Non-Invasive Prenatal Test: An “invasive” innovation in prenatal testing

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Non-Invasive Prenatal Testing (NIPT) is a relatively new offering in prenatal testing. Hospital District of Helsinki and Uusimaa (Finland) started to provide NIPT alternative in January of 2015. The purpose of this study is to investigate the disruptive elements of NIPT in prenatal testing services. This exploratory study shows that the use of NIPT creates certain challenges for both the consumers and the service providers. We argue that genetic counselling is essential and should be tightly integrated to the patient-provider relationship and to the supported peer to peer networks as a way to organize service production and delivery. Our research develops new insights into the use of NIPT and also enriches the research of service innovation with the focus on the implementation of innovation in knowledge intensive services.

1. Introduction

1.1. NIPT background

Prenatal screening and testing for chromosome abnormalities is an essential part of antenatal care for the best reassurance for the pregnancy and to protect the unborn. The screening, testing, diagnosis and intervention are integrated and add value in the service chain (Oepkes et al., 2014). For decades, in case of a screening-based risky case, only invasive diagnostic tests (e.g. *chorionic villus sampling* and *amniocentesis*), entailing a miscarriage risk, were offered (Allahbadia et al., 2015). New generation technologies, e.g. genetic and genomic technologies, facilitate innovative services to provide safer and easier screening with higher precision. Since its introduction to clinical practice in Hong Kong in 2011, Non-Invasive Prenatal Testing (NIPT) based on next-generation sequencing of cell-free DNA in maternal plasma has quickly spread on the landscape with its high sensitivity, specificity and little risk of pregnancy loss to assess the most common fetal aneuploidies-Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome) and Trisomy 13 (Edwards syndrome) (Allahbadia et al., 2015) (Kellogg, Slattery, Hudgins, & Ormond, 2014). NIPT is a prominent application of personalized medicine (PM), a field using diagnostic tools to identify specific biological markers to provide the right treatment in the right dose to the right patient at the right time.

However, despite of the admirable advantage, NIPT still has not been considered as the replacement of the currently conventional screening approaches that can assess a

wider range of chromosome abnormalities beyond those assessed by NIPT (Hui & Hyett, 2013) (Long & Goldblatt, 2014) or the diagnostic testing methods that are more accurate and effective in detecting genetic disorders with more affirmative results (Ryu & Kim, 2015). Because NIPT's false positive rates, follow-up invasive diagnostic testing is necessary to confirm the presence or absence of the abnormality (Oepkes et al., 2014). In this way, NIPT is usually provided as an option with non-absolute advantages in the prenatal screening and testing paradigm. NIPT is not a diagnostic test but an advanced screening test (Ryu & Kim, 2015).

1.2. Research context and objectives

In the recent five years, technical disadvantages and clinical limitations of NIPT have been deeply and widely investigated. But the study of the social effects of NIPT application is still far from being sufficient. Our major point of interest in the present study is the possible interruptions caused by NIPT application in the established business models and service operations and practices in maternal and natal healthcare. We suspect that the application of this non-invasive technology would produce invasions to the current service network and transform the value chains in prenatal testing.

Hospital District of Helsinki and Uusimaa (HUS) started to formally provide this innovative testing approach in January of 2015 as an alternative screening method for the detection of fetal chromosome aneuploidies to the women with increased risk factors. Several private clinics in Finland also offer NIPT. We focus on this case, make efforts to explore the application of NIPT from both the provider's view and the consumer's view and detect the possible interruptions and disruptive elements caused by the entrance of NIPT in current prenatal testing service in the district of Helsinki and Uusimaa. More specifically, we are studying the degree of disruption in prenatal testing services market by modelling and comparing the processes before and after the adoption of NIPT. This is based on the postulation that disruptiveness is one possible attribute of innovation. Innovation attributes affect its rate of adoption, i.e. the relative speed with which an innovation is adopted by members of a social system (Rogers, 2010). As disruption is not necessary binary, the degree of disruption can be studied as a variable in connection with the degree of precision or invasiveness. In addition, we would like to propose possible solutions for converting the interruptive innovation to a constructive innovation.

