The Italian National Recovery and Resilience Plan

Impact on the medical applications of ionizing radiation

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Abstract

In recent years, the world has faced unprecedented challenges, such as the global pandemic and the subsequent strain on healthcare systems. In response, many countries have implemented recovery plans to address the impact of these crises. The Italian National Recovery and Resilience Plan is playing a vital role in addressing the challenges faced by the healthcare sector, particularly in the medical use of ionizing radiation. Ionizing radiation has long been crucial in diagnosing and treating various medical conditions. The present paper explores the impact of the Italian National Recovery and Resilience Plan on the medical use of ionizing radiation, highlighting its significance in improving patient care, enhancing safety standards, fostering research and development, and strengthening healthcare infrastructure.

Keywords

National Recovery and Resilience Plan (NRRP), Ionizing Radiation, Healthcare Radiological Equipment.

1. The National Recovery and Resilience Plan (NRRP) and its impact

he National Recovery and Resilience Plan (NRRP) is an ambitious and comprehensive plan developed by the European Union (EU) to address the economic and social challenges posed by the pandemic Covid-19. The plan sets out how EU countries will use funding from the NextGenerationEU initiative to support their economic recovery and build a more sustainable and resilient future. The reforms and investment in Italy's plan, approved by Council on 13 July 2021, as amended on 19 September 2023, are helping it become more sustainable, resilient and better prepared for the challenges and opportunities offered by the green and digital transitions.

Among other things, the National Recovery and Resilience Plan is bringing about significant improvements in patient care within the health sector. Increased funding is facilitating the acquisition of state-of-the-art equipment and the development of advanced imaging/therapy techniques. This will hopefully lead to

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more accurate and timely diagnoses, enabling physicians to provide more targeted and effective treatments. Additionally, the plan emphasizes the recruitment and training of skilled healthcare professionals, further enhancing the quality of care provided to patients. Improved access to radiology, nuclear medicine and radiation oncology services, reduced waiting times, and enhanced patient experience are some of the notable outcomes of this plan. In particular, the following areas will benefit from the investments envisaged in the National Recovery and Resilience Plan:

Replacement of outdated equipment that use ionizing radiation: the use of ionizing radiation technology in healthcare is progressing at an extraordinary and ever-accelerating pace. Radiology, radiotherapy, and nuclear medicine departments are able to improve both their standards of care and efficiency thanks to ongoing advancements. As part of the National Recovery and Resilience Plan, a significant focus has been placed on the replacement of outdated equipment that use ionizing radiation. This initiative recognizes the importance

of having state-of-the-art technology in the field of radiology, radiation oncology and nuclear medicine to enhance patient care and diagnostic accuracy. Outdated equipment can lead to suboptimal image quality, longer examination times, and limited diagnostic/therapeutical capabilities. By allocating resources for the replacement of such equipment, the plan aims to improve the efficiency and effectiveness of radiological/nuclear medicine procedures and radiation therapy treatments. Upgrading to modern imaging systems, such as digital radiography, computed tomography (CT), and magnetic resonance imaging (MRI), not only enables faster and more precise diagnoses but also contributes to reducing patient waiting times and enhancing overall healthcare outcomes. Along the same lines, stateof-the-art radiotherapy equipment, such as advanced linear accelerators with image-guided radiation therapy (IGRT) and intensity-modulated radiation therapy (IMRT) capabilities, can deliver more targeted and precise radiation doses, sparing healthy tissues while effectively treating tumors.

The replacement of outdated radiological equipment under the National Recovery and Resilience Plan signifies a commitment to providing cutting-edge technology to healthcare providers, ensuring the delivery of high-quality care to patients.

Improved Safety Standards: one of the key focuses of the National Recovery and Resilience Plan is the enhancement of safety standards in the medical use of ionizing radiation. The plan emphasizes the implementation of strict protocols and guidelines to ensure the safe handling and administration of radiation in healthcare settings. Adequate training and education for healthcare professionals involved in radiation procedures are prioritized to minimize the risks associated with ionizing radiation exposure. By enforcing robust safety measures, the plan safeguards patients, healthcare providers, and the general public, mitigating the potential adverse effects of ionizing radiation.

