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Exploring the Use of a Participative Design in the Early Development of a Predictive Test: The Importance of Physician Involvement

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Abstract
In this study, we contribute to the personalized medicine and health care management literature by developing and testing a new participative design approach. We propose that involving gastroenterologists in the development of a predictive test to assist them in their clinical decision-making process for the treatment of inflammatory bowel diseases will increase the likelihood of their acceptance of the innovation. Based on data obtained from 6 focus groups across Canada from a total of 28 physicians, analyses reveal that current tools do not enable discriminating between treatment options to find the best fit for each patient. Physicians expect a new predictive tool to have the capability of showing clear reliability and significant benefits for the patient, while being accessible in a timely manner that facilitates clinical decisions. Physicians also insist on their key role in the implementation process, hence confirming the relevance and importance of participative designs in personalized medicine.

Introduction

Personalized medicine is expanding quickly. In the last decade, it has grown to become an essential topic for physicians, health care organizations and the public [1–4]. Since this expression is singularly widespread, Redekop and Mladsi [4] reviewed its various occurrences since its first reference by Gibson [5] to propose the following definition: "the use of the combined knowledge (genetic or otherwise) about a person to predict disease susceptibility, disease prognosis, or treatment response and thereby improve that person's health." This rationale underscores the fact that medicine was mindful of individual factors in clinical decision making well before genetic information was available. Recent developments such as the Human Genome Project have allowed personalized medicine to take one step further by enabling medicine to find the "therapy with the right drug at the right dose in the right patient" [6] . Such personalized medicine has great potential and is expected to contribute to improving health care management and reduce societal costs [7].

Genetic testing is now a key element of modern personalized medicine. The "treatment fit" that pharmacogenomics facilitates is beneficial for the patients, who may avoid the side effects of many treatments, as well as for health care systems, which do not have to cover the costs of ineffective therapies. Availability of such testing has grown rapidly in the last decades [8]. However, many

physicians report their unfamiliarity with pharmacogenomics testing and its role in therapeutic decision making [9, 10] . Taber and Dickinson [8] even observed confusion about the purpose of pharmacogenomics testing and the process of test ordering and interpretation. This lack of clarity concerning the process and value of predictive tests may deprive patients from technologies that may benefit their health as well as societies from practices that could assist their financial performance as a whole. Even though the decision of listing the tests or not for reimbursement is taken upstream, the physicians are those ultimately responsible for their transfer into patients' clinical decision making [11]. There is a need to understand the reasons for which physicians do not currently fully take on pharmacogenomics.

Clinical practice guidelines are common exercises destined to help health care providers by synthesizing the literature on health care management practices, such as predictive testing, into specific recommendations for care [12]. Najafzadeh et al. [13] hinted that the lack of clinical guidelines and protocols on the use of genomic tests are a key issue in health care management. According to DiMagno et al. [14], the implementation of the same guideline recommendations is variable among physicians. This "evidence-to-care" gap highlights the need for better knowledge of other potential translation strategies.

An excellent example of this aforementioned gap is the treatment of inflammatory bowel diseases (IBD). Rocchi et al. [15] argued that, as part of chronic diseases, IBD is highly amenable to personalized medicine since it represents one of the best-described common diseases from a genetic standpoint. These represent "a group of disorders that cause segments of the gastrointestinal tract to become inflamed and ulcerated. An abnormal response of the body's immune system plays a role in each of the two main forms of IBD: Crohn's disease (CD) and ulcerative colitis (UC)" [15]. Several drugs are available to treat IBD. However, physicians are currently unable to predict which drug would be the most effective for a given patient. As an example, for some biologic therapies such as anti-TNF agents, studies show that up to 2 out of every 5 IBD patients will not respond [16, 17]. Distinguishing patients that respond to biologics from nonresponders would lead to improved therapeutic response rates, better clinical and endoscopic outcomes, less tissue damage (hence reducing the need for surgery), and a decrease in societal costs due to a lack of patient productivity. Even though pharmacogenomics looks promising by using a predictive test in such cases, development of such an innovation would be useless if specialized health care actors, including in particular the treating physicians, do not adopt it in their daily routines.

Plainly, clinical practice guidelines alone have not proven to be the most effective way to entice physicians to use predictive tests. The present study attempts another promising path to involve physicians in the implementation of an innovation such as predictive testing. Known as participative design (PD), this approach has been the focus of ongoing research in different streams of innovation management, marketing, and design for the past 45 years in Europe and America [18]. Briefly, based on the general theory of co-creation, PD is a specific type of approach that favors a high involvement of stakeholders in the design and outcomes of innovations. In addition to the benefits associated with an improved implementation rate, one reason behind the choice of this type of design is that while many current studies investigate the properties of innovations in personalized medicine, the vast majority of these studies are strictly empirical in nature and are not grounded in a solid theoretical background that makes room for generalizations. Such a theoretical background in innovation management would be most helpful and relevant to make sense of the voluminous empirical literature that questioned doctors about what they would like out of personalized medicine and the conditions that would help them fully incorporate these tools into their current practice.

Purpose of the Study

The purpose of this study is to involve physicians in the PD of a genetic predictive test for the treatment of IBD. Specifically, its goal is to answer the following question: How can research and

development teams co-create a predictive test with gastroenterologists to assist their clinical decision making for the personalized treatment of IBD?

In order for physicians to propose the most important design features for them, they first have to verbalize their current practice to help them point to the gaps they see between what they have and what they need. These gaps represent the first step in a PD that will ultimately result in the adoption of a genetic predictive test that will facilitate clinical decision making for the treatment of IBD. In accordance with this approach, the objectives of this study were as follows:
1. To understand the current practices leading to a therapeutic decision for an IBD
2. To learn about physicians' perceptions and level of satisfaction with current practices
3. To investigate physicians' expectations towards characteristics of a genetically based predictive test that could assist them with personalized treatment decision making

The paper is organized as follows: First, the literature on innovation management, clinical decision making, and personalized medicine is reviewed. This paper argues that limitations concerning the latter 2 objectives can be addressed through a PD and subsequently proposes an integrated model for this study. Second, the method is presented and discussed. The results of the study, supported by relevant quotes by the participants and tables summarizing the coding process outcome, are then presented. Lastly, implications for theory and practice are discussed in the concluding sections.

Theoretical Background

The subject of this study, namely the exploration of a PD approach for predictive testing, requires a conceptual framework located at the junction between innovation management and health care management. First, the PD will be positioned among the several streams of research on innovation management as a type of participative innovation, which in turn is a type of co-creation in the global field of the innovation process. Issues surrounding current clinical decision-making processes of physicians, generally and in the context of personalized medicine, will be developed and linked with the potential benefits of a PD.

