THE PONTIFICAL ACADEMY OF SCIENCES

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Statement of the Conference on "Strategies to decrease inequalities in cancer therapeutics/care and prevention"

A Conference organised by the Pontifical Academy of Sciences and the European Academy of Cancer Sciences, February 23-24, 2023 at the Casina Pio IV, The Vatican.

Abstract

- Cancer prevention and therapeutics/care show important disparities between and within countries.
- Health disparities need to be better understood because they tend to be associated with other economic trends (e.g., access to information that decreases risk factors and fosters behaviours to face risk awareness).
- Interactions among important policy actions, including the EU Mission on Cancer, Europe's Beating Cancer Plan, the US Cancer Moonshot by the National Cancer Institute, and cancer-related programs in the Global South, need to be integrated and strengthened to implement comprehensive translational cancer research. The development of innovation ecosystems and policies integrating social needs require international support. Capacity building of national health systems and local research and industrial production capacity must be bolstered.
- International development funds should consider capacity building in cancer research and infrastructures with incentives for innovation and collaboration.
- We must reduce and overcome inequalities resulting from lack of affordability.
- Inequalities in cancer care and treatment require addressing ethical and moral issues.
- The pharmaceutical and medical device industry is critical in the cancer research continuum and is pivotal in developing and testing new drugs and technologies.
- Clinical trials should include re-purposed drugs and agents against tumor promoting conditions such as chronic inflammation.
- Pharmaceutical/medical device firms should play an active role in reducing inequalities.
- New innovative treatments for cancer are possible because of basic biological and technological research but translational and clinical studies need to be integrated.
- Developing capacity in translational and clinical cancer research nationally and internationally is a prerequisite for implementing personalized/precision cancer medicine and limiting inequalities within and between countries.
- Sharing technological resources and patient data will stimulate other research activities focusing on health-related quality of life, like rehabilitation, psycho-oncology, supportive care, survivorship, palliative care and end-of-life care.
- Data sharing and critical mass are essential for innovative research to develop personalized/precision cancer medicine. These will steadily increase, posing a challenge for the future.
- The involvement of patient representatives in structuring translational cancer research should have a high priority.
- Advanced teaching and education are key to increasing innovation and mitigating inequalities.

The background

The conference explored the impact of inequalities in cancer, as cancer is a global problem whose incidence and outcomes are adversely affected by socio-economic and political structures within and across countries. In recent years, analyses of inequalities related to cancer therapeutic/care and prevention have shown important disparities between and within countries, including high-income countries, in addition to low- and middle-income countries. The conference explored how to overcome disparities despite the marked differences in income between countries, with an emphasis on the role of integrated cancer research, care and prevention ecosystems.

Part I – General Recommendation:

1. Cancer prevention and therapeutics/care show important disparities between and within countries, and this needs to be addressed. In the last few decades, the impressive development of basic and technological research has offered unexpected clinical/prevention research opportunities. Still, translating discoveries into cancer therapeutics/care and prevention is severely hindered by a lack of integration with clinical and prevention research necessary to develop personalized/precision cancer medicine for all. Health disparities require better understanding because they are associated with other economic gradients (e.g., access to information that decreases risk factors and foster behaviours to face risk awareness). If countermeasures are not taken, inequalities will further increase disparities in access to innovations in anticancer opportunities. For example, bringing new technologies for the early detection of cancer using biomarkers to low- and middle-income countries is becoming increasingly important. Likewise, liquid biopsies should be used to monitor cancer progression and therapy efficacy.

Part II – Specific Recommendations for Policy Makers:

2. Interactions among important policy actions, including the EU Mission on Cancer, Europe's Beating Cancer Plan, the US Cancer Moonshot by the National Cancer Institute, and cancer-related programs in the Global South, need strengthening to implement comprehensive translational cancer research. The initiatives by the USA and EU offer opportunities for cooperation at scale, and both should seek opportunities for global reach, including low- and middle-income countries. Healthcare, however, is not a competence within the domain of the EU, so the European Commission and Member States should align their priorities and policies to ensure that health expectations are delivered. In contrast, health research is a shared competence of the EU and the Member States, with the European Research Area and comprehensive programs such as the Missions. Nevertheless, to reach the necessary critical mass, a landscape of inclusive international research collaborations must be developed, including sharing advanced infrastructures and patients' data. This might require revisiting the EU General Data Protection Regulation (GDPR). The cancer research and action communities worldwide must strengthen their science policy activities to inform decision-makers and civil society of the benefits that international collaborative research will bring to well-being and national economies.