Our research develops new insights into the application of NIPT with a more practical and phenomenological view and also enriches the research of service innovation with the focus on the implementation and interruptions of innovation in knowledge intensive services. There are several reasons why this type of study is warranted. Health services management is facing many challenges related to rising demands, changing environments and stricter budgets that necessitate the exploration of innovative solutions. This means acquiring deeper understanding of the innovation diffusion process and the disruption opportunities in health care services. Personalized medicine and the use of genome data in clinical practice can fundamentally change the integration, coordination and control of health services. Genomic innovations and

technology create both new opportunities and challenges for all the stakeholders from patients to the producers.

2. Diffusion of innovations in health services

2.1. Innovation attributes – disruptive or complementary?

NIPT raises questions of how innovations, and genomic innovations in particular, diffuse in the provision of healthcare services. According to Rogers, innovation attributes, such as relative advantage, preventiveness, and compatibility, affect innovation's rate of adoption. The innovation diffusion process can take many forms: there are for example centralized (top down), and decentralized (client-controlled) diffusion systems. Innovation sub-processes in organizations can be divided into (1) initiation and (2) implementation phases(Rogers, 2010). Disruption in turn is an innovation making things simpler and more affordable. The three enablers of most disruptions are: 1) a simplifying technology, 2) a business model innovation, and 3) a disruptive value network. Examples of health care business models include Solution Shops, Value-Adding Process Businesses, and Facilitated networks (Christenson, Grossman, & Hwang, 2009).

In this study the degree of disruption is seen as a variable and this line of thought is applied to the use of the NIPT in prenatal screening services to investigate the effects and implications of an emergent technology and related services. How does the genomic innovation diffuse? We ask if NIPT-based services represent more of a disruptive or complementary innovation. Which attribute is the one that dominates in the current maternal care services ecosystem? Can NIPT disrupt the prenatal testing market under certain conditions, and if so what is the impact on e.g. value propositions, channels, key partnerships and customer choices? How are the elements of invasiveness and precision connected to the analysis of the disruption opportunities? The answers are searched via process comparisons before and after the entrance of NIPT in maternal and natal healthcare services. In this paper we focus on a public health organization and try to identify and categorize the ways in which this genomic innovation affects the patient choice environment and managerial integration, coordination and control in a large university hospital.

2.2. NIPT application in Finnish healthcare

HUS is the first Finnish public health organization where NIPT has been introduced. At HUS, NIPT is presented as one of further tests, including *Chorionic Villus Sampling* (CVS) and *Amniocentesis*, for indications including an increased risk (>= 1:250) of chromosomal abnormalities based on the first trimester screening and assessment, abnormal result in the second trimester serum screening, fetus' swelling neck (reaching 3-3.9 mm), a high maternal age (> 40 yrs) and a previous pregnancy with a trisomy. General check-up will be followed up if the result of NIPT is negative. Abnormal result in NIPT can be confirmed by further diagnostic test (CVS and Amniocentesis). It means

that the initial screen-positive subgroup does not necessarily undergo a diagnostic test directly based on their preference but is offered with a further selection, which aims to improve women's reproductive choices and reduce the number of patients who will be subjected to unnecessary or unwanted interventions (Long & Goldblatt, 2014). But meanwhile, people choosing NIPT may have to wait longer for confirmative answers. Figure 1 shows the main process of NIPT application at HUS.

