

Non-invasive prenatal genetic testing technologies, direct to consumer tests for fetal sex, and the limits of bioethics?

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Panel: Emerging prenatal genetic testing technologies: New technologies, old debates?

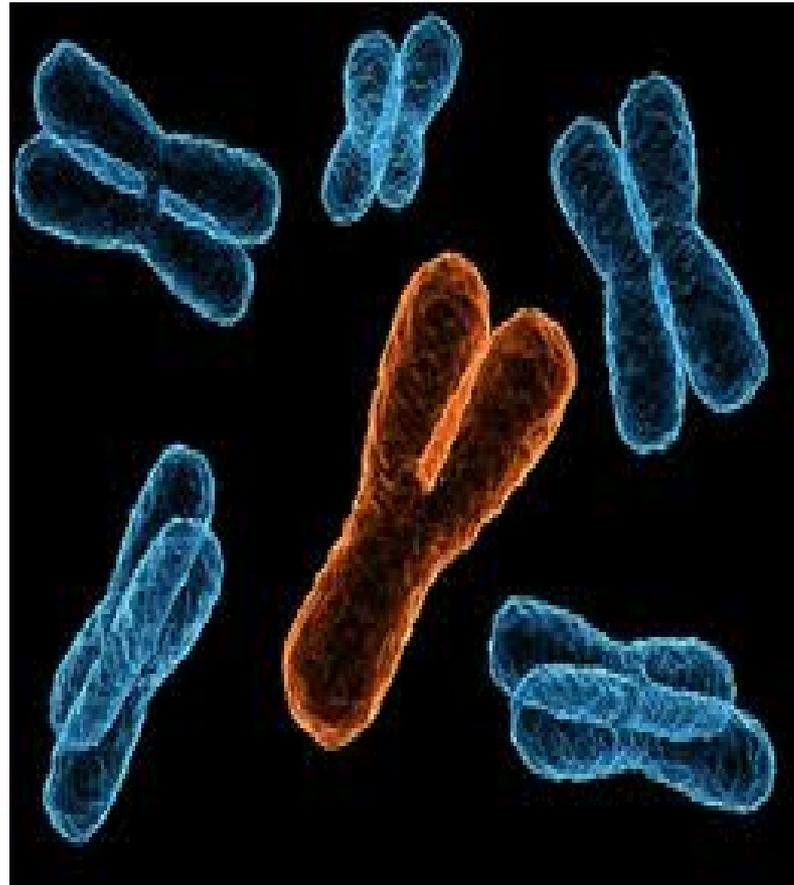


- Prenatal genetic testing has received less attention from STS and ELSI scholars than such reproductive technologies as PGD.
- However, new ‘non-invasive’ prenatal genetic diagnostic (NIPD) tests are currently available or nearing introduction in the UK and elsewhere (e.g., several commercial NIPD tests for DS have been launched in the US, DS testing is clinically available in Hong Kong, LifeCodexx is planning a launch to German-speaking markets soon).
- NIPD will *augment or replace* invasive techniques that pose a small risk of miscarriage, with earlier and safer genetic diagnosis from a sample of maternal blood.



NIPD and Fetal Sex

Testing in the context of risk of sex linked diseases such as haemophilia (when the mother is a carrier) or in the clinical management of fetuses at risk of congenital adrenal hyperplasia (CAH) have been among the most successful clinical applications of this new testing technology (Avent and Chitty 2006).



Intersections of technologies – NIPD and the internet

- Reactivating debates concerning the routinisation and normalization of prenatal testing and termination for disabling conditions such as DS.
- Questioning the social, ethical and policy consensus underlying existing prenatal genetic testing programmes.
- Direct to consumer potential of NIPD tests (e.g., for prenatal identification of fetal sex, paternity and chromosomal abnormalities) raises new questions about if/how regulation should take place in the international ‘reproductive testing marketplace’.

The screenshot shows a web browser window displaying the website for DNA Diagnostics Centre (DDC). The browser's address bar shows the URL <http://www.dna-bioscience.co.uk/prenatal-testing.php>. The website features a navigation menu on the left with links to 'Paternity Test Kit', 'Legal Paternity Test', 'Prenatal Paternity Tests', 'Ancestry Tests', and 'Immigration DNA Tests'. Below the menu, there is a section titled 'Tests Start at £145' with a dropdown menu for 'Select A Test'. The main content area is titled 'Prenatal Test Options' and features a prominent banner for 'DNA Paternity Testing While Pregnant' with the text 'ONLY DDC offers the BEST choice for you' and a call to action: 'Call Today for Your FREE Consultation with a DNA Expert: 0845 408 2084'. Below the banner, there is a section for 'NEW: Non-Invasive Prenatal Paternity Test' with a brief description and a list of key features: 'Highly accurate results in 8 business days', 'Requires only a simple blood collection from the mother & alleged father (The child's DNA is found within in the mother's blood)', 'Can be performed from the 9th week of pregnancy and onwards', and 'DDC has a blood collection facility in London and locations throughout the UK'. A video player at the bottom of the page shows a building labeled 'DNA DIAGNOSTICS CENTER' with the text 'DDC's Non-Invasive Prenatal Paternity Test' overlaid on the image. The video player has a progress bar and a play button. The browser's taskbar at the bottom shows various icons and the system tray with the time 11:11 and date 20/04/2012.