An integrated PD model applied to physician's clinical decision making for personalized medicine summarizes and concludes the theoretical background of this study.

Innovation Process

Pharmacogenomics are relatively innovative in their nature. Lee et al. [19] defined innovation as "any new idea or approach that is applied in fundamentally different ways to create value for the organization and other stakeholders such as customers, suppliers, partner organizations, communities, governments, or even general good of humanity. Thus, innovation is directly tied to value creation" [19]. Value creation can take many forms, but in the current framework of health care management, we have chosen to follow the definition of Porter [20] : "Achieving high value for patients must become the overarching goal of health care delivery, with value defined as the health outcomes achieved per dollar spent. This goal is what matters for patients and unites the interests of all actors in the system. If value improves, patients, payers, providers, and suppliers can all benefit while the economic sustainability of the health care system increases."

There are many paths to innovations that may create value in health care systems [19]. However, due to the main influence of physicians in the provision of care for patients, a co-creation process was integrated in this study to ensure their involvement in the development and success of the innovation.

Co-Creation

Co-creation is broadly defined as "the creation of value by consumers" [21]. While consumer involvement in the innovation process has been occurring since the 1970s, mainly in Scandinavia, the approach has significantly grown in the last decade to include a variety of forms and labels. This

approach is based on a democratic process of dedicated activity that takes people's practices and needs as a starting point to generate business opportunities in the form of products and services. These opportunities are developed through an ongoing collaboration between the people that they address and the companies in charge of their realization [22]. Participative innovation is the general philosophy behind two streams of research, namely, PD – as developed in Scandinavia – and a more recent American trend: co-design. This latter trend is meant to help researchers, designers, and users to jointly make things that include items such as sketches, mockups, or prototypes. Since the development of predictive tests is less likely to emerge from the co-design approach, the present project was based on the long-standing Scandinavian PD approach.

Participative Design

As part of a co-creation approach, PD attempts to bridge the gap between researchers, designers, and users by organizing cooperation among them [18, 23]. Ideally, users are involved from the beginning of a venture as well as during its iterations, and they contribute dynamically and creatively in a multidisciplinary setting [22]. PD arose as a way to address the issue that designers of technologies often knew very little about the end users' work and practice circumstances. It was also a means of guaranteeing that technologies supported and improved end users' knowledge and skills rather than redefining people's trades through the introduction of new technologies into their workplace. However, in order to ensure that PD can be efficiently implemented, information must flow easily between the developers and the adopters of innovation; such a process reduces the cost as well as time and risk inherent to innovation diffusion. PD is, therefore, a design approach, which is different from other approaches such as market research in which users are only invited to evaluate a finished product. The early involvement of users has positive effects on both system success and user satisfaction [24].

Health care management literature also refers to the involvement of stakeholders. As previously stated, physicians are the gatekeepers between the innovations of personalized medicine and patient care. It is expected that the PD approach could fill some of the "evidence-to-care" gaps between guidelines and the actual care given to patients reported in the health care management literature.

Clinical Decision Making

Literature in health care management highlights many factors that influence the clinical decision-making process of a physician as well as those that could motivate a change in this process. The theoretical basis for change in clinical practice among physicians when selecting a test or a treatment can be grouped into the following 4 components: organizational context; patient factors; physician factors; and evidence-based medicine. First, Sanders et al. [25] highlighted the importance of coherence between organizational and interpersonal factors that may help explain the dynamics of implementation. Other environmental factors, such as the impact of availability of diagnostic tools in remote areas [26] and the remuneration system [27], influence physicians' decisions. Then, the process of clinical decision making in the context of personalized medicine underscores the essential role of patient factors, such as quality of life, education, and communication [28–32].

Also important are the organizational and individual factors, as the decision over clinical decision making ultimately resides in the physicians' hands. Research shows that the physicians' education and experience both influence their decision-making process, including their adherence to practice guidelines [13, 33–35]. Empirical findings on test adoption by physicians highlight specific issues to consider while introducing such innovations [36–39]. The development of a predictive test through PD building on the physician's experience and involving them in evidence-based medicine is likely to encourage them to incorporate this tool into their practice. To the best of the authors' knowledge, such an approach has yet to be attempted in the context of an empirical study.

Personalized Medicine

Physicians generally recognize the need to personalize their treatments to the characteristics of their patients [2]. However, as stated above, there are several barriers to the complete integration of personalized medicine into general practice. Studies conducted in Canada by Najafzadeh et al. [13, 40] concluded that the nature of the genetic tests and their availability, the training and guidelines surrounding genetic testing and the issues surrounding the complexity of gene expression and validity of genetic tests, represent the major concerns of physicians concerning the implementation of pharmacogenomics as part of their clinical practice. Wideroff et al. [41] used the results of a national survey in the United States to determine the prevalence of using cancer susceptibility tests by physicians and to assess demographic variables associated with their use. They suggested that the validity of the test, confidentiality, and affordability are among the most prevalent concerns about genetic testing. Finally, Suther and Goodson [42] illustrated how physicians' perceptions about the characteristics of genetic tests influence the likelihood of adopting genomic medicine in their practice. They reported that the barriers identified most frequently in their literature review were inadequate knowledge of basic genetics; lack of detailed or updated family histories; lack of confidence; and lack of referral guidelines. The present study aims to find an approach to remove most of the barriers to the adoption of a predictive test listed above in the context of IBD treatment and management. PD goes beyond simply investigating the obstacles of personalized medicine. As shown in Figure 1, this study proposes that allowing physicians to mobilize their current practices leads them to identify their primary needs and expectations concerning their clinical decision making and, consequently, their decision whether to utilize predictive testing (Fig. 1).

Methodology

Study Design

The present study is part of a larger research project on IBD including both UC and CD in Canada. Its goal is to deepen the understanding of the physician treatment decision-making process in order to maximize the integration of predictive tests that might be developed to personalize IBD patient care. With such a goal, it is considered an exploratory study for which a focus group method is appropriate [43] to reveal the characteristics of the "evidence-tocare" gap and to encourage the emergence of the ideal characteristics of the tools and medical practice through interactions among participants. The focus group methodology involves engaging a small number of people in informal group discussions, focused around a particular topic or set of issues [44]. The informal nature of this method, as compared to questionnaires, creates a less intimidating situation and a freedom that emboldens participants to be more forthcoming [45] as well as to explore matters that the participants recognize as significant [46]. Overall, focus groups enable a collaborative discussion and reflection that is difficult to accomplish by other techniques [47]. Additionally, physicians are used to working in groups, and enabling discussions in circumstances with which they are familiar may allow them to express themselves more extensively about the issues and their opinions on the topic at hand.

