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Direct-to-consumer tests: emerging trends are cause for concern

***Emma Gram and colleagues** argue that the public needs high quality information and effective communication about the evidence behind the marketing of direct-to-consumer tests*

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Advances in diagnostic technology and digital health have increased the variety and volume of direct-to-consumer tests—commercial tests initiated by consumers without clinical consultation.[1] Sales of these tests have surged from $15m in 2010 to $1.15bn in 2022 in the United States alone.[2-4] As well as the better known DTC tests for covid-19, genetics, and HIV, many other types of tests are now available, including for prostate health checks, thyroid function, and food sensitivity.[5-8] However, no dedicated regulatory framework exists to govern the appropriate use of emerging DTC products.

Although DTC tests offer consumers more choice, accessibility, and privacy,[1 9 10] qualitative studies show that users have found decisions on selecting and purchasing tests a challenge.[10] Concerningly, companies use persuasive marketing techniques such as narratives of "women's empowerment" to promote non-evidence based health interventions.[5 8 11] As DTC tests are promoted to broad populations rather than specific groups for which there is evidence of improved health outcomes, consumers are at risk of buying products that do more harm than good. Therefore, availability of DTC tests can trigger unnecessary and inappropriate use.[5 12 13] Indeed, a qualitative study suggests that some users of DTC tests were motivated to repeat testing to seek regular reassurance, whereas others who received abnormal results did not follow-up with a general practitioner.[14] Better information and regulation are essential to protect consumers from potential harms.

Poor accuracy and misleading consumer information

Diagnostic home self-testing kits are increasingly available for consumers to purchase at pharmacies, supermarkets, and online.[15] Government survey data suggest that in January 2022, during the peak of the covid-19 pandemic, 175 million rapid antigen tests were taken across England.[16] Reported reasons for testing included informing health self-management strategies (eg, home quarantining) and peace of mind.[16] Familiarity with rapid antigen tests during the pandemic has triggered uptake of other types of home self-testing.[17] However, a systematic review of the accuracy of self-diagnosis tests for common conditions found an overall poor accuracy of the tests or the interpretation of the results.[18] The Royal College of Obstetricians and Gynaecologists (UK) recommends against over-the-counter tests measuring urine follicle stimulating hormone levels to detect menopause because of their poor accuracy.[19] False positive and false negative results may provide incorrect or misleading information to women regarding fertility or symptoms (box 1). Similarly, the anti-müllerian hormone test is often advertised for predicting the chance of conceiving,[13] a claim not supported by evidence, and may give women false reassurance or lead them to expedite pregnancy plans.[20]

Box 1: Potential harms of direct-to consumer tests

Poor accuracy of home testing kits and misleading consumer information

- False positive results: psychosocial distress, pressure to have health interventions or treatment, overtreatment
- False negative results: false reassurance, delayed access to care, additional transmissions (in case of infectious diseases)
- Misleading information: harms arising from misinformed healthcare decisions: false hope about promises of tests, failing to act appropriately on tests results

Tests used in clinical settings repurposed for assessing "wellness"

- Results may trigger downstream (over)testing or lead to unnecessary (over)use of non-evidence based supplements and treatments with associated costs
- Unnecessary medicalisation of healthy populations—labelling and psychosocial distress associated with abnormal results that are not clinically important
- Digital health inequalities

Premature marketing of multicancer detection tests

- Increased detection of late stage cancer without improvement in mortality or morbidity (earlier but ineffective diagnosis) does not benefit consumers
- Increased healthcare system costs through overdiagnosis, overtreatment, and false positive results

The accuracy of HIV self-testing is also problematic. A systematic review found point-of-care salivary HIV tests had a pooled sensitivity of 92.8% (95% confidence interval 86% to 96.5%) and specificity of 99.8% (99.1% to 99.9%).[18] This is not sufficiently accurate to rule out infection, particularly given the harmful consequences of false reassurance and delayed access to care triggered by false negative results.[21] On the other hand, false positive results can potentially overburden the healthcare system as they cause unnecessary follow-up consultations and confirmatory testing.[22] Therefore, consumers need clear instructions on how to interpret tests in specific contexts and test probabilities.[23]