Research and Development: the National Recovery and Resilience Plan recognizes the importance of fostering research and development in the field of medical use of ionizing radiation. Increased investment in this area has led to significant advancements in radiation therapy techniques, such as intensity-modulated radiation therapy, stereotactic radiosurgery, and brachytherapy. These innovations have revolutionized cancer treatment, allowing for precise targeting of tumors while sparing healthy tissues. Additionally, the plan has supported research efforts to explore alternative applications of ionizing radiation in fields like nuclear medicine and molecular imaging, paving the way for future medical breakthroughs. Digital transformation is another important area where the NRRP can support healthcare innovation. Digital technologies such as artificial intelligence (AI) and machine learning can help radiologists interpret images more accurately and efficiently, enabling faster and more accurate diagnoses. Similarly, AI has the potential to improve the accuracy, precision, efficiency, and overall quality of radiation therapy for cancer patients. The NRRP includes investments in digital infrastructure, such as high-speed broadband connections, that can support the development and deployment of these technologies in healthcare.

Strengthening Healthcare Infrastructure: the National Recovery and Resilience Plan has allocated resources to strengthen the healthcare infrastructure related to the medical use of ionizing radiation. This includes the renovation and expansion of radiation oncology departments, radiology facilities, and nuclear medicine units. Upgraded infrastructure enables healthcare providers to meet the growing demand for radiation-based diagnostic and therapeutic services, ensuring timely access for patients. Additionally, the plan emphasizes the establishment of comprehensive radiation safety programs and quality assurance measures, fostering a culture of excellence and accountability in the delivery of radiation services.

Collaboration and Knowledge Sharing: the National Recovery and Resilience Plan encourages collaboration among healthcare institutions, research organizations, and industry stakeholders involved in the medical use of ionizing radiation. Collaborative networks promote knowledge sharing, research collaborations, and the dissemination of best practices. These partnerships facilitate the exchange of expertise, advancements, and quality assurance protocols, ensuring uniform standards and continuous improvement in the field. By fostering collaboration, the plan creates a dynamic environment that stimulates innovation and contributes to the development of new techniques and technologies.

Investment in resilience can help healthcare providers prepare for and respond to future crises such as pandemics or natural disasters, ensuring that essential imaging services remain available to patients.

2. A focus on the Italian National Recovery and Resilience Plan

Italy's recovery and resilience plan aims to address the urgent need for fostering a strong recovery and preparing Italy for the future in the wake of an unprecedented crisis brought on by the pandemic. Italy will become more resilient, sustainable, and well-prepared for the opportunities and challenges presented by the green and digital transitions thanks to the reforms and the investments in the plan.

The Italian NRRP was launched by the Italian gov-

ernment and approved by the European Union (EU) in April 2021. It aims to modernise the country's infrastructure and make it more resilient to future challenges. It includes a series of measures aimed at improving Italy's competitiveness, strengthening social cohesion and accelerating the country's transition to a more sustainable and digital economy. According to the Recovery and Resilience Facility Regulation, all reforms and investments must be implemented by August 2026.

The total NRRP includes funding of €191.5 billion, of which €68.9 billion is earmarked for investment and €122.6 billion for reform [1]. The plan includes 58 reforms and 132 investments to achieve this. The investments focus on six key areas (or missions), including digitalisation, sustainable infrastructure, green transition, education and research, social inclusion and health. These investments aim to boost economic growth, create jobs and improve the well-being of Italian citizens.

One of the main focuses of the NRRP is the healthcare system, with a significant amount of funding allocated to improving the quality of care and infrastructure in hospitals and medical facilities. The Sixth mission concerns health. a critical sector that has faced historic challenges in the past year. The impact of the Covid-19 crisis on health systems has demonstrated the importance of a full, equitable and uniform right to health across the national territory. Moreover, the pandemic has put personal well-being back at the centre of the political agenda. The reforms and investments proposed by the plan in this area have two main objectives: to strengthen the prevention and treatment capacity of the national health system for the benefit of all citizens to ensure fair and universal access to care, and to promote the use of innovative technologies in medicine. Mission 6 of the NRPP is divided into two components:

 M6C1: Proximity networks, facilities and telemedicine for territorial healthcare assistance. The measures of this component aim to strengthen the services provided in the territory by enhancing and creating local facilities and centers (such as Community Houses and Community Hospitals), strengthening home care, developing telemedicine, and more effectively integrating with all social and health services.

