

How Does Regulation Affect the Quality of Prenatal Diagnosis Services in China?

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Introduction

- MMR and IMR have fallen recently, while the prevalence of birth defects has risen (Figure 1).

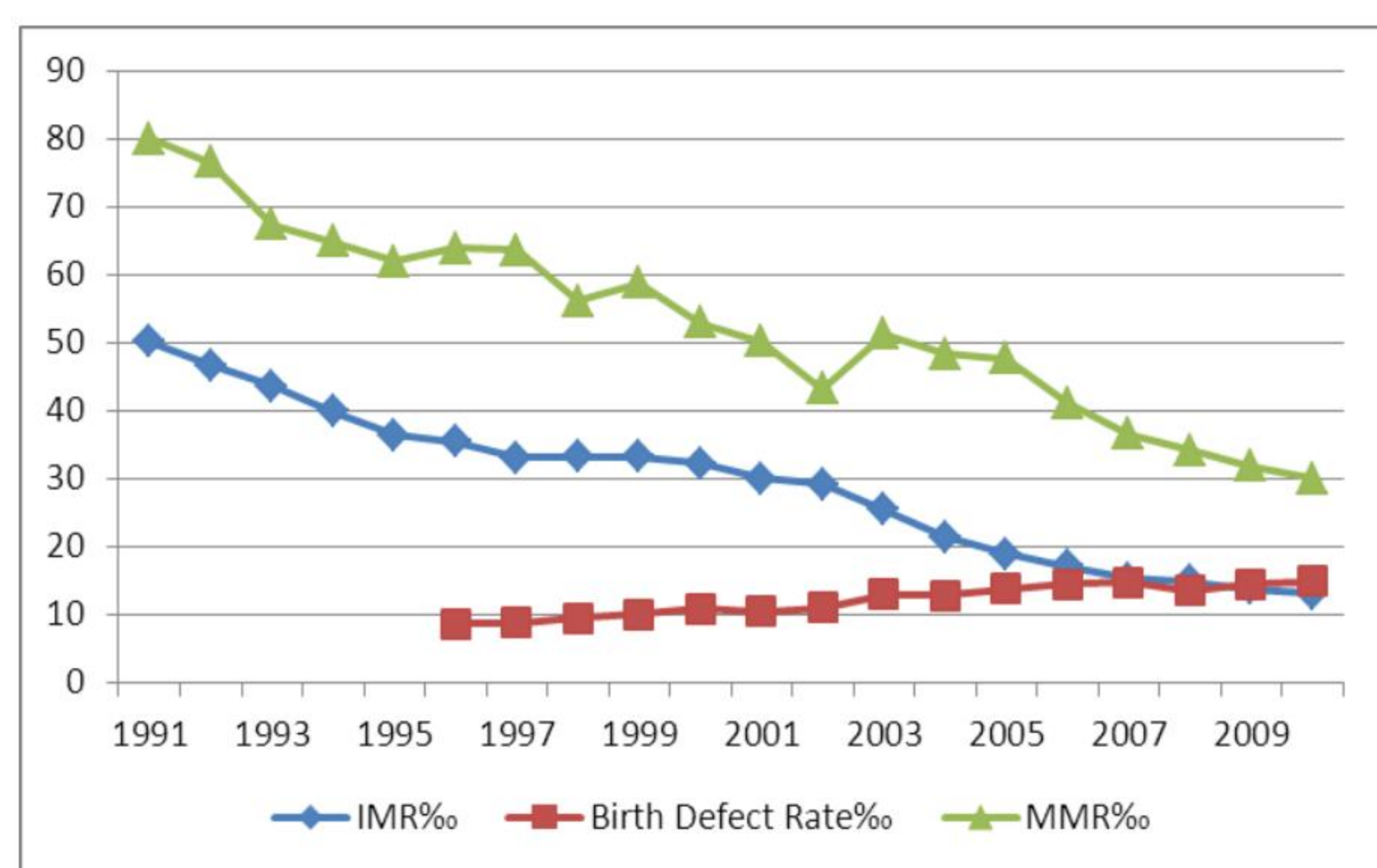


Figure 1 IMR, MMR and Birth Defects Rate from 1996 to 2010 in China

- Children born with birth defects would bring heavy disease burden.
- Prenatal diagnosis (including screening) is to early identify congenital anomalies and genetic disorders.
- Prenatal diagnosis (PD) services are high technology with high risk. So "Administrative regulation of prenatal diagnosis technology" was issued to ensure PD services quality.
- The regulation employed multiple approaches, such as licensure and approval, informed choice, and sanctions.

Objectives

This poster analyzes how the regulation affected the quality of prenatal diagnosis services in Municipality A of China, and provides evidence for improving policy-making.

Methods

The study was based on a case study developed for a larger study, Health System Stewardship and Regulation in Vietnam, India and China (HESVIC). Twenty eight informants, including government officials, service providers, professionals and users, were interviewed to collect qualitative data. Data were managed and analyzed with NVIVO software 8.0.

Results

1. Positive effects

- Approval and certification
Four PD centers have been approved by local government ; personnel are trained and qualified.

- Evaluation and supervision
- ✓ PD centers receive evaluation annually.
- ✓ Personnel receive evaluation every two years.



"Most doctors followed the regulation seriously... in our hospital (prenatal diagnosis center), every doctor providing prenatal screening and diagnosis services has the certification."

- Informed choice was implemented well.

2. Negative effects

- The quality of screening services couldn't be assured.

Technically, screening is used to assess risk, so the result is a probability.

Besides, the screening "cut-off" value (risk criteria) varies when affected by many factors. As a result, some screening centers lower the "cut-off value" to avoid the risk of false negative rate.

- ✓ It raised avoidable anxious of pregnant women



"When I got the [high risk] report [of screening], I was nervous... I thought about it for a long time."

- ✓ PD centers were overload for more high risk cases.
- Poor linkages between screening and diagnosis services. Only a few screening centers established the linkages.
- ✓ Screening centers didn't get assumed supervision and support from PD centers.
- ✓ The referral channels are not seamless.
- The regulation has not been amended for almost 10 years.

Conclusion

- The regulation didn't meet the assumed aims completely.
- The quality of prenatal diagnosis services has improved to some extent based on well administrative framework.
- There are still existing problems limited access to quality of care and needed to be improved in the future. The regulation should be amended according to the changing context.
- ✓ Establish better linkage between prenatal screening and diagnosis with multiple approaches.
- ✓ Improve the monitor and evaluation mechanism.