- This paper addresses these intersections in the emerging DTC market for post-conception fetal sex ‘prediction’
- Ethical arguments against fetal sex selection (e.g., Strange & Chadwick) have been raised by NIPD for fetal sex (e.g. is a sexist practice which promotes socially restrictive conceptions of sex, gender & family)
- I argue that the NIPD/DTCGT intersection changes the kinds of ethical arguments that can be raised against fetal sex , and provides insight into the possibility of further uses of NIPD for consumer choice, lifestyle, or other types of prenatal choice about which ethical objections might be raised.

‘Million missing girls’

- Fetal sex *selection* for non-medical purposes, either pre- or post-conception, remains ethically and socially controversial (Marteau and Chitty 2006).
- Two major areas of concern are:
- Implications for parents, children and society of the selection of individuals on the basis of characteristics unrelated to illness (e.g., Glover, 2006; Sandel, 2007) and,
- Population gender imbalance, and associated effects on society and on female status, that have occurred in some societies where there is a preference for male children (e.g., Chan et al., 2006; George, 2006).



Pink or Blue ®?

- Currently, a test called 'Pink or Blue, the early gender test' is being marketed via the internet on several websites with claims of 95-99% accuracy.
- This test analyses a maternal blood spot for presence of Y chromosomal DNA indicating a male fetus, using essentially the same technology as in the clinical applications discussed above (although a number of situations are identified that will limit the accuracy of the test, such as a recent miscarriage, abortion or blood transfusion).



The screenshot shows the Pink or Blue website. At the top, the logo reads "pink or blue® The Early Gender Test" with contact information: "Toll Free: (866) 6-WHAT-R-U International: (408) 734-2229 Monday - Friday 9:00AM-6:00PM (PST)". A banner features four baby photos and the text "Girl or Boy? Find Out Early." Below the navigation bar, the main heading is "The Pink or Blue Early Gender Test: Video Demonstration". The text explains that the test's accuracy is influenced by specimen collection and provides instructions: "1) to collect them after the Pink or Blue® eligibility date (calculated using our Pregnancy Date Calculator), and 2) to pay keen attention to decreasing the possibility of male DNA contamination." It also states: "Here you will find a video demonstration of the Pink or Blue® Early Gender Test Specimen Collection procedure. Please follow these instructions very closely." A video player shows a thumbnail for "Pink or Blue® The Early Gender Test Sample Collection Instructions" with a duration of 07:13. Below the video, the text asks: "Boy or Girl? Pink or Blue Early DNA Gender Test is the product which will answer that question:". Two product boxes are shown: "Pregnancy Test Kit \$24.95**" and "DNA Gender Test \$179.00**". Both boxes include "Order Now" buttons and footnotes: "**Price does NOT include shipping or lab fees. Kit only." and "**Price includes kit, standard lab fee, 1 way shipping in US."

Pink or Blue ® marketed in the US presents fetal sex prediction as a lifestyle option

‘Early Gender Determination

Standing in the baby aisle, wouldn't it be nice to know whether to choose the pink blanket instead of settling **for the generic green one?**

Now you can find out earlier than ever. Pink or Blue® is a new DNA test which can be collected in the comfort of your own home. Using just drops of the mother's blood you can find out as early as seven weeks after conception (nine weeks after last menstrual period) whether you are having a boy or a girl.

Give yourself the peace of mind and your baby the kind of preparation that only time allows. Use Pink or Blue®, the earliest and most accurate method of prenatal gender detection.’

Blurring the boundaries

- Tell Me Pink or Blue, until recently, accepted samples directly from consumers
- Now must be ordered by a clinic ('Consumer Genetics provides a gender testing service to OB/GYN clinics around the world. The **pink or blue**® Early Gender Test represents a giant leap forward in first trimester fetal testing, offering high accuracy and safe sex determination')
- Marketed as lifestyle but positioned as medical, within clinical space
- **Until recently excluded customers from China and India**
- Now offers instructions in French and Italian

The screenshot shows a web browser window with the URL <http://www.tellmepinkorblue.com/professional.php>. The page features a navigation bar with links for 'Pink or Blue Gender Test', 'Professionals/Distributors', 'Testing Resource Center', and 'About Consumer Genetics'. A prominent headline reads: 'Recent JAMA article confirms Fetal Sex Test accuracy to be 95% at 7 weeks. See article here.' Below this, the article title is 'pink or blue® Early Gender Test'. The text states: 'Consumer Genetics provides a gender testing service to OB/GYN clinics around the world. The pink or blue® Early Gender Test represents a giant leap forward in first trimester fetal testing, offering high accuracy and safe sex determination.' An image shows a fetus with the text 'Fetal DNA passes into the mother's bloodstream' and 'Target sequence indicating gender'. To the right, a list of 'Benefits of the pink or blue® test include:' includes: 'Noninvasive and safe - requires only a finger prick of blood from the mother', 'Early detection - first trimester', 'Highly specific - allows for a distinction between maternal and fetal DNA', 'Highly accurate - confirmed at 95% by an independent study', and 'Keeps patients focused on positive nature of pregnancy'. Further down, 'Publications:' lists a study in the 'Journal of the American Medical Association' and 'NY Times'. 'News Articles:' lists 'Test can tell Baby Sex at 7 weeks, NY Times', 'Blood Test Can Tell Fetus's Sex at Just 7 Weeks', and 'New Blood Test Can Tell Fetal Gender at 7 Weeks'. 'Resources:' lists 'FTA Card Order Form' and 'Gender Test Requisition Form'. The bottom of the page features the 'egenis' logo and the website address www.genomesthetwork.ac.uk/egenis.

