



First results of the international and national empirical survey on patients' and parents' perspectives and needs

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ABSTRACT:

This deliverable presents the first results of the international and national empirical survey on patients' and parents' of minor patients perspectives and needs regarding informed consent and data protection in clinical and clinico-genomic trials. The design of the survey was already described in detail in deliverables 10.5 and 10.6.1. This report presents first results of the German survey focussing on the attitudes and expectations of parents of oncologically treated children.

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1 Executive Summary

A growing number of studies in tissue-based research aim to explore the roles of genes and gene activities in order to improve treatment and prognosis of cancer. Such studies conducted with patients currently affected by cancer raise a number of questions concerning informed consent and the attitude of research subjects towards the handling and processing of data and of data protection. These questions have been discussed intensively in the theoretical discourse on ethical and legal aspects of modern biomedical research. We are, however, unaware of empirical reports on the participants' views on and experience of involvement in clinico-genomic research, Grid structures and Europe-wide data flows.

We have therefore designed an empirical survey on perspectives and needs of persons who did consent to take part in tissue-based cancer research in several European settings (Great Britain, Belgium, Germany and Greece). In particular, the survey aims at elucidating patients' understanding of and motivation for taking part in tissue-based research, their attitudes towards future research, their expectations concerning confidentiality of medical information and the feedback of study findings.

This deliverable wants to give a first insight into the results of the survey. First, we will summarise the current status of the survey involving different study populations. We will continue by concentrating on the data of the German survey on parents of oncologically treated children and on the survey on breast cancer patients in Belgium. As the data will show, these two surveys provide some unexpected results that are important for the implementation of ACGT in the clinical setting.

2 Introduction

Tissue-based research challenges established ethical standards concerning the involvement of patients in clinical research from two angles. First, samples and data are not intended to be used for a single research project, but also for other future research projects which cannot be defined at the time consent is requested. Hence, in the latter case, given consent can – by definition – not be fully informed. Second, clinico-genomic and biobank research conducted with stored tissue samples may provide key links between abstract genomic data and specific patient medical records. Hence, research results may yield information which could be important for the present or future health status of the individual patient and, furthermore, for the present or future health status of genetically related family members.

Though it is widely accepted that informed consent is required when tissue samples and sensible data are used for research purposes, doubts have been raised concerning the applicability of the doctrine in its current form in biobank research. Most scholars still maintain the importance of informed consent as an instrument to implement the principle of autonomy and stress that consent can only be called informed if given for a specified purpose, e.g. one clearly defined research project. In the context of biobank research, however, an increasing number of authors favour broad consent including the use of samples and data in future research projects.

Some scholars argue that broad consent for biobank research cannot be discussed without raising the issue of disclosure, e.g. informing sample donors about the outcomes of future research. There seems to be consensus in the bioethical debate that the general results of research should always be communicated to the research participants. The common practice of not returning individualized study results rests on considerations that most research findings in cohort studies are aggregate findings of an exploratory nature with little or no clinical utility for the individual concerned and, in addition, are usually not linked to identifiable participants. However, biobanks often have the ability to link research findings to individual research participants and, in many cases, to participants' blood relatives. Furthermore, research results may become clinically significant as data production and the meaning to be attached to them rapidly increases.

In the growing body of literature on disclosure it is intensively discussed whether the feedback of research findings to research participants and their families is ethically obligatory. Most authors recently tend to favour considerations of individual autonomy, respect for patients, and the requirement to treat participants as more than a means to an end and call, as a consequence, for an ethical obligation to routinely feed back research results which are or may become relevant for the donor, even if it may be difficult for researchers to fulfil such a duty because of financial or institutional constraints.

Nevertheless, there is general consensus that empirical data are necessary to take soundings what kind of expectations and needs participants who are involved in tissue based research have. Therefore, we have conducted an empirical survey of persons who did consent for themselves or on behalf of their children to take part in clinical trials on cancer. We wanted to find out how they recognize and assess their involvement in such research and what kind of needs they have participating in clinical trials in particular towards the consent requirements, the confidentiality and handling of medical data, and the feedback of research results.

3 The empirical survey: processes and results

The empirical data basis on the patients' perspectives and preferences regarding the challenges of tissue-based research is very limited. Furthermore, existing data have mainly been collected in the US-health care system. For this reason we conducted an empirical study which gathered data on the understanding of tissue donors or their legal representatives and which focused on the European context. To relate empirical data on participants' perspective to the clinical trials within ACGT, we decided on a quantitative and comparative design by use of a standardised questionnaire.¹ In correspondence with the ACGT clinical trials, the survey approaches two different study populations: patients affected by breast cancer in four European countries (Belgium, Great Britain, Germany and Greece) and German parents of children who have been treated oncologically (in particular for paediatric nephroblastoma).

3.1.1 The national survey

The national survey refers to clinico-genomic trials on paediatric nephroblastoma in Germany, one of ACGT's areas of application. Since the number of children participating in clinico-genomic research was small at the time when we conceived the survey – only 281 patients were subscribed in the already running trial SIOP2001/GPOH (see D12.6) – we decided to enlarge the sample and to include children from other, comparable studies as well.

3.1.1.1 The study population

The population we decided to study are parents of oncologically treated children who consented on behalf of their child to treatment and/or study participation. To approach this population we cooperated with the German Childhood Cancer Registry (GCCR) and three rehabilitation centres in Germany.

The German survey conducted in cooperation with the GCCR is a population-based survey. The GCCR is a national registry that collects information on children younger than 15 years affected by all known types of cancer. Approximately 95% of children who fall ill are registered.² The GCCR collects information concerning the diagnosis, development and treatment of the child's disease together with the address of the concerned families. 1465 parents whose children were initially registered in the year 2005 were contacted.³ Further sampling criteria were: the parents lived in Germany at the time of diagnosis, the diagnosis was part of the third edition of the international classification of childhood cancer (ICCC3), the children were under the age of 15 at the time of diagnosis and parents of deceased children were included as well. 126 parents were registered with a deceased child at the due date of March 1, 2009. 832 of the children were aged 5 years or younger. We received 807 filled questionnaires; this is a return rate of 55,1%. Hence, the survey can be assessed as representative.

Regarding indications for treatment, the most frequently mentioned diseases were leukaemias with nearly 40 %, followed by CNS tumours (22%) and neuroblastomas

¹ The design of the study is described in detail in D10.5.

² The attending physicians voluntarily reports the children based on informed consent of their parents to the GCCR.

³ 190 parents were not contacted because of the following reasons: the request of attending clinics was respected to not approach the patients' family; the parents were already involved in surveys conducted by GCCR at the same time; addresses were not available after unsuccessfully searching at the residents registration office.

(8%). About 70% of the children were at the time of the survey aged between five and 14 years; 7% of the children were at this time deceased. About 50% of the questionnaires were filled out by the mother; 14% by the father; and 34% by both of them. Of all families, at least one of the parents has a general qualification: a school-leaving certificate usually taken after the fifth year of secondary school (9%), a school-leaving certificate usually taken after the sixth year of secondary school (31%), or a secondary education for university entrée (45%). In 6% of the families, none of the parents has a training qualification, in 55% of the cases at least one of the parents has finished an apprenticeship and in 37% of the cases at least one of them has a university degree.

