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**ASSESSING THE INFORMATION GIVEN TO CANCER  
PATIENTS ATTENDING DAY HOSPITAL IN A  
COMPREHENSIVE CANCER CENTRE**

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CENTRE**

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*To my parents and grandmother*

*To Filipe*

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## ABSTRACT

**Introduction:** Information is of utmost importance to cancer patients. The physician-patient relationship is based on communication exchange, and in the oncology setting it presents specific challenges. The EORTC has developed a reliable and valid self-assessment instrument to measure the information given to cancer patients.

**Objectives:** The primary objective of this study was to evaluate the self-reported information level (amount, content, type and usefulness) of cancer patients attending Day Hospital in a comprehensive cancer centre. Secondary objectives were the evaluation of the association between the self-reported information level and patients' demographic and clinical characteristics.

**Material and Methods:** This was a cross-sectional observational study including adult cancer patients with a histological diagnosis of solid tumour, receiving chemotherapy treatment at Jules Bordet Institute's Day Hospital (Brussels, Belgium). The questionnaires used for data collection were EORTC QLQ-C30 and its information module EORTC QLQ-INFO25 and were administered on a paper-printed format during the appointment for treatment at the Day Hospital. Demographical and clinical data were also collected.

**Results:** The study comprised 101 patients (22 male, 70 female), mean age of 56.9 years ( $SD = 12.8$ ), mostly Belgian (74.3%). The most frequent tumours were breast (58.4%) and gastrointestinal (19.8%). Patients presented a higher global information level than the sample from the module's validation study; they were better informed about the disease and treatments and seemed to have less additional information needs and find the information given to them more useful. They would like to receive more information on treatment side effects, long-term outcome, nutrition, recurrence symptoms and desired detailed results of the tests they pass. Patients that were part of clinical trials reported having received less information about disease and written information than patients outside clinical trials. Higher information levels were associated with higher QoL scores and also higher patient satisfaction.

**Conclusion:** Associations were found between information levels and clinical and demographical characteristics of these patients. They were well informed and satisfied with the information received but still have unmet information wishes. Additional studies are required to investigate the information provided to patients participating in clinical trials.

## RESUMO

**Introdução:** A informação é de importância vital para os doentes oncológicos. A relação médico-doente assenta na troca de informação e o contexto oncológico reveste-se de desafios particulares. A EORTC desenvolveu um instrumento fiável e válido de auto-administração para medir a informação prestada aos doentes oncológicos.

**Objectivos:** Este estudo teve como objectivo principal a avaliação do nível de informação auto-reportado (quantidade, conteúdo, tipo e utilidade) pelos doentes oncológicos que frequentam o Hospital de Dia de um centro oncológico especializado. Os objectivos secundários foram a avaliação da associação entre o nível de informação auto-reportado e características demográficas e clínicas destes doentes.

**Material e Métodos:** Este foi um estudo observacional transversal que incluiu doentes adultos com o diagnóstico histológico de tumor sólido, a receber tratamento por quimioterapia no Hospital de Dia do Instituto Jules Bordet (Bruxelas, Bélgica). Os questionários utilizados para a recolha de dados consistiram no EORTC QLQ-C30 e no seu módulo de informação EORTC QLQ-INFO25 e foram administrados em formato de papel durante o tratamento previsto em Hospital de Dia. Foram igualmente colhidos dados demográficos e clínicos.

**Resultados:** O estudo compreendeu 101 doentes (22 homens, 70 mulheres), com uma média de idades de 56.9 anos ( $SD = 12.8$ ), predominantemente belgas (74.3%). Os tumores mais frequentes foram mama e gastrointestinais. Os doentes apresentaram um nível de informação mais elevado que a amostra do estudo de validação do questionário; estavam melhor informados acerca da doença e dos tratamentos, pareciam ter menos necessidade de informação adicional e consideravam a informação recebida mais útil. Eles gostariam de receber mais informação sobre efeitos laterais do tratamento, resultado a longo prazo, nutrição, sintomas de recidiva e informação detalhada acerca dos testes por eles realizados. Os doentes que faziam parte de ensaios clínicos reportaram receber menos informação sobre a doença e menos informação escrita que os doentes fora de ensaios clínicos. Níveis de informação mais elevados mostraram-se associados a níveis superiores de qualidade de vida (QdV) e também a maior satisfação dos doentes.

**Conclusão:** Foram encontradas associações entre o nível de informação e variáveis clínicas e demográficas dos doentes. Estes encontravam-se bem informados e satisfeitos com a informação recebida, apresentado contudo necessidades informativas não

colmatadas. São necessários estudos adicionais para investigar a informação prestada a doentes que participam em ensaios clínicos.

# INTRODUCTION

## **1. CANCER: FROM ANCIENT HISTORY TO NOWADAYS**

Cancer has accompanied human beings since ancient times. The first presumed references to cancer are found in the Egyptian Medical Papyri: two of them in the Papyrus Ebers (c.1538 BC) and the other one in the Papyrus Kahun (c.1825 BC), describing treatments for breast carcinoma arising from the milk ducts and also for uterine conditions believed to be malignant (David AR 2010). Advances in the techniques of examination of ancient specimens have led to the identification of several cases of bone sarcomas, nasopharyngeal and breast carcinomas reported on mummies (Pavlidis N 2011) and, recently, histological diagnosis of a rectal cancer in an Egyptian mummy was achieved (David AR 2010).

Hippocrates, in his Hippocratic Corpus developed the black bile theory to explain the aetiology of cancer, and Galen of Pergamum (c.200 AD) build on that idea. Hippocrates was the first to use the Greek word *carcinos* (crab) and *carcinoma* to describe various tumours and swellings, due to their crab-like appearance (David AR 2010, Pavlidis N 2011).

Moving to the Roman period, Celsus (c.30 BC–38 AD) described the phenomenon of the metastatic process and Galenus (129–199 AD) introduced the term *sarcoma* from the Greek word *sarca* (flesh) (Pavlidis N 2011).

The Renaissance period produced some advances in anatomy, namely of interest, the discovery of lymph and its ducts and nodes. But real development would only emerge during the 18th and 19th centuries with the invention of the microscope and the birth of cancer pathology, of which Morgagni, Bichat and Virchow were “fathers” (Pavlidis N 2011).

Surgery, which is considered the oldest cancer therapy, evolved greatly in the 19th and 20th centuries. In the beginning of the 19th century, the German chemist Paul Ehrlich was the first to use the term “chemotherapy” to refer to the use of chemicals to treat disease; he pioneered in the use of animal models to test drug activity and was interested in the use of the first aniline dyes and primitive alkylating agents to treat cancer, although wasn't very confident in their success. But surgery and radiotherapy dominated the field of cancer therapy into the 1960s, until it became clear that cure rates rose to a steady plateau of 33%. The concept of micrometastatic disease gained attention and new data showed that

combination chemotherapy could cure patients with different advanced cancers. This paved the way to the use of chemotherapeutic agents in conjunction with surgery and/or radiotherapy and gave birth to adjuvant chemotherapy. The combined-modality treatments, with tailoring to maximize antitumour effects and minimize toxicity, then became standard clinical practice (De Vita VT Jr 2008).

Thereon, cancer medical treatment has witnessed many treatment breakthroughs, especially due to the discovery of various chemotherapy drugs, endocrine treatments and recently, targeted therapy and immunotherapy. Also, radiotherapy and surgery have suffered immense progression.

Three of the ten leading causes of deaths in 2008 in high-income countries, as reported by the World Health Organization (WHO) are due to malignant neoplasms. Trachea, bronchus and lung cancers occupy the third position of that ranking scale, colon and rectum cancers the seventh and breast cancer the tenth ((WHO) 2011).

In Belgium, cancer is responsible for 163/100,000 deaths in males and 93/100,000 in females. Among men, prostate (29.7%), lung (16.8%) and colorectal cancers (13.6%) are leading in incidence, while among women it's breast (36.2%), colorectal (14.1%) and lung cancers (6.4%). Regarding mortality, lung cancer is the leading cause of death for men (32.5%), followed by colorectal (10.0%) and prostate cancers. For women, the deadliest cancers mirror the most incident, with breast being responsible for 20.6%, colorectal for 12.9% and lung for 11.4% of cancer deaths ((IARC) 2008).

## **2. COMMUNICATION WITHIN THE ONCOLOGY SETTING**

Communication and interpersonal relation competences are a prerequisite to elicit information in order to facilitate accurate diagnosis, counsel, give therapeutic instructions, and establish empathic relationships with patients (Duffy FD 2004, Brédart A 2005). These are the substance clinical skills in medical practice, with the ultimate purpose of effective delivery of health care, upholding the best outcome and patient satisfaction (Duffy FD 2004, Brédart A 2005) . Patients reporting good communication with their doctors are more likely to be satisfied with their care, and especially to share pertinent information for accurate diagnosis of their problems, follow advice, and adhere to the prescribed treatment (Duffy FD 2004, Brédart A 2005, Baile WF 2005). Patient surveys have consistently shown that they want better communication with their doctors (Brédart A 2005). Although information exchange, integrating both patient- and doctor-centred approaches, is currently the dominant model, this was not always the case. Between 1950 and 1970, most oncologists considered inhumane and prejudicial to the patients to disclose bad news because the success rates in treating cancer were very low (Baile WF 2005). However, while treatment advances have changed the course of cancer so that it is much easier now to offer patients hope at the time of diagnosis, they have also created new challenges in communication, such as a need for increased clinician skill in discussing other bad news (Baile WF 2005).

Communication difficulties between medical, nursing and other paramedical staff and cancer patients have long been recognized and received attention over the past decades in published papers (De Valck C 1996, Fallowfield L 1999). Besides, it has been shown that communication problems correlate positively with patient distress and anxiety that can be translated, at times, as anticipatory nausea and vomiting when facing chemotherapy, criticism reported by the patients about the content of information received during hospital visits or admissions or even low rates of patient recruitment to clinical trials (Brédart A 2005, Baile WF 2005). These unsatisfactory circumstances, on the other hand, are also professionally and personally unrewarding for the doctors and ancillary health staff involved (Duffy FD 2004, Brédart A 2005).

Earlier studies concerning the delivery of information according to patients' needs recognized that giving patient-tailored information contributed to lowering their anxiety levels (e.g. patients with a high need for information were anxious when given little information and patients with low-information requirements become anxious when too much information is given) (De Valck C 1996). Such studies have also shown doctors'

decision-making on giving information is based on subjective criteria with a strong cultural influence, correlates poorly with paired patients' assessments and renders, more frequently than desired, the physician to attain a conservative attitude, preventing the openly discussion of diagnosis, treatment and prognosis issues, and shared decision-making (De Valck C 1996, Fallowfield L 1999, Fallowfield LJ 1994). In fact a study by Hardy & Hardy found that within the same country there are differences between hospitals and, similarly, differences within the same hospital between individual physicians and medical specialties (Hardy R 1979). This implies that patients who are transferred from one ward to another can sometimes receive very conflicting information regarding their illness, when there is no communication between the physicians involved about how much the patient has been told. Explanatory reasons, which are complex, include both personality and attitudinal characteristics of patients (e.g. *information-seeker* patients or *information-blunter* patients) and their healthcarers (e.g. the doctor's own uncertainty about the further evolution of the disease, the fear of extreme reactions of anxiety or depression by the patient, the insufficient training skills to deal with such reactions), together with difficulties created by the cancer care delivery systems (e.g. time constraints in routine contacts, insufficient intra-multidisciplinary team information exchange) (Fallowfield L 1999).

## **2.1 COMMUNICATION DIFFICULTIES**

### **2.1.1 HEALTH STAFF COMMUNICATION DIFFICULTIES**

It has been shown that communication skills tend to decline as medical students progress through their medical education, and over time doctors in training tend to lose their focus on holistic patient care (MR 1998). Besides, doctors frequently report feeling of being unprepared in regard to communication skills, particularly for interacting with cancer patients. Sometimes they delegate on specialist nurses, but they, as well, often exhibit similar inabilities (S 1991).

The context and content of communication in oncology can often be challenging and emotionally burdensome and some doctors tend to adopt a cold professional detachment

as a means of preserving their emotional balance. The avoidance behaviour has also been attributed to lack of adequate time to discuss emotional and psychosocial issues (Fong Ha J 2010). DiMatteo remarked the possible discouragement of collaboration made by some doctors, deterring patients from expressing their concerns, expectations and questions (MR 1998). Medical error may also be a reason for doctors to adopt a defensive attitude. Disclosure of errors is difficult for physicians for several reasons, including guilt and shame, the fear of litigation and concerns about the impact on their personal reputation (Yardley IE 2010). Unfortunately, such attitudes prevent the establishment of the therapeutic relationship on which patient care should be based, disempower patients hindering them from achieving their health goals and can even be harmful to them and their families (LJ 1993). The lack of preparedness felt by clinicians, as research shows, leads frequently to stress, lack of job satisfaction and a worrisome escalation of psychological burnout (Whippen DA 1991).

The way that information is conveyed is also of utmost importance. Non-verbal communication in the health context is a field of vast investigation and health staff unaware and untrained on this matter may generate misinterpretation or elicit inadequate reactions on the patients, therefore reinforcing the need for specific skill teaching in this area (Fallowfield L 1999, Shapiro DE 1992).

Doctors rate poor in studies identifying patient misunderstanding, typically underestimating the proportion of patients misreporting information (Gattellari M 1999). These results are in agreement with the body of research demonstrating that most clinicians cannot accurately detect patient emotional states (Gattellari M 1999, Hack TF e Team 2005). Evidence shows few doctors recognise the different preferences that their patients have for both type and amount of information. The desire for more information is sometimes confused with a presumed wish to participate in clinical decision making (D. L. Hack TF 1994). For example, in women with breast cancer, research has shown that the majority prefers a relatively passive role in decision making but require, nevertheless, a large amount of information regarding treatment options (Beaver K 1996).

Specifically regarding clinical trial recruitment, and despite the existence of constraints of many order, studies have shown that a fundamental factor in poor trial recruitment comes down to the communication skills of doctors (Jenkins VA 1999). This also results in an unacceptably low understanding exhibited by patients about the trials they join. This matter may, therefore, be preventing many patients from the benefice of innovative therapies and demands prompt addressing.

## 2.1.2 PATIENT COMMUNICATION DIFFICULTIES

The lay average citizen has less basic biology and medical terminology knowledge than usually assumed by health staff, so he can have real difficulty understanding the physical changes he's experiencing and the explanations he's given (C 1970).

Anxiety about having a life-threatening disease can make interpretation and comprehension of complex information even harder and there is experimental evidence that anxiety level influences the selective attention and recall of information about life threat more than of other neutral information (Beck AT 1988, MacLeod C 1993).

