

Pregnancy outcomes in women exposed to dihydroartemisinin-piperaquine in first trimester of pregnancy in Indonesia

A retrospective record linkage study

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Introduction to the study

Limited safety data restricts the use of artemisinins in first trimester of pregnancy

Indonesia is the first country to have introduced artemisinin based therapy & dihydroartemisinin-piperaquine (DP) for use in 2nd and 3rd trimester

More recently DP has been introduced for first trimester treatment of malaria in Indonesia

More than a decade of data on the use of DP is available in the two main hospitals in Timika, Papua

These are a valuable source to identify inadvertent or intentional use of DP in first trimester of pregnancy

Objectives

Primary aim was to obtain additional safety data on exposure of DP in the first trimester of pregnancy

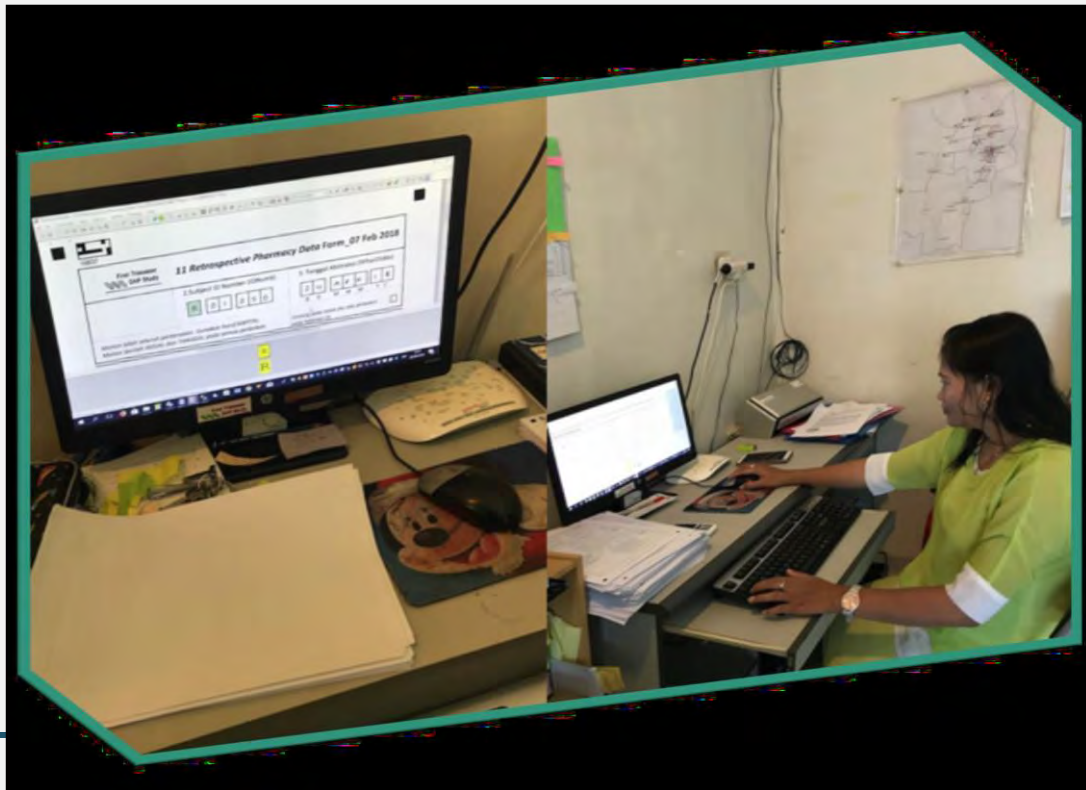
Specific objectives:

- *To provide descriptive analysis of miscarriages, stillbirths and surface congenital anomalies in women exposed to DP in first trimester*
- *To compare the risk of miscarriages, stillbirths and congenital anomalies in women treated with quinine and DP in first trimester*



