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Bratislava Statement: consensus recommendations for improving pancreatic cancer care

Joan Prades ,[1,2] Dirk Arnold,[3,4] Thomas Brunner,[5,6] Antonella Cardone,[7,8] Alfredo Carrato ,[7,9] Cristina Coll-Ortega,[1] Samuel De Luze,[10] Pascal Garel,[11] Maria E Goossens,[12] Roberto Grilli,[13] Meggan Harris,[14] Marleen Louagie,[15] Núria Malats,[7,16] Pamela Minicozzi,[17,18] Stefano Partelli,[19,20] Silvia Pastorekova,[21] Marius Petrulionis,[22,23] Richard Price,[24] Francesco Sclafani ,[25,26] Bozena Smolkova,[21] Josep M Borras [1,27]

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For numbered affiliations see end of article.

Correspondence to
Professor Joan Prades;
jlprades@iconcologia.net

ABSTRACT

Pancreatic cancer is one of the most lethal tumours, and it is the fourth cause of cancer death in Europe. Despite its important public health impact, no effective treatments exist, nor are there high-visibility research efforts to improve care. This alarming situation is emblematic of a larger group of cancer diseases, known as neglected cancers. To address the impact of these diseases, the European Commission-supported Innovative Partnership for Action Against Cancer launched a multi-stakeholder initiative to determine key steps that healthcare systems can rapidly implement to improve their response. A working group comprising 20 representatives from European medical societies, patient associations, cancer plan organisations and other relevant European healthcare stakeholders was organised. A consensus process based on the results of different studies, discussion of research outcomes, and development and endorsement of draft statements resulted in 22 consensus recommendations (the Bratislava Statement). The statement argues that substantial improvements can be achieved in patient outcomes by centralising pancreatic cancer care around state-of-the-art reference centres, staffed by expert multidisciplinary teams capable of providing high-quality care. This organisational model requires a specific care framework encompassing primary, palliative and survivorship care, and a policy environment prioritising the use of quality criteria and performance assessments as well as research investments dedicated to prevention, risk prediction, early detection and diagnosis. In order to address the challenges posed by neglected cancers in general and pancreatic cancer in particular, a specific control strategy tailored to this reality is required.

INTRODUCTION

Pancreatic cancer is one of the most lethal tumours, killing about 92% of patients within 5 years of their diagnosis.[1] It is the fourth cause of cancer death in Europe,[2–5] taking the lives of approximately 128 000 Europeans in 2018, while another 132 600 were diagnosed.[2] This alarming situation is not unique to pancreatic cancer; rather, it is emblematic of a larger group of cancer diseases, which all have an important public health impact but no effective treatments or high-visibility research efforts.

Acknowledging the relevance of this phenomenon, the European Commission-supported Innovative Partnership for Action Against Cancer[6] launched a multi-stakeholder initiative to determine key steps that healthcare systems can rapidly implement to address its impact while maximising the value of healthcare resources. This set the groundwork for prioritising pancreatic cancer as well as other neglected cancers at the national and European level. Neglected cancers are defined as non-rare cancers with moderate incidence (<20 per 100 000 person-year), a high mortality/incidence ratio (≥0.7) and low survival (relative survival ≤40% at 1 year and ≤30% at 3 or 5 years after diagnosis), due to either biological aggressiveness, late diagnosis or lack of effective treatments.[7] In so doing, the European Commission has opened the door to delineating a policy arena concerned specifically with neglected cancers, which—like common and rare cancers—would need to be addressed through a comprehensive strategy.

This initiative (the Bratislava Statement) resulted in consensus recommendations that acknowledge the importance of placing reference centres capable of providing high-quality care on the front lines of managing patients with pancreatic cancer. Reference centres consist of units, hospitals or even provider networks with a specialised multidisciplinary team (MDT).[8] A general breakdown of the rationale for developing the Bratislava Statement is shown in box 1.