There is also the issue of the confrontation between the physician's duty of truth disclosure according to contemporary Western medical values and patients' cognitive and emotional appraisal of bad news (Beadle GF 2004). There is growing evidence that some patients have unrealistic expectations of treatments of minimal or unproven efficacy, including a belief that their cancer is curable, particularly in the context of advanced cancer (Beadle GF 2004). Studies have revealed that, at times, patients demand cancer treatment that clinicians might not be willing to accept for themselves because of high toxicity and a low probability of benefit (Gattellari M 1999). Skills for delivery of bad news are well documented in oncology, but studies also recognise that information can be misunderstood or forgotten (Fallowfield L 1999, Gattellari M 1999, Beadle GF 2004, U. Y. Fujimori M 2009, B. L. Schofield PE 2001). The use of videotapes in medical consultations can help obviate this problem, but for patients with a poor prognosis, this method may increase psychological distress and potentiate maladaptive responses (Beadle GF 2004, B. L. Schofield PE 2001). This phenomenon may occur because patients are not passive recipients of information but resist the monologue of information transfer from doctors by actively reconstructing expert information to assert their own perspectives, integrate with their knowledge of their own bodies and experiences, as well as the societal beliefs and reality (Fong Ha J 2010). This was illustrated by Beadle et al. (Beadle GF 2004), in a study assessing patients' beliefs about curability, where it was shown that 27% of patients with advanced cancer believed their cancer was curable, contrary to the information given by their oncologists, but in fact acknowledged a report of incurability by their oncologist. This kind of response seems to be particularly true for patients with avoidant coping styles (Gattellari M 1999). So, for these patients, the message was adequately communicated but at disparity with their beliefs, hence discarded (Fong Ha J 2010). Moreover, patients not only reshape the experience of adverse information into an illusory positive outcome but they also act upon it. Examples are adopting dangerous or erroneous behaviours,

contrary to their doctors' recommendations, just because their society pressures them to do otherwise (e.g. continued tanning despite knowledge of the risks associated with sun exposure and skin cancer for a particular group of people, because society equated tanned skin with beauty) (Fong Ha J 2010).

This renders patients vulnerable to biased information. Indeed, another growing concern is the source of patient knowledge, namely Internet, where often the information portrayed is misleading and inaccurate and also where advertisements for miraculous cures for cancer abound (Kim K 2010).

### **2.1.3 COMMUNICATION FRAMEWORK, PHYSICAL AND ORGANISATIONAL CONSTRAINTS LEADING TO COMMUNICATION DIFFICULTIES**

The consultation environment sometimes is rather deficient. That can render patients unease. Consultation interruptions have also been shown to block the information flow and to embarrass patients in the middle of a private confession or emotional reaction (Hogbin B 1989).

Another major issue lies on the consultation burden felt in some oncology clinics, so *that a truly patient centred dialogue is sacrificed in favour of the physical examination and a doctor centred monologue* (Fallowfield L 1999).

The transfer of information across the healthcare system, such as between primary, secondary and tertiary care can also present shortcomings. The process of truth telling, often managed by nononcologists until the final referral to the medical oncology facility, should begin with the diagnostic suspicion of cancer, progressively leading the patient to the truth (Numico G 2009). Numico et al. defends that solely when the informative task is well conducted in the preceding phase, can the oncologist disclose the prognostic significance of all the clinical and complementary exams' findings as well as treatment issues be explained. Misconceptions accumulated during the informative process are often the cause of a difficult communication in subsequent phases, as between the patient and the oncologist, and are a common justification of a partial or even false disclosure of the diagnosis and prognosis later on (Numico G 2009).

The quality of the communication within the multidisciplinary team has also been shown to be poor and contribute to confusion about diagnosis, test results and management (De

Valck C 1996, Fallowfield L 1999). Hence, information is sometimes missed, others duplicated, and this can provoke needless anxiety for patients and cause distrust on the multidisciplinary team (B. P. Schofield PE 2004).

Global migration trends have meant that physicians increasingly encounter patients who vary significantly in terms of language, illness-related beliefs and practices and health care expectations (P 2005, Roy R 2005). Cross-cultural communication barriers can be challenging and have a significant impact on care.

Hudelson (P 2005) performed a study to explore professional medical interpreters' experiences and perspectives regarding patient-provider communication difficulties, conducted at the general medicine outpatient clinic of Swiss hospitals, where previous data showed 58% of all patients were foreign-born. Interpreters described three domains where physicians and patients were likely to differ, and where mutual lack of awareness of those differences could lead to misunderstandings: (1) ideas about the patient's health problem; (2) expectations of the clinical encounter; and (3) verbal and non-verbal communication styles. Medical interpreters are uniquely placed to provide insight into general categories and common sources of communication problems because of their bilingual and often bicultural position. Some authors have proposed for them a growing role as "cultural mediators" in consultations, adapted to each specific context, in order to lessen the cross-cultural communication difficulties (P 2005).

## **2.2 COMMUNICATION NEEDS OF CANCER PATIENTS**

Research on this subject has shown that information is rated first among cancer patients' needs (Fallowfield L 1999, Tamburini M 2003, Capirci C 2005). An Italian study comprising admitted patients concluded that four of the top five needs expressed by 40% or more of the responders concerned information needs (diagnosis, future conditions, dialogue with doctors, economic and insurance solutions related to the disease). Only one of the five was concerned with improved "hotel" services (Tamburini M 2003).

Patients' information needs have been extensively addressed in the literature. One review study tried to discern patients' exact information needs and found 795 needs in 91 articles

(Rutten LJ 2005). These were gathered in 10 large information-need categories and 64 subcategories. The former, together with reporting frequency, were as follows: *cancer-specific information* (12.8%), *treatment-related information* (38.1%), *prognosis information* (10.8%), *rehabilitation information* (12.2%), *surveillance and health information* (3.4%), *coping information* (8.8%), *interpersonal information* (6.0%), *financial/legal information* (2.0%), *medical system information* (1.9%), and *body image/sexuality information* (3.9%) (Rutten LJ 2005).

As for the sources from whom/where the patients collect information, the same study found 5 categories and corresponding reporting frequencies that are as follows: health professionals (27.3%), printed materials (26.2%), media (13.5%), interpersonal (18.8%) and organisational and scientific resources (14.2%). Within the category *health professionals* doctors were the most prominent source (43.7%), followed by nurses (28.2%) (Rutten LJ 2005).

When comparing patients' needs and sources of information across the spectrum of disease, Rutten et al. found a statistically significant greater proportion of needs on the cancer-specific information category during the diagnosis/ treatment phase than during the post-treatment phase ( $p < 0.05$ ), and the opposite for rehabilitation information, as would be expected. There was no difference between information sources (Rutten LJ 2005).

One recent systematic review on cancer patients' preferences regarding the communication of bad news and associated factors (U. Y. Fujimori M 2009) concluded they mainly consist on four components: (1) setting, (2) manner of communicating bad news, (3) amount and content of information provided and (4) emotional support.

Focusing on setting, patients state preferring face-to-face consultation (U. Y. Fujimori M 2009, Russell BJ 2011) sufficient consultation time (Fallowfield L 1999, U. Y. Fujimori M 2009, P. P. Fujimori M 2007) and privacy (De Valck C 1996, Fallowfield L 1999, U. Y. Fujimori M 2009, Parker PA 2001). There was a high rate of interindividual variation in patients' responses when asked about the presence of another person when hearing bad news, with some preferring relatives to be present more than others, but almost all declining the wish to have another health professional present (U. Y. Fujimori M 2009). Also, physician's manner should be gentle and polite. On the issue of the manner of communication bad news the majority prefer their physicians to communicate in a clear and honest way, avoiding jargon and carefully choosing words, and offering access to X-ray films and laboratory data, and providing written information (U. Y. Fujimori M 2009, P. P. Fujimori M 2007, Voogt E 2005). This systematic review also showed that among early

studies almost all patients (96–98%) wanted to be told the diagnosis, which is corroborated by other studies (Fallowfield L 1999, Russell BJ 2011, Voogt E 2005, Squiers L 2005). A big proportion wish to receive all available information, be it good or bad (U. Y. Fujimori M 2009, B. L. Schofield PE 2001, Voogt E 2005, Davison BJ 2004). Preferences are also high regarding knowledge of chances of cure (91–97%) and treatment efficacy (79– 98%) (U. Y. Fujimori M 2009). Information regarding all available treatment options, the recent advances in the field and latest treatment option, the future treatment plan, adverse effects and risks of treatment as well as information regarding the impact of the disease/treatment on daily activities, social life and on other services (rehabilitation, social and community help) was also mentioned by patients as relevant (U. Y. Fujimori M 2009, B. L. Schofield PE 2001, P. P. Fujimori M 2007, Parker PA 2001, Davison BJ 2004, Sardell AN 1993). The scenario changes a bit relating to life expectancy and prognosis discussions, with fewer patients wanting to talk about those subjects (27-61%) (U. Y. Fujimori M 2009, B. L. Schofield PE 2001, P. P. Fujimori M 2007). Finally, regarding emotional support patients' preferences fall on empathy towards them and their family members, the use of a hopeful narrative by the doctor, reassurance and opportunity to express their feelings (U. Y. Fujimori M 2009, B. L. Schofield PE 2001, P. P. Fujimori M 2007, Parker PA 2001, Davison BJ 2004, Sardell AN 1993, Gonçalves F 2005).

Regarding the influence of patients' characteristics in communication patterns, studies are controversial.

Contemplating age, younger patients tend to seek more information than older patients (Gattellari M 1999, Hack TF e Team 2005, Numico G 2009, Rutten LJ 2005, Russell BJ 2011, P. P. Fujimori M 2007, Gavin AT 2002, Siminoff LA 2006) and usually prefer a more active role [decision involvement/empowerment) (Hack TF e Team 2005, U. Y. Fujimori M 2009). Regarding specific issues, older patients are more likely than younger patients to seek specific treatment information, but are less interested in support services, psychosocial issues, and prevention/risk factors (Squiers L 2005). Usually, the sources from which individuals seek information appear to be broader in younger patients than in older patients (Rutten LJ 2005). Nevertheless, some studies found no correlation between information and age (Voogt E 2005, Hilarius DL 2007).

In respect to gender, several studies suggest that women seek more information than men (Hack TF e Team 2005, U. Y. Fujimori M 2009, Rutten LJ 2005, Russell BJ 2011, Squiers L 2005, Siminoff LA 2006, Arraras JI 2010). Again, other studies were negative for this effect (Voogt E 2005, Hilarius DL 2007).

Literature also reveals some imbalances according to cultural/ethnic/racial differences: Asian patients were shown to prefer that relatives be present when receiving bad news more than Western patients (U. Y. Fujimori M 2009). Latin-American patients tend to receive less information than White Americans and the former together with African-Americans seem to request greater support on service information and psychosocial issues (U. Y. Fujimori M 2009, Squiers L 2005). Caucasian patients appear to adapt better to the psychological pressures of cancer than Asian patients (Roy R 2005).

Patients with higher socioeconomic status and education level also seek for more information (U. Y. Fujimori M 2009, Rutten LJ 2005, Russell BJ 2011, P. P. Fujimori M 2007, Squiers L 2005).

Previous work has also revealed that professional groups have higher agreement rates with one another on essential and superfluous questions to address more than they agree with a group of their patients. More importantly, there is considerable disagreement within each group. The results imply that the professionals cannot assume that their own information priorities are the same as those of their patients (Capirci C 2005).

### **2.3. PATIENT-PHYSICIAN COMMUNICATION ASSESSMENT INSTRUMENTS**

As stated previously, there is increasing awareness in the healthcare community of the importance of successful patient-doctor communication in achieving desired health outcomes. The number of instruments developed to assess this interaction has grown accordingly, and so a variety of instruments, many of which have not been validated, are available (Boon H 1998).

Older studies on this subject were mostly observational, relying on qualitative measures to assess patients' perceptions. These measures are more difficult to gauge, although allow a deeper understanding of subjective perceptions. In addition, comparisons between studies are difficult as numerous tools are available but no single tool is completely satisfactory (N 2003).

According to Roter & Hall the ideal way to evaluate healthcare communication is to make audio or videotapes of the encounters (H. J. Roter DL 1992). This method allows analysis of the medical encounter in order to code behaviour based on one of the observational instruments with respect to task and socioemotional behaviours (Fong Ha J 2010). This approach, nevertheless, has logistic and privacy issues that can render it unfeasible (H. J. Roter DL 1992). Alternative methods include medical charts reviews, yet audits to these documents have shown that symptom and functional limitations items are commonly not recorded (DiMatteo MR 2003, R. N. Roter DL 1994).

Satisfaction is a complex notion with many determinants and has been used as the ultimate outcome of the delivery of health care services as it is a proxy for health, and its rating provides useful information about the structure, process, and outcomes of care. Patients who experience good processes and outcomes of care are more satisfied and therefore more likely to continue maintaining the existing doctor-patient relationship (Fong Ha J 2010). The majority of the literature often uses patient satisfaction and adherence to determine the efficacy of the doctor-patient relationship (Fong Ha J 2010, N 2003). The possibility to generalise is limited and also depends on the size and representative nature of the specific population studied (Fong Ha J 2010, N 2003). Satisfaction needs to be investigated with a highly homogeneous group of patients to explore cause and effect of various factors on doctor-patient communication (N 2003).

Recently, patient self-reported data are frequently used to evaluate health-related quality of life (HRQoL) evidence, namely communication and information, and collecting it has the advantage of being a low-cost effective method (Taenzer P 2000, Wasson J 1992). In 2005, Hilarius et al. (Hilarius DL 2007) conducted a study to evaluate the extent of agreement between patient self-report and observer ratings of health-related quality of life communication in oncology. This study revealed that oncology patients' self-reports of the HRQoL-related topics discussed during outpatient chemotherapy visits are in reasonably close agreement with those provided by observers, implying that the patient is a legitimate source of information about the HRQoL-related content of medical encounters, and thus can be used in communication studies where the collection of observational data is either too costly or logistically impractical.

## **2.4. PATIENT-PHYSICIAN COMMUNICATION IMPROVEMENT**

The difficulties and issues aforementioned stated have raised the wish to enhance the knowledge on the information being provided to cancer patients.

In addition, the empirical notion derived from clinical practice during a clinical oncology internship in a reference cancer centre in Belgium – Jules Bordet Institute – that cancer patients differ in information level and needs, has set the foundation for a study assessing the information patients' report to receive.

Jules Bordet Institute is a Comprehensive Multidisciplinary Cancer Centre, the only autonomous hospital in Belgium totally dedicated to cancer. It covers both cancer screening and clinical care, is involved in research activities and is at the same time a teaching hospital.

Oncology practice is based on a multidisciplinary therapeutical approach and an intense laboratory and clinical research is also pursued. In fact, a fundamental aspect of Jules Bordet Institute is the close integration of research and practical oncology. Various clinical research programs are carried out in cooperation with national and international centres, especially in the framework of the EORTC (European Organization for Research and Treatment of Cancer) that was founded at the Jules Bordet Institute in 1964.