http://www.intelligender.com/intelligender-international.html

MyExeter Staff 5.0 Amazon.co.uk: pink or blue ge... International

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IntelliGender's Gender Prediction Test™ (GPT) is an international phenomenon as mothers from around the world are learning about the possibility of knowing the gender of their baby sooner and easier than ever before! While the test is sold to many worldwide customers directly from our website, we are pursuing an aggressive international expansion program by partnering with exclusive distributors who have existing sales and marketing channels; companies who understand the varied nuances of local consumer markets. The GPT is now sold in over 15 countries through local pharmacies, doctor's offices and other maternity and retail outlets. And our coverage is growing quickly. Look for us in to expand to Eastern and Western Europe in the fall of 2011. Check the Locator Tab on our website to contact a reseller in your country.

Note: IntelliGender does not sell our GPT test in China or India; nor do we license the sale of our product to either of these countries. If the test is being sold locally in either of these markets, it is not an IntelliGender authorized sale and we do not support this product.

- **Australia:** www.boyorgirl.com.au
- **Brazil:** grupocimed.com.br/intelligender
- **Germany:** www.jungeodermaedchen.eu.com
- **Indonesia:** www.intelligenderindonesia.com/
- **Mexico:** www.ifaceltics.com.mx
- **Middle East:** www.lunatus-me.com (Bahrain, Egypt, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, U.A.E):
- **Poland:** www.intelligender.pl
- **Russia:** www.all4fam.ru
- **South Africa:** www.intelligendersa.co.za
- **China:** See note above
- **India:** See note above



Prenatal Gender Test

Using the latest scientific techniques, it is now possible to determine the gender of your baby as little as **SEVEN WEEKS** after conception using samples collected with a home test kit.

Use our [calculator](#) to discover your eligibility date.

Warning: Please be advised that this is a proven medical DNA test with a sound scientific basis. It is **NOT IN ANY WAY** associated with astrology, a 'birth chart', or a urine gender test - all fraudulent methods thoroughly debunked by science. Our test comes with a full money-back guarantee in the event of a false result. [Learn more...](#)

£179

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- slovenščina
- српски
- Svenska
- Filipino
- Türkçe
- українська
- Tiếng Việt
- 中文 (简体)
- 中文 (繁體)

- It would appear that Consumer Genetics has bypassed the ethical concerns raised by feminists about gender preference and sex selection in the developing world, by moving their product from consumer control into the clinical space, where 'traditional' ethics of the physician/patient relationship are relevant to enacted notions of autonomy. (Note that CG appeals to 'parental virtue').
- However, the legal prescriptions against fetal sex selection in China are against physicians, and this has not been an effective mechanisms for curbing fetal sex selection with existing technologies ("Some private practicing doctors and small hospitals are providing this illegal service. In recent years, the services have become very sophisticated and gender scans can be arranged at the client's home," Zhai said, adding that it was very difficult to catch the offenders.)

Consumption paradigm of medical technologies, and consumer orientated medicine – what is the role of bioethics?

- It also lies in how it signals an important strategy of DTCGT companies with regard to avoiding regulation and ethical debate.
- Also important because it suggests the inadequacy of some of the categories with which bioethics discourse has debated, and framed, the nature of actions taken within the biomedical sphere (particularly reproductive choice, central to most ethical arguments for and against fetal sex selection)
- How does bioethics address this kind of ‘dual use’ technology (medical/lifestyle)? A new social space for ethics?

Not one but multiple technologies

- Users are heterogeneous and contexts in which tests are 'meaningful' are heterogeneous and local, and therefore 'ethical' judgements about the technology or product are contingent on these aspects of the technology/user interface.
- It is not so much the internet as technology, but the heterogeneity of users and user contexts, that make universal ethical judgements about a technology like this difficult – judgements that could form the basis of regulation.
- It is, in a sense, not one technology, but multiple technologies, taking users as part of sociotechnical systems seriously.

- Regulators will need to grapple with the ‘multiple’ nature of NIPD technologies, and the limits of ethics (ethics of consumption of bio-lifestyle technologies, liminal to or outside clinical spaces and regulatory relationships), in formulating regulatory strategies.
- Future ‘intersections’ of NIPD – next generation sequencing and consumer choice

THANK YOU FOR YOUR ATTENTION

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