*STUDY DESIGN: A
retrospective record
linkage study*

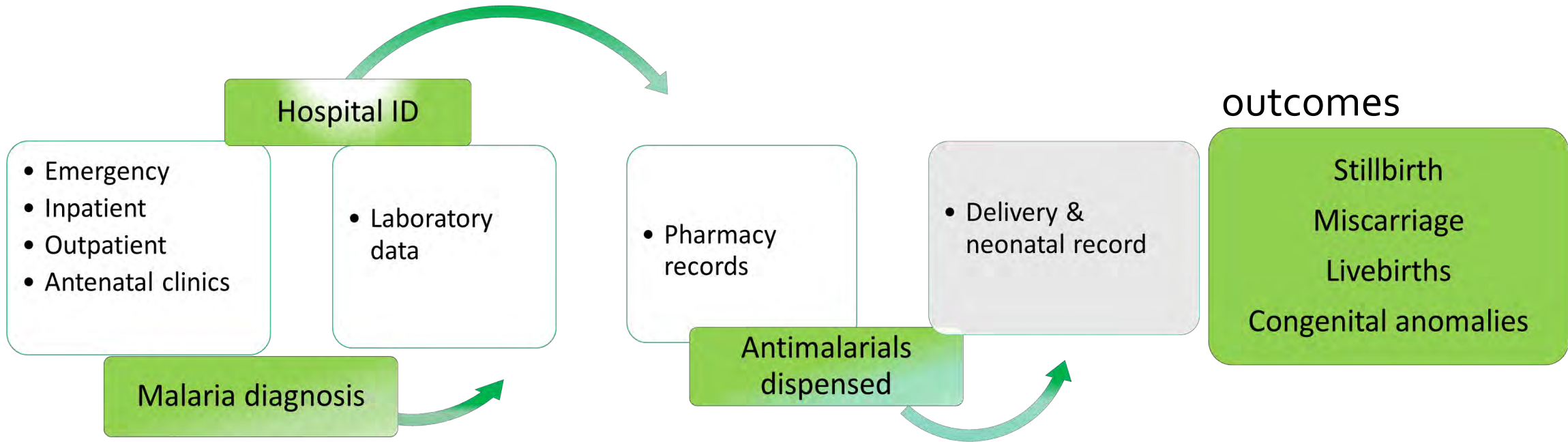
*Data between 2006-2017
was extracted from
electronic and manual
records*