Participants

An estimated 233,000 Canadians suffer from IBD (UC =104,000 and CD = 129,000), which would rank Canada among the countries with the highest IBD rates in the world. There are 765 gastroenterologists in Canada treating patients suffering from these diseases [48]. The data were collected from gastroenterologists to identify the perceptual gap between the current treatment selection process and the potential use of a genetic predictive tool to assist them in their decision regarding personalized treatment.

In order to reach the targeted physician population, the organizers of two major gastroenterology conferences were contacted, namely the Canadian Association of Gastroenterology and the Québec Association of Gastroenterologists. They sent their members an invitation and follow-up reminders to participate in our study during their annual meeting. Respondents were then asked to help organize a focus group with their local colleagues in their hometowns. Even though qualitative studies do not

require the sample to be representative [49] , every effort was made to ensure a diversity of physicians in terms of province of origin, years of experience, and gender. However, the gastroenterologists were all invited, and participation was on a volunteer basis. Six focus group interviews that included a total of 28 gastroenterologists were held. The characteristics of the participants are presented in Table 1.

Interviews and Data Collection

An interview guide for the focus groups was drafted, as summarized in Table 2. Discussions lasted approximately 60 min and covered the following themes: the treatment decision-making process, perceptions of current clinical guidelines and available tests, as well as perceptions toward genetic tests. Each group session was led by one moderator accompanied by a research assistant who covered each of the themes in the interview guide, which concluded with final reflections and a summary of our impressions. Each focus group interview was recorded, anonymized, and subsequently transcribed by a professional bilingual transcription firm.

Ethics

Based on the approval and recommendations from the researchers' university ethics committees, all relevant documentation was sent to potential participants of the study prior to the focus group sessions during the recruitment phase. At the start of each focus group session, the participants were informed on the project in accordance with the focus group interview guide, as shown in Table 2. They were also given a printed document that included information on the aim of the study, anonymity issues, and a field for signing an informed consent. The focus group sessions only proceeded forward once all participants had agreed to participate in the study.

Data Analysis

The focus group discussions were recorded, and then transcribed and verified by an external resource. Then, a tree node using the different categories brought up by the operational framework was developed in order to allow for uniform coding by the research team members and to ensure internal validity with the QDA Miner software. The individual coding process involved detailed coding of the text segments (meaning units), followed by the coding of related meaning units (*i.e.*, categories) and related categories (*i.e.*, themes) [44, 47, 50]. Two individuals from the research team coded them verbatim in line with the preestablished tree node. A cross-verification of the coding was done to ensure neutrality and similarity.

Results

A total of 28 gastroenterologists participated in our study (Table 1). Among these participants, men outnumbered women by a ratio of more than 3: 1, which somewhat accurately reflects the overall gender distribution among Canadian gastroenterologists (71% male and 29% female) [48]. Given that the provinces of Nova Scotia and Saskatchewan have only a few gastroenterologists (23 and 13, respectively), this distribution is represented in our study (1 and 2, respectively). The higher number of participants from British Columbia, Québec, and Ontario also reflect the relative proportion of gastroenterologists in those provinces (72, 224, and 272, respectively). All but 2 participants in our study were certified Fellows of the Royal College of Physicians of Canada (1 non-Fellow MD and 1 PhD), which is consistent with the numbers (100%) reported for the overall population of gastroenterologists. All of the participants were affiliated with a public hospital, clinic, or health science center (the participant with the PhD was a researcher), which is representative of the overall population of gastroenterologists (91%). In terms of age distribution, the majority of the participants (37%) were in the 35- to 44-year age bracket, 32% were aged 55 years and over, and 21% were between 45 and 54 years of age. Thus, most of the characteristics of our sample were, therefore, representative of the overall population of Canadian gastroenterologists.

Physicians are in the best position to discuss their own practice, and the tools they deem most appropriate to assist them in their clinical decision making. In accordance with a PD approach, the

discussions allowed the participants to initially go over the daily issues associated with the treatment of IBD and the current tools available to facilitate their decision-making process. Missing tools and gaps in knowledge emerged from these discussions, and gastroenterologists were given the opportunity to align these gaps with what they considered to be the essential characteristics of a predictive test designed for the treatment of IBD.

Current Practice among Canadian Gastroenterologists concerning IBD Treatment Decision Making
Current practice among Canadian gastroenterologists in IBD treatment decision making generally includes two approaches. The first is the traditional approach to the treatment decision-making process, which follows the standard treatment escalation pyramid, as described in the following quote from a participant:
"…there's a step-wise approach [in which] efficacy and safety are probably inverse, so the less effective, the safer it is, within reason. It's how severe and therefore, whereabouts on the ladder you can start and how quickly you need to do something. That'll determine how far you jump in. Generally, one's not going to go straight to biologics, unless somebody has a severe form of colitis…" (OH6)

In some circumstances, physicians can also choose to accelerate the progression on the treatment pyramid, as the following quotes from participants show: "IBD patients are such a huge spectrum that they don't always fit nicely into one little... […] the guidelines are good general things to have there but don't provide answers […] It's more complicated than that." (SK5)

"Today, we know that the more that you wait for this kind of patient to initiate a biological agent, the more you risk obtaining a response that is not as perfect as if you had been ready from the start. […] Today, though, we have a more proactive approach then it's more... Each patient is unique, but we know this kind of patient there, we must act quickly." (QQ1)

While the traditional stepwise approach is favored in the official guidelines, there is a growing recognition that the second approach, personalized care, yields better results than a "one-size-fits-all" tactic. However, personalized medicine requires individualized information that is not yet available for some aspects of the disease. Another element concerns the current gap in knowledge and practice experienced by physicians regarding missing tools, both in terms of optimizing treatment effectiveness and eliminating ineffective treatment options, as the following quotes suggest: "It's just all over the place. It's just really hard to tell, and I don't think these other tests tell us. Even when we have the whole colon out, they get it wrong." (BV4)

"Each time we choose, we think of the right molecule, but also the patient is exposed to risks. If, from the start, we knew that you did not need to run that risk and to seek more benefits, then for sure that is the dreamed tool there." (QQ1)

"We have certain tools like TPMT that can judge the risk of an agent. We don't have any diagnostic tools that can tell us the chance of an agent working better than other. We have no prognostic factors for how effective these agents will work." (BV4)

The participants were generally confident in their arsenal of treatment options and trusted their judgment in choosing to follow the standard treatment escalation or to accelerate the progression in more severe cases. What emerged as missing in their daily practice are tools that could help them choose the best treatment for each patient, and enable them to avoid both the dangers of undertreating the disease thereby letting the condition deteriorate, and the dangers of overtreatment that would expose patients to inappropriate treatments and long-term side effects. Table 3 presents all aggregated meaning units for the first theme identified above.