The second national survey was set up as a comparison group for the representative survey described above. It was conducted in three German rehabilitation centres for families of children affected by cancer (*Rehabilitationsklinik Katharinenhoehe, Syltklinik, Nachsorgeklinik Tannheim*). About 1800 children per year develop cancer. The intensive care normally lasts six to 12 months after diagnosis. After being treated in hospital normally as an inpatient over several weeks, about 70% of these children are referred to and in rehabilitation (1200 to 1300 patients per year). In rehabilitation, the child stays together with its parents and (if applicable) siblings at these centres for four weeks. About 600 parents staying at the rehabilitation centres were approached and received the questionnaires. We collected 312 completed questionnaires (177 from Rehabilitationsklinik Katharinenhöhe, 79 from Syltklinik, 56 from Nachsorgeklinik Tannheim). This is a return rate of about 50%. We expect that this group differs from the primary population-based survey in the following aspects:

- *Experience with health care:* Patients who have been through treatment are in rehabilitation. Usually, the treatment has had a positive effect and the children recover from surgery and/or chemo or radio therapy. We therefore assumed that parents whose children survived at this stage and who experienced a successful treatment of their child might have a more positive attitude towards medical care and research in general.
- *Time frame:* Since rehabilitation usually starts right after successful treatment, experience of cancer diagnosis, treatment and requests for consent are relatively close to the survey. We therefore assumed that the parents have struggled with the issues raised in the survey lately and still have a vivid memory of them – and the consent process as such.
- *Attitudes and values:* The diagnosis and the period of intensive care usually place a heavy burden on the child and its parents. During rehabilitation, they learn to handle the psychological strain of the diagnosis and have time to reflect on the last months. An important issue in rehabilitation are, for example, conflicts within the family and the role parents play and will play in accompanying their child being chronically ill. We therefore assumed that the parents are in a process in which they carefully reflect and consolidate their attitudes and values towards the issues raised.

In the rehabilitation survey, the most frequently mentioned ICC3 diagnoses are leukaemias with nearly 44 %, followed by Lymphomas (12%) and CNS tumours (11%). Nearly 60% of the children were initially diagnosed in 2007, 2008 or 2009. About 53% of the children were at the time of the survey seven years old or younger. About 41% of the questionnaires were filled out by the mother; 13% by the father; and 46% by both of them. Of all families, at least one of the parents has a school-leaving certificate usually taken after the fifth year of secondary school (11%), a school-leaving certificate usually taken after the sixth year of secondary school (25%) or a general qualification for university entrée (43%). In 4% of the families, none of the parents has a training qualification, in 60% of the cases at least one of the parents has finished an apprenticeship and in 34% of the cases at least one of them has a university degree.

3.1.1.2 The research process

On March 5, 2009 the GCCR distributed the questionnaires among the parents. The data collection lasted until July 15, 2009. In the three rehabilitation centres, the distribution of questionnaires started in December 2008 and lasted until November 2009.

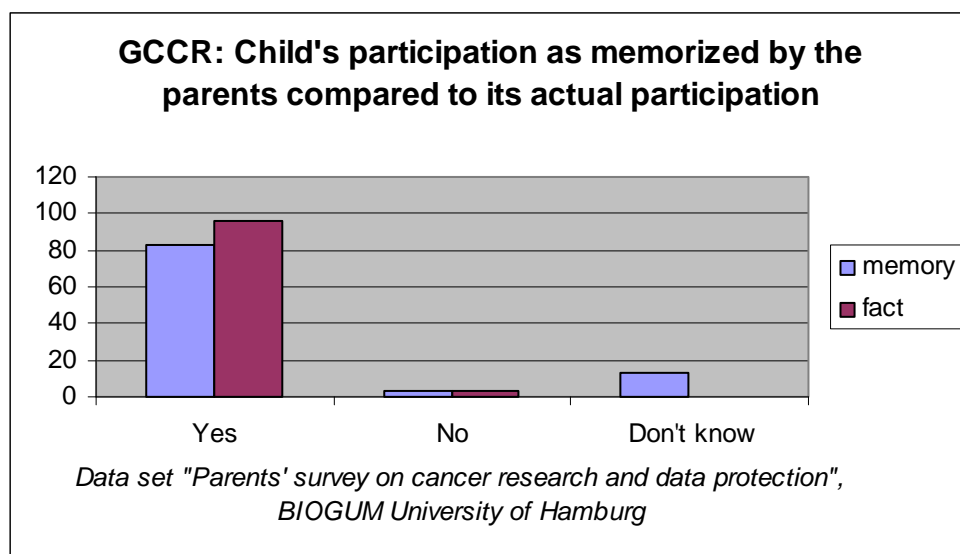
Data processing and analysis of the 1121 received questionnaires have been finished by the time of this report. Publications regarding the national survey are in preparation.

3.1.1.3 The results

(1) Parents' memory of consenting to child's participation in the clinical study and motivation for consenting

About 83% of the parents registered by GCCR remembered that their child was inscribed in a clinical trial on cancer, whereas nearly 14% were insecure about the child's participation. According to the registry's information, 96% of the children were in fact participants. From this follows that 11,5% of the parents have not appropriately remembered that the child took part in the clinical study (see figure 1). The results concerning the comparison group, parents approached during rehabilitation, are about the same.

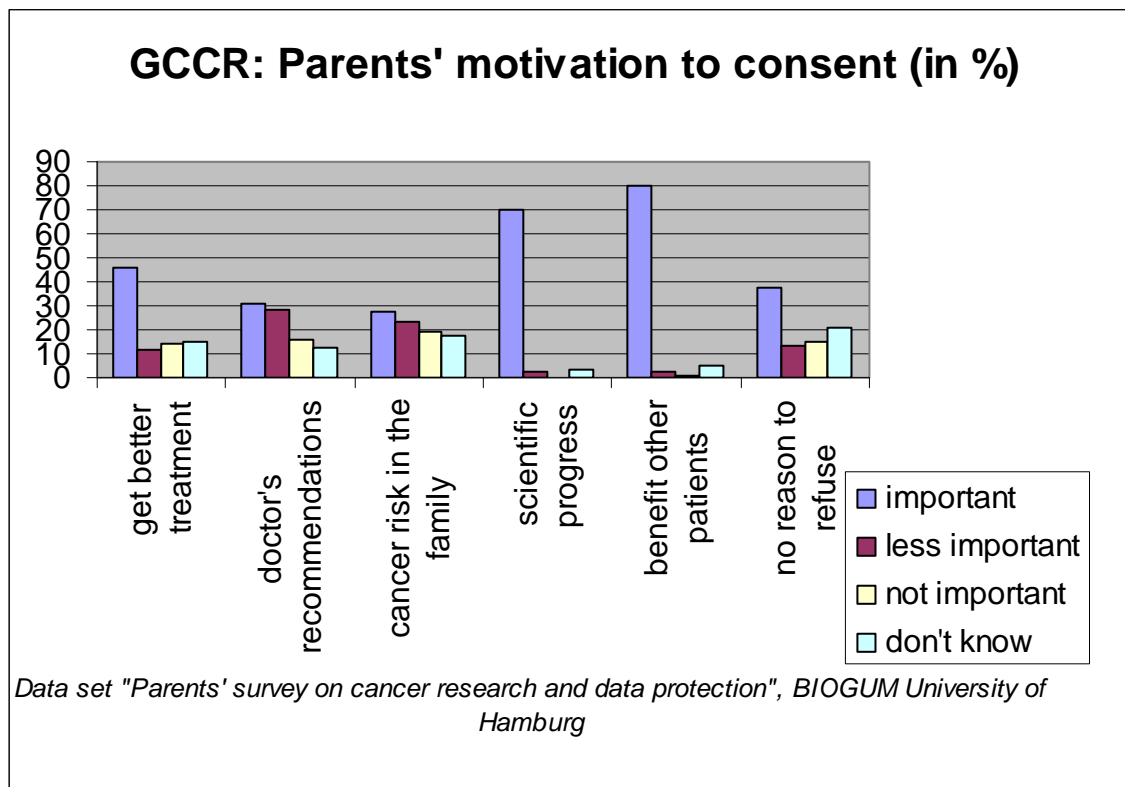
Figure 1:



