

Patient navigation for early detection, diagnosis and treatment of breast cancer Technical brief



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Monitoring and evaluating a patient navigation programme





Annex 2. Patient navigator resources

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Document preparation

This technical brief is a derivative product of the Global Breast Cancer Initiative (GBCI) Implementation Framework (2023). Through a consultative process, WHO convened a working group of global experts with expertise in breast cancer patient navigation who defined the format, structure, scope and priorities required for this document. The working group was balanced for gender, geographical representation and area of expertise and all contributors were volunteers who underwent WHO-conflict-of-interest review processes. Inputs from people with lived experience and non-state actors were gathered throughout all phases of product development. The working document was collated and edited by the WHO GBCI writing team. The final text was reviewed for content and relevance by a smaller expert group which included staff from WHO headquarters and regional offices.

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Abbreviations

ANM	auxiliary nurse midwives	
ASHA	accredited social health activist	
CBE	clinical breast examination	
СІ	confidence interval	
DHIS	District Health Information System	
FNAB	fine needle aspirate biopsy	
GBCI	Global Breast Cancer Initiative	
іт	information technology	
MDT	multidisciplinary team	
SBCC	social and behavioural change communication	
тим	tumour, node and metastasis	
USG	ultrasonography	

Executive summary

Patient navigation is an effective, evidence-informed intervention that can be incorporated to breast cancer programmes to overcome barriers in accessing health care and social services. This publication is the first technical derivative for the implementation framework of the WHO Global Breast Cancer Initiative (GBCI). The overall objective of this document is to provide guidance to support Member States when considering the establishment of breast cancer navigation programmes. It is intended for use by ministries of health, programme managers, technical and funding partners and other practitioners involved in the implementation of breast cancer programmes.

- The roles and required competencies of patient navigators in terms of the three pillars of the GBCI are described, namely with regards to early detection (educating women about the benefits of screening programme participation as well as available services for evaluation of breast complaints), timely breast diagnostics (assisting with the navigation of multiple levels of a health system to obtain a diagnosis within 60 days) and comprehensive breast cancer management (enabling women to understand and make informed decisions about treatment options and ensuring adherence to treatment).
- Operational considerations that policy-makers should be aware of when developing, implementing, monitoring and evaluating breast cancer patient navigation programmes, including the development of training and professional qualifications for patient navigators, the identification of funding mechanisms and supportive stakeholders and mechanisms to deliver and learn from pilot patient navigation programmes are highlighted.
- Finally, implementation research is introduced as a useful approach for consideration in assessing, adapting and scaling up breast cancer patient navigation programmes. By embedding implementation research within patient navigation programmes, the relevance, uptake and sustainability of such initiatives can be ensured.

This document seeks to provide an understanding of context-specific models, highlighting key considerations and specific examples of best practices for sustainable breast cancer patient navigation services as a model that can be adapted for other major malignancies.



Introduction

Background

In 2022 breast cancer was the most common cancer in women in almost every country (157) in the world. In the same year an estimated 2.3 million women were diagnosed with breast cancer and 670 000 deaths were recorded globally. Breast cancer occurs in every country of the world in women at any age after the onset of puberty and with increasing incidence with age. As the leading or second most common cause of female cancer deaths in most countries, it represents a significant public health concern that no country can overlook (1,2).

Major improvements in breast cancer screening and treatment have been achieved over the past few decades. Between 1990 and 2020 twenty high-income countries (Australia, Belgium, Canada, Cuba, Czechia, Denmark, Estonia, Germany, Ireland, Israel, Italy, Kazakhstan, Netherlands (the Kingdom of the), New Zealand, Norway, Singapore, Sweden, the United Kingdom of Great Britain and Northern Ireland, Ukraine and the United States of America) successfully achieved sustained mean reductions in breast cancer agestandardized mortality rate of at least 2.5% per year for three consecutive years, through increasing levels of coverage of essential health services, dedicating funding for early detection programmes and providing early detection guidelines and referral systems (*3*). In contrast, limited progress has been observed in low- and most other middle-income countries, where high mortality rates persist largely due to lack of awareness regarding the benefits of early detection, late-stage diagnoses and limited access to quality treatment and effective therapies.

GBCI pillars

WHO established the Global Breast Cancer Initiative (GBCI) in 2021 with the aim of reducing age-standardized breast cancer mortality by 2.5% per year over a 20-year period in order to save 2.5 million lives. To achieve this, the GBCI has developed three pillars or key strategies and their associated key performance indicators (4).



Pillar 1: health promotion for early detection (the pre-diagnostic interval) refers to the period before an individual seeks evaluation for a breast complaint or participates in breast cancer early detection programmes, ending with a referral for diagnostic evaluation of breast abnormalities. Also known as the patient interval, a decision to seek consultation for screening or review of a symptomatic lesion is dependent on the patient's understanding of the disease, as well as social determinants of health. The key performance indicator for this interval is for at least 60% of all diagnosed breast cancers to be at stage I or II.



Pillar 2: timely breast diagnostics (the diagnostic interval) represents the intermediate period between referral of symptomatic women or women with a positive screening examination result for a diagnosis and the time taken to reach a definitive diagnosis. The GBCI aims for a diagnostic evaluation that includes a clinical breast examination (CBE), imaging, tissue sampling and pathology to be conducted within 60 days of referral.



Pillar 3: comprehensive breast cancer management (the treatment interval) requires treatment for a patient from a multidisciplinary team (MDT) that may include surgery, radiation, chemotherapy and targeted therapy. The aim is for 80% or more of women with invasive breast cancer to undergo and complete multimodality treatment without abandonment.

The nature and delivery of services across the care continuum necessitates interaction of patients with multiple service providers. Transitional care between settings such as home and hospital sectors may be challenging to navigate; patient navigation programmes are specifically designed to overcome such challenges (5).

