Chapter 8
Economic Perspectives: An Overview

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Abstract Economics is the science of describing, explaining, and overcoming scarcity by efficiency. Efficiency compares the outputs and inputs of a system, process, intervention or device, and the knowledge of costs as financial value of the inputs is crucial for avoiding waste of scarce resources. However, calculating the costs is not as simple as it might seem because costs can be tangible and intangible, direct and indirect, core and non-core costs. A thorough analysis of the perspective and the scope of costs is a prerequisite of efficiency and a starting point for the economic evaluation of medical devices.

Introduction

The economic dimension of a medical device plays a major role in its adoption as innovation. *Cum grano salis*, we can state that in particular the costs are the most important single determinant of success and failure of a medical device on the market. If the costs are higher than the revenues, no enterprise will produce or use a medical device, and if the (societal) costs are higher than the benefits of a medical device, the society will not be willing to pay for it. Knowing the costs is crucial for any break-through of medical devices.

8.1 Systems Approach

Figure 8.1 exhibits a simplified business model which is relevant for a wide variety of commodity and service industries, i.e. medical device producers as well as hospitals. Agents of production are transformed into outputs. For instance, a factory uses materials, machines and the expertise of its workers to produce a CT-scanner. This product will be used by the customer (e.g. hospital) to produce a service, i.e. the

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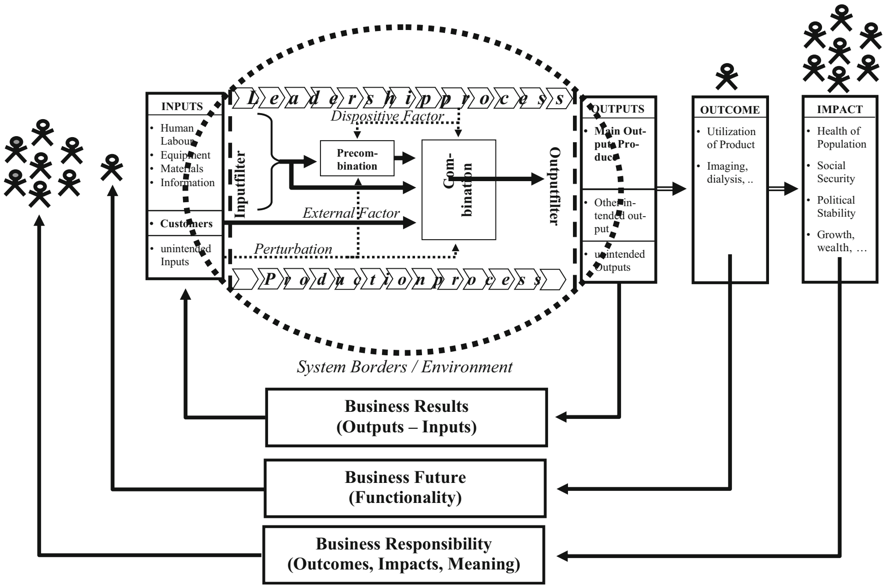

Fig. 8.1 Basic business model, based on [1]

customer experiences an outcome based on the output of the factory. Most likely this imaging will have an impact on the patients and the entire society (health, healing). Consequently, output, outcome, and impact of a product are not identical.

Each business unit has to compare its own output, outcome, and impact with its input of agents of production and its own objectives. The simplest approach is to compare outputs with inputs. The respective quotient is called efficiency, i.e. all business units strive for efficient use of their resources. Efficiency means that a maximum output is generated with a given input or a given output is produced with a minimum of input.

$$\frac{\text{Output}}{\text{Input}} \rightarrow \text{Max!}$$

In addition, any business unit has to compare its outcomes with its inputs and objectives. It is insufficient to produce a commodity or service unless this good has a value for the customer (outcome). The function of any enterprise is to service its customers. Thus, enterprises have to analyse whether the products that they produce fulfill their function. Finally, business units also compare the impact that they have on the wider society with the resources they consume for it. It is their business responsibility to have a positive impact on the society—and the society is only willing to support the business unit with agents of production if it produces worthwhile results.

