Medical devices and health technology per se are often quoted – along with pharmaceuticals – as the key drivers of growing health care budgets. Health technology assessment (HTA) seems a natural tool for harnessing medical technology in this role. The medtech industry, almost by default, accepts its role for keeping rising health care costs at bay by playing along with national and international schemes, projects and institutions, which are promoting the concept of HTA. But does all of this really make sense in pinpointing where money is being spent effectively to treat patients efficiently? Or are there basic flaws in our ability to measure real value?

In reality, once health care is viewed as the broad, complex and adaptive system that it is, a great many reasons can be identified – some completely unrelated to health technology – to explain why health care budgets are rising. So why should industry have to continue accepting its role in the HTA schemes, ultimately playing scapegoat for an ever growing global health expenditure? Surely, it is time to challenge the effectiveness and logic behind the whole HTA concept as it generally operates in countries across Europe, and indeed the world?

A glimpse of history and the questions of purpose
The phenomenon of HTA, in its essential sense of evaluating one intervention against another, can be traced as far back in history as the mid-18th century. Literature dating from that time reported that a James Lind, from an Edinburgh medical school, conducted a controlled trial of six different treatments of scurvy. One example of HTA from the following century comes from Pierre Louis in Paris, who, in 1830, proved that patients suffering from pneumonia received no benefit from phlebotomy.

For a more contemporary view, namely the 1980s and 1990s, the 'call for HTA' can be attributed to the following:
- concerns about the adoption – and sustained use – of unproven technologies;
- rising costs; and
- the rise in consumer expectations.

After a few decades of HTA, there seems but little evidence of the practice helping to stagnate - let alone decrease – overall costs of health care. On the contrary, health care expenditure continues to rise at a pace roughly two percentage points over the respective GDP growth of a country.

So what is going wrong?
Are we using HTA like a panacea, rather than digging deeper into the issue that really needs addressing – namely making health care truly efficient? And why are we failing in this respect? It is because in each and every country, there is a political agenda attached to health care and a fear of making unpopular cuts. So the fundamental question remains: can HTA really bring about what it promises – more effective allocation of money in health care?

To answer this, it is worth broadening the argument to look at health technology in the context of health care interventions overall.

A question of scope
HTA in the general sense of the word covers much more than just technology. When we talk of HTA the first reason for misunderstanding lies in the discrepancy between the term and its scope. Contrary to common practice, to ascertain a real picture of where the most effective or least effective procedures lie, the word ‘intervention’ should be used instead of ‘technology’.

The scope of what is called HTA should include all pharmaceuticals, vaccines, medical devices and diagnostics, medical and surgical procedures, decisions and interventions used to prevent disease and maintain and restore health. If the technology has to prove its case, why not every other intervention?

If we are to consider evidence-based decision making in health care, we should
be looking at evaluating all practices, any intervention, not only those related to technology. More often than not, the term Health ‘Technology’ Assessment implies, that it is health technology in particular that causes health care costs to rise and therefore requires particular attention and evaluation. In other words, is the message being delivered saying that HTA ultimately aims to curb health care costs by putting a finger on the perceived driver of all the financial misery – health technology?

Based on data from the EUCOMED, a body representing 4,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability, the average proportion of health technology over total health care spending in the ‘EU15 + Switzerland’ countries has risen between 2004 and 2008 from 4.98% to 5.84%. That represents a growth of less than one percentage point. At the same time the average per capita health care spending in the same group of countries has risen by 39.25%.

With all respect to market spread and penetration of health technology, it is more than doubtful that health technology does play a significant role in this overall increase in health care spending. So what are the more likely drivers of the high increases in health care costs? Is there possibly a role for health technology to contain costs that may not be seen clearly from the outset? Here are some suggestions.

The first is that there is the ever broadening scope of conditions that are treated or followed-up nowadays. Long ago these conditions had passed the boundaries of actual, perceptible disease and expanded in the realm of abnormality. Let’s not get into a misunderstanding here. There is a natural and commendable tendency to research and to understand the cause of diseases, their natural course and factors leading to them and to adopt a preventative approach. Yet, such an approach leaves scores of people, who appear otherwise healthy, to undergo numerous check-ups, interventions etc, often for the rest of their lives and at times doing more harm than good. Even for certain cancer screening programmes, when looking for hard evidence of outcomes, like reducing mortality rates, they do not hold as much as they promise.

In such cases, the absence of market mechanisms leads to a situation where there is a risk of spending with unproven benefit over a long term. In other words, once a health care facility is “under contract”, that means its services are covered by health insurance or sickness fund schemes and it is rarely seen that such facility is closed down due to low quality or reduced need. Indeed, more services are being opened than closed.

