Abstract

Objective: Clinical analytical tests are now often being marketed to untrained people, in formats normally only used in the laboratory environment. For example, although many home pregnancy tests are designed to be used by women with no training, direct copies of laboratory tests in strip and cassette formats are also available. The objective of this randomised study was to determine whether these types of tests could be used accurately by a lay person, in comparison to tests specifically designed for home use.

Relevance: It is important that the assumption that tests formatted to be simple to use by trained individuals in a clinical environment, such as simple strips or cassette styles which are designed to be used by untrained people, in formats normally only used in the laboratory environment. Therefore it is of relevance to investigate how the effect of environment and training can influence test accuracy.

Methodology: Pregnancy tests of different formats (branded midstream digital, branded midstream easy-use visual, branded midstream visual, store-brand midstream visual, strip and cassette) that are available to purchase from pharmacies, were tested by lay women (n=112) in their own homes. The women completed questionnaires regarding their ability to conduct the test. The same women then attended a study centre where they read the results of the same tests conducted on standards

Introduction

It is important for women who suspect that they may be pregnant to obtain an accurate pregnancy test result that they can rely on. A missed or incorrect result may have clinical consequences. For example, it can lead to a delay in women seeking healthcare advice, which can cause unnecessary anxiety, a false-negative result may lead to a continuation of behaviours that a pregnant woman would normally change, and an uncertain result can lead to a need for the woman to repeat the test.

Many home pregnancy tests are reported to be 99% accurate if performed on the day that menses is due, and with the correct use of these tests, and also problems with interpretation of instructions for use. This is likely to be due to the higher levels of use of these tests, and also problems with interpretation of instructions for use. These tests should only be used by laboratory professionals. Only tests formatted to facilitate use by untrained people, with simple instructions, should be available for home use.

Study population

Inclusion criteria: females aged 18–45 years who had not used a home pregnancy test within the previous 12 months. The study was conducted in the UK.

Part 1

Eligible volunteers were supplied with a study pack, which included a well-formatted and easy-to-use pregnancy test, and with instructions for use and questionnaires for completion after each test.

Six pregnancy tests were evaluated in the study:

- Boots Pharmaceuticals Pregnancy Test (strip midstream visual test, manufactured by Boots Pharmaceuticals, UK)
- One Step Midstream Pregnancy Test (strip test manufactured by ADE Diagnostics Co, Ltd, China)
- Clearblue® COMPACT pregnancy test (branded midstream visual test manufactured by SPD Swiss Precision Diagnostics GmbH, Switzerland)
- Clearblue® PLUS pregnancy test (branded midstream easy-use visual test manufactured by SPD Swiss Precision Diagnostics GmbH, Switzerland)
- Clearblue® DIGITAL pregnancy test (branded midstream digital test manufactured by SPD Swiss Precision Diagnostics GmbH, Switzerland)
- Ovulation tests were randomised to one of six possible sequence orders for performing product testing testing was conducted over 3 days, with approximately 12h between each testing occurrence. A questionnaire (a series of 7-point Likert scales) measuring various attributes of the test device was completed after each test.

A final comparative questionnaire was completed after all home testing

Part 2

Volunteers attended a study centre and were asked to interpret results presented to them using three different urine standards (0, 25, or 50 mIU/mL hCG) by a trained technician. Accuracy of volunteer interpretation of test results was determined for each format. Additional questionnaires were completed regarding study conduct. All testing was randomised.

Statistical analysis

- SAS version 9.2 was used for all statistical analyses. For Questionnaire 3, the number of volunteers scoring 1 or 2 was analysed using an analysis of covariance model appropriate for the cross-over study, the model included terms for subject, within the subject factors of period and product. A correction for multiple comparisons between products was performed.