M6C₂: Innovation. research _ and digitalization of the National Health Service. The measures included in this component will allow the renewal and modernization of existing technological and digital structures, the completion and diffusion of the Electronic Health Record (EHR), a better capacity for providing and monitoring Essential Levels of Assistance (LEA) through more effective information systems. Significant resources are also allocated to scientific research and the propotion of technology transfer, as well as to strengthening the capabilities and human capital of the National Health Service through the improvement of human resource training.

The NRRP has allocated a total of 15.63 billion for the two components of the mission. Overall, Italy's NRRP can play a critical role in driving innovation and improving the quality of care in the use of ionising radiation in healthcare. By supporting investments in digitalisation, sustainable infrastructure, health, resilience, education and research, and social inclusion, the plan can help healthcare providers deliver more accurate diagnoses and efficient therapies, reduce waiting times and improve outcomes for patients. The NRRP represents a significant investment in the future of medical use of radiation and has the potential to transform the field in the years to come.

3. Impact of NRRP in radiology

The Italian technological and digital hospital infrastructure is severely outdated and deficient in many facilities. The efficiency of the system and the quality of services are at risk, which could damage public confidence in the health system.

One of the most ambitious challenges of the NRRP is the modernisation of technological equipment in Italian hospitals, with an investment for the purchase of new high-tech equipment. As anticipated, €15.63 billion (representing 8.16% of the total) will be allocated to health (both M6C1 and M6C2 missions) to support significant reforms and investments for the National Health Service to be implemented by 2026.

A recent report by OASI shows an index of obsolescence of facilities and equipment in public hospitals at 79% [2]. Furthermore, according to Confindustria Medical Devices Observatory [3], which analysed the state of obsolescence of the diagnostic imaging technology park in Italian public and private healthcare facilities. As of 2021, nearly 37,000 diagnostic imaging devices in Italy were no longer aligned with the current level of innovation, with 95% of conventional mammography equipment beyond the update cycle, as well as 54% of nuclear magnetic resonances, 42% of CT scanners, and 51% of PET scanners (figure 1). A closer look at the differences in the geographic distribution of CT scanners, MRI scanners and mammography equipment is provided in figures 2-4, respectively. The PNRR envisages an investment to purchase and test at least 3,100 devices by the end of 2024 to replace the obsolete and unusable devices.

The planned investment of €4.05 billion simultaneously addresses three fronts to improve the technological equipment of the national health system and thus the quality of services provided. The measures are arranged as follows:

- the digital modernisation of the hospitals' technology park through the purchase of 3,133 new high-tech largescale devices (CT scanners, MRI machines, linear accelerators, stationary radiology systems, angiography systems, gamma cameras, gamma camera/ CT scanners, mammography machines and ultrasound machines) older than 5 years;
- interventions aimed at increasing the level of digitisation of 280 health care facilities that are home to Emergency and admission wards (DEA) of level I and II;
- finally, the intervention (implementing Article 2 of Legislative Decree No. 34/2020) provides for the structural strengthening of SSN hospitals through the adoption of a specific plan to improve hospital services to ensure: (i) the increase in ICU bed capacity (+3.500 beds) to ensure the standard of 0.14 beds per 1,000 population and semi-intensive care (+4,225 beds); (ii) the consolidation of segregated pathways within the emergency department; (iii) an increase in the number of vehicles for secondary transport.



Fig. 1. Diagnostic imaging technology park in use at Italian public and private healthcare facilities in 2021, as reported by the Osservatorio parco installato (Opi) di Confindustria Dispositivi Medici. Source: https://www.confindustriadm.it/parco-installato-dati-2021/.

The total expenditure for the investment amounts to 4.05 billion euros. This amount also includes the share already included in the trend (and amounting to €1.41 billion) related to the projects already started by the Ministry of Health to structurally strengthen the SSN in the hospital sector, which are being prepared to deal with the Covid 19 emergency in accordance

with the above-mentioned Article 2 of Legislative Decree No. 34/2020. Regarding the costs, the following can be said:

 Expenditure of 1.19 billion euros for the renewal of medical equipment. This expenditure relates to approximately €0.60 billion for the replacement of 1,568 pieces of equipment by the third quarter of 2023 and another approximately €0.60 billion for the replacement of the remaining 1,565 pieces of equipment by the end of 2024.