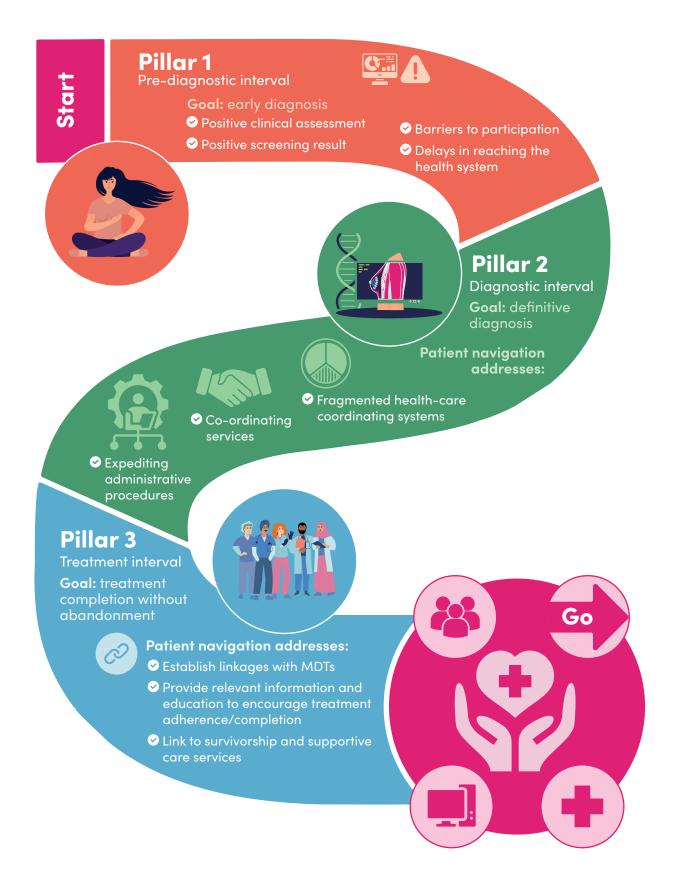
Patient navigation

Historically, cancer disproportionately affects those of lower socioeconomic status as well as other marginalized and vulnerable populations who may experience inequalities in access, lower-quality health care and higher mortality (1). Patient navigation is a strategy that aims to overcome individual- and system-level barriers to the timely diagnosis and treatment of cancer and other chronic disease conditions. It has been demonstrated that the implementation of such a mechanism can be useful in enabling and empowering women to receive appropriate and timely breast cancer care.

Fig. 1 describes how patient navigation can be utilized across all three GBCI pillars for early detection, timely diagnosis and treatment adherence. Patient navigators can identify and address a range of domains (**Fig. 2**): individual-level barriers to accessing care in a culturally safe and sensitive manner; and contextual-level barriers including health system, geographical, cultural and sociodemographic. The mechanism can assist in the development of specific solutions to the challenges of different health systems and cultures, as well as across different levels of literacy and socioeconomic status. Patient navigation aims to facilitate timely access to health-care services to enable and empower women to access required information and services at cancer centres, while incorporating support for both patients and caregivers and the promotion of healing. Finally, a patient navigator will follow an individual until a specific end-point is reached or realized (*5,6*).

Cancer patient navigation programmes have been shown to be effective across the cancer care continuum (related to the three GBCI pillars) (6) and a systematic review has demonstrated their efficacy and cost–effectiveness (7). Chan et al. (6) conducted an overview of published research, identified and critically appraised 61 systematic reviews published between 2012 and 2022, as well as 53 primary studies published since 2021. This overview considered that evidence of the effectiveness of patient navigation was strong for outcomes for which multiple reviews and multiple primary studies reported corresponding positive findings; inconclusive for outcomes for which reviews and primary studies reported conflicting findings; and limited for outcomes that were only included in only one systematic review or a small number of primary studies. **Table 1** summarizes these findings, illustrating how the GBCI pillars relate to the general cancer continuum; please see the overview itself for details of the individual publications reviewed (6).

Fig. 1. Patient navigation and the three pillars of the GBCI breast cancer patient care pathway



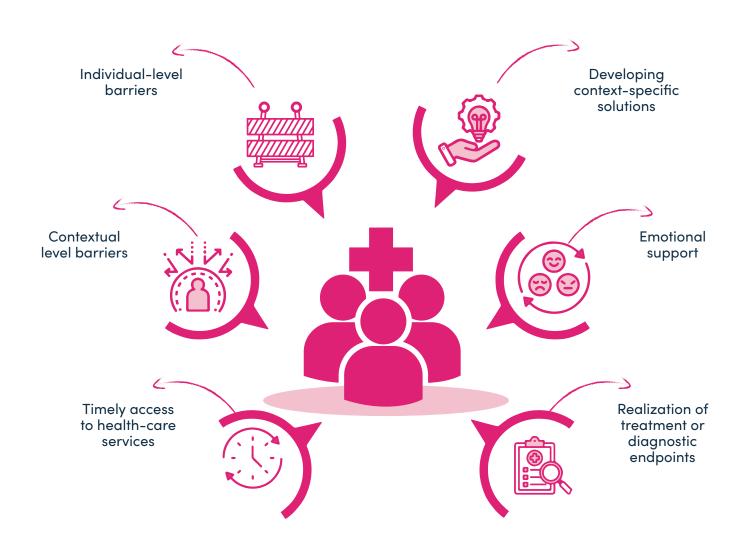


Fig. 2. Some domains addressed by patient navigation

Table 1. Strength of evidence for the effectiveness of patient navigation across the cancer continuum

Primary outcome (GBCI pillar)	Stren	ngth of evidence		
Early detection (pillar 1)				
Cancer screening rates	5	Strong evidence that patient navigation improves rates of cancer screening		
Diagnosis (pillar 2)				
Diagnostic resolution	5	Strong evidence that patient navigation reduces the time to diagnosis		
Treatment (pillar 3)				
Treatment initiation	5	Some evidence that patient navigation reduces the time from diagnosis to initiation of primary treatment		
Treatment completion	53	Evidence is inconclusive on the impact of patient navigation on treatment completion ^a		
Hospital readmission	5	Strong evidence that patient navigation reduces hospital readmissions		
Enrolment and adherence to clinical trials	5	Limited evidence that patient navigation improves clinical trial enrolment and adherence		
Survivorship (pillar 3)				
Adherence to surveillance	53	Strong evidence that patient navigation increases adherence to surveillance appointments		
Decision-making and treatment knowledge	5	Strong evidence that patient navigation improves the decision-making and treatment knowledge of cancer survivors		
Return to work	5	Evidence is inconclusive on the impact of patient navigation on return to work		
Communication	5	Limited evidence that patient navigation improves communication		
Fatigue	5	Limited evidence that patient navigation reduces cancer-related fatigue		
Patient satisfaction	5	Strong evidence that patient navigation improves patient satisfaction with care		
Quality of life (QoL)	5	Strong evidence that patient navigation improves cancer survivor quality of life		
Emotional distress	5	Evidence is inconclusive on the impact of patient navigation on emotional distress		

[°] Further research is required.

Source: adapted from Chan et al (6) licenced under CC BY by the GBCI.

Scope of this document

The aim of this technical brief is to make breast cancer programme managers aware of the importance of patient navigation for breast cancer services and advocate the professionalization of patient navigators. It provides breast cancer programme managers with guidance on establishing patient navigation services as a cost-effective, efficient, evidence-informed intervention that can help to facilitate timely diagnosis and enable treatment completion; a crucial component of the patient experience.

In the following section, the roles and competences of patient navigators are described in terms of the three GBCI pillars. The key features of developing and implementing a patient navigation programme are highlighted in the next. Monitoring and evaluating health-care programmes is key to achieving an effective and efficient service and are outlined in the context of patient navigation systems in the subsequent section, followed by a discussion of implementation research, which is the application of findings from monitoring and evaluation with regards to patient navigation. This technical brief concludes with a summary of the main points discussed.



