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Challenges facing medical device companies in Ireland and why operational excellence is not enough.

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Abstract

Ireland has developed a highly successful medical device cluster. The cluster experience accelerated growth during the 1990s when many USA multinationals established manufacturing sites. Manufacturing is the driving force that created the cluster with linkages between, universities, venture capital, entrepreneurs, suppliers, and supporting industry. Using Lean tools and principles the sites have established a reputation for excellence. A generation since the sites have been established changes outside of the cluster are impacting its competitiveness. Lean tools and systems may no longer be enough to sustain the cluster. This paper examines the key changes affecting the cluster and highlights the reasons lean principles may not be enough for the cluster to continue to thrive for another generation. The paper provides valuable insights into a strategy for individual firms, and the medical device cluster in Ireland and has lessons for any other industrial cluster.

Keywords: Cluster, Medical Devices, Ireland, Lean, Operational excellence

1. Introduction

Ireland's Medtech cluster is seen as a significant success triggered initially by foreign direct investment from USA multinationals [1]. The Med Tech sector in Ireland is dominated by several US multinational companies [2]. The manufacturing sites have matured and developed and reputation for operational excellence and execution [3]. The use of lean tools and principles is engrained in the operations of the sites [4]. In the 1990s medical device regulations enabled Irish sites to commercialise new products faster than USA sites [5, 6]. This significantly improved the competitiveness of an industry where time to market is critical [6]. Also, since the 1990sthe Irish government could offer significant tax incentives to companies. Today because of the OECD/G20 inclusive framework on Base Erosion and Profit Shifting (BEPS) large groups must pay a minimum of 15% in every jurisdiction they operate [7].

The selling price for undifferentiated medical devices declines year on year [8]. Lean tools and systems can help the manufacturing site respond but typically this will not be enough by itself [9]. The sites have a risk of having production relocated to lower-cost locations as has happened in the computer and electronic industries in Ireland [10, 11]. The medical device industry has developed a cluster that can provide a difficult-to-copy competitive advantage [12-14]. The clustering effect can improve competitiveness and make the manufacturing site more "sticky" [15]. The site must employ a strategy of product differentiation for long-term success [16]. Just using lean tools to improve efficiency may delay the closure of a highly efficient site but it will not enable the manufacturing site to thrive [17].

The research objectives for this paper are to review the Irish Medtech cluster and how Lean has helped operational excellence in this sector. The study proposes areas where the cluster is weak and why Lean may not be enough if not expanded into the wider cluster network.

2. Research Methodology

A literature review was completed to assess the nature of the global medical device industry. Academic databases, and other relevant sites such as the World Health Organisation, World Trade Organisation, and European Patent Office, MedTech companies in Ireland and regulatory legislation all provided insights into the medical device sector. These sources gave insight into the global scale of the industry, the growth trends, product categories, and key the nations and clusters that dominate the industry. Based on the data the researchers looked at how the global forces affect the competitiveness of Irish medical device cluster. We used recently published literature and global databases for enterprise excellence awards to assess the maturity of continuous improvement within the Irish cluster. The global changes affecting Ireland and the maturity level of the cluster was distilled into a strategic model describing the cluster.

3.0 Review & Results -Medical Device Industry in Ireland

Medical devices are products, services, or solutions that prevent, diagnose, monitor, treat, and care for human beings by physical means [18]. The medical device industry has become an important part of the Irish economy and is recognized as a global MedTech cluster.

