Subject: 2010-2012 **National Oncology Plan** renamed "**TECHNICAL POLICY DOCUMENT ON THE REDUCTION OF CANCER DISEASE BURDEN – for the years 2010-2013"**

This contribution by the General Directorate for Prevention comprises the following parts:

A) **General aspects of the PON structure and institutional activities**

B) **Summary of contents**

C) **ANNEX 1 Action plan**

A) GENERAL ASPECTS OF THE PON STRUCTURE

1) The reasons for a PON

- Burden of cancer[1]
- International commitments [Council of the European Union - Council conclusions on reducing the burden of cancer 10 June 2008: *"INVITES Member States to develop and implement comprehensive cancer strategies or plans"*]
- It is important for our Country as a whole to:
  - improve the response of the NHS (which in any case in the oncology and hemato-oncology area occupies a position of "excellence" at world level);
  - contribute to bridging inequalities.

2) The PON was drawn up by the "Oncology Planning Committee"

Coordinator: A. Santoro (Director of the Oncology and Hematology Department, Istituto Clinico Humanitas IRCCS, Rozzano, Mi)
External Collaborators: 28 **Ministerial Collaborators**: 14

3) Main goal

The 2010-2012 PON provides strong indications as to where State and Regions should focus their joint efforts in order to further improve the "comprehensive management" of patients by the NHS. Hence the document provides:

- *A theoretical framework of reference*
- *Shared priorities*
- *Common goals*

4) "Key" principles adopted in drawing up the PON

- **Equity**: contribute to bridging the differences that still exist within the Country
- **Quality**: contribute to raising the general "level". This goal is pursued by two main lines of action:
  1. firm attention to the "organizational models for patient management" (pathways, networks, integration of resources available in the country);
  2. strong promotion of research and technological innovation.
- **Knowledge**: contribute to promoting research, IT systems, knowledge-management
- **Information and communication**: encourage awareness and participation by all stakeholders in prevention and treatment processes

[1] Tumours are a health priority for the Country; every year in Italy some 250,000 new cases are diagnosed and the incidence is constantly rising. This figure is further "amplified" by the progressive ageing of the population; today 40% of Italians admitted to hospital facilities are over 65 years of age in spite of the fact that they only account for 20% of the population. Moreover, in 2010, some two million prevalence cases are expected and, also in this case, the figures are steadily increasing.

In 2006, in Italy, more than 168 thousand deaths due to cancer were recorded, namely 30% of all deaths, with cancer being the second cause for death. In particular, it is the first among adults and the second cause among the elderly. However, in the last ten years, mortality due to cancer has decreased, a positive trend that started to appear in the early seventies among the younger age groups and subsequently extended to adults across the national territory.

5) Institutional activities of the PON

- The document was sent to the Regions Coordination body on 10 June 2010
- Regions came together to discuss the document at the meetings with:
  - the "Interregional Public Health Group" on 10/11/10 [2];
  - Interregional Prevention Coordination on 25/11/2010
  - The Health Committee of 15/12/2010: on this occasion it was decided that, owing to the strategic significance of the "Oncology Plan", its name would be changed to **TECHNICAL POLICY DOCUMENT ON THE REDUCTION OF THE CANCER DISEASE BURDEN – 2010-2013**
  - State-Regions Conference: at the meeting held at the technical secretariat on 2/2/2011, the text of the Memorandum proposed by the Ministry was approved, whose essential elements are presented here:

Article 1

("Technical Policy Document on the reduction of the cancer disease burden" - 2011-2013)

The "Technical Policy Document on the reduction of the cancer disease burden" for the years 2011-2013 as per Annex 1, which is an integral part of this Memorandum, is hereby approved. The "Technical Policy Document on the reduction of the cancer disease burden" for the years 2011-2013 is an integral part of the National Health Plan.

Article 2

(Implementation of the "Technical Policy Document on the reduction of the cancer disease burden" - 2011-2013)

In order to enable the Regions and the Public Administrations – within the scope of their autonomous planning activity – to make the best use of the policy indications set forth in the "Technical Policy Document on the reduction of the cancer disease burden" for the years 2011-2013, the Ministry and the Regions and the Public Administrations commit to setting up, through their representatives, mixed working groups to define:

- by 31 December 2011:

[2] From the Minutes of the meeting of the Interregional Public Health Group held on 10 November 2010 at 10:30 at the premises of SISAC, via Nazionale 75 Roma.

