, and Geneva TIS counseling for mAb use in pregnancy and lactation

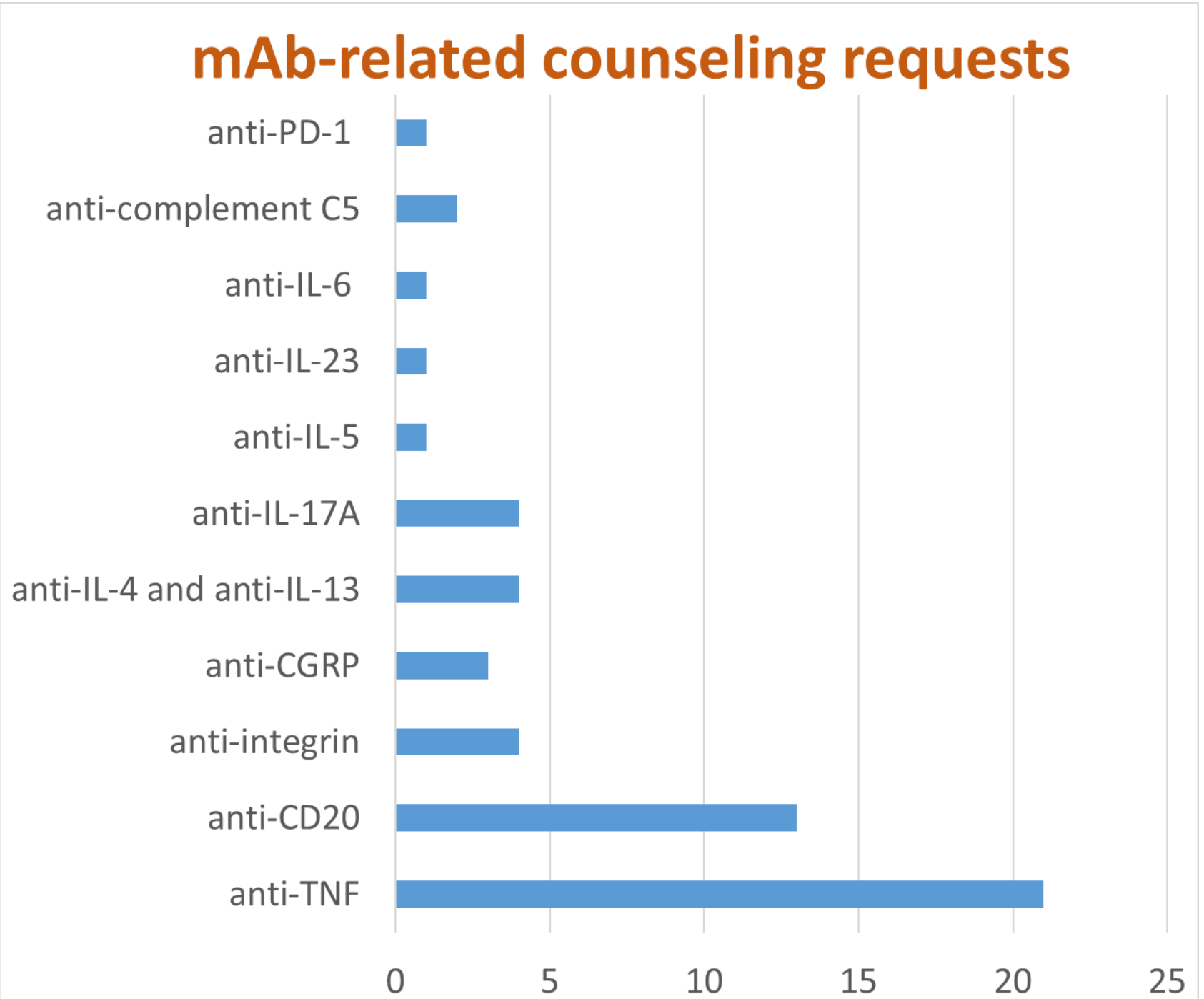
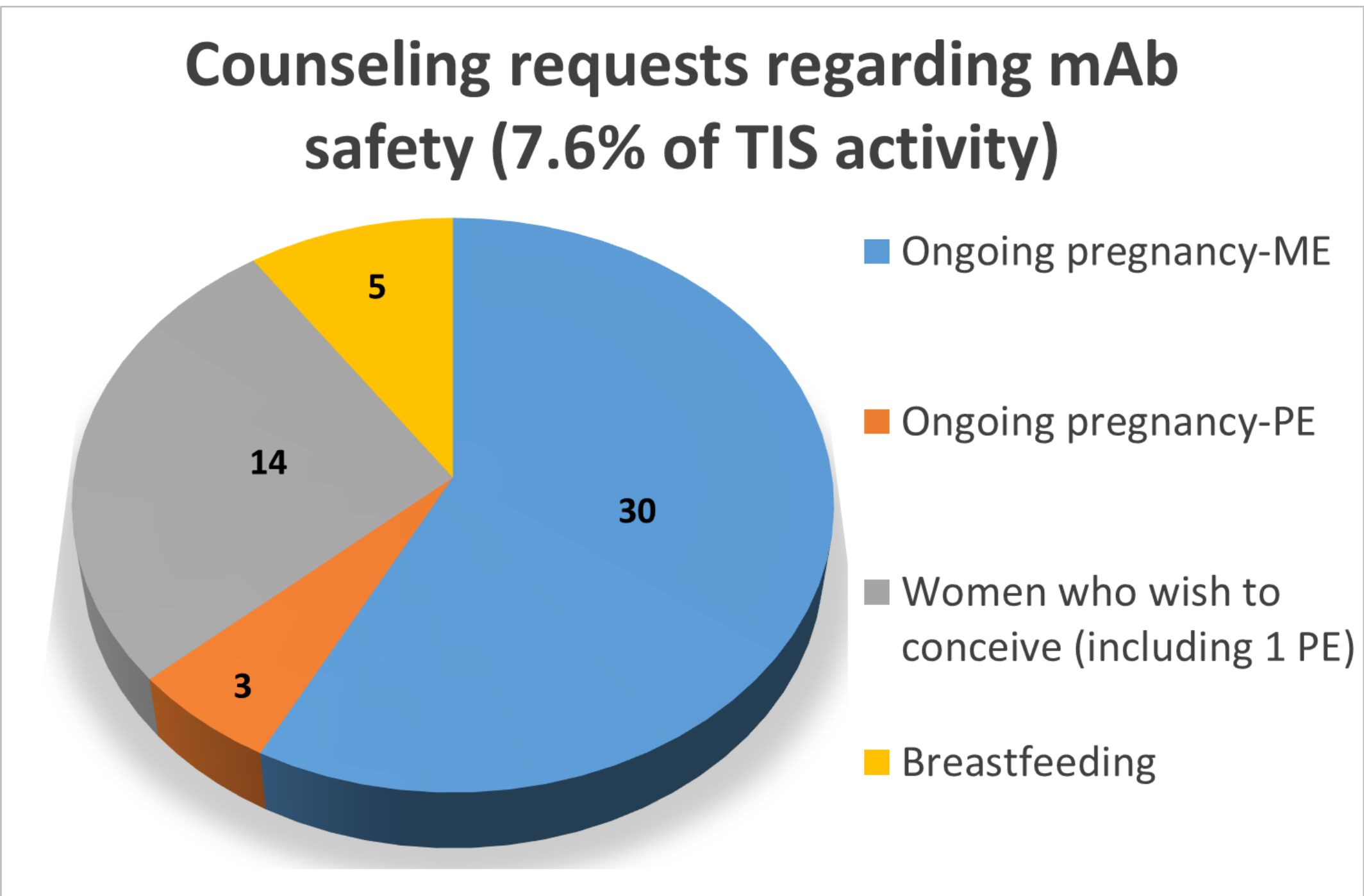
Methods

