

# **Universitat** de les Illes Balears

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# GUT FEELINGS IN THE DIAGNOSTIC PROCESS OF SPANISH FAMILY PHYSICIANS

Bernardino Oliva Fanlo



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Doctoral Programme in Translational Research in Public Health and High Prevalence Diseases

# GUT FEELINGS IN THE DIAGNOSTIC PROCESS OF SPANISH FAMILY PHYSICIANS

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CRITERIS DE FORMAT DE LA TESI DOCTORAL A la UNIVERSITAT DE LES ILLES BALEARS **Annex 3**: Model de certificat de director de tesi i de doctorat internacional



#### FORMAT CRITERIA FOR DOCTORAL THESES IN THE UNIVERSITY OF THE ILLES BALEARS **Annex 3**: Model thesis supervision certificate

Universitat de les Illes Balears
Dr Erik Stopler, of Maastricht University and University of Anrwerp
I DECLARE:
That the thesis titles Gut Feelings in the diagnostic process of Spanish family physicians, presented by Bernardino Oliva Fanlo to obtain a doctoral degree, has been completed under my supervision.
For all intents and purposes, I hereby sign this document.
Signature
Palma de Mallorca, 7/9/21

A Feli, Bernardino, Alexia, Cristina, Ander, Pablo y Marc.

De donde vengo y a donde voy.

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#### **ABBREVIATIONS**

- AUC: area under the curve
- E: Specificity
- EBM: Evidence-based medicine
- EKG: electrocardiogram
- FI: Faith in intuition
- GF: Gut feeling
- GFQ: Gut feelings questionnaire
- **GP:** General practitioner
- LR+: Positive likelihood ratio
- LR-: Negative likelihood ratio
- MF: Médico de familia (Spanish for Family Physician)
- NFC: Need For Cognition
- NPV: Negative predictive value
- OR: odds ratio
- PCA: Principal Component Analysis
- PPV: Positive predictive value
- **REI:** Rational Experiential Inventory
- ROC curve: Receiver operating characteristic curve
- S: Sensitivity

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#### ABSTRACT

'It is not wise to rely only on reason and our limited senses to understand life; there are other tools of perception, such as instinct, imagination, dreams, emotions, intuition'

Isabel Allende

My Invented Country (2003)

#### ABSTRACT

#### **Objectives**

This thesis has several objectives: 1) To explore the existence, significance, determinants, and triggers of gut feelings among Spanish General Practitioners (GPs). 2) To obtain a cross-cultural translation of the Gut Feelings Questionnaire (GFQ) into Spanish and Catalan and to assess the structural properties of the translated versions. 3) To assess the prevalence of gut feelings in general practice, examine their determinants and impact on patient management, and measure their diagnostic value for cancer and other serious diseases.

#### Methods

In order to accomplish the objectives, 3 studies were designed. **Objective 1**: Qualitative study using focus groups and thematic content analysis carried out with 20 purposively sampled GPs working in primary care of Majorca (Spain). **Objective 2**: A six-step procedure including forward- and backward- translations, consensus, and cultural and linguistic validation was performed for both languages. Internal consistency, factorial structure, and content validity were assessed. **Objective 3**: A prospective observational study was performed using the Spanish and Catalan versions of the GFQ. Participants included 155 GPs and 1487 of their patients, from four Spanish provinces. Data recorded includes sociodemographic data from patients and GPs; the reasoning style of GPs; the characteristics of the consultation; the presence and kind of gut feeling; the patient's subsequent contacts with the health system; and new cancer and serious disease diagnoses reported at 2- and 6months post-consultation.

#### Results

**Study 1:** GPs were aware of the existence of gut feelings in their diagnostic reasoning process and recognised 2 kinds of gut feelings: a sense of alarm and a sense of reassurance. A previous physician-patient relationship and the physician's experience had a strong perceived influence on the appearance of gut feelings. GPs attached great significance to gut feelings and considered them as a characteristic of

the primary care working style and as a tool available in their diagnostic process. GPs thought that the notion of gut feelings and their relevance can be transmitted to students and trainees. They tended to follow their gut feelings, although they were not sure of their accuracy. Study 2: Internal consistency was high for both questionnaires (Cronbach's alpha for GFQ-Spa=0.94 and GFQ-Cat=0.95). The principal component analysis identified one factor with the sense of alarm and the sense of reassurance as two opposites, explaining 76% of the total variance for the GFQ-Spa, and 77% for the GFQ-Cat. **Study 3:** GPs experienced a gut feeling during 97.1% of the consultations: a sense of reassurance in 75.3% of consultations and a sense of alarm in 21.7% of consultations. A sense of alarm was felt at higher frequency given an older patient, the presence of at least one cancer-associated symptom, or a non-urban setting. GPs took diagnostic action more frequently after a sense of alarm. After 2 months, the sense of alarm had a sensitivity of 59.3% for cancer and other serious diseases (95%CI 47.1-70.5), a specificity of 79.4% (95%CI 77.1-81.5), a positive predictive value of 12.2% (95%CI 9.06-16.3), and a negative predictive value of 97.5% (95%CI 86.4-98.3).

#### Conclusions

**Study 1:** Spanish GPs recognise the presence and role of gut feelings in their diagnostic reasoning process. Future research should examine the diagnostic accuracy of gut feelings and how to teach about gut feelings in the training of GPs. **Study 2:** Spanish and Catalan versions of the GFQ were obtained. Both have been cross-culturally adapted and showed good structural properties. **Study 3:** Gut feelings are consistently present in primary care medicine, and they play a substantial role in a GP's clinical reasoning and timely diagnosis of serious disease. The sense of alarm must be taken seriously and used to support diagnostic evaluation in patients with a new reason for encounter.

#### RESUM

#### Objectius

Aquesta tesi es centra en tres objectius: 1) Explorar la existència, significat, determinants i desencadenants dels 'pressentiments' entre els metges de família espanyols (MF). 2) Obtenir una traducció transcultural del qüestionari de 'Gut Feelings' (GFQ) en espanyol i català i avaluar les propietats estructurals de les versions traduïdes 3) Avaluar la prevalença de 'pressentiments' en la atenció primària, examinar els seus determinants e impacte en el maneig del pacient i mesurar el seu valor diagnòstic per càncer i altres malalties greus.

#### Mètodes

Per tal d'acomplir els 3 objectius es varen dissenyar 3 estudis. **Objectiu 1:** Estudi qualitatiu de grups focals i anàlisi temàtic del contingut dut a terme en una mostra intencional de 20 MF de Mallorca. **Objectiu 2:** Es va dur a terme un procediment en 6 escalons: traducció i retro-traducció del GFQ, consens d'un comitè d'experts, i validació cultural i lingüística de les dos versions. També es va avaluar la consistència interna, la estructura factorial i validació de contingut. **Objectiu 3:** Un estudi observacional prospectiu es va dur a terme utilitzant les versions espanyola i catalana del QGF Els subjectes foren 155 MF i 1487 dels seus pacients amb un nou motiu de consulta de 4 províncies espanyoles. Variables: sociodemogràfiques de pacients i MF; estil de raonament del MF, característiques de la consulta, presencia de pressentiments i tipus, contactes subseqüents del pacient amb el sistema sanitari, nous casos de càncer i malalties greus aparegudes als 2 i 6 mesos de la consulta índex.

#### **Resultats**

**Estudi 1:** Els MF eren conscients de la existència dels pressentiments en el raonament clínic durant el diagnòstic i reconeixien 2 tipus de : un sentit d'alarma i un sentit de seguretat. Els MF expressaren que la relació prèvia metge-pacient i la experiència del MF influïen de forma important en la aparició dels pressentiments. Els MF donaren gran significat als pressentiments i aquest foren considerats una

característica pròpia d'atenció primària i una eina en el procés diagnòstic. Els MF consideren que la noció de pressentiments i la seva rellevància pot ser transmesa a estudiants i residents Els MF tendeixen a seguir els pressentiments, malgrat no estan segurs de la seva precisió diagnostica. Estudi 2: La consistència interna va ser alta (Alpha de Cronbach per GFQ-espanyol=0,94 i GFQ-Català=0,95). L'anàlisi de components principals va identificar un factor amb els sentit d'alarma i sentit de seguretat com dos oposats, explicant el 76% de la variància per el GFQ-espanyol, i 77% per el GFQ-Català. Estudi 3: Els MF experimentaren un pressentiment en el 97,1% de les consultes: un sentit de seguretat en el 75,3% i un sentit d'alarma en el 21,7% de les consultes. El sentit d'alarma aparegué més freqüentment quan el pacient era major, en entorns no urbans o quan el pacient presentava un símptoma relacionat amb càncer. Els MF van prendre mesures de diagnòstic amb més freqüència després d'una sensació d'alarma. Als 2 mesos el sentit de alarma tenia una sensibilitat del 59,3% per càncer i altres malalties greus, (95%CI 47,1-70,5), una especificitat del 79,4% (95%CI 77,1-81,5), un valor predictiu positiu del 12,2% (95%CI 9,06-16,3), i un valor predictiu negatiu del 97,5% (95%CI 86,4-98,3).

#### Conclusions

**Estudi 1:** El MF espanyols reconeixen la presencia i el rol dels pressentiments en el seu procés de raonament diagnòstic. La recerca futura ha d'avaluar la precisió diagnostica dels pressentiments i com incloure'ls en la educació dels MF. **Estudi 2:** S'obtingueren una versió espanyola i una catalana adaptades transculturalment, ambdues amb bones propietats estructurals. **Estudi 3:** Els pressentiments son presents consistentment en la consulta del MF i juguen un paper substancial en el raonament clínic i en el diagnòstic precoç de malaltia greu. El sentit d'alarma ha de ser tingut en compta de forma seriosa i ser utilitzat per recolzar l'avaluació diagnostica en pacients amb un nou motiu de consulta.

#### RESUMEN

#### Objetivos

Esta tesis se centra en tres objetivos: 1) Explorar la existencia, significado, determinantes y desencadenantes de las 'corazonadas' entre los médicos de familia españoles (MF). 2) Obtener una traducción transcultural del cuestionario de 'Gut Feelings' (GFQ) en español y catalán y evaluar las propiedades estructurales de las versiones traducidas. 3) Evaluar la prevalencia de 'corazonadas' en la atención primaria, examinar sus determinantes e impacto en el manejo del paciente y medir su valor diagnóstico para cáncer y otras enfermedades graves.

#### Métodos

Para cumplir los 3 objetivos se diseñaron 3 estudios. **Objetivo 1**: Estudio cualitativo de grupos focales y análisis temático del contenido, llevado a cabo en una muestra intencional de 20 MF de Mallorca. **Objetivo 2**: Se llevó a cabo un procedimiento en 6 pasos incluyendo la traducción y retro-traducción del GFQ, consenso de un comité de expertos, y validación cultural y lingüística de las dos versiones. También se evaluó la consistencia interna, el análisis factorial y validación de contenido. **Objetivo 3**: Se llevó a cabo un estudio observacional prospectivo utilizando las versiones española y catalana del GFQ. Los sujetos fueron 155 MF y 1487 de sus pacientes con un nuevo motivo de consulta de 4 provincias españolas. Variables: sociodemográficas de pacientes y MF; estilo de razonamiento del MF, características de la consulta, presencia de corazonadas y tipo, contactos subsecuentes del paciente con el sistema sanitario, nuevos casos de cáncer y enfermedades graves aparecidas a los 2 y 6 meses de la consulta índice.

#### **Resultados**

**Estudio 1**: Los MF eran conscientes de la existencia de las corazonadas en el razonamiento clínico durante el diagnóstico y reconocían 2 tipos: un sentido de alarma y un sentido de seguridad. Los MF expresaron que la relación previa médico-paciente y la experiencia del MF influían de forma importante en la aparición de las

corazonadas. Los MF dieron gran valor a las corazonadas y fueron considerados una característica propia del estilo de trabajo de la atención primaria y una herramienta en el proceso diagnóstico. Los MF consideran que la noción de corazonadas y su relevancia puede ser transmitida a estudiantes y residentes. Los MF tienden a seguir las corazonadas, pese a no están seguros de su precisión diagnóstica. Estudio 2: La consistencia interna fue alta (Alpha de Cronbach para GFQ-español = 0,94 y GFQcatalán = 0,95). El análisis de componentes principales identificó un factor con el sentido de alarma y el sentido de seguridad como dos opuestos, explicando el 76% de la varianza para el GFQ-español, y 77% para el GFQ-catalán. Estudio 3: Los MF experimentaron una corazonada en el 97,1% de las consultas: un sentido de seguridad en el 75,3% y un sentido de alarma en el 21,7% de las consultas. El sentido de alarma apareció más frecuentemente cuando el paciente era mayor, en entornos no urbanos o cuando el paciente presentaba un síntoma relacionado con cáncer. Los MF tomaron medidas de diagnóstico con más frecuencia después de una sensación de alarma. A los 2 meses el sentido de alarma tenía una sensibilidad del 59,3% para cáncer y otras enfermedades graves, (95% CI 47,1-70,5), una especificidad del 79,4% (95% CI 77,1-81,5), un valor predictivo positivo del 12,2% (95% CI 9,06 a 16,3), y un valor predictivo negativo del 97,5% (95% CI 86,4-98,3).

#### Conclusiones

**Estudio 1**: Los MF españoles reconocen la presencia y el rol de las corazonadas en su proceso de razonamiento diagnóstico. La investigación futura debe evaluar la precisión diagnóstica de las corazonadas y cómo incluirlas en la educación de los MF. **Estudio 2**: Se obtuvieron una versión española y una catalana adaptadas transculturalmente, ambas con buenas propiedades estructurales. **Estudio 3**: Las corazonadas están consistentemente presentes en la consulta del MF y juegan un papel sustancial en el razonamiento clínico y en el diagnóstico precoz de enfermedad grave. El sentido de alarma debe ser seriamente tenido en cuenta y ser utilizado para apoyar la evaluación diagnostica en pacientes con un nuevo motivo de consulta.

#### BACKGROUND

'Some people have a sixth <u>sense</u>. He has a sixth, a seventh and an eighth'

Col. Turner

Where eagles dare (1968)

A young doctor, recently graduated, is attending patients in a small surgery. It is his first job after leaving the medical school: a locum in a remote town in the mountains of northern Aragon (Spain). After a few quiet days, today is being a busy day. There has been a problem in the supply of drinking water to the community. The waiting room, usually a calm space, is now full of people with symptoms of gastrointestinal infection. Nausea, vomiting, diarrhoea and low-grade fever appear with variable intensity in dozens of patients. The young doctor, nowadays an experienced veteran, still remembers almost running out of endovenous fluids and considering the idea of making homemade isotonic serum in large buckets to supply to all patients who may need it. Suddenly, after attending many patients with similar complaints and similar diagnosis, the doctor's attention is captured by a young woman. She has nausea, mild diarrhoea and a feverish feeling still not confirmed by the thermometer. The doctor feels a hunch. He doesn't ask her the usual questions of the day (about what she ate yesterday, if she has drunk tap or bottled water...). During the clinical interview he selects some different questions and, after agreeing with the patient, he orders a urine test. A few minutes later they have the result. The patient is pregnant.

Another doctor is almost ending her workday. It will soon be 30 years since she works in the same health centre. She knows and has accompanied each vital event of her patients, whether sad or happy, stressful or not. Diseases, recoveries, newborns, agonies, weddings, divorces...She knows them, and they know her. The last patient today is Tomeu, a 60-year-old man who visits the health centre frequently. He doesn't have any important disease, but he is always very concerned about any mild symptom he has. Tomeu has arrived at the surgery without arranging a previous appointment. It is not normal, as Tomeu likes to follow the rules and he knows that the doctor prefers that they make an appointment to visit her. Tomeu salutes as he enters the room, sit down and explain his symptoms: fever and cough. The doctor asks for other symptoms and all the answers are affirmative: Tomeu also has chills, shortness of breath and pain in the right side of the chest. A sudden thought crosses the doctor's mind. Although any medical student may consider pneumonia as the first diagnosis to look for, she somehow 'knows' that Tomeu doesn't have a pneumococcal pneumonia. After examining him and measuring his temperature and oxygen saturation (all completely normal), they agree to take a wait-and-see attitude. Two days later Tomeu is perfectly fine.

These two examples are real testimonials of Spanish family physicians when asked about how they guide and diagnose the cases presented by their patients. They, of course, mention their medical knowledge, their experience, the importance of the continuity of care. But they also point out that sometimes they have experienced unexpected thoughts, unforeseen 'enlightenments', that have guided them through the diagnosis process slowing down or speeding up their decisions and actions. Do all doctors have experienced this type of feelings? What are the triggers for the appearance of these thoughts? Do doctors follow these intuitions? Are these feelings reliable?

Most developed countries have a primary care system of almost universal and equitable access (Starfield, Shi, & Macinko, 2005). In these types of systems, the vast majority of patients' first contacts with the health system take place in primary care (Starfield, 1992). One of the most relevant characteristic of primary care is uncertainty (Dinant, 2004; Gerrity, Earp, DeVellis, & Light, 1992). And this is even more remarkable in the case of first doctor-patient encounters for a new reason (Evans & Trotter, 2009). Patients who consult their primary care physician for a new reason often present signs and symptoms that can be either early stages of a serious disease or irrelevant ailments without pathological significance. The beginning of the diagnosis process in medicine is a crucial moment. Many decisions that can decisively influence the final outcome, such as whether or not to perform certain diagnostic tests, or whether to start a new treatment or adjust an ongoing treatment, depend on this moment. General practitioners (GPs) have to decide in few minutes how to manage their patient's complaints. They must do it walking along a narrow cliff trying to avoid falling into overdiagnosis and overtreatment on the one hand, and into diagnostic delay and diagnostic errors on the other. In this sense, the development and use of tools that can help GPs to make the adequate decisions in each case are essential.

#### **Clinical reasoning**

Clinical reasoning can be defined as the task of sorting 'through a cluster of features presented by a patient and accurately assign a diagnostic label, with the development of an appropriate treatment strategy being the end goal' (Eva, 2005). To better understand these processes different research lines have been developed, using concepts from psychology and mathematics. These varied ways of seeing clinical reasoning are based on two different paradigms: medical problem-solving and clinical decision-making. Each one have their own assumptions and methods (Elstein, Shulman, & Sprafka, 1978; Elstein & Schwartz, 2002).

