

Distribution and utilization of Radiotherapy Units in Greece

By A. Dermitzakis¹, S. Domete², N. Pallikarakis¹

¹Institute of Biomedical Technology, Greece

²Regional Office for Europe, World Health Organisation

ABSTRACT

Biomedical engineering is playing a leading role in the development of medical technology which is one of the pillars of modern medicine, or as differently expressed at the European Economic and Social Committee (EESC) opinion paper: "Biomedical Engineering is not simply a subset of modern medicine. Modern medicine predominantly secures important advances through the use of the products of biomedical engineering."¹ Health technology, according to the World Health Organization (WHO), refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life. Therefore, medical devices (MDs) belong to health technologies, and radiotherapy (RT) is an important subgroup.

RT refers to high-tech MDs that are of high capital value both in terms of initial investment and operation, requiring specially trained personnel for its use and needs regular quality control, preventive maintenance and management procedures, to function properly and safely. Clinical engineering plays a major role in facing of the aforementioned challenges.

The present paper provides an overview of the results of an assessment report under the WHO action on Strengthening Capacity for Universal Coverage Greece/Phase 2 (SCUC2)² aiming to:

- Assess the sufficiency and equity in the distribution of RT and its use in Greece
- Identify eventual inequalities in terms of geographical coverage, specific needs and lack of RT
- Assess the current status of staffing in RT units
- Estimate the costs for the use of high-value capital medical equipment (HVCME)

Since a country-wide medical equipment inventory for Greece does not exist, various sources were used to obtain a clear picture of the installed units in public Greek hospitals, and private clinics.

As a result, it came out that, in terms of the number of units per million population the number of RT units rose by 23% from 4.3 in 2009 to 5.3 in 2017. In terms of the number of acts, a general increasing trend is noticed, resulting in a total cost increase of 25% from 2013 to 2016.

The analysis revealed that in Greece, there are quite pronounced inequalities in terms of availability of RT technologies in different regions. Long term strategic planning is needed based on evidence, such as updated inventory of MDs, acts performed, associated costs etc., which are unfortunately lacking in Greece. Additionally, the role of clinical engineers in effective management and safe use of this technology should be widely recognized and regulated.

Keywords – Radiotherapy Units, Inventory, Clinical Engineering, Distribution, Greece.

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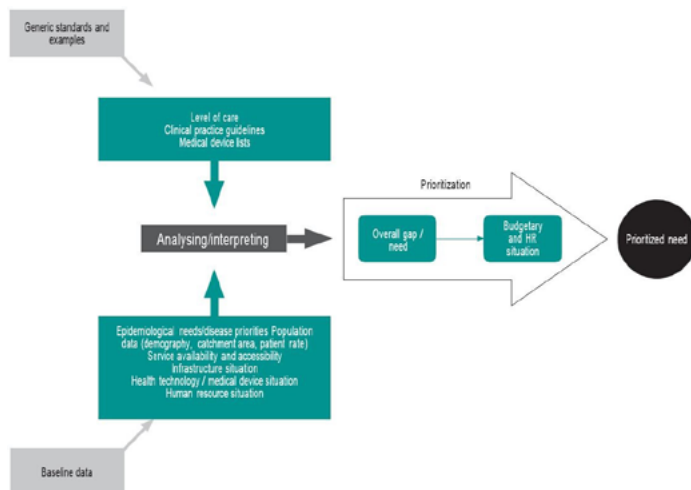
INTRODUCTION

Advances in biomedical research are leading to a storm of innovation and the development of new diagnostic and therapeutic devices has led to a radical change in current healthcare delivery. Modern medicine is strongly dependent on technology.

WHO has published a general approach for performing a needs assessment based on existing and available equipment in a region or country, comparing it with what should be available, considering particular demands and needs, and taking account of epidemiological data, recognized standards, and Clinical Practice Guidelines. By considering this alongside with possible financial restrictions and the human resources available, the actual technological gap can be identified.

The whole approach is depicted in the general needs assessment diagram shown in Figure 1.