Conclusions: "The document entitled the National Oncology Plan (NOP) must be interpreted as a policy document for the activities ensuing from the NOP and concerning the other specific fields that have to do with tumour prevention, diagnosis and treatment. The Representatives of the Regions expressed an overall positive assessment of the contents of the document but highlighted the need for the activities to be prioritized and that such priorities be supported economically in order to enable all Regions to reach high quality standards and reduce the North-South gap. The group that attended the meeting expressed its willingness to work within the scope of their competencies and deepen the examination of specific issues at future meetings. The next meeting has been set for 13 December 2010 at 10:30 at Sisac in via Nazionale".

- guidelines for implementing oncology networks (with technical, scientific and organizational contents based on the analysis of evidence and best practices);
- a document that directs the use of comprehensive resources identifying the "recovery" areas, through the re-engineering of "obsolete" or ineffective practices and of less efficient organizational models;

- by 31 December 2012 an HTA document (based on the summary of evidence available on the cost-effectiveness of the main technologies).

Article 3

(Supporting the fight against cancer)

The Centre for Disease Prevention and Control shall contribute to the fight against tumours by envisaging specific areas of intervention within their annual programmes with special reference to the spreading of best practices and virtuous organizational models and the consolidation of comprehensive procedures.

B) SUMMARY OF CONTENTS

1) "Structure" of the PON

The PON is organized according to the following steps:

- Stating the *areas* of "critical" and priority importance
- Targeting *needs* within the selected Areas
- Identifying the *goals* and definition of the ensuing *action plan* (see details in Annex 1).

2) Issues dealt with:

- cancer in Italy (surveillance systems, epidemiological framework, hospital admissions);
- prevention (details are provided below after Letter C);
- pathways for oncology patients in terms of:
    - integrating the diagnostic-therapeutic steps (from GPs to outpatient services to hospital care);
    - continuity of care at local level (optimization of care delivery and network organization, IT instruments supporting oncology care delivery, simultaneous care model – management of oncology patients, rehabilitation, palliative care and development of pain-relief therapy, development of psycho-oncology and integration with the non-profit and charity workers sector);
- elderly oncology patients;
- paediatric tumours;
- rare tumours;
- oncology-hematology
- technological renewal of equipment for:
    - Anatomical Pathology
    - Imaging Diagnostics
    - Gastroeneterology endoscopy
    - Oncology surgery radiotherapy
- Innovation in oncology in the areas of :
    - Biobanks;
    - Molecular Medicine,
    - Cell therapy and hematopoietic stem cell transplantation,
    - Oncology networks,
    - Clinical research in oncology
    - New drugs
- Training
- Communication

ANNEX 1

Tables summarizing the envisaged "action plans" for the various chapters of the PON are provided below.

TABLE 1.1 **CANCER IN ITALY**

Action Plan for 2010 – 2012

- Define electronic quality standards as to appropriate means and methods for assessing them in order to reduce cancer mortality and reduce waste
- Reduce differences in cancer deaths between Regions through a more rational use of available resources in the fight against cancer
- Reduce health migration between Regions, by reducing the differences in technology, organization and care delivery
- Increase coverage by the Tumour Register from 32% to 50% of the Country
- Facilitate the creation of electronic Networks of Tumour Registers
- Develop oncology networks according to the Hub & Spoke model dedicated in particular to the development and application of new technology-intensive diagnostic and therapeutic methodologies

Table 2.1A **UNIVERSAL PREVENTION (PRIMARY)**

Action Plan for 2010 – 2012

GOAL	CENTRAL SYSTEMATIC ACTIONS[3]
Fight against smoking	• consolidate the application of Act 3/2003 on protection from passive smoking by extending 'No smoking' areas and by monitoring that the law is enforced • Implement the Framework Convention on tobacco control transposed by Act n° 75 of 18 March 2008 - Fiscal policies on tobacco products (price increases, uniform excise duties, use extra income for prevention, etc.) - Control ingredients of tobacco products - Change labelling - Fight against illicit tobacco products - Regulate supply (prohibit sale to minors, monitor dispensers, etc.)
Promote healthy eating habits and exercise	• Promote healthy life-styles through nationwide information campaigns • Promote and support, at local level, physical activity also by providing appropriate facilities in the towns • Make sure, at local level, that healthy food is available, accessible and recognizable,