The present statement, formulated at the European level, summarises these complementary perspectives, indicating evidence-based institutional policies and measures that

Box 1 Rationale for developing the Bratislava Statement

- Pancreatic cancer is comparably lethal worldwide, with most reported variations in outcome attributable to the quality of data rather than the quality of care.[12] However, in Europe it has a relatively high—and rising—incidence compared with other regions.[13 14] And despite a few improvements in treatment in recent years, mortality remains very high, with survival standing at 8% or less at 5 years. This is mainly due to the advanced stage of most tumours at diagnosis, which in turn stems from the late and non-specific symptomatology and the lack of any effective screening tests.[15]
- Pancreatic surgery plus perioperative therapy (current standard of care: adjuvant chemotherapy) is the only potentially curative treatment, but just 20% of patients—at most—are candidates for this approach.[3 4] Furthermore, pancreatic surgery is among the most technically complex and risky interventions that a patient can undergo.
- Improving the poor prognosis of neglected cancers like pancreatic cancer requires urgent efforts in prevention, risk prediction and early detection, but there is scarce evidence on effective interventions in these areas. Thus, patients' best hope in the short to medium term resides in accessing diagnostic procedures and treatment, provided by experienced healthcare professionals in well-equipped reference centres.[16–18] Such measures require strategic changes in care processes at the healthcare system level, including in the development and implementation of cancer plans. For instance, evidence has increasingly accumulated suggesting that centres performing more surgeries with a curative intent achieve better perioperative outcomes.[19]
- While making changes in the administration of care processes is anything but straightforward, European scientific societies are increasingly calling for just that, supplementing traditional clinical practice guidelines (including from such representative bodies as the European Society for Medical Oncology[20]), with recommendations on the organisation of healthcare services. For example, a prominent group of European surgical oncologists argue that pure market-driven approaches are harmful to both patients and society, and they propose implementing centralisation strategies to improve patient outcomes.[21] These statements have been echoed by numerous pancreatic surgical oncologists.[16 17 22]
- Likewise, and in line with the European health policy principle of developing a multidisciplinary cancer care model,[8] the European CanCer Organisation (ECCO) has launched the 'Essential requirements for quality cancer care' initiative, which highlights the key role of expert MDTs and units in the management of patients with cancer.[10] The health system neglect of pancreatic cancer is so striking, in fact, that a multi-stakeholder platform, Pancreatic Cancer Europe,[23] has been established at European level to advocate for increased research and improvements in all areas of care.

policymakers, professionals and patients can promote and support in their efforts to optimise diagnosis, treatment and research in pancreatic cancer in their respective states and regions.

METHODS

A working group comprising representatives from medical societies, patient associations, cancer plan organisations and other relevant European healthcare stakeholders was organised. In representation of their institutions, participants took part in a consensus process based on the results of different studies, discussion of research outcomes, and development and endorsement of draft statements.

The initial research component comprised two systematic reviews. The first focused on the evidence on existing strategies and policy tools for improving access to expert care for patients with pancreatic cancer,[9] and it identified three overarching health policy strategies used alone or in combination to increase quality of care and patients' access to specialised centres. Strategies included centralisation of pancreatic surgery, external assessment of clinical results, and accreditation of centres and professionals. The second review analysed population-based data on the incidence, mortality and survival of solid cancers, in order to create a list of neglected cancers and quantify their health impact. While the list includes tumours of the gallbladder and biliary tract, stomach, liver, brain and central nervous system, the most representative is pancreatic cancer, as it has the highest mortality/incidence ratio and the lowest survival.[7]

The central discussion took place during a meeting in Bratislava on 16–17 September 2019 and involved high-level representatives from all key stakeholder groups, including four national cancer plan organisations. Five key domains for improving the quality of care and patient access to specialised teams in pancreatic cancer were identified: (a) reorganisation of services and coordination of care; (b) reinforcement of the internal structure of centres, care processes and proven expertise; (c) implementation of external quality assessment and feedback; (d) research; and (e) optimisation of the role of patient organisations, scientific societies and European stakeholders.

