THE COMMERCIAL DRIVERS OF CANCER SCREENING

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Summary: In 1968 Wilson and Jungner established a new framework for the evaluation of screening as a public health intervention and enshrined the ideal of screening delivered as an organised programme. There has been a consequent growth in national bodies dedicated to screening governance but efforts to ensure a more evidence-based approach to screening are threatened by the growing power of corporate actors in a new wave of technological innovation in screening.

Keywords: Screening, Early Detection, Cancer, Commercial Drivers, Commercial Determinants

Introduction
Screening a healthy population to detect cancer at an early stage has much appeal to clinicians, the public and policymakers alike. It is assumed that screening is a good thing that can save lives. However, since the publication of seminal work in 1968 by Wilson and Jungner, public health professionals have cautioned against embarking on new screening initiatives (including cancer screening) without rigorous evaluation of the harms and benefits for a population and an adequate evidence-base that demonstrates its efficacy and cost-effectiveness. Following Wilson and Jungner, a growing number of countries now deliver screening as organised programmes, with systems of quality assurance.

Contrary to widely-held beliefs, picking up cancers before they present symptomatically through screening does not necessarily lead to better outcomes at either the individual or population level. In addition, there is now a greater awareness of harms associated with exposing a healthy population to screening, in particular the problems of overdiagnosis and overtreatment. The screening guide published by the World Health Organization in 2020 discusses the difficult trade-offs between benefits and harms as well as the ethical dilemmas faced by policymakers in deciding whether to implement cancer screening programmes in their countries.

Governance of screening is complex and difficult to implement
In 2003, the Council of the European Union (EU) made recommendations on cancer screening, citing evidence that quality-assured, organised screening programmes in high-resource settings can reduce disease-specific mortality and be cost-effective. Based on the evidence at the time, the EU Council recommended screening for cervical, breast and colorectal cancers. Since then, research has continued to assess the benefits and harms of screening for other types of cancer. However, although the evidence base has grown, there is still no clear evidence to support countries embarking on population screening for other...
cancers and the position of WHO and EU Council at the time of writing remained unchanged.

Despite an evidence base that does not support such practices, there is a great deal of opportunistic screening carried out across Europe. Commercial drivers play an important role in promoting screening practices that may do more harm than good.

Although it is recognised that screening is most effective when organised as a programme, much screening across Europe remains opportunistic, with patients being offered screening when they visit the doctor for other purposes. Occasionally, doctors’ belief that screening is a good thing may be in part the result of commercial drivers, such as the influence of firms promoting screening technologies, or sometimes the direct economic benefit they might gain. Furthermore, private sector clinics and laboratories as well as diagnostics’ manufacturers seek to generate a commercial market for screening services and this presents another governance challenge. Even in countries where public health care systems have adopted a programmatic approach to screening with rigorous processes of quality assurance (e.g., in the United Kingdom and the Netherlands), these governance mechanisms may provide limited or no oversight of commercial screening. Such regulatory challenges are heightened by the rapid pace of technological change in cancer screening.

Industry is driving a new wave of screening innovation

The first wave of cancer screening tests was largely developed in the public sector and promoted by charities and professional bodies. There is a new wave of cancer screening innovation and much of it originates in the private sector and is often supported by professionals. Diagnostics firms have become important actors in the promotion of new screening technologies, sometimes acting alone and sometimes in concert with established actors (i.e., charities, professional bodies, key opinion leaders and policymakers). Commercial service providers – private laboratories and clinics – may seek to build a bigger market for screening services by offering new technologies (such as 3D mammography) or expanding into disease areas not covered by national programmes, and this in turn may increase public demand and intensify the political pressure for adoption within public health systems.

In recent years, cancer screening has been the focus of much commercial excitement, with industry analysts predicting the potential for “drug-like blockbuster revenues”.

Firms that are developing new liquid biopsy-based cancer screening technologies have attracted huge billion-dollar sums of private investment. These firms are often investing large amounts on R&D, and as with the pharmaceutical sector, the corporatisation of screening-related research creates two dangers:

- clinical studies that lack the rigour to fully and accurately test the harms and benefits of the technology, and
- the capture of key opinion leaders through research collaboration with industry.