FIGURE 1. WHO needs assessment diagram.



Source: WHO, 2011

It is important to note that reliable baseline data on the existing situation and evidence-based assessment of needs are prerequisites for effective use of such a model. In addition to the international scientific and technical literature, the standards and best practices in use and the current trends on these technologies, the general information sources for this report are data available from international organizations such as WHO; Organisation for Economic Co-operation and Development (OECD),

European Union (EU), National Institute for Health and Care Excellence (NICE), ECRI Institute (ECRI), and other reliable web sources.

In Greece, there is no centralized national inventory for installed HVCME, so the relevant information and data collected and used in this report are based on cross-referenced sources which creates several problems associated with data integrity, reliability, and (in some cases) compatibility.

There are also no available data related to the actual use of these technologies, except for indirect information on those procedures that are reimbursed by the National Organization for Healthcare Provision (EOPYY). However, these data do not present the whole picture of actual use and the associated expenditures since the numbers of diagnostic or treatment procedures not reimbursed by EOPYY are not known. Furthermore, the rebate and claw-back procedures applied in Greece due to the economic crisis, are resulting to partial cost estimation.

Finally, several interviews/discussions with medical specialists in the fields of radiology, RT and nuclear medicine; medical physicists; biomedical engineers; technologists and other specialists provided valuable input.

Radiotherapy planning and acts, require the collaboration of mainly medical doctors and medical physicists, which both have a recognized, distinguished, and established role in the field. Although RT unit's state and quality of maintenance, play a crucial rule for the overall effectiveness, safety and quality of the provided health service, the intervention of clinical engineers which is of utmost importance to achieve these goals, is not yet regulated.

The present assessment report aims to assess the sufficiency and equity in the distribution of RT and its use in Greece, to identify eventual inequalities in terms of geographical coverage, specific needs and lack of RT, estimate the associated costs of use and assess the current status of staffing in RT units.

MATERIALS AND METHOD

In the present assessment report, due to the lack of a concrete set of reliable data, a great number of different sources had to be used. Since there is no centralized national inventory for installed HVCME in Greece, the relevant

information and data collected and used in this report are based on cross-referenced sources from the Greek Atomic Energy Commission (EEAE), National Evaluation Center of Quality and Technology in Health (EKAPTY), Hellenic Association of Medical Physicists (HAMP), Federation of Technologists Radiologists of Greece (OTAE) and the inventory for medical devices (MDs) performed in 2015 by the Biomedical Technology Unit of the University of Patras under an ESPA [in english NSRF (National Strategic Reference Framework)] project. This creates some problems associated with data integrity, reliability, and (in some cases) compatibility.

The data available from international organizations (e.g., OECD, WHO) rely also on sources providing the information (e.g., EKAPTY, EEAE, professional societies) and therefore also present discrepancies in the numbers of equipment installed in Greece. These various sources were not set up to provide a continuously updated and reliable MDs inventory, but for other more specific reasons. For instance, the EEAE database (considered as the most reliable) focuses on licensing and radiation safety issues and does not gather information on the year of manufacture or of entry into service. As a result, the database does not reflect the actual situation of the installed base (i.e., number of units actually in use) of these technologies at any moment.

Additionally, there are no available data related to the actual use of these technologies except for indirect information on those procedures that are reimbursed by EOPYY. However, these data do not provide the whole picture of actual use and the associated expenditures since the numbers of diagnostic or treatment procedures not reimbursed by EOPYY are not known. Furthermore, the rebate and claw-back procedures applied mean that EOPYY's data are also partial.

Taking into account the various sources of information, this analysis focuses on the existing RT installed technology as of November 2017. Existing online information available at the EEAE website was cross-checked against that obtained from the other sources mentioned previously, duplicate entries were deleted and any new data identified were added.

Data are organized and presented per administrative region in which each unit is installed. The administrative regions and their populations are shown in Table 1. All data are based on the 2011 census.

