

Cost-effectiveness evaluation of pre-counseling telephone interviews before face-to-face genetic counseling in cancer genetics

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Abstract One of the main challenges in cancer genetics is responding to the exponential demand for genetic counseling, especially in patients with breast and/or ovarian cancer. To address this demand, we have set up a new procedure, based on pre-genetic counseling telephone interviews (PTI) followed by routing of patients: D1, a PTI is scheduled within 14 days; D7–D14, genetic counselors perform a 20 min PTI in order to establish a pre-genetic counseling file, by collecting personal and family medical history *via* a structured questionnaire and; D10–17, routing: pre-genetic counseling appointment files are analyzed by a cancer geneticist with 3 possible conclusions: (a) priority face-to-face genetic counseling (FTFGC) appointment with a cancer geneticist, if the genetic test results have an immediate therapeutic impact; (b) non-priority FTFGC with a genetic counselor, or (c) no FTFGC required or substitution by a more appropriate index case. In the context of breast and/or ovarian cancer, 1012 patients received PTIs, 39.1%

of which did not lead to FTFGC. The mean delay for non-priority FTFGC was maintained at 18 weeks and priority FTFGC appointments were guaranteed within 8 weeks. The required resources for 1012 patients was estimated at 0.12 FTE secretaries, 0.62 FTE genetic counselors and 0.08 FTE cancer geneticists and the procedure was shown to be cost-effective. This new procedure allows the suppression of up to 1/3 of appointments, guarantees priority for appointments with therapeutic impact and optimizes the interaction and breakdown of tasks between genetic counselors and cancer geneticists.

Keywords Genetic counseling · Genetic counselors · Telephone interviews · Routing · Breast cancer · Ovarian cancer

Introduction

One of the main challenges in cancer genetics is the constant increase in the number of counseling appointments since the progressive identification of genes involved in inherited cancers. In France, there were 63,618 cancer counseling appointments in 2015 under the supervision of the French National Cancer Institute (INCa) versus 12,696 in 2003 [1]. Most genetic counseling appointments concern breast and ovarian cancers. In France, these conditions represent 71% of the overall activity in cancer genetics. This increase is, in part, explained by the drastic impact of identifying a germline *BRCA1/BRCA2* mutation in both patients and their relatives [2]. Mutation carriers should be offered annual breast MRI starting 30 years of age, or 5 years before the earliest case of breast cancer in the family, risk-reducing mastectomy, and risk-reducing salpingo-oophorectomy at 40 years of age, after completing childbearing [3–5]. Identifying

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a germline mutation is not only critical to ensure proper genetic counseling within a patient's family, but also has an immediate therapeutic impact in a patient with cancer. For breast cancer patients, the identification of germline *BRCA1/BRCA2* mutations before surgery should lead to considering complete mastectomy instead of partial mastectomy [6]; mutation carriers with high-grade serous ovarian cancers could benefit from PARP inhibitors [7, 8].

The consequence of this exponential demand for genetic testing in breast and ovarian cancers is the increasingly long wait for genetic counseling appointments. In France, the mean delay, which was 6 weeks in 2009, reached 12 weeks in 2014. In the context of the growing demand for counseling in cancer genetics, which cannot be performed by cancer geneticists alone, genetic counselors play a prominent role. As recently highlighted, cancer genetic counselors may practice their activity with relatively high autonomy and low supervision. However, considering their involvement in patient care and decision-making, there is a need to regulate their activity [9]. Besides cancer geneticists, other physicians prescribe genetic tests outside genetic counseling appointments, especially in patients with ovary cancers, who may benefit from PARP inhibitors. However, these physicians lack the time and expertise to provide genetic counseling. It is essential therefore to maintain counseling in cancer genetics, considering the dual impact of mutation identification for both patients and their families [10, 11].

In order to extend counseling in cancer genetics, to maintain a delay compatible with the therapeutic management of the patient, and to formalize the breakdown of tasks between genetic counselors and cancer geneticists according to their respective expertise, we set up a new procedure within our Centre for Genomic and Personalized Medicine, with a population base in Normandy of 3.3 million. This procedure is based first on pre-counseling telephone interviews (PTI), then on the routing of patients by cancer geneticists. We present here the evaluation of this procedure performed on 1012 patients.