The information provided in enclosed instructions, packaging, and advertising is also an important resource used by consumers for informed decision making, yet this is sometimes incomplete, misleading, or even false.[11 13 24] For example, advertising of covid-19 tests often lacked information about risks of false results, thus overemphasising the trustworthiness of the tests.[24] A randomised trial showed that people using rapid antigen tests for covid-19 misinterpreted the implications of the results and failed to follow official instructions on response.[23]

Clinical tests repurposed for assessing "wellness"

A recent review showed that more than 40% of DTC tests marketed online in Australia were sold as "health checks."[5] These included tests of hormone levels, nutritional profiles measuring trace elements, and full blood count, which are usually used in clinical settings and lack evidence of benefit in asymptomatic healthy populations.[25] Although "health checks" can provide a one-off indicator of whether biometric markers are inside or outside the "normal" range, they do not indicate if and how these results may be clinically meaningful and may carry important harms (box 1).

An example is testosterone tests, which are commonly used in the clinical setting to detect endocrinological conditions.[26] Testosterone tests sold direct to consumers most often target men following recreational fitness regimens, especially bodybuilders, for "optimising" testosterone levels. The concern is that testosterone tests can be misused to justify unsafe supplementation and testosterone replacement therapy, which is now also commercially available.[27-29] Some companies offer subscriptions to hormone tests, triggering repeat testing to monitor the outcome of the recommended supplements or regimens. From 2017 to 2019, there was a 1688% increase in visitors to DTC prescribing and pharmacy websites offering treatment for erectile dysfunction, reaching almost five million a month,[30] and sales of testosterone now account for more than $400m in the US.[31 32] The American Urological Association recommends that patients are informed about the long-term side effects of testosterone replacement, such as infertility,[33] and the FDA has issued a caution about non-clinical use of testosterone products because of the increased risk of major adverse cardiovascular outcomes.[34]

Targeting healthy populations creates an entirely new and potentially lucrative market for test manufacturers but risks medicalisation. However, the health status of healthy people cannot be reliably measured with testing because, without clinical indications or context, there are no agreed protocols or harmonised reference intervals to interpret whether the results fall into a healthy or pathological range for the individual.[5] The pre-test probability is low in healthy populations,[35] and testing increases the chance of false-positive results and overdiagnosis.[36] However, regulation of DTC health checks is challenging as many of these products are labelled as "not for medical purposes," thus circumventing in vitro diagnostic regulation and laboratory quality assurance processes that are primarily targeted at tests used in patient care.

Premature marketing of multicancer detection tests

Multicancer early detection tests are a recently developed technology aiming to detect multiple cancers before symptoms have occurred, including cancers for which there are no specific screening tests. Multicancer tests measure various substances such as abnormal DNA and use complicated proprietary algorithms to derive metrics that indicate the likelihood of cancer and likely tissues of origin.[37]

These tests are currently being marketed and sold in the US without any evidence of reduced mortality and extension of life expectancy (box 1.). Consumers can request the test through their healthcare provider or through a telemedicine portal. The US Preventive Services Task Force recommends screening for four cancers—breast, cervical, colon, and lung—using cancer specific tests.[38] The multicancer tests are designed to detect over 50 types of cancer and are thus inconsistent with current guidelines.[39] Nevertheless, NHS England has announced the purchase of a million of these tests.[40]

In the largest screening study reported to date, over 6000 subjects in seven US medical centres were followed up for one year after having a multicancer test.[41] The sensitivity of the test increases with the stage of the cancer, as small cancers shed fewer, harder to detect fragments of abnormal DNA than larger cancers. Thus, these tests are more likely to detect cancers at advanced stages, limiting their benefits. In addition, the study did not have a comparison group or adequate follow-up and provided no information on whether it prevents more deaths or on the risks of overdiagnosis and overtreatment.[41]

An important problem of multicancer tests is that the harms of finding advanced stage cancer "earlier" could be substantial. Although the cancer is detected and treated, the toxicity, morbidity, and financial burdens associated with earlier, but not more effective, treatment may outweigh any benefits. In the 6000 subjects, 19 solid tumours were detected, 10 of which were cancers for which standard screening programmes are already implemented and all were late stage (III or IV).[41] Furthermore, in 62% (57/92) of participants who had a positive cancer signal, the results were false positive. Invasive procedures were conducted on 88% and workup leading to diagnostic resolution spanned two to eight months. In other words, many people went through unnecessary diagnostic investigation with potential associated costs and anxiety.