The role of patient navigators

The role of a patient navigator is to enable "timely movement of the individual patient through an often complex and fragmented health-care system. Patient navigators can also serve to connect systems of care for individual patients by applying the core function of navigation, which is the elimination of barriers to timely care across all segments of the health care continuum" (8).

Such a role may be fulfilled by health-care staff such as nurses, medical officers or social workers or non-clinical supporters such as cancer survivors, community health workers, volunteers or educators. Patient navigators typically work with qualified health professionals, who may already be performing navigating functions as a component of their role. Although patient navigation services can be delivered by various personnel, the roles of a patient navigator must be clearly defined to meet the expected outcomes, and each navigator must be empowered with the required skills and competencies. These roles and the required skills in terms of the three GBCI pillars are summarized in **Table 2** (*9–16*) and discussed in further detail in the following sections.

Table 2. Patient navigator roles, competencies and outcomes by GBCI pillar

Roles	Competencies							
All GBCI pillars								
 General support: ✓ identify barriers such as an inability to access health-care and social services, and unmet social, financial or transport needs; 								
 facilitate communication and provide a link between different levels of health-care and social services; 	Reading, writing and communication skills to assess patient barriers; knowledge of available resources to overcome barriers							
 serve as a primary contact or reference of care, facilitate appointments and set reminders; 								
 inform and educate patients and community members; 								
provide social, emotional and other (e.g. translation) services; and								
♂ monitor and/or follow-up patients								
Pillar 1: pre-diagr	nostic interval							
Health promotion:								
$igodoldsymbol{arsigma}$ deliver breast health education;	Reading, writing, communication, public							
 increase awareness of available health services; 	speaking, negotiation and IT skills; knowledge of breast cancer risk factors,							
 initiate community-based/social conversations and interventions; and 	signs and symptoms, breast assessment, screening guidelines and referral							
send reminders for screening appointments and encourage participation in screening among eligible women	processes; and knowledge of location of screening facilities and clinical team							
Early detection:								
 address stigma/cultural barriers to early detection; 	Recognizing the local resources to address barriers to screening and CBE; knowledge of referral pathways for CBE and mammography centres, including available agencies, location and costs; and competencies in SBCC							
assess barriers and facilitate mammographic screening and CBE; and								
provide information on screening services, transport and insurance options								
Pillar 2: diagnostic interval								
Promote timely diagnosis:	Awareness of community needs and							
 increase community awareness of diagnostic services in the health system; and 	functioning of the local health system as it relates to diagnosis of breast cancer; and knowledge of locally available diagnostic centres, as well as their processes, costs and possible adverse events and how to mitigate them							
 facilitate access to diagnostic assessment (clinical, radiological, biopsy) and reports (pathology report, immunohistochemistry) 								

Table 2. contd

Roles

Support patients with diagnosis: Ability to communicate, advocate and address system barriers to timely diagnostics negotiate with different players to (scheduling, long waiting time, avoidable facilitate access to diagnostics; ability to multiple visits, financial navigation services); coordinate with different health-care staff; use of digital tools where relevant timely sharing of diagnostic results and to coordinate with patients and collection of all required medical records; and providers of appointments, as well as to provide support for patients and family with inform or remind patients; and diagnosis counselling and SBCC skills for patients with a breast cancer diagnosis Pillar 3: treatment interval Promote completion of treatment: facilitate multidisciplinary treatment planning Understanding of breast cancer and patient appointments for MDT discussions; treatment procedures and decisionfacilitate individual clinical team appointments making processes; knowledge and (e.g. surgery, medical oncology, radiation understanding of role of MDT for breast oncology, palliative care allied health cancer management and ability to professionals); explain MDT decisions to patients; interpersonal skills to facilitate dialogue assist with obtaining medications, transport between members of MDT; ability to and financial navigation support; record data on referrals, attendees, educate about the treatment procedures and treatment completions and side-effects; decision-making processes, and provide and address barriers to accessing counselling on importance of treatment treatment and following through to completion; completion discuss management of side-effects and available resources to treat these; and Iink with peer-support groups or networks Improve patient quality of life: facilitate appointments with supportive care services, e.g. for pain, fatigue, peripheral Knowledge of and ability to assess side neuropathy management, physiotherapy effects and patient concerns; knowledge referral, lymphedema management, of available resources for managing supportive medications, psycho-oncology side-effects and patient concerns; and service (including sexuality) or spiritual services; knowledge of pathways for referral and required criteria assess patient symptoms and concerns; and

Competencies

IT: information technology; SBCC: social and behavioural change communication. Sources: Lopez et al. (9), Willis et al. (10), Battaglia et al. (11), De Mil et al. (12), Allaire et al. (13), Desveaux et al. (14), Valverde et al. (15), Budde et al. (16).

refer to patient education resources for

ongoing concerns



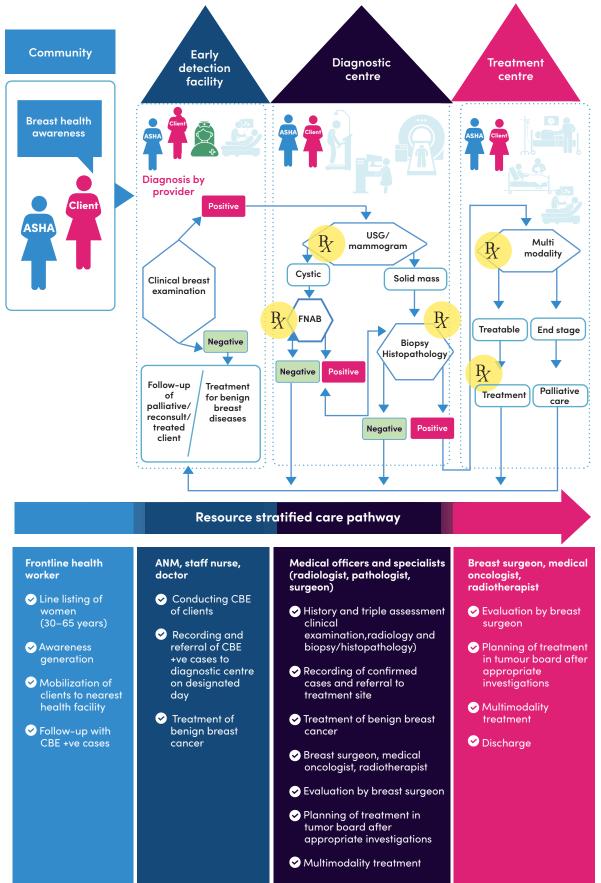
Pillar 1: early detection

During the pre-diagnostic interval it is expected that patients will require navigation through the screening process or symptom presentation. Delays during this phase affect the percentages of invasive breast cancers diagnosed at stages I or II. The objective of patient navigation in the pre-diagnostic phase is, therefore, to link women with services for health promotion and cancer prevention, early detection programmes and higher levels of care for diagnostic services.