- ❖ Analysis of counseling requests regarding mAb safety in the following situations:
 - ❖ Maternal exposure (ME)
 - ❖ Paternal exposure (PE)
 - ❖ Breastfeeding
- ❖ Concordance of Geneva TIS counseling with regulatory (from SmPC) and expert (clinical guidelines) recommendations
- ❖ Clinical outcomes after exposure during pregnancy

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Results

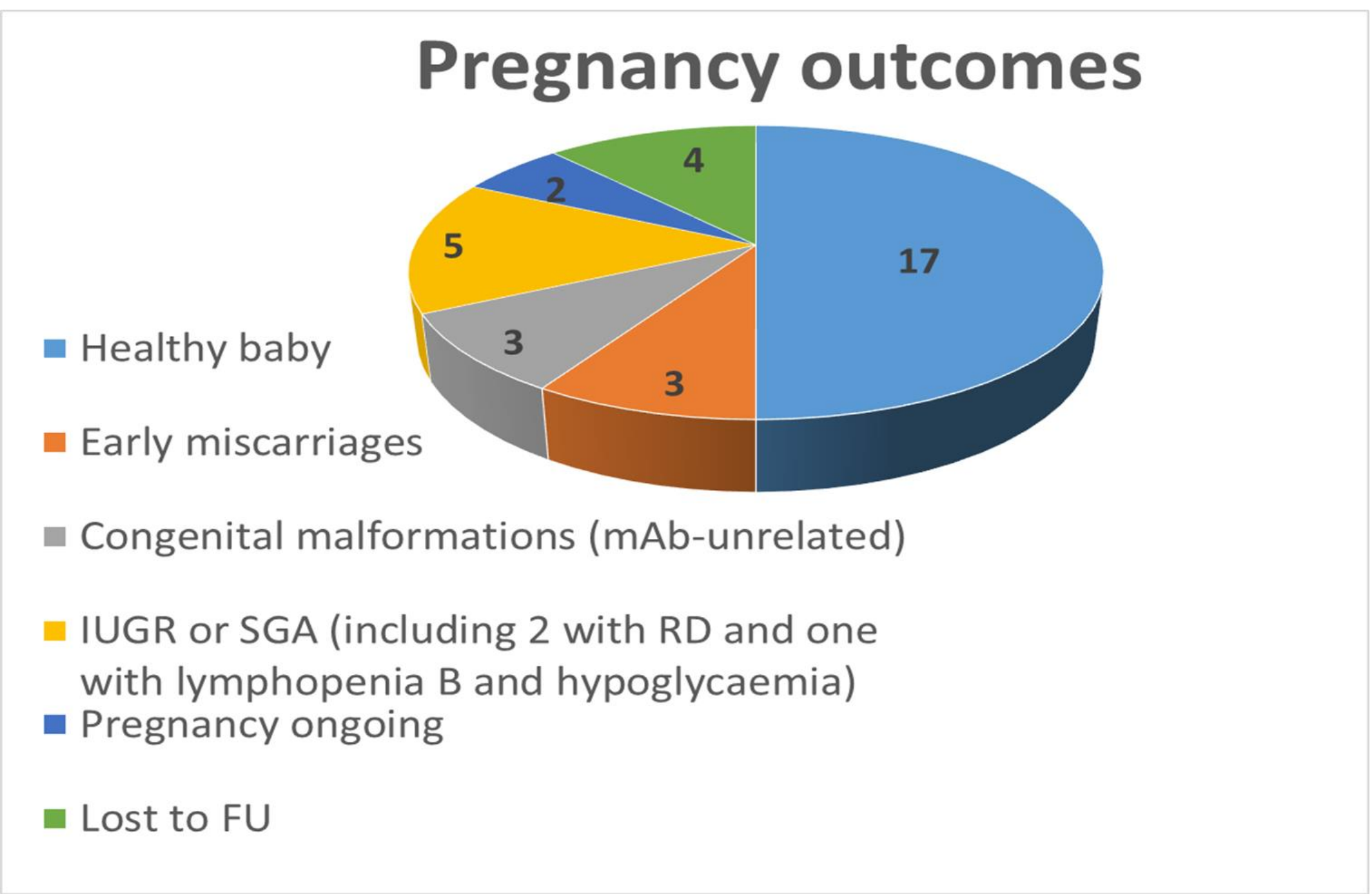


Analysis of concordance between SmPC and expert recommendations	
Concordant recommendations	46%
Discrepancy between SmPC and expert recommendations	42%
Contradictory recommendations between experts	8%
No expert recommendations	4%

When SmPC and expert recommendations conflicted, our TIS counseling aligned with expert recommendation in 15 of 20 cases.



For paternal exposure, no information was available in SmPC, while expert guidelines were found for 2 out of 4 cases



The small number of pregnancies, combined with the diversity of mAb treatments and maternal conditions, hinders definitive conclusions on pregnancy outcomes

Conclusion

- This retrospective analysis highlights the growing need for comprehensive counseling on the use of mAb during pregnancy and breastfeeding
- Expert guidelines for recently approved mAb remain limited, and SmPCs often does not reflect the most current evidence
- Data and recommendations regarding paternal exposure are frequently lacking