Potential benefits of consumer tests

Using DTC tests may be beneficial in some cases. For people with symptoms that warrant investigation or in populations with high prevalence and undertesting, the accessibility and privacy offered by DTC tests may outweigh the limitations posed by low accuracy. One example is sexually transmitted infections.[42 43] Even if accuracy is only modest, HIV self-testing might have a high positive predictive value in settings with high prevalence.[44]

Some DTC tests might empower consumers by providing better access and responding to prominent gaps in the healthcare system. Consumers have reported using DTC tests when general practice appointments are difficult to arrange because of cost, distance, and lengthy waiting times.[12] When consumers felt dismissed by GPs, they used self-testing to justify their need to seek clinical care.[12] However, few studies look beyond the initial access aspect of DTC testing and are yet to demonstrate that their use leads to better health outcomes.

Need for effective management of DTC tests

Despite the promises of new technologies and care models, the marketing of DTC tests often outpaces supporting evidence of health outcomes and clinical value, especially when targeting healthy consumers, who are least likely to benefit from testing. As such, some testing is done because it is technically possible rather than because it is useful.[45]

To address potential consumer harms,[46] professional organisations are calling for action. The UK Royal College of General Practitioners (RCGP) states that tests must have clear interpretations and results, tests should include complete information, and patients need to have clear information about when self-testing is recommended and when it is not.[47] The European Federation for Laboratory

Medicine and Clinical Chemistry taskforce on DTC tests makes similar recommendations and urges involvement of laboratory professionals in supporting consumer decision making about using DTC tests.[1] However, without official policy directives and regulation of commercial suppliers that operate outside the healthcare system, these changes are slow to happen.

Currently, most jurisdictions do not have clear definitions, clinical guidelines, or dedicated regulatory frameworks for DTC tests.[48] Although most home self-testing kits are regulated under in vitro devices regulation, the focus is primarily on quality and efficacy of the devices rather than on appropriateness of test selection and use. Some jurisdictions do require post-market surveillance, but it is insufficient to mitigate the range of potential harms. For example, in England the Care Quality Commission oversees services that perform tests and analysis but has no remit for marketing of consumer self-tests.[22] The same goes for the US Food and Drug Administration, which oversees and reviews DTC tests only for high risk medical purposes. There are few guidelines about appropriate use of DTC tests processed in laboratories, including non-medical laboratories, where most wellness tests and non-evidence based tests take place.[1]

Clearly, current regulatory frameworks are inadequate in responding to the new ways in which DTC tests are being sold and used. A dedicated regulatory framework should be established for DTC tests that has a focus on supporting consumers as decision makers, rather than leaving regulation of different types of tests ancillary to in vitro diagnostic regulation or laboratory accreditation.[1] Importantly, FDA and other regulators must pay particular attention to DTC tests marketed for wellness purposes and analysed in non-medical laboratories.

The Preventing Overdiagnosis Scientific Committee has called for transparent communication in DTC testing.[49] Commercial suppliers should prove product benefit for their consumers, including clearly defining appropriate targeted populations of tests to avoid harmful misinterpretation. In addition, industry and regulatory bodies should engage in broader concepts of harm such as financial burden, psychological and physical harm, overdiagnosis, and ineffective diagnosis associated with DTC testing. These harms should be better recognised and studied as DTC medicine becomes more popular as an alternative model of care.[50 51] In addition, more research on consumers' perspectives and values in self-testing is critical for improving user centred practice, benefit, and safety.