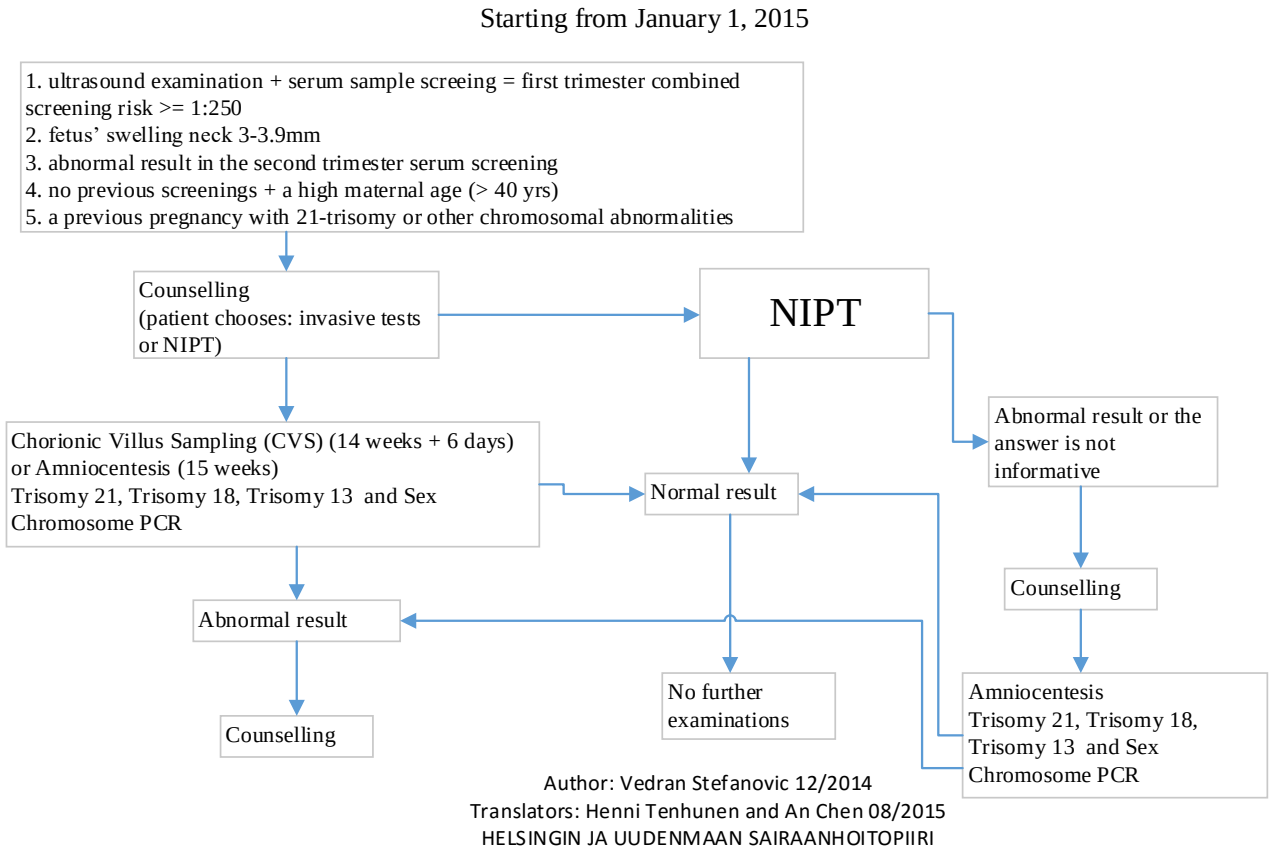

Figure 1. NIPT application in public health service (HUS).

The latest statistical data show that since the introduction of NIPT, nearly 77% of the patients that were given counselling chose NIPT and around 23% of them chose the conventional tests. There are several cases of rejecting the further tests after the screening. The introduction of NIPT has reduced the number of invasive diagnostic procedures (circa 700 procedures per year previously) and thus also the risks of miscarriage have decreased (van der Meer, 2015).