Sample size of 1500 pregnancies



How was record linkage done

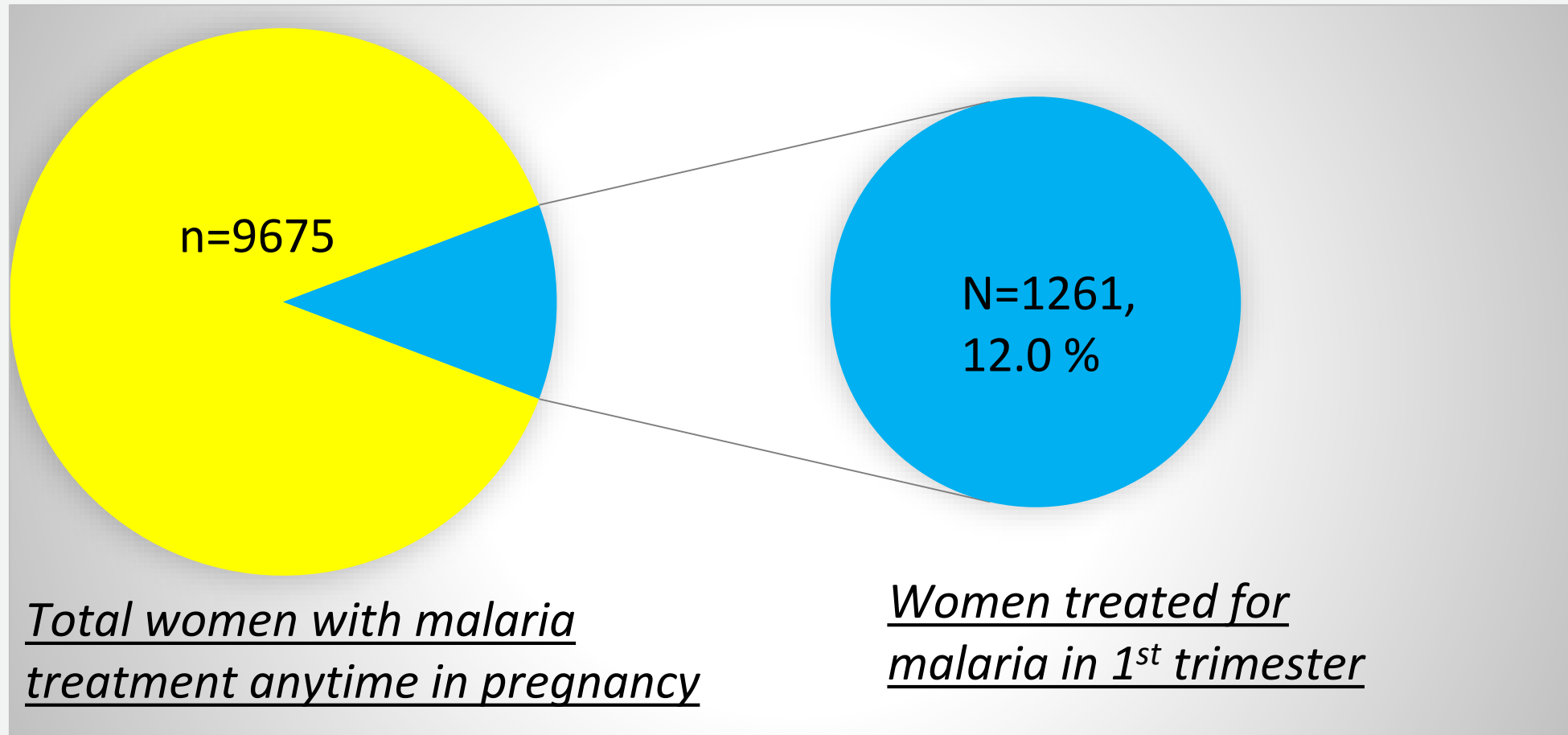


- Demographic, clinical and malaria diagnosis data was obtained from the linked records
- Date of delivery, data drug dispensed and estimated gestational age at delivery was used to estimate gestational age at time of malaria diagnosis and drug exposure