Patients and methods

All patients referred directly or indirectly, through a primary or secondary care physician, for a genetic counseling appointment in the context of personal/familial history of breast and/or ovarian cancer, were prospectively enrolled. Exclusion criteria were individual clinical situations requiring obviously expedited genetic testing within 2 weeks, such as relapsing high-grade serous ovary carcinoma or early-onset breast carcinoma before 36 years or triple negative breast carcinoma before 41 years, prior to surgery, difficulty speaking and/or understanding French, patients under tutelage, patients with anxiety and patients who had already

attended a genetic counseling appointment in our center. The procedure includes four steps:

1. Day 1, a secretary schedules a pre-genetic counseling telephone interview (PTI) and collects minimal information (identity, address, telephone number etc.). Patients are informed of the total procedure.
2. Day 7–14, PTI: a genetic counselor performs a 20-min PTI. Data on personal and family medical histories are collected via a structured questionnaire (Fig. 1). Collected data include the status of the patient (affected or non-affected); the histopathological subtype of cancer; age of diagnosis; mode of diagnosis (clinical signs, self-examination, radiography); treatment achieved, in progress or scheduled; pedigree including number of siblings, children, aunts, uncles and cousins; and familial history of cancer including number of affected relatives, type and age of cancer. For each patient, a pre-genetic counseling file is then established.
3. Day 10–17, routing: pre-genetic counseling files are analyzed by a cancer geneticist in the presence of a genetic counselor with three possible conclusions:
 - a. Priority face-to-face genetic counseling, with a cancer geneticist and genetic testing if the results of the genetic test predict an immediate therapeutic impact (surgery, PARP inhibitors) or in the event of a critical situation (poor prognosis, psychological distress etc.).
 - b. Non-priority face-to-face genetic counseling with a genetic counselor and genetic testing. In this case, the result of the genetic test is delivered by a cancer geneticist.
 - c. No genetic counseling required, due to absence of personal or familial indication and/or substitution by a more appropriate index case.

The indication of a face-to-face genetic counseling was validated when the patient fulfills, at least, one criteria listed in Table 1. If personal or familial medical data are insufficiently documented to conclude, additional medical records are collected after appropriate authorizations have been sent. In this case, pre-genetic counseling files along with the complementary information are subsequently analyzed during the next routing sessions. For each patient, letters summarizing and explaining the routing decision are sent both to the referring physician and to the patient.

The time required for each step of the procedure, taking into account all the different tasks, was evaluated by two internal observers and estimated from 20 subjects enrolled in the procedure: The breakdown of tasks is as follows: a secretary manages PTI scheduling, patient registration, administration and mail; a genetic counselor manages the PTI,

PRE-COUNSELING TELEPHONE INTERVIEW QUESTIONNAIRE				
Pre-counseling genetic file n°:				
Date of first call:				
Writer:		PTI date:		
Patient identity				
Last name:		Maiden name:		
First name:		Date of birth:		
Address:				
Phone number:		E-mail:		
If you are referred by a doctor, please indicate:				
Name:				
Address:				
Specialty:				
Have you or a member of your family already had genetic counseling? YES – NO				
If yes, then complete:				
Degree of relationship:				
Department of genetics (hospital, city):				
Personal medical history				
Are you currently treated for breast or ovary cancer? YES - NO				
If yes, what type of treatment? Neoadjuvant chemotherapy - Adjuvant chemotherapy				
Surgery scheduled/performed on				
Radiotherapy				
Hormone deprivation therapy				
Have you been treated for breast or ovarian cancer? YES-NO				
If yes, specify:				
Cancer	Pathological type	Age of diagnosis	Revelation	Department/hospital
Familial history				
Children				
Number of sons:		Number of daughters:		
Ages:		Ages:		
Have they been treated for breast, ovarian or prostate cancer? YES - NO If yes, specify				
Full name	Date of birth	Type of cancer	Age of diagnosis	Department / Hospital
Brothers and sisters				
Number of brothers:		Number of sisters:		
Ages:		Ages:		
Have they been treated for breast, ovarian, or prostate? YES - NO If yes, specify:				
Full name	Date of birth	Type of cancer	Age of diagnosis	Department / Hospital
Mother				
Date of birth:		If appropriate, date of death:		
Has she been treated for cancer? YES - NO if yes, specify:				
Type of cancer	Age at diagnosis	Department / Hospital		
Maternal family history:				
Number of maternal aunts?		Number of maternal uncles?		
Have they been treated for breast, ovarian or prostate cancer? YES - NO If yes, specify				
Full name	Date of birth	Type of cancer	Age of diagnosis	Department / Hospital
Father				
Date of birth:		If appropriate, date of death:		
Has he been treated for cancer?				
Type of cancer	Age at diagnosis	Department / Hospital		
Paternal family history:				
Number of paternal aunts?		Number of paternal uncles?		
Have they been treated for breast, ovarian or prostate cancer? YES - NO If yes, specify				
Full name	Date of birth	Type of cancer	Age of diagnosis	Department / Hospital
Other relatives with cancer:				
Full name	Date of birth	Type of cancer	Age of diagnosis	Department / Hospital