Satisfaction toward the Current Use of Available Predictive Tools

The second theme relates to the questions as to if and how physicians use the currently available predictive tools to personalize their treatment and management of IBD patients (imagery, serology, and thiopurine methyltransferase [TPMT] levels). The first and second subthemes on this subject relate to the issues of accessibility and turnaround time referred to in the following excerpts: "It all comes down to an accessibility issue; it's an issue of cost, really. If you have easy access and it doesn't cost that much, you'll use it much more often than in much more different circumstances. When it's limited, then we pick and choose what situations will help them the most. In our center, we can get it, but it's a bit of a hassle to get." (OT2A)

"The challenge with us is the turnaround. We order the test, but we actually don't get it for a few weeks, so often it's not in a time frame that's helpful. We have to make a decision to start therapy. It adds another layer of complexity of... you have to give them a call back to get the result before they start the medication. Sometimes it gets bypassed for that reason." (OT2A)

The analysis of the discussions highlights inconsistencies regarding current tests in terms of availability, cost, and coverage as well as issues arising from the delays before the results can be interpreted. If the information is not received in a timeframe that is useful for the patient, the return on the financial investment made on the development and ordering of the tests is significantly diminished. The third subtheme concerning the physicians' satisfaction toward the current use of available predictive tools specifies the main reasons for which physicians order the tests, such as standard of care, patient loss of response, and treatment optimization. The actual integration of the said tests in treatment decision making emerges as an issue, as the following quotes indicate: "If you do have a normal result, you'd just typically start with a full dose rather than having to do the 50 milligrams for two weeks and then go up. That's one of the advantages of having the ability to do the test, so you get off the bat." (OT2A)

"It should be a standard of care when a patient has lost response to tell you what to do next because you have some very expensive and very potentially important decisions to make then." (OT3B)

"It's almost like malpractice in our circles if you don't order it, but the reality is, it's actually quite rare that we act on it. Occasionally, we'll have some TPMT levels that suggest the person may be a heterozygote for the gene, but for the most part, I find that we function pretty much the way we always used to. Correct me if I'm wrong, but I think it's extremely rare that we modify our prescription based on the test." (OT2B)

One can see from the preceding quotes that even when physicians order tests as part of their standard of care, there can be underlying issues that lead them to not consider the results of the test in their clinical decision making, thereby invalidating the initial investment. These core issues resound with the last subtheme, which concerns the reasons for which physicians do not order tests that may predict response to treatment or incorporate them into their practice, as evidenced in the following quotes: "They [serologic test, ANCA and ASCA] tend not to distinguish the people you need to distinguish." (BV4)

"They're not sensitive and specific enough to warrant its use." (OH6)

"[…] we have to come up with criteria to see in what instances it is going to actually make a difference because if it's not going to make a difference, there's no point in doing the test. And that's an expensive test." (BV4)

”Yeah, but I would not just say that, ‘we have no time to read the studies’: we don’t have the knowledge or the training at the university to read the studies. At […] University, they didn’t train us to read the studies properly, to make a critical analysis, to understand the meaning of a study.” (QQ1)

Based on the above, there appear to be many issues surrounding the current use of predictive tests; some are bound to the conditions surrounding the tests per se, and some are related to the nature of the test. A test that is accurate and reliable but not covered by public health care or that takes too long to produce results is less likely to be ordered. Along the same lines, a test that is cost-effective and has a quick turnaround time, but is associated with reliability issues, is also less likely to be fully incorporated into current practice. Some specific characteristics are needed in order for physicians to use predictive tools in a way that would be useful to them and to provide personalized care for IBD patients. Table 4 presents all aggregated meaning units for the second theme described above.

Ideal Characteristics of a Predictive Test

The final theme relates to the ideal characteristics and implementation conditions of any new predictive tool in the care of IBD patients. The first subtheme refers to the characteristics of such a tool and raises concerns about reliability, accessibility, real impacts on the patients’ health care, and user friendliness, as described in the following quotes: “It should be reliable, particularly. That would be the number one thing. If it really is going to be a test that will tell me that this patient will respond to anti-TNF or not, or any other choice, that certainly would be something that I would be very keen to use. Is it going to be something very helpful? Is it reliable?” (OT2A)

“Yes, in the ideal world, if you had three different pathways, if it would actually give you a likelihood not just for one pathway, but for all three pathways, so you could compare them. At the end of the day, that would be the most useful.” (OT2A)

“And it only cost $50. And if you could tell us by the end of tonight…” (BV4)

“Ultimately, if you have a new tool, it would be great to integrate it with other clinical markers that we already have, so that it’s not just learning a tool in isolation. Maybe there’s a scoring system for the tools’ importance.” (OT2A)

These quotes underscore the importance not only of the relevance and reliability of the test, but also of its efficient integration as part of the tools and procedures that are already known and used. Cost and availability represent serious issues to consider, but if the test is reliable and easy to use, most physicians will incorporate it in their standard of care. The second subtheme refers to ideal conditions in which physicians could learn about the tool and how it can be implemented into their current practice. Issues of physician involvement, endorsement, and knowledge transfer are emerging as prominent, as the following quotes show: “Reasonable framework, which you then have to have the knowledge and the experience to build on. I think what would help for a lot of that is being able to build on the experience we have, because what we all do is build individual experience, which is, to some extent, specific to the patients that we’ve seen.” (OH6)

“From my point of view is that the evidence then is translated into something of a guideline and guideline endorsement by a respectable agency, and then bring out the algorithm for management and if it can be included in that, then I think it will be applicable to many people who just don’t know the details and so on, but who control the recommendations of management.” (OT3B)

“Yeah, because, you know, this work, by successfully doing this, you will actually have publications. So that will be the first step that comes out, and then presentations at meetings, and going more locally to make sure that whoever didn’t get to the meetings and missed that month’s article gets to hear about it. It’s gonna be a stepwise process.” (BV4)

"It's always nice if it comes from our peer group. It has to be delivered by the medical community. […] I think we listen to the leaders. The simpler the flow chart or the algorithm the better it is." (SK5)

Based on the above, the construction of any new predictive tool would have to build on the weaknesses identified in current predictive tools, and be endorsed both by a well-designed controlled clinical trial and a reputable agency, as well as by peers and key opinion leaders, and published in trustworthy journals and conferences, in order to help physicians understand their utility in their management of IBD disease. Table 5 presents all aggregated meaning units on this last theme identified above.