The adoption of NIPT has introduced a new level of logistics, as the use of NIPT involves taking blood tests and also midwife counselling before and after the test. Because analyzing the samples is not feasible in Finland at the moment, the samples are sent to the United States via Belgium. The blood samples are taken on Mondays

and Tuesdays and the samples for the test are sent by Express mail to GENDIA‘s lab in Antwerp, Belgium, and the samples arrive there within 2 days. Getting the results from the NIPT can take up to three weeks, ten days being the average waiting time. This can be too long for those approaching the latest possible termination week. HUS is currently the only public health organization offering NIPT but there are plans to adopt NIPT in other university hospitals as well. In conjunction with the NIPT a new Fetomaternal center was founded at HUS and the purpose is to gather together interdisciplinary competences related to fetomaternal care. Women who have higher risk factors can come to FMC for NIPT from all over Finland (van der Meer, 2015).

3. Methodology

3.1. Research approach

The use of genome data in clinical practice illustrates the transition from intuitive medicine to precision medicine. As far as we know, there is no structured innovation diffusion analysis regarding the disruptive elements and challenges related to the implementation of this new innovative service based on NIPT technology. The use of a new emergent technology creates a research frontier that is studied with an exploratory research approach. Exploratory research is conducted for a problem that has not been clearly defined and it can be used to gain significant insights into a given situation and familiarity with a phenomenon in order to formulate a more precise problem or develop hypothesis. Exploratory research is suitable for this study because it is flexible and can address research questions of all types. (Shields & Rangarajan, 2013)

3.2. Methods: Interviews and Netnography

We interviewed practitioners involved in the provision of NIPT services (e.g. midwifes, technicians, specialists, and geneticists). We encouraged the practitioners to compare their daily work before and after the NIPT and inquired them about the disruptive potential of the services based on this genomic innovation. The conversations were organized around several issues: changes in the workflow, informed choice of mothers and families regarding genetic tests, counselling practices and estimations of further development.

We planned to conduct in-depth interviews with women and families (mainly from the high risk subgroup) living in the HUS region, who had undertaken or rejected NIPT or other prenatal testing services. Since our research application to ethical committee was still in the process of review, the original research plan was compromised and we had problems to access the patient base without the approval. Thus we utilized our personal relationship to contact with mothers who had experiences of prenatal screening and testing (with NIPT or without NIPT) and explored their experiences, expectations and opinions regarding NIPT and its application. Totally, we learned from 2 mothers who undertook NIPT, 2 mother who chose conventional tests before the introduction of NIPT and 4 mothers who got normal results at the early-stage screenings.

In order to enrich the data in the context, we applied netnography (Kozinets, 2002), which has been widely used in recent consumer and market research, as a data collection strategy. Online communication (e.g. internet-based forums, online chat rooms and blogs) has been significantly influencing the life of the contemporary consumers and marketers. It provides relatively objective information on expectations, experiences, decisions-making and consumption behaviors of consumers or consumer groups (Kozinets, 1998). Netnography is interpretive method devised to investigate online communities and communications in a faster, simpler, and less expensive way than traditional ethnographies, and it is more naturalistic and unobtrusive than focus groups or interviews (Kozinets, 1998) (Kozinets, 2002). In this study, we sought for online discussions in Finland regarding NIPT by searching google with the keywords ”NIPT foorumi”, ”NIPT testi”, ”NIPT keskustelu”, ”NIPT blogi”, and ”Nipt tutkimus”. Vauva and Kaksplus were the two main websites where people discussing maternal and natal services, with some threads specific to NIPT.

We analyzed practitioners’ interviews, consumers’ interviews and netnographic data. Practitioners’ and consumers’ views on the interruptions caused by NIPT in prenatal testing service were separately and thematically organized and presented.

4. Findings

4.1. NIPT application opportunities and challenges perceived by mothers and families

Our data reveals that the majority of women praise NIPT for its positive advancement in prenatal testing, emphasizing the zero risk of miscarriage and its easiness in practice. Some women in the normal group comment that the introduction of NIPT as an option for further tests after the initial screening can increase their autonomy in reproductive decision making.