## 3. OBJECTIVES

### 3.1 GENERAL OBJECTIVE

The primary objective is to evaluate the self-reported information level of cancer patients attending Day Hospital in a comprehensive cancer centre.

### 3.2 SECONDARY OBJECTIVES

To evaluate the association between self-reported information level and the sociodemographical and clinical characteristics of these patients.

#### 3.2.1. *A priori* hypotheses based on the literature (Fallowfield LJ 1994, Hardy R 1979, S 1991, LJ 1993, U. Y. Fujimori M 2009, Rutten LJ 2005)

- Female patients receive a higher information level than male patients:

*H1: Women's information level > Men's information level*

- Female patients are less satisfied with the level of received information than male patients:

*H2: Women's information satisfaction < Men's information satisfaction*

- Younger patients receive a higher level of information than older patients:

*H3: Younger patients' information level ( $\leq 65$  years) > Older patients' information level (66-84;  $\geq 85$  years)*

- Patients with higher education attainment receive a higher information level than patients with lower education attainment:

*H4: Information level of patients with higher education > Information level of patients with lower education*

- Patients with lower education attainment receive less written information than patients with higher education attainment:

*H5: Written information of patients with lower education < Written information of patients with higher education*

- Patients with lower education attainment wish to receive less information than patients with higher education attainment:

*H6: Wishes of patients with lower education < Wishes of patients with higher education*

- Patients receiving potentially curative treatment receive a different level of information than patients receiving palliative treatment:

*H7: Information level on curative treatment  $\neq$  Information level on palliative treatment*

- Patients on the second or later chemotherapy lines receive a different level of information than patients on the first line of chemotherapy:

*H8: Information level on  $\geq 2^{\text{nd}}$  chemotherapy line  $\neq$  Information level on 1<sup>st</sup> chemotherapy line*

### **3.2.2. Exploratory analysis**

The remaining clinical and demographic characteristics of the patients will be subjected to an exploratory analysis, following non-parametric tests as used by Arraras et al. (Arraras JI 2010), specifically the comparison of item and scale responses between clinical and demographic sub-groups.

## **4. STUDY DESIGN**

This is a cross-sectional observational study intended to assess the information level (amount, content, type and usefulness) of cancer patients attending Day Hospital facilities in a comprehensive cancer centre.

## 5. PATIENT SELECTION CRITERIA

**Inclusion criteria:** Adult cancer patients  $\geq$  18 years-old.

Histological diagnosis of solid tumour (metastatic or not).

Patients attending the Day Hospital at Jules Bordet Institute (JBI), Brussels, Belgium.

Patients receiving chemotherapy treatment.

**Exclusion criteria:** Decline of study participation.

Patients with neurological disorders, causing cognitive impairment or temporospatial disorientation, and hence preventing the comprehension of study purposes and questionnaires.

Non-fluency in French or English.

Illiteracy.

## 6. FORMS AND INSTRUMENTS FOR DATA COLLECTION

These comprise:

- European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) version 3.0 (available in French and English) [Appendices A and B].

The EORTC QLQ-C30 (v. 3.0) is a validated, widely used questionnaire, suitable for observational, experimental and randomized clinical trials, containing five functional scales (physical, role, emotional, social and cognitive function), three symptom scales (fatigue, pain and nausea/vomiting), one global health status/quality of life (QoL) scale and six single items (symptoms and financial impact) (Aaronson NK 1993, Pais-Ribeiro J 2008). It contains 30 questions and the response format is a 4-point Likert scale (1 – not at all, 2 – a little, 3 – quite a bit, 4 – very much) for questions 1-28. The response format for questions 29-30 is a 7-point scale (ranging from 1 – very poor to 7 – excellent). The questions are answered circling the corresponding option the patient considers applicable to him.

- European Organisation for the Research and Treatment of Cancer Quality of Life Information Module (EORTC QLQ-INFO25) (available in French and English) [Appendices C and D].

The EORTC QLQ-INFO25 is a module of the EORTC QLQ-C30 valid for assessing cancer patients' perceptions of received information, which was validated in a multi-lingual and multi-cultural international sample, and presented good psychometric properties. It contains four multi-item scales (information about the disease, information about medical tests, information about treatments and information about other services) and 8 single items (information about different places of care, information about things one can do to help oneself get well, the physical support used to transmit information – written, CD/tape/video – and information satisfaction and usefulness; there are two open questions where patients can write the amount and topic of information desired) (Arraras JI 2010). It contains 25 questions and the response format is a 4-point Likert scale (1 –

not at all, 2 – a little, 3 – quite a bit, 4 – very much), except for questions 51-52 and 54-55 which have a dichotomous format (yes/no). The questions are answered circling the corresponding option the patient considers applicable to him. This questionnaire was adapted to include 1 question directly asking if the patient would like to receive additional information on each specific item being evaluated. The questions are answered boxing an “x” on the corresponding option the patient considers applicable to him (yes/no dichotomous answer choice). Such alteration is admissible according to EORTC guidelines for the use of this instrument, without a permission request.

The scores of EORTC QLQ-C30 (following mentioned at times as QLQ-C30 for simplicity) and its module EORTC QLQ-INFO25 (following mentioned at times as QLQ-INFO25 or INFO25 for simplicity) are linearly transformed to a 0-100 scale, according to the EORTC QLQ-C30 Scoring Manual (Fayers PM 2001).

- Patient demographical data sheet.

It includes basic demographic characteristics of patients (age, gender, marital status, highest level of education [Primary school; High school – 9 or 12 schooling years –; University degree and Master(MSc)/Doctor of Philosophy(PhD)], profession and place of birth [Belgium/outside of Belgium]) to be completed by the investigator – in English [Appendix E].

- Patient clinical data sheet.

This sheet includes patients’ clinical characteristics (primary tumour site, extent of disease [limited/disseminated], WHO performance status [ECOG, Appendix F] and treatment and line received) and will be filled in by the investigator – in English [Appendix G].

## 7. PROCEDURES AND TIMING FOR ASSESSMENTS

Eligible patients were identified from the day hospital treatment schedules of Jules Bordet Institute (JBI).

The sample was composed of consecutive (every 1 out of 3) patients with cancer who received their planned outpatient day hospital treatment between the 30<sup>th</sup> of May and the 8<sup>th</sup> of July 2011.

Patients were invited to participate in the day hospital setting, and participation only took place after informed consent signature.

Questionnaires were administered on a paper-printed format, self-reported on a paper-and-pencil basis. Administration time was estimated to be 10-15 minutes for each of the EORTC questionnaires. The investigator could read out the questions for the patients if required, and write the answers on the form, without exerting any kind of influence towards answer choice. Patients answered the questionnaire in the presence of the investigator and in the absence of proxy (to allow for privacy and avoid interference). The same person (the investigator) applied the questionnaires for all the patients included in this study.

Demographic and clinical data were also collected on appropriate forms.

## 8. STATISTICAL CONSIDERATIONS

Sequencing sampling method was used.

Statistical inferences were based on non-parametric null hypothesis significance tests (cf. Arraras et al. (Arraras JI 2010)).

A power analysis was conducted to estimate the appropriate sample size for this study using the G\*Power3 software (version 3.1.2.) (Faul F 2007). Following the specifications of Arraras et al. (Arraras JI 2010), it was estimated that a sample of 94 patients would have 90% power of detecting a 10-point difference in patients' responses in a two-tailed Mann-Whitney U test at 5% significance.

To address the primary objective (section 3.1. above) of the study, the data collected were summarized by obtaining descriptive statistics of central tendency and variability of the responses of all patients for the whole scale, sub-scales and all items. Descriptive statistics of scale responses for sub-groups of interest were also computed, namely those defined by age ( $\leq 65$ years, 66-84;  $\geq 85$  years), gender (male vs. female), place of birth (Belgium/outside of Belgium), marital status, level of education (Primary school; High school – 9 or 12 schooling years –; University degree and MSc/PhD), profession, primary tumour site, WHO performance status (ECOG), disease extent (limited vs. disseminated) and line of treatment received.

To address the secondary objectives (sections 3.2. and 3.2.1.), eight hypotheses derived from previous studies were tested at a significance level of 0.05:

*H1: Women's information level > Men's information level* (Mann-Whitney U test, one-tailed)

*H2: Women's information satisfaction < Men's information satisfaction* (Mann-Whitney U test, one-tailed)

*H3: Younger patients' information level ( $\leq 65$ years) > Older patients' information level (66-84;  $\geq 85$  years) (Mann-Whitney U test, one-tailed)*

*H4: Information level of patients with higher education > Information level of patients with lower education (Mann-Whitney U test, one-tailed)*

*H5: Written information of patients with lower education < Written information of patients with higher education (Mann-Whitney U test, one-tailed)*

*H6: Wishes of patients with lower education < Wishes of patients with higher education (Mann-Whitney U test, one-tailed)*

*H7: Information level on curative treatment  $\neq$  Information level on palliative treatment (Mann-Whitney U test, two-tailed)*

*H8: Information level on  $\geq 2^{nd}$  chemotherapy line  $\neq$  Information level on  $1^{st}$  chemotherapy line (Mann-Whitney U test, two-tailed)*

The remaining clinical and demographic characteristics of the patients were subjected to an exploratory analysis, and comparison of item and scale responses between clinical and demographic sub-groups were performed by means of Mann-Whitney U tests (for comparisons between two groups) or Kruskal-Wallis one-way analysis of variance (for comparisons between more than two groups). Unplanned exploratory hypotheses tests may lead to the inflation of the Type I error rate due to multiple comparisons. However, because of the potential clinical relevance of the findings, the significance level ( $\alpha$ ) for the exploratory analyses was kept at 0.05, and inferences were performed on uncorrected p-values. Bonferroni corrected results were further calculated and statistically significant comparisons that survive the correction were signalled where appropriate.

Statistical analyses were conducted using Microsoft Excel and SPSS v17.0 (SPSS Inc., Chicago, IL).

## **9. ETHICAL CONSIDERATIONS**

### ***9.1 PATIENT'S PROTECTION***

The responsible investigator has ensured that this study was conducted in agreement with the Declaration of Helsinki ((WMA) 2008) and Belgian regulations, whichever provided the greatest protection on the patient.

The protocol was approved by the Ethics Committee of Jules Bordet Institute as required by the applicable Belgian legislations [Appendix H].

Data was treated in strict confidentiality and there was no patient name in any form to protect patient privacy. Each patient was assigned to an inclusion number, allocated consecutively and starting from 001.

All patients were informed about:

- Study aims;
- Strict confidentiality of any patient data;
- Medical records' reviews for study purposes by study investigator and eventually by other authorized individuals.

Two versions (French and English) of the Patient Information Sheet/Patient Informed Consent (PIS/PIC) were provided.

Documented informed consent was obtained for all patients included in the study prior to beginning. The written informed consent form was signed and personally dated by the patient or by the patient's legally acceptable representative, and witnessed by the investigator performing the consent process.

## 10. RESULTS

### DEMOGRAPHIC AND CLINICAL VARIABLES DESCRIPTIVE STATISTICS

Between the 30<sup>th</sup> of May and 8<sup>th</sup> of July 2011, 102 patients were recruited. One patient was excluded because of questionnaire non-completion due to tiredness. One hundred and one patients (99%) fully completed the questionnaires.

The mean age of the 101 respondents was 56.9 years ( $SD = 12.8$ ). The youngest patient was 23 years old and the oldest 81 ( $Mdn = 58$ ). The majority was 65 years old or less ( $n=72$ ; 71.3%) and the remaining patients were aged between 66-84 years ( $n=29$ ; 28.7%).

Patients' other demographic and clinical characteristics are presented in Table 1.

Table 1 – Demographic characteristics of the patients.

Variable	N	%	Male	Female
<b>Gender</b>				
Male	22	21.8		
Female	79	78.2		
<b>Marital status</b>				
Single	15	14.9	2	13
Married	59	58.4	16	43
Divorced	18	17.8	4	14
Widow	6	5.9	0	6
Co-inhabitant	3	3.0	0	3
<b>Highest level of education</b>				
Primary	2	2	0	2
High school 9 years	9	8.9	2	7
High school 12 years	44	43.6	6	38
University degree	41	40.6	13	28
MSc/PhD	5	5.0	1	4
<b>Occupational sector</b>				
Business/Financial/Administrative	24	23.7	6	18
Education/Science	17	16.8	3	14
Trade/Other services	16	15.8	4	12
Health	12	11.9	1	11
Maintenance services	4	4.0	2	2
Marketing/Media	6	6.0	4	2
Protective services	1	1.0	0	1
Non-working	8	7.9	1	7
Unknown	13	12.9	1	12
<b>Place of birth</b>				
Belgium	75	74.3	16	59
Outside of Belgium	26	25.7	6	20

Patients' clinical characteristics are depicted in Table 2.

**Table 2 – Clinical characteristics of the patients**

<b>Variable</b>	<b>N</b>	<b>%</b>	<b>Male</b>	<b>Female</b>
<b>Primary tumour site</b>				
Breast	59	58.4	0	59
Gastrointestinal	20	19.8	11	9
Gynaecological	5	5.0	0	5
Head and neck	2	2.0	1	1
Lung	5	5.0	3	2
Melanoma	3	3.0	2	1
Sarcoma	1	1.0	0	1
Urogenital	6	5.9	5	1
<b>Disease extent</b>				
Limited	35	34.7	5	30
Disseminated	66	65.3	17	49
<b>Performance status (ECOG)</b>				
0	29	28.7	7	22
1	59	58.4	11	48
2	13	12.9	4	9
<b>Line of treatment</b>				
Neo-adjuvant	11	10.9	2	9
Adjuvant	23	22.8	3	20
Metastatic				
1 <sup>st</sup>	20	19.8	6	14
2 <sup>nd</sup>	10	9.9	4	6
3 <sup>rd</sup>	9	8.9	1	8
4 <sup>th</sup>	3	3.0	0	3
5 <sup>th</sup>	2	2.0	0	2
6 <sup>th</sup>	2	2.0	0	2
Experimental	21	20.8	6	15
<b>Participation in Clinical Trial</b>				
Yes	29	28.7	6	23
No	72	71.3	16	56

Respecting the line of treatment it is noticed that most patients (45.5%) were receiving metastatic treatment in the various lines (19.8% having first-line treatment), 22.8% were undergoing adjuvant chemotherapy, 10.9% were being treated with neo-adjuvant chemotherapy and 20.8% were on experimental treatments (non-standard chemotherapy treatment in a clinical trial context). Twenty-nine patients (28.7%) were currently part of a clinical trial, which included all patients in experimental treatments and also 7 patients on adjuvant chemotherapy and one patient in neo-adjuvant chemotherapy.