[3] These are tasks assigned to the central Health Administration.

	through agreements with producers, with distributors and retail networks and with consumer associations
Fight against the use of alcohol	• Fight against alcohol advertisements • Support non governmental organizations in reducing damage caused by alcohol, in providing information and mobilizing civil society • Monitor the impact of alcohol abuse on health and assess its costs • Raise minimum age for legally purchasing alcohol to 18 and ban the sale of alcohol in motorway stores • Promote information campaigns in the mass media highlighting the health damages caused by alcohol abuse and promote public support for policies against alcohol
Fight against infectious oncogenic agents	• Monitor the selection of blood donors by appropriate patient history, serum screening and identification of viral nucleic acids for HBV, HCV and HIV • Strengthen the information campaigns on the risks of sexual transmission and on means of prevention
Fight against exposure to oncogenic agents in living and working environments	• Control the quality of fuel • Put restrictions on the circulation of polluting vehicles and support the marketing of less polluting vehicles (natural gas/LPG/electric), • Check heating systems, • Check industrial emissions • Enhance integration of registration and epidemiological surveillance systems for tumours having high occupational etiologic fractions • promote epidemiological monitoring activities for tumours having low occupational etiologic fractions • carry out full mapping of sites and buildings for radon and asbestos so as to define areas at greater risk and for the ensuing reclamation measures • extend to the whole Country the search for dioxins and persistent pollutants in food matrices to which the population is exposed • set up a register of the sources of electromagnetic pollution and of the levels of exposure • strengthen the ability of institutions to communicate risks to the population

Table 2.1B **UNIVERSAL PREVENTION (PRIMARY)**

Action Plan for 2010 – 2012

GOAL	*ACTIONS TO BE TAKEN BY THE HEALTH SYSTEM*
Fight against smoking	• *Promote the role and skills of GPs in counselling and management of smokers also through contractual rules* • *Help pregnant women stop smoking through the "Smoking-free Mothers" program with the involvement of health workers* • *Support and encourage the creation of Anti-smoking centres* • *Develop programs for discouraging smoking in the workplace* • *Strengthen interventions in the schools for pre-adolescent children and develop prevention actions addressed to young people who do not attend school* • *Protection from passive smoking in public places and in the workplace*

	• *Assess the efficacy of interventions for the different population targets*
Promote healthy foods and physical activity	• *Promote and support breast-feeding without formulae at least for the first six months of life* • *Encourage correct nutritional choices in school canteens* • *Develop educational activities for children on nutrition, taste and physical activities as an integral part of health education programs* • *Increase the time devoted to physical activity at and after school in children and teenagers*
Fight against the use of alcohol	• *cooperate with the schools for developing programs on health promotion and prevention of damages related to alcohol abuse* • *involve and train GPs to identify individuals at risk of alcohol abuse in the early stages and to implement brief interventions* • *provide accessible, effective and flexible treatment for problematic drinkers based on scientific evidence and an adequate assessment of needs* • *facilitate an integrated approach that involves the health services, the GPs, social services, self-help groups, schools, judicial institutions, the labour world and other institutions involved* • *promote socio-health programs that strengthen the mobilization of the community*
Fight against oncogenic infectious agents	• *reduce the risk of parenteral transmission of infections (HBV, HCV, HIV)* • *monitor respect for universal precaution measures in hospitals and in other contexts where transmission may occur* • *improve vaccine coverage against hepatitis-B in groups at risk (health workers, individuals living with carriers, etc.) and promote vaccination also among travellers to endemic areas* • *the NHS should start anti-HPV vaccination campaigns for twelve year old girls*
Fight against the exposure to oncogenic agents in living and working environments	• *enhance integrated recording and epidemiological monitoring systems for tumours with high occupational etiologic fractions* • *develop epidemiological monitoring projects for tumours with low occupational etiologic fractions*