Only about 60% of the survey parents remembered that the consent or non-consent, respectively, is documented in writing, even though the informed consent/non-consent is always given by signing the documents. Still, about 70% respondents felt adequately informed in the consent process (GCCR). The results concerning the comparison group are about the same.

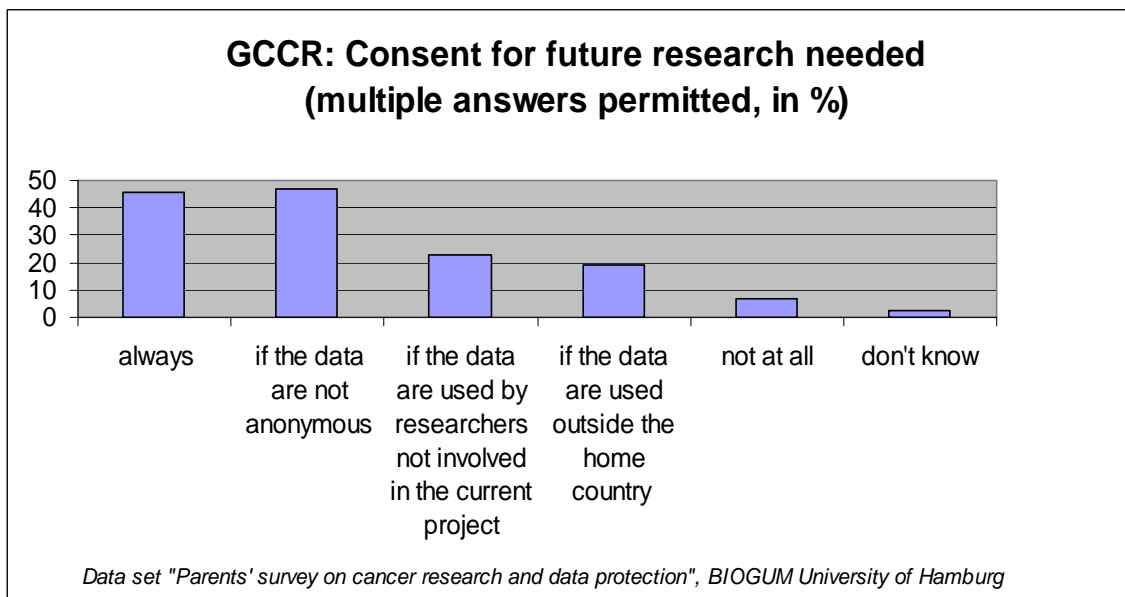
Asking the parents, why they decided that their child should take part in the clinical study, the majority of 80% agreed to the statements *"make a contribution to medical progress"* and *"benefit other patients"*, whereas only half of the respondents agreed to the reasoning *"get better treatment"* and about a third to *"go along with the doctor's recommendations"*, *"get information on cancer risk within my family"*, and *"no special reason to refuse"* (see figure 2). The results concerning the comparison group are about the same.

Figure 2:



Even if the respondents wanted to contribute to medical research, almost half of them thought that the parents should be consulted if researchers want to use stored medical data in future research projects besides the one for which they have given consent. Almost half of the respondents also wanted to be asked again in case of new research projects, if the data are not anonymously stored. One-fifth of the respondents stated that a re-consent of the parents is necessary if the data are used by researchers not involved in the current project or if the data are used by researchers outside of the home country (see figure 3). The results concerning the group of parents in rehabilitation are about the same.

Figure 3:

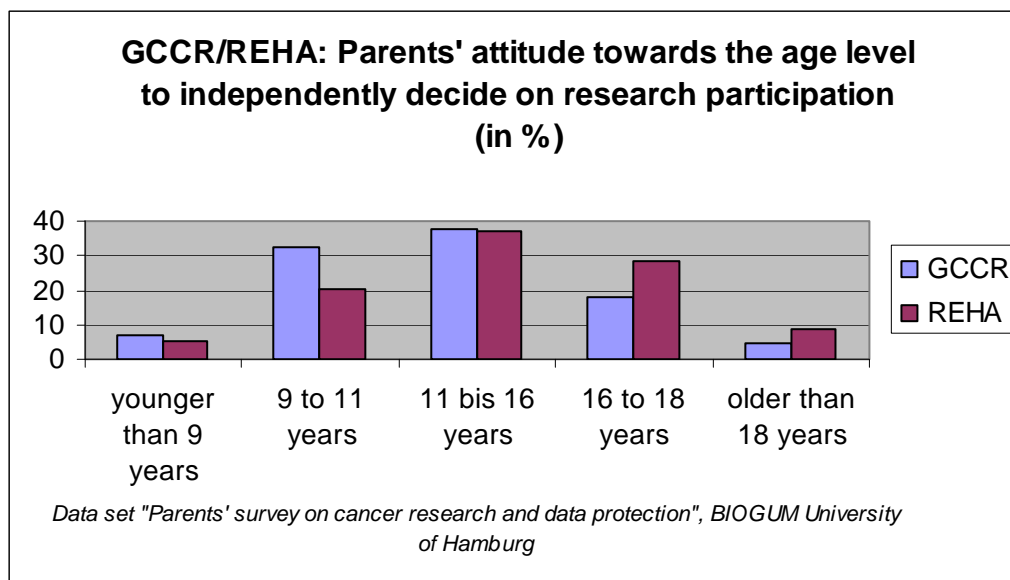


Surrogate consent by an ethics committee for re-using stored medical data was not an option for most of the respondents. 74% did not accept the vote of an ethics committee instead of the parents' consent, only 14% would accept surrogate consent. The results of the survey on the group of parents in rehabilitation are about the same.