## EORTC QLQ-INFO25 QUESTIONNAIRE DESCRIPTIVE STATISTICS

**Table 3 – Descriptive statistics of QLQ-INFO25 scales/items, reliability and comparison with the module’s validation study.**

Scales/items QLQ-INFO25	<i>M</i> <sup>a</sup>	<i>SD</i>	<i>M</i> <sup>a,b</sup>	<i>SD</i> <sup>b</sup>	<i>p</i> <sup>c</sup>	Difference	<i>Mdn</i>	Cronbach’s alpha
Whole questionnaire (items 31-55)	57.9	16.4	43.6	13.4	<u>≤0.001</u> *	14.3	58.7	0.91
Information about the disease (items 31–34)	63.7	21.4	57.4	23.5	<u>0.01</u>	6.3	58.3	0.70
Information about medical tests (items 35–37)	71.6	23.7	67.7	26.9	0.18	3.9	66.7	0.83
Information about treatments (items 38–43)	58.4	21.8	48.7	20.7	<u>≤0.001</u> *	9.7	61.1	0.82
Information about other services (items 44–47)	33.2	28.2	29.4	22.3	0.14	3.8	25.0	0.75
Information about different places of care (item 48)	35.9	38.2	31.2	32.4	0.20	4.7	33.3	
Information about things you can do to help yourself get well (item 49)	42.9	36.9	39.3	34.5	0.35	3.6	33.3	
Written information (item 50) <sup>d</sup>	14.5	16.6	50.5	50.1	<u>≤0.001</u> *	-36.0	0.0	
Information on CD or tape/video (item 51) <sup>d</sup>	30.0	10.0	5.4	22.6	<u>≤0.001</u> *	24.6	33.3	
Satisfaction with the information received (item 52)	65.3	26.6	63.7	29.1	0.61	1.6	66.7	
Wish to receive more information (item 53) <sup>d</sup>	14.9	16.7	47.7	50.1	<u>≤0.001</u> *	-32.8	0.0	
Wish you have received less information (item 54) <sup>d</sup>	32.7	4.7	2.0	14.1	<u>≤0.001</u> *	30.7	33.3	
Overall the information has been helpful (item 55)	74.9	23.3	68.8	25.5	<u>0.03</u>	6.1	66.7	

*M* - Mean; *Mdn* – Median; *SD* – standard deviation

<sup>a</sup> Scores in the QLQ-INFO25 module scales and items range from 0 to 100. Higher scores mean a higher level of information received, higher information wishes and higher satisfaction.

<sup>b</sup> Descriptive statistics from Arraras et al. (Arraras JI 2010), Table 2, Assessment during treatment (n=451).

<sup>c</sup> Independent samples t-tests; significant p-values were underlined for ease of viewing.

<sup>d</sup> Items 50, 51, 53 and 54 have a dichotomous answer (yes/no).

\* Comparisons that remain statistically significant at a level of 0.05 after Bonferroni correction (the *p*-values reported are not corrected for multiple comparisons).

The mean scores of the whole questionnaire ( $M = 57.9$ ) were statistically significantly higher than the ones for the validation study of the INFO25 module ( $M = 43.6$ ),  $p < 0.001$ . The same holds true for the scales on information about the disease ( $M = 63.7$  vs.  $M = 57.4$ ),  $p = 0.01$ , information about treatments ( $M = 58.4$  vs.  $M = 48.7$ ),  $p < 0.001$ , information on CD or tape/video ( $M = 30.0$  vs.  $M = 5.4$ ),  $p < 0.0001$ , helpfulness of the overall information received ( $M = 74.9$  vs.  $M = 68.8$ ),  $p = 0.03$  and wish to receive less information ( $M = 32.7$  vs.  $M = 2.0$ ),  $p < 0.001$ .

The mean scores of the written information ( $M = 14.5$ ) and the wish to receive more information ( $M = 14.9$ ) were statistically significantly lower than the corresponding score of the validation study for the INFO25 ( $M = 50.5$  and  $M = 47.7$ , respectively), both with  $p < 0.001$ .

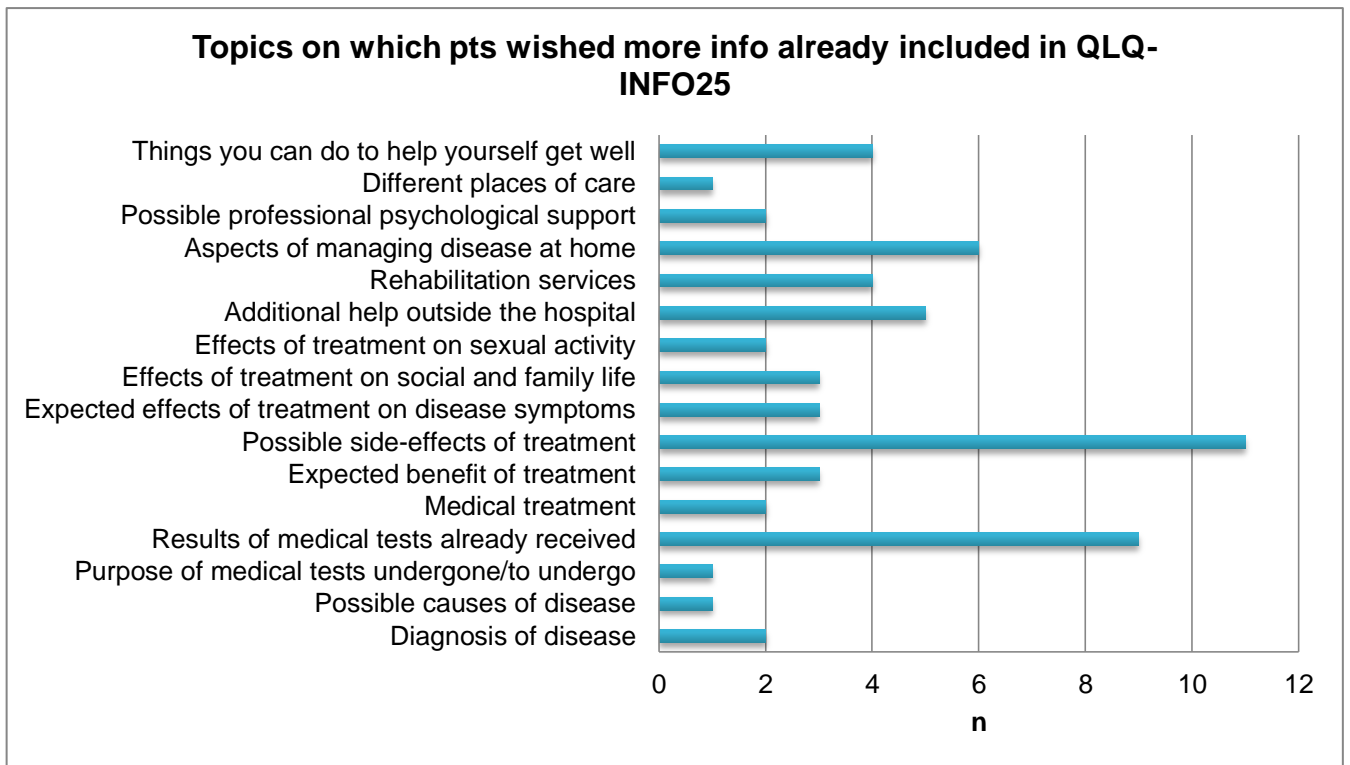
Cronbach's alpha coefficients of all multi-item scales were above  $\geq 0.70$  (minimum of 0.70 for the scale on information about the disease and maximum of 0.83 for the scale on information about medical tests). The internal consistency estimate of the whole questionnaire was very high ( $\alpha = 0.91$ ) and the same as the one obtained by Arraras et al. (Arraras JI 2010).

#### ***Open questions of QLQ-INFO25 description (wishes on more and less information)***

This section describes patients' answers to the two open questions contained in QLQ-INFO25 (items 53b and 54b). They were filled in only in case of affirmative answers to the preceding corresponding questions 53a and 54a. That condition was respected, however, a substantial part of the content of obtained answers was unrelated to the question being posed and such content was discarded for analysis.

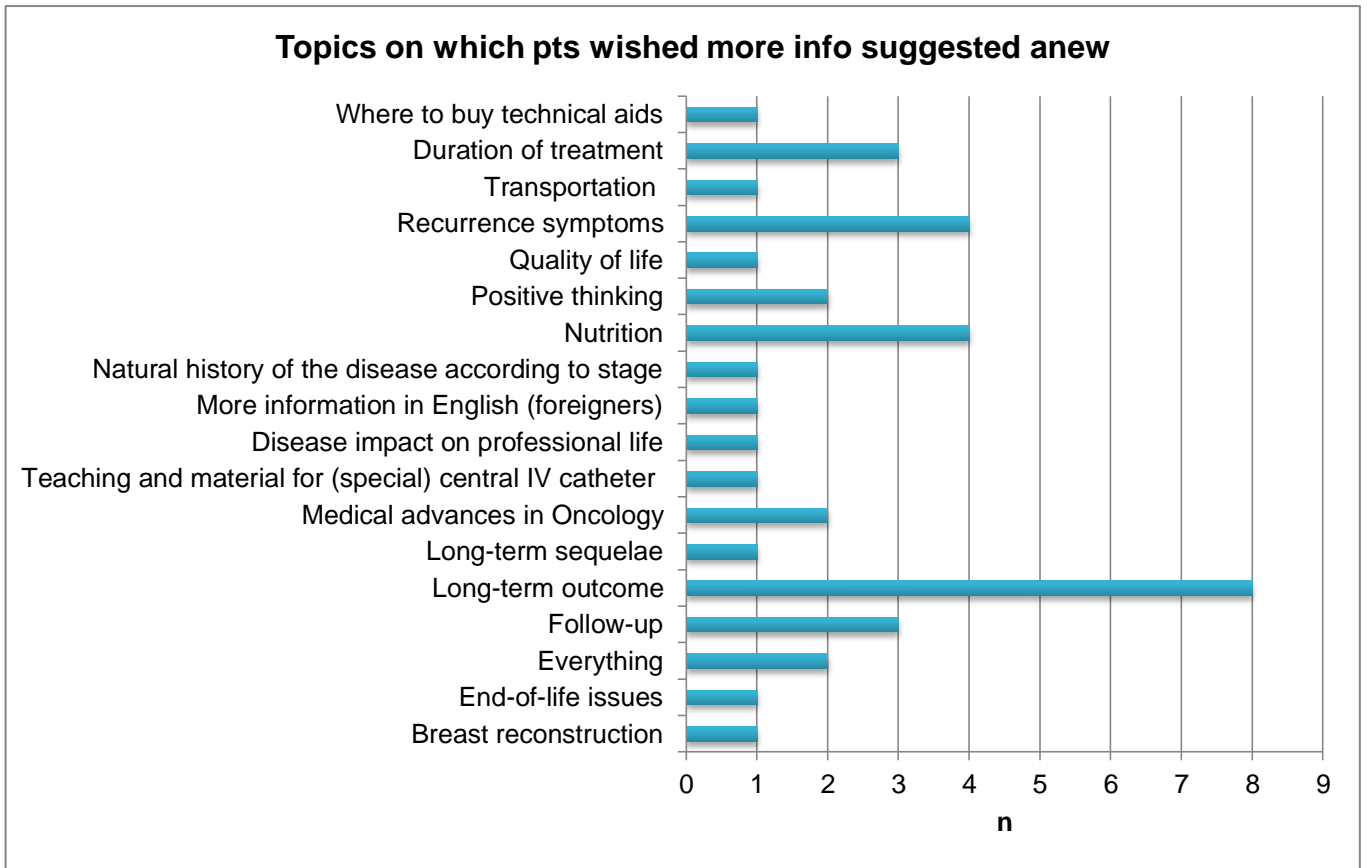
Appropriate answers were organised and classified in order to render them informative. On question 53b, a dichotomous separation of answers into topics already mentioned in QLQ-INFO25 and new topics suggested by the patients was performed. With respect to question 54a, only one patient responded affirmatively, writing she desired to receive less information "*when her health condition would deteriorate*".

On the question "Do you wish to receive more information?" (item 53a) 56 patients answered yes. Of those, 3 forgot to answer question 53b (missing items). The answers of the remaining 53 patients are illustrated on Figures 1 and 2.



**Figure 1 – Patients’ answers to item 53b, illustrating the topics on which they wished to receive more information already included in the questionnaire and their frequency (n).**

The most frequent topics on which patients expressed their wish to receive more information, already mentioned in the questionnaire, were the possible side effects of treatment (item 40 – 11 patients) and the results of the medical tests already received (item 37 – 9 patients).



**Figure 2 - Patients' answers to item 53b, illustrating the topics on which they wished to receive more information that were not mentioned in the questionnaire (i.e. were suggested anew) and their frequency (n).**

The predominant topics on which patients expressed their wish to receive more information that were not included in the questionnaire were long-term outcome (8 patients), nutrition (4 patients) and recurrence symptoms (4 patients).

## INFERENCEAL STATISTICS

This section describes the results of the tests performed on the 8 working hypotheses previously stated.

**Table 4 – Self-reported information according to demographic variables: gender and age.**

QLQ-INFO 25 scales/items	Gender			Age		
	Male (n=22)	Female (n=79)	<i>p</i>	≤ 65 (n=72)	≥ 66 (n=29)	<i>p</i>
	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	57.1 (15.3)	58.2 (16.8)	0.50	58.1 (17.3)	57.6 (14.2)	0.45
Information about the disease (31-34)	61.4 (18.8)	64.4 (22.2)	0.29	63.9 (22.8)	63.2 (18.0)	0.40
Information about medical tests (35-37)	69.7 (26.2)	72.2 (23.1)	0.36	71.9 (23.2)	70.9 (25.3)	0.49
Information about treatments (38-43)	60.9 (21.8)	57.7 (21.9)	0.27	59.0 (22.8)	56.9 (19.6)	0.37
Information about other services (44-47)	30.7 (26.3)	33.9 (28.8)	0.37	33.7 (28.0)	31.9 (29.0)	0.36
Information about different places of care (48)	34.9 (39.1)	36.3 (38.2)	0.41	34.7 (38.1)	39.1 (38.9)	0.31
Information about things you can do to help yourself get well (49)	34.9 (36.3)	45.2 (37.0)	0.12	43.1 (36.5)	42.5 (38.7)	0.46
Written information (50)	54.6 (51.0)	40.5 (49.4)	0.18	36.1 (48.4)	62.1 (49.4)	<u>0.02</u>
Information on CD or tape/video (51)	86.4 (35.1)	91.1 (28.6)	0.38	86.1 (34.8)	100.0 (0.0)	<u>0.03</u>
Satisfaction with information received (52)	65.2 (28.1)	65.4 (26.4)	0.51	67.6 (28.0)	59.8 (22.5)	<u>0.05</u>
Wish to receive more information (53)	40.9 (50.3)	45.6 (50.1)	0.44	48.6 (50.3)	34.5 (48.4)	0.14
Overall information has been helpful (55)	68.2 (24.1)	76.8 (22.8)	0.07	78.2 (22.5)	66.7 (23.6)	<u>0.01</u>

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests. Significant *p*-values were underlined for ease of viewing.