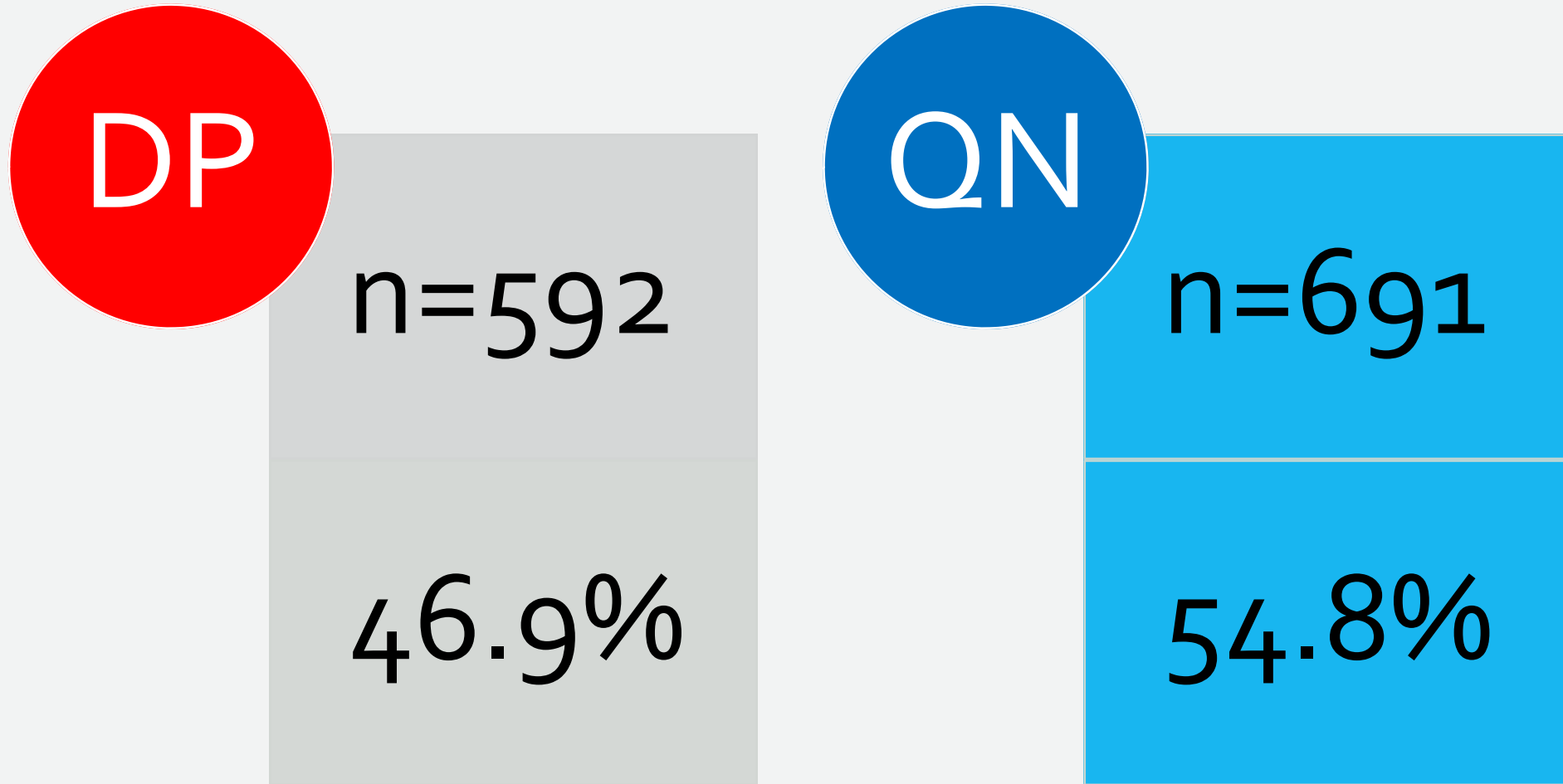


FINDINGS

Total malaria treatment any time in pregnancy and in first trimester



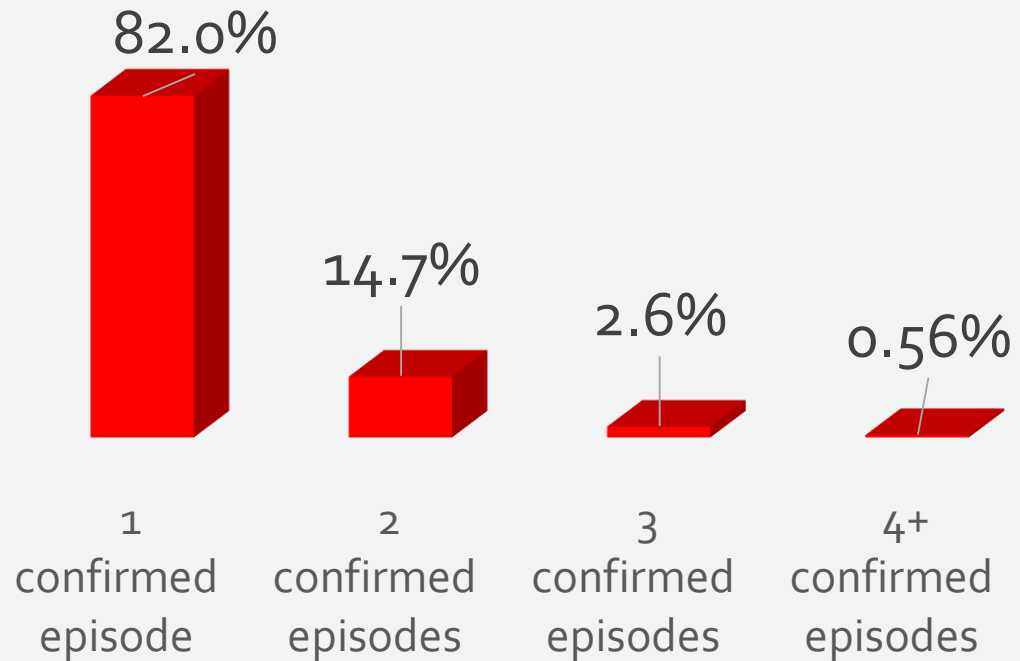
*Number of exposures to DP & quinine
in first trimester*