Potential incentives and instruments to diminish inequalities through innovation may include:

a) Fostering the use of "prizes" oriented towards reducing inequalities (in addition to those based on scientific or technical merit) to complement traditional incentives for innovation;

b) Regulatory frameworks that will encourage pharmaceutical firms to alleviate inequalities in access to drugs;

c) Adopting "advanced market commitments" at national and international levels (e.g., EU), under which governments commit to invest in translational research and/or guarantee

reimbursement for a certain volume of a therapy that does not yet exist if market prospects are limited for some indications;

d) Exploring alternative production methods and promoting local production for access to health technologies and medicines. Governments must support strategic projects to establish these.

e) Promoting funding instruments and mechanisms which have appropriate representation of short-term projects (e.g., ERC and similar institutions) and the long-term programs typically needed for translational programs, for the different stages of the translational continuum from fundamental to implementation research, as well as for the different components of therapeutic/care research and prevention.

f) Considering the potential impact of new technology on increasing cancer inequalities as the new technology is being developed, and taking effective measures to reduce the likelihood of this happening.

3. Inequalities resulting from lack of affordability must be reduced and overcome. Well-equipped cancer treatment centres with expert personnel offering high-quality multidisciplinary cancer care are prerequisites in all countries; this shall be the vision for all nations and peoples. However, low- and middle-income countries require support for collaborative actions to reap substantial benefits from even relatively modest, dedicated cancer treatment centres with good diagnostics, radiotherapy, surgery, and adequate access to a subset of cancer medicines with proven effectiveness, which is likely easier to put in place. Complemented with legislation (including restricting access to tobacco; and differential patenting to avoid patent protection in those countries), public cancer awareness programs, screening for early detection and active prevention (HPV vaccination), this could lead to substantial improvements. Affordability plays a critical role, including information on clinical effectiveness, health economics and the pricing of drugs. International development funds should promote capacity building in cancer research and establishment of the necessary infrastructures, as well as provide incentives for innovation and collaboration. Moreover, new treatments, like chimeric antigen receptor (CAR) T cell therapy and bispecific antibodies, are changing the paradigm in hematologic malignancies, but inequities in access are immense. The high costs of these therapies will play a role in the sustainability of many healthcare systems. Therefore, efforts are needed to address and eliminate these disparities, especially for minorities and those in low- and middle-income countries.

4. Inequalities in cancer care and treatment require addressing ethical and moral issues. The fight against poverty and increasing inequalities in access to cancer care and prevention deserve much more attention in terms of research and innovation efforts, coupled with funding and policies across the translational cancer research continuum. We must actively foster sustainable, healthy environments, not simply accept the implicit moral and ethical failures that result from these inequalities today. Putting those on the margins of our societies at the centre of our actions when advancing cancer research and care/prevention should be a global priority. This requires international support for developing innovation ecosystems and policies integrating social needs, capacity building of national health systems and strengthening local research and industrial production capacity. From a humanitarian point of view, it is important to involve all cancer patients, with specific attention to the Global South (Africa, Asia, and South America), where poverty and population growth in the coming decades could aggravate unequal access to cancer care and prevention. From an innovation point of view, international collaboration based on sharing patients' data, biological materials, technological resources and competencies is necessary for optimizing research for prevention and therapeutics/care.

Part III – Specific Recommendations for Pharmaceutical Industry:

5. The pharmaceutical and medical device industry is a critical partner in the cancer research continuum and is pivotal in developing and testing new drugs and technologies. Pharmaceutical firms should play an active part in reducing inequalities to drug access, including pricing policy. In addition, academia and pharma have to take responsibility for a complete drug development process (which is not the case today), facilitate rapid testing of single agents, evaluate combination therapies, and find ways to secure patient affordability. Similar arguments apply to health technologies. Fair but societally acceptable returns are also motivated by the notion that innovations come from academia with support from public funding. The latter also holds for individual investigators starting up new companies. In the long run, revisiting patent laws to remove counterproductive incentives is desirable. These may include adopting regulatory frameworks based on "differential patenting" for developing countries so that treatments would not be subject to patent protection in those countries. This also applies to the data industry, producers of medical devices and academia and the arrangements between them.

Part IV – Specific Recommendations for Health, Academic and Research Leaders:

6. Basic biological and technological research drives innovative translational cancer research for therapeutics/care and prevention but must be better integrated with clinical research endeavours. The research agenda should aim to decrease cancer incidence through prevention and by increasing cure rates through improved cancer screening as well as better treatment to reduce cancer deaths and avoid burdening healthcare systems by making cancer a chronic disease. Increasing attention should be paid to preclinical research to improve the coherence of the research continuum for translational cancer research. In addition, more interactions are needed between basic and clinical researchers to prioritize and prepare for the effective development of proof of concept clinical trials and prevention strategies. Translational research is bidirectional. With expanding technologies, extensive analyses are possible e.g., fine-needle and liquid biopsies or novel imaging techniques from patients during treatment offering opportunities for bed to bench translational research. Further, the final segments of the drug development and medical device and technologies research, including implementation research and integration of health-related quality of life research, need more support, as do outcomes and health economics research. The costs of cancer therapeutics/care are increasing due to treatment with expensive anticancer agents. Integration of outcomes and health economics research makes assessments of clinical effectiveness and cost-effectiveness possible with tools for prioritization by the healthcare systems.