#### Problem solving

The medical problem-solving process begins with the early generation during the consultation of a limited number, usually between three and five, of diagnostic hypotheses. These hypotheses aim to predict what findings ought to be present if the hypothesis is correct. The hypothesis generated will guide the data gathering, be it in the form of questions to be asked, physical examination or medical investigations to be requested (Elstein et al., 1978). Furthermore, the hypothesis will influence the process of integration of all the information gathered. From this point of view, clinical reasoning is therefore a hypothetico-deductive process. Let's take as an example the case of Tomeu. To test the pneumonia hypothesis temperature has to be measured and a complete cardiopulmonary auscultation has to be performed. With the data obtained the doctor will make the decision to request a chest X-ray or not.

There are great variations in the diagnostic problem-solving performance between individual clinicians. But as both successful and unsuccessful clinicians use the hypothetic-deductive model their differences must be found elsewhere than the method used. Expert physicians in a particular domain tend to generate their diagnostic hypotheses more quickly than novices. It has been proven that hypothesis formulated earlier in the consultation tend to be more accurate (Barrows, Norman, Neufeld, & Feightner, 1982). Some researchers have pointed out that differences in performance and accuracy may depend not on the method but on the clinician's mastery of a particular domain. Experienced physicians may use the hypothesis generation only when confronted with difficult or uncommon cases, and adopt other strategies with more familiar cases (Elstein & Schwartz, 2002). The main strategy used in these cases by experienced clinicians is pattern recognition. Pattern recognition is a cognitive mechanism that pairs the information we are receiving with the information we have stored before. It helps us, for example, to learn to speak our mother tongue when we are little children or to recognize the faces of our relatives and acquaintances. In medicine they have also been described as 'illness scripts'. These are structures used by experienced clinicians that describe the features of prototypical or actual patients. They contain little data about ethiopathogeny or pathophysiology, but lots of relevant information about the disease, its consequences, and the context under which illness develops (Cate & Durning, 2018; Schmidt, Norman, & Boshuizen, 1990). The categorization of a new case could be based either by retrieval of actual patients attended before by the same doctor or by matching to more abstract prototypes. Some sets of symptoms (as the one formed by fever, chills, cough, dyspnoea, and chest pain found by Tomeu's doctor) have become classics. Doctors also can construct their own patterns or scripts based on their clinical experience and their personal greater or lesser ability to build patterns. Patient's self-labelling can also contribute to widen or narrow the number of hypotheses. The migraine patient who assures that this time the headache is different from his usual headaches helps the clinician to add different diagnostic possibilities. Data collected after the search triggered by the cited mechanisms will help the doctor to decide the additional tests to perform. Then the clinician may revise, reject or confirm the diagnostic hypothesis until a final diagnosis is reached (McGuire, 1985).

Errors in the diagnostic process can occur for different reasons: the difficulty in generating the right hypothesis at the beginning, misperception or misinterpretation of the information obtained or an excessive commitment to an erroneous hypothesis. More than 30 cognitive pitfalls and biases that may lead the physician to diagnostic errors have been described in the literature (Bornstein & Christine Emler, 2001; Croskerry, 2003; Dawson & Arkes, 1987; Klein, 2005). Some examples can be cited as illustrations that any physician with an alert and willing to introspection spirit can recognize: confirmatory bias, overconfidence, illusory correlation, and regret.

The confirmation bias is the tendency to seek, recognize and give value to information that confirms and fits with the pre-existing diagnostic hypothesis. At the same time, it tends to diminish the importance of findings that can contradict the pre-existing hypothesis. This bias can lead doctors to ask questions that can confirm their first ideas and avoid questions that can refute them. Consider for example the feverish patient. Most of the first hypotheses in a primary care consultation will lead us to look for an infectious cause and to ignore other possible non-infectious diagnoses (autoimmune diseases, neoplasms, and drug induced complications). Most of the doctors tend to overestimate their knowledge and skills, and to be overconfident about them (Berner & Graber, 2008). It is well known that being confident can help patients to feel more secure about doctors' diagnostics, and that doctors show some reluctance against disclosing uncertainty to patients. But forgetting the limits of our expertise can lead to unnecessary mistakes. Another type of cognitive bias is known as illusory correlation. It has been described as the tendency to perceive two events as causally related, when actually the connection between them is merely casual. The physician can think that his/her diagnosis of acute cystitis in an elder woman is correct because she has had a good response to the antibiotic treatment, thus forgetting the possibility of other diagnostics (chronic urogenital symptoms, chlamydia infection, atrophy of urogenital tissue...) with fluctuating evolution. A last example of cognitive biases that can affect the diagnostic process appears when doctors overestimate the probability of a diagnosis because of the anticipated regret from a missed diagnosis. In one study, urologists reviewed excretory urograms in order to determine whether a lesion was a benign cyst, a malignant tumour, or a normal variation. They overestimated the probability of malignant tumour because of the regret they would have experienced if they had missed the more serious diagnosis (Wallsten, 1981).

#### Decision making

The medical decision-making model or paradigm consider the diagnostic process as a course during which opinion is updated with information from clinical evidence (Elstein & Schwarz, 2002). This model tries to avoid both mental shortcuts that can lead to defective diagnosis (heuristics) and wrong beliefs that can hinder correct decision making (biases) (Elstein, 1999). The medical decision-making model uses evidence-based medicine and the application of Bayes' theorem to modify the initial probability of a given diagnosis. Bayes' theorem is a proposition raised by the English mathematician and preacher Thomas Bayes (1702-1761), published posthumously in 1763. The modern interpretation used nowadays was first developed by the French astronomer and mathematician Pierre-Simon Laplace (1749-1827), and it has evolved during the past 250 years until the Bayesian interpretation of probability has become the dominating statistical thinking (Fienberg, 2006). The Bayes' theorem states that the probability of a hypothesis A conditional on a given body of data B is the ratio of the unconditional probability of the conjunction of the hypothesis with the data to the unconditional probability of the data alone (Joyce & James, 2003). It is mathematically stated as:

$$P(A|B) = \frac{P(B|A) P(A)}{P(B)}$$

In medicine, the conditional probability of a determined diagnosis depends on the known probability of the diagnosis and the previous conditions of a patient. Claims have been made supporting the idea that Bayesian reasoning is the natural way in which clinicians approach the diagnosis of a singular patient (Gill, Sabin, & Schmid, 2005). The authors plead that not only blood tests or radiography are diagnostic tests, but also clinical history questions and physical examination manoeuvres. They have their own sensitivity and specificity values, although these values are usually unknown. Clinicians interpret the positive or negative results of each test as making more or less suggestive the diagnosis of a disease, in qualitative rather than quantitative terms.

Evidence-based medicine (EBM) is, in the words of its pioneers:

The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996).

The individual clinical expertise comprehends the skills, proficiency, wisdom, and discernment acquired during years of clinical practice. And furthermore, the identification, respect, and empathy developed to individual patients' values when making decisions about their medical care. The best available clinical evidence must arise, as regards to diagnosis, from clinically relevant research, especially patient centred, into the accuracy of diagnostic tests. More recently, some authors have argued in favour of incorporating patient preferences into this definition as a useful way to improve health care outcomes (Stewart et al., 2000). Evidence based medicine was announced at the beginning as a 'new paradigm' (Guyatt & Group, 1992). Its success and influence in clinical practice and medical education is undeniable. But lately some criticism has emerged, even from clinicians and academics supporting the evidence-based medicine movement (Greenhalgh & Wieringa, 2011; Wieringa, Engebretsen, Heggen, & Greenhalgh, 2017). They have pointed out some problems that are creating a crisis in EBM. The EBM brand has been misappropriated by vested interests, specially from the drug and medical devices industry trying to mark the research agenda. The amount of evidence, be in form of clinical trials, reviews, or guidelines, has become huge and unmanageable. Not all statistically significant benefits have a translation and relevance in clinical practice. Blind follow-up of action guidelines, closed algorithms with lack of external validity, and computerized decision support systems can divert healthcare towards a management-based care instead of a patient-centred care.

From the decision-making model point of view the diagnosis of a condition in a patient has to have into account the pre-test odds of a disease. Evidence-based testing will perform diagnostic tests taking into account their accuracy (Sackett & Straus, 1998). Several measures are used to assess tests accuracy. Some of these measures are more commonly used in clinical settings. Sensitivity (S) is the proportion of those who have a condition who are correctly classified by the test as having the condition, i.e., persons with a disease who have a positive result. Specificity (E) is the proportion of those who does not have a condition who are correctly classified by the test as not having the condition, i.e., persons without a disease with a negative result in the test. The positive predictive value (PPV) is the proportion of positive results that actually have the condition. The negative predictive value (NPV) is the proportion of negative results that actually does not have the condition. There are other global measures such as odds ratio (OR) or the area under the curve (AUC) that are more frequently used in the academic and research fields. The positive (LR+) and negative (LR-) likelihood ratios are helpful measures that are seldom used because of they are more difficult to interpret (McGee, 2002). They determine, regardless of prevalence, whether and how much a positive or negative test changes the probability that a patient, given a determined pre-test probability, has a condition.

Despite its theoretical superiority this model is used less than expected. The main cause is what Gigerenzer et al. call 'collective statistical illiteracy', a widespread inability to understand the meaning of numbers (Gigerenzer, Gaissmaier, Kurz-Milcke, Schwartz, & Woloshin, 2010). It has been described that less than 25% of physicians take sensitivity and specificity values into account before ordering diagnostic tests. A systematic review found that the commonly used measures of test accuracy are poorly understood by health professionals (Whiting et al., 2015). Fewer of 3% use the Bayesian transformation approach and about only 1% employ methods as ROC curves or likelihood ratios (Carrington Reid et al., 1998). Given the prevalence of the disease, the sensitivity and the false-positive rate of the test, only 21% of 160 gynaecologists were capable to tell a woman who has been tested positive for breast cancer with a mammogram her actual chances of having a breast cancer (Gigerenzer et al., 2010). There are some other reasons that

explain the underuse of this model. The emotional nature of the doctor-patient relationship and the existence of multiple conflicts of interests in the healthcare system can be cited among these reasons, as well as the medical education system failure to teach students statistical thinking (Gigerenzer & Wegwarth, 2013). Sometimes diagnostic values of a determined diagnostic test are not easily available. The test properties of many signs and symptoms are not well studied. In some cases, doctors lack of sufficient training or medical knowledge on a certain domain. Moreover, the available evidence may lack of external validity for the spectrum of patients attended in a specific clinical context. Known cognitive biases as the representativeness and the availability heuristics also interfere with this model of reasoning. The representativeness heuristic is the assumption that if something is similar to other things belonging to a certain category it is itself a member of that category. A patient with a high blood pressure resulting from an isolated measure may drive us to consider all his symptoms as secondary to undiagnosed high blood pressure rather than considering other diagnostic possibilities. The availability heuristic is the disposition to accept as more likely the thoughts or ideas that come more easily to our mind. Recent experiences, like a patient diagnosis, or doctors themselves suffering from a certain pathology, can increase the likelihood of diagnosing this pathology.

Diagnostic models are not independent paths without the possibility of mixing. It has been shown through qualitative research that primary care physicians recognize that they may change and use different strategies depending on how rare or serious they perceive the diagnosis to be, and also on the different stages of the diagnostic process, be the initiation of the diagnosis, the refinement stage or the moment of defining the final diagnosis (Heneghan et al., 2009).

#### Tacit knowledge

Constructivist approaches to knowledge accentuate the importance of tacit knowledge. The term *tacit knowledge* (Polanyi, 1958) makes reference to the knowledge that is difficult or impossible to be transmitted. It is opposed to the formal, codified, explicit knowledge. It is built from experience, shared across 39

communities, and linked to action in context. Remember Tomeu's doctor at the beginning of this manuscript. Her decision about Tomeu was based in her tacit knowledge about Tomeu. It is difficult to share or to explain to other doctors unless they have treated Tomeu before, or work at the same health center, or have experienced situations with patients similar to Tomeu. Tomeu's doctor, as Polanyi would say, 'knows more that she can tell' (Polanyi, 1966). Aristotle would say that she is acting with 'phronesis'. In *Nicomachean Ethics* phronesis is distinguished from other intellectual virtues as a kind of practical wisdom, the ability to decide how to achieve a certain end (Tomeu's wellbeing) and to reflect upon it and to determine good ends. Phronesis cannot be teached, requires experience and is concerned with how to act in particular situations (Aristóteles, (Trad., 2014)). More recently Montgomery, in her book *How doctors think: clinical judgment and the practice of medicine* (Montgomery, 2005), pointed out that the main question that a clinician faces before any patient is: 'What is it best to do, for this individual, at this time, given these particular circumstances?' Clinicians ought to know the evidence-based rules and guidelines, the most up-to-date medical knowledge, and which is the best decision for this unique patient at this unique moment.

What do we find when we go into consultation with clinicians? An ethnographic study of two general practices in England found that clinicians seldom access nor use explicit evidence from research and other sources when attending their patients (Gabbay & May, 2004). Those clinicians rather rely in what the study calls 'mindlines'. These mindlines are collectively reinforced, internalised, tacit guidelines. They are constructed by the clinician's readings and updates, but largely by their own and their colleagues' experience, interactions between them and opinion leaders, pharmaceutical representatives, patients, and many other sources of tacit knowledge. These mindlines are constantly sharpen up by being negotiated through informal interactions (magazines, professional networks, maybe social networks nowadays), resulting in socially constructed 'knowledge in practice'. Mindlines are built on a fluid and intersubjective view of knowledge. They continuously accommodate to the existing context and acknowledge the existence of multiple realities. A systematic review on the mindlines topic concluded that, although mindlines challenge the conventional EBM paradigm, they have potential

to expand EBM's conceptual toolkit to produce richer forms of 'evidence-based' knowledge (Wieringa & Greenhalgh, 2015).

#### Intuition

The role of intuition and emotions in the acquisition of expertise in decision making has long been studied. In the five stages theory of expertise (Dreyfus SE, 2004) the subject goes through a series of learning phases: novice, advanced beginner, competent, efficient and expert. The expert distinguishes himself from others in that, having gained experience in a large number of situations, he is able to distinguish the subtle differences between one and the other in order to intuitively make decisions adapted to each situation. In the hypothesis of the somatic marker (Bechara, Damasio, & Damasio, 2000) emotions and feelings trigger the activation of bioregulatory processes that intervene in the traditionally considered as purely cognitive decision making. In medicine we can find references to intuition as a part of the 'art of medicine', referring to the hunches that experienced physicians have without being able to explain, a tacit knowledge essential to good practice (Montgomery, 2005).

The origins of dual process theories of reasoning can be traced back to Sigmund Freud, who distinguished between a primary system associative and unconscious, and a secondary system conscious and capable of rational thought (Osman, 2004). A bunch of modern dual process theories of reasoning appeared in the late years of the past century. Sloman (Sloman, 1996) distinguished two systems. One system was described as associative because its computations are based in similarity and temporal structure. The other was described as 'rule based' because it operates on symbolic structures that have logical content and variables, characteristics normally assigned to rules. Evans (Evans, 1984) proposed a twostage theory. Heuristics processes select items of the information as relevant, and analytic processes operate on these selected items to generate inferences or judgements. Epstein (Epstein, 1994) stated that people apprehend reality in two fundamental different ways, named experiential and rational. Hammond (Hammond, 1996) found that the judgement process involves an ongoing rivalry between intuition and analysis. Nonetheless the details of these dual-process theories are not always exactly the same, there are apparent similarities. The modern dual process theory establishes two types of cognitive processes, labelled System 1 and System 2 (Kahneman, 2003; Stanovich & West, 2000). The System 1, or intuitive, is fast, automatic, effortless, associative, and implicit. It is influenced by emotions. It is governed by habit, and therefore is more difficult to modify. System 1 makes use of concrete images, metaphors and narratives to encode reality. The System 2, or analytic, is slow, controlled, and effortful. It makes use of logical connections. It is more flexible and easier to change. It uses abstract symbols, words and numbers. The System 2 is also known as rational, paradigmatic or deliberative. Hogarth reminds us that these two systems that we have described are not independent or work in isolation, just as when we study we conveniently separate the circulatory and respiratory systems to understand and describe them, to finally discover that they work together and are strongly interconnected (Hogarth, 2010). Hammond proposed that the expert cognitive processes can be sorted in a continuum ranging from intuition to analysis (Hammond, Hamm, Grassia, & Pearson, 1987).

In environments such as primary care uncertainty is an intrinsic component of each clinical encounter (Gerrity et al., 1992). The continuous increase in multimorbidity adds components of complexity to the already challenging diagnostic process. A GP must constantly integrate factors related to the patient's biopsychosocial spheres, those related to his own personality and situation, and the characteristics of the health system in which he performs his functions. Linear diagnostic reasoning in which physicians are educated is not capable of encompassing complex diagnostic situations, making it necessary to develop new strategies and tools (Stolper, Van Royen, Jack, Uleman, & Olde Rikkert, 2021). In this sense, the intuition of the healthcare professional, defined as the result of nonanalytical processes based on experiences and previous knowledge (Abernathy & Hamm, 1995), may play an important role in decision making.

#### **Gut feelings**

In English there is the term *gut feelings*. This term has been described as 'a useful alarm light that comes on suddenly to announce that there is something unusual' (Hull, 1985). There are expressions with similar meaning in many other languages (Stolper, Van Royen, & Dinant, 2010). In Spanish the word *corazonada* can be the equivalent of the English term, defined by the Spanish Use Dictionary as the 'vague feeling that something good or bad is about to happen' (Moliner, 2007).

The presence and significance of gut feelings (GF) in clinical contexts has been investigated in different fields such as nursing (Mccutcheon & Pincombe, 2001), the diagnosis of cancer and serious diseases, both in primary and hospital care (Hjertholm, Moth, Ingeman, & Vedsted, 2014; Iqbal, Kara, & Hartley, 2015; Johansen, Holtedahl, & Rudebeck, 2012), chest pain (Bruyninckx, Van den Bruel, Hannes, Buntinx, & Aertgeerts, 2009), paediatrics (Lykke, Christensen, & Reventlow, 2008; Van Den Bruel, Thompson, Buntinx, & Mant, 2012), and emergency medicine (Beglinger et al., 2015).