There was no statistically significant association between gender and self-reported levels of information. The self-reported information levels were statistically significantly higher in older patients (≥ 66 years old) regarding written information ( $p = 0.02$ ) and information on CD or tape/video ( $p = 0.03$ ). The self-reported information levels were statistically significantly higher in younger patients (≤ 65 years old) regarding satisfaction with the

information received ( $p = 0.05$ ) and helpfulness of the overall information received ( $p = 0.01$ ).

**Table 5 – Self-reported information according to demographic variables: education level.**

QLQ-INFO 25 scales/items	Education level		<i>p</i>
	Lower education (n=55)	Higher education (n=46)	
	<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	59.0 (17.7)	56.7 (14.8)	0.30
Information about the disease (31-34)	66.2 (23.2)	60.7 (18.9)	0.10
Information about medical tests (35-37)	72.7 (23.9)	70.3 (23.7)	0.27
Information about treatments (38-43)	59.3 (22.8)	57.4 (20.8)	0.37
Information about other services (44-47)	34.2 (30.7)	31.9 (25.2)	0.49
Information about different places of care (48)	37.6 (41.1)	34.1 (34.8)	0.38
Information about things you can do to help yourself get well (49)	47.3 (39.9)	37.7 (32.7)	0.13
Written information (50)	40.0 (49.4)	47.8 (50.5)	0.28
Information on CD or tape/video (51)	90.9 (29.0)	89.1 (31.5)	0.51
Satisfaction with information received (52)	63.6 (28.2)	67.4 (24.8)	0.28
Wish to receive more information (53)	47.3 (50.4)	41.3 (49.8)	0.35
Overall information has been helpful (55)	72.1 (23.8)	78.3 (22.5)	0.11

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests.  
Significant *p*-values were underlined for ease of viewing.

There was no statistically significant association between the education level and self-reported levels of information.

**Table 6 – Self-reported information according to clinical variables: treatment intent and treatment lines.**

QLQ-INFO 25 scales/items	Treatment intent			Treatment line		
	Curative (n=35)	Palliative (n=66)	<i>p</i>	Chemo 1 <sup>st</sup> (n=54)	Chemo ≥ 2 <sup>nd</sup> (n=47)	<i>p</i>
	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	60.2 (16.8)	56.8 (16.2)	0.21	57.8 (16.3)	58.1 (16.7)	0.96
Information about the disease (31-34)	64.7 (22.8)	63.1 (20.8)	0.61	63.4 (22.4)	64.0 (20.5)	0.79
Information about medical tests (35-37)	71.4 (24.5)	71.7 (23.5)	0.90	70.2 (23.5)	73.3 (24.0)	0.60
Information about treatments (38-43)	61.6 (19.6)	56.7 (22.9)	0.33	57.3 (20.4)	59.7 (23.5)	0.75
Information about other services (44-47)	37.6 (30.0)	30.8 (27.1)	0.31	36.7 (28.6)	29.1 (27.4)	0.17
Information about different places of care (48)	38.1 (34.4)	34.9 (40.3)	0.48	37.0 (37.6)	34.8 (39.3)	0.73
Information about things you can do to help yourself get well (49)	60.0 (35.1)	33.8 (34.8)	<u>0.001</u> *	48.8 (37.0)	36.2 (36.0)	0.08
Written information (50)	34.3 (48.2)	48.5 (50.4)	0.21	44.4 (50.2)	42.6 (50.0)	1.00
Information on CD or tape/video (51)	74.3 (44.3)	98.5 (12.3)	<u>&lt;0.001</u> *	81.5 (39.2)	100.0 (0.0)	<u>0.002</u> *
Satisfaction with information received (52)	66.7 (28.0)	64.7 (26.1)	0.64	64.8 (26.2)	66.0 (27.4)	0.81
Wish to receive more information (53)	54.3 (50.5)	39.4 (49.2)	0.21	40.7 (49.6)	48.9 (50.5)	0.43
Overall information has been helpful (55)	82.9 (20.4)	70.7 (23.8)	<u>0.01</u>	76.5 (23.0)	73.1 (23.7)	0.48

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests.

Significant *p*-values were underlined for ease of viewing.

\* Comparisons that remain statistically significant at a level of 0.05 after Bonferroni correction (the *p*-values reported are not corrected for multiple comparisons).

The self-reported information levels were statistically significantly higher in patients undergoing treatment with curative intent ( $M = 60.0$ ) than patients undergoing palliative treatment ( $M = 33.8$ ) with respect to things one can do to help oneself get well ( $p = 0.001$ ) and also to overall helpfulness of information ( $M = 82.9$  vs.  $M = 70.7$ ;  $p = 0.01$ ).

The reverse association was true respecting the information on CD or tape/video, with higher mean scores in patients undergoing palliative treatment ( $M = 98.5$ ) than curative patients ( $M = 74.3$ ),  $p < 0.001$ .

Table 6 also shows there was a statistically significant association between the number of chemotherapy lines received and the level of information on CD/tape/video ( $p = 0.002$ ).

## EXPLORATORY ANALYSIS

This section describes the exploratory analysis done using patients' other demographic and clinical characteristics and also answers to the questionnaire QLQ-C30.

**Table 7 – Self-reported information according to demographic variables: place of birth and marital status.**

QLQ-INFO 25 scales/items	Country of birth			Marital status		
	Belgium (n=75)	Other (n=26)	<i>p</i>	Alone (n=39)	Not alone (n=62)	<i>p</i>
	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	57.3 (17.7)	59.9 (12.1)	0.41	57.7 (15.9)	58.0 (16.9)	1.00
Information about the disease (31-34)	61.9 (22.0)	68.9 (19.1)	0.14	65.8 (20.8)	62.4 (21.9)	0.33
Information about medical tests (35-37)	68.7 (24.7)	79.9 (18.6)	0.06	75.2 (21.6)	69.4 (24.9)	0.26
Information about treatments (38-43)	57.3 (22.3)	61.8 (20.5)	0.41	55.8 (22.2)	60.0 (21.6)	0.46
Information about other services (44-47)	35.0 (30.3)	27.9 (20.4)	0.56	32.7 (30.1)	33.5 (27.1)	0.74
Information about different places of care (48)	37.8 (37.7)	30.8 (39.9)	0.32	29.9 (34.9)	39.8 (40.0)	0.25
Information about things you can do to help yourself get well (49)	43.6 (35.9)	41.0 (40.3)	0.68	41.0 (38.6)	44.1 (36.1)	0.63
Written information (50)	45.3 (50.1)	38.5 (49.6)	0.65	43.6 (50.2)	43.6 (50.0)	1.00
Information on CD or tape/video (51)	88.0 (32.7)	96.2 (19.6)	0.29	87.2 (33.9)	91.9 (27.5)	0.50
Satisfaction with information received (52)	62.2 (27.0)	74.4 (23.7)	<u>0.05</u>	66.7 (21.6)	64.5 (29.5)	0.91
Wish to receive more information (53)	44.0 (50.0)	46.2 (50.8)	1.00	46.2 (50.5)	43.6 (50.0)	0.84
Overall information has been helpful (55)	73.3 (23.9)	79.5 (21.2)	0.29	74.4 (23.5)	75.3 (23.3)	0.87

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests.  
Significant *p*-values were underlined for ease of viewing.

The only statistically significantly association found was a higher score on satisfaction with information received by patients born outside of Belgium. There was no association between the marital status of patients that were alone (single, divorced and widowers) and patients that lived with someone (married and co-inhabitant) regarding self-reported information received.

**Table 8 – Self-reported information according to clinical variables: clinical trial participation.**

QLQ-INFO 25 scales/items	Clinical trial participation		
	Yes (n=29)	No (n=72)	<i>p</i>
	<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	53.5 (16.7)	59.7 (16.1)	0.07
Information about the disease (31-34)	56.9 (19.8)	66.4 (21.6)	<u>0.04</u>
Information about medical tests (35-37)	65.5 (25.1)	74.1 (22.8)	0.10
Information about treatments (38-43)	57.3 (21.4)	58.9 (22.1)	0.51
Information about other services (44-47)	25.6 (24.7)	36.2 (29.1)	0.10
Information about different places of care (48)	28.7 (37.5)	38.9 (38.4)	0.21
Information about things you can do to help yourself get well (49)	33.3 (34.5)	46.8 (37.4)	0.10
Written information (50)	24.2 (43.6)	51.4 (50.3)	<u>0.02</u>
Information on CD or tape/video (51)	86.2 (35.1)	91.7 (27.8)	0.47
Satisfaction with information received (52)	64.4 (29.5)	65.7 (25.6)	0.94
Wish to receive more information (53)	51.7 (50.9)	41.7 (49.7)	0.38
Overall information has been helpful (55)	78.2 (24.0)	73.6 (23.0)	0.34

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests.  
Significant *p*-values were underlined for ease of viewing.

As seen on Table 8, the self-reported information levels were statistically significantly higher in patients not participating in a clinical trial than the ones participating in a clinical trial on information about the disease ( $M = 66.4$  vs.  $M = 56.9$ ),  $p = 0.04$  and on written information ( $M = 51.4$  vs.  $M = 24.2$ ),  $p = 0.02$ .

**Table 9 – Self reported information according to clinical variables: ECOG and primary tumour site.**

QLQ-INFO 25 scales/items	ECOG				Primary tumour site			p
	0 (n=29)	1 (n=59)	2 (n=13)	p	Breast (n=59)	G.I. (n=20)	Other (n=22)	
	M (SD)	M (SD)	M (SD)		M (SD)	M (SD)	M (SD)	
Whole questionnaire (31-55)	58.0 (14.6)	57.9 (17.7)	58.1 (15.5)	0.92	57.7 (18.6)	60.1 (15.1)	56.5 (10.9)	0.96
Information about the disease (31-34)	64.4 (21.5)	63.1 (21.8)	64.7 (21.0)	0.94	63.3 (23.5)	63.8 (18.4)	64.8 (18.7)	0.92
Information about medical tests (35-37)	71.7 (23.9)	70.4 (24.4)	76.9 (21.0)	0.77	71.4 (24.5)	70.0 (25.5)	73.7 (20.4)	0.62
Information about treatments (38-43)	60.7 (20.2)	56.7 (22.4)	61.1 (23.4)	0.60	56.6 (23.2)	61.1 (23.2)	60.9 (16.3)	<u>0.03</u>
Information about other services (44-47)	31.3 (24.5)	35.0 (30.9)	28.9 (24.0)	0.89	34.8 (29.3)	40.8 (24.8)	22.0 (25.7)	0.32
Information about different places of care (48)	32.2 (32.7)	36.2 (39.8)	43.6 (43.9)	0.82	37.3 (37.7)	41.7 (38.8)	27.3 (39.4)	0.13
Information about things you can do to help yourself get well (49)	49.4 (34.1)	40.7 (39.7)	38.5 (30.0)	0.45	45.2 (37.5)	50.0 (33.3)	30.3 (37.0)	0.76
Written information (50)	34.5 (48.4)	49.2 (50.4)	38.5 (50.6)	0.40	40.7 (49.5)	50.0 (51.3)	45.5 (51.0)	0.62
Information on CD or tape/video (51)	65.5 (48.4)	100.0 (0.0)	100.0 (0.0)	<u>&lt;0.001*</u>	88.1 (32.6)	90.0 (30.8)	95.5 (21.3)	0.42
Satisfaction with information received (52)	69.0 (21.7)	62.7 (29.1)	69.2 (25.3)	0.63	65.0 (27.3)	60.0 (27.8)	71.2 (23.7)	0.93
Wish to receive more information (53)	55.2 (50.6)	44.1 (50.1)	23.1 (43.9)	0.16	45.8 (50.3)	45.0 (51.0)	40.9 (50.3)	0.53
Overall information has been helpful (55)	81.6 (19.1)	71.8 (23.8)	74.4 (27.7)	0.21	76.8 (24.2)	71.7 (24.8)	72.7 (19.6)	0.96

M – Mean; Mdn – Median; SD – standard deviation; p – Kruskal-Wallis tests; G.I. – Gastrointestinal.

Significant p-values were underlined for ease of viewing.

\* Comparisons that remain statistically significant at a level of 0.05 after Bonferroni correction (the p-values reported are not corrected for multiple comparisons).

Table 9 shows group comparisons by ECOG (0, 1 or 2) and primary tumour site (breast, gastrointestinal or others). There was a statistically significant association between the ECOG and information on CD/tape/video ( $p < 0.001$ ) and between the information about treatments and the primary tumour site ( $p = 0.03$ ).

Table 10 illustrates comparisons based on the Global Quality of Life (QoL) scale and one of the functional scales, the Emotional Function, of QLQ-C30 questionnaire.

**Table 10 – Self-reported information according to two scales of QLQ-C30: QoL scale and EF scale.**

QLQ-INFO 25 scales/items	Quality of life (QoL)			Emotional Function (EF)		
	Lower QoL (n=59)	Higher QoL (n=42)	<i>p</i>	Lower EF (n=47)	Higher EF (n=54)	<i>p</i>
	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	54.9 (15.2)	62.2 (17.3)	<u>0.05</u>	56.5 (17.3)	59.1 (15.7)	0.54
Information about the disease (31-34)	60.7 (21.7)	67.9 (20.5)	0.07	63.5 (24.0)	63.9 (19.2)	0.81
Information about medical tests (35-37)	65.7 (23.8)	79.9 (21.1)	<u>0.002*</u>	69.5 (24.7)	73.5 (22.9)	0.47
Information about treatments (38-43)	54.6 (20.9)	63.8 (22.2)	0.07	54.4 (23.0)	61.9 (20.3)	0.16
Information about other services (44-47)	31.2 (27.0)	35.9 (29.9)	0.48	33.3 (27.3)	33.0 (29.2)	0.84
Information about different places of care (48)	29.9 (36.5)	44.4 (39.4)	0.07	34.0 (39.0)	37.7 (37.8)	0.62
Information about things you can do to help yourself get well (49)	37.9 (36.3)	50.0 (37.0)	0.10	46.1 (37.1)	40.1 (36.9)	0.41
Written information (50)	50.9 (50.4)	33.3 (47.7)	0.10	44.7 (50.3)	42.6 (49.9)	0.84
Information on CD or tape/video (51)	94.9 (22.2)	83.3 (37.7)	0.09	93.6 (24.7)	87.0 (33.9)	0.33
Satisfaction with information received (52)	59.3 (27.0)	73.8 (23.9)	<u>0.006</u>	62.4 (27.5)	67.9 (25.9)	0.29
Wish to receive more information (53)	37.3 (48.8)	54.8 (50.4)	0.11	38.3 (49.1)	50.0 (50.5)	0.32
Overall information has been helpful (55)	71.2 (24.3)	80.2 (20.9)	0.07	74.5 (26.2)	75.3 (20.7)	0.95

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests.