In this introduction, we will focus on the input-output efficiency. Realistic systems have different inputs (e.g. personnel, materials, equipment) and outputs (e.g. different products); the simple formula must be widened as

$$E = \frac{\text{Outputs}}{\text{Inputs}} = \frac{\sum_{j=1}^{m} w_j * x_j}{\sum_{i=1}^{n} v_i * y_i} \rightarrow \text{Max!}$$

with

x_j	Quantity of output j, $j = 1 \ldots m$
y_i	*Quantity of input i*, $i = 1 \ldots n$
w_j	Weight of output j
v_i	Weight of input i
m	Number of output factors
n	Number of input factors

In principle, any economic evaluation must record all consumption of inputs and all results. Afterwards, inputs and results must be expressed in one dimension so that a performance measurement can be calculated. This fusion of different dimensions to one measurement is very difficult, as hours of labour, kilograms of food, metres of sutures, square metres of space, etc. have to be fused as well as cases, sickness days, death cases, years of life lost, and quality feelings. As most inputs have a market price, the fusion of different resources consumed can be done by using the factor price as input weight. The result is the cost of a service or a programme, i.e.

$$\frac{\sum_{j=1}^{m} p_j * x_j}{\sum_{i=1}^{n} c_i * y_i} \rightarrow \text{Max!}$$

with

x_j	Quantity of result j, $j = 1 \ldots m$
y_i	Quantity of input i, $i = 1 \ldots n$
p_j	Value of one unit of result j
c_i	Costs of one unit of input i [€]
m	Number of result factors
n	Number of input factors

Based on the simple quotient we can ask different guiding questions that allow us to understand the profound business strategies and the role of costs and revenues in making innovative medical devices a success.

- **Inputs**: The analysis has to start with the inputs. Which inputs are used? How can we weigh different inputs in order to bring them in the same dimension (e.g. working hours and kilograms of metal)?

- **Outputs**, **Outcomes**, and **Impact**: Which outputs, outcomes, and impacts are produced? How can we weigh outputs, outcomes, and impacts of medical devices in order to bring them in the same dimension?
- **Quotient**: How do we measure efficiency and performance in different business units? What is the relationship between efficiency, profit, and return on investment (ROI)? Which instruments of economic evaluation are used in business and societal perspectives?
- **Period**: Which period is relevant for the decision-making, i.e. do we analyse the total cost of the entire lift-span of an equipment or only one period (e.g. year of purchase)?

8.2 Costs

The first question is answered by analysing the costs of the production of a commodity or service, i.e. $\sum_{i=1}^{n} c_i * y_i$. *Cost* is a financial expression of the consumption of resources [2, 3]. If a system has a certain level of resources and uses them to produce some services or commodity, the quantity and the value of the resources are reduced. Costs express this reduction of value in currency units, such as US$, €, or Shs (Kenyan currency). If, for instance, a manufacturer uses a piece of steel to produce the CT-scan, the value of this steel is part of his production cost. The consumption of this resource constitutes his cost. In the same way, the use of human labour and the wear and tear of equipment and buildings (depreciation) are costs.

We have to distinguish between payments, expenditure, and cost. A *payment* is the reduction of cash (cash on hand or bank account). However, this does not necessarily mean a loss of value of the enterprise. If we buy steel for the CT-scan production and put it on stock, we do not reduce the value of the enterprise. We pay a certain amount and get steel for exactly the same amount. Therefore, the net value of the enterprise is identical before and after this transaction. If we take the steel out of the stock and use it in the production process, the value of this steel is changed. We do not even know what the value of the CT-scan be. Maybe it cannot be sold and maybe the steel is spoilt during the production process. Therefore, the use of the steel generates cost, not the purchase.

Cost is only the reduction of the net worth of an enterprise if this reduction was necessary for the purpose of the enterprise. If, e.g. a business unit donates to the Red Cross, this reduces its net worth, but it is not necessary for the production process. Therefore, the term *expenditure* covers all reduction of net worth, whereas the term cost means only those expenditures that were necessary for the original purpose of the business unit. However, many authors use these terms interchangeable. More important is the fact that costs do not necessarily have to be connected with payments. For instance, the work of owner of an enterprise does not necessarily lead to a payment as in some forms of legal ownership he does not earn a salary. However, by working for his own enterprise he loses the opportunity to earn a salary