Discussion

Participative Design

Since results show that physicians want to be involved in the development and integration of a test that may predict response to treatment, PD proves to be a relevant approach to involve physicians in the success of an innovation in personalized medicine. Even though earlier studies highlighted some of the issues raised by the physicians in the present study [13, 40–42, 51, 52] , none of these appear to reach beyond a strict description rooted in a broader theoretical and methodological design. Among the most commonly cited barriers to implementation in the present study, as well as in previous publications, are the lack of evidence-based guidelines, conviction in the validity of the test, and training. By involving physicians at the beginning of the development of a predictive tool led by a consortium of researchers, physicians are thus reassured that the developed test will take into account the issues that are relevant to them as well as the identified ideal characteristics. They will become experts on the matter and be able to train their colleagues with regard to its relevance in their practice. They will promote the innovations and find themselves in a key trustworthy position to fill the gap between the development of evidence-based guidelines – in which they will have been involved – and the provision of care in which they also have high stakes.

Clinical Decision Making and Personalized Medicine

The results of the present study are consistent with the health care management literature and clarify the four categories of factors that influence the clinical decision making process of physicians in the specific case of personalized medicine: the organizational context, patient factors, physician factors, and evidence-based medicine.

The perspectives of the clinicians interviewed regarding predictive genetic testing were mostly unanimous and complementary. No regional or gender-related trends were observed. However, since health care in Canada is managed at the provincial level, provincial test reimbursement policies influence and may account for regional differences in the use of a test. As stated above, the involvement of physicians in the development of a predictive test helps to fill the gap between clinical guidelines and actual practice in personalized medicine. As suggested by Najafzadeh et al. [13, 40] , along with the high rate of progress in genomic technologies as well as their emerging clinical applications, the need for more recent information is unavoidable; rapid developments in the field may have modified physicians' perceptions, experiences, and views about pharmacogenomics.

The present findings thus reinforce the factors highlighted by previous studies concerning the barriers to the implementation of personalized medicine by physicians in gastroenterology, albeit in Canada at the present time, thereby contributing to the growing body of knowledge in this field. The present study also contributes to the academic field of innovation management by adding pharmacogenomics as a new field of application. Although the characteristics thus far identified have been incorporated into the larger study in which the test will be developed, the development of this test has yet to be completed. Given that, to the best of our knowledge, no other model features this type of integration in other situations, this represents an initial exploratory step that we must further develop as part of future research. The approach used in this study proposes concepts that can be applied to other health technology development contexts. Physicians must, and indeed wish to, be involved in order to

identify key characteristics to complement the currently available tools. They should also play a key role in transferring knowledge to their colleagues to gain their trust. Their participation throughout the process will facilitate the adoption of the predictive test and avoid the costs of going back to R&D to modify test characteristics to meet needs that were not expressed without their involvement.

Conclusion

The present study is relevant to several stakeholders who are involved in both innovation and health care management. Analyzing the topic of personalized medicine implementation is of great importance, first for firms involved in the development of pharmacogenomics as it increases the likelihood that their products will be ordered and used by physicians, and hence their return on investment in the development of these tools. Their products and services will be better suited to the reality of physicians by having the desired characteristics. Therefore, physicians will be more likely to routinely order the product with which they have been involved since the early development stages.

This is an exploratory study in which we seek to deepen the understanding of the physician treatment decision-making process, in order to maximize the integration of predictive tests that may potentially be developed to personalize IBD patient care. It should be interpreted within the context of certain limitations. First, it focuses on a speciality field of medicine and specific diseases in a single country. While the data collected as part of this study clearly illustrate the perspectives of the clinicians interviewed regarding predictive genetic testing, the extent to which the present findings may be applied to understanding personalized medicine requires a broader assessment.

Second, given that focus groups are considered qualitative studies, the samples are generally rather small. Moreover, research relying upon the perspectives of physicians is particularly challenging given their limited availability [53]. Notwithstanding the limited representativeness of the sample, we are nevertheless confident that the results of our exploratory study provide useful insights. The depth of the discussions achieved using the focus group approach, as well as the number of common mutual issues that were discussed regarding several themes, revealed general agreement among participants. More research through longitudinal and quantitative studies will be needed in order to further address how PD could benefit personalized medicine. Insights from other stakeholders such as health technology assessment bodies should also be included. Future research should also explore the patients' perceptions of such predictive tools as well as issues associated with knowledge transfer aimed at implementing pharmacogenomics testing into clinical settings. Pharmacoeconomic studies could highlight the costs and benefits of such a technology in terms of monetary value, efficiency, as well as enhanced quality of life for the patients.

Appendix

iGenoMed Consortium Members

The active members at the time of the present study were (in alphabetical order): Alain Bitton, MD (McGill University Health Centre); Gabrielle Boucher, MSc (Institut de cardiologie de Montréal); Mijanou Bourque Bouliane, MSc (Université Laval); Mélanie Burnette, MSc (Institut de cardiologie de Montréal); Rita Cohen, PhD (McGill University Health Centre); Guy Charron, PhD (Institut de cardiologie de Montréal); Christine Des Rosiers, PhD (Institut de cardiologie de Montréal, Université de Montréal); Anik Forest, Hugues Gosselin, Philippe Goyette, PhD (Institut de cardiologie de Montréal); Sabine Ivinson, PhD (Child & Family Research Institute, University of British Columbia); Lawrence Joseph, PhD (McGill University); Jean Lachaine, PhD (Université de Montréal); Geneviève Lavallée, MSc (Institut de cardiologie de Montréal); Sylvie Lesage, PhD (Université de Montréal, Hôpital Maisonneuve Rosemont), Guillaume Lettre, PhD (Institut de cardiologie de Montréal, Université de Montréal); Megan Levings, PhD (Child & Family Research Institute, University of British Columbia); Audrey Miron, MSc (Université de Montréal); Isabelle Noiseux, PhD (Université Laval) James Pan, PhD (University of Toronto), Alexandre Paradis, MSc (Université de Montréal, Hôpital Maisonneuve Rosemont), John D. Rioux, PhD (Institut de cardiologie de Montréal, Université

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The authors have no conflicts of interest to disclose.