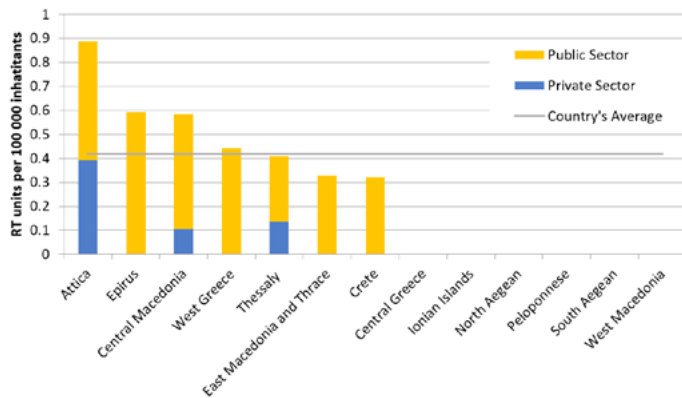
TABLE 1. Populations of Greek Administrative Regions, 2011 Census

Regions	Population
Attica	3.833
Central Greece	547
Central Macedonia	1.882
Crete	623
East Macedonia and Thrace	608
Epirus	336
Ionian Islands	207
North Aegean	199
Peloponnese	577
South Aegean	306
Thessaly	732
West Greece	679
West Macedonia	283

RESULTS

The distribution of RT units is very sparse in comparison with other modalities and only a few regional sectors have these facilities. The distribution of RT units in the different administrative regions is shown in Figure 2. Five of the 13 regions have no RT units – Central Greece, North Aegean, Peloponnese, South Aegean, West Macedonia and Ionian Islands. Of the 7 regions that have RT units available, only 3 have units in the private sector. This is expected since RT facilities are very expensive, need both dedicated infrastructures and specialized human resources, and should be linked to cancer diagnosis and treatment facilities. Conversely, RT units in public hospitals are available

FIGURE 2. Radiotherapy units: distribution per 100 000 inhabitants in each administrative region, 2017.



in all the other 7 regions. Athens (in the region of Attica) has the greatest number of RT units.

With a total of 57 RT units available, resulting in a ratio of 0.53 units per 100 000 inhabitants, Greece meets EU recommendations.³ Of these 57 units, 39 are in the public sector and 18 in the private. The exact number and technologies installed in each region are shown in Table 2. It is important to point out that technologies other than LINAC (Linear Accelerator) and Co-60 are available only in Athens.

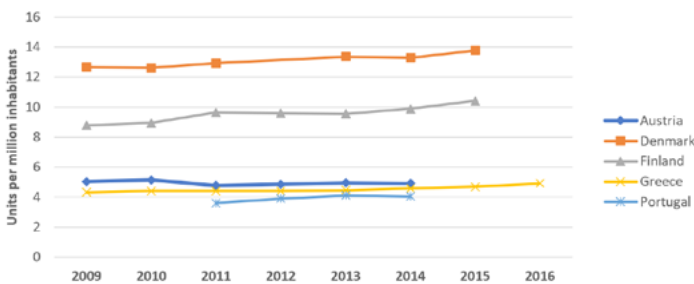
Source for Fig.2 and Table 2: data from EEAE

TABLE 2. Radiotherapy units: absolute number and number of units per 100 000 inhabitants in each health region, 2017

Health region	Total radiotherapy units		Private sector		Public sector	
	Absolute no.	Per 100K inhabitants	Absolute no.	Per 100K inhabitants	Absolute no.	Per 100K inhabitants
Attica (Athens)	34	0.89	15	0.39	19	0.50
Cyberknife	1	0.03	1	0.03		0.00
LINAC	22	0.57	11	0.29	11	0.29
Co-60	8	0.21			8	0.21
Tomotherapy	2	0.05	2	0.05		
γ knife	1	0.03	1	0.03		
Central Macedonia (Thessaloniki)	11	0.58	2	0.11	9	0.48
LINAC	9	0.48	2	0.11	7	0.37
Co-60	2	0.11			2	0.11
Crete (Heraklion)	2	0.32		0.00	2	0.32
LINAC	2	0.32		0.00	2	0.32
East Macedonia and Thrace (Alexandropolis)	2	0.33		0.00	2	0.33
LINAC	1	0.16		0.00	1	0.16
Co-60	1	0.16		0.00	1	0.16
Epirus (Ioannina)	2	0.59		0.00	2	0.59
LINAC	2	0.59		0.00	2	0.59
Thessaly (Larissa)	3	0.41	1	0.14	2	0.27
LINAC	3	0.41	1	0.14	2	0.27
West Greece (Patras)	3	0.44		0.00	3	0.44
LINAC	3	0.44		0.00	3	0.44
Total	57	0.53	18	0.17	39	0.36