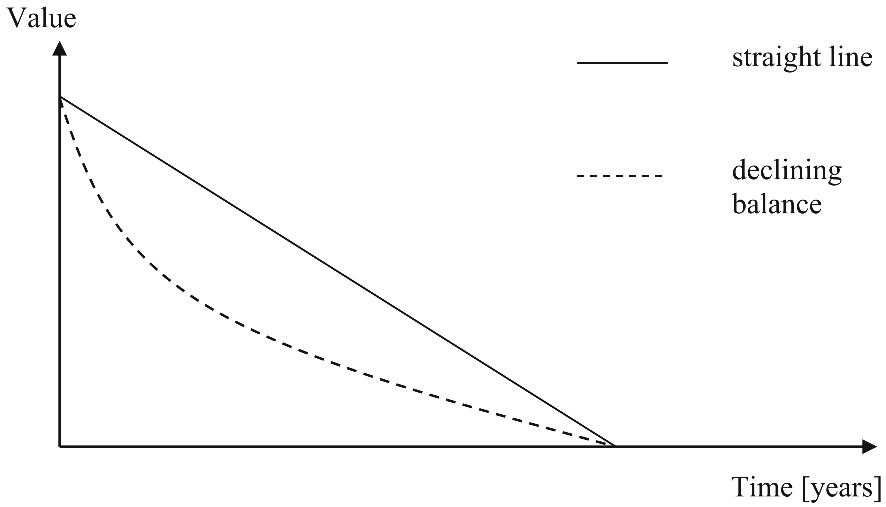

Fig. 8.2 Depreciation

elsewhere. Therefore, the value of a lost opportunity is named *opportunity cost* and has to be included in the total costs, although it is not connected with payments.

The most important resources to produce medical devices are personnel, raw materials, semi-produced goods, equipment, buildings, water, electricity, etc. Therefore, we have personnel costs, materials costs, equipment costs, costs of buildings, water, electricity, etc. We call these costs the *direct provider costs* because they occur directly in the production process. Salaries and wages, bills for materials, for water and electricity are, thus, costs. Buildings and equipment are established in 1 year for many other years to come. It would be completely inappropriate to charge all payments to the year of establishment. They are not consumed in this year, therefore only the wear and tear of the first year should be the cost of this year. Consequently, we only take a certain fraction of the original payment as the annual costs. This share is called *depreciation*.

Buildings and equipment do not lead to periodical payments. However, the wear and tear of these items has to be calculated. There are several possibilities. The easiest approach is to divide the original payment by the number of years that the item will be used. Figure 8.2 shows this as a straight line. It might also be possible to reduce the value of the item by a certain percentage every year, so that the annual depreciation is getting smaller every year (declining balance method). Finally, it is possible to include an interest rate for the investment. However, in most cases it is enough to calculate a linear depreciation.

The analysis has to distinguish *average cost* per service unit (such as cost per delivery) and *marginal cost* (such as additional cost for one additional delivery).

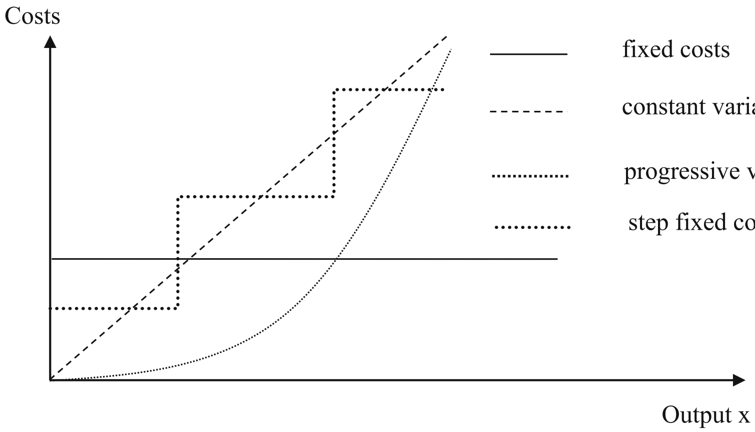

Fig. 8.3 Different cost development pattern

$$\bar{c} = \frac{C(x)}{x}$$
$$c' = \frac{\mathrm{d}C(x)}{\mathrm{d}x}$$

with

$\bar{c}$	unit cost
c'	marginal cost
$C(x)$	total cost
x	number of service units, i.e. bed days, deliveries, consultancies

