A systematic review of at-home semen analysis technologies: A potential supplement to the fertility clinic?

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STUDY QUESTION

The aim was to determine the use and validity of current at-home semen tests, and their potential for screening for improving the treatment of male subfertility.

WHAT IS KNOWN ALREADY:

- Semen analysis remains the primary tool for the diagnosis of male fertility status.
- Conventional spermograms use either automated or manual evaluation under a microscope.
- At-home semen analysis provides an immediate result on basic semen parameters.
- Although at-home sperm tests are commercialized, there are no clear guidelines on their integration into clinical care.
- The use of home sperm tests in primary and secondary care could improve the early correction of subfertility.

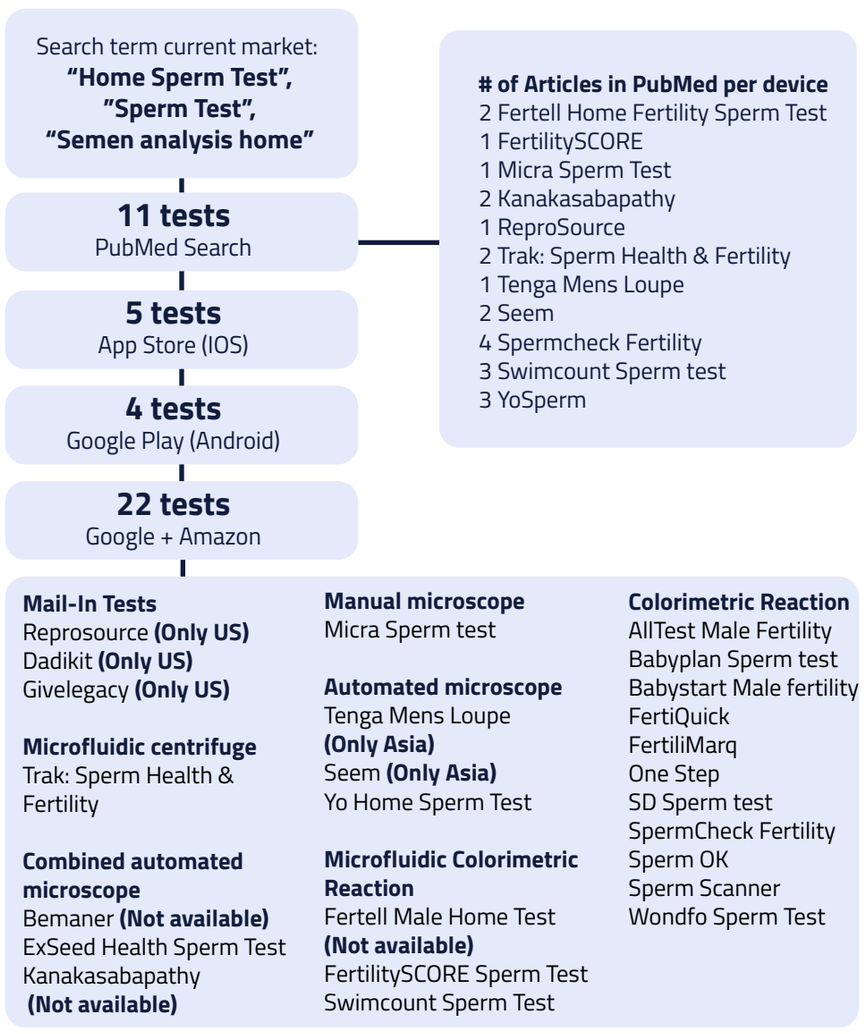
STUDY DESIGN

The research protocol followed the published methodology for Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P), including their extension for Diagnostic Test Accuracy (PRISMA-DTA). The literature search included online databases with a predefined search strategy. An additional search was performed across online markets to find available tests not included in scientific reporting.

MATERIAL AND METHODS

At-home tests were detected via research on Google, PubMed, App Store (iOS), and Google Play (Android). All articles published on testing methods or devices used to analyze semen samples at home or outside the conventional laboratory were included. Each technology and test were reviewed based on an adapted predefined checklist (See figure 1 for an overview).

Figure 1. Overview of search hits



RESULTS

Twenty-five home sperm tests were identified and included in this review (See Figure 1-2). Across the technologies, eight test methods were identified for the 25 identified tests, including a manual microscope, automated microscope, combined automated microscope, microfluidic antibody reaction, colorimetric reaction, paper-based immunoassay, micro-fluidic centrifugation, and mail-in tests (See Table 1). The accuracy of these tests was between 86-98%, and the price ranged between 9.99 USD up to 199.99 USD. Currently, only the combined automated microscope and the Mail-In tests evaluates several semen parameters similarly to the clinic.

Table 1. Overview at home testing methods with their limitations

Analysis method	Evaluation items	Accuracy	Price per test	Tests	Limitations
Mail-In	Reported as clinical results	Not reported	149.99 USD - 199.99 USD	1	High cost; Need to be mailed; Not immediate result
Microfluidic Colorimetric Reaction	Prog. motile conc. (<5 M/ml) Prog. motile conc. (<20 M/ml)	86% - 95%	39.99 USD - 49.99 USD	1	Does not evaluate sperm conc. or volume
Colorimetric Reaction	Sperm conc. (<15 M/ml) Sperm conc. (<20 M/ml)	90% - 98%	9.99 USD - 39.99 USD	1 - 2	Does not evaluate motility or volume; Does not follow WHO
Paper-based Immunoassay	Sperm conc. (<20 M/ml)	98%	27.79 USD	1	Does not evaluate motility or volume
Microfluidic centrifugation	Sperm conc. (<15 M/ml and >55M/ml)	97%	44.99 USD	2 - 6	Does not evaluate motility; Requires user input for volume
Manual microscope	Sperm conc. Sperm motility	Not reported	55 USD	1	Untrained user must count sperm; Does not evaluate volume
Automated microscope	Sperm conc. (<15 M/ml) Sperm motility (<40%) Prog. motile conc.(<6 M/ml)	Not reported - 97%	19.99 USD - 69.95 USD	1 - 4	Does not follow the WHO; Does not evaluate volume; Some do not evaluate sperm conc.
Combined automated microscope	Quantitative measurement of volume, sperm conc. and prog. motility	96%	34.99 - 49.99 USD	2 - 5	Requires user input for volume

Figure 2. Most popular at-home tests on the market in their category.

PERSPECTIVES

Most home sperm tests on the market are now user friendly, accurate, and effective diagnostic tools for male fertility screening. The main limitations of their use include non-standardized evaluation cut-offs and measurements of single semen parameters that do not sufficiently evaluate male reproduction, such as sperm concentration alone. Future tests should focus on providing users with:
1) Accurate measurements of several parameters following WHO criteria, including repeated testing.
2) Thorough information and guidance of the test result.
3) Connection to primary and secondary care in case of low results.

We suggest that institutions, such as the NHS, develop their guidelines to meet the above criteria on at-home semen tests. This will aid the adoption of the technology into the healthcare system while actively promoting the manufacturers to provide better solutions for better patient care.