Some early studies put their focus in exploring the recognition of gut feelings among GPs. A study with Dutch GPs (Stolper, van Bokhoven, et al., 2009) used focus groups discussions to study their concept of gut feelings. The study performed a text analysis of the discussions, with a grounded theory approach, to draw conclusions on the subject. The study finally showed that Dutch GPs were familiar with the concept of gut feelings, and they recognized that GF plays a substantial role in their everyday clinical routine. The participants pointed out to the existence of two types of gut feelings: a 'sense of reassurance' and a 'sense of alarm'. When having a sense of reassurance, GPs feel sure about prognosis and therapy, although they may not have a clear diagnosis in mind. A sense of alarm means that GPs have the feeling that something is wrong even though there are not enough evidence to prove it. GPs were using gut feelings as a compass in which they can trust in uncertain situations. The study also identified the main determinants of gut feelings as: fitting, alerting and interfering factors, sensation, contextual knowledge, medical education, experience and personality. With this starting point, the research team approached the task of looking for an agreement on the description of the senses of alarm and reassurance

(Stolper, Van Royen, et al., 2009). With this objective, twenty-seven Dutch and Belgian GPs and ex-GPs involved in academic educational and research problems participated in a Delphi consensus procedure. After four rounds, 70% or greater agreement was reached in seven statements. In four statements agreement was not reach and then they were rejected. The consensus process was lately repeated among French GPs, reaching very similar conclusions (Le Reste et al., 2013).

The statements about the existence and meaning of GF, agreed in the original Dutch-Flemish consensus and subsequently ratified in the French consensus, are:

- A 'sense of alarm' means that a GP perceives an uneasy feeling as he/she is concerned about a possible adverse outcome.
- A 'sense of alarm' implies that a GP worries about a patient's health status, even though he/she has found no specific indications yet; it is a sense of 'there's something wrong here'.
- A 'sense of alarm' activates the diagnostic process by stimulating a GP to formulate and weigh up working hypotheses that might involve a serious outcome.
- A 'sense of alarm' means that, if possible, the GP needs to initiate specific management to prevent serious health problems
- A 'sense of alarm' will decrease as the diagnosis and the right management become clearer.
- A 'sense of reassurance' means that a GP feels secure about the further management and course of a patient's problem, even though he/she may not be certain about the diagnosis: everything fits in.
- The 'sense of reassurance' and the 'sense of alarm' constitute a dynamic element in a GP's diagnostic process.

Following consensus conclusions on gut feelings in GPs, the Dutch research team constructed and validated a questionnaire about gut feelings in order to 44 objectify their presence during a clinical encounter (Stolper et al., 2013). A linguistic validation procedure was carried out to obtain an English version of this Gut Feelings Questionnaire (GFQ) (Stolper et al., 2013). Researchers performed a Principal Component Analysis. It showed one factor with the sense of reassurance and the sense of alarm items as two opposites that explained 70.2% of total variance. The internal consistency was high (Cronbach's alpha = 0.91). Subsequently the GFQ was translated and validated in French, German and Polish(Barais et al., 2017). Afterwards, two studies were carried out using the questionnaire: a thinkaloud study with Dutch GPs diagnosing and using the questionnaire with six case vignettes, and a feasibility study with French, Dutch, and Flemish GPs using the GFQ in actual consultations (Barais et al., 2018). As a result of these studies some minor additions and changes were made in the GFQ. Finally, an eleven-item questionnaire aimed to determine the presence of gut feelings (either of alarm or reassurance) during the GPs diagnostic process is thus available. The GFQ is a feasible and practical tool to be used in future prospective studies about gut feelings in GPs daily practice. A research agenda on gut feelings in general practice was established using the nominal group technique (Stolper, Van Leeuwen, et al., 2010). Up to twenty research questions were produced during the groups' discussions. The highest priority was granted to research about the prevalence and diagnostic accuracy of gut feelings in general practice.

#### Gut feelings, cancer, and serious diseases

As said before, GPs consider gut feelings as a kind of compass that can help them to handle the many situations of uncertainty they face on a daily basis in their job. One of these uncertain situations, and probably one of the most fearsome, is when a GP has a doubt as to whether or not a patient has a serious disease and, more specifically, whether this disease is cancer. There are many difficulties diagnosing cancer in primary care. A primary care physician with 2000 patients typically sees 6–8 new cases per year (Rubin et al., 2015). Cancer is not a single disease but a heterogeneous entity which comprises many different types of disease. There are types of cancers with different histologic appearance from the same primary site of origin. The type and intensity of symptoms can vary greatly from patient to patient. Diagnosis of any single cancer type is a rare event. A GP will diagnose only one case of each of the most common cancers (colorectal, prostate, breast, and lung) by year. Less frequent cancers might be seen only once or twice during a GP's career (Rubin et al., 2015). Signs and symptoms of cancer, even the ones considered as red flags of alarm, have low PPVs for cancer diagnosis. It has been described that only eight signs and symptoms have PPVs above 5% (Shapley, Mansell, Jordan, & Jordan, 2010).

In the case that accurate tests were available to GPs, as well as infinite resources, one solution might be 'screen everyone for everything'. But, nowadays, we don't need to be epidemiologists or oncologists to guess that it is impossible, and even dangerous. False positives, overdiagnosis, overtreatment, serious side effects, who is eligible to screen and who is not... These are uncertainties that our newest algorithms still cannot solve. We are still unable of determine the right strategy for screening and early diagnosis of the most common cancers (Prasad, Lenzer, & Newman, 2016; Saquib, Saquib, & Pa Ioannidis, 2015). Siddhartha Mukherjee, an oncologist, used to work in the dispassionate world of laboratory, stem cells, proteasome inhibitors, and genetic mutations, had a strong opinion that agreed with that of GPs and their trust in their gut feelings. In his book *The laws of medicine. Field notes from an uncertain science* he stated the law one: 'A strong intuition is much more powerful than a weak test' (Mukherjee, 2015).

The role of gut feelings in serious diseases and cancer diagnosis has been rarely assessed so far. Regarding serious diseases there are few studies evaluating the clinicians' predictions about the expected outcome of their patients. One study tried to validate a prognostic model that estimates survival over a 180-day period for seriously ill hospitalized adults. The best survival estimates were achieved by combining the model under study with the physicians' clinical estimates (Knaus et al., 1995). On the other hand, another study found that statistical models developed from carefully collected data can provide prognostic predictions in coronary artery disease patients that are more accurate than predictions of experienced clinicians made from detailed case summaries (Lee et al., 1986).

There is a recent systematic review and meta-analysis on the role of GPs' gut feelings in the diagnosis of cancer in primary care (Smith, Drew, Ziebland, & Nicholson, 2020). Some qualitative studies explored GPs action during cancer diagnosis. In these studies, gut feelings emerge as an important element in this process. Green et al.(Green, Atkin, & Macleod, 2015), interviewed 55 English GPs about GP's role in the early detection of cancer, cancer awareness, and cancer screening. GPs made reference to gut feelings as a tool developed through experience that has a role in GPs' ability, in the absence of red flag symptoms, to identify patients in need of further investigation (to either rule in or rule out cancer). One of the interviewed GPs said:

In general practice, there's always room for that kind of, well gut feeling as well and that you just develop through experience... I think, you know, you can only take those things [guidelines; risk scores] to a certain level, but you've kind of got to use your common sense and experience and your kind of, I'm just worried about this patient, you know, I need to do something here.

In another study 14 Norwegian GPs were interviewed about their care of people with cancer, and how they come to think of cancer when interviewing a patient (Johansen et al., 2012). They referred to intuitive knowing and gut feelings as one of the four main ways in which awareness of cancer may arise. They defined gut feelings as the sum of medical knowledge, experience and contextual (about the community) and personal (about the patient) knowledge. A GP, talking about gut feelings, introduced allusions to one of the essences of primary health care, knowledge of the community:

it is the sum of all your knowledge, the sum of all your experience ... all your knowing from reading updates, attending courses, all the patients you have had whom you ... have investigated, referred, and received feedback about. And then there is your knowledge of humankind and of the context, namely the person and patient and the community you work in.

There are other studies that, in a similar way, have assessed the presence of gut feelings in the diagnostic process of cancer. GPs recognized that these gut feelings arise in relation with the aspect and behaviour of the patient (Bankhead & Austoker, 2005; Clarke, Jones, Mitchell, & Thompson, 2014; Holtedahl et al., 2017). GPs think that GFs are related with their previous experience (Clarke et al., 2014; Holtedahl et al., 2017) and with the quality of the patient-physician relationship (Pedersen, Andersen, Ingeman, & Vedsted, 2019).

Some studies have approach GFs in the diagnosis of cancer and serious diseases using a quantitative focusing. Barais et al. (Barais et al., 2020) recently studied the diagnostic accuracy of GP's sense of alarm when confronted with dyspnoea and/or chest pain. GPs completed the GFQ right after the consultations with patients with these symptoms. The final diagnosis (life-threatening or non-lifethreatening) 4 weeks after the consultation was used as reference. The researchers found that if the physician experiences a sense of alarm when a patient visits him/her for dyspnoea and/or chest pain, the post-test odds that this patient has a life-threatening disease are about twice as high as the pre-test odds (Positive likelihood ratio of 2.12). There is a study of 4518 consultations of 404 Danish GPs (Hjertholm et al., 2014) in which, after every consultation, the GP had to answer the question: 'Are you left with the slightest suspicion of cancer or another serious disease (new)?'. GPs answered affirmatively 5.7% of the times. The GP's suspicion of cancer had a PPV of 3.1%. The NPV was 99,5% six months after the consultation. Although the PPV may seem low, it has been proved that only nine signs and symptoms of possible cancer have positive PPV values above 5% (Shapley et al., 2010). Additionally, Ingeman et al (Ingeman et al., 2015) asked GPs for the reasons for referring 1,278 patients to a Danish pathway implemented for patients with nonspecific symptoms and signs of cancer. The second most common clinical finding was a GP's gut feeling (22,5% of the cases). These gut feelings achieved the third highest probability of cancer as 24% of the times the case ended with a cancer diagnosis. In Netherlands, Donker and Dorsman (Donker & Dorsman, 2013) found that Dutch GPs have gut feelings related with cancer in 20 cases per 10,000 registered patients/year. After three months, gut feelings about a possible diagnosis of cancer were confirmed in one third of the cases. In a bigger study, Donker et al.(Donker, Wiersma, van der Hoek, & Heins, 2016) asked 59 Dutch GPs to complete a questionnaire in the case they noticed a gut feeling concerning any kind of cancer.

Outcomes of 366 patients were assessed 3 months later. 95% of the GPs acted immediately following their gut feeling. This study introduces interesting findings about triggers of gut feelings. Weight loss, unusual visits to GP, and duration of complaints were the more frequently reported triggers of gut feelings. The PPV of gut feelings for the diagnosis of cancer was 35%, with a significant influence of how long the GP had known the patient, GP's years of experience, and patient and GP's age. The PPV increased 2% for every year a patient became older, and 3% for every year a GP became older. Scheel et al. (Scheel, Ingebrigtsen, Thorsen, & Holtedahl, 2013) investigated GPs' suspicion of cancer among 396 GPs and 51,073 patients. Outcomes were assessed 6 months later. Regarding GP suspicion, 3.8% of the positive were correct, while only 0.6% of patients recorded as not likely to have cancer were finally diagnosed of cancer.

There are studies showing the presence and accuracy of intuition in the prognosis of cancer. Moroni et al. (Moroni et al., 2014) and Moss et al. (Moss et al., 2010) studied, in GPs and oncologists respectively, the prognostic value of what they called the 'surprise question'. This question ('would you be surprised if this patient dies in the next year?') has been used in several palliative care protocols to decide whether the patient is in need of entering these protocols or not. This question can be interpreted as a 'proxy' of intuition about the expected prognosis. Regarding GPs answers, patients in the 'No' group had an odds ratio of 11.55 and a hazard ratio of 6.99 of being dead in the next year compared to patients in the 'Yes' group.

There is little research based on patient's intuition and some experiences considering gut feelings in the pathways for diagnosing cancer. Regarding patient's gut feelings about cancer, we find a review of the current research on the subject. This reveals that emotion, or affect, influences people's cancer-related decisions (Zikmund-Fisher, Fagerlin, & Ubel, 2010). They noticed that even well-informed patients sometimes 'go with their gut, instead of their head', and choose options that appear to increase their risks or conflict with their own stated values. So, we need to be aware that emotions are often more influential in decision making about cancer treatments and prevention behaviours than factual knowledge is. Unaffected women from high-risk breast cancer families were asked about how they

understand and manage their cancer risk (Heiniger, Butow, Charles, Price, & kConFab Psychosocial Group, 2015). Almost all of the 36 interviewed drew on their intuition, describing risk as linked with experiences, emotions, and personally derived theories and assumptions. We can find quotes like:

I don't understand anything, but going with gut feeling, I do have a feeling that I do have a high chance of getting (breast cancer)

I tend to just go on my own instincts about things... I guess I have some intuitive feeling that maybe it would be positive

Data suggest that while women may cognitively understand their risk, many intuitively feel that their risk is higher or lower than their objectively defined level of risk. In some cases, this can have a detrimental effect on risk management, more usually causing over- rather than under-screening.

In another study, 905 patients newly diagnosed of cancer answered a questionnaire. 530 added free-text comments. These comments were analysed with a thematic framework. The authors found that some patients experienced a 'gut feeling' that further influenced their diagnosis pathway, acting either as a barrier or a facilitator of the diagnosis (Parsonage, Hiscock, Law, & Neal, 2017).

Awareness of GP's gut feelings about cancer and their possible accuracy have led some health institutions to take them into account in their strategies to decrease delay in cancer diagnosis. In Denmark they have a three legged strategy for early cancer diagnosis (Vedsted & Olesen, 2015). It consists in, from more urgent and fast to less:

- urgent referral pathways for symptoms suspicious of a specific cancer
- urgent referral to diagnostic centres when a quick and profound evaluation of patients with serious nonspecific symptoms is needed.

 easy access to 'No-Yes-Clinics' for cancer investigations for those patients with common symptoms in whom the diagnosis of cancer should not be missed.

A study analysed the characteristics and cancer probability of patients referred to the serious non-specific symptoms and signs of cancer pathway (Ingeman et al., 2015) GP's gut feelings are among the most likely clinical signs for referral for quick evaluation of patients with nonspecific but serious symptoms, accounting for 22.5% of the patients. 24% of the patients referred to this specific path because of their GP's gut feeling had cancer. In Oxfordshire (UK) the Suspected CANcer (SCAN) pathway for the investigation of 'low-risk but not no-risk' cancer symptoms has been implemented in order to improve early diagnosis (Nicholson et al., 2018). 'GP clinical suspicion of cancer or serious disease/GP gut feeling' is one of the referral criteria considered.

Some ideas summarizing research on GFs and severe diseases and cancer diagnosis are:

- GPs use their gut feelings to identify patients in need of further investigation and they refer to their gut feelings as one of the ways awareness of cancer may arise.
- GPs act immediately after having a gut feeling suspecting cancer.
- Positive predictive value of gut feelings suspecting cancer could range between 3.1 and 35%. These data are comparable with recognized cancer red flag symptoms.
- Negative predictive value of gut feelings for the diagnosis of cancer could be high, up to 99.5%.
- How long a GP and a patient know each other, GP's age, patient's age, and an increase in the frequency of visits to the doctor in recent months, are factors related with the accuracy of cancer gut feelings.

- Patients strongly rely on their gut feelings when taking cancer-related decisions.
- Studies are hardly comparable, lacking an unambiguous and objective definition of when a doctor has a gut feeling or not.
- Studies about gut feelings and the diagnostic of severe diseases are scarce and with conflicting results.

# **Research questions**

The COGITA network group (http://www.gutfeelings.eu/) is a European initiative dedicated to the investigation of the presence, relevance, meaning and validity of GFs in the diagnostic process in primary care. It is a novel line of research with a future development agenda already proposed (E. Stolper, Van Leeuwen, et al., 2010). With this agenda in mind, anecdotes like the ones related at the beginning of this text and the many others heard over the last 30 years from my fellow colleagues, those that I have experienced in the first person, and the conclusions of the research carried out so far, the original idea of this research arose.

The main research questions are:

- Do Spanish GPs recognize the presence of gut feelings in their diagnostic process?
- Do Spanish GPs give the same meaning to gut feelings as GPs from other European countries?
- What is the prevalence of the 'sense of alarm' and the 'sense of reassurance' among Spanish GPs?
- Are there differences in the prevalence of gut feelings between normal surgery hour services and services during out-of-office hours? Are there differences in the prevalence of gut feelings depending on the previous

experience, contextual knowledge, or patient characteristics? Are there other determinants influencing the prevalence of gut feelings?

- Do Spanish GPs act differently with their patients depending on the type of gut feeling they experience?
- What is the diagnostic relevance of gut feelings for the diagnosis of cancer and other serious diseases in primary care? Is it possible to calculate their test properties?
- Are there differences in the diagnostic performance of gut feelings for the diagnosis of cancer and other severe diseases in primary care? What are these differences due to?

# HYPOTHESIS AND OBJECTIVES

'I have often wished for the sense that humans call intuition, or instinct. Since Vulcans are incapable of lying, I must accept the Ambassador's explanation as the truth. But I would still prefer a... 'gut feeling' to back up this conclusion'.

Lt. Commander Data

Star Trek: The Next Generation (1987)

# Hypothesis

Based on previous research (Le Reste et al., 2013; Stolper, van Bokhoven, et al., 2009; Stolper, Van Royen, et al., 2009), we present some hypotheses that we intend to address.

1. Spanish GPs experience GF of two types:

- A sense of reassurance when a family doctor feels safe about the further treatment and evolution of a patient's problem, even though he/she cannot be sure about the diagnosis: everything fits.

- A sense of alarm when a family doctor worries about the health status of a patient, even though he/she has not found specific clues yet; 'there is something wrong here'.

#### 2. A sense of alarm:

- Activates the diagnostic process by stimulating the GP to formulate and weigh work hypotheses that may imply a serious outcome.

- It means that a GP perceives an uncomfortable sensation and worries about a possible adverse outcome.

- It means that, if possible, the GP needs to start a specific case management to prevent serious problems.

3. The experience, knowledge of the context, the personality of the GP, their medical knowledge can justify differences in the appreciation and reliability granted to the GF by Spanish doctors. We do not expect important differences in terms of sex, rural / rural environment or teaching/non-teaching GP trainees.