The working group formulated an overarching policy statement (the Bratislava Statement) to define critical recommendations for healthcare systems in relation to the implementation of new approaches to improve pancreatic cancer care. The initial draft was then widely circulated among participating professionals and organisations for final approval.

RESULTS

Consensus recommendations for improving pancreatic cancer care

The following recommendations reflect the expert consensus on improving pancreatic cancer care along the five areas (a–e) identified. The first 17 recommendations are targeted specifically to policymakers and healthcare system planners, while the last 5 relate to actions that scientific societies, patient groups and other advocacy organisations can take directly.

A. Reorganisation of pancreatic cancer services and coordination of care

Statement 1. Implement integrated healthcare policies that promote specialisation and put expert MDTs at the centre of the decision-making process.

The complexity of managing and operating on pancreatic cancer, together with its relatively low incidence, justifies

the consolidation of expertise within specialised MDTs or units. Such organisational changes are currently among the most effective interventions for improving patient outcomes and optimising the use of healthcare resources.

Statement 2. Identify reference centres and build around these efficient models of centralised care.

While surgical outcomes and especially surgical volume (pancreatectomies/year) are the most frequently studied measure of quality of care in pancreatic cancer, only a minority of patients undergo resection. Therefore, when identifying the centres providing the best care, a range of other domains should be taken into account, including referral pathways, diagnostic procedures, indications for and administration of medical (systemic) treatments, early integration of palliative care, research output and participation in clinical trials, among others.

Statement 3. Shape national or regional care models to allow alignment with international quality criteria.

Rigorous quality criteria, whether developed by a single health system or adapted from international guidance, are a prerequisite for ensuring high-quality care and should lead to a redistribution of cases towards reference centres. ECCO Essential Requirements for Quality Cancer Care are one set of criteria that recognise the need for a multifaceted perspective, providing national and regional health authorities with a valuable tool to define the characteristics of reference centres.[10]

Statement 4. Create policy levers to ensure the adherence of non-specialised providers to established referral pathways.

Healthcare systems may use different mechanisms to endow expert MDTs with the mandate to lead clinical decision-making processes (eg, designation of providers, minimum surgical volumes, publication of surgical outcomes). However, poor adherence among non-specialised providers to optimal referral pathways can pose challenges to achieving system objectives. Different policy tools can favour effective change: establishing some degree of legal enforcement to consolidate such a policy; incorporating financial incentives and/or disincentives for the centres; and allowing a transition period before full adoption of the policy.

Statement 5. Allocate enough resources to reference centres to support implementation of reorganisation strategies and facilitate an orderly transition of patients between institutions, regions and countries.

Designating reference centres in pancreatic cancer produces a net benefit for both patients (better outcomes) and healthcare systems (more efficient use of resources). However, redirecting patient flows to these centres can also increase the pressure to service providers and introduce geographical access barriers, resulting in patient selection biases, whereby certain patient groups—like those with better health or socioeconomic status—are most likely to have access to specialist care. This can increase the 'financial toxicity' of this cancer for patients. Moreover, newly designated pancreatic cancer care units may not have all the tools or training needed to rapidly align their practices with ever evolving state-of-the-art clinical practice guidelines. To fully take advantage of the potential benefits of this model, healthcare authorities should work to support reference centres to absorb the impacts that these organisational changes produce.

Statement 6. Create and/or strengthen networks between reference centres and other providers in order to improve continuity of care, circulation of knowledge and integration among professionals.

Even if most patients are referred to reference centres, non-specialised hospitals and other providers will continue to play an important role in the clinical management of some patients, for example those presenting to the outpatient clinics or emergency departments of non-reference centres without a confirmed diagnosis of pancreatic cancer, those experiencing tumour-related or treatment-related complications, patients refusing referral (often due to old age or numerous comorbidities), and those who receive follow-up and after-care, including chemotherapy, close to home. Nurturing both formal and informal links between providers with different levels of specialisation can help to ensure better outcomes even for those who are managed in non-reference centres.