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Références

1. Bates S: Progress towards personalized medicine. Drug Discov Today 2010;15:115--120.
2. Bonter K, Desjardins C, Currier N, Pun J, Ashbury FD: Personalised medicine in Canada: a survey of adoption and practice in oncology, cardiology and family medicine. BMJ Open 2011;1:e000110.
3. Conti R, Veenstra DL, Armstrong K, Lesko LJ, Grosse SD: Personalized medicine and genomics: challenges and opportunities in assessing effectiveness, cost-effectiveness, and future research priorities. Med Decis Making 2010;30:328--340.
4. Redekop WK, Mladsi D: The faces of personalized medicine: a framework for understanding its meaning and scope. Value Health 2013;16:S4--S9.
5. Gibson W: Can personalized medicine survive? Can Fam Physician 1971;17:29.
6. Mancinelli L, Cronin M, Sadée W: Pharmacogenomics: the promise of personalized medicine. AAPS PharmSci 2000;2:29--41.
7. Postma MJ, Boersma C, Vandijck D, Vegter S, Le HH, Annemans L: Health technology assessments in personalized medicine: illustrations for cost-effectiveness analysis. Expert Rev Pharmacoecon Outcomes Res 2011;11:367--369.
8. Taber KAJ, Dickinson BD: Pharmacogenomic knowledge gaps and educational resource needs among physicians in selected specialties. Pharmacogenomics Pers Med 2014;7:145.
9. Haga SB, Burke W, Ginsburg GS, Mills R, Agans R: Primary care physicians' knowledge of and experience with pharmacogenetic testing. Clin Genet 2012;82:388--394.
10. Stanek E, Sanders C, Taber K, Khalid M, Patel A, Verbrugge R, Agatep B, Aubert R, Epstein R, Frueh F: Adoption of pharmacogenomic testing by US physicians: results of a nationwide survey. Clin Pharmacol Ther 2012;91:450--458.
11. Korf BR, Berry AB, Limson M, Marian AJ, Murray MF, O'Rourke PP, Passamani ER, Relling MV, Tooker J, Tsongalis GJ: Framework for development of physician competencies in genomic medicine: report of the Competencies Working Group of the Inter-Society Coordinating Committee for Physician Education in Genomics. Genet Med 2014;16:804--809.
12. Shah BR, Bhattacharyya O, Yu C, Mamdani M, Parsons JA, Straus SE, Zwarenstein M: Evaluation of a toolkit to improve cardiovascular disease screening and treatment for people with type 2 diabetes: protocol for a cluster-randomized pragmatic trial. Trials 2010;11:1.
13. Najafzadeh M, Davis JC, Joshi P, Marra C: Barriers for integrating personalized medicine into clinical practice: a qualitative analysis. Am J Med Genet A 2013;161A:758--763.
14. DiMagno MJ, Wamsteker E-J, Rizk RS, Spaete JP, Gupta S, Sahay T, Costanzo J, Inadomi JM, Napolitano LM, Hyzy RC, Desmond JS: A combined paging alert and web-based instrument alters clinician behavior and shortens hospital length of stay in acute pancreatitis. Am J Gastroenterol 2014;109:306--315.
15. Rocchi A, Benchimol EI, Bernstein CN, Bitton A, Feagan B, Panaccione R, Glasgow KW, Fernandes A, Ghosh S: Inflammatory bowel disease: a Canadian burden of illness review. Can J Gastroenterol Hepatol 2012;26:811--817.
16. Ben-Horin S, Chowers Y: Review article: loss of response to anti-TNF treatments in Crohn's disease. Aliment Pharmacol Ther 2011;33:987--995.
17. Rutgeerts P, Van Assche G, Vermeire S: Optimizing anti-TNF treatment in inflammatory bowel disease. Gastroenterology 2004;126:1593--1610.
18. Sanders EB-N: From user-centered to participatory design approaches; in Frascara J (ed): Design and the Social Sciences: Making Connections. London, Taylor & Francis, 2002, pp 1--8.
19. Lee SM, Olson DL, Trimi S: Co-innovation: convergenomics, collaboration, and co-creation for organizational values. Management Decision 2012;50:817--831.
20. Porter ME: What is value in health care? N Engl J Med 2010;363:2477--2481.
21. Zwass V: Co-creation: toward a taxonomy and an integrated research perspective. Int J Electron Comm 2010;15:11--48.