Medical Device companies based in Ireland are estimated to have exported €12.2B in 2018 [19]. There are 42,000 people directly employed by the MedTech industry in Ireland, 1.5% of national employment [19, 20]. Ireland has the highest percentage of people employed in MedTech of any European country, (3 times the rate of Germany and 5.5 times the UK rate) [20]. Ireland is the second-largest European exporter of medical devices. Ireland's exports make an impact globally some key exports include [21]:

25% of the world's diabetics are treated with products made in Ireland. 1/3 of global contact lenses are made in Ireland and accounted for exports worth up to $\in 1B$ in 2020. Ireland is the world's largest exporter of cardiology stents, it exported $\in 2B$ worth of product in 2020. Artificial joints accounted for $\in 1.3B$ in 2020, making Ireland the World's fourth-largest exporter of these devices. The country is also the 3rd largest exporter of diagnostic reagents for patient administration. Approximately 50% of ventilators worldwide in acute hospitals are Irish-made.

There are 450 Medical device companies in Ireland [2]. A review of the 450 companies reveals that 90% of medical device employees work in multinational companies that were first established in Ireland before 2000. The 43 largest Medical Technology companies were identified [22]. These 43 companies have 71 sites in Ireland. 75% of these are US-based multinationals, 10% are Irish and 4% are German. The USA is the world's largest producer and market for medical devices [23].

The Irish MedTech cluster is highly dependent on USA multinationals that first invested in Ireland in the 1990s. The data show many of the major global companies have had a presence in Ireland for over 30 years. The sites have matured to become global centres of excellence supporting business units and have developed R&D centres [3].

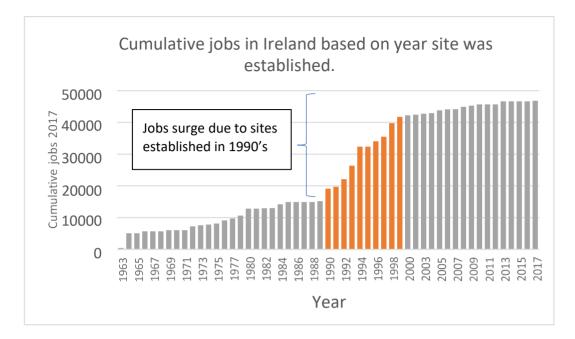


Figure 1 Jobs growth up to 2017 based on the year site was established.

The Irish MedTech cluster is highly dependent on USA-headquartered multinational companies that first invested in Ireland in the 1990s. These data show, many of the major companies have had a presence in Ireland for over 30 years. The sites have matured to become global centres of excellence supporting business units and have developed R&D centres [3].

3.1 Drivers of growth in Medical Devices

Global spending on healthcare has doubled from 2000 to 2020 [24]. An aging population is the most significant factor that causes increased spending on healthcare [25]. There has been a six-fold increase in healthcare spending between those aged over 85 and those aged between 55 and 59 years [26]. Globally, in 2020, there are 728 million people aged 65 or over. This number is projected to double to 1.5 billion in 2050 [27].

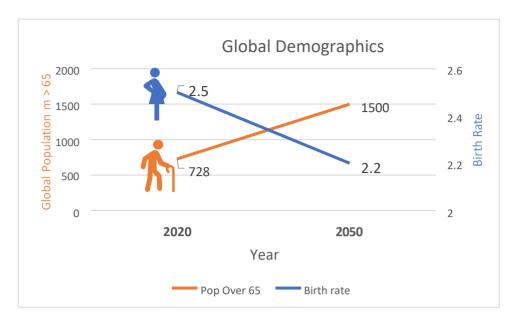


Figure 1 Global population over 65[27] and births per female[28].

Economic development and increasing urbanisation are leading to more sedentary lifestyles and greater consumption of unhealthy foods linked with obesity. This is driving a rise in chronic conditions such as type II diabetes [29]. Early detection and improved treatments mean people are living longer with chronic conditions [29].