Key messages

- Medical tests marketed and sold directly to consumers may help people make personal health decisions and enhance consumer autonomy
- Inappropriate use of such tests can pose harm to consumers through unnecessary treatment or overdiagnosis
- The public needs high quality evidence, effective communication about the evidence, and equitable access to tests with important health benefits
- Regulatory bodies must ensure and enforce transparent communication to protect consumers from unbalanced and misleading marketing

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1 Shih P, Sandberg S, Balla J, etal. Direct-to-consumer testing as consumer initiated testing: compromises to the testing process and opportunities for quality improvement. *Clin Chem Lab Med* 2024;14. doi: 10.1515/cclm-2024-0876 pmid: 39141796

2 Schwartz LM, Woloshin S. Medical marketing in the United States, 1997-2016. *JAMA* 2019;321:-96. doi: 10.1001/jama.2018.19320 pmid: 30620375

3 Keshavan M. These are the key players in the home health testing market. MedCity News. 20 Jan 2016. https://medcitynews.com/2016/01/20-key-players-in-the-direct-to-consumer-lab-testing-market/

4 Precedence Research. Direct-to-consumer laboratory testing market size 2023-2032. 2023. https://www.precedenceresearch.com/direct-to-consumer-laboratory-testing-market

5 Shih P, Ding P, Carter SM, etal. Direct-to-consumer tests advertised online in Australia and their implications for medical overuse: systematic online review and a typology of clinical utility. *BMJ Open* 2023;13:e074205. doi: 10.1136/bmjopen-2023-074205 pmid: 38151277

6 Ryan A, Wilson S, Greenfield S, Clifford S, McManus RJ, Pattison HM. Range of self-tests available to buy in the United Kingdom: an internet survey. *J Public Health (Oxf)* 2006;28:-4. doi: 10.1093/pubmed/fdl051 pmid: 17052990

7 Lovett KM, Mackey TK, Liang BA. Evaluating the evidence: direct-to-consumer screening tests advertised online. *J Med Screen* 2012;19:-53. doi: 10.1258/jms.2012.012025 pmid: 23093732

8 Wong AWY, White HEG, Plant A, Shipman AR, Shipman KE. Issues surrounding consumer-bought food-allergy testing. *Clin Exp Dermatol* 2022;47:-52. doi: 10.1111/ced.14978 pmid: 34655248

9 Exten C, Pinto CN, Gaynor AM, Meyerson B, Griner SB, Van Der Pol BBoard of Directors of the American Sexually Transmitted Diseases Association. Direct-to-consumer sexually transmitted infection testing services: a position statement from the American Sexually Transmitted Diseases Association. *Sex Transm Dis* 2021;48:-9. doi: 10.1097/OLQ.0000000000001475 pmid: 34030157

10 den Oudendammer WM, Broerse JEW. Towards a decision aid for self-tests: users' experiences in the Netherlands. *Health Expect* 2019;22:-92. doi: 10.1111/hex.12903 pmid: 31195432

11 Copp T, Pickles K, Smith J, etal. Marketing empowerment: how corporations co-opt feminist narratives to promote non-evidence based health interventions. *BMJ* 2024;384:e076710. doi: 10.1136/bmj-2023-076710 pmid: 38355160

12 Ryan A, Ives J, Wilson S, Greenfield S. Why members of the public self-test: an interview study. *Fam Pract* 2010;27:-81. doi: 10.1093/fampra/cmq043 pmid: 20576792

13 Johnson A, Thompson R, Nickel B, Shih P, Hammarberg K, Copp T. Websites selling direct-to-consumer anti-mullerian hormone tests. *JAMA Netw Open* 2023;6:e2330192. doi: 10.1001/jamanetworkopen.2023.30192 pmid: 37603332

14 Ickenroth MHP, Grispen JEJ, Ronda G, etal. Motivation and experiences of self-testers regarding tests for cardiovascular risk factors. *Health Expect* 2014;17:-72. doi: 10.1111/j.1369-7625.2011.00733.x pmid: 22032617

15 Parr E. GP workload warning as Tesco starts selling at-home testing range. Pulse. 27 Mar 2023. https://www.pulsetoday.co.uk/news/clinical-areas/womens-health/gp-workload-warning-as-tesco-starts-selling-at-home-testing-range (accessed 11 March 2024)

16 UK Government. COVID-19: general public testing behaviours. GOV.UK. https://www.gov.uk/government/publications/lfd-tests-how-and-why-they-were-used-during-the-pandemic/covid-19-general-public-testing-behaviours

17 Mahase E. Pandemic self-testing has led to boom in unregulated "wellness" tests, researchers warn. *BMJ* 2023;382:. doi: 10.1136/bmj.p1895 pmid: 37586740