22. Buur J, Matthews B: Participatory innovation. Int J Innov Mgt 2008;12:255--273.
23. Pals N, Steen MG, Langley DJ, Kort J: Three approaches to take the user perspective into account during new product design. Int J Innov Mgt 2008;12:275--294.
24. Kujala S: User involvement: a review of the benefits and challenges. Behav Inform Technol 2003;22:1--16.
25. Sanders T, Foster NE, Ong BN: Perceptions of general practitioners towards the use of a new system for treating back pain: a qualitative interview study. BMC Med 2011;9:49.
26. Blaivas M, Kuhn W, Reynolds B, Brannam L: Change in differential diagnosis and patient management with the use of portable ultrasound in a remote setting. Wilderness Environ Med 2005;16:38--41.
27. Munkerud SF: Decision-making in general practice: the effect of financial incentives on the use of laboratory analyses. Eur J Health Econ 2012;13:169--180.
28. Byrne C, Griffin A, Blazeby J, Conroy T, Efficace F: Health-related quality of life as a valid outcome in the treatment of advanced colorectal cancer. Eur J Surg Oncol 2007;33(suppl 2):S95--S104.
29. Muller-Schwefe G, Jaksch W, Morlion B, Kalso E, Schafer M, Coluzzi F, Huygen F, Kocot-Kepska M, Mangas AC, Margarit C, Ahlbeck K, Mavrocordatos P, Alon E, Collett B, Aldington D, Nicolaou A, Pergolizzi J, Varrassi G: Make a CHANGE: optimising communication and pain management decisions. Curr Med Res Opin 2011;27:481--488.
30. Myers RE, Weinberg DS, Manne SL, Sifri R, Cocroft J, Kash K, Wilfond B: Genetic and environmental risk assessment for colorectal cancer risk in primary care practice settings: a pilot study. Genet Med 2007;9:378--384.
31. Ronquillo JG: How the electronic health record will change the future of health care. Yale J Biol Med 2012;85:379--386.
32. Uzark K, King E, Spicer R, Beekman R, Kimball T, Varni JW: The clinical utility of health-related quality of life assessment in pediatric cardiology outpatient practice. Congenit Heart Dis 2012;8:211--218.
33. Cabrera-Pivaral CE, Perez IR, Gonzalez-Perez G, Barrios PO, Lopez CA: Clinical aptitude of family physicians to detect familial dysfunction in family medical units from Guadalajara, Mexico. Salud Mental 2006;29:40--46.
34. Izuora KE, Alazraki N, Byrd-Sellers J, Tangpricha V, Nanes MS: Fracture assessment tool risk scores in bone density reports do not change physician prescribing behavior for osteoporosis. Am J Med Sci 2011;342:5--8.
35. McClave SA, Jones WF, Evans WB: Do physician attitudes and practices limit use of EUS in the staging and the treatment of esophageal carcinoma? Gastrointest Endosc 2005;61:840--848.
36. Ciardiello F, Tejpar S, Normanno N, Mercadante D, Teague T, Wohlschlegel B, Van Cutsem E: Uptake of KRAS mutation testing in patients with metastatic colorectal cancer in Europe, Latin America and Asia. Target Oncol 2011;6:133--145.
37. Li WY, Sasso EH, Emerling D, Cavet G, Ford K: Impact of a multi-biomarker disease activity test on rheumatoid arthritis treatment decisions and therapy use. Curr Med Res Opin 2013;29:85--92.
38. Rosen R, Hart K, Nurko S: Does reflux monitoring with multichannel intraluminal impedance change clinical decision making? J Pediatr Gastroenterol Nutr 2011;52:404--407.
39. Tiernan JF, Gilhooley S, Jones ME, Chalmers JD, McSparron C, Laurenson IF, Hill AT: Does an interferon-gamma release assay change practice in possible latent tuberculosis? QJM 2012;106:139--146.
40. Najafzadeh M, Lynd LD, Davis JC, Bryan S, Anis A, Marra M, Marra CA: Barriers to integrating personalized medicine into clinical practice: a best-worst scaling choice experiment. Genet Med 2012;14:520--526.
41. Wideroff L, Freedman AN, Olson L, Klabunde CN, Davis W, Srinath KP, Croyle RT, Ballard-Barbash R: Physician use of genetic testing for cancer susceptibility results of a national survey. Cancer Epidemiol Biomarkers Prev 2003;12:295--303.

42. Suther S, Goodson P: Barriers to the provision of genetic services by primary care physicians: a systematic review of the literature. Genet Med 2002;5:70--76.
43. Patton MQ: Qualitative Research and Evaluation Method, ed 3. Thousand Oaks, Sage, 2002.
44. Wilkinson S, Joffe H, Yardley L: Qualitative data collection: interviews and focus groups; in Marks D, Yardley L (eds): Research Methods for Clinical and Health Psychology. London, Sage, 2004, pp 39--55.
45. Hammersley M, Atkinson P: Ethnography: Principles in Practice. London, Routledge, 2007.
46. Kontos PC, Naglie G: Tacit knowledge of caring and embodied selfhood. Sociol Health Illn 2009;31:688--704.
47. Høyland S, Haugen AS, Thomassen Ø: Perceptions of time spent on safety tasks in surgical operations: a focus group study. Safety Science 2014;70:70--79.
48. Canadian Association Medical: Gastroenterology Profile https://www.cma.ca/Assets/assets-library/document/en/advocacy/Gastronenterology-e.pdf (accessed May 3, 2017).
49. Marshall MN: Sampling for qualitative research. Fam Pract 1996;13:522--526.
50. Strauss A, Corbin J: Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory. London, Sage, 1998.
51. Levy DE, Youatt EJ, Shields AE: Primary care physicians' concerns about offering a genetic test to tailor smoking cessation treatment. Genet Med 2007;9:842--849.
52. Freedman A, Wideroff L, Olson L, Davis W, Klabunde C, Srinath K, Reeve B, Croyle R, Ballard-Barbash R: US physicians' attitudes toward genetic testing for cancer susceptibility. Am J Med Genet A 2003;120:63--71.
53. Klabunde CN, Frame PS, Meadow A, Jones E, Nadel M, Vernon SW: A national survey of primary care physicians' colorectal cancer screening recommendations and practices. Prev Med 2003;36:352--362.

Table 1. Characteristics of participants (*n* = 28)

	Participants (*n* = 28)		Canadian gastroenterologists (*n* = 765)	
	n	%	*n*	%
Province				
Québec	9	32	224	29
Ontario	6	21	272	36
British Columbia	10	36	72	9
Saskatchewan	2	7	13	2
Nova Scotia	1	4	23	3
Gender				
Male	22	79	543	71
Female	6	21	222	29
Training				
FRCPC[1]	26	93	765	100
Other	2	7	0	0
Practice				
Public hospital	27	96	696	91
Other	1	4	69	9
Age				
<34 years	4	14	77	10
35–44 years	7	25	283	37
45–54 years	8	29	161	21
55–64 years	8	29	153	20
>65 years	1	4	92	12

[1] Certified Fellow of the Royal College of Physicians of Canada.

Table 2. Focus group interview guide

Section step	Details
Opening and introduction	Refreshments are provided and the researchers are introduced, including their roles and functions during the session Handout of information form (with informed consent), plus presentation of the study goals Participants are made aware that the session will be recorded and anonymized
Theme 1: Questions related to the current practice	1. Talk to us about the conduct of the first meeting with a patient potentially diagnosed with IBD (subjects covered, patient's reaction, length, follow-up…) 2. Explain the decision-making processes you follow to establish IBD treatment What is your level of confidence in your decision? What is the involvement of the patient in the decision? How do patients react to these decisions? 3. Are there tests that are systematically or occasionally required? (What are they?) How do you proceed to analyze, interpret, and decide which treatment to apply following the results of the tests? How do you reveal the results to the patients? How do they react? 4. According to your perception, how would you describe the current treatment decision-making processes? 5. What do you think of the tools at your disposal to guide your choice of treatment?
Theme 2: Questions related to current predictive tests	6. What is your perception of the test to measure the enzymatic level or the TPMT gene (thiopurine methyltransferase) in order to begin thiopurine treatment? Do you use this test? Why? 7. What is your impression of the serology tests (e.g. pANCA and, ASCA) for the management of IBD? Do you use them? Why? 8. What is your perception of the serology level test and antibodies against anti-TNF in order to optimize the treatment of IBD? Do you use them? Why? 9. What is an adequate approach in your view for presenting the predictive test results to patients during treatment?
Theme 3: Question related to ideal characteristics of a predictive test	10. What would be important characteristics of a predictive genetic (or other) test that would motivate you to use it?
Conclusion	Do you have any final comments or suggestions you would like to share with us? We thank you once again for accepting to participate in this discussion and we wish you an excellent rest of the day