Statement 7. Articulate clinical services at all levels of the healthcare system through a network approach, by including primary care, palliative care (eg, home care) and survivorship care, among others, in the organisational framework.

The patient journey does not begin or end in a specialised MDT unit: early diagnosis, quality of care for patients who cannot undergo surgery and the organisation of follow-up remain equally important challenges. Family doctors' awareness and suspicion of pancreatic cancer is crucial for achieving early diagnosis and a subsequently better prognosis, and indeed, primary care has an important parallel role to specialist services throughout the treatment phase and beyond.[11] Outpatient palliative care (eg, home care, pain clinics), survivorship and rehabilitation services can likewise greatly improve patients' quality of life. Incorporating supportive care early in the care process is of special importance. To facilitate the patient journey, a single health professional (such as a general practitioner, nurse or specialist) should be designated as a principal contact to help patients navigate different levels of care and ensure effective communication.

B. Reinforcement of the internal structure of centres, care processes and proven expertise

Statement 8. Equip reference centres with appropriate infrastructures as well as material and technical resources to enable MDTs to effectively perform their mission.

Efficiently reorganising the internal structure of the centre and adopting quality care processes can affect patient outcomes more than merely increasing surgical volume. As laid out by ECCO,[10] outcomes may be

associated, for example, with expert tumour boards, highly specialised resources such as intensive care units and molecular pathology departments, and 24/7 on-call surgery and specialists (including interventional radiologists and endoscopists). Such internal structures also influence centres' ability to anticipate and confidently manage acute and sometimes life-threatening complications.

Statement 9. Capitalise on the opportunities offered by reference centres for developing, accumulating and applying expertise.

Centralised teams that manage highly complex diseases are the natural setting for developing professional skills. The experience acquired by providers in caring for patients with tumours such as pancreatic cancer—in terms of shared utilisation of technology and expert knowledge—could translate into a shared benefit, influencing the outcomes of patients with different profiles and enhancing the learning opportunities for healthcare professionals.

Statement 10. Staff MDT units with specialists from all disciplines who have a role in pancreatic cancer care.

The ECCO Essential Requirements for Quality Cancer Care initiative calls for specialised MDT units to include the core specialties of medical oncology, gastroenterology/endoscopy, pathology, radiology/interventional radiology, surgery, nuclear medicine, radiation oncology, nursing and palliative care. An extended MDT should include professionals from fields such as anaesthesia/intensive care, geriatric oncology, nutrition, oncology pharmacy, psycho-oncology, physiotherapy, genetics, and rehabilitation and survivorship.

Statement 11. Consider implementing formal accreditation systems for centres and professionals.

Accrediting centres and professionals may have a significant impact on the reorganisation of healthcare services in cases where having multidisciplinary clinical units for hepatobiliopancreatic diseases have been identified as a quality criterion. At the same time, professional accreditation of clinical competencies for specialists in pancreatic diseases is also a critical element from a European perspective. Standardising training to the point where expert knowledge and skills are equivalent across countries could facilitate professional exchange and mobility, and benefit geographical areas with scarce or inequitably concentrated expertise.

C. Implementation of external assessment of quality and feedback performance systems

Statement 12. Establish standardised electronic health records systems for pancreatic cancer and maintain high-quality cancer registries to generate and share real-world data.

Standardised reporting with electronic health records can generate valuable epidemiological data. At the same time, cancer registries that include information on outcomes and/or quality measures related to pancreatic cancer are fundamental for illustrating the variability of clinical practice and understanding potential differences in quality between centres. Together, these systems can foster research, enhance transparency and help centres improve the quality of their services.

Statement 13. Use external data assessment to inform organisational changes and quality improvement strategies.

Reference centres should be defined and monitored according to criteria defined at a system level. Evaluation may be based on external clinical audits, population-based cancer registries, clinical follow-up registries and national quality programmes, and these assessments can drive the reorganisation of healthcare systems and treatment centres, including in pancreatic cancer care. Feedback performance systems can complement the set of strategies described here.

Statement 14. Determine and report performance indicators along with patient and surgical volumes, to increase transparency and facilitate decisions on treatment centres.