Patient navigation programmes address two issues: (i) barriers to participation in early detection programmes for breast cancer; and (ii) delays in accessing health services when seeking evaluation for a breast complaint or participation in early detection programmes. These issues may be attributed to low community awareness of breast cancer signs and symptoms, limited access to services and a lack of trust in the health-care system. Patient navigation services for the pre-diagnostic phase can be provided by community members (e.g. *promotoras* in Latin America), community health workers, social workers, case managers or health-care professionals (e.g. nurses) and should be sensitive to a range of cultures and languages spoken (17). Patient navigators should also be able to record clinical history and assist with referrals, provide health education and raise awareness, resolve barriers to early detection services, connect individuals with community health and social services and advise on insurance or payment issues. This team of patient navigators should have a general knowledge of breast cancer risk factors, signs and symptoms and be focused on community needs and health behaviours (10).

Case study 1 evaluates the impact of evidence-informed interventions, co-designed and implemented with the stakeholders, on the Breast Health Initiative in India, a national noncommunicable disease programme (18). Fig. 3 depicts the operational framework and resource-stratified care path for this initiative.

Fig. 3. The operational framework and resource-stratified care pathways for breast cancer services as part of the Breast Health Initiative, India



ANM: auxiliary nurse midwife; ASHA: accredited social health activist; FNAB: fine needle aspirate biopsy; USG: ultrasonography.

Source: reproduced with permission of the publisher, John Wiley and Sons, from Kumar et al. (18).

Case study 1. Patient navigation in Pillar 1

Kumar et al. (18) describe the results of the Breast Health Initiative patient navigation implementation in India, which included: (i) training and deployment of female community health workers (referred to as ASHAs) to conduct tailored breast cancer awareness programmes for women aged 30–65 years; and (ii) training ANMs, staff nurses and medical officers from primary health-care clinics in quality CBE.

During the 18-month initiative, 108 112 women received breast health education. Of these, almost half (48.3% or 52 248) visited a health facility for a CBE and 3.3% (1736) of these women had a suspicious CBE result (i.e. were found to have a symptomatic breast lesion) and were referred to a diagnostic facility. The proportion of women adhering to follow-up care (i.e. attending the diagnostic facilities within 1 month of initial screening) as a result of a suspicious CBE result improved considerably during the initiative, from only 14.4% (29/201) during the first 3 months of the implementation to 40.8% (708/1736) overall.

Kumar et al. (18) observed a decrease in time to complete diagnostic evaluation with biopsy from 37 days before the initiative implementation, to 9 days. Of the women participating in the programme diagnosed with breast cancer and for whom staging information was available, most had early stage disease (13/18; 72.2%), 4/18 had locally advanced disease and 1/18 had metastatic disease (18). The study highlights the importance of patient navigation in timely diagnosis and, therefore, clinical downstaging for women who ultimately develop cancer.





Pillar 2: timely breast diagnostics

Patient navigation is critical for reducing time to diagnosis within 60 days of initial presentation, the key performance indicator of pillar 2. A typical breast cancer patient will encounter multiple health-care providers within the health-care system in the process of obtaining a diagnosis. Increasing timely access to diagnostic services through specific measures such as task sharing, reducing waiting times and integration of care to a single-window clinic is vital for definitive timely cancer diagnosis and full staging. Patient navigation programmes can act as a bridge by addressing fragmented health-care systems, coordinating services, expediting administrative procedures and providing guidance for patients during the diagnostic interval.

Specifically, patient navigators can assist in overcoming multilevel barriers across the diagnostic process, thereby decreasing the time from initial presentation to diagnosis.

Case study 2 outlines a patient prioritization intervention in Mexico that aims to reduce the time from presentation to diagnosis (19).

Case study 2. Patient navigation in Pillar 2

Tamez-Salazar et al. (19) describe the patient navigation programme Alerta Rosa introduced in Nuevo Leon, Mexico in December 2017 with the aim of reducing barriers to timely diagnosis of breast cancer.

Women who registered with the programme were classified by trained patient navigators according to their clinical characteristics into one of three priority groups (red, yellow and green for high, medium and low priority, respectively) and their appointments for imaging and consultation with breast specialists scheduled accordingly.

By December 2019, 561 patients had been scheduled according to this triage system. Of these, 59.0% (331/561) were classified as red, 24.6% (138/561) as yellow and 16.4% (92/561) as green. The median time from classification as red, yellow or green to first medical evaluation was 4, 6 and 7 days, respectively. Of the women who had been classified as red and yellow, 20 and one received a cancer diagnosis for the first time, respectively (i.e. excluding those already diagnosed and seeking a second opinion), demonstrating a sensitivity of 95% (95% confidence interval (CI): 75.1–99.9) and specificity of 42% (95% CI: 37.1–47.1). The median times between initial patient contact and diagnosis and treatment initiation were 16 and 39 days, respectively. The majority of patients (72.0%; 404/561) were diagnosed at an early stage (I or II). Efforts to replicate similar navigator-led triage systems in resource-constrained settings where screening programmes are ineffective could prove to be beneficial in reducing diagnostic intervals and achieving early stage diagnoses.

Pillar 3: comprehensive breast cancer management

Patient navigators can help patients to establish communication with an MDT for discussions about their treatment and available options. After discussion with the MDT, patient navigators also assist patients to make decisions with regards to their desired treatment. Patient navigators may assist with these next steps, such as scheduling additional imaging or biopsy.

Assisting with communication with the MDT must be accompanied by a systematic approach to case management; the patient navigator must ensure that patients adhere to their treatment course as much as possible and are able to complete it. Patient navigators must also take an active role in patient care, providing relevant information and education on potential side-effects and expected outcomes and addressing other social, economic, cultural, emotional and supportive care needs that arise during this period. Navigation through this pillar ensures patients can communicate and coordinate with the various members of the MDT, achieving continuity of care so that at least 80% of patients complete multimodal treatment.

Case study 3 provides an example of a patient navigation programme in Malaysia that delivered, among other benefits, significantly improved adherence to treatment (20).

Case study 3. Patient navigation in Pillar 3

Jaganathan et al. (20) describe how public hospitals providing breast cancer management services in 14 different states of Malaysia were invited to participate in a patient navigation programme and, after a successful demonstration of the model, to embed the service within their existing breast cancer management. Three state referral hospitals agreed to participate and were tasked with creating a 1 year historical patient record within their facility. Two patient navigators (one nurse and one community navigator) were recruited and trained. Nurses were trained to provide supportive care along a patient's clinical pathway and to deliver health education and home care plans during home visits to patients and their families. Social workers or individuals with a background in psychosocial support were also trained as community navigators (20).