The average cost is simply the quotient between total cost and the number of service units. For the calculation of the marginal cost, we have to distinguish between fixed and variable cost. *Fixed costs* do not vary with the volume of activity, whereas *variable costs* increase if we produce more goods. Normally, variable costs increase with volume, and the increase can be progressive, linear, or digressive. It has to be analysed, furthermore, whether fixed costs are indeed completely constant irrespective of the amount of services, or whether they are *step fixed*, i.e. they are stable until the activity reaches a certain level and then jump to a higher plateau to remain stable there as well. For instance, the costs for salaries of the sales force could be the same, whether the sales representative visits 10 or 20 clients per month. However, if the workload increases so much that one person cannot do the job alone, a second sales representative has to be hired and the costs jump by 100%. For any analysis, it will be important to know whether additional demand can be covered by the existing buildings, personnel, and equipment (Fig. 8.3).

Assuming a linear cost-function, we receive

$$\overline{c} = \frac{C(x)}{x} = \frac{C_\mathrm{f} + c_\mathrm{v} \cdot x}{x} = \frac{c_\mathrm{f}}{x} + c_\mathrm{v}$$
$$c' = \frac{\mathrm{d}C(x)}{\mathrm{d}x} = \frac{\mathrm{d}\{C_\mathrm{f} + c_\mathrm{v} \cdot x\}}{\mathrm{d}x} = c_\mathrm{v}$$

with

C_f	fixed cost
c'_v	constant variable cost

8.3 Outputs, Outcomes, and Impacts

The second aspect of any efficiency analysis are the outputs of a business unit, i.e. $\sum_{j=1}^{m} p_j * x_j$. If we analyse only the manufacturer of medical devices, the analysis of outputs is rather simple. He just has to add the sales in his different product lines to receive the turnover as total of outputs. However, in the long run this is insufficient. Medical devices make only sense if they have an impact on the health of the population by allowing better diagnostics or therapies. Thus, morbidity, mortality, days of sickness, reduced costs, increased productivity and in particular quality of life (QoL) are highly relevant for the analysis of outputs, i.e. manufacturers must also take a societal perspective to assess their outputs.

In order to understand this perspective, it is worthwhile to realize that diseases do not only have costs of diagnostics and therapy, but also much wider costs. As Fig. 8.4 indicates, the core provider costs are only one of many aspects of costs usually described as “Cost-of-Illness” (CoI) [5–18]. Households have direct and indirect costs. *Direct household costs* imply payments for transport to and from the health services, accommodation for the accompanying relatives, special building facilities for disabled patients (e.g. adapted bathroom), costs for diet and the re-education for both patients and relatives, for instance new training after a paralysis. Private households also have to bear direct payments for user fees and drugs that are an income of the providers.

Indirect household costs summarize all lost opportunities. During the time of illness, a patient and a relative taking care cannot work. Therefore, wage earners lose salaries as well as the economy production force. Sick parents do not have time to take care of their children so that their education will suffer either. Therefore, morbidity leads to indirect costs. The term “socio-economic costs” is used for the total of direct and indirect costs as both have to be shouldered by the society.

Direct and indirect household costs are so-called *tangible costs* because a monetary value can be attached to them. Pain, psychological pressure, reduced joy of life, and social prestige are reductions of the quality of life that do not have a natural monetary value. These *intangible costs* are sometimes evaluated as well and a monetary value is attached to them [19, 20].