Transparency around care quality and outcomes for providers treating patients with pancreatic cancer may factor into decisions about referral to the treatment centre or directly into patients' preferences. Existing performance indicators, like surgical volume and outcomes, should be published, even as other indicators capturing information on other domains of care, should be developed and validated at a national level (eg, by the cancer plan or healthcare system).

D. Research

Statement 15. Establish a research agenda for neglected cancers at the European level, using pancreatic cancer as the archetype.

Prioritisation of this area of work by the European Commission should create ripple effects in member states, enabling advances in basic as well as epidemiological, genetic, translational, clinical and healthcare services research. Indeed, only by supporting a comprehensive research agenda can the outcomes of neglected cancers truly improve. Participation by patient groups in shaping and planning this work will be fundamental in aligning knowledge generation with patient needs.

Statement 16. Prioritise research streams and structures dedicated to prevention, risk prediction, early detection and diagnosis, and rapid referral for treatment.

Risk prediction, early diagnosis and appropriate treatment indications in pancreatic cancer remain central challenges for improving survival outcomes. There are still large evidence gaps about which pancreatic lesions are pre-malignant, how high-risk groups should be defined and identified, which diagnostic tests are most accurate, and who would most benefit from screening. Likewise, there is an urgent need to articulate rapid referral pathways for patients presenting with 'red flag' symptoms in different contexts. Investments are needed in both data repositories (eg, biobanks, tissue banks, healthcare services data) and in sustained research programmes.

Statement 17. Foster the design of collaborative research programmes/platforms within reference centres.

Designating reference centres at regional, national and international level can facilitate these centres' leadership in basic, clinical and translational research as well as in professional training. Research programmes should be developed and carried through in collaboration with national and international partners, patient organisations, and other public and private partners with a special interest in pancreatic cancer, and in alignment with a European research agenda.

E. Optimisation of the role of patient organisations, scientific societies and European stakeholders

Statement 18. Engage patient organisations as equal partners in shaping policies based on a holistic vision of the patient journey, from clinical suspicion to diagnosis, treatment, palliation and survivor care.

Patients are the group with the most to gain from centralising care in highly specialised MDT units; however, they are not always informed of the potential for improved clinical and surgical outcomes nor consulted about how such changes would affect them. Empowering patients to play an active role in the reorganisation of care models can avert potential problems associated with logistics (transport, accommodation) and economic burdens related to treatment. Moreover, embedding their perspective in decisions about patient flows within and between care levels is the only way to achieve a truly patient-centred organisational model.

Statement 19. Empower patient representatives to take ownership and leadership in public debates about optimisation of healthcare models.

Policies denominated 'centralisation strategies' may not be well received by the public based on the concern that these would introduce limitations and discrimination in access to care. Because the most powerful advocates for patients are patients, survivors and their loved ones, patient groups are vital partners in building the political momentum necessary to implement evidence-based improvements. In order to do so, they need to be informed and actively involved in public debates.

Statement 20. Develop guidelines that can help healthcare systems align best practices in healthcare, health services organisation and human resource development.

Scientific societies are uniquely situated at the nexus of research, practice and policy; moreover, their diverse membership ensures both depth and breadth to their expertise. These bodies can build on their experience developing clinical practice guidelines in order to set organisational specifications and define professional competencies, providing solid guidance for healthcare authorities, practitioners and educational institutions.

Statement 21. Shape the policy environment in a way that favours investments in research and evidence-based care models.

This can include forming alliances and collaborations between major stakeholders, including patient organisations and scientific societies dedicated to improving neglected cancer care.

Statement 22. Organise national and international awareness campaigns with a special focus on prevention and early diagnosis.

Awareness campaigns can serve a dual purpose in the field of pancreatic cancer: (a) fostering people's recognition of risk factors and early signs and symptoms of the disease in order to favour better primary and secondary prevention, and (b) building public support for prioritising this disease at the health system level.