However, as NIPT is offered after the early screening as an optional further test to women categorized into the high risk group, these women and families who are going through the traumatic experience face the choice challenges. First, safety, accuracy and certainty are the essential considerations of women and families in making decisions on prenatal care services. Since NIPT and conventional tests have their own strengths and weaknesses at these aspects and they cannot serve all goals, mothers and families have to make trade-offs. In Figure 2 the prenatal testing methods are mapped based on their invasiveness (safety) and precision (accuracy and certainty). This diagram illustrates the service ecosystem of prenatal screening and diagnostics from the consumer decision making perspective. It shows how innovation attributes of invasiveness and precision are emphasized in each of the testing services.

Second, making meaningful and informed choices and decisions requires thorough information. Women have difficulties to concentrate and rationally process the

information on prenatal screening and make choices in an anxious state of mind that they have never prepared to face. Some women even refuse to search for information online or offline, because they want to avoid the scary texts and shocking pictures, which increase their anxieties. In addition, women and families appreciate more experiential information, not just scientific or statistical information about the prenatal testing methods. But since the high-risk subgroup that needs the further tests is minor and the NIPT application in Finland is at early stages, it is impossible for women and families to find a vast amount of experiential information online or offline. Thus, to some extent, the unique and appealing aspects of NIPT do not always bring freedom to women and families, instead NIPT application could complicate women's decision-making processes in prenatal care and women may require more resources and support to make choices that align with their needs and preferences in such out-of-expectation situations (Farrell, Agatisa, Mercer, Smith, & Philipson, 2015).

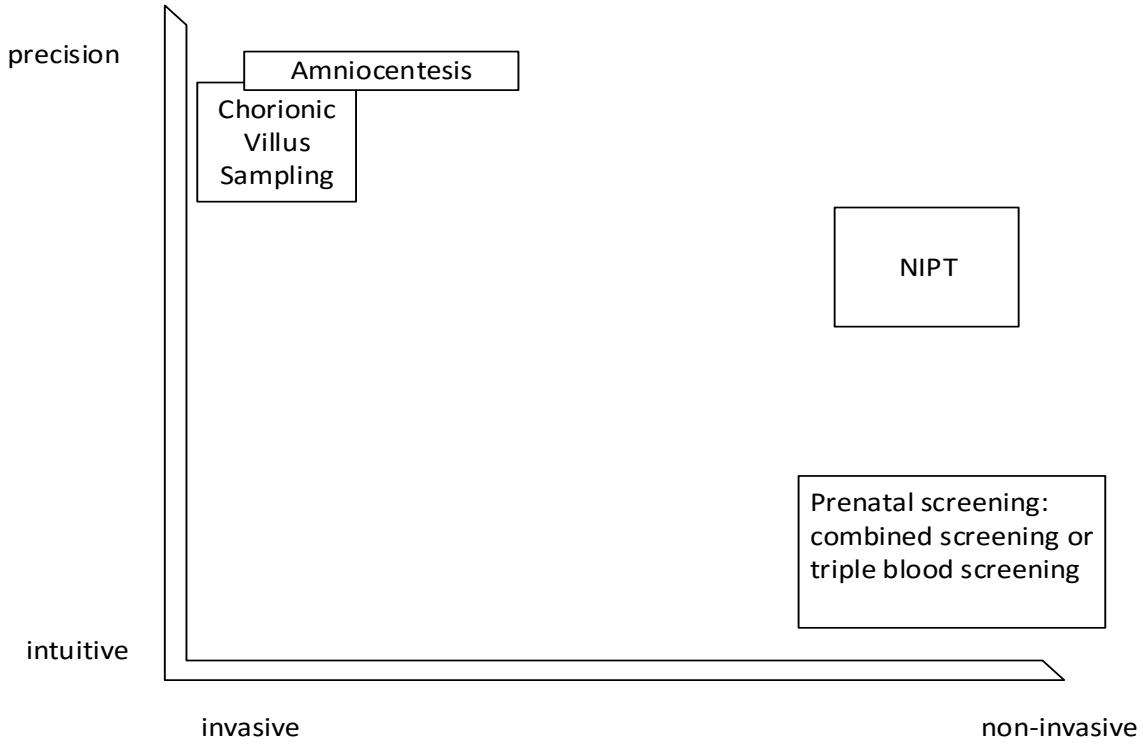

Figure 2. Invasiveness (safety) – Precision (accuracy and certainty) diagram of prenatal screening and testing methods.