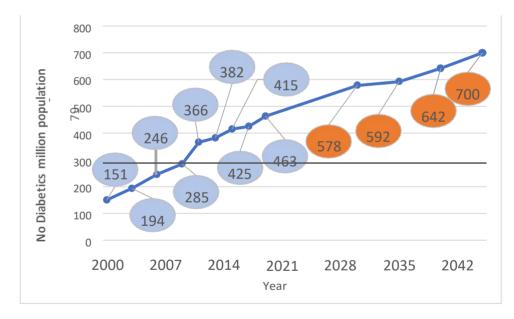


Figure 2 Actual / Prediction of the global number of diabetics (20-79 years of age group)[29]

The availability of novel medical devices to treat unmet clinical needs has created new markets for medical devices. An example of new demand is Endovascular Stroke Therapy (EST). Saber et al showed a continuous increase in EST over the 10-year period from 2006 to 2016. The number of ESTs went from less than 50 in 2006 to 1000 in 2016 [30]. A significant jump in demand occurred when multiple clinical trials confirmed positive outcomes.

There is a growing trend towards minimally invasive interventional surgery. For example, a USA study of Peripheral Arterial Disease showed the use of endovascular interventions grew by a factor of 3 between 1996 and 2006. Simultaneously traditional bypass surgery was reduced by 43%. Overall, the number of procedures completed almost doubled in the decade. Patients benefited as the rate of amputation reduced by 29% [31].

3.2 Impact of regulations

In the 1990s, typically, medical devices could be approved for sale on the European market in 9 months. In January 2022 guidance for approval of medical devices under the Medical Device Regulations (MDR) is a minimum of 18 months with significant uncertainty in the time for approval [5].

The average approval for a medical device in the USA through a 510(k) pathway (2016 to 2020) is 150 days [32]. The regulatory regime for the medical device industry can slow continuous improvement project implementation [33]. The data from the aforementioned studies show that, in the 1990s, medical device companies could get their products to market in Ireland 21 months faster than in the USA. Today Ireland has lost that advantage and it now takes longer to gain approval to sell in the EU. In 2022 most Medical Device manufacturers regard the product registration process under MDR as "cumbersomeand uncertain" [6]. 52% of medical device executives said their company would deprioritise entering the European market as a result of MDR [6].

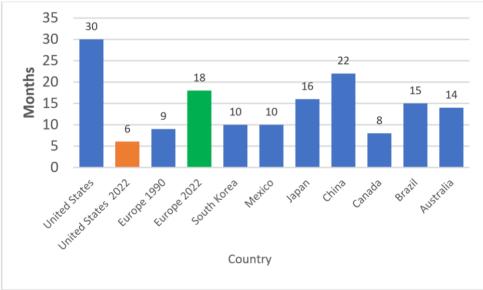


Figure 3 Maximum estimated time to market for high-risk devices. [5]

3.3 Price erosion

The overall medical device market is growing [34]. The price obtained for undifferentiated products is reducing for the following reasons: In the USA, groups of hospitals are pooling their purchasing power to reduce costs. Between 72 and 80 percent of non-labour purchases are completed through a Group Purchasing Organisation (GPOs) or Integrated Delivery Networks (IDNs) [8]. Centralised purchasing results in the standardisation of medical devices and downward price pressure. Increasingly. purchasing decisions and medical device selection are being made by purchasing departments with physicians in an advisory role. Commodity products are particularly affected by downward pricing pressure. For example the Average Selling Price (ASP) for a carotid balloon catheter is expected to drop in value by 26 % from US\$240 to US\$178.90 over the 10 years from 2017 to 2027 [35]. Office-based labs (OBLs) are increasingly used for outpatient procedures. Almost all endovascular procedures are suitable for an

OBL setting. OBL is gaining an increasing share of the USA market. Currently, 25% of peripheral vascular procedures are carried out in OBL settings [35]. OBLs are physician-owned and tend to be more cost-conscious than hospitals. OBLs often receive price discounts of 50 % [35]. OBLs and GPOs are driving down the ASP of medical devices in the USA. China had introduced a centralised public procurement policy for medical devices in 2019. When the coronary stents were put to tender, 20 companies participated, 8 were chosen, and of these, six were Chinese. Only one company, which was Chinese, was given a guaranteed volume based on its price [36]. Reducing selling prices in the Chinese market will make it increasingly difficult for Irish-based MedTech companies to compete in the market.