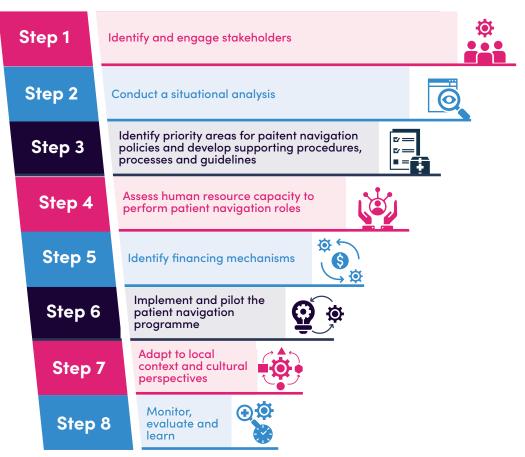
Tailored navigation programmes for patients with cancer were developed to address individual patient needs (counselling, health education, links to follow-up services, treatment adherence) and the various institutional, socioeconomic and personal barriers that hinder timely cancer care, as well as optimize clinical service operations. A dedicated space within each hospital was designated as a breast clinic, providing patient-centred care to those with newly diagnosed breast cancer through a highly competent and dedicated team comprising members of both the Malaysian Ministry of Health and Cancer Research Malaysia. Overall, treatment adherence improved significantly; across the network of breast clinics in Malaysia, 13% (no further data provided) defaulted before implementation of the patient navigation programme compared with only 2% (no further data provided) who defaulted during the implementation (20).



Patient navigation policy

The development and implementation of patient navigation policies across all three GBCI pillars require the consideration of a range of key elements and multilevel (macro, meso and micro) factors (5), as well as active stakeholder participation and continuous health systems review. The perspectives of women and the community are also crucial and such feedback must be acquired and considered. **Fig. 4** depicts the key steps and their most effective order, required in the development and implementation of a patient navigation implementation.

Fig. 4. Key steps for developing, implementing, monitoring and evaluating a patient navigation programme



Development

A breast cancer patient navigation policy can be included in a national cancer control plan or in breast cancer strategy, guidelines or action plans, with clear synergies with other health policies and health system building blocks. A well-crafted policy can ensure that the shaping of national patient navigation programmes is balanced across the care continuum and serves the communities and patients with consistency across cohorts, ensuring equity of access, quality of each activity and cost-effectiveness for the programme. The key for success is collaboration and synergy in developing the programme together with cancer stakeholders and affected communities for ownership.

Key elements of a breast cancer patient navigation policy include:

- a definition of patient navigation within the health-care system and its scope in the national context, taking each GBCI pillar into consideration and drawing on the options of clinical and non-clinical navigators, as well as partnerships with civil society organizations;
- a description of the roles and competencies of patient navigators assigned by pillar and the health system level that may assume the responsibility for their implementation and respective line management (Table 2);
- integration of the patient navigator(s) and navigation services into primary, secondary and tertiary levels of care along the cancer continuum, such that peer-level relationships are developed; communication channels are established; patient navigation services are given equal weighting in terms of training, resourcing and evaluation; and the patient navigator is recognized as a skilled contributor to clinical team and services;
- a definition of education, accreditation and quality control mechanisms such that there is a consistency framing of ongoing professional development and credibility of patient navigators;
- a description of assessment tools, standard operating procedures, workflows, communication and reporting mechanisms, as well as assigning of accountability for monitoring evaluations and learning from patient navigation services, particularly between patient navigators themselves;
- the commitment of financial resources as appropriate to shape financing and sustainability in the longer term, with a sustainable business funding model; and
- the enabling of research for innovation and improvement of patient-reported experience, as well as patient or health system outcomes.

A list of specific policy measures that can support the implementation, monitoring and evaluation of patient navigation services is provided in Annex 1.

Implementation

Macro-level factors

(a) Policy, laws and professional regulation

Policies on skill-mix and changes to regulatory mechanisms can serve as barriers or facilitators to the uptake of skill-mix innovations. Clear definitions of roles and competencies for patient navigators are important facilitators to successful implementation (Table 2). Patient navigation may be part of accreditation standards and guidelines from professional organizations (5).

(b) Education and training

Education and training is critical to ensure patient navigators successfully fulfil their roles (see Annex 2 for education resources). It is important to define the minimum standards of competencies, skills and knowledge required for patient navigation between health professionals and lay workers. Connecting patient navigators with clinically trained professionals enables patient navigators to be supported in the performance of their functions. Continuing professional development ensures that patient navigators maintain and continue to develop their competencies in line with the needs of the patients and communities they serve.

(c) Funding and financing

Investment in implementing breast cancer patient navigation programmes provides returns in terms of improved patient outcomes and cost and time efficiencies in service provision, including reducing missed appointments, repeat tests and unnecessary admissions or other interventions. Although informal patient navigation services can be supportive, formalized programmes integrated within other cancer services are the most impactful. **Table 3** provides examples of financing models for patient navigation employed in the United States of America (21,26) for illustration alone; there may be financing models from other countries not included as it was outside the scope of the document.

Model	Key characteristic	Benefit	Challenges
Fee for service (21)	Patient navigation services billed individually	Easier to establish than value-based methods	High administrative burden; may inadvertently increase disparities by requiring more record-keeping and reinforcing historical models that value volume over value
Value-based purchasing (e.g. Oncology Medical Home) <i>(22)</i>	Patient navigation embedded as a quality metric for payment	Part of predefined care delivery expectations for payment; capitated payments provided up front	May be difficult to establish for small, outpatient practices; difficult to monitor if quality metric standards are being compromised to cut costs; measures shift over time
Bundled payment (23)	Patient navigation embedded as a quality metric for payment	Part of predefined episode for payment	Difficult to monitor if quality metric standards are being compromised to cut costs; measures shift over time
Shared savings (e.g. accountable care organizations) (24)	Patient navigation is an optional strategy for shared savings	Not mandatory, incentivizes efficiency for both providers and payers; may lower premiums in the longer term	Relies on institution to prioritize service as a driver of cost-saving; could result in the prioritizing of patients whose treatment would be less expensive
National coverage determination (25)	Stakeholder-driven request for coverage of reasonable and necessary services for diagnosis or treatment of a particular disease	National, stable coverage for service by Medicare	Strength of evidence must support service as reasonable and necessary for the diagnosis or treatment of cancer
2024 Medicare Physician Fee Schedule <i>(26)</i>	Centres for Medicare and Medicaid Services (private health insurance providers) created four codes that will allow health-care providers to bill for patient navigation	Incentivizes health- care providers to provide patient navigation by covering services.	Relies on patients having Medicare and/ or Medicaid

Table 3. Examples of financing models for patient navigation in the United States of America

Meso-level factors

(a) Organizational frameworks

Patient navigators work in collaboration with other health-care and social service providers. An infrastructure that supports collaboration and workflows can, therefore, enable successful implementation. In particular, shared health IT systems for patient navigators and other care providers, with training on how to use this, would be extremely useful to allow access to informational material and data. Another consideration may be for the provision of integrated services; for example, the integration of breast cancer patient navigation within hypertension and diabetes disease programmes may be beneficial for people with breast cancer and such comorbidities (6).