(2) Attitudes of parents towards child's assent

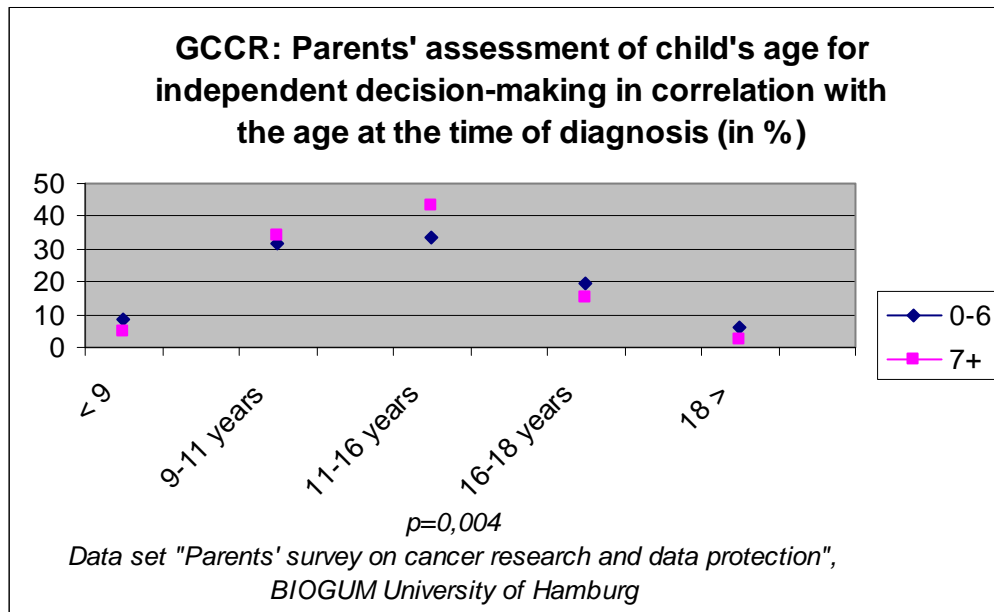
Only very few parents (< 5%) thought that children should generally not be involved in the consent process. More than 90% stated that the child's assent is necessary if he or she is mature enough to nearly or fully understand the goal and course of research they are asked to participate in. Maturity is linked to age: 33% of the parents assumed that the children aged between nine and eleven and 38% of them assumed that children aged between eleven and 16 years are mature enough to independently decide whether or not to participate in research. Here, the results of the comparison group differ from the population-based survey: Parents in rehabilitation who had on average small children (60 % of the children were aged between a few months and three years) stated in general that the child has to be older in order to become involved in the decision whether or not to take part in research (see figure 4a).

Figure 4a:



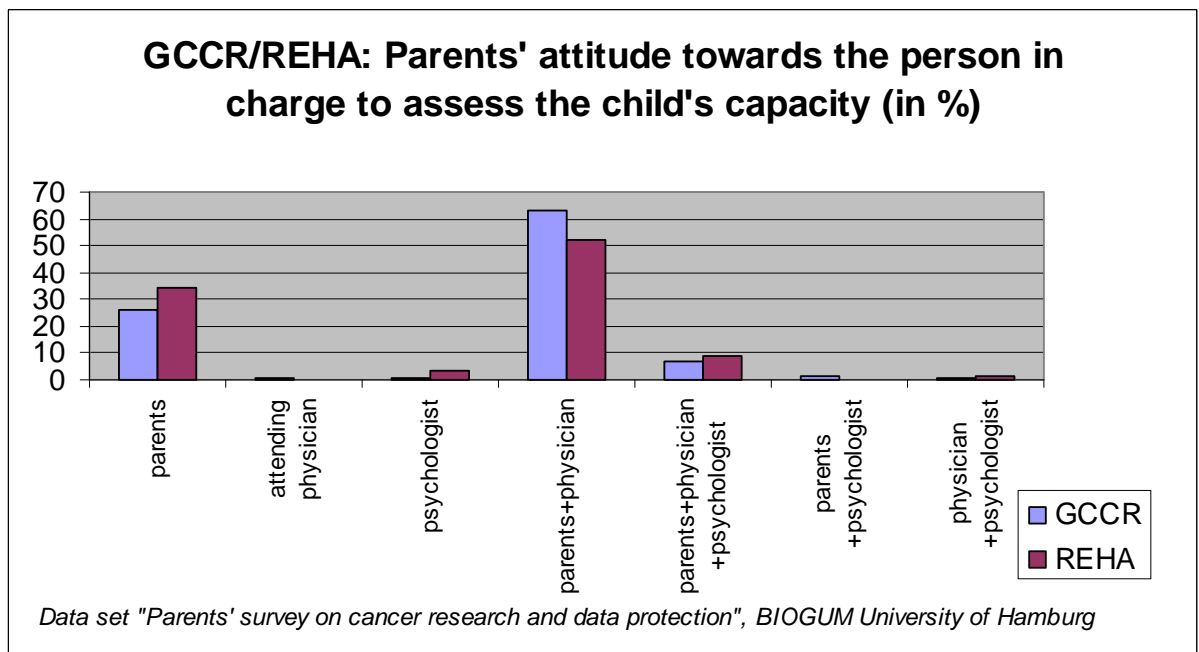
Parents of the GCCR sample with children aged under six years at the time of the survey affirm this consideration: They assess the appropriate age to independently decide significantly higher than parents with older children at the time of the diagnosis (see figure 4b).

Figure 4b:



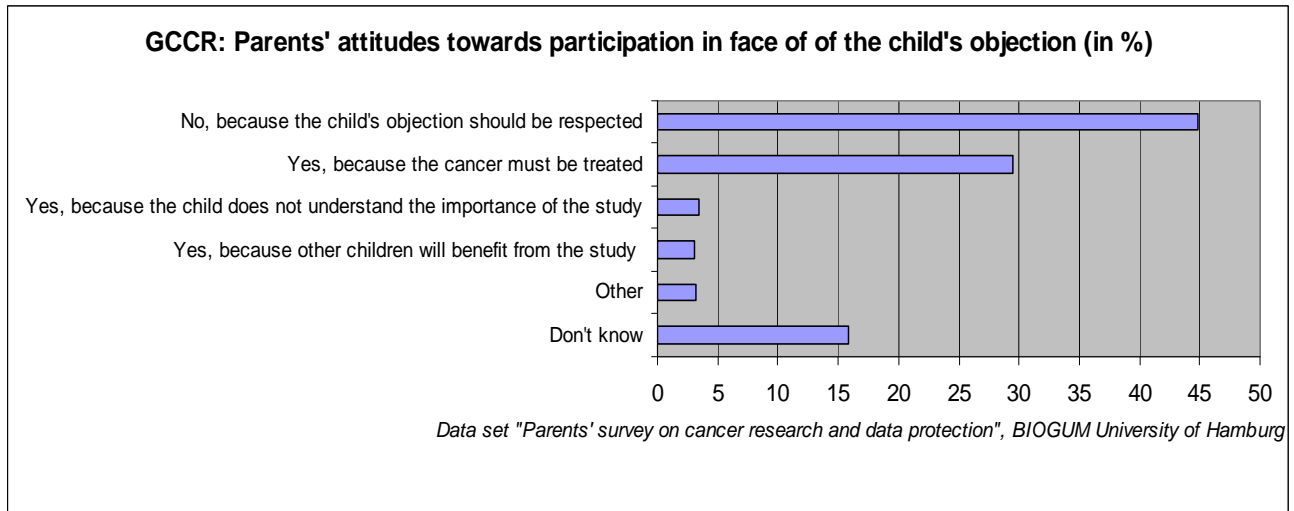
Asked for the person who should be in charge of assessing the capacity of the individual child, the majority of parents wanted to decide together with the attending physician whether or not the child is mature enough to independently decide whether or not to take part in a clinical study. Here, the results of the comparison group differ again from the population-based survey: More parents in rehabilitation wanted to decide by themselves (35% REHA/26% GCCR), whereas less parents in rehabilitation preferred a conjoint decision with the attending physician (52% REHA/63% GCCR; see figure 5).