 Spending of €1.45 billion on the digitisation of Stage I and II DEAs (including €1.09 billion for the digitisation of 210 units by the first quarter of 2024 and €0.36 billion



Figg. 2, 3, 4. Distribution of 2,178 CT scanners (left image), 1,179 MR closed scanners (center image) and 2,039 digital mammography systems (right image) considered tobe in use by the end of 2021 in public and private healthcare facilities in Italy. Source: Osservatorio parco installato (Opi) di Confindustria Dispositivi Medici, https://www.confindustriadm. it/parco-installato-dati-2021/.

for the digitisation of a further 70 units by the end of 2025). The publication of the tender procedure and the signing of the contracts with the providers are expected for the third quarter of 2022.

Total expenditure of € 1.41
billion by the second half
of 2026 for the renewal

of the existing ICU and semi-ICU bed capacities, the modernisation of the emergency rooms and the increase in the number of vehicles for secondary health transport (project already initiated).

The number and types of units to be replaced are: 340 CT (128 slice), 190 units of 1.5 T MRI systems, 81 linear accelerators, 937 stationary X-ray systems, 193 angiographs, 82 gamma cameras, 53 gamma cameras CT, 34 PET, 295 mammography units, 928 ultrasound units.

Every digital hospital should have a data processing centre required to computerise the entire hospital structure, sufficient hardware and software IT technologies, electromedical technologies and additional technologies required to computerise each hospital department. The equipment will be installed where it is needed, depending on the purpose for which it is intended, the area where is to provide health care and the complexity of the diagnostic and therapeutic services it is required to provide.

The opportunity presented by the National Recovery Plan for the renewal of diagnostic imaging technology is unique and should not be wasted. However, a broader perspective is needed to take advantage of this opportunity. This means taking into account the actual needs and the appropriateness of the allocation, including the type of equipment. It is not enough to simply replace old equipment to do a good job. A health technology assessment is needed for rational and effective use of new technologies.

For example, regarding magnetic resonance imaging (MRI), for years Italy was in the upper part of the European rankings in absolute data on the number of technologies, while data on the number of examinations per inhabitant put the nation at the bottom of the average. It follows intuitively that the average utilisation rate of each device is low and well below the European average. In 2018, each MRI machine in Italy performed an average of 2,570 examinations, compared to 4,309 in Germany, 5,371 in Spain and 8,095 in France.

Therefore, regional analysis of imaging technology replacement should be carried out carefully and rigorously. The replacement of obsolete technology in a centre that performs significantly less than the benchmark may not be appropriate (the annual production of 4.000-8.000 MRI examinations is considered average [4]). On the contrary, it would be appropriate to concentrate technologies in centres that have adequate production capacity.

4. Impact of NRRP in radiation therapy

Oncology radiotherapy will also benefit from funding under the NRRP. Significant technological advances in oncology radiotherapy require upgrading of equipment, such as linear accelerators in Italian hospitals, which are often outdated and unable to provide the best treatment to patients.

According to a recent census of oncology radiotherapy centres and equipment in Italy, there are currently 430 external beam radiotherapy machines in operation, of which 377 are linear accelerators and 53 machines are capable of performing radiotherapy with highly complex technologies (30 machines for helical volumetric treatments, 17 machines for radiosurgery with Cyber Knife and Gamma Knife, four hybrid accelerators with magnetic resonance and two machines for proton therapy). Of these devices, 45.5% are older than 10 years and 29% are older than 12 years.

This need for modernisation has finally been recognised by the institutions, and the space dedicated to this topic in the National Rehabilitation and Resilience Plan is significant. The value of this investment is first and foremost one of equity. It is necessary to ensure that all Italian regions have the same capacity to provide treatment that meets international standards and uses the best possible technologies. In addition, hope journeys to distant places where the patient lives to receive the best and most

advanced treatment must be drastically reduced.

The situation is different for high-tech equipment for radiotherapy, which cannot be installed in all hospitals for cost reasons, but whose inclusion must be recognised organically in all regions on the basis of specific characteristics (such as expertise, treatment volume and other factors).

5. Impact of NRRP in radiation protection

As expected, the NRRP's measures include the purchase of about 3,000 pieces of hospital equipment to replace obsolete and out-of-service equipment. More than half of these (64%) will be equipment that uses ionising radiation and is therefore subject to the radiation protection provisions of Legislative Decree No. 101 of 31 July 2020.