Physical resources also need to be considered in the overall organizational structure. Partnership within and between organizations is another key factor that will determine the successful operation; strong relationships with community services and organizations facilitate the integration of health and social services for the population targeted by the patient navigator programme.

(b) Support and leadership

An important facilitating factor in increasing the uptake of patient navigator programmes is the role of leadership. Clinical leadership is also relevant for patient navigators. Certain stakeholders (e.g. physicians, clinical leaders, non-profit-making organizations, researchers and patients) can act as promotors of patient navigation and encourage participation. Professional groups advocating patient navigation initiatives can have a strong influence.

Micro-level factors

(a) Communication and working relationships

At the micro-level, communication is critical to the successful integration of patient navigators within the existing care pathway. Resistance from clinicians can be particularly difficult and the reluctance to share care responsibilities with patient navigators may create a challenging environment as patient navigators attempt to establish trust in their role. Clear, effective and regular communication between those involved in patient navigator programmes, as well as a shared understanding of professional boundaries and an appropriate supervisory structure, will all help to integrate new roles into existing team dynamics. Clearly defined roles, scope of practice and protocols (e.g. task sharing) have also been shown to be factors for successful implementation. The engagement of clinical leads and people with lived experiences in regular meetings can also highlight the importance and value of the programme.



Monitoring and evaluating a patient navigation programme

Optimizing patient navigation, that is, continuously assessing programme outcomes and adapting as necessary, requires the inclusion of processes for monitoring and evaluating. The development of patient navigator policies must consider practical data acquisition factors such as frequency of data collection, where and how to record data and which staff will be responsible for this. A standard protocol for the routine collection of data should be considered for patient navigators.

The procedures and methods of analysis and evaluation of such data must also be standardized, with consideration given to the required actions that may potentially be identified from such data analysis. Options that an evaluation team may identify include either performing continuous improvement of a successfully implemented plan or, in the case of underlying failure, determining the cause of this failure and implementing corrective actions (4).

Stakeholders could select indicators to measure progress, determine programme effectiveness and efficiency and provide actions to improve programme delivery. Examples of such indicators include the proportion of patients with breast symptoms who successfully access primary care after receipt of breast cancer education; the proportion of those with suspicious findings referred for diagnostic care and who successfully access it; the proportion who are diagnosed with cancer who access treatment; or time to screening and diagnostic resolution.

A theoretical illustration of the use of such indicators in measuring the success of a patient navigator programme is provided in **Box 1**.

Box 1. Monitoring and evaluation

Consider the situation in a particular region where women with breast cancer experience long delays in receiving a diagnosis, such that more than 60% have stage III or IV disease at diagnosis.

- A regional health office could perform a situational analysis to map the referral pathways from presentation at primary care to receipt of diagnosis. This analysis may uncover the findings that, of 500 women presenting with breast symptoms at two primary care centres over a 6-month period, 200 (40%) are referred for diagnostic evaluation at a regional hospital, of which 50 (10%) successfully access care and 40 (8%) are diagnosed with cancer. These data would reveal that patients are unable to navigate the health system because of currently unknown barriers to care.
- The health office could pilot a patient navigation programme to address these issues. Three lay patient navigators could be trained, using a standardized

curriculum, in educating women in the community on recognizing signs

and symptoms of breast cancer. Navigators would be tasked with holding community health promotion events and trained in how to provide assistance for women who are referred for diagnostic evaluation overcome barriers to care. After training, patient navigators could then be employed for 1 year. Monitoring of progress would occur every 3 months and data collected from navigators, primary care centres in the catchment area and regional hospitals providing diagnostic evaluation. Evaluation of the patient navigator system could take place at 6 months and 1 year after initiation of the implementation.



Table 4 shows some examples of the potential outcomes of data monitoring and evaluation. Evidence of a successful implementation could be identified from several indicators, including communities receiving education on signs and symptoms of cancer and where to seek care; the proportion of communities holding a breast health education day regularly as agreed, with patient navigators present; trained patient navigators demonstrating increased knowledge of the referral system and recognizing signs and symptoms of breast cancer; more women with symptoms of breast cancer attending primary health-care facilities for CBEs; on referral for diagnostic care, more women successfully accessing a timely diagnosis; the proportion of referred patients receiving patient navigation services; the proportion of patients who received patient navigation services who successfully access diagnostic services; and the proportion of patients who accessed diagnostic services who were diagnosed with cancer.

Table 4. Monitoring and evaluation of breast cancer patient navigation programmes

Indicator	Potential finding	Evaluation	Possible action and/or comment
Average percentage increase in knowledge among patient navigators, calculated by comparing results of baseline questionnaires with those administered post training	> 70% increase in knowledge among trained patient navigators compared with baseline	Further analysis of the three training providers reveal that one obtained an increase of 100%, one 80% and one 30%, i.e. an average of 70%	Set a pass rate of > 70% to ensure that navigators are sufficiently knowledgeable; in this case the results should be reanalysed, and the indicator redefined
Proportion of communities that have a breast health education day once every 2 months, staffed by navigators	Four of four (100%) communities had a breast health education day once every 2 months, staffed by navigators	Successful implementation of breast health education events	Although the breast health education days were implemented successfully, their value to the community is not yet clear; future actions could include interviewing attendees to assess (i) how their knowledge of breast cancer symptoms and when to seek care has changed; (ii) if they interacted with patient navigators, was this interaction helpful; and (iii) effect on health-seeking behaviour
20% increase in the number of women attending primary care with breast symptoms	650 women with breast symptoms attend primary care for evaluation	At baseline 500 women attended primary care; after the intervention there was a 30% increase at 6 months	A 30% increase was achieved, suggesting that community education events are having an effect on health-seeking behaviour
50% increase in patients accessing recommended diagnostic care	650 women with breast symptoms attend primary care for evaluation	At baseline 200 women were referred for diagnostic evaluation and 50 accessed care (25%); the post-implementation rate (40%) represents an absolute increase of 15%	Although the targets may not have been met, the evaluation team might conclude that this is a reasonable achievement during the pilot phase
Proportion of patients referred for diagnostic evaluation who received navigation services	250 women with breast symptoms are referred for care; 100 (40%) women receive recommended care	At baseline 200 women were referred for diagnostic evaluation and 50 accessed care (25%); the post-implementation rate (40%) represents an absolute increase of 15%	Although the targets may not have been met, the evaluation team might conclude that this is a reasonable achievement during the pilot phase
Proportion of patients who received patient navigation services and who accessed diagnostic services	Of 120 patients referred, 100 received diagnostic evaluation services (83%)	83% of patients who received patient navigation successfully accessed diagnostic evaluation	Patient navigation services appear to be successful at helping patients access diagnostic care
Proportion of patients who accessed diagnostic services who were diagnosed with cancer post-implementation	Of 100 patients who received diagnostic evaluation services, 60 (60%) were diagnosed with cancer	At baseline 40 of 50 patients (80%) were diagnosed with cancer, which increased to 60%	The proportion of patients who underwent an unnecessary diagnostic evaluation increased from 20% to 40%, suggesting over-referral for diagnostic evaluation; a root-cause analysis may be beneficial



Implementation research in breast cancer patient navigation

Separate from (but complementary to) monitoring and evaluation, implementation research aims to understand the factors affecting the adoption, implementation and scale-up of a new policy or programme in real-life settings (27). An implementation research approach – involving researchers, policy-makers and implementers – within which monitoring and evaluation is embedded is useful to ensure the relevance, uptake and sustainability of a patient navigation programme. Implementation research can, therefore, be thought of as a framework and set of tools that aim to address the defined outcomes in a patient navigation programme, while addressing the principles of equity in breast cancer detection, care and control. In applying implementation research, practitioners may better understand how to best utilize specific strategies that have been shown to work in similar settings, reduce programme costs, decrease health disparities and improve overall breast health outcomes.