Fig. 1 Structured questionnaire for pre-counseling telephone interview in cancer genetics

establishment of pedigree, data collection from personal and familial medical records, analysis of the pre-genetic counseling files and non-priority face-to-face counseling; the cancer geneticist manages analysis of the pre-genetic counseling files and priority face-to-face counseling.

Results

We prospectively enrolled in this new procedure 1078 patients corresponding to 1078 new families. The majority of patients (757:70%) had a breast or ovarian cancer and the others (321:30%) were unaffected and presented a familial history of breast/ovarian cancer. Most patients were referred by a physician (1052:97.6%), mainly by a secondary care physician (957:88.8%) and, in particular by an oncologist (640:59.4%) or a gynecologist (237:22%).

Among the 1078 patients who had a PTI, routing data were available for 1012 of them. After routing, we considered that face-to-face counseling and genetic testing were not justified in 396 patients (39.1%), due to absence of significant medical history in 304 of them (30%) or because of a more appropriate index case in the families of 92 patients (9.1%). Among the 616 remaining patients, 85 (8.4%) and 531 (52.5%) respectively received either priority or non-priority face-to-face genetic counseling and genetic testing.

The mean delay between the first telephone call requesting a genetic counseling appointment and the PTI was 11 days. The mean delay between the first telephone call and a priority or non-priority face-to-face genetic counseling appointment was about 8 weeks or 18 weeks respectively.

Table 2 presents a comparison of the cost-effectiveness of face-to-face genetic counseling with and without PTI. With PTI, the estimated time per patient, was at 3, 45 and 5 min, for the secretary, genetic counselor and cancer geneticist respectively. For the overall 1012 patients, this represented a total of 51, 759 and 84 h respectively. The duration of a face-to-face genetic counseling appointment performed, either by a genetic counselor or a cancer geneticist was estimated at 30 min. For the secretary, scheduling a face-to-face appointment was estimated to take an additional 15 min. Priority and non-priority face-to-face genetic counseling appointments were performed by cancer geneticists and genetic counselors respectively. With post-PTI routing, the total number of human resources required for the genetic counseling of 1012 patients was estimated at 0.12 FTE secretaries, 0.62 FTE genetic counselors and 0.08 FTE medical geneticists, representing 51 655 euros in salary costs.

We simulated the time and human resources which would have been required to ensure face-to-face genetic counseling for 1012 individuals without PTI (Table 2). The organization of face-to-face counseling varies according to centers and the breakdown of tasks between genetic counselors and

Table 1 Criteria leading to face-to-face genetic counseling*Personal criteria*

Breast carcinoma < 36 years
 Triple negative breast carcinoma (TNBC) < 51 years
 Bilateral breast cancer, the first of which < 51 years
 Medullary breast carcinoma < 61 years
 Male breast carcinoma before < 71 years
 Ovary adenocarcinoma < 71 years

Familial criteria

Two breast carcinomas in first or second-degree relatives (with a transmitting male), with at least one cancer < 51 years and the other before 71 years
 Three breast carcinomas in first or second-degree relatives, with at least one < 61 years
 Breast carcinoma < 51 with first-degree relatives with either prostate cancer < 61 years or pancreatic cancer < 61 years or ovary adenocarcinoma < 71 years
 Other familial presentations suggestive of hereditary breast and/or ovarian cancers

Table 2 Comparison of the cost-effectiveness of face-to-face genetic counseling with and without pre-genetic counseling telephone interviews (PTI)