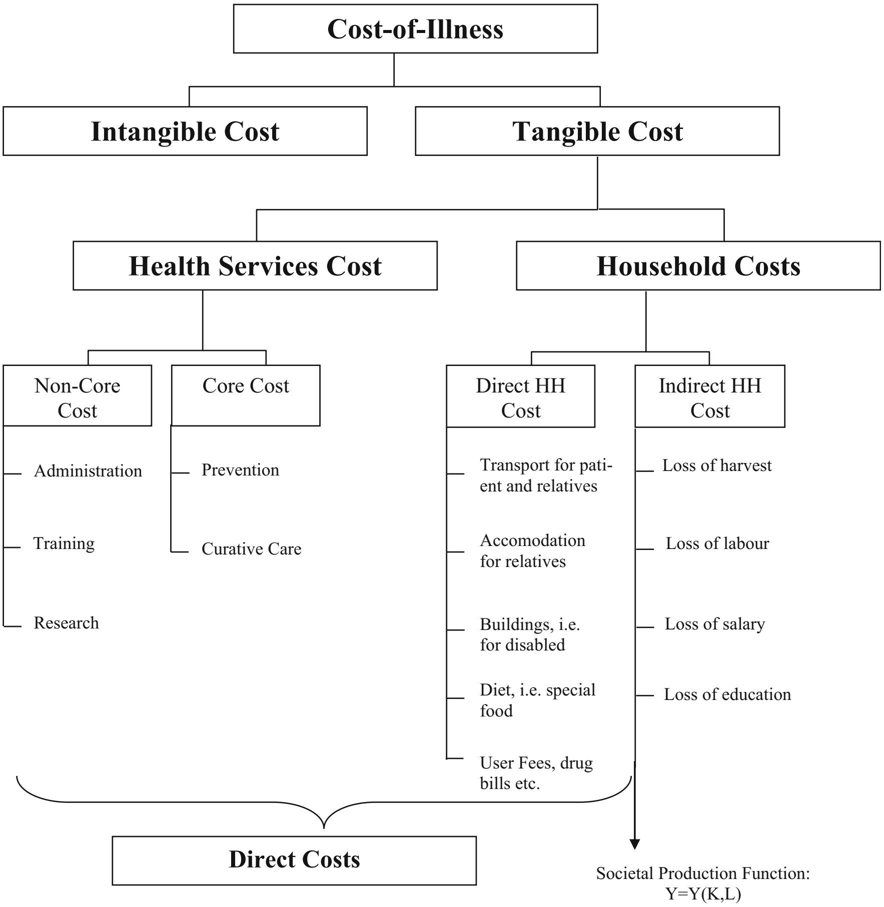

Fig. 8.4 Concept of cost-of-illness, based on ([4], #5563)

Consequently, outputs, outcomes, and impacts can be measured as a reduction of cost-of-illness. Only if an innovative medical device reduces the societal cost-of-illness the society will be willing to finance them. A narrow focus on the outputs of the manufacturer is often too narrow.

8.4 Performance

As stated above, we measure efficiency with the quotient

$$\frac{\sum_{j=1}^{m} p_j * x_j}{\sum_{i=1}^{n} c_i * y_i}$$

Measuring the costs (denominator) is rather simple, but finding a monetary expression for the numerator can be difficult. Some evaluation techniques try to do this. Others restrict the result to one dimension (e.g. life years gained); others artificially combine different results to one statistic according to certain rules. Thus, the degree of fusion differs from one economic evaluation technique to the other. The most important are:

- *Cost minimization*: The methodology [21, 22] assumes that the result of a health system or intervention is constant so that merely the costs have to be analysed. If we compare alternative services or interventions and if the result is equal to each other, the one with the lowest cost is the efficient service or intervention, the others are inefficient, i.e.

$$Z = \frac{\sum_{j=1}^{m} p_j * x_j}{\sum_{i=1}^{n} c_i * y_i} \rightarrow \text{Max!} \Leftrightarrow Z' = \sum_{i=1}^{n} c_i * y_i \rightarrow \text{Min!}$$

  Frequently the mentality of cost minimization has led administrators into the temptation to focus on costs only and to disregard the result of the healthcare activity, e.g. of an innovative technology. Consequently, future chances are neglected even if they were highly efficient because they would have required more resource input.
- *Result maximization*: Taken a given budget for a certain intervention, the efficient alternative is making the best out of these resources, i.e.

$$Z = \frac{\sum_{j=1}^{m} p_j * x_j}{\sum_{i=1}^{n} c_i * y_i} \rightarrow \text{Max!} \Leftrightarrow Z' = \sum_{j=1}^{m} p_j * x_j \rightarrow \text{Max!}$$

  This methodology [21] can be applied if the budget is without competition to other allocations of funds. In reality, healthcare or a particular programme or service is always only one possible allocation of funds, i.e. the amount earmarked for this purpose will vary so that this methodology is restricted to few applications within very limited fields.
- *Cost-benefit analysis*: A cost-benefit analysis [22] expresses inputs and results in monetary terms, i.e. not only the costs, but also the incidence, prevalence, life years, death cases, and quality of life are expressed in currency units, i.e.