The key steps for defining and incorporating implementation strategies within patient navigation intervention are as follows (27)



Assess and identify the intervention: confirm evidence for the intervention based on local, regional and international contexts

Engage all relevant stakeholders and partners to co-create the research





Adapt and pilot the intervention: consider to what extent it is possible to maintain the fidelity to the original intervention and adapt it as needed; and understand the context (e.g. the Consolidated framework for implementation research at https:/cfirguide.org can help to identify the barriers and facilitators to assess during the planning process)

Evaluate the implementation of the intervention: define measurable outcomes for the programme (e.g. acceptability, adoption, appropriateness, feasibility, costs, cost–effectiveness, fidelity, penetration, sustainability, equity) or community or individual outcomes; define how to evaluate the outcomes (e.g. use of logic model or economic evaluation); define how to embed learning within the intervention and how to adjust the implementation plan as new evidence and information is available; and ensure sustainability and scale-up.



See **Box 2** for sample implementation research questions that may be useful across all GBCI pillars in the introduction, adaption or scaling up of a patient navigation intervention.

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Box 2. Sample implementation research questions

Pillar 1: health promotion for early detection

- Is it feasible and acceptable to educate and train community health workers to provide breast health education and awareness in the community?
- 2
- Is the upskilling of community health worker patient navigators associated with an increase in breast awareness in the community?
- 3

1

2

3



- Is the integration of patient navigators trained in breast health associated with a decrease in late-stage (stage III or IV) diagnosis in the catchment area?
 - Does the integration of patient navigators into primary care increase the utilization of breast health services at (primary or secondary) health facilities in the facility catchment area?

Pillar 2: timely breast diagnostics

- Is the integration of patient navigators trained in breast health associated with a decrease in the diagnostic interval?
- What is the (i) efficacy and (ii) cost for a digital health intervention to support data collection and patient reminders for women requiring diagnostic evaluation?
- Is it feasible and acceptable to train nurses as patient navigators in the secondary and/or tertiary health facility to reduce loss to follow-up for women once diagnosed?

Pillar 3: comprehensive breast cancer management

- Is it feasible and acceptable to train nurses as patient navigators in the secondary and/or tertiary health facility to increase patient adherence to their treatment plan?
- 2 Is it feasible and acceptable to train peer mentors as patient navigators in the secondary and/or tertiary health facility to reduce loss to follow-up for women once diagnosed with breast cancer?
- 3 Is it feasible and acceptable to train peer mentors (e.g. women with prior lived experience of breast cancer) as patient navigators to increase patient adherence to their treatment plan?
- 4

5

What functions of patient navigation can be integrated within the roles of the community-based and other cadres of the frontline health-care workers?

What are the enablers related to ensure, increase and sustain the effectiveness of patient navigators deployed in resource constrained health systems?



Summary

Breast cancer patient navigation programmes aim to reduce the barriers faced by some patients in accessing health-care and social services, enable timely diagnosis and treatment and provide relevant support to improve survival rates. These services should be provided by well-trained and competent professional patient navigators who can work alongside clinical staff within a facility. Patient navigators can also educate and inform communities, assisting people with cancer to reduce and eliminate inequities in accessing health care for breast cancer.

Certain populations may be more vulnerable in terms of developing the capabilities needed to navigate health-care systems and to be actively involved in decisions about their health and care, leading to poorer health outcomes for some. These populations may include those with a lower level of education or income, with limited access to medical insurance or experiencing language and cultural barriers. A lack of patient navigation services may mean that these barriers persist, manifest as delays in referrals for diagnostic tests, obtaining the results of examinations, treatment initiation, missed appointments, loss to follow-up and, in some cases, the abandonment of treatment; all of these ultimately impact the health outcomes and even survival of people with breast cancer. Navigation services can also complement social support, including educating and assisting with access to insurance services and payment options, providing transportation and accommodation and responding to questions regarding medication and the side-effects of breast cancer treatment.

This technical brief highlights the importance of patient navigation in enabling the patient to access health-care and social support services and adhere to their treatment. The roles and responsibilities of patient navigators and how they can be effectively integrated and networked within the health system are described; key practical considerations and steps that can be put in place to ensure a successful provision of the service are also highlighted. This brief serves as a general guide that can be adapted and contextualized to specific settings, ensuring that it is both appropriate and useful for the achievement of the goals of a patient navigation programme.



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Annex 1. Breast cancer patient navigation policy checklist

Box A1.1. Checklist for breast cancer patient navigation

Navigation for pillar 1: pre-diagnostic interval

Public, media and community awareness raising and sharing of information on breast cancer early detection services

- The role of patient navigators in issuing invitations to screening and enabling early diagnosis of breast cancer.
- The role of patient navigators in supporting community health workers for dissemination of awareness messages, so that women with breast changes report promptly to a health facility for further assessment.
- The role of patient navigators in training or providing clinical breast assessment as per the national guidelines.
- Any role the patient navigator may play in risk assessment and modality-triage of women to ensure referral of high-risk patients who would benefit from screening.
- The engagement of patient navigators and the role of mobile breast examination services, particularly in reducing health disparities and how they feed into primary and higher levels of health care.

Expedited referral for women with suspicion of cancer

- The role of patient navigators in securing and ensuring the completeness of written and verbal communication, provided and kept as an integrated patient record accessible to each member of the multidisciplinary team (MDT).
- Provision of diagnosis letter (including tumour, node and metastasis (TNM) stage, treatment options/ plan and rights of patients and their families to access this information) and/or access to the patient record for the patient after each consultation.

Box A1.1 contd

The role of patient navigators in training or supporting the work of breast health care; protocols for facilitating seamless transfer to the designated institution for confirmatory diagnosis and treatment; protocols for transfer of care between patient navigators at different levels of health care; referral forms/letters with all relevant data for audit and monitoring and evaluation; patient transport to be made available for patients in need to the designated referral facility to ensure ease of access and to minimize delays; and financial support for vulnerable patients to minimize financial distress and reduce catastrophic expenditure

Navigation for pillar 2: diagnostic interval

- The role of patient navigators in ensuring that patients are diagnosed within 60 days of presentation at a health facility.
- The role of patient navigators in ensuring that for referred patients an advanced breast examination is conducted and that follow-ups for radiology and pathology as indicated occur and links to MDT are enabled.
- The role of patient navigators in establishing contact with those who did not show up for their appointments to inquire about reasons for no-shows and to assign new appointments if needed.
- Audit and comment forms to allow patient navigators and other health-care workers to report barriers to uptake at patient and facility level, as well as track more complex cases.

