Point-of-care diagnostics – health economics is the key

For thirty years I have been reading numerous articles on how point-of care (PoC) diagnostics are going to change the delivery of healthcare and an equal number hypothesising why this has singularly not been the case.

The failure of PoC diagnostics to transform healthcare has been laid at the door of many technical culprits such as the inherent PoC accuracy and precision versus the gold standard, human factors, usability, reliability and connectivity, or otherwise, with clinical information systems. It has also been argued that there are certain performance thresholds that are a necessity for a PoC device to even be considered a potential replacement for an existing test. Perhaps the most cited perpetrator of all has been cost, inarguably this must be the case, but what cost is acceptable and to whom? Undoubtedly, these are all factors that contribute to the clinical adoption. However, a simple view from cost-effectiveness perspective gives clarity when seeking to understand influencing factors and may even suggest that cost is not the biggest single driver and that the threshold of performance may not be as rigid as imagined in certain cases.

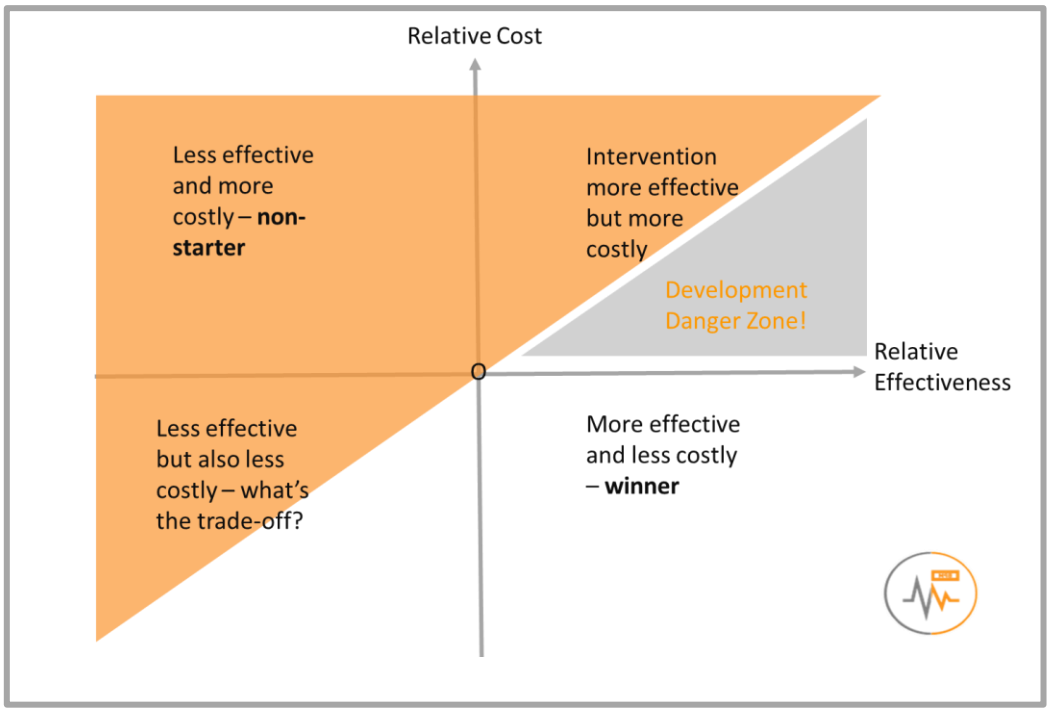
When a new PoC device is brought to market invariably it is replacing an existing solution, in the case of PoC diagnostic this is usually laboratory-based test. Most likely the lab-based test has had years of development, its use inculcated in clinical practice and has the economies of scale to name a few aspects of the inertia that is needed to be overcome. So it is a pretty tough challenge to displace such tests and having clinical and economic data supporting the argument for adoption of the new PoC diagnostic is the only way forward.