TABLE 2.2 **SECONDARY PREVENTION (SCREENING)**

Action Plans for 2010 - 2012

- Extend organized screening programs for cervical, breast and colorectal cancer so as to halve the differential between observed and expected percentage (total coverage of target population)
- Enhance and improve the quality of screening programs delivered by the Regions, as defined by the set of indicators agreed by the National Screening Observatory and the Regions Coordination Body, by means of the instruments of the National Prevention Plan and restraints on the use of quotas of the Regional Health Fund.
- Make the population programs for the screening of breast, cervical-uterine and colorectal cancer sustainable by re-engineering opportunistic screening
- Define a national program in accordance with the Regions for testing out organizational innovations for breast, cervical and colorectal screening programs
- Define accreditation criteria for prostate cancer management
- Setup a steering board for centralized planning of pilot studies on the impact and assessment of cost-effectiveness of new technologies for population programs (starting from the use of colonograph for colorectal cancer screening
- Set up a steering group for defining and developing a National Plan for Public Health Genomics.

TABLE 2.3 **TERTIARY PREVENTION**

Action Plans for 2010-2012

- Promote the organization of patient management pathways at local level for the prevention of complications and relapses through active involvement
- Promote the diffusion of diagnostic-therapeutic integrated management protocols as best-practice standards
- Promote technological upgrading to ensure equal access to cost-effective diagnostic methods and therapies
- Promote the availability of psycho-oncology support
- Promote the participation of associations of volunteers, relatives and families in the definition of support solutions for terminal patients
- Promote lifelong professional upgrading of specialists on follow-up protocols and on the integrated management of oncology patients through a national re-training program
- Promote the review/drafting of follow-up protocols, based on risk category definition

Table 3.1 **TREATMENT PATHWAY FOR ONCOLOGY PATIENTS**

INTEGRATION OF DIAGNOSTIC – THERAPEUTIC PATHWAY

Action Plan for 2010 – 2012

GENERAL PRACTITIONERS (GPs)

- Involvement of GPs in the oncology network
- Involvement of GPs in counselling on the fight against the causes of tumours and on positive behaviours that reduce risk
- Integration of the activities of GPs for the early diagnosis of some tumours
- Integrated home care with the participation of GPs in managing disorders that do not require specialist care
- Participation of GPs in preparing plans for local/hospital diagnosis and therapy
- Promoting the use of specific and shared guidelines by the GPs and paediatricians of free choice
- Introduction of new forms of primary care
- Start 24-hour care

OUTPATIENT CARE

- Integrate hospital and local outpatient units in the Oncology Departments
- Ensure quality control of diagnostic processes and technological equipment
- Promote appropriateness of care
- Participate in the drafting and adoption of diagnostic-therapeutic local-hospital protocols that ensure the continuity of care delivery
- Promote the adoption of shared guidelines
- Appropriate management of waiting lists based on severity of disease and on possible therapeutic treatment
- Promote, where appropriate, the delivery of chemotherapy and radiotherapy in outpatient services as an alternative to ordinary hospitalization

THE HOSPITAL

- Ensure multi-professional and multidisciplinary approach to oncology patients through departmental organization
- Draw up a personalized integrated intervention plan for each patient
- Prepare uniform diagnostic and therapeutic procedures with the involvement of outpatient specialists and GPs
- Define a set of indicators (quality, structure, process, outcome, satisfaction, research activity) for benchmarking healthcare facilities
- After assessing the indicators, identify the hospital facilities that are to provide particularly complex or non routine services
- Promote care safety and clinical risk management
- Ensure waiting time is respected as envisaged in the national and regional plans
- Create a network of top-ranking (excellence) hospitals which includes also minor healthcare facilities
- Delivery of third level integrated home care (home hospitalization) also for terminal patients

Table 3.2 **TREATMENT PATHWAY FOR ONCOLOGY PATIENTS**

CONTINUITY OF HEALTHCARE AT LOCAL LEVEL (TERRITORY)

Action Plan for 2010 – 2012

- Optimize each step in the management of oncology diagnostic-therapeutic pathways
- Harmonize the Single Reservation Centres (CUP) across the Country
- Recognize the discipline of Palliative Care and Pain Therapy
- Integrate the "Hospital without pain" project with the involvement of the territory and of GPs/Paediatricians of free choice and ensure that they operate ("Territory without pain")
- Complete the regional Pain Therapy networks
- Integrate the Pain Therapy Networks, the Oncology Networks and the Palliative Care Networks
- Enhance the role of the GPs in supporting the team that provides palliative care
- Involve non-profit organizations and charity workers in accomplishing these actions

