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ARTICLE

Including ethical considerations in models for first-trimester screening for pre-eclampsia

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Abstract Recent efforts to develop reliable and efficient early pregnancy screening programmes for pre-eclampsia have focused on combining clinical, biochemical and biophysical markers. The same model has been used for first-trimester screening for fetal aneuploidies i.e. prenatal diagnosis (PD), which is routinely offered to all pregnant women in many developed countries. Some studies suggest combining PD and pre-eclampsia screening, so women can be offered testing for a number of conditions at the same clinical visit. A combination of these tests may be practical in terms of saving time and resources; however, the combination raises ethical issues. First-trimester PD and pre-eclampsia screening entail qualitative differences which alter the requirements for disclosure, non-directedness and consent with regard to the informed consent process. This article explores the differences related to the ethical issues raised by PD and pre-eclampsia in order to elucidate which factors are relevant to deciding the type of information and consent required in each context from the perspective of the ethical principles of beneficence and autonomy. Furthermore, it argues that ensuring respect for patient autonomy is context dependent and, consequently, pre-eclampsia screening and PD should be performed independently of one another.

KEYWORDS: ethics, guidelines, informed consent, pre-eclampsia, pregnancy, screening

Introduction

Pre-eclampsia is a hypertensive condition which contributes significantly to maternal and perinatal morbidity and mortality (Sibai et al., 2005). Recent studies have demonstrated the benefits of treating high-risk pregnancies with low-dose aspirin if administered prior to week 16 (Bujold et al., 2010). The effectiveness of such a treatment is thus

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dependent on the development of a screening test that can predict those pregnancies which are at risk prior to week 16.

Demographic and clinical factors known to be associated with the development of pre-eclampsia, such as nulliparity, ethnicity, diabetes, hypertension and obesity, have low predictive values with regard to detecting pregnancies that will develop pre-eclampsia (Poon et al., 2010). Screening for pre-eclampsia is not a new phenomenon, but technological progress and acquired knowledge regarding the pathophysiology has advanced, providing new methods of preventing and treating the disease (Jorgensen et al., 2012). Consequently, many studies have focused on the utility of various biochemical markers in qualifying the prediction of later onset (Akolekar et al., 2011; Cuckle, 2011; Hedley et al., 2010; Poon et al., 2009). Among these studies, a trend has emerged in which the pre-eclampsia screening is combined with first-trimester screening for fetal chromosomal abnormalities i.e. prenatal diagnosis (PD), a test routinely offered to women in many developed countries. However, the ethical issues associated with combined first-trimester pre-eclampsia screening and PD have yet to be investigated.

This paper seeks to pinpoint variables of both a technical and ethical character relevant to deciding an appropriate framework for implementing a screening test for pre-eclampsia with improved discriminatory power, especially focusing on the possible ethical issues related to combined PD and pre-eclampsia screening when seen through the perspective of the ethical principles of beneficence and autonomy. This paper begins by discussing how ethical issues related to the concept of informed consent apply to each type of screening independently, as it is expected that requirements for informed consent are context dependent. If there is reason to believe that requirements of the informed consent procedure vary widely between each screening context, then offering combined first-trimester screening may be problematic.

Protecting and promoting public health and the health of individuals

Public health goals are set with the aim of promoting good health within distinct populations. To realize these goals, new structures and treatments are often implemented into health care, which determines to some extent the framework for clinical practice. At an individual level, the clinical approach based on broad public health goals may have unexpected negative consequences (Childress and Bernheim, 2008). Therefore, when evaluating public health goals and establishing the framework under which they are expected to be met, it is necessary to consider how individuals will be affected in the specific clinical setting. This consideration should, in the authors' opinion, be a part of defining the limitations, restrictions and/or acceptance of the methods employed to reach the predefined public health goals — and of defining the goals themselves.

The cost—benefit balance of any medical intervention is context dependent and it is important to note that some individuals within a screened population may experience 'harm' without 'benefit' as a consequence of their screen results (Gray, 2004). For instance, some interventions may conflict with the personal values and interests of patients. Consequently, the weighing of benefits against the harms associated with a given method is an essential step for achieving a specific public health goal (Beauchamp and Childress, 2008). Disregarding these issues when framing policies in the pursuit of promoting public health may result in negative consequences at the clinical level by limiting the subsequent possibility for patients to make informed decisions (INAHTA Ethics Working Group, 2005).

Public health programmes can be seen as co-ordinated efforts to promote and maintain health. Population-based screening is one method commonly used in this effort. The purpose of screening is to detect and prevent disease through a clinical assessment of a population of apparently healthy individuals. Ultimately, screening programmes aim to maximize the utility of resources by allocating them to those who may gain the most benefit from treatment, and subsequently decrease the number of severe cases of illness (Edwards et al., 2006). In general, screening procedures raise many ethical concerns (e.g. regarding the effect that testing may have on individuals, as screening is directed towards those who are otherwise considered healthy). Therefore, the utility of a screening test varies, depending on the specific context of the test (Dobrow et al., 2004). This context includes the severity and prevalence of the disease, the implication that the condition may have for the patient and his/her family and the invasiveness, risk and availability of treatment for the particular condition.

Practicality of combined first-trimester PD and pre-eclampsia screening

In working towards ensuring that women are offered optimum health care during pregnancy, the National Institute for Health and Clinical Excellence (NCCWCH, 2008; NICE, 2010) in the UK issued specific guidelines recommending that women be screened for pre-eclampsia at their first prenatal visit, which currently includes demographic information combined with blood pressure measurements and urine analysis for proteins (NCCWCH, 2008; NICE, 2010). However, as mentioned previously, demographic and clinical information have a low predictive value with regard to detecting pregnancies which have a high risk of developing pre-eclampsia (Poon et al., 2009). Therefore, many high-risk pregnancies are not noticed before symptoms have developed, producing risk to both mother and child.

In 2011, the World Health Organization (WHO) issued guidelines and recommendations regarding a variety of possible treatment and prevention strategies for pre-eclampsia. Here, WHO underlines that there is a need for optimizing prenatal health care so as to improve prevention and treatment of hypertensive disorders in pregnancy. Furthermore, WHO states that this is an important step towards achieving the Millennium Developmental Goals as set out by the United Nations (Duley, 2009; WHO, 2011).

Over the last decade, much of the research aimed at developing pre-eclampsia screening tests has focused on identifying biochemical markers that could predict the disease before the onset of symptoms. One of the advantages of expanding the screening programme to include the use of biochemical markers is the possibility to lower the number of false-negative results (Jorgensen et al., 2012). The