4.2. NIPT application opportunities and challenges perceived by practitioners

From the viewpoint of the service providers the use of NIPT entails both opportunities and challenges. In the interviews the following advantages and opportunities of NIPT were mentioned: its cost-efficiency and safety, the fact that it empowers women via wider reproductive freedoms and that it reduces the need for invasive tests and thus the risks for miscarriage are smaller. Amid these positive reviews we wanted to dig deeper and ask the service providers about the challenges related to NIPT.

The practitioners brought up the issue of slightly more complicated logistics due to NIPT, most notably the long waiting times, as the blood samples are only taken on Mondays and Tuesdays and sent abroad for analysis. The results then also affect scheduling of counseling with the geneticist and midwifes and of the possible invasive diagnostic tests. The midwife we interviewed pointed out that midwifes currently take on most of the NIPT counseling and in this work they face certain difficulties based on the fact that patients represent a very heterogeneous group: some are highly educated, some need a lot more explaining starting from the basics, some do not understand the strongest common language properly, and then there is the challenge of always maintaining a neutral, unbiased tone in the counseling, not recommending any specific options, merely explaining their meaning and scope. Same has to be achieved also when there is a translator involved delivering the message.

In order to gain insight into the disruptive elements of the NIPT based services, we inquired the opinion of the geneticist and other professionals about whether and to which extent NIPT could disrupt the prenatal testing market and replace the other screening and diagnostic tests. The consensus at this point of time was that although NIPT has decreased the number of invasive procedures and will continue to do so in the future as the technology gets more accurate and wide-ranging, it cannot entirely replace the other prenatal testing methods. Therefore, it will likely remain a complementary innovation for the most part, as long as diagnostic certainty is required for the termination of the pregnancy. In Figure 3 NIPT is positioned in relation to its disruptiveness and precision based on the interviews.

The practitioners explained that the use of NIPT generates an interesting new challenge. The fewer invasive operations there are, the less experience the physicians get and thus the higher the risks in the remaining invasive procedures. The natural solution to this dilemma is to centralize the invasive testing services in the hands of the most experienced physicians who specialize in these procedures. This means that many physicians lose one previously relevant part of their work, which can be seen as a disruptive element of the NIPT-based service. Allahbadia et al. (2015) state that the use of NIPT in low-resource settings has the potential to reduce the need for skilled clinicians doing invasive testing.