Table 3.3 **TREATMENT PATHWAY FOR ONCOLOGY PATIENTS**

ELDERLY ONCOLOGY PATIENTS

Action Plan for 2010 – 2012

- Recognition of the specificity of Geriatric Oncology in the National Health System
- Creation of Oncology-Geriatric Coordination Units (UCOG) with direct responsibility for the management of elderly patients
- Identification, through the UCOGs, of diagnostic-therapeutic pathways that include services, oncology care and geriatric care both inside and outside the hospital
- Management and monitoring of healthcare delivery results and surveying criticalities observed
- Implement and improve the quality of the system
- Start information programs for citizens on healthcare delivery and prevention in elderly oncology patients

Table 3.4 **TREATMENT PATHWAY FOR ONCOLOGY PATIENTS**

PAEDIATRIC TUMOURS

Action Plan for 2010 – 2012

- Recognition of the specificity of Paediatric Oncology in the National Health System
- Recognition of the excellence of accredited facilities for paediatric oncology
- Validation of controlled clinical protocols to be used as therapeutic standards
- Implementation of access to care in paediatric oncology units for all children and adolescents affected by paediatric tumours across the National territory
- Promote the creation of consortia and virtual departments to share the resources of complementary paediatric oncology wards so as to optimize the use of resources and of available skills
- Promote paediatric oncology training in hospitals and universities
- Implement follow-up protocols so as to facilitate social and school re-adjustment of oncology paediatric patients, with the parent associations being the privileged interlocutor

Table 3.5 **TREATMENT PATHWAY FOR ONCOLOGY PATIENTS**
RARE TUMOURS

Action Plan for 2010 – 2012

- Include rare tumours in the National List of Rare Diseases
- Fund information campaigns for the public and patients by clinical centres in partnership with patient associations
- Examine and redress the factors that penalize centres of excellence on rare tumours
- Introduce measures for funding networks providing cooperative care on rare tumours and networks of clinical services
- Include rare tumours in the activities of the Regional Oncology Networks
- Study ways to enhance the cooperative group infrastructure for clinical research on rare tumours
- Extend NHS coverage to drugs having different AIC in selected "non-profit" clinical trials on rare tumours
- Study the peculiarities of rare tumours with regard to Health Technology Assessment
- Envisage coverage by the NHS of drugs that are potentially useful in "very rare" tumours in "compassionate" use or in ordinary clinical practice at specialized centres in accordance with precise rules.

Table 3.6 **TREATMENT PATHWAY FOR ONCOLOGY PATIENTS**

ONCOLOGY - HEMATOLOGY

Action Plan for 2010 – 2012

- Implement regional networks for providing expensive and/or complex diagnostic activities in highly specialized diagnostic units;
- Review adequacy of healthcare delivery in terms of acute hospital beds;
- Coordinate regional and national networks;
- Rationalize distribution of centres for allogeneic CSE transplantation;
- Make sure that day hospitals and outpatient clinics are efficiently distributed across the territory and enhance them as may be required
- Greater integration of hematology and local medical facilities for organizing homecare services;
- Improve coordination with volunteer organizations;
- Rationalize training courses aimed also at ensuring closer integration among different operators also through innovative means like e-learning platforms.

Table 4.1 **TECHNOLOGICAL TURNOVER OF EQUIPMENT – PATHOLOGICAL ANATOMY**

Action Plan for 2010 – 2012

- Harmonize the pathological anatomy services across the National territory by using:

  - Immune histochemical panels for characterizieng neoplasias of special interest

  - Immune histochemical panels for identifying predictive markers

  - Gene amplification studies by means of CISH/FISH/SISH in specific neoplasias

  - In situ hybridization for research on viral infections

- Diffusion of online teleconsultation technology
- Centralization of highly specialized treatment at National level or at Pathological Anatomy units of excellence