As far as the implementation of this measure is concerned, there are unfortunately still significant delays in many regions. It is of utmost importance that the safety of radiological, radiotherapeutic and nuclear medicine treatments is guaranteed by organisational models that conform to the law and not only by state-ofthe-art equipment. With regard to radiological equipment, the recent Legislative Decree 101/2020 places particular emphasis on the role of the quality manual in a programme of continuous improvement of quality standards. In particular, the current legal framework prescribes the following measures:

- Indication of the absorbed dose class for patients following a radiological examination. According to Article 161, paragraph 6, each report must contain information on exposure to ionising radiation "consisting of an indication of the dose class (from I to IV) attributable to the examination in question". The dose class should be determined on the basis of the nature and methods of the radiological and nuclear medicine examinations and the indications given by the medical physics specialist.
- Quality manual and adopted standards. Article
 164 requires the person in charge of the radiological establishment to draw up a quality manual containing "the standards adopted to verify the quality of radiological technique and diag-

nostic quality in radiodiagnostic procedures" (Annex XXVIII).

 Specific training for newly hired workers. "The employer shall ensure that each worker exposed to the risks of exposure to ionising radiation in the context of her/ his assigned tasks receives sufficient and appropriate training in radiation protection, including any specific training" (Article 111). Such training is mandatory before newly recruited workers take up their duties.

6. Impact of NRRP in medical physics

Medical physics plays a vital role in radiology, radiation oncology, and nuclear medicine, contributing to the safe and effective use of radiation in these disciplines. In radiology, medical physicists ensure the optimal performance of imaging equipment, calibrate and maintain radiation dose levels, and implement quality control measures to ensure accurate and high-quality images. They also play a crucial role in dose optimization, ensuring that patients receive the necessary diagnostic information while minimizing radiation exposure of patient

staff [5]. In radiation oncology, medical physicists collaborate with radiation oncologists to develop treatment plans, calculate radiation doses, and ensure the precise delivery of radiation to cancerous tissues. They perform quality assurance checks on radiation therapy equipment, verify treatment accuracy, and monitor patient radiation doses. In nuclear medicine, medical physicists are involved in the safe handling and administration of radiopharmaceuticals, ensuring appropriate dosages and minimizing radiation exposure to patients and staff. They also contribute to image acquisition and analysis, ensuring accurate diagnostic information. Overall, the expertise of medical physicists in radiology, radiation oncology, and nuclear medicine is indispensable in providing safe and effective patient care, optimizing diagnostic accuracy, and ensuring the highest standards of radiation safety.

With this in mind, the Italian NRRP will have an unprecedented impact in the field of medical physics as well. The introduction of new technology utilizing ionizing radiation and the replacement of outdated equipment will require the establishment of robust quality assurance programs and the execution of acceptance tests on all new installations. Within the framework of the National Recovery and Resilience Plan (PNRR) and in compliance with the above mentioned Legislative Decree 101/2020, regarding the actions to be taken in various sectors of the medical physics specialist's expert activities, the following priorities can identified:

- In accordance with Article 163, Legislative Decree 101/2020, acceptance and performance testing must be carried out on all new installations utilizing ionizing radiation before they are put into operation.
- Development of new quality assurance protocols for medical radiological equipment implementing previously unavailable techniques or capable of executing new diagnostic/ therapeutic protocols.
- Identification of medical radiological equipment compliant with the requirements established by the recent legislation (Legislative Decree 101/2020, Art. 163).
- Optimization of all radiological practices in-

volving patient exposure, with particular attention to "Special Practices," as identified and defined in Article 165 of Legislative Decree 101/2020, namely all practices involving medical exposure of individuals: a) in pediatric age; b) exposed within screening programs; c) exposed within radiological practices involving high doses to the patient (as may occur in the case of interventional radiology, computed tomography, nuclear medicine) d) undergoing radiotherapeutic treatments.

7. Conclusions

The Italian National Recovery and Resilience Plan is currently having a significant impact on the medical use of ionizing radiation in Italy. Through increased funding, it has led to advancements in patient care, technological improvements, safety enhancements, and infrastructure development. These positive changes have resulted in improved diagnostic accuracy, enhanced treatment outcomes, and optimized patient experiences. The plan's commitment to investing in the medical use of ionizing radiation underscores the importance of delivering

high-quality healthcare services to the Italian population. By prioritizing enhanced patient care, safety standards, research and development, and healthcare infrastructure, the plan is likely to improve the delivery of radiation-based diagnostic and therapeutic services. As a result, the PNRR has positioned Italy at the forefront of medical advancements, ensuring the continued progress and success of the medical use of ionizing radiation in the country.

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