Table 3. Current practice of Canadian gastroenterologists concerning IBD treatment decision making

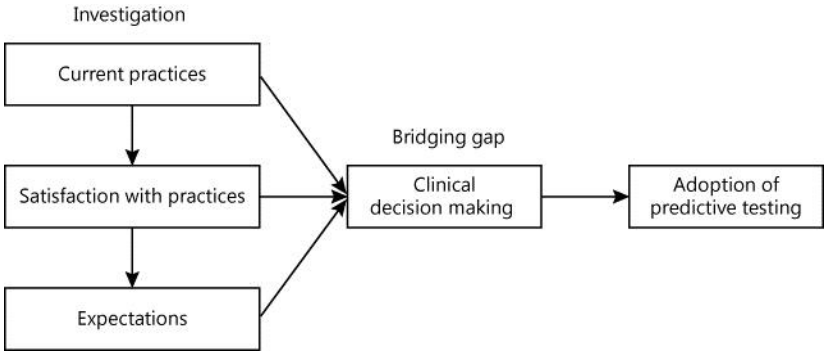
Category	Dimensions	Meaning units
Treatment escalation	Standard treatment escalation	The norm is to follow the treatment pyramid, which is a prudent, stepwise approach to treatment escalation, on which patients begin with the mildest options and then move on to more intensive treatments if needed
		The initial presentation of symptoms will dictate where the patients begin on the treatment pyramid, but the rhythm of the evolution of the disease also impacts the decision for the first and subsequent treatments
		Physicians also have to accommodate patients about their preferences and fears: issues of future pregnancy, ongoing studies, and fear of needles are some of the issues that need to be taken into consideration
	Accelerated treatment pyramid	The severity of the symptoms exhibited may cause physicians to bypass the stepwise approach and move rapidly to more intensive treatments such as biologic agents
		Factors such as smoking, obesity, and poor life hygiene may also cause physicians to move quickly, since such patients are vulnerable to rapid disease degeneration
		The current norms of practice are evolving from the standard stepwise approach and favor more and more rapid movements to biologic agents and to let go of the traditional use of steroids to relieve acute symptoms
Missing tools	Effectiveness of treatment	Every patient has specific pathways by which their disease can be managed: however, there are very few tools that can help physicians determine what pathway is currently the most effective for each patient
		There are reliability problems with current predictive tools that lead to physicians ordering them as a last recourse, and not fully taking their results into account for treatment decision making
	Elimination of ineffective treatment options	It is known by physicians that some patients will not respond to the strongest treatment options in their arsenal; however, they have no predictive tool that tells them which patient will not respond
		There are serious dangers of both over- and undertreating the disease of patients: exposure to serious, long-term side effects and worsening of symptoms can be caused by inappropriate treatment

Table 4. Canadian gastroenterologists' perceptions concerning current predictive tests (serologic and genetic)

Category	Dimensions	Meaning units
Accessibility	Coverage and cost	Not all current predictive tests are covered by provincial health care Provinces that have better accessibility are more likely to include them as standards of care
	Ease of access	Not all current predictive tests are available for order across Canada, and the more there are hurdles to jump over the less likely they are to use them
Turnaround time	Amount of time before reception of results	The turnaround time to receive results is often a few weeks, in which the condition of the patient has time to deteriorate
	Delays in treatment decision making	Even in provinces where ordering predictive tests is a standard of care, the delays arising from the reception of the results create delays in treatment decision making
Reasons to order tests	Standards of care	Predictive tests can be ordered as standards of care in IBD patients as a local or provincial norm However, actual integration of the results in treatment decision making is highly variable
	Patients' loss of response	In cases of a patient's loss of response in his current treatment, predictive tests will be ordered before making a decision to move to a stronger treatment
	Optimization of treatments	A concern regarding the optimization of treatment for the specific condition and symptomatology can drive physicians to order and use predictive tests
Reasons not to order tests	Doubts on reliability	Most physicians report concerns about the reliability and sensitivity of many predictive tests, notably that current tests fail to measure what they are supposed to measure and that they are not reliable enough for them to make an informed decision without other diagnostic tests and imagery tools
	Polygenetic nature of IBD	Issues about the interaction of multiple genes in the symptomatology of IBD patients generate doubts whether a general predictive test could cover the variability in the presentation of the diseases
	Inadequate training	Not all physicians are trained enough to understand the implications of the results of predictive tests and, as such, either do not order them or do not fully integrate them into their practice

Table 5. Characteristics and implementation conditions of an ideal IBD predictive genetic test

Category	Dimensions	Meaning units
Characteristics	Reliability	Physicians desire a predictive tool that is accurate, specific and sensitive enough to discriminate between conditions and treatment pathways in a way that is meaningful to them
	Impact for the patient	Physicians desire a predictive tool that both boosts the effectiveness of treatments and allows them to successfully eliminate ineffective options before exposing patients to dangerous side effects
		The predictive tool would also need to be as noninvasive and painless as possible
	Accessibility	Physicians would like a test with a quick turnaround time and flexibility in the moment of order
		Concerns of cost-effectiveness would also push for a test at the lowest possible cost for the health care system
	Form	Physicians would prefer a test which provides results that are user friendly and easy to understand, in a clear concise format with results that are easily interpreted for clinical application
		Integration with current tools would also be desirable, as predictive tools are likely to multiply and it would facilitate treatment decision making to have all the information in the same place
Implementation	Physician involvement	As primary users, physicians would prefer to be involved in the development and trial of any new predictive test
	Endorsement	In order to trust a new predictive test enough to incorporate it into current practice, it would need to pass through one or more clinical trials
		Endorsement of evidence-based guidelines and simple algorithms by a reputable agency and/or experts would also encourage physicians to implement the test in their practice
	Knowledge transfer	Results from the clinical trials would need to be published in reputable peer-reviewed journals
		Conferences by experts or colleagues endorsing the predictive tool would also contribute to successful implementation
		Formal training in local hospitals to understand the interpretation of the test and its implications for practice and treatment decision making would also be helpful


Investigation
Current practices
Satisfaction with practices
Expectations
Bridging gap
Clinical decision making
Adoption of predictive testing