A comparison between Greece and other EU countries of similar population is shown in Figure 3. As can be seen, Northern EU countries, such as Finland and Denmark, have twice as high a ratio of units per 100 000 inhabitants. While Portugal and Austria have similar ratios to Greece.

FIGURE 3. Evolution of the number of radiotherapy units per million inhabitants: comparison with 4 EU countries, 2009–2016.



Source: data from OECD (other EU countries) and EEA (Greece)

Concerning use and cost, the evolution of the number of reimbursed RT acts and the associated reimbursement costs from 2013 to 2016 are presented in Table 3, based on data provided by EOPYY.

TABLE 3. Radiotherapy acts: analytical data, evolution and comparison of number of acts, installed units and costs reimbursed by EOPYY, 2013–2016.

Year	Number of reimbursed RT acts per year			N° of units		
	Public	Private	Total			
2013	232 574	64%	132 986	36%	365 560	49
2014	248 409	61%	160 617	39%	409 026	50
2015	245 393	58%	174 443	42%	419 836	51
2016	233 892	57%	176 549	43%	410 441	53

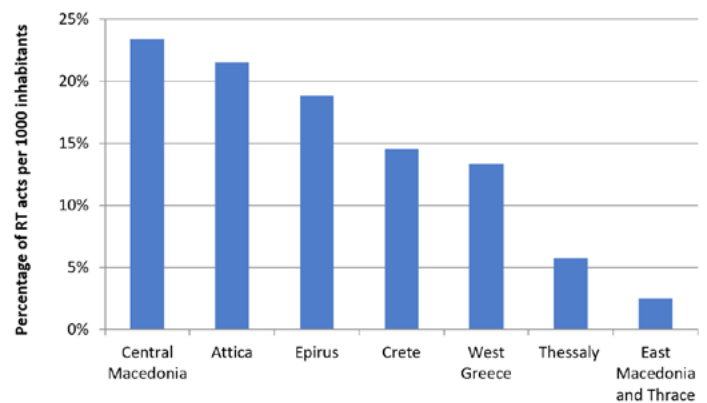
Year	Total EOPYY expenditure per year (€)				
	Public	Private	Total		
2013	18 564 495	50%	18 630 985	50%	37 195 480
2014	19 373 735	47%	21 625 454	53%	40 999 189
2015	19 416 459	44%	24 896 716	56%	44 313 175
2016	18 616 010	40%	27 935 467	60%	46 551 477

RT = radiotherapy; EOPYY = National Organization for Healthcare Provision
Source: data from EOPYY

Despite a few fluctuations, the number of RT acts remains more or less steady between 2013 and 2016. The market share also appears to be almost evenly distributed between the public and the private sector, with a 57/43 ratio.

The relative distribution of RT acts per 1000 inhabitants per administrative region in 2016 is shown in Figure 4. This graph shows only the regions where RT units are available.

FIGURE 4. Relative distribution of radiotherapy acts per 1000 inhabitants in each administrative region, 2016.