Note: some women contribute to more than one pregnancy

Confirmed malaria episodes in 1st trimester

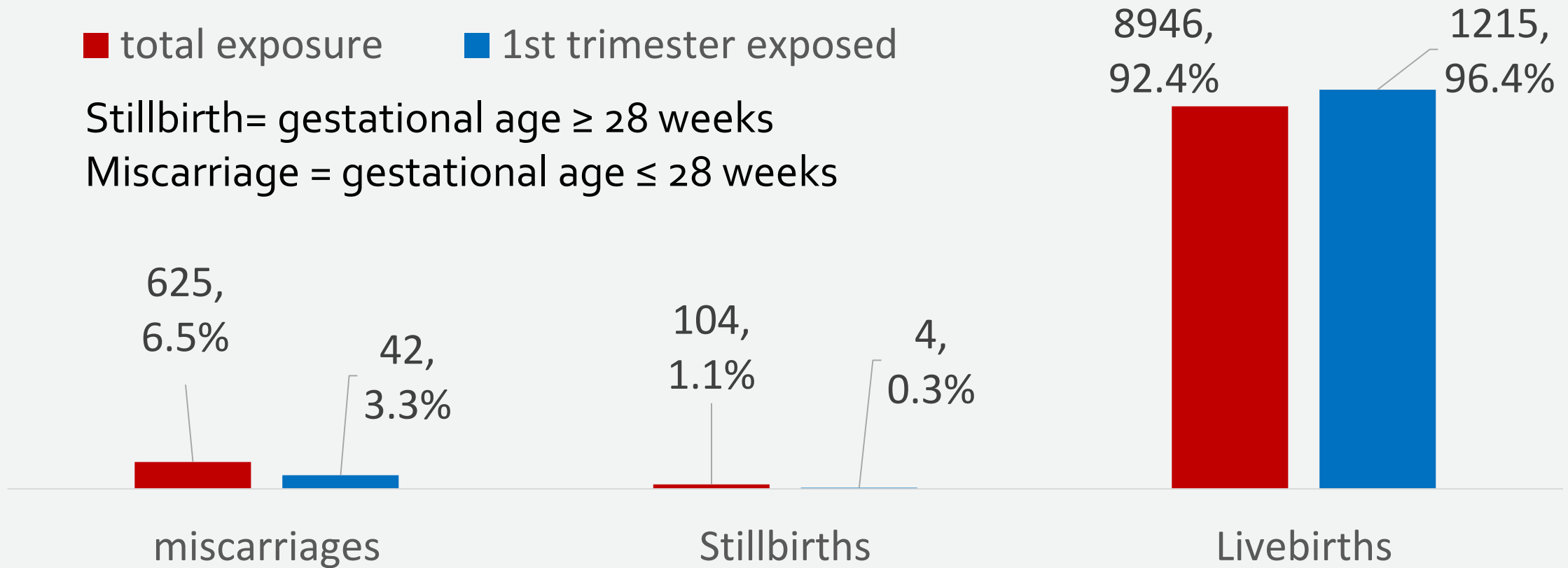
malaria in 1st trimester	n
1 malaria episode	1035
2 malaria episodes	186
3 malaria episodes	33
4+ malaria episodes	7



■ total exposure ■ 1st trimester exposed

Stillbirth = gestational age \geq 28 weeks


Miscarriage = gestational age \leq 28 weeks




No congenital anomalies were recorded in the hospital data

Birth outcomes in women exposed to antimalarials

Conclusion

- It is work in progress with a prospective component following women exposed to DP till 8 weeks post-natal period
 - Subsequent analysis will compare birth outcomes by drug exposure groups
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Key messages

- *The hospital records are a rich source of retrospective data to collect information on safety of antimalarial exposure in pregnancy*
 - *Overall birth outcomes in women treated for malaria anytime in pregnancy were comparable to women who received treatment in first trimester of pregnancy*
 - *A limitation of retrospective hospital data is that miscarriages maybe missed and surface congenital anomalies are not adequately documented*
 - *Prospective component of this study will enable to provide additional information on miscarriages and surface anomalies.*
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Acknowledgments

- *We thank the RSUD and RSMM Hospital Directors and medical records and other department teams for permitting access to past records*
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