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SPECIAL ARTICLE

Methodology Issues in Reproductive Health Research

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Evolving issues

Female plays key role in child bearing and in developing countries, child rearing. Science of women's health or Obstetrics and Gynecology has long been considered as the main part of reproductive health. Human reproduction is concerned by various disciplines; therefore, research in reproductive health is multi-disciplinary and employs a variety of methodology.

The fertility is the most fundamental issue along the social evolution of the human species. Like all living things, human try their best to carry on the genetic information by passing it from one generation to the next. Cross-fertilization via sexual intercourse increases diversity of the gene pool and allow emergence of new breeds. More complex passage involves culture, ethnicity and language, etc. This social information has a much higher speed of changes compared to genetic information. However, in the past few decades, the fertility rate has been declined globally[1]. The momentum of human population as decline of fertility in low-income countries has been associated with industrialization, woman's education and perhaps the change of gender's role. The story has become more complicated by the rising presence of homosexuality and transgender. Human reproduction is therefore not just for maintenance of human population, but the transformation of gender values.

Gender is a social issue whereas sexuality is more influenced by biological components which are strongly controlled by age-dependent neuro-hormonal pathway. While hormonal functions have their peak in youth and age of menarche of the population has been reduced over the decades, pregnancy in adolescence has become associated with social disadvantage and it is often unwanted pregnancy followed by induced abortion and its complications. Perhaps, the pregnancy rate of adolescents is declining at a slower pace than that of full adults. Thus the portion of pregnant mothers who are adolescent is increasing. In fact, the incidence of adolescent pregnancy per 1000 female age 15-19 years is divergent worldwide[2]. It is well accepted that adolescent pregnancy should be avoided and all forms of advocacy have been launched to achieve such delay.

On the other extreme, pregnancy, especially in primigravida aged over 35, also poses a high risk to the woman who is at near the end of her reproductive career and her fetus. Increasing education among women has been known to delay marriage and lead to such problem. There has not been any estimation of obstetric complications caused by this age group and there is no policy to promote earlier marriage and pregnancy. Coupled with the problems of declining population size and increase of elderly proportion of the population, the policy concerning appropriate age of marriage should be reviewed.

Research needs

With improved economy and decrease in population fertility, each pregnancy is crucial to the stability of a family. Access to maternal services and sexual reproductive health is now a part of basic human rights. Relationship between providers and the family of the pregnant woman has never been more sensitive. Quality assurance in obstetric care is one of the main professional concerns. It has been shown that practice consistent with evidence is more often the exception than the rule. Research linking the evidence to real practices and policy to enable evidence-based obstetrics need to be strengthened, especially when there is a conflict of interest between the practitioner's benefits and convenience and the hard-to-follow evidence-based practice guidelines[3-5].

Quality of research data is a serious issue in evaluation of health services. Worldwide, hospital delivery is documented in standard obstetric summary form with WHO prototype. With modern computing facilities, it is relatively easy to retrieve data from the hospital-computer system. As the data are routinely recorded without concern for research quality, the accuracy of certain key variables is far from reality. Obstetric complications are often not recorded in such a computing system. Near misses among fit patients are often underdetected. This leads to over-estimation of the quality of care which conceals the need for improvement and distorts further hypothesis testing process.

Methodology in reproductive health research

Generalizability vs sustainability

Research leading towards sustainable quality improvement may have two extreme approaches. The first is the changing system of organization and standard operating procedures. This top-down trial may be feasible under certain circumstances e.g. the new system is approved by a majority of the stake holders and all agree to document this systematic comparison. The other approach is via a participatory research. This option is somewhat bottom –up in nature suitable for multi-dimensional objectives e.g. including learning the solidarity and human resource development. Generalizability may be weaker, but the overall improvement of the health service may be more sustainable.

Too short follow-up in Obstetrics

Health service in the current paradigm emphasizes on what is immediately perceivable. Long-term maternal health from obstetric intervention needs to be evaluated carefully[6]. Moreover, epidemiological finding suggested that quality should also aim for long-term effects. In the recent decades, fetal in utero health has been shown to link with chronic diseases in adult life[7]. Safe pregnancy should not be judged solely by birth weight and Apgar score but also on exposure of fetus to healthy intrauterine environment and consequently the improvement in physical, psychological and social development during childhood and adulthood. Research in Obstetrics in developing countries is often ended shortly after the postpartum period.

Confounding by indication

Observational study design in obstetric research is more feasible than randomized controlled trial. It is often the only choice in evaluating obstetric care. However, the results from such studies must be interpreted with caution. Relationship may be reverse causal. For example, in evaluation of quality of antenatal care, if everything is equal, preterm birth eliminates the possibility of antenatal visit thus preterm birth reduced the number of antenatal visit, not fewer antenatal visits lead to preterm birth[8].

"Confounding by indication" is always problematic in evaluation of health care. A patient often present with a condition that indicate the need to have a particular type of service. As that particular condition is a strong predictor for bad health outcome, the service will then be associated with bad outcome. The association is not causal, but due to such confounding effect. For example, maternal mortality ratio in primary hospitals would be lower than that in tertiary hospitals where complicated cases are referred to. Unfortunately, for ethical reasons, randomized allocation, which is the solution for the problem of confounding, is often not feasible when the indication is present.

Failure to adhere to intention-to-treat analysis

Intention to treat analysis is well recognized and strongly recommended in randomized trial. In other words, in considering treatment variable, a patient who was randomly allocated to receive treatment A but eventually received treatment B should be analyzed as having had treatment A to which she was initially allocated. This is somewhat against the common sense of most doctors who are trained in pure basic science. In a pharmacological study, the main purpose is to see pharmacologic effects of a drug. If a volunteer had been assigned to receive that drug but actually did not, he/she certainly should be omitted and not analyzed as having received the drug. In clinical trial, the purpose and the condition are under real practice. The treatment planned and received are often different due to various reasons, such as poor professional adherence, poor patient compliance, and uncontrollable circumstances. The outcome of a real patient who gets medical order to receive a treatment would be more similar to that of a patient who was assigned to receive that treatment. The more the treatment in a trial is far from 100% strict, a patient who actually receives the treatment in that trial will be more dissimilar to ordinary patients.

Failure to apply intention to treat in analysis of observational data has been rarely mentioned in the literature, but may be serious. For example, a case in point is evaluation of caesarean section. Most papers in the past analyzed according to the mode of delivery the patient had actually received, not what they were intended to receive. A patient in the study, who at first is intended to have vaginal delivery may end up with abdominal delivery due to failure of the labor to properly progress. Her condition is then becomes less well-prepared compared to that had she undergone the section procedure right away. Analysis with her being put into caesarean section group will underestimate the risk in obstetric complications among ordinary pregnant woman assigned to have vaginal delivery in real practice[9]. Ideally, the study design should be a randomized control trial with intention-to-treat analysis. With such design being impossible, one would have to depend on comparison between vaginal delivery and elective cesarean section, both interventions being consistent with the intention. Most of such analysis revealed higher complication rate in the elective cesarean section[10].

Conclusion

Sexual reproductive health and rights are the elemental issues. Routine recording in the hospital-computer system without a concern for research quality and analysis of routine data without careful thought may lead to wrong answers and should be discouraged. The two approaches in quality improvement, either a top-down or bottom-up, are needed for the improvement of methodology in reproductive health. Appropriate control of potential biases and errors are important.

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