Immediately a novel PoC test enters the market a natural comparison with the incumbent solution is made. Very often marketeers will draw all kinds of benefits derived from the new PoC technology such as fast, lightweight, great user interface, it will be possible in the future to connect to laboratory information systems, all of which are superfluous to the core argument.

When comparing existing solutions with new PoC solutions it is useful to forget the features of the product and to consider only the changes in cost and the improvement in outcomes, often called the Incremental Cost- Effectiveness Ratio, or ICER and the related cost-utility. In the case of effectiveness, we can consider the increase in some healthcare outcome such as event

free days or in the case of utility outcomes such as the now ubiquitous Quality Adjusted Life Year (QALY) it is sufficient to consider the QALY an outcome measure that allows comparisons between different disease states and treatments.

If we plot the values relating to the new PoC on a graph with the axes of change in cost and clinical effectiveness where the existing lab-test sits at the origin of the graph "O", it starts to become clear why things may be the way they are. Also we can plot the value that a payer, such as the NHS guided by NICE, might be willing to pay per QALY (*ca.* £30k - the area shaded orange that bisects the graph) it is clearer still. Where a PoC diagnostic sits in this graph will ultimately be a large determinant on its clinical adoption and commercial success.



This simple analysis leads to the conclusion that the bigger barrier to adoption is not cost but effectiveness/utility, or more precisely the relationship between the two. It also highlights the root cause of PoC diagnostics' biggest challenge. Unlike drugs, diagnostics have no direct impact on patients' health they just prompt a clinical intervention perhaps at an earlier point in time leading to improved intervention. Whilst this is undoubtedly important and of clinical benefit it presents an additional barrier to justify expenditure of limited healthcare resource. Consider that if a product cannot improve the outcome or utility, or more importantly, the data do not exist to prove it can then a product can never move to the right on the graph relative to the existing solution. This leaves a diagnostic absent positive outcome data with the only possibility of moving up or down on the y-axis, that is, the only benefit could be that it is cheaper than the incumbent solution.

Obvious exceptions such as a PoC device that gives more frequent, faster feedback facilitating more frequent titration of therapy leading to better control, or that earlier intervention improves outcomes can move to the right - as long as supporting data exist. More frequent, faster or more accurate do not in themselves drive adoption.

As many have observed, very often a new PoC technology is driven by an exciting new technology. This often results in a test that is inherently more expensive, as it hasn't yet

benefitted from years of cost reduction, economies of scale, is possibly less reliable and any associated change to the care pathway has an intrinsic cost of implementation. Consequently, PoC diagnostics frequently start out in the grey shaded area of the graph – the development Danger Zone. In the real world it is the norm that the initial specifications are rarely fully satisfied, product development, like life is a compromise. So the risk of a product in development drifting backwards on the graph as performance specifications are compromised by practical reality or upwards as the Cost of Goods begin to spiral is high. If this happens and a product falls into the orange shaded area then the product will never achieve wide adoption. I would therefore argue this has befallen a litany of PoC diagnostics that have promised much but ultimately failed to deliver commercially.

This throws up the slightly controversial argument evident from the analysis, that a product that has slightly less good performance but improved cost profile could better serve the market – interesting?

Whilst such health economic considerations have traditionally been the preserve of larger companies, until recently companies often started exploring the heath economics of products near the end of the development life cycle immediately before launch, which was invariably too late. At HecoAnalytics we have developed a web-based platform that allows such analyses at the start of a product's development and throughout its lifetime ensuring that health economic validation is built into a product not ignored or rationalised as an afterthought. Everyone would agree to adopt this approach in regard to medical product regulations would be nothing short of madness, what's the difference?

This short layman discussion necessarily contains sweeping generalisations and avoids contemplation of many other health economic considerations such as willingness-to-pay, perspective and the difficulties associated with determining the real costs in many cases. Nonetheless, in summary consideration of a PoC diagnostic's health economics from inception through development and launch will not guarantee success but stack the odds in its favour and can drive drives a product's adoption.

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