Figure 5:



What did parents think about the child's objection to take part in research? Nearly 50% in both surveys wanted to respect the child's will – independently of his or her age (see figure 5).

Figure 5:

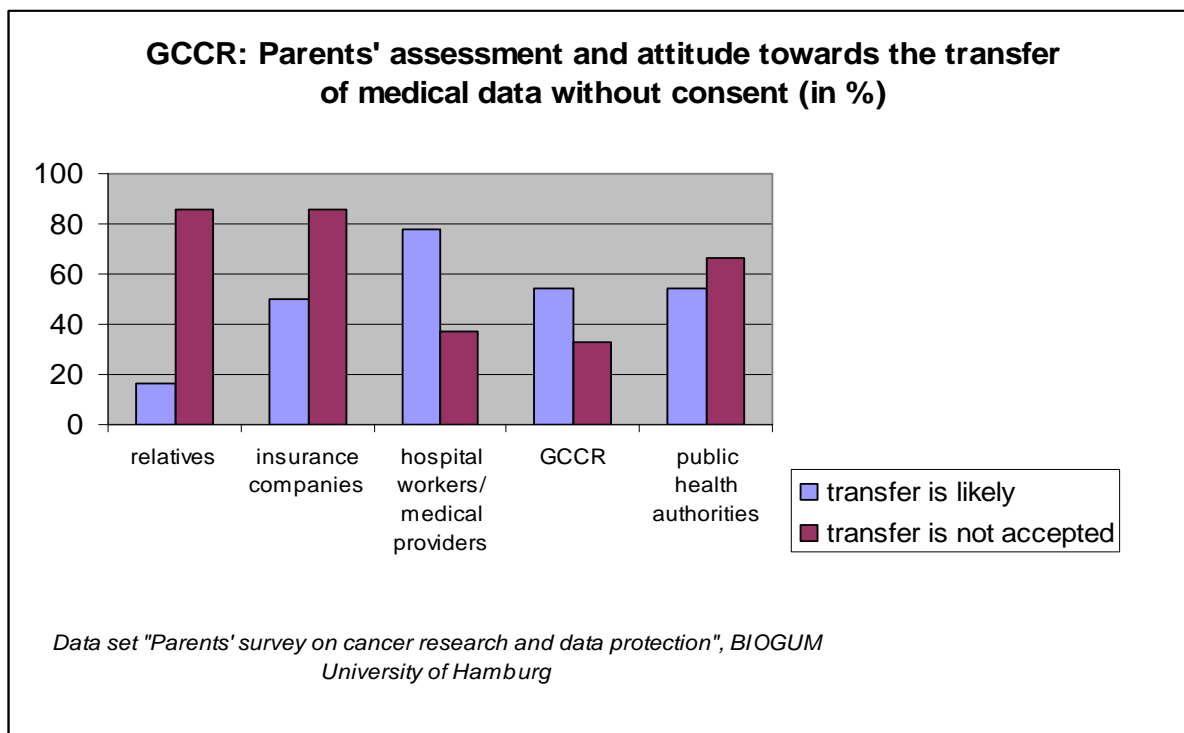


(3) Attitudes of parents towards data protection

Almost half of the parents were uncertain of the legal situation. They did not know whether or not the existing law (in Germany or the European Union) adequately protect medical records. Only 36% of them thought medical information about a patient is protected by law and 18% thought it is not. The results of the rehabilitation survey are about the same.

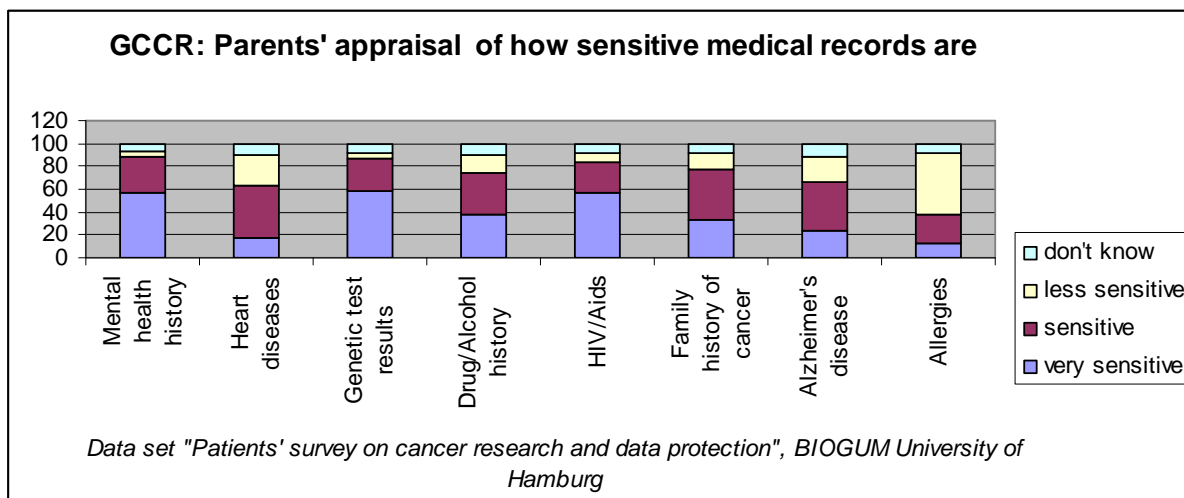
Asked for groups and institutions separately, the majority of parents of both surveys opined that hospital workers, insurance companies and public health authorities were able access patient records without his or her knowledge (see figure 6). However, they did not agree that medical information is given to others without the patient's permission. In particular, the transfer of medical data without consent to relatives and insurance companies were not accepted by more than 85% of the respondents (see figure 6).

Figure 6:



Asking the parents which conditions may be especially sensitive in terms of privacy and hence may need specific privacy protection, genetic test results were assessed as very sensitive data. According to the parents, genetic information should be as much protected as mental health history or HIV/Aids (see figure 7).

Figure 7:



(4) Attitudes of parents towards the communication of research results

Nearly all surveyed parents (94%) would like to receive information on aggregate research results (general outcome of a research project). Three-fourth of the respondents preferred to receive such aggregate results via information letters by mail.

One-third of them wanted to be informed via a website on the internet. Only a few wanted such information communicated in a flyer (19%), at a meeting (13%) or in a scientific journal (11%). The results of the rehabilitation survey are about the same.