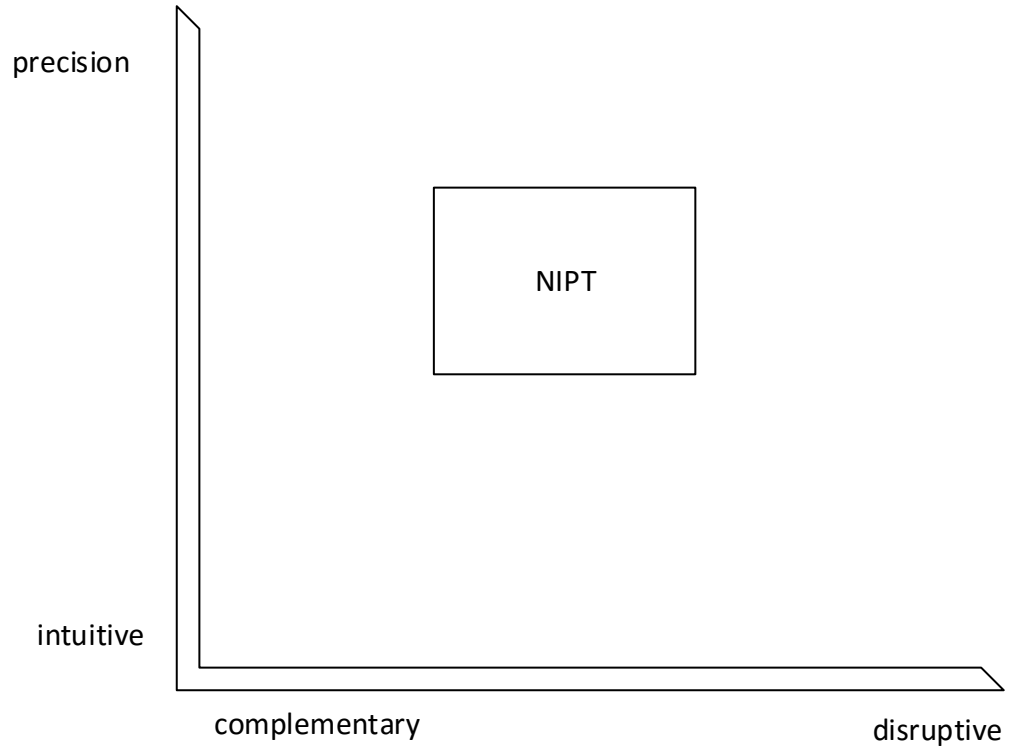

Figure 3. Disruption – Precision diagram of NIPT.

5. Discussion

5.1. Complications related to service operation and decision-making

Challenges in maternal and natal healthcare could be solved by new technology, but the introduction of a new technology may create new challenges. In our case, NIPT application increases the safety in prenatal further screening and testing and brings autonomy for women and family, but it also complicates the service operation and generates choice challenges. Simply applying the new technology to current business models or service chains does not guarantee at all that the true value of the technology will be obtained. This is because the innovation's attributes affect how the innovative service is adopted in healthcare organizations and to what extent it replaces and disrupts the existing market offerings and creates new value propositions, business networks and customer segments.

In the case of NIPT the diffusion process is in the early stages and has been a combination of centralized (top down) and decentralized (client-controlled) diffusion, because the expectations to adopt NIPT at HUS have partly been generated by the use of NIPT in the private clinics. As the service is now available both in the private and public sectors, the disruptive opportunities have increased remarkably, although the complementary elements still dominate as long as the diagnostic invasive tests are required for the termination of pregnancy, and the early screening detects a wider range

of abnormalities than NIPT, although with much lower accuracy. Thus we observe that not all the enablers of disruption have materialized fully: 1) the technology is not sufficiently simplifying, 2) the service is built on existing management traditions, and 3) the role of supporting value networks in the innovative service provision has not been understood and feels distant and unfeasible to the practitioners.

5.2. Solutions: increased counselling tied to supported peer-to-peer networks

To address the complications caused by NIPT, we propose management and decision-making support solutions that facilitate the beneficial use of this safety-increasing and procedure-simplifying technology for all the stakeholders. Regarding integration, midwifes, geneticists and genome data specialists partly disrupt the traditional role of the surgeons and physicians due to the smaller need to use invasive operations to detect abnormalities in pregnancy. Genetic counselling is and will have to be even more tightly integrated to the patient-provider relationship in the prenatal testing environment. When it comes to coordination, supported peer-to-peer networks can be used to organize service production facing the mass customization dilemma. Finally, as for control, the non-invasive prenatal testing lowers the technical and other thresholds for acquiring genomic data about risk factors and this disrupts the way in which risk is avoided.