Significant *p*-values were underlined for ease of viewing.

\* Comparisons that remain statistically significant at a level of 0.05 after Bonferroni correction (the *p*-values reported are not corrected for multiple comparisons).

The self-reported information levels were statistically significantly higher in patients with higher QoL scores concerning the whole questionnaire ( $M = 62.2$  vs.  $M = 54.9$ ),  $p = 0.05$ , information about medical tests ( $M = 79.9$  vs.  $M = 65.7$ ),  $p = 0.002$  and satisfaction with information ( $M = 73.8$  vs.  $M = 59.3$ ),  $p = 0.006$ .

There was no statistically significant association between the Emotional Function scale of QLQ-C30 and self-reported levels of information.

**Table 11 – Self-reported information according to satisfaction with information (item 52) and wishes for more information (item 53a).**

QLQ-INFO 25 scales/items	Satisfaction with information			Wish more information		
	Lower satisf. (n=26)	Higher satisf. (n=75)	<i>p</i>	No (n=56)	Yes (n=45)	<i>p</i>
	<i>M (SD)</i>	<i>M (SD)</i>		<i>M (SD)</i>	<i>M (SD)</i>	
Whole questionnaire (31-55)	43.3 (13.7)	63.0 (14.2)	<u>&lt;0.001*</u>	50.7 (13.8)	66.9 (15.1)	<u>&lt;0.001*</u>
Information about the disease (31-34)	49.7 (23.2)	68.6 (18.6)	<u>&lt;0.001*</u>	58.0 (21.7)	70.7 (19.1)	<u>0.003</u>
Information about medical tests (35-37)	56.8 (25.6)	76.7 (20.8)	<u>&lt;0.001*</u>	66.9 (25.0)	77.5 (20.7)	<u>0.03</u>
Information about treatments (38-43)	43.6 (21.5)	63.6 (19.6)	<u>&lt;0.001*</u>	51.3 (20.4)	67.3 (20.4)	<u>0.001*</u>
Information about other services (44-47)	17.0 (18.9)	38.8 (28.8)	<u>&lt;0.001*</u>	25.6 (22.2)	42.6 (32.0)	<u>0.008</u>
Information about different places of care (48)	12.8 (23.2)	44.0 (39.2)	<u>&lt;0.001*</u>	23.2 (33.0)	51.9 (38.6)	<u>&lt;0.001*</u>
Information about things you can do to help yourself get well (49)	21.8 (29.7)	50.2 (36.5)	<u>&lt;0.001*</u>	32.1 (33.6)	56.3 (36.8)	<u>0.001</u>
Written information (50)	57.7 (50.4)	38.7 (49.0)	0.11	53.6 (50.3)	31.1 (46.8)	<u>0.03</u>
Information on CD or tape/video (51)	96.2 (19.6)	88.0 (32.7)	0.29	94.6 (22.7)	84.4 (36.7)	0.11
Satisfaction with information received (52)	--	--	--	55.4 (27.2)	77.8 (20.1)	<u>&lt;0.001*</u>
Wish to receive more information (53)	11.5 (32.6)	56.0 (50.0)	<u>&lt;0.001*</u>	--	--	--
Overall information has been helpful (55)	43.3 (13.7)	63.0 (14.2)	<u>&lt;0.001*</u>	69.6 (25.6)	81.5 (18.2)	<u>0.02</u>

*M* – Mean; *Mdn* – Median; *SD* – standard deviation; *p* – Mann-Whitney U tests.

Significant *p*-values were underlined for ease of viewing.

\* Comparisons that remain statistically significant at a level of 0.05 after Bonferroni correction (the *p*-values reported are not corrected for multiple comparisons).

Table 11 depicts statistically significant associations between satisfaction with information and all the scales/items of INFO25 depicted, except for items 50 and 51 ( $p = 0.11$  and  $p = 0.29$ , respectively). The same holds true for the association between wishes for information and all the scales/items of INFO25 depicted, again with the exception of item 51 ( $p = 0.11$ ).

As aforementioned, INFO-25 questionnaire was adapted to include 1 question directly asking if the patient would like to receive additional information on that specific item being evaluated. Answers had a dichotomous response (yes/no). In summary, the percentage of affirmative responses to these 21 items was calculated. On average, patients wished more information for 40.8% of the items (SD = 30.6%).

## 11. DISCUSSION

This series is in accord with the data from the QLQ-INFO25 module validation study by Arraras et al. (Arraras JI 2010) in regard to age distribution and gender. The mean age of the participants was similar and a female predominance was also observed, which can be an expression of the high number of breast cancer patients, in line with other studies (U. Y. Fujimori M 2009, Rutten LJ 2005, Squiers L 2005, Cox A 2006). There were no patients above the age of 81 years old, which could be related to the assessment being carried out in an ambulatory setting (whose users need to fulfil certain fitness criteria to withstand cytotoxic therapy in an outpatient context) and also because Jules Bordet Institute has a dedicated Oncogeriatric Unit allowing admittance for treatments in the elderly patients' group ( $\geq 70$  years).

The education level of this sample was very high, reflecting the educational attainment level of the country itself, Belgium, which possessed a 70.5% rate of adults (25-64 years old) having completed at least upper secondary education (raising to 82.5% amongst the younger, above the European mean rate) in 2010 (EUROSTAT 2010).

The majority of patients were Belgian. One quarter was foreigner. This may have to do with the particular geographic position of the country and its capital (where Jules Bordet Institute is sited) in Europe (housing many important European Union Institutions) but also with JBI being a worldwide reference in cancer care.

Breast and gastrointestinal cancers were the most common diagnosis, reflecting, on one hand, cancer epidemiology in Belgium ((IARC) 2008) and worldwide ((WHO) 2011), and on the other hand, the tumours for which available chemotherapy treatments are predominantly administered in an outpatient context. This series included predominantly patients with disseminated disease and good performance status, again in agreement with other studies (U. Y. Fujimori M 2009, Rutten LJ 2005, Squiers L 2005, Cox A 2006).

Overall presented data corroborate the psychometric properties of the QLQ-INFO25 module validation study (Arraras JI 2010). The internal consistency estimate of the full questionnaire had the exact same high reliability (0.91) as Arraras et al. (Arraras JI 2010). Cronbach's alpha coefficients of all multi-item scales and the full INFO25 module met the  $\geq 0.7$  criteria in all measurements, hence representing good reliability.

Patients presented a higher global information level than the sample used on the validation study by Arraras et al. (Arraras JI 2010). They were particularly better informed on the topics about the disease and treatments. They reported receiving less written information but more information on CD or tape/video. Their wishes to receive more information were lower and the helpfulness of the overall information received was higher than the one reported by Arraras et al. (Arraras JI 2010). Only one patient answered affirmatively to wishing less information on the open question 54a, and although this result was statistically significant on comparison with the validation study ( $M = 32.7$  vs.  $M = 2.0$ ,  $p < 0.001$ ), the  $n = 1$  renders it clinically nonsignificant.

Open questions in HRQoL evaluation questionnaires have been shown to be valued by patients, giving them room to list what they consider most important (Hearn J 1999); at the same time, the analysis performed on these data are mainly qualitative. This series' analysis of patients' answers to the two open questions contained in INFO25 revealed they value the side effects of treatment and being given the results of the tests they pass. Patients wanting the results of the medical tests stressed the desire to receive them on a hard-paper copy, be it blood tests or imagery, and also of having radiological findings explained to them during consultations. These findings are in line with other studies showing patients want to be given detailed information about results of medical tests (U. Y. Fujimori M 2009). The most common topics suggested anew on which patients desired to receive more information were the long-term outcome, nutrition and recurrence symptoms. These data are in resonance with other studies in the field (U. Y. Fujimori M 2009, Rutten LJ 2005, Squiers L 2005).

The working hypotheses H1 and H2 were not supported, since no association was found between gender and self-reported levels of information. This is in congruity with some studies (Voogt E 2005, Hilarius DL 2007) but contrary to the majority of knowledge (Hack TF e Team 2005, U. Y. Fujimori M 2009, Rutten LJ 2005, Russell BJ 2011, Squiers L 2005, Siminoff LA 2006, Arraras JI 2010) which bases the explanation on the fact that women generally have higher levels of education. The present sample was homogeneous regarding education, and so no difference in the gender comparison was found.

Regarding age, the hypothesis that younger patients received a higher level of information than older patients (H3) was globally not supported, but was verified regarding the items satisfaction and overall helpfulness of the information received. Contrary to expected, older patients received more written and CD/tape/video information than younger patients. The literature shows younger patients appear to seek broader sources of information than older patients (Rutten LJ 2005). Accordingly, a possible explanation might be that younger

patients have searched for other information sources currently more widespread and in vogue such as the Internet, support groups and organisational and scientific resources (e.g. cancer leagues, cancer telephone information services) (Rutten LJ 2005).

Hypotheses H4, H5 and H6 were also refuted, as no statistically significant association between the education level and self-reported levels of information was found. This again might be a reflection of the global high education level of this sample, even when subdivided in two groups of “lower” and “higher” education levels because the extreme values (primary/lower high school and MSc/PhD) are residual, and the effect is lost.

Working hypothesis H7 (patients undergoing potentially curative treatment receive a different level of information than patients receiving palliative treatment) was only supported for the items on information about things one can do to help oneself get well and overall helpfulness of information. On the subject of things one can do to help oneself get well, other studies have reported similar findings (Voogt E 2005, Squiers L 2005), stating palliative patients are more interested in subjects such as physical symptoms, euthanasia, and alternative or complementary care than curative patients, who are looking for information on prevention/risk factors and rehabilitation. On the other regard, studies have revealed that patients seeking information on complementary and alternative medicine (CAM) often feel a need for additional information and physicians’ are ascribed offering little useful input in this respect (Hack TF e Team 2005).

The data showing that patients on palliative treatment and already submitted to two or more lines of chemotherapy receive more information on CD/tape/video than their corresponding counterparts might be connected to the longer disease duration of the former, making them more likely to have received medical test results on such formats, particularly on CD format, which is becoming increasingly common for computed tomography (CT) and positron emission tomography (PET) scans which are indispensable medical imaging tools in treatment response evaluations in oncology current practice (Vincent T. DeVita Jr 2008).

Foreigner patients presented a higher satisfaction with the information received than native patients. The statistical association was not very strong ( $p = 0.05$ ). This may reflect the impact of the intercultural mediation support offered by JBI, through the means of interpreters in several languages for medical consultations, mediation of cultural conflicts and translation support for written documents. There was no association found between the marital status of the patients and the information level, in opposition to other studies’ findings (Voogt E 2005).

The comparison between information levels of patients on clinical trials and out of clinical trials heralded unexpected results. Patients outside clinical trials appear to have more information about the disease and also written information. Additional statistical tests were carried out to look for additional variables that might have been associated to clinical trial participation. No association between demographical or clinical variables was found. These data are in contradiction with the Good Clinical Practice (GCP) guidelines on the patient informed consent process defined by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) on the regulations for clinical trials involving human subjects ((ICH) 1996). There is a growing body of evidence showing that even after the implementation of skills training interventions about clinical trial communication (Phase I, II and III trials) doctors fail to provide more clinical information or structure their consultations in the recommended fashion (Brown RF 2007, Jenkins V 2011). In addition, studies have shown that in several key areas, information was either missing or had been explained but was misinterpreted by patients. This raises very worrisome concerns and underlines the urgent and proper addressing these issues require in future studies.

The association found between the information levels and quality of life (QoL) was in consonance with the literature (Davies NJ 2008) demonstrating that information provision can facilitate an adjustment to the disease by increasing perceptions of control, reducing feelings of threat and anxiety, and improving perceived quality of life (QoL). This series results did not support other studies' findings (Voogt E 2005, Arraras JI 2010) regarding the association between emotional states and information levels, namely the validation study.

More satisfied patients had received more information in 7 areas, considered the information more useful but still had greater wishes to receive more information (as measured by the item 53 of INFO25, "Do you wish to receive more information?"). However, their wishes to receive more information on specific items (as measured by the percentage of affirmative responses to whether they wished more information in individual items) was smaller ( $M = 33.5\%$ ;  $SD = 26.2\%$ ) than less satisfied patients ( $M = 62.1\%$ ;  $SD = 33.1\%$ ; Mann-Whitney  $p < 0.001$ ). This suggests that the more satisfied patients require less additional information for specific topics (i.e. are well informed on existing information), but continue to be open to novel information in general (item 53).

Patients expressing more information wishes (on the INFO25 item 53, "Do you wish more information?") reported receiving a greater amount of information in 7 areas, being more satisfied and finding the information more useful than their counterparts (but again

requiring more information). This may illustrate the personality and attitudinal characteristics of highly informed patients (i.e. *information-seeker* patients), continuously active in the search for information as a way to cope with disease and to actively be engaged in fighting cancer (De Valck C 1996, Voogt E 2005).

Also, there was dissociation between the responses to wishing more information on item 53 and the percentage of information wishes for individual items (i.e. the percentage of yes answers to the questions added to INFO25, “Do you wish more information on this topic?”). Patients that did not wish additional information on item 53 had more individual information requests throughout the questionnaire ( $M = 57.9\%$ ;  $SD = 27.8\%$ ) than those that wished for more information on item 53 ( $M = 19.6\%$ ;  $SD = 18.4\%$ ; Mann-Whitney  $p < 0.001$ ). This apparently conflicting result suggests that they might have interpreted item 53 “Do you wish to receive additional information?” as “do you wish additional information *beyond those information requests you have already checked earlier in the questionnaire*”.

This study presented limitations, in that it was cross-sectional and included cancer patients exclusively in ambulatory treatment. The sample contained both early and advanced cancer patients, preventing a clear separation among people in different disease stages and such, together with the fact that a longitudinal approach was not carried out, hinders the possibility of an assessment of the information given to cancer patients throughout the disease process from diagnosis to cure or end of life.

It was also a single-institution study and may therefore not represent the reality of Day Hospital patients' of other institutions and also other countries.

The instrument used to assess patients' information levels, the EORTC QLQ-INFO25, may also present shortcomings, particularly on the items about the format on which information was given (item 50 – written information – and item 51 – information on CD or tape/video). On the one hand, those items don't discriminate the content of information (CT scan results? side effects? rehabilitation services?) and that can mislead the patients answering the questionnaire and render the interpretation of results challenging. On the other hand, particularly item 51 may currently be considered outmoded, since the expansion of information access has placed the Internet and other technology-based health resources in the spotlight and in the ranking of patients' preferences, particularly the youngest.