18 McLellan J, Heneghan C, Roberts N, Pluddemann A. Accuracy of self-diagnosis in conditions commonly managed in primary care: diagnostic accuracy systematic review and meta-analysis. *BMJ Open* 2023;13:e065748. doi: 10.1136/bmjopen-2022-065748 pmid: 36627158

19 RCOG. RCOG recommends against using over-the-counter menopause tests. 2022. https://www.rcog.org.uk/news/rcog-recommends-against-using-over-the-counter-menopause-tests/ (accessed 20 March 2024)

20 Copp T, Thompson R, Doust J, etal. Community awareness and use of anti-Müllerian hormone testing in Australia: a population survey of women. *Hum Reprod* 2023;38:-7. doi: 10.1093/humrep/dead111 pmid: 37309652

21 Mourez T, Lemée V, Delbos V, etal. HIV rapid screening tests and self-tests: be aware of differences in performance and cautious of vendors. *EBioMedicine* 2018;37:-91. doi: 10.1016/j.ebiom.2018.10.012 pmid: 30509399

22 Wilkinson E. The rise of direct-to-consumer testing: is the NHS paying the price? *BMJ* 2022;379:. doi: 10.1136/bmj.o2518 pmid: 36288807

23 Woloshin S, Dewitt B, Krishnamurti T, Fischhoff B. Assessing how consumers interpret and act on results from at-home covid-19 self-test kits: a randomized clinical trial. *JAMA Intern Med* 2022;182:-41. doi: 10.1001/jamainternmed.2021.8075 pmid: 35099501

24 Taylor-Phillips S, Berhane S, Sitch AJ, etal. Information given by websites selling home self-sampling COVID-19 tests: an analysis of accuracy and completeness. *BMJ Open* 2020;10:e042453. doi: 10.1136/bmjopen-2020-042453 pmid: 33158838

25 Krogsbøll LT, Jørgensen KJ, Gøtzsche PC. General health checks in adults for reducing morbidity and mortality from disease. *Cochrane Database Syst Rev* 2019;1:CD009009. doi: 10.1002/14651858.CD009009.pub3 pmid: 30699470

26 Ministry of Health. Hormone testing – indications and appropriate use. https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/bc-guidelines/special-endocrine-testing

27 Layton JB, Kim Y, Alexander GC, Emery SL. Association between direct-to-consumer advertising and testosterone testing and initiation in the United States, 2009-2013. *JAMA* 2017;317:-66. doi: 10.1001/jama.2016.21041 pmid: 28324090

28 Schwartz LM, Woloshin S. Low "T" as in "template": how to sell disease. *JAMA Intern Med* 2013;173:-2. doi: 10.1001/jamainternmed.2013.7579 pmid: 23939516

29 Dubin JM, Jesse E, Fantus RJ, etal. Guideline-discordant care among direct-to-consumer testosterone therapy platforms. *JAMA Intern Med* 2022;182:-3. doi: 10.1001/jamainternmed.2022.4928 pmid: 36469030

30 Wackerbarth JJ, Fantus RJ, Darves-Bornoz A, etal. Examining online traffic patterns to popular direct-to-consumer websites for evaluation and treatment of erectile dysfunction. *Sex Med* 2021;9:100289. doi: 10.1016/j.esxm.2020.100289 pmid: 33429245

31 Morden NE, Woloshin S, Brooks CG, Schwartz LM. Trends in testosterone prescribing for age-related hypogonadism in men with and without heart disease. *JAMA Intern Med* 2019;179:-8. doi: 10.1001/jamainternmed.2018.6505 pmid: 30592484

32 Rao PK, Boulet SL, Mehta A, etal. Trends in testosterone replacement therapy use from 2003 to 2013 among reproductive-age men in the United States. *J Urol* 2017;197:-6. doi: 10.1016/j.juro.2016.10.063 pmid: 27789218

33 American Urological Association. Testosterone deficiency guideline. 2024. https://www.auanet.org/guidelines-and-quality/guidelines/testosterone-deficiency-guideline

34 US Food and Drug Administration. FDA drug safety communication: FDA cautions about using testosterone products for low testosterone due to aging; requires labeling change to inform of possible increased risk of heart attack and stroke with use. 2019. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-cautions-about-using-testosterone-products-low-testosterone-due