Fewer parents (64%) would definitely like to be informed about individual research results, whereas only a small minority of 1,5% saw no need to be informed at all. Others wanted to be informed only in case the information is validated (18%) or if treatment or preventive intervention are available (14%). 70 % of the parents preferred to be informed about individual results by the attending physician, whereas 30% wanted to receive this information by mail. The results of the rehabilitation survey are about the same.

3.1.2 The international survey

The international survey refers to clinico-genomic trials on breast cancer. We assumed that the attitudes and expectations of patients differ according to the cultural setting. They might be affected by differences in the patient-physician-relationship, different assessments of the health care system and the state of research as well as different perceptions of data protection or traditional commitments to other family members. Since the ACGT trials on breast cancer have enrolled a relatively small number of patients at the time when we conceived the survey (see D12.6), we decided to enlarge our study population by including breast cancer patients involved in other clinical trials with tissue analysis which do not necessarily take part in ACGT.

3.1.2.1 The study population

The study population comprises breast cancer patients who gave a tumour sample for tissue analysis (e.g. profiling of gene expression and proteomics) and are usually treated in clinical trials (especially patients involved in the MINDACT study organized by EORCT⁴). To get access to cohorts of different European countries we co-operated with the clinical partners within ACGT. In addition, we included a sample of German breast cancer patients by co-operating with the “West-German Study Group” which coordinates the MINDACT study at several breast cancer centres in Germany.

3.1.2.2 The research process

Brussels (Belgium): Data collection in co-operation with the Jules Bordet Institute is completed. The questionnaires were distributed from February 19, 2009 until November 2, 2009. Data of 159 completed questionnaires are processed and analysed. Publications are in preparation.

Heraklion (Greece): Data collection is completed. Only 13 filled questionnaires were collected during the period from December 1, 2008 until December 31, 2009 by the co-operation partner at Crete University Hospital. Data are processed and analysed. However, statistical relevant conclusions are not possible according to the low number of completed questionnaires.

Oxford (Great Britain): After a long-lasting communication process, approvals by the ethics committees of the Oxford Radcliffe Hospitals NHS Trust and the National Research Ethics Service (NHS) regarding the survey at the Oxford University Hospital were obtained on 9th of December 2009 and on 11th of January 2010. The distribution of the questionnaires started right after obtaining the approval. Until now, 60 filled

⁴ For further information please visit: <http://www.eortc.be/protoc/details.asp?protocol=10041>

questionnaires were collected by the cooperating partner at Oxford University Hospital. Data collection will last until July 2010.

Boeblingen/Erlangen/Koeln/Dortmund/Troisdorf/Witten (Germany): Distribution of questionnaires has started in July, August, September, and March depending on the progress of arranging co-operations with the partners at Klinikum Böblingen, St. Elisabethkrankenhaus (Köln), Frauenklinik der Friedrich-Alexander-Universität (Erlangen), St. Johannes Hospital (Dortmund), Hämatologisch-Onkologische Schwerpunktpraxis (Troisdorf), and Marien Hospital (Witten). Until now, 37 filled questionnaires were collected. Data collection will last until July 2010.

We felt impelled to extend the period of data collection at Oxford and at the German centres to receive a comparable number of completed questionnaires at all clinical sites. A sufficient number of respondents in each study population is necessary in order to compare the data and to pool them together in the international survey. A sufficient number of completed questionnaires is also required for being able to compare the data of the international survey with the ones of the national survey concerning the German parents of oncologically treated children. The collection of data from German breast cancer patients is even more important since we are not able to use the Greek study results because of the low number of completed questionnaires which was not foreseeable in advance. In addition, we had to face unexpected hurdles during the research process. In the very beginning it seemed that an approval by the local ethics committees is not necessary. Later on, we were asked by our clinical partners in the different countries (settings) to apply for the study and get a positive vote from the local ethics committee. This was the first time lag; the second was the application and decision making process of the ethics committees itself. It took several months at each clinical site to receive the approval. At Oxford University Hospital it even took over a year. At the German breast cancer centres, we are still struggling with a low return rate because less breast cancer patients are registered in the MINDACT study than expected. That is why we had to set up multiple co-operations for the German sample at the same time. Beyond these hurdles, we are confident that we will receive an appropriate amount of completed questionnaires at Oxford and German centres until the end of July.

3.1.2.3 The results

According to the ongoing process of data collection at several clinical sites, processing and analysing of the data will last until July. In the following, we present first results from the Belgian sample exemplarily. The respondents of this survey were female patients who consented to take part in a clinical trial using techniques of tissue analysis; over half of the respondents were initially diagnosed with breast cancer between 2003 and 2005. 67% were aged 50 years and older. Most of them were married and had one or two children. One-fourth had no school-leaving certificate, whereas one-fifth had a school-leaving certificate. One-fourth finished an apprenticeship and one-fourth had a university degree.

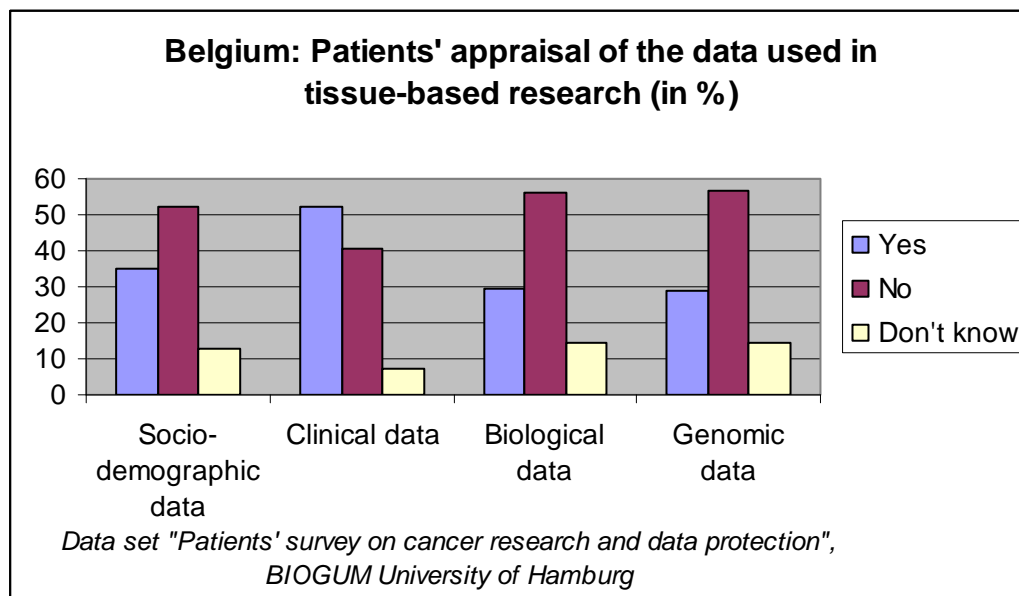
(1) Patients' memory of consenting to participate in the clinical study and motivation for consenting

About 92% of the patients remembered that they were inscribed in a clinical trial on breast cancer, whereas 8% denied that they were participants or were uncertain. According to the information of Jules Bordet Institute, all respondents were in fact participants. From this follows that only 8% of the respondents have not appropriately remembered that they took part in a clinical study. 15% of the participants did not

remember that the consent or non-consent respectively is documented in writing; 90% felt adequately informed in the consent process.