$$Z = \frac{\sum_{j=1}^{m} p_j * x_j}{\sum_{i=1}^{n} c_i * y_i} \rightarrow \text{Max!} \Leftrightarrow \Pi = \sum_{j=1}^{m} p_j * x_j - \sum_{i=1}^{n} c_i * y_i \rightarrow \text{Max!}$$

  The disadvantages of a cost-benefit analysis are obvious: It is very difficult to express human life in monetary terms, and all constructions to do so will bear ethical problems. However, the cost-benefit analysis has strong advantages if we want to compare alternative allocations of funds beyond sector borders. For

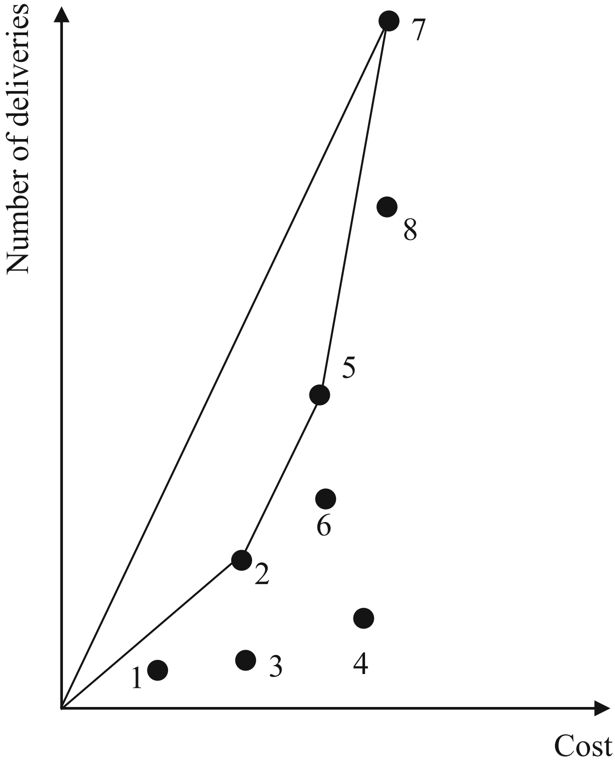

Fig. 8.5 Cost-effectiveness analysis, based on [1]

instance, an investment into education and into healthcare can only be compared if we find a common dimension of results.

Money is a weak common dimension, but maybe the only possible one.

- *Utility analysis*: The utility analysis treats inputs and results as one dimension and expresses all quantities in a single utility score [23, 24]. Therefore, costs for resources are not expressed in financial terms but in an ordinal scale (highest, high, lower ...). Seeing the high importance of costs and budgets in the healthcare sector, this approach is not satisfactory.
- *Cost-effectiveness analysis*: The cost-benefit analysis fuses input and result into one statistic (e.g. surplus). The cost-effectiveness analysis [25, 26] expresses the inputs in monetary terms, but the results are measured in physical units, e.g. number of children immunized. Input and result represent two dimensions, so that this analysis frequently does not produce a single alternative, but a set of alternatives forming an efficiency frontier. Figure 8.5 demonstrates an example of eight health centres in a district offering delivery services. The total costs of this service per health centre are compared with the number of deliveries. It is obvious that health centre seven has the lowest cost per delivery: it is efficient. However, if

we assume economies of scale, it might be useful to include also unit 2 and 5 as efficient, so that units 2, 5, and 7 form the efficiency frontier.

The units on the frontier are efficient and form the set of benchmarks for the other units, i.e. unit 3 should concentrate on the performance of unit 2. If we assume constant elasticity of scale, only unit 7 is efficient, but for the small unit 3 it is not helpful to attempt at learning from this big health centre.

- *Cost-utility analysis*: This analysis allows that the result is not a single physical unit but an indicator that combines several statistics. For instance, quality of life and life years are combined in the Disability Adjusted Life Year (DALY). The combination will always be artificial and subject to discussion.

Most manufacturers of medical devices and a major share of healthcare facilities are for-profit enterprises that can derive their goal function directly from the original efficiency quotient, i.e.

$$Z = \frac{\sum_{j=1}^{m} p_j * x_j}{\sum_{i=1}^{n} c_i * y_i} \rightarrow \text{Max!} \Leftrightarrow \Pi = \sum_{j=1}^{m} p_j * x_j - \sum_{i=1}^{n} c_i * y_i \rightarrow \text{Max!}$$

The term $\prod$ is the profit calculated as the difference of total revenue and total cost. In other words, any for-profit enterprise that maximizes its profit will also maximize its efficiency. Profit is a signal of efficiency. These enterprises will adopt a new medical device as innovation if it allows them to increase their profit—and this is consistent and ethically sound because it will allow them to use the resources most efficiently.