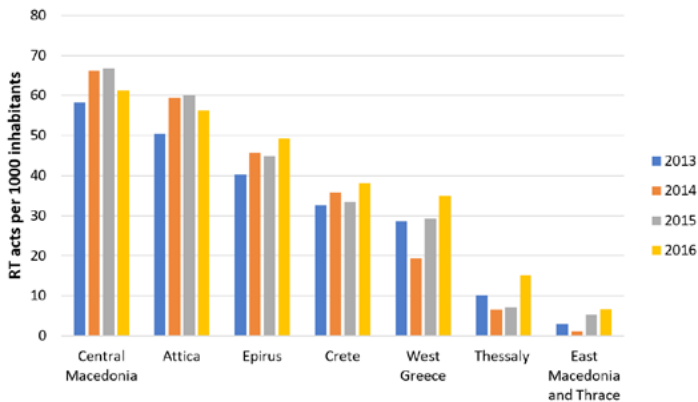


Note: regions without radiotherapy facilities are not shown. Source: data from EOPYY

Central Macedonia and Attica have the highest percentages of acts because they compensate for the lack of RT facilities in surrounding regions. Some technologies (e.g., γ -knife, cyberknife, tomotherapy) are available only in Athens. The time evolution of the number of RT acts per 1000 inhabitants per region between 2013 and 2016 is shown in Figure 5.

The number of acts shows an increasing trend in all regions where RT units are available, except for Attica (Athens) and Central Macedonia (Thessaloniki). These 2 regions show a steady increase from 2013 to 2015 but a slight drop in the number of acts during 2016. This may indicate that fewer patients are moving to these cities from other regions.

FIGURE 5. Time evolution of number of radiotherapy acts per 1000 inhabitants in each administrative region, 2013–2016.



Note: regions without RT facilities are not shown. Source: data from EOPYY

DISCUSSION

In both private and public health sectors, all RT departments in Greece are licensed according to the national law on radiation protection.⁴ In addition, the EEAE closely supervises the terms of radiation protection and compliance with quality and safety regulations for RT treatments. A common practice for the lifetime of RT treatment machines (8–15 years) does not appear to have changed over the last decade. However, in Greece until 2016, the vast majority of RT equipment (mainly LINACs and Co-60 units) in the public sector was more than 15 years old. In 2017, this situation changed radically as a result of the Stavros Niarchos Foundation donating 10 new LINACs to replace old equipment in 7 public hospitals.

European directive guidance on the important issues of accessibility and availability of RT equipment⁵ is based on the corresponding European Society for Radiotherapy & Oncology (ESTRO) and European Federation of Organizations for Medical Physics (EFOMP) guidelines. These guidelines, recommend a ratio of at least one RT equipment available for every 200 000 to 250 000 inhabitants. Given the population of 11.4 million, Greece should have at least 45 to 50 RT machines and therefore it can be concluded that it meets the guidelines on the number of units.

Staff levels in both private and public health sectors fall far below European standards and guidelines. The Hellenic Association of Medical Physicists (HAMP) reported

that the New European Directive 2013/59/EURATOM on basic safety standards for protection against the dangers arising from exposure to ionizing radiation, includes several articles related to the medical physics profession and competency requirements (articles 14 and 18). It also details the tasks required of experts in medical exposures and radiation protection that are pertinent to the roles and responsibilities of the medical physicist – namely the medical physics expert and the radiation protection expert (RPE)⁶.

On the contrary, no regulation and guidelines are existing concerning the role of clinical engineers inside the RT departments. It is well known that maintenance is assigned to private companies under maintenance contracts. Although maintenance is crucial for the quality of provided health service, unfortunately, no data are available on the quality of repair or preventive maintenance acts, safety checks etc. As for the case of medical physicists, which have a clearly stated role with well-defined rules and guidelines, the same should apply for clinical engineers, which should be responsible to closely inspect and supervise the maintenance procedure and the safety status of the RT units.

As reported by HAMP, under-staffing is one reason why RT, as the primary treatment for more than 60% of cancer patients in Europe and the United States, is used to only 30% of cancer patients in Greece.⁷ As a result, health system in Greece is forced to pay for less effective and more expensive treatments such as surgery and extensive chemotherapy.

A structural problem should also be mentioned. The fact that most centers have only one or 2 RT units results in high overhead costs for the accompanying equipment and eventually staff. At the same time, the widespread of equipment critically affects a patient’s treatment. Currently, 28 LINACs are installed in 15 public-sector RT departments in 7 large Greek cities. Of these, 4 have only one unit, 10 have two units and only one has 3 units. In cities with other public RT departments, single-unit RT departments are ineffective in both organization and service provided. Reorganization into bigger RT centers could produce serious resource savings and improvements in the treatment provided.