If our hypotheses are confirmed, we will be able to proceed to the Spanish and Catalan linguistic validation of the Gut Feelings Questionnaire. With this tool we will proceed to address questions related to the prevalence and diagnostic value of gut feelings. 1. Having or not having a GF will be associated with certain symptoms, with the personality of the professional (as it is more oriented towards intuition or rationality), his/her experience, and his/her previous knowledge of the patient.

2. A PPV of 9.8% for cancer and serious diseases is expected, similar to that of the study by Hjertholm et al.(Hjertholm et al., 2014). The sensitivity of the sense of alarm will be low and the specificity high, and vice versa for the sense of reassurance.

3. Adjusted by the rest of the factors, the sensation of alarm will be positively related to requesting tests or referrals to specialists, while that of security with requesting less. We do not expect important differences in terms of sex, rural/rural environment, or teaching/non-teaching GP trainees.

#### Objectives

The objectives of the thesis are:

- To investigate the existence, meaning, determinants, and triggers of GF among Spanish doctors. We will follow the method of Stolper et al.research among Dutch doctors (Stolper, van Bokhoven, et al., 2009). We will use a qualitative methodology to know the opinion of Spanish GPs on the existence, importance and value granted to GFs.
- To perform an English-Spanish and an English-Catalan translations and linguistic validations of the gut feelings questionnaire (GFQ) developed by Stolper et al.(Stolper et al., 2013).
- To study the prevalence of GFs among Spanish GPs using the Spanish and Catalan versions of the GFQ. We also plan to study the influence of some factors in the prevalence of GFs. These factors can be related to the patient (e.g., present symptomatology, previous doctor-patient relationship), the professional (e.g., previous experience, gender, dedication to teaching,

personality), and the context in which the consultation takes place (e.g., appointment on demand or urgency, time of day, urban or rural environment).

- To study the diagnostic value (sensitivity, specificity, predictive values and likelihood ratios) of GFs for the diagnosis of cancer and serious diseases. We plan to study the factors that may influence the diagnostic value of GFs in a similar way to that explained for prevalence.

# RESULTS

'Captain Hastings: I've never known you place much faith in intuition.

Hercule Poirot: Intuition, Hastings, often describes some fact that is so deeply buried in the subconscious that the subject is not aware of its existence'.

Agatha Christie's Poirot [1989]

# **MANUSCRIPT I**

'My father says a hunch is your brain's way of taking a short cut to the truth,' replied Max.

'He's a wise man, your father. What else does he say?'

'That the more you try to hide from the truth, the quicker it finds you.'

Carlos Ruiz Zafón,

The Prince of Mist (1993)

# Manuscript I

Oliva, B., March, S., Gadea, C., Stolper, E., & Esteva, M. (2016). Gut feelings in the diagnostic process of Spanish GPs: a focus group study. *BMJ Open*, 6(12). https://doi.org/10.1136/bmjopen-2016-012847

# **MANUSCRIPT II**

Diane Chambers: Do you believe in intuition?

Woody Boyd: No, but I have the strange feeling that someday I will.

Cheers [1982]

1

# Manuscript II

Oliva-Fanlo, B., March, S., Stolper, E., & Esteva, M. (2018). Cross-cultural translation and validation of the 'gut feelings' questionnaire into Spanish and Catalan.
 *European Journal of General Practice*, *25*(1), 39-43.
 https://doi.org/10.1080/13814788.2018.1514385

The journal had a Journal Impact Factor of 1.617 in 2018, standing in the Q2 of the category 'Medicine, General and Internal' of the Journal Citations Report.

#### **MANUSCRIPT III**

'Do you believe in premonitions? When a black wave breaks over you and you suddenly know something terrible is going to happen?'

Georges Iscovescu

Hold back the dawn (1941)

#### Manuscript III

 Oliva-Fanlo, B., March, S., Medina, D., Martín-Rabadán, M., Tamborero, G., Stolper, E., & Esteva, M. (2019). Prevalence and diagnostic value of GPs' gut feelings for cancer and serious diseases : protocol for a prospective observational study of diagnostic validity. *BMJ Open, 9,* 1–5. https://doi.org/10.1136/bmjopen-2019-032404

The journal had a Journal Impact Factor of 2.496 in 2019, standing in the Q2 of the category 'Medicine, General and Internal' of the Journal Citations Report.

# **MANUSCRIPT IV**

'Understanding was coming so fast, it seemed to bypass thought.'

J.K. Rowling

Harry Potter and the Deathly Hallows (2007)

# PROSPECTIVE OBSERVATIONAL STUDY ON THE PREVALENCE AND DIAGNOSTIC VALUE OF GENERAL PRACTITIONERS' GUT FEELINGS FOR CANCER AND SERIOUS DISEASES

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# Short title: Gut Feelings in Spanish General Practitioners

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## ABSTRACT

#### Background

General practitioners (GPs) have recognized the presence of gut feelings in their diagnostic process. However, little is known about the frequency or determinants of gut feelings or the diagnostic value of gut feelings for cancer and other serious diseases.

#### Objective

To assess the prevalence of gut feelings in general practice, examine their determinants and impact on patient management, and measure their diagnostic value for cancer and other serious diseases.

#### Design

This prospective observational study was performed using the Gut Feelings Questionnaire (GFQ).

#### Participants

Participants included 155 GPs and 1487 of their patients, from four Spanish provinces.

#### Main Measures

Sociodemographic data from patients and GPs; the reasoning style of GPs; the characteristics of the consultation; the presence and kind of gut feeling; the patient's subsequent contacts with the health system; and new cancer and serious disease diagnoses reported at 2- and 6-months post-consultation.

#### Key Results

GPs experienced a gut feeling during 97% of the consultations: a sense of reassurance in 75% of consultations and a sense of alarm in 22% of consultations. A sense of alarm was felt at higher frequency given an older patient, the presence of at least one cancer-associated symptom, or a non-urban setting. GPs took diagnostic action more frequently after a sense of alarm. After 2 months, the sense of alarm had

a sensitivity of 59% for cancer and other serious diseases (95%CI 47-71), a specificity of 79% (95%CI 77-82), a positive predictive value of 12% (95%CI 9-16), and a negative predictive value of 98% (95%CI 86-98).

#### Conclusions

Gut feelings are consistently present in primary care medicine, and they play a substantial role in a GP's clinical reasoning and timely diagnosis of serious disease. The sense of alarm must be taken seriously and used to support diagnostic evaluation in patients with a new reason for encounter.

#### BACKGROUND

Uncertainty around diagnosis is one of the biggest challenges that a clinician faces when caring for a patient. This is particularly relevant for general practitioners (GPs)<sup>1</sup>, whose work is associated with one of the highest perceptions of uncertainty<sup>2</sup>. GPs are confronted with an immense range of symptoms, and in some cases a seemingly minor symptom can indicate a serious diagnosis<sup>3</sup>. For example, most lower-back pain disappears within a year; however, in 1 of 350 patients with backache, the pain will be the guiding sign for a serious diagnosis<sup>4</sup>. This uncertainty forces GPs to optimize the use of their analytical and non-analytical reasoning tools. In this sense, the use of intuition in medicine has long been recognized as part of the *art of medicine* and even as representing *tacit knowledge* essential to good practice<sup>5,6</sup>. Intuitive sensations, called "gut feelings", have been described as a "useful light that goes on suddenly to announce that there is something unusual"7. GPs have been reported to recognize the existence of gut feelings and consider them a useful tool for decision-making<sup>8,9</sup>, and even a separate track in their clinical reasoning<sup>10</sup>. There are two kinds of gut feelings: a *sense of alarm* that leads a GP to worry about a patient's health status even if they have not yet found any specific indication; and a sense of reassurance that leads a GP to feel confident about the patient's management and outcome even though they may not be certain about the diagnosis, a sense that everything fits in<sup>8</sup>.

There are many studies regarding the use of gut feelings by GPs, hospital specialists, and nurses<sup>9,11–17</sup>.GPs reported using their gut feelings in suspecting cancer<sup>9,17–20</sup> and other serious diseases<sup>21,22</sup>.In Denmark and the United Kingdom, the GPs' sense of alarm has been accepted as a valid reason for referring a patient to specific pathways of cancer diagnosis<sup>23,24</sup>. It has been suggested that gut feelings' diagnostic value are routine GP's consultations, where serious diseases and cancer have a low prevalence<sup>25</sup>. However, few studies have evaluated the frequency and diagnostic value of gut feelings in primary care consultations<sup>20</sup>. Hjertholm et al. found that the suspicion of cancer and serious disease in primary care consultations had a prevalence of 5.7% and a positive predictive value (PPV) of 9.8%<sup>26</sup>. Donker et al. observed a PPV of 35% for cancer-related gut feelings, and reported that this value increased according to the ages of the patient and the doctor<sup>12</sup>. In order to objectively measure gut feelings, a Gut Feeling Questionnaire (GFQ) was created and validated in a Dutch context<sup>22</sup>; since then, it has been made available in seven languages<sup>27,28</sup>. The GFQ determines whether a gut feeling has arisen during a consultation. In a study using the GFQ, Barais et al. found that GPs had a gut feeling in 99.16% of consultations concerning patients with dyspnea or chest pain, corresponding to a sense of alarm in 35% of these cases and a sense of reassurance in 65% of the cases. Among patients with dyspnea or chest pain, the presence of a sense of alarm increased the probability of a life-threatening disease from 20% to 35%, while the presence of a sense of reassurance decreased the probability to 12%13.

Non-analytical, intuitive reasoning is a substantial part of the diagnostic process; it induces and guides analytical reasoning and deliberate action. However, the prevalence, diagnostic value, and determinants of gut feelings are not yet fully known. More knowledge of these aspects might lead to a better understanding of the consultation process and help practitioners undertake timely diagnostic evaluation and avoid errors.

This study aimed to assess the prevalence and determinants of gut feelings in general practice, the subsequent management of patients in light of the kind of gut feeling experienced by the GP, and the diagnostic value of gut feelings for cancer and other serious diseases.

#### **METHODS**

In this prospective observational study, we used the Spanish and Catalan versions of the GFQ. The work was carried out in primary care centers of four Spanish provinces (Balearic Islands, Madrid, Barcelona, and Lugo) during 2019-2020. Participants were GPs and their patients. The protocol of the study has already been published<sup>29</sup>.

#### Participants

GPs were invited to participate during workshops held in the health centers. Those who accepted the invitation were instructed on data gathering. During at least one working day, GPs included consecutive patients with at least one new reason for consultation. Exclusion criteria were consultations with non-residents, terminally ill patients, or patients younger than 18 years old, and consultations for bureaucratic reasons. At the end of each consultation (index consultation), patients were given oral and written information about the study and signed an informed consent document.

#### Measurements

We collected sociodemographic and practice data on the participating GPs (age, sex, training tasks, rural/non-rural health center, and years with the same list of patients). We used a 4-item Likert-scale validated by Martínez-Cañabate et al.<sup>30</sup> in her PhD thesis. Each item has 4 possible answers, from completely disagree to completely agree. The scale assesses whether the professional carries out a practice more oriented to the biological (lower scores) or psychosocial (higher scores) sphere<sup>31,32</sup>. GPs completed the Rational-Experiential Inventory (REI)<sup>33</sup>. This Likert-scale has 40 items and has been validated in Spanish population. Each item has 5 possible answers, from completely disagree to completely agree. The REI measures rational and experiential thinking styles and includes subscales of self-reported ability and engagement with each thinking style<sup>34</sup>.

After each index consultation, GPs recorded sociodemographic data obtained from the patient and how long they had been on the doctor's list. Data about the visit were recorded, such as the type and consultation duration (longer or shorter than 6 minutes), the language used, and the presence of cancer-associated symptom(s)<sup>35-38</sup>(Table 1). Finally, the GP completed a printed Spanish or Catalan version of the 11item GFQ<sup>9,28,39</sup>. Item 1 (repeated at the end as item 11) assesses whether the patient's case elicited a gut feeling in the consultation. Items 2-6 are rated using a 5point Likert scale that ranges from completely disagree to completely agree. Item 2 concerns the sense of reassurance and items 3-6 relate to the sense of alarm. A sense of alarm is considered present when the answer to item 1 or 11 indicates a sense of alarm, or when the answer to item 1 or 11 is "not applicable" and at least one of the scores of items 3-6 is higher than 3. A sense of reassurance is considered present when the answer to item 1 or 11 indicates a sense of reassurance or when the answer for item 1 or 11 is "not applicable" and the score for item 2 is higher than 3. A gut feeling is considered to be absent when the answers for items 1 and 11 are both "not applicable", none of the scores for items 3-6 is higher than 3/4, and the score for item 2 is lower than 4/5.

Two months and 6 months after the index consultation, we reviewed primary care and hospital clinical records to collect new diagnoses of cancer (except nonmelanoma skin cancer) and other serious diseases among the participating patients. Recurrence of cancer in patients considered disease-free at the time of the index consultation was regarded as a new diagnosis. Beginning with the list of serious diseases published by Hjertholm et al.<sup>26</sup>, two researchers independently judged whether a newly diagnosed disease was "serious" or not. When there was disagreement, a third researcher made the final decision. Six months after the index consultation, we also recorded patient contacts with health care services.

#### Statistical analysis

We performed a descriptive analysis of all selected variables to describe sample characteristics and the prevalence of gut feelings. A bivariate analysis was carried out, in which the presence of a sense of reassurance or alarm was compared with the characteristics of the GP, patient, and consultation. We used the chi-square test for categorical variables, and the Student's T-test for continuous variables. OR and 95% CI were calculated. A multivariate logistic regression analysis was done to assess the independent relationships between the variables and the kind of gut 76 feeling. Variables with  $p \le 0.20$  were introduced in the model<sup>40</sup>. We assessed changes in the coefficients at each step to detect confusion, and tested interactions. Sensitivity, specificity, positive and negative predictive values (PPVs, NPVs), and positive and negative likelihood ratios (LR+, LR-) were calculated for the sense of alarm and the sense of reassurance. We assumed that the sense of alarm aims to identify patients with high probability for a serious outcome, while the sense of reassurance aims to identify patients with low probability for a serious outcome. Logistic multivariate analysis was also used to calculate the risk of serious disease depending on the type of gut feeling, adjusted for patient age, sex, visit type, visit duration, and cancer-related symptom(s). We assessed goodness of fit for every model with the Hosmer-Lemeshow test. Analysis was done with SPSS.v.25.

#### RESULTS

We invited 272 GPs; of them, 155 participated. The GPs reported on 1487 patients (63.2% female) over 328 working days (see flowchart in Figure 1). Most of the patients were Spanish-born and lived in urban environments; their mean age was 51.9 years. Nearly six of 10 patients presented at least one cancer-associated symptom. The characteristics of the GPs, patients, and consultations are described in Table 2.

#### Prevalence of gut feelings

GPs experienced a gut feeling during 97.1% of the consultations: a sense of reassurance was recorded in 1120 consultations (75.3%) and a sense of alarm was recorded in 324 consultations (21.7%). In 43 consultations, the GFQ did not determine a gut feeling. These cases were excluded from the analysis. The GPs, patients, and consultations characteristics are categorized by the type of GF present in Table3.

We found no difference in the frequency of reassurance or alarm regarding most of the determinants studied. The sense of alarm was more prevalent, and the sense of reassurance was less prevalent under the following conditions: when GPs' NFC engagement scores (rational reasoning) were higher; in consultations with older patients; when a patient presented at least one cancer-associated symptom; in non-urban areas; or when the language used during the consultation was not the GP's native language. Regarding the features of the consultations, the prevalence for a sense of alarm was higher in consultations that lasted longer than 6 minutes or with fewer patients seen that day. Our multivariate analysis (see Table 3) confirmed the above-described results found in the bivariate analysis, except for the number of patients visited in the same day.

#### Actions during follow-up

Table 4 shows the actions taken by GPs during the 6 months after the index consultation, categorized by the kind of gut feeling. Patients visited their GP more frequently after GPs experienced a sense of alarm than a sense of reassurance. GPs more frequently ordered laboratory tests, radiological investigations, and primary care procedures after experiencing a sense of alarm and referred more frequently to both outpatient services and the emergency department. There was no difference in patients' sick leave based on the type of feeling experienced by the GP.

#### Diagnostic value

The presence of a diagnosis of cancer or serious disease could be evaluated in 1385 patients (see Figure 1). At 2 months after the index consultation,64 patients (4.6%) had been newly diagnosed with cancer or another serious disease. At 6 months, a total of 116 patients had been newly diagnosed with a serious disease (8.3%; nine with cancer).

Diagnostic values are shown in Table 5. After 2 months, the sense of alarm for cancer or a serious disease had a sensitivity of 59.3%, specificity of 79.4%, a PPV of 12.2%, an NPV of 97.5%; an LR+ of 2.8, and an LR- of 0.5. After 6 months, most of these figures were similar for the sense of alarm, except that the PPV was 18.3% and the NPV was 94.5%.

The adjusted OR for a serious diagnosis after 2 months was 5.3 after a sense of alarm and 0.19 after a sense of reassurance. Six months after the index consultation, the adjusted OR was 3.6 after a sense of alarm and 0.2 after a sense of reassurance.

#### DISCUSSION

#### Summary of findings

This is the first study seeking to estimate the prevalence and diagnostic value of gut feelings in the consultations of GPs. Our study showed that GPs had a gut feeling almost every time they consulted with a patient for a new reason; these feelings were a sense of reassurance approximately 75% of the time. A more frequent sense of alarm was associated with various determinants, such as the GP being more engaged with analytical reasoning, the patient's age, the practice being located in a non-urban area, the presence of at least one cancer-associated symptom, and incongruence in the native languages of the patient and GP. We also observed that the presence of a sense of alarm increased the number of tests performed and the referrals to secondary care for further investigation. The sense of alarm experienced by the GP increased the possibility that the patient would receive a new diagnosis of cancer or another serious disease by 2 months (adjusted OR 5.3) and 6 months (adjusted OR 3.6) after the initial consultation. This possibility decreased after the GP's perception of a sense of reassurance, with an adjusted OR of 0.19 at 2 months and 0.27 at 6 months. The presence of a sense of alarm increased the likelihood of the diagnosis of a cancer or a serious disease at 2 months from the consultation from 4.6% to 12.3% and from 8.4% to 18.4% at 6 months, while the presence of a sense of reassurance decreased these likelihoods to 2.4% and 5.9%, respectively.