Table 4.2.1 **TECHNOLOGICAL TURNOVER OF EQUIPMENT – IMAGING DIAGNOSTIC SYSTEMS**

RADIOLOGY-NEURORADIOLOGY

Action Plan for 2010 – 2012

- Provide incentives to scrap (replace) traditional analogue radiology technology and replace it with direct digital technology useful for dose-patient reduction and indispensable for the RIS and PACS systems
- Provide incentives to scrap (replace) analogue systems with digital mammographic instruments so as to construct local and regional/national PACS networks
- Install PACS systems and construct regional/national vast area networks integrated with IT patient-databases
- Update the CT and MRI technology park taking into account Regional imbalances in the distribution of such devices, also considering the possibility of having recourse to outsourcing
- Implement hybrid radiology-nuclear medicine (PET-CT) technology with special attention to the development of professional profiles (training) and adequate resources also with a view to having single diagnostic sessions which would include CT with c.m. and PET/PET-CT so as to reduce doses for patients and save resources for the NHS

Table 4.2.2 **TECHNOLOGICAL TURNOVER OF EQUIPMENT**

DIAGNOSTICA PER IMMAGINI - NUCLEAR MEDICINE

Action Plan for 2010 – 2012

- Update the PET-TC technological park paying attention to differences in regional distributions
- Implement hybrid technology (see above)
- Implement – update – regulate technology correlated to the production of radiology drugs and to their distribution
- Expand and activate radio-metabolic therapy techniques

Table 4.3 **TECHNOLOGICAL TURNOVER OF EQUIPMENT**

GASTROENTEROLOGICAL ENDOSCOPY

Action Plan for 2010 – 2012

- **Acquisition of numerical and qualitative data**

It is hoped that the Memorandum of Understanding between FISMAD and the Ministry of Health is renewed and that management data collection is extended to outpatient services. Moreover, the creation of a database network accessible in real time appears to be the best suited instrument for monitoring activities and planning interventions. Quality parameters will include appropriateness, diagnostic/therapeutic outcome and complication rate. The feasibility of the project will be assessed by the Ministry

- **Technological upgrading**

Scrapping the optical instruments, eco-endoscopy and implementation of safety requirements for the endoscopy units are the modernization priorities. For eco-endoscopy it is hoped that a limited network of eco-endoscopic centres having high technological and professional content will be created

- **Training and re-training**

Endoscopic training with its specific program and periodical and final assessments must be part of the curriculum of Gastroenterology and Digestive Endoscopy Specialization schools. Re-training must be promoted and certified.

- **Deep sedation**

Access to adequate sedation is crucial with a view to the efficiency of endoscopic practice in oncology (screening, diagnosis therapy) but also for the humanization of healthcare. In line with the evidence available in the literature and following the experience of other European Countries, the possibility of allowing gastroenterologists to deliver deep sedation also in the absence of the anaesthesiologist will be assessed and coded.

- **New management with GPs**

With respect to the general policy of the Ministry of Health aimed at greater involvement of GPs in the diagnostic and therapeutic process, digestive endoscopy already uses an open access endoscopy system thanks to which the GPs are aware of when to refer symptomatic patients, and in particular those in which there is suspicion of digestive cancer, for

endoscopic tests. Actions are to be taken to improve the knowledge of GPs about the guidelines on appropriateness of indications and about compliance with criteria for urgent requests. They should be involved with a view to verifying the compliance of patients with the regional programs offered but also opportunistic individual screening with the ensuing information report to the Region. In addition, the GPs should prompt the awareness of close relatives of individuals having cancer about a more aggressive type of screening (colonoscopy or CT-colonography).

- **Certification of workers and of facilities**

The Regions, the ASLs and the Hospitals, each for their specific area of competence, should certify workers and facilities for screening colorectal cancer by making specific reference to minimum quality requirements indicated by the National Screening Observatory.