Navigation for pillar 3: treatment interval

- The role of patient navigators in documenting and ensuring that patients with a confirmed diagnosis of breast cancer should receive their first definitive treatment within 60 days of the decision to treat (this may have further details such as the maximum time between surgery and initiation of adjuvant therapy)
- The role of patient navigators in documenting and ensuring that patients with a confirmed diagnosis of breast cancer should receive their first definitive treatment within 60 days of the decision to treat (this may have further details such as the maximum time between surgery and initiation of adjuvant therapy).
- The role of patient navigators in scheduling patients for MDT discussion and being part of the discussions to enable patient-informed decision-making and address any fears, obstacles or barriers.
- The role of patient navigators as the named breast care nurse or counsellor allocated to each breast cancer patient to ensure a point of contact with the MDT
- Audit and comment forms to allow patient navigators to report barriers or delays to uptake at patient or modality level.
- The role of patient navigators in explaining and providing written documentation of intended treatment types, locations and dates for patients and their families.
- The role of patient navigators in supporting patients with preparatory steps such as nutritional advice, as well as referral to psychosocial support and patient support groups.
- The role of patient navigators in coordinating care including supporting patients and their families from the treatment steps (reminders, needs assessments) to completion of intended treatment.
- The role of patient navigators in supporting management of treatment side-effects and provision of liaison for further supportive care as required.
- The role of patient navigators in coordination of palliative care, survivorship care planning and homecare (whether tangible, informational or emotional) to enable women to adjust to life with breast cancer.

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Box A1.1 contd

Enabling environment

- Control Dedicated budget lines (of funding model) for patient navigators that encompass both clinical and non-clinical navigational support
- C Dedicated budget lines (of funding model) for patient navigators that encompass both clinical and non-clinical navigational support.
- C Definition of minimum requirements of physical resources, such as room availability, telephone, IT and Internet access for optimal implementation of patient navigator roles.
- Clear allocation of accountability and leadership for implementation, monitoring and evaluation of patient navigator services for consistency and quality of services, as well as their scale-up and development over time.
- Link to national laws and legislation that describe rights to health and mandate equity of access and availability of services, including access to breast cancer medicines and approaches to universal health coverage.
- Identify and mandate partnerships with experienced and qualified civil society organizations for coordinated and complimentary patient navigator services, including survivorship care.
- The definition of patient navigator roles using a skills and competencies-based approach at each level of the health service (including community) with associated minimum experience, qualifications, training and refresher training requirements that comply with legal, professional, ethical and other standards relevant to the patient navigation professional.
- Documentation of bodies responsible for education and training as well as accreditation and auditing of each patient navigator role (including minimum training requirements in the first year of employment, including training specific to breast cancer).
- Engagement of patient navigators to document delivery of services in a professional manner, consistent with the physical, psychological, spiritual and cultural needs of the individual, as well as review findings, share learnings and develop novel solutions on a regular basis.
- Mandate regular engagement between professions and services to support leadership buy-in, team collaboration as networks of care, review and incremental improvement of workflows and, if appropriate, setting of annual targets (e.g. the percentage early detection uptake, time to diagnostic resolution, percentage completeness of the TNM stage, timeliness of care, treatment/guideline adherence, patient knowledge/satisfaction, continuity of care, quality of life, patient reported outcome measures) (1).
- Mandating of reporting requirements in line with health information systems such as District Health Information System (DHIS) 2 in real time between health-care levels and the MDT as well as at facility, regional and national levels in line with the patient navigator programme goals and the monitoring and evaluation requirements of the breast cancer programme
- Identification of key populations and vulnerable/underserved communities that have specific navigational needs with standardized approaches to ensure safe and culturally sensitive patient navigator services such as patients living in remote communities or with disabilities or marginalized populations.
- Research including or led by patient navigators such as patient and health worker satisfaction surveys requires assessment of key populations or cost–effectiveness studies (2), as well as links to the breast cancer clinical trials portfolio.

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Annex 2. Patient navigator resources

Please visit the WHO Global Breast Cancer Initiative Community on the WHO knowledge action portal for NCDs for additional resources.

Organization	Resource description and link
City Cancer	How to implement a nurse navigation programme for cancer patients
Challenge	https://citycancerchallenge.org/uploads/2023/02/AAFF_Document-How-
Foundation	To-Guide-Nurse-ISBN-Code-LOCK.pdf
RAD-AID International and Breast Course for Nurses	Navigating the patient with breast cancer: a guide for low-resource settings A guide for health-care workers in providing breast care navigation so that individuals are referred for further diagnostic services and treatment when appropriate https://rad-aid.org/wp-content/uploads/Navigating-the-Patient-with- Breast-Cancerv9-y23m03d17-SPREAD.pdf
Oncology	2017 Oncology nurse navigator core competencies
Nursing	List of consensus-based core competencies for oncology nurse navigators
Society	https://www.ons.org/sites/default/files/2017ONNcompetencies.pdf

Table A2.1. Guidelines and toolkit	s available for	patient navigators
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Table A2.1 contd

Organization	Resource description and link		
Oncology Nursing Society	Oncology Nursing Society nurse navigator toolkit		
	A resource for newly assigned ONNs and current ONNs seeking tools and resources to help to improve patient care coordination		
	https://www.ons.org/toolkits/ons-oncology-nurse-navigator-toolkit		
GW School of Medicine and Health Sciences	Patient navigation barriers and outcomes tool (PN-BOT)		
	Case management and evaluation tracking tool to demonstrate the value of patient navigation activities		
	https://cancercontroltap.org/news/patient-navigation-barriers-and- outcomes-tool-pn-bot/		
Boston Medical Center	The Boston Medical Center patient navigation toolkit, 1st edition		
	Toolkit for implementing patient navigation programmes to reduce health disparities		
	https://sites.bu.edu/coeinwomenshealth/files/2016/12/BMC-Patient- Navigation-Toolkit-Vol-1.pdf		
Patient Navigation Evaluation Toolkit	How are we doing? How to evaluate your patient navigation program		
	Toolkit to evaluate patient navigation programmes		
	https://patientnavigatortraining.org/wp-content/uploads/2014/07/PN- Evaluation-Toolkit.pdf		

BCN: Breast Course for Nurses; ONN: oncology nurse navigator.



Department of Noncommunicable Diseases World Health Organization 20 Avenue Appia 1211 Geneva 27, Switzerland https://www.who.int/health-topics/cancer