However, profit is usually insufficient to assess the advantage of an investment, project, or enterprise. One million € of profit is very high for a private practitioner, but it is very little for an international company. Thus, we have to relate the profit to the capital invested. The respective quotient is called “return on investment” (ROI). The following formula defines ROI demonstrating its components of profit (numerator) and capital with its component’s equity (capital from owners of the enterprise) and liability (loans from non-owners). Consequently, an investment (such as the development of a new medical device) is seen as profitable if the ROI is greater than the market interest rate, i.e. the rate which is received if the funds are not invested in the development of the medical device but invested in the capital market.

$$\text{ROI} = \frac{\Pi}{K} = \frac{\sum_{j=1}^{m} p_j * x_j - \sum_{i=1}^{n} c_i * y_i}{E + L} \rightarrow \text{Max!}$$

Consequently, we can state that the costs of healthcare services, projects, and medical devices are highly relevant for any type of economic analysis. Costs are always the starting point and knowing the costs is the prerequisite for any other assessment.

8.5 Period

Usually, a major share of the resources is consumed before any sales are made. Cost for development and marketing of a new medical device can be as high as the production costs during the next years. Consequently, the profitability of a product has to take several periods into consideration. During the first periods, costs will be higher than revenues, later on this will most likely change. If no interest is accounted for, we can just add all costs and revenues and compare them. If interest has to be paid for capital, all costs and revenues have to be discounted so that they can be compared. This is usually done with the formula

$$PV = \sum_{t=1}^{l} (R_t - C_t)(1 + r/_{100})^{-t}$$

with

CV	Present value
R_t	Revenues of period t
C_t	Cost of period t
r	Rate of interest
l	Lengths of life of investment

It is necessary to assess all costs and revenues through the lengths of life of an investment. In the case of a medical equipment producer, this covers developments costs, marketing costs, production costs, disposal costs, etc. For the user of a medical equipment it covers the total cost of acquisition and operation, costs related to replacement or upgrades at the end of the life cycle as well as indirect costs such as training with the new equipment. The wider concept with a life-long perspective is called “total cost of ownership” (TCO).

Conclusion

Inventing, developing, producing, and marketing of medical devices is not different from any other commodity. Even if producers are completely convinced of the superiority of their product, they must also convince customers to buy these products and pay a sufficiently high price for it. According to experience, entrepreneurs and co-workers of medical device factories are quite committed to their products and they see a chance to contribute to the well-being of the human population with them. However, business does not work by good intentions or beliefs, but by sales. All thinking must start with the needs of people. At the end, the sick will decide whether they want this product or not—and whether they are willing to pay for it.

In the reality of modern societies with Health Insurances and Government subsidy, the reality is more complex as many Government bodies (e.g. National Institute for Health and Care Excellence, NICE, UK; Gemeinsamer Bundesausschuss, GBA, FRG) and insurances decide on the portfolio of diagnostic and therapeutic devices. At the same time, medical practitioners have a double role as provider of healthcare services and consultant to the patient indicating what service he requires. Thus, healthcare markets are more complex than traditional commodity markets. However, at the end it is the patient who will be operated on, is x-rayed or receives an implant. And eventually it is the tax payer who decides whether the product is worthwhile its costs on the individual and in particular on the societal level.

Consequently, a thorough analysis of costs and benefits for all stakeholders as well as throughout the entire process states is a crucial prerequisite of successful medical device production. Even the very best product idea without proper management and without precise costing will never benefit anybody.

Take Home Message

- The production and utilization of medical devices induce costs.
- Costs have to be recovered by revenues to be sustainable.
- Customers are only willing to pay sufficiently for a product if it satisfies their needs, i.e. the output, outcome, and impact must be worthwhile.
- Knowing or predicting costs and revenues is essential for the success of medical device production and utilization.
- Medical devices produce outcomes and impacts which are highly relevant for the individual and the society. Proper management and cost control are needed in order to ensure their benefits.

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