CONCLUSIONS

Scientific evidence supports the contention that substantial improvements can be achieved in patient outcomes by organising pancreatic cancer care around state-of-the-art reference centres, staffed by expert MDTs. This organisational model requires a specific care framework that encompasses all levels of healthcare services, incorporating quality criteria and performance assessments. While such measures can produce tangible benefits for patients, the biggest promise for improving outcomes lies in research, especially on prevention, risk prediction and early detection. Patient organisations, scientific societies and advocacy groups play a crucial role in the development of patient-centred policies aligned with current research evidence.

Author affiliations
[1]Catalonian Cancer Strategy, Department of Health, Barcelona, Spain
[2]University of Barcelona (IDIBELL), Barcelona, Spain
[3]Med. Onkologie, Tumorzentrum Hamburg, AK Altona, Hamburg, Germany
[4]European Society of Medical Oncology (ESMO), Lugano, Ticino, Switzerland
[5]Department of Radiation Oncology, University of Magdeburg, Magdeburg, Germany
[6]European Society for Radiotherapy & Oncology (ESTRO), Brussels, Belgium
[7]Pancreatic Cancer Europe, Brussels, Belgium
[8]European Cancer Patient Coalition (ECPC), Brussels, Belgium
[9]IRYCIS, CIBERONIC, Madrid, Spain
[10]Institut National du Cancer, Billancourt, Île-de-France, France
[11]European Hospital and Healthcare Federation, Brussels, Belgium
[12]Cancer Centre–OD Public Health and Surveillance, Sciensano, Brussels, Belgium
[13]Azienda USL-IRCCS of Reggio Emilia, Bologna, Italy
[14]Independent Researcher, Valencia, Spain
[15]Belgian National Institute for Health and Disability Insurance, Brussels, Belgium
[16]Spanish National Cancer Research Centre (CNIO), CIBERONC, Madrid, Spain
[17]London School of Hygiene & Tropical Medicine, London, UK
[18]Analytical Epidemiology and Health Impact Unit, Department of Research, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy
[19]Università Vita Salute San Raffaele, Milano, Lombardia, Italy
[20]European Society of Surgical Oncology (ESSO), Brussels, Belgium
[21]Biomedical Research Center, Slovak Academy of Sciences, Bratislava, Slovakia
[22]Vilnius University Hospital Santariskiu Klinikos, Vilnius, Lithuania
[23]Institute of Clinical Medicine, Faculty of Medicine, Vilnius University, Vilnius, Lithuania
[24]The European Cancer Organisation (ECCO), Brussels, Belgium
[25]Department of Medical Oncology, Institut Jules Bordet, Bruxelles, Belgium
[26]European Organisation for Research and Treatment of Cancer (EORTC), Brussels, Belgium
[27]Faculty of Medicine and Health Sciences, University of Barcelona, Barcelona, Catalunya, Spain

Contributors JP—conceptualisation, methodology, investigation, writing the original draft, writing the review, editing and supervision. DA—resources, writing

the review and editing. T—resources, writing the review and editing. AC—resources, writing the review and editing. AC—resources, writing the review and editing. CC-O—resources, writing the review and editing. SDL—resources, writing the review and editing. PG—resources, writing the review and editing. MEG—resources, writing the review and editing. RG—resources, writing the review and editing. MH—writing the original draft, resources, writing the review and editing. ML—resources, writing the review and editing. NM—resources, writing the review and editing. PM—resources, writing the review and editing. SP—resources, writing the review and editing. SP—resources, writing the review and editing. MP—resources, writing the review and editing. RP—resources, writing the review and editing. FS—resources, writing the review and editing. BS—resources, writing the review and editing. JM—conceptualisation, methodology, writing the original draft, writing the review, editing, supervision and project administration.

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ORCID iDs
Joan Prades http://orcid.org/0000-0003-0416-323X
Alfredo Carrato http://orcid.org/0000-0001-7749-8140
Francesco Sclafani http://orcid.org/0000-0003-0251-2627
Josep M Borras http://orcid.org/0000-0001-7330-6308

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