Table 1 Medical Device price reductions resulting from centralised state procurement in China [36]

| Average price reductions by-product arising from China's Centralised state procurement rounds | | | | |
|---|---------|--|--|--|
| Coronary Stents | 95% | | | |
| Orthopaedics | 55% | | | |
| Intraocular Lens | 41% | | | |
| Pacemakers | 50% | | | |
| Nursing consumables | ~80-90% | | | |

3.4 Response to reducing the sales price

Medical device manufacturers in Ireland attempt to maintain cost-effectiveness through enterprise excellence programs. The use of lean tools in the Irish MedTech cluster is widespread and is used to improve competitiveness [4]. All 19 MedTech companies in the Trubetskaya et al study were actively using lean tools and systems. The widespread use and effectiveness of lean tools can be demonstrated through global recognition of operational excellence. In the years 2011 to 2021 medical device companies in Ireland have won more Shingo Prizes per head of population than any other country in the world [37].

Table 2 Shingo prizes awarded to Medical Device companies per country 2011 - 2021[37].

| | Shingo prizes won (Medical companies) | Population M | Prizes per million population |
|---------------|--|-----------------|-------------------------------------|
| Ireland | 6 | 5 | 1.20 |
| Costa Rica | 3 | 5.094 | 0.59 |
| Lithuania | 1 | 2.79 | 0.36 |
| Denmark | 1 | 5.831 | 0.17 |
| Israel | 1 | 9.2 | 0.11 |
| Mexico | 9 | 128.9 | 0.07 |
| USA | 14 | 329 | 0.04 |
| Canada | 1 | 38 | 0.03 |
| Germany | 1 | 83.24 | 0.01 |

Continuous improvement as part of an enterprise excellence programme can improve profitability, but it is not normally sufficient [9]. Porter gives two reasons for this: 1. the rapid diffusion of best practices and that competitors can quickly copy best practices and 2. competitive convergence -rivals imitate one another's improvements by often using the same suppliers and outsourcing to the same third parties. Medical device multinationals have manufacturing sites globally, with some in low-cost locations. Medtronic, Boston Scientific, Baxter, Abbott and Zimmer all have manufacturing sites in Costa Rica [38]. Ireland's labour costs are average for the euro area but are almost 5 times those of a low-cost location like Bulgaria [39].

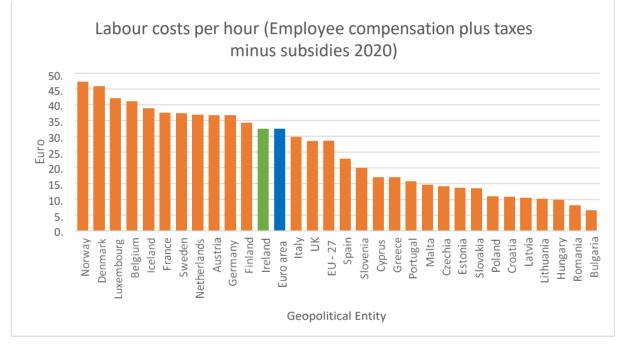


 Table 3 Hourly labour costs (2020 employee compensation plus taxes minus subsidies) [39]

Multinationals can move manufacturing to countries with lower labour costs. Advances in transport and information have reduced the impact of distance. Regions face a more difficult time in anchoring multinational investments [15]. The "stickiness" of a region is its ability to attract and keep industry [15]. Operational excellence can be copied by other regions and so does not, by itself, self-provide a competitive advantage that increases the "Stickiness" of the Irish MedTech sector.

3.5 Strategy to deal with falling prices.

Medical Device manufacturers based in Ireland have a choice of two strategies [16]. The first is a lowcost strategy by focusing on reducing costs or to differentiate their site and product. This strategy requires choices to be made on the manufacturing site. If the site is to gain a competitive advantage through a low-cost strategy, then it is at risk from lower-cost locations within a multinational's list of sites. The cost reduction must stay ahead of price erosion in the product category so as to compete. This necessitates low overheads, careful management of headcount, and minimising spending.