Face-to-face genetic counseling with PTI			Face-to-face genetic counseling without PTI					
			Genetic counseling performed by cancer geneticists		Genetic counseling performed by a genetic counselor and a cancer geneticist		Genetic counseling performed by genetic counselors	
Human resources	Time/patient	Total time	Time/patient	Total time	Time/patient	Total time	Time/patient	Total time
PTI and routing								
Secretary	3 min	51 h (n = 1012) ^a						
Genetic counselor	45 min	759 h (n = 1012) ^a						
Cancer geneticist	5 min	84 h (n = 1012) ^a						
Face-to-face counseling								
Secretary	15 min	154 h (n = 616)	25 min	422 h (n = 1012) ^a	25 min	422 h (n = 1012) ^a	25 min	422 h (n = 1012) ^a
Genetic counselor	30 min	266 h (n = 531) ^a	–	–	30 min	506 h (n = 1012) ^a	60 min	1012 h (n = 1012) ^a
Cancer geneticist	30 min	43 h (n = 85) ^a	60 min	1012 h (n = 1012) ^a	30 min	506 h (n = 1012) ^a	–	–
Total								
Secretary 23 € per hour ^c	205 h/0.12 FTE ^b 4531 €		422 h/0.26 FTE ^b 9817 €		422 h /0.26 FTE ^b 9817 €		422 h /0.26 FTE ^b 9817 €	
Genetic counselor 38€ per hour	1025 h/0.62 FTE ^b 38,404 €		–		506 h /0.31 FTE ^b 19,202 €		1012 h/0.62 FTE ^b 38,404 €	
Cancer geneticist 66 € per hour	127 h/0.08 FTE ^b 8720 €		1012 h/0.62 FTE ^b 67,057 €		506 h/0.31 FTE ^b 33,790 €		–	
Patient cost 18.5 € (gas.+park.) ^d	11,396 €		18,722 €		18,722 €		18,722 €	
Total cost	63,051 €		95,596 € (+30,506 €)		81,531 € (+18,480 €)		66,943 € (+3892 €)	

^aNumber of patients^bEstimated from the working time in France (1645 h/year)^cEstimated from the mean annual salary in France: 37 758 € (secretary); 61 942 € (genetic counselor); 109 000 € (cancer geneticist)^dAverage round-trip mileage for counseling (50 km). The standard mileage rate is 0.25 € for use of an automobile

cancer geneticists varies according to the human resources available within each center. Therefore, we simulated different types of organization (Table 2). This comparative evaluation revealed that face-to-face genetic counseling with post-PTI routing was more cost-effective than without (Table 2).

Discussion

Considering the exponential demand for genetic counseling and testing in patients with breast and/or ovarian cancers, it is essential to regulate patients' requests for face-to-face appointments to prevent long waiting times for priority cases. The main findings of this study are three-fold.

First, by performing routing of patients after PTI, it is possible, in the context of breast and ovarian cancer, to suppress over one-third of unjustified appointments, thus saving time and reducing costs (Table 2). According to BOADICEA [12], these patients had a probability to carry a *BRCA1/2* mutation <4%. We consider that the analysis of pre-counseling files by an experienced cancer geneticist allows a more accurate decision regarding an eventual face-to-face genetic counseling appointment. Indeed, cancer geneticists take into consideration parameters usually not integrated into the algorithm for patients with breast cancers, such as pathological subtype, or diagnosis by self-examination indicative of rapid tumor growth. Besides financial arguments, it should be highlighted that genetic testing in patients, without suggestive history of a mendelian predisposition to cancer, increases the probability of identifying genetic variants of unknown significance. With post-PTI routing, the cost of human resources required to ensure face-to-face genetic counseling for all 1012 patients was estimated at only 0.08 FTE cancer geneticists, representing a significant saving of medical time (Table 2). Meanwhile, this new procedure guarantees that all patients requesting genetic counseling receive the expertise of a cancer geneticist to determine whether genetic testing is appropriate.

Second, post-PTI routing guarantees priority for appointments with therapeutic impact. In our center, post-PTI routing was not proposed to patients who obviously required expedited genetic counseling and testing to guide immediate therapeutic options. Therefore, the 85 patients, to whom we proposed priority counseling and genetic testing, may be considered as rescued patients.