Table 4.4 **TECHNOLOGICAL TURNOVER OF EQUIPMENT**

ONCOLOGICAL SURGERY

Action Plan for 2010 - 2012

- Exploration and technological adaptation of i.o procedures of documented efficacy (e.g ultrasound etc)
- Implementing mini-invasive oncology surgery in sectors with recognized scientific evidence by activating specific programs (e.g. colorectal cancer) under national coordination and broken down by Regions
- Exploration of qualitative and quantitative activities and rationalization of the use of highly complex /high cost technology by activating specific research protocols (robotic surgery)
- Specific training program for the above technologies delivered on regional basis / scientific societies of reference
- Creation of a regional / National register of oncology surgery outcomes or participation in a similar European program
- Identification of dedicated facilities on regional basis where highly complex surgery can be concentrated (oncology centres, IRCCS (teaching and research hospitals), universities, centres of excellence)
- Reorganizing and including oncology surgery in integrated care delivery units set up to cope with clinical problems and with the goal of managing the entire care delivery process of the patient in close relationship with basic and translational research.

Table 4.5 **TECHNOLOGICAL TURNOVER OF EQUIPMENT - RADIOTHERAPY**

Action Plan for 2010 - 2012

- Replace equipment with equipment capable of delivering “targeted” therapy which spares healthy tissues such as IGRT,IMRT,VMAT and tomotherapy (currently available only in few Italian centres)
- Operating Adrotherapy equipment to treat patients with protons and ions
- Deliver combinations of radio-chemotherapy for an increasing number of neoplastic disorders
- Provide beds for ordinary and day hospitals

TABLE 5.1 **INNOVATION IN ONCOLOGY - BIOBANKS**

Action Plan for 2010 - 2012

	QUARTERS											
GOALS	**I 10**	**II 10**	**III 10**	**IV 10**	**I 11**	**II 11**	**III 11**	**IV 11**	**I 12**	**II 12**	**III 12**	**IV 12**
Census of existing biobanks and inventory of its stores of biological material	■	■	■	■								
Regulation of the way in which neoplastic cells and tissues are collected and stored	■	■	■	■								
Definition of the elements of the National oncological biobank network			■	■								
Definition of a network governance system	■	■	■	■								
Development of research programmes shared by different biobanks					■	■	■	■	■	■	■	■
Development of ad hoc clinical trials									■	■	■	■

Tabella 5.2 **INNOVATION IN ONCOLOGY – MOLECULAR MEDICINE**

Action Plan for 2010 - 2012

- Develop and code, in the form of guidelines, a bio-molecular classification of tumours to complement traditional histopathology
- Use information from Molecular Epidemiology for estimating the risk of cancer among given sub-groups (having known genetic and/or environmental risk factors) and individuals with familiarity for tumour forms so as to define:
  a) appropriately targeted screening plans

  b) prevention interventions

- Define monitoring systems and evidence-based predictors (biomarkers) for promoting the appropriate use of new targeted anti-tumour drugs that have a predefined mechanism
- Develop molecular imaging systems as intermediate endpoints for early monitoring of the response to new drugs going beyond the traditional criteria (RECIST) that are not suited to personalized therapy
- Define NETWORKS of operational/management models to reach the goals of economies of scale in introducing molecular diagnostics of tumours and appropriateness in introducing new anti-tumour therapies and having them recognized by the NHS

Table 5.3 **INNOVATION IN ONCOLOGY**

CELL THERAPY AND HEMATOPOIETIC STEM CELL (HSC) TANSPLANTATION

Action Plan for 2010 – 2012

- Rationalization of research and clinical activity aimed at improving the overall quality of treatment
  - From 1/1/2012 the CSE transplantation centres will receive accreditation and will be able to carry out clinical activities reimbursed by the NHS if they are JACIE certified;
  - Simplification of procedures for the issuing of authorization for starting cell therapy studies, without prejudice to the fact that products for CT programs can be used only if generated in AIFA-certified GMP facilities and in any case in compliance with existing legislation
- Coordination and monitoring of cell therapy clinical programs by the competent authorities (AIFA, ISS, CNT) in conjunction with the scientific societies of reference for those sectors
- Creation of a web site-platform to be used by professionals involved in care delivery/research (and by citizens), containing information on clinical CT and HSC transplantation programs available in Italy
  - Improve the exchange of information between Research Institutes and Scientific Societies
  - Facilitate the enrolment of patients in the clinical research programs
- Support, through targeted funding, for Research Institutes/Scientific Societies that carry out programs that may have a clinical impact