In the world of cutting-edge genomics and precision medicine, the introduction of NIPT has to be supported by the rapidly changing information and the availability of information on NIPT and other prenatal screening and testing methods in an objective and appropriate form (Long & Goldblatt, 2014). But merely providing scientific information related to the prenatal tests and helping women and families to understand the tests is not enough. The demand for counselling is increased as NIPT is introduced. Informed choice requires a comprehensive and thorough counselling in this problem-driven choice situation. Counseling services can be expanded in three ways. First, some counselling services regarding further tests should be offered before or during the initial screening and the possible result of the initial screening should be well explained beforehand. It may help to reduce the shock of women and families when they are informed with the need of further testing. Second, the theoretical information on the comparison between NIPT and conventional test methods is not enough for women and families to make informed choice. The possible results and following procedures, treatment and social services should be explained, so that women and families could be somehow prepared for the possible situations. Sensitive information, e.g. stories about how other women went through similar situations, may help pregnant women make easier decisions. Third, psychological counselling and support is required, especially during the weeks when women and families are waiting for the NIPT result. Stress, depression and anxiety are harmful for the women’s health and fetus development. Women undergoing prenatal diagnostic procedures experience more psychological distress (Suzumori et al., 2014), which cannot be underestimated. It is important to listen to women’s worries and give enough psychological support.

The problem of mass customization emerges when there are more options and more specific genetic information available, because this information cannot be rationally used by the consumers without appropriate counselling and help, which in turn brings more costs for organizing the services. We consider that there are many ways to solve the efficiency problems related to the need for increased counselling and one of them is to create a trust-inducing environment, a facilitated network based on powerful online tools and platforms, where women and families, practitioners, and relevant third parties co-create and add value by sharing their personal and professional information about prenatal testing and maternal care. This would be a sophisticated decision-making support platform and a research center that also connects similar cases, patients struggling with same kind of concerns, with each other, and hence addresses the psychological counselling issues. This type of establishment of supported networks, based on the willingness of mothers and families who have experience of further tests, will bring benefits: more experiential information from users and more social support. It is crucial for attaining larger value networks and better innovation diffusion to open more channels to discuss NIPT and the user's experiences.

6. Conclusions

6.1. Summary and contribution

This study provides important insights about the introduction of NIPT into prenatal care. NIPT is supposed be to a powerful screening test, appreciated by users and practitioners alike for its non-invasiveness. However, with this study, we discover the "invasive" elements in its application. We identify both the opportunities and problems related to the introduction and implementation of this new innovative service based on NIPT technology. This study demonstrates that NIPT introduces new challenges for pregnant women in decision making and for healthcare practitioners who are concerned about service efficiency and productivity, especially regarding the mass customization dilemma. These findings call for effective mechanisms to ensure that pregnant women or families are psychologically and intelligently prepared to make informed decisions about NIPT and improve the service operation and provision with the introduction of NIPT. Our proposal is that comprehensive and thorough counselling should be tightly integrated to the supported peer-to-peer networks as a way to organize service production and delivery. The new service production process, increasingly based on precision medicine, is moving from intuitive solution shops to supported peer-to-peer networks. In these networks the users can find directly comparable cases and this is one of the ways to solve the mass customization and patient choice dilemmas. The results of this research can be employed to handle management and choice challenges in maternal and natal health care service production that involves the use of new genomic innovations.

6.2. Limitations and further research

However, we acknowledge that the study has some relevant limitations that should be considered. The results of qualitative research can give indications as to the why, how and when, and gain familiarity of the research problem for further experimentation and hypothesis development, but generalizations cannot be made based on a case study and caution must be exercised when interpreting qualitative data from the literature review and the interviews.

As NIPT is in its early stages of clinical integration into prenatal care, the responses of participants may change once the screen becomes more widely available. Further studies will be needed to examine the findings among larger and more diverse populations and as the noninvasive platform for prenatal testing evolves. Further studies are also warranted regarding the diffusion of potentially disruptive genomic innovations in other healthcare areas. Although the findings may be limited to our sample population, the data provide important insight into the educational, management and decision-making components necessary for informed uptake of this new technology.

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