Whether used for diagnosis or therapy, a healthcare facility should ensure that the equipment is performing as intended by the manufacturer. Uncontrolled use of technology in medicine can result in increased costs for the delivery of healthcare services. Hence, it has become evident that there is a need to develop proper infrastructure for evaluating, supporting and managing biomedical technology. Greece lacks reliable information related to MDs, including the RT technologies addressed in this assessment. Data on the purchase price, annual maintenance costs, downtime, and actual use of devices are lacking. Evidence-based decisions are impossible without adequate data and information and it is impossible to calculate the median age of the installed bases, their value, annual service costs and annual use; or to estimate potential underuse of the machines or calculate incremental costs of corrective actions.

During the last 3 decades, computerized maintenance management systems (CMMs) for medical equipment have been used worldwide, providing all necessary data for cost-effective management and evidence-based decisions. Such systems have been available since the late 1980s but installed in just a few Greek hospitals till today. CMMs have multiple advantages, providing a complete and updated inventory at any time, with at least the following essential information for each machine – make and model, value, annual maintenance costs, weekly operating hours and number of uses. Such a system would have made the data collected within this assessment report available instantly to the Ministry of Health, avoiding a great deal of effort and enabling verification. Additionally, such systems are essential for vigilance purposes, evidence-based decisions on replacement, and control of service providers (i.e., response time, cost, respect of service contract rules) amongst many others, which are under the responsibility of the clinical engineering departments.

Aggregated data on maintenance costs of RT units in the public sector are not available. Most hospitals have maintenance contracts with equipment providers but these are negotiated on a case-by-case basis and the actual costs are not known. As a general rough estimate, the assumption of an annual cost of 8–10% of the initial equipment purchase price could be used. Maintenance

and repair issues are becoming more critical as the equipment ages. After the initial few years period during which maintenance is usually well-defined in the procurement agreement, in many cases price negotiations are under the control of manufacturers.

Additionally, rapid technological developments lead to the high-paced introduction of new or improved devices and require lifelong learning and continuous training for all healthcare professionals. Therefore, necessary means and facilitating conditions should be provided to guarantee the level of knowledge and skills of staff involved. Professional associations should play an important role in such procedures, and assessment should become a priority for all.

CONCLUSIONS

Lack of a continuously updated inventory means that there are no centrally available data concerning medical equipment information on maintenance, age and actual use of devices. The availability of such data is necessary for correct decisions on technology procurement, management, and replacement. This information is generally needed to estimate potential underuse, identify unjustifiably high management costs or calculate incremental costs of corrective actions. Evidence-based decisions are impossible without adequate data and information.

Personnel issues are considered to be a problem in RT departments and there is a discrepancy between the actual number of staff employed (especially non-medical) and the number recommended by (already approved) EU guidelines. Staffing of RT departments should be regulated in line with best practices and guidelines, and in accordance with EU regulations and directives. The application of these regulations should become a priority. Adequate staffing could allow the available infrastructure to be fully exploited, resulting in economy of resources and better patient treatment, the presence of clinical engineers should be regulated. Continuing professional development should also be organized in collaboration with professional societies to assist personnel in keeping pace with recent technological developments.

Improvement of RT investment planning is a critical factor for ensuring that healthcare systems are more

cost-effective and able to respond to patient needs in a most efficient way. Therefore, RT should be installed and used according to well-defined criteria, needs assessment analysis and priority settings. Greece should develop its Health Technology Assessment (HTA) capacity, as suggested by a 2016 WHO mission on HTA in Greece⁷.

The absence of biomedical/clinical engineering departments in most Greek hospitals, is a great obstacle to effective and safe management of medical technology, resulting in incomplete records and no quality and cost control. Maintenance of RT and the relevant costs should be followed using modern computerized systems in all public-sector hospitals.

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