This new wave of molecular diagnostics firms are not only investing in research, they are also spending heavily on the promotion of their products. There is evidence that the new generation of molecular screening tests are marketed using strategies taken directly from the pharmaceutical sector: recruitment of key opinion leaders, direct-to-consumer advertising, physician detailing, and funding of NGOs including patient organisations to provide seemingly independent lobbying for government adoption of new technologies.

There is also evidence of astro-turfing – the creation of fake NGOs solely to promote the manufacturer’s test. This increase in marketing expenditure reflects a broader trend in the health care sector.

As with all health care marketing, there is the danger that the commercial drive to generate revenues will lead to distorted messaging that presents a highly partial view of the evidence, biased towards potential benefits, obscuring potential harms, and resulting in unnecessary public expenditure. Carefully crafted PR strategies can ensure media coverage that reinforces this unbalanced picture; O’Keefe et al. have demonstrated that media coverage of new technologies for early disease detection, such as liquid biopsy molecular tests, 3D mammography and artificial intelligence-based detection, is skewed heavily towards reporting benefits and mostly fails to report conflicts of interest.
The lack of balanced media coverage can impact not only public perceptions but those involved in making decisions about the funding of biomedical research and clinical care, exacerbating cultural capture. Here we refer to the huge enthusiasm for innovation and notably the idea of personalised or precision medicine, rooted in the longstanding belief that genomics will revolutionise the practice of medicine, and now augmented by a faith in the transformative potential of digital technologies, including artificial intelligence. Public policymakers are prone to this form of cultural capture which can have two potential negative impacts on public health, including:

- a willingness to embrace new technologies because they are believed to represent the future of health care, without robust evidence that they improve clinical outcomes, and
- a misallocation of research resources, as funding flows to the discovery and development of new technologies, at the expense of simpler incremental improvements in the delivery of care, such as improving rapid diagnosis for patients presenting with potential cancer symptoms.

Lastly, cultural capture can result in diversion of resources to unevidenced large scale screening programmes and significant opportunity costs. Not only can it be wasteful of resources, but in countries with shortages of skilled technicians in areas such as imagery or endoscopy, it exacerbates these shortages resulting in delays in diagnosis in symptomatic individuals and growing inequality favouring those having access.

The consumerisation of health care further drives screening

The landscape of commercial screening provision is being transformed not only by innovation in diagnostic technologies but by the broader development of the internet as a new mechanism for the consumerisation of health care. Direct-to-consumer testing services sold via the internet have been the target of regulatory action in recent years. An investigation in 2010 by the US Government Accountability Office revealed the profound limitations of polygenic risk scores’ offered by consumer genetics firms, resulting in regulatory action by the United States Food and Drug Administration (FDA), most notably when it shut down the testing service of industry leader 23andme.

More recently, the Silicon Valley firm Theranos was closed down after revelations that its core technology did not work and its clinical laboratory had sent out thousands of incorrect results. Theranos had promised a preventive health care revolution, based on earlier detection of disease through the routinisation of testing for common disease markers. The huge sums invested in the firm demonstrate the continued promise of early detection, and a number of new firms have stepped into the space created by the closure of Theranos. The new European Union In Vitro Diagnostics (EU IVD) regulation will create a stricter regulatory environment for consumer diagnostic devices, but policy responses to the growing consumer market are likely to vary across European countries, given that within the EU regulation of consumer health care remains a Member State competency. Nevertheless, there is scope for coordination across countries, not least in monitoring what is increasingly an international market.

Conclusion

In countries that have adopted a programmatic approach, cancer screening might be considered a paradigm for an evidence-based approach to health care, backed by a systematic approach to quality management. Yet it remains open to commercial pressures. The growth of screening governance mechanisms is a countervailing power to the increasing scale and scope of commercial influence, but policymakers face fresh challenges as ever-greater volumes of private capital are invested in technological change and the push towards consumerisation.

The work on this manuscript has been funded by the European Research Council (ERC) under the European Union’s Horizon 2020 research and innovation programme, under grant agreement No. 716689.

References