35 Power M, Fell G, Wright M. Principles for high-quality, high-value testing. *Evid Based Med* 2013;18:-10. doi: 10.1136/eb-2012-100645 pmid: 22740357

36 Woloshin S, Kramer B. Overdiagnosis: it's official. *BMJ* 2021;375:. doi: 10.1136/bmj.n2854 pmid: 34799371

37 LeeVan E, Pinsky P. Predictive performance of cell-free nucleic acid-based multi-cancer early detection tests: a systematic review. *Clin Chem* 2024;70:-101. doi: 10.1093/clinchem/hvad134 pmid: 37791504

38 US Preventive Services Task Force. A and B recommendations. 2024. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations

39 Galleri. Blood test for cancer screening. Galleri test. 2021. https://www.galleri.com/

40 Lee L. A moment to celebrate in our potentially revolutionary cancer blood tests trial. NHS England blog, 18 Jul 2022. https://www.england.nhs.uk/blog/a-moment-to-celebrate-in-our-potentially-revolutionary-cancer-blood-tests-trial/

41 Schrag D, Beer TM, McDonnell CH3rd, etal. Blood-based tests for multicancer early detection (PATHFINDER): a prospective cohort study. *Lancet* 2023;402:-60. doi: 10.1016/S0140-6736(23)01700-2 pmid: 37805216

42 Deeks JJ, Ashby D, Takwoingi Y, etal. Lessons to be learned from test evaluations during the COVID-19 pandemic: RSS Working Group's report on diagnostic tests. *J R Stat Soc Ser A Stat Soc* 2024;187:-709. doi: 10.1093/jrsssa/qnae053

43 Ngoc BV, Majam M, Green K, etal. Acceptability, feasibility, and accuracy of blood-based HIV self-testing: a cross-sectional study in Ho Chi Minh City, Vietnam. *PLOS Glob Public Health* 2023;3:e0001438. doi: 10.1371/journal.pgph.0001438 pmid: 36962976

44 Albarqouni L, Arab-Zozani M, Abukmail E, etal. Overdiagnosis and overuse of diagnostic and screening tests in low-income and middle-income countries: a scoping review. *BMJ Glob Health* 2022;7:e008696. doi: 10.1136/bmjgh-2022-008696 pmid: 36316027

45 Fiala C, Taher J, Diamandis EP. P4 medicine or O4 medicine? Hippocrates provides the answer. *J Appl Lab Med* 2019;4:-19. doi: 10.1373/jalm.2018.028613 pmid: 31639713

46 Orth M, Vollebregt E, Trenti T, Shih P, Tollanes M, Sandberg S. Direct-to-consumer laboratory testing (DTCT): challenges and implications for specialists in laboratory medicine. *Clin Chem Lab Med* 2022;61:-702. doi: 10.1515/cclm-2022-1227 pmid: 36565304

47 RCGP. RCGP Position statement on non-symptomatic self-tests. 2024. https://www.rcgp.org.uk/representing-you/policy-areas/non-symptomatic-self-tests

48 Menkes DB, Mintzes B, Lexchin J. Direct-to-consumer advertising: a modifiable driver of overdiagnosis and overtreatment. *BMJ Evid Based Med* 2024:bmjebm-2023-112622. doi: 10.1136/bmjebm-2023-112622. pmid: 38754908

49 Gram EG, Macdonald H, Kramer B, Woloshin SPreventing Overdiagnosis Scientific Committee. Call to improve transparent communication in direct-to-consumer test marketing. *BMJ Evid Based Med* 2024;29:-4. doi: 10.1136/bmjebm-2024-112959 pmid: 38937068

50 Rome BN. Direct-to-consumer drug company pharmacies. *JAMA* 2024;331:-4. doi: 10.1001/jama.2024.2911 pmid: 38412063

51 DeFrank JT, Berkman ND, Kahwati L, Cullen K, Aikin KJ, Sullivan HW. Direct-to-consumer advertising of prescription drugs and the patient-prescriber encounter: a systematic review. *Health Commun* 2020;35:-46. doi: 10.1080/10410236.2019.1584781 pmid: 30973021