Consequently, this study opens future perspectives, especially:

- To further investigate the information received by cancer patients on clinical trials (or about to enter them), and to develop strategies to enhance communication with these patients, in order for them to understand the proposal at stake, to be able to do a truly informed and conscious choice and even to try to increase patient recruitment to clinical trials, so that more patients can benefit of this treatment option.
- To examine the role of new information sources available to patients, especially the Internet and other technology-based health resources, in regard to use, accreditation and potential for patient education but also prejudice.
- To perform a transcultural study comparing Belgian and Portuguese cancer patients.
- To validate INFO-25 for the Portuguese population.
- To investigate the correlation between quality of life (QoL) and information and if the latter can predict overall QoL or some of its domains.
- To carry out an interventional study, using a representative sample of the country. A standardised format of delivering information should be chosen. EORTC QLQ-INFO25 and/or other instruments can be used for baseline assessment and intervention measure. Patients should stratified by primary tumour site, disease stage, age groups and site of care (Day Hospital, wards and consultations). The variables not associated in a statistically significant manner with information levels in this study should also be included, since an interventional study is of a different nature.

## 12. CONCLUSION

Information is pivotal to cancer patients. The therapeutic doctor-patient relationship is based on communication exchange, and in the oncology setting it presents specific challenges: the burdensome content (to both the patient and the clinician), the different expectations and goals of both parties, the entourage (ancillary health team, patient's family, and society).

The present study was carried out to evaluate the self-reported information level of cancer patients attending Day Hospital in a comprehensive cancer centre and its association with patients' demographic and clinical characteristics. The instrument used was the EORTC QLQ-INFO25 information module.

Patients attending JBI's Day Hospital present a higher global information level than the sample from the module's validation study. They are better informed about the disease and treatments. They seem to have less additional information needs and find the information given to them more useful. The open questions revealed these patients would like to receive more information about treatment side effects and be given detailed results of the tests they pass. They would also appreciate more information on long-term outcome, nutrition and recurrence symptoms.

Unlike other studies, the education level was not found to be associated with the level of information received because this sample was composed of highly educated patients, and such known effect was lost. Patients on curative treatment have different needs for information than palliative patients, so the information given requires tailoring.

The comparison between information levels of patients on clinical trials and outside clinical trials heralded unexpected results, with the latter having received more information about disease and also more written information. These data contribute to the current debate on the informed consent process of clinical trials. Communication has shown to be defective in this setting, and this requires prompt addressing in future research.

Higher information levels are associated with higher QoL scores, and their possible correlation needs to be further examined. Better informed patients are also more satisfied patients.



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## 14. APPENDICES

# Appendix A: European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) version 3.0 - FRENCH

FRENCH NEUTRAL



## EORTC QLQ-C30 (version 3)

Nous nous intéressons à vous et à votre santé. Répondez vous-même à toutes les questions en entourant le chiffre qui correspond le mieux à votre situation. Il n'y a pas de "bonne" ou de "mauvaise" réponse. Ces informations sont strictement confidentielles.

*Merci de préciser:*

Vos initiales:

Date de naissance (jour/mois/année):

La date d'aujourd'hui (jour/mois/année): 31

---


	Pas du tout	Un peu	Assez	Beaucoup
1. Avez-vous des difficultés à faire certains efforts physiques pénibles comme porter un sac à provisions chargé ou une valise?	1	2	3	4
2. Avez-vous des difficultés à faire une <u>longue</u> promenade?	1	2	3	4
3. Avez-vous des difficultés à faire un <u>petit</u> tour dehors?	1	2	3	4
4. Etes-vous obligé(e) de rester au lit ou dans un fauteuil pendant la journée?	1	2	3	4
5. Avez-vous besoin d'aide pour manger, vous habiller, faire votre toilette ou aller aux toilettes?	1	2	3	4
<b>Au cours de la semaine passée:</b>				
6. Avez-vous été gêné(e) pour faire votre travail ou vos activités de tous les jours?	1	2	3	4
7. Avez-vous été gêné(e) dans vos activités de loisirs?	1	2	3	4
8. Avez-vous eu le souffle court?	1	2	3	4
9. Avez-vous ressenti de la douleur?	1	2	3	4
10. Avez-vous eu besoin de repos?	1	2	3	4
11. Avez-vous eu des difficultés pour dormir?	1	2	3	4
12. Vous êtes-vous senti(e) faible?	1	2	3	4
13. Avez-vous manqué d'appétit?	1	2	3	4
14. Avez-vous eu des nausées (mal au coeur)?	1	2	3	4
15. Avez-vous vomi?	1	2	3	4

Passez à la page suivante S.V.P.



## Appendix B: European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) version 3.0 - ENGLISH

ENGLISH



**EORTC QLQ-C30 (version 3)**

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:

Your birthdate (Day, Month, Year):

Today's date (Day, Month, Year): 31

---

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a <u>long</u> walk?	1	2	3	4
3. Do you have any trouble taking a <u>short</u> walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4
<b>During the past week:</b>				
	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

**During the past week:**

	Not at All	A Little	Quite a Bit	Very Much
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your <u>family</u> life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your <u>social</u> activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

**For the following questions please circle the number between 1 and 7 that best applies to you**29. How would you rate your overall health during the past week?

1      2      3      4      5      6      7

Very poor

Excellent

30. How would you rate your overall quality of life during the past week?

1      2      3      4      5      6      7

Very poor

Excellent

## Appendix C: European Organisation for the Research and Treatment of Cancer Quality of Life Information Module (EORTC QLQ-INFO25) –FRENCH (adapted)

FRENCH



**EORTC QLQ – INFO25**

Nous nous intéressons aux informations que vous avez reçues sur les différents aspects de votre maladie et de son traitement afin d'améliorer les soins de santé qui vous sont apportés. Veuillez répondre à TOUTES les questions vous-même en *entourant d'un cercle* le chiffre correspondant le mieux à votre avis. Il n'y a pas de bonnes ni de mauvaises réponses. Les informations que vous nous communiquerez resteront strictement confidentielles.

<b>Tout au long de votre maladie actuelle ou de son traitement, quelle quantité d'informations avez-vous reçues sur:</b>	Aucune	Un peu	Assez	Beaucoup	Souhaitez-vous recevoir plus d'informations?	
31. Le diagnostic de votre maladie ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
32. L'étendue (la propagation) de votre maladie ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
33. Les causes possibles de votre maladie ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
34. Le fait que votre maladie soit sous contrôle ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
35. Le but des tests médicaux que vous avez subis ou allez subir ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
36. Les procédures des tests médicaux ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
37. Les résultats des tests médicaux que vous avez déjà reçus ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
38. Le traitement que vous suivez actuellement (chimiothérapie, radiothérapie, chirurgie ou autres modalités de traitement) ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
39. Le bénéfice escompté du traitement ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
40. Les effets secondaires éventuels de votre traitement ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
41. Les effets escomptés du traitement sur les symptômes de la maladie ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
42. Les effets du traitement sur votre vie sociale et familiale ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
43. Les effets du traitement sur votre fonctionnement sexuel ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
44. Une aide supplémentaire en dehors de l'hôpital (par ex. : aide pour les activités quotidiennes, groupes d'autoaide, infirmières à domicile) ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
45. Des services de réhabilitation (ex: kinésithérapie, ergothérapie) ?	1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>


[Veuillez passer à la page suivante](#)

					FRANCE					
<b>Tout au long de votre maladie actuelle ou de son traitement, quelle quantité d'informations avez-vous reçues sur:</b>					Aucune	Un peu	Assez	Beaucoup	Souhaitez-vous recevoir plus d'informations?	
					1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
46.	Les différents aspects de la gestion à domicile de votre maladie ?				1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
47.	L'éventualité d'un soutien psychologique professionnel ?				1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
48.	Différents lieux de soins (hôpitaux/services de consultations externes/domicile) ?				1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
49.	Ce que vous pouvez faire pour vous aider à vous sentir bien (repos, contacts avec les autres, etc.) ?				1	2	3	4	Oui <input type="checkbox"/>	Non <input type="checkbox"/>
50.	Avez-vous reçu des informations écrites ?				Oui	Non			Oui <input type="checkbox"/>	Non <input type="checkbox"/>
51.	Avez-vous reçu des informations sur CD, cassette audio ou vidéo ?				Oui	Non			Oui <input type="checkbox"/>	Non <input type="checkbox"/>
					<b>Pas du tout</b>	<b>Un peu</b>	<b>Assez</b>	<b>Beaucoup</b>		
52.	Êtes-vous satisfait(e) de la quantité d'informations reçues ?				1	2	3	4		
53.	a) Souhaitez-vous recevoir <u>davantage</u> d'informations ?				Oui	Non				
	b) Si oui, à quel sujet ?				_____					
54.	a) Auriez-vous souhaité recevoir <u>moins</u> d'informations ?				Oui	Non				
	b) Si oui, à quel sujet ?				_____					
					<b>Pas du tout</b>	<b>Un peu</b>	<b>Assez</b>	<b>Beaucoup</b>		
55.	Globalement, les informations reçues vous ont-elles été utiles ?				1	2	3	4		

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## Appendix D: European Organisation for the Research and Treatment of Cancer Quality of Life Information Module (EORTC QLQ-INFO25) –ENGLISH (adapted)

ENGLISH



**EORTC QLQ – INFO25**

We are interested in the information you have received about aspects of your disease and its treatment, in order to improve your health care. Please answer ALL the questions yourself by *circling* the number that best applies to you. There are no right or wrong answers. The information that you provide will remain strictly confidential.

<b>During your current disease or treatment, how much information have you received on:</b>	Not at all	A little	Quite a bit	Very much	Would you like more information on this subject?
31. The diagnosis of your disease?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
32. The extent (spread) of your disease?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
33. The possible causes of your disease?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
34. Whether the disease is under control?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
35. The purpose of any medical tests you have had or may undergo?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
36. The procedures of the medical tests?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
37. The results of the medical tests you have already received?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
38. The medical treatment (chemotherapy, radiotherapy, surgery or other treatment modality)?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
39. The expected benefit of the treatment?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
40. The possible side-effects of your treatment?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
41. The expected effects of the treatment on disease symptoms?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
42. The effects of the treatment on social and family life?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
43. The effects of the treatment on sexual activity?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
44. Additional help outside the hospital (e.g. help with daily activities, self help groups, district nurses)?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>
45. Rehabilitation services (e.g. physiotherapy, occupational therapy)?	1	2	3	4	Yes <input type="checkbox"/> No <input type="checkbox"/>

Please go to the next page

During your current disease or treatment, how much information have you received on:	ENGLISH				Would you like more information on this subject?	
	Not at all	A little	Quite a bit	Very much		
46. Aspects of managing your illness at home?	1	2	3	4	Yes <input type="checkbox"/>	No <input type="checkbox"/>
47. Possible professional psychological support?	1	2	3	4	Yes <input type="checkbox"/>	No <input type="checkbox"/>
48. Different places of care (hospitals/outpatient services/home)?	1	2	3	4	Yes <input type="checkbox"/>	No <input type="checkbox"/>
49. Things that you can do to help yourself get well (rest, contact with others...)?	1	2	3	4	Yes <input type="checkbox"/>	No <input type="checkbox"/>
50. Have you received written information?		Yes		No	Yes <input type="checkbox"/>	No <input type="checkbox"/>
51. Have you received information on CD or tape / video?		Yes		No	Yes <input type="checkbox"/>	No <input type="checkbox"/>
		Not at all	A little	Quite a bit	Very much	
52. Were you satisfied with the amount of information you received?	1	2	3	4		
53. a) Do you wish to receive <u>more</u> information?		Yes		No		
b) If yes, please specify on which topics?	_____					
54. a) Do you wish that you had received <u>less</u> information?		Yes		No		
b) If yes, please specify on which topics?	_____					
		Not at all	A little	Quite a bit	Very much	
55. Overall has the information you have received been helpful?	1	2	3	4		

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## Appendix E: Patient demographical data sheet

### Demographical data

Assessing the information needs of cancer patients attending Day Hospital in a comprehensive cancer centre.

- Age \_\_\_\_\_ years-old.
- Date of birth \_\_\_/\_\_\_/\_\_\_ (dd/mm/yyyy)

- Place of birth  Belgium  
 Outside of Belgium

- Gender  Male  
 Female

- Marital status  Single  
 Married  
 Divorced  
 Widow/widower  
 Legal co-inhabitant

- Education  Primary school  
 High school  
     (9 schooling years)  
     (12 schooling years)  
 University degree  
 Masters/ PhD

- Profession \_\_\_\_\_.

Subject Code

Version 2.0  
19th May 2011

## Appendix F: WHO (ECOG) Performance status scale

Grade	Performance scale
0	Fully active, able to carry out all normal activity without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out light work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
5	Dead

## Appendix G: Patient clinical data sheet

### Clinical data

Assessing the information needs of cancer patients attending Day Hospital in a comprehensive cancer centre.

• Primary tumour site \_\_\_\_\_

• Disease extent  Limited

Disseminated

• ECOG  0

1

2

3

4

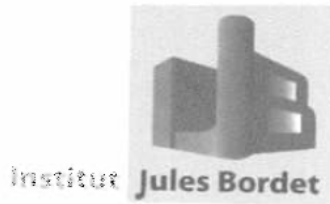
• Treatment received (protocol & line) \_\_\_\_\_

• Patient is part of a Clinical Trial  Yes

No

Subject Code

# Appendix H: Protocol approval by the Ethics Committee of Jules Bordet Institute



Association Hospitalière de Bruxelles  
Centre des Tumeurs de l'ULB  
Association régie par la loi du 8 juillet 1976  
Rue Héger-Bordet, 1 - 1000 BRUXELLES  
Tel : 02 541 31 11  
DEXIA 091-0697278-16

## Comité d'Ethique

Tél : 02/541.35.95  
Fax : 02/541.37.95  
Secrétariat email :  
Comite.ethique@bordet.be

Président  
Dr. Th. Gil

Vice-Président  
Dr. D. Bron

Secrétaire  
Dr. D. Lossignol

Membres  
Dr. H. Bleiberg  
Dr. E. de Azambuja  
Dr. J. Klastersky  
Dr. M. Sosnowski  
Dr. Th. Renard  
M. P. Crombez  
(suppléante : Mme B. Femez)  
Mme M. Colin  
Mme M. Paesmans  
Mme L. Van Ingelgem  
Mme E. Ceysens  
(suppléante : Mme D. van Vyve)

### LIST OF DOCUMENTS REVIEWED BY THE MEDICAL ETHICS COMMITTEE OF INSTITUT JULES BORDET - LEC

Réf. : as

Date : 26/05/2011  
BECT : B079201111287  
Intern number : 1837  
Coordinating investigator : Dr. RAZAVI

#### Title

Assessing the information needs of cancer patients attending Day Hospital in a comprehensive cancer centre

#### Including

- Demande d'avis
- Insurance certificate
- Résumé
- Protocole v 2.0 19/05/2011 (incl. EORTC questionnaires)
- ICF v 2.0 dd 19/05/2011 (French, English)

### LEADING ETHICS COMMITTEE'S DECISION

- Approval  
 Approval with conditions  
 Need for extra information  
 Disapproval

Signature of the Chairman of the Central Ethics Committee

Name : Dr. Th. GIL

Date : 26/05/2010



## Appendix I: PIS/PIC – FRENCH

Information au patient

**ETUDE de l'évaluation des besoins informatifs chez les personnes atteintes d'un cancer qui reçoivent traitement dans l'Hôpital de Jour d'un centre oncologique.**

Chère Madame, cher Monsieur,

Vous êtes invité à participer à ce projet de recherche. Avant que vous acceptiez de participer à ce projet, il est important que vous compreniez pourquoi il a été mis en place et ce que cela implique pour vous. Il vous est possible de poser toutes les questions que vous souhaitez si quelque chose ne vous semble pas clair ou si vous souhaitez obtenir d'autres informations.

