

Health as an investment and the ATMP

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1. Health as an investment

COVID-19 has highlighted that **healthcare is a fundamental investment** and determines countries economic and social sustainability

Key point: an increasing significant share **of health expenditure** has clear **investment characteristics** (multi-year benefits)

Expenditure on ATMPs can be largely assimilated to **gross fixed capital formation**

‘Acquisitions of movable property, machinery and equipment’, or production subsidies, intangibles, human capital, R&D, etc.



2. current and capital expenditures

Distinction between **current and capital expenditure** is not an **easy task**... economists have been debating this issue since decades...

Distinction is controversial: essentially, it is based on the **different duration of the effects** produced by good and services, provided with various public expenditures

Current if *'the economic utility of goods and services ends within the same annual budget process (year)'*

Capital when *'the economic effect lasts more than one year'* (multiannual)

Current if it is related to the purchase of goods and services whose 'economic usefulness is exhausted in the accounting year in which the expenditure took place'; capital account when it 'exceeds the year and affects several years'



2. current and capital expenditures

Definition in the **Italian public accounting rules** (RGS-MEF, 2019)

Investment expenditures identify 'all expenditures that **directly or indirectly affect the formation of national, physical and human capital**'

Public investment is represented by the "*volume of expenditure that the State, Regions, and other public Administrations bear with the aim of increasing the stock of physical and technological capital available to the country*".



3. Revisions of national accounts: recent experiences

In the **1993 SNA**, the **scope of investment** was expanded to include **software, mining exploration, artistic originals, and valuables expenses**

In the **SNA 2008**, the scope of investment was further expanded to include **R&D and defense spending**, since it produces "**value in terms of future economic benefits**" (SEC 2010, p. 216).

The **2010 ESA** expressly acknowledges that "research and development expenditure" and "military expenditure" are *"investment in nature, so they are recorded as gross fixed capital formation and no longer as current expenditure"*. (bullet, hand-grenade,)

In the Italian context, **Manual on Public Deficit and Debt** (for R&D and defence sector)



4. The ATMPs

Considerable increase of number of ATMPs: **by 2030, up to 60 new genetic and cells therapies** and **350.000 patients potentially eligible**

Huge cost is a key challenge for national public budgets and health care systems

But in some years it will emerge a considerable demand for these therapies

Sensitive **issue for hard choice and rationing**: who (and how) will define patients' access? who is going to be treated? implications and effect on health systems



5. The value of ATMPs

ATMPs are potentially "**curative**" (many drugs slow the course of a disease, but do not cure it)

They concern '**limited**' populations and are generally considered to be **orphan drugs**

In many cases there are **no comparators** to set up non-inferiority studies or to test superiority

Require a **single administration**, while clinical and economic benefits spread over time

However, there is a potential for '**uncertainty**' about how long the effects and outcomes will persist



6. The main characteristics of ATMPs

- a. They are **one-shot, patient-specific**; there is only a single treatment
- b. They show high **investment costs** but also many **benefits in clinical terms for patients**
- c. Provide patients with a perspective of a **long-lasting recovery**
- d. ATMPs do not mitigate symptoms, but act directly of the **cause of illness**
- e. Have a **high timing asymmetry** between the **emergence of costs** – which are almost all **upfront** – and that of **benefits**
- f. **Produce direct and indirect benefits over time:** (health care savings, expenditure reduction, the increase in life expectancy, increased productivity, higher tax revenues....)



7. The key points on the sustainability of ATMPs



Are ATMPs challenging healthcare system's sustainability?



A **new value framework** is needed to properly assess ATMPs?



If yes, why a **new model** is needed and how it should look like?



How to finance ATMPs?



8. New evaluation framework for the ATMPs

The decision on **which therapy is worthy of funding** should be based on an **estimate of the overall economic effects on the health system** and the health of citizens

Not only by considering the **frontal and immediate costs**, but also the **long-term value to society**

Costs are concentrated in the **single initial year**, when the financial requirement arises; **benefits** are instead **multi-annual**

The usual economic valuation, based on the estimation of the cost of traditional therapies (drugs) and on the **accrual basis of public budget** (financial statements), is **not very suitable for advanced therapies** and their particular technological and industrial characteristics.

A **new budget economic approach** is required



9. ATMPs as investments

Sars-CoV-2 pandemic 'comes to our aid': the **health of EU citizens** is crucial for **economic, social and financial sustainability**

Trade-off between health and economy, in reality this is not the case at all: without good health conditions, economies will not recover again

After Sars-CoV-2, the **value** of human life and **good health** for **growth potential is evident**: vaccines solve, more or less permanently, epidemic; in the same way, ATMP permanently treats different pathologies

Flow of (direct and indirect) **benefits** for many years and **cost savings** (lower consumption of drugs and facilities, lower costs for family, etc.)

Can we deny the **enrichment of the physical, human and technological** capital stock of a nation that derives from ATMPs?

NO, **but then how can they be economically accounted for?**



10. Why is important to acknowledge the investment dimension of ATMP?

Current budgetary procedures are based on the principle of **economic accrual (expenditure commitments**, not cash budget)

The **budgetary rules** provide that the total cost of a medicine (therapy) is **fully accounted in the budget of the first year**, based on defined expenditure commitments

This expenditure can also be settled and paid in subsequent years, but its total amount must be charged in the year in which the accounting obligation arises. **This is an important barrier** for the application of any **annuity payment models**, that would allow the national health system **to spread the cost of the advanced therapies overtime**, along with the **benefits (outcome based)** (hence, to pay for value)

Need to build a **budget accountancy scheme** compatible with **annuity payment models**, able to align ATMP payments to the benefits of the therapy



11. ATMPs require a revision of public accounting criteria

The decision of which therapy is worthy of funding must be based **not only on frontal and immediate costs**, but also on the **long-term value to** society, with an estimate of the overall economic effects on the health system and citizens' health

A **broad revision of the public accounting criteria** is probably needed, to be used in the appraisal procedure of public expenditure

Some **skepticism** by the Eu Commission to **partially allow investments** within the framework of national public budget

Not easy to estimate and some risks of forms of *creative accounting*

New accounting approach in the Eu public finances is needed



12. The revision of accounting criteria and the concept of 'capital'

Technological development have made clear that a **rethinking of the concept of capital** is needed (statistical and national accounting)

Traditional approach: the **notion of capital** is only referred to the **economic** (physical) **dimension**

Innovative approach: **capital is a broader concept, we need also to include human, social and natural capital** (environment, health conditions, etc.)

The **chance of NEGU** is therefore critical to rebuild an **adequate stock of net capital**, especially in the domain of health, environment and social sustainability



13. The road ahead to qualify ATMPs as investment expenditure

The time has come to **review and update the current accounting conventions** in a serious way, considering that some of the current expenditure is necessary to **increase a nation's capital stock and economic assets**

The **accounting criteria** are the result of a **compromise and are an accounting convention**

It can and must **be updated** when technological conditions evolve, the degree of social development changes and the **common feeling of Nations and Peoples of the Community**