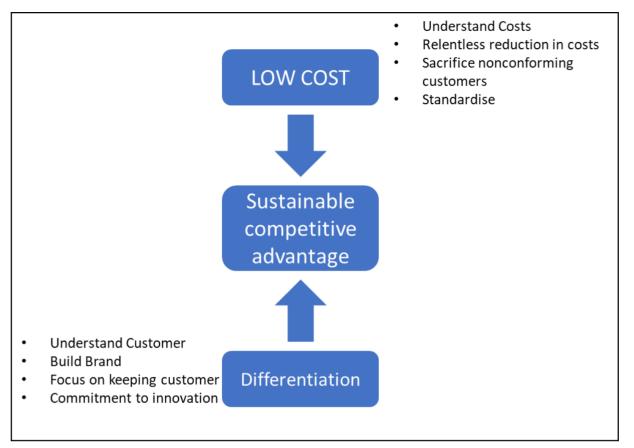


Figure 4 Focus for low-cost v differentiated strategy [16]

A low-cost strategy effectively prevents the site from moving up the value chain and attracting additional responsibilities to the site. To increase the remit of the site and expand its responsibilities it's recommended to "Over hire" and have capacity available [3]. In a low-cost strategy, there will always be a lower-cost region that multinationals can move to. Costa Rica has successfully attracted many of the same multinational companies to their shores [40]. The computer industry is an example of an industry that failed to stick as it largely left Ireland and moved to Asian countries in the 1990s [11], [10].

The second is a differentiated strategy. In a differentiated strategy, the focus is on the site developing new products for unmet clinical needs. Differentiated products enable the creation of new markets with little competition [30, 31]. Multinational companies find it difficult to capitalise on disruptive innovation [41]. In effect, multinationals have outsourced much of their R&D to start-ups [42]. Small and medium firms are twice as likely to launch a disruptive innovation in the market [40]. In effect, multinational sites in Ireland face a dilemma. They must reduce costs to ensure their site remains competitive as the sales price of today's products inevitably reduces. At the same time, the site must introduce new differentiated products that will provide long-term commercial success.

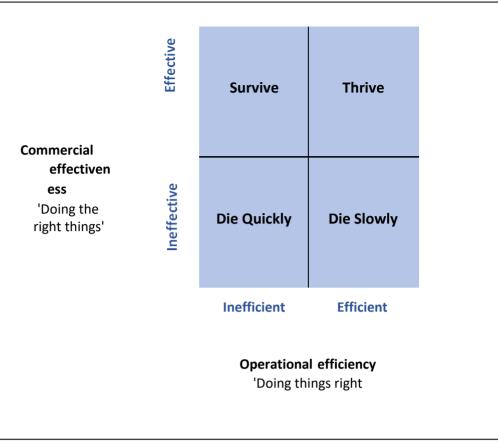


Figure 5 Efficiency / Effectiveness matrix [17]

3.6 Medical Device cluster

"Clusters are geographic concentrations of industries related by knowledge, skills, inputs, demand, and/ or other linkages" [12]. Clusters have a positive impact on regions' industrial performance including job creation [12]. These clusters should be considered a regional ecosystem. The clustering effect matters, as 39% of European jobs and 55% of European wages are located in clusters [43]. According to Porter, clusters are a source of strategic competitive advantage [44]. An example of a medical device cluster is Tuttlingen in Germany. This town has a population of 34,000 people but is recognized as a world leader in surgical instruments. In 1995, 90% of all surgical instruments firms in Germany were based in Tuttlingen [14]. Hill and Brennan states that industrial clusters require driver industries at the centre [45]. Multinational companies are the driver of the medical device cluster in Ireland.