### Invitation à participer à cette étude

Il existe actuellement un intérêt croissant pour connaître les besoins des malades ayant un cancer de façon à pouvoir dispenser les soins qui correspondent aux attentes et qui puissent contribuer à une meilleure satisfaction des malades. Les études montrent que les besoins d'information sont à la première place des préoccupations des malades oncologiques et que ce thème requiert plus d'investigation et plus d'intervention. En outre, la communication entre les médecins, les autres éléments de l'équipe de santé et les malades est constamment à l'ordre du jour, l'échange d'information étant pour cela d'une extrême importance.

### Quel est l'objectif de cette étude?

Cette étude prétend évaluer la quantité et la qualité de l'information que les malades considèrent recevoir de leurs soignants et s'ils aimeraient recevoir plus d'informations sur certains aspects.

### Pourquoi l'étude vous est-elle proposée?

Nous vous demandons de participer à cette étude compte-tenu de votre maladie actuelle, où la qualité de l'information que vous recevez est d'une extrême importance.

Version 2.0  
19th May 2011

### **Quelles sont les implications si vous acceptez de participer à l'étude ?**

L'investigateur réalisera, sous la forme d'un questionnaire détaillé, une évaluation du niveau de l'information que vous possédez sur votre problème de santé et des soins qui en découlent.

Le questionnaire a été élaboré de façon à ce que vous puissiez le remplir seul mais si vous avez des doutes, l'investigateur sera à vos côtés pour répondre à vos questions. Lire et compléter ce questionnaire ne devrait pas prendre plus de 30 minutes de votre temps. Nous recueillerons également de votre dossier clinique des données sur votre maladie et votre état actuel.

### **Suis-je obligé de participer?**

Votre participation à l'étude est volontaire: ceci signifie que vous avez le droit de ne pas y participer ou de vous retirer sans justification même si vous aviez accepté préalablement d'y participer. Votre décision ne modifiera en rien vos relations avec les médecins traitants.

### **Quels sont les inconvénients et les risques associés à ma participation?**

Passer en revue l'information ou répondre aux questions peut vous sembler difficile, dans l'étude à laquelle nous vous proposons de participer.

### **Quels sont les éventuels avantages associés à ma participation?**

Votre participation ne vous apportera aucun avantage direct. Aucun financement ou dédommagement n'est prévu dans le cadre de cette étude.

Toutefois, il est possible que par la suite de cette évaluation approfondie, qui ne se fait pas (encore) dans la pratique courante, certains problèmes par rapport à l'information que vous recevez soient révélés pour lesquels des solutions peuvent être trouvées.

### **Ma participation à cette étude restera-t-elle confidentielle?**

Votre participation à l'étude signifie que vous acceptez que l'investigateur recueille des données vous concernant et les utilise dans un objectif de recherche.

Vous avez le droit de demander à l'investigateur quelles sont les données collectées à votre sujet et quelle est leur utilité dans le cadre de l'étude. Vous disposez d'un droit de regard sur ces données et le droit d'y apporter des rectifications au cas où elles seraient incorrectes<sup>1</sup>.

---

<sup>1</sup>Ces droits vous sont garantis par la loi du 8 décembre 1992 (amendée par la loi du 11 décembre 1998) suivie de la directive 95/46/CE du 24 octobre 2002 qui protégé la vie privée et par les droits des patients définis par la loi du 22 août 2002.

L'investigateur a un devoir de confidentialité vis à vis des données collectées. Ceci veut dire qu'il s'engage non seulement à ne jamais divulguer votre nom dans le cadre d'une publication ou d'une conférence mais aussi qu'il codera vos données avant de les transmettre au gestionnaire de la base des données collectées (à identifier). Il sera donc le seul à pouvoir faire le lien entre les données transmises et votre dossier médical pendant toute la durée de l'étude.

Pour le gestionnaire des données de recherche, les données transmises sont codées. Ce dernier est responsable de la collecte des données recueillies par l'investigateur de la recherche, de leur traitement et de leur protection en conformité avec les impératifs de la loi belge relative à la protection de la vie privée (1992).

### **Qui organise cette étude?**

Cette étude est organisée et réalisée dans 1 centre hospitalier en Belgique, l'Institut Jules Bordet (Bruxelles).

### **Qui a revu l'étude ?**

L'étude a été évaluée par un groupe de personnes indépendantes, appelé comité d'éthique, dont le rôle est de s'assurer que vos droits sont respectés et que l'étude ne vous met pas en danger. Dans le cas présent, l'étude a reçu un avis favorable du comité d'éthique de l'Institut Jules Bordet le \_\_\_\_\_ (date). Cet avis favorable ne doit cependant pas vous inciter à participer à cette étude.

### **Assurance**

Dans l'étude à laquelle nous vous proposons de participer, le seul risque éventuel serait une faille dans les mesures prises pour protéger la confidentialité des renseignements à caractère privé vous concernant. L'investigateur assume, même sans faute, la responsabilité du dommage causé au participant et lié de manière directe ou indirecte à la participation à cette étude. Dans cette optique, l'investigateur a souscrit un contrat d'assurance<sup>2</sup>.

---

<sup>2</sup> Conformément à l'article 29 de la loi belge relative aux expérimentations sur la personne humaine (7 mai 2004).

**Besoin de plus d'informations ?**

L'investigateur se fera un plaisir de répondre à toute question relative à votre participation à l'étude ou de discuter tout problème pouvant survenir (cf coordonnées ci-dessous):

Nom de l'investigateur : .....

Tél : .....

Nous vous remercions d'avoir pris connaissance de cette information.

## CONSENTEMENT ECLAIRE

**ETUDE de l'évaluation des besoins informatiques chez les personnes atteintes d'un cancer qui reçoivent traitement dans l'Hôpital de Jour d'un centre oncologique.**

Je soussigné(e), \_\_\_\_\_  
déclare avoir lu la feuille d'information pour la participation et accepte de participer à l'étude.

1. J'ai reçu un exemplaire du consentement éclairé daté et signé, ainsi que la feuille d'information pour le participant. J'ai été informé sur la nature de l'étude, son but et les résultats espérés. J'ai également été informé de ce que l'on attend de moi. Les risques éventuels et bénéfiques m'ont été expliqués et j'ai eu suffisamment le temps pour poser des questions au sujet de l'étude, questions auxquelles j'ai eu une réponse claire.
2. Je sais que cette étude a obtenu un avis favorable du Comité d'Éthique de l'Institut Jules Bordet.
3. Je suis libre de participer à cette étude, ainsi que d'arrêter ma participation à tout moment sans obligation de justifier ma décision. Ma décision n'aura aucun effet négatif sur la poursuite de mon traitement.
4. Mes données médicales, nom et adresse resteront confidentiels.
5. J'accepte de participer volontairement à cette étude.

\_\_\_\_\_  
*Signature patient*

\_\_\_\_\_  
*Date*

Je suis conscient que je prends une décision de participation de la personne que je représente au mieux des intérêts de cette personne et en tenant compte de sa probable volonté. Je sais que je peux à tout moment revenir sur cette décision sans justification et sans que ce retrait de l'étude ne modifie en rien la poursuite de la prise en charge thérapeutique de la personne que je représente.

\_\_\_\_\_  
*Signature représentant du patient*

\_\_\_\_\_  
*Date*

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Je soussigne, médecin investigateur, confirme avoir fourni oralement les informations nécessaires sur l'étude, avoir remis un exemplaire de la feuille d'information et de consentement signé par les diverses parties, être prêt à répondre à toutes les questions supplémentaires, le cas échéant et n'avoir exercé aucune pression pour que le patient participe à l'étude. Je déclare travailler en accord avec les principes éthiques énoncés notamment dans la "Déclaration d'Helsinki" et dans la loi belge du 7 mai 2004, relative aux expérimentations sur la personne humaine. Le patient/représentant du patient confirme son accord pour participation par sa signature datée personnelle.

\_\_\_\_\_  
*Signature investigateur*

\_\_\_\_\_  
*Date*

Version 2.0  
19th May 2011

## Appendix J: PIS/PIC – ENGLISH

Patient information

### **Assessing the information needs of cancer patients attending Day Hospital in a comprehensive cancer centre.**

Dear Madam, dear Sir

We would like to invite you to take part in this study.

Before deciding to participate you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

#### **Invitation to participate in this study**

Nowadays there's a growing interest in assessing cancer patients' needs, so that tailored care is given to them and more satisfaction with healthcare can be derived. Studies have shown that information needs are among the top priority concerns of cancer patients and that this subject requires further research and intervention. Besides, communication between doctors and the rest of the healthcare team and their patients is constantly used in the process of care, so adequate information exchange is of utmost importance.

#### **What is the purpose of the study?**

This study's purpose is to evaluate what kind, how much, on which format and how relevant is the information cancer patients think they are receiving from their healthcarers and also what kind and amount of information would they like to be given.

#### **Why have I been invited?**

We have invited you because of your illness, where the quality of the information you receive is of utmost importance.

Version 2.0  
19th May 2011

### **What will it involve if I participate?**

The researcher will submit you to an information assessment on your knowledge about your health condition and the exams and treatments it carries, on the form of a detailed questionnaire. The questionnaire was designed to be self-completed but if you require help the researcher can aid you in that process. Reading and fulfilling the questionnaires is estimated around 30 minutes. Data about your clinical status will also be collected.

### **Do I have to take part?**

Your participation in this study is entirely voluntary. If you do decide to participate, you are free to withdraw your consent, and to discontinue participation at any time without giving any reason and without prejudice to you, or any effect on your medical care.

### **What are the risks of taking part?**

Reading and interpreting or answering the questions may seem difficult to you, in this study you're being invited to.

### **What are the possible advantages of taking part?**

Your participation will not bring you any direct advantage. No payment or compensation is foreseen in the context of this study. Nevertheless, it is possible that after this comprehensive evaluation, which is (still) not routinely used in daily practice, certain problems concerning the information you receive are identified and solutions to solve them can be found.

### **Will my involvement in the study be kept confidential?**

If you consent to take part in the study, all information that is collected about you during the course of the study will be kept strictly confidential. If you join the study, you allow data collected during your participation in the study to be used for research purposes.

Test results will be coded in such a manner that researchers working on the data cannot identify you. (You will only be identified by a patient code given by your study doctor, and a unique sequential patient number for the study given once your participation in the study has been accepted). In order to check that the information recorded in our database is accurate, staff from the organization may wish to see your medical records.

You may at any time make a request to your study doctor to view your data<sup>1</sup>. The results of this research study may be presented at scientific or medical meetings or be published in scientific journals. However, your identity will not be disclosed.

For the data manager, the data transmitted about you are coded. He is responsible for the data collected by the study investigator, its treatment and its protection according to the imperatives of the Belgian law on the protection of the private life (1992).

#### **Who is organising the study?**

This study is being organized and carried out on a hospital in Belgium, Jules Bordet Institute (Brussels).

#### **Who has reviewed the study?**

This study has been reviewed by an independent group of people, called an ethics committee, whose purpose is to verify that all conditions with regard to your safety and rights are respected. This study has been reviewed and given a favourable opinion by the ethics committee of Jules Bordet Institute on \_\_\_\_\_ (date). This favourable opinion should not, nonetheless, incite you to participate in this study.

#### **Insurance**

In the study to which you are being invited to participate, the only eventual risk would be a failure in the measures taken to protect the confidentiality of your private information. The investigator takes responsibility, even without liability, for the damage caused to the participant and linked directly or indirectly to the participation in this study. As such, the investigator has signed an insurance contract<sup>2</sup>.

#### **Further information and contact details**

Your study doctor will be pleased to answer any questions about your participation in this study or to discuss problems whenever you wish (see contact details below):

Name of the physician: .....

Hospital: .....

Telephone: .....

We thank you for having become aware of this information.

---

<sup>1</sup>These rights are guaranteed by the law of December 8, 1992 (amended by the law of December 11, 1998) in line with the directive 95/46/CE from October 24, 2002 that protects the private life and by the patients' rights defined by the law of August 22, 2002.

<sup>2</sup>Accordingly with the article 29 of the Belgian law on the experimentation on Human Beings (May 7, 2004).

## INFORMED CONSENT FORM

### **Assessing the information needs of cancer patients attending Day Hospital in a comprehensive cancer centre.**

I undersigned, \_\_\_\_\_  
declare having read the patient's information sheet about this study and I agree to participate.

- 1 I've received a dated and signed copy of the informed consent, as well as the patient's information sheet. I have been properly informed about the clinical study, its purpose and expected results. Likewise, I've been informed of what is expected from me. The risks and advantages have been explained to me and I had enough time to ask questions to the study investigator, which have been clearly answered.
2. I know this study has received a favourable opinion from the Ethics Committee of Jules Bordet Institute.
3. I understand that my participation is totally voluntary and that I have the right to suspend my participation in the study at any time without giving any reason. This will not affect my medical care, any of my legal rights nor my relationship with my study doctor, the hospital staff or other health care professionals.
4. My medical data, name and address will remain confidential.
5. I voluntarily agree to participate in this study.

\_\_\_\_\_  
*Patient's Signature*

\_\_\_\_\_  
*Date*

I am aware that I decide to participate on behalf of the person I represent to the best of his/her interests and concerning his/her probable will. I know I can at any time redraw this decision without having to present justification and without it compromising in any way the relationship and healthcare this person I legally represent is being given.

\_\_\_\_\_  
*Patient's representative Signature*

\_\_\_\_\_  
*Date*

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I undersigned investigator, confirm having orally explained the necessary information about this study, having given the patient a copy of the patient's information sheet and of the informed consent signed and dated by all parties involved, being available to answer any supplementary questions, and having exerted no pressure for the patient's participation in this study. I declare to work accordingly to the ethical principles, namely the "Helsinki Declaration" and the Belgian law from May 7, 2004, regarding the experiments on Human Beings. The patient/representative confirms agreeing to his/her participation by signing and dating this document.

\_\_\_\_\_  
*Investigator's Signature*

\_\_\_\_\_  
*Date*

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