Third, post-PTI routing optimizes the breakdown of tasks between cancer geneticists and genetic counselors. Currently, the role of genetic counselors varies according to centers and countries and, as recently highlighted, genetic counselors may perform genetic counseling, independently. We consider that, in genetic counseling, medical expertise and permanent interaction between genetic counselors and cancer geneticists should be maintained. This interaction is

crucial to determine whether or not genetic counseling and genetic testing are appropriate, to deliver accurate medical information to a patient for whom genetic tests may modify immediate therapeutic options and finally to interpret results of genetic testing. According to the post-PTI procedure, genetic counselors prepare appointments, analyze genetic files together with cancer geneticists and perform non-priority face-to-face genetic counseling. Cancer geneticists perform face-to-face priority genetic counseling with potential immediate therapeutic impacts. This post-PTI procedure formalizes the interaction and breakdown of tasks between genetic counselors and cancer geneticists, according to their respective expertise and should reduce the risk of misconduct related to the high autonomy and low supervision of genetic counselors in the field of cancer genetics [9].

Our study has several limitations: first, considering the heterogeneity of practices in cancer genetics and differences in health organization and reimbursement among countries, the cost-effectiveness benefits of the post-PTI routing procedure may vary from one centre to another. Furthermore, to estimate, costs we only considered the salaries of health-care professionals and the travel expenses of patients but not patients' time or overhead. Since face-to-face genetic counseling will lead, in most cases, to genetic testing, a complete cost-effectiveness evaluation should also include the cost of genetic testing. Second, in contrast to other studies presenting new types of genetic counseling procedures [13–16], we did not measure the satisfaction of patients or healthcare professionals. However, even though this was not objectively quantified, most patients and healthcare professionals appreciate, in particular, the fact that their request for genetic counseling was quickly taken into consideration and that, when a therapeutic impact was considered, face-to-face genetic counseling was rapidly offered for cases with therapeutic impact in order not to delay the treatment. Moreover, during PTI, level of anxiety was considered. This procedure did not seem to increase anxiety but, in contrast, it appears that having a first contact within 7–14 days with a genetic counselor reassured worried patients.

Other types of procedures have been developed in other centers and countries to address the challenge of the exponential demand for genetic counseling in cancer genetics. In particular, telephone-based genetic counseling without face-to-face counseling, before genetic testing, has been set up in certain countries, such as the USA and the Netherlands [13–15, 17], and has been shown to be effective in increasing access and reducing the costs of genetic counseling, without altering patient satisfaction [13, 15, 17]. An alternative approach, based on direct *BRCA* testing in all newly diagnosed patients with breast or ovarian cancers followed by face-to-face genetic counseling restricted to patients with deleterious variations and/or familial or personal history suggestive of a high risk, has been

developed in Norway [16]. Nevertheless, it should be highlighted that, in this study, genetic testing was restricted to the recurrent *BRCA* mutations observed in the Norwegian population. Furthermore, the subsequent analysis of the experiences of women, who had been offered this procedure, has shown that a face-to-face consultation with a health professional qualified in medical genetics appears to be essential to assist women in their decision-making process [18]. Many centers prepare genetic counseling by sending patients a self-questionnaire in order to collect personal and familial information. However, filling a self-questionnaire cannot be compared to a PTI performed by a genetic counselor, as it does not guarantee accurate and complete collection of information and is open to bias due to non-returned questionnaires. Furthermore, while PTI leads to a structured and accurate medical questionnaire, it also allows the genetic counselor to perceive a patient's anxiety thus giving the opportunity to stratify a genetic appointment based on a patient's psychological situation.

Although patients' perceptions of genetic counseling vary considerably depending on countries, we consider that the strategy based on post-PTI routing procedure combines the efficiency of telephone interviews and the quality of information delivered by face-to-face genetic counseling and might be more cost-effective than the other strategies, thanks to the suppression of unjustified face-to-face genetic counseling sessions and genetic tests.

In conclusion, post-PTI routing is a simple procedure, which allows the suppression of unjustified genetic counseling appointments, guarantees priority for appointments with therapeutic impact, and optimizes the interaction and breakdown of tasks between genetic counselors and cancer geneticists, for the overall benefit of the patients.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Research involving human and animal participants This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all individual participants included in the study.

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