#### Strengths and Limitations

The GFQ is a validated measure for determining gut feelings. Our prospective design enabled us to obtain accurate and reliable results. The use of primary care and hospital electronic clinical records prevented loss of information, such as unrecorded diagnoses.

We did not reach the estimated sample size of consultations<sup>29</sup>, as 43% of the GPs decided not to participate. Therefore, our data lacked the power needed for us to draw conclusions about the diagnostic value of GFs related exclusively to cancer. The distributions of participant GPs by age, sex, and non-urban vs. urban

environment were essentially the same as those previously observed among Spanish GPs<sup>41,42</sup>.

The outbreak of the COVID-19 pandemic during the last months of data collection might have influenced our results. All the index consultations occurred prior to the pandemic, but the follow-up periods for 1/3 of the cases ended after the pandemic started. Thus, although COVID-19 was not a diagnostic possibility during the index consultation, patients were exposed to the new disease during the follow-up period. Moreover, the Spanish National Health System stopped all non-urgent activity during the first months of the pandemic, probably delaying some cancer diagnoses<sup>43,44</sup>. We considered COVID-19 to be a serious disease when patients suffered complications, needed hospitalization, or died. We found 36 confirmed COVID-19 cases among participants, including 35 mild cases and 1 with pneumonia. Otherwise, the prevalence of cancer and the other serious diseases was comparable between the present study and previous relevant reports<sup>26</sup>.

#### Comparison with existing literature

The consistent appearance of gut feelings during the consultations indicates that GPs habitually use intuitive reasoning. The intuitive decision-making system is fast, automatic, effortless, and difficult to control<sup>45,46</sup>. In primary care health centers, which are characterized by massive numbers of consultations and strict time constraints, the contribution of 'intuition' to the decision-making process is obvious. The high prevalence of gut feelings involving a sense of reassurance is in line with the low probability of serious disease in primary care, as many complaints are innocent and temporary indispositions<sup>47</sup>.

Studies measuring gut feelings with non-validated tools found a much lower prevalence of the sense of alarm<sup>26,37,48</sup>. The Hawthorne effect<sup>49</sup>, which is how the awareness of being studied may impact the behavior of the study subjects<sup>50</sup>, should be considered as a possible source of bias. Although the GPs did not know if their answers to the GFQ would reflect a sense of alarm or a sense of reassurance, they might have changed their behavior and been more suspicious when interpreting the patient's symptoms during their participation in the study, potentially leading to an overestimation of the sense of alarm. If the high prevalence of the sense of alarm found in our study using the GFQ was an overestimation, then it had inevitably influenced the predictive value. Barais et al.<sup>13</sup> used the GFQ among French GPs in patients consulting for dyspnea or chest pain; the authors observed that gut feelings were present in 99.15% of consultations, with 35% of them representing a sense of alarm and 65% representing a sense of reassurance. The higher prevalence of a sense of alarm, compared to that found our study, can be easily explained because these authors selected patients with dyspnea and chest pain, who have a much higher risk of serious outcome. We assume that the Hawthorne effect is at least partially responsible for our finding that a high proportion of the gut feelings experienced by GPs corresponded to a sense of alarm. To mitigate this effect, several strategies have been proposed that should be considered in future research on gut feelings, such as assuring the participants that the objective of the study is to identify gut feelings without judging the clinician's performance, triangulating the collection of information, and collecting information over long periods of time while discarding the first set of data collected<sup>51</sup>. Another less probable explanation could be that case vignettes from real practice were used to validate the GFQ and perhaps the cut-off values need to be refined in the context of real consultations<sup>39</sup>.

Our results showed that the kind of gut feelings was influenced by some characteristics of the GPs, patients, and/or of the consultations. The style of reasoning (rational or intuitive) did not appear to generally affect the occurrence of gut feelings. However, somewhat to our surprise, GPs prone to rational reasoning had more frequent experiences of a sense of alarm. The Spanish non-urban population is older than the urban population, which could explain the higher prevalence of GPs having a sense of alarm in non-urban areas<sup>42</sup>. The presence of at least one cancer-associated symptom increased the prevalence of a sense of alarm, which is consistent with previous published evidence<sup>36,37</sup>. The sense of alarm may activate the diagnostic process by stimulating a GP to formulate and weigh working hypotheses involving a serious outcome<sup>11</sup> that is, the sense of alarm was associated with a longer consultation.

Doctors of different specialties have acknowledged the presence of gut feelings in their diagnostic process<sup>14,15,21</sup>, although they considered that it is more

frequent and appropriate among GPs because of the greater number of diagnostic possibilities a GP faces after a patient. Intuition played a greater role and was more widely accepted in specialties like general internal medicine, pediatrics and psychiatry<sup>15</sup>. These specialties, along with family medicine, are the ones where physicians have a higher perception of uncertainty in their daily work<sup>2</sup>.

We found an increasing number of GP visits, tests, and referrals for patients with whom the GP experienced a sense of alarm. Our results are comparable with those observed by Hjertholm et al<sup>26</sup>, where the number of GP consultations, primary-care specialist, and diagnostic imaging increased in the 2-month period after a consultation when the GP had a suspicion of serious disease, while the use of hospital services (inpatient and outpatient increased both 2 and 6 months after. These findings could be expected, as this gut feeling induces the diagnostic process of gathering more data.

Regarding the diagnostic value of gut feelings, other authors also observed increased probabilities of serious disease after a sense of alarm. Hjertholm et al<sup>26</sup> found that the risk of a diagnosis of cancer or another serious disease was 2.98 higher 2 months after the index consultation in the case of an sense of alarm. Ingeman et al<sup>52</sup> found that 24% of patients with whom the GP felt a gut feeling of cancer were finally diagnosed with cancer. A meta-analysis on the diagnostic utility of gut feelings in diagnosing cancer in primary care showed that a gut feeling associated with cancer increased the odds of cancer four times<sup>20</sup>. These results justified the decision made in Denmark and the UK to accept the GPs' gut feeling as a valid reason for referring a patient to specific pathways of cancer diagnosis<sup>23,24</sup>.

The value of LR+ of a sense of reassurance (1.95) implies that the pretest probability of serious disease decreases from 8.4% to 5.5%, and thus did not contribute greatly to ruling out cancer or a serious disease, so still the GP has to consider several hypotheses before discarding a serious diagnosis. The LR+ of a sense of alarm (2.8) modified the pretest probability for cancer or serious disease from 8.4% to 18.4%. As proposed by Barais<sup>51</sup>, given the very low prevalence of serious diseases, LR+ values between 2 and 5 could be of interest since they increase the probability of serious disease by 15-30%. Therefore, a sense of alarm should be

taken seriously in general practice, and clinicians should follow up patients with an analytical reasoning track.

#### Conclusions

The results of our study showed that gut feelings have a sustained presence in primary care medicine. Gut feelings, especially a sense of alarm, must be taken seriously when patients have a new reason for encounter, and this should lead to diagnostic evaluation. A gut feeling is a substantial part of clinical reasoning and supports the ability of GPs to diagnose serious diseases in a timely manner. Rational reasoning-prone GPs did not differ from their intuitive reasoning-prone colleagues with respect to experiencing gut feelings. Medical students must be trained in recognizing their own gut feelings and how to deal with them. Further research should focus on the significance of gut feelings related to specific symptoms and signs, and on the factors that could increase the prognostic and diagnostic value of GPs' gut feelings.

#### Declarations

#### Ethic approval and consent

All GP participants and patients were informed about the study orally and with written information. They provided written consent prior to being enrolled in the study. The study was approved by the Majorcan Primary Care Research Committee and by the Balearic Islands Ethical Committee, with reference number IB 3210/16 PI.

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#### Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### **Competing interests**

The authors declare that they have no competing interests.

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#### Author contributions:

The study was conceived and designed by BO, SM and ME. ES critically reviewed the study protocol. SM elaborated the questionnaire and study procedures. BO, CG and ME coordinated data acquisition and the statistical analysis. ME, ES and BO

interpreted the results. BO wrote the manuscript and ME, SM, CG and ES critically reviewed the manuscript and made relevant contributions.

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#### List of abbreviations:

- GP: General Practitioner
- GF: Gut Feeling
- GFQ: Gut Feelings Questionnaire
- REI: Rational Emotional Inventory
- NFC: Need For Cognition
- FI: Faith in Intuition
- EKG: Electrocardiogram
- OR: Odds Ratio
- CI: Confidence Interval

- LR: Likelihood Ratio
- PPV: Positive Predictive Value
- NPV: Negative Predictive Value
- SD: Standard Deviation

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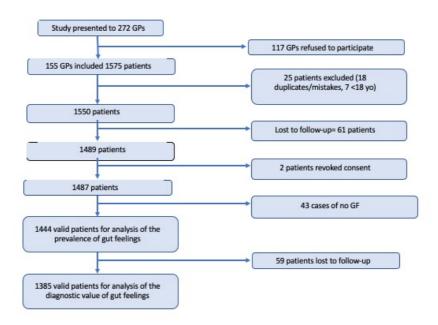
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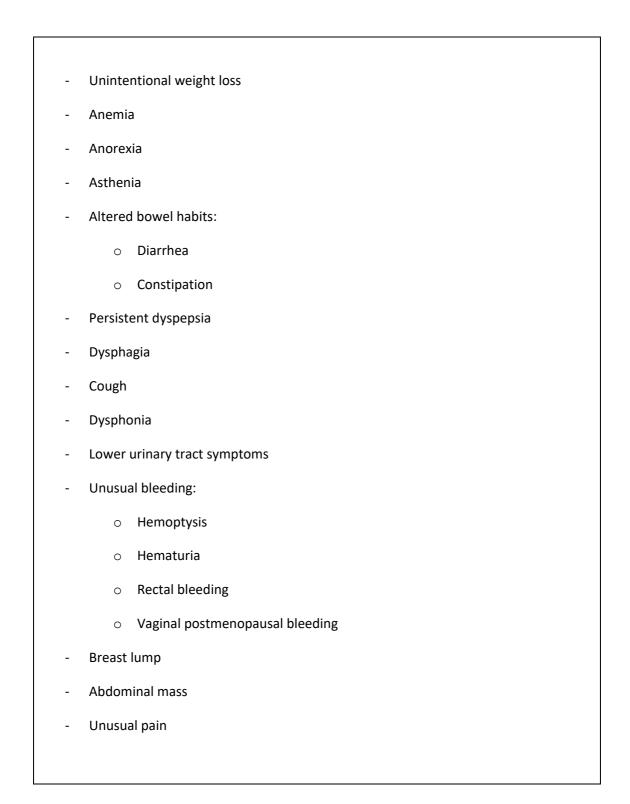
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#### Figure 1: Flowchart of General practitioners and patients included



# Table 1: Signs and symptoms associated with a higher predictive value for cancer<sup>19,20,28,29</sup>



Female	109 (70.3)
Male	46 (29.6)
Spanish	112 (72.2)
Catalan	42 (27.1%
Other	1 (0.6)
Urban	134 (86.4)
Extra-urban	21 (13.5)
Yes	63 (40.6)
No	92 (59.3)
	46.1 (9.67)
)	7.8 (7.28)
Aean (SD)	2.1 (1.25)
n GP, Mean (SD)	9.5 (5.37)
(SD)	3.6 (0.51)
	3.5 (0.4)
)	3.2 (0.4)
	3.3(0.5)
n (SD)	9.7 (2.4)
	Spanish Catalan Other Urban Extra-urban Extra-urban Yes No Yes No GR, <i>Mean (SD)</i>

## Table 2. Characteristics of general practitioners, patients, and index consultations

Patients		N (%)
Sex	Female	911 (61.2)
	Male	530 (35.6)
	Unknown	46 (3.0)

Age, Mean (SD)		51.9 (19.2)
Country of origin	Spain	1096 (75.1)
	Other	362 (24.8)
	Unknown	29
Patient language	Spanish	1118 (75.4)
	Catalan	237 (16.0)
	Other	126 (8.5)
	Unknown	6
Environment	Urban	1268 (85.2)
	Extra-Urban	219 (14.7)
Prior knowledge	Yes	1056 (74.4)
	No	363 (25.6)
Number years of GP-		
patient prior knowledge,		
Mean (SD)		
		4.78 (5.7)
Symptoms of possible cancer	No	595 (40.0)
	>=1	892 (59.9)

Index consultations		N%
Same language patient-GP during	Yes	1086 (74.2)
consultation	No	387 (25.7)
	Unknown	14
Same sex patient-GP	Yes	778 (55.8)
	No	611 (44.1)
	Unknown	98

Length of consultation >6 min	Yes	991 (70.1)
	No	421 (29.8)
	Unknown	75
Gut feeling	Sense of reassurance	1120 (75.3)
	Sense of alarm	324 (21.7)
	Inconclusive	43 (2.8)
Type of visit	Scheduled	1145 (77.0)
	Non-scheduled	342 (23.0)
Patients visited Mean (SD)		26.44 (8.04)

GP: General Practitioner, SD: Standard Deviation, NFC: Need for Cognition, FI: Faith in Intuition

# Table 3.-Relationship of General Practitioners, patients and consultation characteristics and type of gut feeling

Variables	Global	SA	SR	OR SA/SR (CI95%)	Р	OR SA/SR (C195%)	Ρ
	N (%)	N (%)	N (%)	(Non-Adjusted)		(Adjusted model)	
Total	1444	324 (22.4)	1120 (77.6)			-	
			GPs Cha	aracteristics			
Sex (GP)							
Female	1005 (69.6)	237 (23.6)	768 (76.4)	1			
Male	439 (30.4)	87 (19.8)	352 (80.2)	0.80 (0.6 - 1.06)	0.11	-	-
Environment							
Non-urban	216 (14.9)	68 (31.4)	148 (68.5)	1		1	
Urban	1228 (85.04)	256 (20.8)	972 (79.1)	0.50 (0.40 - 0.70)	0.001	1.57 (1.09-2.25)	0.015
GP trainer							
Yes	606 (41.9)	146 (24.0)	460 (75.9)	1			
No	838 (58.0)	178 (21.2)	660 (78.7)	0.85 (0.60 - 1.10)	0.20	-	-
Age (GP)							
Mean (SD)	46.0 (9.6)	46.43 (9.8)	46.03 (9.5)	1.04 (0.99-1.01)	0.51	-	-
Years same list							
Mean (SD)	7.95 (7.36)	7.74 (6.79)	8.09 (7.56)	0.99 (0.97-1.01)	0.45	-	-
GP's NFC engagement							
Mean (SD)	3.6 (0.48	3.7 (0.4)	3.6 (0.4)	1.58 (1.21-2.06)	0.001	1.68 (1.25-2.27)	0.001
GP's NFC ability							
Mean (SD)	3.5 (0.4)	3.5 (0.4)	3.5 (0.4)	1.18 (0.88-1.57)	0.25	-	-
GP's FI engagement							
Mean (SD)	3.2 (0.4)	3.3 (0.4)	3.2 (0.4)	1.13 (0.85-1.51)	0.37	-	-

GP's FI ability							
Mean (SD)	3.4 (0.7)	3.4 (0.6)	3.4 (0.8)	0.98 (0.83-1.16)	0.88	-	-
Martínez-Cañabate							
Scale	9.4 (2.4)	9.3 (2.4)	9.4 (2.4)	0.98 (0.93-1.03)	0.50	-	-
Mean (SD)							
			Patient c	haracteristics			
Sex (patient)							
Female	887 (63.4)	199 (22.4)	688 (77.6)	1			
Male	512 (36.6)	111 (21.7)	401 (78.3)	0.9 (0.7 - 1.2)	0.74	-	-
Age (patient)							
Mean (SD)	51.9 (19.2)	55.3 (19.6)	51.0 (19.0)	1.01 (1.005-1.018)	0.001	1.01 (1.03-1.02)	0.004
Country of origin							
Spain	1069 (75.5)	238 (22.3)	831 (77.7)	1			
Other	347 (24.5)	77 (22.2)	270 (77.8)	0.9 (0.7 - 1.3)	0.97	-	-
Prior knowledge							
Νο	363 (25.6)	81 (22.3)	282 (77.7)	1			
Yes	1056 (74.4)	235 (22.3)	821 (77.7)	1.003 (0.7 - 1.3)	0.98	-	-
Years of prior							
knowledge						-	-
Mean (SD)	4.7 (5.7)	4.5 (5.3)	4.9 (5.9)	0.99 (0.96-1.01)	0.38		
Cancer related							
symptoms							
No	582 (40.3)	94 (16.2)	488 (83.8)	1		1	
>=1	862 (59.7)	230 (26.7)	632 (73.3)	1.8 (1.4-2.4)	<0.001	1.83 (1.36-2.46)	<0.001

**Consultation characteristics** 

Language used							
(GPs)							
No	374 (26.2)	112 (29.9)	262 (70.1)	1		1	
Yes	1056 (73.8)	208 (19.7)	848 (80.3)	0.5 (0.4 - 0.7)	<0.001	1.62 (1.20-2.18)	<0.001
Same sex Patient- GP							
Νο	620 (44.3)	137 (22.1)	483 (77.9)	1			
Yes	778 (55.7)	173 (22.2)	605 (77.8)	1.01 (0.7 – 1.3)	0.95	-	-
Length of consultation >6'							
No							
Yes	410 (29.9) 959 (70.1)	42 (10.2) 260 (27.1)	368 (89.8) 699 (72.9)	1 3.2 (2.2-4.6)	<0.001	1 2.76 (1.92-3.97)	<0.001
Type of visit							
Type of visit							
Scheduled	1111 (76.9)	252 (22.7)	859 (77.3)	1			
Rest of visits	333 (23.1)	72 (21.6)	261 (78.4)	0.9 (0.6- 1.2)	0.68	-	-
Patients visited							
Mean (SD)	26.4 (8.05)	25.4 (8.2)	26.7 (7.8)	0.97 (0.96-0.99)	0.01	-	-

GPs= General practitioners. SA= Sense of Alarm; SR= Sense of reassurance; No GF= no gut feelings detected; CI= Confidence Interval; SD= Standard Deviation; R<sup>2</sup>Nagelkerke= 0.114 Hosmer and Lemeshow goodness of fit test = 0.114