Another approach which carries of risks of ineffective spending is the concept of entitlement to service. The original idea of a universal health insurance system was to secure access to care for all; but more recently, during the 20th century – at least in Europe – the population’s perception has moved to a notion of entitlement to health service – almost like a state pension or other types of benefits. We all perceive we have a right to care and treatment when we want and need it. And to challenge such an attitude in the political arena is not a means for gaining popularity, and therefore given a wide berth.

![Figure 1: Regaining perspective – technology and the other health care expenses, 2008](image-url)
Budgets creating demand, not technology driving budgets?

Another cause of soaring health care costs is the fragmentation of health services, the absence of coordination of care, and the duplication of procedures. In some aspects, waste is also generated when services fail to provide minimum quality requirements. If medical technology plays a role in any of the above factors that push up health care costs, it may do so in the ever increasing spread of supply of diagnostic and therapeutic procedures. However, how much influence the medtech industry and the medical profession (or health care providers in the broader sense) have on inflating the volume of procedures carried out remains largely a chicken-or-egg question.

Is it the industry luring health care professionals into an ever larger supply of procedures, for all of which eventually there will be patients recruited and the costs paid? Or is it the medical profession trying to dig ever deeper into the roots of disease, inventing newer and finer methods that the industry can deliver in a profitable way?

In any case both – industry and medical professionals – are driven by the fundamental incentive of doing business and making acceptable profit from monies that are just sitting there waiting to be spent on health care. But contrary to the widespread belief that health technology is one of the few key drivers of health care expenditure, there are deeper reasons behind soaring health care budgets.

The underlying question of health care financing is not whether this or that technology is marginally/significantly more (cost-) effective. The underlying question is: do we need this much care as provided today?

If we delve further into this question, we would go beyond the scope of this article. But briefly considering this fundamental question, surely, there is no linear correlation between ‘more medicine’ and ‘better outcomes’ – neither from the point of the patient, who is largely kept in ignorance over this, nor from the point of the health care payers – who in contrast to patients are already very vocal.

Medtech wish-list for HTA

The industry wants to avoid being drawn into the HTA game of apologetics, where medtech needs to prove its ‘right for life’ over and over again. However, HTA cannot be stopped and the medtech industry can hardly bypass the hurdles set out in the various forms of HTA. But given the perceived shortfalls in HTA, as established in this article, how would industry propose that HTA policies be modified in order to truly evaluate the comparative costs of health care technology against other health care practices and decisions?

What should be measured?

There are basically two dimensions that should be evaluated: whether “it” works; and how much “it” should cost? Let us stick to efficacy for now. For the individual person, the case seems to be very straightforward in favour of a novel technology. For example, a circular CT is more sensitive and therefore superior in detecting early stage lung cancer than the common chest X-ray. However, opening this argument out to the population can result in a different efficacy ration. For instance, from the point of a population, routinely screening smokers and former smokers with circular CT for early stage lung cancer to prevent death is equivocal. Research suggests that by routinely applying this technique with consequent surgical removal of the tumours, long term survival rates have not improved. One explanation is that there are certain tumours that would not have killed the carriers if left alone, whilst the truly dangerous cancers might still get missed. So the setting – the individual versus the population – can be of decisive difference in respect to the question: does “it” work or not?

The same consideration then flows into the financial aspect. If ‘it’ works, how much does it cost to achieve the effect? Here the industry calls for a level playing field. If an innovative technology is evaluated, so should the long established alternatives. If a technological procedure ‘candidate’ is checked for cost per QALY (quality-adjusted life year) or cost per life saved etc, so should be the other treatment options as well. Many of these are widely accepted, and perhaps were never evaluated in such a manner, having mostly have entered the arena long before health care costs was such a pressing issue.

Once the evaluation is done, what should the outcome be?

There should be clear a consequence of HTA (or to use a better term, HIA) evaluation. A decision: to use or not to use; to fund or not to fund; under what conditions? The last thing the industry is looking for is yet another hurdle in the form of a HTA evaluation without the prospect of obtaining reimbursement for an innovative technology. Better still, HTA should be used to weed out well established procedures of doubtful efficacy and value.

Even though the will for the latter has been expressed in personal communication by stakeholders and academics working on HTA, putting this into reality is still a bit further down the road.

In conclusion, the medtech industry is right to watch the whole notion of HTA with a degree of suspicion. There may be good reasons for industry to fear it is being drawn into the position of the sole (along with pharma) agent responsible for ever rising health care costs. By accepting the HTA game without challenge, the industry – by default – accepts this role and can do nothing but remain apologetic: "yes, we are expensive, but at least we can prove our products work and are worth the money".

Now, however, with all the medical progress that has come with innovative medtech products, the industry can be bolder about the value its products and demand a level playing field with other interventions in health care. It is time for industry to be vocal too.