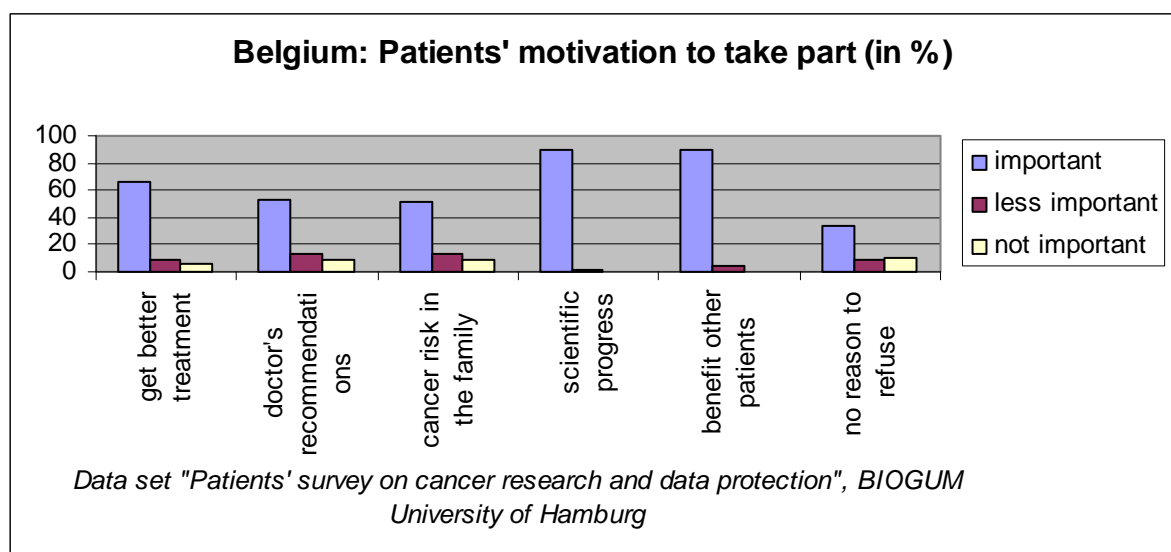
However, we wanted to verify how well informed the respondents were about the tissue and data use in breast cancer research and asked for the different types of data that are generally used in tissue-based research. 52% had the opinion that socio-demographic data are not used in research, 56% thought that biological data and 57% thought that genomic data are not used in research (see figure 8). That is, of course, a misconception of the data processing in tissue-base research, in particular in clinico-genomic trials. In addition, only 60% of the respondents confirmed that tumour or blood analyses may provide information about a patient's hereditary condition.

Figure 8:



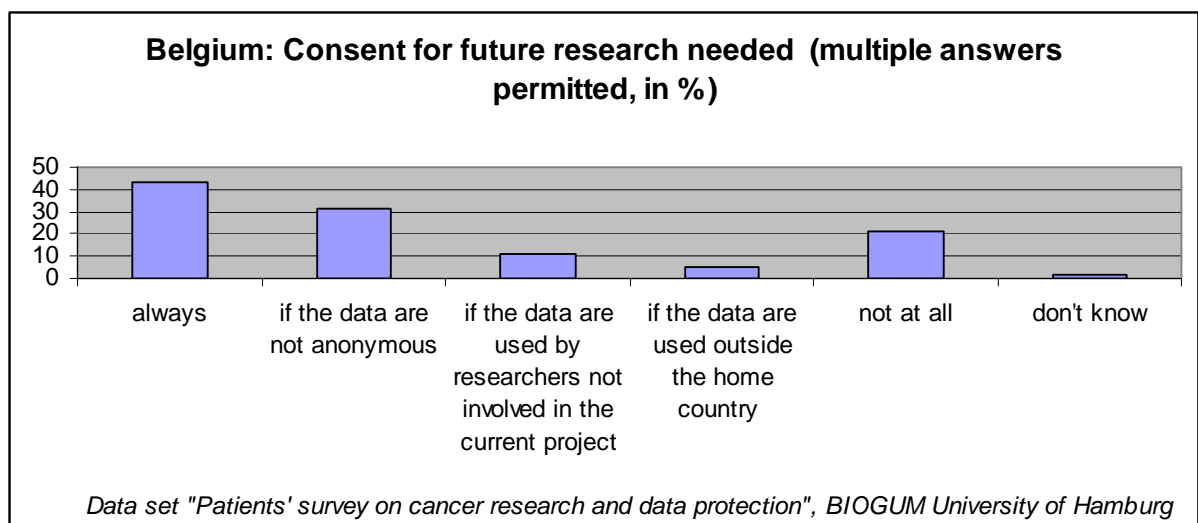
The respondents had different motives for participating in research. The percentages are more or less evenly distributed across the given reasons to take part in the clinical trial (see figure 9). Outstanding were only the altruistic statements “make a contribution to medical progress” and “benefit other patients” with nearly 90% acceptance.

Figure 9:



Nearly half of the respondents took the view that researchers should ask the patient again if they want to use stored medical data in future research projects besides the one for which the respondents had given consent. About 30% of the respondents only wanted to be asked again if the data are not anonymously stored. However, 20% did not want to be asked for re-consenting if the data is used in future research (see figure 10). This result is in line with the subsequent question concerning the surrogate consent by an ethics committee. 20% of the respondents did not accept the vote of an ethics committee instead of personal consent; 27% would agree with the surrogate consent, and 55% were uncertain regarding this issue.

Figure 10:

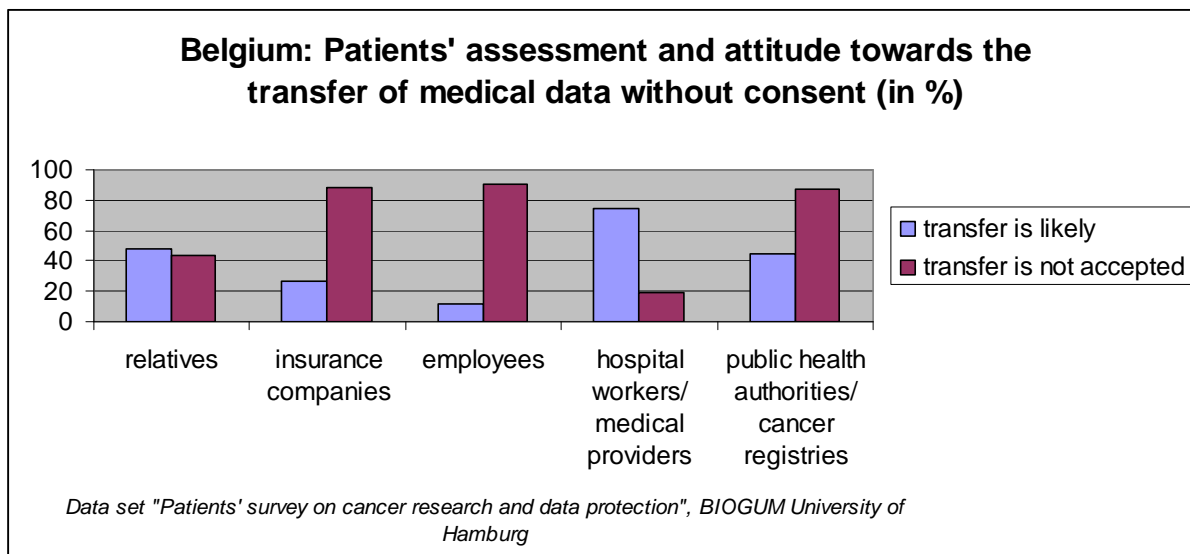


(3) Attitudes of patients towards data protection

In the Belgian survey, almost half of the patients were uncertain whether or not the existing laws adequately protect medical records. However, 40% of them thought that medical data are protected by law and 12% thought they are not.