## Table 4.-Actions taken during the subsequent 6 months.

	SA	SR	Р
	N=324	N=1120	
Patients visiting a GP (%)	310 (95.7)	960 (85.7)	<0.001
Mean (SD)	4.8 (4.1)	3.56 (3.6)	<0.001
Patients with Laboratory tests (%)	200 (61.7)	463 (41.3%)	<0.001
Mean (SD)	0.8 (0.9)	0.5 (0.7)	<0.001
Patients with Radiology tests (%)	99 (30.6)	226 (20.2)	<0.001
Mean (SD)	0.3 (0.6)	0.19 (0.4)	<0.001
Patients referred to Outpatients services (%)	169 (52.2)	361 (32.2)	<0.001
Mean (SD)	0.65 (0.7)	0.3 (0.6)	<0.001
Patients referred to ED (%)	82 (25.3)	115 (10.3)	<0.001
Mean (SD)	0.2 (0.4)	0.08 (0.3)	<0.001
Patients with Primary care procedures (%)	128 (39.5)	317 (28.3)	<0.001
Mean (SD)	0.6 (1.1)	0.4 (1.01)	0.002
Patients with Sick leaves (%)	148 (43.8)	452 (40.4)	0.26

Mean (SD)	0.2 (0.5)	0.2 (0.6)	0.44
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SA= Sense of Alarm; SR= Sense of reassurance; No GF= no gut feelings detected; CI= Confidence Interval; SD= Standard Deviation

Time after	Sensitivity	Specificity	PPV	NPV	LR+	LR-	Accuracy	Non-adjusted	Adjusted OR
consultation	%	%	%	%	(95% CI)	(95% CI)	(95% CI)	OR	(95% CI)
	(95% CI)	(95% CI)	(95% CI)	(95% CI)				(95% CI)	
	59.3	79.4	12.2	97.5	2.8	0.5	78.4	5.63	5.3*
	(47.1-70.5)	(77.1-81.5)	(9.06-16.3)	(86.4-98.3)	(2.7-3.0)	(0.4-0.5)	(76.2-80.5)	(3.36-9.44)	(3.09-9.08)
2 months									
after SA									
	49.14	80.1	18.3	94.5	2.4	0.6	77.4	3.88	3.67**
	(40.2-58.1)	(77.7-82.1)	(14.4-23.1)	(92.9-95.7)	(2.3-2.5)	(0.61-0.66)	(75.2-79.6)	(2.62-5.72)	(2.42-5.56)
6 months									
after SA									
2 months	79.4	59.3	97.5	12.2	1.9	0.3	78.4	0.17	0.19***
after SR	(77.1-81.5)	(47.1-70.5)	(6.4-98.3)	(9.06-16.3)	(1.8-2.1)	(0.33-0.36)	(76.2-80.5)	(0.1-0.29)	(0.1-0.33)
6 months	80.1	49.14	94.5	18.3	1.57	0.4	77.4	0.25	0.27****
after SR	(77.7-82.1)	(40.2-58.1)	(92.9-95.7)	(14.4-23.1)	(1.5-1.6)	(0.390.42)	(75.2-79.6)	(0.17-0.38)	(0.17-0.41)

Table 5. Diagnostic value parameters of gut feelings for cancer and serious disease and risk of cancer and serious disease depending on the type of gut feeling (N=1385)

PPV= Positive predictive value. NPV= Negative predictive value. LR+= Positive. Likelihood Ratio. LR-= Negative Likelihood Ratio.

\*Hosmer

#### DISCUSSION

'Yes, but use your feelings, Anakin. Something is out of place.' Obi-Wan Star Wars: Episode III – Revenge of the Sith (2005) This thesis is based on three studies carried out in primary care. The first study was performed with the objective of substantiating the existence and significance of gut feelings among Spanish GPs, identifying the determinants and triggers of these gut feelings, and comparing the results with those previously described for primary care doctors of other European countries. To determine whether Spanish GPs have the same concept of gut feelings as that previously described by Dutch researchers (Stolper, van Bokhoven, et al., 2009), we used the same qualitative design.

Once we ascertained the existence of gut feelings among Spanish GPs, our next study focused on translating and validating Spanish- and Catalan-language versions of the Gut Feelings Questionnaire (GFQ) created by Stolper et al. (Stolper et al., 2013). The GFQ enables researchers to objectively establish the presence of gut feelings in the consultations of GPs. With this validated instrument, we performed the third study, which focused on investigating the prevalence and determinants of gut feelings during GPs' consultations, and the diagnostic value of gut feelings for diagnosing cancer and serious diseases.

The results of each study are presented and discussed in separate papers that comprise the Results section of this thesis. The present section aims to recapitulate the main findings and contrast them with those in the literature.

#### Gut feelings in the diagnostic process of Spanish GPs: a focus group study

Our thematic analysis of the focus group transcripts showed that Spanish GPs recognized the presence of gut feelings in their diagnostic process. They described a gut feeling as something that makes them feel concerned about a patient, despite the absence of objective evidence. As in similar studies done in other European countries (Le Reste et al., 2013; Stolper, van Bokhoven, et al., 2009; Stolper, Van Royen, & Dinant, 2010; Stolper, Van Royen, et al., 2009), Spanish doctors distinguished two kinds of gut feelings: a sense of alarm that is felt when something does not fit in the patient presentation; and a sense of reassurance that indicates nothing serious will happen, even though a diagnosis is lacking. The GPs regarded gut feelings as being more related to the prognosis (the perceived potential severity

of a patient's condition) than to a precise diagnosis. GPs described numerous factors related to the onset of gut feelings in their consultations. Some of these determinants were related to the patients, including their physical appearance, non-verbal communication, and verbal and paralinguistic communication. A sudden increase in the frequency of a patient's visits or a visit involving a patient who rarely saw their GP was likely to elicit a sense of alarm in the GP. The symptoms that a patient presented were also reported to influence the presence and type of gut feeling: Illdefined complaints, symptoms mimicking anxiety or depression, and those suggesting a serious illness tended to raise a sense of alarm. Other determinants were related to the physician and the context of the clinical encounter. Professional expertise was a crucial factor in whether a GP experienced a gut feeling and how they dealt with it. Most of the participating GPs declared that although they had been aware of gut feelings since their GP traineeship, their accumulation of medical knowledge and experience had made them more aware of and willing to trust their gut feelings. GPs thought that the physician's personality, but not gender, significantly influenced whether they would have and trust a gut feeling. Regarding the context and circumstances of the consultation, GPs reported that consultations happening off-hours and/or in a rural environment were more likely to trigger a gut feeling. Continuity of care is an important characteristic of primary care, and the participating GPs frequently mentioned this feature as a determinant of gut feelings. The studied Spanish GPs used their contextual knowledge based on continuity of care (knowing the patient, their social and family context, and their medical history and attitude) when considering whether a patient might have a serious disease.

The studied GPs considered gut feelings to be a substantial part of their clinical reasoning, and even a main feature of working in a primary care setting. A sense of alarm tended to motivate the diagnostic process, spurring the doctor to more thoroughly investigate the background of the patient's complaints. Moreover, the doctors felt satisfied when they act following a sense of alarm, and worried if they do not. However, the GPs had doubts about the diagnostic accuracy of gut feelings, believing that their recall was biased toward remembering gut feeling-related diagnostic successes rather than failures. Spanish GPs believed that students and trainees must be taught about the existence of gut feelings and how to take them into account when discussing a clinical case.

The results of our study were consistent with previous findings from the Netherlands, Belgium, and France in terms of GPs recognizing the existence and significance of gut feelings (Le Reste et al., 2013; Stolper, van Bokhoven, et al., 2009; Stolper, Van Royen, et al., 2009). These studies corroborated the existence of GFs among family doctors. In these studies, gut feelings were described as the GP being worried (sense of alarm) or not (sense of reassurance) about a patient's management and prognosis, even in the absence of specific findings. Participating GPs described gut feelings as playing roles in their decisions to take diagnostic actions or initiate a specific treatment. However, we found some small differences in the way Spanish and Dutch GPs thought about their gut feelings. Both Spanish and French GPs reported cautiousness concerning the sense of reassurance; when they experienced this gut feeling, they tended to remain alert and willing to review their decisions. A study on cross-national differences in medical communication found that GPs and patients from the European countries included in this study with greater Latin cultural heritage tended to have higher uncertainty avoidance (Meeuwesen, van den Brink-Muinen, & Hofstede, 2009). In a French Delphi consensus study on gut feelings, Le Reste et al. noted that this difference in uncertainty avoidance and the longer tradition of research and acceptance of gut feelings in the Netherlands compared to France and Spain might also help explain these differences (Le Reste et al., 2013). Spanish GPs are in accordance with French GPs in reporting the sense of alarm as a trigger for the diagnostic process and a need for understanding and diagnosing as well as with Dutch GPs in considering the sense of alarm as a trigger for patient specific management.

Some of characteristics and determinants of gut feelings found among Spanish GPs in the present study were also mentioned in previous studies. In Oxfordshire (UK), a referral pathway for patients with non-specific symptoms of cancer includes 'GP clinical suspicion of cancer or serious disease/GP gut feeling' as a referral criterion (Nicholson et al., 2018). In an interview-based study by Friedemann Smith et al., 19 GPs that mentioned their gut feelings as an indication to refer patients to this pathway (Friedemann Smith et al., 2020). These GPs considered gut feelings to be a valuable part of their decision-making process. They associated gut feelings with clinical knowledge and expertise. Gut feelings were considered to be particularly relevant when GPs saw patients in the 'gray area', i.e., those with symptoms that are inadequately (or not at all) represented in clinical guidelines. GPs from Oxford declared that they would be unlikely to ignore a gut feeling, and that this would only happen for a sense of reassurance. Norwegian GPs considered intuition as a way to become suspicious of cancer (Johansen, Holtedahl, & Rudebeck, 2012). They talked about experiencing a difficult-to-verbalize but helpful 'tacit feeling of alarm' that is based on clinical knowledge, expertise, and interpersonal awareness, the latter of which included contextual knowledge and previous familiarity with the patient's usual appearance. In line with our results, a German study found that an increase in contact frequency was associated with a GP becoming suspicious that a patient might have a serious disease (Hauswaldt, Hummers-Pradier, & Himmel, 2016). Similarly, Donker et al. found that alerting symptoms like weight loss, a visit by a patient who rarely visited the GP, and/or the patient's appearance were triggers for cancer-related gut feelings among Dutch GPs (Donker, Wiersma, van der Hoek, & Heins, 2016).

We herein found that Spanish GPs, as seen for their counterparts in other European countries, recognized the presence of gut feelings during the diagnostic process. They identified two kinds of gut feelings: a sense of alarm that is felt when something does not fit in the patient; and a sense of reassurance indicating that the doctor feels secure about the further management and course of the patient's problem. Some patient-, doctor-, and context-specific characteristics were found to be determinants related to the presence of gut feelings.

### Cross-cultural translation and validation of the GFQ into Spanish and Catalan

Spanish GPs appeared to conceive gut feelings in a manner similar to their Dutch and French counterparts. Therefore, we set out to translate and validate the GFQ validated with Dutch GPs in the Spanish and Catalan languages, with the goal of using the validated instruments to investigate the prevalence and determinants of gut feelings among Spanish- and Catalan-speaking GPs, and assess their diagnostic value.

A six-step procedure (forward and backward translations, consensus, and cultural and linguistic validation) was performed for each language. We followed the standard criteria for linguistic validation found in previous literature and adapted the procedural scheme used in previous validations of the modified GFQ (Barais et al., 2017; Beaton DT, Bombardier, Guillemin, & Ferraz, 2000).

To identify Spanish and Catalan terms equivalent to the English phrase 'gut feelings', the research team and translators discussed the terms used by the GPs who participated in the focus groups. The Spanish term 'corazonada' was chosen by consensus. It is defined by the *Diccionario de Uso del Español (2aEd)* as a 'vague belief that something happy or unhappy is going to happen'. The Catalan term selected was 'pressentiment', which is defined by the *Gran Diccionari de la Llengua Catalana (1aEd)* as the 'impression or conviction that something is going to happen'.

For cultural validation of the GFQ, the pre-final Spanish version was sent to 18 Spanish-speaking GPs: nine from different Spanish regions and nine from eight Latin American Spanish-speaking countries. The pre-final Catalan version was sent to eight Catalan-speaking GPs from the Balearic Islands and Catalonia. The Spanishor Catalan-speaking GPs were asked to judge their comprehension of the items, predict possible misunderstandings, and identify any lack of clarity in the statements. Their answers enabled the research team to determine final Spanish and Catalan versions.

The final versions of the questionnaires presented good structural properties. We purposively selected 15 GPs to fill out the Spanish version and eight GPs to fill out the Catalan version during a single working day. Patients with new reasons for encounter were included. We obtained 150 completed Spanish GFQ and 79 completed Catalan GFQ. The internal consistency was evaluated using Cronbach's alpha test, which yielded values greater than 0.9. The factorial structure of the questionnaire, which was explored with principal component analysis (PCA), showed one factor with the sense of alarm and the sense of reassurance as opposites.

Prospective observational study on the prevalence and diagnostic value of GPs' gut feelings for cancer and serious diseases

In the final phase of our study, we investigated the prevalence and diagnostic value of gut feelings for cancer and serious diseases in the consultations of 155 GPs.

To establish the presence and type of gut feelings, we used the Spanish and Catalan versions of the GFQ. Our results showed that GPs had a gut feeling almost every time (97.1%) they saw a patient for a new reason; of these feelings, 77.6% were a sense of reassurance, while 22.4% were a sense of alarm. GPs that were more engaged with analytical reasoning, increasing patient age, patients living in non-urban areas, patients presenting cancer-associated symptoms, and an incongruity between the native tongue of the GP and that of the patient were associated with a higher presence of a sense of alarm. The presence of a sense of alarm increased the numbers of tests performed and referrals to secondary care for further investigation. The GP having experienced a sense of alarm increased the chance of the patient having received a new diagnosis of cancer or another serious disease at 2 months (adjusted OR 5.3) and 6 months (adjusted OR 3.67) post-consultation. Conversely, the GP having experienced a sense of reassurance decreased this chance at 2 months (adjusted OR 0.19) and 6 months (adjusted OR 0.27). The likelihood of cancer or a serious disease being diagnosed within 6 months after the consultation increased from 8.4% to 18.4% in the presence of a sense of alarm and decreased to 5.5% in the presence of a sense of reassurance.

The almost universal presence of a gut feeling in GPs' consultations highlights their habitual use of intuitive reasoning. The intuitive part of the decision-making process is fast, automatic, effortless, and difficult to control (Osman, 2004; Stanovich & West, 2000). These characteristics justify its use in environments like primary care health centers, where doctors have many consultations and work under time constraints. The GFQ is a validated measure for determining gut feelings. Its use overcomes the limitations of other non-validated methods used in previous studies examining the presence of gut feelings in GPs' consultations. These studies found a lower prevalence of the sense of alarm (Hjertholm, Moth, Ingeman, & Vedsted, 2014; Scheel, Ingebrigtsen, Thorsen, & Holtedahl, 2013; Stolper, 2010) than found in the present study. This might indicate that the GFQ overestimates the presence of gut feelings. Barais et al. (Barais et al., 2020) used the GFQ among French GPs consulting with patients who presented with dyspnea or chest pain; they found a high prevalence of gut feelings (99.15%), with GPs reporting a sense of alarm 35% of the time and a sense of reassurance 65% of the time. However, this high proportion of a sense of alarm makes sense given that the authors selected patients with dyspnea

and chest pain, in whom the possibility of a serious outcome was high. The frequent observation of a sense of alarm in the present study might also reflect the use of an incorrect GFQ cut-off value. That said, the common presence of a sense of reassurance found in our work is consistent the low probability of serious disease in primary care, as many complaints are just innocent and temporary indispositions (Knottnerus, 1991).

The kind of gut feeling was influenced by specific characteristics of the GPs, patients, and consultations. GPs with higher engagement with analytical reasoning were more prone to experiencing a sense of alarm. Stolper et al. proposed that a GP will use either analytical or the non-analytical reasoning depending on the nature of the task (routine vs. complicated) and the level of familiarity with the perceived situation, and that experienced doctors tend to use non-analytical reasoning overall, but switch to analytical reasoning when they become aware of a sense of alarm (Stolper et al., 2011). According to Witteman et al., the rational subscale of the REI is positively correlated with rational performance on tasks (Witteman et al., 2009). GPs more frequently experienced a sense of alarm in consultations with older patients, which is in line with the higher risk of serious disease in older people. Notably, the Spanish non-urban population is older than the urban population (Subdirección General de Análisis, Prospectiva y Coordinación, 2009), which may explain the higher prevalence of a sense of alarm related to patients in non-urban areas. The presence of at least one cancer-related symptom increased the prevalence of a sense of alarm, which was in line with our expectations (Ingebrigtsen, Scheel, Hart, Thorsen, & Holtedahl, 2013; Scheel et al., 2013). Regarding language, those speaking a non-native language have been found to reduce their emotionality and make more utilitarian decisions (Shin & Kim, 2017). Consultations in a language other than the mother tongue of the GP constitute a scenario that encourages the use of more analytical reasoning and the appearance of a trigger for the change to a rational thinking style, such as the sense of alarm. GPs in this situation may tend to pay less attention to details that may qualify the seriousness of the patient's complaint. Regarding the length of consultations, which increased with a sense of alarm, previous work indicated that a sense of alarm may activate the diagnostic process by stimulating a GP to formulate and weigh working hypotheses that might involve a serious outcome (Stolper, van Bokhoven, et al.,

2009), resulting in longer consultations. Interestingly, there was no gender-related difference among GPs in the frequency or kind of gut feelings.

The higher number of actions taken by GPs after experiencing a sense of alarm supports the tendency of GPs to use a gut feeling when deciding whether to further investigate the case or pause and adopt a wait-and-see attitude (Friedemann Smith et al., 2020; Oliva, March, Gadea, Stolper, & Esteva, 2016). The number of sick leave days needed was the only studied action that did not show a statistically significant difference between patients who triggered a sense of alarm versus a sense of reassurance. One possible explanation is that the sense of alarm was raised more frequently as the patient's age increased, and older patients would be more likely to be retired and not require sick leave.