Table 5.4 **INNOVATION IN ONCOLOGY – THE ONCOLOGY NETWORK**

Action Plan for 2010 – 2012

- Define the healthcare pathways planned for the main disorders and clinical situations
- Ensure management of patients throughout the healthcare delivery pathway
- Ensure the multidisciplinary nature of the care through the setting up of specific groups per disorder
- Facilitate the enrolment of patients in clinical research programs
- Promote the creation of infrastructure designed for clinical research (for instance biobanks)
- Ensure equal access to oncology treatment for all patients
- Define the same treatment pathways for specific oncology disorders (clinical pathways or PDTA)
- Develop organizational models aimed at optimizing coordination and integration of oncology, rehabilitation and palliative care pathways in accordance with the needs expressed by the patients
- Test new management systems based on payment for treatment pathways rather than payment for individual service
- Define a shared platform of information about the patient available to institutions / professional figures involved in care delivery: IT systems, digital patient records, guidelines, disease registers, etc.
- Enhance operational volunteer resources in hospitals and in the community
- Create a network of regional oncology networks, networks of networks, governed by the Ministry of Health

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Table 5.5 **INNOVATION IN ONCOLOGY - CLINICAL RESEARCH**

Action Plan for 2010 - 2012

- Update the regulations concerning minimum requirements for clinical centres involved in Phase I trials
- Support (scientific, regulatory, economic and training) for the establishment of clinical centres dedicated to "early phase" clinical studies
- Simplification of procedures for issuing authorizations for starting clinical trials
- Checking and reorganizing the current network of Ethics Committees as regards clinical trials on drugs
- Creation of networks by therapeutic area for carrying out multicentre clinical trials
- E-Submission project for the digital management (through the National Observatory on Clinical Trials) of all procedures related to the execution of clinical trials (request for the opinion of the Ethics Committee, authorizations, the issuing of opinions to promoters, start of clinical trial, conclusion of clinical trial, forwarding of final reports)

Table 5.6 **INNOVATION IN ONCOLOGY**
NEW DRUGS IN ONCOLOGY
Action Plan for 2010 – 2012

Pre-marketing

- Enhancing and stimulating research carried out in Italy through flexibility and constant updating of all research-related decision-making, scientific and administrative processes
- Contribution to implementing early stage clinical research
- Scientific support for assessing Phase I Trials, with special reference to biotechnological research (gene, cell therapy)
- Development of specific targets that are predictive of responses/resistance for selecting patients for new high cost therapies
- Definition of the issue of so-called "rare" tumours

Post-marketing

- Enhancement of monitoring mechanisms for newly marketed drugs
- Identification of the best strategies for negotiating costs with the pharmaceutical industries
- Creation of a National Network of oncology operators through which they can receive feedback in real time on the results of all the efforts made to monitor recently marketed drugs

Table 7.1 **COMMUNICATION**

Action Plan for 2010 - 2012

<table>
<tr><th colspan="2"></th><th>2010</th><th>2011</th><th>2012</th></tr>
<tr><td rowspan="5">General Population</td><td rowspan="5">Primary prevention</td><td>Communication campaign against smoking</td><td>Communication campaign against smoking</td><td>Communication campaign against smoking</td></tr>
<tr><td>Communication campaign against alcohol abuse</td><td>Communication campaign against alcohol abuse</td><td>Communication campaign against alcohol abuse</td></tr>
<tr><td>Campaign promoting healthy lifestyles</td><td>Campaign promoting healthy lifestyles</td><td>Campaign promoting healthy lifestyles</td></tr>
<tr><td>“Health Day” to raise people’s awareness on healthy food and physical activity ”</td><td></td><td></td></tr>
<tr><td></td><td>Campaign for the prevention of melanomas</td><td rowspan="3">Communication campaign on tumour prevention
(primary and secondary prevention)</td><td></td></tr>
<tr><td rowspan="2">Individuals at risk</td><td rowspan="2">Secondary prevention</td><td>Campaign promoting oncology screening
- Breast cancer
- Cervical cancer
- Colorectal cancer</td><td>Campaign promoting oncology screening
- Breast cancer
- Cervical cancer
- Colorectal cancer</td><td rowspan="2"></td></tr>
<tr><td>Campaign promoting HPV vaccination</td><td></td></tr>
</table>

Pazienti oncologici **Associazioni volontariato**	Celebration of the national oncological patient day	Celebration of the national oncological patient day	Celebration of the national oncological patient day