3.6.1 Elements of the medical device cluster

Multinationals, start-ups, support companies and for example companies that will design and manufacture products to meet the start-up's needs are all part of the cluster. Other elements include universities who provide skilled labour, generate ideas and host incubators. Funding is essential for start-ups, particularly innovation driven enterprises (IDEs). Sources of funding start-ups include Enterprise Ireland's high potentials funds, venture capital and angel investors. These elements are interrelated and support each other. For example, it is important that medical practitioners can identify unmet clinical needs and provide knowledge to medical companies on how to improve medical devices. Reducing the effectiveness of this link hasbeen shown to directly reduce innovation in both the volumes of innovations and the inventiveness of them [46].

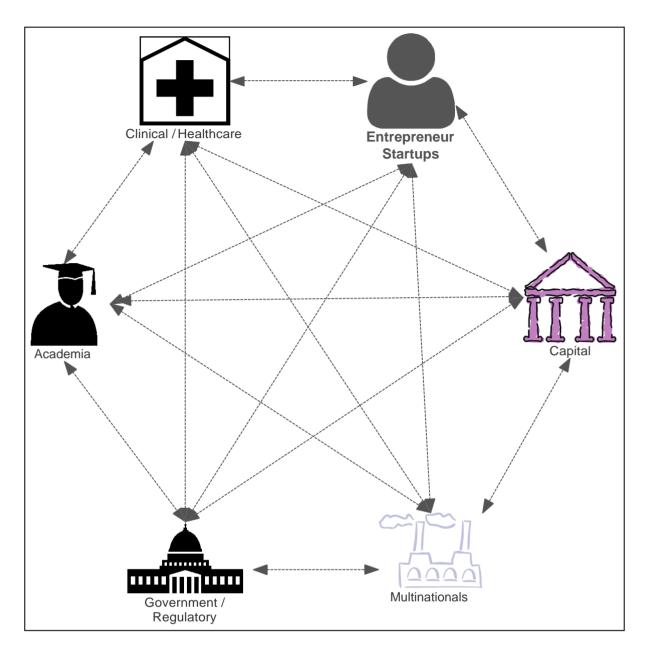


Figure 6 Medical Device cluster Ireland

Start-ups are a key part of the ecosystem. They are well-positioned to develop disruptive technologies that open new opportunities for products and can create completely new markets. For multinationals in Ireland, partnering with start-ups could be a key part of the site strategy. It will help the multinational's site to gain access to disruptive technologies while still having a focus on maintaining costs. It will enable the site to have a differentiated strategy, create newbusiness opportunities and reduce impact of price erosion. To execute a strategy of differentiation that is integrated within this ecosystem, the site needs to ensure it has competencies, for example, in integrating new companies, quickly scaling, and regulatory skills to launch the product in new markets. This is a different focus for the enterprise excellence program that must focus more on growing capabilities than cost savings. A wider focus on the ecosystem is required for long-term success.

4. 0 Discussion & Conclusion

Ireland has developed a highly successful medical device industry that has proven to be resilient. Global spending on healthcare has doubled in the past 20 years. This is largely driven by an increasingly aging

population. New innovations also create completely new market opportunities and benefit society through improved healthcare outcomes. During a rapid expansion of the Irish medical device industry, the time to market for the Irish subsidiary was significantly faster than the USA-based headquarters. This competitive advantage is now lost due to changes in European medical device regulations. The ASP of undifferentiated medical devices is falling year on year. This makes the cluster highly vulnerable to USA multinationals that could move manufacturing to lower-cost locations. Lean tools are widely deployed, with the Irish subsidiaries recognized for their application of operational excellence. However, Lean tools are unlikely to be enough to sustain the cluster. To obtain a long-term competitive advantage the Irish sites must have a strategy of differentiation. The sites must focus not just on internal metrics but on how the individual site integrates with the wider medical device cluster. The site must be prepared to spend money today in order to grow capabilities to innovate and differentiate itself from low-cost locations.

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