Two relevant features of the primary care context are a high level of uncertainty and a very low prevalence of serious disease (Buntinx, Mant, Van den Bruel, Donner-Banzhof, & Dinant, 2011). In a situation with a very low prevalence of serious disease, such as in primary care, LR+ values between 2 and 5 could be considered interesting since they increase the probability of serious disease between 15% and 30% (McGee, 2002). In this sense, it is notable that we observed a LR+ of 2.8 for the sense of alarm, which modified the pre-test probability for cancer or serious disease from 8.4% to 18.4%. The LR+ for the sense of reassurance was 1.9, suggesting that the presence of this type of gut feeling did not definitively rule out a serious disease at 6 months after the GP noted a sense of alarm (3.67) or reassurance (0.27) support the decision made in Denmark and Oxfordshire (UK) to include GPs' gut feelings as a criterion for referring a patient to a specific diagnostic center for nonspecific but serious symptoms (Nicholson et al., 2018; Vedsted & Olesen, 2015).

#### **Strengths and limitations**

The use of the focus group technique allowed us to select physicians with personal and professional characteristics that could be relevant to the discourse on gut feelings, such as experience, gender, traineeship, rural/non rural practice location, and region or country of origin. We found a wide consensus among GPs who differed in their experience, gender, teaching profiles, and/or practice locations. Saturation of information was quickly reached.

The organization of medical practice and GP traineeship is very similar throughout Spain. At the time of the study there was no school of medicine in Majorca; thus, GPs working in Majorca had studied medicine elsewhere in Spain and had the same medical culture as residents of the Spanish mainland. The GPs that we interviewed and those working in the Majorca Primary Care Department were native to different regions of Spain and Spanish-speaking countries of Central and South America. Therefore, we believe that the GPs interviewed in our study are representative of Spanish GPs.

Regarding the limitations of our cross-cultural translation validation, it should be noted that we did not use a Delphi consensus procedure when determining the content validity with Spanish- and Catalan-speaking GPs. However, our results are similar to those obtained from focus group studies carried out in the Netherlands, as well as those using Delphi procedures in the Netherlands and France (Le Reste et al., 2013; E. Stolper, van Bokhoven, et al., 2009; E. Stolper, Van Royen, et al., 2009). This allowed us to assume that gut feelings are a cross-border concept. Thus, in accordance with the developers of the original GFQ, we chose not to repeat the Delphi consensus procedure that had been used already in other countries.

Both Spanish (in particular) and Catalan are spoken in numerous regions and countries, wherein different historical evolutions have yielded diverse linguistic variants with particular phonetic, lexical, and morphosyntactic features (Matias Miranda & Monhaler, 2017). Our intention was to translate/validate the GFQ such that it could be used by speakers from all provenances. The inclusion of GPs from nine different Spanish-speaking countries and two Catalan-speaking regions ensured that the validated GFQ can be used widely in Spanish- and Catalan-speaking countries.

There is some controversy regarding the definition of 'serious disease', which was used in our study of the diagnostic value of gut feelings. From the palliative-care point of view, a serious disease is a condition that carries a high risk of mortality, negatively impacts quality of life and daily function, and/or is burdensome in its symptoms, treatments, or caregiver stress; however, more flexible definitions have been proposed (Chrvala & Sharfstein, 1999; Kelley, 2014). Additionally, the perception of the seriousness of a disease might vary among patients depending on their life expectations. A disease might be considered serious because of its life-threatening potential, or just because it affects the person's work activity or ability to care for themselves or others. We tried to overcome this problem by using an elaborated list that was previously adopted for a similar study (Hjertholm et al., 2014). Also, we sought input from a third reviewer when the first two disagreed in defining a disease as serious.

The outbreak of the COVID-19 pandemic during the last months of data collection could raise concern about the results of the study. Although all of the index consultations occurred before the onset of the pandemic, the follow-up of about one third of the cases ended after that point. Thus, COVID-19 was not a possible diagnosis at the time of the initial consultation, but the patients could have been exposed to the new disease during the data collection period. Moreover, the Spanish National Health System stopped all non-urgent activity during the first months of the pandemic, meaning that many cancer diagnoses were likely to have been delayed during this time (Rogado, Obispo, Gullón, & Lara, 2021; Suárez et al., 2021). The severity of COVID-19 is highly variable, ranging from mild illness in most cases to serious and life-threatening conditions. We considered COVID-19 infection to be a serious disease when the patient suffered complications (e.g., pneumonia), needed hospitalization, or died. Serious disease was not registered for mild cases of COVID-19 or mild suspicious cases in which diagnostic tests were not carried out (e.g., at the beginning of the pandemic and/or due to lack of materials). Even with these considerations, the prevalence of cancer and other serious diseases diagnosed in our study is comparable to that found in previous similar research (Hjertholm et al., 2014).

The Hawthorne effect (Parsons, 1974), which is defined as how the behavior of study subjects may be impacted by their awareness of being studied (McCambridge, Witton, & Elbourne, 2014), must be considered as a possible source of bias in studies regarding behavior. We can assume that the Hawthorne effect is partially responsible for the high rate at which a sense of alarm was identified in our work. Although the participating GPs did not know if the GFQ would reflect a sense of alarm or reassurance, they might have changed their behavior and been more suspicious when interpreting the patient's symptoms. This may have led us to overestimate the prevalence of a sense of alarm. Among the strategies that could be considered to avoid this bias, future researchers might work to assure the participants that the objective of the study is to improve and not judge their performance; they might also triangulate the collection of information and/or collect information over long periods of time while discarding the first set of collected data (BK, Reddy, & Pathak, 2019).

Another limitation of our study is that 43% of the invited GPs decided not to participate, meaning that we did not reach the number of consultations needed to meet the estimated sample size (Oliva-Fanlo et al., 2019). Therefore, our data lacked sufficient power to enable us to draw conclusions about the diagnostic value of gut feelings specific to cancer. Regardless, the distribution of participant GPs by age, gender, and non-urban vs. urban environment was tantamount to those observed among Spanish GPs (Barber Pérez & González López-Valcárcel, 2019; Subdirección General de Análisis. Prospectiva y Coordinación, 2009).

### **Implications for practice**

In general, the focus group study confirmed that Spanish GPs experience gut feelings, and that their concept (definition and meaning) of gut feelings is shared with other European primary care physicians.

The GFQ can be used for multiple research purposes. For example, it can facilitate research on the cues that elicit a gut feeling in GPs and deepen our understanding of the determinants of gut feelings (beyond doctors' expertise, medical education, and personality; doctor-patient communication; patient presentation; and consultation characteristics). This could potentially help increase the prognostic and diagnostic value of GPs' gut feelings. The GFQ may also represent a useful tool in medical education, as it could help trainers and teachers educate

their trainees and students about the existence and use of an intuitive approach in the decision-making process.

Finally, this is the first study seeking to determine the prevalence and diagnostic value of gut feelings in the consultations of GPs. We show that gut feelings are present in most consultations and that they influence clinical reasoning and appear to be a substantial part of GPs' clinical decision-making process. We hope that this research will be followed by other studies seeking to further clarify the role, strengths, and limitations of gut feelings in general practice.

## CONCLUSIONS

'Guybrush Threepwood: Well, I'm pretty tough myself! Wally: You! Don't make me laugh! You couldn't even grow a decent beard! Guybrush Threepwood: Hey... How did you know about my attempted beard? Wally: Er... Pirate's intuition.

The Curse of Monkey Island [1997]

- The studied Spanish GPs recognized the presence of gut feelings during the diagnostic process. They identified two kinds of gut feelings: a sense of alarm that is felt when something does not fit in the patient; and a sense of reassurance that arises when they feel secure about the further management and course of a patient's problem.
- Spanish GPs reported that some patient, doctor, and context characteristics, as clinical experience, duration of the patient relationship, and frequency of patient contact, are determinants related to the presence of gut feelings.
- Spanish GPs reported that they use their gut feelings in their diagnostic process and are interested in knowing more about the diagnostic value of gut feelings, the factors that may improve their accuracy, and how to include gut feelings in medical education.
- The validated versions of the GFQ are useful instruments for studying:
  - the prevalence of gut feelings in daily practice and the determinants that influence their appearance;
  - changes in the attitude of GPs after experiencing either kind of gut feeling; and
  - the diagnostic value of gut feelings for serious diseases in general or for specific symptoms/diseases.
- The validated Spanish and Catalan versions of the GFQ can be used for research on gut feelings among Spanish- or Catalan-speaking GPs, such as those in the more than 20 Spanish-speaking countries and four Catalan-speaking countries
- The GFQ can be used in the field of medical education to help trainers and teachers educate clinicians on the existence of an intuitive approach in the decision-making process. The GFQ can also be used among medical students and GP trainees to increase awareness of their own gut feelings and explore how to refine and use gut feelings.

- GPs have a gut feeling in almost every consultation for a new reason of encounter. A sense of reassurance is 3.5 times more frequent than a sense of alarm.
- Some patient, doctor, and contextual characteristics as GPs with higher engagement with analytical reasoning, older patients, non-urban practice, the presence of cancer-related symptoms, incongruity in the native languages of the GP and patient, and consultations lasting longer than 6 minutes, are related to a higher prevalence of sense of alarm.
- GPs act differently depending on the kind of gut feeling perceived, asking for more tests, and referring their patients more frequently when they experience a sense of alarm.
- The presence of a sense of alarm during a consultation for a new reason of encounter increases the possibility of a diagnosis of cancer or serious disease at both 2 months (from a pre-test probability of 4.6% to a post-test probability of 12.3%) and 6 months (from 8.4% to 18.4%) post-consultation.
- The presence of a sense of reassurance during a consultation for a new reason of encounter decreases the possibility of a diagnosis of cancer or serious disease at both 2 months (from 4.6% to 2.4%) and 6 months (from 8.4% to 5.5%) post-consultation.
- Gut feelings might help GPs avoid diagnostic delays and errors by motivating them to more quickly initiate the diagnostic process, while also helping them avoid unnecessary tests and overdiagnosis.
- GPs and trainees should be informed about the existence and meaning of gut feelings, especially the sense of alarm, as it can alert them to shift from the intuitive to analytical mode of reasoning.

Future research should focus on identifying the cues that elicit a gut feeling in GPs and deepening our understanding of factors that may increase the prognostic and diagnostic value of GPs' gut feelings.

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## ANNEXES

ANNEX I.

#### **Research Committee Certificate for Manuscript I**



Palma, 29 de juny de 2015

Alberto Anguera Puigserver, gerent d'Atenció Primària de Mallorca, d'acord amb la Comissió d'Investigació, autoritza a què es realitzi l'estudi amb títol: "A focus group study on the concept and importance of gut feelings among Spanish general practitioners" del qual és investigador principal el Dr. Bernardino Oliva Fanlo, metge del Centre de Salut de Son Ferriol. I col·laboren Magdalena Esteva Cantó, tècnica de salut de la Unitat d'Investigació d'Atenció Primària, el Dr. Erik Stolper, investigador de la Maastricht University i Antwerp University, Sebastià March Llull, sociòleg de la Unitat d'Investigació d'Atenció Primària i la Dra. Cristina Gadea Ruiz, de la Unitat Bàsica de la Platja de Palma.



Gerent d'Atenció Primària de Mallorca Servei Balear de Salut (Ib-Salut) ANNEX II.

#### **Research Ethics Committee Certificate**



Dr. Bernardino Oliva Fanlo Centro de Salud de Calvià Atención Primaria



Conselleria de Salut Direcció General d'Acreditació, Docència i Recerca en Salut

GOVERN DE LES ILLES BALEARS CONSEJERÍA DE SALUD- OF. C/ JESUS L18S25361/2016 15/07/2016 08:02:36

### Asunto: Informe del Comité de Ética de la Investigación de las Islas Baleares

Con relación al estudio nº IB 3210/16 PI, denominado VALIDEZ DE LAS CORAZONADAS DE LOS MÉDICOS DE FAMILIA PARA EL DIAGNÓSTICO DE ENFERMEDAD GRAVE Y CÁNCER, del investigador principal, se adjunta Informe del Comité de Ética de la Investigación de las Islas Baleares.

Se recuerda la obligación, según la normativa vigente, de informar periódicamente (al menos de forma anual) sobre la marcha del estudio. En caso de no hacerlo, este CEI lo tendrá en consideración en el momento de la revisión de propuestas posteriores por parte del investigador, así como en el momento de evaluar su idoneidad.

Palma, 13 de julio de 2016

La Secretaria Técnica del CEI de las Islas Baleares



Gemma Melero Quiñonero

Comité d'Ètica de la Investigació de les Illes Balears (CEI-IB) C/ de Jesús, 38A 07010 Palma Illes Balears Tel.: 971 17 73 78 Fax: 971 17 73 07 A/e: ceic\_ib@caib.es Web: http://ceisalut.caib.es

# ANEXX III.

# Gut Feelings Questionnaire (Spanish version)

С	uestionario de corazonadas	Completamente en desacuerdo	En desacuerdo	Ni de acuerdo ni en desacuerdo	De acuerdo	Completamente de acuerdo
		1	2	3	4	5
1.	Indique qué clase de corazonada ha tenido al final d esta pregunta ahora, conteste las 9 preguntas sigui esta pregunta. O Algo no va bien en este paciente. O Todo encaja. O No puedo contestar, o no procede.					
2.	Todo encaja. Tengo confianza en mi plan de actuación y/o en el desenlace.	0	0	0	0	0
3.	Algo no encaja. Me preocupa el estado de salud de este paciente.	0	0	0	0	0
4.	En este caso concreto sopesaré algunas hipótesis provisionales con desenlaces potencialmente graves.	0	0	0	0	0
5.	Tengo una cierta inquietud porque me preocupa un desenlace potencialmente grave.	0	0	0	0	0
6.	Este caso require un manejo específico para evitar subsiguientes problemas graves de salud.	0	0	0	0	0
7.	El estado de este paciente me da motivos para concertar una visita de seguimiento o derivarlo a atención especializada antes de lo habitual.	0	0	0	0	0
	<ul> <li>¿En qué diagnósticos está pensando? (máximo 3)</li> <li>¿Qué plan de actuación ha elegido? (marque una s O No tomar medidas todavía, mantener una acti O No tomar medidas todavía, pero recomendar persiste.</li> <li>O No tomar medidas todavía, pero concertar con presencial o telefónica.</li> <li>O Solicitar pruebas complementarias (analíticas O Solicitar pruebas complementarias y mientras tipo).</li> <li>O Iniciar tratamiento sin concertar seguimiento.</li> <li>O Iniciar tratamiento y recomendar al paciente q O Iniciar tratamiento y concertar con el paciente telefónica.</li> </ul>	itud expect al paciente n el pacien , radiograf tanto inici ue vuelva	tante. e que vi ite una ías, etc ar trata si el pr	visita de ). miento oblema	e segu (médic persis	iimiento co o de otro te.
10	O Derivar el paciente. ¿Qué diagnóstico ha determinado el plan de actuac	ión elegido	)?			
	<ul> <li>Esta pregunta es la misma que la primera. Si ya la l contestar. Indique qué clase de corazonada tiene al O Algo no va bien en este paciente. O Todo encaja. O No puedo contestar, o no procede.</li> </ul>	na respond	lido no		ue volv	/er a

(CC) BY-NC-SA

# ANEXX IV.

# Gut Feelings Questionnaire (Catalan version)

Qüestionari de Pressentiments		Completament en desacord	En desacrod	Ni s'acord ni en desacord	D'acord	Completament d'acord
		1	2	3	4	5
<ol> <li>Indiqueu quin tipus de presentiment heu tingut or respondre-hi en aquest moment, contesteu les es repeteix aquesta pregunta.</li> <li>O Alguna cosa no va bé en aquest pacie</li> <li>O Tot encaixa.</li> <li>O No hi puc contestar, o no escau.</li> </ol>	9 pregur					
2. Tot quadra. Em semto segur amb el meu pla d'actuació i/o el possible resultat		0	0	0	0	0
<ol> <li>Alguna cosa no quadra. Em preocupa l'estat de salut d'aquest pacient.</li> </ol>	•	0	0	0	0	0
4. En aquest cas sospesaré algunes hipòtesis provisionals amb resultats potencialment greus		0	0	0	0	0
<ol> <li>Tinc una certa inquietud perquè em preocupa la possibilitat d'un resultat desfavorable.</li> </ol>	3	0	0	0	0	0
<ol> <li>Aquest cas requereix una actuació especifica p evitar subsegüents problemes greus de salut.</li> </ol>	er	0	0	0	0	0
<ol> <li>La situació d'aquest pacient em dona motius per concertar una visita de seguiment o una derivar a l'atenció especiatlizada abans de l'habitual.</li> </ol>		0	0	0	0	0
8. En quins diagnostics esteu pensant? (màxim 3)						
<ul> <li>9. Quin pla d'actuació heu triat? (marqueu una sol O No prendre mesuras encara, mantenir un O No prendre mesures encara, però aconse persisteix.</li> <li>O No prendre mesures encara, però conce presencial o telefònica.</li> <li>O Demanar proves complementàries (analít O Demanar proves i menstrentant iniciar tra O Iniciar tractament sense concertar seguin O Iniciar tractament i recomanar al pacient o O Iniciar tractament i concertar amb el pacie telefònica.</li> <li>O Derivar el pacient.</li> </ul>	a actitud ellar al pa rtar amb iques, ra ctament nent. que torni	l expec acient c el paci adiogra (medic si el pr	ue torr ent una fies, etc o d'un roblema	a visita c). la altra l a persis	de cor mena) .teix.	ntrol
10. Quin diagnòstic ha motivat el pla d'actuació que	e heu pre	es?				
<ul> <li>11. Aquesta pregunta és la mateixa que la primera.</li> <li>Indiqueu quin tipus de pressentiments heu tingu</li> <li>O Alguna cosa no va bé en aquest pacie</li> <li>O Tot encaixa.</li> <li>O No hi puc contestar, o no escau.</li> </ul>	ut en aca					ar a fer-ho.



#### ANEXX V.

#### **Patient information sheet**

# HOJA DE INFORMACIÓN AL PACIENTE PARA LA REALIZACIÓN DE PROYECTOS DE INVESTIGACIÓN

#### (v3 abril 2019)

TÍTULO DEL ESTUDIO: VALOR DIAGNÓSTICO GUT FEELINGS CÓDIGO DEL PROMOTOR: PROMOTOR: Gabinete Técnico GAP Mallorca INVESTIGADORES PRINCIPALES: Dr Bernardino Oliva Fanlo y Dra Magdalena Esteva Cantó CENTRO: Unidad de Investigación. Gerencia Atención Primaria, Mallorca. Ibsalut Teléfono contacto: 971175897. E-mail: <u>boliva@ibsalut.caib.es</u> y mesteva@ibsalut.caib.es

#### INTRODUCCIÓN

Nos dirigimos a usted para informarle sobre un estudio en el que se le invita a participar. El estudio ha sido aprobado por el Comité de Ética de la Investigación de las Islas Baleares, de acuerdo a la legislación vigente, y se lleva a cabo con respeto a los principios enunciados en la declaración del Helsinki y a las normas de buena práctica clínica.

Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno. Si tiene alguna duda diríjase al investigador principal.

#### DESCRIPCIÓN GENERAL

Se trata de un estudio para valorar la toma de decisiones por parte del médico de familia a lo largo de una consulta médica. No se va a producir ninguna intervención ni en el paciente ni en el médico. Al acabar la consulta su MF tomará algunos datos anonimizados de los síntomas y signos apreciados y de las actuaciones consideradas. Seis meses después se accederá a su historial médico para comprobar el resultado de las decisiones tomadas. No se le solicitará ninguna visita ni prueba extra. Este proceso se repetirá con otros 3000 pacientes.

#### CONFIDENCIALIDAD

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los sujetos participantes se debe ajustar al lo que dispone la Ley orgánica 3/2018, de 5 de diciembre, de protección de datos de carácter personal y garantía de los derechos digitales.

De acuerdo con lo que establece la legislación nombrada, podéis ejercer los derechos de acceso, rectificación, supresión, oposición, limitación del tratamiento de los datos, incluso, a trasladar les vuestros datos a un tercero autorizado (portabilidad), para lo cual os tenéis que dirigir al delegado de protección de datos de la institución donde se realizará la investigación (*Antonia Roca Casas, 971175897*).

Vuestros datos serán tratados informáticamente y se incorporaran a un fichero automatizado de datos carácter personal el responsable de los cuales es (Dr Bernardino Oliva Fanlo y Dra Magdalena Esteva Cantó 971.17.58.97), que cumple con todas las medidas de seguridad de acceso restringido con el objetivo descrito en este documento.

Para garantizar la confidencialidad de la información obtenida sus datos estarán identificados mediante un código y solo su médico del estudio y colaboradores podrán relacionar dichos datos con usted y con su historia clínica. Por lo tanto, su identidad no será revelada a persona alguna salvo en caso de urgencia médica, requerimiento de la administración sanitaria o requerimiento legal.

Sólo se transmitirán a terceros los datos recogidos para el estudio que en ningún caso contendrán información que le pueda identificar directamente, como nombre y apellidos, iniciales, dirección, nº de la seguridad social, etc. En el caso de que se produzca esta cesión, será para los mismos fines del estudio descrito y garantizando la confidencialidad como mínimo con el nivel de protección de la legislación vigente en nuestro país.

El acceso a su información personal quedará restringido al médico del estudio/colaboradores, autoridades sanitarias, al Comité de Ética de la Investigación de las Illes Balears y personal autorizado, cuando lo precisen para comprobar los datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de los mismos de acuerdo a la legislación vigente.

#### COMPENSACIÓN ECONÓMICA

Su médico no recibe compensación económica y ha declarado no tener conflicto de intereses.

#### PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin dar ningún tipo de explicación, sin que por ello se altere la relación con su médico o el tratamiento que debe Ud. recibir.

#### AGRADECIMIENTO

Sea cual sea su decisión, tanto el promotor como el equipo investigador quieren agradecer su tiempo y atención. Usted está contribuyendo al mejor conocimiento y cuidado de su enfermedad lo que en el futuro puede beneficiar a multitud de personas.

**Informed consent** 

# CONSENTIMIENTO INFORMADO PARA LA REALIZACIÓN DE PROYECTOS DE INVESTIGACIÓN

(Versión julio 2019)

TÍTULO DEL ESTUDIO: VALOR DIAGNÓSTICO GUT FEELINGS CÓDIGO: IB 3210/16 PI PROMOTOR: Gerencia Atención Primaria Mallorca INVESTIGADOR PRINCIPAL: Bernardino Oliva Fanlo, UBS Badía Gran (CS Trencadors, Llucmajor), Tfno 620282605

Yo,\_\_\_

He leído la hoja de información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

He recibido suficiente información sobre el estudio.

He hablado con mi médico de familia.

Comprendo que mi participación es voluntaria.

Comprendo que puedo retirarme del estudio:

- Cuando quiera.
- Sin tener que dar explicaciones.
- Sin que esto repercuta en mis cuidados médicos.

Comprendo que, si decido retirarme del estudio, los resultados obtenidos hasta ese momento podrán seguir siendo utilizados.

Comprendo que tengo los derechos de acceso, rectificación, supresión, oposición, limitación del tratamiento de datos, incluso a trasladar mis datos a un tercero autorizado (portabilidad), de acuerdo con lo dispuesto en el nuevo Reglamento General de Protección de Datos (RGPD) de 2016/679 del Parlamento Europeo y del Consejo del 27 de abril de 2016 y la Ley Orgánica 3/2018, de 5 de diciembre, de protección de datos de carácter personal y garantía de los derechos digitales.

Presto libremente mi conformidad para participar en el estudio y doy mi consentimiento para el acceso y utilización de mis datos en las condiciones detalladas en la hoja de información al paciente.

Firma del paciente:

Firma del investigador:

Nombre: Fecha: Nombre: Fecha

Este documento se firmará por duplicado quedándose una copia el investigador y otra el paciente

## ANNEX VII.

## Data sheet for GPs characteristics

			2826377
CUESTIONARIO C	ORAZONADAS	G (MÉDICOS	5)
Código			
Edat	Años en el mismo cupo		
Sexe			
Medio en el que se encuentra mi consi	ulta 🛛 Rural 🗋 Urbano 🗋 Mixto	Tutor MIR MFyC	□ Sí, actualmente □ Sí, anteriormente □ No, nunca
Idioma materno 🛛 Castellano 🖾 Cat	alán 🔲 Otro		
A continuación te rogamos que responda 1.Los médicos, al estar sobrecargados las que hemos sido capacitados	•	0	
Muy en desacuerd	o 🛛 En desacuerdo	De acuerdo	Muy de acuerdo
2.Mi capacidad como médico se malga "clínico"	asta con frecuencia en ver a	a personas que no p	resentan un problema
Muy en desacuerd	o 🛛 En desacuerdo	De acuerdo	☐ Muy de acuerdo
3.En el poco tiempo que dura una cons pacientes	sulta, es prácticamente imp	oosible conseguir da	ar apoyo psicológico a los
Muy en desacuerd	o 🛛 En desacuerdo	De acuerdo	☐ Muy de acuerdo
4.Diagnosticar y tratar los problemas p la medicina en atención primaria	osicosociales de los pacien	ites es la parte más	interesante de la práctica de
☐ Muy en desacuerd	o 🛛 En desacuerdo	De acuerdo	☐ Muy de acuerdo
A continuación te rogamos que responda resolver problemas. Marca con una cruz		•	
			Contraction Contra
1. Intento evitar las situaciones que requieren			
2. Me gusta confiar en mis impresiones intuiti			
3. Al resolver problemas en mi vida, normalm	-	o caso a mis impulsos	
<ul><li>4. No soy muy bueno resolviendo problemas</li><li>5. Me gustan los retos intelectuales</li></ul>	complicauos		
<ol> <li>6. Cuando hay que confiar en la gente, norma</li> </ol>	almente me fío de mis impulsos		$\Box 1 \Box 2 \Box 3 \Box 4 \Box 5$ $\Box 1 \Box 2 \Box 3 \Box 4 \Box 5$
7. No soy muy bueno resolviendo problemas			
8. Confío en mis corazonadas			
9. La intuición puede ser un medio muy útil pa	ara solucionar los problemas		
10. Con frecuencia me dejo llevar por mi insti	nto al decidir un curso de acciór	n	

# 



	CONDECTOR	Lotanentrio
11. No me gusta tener que reflexionar prolongadamente		]4 🗆 5
12. Normalmente tengo razones claras y explicables para mis decisiones		]4 🗆 5
13.Confío en mis primeras impresiones acerca de la gente		]4 🗆 5
14.No tengo una intuición muy buena		]4 🗆 5
15.No creo que reflexionar sea una actividad divertida		]4 🗆 5
16.Si confiara en mis impulsos, con frecuencia cometería errores		]4 🗆 5
17.Me es muy atractivo aprender nuevas formas de pensar		]4 🗆 5
18.Los razonamientos profundos no son uno de mis puntos fuertes		]4 🗆 5
19. Prefiero los problemas complejos a los simples		]4 🗆 5
20.No me gustan las situaciones en las que he de confiar en mi intuición		]4 🛛 5
21. Pensar mucho y durante mucho tiempo sobre algo me produce poca satisfacción		]4 🗆 5
22.Para las decisiones importantes, no creo que sea buena idea confiar en la propia intuición		]4 🗆 5
23.Creo que hay ocasiones en las que uno debe confiar en su propia intuición		]4 🗆 5
24.No puedo reflexionar bajo presión		]4 🗆 5
25. Resolviendo cosas lógicamente soy bastante mejor que la mayoría de la gente		]4 🗆 5
26.No me gustaría depender de alguien que se describe a sí mismo como intuitivo		]4 🗆 5
27.No tengo problemas para pensar las cosas con detenimiento		]4 □5
28.Creo que es una locura tomar decisiones importantes basándose en impresiones		]4 🗆 5
29.Cuando hago juicios rápidos, probablemente no soy tan bueno como la mayoría de la gente		]4 🗆 5
30.Tengo una mente lógica		]4 🗆 5
31. Tiendo a utilizar el corazón como guía de mis acciones		]4 🗆 5
32.Me gusta pensar en abstracto		]4 🛛 5
33.Con frecuencia me doy cuenta cuando alguien acierta o se equivoca, incluso cuando no puedo explicar cómo llego a saberlo		]4 🗆 5
34.La utilización de la lógica es algo que me funciona al solucionar problemas de mi vida		]4 🗆 5
35.Normalmente no utilizo las corazonadas para ayudarme a tomar decisiones		]4 🗆 5
36.Cuando le hago caso a mis impulsos, pocas veces me equivoco de respuesta		]4 🛛 5
37.Me basta con conocer la respuesta, aunque no conozca los razonamientos en que dicha respuesta se basa		]4 🗆 5
38.Me gustan los problemas que requieren pensar mucho		]4 🗆 5
39. Supongo que mis corazonadas aciertan tanto como se equivocan		]4 🗆 5
40.No soy un pensador muy analítico		]4 🗆 5

MUCHAS GRACIAS POR SU COLABORACIÓN

ANNEX VIII.

Data sheet for patient and consultation characteristics (Spanish version)

				3129282
CUEST	ΓΙΟΙ	NARIO CORAZONADAS	(CONSUL	TA)
Código médico				
NHC				
Fecha de consulta				
Pais de origen del paciente	e	□ España □ Otros		
Idioma materno del pacien	ite	☐ Castellano Idioma de la consu ☐ Catalán ☐ Otro	Ita ☐ Castelland ☐ Catalán ☐ Otro	0
<b>Tipo de visita</b> ☐ Cita pro ☐ Sin cita		Ha durado la consulta má	is de 6 minutos?	🗆 Sí 🛛 No
☐ Telefór ☐ Domici	nica	¿Conocía previamente al p	aciente?	🗆 Sí 🛛 No
C Atenció	ón con	tinuada ¿Hace cuantos años?		
Marque con una cruz si el	pacie	nte presenta alguno de estos SÍNTOMAS. I	Puede seleccionar	varios.
1. Alteraciones de mama (ı	nódule	o, retracción, pezón)		
2. Anemia		11. Hematuria		
3. Anorexia		12. Hemoptisis		
4. Astenia		13. Lesiones pigmentadas piel		
5. Diarrea		14. Masa abdominal		
6. Disfagia		15. Perdida de peso		
7. Disfonía origen incierto		16. Rectoragia		
8. Dispepsia persistente		17. Sangrado vaginal postmenopáusico		
9. Dolor inusual		18. Síntomas tracto urinario inferior		
10. Estreñimiento		19. Tos		

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1. Indique qué clase de corazonada ha tenido al final de la consulta. Si no puede responder a esta pregunta ahora, conteste las nueve preguntas siguientes. Al final del cuestionario se repite esta pregunta.

I	□ Algo no va bien en este paciente □ Todo encaja □ No puedo contestar, o no procede	Completamente en desacuerdo	En desacuerdo	Ni de acuerdo ni en desacuerdo	De acuerdo	Completamente de acuerdo
2.	Todo encaja. Tengo confianza en mi plan de actuación y/o en el desenlace.	□ 1	□2	□3	□4	□5
3.	Algo no encaja. Me preocupa el estado de salud de este paciente.	□1	□2	□3	□4	□5
	En este caso concreto sopesaré algunas hipótesis provisionales con senlaces potencialmente graves.	□ 1	□2	□3	□4	□ 5
	Tengo una cierta inquietud porque me preocupa un desenlace encialmente grave.	□ 1	□2	□3	□4	□5
	Este caso requiere un manejo específico para evitar subsiguientes blemas graves de salud.	□ 1	□2	□3	□4	□ 5
	El estado de este paciente me da motivos para concertar una visita de juimiento o derivarlo a atención especializada antes de lo habitual.	□1	□2	□3	□4	□5

8. ¿En qué diagnósticos está pensando?(máximo 3). Escribe con mayúsculas

#### 9. ¿Qué plan de actuación ha elegido? (marque una sola respuesta).

□ No tomar medidas todavía, mantener una actitud expectante.

D No tomar medidas todavía, pero recomendar al paciente que vuelva si el problema persiste.

D No tomar medidas todavía, pero concretar con el paciente una visita de seguimiento presencial o telefónica.

Solicitar pruebas complementarias (analíticas, radiografías, etc).

Solicitar pruebas complementarias y mientras tanto iniciar tratamiento\_(médico o de otro tipo)

□ Iniciar tratamiento sin concretar seguimiento

Iniciar tratamiento y recomendar al paciente que vuelva si el problema persiste.

□ Iniciar tratamiento y concretar con el paciente una visita de seguimiento presencial o telefónica

Derivar el paciente

#### 10. ¿Qué diagnóstico ha determinado el plan de actuación?

11. Esta pregunta es la misma que la primera. Si ya la ha respondido no tiene que volver a contestar. Indique qué clase de corazonada tiene al final de la consulta:

Algo no va bien en este paciente

Todo encaja

□ No puedo contestar, o no procede



ANNEX IX.

Data sheet for patient and consultation characteristics (Catalan version)

					<b>11</b>	523334	
QÜEST		NARI PRESSENTIMENT	S ((	CONSU	LTA	)	
Codi metge							
NHC							
Data de consulta							
País d'origen del pacient		☐ Espanya ☐ Altres					
Idioma matern del pacient		□ Castellà Idioma de la consu □ Català □ Altres	ılta	□ Castellà □ Català □ Altres			
Tipus de visita □ Cita pré		Ha durat la consulta més c	de 6 m	inuts?	🗆 Sí	□ No	
☐ Telefòr □ Domici	nica	Coneixia prèviament al pa	cient?		🗆 Sí	□ No	
Atencić	o conti	nuada Fa quants anys?					
Marqueu amb una creu si e	el pac	ent presenta algun d'aquests SÍMPTOMES	S. Pod	eu seleccior	ar-ne di	versos	
1. Alteracions en mama (no	òdul, ı	etracció mugró)					
2. Anèmia		11. Hemoptisis					
3. Anorèxia		12. Lesions pigmentades pell					
4. Astènia		13. Massa Abdominal					
5. Diarrea		14. Pèrdua de pes					
6. Disfàgia		15. Rectorràgia					
7. Disfonia d'origen incert		16. Restrenyiment					
8. Dispèpsia persistent		17. Sagnat vaginal postmenopàusic					
9. Dolor inusual		18. Símptomes del tracte urinari inferior					
10. Hematúria		19. Tos					

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1. Indiqueu quin tipus de presentiment heu tingut en acabar aquesta consulta. Si no podeu respondre-hi en aquest moment, contesteu les 9 preguntes següents. Al final del qüestionari es repeteix aquesta pregunta.

☐ Alguna cosa no va bé en aquest pacient. ☐ Tot encaixa. ☐ No hi puc contestar, o no escau.	Completament en desacord	En desacrod	Nis'acord ni en desacord	D'acord	Completament d'acord
2. Tot quadra. Em semto segur amb el meu pla d'actuació i/o el possible resultat.	□1	□2	□3	□4	□5
3. Alguna cosa no quadra. Em preocupa l'estat de salut d'aquest pacient.	□ 1	□2	□3	□4	□5
<ol> <li>En aquest cas sospesaré algunes hipòtesis provisionals amb resultats potencialment greus.</li> </ol>	□ 1	□2	□3	□4	□5
5. Tinc una certa inquietud perquè em preocupa la possibilitat d'un resultat desfavorable.	□1	□2	□3	□4	□ 5
6. Aquest cas requereix una actuació especifica per evitar subsegüents problemes greus de salut.	□1	□2	□3	□4	□5
7. La situació d'aquest pacient em dona motius per concertar una visita de seguiment o una derivació a l'atenció especiatlizada abans de l'habitual.	□1	□2	□3	□4	□5

8. En quins diagnostics esteu pensant? (màxim 3). Escrigui amb majúscules

#### 9. Quin pla d'actuació heu triat? (marqueu una sola resposta).

□ No prendre mesuras encara, mantenir una actitud expectant.

□ No prendre mesures encara, però aconsellar al pacient que torni si el problema persisteix.

D No prendre mesures encara, però concertar amb el pacient una visita de control presencial o telefònica.

Demanar proves complementàries (analítiques, radiografies, etc).

Demanar proves i menstrentant iniciar tractament (medic o d'una altra mena).

□ Iniciar tractament sense concertar seguiment.

□ Iniciar tractament i recomanar al pacient que torni si el problema persisteix.

Iniciar tractament i concertar amb el pacient una visita de control presencial o telefònica.

Derivar el pacient.

#### 10. Quin diagnòstic ha motivat el pla d'actuació que heu pres?

-	_			_			_						-		

11. Aquesta pregunta és la mateixa que la primera.Si ja l'heu contestat no heu de tornar a fer-ho. Indiqueu quin tipus de pressentiments heu tingut en acabar aquesta consulta:

Alguna cosa no va bé en aquest pacient.

Tot encaixa.

□ No hi puc contestar, o no escau.