Asked for groups and institutions separately, the respondents expected that hospital workers (74%), relatives (48%) and public health authorities (44%) are able to access patient records without his or her knowledge (see figure 10). However, they did not agree that medical information is passed to someone without the patient's permission. In particular, the transfer of medical data to the public and professional sphere without consent was not accepted by nearly 90% of the respondents (see figure 11).

Figure 11:



(4) Attitudes of parents towards the communication of research results

Only 12% of the respondents did not want to be informed about aggregate research results; the overwhelming majority (88%) would like to receive this kind of information. 60% of the respondents preferred to receive aggregate results via information letters by mail. One-third of them wanted to be informed via a website on the internet and almost one-third wanted the information via a flyer that is available in the public (e.g. at the clinical site). Only few respondents would like to receive aggregate research results at a meeting (13%) or by reading scientific journals (18%).

Fewer patients – only 60% – would definitely like to be informed about individual research results, whereas only a handful of respondents (0,7%) would not like to be informed at all. Others wanted to be informed only if the information is validated (20%) or if treatment or preventive intervention is available (13%). 65% of the respondents preferred to be informed about individual results by the attending physician, whereas about one-fourth of them wanted to receive this information by mail.

4 Conclusions and perspectives

In this deliverable, we have given a first insight into the results of the survey on patients' and parents' perspectives, preferences and needs regarding informed consent and data protection. As the presented data show, the two surveys – the German survey on parents of children affected by cancer and the European survey on breast cancer patients – provide some unexpected results even at this early stage of data analysis.

We assumed that parents and patients primarily consent to research participation if they assume any personal benefit for themselves or their child by taking part in this study or, alternatively, if the doctor-patient-relationship is recognized as a relationship of trust.⁵ However, these two motives did not play a significant role in the decision-making process in the parents' survey; on the other hand, the Belgian breast cancer patients placed some weight on both motives. Nevertheless, altruistic reasons – to contribute to medical progress and to benefit other patients – were seen as the dominant motives for taking part in both surveys (see figure 2 and figure 9).

In all presented surveys a relatively high percentage of respondents (parents: 70%, patients: 90%) felt adequately informed in the consent process. However, we asked the respondents how they have memorised different elements of the informed consent process regarding the research participation itself, the donation of tissue or blood samples, the documentation in writing, and the contents of tissue-based research (in particular data and tissue use). The results of the surveys reveal different shortcomings in the memorisation process. More parents than patients had problems to remember correctly whether they have been enrolled in a study or not (see figure 1), whereas both responder groups had difficulties to remember that the consent was documented in writing (78% of the parents and 83% of the patients remembered to consent in written form). Regarding the assessment of the data used in tissue-based research the Belgian survey reveals that the patients have deficits in understanding what kind of data are used in research (see figure 8). Hence, it can be argued that – even if the majority of respondents is satisfied with the given information – the contents of research are not well enough understood and memorised, provided that they were informed correctly. As the goals and course of research have to be adequately conceived in order to make an informed decision, it can be tentatively concluded that in this respect the information process in tissue-based research, in particular in clinico-genomic trials, probably needs some improvement. This does not necessarily mean more information, but also other ways of imparting it. Here, other formats than the written documents only (e.g. multi-media) are discussable since documentation of consent in writing is not well stored in the memory of both surveys.

This is even more important as the data show that the respondents take their role in research seriously: Almost half of the respondents in the German surveys wanted always to be asked again if their child's medical data is used in future research projects. The data of the Belgian survey goes in the similar direction, but the results are not as distinct as the German results. One-fifth of the respondents did not want to be asked for re-consent at all and one-fifth did not accept the surrogate vote of an ethics committee. More than half of the Belgian sample was instead uncertain about this issue, whereas the German respondents' position was very clear: Three-third did not accept the votes of an ethics committee in lieu of personal re-consent. This different assessment might be linked to the position of ethics committees in the

⁵ The research guiding questions and hypotheses are presented in detail in D 10.5.

different national health care systems, but could also be due to the fact that in one case patients themselves, and in the other one parents of children were asked, who would rather be involved themselves in decision making instead of delegating it to ethics committees.

Parents asked about their attitude towards their child's assent assumed that children in the age between nine and 11 years or 11 and 16 years are mature enough to independently decide on research participation (see figure 4a). Most of their children were between five and 14 years old at the time of the survey. Here, the survey of the comparison group – parents in rehabilitation – differs in two aspects: The majority of these parents assessed the maturity between the ages of 11 and 16 years or 16 to 18 years, whereas their own children were comparably young – 60% were aged between a few months and three years at the time of the survey. Hence, the personal experience of having a younger or older child seems to be decisive in the assessment of maturity. Interestingly, nearly half of the parents in both German surveys wanted to respect the child's will if he or she refuses to take part in a clinical study. This statement is independent from the child's age.

The attitudes towards data protection reveal that there were strong aversions to data transfer without consent. In particular, disclosure to insurance companies and, surprisingly, relatives was not accepted. In the Belgian sample, not relatives but insurance companies, employees and public health authorities like cancer registries were assessed negatively. According to the parents' survey, genetic test results were assessed as equally sensitive as mental health history or HIV/Aids (see figure 7). However, we expected that respondents want medical data related to socially stigmatizing diseases (e.g. drug history, HIV) to be more protected than genetic data which may have a possible stigmatizing effect in future. The assessment of the genetic test results as very sensitive data points to a growing perception of how relevant genetic data might/are be in the view of the public.

Regarding the demand of feedback, the respondents differentiate between the feedback of aggregate and individual research results. We assumed that the respondents are more interested in personally relevant results than in general feedback of the study. However, nearly all surveyed persons stated that they wanted to be informed about aggregate research results, whereas only two-third of them would definitely like to be informed about individual study findings. Other wanted to be informed only if the results are validated or if treatment is available. From this follows, that the communication of aggregate research results to research participants is an important demand not recently met in the research practice. Regarding the disclosure of individually relevant results, it should be considered that the results should be evaluated carefully before feeding back to participants.

These first results and their preliminary interpretation illustrate that the survey on patients' and parents' attitudes and expectations will deliver important information towards the implementation of informed consent, data protection, and disclosure in ACGT and comparable projects. In the next months, we will conclude data collection and interpretation and especially elaborate on the cultural comparison of the different data sets as the analysis of the German and Belgian surveys show some significant differences.