7. Structuring translational and clinical cancer research nationally is a prerequisite for implementing personalized/precision cancer medicine and limiting inequalities within countries. Translational research has to cover all cancer therapeutics/care and prevention components. Integration with healthcare is essential, and Comprehensive Cancer Centers (CCCs) should be responsible for orchestrating multidisciplinary cancer therapeutics/care, reaching out to areas with several million inhabitants. Quality of care and innovation through research are two sides of the same coin. Moving towards personalized/precision cancer medicine, requires complex infrastructures for molecular pathology, genomics and advanced imaging enabling clinical trials with molecularly stratified patients. These infrastructures are presently only available in advanced cancer research centres, and today most patients are diagnosed and treated outside such centres. New forms of collaboration with centralized molecular pathology directing treatment of patients where they live can increase innovation and at the same time mitigate inequalities.

8. Sharing technological resources and patient data will stimulate other research activities focusing on health-related quality of life, like rehabilitation, psycho-oncology, survivorship, and supportive and palliative care. CCCs should establish clinical cancer registries for all their patients. This will enable outcomes research to assess the clinical effectiveness of therapeutics/care. Proper integration/exchange with national and international registries can enhance their utility. Health economics research to evaluate cost-effectiveness based on outcomes data provides important information for prioritization. Furthermore, concerted actions and an open registry initiated by the Mission on Cancer and Europe's Beating Cancer Plan can pave the way for mitigating economic and social inequalities in low- and middle-income countries with less-developed health systems. In the long run, these efforts will also ensure that science-driven and social innovations reach patients across the healthcare systems. They need to be complemented by the social appreciation of cancer research and care, and this requires further promoting science awareness and science education for all.

9. Data sharing and critical mass are required for innovative research to develop personalized/precision cancer medicine. The amount of data will steadily increase, posing a challenge for preserving and sharing these in the future. The number of patients needed, the biological diversity of tumours and normal samples, the fast-rising amount of clinical and biological information, and the rapidly growing portfolio of medical and technological therapeutic approaches require increasingly sophisticated infrastructures and highly specialized staff to conduct research aimed at personalized/precision cancer medicine, including data handling and processing. The digitalization of the cancer research continuum is already becoming a reality, from digital pathology to digital outcome research. International collaboration based on sharing patient data and referring patients to specialized services with the necessary resources and technological competencies is required to optimize prevention and therapeutics/care research. In addition, promoting open access to new knowledge through "digital observatories" of cancer research and care should be prioritised.

10. Broadening the information base in line with populations' genomic diversity

It is important to prioritize the inclusion of a wider diversity of genomes in genomic databases to translate precision medicine research into practice in different populations. Most studies contributing to this knowledge are based on populations of European ancestry, providing a reasonable genetic representation of individuals of European origin but a poor representation of other ethnic groups. The underrepresentation of non-European populations in genomic databases is problematic because it may miss gene-disease relationships for which the exposure or outcome is rare in European people. Furthermore, it limits the generalizability of findings from genomic research and its translation into clinical care in diverse populations.

11. Involvement of patient representatives in structuring translational cancer research should have a high priority. By definition, translational cancer research, a coherent cancer research continuum, is aimed at patients' health problems and individuals at risk. In addition, the patients' experiences are fundamental for cancer therapeutics/care, with health-related quality of life as an important endpoint. With this background, patient representatives need to collaborate more directly with decision-makers for cancer therapeutics/care and research. They are often participants in the leadership of funding agencies, CCCs and major research programs and involved in the prioritization, planning and execution of research projects. EACS has a patient representative on the Board. The involvement of patients guarantees that high-quality multidisciplinary cancer care is the goal of a CCC and that translational research, also for prevention, has a strong focus on prioritized research areas of relevance for patients and individuals at risk.

12. Advanced education and research are key to increasing innovation and mitigating inequalities and demands for improved research career paths. Education must promote the integration of basic, preclinical and early clinical/prevention research to enhance the link between basic and clinical sciences. The education of young researchers should include translational research with a clear focus on patient needs. Attractive MD/PhD programmes should be put in place. Exchange programs for young researchers should be further expanded, thereby contributing to the sustainability of CCCs, which will secure the education of the next-generation of leaders. The success of international cooperation will depend on the career paths at the institutional level in each region/country. The latter will require improving recruitment, rewarding and assessment systems to increase the appreciation and value of research performance beyond scientometry, thus encouraging openness, humanism, collaboration and sharing to increase research quality and impact.

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